UNICORN™ 7 software

SYSTEM CONTROL SOFTWARE

UNICORN™ system control software provides you with built-in knowledge for planning and controlling runs, as well as analyzing results. The software lets you control your chromatography, bioreactor, and filtration systems (Fig 1).

UNICORN control software is fully scalable, which means it can be used for small-scale research and all the way to full-scale manufacturing.

Trusted for more than 25 years by researchers in academia and industry, UNICORN software continues to evolve based on requirements and inputs from our users. UNICORN 7 gives you the advantages of previous versions, with the added benefit of quick and easy evaluation of your results.

Key benefits include:

- **Ease-of-use:** The intuitive user interface, with an interactive process picture and simplified evaluation, makes UNICORN 7 control software easy for you to learn and use.
- **Flexibility:** UNICORN 7 can be adjusted to fit your needs through possibilities to add on more features, as well as easy modification of methods.
- **Efficiency:** By easy sharing of methods and results along with remote access capabilities to systems, UNICORN 7 helps you save valuable time and resources.
- **Data security:** UNICORN 7 makes sure your data is secure through robust database handling.

Description

UNICORN control software is based on an integrated controller and an intuitive computer-based interface. To minimize the learning curve, the interface uses a familiar Windows environment. The run sequence is fully determined by the end-user for maximum control of the process. A graphical interface helps you create the process sequence. Advanced users can perform conventional line programming.

UNICORN control software contains the tools needed to perform a wide range of applications, such as protein purification, filtration and cell culture at different scales, from setting up and running a method to evaluating the data.

Fig 1. Evaluation of several chromatography runs using overlay view in UNICORN 7 control software.

The software has four modules:

Method Editor: provides an easy interface to create or modify methods.

System Control: lets you perform and monitor the run in real time.

Evaluation: supports data analysis and report generation.

Administration: used to set up user access, view logs, and manage built-in SQL Server database.

Integrated tools such as ***Column Handling**** and ***BufferPro***† extend across the different modules, helping to increase productivity.

UNICORN online and ***My Instruments*** are web apps that supports control and monitoring of runs when you need to be away from the lab.

* Use of the ***Column Handling*** tool requires an additional e-license.
† The ***BufferPro*** tool is available for ÄKTA™ avant systems.

Method Editor

The ***Method Editor*** module allows you to create or adjust methods to suit your application needs (Fig 2). It contains all the instructions used for controlling the run. The ***Method Editor*** includes built-in application support for chromatography runs. The interface provides easy viewing and editing of the run parameters.

Using ÄKTA go™, ÄKTA pure™, or ÄKTA™ avant chromatography systems, the ***Method Editor*** provides a choice of predefined methods for different chromatography techniques and maintenance procedures. Methods are built using phases. Each phase reflects a step in the run, such as sample application or wash. UNICORN includes a library of predefined phases for creating or editing your own methods. A method is created or edited by dragging-and-dropping phases from the ***Phase Library*** to the ***Method Outline*** and setting important parameters in the ***Phase Properties*** pane (Fig 2).

