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 yr by researchers in academia and industry, UNICORN™ 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 **Design of Experiments** (DoE), **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 **DoE** and **Column Handling** tools requires an additional e-license.
† The **BufferPro** tool is available for ÄKTA™ avant systems.

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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, 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).
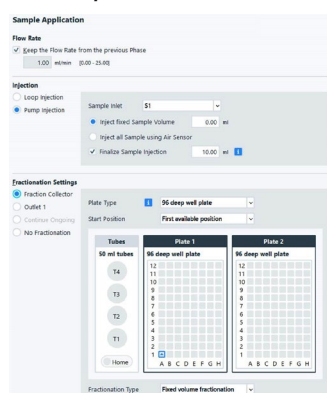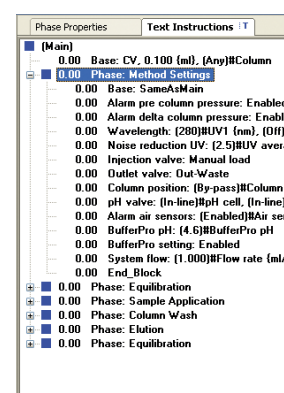

Fig 2. The different parts of the **Method Editor**.

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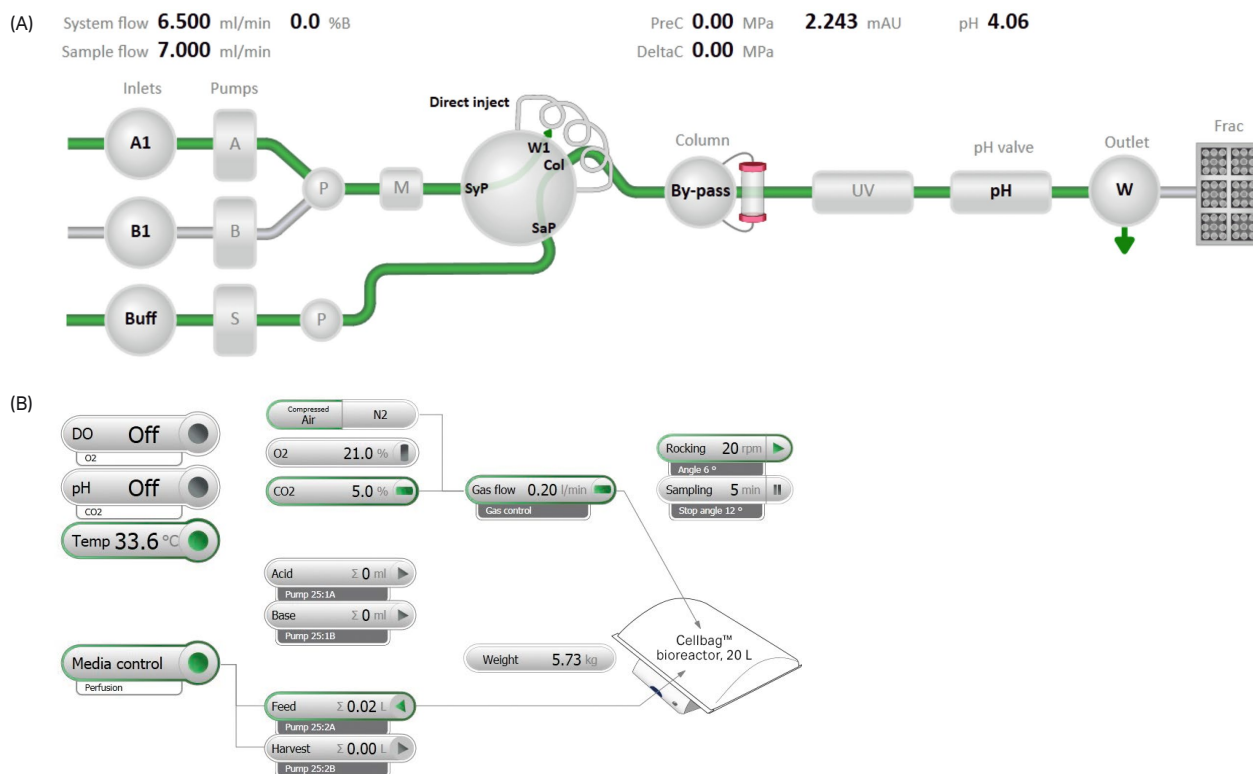
Fig 4. Examples of UNICORN™ interface with interactive process picture from (A) ÄKTA pure™ system equipped with sample pump, column valve, and Fraction Collector F9-C; (B) ReadyToProcess WAVE™ 25 system, using a Cellbag™ bioreactor.

