GE Healthcare

ÄKTA™ pilot 600

ÄKTA pilot 600 (Fig 1) is a bench-top chromatography system well-suited for both GMP and non-GMP work. The wide flow and pressure range allows both production of technical batches and scale-up studies as well as small-scale production of GMP-grade material.

The ÄKTA pilot 600 system is designed to simplify everyday operations (Fig 2). It has a modular design where functionality can be added or removed as your requirements change. The interactive process picture allows changes to be made in real-time and deviations are quickly identified. As part of the ÄKTA chromatography system family, scaling and technology transfer is made easy. The high accuracy and wide range of the pumps enables precise gradient formation, covering a large range of column sizes.

Experience compact scalability

- Speed up projects through easy handling and changeover
- Match product yield to project needs
- Access wide scalability both within and between systems

System overview

ÄKTA pilot 600 supports columns sizes from 26 to 200 mm i.d. The system works seamlessly with AxiChrom™ chromatography columns through the Intelligent packing function and the dedicated packing port. This helps ensure packing success at first try. For further time savings, prepacked 1 and 2.5 L ReadyToProcess™ columns can also be used with the system.

Thanks to the compact design, the system can be placed on a lab bench or a ReadyKart mobile station, for example. The light weight means the system can be easily moved if required. All functional parts are placed on one side for easy access.

Fig 1. The ÄKTA pilot 600 system is available in two versions, 600S for non-GMP and 600R for GMP environments. Thanks to the modular design, both versions can easily be modified to match specific needs at different times.

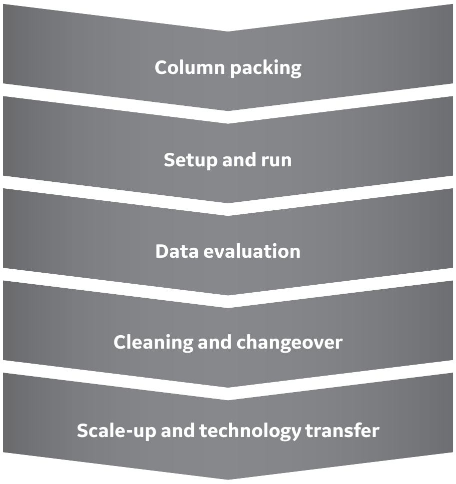


Fig 2. ÄKTA pilot 600 helps simplify operations from column packing to scale up and technology transfer.

Method programming, system operations, and data evaluation are powered by UNICORN™ software. The software provides an intuitive environment covering chromatography systems from research to manufacturing scale. You also get easy access to packing and run parameters for most resin types, offered by GE Healthcare, and applicable AxiChrom column sizes.

The product is available in two versions, ÄKTA pilot 600S and ÄKTA pilot 600R. The 600S model is suitable for non-GMP environments whereas 600R is suitable for GMP environments. Both versions can be modified to fit specific needs thanks to the modular design.

ÄKTA pilot 600S

ÄKTA pilot 600S has a standard configuration easily modified to your needs using extra modules. As your requirements change, the system set-up can grow with it by simply adding or removing modules. ÄKTA pilot 600S is supplied with a generic product documentation and operating instructions. Validation products are available if required.

ÄKTA pilot 600R

ÄKTA pilot 600R systems are configured at point of order. The system is delivered mounted, calibrated, and performance tested. It comes with an industrial-standard documentation package, complying with the ASME-BPE standard (Table 1). The package is suitable for work in GMP environments and specific for your system. Surface area and hold-up volume information is also readily available to ensure reliable risk analyses and follow up studies.

Both validation products and change control notification services are available for ÄKTA pilot 600R. The system configuration can also be changed with custom upgrade packages at a later point. This package includes the extra modules and accessories, an updated documentation package, and material certificates reflecting the changes. Easy identification is also used to simplify audits and prevent user errors. For example, unique identifiers are used for naming and annotations in documentation, hardware, and software.

