

ÄKTA pilot™ 600

CHROMATOGRAPHY SYSTEMS

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.

ÄKTA pilot 600 system is designed to simplify everyday operations (Fig 2). The modular design of the system ensures that 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 column 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 the first attempt. 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. The light weight of the system means that it can be easily moved if required. All functional parts are placed on one side for easy access.



Fig 1. 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.

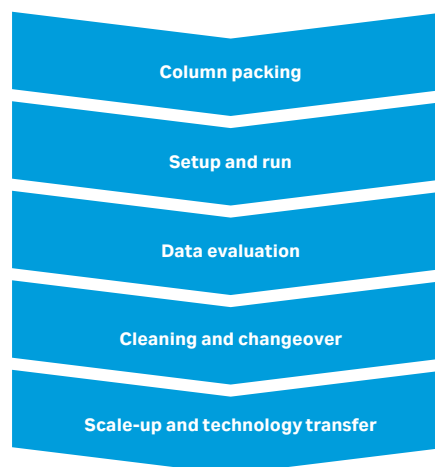


Fig 2. ÄKTA pilot 600 helps simplify operations from column packing to scale up and technology transfer.

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 Cytiva, 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 configured 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. The system setup can grow as your requirements change 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 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.

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.

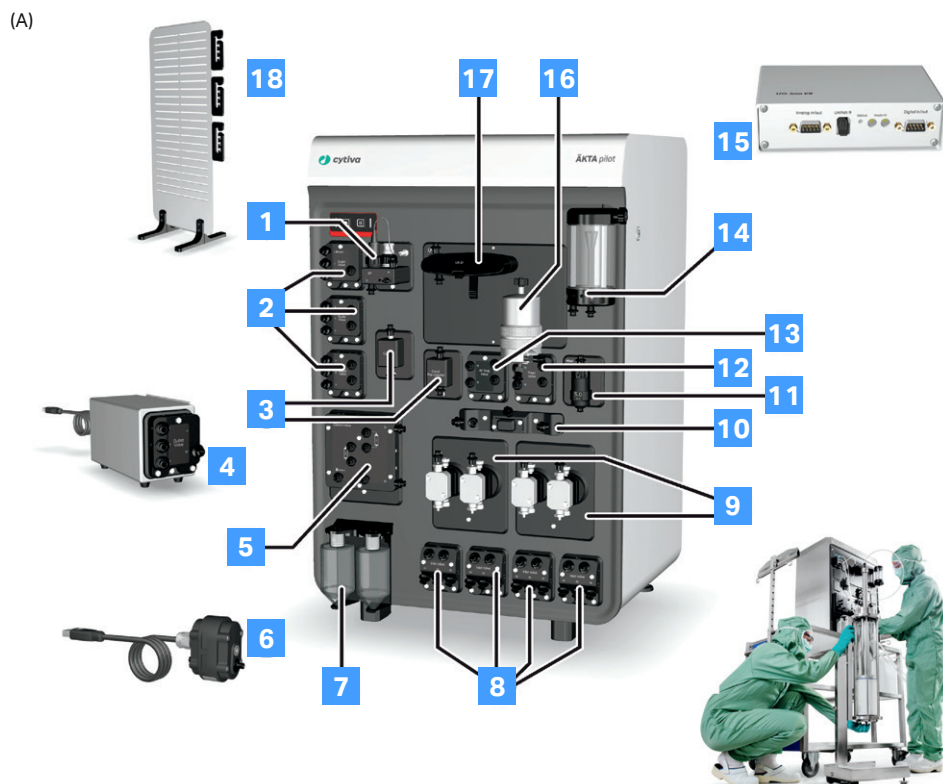
Table 1. Examples of content from ÄKTA pilot 600R documentation complying with ASME-BPE standard.

Document	Purpose/content
Operating instructions	Installation, operation, and maintenance of system and components
Piping and instrumentation diagram (PID)	Schematic overview of process flow components
General specification	Technical data for the system
Drawing and schematics	Assembly drawing (physical layout provides dimensional data)
Bill of material	Description of process-related components
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
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 when ordered separately

Adapt functionality to your needs

Starting with a basic configuration, ÄKTA pilot 600s can be equipped with a range of modules depending on specific needs and then extended as these requirements change (Fig 3). Whether the need is for high flexibility to work with low or high flow rates or to obtain maximum fraction possibilities, the system can be configured in the way most suitable for the specific application. Module installation is easy using a supplied tool and quick

activation in UNICORN software. It can be performed on-site by you or a Cytiva 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-box E9 units are also available for connection of four analog and eight digital external sensors or equipment.



