ÄKTA ready™ chromatography system XL

SINGLE-USE SYSTEM FOR MANUFACTURING SCALE

The ÄKTA ready™ chromatography system XL is a liquid chromatography system designed with a wide operating range to cover the manufacturing capacity needed from clinical to commercial 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 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 production runs, while eliminating the risk of carryover. The system offers the accuracy and documentation required for use in a GMP-regulated environment.

Features and benefits

- Takes single-use chromatography to manufacturing scale
- Wide operating range in a compact format
- Flexibly adapts to operation in multiproduct facilities
- Easily integrates and connects to the site automation infrastructure

Fig 1. The ÄKTA ready chromatography system XL offers flexibility at manufacturing scale.

Designed for large-scale manufacturing

The ÄKTA ready chromatography system XL supports columns packed with modern resins for high capacity and fast processing at high flow rates, making it well suited for purification of high-titer entities or for drug substances produced in large-volume bioreactor cultures. Its wide operating range supports early production and later clinical scale-up without adding process cycles per batch, reducing overall process time and maintaining high throughput.

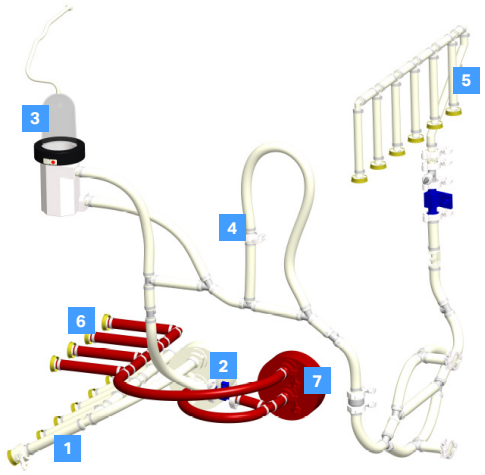
The small system footprint enables efficient use of facility cleanroom space. You can easily move the system to quickly rearrange equipment, and you can conveniently access all components when needed. You control the fully automated ÄKTA ready chromatography system XL through an integrated human machine interface (HMI) on the system hardware.

The standard configuration system (SCS) version includes HMI preinstalled with the UNICORN™ system control software.

The system uses an open platform communications-unified architecture (OPC-UA) interface, standard for data exchange, making the system compatible with third-party system control software. Other automation software can be incorporated on request.

Flexible use in a broad range of applications

The ÄKTA ready chromatography system XL can be used for both isocratic and gradient elution with two sizes of flow kits which enable an extensive operating flow rate range. The ¾ inch-flow kit covers the flow range 45 to 1900 L/h and the 1 inch-flow kit covers 90 to 3500 L/h. The system for isocratic operations can be equipped with a tubing section that provides gradient capability to the flow path (Fig 2). The sensor ranges and performance allow the system to purify a wide variety of molecules and entities, such as mAbs, viruses, and nucleic acids.



1 **Inlets of isocratic flow kit**
2 **Pump head of isocratic flow kit**
3 **Air trap**
4 **Location of pre-filter insertion**
5 **Outlets of isocratic flow kit**
6 **Inlets of gradient section**
7 **Pump head of gradient section**

Fig 2. The isocratic flow kit includes six inlets, pump head, air trap, pre-filter position, sensors post column as well as six outlets. The gradient section (red) with four inlets is provided separately and contains an additional pump head.

System overview

Flow path

The ÄKTA ready chromatography system XL flow path has six inlets in isocratic mode and when the gradient section is added, four more inlets are enabled on the B pump. An inlet air sensor is provided with the flow kit and can be connected to one of the inlets to detect air entering the system flow path. One or two (gradient mode) membrane pumps are used to pump liquid through the system. Sensors included in the flow kit for monitoring air, conductivity, flow, pH, pressure, and UV are described below. The flow path includes six outlets where liquids can be directed into separate containers. Automated pinch valves on the system direct the liquid in the correct direction in the flow path. See the piping and instrumentation diagram in Figure 3.