Table 1. Examples of content from ÄKTA pilot 600R documentation complying with ASME-BPE standard

Document	Purpose/content
Operating instructions	Installation, operation, and maintenance of system and components, including lubrication manuals
Piping and instrumentation diagram (PID)	Schematic overview of process flow, components, instruments, and control system
General specification	Technical data for the system
Drawing and schematics	Assembly drawing (physical layout, provides dimensional data), wiring schematics (electrical wiring, communication, and steering)
Bill of material	Description of process-related components, including wetted materials and material specifications
Declaration of conformity	Declaration of conformity for EU (or other regions)
Certified performance report	Functional test record (FTR) from manufacturing and installation test record (ITR), including QMS release documentation
Instrument calibration report	Calibration certificates from manufacturing
Certificate of compliance for materials	Wetted/semi-wetted and pressure holding parts and their compliance with regulatory requirements, such as USP class VI, Animal origin free, Part 177
Software configuration description	Contains all software commands, watch and feedback functions, as well as alarm signals
Spare parts list	List of available spare parts
Regulatory guides and calculations	Extractables guide and sizing calculations
Validation documentation	IQ/OQ performance test and documentation

Adapt functionality to your needs

Thanks to the modular system design, functionality can be added to the system as requirements change over time (Fig 3). Module assembly is easy using a supplied tool and quick activation in UNICORN software. It can be performed on-site by you or a GE representative. Adding or removing modules is automatically linked to the comprehensive and customizable maintenance manager. This enables preemptive maintenance as you receive notifications on when to plan for change. A maximum of two I/O-boxes are also available for connection of at least four analog and eight digital external sensors or equipment.

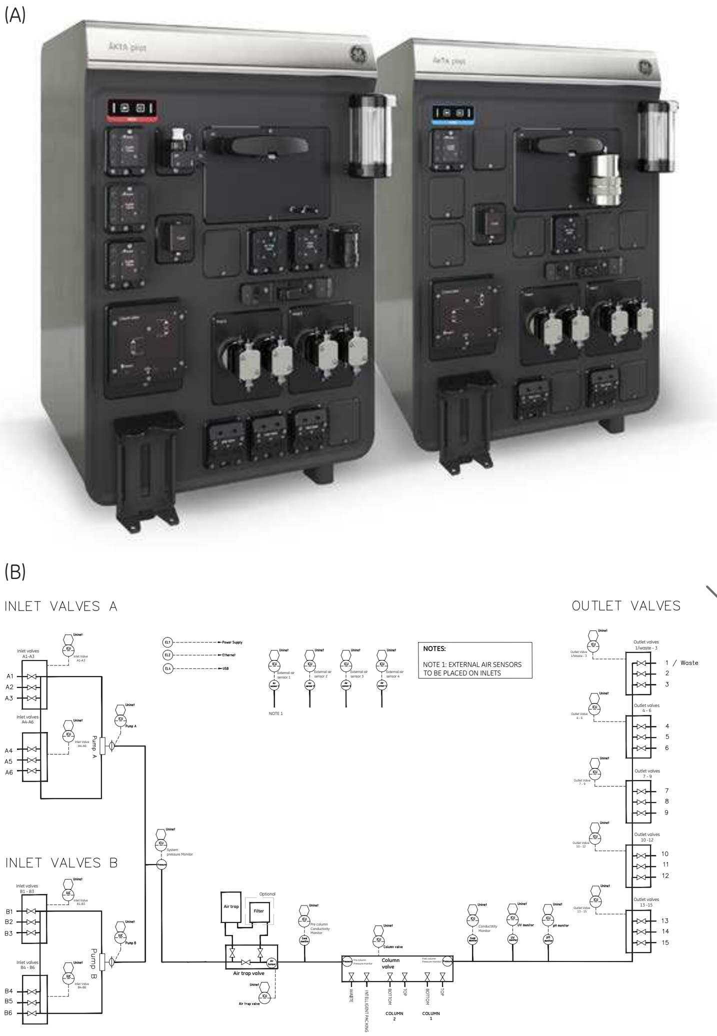


Fig 3. Two different configurations of ÄKTA pilot 600S; (B) PID for ÄKTA pilot 600R with maximum configuration. More inlets and outlets are available for ÄKTA pilot 600S.

