



ReadyToProcess™

ÄKTA™ ready XL

ÄKTA ready XL is a liquid chromatography system designed for manufacturing scale (Fig 1). To meet the capacity demands from single-use upstream processes (2000 L high-titer feeds), the system operates large-scale columns (up to 1200 mm), using the two flow kit sizes that cover a broad range of flow rates from 45 to 3500 L/h. The single-use flow path minimizes the need for cleaning and cleaning validation, allowing for quick changeover between productions, while eliminating the risk of carryover. ÄKTA ready XL offers the accuracy and documentation required for use in a GMP-regulated environment.

Taking single-use chromatography to manufacturing scale:

- High capacity in a compact format.
- Flexibility supporting use in multiproduct facilities.
- Reliability suitable for GMP production.

Suited for large-scale manufacturing

ÄKTA ready XL provides high flow capacity, making the system well suited for purification of high-titer entities or for products produced in large-volume bioreactor cultures. The possibility of using high flow rates allows for few process cycles per batch, shortening the overall process time and enhancing lifetime of the chromatography equipment.

The small system footprint enables an efficient facility use. The system is movable and all system components are easily accessed for operator convenience. ÄKTA ready XL is controlled from an industrial computer installed with the UNICORN™ system control software. Using a standard for open platform communication (OPC), the interface is compatibility with third-party system control software. Both the system and computer are designed to withstand the sanitization conditions used in cleanroom environments.



Fig 1. ÄKTA ready XL offers flexibility at manufacturing scale.

Flexible use in a broad range of applications

ÄKTA ready XL can be used for both isocratic and gradient elution. The flow kit for isocratic operations can be equipped with a section that provides gradient capability to the flow path (Fig 2). An ergonomic system design makes flow kit installation easy, and is quickly performed using the software-aided installation wizard. Markings on the system provides information on where the tubing should be placed and sensors connected. An installation test ensures proper connection of the sensors before start of the purification process. The system is ready for use within 1 h.

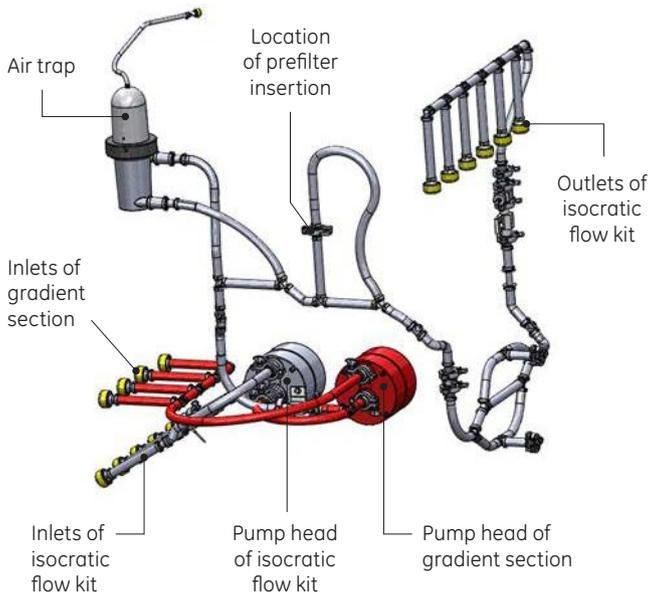


Fig 2. The isocratic flow kit, including six inlets, pump head, air trap, as well as sensors for pre- and post-filter pressure, precolumn air, and post-column pressure, conductivity, temperature, pH, flow, and UV monitoring. The gradient section (red) with four inlets is provided separately and contains a pump head for a second pump as well as a conductivity sensor for conductivity-controlled gradient feed-back.

The flow kits are produced in clean room ISO 7, packed in double bags, and gamma irradiated before delivery. Upon completion of the run, the single-use flow path is conveniently disposed to prevent carryover between production batches or campaigns, facilitating use of the system in a multiproduct facility.

ÄKTA ready XL allows for operation of the chromatography column in upward or downward flow, depending on the operation mode. With the ability to monitor UV at three different wavelengths and with multiple fluid inlets, the system is easily adapted to different process requirements.

Offering the reliability required for GMP production

Single-use sensor technology

Single-use sensors with high accuracy allows for reliable monitoring and control of the purification process (Fig 3). Together with precolumn air sensors at the inlet and in the flow path, the air trap automatically detects and prevents introduction of air into the column. Post-column sensors monitor the pressure, conductivity, temperature, pH, flow, and UV.

