

User's Guide

AU480 Chemistry Analyzer

For *In Vitro* Diagnostic Use



PN B28624AA
December 2013



Beckman Coulter, Inc.
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- Replace the current regional User's Guides with a single global document
- Improve the content and usability of the instructions

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Glossary

Introduction

The AU480[®] Chemistry Analyzer measures analytes in samples, in combination with appropriate reagents, calibrators, quality control (QC) material, and other accessories. This system is for in vitro diagnostic use only.

To ensure optimal performance and prevent system failure, always operate the system in accordance with the procedures outlined.

This chapter discusses the following:

1.1 Beckman Coulter Guarantee

1.2 Using this Guide

1.2.1 Assumptions

1.2.2 Where to Start

1.2.3 System Installation

1.2.4 Users New to Automated Analyzers

1.2.5 System Administrators

1.3 Typographical Conventions Used in this Guide

1.3.1 Tips, Cautions, and Warnings

1.3.2 Software Paths, Menus, and Tabs

1.3.3 Software Buttons

1.3.4 Images of Software Screens

1.3.5 Analyzer Modes

1.3.6 Notation of Units

1.3.7 Third-Party Trademarks and Trade Names

1.1 Beckman Coulter Guarantee

Beckman Coulter guarantees this analyzer to be free from defects in materials or workmanship under normal use for a period of one year from the day of purchase. If the system is found to be defective within the guarantee period, the analyzer is repaired onsite free of charge. The Beckman Coulter guarantee does not cover the following:

- Defect or damage caused by natural disasters such as fires or floods.
- Defect or damage caused by carelessness or abuse.
- Defect or damage resulting from maintenance performed by personnel not approved by Beckman Coulter.
- Defect or damage caused by the use of consumables or fitting replacement parts not supplied by Beckman Coulter.
- Malfunction caused by unauthorized disassembly.
- Corrosion of the electrical system caused by exposure to a system environment other than that stated in this guide.
- Loss of stored data caused by inadequate or incorrect system maintenance.

Beckman Coulter does not assume any liability for any consequential damages such as loss of profit or business that might arise from the misuse of this system.

Beckman Coulter offers a maintenance and repair service after the guarantee period has expired. For details, contact Beckman Coulter Technical Services.

1.2 Using this Guide

This User's Guide explains how to use the system effectively and safely. It also serves as a maintenance and troubleshooting guide and is intended as a primary source of reference for all AU480 users, including all medical laboratory personnel who may operate the system or prepare samples to be processed by the system. The following describes how to use this User's Guide.

- [1.2.1 Assumptions](#)
- [1.2.2 Where to Start](#)
- [1.2.3 System Installation](#)
- [1.2.4 Users New to Automated Analyzers](#)
- [1.2.5 System Administrators](#)

1.2.1 Assumptions

It is assumed that the user has a general understanding of biochemical analysis and has special knowledge of sample handling. This guide also assumes that users have basic PC operating skills and knowledge of the MS Windows® operating system. Users who have never used a PC or a PC operating system should get basic PC skills training before using the system.

1.2.2 Where to Start

This User's Guide covers each system procedure in a step-by-step manner.

When looking for information related to a specific concept or topic, use the search function in the PDF version of this User's Guide, or the index at the back of this User's Guide. The index lists every topic in alphabetical order with page number.

For information on using the online help, refer to [3.5.6 Using the Online Help](#) in chapter 3.

When looking for a specific chapter, either use the fast find tabs or the table of contents at the beginning of the User's Guide.

1.2.3 System Installation

This guide contains information related to the system environment and hardware, but it is not an installation guide. Installation of the AU480 should be performed by Beckman Coulter approved engineers only. There is no installation information supplied with this system. To change any aspect of the installation, contact Beckman Coulter Technical Services or seek the help of a Beckman Coulter approved installation engineer.

1.2.4 Users New to Automated Analyzers

Study and read this User's Guide thoroughly before operating this system, even if the operator has completed a Beckman Coulter approved training course.

1.2.5 System Administrators

Read chapters 1, 2, and 3 carefully and follow the procedures outlined. The computer hardware and software parameters should be part of an internal maintenance routine, and all data produced by the system should be backed up regularly and stored in a secure location.

Read section [4.11 Program a User Name and Password](#) in chapter 4.

This allows administrators to:

- Create a secure operating environment where unauthorized users cannot interfere with the system while it is in operation.
- Track the actions of each user.

For information on how to set a user name and password, refer to [4.11 Program a User Name and Password](#) in chapter 4.

1.3 Typographical Conventions Used in this Guide

This section describes the conventions used in this User's Guide:

- 1.3.1 Tips, Cautions, and Warnings
- 1.3.2 Software Paths, Menus, and Tabs
- 1.3.3 Software Buttons
- 1.3.4 Images of Software Screens
- 1.3.5 Analyzer Modes
- 1.3.6 Notation of Units
- 1.3.7 Third-Party Trademarks and Trade Names

1.3.1 Tips, Cautions, and Warnings

This guide uses the following symbolic icons and terms according to the content of information. Each convention and term indicates the level of its importance. A thorough understanding of this information is necessary to use the system safely and correctly.



Orange Warning Labels with an orange background indicate to use caution to avoid serious injury or death. Failure to observe these warnings may lead to serious degradation of system performance or generation of incorrect sample data.



This symbol indicates a caution. Cautions mean that appropriate care must be taken. Failure to follow these cautions may result in minor injury, sub-optimal system performance, operation, or damage, which could lead to other hazards.

TIP Tips contain important information that users should take into consideration when performing procedures and understanding concepts.

For other precautions, refer to [CHAPTER 2, Precautions, Installation, and Specifications](#).

1.3.2 Software Paths, Menus, and Tabs

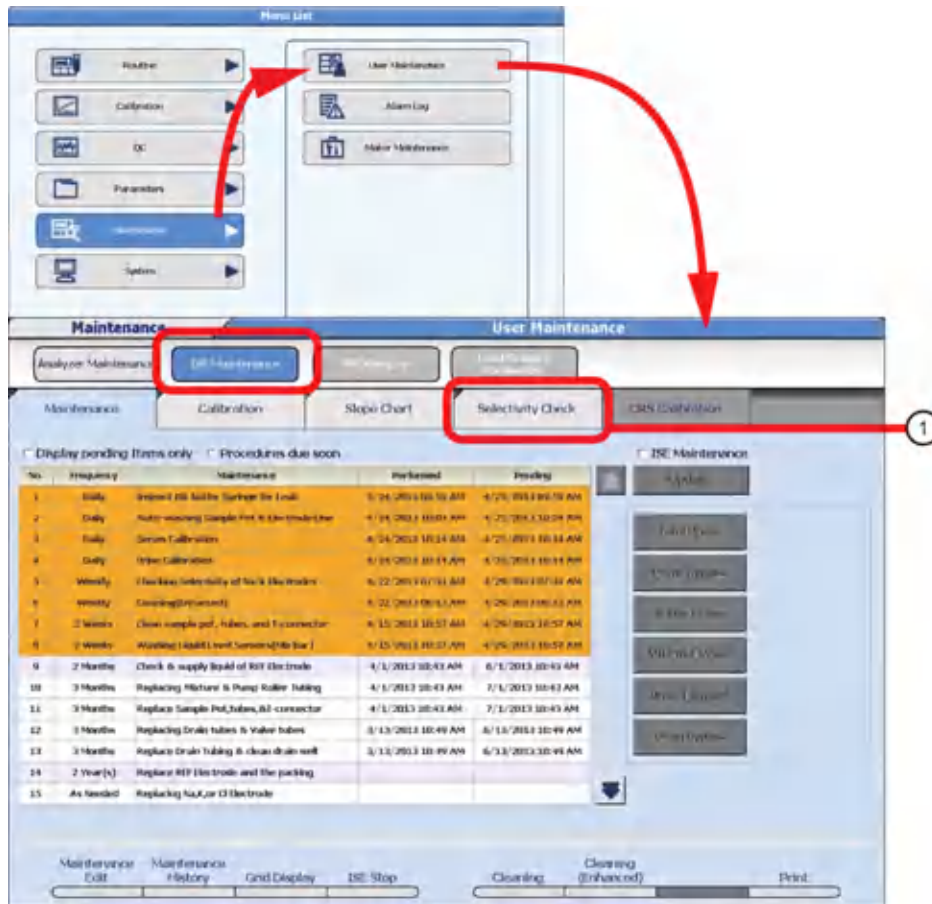
A software path is a sequence of options selected in the software interface in the order indicated. All menus and tabs appear in a **Bold font**.

Software paths in this guide are expressed as follows:

Select **Maintenance > User Maintenance > ISE Maintenance**.

Following this path, first select the **Maintenance** menu, then **User Maintenance** and finally **ISE Maintenance** on the resulting submenu.

Figure 1.1 Software paths, menus, and tabs

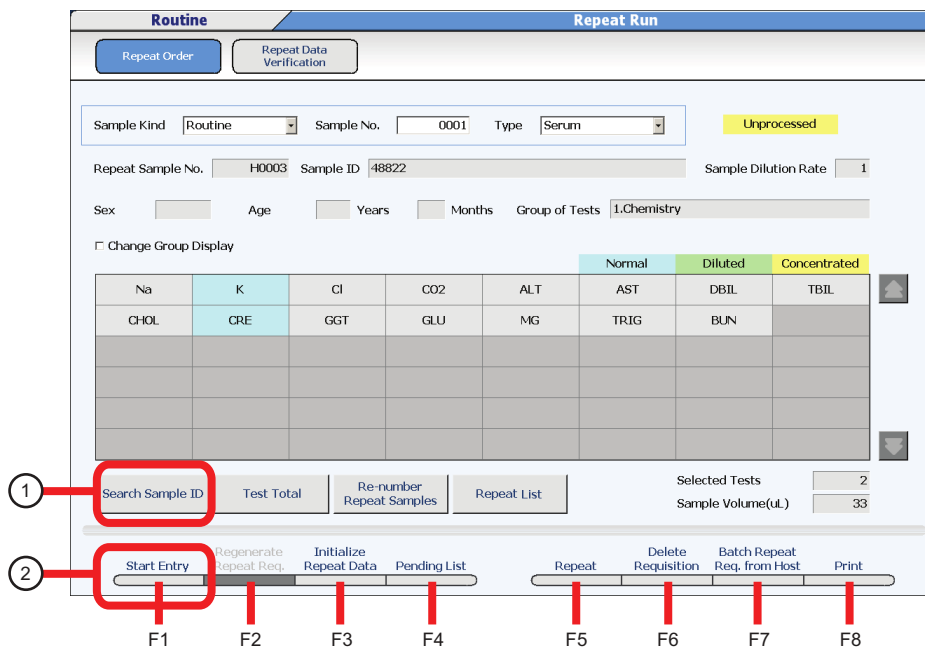


1. Selectivity Check tab

1.3.3 Software Buttons

All buttons that appear in the software interface are part of a single procedural step and appear in a **Bold** font. Some software buttons have a corresponding function key that can be accessed from the keyboard. These buttons appear in **Bold** font with the corresponding keyboard function number in parenthesis. Refer to the following screen shot for an example.

Figure 1.2 Software Buttons



1. Search Sample ID button
2. Start Entry (F1) button

1.3.4 Images of Software Screens

Images of the software screens in this User’s Guide can differ from the actual appearance of the software screen depending on how the system parameters are programmed.

1.3.5 Analyzer Modes

Analyzer modes are written in italics. For example, *Standby* and *Measure* are normal analyzer modes.

1.3.6 Notation of Units

In this User's Guide, units are denoted with the International System of Units (SI).

1.3.7 Third-Party Trademarks and Trade Names

All third-party trademarks and trade names referenced in this User's Guide are the property of their respective owners.

Precautions, Installation, and Specifications

Operators must understand how to operate the AU480 safely before beginning to use the system. This chapter provides instructions on:

2.1 Safe Use of the System

- 2.1.1 Observing Warning Labels
- 2.1.2 Preventing Fire and Damage
- 2.1.3 Preventing Electric Shocks
- 2.1.4 Preventing Damage to Other Equipment and Facilities
- 2.1.5 Preventing Personal and Serious Injury
- 2.1.6 Preventing Infection
- 2.1.7 Handling the PC and Printer
- 2.1.8 Precautions for Operating the System
- 2.1.9 Ensuring Optimal Analytical Performance
- 2.1.10 Performing Important Checks at Analysis
- 2.1.11 Handling Reagents, Wash Solutions, Calibrators, and QC Samples
- 2.1.12 Handling Samples
- 2.1.13 Managing Liquid Waste
- 2.1.14 Managing Solid Waste
- 2.1.15 Preventing Water Leaks
- 2.1.16 Electromagnetic Wave and Noise Precautions
- 2.1.17 Replacing Parts and Routine Maintenance
- 2.1.18 Setting Analysis Parameters
- 2.1.19 Precautions for Using the Analyzer Independently
- 2.1.20 Precautions for Using External Storage Unit
- 2.1.21 Cleaning Contaminants from the Covers
- 2.1.22 Other Precautions
- 2.1.23 System Disposal

2.2 Installation Environment Precautions

- 2.2.1 Installation Environment
- 2.2.2 Installation Space Requirements

- 2.3 Major Specifications of the System
 - 2.3.1 System Specifications
 - 2.3.2 Sample Barcode Specifications
- 2.4 System Labels and Displays

2.1 Safe Use of the System

To ensure safe operation of this system, follow all safety procedures contained in this User's Guide. Failure to follow these procedures could jeopardize the safety features of the system.






Read, understand, and follow the safety precautions carefully before using the system.

If the system is not operated following these precautions, the manufacturer or provider cannot be held liable for any resulting damage or injury.

- 2.1.1 Observing Warning Labels
- 2.1.2 Preventing Fire and Damage
- 2.1.3 Preventing Electric Shocks
- 2.1.4 Preventing Damage to Other Equipment and Facilities
- 2.1.5 Preventing Personal and Serious Injury
- 2.1.6 Preventing Infection
- 2.1.7 Handling the PC and Printer
- 2.1.8 Precautions for Operating the System
- 2.1.9 Ensuring Optimal Analytical Performance
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- 2.1.12 Handling Samples
- 2.1.13 Managing Liquid Waste
- 2.1.14 Managing Solid Waste
- 2.1.15 Preventing Water Leaks
- 2.1.16 Electromagnetic Wave and Noise Precautions
- 2.1.17 Replacing Parts and Routine Maintenance
- 2.1.18 Setting Analysis Parameters
- 2.1.19 Precautions for Using the Analyzer Independently
- 2.1.20 Precautions for Using External Storage Unit
- 2.1.21 Cleaning Contaminants from the Covers
- 2.1.22 Other Precautions
- 2.1.23 System Disposal

2.1.1 Observing Warning Labels

Use caution, observe, and follow all warning labels attached to the system. Do not cover or remove these labels. If the labels peel off or become illegible, inform Beckman Coulter Technical Services to have them replaced. Orange labels indicate that there is a risk of Serious Injury. Yellow labels indicate that there is a risk of Personal Injury, Fire, or Damage.

Label	Type	Explanation
	Electric shock	This symbol indicates an area of the system that should not be accessed under any circumstances, due to risk of electrical shock.
	High temperature danger	This symbol indicates the risk of burning by touching the hot photometer lamp directly when replacing the lamp.
	Biological risks	This symbol indicates the use of biohazards material. Wear protective gear and follow universal precautions as dictated by local or national regulations (CLSI GP17-A2, ISO15190 or 29CFR 1910.1030).
	Laser radiation	This symbol warns that a laser is in use in this part of the system. To avoid eye injuries, do not look directly into the laser beam.
	Danger	This label indicates a potential hazard which, if not avoided, can result in injury to an operator and/or serious property damage.
	Personal injury	This symbol denotes areas where a risk of injury due to system movement—fingers or other body parts should be kept clear of these areas during system operation.

2.1.2 Preventing Fire and Damage

- Install this system correctly and in accordance with the installation environments and conditions described in this guide.
- This system should only be installed by Beckman Coulter authorized personnel.
- If the analyzer installation needs to be altered, contact Beckman Coulter Sales or Beckman Coulter Technical Services.
- In the event of a system malfunction, the system must be completely powered off using the main breaker located on the right side of the analyzer prior to any repair service.
- If fluid is spilled on the system, turn off the main breaker located on the right side of the analyzer immediately. Wipe up the spill only after turning off the main system breaker. Entry of fluid into the instrument after a spill should be reported to Beckman Coulter Technical Services prior to re-starting the instrument.
- Do not use any flammable or combustible gases near the system due to the risk of explosion.

2.1.3 Preventing Electric Shocks



- Never remove surfaces secured by screws, including the rear and side covers.
- If liquid spills or leaks within the system, contact the Beckman Coulter Technical Services immediately. Careless handling of liquids around the system may result in electric shock.
- To ensure all power to the system is off, turn off the facility distribution circuit breaker to the analyzer.

2.1.4 Preventing Damage to Other Equipment and Facilities

The system should be connected to a separate power outlet to avoid electrical noise from other devices.

2.1.5 Preventing Personal and Serious Injury

- Always operate the system with all covers closed.
- Never place fingers or hands into any openings.
- While the system is in operation, do not touch any moving parts.
- Some reagents and wash solutions used in this system are either strong acids or strong bases (alkaline). Avoid contact with bare hands and clothing. When handling a reagent or wash solution, wear appropriate protective gear (protective gloves, goggles, mask, and protective clothing) or other requirements in the laboratory Standard Operating Procedures (SOPs).
- When the system is powered on, avoid looking directly into the lens of the sample ID barcode reader because of the laser beam. Looking at the barcode reader light may result in eye damage.



Use of other controls and adjustments not specified in this guide may result in hazardous radiation exposure.

- Avoid personal injury by wearing protective gloves when handling sample probes, reagent probes, mix bars, or any sharp part.
- When replacing the photometer lamp, allow the lamp to cool down for at least five minutes. The photometer lamp operates at high temperatures. Direct contact with a hot lamp may cause burns.

2.1.6 Preventing Infection

- Always wear personal protective clothing when handling samples and racks, performing maintenance, and managing waste.
- Handle all patient samples as potentially infectious and follow universal precautions as dictated by local or national regulations (Clinical and Laboratory Standards Institute CLSI GP17-A2, ISO15190 or 29CFR 1910.1030).
- If infectious substances come in contact with the skin of the user, flush the area with water and seek medical advice.
- Wipe off any spilled contaminant immediately from the system.
- If any of the reagents or samples are accidentally swallowed, seek medical attention immediately.
- While the system is in operation, avoid touching any moving parts.

2.1.7 Handling the PC and Printer

- To keep the touch screen, keyboard, and mouse in good working order, prevent all liquids from coming into contact with them.
- This system is not designed ergonomically for extended periods of keyboard activity. If users spend long periods of time (longer than 30 minutes), refer to local RSI guidelines and adjust the workstation as needed to ensure a comfortable position and take frequent breaks.
- See the Personal Computer and Printer (option) Operation Manuals for information on operating those devices safely.

2.1.8 Precautions for Operating the System

- Be careful when placing calibrators, controls, and patient samples on the instrument for testing. Incorrect placement of calibrators, controls, or samples may result in erroneous analysis.
- After transferring the analysis results to a host computer, check the sample numbers and sample IDs. Transfer all data correctly.
- Operate this system in accordance with the procedures described in this guide. Improper operation may cause improper results, or could result in system failure.

2.1.9 Ensuring Optimal Analytical Performance

Substances such as Lipemia, Icterus, and Hemolysis can interfere with test results. Refer to the reagent Instructions for Use (IFU) for specific substance interference information.

2.1.10 Performing Important Checks at Analysis

To ensure the validity of analytical data:

- Verify system maintenance is performed adequately.
- Verify the quality of Deionized (DI) water is within specifications.
- Check the probe washing and cuvette washing functions in daily maintenance.
- Check the samples for contaminants (dust, fibrin, and particulate matter).
- Check the quantity of each sample and that no bubbles are present.
- Verify all tests have passed calibration, and calibration is not expired.
- Check the quality control data.
- Check the individual analysis results for flags.
- Check an obtained analysis result and the control sample measurement results obtained before and after the analysis result. Verify there is no abnormality in these results.
- Check the reaction data.
If any flag (*,?, @, \$, D, B,!) is generated in relation to the reaction OD, check the processed reaction data immediately before and after the flagged abnormal result. If any abnormality is present, check the cuvettes and the cuvette wash nozzle unit for an overflow. Recheck any processed results before and after the flagged result.

2.1.11 Handling Reagents, Wash Solutions, Calibrators, and QC Samples

- Use the appropriate reagent, calibrator, and control to analyze samples. These products are produced commercially by reagent manufacturers. For information about which reagent to use, consult the reagent manufacturer or distributor.
- Strictly adhere to any safety instructions supplied with reagents, calibrators, and QC samples. MSDS information for Beckman Coulter products can be found on the Beckman Coulter website.
- To use reagents in the system, follow the instructions in this guide and those from the reagent manufacturer or distributor. Avoid excessive reagent agitation, which can cause bubbles. If bubbles are visible on the surface of the reagent, remove them. Verify the reagent bottles are placed securely on the reagent tray with the appropriate adapters and partitions as required. If the bottles are tilted, appropriate results may not be obtained, or the reagent probe may be damaged.
- Prepare reagents, wash solutions, calibrators, and QC samples in accordance with the Instructions For Use (IFU), paying particular attention to any reconstitution, mixing, and pretreatment instructions.
- Follow all applicable warnings or advice regarding carryover effects between analysis tests. If a reagent is contaminated with another reagent during analysis operation, results may be affected. The actual effect of interference differs depending on the reagent. For detailed information, contact the reagent manufacturer or distributor. For information about how to check the interference between analysis tests, contact Beckman Coulter Technical Services.

2.1.12 Handling Samples

Samples available for analysis

- This system is designed to analyze serum, plasma, urine, and other sample types. Other refers to other body fluids such as cerebrospinal fluid (CSF). Some samples cannot be analyzed depending on the analysis test, reagent, and sample tubes used. Refer to Beckman Coulter Technical Services for questions regarding reagent and sample tube type.
- Use serum or plasma that is clot free, or urine that is free from suspended matter. If serum or urine contains clots or suspended matter, the probe may clog and adversely affect the analysis results.
- Chemicals present in the sample (medicine, anti-coagulant, preservative, and so forth.) may significantly interfere with the results.
- Highly viscous samples may interfere with the testing of the samples and the reliability of data.
- Sample to Sample carryover is one potential source of analytical error in the clinical laboratory. Do not use the same sample run on an AU Chemistry system for analysis of analytes for which a small quantity of carryover could adversely affect the results.

Precautions in handling and storing samples

Refer to the Instructions for Use (IFU) for each test for proper sample collection and storage. Improper storage of samples may alter the analyte in a sample. For example, refrigeration of blood increases K (potassium) in the blood if the serum is not separated from the cells.

Pretreating samples

- Use only blood collection tubes and sample tubes specified by Beckman Coulter.
- Serum and plasma specimens should be adequately centrifuged and then separated from blood cells as soon as possible, to reduce the risk of interference. Prior to analysis, specimens should be free from suspended matter, such as fibrin. While the system has a sophisticated clot detection mechanism, this mechanism is not able to detect all clots. Carefully inspect the samples.
- Urine samples should be collected using appropriate preservatives and any suspended matter removed by centrifugation prior to analysis (CLSI GP16-A2).
- Verify that any anticoagulants or collection devices that employ a barrier are compatible with the test reagent being used. Refer to the Instruction for Use for the specimen types that are suitable, validated sample types. Take care when using sample tubes containing barriers or gels. Verify the suitability of all collection devices in use.
- For information about whether a serum separating agent is appropriate or not, contact the chemical reagent manufacturer or distributor.
- When using blood collection tubes containing a separating medium, verify that there is an adequate amount of serum to avoid contaminating or blocking the sample probes with the separating medium.
- Verify an adequate amount of sample is present for correct sampling to occur. For example, if the absolute minimum sample volume for 20 tests is in a sample (plus the dead volume), the

small amount of wash water left on the sample probe may dilute the volume of sample left in the tube.

- Prevent sample evaporation and contamination prior to analysis.
- Make sure no bubbles are present in the sample.

2.1.13 Managing Liquid Waste



This system is designed to discard the concentrated waste liquids (mixture) and washing waste fluids (wash water and wash solutions) separately.

- Treat and handle all liquid waste as potentially infectious.
- Before disposal, some liquid waste and mixtures may require special treatment. For proper waste disposal, refer to relevant local, state, and other governing authority guidelines.
- Some substances in the reagents, quality control (QC) samples, calibrators, and wash solutions are regulated under the pollution ordinance and effluent standard. Treat such substances in accordance with the effluent standard applied to the facilities, consulting the relevant reagent manufacturer or distributor.

2.1.14 Managing Solid Waste



- All solid waste should be handled and treated as potentially infectious.
- Before disposal some waste solids and mixtures may require special treatment. For proper waste disposal, refer to relevant local, state, and other governing authority guidelines.
- Any used or replaced peristaltic tubes, mixing bars, sample probes, reagent probes, cuvettes and wash nozzles should be handled as infectious waste materials. When disposing of these materials, implement appropriate treatment in compliance with the law.

2.1.15 Preventing Water Leaks

To prevent water leaks, ensure water supply and drainage hoses are fitted by Beckman Coulter authorized personnel in accordance with local guidelines.

2.1.16 Electromagnetic Wave and Noise Precautions

- Do not locate this system near equipment generating extreme levels of electronic noise.
- Do not use mobile or cordless telephones and transceivers in the room where the system is installed.
- Do not use medical equipment that may be susceptible to malfunctions caused by Electric Magnetic Field (EMF) near the analyzer Data Processing Unit (DPR) or the monitor.

2.1.17 Replacing Parts and Routine Maintenance

To verify system performance, maintain and inspect the system periodically by replacing the parts according to the instructions in this guide.

- Calibration may be required after replacement of key parts such as syringes or probes. After any part replacement or significant maintenance, it is strongly recommended that QC analysis is performed. If any shifts are observed, calibrate the system.
- Have and follow a maintenance schedule for this system, refer to [CHAPTER 8, Maintenance](#) for recommended maintenance. System performance and safe operation cannot be guaranteed if the system is not maintained using these guidelines.
- Create a maintenance routine for the computer software and hardware, including frequent backing up of data containing analysis parameters, results history, and the alarm log list file. For details on backing up data, refer to [7.8.2 Save or Load Parameters](#) in chapter 7.
- Back-up discs should not be stored on-site. Keep one copy on-site for reference and one copy off-site.
- Only Beckman Coulter authorized engineers are authorized to replace the fuse near the breaker on the back of the rack feeder unit.

2.1.18 Setting Analysis Parameters

Before using the system for the first time, parameters for the reagent and sample quantity, measurement wavelength, calibrator values, and so forth must be set. Enter test specific parameters from the chemistry setting sheet to ensure optimum system performance. Any update to these settings should be entered into the system immediately. For details on setting analysis parameters, refer to [CHAPTER 4, Parameters](#).

2.1.19 Precautions for Using the Analyzer Independently

The computer hardware should be dedicated to running the system software only and should never be connected to the Internet except when instructed to do so by Beckman Coulter, in order to isolate it from harmful software viruses.

2.1.20 Precautions for Using External Storage Unit

It is possible to save and load analysis data and parameters between the AU480 and an external storage unit.

- Format the floppy disk for data or parameters. Refer to [7.8.1 Save Data to External Media](#) and [7.8.2 Save or Load Parameters](#). Set the write protect tab to the LOCK position before inserting it into the computer.
- Run a virus check on a separate computer for floppy disks, CD-Rs, or USB flash drives and verify no viruses are detected before inserting the media into the analyzer computer.
- When using a CD-R, write data on the CD-R and set it to "unrecordable."

TIP Virus pattern files are information files necessary for virus detection. Update antivirus software with the latest virus pattern files from the anti-virus software manufacturer on a regular basis. Contact the antivirus manufacturer if needed.

2.1.21 Cleaning Contaminants from the Covers

Wipe up spills with a damp or dry cloth.

2.1.22 Other Precautions

If the reagents or samples come into contact with the mucous membranes, or if they are accidentally swallowed, immediately follow the instructions given in the specific reagent Material Safety Data Sheets (MSDS) and seek immediate medical attention.

Keep the analyzer covers closed except for startup procedures and maintenance. If the covers are open for extended periods of time, excess condensation can be generated in the reagent refrigerators and cause errors.

2.1.23 System Disposal

The disposal of this system may require special treatment before being discarded. Observe local, state, and federal regulations relative to disposal.



DISPOSAL OF ELECTRICAL INSTRUMENTATION



It is very important that customers understand and follow all laws regarding the safe and proper disposal of electrical instrumentation. The symbol of a crossed-out wheeled bin on the product is required in accordance with the Waste Electrical and Electronic Equipment (WEEE) Directive of the European Union. The presence of this marking on the product indicates that the device:

1. Was put on the European Market after August 13, 2005.
2. Is not to be disposed via the municipal waste collection system of any member state of the European Union.

For products under the requirement of WEEE directive, contact Beckman Coulter Sales or Beckman Coulter Technical Service for the proper decontamination information and take back program which will facilitate the proper collection, treatment, recovery, recycling, and safe disposal of the device.

FOR THE JAPANESE MARKET:

This AU480 system is an industrial waste subject to special control as an infectious waste, if it is discarded, according to "Waste Disposal and Public Cleaning Law." Implement appropriate treatment in compliance with the law prior to disposal.

2.2 Installation Environment Precautions

Although this is not an installation guide, it is still important to be aware of requirements described in this section:

[2.2.1 Installation Environment](#)

[2.2.2 Installation Space Requirements](#)

2.2.1 Installation Environment

To operate this system safely and accurately, ensure that the installation room:

- Is not subject to direct sunlight.
- Is not excessively dusty or subject to large amounts of airborne particles. This system is designed to withstand up to pollution degree 2 as defined by IEC and UL standards.
- Is level, with a gradient less than 1/200.
- Is not subject to vibration.
- Has a floor that can support at least 500 kg (1100 pounds). This weight includes the personal computer attached to the system.
- Is located less than 6,561 feet or 2,000 meters above sea level.
- Contains no corrosive gases.

Electrical and Noise Conditions

The power source must be prepared before delivery of this system. The site should:

- Have a power connector within 33 feet, or 10 meters of the location of the system.
- Have a 20A capacity of the circuit breaker on the power switchboard.
- Have a power source with maximum voltage fluctuations ($\pm 10\%$) and transient overvoltage less than 2500V.

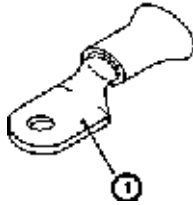
TIP To avoid electrical damage to the system due to uneven current, use an uninterruptible power supply (UPS) to connect the system to electrical power. For detailed information, contact Beckman Coulter Technical Services.

- Verify that the system is always grounded. The grounding terminal should be less than 100 Ω of grounding resistance defined in the technical standards for electrical facilities.
- Not locate this system near equipment that generates extreme levels of electromagnetic or electrical noise.
- Not use mobile or cordless telephones and transceivers in the room where the system is installed.
- Not use medical equipment that may be susceptible to malfunctions caused by Electric Magnetic Field (EMF) near the analyzer Data Processing Unit (DPR) or the monitor.

⚠ WARNING

Make sure to connect all the grounding terminals provided on the system and distribution panel to ground. Failure to ground the terminals could cause electric shock and system malfunction.

Figure 2.1



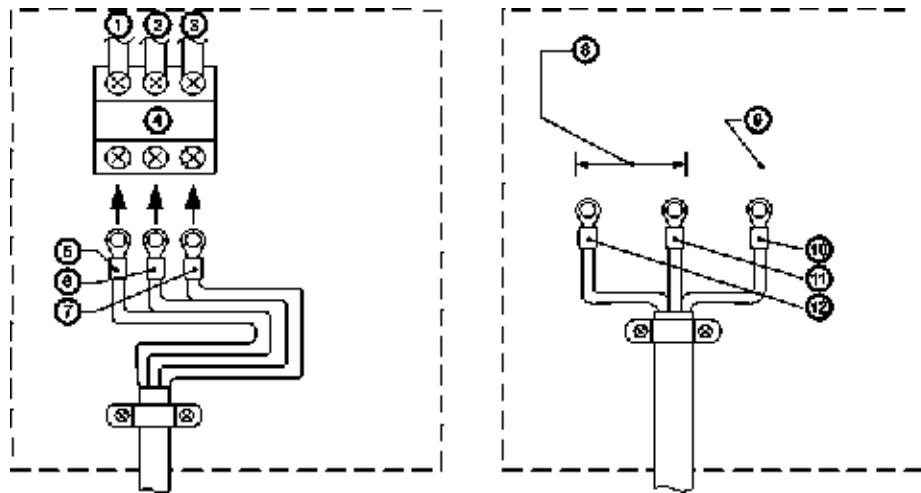
1. Crimp terminal hole diameter 5.4 mm

⚠ CAUTION

Power cable connection should be performed by Beckman Coulter authorized technical personnel.

- When connecting the power cables to the system, connect the grounding terminal first. To disconnect the cables, disconnect the grounding terminal last.
- Connect the power cables to the distribution panel as shown below.

Figure 2.2



- | | |
|---|---|
| <ol style="list-style-type: none"> 1. Gray 2. White 3. Green 4. Terminal board 5. Black 6. White (All markets except Europe), or Blue (Europe market) 7. Green (All markets except Europe) or Yellow/Green (Europe market) | <ol style="list-style-type: none"> 8. Connect these terminals to the power source specified for this system 9. Connect this terminal to a grounding terminal that measures less than 100 Ω 10. Green (All markets except Europe), or Yellow/Green (Europe market) 11. White (All markets except Europe), or Blue (Europe market) 12. Black |
|---|---|

For Europe, Black/Blue/Yellow Green is required for Live/Neutral/Ground.

For all markets except Europe, Black/White/Green is required for Live/Neutral/Ground.

Temperature and Humidity Conditions When in Use

Heat output by the system during operation is approximately 8,820 kJ/h (8361 BTU).

When the specified room temperature and humidity ranges fluctuate, the system data may not be reliable. When the system is in operation, make sure the following requirements are met:

- The temperature of the installation room is between 18 °C (64 °F) and 32 °C (90 °F).
- The temperature does not fluctuate more than ± 2 °C (3.6 °F).
- The humidity is between 20% RH and 80% RH with no condensation.
- The system is not exposed to direct airflow from air conditioners.
- The site is well ventilated. Use ventilation equipment if necessary.

CAUTION

The installation site must be well ventilated. To ensure proper location dimensions, refer to [2.2.2 Installation Space Requirements](#).

Temperature and Humidity Conditions When Not in Use

Ensure that:

- The temperature is between 5 °C (41° F) and 40 °C (104° F).
- The humidity is between 15%RH and 90%RH.

Water Supply

The water supply and liquid waste facilities must be installed with the following requirements:

- The system is located within 10m (33 feet) of the DI water outlet. A drain should be within 10m (33 feet) and less than 1.5 meters high.
- The purity of the DI water should have the electric conductivity of 2 $\mu\text{S}/\text{cm}$ or less (resistivity: 0.5 $\text{M}\Omega \cdot \text{cm}$ or more).
- Water should be filtered using a filter of 0.5 μm or less.
- The temperature of the DI water should be between 5 °C (41° F) and 28 °C (83° F).
- The pressure of the DI water should be between $0.49 \times 10^5 \text{ Pa}$ and $3.92 \times 10^5 \text{ Pa}$ (or 7 to 57 psi).
- DI water supplied to the system should not contain excessive air bubbles.
- Average water consumption is approximately 20 liters per hour.
- Maximum water demand is approximately 0.6 liter per minute.

The system includes the following tubing:

- Water supply hose: Braided hose 12 mm (ID) x 18 mm (OD), L=10 m (33 feet), 1 piece.
- Exhaust Air hose: Braided hose 12 mm (ID) x 18 mm (OD), L=10 m (33 feet), 1 piece.
- Waste liquid hose: Braided hose 15 mm (ID) x 22 mm (OD), L=10 m (33 feet), 2 pieces.



If the tap water temperature exceeds the optimal temperature range for the deionizer, consult the deionizer manufacturer.

When using the existing water supply tubing and deionizer, verify it is micro-organism free.

TIP The water pressure for this system operates at a range from 0.49×10^5 to $3.92 \times 10^5 \text{ Pa}$. For the correct water pressure for the deionizer, contact the deionizer manufacturer.

Use of a reverse osmotic membrane as the deionizer is recommended. For detailed information, contact Beckman Coulter Technical Services.

Drainage and Exhaust



Follow local, state, and federal regulations for disposal of all liquid and infectious waste if applicable.

The system discharges waste liquids by forced drain and moist air containing the components of waste liquids.

- Condensed waste liquid: Compound liquid of sample and reagent retrieved from cuvettes and wash solution.
- Diluted waste liquid: Waste liquid used for washing cuvettes, mix bars, and so forth.

The drainage and exhaust should meet the following conditions:

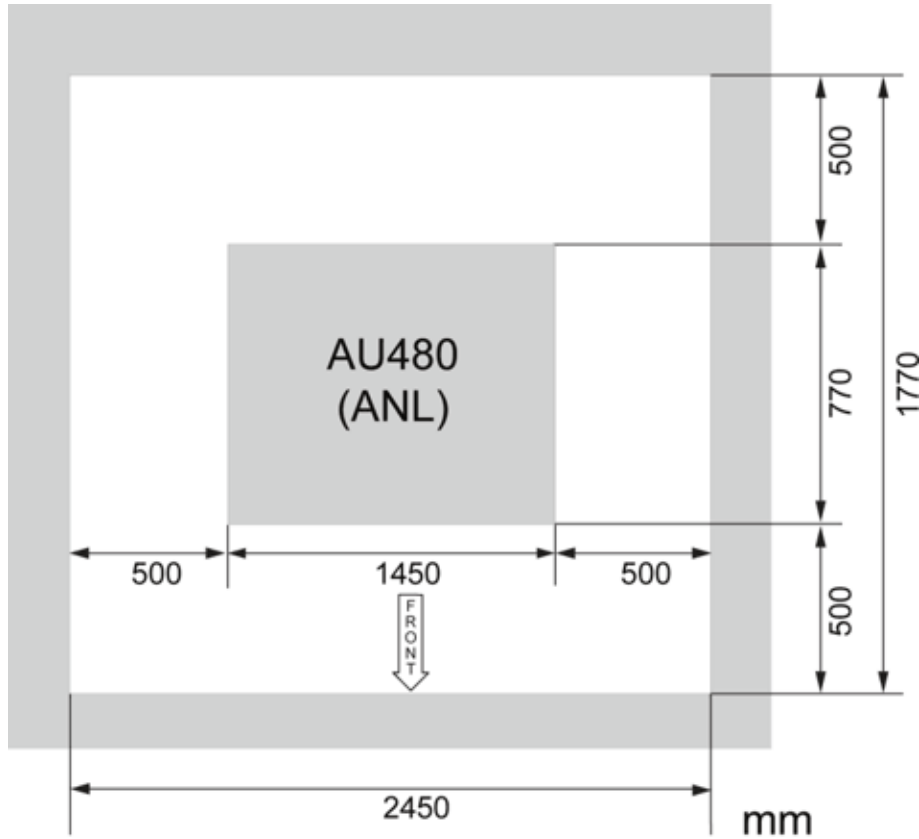
- The drain hole should be located within 10 m (33 feet) from this system.
- The drain should be connected to infectious waste collection tank as required by law.
- The drain must be located no higher than 1.5 m and the exhaust no higher than 0.1 m above the system installation floor.
- The ends of exhaust air hoses and the waste liquid hoses, which are inserted into the drain, should be kept above the liquid level of the drain.
- Ensure the liquid waste hoses are not bent or crushed.
- Drainage capability for concentrated and diluted liquid waste is as follows:
 - Concentrated waste liquid: 6 L/hour
 - Diluted waste liquid: 14 L/hour

2.2.2 Installation Space Requirements

The System

This system requires space of at least 500 mm (20 inches) from the wall around it for safe installation and maintenance.

Figure 2.3



Dimensions:

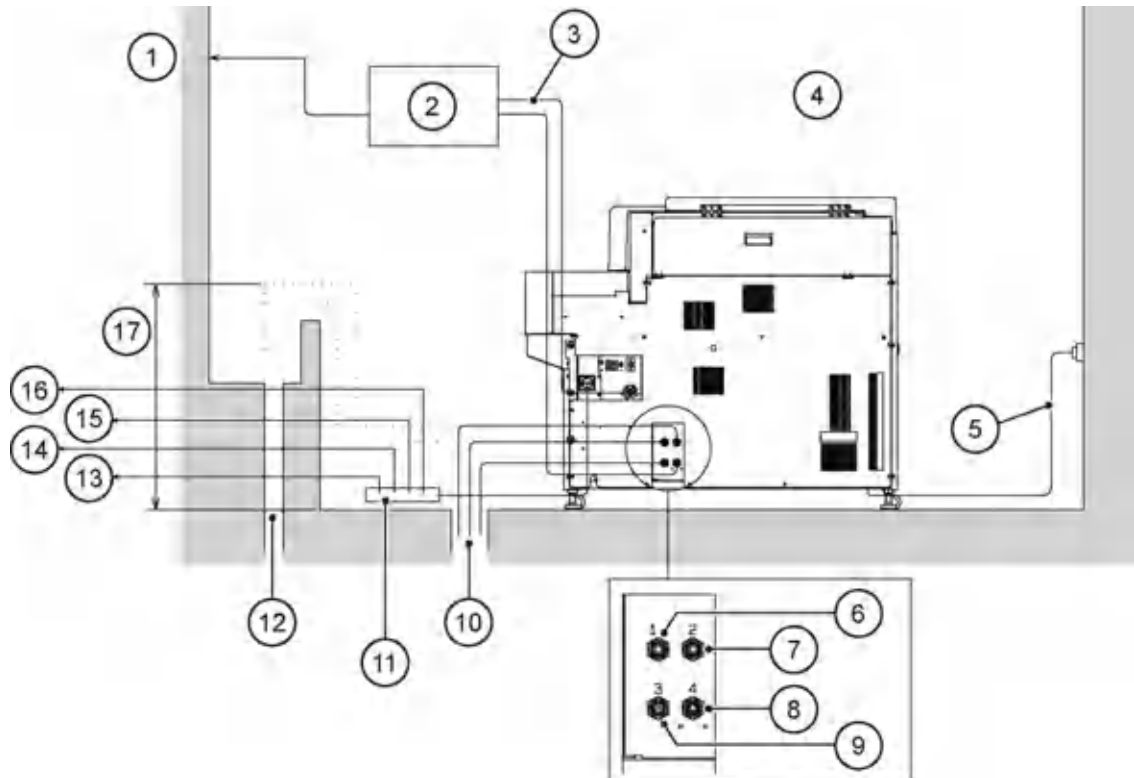
	Width	Depth	Height	Weight
Analyzer	1450 mm (5 feet)	770 mm (2.5 feet)	1205 mm (4 feet)	420 kg (925 pounds)
PC/Monitor (when mounted on analyzer)	1450 mm (5 feet)	790 mm (2.6 feet)	1570 mm (5.1 feet)	420 kg (925 pounds)

A printer is optional and requires additional space.

2.2.3 System Connections

Devices connected to the system

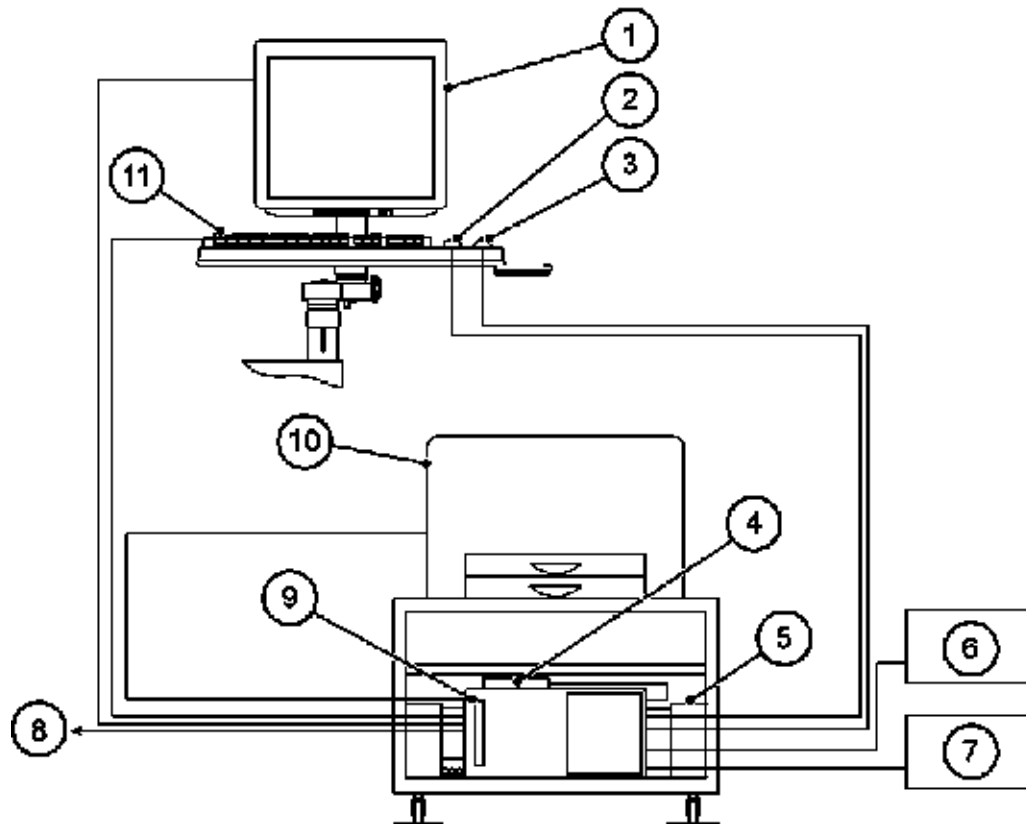
Figure 2.4



- | | |
|--|-------------------|
| 1. To deionizer | 10. Drain hole |
| 2. Water supply equipment | 11. Power strip |
| 3. Water supply equipment connector | 12. Drain hole |
| 4. Rear view of system | 13. To speaker |
| 5. Power cable (10 m) | 14. To Display |
| 6. Concentrated waste liquid hose (10 m) | 15. To HUB |
| 7. Washing waste liquid hose (10 m) | 16. To DPR |
| 8. Water supply tube (10 m) | 17. 1.5 m or less |
| 9. Exhaust air host (10 m) | |

Devices connected to DPR

Figure 2.5



- | | |
|---------------------------------------|----------------------|
| 1. Monitor | 7. Router (option) |
| 2. Mouse | 8. To ANL |
| 3. Hand scanner (option) | 9. DPR |
| 4. External memory unit (HD) (option) | 10. Printer (option) |
| 5. Speaker | 11. Keyboard |
| 6. Host computer | |

TIP The cable connecting the DPR and ANL must be 5 m (16 feet) in length.

CAUTION

The printer should use a power outlet located in the facility and not a system power outlet located on the system. Use of a system outlet could trip the system circuit breaker interrupting power.

2.3 Major Specifications of the System

2.3.1 System Specifications

2.3.2 Sample Barcode Specifications

2.3.1 System Specifications

System Specifications	
1. System size and mass	
	Analyzer (ANL): 1450 mm (W) x 770 mm (D) x 1205 mm (H), 420 kg
2. Water supply and drain	
DI water conductivity	2.0 μ S/cm or less (water transmitted through a filter of 0.5 μ m or less)
Water pressure	0.49 \times 10 ⁵ to 3.92 \times 10 ⁵ Pa
Water consumption	Average: 20 L/hour (50/60 Hz) Maximum water demand: 0.6 L/minute (50/60 Hz)
DI water temperature	5 to 28 °C (41 to 83 °F)
Water-supply hose	12 mm x 18 mm x 10 m
Concentrated waste solution hose, diluted waste solution hose	15 mm x 22 mm x 10 m
Exhaust hose	12 mm x 18 mm x 10 m
Drainage height	1.5 m or less from the floor
Exhaust outlet	0.1 m or less from the floor surface
3. Operating environments	
Temperature	18 to 32 °C (64 to 90 °F)
Temperature fluctuation	\pm 2 °C (3.6 °F) or less during measurement
Humidity	20 to 80% RH (with no condensation)
4. Power supply	
Voltage, Frequency	AC 208 V 50/60 Hz (USA) AC 230 V 50/60 Hz (Europe) AC 220 V 50/60 Hz (Asia) AC 240 V 50/60 Hz (Australia) AC 200 V 50/60 Hz (Japan)
Maximum rated power consumption	3.5 kVA

The following table summarizes the general specifications.

General Specifications	
1. Method of analysis	
	Discrete method
2. Configuration	
	Analyzer Data processor
3. Option	
	ISE Printer Hand scanner Water supply equipment External storage device Monitor arm unit
4. Type of sample	
	Serum, plasma, urine, other fluids with viscosities in the same range as serum
5. Number of simultaneous analytes	
	Maximum of 60 photometric + 3 ISE tests on board
6. Throughput	
	Maximum 400 photometric tests/hour or 800 photometric + ISE tests/hour Maximum 200 samples/hour when analyzing only ISE tests
7. Data input methods	
	Touch screen Keyboard Mouse Online (RS232C) Hand scanner CD
8. Data output methods	
	Monitor display Printer (option) Online (RS232C) External storage device (option) Internal hard disk

This system complies with IEC60825-1:2007.

BD indicates a Becton Dickinson part number. The BD tube or its equivalent can be used.

Cup or Tube Available for Racks or STAT Table			
Cup or Tube	Size	Part Number	Dead Volume (µL)
Hitachi cup	2.0 mL	MU853200	50
Auto aliquot tube	13 mm	2910034	90
Serum Separator Tube	13 x 100 mm	BD 367986	4 mm below sample surface
Serum Separator Tube	16 x 100 mm	BD 367988	4 mm below sample surface
Lithium heparin with gel separator (light green top)	13 x 75 mm	BD 367960	4 mm below sample surface
Lithium heparin with gel separator (light green top)	13 x 100 mm	BD 367962	4 mm below sample surface
Lithium heparin (green top)	13 x 75 mm	BD 367884	4 mm below sample surface
Lithium heparin (green top)	13 x 100 mm	BD 367886	4 mm below sample surface
Primary tube (red top)	13 x 75 mm	BD 366668	140
Primary tube (red top)	13 x 100 mm	BD 367815	140

Cup Nested (Inserted) in Tube Available for Racks				
Cup, Size	Part number	Tube	Part number	Dead Volume (µL)
DxC cup, 2.0 mL	652730	DxC transfer	979272	60
Access 2 cup, 2.0 mL	81902	DxC transfer	979272	60
Access 2 cup, 1.0 mL	81915	13 x 75 mm	BD 367960 BD 367884 BD 366668	140
Hitachi cup, 2.0 mL	MU853200	SST 16x100 mm	BD 367988	50
EZ Nest cup	1270013000	13 x 75 mm	BD 367960 BD 367884 BD 366668	60
EZ Nest cup	1270013000	13 x 100 mm	BD 367962 BD 367886 BD 367815	60
EZ Nest cup	1270016000	16 x 75 mm	BD 364976	50
EZ Nest cup	1270016000	16 x 100 mm	BD 367988	50

Precautions, Installation, and Specifications

2.3 Major Specifications of the System

Cup Nested (Inserted) in Tube Available for STAT Table				
Cup, Size	Part number	Tube	Part number	Dead Volume (µL)
DxC cup, 2.0 mL	652730	DxC transfer	979272	60
Access 2 cup, 2.0 mL	81902	DxC transfer	979272	60
Access 2 cup, 1.0 mL	81915	13 x 75 mm	BD 367960 BD 367884 BD 366668	140
EZ Nest cup	1270013000	13 x 75 mm	BD 367960 BD 367884 BD 366668	60
EZ Nest cup	1270016000	16 x 75 mm	BD 364976	50

Sampling	
Sample Capacity	
Maximum 80 samples (8 racks)	
Sample dispensing system	
Micro-syringe system	
The system is provided with the following functions:	
<ul style="list-style-type: none"> • Liquid level detection • Clot detection • Bubble detection • Collision detection • Pre-dilution 	
Sample Volume	
Normal dispensing	1.0 to 25.0 µL/test, in steps of 0.1 µL
Dispensing with dilution	1.0 to 20.0 µL/test, in steps of 0.1 µL
Rack type: NE racks are required on the system	
Blue rack Yellow rack Green rack White rack Red rack Orange rack	

The following table summarizes the specifications for reagent setting and reagent dispense.

Reagents	
1. Storage capacity	
Refrigeration unit	76 with serial reagent bottle capability
2. Refrigeration	
Refrigeration temperature	4 to 12 °C (39.2 to 53.6 °F)
3. Reagent setting method	
Turn table method	
4. Type of reagent	
Normal concentration reagent	
Highly concentrated reagent	
5. Reagent dispensing system	
Micro-syringe with collision detection function for the probe	
6. Number of reagent steps	
Maximum 2 steps	
7. Reagent volume setting range	
Normal Dispensing: 10 to 250 µL in 1.0 µL increments	
Dilution Dispensing: 10 to 240 µL in 1.0 µL increments	

The following table summarizes the reaction unit specifications.

Reaction unit	
1. Reaction incubation method	
Dry bath system	
2. Reaction temperature	
Dry bath: 37± 0.3 °C (98.6± 0.5 °F)	
3. Reaction solution amount	
90 to 350 µL (5 x 5 mm cuvette)	
4. Reaction time	
Maximum 8 minutes 37.5 seconds	
5. Mixing system	
Rotative mixing bar system	
6. Reaction cell	
Glass square cuvette (optical path length: 5 mm)	
7. Reaction line	
Rotary disk system: 88 cuvettes	

The following table summarizes the analysis processing specifications.

Analytical method	
1. Photometric points	
	28
2. Type of Measurement	
	End point assay Rate assay Fixed point assay Electrode method (ISE) (option)

The following table summarizes the optical system specifications.

Optical system	
1. Photometer	
	Multi-wavelength diffraction grating spectrophotometer
2. Photometric Modes	
	Monochromatic or bichromatic
3. Wavelengths	
	340 to 800 nm (13 steps of 340, 380, 410, 450, 480, 520, 540, 570, 600, 660, 700, 750, and 800 nm)
4. Photodetector	
	Silicon photodiode array
5. Light source	
	Halogen lamp 12 V/20 W
6. Measurable absorbance range	
	0 to 3.0 Abs (converted in units of 10 mm of optical path length)
7. Photometric resolution	
	0.0001 Abs

The following table summarizes the data processing specifications.

Data processing							
1. Storage capacity							
	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%;">Data storage capacity</td> <td>Hard disk</td> </tr> <tr> <td>Patient samples</td> <td>100,000 samples 9999 samples/index Reaction Monitor data: A maximum of 10,000 tests per index and a maximum of 100,000 tests in multiple indexes</td> </tr> <tr> <td>QC samples</td> <td>999 samples/index Maximum 300 indexes</td> </tr> </table>	Data storage capacity	Hard disk	Patient samples	100,000 samples 9999 samples/index Reaction Monitor data: A maximum of 10,000 tests per index and a maximum of 100,000 tests in multiple indexes	QC samples	999 samples/index Maximum 300 indexes
Data storage capacity	Hard disk						
Patient samples	100,000 samples 9999 samples/index Reaction Monitor data: A maximum of 10,000 tests per index and a maximum of 100,000 tests in multiple indexes						
QC samples	999 samples/index Maximum 300 indexes						
2. Data processing unit configuration							
	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%;">Hard disk: 200 GB or more</td> </tr> <tr> <td>Memory capacity: 2 GB or more</td> </tr> <tr> <td>Keyboard: 101-109 keyboard</td> </tr> <tr> <td>17-inch touch panel display</td> </tr> <tr> <td>CD-R drive</td> </tr> <tr> <td>Printer (option)</td> </tr> </table>	Hard disk: 200 GB or more	Memory capacity: 2 GB or more	Keyboard: 101-109 keyboard	17-inch touch panel display	CD-R drive	Printer (option)
Hard disk: 200 GB or more							
Memory capacity: 2 GB or more							
Keyboard: 101-109 keyboard							
17-inch touch panel display							
CD-R drive							
Printer (option)							

The following table summarizes the calculation processing specifications.

Calculation processing	
1. Calculation	
	Calibration
	Analytical method End point assay Rate assay Fixed point assay Electrode method (ISE) Calibration method ACAL AA ACAL AB ACAL 2AB to ACAL 7AB 4 MC to 10 MC MCAL MB MCAL 2MB to MCAL 7MB Calibration curve type Straight line Polygonal line Quadratic expression Tertiary expression (2 types) EIA-TYPE 1 to 4 Spline
	Correction
	Water blank correction Reagent blank correction Sample blank correction Data correction
2. Quality control (QC)	
	QC samples Maximum 10 types/test Maximum 100 types in total
	Quality control method Shewhart day-to-day management (Levey-Jennings method) Multi-rule control (Westgard method) Twin-plot control

The following table summarizes the input/output specifications.

Input/Output	
1. Worksheet	
	Routine sample worksheet Emergency sample worksheet Repeat sample worksheet QC sample worksheet Calibration worksheet
2. Data input/output	
Test requisitions	Keyboard entry, real-time online, batch online
Analysis result output	Real-time, batch online
3. Input/output from/to an external device	
Online input/output	RS232C
Offline output	CD-R External storage device (HD) (option)

The following table summarizes the ISE (option) specifications.

ISE (option)			
1. Reagents			
	ISE Buffer	2L bottle	
	ISE Mid Standard	2L bottle	
	ISE Reference	1L bottle	
2. Measurement method			
	Indirect (diluted) ion-selective electrode		
3. Measurement items			
	Na, K, and Cl ions in serum/urine		
4. Throughput			
	200 samples/hour		
5. Sample volume			
	20 µL plus 10 µL DI water		
6. Dilution ratio			
	32.4 times (DI water 10 µL, buffer solution 618 µL)		
7. Measuring range (unit: mmol/L)			
	Test item	Serum	Urine
	Na	50 to 200	10 to 400
	K	1.0 to 10.0	2.0 to 200
	Cl	50 to 200	15 to 400
8. Calibration curve			
	Automatic calibration curve: Measures the high-concentration calibrator and low-concentration calibrator to set two points on the chart.		
9. Data correction			
	Enables manual calibration chart correction (M-CAL) and automatic calibration chart correction (A-CAL, 3-point regression CAL).		
10. Drift correction			
	Automatic correction: Measures the electrical potential of MID solution for each sample to perform drift correction.		
11. Types of consumables and approximate consumption			
	Name	Approximate daily consumption	
	ISE buffer solution	Approx. 180 mL (in case of 200 serum samples/day)	
	ISE MID solution	Approx. 260 mL (in case of 200 serum samples/day)	
	ISE REF solution	Approx. 35 mL (in case of 200 serum samples/day)	
	ISE Clean solution	Approx. 1 mL (in case of 200 serum samples/day)	

The following table summarizes the monitor arm unit (optional) specifications:

Monitor arm unit (optional)
1. Maximum weight of display: 8 kg
2. Maximum weight of keyboard table: 2kg

2.3.2 Sample Barcode Specifications

Analysis can be executed by using a barcode label as a sample ID. The following items define the barcode specifications used for identifying samples of the AU480.

Barcode type

Sample barcodes include the following types:

- NW-7
- CODE 39
- CODE 128, ISBT-CODE 128
- INT (Interleaved 2 of 5)
- Standard 2 of 5

The system can read multiple barcodes when using a mixture of NW-7, CODE 39, CODE 128, INT (interleaved 2 of 5), or Standard 2 of 5.

The specifications of individual barcodes comply with the following standards.

Barcode	Compatible standard
NW-7	JIS-X-0506, USS-NW7
CODE 39	JIS-X-0503, USS-CODE 39
CODE 128	JIS-X-0504, USS-CODE 128
ISBT-CODE 128	ISBT 128
INT (Interleaved 2 of 5)	JIS-X-0502, USS-I2/5

Character font

Barcode	Character font
NW-7	0 to 9
CODE 39	Alphanumerics, special characters
CODE 128	Alphanumerics, special characters
ISBT-CODE 128	Alphanumerics, special characters
INT (Interleaved 2 of 5)	0 to 9
Standard 2 of 5	0 to 9

Barcode digit number

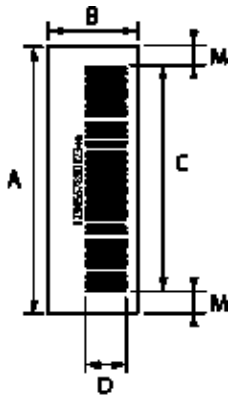
Maximum 26 digits

Label size

The size of sample barcode labels must follow the following specifications. (The unit is in millimeters.)

- Label length (A) < Sample tube length -12
- Label width (B): At least D+10mm, and not so wide that the label interferes with the barcode area.
- Barcode height (D) ≥ 10
- Top/bottom margin (M): shown below
 CODE 128: 10 times the X dimension or 2.54, whichever is larger, or more (quiet zone)
 Other than CODE 128: 3 or more
- Barcode area (C) = A - 2 x M

Figure 2.6



Bar and space widths

Bar and space widths must be as follows.

	NB (narrow bar)	NS (narrow space)	WB (wide bar)	WS (wide space)	G (gap)	X ^(a) (size)
Min	0.165 to 0.2 mm	NB to 1.25 NB	2.2 NB to 3.0 NB	2.2 NB to 3.0 NB	NB to 3.0 NB	0.191 or more
Max	0.2 to 0.5 mm		2.0 NB to 3.0 NB	2.0 NB to 3.0 NB	NB to 3.0 NB	

a. : In case of CODE128

Barcode check character

A barcode can be selected from the following three methods:

1. The check method is used from the following table.
2. No check character is used.
3. No check is performed although a check character is included.

Barcode	Check character method
NW-7	Least significant digit, MODULUS-16
CODE 39	Least significant digit, MODULUS-43
CODE 128, ISBT-CODE 128	Least significant digit, MODULUS-103
INT (Interleaved 2 of 5) and Standard 2 of 5	Least significant digit, MODULUS-10

CODE 128 and ISBT-CODE 128 require a check character. These codes cannot be selected with the above methods 2 and 3.

Barcode label print

Print barcode labels according to the following requirements to maintain readout accuracy.

- PCS value
 If NB (narrow bar) width is between 0.165 and 0.50 mm the PCS value must be 0.60 or more.
 If NB (narrow bar) width is between 0.130 and 0.165 mm the PCS value must be 0.85 or more.

$$\text{PCS Value} = \frac{R_L - R_D}{R_L}$$



R_L : white bar and margin reflection rate
 R_D : black bar reflection rate

- CODE 128: MRD must be 37.5% or more.
- A void on a white bar (damage or print loss on a bar), ink spot (ink stain) and thin spot must meet the following requirements:
 - A spot diameter is 0.05 mm or less.
 - The void is 25% or less in a circular area with a diameter of 0.1 mm.
 - There is no marked blurring.

2.4 System Labels and Displays

Display

The following labels represent the switches and the breaker unit.

ON	OFF	GND Terminal
		





Labels

The following labels are displayed on the system:

- **Stripes**
 Orange stripes affixed to the system surface indicate the movement areas of the mechanisms. Avoid these areas during operation.
- **Warning Labels**
 Identify areas of the system where hazards exist and indicate that care must be taken to avoid serious injury or death.
- **Instruction label**
 Instruction labels are pasted on the relevant locations in addition to the warning labels for the operator to properly operate the system.
 Become familiar with sample test procedures before operating the system and use it with due caution.

Background Colors of Warning Labels

Color	Type	Explanation
Orange	Warning	Labels with an orange background indicate to use caution to avoid serious injury or death. Failure to observe these warnings may lead to serious degradation of system performance or generation of incorrect sample data.
Yellow	Caution	Labels with a yellow background indicate that care or action must be taken to avoid minor injury, sub-optimal system performance, or damage, which could result in other hazards.

Label	Type	Explanation
	Electric	This symbol indicates an area of the system that should not be accessed under any circumstances, due to risk of electrical shock. (Labeling Position: near the inlet of the power code on the rear left side of the analyzer.)
	High Temperature Danger	This symbol indicates the risk of burning by touching the hot photometer lamp directly when replacing it. (Labeling Position: near the light source lamp.)
	Biological Risk	<p>This symbol indicates the use of biohazardous material. Wear protective clothing and follow universal precautions as dictated by local or national regulations (CLSI GP17-A2, ISO15190 or 29CFR 1910.1030).</p> <p>Risk of biohazardous materials such as sample probes, mix bars, sample rack, cuvette wash nozzle, cuvette, sample probe wash well, condensed waste liquid drain hole, ISE sample pot, ISE roller tube, drain hole, and so forth. (Labeling Position: On the surface of the analyzer and the rear cover.)</p>
	Laser Radiation	<p>CLASS 1 LASER PRODUCT complies with IEC60825-1. (Labeling Position: near the power supply on the rear left side of the analyzer.)</p> <p>CAUTION-CLASS 3R LASER RADIATION WHEN OPEN AND INTERLOCKS DEFEATED AVOID DIRECT EYE EXPOSURE (Labeling position: near the interlock switch of the rack feeder unit, near the interlock switch of the large STAT cover, near the small STAT cover, and near the reagent refrigerator cover).</p> <p>CAUTION-CLASS 3R LASER RADIATION WHEN OPEN AVOID DIRECT EYE EXPOSURE. (Labeling Position: near the sample ID barcode reader window for the STAT table and rack feeder unit.)</p>


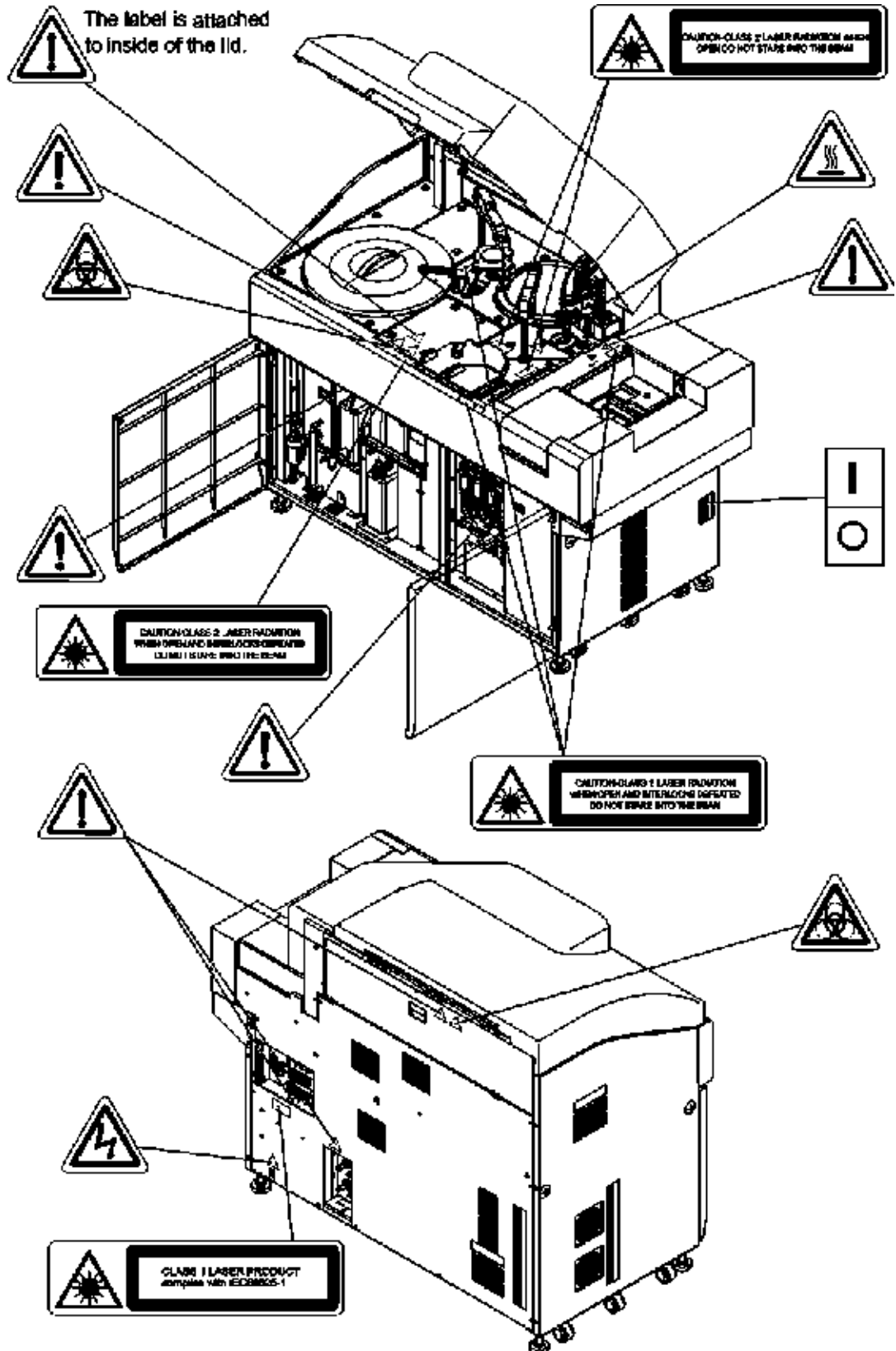
Label	Type	Explanation
	Danger	<p>Personal injury: This symbol indicates areas where a risk of injury due to system movement is possible. Fingers or other body parts should be kept clear of these areas during system operation.</p> <ul style="list-style-type: none"> • Danger of injury by moving parts of the sample probes, reagent probes, mix bars, cuvette wash nozzle unit, and so forth. (Labeling Position: on the analyzer surface and rear cover.) • Danger of injury by operation parts of syringe. (Labeling Position: near the sample, reagent, and wash syringes.) • Danger of injury by moving parts, for example the Wash Solution rolling pump, and so forth. (Labeling Position: near the Wash Solution rolling pump or other moving part.) • Danger of injury by moving parts, for example the ISE roller pump unit, and so forth. (Labeling Position: back of the ISE cover) <p>Danger: Indicates a potentially hazardous situation which, if not avoided, could result in operator's injury and/or serious physical damage.</p> <ul style="list-style-type: none"> • Danger of leak from water supply and discharge unit. (Labeling Position: near the water outlet) • To avoid electrical shock, do not remove the cover connector screws to access the water supply unit. (Labeling Position: near the power outlet of water supply unit (option).) • Do not lean against the PC rack unit (option), which could result in it falling down. (Labeling Position: near the keyboard for the PC rack unit.)

Figure 2.7



System Outline

This chapter provides a general overview of how the system functions. It introduces key processes that are explained in later chapters of this User's Guide.

It also describes the system hardware. This enables the operator to better understand the technical composition of the system.

3.1 How the AU480 Analyzes Samples

- 3.1.1 Reagent Blank
- 3.1.2 End Point Assays
- 3.1.3 Rate Assays
- 3.1.4 Fixed Point Assay
- 3.1.5 Quality Control
- 3.1.6 Summary of Calibration Types
- 3.1.7 Principle of the ISE Measuring Method
- 3.1.8 Principle of the Realtime Water Blank Check

3.2 Key Sub-Processes

- 3.2.1 Computer
- 3.2.2 Sample Identification
- 3.2.3 Sample Transfer
- 3.2.4 Reagent Transfer
- 3.2.5 Reaction Fluid Mixing
- 3.2.6 Reaction Fluid Incubation and Washing
- 3.2.7 Photometric Measurement
- 3.2.8 Online Analysis and Analysis Using Keyboard Entries
- 3.2.9 Sample Identification and Date and Time

3.3 Understanding and Handling Reagents, Calibrators, and Controls

- 3.3.1 Reagents
- 3.3.2 Sample Diluent
- 3.3.3 Calibrator
- 3.3.4 Quality Control Sample
- 3.3.5 ISE Quality Control Material

- 3.4 Understanding the System Hardware
 - 3.4.1 Breakers and Fuse
 - 3.4.2 Operation Buttons
 - 3.4.3 Rack Feeder Unit
 - 3.4.4 STAT Table
 - 3.4.5 Sample Transfer Unit
 - 3.4.6 Reagent Transfer Unit
 - 3.4.7 Mixing Unit
 - 3.4.8 Cuvette Wheel Unit
 - 3.4.9 Photometry Unit
 - 3.4.10 Wash Nozzle Unit
 - 3.4.11 Reagent Refrigerator
 - 3.4.12 Syringe Unit
 - 3.4.13 Tank Storage
 - 3.4.14 Wash Solution Roller Pump
 - 3.4.15 ISE Unit (optional)
 - 3.4.16 Data Processing Unit (DPR)
 - 3.4.17 Touch Screen, Mouse, and Keyboard
- 3.5 Software Description
 - 3.5.1 Organization of Operation Window
 - 3.5.2 Main Button Bar
 - 3.5.3 Home Outline
 - 3.5.4 Menu List Organization and Outline
 - 3.5.5 User Menu Overview
 - 3.5.6 Using the Online Help
 - 3.5.7 Analyzer Modes

3.1 How the AU480 Analyzes Samples

This system performs automated analysis of serum, urine, and other fluids. It measures sample components and automatically generates results.

This section provides an overview of how the AU480 tests samples. It also describes the ISE Measuring Method.

- 3.1.1 Reagent Blank
- 3.1.2 End Point Assays
- 3.1.3 Rate Assays
- 3.1.4 Fixed Point Assay
- 3.1.5 Quality Control
- 3.1.6 Summary of Calibration Types
- 3.1.7 Principle of the ISE Measuring Method
- 3.1.8 Principle of the Realtime Water Blank Check

3.1.1 Reagent Blank

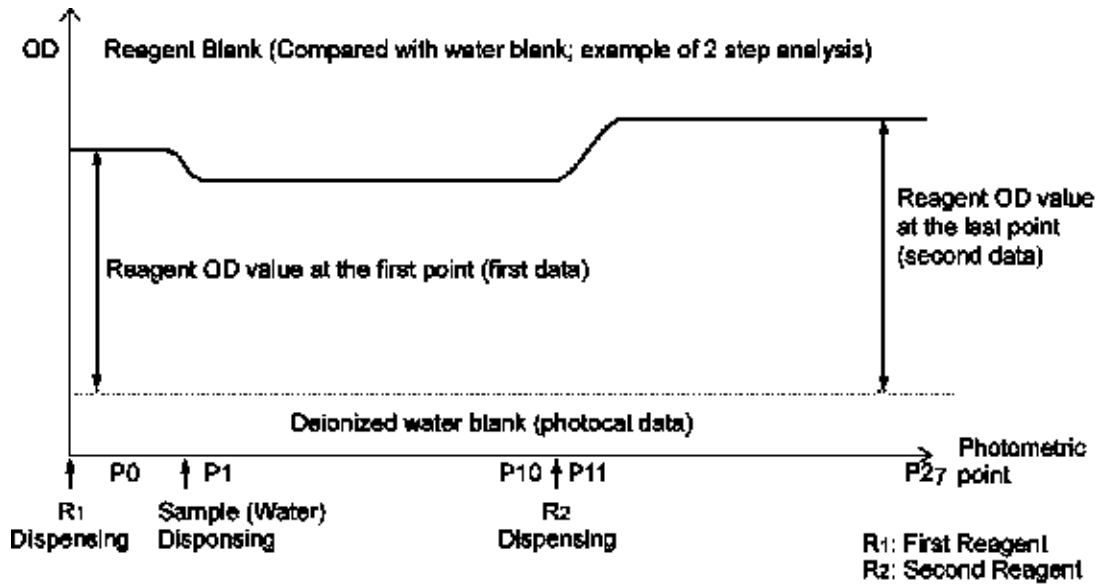
To calculate a measurement value (reaction OD), the reagent blank OD (reagent OD at each photometric point of P0 to P27) and the Deionized (DI) water blank OD values (photocal data) are subtracted from the measured OD of a sample reacted with a reagent.

By performing a reagent blank measurement, the reagent blank OD values (RB) at all photometric points shown in the following chart can be obtained.

Reagent blank is measured using the blue rack. Program position 1 and 2 of the blue racks for serum, urine, other-1, and other-2 in **Parameters > Calibration Parameters > Calibrators**. Typically, position 1 is programmed for serum, urine, other-1, and other-2, and position 2 is not used. Place the sample (DI water) in position 1 of the blue rack.

The system measures up to four replicates of the sample and determines the reagent blank data (reagent blank OD value).

- 1 replicate OD value.
- 2 replicates Mean value of two OD values.
- 3 replicates Mean value of two closest OD values.
- 4 replicates Highest and lowest OD values are discarded and the two remaining OD values are averaged.



The following describes the first point reagent OD value (first data) and last-point reagent OD value (second data).

First point reagent OD value (first data)

- First point reagent OD value (RB) = {first point measured OD value} - {DI water blank (photocal data)}.
- If the first point reagent OD value is outside the reagent OD range that was programmed in **Parameters > Specific Test Parameters > Reagent OD Limit First**, abnormal flags “y” (for over range) or “u” (for under range) are attached to the data.

Last point reagent OD value (second data)

- Last point reagent OD value (RB) = {last point measured OD value} - {DI water blank (photocal data)}.
- If the last point reagent OD value is out of the reagent OD range that was programmed in **Parameters > Specific Test Parameters > Reagent OD Limit Last**, abnormal flags “Y” (for over range) or “U” (for under range) are added to the data.

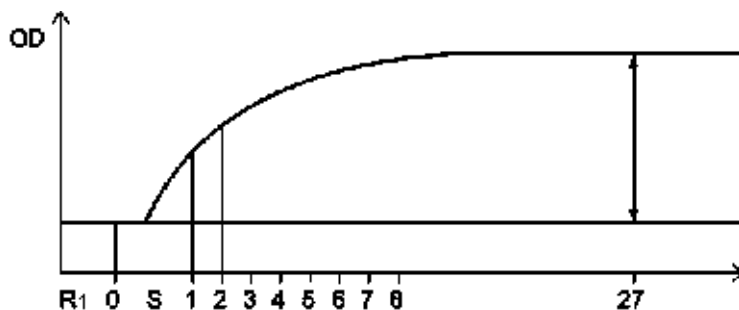
3.1.2 End Point Assays

This section describes the end point assay.

1-point assay

This is a general end point assay that determines the reaction mixture OD from the OD measured at a specified photometric position.

Reaction mixture OD = OD (at specified position) - OD0 (at position 0)



2-point assay (self-blank method)

This is for an end point assay that requires a sample blank adjustment. The OD values before dispensing the reagent 2 should be eliminated as the blank channel. The OD values of the blank channel are subtracted from those measured after dispensing the reagent 2 to obtain correct data without influences from turbidity or color of the serum.

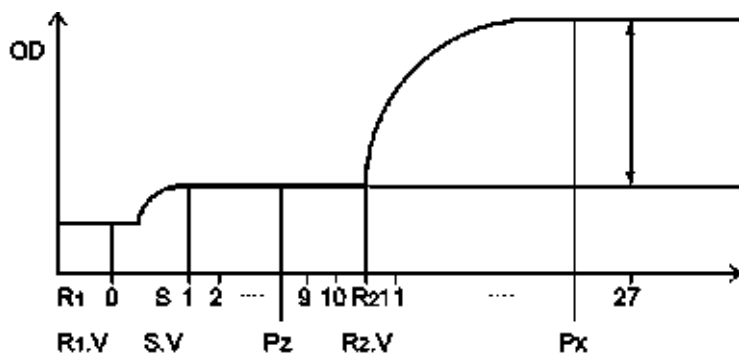
The OD value in this assay is given by the following expression:

$$K2 = \{R1.V / (R1.V + R2.V + S.V)\}$$

$$K3 = \{(R1.V + S.V) / (R1.V + R2.V + S.V)\}$$

$$\text{Reaction OD value} = (Px - K2 \times P0) - (K3 \times Pz - K2 \times P0).$$

This calculation result is defined as the reaction OD value.



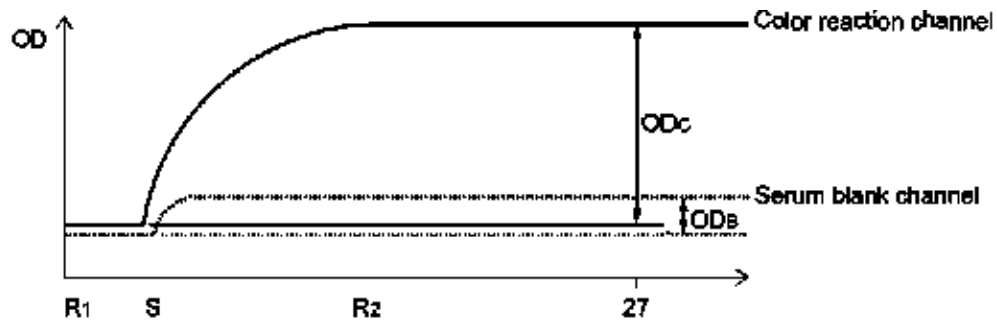
- R1.V: Reagent 1 dispense volume
- R2.V: Reagent 2 dispense volume
- S.V: Sample dispense volume
- P0: OD value at the first point
- Pz: OD value before dispensing reagent 2
- Px: OD value after dispensing reagent 2

End assay (sample blank correction)

Two cuvettes are used in this type of assay, a cuvette for the color reaction and a cuvette for the sample blank. Blank item OD values, which include serum quality issues, are measured first. Then, the blank item value is subtracted from the measured OD value of the actual sample (OD value of the color item).

With this end assay (sample blank correction), higher accuracy data can be obtained than the 2-point assay even when serum quality issues (dotted line in the figure below) are unavoidable.

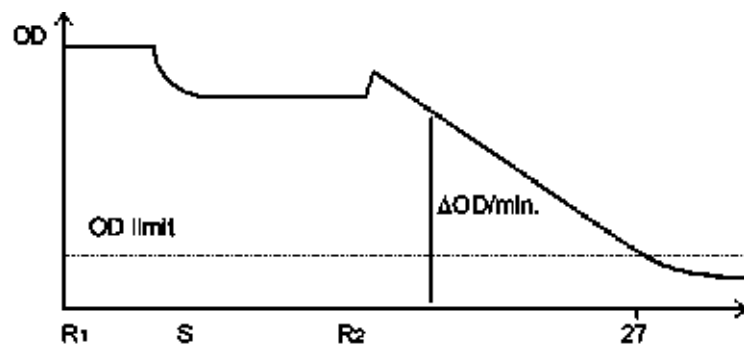
$$\text{Reaction OD value} = [\text{Color item OD value (OD}_C\text{)}] - [\text{Blank item OD value (OD}_B\text{)}]$$



3.1.3 Rate Assays

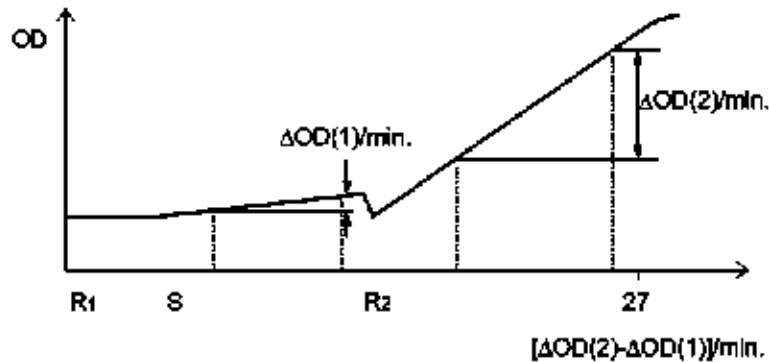
Rate assay

This assay determines the rate of absorbance variation per minute by calculating the average of the absorbance variations (ΔOD) between photometric points using the least squares method.



Double rate assay

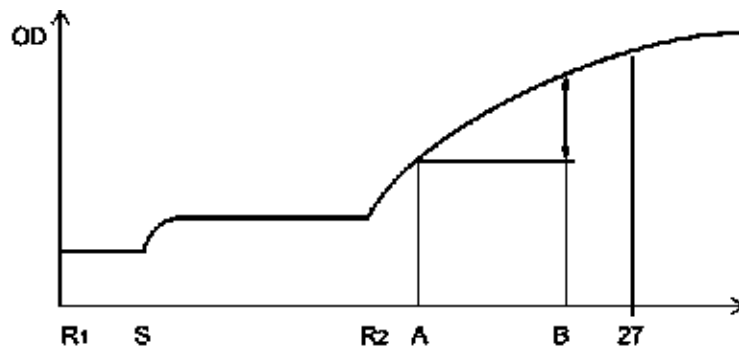
This assay determines the rate of absorbance variation per minute by calculating the average of the absorbance variations (ΔOD) between photometric points using the least squares method. Next, the system obtains the OD rate of the objective substance from the calculation expression.



3.1.4 Fixed Point Assay

A fixed point assay measures the OD value at two specified photometry points. The two photometry points are measured after the beginning of reaction between sample and reagent.

$$\text{Reaction OD value} = OD_B - OD_A$$



3.1.5 Quality Control

A wide variety of quality control techniques are used to monitor instrument accuracy.

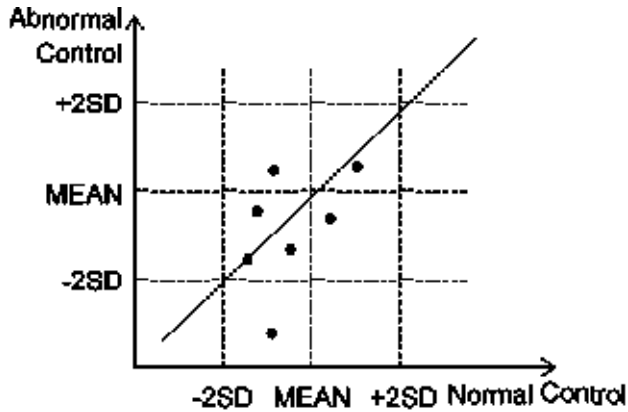
The analyzer software has single rule, multi rule, and twin plot QC evaluation. Single rule is the most widely used technique, multi rule is used to prevent notification of insignificant errors, and twin plot is used for easier classification of system and accidental errors.

This chapter describes the twin plot control and multi-rule control.

For details about the day-to-day control, refer to [7.3.5 Check QC](#) in chapter 7.

Twin plot control

QC material with normal and abnormal expected values are evaluated together.



If the control samples of normal and abnormal levels are within the control limit, and both samples either recover high or both recover low, a check of calibration system should be made to determine system errors.

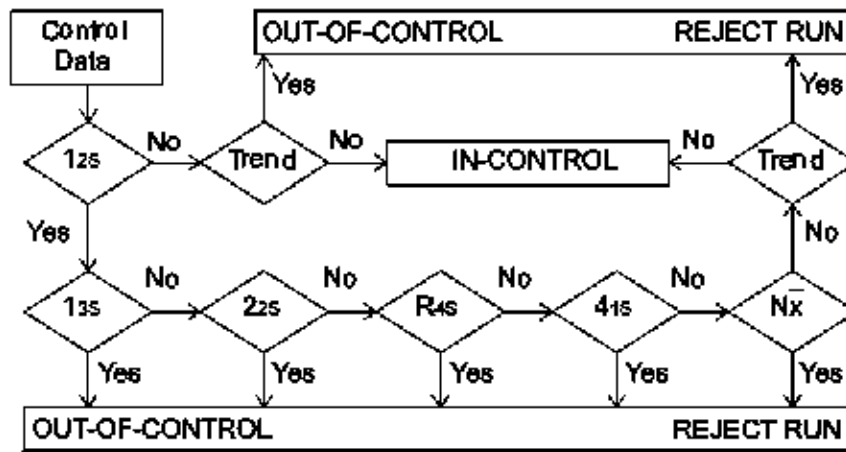
If an abnormal control recovers low, a reagent problem may be suspected. The twin plot control technique offers the advantage of classification of a system error or a random error.

Multi-rule control

In the day-to-day control, a control error is checked by examining the control chart, but it is difficult to do confirmation of numerous tests on a real time basis. The multi-rule control technique makes it possible to speedily cope with an error realtime, as this control method identifies the rule out of range based on a specific flag.

When employing this control technique, it is necessary to prepare a normal and abnormal level control.

For details of the multi-rule control, refer to the figure shown below.



Standard of judgement based on the multi-rule Shewhart technique.
(Logic diagram Applicable to Control Rules)

The Explanation of symbols for the multi-rule control and the logic is as follows

- 1_{2s} indicates that five judgment levels given in the accompanying table on the next page are sequentially checked to see whether or not there is any violation of the applicable rule if one piece of control is exceeding the control limit determined as ‘MEAN ±2 SD.’
- 1_{3s} is a judgment level for determining if one piece of control has exceeded the control limit determined as ‘MEAN ±3 SD.’ If these are not beyond the control limit, an inquiry is made to 2_{2s} for the next judgment level. If the control is exceeded, it is judged that quality control has not been properly attained.
- 2_{2s} is a criteria level for judging whether or not the two continuous pieces of control data have exceeded the control limit determined as ‘MEAN ±2 SD’ in one direction. If these are not beyond the control limit, an inquiry is made to R_{4s} for the next judgment level. If the control is exceeded, it is judged that quality control has not been properly attained.

TIP The term “continuous” above can have the following meanings:

- To be continuous in both directions for one identical control substance.
- To have continuity of high-concentration and low-concentration between control substances.

- R_{4s} is a judgment level for determining whether either of two continuous pieces of data with high and low concentrations has exceeded the control limit specified as ‘MEAN + 2SD’ and whether the other has exceeded the control limit of ‘MEAN -2SD.’ In other words, it judges whether the two continuous pieces of data have exceeded 4SD in the same range. If the data is within the control limit, judgment is advanced to the next judgment level, 4_{1s}. If the data is out of the control limit, quality control has not been properly attained.
- 4_{1s} is a judgment level for determining whether or not four continuous pieces of control data have exceeded the control limit of either ‘MEAN +1 SD’ or ‘MEAN -1 SD.’ If they have not exceeded either control limit, an inquiry is made to the next judgment standard Nx for necessary judgment, but if they have exceeded the limit, quality control has not been properly attained.

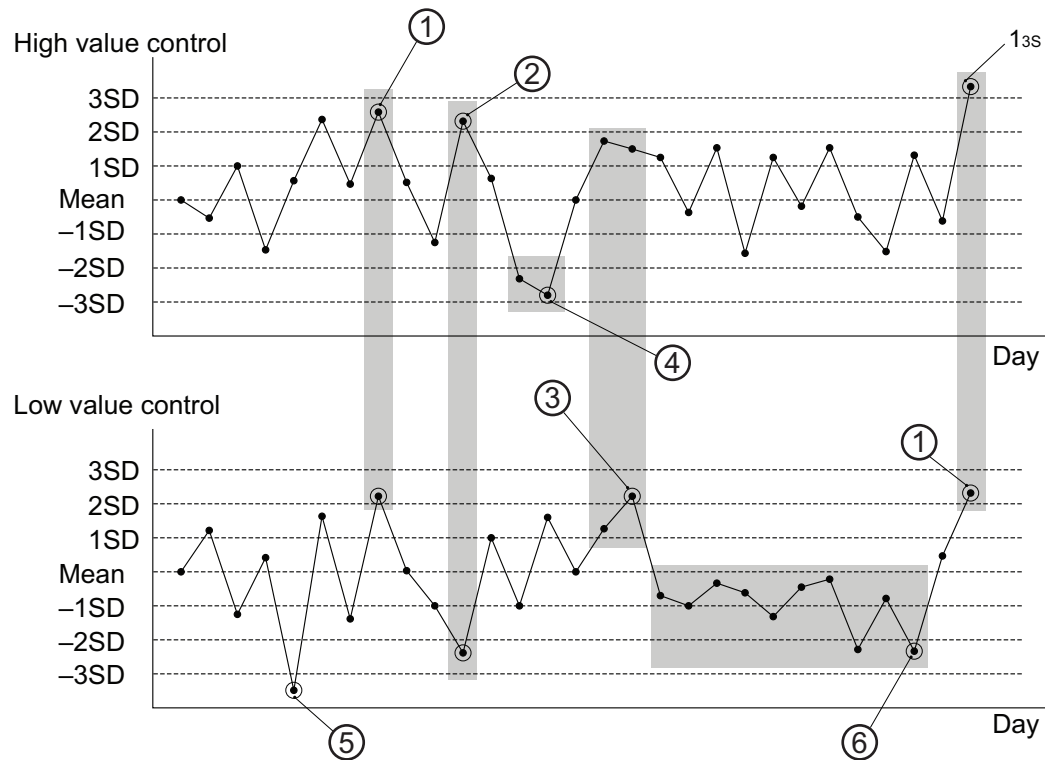
- N_x is a judgment level for determining whether or not continuous N (7 to 10) pieces of control data are above or below the control mean. If the controls have not exceeded the control limit, quality control has been properly attained. If the controls have exceeded the limit, quality control has not been properly attained. The N_x rule uses a maximum of 10 pieces of previous data for judgment.
- Trend evaluates if 4 to 10 sequential results of measurement of the same control material are increasing or decreasing.

If an error is generated by exceeding one of the 7 multi-rule controls, an abnormal data flag is attached to the control data. The abnormal data flags and causes are described below.

Control Limit	Error Symbol	Cause of Error
Exceeds 1_{3S}	2Q	Random error
Exceeds 2_{2S}	3Q	Systematic error
Exceeds R_{4S}	4Q	Random error
Exceeds 4_{1S}	5Q	Systematic error
Exceeds N_x	6Q	Systematic error
Trend abnormality	7Q	Increase or decrease in continuous quality control data

Example of control errors according to the multi-rule control are shown below

Figure 3.1



1. 2_{2S} : Systemic error. The high and low value controls both exceeded the 2 SD level in one direction. A 3Q error flag is generated.
2. R_{4S} : Random error. The high value control exceeded the 2 SD level and the low value control exceeded the -2 SD level. A 4Q error flag is generated.
3. 4_{1S} : Systemic error. Four continuous QC results exceeded the 1 SD level in one direction. A 5Q error flag is generated.
4. 2_{2S} : Systemic error. The high value control had two continuous results over 2 SD or under -2 SD in one direction. A 3Q error flag is generated.
5. 1_{3S} : Random error. One result is either over 3 SD or under -3 SD. A 2Q error flag is generated.
6. N_x : Systemic error. Ten continuous results are below the mean. A 6Q error flag is generated.

The following describes the possible causes and check items for the random errors and systematic errors shown in the figure above. To troubleshoot the errors, refer to the following:

Random errors

- Dispense accuracy error (sample or reagent)
Poor syringe (sample, reagent) dispense accuracy due to syringe integrity or improper installation, air introduced into plumbing system, dirty probe, reagent empty, and so forth.
- Poor photometer accuracy
Lamp deterioration.
- Reagent degeneration
Improper reagent storage or contamination.

- Poor quality control sample
Incorrect sample, different lot, etc.
- Insufficient cleaning
Mix bar cleaning improper or insufficient.
- Poor mixing
Mix unit defective, incorrect mix bar used, cuvette wheel defective.

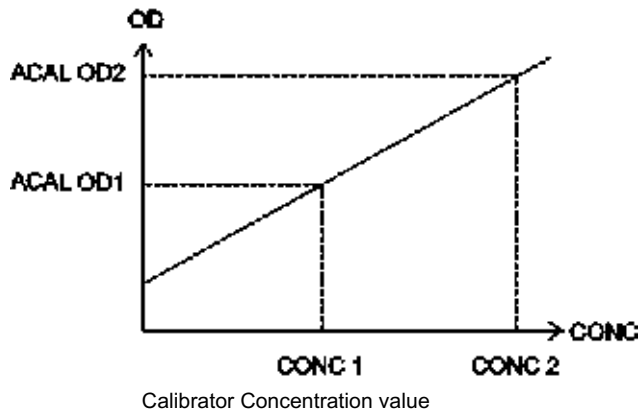
Systematic errors

- Incorrect calibration
Incorrect reconstitution of calibrators.
- Deteriorated reagent
Reagent degeneration, different lot, etc.
- Temperature
Improper temperature control.

3.1.6 Summary of Calibration Types

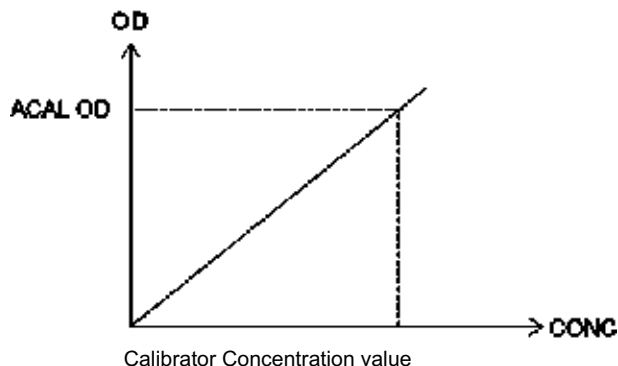
This system allows the operator to generate a maximum of 15 types of calibration curves. The 6 major types of calibration curves are described below.

ACAL AA



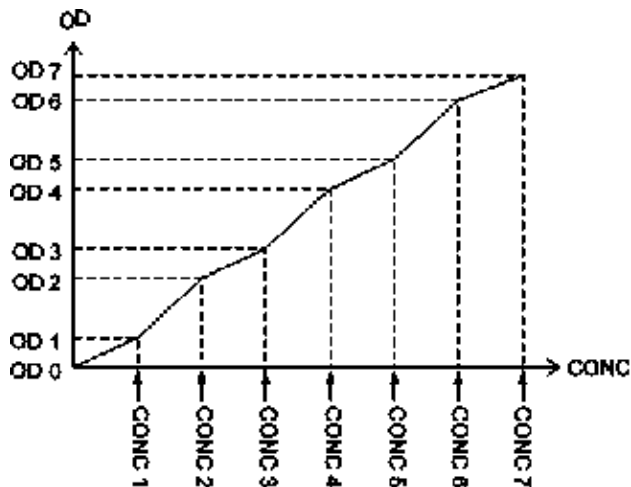
- This calibration curve is generated using two different calibrators. The Y intercept is above or below 0 but does not pass through 0 (reagent blank).
- This type of calibration curve is used for fixed point assays having a limited range of linearity.

ACAL AB



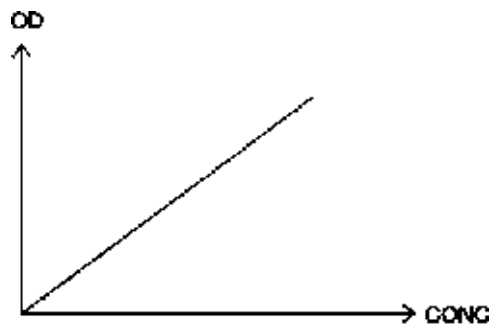
- This calibration curve is generated using a single calibrator and the reagent blank. The Y intercept passes through 0.
- This type of calibration curve is used for end point assays. An example of a test using this type of calibration is Glucose.

ACAL 7AB



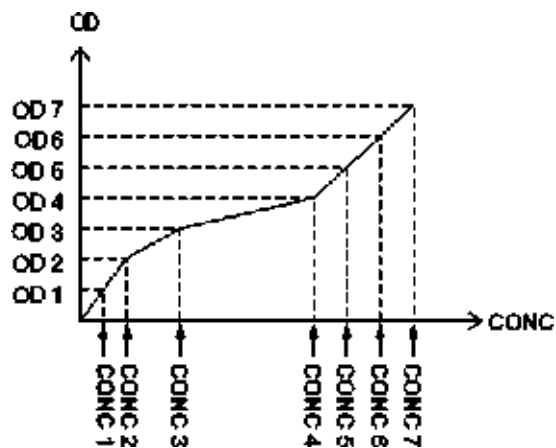
- This calibration curve is generated using a minimum of two calibrators up to a maximum of 7 calibrators. The Y intercept passes through 0.
- This type of calibration curve is used for immunoturbidimetric assays. An example of a test using this type of calibration is C-Reactive Protein.

MCAL MB



- Set the calibration coefficient with a theoretical or traceable reference method.
- MB factor derived from extinction coefficient or IFCC reference labs that is a derived factor.
- An example of a test using the Lactate Dehydrogenase calibration.

MCAL 7MB



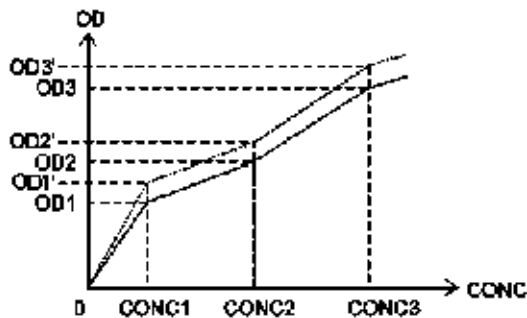
- This calibration curve is generated by entering the OD and concentration for a maximum of 7 calibrators.
- This type of calibration curve is used for immunoturbidimetric assays with constantly curving characteristics.

ACAL nAB (single-point correction processing)

First, analyze one of multiple standard solutions for 2AB to 7AB. By using the ratio between the reaction OD values of this standard solution and the previously measured standard solution, correct the reaction OD values of other standard solutions, and then recreate the calibration chart.

It is possible to correct the calibration chart with two points of OD0 and another OD value, if the standard solution with a concentration of 0 is available.

Example 1: If none of multiple standard solutions has a concentration of 0.

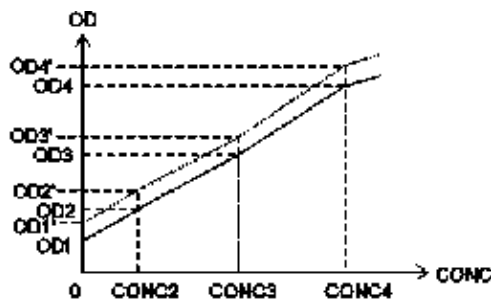


- A single point update to the calibration curve can be performed for calibrations defined as 2AB to 7AB. A single calibrator is used to obtain a new reaction OD. The ratio between the previously obtained OD and the current OD causes the OD of the other calibrators to be adjusted, and the new calibration curve is calculated.
 1. Perform the single-point correction.

$$ODn' = ODn \times \frac{OD2'}{OD2}$$

2. Recalculate for the calibration curve.

Example 2: If any standard solution has a concentration of 0.



ODn: previous OD value ODn': OD value after correction

- If correction is performed with two points of CONC1 and another (CONC3), execute the following calculation.
 1. Use the reaction OD values of CONC1 and CONC3 (OD1' and OD3') as they are.

- Correct each point as follows.

$$ODn' = \alpha \times (ODn - OD1') + \beta$$

$$\alpha = \frac{OD3' - OD1'}{OD3 - OD1}$$

$$\beta = OD1'$$

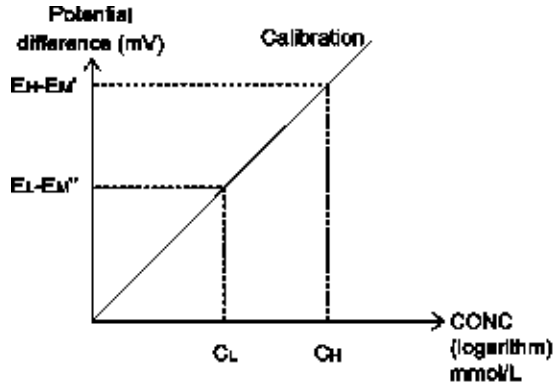
3.1.7 Principle of the ISE Measuring Method

Sample and buffer solution are mixed using a specified dilution ratio in the dilution pot of the ISE unit (optional). The mixture is aspirated and passed to the Na, K, and Cl electrodes. The potential generated at the electrodes is measured. MID solution is cycled between samples to measure the reference potential and to prevent carry-over.

Calibration processing on the ISE

During calibration of the ISE, both MID solution and external standards (HIGH, LOW), which have a known concentration, are measured. The relationship between the electrode potential and ion concentration at that time is obtained, and Na, K, and Cl calibration setup coefficient S (slope) is calculated.

Calibration



C_H :A known concentration of HIGH STANDARD liquid used for calibration

C_L :A known concentration of LOW STANDARD liquid used for calibration

$E_H - E_M'$:A potential difference between HIGH STANDARD liquid and MID solution

$E_L - E_M''$:A potential difference between LOW STANDARD liquid and MID solution

Set a calibration using a potential difference between the two points of known concentration.

Correction by M-CAL

M-CAL at the ISE is data correction using a calculation formula, $Y = AX + B$.

Y: corrected value, X: actual measurement.

Coefficients A and B are obtained in the following way.

Correlation regression with a measurement (y) obtained from the system before correction and value (x) obtained from any conventional method or standard method.

Coefficients A and B can be obtained by a 3-point regression calibration or Manual calculation.

$$y = ax + b$$

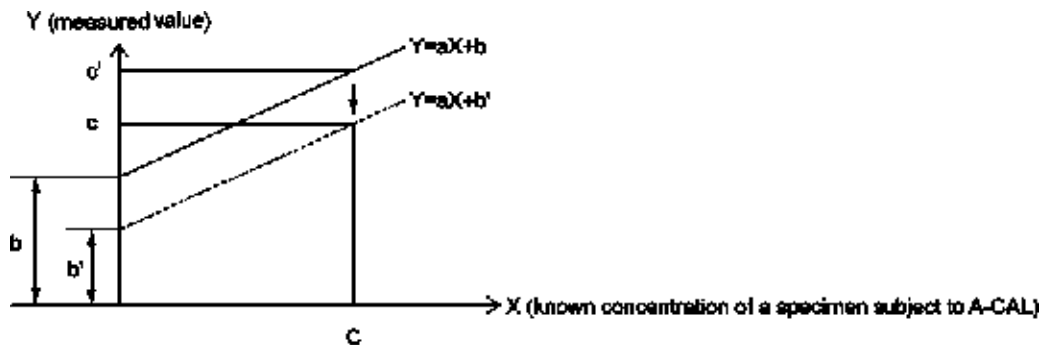
gives

$$x = (1/a)y - (b/a)$$

Therefore; $A = -1/a$, $B = -b/a$

- Manual
Obtain A and B with the above listed equations and enter them as the factors.
- CRS (3-point regression CAL)
Used only in Japan.

Correction by A-CAL



- Corrected value: $c' - c$
- $b' = b - (c' - c)$
a = factor
b = offset

Let a known concentration of a specimen for A-CAL be c, and let the measurement obtained by this system from a specimen for A-CAL after an M-CAL correction be c'. In order to make the known concentration of the specimen for A-CAL and a measurement obtained by this system consistent, correct the difference between c and c' using A-CAL. In this case $Y = aX + b$ is $Y = aX + b'$.

This A-CAL correction can be applied to values that have been subject to an M-CAL correction.

3.1.8 Principle of the Realtime Water Blank Check

The realtime water blank check method compares the water blank reading obtained during analysis to the previous water blank reading. If the deviation in the water blank reading on a cuvette exceeds a tolerance level, a "Photometry Error During Cuvette Wash" alarm is generated.

A "Photometry Error During Cuvette Wash" alarm is generated when a cuvette overflow is detected, and when unstable photometry is detected. Unstable photometry can be caused by:

- Improperly placed cuvettes in the cuvette wheel
- Dirty cuvettes
- Insufficient amount of wash solution being supplied to clean the cuvettes
- A deteriorating lamp

When a "Photometry Error During Cuvette Wash" alarm is generated, check to see if a cuvette overflow has occurred. Refer to [CHAPTER 11, 11.9 Recovering from a "Photometry Error During a Cuvette Wash" Alarm](#).

- If a cuvette overflow occurs, refer to [CHAPTER 11, 11.10 Recovering from a Cuvette Wheel Overflow](#). It is necessary to identify and re-analyze all samples affected by the cuvette overflow.
- If a cuvette overflow did not occur, the "Photometry Error During Cuvette Wash" alarm was generated by unstable photometry. Refer to [CHAPTER 11, 11.11 Recovering from an Unstable Photometry Error](#) to determine the cause of the error and perform corrective actions.

3.2 Key Sub-Processes

This section describes some important analysis steps.

3.2.1 Computer

3.2.2 Sample Identification

3.2.3 Sample Transfer

3.2.4 Reagent Transfer

3.2.5 Reaction Fluid Mixing

3.2.6 Reaction Fluid Incubation and Washing

3.2.7 Photometric Measurement

3.2.8 Online Analysis and Analysis Using Keyboard Entries

3.2.9 Sample Identification and Date and Time

3.2.1 Computer

The analysis process is controlled by software in the data processor unit. The system uses Microsoft Windows® as a graphical interface. It allows the use of a mouse or the touch screen for selection of a field. While the computer manages the analysis process, systems are often connected to a clinical laboratory host computer system. This allows requesting of tests, reporting of samples, and analysis to all occur simultaneously.

The computer system allows the operator to:

- Save and load test data and parameter files with several kinds of media and devices.
- Enter test requisitions (programming each sample test).
- Monitor the sample Status.
- Analyze and edit analysis results.
- Print analysis results.
- Track which users use the system and at which times.
- Enforce security by limiting the functions accessible to those required by the task requirements of the user.

3.2.2 Sample Identification

A test requisition is an instruction to perform specified tests on a sample. When a sample is placed onto the system, the test requisition information is used to link the sample to the required tests. The system must be able to identify samples correctly. Basic information on the sample is coded in the rack barcode. This barcode is used to identify the sample type (for example, serum, urine, others) loaded on the rack. The system can also use sample barcodes to link test requisition information to each sample to be tested.

There are three analysis modes for recognizing samples on racks.

Barcode (Sample ID) analysis mode

The system reads the sample barcode on each sample cup and then links this information to a corresponding requisition to perform analysis. Samples can be in any order, and empty spaces are allowed on the racks. It is critical to test results that sample barcodes match sample requisitions.

Sequential mode

The system analyzes the first sample on the first rack presented, using the information in the first test requisition. It uses the second test requisition for the second sample on the rack and so on. The sample barcode is not read in sequential mode. There is a Sequential Sample ID Read option to have the system read a sample barcode in sequential mode. Refer to [4.10.1 Analysis Mode Menu](#) for more information.

Samples should be placed on the racks in numerical order, without empty spaces on the rack.



Running the system in sequential mode (i.e. without reading sample barcode ID) is not recommended due to the possibility of sample/result mismatch. If a sample must be run without sample barcode ID, be extremely careful and have additional cross checks in place.

To ensure correct sample analysis in sequential mode, make sure that there are no empty spaces in the racks. Never mix different sample types on one rack.

Rack No. analysis mode

The system reads the Rack No. (rack ID) and assigns the sample number. according to the cup position in the rack. The samples must be set in the rack in the order entered for the samples at the time of sample requisition. Sample barcodes are not read in Rack No. analysis mode.

For example, when the samples from number 1 to number 10 are set on Rack No. 1 and the samples from number 11 to number 20 are set on Rack No. 2, sample number 14 can be found in position 4 on Rack No. 2 and sample number 57 can be found in position 7 on Rack No. 6. In Rack No. analysis mode, the racks can be placed onto the feeder in any order.

The maximum Rack No. (rack ID) for Rack No. analysis mode is 999.



In Rack No. analysis mode, use extreme caution when placing the samples in the racks to avoid concordance errors (incorrect sample and result). Take time to perform crosschecks on racks and samples.

3.2.3 Sample Transfer

Sample tubes or cups containing sample are placed in the sample racks or STAT table and placed on the system. Once **Start** has been selected, the system moves racks to the sample probes. Samples are

started from the STAT table by selecting **STAT Start (F1)** from **Home > STAT Status**. The sample is aspirated by the sample probe based on the test requisition information.

The sample volume and diluent volume for each test are programmed in **Specific Test Parameters**.

After dispensing, the sample probe is washed in the wash well with DI water internally and externally.

3.2.4 Reagent Transfer

The system has one reagent transfer probe. Any required reagent is aspirated from the corresponding reagent bottle in the reagent refrigerator and dispensed into the cuvette in the incubation bath. The system uses information programmed in **Specific Test Parameters** to determine the quantity of reagent to use. A mixture of sample and reagent which has been dispensed into one cuvette is called “reaction fluid.”

The reagent probes are washed internally and externally with DI water, between each reagent dispense, to ensure minimal reagent carryover. In addition, contamination avoidance parameters can be programmed. Refer to [4.8 Contamination Parameters Menu](#) in chapter 4 for more information.

3.2.5 Reaction Fluid Mixing

The mixing unit uses Teflon-coated mixing bars to mix the reaction fluid in the cuvette to a uniform mixture. The mixing unit has two sets of mix bars, and while one set of mix bars is mixing, the other set is being washed simultaneously.

3.2.6 Reaction Fluid Incubation and Washing

The cuvette wheel is set in an incubation bath to keep the reaction temperature in the cuvette at a constant level.

Once the photometer readings are complete, the reaction fluid in a cuvette is aspirated by the wash nozzle unit, and the cuvette is washed and dried.

3.2.7 Photometric Measurement

Various chemical components in the sample and the reagents have a color reaction in the cuvette. Light from a halogen bulb is passed through the reaction fluid, and is separated into specific wavelengths by a diffraction grating. A photodetector measures the optical density of reaction fluid. Measurement is performed at 18 second intervals throughout the reaction period. The measured values for the reaction period and wavelengths defined in the specific test parameters are used for concentration calculation.

3.2.8 Online Analysis and Analysis Using Keyboard Entries

Real-time online

Realtime online analysis is possible when **System > Online > Setup** Test Requisition Information Receive is programmed to Realtime, and the AU480 is interfaced to an LIS. In responding to any inquiry from the analyzer to the host computer, everything is automatically processed.

If a host computer and the AU480 are connected real-time online, the operator does not have to perform test requisitions from the AU480 computer.

Batch online

Batch online analysis is possible when **System > Online > Setup** Test Requisition Information Receive is programmed to Batch, and the AU480 is interfaced to an LIS. The sample information (such as test item, etc.) of multiple samples is batch-inquired to the host computer through the operation at the AU480.

Keyboard entry

Manual sample requisition is performed by sample number or sample ID number at the AU480 computer.

Manual sample requisition at the AU480 computer can be performed with or without a host computer.

3.2.9 Sample Identification and Date and Time

This system uses the following.

Sample No.

This is a 4-digit number used to identify each sample. Sample number calculation method varies for each analysis mode.

For additional information on Sample ID and Rack ID, refer to [3.2.2 Sample Identification](#).

Sample ID

A sample barcode number used to identify each sample.

In the sample ID (barcode) analysis, the barcode label attached to each sample cup is read and handled as the sample ID.

Rack No.

A rack ID is used for identifying each rack. In rack No. analysis, the sample No. of each sample is automatically assigned based on the rack ID.

System date and time

This is the system date and time under the management of the internal clock of the system.

Index date and time

An index, created by setting the date and time, is a data file used as the main search key for sample data.

The current date and time is automatically set as the index date and time on starting up the system; however, this can be modified at the option of the operator.

3.3 Understanding and Handling Reagents, Calibrators, and Controls

This section discusses the reagents used on the AU480.

3.3.1 Reagents

3.3.2 Sample Diluent

3.3.3 Calibrator

3.3.4 Quality Control Sample

3.3.5 ISE Quality Control Material

3.3.1 Reagents

Beckman Coulter reagents are highly concentrated, and most reagents are ready to use.

The system can use reagents, calibrators, and QC samples supplied by manufacturers other than Beckman Coulter. Verify usability with the reagent manufacturer or distributor.

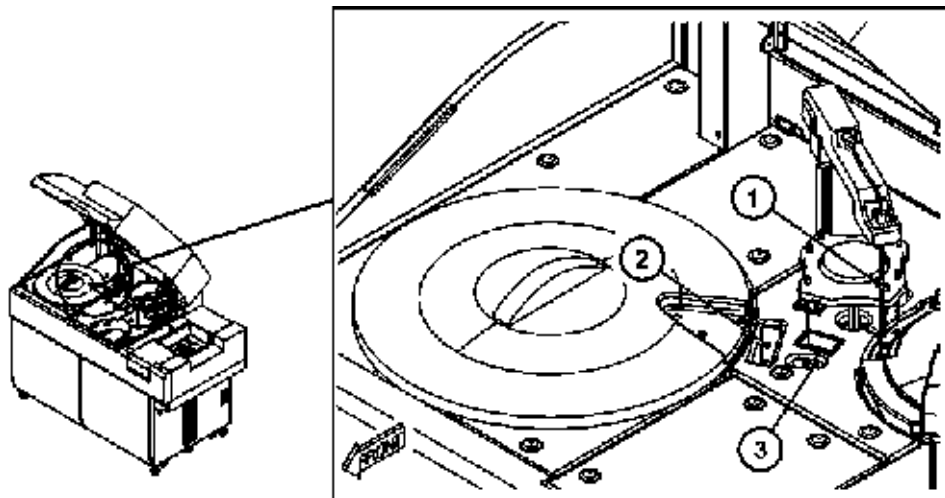
Reagents are supplied in bottles of 15 mL, 30 mL, or 60 mL. Reagent bottles containing reagents are set in the reagent refrigerator fixed by adapters and separators, depending on the size.

The barcode label on a reagent bottle is read and registered with the system.

3.3.2 Sample Diluent

For samples with a high concentration, DI water or other diluent can be used for automatic dilution analysis. The diluent is in a 60 mL bottle placed in a designated diluent bottle position near the reagent refrigerator.

Figure 3.2



1. Reagent probe
2. Sample diluent bottle
3. Wash Well

3.3.3 Calibrator

A maximum of 200 different calibrators can be programmed on the system.

Calibration should be performed in the following situations:

- When a reagent lot has changed.
- When the same lot has been used on the system for a predefined number of days.
- QC recovery is outside specified limits.
- There has been major preventive maintenance, or critical part replacement, and QC performance is affected.

For further information for assay specific calibration, refer to the Instructions For Use (IFU).

For details on operation precautions, refer to [2.1.11 Handling Reagents, Wash Solutions, Calibrators, and QC Samples](#) in chapter 2.

3.3.4 Quality Control Sample

Quality Control (QC) analysis should be performed after calibration to verify the system is working properly. QC analysis should also be performed at regular intervals for verification of system stability. Perform this check using a QC sample from the QC supplier.

For details on operation precautions, refer to [2.1.11 Handling Reagents, Wash Solutions, Calibrators, and QC Samples](#) in chapter 2.

3.3.5 ISE Quality Control Material

Commercial control material for the ISE

Beckman Coulter advises using the most widely accepted, reliable ISE control material available locally. ISE tests can be influenced by substances in control serum.

- Commercial control material contains additives for regulating the density of components, as well as various preservatives. If this kind of control material is measured using an ion selective electrode, the added materials may adversely affect the electrode, and could cause measurement errors including abnormal data.



The following items affect measurement:

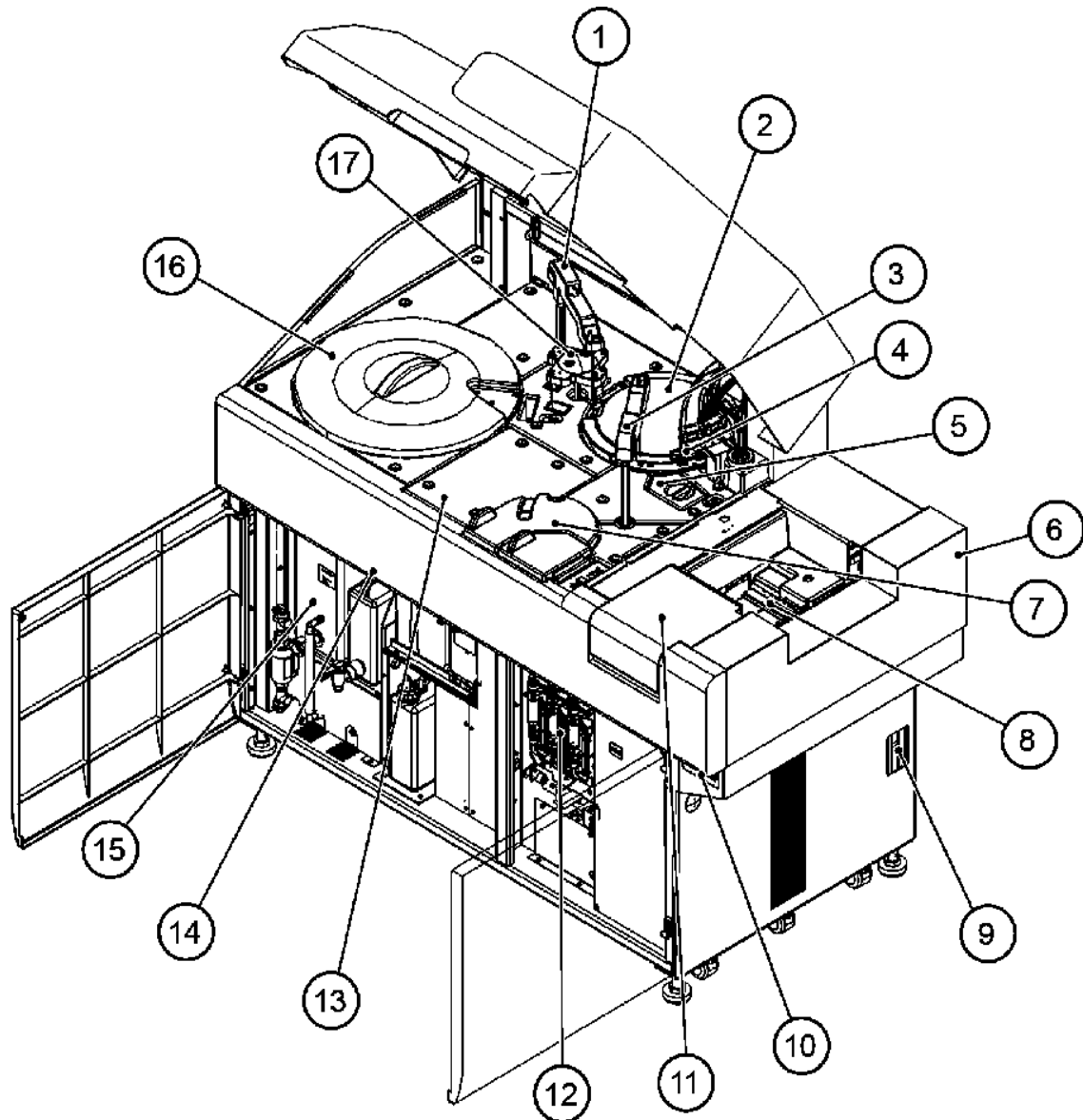
- Errors may result in samples containing antibiotics or other drugs.
- The K and Cl electrodes are not affected by bilirubin, but small positive errors occur in the Na electrode.
- Positive errors occur in the Cl electrode due to halogen ions (Br, I).
- A positive error is recognized in the K electrode for samples where the hematocrit value is 65% or more. If a hemolytic sample is used, K shows an excessively positive error.
- Use the anticoagulant Lithium Heparin. Any other anticoagulants may cause an error in measured values. Use the anticoagulant immediately after collecting blood.
- In order to prevent fluctuations due to the sample evaporation, serum and plasma samples should be kept tightly-closed in a refrigerator. Also, samples stored in a refrigerator should be measured after the temperature of the sample has returned to room temperature.

3.4 Understanding the System Hardware

This section provides an overview of the main components in the AU480.

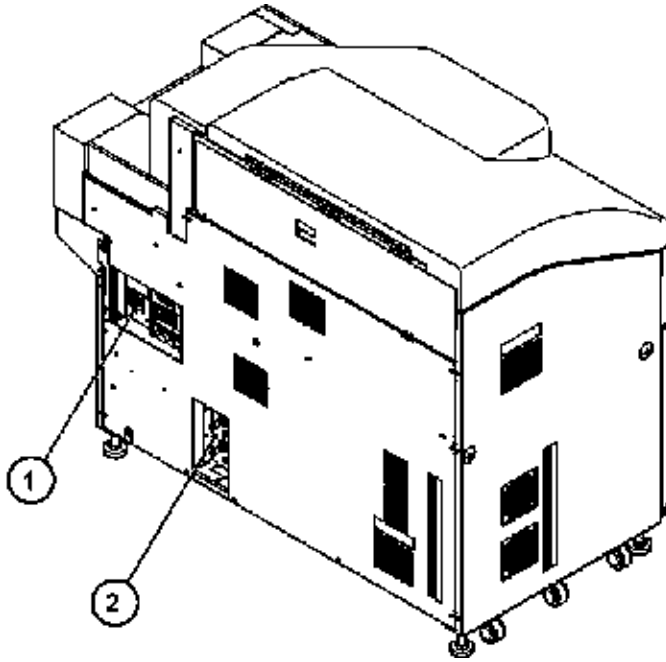
- 3.4.1 Breakers and Fuse
- 3.4.2 Operation Buttons
- 3.4.3 Rack Feeder Unit
- 3.4.4 STAT Table
- 3.4.5 Sample Transfer Unit
- 3.4.6 Reagent Transfer Unit
- 3.4.7 Mixing Unit
- 3.4.8 Cuvette Wheel Unit
- 3.4.9 Photometry Unit
- 3.4.10 Wash Nozzle Unit
- 3.4.11 Reagent Refrigerator
- 3.4.12 Syringe Unit
- 3.4.13 Tank Storage
- 3.4.14 Wash Solution Roller Pump
- 3.4.15 ISE Unit (optional)
- 3.4.16 Data Processing Unit (DPR)
- 3.4.17 Touch Screen, Mouse, and Keyboard

Figure 3.3



- | | |
|--------------------------|--------------------------------|
| 1. Reagent transfer unit | 10. Operation buttons |
| 2. Cuvette wheel unit | 11. Rack supply unit |
| 3. Sample transfer unit | 12. Syringe unit |
| 4. Wash nozzle unit | 13. ISE unit (option) |
| 5. Photometry unit | 14. Roller Pump unit |
| 6. Rack feeder unit | 15. Tank storage |
| 7. STAT table unit | 16. Reagent refrigeration unit |
| 8. Rack collection unit | 17. Mixing unit |
| 9. Breaker and fuses | |

Figure 3.4



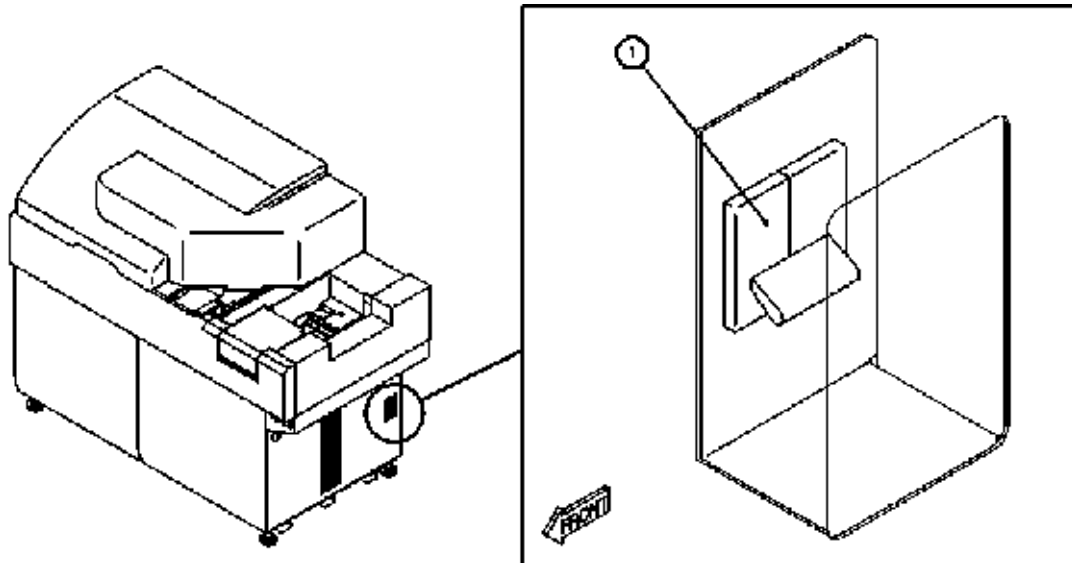
- 1. Breakers and fuse
- 2. Water supply/drain connections

3.4.1 Breakers and Fuse

The main system breaker board allows the power in specific areas of the system to be isolated. The main breaker (main power switch) automatically shuts down all the breaker switches. The main breaker should be in the ON position in normal conditions.

The main breaker is on the right side of the analyzer.

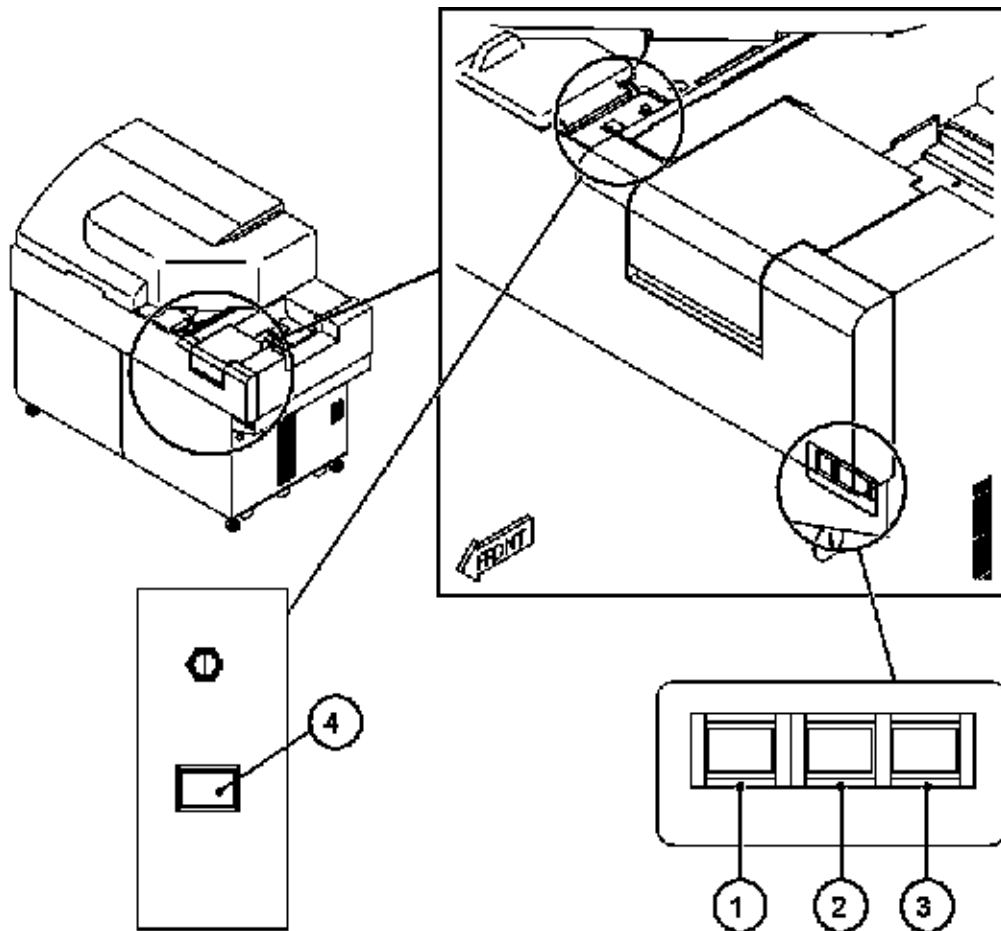
Figure 3.5



1. Main Breaker (main power switch)

3.4.2 Operation Buttons

Figure 3.6



1. ON button (Green)
2. EM STOP button (Red)
3. RESET button (White)
4. TABLE ROTATION/DIAG button

- ON (sub power) button

The ON button turns on the analyzer and PC, and the system initializes.

- EM STOP (Emergency Stop) button

The EM STOP button turns off all power to the analyzer immediately. Use this button in case of an emergency, or to completely turn off the system after an **End Process**. The power to the PC is not turned off by pressing the EM STOP button.

- RESET button

The RESET button supplies the main power to the system, and is used after an EM STOP or power failure. To ensure proper synchronization after an EM STOP, turn off the PC by performing an **End Process**. In rare cases, an **End Process** takes a long time or cannot be performed because there is no response from the analyzer. In these cases, select Ctrl + Alt + Delete, then the Shutdown button to turn off the PC. Press RESET then ON to re-boot the system. After an EM STOP, wait 5 seconds before pressing RESET, then wait 5 seconds before pressing

ON. RESET also resets the power failure detection circuit and appropriate notification with the "Power Failure Detected" alarm.

- TABLE ROTATION/DIAG button

The TABLE ROTATION/DIAG button rotates the STAT table for loading samples on the STAT table. In Maintenance and Diagnostics menus, this button initiates the maintenance or diagnostic function.

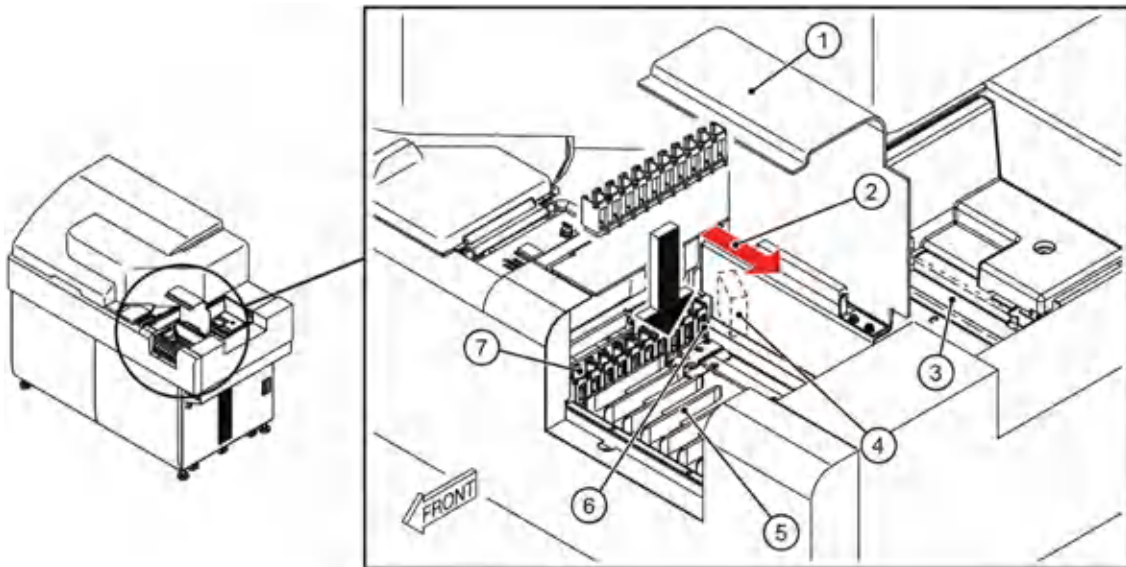
3.4.3 Rack Feeder Unit

This unit is for loading and collecting racks.

Racks are loaded on the rack supply unit. The rack ID and sample ID are read by the barcode readers, and the information is automatically transferred to the analyzer PC. Covers prevent dirt or dust from getting into samples during analysis, and the main covers should be closed during normal operation.

After sample aspiration and repeat sample aspiration (if Auto Repeat is in use) are complete, the racks move to the rack collection unit. Remove racks at any time from the rack collection unit. When the 8th rack is moved into the rack collection area, a "Rack Full" alarm is generated.

Figure 3.7 Top View of Rack Feeder Unit



- | | |
|---|-------------------------------------|
| 1. Sample protection cover | 5. Rack supply unit |
| 2. Barcode reader laser radiation (Sample ID) | 6. Surface where rack ID is applied |
| 3. Rack collection unit | 7. Rack |
| 4. Window for reading rack ID | |

The following table summarizes the specifications for the barcode readers.

Barcode Reader Specifications	
Wave length:	650 ± 10 nm
Maximum output:	6.2 mW
Pulse width:	0.18 µS
Frequency:	2.5 MHz
Class:	2
Scan rate:	100 ± 20 Hz
Beam divergence:	54 ± 5 degrees

3.4.4 STAT Table

The STAT table is used to process priority STAT samples and is the fastest way to process a sample.

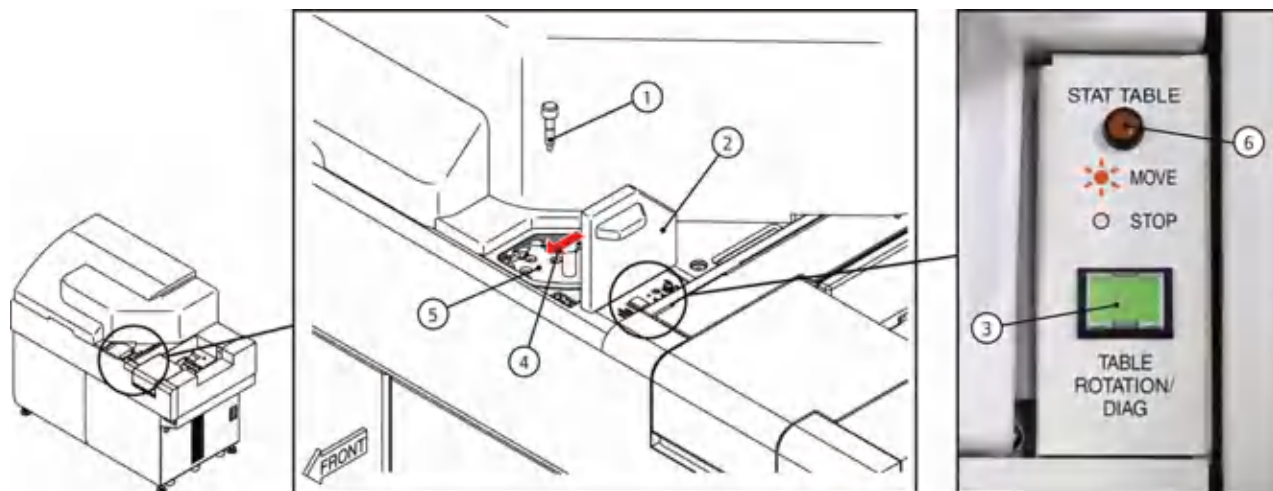
The STAT table compartment is maintained between 4 °C and 12 °C even after an **End Process** is performed to turn off the system.

The STAT table has 22 user-defined positions that can be programmed for priority STATs, repeats, calibrators, and QC. Inner positions on the STAT table are used for ISE calibration and ISE maintenance procedures.



To avoid injury, do not touch or open the STAT table cover while the amber STAT TABLE LED is blinking.

Figure 3.8



- 1. Sample cup
- 2. STAT table cover
- 3. TABLE ROTATION/DIAG button
- 4. Barcode reader laser radiation (Sample ID)
- 5. STAT table
- 6. STAT TABLE LED

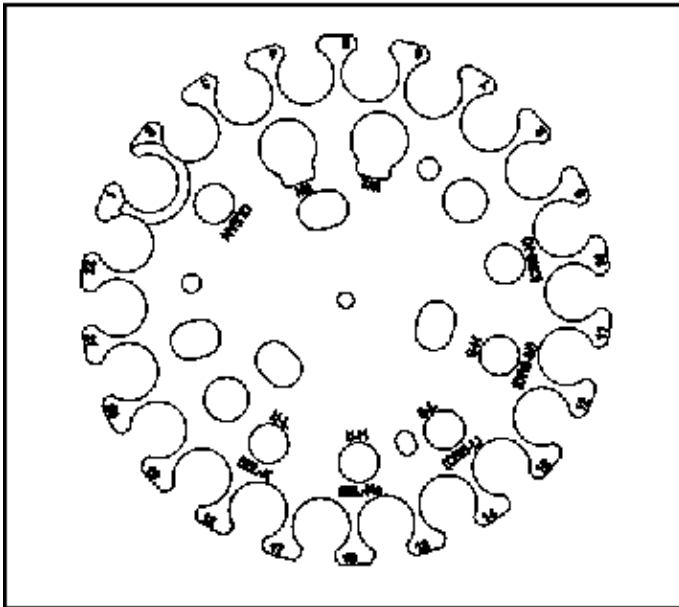
The amber STAT TABLE LED blinks either quickly or slowly.

STAT TABLE LED	Description
Quick Blink	The STAT table rotates before sample aspiration. The sample probe moves over to the STAT table.
Slow Blink	The STAT table is in a "Waiting" mode. The STAT table is continuously in a Waiting mode when the analyzer is in a <i>Measure</i> mode if: <ul style="list-style-type: none"> Contamination parameters for sample probe carryover are programmed. Reagent blank or calibrators are programmed on the STAT table. Cyclic QC after a defined number of tests or samples is programmed on the STAT table.

CAUTION

An alarm is generated if the STAT cover is opened when the STAT TABLE LED is blinking.

Figure 3.9
Top view of STAT table



Position	Sample
No.1 to No.22	Priority STAT, repeat, calibrator, and QC
S-H	ISE Serum Standard Solution H
S-L	ISE Serum Standard Solution L
U-H	ISE Urine Standard Solution H
U-L	ISE Urine Standard Solution L
CRS-H	ISE Certified Reference Standard Solution H (Japan market only)

Position	Sample
CRS-M	ISE Certified Reference Standard Solution M (Japan market only)
CRS-L	ISE Certified Reference Standard Solution L (Japan market only)
CLEAN	ISE Cleaning solution
SEL-K	ISE Selectivity Check Liquid (K)
SEL-Na	ISE Selectivity Check Liquid (Na)
W1, W2	Sample Probe Wash Solution

 **CAUTION**

- The STAT table can only read barcodes on samples (when the STAT table is programmed for Barcode analysis) that are placed on the outer positions of the table. Always keep the cover on the table to maintain the temperature and sample integrity. Although the STAT table compartment is cooled, it should not be used to store samples or leave samples for an extended period of time.
- Only open the STAT table cover as required. Excessive opening and closing may cause damage to the cover hinges.

The following table summarizes the specifications for the barcode readers.

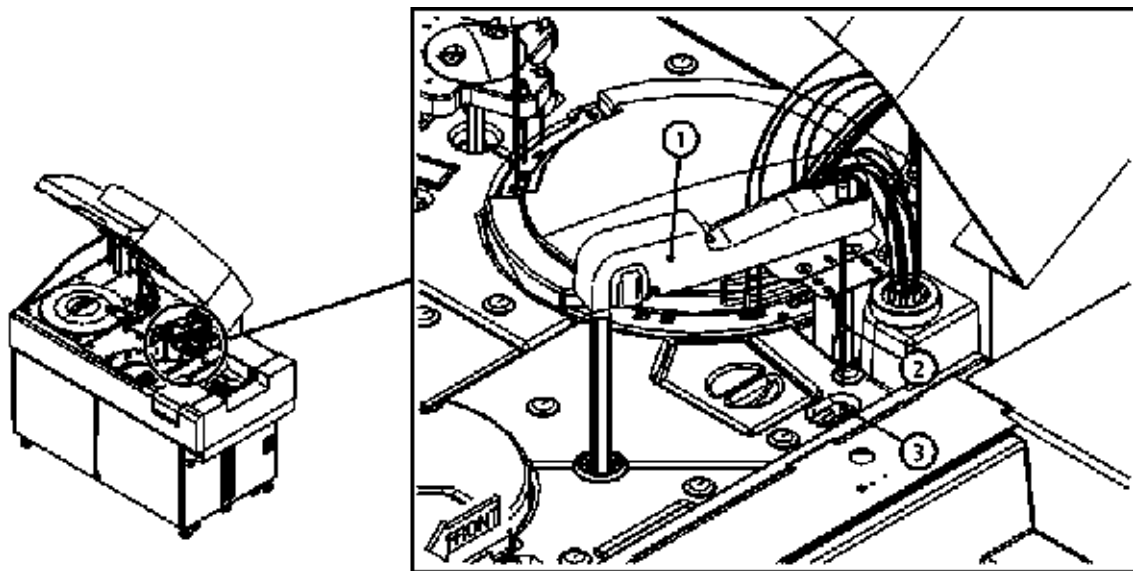
Barcode Reader Specifications	
Wave length:	650 ± 10 nm
Maximum output:	6.2 mW
Pulse width:	0.18 µS
Frequency:	2.5 MHz
Class:	2
Scan rate:	100 ± 20 Hz
Beam divergence:	54 ± 5 degrees

3.4.5 Sample Transfer Unit

The sample (S) probe/liquid level detector dispenses sample and/or diluent, and detects liquid level. The probe assembly is designed for up/down collision detection and clot detection. Sample is aspirated from the tube/cup and dispensed into the cuvette wheel. The sample probe is rinsed with DI water internally and externally in the sample probe wash well between each sample dispense.

When the ISE unit is installed, sample is aspirated from the tube/cup and dispensed into the ISE sample pot for analysis.

Figure 3.10

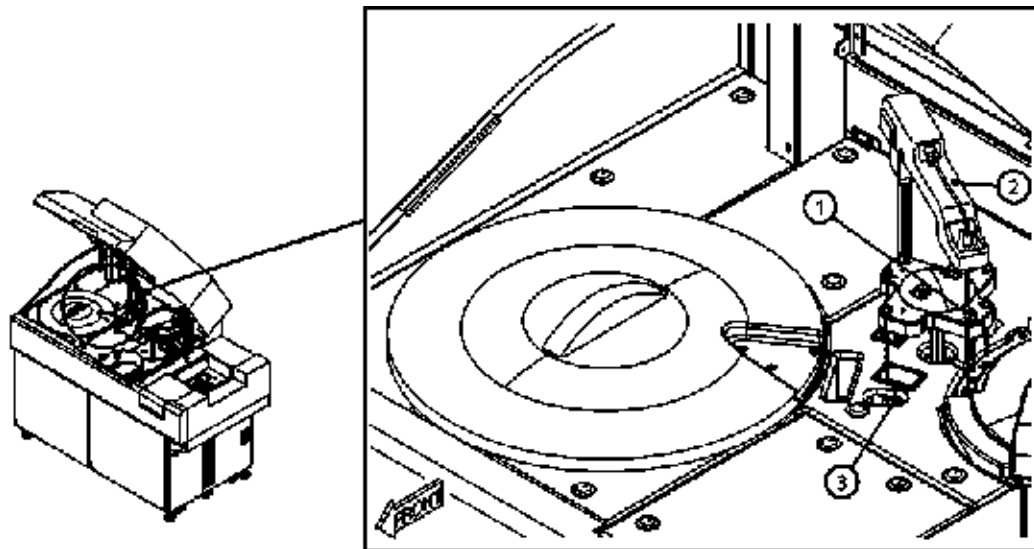


1. Sample transfer unit
2. Sample probe
3. Sample probe wash well

3.4.6 Reagent Transfer Unit

The reagent (R) probe/liquid level detector dispenses reagent and/or diluent, and detects liquid level. The probe assembly is designed for up/down collision detection. Reagent is aspirated from the reagent refrigerator and dispensed into the cuvette wheel. The probe is rinsed with DI water internally and externally in the reagent probe wash well between each reagent dispense.

Figure 3.11

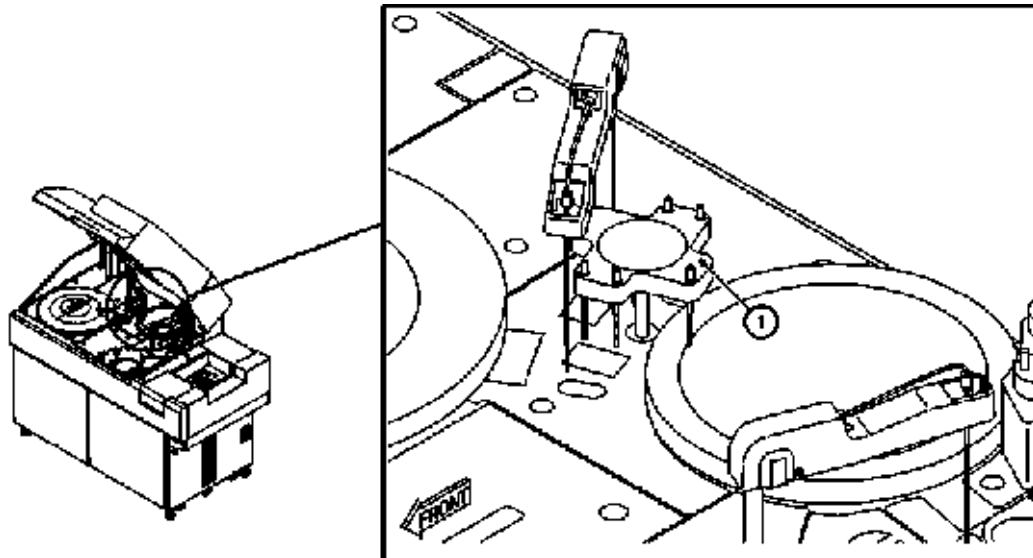


1. Reagent probe
2. Reagent transfer unit
3. Reagent probe wash well

3.4.7 Mixing Unit

Mix bars are used to mix the reagent and sample in the cuvette. The mix unit contains four spiral-shaped R1 and S mix bars. A mix occurs after R1 and sample dispense. The mix unit contains two L-shaped R2 mix bars identified by the green top. A third mix occurs after the R2 dispense. After mixing in the cuvette, the mix bars are cleaned in diluted wash solution, then rinsed in DI water in the wash wells.

Figure 3.12



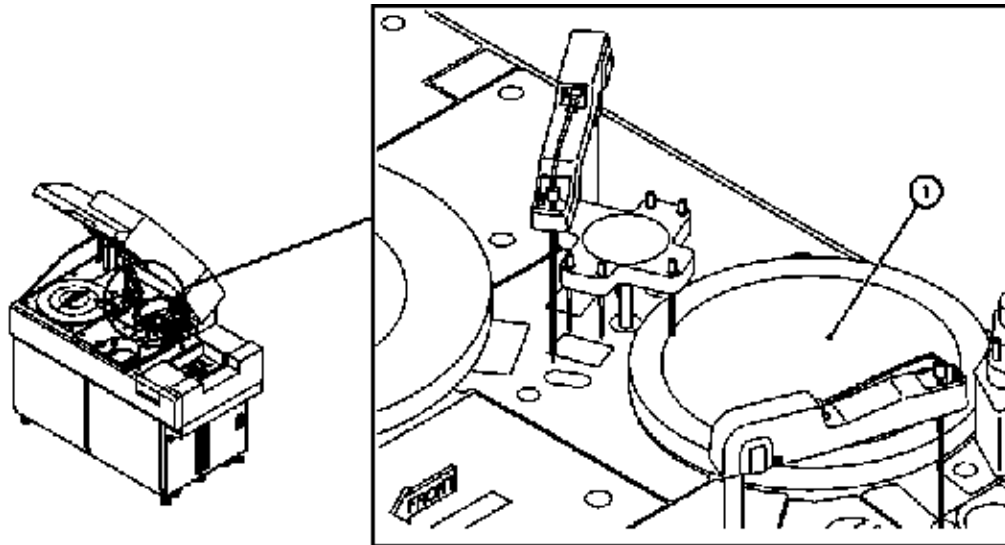
1. Mixing unit

3.4.8 Cuvette Wheel Unit

The incubation bath keeps the reaction temperature of the cuvettes at 37°C. A cuvette is made from optical glass with a light path of 5 mm.

- Minimum reaction volume: 90 µL.
- Maximum reaction volume: 350 µL.

Figure 3.13



1. Cuvette wheel

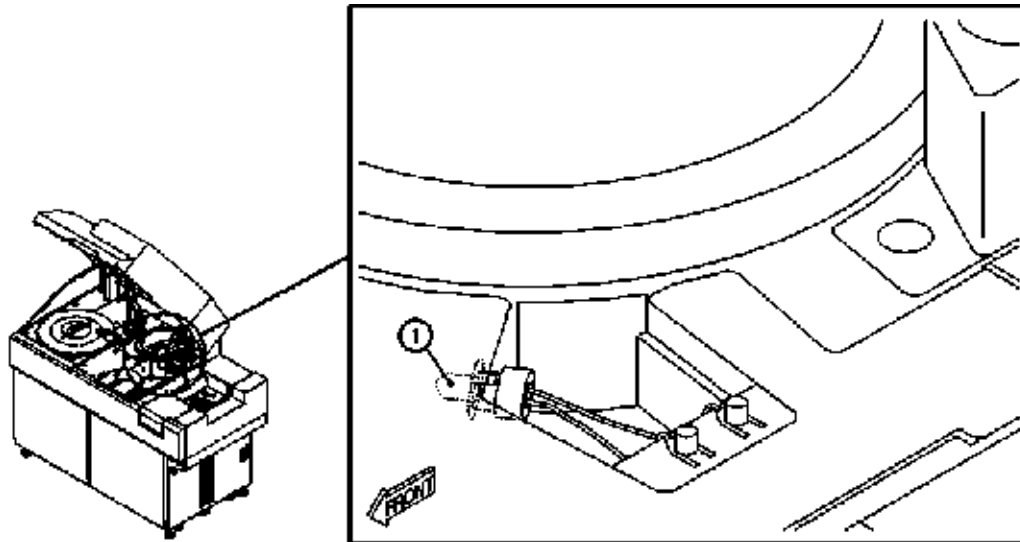
The cuvette wheel unit contains a total of 88 cuvettes in a single wheel. The cuvettes are cleaned automatically by the wash nozzle unit. Cuvette integrity is checked during the weekly Photocal maintenance procedure, and cuvettes are cleaned or replaced as needed based on the Photocal results.

Cuvettes are continuously monitored in a *Measure* mode by the realtime water blank check method. The realtime water blank check method compares the water blank reading obtained during analysis to the previous water blank reading. If the water blank reading check fails the specification, a "Photometry Error During Cuvette Wash" alarm is generated. A "Photometry Error During Cuvette Wash" alarm is generated when a cuvette overflow is detected, and when unstable photometry is detected.

3.4.9 Photometry Unit

The photometry unit consists of a halogen lamp, lenses, a diffraction grating, and a photodetector to measure the amount of light transmitted through the reaction solution in the cuvette. The diffraction grating splits the light into 13 wavelengths.

Figure 3.14



1. Lamp



Never touch the photometer lamp or look directly into the photometer lamp when the lamp is illuminated. The lamp is hot when the system is On.

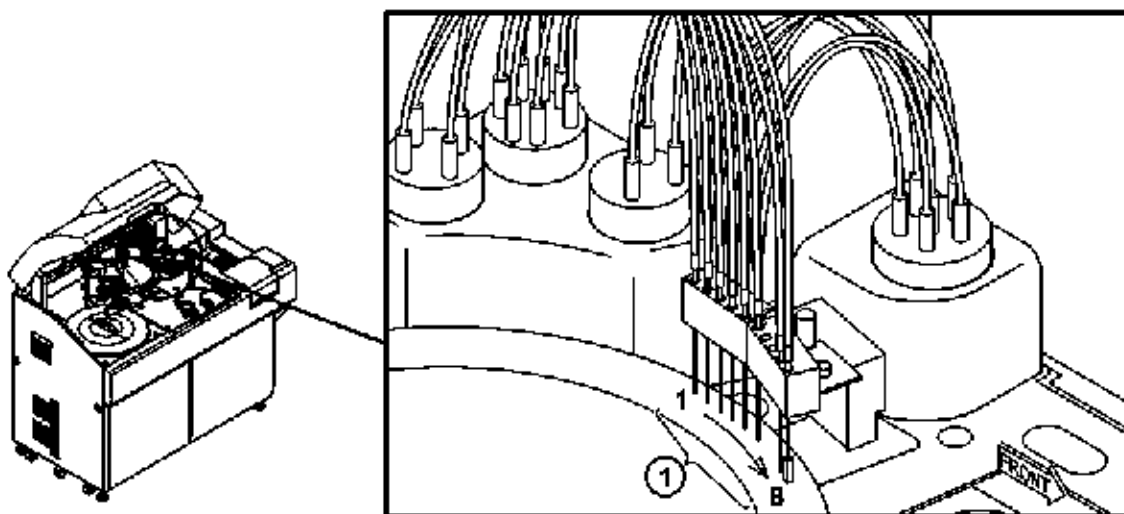
3.4.10 Wash Nozzle Unit

The wash nozzle unit cleans, rinses, and dries the cuvettes automatically. The unit consists of six wash nozzles, one aspiration nozzle, and one dry nozzle.

Each wash nozzle is a 3-way nozzle used to clean the cuvettes. The longest nozzle aspirates liquid, the middle nozzle dispenses, and the shortest nozzle aspirates any overflow liquid.

The aspiration nozzle aspirates any remaining liquid in the cuvette. The dry nozzle uses the teflon tip to bring any remaining moisture to the bottom of the cuvette, then aspirates to completely dry the inside of the cuvette.

Figure 3.15

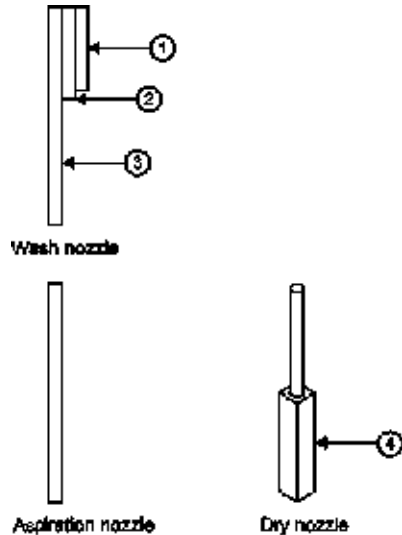


1. Wash, aspiration, and dry nozzles

The dispensing sequence of the wash nozzles, from left to right in the diagram, is as follows:

- Wash nozzles 1 and 2 - Diluted Wash Solution
- Wash nozzles 3 to 6 - Warm DI water
- Aspiration nozzle 7 - Aspiration
- Dry nozzle 8 - Drying

Figure 3.16



1. Overflow nozzle
2. Liquid (wash solution and warm DI water) dispense nozzle
3. Liquid (reaction, wash solution, and warm DI water) aspirating nozzle
4. Drying tip

3.4.11 Reagent Refrigerator

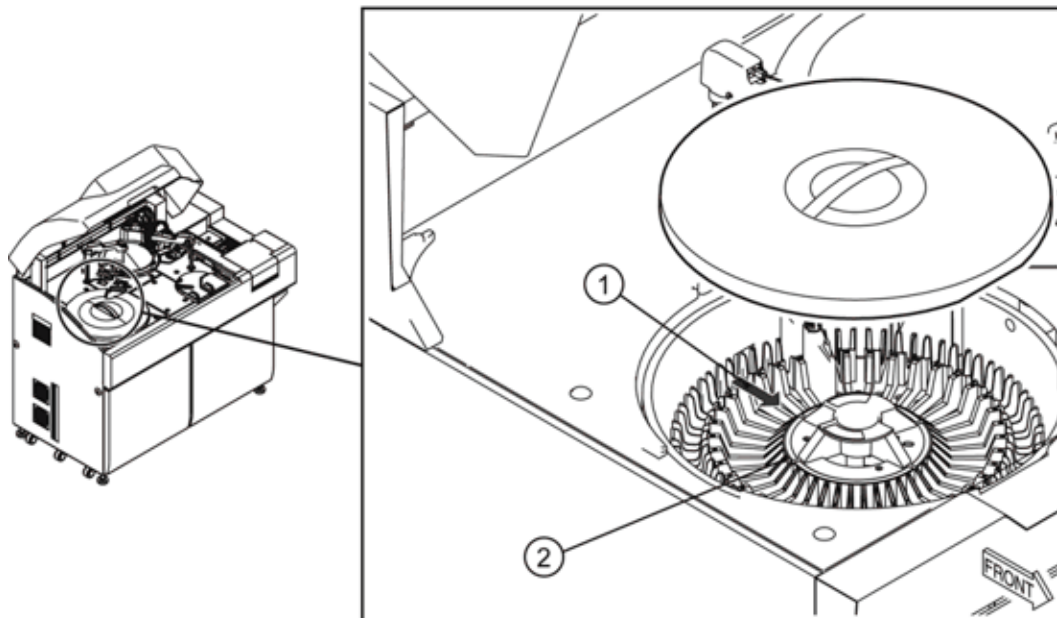
One reagent refrigerator contains the 1st reagent (R1) and second reagent (R2). Even when an **End Process** is performed, the temperature of the refrigerator is maintained between 4°C (39.2 °F) and 12°C (53.6 °F).