Base configuration

Optional modules available

- 1 pH monitor**
- 2** Outlet valves (1–3, **4–15**)*
- 3** Conductivity monitor (post-column, **pre-column**)
- 4 Extension box**
- 5** Column valve
- 6 External air sensor (max. 4)**
- 7** System pump rinse bottles
- 8** Inlet valves (A1–3 and B1–3, **A4–9, and B4–6**)
- 9** System pump A and B
- 10** System restrictor
- 11 Mixer chamber**
- 12 Mixer bypass valve**
- 13** Air trap bypass valve
- 14** Air trap
- 15 I/O-box E9 (max. 2)**
- 16 Filter housing (shown in picture) or single-use filter holder**
- 17** UV monitor
- 18 Extension stand**

*If more outlets are needed, contact Cytiva for further information.

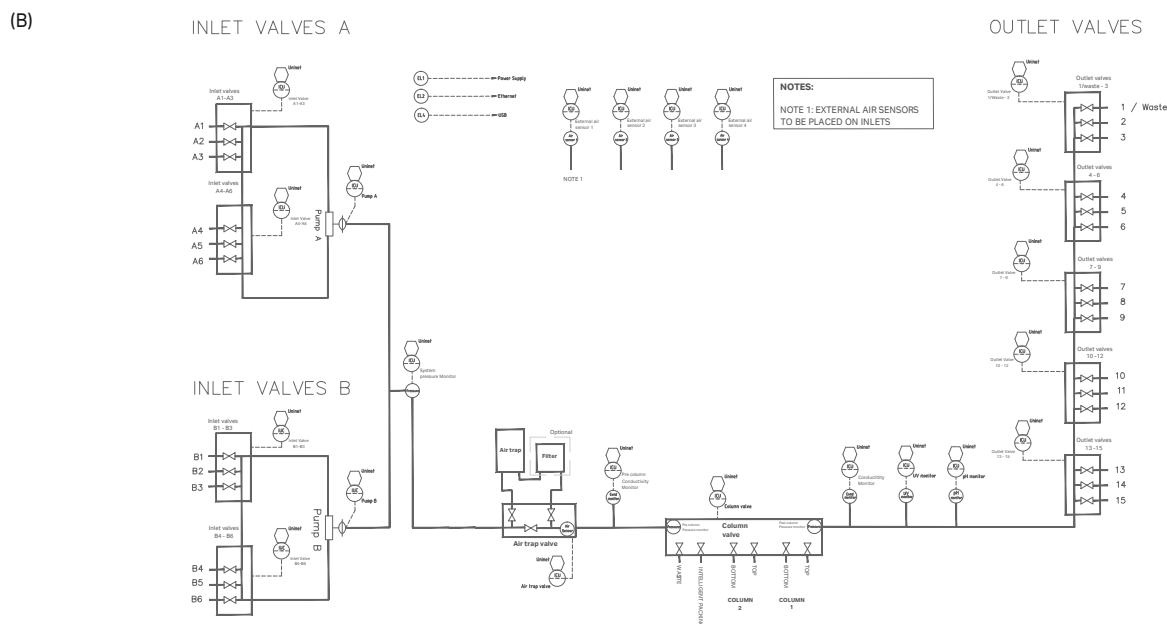


Fig 3. (A) Base configuration and optional modules of ÄKTA pilot 600s; (B) PID for ÄKTA pilot 600r with maximum configuration.

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 velocity 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.

Scalability over a wide range

The wide flow and pressure range and high pump accuracy of ÄKTA pilot 600 allows the use of column inner diameters ranging from 26 mm up to 200 mm (Fig 5). The sanitary design of valves, pumps, modules, and fittings ensures reliable runs with both non-sanitizable and sanitizable columns. Within the optimum flow range of the system (50 to 140 mm columns), most Cytiva resins are compatible at their recommended flow rates.