System Control features give you:

- Full control during manual or programmed runs. You can change at any time and 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).
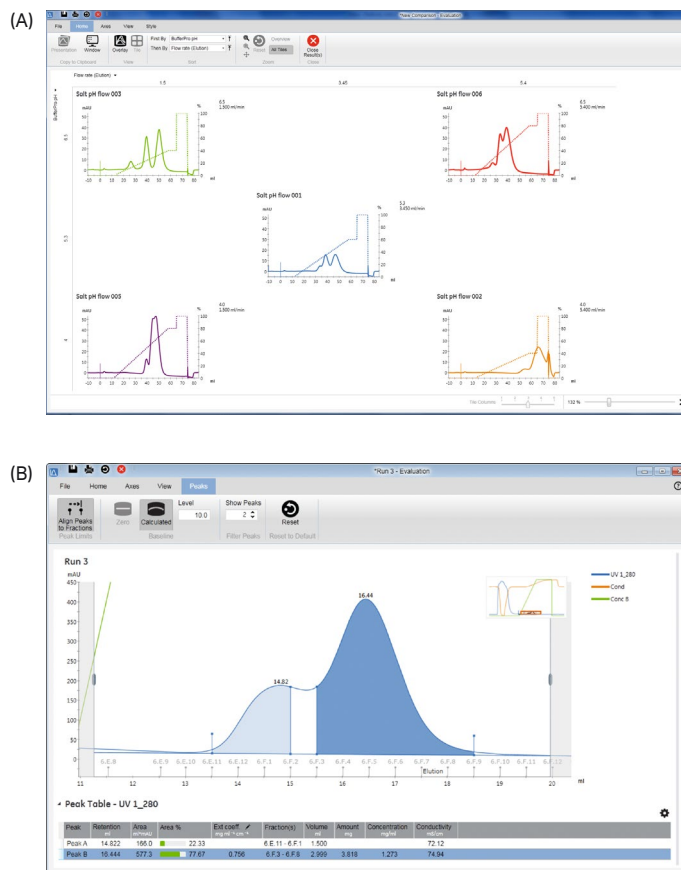- Possibility to align peaks to fractions.

Fig 5. Two different views from the **Evaluation** module (A) comparing results in tile view, a typical view for presenting DoE 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

To evaluate operations like DoE, you can easily switch to the optional **Evaluation Classic*** module. **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:

- **DoE** tool.
- **Column Logbook** for logging and trending of performance parameters for individual columns.
- 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

DoE for chromatography systems

When used in connection with ÄKTA™ avant or ÄKTA pure™, UNICORN™ 7 control software features a DoE functionality (Fig 6). The **DoE** tool allows retrieving maximum amount of information from a minimum number of experiments, thus reaching the required level of understanding of a process or an experiment faster. Using a DoE approach can save both time and money.
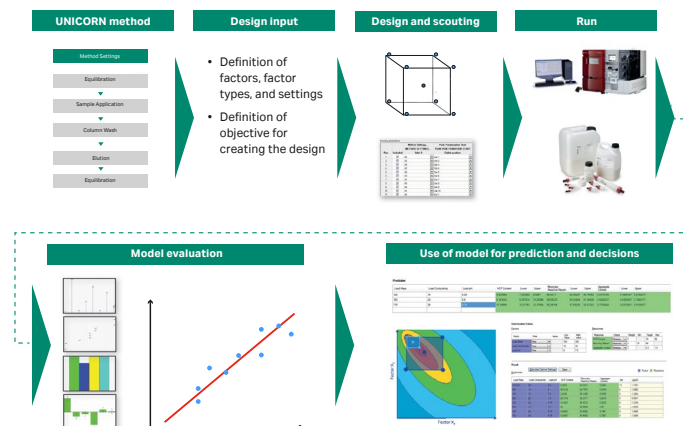

Fig 6. In the **DoE** tool, multiple factors are varied simultaneously and the resulting data is used to generate a statistical model. The model is validated and used to produce maps that support decision making.