Scalability and technology transfer

The wide flow rate and pressure ranges enables more than 40-fold scaling for columns within a 26 to 200 mm i.d. range. This wide range makes the ÄKTA pilot 600 an excellent system to bridge the transition into GMP environments (Fig 4). Naming, phase programming, process picture, and sensor technologies are aligned with other lab-scale ÄKTA systems, which simplifies process transfer and operations. UNICORN software also enables programming with flow rate in column volume per hour (CV/h) and normalization of UV signal. This possibility makes scaling and transfer of methods, as well as data comparison, easier.

Validated methods are also transferrable between ÄKTA pilot 600S and 600R versions. In addition, the extractables profiles and material standards are the same between ÄKTA pilot 600S and ÄKTA pilot 600R, further simplifying transfer.

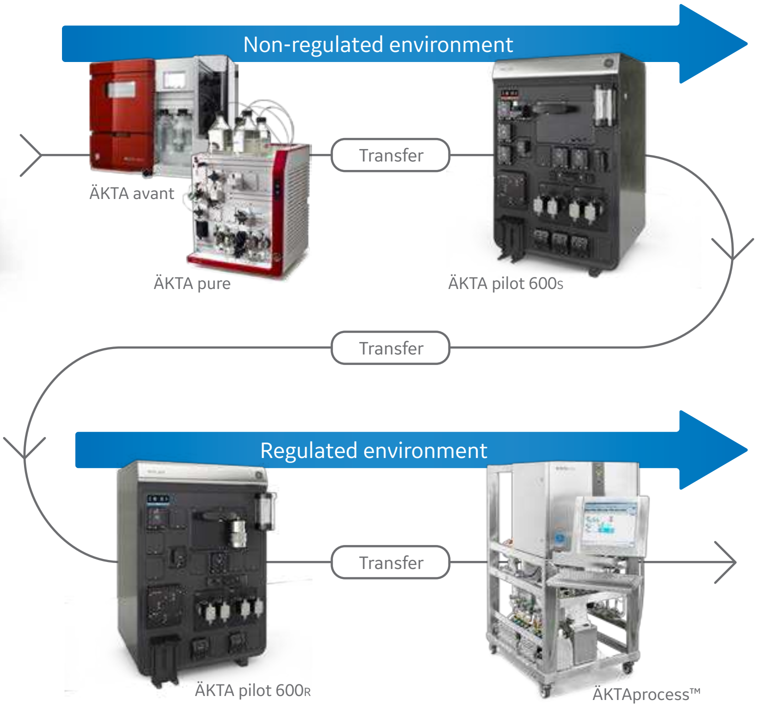


Fig 4. ÄKTA pilot 600 simplifies scaling between column sizes and systems.