Place the reagent bottle on the reagent tray in the reagent refrigerator.

There are 76 positions on the reagent tray. The inner ring of the reagent tray holds a maximum of 38 60 mL, 30 mL, or 15 mL bottles. Use the appropriate adapter with a 30 mL or 15 mL bottle. The outer ring of the reagent tray holds a maximum of 38 30 mL or 15 mL bottles. Use the appropriate adapter with the 15 mL bottle.

Each bottle position can be designated as reagent ID (barcoded) or fixed (non-barcoded). During a reagent check, reagent bottles are detected, reagent IDs are read, and reagent volume is calculated.

Figure 3.17



1. Barcode reader laser radiation (Reagent ID)
2. Reagent refrigerator

The following table summarizes the specifications for the barcode readers.

Barcode Reader Specifications	
Wave length:	650 ± 10 nm
Maximum output:	6.2 mW
Pulse width:	0.18 μS
Frequency:	2.5 MHz
Class:	2
Scan rate:	100 ± 20 Hz
Beam divergence:	54 ± 5 degrees

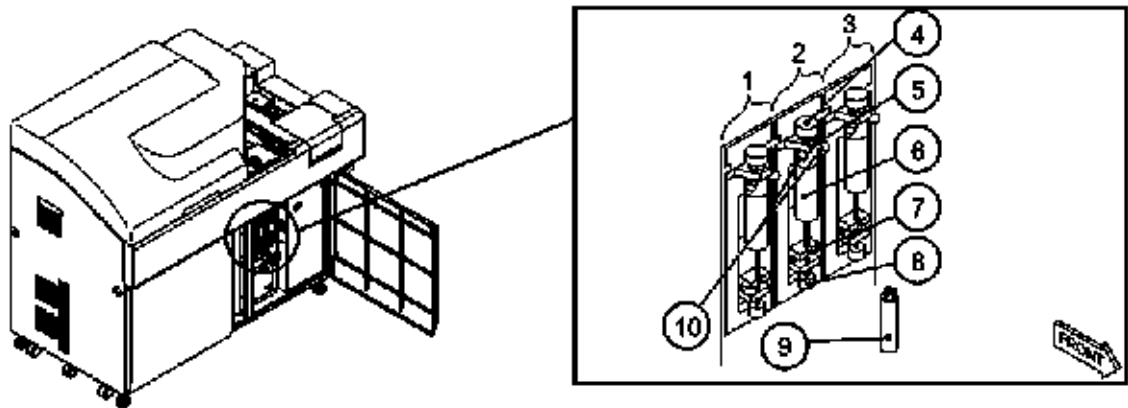
CAUTION

Verify the reagent bottles are placed in the refrigerator with the reagent ID facing outwards. Verify that all reagent bottle caps are removed before placing them in the refrigerator.

3.4.12 Syringe Unit

This system has a sample (S) syringe, a reagent (R) syringe, and an additional syringe for the ISE Buffer solution, if the ISE option is installed. Syringes are used to dispense the required volume of sample or reagent.

Figure 3.18



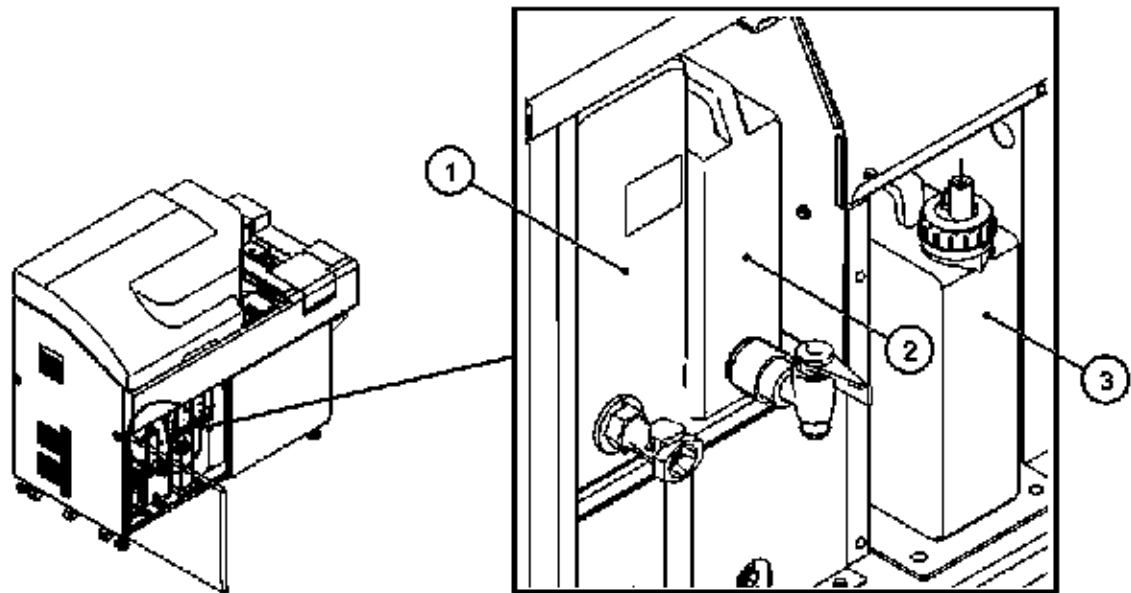
- | | |
|---------------------------|---|
| 1. Reagent (R) syringe | 6. Syringe case |
| 2. ISE Buffer (R) syringe | 7. Mounting groove |
| 3. Sample (S) syringe | 8. Piston fixing screw |
| 4. Fixing nut | 9. Electromagnetic valve (below syringe unit) |
| 5. Mounting groove | 10. Fixing screws |

3.4.13 Tank Storage

The tank storage area has a deionized water tank, a wash solution tank, and a diluted wash solution tank.

The solutions required for analysis are supplied from these tanks.

Figure 3.19



- 1. Deionized water tank
- 2. Diluted wash solution tank
- 3. Wash solution tank

Diluted wash solution tank

The diluted wash solution tank has a capacity of 2 liters. Diluted wash solution (1%) is used to wash cuvettes and mix bars.

Wash solution tank

The wash solution tank has a capacity of 2 liters. A float sensor indicates when the volume in the tank is low and generates an alarm to alert the operator to supply a new wash solution tank.

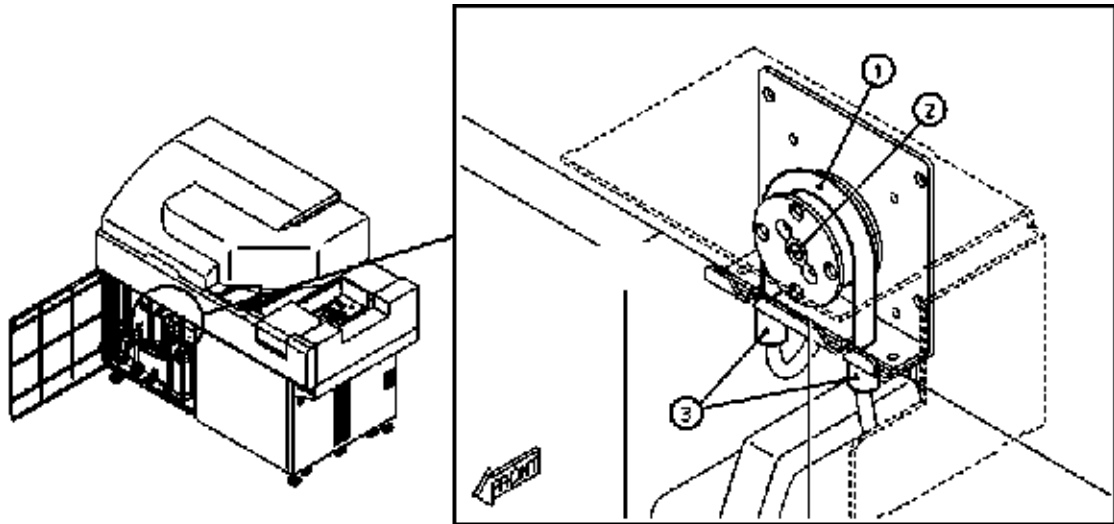
Deionized water tank

The deionized water tank has a capacity of 10 liters. A float sensor indicates when the volume in the tank is low and opens a valve to automatically fill it. Water conforming to CAP Type II water should be provided by the facility's deionized water system.

3.4.14 Wash Solution Roller Pump

The wash solution roller pump is used to supply wash solution to the diluted wash solution tank from the wash solution tank.

Figure 3.20



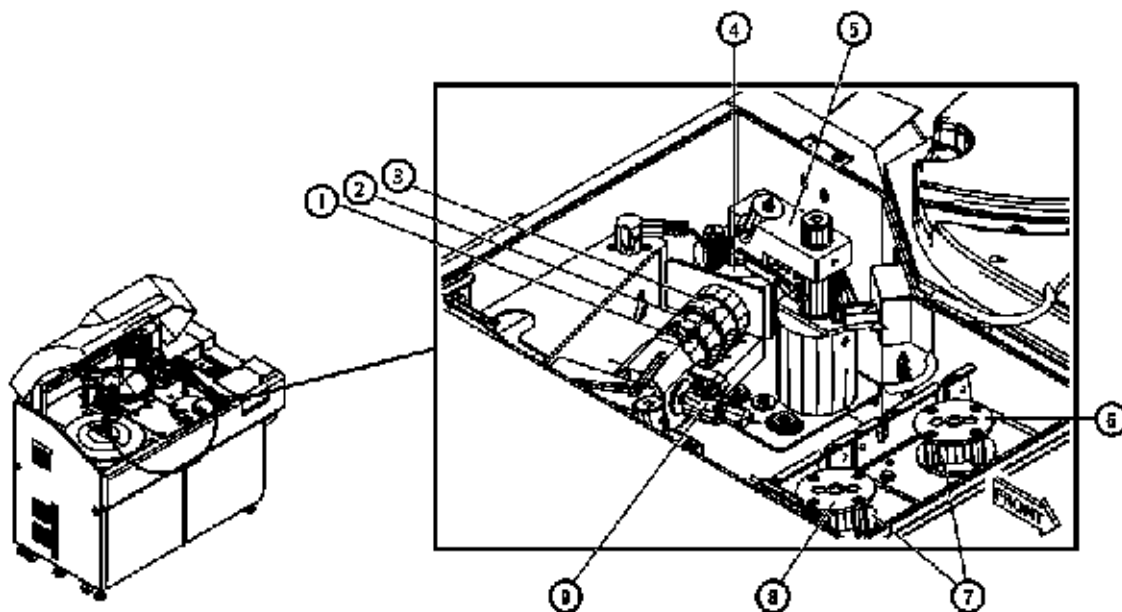
1. Roller pump tubing
2. Wash solution roller pump
3. Connectors

3.4.15 ISE Unit (optional)

Diluted sample is passed through Na, K, and Cl ion selective electrodes to determine the concentration by comparing the electrical potential difference to the reference electrode.

There is a common sample probe and sample syringe for photometric and ISE analysis.

Figure 3.21



- | | |
|-----------------|--------------------------------------|
| 1. K electrode | 6. MID Standard solution roller pump |
| 2. Na electrode | 7. Roller pump tubing |
| 3. Cl electrode | 8. Mixture aspiration roller pump |
| 4. Sample pot | 9. REF electrode |
| 5. Mixing unit | |

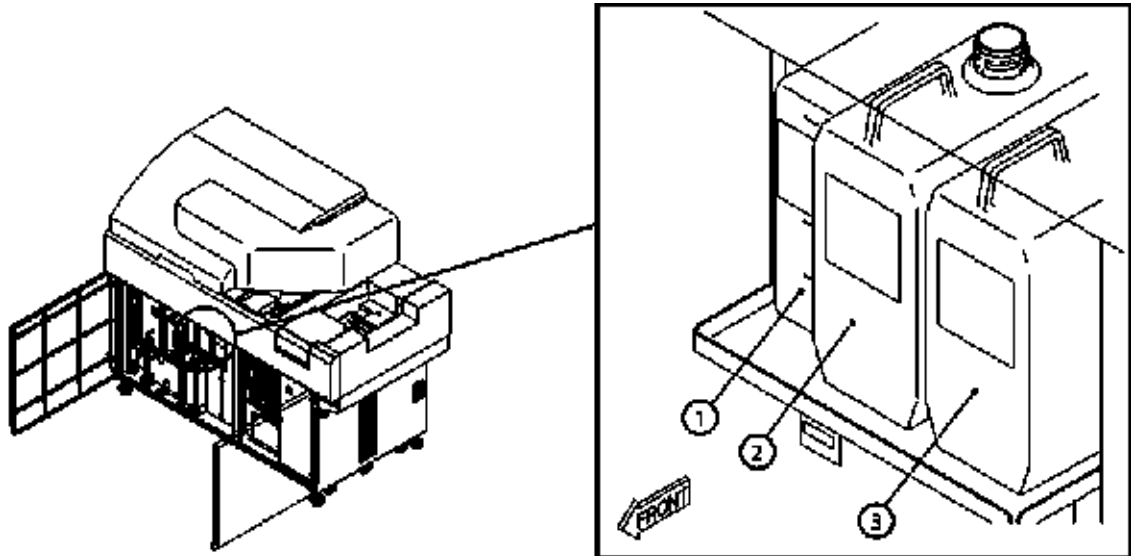
- **Mixing unit**
This unit mixes sample and buffer solution dispensed into the sample pot. It is equipped with two liquid-level sensors to detect proper drainage.
- **Sample pot**
Sample and buffer are dispensed into the sample pot and mixed. Following are the volumes dispensed for serum and urine:
 - Buffer solution: 618 μ L (fixed)
 - Sample: 20 μ L (fixed)
 - DI water: 10 μ L (fixed)
- **Cl electrode, Na electrode and K electrode (referred to as the flowcell)**
These electrodes are used for measuring the potential of Cl, Na and K ions in the sample and MID Standard solution. The concentrations of individual ions in the sample can be calculated from the potential differences between each ion in the sample and in the MID Standard solution.
- **REF electrode**
This is the reference electrode with respect to the Cl, Na and K electrodes.

- Pinch valve
This valve has two functions:
 1. Allows sample in the sample pot to enter the flowcell for measurement.
 2. Allows excess sample to pass through the bypass tubing to waste.
- Roller pump
There are two pumps.
Mixture Aspiration Pump (pump on left):
 1. Aspirates liquid from the sample pot through the flowcell or bypass tubing and out to waste.
 2. Aspirates reference solution from the reference bottle past the reference electrode and out to waste.Mid Solution Pump (pump on right):
Aspirates Mid Solution from the Mid Solution bottle to the sample pot.
- Roller tube
These tubes are made of rubber and wrap around the roller pump. As the roller pump rotates, the tubes are squeezed by the rollers on the pump, and solution is supplied or removed.

The ISE Reagent Bottles

There is a Buffer Solution bottle, MID Solution bottle, and Reference Solution bottle.

Figure 3.22

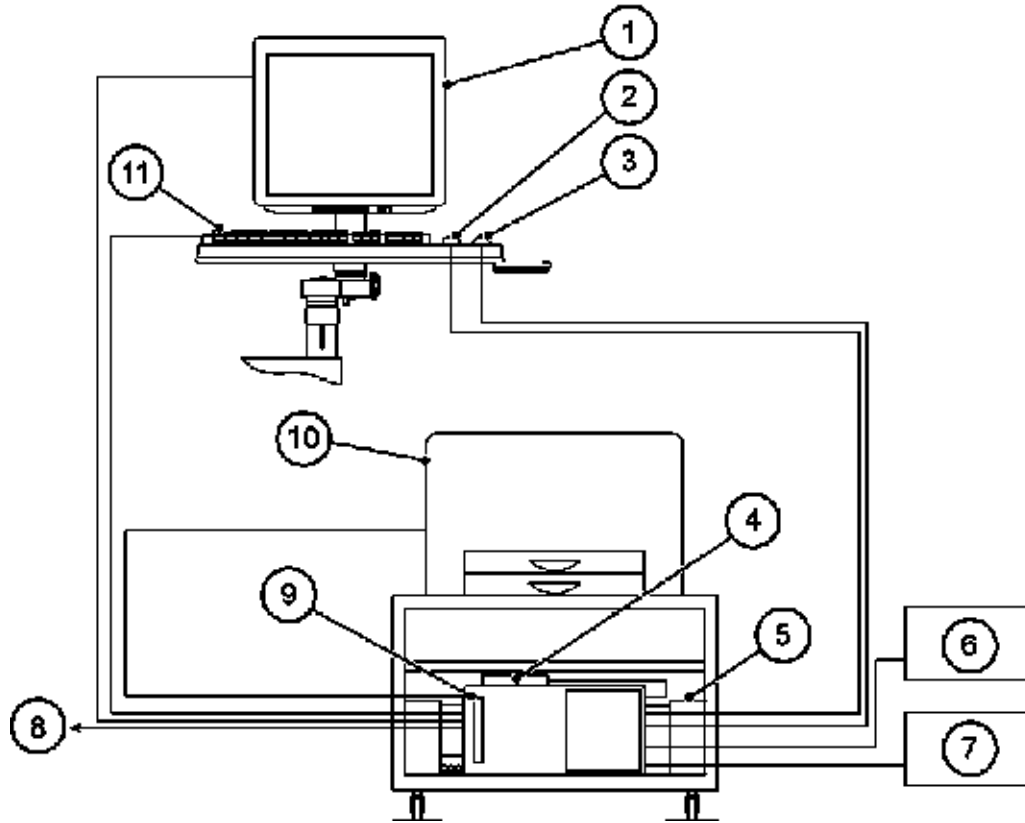


1. REF solution bottle
2. MID solution bottle
3. Buffer solution bottle

- Buffer solution bottle
Stores the buffer solution used for diluting the sample. The capacity of this container is 2 liters.
- MID solution bottle
Stores the MID solution. The MID solution is used to condition the electrodes between analysis. The capacity of this container is 2 liters.
- REF solution bottle
Stores the reference solution. The reference solution is used as a reference point in relation to the three electrodes. The capacity of this container is 1 liter.

3.4.16 Data Processing Unit (DPR)

Figure 3.23



- | | |
|---------------------------------------|----------------------|
| 1. Monitor | 7. Router (option) |
| 2. Mouse | 8. To ANL |
| 3. Hand scanner (option) | 9. DPR |
| 4. External memory unit (HD) (option) | 10. Printer (option) |
| 5. Speaker | 11. Keyboard |
| 6. Host computer | |

TIP Figure 3.23 is one example of the Data Processing Unit (DPR) configuration available for the AU480.

Monitor unit

The monitor displays the operating software, and the keyboard and mouse allow user input.

Data processing unit

A personal computer is used as the data processing unit to perform various data processing. Incorporated is a hard disk to store programs, analysis parameters, an analysis database and a DVD R/W unit. An external hard disk option is also available.

Printer unit (optional)

Analysis results and various setup contents can be output as a report or list.

Hand scanner (optional)

The hand scanner reads barcodes for input to the software. A sample ID can be scanned in the Sample ID field in **Home > Rack Requisition Sample**.

Assays programmed with the Master Curve option require a 2-dimensional barcode that contains calibration information. The hand scanner is used to manually scan the 2-dimensional barcode located on the R1 bottle label of appropriate AU reagents.

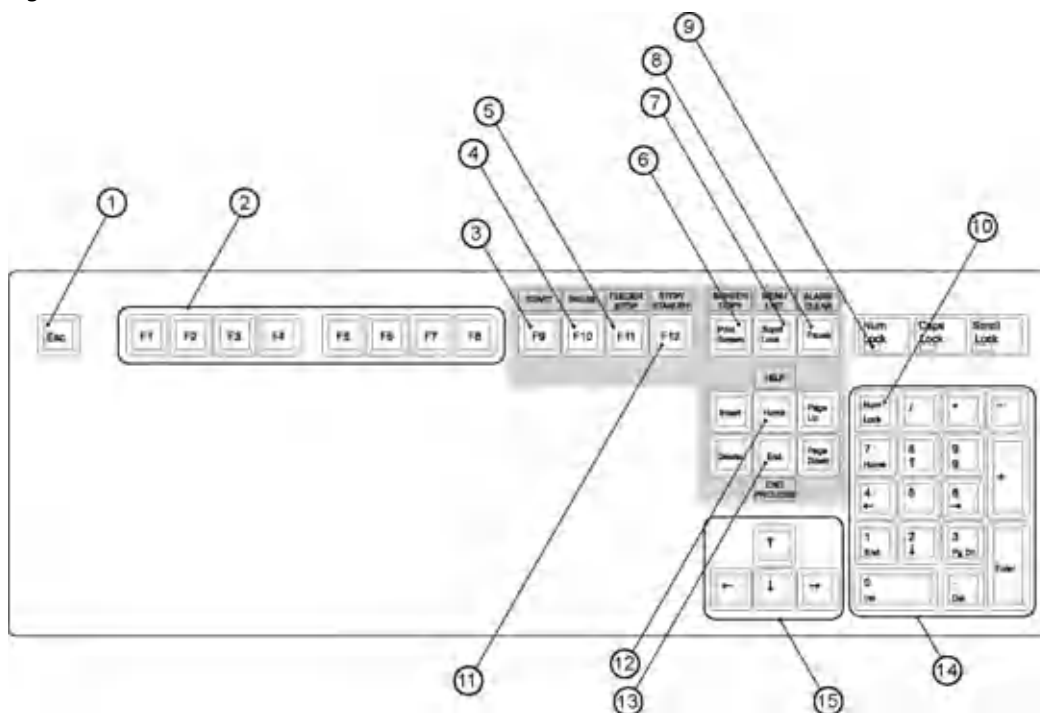
The following table summarizes the specifications for the hand scanner:

Hand Scanner Specifications	
Wavelength	630 to 680 nm
Output	1.0 mW
Class	2

3.4.17 Touch Screen, Mouse, and Keyboard

The system can be operated by using either the touch screen, mouse, or keyboard, in any combination.

Figure 3.24



- 1. ESC key
- 2. Function keys
- 3. Start key
- 4. Pause key
- 5. Feeder Stop key
- 6. Print Screen key
- 7. Menu List key
- 8. Alarm Clear key
- 9. Num Lock lamp
- 10. Num Lock key
- 11. Stop/Stand-by key
- 12. Home key
- 13. End Process key
- 14. Numeric key pad
- 15. ↑, ↓, ←, → Key

3.5 Software Description

The system is controlled using the standard windows graphical user interface (GUI).

3.5.1 Organization of Operation Window

3.5.2 Main Button Bar

3.5.3 Home Outline

3.5.4 Menu List Organization and Outline

3.5.5 User Menu Overview

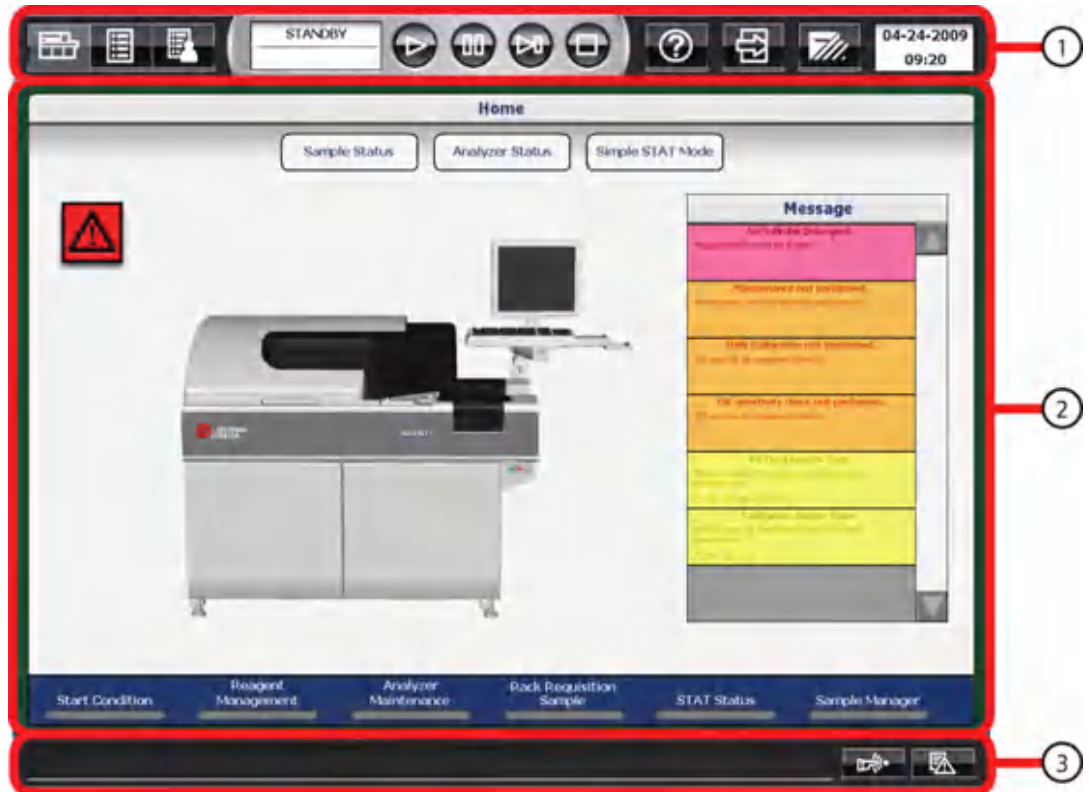
3.5.6 Using the Online Help

3.5.7 Analyzer Modes

3.5.1 Organization of Operation Window

This interface is composed of three main window display areas.











Figure 3.25



1. **Main button bar**
Display the main menus (**Home**, **Menu List**, **User Menu**) and access **Help**. **Start**, **Pause**, **Feeder Stop**, **Stop**, and **End Process** are the main operational buttons for the analyzer.
2. **Menu area**
A display and operation area for each menu or button selected.
3. **Alarm area**
The display area for the alarm messages generated during system operation, and the **Alarm Clear** and **Alarm List** buttons.

3.5.2 Main Button Bar

The system can be navigated by using the main buttons:

Button	Item	Actions
	Home	Returns to the Home menu.
	Menu List	Displays the Menu List menu.
	User Menu	Displays the User Menu set by the user. Refer to 4.10.7 Program a User Menu .
STANDBY	Mode Display area	Displays the current mode. The time to completion displays for some maintenance procedures.
	Start	Starts analysis.
	Pause	Pauses analysis. The system pauses at the first test for which no R1 reagent was dispensed.
	Feeder Stop	Stops the rack feeder. The analysis of samples in racks which have already been loaded continues.
	Stop/Standby	Stops analysis. In <i>Stop</i> mode, select this button to return the system to <i>Standby</i> mode.
	Help	Displays a menu to access user documentation and a maintenance video directory.
	Logout	Logs out and logs in a user.
	End	Performs an End Process . The End Process turns off the auxiliary power supply, including the lamp and computer.
12/20/2010 12:49	Time Display area	Displays the present date and time.

3.5.3 Home Outline

The system can be navigated by using the main buttons.

This is the screen to check system messages relating to sample Status and analyzer Status. Jump buttons provide direct menu access to the most frequently used menus to simplify software navigation.

Figure 3.26



1. Menu buttons
2. Message display
3. Jump buttons

Menu buttons

Menu buttons display menus.

Table 3.1 Menu buttons

Menu Button	Action
Sample Status	Displays the sample status under analysis, estimated time of completion, and results.
Analyzer Status	Displays the analyzer status and temperatures.
Simple STAT Mode	Processes STAT samples one at a time with minimal operator actions required. It is not possible to process samples in the normal analyzer operation modes.

Message display

Displays messages regarding system conditions that could affect analysis results.

Color-coding indicates the level of the message:

Table 3.2 Message display

Color	Meaning
Red	Analysis cannot be started until the message is addressed.
Orange	Analysis can be started. Review the message carefully and take appropriate action.
Yellow	Analysis can be started. Review the message carefully and take appropriate action. The message can shift to Orange Status (more critical).
Green	A notification of system Status. There are no operational problems.

If a message is selected, a window opens with information and corrective actions for the message. Select **OK** to close the window.

TIP A red Message or highlight on the analyzer picture indicates a condition that prevents starting the analyzer.

Jump buttons

Jump buttons provide direct menu access to the most frequently used menus to simplify software navigation.

Table 3.3 Jump buttons

Jump Button	Action
Start Condition	Sets a new data index, the Group of tests in use, the Operator name, and Start Sample numbers.
Reagent Management	Displays the R1 and R2 reagent Status and cleaning solution Status.
Analyzer Maintenance	Displays the analyzer and ISE maintenance schedules. Use this menu to start some maintenance procedures and update the schedule when maintenance has been performed.

Table 3.3 Jump buttons

Jump Button	Action
Rack Requisition Sample	Displays sample information and test requisitions for patient samples, calibration, and QC.
STAT Status	Displays, starts, and monitors priority STAT samples for analysis from the STAT table.
Sample Manager	Views, prints, and batch transfers to host computer reagent blank, calibration, QC, and sample data.

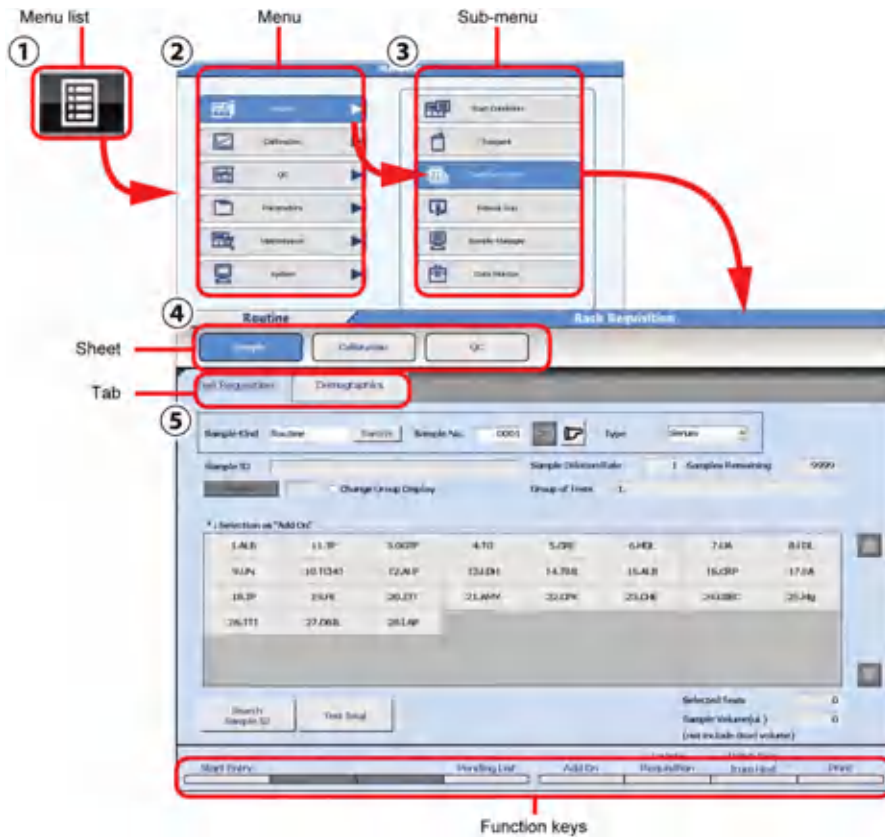
3.5.4 Menu List Organization and Outline

To setup the required parameters, access analysis information and to check analysis results, select the appropriate menu and sub-menu category in the following order **Menu List > Menu > Submenu > Sheet > Tab**.

The following example displays the pathway using the Rack Requisition Screen.

- 1 Select the **Menu List** button from the main button bar.
- 2 Select **Routine** from the menu.
- 3 Select **Rack Requisition** from the sub-menu.
- 4 Select **Sample** from the sheet.
- 5 Select **Test Requisition** from the tab.

Figure 3.27



TIP Access Menu List from the main button bar from any screen.

Organization and functional outline of Routine menu

This menu is used for various basic operational tasks.

Some menus require initial programming in System Maintenance before they can be used.

Menu	Sub-menu	Choice
Routine	Start Condition	Used to set the index, Group of tests, operator name, and start sample numbers before starting analysis. Refer to 5.1.2 Set the Start Conditions .
	Reagent	Reagent Management Used to check the quantity of reagent and the number of tests available in a bottle. Refer to 5.5 Check Reagent Status and 7.4 Reagent Management .
		Reagent Inventory A breakdown of the volume or shots of R1 and R2 (for each reagent) used for each day of the week for a specified time frame. Refer to 7.4.5 Reagent Inventory .
		Reagent Consumption A breakdown of reagent used for a specified time frame by volume or shots of R1 and R2 by each rack type. Refer to 7.4.6 Reagent Consumption .
	Rack Requisition	Sample Used to manually program patient samples (demographics and tests). Refer to 6.3 Requisition for Routine and Emergency Samples .
		Calibration Used to requisition reagents for calibration. Refer to 5.6 Perform Calibration .
		QC Used to requisition quality control samples. Refer to 5.7 Perform Quality Control (QC) .
	STAT Requisition	STAT Status Used to view the Status of the STAT table and start STAT sample analysis.
		Sample Used to perform priority STAT sample requisitions for STAT analysis on the STAT table.
		Calibration Used to perform calibration requisitions for calibration analysis from the STAT table.
		QC Used to perform QC requisitions for QC analysis from the STAT table.

Menu	Sub-menu	Choice
Routine (Continued)	Repeat Run	Repeat Order Used to add, change or delete repeat test requisitions. Refer to 6.6 Performing a Repeat Run .
		Repeat Data Verification Used to view repeat results with the original results and to overwrite data. Refer to 7.3.6 Verify Repeat Results .
	Sample Manager	Sample Used to display analysis results, perform data correction, print a data list and batch transfer data online. <ul style="list-style-type: none"> • Refer to 7.6 Edit Analysis Data. • Refer to 6.7 Print Results. • Refer to 6.8 Transfer Data to Host Computer.
		RB/CAL/QC Used to print and batch transfer RB/CAL/QC data Refer to 6.7 Print Results .
	Data Monitor	Reaction Monitor Displays information about reaction processes of analysis results. Refer to 7.3.2 Display Reaction Monitor .
		Data Statistics Displays key statistics of patient sample results and the results of a test within one index as bar charts. Refer to 7.7.1 View Data Statistics .
		Correlation Chart Displays a correlation chart. Refer to 7.7.2 Create a Correlation Chart .

Organization and functional outline of Calibration menu

Display a history of calibration information and perform calibration verification.

Menu	Sub-menu	Choice
Calibration	Calibration Monitor	View the current reagent blank and calibration Status as well as a history of the reagent blank and calibration data on a graph. Refer to 7.3.4 Check the Reagent Blank and Calibration .
	Calibration verification	Calibration Verification Verifies the calibration performance. Refer to 7.9.2 Verify Calibration .
		Material Parameters Enter Parameters for calibration verification and view or print a chart. Refer to 7.9.1 Enter Material Parameters .

Organization and functional outline of QC menu

Display and edit the result and history of quality control.

Menu	Sub-menu	Choice
QC	QC Monitor	Daily Chart Displays the QC data variation within the same or between index dates as a daily chart. Refer to 7.3.5 Check QC .
		Day to Day Chart Displays the QC data variation within the same or between index dates as a day to day chart. Refer to 7.3.5 Check QC .
		Twin Plot Chart Displays the QC data variation of two QC samples as a twin plot chart. Refer to 7.3.5 Check QC .
	QC Data Review	Used to edit QC result Refer to 7.5 Edit Quality Control Data .

Organization and functional outline of Parameter menu

Use this menu to program information for all tests. This information is required prior to running the system.

Parameters must be programmed in advance of running the analyzer for the first time.

Menu	Sub-menu	Choice
Parameters	Common Test Parameters	Test Name Program basic parameters such as test name and reagent ID. Refer to 4.2.1 Test Name Menu .
		Profile Program profiles for samples, reagent blank, calibration, and QC. Refer to 4.2.2 Profile Menu .
		Group of Tests Assign tests to a Group. A maximum of three Groups of tests can be programmed. A maximum of 60 photometric tests and 3 ISE tests can be programmed in a Group. Refer to 4.2.3 Group of Tests Menu .
	Specific Test Parameters	General Used to set detailed parameters for general test items. Refer to 4.3.1 General Menu .
		LIH (Serum Index) Used to set detailed parameters for the Lipemia/Icterus/Hemolysis test. Refer to 4.3.2 LIH Menu .
		ISE Used to set detailed parameters for the ISE tests. Refer to 4.3.3 ISE Menu .
		Calculated Tests Used to set detailed parameters for calculated tests. Refer to 4.3.4 Calculated Tests Menu .
		Range Used to set parameters for the reference range. Refer to 4.3.5 Range Menu .
	Repeat Parameters	Repeat Common Used to set the common parameters for a repeat run analysis. Refer to 4.4.1 Repeat Common Menu .
		Repeat Specific Used to set the repeat and reflex decision ranges and the repeat dilution rate of repeat run analysis for individual test items. Refer to 4.4.2 Repeat Specific Menu .

Menu	Sub-menu	Choice
Parameters (Continued)	Calibration Parameters	Calibrators Used to set common calibrator parameters such as name, ID and lot number. Refer to 4.5.1 Calibrators Menu .
		Calibration Specific Used to set specific calibration parameters for individual test items. Refer to 4.5.3 Calibration Specific Menu .
		STAT Table Calibration Used to set parameters for calibration analysis using the STAT Table.
	QC Parameters	Controls Used to set the common parameters for a quality control analysis. Refer to 4.6.1 Controls Menu .
		QC Specific Used to set the mean value and standard deviation for quality control. Refer to 4.6.2 QC Specific Menu .
		STAT Table QC Used to set parameters for QC analysis using the STAT Table.
	Misc	Checked Tests Used to set parameters for logic checked tests. Refer to 4.7 Checked Tests Menu .
		Contamination Parameters Used to set parameters to prevent contamination of tests. Refer to 4.8 Contamination Parameters Menu .
		Data Check Parameters Used to set parameters for data check such as diagnosis of prozone. For detailed information, contact Beckman Coulter Technical Services. Refer to 4.9 Data Check Parameters Menu .

Organization and functional outline of Maintenance menu

Use this menu to monitor analyzer and ISE maintenance, review a detailed alarm log, and perform diagnostic functions.

Menu	Sub-menu	Choice
Maintenance	User maintenance	Analyzer Maintenance Displays the maintenance schedule and perform maintenance procedures. Refer to CHAPTER 8, Maintenance .
		ISE Maintenance Displays the maintenance schedule of the ISE unit and perform ISE maintenance procedures. Refer to CHAPTER 8, Maintenance .
	Alarm log	Chronologically lists the alarms that have occurred.
	Maker Maintenance	Program Version Displays DPR program, PROService and Help version/revision and program version/revision/station ID of Analyzer.
		Analyzer Diag Checks each analyzer component for abnormal conditions. Some checks should only be performed by Technical Services.
		ISE Diag This menu contains the following major operations. Some checks should only be performed by Technical Services. <ul style="list-style-type: none"> • Checks the ISE component for any abnormal conditions • Performs calibration and sample measurement • Performs Buffer, MID/REF, or Total Primes.

Organization and functional outline of System menu

This is a menu to set online conditions, list formats, comments, barcode options, various system settings, and data management.

Menu	Sub-menu	Choice
System	Online	Used to set the parameters for online communication between a host computer and the system. Refer to 4.12 Program Online Parameters .
	Format	Requisition Format Used to enter the sample requisition parameters. Refer to 4.13 Program the Requisition Format .
		List Format Used to set the common format parameters for printing the pending list, work list, repeat list and the data list. Refer to 4.14 Print Formats .
	Comment Masters	Used to customize the comments appended to the analysis results. Refer to 4.10.6 Program Master Comments .
	System condition	Analysis Mode Used to set the analysis mode, barcode definition, auto/standard repeat and other system parameters. Refer to 4.10.1 Analysis Mode Menu .
		Set Date and Time Used to set the system date and time. Refer to 4.10.4 Set the System Time .
		Auto Power On Used to set the auto power on time for each day of the week. Refer to 4.10.5 Program the Automatic Startup Function .
		Password Used to set and change passwords. Refer to 4.11.2 Set a User Name and Password .
		Login Condition Used to set login information. Refer to 4.11 Program a User Name and Password .
	User Menu	Used to add a menu to the User Menu button on the main button bar. Refer to 4.10.7 Program a User Menu .

Menu	Sub-menu	Choice
System (Continued)	Data Management	External Data Management Saves the analysis data on an external storage device or media. Refer to 7.8.1 Save Data to External Media .
		File Management Used to save and up load parameter files on an external storage device or media. Refer to 7.8.2 Save or Load Parameters .
		Offline format Used to set the output format of results and save data in a delimited format for use in external applications (spreadsheets, etc). Refer to 7.8.3 Offline Criteria .

3.5.5 User Menu Overview

Select **User Menu**:

Figure 3.28



- A customized (user-defined) list of common menus.
- Customize (user-defined) menu names.
- Select **User Menu**, then select the required menu for direct access.

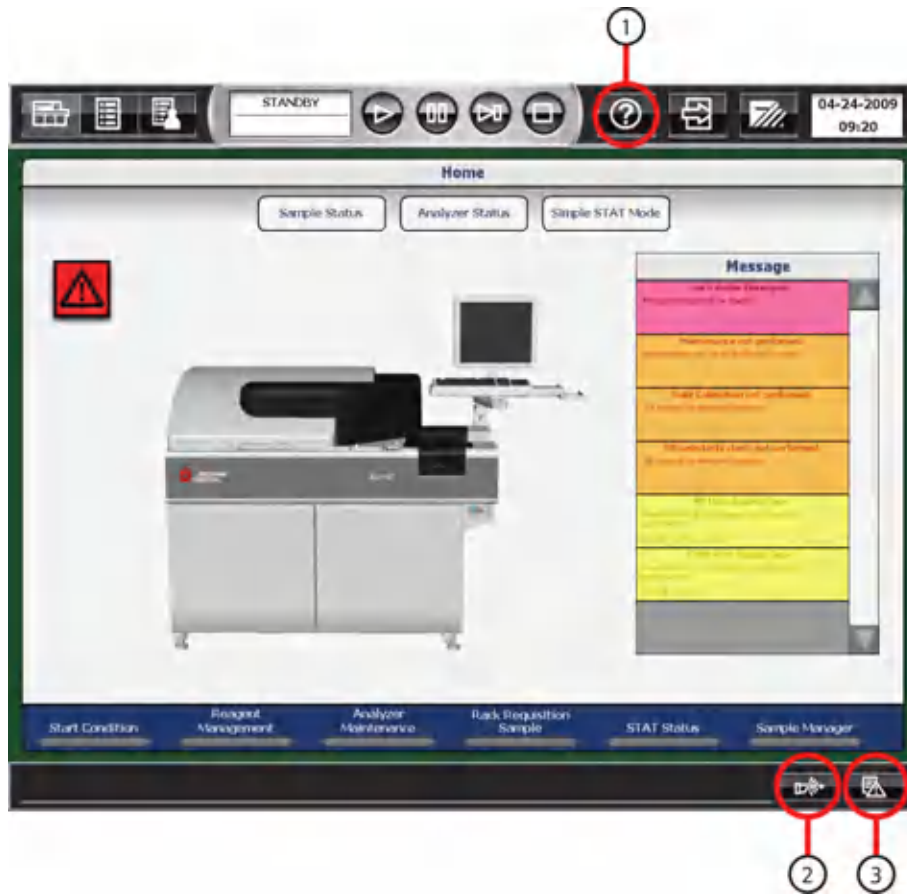
3.5.6 Using the Online Help

The **Help** button displays a menu to access user documentation and a maintenance video directory.

The **Alarm List** button provides alarm descriptions and corrective actions.

TIP To stop the audible alarm, select **Alarm Clear**. Select **Alarm Clear** a second time to clear the alarm message from the screen.

Figure 3.29



1. Help
2. Alarm Clear
3. Alarm List

Four types of help are shown in the following table.

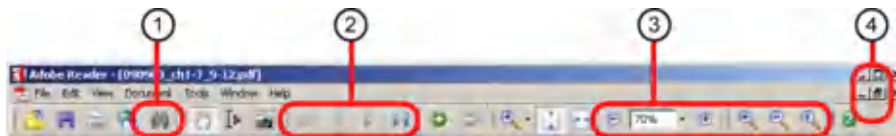
Type of Help	Displayed Description
Help	Displays the PDF version of this document and Maintenance videos. Select the Help button. The Help button can only be accessed in <i>Warm Up</i> , <i>Standby</i> , or <i>Stop</i> .
Alarm List	Displays alarm descriptions and corrective actions. Select Alarm List to display the Alarm List window. Select the Help button on the Alarm List window.
Input Help	Displays the range of allowable input values. Move the cursor over the input area to display the pop-up Input Help .
Button Help	To determine the function of a button, move the mouse pointer over the button and a pop-up message indicates the function of the button.

This document does not describe alarms or corrective actions. Select **Alarm List** for alarm help.

How to use Operation Help

PDF files are viewed using the Adobe Reader® software.

Figure 3.30



1. Search for information by entering a search string
2. Browse from one page to another
3. Zoom in and out
4. Maximize and resize

Major features of the Adobe Reader® software include:

- Search for information by entering a search topic.



Click the binoculars symbol. Enter the search topic or word and click search.

- Browse from one page to another:



Use the Next Page and Previous Page buttons at the bottom of the window.

- Zoom in and out:



Use either the plus or minus button to the left and right of the percentage reading or click the magnifier and then click the page. To decrease the size of the page, select the minus magnifier from the drop-down list.

- Maximize and resize:



To resize the reader window (e.g. to make it smaller), click the Restore Down button in the top right-hand corner of the window. Position the cursor at the edge of the window and when it changes to a double-ended arrow, drag the borders of the window to the desired size. As the border is dragged, the size of the document automatically zooms allowing more text to become readable.



To expand the window to fit the full size of the window again, click the Maximize button.

- Close the Adobe Reader®:



To close the PDF file when finished using it, click the X button in the top right-hand corner of the Reader® window.

3.5.7 Analyzer Modes

The system measure modes displayed in the “Mode Display Area” are shown below.

Mode	Contents
<i>Initial</i>	Displays after the green ON button is pressed. The software loads and the hardware initializes.
<i>Warm up</i>	After the system initializes, the mode changes to <i>Warm Up</i> for approximately 20 minutes to allow the lamp to warm up and stabilize.
<i>Standby</i>	When the system is ready to perform sample analysis, the operation mode changes to <i>Standby</i> . Analysis can be started.
<i>Measure 1</i>	<i>Measure 1</i> occurs when the Start button is selected. Racks are present on the rack supply unit, and are moving to the sample aspiration position.
<i>Measure 2</i>	<i>Measure 2</i> occurs when there are no more racks on the rack supply unit. To start additional racks, press the Start button.
<i>Stop</i>	<i>Stop</i> mode occurs when there is a system error, or when the operator presses the Stop/Standby button. The analyzer cannot be started from <i>Stop</i> mode. To return to <i>Standby</i> mode, press the Stop/Standby button. The mode displays as <i>Reset</i> while the hardware is initializing, then it goes to <i>Standby</i> . All tests in progress must be repeated.
<i>Pause</i>	<i>Pause</i> mode occurs when there is a system error, or when the operator selects the Pause button. Analysis can be re-started from <i>Pause</i> by selecting Start button. All tests in progress are completed.

Processing time

The analysis processing time is defined as the time from aspiration of a sample by the sample probe until the end of measurement. The necessary time for analysis is approximately 8 minutes and 30 seconds.



If a Stop or Emergency Stop occurs, sample can remain in the sample probe, and reagents can remain in the cuvettes. Perform a W1 to clean the sample probe and cuvettes.

For details on how to perform a W1, refer to [8.8.11 Perform a W1](#) in chapter 8.

Parameters

This chapter describes how to program a new test on the system and contains a detailed description of all the Parameters menus.

- 4.1 Program a New Test
- 4.2 Common Test Parameters Menu
 - 4.2.1 Test Name Menu
 - 4.2.2 Profile Menu
 - 4.2.3 Group of Tests Menu
- 4.3 Specific Test Parameters Menu
 - 4.3.1 General Menu
 - 4.3.2 LIH Menu
 - 4.3.3 ISE Menu
 - 4.3.4 Calculated Tests Menu
 - 4.3.5 Range Menu
- 4.4 Repeat Parameters Menu
 - 4.4.1 Repeat Common Menu
 - 4.4.2 Repeat Specific Menu
- 4.5 Calibration Parameters Menu
 - 4.5.1 Calibrators Menu
 - 4.5.2 Program Calibrator Concentrations
 - 4.5.3 Calibration Specific Menu
 - 4.5.4 STAT Table Calibration Menu
- 4.6 QC Parameters Menu
 - 4.6.1 Controls Menu
 - 4.6.2 QC Specific Menu
 - 4.6.3 STAT Table QC Menu
- 4.7 Checked Tests Menu

- 4.8 Contamination Parameters Menu
 - 4.8.1 Contamination Prevention Tab
 - 4.8.2 Carry-Over Prevention (Type Changes) Tab
 - 4.8.3 Carry-Over Prevention (Test) Tab
- 4.9 Data Check Parameters Menu
- 4.10 System Parameters
 - 4.10.1 Analysis Mode Menu
 - 4.10.2 Program the Rack Number Limit
 - 4.10.3 Program STAT Table Parameters
 - 4.10.4 Set the System Time
 - 4.10.5 Program the Automatic Startup Function
 - 4.10.6 Program Master Comments
 - 4.10.7 Program a User Menu
- 4.11 Program a User Name and Password
 - 4.11.1 Set the Access Level
 - 4.11.2 Set a User Name and Password
 - 4.11.3 Security Settings
- 4.12 Program Online Parameters
 - 4.12.1 Program Online Parameters with RS232C Connection
- 4.13 Program the Requisition Format
- 4.14 Print Formats
 - 4.14.1 Format Realtime Reports and Lists
 - 4.14.2 Program Realtime Print Options
 - 4.14.3 Save Data to a File
 - 4.14.4 Copy Format Parameters
 - 4.14.5 Add or Change a Comment
- 4.15 Lipemia, Icterus, and Hemolysis (LIH)

4.1 Program a New Test

Program the new test using the chemistry setting sheet. Refer to the following menu descriptions in this chapter for detailed explanations of menu items.

1 Select **Menu List > Parameters > Common Test Parameters > Test Name.**

- Select **Edit (F1)**.
- Test Name: Enter a maximum of 6 characters.

 **CAUTION**

Changing the test name affects all results associated with that test number. Any previously reported results (with the old test name) are assigned the new test name. Extreme caution must be applied when making any changes to the test name.

DO NOT CHANGE THE TEST NAME WITHOUT NOTING THE TIME AND DATE THAT THE CHANGE OCCURRED AND THEN ENSURING ANY RESULTS PRINTED OUT PRIOR TO THIS TIME AND DATE ARE REVIEWED AND CORRECTLY IDENTIFIED.

Tests are processed on a sample in the test number order (1 to 120) displayed, with some exceptions. For information on contamination prevention, refer to [4.8 Contamination Parameters Menu](#).

- Long Name: (Optional) Enter a maximum of 20 characters.
- Reagent ID: Enter the first 3 digits of the reagent ID, or refer to the chemistry setting sheet for the reagent ID 3-digit code.
- Alarm Shots: Enter the remaining test number to generate a Reagent Short alarm. The default is 32.
- Multi Reagent Switch: Select **Yes**. This allows the analyzer to switch to a new sequence of R1/R2 when either the R1 or R2 of a sequence becomes empty.
- Verify the information and select **Confirm (F1)**.

2 Select **Group of Tests.**

- Select Group 1, 2, or 3 from the "Group" drop-down list.
- Select **Edit (F1)**.
- Select **Test Setting (F5)**.
- Select the test to add to the Group. The test name highlights in blue. Select **Close**.
- To change the print order: Select a test to enable **Forward (F2)** and **Backward (F3)**. Move the test in the Group as needed to change the print order.
- Verify the information and select **Confirm (F1)**.

3 Select **Profile**.

- Select **Edit (F1)**.
- Select **Sample, RB/Calibration**, and **QC** as needed to add the test to any required profile. Verify the Sample Type for each profile.

TIP In the **Sample** tab, a user-defined default profile (number 0) can be programmed for each sample type. The sample default profile is performed when there is no requisition available for a sample, for example with a sample ID read error. In the **QC** tab, default QC profiles (numbers 87-98) can be programmed based on sample type and Group. The QC default profile is the automatic QC requisition made after a reagent volume check, and after processing QC samples.

- Select a profile from the "Profile Name" drop-down list.
 - Select the test. The selected tests highlight in blue.
 - Verify the information and select **Confirm (F1)**.
-

4 Select **Menu List > Parameters > Specific Test Parameters > General**.

- Select **Edit (F1)**.
- Select the test from the "Test Name" drop-down list.
- Select the sample type from the "Type" drop-down list. Verify **Yes** is selected for the sample type from the "Operation" drop-down list.
- Enter the specific test parameters from the chemistry setting sheet.
- Verify the information and select **Confirm (F1)**.

TIP Display the parameters for a maximum of 6 tests at a time for verification. Select **List Display (F7)**. The first 6 tests display. Use the arrows to page to the new test.

5 Select **Range**.

- Verify the test name from the "Test Name" drop-down list.
- Select the sample type from the "Type" drop-down list.
- Select **Edit (F1)**.
- Select **Set Decimal Places (F5)**. Select **0-4** for the appropriate decimal place for the results. Select **Close**.
- "Value/Flag":
 - Select **Value** to access "Specific Ranges" to set high (H flag) and low ranges (L flag).
 - Select **Flag** to access "Level" to set a positive limit (P flag) or negative limit (N flag), typically used for drugs of abuse testing.

- “Specific Ranges”: Set a reference range to generate high (H) and low (L) flags.
 - Check 1 – 6 to enter a range based on sex and age.
 - 7: Standard demographics: Enter a generic normal range. This range is used for the sample without patient demographic information (age and gender).
 - 8: Not within expected values: This range is used for the sample with patient demographic information (age or gender), but the age or gender information did not meet the age and gender defined in the specific range 1-6.
- “Panic Value”: Set a range to generate a panic alarm and “pl” or “ph” flags (Optional).
- “Unit”: Enter units. Units print if they are formatted on the report.
- Verify the information and select **Confirm (F1)**.

6 Select **Menu List > Parameters > Calibration Parameters > Calibrators**.

- If it is necessary to program new calibrator material:
 - Select **Edit (F1)**.
 - Select an available Calibrator No. and Type.
 - Enter the Calibrator Name, ID, Lot No., and Expiration.

TIP The Calibrator Name is necessary to identify the calibrator material associated with the Calibrator No. The ID is necessary if calibrator barcode operation is in use to enter the calibrator ID. Lot No. and Expiration are optional fields.

- Verify the information and select **Confirm (F1)**.

7 Select **Calibration Specific**:

- Select the test name from the "Test Name" drop-down list. Select the sample type from the "Type" drop-down list.
- Refer to the chemistry setting sheet to determine if the Calibration Type is “AB” or “MB”, and enter Calibration Specific parameters.
- If the Calibration Type is “AB”:
 - Refer to the chemistry setting sheet for Formula, Slope Check, Factor Range, Allowable Range Check, Advanced Calibration, Lot Calibration, and Stability.
 - Counts (replicates): Enter a number from 1 to 4. For more information, refer to [4.5.3 Calibration Specific Menu](#).
 - Select the calibrator material from the "Calibrator" drop-down list.
 - Enter the calibrator concentration from the package insert for "Conc."
- If the Calibration Type is “MB”:
 - Refer to the chemistry setting sheet for Formula, Allowable Range Check, Advanced Calibration, MB Type Factor, and Stability.
 - Counts (replicates): Enter a number from 1 to 4. For more information, refer to [4.5.3 Calibration Specific Menu](#).
- Verify the information and select **Confirm (F1)**.

8 Select **Menu List > Parameters > QC Parameters > Controls.**

- If it is necessary to program new control material:
 - Select **Edit (F1)**.
 - Select an available QC No. and Type.
 - Enter the Control Name, ID, Lot No., Expiration, and STAT Uses.
 - Verify the information and select **Confirm (F1)**.
-

9 Select **QC Specific:**

- Select **Preset** tab.
 - Select the test name from the "Test Name" drop-down list. Select the sample type from the "Type" drop-down list.
 - Select **Edit (F1)**.
 - Select the QC name from the "Control" drop-down list.
 - Select **Multi** or **Single** from the "Multi/Single" drop-down list.
 - Use the QC package insert or known values to enter the Mean, SD, and Range. QC is determined to be in or out of these preset ranges when QC Mode is set to "Preset" (on the **Check** Tab.).
 - Enter the QC mean at "Mean."
 - Enter a 1 SD value at "SD."
 - Enter the value of the range at "Range." The Range is the high value minus the low value.
 - Verify the information and select **Confirm (F1)**.
-

10 Select **Menu List > System > Format > List Format.**

Do not change any parameter settings for items in Basic Condition, Print Information, or Layout. These parameters affect the format of the printout.

11 Select **Test Item.**

- Select **Edit (F1)**.
- The new test must be added to any required realtime printouts (reagent blank, calibration, QC, and samples) and lists in use before it prints. Select all required reports and lists from the "List Name" drop-down list. Select the test to add it to the report and/or list. The test is highlighted in blue when it is selected.
- Verify the information and select **Confirm (F1)**.

12 Select **Menu List > Parameters > Misc > Contamination Parameters**.

TIP Contact Beckman Coulter Technical Services for assay specific contamination parameter information.

- Select **Edit (F1)**.
- Program the Preceding Test Name, Following Test Name, Reagent Probe Cleaner Kind, Wash Count, Effectiveness of Water Cleaning, Mixer, and Cuvette if additional contamination prevention parameters are required.
- Verify the information and select **Confirm (F1)**.

13 If online communication with a laboratory information (host) system or middleware system is in use, it is necessary to program an online test number. Select **Menu List > System > Online > Online Test No.**

- Select **Edit (F1)**.
- Enter the "Online Test No.". The combination of the online test number and test must coincide with the clinical laboratory host system. Set the number as a blank when online communication is not required.
- Verify the information and select **Confirm (F1)**.

TIP When the test number of the host system and the online test number differ, the data may not be transmitted correctly.

14 Run the test to verify the programming of the new test(s).

- Load the reagent and any required cleaning solution on the analyzer.
 - Perform a reagent volume check.
 - Verify that calibration is requisitioned for the new test(s).
 - Requisition QC on the new test(s) if the test(s) was not added to the default QC requisition.
 - Perform a reagent blank, calibration, and QC on the new test(s).
 - Review the printout and verify the reagent blank, calibration, and QC data.
-

4.2 Common Test Parameters Menu

4.2.1 Test Name Menu

4.2.2 Profile Menu

4.2.3 Group of Tests Menu

4.2.1 Test Name Menu

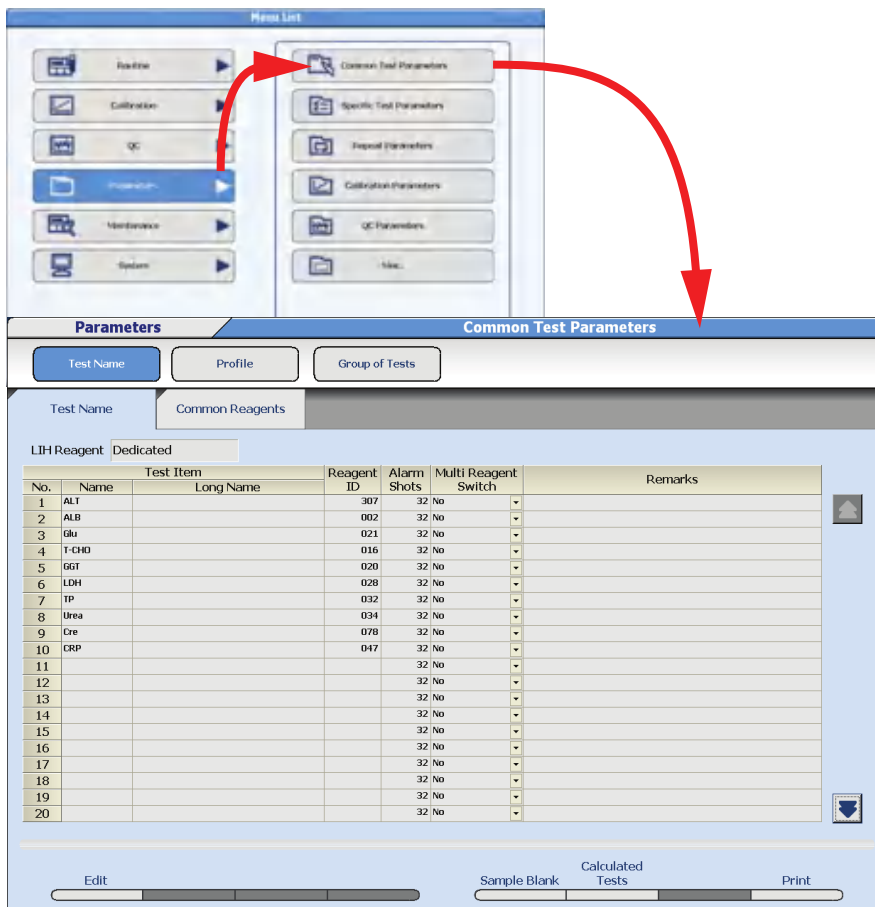
Use this menu to program test parameters including the test name, reagent ID, and reagent short alarm.

A maximum of 120 tests can be programmed. The contents of this menu may be printed.

Test Name Tab


Select **Menu List > Parameters > Common Test Parameters > Test Name.**

Figure 4.1



Set the following items as required.

Item	Contents	Input Notes
LIH Reagent	Dedicated or Non Dedicated	<p>Dedicated means using test number 96. LIH with LIH Reagent (OSR62166) as the reagent. LIH Reagent has a reagent ID and can be placed in any open position in the reagent refrigerator.</p> <p>Non Dedicated means using an existing (on-board) test and reagent for LIH testing. A maximum of three tests can be programmed to the Group for LIH analysis.</p> <p>To program Dedicated or Non Dedicated, select Edit (F1) > LIH (F7). Select Dedicated or Non Dedicated from the "LIH Reagent" drop-down list. Select Close.</p>
No.	1 to 120	<p>A maximum of 120 tests can be programmed on the system. Tests are processed on a sample in the order (1 to 120) displayed. Tests 96. LIH, 97. Na, 98. K, and 99. Cl are pre-programmed test numbers that cannot be changed.</p>
Test Name	An abbreviated test name.	<p>A maximum of 6 characters.</p> <p>Test names for test numbers 96 to 102 are preset in the software and cannot be changed.</p>
Long Name	A complete test name.	<p>A maximum of 20 characters.</p>
Reagent ID	3 digits (000 to 999).	<p>The 3-digit "Reagent ID" located on the top, right side of the chemistry setting sheet, or the first 3 digits from the reagent ID label.</p> <p>Enter the same reagent ID for two tests to use the same bottle of reagent. Available for reagent ID or fixed reagents. In Reagent Management, both test names display for the bottle.</p>
Alarm Shots	1 to 200. The default is 32.	<p>Number of tests remaining when a reagent short alarm is generated.</p>

Item	Contents	Input Notes
Multi Reagent Switch  CAUTION Beckman Coulter recommends programming Multi Reagent Switch to "Yes" for all Beckman Coulter reagents.	Yes or No	<p>“Yes”: When multiple sets of an R1/R2 are in use, and the R1 or R2 becomes empty in the first set, the analyzer switches to the second set of R1/R2 at the same time. One indicator bar displays for R1 and R2 in Reagent Management.</p> <p>“No”: The default setting is “No”. If an R1 or R2 becomes empty, the analyzer does not switch to the second set of R1/R2 at the same time. An indicator bar displays for R1 and R2 in Reagent Management.</p>
Remarks	Displays a comment indicating the test is a sample blank test or a calculated test.	Remarks appear automatically and cannot be entered.

 **CAUTION**

Changing the test name affects all results associated with that test number. Any previously report results (with the old test name) are assigned the new test name. Extreme caution must be applied when making any changes to the test name.

DO NOT CHANGE THE TEST NAME WITHOUT NOTING THE TIME AND DATE THE CHANGE OCCURRED AND THEN ENSURING ANY RESULTS PRINTED OUT PRIOR TO THIS TIME AND DATE ARE REVIEWED AND CORRECTLY IDENTIFIED.

Tests are processed on a sample in the test number order (1 to 120) displayed, with some exceptions. For information on contamination prevention, refer to [4.8 Contamination Parameters Menu](#).

Sample Blank (F5):

Interference from other substances in the serum may affect the optical density measured. To correct this interference, a sample blank correction is performed. Sample blank correction uses the terms “color” and “blank”. These identify the active reagent (color) and the inert reagent (blank). The OD value of Y obtained from the formula $Y = X - B$ (X is the OD value of a color item and B is the OD value of a blank item) is multiplied with a factor. A maximum of 10 sample blank tests can be set.

Sample Blank assays are total and direct bilirubin. These assays contain an R1 color reagent and an R1 blank reagent. Program these assays in **Sample Blank (F5)** to perform the sample blank correction.

- Select **Sample Blank (F5)**. The Sample Blank window opens.

Figure 4.2

	Color Item		Blank Item
1	32.TBIL	-	33.TBILB
2	None	-	None
3	None	-	None
4	None	-	None
5	None	-	None
6	None	-	None
7	None	-	None
8	None	-	None
9	None	-	None
10	None	-	None

Close

- Select the test item to assign a color item from the “Color Item” column drop-down list.
- Select the test item to assign a blank item from the “Blank Item” column drop-down list.
- Select **Close**. The window closes and the contents are programmed.

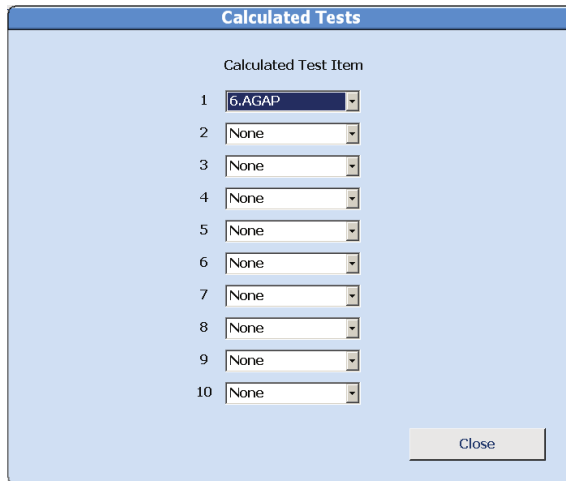
TIP Calculated tests cannot be programmed as Color Items or Blank Items.

Calculated Tests (F6)

A maximum of 10 tests can be programmed as a calculated test. Refer to [4.3.4 Calculated Tests Menu](#) to program the specific tests and formula for the calculation.

- Enter a Test Name for the calculated test.
- Select **Calculated Tests (F6)**. The Calculated Tests window opens.

Figure 4.3



- Select the calculated test name from the drop-down list. Select **Close**. The settings are programmed.

4.2.2 Profile Menu

A profile is a group of tests that are usually requested at the same time. Using a profile reduces the number of selections needed, as a single profile is selected instead of multiple tests. A maximum of 100 profiles (Number 0 to Number 99) can be registered for samples, reagent blank, calibration, and QC. A maximum of 99 tests can be programmed in a profile. The number of tests that can be programmed in a profile is limited by the number of sample blank tests, LIH, and sample type.

Each profile is assigned a profile name.

TIP Profile 0 is the Default profile in the **Sample** tab. Profile 0 can be automatically performed in the following situations:

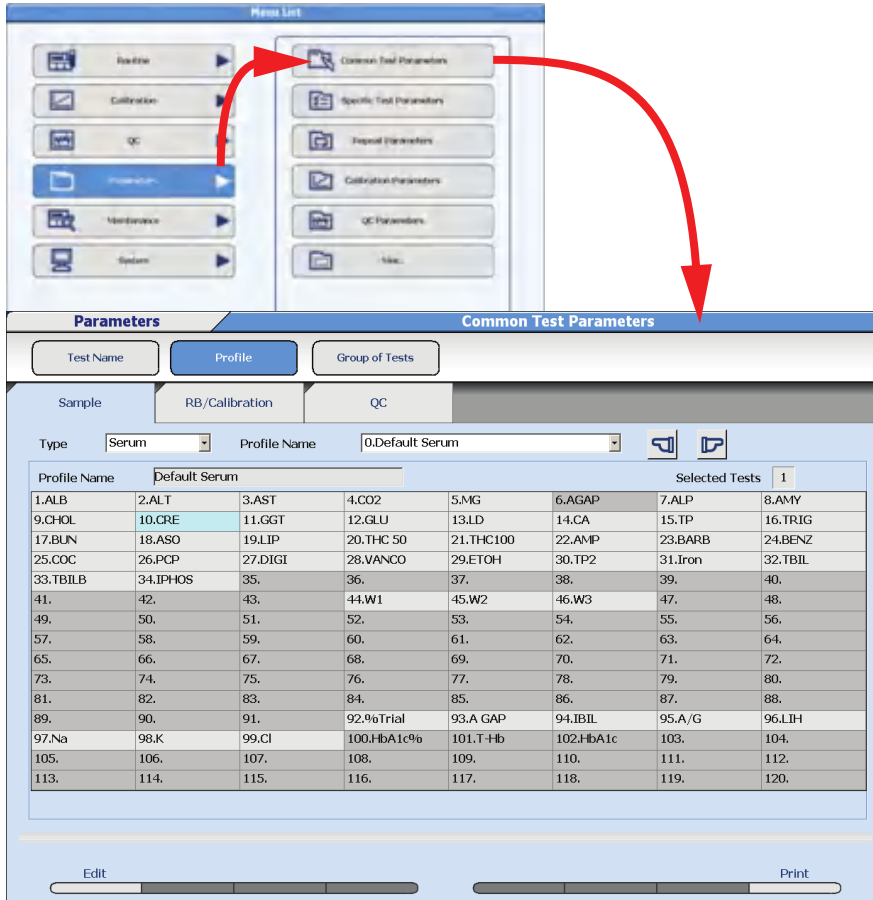
- There is a barcode read error.
- There is no requisition found for a sample.
- There are online errors.

Contact Beckman Coulter Technical Services for additional information.

Sample Tab

Select **Menu List > Parameters > Common Test Parameters > Profile > Sample**.

Figure 4.4



Item	Contents	Input Notes
Type	Serum, Urine, Other-1, or Other-2	
Profile Name drop-down	0 to 99	Profile 0 is the default profile.
Profile Name	Profile name	A maximum of 20 characters.
Selected Tests	Displays the number of tests selected (highlighted in blue) in the Profile.	

TIP Tests that are grayed out cannot be selected.

ISE tests can be selected only when the sample type is "Serum" or "Urine."

RB/Calibration Tab

Select **Menu List > Parameters > Common Test Parameters > Profile > RB/Calibration.**

Figure 4.5

Item	Contents	Input Notes
Profile Name drop-down	0 to 99	
Profile Name	Profile name.	A maximum of 20 characters.
Type	Serum, Urine, Other-1 or Other-2	
Selected Tests	Displays the number of tests selected (highlighted in yellow, green, or blue) in the Profile.	Select Edit (F1) > Calibration Option (F5) to change between the available calibration options: ACAL + RB (yellow) One Point (green) RB Only (blue) Refer to 3.1.6 Summary of Calibration Types in chapter 3 and 4.5.3 Calibration Specific Menu in chapter 4 for more information.

TIP The programming in **Calibration Specific** determines the calibration options available in **Calibration Options (F5)**.

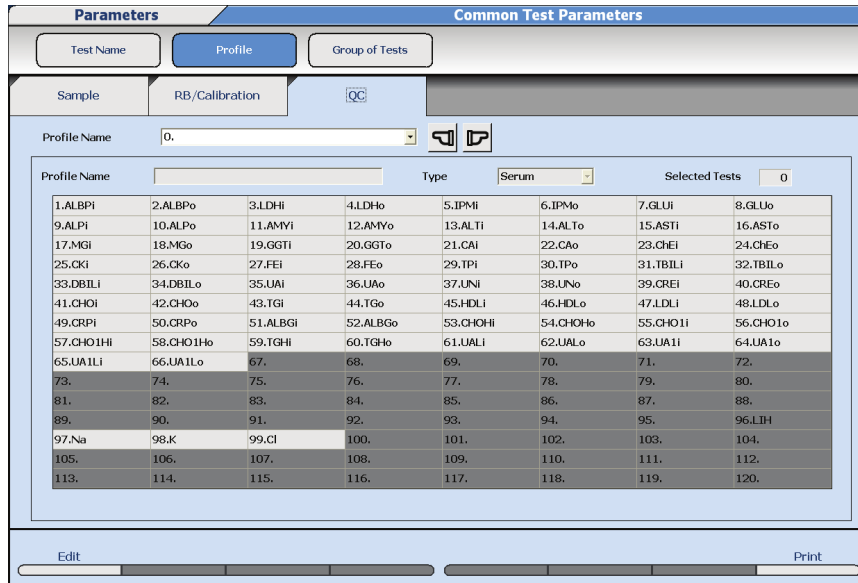
Tests that are grayed out cannot be selected.

ISE tests can be selected when the ISE calibration type is “ACAL.”

QC Tab

Select **Menu List > Parameters > Common Test Parameters > Profile > QC.**

Figure 4.6



Item	Contents	Input Notes
Profile Name drop-down	0 to 99	Profile numbers 87 to 98 are default QC profiles based on Group and Type. Refer to the following TIP.
Profile Name	Profile name.	A maximum of 20 characters.
Type	Serum, Urine, Other-1 or Other-2	
Selected Tests	Displays the number of tests selected (highlighted in blue) in the Profile.	

TIP Tests that are grayed out cannot be selected.

TIP QC profiles 87 to 98 are the default QC profiles that are automatically requisitioned in **Home > Rack Requisition Sample > QC**. The QC profile numbers 87 to 98 correspond to a specific Group and sample type:

- Number 87: Serum: For Group 1
- Number 88: Serum: For Group 2
- Number 89: Serum: For Group 3
- Number 90: Urine: For Group 1
- Number 91: Urine: For Group 2
- Number 92: Urine: For Group 3
- Number 93: Other-1: For Group 1
- Number 94: Other-1: For Group 2
- Number 95: Other-1: For Group 3
- Number 96: Other-2: For Group 1
- Number 97: Other-2: For Group 2
- Number 98: Other-2: For Group 3

4.2.3 Group of Tests Menu

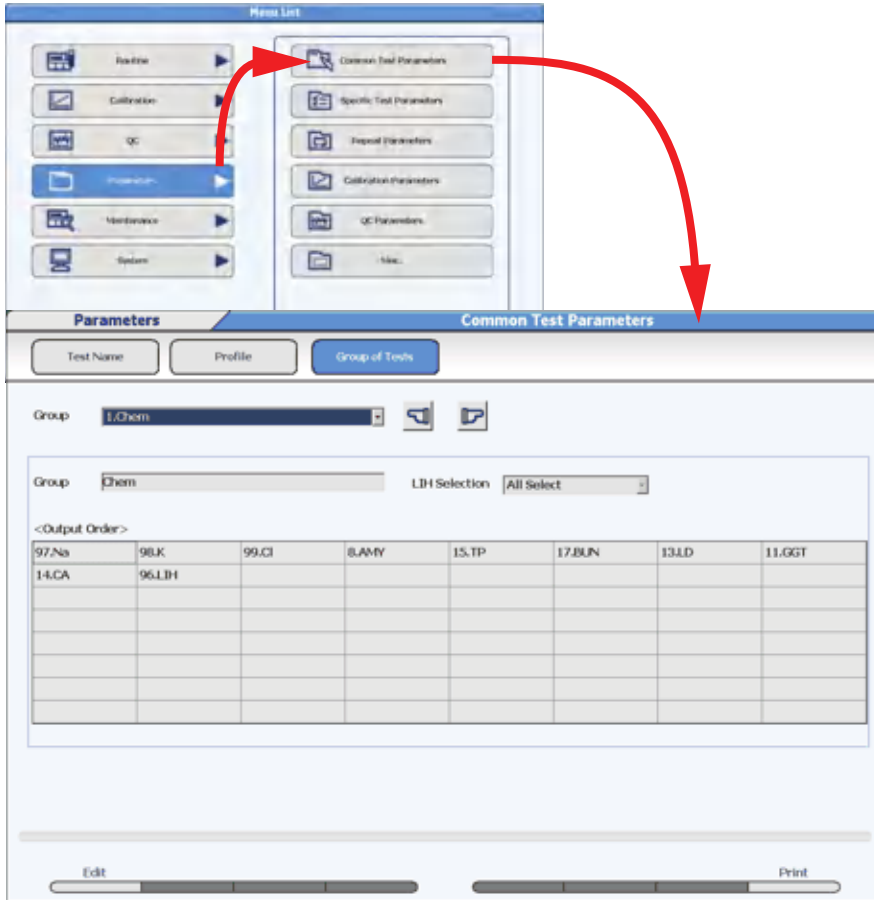
A Group is a programmed group of tests. Three Groups of tests can be programmed. The Group is specified in **Start Condition**, and the system verifies the reagents required for the Group selected are in the reagent refrigerator during the reagent check.

A maximum of 60 photometric tests plus the 3 ISE tests (63 total) can be programmed in each Group.

TIP Tests print in the order tests are assigned to the Group. To change the test print order, select **Menu List > Parameters > Common Test Parameters > Group of Tests > Edit (F1)**. Select then test to move, then select **Forward (F2)** or **Backward (F3)**. LIH and calculated tests print last.

Select **Menu List > Parameters > Common Test Parameters > Group of Tests.**

Figure 4.7



Item	Contents	Input Notes
Group drop-down	1, 2, or 3	
Group	Group Name	A maximum of 20 characters.
LIH Selection	All Select or Selectable	All Select means LIH is automatically requisitioned on every sample. Selectable means LIH is requisitioned as needed on samples. If All Select is programmed, test 96. LIH must be added to any Group (1, 2, or 3) that has tests programmed, or a red "Incorrect Parameter" message appears, and analysis cannot be started.

Item	Contents	Input Notes
LIH Test Item Setting (F6)	A maximum of 3 tests for LIH analysis.	This option is only available if LIH Reagent is set to "Non Dedicated" in Menu List > Parameters > Common Test Parameters > Test Name . Non Dedicated means using an existing (on-board) test and reagent for LIH testing. A maximum of 3 tests from the Group can be selected for LIH analysis.
Test Item Setting (F5)	Select (highlight in blue) the test(s) to include in the Group.	Select tests in the order to display and print. The <Output Order> displays the order the tests print. Calculated tests are inaccessible (gray) to select (highlight in blue) to include in the Group because calculated tests are performed automatically when all tests that are part of the calculated test are requisitioned on a sample.
Forward (F2) and Backward (F3)	Change the display and print order (<Output Order>) of the tests.	Select Edit (F1) , then select the test to move, then select Forward (F2) and Backward (F3) . LIH and calculated tests print last.

Test Setting (F5) window:

Figure 4.8

Test Item Setting							
Group No.	1 Chem						
							Selected Tests
							10
1.ALB	2.ALT	3.AST	4.CO2	5.MG	6.AGAP	7.ALP	8.AMY
9.CHOL	10.CRE	11.GGT	12.GLU	13.LD	14.CA	15.TP	16.TRIG
17.BUN	18.ASO	19.LIP	20.THC 50	21.THC100	22.AMP	23.BARB	24.BENZ
25.COC	26.PCP	27.DIGI	28.VANCO	29.ETOH	30.TP2	31.Iron	32.TBIL
33.TBILB	34.IPHOS	35.	36.	37.	38.	39.	40.
41.	42.	43.	44.W1	45.W2	46.W3	47.	48.
49.	50.	51.	52.	53.	54.	55.	56.
57.	58.	59.	60.	61.	62.	63.	64.
65.	66.	67.	68.	69.	70.	71.	72.
73.	74.	75.	76.	77.	78.	79.	80.
81.	82.	83.	84.	85.	86.	87.	88.
89.	90.	91.	92.%Trial	93.A GAP	94.IBIL	95.A/G	96.LIH
97.Na	98.K	99.Cl	100.HbA1c%	101.T Hb	102.HbA1c	103.	104.
105.	106.	107.	108.	109.	110.	111.	112.
113.	114.	115.	116.	117.	118.	119.	120.

Close

4.3 Specific Test Parameters Menu

Program specific test parameters, LIH parameters, ISE parameters, calculated tests, and reference ranges for tests.

[4.3.1 General Menu](#)

[4.3.2 LIH Menu](#)

[4.3.3 ISE Menu](#)

[4.3.4 Calculated Tests Menu](#)

[4.3.5 Range Menu](#)



Incorrect specific test parameters causes errors in analysis results, and can lead to an incorrect diagnosis. Specific test parameter settings should be visually verified against published settings, as well as by analysis using materials with known concentrations.

- For details on displaying a list of programmed values, refer to [List Display \(F7\)](#) in section [4.3.1 General Menu](#) in this chapter.

4.3.1 General Menu

Program the specific analysis parameters for each test. The test name must be programmed in **Common Test Parameters > Test Name** before programming specific test parameters.

For details on programming the test name, refer to [4.2.1 Test Name Menu](#) in this chapter.

Select **Menu List > Parameters > Specific Test Parameters > General**.

Figure 4.9

The screenshot displays the 'Specific Test Parameters' menu with the 'General' tab active. The test name is 'LALP' and the type is 'Serum'. The parameters are organized into several sections:

- Sample and Dilution:** Sample Volume (1.8 uL), Dilution (0 uL), OD Limit (Min: -0.1000, Max: 2.5000).
- Reagents:** Reagent OD Limit (First: Low -0.1000, High 1.2000; Last: Low -0.1000, High 1.2000), Dynamic Range (Low 5.0, High 1500.0).
- Wave Length and Method:** Wave Length (Pri: 410 nm, Sec: 480 nm), Method (RATE).
- Reaction and Measuring Points:** Reaction Slope, Measuring Point-1 (First: 16, Last: 27), Measuring Point-2 (First: , Last:).
- Linearity and Checks:** Linearity Limit (15 Au), Lag Time Check (No).
- Influence Checks:** Lipemia (++++), Icterus (++++), Hemolysis (++++).

Buttons at the bottom include 'Exit', 'List Display', and 'Print'.

Enter specific test parameters from the chemistry setting sheet. If a field is grayed out, it is not programmable.

Item	Contents	Input Notes
Test Name	Abbreviated test name selected from drop-down.	The abbreviated test name is programmed in Common Test Parameters > Test Name .
Type	Serum, Urine, Other-1, or Other-2	
Operation	Yes or No	“Yes”: the test is operational for the Type displayed. “No”: the test is not operational for the Type displayed. If a test is programmed to “No”, it is not available to requisition or run. The test appears gray and is inaccessible in menus.
Sample Volume and Dilution	If Dilution is 0 μL , then Sample Volume can be set from 1.0 μL to 25.0 μL . If Dilution is 10 μL , then Sample Volume can be set from 1.0 to 20.0 μL . Minimum Sample Volume is 1.0 μL .	Sample Volume can be set in increments of 0.1 μL . Dilution is Deionized (DI) water (0 or 10 μL) dispensed for a sample dilution following the sample dispense. If Dilution is set to 0 μL , then an additional 2.9 μL of sample is aspirated for dispensing accuracy.
Pre-Dilution Rate	1, 3, 5, 10, 15, 20, 25, 50, 75, or 100	Defines the automatic pre-dilution to be performed on the analyzer in a “dilution” cuvette with sample and DI water or other diluent. Refer to Pre-Dilution Rate Volumes in 4.4.2 Repeat Specific Menu for a list of the sample volume required for each pre-dilution rate. The test sample volume is dispensed from the dilution cuvette into the reaction cuvette.
Reagent Volume	R1(R1-1): 10 to 250 μL R2(R2-1): 0, 10 to 250 μL	Reagent volumes can be set in increments of 1.0 μL .
Dilution	R1(R1-1): 0, 10 to 240 μL R2(R2-1): 0, 10 to 240 μL	The total Reagent Volume and Dilution is a maximum of 250 μL .
Wave Length Pri.	340, 380, 410, 450, 480, 520, 540, 570, 600, 660, 700, 750 and 800 nm	
Wave Length Sec.	None, 340, 380, 410, 450, 480, 520, 540, 570, 600, 660, 700, 750 and 800 nm	
Method	END, RATE, FIXED, END1, RATE1, FIXED1	The 1 at the end of a method name indicates a method not using a reagent blank correction. The reagent blank is not subtracted from the measuring points.

Item	Contents	Input Notes
Reaction Slope	+, -	+ used for an increasing reaction curve - used for a decreasing reaction curve
Measuring Point-1 Measuring Point-2	END method, FIXED method <ul style="list-style-type: none"> • 1st: 0 to 26 • Last: 1 to 27 RATE method <ul style="list-style-type: none"> • 1st: 0 to 25 • Last: 1 to 27 	"Self blank": the absorbance of Measuring Point-2 data (due to sample) is subtracted from Measuring Point-1 data (reaction data).
Linearity Limit	0 to 100	A check for Rate Methods to verify if the reaction is non-linear due to exceeding the defined % variance or OD limits between photometer read points. A "*" flag is generated if the limits are exceeded.
Lag Time Check	YES/NO	Yes can only be set for Rate Methods. Lag time is the time after all reagents have been added to the sample and before any read points are taken to determine the reaction rate.
OD Limit	-2.0000 to 3.0000	Programming is only available for Rate and Fixed methods. Generates a "B" flag for less than the minimum OD and a "D" flag for greater than the maximum OD.
Reagent OD Limit	-2.0000 to 3.0000	Reagent blank OD limits at the first and last read points. A "u" or "U" flag is generated if the reagent OD is under the acceptable limit. A "y" or "Y" flag is generated if the reagent OD is over the acceptable limits.
Dynamic Range	Low: -9999999 to 9999999 High: Low value to 9999999	Enter a 7-digit numerical value, not including sign and decimal point. The range the analyzer is capable of measuring for a reagent. If the range is exceeded, "F" (over) or "G" (under) flag is generated. If a concentration value cannot be calculated, the OD value is used to indicate if the dynamic range was exceeded. If the OD value is greater than the OD of the upper limit of the dynamic range, an "Fx" flag is generated. If the OD value is less than the OD of the lower limit of the dynamic range, an "Gx" flag is generated. Set the decimal place in the Range tab.

Item	Contents	Input Notes
Correlation Factor	A: -9999999 to 9999999 B: -9999999 to 9999999	The Correlation Factor corrects the concentration value with the equation $Y = AX + B$. The Correlation correction is performed after checking the dynamic range. If a Correlation Factor and a Factor for Maker are programmed, the results are calculated with both factors.
Factor for Maker	Display only	The Factor for Maker coefficient corrects the concentration value with an equation of $Y=AX+B$. The Factor for Maker correction is performed before checking the dynamic range. If a Correlation Factor and a Factor for Maker are programmed, the results are calculated with both factors.
Onboard Stability Period	Days (0 to 999) and hours (0 to 23)	The onboard stability period starts when the reagent check is performed, regardless of the reagent being used or not.
LIH Influence Check	YES/NO	LIH Influence Check only displays if the optional Assay Specific LIH is enabled in System Maintenance by Beckman Coulter Technical Services. Yes: Flags the test result with "l", "i", or "h" if the level of LIH exceeds the assay's specific limits. An "n" flag is generated if LIH testing is not performed on the sample. No: Assay specific LIH is not evaluated for the assay.
Lipemia	+, ++, +++, +++++, ++++++	If LIH Influence Check is Yes, program assay specific LIH criteria from the chemistry setting sheet.
Icterus		
Hemolysis		
Change Reagent Type (F5)	Select R1-2 to program a 3-part reagent.	
Set Common Reagent (F6)	Program the R1-2 of a 3-part reagent to be used for two tests.	
List Display (F7)	Displays a list of all Specific Test Parameters	Use the list to verify parameters. Six tests display at a time. Select the sample type to display from the Type drop-down.

Linearity Limit:

Linearity Calculation Method

$$(|a-b|/(|c|* 0.5))*100 = \text{Linearity limit value (parameter)}$$

a: OD value change quantity of the first half of the reaction curve

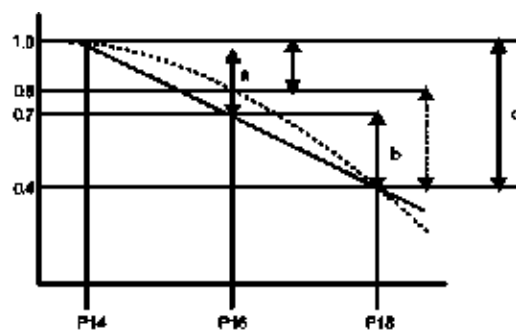
b: OD value change quantity of the last half of the reaction curve

c: OD value change quantity of the reaction curve (between photometry start point and end point)

| |: Absolute value

- In the case of a straight line (similar to the solid line shown), the values of a and b become almost the same and linearity becomes 0%.
- In the case of a curve (similar to the dotted line shown), a becomes smaller and b becomes larger, and linearity becomes 67% approximately.

Figure 4.10



Lag Time Check

If Lag Time Check is Yes, the following check is performed:

- The Predicted maximum reaction OD (ΔOD) is calculated to the concentration.
- The converted concentration is checked versus the dynamic range. If the concentration is higher than twice the dynamic range, the converted concentration and an "E" flag is resulted. If the concentration is lower than twice the dynamic range, the calculation is done using the measuring points set in specific tests parameters. Otherwise, the OD is calculated using the measuring points **before** the specified points in specific test parameters, for example P11.

4.3.2 LIH Menu

If LIH is assigned to Test No. 96 LIH using “Dedicated” LIH Reagent, program the LIH parameters. Refer to [4.2.1 Test Name Menu](#) in this chapter.

Select **Menu List > Parameters > Specific Test Parameters > LIH**.

Figure 4.11

The screenshot shows the 'Menu List' interface. On the left, a vertical menu has 'Parameters' selected. On the right, a sub-menu is open, showing 'Specific Test Parameters' selected. Below this, the 'LIH' sub-menu is active. The 'LIH' sub-menu contains several tabs: 'General', 'LIH', 'ISE', 'Range', 'Calculated Tests', and 'Range'. The 'LIH' tab is selected, displaying the following parameters:

Test Name: 96.LIH LIH Reagent: Dedicated

Sample Volume: 1.0 uL Dilution: 0 uL

Reagent R1(R1-1) Volume: 20 uL Dilution: 100 uL

Onboard Stability Period: 90 Day 0 Hour

LIH Judgement Level

	Lipemia	Icterus	Hemolysis
+	0.0150	0.1100	0.1700
++	0.0400	0.2100	0.3500
+++	0.0800	0.4300	0.7000
++++	0.1200	0.8500	1.0000
+++++	0.2000	1.7000	1.7000

At the bottom of the screen, there are 'Edit' and 'Print' buttons.

TIP LIH Judgement Level

The system is programmed with OD limits to flag samples for lipemia, icterus, and hemolysis. Each sample prints with “LIP” (lipemia), “ICT” (icterus), and “HEM” (hemolysis) tests with normal, +, ++, +++, +++++, ++++++.

TIP LIH Reagent (OSR62166) is the only valid reagent for sample and assay specific LIH testing.

Item	Contents	Input Notes
LIH Reagent	Dedicated or Non Dedicated	Dedicated or Non-Dedicated displays from Common Test Parameters > Test Name . Sample Volume, Dilution, Reagent Volume, and Onboard Stability Period can only be entered if LIH is Dedicated. If LIH is Non Dedicated, the parameters from the on-board test used for LIH analysis are used.
Sample Volume and Dilution	Dilution: Sample Volume: 0 µL 1.0 to 25.0 µL 10 µL 1.0 to 20.0 µL	In steps of 0.1 µL
Reagent R1 (R1-1) Volume and Dilution	Reagent Volume: 10 to 250 µL Dilution: 0, 10 to 240 µL	In steps of 1 µL The total Reagent Volume and Dilution is a maximum of 250 µL.
Onboard Stability Period	Days (0 to 999) and Hours (0 to 23)	
LIH Judgment Level	The judgment level is set separately for Lipemia, Icterus, and Hemolysis. + : 0.0 to 3.0 ++ : + value to 3.0 +++ : ++ value to 3.0 ++++ : +++ value to 3.0 +++++ : ++++ value to 3.0	Refer to the LIH chemistry setting sheet or enter values established by the facility. LIH Reagent with LIH parameters from the chemistry setting sheet is the only validated option for assay specific LIH.

4.3.3 ISE Menu

If the ISE option is used, program the operation, dynamic range, and correlation factor for the serum and urine sample types.

Select **Menu List > Parameters > Specific Test Parameters > ISE.**

Figure 4.12

The screenshot shows the 'Menu List' on the left with 'Specific Test Parameters' highlighted. A red arrow points from this menu item to the 'Specific Test Parameters' screen. Another red arrow points from the 'Specific Test Parameters' screen to the 'ISE' tab. The 'Parameters' section at the top of the screen includes 'General', 'LDH', 'ISE', 'ISE', 'Calculated Tests', and 'Range'. The 'ISE' tab is selected.

	Type : Serum			Type : Urine		
	97.Na	98.K	99.Cl	97.Na	98.K	99.Cl
Operation	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes
Sample Volume	20.0 μ L	—	—	20.0 μ L	—	—
Dilution	10.0 μ L	—	—	10.0 μ L	—	—
MID CONC	140.0	4.0	100.0	140.0	4.0	100.0
STD CONC Low	130.0	3.5	85.0	50.0	10.0	50.0
STD CONC High	160.0	6.0	120.0	200.0	100.0	180.0
Dynamic Range	Low	50.00	1.00	50.00	10.00	2.00
	High	200.00	10.00	200.00	400.00	200.00
Correlation Factor	A	1	1	1	1	1
	B	0	0	0	0	0

TIP Sample Volume, Dilution, MID CONC, STD CONC Low, and STD CONC High display the pre-programmed values and cannot be changed.

Program the Dynamic Range and Correlation Factor for Serum and Urine.

Item	Contents	Input Notes
Operation	Yes or No	Select Yes to enable operation for Na, K, and Cl testing for Serum and/or Urine.
Dynamic Range	Low: -9999999 to 9999999 High: Low value to 9999999	Refer to the ISE Reagents Instructions for Use. Enter a 7-digit numerical value, not including the sign and decimal point. The number of decimal places is programmed in the Range tab.
Correlation Factor	A: -9999999 to 9999999 B: -9999999 to 9999999	Correlation value = A x measuring value + B. Enter a 7-digit numerical value, not including sign and decimal point.

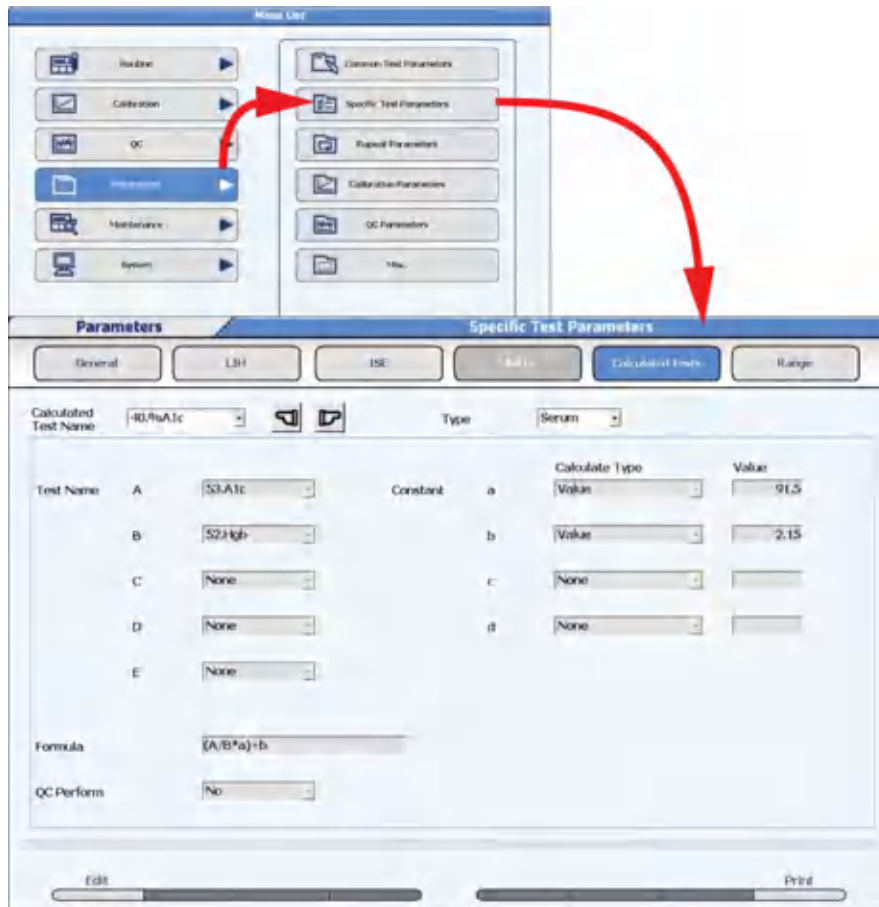
4.3.4 Calculated Tests Menu

Program the calculation parameters for a maximum of 10 calculated tests. The calculated test name must be defined in **Common Test Parameters > Test Name > Calculated Tests (F6)** before it is available to enter parameters. Once programmed, calculated tests are performed and print automatically when all the tests in the calculation are requisitioned and run simultaneously. A reference range can be assigned to the calculated test in the **Range** menu.

To program the calculated test name, refer to [4.2.1 Test Name Menu](#) in this chapter.

Select **Menu List > Parameters > Specific Test Parameters > Calculated Tests**.

Figure 4.13



Item	Contents	Input Notes
Calculated Test Name	Calculated test number 1 to 10	A calculated test name must be assigned to a calculated test number in Common Test Parameters > Test Name > Calculated Tests (F6) before it is available.
Type	Serum, Urine, Other-1, or Other-2	
Test Name	Select the tests involved in the calculation at "A", "B", "C", "D", and "E".	A maximum of 5 tests can be set.
Constant	If "Calculate Type" is set to "Value", enter a numerical constant (-999999 to 9999999) for "a" through "d". If "Calculate Type" is set to Patient Inf.-1 through -6, then Patient Information 1 to 6 defined as a Numeric Attribute can be used.	A maximum of 4 constants can be set. A 7-digit numerical value, not including sign and decimal point. Patient Information can be programmed in Menu List > System > Format > Requisition Format . Set "Attribute" to Numeric Attribute to allow entering a numerical value as a patient demographic used as a constant "a" through "d" in the calculated test.
Formula	Calculated test formula	A maximum of 20 characters. Combination of +-*/()ABCDEabcd
QC Perform	Yes, No	If Yes is selected, a QC range can be programmed for the calculated test in QC Parameters .

TIP The calculation formula uses A to E, arithmetic calculation, and the coefficients a to e. The coefficients can use numerical patient information (weight etc.).

If Yes is selected at "QC Perform", a QC range can be programmed for the calculated test in **QC Parameters**. For example, the QC may be in range for TP and ALB. If an albumin/globulin ratio calculation is performed with a QC range programmed, the calculated test QC may be out of range.

A calculated test is repeated if the calculated test generates a repeat flag, or if all tests that are part of the calculated test generate a repeat flag. A calculated test can be programmed to generate ph, pl, P, N, H, L, J, and K flags.

Sample blank tests (color and blank), the LIH test, and calculated tests cannot be used in the calculated test formula.

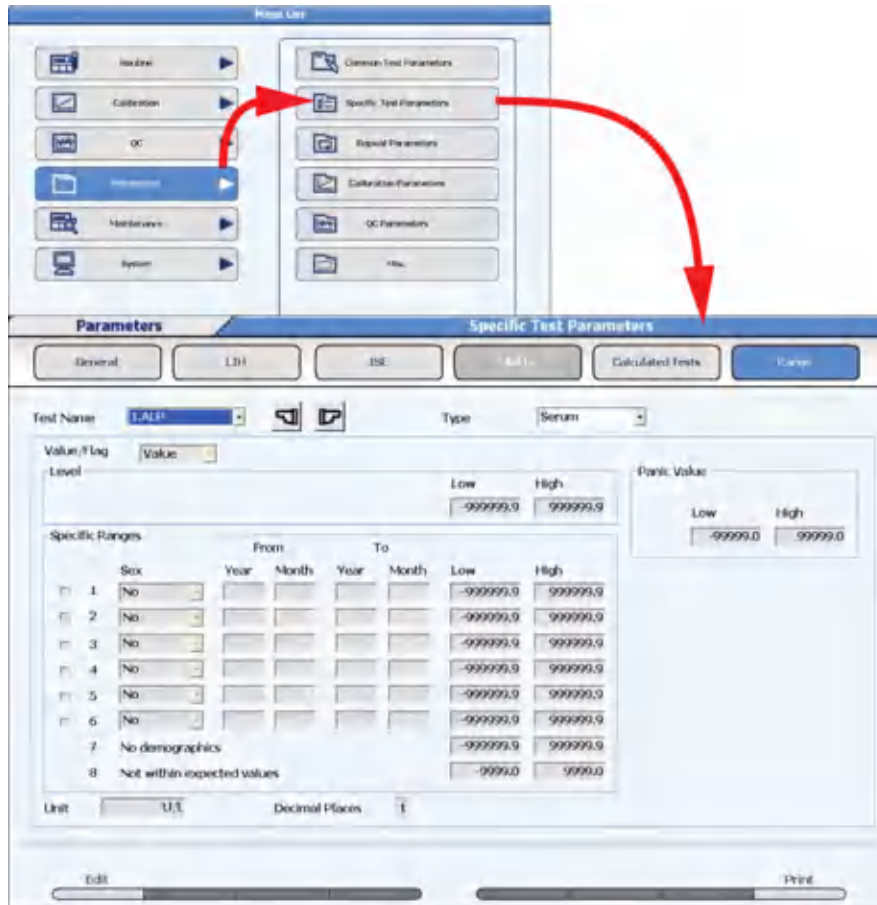
4.3.5 Range Menu

Program the reference range values for tests.

Data judgment is performed according to the quantitative method by values or according to the qualitative method by flags.

Select **Menu List > Parameters > Specific Test Parameters > Range**.

Figure 4.14



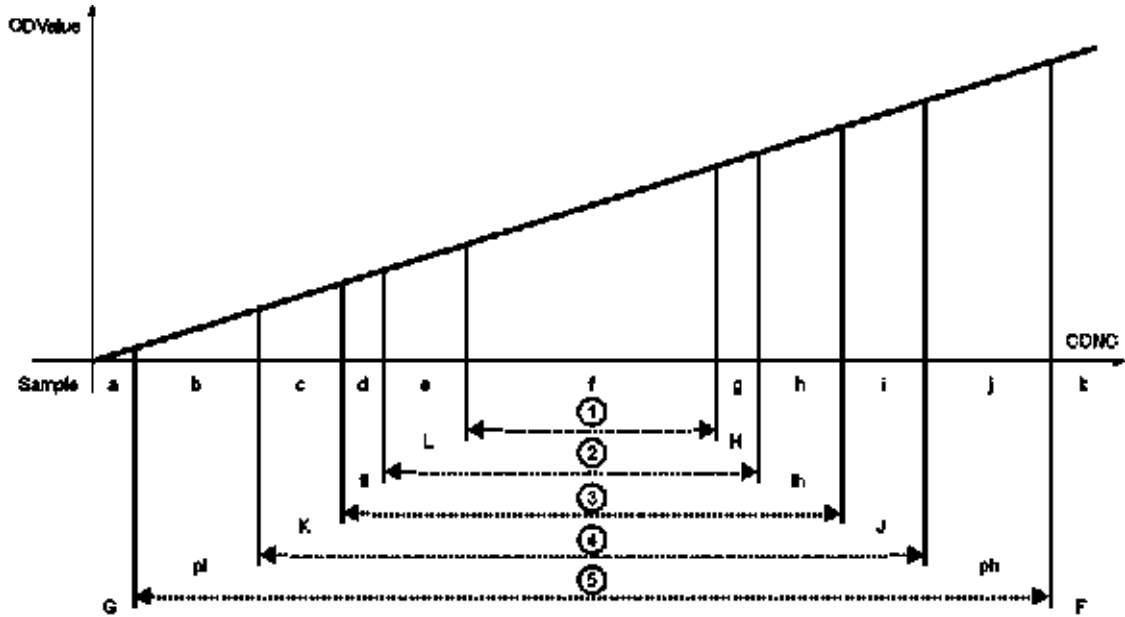
Item	Contents	Input Notes
Test Name	A test name	
Type	Serum, Urine, Other-1, or Other-2	
Value/Flag	Value or Flag. If Flag is programmed, then enter a number (-999999 to 9999999) for Level Low and High.	Value: Set a normal reference range in Specific Ranges (1 to 8) to generate "L" (low) or "H" (high) flags on tests. Specific reference ranges can be programmed by sex and age. Flag: Set a range in Level Low and High to generate a "P" (positive) flag if over the High limit, or "N" (negative) flag if below the Low limit. Typically this is programmed for qualitative drugs of abuse testing.
Panic Value	Enter a number (-999999 to 9999999) for Low and High.	Enter a user-defined critical range. A "pl" flag is generated if the result falls below the Low limit, and a "ph" flag is generated if the result falls above the High limit. An audible alarm is also generated if the panic range is exceeded.
Unit	The units to print on a report.	
Specific Ranges 1 - 8	Low: -9999999 to 9999999 High: Low value to 9999999	A 7-digit numerical value, not including sign and decimal point. The number of decimal place is programmed in Decimal Places (F5) . Set ranges to generate "L" flags for data less than the Low limit or "H" flags for data greater than the High limit. 1-6: Select the check box to enter normal ranges that are age and gender specific. Patient demographics must be programmed to use this feature. 7: Standard demographic: Enter a generic normal range. This range is used for the sample without patient demographic information (age and gender). 8: Not within expected values: This range is used for the sample with patient demographic information (age or gender), but the age or gender information did not meet the age and gender defined in the specific range 1-6.
Decimal Places (F5) displays after selecting Edit (F1) .	0 to 4	The decimal places entered affect software prompts and printed results.

Figure 4.15



Error flags by range setting (setting example)

Figure 4.16



- 1. Normal value range
- 2. Reflex range
- 3. Repeat run range
- 4. Panic value
- 5. Dynamic range

• Up to 4 error flags may be attached to abnormal data according to priority.

Sample	a	b	c	d	e	f	g	h	i	j	k
Error flag	G,pl, L,K,(fl)	pl,L, K,fl	L,K, fl	L,fl	L	none	H	H,fh	H,J, fh	ph,H, J,fh	F,ph, H,J,(fh)

- As sample f is within the normal value range, it has no error flag.
- The four error flags with the highest priorities are displayed on the monitor and are printed out.
- Online parameters can be programmed to transmit two or four result error flags. Refer to [4.12 Program Online Parameters](#) for additional information.
- The repeat run range and reflex range are set within the dynamic range.

Menu to Program each Range:

Contents	Menu
Normal Reference range	Parameters > Specific Test Parameters > Range
Panic range	Parameters > Specific Test Parameters > Range
Dynamic range	Parameters > Specific Test Parameters > General and ISE
Repeat Decision range	Parameters > Repeat Parameters > Repeat Specific
Reflex range	Parameters > Repeat Parameters > Repeat Specific

4.4 Repeat Parameters Menu

The AU480 allows either manual or automatic repeat sample analysis. This section describes how to program the repeat mode.

4.4.1 Repeat Common Menu

4.4.2 Repeat Specific Menu

Normal repeat:

Analysis is performed with the same parameters used for the initial analysis.

Repeat run with dilution:

Analysis is performed with a pre-dilution or a smaller sample volume than the initial run. Pre-dilution means a “dilution” cuvette of sample and diluent is made on-board the analyzer. The sample is dispensed from the dilution cuvette into the reaction cuvette.

1. Reduce the sample dispense volume.
2. Increase the dilution ratio.

Repeat run with condense:

Analysis is performed with a larger sample volume than the initial analysis.

1. Increase the sample dispense volume.
2. Reduce the dilution ratio.

WARNING

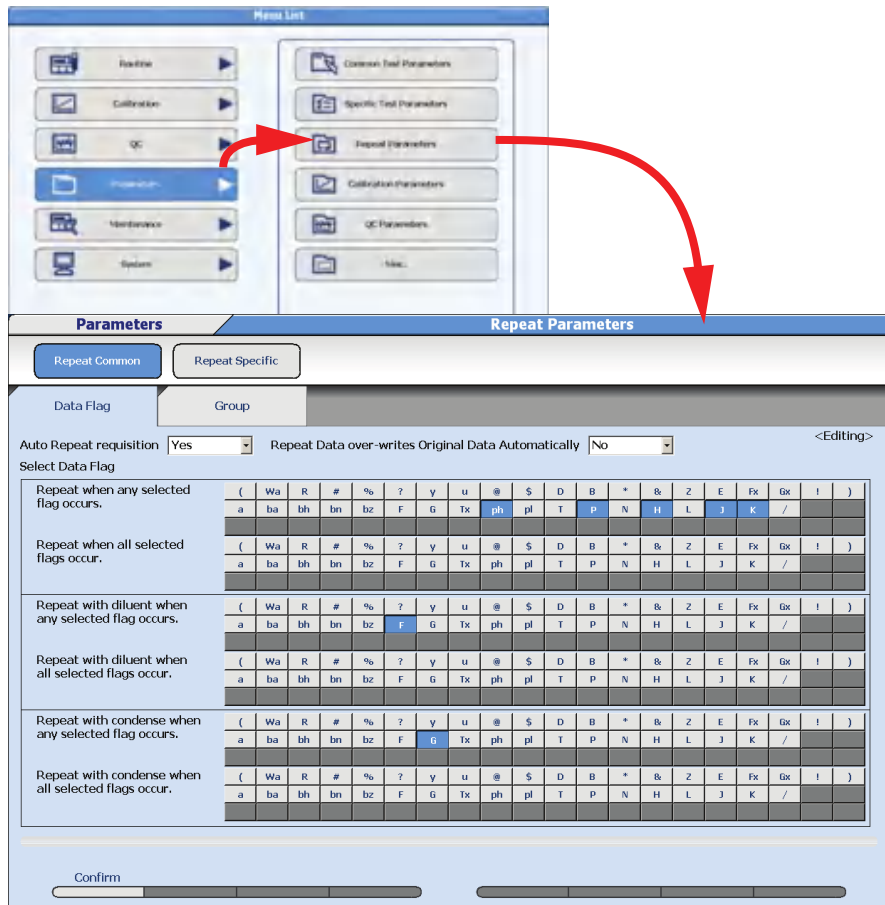
- **Whenever parameters are user-defined, the user must verify that the results meet their requirements for test performance including reproducibility and accuracy.**
- **The measured value with the repeat dilute or condense sample volume and dilution ratio should be well within the dynamic range of the test for best performance.**
- **When possible, change either the sample volume or the dilution ratio and avoid changing both for dilution or condense.**

4.4.1 Repeat Common Menu

Data Flag Tab

Select **Menu List > Parameters > Repeat Parameters > Repeat Common > Data Flag.**

Figure 4.17



Item	Contents	Input Notes
Auto Repeat Requisition	Yes or No	Select Yes to generate automatic repeat requisitions. Yes should be selected for Auto or Manual Repeat mode. If No is selected, repeat requisitions are not made and the repeat requisitions must be retrieved manually in Routine > Repeat Order > Regenerate Repeat Req. (F2) .
Repeat Data Over-Writes Original Data Automatically	Yes or No	Select Yes to automatically over-write original data with repeat data. Select No to review the original data and repeat data prior to over-writing.
Repeat when any selected flag occurs.	Select (highlight) the flag(s) to generate a repeat requisition.	A repeat requisition is generated when any of the highlighted flag(s) are generated.
Repeat when all selected flags occur.	Select (highlight) a flag(s) to generate a repeat requisition.	A repeat requisition is generated only when all highlighted flags are generated.
Repeat with diluent when any selected flag occurs.	Select (highlight) a flag(s) to generate a repeat requisition.	A repeat dilution requisition is generated when any of the highlighted flag(s) are generated.
Repeat with diluent when all selected flags occur.	Select (highlight) a flag(s) to generate a repeat requisition.	A repeat dilution requisition is generated only when all highlighted flags are generated.
Repeat with condense when any selected flag occurs.	Select (highlight) a flag(s) to generate a repeat requisition.	A repeat condense requisition is generated when any of the highlighted flag(s) are generated.
Repeat with condense when all selected flags occur.	Select (highlight) a flag(s) to generate a repeat requisition.	A repeat condense requisition is generated only when all highlighted flags are generated.

TIP The same flag cannot be set to more than one (normal, dilute, condense) “any selected” section. The flag is cancelled from any previous selections and set to the last selection made.

The same flags cannot be set to more than one (normal, dilute, condense) “all selected” section. When **Confirm (F1)** is selected, a Parameter Error window opens.

For details on error flags, refer to [CHAPTER 9, Error Flags](#).

All tests programmed as part of a calculated test are repeated if any test in the calculation generates a repeat flag. If the flag is programmed to repeat with a dilution, then that test is diluted. Other tests in the calculation without repeat flags repeat with original sample volumes.

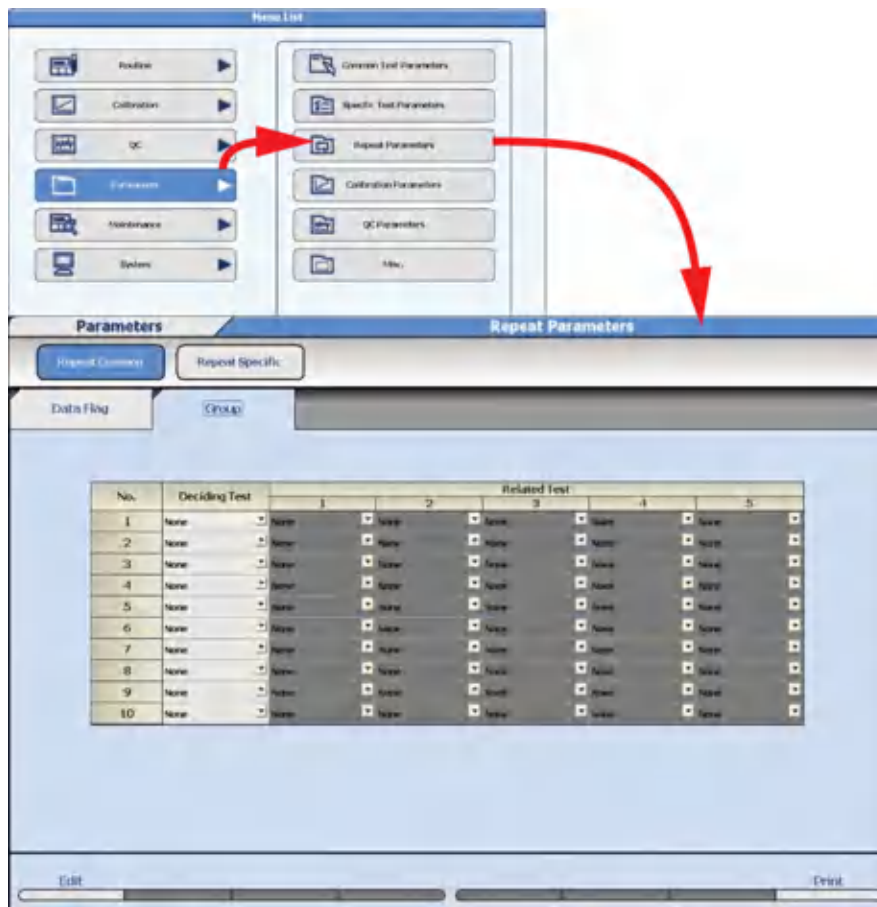
Group Tab

Program a Deciding Test to perform repeat analysis on up to five Related Tests. When the Deciding Test repeats, the Related Tests also repeat. For example, when ALB is the Deciding Test and TP is a Related Test, if ALB repeats, TP will also repeat whether or not TP had a repeat requisition.

A maximum of 10 repeat run groups can be programmed, and a maximum of five tests can be programmed as the related tests for each group.

Select **Menu List > Parameters > Repeat Parameters > Repeat Common > Group**.

Figure 4.18



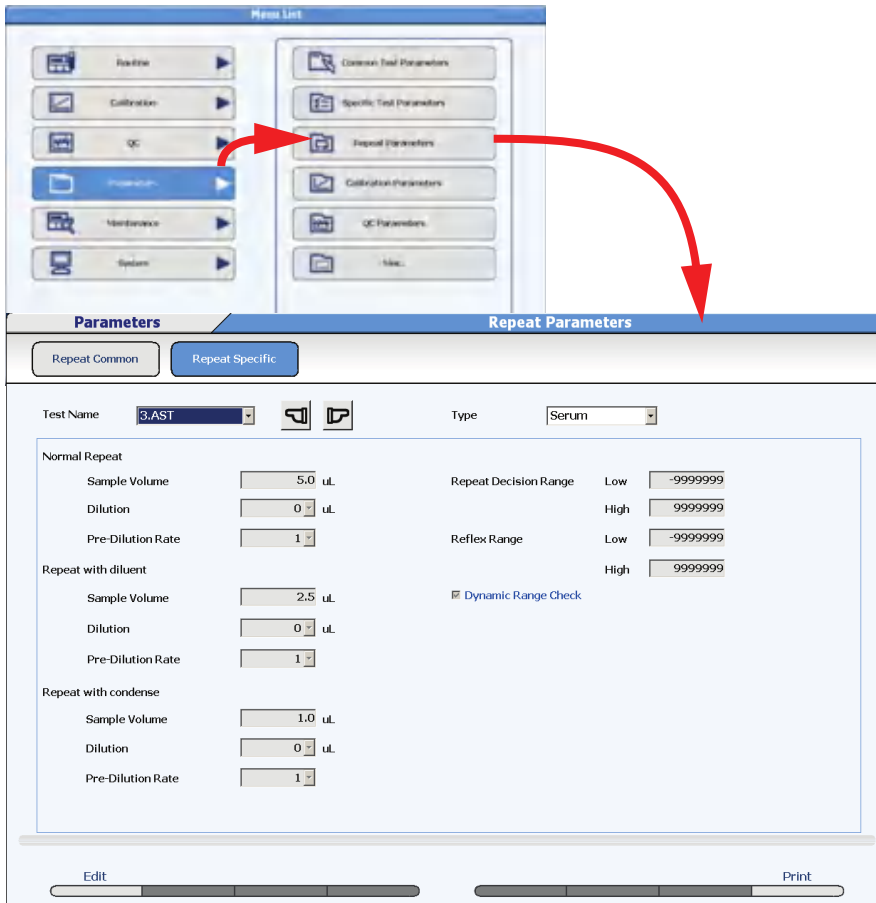
Item	Contents	Input Notes
Deciding Test	Name of test	Select the Deciding Test to perform repeat analysis on up to 5 Related Tests when the Deciding Test performs a repeat.
Related Test	Name of test	Select Related tests to repeat when the Deciding Test repeats whether or not the Related test had a repeat requisition.

4.4.2 Repeat Specific Menu

Program the sample volume, diluent volume and pre-dilution rate for a normal repeat run, repeat run with dilution, and repeat run with condense.

Select **Menu List > Parameters > Repeat Parameters > Repeat Specific**.

Figure 4.19



Item	Contents	Input Notes
Test Name	Test name	
Type	Serum, Urine, Other-1, or Other-2	
Normal Repeat <ul style="list-style-type: none"> Sample Volume Dilution Pre-Dilution Rate 	Sample Volume, Dilution, and Pre-Dilution Rate display from Specific Test Parameters .	

Item	Contents	Input Notes						
Repeat with diluent and Repeat with condense <ul style="list-style-type: none"> Sample Volume Dilution 	<table> <tr> <td>Diluent</td> <td>Sample</td> </tr> <tr> <td>0 μL</td> <td>1.0 to 25.0 μL</td> </tr> <tr> <td>10 μL</td> <td>1.0 to 20.0 μL</td> </tr> </table>	Diluent	Sample	0 μ L	1.0 to 25.0 μ L	10 μ L	1.0 to 20.0 μ L	<p>Sample Volume can be programmed in 0.1 μL increments.</p> <p>Dilution can be programmed to 0 μL or 10 μL. DI water is dispensed from the sample probe following the sample dispense.</p>
Diluent	Sample							
0 μ L	1.0 to 25.0 μ L							
10 μ L	1.0 to 20.0 μ L							
Pre-Dilution Rate	1, 3, 5, 10, 15, 20, 25, 50, 75, 100	A "dilution cuvette" is made on-board the analyzer with sample and diluent. Refer to the table below for sample and diluent dispense volumes. The "Repeat with diluent" Sample Volume is then dispensed from the dilution cuvette into the test cuvette, and results are calculated.						
Repeat Decision Range Low and High	a number (-999999 to 9999999)	A user-defined range to generate a repeat requisition. Results below the Low limit generate a "K" flag. Results above the High limit generate a "J" flag.						
Reflex Range Low and High	a number (-999999 to 9999999)	Program a specific range to trigger the test's reflex testing parameters programmed in Repeat Common > Group . The Deciding Test is not performed in the repeat run. Results below the Low limit generate an "fl" flag. Results above the High limit generate an "fh" flag. Program the Reflex Range within the values for the Repeat Decision Range.						
Dynamic Range Check	Checked or Not Checked	If Checked, when a test generates "F," "G," "Fx," or "Gx" and the corresponding flag is selected in Repeat Common , the test is repeated. If Not Checked, when a test generates "F," "G," "Fx," or "Gx" and the corresponding flag is selected in Repeat Common , the test is not repeated. The default setting is Checked.						

Pre-Dilution Rate Volumes

Refer to the Pre-Dilution Rate Item in the preceding table for information on pre-dilution rate.

Pre-Dilution Rate	Sample Volume (µL)	Dilution Volume (µL)	Volume in Cuvette (µL)
3	50	100	150
5	30	120	150
10	20	180	200
15	15	210	225
20	10	190	200
25	8	192	200
50	4	196	200
75	3	222	225
100	2	198	200

4.5 Calibration Parameters Menu

Program the calibrators used for calibration analysis and the calibration parameters.

Typically calibrators are assigned to positions in the yellow rack, or calibrator barcode operation is enabled and the calibrators are placed in any position in the yellow rack.

Calibrators can be assigned to positions on the STAT table, or calibrator barcode operation can be enabled and the calibrators can be placed in any position on the STAT table.

[4.5.1 Calibrators Menu](#)

[4.5.2 Program Calibrator Concentrations](#)

[4.5.3 Calibration Specific Menu](#)

[4.5.4 STAT Table Calibration Menu](#)



Incorrect calibration parameters cause errors in analysis results, and can lead to misdiagnosis. Specific test calibration parameter settings should be visually verified against the published settings, as well as through analysis using Quality Control materials.

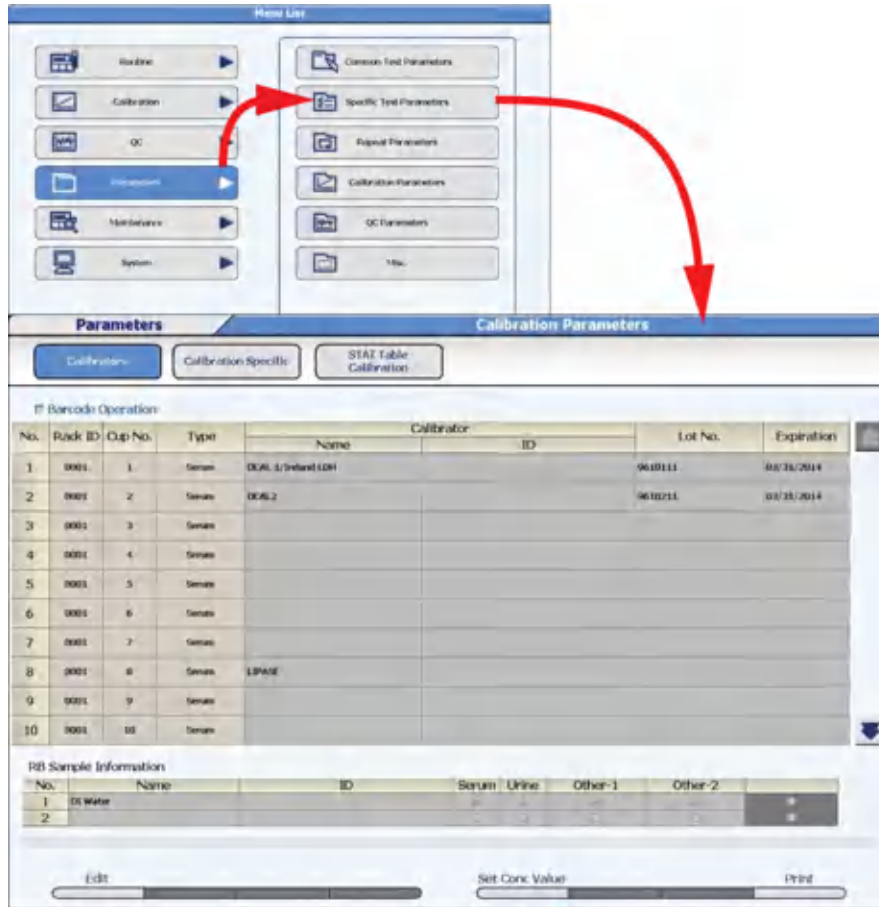
- For details on displaying a list of set values, refer to [List Display \(F7\)](#) in section [4.5.3 Calibration Specific Menu](#) in this chapter.

4.5.1 Calibrators Menu

Program a maximum of 200 calibrators required for specific assays programmed on the system. Calibrator numbers 1 to 200 are programmed to a Type (Serum, Urine, Other-1, or Other-2) by Beckman Coulter Technical Services based on laboratory requirements.

Select **Menu List > Parameters > Calibration Parameters > Calibrators**.

Figure 4.20



Item	Contents	Input Notes
Barcode Operation	Check or No Check	If Barcode Operation is checked, calibrator IDs are assigned to calibrator material and calibrators can be placed in any position in the yellow rack. The highest calibrator number (1 to 200) must be the last sample in the yellow rack. If Barcode Operation is not checked, calibrators are assigned to positions in the yellow rack.
Name	Calibrator name	A maximum of 20 characters.
ID	Calibrator ID (barcode)	A maximum of 26 alphanumeric characters for the calibrator ID when Barcode Operation is checked.
Lot No.	Calibrator lot number	A maximum of 15 alphanumeric characters.
Expiration	Calibrator expiration date	Enter a date, for example YYYY/MM/DD.
RB Sample Information	Reagent blank No., Name, ID, and Sample Type.	Two types of reagent blank material (No. 1 and No. 2) can be defined. All assays currently use DI water, typically assigned to position 1. Check Serum, Urine, Other-1, and Other-2 for No. 1. Enter a reagent blank name (a maximum of 20 characters), typically "DI water". Enter a reagent blank ID (a maximum of 26 characters) if Barcode Operation is checked.
Set Conc Value (F5)	Calibrator concentration	Use to enter calibrator concentrations for a new lot number. For tests with a multi-point calibration curve, verify the concentration of all calibrator levels.

4.5.2 Program Calibrator Concentrations

Use this function to verify and change calibrator concentrations. Select the calibrator name to verify and change the concentrations of all tests in a calibrator from the same screen. This is the easiest way to change all concentrations when the calibrator lot number changes.

 **CAUTION**

Confirm calibrator concentration values in Calibration Specific.

IT IS CRITICAL ALL CALIBRATOR VALUES ARE ENTERED CORRECTLY.

For details on calibration specific test parameters, refer to [4.5.3 Calibration Specific Menu](#).

1 Select **Menu List** > **Parameters** > **Calibration Parameters** > **Calibrators**.

2 Select **Edit (F1)**. The window changes to the edit mode.

- 3 Select the calibrator name to edit.
- 4 Select **Set Conc Value (F5)**. The Set Conc Value window opens.

Figure 4.21

The screenshot shows the 'Set Conc Value' window with the 'Calibrator' dropdown set to '1.ALB,ALT'. The window contains a table with columns for Test Name, Point, and Conc, repeated three times. The data is as follows:

Test Name	Point	Conc	Test Name	Point	Conc	Test Name	Point	Conc
1.ALB		2.ALB	1	4.13	3.1D#	1	4.13	4.13
4.1D#	1	4.13	5.1P	1	4.13	6.1P	1	4.13
7.6L#	1	4.13	8.6L#	1	4.13	9.ALT	1	4.13
10.ALT	1	4.13	11.A5T	1	4.13	12.A5T	1	4.13
13.8#	1	85.1	14.8#	1	85.1	15.6T	1	85.1
16.6T	1	85.1	17.6L1201	1	85.1	18.6L1200	1	85.1
19.1P901	1	85.1	20.1P900	1	85.1	21.1D1201	1	85.1
22.1D1200	1	85.1	23.1P901	1	85.1	24.1P900	1	85.1
25.1P1201			26.1P1200			27.1P901		
28.1P900			29.1N1201			30.1N1200		
31.1CP901			32.1CP900			33.1CP1201		
34.1CP1200			35.1340n1			36.1340n1		
37.1480n1			38.1480n1			39.1600n1		
40.1600n1			41.1340n2			42.1340n2		
43.1480n2			44.1480n2			45.1600n2		
46.1600n2			47.1340n3			48.1340n3		
49.1480n3			50.1480n3			51.1600n3		
52.1600n3			53.511			54.5101		
55.521			56.52n1			57.551		
58.55n1			59.5112			60.51n2		

- 5 The concentration value(s) of the selected calibrator display. To display or edit a different calibrator, select the calibrator name from the "Calibrator" drop-down list.
- 6 Enter the concentration values (Conc) for each test (Test Name) in the calibrator. The concentration values can only be entered for tests programmed to the calibrator in **Calibration Specific**.
- 7 Repeat steps 5 and 6 for any other calibrator to verify or change the concentration.
- 8 Select **Close** to close the Set Conc Value window.
- 9 If a calibrator concentration was changed, a confirmation message appears in the Set Conc Value window. Select **OK**.
- 10 Select **Confirm (F1)**.

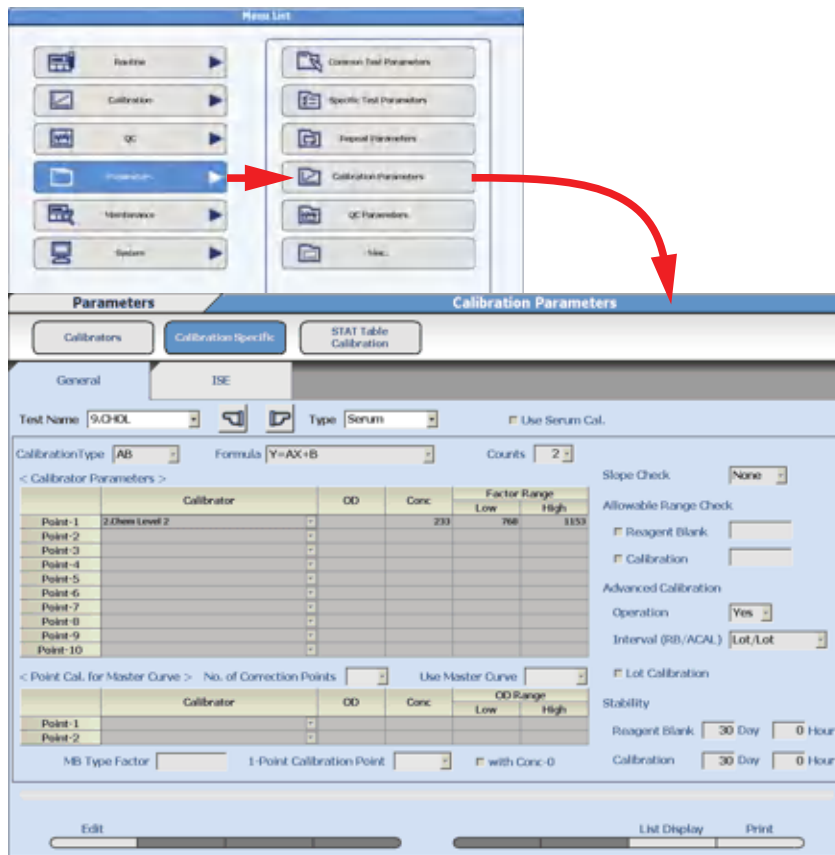
4.5.3 Calibration Specific Menu

Program all specific calibration parameters for each test. Program and verify information from the chemistry setting sheet.

General Tab

Select **Menu List > Parameters > Calibration Parameters > Calibration Specific.**

Figure 4.22



Parameters

4.5 Calibration Parameters Menu

Item	Contents	Input Notes
Test Name	Test name	
Type	Serum, Urine, Other-1, or Other-2	
Use Serum Cal.	Check or no check	Check this option to use the Serum calibration curve for the Urine, Other-1, or Other-2 test. The Urine, Other-1, and/or Other-2 test is not calibrated and uses the serum calibration curve.
Calibration Type	MB to 7 MB, AA, AB to 7 AB, 4 MC to 10 MC	Enter the Calibration Type from the chemistry setting sheet. For a description of the different calibration types, refer to 3.1.6 Summary of Calibration Types in chapter 3.
Formula	Interpolation formula for the calibration curve.	Select the formula from the chemistry setting sheet. The formulas that can be selected for a test are limited by the calibration type.
Counts	1, 2, 3, or 4	The number of reagent blank and calibration replicates used for calculation. If "1" is set, the reagent blank or calibrator OD is used for calculation. If "2" is set, the mean value of the replicates is used. If "3" is set, the mean value of the two closest replicates is used. If "4" is set, the highest and lowest replicate values are discarded, and the mean value of the two replicates is used.
Slope Check	+ or -	Refer to the chemistry setting sheet. For multi-point calibrations (AA and 2 AB to 7 AB) the software checks to verify all OD values are increasing (+) or decreasing (-).
Allowable Range Check	OD value (0.0000 to 3.0000)	Refer to the chemistry setting sheet. An acceptable dispersion of OD values (OD delta check) for the reagent blank and calibration for AA, AB to 7AB, and 4MC to 10MC.
Advanced Calibration Operation	Yes or No	Refer to the chemistry setting sheet. Advanced calibration allows reagent blank and calibration for up to 5 bottles or lot numbers of the same test.
Advanced Calibration Interval (RB/ACAL)	Lot/Lot Bottle/Lot Bottle/Bottle	

Item	Contents	Input Notes
Lot Calibration	Check or no check	<p>Only available when Advanced Calibration is set to Lot/Lot. Affects the reagent blank and calibration stability when a second bottle of reagent with the same lot is placed on the system.</p> <p>If checked, when the second bottle of reagent is placed on the system, the calibration factor from the first bottle of reagent (base factor) is used for the second bottle of reagent. The reagent blank and calibration stability for the first bottle continues to be tracked, and the reagent blank and calibration stability for the second bottle is set to the programmed stability in Calibration Specific.</p> <p>If unchecked, when the second bottle of reagent is placed on the system, the reagent blank and calibration stability is tracked at the first bottle's remaining stability period for both bottles.</p>
1-Point Calibration Point	Calibrator Point-1 to Point-7	For a multi-point calibration, enter the calibrator number to adjust the multi-point calibration curve by a single point.
with Conc-0	Check or no check	Enter a check for a multi-point calibration to include the zero concentration. If 1-Point Calibration Point is used and zero concentration is the origin, check "with Conc-0" and enter the calibrator number in "1-Point Calibration Point".
Calibrator	Calibrator name	The calibrator material must be programmed in Calibrators before it is available.
OD	OD value	Enter the OD (-2.0000 to 3.0000) for calibration types 2 MB to 7 MB.
Conc	Calibrator concentration	A maximum of 9 digits including the decimal place and sign from -99999999 to 99999999.
Factor Range or OD Range	OD range: -2.0000 to 3.0000 Factor range: -9999999 to 9999999	Refer to the chemistry setting sheet. When the calibration type is 2AB to 7AB, an OD Range is programmable. When the calibration type is AB or AA, a Factor Range is programmable. A Calibration Factor/OD Range alarm is generated if the range is exceeded.

Item	Contents	Input Notes
<Point Cal. For Master Curve>	Calibrator, Conc, OD Range	A master curve using a one or two point calibration can be used to update a multi-point calibration. Refer to the chemistry setting sheet. The reagent bottle has a 2-dimensional ID that contains the OD values for each lot number for the master curve concentrations. These values are scanned in with the hand-held barcode reader in Reagent Management .
MB Type Factor	MB factor	Refer to the chemistry setting sheet. When the calibration type is MB to 7 MB, enter the MB Type Factor (-99999999 to 999999999).
Stability: Reagent Blank and Calibration	0-999 (Day) and 0-23 (Hour)	
List Display (F7)	Displays a list of all Calibration Specific test parameters.	Use the list to verify parameters. Select the sample type, and a maximum of six tests to display at a time.

TIP Advanced Calibration allows calibration of up to 5 bottles or lot numbers of the same reagent in advance of the patient run. When the system switches to the new bottle or lot number of reagent, the appropriate calibration curve is used. Advanced Calibration can be used for reagent ID positions, or fixed (assigned) positions. For detailed information, contact Beckman Coulter Technical Services.

TIP Lot Calibration

- When Lot Calibration is checked, a maximum of 2 sets of reagent bottles can be used on the system.
- When Lot Calibration is checked, the first successful calibration factor (base factor) is used for both sets of bottles.
- Additional calibrations can be performed on the bottles for verification, and the results can be monitored in **Calibration Monitor**.

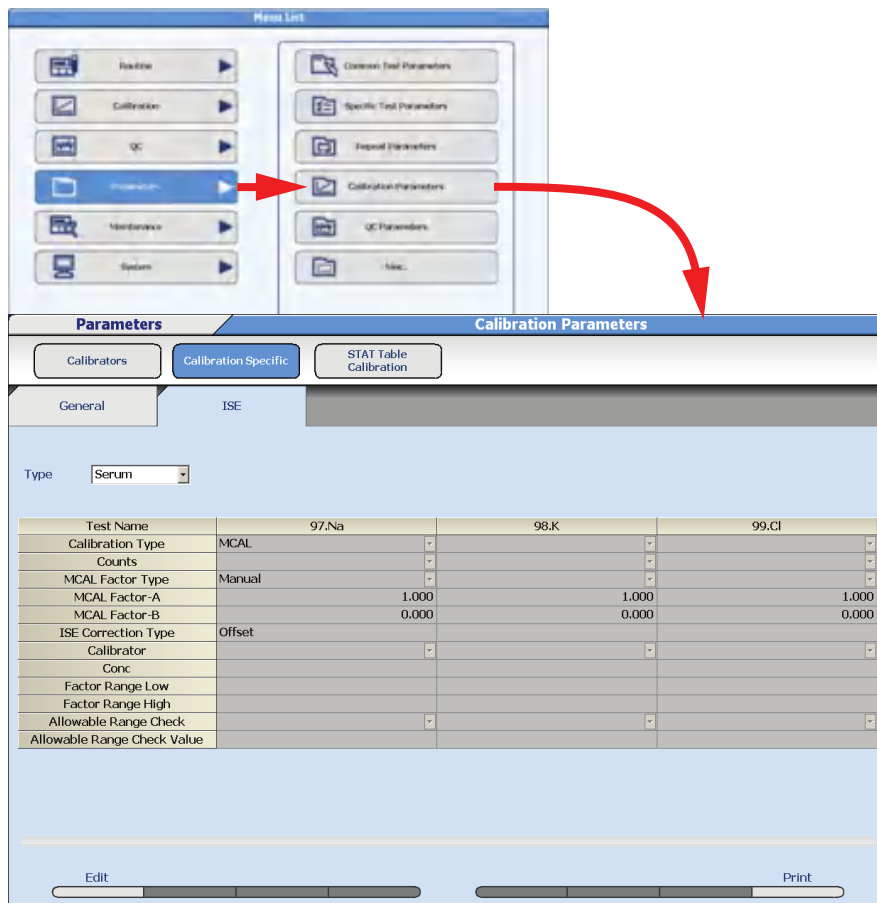
TIP When the “Use Serum Cal.” check box is selected, the serum calibration curve is used for Urine, Other-1, or Other-2 sample types.

ISE Tab

Program specific calibration parameters for the ISE tests (Na, K, and Cl).

Select **Menu List > Parameters > Calibration Parameters > Calibration Specific > ISE.**

Figure 4.23



Item	Contents	Input Notes
Type	Serum or Urine	
Calibration Type	MCAL or ACAL	MCAL means ISE calibration is performed from ISE Maintenance > Calibration using the High and Low Serum and/or Urine Standards. ACAL means a calibration is also performed from calibrator material in the yellow rack or STAT table. MCAL or ACAL is common for Na, K, and Cl and cannot be programmed individually by test.
Counts	1 to 4	If ACAL is programmed, select the number of calibration replicates.
MCAL Factor Type	Manual or CRS Calibration	CRS Calibration is only available in Japan.

TIP It is only possible to program Calibrator, Conc, Factor Range (Low and High), Allowable Range Check, and Allowable Range Check Value if the Calibration Type is programmed to ACAL.

Item	Contents	Input Notes
Calibrator	Calibrator for Na, K, and Cl	If ACAL is programmed, select the calibrator material to use for Na, K, and Cl.
Conc	Calibrator concentration	If ACAL is programmed, enter the calibrator concentration for Na, K, and Cl (-9999999 to 9999999).
Factor Range Low and High	Factor range	If ACAL is programmed, enter the calibration Low factor limit (-9999999) to High factor limit (9999999) for Na, K, and Cl.
Allowable Range Check	Yes or No	If ACAL is programmed, select Yes to perform an OD delta check on the calibrator OD values.
Allowable Range Check Value	OD value	If Allowable Range Check is Yes, enter the OD value for the OD delta check.

4.5.4 STAT Table Calibration Menu

All required calibrators and the reagent blank must be programmed for STAT table analysis when using Fixed Positions for calibrators.

- If calibrator barcode operation is in use, the calibrators can be placed in any of the Fixed Positions for calibrators.
- If calibrator barcode operation is not in use, the calibrators must be placed in the Fixed Position specifically programmed for each calibrator.

For information on Fixed Positions, Variable Positions, and Free Positions, refer to [4.10.3 Program STAT Table Parameters](#).

 **CAUTION**

The inside of the STAT table compartment is refrigerated, but it is not intended for long-term storage of samples. Calibrators should be set on the STAT table only for the shortest time required.

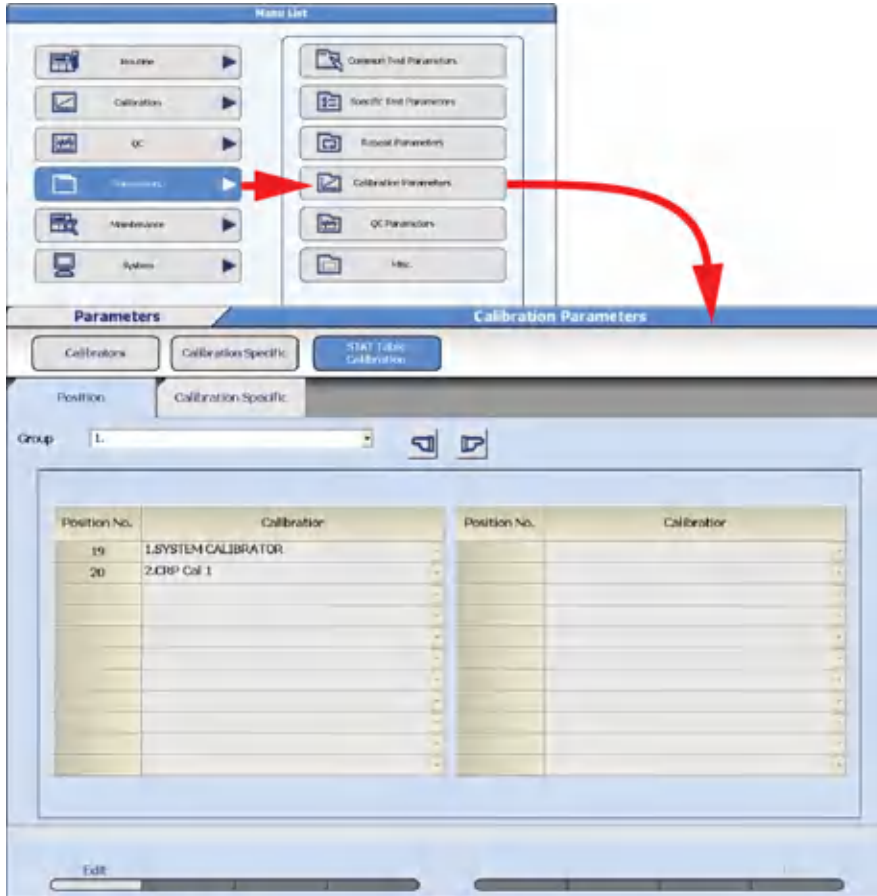
For details on programming calibrators and barcode operation, refer to [4.5.1 Calibrators Menu](#).

TIP Menu > Parameters > Calibration Parameters > STAT Table Calibration > Position and Calibration Specific tabs cannot be programmed when using Free Positions or Variable Positions on the STAT table. These tabs are grayed out after selecting **Edit (F1)**. For information on programming STAT table positions, refer to [4.10.3 Program STAT Table Parameters](#).

Program Calibrators on the STAT Table:

Select **Menu List > Parameters > Calibration Parameters > STAT Table Calibration > Position.**

Figure 4.24



Item	Contents	Input Notes
Group	Group 1, 2, or 3	Select Group 1, 2, or 3 to program calibrators on the STAT table from the "Group" drop-down list.
Position No. (displays if calibrator Barcode Operation is No) or Number (displays if calibrator Barcode Operation is Yes)	Position 1 to 22 Sequential number	Displays the available calibrator position numbers. Positions are assigned for calibrators in Analysis Mode . Refer to 4.10.3 Program STAT Table Parameters for programming information. Displays the number of available calibrator positions beginning with one. Positions are assigned to calibrators in Analysis Mode . Refer to 4.10.3 Program STAT Table Parameters .
Calibrator	Calibrator name	Select the calibrator from the "Calibrator" drop-down list.

Program Specific Calibrator Parameters on the STAT Table

Automatic STAT calibration is available by programming **All points** or **RB** in Calibration Mode. Automatic STAT calibration occurs during sample analysis when the event programmed for Execution Type occurs, and the necessary calibrator(s) is available on the STAT table.

TIP If the automatic STAT calibration is programmed, the amber STAT TABLE LED continuously blinks slowly during analysis.

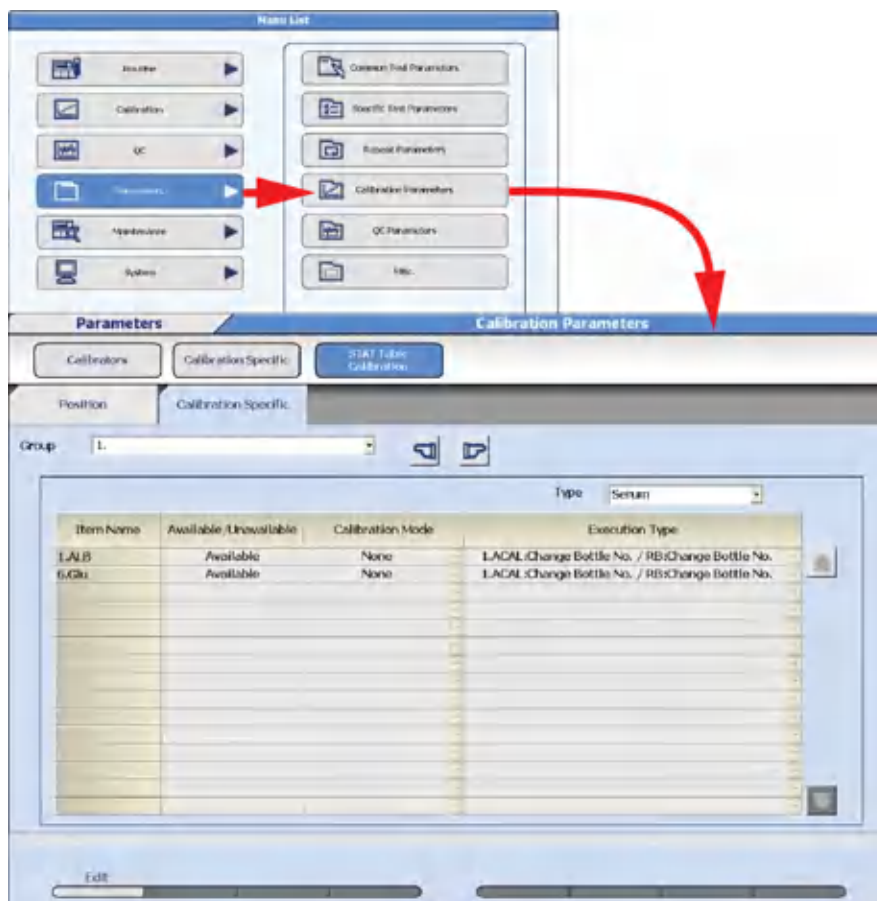
Program **None** for all items in Calibration Mode if automatic STAT calibration is not required.

TIP To perform calibration in advance of QC and sample analysis, refer to [4.5.3 Calibration Specific Menu](#). Advanced Calibration is available for a maximum of five Bottle No.s or five Lot No.s of reagent.

TIP **Menu > Parameters > Calibration Parameters > STAT Table Calibration > Calibration Specific** tab cannot be programmed when using Free Positions or Variable Positions on the STAT table. For information on programming STAT table positions, refer to [4.10.3 Program STAT Table Parameters](#).

Select **Menu List > Parameters > Calibration Parameters > STAT Table Calibration > Calibration Specific**.

Figure 4.25



Item	Contents	Input Notes
Group	Group 1, 2, or 3	Select Group 1, 2, or 3 to program calibrators on the STAT table from the "Group" drop-down list.
Type	Serum, Urine, Other-1, or Other-2	Select the sample type from the "Type" drop-down list.
Item Name	Test Name	Display the test names assigned to Group.
Available/Unavailable	Available or Unavailable	Displays "Available" if all the necessary calibrators are listed in the Position tab.
Calibration Mode	None	Automatic STAT calibration according to the programming in Execution Type is not performed.
	All points	Reagent blank and calibration are performed for all points according to the programming in Execution Type.
	RB	Only reagent blank is performed according to the programming in Execution Type.
Execution Type	ACAL: Bottle No. change/RB: Bottle No. change	Reagent blank and calibration are performed when the system switches to the second sequenced reagent bottle because the first sequenced reagent bottle becomes empty during sample analysis. Each sequenced reagent bottle has a unique bottle number. Bottles have the same reagent lot number.
	ACAL: Lot No. change/RB: Lot No. change	Calibration and reagent blank are performed when the system switches to a reagent bottle with a new lot number during analysis. This occurs when all sequenced reagent bottles with the same lot number become empty during sample analysis.
	ACAL: Lot No. change/RB: Bottle No. change	Calibration is performed when the system switches to a reagent bottle with a new lot number during analysis. This occurs when all sequenced reagent bottles with the same lot number become empty during sample analysis. Reagent blank is performed when the system switches to the second sequenced reagent bottle because the first sequenced reagent bottle becomes empty during sample analysis. Each sequenced reagent bottle has a unique bottle number. All reagent bottles have the same reagent lot number.

TIP Automatic STAT calibration occurs during sample analysis. To perform calibration in advance of QC and sample analysis, Advanced Calibration by Bottle No. or Lot No. is available. Refer to [4.5.3 Calibration Specific Menu](#).

4.6 QC Parameters Menu

Program the controls used for QC analysis, and all specific QC parameters.

[4.6.1 Controls Menu](#)

[4.6.2 QC Specific Menu](#)

[4.6.3 STAT Table QC Menu](#)

Quality control (QC) samples are used to verify system performance and are an integral part of any diagnostic device.

Check the performance of the AU480 regularly by analyzing QC samples. Each laboratory should establish its own control frequency. Good laboratory practice suggests QC samples be tested each time patient samples are tested and each time calibration is performed. If any trends or sudden shifts in values are detected, review all operating parameters.

Each laboratory should also establish guidelines to ensure corrective action if controls do not recover within the specified limits.

QC analysis can be performed in the green racks or the STAT table. When QC Barcode Operation is enabled, controls can be placed in any position in the green racks or STAT table.

 **CAUTION**

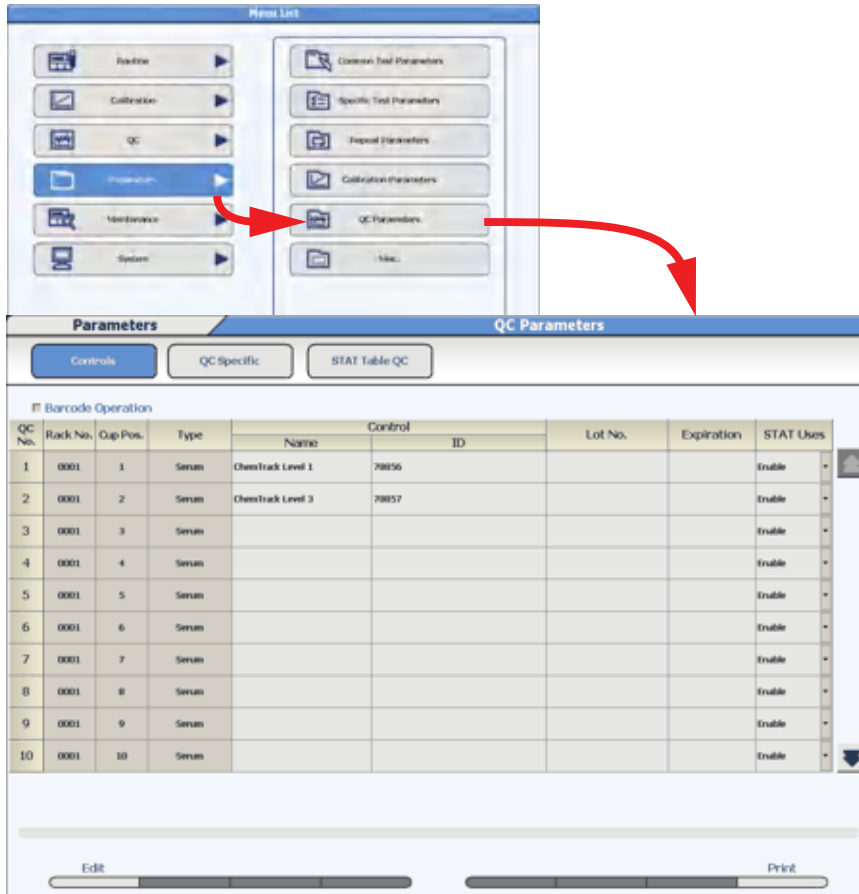
Erroneous analysis data can lead to erroneous diagnosis results. Always perform QC analysis at the same time as analysis of general patient samples to confirm that analysis is performed normally.

4.6.1 Controls Menu

Program a maximum of 100 controls required for specific assays. Control numbers 1 to 100 are programmed to a Type (Serum, Urine, Other-1, or Other-2) by Beckman Coulter Technical Services based on laboratory requirements.

Select **Menu List > Parameters > QC Parameters > Controls**.

Figure 4.26



Item	Contents	Input Notes
Barcode Operation	Check or no check	If Barcode Operation is checked, control IDs are assigned to control material and controls can be placed in any position in the green rack or STAT table. The highest control number (1 to 100) must be the last sample in the green rack, or highest position number on the STAT table. If Barcode Operation is not checked, controls are assigned to positions in the green rack or STAT table.
Name	Control name	A maximum of 20 characters.
ID	Control ID (barcode)	A maximum of 26 alphanumeric characters for the control ID when Barcode Operation is checked.
Lot No.	Control lot number	A maximum of 15 alphanumeric characters.
Expiration	Control expiration date	Enter a date, for example YYYY/MM/DD.
STAT Uses	Enable or Unable	Set to Enable to enable programming for the control on the STAT table.

4.6.2 QC Specific Menu

Program the specific control parameters for each test.