In the traditional approach, you can determine optimal conditions by varying one parameter at a time while other parameters remain fixed. Important information, such as interaction data between different parameters, might be missed. DoE is an organized, statistical approach that varies multiple factors simultaneously to significantly reduce the number of experiments you need to perform. The effect of all parameters and their interactions are detected and described in a validated statistical model (Fig 7A). Furthermore, DoE lets you analyze variability and noise as well, providing you a way to discriminate meaningful values from nonsignificant values.

The **DoE** tool features experimental designs for:

- Screening to determine which factors are important in a process.
- Optimization to find the optimal factor settings for a process.
- Robustness testing to investigate how a process is affected by adjusting different parameters.

The **DoE** tool is fully integrated into UNICORN™ 7 control software. It provides the guidance you need if you do not have the statistical expertise. The runs are performed automatically on an ÄKTA™ chromatography system.

You can use the outcome of the DoE analysis directly in the form of:

- A summary of fit plot that shows the model shows a good fit to the data (Fig 7A).
- Response contour plots, which graphically show the interactions between parameters (Fig 7B).
- A predictor chart, which calculates the predicted responses for a set of input parameter values.
- An optimizer chart, which proposes parameter values that will ensure reaching the desired target responses.
- a sweet spot plot, which graphically displays the range where two or more selected response criteria are fulfilled.
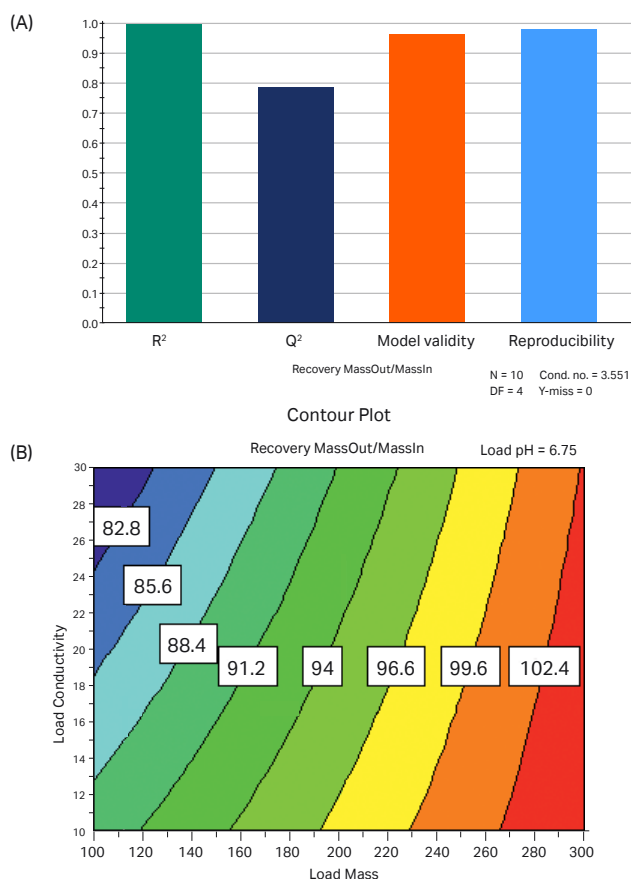

Fig 7. Plots from the *DoE* tool. (A) A summary of fit plot tells you that the model fits the data well; (B) a response contour plot shows you how process parameters affect the response.

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.

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 8) 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.
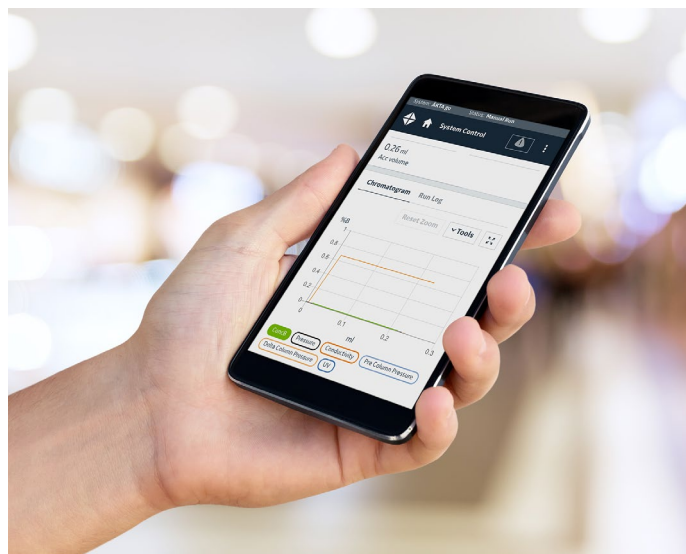

Fig 8. Control, monitor, and view result on your phone using UNICORN™ online.