Air trap and pre-filter

An air trap with level sensors that automatically fills liquid to the appropriate liquid level removes unwanted air bubbles efficiently. Despite the high flow capacity of the system, the swirl design of the air trap provides low hold-up volume. An optional pre-filter helps protect the column from particles that could clog or contaminate the chromatography column and resin. You can bypass the air trap or pre-filter if they are not needed.

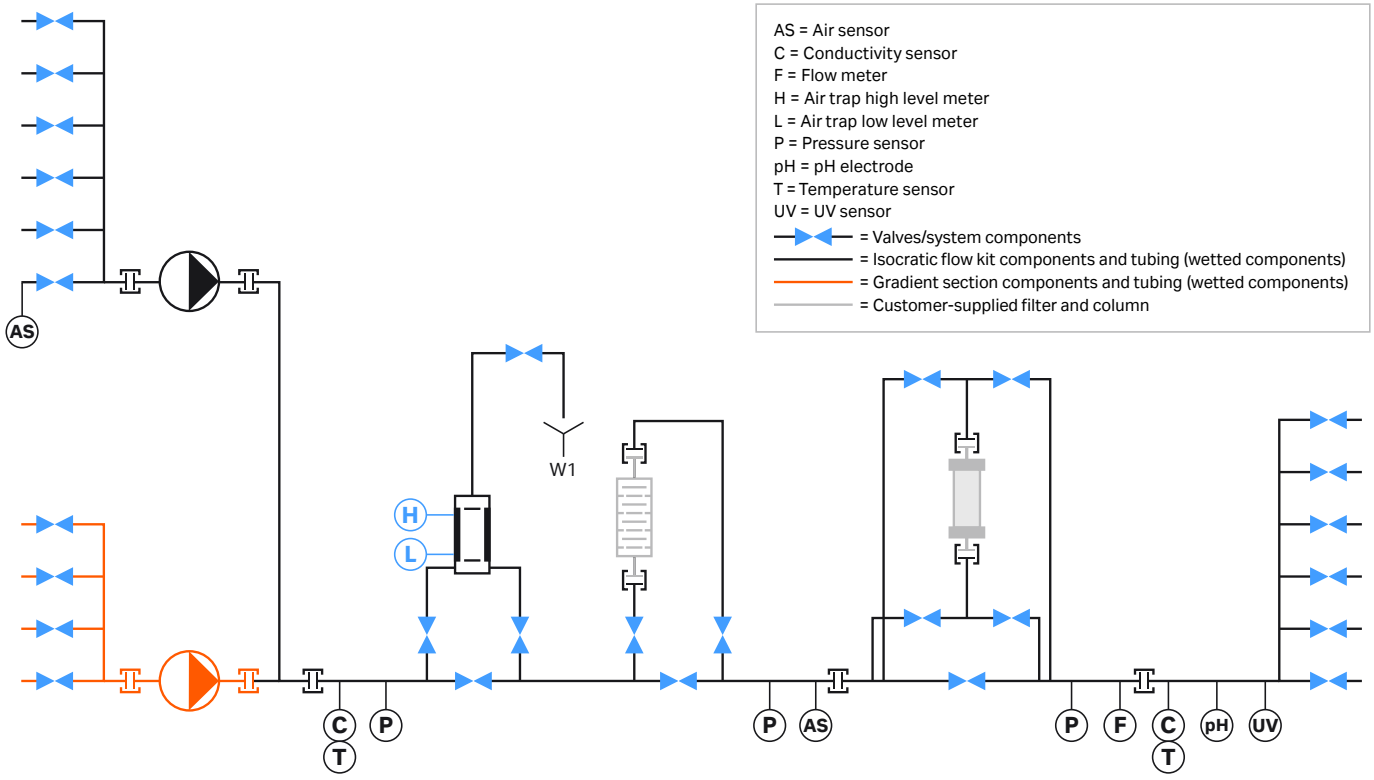


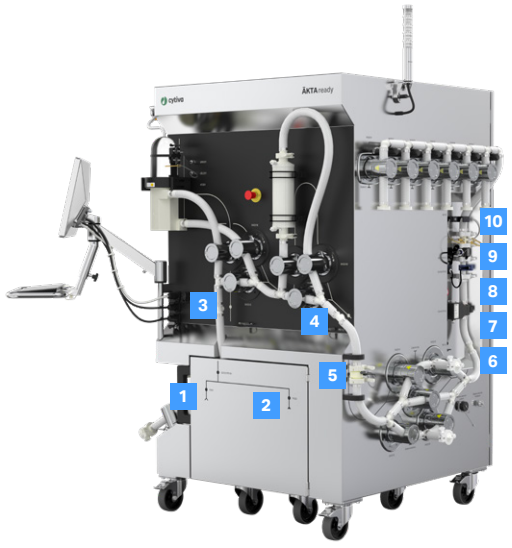
Fig 3. Piping and instrumentation diagram for the ÄKTA ready chromatography system XL, indicating the system configuration, the process components of the system, and the flow path. Sensors are also listed. The portion in orange is the optional gradient section.

Sensors

The sensors are labeled in Figure 4. There is a movable air sensor that can be placed on the desired inlet line. Pressure sensors are located post-pump, pre-column, and post-column which measure the system pressure as well as the pressure drop over the pre-filter, and the column. A pre-column conductivity sensor monitors the conductivity and can be used for generating a conductivity-controlled gradient. An air sensor pre-column protects the column by detecting air that could damage the column and can alert the user by pausing the active run. The column position allows liquid to be pumped through the column in up- or down-flow directions or to bypass the column. Post-column sensors are pressure, flow, conductivity, pH, and UV sensors.

An induction flow meter ensures correct flow through the column, independent of changes in liquid properties such as temperature and viscosity. The integrated gamma-stable pH sensor protects the flow path from contamination by insertion of a conventional pH probe. The pH sensor needs no calibration, once you enter the two calibration constants provided on the sensor unit into the software.

The variable wavelength UV monitor can monitor three wavelengths simultaneously in the range of 206 to 700 nm, providing flexibility to meet different process requirements. You can calibrate the UV sensor automatically using built-in and certified reference filters.



1. **Inlet air sensor**
2. **Pre-column conductivity sensor**
3. **Pre-filter pressure sensor**
4. **Post-filter pressure sensor**
5. **Pre-column air sensor**
6. **Post-column pressure sensor**
7. **Flow meter**
8. **Post-column conductivity/ temperature sensor**
9. **pH sensor**
10. **UV sensor**

Fig 4. ÄKTA ready chromatography system XL with flow kit and sensors.