There are two quality control methods:

- Single check using the mean value and the standard deviation of the control
- Multi check with multiple rules including the tendencies of past results in the control

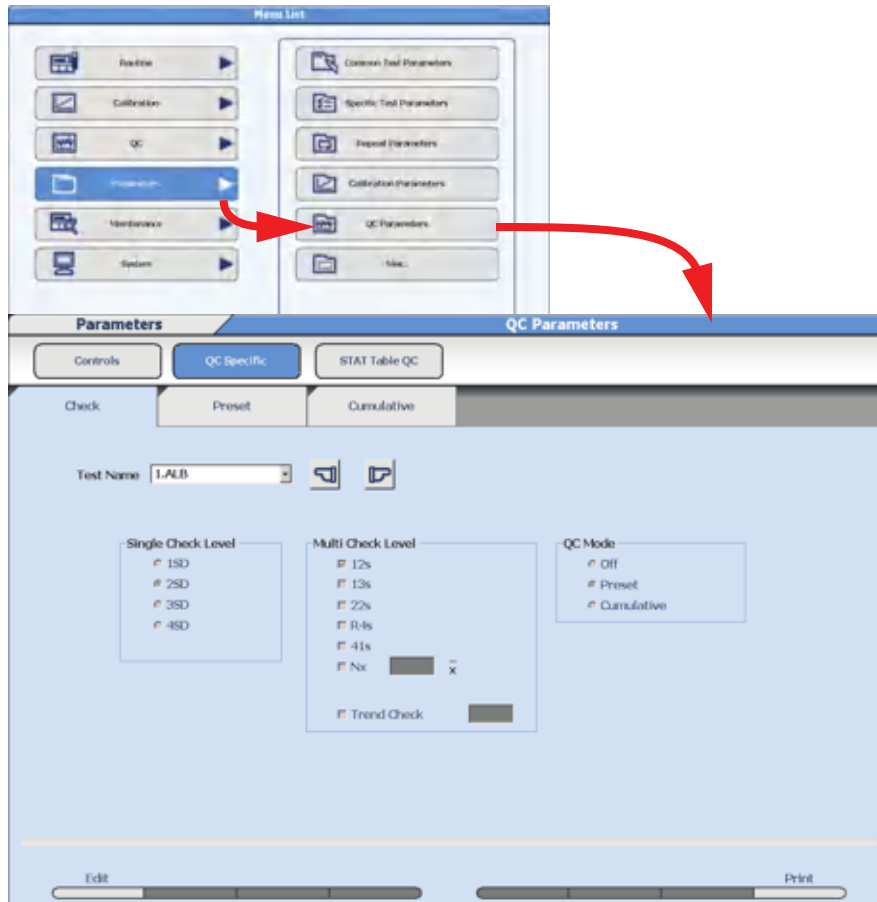
QC can be evaluated using a Preset mode or Cumulative mode. In the Preset mode, the QC mean, SD, and Range are entered in the **Preset** tab. In the Cumulative mode, the QC mean, SD, and Range are calculated from QC run on the analyzer.

For details on quality control, refer to [3.1.5 Quality Control](#) in chapter 3.

Check Tab

Select **Menu List > Parameters > QC Parameters > QC Specific > Check**.

Figure 4.27



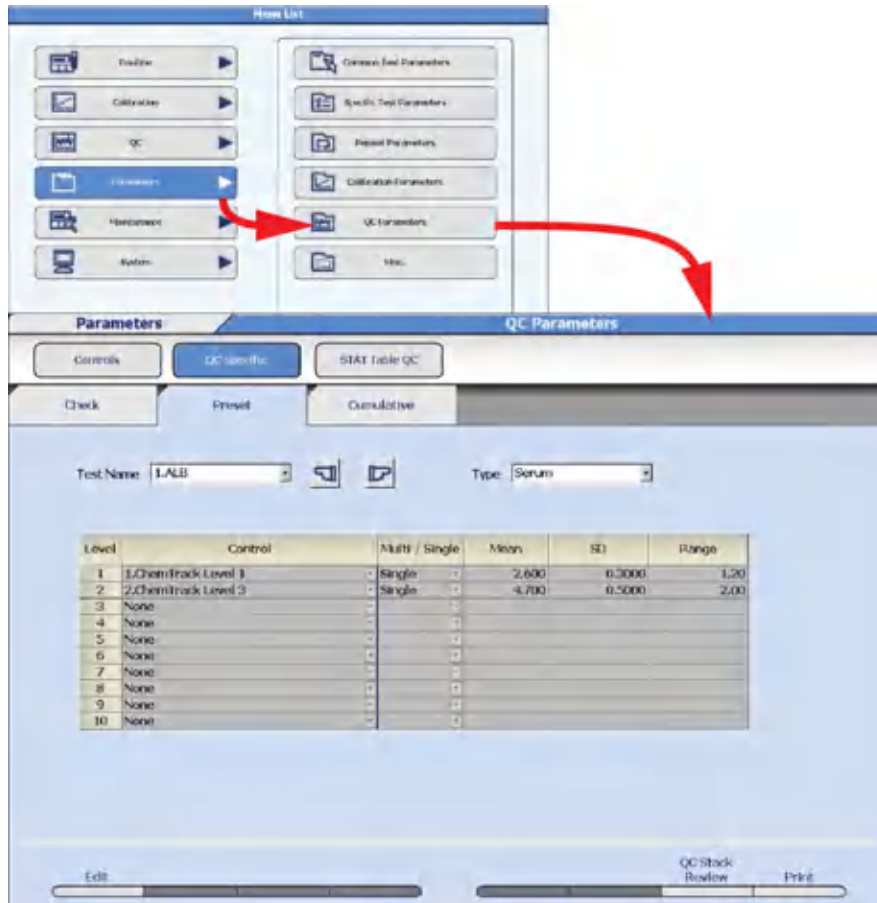
Item	Contents	Input Notes
Test Name	Test name	
Single Check Level	1SD, 2SD, 3SD, or 4SD	The standard deviation is checked as the control limit. Set the deviation level (1SD to 4SD). The error flag is "1Q" for any QC value that exceeds the SD level selected.
Multi Check Level	Check 1_{2s} , 1_{3s} , 2_{2s} , R_{4s} , 4_{1s} , N_x , and/or Trend Check	<ul style="list-style-type: none"> • If 1_{2s} is checked and the control data on one side exceeds +/- 2SD, a "1Q" error flag is generated. • If 1_{3s} is checked and the control data on one side exceeds +/- 3SD, a "2Q" error flag is generated. • If 2_{2s} is checked and two consecutive control data exceeds +/- 2SD in the same direction, a "3Q" error flag is generated. • If R_{4s} is checked and consecutive high and low control data exceeds + 2SD and - 2SD, a "4Q" error flag is generated. • If 4_{1s} is checked and four consecutive control data exceeds +/- 1SD in any direction, a "5Q" error flag is generated. • If N_x is checked, program from 7 to 10 points to check if consecutive control data is above or below the mean value. A "6Q" flag is generated. • If Trend Check is checked, program from 4 to 10 points to check for consecutively increasing or decreasing values. A "7Q" flag is generated. <p>When using Multi Check, the 1_{2s} must be checked to initiate the process in order for the following checks to be implemented when the 1_{2s} is exceeded.</p>
QC Mode	Off, Preset, or Cumulative	<ul style="list-style-type: none"> • If Off is selected, a QC check is not performed and QC alarms and error flags are not generated. • If Preset is selected, QC alarms and error flags are generated from the values programmed in the Preset tab. • After QC has been run on the analyzer for a user defined number of QC samples, the QC mean, Standard deviation, and range can be calculated in the Cumulative tab. If Cumulative is checked, QC alarms and error flags are generated from the calculated QC values obtained from the analyzer.

Preset Tab

When Preset mode is selected, known values must be entered for the mean, SD, and range. A maximum of 10 controls can be programmed for each test and sample type.

Select **Menu List > Parameters > QC Parameters > QC Specific > Preset.**

Figure 4.28



Item	Contents	Input Notes
Test Name	Test name	
Type	Serum, Urine, Other-1, or Other-2	
Control	Control material	The available QC material programmed in the Controls Menu for the sample type is displayed in the drop-down list.
Multi/Single	Multi or Single	Program each Control to use Single Check or Multi Check rules. Two controls must be programmed to use Multi Check.
Mean	QC mean value	
SD	Standard deviation	Enter the value of one standard deviation.
Range	Range value	Enter the value of the range for acceptable QC.
QC Stack Review (F7)	Displays the last 10 QC results for the low and high control for the test.	QC data only displays if the test is programmed to Multi. Select Close to close the window.

Figure 4.29

QC Stack Review

Test Name 1.ALB Type Serum

No.	Control No.	Control No.
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		

<- Recent

Close

TIP Only controls that are common to all tests in the calculation can be programmed for QC on calculated tests.

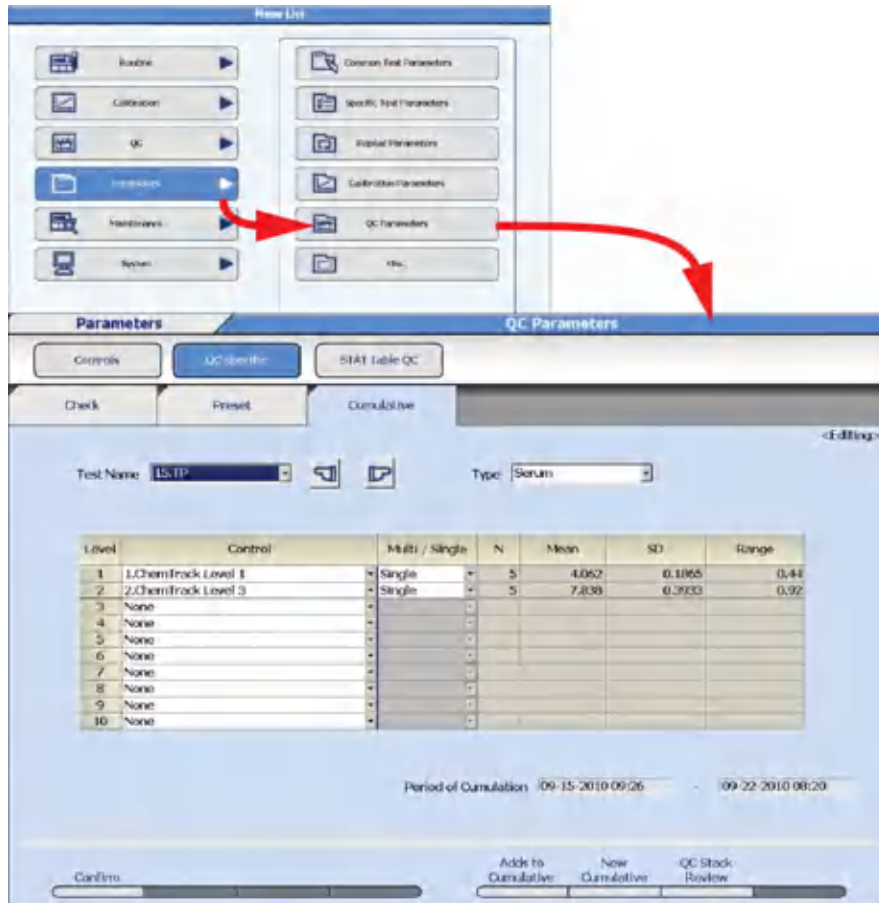
If two controls are programmed to Multi, it is possible to display the Twin Plot chart in **QC Monitor**.

Cumulative Tab

When the QC Mode is set to Cumulative, the QC mean, standard deviation, and range can be calculated from QC data run on the analyzer.

Select **Menu List > Parameters > QC Parameters > QC Specific > Cumulative**.

Figure 4.30



Item	Contents	Input Notes
Test Name	Test name	
Type	Serum, Urine, Other-1, or Other-2	
Control	Control material	The available QC material programmed in the Controls Menu for the sample type displays from the drop-down list.
Multi/Single	Multi or Single	Program each Control to use Single Check or Multi Check rules. Two controls must be programmed to use Multi Check.
Adds to Cumulative (F5)	Start Index and End Index to calculate QC Statistics.	Adds QC data from the selected Start Index and End Index to any existing QC Statistics, and calculates a new QC mean, SD, and range.
New Cumulative (F6)	Start Index and End Index to calculate QC Statistics.	Calculates a new QC mean, SD, and range based on the Start Index and End Index.
Period of Cumulation	Displays the Start Index and End Index selected for the calculation of QC Statistics.	When OK is selected in the New Cumulative or Adds to Cumulative window, the number of QC data points (N), QC Mean, SD, and Range are calculated and displayed.

Figure 4.31



TIP Only controls that are common to all tests in the calculation can be programmed for QC on calculated tests.

4.6.3 STAT Table QC Menu

All required controls must be programmed for STAT table analysis when using Fixed Positions for controls.

- If QC barcode operation is in use, the controls can be placed in any of the Fixed Positions for controls.
- If QC barcode operation is not in use, the controls must be placed in the Fixed Position specifically programmed for each control.

For information on Fixed Positions, Variable Positions, and Free Positions, refer to [4.10.3 Program STAT Table Parameters](#).



The inside of the STAT table compartment is refrigerated, but it is not intended for long-term storage of samples. Controls should be set on the STAT table only for the shortest time required.

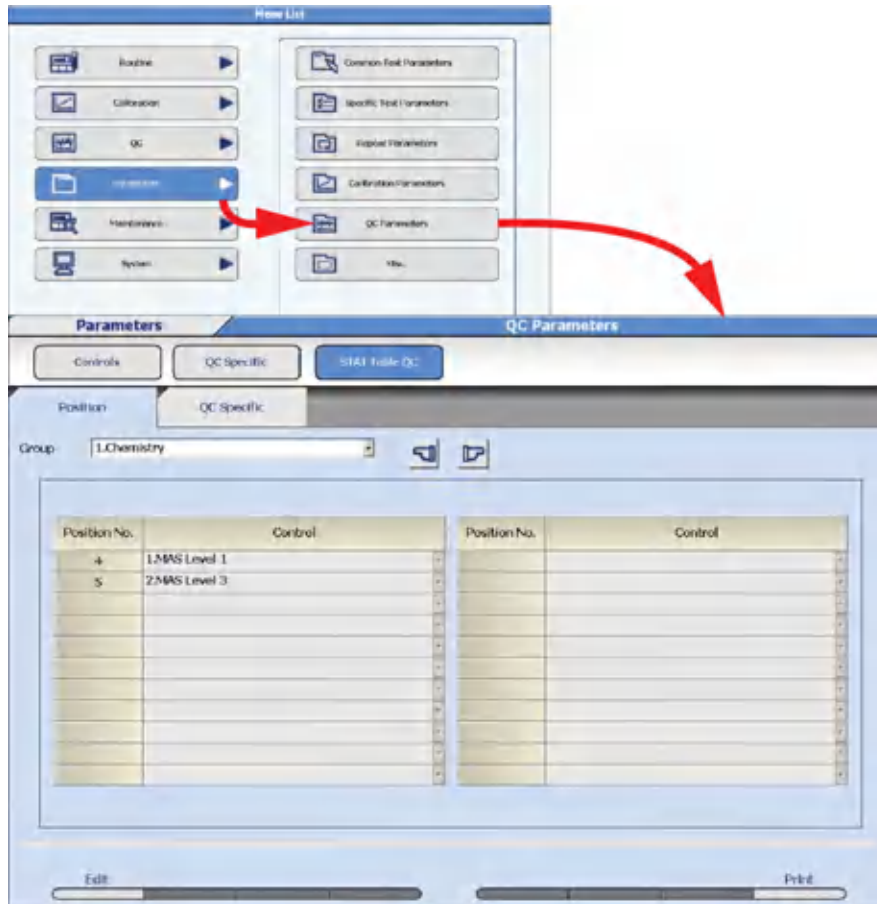
For details on QC barcode operation, refer to [4.6.1 Controls Menu](#).

TIP Menu > Parameters > QC Parameters > STAT Table QC > Position and QC Specific tabs cannot be programmed when using Free Positions or Variable Positions on the STAT table. These tabs are grayed out after selecting **Edit (F1)**.

Program Controls on the STAT Table:

Select **Menu List > Parameters > QC Parameters > STAT Table QC > Position.**

Figure 4.32



Item	Contents	Input Notes
Group	Group 1, 2, or 3	Select Group 1, 2, or 3 to program controls on the STAT table from the "Group" drop-down list.

Item	Contents	Input Notes
Position No. (displays if QC Barcode Operation is No) or Number (displays if QC Barcode Operation is Yes)	Position 1 to 22	Display the available control position numbers. Positions are assigned for controls in Analysis Mode . For programming information, refer to 4.10.3 Program STAT Table Parameters .
	Sequential number	Display the number of available control positions beginning with one. Positions are assigned for controls in Analysis Mode . Refer to 4.10.3 Program STAT Table Parameters .
Control	Control name	Select the control from the "Control" drop-down list.

Program Specific Control Parameters on the STAT Table

Automatic STAT QC is available by programming **Test** or **Sample** in Cyclic Type, or **Yes** in Execute after Calibration.

Automatic STAT QC occurs during sample analysis after calibration, or a specified number of samples or tests are processed, and the necessary control(s) is available on the STAT table.

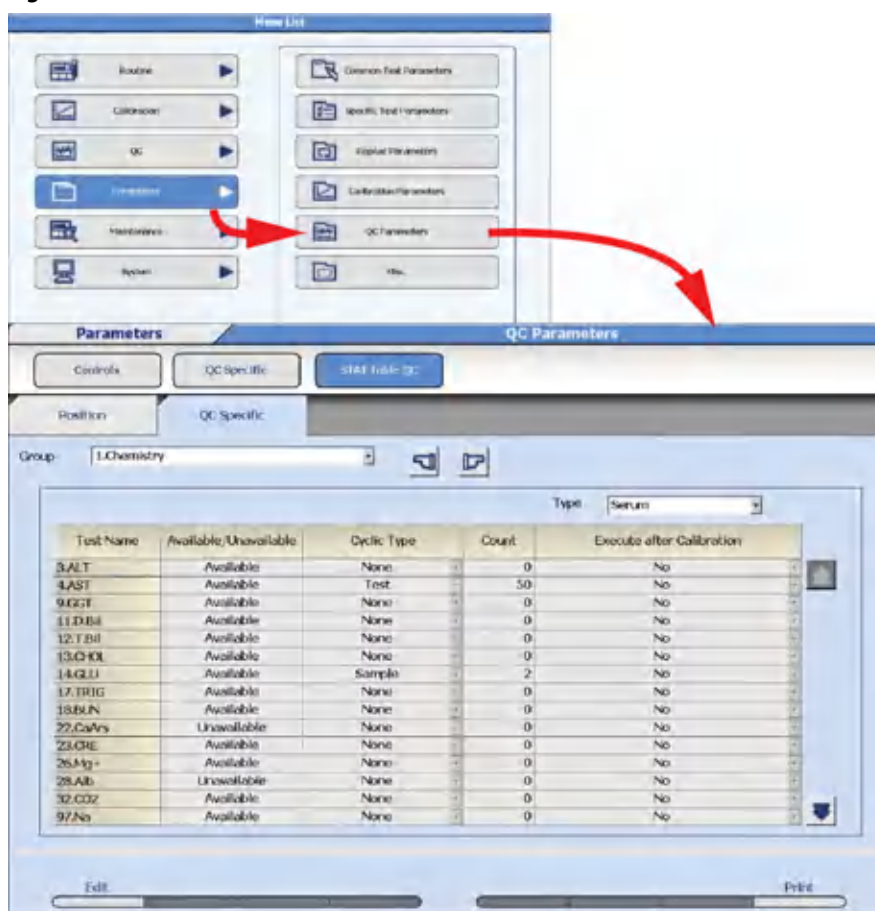
TIP When automatic STAT QC is programmed, the amber STAT TABLE LED continuously blinks slowly during analysis.

Program **None** for all items in Cycle Type if cyclic automatic STAT QC is not required.

Program **No** for Execute after Calibration if automatic STAT QC after calibration is not required.

Select **Menu List > Parameters > QC Parameters > STAT Table QC > QC Specific**.

Figure 4.33



Item	Contents	Input Notes
Group	Group 1, 2, or 3	Select Group 1, 2, or 3 to program controls on the STAT table from the "Group" drop-down list.
Type	Serum, Urine, Other-1, or Other-2	Select the sample type from the "Type" drop-down list.
Item Name	Test Name	Display the test names assigned to Group.
Available/Unavailable	Available or Unavailable	Display "Available" if all the necessary controls are listed in the Position tab.
Cyclic Type	None	QC analysis is not performed automatically from the STAT table.
	Test	QC is performed automatically from the STAT table after analysis of the programmed number of tests (Count).
	Sample	QC is performed automatically from the STAT table after analysis of the programmed number of samples (Count).
Count	1 to 999	The test or sample number interval before QC is performed automatically from the STAT table.
Execute after Calibration	Yes or No	Select Yes to perform QC automatically from the STAT table after reagent blank or calibration.

4.7 Checked Tests Menu

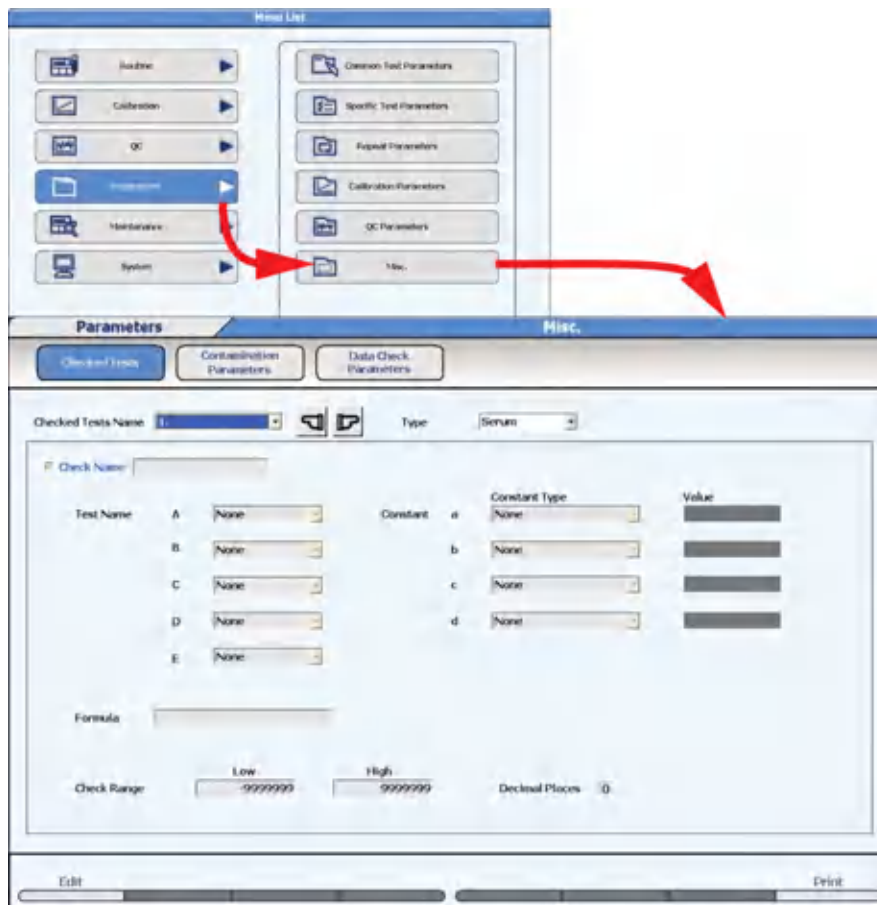
Obtain a value with optional calculated tests using multiple tests and check if this value is within a range set in advance. If the check result is out of range, an error flag (T) is added to the result.

For each sample type, a maximum of 10 calculations can be programmed.

Program the calculations for the tests to be checked.

Select **Menu List > Parameters > Misc. > Checked Tests**.

Figure 4.34



Item	Contents	Input Notes
Checked Test Name	Checked test name	The checked test name must be programmed in "Check Name" before it displays in the "Checked Test Name" drop-down list.
Check Name	Checked test name	Check "Check Name" to enable checked test programming. Enter a maximum of 8 characters for the checked test name.
Type	Serum, Urine, Other-1, or Other-2	
Test Name A, B, C, D, E	Test name	
Constant a, b, c, d	Value or Patient Inf.-1 to Patient Inf.-6	If Value is selected, enter a numerical value (maximum of 7 digits) in "Value". If Patient Inf.-1 to Patient Inf.-6 is selected, a value entered in patient demographics in the requisition is used for the constant.
Formula	Check calculation formula	Enter the formula with the characters +, -, *, /, (,), A, B, C, D, E, a, b, c, d using a maximum of 20 characters.
Set Decimal Places (F5)	0 to 4	Enter the number of decimal places for the Check Range.
Check Range	Low and High limit for the check range	A "T" flag is generated if the Check Range is exceeded.

Figure 4.35

The screenshot shows a dialog box titled "Set Decimal Places". It contains a label "Decimal Places" followed by a dropdown menu currently set to "0". At the bottom of the dialog is a "Close" button.

4.8 Contamination Parameters Menu

Although the system has sufficient washing capability, cross contamination can occur in easily affected samples, or in analysis tests with high sensitivity. Extra washing conditions and avoidance parameters can be programmed to prevent such contamination.

TIP Contact Beckman Coulter Technical Service for assay specific contamination parameters information.

[4.8.1 Contamination Prevention Tab](#)

[4.8.2 Carry-Over Prevention \(Type Changes\) Tab](#)

[4.8.3 Carry-Over Prevention \(Test\) Tab](#)



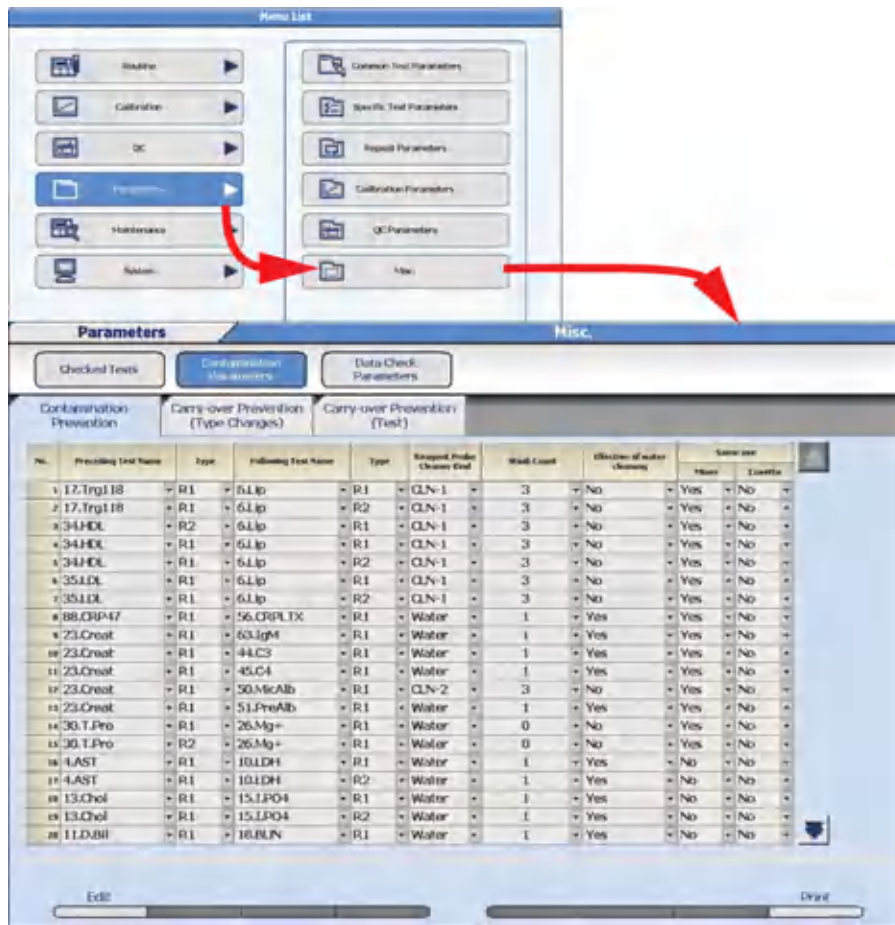
When contamination prevention conditions are set, the analysis processing speed may decrease. Consult the Instruction for Use (IFU) or the reagent manufacturer.

4.8.1 Contamination Prevention Tab

Program reagent, mix bar, and cuvette contamination avoidance conditions for easily affected items.

Select **Menu List > Parameters > Misc. > Contamination Parameters > Contamination Prevention**.

Figure 4.36



Item	Contents	Input Notes
Preceding Test Name	Test name	Select the test and type to perform extra washing before the test analysis. The cleaning solution (CLN-1, CLN-2), or All can also be selected for the preceding test.
Type	R1 or R2	
Following Test Name	Test name	Select the test and type, or All that is affected by the preceding test.
Type	R1 or R2	
Reagent Probe Cleaner Kind	Water, CLN-1 or CLN-2	The reagent probe is cleaned with water, CLN-1 (cleaning solution 1), or CLN-2 (cleaning solution 2). The required cleaning solution is fixed in the reagent refrigerator. Refer to 7.4.1 Fix (Assign) a Reagent Position .
Wash Count	1 to 5	Enter the number of times the reagent probe is washed in water or cleaning solution.
Effective of Water Cleaning	Yes or No	“Effective of Water Cleaning” Yes means that the normal rinsing of the reagent probe with DI water between tests has the same cleaning effect as the programmed contamination avoidance cleaning. If the Wash Count is set to 5 for CLN-1, and 5 or more tests are run between the two affected tests, the additional cleaning with the CLN-1 solution is not required. If “Effective of Water Cleaning” is No, cleaning 5 times in CLN-1 will always occur before the affected test, even if 5 or more tests were run between the two affected tests.
Mixer	Yes or No	If Yes is selected, the mix bar is not used for the Following Test immediately after the Preceding Test. If No is selected, the mix bar may be used for processing of the Following Test.
Cuvette	Yes or No	If Yes is selected, the cuvette is not used for the Following Test immediately after the Preceding Test. If No is selected, the cuvette may be used for processing the Following Test.

TIP The information programmed for Preceding Test Name R1 and Following Test Name R1 is automatically programmed for Preceding Test Name R2 and Following Test Name R2. The Preceding Test Name R2 and Following Test Name R2 information does not display. The extra washing is performed for both combinations.

TIP The example below shows the difference between when “Effective of water cleaning” is set to “Yes” and “No”.

Other settings:

- Preceding Test Name: A
- Following Test Name: B
- Reagent Probe Cleaner Kind: CLN-1 or CLN-2
- Wash Count: 5

In these settings, test sequence of two samples that require seven test items, A, B, C, D, E, F and G is as following. In this sequence, “w” is a cycle of cleaner washing.

- Effective of water cleaning is “Yes”:
First sample: B, A, C, D, E, F, G
Second sample: B, A, C, D, E, F, G
- Effective of water cleaning is “No”:
First sample: B, A, C, D, E, F, G
Second sample: A, C, D, E, F, G, w, w, w, w, w, B

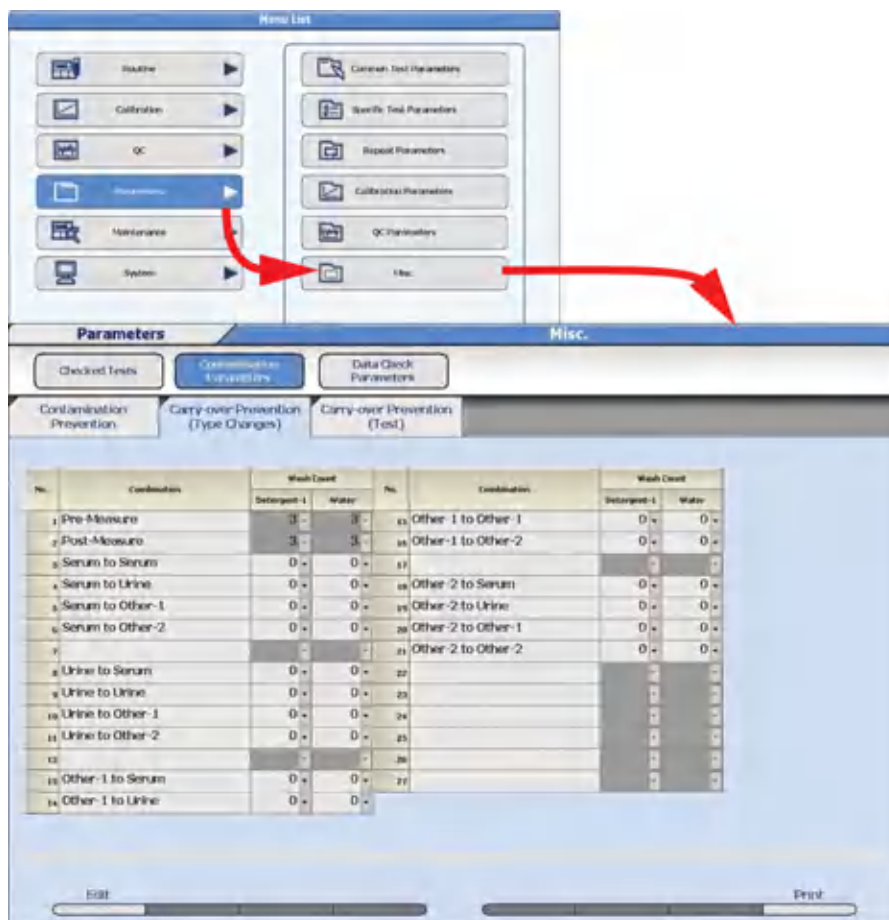
4.8.2 Carry-Over Prevention (Type Changes) Tab

Program extra cleaning for the sample probe between different sample types.

TIP If the sample probe is programmed for Detergent-1, the amber STAT TABLE LED continuously blinks slowly. This indicates the sample probe moves to the W1 position on the STAT table to be cleaned automatically with the sample probe wash solution between the programmed sample types.

Select **Menu List > Parameters > Misc. > Contamination Parameters > Carry-Over Prevention (Type Changes)**.

Figure 4.37



Item	Contents	Input Notes
Wash Count: Detergent-1, Water	0 to 6	Select the number of times the sample probe is cleaned in water, and/or Detergent-1 when changing between sample types designated by the rack ID. Detergent-1 is a cleaning solution placed in the W1 position on the STAT table.

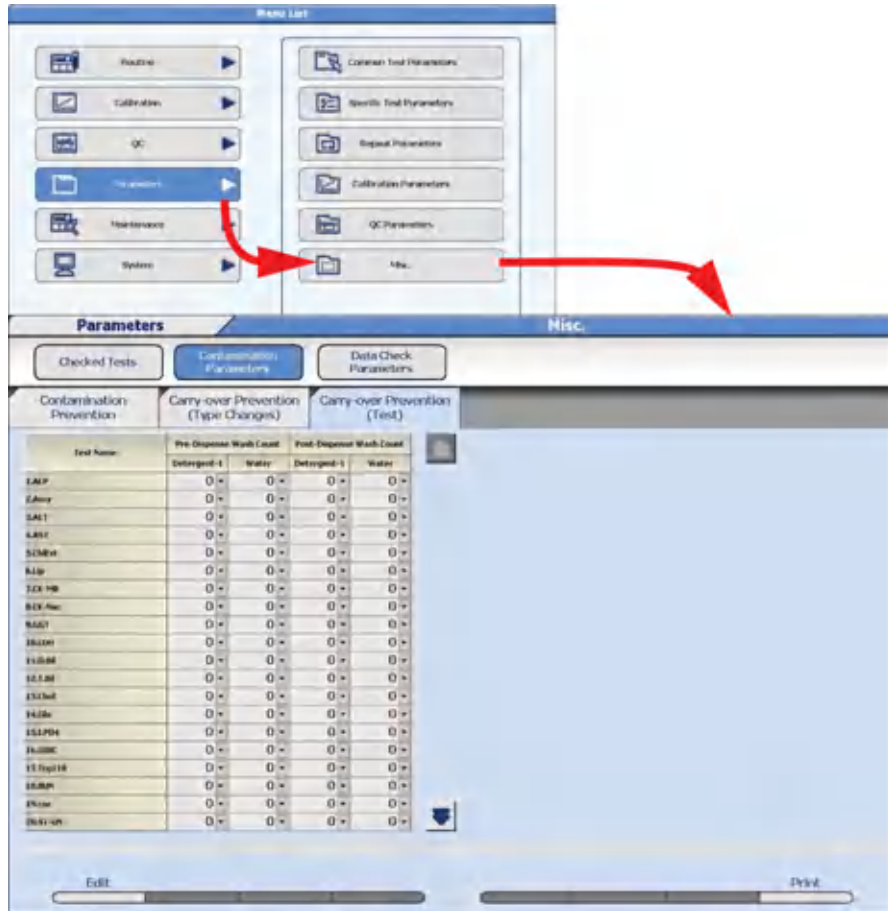
4.8.3 Carry-Over Prevention (Test) Tab

Program extra sample probe washes before and/or after tests that are highly sensitive.

TIP If the sample probe is programmed for Detergent-1, the amber STAT TABLE LED continuously blinks slowly. This indicates the sample probe moves to the W1 position on the STAT table to be cleaned automatically with the sample probe wash solution between the programmed tests.

Select **Menu List > Parameters > Misc. > Contamination Parameters > Carry-Over Prevention (Test)**.

Figure 4.38



Item	Contents	Input Notes
Pre-Dispense Wash Count: Detergent-1, Water	0 to 6	Select the number of times the sample probe is cleaned in water, and/or Detergent-1 before dispensing the test (Test Name). Detergent-1 is a cleaning solution placed in the W1 position on the STAT table.
Post-Dispense Wash Count: Detergent-1, Water	0 to 6	Select the number of times the sample probe is cleaned in water, and/or Detergent-1 after dispensing the test (Test Name). Detergent-1 is a cleaning solution placed in the W1 position on the STAT table.

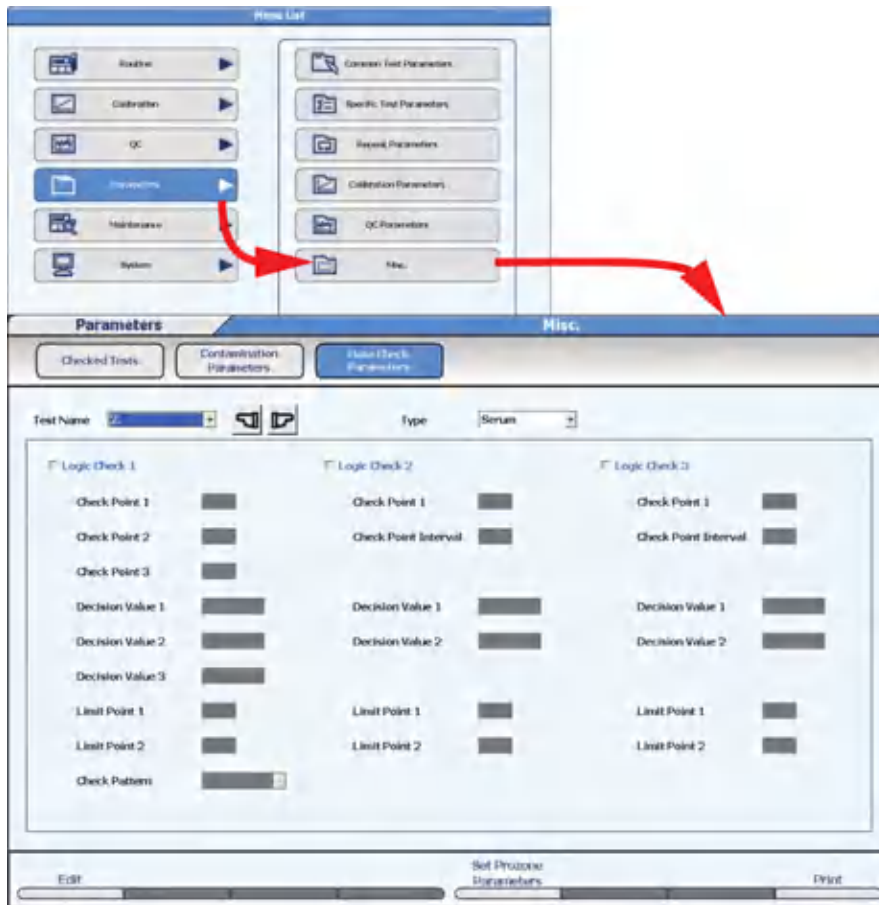
TIP Set the washing count after analysis for tests affecting other tests. Set the washing count before analysis for tests easily affected by other tests.

4.9 Data Check Parameters Menu

Program check points and decision limits to detect 1 of 4 different abnormal reaction types for prozone effects in an increasing turbidimetric assay. Data check parameters are provided on the chemistry setting sheet, if required. For additional information, contact Beckman Coulter Technical Services.

- 1 Select **Menu List > Parameters > Misc. > Data Check Parameters.**

Figure 4.39



TIP Check Point 1 to 3

Enter the photometric measuring point for judgment or the photometric measuring point for start of judgment.

Check Point Interval

Enter the point interval from the judgment start point for check. No input is possible for logic check 1.

Decision Value 1 to 3

Enter the OD to be used for judgment.

Limit Point 1, 2

Set judgment points other than check points.

When the low concentration reaction and Prozone draw similar curves, this may be used to cancel low concentration.

Check Pattern (Only Logic Check 1)

Pattern 1: Judgment formulas 1 and 2 are applied.

Pattern 2: Only judgment formula 1 is applied.

Pattern 3: Only judgment formula 2 is applied.

Pattern 4: Both judgment formulas 1 and 2 are not applied (a case where the center part is taken).

- 2 Select **Edit (F1)**. The window changes to the edit mode. Programming is enabled for each test and sample type.
- 3 Enter a check for one of the data check items 1 through 3 and set the data check tests. Multiple data checks can be checked.
- 4 When **Set Prozone Parameters (F5)** is selected, data calculation using a dedicated calibration type can be done. The Set Prozone Parameters window opens.

Figure 4.40

	OD	Conc
Point-1		
Point-2		
Point-3		
Point-4		
Point-5		
Point-6		

This is a polygonal line of the 6MB formula type, and the concentration value for OD is set.

- 5 Select **Close** to close the “Set Prozone Parameters” window.
- 6 Verify the contents set and select **Confirm (F1)**. The set contents are programmed.

4.10 System Parameters

System parameter options affect system operations and software.

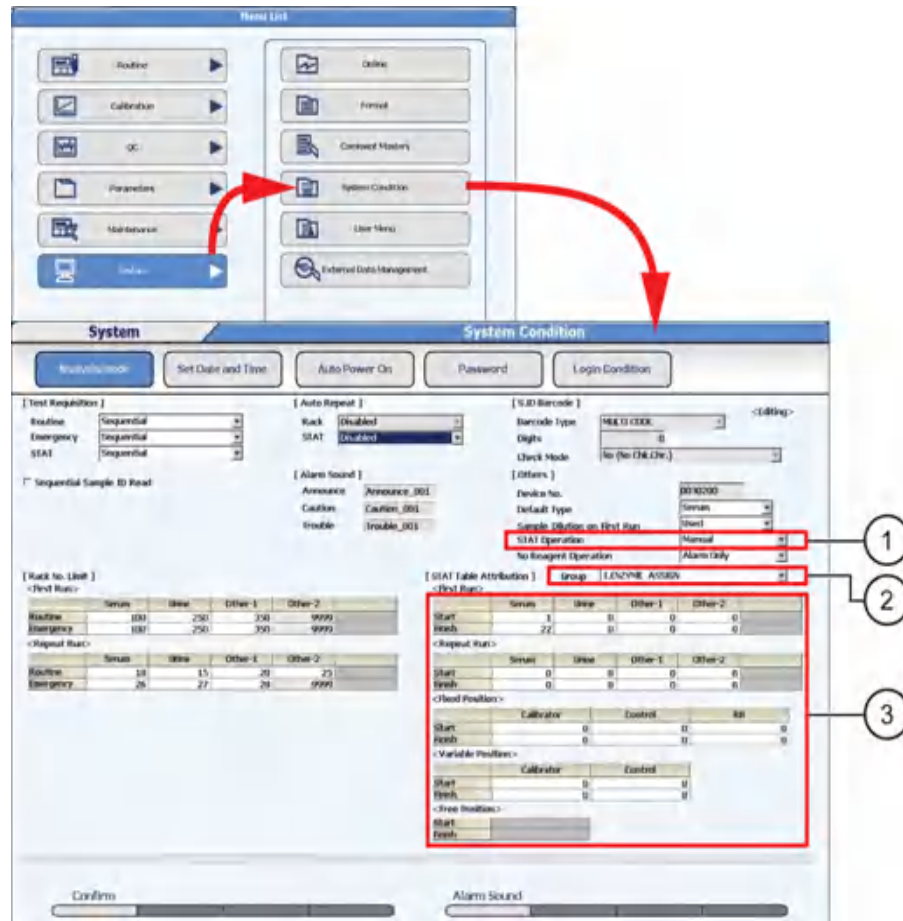
- 4.10.1 Analysis Mode Menu
- 4.10.2 Program the Rack Number Limit
- 4.10.3 Program STAT Table Parameters
- 4.10.4 Set the System Time
- 4.10.5 Program the Automatic Startup Function
- 4.10.6 Program Master Comments
- 4.10.7 Program a User Menu

4.10.1 Analysis Mode Menu

Program the sample identification mode (sequential, Rack No., or barcode), auto repeat option, rack number limit for sample type, alarm sound, and STAT table options in the **Analysis Mode** menu.

- 1 Select **Menu List > System > System Condition > Analysis Mode**.

Figure 4.41



1. STAT Operation
2. Group to program STAT Parameters
3. STAT Table Positions

- **[Test Requisition]**
Set the test requisition mode.
- **[Auto Repeat]**
Set the auto repeat mode.
- **[S.ID Barcode]**
Set the barcode type to be used for sample identification. Selection is possible from five types of barcodes.
A MULTI CODE setting for use of multiple barcode types is also possible. Contact Beckman Coulter Technical Service if MULTI CODE use is desired.
- **[Alarm Sound]**
Set the alarm sound generated by the system. If multiple systems are in use, each system can be identified by a different alarm sound.
- **[Others]**
Set other system conditions.
- **[Rack No. Limit]**
Program the rack ID number limit for each sample type for the original and repeat run.
- **[STAT Table Attribution]**
Program the STAT table positions for each sample type for the original and repeat run, and other STAT table options.

2 Select **Edit (F1)**. The window changes to the edit mode.

3 Set the system parameters for each Item in the table:

Item	Contents	Input Notes	
Test Requisition			
Routine	Sequential Rack No.	Sequential:	Performs an item inquiry in the order of sample tube detection.
Emergency	Barcode	Rack No.:	Performs an item inquiry in the order of rack ID number and sample position in the rack. Not available for STAT analysis.
STAT		Barcode:	Performs an item inquiry according to the barcode ID attached to the sample tube or cup.
Sequential Sample ID Read	Check box	Checked:	If the Test Requisition mode is set to Sequential and the sample has a barcode label, the analyzer can read the barcode but does not link this number to the test requisition. The Barcode is stored as the sample ID in Sequential and Rack Number Mode.

Item	Contents	Input Notes
Auto Repeat		
Rack	Disabled Enabled	Disabled: A repeat run list is generated after the initial run. The operator determines the samples to be repeated, and the repeat run is performed in the orange racks or STAT table repeat positions. Enabled: The system automatically performs the repeat run using the repeat run parameters. The Auto Repeat mode is automatically Disabled when Sequential or Rack ID is programmed for [Test Requisition] Routine, Emergency, or STAT. The Auto Repeat mode can only be Enabled when Barcode is programmed for [Test Requisition] Routine, Emergency, and STAT.
STAT		
S. ID Barcode^a		
Barcode Type	Selection from 7 types	Refer to 2.3.2 Sample Barcode Specifications for available barcode types.
Digits	0 to 26 digits	Including the check digit 0 means the number of digits is not specified.
Check Mode ^b	No (No Chk. Chr.) No (With Chk. Chr.) Yes	No (No Chk. Chr.): Checking is not possible because barcodes without a check character are used. No (With Chk. Chr.): Barcodes with check characters are used, but checking is not done. Yes: The check is performed.
Others		
Device No.	A 7-digit number	Beckman System ID (display only)
Default type	Serum, Urine, Other-1, or Other-2	Select the default sample type to display on all menus from the "Type" drop down.
STAT Operation	Auto or Manual	Auto means a STAT table check is performed automatically when STAT analysis is started. Manual means a STAT table check must be performed by selecting STAT Check (F3) in STAT Status before STAT analysis can be started.
No Reagent Operation	Alarm Only With Pause	Alarm Only: Analysis continues except for the empty reagent. With Pause: Analysis stops for all tests and the system shifts to <i>Pause</i> mode.

a. Programming is only available when the inquiry method is Barcode or if "Sequential Sample ID Read" is checked.

b. The "Check Character" is not included as a component of the sample ID. It is not displayed or stored.

CAUTION

When the number of digits is set as “0 (no setting)” for interleaved 2 of 5, a reading with missing digits may be interpreted as a correct reading. For example, when the digits at the edge of the label cannot be read because a label has been attached incorrectly, correct analysis is impossible. The same also applies when interleaved 2 of 5 is included in “MULTI CODE.”

CAUTION

Use of sequential analysis is not recommended for samples, as positive patient identification cannot be guaranteed.

BE AWARE THAT ANALYSIS WITHOUT A SAMPLE ID CAN LEAD TO INCORRECT PATIENT RESULTS.

- 4 Select **Alarm Sound (F5)**. The Alarm Sound window opens.

Figure 4.42



- 5 Select the alarm sound to be used for “Announce,” “Caution,” and “Trouble” from the respective drop-down list.
Announcements can be selected from seven types, cautions from five types, and troubles from six types.
TIP The selected alarm sound is played back when **Play** is selected. The alarm sound stops after a specified time, or when **Stop**, **OK**, or **Cancel** is selected.
- 6 Select **OK**. The Alarm Sound window is closed and alarm sound set as “Alarm Sound” on the edit window opens.
- 7 Select **Confirm (F1)**. The contents are programmed.

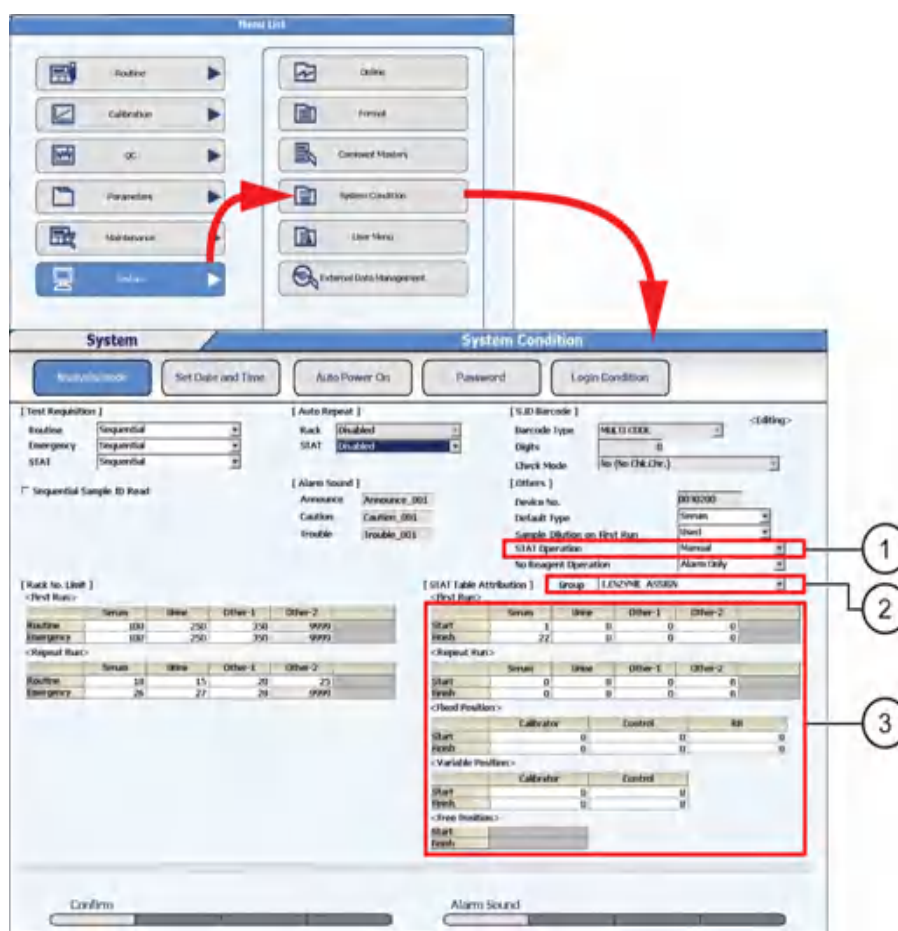
4.10.2 Program the Rack Number Limit

The system recognizes the sample type from the rack number barcode label. Set a rack ID number limit for each sample type. First run routine samples correspond to a white rack, first run emergency samples to a red rack, and repeat run samples to an orange rack.

TIP It is possible to program the system to run serum, urine, and other sample types in the same rack in specific conditions. Contact Beckman Coulter Technical Services for more information.

- 1 Select **Menu List > System > System Condition > Analysis Mode**.

Figure 4.43



1. STAT Operation
2. Group to program STAT Parameters
3. STAT Table Positions

- 2 Select **Edit (F1)**. The window changes to the edit mode.

- 3** Enter the upper limit value for the rack ID number according to the following input value limitations into the table “Rack No. Limit.”

<First run>

	Serum	Urine	Other-1	Other-2
Routine	0 to 9999	0 or Serum column + 1 to 9999	0 or 9999 displays. Input is not possible.	0 or 9999 displays. Input is not possible.
Emergency				

<Repeat run>

	Serum	Urine	Other-1	Other-2
Routine	0 to 9999	0 or Serum column + 1 to 9999	0 or Urine column + 1 to 9999	0 or Other-1 column + 1 to 9999
Emergency	0 or Routine other-2 column + 1 to 9999	0 or Emergency Serum column + 1 to 9999	0 or 9999 displays. Input is not possible.	0 or 9999 displays. Input is not possible.

TIP The number of digits of the rack ID number is four or five digits according to the setting at installation. The standard is four digits. The explanations apply for four digits.

The corresponding racks are white racks for first run routine samples, red racks for first run emergency samples, and orange racks for repeat run routine and emergency samples.

The number entered for each sample type is the rack ID upper limit. Starting with the Serum column, then Urine, Other-1 and finally Other-2, the number entered must be higher (up to 9999) or 0.

Sample types with “0” set cannot be analyzed.

Columns have “0” or “9999” assigned automatically.

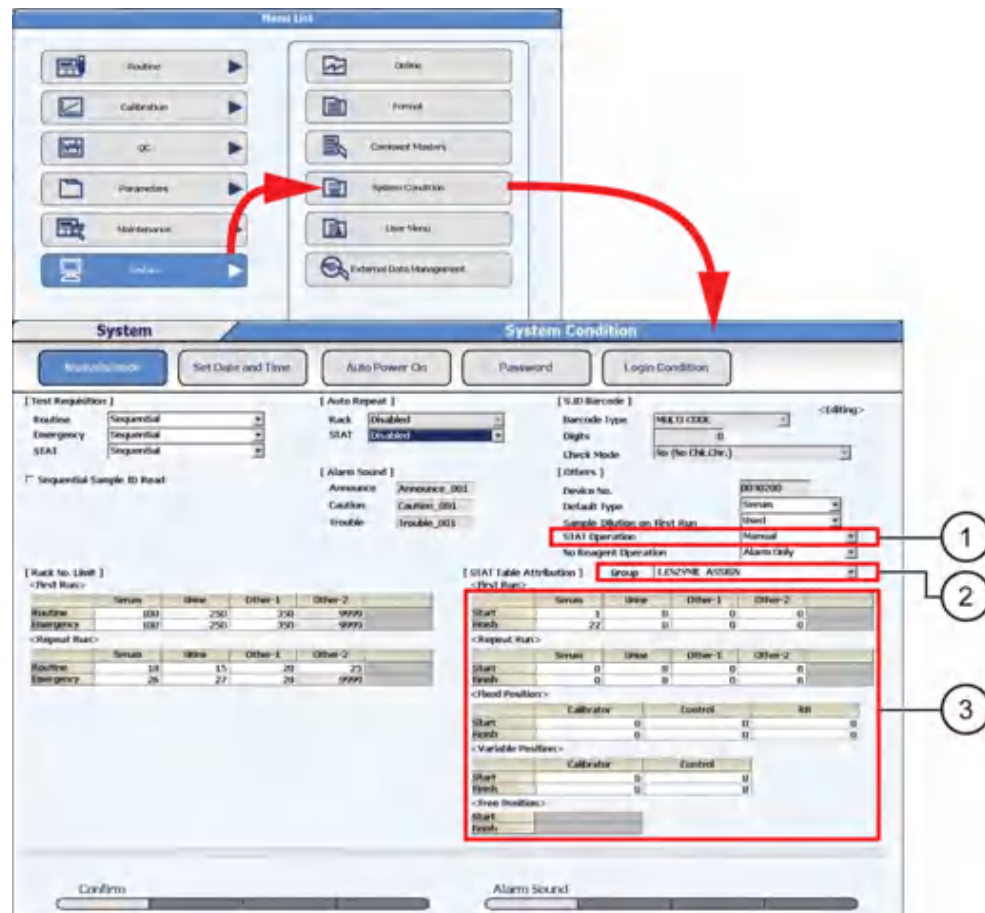
- 4** Select **Confirm (F1)**. The contents are programmed. If there is a discrepancy, the setting with the discrepancy is highlighted, and the display returns to the Edit mode.

4.10.3 Program STAT Table Parameters

Program the STAT table positions 1 to 22 for STAT samples, repeats, calibrators, or QC for each sample type.

- 1 Select **Menu List > System > System Condition > Analysis Mode.**

Figure 4.44



1. STAT Operation
2. Group to program STAT Parameters
3. STAT Table Positions

- 2 Select **Edit (F1).**

- 3 Set the system parameters for each Item in the table, and for each Group in use on the system.

TIP There are 22 total positions on the STAT table. When programming <First Run>, <Repeat Run>, <Fixed Position>, <Variable Position>, and <Free Position>, the position numbers 1 to 22 cannot be duplicated or overlap. The Start number must always be less than the Finish number for all categories.

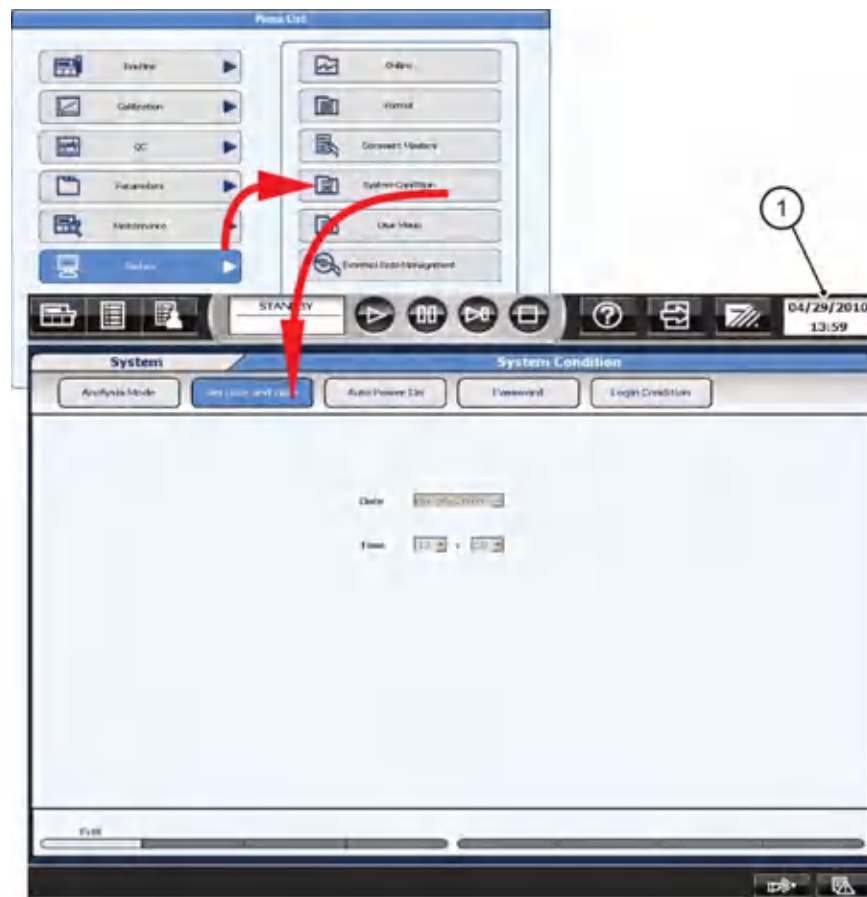
Item	Contents	Input Notes
STAT Operation	Auto or Manual	Auto enables an automatic STAT table check when starting analysis on the STAT table. Manual requires the operator to initiate a STAT table check before starting analysis on the STAT table. A STAT table check detects sample cups and reads sample IDs for positions 1 to 22 on the STAT table.
Group	Group 1, 2, or 3	Select Group 1, 2, or 3 from the "Group" drop-down list.
<First Run> Start and Finish for Serum, Urine, Other-1 and Other-2	1 to 22	Program the Start and Finish position numbers for each sample type for priority STAT analysis. Program all positions (1 to 22) without overlapping numbers. The Start number must be less than the Finish number for each sample type.
<Repeat Run> Start and Finish for Serum, Urine, Other-1 and Other-2	1 to 22	Program the Start and Finish position numbers for each sample type for repeat priority STAT analysis. Program all positions (1 to 22) without overlapping numbers. The Start number must be less than the Finish number for each sample type. <Repeat Run> positions are only required for STAT Manual Repeat. If STAT Auto Repeat is enabled, the STAT sample automatically repeats in the <First Run> position.
<Fixed Position> Start and Finish for Calibrator and Control	1 to 22	Program the Start and Finish position numbers for calibrators and controls. For information on programming the calibrators to the calibrator positions, and calibration specific parameters, refer to 4.5.4 STAT Table Calibration Menu . For information on programming the controls to control positions, and QC specific parameters, refer to 4.6.3 STAT Table QC Menu .
<Variable Position> Start and Finish for Calibrator and Control	1 to 22	Program the Start and Finish position numbers for calibrators and controls. Calibrators and control Barcode Operation are not enabled. The calibrator or control position is determined during the calibrator and QC requisition process. The calibrator and control are placed in a <Variable Position>. It is not necessary to have a <Fixed Position> for calibrator or control.
<Free Position> Start and Finish	1 to 22	Priority STAT samples, repeats, calibrators, and controls can be processed in any "free" position. "Sample Kind Mix" must be Enabled in System Maintenance by Beckman Coulter Technical Services. When Enabled, all sample types can be run in any position on the STAT table. If Disabled, calibration and QC are performed, but samples are not processed from <Free Position> on the STAT table. Calibrator and Control Barcode Operation must be enabled to process calibrators or controls in the Free positions.

4.10.4 Set the System Time

The system time is the current date and time and is displayed on the top right corner of the main button bar. The Current Date and Time are updated for daylight savings time depending on regional settings.

- 1 Select **Menu List > System > System Condition > Set Date and Time**.

Figure 4.45



1. Current Date and Time

- 2 Select **Edit (F1)**. The window changes to the edit mode.
- 3 Set the current date from the "Date" drop-down list. Set the current time as a 24 hour display from the "Time" drop-down list.
- 4 Select **Confirm (F1)**. The system time is programmed.

4.10.5 Program the Automatic Startup Function

The lamp requires approximately 20 minutes to warm up after power ON before analysis can be started.

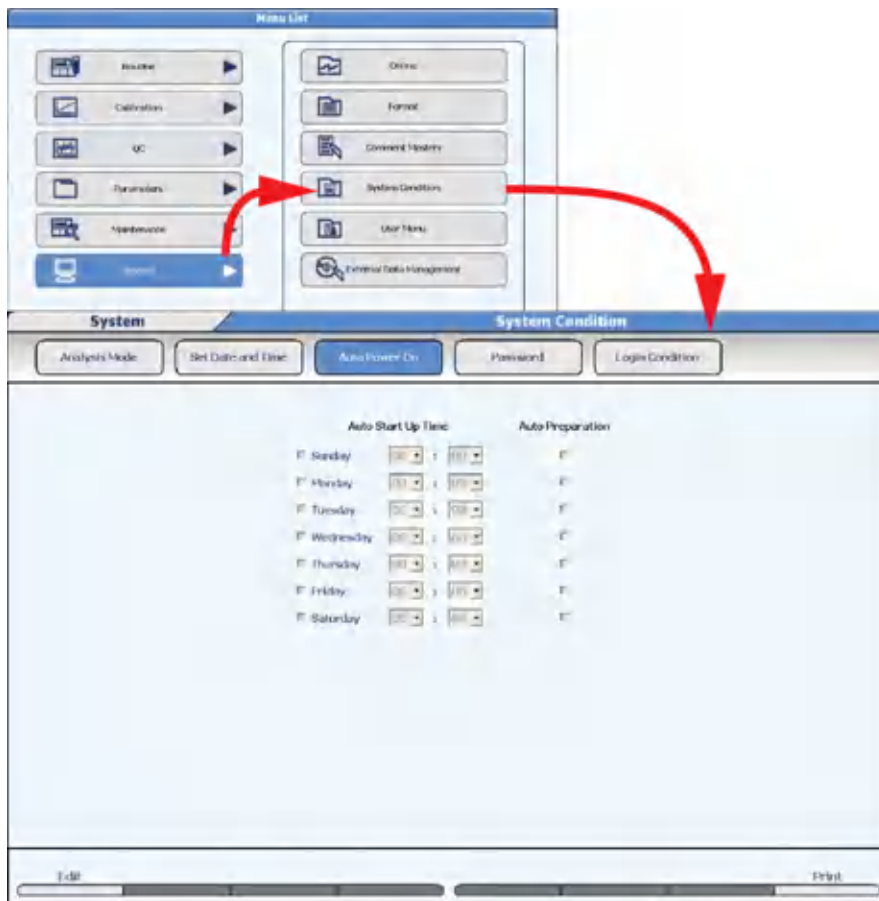
The system can be programmed to turn ON automatically at a specified time for each day of the week.



The automatic ON option does not open and close the main water valve, so it must be left open. Follow laboratory Standard Operating Procedures for inspecting the DI water system and main water valve.

- 1 Select **Menu List > System > System Condition > Auto Power On**.

Figure 4.46



- 2 Select **Edit (F1)**.

3 Select the check box of the desired day to start the Auto Power On function.

4 Set “Hours” and “Minutes” from the drop-down list.

5 To perform Auto Preparation, select the “Auto Preparation” check box.

TIP The ability to perform "Auto Preparation" is enabled for each day of the week in System Maintenance by Beckman Coulter Technical Services. The three auto preparation options are:

- W1
- Photocal
- W1 + Photocal

Once System Maintenance is enabled, check the day of the week to perform the Auto Preparation

6 Repeat steps 3 to 5 for each day to be set.

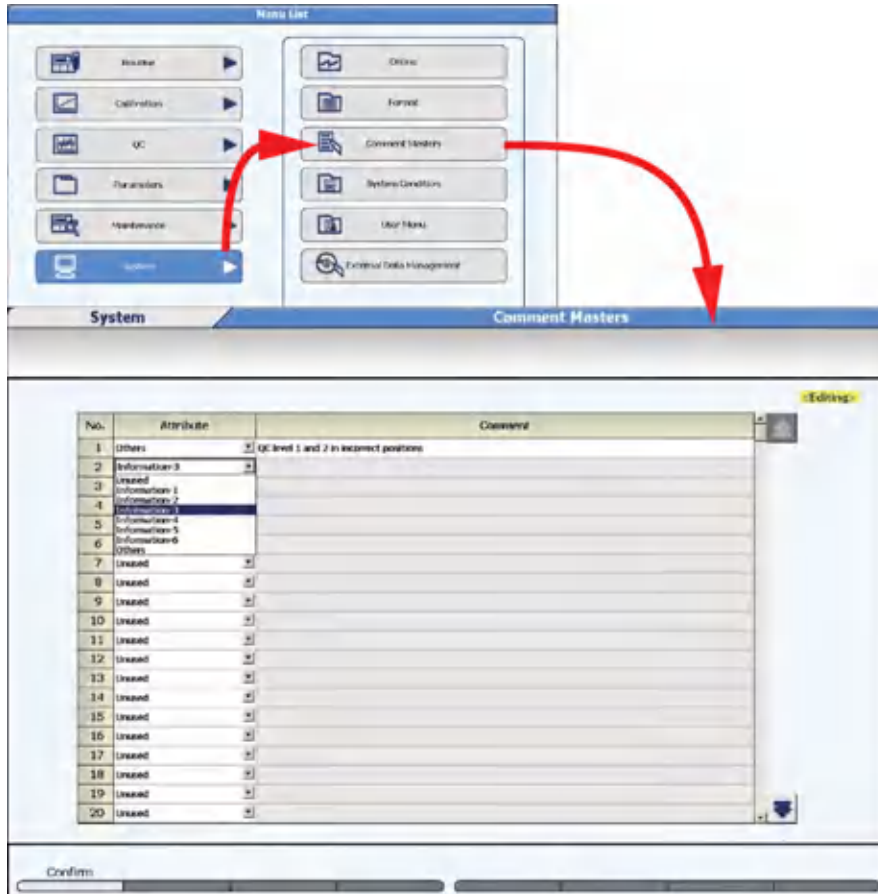
7 Select **Confirm (F1)**. The programming is registered.

4.10.6 Program Master Comments

Program a list of standard comments that can be included easily with a Comment Master button, instead of re-entering the comment manually. Up to 240 comments can be programmed.

- 1 Select **Menu List > System > Comment Masters**.

Figure 4.47



- 2 Select **Edit (F1)**.

- 3 Select the comment attribute from the “Attribute” drop-down list.

- Unused: The comment is not used (no comment).
- Information 1 to 6: The comment can be selected in **Rack Requisition Sample > Demographics** and **Home > STAT Status > Sample > Demographics**, the 1 to 6 demographic fields.
- Others: The comment can be selected in **Start Condition** “Operator Name,” **Rack Requisition Sample > Demographics** “Comment,” **Calibration Monitor**, **QC Monitor**, and **Calibration Verification**.

4 Enter the “Comment.”

- **Unused** Cannot be edited.
If the attribute of a comment that has already been entered was changed to “Unused”, the entered comment is retained.
- **Information 1 to 6:** Up to 20 characters can be entered.
- **Other:** Up to 50 characters can be entered.

TIP Program the 1 to 6 patient demographic titles that display in **Home > Rack Requisition Sample > Demographics** and **Home > STAT Status > Sample > Demographics** in **Menu List > System > Format > Requisition Format <Patient Information>**. Refer to [4.13 Program the Requisition Format](#) in this chapter.

5 Select **Confirm (F1)**. The programming is registered.

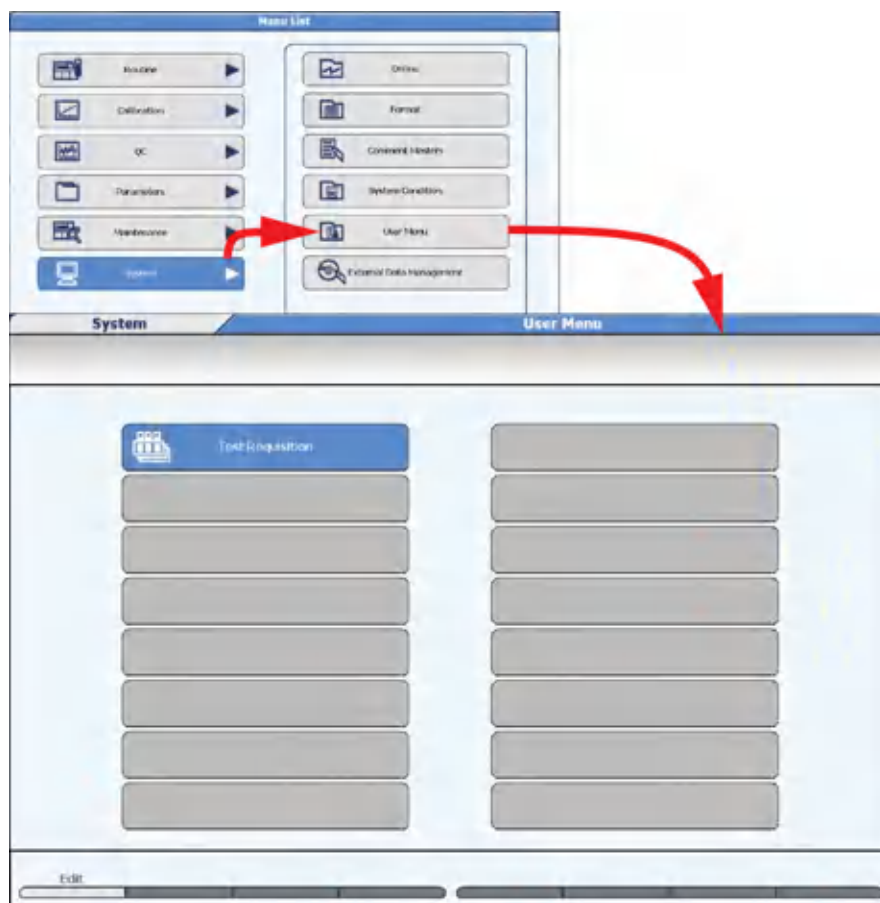
4.10.7 Program a User Menu

The User Menu function allows the selection of up to 16 menus most frequently used by the operator. User-defined menu names can be programmed. Menus selected from the **User Menu** button have direct access to the menu to save time.

Edit the User Menu

- 1 Select **Menu List > System > User Menu**.

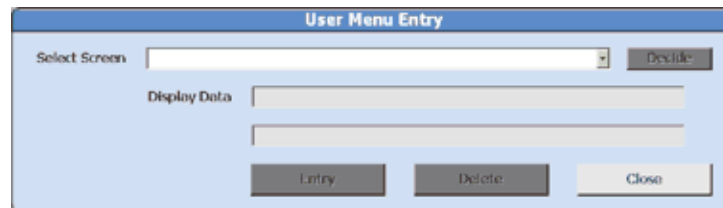
Figure 4.48



- 2 Select **Edit (F1)**. The next available menu to program changes from the gray box to a blue button.

-
- 3 Select the blue button. The User Menu Entry window opens.

Figure 4.49



-
- 4 From the “Select Screen” drop-down list, select the menu to put in the **User Menu** list.
-
- 5 Select **Decide**.
-
- 6 For Display Data, enter the user-defined menu name. Up to 28 characters can be entered on each of the two lines.
-
- 7 Select **Entry**.
-
- 8 Select **Confirm (F1)**. The programming is registered.

TIP The original menu name displays below the main button bar even when menus are accessed by the **User Menu** button.

Delete

To remove a menu from the **User Menu**:

-
- 1** Select **Menu List > System > User Menu**.

 - 2** Select **Edit (F1)**.

 - 3** Select the **Menu** to be deleted. The User Menu Entry window opens.

 - 4** Select **Delete**. The specified menu is deleted.

 - 5** Select **Confirm (F1)**.

4.11 Program a User Name and Password

The system can be programmed with user names and passwords. The **Log Out** button on the main button bar is used to log in/out for each user, and this information is then registered in the system.

Each user name is assigned to an access level. Access levels are assigned to menus, submenus, and functions such as “Parameters Edit” or “QC Edit”.

Up to 30 user names can be set.

[4.11.1 Set the Access Level](#)

[4.11.2 Set a User Name and Password](#)

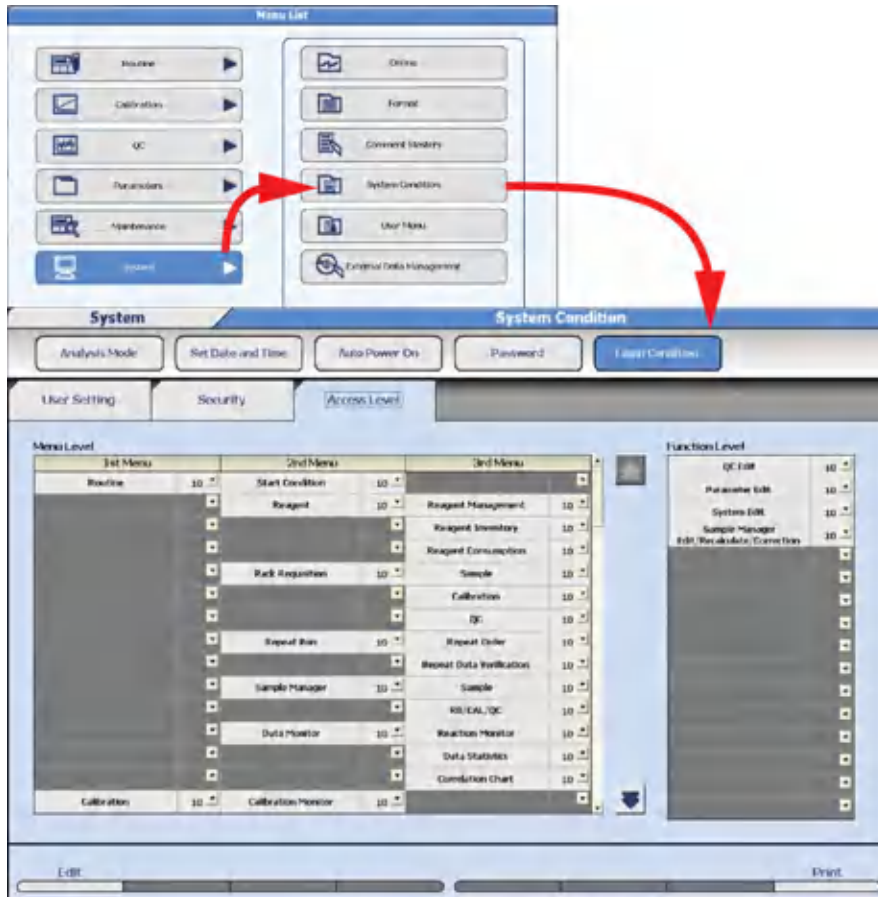
[4.11.3 Security Settings](#)

4.11.1 Set the Access Level

Access levels can be programmed from 1 to 10 for each user name. The initial access level is 10, so all users assigned to “1” through “10” have access to menus. The most secure menu access level is 1, as only users assigned as a “1” have access. A user assigned to a “5” for example, has access to menus assigned from 5 to 10. Verify a user is programmed to have full access to all menus. Refer to [4.11.2 Set a User Name and Password](#) in this chapter.

- 1 Select **Menu List > System > System Condition > Login Condition > Access Level**.

Figure 4.50



- 2 Select **Edit (F1)**.
- 3 Set the menu level within the range from 1 to 10 from the drop-down list.
TIP Set the level for the menu to the same or higher number than the number for sub-menu.
If a lower number is set, a window announcing a level setting conflict is displayed. Select **Cancel** to correct the menu number.
- 4 Repeat step 3 for all Menus, Sub-Menus, and Function Levels.
- 5 Select **Confirm (F1)**. The Confirmation window opens.

- 6 Select **OK**. The settings are programmed and the menu is closed. If there is any conflict in access levels between the menu and a sub-menu, an alarm window opens. The contents are programmed when **OK** is selected. Select **Cancel** to continue programming.

CAUTION

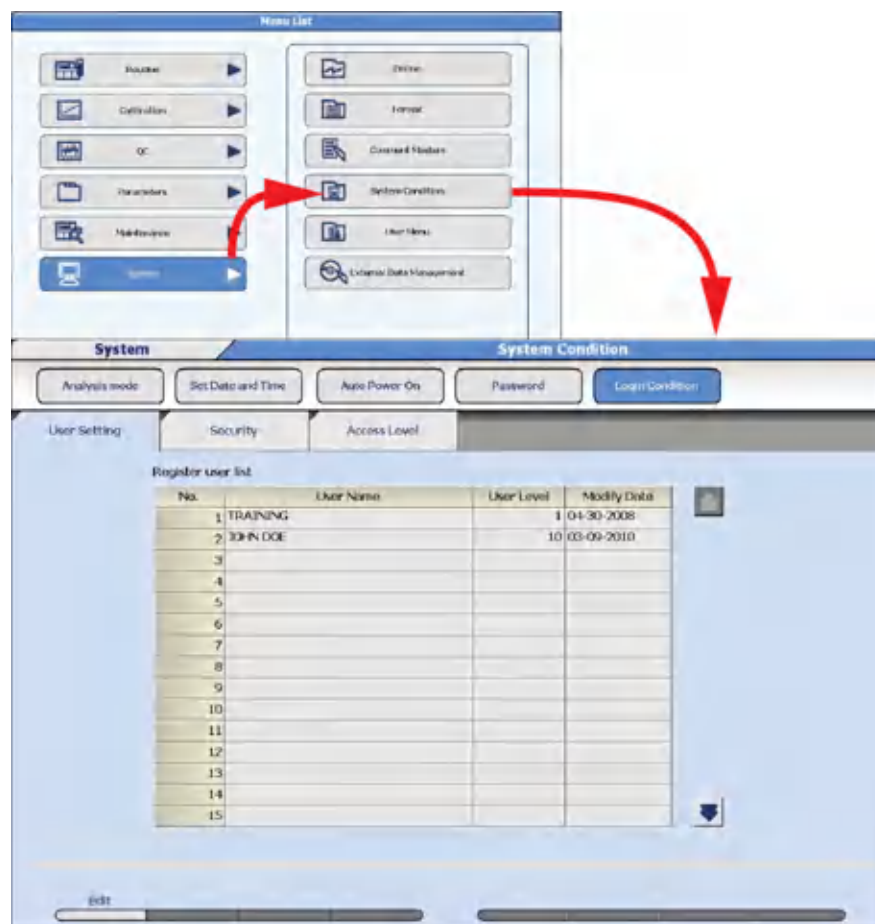
A sub-menu cannot be programmed with a higher number than the menu.

4.11.2 Set a User Name and Password

Register a new user name and password

- 1 Select **Menu List > System > System Condition > Login Condition > User Setting**.

Figure 4.51

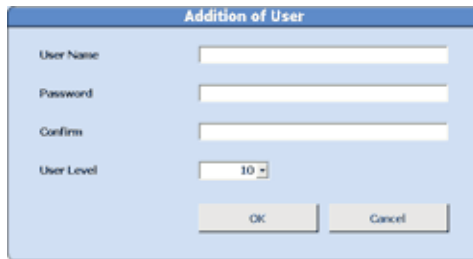


2 Select **Edit (F1)**.

3 Select an available “No.” (from 1 to 30).

4 Select **Addition of User (F2)**.
The Addition of User window opens.

Figure 4.52



5 Enter the User Name. Upper and lower case characters can be used for up to 20 characters.

6 Enter the new password of the user in Password. Upper and lower case characters can be used for up to 20 characters. Use of a Password is optional. If a Password is not entered, the User Name entered for Log In has access to the assigned user level.

7 For confirmation, re-enter the password entered in step 6 in Confirm.

8 Select 1 to 10 from the "User Level" drop-down list. A smaller number means a higher level of access to menus and functions.

9 Select **OK**.

10 Repeat steps 3 to 9 for each user.

11 Select **Confirm (F1)**. The Confirmation window opens.

12 Select **OK**. The set contents are programmed.

TIP Functions and menus that are not accessible mean that the user's "User Level" does not allow them to access these items. If the user needs access to these items, ask an administrator to change the user's "User Level".

For details on setting the level of each menu, refer to [4.11.1 Set the Access Level](#) in this chapter.

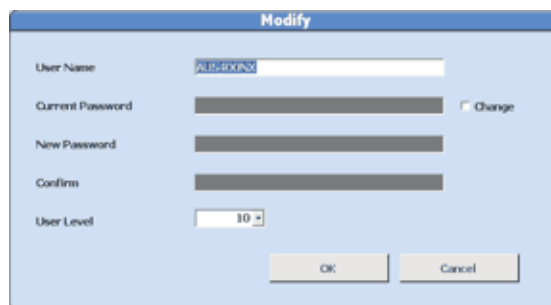
Change the User Name, Password, or User Level

1 Select **Edit (F1)**.

2 Select the user name to be changed from the list of "Register user list".

3 Select **Modify (F3)**. The Modify window opens.

Figure 4.53



4 Change the User Name if necessary.

5 Check the Change box to change the password if necessary.

6 Enter the Current Password.

7 Enter the New Password.

8 For confirmation, re-enter the password entered in step 7 in Confirm.

9 If necessary to change the user access level, select 1 to 10 from the "User Level" drop-down list. A smaller number means a higher level of access to menus and functions.

10 Select **OK**.

11 Select **Confirm (F1)**. The Confirmation window opens.

12 Select **OK**. The contents are programmed.

TIP To change the password for the user currently logged in the system, select **Password**.

Delete Users

1 Select **Edit (F1)**.

2 Select the user name to be deleted and select **Delete (F4)**. The delete message appears.

3 Select **OK**. The user name is deleted.

4 Select **Confirm (F1)**. The Confirmation window opens.

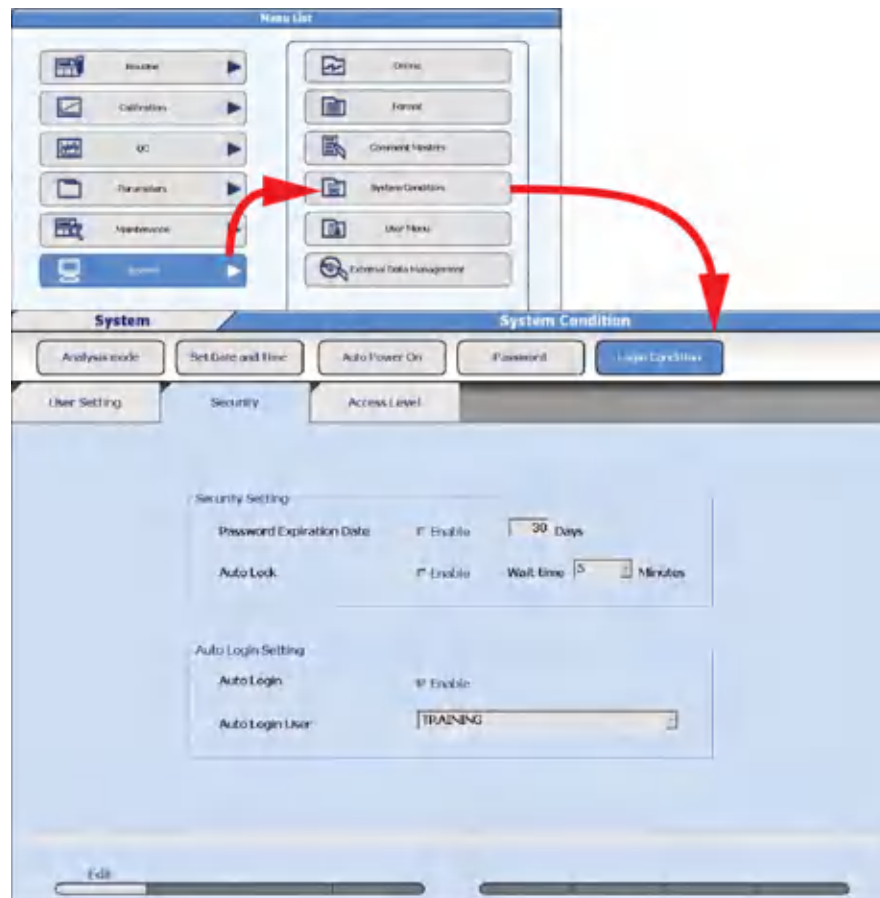
5 Select **OK**. The user name is deleted.

4.11.3 Security Settings

Security options include programming a password expiration date, an auto lock of the computer, and an auto login feature.

- 1 Select **Menu List > System > System Condition > Login Condition > Security**.

Figure 4.54



- 2 Select **Edit (F1)**.
- 3 To set an expiration date for a password, check the Enable check box next to Password Expiration Date. Enter the number of days that the password is effective before it has to be changed.
A number between 1 and 60 days can be set as an expiration date for a password.
- 4 To auto lock the window, check the Enable check box next to Auto Lock. Select a time from 5 to 60 minutes before the auto lock is activated from the "Wait time" drop-down list.

5 To enable the auto login function without inputting a user name and password at system startup, check the Enable check box next to Auto Login. Select the user name to set up for auto login from the "Auto Login User" drop-down list.

6 Select **Confirm (F1)**. The Confirmation window opens.

7 Select **OK** to save any changes. The values are programmed.

TIP The password expiration date is effective for all user names.

TIP Auto Login cannot be used when Auto Lock is Enabled.

4.12 Program Online Parameters

Set the I/O (input/output) conditions for online connection of this system, a clinical laboratory host computer and/or a Remisol/DataWizard middleware solution. Online parameters are typically programmed by Beckman Coulter Technical Services.

4.12.1 Program Online Parameters with RS232C Connection

4.12.1 Program Online Parameters with RS232C Connection

Set Up Tab for RS232C

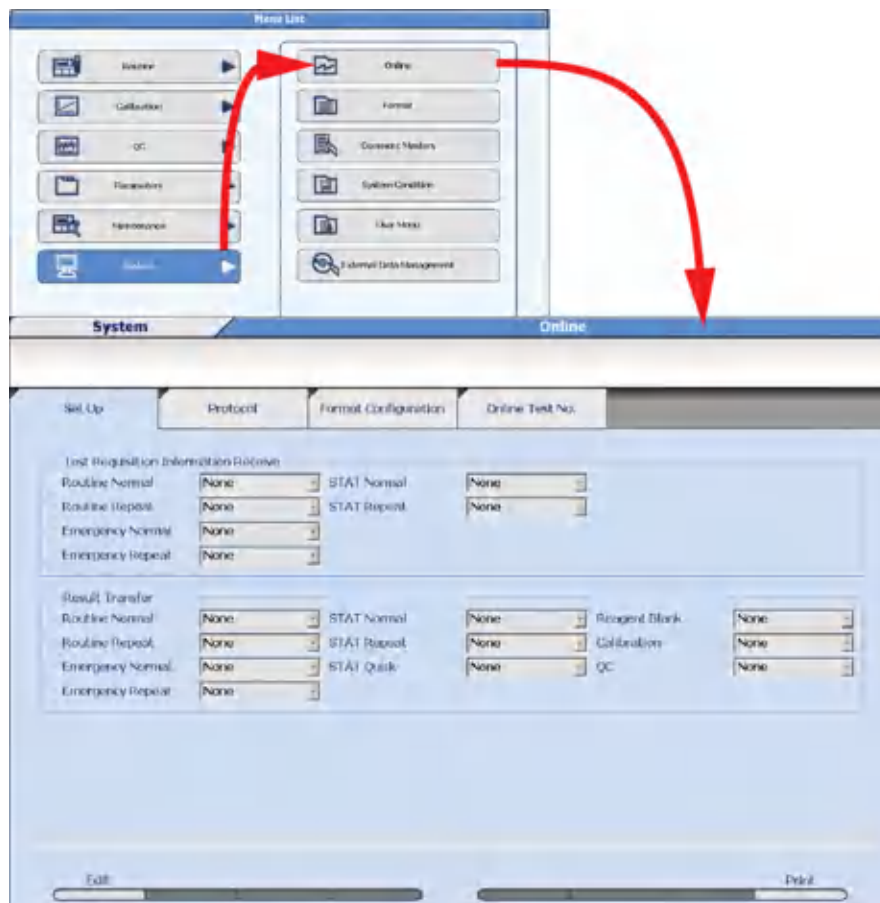
The communication method can be selected from the following three methods.

- | | |
|------------------|---|
| Realtime: | Test requisition inquiries and analysis result output are performed during analysis. |
| Batch: | Test requisition inquiries and analysis result output are performed by operator intervention. |
| None: | No online input/output is made. |

Use the following procedures.

- 1 Select **Menu List > System > Online > Set Up.**

Figure 4.55



TIP Test Requisition Information Receive

Program the test requisition inquiry mode. Three types of analysis modes can be programmed for routine, emergency, repeat racks, and STAT:

1. Realtime
2. Batch
3. None

The default is None.

Result Transfer

Program the output method for analysis results. Three output options are available for routine, emergency, repeat, STAT, reagent blank, calibration, and QC:

1. Realtime
2. Batch
3. None

- 2 Select **Edit (F1)**. The window changes to the edit mode.

3 Select the communication method from the drop-down list for each sample kind.

4 Select **Confirm (F1)**. The settings are programmed.

Protocol Tab for RS232C

The online communication protocol can be assigned and set.

1 Select **Menu List > System > Online > Protocol**.

Figure 4.56

The screenshot shows the 'Online Protocol' configuration window. The window title is 'System' and 'Online'. The 'Protocol' tab is selected. The 'Upper Protocol' section has 'T.R.I Receive Error Control' and 'Results Transfer Error Control' both set to 'Stop'. The 'Lower Protocol' section is divided into four sub-sections: '<Character Format>', '<Basic Data Format>', '<Communication Control>', and '<Time Out[x100msec.]>'. Under '<Character Format>', 'Character Length' is 8 Bits, 'Parity Bit' is Even, and 'Stop Bit' is 1 Bits. Under '<Basic Data Format>', 'Start Code' 1st is 02h:STX and 2nd is None; 'End Code' 1st is 03h:ETX and 2nd is None; 'Text Length' is 1024 Bytes; 'Device No.' and 'ETB Control' are unchecked. Under '<Communication Control>', 'Bit/Sec.' is 9600 bps, 'Class' is Class A, 'Retry' is 1, and 'BCC Check' is unchecked. Under '<Time Out[x100msec.]>', T1=20, T2=15, T3=15, T4=20, T5=20, T6=10, and T7=20. At the bottom, there are 'Edit' and 'Print' buttons.

2 Select **Edit (F1)**. The window changes to the edit mode.

3 Program the required parameters.

4 Select **Confirm (F1)**. The settings are programmed.

Setting item		Setting range	Initial value	
TIP: Online parameters are typically programmed by Beckman Coulter Technical Services.				
Upper Protocol				
T.R.I Receive Error Control		Stop / Continue ^a	Stop	
Results Transfer Error Control		Stop / Continue ^a	Stop	
Lower Protocol				
	Character Format	Character Length	7 / 8	7
		Parity Bit	None / Even / Odd	None
		Stop Bit	1 / 2	1
	Basic Data Format	Start Code (1st.)	01h:SOH to 1Fh:US	02h:STX
		Start Code (2nd.)	None / 01h:SOH to 1Fh:US	None
		End Code (1st.)	01h:SOH to 1Fh:US	03h:ETX
		End Code (2nd.)	None / 01h:SOH to 1Fh:US	None
		Text Length	256 / 512 / 1024	1024
		Device No.	Unchecked / Checked	Unchecked
		Device No. (checked)	00 to 99	00
	Communication Control	ETB Control	Unchecked / Checked	Unchecked
		Bit/Sec.	4800 / 9600	9600
		Class	Class A (No ACK/NACK) Class B (With ACK/NACK)	Class A
		Retry	0 to 3	1
	Time Out [x 100msec.]	BCC Check	Unchecked / Checked	Unchecked
		<Time Out [x100 msec.]> T1	1 to 99 msec.	20
		<Time Out [x100 msec.]> T2	1 to 99 msec.	15
		<Time Out [x100 msec.]> T3	1 to 99 msec.	15
		<Time Out [x100 msec.]> T4	1 to 99 msec.	20
		<Time Out [x100 msec.]> T5	1 to 99 msec.	20
<Time Out [x100 msec.]> T6		1 to 99 msec.	10	
<Time Out [x100 msec.]> T7	1 to 99 msec.	20		

- a. Stop: When a communication error occurs, there is no more communication after the sample with the communication error.
Continue: Even when a communication error occurs, T.R.I. is executed for the next sample.

TIP Program the protocol after confirmation with the system administrator of the host computer. Correct communication may not be possible if there is a discrepancy with the settings on a clinical laboratory host computer.

Format Configuration Tab for RS232C

Program the additional information and digit number of data used for online communication.

- 1 Select **Menu List > System > Online > Format Configuration**.

Figure 4.57



- **Used/Unused**
Program the information to be added to online communication messages. Items that have a check in the box are sent through online communication.
- **Others**
Rack No. Digit: Four or five digits
Online Test No. Digit: Program the number of digits (two or three) for the test No. set in “Online Test No.”
Result Digit: Program the number of digits (six or nine) for the data to be added to the message.
No. of Data Flags: Program the number of the data flags (two or four) to be added to the message.
Cal. No./Control No. Digit: Two or three digits

CAUTION

On the host computer, the system administrator must set the data format after confirmation.

If there is a discrepancy with the settings, it may affect communications with the host computer.

- 2 Select **Edit (F1)**. The window changes to the edit mode.
- 3 Select the “Used/Unused” check box item(s) to be used for online communication.

TIP The check box for R1-2/R2-2 Use cannot be selected (grayed out) because the option is not available.
- 4 Select the digits for each item from the “Others” drop-down list.
- 5 Select **Confirm (F1)**. The settings are programmed.

Online Test No. Tab for RS232C

Assign each test name to an online test number for online communication.

TIP Total and direct bilirubin are programmed as sample blank assays. Refer to [4.2.1 Test Name Menu](#) for additional information.

For the blank test in sample blank assays, it is not possible to program an Online Test No. because the blank test result is only used for the calculation and is not a reported result.

- 1 Select **Menu List > System > Online > Online Test No.**

Figure 4.58

Test Name	Online Test No.	Test Name	Online Test No.	Test Name	Online Test No.	Test Name	Online Test No.	Test Name	Online Test No.
1.Test1	001	2.Test2	002	3.	003	4.	004	5.	005
6.	006	7.	007	8.	008	9.	009	10.	010
11.	011	12.	012	13.	013	14.	014	15.	015
16.	016	17.	017	18.	018	19.	019	20.	020
21.	021	22.	022	23.	023	24.	024	25.	025
26.	026	27.	027	28.	028	29.	029	30.	030
31.	031	32.	032	33.	033	34.	034	35.	035
36.	036	37.	037	38.	038	39.	039	40.	040
41.	041	42.	042	43.	043	44.	044	45.	045
46.	046	47.	047	48.	048	49.	049	50.	050
51.	051	52.	052	53.	053	54.	054	55.	055
56.	056	57.	057	58.	058	59.	059	60.	060
61.	061	62.	062	63.	063	64.	064	65.	065
66.	066	67.	067	68.	068	69.	069	70.	070
71.	071	72.	072	73.	073	74.	074	75.	075
76.	076	77.	077	78.	078	79.	079	80.	080
81.	081	82.	082	83.	083	84.	084	85.	085
86.	086	87.	087	88.	088	89.	089	90.	090
91.	091	92.	092	93.	093	94.	094	95.	095
96.LIH	096	97.Na	097	98.K	098	99.Cl	099	100.	
101.		102.		103.		104		105.	105
106.		106		107		108		109	110
111.		111		112		113		114	115
116.		116		117		118		119	120.

-
- 2 Select **Edit (F1)**. The window changes to the edit mode.

 - 3 Move the cursor to the test name to be set.

 - 4 Enter the "Online Test No.". The combination of the online test number and test must coincide with the clinical laboratory host system. Set the number as a blank when online communication is not required.

TIP When the test number of the host system and the online test number differ, the data may not be transmitted correctly.

 - 5 Repeat steps 3 to 4 for each test item to be set.

 - 6 Select **Confirm (F1)**. The settings are programmed. When numbers are duplicated, a window displays a parameter error.
Select **Cancel** and correct.
-

4.13 Program the Requisition Format

Program the test requisition format including sample ID and demographic information.

TIP Information programmed in **Requisition Format** is part of the data communication protocol, and impacts LIS communication.

- 1 Select **Menu List > System > Format > Requisition Format**.

Figure 4.59

The screenshot shows a software interface with a 'Menu List' on the left and a main configuration area on the right. The 'Menu List' contains items like 'Routine', 'Calibration', 'QC', 'Parameters', 'Maintenance', and 'System'. The 'System' menu is expanded to show 'Online', 'Format', 'Comment Masters', 'System Condition', 'User Menu', and 'External Data Management'. A red arrow points from 'Format' in the menu list to the 'Format' tab in the main area. The main area has two tabs: 'Requisition Format' (selected) and 'List Format'. Below the tabs, there are fields for 'Sample ID' (Digits: 20), 'Sex', and 'Age'. A section titled '< Patient Information >' contains a table with 6 rows of attributes. Below the table are 'Representation-1' and 'Representation-2' dropdown menus, both set to 'None'. A 'Confirm' button is at the bottom.

No.	Enable	Attribute	Title	Digits	Comment Master Selection
1	<input checked="" type="checkbox"/>	Character	Name:	20	Information-1
2	<input checked="" type="checkbox"/>	Character	Facility:	20	Information-2
3	<input checked="" type="checkbox"/>	Character	Accession No:	20	Information-3
4	<input checked="" type="checkbox"/>	Character	Location:	20	Information-4
5	<input checked="" type="checkbox"/>	Character	Doctor:	20	Information-5
6	<input checked="" type="checkbox"/>	Character	Medical Record No:	20	Information-6

2 Program the requisition format for each Item in the table.

Item	Contents	Input Notes
Sample ID	Check or no check	Check to enable Sample ID in Home > Rack Requisition Sample > Sample and STAT Status > Sample .
Digits	4 to 26	The number of digits entered here affects how many digits can be entered for the Sample ID in Home > Rack Requisition Sample > Sample and STAT Status > Sample , and the sample ID field length for the host online records. The number of sample ID digits and barcode parameters are programmed in Menu List > System > System Condition . The number of digits should be greater than or equal to the digits in System Condition .
Sex	Check or no check	Check Sex to enable "Sex" in Home > Rack Requisition Sample > Sample > Demographics and STAT Status > Sample > Demographics , or receive the information from the LIS. Affects the host online records.
Age	Check or no check	Check Age to enable "Age" in Home > Rack Requisition Sample > Sample > Demographics and STAT Status > Sample > Demographics , or receive the information from the LIS. Affects the host online records.
Patient Information	A maximum of 6 patient demographics can be programmed for entry in Home > Rack Requisition Sample > Sample > Demographics and STAT Status > Sample > Demographics . Affects host online records.	
Enable	Check or no check	Check to enable programming for patient demographics No. 1 to 6.
Attribute	Character or Numeric	Program if letters or numbers are required for entry in Home > Rack Requisition Sample > Sample > Demographics and STAT Status > Sample > Demographics for Patient Information. Select Character to enter letters. Select Numeric to enter numbers for calculated tests and checked tests.
Title	A title name	Enter a maximum of 20 characters that display as the Patient Information title in Sample > Demographics .

Item	Contents	Input Notes
Comment Master Selection	Information-1 to Information-6	Program System > Comment Master "Attribute" with "Information -1 to Information-6". The master comment can then be selected in Sample > Demographics .
Representation-1 and Representation-2	1 to 6	Select from Patient Information No. 1 to 6 for the Title to appear in Home > Sample Status .

Example of Representation-1 and Representation-2 Options

Figure 4.60 Sample Status without Representation-1 or Representation-2 Programmed

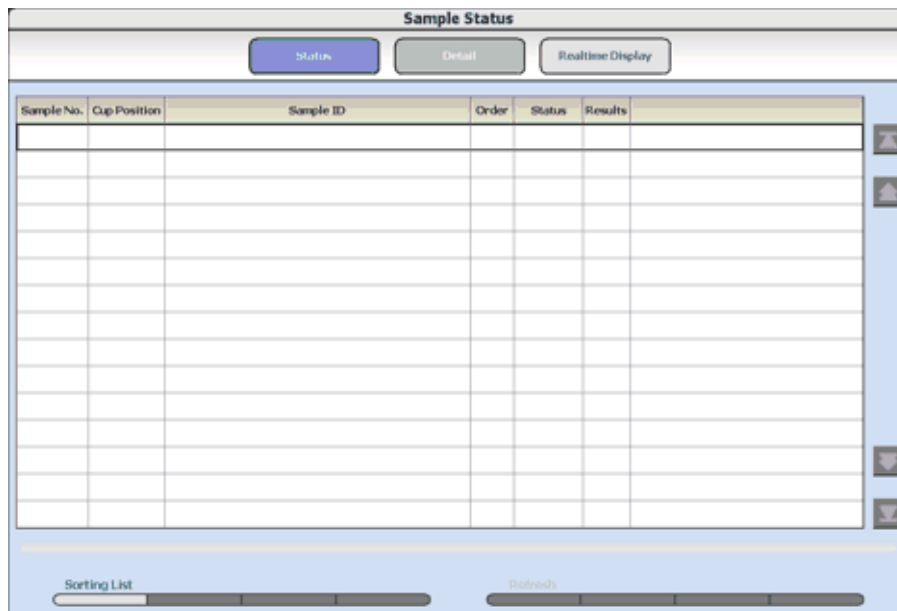


Figure 4.61 Sample Status with Representation-1 Programmed and Representation-2 Not Programmed

Sample No.	Cup Position	Sample ID	Order	Status	Result	Names

1. Representation-1

Figure 4.62 Sample Status with Representation-1 and Representation-2 Programmed

Sample No.	Cup Position	Names	Order	Status	Results	Facility

1. Representation-1
2. Representation-2

4.14 Print Formats

All realtime reports and data logs for reagent blank, calibration, QC, and samples, as well as worklists, pending lists, and repeat lists must be formatted before they are available to print.

A maximum of 15 formats can be programmed using seven available types of print layouts.

Printing reports is optional.

[4.14.1 Format Realtime Reports and Lists](#)

[4.14.2 Program Realtime Print Options](#)

[4.14.3 Save Data to a File](#)

[4.14.4 Copy Format Parameters](#)

[4.14.5 Add or Change a Comment](#)

List Types Available in Specific Menus

List Types									
	Menu	Table Type	Enumeration Type	Data List	Result (Fix) Type	Result (Seq.) Type	Repeat List	Repeat Data List	
Applicable lists	Requisition Sample	Work list							
		Pending list							
	Repeat Order						Work list		
							Pending list		
	Repeat Data Verification							Repeat data list	
	Sample Manager > Sample	Abnormal value list	Abnormal value list		Abnormal value list	Abnormal value list			
		Data List	Data List						
					Report	Report			
	Sample Manager > RB/QC/CAL			Data list					
	List Format > Realtime List (F5)		Patient	RB/CAL/QC	Patient	Patient			

Format Parameters for Each List Type

List of possible output settings for each list type

•: Required

o: Available to edit

x: Not available to edit

	Menu	Table Type	Enumera- tion Type	Data List	Result (Fix) Type	Result (Seq.) Type	Repeat List	Repeat Data List							
Basic Condition	List Name	Within 20 single-byte characters													
	Data Format	6/9	6/9	6/9	6/9	6/9	6/9	6/9							
	Data Justify	Right/ Left	Right/ Left	Right/ Left	Right/ Left	Right/ Left	Right/ Left	Right/ Left							
	Patient Sample	o	o	x	x	x	o	o							
	Calibration Sample	x	x	o	x	x	x	x							
	RB Sample	x	x	o	x	x	x	x							
	QC Sample	x	x	o	x	x	x	x							
	Sheet Number ^a ^d	x	x	x	1 to 4	1 to 4	x	x							
	Character in sheet ^b ^d	x	x	x	o	o	x	x							
	FormMethod of Item Name ^c ^d	x	x	x	o	o	x	x							
	Number of Data Flag	x	x	x	1 to 4	1 to 4	x	x							
	Form Method of Unanalysis Data	x	x	x	o	x	x	x							
	Change Page	x	x	x	o	o	x	x							
	Line	x	x	x	o	o	x	x							
Fixed Comment	x	x	x	o	o	x	x								
Page Header	Header Width ^d	1 to 10 (lines of the form header)													
	Device No.	•	•	•	•	•	•	o	o	o	o	•	•	•	•
	List Name	o	o	o	o	o	o	o	o	o	o	o	o	o	o
	Page	o	o	o	o	o	o	o	o	o	o	o	o	o	o
	Index	o	o	o	o	o	o	o	o	o	o	o	o	o	o
	Group	o	o	o	o	o	o	o	o	o	o	o	o	o	o
	Print time	o	o	o	o	o	o	o	o	o	o	o	o	o	o
	Operator	o	o	o	o	o	o	o	o	o	o	o	o	o	o
	Reporter	o	o	o	o	o	o	o	o	o	o	o	o	o	o

Parameters
4.14 Print Formats

	Menu	Table Type		Enumera- tion Type	Data List	Result (Fix) Type	Result (Seq.) Type	Repeat List	Repeat Data List						
Sample information	Sample Width ^d	1 to 10 (lines of the form header)													
	S. No.	o	o	o	o	o	o	o	o	o	o	o	o	o	o
	Org S. No.	x	x	x	x	x	x	o	o	o	o	o	o	o	o
	Rack No. - Cup Pos.	o	o	o	o	o	o	o	o	o	o	o	o	o	o
	S. ID	o	o	o	o	o	o	o	o	o	o	o	o	o	o
	Sex	o	o	o	o	x	x	o	o	o	o	o	o	o	o
	Age	o	o	o	o	x	x	o	o	o	o	o	o	o	o
	Month	o	o	o	o	x	x	o	o	o	o	o	o	o	o
	Type	o	o	o	o	o	o	o	o	o	o	o	o	o	o
	S Vol.	o	o	o	o	o	o	o	o	o	o	o	o	o	o
	Patient Inf. 1 to 6	o	o	o	o	x	x	o	o	o	o	o	o	o	o
	Patient Comment	x	x	x	x	x	x	o	o	o	o	x	x	x	x
Sample Name	x	x	x	x	o	o	x	x	x	x	x	x	x	x	
Kind No.- Seq. No.	x	x	x	x	o	o	x	x	x	x	x	x	x	x	
Lot No.	x	x	x	x	o	o	x	x	x	x	x	x	x	x	
Item Information	Item Name	x	•	x	o	x	•	x	o	x	o	x	•	x	o
	Test Data	x	o	x	•	x	•	x	•	x	•	x	x	x	•
	Data Flags	x	o	x	o	x	o	x	o	x	o	x	x	x	o
	R. Bottle Inf.	x	o	x	o	x	o	x	o	x	o	x	x	x	o
	Unit	x	x	x	x	x	x	x	o	x	o	x	x	x	x
	Normal Range	x	x	x	x	x	x	x	o	x	o	x	x	x	x
	Output	o	o	o	o	x	x	x	x	x	x	x	x	x	x

	Menu	Table Type	Enumeration Type	Data List	Result (Fix) Type	Result (Seq.) Type	Repeat List	Repeat Data List
Tail Information	Total Tests	o	o	x	x	x	o	o
	Total Samples	o	o	x	x	x	o	o
	Reagent Consumption	o	o	x	x	x	o	o
	Tail name	o	o	x	x	x	o	o

- Set the number of samples to print on one form sheet.
- The maximum number of characters per line differs according to the Print Direction, the Paper Size, and the Sheet Number.
 - Portrait A4 1 sheet 136 characters per line
 - Landscape A4 1 sheet 168 characters per line
 - Portrait A3 1 sheet 192 characters per line
 - Landscape A3 1 sheet 240 characters per line
 - Portrait Letter 1 sheet 136 characters per line
 - Landscape Letter 1 sheet 156 characters per line
 - Portrait Tabloid 1 sheet 180 characters per line
 - Landscape Tabloid 1 sheet 240 characters per line
 - Portrait Legal 1 sheet 136 characters per line
 - Landscape Legal 1 sheet 192 characters per line
 For two sheets or more, the above number of lines is the number of lines divided by the sheet number.
- Program whether the abbreviated name or long name is to be used as the Test Name.
- The layout setting is cancelled when the Print Direction, the Paper Size, the Sheet Number, the Character in sheet, the Header Width, or the Sample Width is changed. Program the layout again.

Layout Setting Parameters

	Menu	Table Type	Enumeration Type	Data List	Result (Fix) Type	Result (Seq.) Type	Repeat List	Repeat Data List
Layout	Page Header	o	o	o	o	o	o	o
	Sample Information	o	o	o	o	o	o	o
	Item Information	x	x	x	o	o	x	x

For the Result (Fix) Type, the test information print position is formatted to a specific column and line for each test.

For the Result (Seq.) Type, the start position for printing test information is set. The specific tests requisitioned on a sample start printing in consecutive lines at the formatted start print position.

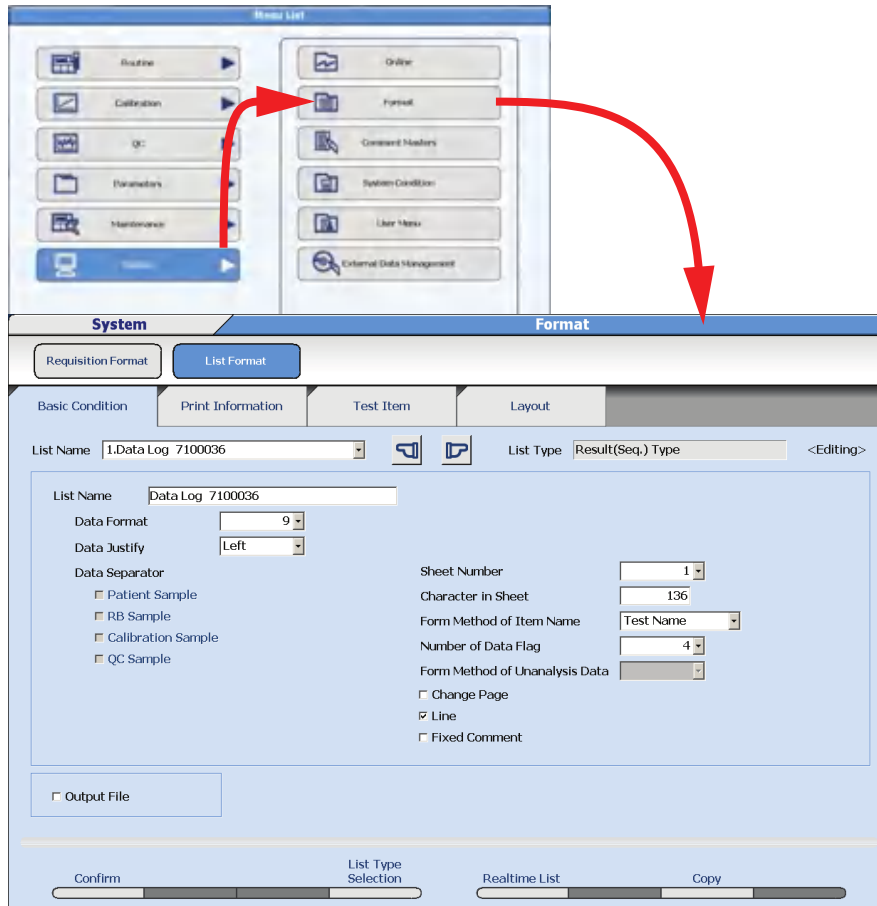
For types other than Result Type, the test information print position cannot be set.

4.14.1 Format Realtime Reports and Lists

Program the format parameters for realtime reports and lists.

- 1 Select **Menu List > System > Format > List Format > Basic Condition.**

Figure 4.63



- 2 Select **Edit (F1)**. The window changes to the edit mode.
- 3 Select the List No. to be formatted from the "List Name" drop-down list.
- 4 For List Name, enter a list name with a maximum of 20 characters.
- 5 Select **List Type Selection (F4)** to change the list type. The List Type Selection window opens.
- 6 Select the list type from the "List Type" drop-down list.

- 7 Select **OK**.
- 8 Select or enter the required setting items on the list format.
- 9 Select the **Print Information** tab.

Figure 4.64

The screenshot shows the 'Format' window with the 'Print Information' tab selected. The window title is 'System' and 'Format'. There are two buttons at the top: 'Requisition Format' and 'List Format'. Below the tabs, there are fields for 'List Name' (1.Data Log 7100036) and 'List Type' (Result(Seq.) Type). The main area contains three tables for selecting items to print:

Page Header		
Method	Title	Data
Device No.	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
List Name	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Page	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Index	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Group	<input type="checkbox"/>	<input type="checkbox"/>
Print Time	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Operator	<input type="checkbox"/>	<input type="checkbox"/>
Reportor	<input type="checkbox"/>	<input type="checkbox"/>

Sample Information		
Method	Title	Data
S.No.	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
ORG S.No.	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Rack No. -Cup Pos.	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
S.ID	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Sex	<input type="checkbox"/>	<input type="checkbox"/>
Age	<input type="checkbox"/>	<input type="checkbox"/>
Month	<input type="checkbox"/>	<input type="checkbox"/>
Type	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
S.Vol.	<input type="checkbox"/>	<input type="checkbox"/>
Patient Inf.1	<input type="checkbox"/>	<input type="checkbox"/>
Patient Inf.2	<input type="checkbox"/>	<input type="checkbox"/>
Patient Inf.3	<input type="checkbox"/>	<input type="checkbox"/>
Patient Inf.4	<input type="checkbox"/>	<input type="checkbox"/>
Patient Inf.5	<input type="checkbox"/>	<input type="checkbox"/>
Patient Inf.6	<input type="checkbox"/>	<input type="checkbox"/>
Patient Comment	<input type="checkbox"/>	<input type="checkbox"/>
Sample Name	<input type="checkbox"/>	<input type="checkbox"/>
Kind No. -Seq.No.	<input type="checkbox"/>	<input type="checkbox"/>
Lot No.	<input type="checkbox"/>	<input type="checkbox"/>

Item Information		
Method	Title	Data
Item Name	-	<input checked="" type="checkbox"/>
Test Data	-	<input checked="" type="checkbox"/>
Data Flags	-	<input checked="" type="checkbox"/>
R.Bottle Inf.	-	<input type="checkbox"/>
Unit	-	<input type="checkbox"/>
Normal Range	-	<input type="checkbox"/>
Output	<input type="checkbox"/>	<input type="checkbox"/>

Tail Information	
Method	Output
Total Tests	<input type="checkbox"/>
Total Samples	<input type="checkbox"/>
Reagent Consumption	<input type="checkbox"/>
Tail Name	<input type="checkbox"/>

At the bottom, there is a 'Confirm' button and a progress bar.

- 10 Select the information to print on the list.

11 Select the **Test Item** tab.

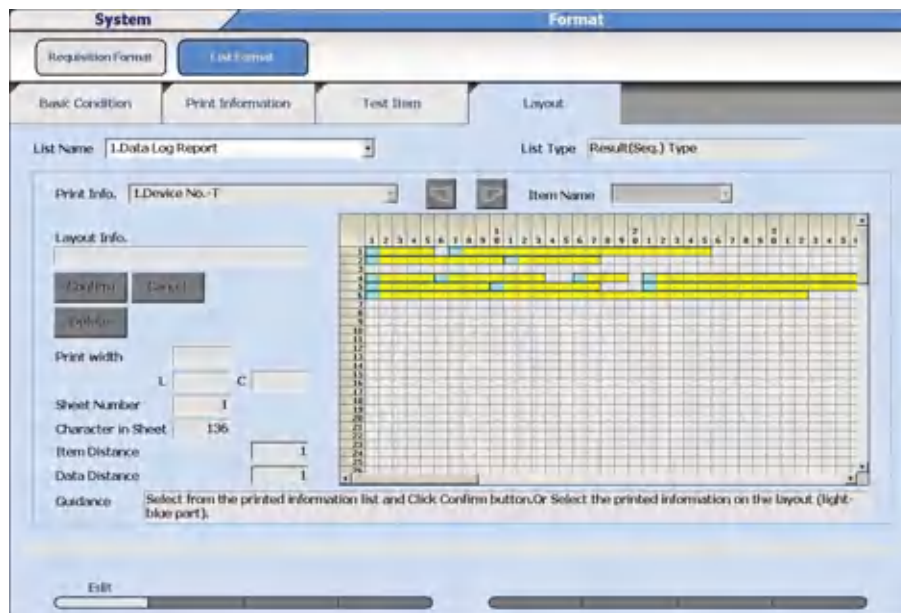
Figure 4.65



12 Select the test items to be printed by selecting them in the test items list.

TIP The selected tests change to skyblue color. The number of selected tests is displayed at the bottom right of the page.

TIP Select **Select All Tests (F5)** and **Deselect All Tests (F6)** as required .

13 Select **Layout**.**Figure 4.66**

14 Select the item to print from the "Print Info." drop-down list. Items that can be selected have been programmed to print in the **Print Information** tab. This includes the Page Header, Sample Information, Item Information, Comment, and Line options.

15 Select the **Confirm** button. Move the cursor to the column and line on the grid to start printing the selected item. Select the **Set** button. The position selected to start printing the item is displayed in a blue box, and the rest of the information for the item is displayed in yellow boxes. Repeat steps 14 and 15 for all layout information.

16 Select **Confirm (F1)**. The set contents are programmed.

4.14.2 Program Realtime Print Options

Program a realtime print format for samples, reagent blank, calibration, and QC. The appropriate List Type must be formatted for samples, reagent blank, calibration, and QC before it is available to print realtime.

- 1 Select **Menu List > System > Format > List Format > Basic Condition**.

Figure 4.67

The screenshot shows a software interface for configuring a list format. The window is titled "System" and "Format". It has a tabbed interface with "Regulation Format" and "List Format" tabs. The "List Format" tab is active, and it has sub-tabs for "Basic Condition", "Print Information", "Test Item", and "Layout". The "Basic Condition" sub-tab is selected. The "List Name" is "I.Data Log 7100036" and the "List Type" is "Result(Seq.) Type". The "Basic Condition" section contains the following fields and options:

- List Name: Data Log 7100036
- Data Format: 9
- Data Justify: Left
- Data Separator: Patient Sample, RB Sample, Calibration Sample, QC Sample
- Sheet Number: 1
- Character in Sheet: 136
- Form Method of Item Name: Test Name
- Number of Data Flag: 4
- Form Method of Uhanalysis Data: [dropdown]
- Change Page
- Line
- Fixed Comment

At the bottom of the window, there is an "Output File" checkbox and a row of buttons: "Confirm", "List Type Selection", "Realtime List", and "Copy".

- 2 Select **Edit (F1)**. The window changes to the edit mode.

- 3 Select **Realtime List (F5)**. The Realtime List window opens.

Figure 4.68

Realtime List

Data Log

Data Log Format

Patient: 1.Data Log 7100036

Calibration: 2.RB/CAL/QC Log

Reagent Blank: 2.RB/CAL/QC Log

QC: 2.RB/CAL/QC Log

Quick Output

Routine

Emergency

STAT

Calibration

RB

QC

Quickly

OK Cancel

TIP Data Log

Check the box to enable realtime printing.

Data Log Format

Select the list name for Patient, Calibration, Reagent Blank, and QC.

Quick Output

When checked, one sample prints when it is complete per page.

Quickly

When checked, quick test results from samples processed on the STAT table are printed before the normal print time for all tests on a sample. Quick test results are those with R1 only (read points before P10) and ISE tests.

- 4 Check the check box of Data Log.
- 5 Select the print format from the "Patient", "Calibration", "Reagent Blank", and "QC" drop-down lists.
- 6 Check the check box of samples for Quick Output.
- 7 Select **OK**. The Realtime List window is closed.
- 8 Select **Confirm (F1)**. The set contents are programmed.

4.14.3 Save Data to a File

Data is saved to an AU480_List_Image.txt file, and does not print realtime when Output File is checked.

- 1 Select **Menu List > System > Format > List Format > Basic Condition**.
- 2 Check the check box Output File.

4.14.4 Copy Format Parameters

Format parameters from one list can be copied to an available list number.

- 1 Select **Menu List > System > Format > List Format > Basic Condition**.
- 2 Select **Edit (F1)**. The window changes to the edit mode.
- 3 Select an available list number (place to copy another list) from the "List Name" drop-down list.
- 4 Select **Copy (F7)**. The Copy window opens.
- 5 Select the list to be copied from the "List Name" drop-down list.
- 6 Select **OK**. The list parameters are copied. At List Name, enter a list name.

4.14.5 Add or Change a Comment

TIP The Fixed Comment option must be checked in the **Basic Condition** tab before **Layout > Comment (F3)** is accessible.

-
- 1 Select **Menu List > Format > List Format > Layout**.

 - 2 Select **Edit (F1)**.

 - 3 Select **Comment (F3)**.

 - 4 Enter a comment (maximum of 20 characters) in **Comment**.

 - 5 Select **Horizontal** or **Vertical** in Direction.

 - 6 Select **OK**.

 - 7 Select the Comment from the "Print Info." drop-down list. The squares available to format the selected item display in white.

 - 8 Select the **Confirm** button. Move the cursor to the position on the grid to start printing the selected item. Select the **Set** button. The position selected to start printing the item is displayed in a blue box, and the rest of the information for the item is displayed in yellow boxes.

 - 9 Select **Confirm (F1)**. The contents are programmed.
-

4.15 Lipemia, Icterus, and Hemolysis (LIH)

LIH Reagent OSR62166 is a photometric test for the semi-quantitative assessment of lipemia/turbidity, icterus, and hemolysis (LIH) in human serum and plasma on the AU analyzer.

A number of diseases and pre-analytical conditions can result in increased concentrations of chromogens like bilirubin, hemoglobin, and lipids/turbidity in body fluids. Chromogens can interfere with photometric tests.

Patient samples are diluted with the LIH reagent and the absorbance is measured at six wavelengths. If one or more chromogen in a potentially interfering concentration is present in a sample, applicable flags are generated and reported along with the results of the sample. These flags characterize the kind of chromatic substance (LIP: lipemia/turbidity, ICT: bilirubin, HEM: hemoglobin) and the approximate concentration of the interferents.

The following table shows the approximate concentration of chromatic substance.



The concentrations listed in the table are for a reference. Depending on the matrix effect with an individual serum sample, some results may not meet the listed concentrations.

Flag	LIP (mg/dL Intralipid)	ICT (mg/dL Bilirubin)	HEM (mg/dL Hemoglobin)
N	< 40	< 2.5	< 50
+	40 - 99	2.5 - 4.9	50 - 99
++	100 - 199	5.0 - 9.9	100 - 199
+++	200 - 299	10.0 - 19.9	200 - 299
++++	300 - 500	20 - 40	300 - 500
+++++	> 500	> 40	> 500

If a sample has one or more flags from the table, refer to the "Interfering Substance" section of the reagent IFU to verify the accuracy of the test results of that sample.

The AU480 can be programmed for Sample Specific LIH and Assay Specific LIH. Sample Specific LIH tests the level of LIH in the sample. Assay Specific LIH determines the effect this level of LIH has on individual assays.

- Sample Specific LIH:** The level of lipemia, icterus, or hemolysis is optically identified by measuring the sample and LIH Reagent in the cuvette. Based on the programmed absorbance limits for Lipemia, Icterus, and Hemolysis in the LIH Test, a flag is generated for each interfering substance as N (normal), +, ++, +++, +++++, ++++++, or ABN (abnormal).

Each sample displays the results of the LIH Test. For example:

- LIP +
- ICT N
- HEM ++

2. **Assay Specific LIH:** The level of lipemia, icterus, or hemolysis in the sample is used to determine the effect on individual assays. Each specific assay is programmed to generate "l," "i," or "h" flags if the Lipemia, Icterus, or Hemolysis limit is exceeded. For example, a DBIL that is affected by the level of hemolysis in the sample:

- DBIL 0.3 h

ISE tests (Na, K, and Cl) are *not evaluated* for assay specific LIH.

LIH Reagent

LIH Reagent (OSR62166) is the only valid reagent for assay specific LIH testing.

The LIH Reagent is supplied in a 60 mL bottle with a reagent ID, R1 only. The kit configuration is 2400 tests per bottle and 16 bottles per kit. The Onboard Stability is 90 days.

Program LIH

- 1 Select **Menu List > Parameters > Common Test Parameters**. The system displays the **Test Name** menu and **Test Name** tab.

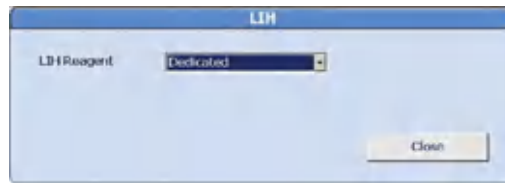
Figure 4.69

No.	Name	Test Item	Long Name	Reagent ID	Alarm Shots	MULTI Reagent Switch	Remarks
81		HE HEMOGLOBIN		526	10	Yes	
82	OPIN	OPINATE		528	10	Yes	
83		PHENYLEPHEDRINE		529	10	Yes	
84	PROPY	PROPIONIC ACID		535	10	Yes	
85	COF	COCOA			10	Yes	
86		URINE FIX CREATININE		550	10	Yes	
87	DBLR	BLANK DBLR		010	10	Yes	Blank Item (Color:0.000)
88	DBLR	DIRECT HEMOGLOBIN		011	10	Yes	Color Item (Color:07.2000)
89	DBLR	BLANK DBLR		025	10	Yes	Blank Item (Color:0.000)
90	DBLR	TOTAL HEMOGLOBIN		027	10	Yes	Color Item (Color:0.000)
91	HAES2	HEMOGLOBIN A1C		033	5	Yes	
92	THPS2	TOTAL HEMOGLOBIN		032	5	Yes	
93	HAES	HAES					Calculated test
94	DBLR	DBLR			10	Yes	
95	DBLR	DBLR			5	Yes	
96	LIH			166	32	Yes	
97							
98							
99							
100							

Calculated Tests: LIH

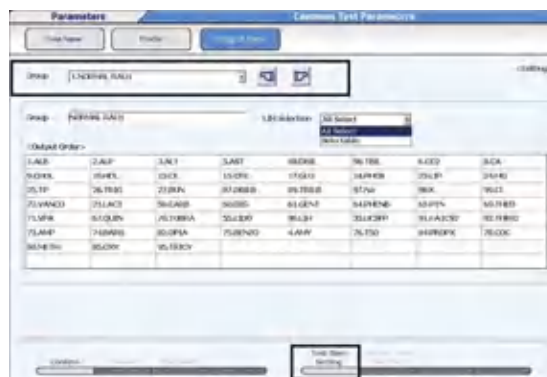
- Select **Edit (F1)**.
- Scroll down to No. 96.
- For Reagent ID, enter 166.
- For Alarm Shots, enter the remaining shots (tests) to generate a Reagent Short alarm. The default is 32.
- Select **LIH (F7)**.
- Verify “LIH Reagent” is set to Dedicated.

Figure 4.70



- Select **Close**.
- Select **Confirm (F1)**.
- Select the **Group of Tests** menu.

Figure 4.71



- Select Group 1, 2, or 3 from the "Group" drop-down list to add LIH.
- Select **Edit (F1)**.
- Select All Select or Selectable at the "LIH Selection" drop-down list.
 - Select All Select to automatically requisition LIH on every sample.
 - Select Selectable to requisition LIH as needed on each sample.
- Select **Test Item Setting (F5)**.
- Select (highlight) Test 96. LIH and then select **Close**.
- Verify LIH displays under <Output Order>.
- Repeat for multiple Groups if needed.
- Select **Confirm (F1)**.

2 Select **Parameters > Specific Test Parameters > LIH**.

TIP Program 96. LIH Test using the LIH chemistry setting sheet. Sample Specific LIH limits are determined by the LIH Test parameters entered in this **LIH** menu.

Parameter values found on the LIH chemistry setting sheet are only valid if using LIH Reagent OSR62166.

- Select **Edit (F1)**.
- Enter the parameters found on the LIH chemistry setting sheet.
- Select **Confirm (F1)**.

Figure 4.72



3 Select the **General** menu.

TIP 97. Na, 98. K, and 99.Cl are inaccessible (grayed out) and cannot be programmed for assay specific LIH criteria. ISE tests are not evaluated for LIH.

“LIH Influence Check” only displays for programming for Serum sample type. Any values programmed affect Other-1 and Other-2 sample types, if System Maintenance is enabled for Other-1 and Other-2.

- Select **Edit (F1)**.
 - From the "Test Name" drop-down, select a test to program assay specific LIH parameters. For an example, in [Figure 4.73](#), TBIL is selected at the "Test Name" drop-down.
 - Select **Yes** at the "LIH Influence Check" drop-down to perform assay specific LIH analysis. Select **No** at the "LIH Influence Check" drop-down if assay specific LIH analysis is not required for a test.
 - Refer to the chemistry setting sheet for each specific test for the assay specific LIH parameters. For this example in [Figure 4.73](#), refer to the Total Bilirubin (TBIL) chemistry setting sheet.
 - Repeat for all tests on the Group(s).

- Select **Confirm (F1)**.

Figure 4.73

The screenshot displays the 'Parameters' window with the 'Specific Test Parameters' tab selected. The 'Test Name' dropdown is highlighted with a red box and contains the text '12.T.BI'. Below it, various test parameters are configured, including Sample Volume (5.0 uL), Pre-Dilution Rate (1), Reagent Volume R1 (26 uL), Dilution (95 uL), Wave Length (570 nm), and Onboard Stability Period (90 Day). A red box highlights the 'LIH Influence Check' section, which includes 'Lipemia' (++++), 'Icterus' (++++), and 'Hemolysis' (+).

4 Select Menu List > System > Format > List Format > Test Item.

- Select **Edit (F1)**.
- Highlight LIH to add it to all required printouts and lists. “List Name” contains a list of all the realtime printouts and lists available.
- Select **Confirm (F1)**.

Running the LIH Assay

- Only one additional cycle time (9.0 seconds) per sample is required to run the LIH test.
- Place the barcoded LIH reagent bottle in the reagent refrigerator and follow procedures for checking reagents.
- LIH may be programmed to run automatically on all samples or may be requisitioned on individual samples as needed. If LIH is programmed to automatically run on all samples, LIH is highlighted in blue in **Home > Rack Requisition Sample**. Requisition LIH using normal requisition procedures. LIH can be requisitioned by realtime query with the LIS, or manually.
- LIH results print automatically after programming.
- LIH criteria only apply to Serum/Plasma, Other-1, and Other-2 sample types. For Urine sample types, the LIH test is grayed out and is not operational.

Interpreting Results

The following shows a printout example.

S.No. 0001	0003-01	S.ID 123456	
CRE 0.6	CHOL 280	TBIL 0.3	DBIL 0.3 h
LIP +	ICT N	HEM ++	

Sample Specific LIH

Each sample prints with a flag for Normal (N) through Abnormal (ABN) levels of lipemia (LIP), icterus (ICT), and hemolysis (HEM) by the LIP, ICT, and HEM abbreviated names. Each flag is generated based on the LIH Test specific test parameters.

Abbreviated Name	Flags
LIP (lipemia)	N + ++ +++ +++++ ++++++ ABN
ICT (icterus)	N + ++ +++ +++++ ++++++ ABN
HEM (hemolysis)	N + ++ +++ +++++ ++++++ ABN

A result of ABN (abnormal) means the mathematical logic in determining the amount of interference failed one or more internal checks. The sample should be visually inspected to determine the amount of lipemia, icterus, and hemolysis present in the sample.

Assay Specific LIH

When the level of interfering substances exceeds the criteria programmed for a specific assay in **Specific Test Parameters**, an "l," "i," or "h" flag is attached to the test result affected by lipemia, icterus, or hemolysis.

When LIH testing is not performed on a sample, an "n" flag is attached to the test result. The "n" flag differentiates LIH testing not being performed, and LIH not influencing the test. The "n" flag is typically generated when the LIH reagent is empty, or the LIH test was not requisitioned.

Na, K, and Cl tests are not evaluated for assay specific LIH criteria and do not generate the "n" flag.

LIH Reagent IFU:

The following table shows the approximate concentration of chromatic substance.

Flag	LIP (mg/dL Intralipid)	ICT (mg/dL Bilirubin)	HEM (mg/dL Hemoglobin)
N	< 40	< 2.5	< 50
+	40 - 99	2.5 - 4.9	50 - 99
++	100 - 199	5.0 - 9.9	100 - 199
+++	200 - 299	10.0 - 19.9	200 - 299
++++	300 - 500	20 - 40	300 - 500
+++++	> 500	> 40	> 500

According to the Direct Bilirubin IFU, Interfering Substances are:

- Hemolysis: No significant Interference up to 10 mg/dL Hemolysate
- Lipemia: No significant Interference up to 300 mg/dL Intralipid

According to the LIH Reagent IFU Table:

- A hemoglobin rating of ++ is equivalent to 100 to 199 mg/dL in the sample. Since the Direct Bilirubin IFU indicates no significant interference only up to 10 mg/dL, an "h" flag was attached to the DBIL result in the printout example at the top of the previous page to indicate the performance of this test could have been affected by hemolysis.
- A lipemia rating of + is equivalent to 40 - 99 mg/dL of Intralipid in the sample. Since the Direct Bilirubin IFU indicates no significant interference up to 300 mg/dL, an "l" flag was not attached to the DBIL test result.

Daily Startup

This chapter describes how to perform the daily startup procedures.

5.1 Start the System

5.1.1 Turn On the System

5.1.2 Set the Start Conditions

5.2 Perform Daily Maintenance

5.3 Check Analyzer Status

5.4 ISE (Option) Startup

5.4.1 Check the ISE Reagent

5.4.2 Perform ISE Daily Maintenance

5.5 Check Reagent Status

5.5.1 Check Reagent Quantity and Status

5.5.2 Review Detailed Information

5.5.3 Reagent Replacement

5.6 Perform Calibration

5.6.1 Requisition and Perform Calibration from Racks

5.6.2 Requisition and Perform Calibration from the STAT Table

5.7 Perform Quality Control (QC)

5.7.1 Requisition and Perform QC from Racks

5.7.2 Requisition and Perform QC from the STAT Table

5.8 Start Analysis

5.8.1 Start Rack Analysis

5.8.2 Start STAT Table Analysis

5.9 Startup Checklist (Analyzer and ISE)

5.1 Start the System

5.1.1 Turn On the System

5.1.2 Set the Start Conditions

5.1.1 Turn On the System

- 1 If the system is already On, proceed to [5.1.2 Set the Start Conditions](#); otherwise, press the green **ON** button. The software loads and the system initializes. The system is in *Warm up* mode for approximately 20 minutes, then goes to *Standby*.

TIP Automatic On Option

The system can be programmed to automatically turn on at a user-defined time for each day of the week. Refer to [4.10.5 Program the Automatic Startup Function](#) in chapter 4.

- 2 Log in to the system if necessary.

Figure 5.1



TIP User Names and Passwords

User Names and Passwords can be programmed and assigned to different security levels for menu access. Refer to [4.11 Program a User Name and Password](#). There is an auto login feature available if passwords are not in use. Refer to [4.11.3 Security Settings](#) in chapter 4.

- a. Enter the User Name.
- b. Enter the Password.
- c. Select **OK**. The New Index window opens.

TIP If the system was shut down without performing an End Process, the System Start window to retrieve the Database appears. Select **OK**.

The New Index window is only displayed at the time of system startup.

Figure 5.2

The screenshot shows a dialog box titled "New Index" with the subtitle "Create a New Index?". It features two radio buttons: "New Index" (which is selected) and "Index". The "New Index" option includes a date field set to "2009/09/11", a time field set to "13", and a minute field set to "41". The "Index" option includes a date and time field set to "2009/09/11 07:57". Below these options is a "Group of Tests" dropdown menu currently showing "1.". An "OK" button is located at the bottom right of the dialog.

-
- 3** Select the Index and Group of Tests as needed.
 - a.** Select **New Index** to create a new index, or **Index** to return to the previous index.
 - b.** Select the group of tests to process from the "Group of Tests" drop-down list.
 - c.** Select **OK**. The **Home** menu displays.
-

5.1.2 Set the Start Conditions

This menu is used to create a data index, select a Group of tests, and input the operator name.

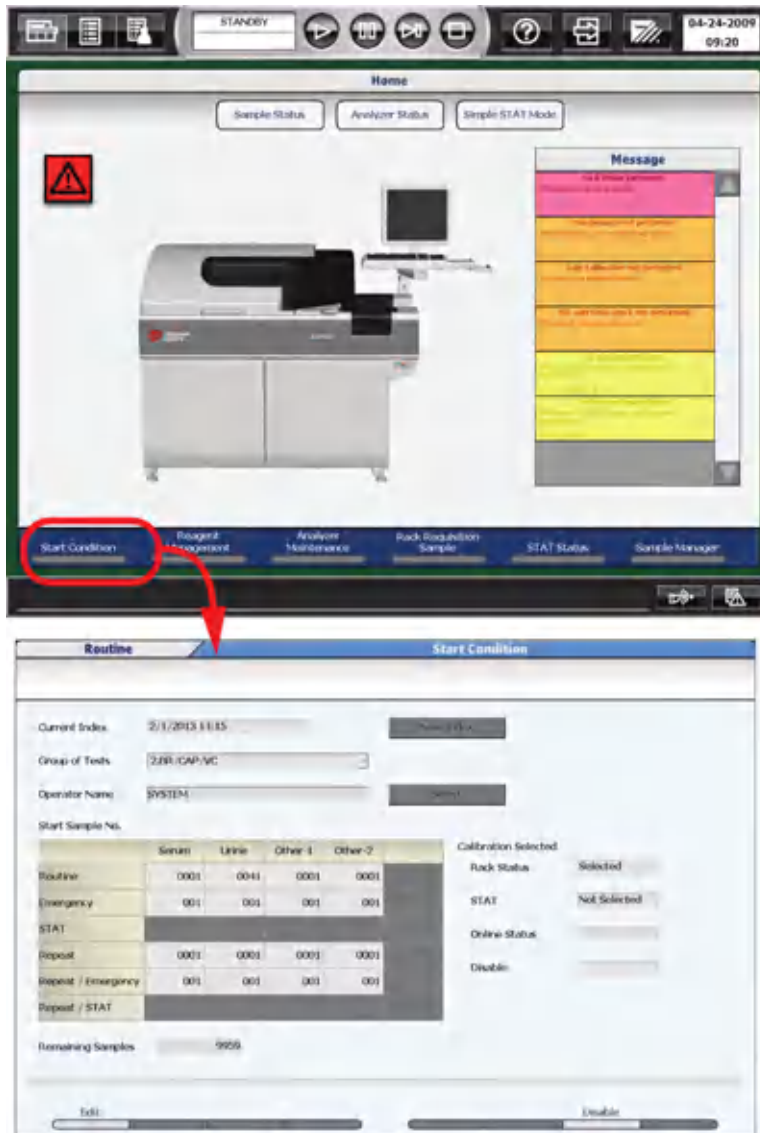
An index is a data file identified by the date and time. An index is used to retrieve reagent blank, calibration, QC, and patient results. Create a new index daily, or for each shift, or as needed. A maximum of 100,000 samples or 300 indexes can be saved on the hard drive. A maximum of 9999 samples can be processed in an index.

TIP If the system was just turned on, the Index and Group can be set from the New Index window. Refer to [5.1.1 Turn On the System](#).

-
- 1** Select **Home > Start Condition**.

2 Select **Edit (F1)**.

Figure 5.3



TIP Index

Displays the current index. Changes when **New Index** or **Date Index (F8)** is selected.

Group of Tests

Selects the group of on-board tests to perform.

Operator Name

Enters the operator name, or selects the **Select** button to select a name from the comment master list.

Start Sample No.

Displays the next sample number to be processed on the analyzer for each sample type and kind. When a new index is created, the Start Sample Numbers go to the default sample numbers, typically 0001.

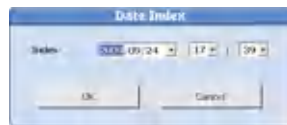
Disable (F7)

Stops analysis (disable) on a test even when the test has a requisition. Refer to [7.2 Disable a Test](#).

Default Start Sample No. (F7) displays after selecting Edit (F1).

Programs the default start sample numbers to be assigned to Start Sample Number when a new index is created. If 2 or more analyzers are in the lab, it may be convenient to have one analyzer start at 0001, and another analyzer start at 1001, for example. The purpose of this is to easily identify data from a specific analyzer.

-
- 3 Select **New Index** or **Date Index (F8)**. If **Date Index (F8)** is selected, the Date Index window opens.

Figure 5.4

- a. Select the date and time from the "Index" drop-down list.
- b. Select **OK**.

-
- 4 Select a group of tests to process from the "Group of Tests" drop-down list.

-
- 5 Enter the operator name in **Operator Name** (optional).

-
- 6 Verify Start Sample No. is 0001, or the default start number for each sample type and kind.

-
- 7 Select **Confirm (F1)**. The Start Condition window displays "Create a New Index?".

-
- 8 Select **OK**. The programming is registered.
-

Set the default start sample numbers

- 1 Select **Edit (F1) > Default Start Sample No. (F7)**. The Default Start Sample No. window is displayed.

Figure 5.5



- 2 Enter the default start sample numbers.
-

- 3 Select **OK**.
-

5.2 Perform Daily Maintenance

Perform daily maintenance to ensure system performance and safety.

- Inspect the syringes for leaks
- Inspect the wash solution roller pump for leaks
- Inspect, clean, and prime the sample probe, reagent probe, and mix bars
- Inspect the wash solution and replenish as needed
- Inspect the printer (optional) and paper
- Replace the Deionized (DI) water or diluent in the pre-dilution bottle
- Prepare the sample probe wash solution
- Inspect the stability of the upper cover

For details on performing daily maintenance, refer to [8.3 Daily Maintenance](#) in chapter 8.

 **CAUTION**

To prevent injury or infection, wear protective gloves and other protective equipment when performing maintenance.

For additional protection, observe the WARNING and CAUTION statements in this User's Guide.

5.3 Check Analyzer Status

Check **Analyzer Status** to display a color-coded overview of the system, and the temperatures of the incubator and reagent refrigerator. The STAT table, DI water tank, wash solution tank, waste tank, printer, and LIS communication are monitored.

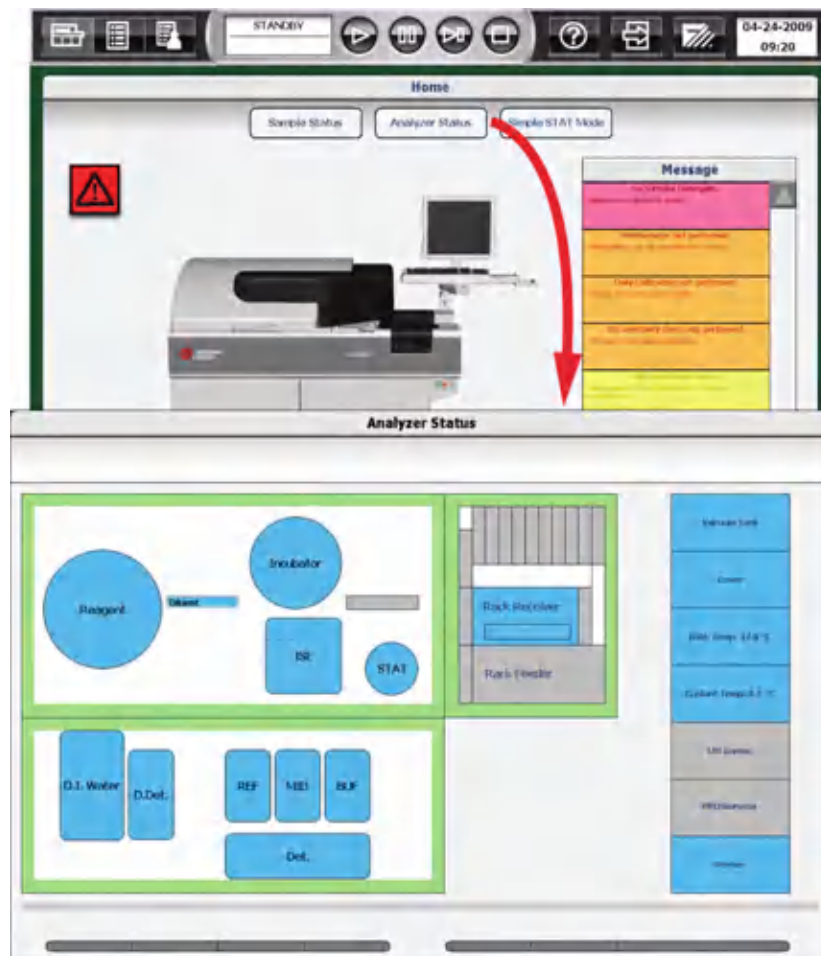
Blue	No errors
Yellow or Orange	Non-fatal error. The analyzer can be started
Red	Fatal error. The analyzer cannot be started

The ISE unit and reagents are monitored when the ISE unit is installed.

Review Analyzer Status:

Select **Home > Analyzer Status**.

Figure 5.6



For details on **Analyzer Status**, refer to [7.1.4 Analyzer Status Menu](#) in chapter 7.

5.4 ISE (Option) Startup

Perform ISE startup and daily maintenance procedures.

5.4.1 Check the ISE Reagent

5.4.2 Perform ISE Daily Maintenance

5.4.1 Check the ISE Reagent

- 1 Open the left front door of the analyzer.
- 2 Verify the ISE reagents are within the 90-day onboard stability. Verify the solution level is sufficient for typical daily analysis, or above the ISE Reagent Short notification alarm.

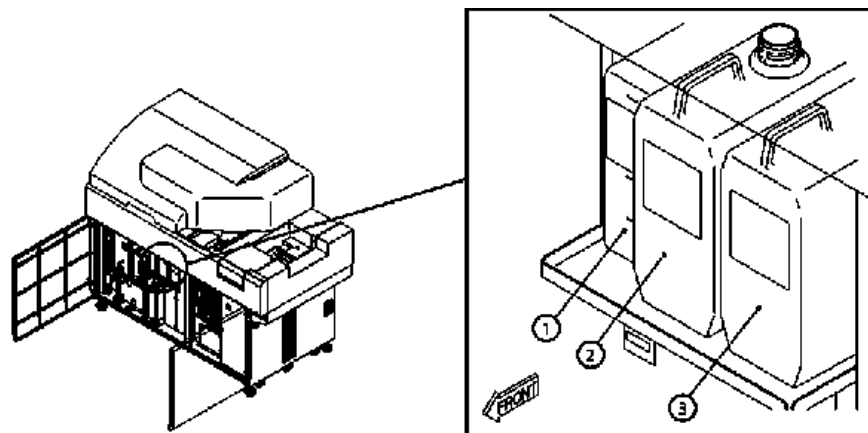
TIP The ISE Reagent Short level notification alarm occurs at 5.2 cm above the bottom of the bottle. After the alarm, about 180 samples of MID Standard solution, about 600 samples of Reference solution, and about 240 samples of Buffer solution can be dispensed. Replace the bottle if necessary.

NEVER ADD NEW REAGENT TO EXISTING BOTTLES

- Buffer solution bottle
- MID Standard solution bottle
- Reference solution bottle

TIP Verify there is sufficient reagent before starting analysis. If a reagent becomes empty during *Measure*, it is necessary to stop the analyzer, replenish and prime the new reagent, and calibrate the ISE for all sample types in use.

Figure 5.7



1. REF solution bottle
2. MID solution bottle
3. Buffer solution bottle

For information about loading ISE reagents, refer to [8.19.5 Replacing ISE Reagents](#) in chapter 8.

3 Close the left front door of the analyzer.

5.4.2 Perform ISE Daily Maintenance

Perform ISE daily maintenance to ensure system performance and safety.

TIP Beckman Coulter recommends cleaning the ISE after daily analysis if the analyzer is shut down (**End Process** performed) for a period of time.

- ISE Cleaning
- ISE Calibration

For details on performing ISE daily maintenance, refer to [8.12 ISE Daily Maintenance](#) in chapter 8.



To prevent injury or infection, wear protective gloves and other protective equipment when performing maintenance.

For additional protection, observe the WARNING and CAUTION statements in this User's Guide.

5.5 Check Reagent Status

5.5.1 Check Reagent Quantity and Status

5.5.2 Review Detailed Information

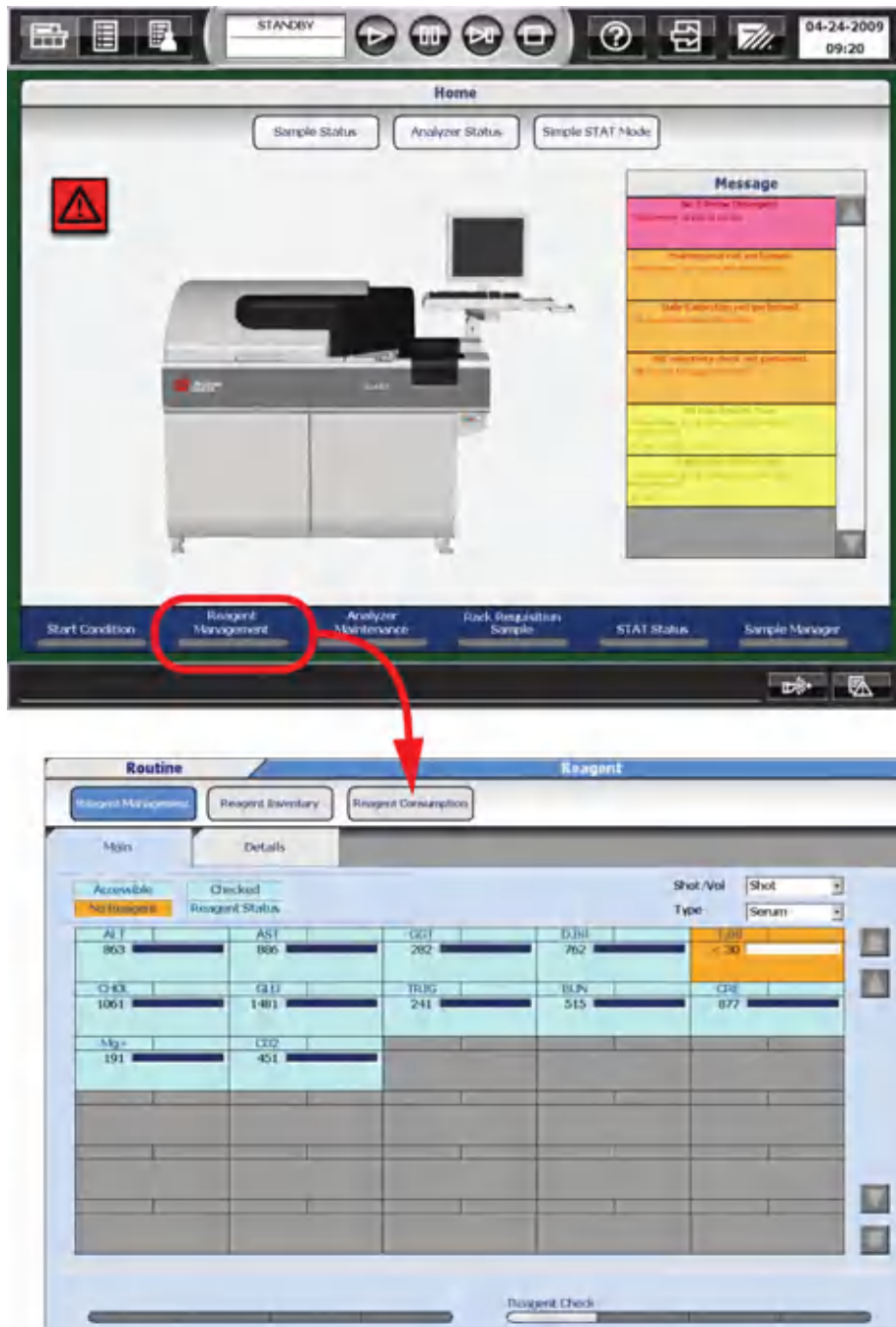
5.5.3 Reagent Replacement

5.5.1 Check Reagent Quantity and Status

View the status of the reagents currently onboard the analyzer. Perform a reagent check to update the reagent status when reagents have been loaded or unloaded, and following an **End Process** or Emergency Stop.

- 1 Select **Home > Reagent Management > Main**.

Figure 5.8



2 Select a sample type from the “Type” drop-down list.

3 Select **Reagent Check (F5)**.

4 Select one of the Check methods.

Figure 5.9



TIP Reagent Check (F5) options:

- **Check all positions**
Checks the remaining volume of reagent at all positions, including the bottle position outside of the reagent refrigerator. Select this check as part of the daily startup, when changing any parameter, changing the Group, and loading numerous reagents.
- **Check specified positions**
Checks the remaining volumes of reagent at the specified positions. Select this check when replacing a reagent bottle. If the reagent is an R1/R2, check both the R1 and R2.
- **Check changed positions**
Checks the remaining reagent for any reagent ID that is new or has been moved since the previous reagent check.
- **Reset Only**
Select this when the reagent refrigerator cover was only opened and closed without changing any reagent. The reagent volume check is not performed.
- **Read Reagent ID**
Select this if the reagent barcode is to be read.

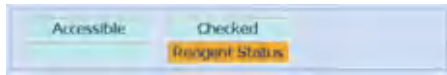
If contamination prevention parameters are programmed, the prevention parameters are applied during a reagent check.

5 Select **Start**.

Reagent check starts. During the reagent check, Checking displays in red on the screen, and the bar graph displays the reagent check progress. When the check is complete, Checked displays in blue.

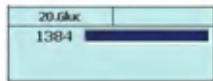
- 6 View the Reagent Status box in the upper left corner of the **Main** tab. The Display and Background color indicate the Status of the reagent refrigerator and reagent check, and errors with onboard reagents. Review Comments in the **Details** tab if yellow, orange, or red is present. Refer to [5.5.2 Review Detailed Information, Reagent Status](#) for a description of Reagent Status.

Figure 5.10



- 7 View the status of each individual test displayed on the **Main** tab. Verify that required reagents are present and that all reagents have sufficient volume. The blue indicator bar displays the maximum number of tests calculated in **Reagent Inventory**. Refer to [7.4.5 Reagent Inventory](#) for more information. Identify reagents that need to be loaded.

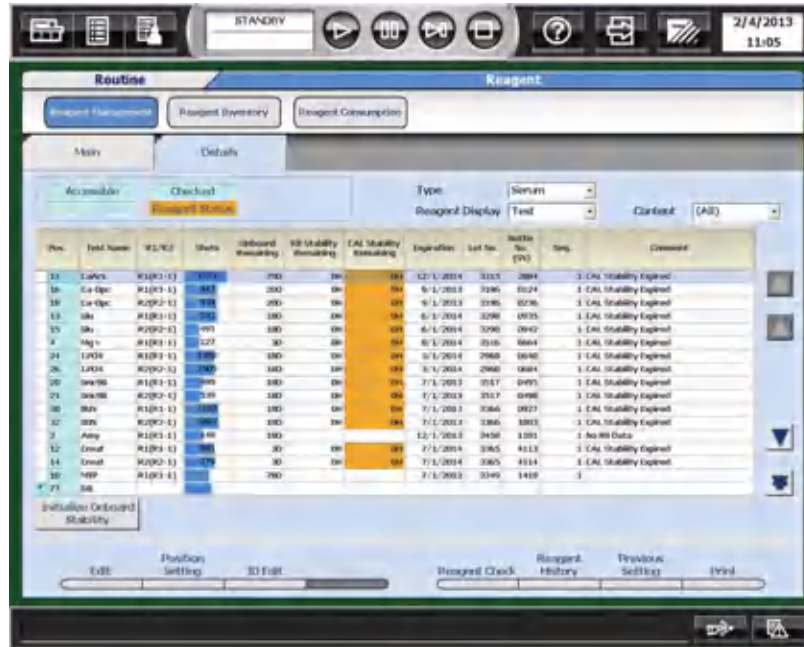
Figure 5.11



Refer to [5.5.2 Review Detailed Information, Test Status](#) for a description of Test Status.