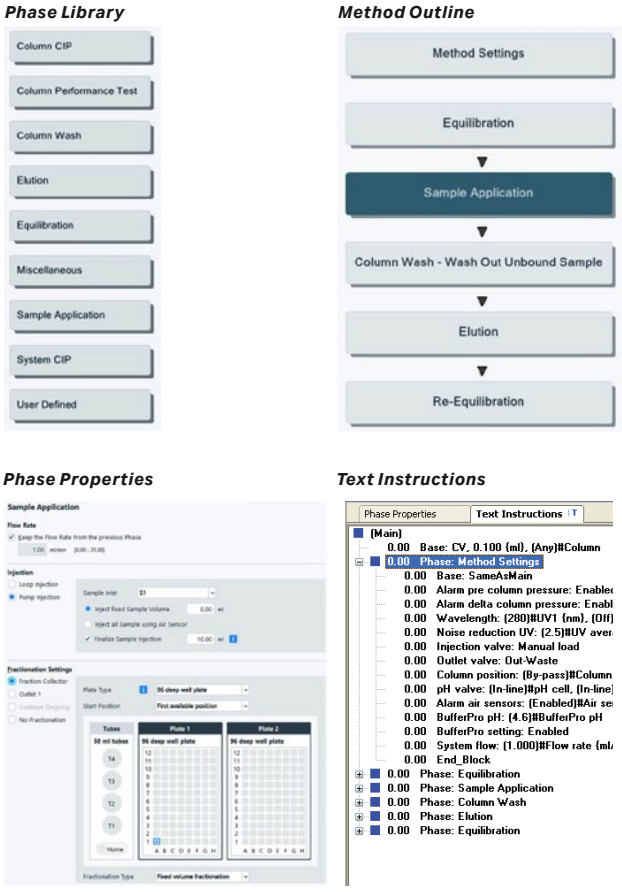


Fig 2. The different parts of the ***Method Editor.***

UNICORN control software includes a library of predefined Cytiva columns. By selecting the column in the ***Phase Properties*** pane, column parameters (e.g., flow rate and pressure limits) are automatically programmed into the method. For added flexibility, advanced users can edit programming instructions directly in the ***Text Instructions*** pane.

The user-friendly toolbar includes convenient buttons such as ***Undo/Redo***, and provides easy access to tools such as ***Scouting*** and ***Column Handling***.

System Control

The ***System Control*** module lets you start, monitor, edit, and control a run in real time. The ***System Control*** window has customizable and dockable panes showing the curve chart, current run data values, run log, and actual flow scheme. You have the flexibility to choose which docking panes are displayed, and can customize the layout to suit your needs (Fig 3).

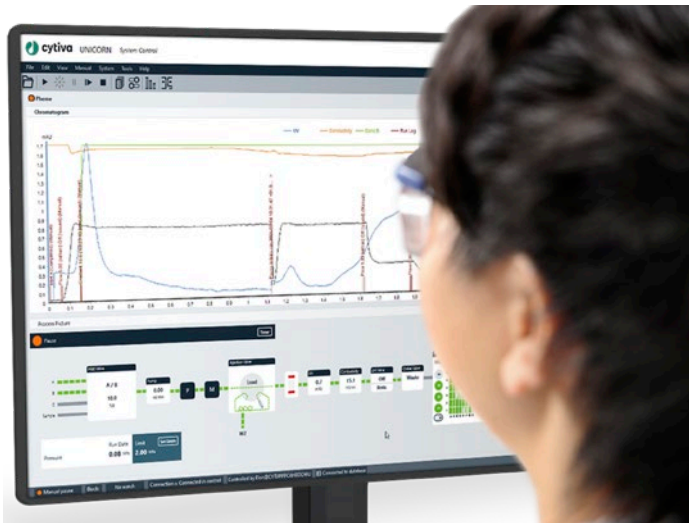


Fig 3. In ***System Control***, the view and layout of the docking panes can be customized by dragging-and-dropping each pane.

The UNICORN ***Watch*** function enables you to control processes with regards to monitor signals. In a ***Watch*** instruction, an action specified by the user is executed if a certain condition is met. For example, a ***Watch*** instruction can terminate column equilibration earlier if the eluent conductivity reaches a certain value defined by the user. The ***Watch*** instruction can be used for various purposes such as improving accuracy of collection, improving robustness of a chromatographic step, ending a concentration step, stopping the media feed in a bioreactor (saving time and material), and automating entire runs.

You can set ***Alarms*** for every monitor signal by defining the high and low ***Alarm*** limits. An ***Alarm*** stops or pauses a process to protect the system, column, or sample.