System operation

The system has a 24-inch HMI that allows you to control and interact with it. Depending on the software used, an operator can initiate the production run and monitor the production progress. Use the manual switch on the left side when you install, uninstall, or drain a flow kit. When the system is in installation or drain mode, the valves can be put in safe mode for operator protection while the flow kit is installed or removed. A stack light at the top of the system clearly shows the current status of the system from a distance in accordance with IEC/EN 60073.

Robust control with UNICORN software

The standard system configuration (SCS) model of the ÄKTA ready chromatography system XL has UNICORN software pre-installed and configured. Hence, the system is fully functional directly after power-up without any further software configuration.

UNICORN software provides an interface for both chromatography and membrane separations, offering efficient control of process, flexible method programming, extensive data evaluation, and robust reporting functionality. The software supports chromatography operations and enables users to set up runs, evaluate and analyze data, and generate reports. Key run data are visible in the interactive ***Process Picture*** (Fig 5). Should you need to troubleshoot or interact manually with the system, you can set and view manual instructions and alarm limits for each component in the ***Process Picture***.

We designed the UNICORN software according to GAMP 5 guidelines (ISPE) and it can be used in a manner that follows 21 CFR Part 11, the US Food and Drug Administration's regulation on electronic records and signatures. The system logs user activities in audit trails for usage history. The software supports full data integrity and consistency throughout the process, enabling digitized and validated manufacturing. The system stores process data and user administration in a database repository, either locally or on an external central server. Users access the system securely through a password-protected login.

Fig 5. You can control the ÄKTA ready chromatography system XL with the interactive process picture in the UNICORN control software.

Connectivity and automation integration

The system can be used for standalone operations with UNICORN software (see above section) or the system can be integrated into a plant-wide control system and manufacturing environments using OPC-UA or EtherNet/IP gateway. For automation solutions such as DeltaV, Siemens, or Rockwell PlantPAx control software, contact us for a quote.