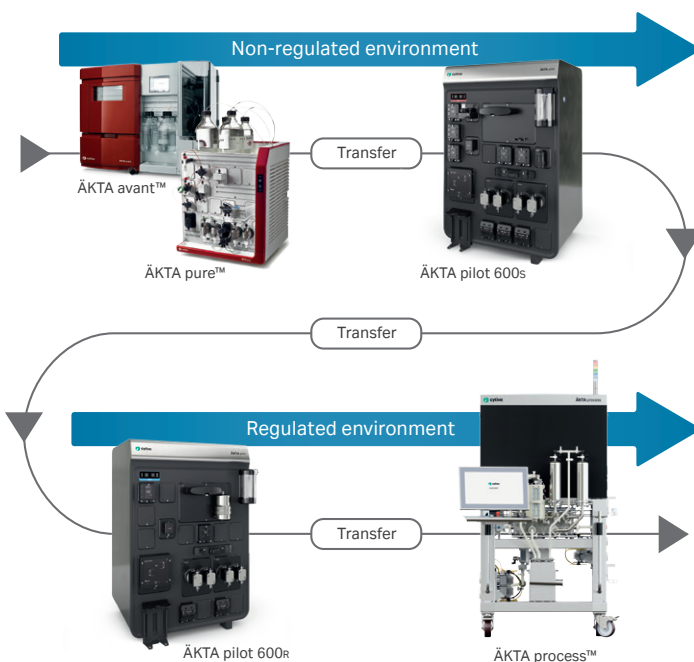


Fig 4. ÄKTA pilot 600 simplifies scaling between column sizes and systems.

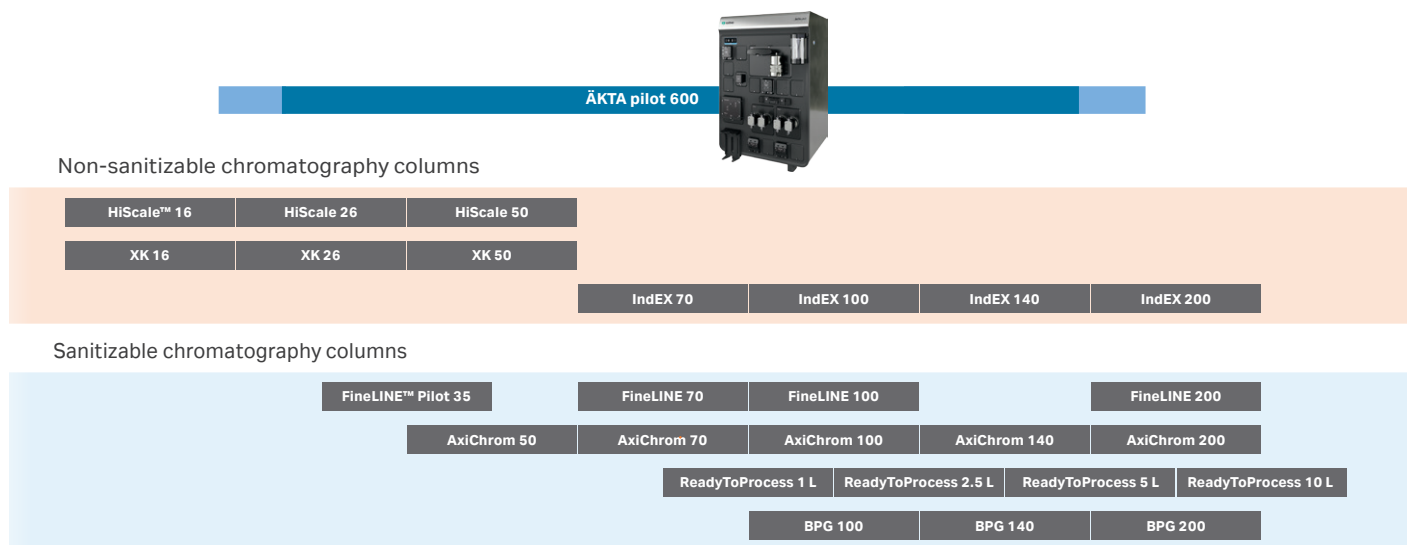


Fig 5. Chromatography column compatibility for ÄKTA pilot 600 systems.