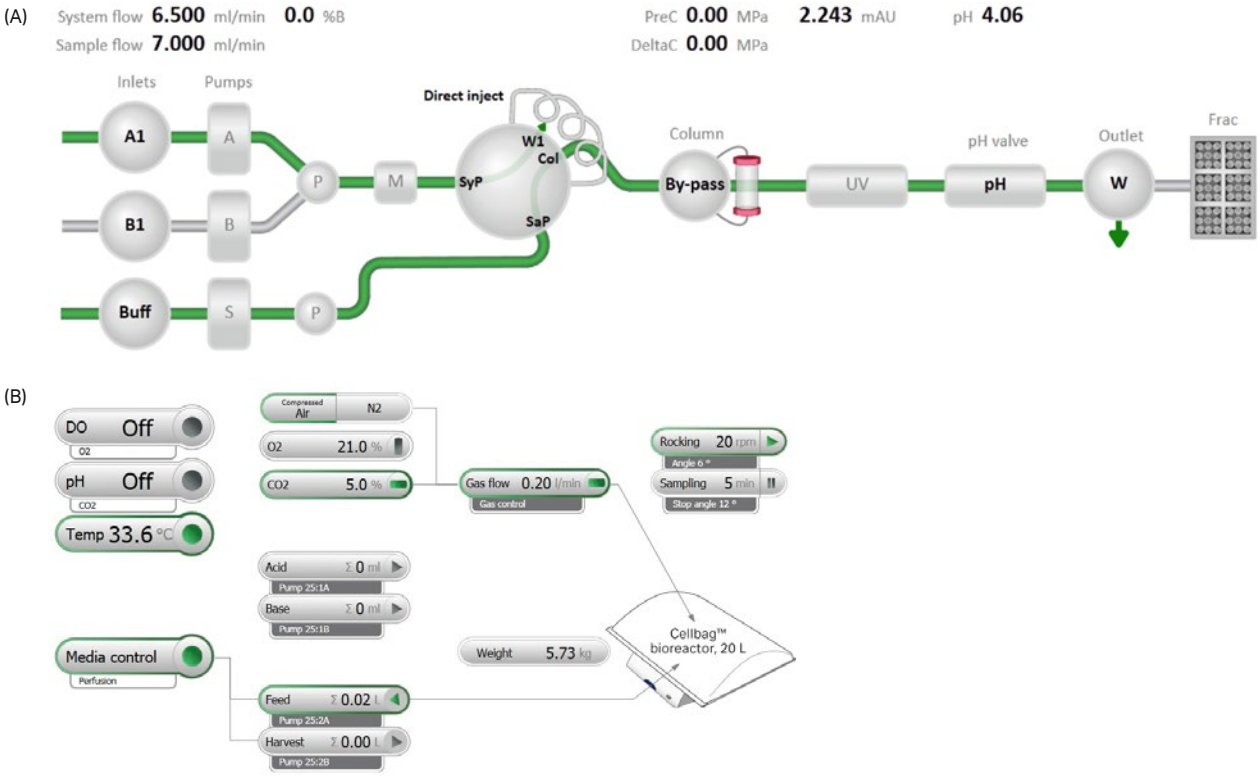


Fig 4. Examples of UNICORN interface with interactive process picture from (A) ÄKTA pure system equipped with sample pump, column valve, and Fraction Collector F9-C; (B) ReadyToProcess WAVE™ 25 system, using a Cellbag™ bioreactor.

System Control features give you:

- Full control during manual or programmed runs. You can change run parameter settings at any time. The changes are included in the run log.
- Real-time flow scheme shows you the current flow path, valve positions, and monitor values (Fig 4).
- Control of up to three instruments simultaneously, with an individual layout for each system.
- ***Method Queues*** function gives you the option of unattended operation of multiple methods in sequence.

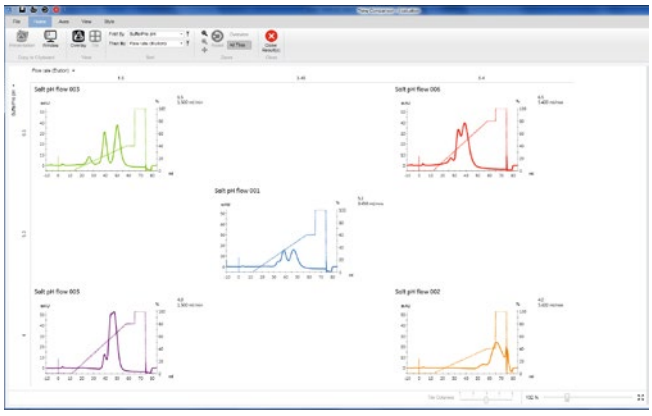
Evaluation

With UNICORN 7 control software, the ***Evaluation*** module provides a simplified user interface optimized for most commonly used workflows like quick evaluation, comparison of results, and work with peaks and fractions. The ***Evaluation*** module is optimized for chromatography evaluations, but can be used to view results from all application areas.

Evaluation features give you:

- Simplified interface, including single-click operations with instant feedback for operations like peak integration and shift offset.
- Preview of results for quick evaluation.
- Comparison of results in column volumes (CV) for scale-up/down.
- Comparison of results in overlay and tile view. Sort results according to running parameters to see trends in data (Fig 5A).
- Auto peak integration.
- Amount and concentration calculation in peaks (Fig 5B).