As reliable control of pH, flow, and UV is critical for a consistent process performance, these sensors have been improved further from predecessor products. The gamma-stable pH sensor is integrated with the flow path to prevent contamination of the flow path by insertion of a conventional pH probe. The pH sensor needs no calibration. Two calibration constants provided on the sensor unit are entered in the UNICORN software. An induction flow meter ensures correct flow through the column independent on liquid properties such as temperature and viscosity. The UV sensor has the option of using three wavelengths in the range of 206 to 700 nm.

A precolumn filter can be placed after the air trap and is easily connected using the TC end connectors of the flow path. The filter is held in place by the system filter holder. Together with a precolumn pressure sensor, the prefilter pressure sensor enables measuring the pressure drop over the precolumn filter. Although the high flow capacity of the system, the swirl design of the air trap provides low hold-up volumes.

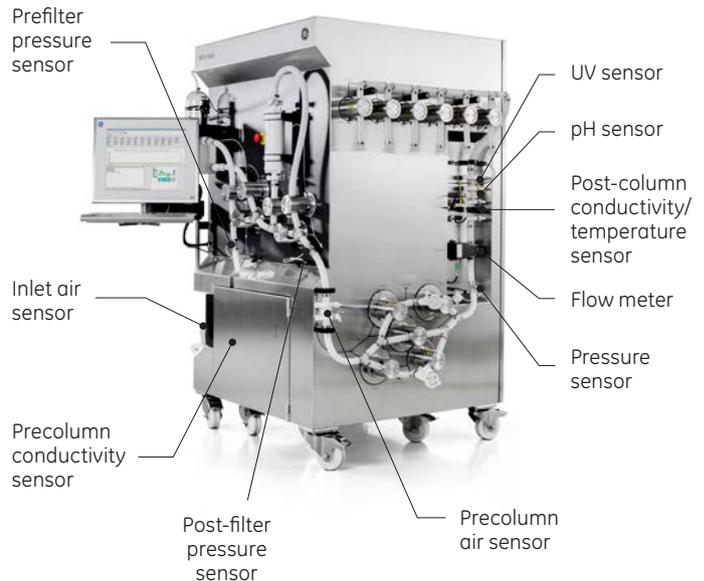


Fig 3. ÄKTA ready XL installed with flow kit.