- 8 Select **Details**. Verify the Onboard Remaining, RB Stability Remaining, and Cal Stability Remaining time is sufficient for the run. Review the Comments and perform necessary corrective actions.

Figure 5.12



- 9 Add new reagents as needed based on steps 6 to 8.
For details on loading new reagents, refer to [5.5.3 Reagent Replacement](#).
- 10 If reagent is short or empty, load additional reagent(s) and perform a reagent check again.

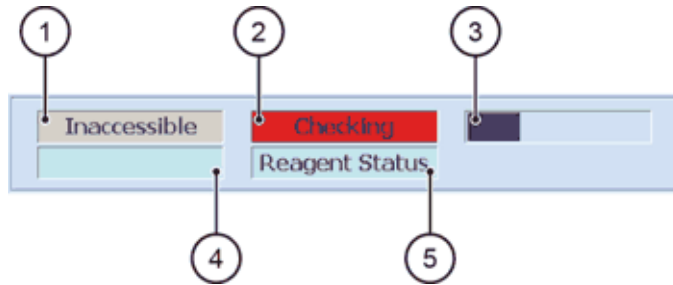
For details on how to edit reagent bottle settings, refer to [7.4 Reagent Management](#) in chapter 7.

5.5.2 Review Detailed Information

Reagent Status

Home > Reagent Management > Main

Figure 5.13

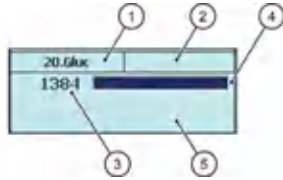


	Display	Background Color	Description
1	Accessible	Light blue	Accessible displays if reagent bottles can be loaded. Inaccessible displays if reagent bottles cannot be loaded.
	Inaccessible	Red	
2	Unchecked	Red	Displays status of reagent check.
	Checking	Red	
	Checked	Light blue	
3	Progress bar	-	Displays the progress of reagent check. Display appears only when checking.
4	No Reagent	Orange	A reagent assigned to the Group is missing from the reagent refrigerator, the on-board stability is expired, the reagent is expired, or the bottle is empty.
	Reagent short	Yellow	Reagent volume is short (low).
	No display	Light blue	Necessary reagents are on-board.
5	Reagent Status	Orange	Displays an error level of reagents in the reagent refrigerator.
		Yellow	
		Light blue	

Test Status

Home > Reagent Management > Main

Figure 5.14



	Display	Display Color	Description
(1)	Test name 1	-	Displays test names in the output order that have been set in the Group. ISE and non dedicated LH reagents are not displayed.
(2)	Test name 2	-	In case of 2-tests/1-reagent *, another test name is displayed.
(3)	Number of shots or remaining volume	-	The number of shots (tests) remaining or volume in mL. Select the Shot/Vol. drop down to change the display. Select the Type drop down to view the shots or volume for the specified sample type.
(4)	Indicator	-	Displays the remaining reagent volume. If more than one bottle is on the system, the total reagent volume displays. The length of the bar displays the maximum number of tests calculated in Reagent Inventory , and estimates the reagent consumption required for the day. Reagent quantity indicator bar(s): The R1 indicator bar displays on top of the R2 indicator bar if Advanced Calibration is set to No and Multi Reagent Switch is set to No in Parameters . If Advanced Calibration is set to Yes and Multi Reagent Switch is set to Yes in Parameters (as in most cases), there is a single indicator bar even for an R1/R2 assay. Beckman Coulter recommends programming Multi Reagent Switch to Yes.
(5)	Background color	Orange	A reagent assigned to the Group is missing from the R1 or R2, the on-board stability is expired, the reagent is expired, or the bottle is empty.
		Yellow	Reagent volume is short (low).
		Light Blue	Required reagents are set.
		Gray	The test operation is programmed to No for the sample type displayed from the Reagent Management > Main "Type" drop-down list. Change the sample type from the "Type" drop-down list to view the background color of the reagent.

TIP When the analyzer has turned on after an End Process, all tests initially show <30 shots without a volume indicator bar. Select **Reagent Check (F5) > Check all positions** to determine the number of shots (tests) remaining.

* 2-tests/1 reagent means the same reagent is used for two tests. Program this option in **Menu List > Parameters > Common Test Parameters > Test Name** by assigning the same reagent ID for both tests.

Details Tab

Home > Reagent Management > Details

Figure 5.15

STANDBY 2/4/2013 11:05

Routine **Reagent**

Reagent Management | Reagent Inventory | Reagent Consumption

Main | Details

Accountable: [] | Checklist: [] | Reagent Status: []

Type: Serum | Reagent Display: Text | Control: (All)

Item No.	Reagent Name	Wavelength	Units	Inboard Remaining	YR Stability Remaining	CAL Stability Remaining	Expiration	Lot No.	Bottle No.	Qty.	Comment
11	Calc	810(3-1)	100	780	100	100	12/1/2014	3133	2894	1	CAL Stability Expired
16	Ca Dip	810(3-1)	100	200	100	100	6/1/2013	3296	1024	1	CAL Stability Expired
18	Ca Dip	820(2-1)	100	200	100	100	6/1/2013	3296	1026	1	CAL Stability Expired
12	alk	810(3-1)	100	180	100	100	6/1/2014	3290	1025	1	CAL Stability Expired
15	alk	820(2-1)	100	180	100	100	6/1/2014	3290	1042	1	CAL Stability Expired
4	Mg v	810(3-1)	100	30	100	100	6/1/2014	3245	1004	1	CAL Stability Expired
24	TPPv	810(3-1)	100	180	100	100	6/1/2014	2968	1040	1	CAL Stability Expired
26	TPPv	820(2-1)	100	180	100	100	6/1/2014	2968	1004	1	CAL Stability Expired
30	urea	810(3-1)	100	180	100	100	7/1/2013	3117	1045	1	CAL Stability Expired
71	urea	820(2-1)	100	180	100	100	7/1/2013	3117	1046	1	CAL Stability Expired
10	ure	810(3-1)	100	180	100	100	7/1/2013	3266	1027	1	CAL Stability Expired
10	ure	820(2-1)	100	180	100	100	7/1/2013	3266	1003	1	CAL Stability Expired
5	Any	810(3-1)	100	180	100	100	12/1/2013	3458	1201	1	No RR Data
12	creat	810(3-1)	100	30	100	100	7/1/2014	3265	1113	1	CAL Stability Expired
14	creat	820(2-1)	100	30	100	100	7/1/2014	3265	1111	1	CAL Stability Expired
10	MP	810(3-1)	100	780	100	100	7/1/2013	3149	1419	1	
77	SR										

Initialization Complete
Stability

Exit | Position Setting | Edit | Reagent Check | Reagent History | Reagent Settings | Help

Item	Description
Type:	Select Serum, Urine, Other-1, Other-2.
Reagent Display:	Select Test (displayed by test) or Position (displayed by position).
Content:	Select All or a specific test.
Pos.:	R1 or R2 reagent position.
R1/R2:	Select R1 or R2.
Shots:	Number of tests remaining in the bottle. The blue indicator bar is proportional to the level in the bottle (0-100%).
Onboard Remaining:	Hours (H) or Days (D) remaining until the reagent on-board stability expires.
RB Stability Remaining:	Hours (H) or Days (D) remaining until the reagent blank stability expires.
Cal Stability Remaining:	Hours (H) or Days (D) remaining until the calibration stability expires.
Expiration:	The expiration date of the reagent lot number.
Bottle No. (SN):	A unique 4-digit number to identify each bottle of reagent.
Seq.:	Sequence number 1-5 of the same reagent in the R1/R2.
Comment:	A caution or error message for the reagent.
Edit (F1)	Edit the test name, lot number, bottle number, and bottle size for fixed reagents.
Position Setting (F2)	Assign a position as Reagent ID or Fixed. When the position is fixed, an * appears to the left of the Position number.
ID Edit (F3)	Edit the 20-digit reagent ID. Use this option to edit the reagent ID after a reagent ID read error.
Read Master Curve (F4)	Scan the 2-dimensional reagent ID for master curve assays.
Reagent Check (F5)	Perform the reagent check.
Reagent History (F6)	Display the lot number, bottle number, position, and on-board stability (hours) for 100 lines of data for R1 and R2 reagents.
Previous Setting (F7)	Display the most recent reagent bottle position. Available only in <i>Pause</i> mode.
Print (F8)	Print all the Details tab information.

TIP The time remaining displays in hours (H) up to 72 hours, and days (D) over 72 hours.

If two tests are programmed to use one reagent, the RB Stability Remaining and Cal Stability Remaining display as lower Test No./higher Test No.

Initialize Onboard Stability resets the onboard stability for fixed reagents to the Onboard Stability Period programmed in **Parameters > Specific Test Parameters**. A Lot No. and Bottle No. (SN) must be entered using **Edit (F1)** before the Initialize Onboard Stability function is operational.

5.5.3 Reagent Replacement

If the reagent volume is insufficient, on-board stability has expired, or the reagent is expired, remove the old reagent bottles and replace them with a new set.

NEVER ADD NEW REAGENT TO EXISTING BOTTLES.

If the analyzer is in *Measure* and more than one sequence of bottles is on-board, the analyzer only switches to the next bottle sequence when the current bottle sequence is empty, and not when the calibration or reagent is expired.

Reagent preparation

Most Beckman Coulter reagents are liquid and ready to be placed in the reagent refrigerator after removing the cap. If a Beckman Coulter or other manufacturer's reagent requires preparation, refer to the reagent specific IFU before loading the reagent in the reagent refrigerator.

There are three types of reagent bottles that can be used with this system.

- 60 mL reagent bottle
- 30 mL reagent bottle
- 15 mL reagent bottle

Setting reagents into the reagent refrigerator

WARNING

- Condensation can form on the walls of the reagent refrigerator, in the bottle neck, or on the barcode label on the bottle. If the bottle neck has condensation, a level detection error may occur. If the bottle surface with the barcode label has condensation, detection of the bottle may fail. If condensation is present, remove the condensation using a dry paper towel.
- When using 15 mL bottles, verify they are placed on the reagent tray with the barcode facing out. Setting the bottles incorrectly may damage the bottle and reagent probe.
- If bubbles are present in the bottles, correct analysis may not occur. Check the bottles for bubbles, and remove any bubbles before placing bottles in the reagent refrigerator.

CAUTION

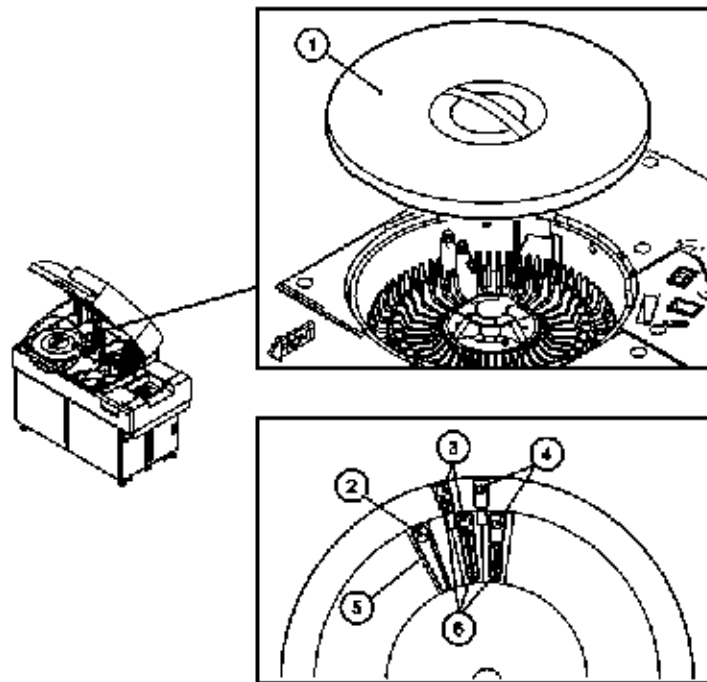
- 15 mL and 30 mL bottles require adapters to hold them securely in position in the reagent refrigerator. Verify adapters are used and securely in place.
A maximum of 76 bottles can be placed in the reagent refrigerator. There are thirty eight 60 mL bottle positions available.

Replace a reagent

- 1 Open the front main cover.

- 2 Lift and remove the reagent refrigerator cover.

Figure 5.16



- | | |
|-------------------------------|---------------------------|
| 1. Reagent refrigerator cover | 4. Reagent bottle (30 mL) |
| 2. Reagent bottle (60 mL) | 5. Partition plate |
| 3. Reagent bottle (15 mL) | 6. Adapter |

- 3 Place R1 and R2 bottles in the reagent refrigerator.

TIP If the bottle has a reagent ID, it can be placed in any available (not fixed) position in the reagent refrigerator.

If the bottle does not have a reagent ID, place it in the appropriate fixed position. Fixed positions are indicated by a blue "*" to the left of the position column on the **Details** tab. To assign a reagent without a reagent ID to a position, refer to [7.4.1 Fix \(Assign\) a Reagent Position](#) in chapter 7.

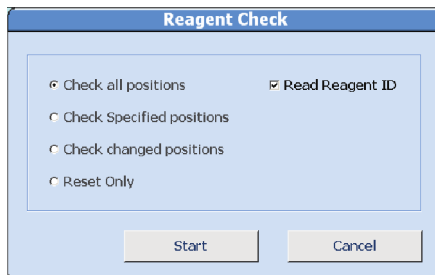
- 4 Replace the reagent refrigerator cover.

- 5 Close the main cover.

- 6 Select **Home > Reagent Management**.

- 7 Select **Reagent Check (F5)**. The Reagent Check window opens.

Figure 5.17



- 8 Select the check method to perform. Select **Start** to begin the reagent check. Review **Main** and **Detail** to verify the results.

 **CAUTION**

When the barcode label on a reagent bottle is dirty or has moisture on it, barcode reading errors can occur. Check the barcode label of the reagent bottle.

If the barcode label is dirty or has moisture adhering to it, wipe it off.

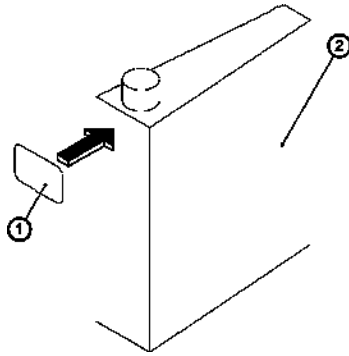
If the barcode cannot be read even after wiping off dirt or moisture, enter the barcode ID manually. For details on ID editing, refer to [7.4.2 Edit a Reagent ID](#) in chapter 7.

 **CAUTION**

Cautions for use of commercial reagent bottles:

- A commercial reagent bottle is not sold by Beckman Coulter for use on the AU systems. Commercial reagent bottles are only available in the Japanese and Asian markets.
- If the color of the commercial reagent bottle is too light to be detected by the bottle sensor, apply a label as shown in the diagram below. The consumable part number for the labels is MU9879.
- When using commercial reagent bottles, the test count displayed in Reagent Management may differ from the actual test count remaining because the bottle is different than the Beckman Coulter reagent bottles. The liquid level in the bottle is used to calculate the test count.

Figure 5.18



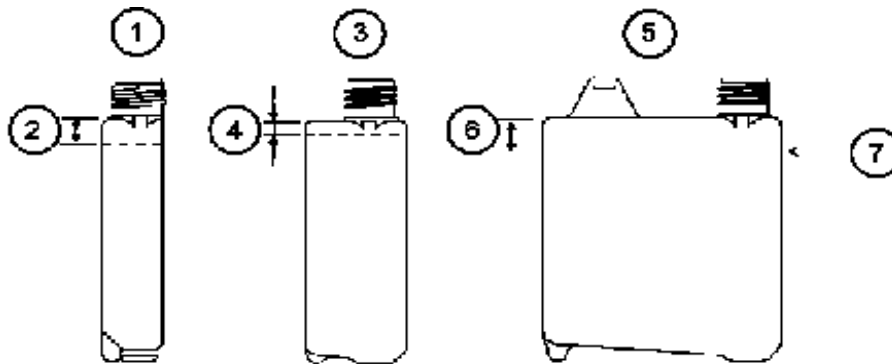
- 1. Label
- 2. Reagent bottle

Precautions in Filling a Reagent Bottle

Observe the following precautions when handling reagent bottles.

- If a reagent bottle is filled over the maximum liquid level limit for the bottle size, bubbles can occur and cause a level detection error.
- Verify that no bubbles exist in the bottles.
- When filling AU bottles with reagent or wash solution, do not exceed the maximum volume.

Figure 5.19 Maximum Liquid Level for the 15 mL, 30 mL, and 60 mL Bottles



- 1. 15 mL Bottle
- 2. 8 mm
- 3. 30 mL Bottle
- 4. 4 mm
- 5. 60 mL Bottle
- 6. 12 mm
- 7. Maximum Liquid Level

5.6 Perform Calibration

5.6.1 Requisition and Perform Calibration from Racks

5.6.2 Requisition and Perform Calibration from the STAT Table

Requisition reagent blanks and calibrations as needed. Automatic reagent blank and calibration requisition occurs with the following conditions:

- Reagent blank or calibration Expired
- Reagent blank or calibration Expired Soon
- New bottle or lot number of reagent (if Advanced Calibration is in use)
- Reagent blank or calibration failed

TIP The automatic reagent blank or calibration requisition does not occur until after a reagent check is performed.

Review the Comment in **Reagent Management > Details** to determine what tests need to be calibrated.

TIP Calibration consists of a reagent blank and calibration. Calibration can be performed from the blue and yellow racks or the STAT table.

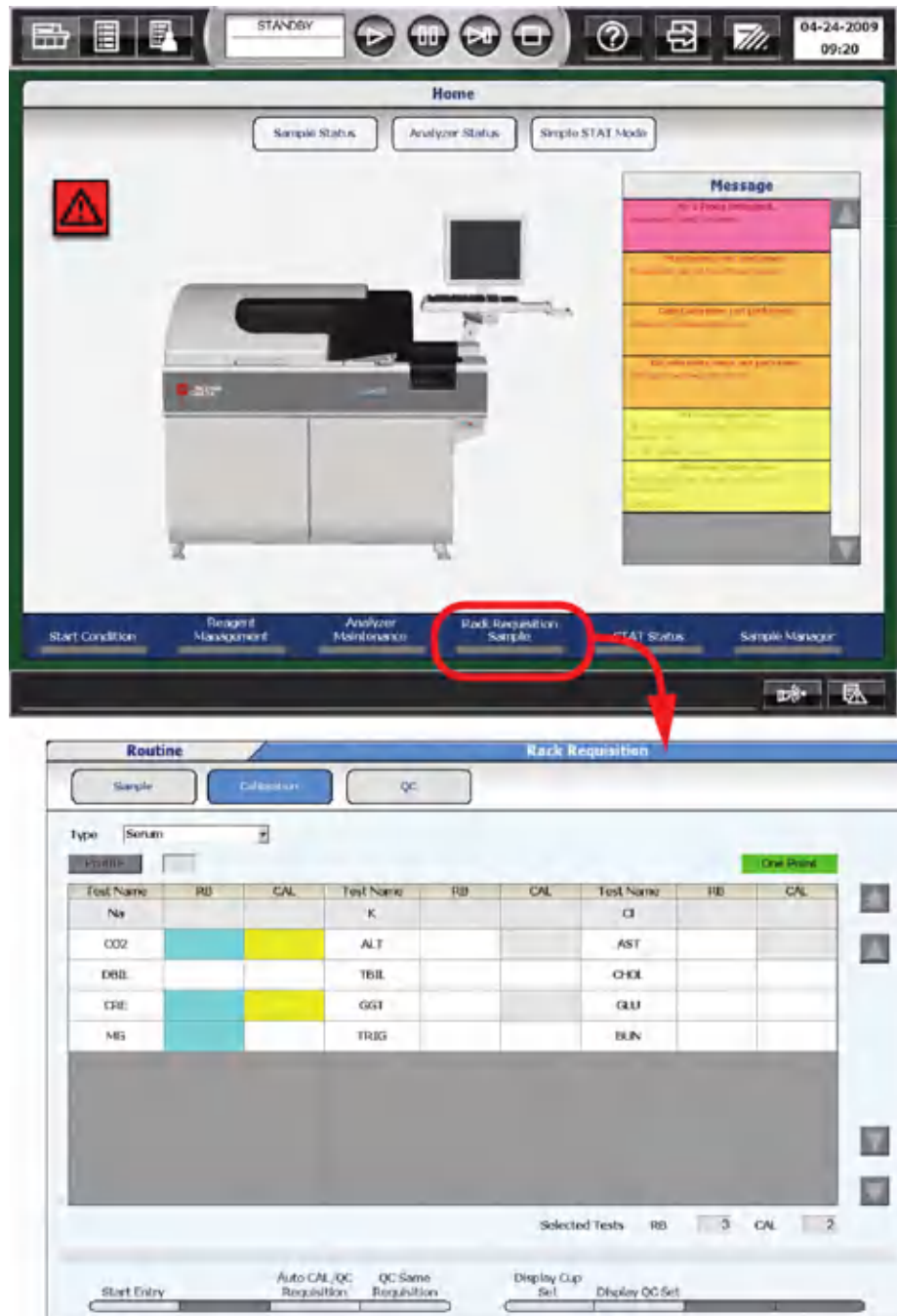
The STAT table has numerous options for calibrating from the STAT table, including calibrator ID, and fixed, variable, or free calibrator positions on the table. Refer to [4.5.4 STAT Table Calibration Menu](#) in chapter 4. Contact Beckman Coulter Technical Services for information on programming the STAT table for calibration.

The most common method to calibrate is from the yellow racks. Refer to [5.6.1 Requisition and Perform Calibration from Racks](#).

5.6.1 Requisition and Perform Calibration from Racks

- 1 Select Home > Rack Requisition Sample > Calibration.

Figure 5.20



- 2 Select the sample type from the "Type" drop-down list.

3 Select **Auto Cal/QC Requisition (F3)** to select the automatic requisition.

This step is not required if a reagent check was just performed. A reagent check selects and displays the automatic requisition in **Calibration**.

4 If the analyzer automatic requisition is correct, proceed to step 7.

TIP Automatic reagent blank and calibration requisition occurs in the following conditions:

- Reagent blank or calibration Expired
- Reagent blank or calibration Expired Soon messages are based on a user-defined number of hours programmed in System Maintenance. The Default setting is 180 minutes and is programmable in 1 minute increments. Contact Beckman Coulter Technical Services for additional information.
- New bottle or lot number of reagent (if Advanced Calibration is in use)
- Reagent blank or calibration failed

TIP The automatic reagent blank or calibration requisition does not occur until after a reagent check is performed.

Tests display with a blue box in the RB column when requisitioned for reagent blank. Tests display with a blue box in the RB column and a yellow box in the CAL column when requisitioned for calibration.

Select **QC Same Requisition (F4)** to requisition the same tests for QC analysis as the tests selected for reagent blank and calibration analysis. Select **Display QC Set (F6)** to display the QC material, QC racks, and QC positions required based on the QC requisition.

In **Reagent Management**, any of the **Reagent Check (F5)** options, including **Reset**, resets the calibration requisitions to the analyzer automatic requisitions.

A one-point calibration correction can be requisitioned and performed if the test is a multi-point calibration, and 1-Point Calibration Point is programmed in **Calibration Parameters**. Refer to [4.5.3 Calibration Specific Menu](#).

5 Select **Start Entry (F1)**.

- To select a profile, select **Profile** to open the Profile window and select a profile, then select **OK**.
- To select a specific test(s), select from the RB or CAL column to the right of the test name. Selecting from the RB column requisitions only a reagent blank. Selecting from the CAL column requisitions a reagent blank and calibration.
- Select **Individual Requisition (F3)** to requisition sequenced bottles (1, 2, 3, 4, 5) of the same test. Select a specific test and bottle sequence by selecting the RB or CAL column, **Select All by Test** (requisitions all bottles of the selected test), or **Select All** (requisitions all bottles for all tests). Select **Close** to register the requisition, or **Cancel** to cancel the requisition.

TIP Calibration profiles must be programmed in **Menu List > Parameters > Common Test Parameters > Profile > RB/Calibration** before a profile is available to requisition. Refer to [4.2.2 Profile Menu](#) for more information. A maximum of 99 different profiles can be programmed, including daily, weekly, and monthly calibration requirements.

A test must be programmed for Advanced Calibration in **Menu List > Parameters > Calibration Parameters > Calibration Specific** before it is available to requisition by bottle sequence number in **Individual Requisition (F3)**. Refer to [4.5.3 Calibration Specific Menu](#) in chapter 4 for more information.

6 Select **Entry (F1)** to register the requisition. Select **Exit (F2)** to cancel the requisition.

7 Select **Display Cup Set (F5)** to view the reagent blank, calibrator(s), racks, and positions required for reagent blank and calibrator(s). Load the reagent blanks and calibrators according to the list in the correct blue and yellow racks. Select **Close** to close the window.

TIP In **Display Cup Set (F5)**, the Volume (μL) is the sample volume required based on the requisitioned tests. The dead volume is not included.

If calibrator barcode operation is in use, the Rack No. in **Display Cup Set (F5)** displays as 000x.

To requisition QC the same as the calibration requisition, select **QC Same Requisition (F4)**.

8 Load the racks on the rack supply unit. Load the blue rack first, followed by the yellow rack(s).

9 Select **Start**.

5.6.2 Requisition and Perform Calibration from the STAT Table

TIP Requisition calibrators before calibrating from the STAT table. Calibration requisitions are not automatic from the STAT table.

Tests display with a blue box in the RB column when requisitioned for reagent blank. Tests display with a blue box in the RB column and a yellow box in the CAL column when requisitioned for calibration.

- 1 Select **Home > STAT Status > Calibration.**

Figure 5.21



- 2 Select a sample type from the "Type" drop-down list.
- 3 Select **Auto CAL/QC Requisition (F3)** to requisition the automatic analyzer calibration requisition. The automatic analyzer calibration requisition is expired calibrations, calibration expires soon, new bottle numbers or lot numbers of reagent depending on Advanced Calibration programming, or failed reagent blank/calibrations. This also automatically requisitions the same tests for QC analysis in the QC requisition menu.
- 4 Select **Start Entry (F1)** to requisition calibrators.
 - Select **Profile** to open the Profile window and select a profile, then select **OK**.
 - To select a specific test(s), select from the RB or CAL column to the right of the test name. Selecting from the RB column requisitions only a reagent blank. Selecting from the CAL column requisitions a reagent blank and calibration.
 - Select **Individual Requisition (F3)** to requisition sequenced bottles (1, 2, 3, 4, 5) of the same test. Select a specific test and bottle sequence by selecting the RB or CAL column, **Select All by Test** (requisition all bottles of the selected test), or **Select All** (requisition all bottles for all tests). Select **Close** to register the requisition, or **Cancel** to cancel the requisition.
- 5 Select **Entry (F1)**.
- 6 Select **Display Cup Set (F5)** to view the calibrator positions on the STAT table if the calibrator barcode option is not enabled. View the calibrator volume required based on the requisition.

Figure 5.22

Kind	No.	Name	ID	Lot No.	Expiration Date	Pos.
RB	1	RB Water				0261
Calibrator	1	1. (CAL) 1. Control (10)		942011	03/31/2014	22 (2)
Calibrator	2	2. (CAL) 2		942011	03/31/2014	49 (2)
Control	1	1. Control (HbA1C) 04101				5 (2)
Control	2	2. Control (HbA1C) 04101				5 (2)

7 Load the required reagent blank and calibrators on the STAT table according to the CAL/QC/RB Position window. Use the TABLE ROTATION/DIAG button to rotate the table if necessary. Select **Print** to print a list of the CAL/QC/RB Position window contents, or **Close** to close the window.

- If the Calibrator Barcode Operation is not enabled, place the calibrators in the correct positions according to the "Pos.".
- If the Calibrator Barcode Operation is enabled with Fixed Calibrator positions, place the calibrators in any Calibrator position (listed under "Kind").
- If the STAT table is programmed for Free positions (listed under "Kind"), place the barcoded calibrator in any position.

8 Select **STAT Status > STAT Start (F1)**. Review the Error List in the STAT Start window. Verify the required reagent blank and calibrators are on the STAT table.

Figure 5.23

Start Sample No. [Field]

Routine [Field]

Repeat [Field]

Error List

- Test has no RB Data. Please open Calibration Requisition menu and requisition the test.
- Calibration stability is expired. Please open Calibration Requisition menu and requisition the test.
- RB stability is expired. Please open Calibration Requisition and requisition the test.
- Maintenance item is expired. Please perform maintenance.
- Error sample(s) exists. Please check sample(s) in STAT Status menu.
- Maintenance item will be expired soon. Please check it.

Start [Button] Cancel [Button]

-
- 9** Select **Start** to initiate the automatic STAT table check (detects reagent blank and calibrators) or **Cancel** to take corrective actions.
-
- 10** If there are no errors specific to the STAT table after the STAT table check, analysis starts. If there are STAT table errors, review the errors in the STAT Start window. Select **Start** to begin analysis, or **Cancel** to perform corrective actions.
-

5.7 Perform Quality Control (QC)

5.7.1 Requisition and Perform QC from Racks

5.7.2 Requisition and Perform QC from the STAT Table

Quality control analysis is used for confirming the system performance. It is necessary for all diagnostic equipment.

Check the performance of the AU480 regularly by analyzing QC samples. Each laboratory should establish its own control frequency. QC samples should be tested each time patient samples are tested and each time calibration is performed. If any trends or sudden shifts in values are detected, review all operating parameters.

Each laboratory should also establish guidelines to ensure corrective action if controls do not recover within the specified limits.

TIP QC can be performed from the green racks or the STAT table.

The STAT table has numerous options for performing QC from the STAT table, including control ID, and fixed, variable, or free control positions on the table. Refer to [4.6.3 STAT Table QC Menu](#) in chapter 4. Contact Beckman Coulter Technical Services for information on programming the STAT table for controls.

The most common method to perform QC is from the green racks. Refer to [5.7.1 Requisition and Perform QC from Racks](#).

TIP A default QC requisition can be programmed in **Menu List > Parameters > Common Test Parameters > Profile > QC** for each sample type and Group in use. Refer to [4.2.2 Profile Menu](#) in chapter 4 for more information. Specific profile numbers are designated for each sample type and Group:

Profile Number	Sample Type/Group
87	Serum/1
88	Serum/2
89	Serum/3
90	Urine/1
91	Urine/2
92	Urine/3
93	Other-1/1
94	Other-1/2
95	Other-1/3
96	Other-2/1
97	Other-2/2
98	Other-2/3

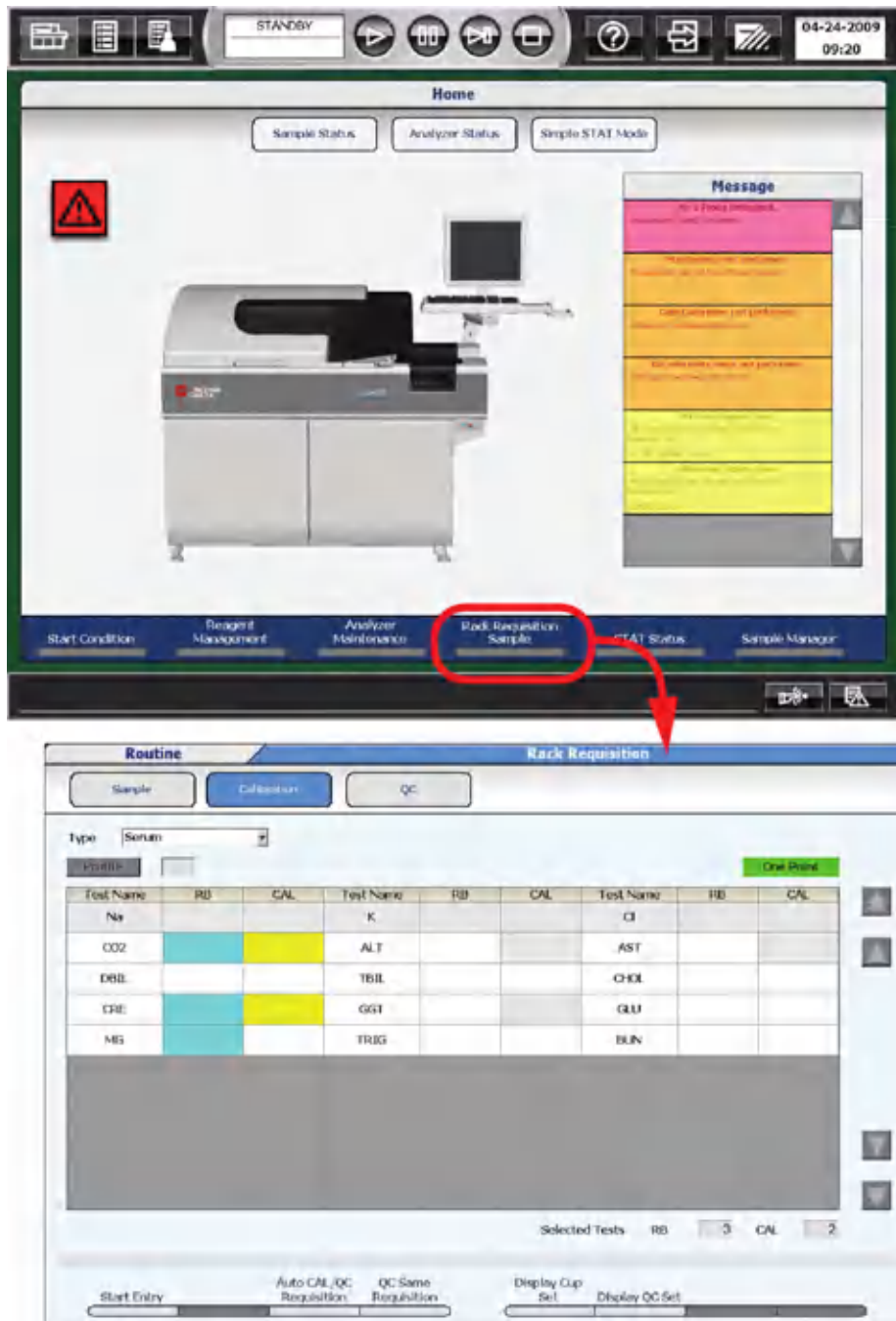
TIP The default QC profile is automatically requisitioned.

In **Reagent Management**, if any of the **Reagent Check (F5)** options are performed, the QC requisitions are reset back to the default.

5.7.1 Requisition and Perform QC from Racks

- 1 Select **Home** > **Rack Requisition Sample** > **QC**.

Figure 5.24



- 2 Select the sample type from the "Type" drop-down list.

3 If the default QC profile displayed is correct, proceed to step 6.

TIP QC profiles must be programmed in **Menu List > Parameters > Common Test Parameters > Profile > QC** before a profile is available to requisition. Refer to [4.2.2 Profile Menu](#) for more information. A maximum of 98 different profiles can be programmed, including the default profiles.

A test must be programmed for Advanced Calibration in **Menu List > Parameters > Calibration Parameters > Calibration Specific** before it is available to requisition by bottle sequence number in **Individual Requisition (F3)**. Refer to [4.5.3 Calibration Specific Menu](#) for more information.

4 Select **Start Entry (F1)**.

- a. Select **Profile** to open the Profile window and select a profile, then select **OK**.
 - b. Select a test(s) to requisition QC (blue highlight) or de-select QC (no blue highlight).
 - c. Select **Individual Requisition (F3)** to requisition sequenced bottles (1, 2, 3, 4, 5) of the same test. Select a specific test and bottle sequence, **Select All by Test** (requisitions all bottles of the selected test), or **Select All** (requisitions all bottles for all tests). Select **Close** to register the requisition, or **Cancel** to cancel the requisition.
-

5 Select **Entry (F1)** to register the QC requisition. Select **Exit (F2)** to cancel the requisition..

6 Select **Display Cup Set (F6)** to view the control(s), racks, and positions required for the control(s). Load the controls according to the list in the correct green racks. Select **Close** to close the window.

TIP In **Display Cup Set (F6)**, the Volume (μL) is the sample volume required based on the requisitioned tests. The dead volume is not included.

If QC barcode operation is in use, the Rack No. in **Display Cup Set (F5)** displays as 000x.

7 Load the green racks on the rack supply unit.

8 Select **Start**.

5.7.2 Requisition and Perform QC from the STAT Table

Perform QC

TIP Requisition QC before QC analysis from the STAT table. QC requisitions are not automatic from the STAT table.

- 1 Select **Home > STAT Status > QC**.

Figure 5.25



- 2 Select a sample type from the "Type" drop-down list.
- 3 Select **Start Entry (F1)** to requisition QC.
 - Select Profile to open the Profile window and select a profile, then select OK
 - Select a test(s) to requisition QC (blue highlight) or de-select QC (no blue highlight).
 - Select **Individual Requisition (F3)** to requisition sequenced bottles (1, 2, 3, 4, 5) of the same test. Select a specific test and bottle sequence, **Select All by Test** (requisition all bottles of the selected test), or **Select All** (requisition all bottles for all tests). Select **Close** to register the requisition, or **Cancel** to cancel the requisition.
- 4 Select **Entry (F1)**.

- 5 Select **Display Cup Set (F5)**. The QC material and volume required based on the requisition displays.

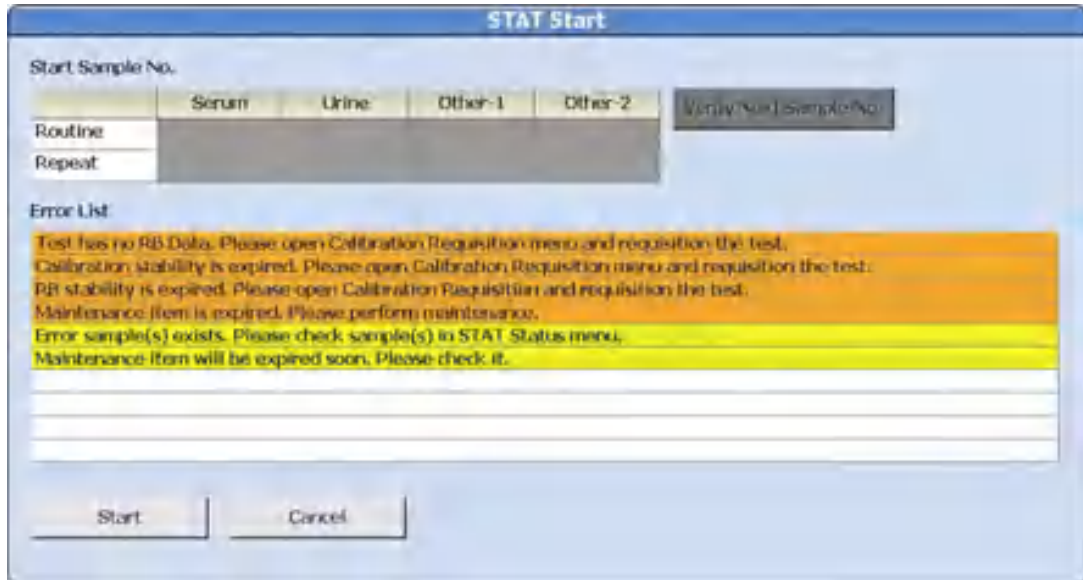
Figure 5.26

Kind	No.	Name	ID	Lot No.	Expiration Date	Intended U	Pos.
app	1	1st Water					000-1
Calibrator	1	10.40.1 Control 1.00		9610111	05/31/2014		20-31
Calibrator	2	10.40.2		9610111	05/31/2014		40-52
Control	1	10.40.1 10.40.1					5-10
Control	2	10.40.2 10.40.2					5-20

- 6 Load the required QC on the STAT table according to the CAL/QC/RB Position window. Use the TABLE ROTATION/DIAG button to rotate the table if necessary. Select **Print** to print a list of the CAL/QC/RB Position window contents, or Close to close the window.
 - If the QC Barcode Operation is not enabled, place the QC in the correct positions according to the "Pos."
 - If the QC Barcode Operation is enabled with Fixed Control positions, place the QC in any Control position (listed under "Kind").
 - If the STAT table is programmed for Free positions (listed under "Kind"), place the barcoded QC in any position.

- 7 Select **STAT Status > STAT Start (F1)**. Review the Error List in the STAT Start window. Verify the required samples are on the STAT table.

Figure 5.27



- 8 Select **Start** to initiate the automatic STAT table check (detects samples) or **Cancel** to take corrective actions.
- 9 If there are no errors specific to the STAT table after the STAT table check, analysis starts. If there are STAT table errors, review the errors in the STAT Start window. Select **Start** to begin analysis, or **Cancel** to perform corrective actions.

5.8 Start Analysis

The reaction time is approximately 8 minutes and 40 seconds for the first result to be obtained after the sample is dispensed. Every 9.0 seconds another test can be sampled.

Results can be viewed on the monitor and printed.

5.8.1 Start Rack Analysis

5.8.2 Start STAT Table Analysis

5.8.1 Start Rack Analysis

- 1 Select **Start** to display the Start window with an Error List if any errors are present. Review errors carefully and perform necessary corrective actions before starting analysis. If an error is in red, it is necessary to perform corrective actions before the analyzer can be started.

TIP Select **Edit Sample No.** to edit the starting sample number. This is only necessary in Sequential analysis.

- 2 Select **Start**. The system initializes and analysis starts if no errors are detected. The mode changes from *Standby* to *Measure 1*.

Figure 5.28

The screenshot shows a software window titled "Start". At the top, it says "Start Sample No." followed by a table with columns: Type, Serum, Urine, Other-1, and Other-2. The rows are: Routine (0001, 0001, 0001, 0001), Emergency (001, 001, 001, 001), Repeat (0001, 0001, 0001, 0001), and Repeat/Emergency (001, 001, 001, 001). To the right of the table is a button labeled "Edit Sample No.". Below the table is an "Error List" section with a yellow background containing two error messages: "No reagent volume to analyze anymore. Please check it at Reagent Management." and "Outdated Stability is expired. Please check Reagent Management and set new reagent to the refrigerator." At the bottom of the window are "Start" and "Cancel" buttons.

Type	Serum	Urine	Other-1	Other-2
Routine	0001	0001	0001	0001
Emergency	001	001	001	001
Repeat	0001	0001	0001	0001
Repeat/Emergency	001	001	001	001

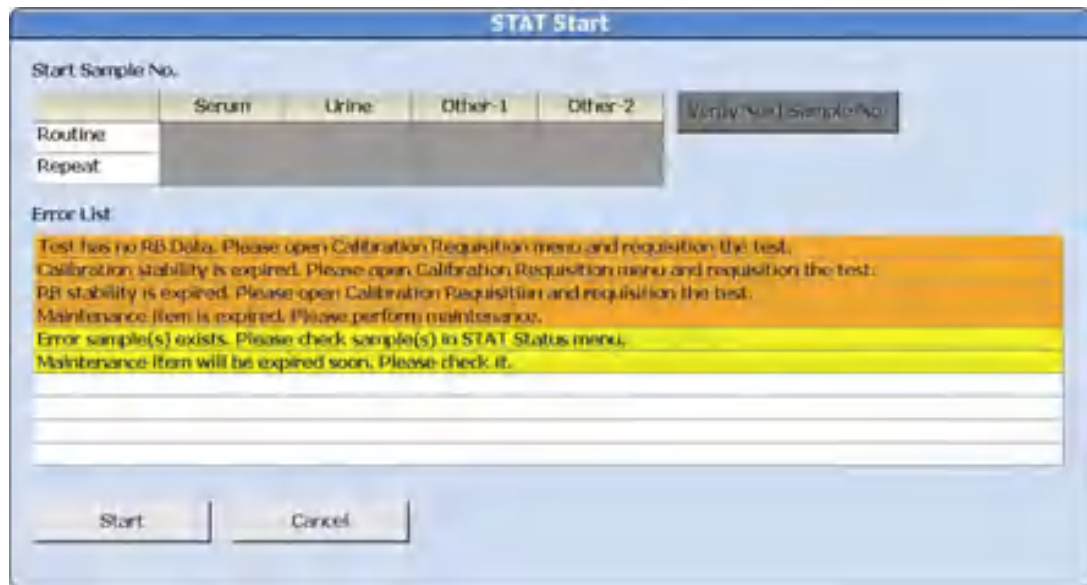
Error List

- No reagent volume to analyze anymore. Please check it at Reagent Management.
- Outdated Stability is expired. Please check Reagent Management and set new reagent to the refrigerator.

5.8.2 Start STAT Table Analysis

- 1 Select **STAT Status > STAT Start (F1)**. Review the Error List in the STAT Start window. Verify the required samples are on the STAT table.

Figure 5.29



- 2 Select **Start** to initiate the automatic STAT table check (detects samples) or **Cancel** to take corrective actions.
- 3 If there are no errors specific to the STAT table after the STAT table check, analysis starts. If there are STAT table errors, review the errors in the STAT Start window. Select **Start** to begin analysis, or **Cancel** to perform corrective actions.

5.9 Startup Checklist (Analyzer and ISE)

The Startup Checklist is a brief summary of the startup procedures required for the analyzer and ISE. For detailed procedures and explanations, refer to this chapter.

Check if Completed	Items to Be Completed
	<p>Set a New Index:</p> <ol style="list-style-type: none"> 1. Select Home > Start Condition. 2. Select Edit (F1) to set up the Index, Group of Tests, and Operator Name. <p>TIP If the system is not On, press the green ON button to turn on the system. Log in to the system if necessary. From the New Index window, select New Index and the "Group of Test."</p>
	<p>Perform Analyzer Daily Maintenance:</p> <ol style="list-style-type: none"> 1. Inspect the syringes for leaks (include ISE syringe). 2. Inspect the Wash Solution Roller Pump for Leaks. 3. Inspect, clean, and prime the sample probe, reagent probe, and mix bars. 4. Inspect the Wash Solution and Replenish As Needed 5. Inspect the printer (optional) and paper. 6. Replace the DI water or diluent in the pre-dilution bottle. 7. Inspect the stability of the upper cover. 8. Prepare the sample probe wash solution. <p>Refer to 8.3 Daily Maintenance for details.</p>
	<p>Check Analyzer Status.</p>
	<p>Perform ISE (Optional Unit) Startup:</p> <ol style="list-style-type: none"> 1. Check the ISE reagent onboard stability and volume. Load as needed. 2. Perform ISE Daily Maintenance: <ul style="list-style-type: none"> • ISE Cleaning. • ISE Calibration. <p>Refer to 8.12 ISE Daily Maintenance for details.</p>
	<p>Perform a Reagent Volume Check:</p> <ol style="list-style-type: none"> 1. Select Home > Reagent Management. Verify sufficient shots remain and "No Reagent" is not displayed in orange. 2. Select Details. Verify Onboard, RB, and Cal stabilities. Check expirations, comments, and fixed bottle positions. 3. Load reagents as needed. 4. Reagent Check (F5) > Check All Positions. 5. Review comments and RB/calibrations required.
	<p>Perform Reagent Blank and Calibration.</p> <p>Refer to 5.6 Perform Calibration for details.</p>
	<p>Perform QC.</p> <p>Refer to 5.7 Perform Quality Control (QC) for details.</p>

Daily Startup

5.9 Startup Checklist (Analyzer and ISE)

Sample Programming and Processing

This chapter describes how to prepare racks and samples for analysis, requisition for samples, process emergency and priority STAT samples, perform repeat analysis, print results, and transfer data to a host computer.

6.1 Prepare Samples for Analysis

6.1.1 Sample Cup and Tube Preparation

6.1.2 Apply Barcode Labels to Sample Tubes

6.1.3 Sample Preparation

6.1.4 Place the Sample Cups/Tubes in the Rack

6.2 Placing Racks on the Rack Supply Unit

6.3 Requisition for Routine and Emergency Samples

6.3.1 Enter Manual Requisitions for Routine and Emergency Samples

6.3.2 Enter Batch Requisitions

6.3.3 Download Requisitions from a Host Computer

6.4 Processing Emergency Samples

6.5 Priority STAT Samples

6.5.1 Enter Manual Requisitions for Priority STAT Samples

6.5.2 Processing Priority STAT Samples

6.5.3 Simple STAT mode

6.6 Performing a Repeat Run

6.6.1 Auto Repeat for Racks and the STAT Table

6.6.2 Repeat Requisitions for Manual Repeat

6.6.3 Perform a Manual Repeat in an Orange Rack

6.6.4 Perform a Manual Repeat from the STAT Table

6.7 Print Results

6.7.1 Print Sample Data Reports

6.7.2 Print Reagent Blank, Calibration, and QC Results

6.8 Transfer Data to Host Computer

6.8.1 Sample Data

6.8.2 Reagent Blank, Calibration, and QC Data

6.1 Prepare Samples for Analysis

- 6.1.1 Sample Cup and Tube Preparation
- 6.1.2 Apply Barcode Labels to Sample Tubes
- 6.1.3 Sample Preparation
- 6.1.4 Place the Sample Cups/Tubes in the Rack

6.1.1 Sample Cup and Tube Preparation

The following table lists the sample cups and sample tubes that can be used for the AU480.



Use only sample cups and tubes listed in the specifications and recommended by Beckman Coulter. If other cups or tubes are used, analysis cannot be performed, or errors can result.

TIP BD indicates a Becton Dickinson part number. The BD tube or its equivalent can be used.

Cup or Tube Available for Racks or STAT Table			
Cup or Tube	Size	Part Number	Dead Volume (µL)
Hitachi cup	2.0 mL	MU853200	50
Auto aliquot tube	13 mm	2910034	90
Serum Separator Tube	13 x 100 mm	BD 367986	4 mm below sample surface
Serum Separator Tube	16 x 100 mm	BD 367988	4 mm below sample surface
Lithium heparin with gel separator (light green top)	13 x 75 mm	BD 367960	4 mm below sample surface
Lithium heparin with gel separator (light green top)	13 x 100 mm	BD 367962	4 mm below sample surface
Lithium heparin (green top)	13 x 75 mm	BD 367884	4 mm below sample surface
Lithium heparin (green top)	13 x 100 mm	BD 367886	4 mm below sample surface
Primary tube (red top)	13 x 75 mm	BD 366668	140
Primary tube (red top)	13 x 100 mm	BD 367815	140

Cup Nested (Inserted) in Tube Available for Racks				
Cup, Size	Part number	Tube	Part number	Dead Volume (µL)
DxC cup, 2.0 mL	652730	DxC transfer	979272	60
Access 2 cup, 2.0 mL	81902	DxC transfer	979272	60
Access 2 cup, 1.0 mL	81915	13 x 75 mm	BD 367960 BD 367884 BD 366668	140
Hitachi cup, 2.0 mL	MU853200	SST 16x100 mm	BD 367988	50
EZ Nest cup	1270013000	13 x 75 mm	BD 367960 BD 367884 BD 366668	60
EZ Nest cup	1270013000	13 x 100 mm	BD 367962 BD 367886 BD 367815	60
EZ Nest cup	1270016000	16 x 75 mm	BD 364976	50
EZ Nest cup	1270016000	16 x 100 mm	BD 367988	50

The analyzer has five sensors to detect the height of the cup or tube in a rack. The following restrictions apply when using more than one cup or tube simultaneously:

1. One type of cup or tube can be selected for each sensor.
2. More than one type of cup or tube can be selected for each sensor *only if* the cup or tube is the same Level A, B, C, D, E, or F.

 **WARNING**

If more than one type of cup or tube is in use for a sensor and the cup or tube is not the same Level (A, B, C, D, E, or F):

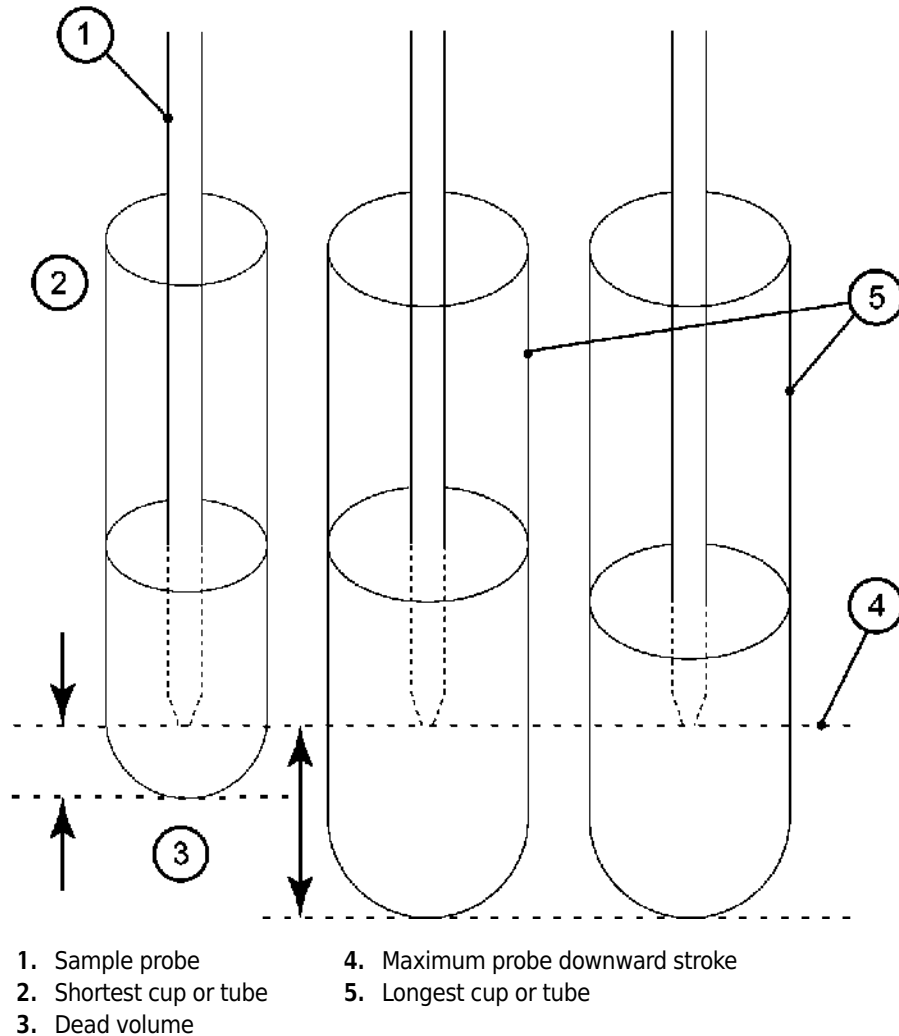
- If the maximum probe stroke is programmed to the shortest cup or tube, it is possible that no sample is aspirated, or the dead volume is increased for the longest cup or tube.
- If the maximum probe stroke is programmed to the longest cup or tube, the shortest cup or tube must contain sufficient sample to avoid a probe crash.

Sample Programming and Processing
 6.1 Prepare Samples for Analysis

Racks				
Sensor	Level	Cup or Tube		Tube
1	A	Hitachi cup	MU853200	
2	A	Lithium heparin with gel separator (light green top)	BD 367960	
	A	Lithium heparin (green top)	BD 367884	
	A	Primary tube (red top)	BD 366668	
	B	DxC cup	652730	DxC transfer tube (979272)
	C	Access 2 cup	81902	
	D	Access 2 cup	81915	13 x 75 mm tube
	E	EZ Nest cup	1270013000	
	F	EZ Nest cup	1270016000	16 x 75 mm tube
3	A	Hitachi cup	MU853200	16 x 75 mm tube
4	A	Serum Separator Tube	BD 367986	
	A	Lithium heparin with gel separator (light green top)	BD 367962	
	A	Lithium heparin (green top)	BD 367886	
	B	Auto aliquot tube	2910034	
	C	Access 2 cup	81915	13 x 100 mm tube
	D	EZ Nest cup	1270013000	
	E	EZ Nest cup	1270016000	16 x 100 mm tube
5	A	Hitachi cup	MU853200	16 x 100 mm tube

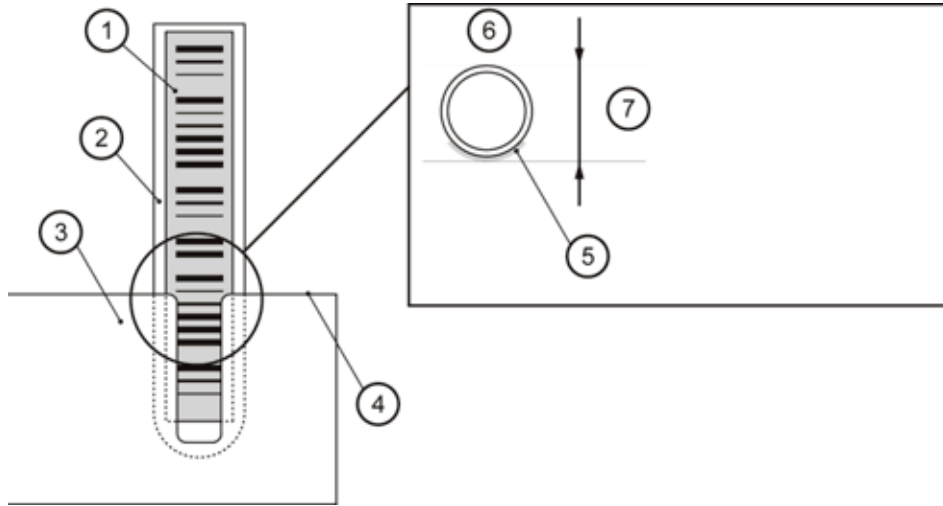
The default probe setting in the software for each cup and tube is Level A. If using a cup or tube other than Level A, contact Beckman Coulter Technical Services. Your field service engineer (FSE) is required to make probe setting changes.

Figure 6.1



The maximum outer tube or cup diameter is 16 mm, including a sample barcode label. If the tube or cup has a protrusion or lip at the top, the maximum outer diameter is 17.5 mm. If the diameter is greater than 17.5 mm, the tubes interfere when placed next to each other in the rack.

Figure 6.2



- | | |
|------------------|--|
| 1. Barcode label | 5. Barcode label |
| 2. Sample cup | 6. Top view |
| 3. Rack | 7. 16.0 mm or less |
| 4. Rack top | (outside diameter including the barcode label) |

The following information applies when using the STAT table:

WARNING

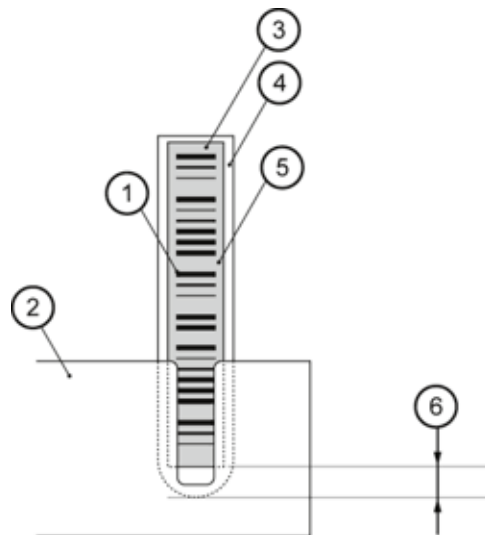
The analyzer has only *one* sensor to detect the cup or tube on the STAT table; therefore, only one maximum probe downward stroke can be programmed. The maximum probe downward stroke must be programmed for the cup or tube with the lowest bottom position. If primary tubes and tubes with nested cups are both being used on the STAT table, the nested cup must contain sufficient sample to avoid a probe crash into the nested cup.

Cup Nested (Inserted) in Tube Available for STAT Table				
Cup, Size	Part number	Tube	Part number	Dead Volume (µL)
DxC cup, 2.0 mL	652730	DxC transfer	979272	60
Access 2 cup, 2.0 mL	81902	DxC transfer	979272	60
Access 2 cup, 1.0 mL	81915	13 x 75 mm	BD 367960 BD 367884 BD 366668	140
EZ Nest cup	1270013000	13 x 75 mm	BD 367960 BD 367884 BD 366668	60
EZ Nest cup	1270016000	16 x 75 mm	BD 364976	50

6.1.2 Apply Barcode Labels to Sample Tubes

- 1 Affix the barcode labels to the outside of the sample tube so the end of each label is at least 7 mm from the bottom of the tube.
- 2 Rub the label gently using a finger to ensure that it is firmly attached and does not peel off.

Figure 6.3



- | | |
|---|-----------------|
| 1. Barcode | 4. Sample tube |
| 2. NE rack (see TIP below) | 5. Label |
| 3. The inclination angle must be 5° or less | 6. 7 mm minimum |

Barcode Labels for Rack Analysis



WARNING

Barcode labels that are too long or too short might not be identified by the barcode reader.

Barcode labels must not protrude from the top of a sample cup or tube. The label must be positioned perpendicularly. The angle can vary by a maximum of 5°.

For details on barcode specifications, refer to [2.3.2 Sample Barcode Specifications](#) in chapter 2.

TIP An NE rack has the slit shown in the diagram above to enable the barcode label to be placed below the top surface of the rack. This “flexible” rack allows for various tube diameters to be used with or without adapters. Use only NE racks on the AU480.

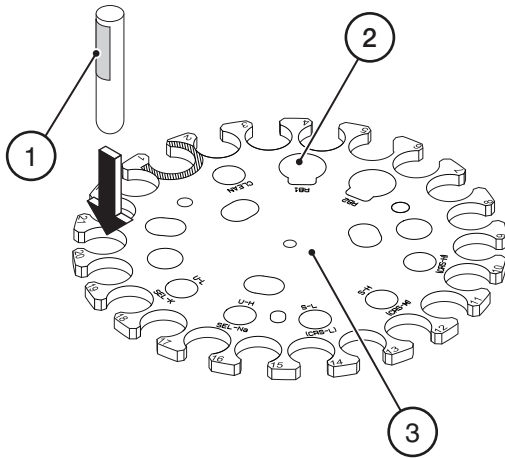
Racks that are not NE have a solid top surface with holes for the tubes with a set diameter.

Barcode Labels for STAT Table Analysis

Placing samples with barcode labels on the STAT table:

The outer positions (1-22) are used for STAT analysis. Place the tube on the table with the barcode label facing out from the center of the table.

Figure 6.4



1. Place the tube in outer position 1-22 with the label facing out from the center of the table
2. The inner positions are not available for barcode analysis
3. STAT table

6.1.3 Sample Preparation

Verify that there is sufficient sample for analysis in addition to the dead volume. To display the volume needed for the required tests, select **Home > Rack Requisition Sample** or **STAT Status > Sample**. The sample volume required for requisitioned tests displays at the lower right hand side of the window. The sample volume does not include the dead volume.

The minimum dead volume required for sample detection varies depending on the sample cup/tube.

After centrifuging sample tubes, verify there is sufficient volume of serum or plasma. If the serum or plasma level is too low, transfer it to a smaller sample cup to avoid blood cells or gel separator being aspirated.

Follow laboratory best practices and Standard Operating Procedures to ensure the sample is dispensed into the center of the cup or tube. The sample surface should be level with no bubbles present before analysis.

 **WARNING**

Pay attention to the following items. The analysis results can be affected and system errors may occur.

- The sample should not contain fibrous material or fibrin.
- Verify that no air bubbles are in the samples.
- Dispense sample volume in the quantity required for analysis plus the dead volume.

For information about dead volumes for tubes and cups, refer to [6.1.1 Sample Cup and Tube Preparation](#).

- In Specific Test Parameters, the Sample Volume Dilution can be set to 0 μL (default) or 10 μL . When Dilution is set to 0 μL , an additional 3 μL per test is aspirated in addition to the required sample volume for dispensing accuracy. For example, if the sample volume of a test is 3 μL , the sample aspiration volume is 6 μL . If 10 tests are requisitioned on a sample, the required volume is the sample volumes for the 10 tests, plus 30 μL . When Dilution is set to 10 μL , no additional sample volume is dispensed per test.
- After sample aspiration, the sample probe is rinsed in the wash well, and a small amount of water is transferred to the sample when the next test is aspirated. If there is a very small initial sample volume, and 20 tests or more are being analyzed on the sample, it is recommended to add an additional 200 μL to the required sample volume to avoid diluting the sample.
- Verify that a volume of serum or plasma sufficient for analysis plus the dead volume needed is present in a primary sample container. The dead volume required in a primary sample container is 4 mm above the non-sample (cells or gel layer). The dead volume required for a sample cup is 4 mm above the bottom of the cup.
- When the serum quantity is small, perform analysis after transferring the sample to a smaller sample cup.
- When the serum quantity is small, blood cells below the serum may be aspirated and results may be affected.

6.1.4 Place the Sample Cups/Tubes in the Rack













Rack preparation

Before starting analysis, dispense a sample into sample cups/tubes and set these cups/tubes in the correct rack.

The racks come in six different colors. Each rack color has a specified purpose or application. Racks are placed on the rack supply unit. A maximum of 8 racks, or 80 samples can be placed on the rack supply unit. Racks can be continuously loaded on the rack supply unit as space is available.

Rack types

The system identifies the rack type from the combination of magnets set into the rack bottom. The rack colors, applications, and magnet combinations are shown below.

Color	Rack Application	Magnet 1 2 3
White 	Used for analyzing routine samples and Auto Repeat run samples.	
Blue 	Used for calculation of reagent blanks for creation of calibration curves.	
Yellow 	Used for creation of calibration curves.	
Green 	Used for analysis of QC samples.	
Orange 	Used for manual repeat run analysis.	
Red 	Used for emergency sample analysis.	

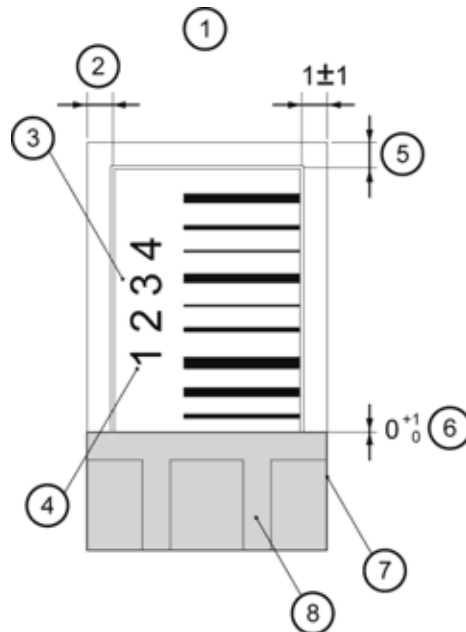
The rack positions are numbered 1 to 10. The magnets are located on the bottom of the rack at the position number 1 end.

Placing a barcode label (rack ID) on the rack

All racks (yellow, green, white, red, orange) except the blue rack require a barcode before they are processed.

- 1 Apply the rack ID label to the front (position 1 end) of the rack, perpendicular to the protruding part of the rack. Refer to the diagram below. The units are in mm.

Figure 6.5



- | | |
|--|---|
| <ol style="list-style-type: none"> 1. Rack front 2. The label should not stick out from the rack. 3. Rack ID label (Stick the label on the rack parallel with the side face.) 4. Orient the label so the numbers are located to the left if viewed from the front. | <ol style="list-style-type: none"> 5. The label should not stick out from the rack. 6. The label cannot be placed on the protruding part of the rack. 7. Rack side 8. Protruding part of the rack |
|--|---|

WARNING

Barcode labels in bad condition may cause them to be read incorrectly.

Replace barcode labels if any of the following conditions are observed.

- The Barcode label is smudged, scratched, or damaged.
- The Barcode is stained or dirty.
- The Barcode label is torn or peeling.

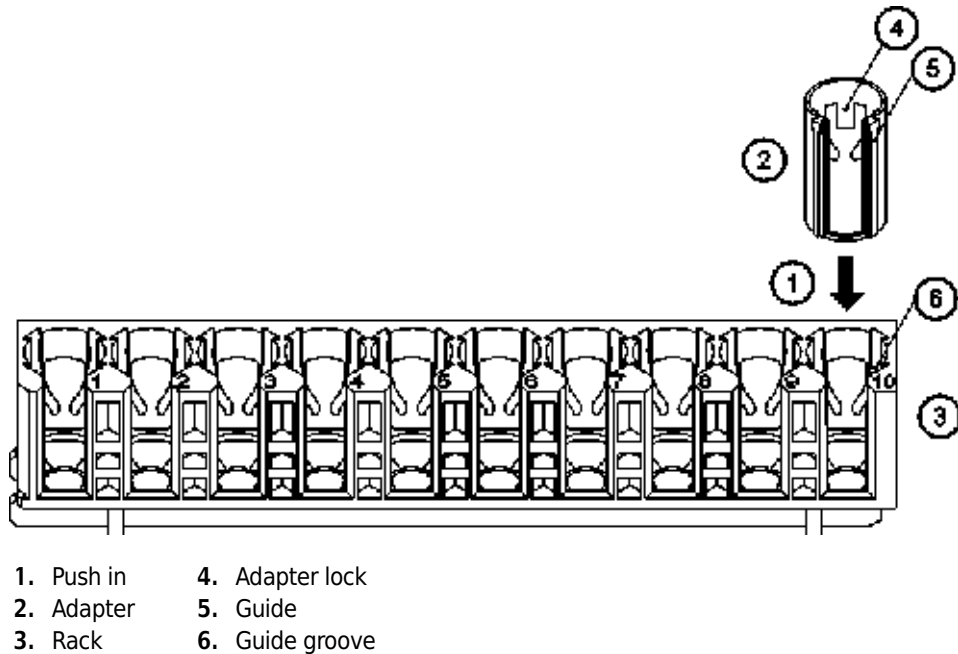
Using Adapters on Sample Racks

Adapters are required to hold smaller diameter tubes (approximately 11.5 to 13.5 mm) firmly in place in the racks. Larger diameter tubes (approximately 13.6 to 16 mm) do not require adapters. To ensure a tube fits correctly, place the tube into a rack with and without an adapter and determine which option holds the tube most securely.

To insert an adapter:

- 1 Align the adapter opening and the rack opening.
- 2 Insert the adapter guide into the guide groove of the rack.
- 3 Push the adapter into the rack until a click is heard.
- 4 Ensure the adapter has engaged the rack.

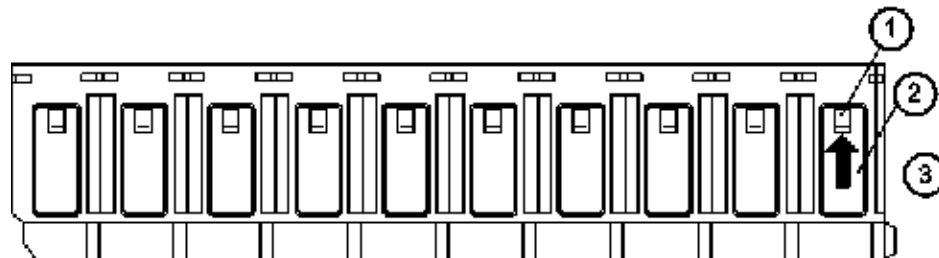
Figure 6.6



To remove an adapter:

- 1 Push the adapter lock lightly with a finger from the outside of the rack window to disengage the lock.
- 2 When the upper edge of the adapter comes out from the rack, pull it out the rest of the way.

Figure 6.7



1. Adapter lock
2. Rack window
3. Push up lightly with a finger

Placing Samples into each Rack Type

White, red, and orange racks are designated for serum, urine, Other-1, or Other-2 sample types in **Menu List > System > System Condition**. In addition to the following specifications, samples must be placed in the correct rack for sample type.

White rack (Routine analysis)

Set the sample cups or tubes according to the analysis mode.

- Sequential analysis
Place cups or tubes in numeric order according to the requisition without leaving empty spaces in the rack.
- Rack ID analysis
Place samples in Sample No. order according to the rack ID and sample position (1 to 10) in the rack. The Sample No. equals (rack ID number -1) x 10 + position.

For example:

Sample No.	Rack No.	Position
1	1	1
12	2	2
25	3	5

- Barcode analysis
Samples can be placed in any order.

 **WARNING**

- In Sequential analysis, place samples in numeric Sample No. order according to the requisition without leaving any empty positions in the racks. **IF THERE ARE EMPTY POSITIONS IN THE RACKS, THE REQUISITIONED SAMPLE NO. AND THE SAMPLE NO. DETERMINED DURING ANALYSIS DOES NOT COINCIDE, AND CONCORDANCE ERRORS CAN OCCUR.**
- Beckman Coulter does not recommend running patient samples in sequential mode as positive patient identification cannot be maintained.

For details on the analysis modes, refer to [4.10.1 Analysis Mode Menu](#) in chapter 4.

Blue rack (Reagent Blank)

Place a sample cup/tube filled with Deionized (DI) water in position 1 in the blue rack. Refer to [4.5.1 Calibrators Menu](#) in chapter 4 for reagent blank programming options.

Yellow rack (Calibrators)

In **Calibration Parameters**, calibrator material is programmed to a calibrator number (1 to 200).

Calibrator numbers 1 to 200 are identified by the rack ID and position. For example, calibrator numbers 1 to 10 are placed in rack ID 0001, calibrator numbers 11 to 20 are placed in rack ID 0002, and so on.

For details on setting the positions for calibrators, refer to [4.5.1 Calibrators Menu](#) in chapter 4.

A calibrator ID can be assigned to the calibrator material if the calibrator barcode operation option is turned on. Calibrators with barcodes can be placed in any position in the yellow racks, except the highest calibrator number must be last in the highest rack ID for the run.

Green rack (Quality Control)

In **QC Parameters**, control material is programmed to a QC number (1 to 100).

Control numbers 1 to 100 are identified by the rack ID and position. For example, control numbers 1 to 10 are placed in rack ID 0001, control numbers 11 to 20 are placed in rack ID 0002, and so on.

For details on setting the position for controls, refer to [4.6.1 Controls Menu](#) in chapter 4.

A QC ID can be assigned to the control material if the QC barcode operation option is turned on. Controls with barcodes can be placed in any position in the green racks, except the highest control number must be last in the highest rack ID for the run.

Orange rack (Manual repeats)

If Sequential analysis is in use, place samples in numeric Sample No. order according to the repeat run requisition without leaving empty positions in the racks. Use a rack programmed for the correct sample type.

If Barcode analysis is in use, place samples in any position in the rack programmed for the correct sample type.

Red rack (Emergency analysis)

In Sequential analysis, place samples in numeric requisition order. The system automatically assigns sample numbers based on the tubes or cups detected, so empty spaces can be left in the rack.

Use a rack programmed for the correct sample type. For example, if three samples are requisitioned and put in positions 1, 3, and 5, the system assigns E001 to the sample in position 1, E002 to the sample in position 3, and E003 to the sample in position 5.

In Barcode analysis, the tubes can be placed in any order in the rack programmed for the correct sample type.

 **WARNING**

- **When red racks are used for sequential analysis, use a worklist to confirm the results correspond to the samples as processed in the rack.**
- **Beckman Coulter recommends the use of bar coded samples to guarantee positive patient identification.**

Place the sample cups/tubes in a rack

The following section provides information on the correct placement of cups/tubes in a rack.

1 Place each sample in the correct rack.

Racks are color coded. Each color indicates a different type of analysis. If racks are programmed for different sample types (serum, urine, other-1, and other-2), place the sample in the correct rack for the sample type.

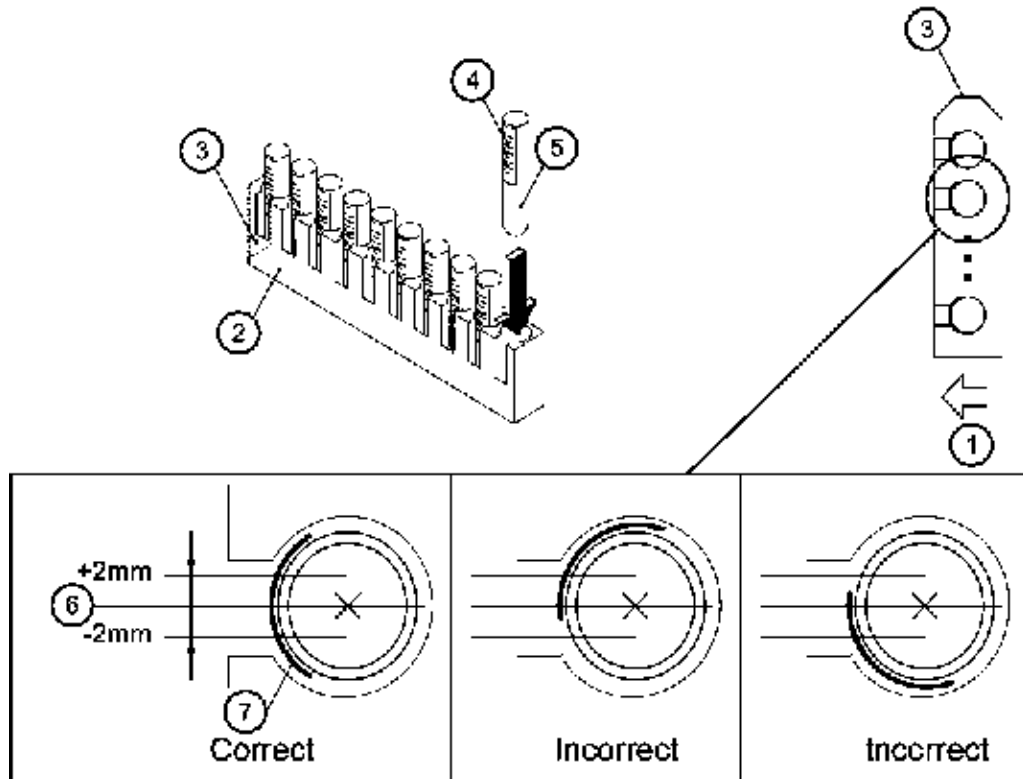
For details on assigning rack ID numbers for specific sample types, refer to [4.10.2 Program the Rack Number Limit](#) in chapter 4.

 **WARNING**

Insert the sample tubes/cups properly into the rack. If the tube or cup is not pushed down to the bottom of the rack, cup detection does not work properly and rack jams can occur.

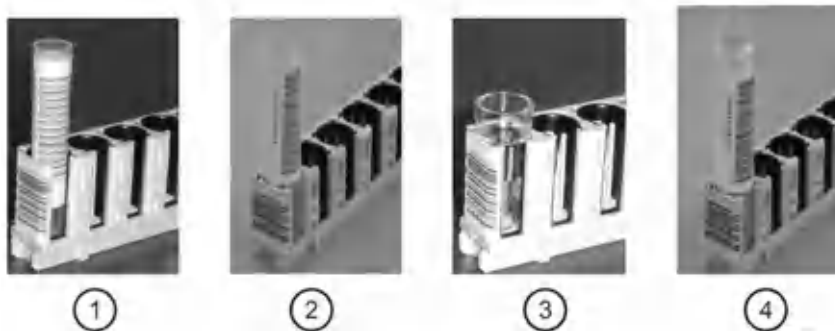
- Look at each opening in the rack and ensure the barcode is aligned in the center. 2 mm is the most each barcode should deviate from the center. If a barcode label is not aligned with the opening in the rack, lift it out and place it in correctly.

Figure 6.8



- | | |
|--|------------------|
| 1. Direction that rack moves | 5. Sample cup |
| 2. NE Rack | 6. Center |
| 3. The rack ID label is applied to this surface. | 7. Barcode label |
| 4. Barcode label | |

Figure 6.9



- | | |
|--------------------------------|--|
| 1. Small diameter tube with ID | 3. Hitachi cup |
| 2. Large diameter tube with ID | 4. Large diameter tube with ID + Hitachi cup |



WARNING

- For sample tubes with barcode labels, do not rotate the tube while it is in the rack. Rotating may cause barcode contamination or damage, resulting in barcode read errors. Rotate sample tubes after they have been removed from the racks.
- **RUNNING THE SYSTEM IN SEQUENTIAL ANALYSIS MODE (NOT READING A SAMPLE ID) IS NOT RECOMMENDED. THERE IS A POSSIBILITY OF SAMPLE/ RESULT MISMATCH. IF RUNNING IN SEQUENTIAL ANALYSIS MODE, BE AWARE OF THE RISKS INVOLVED. CONTACT BECKMAN COULTER TECHNICAL SERVICES FOR MORE INFORMATION.**
- Use only NE racks.

TIP An NE rack has a window on the side to facilitate setting different sample cup types in the rack and not compromise barcode readability.

6.2 Placing Racks on the Rack Supply Unit

A maximum of 8 racks (80 samples) can be placed on the rack supply unit.

WARNING

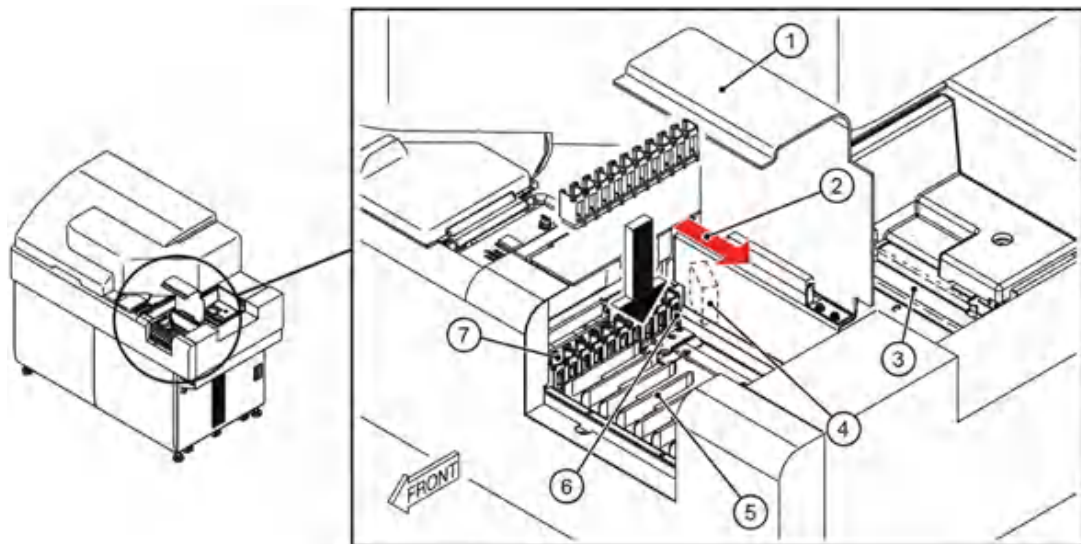
Never look directly into the barcode readers. The LED can cause serious eye damage.

To place racks on the rack supply unit:

TIP If Auto Repeat is in use, the rack supply unit automatically moves approximately every 30 seconds to move racks with samples requiring repeat analysis. Do not place racks on the rack supply unit if the rack supply unit is moving.

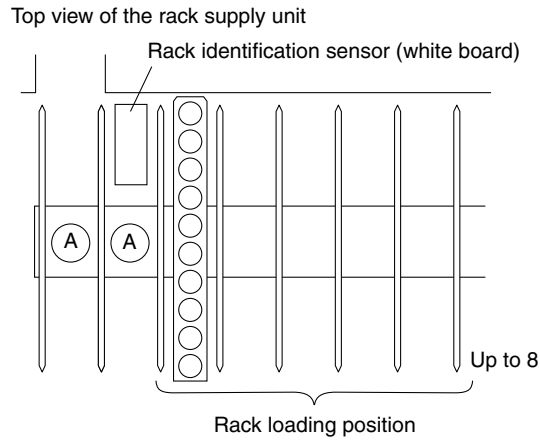
- 1 Open the sample protection cover.
- 2 Place the racks on the rack supply unit.

Figure 6.10 Top View of Rack Feeder Unit



- | | |
|---|-------------------------------------|
| 1. Sample protection cover | 5. Rack supply unit |
| 2. Barcode reader laser radiation (Sample ID) | 6. Surface where rack ID is applied |
| 3. Rack Collection Unit | 7. Rack |
| 4. Window for reading rack ID | |

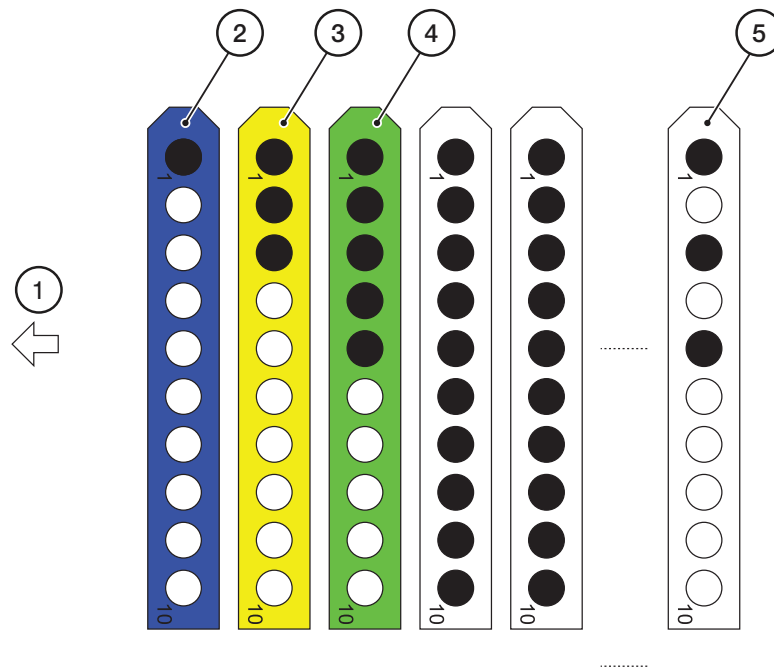
Figure 6.11



Place the first rack to the right of position A. The rack supply unit does not operate properly when it is placed on position A.

- 3** For calibration and QC, place the blue rack followed by the yellow rack(s), followed by the green rack(s). Place the white racks for routine patient samples.

Figure 6.12



1. Direction that the racks move on the rack supply unit.
2. Place a cup filled with DI water or diluent in position 1 or 2
3. Place in any order
4. Place in any order
5. Place in any order

TIP DI water or diluent can be assigned to position 1 or 2 in the blue reagent blank rack in **Parameters > Calibration Parameters > Calibrators** in the RB Sample Information fields for each sample type.



- When several yellow racks are required for creation of calibration curves, set the yellow racks one after the other.
- When several green racks are required for QC analysis, set the green racks one after the other. Close the sample protection cover.

4 Close the sample protection cover.

6.3 Requisition for Routine and Emergency Samples

Sample information and the tests requested to run on a sample (requisitions) must be entered for each sample to be analyzed.

The system uses these requisitions to process each sample.

To run an emergency sample, requisition the sample as Emergency, and place the sample in a red rack. Place the red rack in front of routine white racks on the rack supply unit.

[6.3.1 Enter Manual Requisitions for Routine and Emergency Samples](#)

[6.3.2 Enter Batch Requisitions](#)

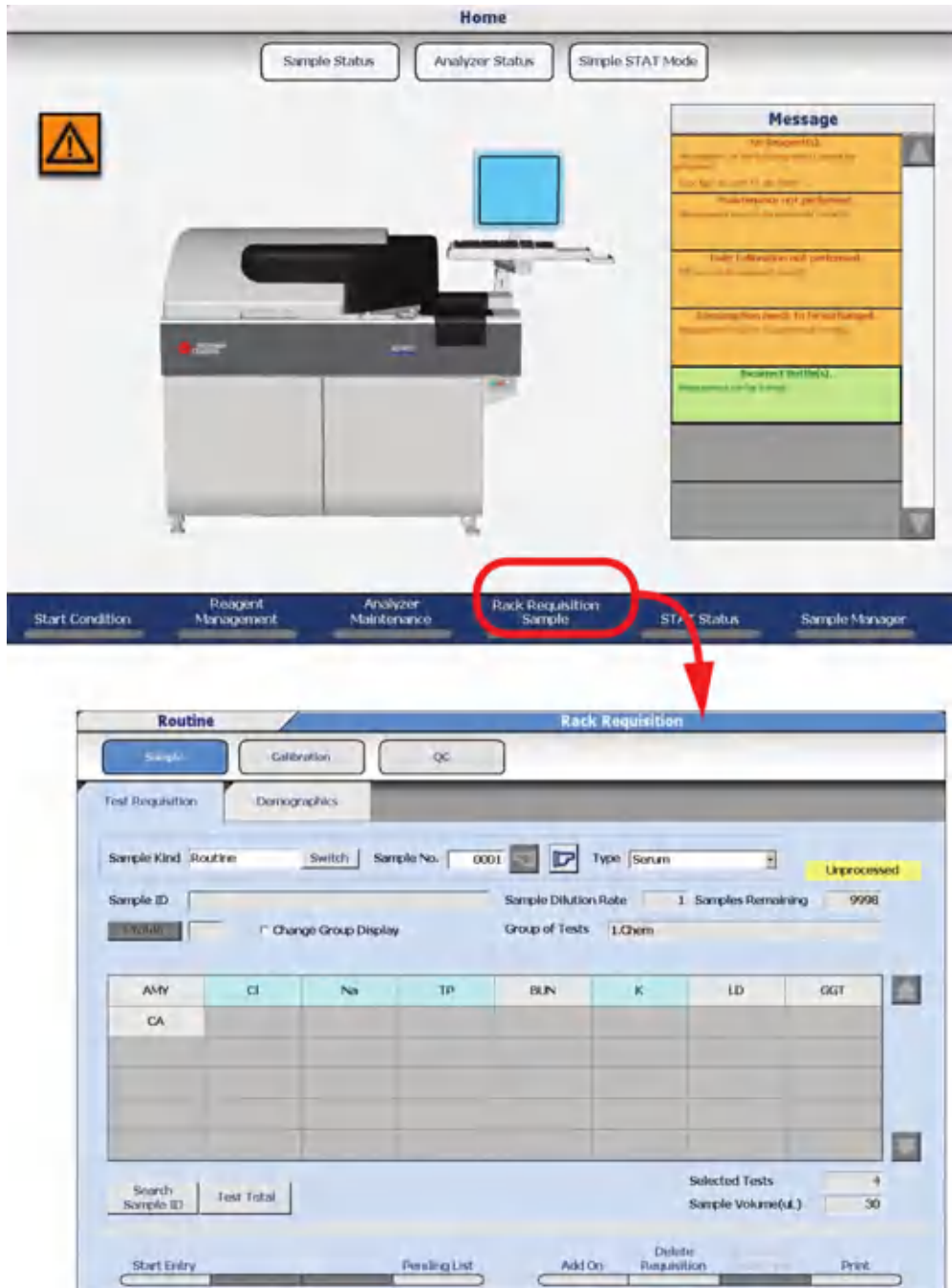
[6.3.3 Download Requisitions from a Host Computer](#)

6.3.1 Enter Manual Requisitions for Routine and Emergency Samples

TIP The following operations are not necessary when LIS programming is available.

- 1 Select **Home > Rack Requisition Sample > Sample > Test Requisition**. The Group of tests display from the Group selected in **Start Condition**.

Figure 6.13



-
- 2** Select **Switch** for Sample Kind to select **Routine** or **Emergency** samples.

Routine: Routine analysis in a white rack

Emergency: Analysis in a red rack

- 3** Select the sample type from the "Type" drop-down list.
-

- 4** Select **Start Entry (F1)**. The window changes to the edit mode.

TIP When a test not in the present group is to be selected, select the "Change Group Display" check box. The tests for all groups are displayed on the list.

- 5** For Sample ID, enter the sample barcode number.
-

- 6** If a manual dilution was made on the sample, select **Sample Dilution (F7)** and enter the sample dilution rate.
-

- 7** Select the test(s) to run on the sample. A test highlights in blue when it is requisitioned. Select the test again to cancel the requisition. Tests highlighted in gray are not operational for the sample type selected.

When selecting a profile, perform one of the following operations.

- a. Select **Profile** to open the profile window and select a profile (or multiple profiles).
- b. Use the keyboard to enter a profile number into Profile and press **Enter**.

TIP It is necessary to program profiles in **Menu List > Parameters > Common Test Parameters > Profile > Sample** before a profile is available to requisition. A maximum of 99 profiles can be created for each sample type.

Each time a test is selected, the Selected Tests and Sample Volume fields are updated.

- 8** Select the **Demographics** tab to enter any required patient demographic information.
-

- 9** Confirm the entered information and select **Entry (F1)**. The entered information is programmed.
-

- 10** Repeat steps 5 through 12 to requisition additional samples in the same Sample Kind and Type. To change the Sample Kind or Type, select **Exit (F2)** and repeat steps 2 through 12.

11 Select **Exit (F2)**.

TIP Pending List (F4)

View a list of samples that have been requisitioned, but not yet processed on the analyzer. Select a Sample No. or Sample ID number, then select **Go** to view the specific sample requisition.

Add-On (F5)

“Add-On” a test to a previously processed sample in the white rack. Run the sample again in the white rack to perform the add-on test(s).

Delete Requisition (F6)

This function is used to delete registered requisition information before the start of analysis. Select each “Sample Kind”, then specify the Sample No. or Sample ID to delete.



“Sample Volume (μL)” does not include the dead volume. Approximate values are shown.

6.3.2 Enter Batch Requisitions

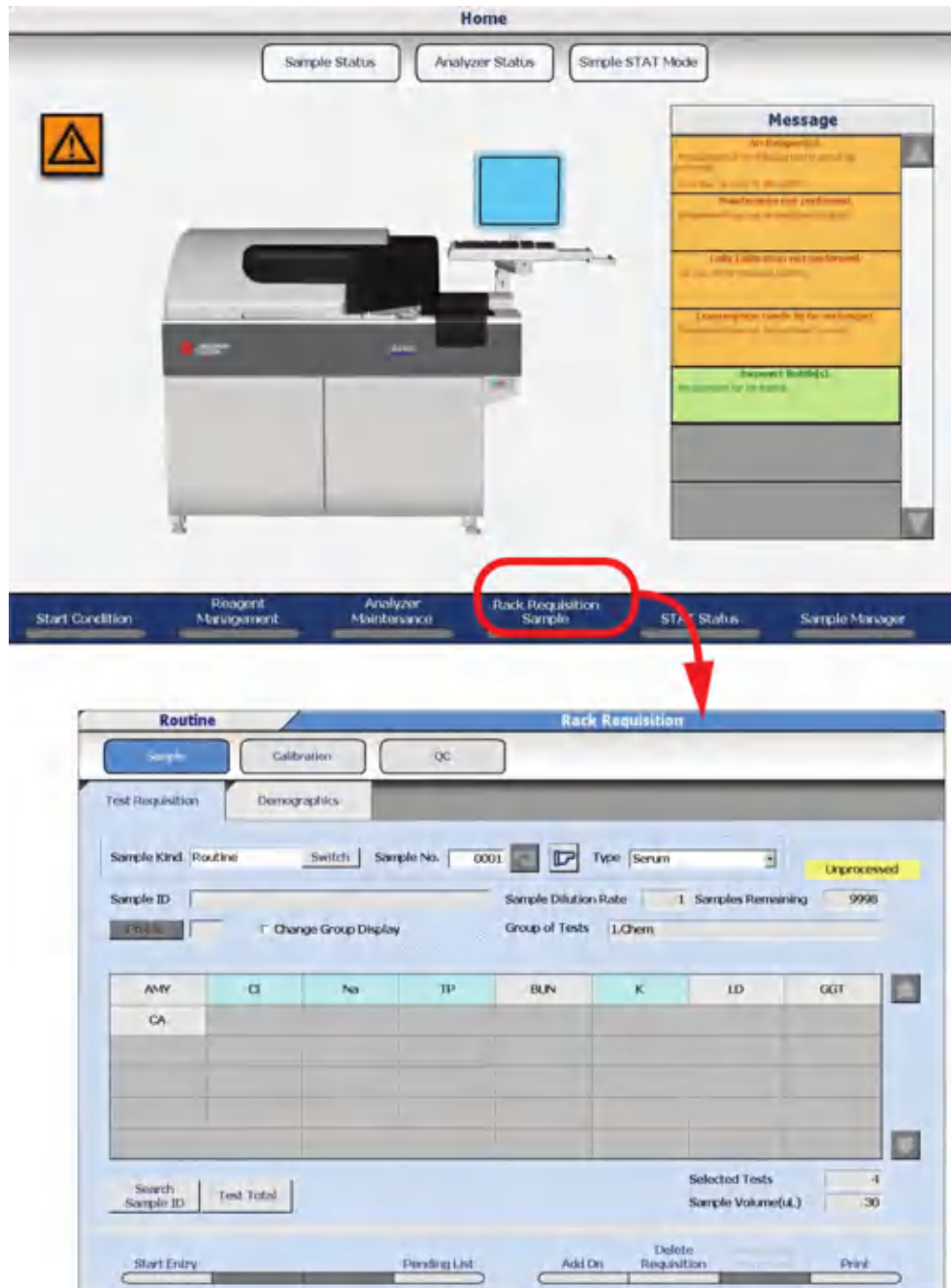
To perform the same tests on a number of samples, enter the requisitions in a single batch.

Tests requisitioned for one sample are requisitioned for all samples in the batch. Patient information entered for a single sample in the **Demographics** tab is requisitioned for all samples in the batch. If barcode analysis is in use, the Sample ID entered for the first sample automatically increments by one digit for subsequent samples.

To enter batch requisitions:

- 1 Select **Home > Rack Requisition Sample > Sample**. The Group of tests display from the Group selected in **Start Condition**.

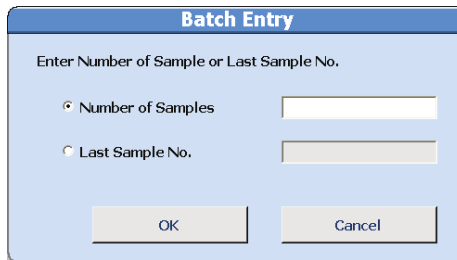
Figure 6.14



- 2 Select **Start Entry (F1)**.

- 3 Select the test(s) or profile for batch requisition for one sample. For details on manually requisitioning tests, refer to [6.3.1 Enter Manual Requisitions for Routine and Emergency Samples](#).
- 4 Select **Batch Entry (F3)**. The Batch Entry window opens.

Figure 6.15



The screenshot shows a dialog box titled "Batch Entry" with the subtitle "Enter Number of Sample or Last Sample No.". There are two radio buttons: "Number of Samples" (which is selected) and "Last Sample No.". Each radio button is followed by a text input field. At the bottom of the dialog are two buttons: "OK" and "Cancel".

- 5 Select **Number of Samples** to enter the actual number of samples required in the batch, or select **Last Sample No.** to enter the last sample number in the batch.
- 6 Select **OK**.
- 7 Select **Exit (F2)**.

6.3.3 Download Requisitions from a Host Computer

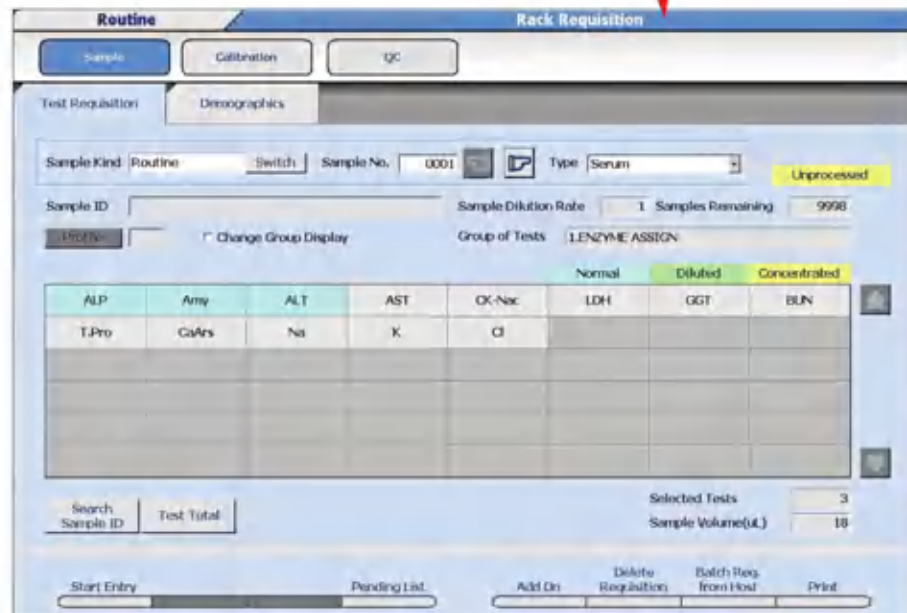
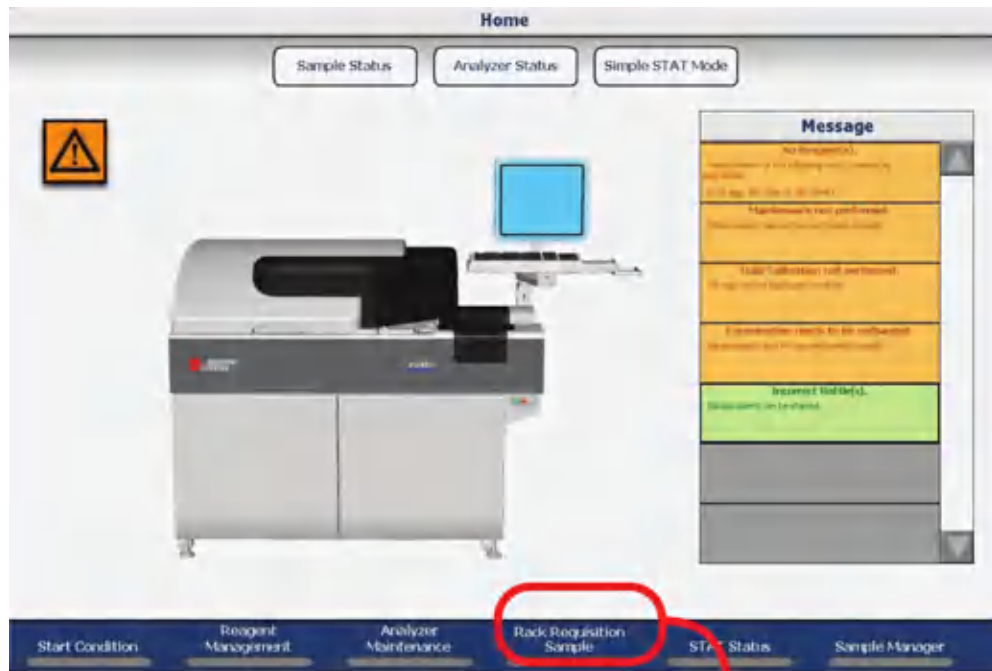
Requisitions can be downloaded from a clinical laboratory host computer system. Downloading can be:

- Realtime: the system downloads and executes requisitions automatically.
- Batch: the system waits for a user to instruct it to download and execute requisitions.

For information on how to configure these modes, refer to [4.12 Program Online Parameters](#) in chapter 4.

- 1 Select **Home > Rack Requisition Sample > Sample**.

Figure 6.16



- 2 Select **Batch Req. from Host (F7)**.

- 3 Select the sample kind and type to download from the host computer from the "Sample Kind" drop-down list.
- 4 For Sample No. enter the starting and ending sample numbers to download from the host computer.
- 5 Select **OK**. A message displays while the requisitions are downloading. When the download is complete, the message window closes.

Figure 6.17



6.4 Processing Emergency Samples

Red racks are used for analysis of emergency samples. Emergency samples can be processed with priority over routine samples by placing the red racks in front of the white racks on the rack supply unit. Emergency samples are identified by an “E” sample number prefix in the requisition and sample results.

The quickest way to process a sample is from the Priority STAT Table. Refer to [6.5.2 Processing Priority STAT Samples](#).

6.5 Priority STAT Samples

The STAT table is used for analysis of priority STAT samples. Priority STAT samples run on the STAT table interrupt the routine and emergency samples being processed from the rack transport belt. A priority STAT is the fastest way to process a sample. Priority STAT samples are identified by a "P" sample number prefix in the requisition and sample results.

6.5.1 Enter Manual Requisitions for Priority STAT Samples

6.5.2 Processing Priority STAT Samples

6.5.3 Simple STAT mode

6.5.1 Enter Manual Requisitions for Priority STAT Samples

TIP If communication with the LIS is not functioning, requisitions can be made for priority STAT samples in **STAT Status**.

- 1 Select **Home > STAT Status > Sample**.

Figure 6.18



- 2 Select **Start Entry (F1)**.
- 3 Select the sample type from the "Type" drop-down list.
- 4 Enter the sample ID (barcode number) at Sample ID.
- 5 Select the test(s) or profile to be performed.

-
- 6** Select **Entry (F1)**.
-
- 7** Repeat steps 4 through 6 to requisition another sample with the same sample type.
-
- 8** Select **Exit (F2)** to end the requisition process.
-
- 9** To requisition for a sample with a different sample type, repeat steps 2 through 8.
-

6.5.2 Processing Priority STAT Samples

Use **STAT Status** to run and monitor the progress of priority STAT samples, reagent blank, calibrators, and controls.

STAT Start (F1):	Starts priority STAT analysis on the STAT table.
STAT Pause (F2):	Moves the STAT table to <i>Pause</i> . Use the button to load a new sample or remove dispensed sample(s) when the amber STAT TABLE LED is blinking.
STAT Check (F3):	Checks for the presence of a cup or tube and reads the sample ID (if Barcode Analysis is in use) for all 22 STAT table positions. Use this button before starting analysis if the STAT Operation in System > System Condition is programmed to Manual. If STAT Operation is programmed to Auto, the STAT table check is automatically performed after STAT Start (F1) is selected.
CAL/QC Position (F5):	Displays the required calibrator and QC cup/tube positions on the STAT table based on the calibrator and QC requisitions.
Previous Cup Set (F7):	Displays the sample cup/tube positions on the STAT table that were analyzed during the previous run initiated by STAT Start (F1) . This button is only available when STAT Sequential Analysis is in use.
Sample ID Edit (F8):	Allows editing of the sample ID for the selected position.

Processing Priority STAT Samples in Barcode Analysis

TIP STAT table positions 1 to 22 are programmed by Beckman Coulter Technical Services for priority STAT samples as <First Run> (fixed) or <Free Position> (open). Refer to [4.10.3 Program STAT Table Parameters](#) for information on programming the STAT table positions. In **STAT Status**, Kind displays as Routine if the position is programmed as <First Run>, and Free if the position is programmed as <Free Position>.

1 Select **Home > STAT Status**.

Figure 6.19

The screenshot shows the 'STAT Status' screen with a table of STAT table positions. The table has columns for Pos., Kind, Type, Code, Status, Sample No., Cap Information, and Comment. Position 27 is highlighted in yellow and shows 'Checked Level' and '9324' in the Cap Information column, and 'Microsome Cap' in the Comment column. Below the table is a 'Bil Cup Information' section with fields for Pos., Cup, Status, Cap Information, and Comment. At the bottom, there are buttons for 'STAT Start', 'STAT Pause', 'STAT Check', 'Cap, CC, Position', 'Microsome Cap', and 'Sample Default'.

Pos.	Kind	Type	Code	Status	Sample No.	Cap Information	Comment
1	Free	None					
2	Free	None					
3	Free	None					
4	Free	None					
5	Free	None					
6	Free	None					
7	Free	None					
8	Free	None					
9	Free	None					
10	Free	None					
11	Free	None					
12	Free	None					
13	Free	None					
14	Free	None					
15	Free	None					
16	Free	None					
17	Free	None					
18	Free	None					
19	Free	None					
20	Free	None					
21	Free	None					
22	Free	None					
23	Free	None					
24	Free	None					
25	Free	None					
26	Free	None					
27	Free	None					
28	Free	None					
29	Free	None					
30	Free	None					
31	Free	None					
32	Free	None					
33	Free	None					
34	Free	None					
35	Free	None					
36	Free	None					
37	Free	None					
38	Free	None					
39	Free	None					
40	Free	None					
41	Free	None					
42	Free	None					
43	Free	None					
44	Free	None					
45	Free	None					
46	Free	None					
47	Free	None					
48	Free	None					
49	Free	None					
50	Free	None					
51	Free	None					
52	Free	None					
53	Free	None					
54	Free	None					
55	Free	None					
56	Free	None					
57	Free	None					
58	Free	None					
59	Free	None					
60	Free	None					
61	Free	None					
62	Free	None					
63	Free	None					
64	Free	None					
65	Free	None					
66	Free	None					
67	Free	None					
68	Free	None					
69	Free	None					
70	Free	None					
71	Free	None					
72	Free	None					
73	Free	None					
74	Free	None					
75	Free	None					
76	Free	None					
77	Free	None					
78	Free	None					
79	Free	None					
80	Free	None					
81	Free	None					
82	Free	None					
83	Free	None					
84	Free	None					
85	Free	None					
86	Free	None					
87	Free	None					
88	Free	None					
89	Free	None					
90	Free	None					
91	Free	None					
92	Free	None					
93	Free	None					
94	Free	None					
95	Free	None					
96	Free	None					
97	Free	None					
98	Free	None					
99	Free	None					
100	Free	None					

2 Check the Pos. and Kind for available Routine and Free positions on the STAT table.

TIP

- When the amber STAT TABLE LED is blinking, select **STAT Pause (F2)** to move the STAT table to *Pause*.
- To continue analysis, verify the STAT table cover is closed and select **STAT Start (F1)**.

 **CAUTION**

- The analyzer shifts to *Pause* if the STAT table is in *Pause* for an extended period of time. The time for the analyzer to move to *Pause* depends on why the STAT TABLE LED continuously blinks slowly:
 - Sample contamination parameters
 - Reagent blank or calibrator programmed on the STAT table
 - Cyclic QC programmed on the STAT table
- Do not remove pending reagent blank, calibrator, QC, or samples from the STAT table. After STAT Start (F1), an alarm is generated if pending samples are removed from the STAT table.

-
- 3** Lift the small cover over the STAT table and load samples. Press the TABLE ROTATION/DIAG button as required to rotate the table. Close the small cover.
-
- 4** Select **STAT Start (F1)**.
-
- 5** Review the Error List in the STAT Start window.
-
- 6** Select **Start** to initiate the automatic STAT table check, or **Cancel** to take corrective actions.
-
- 7** If there are no errors specific to the STAT table after the STAT table check, analysis starts. If there are STAT table errors, review the errors in the STAT Start window. Select **Start** to begin analysis, or **Cancel** to perform corrective actions.
-
- 8** Verify the Cup(s) displays as Present, the Status, and Comment.
-

TIP The amber STAT TABLE LED blinks until sample aspiration is complete. The small STAT table cover can be opened when the amber STAT TABLE LED is not blinking to remove existing samples and load new samples. If the small STAT table cover is opened when the amber STAT TABLE LED is blinking, a "STAT Small Cover Open" alarm is generated.

Processing Priority STAT Samples in Sequential Analysis

- 1 Select **Home > STAT Status**.

Figure 6.20

Row	Kind	Type	Cup	Status	Sample No.	Description	ID	Comment
1	Normal	Serum	Present					
2	Normal	Serum	Present					
3	Normal	Serum	Present					
4	Normal	Serum	Present					
5	Normal	Serum	Present					
6	Normal	Serum	Present					
7	Normal	Serum	Present					
8	Normal	Serum	Present					
9	Normal	Serum	Present					
10	Normal	Serum	Present					
11	Normal	Serum	Present					
12	Normal	Serum	Present					
13	Normal	Serum	Present					
14	Normal	Serum	Present					
15	Normal	Serum	Present					
16	Normal	Serum	Present					
17	Normal	Serum	Present					
18	Normal	Serum	Present					
19	Cal	Serum	Present			001 - W/STN CALIBRATION		No Cup
20	Cal	Serum	Present			002 - REF Cal 1		No Cup
21	QC	Serum	Present			001 - control 1		No Cup
22	QC	Serum	Present			002 - control 2		No Cup
23	Cal	Serum	Not Present					
24	QC	Serum	Not Present					
25	QC	Serum	Not Present					

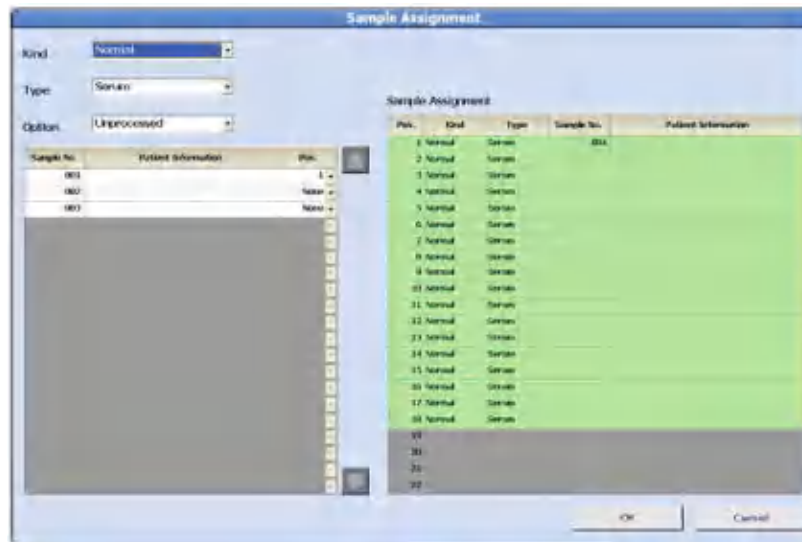
- 2 Lift the small cover over the STAT table and load samples. Verify the sample positions: each outer position of the STAT table (1-22) is programmed for Kind (Normal, Repeat, Calibrator, or QC) and Type (Serum, Urine, Other-1, or Other-2). Press the TABLE ROTATION/DIAG button as required to rotate the table. Close the small cover.

- 3 Select **STAT Check (F3)**. The table rotates and the tube(s) are detected. Cup displays “Present” in yellow for each sample.

TIP In Sequential Analysis on the STAT table, it is necessary to requisition for STAT samples from **STAT Status > Sample**. Refer to [6.5.1 Enter Manual Requisitions for Priority STAT Samples](#).

- 4 A green highlight appears over Sample Assignment based on the Kind and Type. Select **Sample Assignment (F4)**:
 - Verify the Kind (Normal or Repeat)
 - Verify the Type (Serum, Urine, Other-1, Other-2)
 - Select Unprocessed (unprocessed samples) or All Samples (processed samples are inaccessible) at the "Option" drop-down list.
 - Assign a position for each Sample No. on the STAT table from the "Pos." drop-down list.

Figure 6.21



- 5 Select **OK**.
- 6 Select **Stat Start (F1)**. The STAT Start window opens.
- 7 Review the Error List in the STAT Start window. Select **Cancel** to perform corrective actions.
- 8 Select **Start**.
Analysis is started.

TIP The amber STAT TABLE LED blinks until sample aspiration is complete. The small STAT table cover can be opened when the amber STAT TABLE LED is not blinking to remove existing samples and load new samples. If the small STAT table cover is opened when the amber STAT TABLE LED is blinking, a "STAT Small Cover Open" alarm is generated.

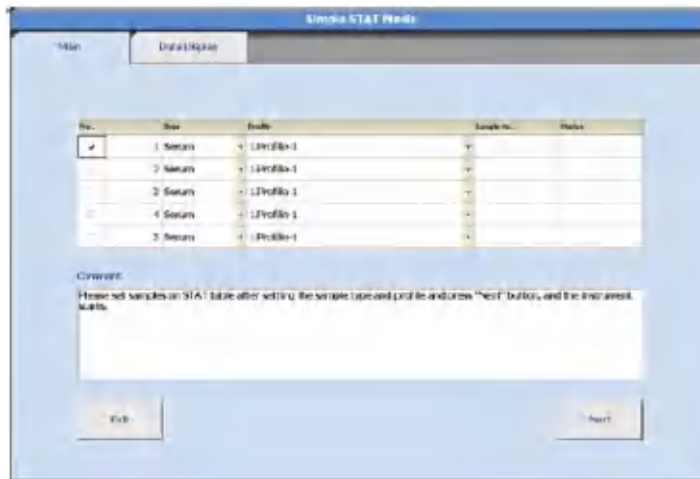
6.5.3 Simple STAT mode

A special STAT analysis mode to easily process a maximum of 5 samples at a time. The simple STAT mode is ideal for operators with limited analyzer experience, as there is minimal chance of error.

Starting and Ending Simple STAT Mode

- 1 Select **Home > Simple STAT Mode**. The system goes into Simple STAT mode.

Figure 6.22



- 2 Select **Exit**. Simple STAT mode ends, and the **Home** menu displays.

Analysis in Simple STAT mode

- 1 Select the check box for Pos. numbers 1 to 5 for a maximum of 5 samples. Select the sample type from the "Type" drop-down list. Select the profile from the "Profile" drop-down list.
- 2 Open the STAT cover and place all samples in the correct position on the STAT table according to the Pos. number displayed. Close the STAT cover.
- 3 Select **Next**.
The system starts automatically.

4 Select the **Data Display** tab.

The analysis results are displayed. When the sample results are complete, the results print (printer option).

5 Select the **Main** tab.

When analysis has ended, a message prompting for sample removal is displayed.

6 Remove all samples, close the cover, and select **Next**.

The system verifies all samples have been removed, and simple STAT mode analysis is complete.

6.6 Performing a Repeat Run

6.6.1 Auto Repeat for Racks and the STAT Table

6.6.2 Repeat Requisitions for Manual Repeat

6.6.3 Perform a Manual Repeat in an Orange Rack

6.6.4 Perform a Manual Repeat from the STAT Table

There are two ways to perform a repeat for racks and the STAT table:

- **Manual:** Repeat run criteria is programmed in **Repeat Parameters** to generate repeat run requisitions. A repeat run worklist is viewed or printed, and the samples to be repeated are placed in the orange racks or programmed repeat positions on the STAT table for the repeat run.
- **Automatic:** Repeat run criteria is programmed in **Repeat Parameters** to generate repeat run requisitions. The repeat run is performed automatically on the samples in the white or red racks, or from the STAT table.

TIP The operator is allowed to program whether or not to automatically rewrite the original data with the result data of the repeat test.

For details on how to program repeat run criteria, refer to [4.4 Repeat Parameters Menu](#) in chapter 4.

6.6.1 Auto Repeat for Racks and the STAT Table

The Auto Repeat feature is enabled in **Analysis Mode**. Refer to [4.10.1 Analysis Mode Menu](#) in chapter 4.

The routine or emergency rack moves back to the rack supply unit if any tests generated a repeat requisition after the original run. The rack moves for repeat sample aspiration, then to the rack collection unit. Only the tests that generated a repeat requisition are performed. **Do not use duplicate rack ID numbers.**

A priority STAT on the STAT table automatically repeats. Stat analysis must be programmed to barcode in **System Condition** to use Auto repeat on the STAT table.

The repeat requisitions cannot be modified. Repeats are automatic.

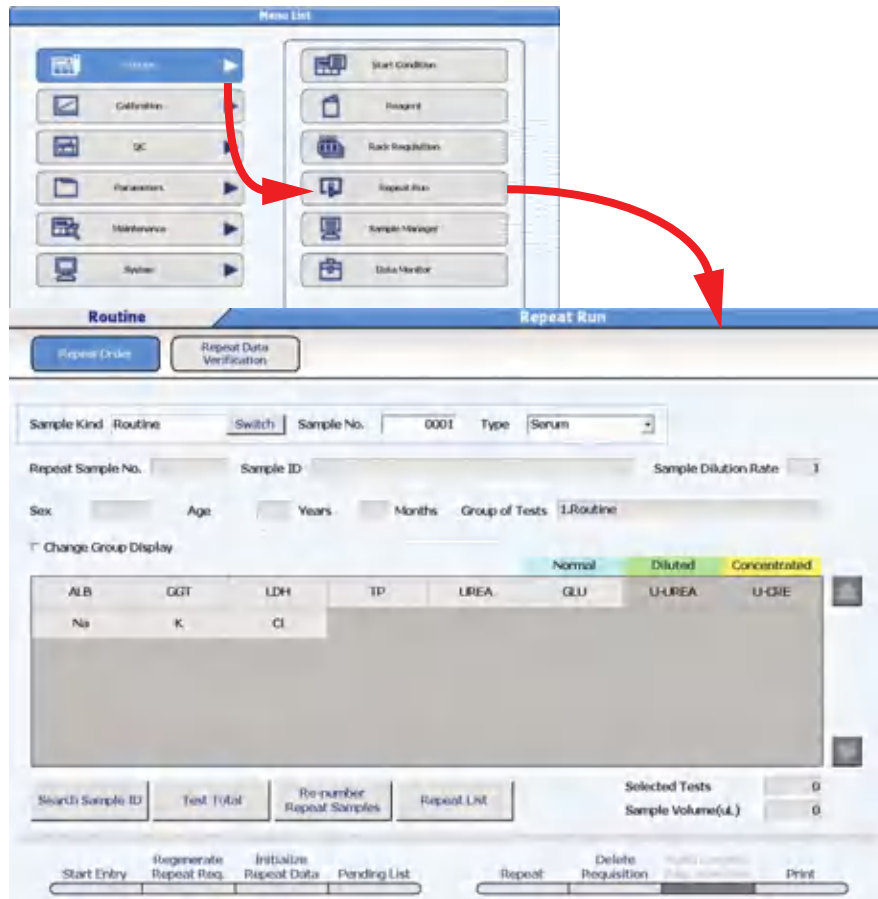
6.6.2 Repeat Requisitions for Manual Repeat

Repeat run requisitions are generated automatically from the repeat criteria programmed in **Repeat Parameters**. Verify the samples to repeat using a repeat run worklist. Changes can be made to the worklist in the repeat run requisition menu.

Modify a Repeat Requisition

- 1 Select **Menu List > Routine > Repeat Run > Repeat Order**.

Figure 6.23



- 2 Select **Switch** for Sample Kind to select **Routine** , **Emergency** , or **Stat**.
- 3 Enter the Sample No. of the sample to perform the repeat test.
- 4 Select the sample type from the "Type" drop-down list.
- 5 Select **Start Entry (F1)**.
- 6 If required, select **Sample Dilution (F7)**. The Sample Dilution Rate window opens. Enter the dilution rate (1 to 999), and make a manual dilution of the sample. The result is calculated according to the dilution rate. Select **OK**. The sample dilution rate is changed.

-
- 7** If required, select **Test Dilution (F8)**. Select a test to change from Normal (blue), Diluted (green), or Concentrated (yellow) analysis, according to programming in **Repeat Specific** parameters.
-
- 8** Select **Entry (F1)**. Once the settings have been entered, the window displays the requisition for the next Sample No.
-
- 9** Repeat the steps 3 through 10 to modify additional repeat sample requisitions.
-
- 10** Select **Exit (F2)**.
-
- 11** If changes were made to the repeat requisitions, print a repeat worklist. Refer to the following section [Print and check the Repeat Run worklist](#).

TIP Search Sample ID

Samples are searched using the sample ID as the key.

Test Total

The test total for repeat runs is displayed.

Re-number Repeat Samples

If repeat samples are deleted from the worklist, the repeat sample numbers are not sequential. Select **Re-number Repeat Sample** to re-number the repeat samples sequentially.

Repeat List

The repeat run candidate samples for which repeat run batch extraction has been performed are displayed as a list. Repeat run candidate samples are samples for which the repeat run sample number has not been established.

Repeat run sample numbers should be generated automatically if programmed in System Maintenance. Contact Beckman Coulter Technical Services if repeat sample numbers are not being generated automatically.

Regenerate Repeat Req. (F2)

Manually generate the repeat requisitions based on the flags programmed correctly in **Repeat Parameters**. Use this option if the Auto Repeat Requisition option is not turned on in **Repeat Parameters**.

Initialize Repeat Data (F3)

All repeat requisition information is deleted.

Pending List (F4)

Displays a list of pending repeat samples. Place the samples in an orange rack for repeat analysis.

Delete a Repeat Requisition

- 1 Select **Menu List > Routine > Repeat Run > Repeat Order**.

- 2 Select **Delete Requisition (F6)**.

- 3 Check the Sample Kind to delete.

- 4 Leave the "*" to delete all sample numbers, or enter a specific sample number or sample ID number to delete.

- 5 Select **Delete**.

- 6 Select **Re-number Repeat Samples** to re-number the repeat sample numbers sequentially.

- 7 Print a repeat worklist. Refer to the following section [Print and check the Repeat Run worklist](#).

Print and check the Repeat Run worklist

- 1 Select **Menu List > Routine > Repeat Run > Repeat Order**.

 **CAUTION**

The "Sample Volume (µL)" indicates the sample dispensing volume used for analysis. The dead volume is not included.

- 2 Select **Switch** for Sample Kind to select **Routine, Emergency, or STAT**.

- 3 Select **Print (F8)**. The Print window opens.

- 4 Select any print worklist from the "Print Type" drop-down list. A list must be formatted as List Type "Repeat List" in **System > Format > List Format** before it is available to print.

- 5 For List Format, select the list format to print.

-
- 6 For Reporter, the Operator Name entered in **Start Condition** displays. If necessary, enter a new name or use **Select** to enter a pre-programmed Comment Master. “Reporter” is an option that can be added to a list format, and only prints if it is formatted.

 - 7 Set the “Type” and “Search Sample ID” options.

 - 8 Select **OK**. The repeat run worklist begins printing.

 - 9 Check the contents of the printed repeat run worklist. Process the repeat run samples based on the worklist contents.
-

6.6.3 Perform a Manual Repeat in an Orange Rack

Orange racks are defined for sample type (serum, urine, other-1, or other-2) and sample kind (routine or emergency) in **System > System Condition**.

-
- 1 Obtain the samples for the repeat run using the repeat run worklist.

 - 2 Place the repeat samples in the correct orange rack for sample type and kind according to the repeat run requisition (worklist).

 - 3 Select **Start** to start repeat analysis.
-

6.6.4 Perform a Manual Repeat from the STAT Table

-
- 1 View a pending repeat list, or print a repeat pending list or repeat worklist. Modify the repeat worklist if necessary.

 - 2 Select **Home > STAT Status**: Place samples in STAT repeat positions on the STAT table for the correct sample types.
If Sequential mode is in use, select **STAT Check (F3)** and verify the Cup displays as “Present”. Select **Sample Assignment (F4)** and assign a position for each sample number. Press the TABLE ROTATION/DIAG button as needed to rotate the STAT table.

If Barcode mode is in use, samples can go in any order on the STAT table repeat positions. Press the TABLE ROTATION/DIAG button as needed to rotate the STAT table.

3 Select **STAT Start (F1)**. Review any error messages.

4 Select **Start**.

6.7 Print Results

To print test results in the form of report or data log list, the report format must be programmed in advance.

For details on how to program a report format, refer to 4.14.1 Format Realtime Reports and Lists in chapter 4.

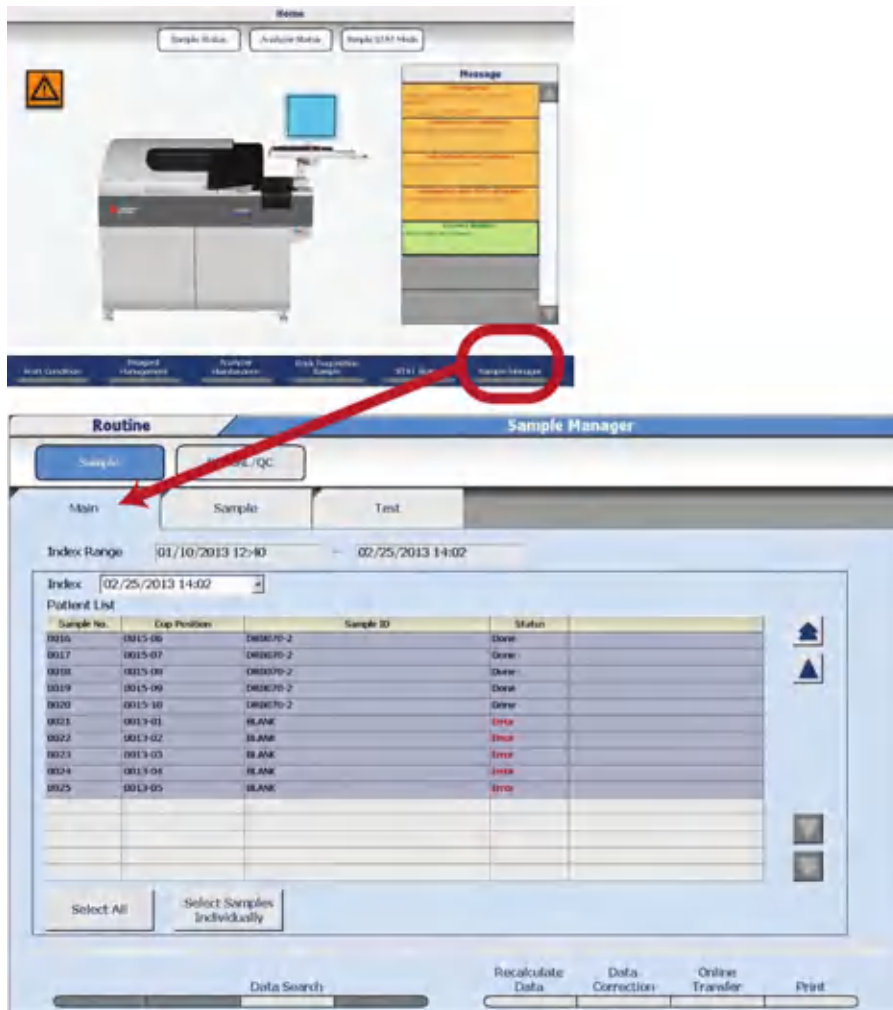
6.7.1 Print Sample Data Reports

6.7.2 Print Reagent Blank, Calibration, and QC Results

6.7.1 Print Sample Data Reports

- 1 Select Home > Sample Manager > Main.

Figure 6.24



2 The data from the current index displays. All samples are selected to print (highlighted in gray). Use **Select All** and **Select Samples Individually** as required.

3 Select **Data Search (F3)** to search for data by an Index Range, Sample Number(s), Sample ID, Data Not Transferred to Host, Data Not Printed, or Abnormal data.

4 Select **OK**.

5 Select **Print (F8)**. The Print window opens.

6 Select the report to print from the "Data List No." drop-down list.

TIP For Reporter, the Operator Name entered in **Start Condition** displays. If necessary, enter a new name or use **Select** to enter a pre-programmed comment. "Reporter" is an option that can be added to a list format, and only prints if it is formatted.

7 Select **OK**. Printing begins.

TIP Select **Print Stop (F8)** to abort printing.

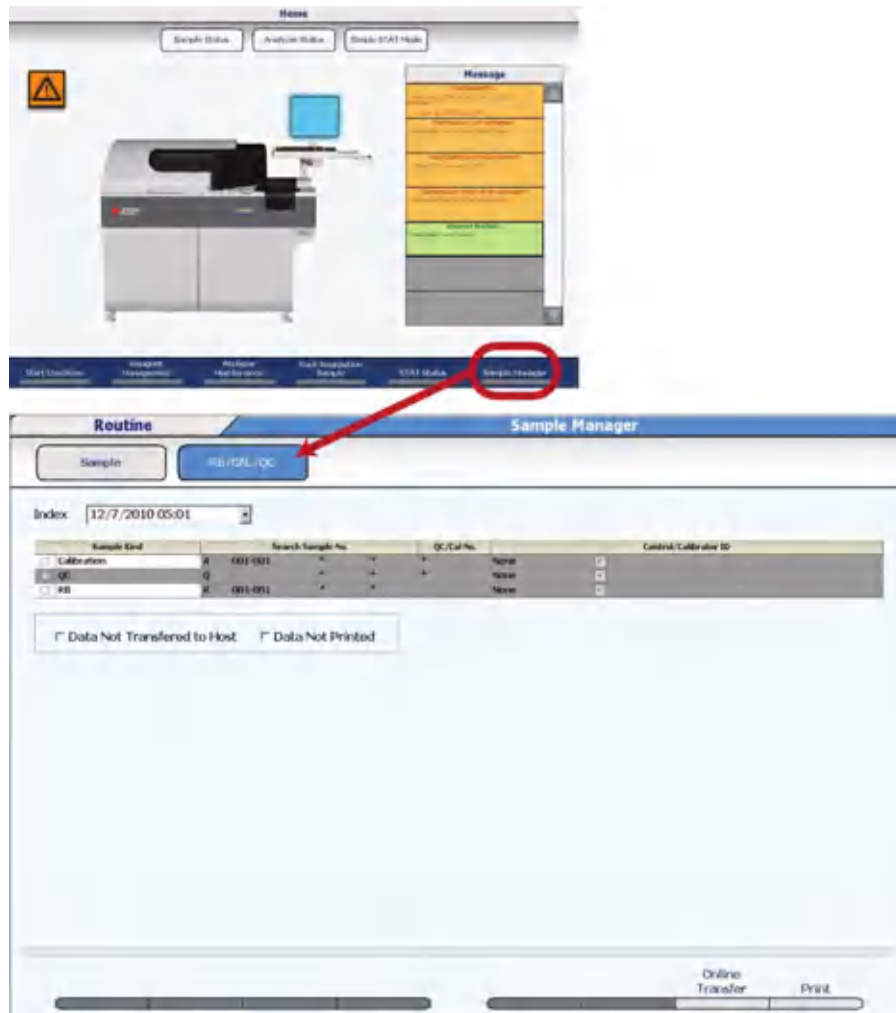
TIP The report format must be programmed in advance.

Users can select and print any available predefined report, according to the format selected in step 6.

6.7.2 Print Reagent Blank, Calibration, and QC Results

- 1 Select **Home** > **Sample Manager** > **RB/CAL/QC**.

Figure 6.25



- 2 Select the index of the RB/CAL/QC data to search from the “Index” drop-down list.

- 3 Select the Sample Kind check box of the samples desired.

- 4 For Search Sample No., enter the sample number range to print, or leave the “*” to print all samples.

TIP If the Search Sample No. is left blank or empty no search criteria is used to perform the search.

-
- 5** For QC/Cal. No., enter the QC number (1 to 100) or the calibrator number (1 to 200), or leave the "*" to print all QC and calibrator numbers.
-
- 6** For Control/Calibrator ID, enter the QC or calibrator barcode number to print samples with a specific QC or calibrator ID.
-
- 7** Check the Data Not Transferred to Host box to print only the reagent blank, calibrator, and QC samples that have not been transferred to the host. Check the Data Not Printed box to print only the reagent blank, calibrator, and QC samples that have not been printed.
-
- 8** Select **Print (F8)**.
-
- 9** Select the report to print from the "Data List No." drop-down list.
- TIP** For Reporter, the Operator Name entered in **Start Condition** displays. If necessary, enter a new name or use **Select** to enter a pre-programmed comment. "Reporter" is an option that can be added to a list format, and only prints if it is formatted.
-
- 10** Select **OK**. This list begins printing.
- TIP** Select **Print Stop (F8)** to abort printing.
-

6.8 Transfer Data to Host Computer

6.8.1 Sample Data

6.8.2 Reagent Blank, Calibration, and QC Data



Before transfer, confirm that the system is online and connected to a clinical laboratory host computer system.

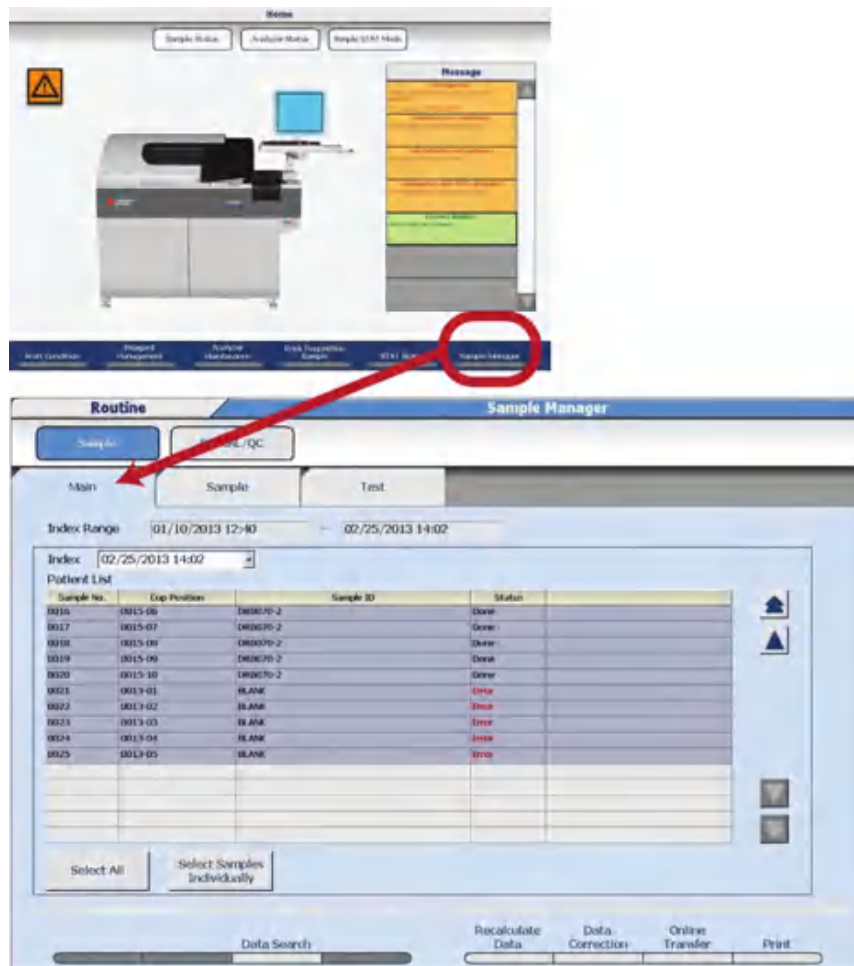
6.8.1 Sample Data

Batch data transfer to a host computer.

TIP Online Transfer (F7) is only available when the Online menu is programmed to Realtime or Batch for Results Transfer. If Realtime is programmed, data can only be transferred in *Standby*.

- 1 Select Home > Sample Manager > Main.

Figure 6.26



- 2 The data from the current index displays with all samples selected (highlighted in gray). Use **Select All**, **Select Samples Individually**, or select Sample No. (s) individually to transfer to the host computer.
- 3 Select **Data Search (F3)** to search for data by an Index Range, Sample Number(s), Sample ID, Data Not Transferred to Host, Data Not Printed, or Abnormal data.

4 Select **Online Transfer (F7)**. The Online Transfer window opens.

5 Select **OK**. The data is transferred.

TIP An “r” flag is attached to data that has been transferred to the host computer.

6.8.2 Reagent Blank, Calibration, and QC Data

Reagent blank, calibration, and QC data can be transferred to a host computer system.

TIP **Online Transfer (F7)** is only available when the Online menu is programmed to Realtime or Batch for Results Transfer. If Realtime is programmed, data can only be transferred in *Standby*.

1 From the **RB/CAL/QC** screen, select the samples and criteria to transfer.

2 Select **Online Transfer (F7)** to display the Online Transfer window.

3 Select **OK**. Online transfer is performed.

TIP Select **Online Transfer Stop (F7)** to stop the transfer.

System Monitoring and Results

This chapter describes how to monitor analyzer status, review and edit results, manage data, manage reagents, and change analyzer modes.

7.1 Monitoring Analysis

7.1.1 Monitor Results

7.1.2 Identifying Sample Kinds and Types by Sample Data Prefix

7.1.3 Sample Status Menu

7.1.4 Analyzer Status Menu

7.1.5 ISE Status

7.2 Disable a Test

7.3 Check Results

7.3.1 Check the Test Results

7.3.2 Display Reaction Monitor

7.3.3 Check for Error Flags and Alarms

7.3.4 Check the Reagent Blank and Calibration

7.3.5 Check QC

7.3.6 Verify Repeat Results

7.4 Reagent Management

7.4.1 Fix (Assign) a Reagent Position

7.4.2 Edit a Reagent ID

7.4.3 Read the Master Curve

7.4.4 Review and Delete Reagent History

7.4.5 Reagent Inventory

7.4.6 Reagent Consumption

7.5 Edit Quality Control Data

- 7.6 Edit Analysis Data
 - 7.6.1 Rewrite Patient Sample Data
 - 7.6.2 Correct Patient Sample Data
 - 7.6.3 Recalculate Analysis Data Using a Previous Calibration Curve
 - 7.6.4 Transfer the Edited Data Online
- 7.7 Calculate Data Statistics
 - 7.7.1 View Data Statistics
 - 7.7.2 Create a Correlation Chart
- 7.8 Data Management
 - 7.8.1 Save Data to External Media
 - 7.8.2 Save or Load Parameters
 - 7.8.3 Offline Criteria
- 7.9 Calibration Verification
 - 7.9.1 Enter Material Parameters
 - 7.9.2 Verify Calibration
- 7.10 System Shutdown (End Process)
- 7.11 Pause Analysis
- 7.12 Rack Feeder Stop
- 7.13 Transfer the Analyzer to Stop Mode
- 7.14 Perform an Emergency Stop
- 7.15 Identifying and Re-analyzing Samples after a Cuvette Overflow

7.1 Monitoring Analysis

The system status is continuously updated while the system is operating. This means that progress is constantly monitored.

[7.1.1 Monitor Results](#)

[7.1.2 Identifying Sample Kinds and Types by Sample Data Prefix](#)

[7.1.3 Sample Status Menu](#)

[7.1.4 Analyzer Status Menu](#)

[7.1.5 ISE Status](#)

7.1.1 Monitor Results

It is important to verify that daily reagent blank, calibration, and control (QC) results are acceptable before reporting sample results. All results including reagent blank, calibration, QC, and samples should be reviewed for error flags, and appropriate corrective actions should be taken before reporting the results. In addition, the **Alarm List** should be reviewed and appropriate corrective actions taken for any alarms generated.

Refer to [7.3 Check Results](#) for more information on monitoring reagent blank, calibration, QC, and sample results.

For more information on troubleshooting and corrective actions, refer to [11.3 Troubleshooting the System - Reagents, Calibrators, Quality Control and Samples](#) in chapter 11.

7.1.2 Identifying Sample Kinds and Types by Sample Data Prefix

Type		Normal Run	Repeat Run
Routine	Serum	(None)	H
	Urine	U	HU
	Other-1	X	HX
	Other-2	Y	HY
Emergency sample	Serum	E	HE
	Urine	UE	HUE
	Other-1	XE	HXE
	Other-2	YE	HYE
STAT sample	Serum	P	HP
	Urine	UP	HUP
	Other-1	XP	HXP
	Other-2	YP	HYP
QC		Q	
CAL		A	
RB		R	

7.1.3 Sample Status Menu

Select **Sample Status** to view sample information, estimated time of completion, and results.

- 1 Select **Home** > **Sample Status**.

Figure 7.1

Sample No.	Cup Position	Sample ID	Order	Status	Results
A001	0001-04		11:10	Done	
A001	0002-01		11:16	Done	
Q001	0001-01		11:19	Done	
Q001	0002-02		11:19	Done	
Q001	0003-01		11:20	Done	
Q001	0002-02		11:20	Done	
0001	0013-01	78709	11:23	Done	
0002	0013-02	78710	11:23	Done	
0003	0013-05	78711	11:23	Done	
P002	STAT-02	00089	11:25	Done	
P001	STAT-03	65732	11:26	Done	
H001	STAT-02	00089	11:25	Done	
H001	0013-01	78709	11:28	Done	
H002	0013-02	78710	11:28	Done	
H003	0013-05	78711	11:28	Done	

1. User-defined patient demographic can be programmed

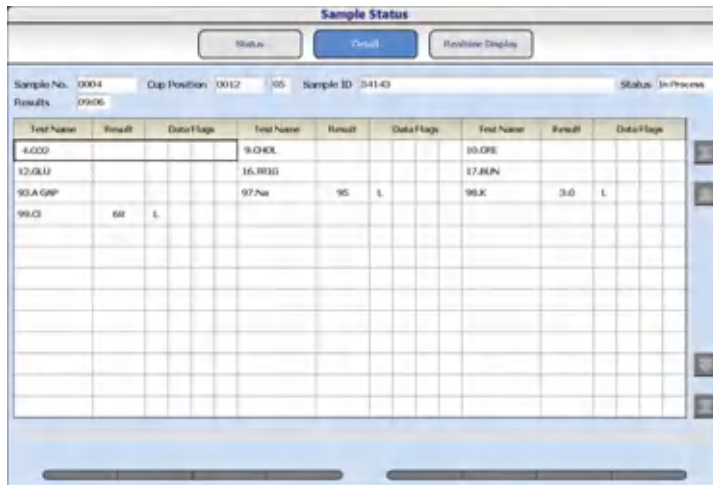
The **Status** menu displays:

- Sample No.: The sample number displays highlighted in the color of the rack.
- Cup Position: The rack ID and cup position display highlighted in the color of the rack.
- Sample ID: The sample ID (barcode) displays.
- Order: The time the cup in the rack went past the cup detector on the rack transport belt.
- Status: Displays “In Process” while sample analysis is in process, or “Done” when sample analysis is complete.
- Results: Displays the estimated time of completion when the sample is in process, or “Error” if the sample is complete and an error flag is present.

TIP Two user-defined patient demographic fields can be programmed to display. Refer to [4.13 Program the Requisition Format](#).

- Highlight a sample, then select **Detail** to view detailed sample information. The test name displays with the result when the result is complete.

Figure 7.2



- Select **Realtime Display** to view the sample results. Tests without error flags display in black, and tests with error flags display in red. The **All** tab displays the samples in completion order when all tests requisitioned on the sample are complete. The **Quick** tab is for results from the STAT table only, and displays the ISE tests, and tests with only an R1 reagent with read points before P10 when these tests are complete. The **ISE** tab displays the ISE tests when the ISE tests are complete.

Figure 7.3



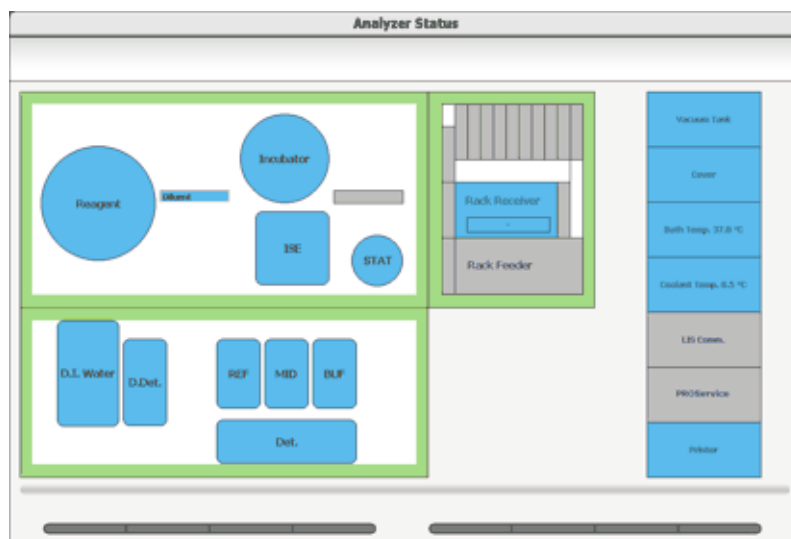
7.1.4 Analyzer Status Menu

Analyzer Status displays an overview of the analyzer status by color-coding the components.

TIP Some printer errors cause the Printer box to display in red, a red Message on the **Home** menu, and a print error in the Measure Start window. In this situation, **Printer Control (F5)** displays on **Analyzer Status**. To clear the red error and resume normal operation, select **Printer Control (F5)** for options to either **Resume** (print any information that did not print) or **Cancel** (cancel the print).

- 1 Select **Home > Analyzer Status**.

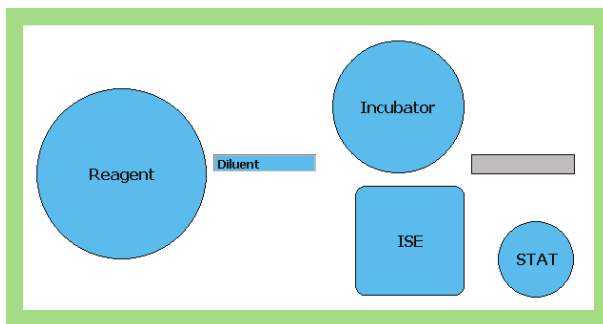
Figure 7.4



- 2 Perform the following verifications from **Analyzer Status**.

Analyzer Top Unit

Figure 7.5



- Reagent refrigerator status: The display color shows the status of the reagent refrigerator.

Display Color	Status
Blue	Normal
Yellow	The temperature is outside the normal temperature range (4 to 12°C).
Red	The refrigerator cover is open.

- Bath status: The display color shows the status of the Incubator.

Display Color	Status
Blue	Normal
Yellow	The temperature is outside the normal temperature range (37 +/- 0.3° C), or a cuvette(s) failed the Photocal cuvette check.
Red	A cuvette(s) failed the Photocal cuvette check.

TIP The Display Color can be Yellow or Red if a cuvette(s) failed the Photocal cuvette check depending on the system programming by Beckman Coulter Technical Services.

- Diluent: The display color indicates the volume remaining in the bottle.

Display Color	Status
Blue	More than 50 mL
Blue (3/4) : Gray (1/4)	More than 30 mL and less than or equal to 50 mL
Blue (1/2) : Gray (1/2)	More than 15 mL and less than or equal to 30 mL
Yellow (1/5) : Gray (4/5)	Less than or equal to 15 mL
Red	DI water or diluent is empty
Gray	The DI water or diluent is not used by any of the tests in the Group.

- STAT table: The display color indicates the status of STAT table.

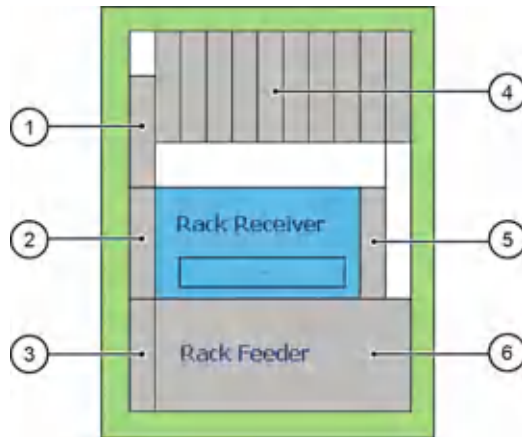
Display Color	Status
Blue	Normal
Yellow	The temperature is outside the normal temperature range (4 to 12°C).
Red	The small or large STAT table cover is open.

- ISE (option): The display color indicates the status of ISE.

Display Color	Status
Blue	Normal
Yellow	The ISE is in <i>Stop</i> mode.
Red	The ISE cover is open, or the ISE is Busy (performing maintenance).

Rack Feeder Unit

Figure 7.6



- | | |
|-------------------------------|-------------------------|
| 1. Sample aspiration position | 4. Rack buffer unit |
| 2. Middle rack position | 5. Rack collection unit |
| 3. Sample ID read position | 6. Rack supply unit |

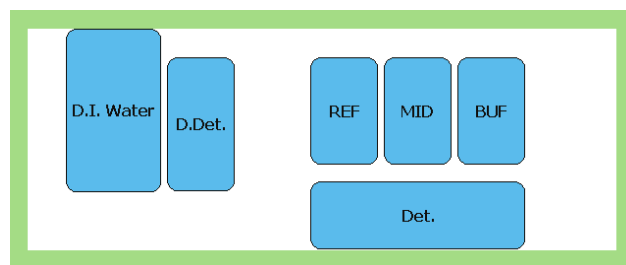
- Rack buffer unit: Moves racks to the rack collection unit when analysis is complete, or the rack supply unit for Auto Repeat analysis.
- Rack collection unit: The display color indicates the status of the rack collection unit.

Display Color	Status	
Blue	Normal	
Red	The rack collection unit is full, or there is a mechanical error.	
Display within the square frame	Rack full	The rack collection unit is full.
	- (hyphen)	The rack collection unit is not full.

- Rack position display: The display color and position depend on the rack type. If a rack is not present, the position displays in gray. The rack ID number of the rack displays.

Analyzer Front Unit

Figure 7.7



- Deionized water (D.I. Water) tank, diluted wash solution (D. Det.) tank, and wash solution (Det.) tank: The display color shows the liquid quantity in each tank.

Display Color	Status
Blue	Normal
Yellow	Over-full
Red	Insufficient

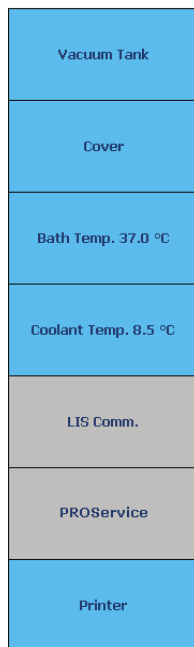
TIP The status becomes over-full when the top float sensor in the tank moves to the maximum "up" position. The status becomes insufficient when the bottom float sensor in the tank moves to the maximum "down" position.

- REF, MID, and BUF: The display color shows the liquid quantity in each ISE (option) solution bottle.

Display Color	Status
Blue	Normal
Yellow	Insufficient

Unit Status Descriptions

Figure 7.8

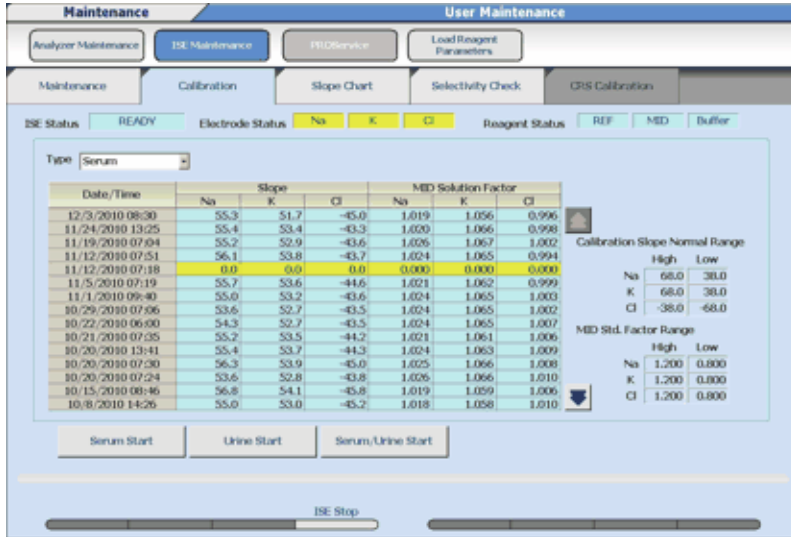


Unit	Display Color		
	Blue	Yellow	Red
Cover	The R1, STAT table (large and small), and ISE covers are closed.	–	One or more of the following covers is open: R1, STAT table (large or small), or ISE.
Vacuum Tank	Normal	–	Full
Bath Temp	Normal	Exceeds temperature specification	–
Coolant Temp	Normal	Exceeds temperature specification	–
Printer	Normal	–	Error
LIS Comm	Under realtime online communication	Under Batch online communication	–

7.1.5 ISE Status

Select **Home > Analyzer Maintenance > ISE Maintenance > Calibration.**

Figure 7.9



Review the Calibration menu

- **ISE Status**
Displays the ISE operation mode.

Message	Background color	Meaning
READY	Blue	Ready to start analysis or maintenance.
BUSY	Red	Operating.
MEASURE	Blue	Analysis is in progress (ISE).
STOP	Yellow	The ISE is in <i>Stop</i> mode. Select ISE Ready (F4) to start analysis or maintenance.
INITIAL	Yellow	The ISE is initializing.

- **Electrode Status**
Indicates if the most recent slope value is in range for Na, K, and Cl.

Background color	Meaning
Blue	The slope value is within the acceptable range.
Yellow	<ol style="list-style-type: none"> 1. The slope value is not within the acceptable range. 2. An End Process was performed, the analyzer was turned On, and the ISE calibration has not been performed. The system uses the most recent ISE calibration results. 3. There is no calibration data for the electrode.

- **Reagent Status**
Indicates if the reagent level is short for Buffer, Mid Standard, and Reference.

Background color	Meaning
Blue	The reagent level is above the reagent short level sensor, indicating reagent is sufficient.
Yellow	The reagent is below the reagent short level sensor, indicating reagent is not sufficient.

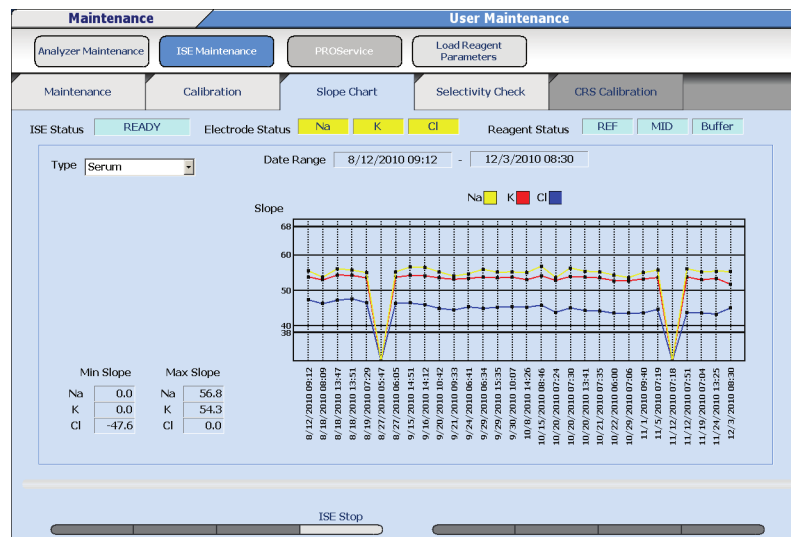
- **Date/Time**
The date and time the calibration was performed.
- **Slope**
Indicates the calibration slope for Na, K, and Cl. A larger slope value indicates a steeper slope, i.e. a larger potential.
- **MID Solution Factor**
A value which is obtained based on the concentration of the MID Standard solution to establish a reference for measuring Na, K, and Cl ion concentrations.

Check the Slope Chart

Records of slope values obtained from calibration can be viewed in a graph form for Na, K, and Cl.

- 1 Select the **Slope Chart**.

Figure 7.10



- 2 Check a slope chart for each sample type by changing the sample type to serum or urine with the "Type" drop-down list.