(A)



(B)

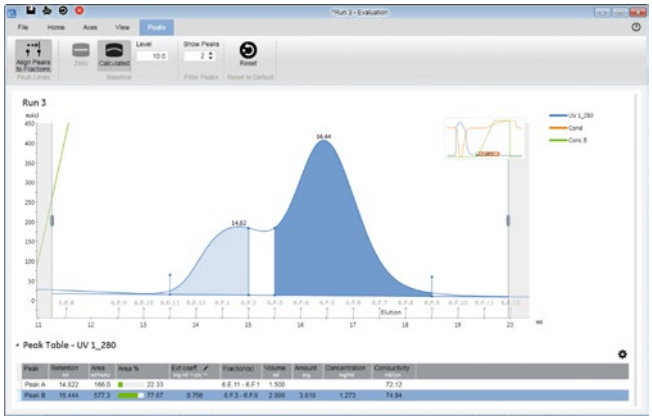


Fig 5. Two different views from the ***Evaluation*** module (A) comparing results in tile view, a typical view for presenting scouting results; (B) peak area calculation of protein amount and concentration.

The user experience is greatly improved compared to previous versions of UNICORN control software. These improvements give you:

- Quick filtering and sorting of results
- Instant feedback
- Second y-axis in the chart
- Single-click peak integration
- Shift offset along both x- and y-axes
- Zoom-function with overview and panning

Evaluation Classic

You can easily switch to the optional ***Evaluation Classic**** module to perform further evaluation operations. ***Evaluation Classic*** allows automatic, semi-automatic, or manual data processing. It offers extensive data evaluation, including mathematical operations on curves as well as creation and execution of automatic evaluation procedures. The ***Multi-result Peak Compare*** function allows you to compare data from different runs and scouting schemes, simplifying for example, method reproducibility studies.

Evaluation Classic features give you:

- Multi-result peak comparison, to compare data from different runs.
- Creation and execution of automatic evaluation procedures.
- Customization of report layout.
- Wide range of mathematical curve operations (add, subtract, and differentiate, etc.).

Administration

The ***Administration*** module shows the system logs and system properties. It also gives you control of database management and user setup. Starting from UNICORN 6.0 control software, data is stored in a SQL Server based database, which provides a secure and robust data storage where data can be easily accessed, archived, and searched. Depending on the number of users and integrated systems simultaneously accessing the same database, SQL Server Express (included) or full Microsoft SQL Server is suggested for optimal operation.

Administration features give you:

- Advanced user and system administration (LDAP authentication supported).
- Database functions such as ***Archive/Retrieve*** and ***Backup/Restore*** scheduling of backups.
- Automated system messages through email notifications. Receive an email if, for example, an alarm or error occurs during run.

* Use of the **Evaluation Classic** module requires an additional e-license.

Integrated tools in UNICORN 7 control software

Column Logbook

To increase operational safety, UNICORN software offers ***Column Logbook*** as an optional feature, providing traceability by keeping track of important column and run data. The ***Column Logbook*** provides you with the history of an individual column.

Individual columns are identified using a 2-D barcode scanner. The information can also be entered manually into the system. Some columns, such as HiScreen™ columns, are labeled with barcodes. For other columns, labels containing preprinted barcodes are available.

By tracking individual columns, information is recorded for each run regarding column type, production lot, column ID, type of resin, run data, and more. This information is used to notify you when it is time for column maintenance. The notification limits are defined by the user. For instance, you can define the number of times the column can be run before cleaning or between column performance tests. All results for the column are listed under ***Column History***, providing easy access to all run data.

BufferPro for chromatography systems

Automatic buffer preparation with ***BufferPro*** in the ÄKTA avant system allows you to easily prepare single buffers as well as screen for optimal buffer compositions. You can use ***BufferPro*** for pH scouting in rapid method optimization. Automatic buffer preparation eliminates time-consuming buffer preparation and titration for experiments requiring pH changes. Stable stock solutions can be prepared, stored, and used repeatedly, while titrated buffers are mixed fresh, online. ***BufferPro*** includes an improved algorithm and more buffer systems than its predecessor, BufferPrep.

UNICORN DoE integrate extension

An extension can be added to UNICORN software to streamline the execution of your design of experiments (DoE) plans with ÄKTA avant system.

The UNICORN DoE integrate extension enables the automated integration of DoE experimental plans from your DoE software into UNICORN scouting runs. You'll reduce the risk of errors and save time. You can do it from the DoE software of your choice since the extension can be used with commonly used DoE software products available on the market.

Companion tools

UNICORN online

UNICORN online provides intuitive real-time control and monitoring of your system, and lets you easily view results from any mobile device (Fig 6) or remote computer. For example, with UNICORN online, you can adjust a run parameter while sitting in a conference room — away from the lab.

You can access UNICORN online from a web browser without installing any applications. UNICORN online supports ÄKTA go, ÄKTA pure, ÄKTA avant, and ÄKTA pilot™ 600 systems.