Reliable column packing

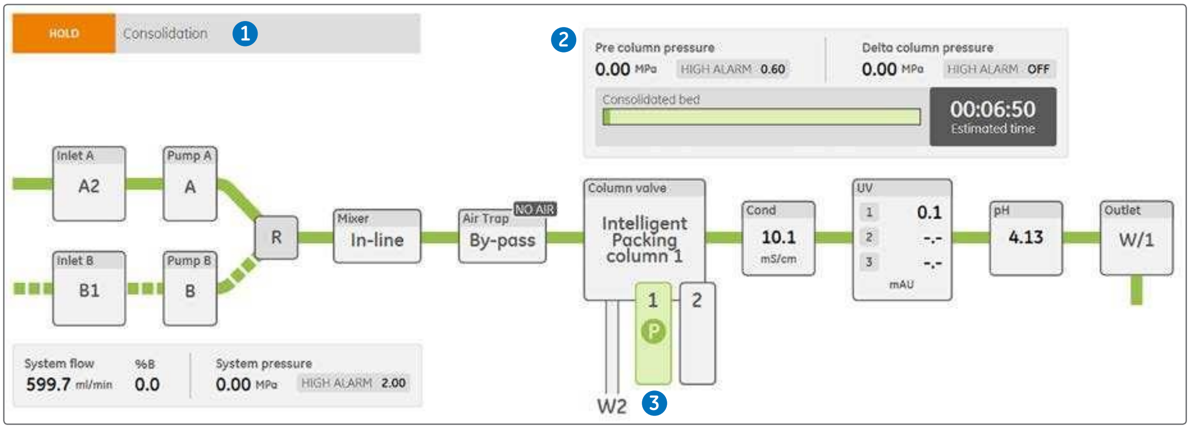
ÄKTA pilot 600 help you achieve well-consolidated beds quickly. The simple and interactive graphical workflows for Intelligent packing in UNICORN aid in both column packing and testing packing procedures (Fig 5). Packing progress can easily be monitored in the process picture and with the time to bed clearly visible. The integrated HETP workflow allows for one-click updates of column statistics. The packing parameter list, which contains resins and columns from GE, shows column characteristics and packing parameters, simplifying both packing and running.

Time-saving column features

The column logbook and the Intelligent packing method in UNICORN together with the dedicated packing port on the column valve facilitates column handling through the entire column life cycle. Values set during the packing procedure will be used as default values when calculating column performance and evaluating packing. These default values can be edited if needed. After verified packing quality, the column can easily be saved into the column logbook. Once saved, the column can be used for different applications. The column can also be monitored during its lifetime with an audit trail of re-packing, cleaning, column performance, and other user-defined statistics. Hence, application methods can easily be reused for repacked columns by simply updating the bed height, saving time and resources.

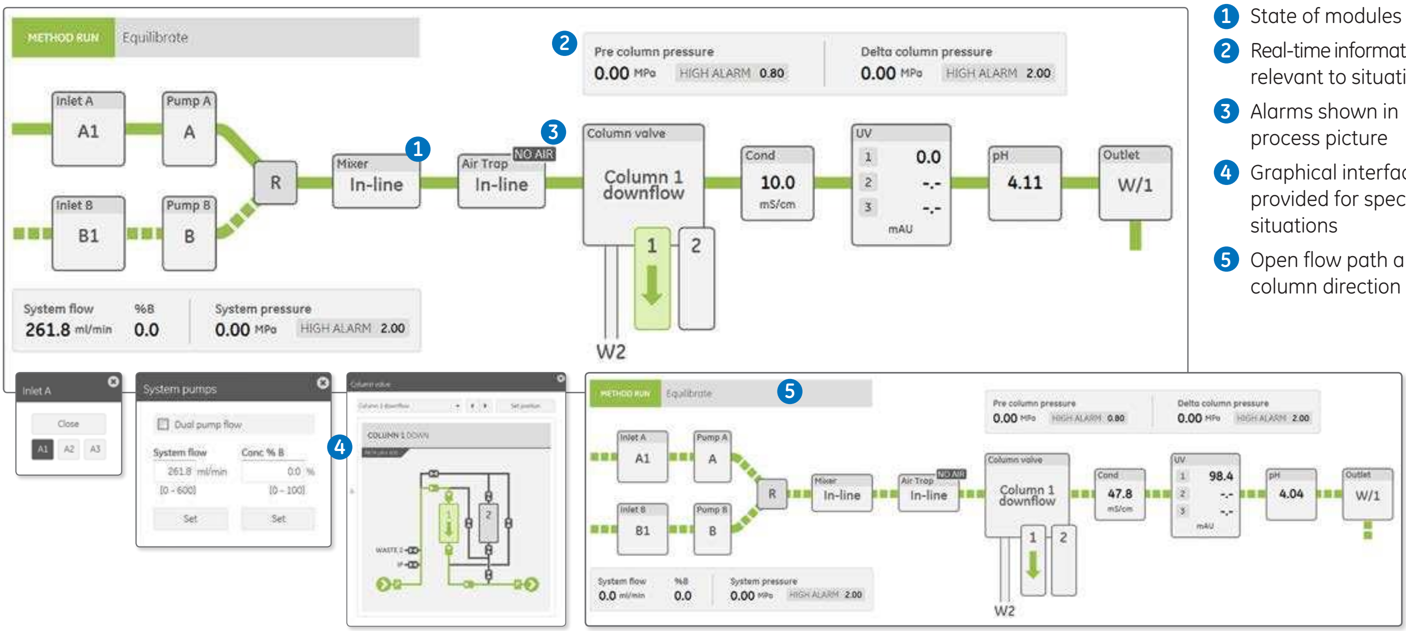
Interactive process picture and phase programming