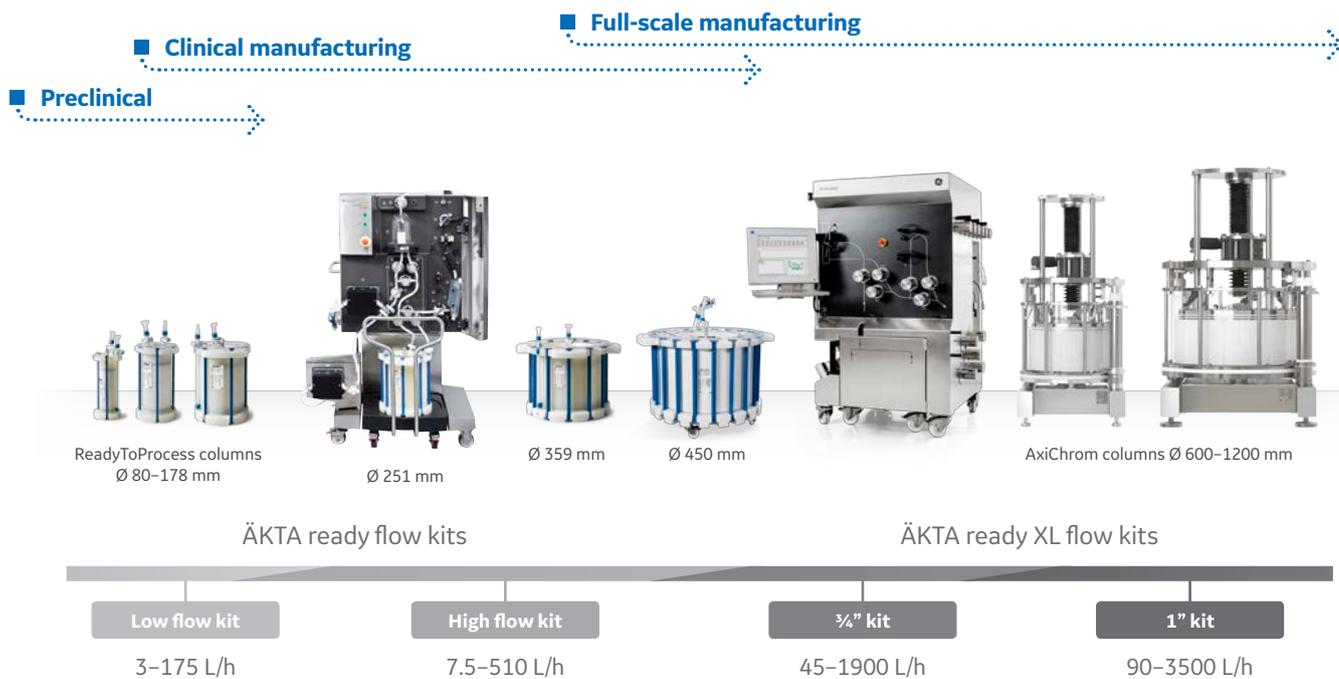


Fig 4. ÄKTA ready and ÄKTA ready XL operate ReadyToProcess columns with inner diameters from 80 to 450 mm for purification of biomolecules from bioreactor culture volumes of 10–2000 L. For larger bioreactor volumes, ÄKTA ready XL can also operate AxiChrom columns with inner diameters of up to 1200 mm. The common UNICORN software platform simplifies transfer of processes between systems.

Extensive product documentation

The system is delivered with comprehensive operating instructions and extensive system documentation including assembly drawings, piping and instrumentation diagrams (PID), and system specifications. Installation and operation qualification (IQ/OQ) protocols are available. IQ/OQ can be performed either by the user or by a certified specialist from GE.

Reliable process control

The UNICORN software is designed according to GAMP™ 5 guidelines (ISPE) and can be used in a manner that complies with 21 CFR part 11. The software supports full data integrity and consistency throughout the process, enabling a digitized and validated manufacturing. Process data is reliably stored in a database repository. For access control, the software is secured by password-protected user login. User activities are logged in audit trails for usage history. The UNICORN software provides the ability to generate reports, and data is exported in a tabular spreadsheet.

Part of a scalable single-use chromatography platform

ÄKTA ready XL is preferably used with ReadyToProcess disposable columns with inner diameters of up to 450 mm. For design of a disposable production line from upstream to downstream, ÄKTA ready XL and ReadyToProcess columns can be used with Xcellerex™ XDR single-use bioreactor systems, covering working volumes in the range from 10 to 2000 L, as well as Xcellerex XDM and XDUO single-use mixing systems. As the smaller ÄKTA ready system, ÄKTA ready XL is controlled through the UNICORN software, simplifying tech transfer between systems (Fig 4). ÄKTA ready XL can also operate AxiChrom™ clean-and-reuse columns with inner diameters of up to 1200 mm. Consistency in column geometries allows for convenient scaling, from early preclinical to commercial manufacturing scale.

Specifications

System specifications are listed in Table 1.

Table 1. ÄKTA ready XL system specifications

ÄKTA ready XL

Dimensions W × H × D 1280 × 1950 × 1150 mm

Flow kit

Operating max. pressure 4 bar

Pressure sensor Range: 0.1–4 bar.
Accuracy: ± 0.1 bar, or ± 5% of actual value

Temperature sensor Range: 10°C to 30°C. Accuracy: ± 2°C

Conductivity sensor Range: 2–140 mS/cm. Accuracy:
± 0.15 mS/cm, or ± 7% of actual value*

UV sensor Range: 0–1 AU. Accuracy: linearity ± 2%

pH sensor Range: 4–10. Accuracy: ± 0.3

Flow rate, ¾ inch i.d. Range: 45–1900 L/h
Accuracy, 45 to 300 L/h: 5% to 2%
Accuracy, 300 to 1900 L/h: 2%

Flow rate, 1 inch i.d. Range: 90–3500 L/h
Accuracy, 90 to 600 L/h: 5% to 2%
Accuracy, 600 to 3500 L/h: 2%

*Accuracy can be improved to 3% using the calibration function of the UNICORN software.

Wetted parts

Tubing	Silicone
Connectors	Polypropylene (PP)
Flow meter	Polysulfone (PS), SS 316L
Air trap	Ethylene propylene rubber (EPDM), polyamid (PA), PP
Air sensor	PP
pH sensor	High-density polyethylene (HDPE), EPDM, porous zirconia, LBF360 glass
Conductivity sensor	PS, gold
Temperature sensor	PS, gold
UV sensor	Polyetheretherketone (PEEK), EPDM, quartz, titanium
Pressure sensor	PS
Pump chamber	EPDM, thermoplastic elastomer (TPE), PP, 316L stainless steel
Material compliance	USP class VI, animal origin free, or EMA 410/01

System control

Software UNICORN 7.1 or higher

Ordering information

To order ÄKTA ready XL, please contact your local sales representative.

gelifesciences.com/bioprocess

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The use of ÄKTA ready XL ¾ and 1 inch flow kits may require a license under the following US patents and their equivalents in other countries: US patent numbers 6,712,963 and 7,052,603 (assignee: Parker-Hannifin Corporation.). A free, non-transferable license limited to using these products under above mentioned patents accompanies the purchase of the product from any GE Healthcare company and its licensed distributors.

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