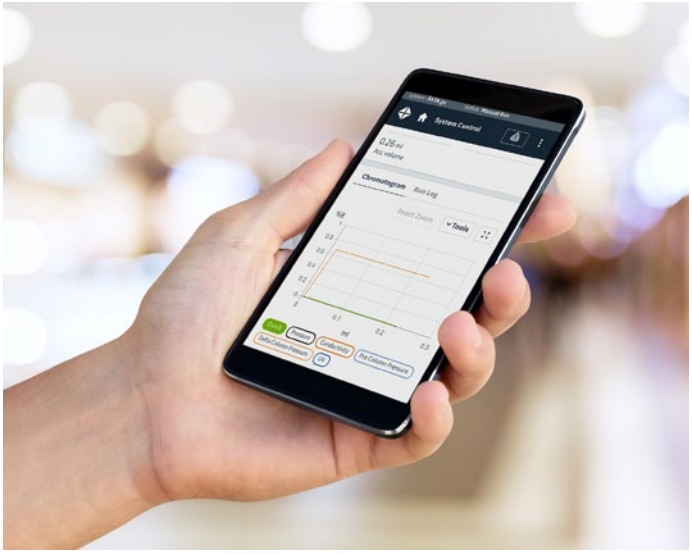


Fig 6. Control, monitor, and view result on your phone using UNICORN online.

My Instruments

My Instruments offers a real-time overview of your entire fleet of systems. At a glance, you can view the status of your systems and any alarms that need your attention (Fig 7). Just click to see additional system information like logged-in users and running method status. You can also open the system in UNICORN online to control and monitor a run.

My Instruments can display systems controlled by UNICORN software version 7.6 or higher. You can access it in a web browser without installing any applications.

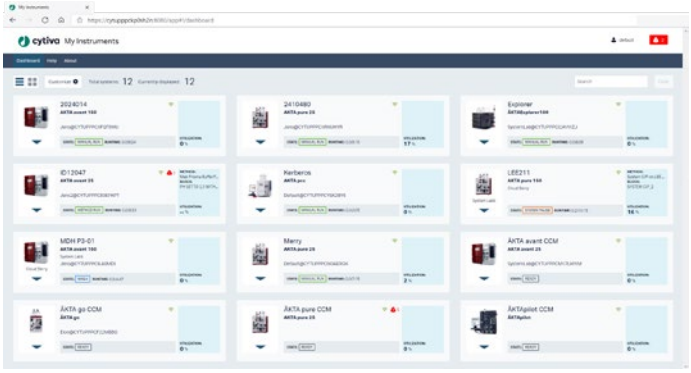


Fig 7. My Instruments offers a real-time overview of your systems including status of your systems and any alarms that need your attention.

Regulatory support

We have more than two decades of experience in developing regulatory-compliant software and have taken many steps to support good-x-practice (GxP) to comply with regulatory requirements, utilizing procedures and documentation that comply with standards accepted throughout the biopharmaceutical industry. UNICORN software is present in many registered and approved manufacturing processes.

UNICORN software products support a current good manufacturing practice (cGMP)-regulated environment and help maintain electronic records. All data (e.g., results and extensive run documentation records), events, and configurations are stored in a single, unalterable database, in line with GAMP 5 and related good practice guides. The software offers functionality that helps manufacturers meet US Food and Drug Administration (FDA) 21 CFR Part 11 and EU GMP Annex 11 regulatory guidelines, including a system audit trail, electronic signatures, and electronic records (1, 2).

Validation support is accessible through our Regulatory Support page. After registration, you have access to comprehensive documentation on control system validation, installation qualification (IQ), and operational qualification (OQ) services.

Available support documentation includes:

- Detailed description of the development model used for UNICORN 7 software.
- 21 CFR Part 11 system assessment in checklist format.
- Self-Assessment Questionnaire (SAQ) provided in the Validation Support File (VSF).

Visit Cytiva.com/rsf to register for change control notifications and access to validation guides and regulatory support files.

OPC protocols

UNICORN Open Platform Communication Unified Architecture (OPC-UA) server provides a standardized integration interface to support integration between UNICORN and other software systems such as Laboratory Information Systems (LIMS) and Manufacturing Execution Systems (MES) or supervisory control and data acquisition (SCADA).

OPC-UA enables open connectivity via open standards created in collaboration with leading automation manufacturers worldwide, including Microsoft. OPC-UA provides interoperability between system components by creating and maintaining open standard specifications.