Reliable column packing

ÄKTA pilot 600 helps you to achieve well-consolidated beds quickly. The simple and interactive graphical workflows for Intelligent packing in UNICORN software aid in both column packing and testing packing procedures (Fig 6). 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 Cytiva, shows column characteristics and packing parameters to simplify both packing and running.

Time-saving column features

The column logbook and the Intelligent packing method in UNICORN software 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 repacking, 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 software 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 7).

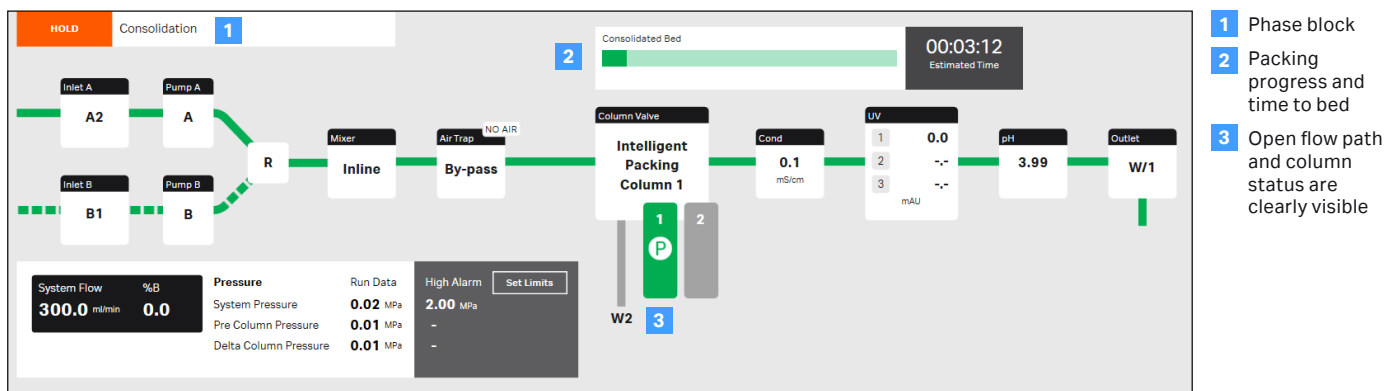


Fig 6. The simple and interactive graphical workflows for Intelligent packing aid in both column packing and testing packing success.



Fig 7. The process picture in UNICORN software 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 software. You can also easily create new methods by combining preprogrammed phases (Fig 8). 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.

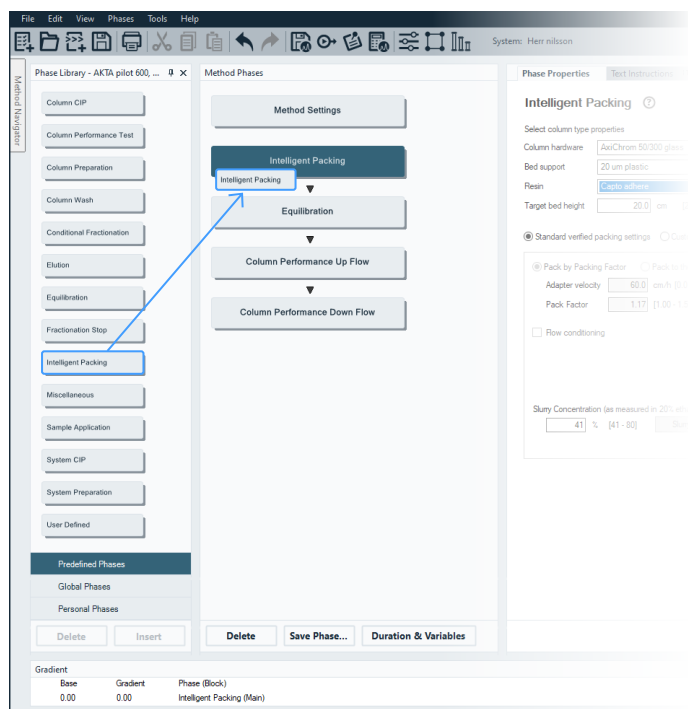


Fig 8. Methods are easily created by dragging and dropping preprogrammed phases. These phases can also be modified and customized using text programming.