The EtherNet/IP connection is available for communication to supported Cytiva equipment. See Figure 6 for the connection ports available on the system.

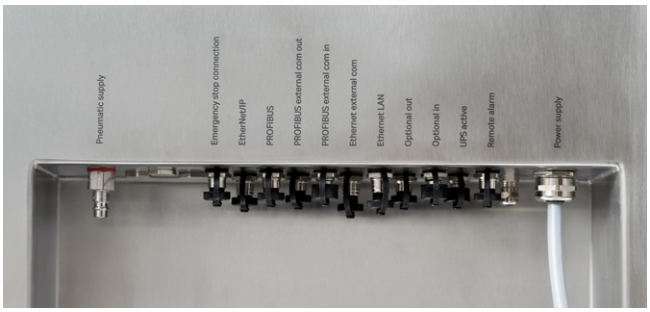


Fig 6. Connection points on the ÄKTA ready chromatography system XL.

A column bypass-valve kit can also be connected to the system (Fig 7), enabling easy priming of flow paths and removal of air when connecting a new column to the system. The valves become visible in the process picture when you connect the bypass kit. This allows you to control the valve kit from the system HMI, which provides instrument air and signals to actuate the valves in the bypass kit.

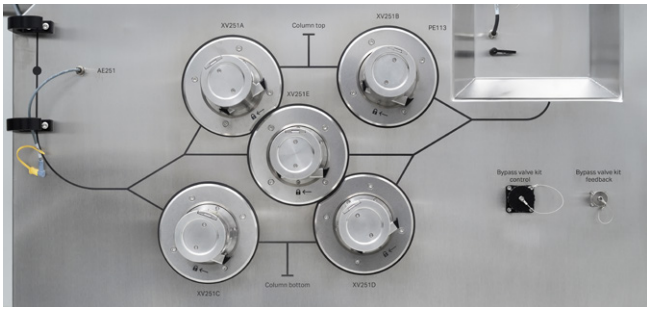


Fig 7. The connection to the valve bypass kit allows easy priming of the flow paths and removal of air when connecting a new column to the ÄKTA ready chromatography system XL.

The system can connect to five Xcellerex™ XDUO mixers through a PROFIBUS connection. This allows monitoring of weight, temperature, conductivity, and pH depending on the mixer functionality. The mixer parameters—such as mixing speed, addition pumps, and temperature—can also be controlled through UNICORN software from the system HMI, and mixing data will be stored in the UNICORN result file for each run.

There are two additional digital input/output and signals for remote alarms and uninterrupted power supply (UPS).

Suitable for use in GMP-compliant environments

The system, computer, and flow kits are designed for use in cleanroom environments.

We produce flow kits in an ISO 7 cleanroom, pack them in double bags, and gamma-irradiate them before delivery. The double bags make it easy to transfer the flow kit into a cleanroom while still protecting the flow kit until it is installed on the system. The production procedure and packaging shorten the set-up time and reduce the risk of contamination.

The ergonomic system design simplifies flow-kit installation, allowing you to complete it quickly. System markings help you place tubing and connect sensors correctly. Once the flow kit is installed, the system automatically detects that the sensors are correctly connected and ready for the purification process. The system is ready for use within one hour. Both the system and HMI are designed for use in cleanrooms and to withstand the sanitization conditions normally used in cleanroom environments.

When the run is complete, you can conveniently dispose of the single-use flow path to prevent carryover between production batches or campaigns, supporting multiproduct facility use.

Extensive product documentation

We deliver the system with comprehensive operating instructions and extensive system documentation including several documents detailing the specifics of the system, for example assembly drawings, piping and instrumentation diagrams (PID), and system specifications. Installation and operation qualification (IQ/OQ) protocols are available. Either you, or one or our certified specialists, can perform the IQ/OQ. We provide certificates for the single-use flow kits with product claims. Comprehensive extractables data are available for all wetted materials in the flow kit.