- UNICORN OPC data access server (DA server) gives access to all process data.
- UNICORN Alarms and Events server (AE server) informs an OPC client that a system parameter has exceeded an upper or lower limit value.
- UNCORN historical data access (HDA) allows any OPC client application to access the batch result generated by UNICORN software.
- UNICORN OPC Security controls client access to the above data, while protecting sensitive information and guarding against unauthorized modification of process parameters.

For more information, see the UNICORN OPC manual.

Integration and remote capabilities

UNICORN 7 software can be deployed in several different ways, to allow availability of functionality in a networked configuration (Fig 8). Advantages of network setup include data sharing, remote control and a centralized administration. Floating licenses are also available for optimized usage.

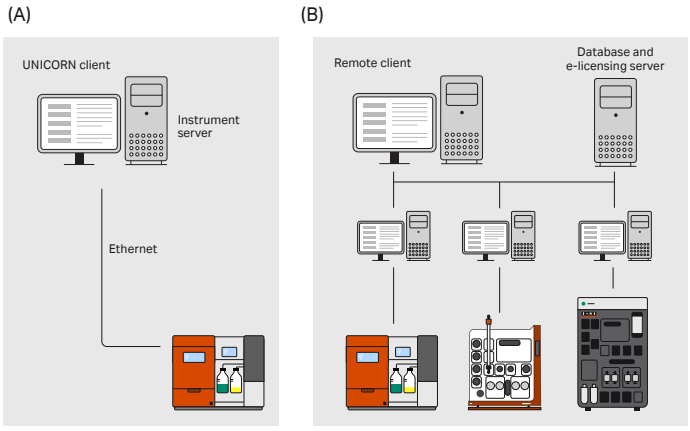


Fig 8. (A) You can control each ÄKTA instrument by a dedicated instrument server; (B) In a network with multiple instruments, you can connect ÄKTA instrument to its own instrument server and an additional server is used as the database and e-licensing server.

Requirements

Operating system: Windows

Database: UNICORN software includes SQL Server Express 2022. This can support up to three systems in a networked environment. For more than three systems, performance improvements are seen with SQL Server Standard, SQL Server Enterprise, or SQL Data Warehouse (available separately from Microsoft).

Contact your local Cytiva representative for full technical specifications.

UNICORN 7 software is tested using an English operating system. Using other language versions may cause errors.

Ordering information

Products	Code number
License packages (see the product web page for details)	
UNICORN 7 academia	29708933
UNICORN 7 process development	29879315
UNICORN 7 package for filtration/WAVE	29708936
Workstation license for all systems	
UNICORN 7 WrkStn pure-BP-exp	29128116
Workstation license for ÄKTA avant system	
Workstation license for ÄKTA avant system	29879752
Optional licenses	
UNICORN 7 remote	29702882
UNICORN 7 dry	29702884
UNICORN 7 column logbook lic	29702892
UNICORN 7 standalone evaluation	29702886
UNICORN 7 evaluation classic	29702888
UNICORN DoE integrate extension	29875086
Related products	
ÄKTA avant 25 system	28930842
ÄKTA avant 150 system	28976337
ÄKTA pilot 600S system	29274325
ÄKTA pilot 600R system	29274328
ReadyToProcess WAVE 25 Rocker system	28988000
ÄKTA go system	29383015
ÄKTA pure 25 L system	29018224
ÄKTA pure 25 T system	29707636
ÄKTA pure 25 M system	29018226
ÄKTA pure 150 L system	29046665
ÄKTA pure 150 T system	29707638
ÄKTA pure 150 M system	29046694
ÄKTA pure micro system	29302479
Other equipment supported by UNICORN control software	
For more details on UNICORN software used with manufacturing-scale systems, see the industrial data file	CY50315

Related information	Reference
ÄKTA go system	cytiva.com/aktago
ÄKTA pure system	cytiva.com/aktapure
ÄKTA avant system	cytiva.com/aktaavant
ÄKTA pilot 600 system	cytiva.com/aktapilot600
ReadyToProcess WAVE 25 system	cytiva.com/wave

Purifying proteins?

Visit the Purify app to select chromatography columns and resins, configure ÄKTA systems, and find accessories.

Go to **cytiva.com/purify-app**

References

1 EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines. https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en

2 U.S. Food & Drug Administration. 21 CFR Part 11, Electronic Records; Electronic Signatures — Scope and Application. www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11

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For local office contact information, visit cytiva.com/contact

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