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 (Fig 9).

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.

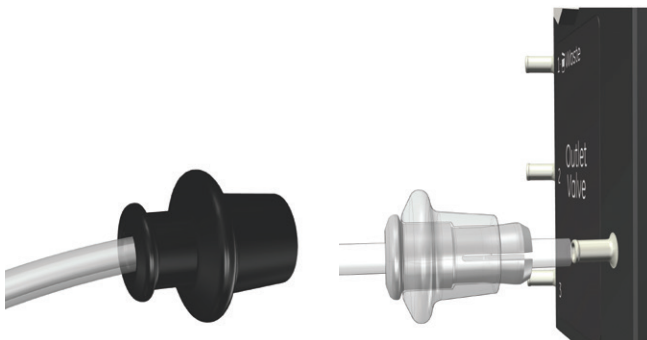


Fig 9. Snap connectors are used to form a tight connection to the ports of the flow path components. The novel design helps to speed up the exchange of tubing. The tubing is simply cut to the desired length, attached to the Snap connector, and attached to the valve nipple. No O-rings, threading, extra packing, or large clamps are needed.

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. Materials used 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.

System specifications

System model	ÄKTA pilot 600
Space requirements system, W × H × D	58 × 86 × 52 cm
Actuator operations	Electromechanical (no pressurized air needed)
Enclosure protection	IP23 (extension modules IP21)
System weight	78 to 83 kg (depending on configuration)
Power supply system	100, 120, 200, 208, 230, 240 VAC, 50-60 Hz
UV path length	2 or 5 mm path length
External sensors/equipment	Connections for a maximum of four analog in, four analog out, eight digital in, eight digital out
Operating system	Windows®
UNICORN version	7.6 or later, OPC available
Operating flow rate	0.1 to 1200 mL/min (viscosity: 0.7 to 5 cP)
Gradient function	Yes, 0% to 100%B (100% to 0% A) within flow rate of 4 to 600 mL/min
Number of inlets	ÄKTA pilot 600s max. 15; ÄKTA pilot 600R max. 12
Number of outlets	ÄKTA pilot 600s max. 15; ÄKTA pilot 600R; 9 to 15 dependent on configuration*
Number of columns	Up to two columns
Column valve functionality	Up-flow, down-flow, serial and by-pass, Intelligent packing port, and waste port
Inlet feed	-0.1 bar ≤ inlet pressure < 0.1 bar
Outlet feed	0 bar ≤ outlet pressure < 1 bar
Pressure rating	Up to 20 bar (2 MPa)
Air sensors	Adjustable to 30 µL or 1 mL; four external sensors, one internal
Air trap	70 mL with bypass
Mixer	5 mL with bypass

* If more outlets are needed, contact Cytiva for further information.

Hold-up volumes

	(Volume, mL)
Total hold-up volume standard 600s ¹	38.0
Additional inlet valve	1.7
Additional mixer valve (in bypass)	1.7
Additional outlet valve	1.7
pH monitor ²	0
Additional tubing 3.2 mm i.d. (per 10 cm)	0.8
Additional tubing 4.8 mm i.d. (per 10 cm)	1.8

¹ The volumes are counted from inlet A1 to outlet O2.

² Configurations including a pH monitor have shorter tube length, which compensates for the extra volume. The internal volume of the pH monitor is 1.0 mL.

Instrumentation and acceptance criteria

Description	Unit	Range	Acceptance range	Accuracy within acceptance range
Flow rate	mL/min	0.1 to 1200	2 to 1200	± 2% ¹
Conductivity (pre-column)	mS/cm	0.01 to 999.99	0.3 to 300 ²	± 3% or 0.10 mS/cm ⁽³⁾
Temperature (pre-column) ⁴	°C	2 to 70	4 to 35 ⁵	± 2°C
Pressure (pre-column)	bar g	0 to 20	0.2 to 20 ⁶	± 2%
Pressure (post-column)	bar g	0 to 20	0.2 to 20 ⁶	± 2%
Conductivity	mS/cm	0.01 to 999.99	0.3 to 300 ¹	± 3% or 0.10 mS/cm ⁽³⁾
Temperature ⁴	°C	2 to 70	4 to 35 ⁵	± 2°C
UV absorbance	AU	-6 to +6	0 to 2	Linearity ± 2%
UV wavelength (3 simultaneous)	Nm	190 to 700	190 to 700	± 2
pH	pH	0 to 14	2 to 12 ⁷	± 0.15 pH
Gradient	%B	0 to 100	1 to 99 ²	± 1%B