The process picture in UNICORN quickly gives an overview of system function and operations and alarms by only providing the necessary information at each given time. The active flow path is always displayed in the process picture to minimize user errors. You can make changes in real-time by giving commands directly from the process picture. For added convenience and control, graphical interfaces are provided for specific sections, such as the column valve (Fig 6).



1. Phase block
2. Packing progress and time to bed
3. Open flow path and column status are clearly visible.

Fig 5. The simple and interactive graphical workflows for Intelligent packing aid in both column packing and testing packing success.



1. State of modules
2. Real-time information relevant to situation
3. Alarms shown in process picture
4. Graphical interfaces provided for specific situations
5. Open flow path and column direction

Fig 6. The process picture in UNICORN is interactive and only provides the necessary information at each stage. The process picture is updated to display connected modules.

Straightforward method creation

There are several predefined methods available in UNICORN. You can also easily create new methods by combining preprogrammed phases (Fig 7). The phases provide simple building blocks for easy drag-and-drop programming and gives a good overview of a method or process. This method creation is suitable for most runs and daily operations, such as cleaning in place (CIP) and column packing. The preprogrammed phases can be modified and saved as user-defined phases for added customization. Text programming is also available for exact operations. For example, you can access extra column valve instructions related to column overloading, extend the gradient range beyond 600 mL/min, and program using CV/h for easy scalability. By using watch-functionalities, logic loops can also be programmed.

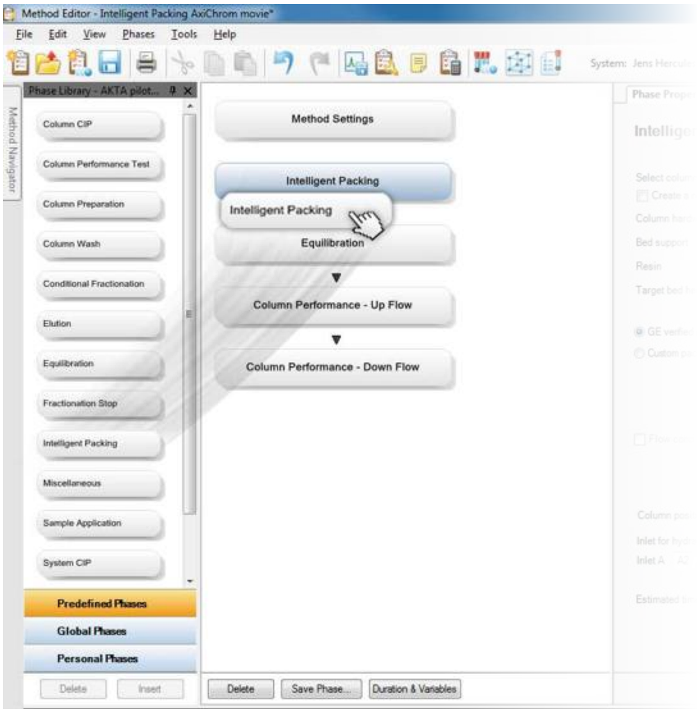


Fig 7. Methods are easily created by dragging and dropping preprogrammed phases. These phases can also be modified and customized using text programming.