The 30 most recent slope values are displayed in a chart. The Na, K, and Cl slope charts are identified by their specific color. On the left of the chart the maximum and minimum Na, K, and Cl slope values are displayed.

TIP Although Cl slope values are negative values, the slope chart displays their absolute values.

7.2 Disable a Test

Specific tests can be selected to stop analysis (disable) even when the test has a requisition. Examples of when it may be useful to disable a test are if the calibration failed for that test, or QC fails and samples are in process.

TIP A test can be disabled or enabled during a Measure mode. Analysis of the test(s) stops or re-starts after selection in **Disable (F7)**.

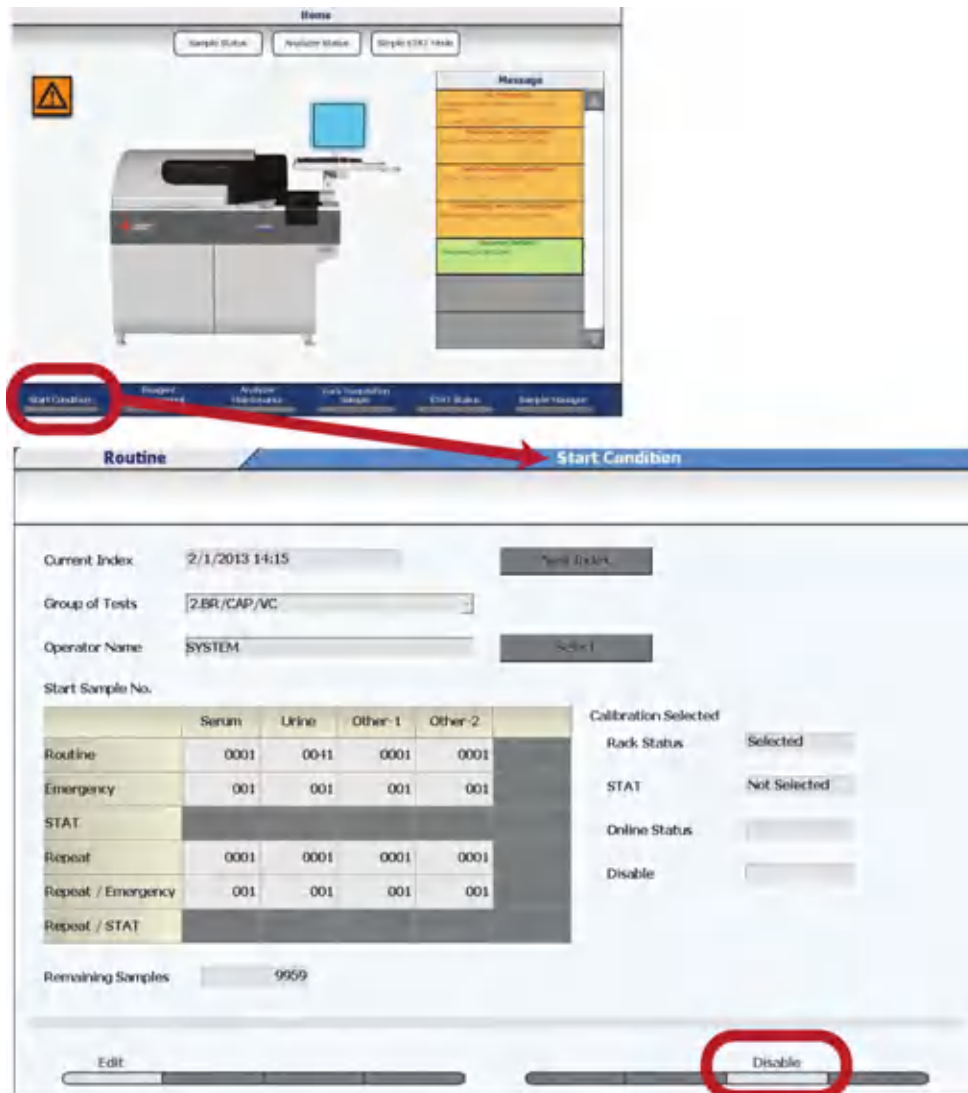
Tests are not disabled for reagent blank, calibration, and QC samples.

Tests that are disabled display and print with a "/" error flag, indicating the test was requisitioned but not performed.

Selections in the Disable window are effective until a new index is made, or an End Process is performed.

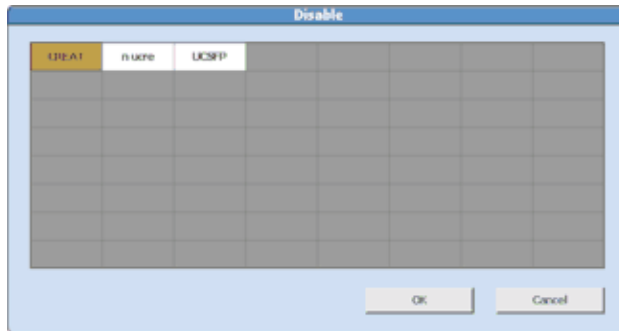
- 1 Select Home > Start Condition.

Figure 7.11



-
- 2 Select **Disable (F7)**. The Disable window opens. A list of tests to disable is displayed.

Figure 7.12



-
- 3 Select the test(s) to be disabled. Tests that are disabled are highlighted in orange.
 - 4 Select **OK**. Test selections are registered, and the display returns to **Start Condition**.
-

7.3 Check Results

After results have been generated, it is important to review them for analytical validity. Follow these procedures:

- 7.3.1 Check the Test Results
- 7.3.2 Display Reaction Monitor
- 7.3.3 Check for Error Flags and Alarms
- 7.3.4 Check the Reagent Blank and Calibration
- 7.3.5 Check QC
- 7.3.6 Verify Repeat Results

7.3.1 Check the Test Results

Check test results in **Sample Status** or the printout. Refer to [7.1.3 Sample Status Menu](#) for details on the **Sample Status** screen.

All test results should be reviewed for error flags and alarms, and appropriate corrective actions taken.

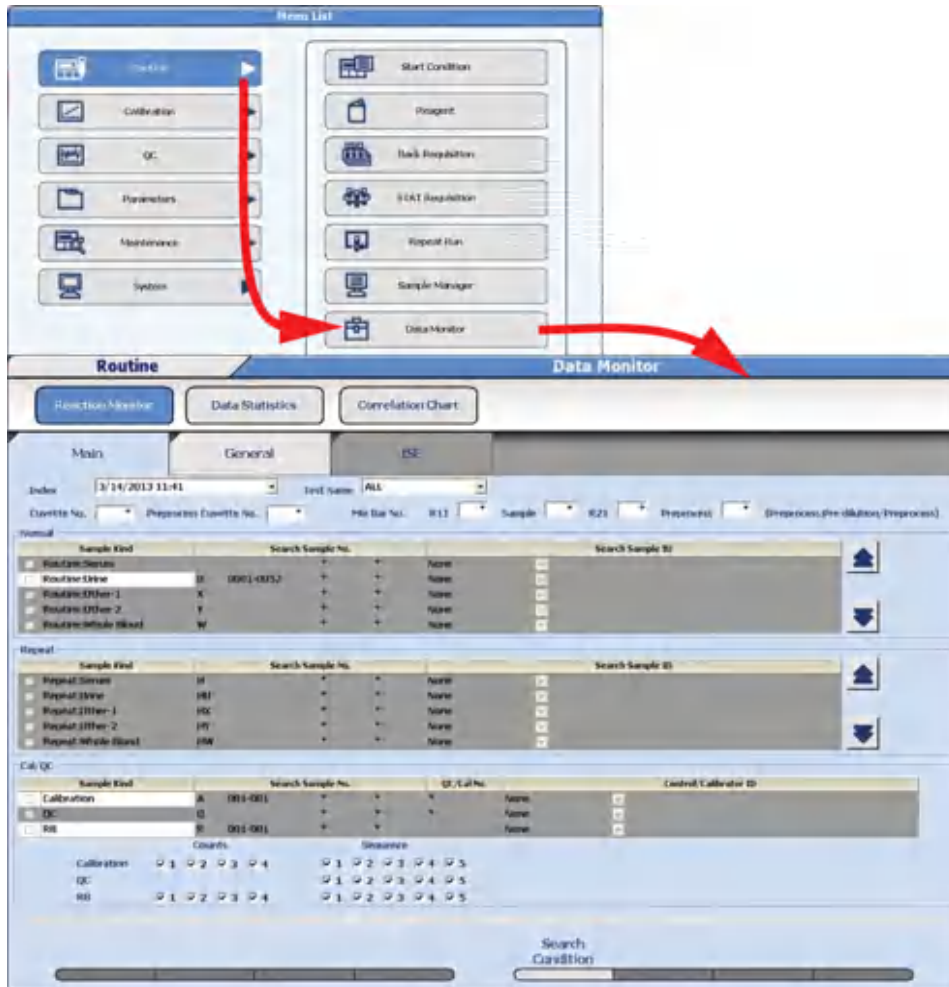
7.3.2 Display Reaction Monitor

Reaction Monitor displays sample information, reagent information, specific test parameters, reaction data, and analyzer components used for analysis for reagent blank, calibration, QC, and samples. **Reaction Monitor** can be used for checking data or troubleshooting.

- A maximum of 10,000 tests per index are saved and can be displayed in **Reaction Monitor**.
- A maximum of 100,000 tests in multiple indexes are saved and can be displayed in **Reaction Monitor**.

- 1 Select **Menu List > Routine > Data Monitor > Reaction Monitor > Main.**

Figure 7.13



2 Enter the search parameters for the data to display according to the following table.

Item	Contents	Input Notes
Index	Index	All available indexes are available to select, from the newest index to the oldest.
Test Name	Test Name	Calculated tests are not available to be selected.
Cuvette No.	1 to 88, or "*".	Specify the cuvette number used for analysis. Enter "*" when no cuvette is specified to view each cuvette.
Preprocess Cuvette No.	1 to 88, or "*".	Specify the cuvette number used for pre-processing. Enter "*" when no cuvette is specified to view each cuvette.
Mix Bar No.	1 to 3, or "*".	Specify the mix bar for R1 (R11), Sample, R2 (R21), and Preprocess used for analysis. Enter "*" when no mix bar is specified to view each mix bar.
Normal, Repeat, Cal/QC	Enter the search parameters for sample number and sample ID for each type.	Sample kinds and types not processed are gray and inaccessible.
Sample Kind	Select (place a check mark) by the sample kind and type to search.	Sample kinds and types not processed are gray and inaccessible.
Search Sample No.	Leave the "*" to search all the sample numbers processed, or enter a specific sample number or range of sample numbers to search.	The starting and ending sample numbers processed display under the Search Sample No. column.
Search Sample ID	Leave the "*" to search all sample IDs processed, or enter a specific sample ID to search.	An asterisk displays under the Search Sample ID column.
Control/ Calibrator ID	Select None / Partial Match / Complete Match from drop-down list.	<ul style="list-style-type: none"> • None: Not using sample ID as the search criteria. • Partial Match: Retrieve the sample(s) with a partial sample ID match. • Complete Match: Retrieve the sample with a complete sample ID match.
Counts	Select the check box of Counts for Calibration and RB replicate 1 to 4.	Available only for Calibration and RB (reagent blank) data. The replicate number 1 to 4 is programmed in Calibration Specific .
Sequence	Select the check box of the reagent bottle Sequence 1 to 5 for Calibration, QC, and RB.	Available only for Calibration, QC, and RB (reagent blank) data. Sequence is the serial reagent bottle number 1 to 5 for each test. When nothing has been checked, data matching the specified Sample No. and bottle sequence number is displayed.

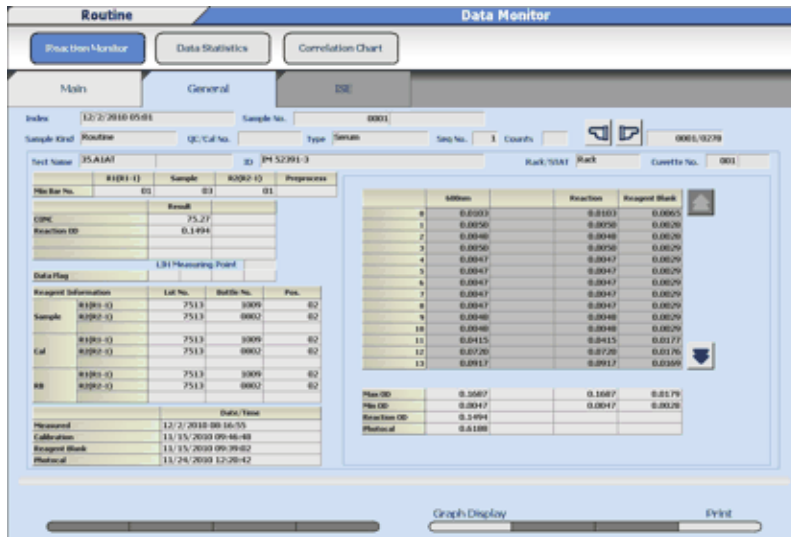
The following additional search criteria must be selected after Patient, Repeat Run, or RB/CAL/QC is selected:

- Under the Sample Kind column, select (place a check mark) by the sample kind and type to search. Sample kinds and types not processed are gray and inaccessible.
- The starting and ending sample numbers processed display under the Search Sample No. column. Leave the “*” to search all the sample numbers processed, or enter a specific sample number or range of sample numbers to search.
- An asterisk displays under the Search Sample ID column. Leave the “*” to search all sample IDs processed, or enter a specific sample ID to search.
- If RB/CAL/QC is selected, the Counts (replicates) and Sequence (bottle sequence number 1-5) can be specified to search.

3 Select the **General** tab. The search starts. If there is data based on the search criteria, the **General** tab screen displays with the first sample found. If no data is found based on the search criteria, a message “No Data Found” displays. Select **OK** to return to the **Main** tab.

4 Review the data in the **General** tab.

Figure 7.14



Sample Number

- Left column: The sample number of the currently displayed reaction data is displayed.
- Right column: If the sample number is from the original run, the display is blank. If the sample number is from the repeat run, the original sample number displays.

	Sample No. (left)	Sample No. (right)
Original run data display	Original Sample No.	Blank display
Repeat run data display	Repeat Sample No.	Original Sample No.

Type		Normal Run	Repeat Run
Routine	Serum	(None)	H
	Urine	U	HU
	Other-1	X	HX
	Other-2	Y	HY
Emergency sample	Serum	E	HE
	Urine	UE	HUE
	Other-1	XE	HXE
	Other-2	YE	HYE
STAT sample	Serum	P	HP
	Urine	UP	HUP
	Other-1	XP	HXP
	Other-2	YP	HYP
QC		Q	
CAL		A	
RB		R	

- 5 Select **Graph Display (F5)**.
The display changes to graph display. The primary wavelength, secondary wavelength, and calculation of the reaction absorbance are displayed color-coded on the graph.

Figure 7.15



- TIP** When the total dispensing volume is below the minimum test liquid quantity (90 μ L), the graph is displayed as a dotted line.
- In case of $(R1[R1-1] \text{ dispensing volume} + R1[R1-1] \text{ diluent quantity}) < \text{minimum test liquid quantity}$, the straight line between P0 and P1 is displayed as a dotted line.
 - In case of $(R1[R1-1] \text{ dispensing volume} + R1[R1-1] \text{ diluent quantity}) + (\text{sample dispensing volume} + \text{sample diluent quantity}) < \text{minimum test liquid quantity}$, the straight lines between P0 and P10 are displayed as dotted lines.

- 6 Select **Scale Change (F6)** to change the absorbance scale of the graph. The Scale Change window opens.
- 7 Enter the lower limit value and the upper limit value and select **Manual**. The setting range for the lower limit value and the upper limit value is from -2.000 to 3.000 (in units of 0.001). When **Auto** is selected, the scale is set automatically.

7.3.3 Check for Error Flags and Alarms

Check for Error flags

If a problem occurred during analysis, the system appends a flag to the analysis results. Check all generated results carefully for error flags and take the appropriate action.

For details on error flags, refer to [CHAPTER 9, Error Flags](#).

Check for alarms

Check to see if an alarm occurred during analysis:


Select **Alarm List**  (the button on the lower, right corner of the screen).

Figure 7.16



“Level” shows the alarm level by numbers and colors.

Level	Background color	Extent
Level 1	Red	A fatal system abnormality exists.
Level 2	Yellow	An abnormality influencing the data exists.
Level 3	Green	There is no system abnormality. The operation log is displayed.

The Count at the right top of the window indicates the number of alarms within “Date Range”. Nine hundred and ninety-nine (999) cases can be stored and displayed using the scroll bar.

From this window, the following options can be performed:

- **Print:** Prints a list of all alarms.
- **Refresh:** Returns the display to the most recent alarms.
- **Help:** Displays a description of the alarm and corrective actions.
- **Search:** Searches for alarms by date, alarm number, and/or alarm level.
- **Close:** Closes the Help window.

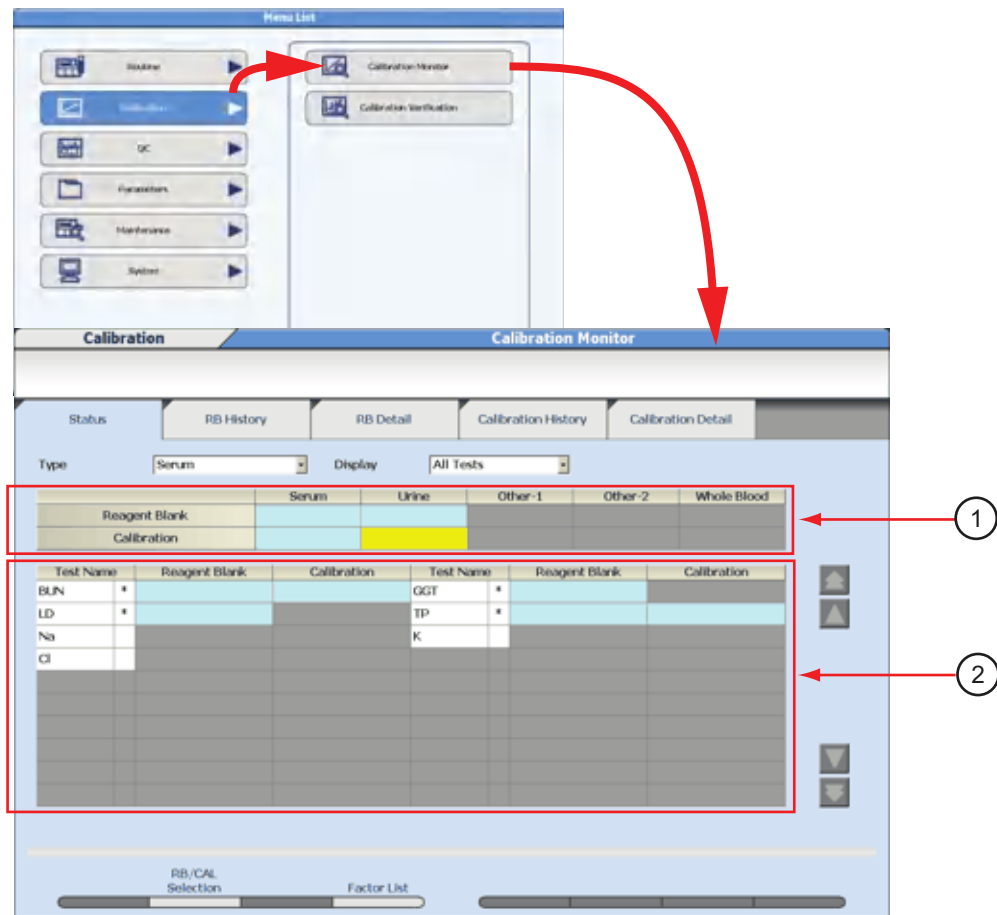
7.3.4 Check the Reagent Blank and Calibration

Use the following procedure to verify reagent blank and calibration results.

Reagent Blank and Calibration Status

- 1 Select **Menu List > Calibration > Calibration Monitor > Status**.

Figure 7.17



1. Sample Type list
2. Test list

- **Sample Type List**

Display Color	Status
Orange	No calibration data, Failed, or Expired.
White	Reagents “Unchecked” and judgement is not possible.
Gray	The sample type is not available according to the “Type” drop-down setting.
Blue	No errors.
Yellow	Calibration Expires Soon.

- **Test List**

List of analysis tests registered for each group. The "*" by Test Name indicates Advanced Calibration is programmed for the test.

Display	Display Color	Status
No data	Orange	Bottles without calibration data exist.
Updating failure		Bottles with failed calibration exist.
Expired		Bottles with expired calibration exist.
--	Yellow	Bottles with calibration data that expires soon exist.
--	Blue	No errors.
--	White	Reagent “Unchecked” and judgement is not possible.

2 Select the sample type from the “Type” drop-down list. The present reagent blanks and calibration status are displayed as a list. Items displaying “*” are items with an advanced calibration setting.

3 Select **All Tests** or **Tests with Error** from the “Display” drop-down list.

All Tests: Displays all the test data for the Group.

Tests With Error: Displays data with an error in calibration or reagent blanks.

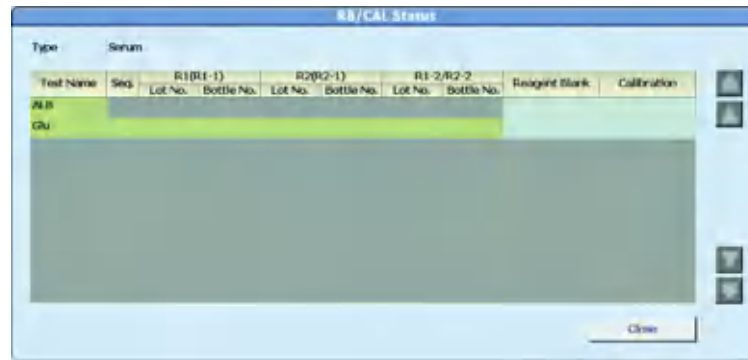
4 Select the **Reagent Blank** column or **Calibration** column of a test to view the **RB History** tab or **Calibration History** tab. The most recent reagent blank or calibration data displays.

TIP Select the date on the x-axis of the graph to view the corresponding calibration data.

5 Select the **RB Detail** tab to display and print the detailed reagent blank data for each test. Select the **Calibration Detail** tab to display and print the detailed calibration data and graphs for each test.

- 6 For reference to the individual status when multiple bottles have been set, select **RB/CAL Selection (F2)**. The RB/CAL status window opens.

Figure 7.18



- 7 Select **Reagent Blank** or **Calibration** for reference. The display changes to the respective **RB Detail** tab or **Calibration Detail** tab, and the detailed information appears. Select the **Status** tab to return to reagent blank and calibration status.
- 8 Select **Factor List (F4)**. The Factor List window opens. Factor A for tests where the interpolation formula for the calibration curve is the type $Y = AX + B$ is displayed.
- 9 After confirmation of the factor, select **Close**. The Factor List window closes.

Review Reagent Blank and Calibration History

Review RB History

- 1 Select **Menu List > Calibration Monitor**. From the **Status** tab, select the Reagent Blank box to the right of the test name to go to the **RB History** tab.

Figure 7.19



- 2 View a graph of the OD of the reagent blank. The system saves a maximum of 100 points of data per sample type per test. The vertical line indicates a new lot number of reagent. If Advanced Calibration is programmed to Lot + Bottle, the vertical line indicates a new lot number or a new bottle of reagent.
- 3 Select the test to display from the "Test Name" drop-down list.

Review Calibration History

- 1 Select **Menu List > Calibration Monitor**. From the **Status** tab, select the Calibration box to the right of the test name to go to the **Calibration History** tab.

Figure 7.20



- 2 View the calibration OD on a graph. The system saves a maximum of 100 points of data per sample type per test. The vertical line indicates a new lot number of reagent. If Advanced Calibration is programmed to Lot + Bottle, the vertical line indicates a new lot number or a new bottle of reagent.
- 3 Select the test to display from the "Test Name" drop-down list.

Review Reagent Blank and Calibration Detailed Data

Review RB Detail

- 1 Select **Menu List > Calibration Monitor**. From the **Status** tab, select the Reagent Blank box to the right of the test name to go to the **RB Detail** tab.

Figure 7.21



- 2 View detailed reagent blank data information.
- 3 Select the test to display from the "Test Name" drop-down list.

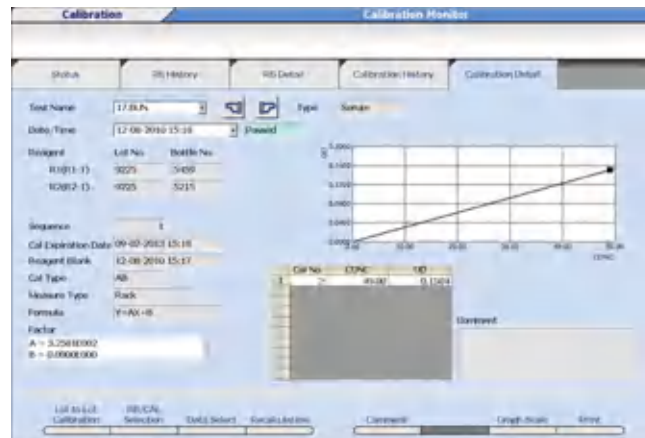
Print Reagent Blank Data:

- 1 From the **RB Detail** tab, select **Print (F8)**.
- 2 The Print window opens with options.
 - Recent/History: Recent data or History (maximum of 100 points)
 - Data Options: Result (OD for all read points) or Representation (OD for P0, Px and Py. Px and Py are the read points of the test)
 - Test Print Options: Display Test or All Tests
- 3 Select **OK** to print.

Review Calibration Detail

- 1 Select **Menu List > Calibration Monitor**. From the **Status** tab, select the Calibration box to the right of the test name to go to the **Calibration Detail** tab.

Figure 7.22



- 2 View detailed calibration data information.
- 3 Select the test to display from the "Test Name" drop-down list.

Print Calibration Data

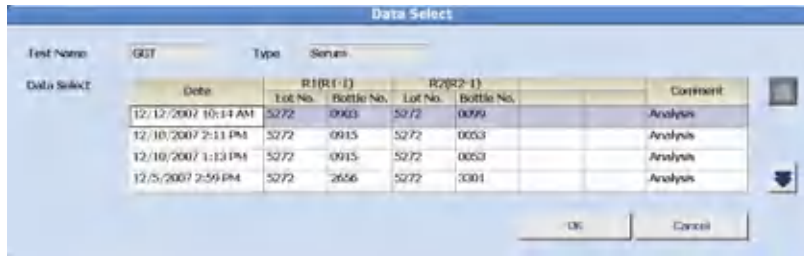
- 1 From the **Calibration Detail** tab, select **Print (F8)**.
- 2 The Print window opens with options.
 - Recent/History: Recent data or History (maximum of 100 points)
 - Test Print Options: Display Test or All Tests
 - Factor: Without Factor or With Factor
- 3 Select **OK** to print.

Display Data History and Add a Comment are common to the **RB History**, **RB Detail**, **Calibration History**, and **Calibration Detail** tabs. Change the Graph Scale is common to the **RB History**, **Calibration History**, and **Calibration Detail** tabs.

Display Data History

- 1 Select **Data Select (F3)** to display a history of the R1 and R2 lot number and bottle number.

Figure 7.23



- 2 Select the reagent blank data to display from the Date column, then select **OK**.

TIP Reagent Blank and Calibration history data can also be displayed by selecting a date and time from the “Date/Time” drop-down list in the **RB History** tab or **Calibration History** tab, or by selecting the date on the x-axis of the graph.

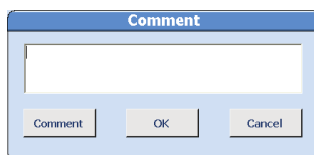
Add a comment

“Master Comments” are pre-programmed comments that can be selected to avoid re-typing common comments. Refer to [4.10.6 Program Master Comments](#) in chapter 4 to program a master comment.

Comments created in **RB History** or **RB Details** display in both tabs. Comments created in **Calibration History** and **Calibration Details** display in both tabs.

- 1 Select **Comment (F5)**. The Comment window opens.

Figure 7.24



- 2 Select **Comment**. The window to select a master comment appears.
- 3 Select the comment to be set.
- 4 Select **OK**. The window is closed and the selected comment is displayed in the window to edit the comment if necessary.
- 5 If master comments are not programmed, enter a comment.
- 6 Select **OK**. The window is closed and the entered comment is registered.

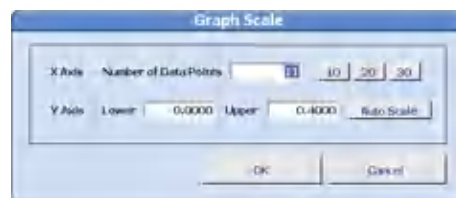
For details on programming a master comment, refer to [4.10.6 Program Master Comments](#) in chapter 4.

Change the graph scale

The graph display size can be changed.

- 1 Select **Graph Scale (F7)**. The Graph Scale window opens.

Figure 7.25



- 2 Select the **10**, **20**, or **30** button to enter the Number of Data Points, or enter a number.
- 3 For the Y Axis, set the “Lower” limit value and “Upper” limit value.

TIP When **Auto Scale** is selected, the upper limit value and the lower limit value are automatically set, and the scale calculation is displayed.

- 4 Select **OK**. The graph is redrawn with the set scale.

“Lot Calibration” Option

This option is programmed in **Parameters > Calibration Parameters > Calibration Specific**. It is functional if a check is placed by “Lot Calibration” and Advanced Calibration is set to Lot/Lot. The option affects the reagent blank and calibration stability when a second bottle of reagent is placed on the system. When "Lot Calibration" is checked, a maximum of two bottles of reagent can be on-board instead of five.

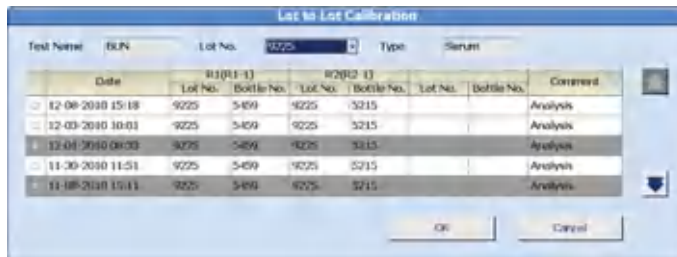
If checked, when the second bottle of reagent is placed on the system, the calibration factor from the first bottle of reagent (base factor) is used for the second bottle of reagent. The reagent blank and calibration stability for the first bottle continues to be tracked, and the reagent blank and calibration stability for the second bottle is set to the programmed stability in **Calibration Specific**.

If unchecked, when the second bottle of reagent is placed on the system, the reagent blank and calibration stability is tracked at the first bottle’s remaining stability period for both bottles.

In **Calibration Monitor > Calibration Details** tab, the calibration factor can be selected for “Base” or “Analysis” data.

- 1 Select **Calibration Detail > Lot to Lot Calibration (F1)**.

Figure 7.26



Calibration data status is displayed in the Comment column.

Comment	Meaning
Base	The calibration factor from the first bottle of reagent is used for the second bottle of reagent.
Analysis	The calibration factor is obtained from calibration analysis.
Base (Copy)	The calibration data is copied from the Base data.
Unuse	Calibration data has been deleted from the Base (Copy) data, and selection is not possible.

- 2 Select the calibration data to be used.
- 3 Select **OK**. The Lot to Lot Calibration window is closed and the settings are registered.

7.3.5 Check QC

The following are options for checking QC results:

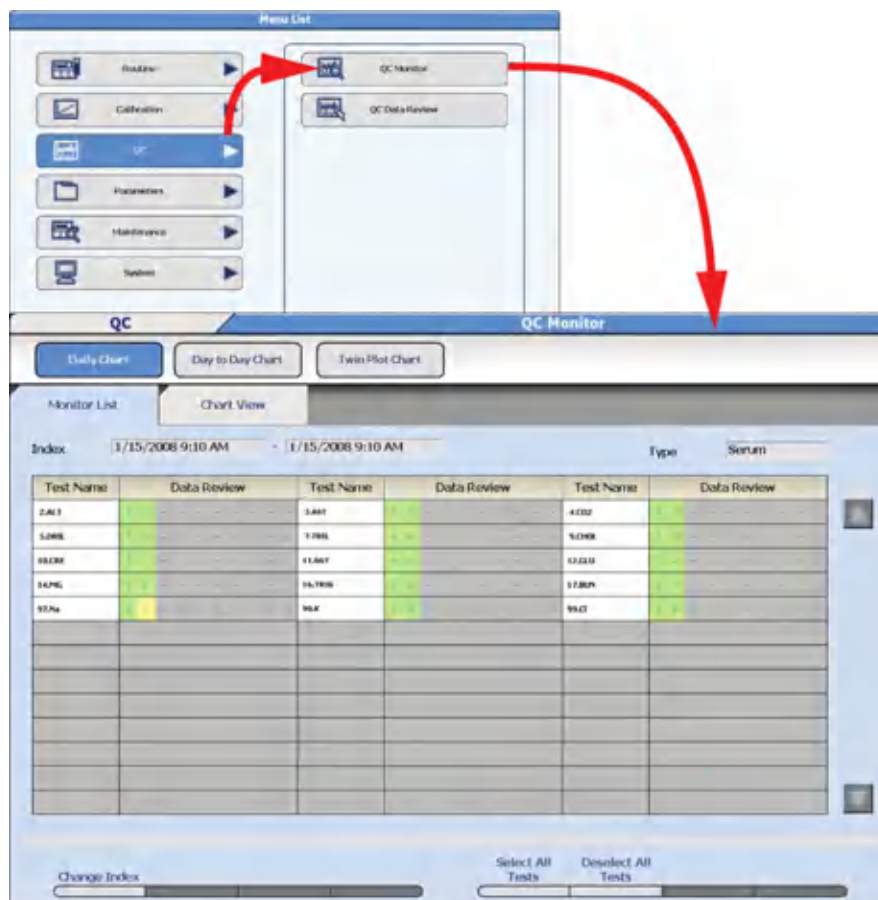
- Check the daily variation chart.
- Check the day-to-day variation chart.
- Check the twin-plot chart.

Check the Daily Variation Chart

QC results can be reviewed by plotting the individual QC points from one index or a range of indexes on a single chart. Always review the daily variation chart after performing daily QC analysis.

- 1 Select **Menu List > QC > QC Monitor > Daily Chart > Monitor List.**

Figure 7.27



TIP The colors of "Data Review" indicate as follows:

- Green: Normal data
- Yellow: Data outside the range of the Single Check Level programmed in **QC Specific**
- Orange: Abnormal data (data not included in the QC statistical values)

2 Select **Change Index (F1)**. The Change Index window opens. Select the index or index range to display from the "Start Index" and "End Index" drop-down lists. Select the sample type from the "Type" drop-down list.

3 Select **Data Search** to search for QC data based on the index and sample type selected.

4 Select the test(s) to display.

TIP When **Select All Tests (F5)** is selected, all displayed test names are selected.

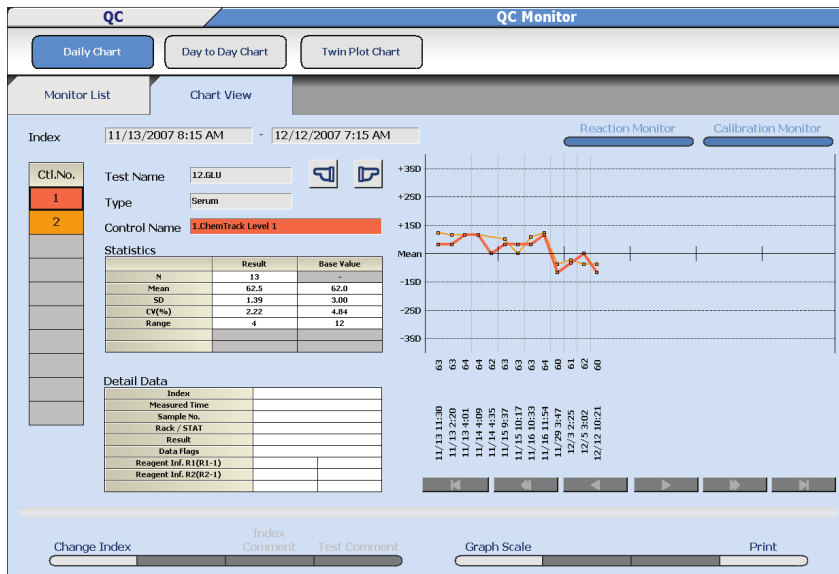
When **Deselect All Tests (F6)** is selected, all selected test names are deselected.

5 Select the **Chart View** tab. The Daily Variation chart is displayed.

TIP A chart is displayed for each test. Each control material assigned to the test is displayed in a different color listed under "Ctl No.". Select the control number to highlight the control on the graph and display the control number Detail Data.

When $\pm 3SD$ from the mean value is exceeded, the point is outside the display range.

Figure 7.28



TIP Control Name

Select a control number assigned to the test under “Ctl No.” to display the control on the graph and Detail Data.

Statistics



The statistical values for the selected Ctl No. are displayed.

Detail Data

Select the date and time on the x-axis of the graph to display the detailed data for that control.

Graph Scale (F5)

When selected, the number of data to display on the X-axis can be selected as 10, 20, or 30. The display of the Y-axis cannot be changed.

-
- 6** Select  or .
- The QC daily variation chart for the preceding and following test names is displayed.
-
- 7** Select **Reaction Monitor**. The reaction monitor for the displayed data is displayed.
-
- 8** Select **Back** from **Reaction Monitor**. The display returns to **Chart View**.
-
- 9** Select **Calibration Monitor**. The calibration monitor for the displayed test is displayed.
-
- 10** Select **Back** from **Calibration Monitor > Calibration History**. The display returns to **Chart View**.
-
- 11** Select **Print (F8)**. The Print window opens.
-
- 12** Select the List Type options (statistics, Detail Data, Graph, and with Comments) to print. Select the Output Data (Current Test or All Test) to print.
-
- 13** Select **OK**. Printing starts.
-

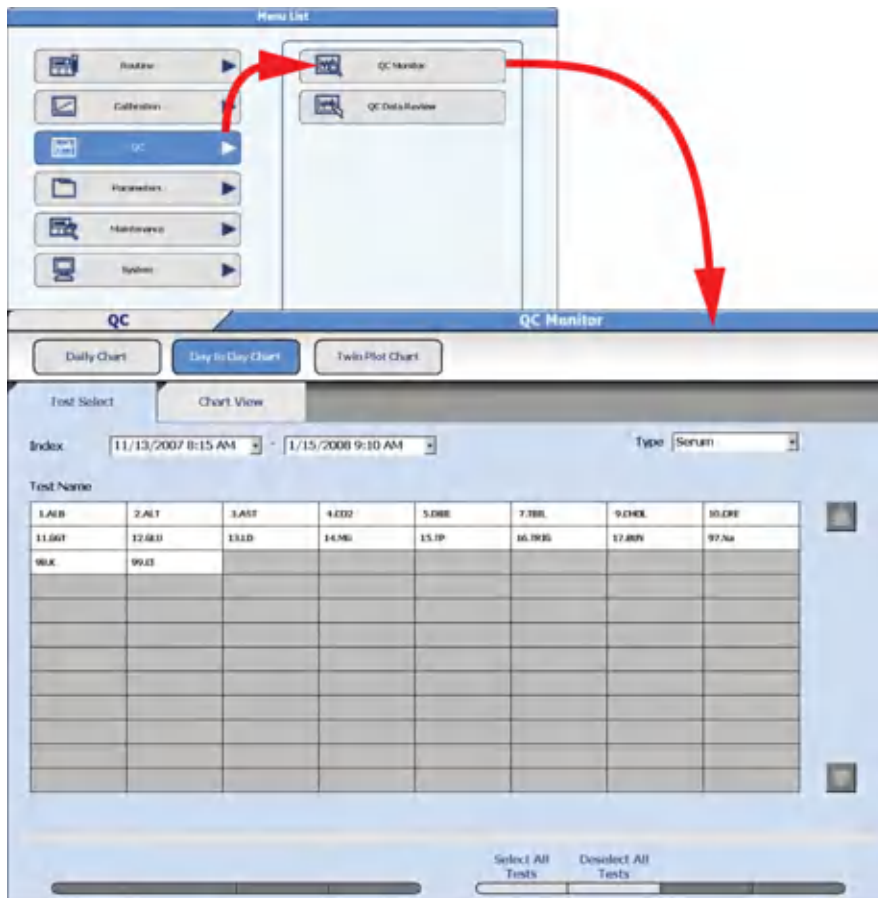
Check the Day-to-Day Variation Chart

The day to day variation chart compares QC results by plotting a number of days of QC analysis on a chart that displays the variation. All QC points for a specific control within an index are averaged, then plotted on the day to day chart.

Select the range of indexes to display.

- 1 Select **Menu List > QC > QC Monitor > Day to Day Chart > Test Select**.

Figure 7.29



- 2 Select the starting and ending index range to display from the "Index" drop-down list. Select the sample type from the "Type" drop-down list.

- 3 Select the test(s) to display.

TIP When **Select All Tests (F5)** is selected, all displayed test names are selected.
When **Deselect All Tests (F6)** is selected, all selected test names are deselected.

- Select the **Chart View** tab. The selected day-to-day control chart appears.

Figure 7.30



TIP Control Name

Select a control number assigned to the test under “Ctl No.” to display the control on the graph and Detail Data.

Statistics

The statistical values for the selected Ctl No. are displayed.

Detail Data

Select the date and time on the x-axis of the graph to display the detailed data for that control.

Graph Scale (F5)

Select 10, 20, or 30 QC data points to display on the X-axis. The display of the Y-axis cannot be changed.

- Select the test name to display the data as the QC daily variation chart using or . The QC daily variation chart for the preceding and the following test is displayed.
- Select **Print (F8)**. Select the List Type options (statistics, Detail Data, Graph, and with Comments) to print. Select the Output Data (Current Test or All Test) to print.

Check QC Results Using Twin Plot

Use Twin Plot analysis to determine whether a QC variation is caused by the system or is the result of a random error. QC analysis is usually performed using two QC samples:

- A sample in the reference range
- A sample in the pathological range

The twin plot function displays the first QC sample on the x-axis of a 2-dimensional plot and the second QC sample on the y-axis. All points should fall within the 2SD range in the center of the twin plot.

To view the Twin Plot display:

-
- 1** Select **Menu List > QC > QC Monitor > Twin Plot Chart > Test Select**.

 - 2** Select the starting and ending index range to display from the "Index" drop-down list. Select the sample type from the "Type" drop-down list.

 - 3** Select the test names to display in the list of "Test Name". This changes the display color of the selected test names. Selecting again cancels the selection.



TIP When **Select All Tests (F5)** is selected, all displayed test names are selected.
When **Deselect All Tests (F6)** is selected, all selected test names are deselected.

- 4 Select the **Sample** tab. Display QC data by sample number for the range of indexes selected.

Figure 7.31

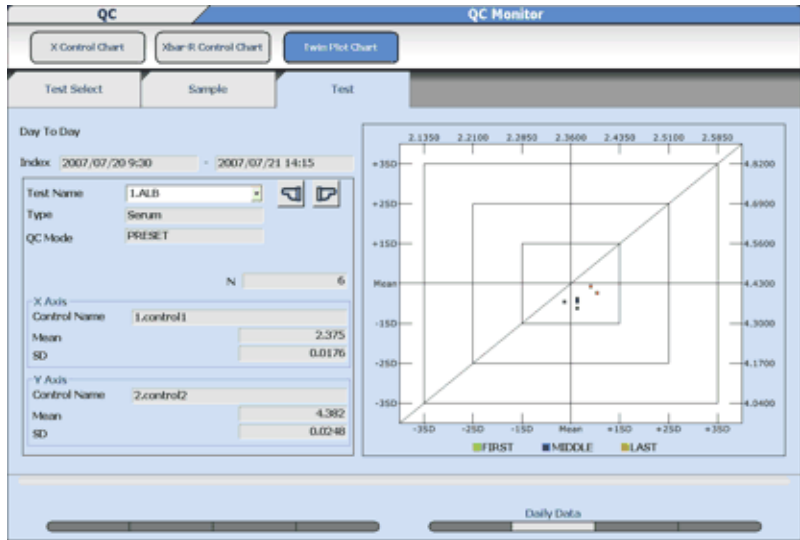


TIP As the tests selected with the **Test Select** tab are displayed together, the causes for fluctuations in regard to temperature and calibrator can be estimated more easily.
Check the box next to “Display Test Name” to display test names on the chart.
When a test name is selected, the test name is displayed on the graph highlighted in red.

- 5 Select a QC sample number to view from the “QC Sample No.” drop down, or by selecting  or .
- 6 When any abnormal condition occurs, refer to [CHAPTER 11, Troubleshooting](#).

7 Select the **Test** tab.

Figure 7.32



The tests selected in the **Test Select** tab are displayed for each test.

QC data is displayed chronologically, divided into three blocks to review high shifts or other errors.

TIP To display the daily statistical results, select **Daily Data (F6)**.

Adding a comment

“Master Comments” are pre-programmed comments that can be selected to avoid re-typing common comments. Master comments can be programmed in **System > Comment Master**. Master comments can be added to QC data.

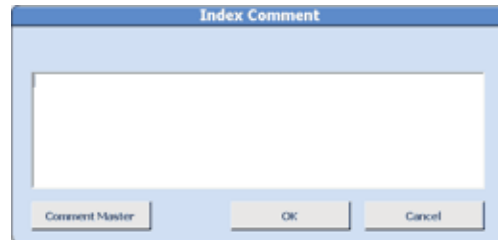
Comments can be added in the **Chart View** tab in **Daily Chart** or **Day to Day Chart**. An Index Comment adds the comment by the Index title for all QC in the index. A Test Comment adds the comment by a specific test within the index.

Index comments

- 1 Select **Menu List > QC > QC Monitor > Daily Chart** or **Day to Day Chart > Chart View**. Select the date and time below the x-axis of the graph for the comment.

- 2 Select **Index Comment (F3)**. The Index Comment window opens.

Figure 7.33



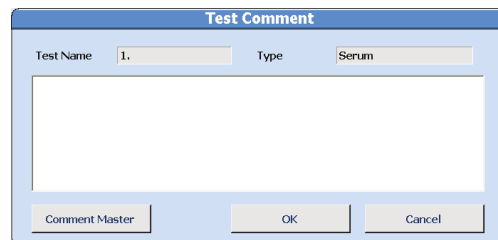
- 3 Enter a comment or select a comment from **Comment Master**.
- 4 Select **OK**. The window closes. Comments can be viewed by selecting **Index Comment (F3)**, or printed by selecting **Print (F8)** "With Comments".

For details on programming a comment, refer to [4.10.6 Program Master Comments](#) in chapter 4.

Test comments

- 1 Select **Menu List > QC > QC Monitor > Daily Chart** or **Day to Day Chart > Chart View**. Select the date and time below the x-axis of the graph for the comment.
- 2 Select **Test Comment (F4)**. The Test Comment window opens.

Figure 7.34



- 3 Enter a comment or select a comment from **Comment Master**.

- 4 Select **OK**. The window closes. Comments can be viewed by selecting **Test Comment (F4)**, or printed by selecting **Print (F8)** “With Comments”.

For details on programming a comment, refer to [4.10.6 Program Master Comments](#) in chapter 4.

7.3.6 Verify Repeat Results

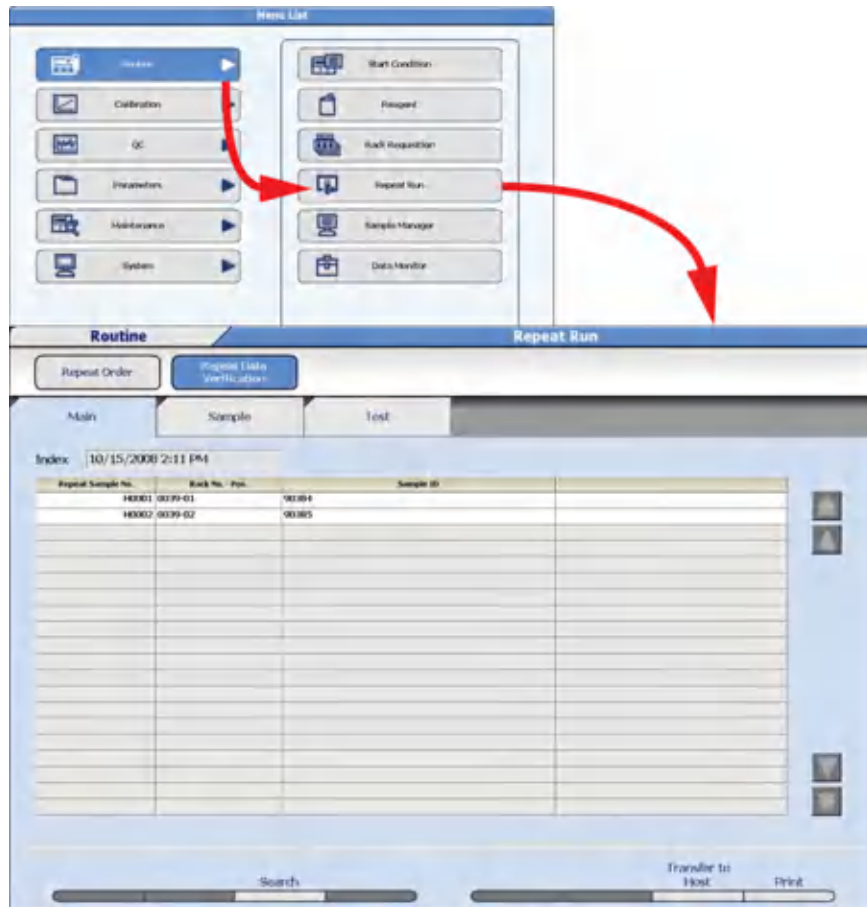
Verify the original and repeat test results. The original result can be automatically overwritten with the repeat result, depending on the programming in **Repeat Parameters**.

For details on programming the automatic overwrite option, refer to [4.4.1 Repeat Common Menu](#) in chapter 4.

Overwriting the data

- 1 Select **Menu > Routine > Repeat Run > Repeat Data Verification > Main**.

Figure 7.35



- 2 The screen displays the current index data. Select **OK** if No Data Found displays. Select an index from the "Index" drop-down list.
- 3 Select **Search (F3)** to search for data by an Index, Sample Number(s), Sample ID, or Data Not Transferred to Host. Use the scroll bars to change Sample Kind to Priority STAT or Emergency. Select **OK** to update the contents of the **Main** tab.
- 4 Select the **Sample** tab to review original and repeat data by repeat sample number. Select the **Test** tab to review original and repeat data by test.
- 5 In the **Sample** tab, select the **Sample No.**, then select the test(s) to overwrite. In the **Test** tab, select the **Test Name**, then the repeat sample number(s) to overwrite.
- 6 Select **Overwritten by Repeat (F5)**. Select **OK** to overwrite data. An "S" flag is attached to data if the original result is overwritten with the repeat result.



The original data is no longer available after it is overwritten with repeat data.

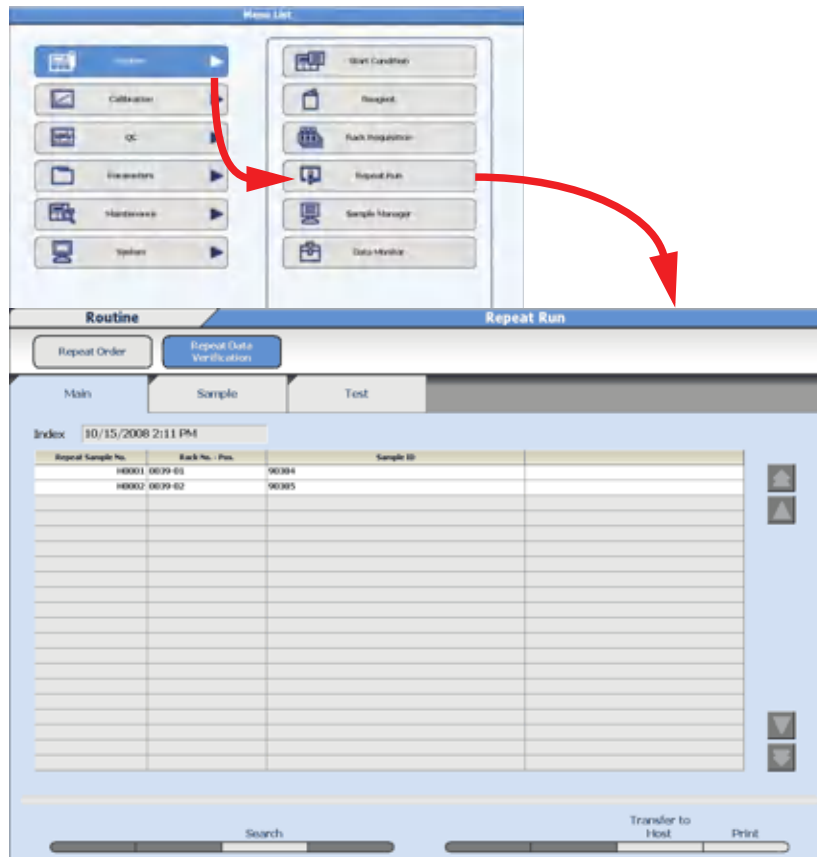
Printing the Overwritten Data

- 1 Select **Menu List > Routine > Repeat Run > Repeat Data Verification > Main**.
- 2 Select **Print (F8)**. The Print window opens.
- 3 Select the list format from the "List Format" drop-down list.
- 4 For Reporter, the Operator Name entered in **Start Condition** displays. If necessary, enter a new name or use **Select** to enter a pre-programmed Comment Master. "Reporter" is an option that can be added to a list format, and only prints if it is formatted.
- 5 Select **OK**.

Online Transfer of Overwritten Data

- 1 Select **Menu List > Routine > Repeat Run > Repeat Data Verification > Main.**

Figure 7.36



- 2 The data from the current index displays. Select **OK** if No Data Found displays. Select an index from the "Index" drop-down list.
- 3 Select **Search (F3)** to search for data by an Index, Sample Numbers(s), Sample ID, Data Not Transferred to Host, or Data Not Printed.
- 4 Select **Transfer to Host (F7)**. The Transfer to Online window opens.
- 5 Select **OK**. Online data transfer is performed.

-
- 6** To cancel the online data transfer, select **Online Transfer Stop (F7)**. Online data transfer is cancelled.
-

7.4 Reagent Management

- 7.4.1 Fix (Assign) a Reagent Position
- 7.4.2 Edit a Reagent ID
- 7.4.3 Read the Master Curve
- 7.4.4 Review and Delete Reagent History
- 7.4.5 Reagent Inventory
- 7.4.6 Reagent Consumption

7.4.1 Fix (Assign) a Reagent Position

Fix (assign) reagents that are not barcoded. The analyzer does not read barcodes on reagents in fixed positions.

Non-barcoded reagents must be placed in the assigned reagent position.

Reagent ID Read Errors only display in the **Details** tab when “Reagent Display” is set to Position.

-
- 1 Select **Home > Reagent Management > Details**.

TIP Reagent status must be “checked” before a position can be fixed. Select **Reagent Check (F5) > Reset**. Use **Reset** only if no other changes have been made.

-
- 2 Select **Position** from the "Reagent Display" drop-down list.

-
- 3 Select an available bottle position to fix the reagent.

-
- 4 Select **Position Setting (F2)**.

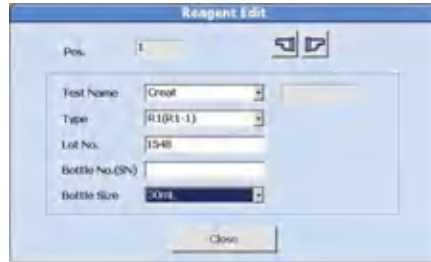
Figure 7.37



5 Select **Fixed Reagent > Close**. A blue box with an "*" displays to the left of "Pos." for fixed reagents.

6 Select **Edit (F1)**.

Figure 7.38



TIP Fields a, b, and e are required. Fields c and d are optional based on laboratory Standard Operating Procedures.

- a. Select the test name from the "Test Name" drop-down list.
- b. R1 (R1-1) or R2 (R2-1) displays from the "Type" drop-down list.
- c. Enter a Lot No. according to laboratory Standard Operating Procedures.
- d. Enter a Bottle No. (SN) according to laboratory Standard Operating Procedures.
- e. Select a bottle size from the "Bottle Size" drop-down list.

7 Select **Close**. Repeat steps 3-6 if the reagent has both an R1 and an R2.

8 Verify a blue box with an "*" displays to the left of "Pos." for fixed reagents.

9 Select **Reagent Check (F5) > Check Specified Positions**, then select the reagent(s) loaded into the fixed positions to update the test count.

7.4.2 Edit a Reagent ID

Edit the reagent ID after a reagent ID read error occurs on a barcoded reagent bottle.

A notification alarm occurs during the reagent check (“Reagent ID Read Error”), and the Comment “ID Edit” displays until the reagent bottle is removed from the refrigerator.

- 1 Select **Home > Reagent Management > Details**.
- 2 Select **Position** from the "Reagent Display" drop-down list.
- 3 Place the cursor on the position with the reagent ID read error.
- 4 Select **ID Edit (F3)**.

Figure 7.39



- 5 Type in the 20-digit reagent ID from the reagent bottle. Select **OK**. The onboard stability, expiration, lot number, and bottle number are updated with a “No Volume to Process” comment.
- 6 Select **Reagent Check (F5) > Check Specified Positions** to update the test count. An advisory alarm “Reagent ID Read Error” and “ID Edit” comment display. The RB stability and cal stability are updated.

7.4.3 Read the Master Curve

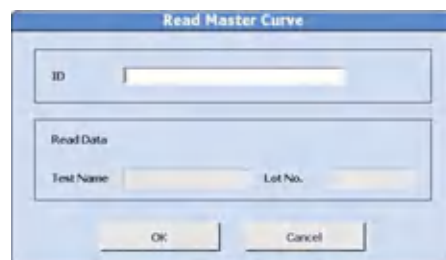
This function reads the 2D barcode of the AU reagent with the hand scanner (option) to read the master curve information.

If there is no master curve information, the comment “No Master Curve” is displayed in the Comment column in **Reagent Management > Details**.

This function requires the hand scanner (option). Contact Beckman Coulter Sales Department or Service Department for the hand scanner.

- 1 Select **Read Master Curve (F4)** from **Reagent Management > Details**. The Read Master Curve window opens.

Figure 7.40



The screenshot shows a dialog box titled "Read Master Curve". It has a blue title bar. Below the title bar, there is a text input field labeled "ID". Underneath that is a section titled "Read Data" which contains two text input fields: "Test Name" and "Lot No.". At the bottom of the dialog box, there are two buttons: "OK" and "Cancel".

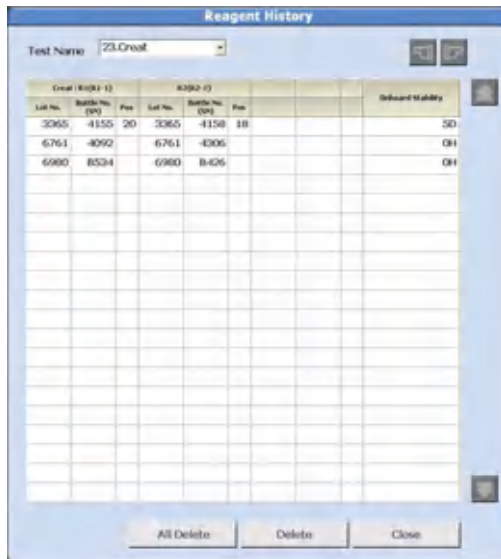
- 2 Scan the 2D barcode with the hand scanner. The ID is read, and the corresponding test name and reagent lot number are displayed on the window.
- 3 Select **OK**. The scanned data is registered.

7.4.4 Review and Delete Reagent History

Display the lot number, bottle number, position, and on-board stability for the history of R1 and R2 reagents. If conflicting information is programmed in **Calibration Parameters** (auto calibration and advanced calibration for the same test), it may be necessary to delete the reagent history for that bottle of reagent.

- 1 Select **Home > Reagent Management > Details > Reagent History (F6)**.

Figure 7.41



The screenshot shows a window titled "Reagent History" with a "Test Name" dropdown set to "23.Creat". Below the dropdown is a table with columns for "Lot No.", "Bottle No.", "Pos", and "Reagent Stability". The table contains three rows of data:

Lot No.	Bottle No.	Pos	Lot No.	Bottle No.	Pos	Reagent Stability
3065	4155	20	3065	4158	18	SD
6761	4090		6761	4306		OH
6980	8534		6980	8426		OH

At the bottom of the window are three buttons: "All Delete", "Delete", and "Close".

- 2 Select the test to display from the "Test Name" drop-down list. For sample blank tests (total and direct bilirubin), use the arrow buttons to change the display between the color and blank reagent.

A list of the previous lot numbers and bottle numbers is displayed. The most current bottle data appears on the first line and includes the R1/R2 reagent position and remaining on-board stability.

- 3 To delete the combination, select **All Delete** or **Delete**. The Reagent History window opens.

- 4 Select **OK**. Selected information is deleted.

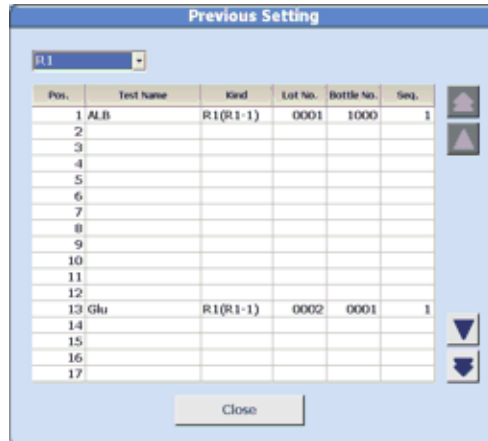
- 5 Select **Close** to close the window.

Check Information Before Reagent Check

After a bottle position error occurs, check the reagent bottle status from the previous reagent check. **Previous Setting (F7)** is only accessible in *Pause* mode.

- 1 Select **Home > Reagent Management > Details > Previous Setting (F7)**.

Figure 7.42



- 2 Select **R1** or **R2** from the drop-down list. Reagent information is displayed.
- 3 Confirm the information, and select **Close** to close the window.

Initialize Onboard Stability

This function initializes the reagent on-board stability. It is only available for reagents in fixed positions. A Lot No. and Bottle No. (SN) must be entered before the **Initialize Onboard Stability** function is operational.

Select **Initialize Onboard Stability** when replacing the reagent bottles.

7.4.5 Reagent Inventory

Reagent volume required for each test by the day of the week can be calculated from data obtained from the analyzer (Auto), or a value can be entered for each test and day of the week (Manual).

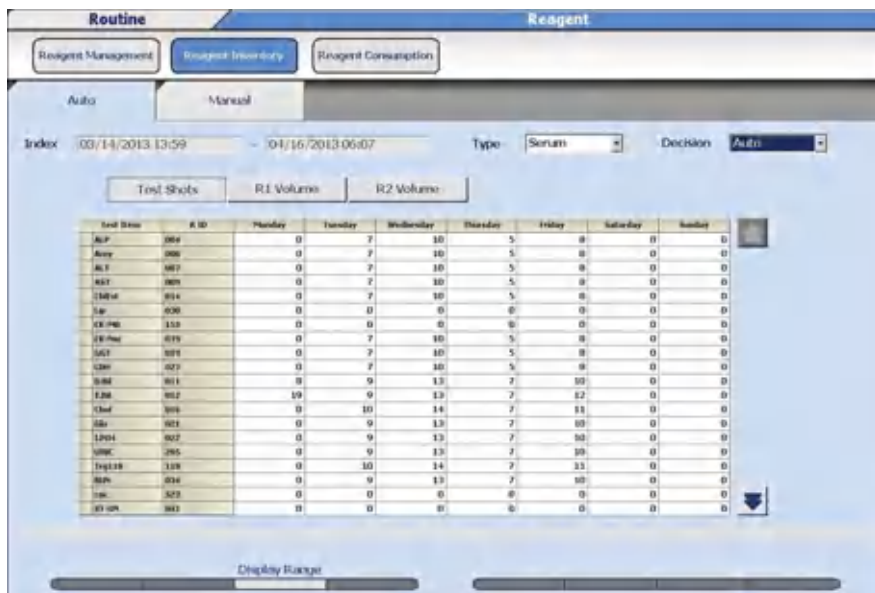
Reagent Inventory displays the number of test shots used each day of the week for each sample type within the period set by the index range. Use **Reagent Inventory** to determine how much reagent should be on-board for each day of the week.

The blue indicator bar in **Reagent Management > Main** displays the maximum number of tests calculated in **Reagent Inventory**.

Auto Calculation of Reagent Inventory

- 1 Select **Home > Reagent Management > Reagent Inventory > Auto**.

Figure 7.43



TIP Auto calculations can be entered one day in advance.

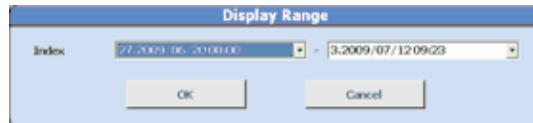
Display Range (F3)

Set the starting and ending indexes to calculate the reagent usage.

- 2 Select the sample type from the “Type” drop-down list.

- 3 Select **Display Range (F3)**. The Display Range window opens.

Figure 7.44



- 4 Select the start index and the end index from each drop-down list.
- 5 Select **OK**. The number of tests selected within index range is displayed on the list.
- 6 Select **R1 Volume** or **R2 Volume**. The reagent consumption is automatically calculated based on an actual result and then displayed on the list by mL.
The reagent consumption is calculated by the following formula:
Actual result * (the amount of reagent dispensing + the amount of surplus dispensing).
- 7 Select **Auto** from the “Decision” drop-down list. The calculated reagent consumption is set as the required reagent volume indicator in **Reagent Management**.

Manual Calculation of Reagent Inventory

- 1 Select **Home > Reagent Management > Reagent Inventory > Manual**.
- 2 Select **Edit (F1)**. The window changes to the edit mode.
- 3 Select the sample type from the “Type” drop-down list.
- 4 Enter the number of tests run for each test for each day of the week.
- 5 Select **Confirm (F1)**. The window changes to reference mode.
- 6 Select **R1 Volume** or **R2 Volume**. The reagent consumption input is automatically calculated based on entered test numbers and then displayed on the list by mL.

7 Select **Reagent Inventory > Auto**.

8 Select **Manual** from the “Decision” drop-down list. The test count entered for reagent consumption is set as the required reagent volume indicator in **Reagent Management**.

7.4.6 Reagent Consumption

Reagent Consumption displays the amount of reagent used for each test programmed on the analyzer. Set a range of indexes to display the reagent consumption used for analysis for each test by sample type.

- 1 Select **Home > Reagent Management > Reagent Consumption**.

Figure 7.45

Test Item	Reagent ID	Routine	Emergency	STAT	Sub Total	Repeat	RB	ACAL	QC	Total
Total		163392	0	143	163535	1318	14088	31140	110	210191
Samples										
ALB	002	2899	0	0	2899	20	240	236	10	3405
ALP	004	2474	0	2	2476	14	266	0	0	2756
ALT	007	2466	0	1	2467	18	274	0	18	2777
AMY	006	2793	0	1	2794	52	312	0	0	3158
AST	009	2461	0	1	2462	3	302	0	0	2767
CEP	037	1956	0	13	1969	7	332	656	0	2964
CADPC	013	2394	0	0	2394	2	320	636	0	3352
CA-AR	117	2500	0	0	2500	2	284	568	0	3354
CHOL	016	2140	0	1	2141	1	324	320	14	2800
HDL	095	1940	0	0	1940	1	192	188	2	2323
LDL	096	1726	0	0	1726	7	180	172	0	2085
CHE	014	892	0	0	892	17	100	4	0	1013
CK	078	2444	0	0	2444	5	278	0	0	2727
CK-MB	155	0	0	0	0	0	0	0	0	0
CREAT	078	2246	0	0	2246	15	320	624	2	3207
GGT	019	2602	0	0	2602	15	290	0	0	2907
GLU	021	2592	0	2	2594	1	316	312	12	3235
IPROS	022	1673	0	0	1673	21	216	216	0	2126
IRON	086	1943	0	0	1943	12	184	184	0	2323
UBIC	285	1510	0	0	1510	19	148	146	0	1823

TIP Reagent Consumption defaults to display **Shot Total**. The **Shot Total** is the cumulative number of tests run on the analyzer from the installation of the instrument.

- 2 Select the sample type from the “Type” drop-down list.
- 3 Select **Display Range (F3)**.
- 4 Select the start index and the end index from each drop-down list.
- 5 Select **OK**. The number of cumulative tests is displayed.

Check reagent consumption by samples measured and reagent dispense

- 1** Select **Test Shots** after setting the index range and sample type. The number of actual reagent dispenses, including repeat tests and re-analyzed tests displays for each test and sample type. The number of reagent dispenses displays for Routine, Emergency, STAT, Repeat, Reagent Blank, Calibration, and QC. The number of dispenses for ISE measurement displays as the number of ISE samples.
 - 2** Select **R1 Volume** or **R2 Volume**.
The volume in mL of reagent dispensed for each test and sample type displays.
The reagent consumption is calculated by the following formula:
Actual analysis result × (the amount of reagent dispensing + the amount of surplus dispensing)
 - 3** Select **Test Total** after setting the index range and sample type. The number of analyzed tests not including repeat tests and re-analyzed tests displays for each test and sample type. The number of Samples displays for Routine, Emergency, STAT, Repeat, Reagent Blank, Calibration, and QC. The number of dispenses for ISE measurement displays as the number of ISE tests (Na, K, and Cl).
-

Save reagent consumption data

- 1** Select **Report (F7)**.
 - 2** Select FD, CD-R, or External Memory Stick.
 - 3** Select the starting and ending index to save data from the "Start Index" and "End Index" drop-down lists.
 - 4** Select **OK**. The reagent consumption data is saved as a csv file.
-

7.5 Edit Quality Control Data

Analyzed QC data can be reviewed and edited.

Editing, deleting, or adding a comment can be performed by QC sample number or test.

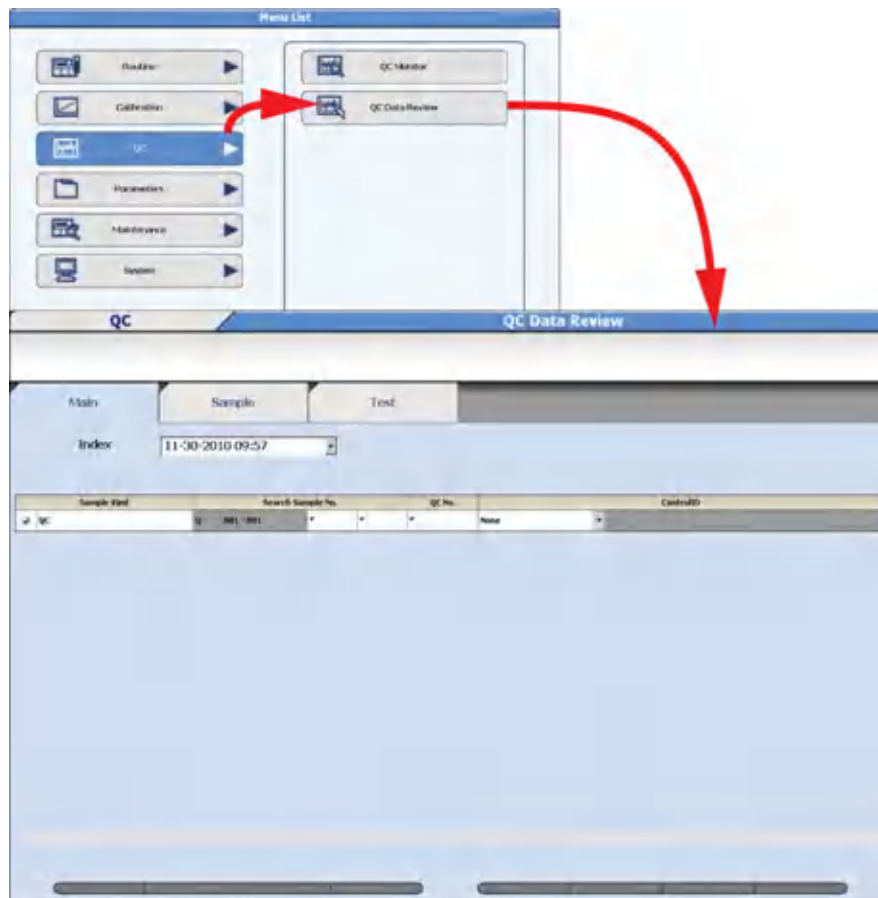
CAUTION

Analyzed QC results can be edited. To prevent an erroneous diagnosis due to numerous changes to the quality control data, editing should be done according to laboratory Standard Operating Procedures.

TIP When the QC analysis data results have been edited, confirm that the edited data falls within the cumulative period. If it falls within the cumulative period, the editing of the contents must be reflected in the cumulative values. To reflect the editing of contents in the cumulative values, update the cumulative values. Refer to [4.6.2 QC Specific Menu](#) in chapter 4 for updating and calculating cumulative QC values.

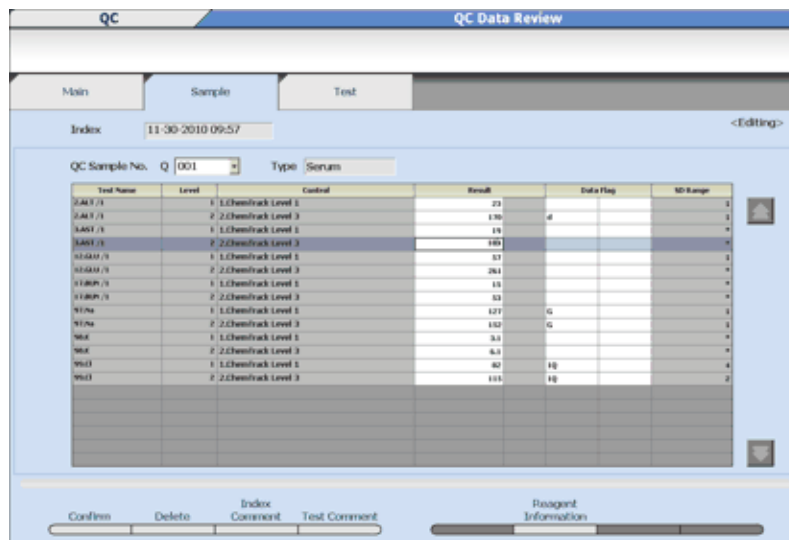
- 1 Select **Menu List > QC > QC Data Review > Main**.

Figure 7.46



- 2 Select the index from the "Index" drop-down list.
- 3 Place a check mark by QC in the Sample Kind column. Set the search range by entering the Search Sample No., the QC No., and the Control ID. The "*" searches for all data.
- 4 Select the **Sample** or **Test** tab to display the search results. A message window displays if no results are found. Select **OK** to return to the **Main** tab.
- 5 Select the **Sample** tab to edit QC by QC sample number.

Figure 7.47



- Select **Edit (F1)**.
- To edit a test(s) in the sample, select the Result or Data Flag to edit. To delete a test(s) enter a "d" flag in Data Flag.
- To delete the entire QC sample (Q001 for example includes all controls in the first QC run), select **Delete (F2)**. A "d" flag is attached to all tests in the sample. Select **OK** in the Confirmation window.
- To edit a comment, select **Index Comment (F3)** or **Test Comment (F4)**.
- Select **Confirm (F1)** to program the QC edits or deletions.

TIP When test results have been edited, an "e" flag is added to the Data Flags. Once an "e" flag has been added, it cannot be deleted. When a "d" flag is added to the Data Flags, the data is not included in the QC statistic calculations.

- 6 Select the **Test** tab to edit QC by test.

Figure 7.48

QC Sample No.	Type	Level	Control	Result	Data Flag	SD Range
Q001	Normal	1	1.125mMol/L Level 1	115		+
Q001	Normal	2	2.25mMol/L Level 2	245		+
Q002	Normal	1	1.125mMol/L Level 1			-
Q002	Normal	2	2.25mMol/L Level 2			-

- Select **Edit (F1)**.
- Select the test to edit or delete from the "Test Name" drop-down list.
- Select the Result or Data Flag to edit. To delete a sample(s) enter a "d" flag in Data Flag.
- To edit a comment, select **Index Comment (F3)** or **Test Comment (F4)**.
- Select **Confirm (F1)** to program the QC edits or deletions.

TIP When test results have been edited, an "e" flag is added to the Data Flags. Once an "e" flag has been added, it cannot be deleted. When a "d" flag is added to the Data Flags, the data is not included in the QC statistic calculations.

7.6 Edit Analysis Data

[7.6.1 Rewrite Patient Sample Data](#)

[7.6.2 Correct Patient Sample Data](#)

[7.6.3 Recalculate Analysis Data Using a Previous Calibration Curve](#)

[7.6.4 Transfer the Edited Data Online](#)

If the analysis data is manually edited, the edited data is displayed with the data flag “e” indicating manual data edit. Also, if the analysis data has been edited using a correction formula, the edited data is displayed with the data flag “c” indicating manual data correction.

- Edit analysis data
- Edit analysis data using a correction formula
- Recalculation of analysis data using a previous calibration curve
- Transfer the edited data online



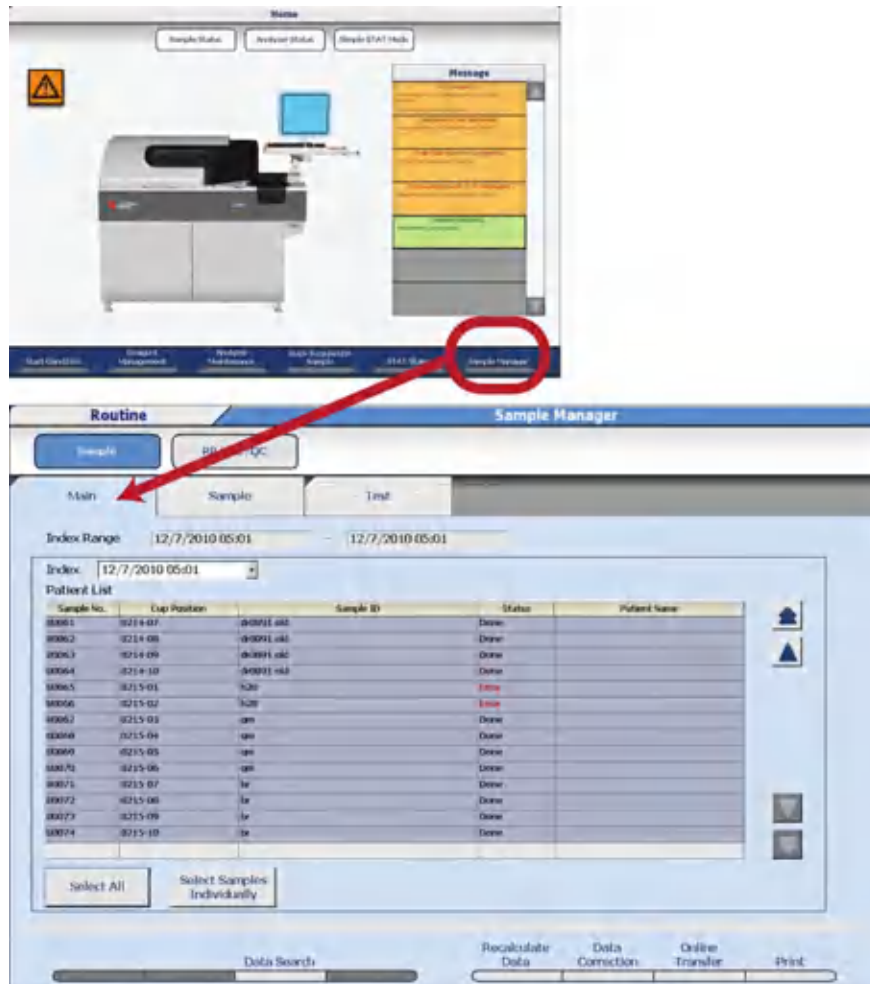
Editing should only be performed according to laboratory Standard Operating Procedures.

7.6.1 Rewrite Patient Sample Data

Results and error flags can be reviewed and edited. If a result or error flag is edited, an "e" flag is attached to the result.

- 1 Select **Home** > **Sample Manager** > **Sample** > **Main**. A list of samples in the index is displayed.

Figure 7.49



TIP Select All

All samples displayed in the list are selected (highlighted in gray).

Select Samples Individually

All samples displayed in the list are de-selected.

Recalculate Data (F5)

Re-calculate results using a previous calibration factor.

Data Correction (F6)

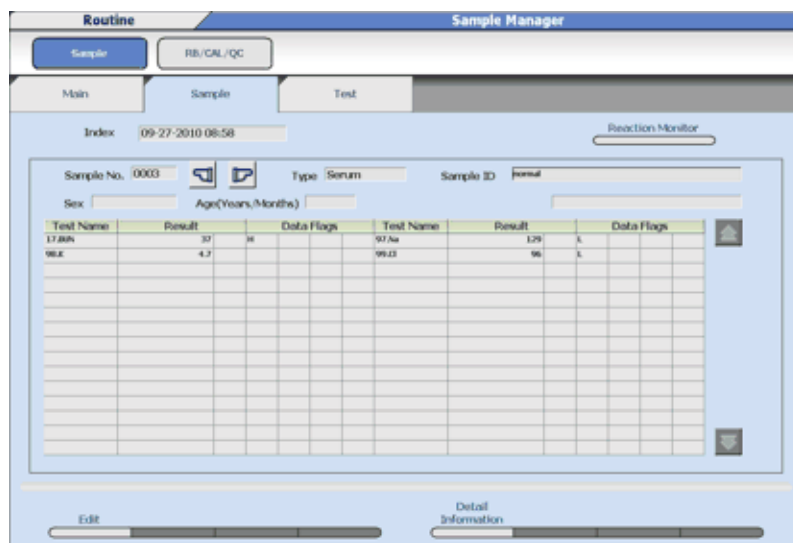
Correction by A and B of the correction coefficient $AX + B$ is possible by test and by sample type.

Print (F8)

Print the selected samples in a list format.

- 2 Select **Search (F3)** to search for data by an Index Range, Sample Number(s), Sample ID, Data Not Transferred to Host, Data Not Printed, or Abnormal Data.
- 3 Select **OK** to update the contents of the **Main** tab.
- 4 Select the “Sample No.” for the sample number to edit.
 - Select **Select All** to select all samples displayed.
 - Select **Select Samples Individually** to cancel the selection.The selected samples are displayed in gray color.
- 5 Select the **Sample** tab or **Test** tab. The search results are displayed.

Figure 7.50



TIP Results and data flags can be reviewed and edited. If a result is edited, an “e” flag is attached to the result.

If the data indicates problems, select **Reaction Monitor** to display the **Reaction Monitor** and review specific information regarding the sample. Select **Back** in **Reaction Monitor** to return to **Sample Manager**.

- 6 Select **Edit (F1)**. Results or flags can be edited.

-
- 7 In the **Sample** tab, select the Test Name to perform edits. In the **Test** tab, select the Sample No. to perform edits. Select **Detail Information (F5)** to view the sample dilution rate, reagent lot number, and reagent bottle number.

 - 8 Edit “Result” or “Data Flags”.

 - 9 Select **Confirm (F1)**. The edited data are registered.
-

7.6.2 Correct Patient Sample Data

The correction formula $Y = AX + B$ is used to correct the data for the selected sample(s) by test or all tests.

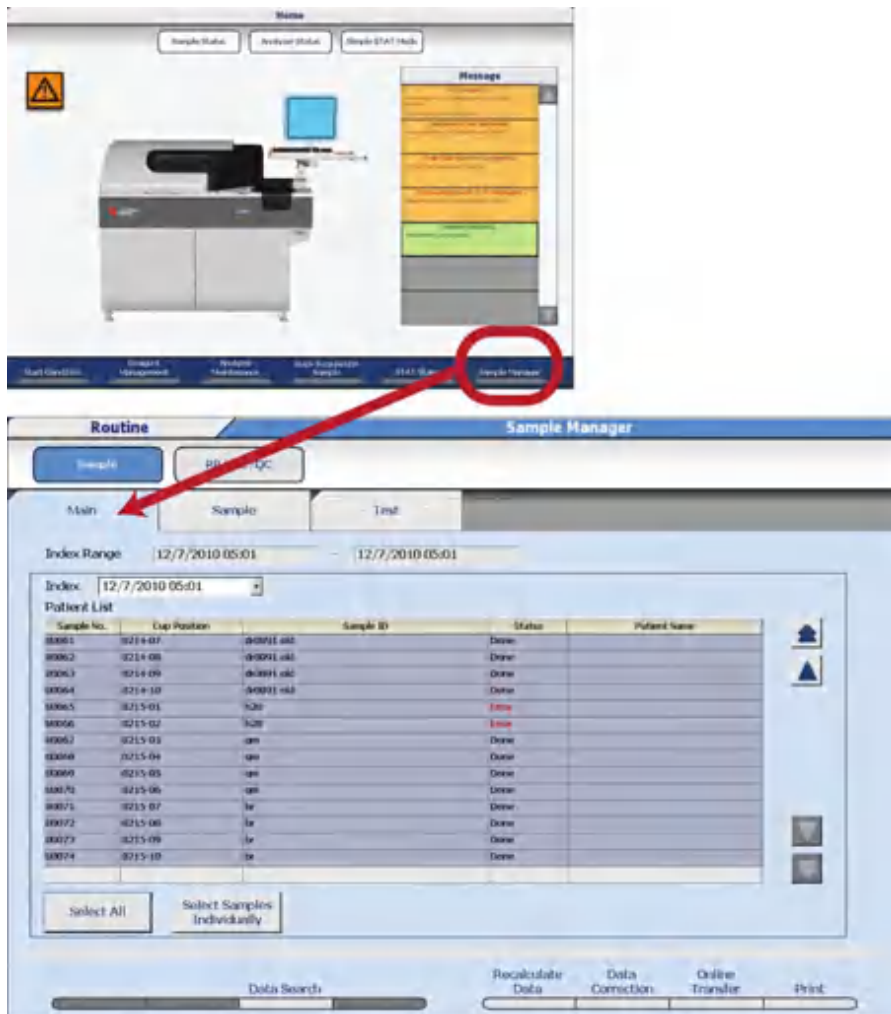
Y: Data after correction

X: Data before correction

A, B: An optional correction coefficient (9 digits, including sign and decimal point)

- 1 Select **Home > Sample Manager > Sample > Main**.

Figure 7.51



- 2 The screen displays the current index data.

- 3 Select **Search (F3)** to search for data by an Index Range, Sample Number(s), Sample ID, Data Not Transferred to Host, Data Not Printed, or Abnormal Data.

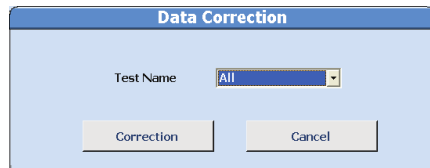
Figure 7.52



- 4 Select **OK**. The **Main** tab displays with the samples found using the search criteria.

- 5 Select **Data Correction (F6)**. The Data Correction window opens.

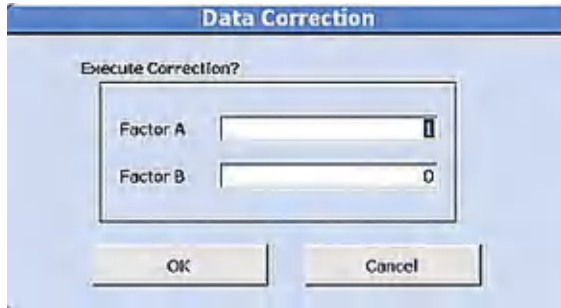
Figure 7.53



- 6 Select the test to be corrected or select **All** from the “Test Name” drop-down list and select **Correction**.

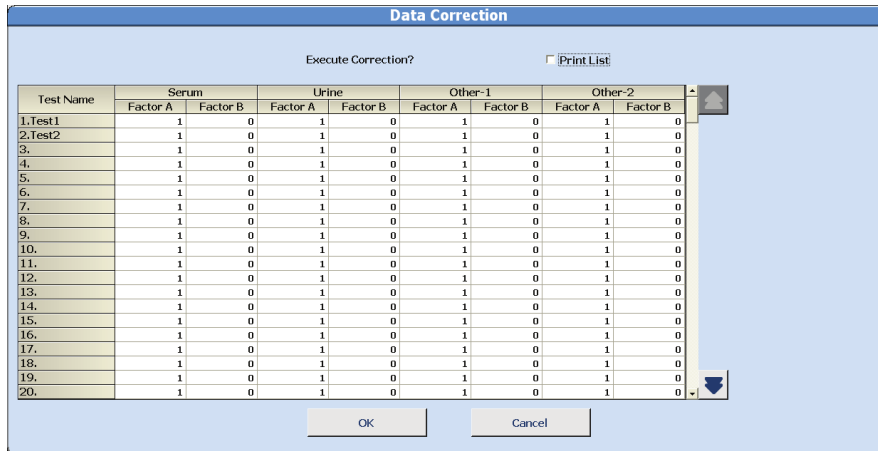
When a specific test has been selected, the window to enter coefficients A and B opens.

Figure 7.54



When **All** has been selected, the window for setting the coefficients A and B for all tests opens. The coefficient list is printed when a check is entered into the Print List check box.

Figure 7.55



- 7 Enter the coefficients A and B and select **OK**.

The Data Correction window opens with the message “Operating: Please wait”. When the correction is complete, a message appears with the last sample number corrected.

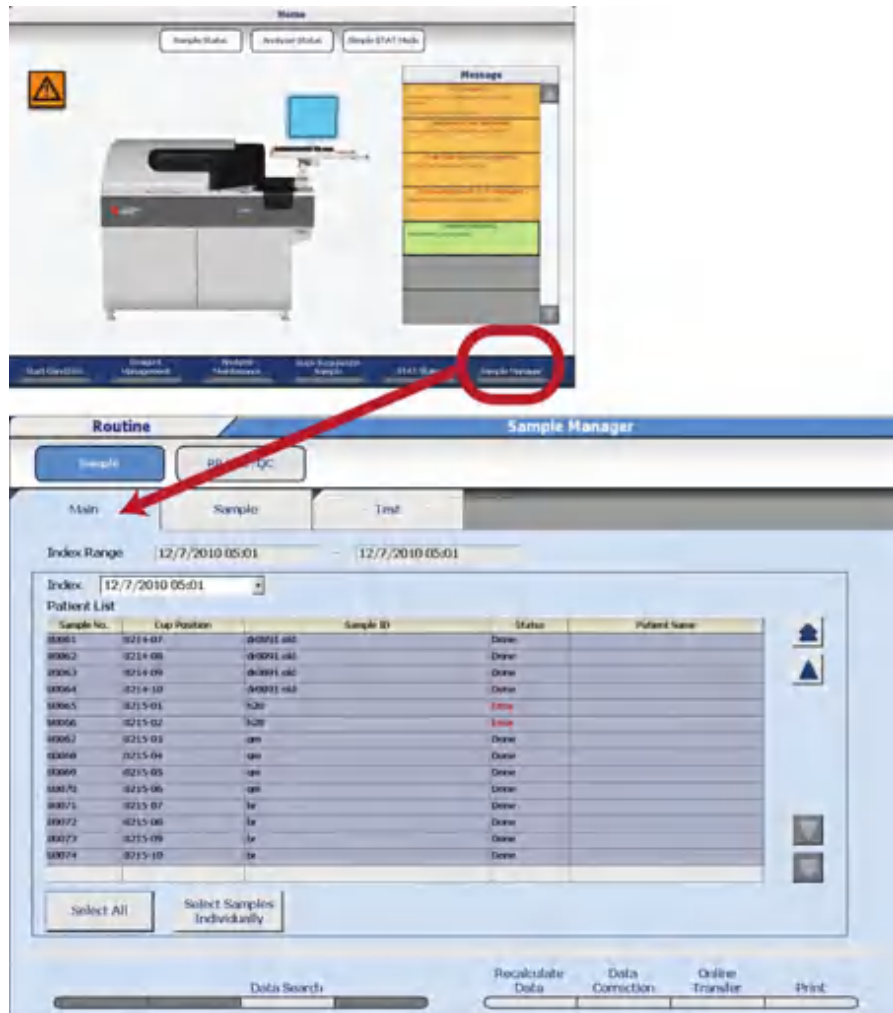
- 8 Select **OK**. The window closes and returns to the **Main** tab.

TIP A “c” flag is attached to any result that has been corrected.

7.6.3 Recalculate Analysis Data Using a Previous Calibration Curve

- 1 Select **Home > Sample Manager > Sample > Main**.

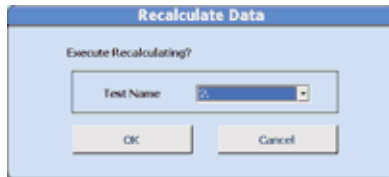
Figure 7.56



- 2 The data from the current index displays. Select **Search (F3)** to search for data by an Index Range, Sample Number(s), Sample ID, Data Not Transferred to Host, Data Not Printed, or Abnormal Data.

-
- 3 Select **Recalculate Data (F5)**. The Recalculate Data window opens.

Figure 7.57



-
- 4 Select the test to be recalculated from the "Test Name" drop-down list.

-
- 5 Select **OK**.

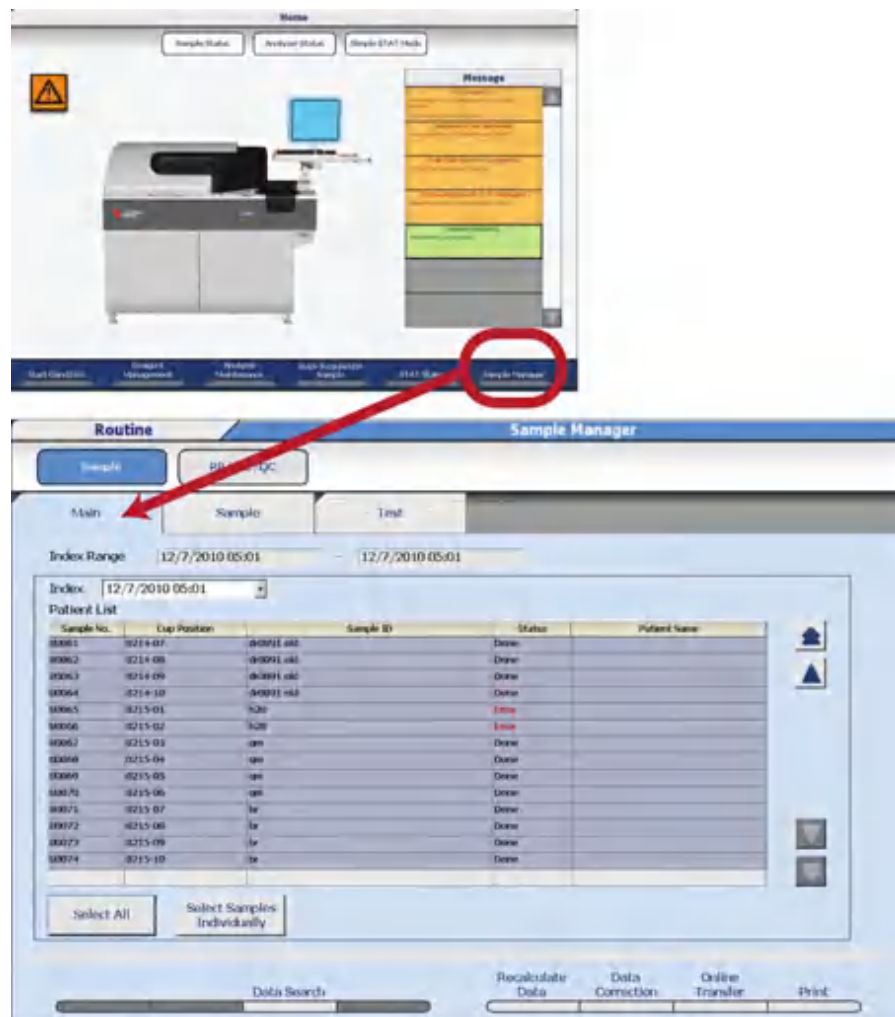
When the recalculation is complete, a message appears with the last sample number involved in the recalculation. A window displays "No Data Found" if the test was not included in the search criteria. There is not a flag attached to the recalculated data.

7.6.4 Transfer the Edited Data Online

Online transfer is possible if “Batch” or “Realtime” is selected for Result Transfer in **Menu List > System > Online**. For details on editing online conditions, refer to [4.12 Program Online Parameters](#) in chapter 4.

- 1 Select **Home > Sample Manager > Sample > Main**.

Figure 7.58



- 2 The data from the current index displays with all samples selected (highlighted in gray). Select an index from the “Index” drop-down list.

Use **Select All**, **Select Samples Individually**, or select **Sample No. (s)** individually to transfer to the host computer.

3 Select **Search (F3)** to search for data by an Index Range, Sample Number(s), Sample ID, Data Not Transferred to Host, Data Not Printed, or Abnormal Data. Select **OK**.

4 Select **Online Transfer (F7)**. The Online Transfer window opens.

5 Select **OK**. The data is transferred.

TIP Select **Online Transfer Stop (F7)** to stop the transfer.

7.7 Calculate Data Statistics

The statistical values of analyzed patient sample results are displayed with graphs and numerical data, providing easy-to-understand views such as variations in test results and changes in the same sample.

7.7.1 View Data Statistics

7.7.2 Create a Correlation Chart

7.7.1 View Data Statistics

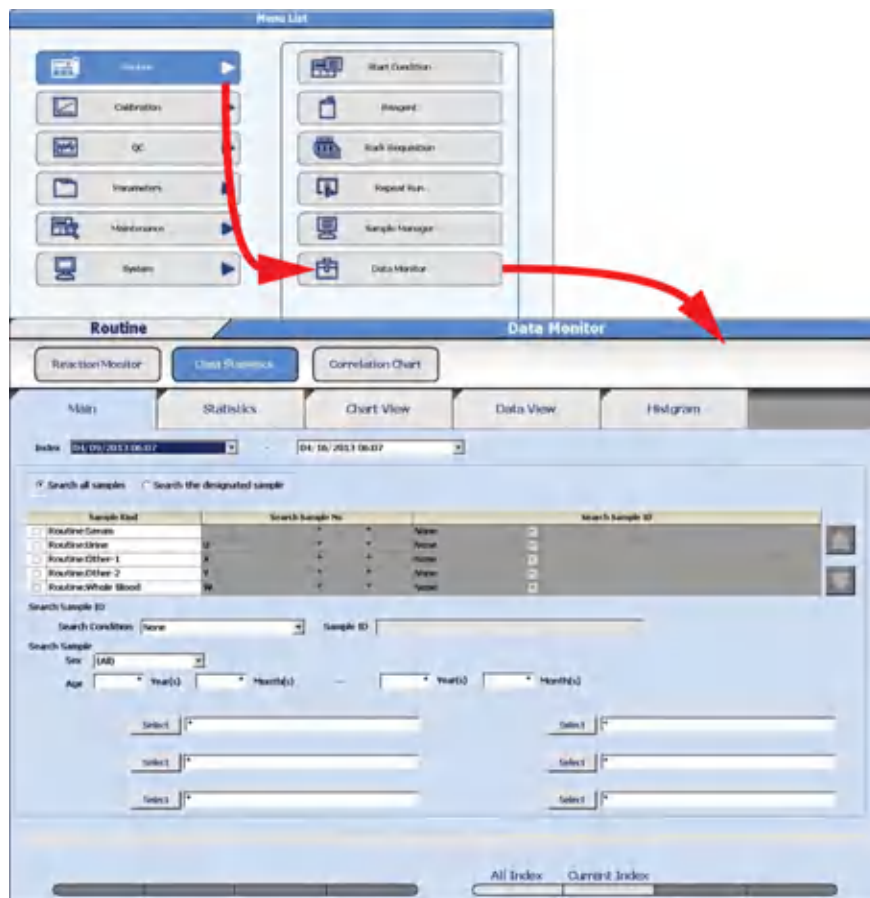
View Data Statistics

Review key statistics of sample results over a specified range of indexes.

To select samples to be used to generate sample statistics.

- 1 Select **Menu List > Routine > Data Monitor > Data Statistics > Main.**

Figure 7.59



2 Select the index range from the “Index” drop-down lists.

TIP Select **All Index (F5)** to select the oldest saved index as the starting index and the current index as the ending index range. Select **Current Index (F6)** to select the current index as the starting and ending index range.

3 Select **Search all samples** or **Search the designated sample**.

4 If **Search all samples** is selected, a specific sample ID can be searched. Under Search Sample ID, select **Complete** or **Partial** to match the sample ID from the "Search Condition" drop-down list. Enter the sample ID to search in Sample ID.

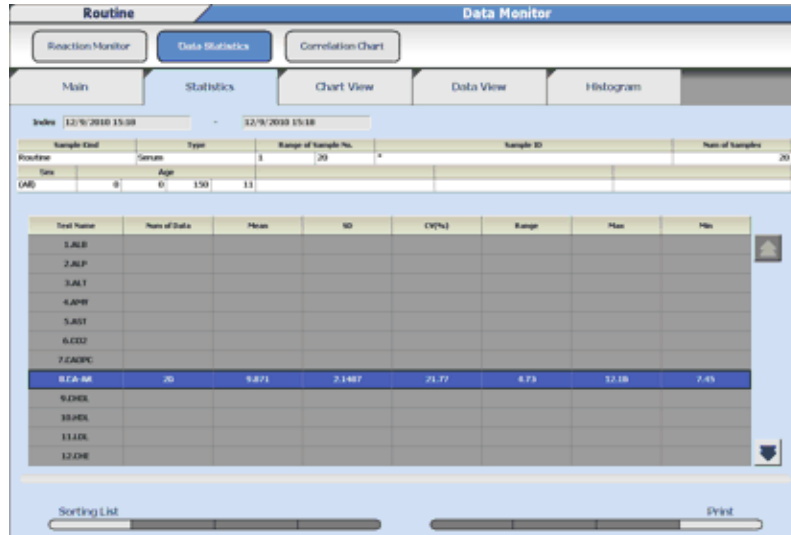
5 When **Search the designated sample** is selected, set the search conditions from the list. Check the Sample Kind to search. The Search Sample No. and Search Sample ID fields default to search all (indicated by the *) sample numbers and ID numbers. Enter a specific sample number or sample ID to search as required.

6 Set the search conditions (Sex, Age range, and/or patient demographic information 1 to 6).

TIP User-defined patient demographic information is programmed in **System > Format > Requisition Format**.

- 7 Select **Statistics** to display the data statistics, including the number of data points, mean, SD, CV (%), range, and maximum and minimum results.

Figure 7.60

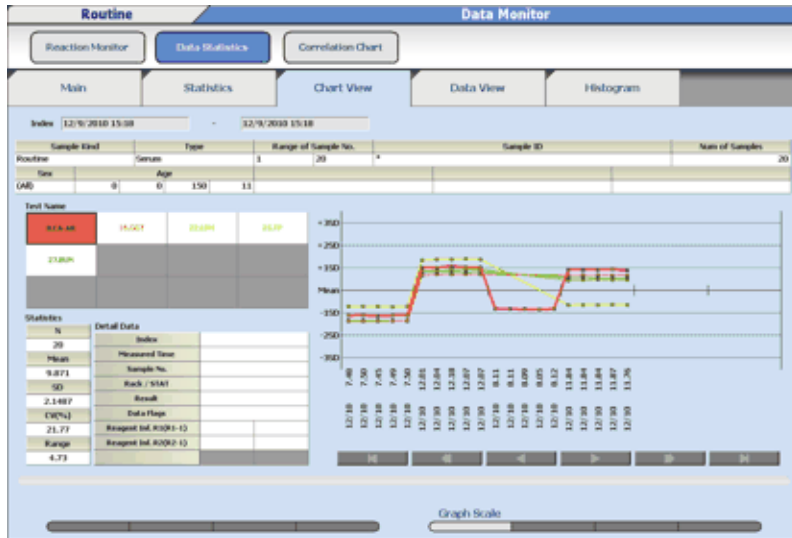


TIP Select **Sorting List (F1)** to change the sorting order of the data display. Select **Test Name** to display tests in test number order from 1 to 120, **Num of Data** to display tests from the highest to lowest number of data points, and **CV%** to display tests from the highest to lowest CV. Select **OK**.

- 8 Select up to 12 tests to display data statistics in **Chart View**, **Data View**, or **Histogram**.

- Select **Chart View** to display data statistics and a graph.

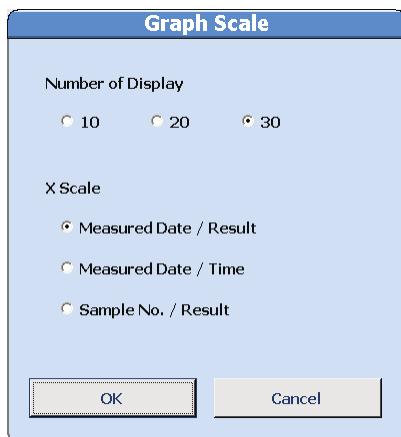
Figure 7.61



TIP Select a test in Test Name to display the statistical information for that test in statistics. The test selected displays with a thick line on the graph. Select a specific date, time, result, or sample number displayed on the X axis of the graph to display the information in Detail Data.

- To change the graph display parameters, select **Graph Scale (F5)**. The Graph Scale window opens.

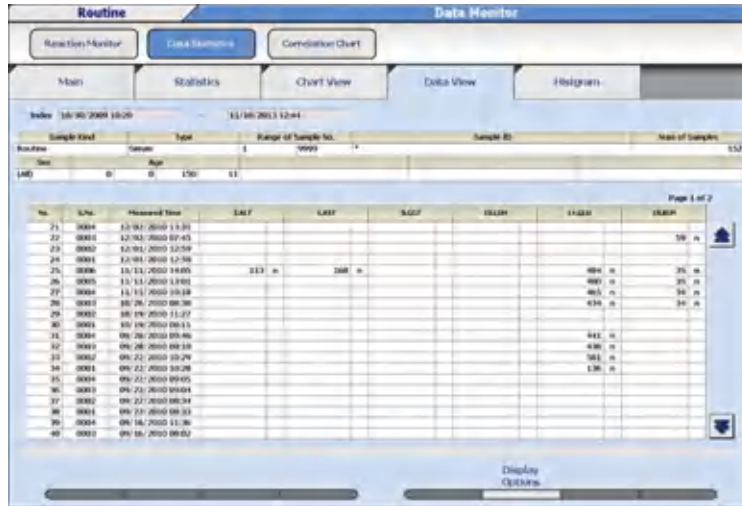
Figure 7.62



- Select the **Number of Display** and **X Scale** option required, then **OK**. The graph display changes.

- 12 Select **Data View** to display the sample numbers, measure times, and results for the tests selected in **Statistics**.

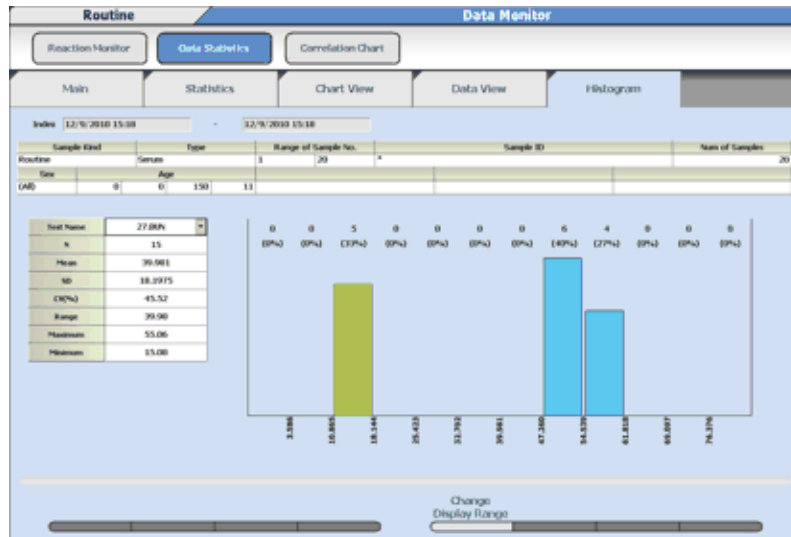
Figure 7.63



TIP Data corresponding to 10,000 samples can be displayed using the up or down scroll button. Select **Display Options (F6)** to change the test display page.

- 13 Select **Histogram** to display test data statistics and a bar graph of the data.

Figure 7.64



TIP Data within the range of the mean +/- 1 SD is displayed by a blue bar. Data outside of the mean +/- 1 SD is displayed by an orange bar.

14 Select the test name from the "Test Name" drop-down list.

15 Select **Change Display Range (F5)** to change the display range of the histogram.

- Select **Auto Scale** to display the entire range of results.
- Enter the lowest result and highest result to display in Range of Display. Select **OK**.

Figure 7.65



7.7.2 Create a Correlation Chart

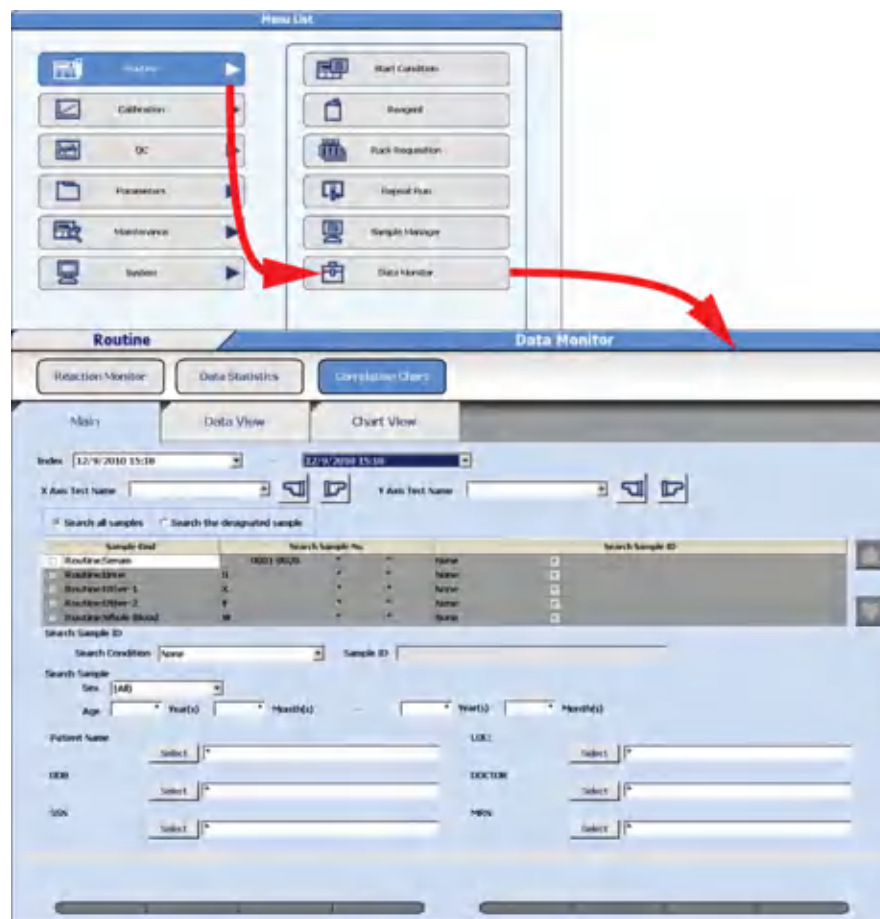
The Correlation Chart allows a comparison of two tests on the same samples within a specified index range.

This function calculates how well two tests correlate using different parameters.

To create a correlation chart, take the following steps.

- 1 Select **Menu List > Routine > Data Monitor > Correlation Chart > Main**.

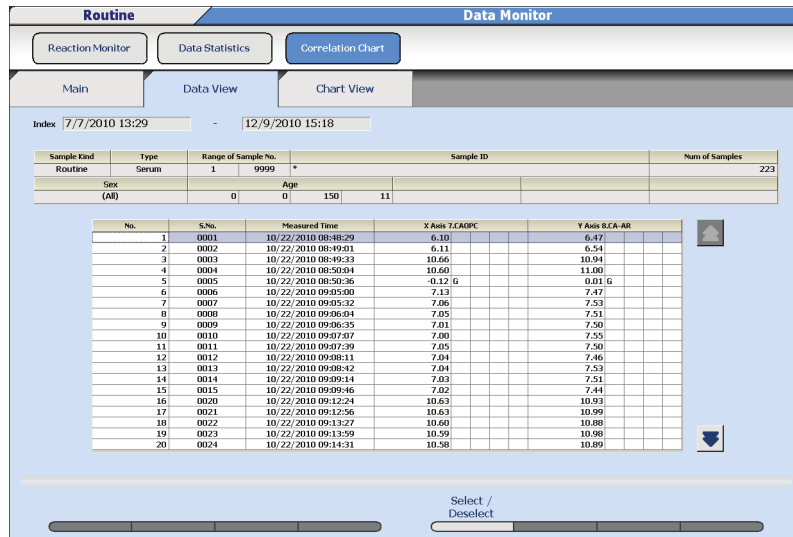
Figure 7.66



- 2 Select the index range from the “Index” drop-down lists.
- 3 Select the respective test name from the “X Axis Test Name” and “Y Axis Test Name” drop-down lists.
- 4 Select **Search all samples** or **Search the designated sample**.

- 5 If **Search all samples** is selected, a specific sample ID can be searched. Under Search Sample ID, select **Complete** or **Partial** to match the sample ID from the "Search Condition" drop-down list. Enter the sample ID to search in Sample ID.
- 6 When **Search the designated sample** is selected, enter the search conditions. Check the Sample Kind to search. The Search Sample No. and Search Sample ID fields default to search all (indicated by the *) sample numbers and ID numbers. Enter a specific sample number or sample ID to search as required.
- 7 Set the search conditions (Sex, Age range, and/or patient demographic information 1 to 6) as required.
- 8 To exclude data from the correlation chart, select **Data View**.

Figure 7.67

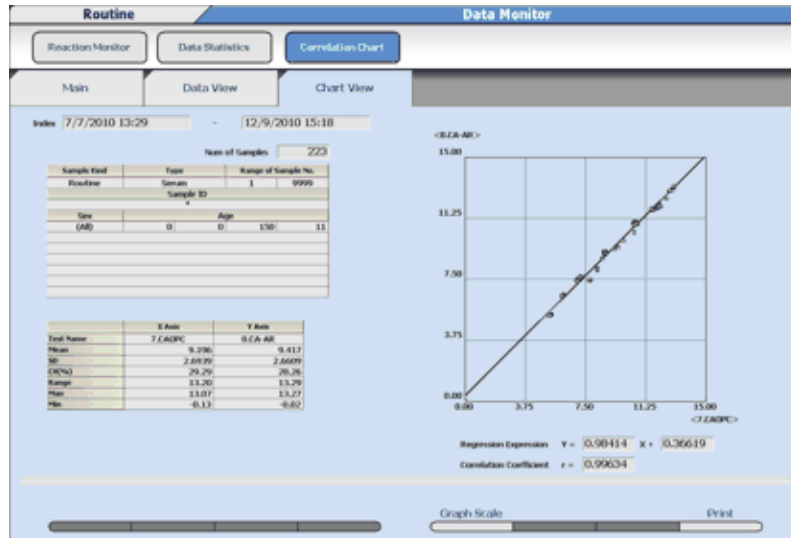


TIP Data corresponding to 10,000 samples can be displayed using the up or down scroll button.

- 9 Select the item to be excluded.
- 10 Select **Select/Deselect (F5)**.
The color of the item row changes and the item is deleted from the **Chart View** tab. If **Select/Deselect (F5)** is selected again, the item is restored. The background color of the excluded sample becomes pink.

11 Select **Chart View** to display the correlation chart.

Figure 7.68



12 To change the display size of a correlation chart, select **Graph Scale (F5)**.

- When **Auto** is selected, the correlation chart displays the maximum range of all the data.
- Set the lower limits (Lower) and upper limits (Upper) for both the X axis and Y axis. Select **Manual** to display the correlation chart with the defined limits.

Figure 7.69

13 To print the statistics and correlation chart, select **Print (F8)**. The Print Start window opens. Select **OK**.

7.8 Data Management

Data can be stored on external storage media to be used on a separate computer.

Parameters can be backed up on external storage media to be used to recover if the hard drive of the computer becomes inoperable.

[7.8.1 Save Data to External Media](#)

[7.8.2 Save or Load Parameters](#)

[7.8.3 Offline Criteria](#)

WARNING

CD-ROMs and external USB storage devices such as flash drives and memory sticks increase the potential of harmful viruses infecting the analyzer's computer. To avoid damage to the computer and the data, before loading or saving data to any storage media, always perform a virus check on the media using any commercially available virus protection software, to ensure the media is free from harmful viruses.

TIP: U3 USB devices are not compatible with the analyzers software.

From the external data management menu, analysis results can be transferred to an external storage media by index.

For details on programming conditions to save or output the analysis results, refer to [7.8.3 Offline Criteria](#) in this chapter.

External storage device

Transfer data using the following external storage media.

- CD-R
- Floppy disk (FD)
- Optional external storage devices (HD) connected by USB.

CAUTION

- **The system only uses CD-R disks to transfer data using the CD drive. CD-RW and DVD disks are incompatible with the CD drive and cannot be used.**
- **Only 2HD FD can be used. 2DD FD cannot be used.**

Data that can be saved to external media:

- Patient samples (normal samples, emergency samples, STAT samples)
- Repeat Run samples
- Reagent blank, calibrator, and quality control samples
- Parameters

7.8.1 Save Data to External Media

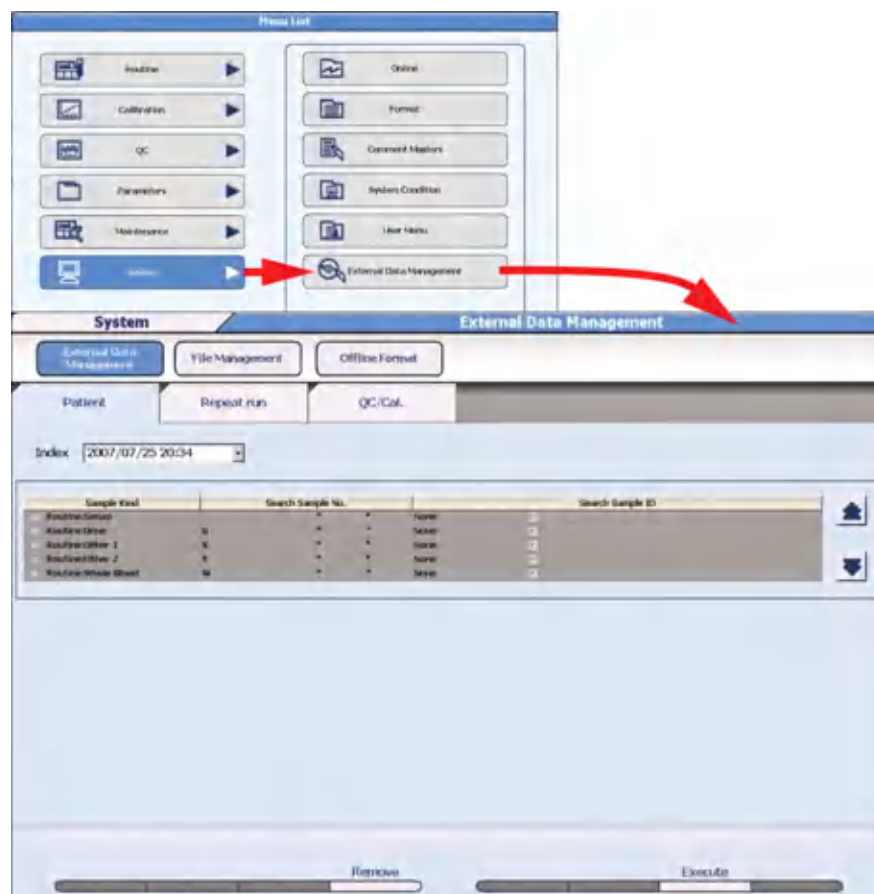
Save analysis data to external media for a backup of data, or to transfer the data to another computer. Data is saved to an “AU Data” folder. The data files are identified by the index. For example: 20100405_0732_000.csv is data saved from the index April 5, 2010 at 07:32. If data is saved from the same index again, the file would be 20100405_0732_001.csv.

Sample data, repeat sample data, reagent blank, calibration, and QC data can be saved to external media.

Save Samples (routine, emergency, and STAT), Repeat Samples, Reagent Blank, Calibration, and QC Data

- 1 Select **Menu List > System > External Data Management > External Data Management**.

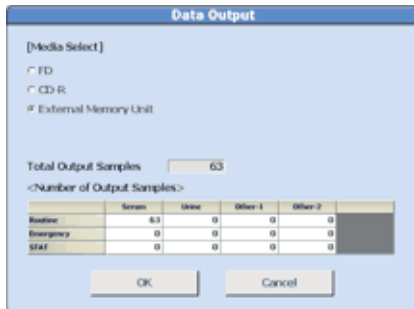
Figure 7.70



- 2 Select **Patient** to save routine, emergency, and STAT samples, **Repeat Run** to save repeat samples, or **QC/Cal.** to save reagent blank, calibration, or QC samples.

- 3 Select the index from the "Index" drop-down list.
- 4 Check the Sample Kind to save. Enter the Search Sample No. and Search Sample ID number to save, or leave the "*" to save all data. Use the up/down arrow buttons to change to Emergency or STAT samples.
- 5 Select **Execute (F7)**. Verify the Total Output Samples and <Number of Output Sample> information.

Figure 7.71



- 6 Select **FD**, **CD-R**, or **External Memory Unit**.
TIP If FD is selected, a check box is available to format the FD.
- 7 Select **OK**. The Data Output window opens and displays a confirmation message.
- 8 Select **OK**. A Data Output window displays a comment and the save progress.
TIP A confirmation or warning message appears depending on the save progress.
A comment indicating the data save has been successfully completed appears on the Data Output window.
- 9 Select **OK**. Remove the media.

7.8.2 Save or Load Parameters

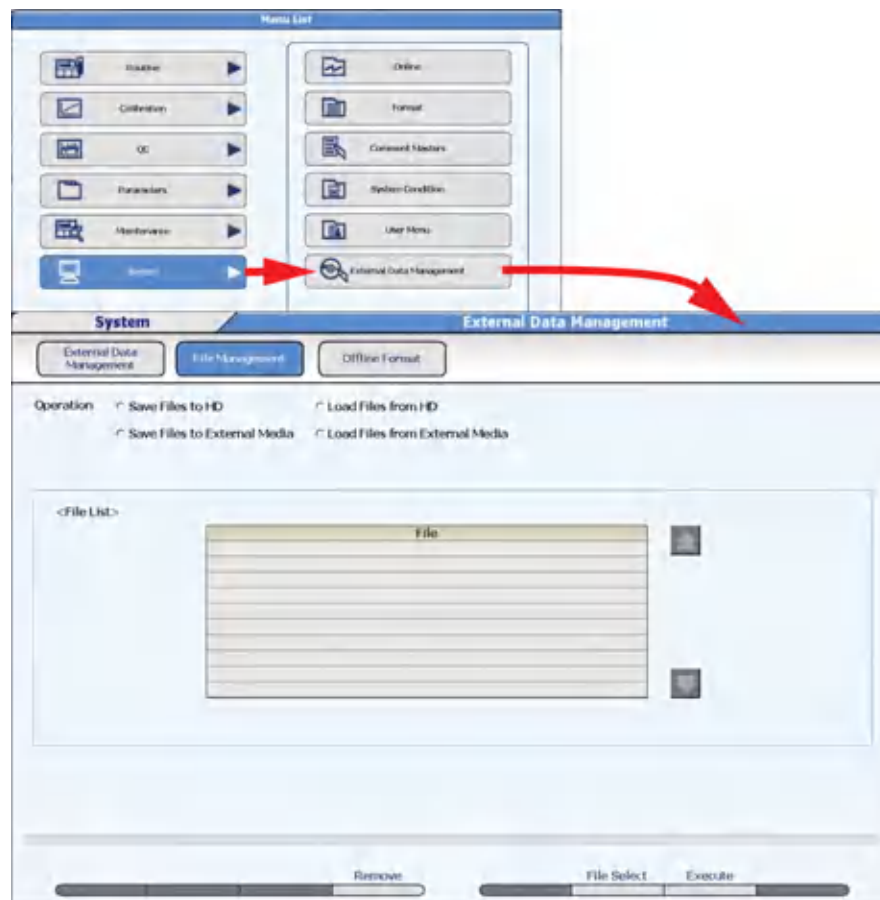
The system can save or load parameters to a backup folder on the hard drive or external media. Beckman Coulter recommends saving parameters when programming changes are made, or following laboratory Standard Operating Procedures.

TIP If there are multiple AU480s in the laboratory, Beckman Coulter recommends saving the parameter files for each AU480 to external media.

Saving or Loading Parameter files

- 1 Select **Menu List > System > External Data Management > File Management**.

Figure 7.72

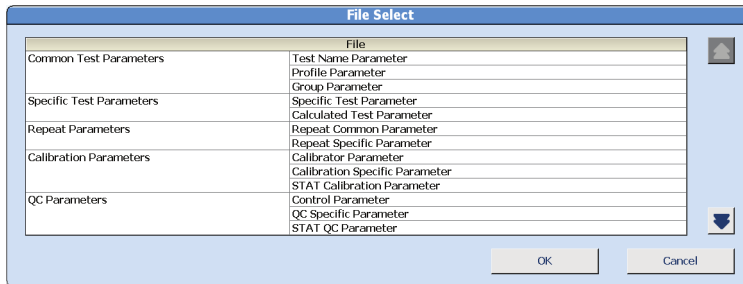


- 2 For Operation, select **Save Files to HD, Load Files from HD, Save Files to External Media, or Load Files from External Media**.

TIP Saving or loading files to “HD” is a backup folder on the hard drive.

- 3 Select **File Select (F6)**. The File Select window opens.

Figure 7.73



- 4 Select the file(s) to be saved or loaded. Select a menu from the left column to include all the submenus, or select only the submenu from the right column.
- 5 Select **OK**.
The selected files are displayed.
- 6 Select **Execute (F7)**. If saving or loading using external media, select **FD, CD-R, or External Memory Unit**, then **OK**. “Insert Disk. Start?” or “Connect External Memory Unit. Start?” displays. Select **OK**.

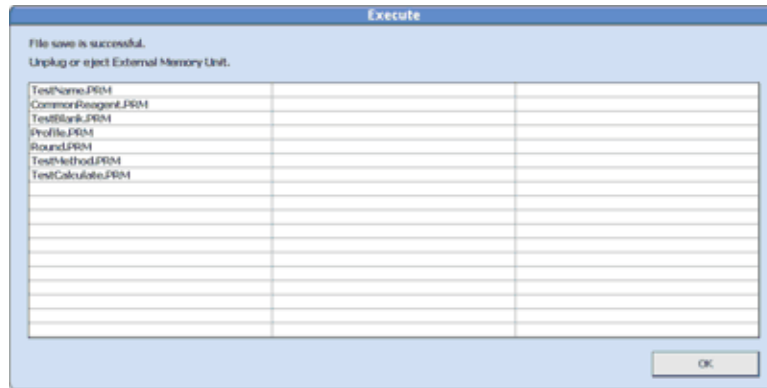
 **CAUTION**

In the case of saving parameters to HD, FD, CD-R, or External Memory Unit, the existing parameters are overwritten without warning.

TIP If FD is selected, a check box is available to format the FD. When the format is complete, select **Execute (F7)** to save the files.

The Execute window displays when the operation is complete.

Figure 7.74



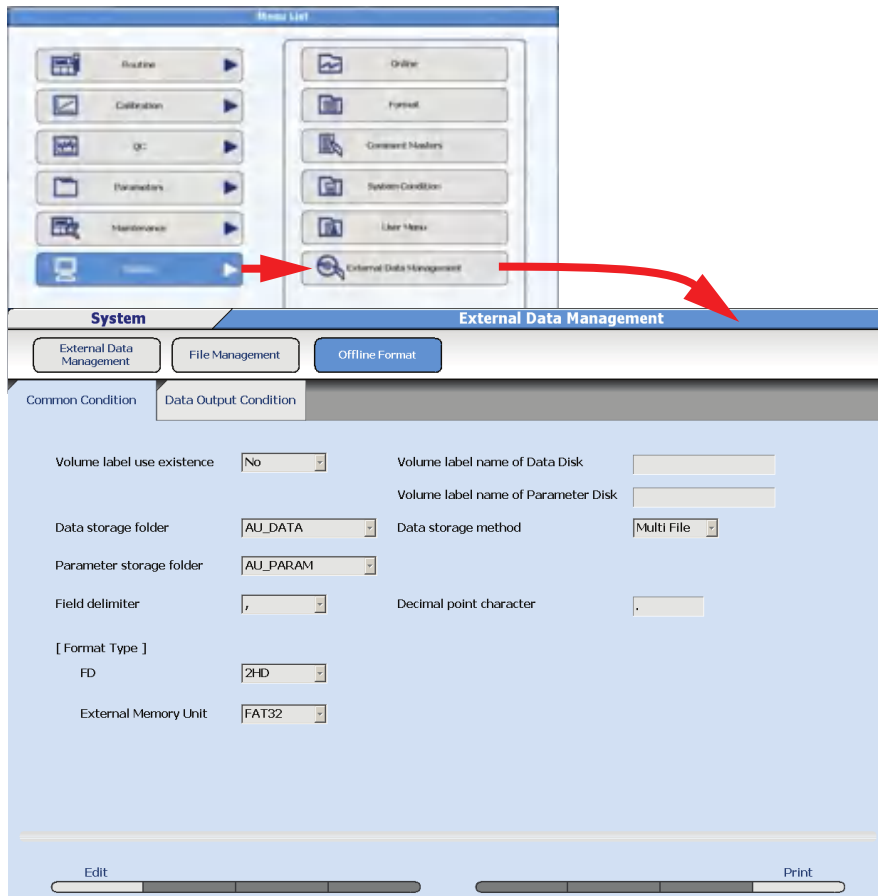
7 Select **OK**. The External media can be removed.

7.8.3 Offline Criteria

Program the criteria for saving analysis data (samples, repeats, reagent blank, calibration, and QC) and parameter files to external media.

- 1 Select **Menu List > System > External Data Management > Offline Format > Common Conditions.**

Figure 7.75



TIP Volume Label Use Existence

Yes: If the volume name registered on the medium does not match the entered name in Volume Label Name the medium is rejected.

No: The volume name is not checked.

Data Storage Folder

AU_DATA: Folder "AU_DATA" is created, and data files are saved in it.

Root: A folder is not created. The data files are saved directly below the root.

Data Storage Method

Multi File: The record numbers of files belonging to the same index are added, and saved as different files.

Single File: Files belonging to the same index are saved after over writing.

Parameter Storage Folder

AU_PARAM: The folder "AU_PARAM" is created, and parameter files are saved in it.

Root: A folder is not created. The parameter files are saved directly below the root.

Field Delimiter

Defines the delimiter to be added between each item of data.

Format Type

Specifies the format type for each medium.

FD:2HD

External Memory Unit: FAT32

Data filename

AU_YYYYMMDD_HHMM_XXX.csv

YYYYMMDD_HHMM: Year, month, day, hours, minutes of index

XXX: Record No. 000 - 999

When the storage method is specified in one file, the record No. is fixed at 000.

Setting Common Conditions

- 1 Select **Edit (F1)**. The window changes to the edit mode.

- 2 Select **Yes** or **No** from the "Volume label use existence" drop-down list in order to set whether or not to use a volume name for the data output medium.

- 3 Select a data storage folder from the "Data storage folder" drop-down list.

- 4 Select the data storage method from the "Data storage method" drop-down list. Select multiple files or one file. When multiple files are selected, in the case where files belonging to the same index were saved, they are saved as different files without being overwritten.

- 5 Select the file storage folder from the "Parameter storage folder" drop-down list.

- 6 Select the field delimiter from the "Field delimiter" drop-down list.

7 Select **FAT32** from the “External Memory Unit” drop-down list.

8 Select **Confirm (F1)**. The programmed values are registered.

Data Output Conditions

1 Select **Menu List > System > External Data Management > Offline Format > Data Output Condition**.

Figure 7.76

The screenshot shows the 'Data Output Condition' screen. At the top, there are three tabs: 'External Data Management', 'File Management', and 'Offline Format'. Below the tabs, there are two sections: 'Common Condition' and 'Data Output Condition'. The 'Common Condition' section has three dropdown menus: 'Field number limitation' (set to 'Yes'), 'DB record use existence' (set to 'Yes'), and 'DE record use existence' (set to 'Yes'). The 'Data Output Condition' section has two tables. The first table is titled '<Output condition of Sample block>' and has two columns: 'Field Name' and 'Output'. The second table is titled '<Output condition of Test item block>' and also has two columns: 'Field Name' and 'Output'. At the bottom of the screen, there are three buttons: 'Edit', 'Item Order', and 'Print'.

Field Name	Output
Sample No.	<input checked="" type="checkbox"/>
Rack No.	<input checked="" type="checkbox"/>
Cup pos.	<input checked="" type="checkbox"/>
Type	<input checked="" type="checkbox"/>
ID	<input checked="" type="checkbox"/>
Kind No.	<input checked="" type="checkbox"/>
Org. Sample No.	<input checked="" type="checkbox"/>
Sex Age	<input type="checkbox"/>
Patient Information-1	<input type="checkbox"/>
Patient Information-2	<input type="checkbox"/>
Patient Information-3	<input type="checkbox"/>
Patient Information-4	<input type="checkbox"/>
Patient Information-5	<input type="checkbox"/>
Patient Information-6	<input type="checkbox"/>

Field Name	Output
CONC Data	<input checked="" type="checkbox"/>
Data Flag	<input checked="" type="checkbox"/>
OD Data	<input checked="" type="checkbox"/>
Lot/Bottle	<input type="checkbox"/>
Method	<input type="checkbox"/>

TIP Field Number Limitation

Yes: A cautionary message is displayed if the number of fields (number of sets of item data) is set to 256 or more.

If the number of fields is 256 or more, an Excel display cannot be made.

“DB” Record Use Existence

Yes: “DB” is added to the beginning of the record data string.

“DE” Record Use Existence

Yes: “DE” is added to the end of the record data string.

Information Block Use Existence

Yes: The field name and test name are added after “DB” at the beginning of the record data string.

Output Date Field Use Existence

Yes: The date & time data which outputs files is added after “DE” at the end of the record data string.

Output Condition of Sample Block

Sets the items to be output by the sample information.

Output Condition of Test Block

Sets the items to be output by the data for each item.

Item Order

Sets the test items to be output by the data

-
- 2** Select **Edit (F1)**. The window changes to the edit mode.
-
- 3** Select **Yes/No** from each of the “Field number limitation,” “DB Record Use Existence,” “DE Record Use Existence,” “Information Block Use Existence,” and “Output date Field Use Existence” drop-down lists.
-
- 4** Check the sample block output conditions to be output. Conditions displayed in gray can be confirmed but not changed.
-
- 5** Select **Item Order (F5)**. The Test Order window opens.
-
- 6** Select the item to be offline output.
-
- 7** Select **OK**.
-
- 8** Select **Confirm (F1)**. The programmed values are registered.
-

7.9 Calibration Verification

Calibration verification should use material appropriate for the testing system and when possible traceable to a reference method or material of known value with stated acceptable variations.

Program material parameters, then perform analysis of the calibration verification material. View a graph of the actual versus expected values. Three replicates of each test level (a maximum of 6 levels per test) can be plotted on the graph.

[7.9.1 Enter Material Parameters](#)

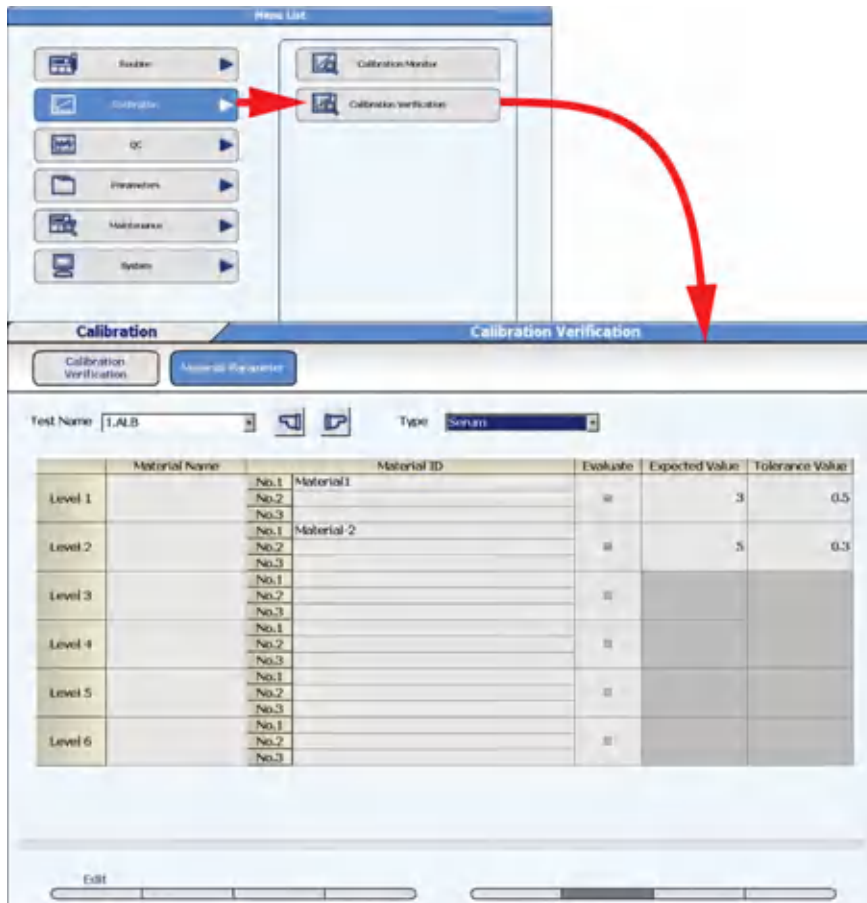
[7.9.2 Verify Calibration](#)

7.9.1 Enter Material Parameters

To enter information concerning the standard material:

- 1 Select **Menu List > Calibration > Calibration Verification > Material Parameters**.

Figure 7.77



-
- 2 Select **Edit (F1)**. The window changes to the edit mode.

 - 3 Select the test name from the “Test Name” drop-down list.

 - 4 Select the type from the “Type” drop-down list.

 - 5 Enter the Material Name for each level. Enter up to 8 characters.

 - 6 If sample ID is in use, enter the sample barcode number (maximum of 20 characters) in Material ID. Up to three sample IDs can be assigned to each level for three replicates.

 - 7 Select the Evaluate check box to include the material for calibration verification. Uncheck to exclude the registered material.

 - 8 Enter the Expected Value and Tolerance Value (refer to the calibration verification material package insert for specifications).

 - 9 Select **Confirm (F1)** to save the settings.

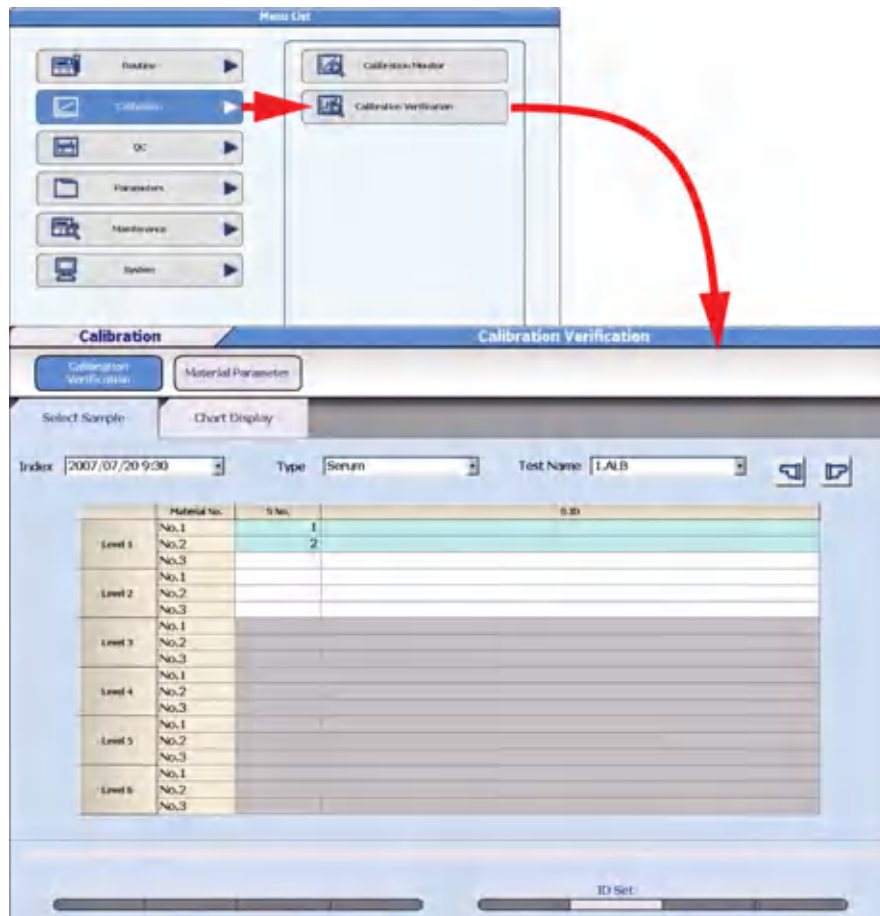
 - 10 Perform analysis on the calibration verification material with up to three replicates.
-

7.9.2 Verify Calibration

Display the expected value and allowable tolerance for each level using vertical lines. If the measurement value of each material is in this range, judge the calibration curve to be satisfactory.

- 1 Select **Menu List > Calibration > Calibration Verification > Calibration Verification > Select Sample**.

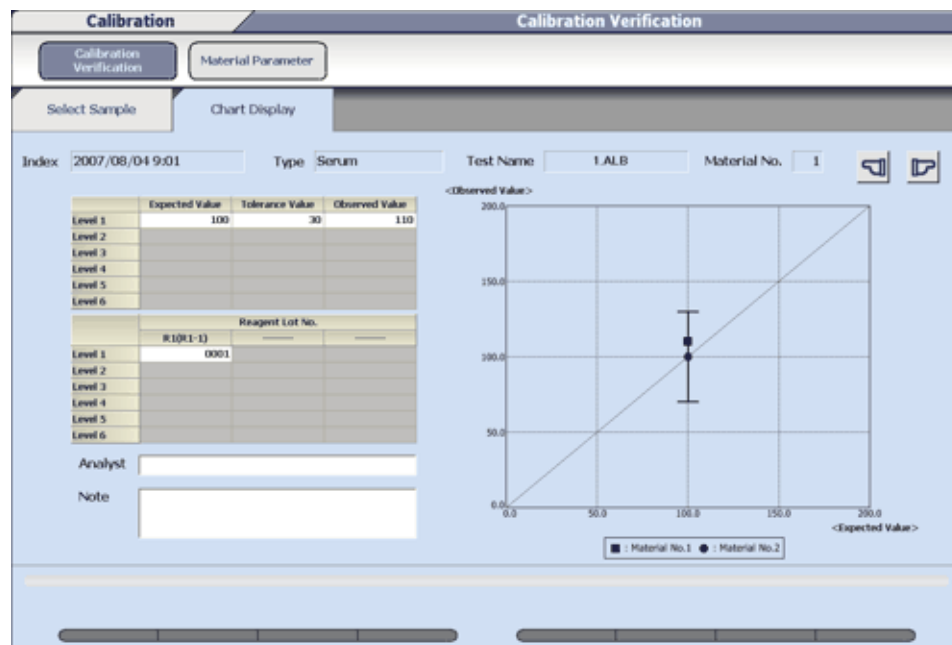
Figure 7.78



- 2 Select the index from the “Index” drop-down list.
- 3 Select the type from the “Type” drop-down list.
- 4 Select the test name from the “Test Name” drop-down list.

- 5 Enter the sample numbers processed for each Level and Material No. at “S. No.”. If barcode analysis was used to process the material, enter the sample ID number for each Level and Material No., or select **ID Set (F6)** to use the sample ID numbers programmed in **Material Parameters**.
- 6 Select **Chart Display** to display a graph of the observed versus the expected values. All specified levels are displayed on the graph.

Figure 7.79



- 7 Verify the data. The graph displays the tolerance range with vertical lines centered on the expected value. Acceptable results should appear within the vertical lines. A calibration curve is drawn through the expected values. For Analyst, the name of the person performing the calibration verification can be entered (up to 20 characters). For Note, a comment can be entered (up to 100 characters).

TIP A notification window opens if data cannot be found. Select **OK** to return to **Select Sample**.

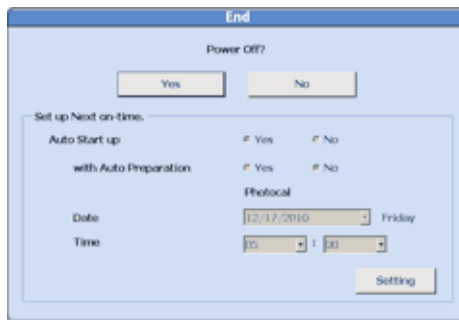
7.10 System Shutdown (End Process)

An **End Process** turns off the analyzer lamp and the computer. The refrigerator, incubator, and STAT table temperatures are maintained. The ISE unit performs an automatic prime with Mid Standard every hour to keep the electrodes conditioned.

An **End Process** can be initiated after a W2 and/or Photocal is started. In this case, the W2 and/or Photocal completes, then the system shuts down. Refer to 8.4.2 [Perform a W2](#) to start the W2 and/or Photocal.

- 1 Select **Home**.
- 2 Select **End** from the main button bar. The End window opens.

Figure 7.80



- 3 Verify the next auto on time. To set an auto on time, select **Setting**. Select **Yes** at Auto Start Up. Select the Date and Time for the system to turn on from the "Date" and "Time" drop-down lists. To turn off the auto on time, select **No** at Auto Start Up. Select **Confirm**.
- 4 Select **Yes**. The system shuts down.
- 5 Follow laboratory Standard Operating Procedures for turning off the DI water supply.

 **CAUTION**

Follow laboratory Standard Operating Procedures for turning off the DI water supply. Special considerations include weekends, holidays, and automatic maintenance procedures that may be scheduled.

TIP Auto Preparation must be programmed in the System Maintenance menu by Beckman Coulter Technical Services at installation. Auto Preparation can be programmed for the weekly Photocal. The system can be programmed for an Auto On time and Auto Preparation for each day of the week.

For details on using the auto power on function, refer to [4.10.5 Program the Automatic Startup Function](#) in chapter 4.

7.11 Pause Analysis

The analyzer can be paused to add reagent and then resume analysis for the remaining items.

CAUTION

- **Do not leave the system paused for long periods of time. When the analyzer is paused for an extended period of time, the concentration of the samples in the sample cups increases due to evaporation and can affect data results.**
- **DO NOT REMOVE OR ADD RACKS WHILE THE SYSTEM IS IN PAUSE AS THIS CAN RESULT IN CONCORDANCE ERRORS.**

Pause Analysis

1 Select **Pause**. The Pause window opens.

2 Select **OK**.

The analyzer mode displays => **PAUSE** until all samples in progress are complete. When the analyzer mode display changes to *Pause*, reagent can be added and a reagent check performed.

CAUTION

Verify the analyzer mode is in Pause before adding reagents or performing a reagent check to avoid personal injury or damage to the reagent probes.

Resuming Analysis from Pause

Analysis begins at the next sample to be analyzed after Pause was selected.

1 Select **Start**. The Start window opens.

2 Select **Start**. Analysis is restarted.

7.12 Rack Feeder Stop

The rack feeder can be stopped to insert an emergency or routine rack ahead of other racks during analysis.

When the rack feeder is stopped, analysis continues for the racks already fed by the rack feeder.



Do not leave the rack feeder stopped for extended periods of time. When the rack feeder is stopped for an extended period of time, the concentration of the samples in the sample cups increases due to evaporation and can affect data results.

Stop the rack feeder

- 1 Select **Feeder Stop** from the main button bar. The Feeder Stop window opens.
 - 2 Select **OK**. The rack feed operation stop message appears. Analysis of the racks already moved from the rack feeder unit continues.
-

Restart analysis after rack feeder stop

- 1 With the rack feeder stopped, perform usual requisition procedures. For details, refer to [6.3 Requisition for Routine and Emergency Samples](#) in chapter 6.
 - 2 Select **Start**.
-

7.13 Transfer the Analyzer to Stop Mode

To immediately stop the analysis operation perform a system Stop.

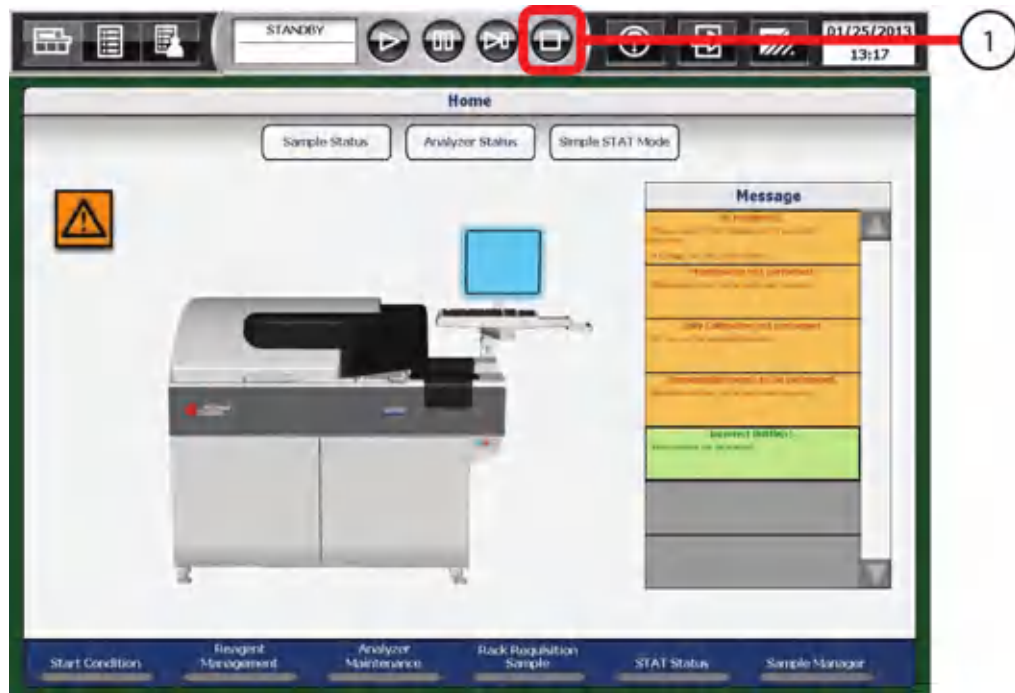
CAUTION

- When the system is transferred to *Stop* mode, any data that is not complete is lost and must be repeated.
- Reagents remain in the cuvettes after performing a Stop. Perform a W1 to remove reagents before performing an End Process or resuming analysis.

Stop analysis

- 1 Select **Stop/Standby** during analysis operation. The Stop window opens with the message “Transfer to Stop Mode.”

Figure 7.81



1. Stop/Standby

- 2 Select **OK**. All analysis operation stops, and the system goes to *Stop* mode.

- 3 Remove racks from the rack transport belts.

Return to *Standby* mode

- 1 Select **Stop/Standby** in *Stop* mode. The Warm up/Standby window opens with the message “Reset Analyzer and Transfer to Standby mode?”.
 - 2 Select **OK**. The system reset operation is performed. After the reset operation completes, the system goes to *Standby* mode or *Warm up* mode.
 - 3 Perform a W1.
Refer to [8.8.11 Perform a W1](#) in chapter 8.
-

7.14 Perform an Emergency Stop

Select the EM STOP button (red button on the front, right side of the analyzer) to immediately turn off power to the analyzer and ISE. All analysis immediately stops.

 **CAUTION**

- When the EM STOP button is pressed, any data that is not complete is lost and must be repeated.
- Reagents remain in the cuvettes after performing an Emergency Stop. Perform a W1 to remove reagents before performing an End Process or resuming analysis.

-
- 1 Press the EM STOP button. All power to the analyzer and ISE turns off immediately. The computer remains On. To turn off the computer, press **Ctrl** + **ALT** + **Delete**. A Windows Security window opens. Select the **Shutdown** button.
 - 2 Remove all racks from the rack transport belts.
-

Return to *Standby* mode

- 1 Press the RESET button, then wait 5 seconds.
- 2 Press the **ON** button. (The lamp turns on and the software loads.) A pop-up window appears to confirm the retrieval of the database.

-
- 3 Select **OK**.

 - 4 In the New Index window, select **Current Index** to continue analysis in the current index.

 - 5 The system stays in *Warm Up* mode for 1.5 hours. After the required 20-minute lamp warm up time, wait until the temperature of the cuvette wheel is 37 degrees, then select **Home > Analyzer Maintenance > Stand By (F4)** to return to *Standby*.

 - 6 Perform a W1.
Refer to [8.8.11 Perform a W1](#) in chapter 8.
-

7.15 Identifying and Re-analyzing Samples after a Cuvette Overflow

A cuvette overflow may have occurred 60 minutes before the "PHOTOMETRY ERROR DURING CUVETTE WASH" alarm is generated. The results measured during the 60 minutes before the alarm are invalid and must be analyzed again.

The analyzer goes to *Stop* mode immediately after the "PHOTOMETRY ERROR DURING CUVETTE WASH" alarm is generated.

TIP PHOTOMETRY ERROR DURING CUVETTE WASH (aa)

aa: Cuvette number (1 to 88) with a photometric error.

 **WARNING**

The tests performed during the 60 minutes before the "PHOTOMETRY ERROR DURING CUVETTE WASH" alarm may have an incorrect result due to the overflow. The results are invalid. If these results have already been transferred to the Host Computer or reported, take corrective actions according to laboratory Standard Operating Procedures.

The 60-minute time frame is the time the analyzer is in a *Measure* mode. If the analyzer goes into *Standby* mode, the time the analyzer is in *Standby* must be added to the 60-minute time frame. For example, if the analyzer goes into *Standby* for 20 minutes, an 80-minute time frame must be used to search for samples affected by the overflow.

Searching for results measured during the 60 minutes before the "PHOTOMETRY ERROR DURING CUVETTE WASH" alarm while the analyzer is in *Measure* mode

- 1 Select **Home > Alarm List**.

Figure 7.82



- 2 Search for the alarm message “PHOTOMETRY ERROR DURING CUVETTE WASH (aa).”

- 3 Note the Date and Time.

Example: 2012/03/21 11:32 PHOTOMETRY ERROR DURING CUVETTE WASH (36)

- 4 Search for the “MEASURE START” message to obtain the time the analyzer went into *Measure* mode to obtain the search time.

- a. If the “MEASURE START” time is 60 minutes or more before the “PHOTOMETRY ERROR DURING CUVETTE WASH” message, the search time is 60 minutes.
- b. If the “MEASURE START” time is less than 60 minutes before the “PHOTOMETRY ERROR DURING CUVETTE WASH” message, the time the analyzer went into *Standby* must be calculated and added to 60 minutes. Calculate the time between the “STANDBY” message and the next “MEASURE START” message and add this time to 60 minutes. This time is used as the search time.

- 5 Search for the alarm message "INDEX UPDATED" that was performed within the search time for the "PHOTOMETRY ERROR DURING CUVETTE WASH (aa)" alarm message. Note all the "INDEX UPDATED" alarm messages after this index.

Example:

2012/03/21	11:32	PHOTOMETRY ERROR DURING CUVETTE WASH (36)
2012/03/21	10:55	MEASURE START
2012/03/21	10:43	INDEX UPDATED (2012/03/21 10:43)
2012/03/21	10:33	STANDBY
2012/03/21	09:27	MEASURE START
2012/03/21	09:23	INDEX UPDATED (2012/03/21 09:23)
2012/03/21	09:10	STANDBY
2012/03/21	08:07	MEASURE START

TIP The preceding information is for an example only. Typically, a new index is created once a day or once a shift.

In the above example, the search time is 82 minutes (time between 10:33 and 10:55 = 22 minutes + 60 minutes). 82 minutes before the PHOTOMETRY ERROR DURING CUVETTE WASH alarm (2012/03/21 11:32) is 2012/03/21 10:10. The top two Indexes displayed in bold are affected.

- 6 Select **Menu List > Routine > Data Monitor > Reaction Monitor**.

Figure 7.83

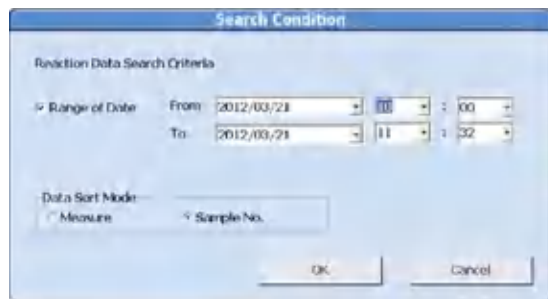


7 Select the index obtained in step 5 from the "Index" drop-down list. In this example, the first INDEX UPDATED is 2012/03/21 09:23.

8 Select (check the box) for each Sample Kind and all sample types with results.

9 Select **Search Condition (F5)**.

Figure 7.84



10 Check the Range of Date box. When Range of Date is checked, results are searched based on the dates and times in the "From" and "To" drop-down lists. If Range of Date is not checked, results are searched based on the index.

11 Enter the starting search date and time obtained in step 5 in the "From" drop-down list. In this example, the starting search date and time is 2012/03/21 10:10.

12 Enter the ending search date and time obtained in step 5 in the "To" drop-down list. In this example, the ending search date and time is 2012/03/21 11:32.

13 Check the box next to **Sample No.**

14 Select **OK** to return to **Reaction Monitor > Main** tab.

15 Select the **General** tab.

Figure 7.85



16 Select **List Display (F3)**. The list of samples with invalid data appears. It is necessary to analyze these samples again.