¹ With water at room temperature, between 20°C to 25°C

² Measurement performed at room temperature, approximately 20°C

³ Whichever is greater

⁴ Integrated in conductivity meter

⁵ Water at 10 mL/min

⁶ Testing performed at maximum operating pressure

⁷ Within ± 2°C from calibration temperature

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

Compliant with	CE, cETLus, EAC, FCC, ICES-001, KC, RCM
Safety	IEC/EN/UL/CSA-C22.2 61010-1, IEC/EN/UL/CSA-C22.2 61010-2-081, EN ISO 12100, EN 60529
EMC compliance	EN/IEC 61326-1, EN 301 489-1, EN 301 489-3, US 47 CFR FCC Part 15 Subpart B, ICES-001, KN 61000-6-2, KN 61000-6-4
Material specification wetted parts	USP class VI, 21 CFR 177, animal origin free or in compliance with EMA/410/01

Ordering information

Systems

Product	Quantity	Product code
ÄKTA pilot 600s	1	29274325
Standard product. Comes with a generic and basic product documentation. Extra modules might need to be ordered.		
ÄKTA pilot 600r	1	Order specific
Configured product. Configured and mounted at point of order and tested before delivery. Comes with extensive configuration-specific documentation for use in GMP environments.		

Common accessories

Product	Quantity	Product code
Computer mini desktop	1	29740281
Computer laptop model	1	18116852
Accessory kit ÄKTA pilot 600	1	29317674
Outlet valve 4–6 ÄKTA pilot 600	1	29289781
Outlet valve 7–9 ÄKTA pilot 600	1	29289782
Outlet valve 10–12 ÄKTA pilot 600	1	29289783
Outlet valve 13–15 ÄKTA pilot 600	1	29289784
Inlet valve A4–6 ÄKTA pilot 600	1	29289785
Inlet valve A7–9 ÄKTA pilot 600	1	29289786
Inlet valve B4–6 ÄKTA pilot 600	1	29289787
pH monitor ÄKTA pilot 600	1	29289780
pH electrode with certificate	1	29358613
Pre-column conductivity monitor ÄKTA pilot 600	1	29289779
ÄKTA pilot 600 HiScale 50 column connection kit	1	29317669
ÄKTA pilot 600 HiScale 26 column connection kit	1	29318188
ÄKTA pilot 600 TC 25 column connection kit	1	29318191
Tubing Kit for connecting AxiChrom 50 on bench to ÄKTA pilot	1	28905676
Tubing Kit for connecting AxiChrom 50 and AxiChrom 70 on floor to ÄKTA pilot, i.d. 1.7 mm	1	28913613
ÄKTA pilot 600 mixer upgrade kit	1	29289788
ÄKTA pilot 600 capsule filter mounting kit	1	29318192
In-line restrictor snap 3.2 mm	1	29713103
FEP tubing, i.d. 3.2 mm	30 m	29274549
FEP tubing, i.d. 4.8 mm	15 m	29274550
ÄKTA pilot 600 valve membrane kit	3	29274820
Air Sensor 1 L9 Snap connector 4.8 mm	1	29274543
Air Sensor 2 L9 Snap connector 4.8 mm	1	29274544
Air Sensor 3 L9 Snap connector 4.8 mm	1	29274545
Air Sensor 4 L9 Snap connector 4.8 mm	1	29274546
Superloop 150 Snap connector 3.2 mm	1	29275602
Snap connector 3.2 mm	6	29274567
Snap connector 4.8 mm	6	29274568
Filter house 20 bar Snap connector 3.2 mm	1	29318190
Extension stand	1	29274819
Extension stand tube holder	1	29295367

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