Designed for easy sanitization

ÄKTA pilot 600 is designed for sanitary environments. For example, the system chassis is easy to wipe down and have minimal areas where dust and liquid can get trapped. In addition, the SNAP-connectors remove the need for O-rings or welding, which might otherwise present a sanitary weakness.

Both the pH meter, with in-line calibration, and the column valve packing port allows a closed flow path through operations. The system also has membrane valves and a flow path with minimized dead space and hold-up volumes.

Meeting regulatory requirements

All wetted materials and/or pressure holding parts used in ÄKTA pilot 600 have been tested and classified according to USP <88> Class VI; Biological Reactivity Tests in vivo, FDA 21 Code of Federal Regulations (CFR) Part 177; Indirect food additives: polymers, and are free from animal-derived components or in compliance with EMA 410/01, Rev.3. Used materials are traceable back to their production batches. Industrial-standard documentation, complying with the ASME-BPE standard, is also available for ÄKTA pilot 600R.

External audits have shown that the UNICORN software development process offers good adherence to the framework, principles, and practices described in the GAMP™ 5 framework and that the functionalities are acceptable for use in a cGMP regulated environment in a manner that complies with 21 CFR part 11.

Key system specifications

General specifications

System pumps:	Two (A and B)
Footprint main system:	575 × 440 mm
Weight main system:	77–83 kg (depending on configuration)
Control system:	UNICORN 7.3 software or later, open platform communications (OPC) is also enabled
User interface:	Interactive process picture, phase programming, or text editing
Enclosure protection:	IP23 (extension modules IP 21)
Compressed air:	No compressed air needed
External sensors and equipment:	Connections for a maximum of four analog in, four analog out, eight digital in, eight digital out

System capacity

Flow rate range:	1 to 1200 mL/min
Viscosity:	0.7 to 10 cP
Continues gradient flow range:	4 to 600 mL/min (acceptance range: 5% to 95%)
Pressure rating:	Up to 20 bars
Maximum inlets:	ÄKTA pilot 600S: 15 ÄKTA pilot 600R: 12
Maximum outlets:	15
Column positions:	up to 2 columns
Valve functionality	
Column valve function:	Up-flow, down-flow, serial and by-pass
Additional valve ports:	Intelligent packing port and waste port

Sensor acceptance ranges and accuracy

Temperature sensor:	2°C to 50°C (±2°C)
Pressure sensor:	0.0 to 2.0 bar (±2% or 0.01 bar)
pH sensor:	2 to 12 pH (±0.15 pH)
Conductivity sensor:	0.1 to 300 mS/cm (±3% or 0.2 mS/cm)
UV module:	Three simultaneous wavelengths, 2 or 5 mm path length
UV absorbance:	0 to 6 AU (linearity 2% in the range 0 to 2 AU)
UV wave lengths:	190 to 700 nm (±2nm)

Environmental ranges and electrical standards

Ambient temperature range:	4°C to 35°C
Ambient temperature, storage:	-25°C to 60°C
Ambient humidity range:	20% to 95% room humidity (RH), non-condensing
Power supply system:	100 to 240 VAC, 50 to 60 Hz
Short circuit current ratio (SCCR):	N/A since EN 61010
Minimum fuse rating:	10 A

Applicable codes and standards

Safety:	IEC/EN/UL61010-1 including latest amendment and corrigendum IEC/EN ISO 12100, CAN/CSA-C22.2 No 1010.1
EMC compliance:	IEC 61326-1 (EMC (CISPR 11, Group 1, class A), EN 61326-1 (EMC)(CISPR 11, Group 1, class A), ICES-001, US 47 CFR FCC Part 15 Subpart B Class A
Ingress protection classification:	EN 60529
Material specification wetted parts:	USP class VI, 21 CFR 177, animal origin free or in compliance with EMA/410/01

Ordering information

Please contact your local sales representative.