Part of a scalable single-use chromatography platform

The ÄKTA ready chromatography system XL supports single-use production lines from upstream to downstream, integrating with ReadyToProcess™ prepacked columns (up to 600 mm i.d.), Xcellerex XDR bioreactors (10–2000 L), and Xcellerex XDUO mixing systems. Purification processes can be scaled up in single-use chromatography systems, using UNICORN software and the scalable ReadyToProcess columns to simplify technology transfer between systems and scales (Fig 8). The ÄKTA ready chromatography system XL can also operate AxiChrom™ clean-and-reuse columns with recommended inner diameters of up to 1200 mm. Consistent column geometries make it easier to scale processes, from early preclinical to commercial manufacturing production.

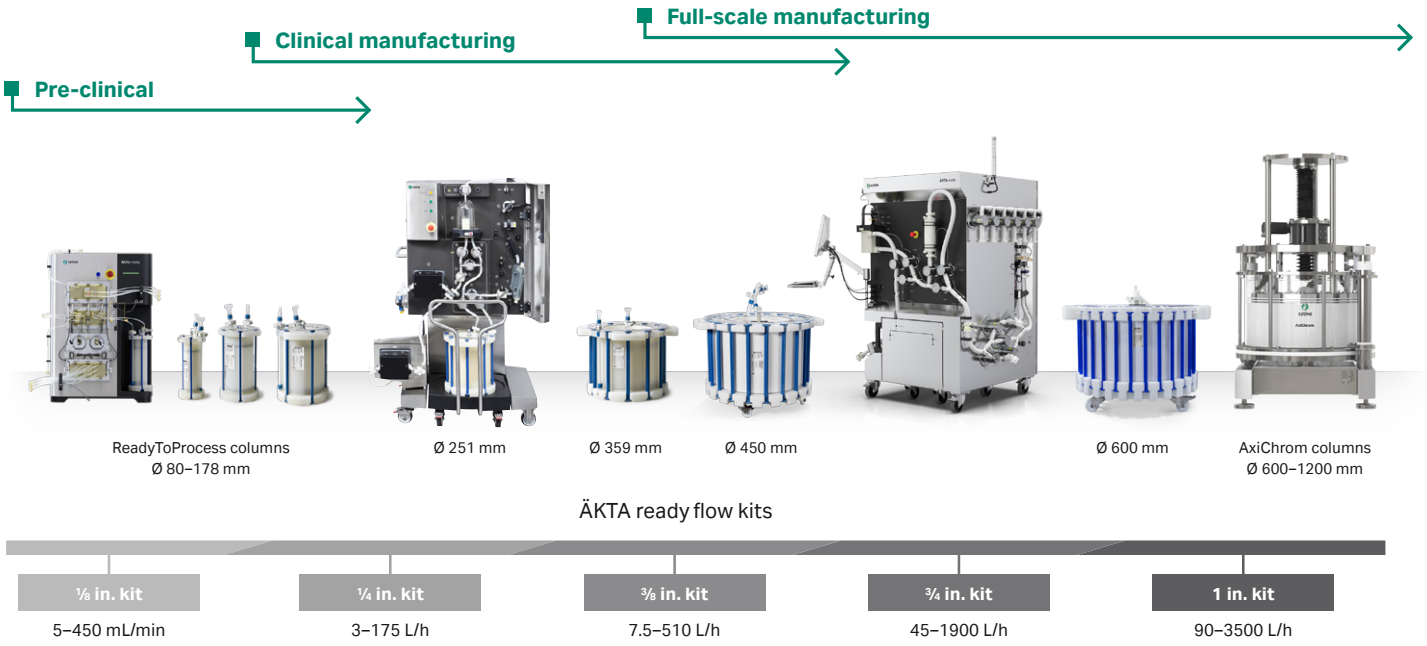


Fig 8. ÄKTA ready chromatography systems operate ReadyToProcess columns with inner diameters from 80 to 600 mm for purification of biomolecules from bioreactor culture volumes of 10 to 2000 L. For larger bioreactor volumes, ÄKTA ready chromatography system XL can also operate AxiChrom columns with inner diameters of up to 1200 mm. The common UNICORN software platform simplifies transfer of processes between systems.

Equipment service solutions

Regulatory authorities require chromatography systems to be qualified and maintained within specifications during use in process scale-up and GMP-manufacturing. Our comprehensive range of services (Table 1) provide support throughout the product's life cycle to optimize performance and enable smarter equipment ownership.