Figure 7.86

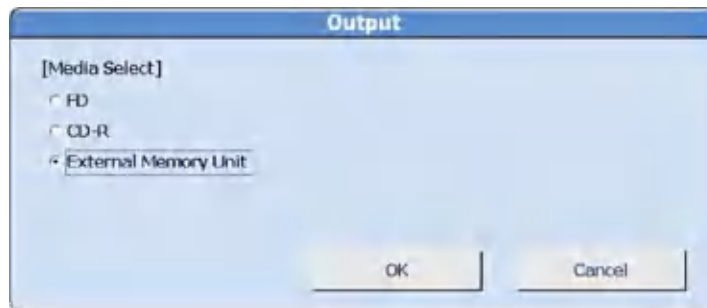


- 17** If there are two or more indexes to search, repeat steps 6 through 16 for all indexes required to search.

Output the list to media.

- 1** Select **Output**. The Output window appears.

Figure 7.87



- 2** Select the media from **[Media Select]**.
- 3** Select **OK**. The Data Output window opens and displays a confirmation message.
- 4** Select **OK**. The Data Output window displays a comment and the save progress. The name of the saved file is **MeasureList_YYYYMMDD_HHMM.csv**. YYYYMMDD_HHMM is the name of the INDEX.

CAUTION

The pending samples are not included in this List.

- 5** Select **OK** to return to the List Display window. Remove the media.
- 6** Data is saved as a cvs file named by the search date and time. Use a separate PC to open the file and view or print the list of samples with invalid data.

Print the list.

- 1** Select **Print**. The Print window appears.

Figure 7.88



- 2** Select **OK**.
 - 3** Select **Close** to return to **Reaction Monitor**.
-

Maintenance

This chapter illustrates how to keep the analyzer operating in good condition through scheduled maintenance procedures.

The maintenance frequency described in this chapter is based on analysis of 2,000 or less tests per day.

Laboratories may have to increase the amount of maintenance required depending upon the number of tests and local environmental conditions.

The ISE maintenance schedule for biweekly or longer periodic maintenance should be managed either periodically or by the number of samples analyzed. The ISE maintenance frequency described in this chapter is based on analysis of 200 ISE samples per day.

8.0 Warnings and Cautions

8.1 Using the Routine Maintenance Schedule

8.1.1 Maintenance Schedule List

8.1.2 Maintenance Log

8.2 Parts Used for Analyzer Maintenance

8.3 Daily Maintenance

8.3.1 Inspect the Syringes for Leaks

8.3.2 Inspect the Wash Solution Roller Pump for Leaks

8.3.3 Inspect, Clean and Prime the Sample Probe, Reagent Probe, and Mix Bars

8.3.4 Inspect the Wash Solution and Replenish As Needed

8.3.5 Inspect the Printer and Paper

8.3.6 Replace the DI Water or Diluent in the Pre-dilution Bottle

8.3.7 Inspect the Stability of the Upper Cover

8.3.8 Prepare the Sample Probe Wash Solutions

8.4 Weekly Maintenance

8.4.1 Clean the Sample Probe and Mix Bars

8.4.2 Perform a W2

8.4.3 Perform a Photocal

8.4.4 Clean the Pre-dilution Bottle

8.5 Monthly Maintenance

- 8.5.1 Clean the Sample Probe and Reagent Probe Wash Wells
- 8.5.2 Clean the Mix Bar Wash Wells
- 8.5.3 Clean the Wash Nozzle Unit and Check the Tube Mounting Joints
- 8.5.4 Clean the DI Water Tank, DI Filter, and Sample Probe Filter

8.6 Quarterly Maintenance

- 8.6.1 Clean the Air Filters
- 8.6.2 Inspect and if Needed, Replace the DI Water Filter, Sample Probe Filter, and Replace the O-ring
- 8.6.3 Replace the Wash Solution Roller Pump Tubing

8.7 6-Month Maintenance

- 8.7.1 Clean the Cuvettes and the Cuvette Wheel

8.8 Yearly or As Needed Maintenance

- 8.8.1 Replace O-rings in the Water Supply Tube Mounting Joint
- 8.8.2 Clean the Reagent Probe
- 8.8.3 Replace a Sample and Reagent Probe
- 8.8.4 Replace Mix Bars
- 8.8.5 Replace the Wash Nozzle Joint
- 8.8.6 Replace Packing in the Wash Nozzle Tube Mounting Joints
- 8.8.7 Replace Syringes or Syringe Case Heads
- 8.8.8 Clean the Inside of the Reagent Refrigerator and STAT Table Compartments
- 8.8.9 Clean or Replace the Anti-static Brushes
- 8.8.10 Replace the Sample and Reagent Probe Tubing
- 8.8.11 Perform a W1
- 8.8.12 Replace Rack ID Labels
- 8.8.13 Clean or Replace Individual Cuvettes
- 8.8.14 Replace the Photometer Lamp
- 8.8.15 Save Parameters

8.9 Reset the System from Stop Mode to Standby

8.10 ISE Parts Used for ISE Maintenance

8.11 ISE Tubing Block Diagram

8.12 ISE Daily Maintenance

- 8.12.1 ISE Cleaning
- 8.12.2 ISE Calibration

8.13 ISE Weekly Maintenance

- 8.13.1 Check the Selectivity of the Na/K Electrodes
- 8.13.2 Enhanced Cleaning of the ISE Electrode Line

- 8.14 ISE Maintenance Every Other Week or Every 3,000 Samples
 - 8.14.1 Manually Clean the ISE Mix Bar, Liquid Level Sensors, Sample Pot, and Sample Pot Tubing
- 8.15 ISE Maintenance Every Other Month or Every 20,000 Samples
 - 8.15.1 Check and Add REF Electrode Solution
- 8.16 ISE Quarterly Maintenance or Maintenance Every 20,000 Samples
 - 8.16.1 Replace the Mixture Aspiration and MID Standard Roller Pump Tubing
 - 8.16.2 Replace the Tubing between Sample Pot, Electrode Unit, and T-Connector
 - 8.16.3 Replace the REF Electrode Block-side Drain Tube and Pinch Valve Tubing
 - 8.16.4 Manually Clean the Drain Well and if Needed, Replace the Drain Tube
- 8.17 ISE Maintenance Every Six Months or Every 40,000 Samples
 - 8.17.1 Replace the Na, K, or Cl Electrode
- 8.18 ISE Maintenance Every Two Years or Every 150,000 Samples
 - 8.18.1 Replace the ISE REF Electrode and Packing
- 8.19 ISE As Needed Maintenance
 - 8.19.1 Replace the Sample Pot
 - 8.19.2 Clean the ISE Electrode Block (Inlet Side)
 - 8.19.3 Manually Clean the ISE K Electrode
 - 8.19.4 Manually Clean and Replace the ISE REF Electrode Block
 - 8.19.5 Replacing ISE Reagents
 - 8.19.6 Enhanced ISE Cleaning (Manual)

8.0 Warnings and Cautions

 **CAUTION**

Failure to perform user maintenance according to the instructions within this User's Guide can adversely affect system performance and might invalidate the service agreement.

 **WARNING**

The analyzer should be operated with the lids down. If the operator needs to have the lids up during maintenance, it is important to keep all body parts out of the way of the probes and other moving parts of the analyzer. If neglected, this could cause serious injury or damage to the analyzer.

 **CAUTION**

The first time the TABLE ROTATION/DIAG button is pressed after a maintenance procedure is selected, the system initializes.

To avoid injury, do not touch any moving parts until the analyzer is ready by signaling the operator with alarms, modes, and LEDs.

 **CAUTION**

Always wear personal protective gear when performing any maintenance procedure.

To avoid injury, observe and follow all the WARNINGS and CAUTIONS throughout this User's Guide.

8.1 Using the Routine Maintenance Schedule

To obtain optimal performance, users must perform scheduled maintenance on the system.

Use the Maintenance Schedule List or Maintenance Log to manage the proper maintenance schedule.

Beckman Coulter recommends that users place a CHECK MARK or initial after each task is completed on the Maintenance Schedule List provided in [8.1.1 Maintenance Schedule List](#).

[8.1.1 Maintenance Schedule List](#)

[8.1.2 Maintenance Log](#)

Maintenance

8.1 Using the Routine Maintenance Schedule

8.1.1 Maintenance Schedule List

Copy the AU480 Maintenance Schedule List, then place a CHECK MARK or initial after each task when it is complete.

AU480 Analyzer and ISE (optional unit) Maintenance Schedule List

Maintenance																															
	Month Year:																														
Daily	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Inspect the Syringes for Leaks																															
Inspect the Wash Solution Roller Pump for Leaks																															
Inspect, Clean and Prime the Sample Probe, Reagent Probe, and Mix Bars																															
Inspect the Wash Solution and Replenish As Needed																															
Inspect the Printer (Option) and Paper																															
Replace the DI water or diluent in the Pre-dilution Bottle																															
Inspect the Stability of the Upper Cover																															
Prepare the Sample Probe Wash Solutions																															
ISE Cleaning (optional unit)																															
ISE Calibration (optional unit)																															
Weekly	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Clean the Sample Probe and Mix Bars																															
Perform a W2																															
Perform a Photocal																															
Clean the Pre-dilution Bottle																															
Check Selectivity of the Na/K Electrodes (ISE optional unit)																															
Enhanced Cleaning of ISE Electrode Line (ISE optional unit)																															
Every Other Week or 3,000 Samples (ISE optional unit)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Manually Clean ISE Mix Bar, Liquid Level Sensors, Sample Pot, and Sample Pot Tubing																															

Maintenance

Month Year:

Monthly	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
Clean the Sample Probe and Reagent Probe Wash Wells																																
Clean the Mix Bar Wash Wells																																
Clean the Wash Nozzle Unit and Check the Tube Mounting Joints																																
Clean the DI Water Tank, DI Filter, and Sample Probe Filter																																

Every Other Month or Every 20,000 Samples (ISE optional unit)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
Check and Add REF Electrode Solution																																

Quarterly	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
Clean the Air Filters																																
Inspect and if needed, Replace the DI Water Filter and Sample Probe Filter																																
Replace the Wash Solution Roller Pump Tubing																																

Quarterly or Every 20,000 Samples (ISE optional unit)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
Replace the Mixture Aspiration and MID Standard Roller Pump Tubing																																
Replace the Tubing between Sample Pot, Electrode Unit, and T-Connector																																
Replace the REF Electrode Block-side Drain Tube and Pinch Valve Tubing																																
Manually Clean the Drain Well and if needed, replace the Drain Tube																																

Every 6 Months	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
Clean the Cuvettes and the Cuvette Wheel																																

Every 6 Months or Every 40,000 Samples (ISE optional unit)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
Replace the Na, K, or Cl Electrode																																

Every two Years or Every 150,000 Samples (ISE optional unit)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
Replace the ISE REF Electrode and Packing																																

Maintenance

8.1 Using the Routine Maintenance Schedule

Maintenance

Month Year:

Yearly or As Needed	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
Replace O-rings in the Water Supply Tube Mounting Joint																																
Clean the Reagent Probe																																
Replace a Sample and Reagent Probe																																
Replace Mix bars																																
Replace the Wash Nozzle Joint																																
Replace Packing in the Wash Nozzle Tube Mounting Joints																																
Replace Syringes or Syringe Case Heads																																
Clean the Inside of the Reagent Refrigerator or STAT Table Compartments																																
Clean or Replace the Anti-static Brushes																																
Replace Rack ID Labels																																
Replace the Sample and Reagent Probe Tubing																																
Perform a W1																																
Clean or Replace Individual Cuvettes																																
Replace the Photometer Lamp																																
Save Parameters																																

As Needed (ISE optional unit)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
Replace the Sample Pot																																
Clean the ISE Electrode Block (Inlet Side)																																
Manually Clean the ISE K Electrode																																
Manually Clean and Replace the ISE REF Electrode Block																																
Replace Reagents																																
Replace Buffer Solution																																
Replace MID Standard																																
Replace REF Solution																																
Enhanced ISE Cleaning (Manual)																																

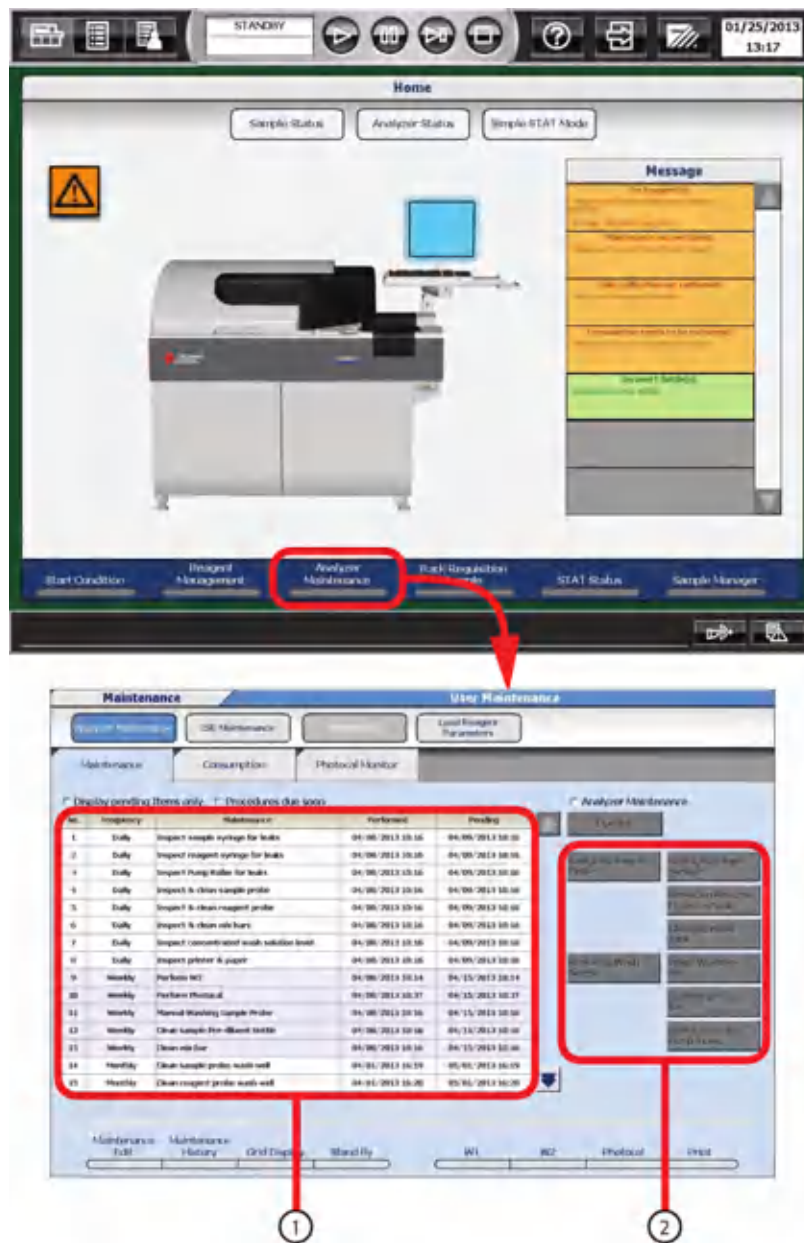
8.1.2 Maintenance Log

The Maintenance Log displays the maintenance frequency, the maintenance procedure, the date the maintenance was performed, and the next date the maintenance is due.

Confirm the Maintenance Schedule

- 1 Select **Home** > **Analyzer Maintenance**.

Figure 8.1



1. Maintenance log
2. Operation buttons

TIP Any items that have expired or are due to expire are displayed with different background colors.

- Orange: overdue
- Yellow: expiring

The background colors for daily maintenance appear three hours before the maintenance time.

2 To display the overdue task, place a check mark next to Display Pending Items Only.

3 To display the soon to expire task, place a check mark next to Procedures Due Soon. The unscheduled and as needed tasks are not listed if either Display Pending Items Only or Procedures Due Soon is selected.

4 Confirm the task to be performed.

Add a Maintenance Task

Users can add tasks to the list of maintenance activities.

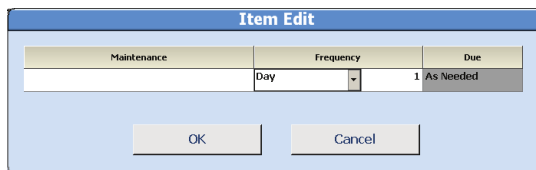
Beckman Coulter specified maintenance items have already been programmed.

To add a maintenance task:

1 Select the next free position from the maintenance activity list.

2 Select **Maintenance Edit (F1)**. The Item Edit window opens.

Figure 8.2



3 Enter the maintenance name in the Maintenance column.

4 Select the performance interval (Day, Week, Month, or Year) from the "Frequency" drop-down list. Select the interval value from 1 to 180.

-
- 5 Select **OK**. The added maintenance item appears in the activity list according to the frequency selected.
-

Delete a Maintenance Task

Users can delete maintenance tasks that are programmed by users.

TIP Beckman Coulter programmed maintenance items cannot be deleted.
If any maintenance item is deleted, the history data is also deleted.

-
- 1 Select the task to be deleted.
-
- 2 Select **Maintenance Edit (F1)**. The Item Edit window opens.
-
- 3 Delete the work name in the Maintenance column.
-
- 4 Select **OK**. A confirmation message window opens. Select **OK**.
-

Update the Maintenance Log

After performing maintenance tasks, maintenance records should be updated.

-
- 1 Select the maintenance task to check in the displayed list.
-
- 2 Select **Update**. Confirm the maintenance item to be updated.
-
- 3 Select **OK**.
-

TIP If the update is not performed after performing maintenance, moving to another operation or window may be impossible.

View Maintenance History

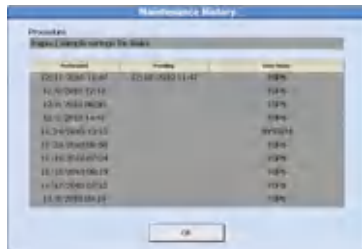
The system keeps track of the previous ten completed maintenance tasks.

1 Select the maintenance task to view in the work list.

2 Select **Maintenance History (F2)**.

The Maintenance History window opens. The last ten maintenance dates, the next due date, and the User Name are displayed. The User Name is the name entered for the Operator in the **Start Condition** menu for the day that the maintenance was updated.

Figure 8.3



3 Select **OK**.

4 Select **Grid Display (F3)** to confirm the maintenance history date as a list.

Figure 8.4



The Grid Display window displays scheduled maintenance procedures and status for the current month, preceding month, and following month.

If the ISE check box is selected, the ISE maintenance items are also displayed at the same time. Different colors display on the grid to indicate the status of the maintenance item.

Analyzer Maintenance

8.2 Parts Used for Analyzer Maintenance

Maintenance Interval	Maintenance Item	Parts to be Used	Part Number
Daily	8.3.1 Inspect the Syringes for Leaks	Lint-free cloth	Commercial Item
	8.3.2 Inspect the Wash Solution Roller Pump for Leaks	Lint-free cloth	Commercial Item
	8.3.3 Inspect, Clean and Prime the Sample Probe, Reagent Probe, and Mix Bars	Alcohol prep or 70% Isopropyl Alcohol using lint-free cloth	Commercial Item
	8.3.4 Inspect the Wash Solution and Replenish As Needed	Wash solution	OSR0001
	8.3.5 Inspect the Printer and Paper	–	–
	8.3.6 Replace the DI Water or Diluent in the Pre-dilution Bottle	DI water or diluent	
	8.3.7 Inspect the Stability of the Upper Cover	–	–
	8.3.8 Prepare the Sample Probe Wash Solutions	Wash solution	OSR0001
Glass tube or Plastic tube		ZM006200 (Glass) or ZM006300 (Plastic)	

Maintenance

8.2 Parts Used for Analyzer Maintenance

Maintenance Interval	Maintenance Item	Parts to be Used	Part Number
Weekly	8.4.1 Clean the Sample Probe and Mix Bars	Alcohol prep or 70% Isopropyl Alcohol using lint-free cloth	Commercial Item
		Stylet ϕ 0.2	MU941300
	8.4.2 Perform a W2	1N HCl	Commercial Item
		Sodium hypochlorite solution (0.5%) <ul style="list-style-type: none"> Beckman Sodium Hypochlorite (5%) diluted 1:10 or ISE Cleaning Solution diluted 1:10 	A32319 (US) OE66039 (Outside of US)
		One 60 mL reagent bottle	MU960500
		Glass tube or Plastic tube	ZM006200 (Glass) or ZM006300 (Plastic)
		ISE Cleaning Solution	OE66039 (Outside US) and AUH1019 (US)
		Hitachi Cup	MU853200
		8.4.3 Perform a Photocal	-
	8.4.4 Clean the Pre-dilution Bottle	DI water	
		Sodium hypochlorite solution (0.5%) <ul style="list-style-type: none"> Beckman Sodium Hypochlorite (5%) diluted 1:10 or ISE Cleaning Solution diluted 1:10 	A32319 (US) OE66039 (Outside of US)

Maintenance Interval	Maintenance Item	Parts to be Used	Part Number
Monthly	8.5.1 Clean the Sample Probe and Reagent Probe Wash Wells	Sodium hypochlorite solution (0.5%) <ul style="list-style-type: none"> • Beckman Sodium Hypochlorite (5%) diluted 1:10 or • ISE Cleaning Solution diluted 1:10 	A32319 (US) OE66039 (Outside of US)
		Pipette or injector	Commercial Item
		Cotton swab	Commercial Item
	8.5.2 Clean the Mix Bar Wash Wells	Sodium hypochlorite solution (0.5%) <ul style="list-style-type: none"> • Beckman Sodium Hypochlorite (5%) diluted 1:10 or • ISE Cleaning Solution diluted 1:10 	A32319 (US) OE66039 (Outside of US)
		Cotton swab	Commercial Item
	8.5.3 Clean the Wash Nozzle Unit and Check the Tube Mounting Joints	O-rings	MU963800
	8.5.4 Clean the DI Water Tank, DI Filter, and Sample Probe Filter	DI Water	
		Bucket	
		Brush	
		Sodium hypochlorite solution (1.0%) <ul style="list-style-type: none"> • Beckman Sodium Hypochlorite (5%) diluted 1:5 or • ISE Cleaning Solution diluted 1:5 	A32319 (US) OE66039 (Outside of US)
Quarterly	8.6.1 Clean the Air Filters	Air filter	MU844700 (378 x 50 mm) MU959300 (140 x140 mm)
	8.6.2 Inspect and if Needed, Replace the DI Water Filter, Sample Probe Filter, and Replace the O-ring	DI Water Filter Sample Probe Filter O-rings	ZM307900 ZM307900 MU963700
	8.6.3 Replace the Wash Solution Roller Pump Tubing	Roller Pump Tubing	MU962300
Every 6 Months	8.7.1 Clean the Cuvettes and the Cuvette Wheel	Wash Solution	OSR0001

Maintenance

8.2 Parts Used for Analyzer Maintenance

Maintenance Interval	Maintenance Item	Parts to be Used	Part Number
Yearly or As Needed	8.8.1 Replace O-rings in the Water Supply Tube Mounting Joint	O-rings	MU963800
	8.8.2 Clean the Reagent Probe	Alcohol prep or 70% Isopropyl Alcohol using lint-free cloth	Commercial Item
		Stylet $\varphi 0.3$	ZM022700
	8.8.3 Replace a Sample and Reagent Probe	Sample Probe	MU993400
		Reagent Probe	MU995800
	8.8.4 Replace Mix Bars	Spiral shape mix bar	MU959900
		L shape mix bar	MU826700
	8.8.5 Replace the Wash Nozzle Joint	Joint	ZM113100
	8.8.6 Replace Packing in the Wash Nozzle Tube Mounting Joints	Packing	MU842700
	8.8.7 Replace Syringes or Syringe Case Heads	S Syringe	ZM011100
		R Syringe	ZM011200
		S Syringe Case	ZM022900
		ISE Syringe Case	ZM136200
	8.8.8 Clean the Inside of the Reagent Refrigerator and STAT Table Compartments	Alcohol prep or 70% Isopropyl Alcohol using lint-free cloth	Commercial Item
	8.8.9 Clean or Replace the Anti-static Brushes	Anti-static Brush 1	MU854300
		Anti-static Brush 2	MU854400
	8.8.10 Replace the Sample and Reagent Probe Tubing	Sample Probe Tubing	MU854200
		Reagent Probe Tubing	MU854100
	8.8.11 Perform a W1	-	-
	8.8.12 Replace Rack ID Labels	Rack ID labels	MU906600 to MU908500
	8.8.13 Clean or Replace Individual Cuvettes	Cuvette	MU846500
Cotton swab		Commercial Item	
Wash Solution		OSR0001	
Plastic container		Commercial Item	
8.8.14 Replace the Photometer Lamp	Photometer lamp	MU988800	

8.3 Daily Maintenance

To obtain the highest performance from the system and to use the analyzer safely, perform the following daily maintenance.

- 8.3.1 Inspect the Syringes for Leaks
- 8.3.2 Inspect the Wash Solution Roller Pump for Leaks
- 8.3.3 Inspect, Clean and Prime the Sample Probe, Reagent Probe, and Mix Bars
- 8.3.4 Inspect the Wash Solution and Replenish As Needed
- 8.3.5 Inspect the Printer and Paper
- 8.3.6 Replace the DI Water or Diluent in the Pre-dilution Bottle
- 8.3.7 Inspect the Stability of the Upper Cover
- 8.3.8 Prepare the Sample Probe Wash Solutions

8.3.1 Inspect the Syringes for Leaks

The system has a sample syringe, a reagent syringe, and an ISE (option) buffer syringe.

The sample and reagent syringes are responsible for accurately measuring the volume of sample or reagent to be used in a reaction.

The ISE buffer syringe is responsible for measuring the correct volume of buffer for the ISE.

If a syringe leaks, it causes possible failure to the syringe, probe, and analyte(s) being tested.

Although the syringes may be different sizes and serve different functions, the proper performance can be gauged in the same way for each.

Inspect all components of the syringes, including the syringe case head, the syringe case, the fixing nut, and the piston fixing screw for leaks and proper installation.

Inspect the syringes for leaks

The system is provided with a sample syringe, reagent syringe, and ISE buffer syringe inside the right front analyzer door.

The procedure for inspecting the syringes for leaks is the same for all types of syringes.

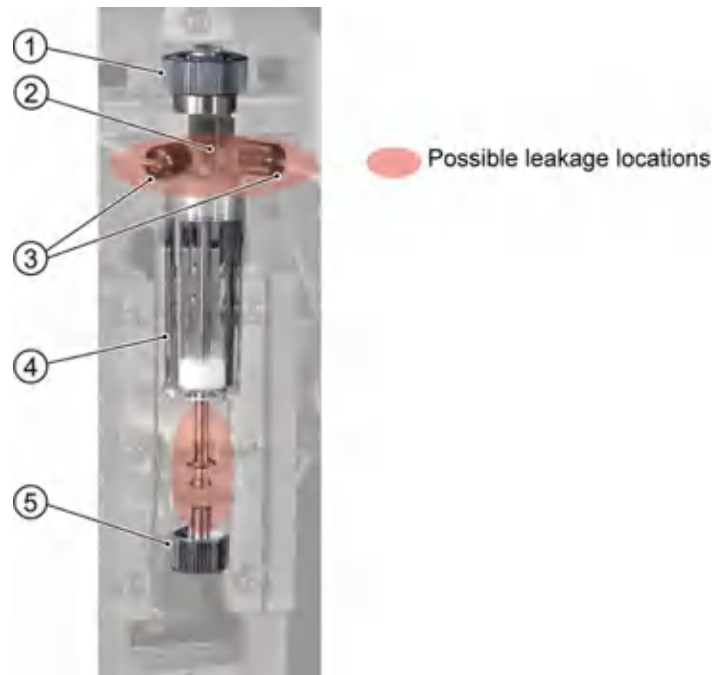
The following procedure describes how to inspect for leaks on the reagent syringe.

Refer to [8.2 Parts Used for Analyzer Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

- Clean, dry, lint-free cloth

Syringe parts:

Figure 8.5

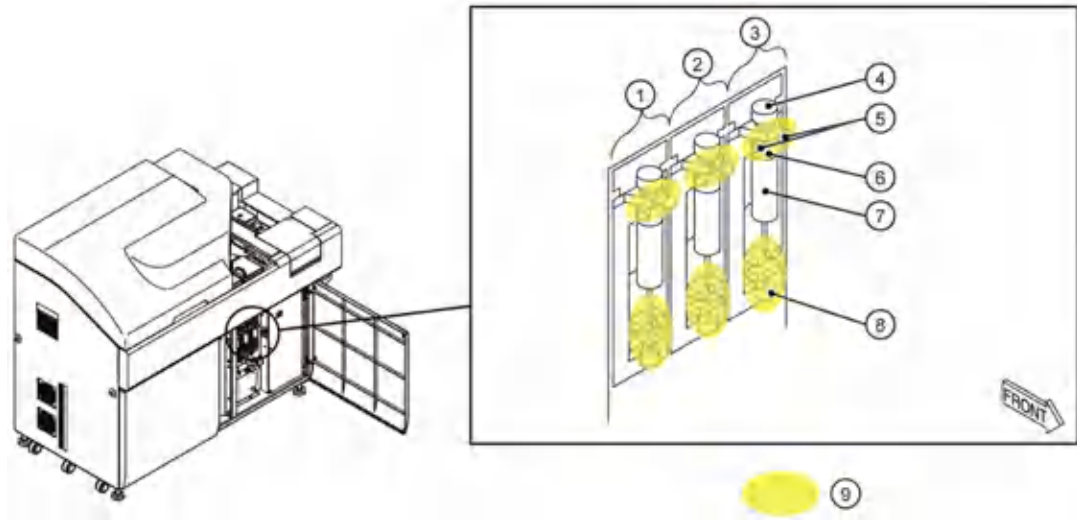


- 1. Fixing nut
- 2. Case head
- 3. Fixing screws
- 4. Syringe case
- 5. Piston fixing screw

1 Verify the analyzer is ON in *Warm up*, *Standby*, or *Stop* mode.

- 2 Open the front right door of the analyzer.

Figure 8.6



- | | |
|-----------------------|-------------------------------|
| 1. Reagent syringe | 6. Case head |
| 2. ISE buffer syringe | 7. Syringe case |
| 3. Sample syringe | 8. Piston fixing screw |
| 4. Fixing nut | 9. Possible leakage locations |
| 5. Fixing screws | |

CAUTION

Make sure that the syringe case is not contaminated with any strong alkali such as wash solution.

If the syringe case is contaminated with a strong alkali, it may be broken.

If the case comes in contact with the strong alkali, remove the syringe case and flush the contamination.

- 3 Visually inspect the syringe case head for any cracks or leaks. Using the cloth or paper towel, check the top and bottom connections of the syringe case head and the bottom fixing screw for leaks. If there is a crack or leak, the syringe must be replaced. For details on replacing the syringe, refer to [8.8.7 Replace Syringes or Syringe Case Heads](#) in this chapter.

- 4 Verify the fixing nut and piston fixing screw are tight.

CAUTION

If any leak persists even after tightening, the syringe must be replaced.

If the skin comes in contact with any liquid, immediately wash with water thoroughly.

5 Close the front right door of the analyzer.

6 For analyzer syringes, select **Home > Analyzer Maintenance**.
For ISE syringes, select **Home > Analyzer Maintenance > ISE Maintenance**.

7 Select the performed maintenance task in the Maintenance List.

Inspected Syringe	Maintenance
Sample syringe	Inspect sample syringe for leaks
Reagent syringe	Inspect reagent syringe for leaks
ISE Buffer syringe	Inspect ISE buffer syringe for leaks

8 Select **Update**. The Update window opens.

9 Select **OK**.

For details on updating the maintenance record, refer to [Update the Maintenance Log](#) in section [8.1.2 Maintenance Log](#) in this chapter.

8.3.2 Inspect the Wash Solution Roller Pump for Leaks

The wash solution roller pump supplies the required amount of wash solution to the diluted wash solution tank. If the wash solution roller pump tubing leaks, the concentration of diluted wash solution may be incorrect, or problems could occur with the wash solution roller pump.

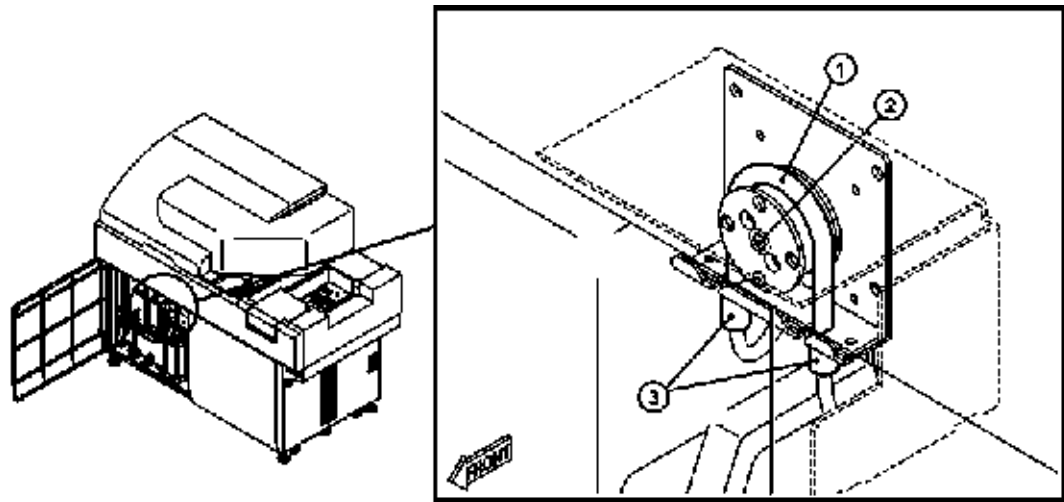
Inspect the wash solution roller pump

Material Needed: Clean dry cloth

1 Verify the system is in *Warm Up* or *Standby* mode.

- 2 Open the left front door of the analyzer

Figure 8.7



1. Wash solution roller pump tubing
2. Wash solution roller pump
3. Connectors

CAUTION

If the skin comes in contact with wash solution, immediately wash with water thoroughly.

- 3 Visually inspect the wash solution roller pump tubing for cracks or leaks. If cracks are found, replace the wash solution roller pump tubing. After the replacement, proceed to step 6.
- 4 Wipe the peripheral part of the wash solution roller pump tubing and wash solution roller pump with a clean dry cloth to check for any leaks. Wipe any liquid with the cloth.
- 5 Verify the connectors of the wash solution roller pump tubing are tight. If loose, turn the connector clockwise to tighten. If the connectors were loose, tighten, wait 5 minutes, then check for leaks again.

-
- 6 Close the left front door of the analyzer.



If leaking persists after tightening the wash solution roller pump tubing connectors, replace the wash solution roller pump tubing.

For details on replacement of the wash solution roller pump tubing, refer to [8.6.3 Replace the Wash Solution Roller Pump Tubing](#).

-
- 7 Select **Home > Analyzer Maintenance**. Select Inspect Pump Roller for Leaks to update the task in the Maintenance List.

For details on updating the maintenance record, refer to [8.1.2 Maintenance Log](#).

8.3.3 Inspect, Clean and Prime the Sample Probe, Reagent Probe, and Mix Bars

The probes are responsible for delivering precise quantities of either reagent or sample to the cuvettes.

If they are clogged, bent, or otherwise damaged, proper analysis may not be achieved.

The mix bars mix the contents in the cuvettes.

Prior to starting analysis, inspect the sample probe, reagent probes, and mix bars for damage or deterioration. Verify proper operation of each probe.

Inspect the sample and reagent probe for damage or deterioration

Refer to [8.2 Parts Used for Analyzer Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

- Alcohol Prep (70% Isopropyl alcohol using lint-free cloth)
- Clean dry lint free cloth

-
- 1 Visually inspect that each probe is not bent or damaged.

If a probe is bent or damaged, replace the probe. Refer to [8.8.3 Replace a Sample and Reagent Probe](#) in this chapter.

-
- 2 Verify each probe is free of debris.

If any contaminants or crystallization adhere to the probes, wipe the outside surface with an alcohol prep (70% Isopropyl alcohol using lint-free cloth).

 **CAUTION**

Be careful not to bend the sample probe and reagent probe during cleaning.

-
- 3 If there is a problem with the alignment of the probe, contact Beckman Coulter Technical Services.
-

Inspect the Mix bars for damage or deterioration

- 1 Inspect each mix bar for deformities.

If a mix bar is bent, scratched, or chips are found in the Teflon coating, the mix bar must be replaced. Refer to [8.8.4 Replace Mix Bars](#) in this chapter.

-
- 2 Visually inspect each mix bar.

If any contaminants or crystallization adhere to the mix bar, wipe the outside surface with an Alcohol Prep (70% Isopropyl alcohol using lint-free cloth).

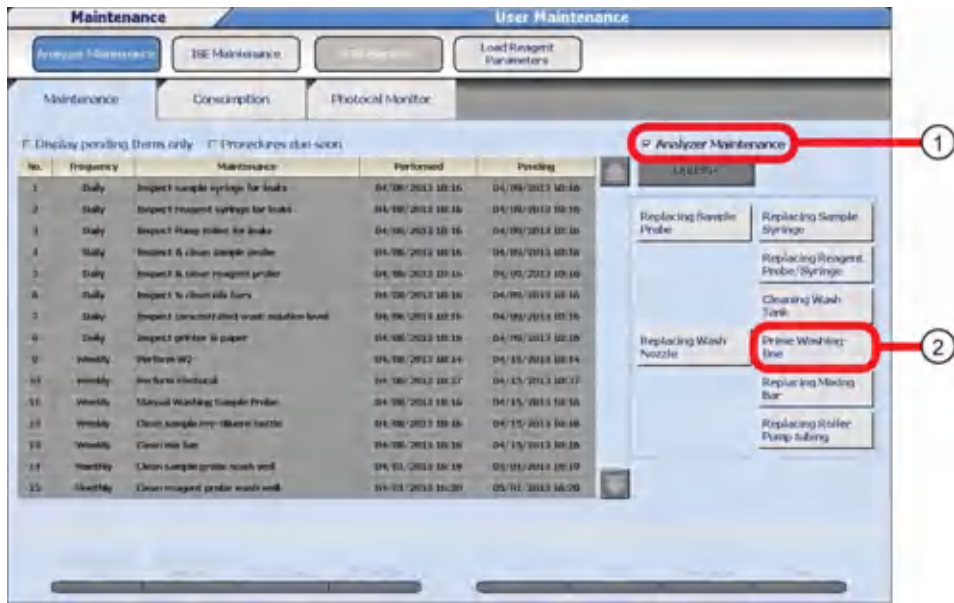
Verify proper operation of the probes and mix bars

- 1 Verify the analyzer is in *Warm up* or *Standby* mode.
-

- 2 Select **Home > Analyzer Maintenance**.

- Place a check mark in the box next to the Analyzer Maintenance option.

Figure 8.8



- Analyzer Maintenance
- Prime Washing-line

- Select **Prime Washing-line**. The Start window opens.

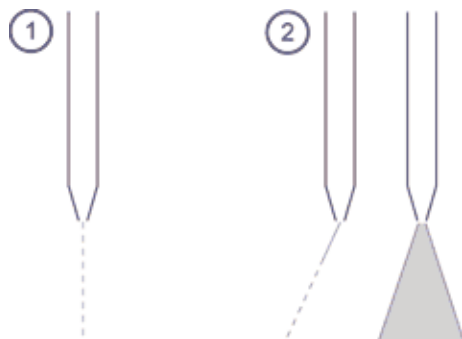
- Select **OK**.

- Open the main cover of the analyzer.

- Press the TABLE ROTATION/DIAG button. After initializing the probes and mix units, the system performs the following actions:
 - Dispenses DI water from the sample probe.
 - Dispenses DI water from the reagent probe.
 - The mix unit and wash nozzle unit perform a sequence.

8 Observe the probes:

- Verify a thin straight stream of water is dispensed from the probe and that water is present in the wash wells.
- If the water is spraying or not dispensing straight from any probe tip, clean the probe.
- If the dispensing is incorrect after cleaning the probe, replace the probe.

Figure 8.9

1. Correct dispense
2. Incorrect dispense

For details on cleaning the sample probe, refer to [8.4.1 Clean the Sample Probe and Mix Bars](#) in this chapter.

For details on replacing the sample and reagent probe, refer to [8.8.3 Replace a Sample and Reagent Probe](#) in this chapter.

9 Observe the mix unit:

- Watch the mix unit perform a sequence to verify proper operation.
- When the mix bar does not align correctly in the wash wells, system damage may occur. If this occurs, contact Beckman Coulter Technical Services.

10 Repeat steps 7 through 9 if necessary to check all probes and mix bars.

11 Close the main cover.

12 Deselect the check box next to Analyzer Maintenance to exit the menu.

13 Update the Maintenance record.

Select the performed maintenance task from the Maintenance Log.

Analyzer Maintenance:

- Inspect and clean sample probe
- Inspect and clean reagent probe
- Inspect and clean mix bars

14 Select **Update**. The Update window opens.

15 Select **OK**.

For details on updating the maintenance record, refer to [Update the Maintenance Log](#) in section [8.1.2 Maintenance Log](#) in this chapter.

8.3.4 Inspect the Wash Solution and Replenish As Needed

Inspect the Wash Solution level daily, and replenish as needed. The analyzer goes to *Pause* mode if the Wash Solution becomes empty during analysis.

Inspect the Wash Solution level

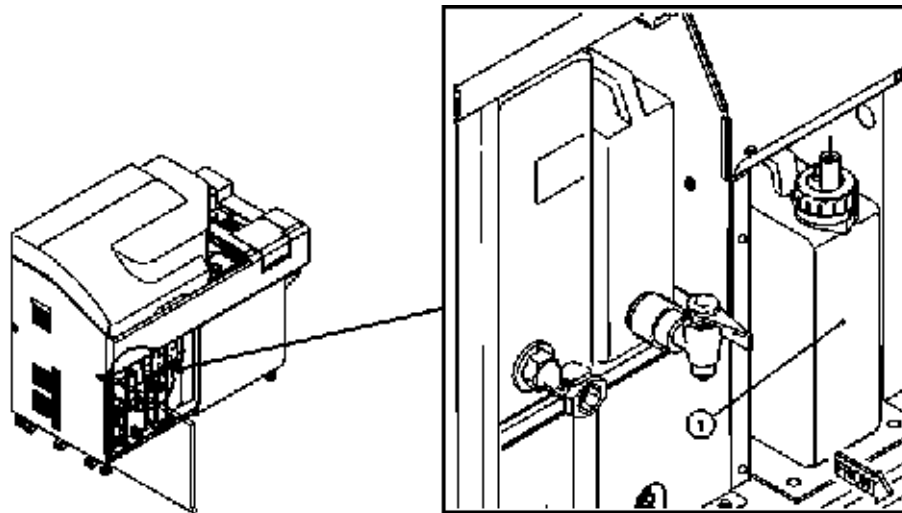
Materials Needed:

- Wash Solution
- Clean dry cloth

1 Verify the system is in *Warm Up* or *Standby* mode.

- 2 Open the left front door of the analyzer.

Figure 8.10



1. Wash Solution Tank

- 3 Verify there is a sufficient quantity of wash solution for typical daily use. The system uses approximately 0.25 L per day for 2,000 tests per day. The wash solution tank is 2 L. The volume of wash solution is insufficient below the small mark etched on the wash solution tank (approximately 200 mL).
- 4 Close the left front door of the analyzer.

Replenishing the wash solution

Replenish the wash solution properly when the volume is insufficient.

WARNING

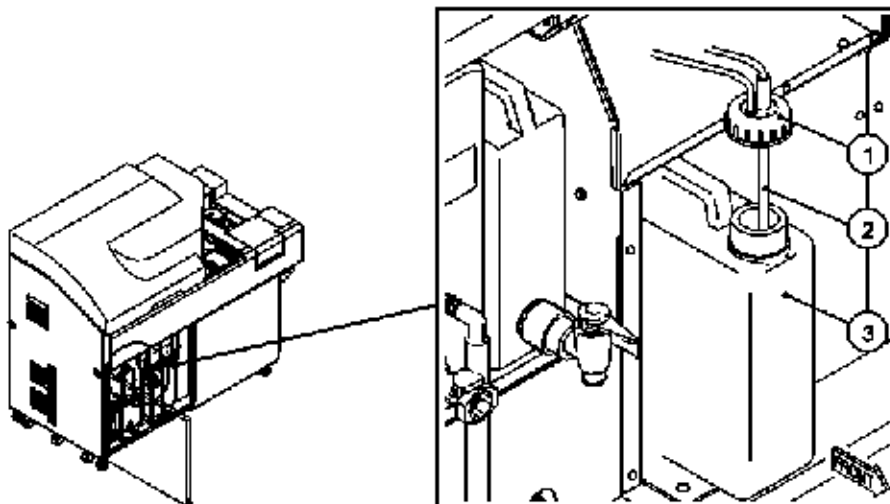
- When removing the wash solution cap, wear protective gear to prevent the hands and body from coming in contact with the wash solution. If hands or clothes come in contact with wash solution, immediately wash with water. If the wash solution comes in contact with the eyes or mouth, immediately flush with water and consult a physician.
- If the wash solution splashes or spills outside the tank, wear protective gear and wipe the area with a dry cloth or paper towel immediately. If any spill is left untreated, it may generate toxic gas and may cause parts of the analyzer to corrode. If applicable, consult the site procedure for a spill.

- 1 Carefully pull the wash solution tank forward to access the wash solution tank cap.
- 2 Unscrew the wash solution tank cap, and remove the cap and float sensor from the tank.

CAUTION

Dripping may occur when the float sensor is removed from the tank. If it occurs, immediately wipe any spills with a dry cloth with gloved hands.

Figure 8.11



1. Cap
2. Float sensor
3. Wash solution tank

-
- 3 Replace the tank with a new wash solution tank, or add wash solution up to the 2L graduation mark on the front of the tank.

 - 4 Insert the float sensor in the tank, and tighten the cap.

 - 5 Replace the wash solution tank in the analyzer.

 - 6 Select **Home > Analyzer Maintenance**. Select Inspect concentrated wash solution level. Select **Update**, then **OK**.
-

8.3.5 Inspect the Printer and Paper

The Printer is an optional part.

-
- 1 Verify the printer is on. A Ready message appears on the printer display.

 - 2 Verify that there is enough paper in the printer.
-

For additional information on printer usage, refer to the printer user's guide supplied with the printer.

8.3.6 Replace the DI Water or Diluent in the Pre-dilution Bottle

-
- 1 Discard the DI water or diluent in the pre-dilution bottle. The pre-dilution bottle is located between the reagent refrigerator and mix unit.

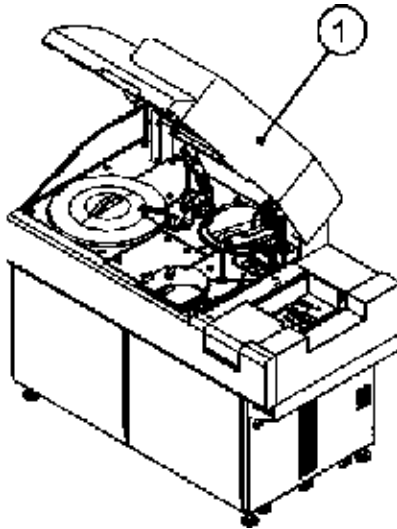
 - 2 Rinse the bottle twice with DI water.

 - 3 Fill the bottle with DI water or diluent and replace it on the instrument.
-

8.3.7 Inspect the Stability of the Upper Cover

Before starting daily analysis, check the stability of the upper cover of the analyzer to verify that it is stable and remains in the upright position when raised. If the upper cover starts to descend when opened, have the cover supports inspected and replaced by Beckman Coulter Technical Service.

Figure 8.12



1. Upper cover

8.3.8 Prepare the Sample Probe Wash Solutions

For normal analysis:

Normal analysis means there is not an unusually high volume of samples, and the sample quality is not highly viscous.

-
- 1 Fill a tube (part number ZM006200 or ZM006300) with approximately 5 mL of 2% wash solution and place it in the W1 position of the STAT table.
-

8.4 Weekly Maintenance

To obtain the highest level of performance from the system, perform these tasks on a weekly basis.

8.4.1 Clean the Sample Probe and Mix Bars

8.4.2 Perform a W2

8.4.3 Perform a Photocal

8.4.4 Clean the Pre-dilution Bottle

8.4.1 Clean the Sample Probe and Mix Bars



If the sample probe or mix bars become contaminated or stained, carryover between samples may result.

To prevent contamination and ensure proper analysis and results, clean the sample probe and mix bars on a weekly basis.

Clean the Sample Probe

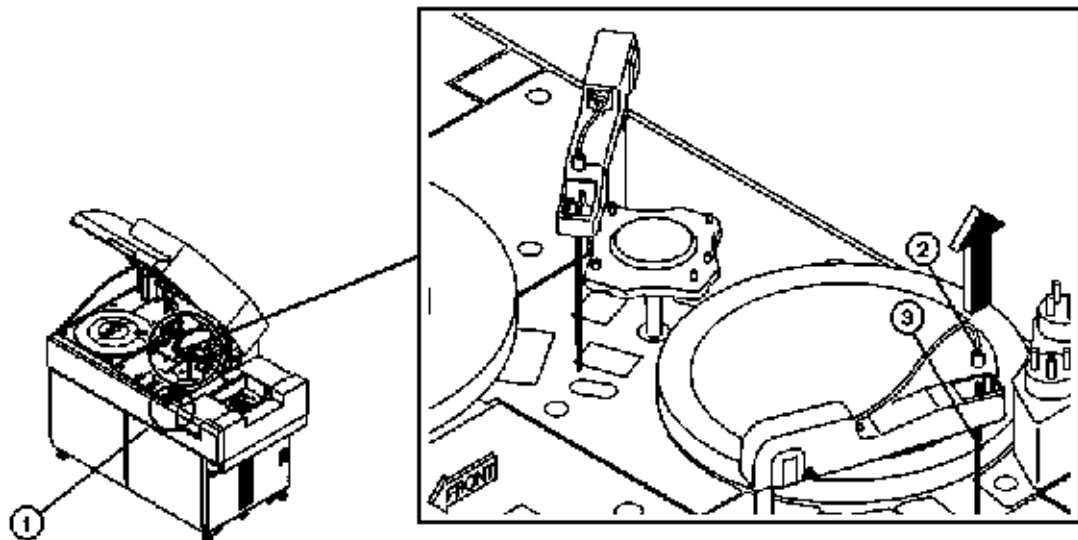
Refer to [8.2 Parts Used for Analyzer Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

- Alcohol Prep (70% Isopropyl alcohol using lint-free cloth)
- Clean lint-free cloth
- Stylet (included in start-up kit)

1 Verify the system is in *Warm up* or *Standby* mode.

- 2 Open the main analyzer cover.

Figure 8.13



1. TABLE ROTATION/DIAG button
2. Silver connector
3. Sample probe

- 3 Unscrew the silver connector above the probe.

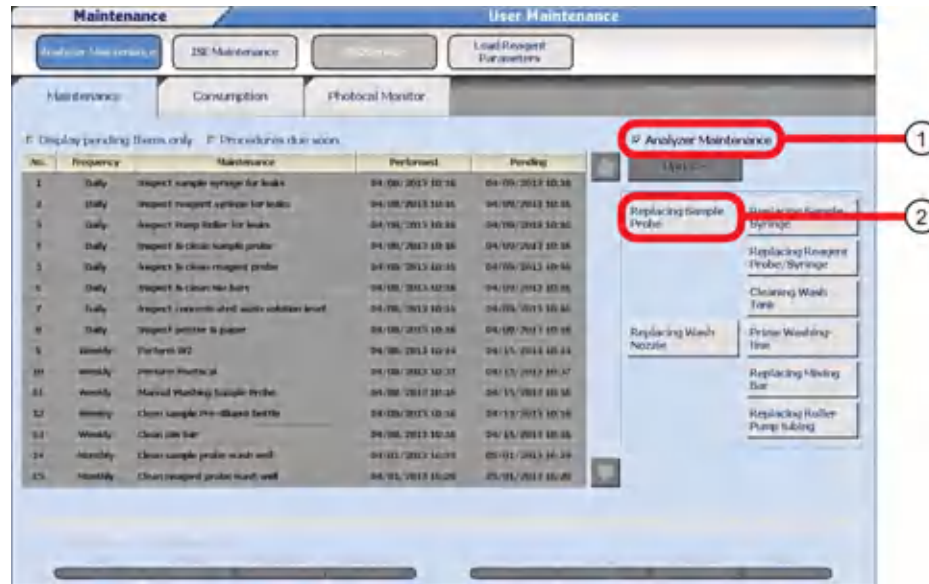


When replacing the sample probe, make sure not to bend or damage the probe.

- 4 After all the liquid drips from the probe, lift the probe from the arm.
- 5 Wipe the tip of the probe with an alcohol prep (70% Isopropyl alcohol using lint-free cloth).
- 6 Carefully insert the stylet into the probe tip to remove any potential blockage.
- 7 Reinstall the probe into the arm, attach the silver connector to the top of the probe, and tighten the silver connector.
- 8 Select **Home > Analyzer Maintenance**.

- Place a check mark in the box next to the Analyzer Maintenance option. The maintenance operation buttons become functional.

Figure 8.14



- Analyzer Maintenance
- Replacing Sample Probe

- Select **Replacing Sample Probe** from the maintenance operation buttons. The Start window opens.

- For Times, enter 3 or more, then select **OK**.

- Press the TABLE ROTATION/DIAG button. Verify a thin straight stream of water is dispensed from the probe. Water should not spray or dispense at an angle. If this occurs, replace the probe and refer to [8.8.3 Replace a Sample and Reagent Probe](#) in this chapter.

- Close the main cover.

- Deselect the check box next to Analyzer Maintenance to exit the menu.

- Update the Maintenance record. Select the performed maintenance task from Maintenance Log.

- Manual Washing Sample Probe

For details on updating the maintenance record, refer to [Update the Maintenance Log](#) in section [8.1.2 Maintenance Log](#) in this chapter.

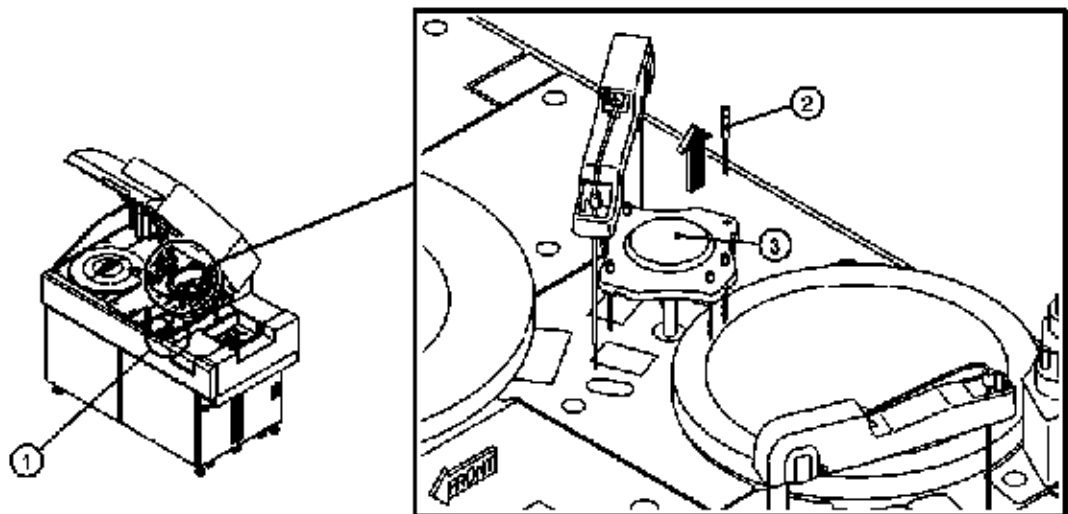
Clean the Mix bars

Refer to [8.2 Parts Used for Analyzer Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

- Alcohol Prep (70% Isopropyl alcohol using lint-free cloth)
- Clean, dry lint free cloth

- 1 Lift to remove each mix bar and wipe with an alcohol prep (70% Isopropyl alcohol using lint-free cloth).

Figure 8.15



1. TABLE ROTATION/DIAG button
2. Mix bar
3. Mix bar unit

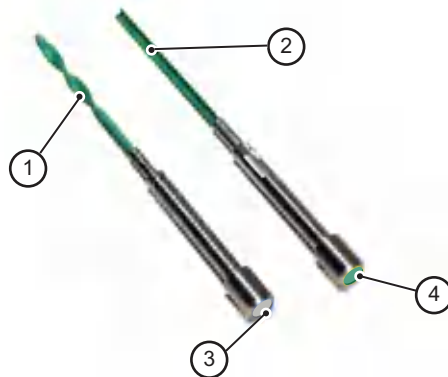
CAUTION

When cleaning the mix bars, ensure that the mix bars are not bent, or the coating is not scratched. Replace if damaged.

When inserting the mix bars into the mix unit, be careful not to scratch the mix bars.

- 2 Insert the four spiral-shape mix bars in the positions labeled R1 and S, and the two L-shape mix bars in the positions labeled R2.
Rotate each bar slightly to insert completely.

Figure 8.16



- | | |
|--------------------------|-----------|
| 1. Spiral-shaped mix bar | 3. Silver |
| 2. L-shaped mix bar | 4. Green |

CAUTION

The shapes of the mix bars differ between mix types/times.

Note the placement of each mix bar shape in the following.

- R1 and S positions: spiral-shaped mix bar
- R2 positions: L-shaped mix bar

- 3 Place a check mark in the box next to the Analyzer Maintenance option. The maintenance operation buttons become functional.
- 4 Select **Replacing Mixing Bar** from the maintenance operation button. The Start window opens.
- 5 In the Times box, enter 3. Select **OK**.
- 6 Press the TABLE ROTATION/DIAG button. Watch the mix unit perform a sequence to verify proper operation. If an abnormal noise occurs during mixing, replace the mix bar.
For details on replacing the mix bar, refer to [8.8.4 Replace Mix Bars](#) in this chapter.
- 7 Close the main cover.

8 Deselect the check box next to Analyzer Maintenance to exit the menu.

9 Update the Maintenance record.

Select the performed maintenance task from Maintenance Log.

- Clean mix bar

For details on updating the maintenance record, refer to [Update the Maintenance Log](#) in section [8.1.2 Maintenance Log](#) in this chapter.

8.4.2 Perform a W2

To obtain appropriate analysis results, clean the cuvettes once a week. The sample probe, reagent probe, mix bars, and waste lines are thoroughly cleaned during the W2 process.

The W2 prepares the cuvettes for the photocal by thoroughly cleaning them.

Perform a photocal to check the integrity of the cuvettes. Cuvettes that show an abnormal value during a photocal should be cleaned or replaced.

TIP The W2 is accomplished by running 1N HCl or sodium hypochlorite solution (0.5%) through the system.

- Each week, alternate the cleaning solution used.
- The 1N HCl removes stains that are formed by protein deposits left in the cuvettes.
- The sodium hypochlorite solution (0.5%) removes a very small quantity of inorganic substances such as metallic ions as well as any bacterial contamination.

For more information on performing the Photocal, refer to [8.4.3 Perform a Photocal](#) in this chapter.

Perform a W2

A W2 takes about 25 minutes to complete from start to finish.

 **WARNING**

Exercise care for the following points:

- Avoid mixing sodium hypochlorite solution (0.5%) and HCl; all cleaning solution containers onboard the analyzer should contain the same cleaning solution.

The mixing of sodium hypochlorite solution (0.5%) and HCl results in the formation of chlorine gas, which is highly toxic.

To avoid such risk, clearly label containers designated for sodium hypochlorite solution (0.5%) and HCl and verify that all positions requiring W2 cleaners contain the same cleaning solution.

- Always prepare a fresh sodium hypochlorite solution (0.5%) for each procedure.
- Keep hands and clothing from coming into contact with the HCL or sodium hypochlorite solution (0.5%).
If the hands or clothing of the operator come into contact with the HCL or sodium hypochlorite solution, rinse it off immediately with water.
If the HCL or sodium hypochlorite solution comes into contact with the eyes or mouth, rinse the affected area immediately with water and consult a physician.
- Avoid spilling cleaning solution on the system. If cleaning solution is spilled on the system, wipe the spill area with a cloth or paper towel saturated with water, then wipe with a dry cloth or paper towel until the area is thoroughly dry.

TIP The ISE cleaning procedure is optional during the W2. To run the ISE cleaning procedure, place a check mark next to the ISE Cleaning prompt and refer to the ISE maintenance chapter in the ISE section for instructions on how to clean the ISE.

Refer to [8.2 Parts Used for Analyzer Maintenance](#) for a complete list of part numbers.

Materials needed for the W2:

- One labeled tube (part number ZM006200 or ZM006300) for cleaning the sample probe.
- One labeled 60 mL bottle.
Use the exact solution that is labeled on the cleaning solution bottle.
- Cleaning Solutions.
Approximately 65 mL of 1N HCl or 65 mL of sodium hypochlorite solution (0.5%).

Materials needed for ISE (optional unit) cleaning during W2:

- 2 mL Hitachi cup.
- ISE Cleaning Solution.

1 Verify the system is in *Warm up* or *Standby* mode.

- 2** Fill one 60 mL bottle with approximately 60 mL of the cleaning solution in use for the W2 this week.
Be careful not to fill into the neck of the bottle. (If sodium hypochlorite solution (0.5%) is used previously for the W2, use HCl for the current procedure.)
- 3** Fill one tube with approximately 5 mL of the cleaning solution in use for the W2 this week.
- 4** If the ISE cleaning is performed, fill a Hitachi cup with approximately 1.5 mL of the ISE Cleaning Solution.
- 5** Open the main cover. Place the 60 mL bottle in the W2 bottle position located between the reagent probe and mix unit. If a photocal is also selected, close the main cover.

Figure 8.17



1. W2 Bottle

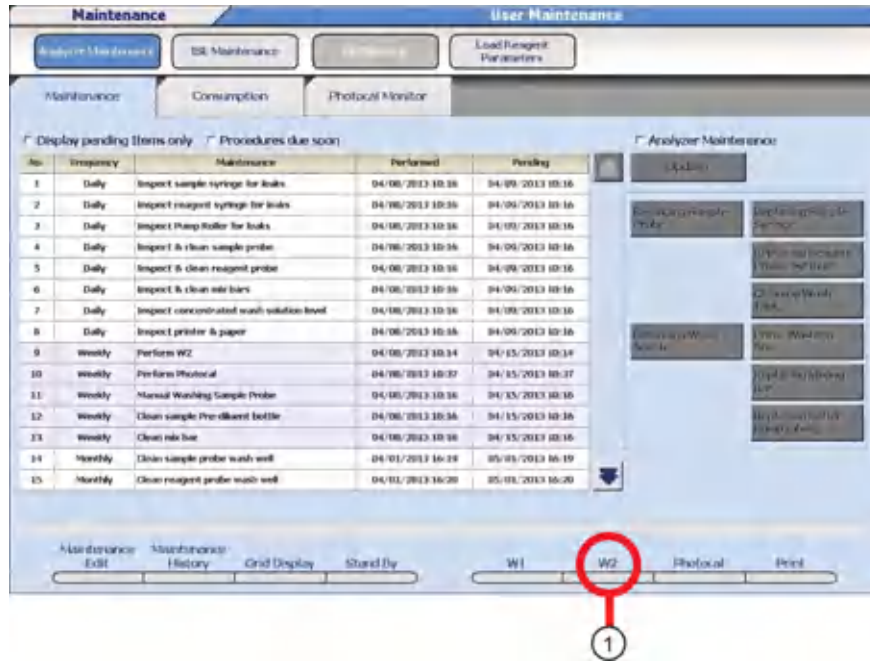
CAUTION

Avoid spilling cleaning solution on the system. If cleaning solution is spilled on the system, clean the area with a wet (water) cloth or paper towel and wipe it dry with a clean cloth or paper towel.

- 6** Place the tube filled with the cleaning solution chosen for the week in the W2 position in the STAT table.

7 Select Home > Analyzer Maintenance.

Figure 8.18



1. W2

8 Select W2 (F6). The W2 window opens.

Figure 8.19



-
- 9 Decide whether the photocal should start immediately upon completion of the W2 without operator input. Also, the weekly ISE cleaning procedure may be run with the W2 without adding any time to the procedure.
- If the photocal should start after completion of the W2, place a check mark next to the **After W2 ends, perform the photocal** option.
 - If the ISE cleaning procedure should start during the W2, place a check mark next to the **ISE Cleaning (Enhanced)** prompt and refer to the ISE maintenance chapter in the ISE section for instructions on how to clean the ISE.

-
- 10 Select **Start**. The W2 starts and takes 25 minutes to complete. A time countdown may be viewed in the mode display window. When the W2 is complete, the photocal automatically starts if it was selected in step 9. If it was not selected, at completion of W2, the analyzer enters the *Standby* mode.



Gas may be generated from the cleaning solution bottles. After the W2 is completed, remove the W2 cleaning solution bottles from the system immediately.

-
- 11 Remove all maintenance materials used for the W2 procedure.

-
- 12 The maintenance list is automatically updated.
-

8.4.3 Perform a Photocal

When the W2 is finished, a photocal should be performed.

The photocal is a check on the integrity of the cuvettes. It detects dirt, stains, or scratches and identifies cuvettes that require cleaning or replacing.

The photocal may be started from the W2 Start window.

If it was not selected with the W2 procedure, it may be started in the following way.

Perform a Photocal



To obtain optimal results, always perform photocal measurement only when the photometer lamp has been stabilized after the system startup.

The photometer lamp needs approximately 20 minutes to stabilize after the system startup.

- 1 Verify the system is in *Standby* mode.
- 2 Verify the main cover is closed.
- 3 Select **Home > Analyzer Maintenance**.

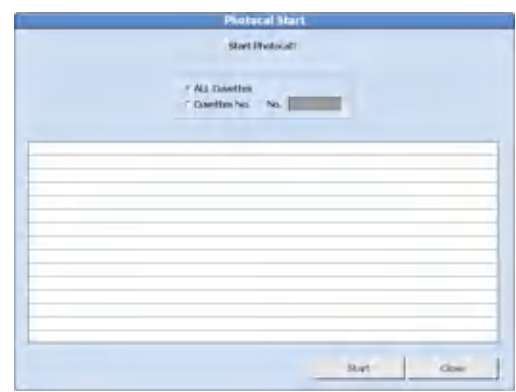
Figure 8.20



1. Photocal

- 4 Select **Photocal (F7)**. The Photocal Start window opens.

Figure 8.21



5 Select **ALL Cuvettes** to perform the weekly check.

TIP If individual cuvettes fail, they may be cleaned or replaced and checked again by selecting their specific number.

Select **Cuvettes No.**, and enter the cuvette number to check.

6 Select **Start**. The photocal starts. The photocal takes 23 minutes to complete. For a specific cuvette, it takes approximately 7 minutes. The system automatically moves to *Standby* mode after the photocal is complete. The maintenance list is updated automatically.

TIP The first photocal value after selecting Replacing Photometer Lamp in **Consumption** is updated and saved automatically as the reference values in **Photocal Monitor > Graph**.

View the Photocal Results

The system generates an audible alarm if a cuvette fails the photocal.

1 Select **Home > Analyzer Maintenance > Photocal Monitor**. A cuvette number displays in color if it failed the photocal.

Figure 8.22



- Cuvettes failing the Mean Check display in red. The cuvette is most likely dirty and can be cleaned. Refer to [8.7.1 Clean the Cuvettes and the Cuvette Wheel](#).
- Cuvettes failing the Cuvette Check display in green. The cuvette is most likely scratched and needs to be replaced. Refer to [8.8.13 Clean or Replace Individual Cuvettes](#).
- Cuvettes failing the Lamp Check display in orange. The photometer lamp is deteriorating and needs to be replaced. Refer to [8.8.14 Replace the Photometer Lamp](#).

- 2 Clean or replace any cuvettes failing the Mean Check (red) or Cuvette check (green).
- 3 Replace the photometer lamp if any cuvettes failed the Lamp Check (orange).
- 4 Select the **Maintenance** Tab.
- 5 Select **Photocal (F7)**. The Photocal Start window opens.
 - Repeat the photocal on each cuvette that failed the Mean Check or Cuvette Check. Select **Cuvettes No.**, and enter the cuvette number to check. The photocal takes approximately 7 minutes to complete.
 - Repeat the photocal on all cuvettes if any cuvettes failed the Lamp Check and the lamp was replaced, or numerous cuvettes failed the Mean Check or Cuvette Check . Select **All Cuvettes** in the Photocal Start window. The photocal takes 23 minutes to complete.
- 6 Repeat steps under the View Photocal Results heading.
- 7 To print photocal results, go to the **Photocal Monitor** tab. Select **Print (F8)** and then **OK**.

For details on removal and replacement of cuvettes, refer to [8.7.1 Clean the Cuvettes and the Cuvette Wheel](#) in this chapter.

TIP If a cuvette fails the photocal after cleaning, replace the cuvette with a new cuvette and repeat the photocal.



Verify all cuvettes have passed the photocal and run QC before processing samples.

8.4.4 Clean the Pre-dilution Bottle

When the pre-dilution bottle remains on the analyzer without being periodically cleaned, bacterial contamination may occur.

To maintain the reliability of the instrument and prevent contamination, clean the pre-dilution bottle once each week.

Refer to [8.2 Parts Used for Analyzer Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

- Extra 60 mL bottles (optional)
- Sodium hypochlorite solution (0.5%)

-
- 1 Open the main cover.

 - 2 Verify the system is in *Warm-up* or *Standby* mode.

 - 3 Remove the pre-dilution bottle from the analyzer and discard the DI water. The pre-dilution bottle is located between the reagent refrigerator and mix unit.

 - 4 Wash the pre-dilution bottle by filling it with sodium hypochlorite solution (0.5%).

 - 5 Rinse well using DI water.

 - 6 If an extra 60 mL bottle is available, fill it with DI water and place it on the analyzer while the original bottle is thoroughly rinsed and allowed to air dry. Alternate the weekly use of each bottle. If an extra bottle is not available, thoroughly rinse the bottle to remove any sodium hypochlorite solution (0.5%) residue which affects analysis results.

 - 7 Update the Maintenance record. Select **Home > Analyzer Maintenance**.
Select the performed maintenance task from Maintenance Log.
 - Clean Sample Pre-Dilution Bottle
-

For details on updating the maintenance record, refer to [Update the Maintenance Log](#) in section [8.1.2 Maintenance Log](#) in this chapter.

8.5 Monthly Maintenance

To obtain the highest level of performance from the system, perform the following maintenance procedures on a monthly basis.

[8.5.1 Clean the Sample Probe and Reagent Probe Wash Wells](#)

[8.5.2 Clean the Mix Bar Wash Wells](#)

[8.5.3 Clean the Wash Nozzle Unit and Check the Tube Mounting Joints](#)

[8.5.4 Clean the DI Water Tank, DI Filter, and Sample Probe Filter](#)

8.5.1 Clean the Sample Probe and Reagent Probe Wash Wells

Dirty wash wells could result in improperly cleaned probes, which could contaminate reagents or samples.

To maintain the reliability of the instrument and prevent contamination, clean the wash wells each month.

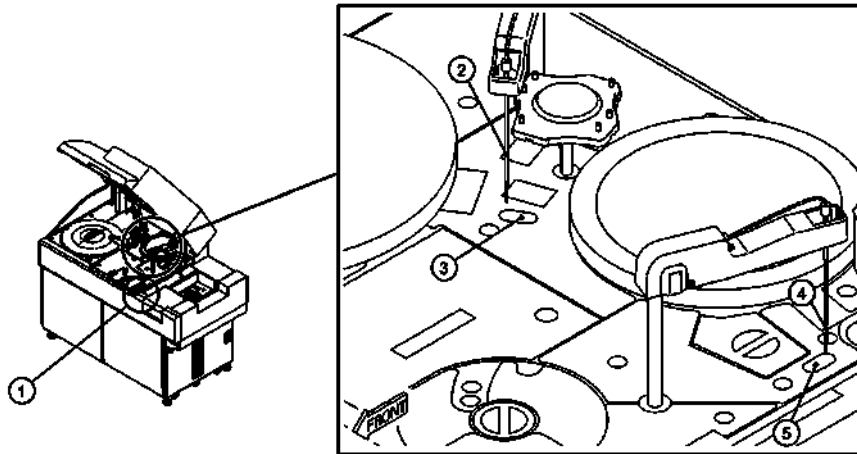
Refer to [8.2 Parts Used for Analyzer Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

- Sodium hypochlorite solution (0.5%)
- Cotton swab
- Disposable pipette

1 Verify the system is in *Warm up* or *Standby* mode.

- 2 Open the main cover of the analyzer.

Figure 8.23

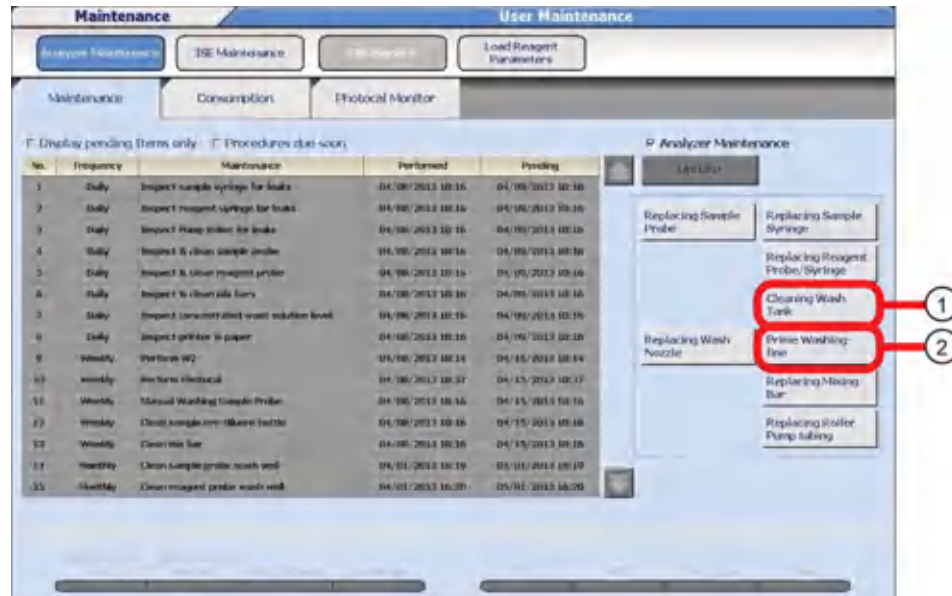


- | | |
|-------------------------------|---------------------------|
| 1. TABLE ROTATION/DIAG button | 4. Sample probe |
| 2. Reagent probe | 5. Sample probe wash well |
| 3. Reagent probe wash well | |

- 3 Select **Home > Analyzer Maintenance**.

- Place a check mark in the box next to the Analyzer Maintenance. The maintenance operation buttons become functional.

Figure 8.24



- Cleaning Wash Tank
- Prime Washing-line

- Select **Cleaning Wash Tank** from the maintenance operation buttons. Select **OK**.

CAUTION

The sample and reagent probes move when the **TABLE ROTATION/DIAG** button is pressed in step 6. Do not touch the moving sample and reagent probes.

- Press the **TABLE ROTATION/DIAG** button. The sample and reagent probes initialize. All probes move from their home positions over the wash wells to the cuvettes.

CAUTION

- Avoid spilling sodium hypochlorite solution outside the wash well. If spilled, wipe it off immediately.
- While cleaning the inside of the wash well, avoid touching the sample probe and reagent probe.

- Using a pipette, dispense the Sodium hypochlorite solution (0.5%) into the sample probe and reagent probe wash wells.

-
- 8** Use a cotton swab to clean each well. Use a different cotton swab for each wash well to avoid any contamination.
-
- 9** Press the TABLE ROTATION/DIAG button. All probes move back to the home position over the wash wells.
-
- 10** Select **Prime Washing-line** from the maintenance operation buttons. Select **OK**.
-
- 11** Press the TABLE ROTATION/DIAG button. After initialization, the system primes water through the probes and wash wells. Visually check the probe wash wells for proper drainage. If drainage is poor, repeat steps 5 through 11 again.
-
- 12** Close the main cover.
-
- 13** Deselect the check box next to Analyzer Maintenance to exit the menu.
-
- 14** Update the Maintenance record.
Select the performed maintenance task from Maintenance Log.
- Clean Sample Probe Wash Well
 - Clean Reagent Probe Wash Well
-

For details on updating the maintenance record, refer to [Update the Maintenance Log](#) in section [8.1.2 Maintenance Log](#) in this chapter.

8.5.2 Clean the Mix Bar Wash Wells

In normal operation, the mix bar wash wells clean the outside surface by washing each mix bar in 1% wash solution and then they are rinsed with DI water.

Dirty wash wells could result in improperly cleaned mix bars, which could lead to carryover problems.

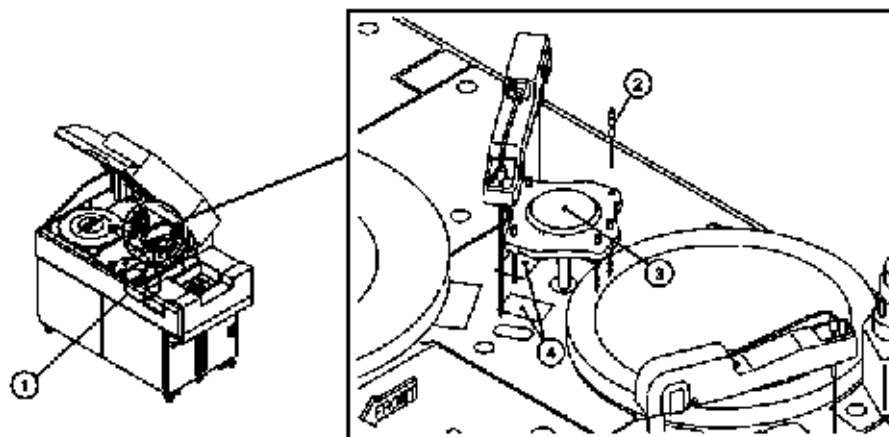
To maintain the reliability of the instrument and prevent contamination, clean the wash wells once each month.

Refer to [8.2 Parts Used for Analyzer Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

- Sodium hypochlorite solution (0.5%)
- Cotton swab
- Disposable pipette

- 1 Verify the system is in *Warm up* or *Standby* mode.
- 2 Open the main cover of the analyzer.
- 3 Manually turn the mix bar unit so the mix bars are not over the wash wells.

Figure 8.25



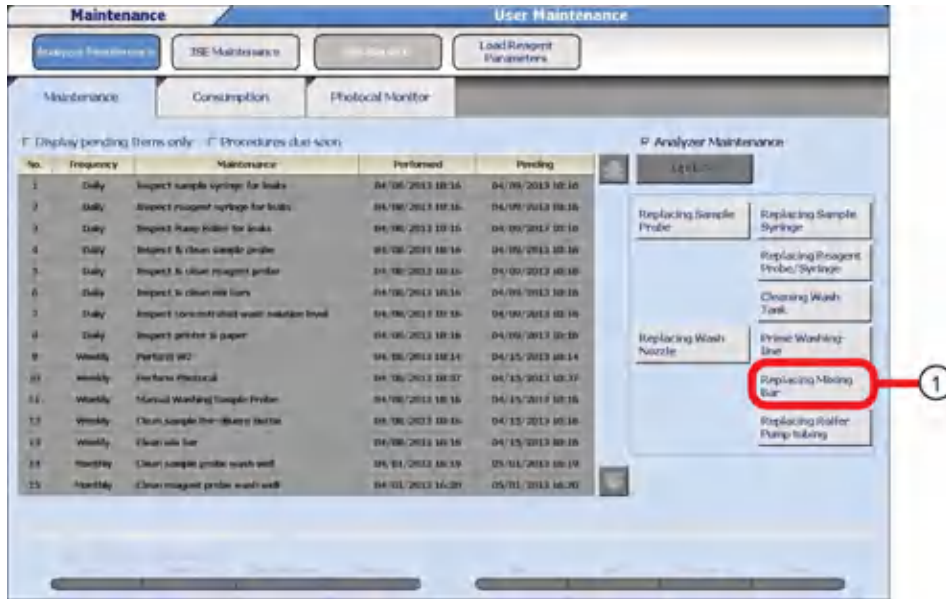
- | | |
|-------------------------------|----------------------|
| 1. TABLE ROTATION/DIAG button | 3. Mix unit |
| 2. Mix bar | 4. Mix bar wash well |

CAUTION

**Avoid spilling the sodium hypochlorite solution outside the mix bar wash well.
If it is spilled, wipe it up immediately.**

- 4 Dispense sodium hypochlorite solution (0.5%) into each of the two wash wells while cleaning them with a cotton swab.
Use a different cotton swab for each wash well to avoid spreading any contamination.
- 5 Turn the mix bar units so the mix bars are over the mix bar wash wells.
- 6 Select **Home > Analyzer Maintenance**.
- 7 Place a check mark in the box next to the Analyzer Maintenance option. The maintenance operation buttons become functional.

Figure 8.26



1. Replacing Mixing Bar

- 8 Select **Replacing Mixing Bar** from the maintenance operation buttons. The Start window opens.

Figure 8.27



9 For **Times**, enter 1 and select **OK**.

10 Press the **TABLE ROTATION/DIAG** button. The mix unit initializes and performs a sequence.

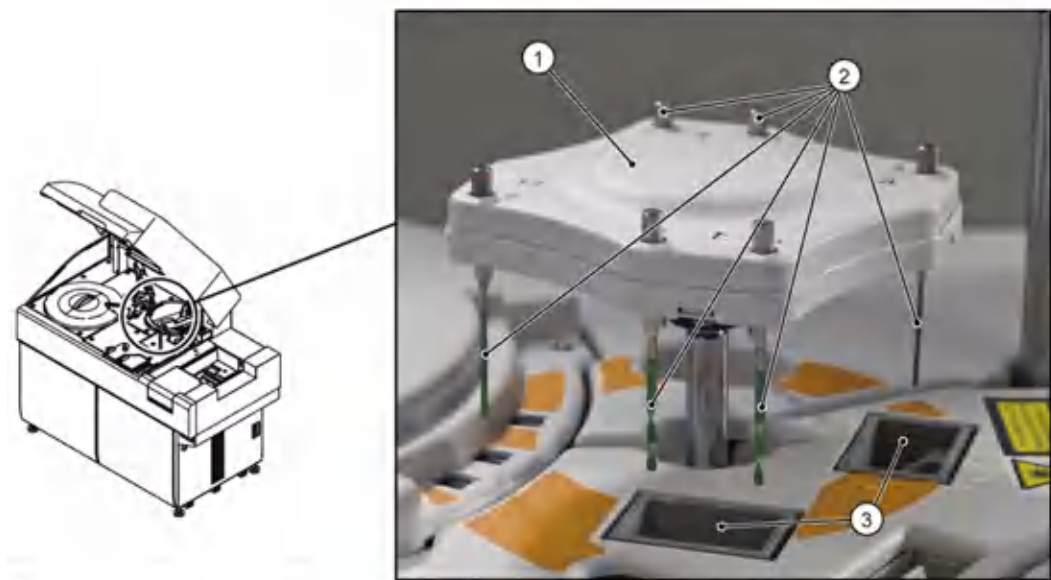
11 Visually check the mix bar wash wells for proper water drainage. If drainage is poor, repeat steps 3 through 11 again.

CAUTION

The shapes of the mix bars differ between mix types/times:

- R1 and S positions: spiral shaped mix bar
- R2 positions: L shaped mix bar

Figure 8.28



1. Mix unit
2. Mix bars
3. Wash wells

12 Close the main cover.

13 Deselect the check box next to **Analyzer Maintenance** to exit the menu.

14 Update the Maintenance record.

Select the performed maintenance task from Maintenance Log.

- Clean mix bar wash wells

For details on updating the maintenance record, refer to [Update the Maintenance Log](#) in section [8.1.2 Maintenance Log](#) in this chapter.

8.5.3 Clean the Wash Nozzle Unit and Check the Tube Mounting Joints

The wash nozzle unit consists of eight nozzles, responsible for aspirating liquid out of the cuvettes, dispensing diluted wash solution and DI water into the cuvettes, and drying the cuvettes.

If any of the nozzles become clogged, their functionality may suffer, resulting in inefficient cleaning of the cuvettes.

Inspect the mounting joints for cracks or leaks. If any damage exists, the aspiration and dispense by nozzles could be affected.

Refer to [8.2 Parts Used for Analyzer Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

- Clean, dry lint free cloth
- Sonicator filled with DI water

Remove the wash nozzle unit and check the tube mounting joints

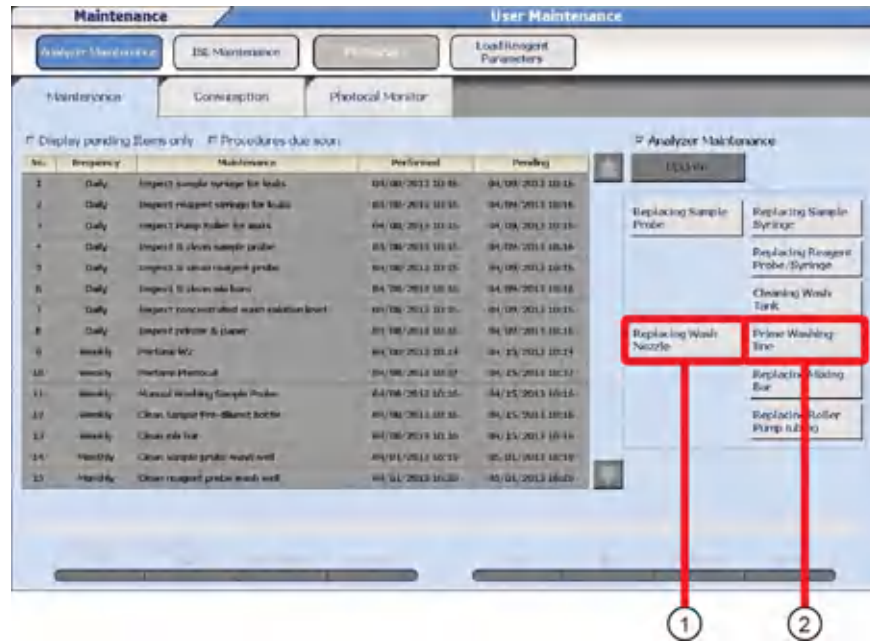
1 Verify the system is in *Warm up* or *Standby* mode.

2 Open the main upper cover.

3 Select **Home > Analyzer Maintenance**.

- Place a check mark in the box next to the Analyzer Maintenance option. The maintenance operation buttons become functional.

Figure 8.29



- Replacing Wash Nozzle
- Prime Washing-line

- Select **Replacing Wash Nozzle** from the maintenance operation button. The Start window opens.
- Select **OK**.

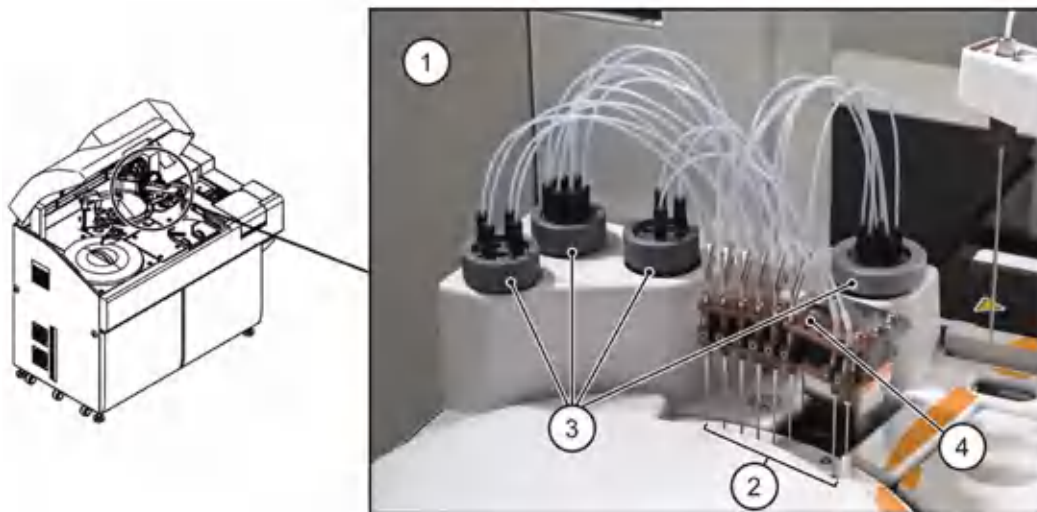
- 7 Press the TABLE ROTATION/DIAG button. The liquid drains from the tubes.

CAUTION

Always drain the water remaining in the wash nozzles before cleaning or replacing the tube mounting joints.

If any tube mounting joint is loosened without draining the remaining water, the water spills out of the nozzle. If the water spills onto the cuvettes, refer to [8.8.13 Clean or Replace Individual Cuvettes](#).

Figure 8.30



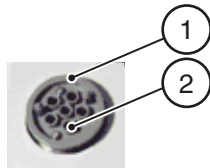
1. Wash nozzle unit
2. Wash nozzles 1 through 8
3. Gray manifold
4. Silver knob

-
- 8 Loosen the four grey manifolds and remove them from their mounting positions.

CAUTION

A total of six O-rings are used inside the water supply tube mounting joint of the wash nozzle unit. When the joint has been removed, make sure that there are six O-rings inside the joint.

Figure 8.31



1. Water supply tube mounting joint
2. O-ring

If an O-ring is missing, check the back of the joint to verify the O-ring is not stuck to the area around the tube mounting joint. If it cannot be found, install a new O-ring in the place concerned.

For detailed information about cleaning or replacing an O-ring of the tube mounting joint, refer to [8.8.1 Replace O-rings in the Water Supply Tube Mounting Joint](#) in this chapter.

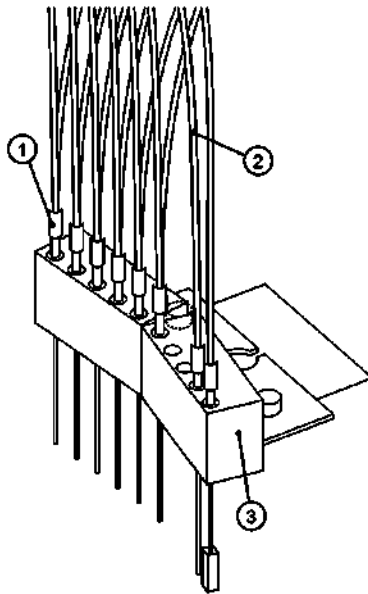
-
- 9 Loosen the silver knob holding the wash nozzle unit in place. Loosen the knob until it stops turning.

- 10 Lift the wash nozzle unit up over the positioning screws. Be careful not to bump or bend the nozzles.

CAUTION

When loosening the knob on the wash nozzle unit, do not loosen the positioning screws on either side of the knob. These screws are used for positioning the wash nozzle unit.

Figure 8.32



1. Wash nozzle joint
2. Tubing
3. Wash nozzle unit

- 11 Remove the wash nozzle unit along with the tubing and inspect the joints for cracks. If a crack is found, the joint should be replaced.

For details, refer to [8.8.5 Replace the Wash Nozzle Joint](#) in this chapter.

Clean and inspect the wash nozzle unit

CAUTION

- When cleaning the wash nozzle unit using a sonicator, avoid damaging the wash nozzles.
- When mounting the wash nozzle unit, do not hit the nozzle tips on the cuvette wheel cover.

-
- 1 Sonicate the wash nozzle unit in DI water for 15 minutes. Only the nozzle portion needs to be submerged. Take care not to get the springs above the nozzles wet. If water does get into the springs, dry them well using a clean, dry lint free cloth, or canned air.

TIP A sonicator is recommended for cleaning the wash nozzles.

If a sonicator is not available, clean the inside of each nozzle using the supplied stylet and DI water. After cleaning the wash nozzle unit in water, wipe any drops using a clean, dry lint free cloth.

-
- 2 Remove the wash nozzle unit from the sonicator, and dry thoroughly with a clean, dry lint free cloth.

-
- 3 Inspect the O-rings of the manifold. Check that all six O-rings are properly inserted in individual grooves. Verify that the O-rings are not ripped or over-stretched. Look for dust or detergent crystals around each O-ring. If faults are found with the O-rings, they should be replaced.

For detailed procedures on cleaning or replacing an O-ring in the tube mounting joint, refer to [8.8.1 Replace O-rings in the Water Supply Tube Mounting Joint](#) in this chapter.

 **CAUTION**

Verify that the following precautions are followed to ensure tests are performed correctly and avoid system damage.

- When installing the tube mounting joints, make sure the joints are in the correct, color-coded positions. Firmly tighten the joints.
- Verify all tubing from the nozzles to the tube mounting joints is present and connected.
- Do not damage any of the joints or tubing.
- Damaged parts may cause leaks and contaminate or flood the cuvette wheel.

-
- 4 Return the wash nozzle unit into its original position. Place the wash nozzle unit over the positioning screws, then tighten the silver knob to hold the wash nozzle unit in place.
-
- 5 Return each of the manifolds into its original position. Match the colored dot on the manifold with the one next to its position. Tighten the manifolds without cross threading them. Verify the manifolds are finger-tight to prevent a cuvette wheel overflow, but do not over-tighten.
-
- 6 Select **Prime Washing-line** from the maintenance operation buttons. The Start window opens.
-
- 7 Select **OK**.

-
- 8 Press the TABLE ROTATION/DIAG button. The air in the tubing is purged as the wash nozzle unit moves up and down.



Verify that the wash nozzle unit moves freely without interference and no leaks occur.

If leaks occur, remove the water supply tube mounting joint again, and verify there are 6 O-rings correctly placed in the mounting positions. Inspect each O-ring, and replace any damaged O-ring with a new one.

-
- 9 Close the rear cover and main cover of the analyzer.

-
- 10 Deselect the check box next to Analyzer Maintenance to exit the menu.

-
- 11 Update the Maintenance record.

Select the performed maintenance task from Maintenance Log.

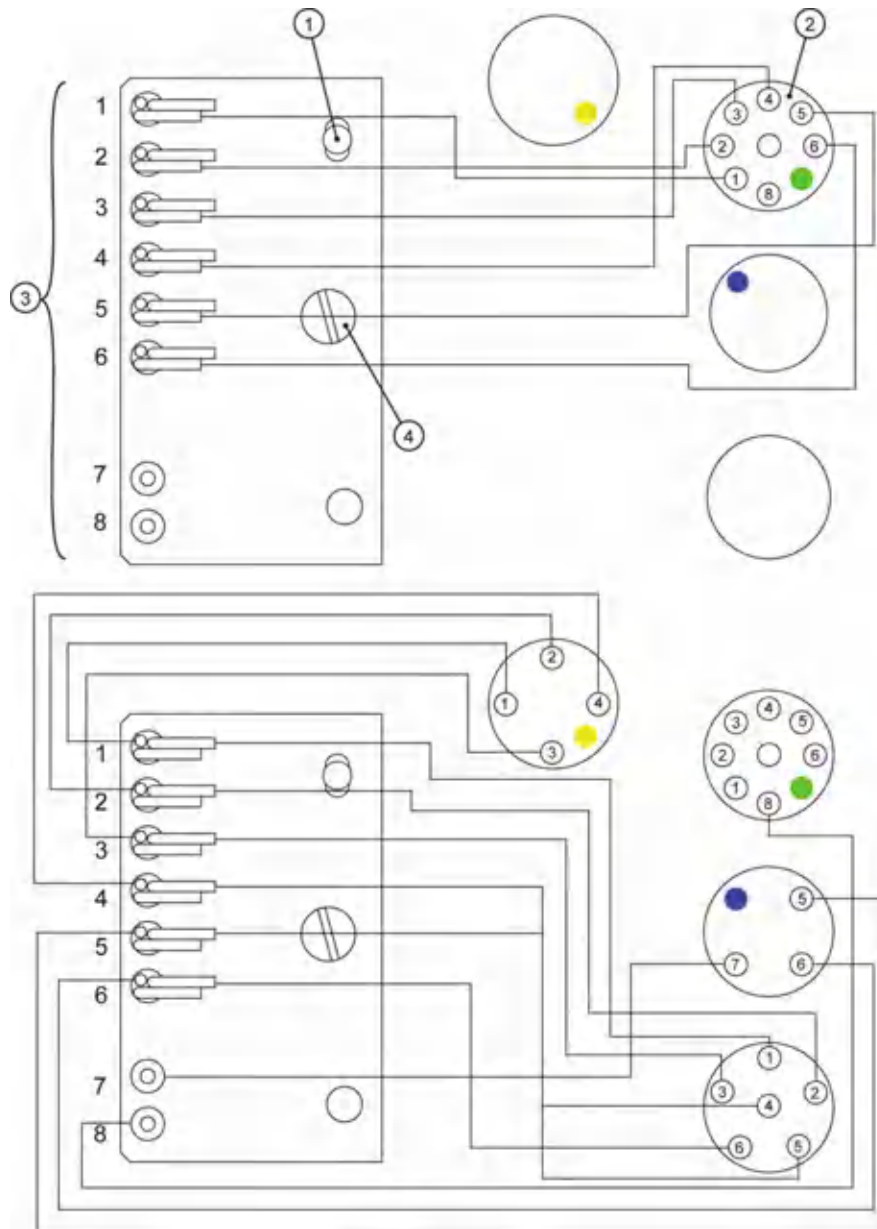
- Clean and Inspect Wash Nozzle

For details on updating the maintenance record, refer to [Update the Maintenance Log](#) in section [8.1.2 Maintenance Log](#) in this chapter.

Tubing Diagram of the Wash Nozzles and Tube Mounting Joints

For easy understanding, the tubing diagram below is separated into two tubing groups.

Figure 8.33



1. Positioning screw
2. Tube mounting joint
3. Wash nozzles
4. Knob

8.5.4 Clean the DI Water Tank, DI Filter, and Sample Probe Filter

The DI water filter and sample probe filter are used to prevent particles from entering the internal DI water system. The DI water tank must be cleaned to avoid bacterial contamination of the system.

Refer to [8.2 Parts Used for Analyzer Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

- Clean, dry lint free cloth
- Basin
- Sonicator filled with DI water
- Brush
- Extra DI water tank, filled with 5 L of DI water
- Sodium hypochlorite solution (1.0%)

TIP In this procedure, use Beckman Sodium Hypochlorite (5%) diluted 1:5 or ISE Cleaning Solution diluted 1:5.

Clean the DI Water Tank, and Remove the DI Filter and Sample Probe Filter



Turn off the system before starting this procedure.

If this procedure is performed with the system ON (*Standby mode*), DI water is supplied through the supply tube, and the float sensor in the DI water tank activates, and water drains continuously from the tube.

- 1** Perform an **End Process**. Refer to [7.10 System Shutdown \(End Process\)](#) in chapter 7.
- 2** Open the front left door of the analyzer.
- 3** Position a basin on the floor under the DI water tank to catch spilled water.
- 4** Unplug the black float sensor connector labeled 879.

- 5 Press the grey button of the quick disconnect joint on the front of the tank and remove the tubes.

⚠ CAUTION

When the float sensor and tubing are removed from the tank, DI water may drip off.

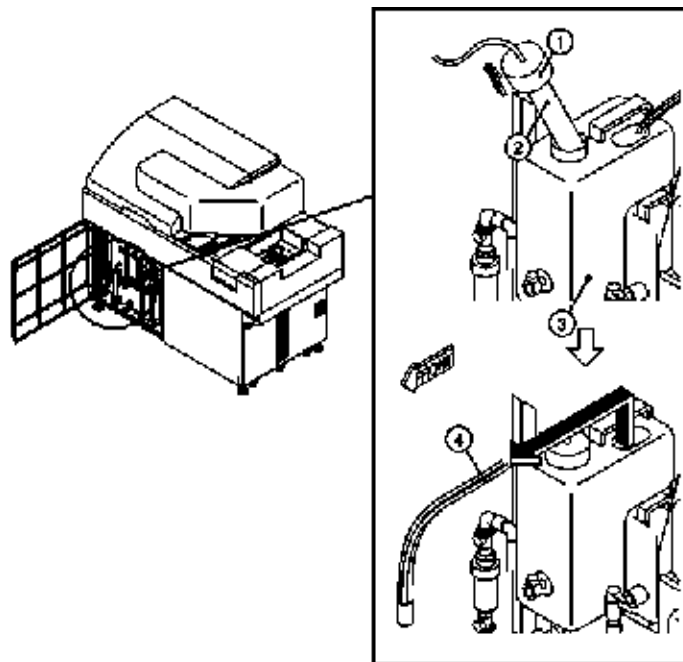
If the liquid drips off, immediately wipe it off with a clean, dry lint-free cloth.

Loosen the DI filter case and sample probe filter case over the basin.

- 6 Pull the DI water tank out of the analyzer. Make sure the tubes clear the top of the tank and wrap them in a clean cloth.

- 7 Unscrew the cap of the tank and remove the float sensor.

Figure 8.34

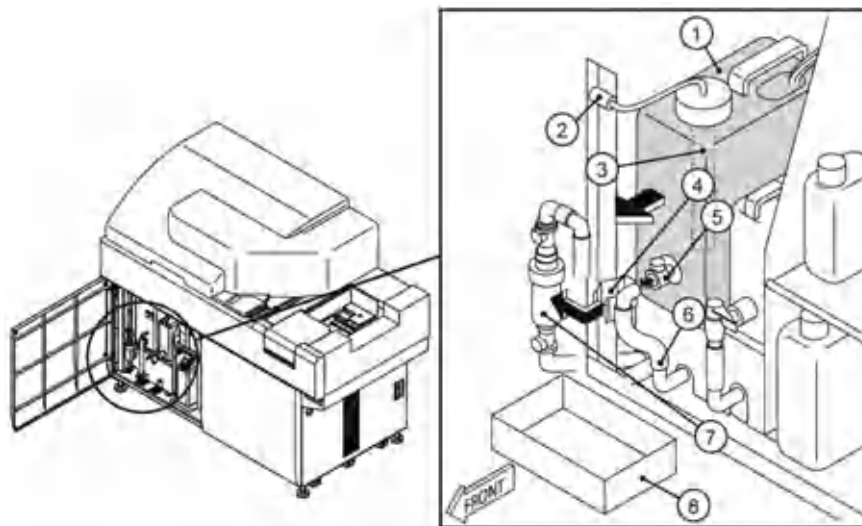


1. Cap
2. Float sensor
3. Deionized water tank
4. Water supply tubing

- 8 Discard the DI water in the tank.

-
- 9** Clean the tank and the exterior part of the tubing with sodium hypochlorite solution (1.0%).
-
- 10** Rinse the tank and the exterior part of the tubing thoroughly using DI water and set aside and allow the tank to dry.
-
- 11** Clean float sensor with DI water.
-
- 12** Remove the DI water filter from the case attached to the water supply tube over the basin by unscrewing it.

Figure 8.35

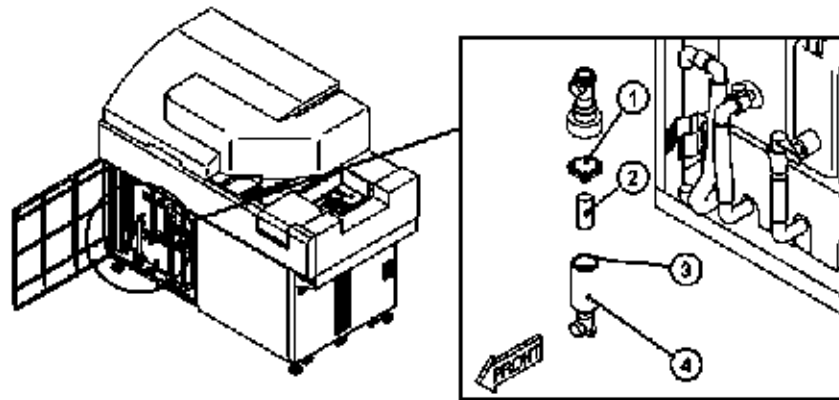


- | | |
|-------------------------|----------------------------------|
| 1. Deionized water tank | 5. Joint |
| 2. Connector | 6. Deionized water drainage hose |
| 3. Float sensor | 7. Sample probe filter case |
| 4. Bracket | 8. Basin |

-
- 13** Locate the sample probe filter case directly to the left of the DI water tank and remove it from the bracket.
-
- 14** Press the grey button of the quick disconnect joints and pull to remove the tubes from the top and bottom of the filter case.

- 15 Unscrew the filter case over the basin and remove the sample probe filter.

Figure 8.36



- | | |
|------------------------------|----------------|
| 1. Filter positioning insert | 3. O-ring |
| 2. Sample probe filter | 4. Filter case |

Clean the DI Water filter and Sample Probe filter

- 1 Place the DI water filter and the sample probe filter in the sonicator filled with DI water.
- 2 Sonicate the filters for 10 minutes.

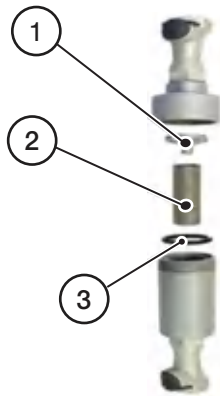
CAUTION

When working with the sample probe filter, do not lose the O-ring.

- 3 Reinsert the clean DI water filter into its case and tighten the cap.

-
- 4 Reinsert the clean sample probe filter into the filter case.

Figure 8.37



1. Filter positioning insert
2. Sample probe filter
3. O-ring

-
- 5 Tighten the filter case firmly.



**Do not connect the filter case to the joints upside down.
If the filter case is connected upside down, debris could cause data errors.**

-
- 6 Reconnect the quick disconnects by forcing the tubes into their connections until a distinct click is heard.

-
- 7 Push the filter case into the metal bracket.
-

Replace the DI Water Tank

- 1 Fill the clean tank with 5 L of DI Water.
- 2 Place the float sensor into the DI water tank. Tighten the cap.

 **CAUTION**

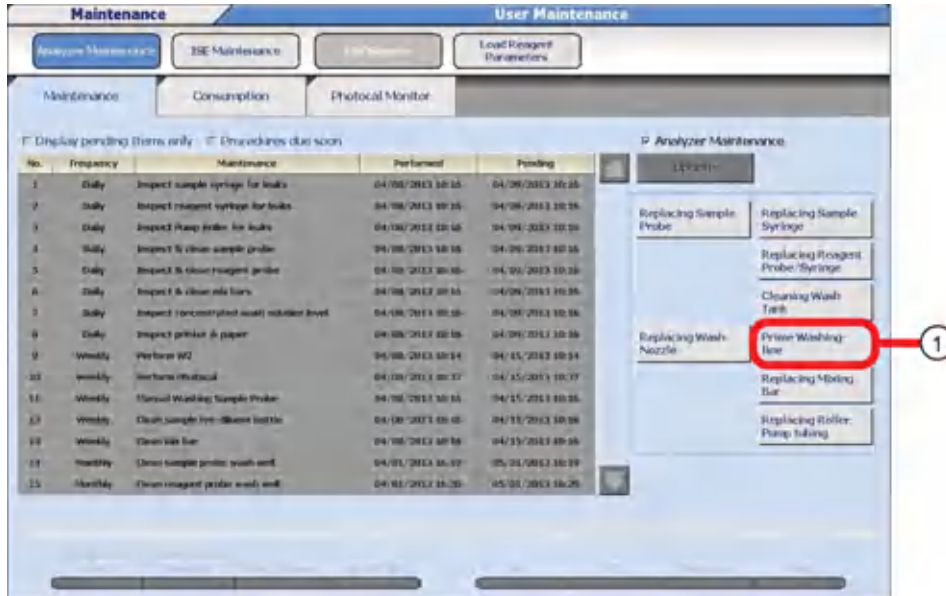
Fill the DI water tank with 5 L of DI water before turning the system ON. A malfunction may result if the DI tank is empty, and the pump turns on after the system is turned ON.

- 3 Place the tank into the system and reinsert all water supply tubes into the top of the tank. Push the tank back into place.
 - 4 Reconnect the quick disconnect to the tank by forcing the tube into its connection until a distinct click is heard.
 - 5 Reconnect the float sensor connector labeled 879.
 - 6 Wipe any spilled water from the analyzer surface and remove the basin.
 - 7 Press the **ON** button. The system powers on and initializes, enters into *Warm Up* for 20 minutes, and then enters *Standby*.
-

Perform a Prime Washing Line

- 1 Select **Home > Analyzer Maintenance**.

Figure 8.38



1. Prime Washing-line

- 2 Place a check mark in the box next to the Analyzer Maintenance option.
- 3 Select **Prime Washing-line** from the maintenance operation button. The Start window opens.
- 4 Select **OK**.
- 5 Press the TABLE ROTATION/DIAG button. Watch as the prime is performed. Repeat the prime if necessary by pressing the TABLE ROTATION/DIAG button again until all bubbles are removed from the line.
- 6 Close the door.
- 7 Deselect the check box next to Analyzer Maintenance to exit the menu.

8 Update the Maintenance record.

Select the performed maintenance task from Maintenance Log.

- Clean deionized-water filter
- Clean sample probe filter
- Clean deionized-water tank

For details on updating the maintenance record, refer to [Update the Maintenance Log](#) in section [8.1.2 Maintenance Log](#) in this chapter.

8.6 Quarterly Maintenance

To obtain the highest level of performance from the system, perform the following maintenance tasks on a quarterly basis (every three months).

8.6.1 Clean the Air Filters

8.6.2 Inspect and if Needed, Replace the DI Water Filter, Sample Probe Filter, and Replace the O-ring

8.6.3 Replace the Wash Solution Roller Pump Tubing

8.6.1 Clean the Air Filters

The air filters prohibit dust and other contaminants from entering the system.

Clean the air filters



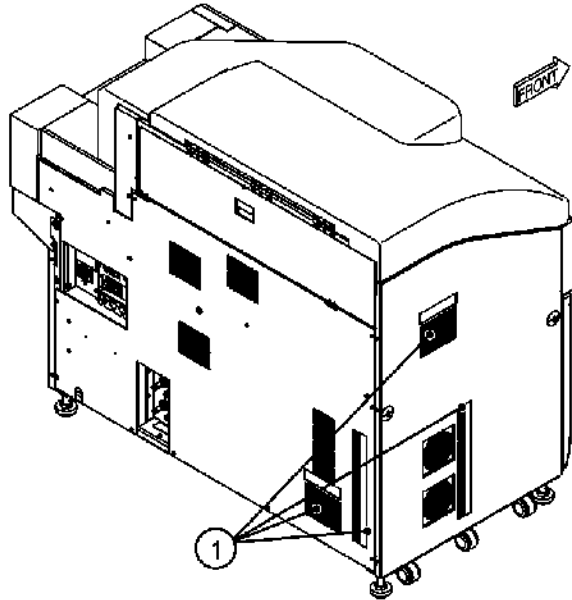
Do not run the instrument without filters in place.

If filters are missing, heaters and the power supplies get dusty, which can cause a short circuit and fire.

-
- 1 Select **End Process** to shut down the system.
-
- 2 Press EM STOP to completely turn off the power, including the fans. An EM STOP is necessary to avoid the risk of the fans bringing dust into the analyzer while the filters are removed.

- 3 Remove the four air filters shown in the diagram.

Figure 8.39



1. Air filters

- 4 Vacuum the dust from the filters or clean the filters with water and allow the filters to completely dry.

TIP Replace the air filters if they are torn.

The air filters can be cleaned with a vacuum without being removed from the analyzer. If the filter is moved from its original position after cleaning, re-position the filter to its original flat condition and position.

CAUTION

If cleaning the filters with water, verify the filters are completely dry before replacing them on the system to avoid moisture from getting into the system.

- 5 Replace the filters in their original positions.
- 6 Press the white RESET button to turn on the main power, and then wait 5 seconds.
- 7 Press the green ON button to turn on the system.

8 Select **Home > Analyzer Maintenance**.

Figure 8.40



9 From the Maintenance Log, select **Clean the air filters**.

10 Select **Update**. The Update window opens.

11 Select **OK**.

8.6.2 Inspect and if Needed, Replace the DI Water Filter, Sample Probe Filter, and Replace the O-ring

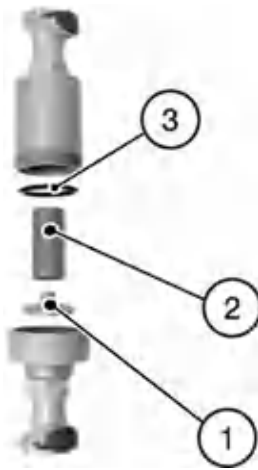
Refer to [8.2 Parts Used for Analyzer Maintenance](#) for a complete list of part numbers.

Materials needed:

- Sample Probe Filter and DI Water Filter
- O-ring

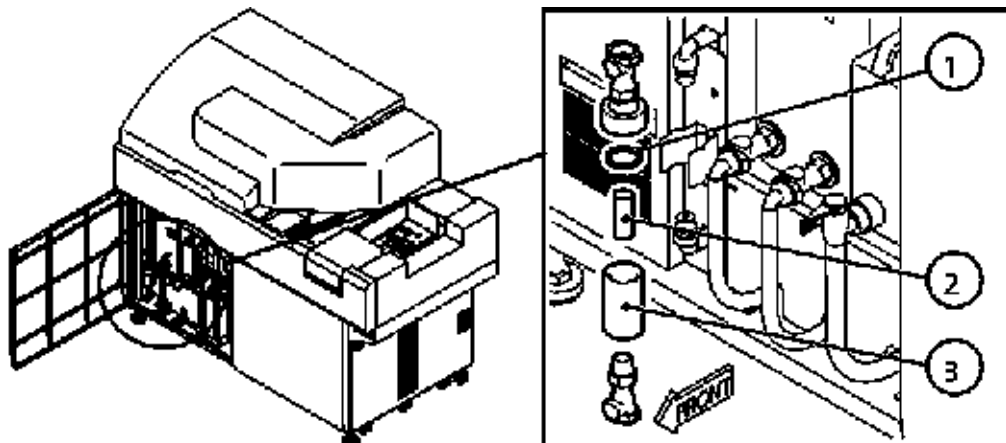
For information on how to remove the filters, refer to [8.5.4 Clean the DI Water Tank, DI Filter, and Sample Probe Filter](#).

Figure 8.41



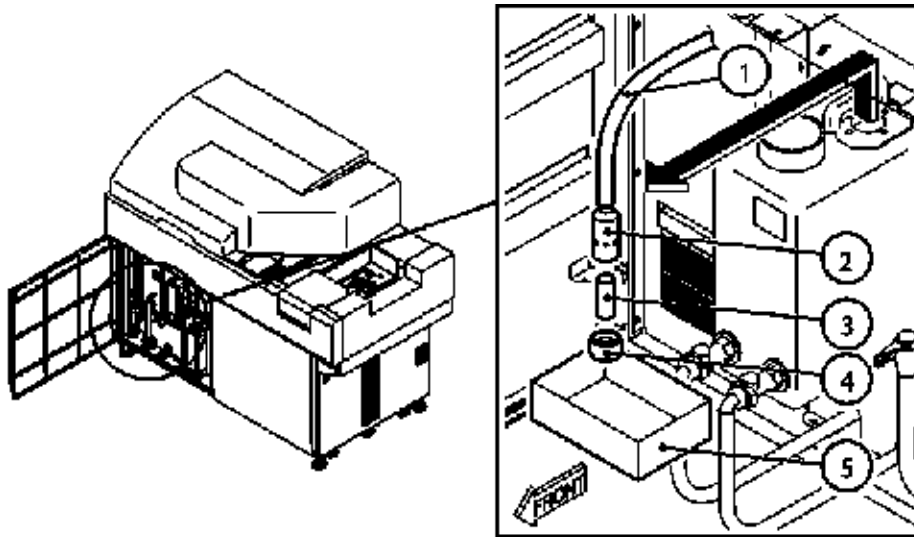
1. Filter positioning insert
2. Sample probe filter
3. O-ring

Figure 8.42



1. O-ring
2. Sample probe filter
3. Filter case

Figure 8.43



- | | |
|----------------------|--------------------|
| 1. Water supply tube | 4. Filter case cap |
| 2. Filter case | 5. Basin |
| 3. DI water filter | |

1 When the filters are removed for cleaning, inspect them. If the filters cannot be cleaned successfully, replace them.

2 Replace the O-ring.
Refer to [8.5.4 Clean the DI Water Tank, DI Filter, and Sample Probe Filter](#) in this chapter.

3 Update the Maintenance record.
Select the following maintenance task from Maintenance Log.

- Inspect Deionized W. Filter
- Inspect S. probe filter

For details on updating the maintenance record, refer to [Update the Maintenance Log](#) in section [8.1.2 Maintenance Log](#) in this chapter.

8.6.3 Replace the Wash Solution Roller Pump Tubing

The roller pump tubing deteriorates gradually due to abrasion and vibration by the roller pump. If the roller pump tubing is used for an extended period, it does not function properly. Replace the roller pump tubing with a new one every three months.

 **CAUTION**

When replacing the roller pump tubing, wear gloves to prevent hands from coming in contact with the wash solution. Do not let wash solution drip on the surrounding area. If hands or clothing come in contact with wash solution, immediately rinse with water. If the wash solution comes into contact with the eyes or mouth, immediately rinse with water and consult a physician.

Replace the Wash Solution Roller Pump Tubing

Materials Needed:

Roller pump tubing

1 Check that the system is in *Warm Up* mode or *Standby* mode.

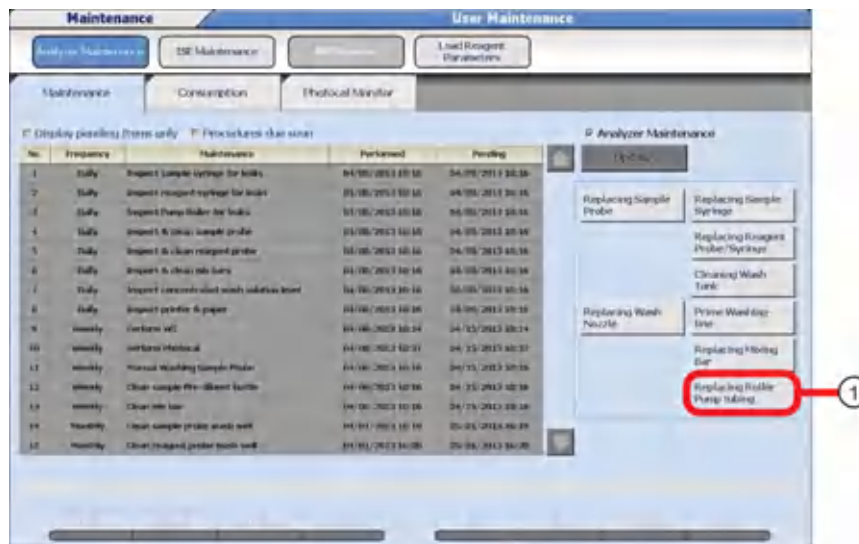
2 Open the left front door of the analyzer.

TIP Perform the procedure in the described conditions to avoid wash solution leaking from the connection tubing while the wash solution roller pump tubing is disconnected.

3 Select **Home > Analyzer Maintenance**.

- Place a check mark in the box next to the Analyzer Maintenance option.

Figure 8.44



- Replacing Roller Pump tubing

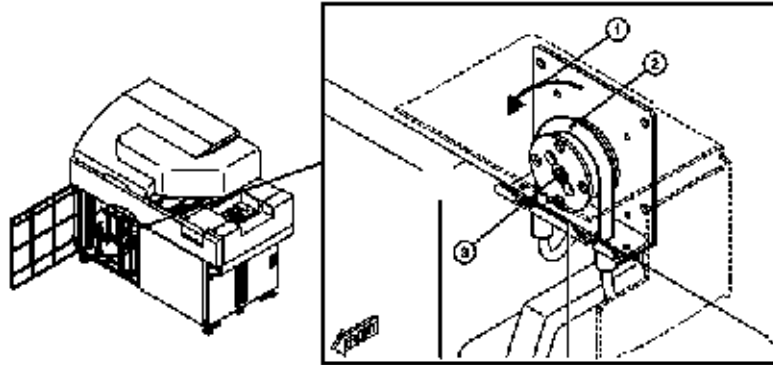
- Select **Replacing Roller Pump tubing** from the maintenance operation buttons. Select **OK**.

- Press the TABLE ROTATION/DIAG button.

The roller pump rotates in the reverse direction to drain the wash solution back to the wash solution tank.

- 7 Remove the tubing from the roller pump unit by unscrewing the wash solution roller pump connectors.

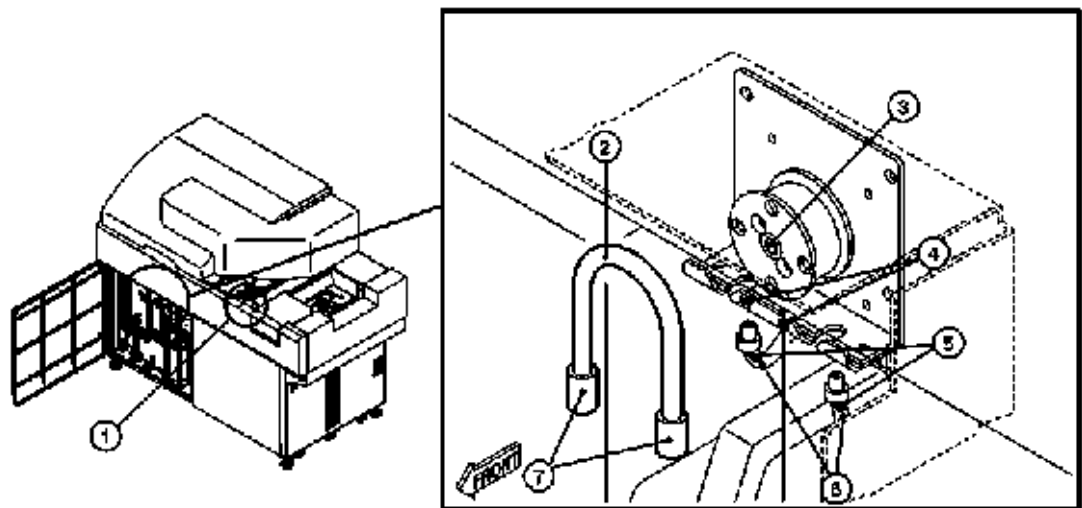
Figure 8.45



1. Normal rotation direction of roller pump
2. Roller pump tubing
3. Roller pump unit

- 8 Remove the roller pump tubing from the relay tubes by unscrewing the connectors.

Figure 8.46



1. TABLE ROTATION/DIAG button
2. Roller pump tubing
3. Wash solution roller pump
4. ID No.
5. ID No.
6. Relay tubes
7. Connectors

-
- 9** Connect the connectors of new roller pump tubing to each relay tube.
-
- 10** Stretch the roller pump tubing around the roller pump unit, and slide the connectors into the grooves under the roller pump unit. Verify the ID No.s on the relay tubes match the ID No.s on the roller pump unit plate.
-
- 11** Press the TABLE ROTATION/DIAG button.
The roller pump rotates in the normal direction to fill the tubing with wash solution.
-
- 12** Deselect the check box next to Analyzer Maintenance.
-
- 13** Update the Maintenance record. Select Replacing Pump Roller Tubes. Select **Update**, then **OK**.
-
- 14** Close the left front door of the analyzer.
-

8.7 6-Month Maintenance

To obtain the highest level of performance from the system perform the following maintenance tasks every 6 months.

8.7.1 Clean the Cuvettes and the Cuvette Wheel

8.7.1 Clean the Cuvettes and the Cuvette Wheel

To ensure proper operation of the photometry system, the cuvettes and the wheel must be clean. There are 88 cuvettes in the cuvette wheel.

The cuvettes are checked weekly during the Photocal procedure. This procedure is performed every six months to keep the cuvettes in optimal condition. Perform this procedure every six months or if a wheel overflow occurs. In the US market, this procedure is performed as part of the Preventive Maintenance performed by the Field Service Engineer.

Refer to [8.2 Parts Used for Analyzer Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

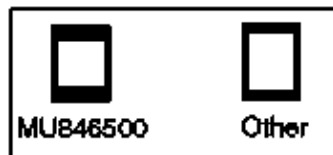
- Cotton tip applicator
- 2% Wash Solution
- Sonicator
- Clean, dry lint-free cloth

- Plastic containers to hold cuvettes in the sonicator

⚠ CAUTION

The AU480 uses a cuvette (Part No. MU846500). The interior size is (5x5 mm) and is different from the other AU analyzers. Do not use a cuvette from another AU analyzer on the AU480. Use of a cuvette other than the AU480 cuvette (Part No. MU846500) on the AU480 causes erroneous results.

Figure 8.47

**Remove the Cuvette Wheel**

Perform this procedure on a work surface protected with clean, dry lint-free cloth.

- 1 Verify the system is in *Warm Up*, *Standby*, or *Stop* mode.
- 2 Open the main and rear covers of the analyzer.

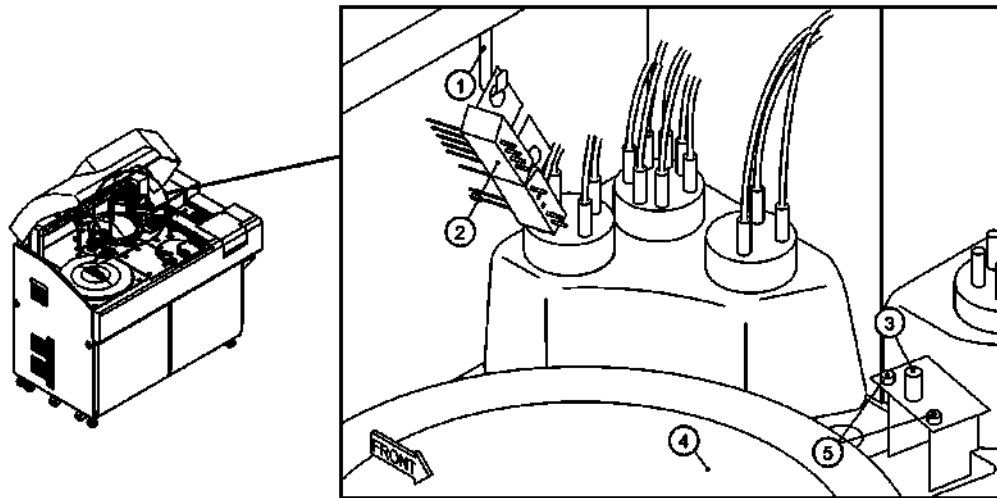
⚠ CAUTION

When removing the wash nozzle unit, be careful not to damage the wash nozzles. Avoid contact between the wash nozzles and the cuvette wheel cover.

When removing the wash nozzle unit, do not remove the positioning screws on either side of the knob. The positioning screws are used to correctly align the wash nozzle unit. Only loosen the knob to remove the wash nozzle unit.

- 3 Loosen the knob of the wash nozzle unit. Without disconnecting the tubing, remove the nozzle portion and hang it on the hook.

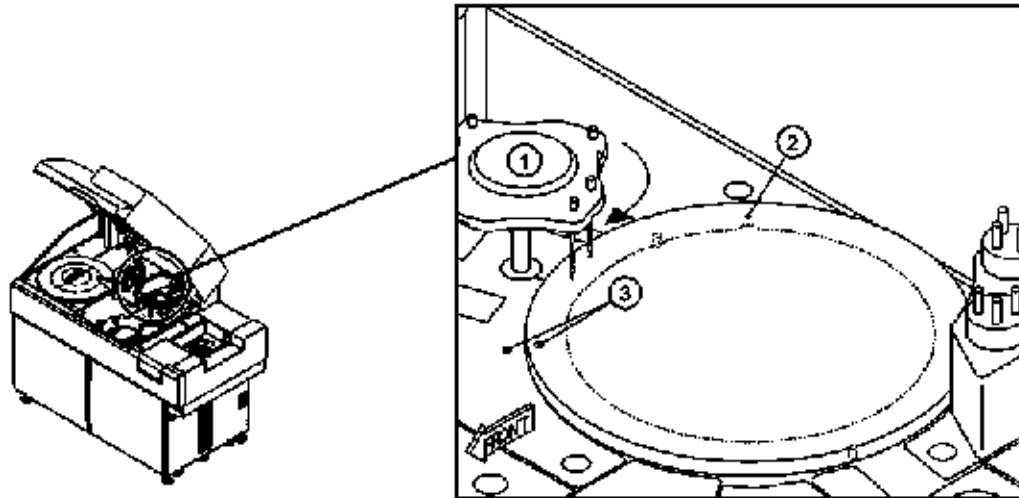
Figure 8.48



1. Hook
2. Wash nozzle unit
3. knob
4. Cuvette wheel cover
5. Positioning screws

- 4 Manually rotate the mix bar unit approximately 45 degrees so the mix bars are not over the cuvette wheel cover.

Figure 8.49



1. Mix bar unit
2. Cuvette wheel cover
3. Green positioning marks

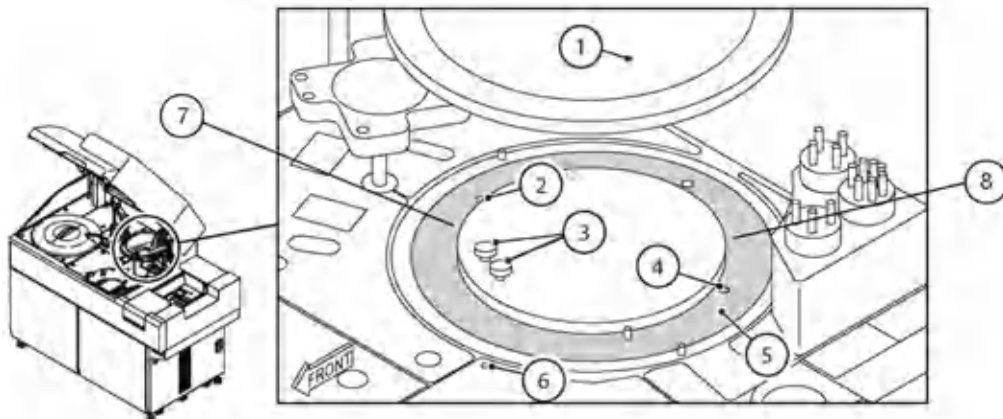
CAUTION

When removing the cuvette wheel cover, be careful not to damage the sample probe, reagent probe, and mix bars.

- 5 Carefully lift the cuvette wheel cover and remove it from the analyzer.

- 6 Remove the two black screws located in the center of the cuvette wheel. Tighten the screws into the two holes in the cuvette wheel as shown in the diagram below.

Figure 8.50



- | | |
|------------------------|--|
| 1. Cuvette wheel cover | 5. Cuvette wheel |
| 2. Hole | 6. Green positioning mark |
| 3. Knob screws | 7. Positioning screw (between cuvette numbers 30 and 40) |
| 4. Hole | 8. Positioning screw (between cuvette numbers 70 and 80) |

CAUTION

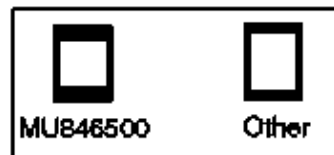
Do not loosen or remove the positioning screws. The positioning screws keep the cuvette wheel in proper alignment.

- 7 Use the two screws as handles to carefully lift the cuvette wheel from the analyzer.

CAUTION

- When removing the cuvette wheel, be careful not to bring it into contact with the peripheral components.
- When removing cuvettes, take care not to scratch them.
- To ensure correct photometric analysis, avoid getting fingerprints on the photometric surface of the cuvettes. Always wear gloves when handling the cuvettes.
- In laboratories with multiple AU analyzers, only use the AU480 cuvettes (part number MU846500) on the AU480. The other AU analyzers may use a different cuvette (different part number) depending on the geographical market and AU analyzer.

Figure 8.51



Remove the Cuvettes from the Wheel

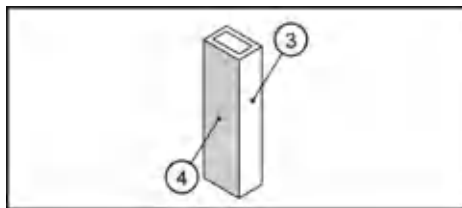
Perform this procedure over a protected work surface.

- 1 Use the reverse end of a cotton-tipped applicator stick to push each cuvette from the bottom to remove it from the wheel. All 88 cuvettes must be removed.

Figure 8.52



Cuvette



- | | |
|---------------------|-----------------------|
| 1. Cuvette | 3. Photometric face |
| 2. Applicator stick | 4. Frosted glass face |

Clean the Cuvettes and Cuvette Wheel



When cleaning cuvettes, do not scratch them. If a cuvette is scratched, the photometric data is inaccurate, and the cuvette must be replaced.

- 1 Submerge all cuvettes in a plastic container filled with 2% wash solution.



Do not use wash solution to clean the cuvette wheel. The metallic plating on the wheel may be removed if wash solution is used.

-
- 2 Sonicate for 15 minutes.

 - 3 Thoroughly rinse the cuvettes in DI water, or sonicate them in DI water for 10 minutes to remove any residual wash solution.

 - 4 Allow the cuvettes to dry completely.

 CAUTION

Use one of the following cuvette drying methods:

- Allow cuvettes to air dry.
- Use an oven with the heat set under 50 degrees Celsius (122 Fahrenheit). (A hair dryer works well).
- Use a lint free cloth.

-
- 5 Rinse the cuvette wheel with DI water and dry thoroughly with a clean, dry lint free cloth.

 - 6 Insert the cuvettes back into the wheel. Verify that each cuvette is gently pushed down completely into the wheel.

 CAUTION

- Verify all 88 cuvettes are properly inserted in the cuvette wheel. If even a single cuvette is missing, liquid spills into the cuvette wheel causing a cuvette wheel overflow, and correct analysis is not possible.
- Do not scratch cuvettes when inserting cuvettes into the wheel.
- Never touch the photometric surface of a cuvette. If the photometric surface is stained, analysis data is inaccurate.

-
- 7 Dry the incubation bath with a lint free cloth if the incubation bath is wet. The incubation bath is only wet if a cuvette overflow occurs.

 - 8 Replace the cuvette wheel in the original position on the analyzer.

 - 9 Remove the two screws used as handles to remove the wheel and return to the positions in the center of the cuvette wheel.

 - 10 Replace the cuvette wheel cover and wash nozzle unit. Rotate the mix bar units so the mix bars are over the cuvette wheel.

11 Close the main and rear cover.

12 Update the Maintenance record.

Select the performed maintenance task from Maintenance Log.

- Washing Cuvettes & Cuvette Wheel

13 Select **Update**. The Update window opens.

14 Select **OK**.

For details on updating the maintenance record, refer to [Update the Maintenance Log](#) in section [8.1.2 Maintenance Log](#) in this chapter.

15 Perform a photocal.

For details on how to perform a photocal measurement, refer to [8.4.3 Perform a Photocal](#) in this chapter.

16 Verify all cuvettes have passed the photocal and run QC before processing samples.

 **CAUTION**

- **After cleaning cuvettes, perform a Photocal to verify the cuvettes were cleaned correctly.**
- **To obtain optimal analysis data, do not start the Photocal until the lamp has stabilized after turning on the system. The lamp requires 20 minutes to stabilize after pressing the ON button.**

8.8 Yearly or As Needed Maintenance

This section describes the procedures performed yearly or as needed maintenance.

Yearly Maintenance

8.8.1 Replace O-rings in the Water Supply Tube Mounting Joint

As Needed Maintenance

8.8.2 Clean the Reagent Probe

8.8.3 Replace a Sample and Reagent Probe

8.8.4 Replace Mix Bars

8.8.5 Replace the Wash Nozzle Joint

8.8.6 Replace Packing in the Wash Nozzle Tube Mounting Joints

8.8.7 Replace Syringes or Syringe Case Heads

8.8.8 Clean the Inside of the Reagent Refrigerator and STAT Table Compartments

8.8.9 Clean or Replace the Anti-static Brushes

8.8.10 Replace the Sample and Reagent Probe Tubing

8.8.11 Perform a W1

8.8.12 Replace Rack ID Labels

8.8.13 Clean or Replace Individual Cuvettes

8.8.14 Replace the Photometer Lamp

8.8.15 Save Parameters

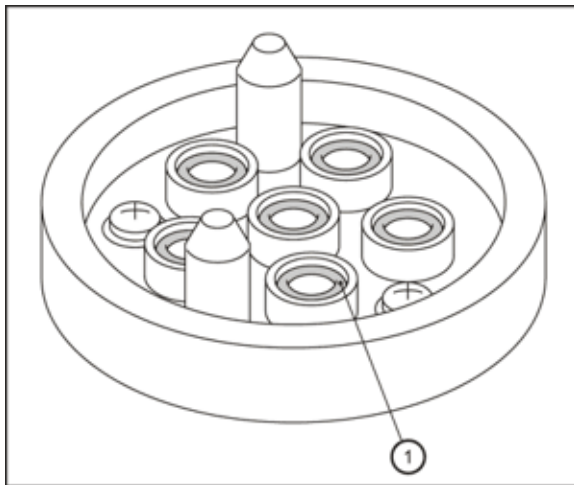
8.8.1 Replace O-rings in the Water Supply Tube Mounting Joint

Replace each O-ring in the water supply tube mounting joint with a new one yearly.

When installing the water supply tube mounting joint of the wash nozzle unit, check the following items.

- All six O-rings (see the figure below) should be seated in a groove.
- Particles such as dust or wash solution crystals should not be observed on or around the O-rings.

Figure 8.53



1. O-ring

Replace O-rings

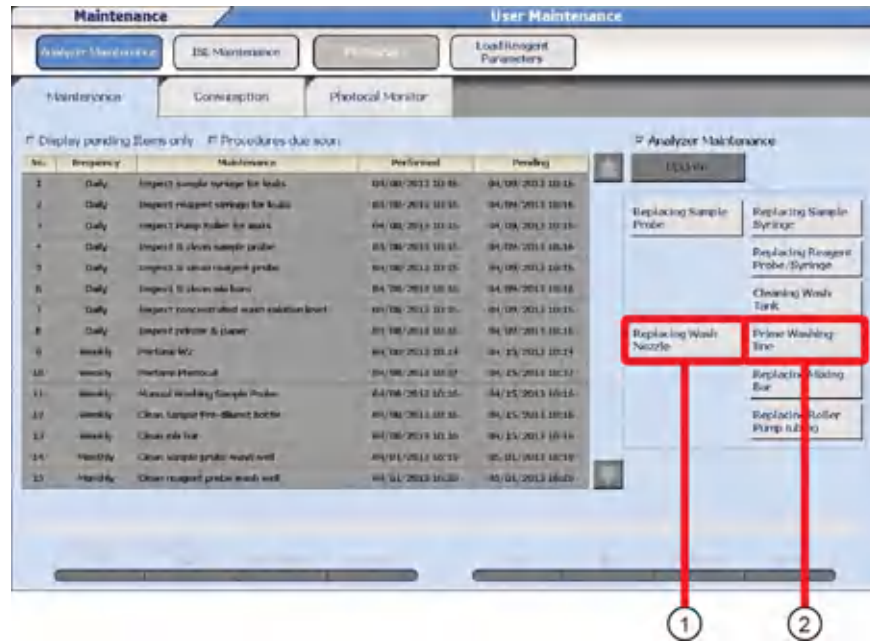
Refer to [8.2 Parts Used for Analyzer Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

- O-rings
- Clean, dry lint-free cloth
- Pair of tweezers

-
- 1 Open the rear cover of the analyzer.
-
- 2 Verify the system is in *Warm up* or *Standby* mode.
-
- 3 Select **Home > Analyzer Maintenance**.

- Place a check mark in the box next to the Analyzer Maintenance option. The maintenance operation buttons become functional

Figure 8.54



- Replacing Wash Nozzle
- Prime Washing-line

- Select **Replacing Wash Nozzle**, and then **OK**.

- Press the TABLE ROTATION/DIAG button two or three times. The liquid in the tubes is drained.

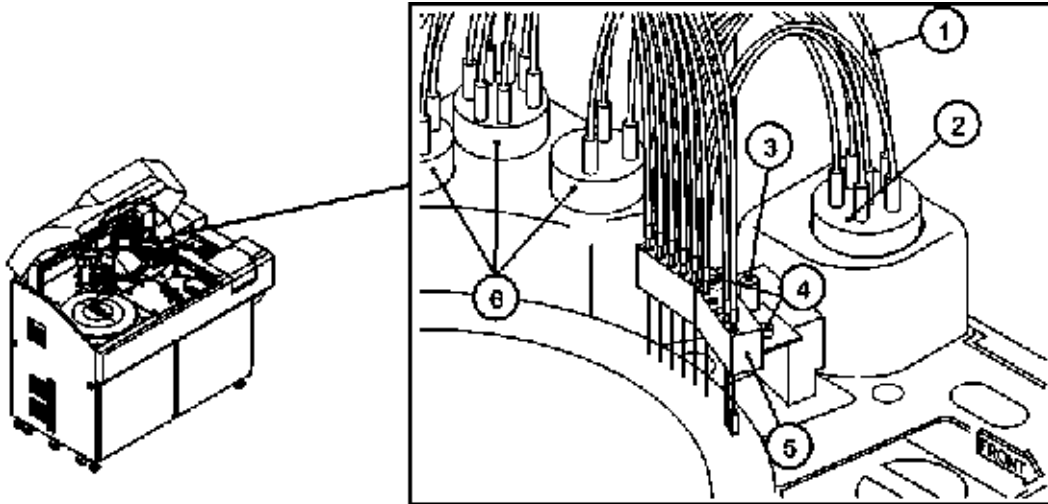
CAUTION

Always drain the water remaining in the wash nozzles before cleaning or replacing the tube mounting joints.

If any tube mounting joint is loosened without draining the remaining water, the water spills out of the nozzle. If the water spills onto the cuvettes, refer to [8.8.13 Clean or Replace Individual Cuvettes](#).

- 7 Loosen the gray manifold for the water supply tube mounting joint and remove from the mounting position.

Figure 8.55



1. Tubes
2. Water supply tube mounting joint (Six O-rings are used inside the tubes)
3. Knob
4. Position pin
5. Wash nozzle station
6. Wash nozzle tube mounting joint

- 8 Using a pair of tweezers, remove each O-ring from its position. Wipe away any crystallization or foreign matter found around O-ring receptacles.
- 9 Set new O-rings into their receptacles.
- 10 Replace the gray manifold into its position on the analyzer. Tighten the manifold without cross threading and take care not to over tighten.
For details refer to [8.5.3 Clean the Wash Nozzle Unit and Check the Tube Mounting Joints](#) in this chapter.
- 11 Select **Prime Washing-line** from the maintenance operation button. The Start window opens.
- 12 Select **OK**.
- 13 Press the **TABLE ROTATION/DIAG** button.

-
- 14** Verify there are no leaks from the tube mounting joint. If a leak is detected, unscrew the manifold of the water supply tube mounting joint, and verify the O-rings are properly installed.

 **CAUTION**

If the O-rings are used for an extended period of time without being cleaned or if the joint manifold has been replaced without the O-rings set properly in each groove, detergent crystals generate, which could cause errors with the cuvettes.

Be sure to check the O-rings along with the monthly maintenance of the wash nozzle unit.

-
- 15** Close the rear cover.

-
- 16** Deselect the check box next to Analyzer Maintenance to exit the menu.

-
- 17** Update the Maintenance record.

Select the performed maintenance task from Maintenance Log.

- Replacing O-ring of the Wash Nozzle

For details on updating the maintenance record, refer to [Update the Maintenance Log](#) in section [8.1.2 Maintenance Log](#) in this chapter.

8.8.2 Clean the Reagent Probe

 **CAUTION**

If the reagent probe becomes contaminated or stained, carryover between reagents may result. To prevent contamination and ensure proper analysis and results, clean the reagent probe as needed.

Clean the reagent probe

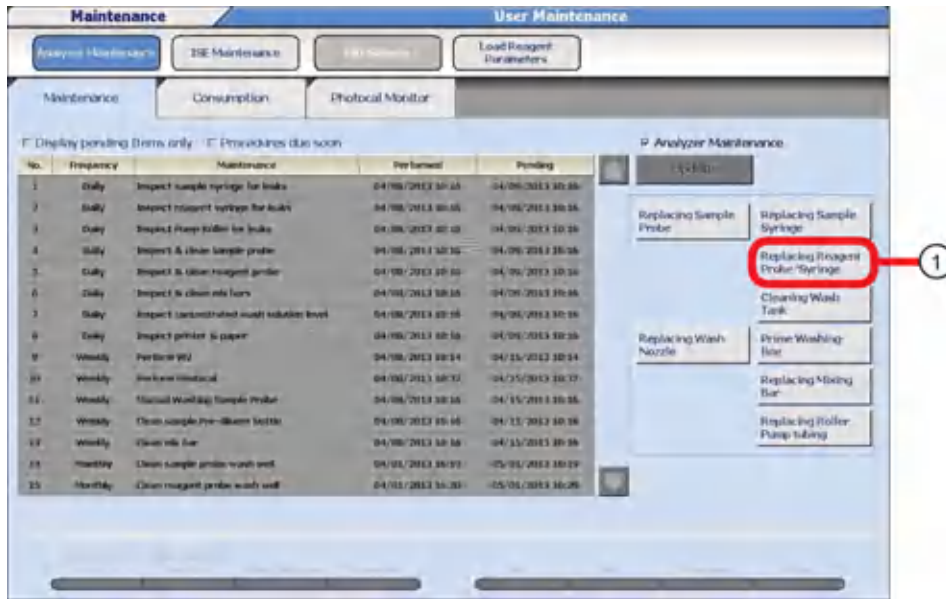
The cleaning procedure for each probe is identical.

Refer to [8.2 Parts Used for Analyzer Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

- Alcohol Prep (70% Isopropyl Alcohol using lint-free cloth)
- Clean, dry lint-free cloth
- Stylet

- 1 Verify the system is in *Warm up* or *Standby* mode.
- 2 Select **Home > Analyzer Maintenance**.
- 3 Place a check mark in the box next to the Analyzer Maintenance option. The maintenance operation buttons become functional.

Figure 8.56



1. Replacing Reagent Probe/Syringe

- 4 Select **Replacing Reagent Probe/Syringe** from the maintenance operation button. The Start window opens.
- 5 For Times, enter 3 or more and select **OK**.
- 6 Open the main cover of the analyzer.
- 7 Press the TABLE ROTATION/DIAG button. When the TABLE ROTATION/DIAG button is pressed, the reagent probe initializes, then drains the DI water in the probe.

-
- 8 Unscrew the silver connector above the probe.



When handling the probe, do not bend or damage the probe tip.

-
- 9 Lift the probe from the arm.

-
- 10 Wipe the tip of the probe with an alcohol prep (70% Isopropyl Alcohol using lint-free cloth).

-
- 11 Carefully insert the stylet into the probe tip to remove the blockage.

-
- 12 Return the probe to its arm and tighten the silver connector over the top.

-
- 13 Press the TABLE ROTATION/DIAG button. Watch the dispense to ensure the probe was reinstalled properly.

-
- 14 If the water is spraying or not dispensing straight from the probe tip, replace the probe.

-
- 15 Close the main cover.

-
- 16 Deselect the check box next to Analyzer Maintenance to exit the menu.

-
- 17 Update the Maintenance record.
Select **Clean the Reagent Probe** from Maintenance Log.

-
- 18 Select **Update**. The Update window opens.

-
- 19 Select **OK**.
For details on updating the maintenance record, refer to [Update the Maintenance Log](#) in section [8.1.2 Maintenance Log](#) in this chapter.
-

8.8.3 Replace a Sample and Reagent Probe

The probes deliver precise quantities of sample or reagent to the cuvettes.

If they are clogged, bent, or damaged, correct analysis could be affected.

If the probes are still contaminated after cleaning, replace them.

Replace the sample or reagent probe

Refer to [8.2 Parts Used for Analyzer Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

- Sample probe
- Reagent probe

 **CAUTION**

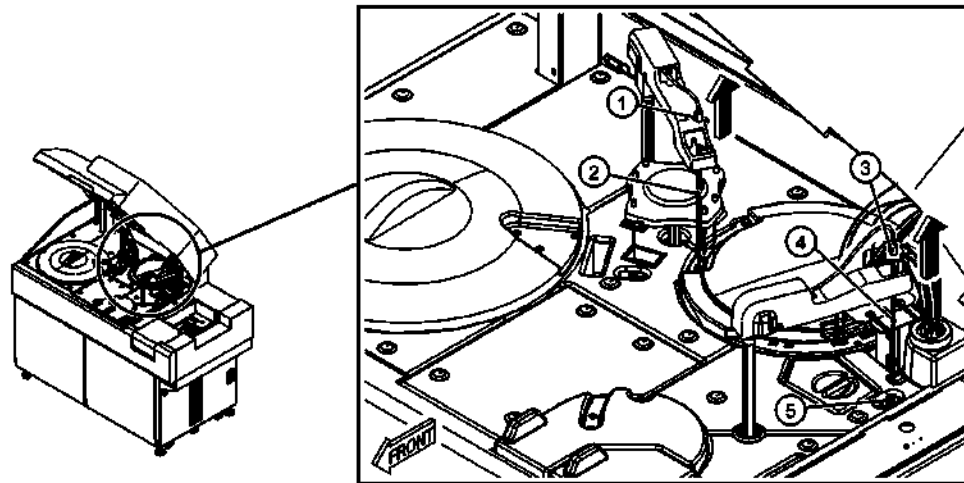
- **Check that the sample or reagent probe is just above the wash well and then replace it with a new one. DI water drips from the probe tip as the silver connector is unscrewed.**
- **When handling the sample or reagent probe, exercise care not to bend or damage the probe tip.**

1 Verify the system is in *Warm up* or *Standby* mode.

2 Open the main cover of the analyzer.

- 3 Unscrew the silver connector above the probe.

Figure 8.57



- | | |
|----------------------------|---------------------------|
| 1. Reagent probe connector | 3. Sample probe connector |
| 2. Reagent probe | 4. Sample probe |

- 4 Allow water to drip from the probe, then lift the probe from the arm.

- 5 Place the new probe into its position and tighten the silver connector over the top. Firmly tighten the connector so that no leaks occur.

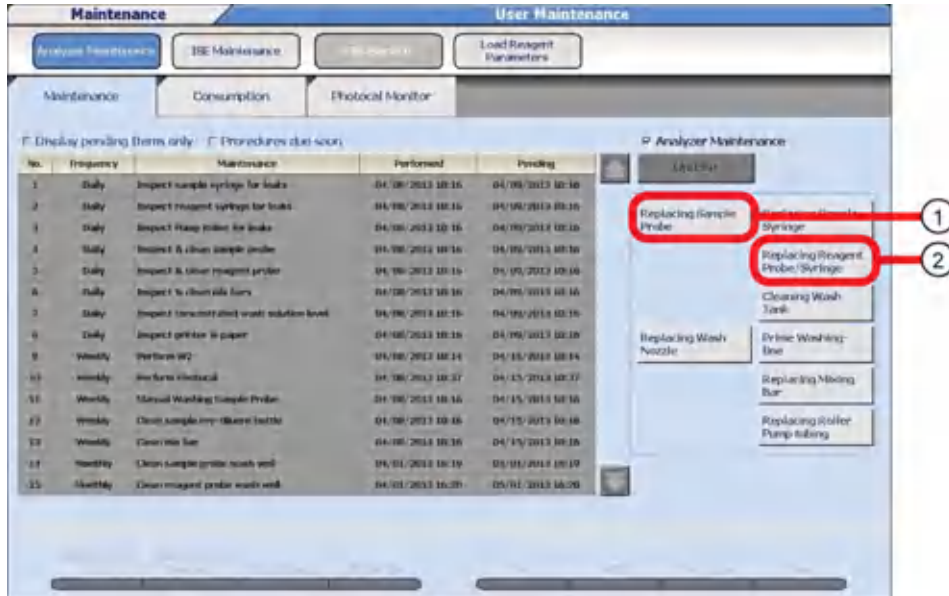
TIP Verify that the proper probe type is chosen.

The sample probe has a smaller diameter than the reagent probe.

- 6 Select **Home > Analyzer Maintenance**.

- Place a check mark in the box next to the Analyzer Maintenance. The maintenance operation buttons become functional.

Figure 8.58



- Replacing Sample Probe
- Replacing Reagent Probe/Syringe

- Select the maintenance operation button for the probe being replaced.

Probe	Maintenance operation button
Sample probe	Replacing Sample Probe
Reagent probe	Replacing Reagent Probe/Syringe

- Enter 3 or more as Times then select **OK**.

- Press the TABLE ROTATION/DIAG button. DI water is dispensed from the probe tip. Verify that the DI water is dispensed in a thin straight stream. It should not spray or dispense at an angle.

- Close the main cover.

- Deselect the check box next to Analyzer Maintenance to exit the menu.

13 Update the Maintenance record.

Select the performed maintenance task from Maintenance Log.

- Replacing Sample Probe
- Replacing Reagent Probe

14 Select **Update**. The Update window opens.

15 Select **OK**.

For details on updating the maintenance record, refer to [Update the Maintenance Log](#) in section 8.1.2 [Maintenance Log](#) in this chapter.

TIP Analyze quality control material and check the results after replacing a sample or reagent probe.

8.8.4 Replace Mix Bars

Replace the mix bars if they are stained, damaged, or if the teflon coating is chipped.

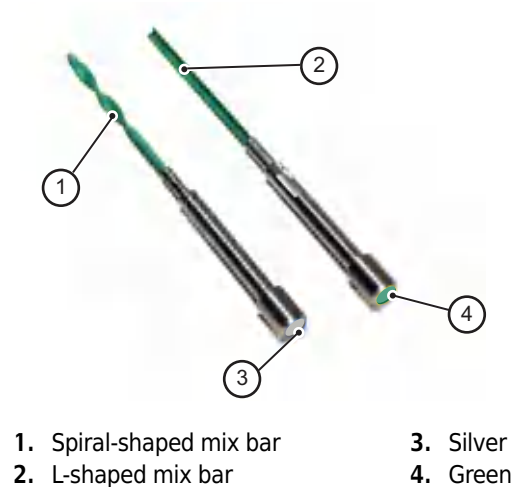
Replace mix bars

Refer to [8.2 Parts Used for Analyzer Maintenance](#) for a complete list of part numbers.

Materials needed for this procedure:

- R1/S: spiral shape mix bar
- R2: L shape mix bar

Figure 8.59



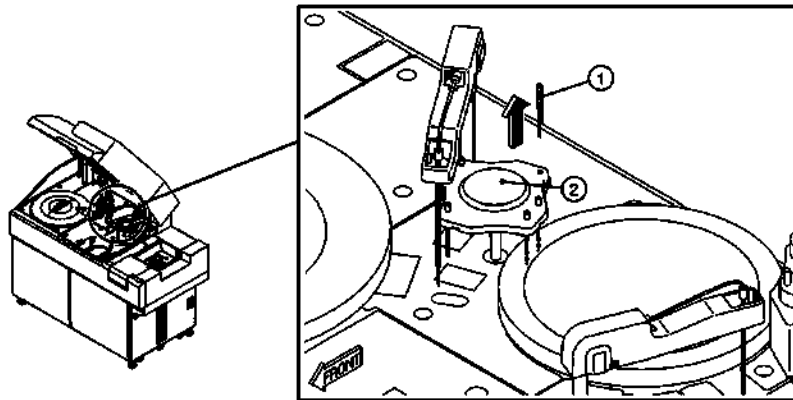
CAUTION

Do not operate the mix unit when replacing a mix bar.

Replacement of the mix bar during operation could result in an injury.

- 1 Verify the system is in *Warm up* or *Standby* mode.
- 2 Open the main cover of the analyzer.
- 3 Pull out the mix bar to be replaced.

Figure 8.60



1. Mix bar
2. Mix unit

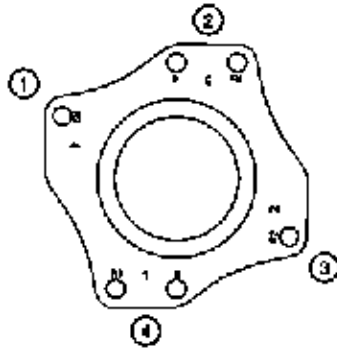
CAUTION

Do not scratch the mix bar when inserting the mix bar into the mix unit.

- 4 Insert a new mix bar into the mix unit. After inserting the mix bar, rotate it slightly to engage the notch on the mix bar with the gear in the hole of the mix unit.

TIP Insert the spiral shaped mix bars into the positions marked R1 and S.
Insert the L shaped mix bars into the positions marked R2.

Figure 8.61

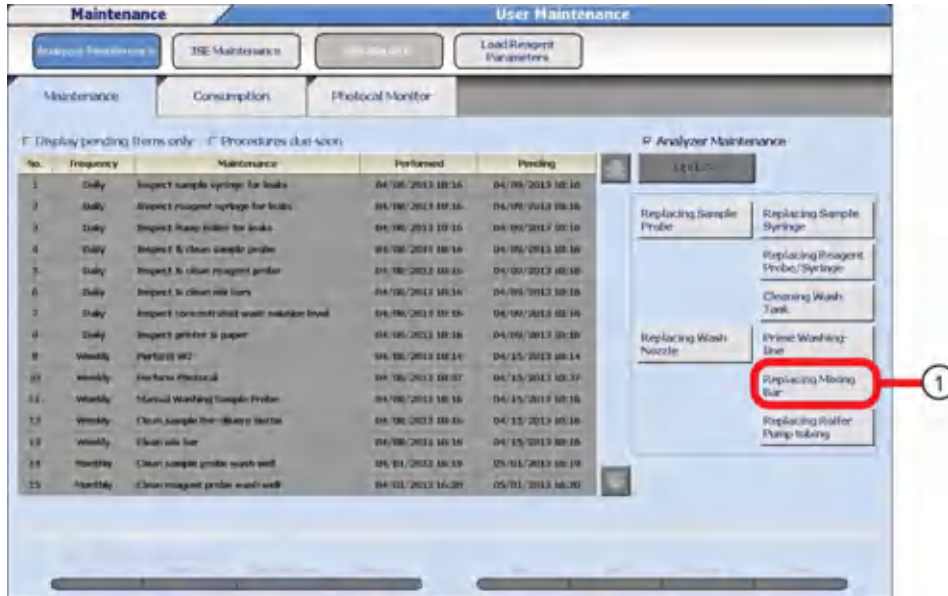


1. Mix bar for R2
2. Mix bar for R1 and S
3. Mix bar for R2
4. Mix bar for R1 and S

- 5 Select **Home > Analyzer Maintenance**.