Table 1. Equipment service solutions for ÄKTA ready chromatography system XL

Services	Description
Equipment installation	We must install your system to ensure it's eligible for manufacture warranty.
Online equipment management	Our online portal My Equipment keeps track of your instrument service contracts and service records for your Cytiva equipment.
Preventive maintenance	Replacement of wear-and-tear parts, and functional testing ensure continuous performance of your instrument.
IQ/OQ and requalification (RQ)	Standard and custom qualification services for Cytiva equipment throughout its life cycle, including IQ/OQ, RQ, and continuous verification.
Repairs	Field, remote, and mail-in repairs are available depending on your instrument type and environment.
Digital services	Comprehensive digital solutions, from remote assistance to network setup and virtual training.
Spare parts	High quality spare parts for use in GxP environment. We can advise on your spare parts strategy.
Relocation support	Preparing your equipment for moving and reinstalling it in its new location.
Training	Tailored and standardized training for operators and maintenance, including eLearning courses.
Service plans	A range of plans to support your operations and instrument performance.

Specifications

General specifications

W × H × D	1295 × 1920 × 1215 mm (excluding light stack and HMI) 1295 × 2212 × 1215 mm (with light stack)
Weight	685 kg
Ingress protection	IP55, field-mounted transmitter IP54
Compressed air interface	6.5 to 10 bar, 50 NL/min, oil- and particle-free

Sensor specifications

Pressure sensor	Range 0.1 to 4 bar Accuracy 0.1 bar, or ± 5% of actual value
Temperature sensor (in pH sensor)	Range 5°C to 30°C Accuracy ± 2°C
Temperature sensor (in conductivity sensor)	Range 5°C to 30°C* Accuracy ± 4°C
Conductivity sensor	Range 1 to 200 mS/cm Accuracy ± 0.5 mS/cm, or ± 7% of actual value
UV sensor	206 to 700 nm Range 0 to 2 AU Accuracy linearity ± 2%†
pH sensor	Range 3 to 10 Accuracy ± 0.3
Flow rate: ¾ in. i.d.	Range 45 to 1900 L/h Accuracy ± 5 L/h or 2% whichever is greater
Flow rate: 1 in. i.d.	Range 90 to 3500 L/h Accuracy ± 5 L/h or 2% whichever is greater

* Valid only when buffer and room temperature are within 5°C.
† Valid for 250 to 700 nm, 2% linearity 0 to 1 AU for 206 to 250 nm.

Operating conditions	
Maximum pressure	4.0 bar
Surrounding temperature	5°C to 30°C
Fluid temperature	5°C to 30°C
Fluid density	800 to 1200 kg/m^3

System capacity	¾ in. flow kit	1 in. flow kit
Volumetric flow rates	45 to 1900 L/h	90 to 3500 L/h
Gradient flow range	450 to 1900 L/h	450 to 3500 L/h
Pump speed	1300 rpm (100%)	2500 rpm (100%)
Conductivity feedback gradient	10% to 90% gradient 450 to 900 L/h ±4% 900 to 1900 L/h ±3%	10% to 90% gradient 900 to 3500 L/h ±5%

Wetted materials

Details on flow kit wetted materials are in the corresponding product documentation file or the validation guide for each flow kit.

We assemble cleaned parts in an ISO Class 7 cleanroom and gamma-irradiate the complete flow kits.

Ordering information

System	Product code
ÄKTA ready XL SCS (UL)	29876404
ÄKTA ready XL SCS (CE)	29876403

Software control: UNICORN software 7.11 or higher
For requests on systems with automation software other than UNICORN software, please contact your local sales representative.

Flow kit	Product code
¾ in. gradient section, ÄKTA ready XL	29279665
1 in. gradient section, ÄKTA ready XL	29281931
ÄKTA ready XL flow kit, ¾ in.	29482435
ÄKTA ready XL flow kit, 1 in.	29482436

We deliver standard flow kits with sanitary clamp connecters. Other combinations of connectors are available.

Qualification	Product code
IQ/OQ binder	Contact us
IQ/OQ performance	Contact us

cytiva.com/aktaready

CY13866-02Dec25-DF