- Place a check mark in the box next to the Analyzer Maintenance option. The maintenance operation buttons become functional.

Figure 8.62



- Replacing Mixing Bar

- Select **Replacing Mixing Bar** from the maintenance operation buttons. The Start window opens.

- For **Times** enter 3 and select **OK**.

- Press the TABLE ROTATION/DIAG button. The mix unit initializes and performs a sequence three times.

- Close the main cover.

- Deselect the check box next to Analyzer Maintenance to exit the menu.

- Update the Maintenance record.

Select the performed maintenance task from Maintenance Log.

- Replacing Mixing Bars

- Select **Update**. The Update window opens.

14 Select **OK**.

For details on updating the maintenance record, refer to [Update the Maintenance Log](#) in section [8.1.2 Maintenance Log](#) in this chapter.

8.8.5 Replace the Wash Nozzle Joint

If a wash nozzle joint is damaged or cracked, leaks or insufficient aspiration of a cuvette may occur. To avoid errors, immediately replace the damaged wash nozzle joint.

Replace the Wash Nozzle Joint

Refer to [8.2 Parts Used for Analyzer Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

- Wash nozzle joint

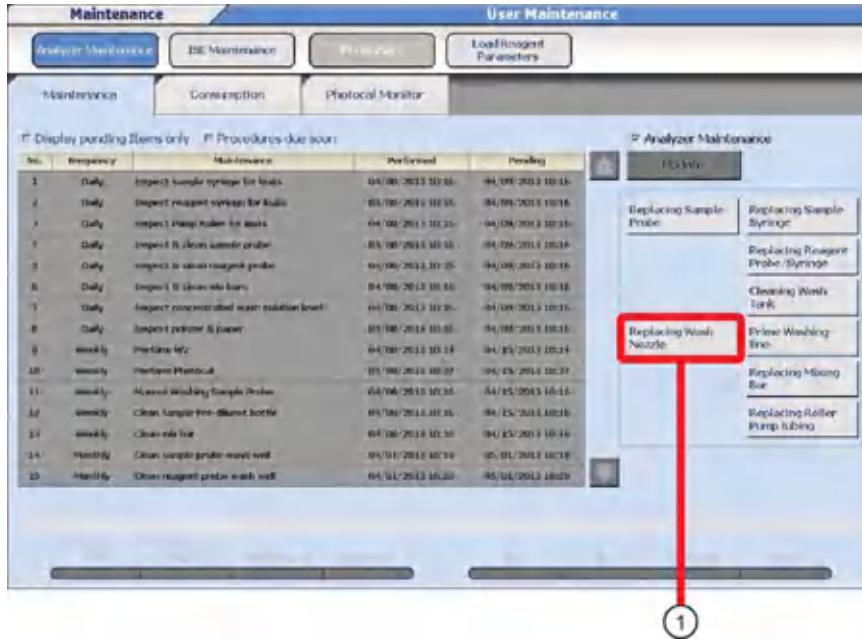
-
- 1** Open the rear cover of the analyzer.

 - 2** Verify the system is in *Warm up* or *Standby* mode.

 - 3** Select **Home > Analyzer Maintenance**.

- Place a check mark in the box next to the Analyzer Maintenance option. The maintenance operation buttons become functional.

Figure 8.63



- Replacing Wash Nozzle

- Select **Replacing Wash Nozzle** from the maintenance operation button. The Start window opens.

- Select **OK**.

- Press the TABLE ROTATION/DIAG button. The liquid drains from the tubes.

CAUTION

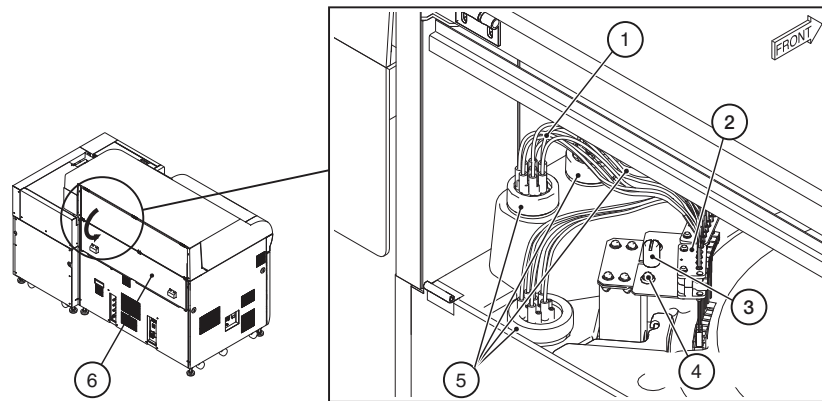
Always drain the water remaining in the wash nozzles before cleaning or replacing the wash nozzle joints.

If any wash nozzle joint is loosened without draining the remaining water, the water spills out of the nozzle. If the water spills onto the cuvettes, refer to [8.7.1 Clean the Cuvettes and the Cuvette Wheel](#).

- 8 Remove the wash nozzle unit along with the tubing and place it on an appropriate surface such as a table.

For details refer to [8.5.3 Clean the Wash Nozzle Unit and Check the Tube Mounting Joints](#) in this chapter.

Figure 8.64

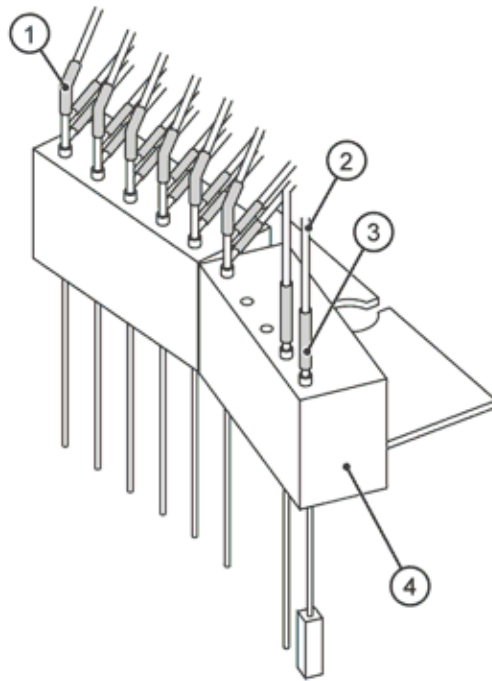


- | | |
|---------------------|------------------------|
| 1. Tubing | 4. Positioning pin |
| 2. Wash nozzle unit | 5. Tube mounting joint |
| 3. Knob | 6. Rear cover |

CAUTION

Replace one wash nozzle joint at a time. If the tubing is not connected to the correct nozzle by the wash nozzle joint, correct analysis is not performed.

Figure 8.65



1. Wash nozzle joint
2. Tubing
3. Wash nozzle joint
4. Wash nozzle unit

⚠ CAUTION

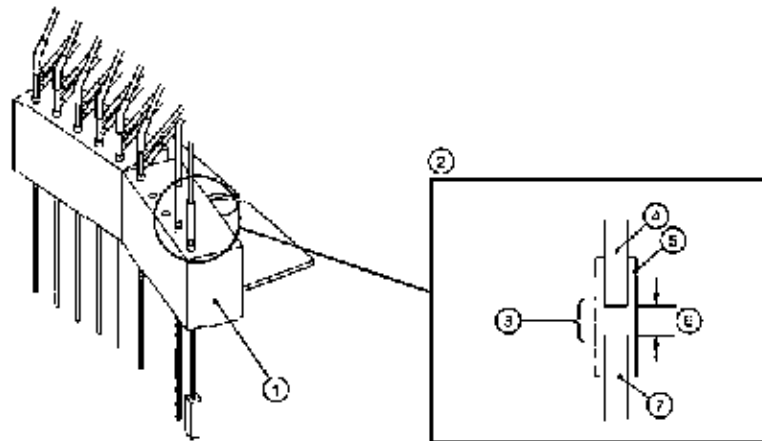
- When handling the wash nozzles, be careful not to damage the wash nozzles.
- When removing the wash nozzle unit, be careful not to bring the nozzle tips into contact with the cuvette wheel cover.

9 Remove the wash nozzle joint to be replaced.

- 10** Insert the new wash nozzle joint onto the open end of the tube, and then insert the nozzle into the other end of the wash nozzle joint.

Center the tube and nozzle in the joint, allowing approximately 1 mm between them.

Figure 8.66



- | | |
|---|----------------------|
| 1. Wash nozzle unit | 4. Tube |
| 2. Cross-sectional View | 5. Wash nozzle joint |
| 3. Position both ends of the tube and nozzle in the center of the wash nozzle joint | 6. Approx. 1 mm |
| | 7. Nozzle |

CAUTION

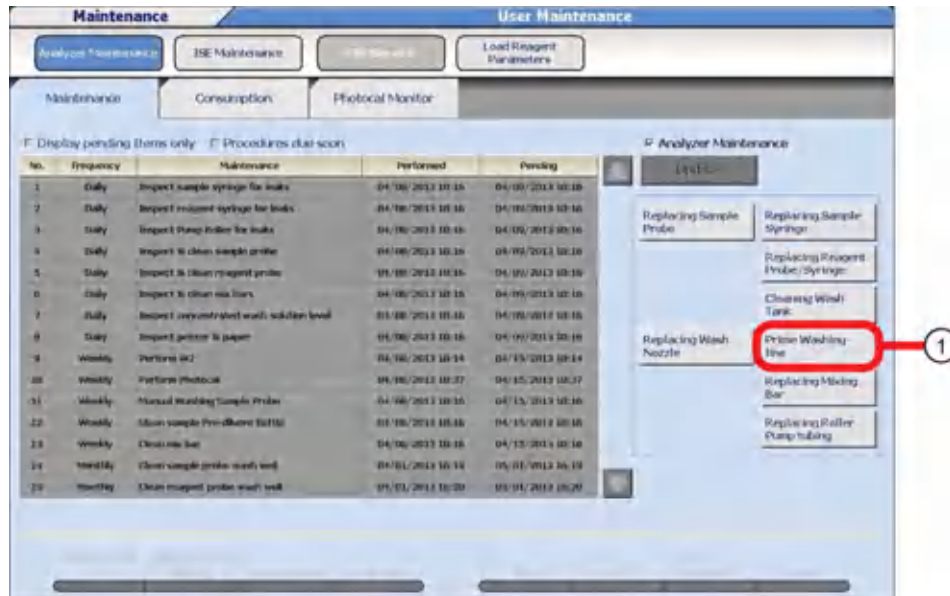
- When handling the wash nozzles, do not damage the nozzles.
- When mounting the wash nozzle unit, be careful not to bring the nozzle tips into contact with the cuvette wheel cover.
- Verify the tubing is not crossed. If the tubing is crossed, it may be pulled out from the wash nozzle joint causing problems.

- 11** Replace the wash nozzle unit.

For details refer to [8.5.3 Clean the Wash Nozzle Unit and Check the Tube Mounting Joints](#) in this chapter.

- 12 Press the TABLE ROTATION/DIAG button again to confirm that the wash nozzle unit is correctly placed back on the analyzer.

Figure 8.67



1. Prime Washing-line

- 13 Select **Prime Washing-line** from the maintenance operation button.

- 14 Select **OK**.

- 15 Press the TABLE ROTATION/DIAG button. The air in the tubing is purged as the wash nozzle unit moves up and down. Verify this movement is completed without interference.

- 16 Close the rear cover.

- 17 Deselect the check box next to Analyzer Maintenance.

- 18 Update the Maintenance record.

Select the performed maintenance task from Maintenance Log.

- Replacing Wash Nozzle Joint Tubes

For details on updating the maintenance record, refer to [Update the Maintenance Log](#) in section [8.1.2 Maintenance Log](#) in this chapter.

8.8.6 Replace Packing in the Wash Nozzle Tube Mounting Joints

When inspecting a wash nozzle tube mounting joint, replace the packing if it is overstretched, cracked, or torn.

Refer to [8.2 Parts Used for Analyzer Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

- Packing
- A pair of tweezers

 **CAUTION**

Always drain the water remaining in the wash nozzles before cleaning or replacing the tube mounting joints or packing.

Replace the tube mounting joint in the correct position.

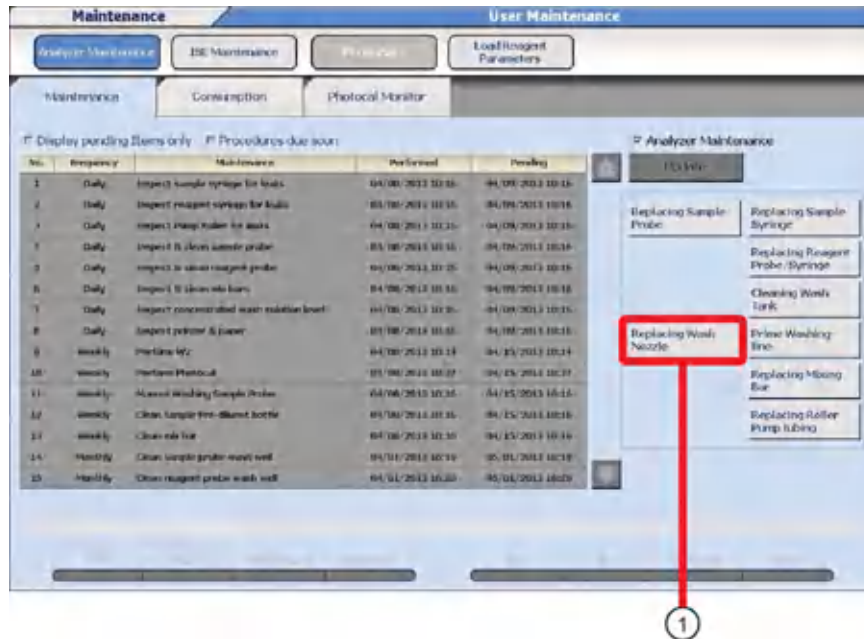
Tighten the cap for the tube mounting joint firmly when replacing the tube mounting joint on the analyzer, or leaks result.

Place the packing in the groove of the tube mounting joint.

-
- 1 Select **Home > Analyzer Maintenance**.

- Place a check mark in the box next to the Analyzer Maintenance option. The maintenance operation buttons become functional.

Figure 8.68



- Replacing Wash Nozzle

- Select **Replacing Wash Nozzle** from the maintenance operation button. The Start window opens.

- Select **OK**.

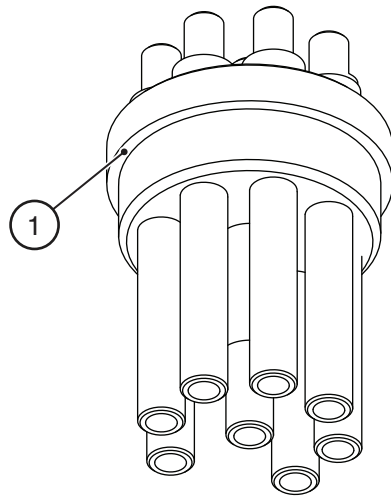
- Press the TABLE ROTATION/DIAG button. The liquid drains from the tubes.

- Remove the wash nozzle tube mounting joints.

- Remove the packing with tweezers from the tube mounting joints.

-
- 8** Mount new packing on the tube mounting joint.

Figure 8.69



1. Groove of the tube mounting joint

-
- 9** Mount wash nozzle tube mounting joints into their original position.

TIP The tube mounting joints are color coded to match where the placement of each joint belongs on the analyzer.

-
- 10** Select **Prime Washing-line**.

-
- 11** Press the TABLE ROTATION/DIAG button and verify the wash nozzle unit is operating correctly.

-
- 12** Update the Maintenance record.

Select the performed maintenance task from Maintenance Log.

- Replacing Packing in The Wash Nozzle Joint

-
- 13** Select **Update**. The Update window opens.

-
- 14** Select **OK**.

For details on updating the maintenance record, refer to [Update the Maintenance Log](#) in section [8.1.2 Maintenance Log](#) in this chapter.

8.8.7 Replace Syringes or Syringe Case Heads

If a leak, crack, or any other damage is found when the syringes are inspected, the syringe must be replaced.

If syringe performance is questionable because of abnormal data, remove and check the syringe.

Replace a syringe when:

- There is no longer a smooth resistance when pulling on the piston. A worn or damaged syringe has a pulling movement that may be too hard or too loose.
- The Teflon tip is worn, damaged or there is evidence of teflon flaking.
- There are leaks around the syringe or case head even after proper installation.
- The head of the syringe is cracked.

Replace a syringe case head when:

- The case head is chipped, worn, or damaged in any way.

Refer to [8.2 Parts Used for Analyzer Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

- Sample syringe
- Reagent syringe
- S syringe case head
- ISE buffer syringe case head
- Clean, dry lint-free cloth



- The S syringe and R syringe are identified by the piston shaft diameter.

Figure 8.70

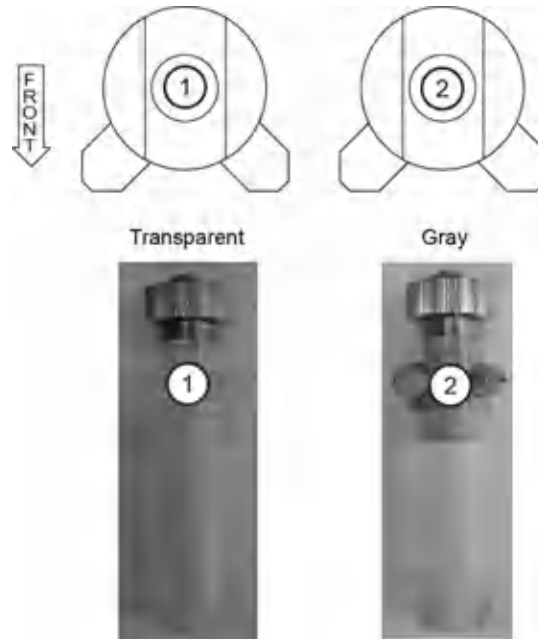


- Do not remove the piston from a new syringe. If the piston is removed, the performance of the syringe can be unreliable.

CAUTION

The S syringe case head differs in color from the ISE Buffer syringe case head.

Figure 8.71



1. S syringe case head
2. ISE buffer syringe case head

The combinations of syringes and syringe case heads are shown below.

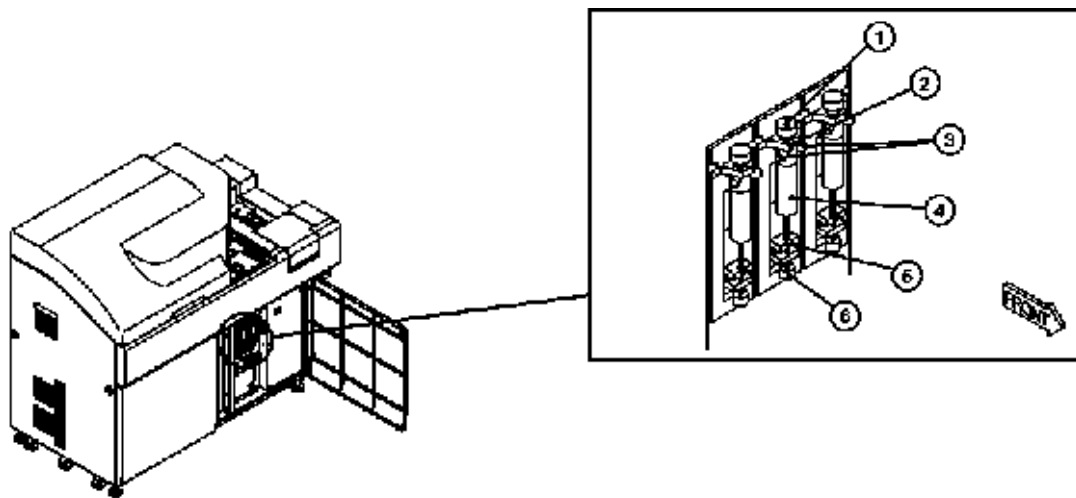
		Syringe		Syringe Case Heads	
		S	R	S	ISE
Analyzer	Sample syringe	*		*	
	Reagent syringe		*	*	
ISE (Option)	Buffer syringe		*		*

Remove the syringe

Procedures for replacing the sample syringe, reagent syringe, and ISE buffer syringe are identical.

- 1 Verify the system is in *Warm up* or *Standby* mode.
- 2 Open the front right door to access the syringes.
- 3 Loosen the piston fixing screw (bottom).
- 4 Loosen the fixing nut (top).
- 5 Pull the syringe case forward to remove it from the mounting grooves.

Figure 8.72



1. Fixing nut
2. Mounting groove
3. Fixing screws

4. Syringe case
5. Mounting groove
6. Piston fixing screw

CAUTION

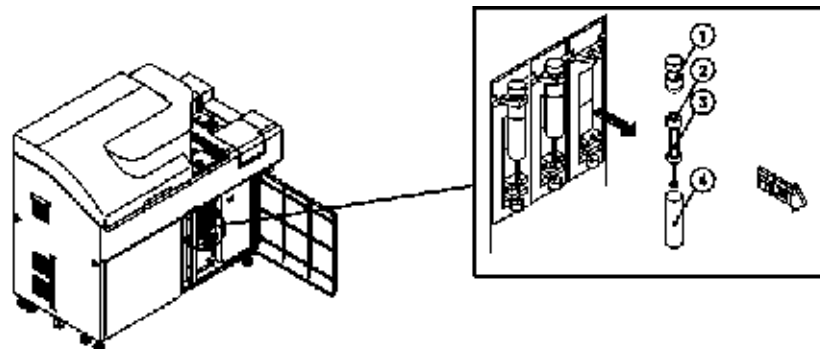
- When removing the syringe case, hold the bottom with a dry clean cloth. Be careful not to bend the tubing when removing the syringe case.
- When removing the syringe case, do not apply excessive force to the fixing screws because excessive force may damage the syringe case.
- If the skin comes in contact with any liquid, immediately wash with water thoroughly.

6 Tilt the syringe head and case upside down before removing the syringe. This prevents air from entering the tubing lines and keeps the water from leaking into the syringe case.

7 Remove the syringe case by turning it counterclockwise while holding the case head. Pull the syringe from the case head.

Exercise care so as not to lose the O-ring, which may easily drop from the case head. If the O-ring remains in the case head, carefully remove it with tweezers.

Figure 8.73



- | | |
|--------------|-----------------|
| 1. Case head | 3. Syringe |
| 2. O-ring | 4. Syringe case |

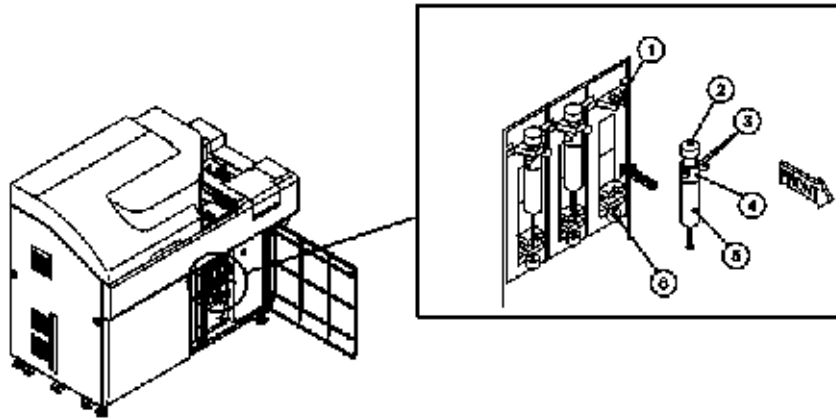
Install a new syringe or a new syringe case head

1 Obtain a new syringe case head if necessary.

2 Insert the new syringe into the case head.

- 3 Dry excess water from the syringe and case head to prevent condensation from forming in the case. Screw the syringe case into the case head by twisting clockwise. Do not over tighten. Tighten the syringe case by 45 to 60 degrees from the position at which it lightly becomes tight.
- 4 Re-install the syringe by placing the case head into the mounting groove. Align the syringe piston into the drive shaft. Secure the top fixing nut and then tighten the bottom piston fixing screw.

Figure 8.74



- | | |
|--------------------|------------------------|
| 1. Mounting groove | 4. Case head |
| 2. Fixing nut | 5. Syringe case |
| 3. Fixing screws | 6. Piston fixing screw |

CAUTION

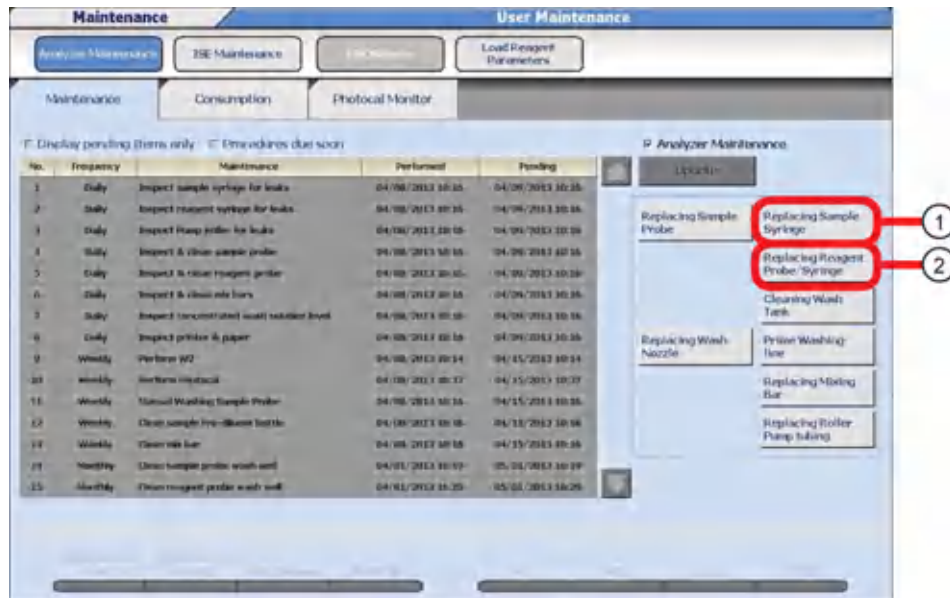
- Do not allow a strong alkali such as the Wash Solution to come into contact with the syringe case and syringe case head. If strong alkali adheres to the syringe case or syringe case head, cracks can occur.
- If strong alkali has come into contact with or adhered to the syringe case or syringe case head, remove the syringe case or syringe case head and wash with water.

Prime new syringes

New syringes must be primed:

- 1 Select **Home > Analyzer Maintenance**. For the ISE buffer syringe, select **Home > Analyzer Maintenance > ISE Maintenance**.
- 2 Place a check mark in the box next to the Analyzer Maintenance option. For the ISE, place a check mark in the box next to the ISE Maintenance option. The maintenance operation buttons become functional.

Figure 8.75



1. Replacing Sample Syringe
2. Replacing Reagent Probe/Syringe

- 3 After replacing the syringe, select the maintenance operation button.

Syringe	Maintenance Operation Button
Sample syringe (S syringe)	Replacing Sample Syringe
Reagent syringe (R syringe)	Replacing Reagent Probe/Syringe
ISE buffer syringe (R syringe)	(ISE) Buffer Prime

The Start window opens.

-
- 4 In the Start window, select the number of cycle times, then select **OK**.

Maintenance Operation Button	Items
Replacing Sample Syringe	<ul style="list-style-type: none">• "Times" is preset at 260.
Replacing Reagent Probe/Syringe	<ul style="list-style-type: none">• For "Times," select 5 or more.
(ISE) Buffer Prime	

-
- 5 Press the TABLE ROTATION/DIAG button.

TIP DI water primes the tubing to remove the air.

- After replacing the reagent syringe, repeat the prime until all bubbles are cleared from around the reagent syringe and the tubing.
- The sample syringe prime could take from 12 to 44 minutes to complete. The sample syringe primes until no air is detected by pressure changes. To stop the operation, press the TABLE ROTATION/DIAG button. At this time an abort error alarm is generated. The alarm can be cleared and no corrective actions are required.

-
- 6 If the Replacing Sample Syringe prime fails (air is still detected), a "Sample Syringe Prime Incomplete" message displays. Refer to "Remove the Syringe" and perform steps 1 through 5, then continue with step 7. If there are not any errors after performing the Replacing Sample Syringe prime, continue with step 10.

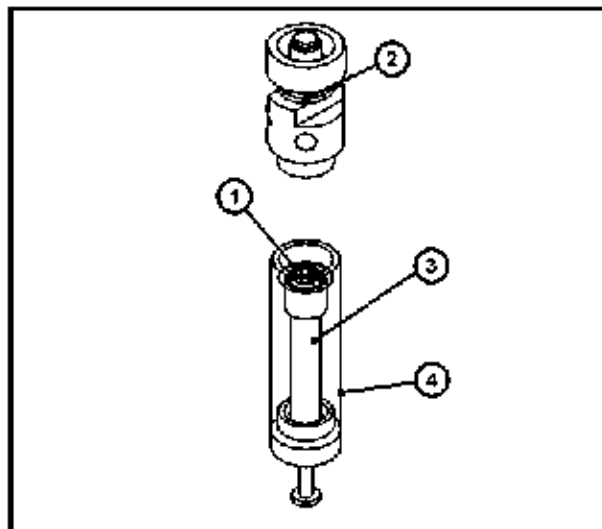
-
- 7 Loosen the piston fixing screw and the fixing nut to remove the syringe case from the mounting grooves again.

- 8 Move the piston of the syringe up and down slowly by hand, and confirm that there are no bubbles on the syringe head.
If bubbles are still present, move the piston up and down until the bubbles are purged.

CAUTION

Do not move the piston by hand without mounting the syringe on the syringe case.
If the piston is moved without being mounted on the syringe case, the accuracy may not be retained due to deformation of the piston. This may decrease the time a syringe is in use before requiring replacement.

Figure 8.76



- | | |
|---|-----------------|
| 1. Confirm that no bubbles are attached | 3. Syringe |
| 2. Case head | 4. Syringe case |

- 9 Re-install the syringe by placing the syringe case into the mounting groove.
- 10 Close the front right door.
- 11 Deselect the check box next to Analyzer Maintenance or ISE Maintenance to exit the menu.
- 12 Update the Maintenance record.
Select the performed maintenance task from Maintenance Log.
- Replacing Sample Syringe
 - Replacing Reagent Syringe
 - (ISE) Replacing Buffer Syringe

13 Select **Update**. The Update window opens.

14 Select **OK**.

15 Check the data and re-calibrate if necessary for the quality control material.

For details on updating the maintenance record, refer to [Update the Maintenance Log](#) in section [8.1.2 Maintenance Log](#) in this chapter.

8.8.8 Clean the Inside of the Reagent Refrigerator and STAT Table Compartments

Due to exposure to outside air, condensation forms inside the reagent refrigerator and STAT table compartments.

Be sure to keep the reagent refrigerator cover and STAT table covers in place to diminish the amount of condensation formed.

Clean the inside of compartments when a reagent or sample is spilled, or as needed after inspection.

TIP If bacterial contamination is suspected, or mold is observed, call Beckman Coulter Technical Services for the proper decontamination procedure.



Avoid wiping the barcode reader glass window inside of the reagent refrigerator and STAT table compartments. If the glass window becomes smudged from wiping, reagent ID or sample ID read errors can occur.

Clean the Inside of the Reagent Refrigerator

Refer to [8.2 Parts Used for Analyzer Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

- Clean, dry lint-free cloth
- Alcohol prep (70% Isopropyl alcohol using lint-free cloth)

1 Verify the system is in *Warm up* or *Standby* mode.

2 Remove the reagent refrigerator cover.

3 Remove the reagents along with the reagent tray by lifting the white securing pins until they unclip from the base, lift the tray up from the center and gently place the tray in a safe place.

-
- 4 Wipe off the condensation and stains on the wall, bottom, and central area inside the reagent refrigerator with a dry clean cloth.

 - 5 Wipe the same components again with an alcohol prep (70% Isopropyl alcohol using lint-free cloth) to clean the refrigerator. Then, rinse with DI water and dry with a clean, dry lint free cloth.

 - 6 Return reagents and reagent tray to its original position.
Set the tray onto the metal pin. Press down on the white securing pins to secure the reagent tray.

 - 7 Replace the reagent refrigerator cover.

 - 8 Update the Maintenance record.
Select the performed maintenance task from Maintenance Log.
 - Cleaning Inside of Reagent Refrigerator
-

For details on updating the maintenance record, refer to [Update the Maintenance Log](#) in section [8.1.2 Maintenance Log](#) in this chapter.

Clean the Inside of the STAT Compartment

- 1 Check that the system is in *Warm up* or *Standby* mode.

- 2 Open the main cover and remove the large and small STAT table covers.

- 3 Loosen the two fixing screws near the center of the STAT table with fingers. Remove the STAT table by lifting up the central column. Place the STAT table gently in a safe place.

- 4 Wipe off the condensation and stains on the wall, bottom, and central area inside the STAT table unit with a dry clean cloth. Also wipe off the condensation and stains on the removed STAT table.

- 5 Wipe the wall, bottom, and central area inside the STAT table compartment and the STAT table with an alcohol prep (70% Isopropyl alcohol using lint-free cloth).

-
- 6 Replace the STAT table in the STAT table compartment. While engaging the guide hole on the STAT table with the guide pin on the table unit, tighten the two fixing screws near the center with fingers.

 - 7 Remount the STAT table covers in the original position and close the main cover.

 - 8 Select **Home > Analyzer Maintenance**.

 - 9 Update the Maintenance record by selecting the performed maintenance task from Maintenance Log.
 - Cleaning Inside of STAT Compartment
-

8.8.9 Clean or Replace the Anti-static Brushes

Anti-static brushes reduce the chance of static electricity affecting a sample by removing static electricity before sampling takes place.



To avoid infection, always wear gloves to clean or replace the anti-static brushes.

If hands come in contact with the anti-static brushes, wash the affected area thoroughly.

Clean or replace the antistatic brushes:

Refer to [8.2 Parts Used for Analyzer Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

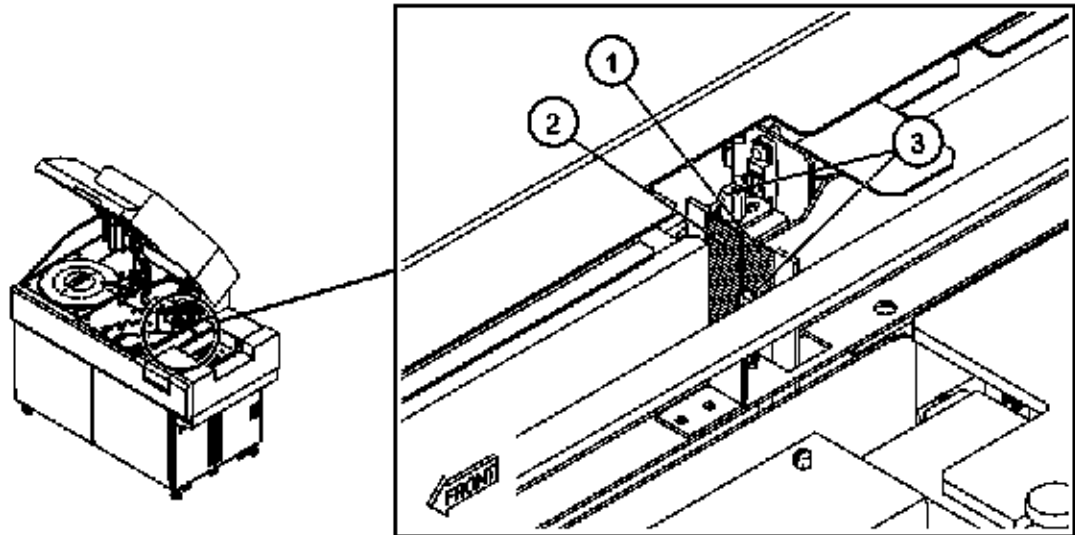
- Anti-static brushes

-
- 1 Verify the system is in *Warm up* or *Standby* mode.

 - 2 Open the main cover. Remove the dark acrylic cover from the rack feeder unit.

- 3 Loosen the fixing screw at the top of the anti-static brush, and remove the anti-static brush.

Figure 8.77



1. Anti-static brush 2
2. Anti-static brush 1
3. Fixing screw

- 4 Follow the same procedure with the brush assembly on the other side of the rack transport.
- 5 Clean any stains on the brushes with an alcohol prep (70% Isopropyl alcohol) from the base to the end of the bristle tips.
- 6 If the static discharge brushes are still stained after cleaning or show signs of wear, replace them.
- 7 Dispose of the old brushes in a receptacle for biohazard waste.
- 8 Reinstall the anti-static brush and tighten the fixing screw on top.
- 9 Replace the dark acrylic cover over the rack feeder unit and close the main cover.

- 10** Update the Maintenance record.
Select the performed maintenance task from Maintenance Log.
 - Replace anti-static Brush
-

For details on updating the maintenance record, refer to [Update the Maintenance Log](#) in section [8.1.2 Maintenance Log](#) in this chapter.

8.8.10 Replace the Sample and Reagent Probe Tubing

Replace the sample or reagent probe tubing if the tubing leaks or breaks.

Replace Sample and Reagent Probe Tubing

Replace the sample probe and reagent probe tubing using the same procedure.

Refer to [8.2 Parts Used for Analyzer Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

- Tubing for sample probe
- Tubing for reagent probe



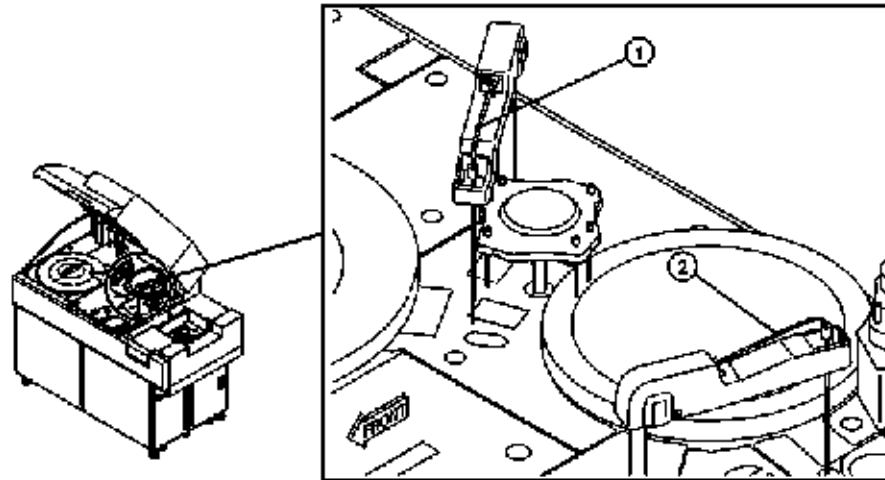
Before disconnecting the tubing, verify the probe is positioned over the wash well. Dripping occurs.

- 1** Verify the system is in *Warm up* or *Standby* mode.

- 2** Open the main cover of the analyzer.

-
- 3 Loosen the connectors on both sides of the probe tubing to remove it.

Figure 8.78



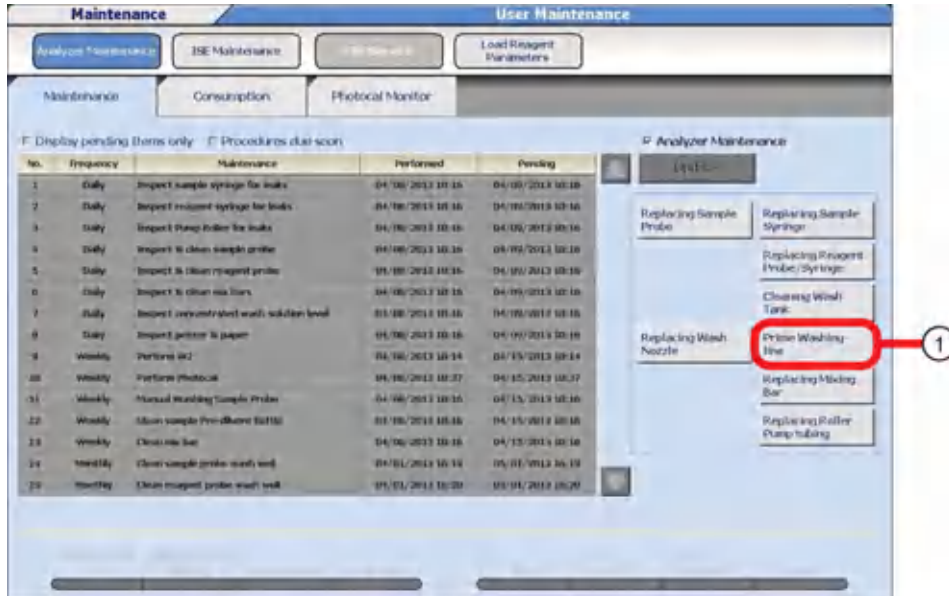
1. Reagent probe tubing
2. Sample probe tubing

-
- 4 Tighten the new tubing connectors to secure both ends of the probe tubing. Tighten the connectors firmly to ensure that no liquid leaks.

-
- 5 Select **Home > Analyzer Maintenance**.

- Place a check mark in the box next to the Analyzer Maintenance option. The maintenance operation buttons become functional.

Figure 8.79



- Prime Washing-line

- Select **Prime Washing-line** from the maintenance operation button. The Start window opens.

- Select **OK**.

- Press the TABLE ROTATION/DIAG button. Verify that the tubing is not leaking and that the probe is dispensing properly.

- Close the main cover.

- Deselect the check box next to Analyzer Maintenance.

- Update the Maintenance record.

Select the performed maintenance task from Maintenance Log.

- Replacing Sample Probe Tubes
- Replacing Reagent Probe Tubes

For details on updating the maintenance record, refer to [Update the Maintenance Log](#) in section 8.1.2 [Maintenance Log](#) in this chapter.

8.8.11 Perform a W1

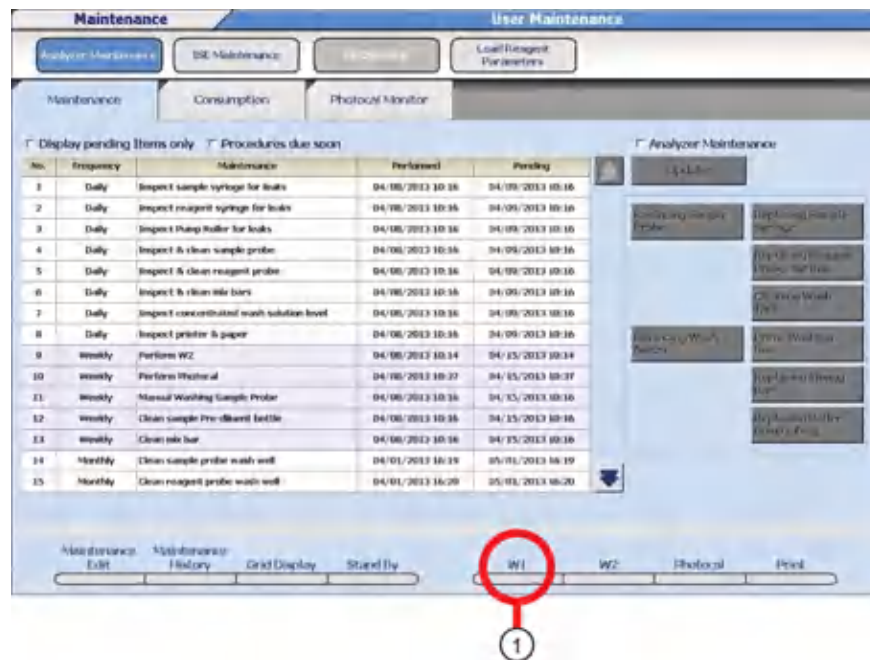
If the analyzer was put into *Stop* mode during analysis, reagents and sample remain in the cuvettes for longer than normal operation. A W1 cleans the entire cuvette wheel automatically using the wash nozzle unit.

Perform a W1 (Cuvette Wash) on an as needed basis.

1 Verify the system is in *Warm up* or *Standby* mode.

2 Select **Home > Analyzer Maintenance**.

Figure 8.80



1. W1

3 Select **W1(F5)**. The W1 Start window opens.

4 Select **Start**. W1 starts. W1 takes approximately 9 minutes.

5 Select **Update**. The Update window opens.

6 Select **OK**.

8.8.12 Replace Rack ID Labels

If a rack ID label is scratched, stained, or deteriorated, an ID read error results. Replace the rack ID label with a new one.



Rack ID labels may deteriorate with time.

If a rack ID read error occurs on a label used for an extended period of time and if the label shows none of the following anomalies, the label is assumed to have deteriorated due to discoloration, reduction in reflectivity, etc.

If this is the case, replace all the labels that have been used for the same period of time as the label concerned.

- **The barcode on a label has become faint, or scratched due to abrasion, scraping, etc.**
- **A label is stained or blurred due to adhesion of foreign matters (liquid or solid).**
- **A label has been peeled or torn.**

Replace rack ID labels:

Refer to [8.2 Parts Used for Analyzer Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

- New rack ID label



- **If it is difficult to remove a label, dampen the label with water and use a tool to scrape it off, such as a razor blade or scissors.**
- **NEVER use an organic solvent such as ethyl alcohol (ethanol) because it alters the quality of the plastic surface on a rack.**
- **If water is used, wipe it off completely so that no moisture remains on the rack.**
- **Do not scratch the rack surface.**

- 1 Remove the rack ID label.

Figure 8.81



- 2 Stick a new rack ID label on the rack. The label should be placed on the beveled edge of the rack with the numbers on the left (when looking at the rack).

For details on attaching rack ID labels, refer to [6.1.4 Place the Sample Cups/Tubes in the Rack](#) in chapter 6.

CAUTION

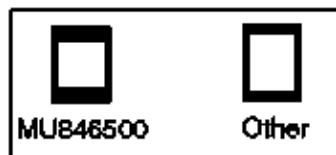
When replacing rack ID labels, do not use labels with the same rack ID on more than one rack. This could result in concordance errors between samples.

8.8.13 Clean or Replace Individual Cuvettes



The AU480 uses a cuvette (Part No. MU846500). The interior size is (5x5 mm) and is different from the other AU analyzers. Do not use a cuvette from another AU analyzer on the AU480. Use of a cuvette other than the AU480 cuvette (Part No. MU846500) on the AU480 causes erroneous results.

Figure 8.82



Verify that all the removed cuvettes are replaced without any omission. If one of the cuvettes is missing, the mixture, reagent, or detergent spills into the cuvette wheel causing a flood, hampering the analysis to be successfully performed.

When replacing cuvettes on the cuvette wheel, be careful not to scratch the cuvettes. To ensure correct photometric analysis, avoid getting fingerprints on the photometric surface of the cuvettes. Always wear gloves when handling the cuvettes.

Clean or replace individual cuvettes that failed the weekly Photocal procedure. This procedure can also be used if a small number of cuvettes need to be cleaned or replaced after a cuvette wheel overflow.

Refer to [8.2 Parts Used for Analyzer Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

- Cuvettes
- Cotton tip applicators
- Clean, dry lint-free cloth
- 2% Wash Solution
- Plastic container
- Sonicator

1 Ensure the system is in *Warm up*, *Standby*, or *Stop* Mode.

2 Open the main cover and the rear cover.

-
- 3** Loosen the knob of the wash nozzle unit. Without disconnecting the tubing, remove the nozzle portion from its stand and hang it on the nearby hook.

 - 4** Manually rotate the mix bar unit approximately 45 degrees so the mix bars are not over the cuvette cover.

 - 5** Lift the cuvette wheel cover, carefully remove it from the analyzer, and set aside.

 - 6** Locate the failed cuvette. Every 10th cuvette is numbered.

 - 7** Using two cotton tipped applicators, gently insert them in the cuvette to be removed and pull up.

Figure 8.83



-
- 8** Determine if the cuvette needs to be replaced or cleaned.
 - To replace individual cuvettes: Insert the new cuvette into the wheel. Gently push the cuvette completely into the wheel.
 - To clean individual cuvettes: Sonicate cuvettes in a 2% Wash Solution for 15 minutes. If a sonicator is not available, soak them in a 5% Wash Solution overnight. Rinse the cuvette in DI water. Allow the cuvettes to dry completely.

 - 9** Replace the new or cleaned cuvette into its position. Gently push the cuvette completely into the wheel.

 - 10** Replace the cuvette wheel cover.

 - 11** Manually turn the mix bar unit back to the original position.

12 Replace the wash nozzle unit.

13 Select **Home > Analyzer Maintenance**.

14 Place a check mark in the box next to the **Analyzer Maintenance** option. The maintenance operation buttons become functional.

15 Select **Prime Washing-line**, and then **OK**. Press the green TABLE ROTATION/DIAG button. Watch as the wash nozzle unit moves, and verify the downward motion is not inhibited.

16 Perform a Photocal on the individual cuvette.

8.8.14 Replace the Photometer Lamp

Over time, the intensity of the photometer lamp diminishes, and results are affected.

The lamp is under warranty for 1,000 hours. Beckman Coulter recommends replacing the photometer lamp every 1,000 hours.

Replace the lamp when a cuvette(s) displays in orange for Lamp Check Error in the Photocal Monitor menu, or when troubleshooting indicates the need for a new lamp, even if 1000 hours has not passed since the lamp was replaced.

After replacing the lamp, a photocal is required to evaluate the quality and intensity of the new lamp.

WARNING

- **To prevent electric hazards, perform an End Process before replacing the photometer lamp.**
- **Wait 5 minutes or more after the system shutdown process has been completed. Do not touch the lamp with bare hands, until the photometer lamp has cooled down completely. The lamp is very hot and can cause burns.**

 **CAUTION**

Never touch the glass of the photometer lamp with bare hands. If oil from the skin or fingerprints is left on the glass, it burns. This changes the light intensity of the lamp and decreases the measuring accuracy.

Replace the photometer lamp:

Refer to [8.2 Parts Used for Analyzer Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

- Photometer lamp

1 Perform an **End Process**. Allow the lamp to cool for a minimum of five minutes.

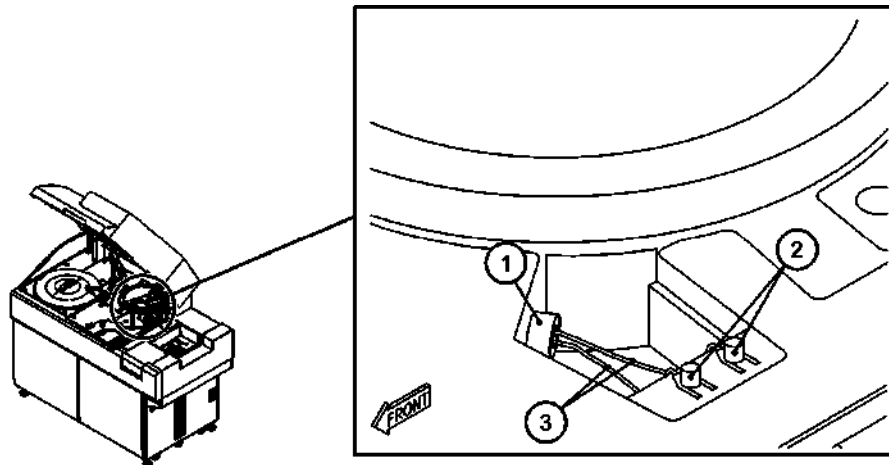
2 Open the main cover of the analyzer.

 **CAUTION**

When removing the lamp unit cover, avoid bumping the cover against the reagent probe.

- 3 Remove the lamp unit cover.

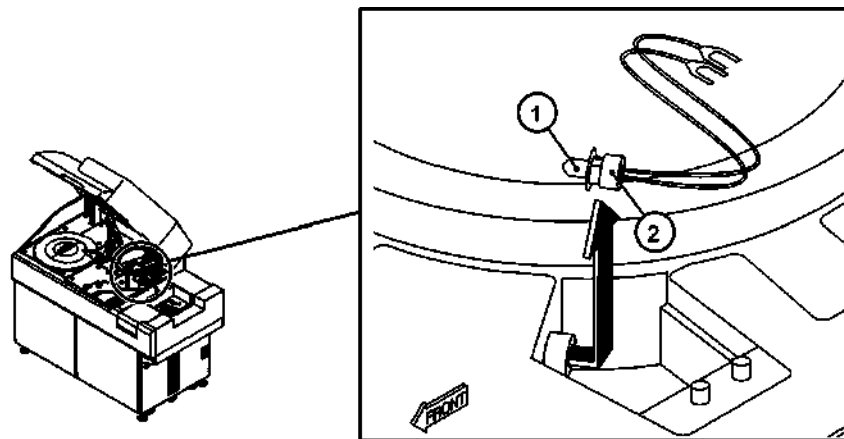
Figure 8.84



1. Lamp holder
2. Knobs
3. Lamp lead wires

- 4 Loosen the two knobs on the terminals, then disconnect the lamp lead wires.

Figure 8.85



1. Photometer lamp
2. Lamp holder

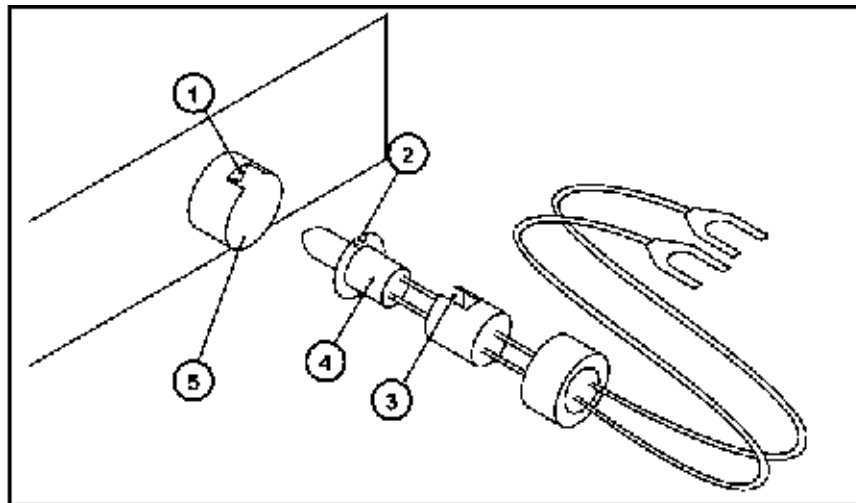
- 5 Remove the lamp by turning the silver holder counterclockwise, then pulling the lamp from the lamp receptacle. Handle the lamp by the lead wires.

CAUTION

Never touch the glass of the photometer lamp with bare hands. If oil from the skin or fingerprints is left on the glass, it burns. This changes the light intensity of the lamp and decreases the measuring accuracy.

- 6 Remove the silver holder and black collar from the lamp and keep them for future use.

Figure 8.86



- | | |
|-----------------|--------------------|
| 1. Protrusion | 4. Guide key |
| 2. Notch | 5. Lamp receptacle |
| 3. Collar notch | |

- 7 Obtain a new lamp. Take care to handle it by the wires only. The bulb may be damaged if touched.
- 8 Slide the black, notched collar along the lead wires with the opening of the notch toward the rear of the lamp. Align the notched collar with the notch of the guide key of the lamp.
- 9 Insert the lamp into the receptacle with the notches lined up on the top. Slide the notches into the keyed protrusion of the receptacle.

10 Slide the silver holder along the wires behind the lamp and tighten to hold it in place.



Verify the silver holder is securely in place. If the silver holder is loose, accurate analysis data cannot be obtained.

11 Connect the lead wires to the terminals and tighten with the knobs.

TIP Each lead wire can be connected to either terminal.

12 Replace the lamp unit cover.

13 Close the main cover.



After replacing the lamp, perform a Photocal to verify that the lamp does not have any defects. To obtain optimal analysis data, wait 20 minutes to stabilize the lamp after turning on the system, then perform the Photocal.

14 Press the **ON** button. The system powers up and initializes.

15 Select **Home > Analyzer Maintenance > Consumption**.

Figure 8.87

No.	Consumable Item	Unit	Status	Quantity	Change
1	Replacing Photometer Lamp	Unit	Alert	1000	00:00:00 00:00:00
2	Sample Vial	Unit	Normal	10	00:00:00 00:00:00
3	Reagent Vial	Unit	Normal	10	00:00:00 00:00:00
4	Reagent Vial	Unit	Normal	10	00:00:00 00:00:00
5	Sample Probe	Unit	Normal	10	00:00:00 00:00:00
6	Wash Solenoid pump tubing	Unit	Normal	10	00:00:00 00:00:00
7	Inlet filter pump tubing	Unit	Normal	10	00:00:00 00:00:00
8	ISE probe cable tubing	Unit	Normal	10	00:00:00 00:00:00
9	Wash Filter	Unit	Normal	10	00:00:00 00:00:00
10	Wash Solenoid pump	Unit	Normal	10	00:00:00 00:00:00
11	ISE probe tubing	Unit	Normal	10	00:00:00 00:00:00

16 Select **Replacing Photometer Lamp**.

17 Select **Update**. The User Maintenance window opens.

18 Select **OK** to indicate the lamp was replaced and reset the lamp "Used" time.

TIP The first photocal value after selecting Replacing Photocal Lamp in **Consumption** is updated and saved automatically as the reference value in **Photocal Monitor**.

19 Allow the lamp 20 minutes to warm up and come to the proper intensity before completing the procedure.

20 Perform a photocal.

21 Verify all cuvettes have passed the photocal and run QC before processing samples.

For details on performing a photocal, refer to [8.4.3 Perform a Photocal](#) in this chapter.

TIP Analyze quality control material, check the data, re-calibrate if necessary.

Errors may occur after the Photocal. If numerous cuvettes fail the Photocal, the lamp may have been replaced incorrectly, or the lamp may be defective. If only a few cuvettes fail the Photocal, the cuvettes may be dirty or stained. Clean the cuvettes, and if the error is not corrected after cleaning, replace the cuvettes.

8.8.15 Save Parameters

Beckman Coulter recommends saving parameters when programming changes are made or following laboratory Standard Operating Procedures.

TIP If multiple AU480s are in the laboratory, Beckman Coulter recommends saving the parameter files for each AU480 to external media.

For details on saving parameters, refer to [7.8.2 Save or Load Parameters](#) in chapter 7.

8.9 Reset the System from Stop Mode to Standby

When the system is in a *Stop* mode to perform maintenance, reset it with the following procedure.

- 1 Deselect the check box next to *Analyzer Maintenance* or *ISE Maintenance* to exit the menu.
 - 2 Select the AU480 **Home** button.
 - 3 Select **Stop/Standby**. After initialization, the system enters *Warm up* or *Standby* mode.
-

ISE (Option) Maintenance

- 8.10 ISE Parts Used for ISE Maintenance
- 8.11 ISE Tubing Block Diagram
- 8.12 ISE Daily Maintenance
 - 8.12.1 ISE Cleaning
 - 8.12.2 ISE Calibration
- 8.13 ISE Weekly Maintenance
 - 8.13.1 Check the Selectivity of the Na/K Electrodes
 - 8.13.2 Enhanced Cleaning of the ISE Electrode Line
- 8.14 ISE Maintenance Every Other Week or Every 3,000 Samples
 - 8.14.1 Manually Clean the ISE Mix Bar, Liquid Level Sensors, Sample Pot, and Sample Pot Tubing
- 8.15 ISE Maintenance Every Other Month or Every 20,000 Samples
 - 8.15.1 Check and Add REF Electrode Solution
- 8.16 ISE Quarterly Maintenance or Maintenance Every 20,000 Samples
 - 8.16.1 Replace the Mixture Aspiration and MID Standard Roller Pump Tubing
 - 8.16.2 Replace the Tubing between Sample Pot, Electrode Unit, and T-Connector
 - 8.16.3 Replace the REF Electrode Block-side Drain Tube and Pinch Valve Tubing
 - 8.16.4 Manually Clean the Drain Well and if Needed, Replace the Drain Tube
- 8.17 ISE Maintenance Every Six Months or Every 40,000 Samples
 - 8.17.1 Replace the Na, K, or Cl Electrode
- 8.18 ISE Maintenance Every Two Years or Every 150,000 Samples
 - 8.18.1 Replace the ISE REF Electrode and Packing
- 8.19 ISE As Needed Maintenance
 - 8.19.1 Replace the Sample Pot
 - 8.19.2 Clean the ISE Electrode Block (Inlet Side)
 - 8.19.3 Manually Clean the ISE K Electrode
 - 8.19.4 Manually Clean and Replace the ISE REF Electrode Block
 - 8.19.5 Replacing ISE Reagents
 - 8.19.6 Enhanced ISE Cleaning (Manual)

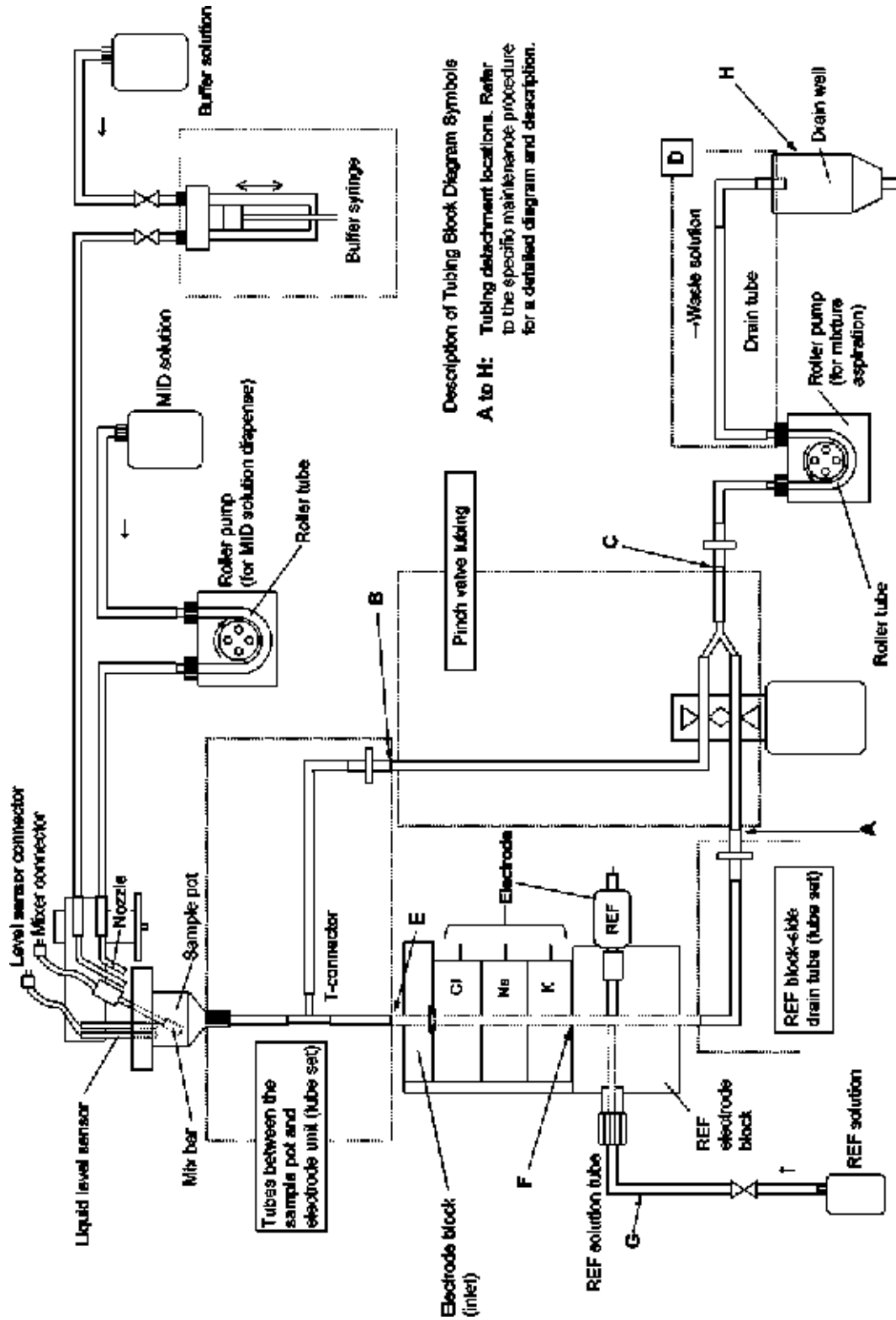
8.10 ISE Parts Used for ISE Maintenance

Maintenance Interval	Maintenance Item	Parts to be Used	Part Number
Daily	8.12.1 ISE Cleaning	ISE Cleaning Solution	OE66039
		Hitachi Cup	MU853200
	8.12.2 ISE Calibration	Serum Standard Solution H	OE66316 (Outside US) AUH1015 (US)
		Serum Standard Solution L	OE66317 (Outside US) AUH1014 (US)
		Urine Standard Solution H and L	OE66315 (Outside US) AUH1016 (US)
		4 Hitachi Cups	MU853200
Weekly	8.13.1 Check the Selectivity of the Na/K Electrodes	Selectivity Check Liquid	OE66313 (Outside US) AUH1018 (US)
	8.13.2 Enhanced Cleaning of the ISE Electrode Line	ISE Cleaning Solution	OE66039
Every Other Week or 3,000 Samples	8.14.1 Manually Clean the ISE Mix Bar, Liquid Level Sensors, Sample Pot, and Sample Pot Tubing	Alcohol Prep or 70% Isopropyl Alcohol using lint-free cloth	Commercial Item
		Wash Solution	OSR0001
Every Other Month or 20,000 Samples	8.15.1 Check and Add REF Electrode Solution	REF Electrode Solution	OE66314 (Outside US) AUH1017 (US)
Quarterly or 20,000 Samples	8.16.1 Replace the Mixture Aspiration and MID Standard Roller Pump Tubing	Roller pump tubing	MU962300
	8.16.2 Replace the Tubing between Sample Pot, Electrode Unit, and T-Connector	Tube Set	MU538600
	8.16.3 Replace the REF Electrode Block-side Drain Tube and Pinch Valve Tubing	Tube Set 2	MU824700
		Pinch Valve Tubing	ZM297000
	8.16.4 Manually Clean the Drain Well and if Needed, Replace the Drain Tube	Drain Tube 2	MU830200
		Sodium hypochlorite solution (0.5%): - Beckman Sodium Hypochlorite (5%) diluted 1:10 or - ISE Cleaning Solution diluted 1:10	A32319 (US) OE66309 (Outside US)

Maintenance Interval	Maintenance Item	Parts to be Used	Part Number
Every Six Months or 40,000 Samples	8.17.1 Replace the Na, K, or Cl Electrode	Na Electrode	MU919400
		K Electrode	MU919500
		Cl Electrode	MU919600
		O-ring	MU990000
Every Two years or 150,000 Samples	8.18.1 Replace the ISE REF Electrode and Packing	REF Electrode (With Packing)	MU919700
		REF Electrode Packing	MU920200
As Needed	8.19.1 Replace the Sample Pot	Sample Pot	MU962700
	8.19.2 Clean the ISE Electrode Block (Inlet Side)	String(Φ0.3)	ZM022700 (Standard Accessory)
	8.19.3 Manually Clean the ISE K Electrode	-	-
	8.19.4 Manually Clean and Replace the ISE REF Electrode Block	REF Electrode Block	MU824500
		Wash Solution	OSR0001
	8.19.5 Replacing ISE Reagents	Buffer Solution	OE66320 (Outside US) AUH1011 (US)
		MID Standard	OE66319 (Outside US) AUH1012 (US)
		REF Solution	OE66318 (Outside US) AUH1013 (US)
	8.19.6 Enhanced ISE Cleaning (Manual)	ISE Cleaning Solution diluted 1:10	OE66039
		Pipette	Commercial Item

8.11 ISE Tubing Block Diagram

Figure 8.88



8.12 ISE Daily Maintenance

TIP Additional checks for the ISE buffer syringe are included in the Analyzer Daily Maintenance section. Please refer to [8.3.1 Inspect the Syringes for Leaks](#) in this chapter.

[8.12.1 ISE Cleaning](#)

[8.12.2 ISE Calibration](#)

8.12.1 ISE Cleaning



Always wear personal protective gear (including gloves and safety glasses) when handling ISE cleaning solution. If skin or clothing comes in contact with ISE cleaning solution, rinse with large amounts of water. If ISE cleaning solution gets in eyes or mouth, immediately rinse with water and consult a physician.

After completing daily analysis, clean the sample pot and electrode lines. Contamination or inaccurate results may occur if the cleaning cycle is not performed. This procedure requires approximately 4 minutes to complete.

TIP If the ISE is not going to be used for a period of time, Beckman Coulter recommends performing the ISE Cleaning after the sample run to remove any build-up.

Clean the ISE before analyzing samples

Refer to [8.10 ISE Parts Used for ISE Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

- ISE Cleaning Solution
- 1 Hitachi Cup

-
- 1** Verify that the system is in the *Warm up* or *Standby* mode.

 - 2** Open the main cover of the analyzer and the small STAT table cover. Press the TABLE ROTATION/DIAG button to rotate the STAT table until the "CLEAN" position is accessible.

 - 3** Fill the sample cup with approximately 1 mL of ISE cleaning solution.

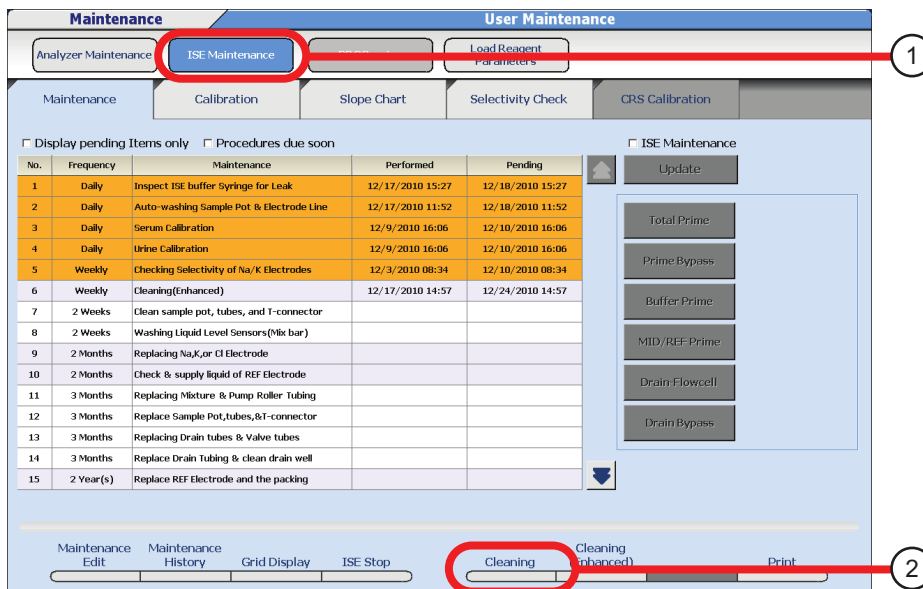
- 4 Set the sample cup filled with the ISE cleaning solution in the “CLEAN” position on the STAT table.



Wipe up spill(s) of ISE cleaning solution immediately by following the facility/site spill procedures.

- 5 Select **Home > Analyzer Maintenance > ISE Maintenance**.

Figure 8.89



1. ISE Maintenance
2. Cleaning

- 6 Select **Cleaning (F5)**, and then **OK**.
- 7 After completing a cleaning operation, remove the sample cup from the STAT table.
- 8 Close the small STAT table cover.

8.12.2 ISE Calibration

Calibrate the ISE once every 24 hours, following specific ISE maintenance procedures and when new bottles of ISE reagents are loaded on the system.

Refer to [8.10 ISE Parts Used for ISE Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

- Serum Standard Solution H and L
- Urine Standard Solution H and L
- 4 Hitachi Cups

TIP Calibrating serum or urine only takes approximately 4 minutes. Calibrating serum and urine takes approximately 7 minutes.

 **CAUTION**

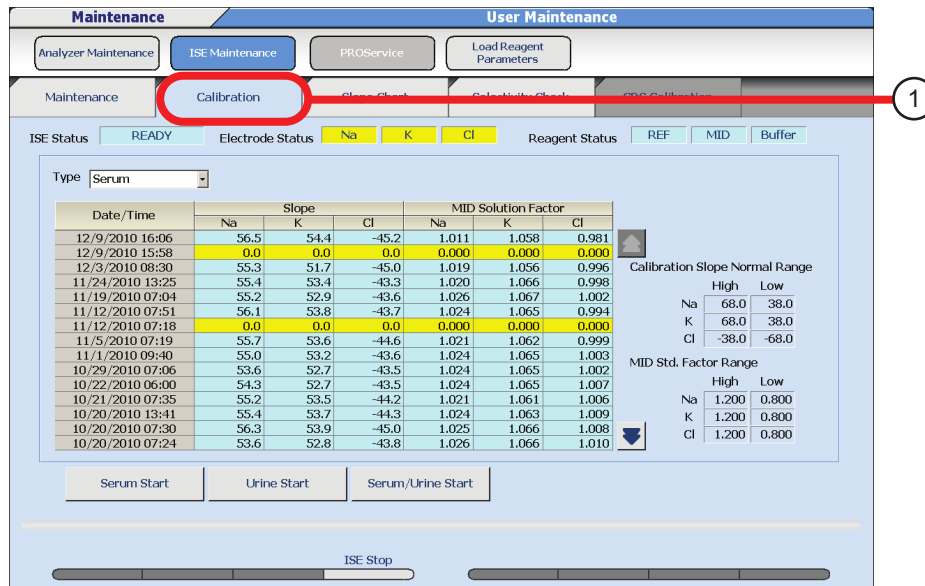
When analysis is in process, or ISE status is "BUSY", do not open the STAT table cover(s) to add standard solutions to the STAT table, or place hands in the path of the sample probe.

-
- 1 Verify that the analyzer is in the *Warm up* or *Standby* mode.
-
- 2 Perform a **Total Prime** to clear the lines of the cleaning solution if the calibration is performed immediately after the ISE Cleaning.
 - Select **Home > Analyzer Maintenance > ISE Maintenance**.
 - Place a check mark in the box next to the ISE Maintenance option. The maintenance operation buttons become functional.
 - Select **Total Prime** and then **OK**.
 - Press the TABLE ROTATION/DIAG button to initiate the prime.

TIP If an End Process is performed once every 24-hours, perform the daily [8.12.1 ISE Cleaning](#) procedure before the End Process, and then the Total Prime is not necessary.
-
- 3 Open the small cover of the STAT table. Press the TABLE ROTATION/DIAG button to rotate the STAT table until the "S-H", "S-L", "U-H", and "U-L" positions are accessible.
-
- 4 Fill the sample cups with approximately 500 µL of Serum Low and High Standard Solution and 500 µL of Urine Low and High Standard Solution separately.
-
- 5 Set the sample cups filled with Serum Standard Solution or Urine Standard Solution in the "S-H" (serum high), "S-L" (serum low), "U-H" (urine high), and "U-L" (urine low) positions on the STAT table.
-
- 6 Select **Home > Analyzer Maintenance > ISE Maintenance**.

7 Select the **Calibration** tab.

Figure 8.90



1. Calibration

8 Select **Serum/Urine Start**. To analyze just the serum, select **Serum Start**, or to analyze just the urine, select **Urine Start**, and then **OK**.

9 Check the calibration results. Verify the analysis result appears in blue.

TIP "Slope" and "MID Standard Factor" are highlighted in blue if the results are within the normal range, and yellow if the results exceed the normal range.

10 After completing calibration, remove the sample cups from the STAT table.

11 Close the small STAT table cover.

8.13 ISE Weekly Maintenance

8.13.1 Check the Selectivity of the Na/K Electrodes

8.13.2 Enhanced Cleaning of the ISE Electrode Line

8.13.1 Check the Selectivity of the Na/K Electrodes

The Na electrode and K electrode are ion-selective electrodes. If the selectivity of the electrodes deteriorates, the electrodes could be affected by ions other than Na or K, and results could be affected.

To check the ion selectivity of the electrodes, it is important to perform a selectivity check of the Na/K electrodes every week.

 **CAUTION**

Do not leave the bottle of selectivity check liquid open. Concentration or crystallization of the selectivity check liquid may occur.

Refer to [8.10 ISE Parts Used for ISE Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

- ISE Na/K Selectivity Check Solution
- 2 Hitachi Cups

-
- 1** Verify that the analyzer is in the *Warm up* or *Standby* mode.

 - 2** Open the small cover of the STAT table. Press the TABLE ROTATION/DIAG button to rotate the STAT table until the "SEL-Na", and "SEL-K" positions are accessible.

 - 3** Fill the sample cups with approximately 500 μ L of Selectivity Check solution (Na) and 500 μ L of Selectivity Check solution (K) separately.

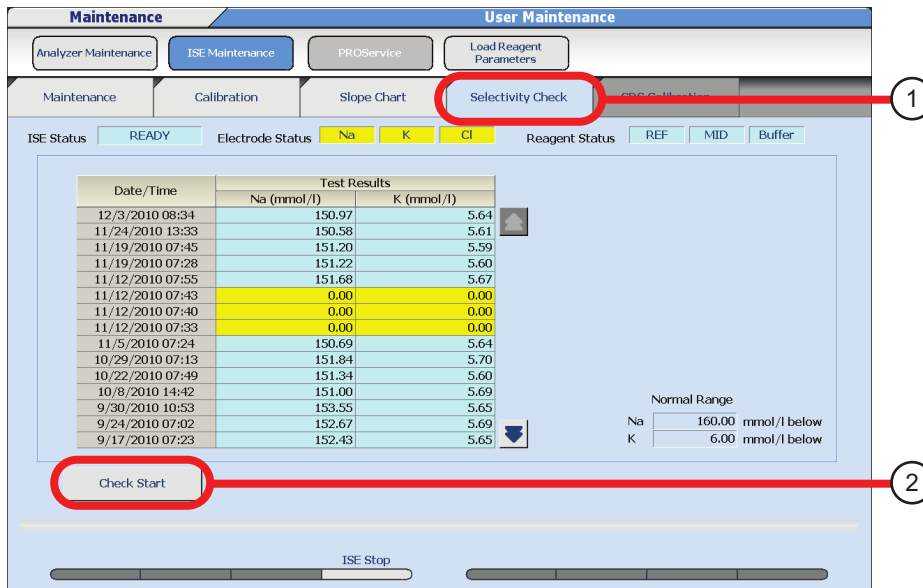
 - 4** Set the Check Liquid (Na) in the "SEL-Na" position. Set the Check Liquid (K) in the "SEL-K" position.

 - 5** Close the small STAT table cover.

 - 6** Select **Home > Analyzer Maintenance > ISE Maintenance**.

7 Select the **Selectivity Check** tab.

Figure 8.91



1. Selectivity Check
2. Check Start

8 Select **Check Start**. The Selectivity Check window opens.

9 Select **OK**.

10 Check the selectivity data.

For abnormal data, the background for the result is displayed in yellow. The system judges a result more than 160 mmol/L for Na-electrode and a result more than 6 mmol/L for K-electrode as abnormal data.

If the selectivity check results are abnormal, verify the Selectivity Check Solutions by repeating the procedure with new bottles of Selectivity Check Solutions. The Selectivity Check must be performed with a valid ISE Calibration. However, if the ISE Calibration passes, and the Selectivity Check fails, it is necessary to replace the relevant electrode.

For detailed information on replacing the electrode, refer to [8.17.1 Replace the Na, K, or Cl Electrode](#) in this chapter.

-
- 11** Perform a MID/REF Prime 3 times to clear the electrode stack of any ions remaining from the selectivity procedure.
 - Select the **Maintenance** tab.
 - Check the ISE Maintenance box.
 - Select **MID/REF Prime**, then **OK**.
 - Press the TABLE ROTATION/DIAG button to start the priming. The TABLE ROTATION/DIAG LED comes ON after the priming is complete.
 - Initiate the MID/REF prime two more times by pressing the TABLE ROTATION/DIAG button.
-
- 12** After completing the operation, remove the sample cups from the STAT table.
-
- 13** Close the small STAT table cover.
-

8.13.2 Enhanced Cleaning of the ISE Electrode Line

Contamination or inaccurate results may occur if the ISE enhanced cleaning cycle is not performed.

TIP This cleaning procedure requires 30 minutes to complete. If the ISE cleaning is performed with the W2, both procedures are complete in approximately 30 minutes.

Refer to [8.10 ISE Parts Used for ISE Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

- ISE Cleaning Solution
- One Hitachi Cup

 **CAUTION**

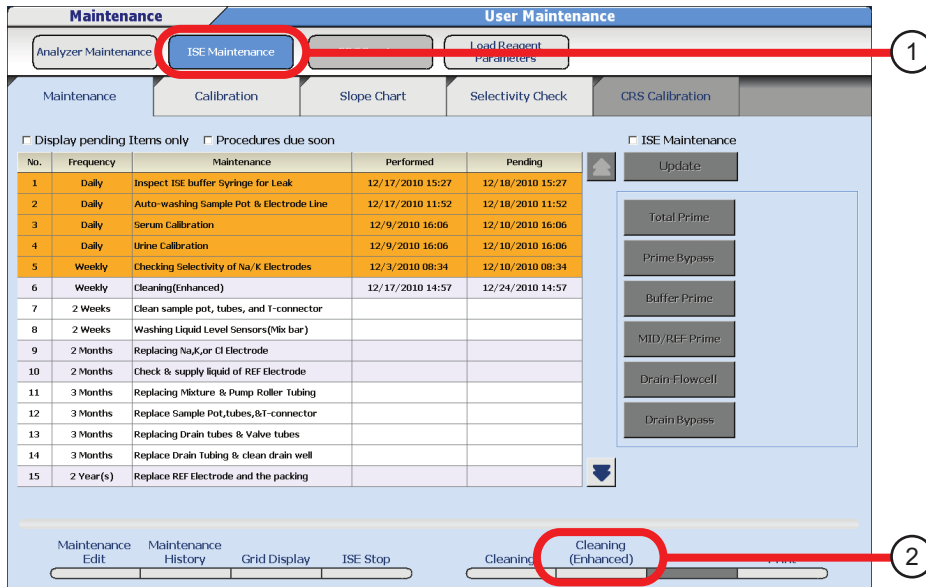
Failure to perform user maintenance according to the instructions within this User's Guide can adversely affect system performance and might invalidate the service agreement.

-
- 1** Verify that the analyzer is in the *Warm up* or *Standby* mode.
-
- 2** Open the small STAT table cover. Press the TABLE ROTATION/DIAG button to rotate the STAT table until the "CLEAN" position is accessible.
-
- 3** Fill the sample cup with approximately 1.5 mL of ISE Cleaning Solution.
-

4 Set the sample cup filled with ISE Cleaning Solution in the “CLEAN” position on the STAT table.

5 Select **Home > Analyzer Maintenance > ISE Maintenance**.

Figure 8.92



1. ISE Maintenance
2. Cleaning (Enhanced) (F6)

6 Select **Cleaning (Enhanced) (F6)**, and then **OK**. The enhanced cleaning operation starts. This process requires 30 minutes to complete.

7 After performing the enhanced cleaning operation, remove the ISE clean Cleaning Solution.

8 Close the small STAT table cover.

8.14 ISE Maintenance Every Other Week or Every 3,000 Samples

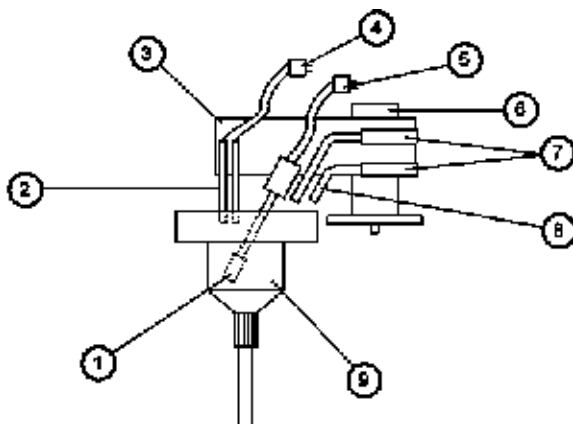
8.14.1 Manually Clean the ISE Mix Bar, Liquid Level Sensors, Sample Pot, and Sample Pot Tubing

8.14.1 Manually Clean the ISE Mix Bar, Liquid Level Sensors, Sample Pot, and Sample Pot Tubing

To obtain accurate results and optimum system performance without unexpected analyzer downtime, perform the following ISE maintenance procedure every two weeks or every 3,000 samples, whichever comes first. Perform cleaning based on laboratory Standard Operating Procedures after careful monitoring of calibration and QC data.

Refer to [8.11 ISE Tubing Block Diagram](#) for additional information.

Figure 8.93



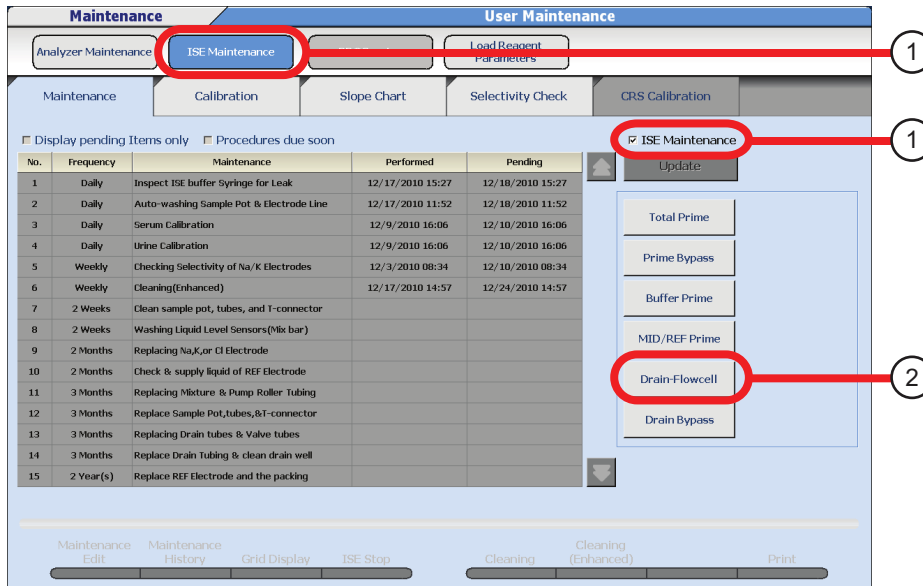
- | | |
|---------------------------|--|
| 1. Mix bar | 6. Mixing unit clamp knob |
| 2. Liquid level sensor | 7. Buffer solution and MID solution connecting tubes |
| 3. Mixing unit | 8. Nozzle |
| 4. Level sensor connector | 9. Sample pot |
| 5. Mixing motor connector | |

Prepare the ISE for Maintenance

- 1 Verify that the analyzer is in the *Warm up* or *Standby* mode.
- 2 Select **Home** > **Analyzer Maintenance** > **ISE Maintenance**.

- Place a check mark in the box next to the ISE Maintenance option. The maintenance operation buttons become functional.

Figure 8.94



- ISE Maintenance
- Drain Flowcell

- Select **Drain Flowcell** from the ISE maintenance operation button, and then **OK**.
- Open the main analyzer cover.
- Open the ISE cover.
- Press the TABLE ROTATION/DIAG button once. Solution is drained from the flowcell.

Clean the Nozzles, Mix Bar and Liquid Level Sensors

Refer to 8.10 ISE Parts Used for ISE Maintenance for a complete list of part numbers. Materials needed for this procedure:

- Alcohol Prep (70% Isopropyl alcohol using lint-free cloth)
- Clean, dry lint-free cloth

- Disconnect the mixing unit liquid level sensor connector 714 and mixing motor connector 706.

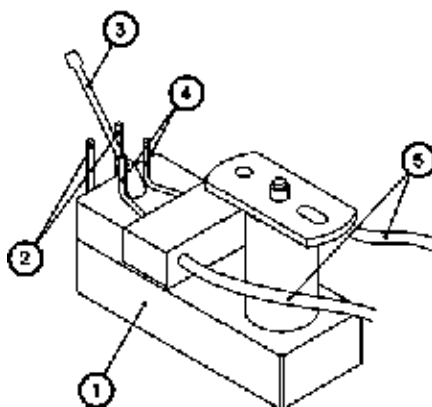
- 2 Loosen the knob securing the mixing unit. Gently lift the mixing unit to unseat it.

⚠ CAUTION

Be careful not to bend or break the liquid level sensors when cleaning.

- 3 Use an Alcohol Prep or 70% Isopropyl alcohol using lint-free cloth to wipe the two nozzles, the liquid level sensors, and the mix bar.

Figure 8.95



- | | |
|-------------------------|----------------------|
| 1. Mixing unit | 4. Nozzle |
| 2. Liquid level sensors | 5. Connecting tubing |
| 3. Mix bar | |

- 4 Place the mixing unit on the mixing unit holder.

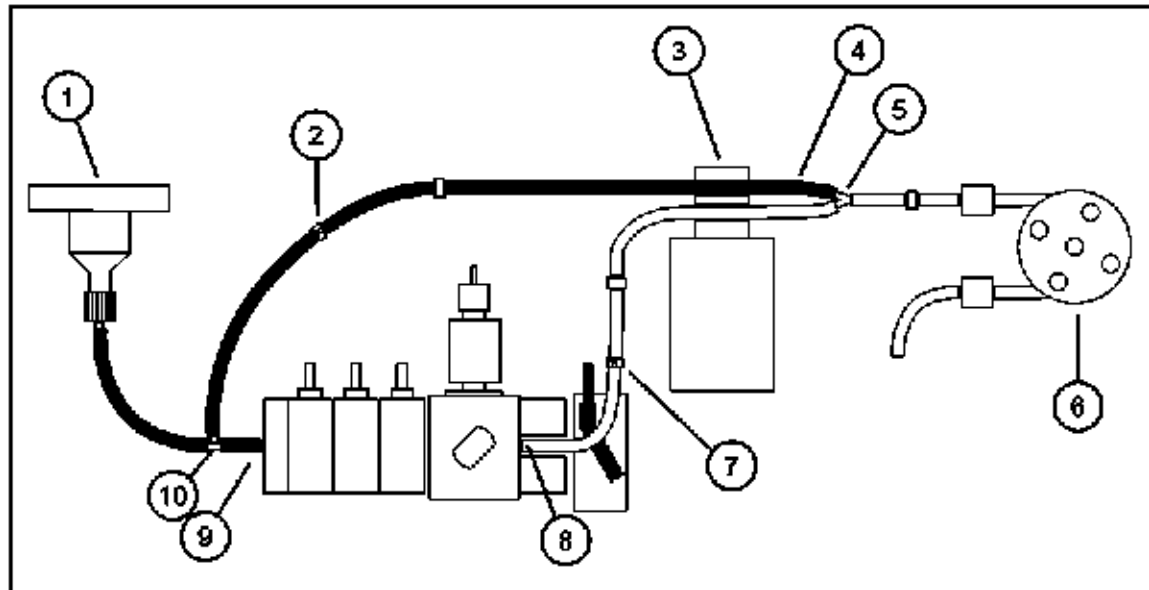
⚠ CAUTION

Do not change the orientation position of the two nozzles attached to the mixing unit. Do not apply excess pressure to the tubing.

Clean the Sample Pot and Tubing

Refer to [8.11 ISE Tubing Block Diagram](#) for additional information.

Figure 8.96



- | | |
|-----------------------|----------------------------|
| 1. Sample pot | 6. Mixture Aspiration Pump |
| 2. Bypass tubing | 7. Tubing |
| 3. Pinch valve | 8. Flow Cell outlet |
| 4. Pinch valve tubing | 9. Flow Cell inlet |
| 5. Y-connector | 10. T-connector |

Clean the Sample Pot and Tubing

Refer to [8.10 ISE Parts Used for ISE Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

- Freshly prepared 1% Wash Solution
- DI water
- Clean, dry lint-free cloth
- Sonicator

- 1 Loosen the retaining knob securing the sample pot, and lift the pot from the peg.
- 2 Hold the sample pot with one hand while removing the sample pot tubing from the inlet of the flowcell.
 - a. Follow the bypass tubing labeled "5" connected to the pinch valve tubing and remove it from the pinch valve.
 - b. Disconnect the pinch valve tubing at the Y-connector near the mixture aspiration roller pump.

-
- 3** Fill the sample pot tubing and bypass tubing with 1% wash solution. This is best accomplished by using a disposable pipette tip attached to a squeeze bottle or a syringe.
 - a.** Place the pipette tip or syringe inside the bottom of the sample pot tubing.
 - b.** Force the wash solution through the sample pot tubing.
 - c.** Place the pipette tip or syringe in the end of the bypass tubing. Force the wash solution through it.

 - 4** Submerge the sample pot and all attached tubing into a beaker filled with 1% wash solution.

 - 5** Place the beaker in the sonicator filled with DI water and sonicate for 10 minutes.

 - 6** Rinse the sample pot and tubing with DI water.
 - a.** Place the pipette tip or syringe at the bottom of the sample pot tubing.
 - b.** Force DI water through the sample pot tubing.
 - c.** Place the pipette tip or syringe in the bypass tubing. Force DI water through it.
 - d.** Verify that the lines have been flushed thoroughly. Rinse the sample pot with DI water.

 - 7** Use a clean, dry lint-free cloth to dry the sample pot and tubing before returning it to the ISE unit.
-

Re-install the sample pot, tubing, and mixing unit

- 1** While holding the sample pot, connect the sample pot tubing to the inlet of the flowcell.

- 2** Re-install the sample pot. Align the hole on the top of the sample pot with the peg and slide the screw post into the groove on the opposite side. Tighten the screw.

- 3** Connect the pinch valve tubing onto the Y-connector located near the mixture aspiration roller pump.

- 4** Slide the pinch valve tubing into the top slot of the pinch valve.

- 5** Mount the mixing unit on the two positioning pins. Tighten the knob to secure the unit.

- 6** Reconnect the mixing unit liquid level sensors connector 714 and mixing motor connector 706.

TIP The connectors are specially keyed to fit each plug. To avoid damage to the pins, do not force a connector into its plug. If the pins are damaged, the mix bar does not rotate, or the liquid level sensors do not function.



When remounting the mixing unit, verify that the tubing is not pinched between the mixing unit and its stand.

- 7** Press the TABLE ROTATION/DIAG button to re-prime the lines with MID solution. Confirm that liquid is properly dispensed from the sample pot to the electrode unit by verifying that no bubbles are present in the tubing labeled “6” coming from the bottom of the flowcell. If necessary, repeat the prime, by pressing the TABLE ROTATION/DIAG button again. Repeat until all bubbles are cleared from the lines.
-

- 8** Perform a Buffer Prime.

During the prime, confirm that buffer is properly dispensed into the sample pot and flows to waste without generating alarms:

- Select **Buffer Prime**, then **OK**.
 - Press the TABLE ROTATION/DIAG button to start the priming. The TABLE ROTATION/DIAG LED comes ON after the priming is complete.
-

- 9** Perform a Total Prime to prime the ISE unit with fresh Buffer, MID Standard, and Reference reagent.

- Select **Total Prime**, then **OK**.
 - Press the TABLE ROTATION/DIAG button to start the priming. The TABLE ROTATION/DIAG LED comes ON after the priming is complete.
-

- 10** Close the ISE cover.
-

- 11** Close the main cover of the analyzer.
-

- 12** Deselect the check box next to ISE Maintenance to exit the menu.
-

- 13** Perform a calibration to verify that the ISE is working properly after the maintenance procedure.

14 Update the maintenance record.

Select the performed maintenance task from Maintenance Log.

- Clean sample pot tubes and T-connector
- Washing Liquid Level Sensor (Mix bar)

For details on updating the maintenance record, refer to [Update the Maintenance Log](#) in section [8.1.2 Maintenance Log](#) in this chapter.

8.15 ISE Maintenance Every Other Month or Every 20,000 Samples

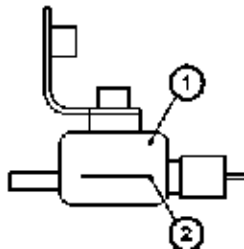
8.15.1 Check and Add REF Electrode Solution

8.15.1 Check and Add REF Electrode Solution

Visually inspect the REF electrode. Add REF electrode solution when it is less than the reference line.

Refer to [8.11 ISE Tubing Block Diagram](#) for additional information.

Figure 8.97



1. REF electrode
2. Reference line

Refer to [8.10 ISE Parts Used for ISE Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

- REF Electrode Solution

1 Open the ISE cover.

-
- 2 Remove the cap of the REF electrode. Add REF electrode solution up to, but not over the reference line.



Use care to avoid breaking or damaging the glass REF electrode.

-
- 3 Replace the REF electrode cap.

-
- 4 Select **Home > Analyzer Maintenance > ISE Maintenance**.

-
- 5 Select **Check & supply liquid of REF Electrode** from the list of maintenance items.

-
- 6 Select **Update**. The Update window opens.

-
- 7 Select **OK**.

-
- 8 Wait 15 minutes to allow the solution to equilibrate.

-
- 9 Perform a **Total Prime**.

- Check the ISE Maintenance box.
- Select **Total Prime**, then **OK**.
- Press the TABLE ROTATION/DIAG button to start the priming. The TABLE ROTATION/DIAG LED comes ON after the priming is complete.

-
- 10 Calibrate the ISE and verify that the calibration is within specified limits.
-

8.16 ISE Quarterly Maintenance or Maintenance Every 20,000 Samples

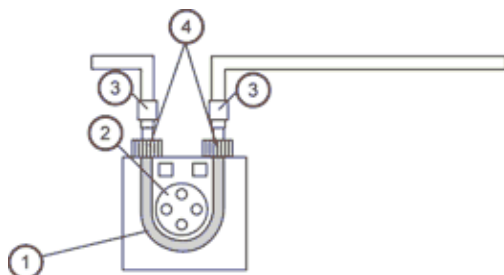
To obtain accurate results and optimum system performance, perform the following ISE maintenance procedures every three months or every 20,000 samples, whichever comes first.

- 8.16.1 Replace the Mixture Aspiration and MID Standard Roller Pump Tubing
- 8.16.2 Replace the Tubing between Sample Pot, Electrode Unit, and T-Connector
- 8.16.3 Replace the REF Electrode Block-side Drain Tube and Pinch Valve Tubing
- 8.16.4 Manually Clean the Drain Well and if Needed, Replace the Drain Tube

8.16.1 Replace the Mixture Aspiration and MID Standard Roller Pump Tubing

The roller pump tubing deteriorates due to the friction of each roller pump and vibrations. If the roller tubing is not replaced for an extended period of time, it may become flat or worn and leaks may occur. Replace the roller pump tubing every three months or every 20,000 samples.

Figure 8.98



- | | |
|-----------------------|--------------------|
| 1. Roller pump tubing | 3. Tube number |
| 2. Roller pump | 4. Tube connectors |

Replace the Roller Pump Tubing

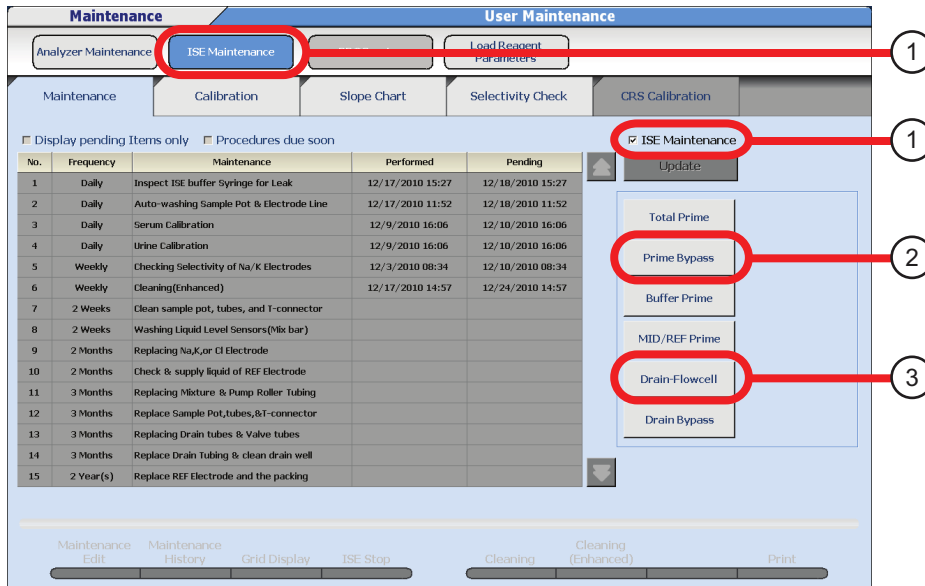
Refer to [8.10 ISE Parts Used for ISE Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

- Roller Pump Tubing

-
- 1 Verify the analyzer is in the *Warm up* or *Standby* mode.
-
- 2 Select **Home** > **Analyzer Maintenance** > **ISE Maintenance**.

- Place a check mark in the box next to the ISE Maintenance option. The maintenance operation buttons become functional.

Figure 8.99

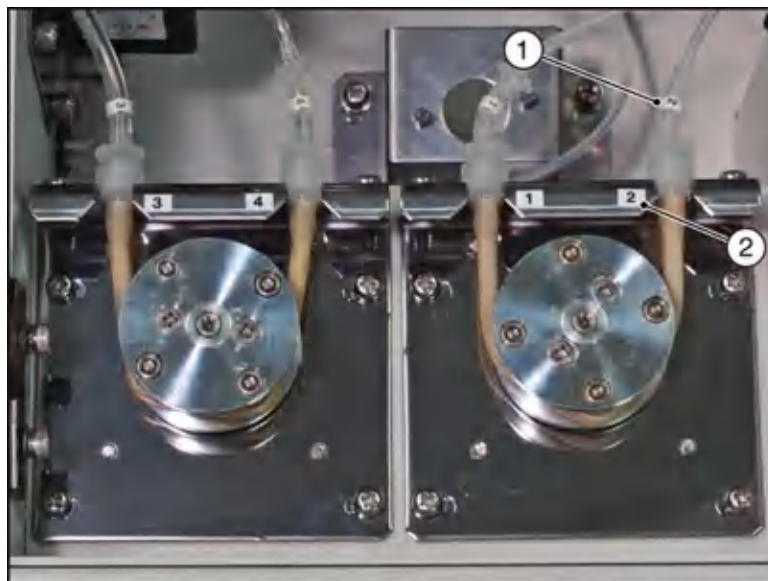


- ISE Maintenance
- Prime Bypass
- Drain Flowcell

- Select **Drain Flowcell** from the ISE maintenance operation button, and then **OK**.
- Press the TABLE ROTATION/DIAG button once.
- Open the main analyzer cover.
- Open the ISE cover.
- Remove each roller pump tubing from the pump brackets.
- Remove the MID solution roller pump tubing and the mixture aspiration roller pump tubing by twisting the connectors at each end apart.
- Connect a new roller pump tubing. Turn the connectors at both ends to secure it.

- 11 Place the roller pump tubing on the correct roller pump, then match the tubing connector number to their corresponding numbers on the pump bracket. Hook one end of the tubing in the bracket, stretch the tubing around the pump, and hook the other end in the bracket.

Figure 8.100



1. Tubing connector "2"
2. Pump bracket "2"

- 12 Select **Prime Bypass**, and then **OK**.
- 13 Press the **TABLE ROTATION/DIAG** button. The two roller pumps are activated to prime liquid through the tubing. The roller pumps rotate for approximately one minute to bleed the air from the tubing.
- 14 Close the ISE cover.
- 15 Close the main analyzer cover.
- 16 Deselect the check box next to ISE Maintenance to exit the menu.
- 17 Update the maintenance record.
 - Replacing Mixture & Roller Pump Tubing

For details on updating the maintenance record, refer to [Update the Maintenance Log](#) in section [8.1.2 Maintenance Log](#) in this chapter.

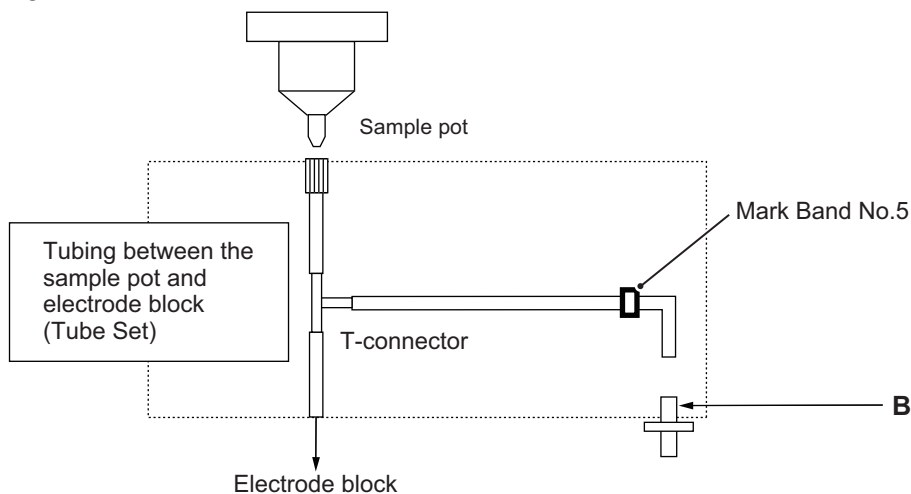
8.16.2 Replace the Tubing between Sample Pot, Electrode Unit, and T-Connector

If the system analyzes certain samples (such as dialysis samples) that contain large amounts of fibrin and protein, it may accumulate near the T-connector between the sample pot and electrode unit, possibly causing errors.

To obtain accurate results and optimum system performance without unexpected analyzer downtime, perform the following ISE maintenance procedure quarterly or every 20,000 samples. Perform cleaning based on laboratory Standard Operating Procedures after careful monitoring of calibration and QC data.

For details on how to clean the sample pot, tubing, and T-connector, refer to [8.14.1 Manually Clean the ISE Mix Bar, Liquid Level Sensors, Sample Pot, and Sample Pot Tubing](#).

Figure 8.101



Refer to [8.10 ISE Parts Used for ISE Maintenance](#) for a complete list of part numbers.

Materials needed for this procedure:

- Tube Set

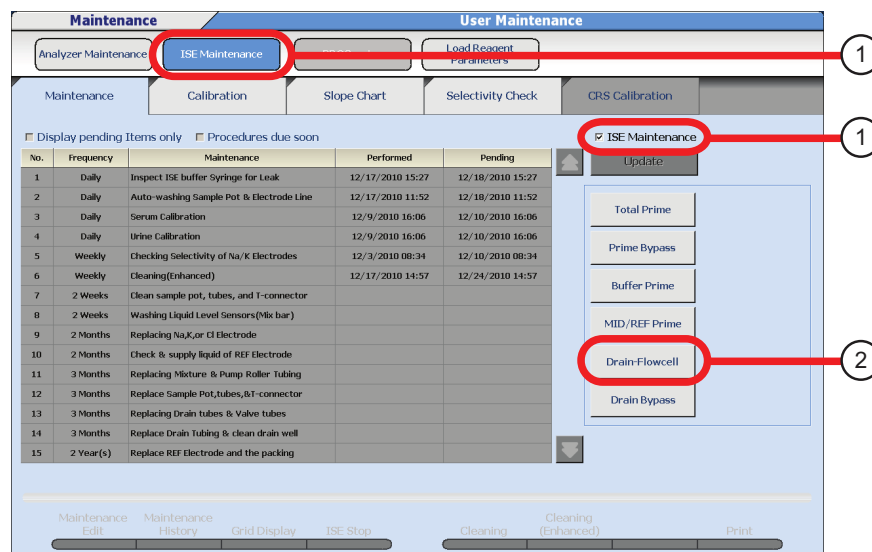
Prepare the ISE for maintenance

CAUTION

- Always prepare the system for maintenance procedures which require the ISE to be taken apart. This procedure keeps liquid from being dispensed while tubing is disconnected.
- Be aware that the ISE primes MID Standard through the electrodes every hour. Perform the following procedures to prevent any MID Standard from dispensing from the nozzles during the periodic priming cycle.

- 1 Verify that the analyzer is in the *Warm up* or *Standby* mode.
- 2 Select **Home > Analyzer Maintenance > ISE Maintenance**.
- 3 Place a check mark in the box next to the ISE Maintenance option. The maintenance operation buttons become functional.

Figure 8.102



1. ISE Maintenance
2. Drain Flowcell

- 4 Select **Drain Flowcell** from the ISE maintenance operation button, and then **OK**.

- 5 Open the ISE unit cover.

-
- 6** Press the TABLE ROTATION/DIAG button once. The liquid is drained from the electrodes.
-

TIP Select **Drain Flowcell** and then press the TABLE ROTATION/DIAG button. The first time this button is pressed, liquid is drained from the electrodes. Each additional time the button is pressed, MID solution is primed through the electrodes.

Replace the Tubing between Sample Pot, Electrode Unit, and T-Connector

- 1** Disconnect the mixing unit liquid level sensors connector 714 and mixing motor connector 706.
-
- 2** Loosen the knob securing the mixing unit. Gently lift the mixing unit to dismount it and place it on the mixing unit holder.
-
- 3** Loosen the retaining screw securing the sample pot, and lift the pot from the peg.
-
- 4** Follow the tubing from the bottom of the sample pot to its connection at the top of the flowcell. Disconnect the tubing from the flowcell.
-
- 5** Follow the bypass tubing #5 from the T-connector to its junction with the pinch valve tubing. Disconnect the bypass tubing from the pinch valve tubing.
-
- 6** Unscrew the tubing connected to the bottom of the sample pot, and discard the tubing.
-
- 7** Attach the new set of tubing to the sample pot by screwing on the silver connector.
-
- 8** Connect the new set of tubing to the top of the flowcell, and then to the pinch valve tubing.
-
- 9** Attach the tubing to the sample pot by screwing on the silver connector.
-

 **CAUTION**

To connect the T-connector and tubing, push them all the way so each joint does not leak. To attach the tubing to the bottom of the sample pot, finger-tighten the silver connector.

- 10** Return the sample pot to its position. Align the hole on the top of the sample pot with the peg and slide the screw post into the groove on the opposite side. Tighten the screw.
-

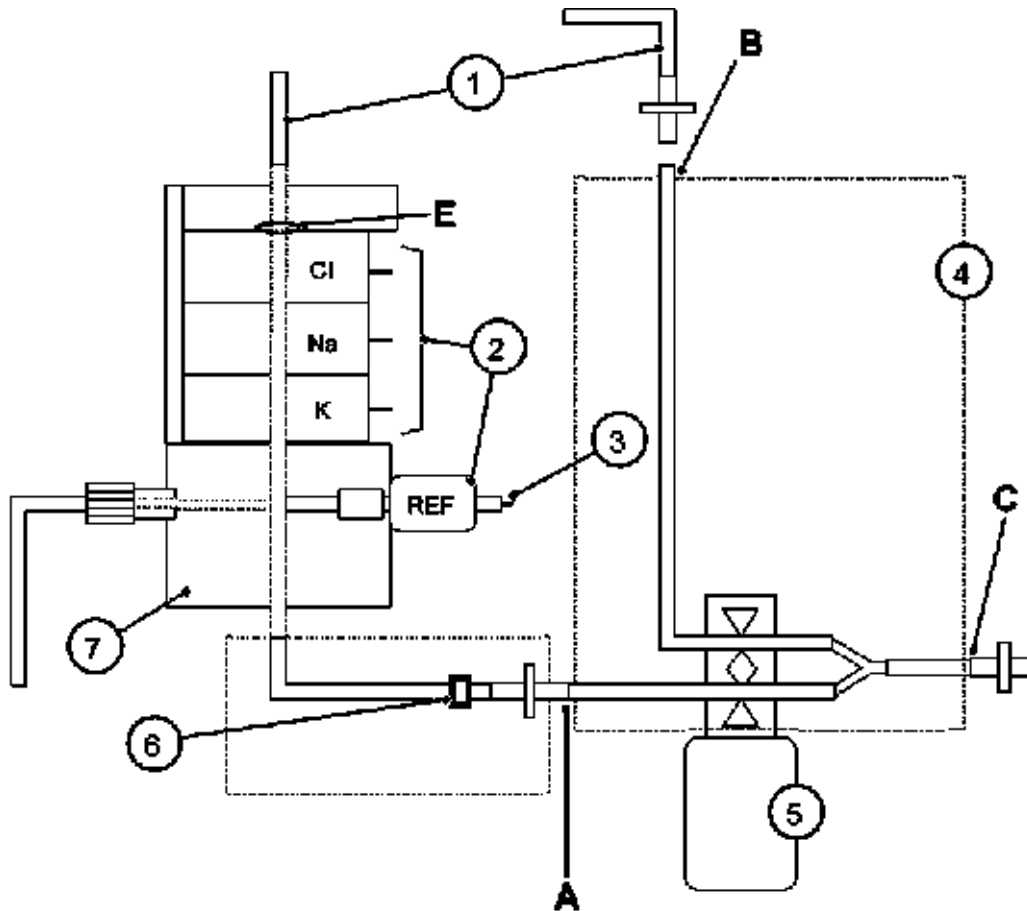
-
- 11** Replace the mixing unit on the two positioning pins. Tighten the knob to secure the mixing unit.
-
- 12** Reconnect the mixing unit liquid level sensors connector 714 and mixing motor connector 706.
-
- 13** Confirm that **Drain Flowcell** is selected.
-
- 14** Press the TABLE ROTATION/DIAG button. Confirm that liquid properly drains from the sample pot to the electrode unit, by verifying that no bubbles come from the bottom of the flowcell in the tubing labeled “6”. Repeat the prime by pressing the TABLE ROTATION/DIAG button again if necessary.
-
- 15** Close the ISE cover.
-
- 16** Close the main analyzer cover.
-
- 17** Deselect the check box next to ISE Maintenance.
-
- 18** Update the maintenance record.
- Replace sample pot, tubes & T-connector
- For details on updating the maintenance record, refer to [Update the Maintenance Log](#) in section [8.1.2 Maintenance Log](#) in this chapter.
-
- 19** Perform a calibration after the maintenance procedure to verify the ISE is running properly.
-

8.16.3 Replace the REF Electrode Block-side Drain Tube and Pinch Valve Tubing

If the REF electrode block-side drain tube and the pinch valve tubing are used for an extended period of time, the tubing may deteriorate. Beckman Coulter recommends to replace the REF electrode block-side drain tube and pinch valve tubing every three months or every 20,000 samples.

Refer to [8.11 ISE Tubing Block Diagram](#) for additional information.

Figure 8.103



- | | |
|---|---|
| 1. Tubing between the sample pot and electrode block (tube set) | 5. Pinch valve |
| 2. Electrodes | 6. REF block-side drain tube set (Mark band No.6) |
| 3. REF electrode wire (green) | 7. REF electrode block |
| 4. Pinch valve tubing | |

Refer to [8.10 ISE Parts Used for ISE Maintenance](#) for a complete list of part numbers.

Materials needed for this procedure:

- Tube Set 2
- Pinch Valve Tubing

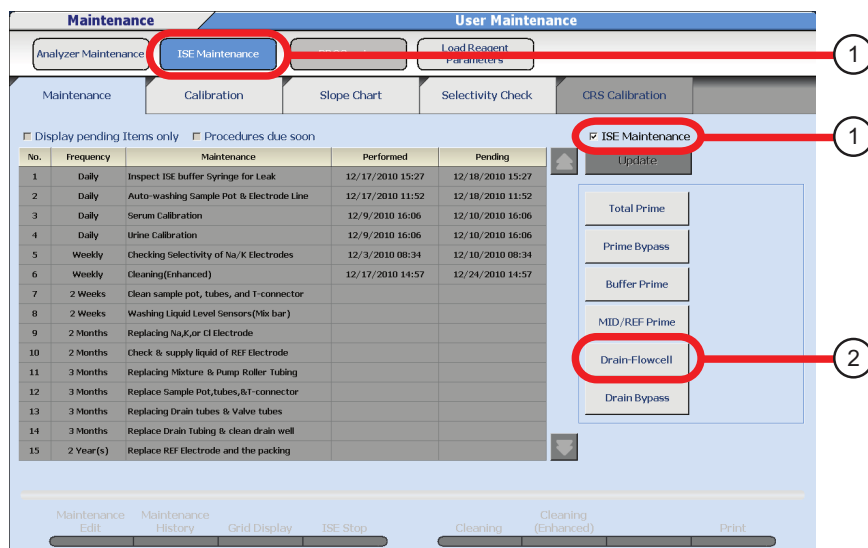
Prepare the ISE for maintenance

CAUTION

- Always prepare the system for maintenance procedures which require the ISE to be taken apart. This procedure keeps liquid from being dispensed while tubing is disconnected.
- Be aware that the ISE primes MID Standard through the electrodes every hour. Perform the following procedures to prevent any MID Standard from dispensing from the nozzles during the periodic priming cycle.

- 1 Verify that the analyzer is in the *Warm up* or *Standby* mode.
- 2 Select **Home > Analyzer Maintenance > ISE Maintenance**.
- 3 Place a check mark in the box next to the ISE Maintenance option. The Maintenance operation buttons become functional.

Figure 8.104



1. ISE Maintenance
2. Drain Flowcell

- 4 Select **Drain Flowcell** from the ISE maintenance operation button, and then **OK**.

- 5 Open the main analyzer cover.

6 Open the ISE cover.

7 Press the TABLE ROTATION/DIAG button once. The liquid is drained from the electrodes.

TIP Select **Drain Flowcell** and then press the TABLE ROTATION/DIAG button. The first time this button is pressed, liquid is drained from the electrodes. Each additional time the button is pressed, MID solution is primed through the electrodes.

Replace the REF Electrode Block-side Drain Tubing

1 Move the lock lever to the left to release the electrode stack.

2 Disconnect the green REF electrode wire.

3 Gently lift up the REF electrode block.

4 While holding the REF electrode block, disconnect Tube Set 2. Tube Set 2 is the tubing labeled #6 from the REF electrode block and connected to the pinch valve tubing. Refer to [Figure 8.103](#).

5 Attach a new Tube Set 2 by connecting the tubing labeled #6 to the REF electrode block and the pinch valve tubing.

6 Set the REF electrode block in the original position and reconnect the green REF electrode wire.

7 Align the electrodes in a straight stack with the electrode pegs in the holes, and move the lock lever to the right to securely hold the stack.

Replace the Pinch Valve Tubing

1 Remove the pinch valve tubing from the pinch valve grooves by pulling out and then up.

2 Refer to the diagram at the beginning of this procedure. Disconnect the pinch valve tubing at the three connections labeled A, B, and C.

-
- 3 Replace the pinch valve tubing by connecting the short end to position C in the diagram, the shorter of the two remaining pieces of tubing to position A, and the longest tubing to position B.

**CAUTION**

Mount the shorter tubing in the bottom groove of the pinch valve (between A and C in the tubing block diagram). Mount the longer tubing in the top groove of the pinch valve (between B and C in the tubing block diagram). Refer to [8.11 ISE Tubing Block Diagram](#).

-
- 4 Insert pinch valve tubing A and B into the grooves of the pinch valve. Verify that the tubing is inserted all the way into the groove. According to the diagram, put tubing labeled "6" into position A (bottom groove of pinch valve), and put tubing labeled "5" into position B (top groove of pinch valve).
 - 5 Confirm that **Drain Flowcell** has been selected from the ISE Maintenance buttons.
 - 6 Press the TABLE ROTATION/DIAG button. The two roller pumps are activated to prime liquid through the ISE. Repeat this prime until all air bubbles are cleared from the tubing labeled "6". This may require as many as five repetitions.
 - 7 Close all the covers.
 - 8 Deselect the check box next to ISE Maintenance to exit the menu.
 - 9 Update the maintenance record.
 - Replace Drain tubes & Valve tubes
-

For details on updating the maintenance record, refer to [Update the Maintenance Log](#) in section [8.1.2 Maintenance Log](#) in this chapter.

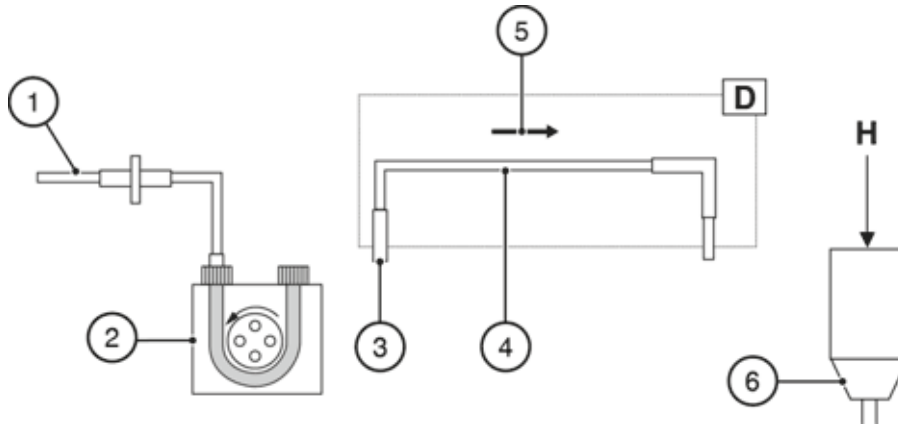
8.16.4 Manually Clean the Drain Well and if Needed, Replace the Drain Tube

If the system analyzes samples that contain large amounts of fibrin and protein, it may accumulate near the drain tube outlet and drain well, possibly causing errors.

Manually clean the drain well quarterly, and replace the drain tube as needed.

Refer to [8.11 ISE Tubing Block Diagram](#) for additional information.

Figure 8.105



- | | |
|---|-------------------------------------|
| 1. Pinch valve tubing | 4. Drain Tube |
| 2. Roller pump (for mixture aspiration) | 5. Flow direction of waste solution |
| 3. Tube joint #3 | 6. Drain well |

Refer to [8.10 ISE Parts Used for ISE Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

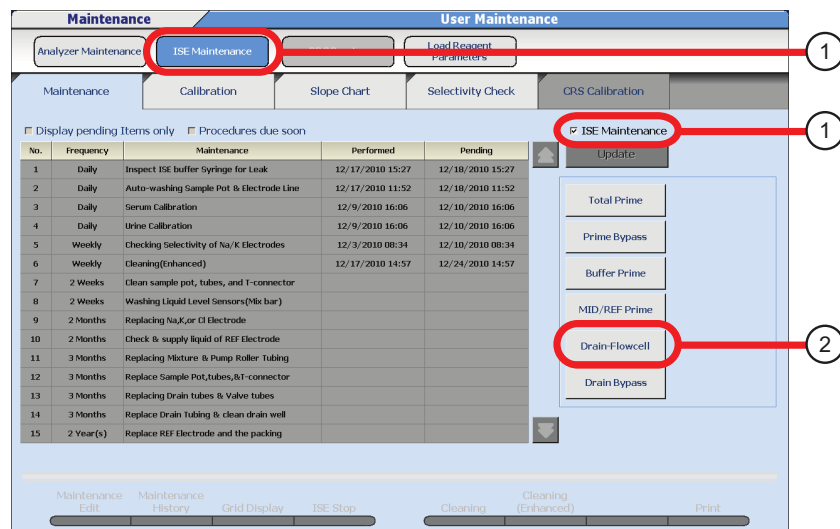
- Drain Tube 2
- Sodium hypochlorite solution (0.5%)

Prepare the ISE for maintenance

- 1 Verify that the analyzer is in the *Warm up* or *Standby* mode.
- 2 Select **Home > Analyzer Maintenance > ISE Maintenance**.

- 3 Place a check mark in the box next to ISE Maintenance option. The maintenance operation buttons become functional.

Figure 8.106



1. ISE Maintenance
2. Drain Flowcell

- 4 Select **Drain Flowcell**, then **OK**.

- 5 Open the main analyzer cover.

- 6 Open the ISE cover.

- 7 Press the TABLE ROTATION/DIAG button once. The liquid is drained from the electrodes.

Clean the Drain Well

- 1 Remove the waste station from the hook over the drain well. Refer to the diagram (block D) in [Figure 8.105](#).

 **CAUTION**

When handling sodium hypochlorite, wear personal protective gear and gloves to avoid contact with the sodium hypochlorite solution.

If hands or clothing come into contact with the sodium hypochlorite solution, immediately wash the solution off with water. Should any sodium hypochlorite solution get in the eyes or mouth, immediately rinse with water and consult a physician.

- 2 Prepare approximately 50 mL of sodium hypochlorite solution (0.5%).
 - 3 Refer to the diagram ([Figure 8.105](#) position H) at the beginning of this procedure. Pour the sodium hypochlorite solution (0.5%) into the drain well directly from the top.
 - 4 Allow the sodium hypochlorite solution (0.5%) to sit for approximately 10 minutes, and then pour a sufficient amount of DI water into the drain well to rinse out the sodium hypochlorite solution.
 - 5 Inspect the drain tube by verifying the tubing is clear (transparent) and checking for internal surface damage. If the drain tube appears opaque or damaged, replace it with a new drain tube.
-

 **CAUTION**

Verify the drain tube is securely connected to the mixture aspiration pump tubing and waste station so leaks do not occur.

- 6 Replace the waste station over the drain well.
- 7 Press the TABLE ROTATION/DIAG button to re-prime the lines with MID standard. Verify there are no bubbles present in tubing labeled "6." Press the TABLE ROTATION/DIAG button to repeat until all bubbles are cleared from the line.
- 8 Close the ISE cover.
- 9 Close the main analyzer cover.

10 Deselect the check box next to ISE Maintenance to exit the menu.

11 Update the maintenance record.

- Clean Drain well, if needed Replace Tube.

For details on updating the maintenance record, refer to [Update the Maintenance Log](#) in section [8.1.2 Maintenance Log](#) in this chapter.

8.17 ISE Maintenance Every Six Months or Every 40,000 Samples

8.17.1 Replace the Na, K, or Cl Electrode

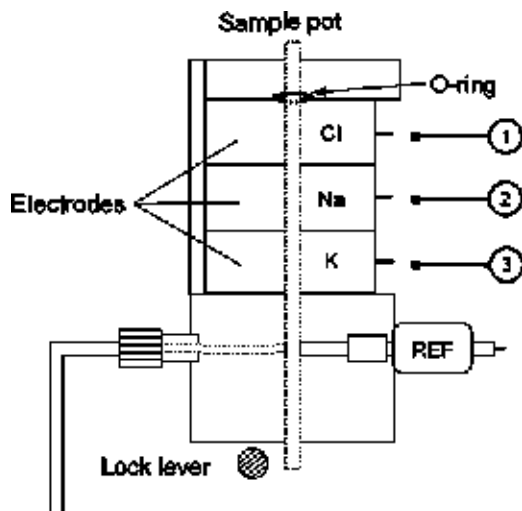
8.17.1 Replace the Na, K, or Cl Electrode

If the electrodes have deteriorated, appropriate analysis results cannot be obtained. Replace the electrode when calibration or Selectivity Check results are out of range, and troubleshooting has been performed. Electrode performance is under guarantee for 40,000 samples or 6 months, whichever comes first, on the condition that calibration and Selectivity Check results are in range.

Replacing the electrode at the guarantee period ensures continuous and reliable electrode performance without unexpected analyzer down-time.

Refer to [8.11 ISE Tubing Block Diagram](#) for additional information.

Figure 8.107



1. Cl electrode wire (blue)
2. Na electrode wire (yellow)
3. K electrode wire (red)

Refer to [8.10 ISE Parts Used for ISE Maintenance](#) for a complete list of part numbers.

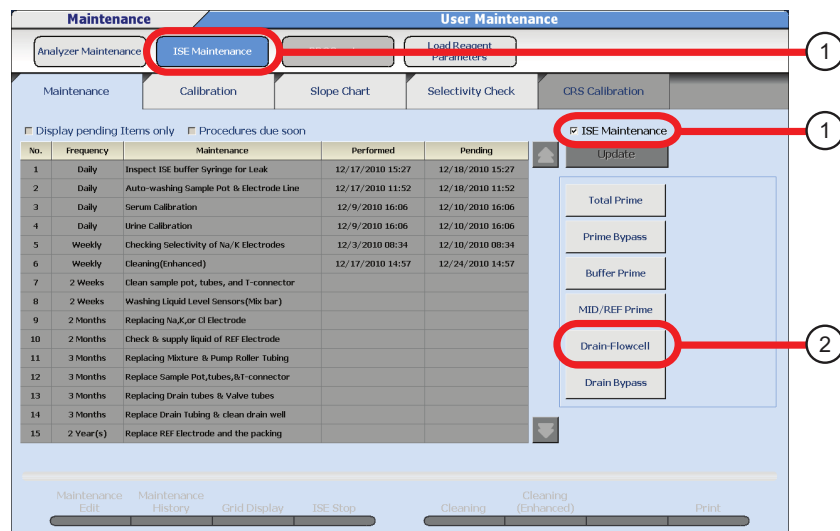
Materials needed for this procedure:

- Na Electrode
- K Electrode
- Cl Electrode
- O-ring

Prepare the ISE for maintenance

- 1 Verify that the analyzer is in the *Warm up* or *Standby* mode.
- 2 Select **Home > Analyzer Maintenance > ISE Maintenance**.
- 3 Place a check mark in the box next to ISE Maintenance option. The maintenance operation buttons become functional.

Figure 8.108



1. ISE Maintenance
2. Drain Flowcell

- 4 Select **Drain Flowcell** from the ISE maintenance operation button, and then **OK**.
- 5 Open the main analyzer cover.
- 6 Open the ISE cover.

-
- 7** Press the TABLE ROTATION/DIAG button. The liquid is drained from the flowcell.



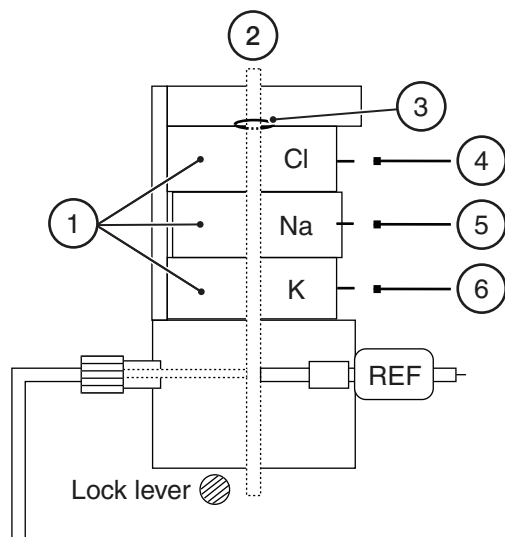
Always drain the flowcell before moving the lock lever to release the electrode stack. If the solution is not drained, REF reagent can flow up into the electrode stack and adversely affect the electrode measuring capability. REF reagent only flows past the REF electrode (not Na, K, or Cl electrode) in normal operation. REF is more concentrated than the MID standard reagent or samples that flow through the flowcell stack.

-
- TIP** Select Drain Flowcell and then press the TABLE ROTATION/DIAG button. The first time this button is pressed, liquid is drained from the flowcell. Each additional time the button is pressed, MID solution is primed through the flowcell.

Replace the Na, K, and Cl Electrodes

- 1 Move the lock lever to release the electrode stack.
- 2 Remove the three electrodes.

Figure 8.109



- | | |
|---------------|-------------------------------|
| 1. Electrodes | 4. Cl electrode wire (blue) |
| 2. Sample pot | 5. Na electrode wire (yellow) |
| 3. O-ring | 6. K electrode wire (red) |

- 3 Disconnect the lead wires from each of the electrodes.

CAUTION

Each electrode has an O-ring. Be careful not to lose the O-rings when mounting the electrodes. An additional O-ring is seated in the top of the flowcell, next to the Cl electrode. Verify all four O-rings are in place before using the lock lever to secure the electrodes. The O-rings are necessary to create an airtight seal for the flowcell.

- 4 Replace the failed electrode with a new one.
- 5 Connect the blue wire to the Cl electrode, yellow wire to the Na electrode, and red wire to the K electrode.
- 6 Verify that the green wire is connected to the reference electrode.

-
- 7** Before mounting the electrodes, wipe the electrode block with a clean, dry lint-free cloth.
-
- 8** Mount the three electrodes on the electrode block. Mount the electrodes according to the label of Cl, Na, and K from the sample pot side to the reference block side.
-
- 9** Push the lock lever to secure the electrodes.
-
- 10** Press the TABLE ROTATION/DIAG button to re-prime the lines with MID solution. After the cycle is complete, press the button a minimum of four more times (five primes total). Confirm that liquid is properly aspirated from the sample pot to the flowcell by verifying that no bubbles are present in the tubing labeled “6” coming from the bottom of the flowcell.
- TIP** If bubbles are present after priming MID Standard, verify the stack of electrodes is in a straight stack and properly secured with the lock lever.
-
- 11** Close the ISE cover.
-
- 12** Close the main analyzer cover.
-
- 13** Deselect the check box next to ISE Maintenance to exit the menu.
-
- 14** Update the maintenance record.
Select the performed maintenance task from Maintenance Log.
- Replacing the Na, K, or Cl Electrode
-
- 15** Select **Update**. The Update window opens.
-
- 16** Select **OK**.
For details on updating the maintenance record, refer to [Update the Maintenance Log](#) in section [8.1.2 Maintenance Log](#) in this chapter.
-
- 17** Allow at least five minutes after closing the main cover, and then perform calibration.
-

 **CAUTION**

To obtain the best possible analysis data, perform two calibration measurements to confirm the electrode stability.

If the difference in factor value between the first and second calibrations is within the following values, the electrodes are stable. The MID solution concentrations in the following table are those that have been set from the System Maintenance menu.

	Na	K	Cl
MID Standard concentration	140	4.0	100
Difference between 1st and 2nd factors	0.020	0.045	0.025

- If the difference between the factor values is not within each value shown above, or if the slope result is 0 at the first calibration:
There is a possibility that air remains inside the flowcell. First, open the main cover and ISE cover.
 - Select **Home > Analyzer Maintenance > ISE Maintenance**.
 - Place a check mark in the box next to ISE Maintenance option.
 - Select **MID/REF Prime**, press the TABLE ROTATION/DIAG button.
 - Repeat the ISE calibration two more times and compare the results to the chart.
- If slope results are 0 for both calibrations:
The electrodes might not be set correctly. Remove the electrodes once, then repeat steps 1 through 13 in the above maintenance procedure.

8.18 ISE Maintenance Every Two Years or Every 150,000 Samples

8.18.1 Replace the ISE REF Electrode and Packing

8.18.1 Replace the ISE REF Electrode and Packing

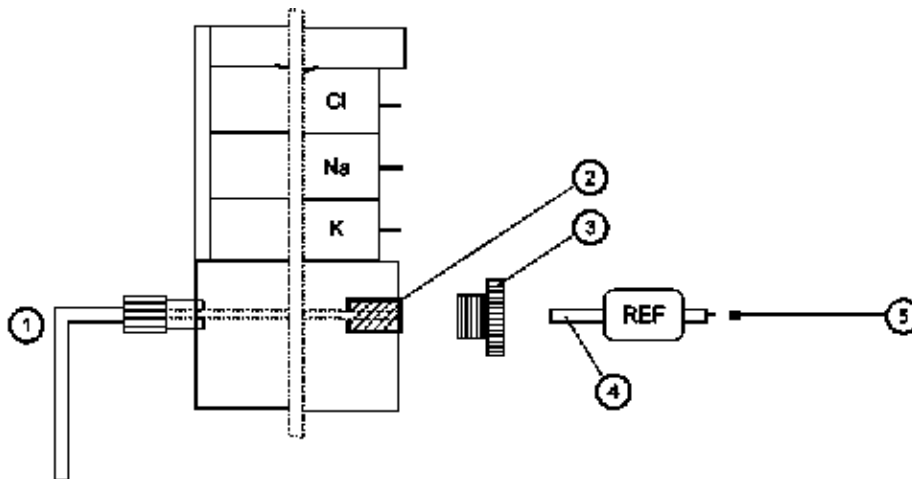
Replace the electrode when calibration or Selectivity Check results are out of range for Na, K, and Cl, or the Na, K, and Cl results fluctuate significantly higher or lower than the previous measurement, and troubleshooting has been performed. Electrode performance is under guarantee for two years or 150,000 samples, whichever comes first.

Replacing the electrode at the guarantee period ensures continuous, reliable electrode performance without unexpected analyzer down-time.

If all calibration measurement values of Na, K, and Cl fluctuate markedly, higher or lower than previous measurements, or if an alarm message appears on the window, contact Beckman Technical Services.

Refer to [8.11 ISE Tubing Block Diagram](#) for additional information.

Figure 8.110



- | | |
|--------------------------|-------------------------------|
| 1. REF solution | 4. REF electrode |
| 2. REF electrode packing | 5. REF electrode wire (green) |
| 3. Cap screw | |

Replace the REF Electrode and Packing

Refer to [8.10 ISE Parts Used for ISE Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

- REF Electrode (with the packing)
- REF Electrode Packing

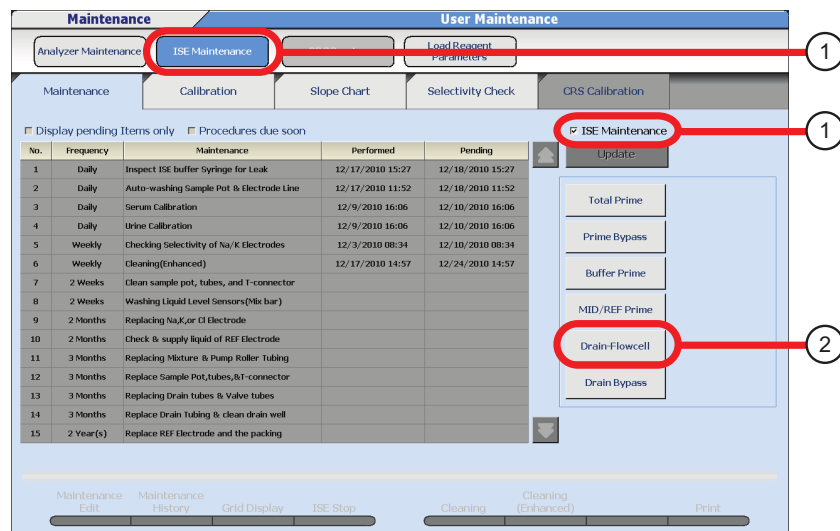
CAUTION

To avoid damage when replacing the REF electrode, do not use force mounting or dismantling the electrode. When dismantling or mounting the electrode, be careful not to break the electrode unit.

Prepare the ISE for maintenance

- 1 Verify that the system is in the *Warm up* or *Standby* mode.
- 2 Select **Home > Analyzer Maintenance > ISE Maintenance**.
- 3 Place a check mark in the box next to ISE Maintenance option. The maintenance operation buttons become functional.

Figure 8.111



1. ISE Maintenance
2. Drain Flowcell

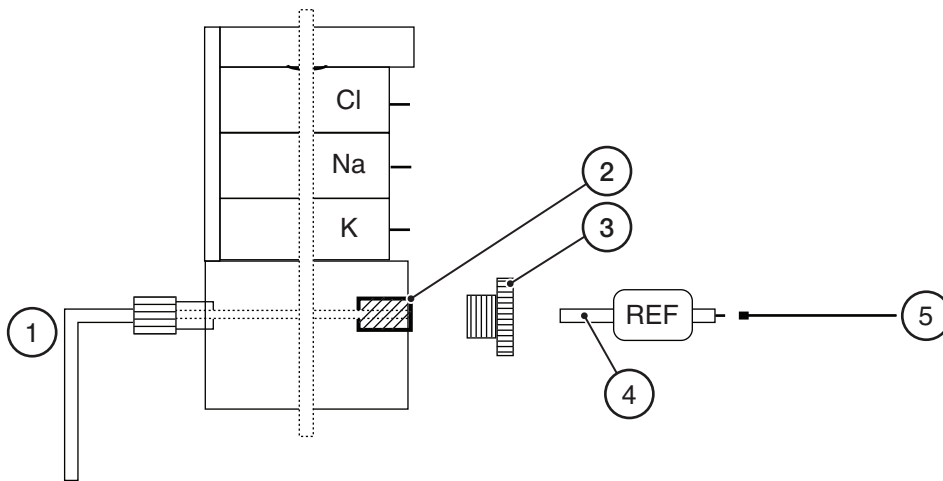
- 4 Select **Drain Flowcell** from the ISE maintenance operation button, and then **OK**.
- 5 Open the main analyzer cover.
- 6 Open the ISE cover.

-
- 7** Press the TABLE ROTATION/DIAG button once. The liquid is drained from the electrodes.
-

Remove the REF Electrode and Packing

- 1** Move the lock lever to release the electrodes.
-
- 2** Remove the Na, K, and CL electrodes from the ISE away from the reference electrode. Any contact of the flowcell with the reference solution can deteriorate the flowcell.
-
- 3** Disconnect the green wire from the REF electrode.
-
- 4** Gently lift the REF electrode block.
-
- 5** Carefully unscrew the REF electrode cap screw, then gently remove the REF electrode along with the cap screw.
-

Figure 8.112



- | | |
|--------------------------|-------------------------------|
| 1. REF solution | 4. REF electrode |
| 2. REF electrode packing | 5. REF electrode wire (green) |
| 3. Cap screw | |

-
- 6** Remove the REF electrode packing.
-

Replace the REF Electrode and Packing

- 1** Verify that no air bubbles are in the electrode tip on a new REF electrode. If air bubbles are found in the tip of the new REF electrode, remove the bubbles by pointing the electrode tip downward and tapping it with a finger.

- 2** Insert new packing into the REF electrode block.

- 3** Place the cap screw on the REF electrode, then place the REF electrode in the REF electrode block so that the electrode tip is centered in the packing.

- 4** Insert the cap screw into the REF electrode block and screw it in carefully. Finish tightening the cap screw by 1/4 to 1/2 turn to orient the REF electrode correctly.
TIP The REF electrode tip can be easily inserted into the packing if it is dampened with DI water.

- 5** Remount the REF electrode block.

- 6** Connect the green REF electrode wire to the REF electrode.

- 7** Wipe the top of the block with a clean, dry lint-free cloth. Rinse reference solution from hands.

- 8** Replace the rest of the flowcell.

- 9** Clamp the lock lever.

- 10** Reconnect the wires to the electrodes.

- 11** Select **MID/REF Prime** from the ISE maintenance operation button, and then **OK**.

- 12** Press the TABLE ROTATION/DIAG button to re-prime the lines with MID solution. After the cycle is complete, press the button a minimum of four more times (five primes total). Confirm that liquid is properly aspirated from the sample pot to the flowcell by verifying that no bubbles are present in the tubing labeled “6” coming from the bottom of the flowcell.

- 13** Deselect the check box next to ISE Maintenance to exit the menu.

14 Update the maintenance record.

- Replace the REF Electrode and Packing

For details on updating the maintenance record, refer to [Update the Maintenance Log](#) in section [8.1.2 Maintenance Log](#) in this chapter.

15 Close the ISE cover.**16** Close the main analyzer cover.**17** Allow at least five minutes after closing the main cover, and then perform calibration analysis.
 **CAUTION**

To obtain the best possible analysis data, perform two calibration measurements to confirm the electrode stability.

If the difference in factor value between the first and second calibrations is within the following values, the electrodes are stable. The MID solution concentrations in the following table are those that have been set from the System Maintenance menu.

	Na	K	Cl
MID Standard concentration	140	4.0	100
Difference between 1st and 2nd factors	0.020	0.045	0.025

- If the difference between the factor values is not within each value shown above, or if the slope result is 0 at the first calibration:

There is a possibility that air remains inside the flowcell. First, open the main cover and ISE cover.

- Select **Home > Analyzer Maintenance > ISE Maintenance**.
- Place a check mark in the box next to ISE Maintenance option.
- Select **MID/REF Prime**, press the TABLE ROTATION/DIAG button.
- Repeat the ISE calibration two more times and compare the results to the chart.

- If slope results are 0 for both calibrations:

The electrodes might not be set correctly. Remove the electrodes once, then repeat steps 1 through 13 in the above maintenance procedure.

8.19 ISE As Needed Maintenance

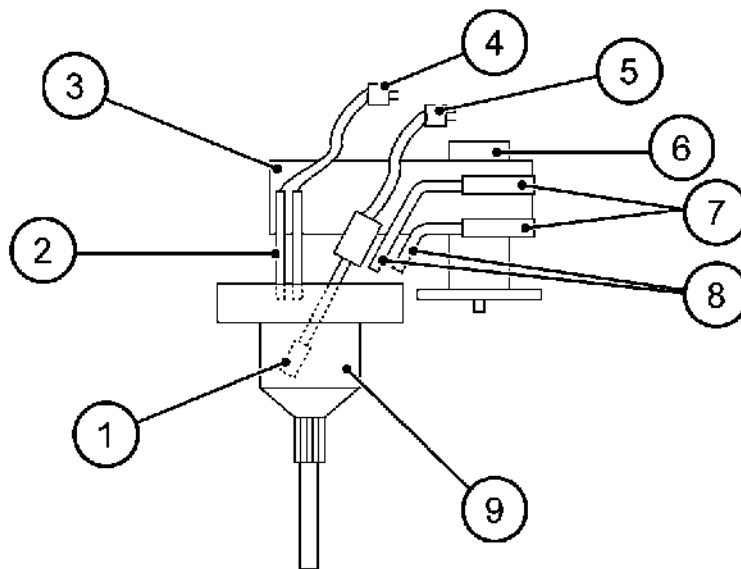
- 8.19.1 Replace the Sample Pot
- 8.19.2 Clean the ISE Electrode Block (Inlet Side)
- 8.19.3 Manually Clean the ISE K Electrode
- 8.19.4 Manually Clean and Replace the ISE REF Electrode Block
- 8.19.5 Replacing ISE Reagents
- 8.19.6 Enhanced ISE Cleaning (Manual)

8.19.1 Replace the Sample Pot

Replace the sample pot if contaminants accumulate and cannot be removed during the bi-weekly cleaning procedure. Also replace the pot if any cracks or flaws are found in the pot.

Refer to [8.11 ISE Tubing Block Diagram](#) for additional information.

Figure 8.113



- | | |
|---------------------------|--|
| 1. Mix bar | 6. Mixing unit knob |
| 2. Liquid level sensor | 7. Buffer solution and MID solution connecting tubes |
| 3. Mixing unit | 8. Nozzles |
| 4. Level sensor connector | 9. Sample pot |
| 5. Mixing motor connector | |

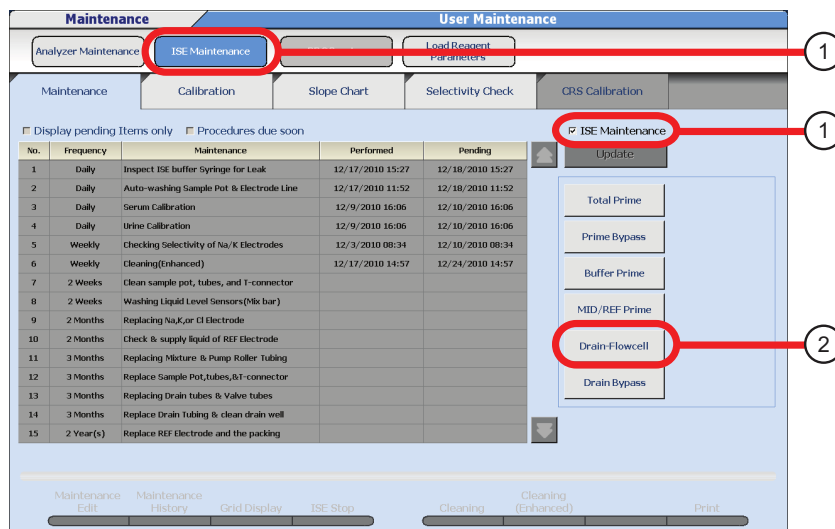
Refer to [8.10 ISE Parts Used for ISE Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

- Sample Pot

Prepare the ISE for maintenance

- 1 Verify that the analyzer is in *Warm up* or *Standby* mode.
- 2 Select **Home > Analyzer Maintenance > ISE Maintenance**.
- 3 Place a check mark in the box next to ISE Maintenance option. The maintenance operation buttons become functional.

Figure 8.114



1. ISE Maintenance
2. Drain Flowcell

- 4 Select **Drain Flowcell** from the ISE maintenance operation button, and then **OK**.
- 5 Open the main analyzer cover.
- 6 Open the ISE cover.
- 7 Press the TABLE ROTATION/DIAG button once. The liquid is drained from the electrodes.

TIP Select **Drain Flowcell** and then press the TABLE ROTATION/DIAG button. The first time this button is pressed, liquid is drained from the flowcell. Each additional time the button is pressed, MID standard is dispensed into the sample pot and through the flowcell.

Replace the Sample Pot

- 1 Disconnect the mixing unit liquid level sensors connector 714 and mixing motor connector 706.

 - 2 Loosen the knob holding the mixing unit. Gently lift the mixing unit to dismount it and place it on the mixing unit holder.

 - 3 Loosen the retaining knob securing the sample pot, and lift the pot from the peg.

 - 4 Disconnect the sample pot from the tubing by twisting the silver connector from the bottom of the sample pot.

 - 5 Reattach the tubing to the new sample pot. Re-install the sample pot.

 - 6 Align the hole on the top of the sample pot with the peg and slide the screw post into the groove on the opposite side. Tighten the screw.

 - 7 Re-install the mixing unit, and then secure the unit by tightening the knob.

 - 8 Reconnect the mixing unit liquid level sensors connector 714 and mixing motor connector 706.

 - 9 Press the TABLE ROTATION/DIAG button. Confirm that the liquid properly dispenses into the sample pot and drains through the flowcell. Verify that no bubbles are present in the tubing labeled "6" coming from the bottom of the flowcell. This may require as many as five repetitions.

 - 10 Close the ISE cover.

 - 11 Close the main analyzer cover.

 - 12 Deselect the check box next to ISE Maintenance to exit the menu.

 - 13 Update the maintenance record.
 - Replacing Sample Pot
-

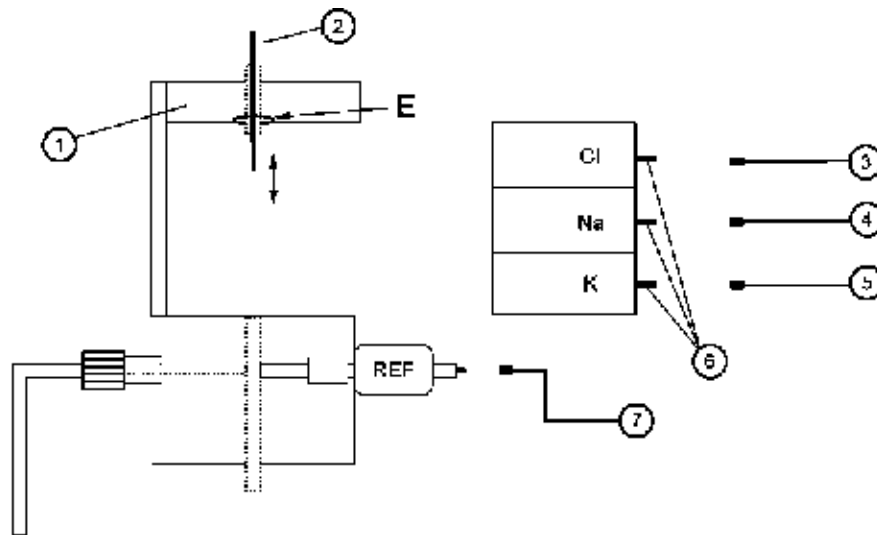
For details on updating the maintenance record, refer to [Update the Maintenance Log](#) in section [8.1.2 Maintenance Log](#) in this chapter.

8.19.2 Clean the ISE Electrode Block (Inlet Side)

Check the inlet side of the electrode block for contaminants that may have accumulated. Perform maintenance to clean the inlet side of the electrode block as needed.

Refer to [8.11 ISE Tubing Block Diagram](#) for additional information.

Figure 8.115



- | | |
|---------------------------------|-------------------------------|
| 1. Electrode block (inlet side) | 5. K electrode wire (red) |
| 2. Stylet | 6. Electrodes |
| 3. Cl electrode wire (blue) | 7. REF electrode wire (green) |
| 4. Na electrode wire (yellow) | |

Refer to [8.10 ISE Parts Used for ISE Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

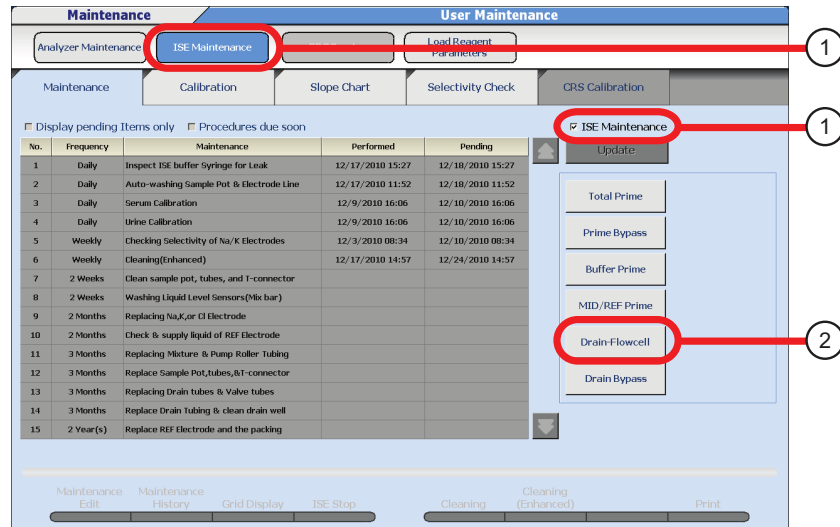
- Stylet

Prepare the ISE for maintenance

- 1 Verify that the analyzer is in the *Warm up* or *Standby* mode.
- 2 Select **Home > Analyzer Maintenance > ISE Maintenance**.

- Place a check mark in the box next to ISE Maintenance option. The maintenance operation buttons become functional.

Figure 8.116



- ISE Maintenance
- Drain Flowcell

- Select **Drain Flowcell** from the ISE maintenance operation button, and then **OK**.

- Open the main analyzer cover.

- Open the ISE cover.

- Press the TABLE ROTATION/DIAG button. The liquid is drained from the flowcell.

TIP Select **Drain Flowcell** and then press the TABLE ROTATION/DIAG button. The first time this button is pressed, liquid is drained from the flowcell. Each additional time the button is pressed, MID standard is dispensed into the sample pot and through the flowcell.

Clean the ISE Electrode Block (inlet side)

- Move the lock lever to release the electrode stack.

-
- 2 Remove the Na, K, and Cl electrodes from the flowcell.



Three O-rings are attached to each side of three electrodes and the metal part (location E in the tubing block diagram) that comes in contact with the Cl electrode. Be careful not to lose the O-rings when removing the electrodes.

-
- 3 Detach the wires connected to the Cl electrode, Na electrode, and K electrode.

-
- 4 Remove the tubing connecting to the sample pot from the electrode block inlet.

-
- 5 Pass the stylet through the flow path hole on the inlet side of the electrode block.
Contamination may lodge in the mixture flow path in the electrode block. Bind the stylet up to the maximum thickness that can pass through the flow path.

-
- 6 Remove contamination in the block by turning the stylet. When contaminants stick on the stylet, wipe them with a clean, dry lint-free cloth several times.

-
- 7 Connect the blue wire, yellow wire, and red wire to the Cl electrode, Na electrode, and K electrode.

-
- 8 Mount the three electrodes on the electrode block.
Attach the electrodes in order of Cl, Na, and K from the sample pot side.

-
- 9 Move the lock lever so that the electrodes are seated in place.

-
- 10 Attach the tubing connecting the sample pot to the electrode block.

-
- 11 Press the TABLE ROTATION/DIAG button. Confirm that liquid properly drains from the sample pot to the flowcell, by verifying that no bubbles are present in the tubing labeled "6" coming from the bottom of the flowcell. This step may need to be repeated as many as five times.

-
- 12 Close the ISE cover.

-
- 13 Close the main analyzer cover.

14 Deselect the check box next to ISE Maintenance to exit the menu.

15 Update the maintenance record.

- Cleaning Block of Electrode

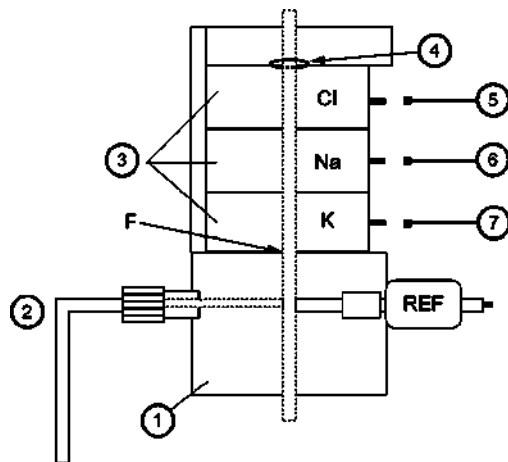
For details on updating the maintenance record, refer to [Update the Maintenance Log](#) in section 8.1.2 [Maintenance Log](#) in this chapter.

8.19.3 Manually Clean the ISE K Electrode

If calibration errors, such as slope readings of 0, occur frequently for the K electrode only, the reference reagent may have contaminated the K electrode. In this situation, perform the manual cleaning of the K electrode.

Refer to [8.11 ISE Tubing Block Diagram](#) for additional information.

Figure 8.117



- | | |
|------------------------|-------------------------------|
| 1. REF electrode block | 5. Cl electrode wire (blue) |
| 2. REF solution | 6. Na electrode wire (yellow) |
| 3. Electrodes | 7. K electrode wire (red) |
| 4. O-ring | |

Refer to [8.10 ISE Parts Used for ISE Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

- Clean dry lint-free cloth

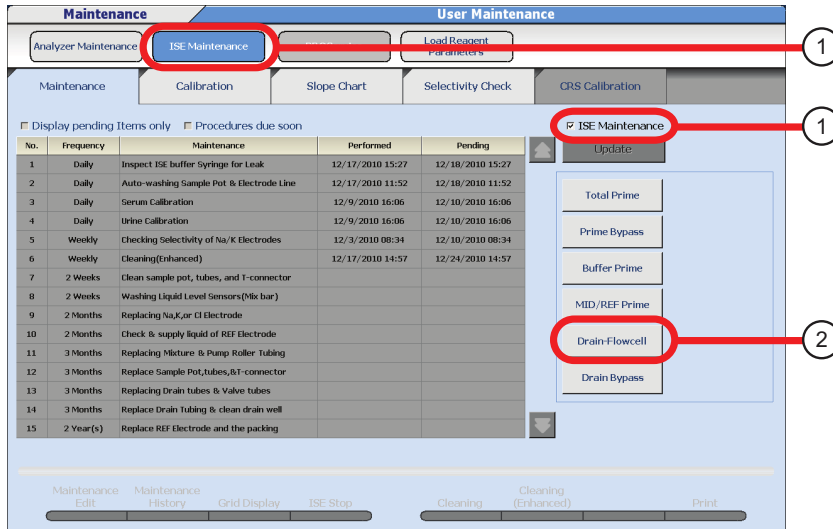
Prepare the ISE for maintenance

1 Verify that the analyzer is in the *Warm up* or *Standby* mode.

2 Select **Home > Analyzer Maintenance > ISE Maintenance**.

3 Place a check mark in the box next to ISE Maintenance option. The maintenance operation buttons become functional.

Figure 8.118



1. ISE Maintenance
2. Drain Flowcell

4 Select **Drain Flowcell** from the ISE maintenance operation button, and then **OK**.

5 Open the main analyzer cover.

6 Open the ISE cover.

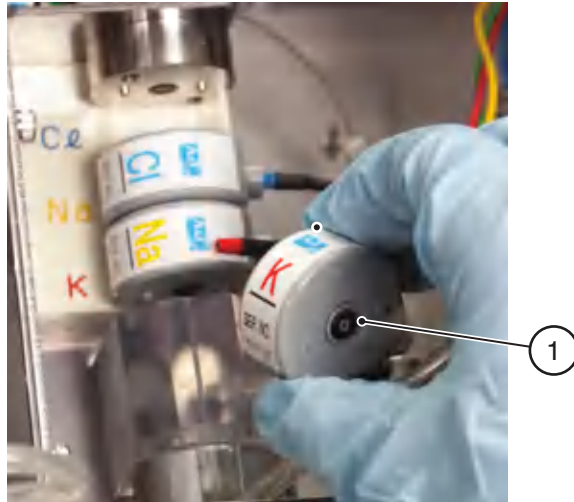
7 Press the TABLE ROTATION/DIAG button. The liquid is drained from the flowcell.

TIP Select **Drain Flowcell** and then press the TABLE ROTATION/DIAG button. The first time this button is pressed, liquid is drained from the flowcell. Each additional time the button is pressed, MID standard is dispensed into the sample pot and through the flowcell.

Manually Clean the K Electrode

- 1 Move the lock lever to release the electrode stack.
-
- 2 Remove the K electrode from the electrode unit.

Figure 8.119



1. O-ring

- 3 Disconnect the lead wire of the K electrode.
-
- 4 Remove the O-ring of the K electrode.
-
- 5 Use a squeeze bottle to dispense DI water to clean the O-ring and O-ring groove of the electrode. DI water that gets into the electrode flow path does not cause a problem.
-
- 6 Wipe the side face (location F in the tubing block diagram) of the REF electrode block in contact with the K electrode using a clean, dry lint-free cloth dampened with DI water.
-
- 7 Using a clean, dry lint-free cloth, sufficiently dry the K electrode, O-ring, and REF electrode block surfaces.
-
- 8 Connect the red lead wire to the K electrode.

9 Remount all electrodes in order.



Three O-rings are included, one for each of the electrodes and one for the top of the flowcell. Be careful not to lose the O-rings when mounting the electrodes.

10 Move the lock lever so that the electrodes are seated in place.

11 Confirm that **Drain Flowcell** from the ISE maintenance operation button has been selected in ISE Maintenance.

12 Press the TABLE ROTATION/DIAG button. Confirm that liquid properly drains from the sample pot to the flowcell, by verifying that no bubbles are present in the tubing labeled “6” coming from the bottom of the flowcell. This step may need to be repeated as many as five times.

13 Close the ISE cover.

14 Close the main analyzer cover.

15 Deselect the check box next to ISE Maintenance to exit the menu.

16 Update the maintenance record.

- Cleaning K-Electrode

For details on updating the maintenance record, refer to [Update the Maintenance Log](#) in section [8.1.2 Maintenance Log](#) in this chapter.

17 Wait at least five minutes before performing calibration analysis.

 **CAUTION**

To obtain the best possible analysis data, perform two calibration measurements to confirm the electrode stability.

If the difference in factor value between the first and second calibrations is within the following values, the electrodes are stable. The MID solution concentrations in the following table are those that have been set from the System Maintenance menu.

	Na	K	Cl
MID Standard concentration	140	4.0	100
Difference between 1st and 2nd factors	0.020	0.045	0.025

- If the difference between the factor values is not within each value shown above, or if the slope result is 0 at the first calibration.

There is possibility that air remains inside the flowcell. First, open the main cover and ISE cover.

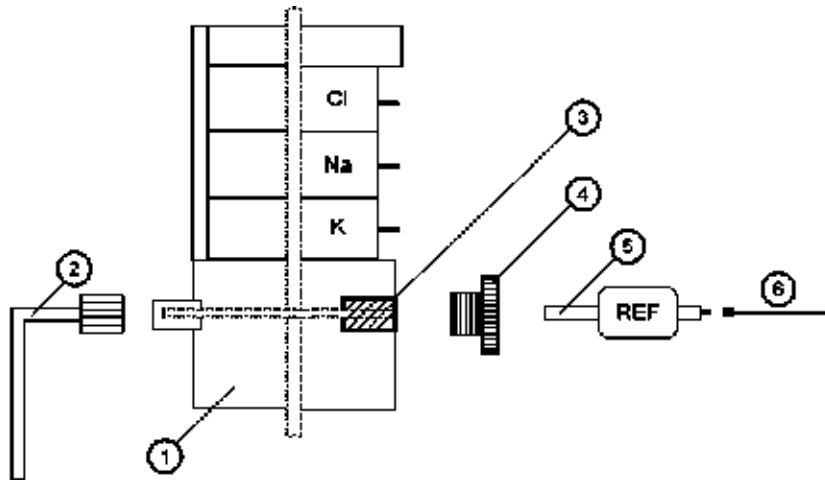
- Select **Home > Analyzer Maintenance > ISE Maintenance**.
- Place a check mark in the box next to ISE Maintenance option.
- Select **MID/REF Prime**, press the TABLE ROTATION/DIAG button.
- Repeat the ISE calibration two more times and compare the results to the chart.
- If slope results are 0 for both calibrations:
The electrodes might not be set correctly. Remove the electrodes once, then repeat steps 9 through 15 in the above maintenance procedure.

8.19.4 Manually Clean and Replace the ISE REF Electrode Block

Data can be adversely affected by the accumulation of contaminants or crystals, a reduction in the flow rate, or noise interference. Manually clean or replace the ISE REF block as needed if indicated by data.

Refer to [8.11 ISE Tubing Block Diagram](#) for additional information.

Figure 8.120



- | | |
|--------------------------|-------------------------------|
| 1. REF electrode block | 4. Cap screw |
| 2. REF solution tubing G | 5. REF Electrode |
| 3. REF electrode packing | 6. REF electrode wire (green) |

Refer to [8.10 ISE Parts Used for ISE Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

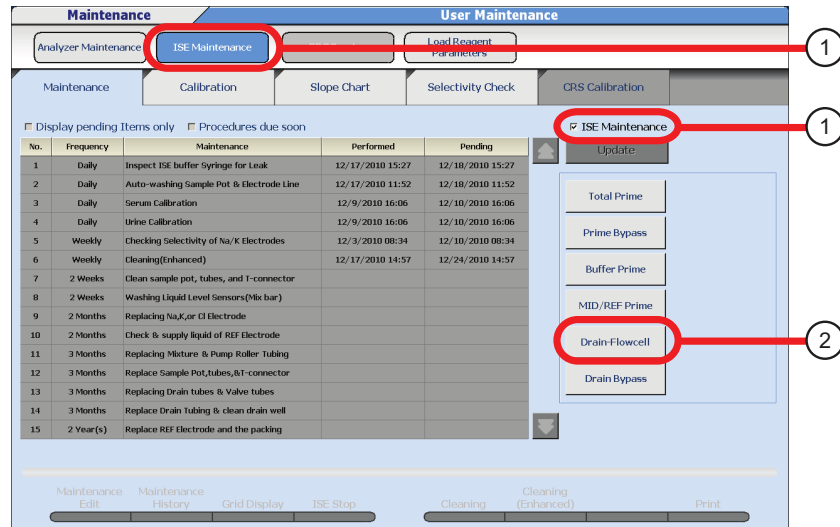
- REF Electrode Block
- Wash Solution

Prepare the ISE for maintenance

- 1 Verify that the analyzer is in the *Warm up* or *Standby* mode.
- 2 Select **Home > Analyzer Maintenance > ISE Maintenance**.

- Place a check mark in the box next to ISE Maintenance option. The maintenance operation buttons become functional.

Figure 8.121



- ISE Maintenance
- Drain Flowcell

- Select **Drain Flowcell** from the ISE maintenance operation button, and then **OK**.

- Open the main analyzer cover.

- Open the ISE cover.

- Press the TABLE ROTATION/DIAG button. The liquid is drained from the flowcell.

TIP Select **Drain Flowcell** and then press the TABLE ROTATION/DIAG button. The first time this button is pressed, liquid is drained from the flowcell. Each additional time the button is pressed, MID standard is dispensed into the sample pot and through the flowcell.

Clean and Replace the REF Electrode Block

- Move the lock lever to release the electrode stack.

-
- 2 Disconnect the Na, K, and Cl lead wires, and remove the electrodes from the electrode block. If REF solution comes into contact with the electrode stack, all 3 electrodes can become contaminated.

 - 3 Gently lift up the block on which the REF electrode is mounted.

 - 4 Disconnect the REF electrode wire (green) from the REF electrode.

 - 5 Loosen the cap screw on the REF electrode and gently remove the electrode along with the cap screw. Remove the REF electrode packing in the block.

 - 6 While holding the REF electrode block by hand, pull the waste liquid drain tubing out of the REF electrode block.

 - 7 Remove the REF solution tubing (location G in the tubing block diagram) connected to the lower side of the REF electrode block. Dismount the REF electrode block.

 **CAUTION**

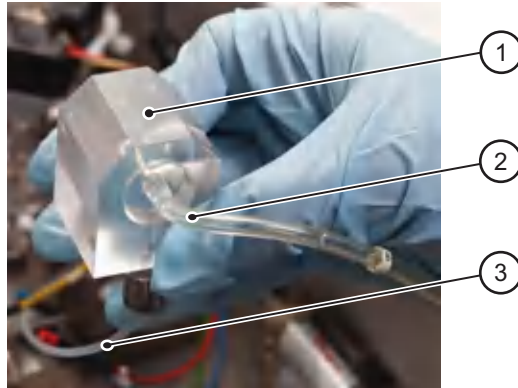
To prevent the REF electrode block from becoming deformed due to ultrasonic cleaning, follow these precautions. If the REF electrode block has been deformed or cracked, replace it.

- **Do not perform ultrasonic cleaning for more than ten minutes.**
- **Use a cleaning liquid at room temperature.**
- **Use a sonicator rated at 600W or less. If the output of the sonicator is uncertain, contact the manufacturer of the sonicator.**

-
- 8 To clean the REF electrode block, sonicate for 10 minutes in 2% wash solution. If a sonicator is not available, soak it in the 2% wash solution for more than 30 minutes. Make sure that 2% wash solution can flow through the flow path in the REF electrode block.

- 9 Thoroughly rinse the REF electrode block in DI water, and dry with a clean, dry lint-free cloth. Obtain a new REF electrode block if replacing it.

Figure 8.122



1. REF electrode block
2. Waste liquid drain tubing
3. REF solution tubing

- 10 Attach the waste liquid drain tubing and the REF solution tubing (location G in the tubing block diagram) to the clean or a new REF electrode block.

- 11 Verify that no air bubbles are in the REF electrode tip. If air bubbles are found in the tip, remove the bubbles by pointing the electrode tip downward while tapping it with a finger.

- 12 Insert the REF electrode packing into the REF electrode block. Verify that the packing is not cracked or broken. If so, replace the packing.

- 13 Place the cap screw on the REF electrode, then place the REF electrode in the REF electrode block so that the electrode tip is centered in the packing.

- 14 Insert the cap screw into the REF electrode block and thread it in carefully. Finish tightening the cap screw by 1/4 to 1/2 turn to orient the REF electrode correctly.

TIP The REF electrode tip can be easily inserted into the packing if it is dampened with DI water.

- 15 Remount the REF electrode block.

- 16 Connect the green REF electrode wire to the REF electrode.

-
- 17** Wipe the top of the block. Rinse reference solution from hands.
-
- 18** Replace the Na, K, and Cl electrodes.
-
- 19** Move the lock lever to secure the flowcell.
-
- 20** Attach the Na, K, and Cl lead wires.
-
- 21** Confirm that **Drain Flowcell** is selected from the ISE maintenance operation button.
-
- 22** Press the TABLE ROTATION/DIAG button. Confirm that liquid properly drains from the sample pot to the flowcell, by verifying that no bubbles are present in the tubing labeled “6” coming from the bottom of the flowcell. This step may need to be repeated as many as five times.
-
- 23** Close the ISE cover.
-
- 24** Close the main analyzer cover.
-
- 25** Deselect the check box next to ISE Maintenance to exit the menu.
-
- 26** Update the maintenance record.
- Clean/Replace REF electrode block
-

For details on updating the maintenance record, refer to [Update the Maintenance Log](#) in section [8.1.2 Maintenance Log](#) in this chapter.

8.19.5 Replacing ISE Reagents

Replace the ISE reagents when the on-board stability expires, the reagent is expired, or the quantity of reagent is insufficient. Do not add the old reagent to a new reagent bottle. When the quantity of reagent becomes insufficient, an alarm message is displayed. The number of samples the system is capable of running after the alarm occurs is listed below for each reagent. Replace the reagent before the bottle empties.

- Buffer: 240 samples
- MID: 180 samples
- REF: 600 samples

On-board Stability of Reagents for the ISE Unit

Check the Instruction for Use (IFU) for on-board stability claims.

Refer to [8.10 ISE Parts Used for ISE Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

- Buffer Solution
- MID Solution
- REF Solution

 **CAUTION**

Reference solution is highly concentrated. Do not contaminate other bottles with reference solution.

-
- 1** Open the front, left door of the analyzer.

 - 2** Pull out the reagent bottle to be replaced.

 - 3** Loosen the cap of the reagent bottle, then remove the aspiration tube.

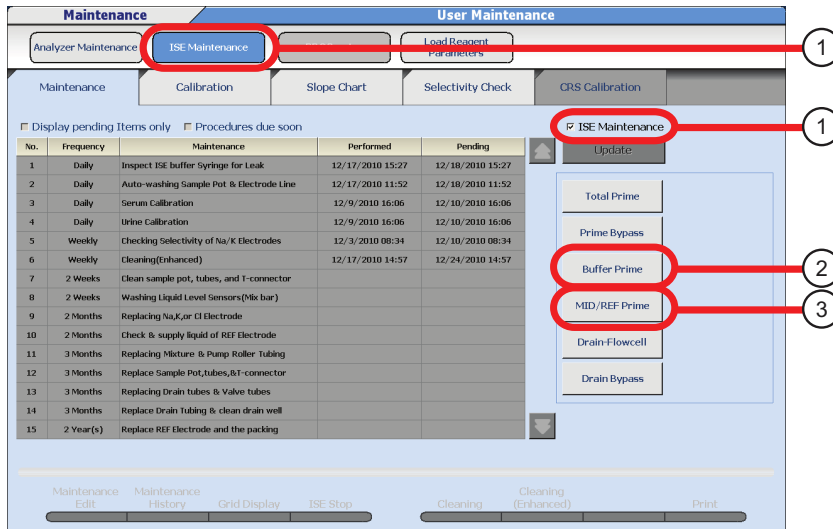
 - 4** Place the aspiration tube in a new bottle, tighten the cap, and place it on the instrument. Dispose of the old solution as waste solution is handled.

 - 5** Push the reagent bottle back into its position.

 - 6** Select **Home > Analyzer Maintenance > ISE Maintenance**.

- Place a check mark in the box next to ISE Maintenance option. The maintenance operation buttons become functional.

Figure 8.123



- ISE Maintenance
- Buffer Prime
- MID/REF Prime

- Select one of the following buttons from the “Maintenance Operation” buttons. If all reagents are being replaced at one time, replace them in the following order:

- For replacing Buffer solution: **Buffer Prime**
- For replacing MID solution: **MID/REF Prime**
- For replacing REF solution: **MID/REF Prime**

- Select **OK**.

- Press the **TABLE ROTATION/DIAG** button. The reagent is primed for approximately 90 seconds.

- Close the analyzer door.

- Deselect the check box next to ISE Maintenance to exit the menu.

13 Update a maintenance record.

- Replace Buffer Solution
 - Replace MID Standard
 - Replace REF Solution
-


For details on updating the maintenance record, refer to [Update the Maintenance Log](#) in section [8.1.2 Maintenance Log](#) in this chapter.

8.19.6 Enhanced ISE Cleaning (Manual)

This method should be used when the ISE calibration slopes are in the mid-to-low forties, or if a build-up/residue is present upon inspection of the sample pot or T-tubing.

Refer to [8.10 ISE Parts Used for ISE Maintenance](#) for a complete list of part numbers. Materials needed for this procedure:

- ISE Cleaning Solution diluted 1:10
- ISE MID Standard reagent
- Pipette (that is commercially available and can collect more than 1 mL of liquid)

 **CAUTION**

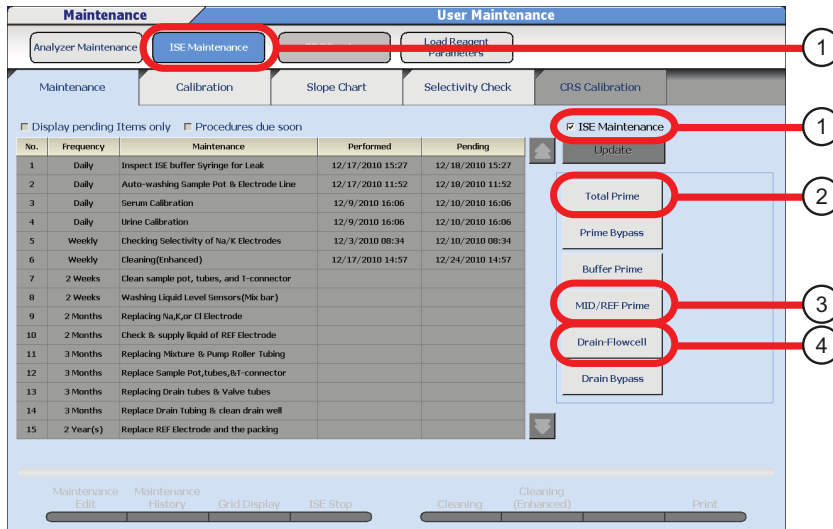
When handling ISE Cleaning Solution, wear personal protective gear and gloves to avoid contact with the ISE Cleaning Solution. If hands or clothing come in contact with the ISE Cleaning Solution, immediately wash the solution off with water. Should any ISE Cleaning Solution get in the eyes or mouth, immediately rinse with water and consult a physician.

1 Verify that the analyzer is in the *Warm up* or *Standby* mode.

2 Select **Home > Analyzer Maintenance > ISE Maintenance**.

- Place a check mark in the box next to ISE Maintenance option. The maintenance operation buttons become functional.

Figure 8.124



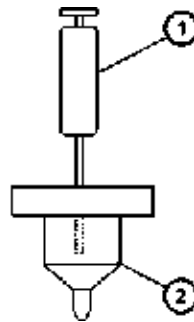
- ISE Maintenance
- Total Prime
- MID/REF Prime
- Drain Flowcell

- Select **Drain Flowcell** from the ISE maintenance operation button, and then **OK**.
- Open the main analyzer cover.
- Open the ISE cover.
- Press the TABLE ROTATION/DIAG button once.
- Loosen the mixing unit knob, lift the mixing unit from the two positioning pins, and place the mixing unit on the mixing unit holder.
- Remove the tubing labeled "5" and "6" from the pinch valve.

-
- 10** For the first 2 minutes, pipette the ISE Cleaning Solution into the ISE sample pot and manually turn the roller pump assembly on the left clockwise until most of the ISE Cleaning Solution empties from the sample pot into the ISE tubing. Continue filling the sample pot with the ISE Cleaning Solution while turning the roller pump assembly.

TIP Do not empty the sample pot completely before adding more ISE Cleaning Solution.
Ensure the tubing is filled with the ISE Cleaning Solution.

Figure 8.125



1. Pipette
2. Sample pot

-
- 11** Let the ISE Cleaning Solution remain in the tubing for 5 minutes.
-
- 12** Manually turn the roller pump to clear the ISE Cleaning Solution from the tubing.
-
- 13** Pipette 10 mL of ISE MID Standard Solution into the sample pot and manually turn the roller pump to clear the MID Standard Solution. Repeat 3-5 times.
-
- 14** Replace the mixing unit and the pinch valve tubing.
-
- 15** Perform a **MID/REF Prime** three to four times.
-
- 16** Perform a **Total Prime**.
-
- 17** Deselect the check box next to ISE Maintenance exit the menu.

18 Calibrate and process QC on the ISE.

TIP If the tubing is not clean after performing this procedure, replace the tubing according to the following procedures:

8.16.2 Replace the Tubing between Sample Pot, Electrode Unit, and T-Connector

8.16.3 Replace the REF Electrode Block-side Drain Tube and Pinch Valve Tubing

8.16.4 Manually Clean the Drain Well and if Needed, Replace the Drain Tube

Error Flags

Error flags are generated by the system when it encounters a condition that can affect the result. This condition can range from minor warnings to severe errors that require immediate attention. It is important that the operator review each flag as it is generated and identifies the root cause, and takes appropriate action.

No result should be reported with an unresolved or unexpected flag. When in doubt, always consider repeating the sample analysis, and diluting/condensing the sample if necessary.

This chapter contains a list of all error flags in order of priority, suggestions of their cause, and action to take.

9.1 Summary of Error Flags (Alphabetical order)

9.2 Summary of Error Flags (In order of priority)

9.3 Error Flag Details

d: QC result is excluded by user

e: Data edited by user

(: Shortage of cleaning solution for contamination parameters

Wa: Result has been analyzed with an erroneous cuvette

R: Insufficient reagent detected

#: Insufficient sample detected

?: Clot detected

?: Unable to calculate a result

n: LIH test not performed

l: Result may be affected by lipemia

i: Result may be affected by icterus

h: Result may be affected by hemolysis

Y: Reagent Blank OD exceeds the high limit set at the last photometric read point

U: Reagent Blank OD exceeds the lower limit set at the last photometric read point

y: Reagent blank/routine OD at first photometric point high

u: Reagent blank/routine OD at first photometric point low

@: OD is higher than 3.0

\$: Not enough data to determine linearity of reaction

D: OD of reaction is higher than the maximum OD range

B: OD of reaction is lower than the minimum OD range
*: Linearity error in rate method
&: Prozone test data is abnormal
Z: Prozone error
E: Overreaction in a rate assay detected
Fx: Result (OD) is higher than the dynamic range
Gx: Result (OD) is lower than the dynamic range
!: Unable to calculate concentration
) : Reagent lot number used for sample analysis is different from the lot number used for RB/Calibration
a: Reagent expired
ba: No calibration data or expired
bh: The latest calibration/RB has not been used
bn: Mastercurve used
bz: Calibration curve for Prozone data used
F: Result is higher than the dynamic range
G: Result is lower than the dynamic range
ph: Result is higher than the upper panic value
pl: Result is lower than the low panic value
T: Abnormality found in inter-chemistry check
P: Positive
N: Negative
H: Result is higher than reference range
L: Result is lower than reference range
J: Result is higher than the repeat decision range
K: Result is lower than the repeat decision range
fh: Result is higher than the repeat run reflex range
fl: Result is lower than the repeat run reflex range
Va: Deviation of multiple measurements check is out of range
xQ: Multi-rule QC has detected failure on one control
1Q: QC data exceeds the range entered in Single Check Level field
2Q: QC data exceeds a 1_{3s} control range
3Q: QC data exceeds 2_{2s} control range
4Q: QC data exceeds R_{4s} control range
5Q: QC data exceeds 4_{1s} control range
6Q: A preset number of consecutive QC results fall on one side of the mean
7Q: Consecutive QC results show steadily increasing or decreasing values
S: Sample repeated and original results replaced by repeat result

/: Test pending or not analyzed

r: Result has been transferred to LIS (HOST Computer) through on-line communication

c: Result corrected by user

9.4 Application of Flags (F, G, p, J, K, H, L, P, and N) During Calculation of Final Result Flowchart

9.1 Summary of Error Flags (Alphabetical order)

The following table summarizes the error flags in alphabetical order:

Flag	Definition	Reference
!	Unable to calculate concentration	9-17
#	Insufficient sample detected	9-9
\$	Not enough data to determine linearity of reaction	9-14
%	Clot detected	9-10
&	Prozone test data is abnormal	9-16
(Shortage of cleaning solution for contamination parameters	9-8
)	Reagent lot number used for sample analysis is different from the lot number used for RB/Calibration	9-18
*	Linearity error in rate method	9-16
/	Test pending or not analyzed	9-27
?	Unable to calculate a result	9-10
@	OD is higher than 3.0	9-13
1Q	QC data exceeds the range entered in Single Check Level field	9-23
2Q	QC data exceeds 1_{3s} control range	9-24
3Q	QC data exceeds 2_{2s} control range	9-24
4Q	QC data exceeds R_{4s} control range	9-25
5Q	QC data exceeds 4_{1s} control range	9-25
6Q	A preset number of consecutive QC results fall on one side of the mean	9-25
7Q	Consecutive QC results show steadily increasing or decreasing values	9-26
a	Reagent expired	9-18
B	OD of reaction is lower than the minimum OD range	9-15
ba	No calibration data or expired	9-18
bh	The latest calibration/RB has not been used	9-19
bn	Mastercurve used	9-19
bz	Calibration curve for Prozone data used	9-19
c	Result corrected by user	9-27
d	QC result is excluded by user	9-8
D	OD of reaction is higher than the maximum OD range	9-14
e	Data edited by user	9-8
E	Overreaction in a rate assay detected	9-17
F	Result is higher than the dynamic range	9-19
fh	Result is higher than the repeat run reflex range	9-22
fl	Result is lower than the repeat run reflex range	9-22

Flag	Definition	Reference
Fx	Result (OD) is higher than the dynamic range	9-17
G	Result is lower than the dynamic range	9-20
Gx	Result (OD) is lower than the dynamic range	9-17
h	Result may be affected by hemolysis	9-11
H	Result is higher than reference range	9-21
i	Result may be affected by icterus	9-11
J	Result is higher than the repeat decision range	9-21
K	Result is lower than the repeat decision range	9-22
l	Result may be affected by lipemia	9-11
L	Result is lower than reference range	9-21
n	LH test not performed	9-10
N	Negative	9-21
P	Positive	9-21
ph	Result is higher than the upper panic value	9-20
pl	Result is lower than the low panic value	9-20
R	Insufficient reagent detected	9-9
r	Result has been transferred to LIS (HOST Computer) through on-line communication	9-27
S	Sample repeated and original results replaced by repeat result	9-26
T	Abnormality found in inter-chemistry check	9-20
U	Reagent Blank OD exceeds the lower limit set at the last photometric read point	9-12
u	Reagent blank/routine OD at first photometric point low	9-13
Va	Deviation of multiple measurements check is out of range	9-22
Wa	Result has been analyzed with an erroneous cuvette	9-9
xQ	Multi-rule QC has detected failure on one control	9-23
Y	Reagent Blank OD exceeds the high limit set at the last photometric read point	9-11
y	Reagent blank/routine OD at first photometric point high	9-12
Z	Prozone error	9-17

9.2 Summary of Error Flags (In order of priority)

The following table summarizes the error flags in order of priority:

Flag	Definition	Reference
d	QC result is excluded by user	9-8
e	Data edited by user	9-8
(Shortage of cleaning solution for contamination parameters	9-8
Wa	Result has been analyzed with an erroneous cuvette	9-9
R	Insufficient reagent detected	9-9
#	Insufficient sample detected	9-9
%	Clot detected	9-10
?	Unable to calculate a result	9-10
n	LIH test not performed	9-10
l	Result may be affected by lipemia	9-11
i	Result may be affected by icterus	9-11
h	Result may be affected by hemolysis	9-11
Y	Reagent Blank OD exceeds the high limit set at the last photometric read point	9-11
U	Reagent Blank OD exceeds the lower limit set at the last photometric read point	9-12
y	Reagent blank/routine OD at first photometric point high	9-12
u	Reagent blank/routine OD at first photometric point low	9-13
@	OD is higher than 3.0	9-13
\$	Not enough data to determine linearity of reaction	9-14
D	OD of reaction is higher than the maximum OD range	9-14
B	OD of reaction is lower than the minimum OD range	9-15
*	Linearity error in rate method	9-16
&	Prozone test data is abnormal	9-16
Z	Prozone error	9-17
E	Overreaction in a rate assay detected	9-17
Fx	Result (OD) is higher than the dynamic range	9-17
Gx	Result (OD) is lower than the dynamic range	9-17
!	Unable to calculate concentration	9-17
)	Reagent lot number used for sample analysis is different from the lot number used for RB/Calibration	9-18
a	Reagent expired	9-18
ba	No calibration data or expired	9-18
bh	The latest calibration/RB has not been used	9-19
bn	Mastercurve used	9-19

Flag	Definition	Reference
bz	Calibration curve for Prozone data used	9-19
F	Result is higher than the dynamic range	9-19
G	Result is lower than the dynamic range	9-20
ph	Result is higher than the upper panic value	9-20
pl	Result is lower than the low panic value	9-20
T	Abnormality found in inter-chemistry check	9-20
P	Positive	9-21
N	Negative	9-21
H	Result is higher than reference range	9-21
L	Result is lower than reference range	9-21
J	Result is higher than the repeat decision range	9-21
K	Result is lower than the repeat decision range	9-22
fh	Result is higher than the repeat run reflex range	9-22
fl	Result is lower than the repeat run reflex range	9-22
Va	Deviation of multiple measurements check is out of range	9-22
xQ	Multi-rule QC has detected failure on one control	9-23
1Q	QC data exceeds the range entered in Single Check Level field	9-23
2Q	QC data exceeds 1_{3s} control range	9-24
3Q	QC data exceeds 2_{2s} control range	9-24
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9.3 Error Flag Details

This chapter contains a list of all error flags in order of priority, suggestions of their cause, and action to take.

d: QC result is excluded by user

QC data has been manually excluded from calculation by the user. This flag is applied in **Menu List > QC > QC Data Review**. For details on excluding QC data, refer to [7.5 Edit Quality Control Data](#) in chapter 7.

Action:

No action is specifically required. Prior to excluding any QC data, investigate and record the cause of the value with the error flag, as dictated by laboratory Standard Operating Procedures.

e: Data edited by user

Data has been edited.

- For details on editing results, refer to [7.6 Edit Analysis Data](#) in chapter 7.
- For details on viewing analysis results, refer to [7.3.2 Display Reaction Monitor](#) in chapter 7.

Action:

No action is specifically required. Review any edited or changed data carefully prior to reporting results, as dictated by laboratory Standard Operating Procedures.

(: Shortage of cleaning solution for contamination parameters

The cleaning solution set for contamination parameters in fixed positions in the reagent refrigerator is empty. Contamination parameters are suspended for the related cleaning solution. Carry-over might have occurred on tests that have this flag.

Action:

1. Fill the cleaning solution bottles.
2. Perform a reagent check on the cleaning solution bottle(s). Refer to [5.5.1 Check Reagent Quantity and Status](#) in chapter 5.
3. Repeat analysis.

Wa: Result has been analyzed with an erroneous cuvette

The result has been analyzed using cuvette(s) which failed photocal criteria.

Action:

1. Clean the affected cuvette and perform a photocal.
Refer to [8.8.13 Clean or Replace Individual Cuvettes](#) and [8.4.3 Perform a Photocal](#).
2. If the error still occurs, replace the cuvette. Refer to [8.8.13 Clean or Replace Individual Cuvettes](#).
3. Repeat analysis.

R: Insufficient reagent detected

Level detection indicates reagent volume not sufficient for analysis.

Action:

1. Review all results generated immediately prior to this flag for consistency and validity (especially low or high results), and repeat if necessary.
2. Place new reagent onto the system and repeat analysis.
3. If the error occurs in spite of sufficient reagent, the reagent bottle may contain bubbles. Remove the bubbles and perform another reagent check.
4. Dry the reagent bottle opening if it is wet. Inspect the reagent probe, and clean or replace as necessary. For details on inspecting, cleaning and priming reagent probe, and wash wells, refer to [8.3.3 Inspect, Clean and Prime the Sample Probe, Reagent Probe, and Mix Bars](#) and [8.5.1 Clean the Sample Probe and Reagent Probe Wash Wells](#) in chapter 8.
5. Verify the reagent probe is correctly installed and connected.

#: Insufficient sample detected

The sample probe cannot detect sufficient sample volume. This is caused by one of the following:

- Insufficient sample volume.
- Malfunction of the sample level detection system.
- Inappropriate sample cup or tube.

Action:

1. Review all other results that were generated on the same sample prior to generating the flag [#] to verify validity and consistency-no extremely low or high values.
2. Wipe the probe with an alcohol prep or 70% Isopropyl alcohol and check the probe to verify that it is installed and connected correctly.
3. Replace the sample probe. For details on replacing a sample probe, refer to [8.8.3 Replace a Sample and Reagent Probe](#) in chapter 8.
4. Add more sample to the sample cup, and repeat the test.
5. Verify an appropriate sample cup or tube is in use. For a list of validated cups and tubes on the AU480, refer to [6.1.1 Sample Cup and Tube Preparation](#) in chapter 6.

%: Clot detected

The sample probe is blocked or partially blocked during sample aspiration.

Action:

1. Review all other results that were generated on the same sample prior to generating the flag [%] to verify validity and consistency-no extremely low or high values.
2. Verify that the sample is free of clots, and remove any present. Follow laboratory Standard Operating Procedures regarding centrifuging samples. Repeat analysis.
3. If the error still occurs, clean or replace the sample probe. Refer to [8.4.1 Clean the Sample Probe and Mix Bars](#) in chapter 8. For details on replacing the sample probe, refer to [8.8.3 Replace a Sample and Reagent Probe](#) in chapter 8.

?: Unable to calculate a result

A result cannot be calculated for this sample because:

- In a rate reaction, fewer than three photometric readings satisfy the assay criteria specified in the specific test parameters.
- Outside of cuvette walls or the cuvette wheel is wet.
- A mechanical error has occurred.

Action:

1. The sample can be severely lipemic, icteric, hemolytic or can contain excessively large amounts of the analyte being tested. Dilute the sample and run the test again.
2. Verify the reagent condition.
3. The system generates an error flag or other alarm identifying the malfunction. Select **Alarm List** for a description of the alarm and corrective actions. Once the problem is solved, repeat analysis.
If the issue persists, contact Beckman Coulter Technical Services.
4. Check the reaction data including those processed immediately before and after the flagged result. In the presence of any abnormality, verify the cuvette wheel is not wet. If the cuvette wheel is wet, take appropriate action to recover. Refer to [11.10 Recovering from a Cuvette Wheel Overflow](#) in chapter 11 and [8.7.1 Clean the Cuvettes and the Cuvette Wheel](#) in chapter 8.

n: LIH test not performed

The LIH test has not been performed for items with LIH influence check set to “Yes” in **Specific Test Parameters**.

Action:

1. Examine the sample and repeat if necessary.
2. Check the LIH reagent.

l: Result may be affected by lipemia

The result may be affected by lipemia or samples are extremely turbid.

Action:

Follow laboratory Standard Operating Procedures for lipemic samples.

i: Result may be affected by icterus

The result may be affected by bilirubin.

Action:

Follow laboratory Standard Operating Procedures for icteric samples.

h: Result may be affected by hemolysis

The result may be affected by hemolysis.

Action:

Follow laboratory Standard Operating Procedures for hemolytic samples.

Y: Reagent Blank OD exceeds the high limit set at the last photometric read point

Reagent blank OD is higher than the reagent OD limit range defined for the last photometric point. This is programmed in **Menu List > Parameters > Specific Test Parameters > General**. This could be caused by:

- Reagent expired.
- Reagent contamination.
- Improperly prepared reagents.
- Incorrect range programmed in **Specific Test Parameters**.

Action:

1. Check the reagent expired and on-board expiration date.
2. Check the reagent condition.
3. Prepare fresh reagent and repeat analysis.
4. Verify the Reagent OD Limit range programmed in **Specific Test Parameters** is correct.

U: Reagent Blank OD exceeds the lower limit set at the last photometric read point

Reagent blank OD is lower than the reagent OD limit range defined for the last photometric point. This is programmed in **Menu List > Parameters > Specific Test Parameters > General**. This could be caused by:

- Reagent expired.
- Reagent contamination.
- Improperly prepared reagents.
- Incorrect range programmed in **Specific Test Parameters**.

Action:

1. Check the reagent expired and on-board expiration date.
2. Check the reagent condition.
3. Prepare fresh reagent and repeat analysis.
4. Verify the Reagent OD Limit range programmed in **Specific Test Parameters** is correct.

y: Reagent blank/routine OD at first photometric point high

The first photometric point OD of the reagent blank or the OD at P0 of normal analysis is higher than the reagent OD limit range defined for the first photometric point. This is programmed in **Menu List > Parameters > Specific Test Parameters > General**. This could be caused by:

- Reagent expired.
- Reagent contamination.
- Improperly prepared reagents.
- Incorrect range programmed in **Specific Test Parameters**.

Action:

1. Check the reagent expired and on-board expiration date.
2. Check the reagent condition.
3. Prepare fresh reagent and repeat analysis.
4. Verify the Reagent OD Limit range programmed in **Specific Test Parameters** is correct.

u: Reagent blank/routine OD at first photometric point low

The first photometric point OD of the reagent blank or the OD at P0 of normal analysis is lower than the reagent OD limit range defined for the first photometric point. This is programmed in **Menu List > Parameters > Specific Test Parameters > General**. This could be caused by:

- Reagent expired.
- Reagent contamination.
- Improperly prepared reagents.
- Incorrect range programmed in **Specific Test Parameters**.

Action:

1. Check the reagent expired and on-board expiration date.
2. Check the reagent condition.
3. Prepare fresh reagent and repeat analysis.
4. Verify the Reagent OD Limit range programmed in **Specific Test Parameters** is correct.

@: OD is higher than 3.0

An abnormally high value. A reaction OD is over the limit of 3.0. In a dual wavelength measurement, an error occurs if either of the two wavelengths is over the limit of 3.0 OD.

This error occurs if one of the following three conditions is met:

- Primary wavelength is over the limit (3.0).
- Secondary wavelength is over the limit (3.0).
- Reaction wavelength is over the limit (3.0).

TIP This error only occurs on END or FIXED reaction methods, not on RATE reaction methods.

This is caused by:

- Sample quality. The sample can be severely lipemic, icteric, hemolytic or can contain excessively large concentration of the analyte being tested.
- Faulty photometer lamp.
- Cuvette Overflow.

Action:

1. Dilute the sample and repeat analysis.
2. Perform a Photocal to check the integrity of the lamp, and replace if necessary. Refer to [8.4.3 Perform a Photocal](#).
3. Verify the cuvette wheel is not wet. If the cuvette wheel is wet, take appropriate action to recover. Refer to [11.10 Recovering from a Cuvette Wheel Overflow](#) in chapter 11 and [8.7.1 Clean the Cuvettes and the Cuvette Wheel](#) in chapter 8.

\$: Not enough data to determine linearity of reaction

Fewer than three read points of a rate reaction are within the acceptable optical density range specified. In order to calculate a rate reaction properly, at least three readings must be taken before reaching maximum or minimum optical density. If these optical density limits are exceeded, the reaction might go into substrate depletion due to a high concentration or a problem with the condition of the reagent. Linearity calculations are not made when this error occurs.

Action:

1. The sample can be severely lipemic, icteric, hemolytic or can contain excessively large concentration of the analyte being tested. Dilute the sample and repeat analysis.
2. Check the probes and syringes for proper functioning. Refer to [8.3.1 Inspect the Syringes for Leaks](#) and [8.3.3 Inspect, Clean and Prime the Sample Probe, Reagent Probe, and Mix Bars](#) in chapter 8.
3. Check the reaction data including those processed immediately before and after the flagged result. In the presence of any abnormality, verify the cuvette wheel is not wet. If the cuvette wheel is wet, take appropriate action to recover. Refer to [11.10 Recovering from a Cuvette Wheel Overflow](#) in chapter 11 and [8.7.1 Clean the Cuvettes and the Cuvette Wheel](#) in chapter 8.

D: OD of reaction is higher than the maximum OD range

The OD of a Rate or Fixed reaction cannot meet the maximum OD criteria programmed in OD Limit in **Specific Test Parameters**:

- A specified read point FST+2 (first photometry point plus two) in a positive rate reaction method: High concentration.
- A specified read point LST-2 (last photometry point minus two) in a negative rate reaction method: Low concentration.
- A photometry read point in a positive fixed reaction method: High concentration.
- A photometry read point in a negative fixed reaction method: Low concentration.

Action:

If this flag is only generated on one or a few samples, check the sample quality:

- If the sample has a high concentration, the sample may be severely lipemic, icteric, hemolytic or may contain excessively large concentration of the analyte being tested. Dilute the sample and run the test again.
- If the sample has a low concentration, no reaction occurs in the cuvette. Verify there is enough sample volume in the tube.

If this flag is only generated on one reagent, check the reagent quality and for reagent contamination:

- Verify the reagent on-board stability, expiration, and reagent blank expiration.
- Verify the reagent was prepared correctly.
- Verify fixed reagents are in the correct position.

If this flag is generated randomly on several samples and several different tests:

- The lamp might need to be replaced. Perform a Photocal (refer to [8.4.3 Perform a Photocal](#)) to assess the condition of the photometer lamp.
- Verify the cuvette wheel is not wet. If the cuvette wheel is wet, take appropriate action to recover. Refer to [11.10 Recovering from a Cuvette Wheel Overflow](#) in chapter 11 and [8.7.1 Clean the Cuvettes and the Cuvette Wheel](#) in chapter 8.

B: OD of reaction is lower than the minimum OD range

The OD of a Rate or Fixed reaction cannot meet the minimum OD criteria programmed in OD Limit in **Specific Test Parameters**:

- A specified read point FST+2 (first photometry point plus two) in a negative rate reaction method: High concentration.
- A photometry read point in a negative fixed reaction method: High concentration.
- A photometry read point in a positive fixed reaction method: Low concentration.

Action:

If this flag is only generated on one or a few samples, check the sample quality:

- If the sample has a high concentration, the sample may be severely lipemic, icteric, hemolytic or may contain excessively large concentration of the analyte being tested. Dilute the sample and run the test again.
- If the sample has a low concentration, no reaction occurs in the cuvette. Verify there is enough sample volume in the tube.

If this flag is only generated on one reagent, check the reagent quality and for reagent contamination:

- Verify the reagent on-board stability, expiration, and reagent blank expiration.
- Verify the reagent was prepared correctly.
- Verify fixed reagents are in the correct position.

If this flag is generated randomly on several samples and several different tests:

- The lamp might need to be replaced. Perform a Photocal to assess the condition of the photometer lamp. Refer to [8.8.14 Replace the Photometer Lamp](#) and [8.4.3 Perform a Photocal](#) in chapter 8.
- Verify the cuvette wheel is not wet. If the cuvette wheel is wet, take appropriate action to recover. Refer to [11.10 Recovering from a Cuvette Wheel Overflow](#) in chapter 11 and [8.7.1 Clean the Cuvettes and the Cuvette Wheel](#) in chapter 8.

*: Linearity error in rate method

This flag is generated when the rate of a reaction varies by more than the defined % variance, as defined in **Menu List > Parameters > Specific Test Parameters > General** and is therefore deemed non-linear, or the reverse reaction check on a rate method failed. Possible causes are:

- Unusually high result.
- Contaminated reagent.
- Dirty or defective mix bars.
- Defective cuvettes or lamp deteriorated.
- Reagent or sample probe alignment problem.
- Outer cuvette walls or the cuvette wheel is wet.
- The concentration is near zero for DAU analysis using the rate method.

Action:

1. Dilute the sample and run it again or perform a diluted repeat run.
2. Replace reagent if contaminated or out-of-date.
3. Clean all mix bars and check them for damage. Replace any that have scratches or chips in the teflon coating. Refer to [8.8.4 Replace Mix Bars](#) in chapter 8.
4. Perform a Photocal to check the lamp and cuvette integrity. Replace the lamp or cuvettes as necessary and perform another Photocal. Refer to [8.8.14 Replace the Photometer Lamp](#), [8.8.13 Clean or Replace Individual Cuvettes](#), and [8.4.3 Perform a Photocal](#) in chapter 8.
5. Verify the sample probe and reagent probe alignment. If the probe is bent, replace the probe. Refer to [8.8.3 Replace a Sample and Reagent Probe](#) in chapter 8.
6. Verify the cuvette wheel is not wet. If the cuvette wheel is wet, take an appropriate action to recover. Refer to [11.10 Recovering from a Cuvette Wheel Overflow](#) in chapter 11 and [8.7.1 Clean the Cuvettes and the Cuvette Wheel](#) in chapter 8.
7. No action required. If the method is Rate, the reverse reaction check is performed. If the concentration is near zero, the reaction curve is flat and triggers the "*" flag. Verify there is no other cause for the "*" flag before reporting the result.

&: Prozone test data is abnormal

The data for prozone judgement is abnormal.

Action:

Dilute the sample and repeat analysis.

If the issue persists, contact Beckman Coulter Technical Services.

Z: Prozone error

The data check equation for any one of logic check 1, 2 or 3 is satisfied. This is often caused by an abnormally high concentration of analyte in a sample.

Action:

Dilute the sample and repeat analysis.

E: Overreaction in a rate assay detected

In the rate assay, the result is judged as an error by checking an overreaction in which the reaction was finished in an excessively short time. This is often caused by an abnormally high concentration of analyte in a sample.

Action:

Dilute the sample and repeat analysis.

Fx: Result (OD) is higher than the dynamic range

No concentration could be calculated. The OD of the sample exceeded the OD of the upper limit of the dynamic range.

Action:

Dilute the sample and repeat analysis.

Gx: Result (OD) is lower than the dynamic range

No concentration could be calculated. The OD of the sample is lower than the OD of the low limit of the dynamic range.

Action:

1. Review the result in the clinical context of the patient and repeat if necessary.
2. Check the reagent probes and reagent bottles for proper position.
3. Check the reagents for bubbles.

!: Unable to calculate concentration

The system has failed to calculate a result.

Action:

1. If this is a single sample issue, repeat and dilute if necessary.
2. If multiple samples are affected, review all operating parameters such as:
 - Reagent quality
 - Calibration
 - Sample integrity

- General system issues
3. Check the reaction data including those processed immediately before and after the flagged result. In the presence of any abnormality, verify the cuvette wheel is not wet. If the cuvette wheel is wet, take appropriate action to recover. Refer to [11.10 Recovering from a Cuvette Wheel Overflow](#) in chapter 11 and [8.7.1 Clean the Cuvettes and the Cuvette Wheel](#) in chapter 8.
 4. If the flag is generated on Na, K, or Cl, repeat a sufficient number of samples which preceded the appearance of the "!" flag in order to verify that no incorrect results were reported. It is possible that air in the flowcell affected samples before the "!" flag was generated.
 - Perform a MID/REF Prime and verify no bubbles are in the tubing at the bottom of the flowcell to ensure there are no obstructions in the flowcell path.
 - Verify all tubing is properly connected.

) : Reagent lot number used for sample analysis is different from the lot number used for RB/Calibration

The reagent lot number does not match the calibrated reagent lot number.

Action:

1. Calibrate the reagent used for the test that generated the flag.
2. Calculate the results manually by selecting **Menu List > Routine > Sample Manager > Main**. Select **Recalculate Data (F5)** .

a: Reagent expired

The reagent has either expired or has been onboard beyond the period defined in **Specific Test Parameters**.

Action:

Replace the reagents and perform a reagent check and a calibration if necessary.

ba: No calibration data or expired

There is no reagent blank or calibration data, or the data is expired.

Action:

1. Perform calibration. For details on calibrating tests, refer to [5.6 Perform Calibration](#) in chapter 5.
2. Review calibration in **Menu List > Calibration > Calibration Monitor**.
3. Carefully review any results generated with this flag and repeat if necessary.

bh: The latest calibration/RB has not been used

The most recent reagent blank or calibration failed or is expired. Results can be erroneous and should not be reported.

Action:

1. Perform calibration.
For details on calibrating tests, refer to [5.6 Perform Calibration](#) in chapter 5.
2. Review calibration in **Menu > Calibration > Calibration Monitor**.
3. Repeat samples using a valid calibration.

bn: Mastercurve used

Calibration has either not been performed, or was not successful. The system has used the master curve to generate the result. Review calibration in **Menu List > Calibration > Calibration Monitor**.

Action:

Results can be erroneous and should not be reported.

1. Perform a calibration.
2. Repeat samples using a valid calibration.

bz: Calibration curve for Prozone data used

The system has used the calibration curve for prozone data to generate the result. It is similar to a real result and should be used to estimate the dilution rate for repeat run.

Action:

Carefully review any results generated with this flag and repeat the analysis in diluted mode.

F: Result is higher than the dynamic range

The concentration of the sample is above the dynamic range high limit, programmed in **Menu List > Parameters > Specific Test Parameters > General**.

Action:

1. Verify if the correct dynamic range is programmed in **Specific Test Parameters**.
2. Dilute the sample with the appropriate sample diluent and re-analyze. Samples should be diluted so that they yield a value in the middle of the measuring range.

G: Result is lower than the dynamic range

The concentration of the sample is below the dynamic range low limit, programmed in **Menu List > Parameters > Specific Test Parameters > General**, or the reagent was not pipetted properly. This is caused by:

- Incorrect Dynamic Range is programmed.
- The clinical context of the patient.
- Insufficient reagent dispensing.
- Insufficient sample dispensing

Action:

1. Verify if the correct dynamic range is programmed in **Specific Test Parameters**.
2. Review the result in the clinical context of the patient and repeat if necessary.
3. Verify the reagent probe and reagent bottles for proper position. Verify there are not any bubbles on the reagent surface.
4. Verify there are not any bubbles on the sample surface.

ph: Result is higher than the upper panic value

The result is higher than the upper panic value. This is programmed in **Menu List > Parameters > Specific Test Parameters > Range**.

Action:

This denotes that the result is outside user-defined panic ranges. Follow laboratory Standard Operating Procedures for abnormal test results.

pl: Result is lower than the low panic value

The result is lower than the low panic value. This is programmed in **Menu List > Parameters > Specific Test Parameters > Range**.

Action:

This denotes that the result is outside user-defined panic ranges. Follow laboratory Standard Operating Procedures for abnormal test results.

T: Abnormality found in inter-chemistry check

A checked test result exceeds the check range specified in **Menu List > Parameters > Misc. > Checked Tests**.

Action:

1. Repeat analysis.
2. Follow laboratory Standard Operating Procedures for abnormal test results.

P: Positive

Qualitative result: Sample result exceeds the upper value. This is programmed in **Menu List > Parameters > Specific Test Parameters > Range**. Program **Flag** in the "Value/Flag" drop-down list to enable programming in the Level High field. Results over the Level High generate the P flag.

Action:

Follow laboratory Standard Operating Procedures.

N: Negative

Qualitative result: Sample result is lower than the low value. This is programmed in **Menu List > Parameters > Specific Test Parameters > Range**. Program **Flag** in the "Value/Flag" drop-down list to enable programming in the Level Low field. Results under the Level Low generate the N flag.

Action:

Follow laboratory Standard Operating Procedures.

H: Result is higher than reference range

Sample result is higher than the high value set in Specific Ranges in **Menu List > Parameters > Specific Test Parameters > Range**.

For details on setting reference intervals, refer to [4.3.5 Range Menu](#) in chapter 4.

Action:

Follow laboratory Standard Operating Procedures for abnormal test results.

L: Result is lower than reference range

Sample result is lower than the low value set in Specific Ranges in **Menu List > Parameters > Specific Test Parameters > Range**.

For details on setting reference intervals, refer to [4.3.5 Range Menu](#) in chapter 4.

Action:

Follow laboratory Standard Operating Procedures for abnormal test results.

J: Result is higher than the repeat decision range

The result is higher than the repeat decision range. This is programmed in **Menu List > Parameters > Repeat Parameters > Repeat Specific**.

Action:

Follow laboratory Standard Operating Procedures.

K: Result is lower than the repeat decision range

The result is lower than the repeat decision range. This is programmed in **Menu List > Parameters > Repeat Parameters > Repeat Specific**.

Action:

Follow laboratory Standard Operating Procedures.

fh: Result is higher than the repeat run reflex range

The result is higher than the user specified reflex range, set in **Menu List > Parameters > Repeat Parameters > Repeat Specific**.

Action:

Follow laboratory Standard Operating Procedures.

fl: Result is lower than the repeat run reflex range

The result is lower than the user specified reflex range, set in **Menu List > Parameters > Repeat Parameters > Repeat Specific**.

Action:

Follow laboratory Standard Operating Procedures.

Va: Deviation of multiple measurements check is out of range

The precision of replicates for the reagent blank or calibration exceeds the allowable range set in **Menu List > Parameters > Calibration Parameters > Calibration Specific (Allowable Range Check)**.

Action:

Perform the appropriate maintenance:

- Check syringes.
For details on inspecting syringes and tubing for air bubbles and leaks, refer to [8.3.1 Inspect the Syringes for Leaks](#) in chapter 8.
- Check sample probe.
For details on how to check sample probes, refer to [8.3.3 Inspect, Clean and Prime the Sample Probe, Reagent Probe, and Mix Bars](#) in chapter 8.
- Verify the correct sample material was used for the reagent blank or calibration.
- Check for signs of system contamination.

xQ: Multi-rule QC has detected failure on one control

If one of the two pairs of data for QC using multi-check QC rules is out of range, the other piece of data is flagged. This is programmed in **Menu List > Parameter > QC Parameters > QC Specific**.

For details on setting single or multi-check QC rules (all samples), refer to [4.6.2 QC Specific Menu](#) in chapter 4.

Action:

If QC results fall outside the acceptable range, investigate the cause before deciding whether to report patient results. If any trends or sudden shifts in values are detected, review all operating parameters.

Follow laboratory Standard Operating Procedures for out-of-range QC results such as:

- Repeat with fresh QC material.
- Perform calibration as required.
- Perform maintenance as appropriate.

1Q: QC data exceeds the range entered in Single Check Level field

One point of QC data exceeds the SD defined in the Single Check Level on the **Check** tab in **Menu List > Parameters > QC Parameters > QC Specific**.

For details on setting single or multi-check QC rules (all samples), refer to [4.6.2 QC Specific Menu](#) in chapter 4.

Action:

If QC results fall outside the acceptable range, investigate the cause before deciding whether to report patient results. If any trends or sudden shifts in values are detected, review all operating parameters.

Follow laboratory Standard Operating Procedures for out-of-range QC results such as:

- Repeat with fresh QC material.
- Perform calibration as required.
- Perform maintenance as appropriate.

2Q: QC data exceeds a 1_{3s} control range

One point of QC data exceeds the $\pm 3SD$ limit defined in the Multi Check Level on the **Check** tab in **Menu List > Parameters > QC Parameters > QC Specific**.

For details on setting single or multi-check QC rules (all samples), refer to [4.6.2 QC Specific Menu](#) in chapter 4.

Action:

If QC results fall outside the acceptable range, investigate the cause before deciding whether to report patient results. If any trends or sudden shifts in values are detected, review all operating parameters.

Follow laboratory Standard Operating Procedures for out-of-range QC results such as:

- Repeat with fresh QC material.
- Perform calibration as required.
- Perform maintenance as appropriate.

3Q: QC data exceeds 2_{2s} control range

Two contiguous QC data points exceed the control limit of $\pm 2SD$ in the same direction. This is programmed in Multi Check Level on the **Check** tab in **Menu List > Parameters > QC Parameters > QC Specific**.

For details on setting single or multi-check QC rules (all samples), refer to [4.6.2 QC Specific Menu](#) in chapter 4.

Action:

If QC results fall outside the acceptable range, investigate the cause before deciding whether to report patient results. If any trends or sudden shifts in values are detected, review all operating parameters.

Follow laboratory Standard Operating Procedures for out-of-range QC results such as:

- Repeat with fresh QC material.
- Perform calibration as required.
- Perform maintenance as appropriate.

4Q: QC data exceeds R_{4s} control range

One of the two consecutive high and low concentration QC data points exceeds the control limit of +2SD and the other exceeds the control limit of -2SD, or the difference between the two controls exceeds 4 SD. This is programmed in Multi Check Level on the Check tab in **Menu List > Parameters > QC Parameters > QC Specific**.

For details on setting single or multi-check QC rules (all samples), refer to [4.6.2 QC Specific Menu](#) in chapter 4.

Action:

If QC results fall outside the acceptable range, investigate the cause before deciding whether to report patient results. If any trends or sudden shifts in values are detected, review all operating parameters.

Follow laboratory Standard Operating Procedures for out-of-range QC results such as:

- Repeat with fresh QC material.
- Perform calibration as required.
- Perform maintenance as appropriate.

5Q: QC data exceeds 4_{1s} control range

Four consecutive QC data point results have exceeded the 1SD limit. This is programmed in Multi Check Level on the **Check** tab in **Menu List > Parameters > QC Parameters > QC Specific**.

For details on setting single or multi-check QC rules (all samples), refer to [4.6.2 QC Specific Menu](#) in chapter 4.

Action:

If QC results fall outside the acceptable range, investigate the cause before deciding whether to report patient results. If any trends or sudden shifts in values are detected, review all operating parameters.

Follow laboratory Standard Operating Procedures for out-of-range QC results such as:

- Repeat with fresh QC material.
- Perform calibration as required.
- Perform maintenance as appropriate.

6Q: A preset number of consecutive QC results fall on one side of the mean

Results for a preset number (7-10) of consecutive data points falls either above or below the mean. This is programmed in Multi Check Level on the **Check** tab in **Menu List > Parameters > QC Parameters > QC Specific**.

For details on setting single or multi-check QC rules (all samples), refer to [4.6.2 QC Specific Menu](#) in chapter 4.

Action:

If QC results fall outside the acceptable range, investigate the cause before deciding whether to report patient results. If any trends or sudden shifts in values are detected, review all operating parameters.

Follow laboratory Standard Operating Procedures for out-of-range QC results such as:

- Repeat with fresh QC material.
- Perform calibration as required.
- Perform maintenance as appropriate.

7Q: Consecutive QC results show steadily increasing or decreasing values

Results for a preset number (4-10) of consecutive data points are increasing or decreasing. This is programmed in Multi Check Level on the **Check** tab in **Menu List > Parameters > QC Parameters > QC Specific**.

For details on setting single or multi-check QC rules (all samples), refer to [4.6.2 QC Specific Menu](#) in chapter 4.

Action:

If QC results fall outside the acceptable range, investigate the cause before deciding whether to report patient results. If any trends or sudden shifts in values are detected, review all operating parameters.

Follow laboratory Standard Operating Procedures for out-of-range QC results such as:

- Repeat with fresh QC material.
- Perform calibration as required.
- Perform maintenance as appropriate.

S: Sample repeated and original results replaced by repeat result

A sample test has been repeated and this repeat result has replaced the previous result to become the final result.

Action:

No action required.

/: Test pending or not analyzed

The test was not performed, even though it was requested (usually because of a reagent shortage), or the testing is still in process.

Action:

Review all results generated immediately prior to this flag for consistency and validity (especially low or high results) and repeat if necessary.

1. If the reagent is empty, place new reagent onboard and repeat analysis.
2. If the reagent positions are fixed, verify the reagent is in the correct position.
3. Inspect the reagent probe, clean or replace as necessary.
4. Verify the reagent probe is correctly installed and connected.

r: Result has been transferred to LIS (HOST Computer) through on-line communication

Action:

No action required.

c: Result corrected by user

Data has been corrected.

For details on correcting results, refer to [7.6 Edit Analysis Data](#) in chapter 7.

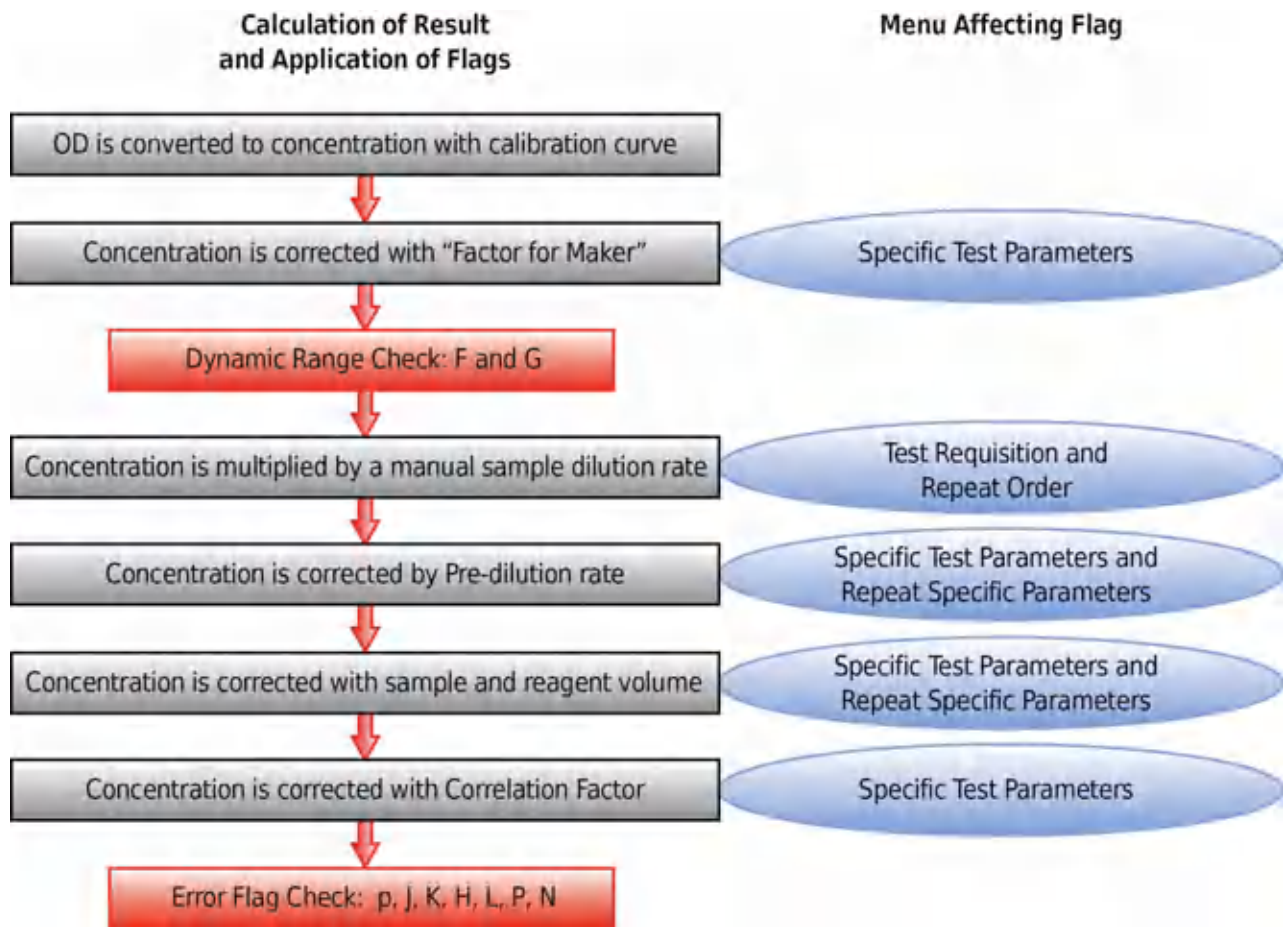
Action:

Follow laboratory Standard Operating Procedures. Review any edited or changed data carefully prior to reporting results.

9.4 Application of Flags (F, G, p, J, K, H, L, P, and N) During Calculation of Final Result Flowchart

This flowchart shows the calculations that occur to obtain the final concentration result, and when the flags are applied.

Figure 9.1 Application of F, G, p, J, K, H, L, P, and N flags



Factor for Maker is programmed by Beckman Coulter Technical Services, and is displayed in **Specific Test Parameters**. “A” is a multiplication factor and “B” is an addition/subtraction factor.

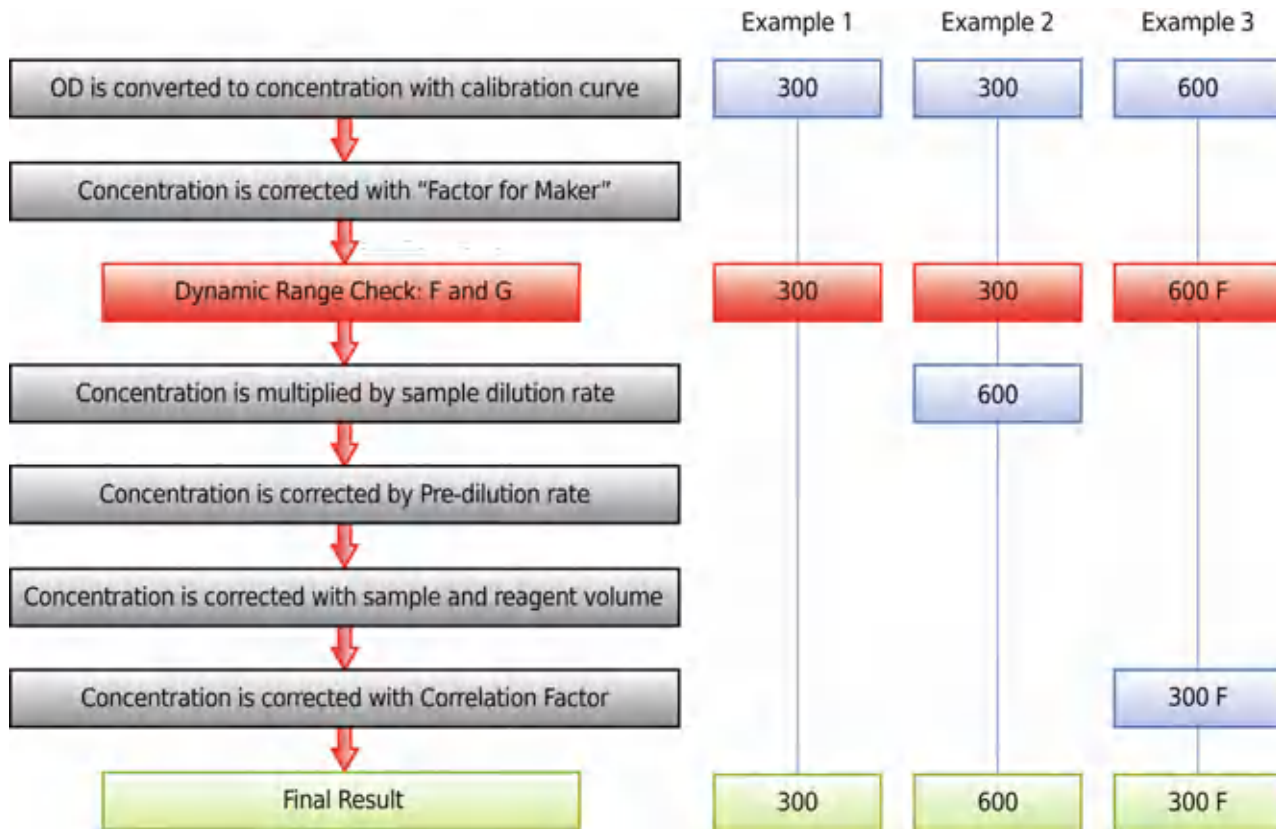
In the Test Requisition and Repeat Order (Requisition) menus, **Sample Dilution (F7)** allows input of a dilution rate when making a manual dilution of the sample for the original or repeat run.

A calculation is made for “Pre-Dilution Rate” defined in **Specific Test Parameters**, as well as “Pre-Dilution Rate” defined in **Repeat Specific Parameters** for “Repeat with diluent” and “Repeat with condense.”

A calculation is made based on the sample and reagent volume defined in **Specific Test Parameters** and **Repeat Specific Parameters**.

Correlation Factor is programmed in **Specific Test Parameters**. “A” is a multiplication factor and “B” is an addition/subtraction factor.

Figure 9.2 Examples with F flag: Dynamic Range is 1 to 500



Example 1:
A final result of 300 without F or G flag.

Example 2:
A final result of 600 without an F flag because the dynamic range check occurs (in range), then the concentration is multiplied by 2 for a manual dilution.

Example 3:
A final result of 300 with an F flag because the dynamic range check occurs (over range), then a Correlation Factor "A" of 0.5 is applied.

Error Flags

9.4 Application of Flags (F, G, p, J, K, H, L, P, and N) During Calculation of Final Result Flowchart

Error Messages

The following error messages can be displayed after selecting the **Start** button. This chapter describes the cause of the error message and corrective actions to perform.

After checking cups on STAT table, please perform STAT check in STAT Status menu.

After checking printer, please resume printer in Analyzer Status menu.

Calibration requisition is renewed. Please set new calibrator on STAT table.

Calibration stability is expired. Please open Calibration Requisition menu and requisition the test.

Calibration stability will be expired soon.

Can't perform Realtime online. Please reconnect LAN port or set unavailable at Start Condition menu.

Cuvette Error found. Please check it at User Maintenance.

Detergent short.

Diluted Detergent short.

Dispensed STAT sample exists.

Error sample(s) exists. Please check sample(s) in STAT Status menu.

Full of Conc Waste tank.

Full of rack at Rack Collection.

Full of Waste tank.

Incorrect parameter is found. Please open [MM...MM/NN...NN] menu and check the parameters.

ISE BUF Solution short.

ISE cover is open.

ISE MID Solution short.

ISE select error(K).

ISE select error(Na).

ISE slope is over (under) the range [MMMMMM, NN...NN].

ISE slope is zero [MMMMMM, NN...NN].

ISE Status is stop.

Lack of Diluent. Please check it at Reagent Management.

Lack of R Probe Detergent. Please check it at Reagent Management.

Lack of S Probe Detergent. Please check it at Reagent Management.

LAN port is disconnect. Please check it Analyzer Status.

Liquid is remained in vacuum tank.

Maintenance item is expired. Please perform maintenance.

Maintenance item will be expired soon. Please check it.

Master Curve is not scanned. Please check it at Reagent Management.

No Cup to be processed on STAT table.

No deionized water. Please check water supply valve.

No Diluent. Please check it at Reagent Management menu.

No Photocal Data. Please perform photocal at User Maintenance.

No R Probe detergent at Reagent Management menu.

No Reagent. Please check it at Reagent Management.

No S Probe Detergent.

Onboard Stability is expired. Please check Reagent Management and set new reagent in the refrigerator.

Overflow of Deionized water. Please check the tank.

Overflow of Diluted detergent. Please check the tank.

Please check STAT Status and set calibrators to be needed.

Please check STAT Status and set controls to be needed.

Please check STAT Status and set RB cup to be needed.

Please perform Reagent Check.

QC requisition is renewed. Please set new control on STAT table.

RB stability is expired. Please open Calibration Requisition and requisition the test.

RB stability will be expired soon.

Reagent error found. Please check it at Reagent Management.

Reagent is expired. Please check Reagent Management and set new reagent in the refrigerator.

Temperature of the incubator bath is over(under) the normal range.

Temperature of the refrigerator is over(under) the normal range.

Test has no Calibration Data. Please open Calibration Requisition and requisition the test.

Test has no RB Data. Please open Calibration Requisition menu and requisition the test.

Test item(s) is set as "Disabled" at Start Condition.

The cover of Dispensing Position is open.

The cover of reagent refrigerator is open.

The main cover of STAT table is open.

The sample on STAT table is incorrect. Please check it on STAT Status menu.

The sub cover of STAT table is open.

The volume is reached to Alarm volume. Please check it at Reagent Management.

Under communicating with HOST.

Under printing to printer.

10 Error Messages

After checking cups on STAT table, please perform STAT check in STAT Status menu.

Cause:

The STAT table cover has been opened, or a parameter was changed in **Parameters**.

Action:

1. Verify the required sample cups are in the correct positions on the STAT table.
2. Perform a STAT table check from **STAT Status > STAT Check (F3)**.

After checking printer, please resume printer in Analyzer Status menu.

Cause:

The printer Status is abnormal.

Action:

1. Verify that the printer is turned on, and correct any errors with the printer.
2. Select **Home > Analyzer Status**.
3. Select **Printer Control (F5)**, then **Resume** or **Cancel**.

Calibration requisition is renewed. Please set new calibrator on STAT table.

Action:

1. Check **STAT Status** to verify the required calibrators are in the correct positions on the STAT table.
2. Perform a STAT table check from **STAT Status > STAT Check (F3)**. This step is only required if STAT Operation is programmed to Manual in **Analysis Mode**.

Calibration stability is expired. Please open Calibration Requisition menu and requisition the test.

Cause:

Calibration data has expired.

Action:

1. Requisition the tests to calibrate in the **Calibration** menu.
2. Perform calibration analysis.

Calibration stability will be expired soon.

Cause:

Calibration data is close to expiration.

Action:

1. Requisition the tests to calibrate in the **Calibration** menu.
2. Perform calibration analysis.

Can't perform Realtime online. Please reconnect LAN port or set unavailable at Start Condition menu.

Cause:

The LAN port is disconnected.

Action:

Reconnect a LAN port, or stop the online communication in **Start Condition > Realtime Online (F8)**.

Cuvette Error found. Please check it at User Maintenance.

Cause:

One or more cuvettes has failed the Photocal.

Action:

1. Check the cuvette Status in **Home > Analyzer Maintenance > Photocal Monitor**.
2. Repeat the Photocal on any cuvette(s) that failed the Photocal. Refer to [8.4.3 Perform a Photocal](#) in chapter 8.

Detergent short.

Cause:

The wash solution is insufficient.

Action:

Check the wash solution and replenish as necessary. Refer to [8.3.4 Inspect the Wash Solution and Replenish As Needed](#).

Diluted Detergent short.

Cause:

The diluted wash solution is insufficient.

Action:

1. Check the wash solution and replenish as necessary. Refer to [8.3.4 Inspect the Wash Solution and Replenish As Needed](#).
2. Verify that DI water is in the DI water tank.
3. Check the wash solution roller pump. Refer to [8.3.2 Inspect the Wash Solution Roller Pump for Leaks](#).

Dispensed STAT sample exists.

Cause:

Sample aspiration is complete for a sample in a priority STAT or repeat STAT position on the STAT table.

Action:

1. Refer to **STAT Status**, and remove the sample from the STAT table.
2. If in **Analysis Mode** STAT Operation is programmed to Manual, it is necessary to perform a STAT table check in **STAT Status**.

Error sample(s) exists. Please check sample(s) in STAT Status menu.

Cause:

An anomaly has been found in a sample that has been set on the STAT table.

Action:

1. Check the error information from the **STAT Status** menu.
2. Take an appropriate action for the error.
3. Perform a STAT table check from **STAT Status > STAT Check (F3)**. This step is only required if STAT Operation is programmed to Manual in **Analysis Mode**.

Full of Conc Waste tank.

Cause:

The tank is full of concentrated waste liquid.

Action:

Call Beckman Coulter Technical Services.

Full of rack at Rack Collection.

Cause:

The rack collection unit is full.

Action:

Remove the racks from the rack collection unit.

Full of Waste tank.

Cause:

The waste tank is full of liquid waste.

Action:

Call Beckman Coulter Technical Services.

Incorrect parameter is found. Please open [MM...MM/NN...NN] menu and check the parameters.

Cause:

A programming error exists in **Parameters**.

Action:

Check the **Parameter** menu listed in the Error Message for a programming error. The menu name appears in place of "[MM...MM/NN...NN]" in the Error Message.

ISE BUF Solution short.

Action:

Replace the Buffer Solution bottle.

ISE cover is open.

Action:

Close the ISE cover.

ISE MID Solution short.

Action:

Replace the Mid Standard Solution bottle.

ISE select error(K).

Action:

1. Perform a Selectivity Check. Refer to [8.13.1 Check the Selectivity of the Na/K Electrodes](#) in chapter 8.
2. If the error is not resolved, replace the K electrode. Refer to [8.17.1 Replace the Na, K, or Cl Electrode](#) in chapter 8.

ISE select error(Na).

Action:

1. Perform a Selectivity Check. Refer to [8.13.1 Check the Selectivity of the Na/K Electrodes](#) in chapter 8.
2. If the error is not resolved, replace the K electrode. Refer to [8.17.1 Replace the Na, K, or Cl Electrode](#) in chapter 8.

ISE slope is over (under) the range [MMMMMM, NN...NN].

Action:

1. Calibrate the ISE. Refer to [8.12.2 ISE Calibration](#).
2. If the error is not resolved, replace the appropriate electrode. Refer to [8.17.1 Replace the Na, K, or Cl Electrode](#) in chapter 8.

ISE slope is zero [MMMMMM, NN...NN].

Action:

1. Calibrate the ISE. Refer to [8.12.2 ISE Calibration](#).
2. If the error is not resolved, replace the appropriate electrode. Refer to [8.17.1 Replace the Na, K, or Cl Electrode](#) in chapter 8.

ISE Status is stop.

Cause:

ISE is in *Stop* mode.

Action:

Select **Home** > **Analyzer Maintenance** > **ISE Maintenance** > **ISE Ready (F4)** to reset the ISE to *Ready* mode.

Lack of Diluent. Please check it at Reagent Management.

Cause:

The DI water or diluent in the pre-dilution bottle is short.

Action:

1. Replace the DI water or diluent in the pre-dilution bottle.
2. Perform a reagent check.

Lack of R Probe Detergent. Please check it at Reagent Management.

Cause:

The cleaning solution for contamination parameters in the cleaning solution bottle is short.

Action:

1. Replace the cleaning solution for contamination prevention in the CLN-1 and CLN-2 bottles located in fixed positions in the reagent refrigerator.
2. Perform a reagent check.

Lack of S Probe Detergent. Please check it at Reagent Management.

Cause:

The 2% Wash Solution in the tube on the W1 position on the STAT table is short.

Action:

1. Replace the 2% Wash Solution in the tube on the W1 position on the STAT table.
2. Perform a reagent check.

LAN port is disconnect. Please check it Analyzer Status.

Cause:

LAN port is disconnected.

Action:

1. Check LAN port Status in **Analyzer Status** menu.
2. Reconnect the LAN port.

Liquid is remained in vacuum tank.

Cause:

Waste liquid exists in the Vacuum tank.

Action:

Call Beckman Coulter Technical Services.

Maintenance item is expired. Please perform maintenance.**Action:**

1. Check items in detail in the **Maintenance** menu.
2. Perform necessary maintenance.

Maintenance item will be expired soon. Please check it.**Cause:**

The maintenance item is close to expiration.

Action:

1. Check items in detail in the **Maintenance** menu.
2. Perform necessary maintenance.

Master Curve is not scanned. Please check it at Reagent Management.**Cause:**

A new lot of reagents are set and the 2-D barcode was not scanned.

Action:

1. Check details in **Home > Reagent Management > Details**.
2. Use the hand held scanner to scan the 2-D barcode on the reagent and perform a reagent check.

No Cup to be processed on STAT table.**Cause:**

No sample has been set on the STAT table.

Action:

Refer to **STAT Status**, and place the samples to be analyzed in appropriate positions on the STAT table.

No deionized water. Please check water supply valve.**Cause:**

Deionized water tank is empty.

Action:

1. Check the water outlet valve on the deionized water system.
2. If no abnormality is found in the deionized water system, contact Beckman Coulter Technical Services.

No Diluent. Please check it at Reagent Management menu.

Cause:

The DI water in the pre-dilution bottle is empty.

Action:

1. Replace the DI water in the pre-dilution bottle
2. Perform a reagent check.

No Photocal Data. Please perform photocal at User Maintenance.

Cause:

No Photocal data exists.

Action:

Perform a Photocal. Refer to [8.4.3 Perform a Photocal](#) in chapter 8.

No R Probe detergent at Reagent Management menu.

Cause:

The cleaning solution for contamination parameters in the cleaning solution bottle is empty.

Action:

1. Replace the cleaning solution for contamination prevention in the CLN-1 and CLN-2 bottles located in fixed positions in the reagent refrigerator.
2. Perform a reagent check.

No Reagent. Please check it at Reagent Management.

Cause:

A test cannot be performed due to insufficient reagent required for analysis.

Action:

1. Select **Home > Reagent Management** to determine the insufficient reagent(s). Place the required reagents in the reagent refrigerator.
2. Perform a reagent check.

No S Probe Detergent.

Cause:

The 2% Wash Solution in the tube in the W1 position on the STAT table is empty.

Action:

1. Replace the 2% Wash Solution in the tube in the W1 position on the STAT table.
2. Perform a reagent check.

Onboard Stability is expired. Please check Reagent Management and set new reagent in the refrigerator.

Cause:

There are reagents that have exceeded the onboard stability expiration date.

Action:

1. Check reagents in detail from the **Reagent Management** menu.
2. Add a new reagent bottle.
3. Perform a reagent volume check.

Overflow of Deionized water. Please check the tank.

Cause:

Overflow of deionized water.

Action:

1. Verify the DI water float sensor connector is plugged in correctly.
2. If no abnormality is found with the DI water float sensor, contact Beckman Coulter Technical Services.

Overflow of Diluted detergent. Please check the tank.

Cause:

Overflow of diluted wash solution.

Action:

1. Check the diluted wash solution tank.
2. If no abnormality is found in the system, contact Beckman Coulter Technical Services.

Please check STAT Status and set calibrators to be needed.

Cause:

The calibrators required for the calibration analysis are not set on the STAT table.

Action:

1. Check **STAT Status** to determine which calibrators are required.
2. Place the calibrators in the appropriate positions on the STAT table.
3. Perform a STAT table check from **STAT Status > STAT Check (F3)**. This step is only required if STAT Operation is programmed to Manual in **Analysis Mode**.

Please check STAT Status and set controls to be needed.

Cause:

The controls required for the QC analysis are not set on the STAT table.

Action:

1. Check **STAT Status** to determine which controls are needed.
2. Place the controls in the appropriate positions on the STAT table.
3. Perform a STAT table check from **STAT Status > STAT Check (F3)**. This step is only required if STAT Operation is programmed to Manual in **Analysis Mode**.

Please check STAT Status and set RB cup to be needed.

Cause:

The RB cup required for the reagent blank analysis is not set on the STAT table.

Action:

1. Check **STAT Status** to determine which reagent blank is required.
2. Place the reagent blank in the appropriate position on the STAT table.
3. Perform a STAT table check from **STAT Status > STAT Check (F3)**. This step is only required if STAT Operation is programmed to Manual in **Analysis Mode**.

Please perform Reagent Check.

Cause

Reagent Status is “Unchecked” because the reagent refrigerator lid was opened or a parameter was changed.

Action:

Select **Home > Reagent Management** menu. Perform a reagent volume check.

QC requisition is renewed. Please set new control on STAT table.

Action:

1. Check **STAT Status** to determine which controls are needed.
2. Perform a STAT table check from **STAT Status > STAT Check (F3)**. This step is only required if STAT Operation is programmed to Manual in **Analysis Mode**.

RB stability is expired. Please open Calibration Requisition and requisition the test.

Cause:

Reagent blank data has expired.

Action:

1. Requisition the required test for reagent blank in the **Calibration** menu.
2. Perform a reagent blank analysis.

RB stability will be expired soon.

Cause:

Reagent blank data is close to expiration.

Action:

1. Requisition the required test for reagent blank in the **Calibration** menu.
2. Perform a reagent blank analysis.

Reagent error found. Please check it at Reagent Management.

Cause:

An error has been found in the **Reagent Management** menu.

Action:

Select **Home > Reagent Management > Detail** and review the Comments for errors. Check the reagent bottle position.

Reagent is expired. Please check Reagent Management and set new reagent in the refrigerator.

Cause:

The reagent expiration date has been exceeded.

Action:

1. Check reagents in detail in the **Reagent Management** menu.
2. Replace the expired reagent bottle with a new reagent bottle.
3. Perform a reagent check.

Temperature of the incubator bath is over(under) the normal range.

Cause:

The temperature of the cuvette wheel is out of specification.

Action:

Verify that the cover is on the cuvette wheel. If the problem continues, contact Beckman Coulter Technical Services.

Temperature of the refrigerator is over(under) the normal range.

Cause:

The reagent refrigerator temperature is abnormal.

Action:

Check the refrigerator cover. If the problem continues, contact Beckman Coulter Technical Services.

Test has no Calibration Data. Please open Calibration Requisition and requisition the test.

Cause:

No calibration data exists or calibration analysis failed.

Action:

1. Perform a calibration requisition from the **Calibration** menu.
2. Perform a calibration analysis.

Test has no RB Data. Please open Calibration Requisition menu and requisition the test.

Cause:

No reagent blank data exists or reagent blank analysis failed.

Action:

1. Perform a reagent blank requisition from the **Calibration** menu.
2. Perform a reagent blank analysis.

Test item(s) is set as "Disabled" at Start Condition.

Cause:

A test(s) has been selected as "disabled" in the **Start Condition** menu. The disabled test items will not be analyzed for any patient samples.

The cover of Dispensing Position is open.

Cause:

The cover on the rack lane is open.

Action:

Close the cover.

The cover of reagent refrigerator is open.

Cause:

The reagent refrigerator cover is open.

Action:

Close the cover.

The main cover of STAT table is open.

Cause:

The STAT table cover (large) is open.

Action:

Close the STAT table cover (large).

The sample on STAT table is incorrect. Please check it on STAT Status menu.

Cause:

An error exists with a sample(s) on the STAT table.

Action:

1. Select **STAT Status** to review error information.
2. Take an appropriate action for the error.
3. Perform a STAT table check from **STAT Status > STAT Check (F3)**. This step is only required if STAT Operation is programmed to Manual in **Analysis Mode**.

The sub cover of STAT table is open.

Cause:

The STAT table cover (small) is open.

Action:

Close the STAT table cover (small).

The volume is reached to Alarm volume. Please check it at Reagent Management.

Cause:

The remaining reagent shots (tests) have reached the Alarm Shots programmed in **Parameters > Common Test Parameters**.

Action:

1. Check reagents in detail in the **Reagent Management** menu.
2. Add a new reagent bottle.
3. Perform a reagent check.

Under communicating with HOST.

Cause:

The analyzer is communicating with the host computer.

Action:

Check the analyzer for the Status of communication with the host computer in the **Analyzer Status** menu.

Under printing to printer.

Cause:

Batch print or real-time print is being performed.

Action:

Check the printer Status on the **Analyzer Status** menu.

Troubleshooting

This chapter can assist in locating and solving problems that may occur when operating the AU480.

- 11.1 Troubleshooting
- 11.2 Troubleshooting Considerations
- 11.3 Troubleshooting the System - Reagents, Calibrators, Quality Control and Samples
 - 11.3.1 Reagent Blank Issues and Corrective Actions
 - 11.3.2 Calibration Issues and Corrective Actions
 - 11.3.3 QC Related Issues and Corrective Actions
 - 11.3.4 Sample Related Issues
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 - 11.3.7 Items in Common on the AU480 that may Aid in Troubleshooting
- 11.4 Troubleshooting the System - Mechanical Problems
 - 11.4.1 Syringe Problems
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- 11.5.13 Reagent Probe or Sample Probe not Aligned over the Cuvette
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- 11.6 Troubleshooting the System - Data Processor Problems
 - 11.6.1 Menu Cannot be Selected
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 - 11.7.2 Resetting the System after a Power Failure or an Emergency Stop
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- 11.9 Recovering from a "Photometry Error During a Cuvette Wash" Alarm
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- 11.10 Recovering from a Cuvette Wheel Overflow
 - 11.10.1 What Causes an Overflow?
 - 11.10.2 Recognizing an Overflow
 - 11.10.3 Items to Check when Recovering from an Overflow
 - 11.10.4 After the Overflow is Fixed

11.11 Recovering from an Unstable Photometry Error

11.11.1 Inspect the Cuvette Placement

11.11.2 Inspect the Cuvette Condition

11.11.3 Inspect the Lamp

11.1 Troubleshooting

Regular preventative maintenance is essential for optimum system performance. A significant number of problems outlined in this chapter are caused by neglecting to perform preventative maintenance and required care.

For each aspect of troubleshooting, useful information can be found by referring to the corresponding section of the maintenance chapter.

For details on maintenance, refer to [CHAPTER 8, Maintenance](#).

11.2 Troubleshooting Considerations

TIP Operator Errors and Mechanical Errors can affect the following:

- Reagent performance
- Calibration
- QC results

Operator Errors

- Review reagent, cal, QC storage, preparation, and expiration
- Rack set up and loading
- Improper maintenance or component replacement
- Lack of knowledge of analyzer operations

Mechanical Errors

- Review Alarm Log
- Review data error flags
- Improper maintenance or component replacement

Other Considerations

- Water
- Mixing
- Waste
- Cuvette Wheel Overflow
- Power
- No Wash Solution
- Environmental Conditions

Reagent Blank Data

- 1 Review printout and look for any flags.
- 2 Review the **Alarm List** for “RB Data Error” alarms.
- 3 Reagent blank is a check of the reagent system.
Reagent System includes: Reagent, Reagent Probe, and Reagent Syringe.
- 4 Review reagent blank data in **Menu List > Calibration > Calibration Monitor > RB History and RB Detail**.

Calibration Data

- 1 Review the **Alarm List** for any Calibration alarms.
- 2 Review the printout.
- 3 Look at precision of replicates for each test. The OD readings should have a similar value.
- 4 Look for separation between calibrators for a multi-point calibration.
- 5 Calibration is a check of the sampling system. The sampling system includes: the Sample, Sample Probe, Sample Syringe, and Sample Wash Syringe.
- 6 If Cal replicates are 0 or close to 0, the problem may be:
 - Wrong cal used
 - Sample did not dispense into cuvette (probe or syringe problem)
 - Reagent may be the problem
- 7 Review calibration data in **Menu List > Calibration > Calibration Monitor > Calibration History and Calibration Detail**.

QC Data

-
- 1 Review the **Alarm List** for QC alarms.

 - 2 Review the printout for QC flags “1Q” through “7Q”.

 - 3 Review daily QC charts:
 - QC validates calibration.
 - If all QC is increasing or decreasing (one direction only) this can be related to the calibration factor and indicates calibration problems.
 - If QC was performed on multiple tests from the same QC material, but was only out of range for a specific test, check the QC test parameters, reagent, and calibration.
 - If tests from only one level of QC are out of range, verify the correct QC material was poured in the cup.

 - 4 If available, run a secondary QC (assayed) and view results.

11.3 Troubleshooting the System - Reagents, Calibrators, Quality Control and Samples

The following section outlines specific system issues that can lead to erroneous results.

[11.3.1 Reagent Blank Issues and Corrective Actions](#)

[11.3.2 Calibration Issues and Corrective Actions](#)

[11.3.3 QC Related Issues and Corrective Actions](#)

[11.3.4 Sample Related Issues](#)

[11.3.5 Wash Solution Related Issues](#)

[11.3.6 Deionized \(DI\) Water Related Issues](#)

[11.3.7 Items in Common on the AU480 that may Aid in Troubleshooting](#)

11.3.1 Reagent Blank Issues and Corrective Actions

- Check the reagent system consisting of the reagent, reagent probe, and reagent syringe. Refer to the next section for [Reagent Blank Corrective Actions](#).
- Review the printout and look for flags.
 - Flags “u” or “y” if the RB data of the first read point of the test fails.
Flags “U” or “Y” if the RB data of the last read point of the test fails.
Limits are programmed in **Menu List > Parameters > Specific Test Parameters > General**.
 - Review the **Alarm List** for “RB Data Error” alarms that are generated if the reagent blank fails.

Reagent Blank Corrective Actions

- **Reagent**
 - Check reagent expiration date.
 - Check reagent on-board expiration date.
 - Verify correct reagent preparation.
 - Verify that fixed reagents are in the correct position.
 - Put on a new bottle of reagent and perform a reagent blank/calibration.
 - Replace fixed reagent bottles.
 - Verify a barcoded reagent is not in a position fixed for a different test.
- **Reagent Probe**
 - Inspect the reagent probe. Refer to [8.3.3 Inspect, Clean and Prime the Sample Probe, Reagent Probe, and Mix Bars](#) in chapter 8.
 - Clean the reagent probe. Refer to [8.8.2 Clean the Reagent Probe](#) in chapter 8.
 - Clean the reagent probe wash wells. Refer to [8.5.1 Clean the Sample Probe and Reagent Probe Wash Wells](#) in chapter 8.
 - Replace the reagent probe. Refer to [8.8.3 Replace a Sample and Reagent Probe](#) in chapter 8.

- **Reagent Syringe**
 - Inspect the reagent syringe. Refer to [8.3.1 Inspect the Syringes for Leaks](#) in chapter 8.
 - Replace the reagent syringe. Refer to [8.8.7 Replace Syringes or Syringe Case Heads](#) in chapter 8.

11.3.2 Calibration Issues and Corrective Actions

- Check the sampling system consisting of the calibrator, sample probes, and sample syringes. Refer to the next section for Calibration Corrective Actions.
- Review the **Alarm List** and printout:
 - “Calibration Factor High/Low” and “Calibration Error” alarms are generated if the calibration factor range programmed in **Parameters > Calibration > Calibration Specific** menu is exceeded.
 - Check for precision of the OD replicates on the printout.
 - Verify the OD is not zero, which may indicate the calibrator material was not aspirated.

Calibration Corrective Actions

- **Calibrator**
 - Verify the correct calibrator material was poured for the calibration.
 - Verify the integrity of the calibrator material: expiration date, open-bottle stability, time at room temperature, contamination.
 - Verify the calibrator was placed in the correct position in the yellow rack.
 - Verify the calibrator lot # in use and lot # concentration programmed in **Parameters > Calibration > Calibration Specific**.
- **Sample Probe**
 - Inspect the sample probe. Refer to [8.3.3 Inspect, Clean and Prime the Sample Probe, Reagent Probe, and Mix Bars](#) in chapter 8.
 - Clean the sample probe. Refer to [8.4.1 Clean the Sample Probe and Mix Bars](#) in chapter 8.
 - Clean the sample probe wash wells. Refer to [8.5.1 Clean the Sample Probe and Reagent Probe Wash Wells](#) in chapter 8.
 - Replace the sample probe. Refer to [8.8.3 Replace a Sample and Reagent Probe](#) in chapter 8.
- **Sample Syringe**
 - Inspect the sample syringe. Refer to [8.3.1 Inspect the Syringes for Leaks](#) in chapter 8.
 - Replace the sample syringe. Refer to [8.8.7 Replace Syringes or Syringe Case Heads](#) in chapter 8.

11.3.3 QC Related Issues and Corrective Actions

- QC validates the calibration. Check for a reagent, calibration, or QC issue. Refer to the next section for QC Corrective Actions.
 - Reagent problem
 - Calibrator problem
 - QC problem
- Review the **Alarm List** and printout:
 - “QC test name over/under” alarms are generated if a QC range programmed is exceeded in **Parameters > QC Control > QC Specific menu**.
 - Review the printout for QC flags “1Q” through “7Q”.

Corrective Actions

- **Review all Reagent Blank Issues and Corrective Actions.**
- **Review all Calibration Issues and Corrective Actions.**
- **Check QC Sample**
 - Verify the correct QC material was poured for the QC analysis.
 - Verify the integrity of the material: expiration date, open-bottle stability, time at room temperature, and contamination.
 - Verify the QC was placed in the correct position in the green rack.
 - Verify the QC lot number in use and range programmed in **Parameters > QC Control > QC Specific** are the same.
 - Run assayed QC material.

11.3.4 Sample Related Issues

The following two items cause most data problems:

- **Sample evaporation:** This can cause unusually high results. Store samples properly, and keep sample caps closed tightly if they need to be stored for a short period before analysis.
- **Incorrect sample handling:** Refer to the relevant Instructions for Use (IFU) supplied with reagents to find the correct procedures for sample collection, handling, and storage.

Please note the following sample requirements:

- This system is designed to analyze serum, urine, and other fluids. If problems are encountered when analyzing a specific test, or when using a specific reagent, refer to the relevant reagent IFU or contact Beckman Coulter Technical Services.
- Use serum or plasma that is adequately separated from cells, and urine that is free of suspended matter, to prevent the sample probe from becoming blocked and adversely affecting analysis.
- Check that blood samples are sufficiently coagulated before serum separation. Remove any suspended fibrin before placing serum on the system.

- If there is any suspended matter present in urine to be tested, centrifuge the sample prior to testing.
- If a sample requires pretreatment depending on the analysis test, refer to the relevant reagent IFU.
- A minimum quantity of sample is required for analysis. Verify that an appropriate quantity of sample is available for analysis. Refer to [6.1 Prepare Samples for Analysis](#) in chapter 6.
- To prevent sample evaporation, do not leave samples uncovered for an extended period of time. Evaporation can lead to biased results being observed.
- Bubbles on the surface of samples, QC and calibrator material, may result in level sensing problems or erroneous results. Verify all bubbles are removed from the surface of the sample before placing onto the system.
- Verify that the sample cups and racks are set properly. For details on preparing samples for analysis, refer to [6.1.4 Place the Sample Cups/Tubes in the Rack](#) in chapter 6.
- Check the serum for the extent of hemolysis, lipemia, bilirubin, and so forth.
- If the sample has evaporated or deteriorated, or if the QC sample was incorrectly prepared, obtain a new sample or correctly prepare the QC sample and repeat analysis.

11.3.5 Wash Solution Related Issues

Wash Solution is the only approved detergent for use on the system. Verify Wash Solution is in the Wash Solution tank. If there appears to be contamination in the Diluted Wash Solution tank, or the diluted Wash Solution does not seem like it is being used on the system, contact Beckman Coulter Technical Services.

11.3.6 Deionized (DI) Water Related Issues

Check the following if the deionized water causes data problems:

- Check water quality by checking if the facility's deionized water supply system needs to be serviced.
- If the deionized water tank is contaminated, refer to [8.5.4 Clean the DI Water Tank, DI Filter, and Sample Probe Filter](#) in chapter 8.
- If the deionized water filter is dirty, refer to [8.5.4 Clean the DI Water Tank, DI Filter, and Sample Probe Filter](#) in chapter 8.

11.3.7 Items in Common on the AU480 that may Aid in Troubleshooting

Abnormal data can arise if scheduled maintenance is not performed or is overdue. Be sure to perform all scheduled maintenance along with regular preventative maintenance.

For details on maintenance, refer to [CHAPTER 8, Maintenance](#).

- Incoming water quality (purity, temperature, and conductivity) and circumstance may affect the analysis results. For details on precautions, installation, and specifications, refer to [2.2.1 Installation Environment](#) in chapter 2 or contact Beckman Coulter Technical Services.

- This system is designed to use the specific sample probe, reagent probe, and cuvettes supplied by Beckman Coulter. Use only genuine Beckman Coulter parts.
- If a mosquito coil or insecticides were used in the vicinity of the system, it may markedly affect the cholinesterase (CHE). If an abnormality is experienced, replace the sample cups, reagents, and reagent bottles with new ones. Clean the sample probe, reagent probe, mix bars, and cuvettes.
 - For details on how to clean the sample probe, reagent probe, and mix bars, refer to [8.4.1 Clean the Sample Probe and Mix Bars](#) and [8.8.2 Clean the Reagent Probe](#) in chapter 8.
 - For details on how to clean the cuvettes, refer to [8.7.1 Clean the Cuvettes and the Cuvette Wheel](#) in chapter 8.

11.4 Troubleshooting the System - Mechanical Problems

Erroneous results can also be caused by hardware malfunctions.

For details on cleaning and replacing system parts, refer to [CHAPTER 8, Maintenance](#).

[11.4.1 Syringe Problems](#)

[11.4.2 Probe Problems](#)

[11.4.3 Abnormal Data Caused by Cuvette Wheel or Wash Nozzles](#)

[11.4.4 Abnormal Data Caused by Photometer Lamp or Photometer Unit](#)

[11.4.5 Mixing Problems](#)

[11.4.6 DI Water Tank Problems](#)

[11.4.7 DI Water or Filter Problems](#)

[11.4.8 Incubation Temperature Problems](#)

[11.4.9 Tubing and Pump Problems](#)

[11.4.10 Reagent Refrigerator Problems](#)

[11.4.11 STAT Table Problems](#)

[11.4.12 Rack Problems](#)

11.4.1 Syringe Problems

Check for:

- **Water leaking at syringes:** Tighten the syringe cases and case heads of the sample and reagent syringes.
Also, check for damage to sample syringes and the abrasion Status of pistons. For details on replacing syringes, refer to [8.8.7 Replace Syringes or Syringe Case Heads](#) in chapter 8.
- **Bubbles in the tubing connected to the syringe:** Select **Home > Analyzer Maintenance**. Then select **Prime Washing-line** and press TABLE ROTATION/DIAG button to start removing air from the tubing. For details on replacing syringes, refer to [8.8.7 Replace Syringes or Syringe Case Heads](#) in chapter 8.
- **General Syringe Troubleshooting:**
 - Verify the top and bottom screws are tightened.
 - Verify the bottom screw is finger tight against the piston. Over-tightening can damage the syringe.
 - Verify there is a smooth resistant pull.
 - Verify the correct size syringe (Sample or Reagent) is in the proper position.
 - Verify only one O-ring is being used and that it is not flattened or damaged.
 - Verify the syringe is installed on the system properly.
 - Check the tubing connected to the syringe head for scratches, bending or leaks.
 - Verify the creases in the teflon tip of the syringe do not have any build up or flaking of the teflon coating.

- Verify the probes are not blocked. Refer to [8.4.1 Clean the Sample Probe and Mix Bars](#) and [8.8.2 Clean the Reagent Probe](#) in chapter 8. Syringe operation can be affected if the probes are blocked.

11.4.2 Probe Problems

Check for:

- **General Probe Troubleshooting:**
 - Verify water is dispensed in a straight stream.
 - Verify the metal screw cap for the probe connection is tight.
 - Verify the probe tubing does not have bubbles.
- **Reagent or sample probe leaking from loose probe connectors:** Tighten the probe connectors. Verify the tubing is firmly connected.
- **Reagent or sample probe is blocked:** Refer to [8.4.1 Clean the Sample Probe and Mix Bars](#) and [8.8.2 Clean the Reagent Probe](#) in chapter 8.
- **Reagent or sample probe is bent or damaged:** Replace the probe. For details on replacing probes, refer to [8.8.3 Replace a Sample and Reagent Probe](#) in chapter 8.
- **Sample aspiration position of the sample probe incorrect:** The sample probe moves down to aspirate sample. The maximum distance the probe can move downward is defined in the system software, but can be changed by a service engineer. If the sample probe is set incorrectly, the probe might hit the bottom of the sample cup or tube. Contact Beckman Coulter Technical Services.
- **Reagent probe not aligned over refrigerator:** If the reagent probe is hitting the reagent bottle or refrigerator cover, examine the reagent probe for abnormalities. If the probe is bent, replace it. If the probe is not bent, and the reagent aspiration position is still not right, contact Beckman Coulter Technical Services. For details on replacing reagent probe, refer to [8.8.3 Replace a Sample and Reagent Probe](#) in chapter 8.
- **Sample probe or reagent probe not aligned over the cuvette:** If the sample probe or reagent probe is coming into contact with the cuvettes, examine the sample probe or reagent probe for abnormalities. If a probe is bent, replace it. If the probe is not bent but still not aligned properly, contact Beckman Coulter Technical Services. For details on replacing sample or reagent probes, refer to [8.8.3 Replace a Sample and Reagent Probe](#) in chapter 8.
- **Abnormal wash position of reagent probe and sample probe:** If the probe is hitting the wash well, examine the probe. If a probe is bent, replace it. If the probe is not bent, but the probe wash position is still abnormal, contact Beckman Coulter Technical Services. For details on replacing sample or reagent probes, refer to [8.8.3 Replace a Sample and Reagent Probe](#) in chapter 8.
- **Basic troubleshooting for the reagent transfer unit and sample transfer unit:** Verify no drops remain on the path of the transfer. If drops are seen on the path of the sample or reagent transfer, contact Beckman Coulter Technical Services.

- **The sample contains a significant amount of fibrin and protein.**
 - Remove fibrin or filter the sample.
 - Check whether any other contaminant is mixed in the sample.
 - Remove any clots from the sample probe. Refer to [8.4.1 Clean the Sample Probe and Mix Bars](#) in chapter 8.

11.4.3 Abnormal Data Caused by Cuvette Wheel or Wash Nozzles

- **Scratches, fingerprints, stains, or foreign matter on the cuvettes:** Clean the cuvettes. If abnormal data is not corrected after cleaning, replace the cuvettes with new ones.
 - For details on cleaning or replacing cuvettes, refer to [8.7.1 Clean the Cuvettes and the Cuvette Wheel](#) or [8.8.13 Clean or Replace Individual Cuvettes](#) in chapter 8.
- **The outside of the cuvette and/or the cuvette wheel was wet or flooded:** Check the tube joints on the wash nozzle and tighten if they are loose. The wash nozzles may be clogged. Clean the wash nozzles.
 - For details on how to clean the wash nozzles, refer to [8.5.3 Clean the Wash Nozzle Unit and Check the Tube Mounting Joints](#) in chapter 8.
 - Clean any cuvettes and the cuvette wheel where it is wet, refer to [8.7.1 Clean the Cuvettes and the Cuvette Wheel](#) in chapter 8.
- **The DI water or wash solution is dripping from the wash nozzles:** Check the tube joints on the wash nozzles and tighten if they are loose. The wash nozzles may be clogged. Clean the wash nozzles.
 - For details on how to clean the wash nozzles, refer to [8.5.3 Clean the Wash Nozzle Unit and Check the Tube Mounting Joints](#) in chapter 8.
- **After washing the cuvettes, a large amount of water remained in the cuvettes:** Check the tube joints on the wash nozzles and tighten if they are loose. The wash nozzles may be clogged. Clean the wash nozzles.
 - For details on how to clean the wash nozzles, refer to [8.5.3 Clean the Wash Nozzle Unit and Check the Tube Mounting Joints](#) in chapter 8.
 - Remove the excess water from inside the cuvettes, refer to [8.7.1 Clean the Cuvettes and the Cuvette Wheel](#) in chapter 8.
- **The tube in the wash solution tank floats:** Straighten the tube, then insert it toward the tank bottom so that it does not come into contact with the tank opening.
- **The system has trouble with the float sensor in the wash solution tank or the diluted wash solution tank:** Connect the float sensor connector firmly, and bring the tube in the tank out of contact with the float sensor. If the problem is not corrected, the float sensor needs to be replaced. Contact Beckman Coulter Technical Services.

- **Some cuvettes are contaminated with foreign matter:** Clean the cuvettes. If abnormal data is not corrected after cleaning the cuvettes or if any cuvettes are broken, replace those cuvettes.
 - For details on cleaning or replacing cuvettes, refer to [8.7.1 Clean the Cuvettes and the Cuvette Wheel](#) or [8.8.13 Clean or Replace Individual Cuvettes](#) in chapter 8.
- If the cuvette wheel was removed from the analyzer for an extended period of time, then placed back on the analyzer, do not use the analyzer immediately. It is necessary to leave the cuvette wheel in the dry bath incubator for at least an hour for the cuvettes to stabilize to temperature specifications of $37\text{ }^{\circ}\text{C} \pm 0.3\text{ }^{\circ}\text{C}$.

11.4.4 Abnormal Data Caused by Photometer Lamp or Photometer Unit

- **The quality of the photometer lamp has deteriorated:** Check the record of photocal measurement results for abnormal data. If abnormal data is encountered, replace the photometer lamp.
 - For details on the photocal measurement result record, refer to [8.4.3 Perform a Photocal](#) in chapter 8.
 - For details on replacing the Photometer Lamp, refer to [8.8.14 Replace the Photometer Lamp](#) in chapter 8.
- **The photometer lamp is not stable:** Perform the photocal measurement 2 times to check the difference between 2 sets of measurement data. If there is a great difference between them, the photometer lamp may be defective. Replace the lamp. For details on replacing the Photometer Lamp, refer to [8.8.14 Replace the Photometer Lamp](#) in chapter 8.

11.4.5 Mixing Problems

- **The mix bars are contaminated:** Clean the mix bars.
For details on cleaning the mix bars, refer to [8.4.1 Clean the Sample Probe and Mix Bars](#) in chapter 8.
- **The teflon coating on the mix bars is chipped:** Replace the mix bars.
For details on how to replace mix bars, refer to [8.8.4 Replace Mix Bars](#) in chapter 8.
- **The mixing unit malfunctions, there is abnormal noise from the system during the mixing motion:** If there is an audible abnormal noise coming from the mix bar unit, check for bent mix bars. If the mix bar is bent, replace the mix bar. Refer to [8.8.4 Replace Mix Bars](#) in chapter 8. If the mix bars are not bent, contact Beckman Coulter Technical Services.
- **The wash water and wash solution are not properly drained from the mix bar wash wells:** Contact Beckman Coulter Technical Services.
- **The mix bars are not positioned properly causing contact between the mix bars and the mix bar wash well or the cuvettes.** If the mix bar is bent, replace the mix bar. Refer to [8.8.4 Replace Mix Bars](#) in chapter 8. If the mix bar is not bent, contact Beckman Coulter Technical Services.
- **The mix bars are not properly installed on the mixing unit, causing insufficient mixing of the sample and reagents:** Install the mix bars properly.
For details on mounting mix bars, refer to [8.8.4 Replace Mix Bars](#) in chapter 8.

11.4.6 DI Water Tank Problems

- **The DI water tank is contaminated or dirty:** If there are signs of particulate contamination on the inside of the tank, clean the tank thoroughly. For details on cleaning the DI water tank and DI filter, refer to [8.5.4 Clean the DI Water Tank, DI Filter, and Sample Probe Filter](#) in chapter 8.
- **Residual sodium hypochlorite solution remains in the DI water tank after cleaning:** Clean the tank again and rinse thoroughly with DI water.

11.4.7 DI Water or Filter Problems

Check water quality by performing a water quality check. Check for:

- DI water supply to determine if it meets the required specifications. Refer to [2.3.1 System Specifications](#) in chapter 2.
- **Dirty, stained or blocked filters:** Clean the DI water filter and the sample probe filter. Replace filters if data continues to be abnormal after cleaning. For details on cleaning and replacing the DI filter and sample probe filter, refer to [8.5.4 Clean the DI Water Tank, DI Filter, and Sample Probe Filter](#) in chapter 8.
- Tap water below 5°C used: The water supply to the deionizer must be above 5°C. Contact Beckman Coulter Technical Services for detailed information.

11.4.8 Incubation Temperature Problems

- Check that there is adequate space surrounding the system for air to circulate effectively. Verify this space is in accordance with Beckman Coulter recommendations. For details on installation environment, refer to [2.2.2 Installation Space Requirements](#) in chapter 2.
- Do not fill adjoining space around analyzers with boxes or other equipment. Space left at installation is required for proper air circulation.
- Clean the air filter.
- Verify the room temperature is between 18 °C and 32 °C and should not vary by more than ± 2 °C per hour. Failure to do this results in more required calibration events.
- If the cuvette wheel was removed from the analyzer for an extended period of time, then placed back on the analyzer, do not use the analyzer immediately. It is necessary to leave the cuvette wheel in the dry bath incubator for at least an hour for the cuvettes to stabilize to temperature specifications of $37\text{ °C} \pm 0.3\text{ °C}$.

11.4.9 Tubing and Pump Problems

The filters are dirty or clogged: Clean the DI water filter and the sample probe filter. If abnormal data is not corrected after cleaning filters, replace the filters.

- For details on how to clean the DI water filter, refer to [8.5.4 Clean the DI Water Tank, DI Filter, and Sample Probe Filter](#) in chapter 8.
- For details on how to clean the sample probe filter, refer to [8.5.4 Clean the DI Water Tank, DI Filter, and Sample Probe Filter](#) in chapter 8.
- For details on how to replace the DI water filter, refer to [8.6.2 Inspect and if Needed, Replace the DI Water Filter, Sample Probe Filter, and Replace the O-ring](#) in chapter 8.
- For details on how to replace the sample probe filter, refer to [8.6.2 Inspect and if Needed, Replace the DI Water Filter, Sample Probe Filter, and Replace the O-ring](#) in chapter 8.

11.4.10 Reagent Refrigerator Problems

If the reagent refrigerator temperature is out of range:

-
- 1** Select **Home > Analyzer Status** and check the coolant temperature for the reagent refrigerator.
-
- 2** Open the reagent refrigerator and verify the reagent bottles are cool.
-
- 3** If the problem persists, contact Beckman Coulter Technical Services.
-

11.4.11 STAT Table Problems

If the STAT table compartment temperature is out of range:

-
- 1** Select **Home > Analyzer Status** and check the coolant temperature of the STAT table compartment.
-
- 2** Verify the large and small STAT table covers are properly mounted. If the covers are opened frequently or for extended periods of time, the STAT table compartment temperature increases.
-
- 3** If the problem persists, contact Beckman Coulter Technical Services.
-

11.4.12 Rack Problems

Check for the following general problems:

- Verify that the rack is clean and that the surface is not sticky.
- Check barcode positioning.

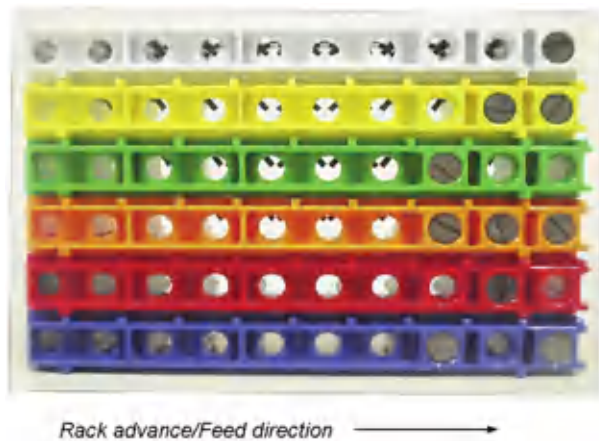
For details on attaching the barcode label to the sample rack, refer to “Placing a barcode label (rack ID) on the rack” in [6.1.4 Place the Sample Cups/Tubes in the Rack](#) in chapter 6.

- Verify the rack was loaded correctly.

For details on placing the sample cups/tubes in the rack, refer to [6.1.4 Place the Sample Cups/Tubes in the Rack](#) in chapter 6.

- Verify the correct number of magnets are in the bottom of the rack. Compare the configuration of magnets on the underside of the rack with that of another rack of the same color. The configuration should be identical. Discard the rack if a magnet is missing.

Figure 11.1



Rack Color	Magnet Position (1 to 10)
White	Position 1
Yellow	Positions 1 and 2
Green	Position 3
Orange	Positions 1, 2, and 3
Red	Position 2
Blue	Positions 1 and 3

11.5 Troubleshooting the System - System Problems

The following lists potential system problems:

- 11.5.1 Alarm for Reagent Refrigerator Temp
- 11.5.2 Abnormal Sound from Inside the System
- 11.5.3 Alarm for DI Water
- 11.5.4 Leaks from the Wash Solution Roller Pump
- 11.5.5 Barcode Errors
- 11.5.6 Leaks from the Bottom of the System
- 11.5.7 No Wash Solution to Mix Bar Wash Wells
- 11.5.8 Reagent Alarm when Sufficient Reagent Remains in Bottles
- 11.5.9 Sample Alarm when Sufficient Sample Remains
- 11.5.10 No Sample Cup Alarm when Sample Cup is Present
- 11.5.11 No Sample Cup Alarm when Sample Cup is Present on the STAT Table
- 11.5.12 Liquid Leaking from the Reagent Probe or Sample Probe
- 11.5.13 Reagent Probe or Sample Probe not Aligned over the Cuvette
- 11.5.14 Error flag [#] (Sample Level Detection Error) Generated during the Sample Dispense Operation
- 11.5.15 TEMP DIL Alarm for the Wash Water Heater
- 11.5.16 Sample Rack Jammed
- 11.5.17 Printer Problems

11.5.1 Alarm for Reagent Refrigerator Temp

- If there is a problem with the reagent refrigerator unit, check that there is adequate space surrounding the system for air to circulate effectively. For details on installation environment precautions, refer to [2.2.2 Installation Space Requirements](#) in chapter 2.
- Verify the room temperature is from 18° C to 32° C with a +/-2° C variation. If the room temperature is over 32° C, the reagent refrigerator temperature is over 12° C. If the problem persists, contact Beckman Coulter Technical Services.

11.5.2 Abnormal Sound from Inside the System

- **Air bubbles trapped in tubing:** Check the DI water filter. If the filter is damaged, replace it. Check the sample probe filter for placement of the filter. Refer to the photo for proper positioning of the filter.

Figure 11.2



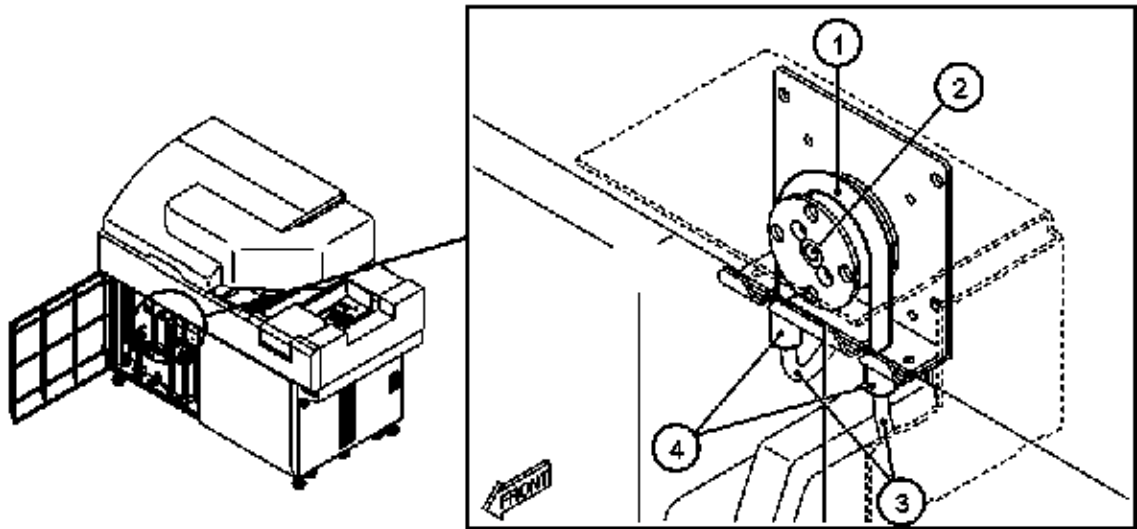
- **Deionized Water Tank Empty alarm:** The ion-exchange capability of the deionizer can be insufficient. Replace the deionizer if it is not up to required specification. Check the DI water filters. If they have become dirty or blocked, clean or replace them.
 - For details on cleaning the DI Water Filter and the Sample Probe Filter, refer to [8.5.4 Clean the DI Water Tank, DI Filter, and Sample Probe Filter](#) in chapter 8.
 - For details on replacing the DI Water Filter, refer to [8.6.2 Inspect and if Needed, Replace the DI Water Filter, Sample Probe Filter, and Replace the O-ring](#) in chapter 8.
- For all other sources of noise, contact Beckman Coulter Technical Services.

11.5.3 Alarm for DI Water

- **The deionizer is turned off:** Turn on the deionizer. Perform an **End Process**, then turn on the system.
- **The ion exchange capability of the deionizer is insufficient:** Check if the deionizer meets the specification. If the deionizer does not meet the specification, replace it. For detailed information, consult the deionizer manufacturer.
- **The DI water filter is clogged:** Check the DI water filter with a finger to check for sliminess. If the filter surface is slimy, the filter may be clogged. Clean the DI water filter. For details on how to clean the DI water filter, refer to [8.5.4 Clean the DI Water Tank, DI Filter, and Sample Probe Filter](#) in chapter 8.

11.5.4 Leaks from the Wash Solution Roller Pump

Figure 11.3



- | | |
|------------------------------|----------------|
| 1. Roller pump tubing | 3. Relay tubes |
| 2. Wash solution roller pump | 4. Connector |

- The roller pump tubing may be deteriorated: Check the roller pump tubing for cracks due to deterioration. If deteriorated, replace the roller pump tubing. For details on replacing the roller pump tubing, refer to [8.6.3 Replace the Wash Solution Roller Pump Tubing](#).
- A connector may be loose: Check the connectors, and firmly tighten if the connectors are loose.

11.5.5 Barcode Errors

- **Reagent Barcode Reader Dirty:** Wipe the barcode reader window with a clean, DI water dampened, lint free cloth to remove any particles on the read window. If necessary, follow up with a clean, dry, lint free cloth to dry the reader so there are no smear marks left to cause errors.
- **Barcode labels on sample cups or racks are damaged and discolored:** Replace any sample or rack barcodes that are worn or damaged.
- **Barcode labels on reagent bottles are damaged:** If the reagent ID is damaged, the operator can edit the reagent ID and still use the bottle of reagent. Refer to [7.4.2 Edit a Reagent ID](#) in chapter 7.

- **Barcode labels are not properly attached to racks or sample cups:** For details on how to put barcodes on properly, refer to “Placing a barcode label (rack ID) on the rack” in section [6.1.4 Place the Sample Cups/Tubes in the Rack](#) and [6.1.2 Apply Barcode Labels to Sample Tubes](#) in chapter 6.



Looking directly into a laser beam can cause permanent eye damage.

- For details on replacing rack ID labels, refer to [8.8.12 Replace Rack ID Labels](#) in chapter 8.

11.5.6 Leaks from the Bottom of the System

- **Wash line obstructed:** Check for obstructions in the wash wells for the sample probe and reagent probes. Clean the wells if any blockages exist. Refer to [8.5.1 Clean the Sample Probe and Reagent Probe Wash Wells](#) in chapter 8.
- **Waste line not installed properly:** If the waste line is leaking or if the tubing is too long, contact Beckman Coulter Technical Services.
- **Any leaks from the bottom of the instrument are potentially dangerous:** If the source is not clearly visible (e.g. leaking syringe), contact Beckman Coulter Technical Services.

11.5.7 No Wash Solution to Mix Bar Wash Wells

The DI water filter may be clogged. Verify the last time the DI water tank and filter were cleaned.

With a gloved hand, feel the inside of the DI water tank by either sliding your hand on the gray float sensor in the tank or the side of the tank for a slick, slimy build up. This can cause the DI water and sample probe filters to become clogged. Clean both the DI water and sample probe filters, and the DI water tank.

For details on how to clean the DI water filter, sample probe filter, and DI water tank, refer to [8.5.4 Clean the DI Water Tank, DI Filter, and Sample Probe Filter](#) in chapter 8.

11.5.8 Reagent Alarm when Sufficient Reagent Remains in Bottles

The liquid level sensor could be faulty. Select **Alarm List** for the cause and corrective actions.

- Check the reagent bottle for bubbles that may occur from replacing reagents or a bottle that is not properly placed in the reagent refrigerator.
- Perform a reagent volume check to verify if the alarm is still occurring.
- Contact Beckman Coulter Technical Services.

11.5.9 Sample Alarm when Sufficient Sample Remains

There is a possibility that the sample probe does not move down to the liquid level of the sample due to incorrect detection of the height of the cup. Verify the appropriate tube or cup is used and placed properly in the rack. Check for bubbles in the sample cup. If an error still occurs, contact Beckman Coulter Technical Services.

11.5.10 No Sample Cup Alarm when Sample Cup is Present

Unspecified cup used: Check that the appropriately specified sample cups were used in each rack. Refer to [6.1.1 Sample Cup and Tube Preparation](#) in chapter 6 for the specifications on sample cups or tubes.

11.5.11 No Sample Cup Alarm when Sample Cup is Present on the STAT Table

- The required test was not requisitioned for the STAT sample, or the requisition was not for the correct position on the STAT table. Repeat the STAT sample requisition.
- Verify the sample cup was placed correctly on the STAT table with the appropriate adaptor for the sample cup diameter.
- Verify the sample cup meets specifications. Refer to [2.3.1 System Specifications](#).

11.5.12 Liquid Leaking from the Reagent Probe or Sample Probe

Verify that the reagent probe or sample probe is installed correctly:

-
- 1** Select **Home > Analyzer Maintenance > Maintenance**. Place a check mark in the Analyzer Maintenance box.
-
- 2** Select **Prime Washing Line** to check the reagent probes and sample probe.
-
- 3** Select **OK** to dispense water from the reagent probe and sample probe. If the deionized water does not dispense normally, a reagent probe or sample probe might be improperly installed. Check the reagent probe or sample probe installation. If it is necessary to replace the probe, refer to [8.8.3 Replace a Sample and Reagent Probe](#) in chapter 8.
-

11.5.13 Reagent Probe or Sample Probe not Aligned over the Cuvette

Check if the Reagent probe or Sample probe is bent: Examine the probe and replace it if it is bent.

For details on replacing sample or reagent probes, refer to [8.8.3 Replace a Sample and Reagent Probe](#) in chapter 8.

11.5.14 Error flag [#] (Sample Level Detection Error) Generated during the Sample Dispense Operation

Check if the sample volume is too low: Verify there is sufficient sample for the requested tests. The dead volume for the different cups has to be considered. For details on sample preparation, refer to [6.1.3 Sample Preparation](#) in chapter 6.

11.5.15 TEMP DIL Alarm for the Wash Water Heater

- The water temperature may not be within the specified range. Contact Beckman Technical Services for assistance.

11.5.16 Sample Rack Jammed

Check for:

- **Contamination on the rack:** Verify that nothing has fallen onto the rack and that the rack ID label, or sample ID labels have not peeled off, causing the rack to jam.
- **Rack feeder unit sticky or dusty:** Clean surfaces with deionized water using a lint free dampened cloth.
- **Object sticking to the magnet on the bottom of a rack:** Check for small metal objects such as staples or paper clips on the magnets on the bottom of a rack. If foreign matter sticks to the magnet, remove it from the magnet.

11.5.17 Printer Problems

See the printer manual for assistance with all printer troubleshooting.

- Printer is disconnected. Check the plug and socket and connecting lead.
- The power to the printer is not turned ON. Check whether the power to the printer is turned ON.
- Printer toner is empty and needs to be replaced.
- Verify the online button is on.
- Verify paper is loaded properly.

11.6 Troubleshooting the System - Data Processor Problems

The following lists potential data processor problems:

- 11.6.1 Menu Cannot be Selected
- 11.6.2 Number Key Pad on Keyboard Does Not Work
- 11.6.3 Keyboard Not Responding
- 11.6.4 Inaccessible Floppy Disk
- 11.6.5 Results Do Not Print Automatically
- 11.6.6 Online Auto-Output by Host Computer Not Executed
- 11.6.7 No Data Stored on Disk

11.6.1 Menu Cannot be Selected

- Function is inaccessible: Menu items which are grayed out are inaccessible due to the programmed parameters.
- System software crashes: To reset the system:
 - Press **Ctrl** + **Alt** + **Delete** together.
 - Select **Shutdown**, then **OK**.
An audible alarm is generated.
 - Once the PC shuts down, press EM STOP, wait 5 seconds before pressing RESET, then wait 5 seconds before pressing ON.
 - The software and analyzer should synchronize and load at the same time.
 - The System Start pop-up window opens with “Program Down Load to Analyzer”.
 - The System Start pop-up window changes to "**End Process** was not completed at previous shutdown. Database retrieval is required." Select **OK**.
 - The New Index pop-up window opens prompting the operator to “Create a New Index?”. If the operator wants to stay in the current index select **Index**. If a New Index is necessary select **New Index**.
 - The analyzer goes into *Warm Up* mode for 90 minutes. If the analyzer has been down longer than 5 minutes, then allow the 20 minute warm-up. The operator can then select **Home > Analyzer Maintenance**, and select **Stand By (F4)**. The analyzer bypasses *Warm Up* to *Standby*.

TIP The incubator remains red in **Analyzer Status** until the temperature returns to 37 °C ± 0.3 °C.

- If unable to recover from a software crash, contact Beckman Coulter Technical Services.

11.6.2 Number Key Pad on Keyboard Does Not Work

Num Lock is not selected: Press the **Num Lock** key and then check that the LED light over Num Lock on the keyboard is on.

11.6.3 Keyboard Not Responding

Possible causes:

- **Keyboard cable:** Verify that the cable connector is in the right socket in the back of the computer (color coded).
- **System crash:** For details on system crash, refer to [11.6.1 Menu Cannot be Selected](#).
- **System busy:** The system might be saving data or performing a series of tasks simultaneously. Wait for a few minutes until the system is ready. If this happens frequently, contact Beckman Coulter Technical Services.
- **Data processing, such as data saving, is being executed:** Wait until data processing has been completed.
- **Electrical Noise:** If a buzzing noise is heard, unplug the keyboard and then firmly replace it.

11.6.4 Inaccessible Floppy Disk

Check for:

- The floppy disk is not formatted properly: Format the floppy disk. Select **Menu List > System > External Data Management > External Data Management**. Select **Parameters** or **Data > Media Initialize (F2)**. The following two types of disks can be used:
 1. Formatted, 2HD 1.44 MB
 2. Formatted, 2DD 720 KB
- Floppy disk is write-protected: Slide the tab on the disk cover. If the diskette is punched, put in a new blank unpunched diskette.
- Floppy disk is damaged: If writing is continuously unsuccessful, the floppy disk is probably damaged. Use a new disk.
- Floppy disk drive damaged: If the floppy disk is new and properly formatted and data still cannot be saved, then the floppy disk drive might be broken. Contact Beckman Coulter Technical Services.

11.6.5 Results Do Not Print Automatically

Check for:

- **Realtime output is not set:** Set the realtime output of reports from **Menu List > System > Format > List Format > Edit (F1) > Realtime List (F5)**. For details on how to set the realtime output, refer to [4.14.1 Format Realtime Reports and Lists](#) in chapter 4.
- **Printer is not available during analysis (out of paper, printer is turned off, printer is off-line.):** Turn on the printer, verify the printer is online, and add paper as needed.
 - Select **Home > Analyzer Status**.
 - Select **Printer Control (F5)**.
 - Select **Resume** to start printing the analyzed data.

11.6.6 Online Auto-Output by Host Computer Not Executed

Check for:

- **Interface cable to the host computer disconnected:** Connect the cable.
- **Interface cable defective:** Contact Beckman Coulter Technical Services.
- **Host I/O parameters incorrectly modified:** Set the appropriate I/O parameters by selecting the Online window.
- For details on how to set host I/O parameters, refer to [4.12 Program Online Parameters](#) in chapter 4.

11.6.7 No Data Stored on Disk

Check for:

An error might have occurred on the hard disk: Repair and rebuild the database(s) using the Retrieve database function as follows:

- 1 Select **Maintenance > Data Operation > Database Retrieval**.
- 2 Select the databases to rebuild by checking the boxes.
- 3 Select the database index from the “Index” drop-down list.
- 4 Select **Perform (F5)** and then Yes, when prompted, to start retrieving.

 **CAUTION**

If the system does not start up automatically after executing Retrieve database, the hard disk may be seriously damaged and may require replacement. Contact Beckman Coulter Technical Services.

11.7 Recovering from an Emergency Stop or Power Loss

In the event of power failure or an emergency stop, the main power is cut off immediately. Power to the incubator and reagent refrigerator is also cut off.

11.7.1 Performing an Emergency Stop

11.7.2 Resetting the System after a Power Failure or an Emergency Stop



- If an emergency stop or power failure occurs during Measure, any data that is not complete is lost and must be repeated.
- Reagents remain in the cuvettes after performing an emergency stop. Perform a W1 to remove reagents before performing an End Process or resuming analysis.
- If the system is without power for a lengthy period of time after a power loss or an emergency stop, verify the reagent integrity before resuming analysis.

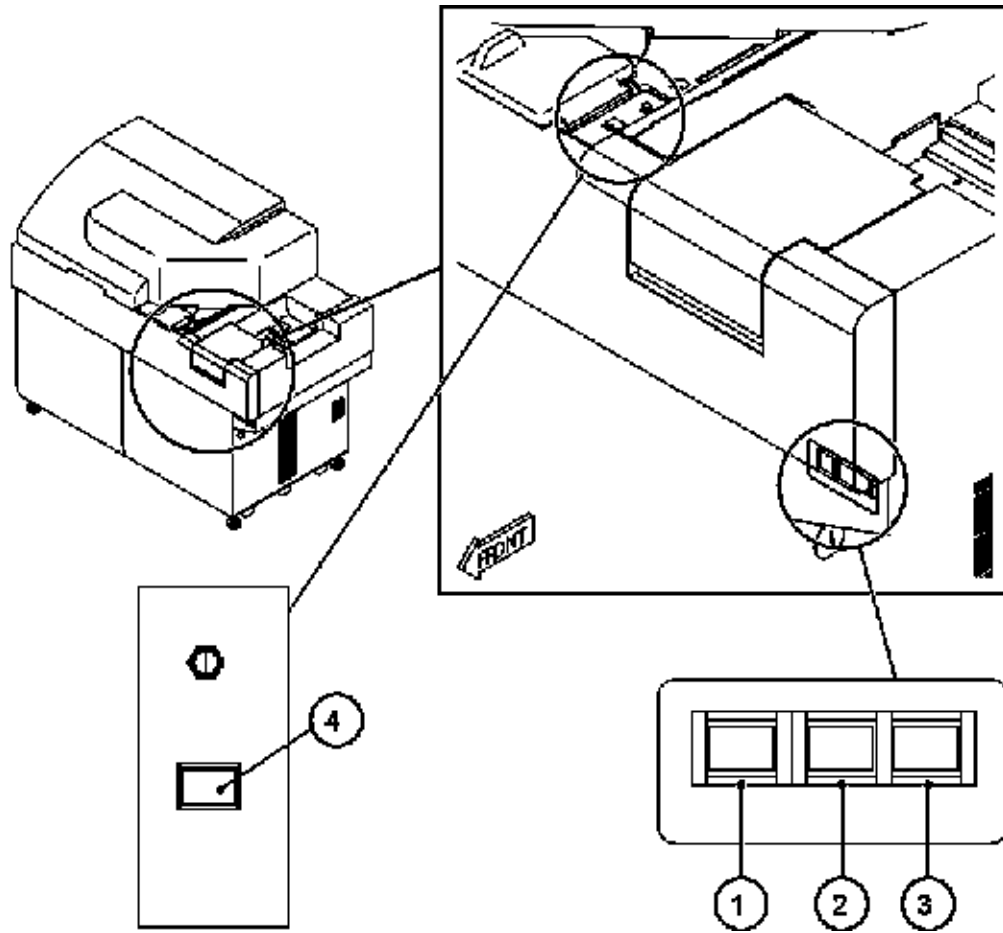
11.7.1 Performing an Emergency Stop

To perform an emergency stop:

- 1 Press the EM STOP button on the front right door to turn off all power to the analyzer.
- 2 To turn off the computer, press **Ctrl** + **Alt** + **Delete**. A Windows Security window opens. Select the **Shutdown** button.

- 3 Remove all racks from the rack transport belts.

Figure 11.4



1. ON button
2. EM STOP button
3. RESET button
4. TABLE ROTATION/DIAG button

11.7.2 Resetting the System after a Power Failure or an Emergency Stop

After power failure or emergency stop, follow the steps below to reset the system.

Resetting the System

- 1 Press RESET, wait 5 seconds, then press ON.
 - The software and analyzer should synchronize and load at the same time.
 - The System Start pop-up window opens with “Program Down Load to Analyzer.”
 - The System Start pop-up window changes to “End Process was not completed at previous shut down. Database retrieval is required”. Select **OK**.
- 2 In the New Index window, select **Index** to continue analysis in the current index, or **New Index** to create a new index.
- 3 The system stays in *Warm Up* mode for 90 minutes. If the analyzer has been down longer than 5 minutes, wait the required 20 minute warm up time. Select **Home > Analyzer Maintenance > Stand By (F4)** to return to *Standby* mode.
- 4 Perform a W1. For details on performing a W1, refer to [8.8.11 Perform a W1](#) in chapter 8.

TIP The incubator remains red in **Analyzer Status** until the temperature returns to $37\text{ °C} \pm 0.3\text{ °C}$.

Checking Samples

TIP The following list is available for samples in the current index. If an End Process is performed and the system turned ON, the operator is prompted to create a new index in the New Index window.

- 1 Select **Home > Sample Manager > Sample > Main**. A list of samples processed in the current index displays.
- 2 Confirm the sample number of the last completed sample.

Checking Reagents

- 1** Select **Home > Reagent Management > Main**.

 - 2** Select **Reagent Check (F5)**. The Reagent Check window opens.

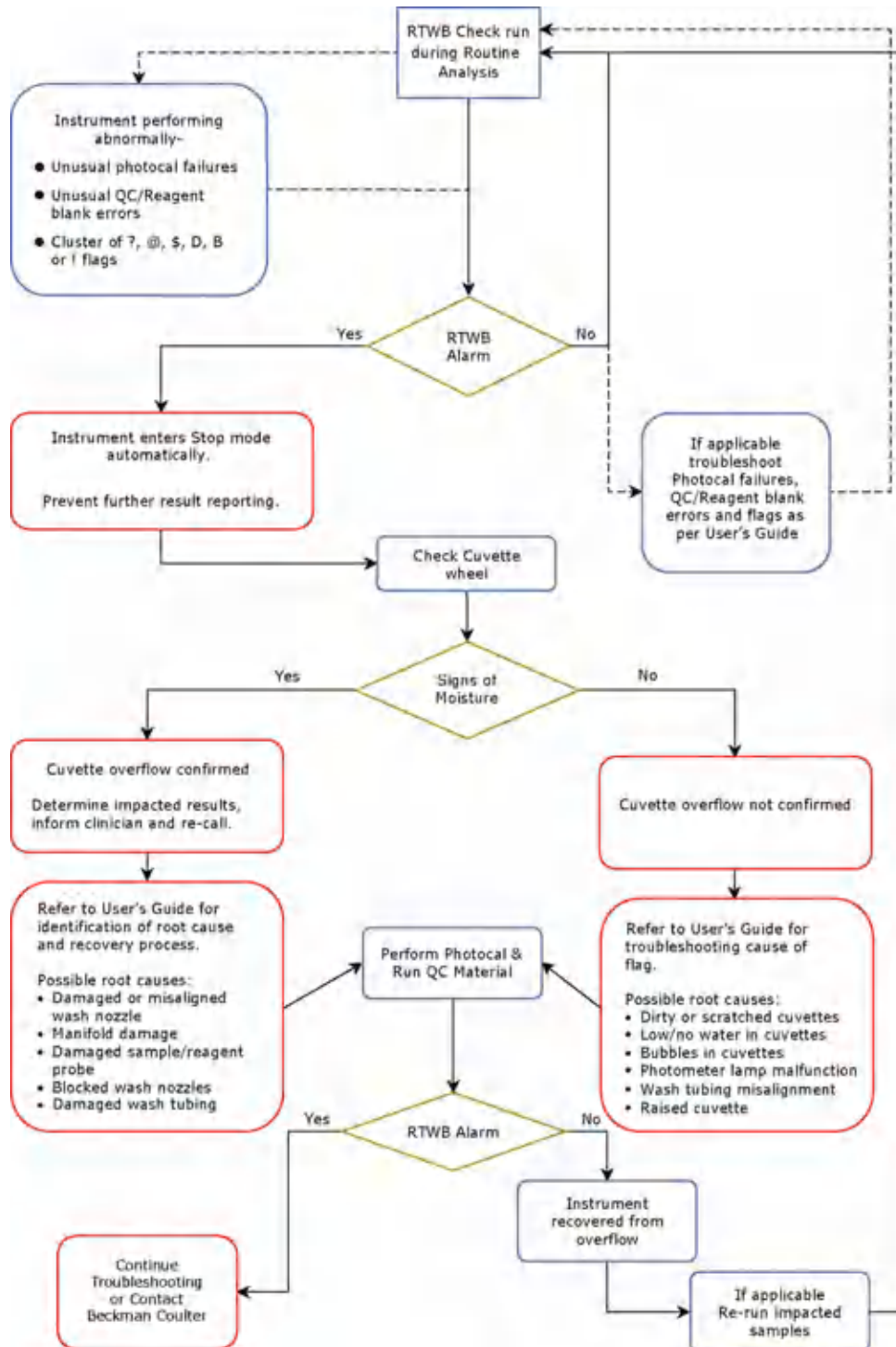
 - 3** Select **Check all positions**.

 - 4** Select **Start**. Reagent check starts and “Checking” is displayed. After check completion, “Reagent check completed” is displayed.
-

11.8 RTWB Troubleshooting Overview Flowchart

The following flowchart shows an overview of errors and corrective actions for monitoring the automatic RTWB check function while the system is in operation.

Figure 11.5



11.9 Recovering from a "Photometry Error During a Cuvette Wash" Alarm

Inspect the cuvettes to determine if a cuvette overflow occurred when a "PHOTOMETRY ERROR DURING CUVETTE WASH" alarm is generated. The recovery procedures are different if a cuvette overflow occurred, or if unstable photometry caused the error.

The analyzer goes to *Stop* mode immediately after the "PHOTOMETRY ERROR DURING CUVETTE WASH" alarm is generated.

11.9.1 Inspect the Cuvettes to Determine if an Overflow Occurred

To confirm a cuvette overflow has occurred, remove the cuvette wheel cover after initializing system. The cuvettes should appear frosty or white. If the cuvettes appear dark, black, or are wet when removed, a cuvette overflow has occurred. In addition, remove the cuvette number "aa" identified in the "PHOTOMETRY ERROR DURING CUVETTE WASH (aa)" alarm. The "aa" identifies the cuvette number that generated this alarm. Visually inspect the cuvette to determine if it is wet. If the cuvette is wet on the outside, refer to [11.10 Recovering from a Cuvette Wheel Overflow](#) and perform all system recovery procedures. If the cuvette is not wet on the outside, refer to [11.11 Recovering from an Unstable Photometry Error](#) and perform the required system recovery procedures based on the cause of the error.

TIP PHOTOMETRY ERROR DURING CUVETTE WASH (aa)

aa: Cuvette number (1 to 88) with a photometric error.

TIP For information on how to remove the cuvette wheel, refer to [8.7.1 Clean the Cuvettes and the Cuvette Wheel](#) in chapter 8.

11.10 Recovering from a Cuvette Wheel Overflow

11.10.1 What Causes an Overflow?

11.10.2 Recognizing an Overflow

11.10.3 Items to Check when Recovering from an Overflow

11.10.4 After the Overflow is Fixed

The following procedure explains what can cause an overflow and how to recognize and recover.

TIP Performing scheduled maintenance greatly reduces the chances of a cuvette wheel overflow. For more information about maintenance for each system component, refer to [CHAPTER 8, Maintenance](#)

11.10.1 What Causes an Overflow?

A cuvette wheel overflow may be caused by any of the following:

- A wash nozzle is clogged or partially clogged. When this happens, liquid is not aspirated from the cuvette completely and eventually liquid spills over the side. This can occur when the wash nozzles are not cleaned properly, or when particles such as glass are aspirated into the nozzle.
- A wash nozzle is bent or damaged.
- There are damaged or missing o-rings on the water supply tube mounting joint manifold.
- The reagent probe is bent. A bent probe could be dispensing outside of the cuvette.
- The sample probe is bent. A bent probe could be dispensing outside of the cuvette.
- Cuvettes are chipped or cracked due to alignment problems with the reagent probe or wash nozzles.
- The wash nozzle tubing is not connected to the nozzle.

11.10.2 Recognizing an Overflow

A "PHOTOMETRY ERROR DURING CUVETTE WASH" alarm is generated. The overflow may have occurred 60 minutes before the alarm was generated. Results obtained during the 60 minutes before the alarm are invalid and need to be analyzed again. The 60 minute time frame is the time the analyzer was in a Measure mode. For detailed instructions, refer to [7.15 Identifying and Re-analyzing Samples after a Cuvette Overflow](#) in chapter 7.

The error flags *, ?, @, \$, D, B, and ! may indicate a cuvette wheel overflow. The data, alarms, and/or flags vary depending on the severity of the overflow. One or all tests could be affected by an overflow. Items to check:

- QC error flags or alarms
- Reagent blank error flags
- Analyzer not performing as normal operation
- Numerous cuvettes fail after photocal

Lift the cuvette wheel cover: the cuvettes should appear frosty or white. If they are dark, black, or wet when removed, the cuvette wheel has overflowed.

11.10.3 Items to Check when Recovering from an Overflow



Immediate attention should be given to an overflow. If nothing is done to fix the problem, the wheel continues to overflow. Contact Beckman Coulter Technical Services for assistance with performing these checks.

- The wash nozzle should be aligned over the cuvettes. Visually inspect and ensure the wash nozzles are centered over the cuvettes and check the alignment.
- Sonicate and clean the wash nozzles with a stylus to remove any debris. Refer to [8.5.3 Clean the Wash Nozzle Unit and Check the Tube Mounting Joints](#) in chapter 8.
- Check the reagent and sample probes to be sure they are properly aligned. Rotate the sample and reagent probes over the cuvette wheel.
- Check for chipped or cracked cuvettes. Replace them if necessary. For information about replacing cuvettes, refer to [8.7.1 Clean the Cuvettes and the Cuvette Wheel](#) in chapter 8.
- Verify the wash nozzle tubing connections are secure.
- Verify the o-rings on the manifold are in place and not damaged.

11.10.4 After the Overflow is Fixed

- After the cuvette wheel overflow is fixed, refer to [8.7.1 Clean the Cuvettes and the Cuvette Wheel](#) in chapter 8.

11.11 Recovering from an Unstable Photometry Error

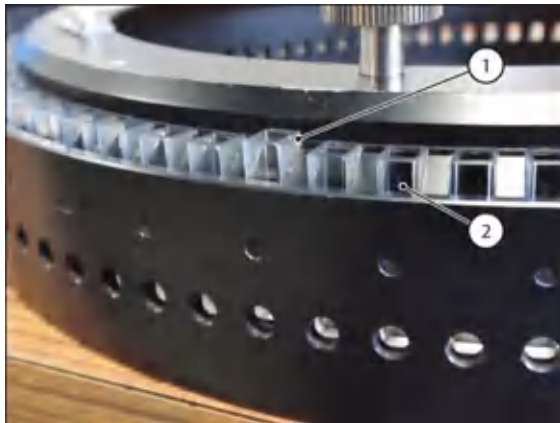
When the "PHOTOMETRY ERROR DURING CUVETTE WASH" alarm is generated, and a cuvette overflow did not occur, the alarm is due to unstable photometry. Unstable photometry can be caused by improperly placed cuvettes in the cuvette wheel, an insufficient amount of wash solution being supplied to clean the cuvettes, bubbles in the bottom of the cuvettes, dirty or scratched cuvettes, or a deteriorating lamp.

Perform the following procedures in this section. After the error is identified and corrected, perform a Photocal. Refer to [8.4.3 Perform a Photocal](#) in chapter 8. If the error still occurs, contact Beckman Coulter Technical Services.

11.11.1 Inspect the Cuvette Placement

Inspect the cuvette identified by the "PHOTOMETRY ERROR DURING CUVETTE WASH" alarm to determine if it is placed in the cuvette wheel correctly. Push the cuvette down into the cuvette wheel until the top of the cuvette is even with the cuvette wheel.

Figure 11.6



1. Incorrect cuvette placement
2. Correct cuvette placement

11.11.2 Inspect the Cuvette Condition

- 1 Inspect the cuvettes identified by the "PHOTOMETRY ERROR DURING CUVETTE WASH" alarm to determine if there is sufficient wash solution in the cuvette.
If the remaining wash solution volume is insufficient or empty, there is a possibility of system malfunction. Contact Beckman Coulter Technical Services.

Figure 11.7



- 2 Inspect the cuvette to determine if there are any bubbles at the bottom of the cuvette.

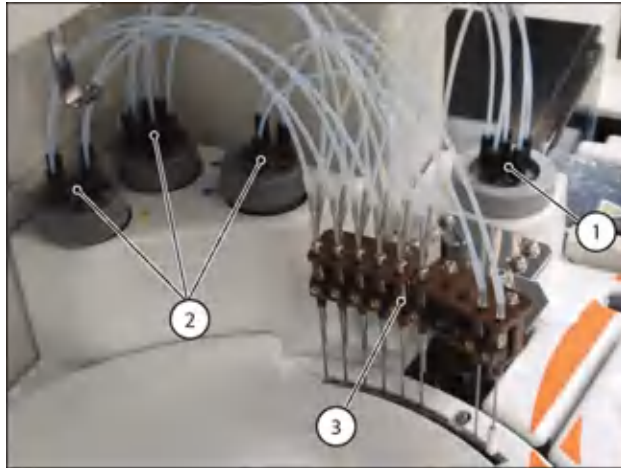
Figure 11.8



- 3 If bubbles exist in the cuvette, inspect the water and wash solution supply tubing on the wash nozzle unit to determine if bubbles are present. The aspiration tubing has bubbles in normal operation.

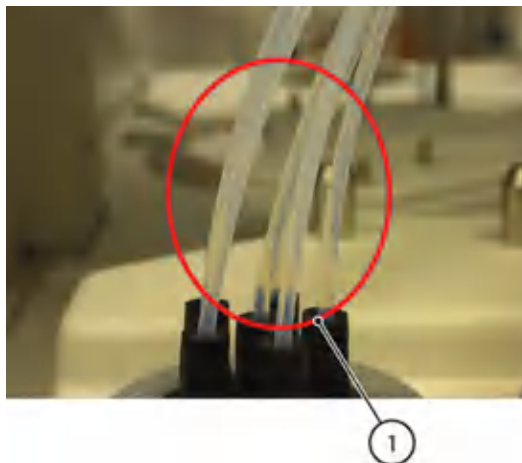
- 4 If bubbles exist in the water and wash solution supply tubing on the wash nozzle unit, tighten the tube mounting joints and remove the bubbles by performing a W1 or Prime Wash Nozzle.

Figure 11.9



1. Water and wash solution supply tube mounting joint manifold (A total of six O-rings are used inside)
2. Aspiration tube mounting joint manifold
3. Wash nozzle unit

Figure 11.10



1. Inspect water and wash solution supply tubing for bubbles

For information on how to perform a W1, refer to [8.8.11 Perform a W1](#) in chapter 8.

For information on how to perform a Prime Wash Nozzle, refer to [8.8.1 Replace O-rings in the Water Supply Tube Mounting Joint](#) in chapter 8.

- 5 Inspect the cuvette to determine if it is dirty or scratched. As needed, clean or replace the cuvette. Refer to [8.8.13 Clean or Replace Individual Cuvettes](#) in chapter 8.

11.11.3 Inspect the Lamp

Select **Home > Analyzer Maintenance > Consumption**.

Confirm the number of hours the lamp has been in use. If the lamp has been in use for over 1,000 hours, replace the lamp.

For information on how to replace the photometer lamp, refer to [8.8.14 Replace the Photometer Lamp](#) in chapter 8.

Troubleshooting

11.11 Recovering from an Unstable Photometry Error

Glossary

ACAL (Auto calibration) — AB type (or ACAL) uses calibrator material to automatically calculate a calibration factor and creates a calibration curve each time a calibration is performed. The calibration types are defined in parameters as AB (single point) or 2AA, 2AB-7AB (multi-point) for each test.

Advanced Calibration — Calibration of multiple bottles (a maximum of 5 bottles) of the same reagent set in the reagent refrigerator can be performed together in advance of using the reagent.

Alarm Shots — The Alarm Shots function enables the operator to set the number of remaining reagent shots (tests) which when reached, prompts a reagent short alarm.

Auto Power On — Allows the operator to set a date and time when the analyzer will automatically power on.

Calibration Curve — The calibration curve is calculated from the absorbance and concentration of the calibrator. The analyte concentration for a sample is then calculated using this calibration curve.

Calibration History — The system saves a maximum of 100 points of calibration data per sample type per test. Calibration data and status can be viewed in **Calibration Monitor**.

Calibrator — Material with a known value which is used to establish the measurement relationship.

Consumable — Consumables are materials required by the system such as photometer lamps, probes, and syringes.

Cuvette — A glass vessel that is used as the reaction vessel containing the sample and reagent.

Dead volume — Sample volume that cannot be aspirated by the system but remains in the tube/cup. The dead volume depends on the type of cup/tube that is used.

Disabling (a Test) — The option to prevent analysis for requisitioned tests. Only patient samples are disabled with this option. A reagent blank, calibration and QC will be performed, if requisitioned, even if a test is disabled. This feature is used if calibration or QC fails but samples are already on the rack supply unit and the system is running.

DI water - Deionized water — Deionized water, also known as demineralized water, is water that has had its mineral ions removed, such as ions from sodium, calcium, iron, copper, and anions such as chloride and bromide.

END (End Point Assay) — There are three types of end-point assay:

- **One-point assay** is a general end-point assay that determines the optical density of the reaction mixture from the optical density measured at a specified photometric measuring point. **Two Point (Self-blank method) assay** provides sample blank adjustment. The optical density values before dispensing reagent are eliminated as the sample blank. This optical density value is then subtracted from those calculated after dispensing the second reagent. Any contribution to the final reaction OD from the sample (turbidity, icterus etc.) is removed to improve measurement reliability.
- **Blanked End Assay** measures the blank channel and then subtracts this from the measured optical density, to calculate the actual optical density of the reaction. This requires an additional blank.

END1 does not use the reagent blank absorbance as the reference for measurement data at each photometric point.

Error Flag — Symbols that appear beside analysis results, indicating that a problem or an error has occurred during analysis. A result with an error flag must be reviewed and appropriate corrective actions performed before reporting results.

FIXED (Fixed Point Assay) — Fixed-Point Assay is a method of calculation that determines the difference between the optical densities at two specific time points within a reaction.

FIXED1 does not use the reagent blank absorbance as the reference for measurement data at each photometric point.

Group — A Group is a user-defined group of tests that is selected in the Start Condition menu. The tests in the Group selected have reagents on-board the analyzer and are available to perform analysis. Three Groups can be programmed in **Menu List > Parameters > Common Test Parameters > Group of Tests**.

For example, designate the analysis tests frequently used for routine analysis to Group 1, and the analysis tests used for specific analysis to Group 2. Perform routine analysis under Group 1 and switch to Group 2 for specific analysis as required.

LAG_TIME Check — If a reaction is terminated too quickly, effective data at two points or more may not be acquired. In this case, the system can be set up to calculate the analysis result using the data in the lag phase.

Used for analysis tests in the rate assay method. Refer to the individual method parameters to determine the correct setting for the assay.

LIH Testing - Serum Index — Evaluates and performs test of lipemia (L), icterus (I), and hemolysis (H) in serum and plasma. LIH is the symbol used for testing lipemia (L), icterus (I), and hemolysis (H).

Linearity — Ability of a measuring method to generate test results that are proportional to the analyte concentration in a sample.

MCAL (MB) — A type of calibration that does not use any calibrator material. A preset MB factor has been determined and is entered per the chemistry setting sheet provided for this type of assay.

Photocal Measurement — This measurement checks the integrity of the cuvettes used to obtain appropriate analysis results. Confirm the photocal data obtained from a photocal measurement from **Home > Analyzer Maintenance > Photocal Monitor**.

- For details on performing photocal measurement, refer to [8.4.3 Perform a Photocal](#) in chapter 8.

QC Monitor — The QC Monitor gives an instant visual summary of QC analysis results.

QC Sample — Material used to verify the performance characteristics of an in vitro diagnostic medical device.

Quality Control (QC) Analysis — The process of analyzing samples with known concentrations of analytes in order to test the quality of reagents, calibrators, equipment and procedures.

RATE (Rate Assay)

- Normal rate assay measures the variation in the rate of absorbance per minute by calculating the average change in absorbance between two photometric points, using the least squares method.
- Double rate assay determines the rate of absorbance variation per minute by calculating the average of the absorbance variations between two measuring points, using the least squares method. The rate of absorbance before dispensing reagent 2 is subtracted from those calculated after dispensing the second reagent.

RATE1 does not use the reagent blank absorbance as the reference for measurement data at each photometric point.

RB (Reagent Blank) — In routine analysis, the reagent blank serves as the reference value for the reagents at each photometric point of individual analysis tests. It also becomes the Y-intercept of calibration curves created by ACAL.

Reagent — A reagent is a combination of chemicals that react with the target analyte in the sample. The AU480 uses one or two reagents (R1 and R2) per analyte.

Reagent ID — The system identifies reagents placed on board the system using the barcode.

Reflex Testing — Reflex testing enables a test to be automatically run by linking it to a repeat flag generated by another test. Up to 10 sets of tests can be programmed as Reflex tests. Therefore, if a test generates a value outside of a given range, another test is automatically performed.

Repeat Run — A repeat run is a process whereby samples are tested again, either manually or automatically by the system.

Sample Diluent — Solution used for manual or automatic dilution of samples.

Standard Deviation — Most commonly used measure of statistical dispersion. In multiple measurements of the same sample, it measures how spread out the values are.

Test Requisitions — An instruction to perform tests on a sample. When a sample is placed into the system, the test requisition information is used to link the sample to the required tests.

Twin Plot — Twin Plot is used to determine whether a problematic variation in QC is caused by the system or just a random error. QC analysis is usually performed using two controls: normal and abnormal. The twin plot function displays the first control on the x-axis of a 2-dimensional plot and the second control on the y-axis.

W1 (Automatic Wash of Cuvettes) — The cuvettes are cleaned automatically by the wash nozzle unit before and after analysis in routine operation.

If analysis operation was forcibly stopped, a W1 is performed to clean the cuvettes. Refer to [8.8.11 Perform a W1](#) in chapter 8.

W2 (Automatic Wash of Cuvettes, Sample Probe, Reagent Probe, and Mix Bars) —

Perform W2 operation weekly. After performing W2, perform Photocal measurement.

Alternate between the usage of either sodium hypochlorite solution (0.5%) or 1N HCl.

For details on W2, refer to [8.4.2 Perform a W2](#) in chapter 8.

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