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 9). 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 UNICORN™ 7.6 controlled systems. You can access it in a web browser without installing any applications.
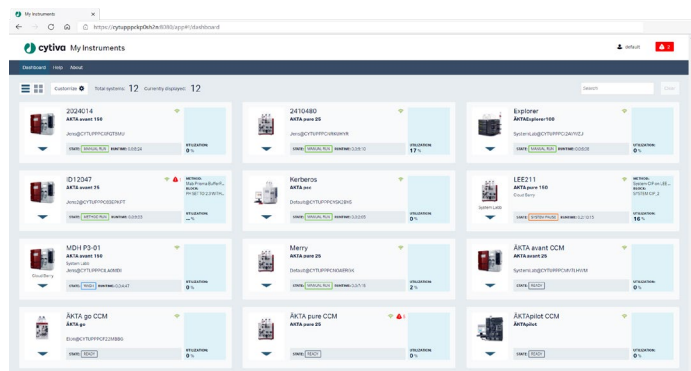

Fig 9. My Instruments offers a real-time overview of your systems including status of your systems and any alarms that need your attention.

Regulatory support

UNICORN™ control software is technically compatible with the relevant sections of the Food and Drug Administration (FDA) 21 Code of Federal Regulations (CFR) Part 1 and is developed according to Good automatic manufacturing practices (GAMP) 5 guidelines. UNICORN™ features a system audit trail, electronic signatures, and electronic records. Individual user access permissions can be set, and individual users are password protected. The ability to lock the system according to a defined time schedule with user passwords provides a high level of security. This means that you can lock active processes for unattended operation without the risk of unauthorized interference.

All your records are maintained and stored in a single, unalterable database, including results and extended run documentation. You have access to additional validation support including comprehensive documentation on control system validation, installation qualification, and operational qualification services.

Available validation support documentation gives you:

- Detailed description of the development model used for UNICORN™ control software.
- 21 CFR Part 11 system assessment in checklist format.
- Audit report and 21 CFR Part 11 conclusions on functionality by an external and independent expert.

OPC extension

An optional extension is available to enable data transfer via OPC HDA into the software. The extension lets you take advantage of the evaluation capabilities within UNICORN™. For more details about this extension, *see* the OPC Import UNICORN™ extension data file.

Networking capabilities

UNICORN™ control software can be deployed in several different ways, to let you take advantage of the functionality available in a networked configuration (Fig 10).

The network setup gives you these advantages:

- Remote control
- Data sharing
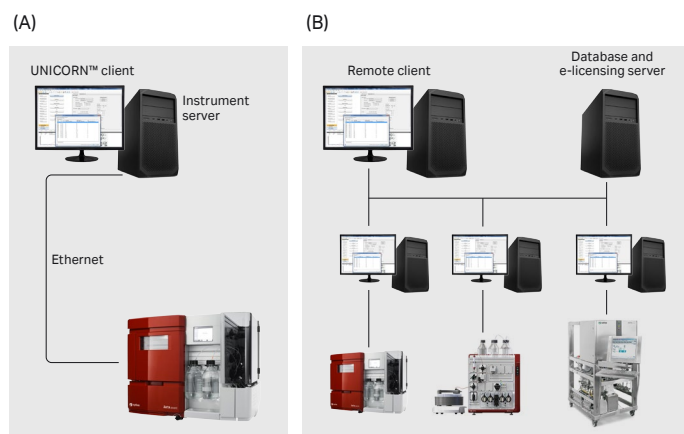- Floating licenses for optimized usage
- Centralized administration

Fig 10. (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®

Please refer to *Software change description* for specific information.

Database: UNICORN™ control software includes SQL Server® Express 2014 SP1. 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 control software is tested using an English operating system. Using other language versions might cause errors.

Ordering information

Products	Code number
UNICORN™ 7 Academia	29708933
UNICORN™ 7 Process Development	29708934
UNICORN™ 7 Manufacturing	29708935
UNICORN™ 7 WrkStn pure-BP-exp	29702890
UNICORN™ 7 WrkStn avant includes DoE, Column Logbook, and Evaluation Classic	29702894
UNICORN™ 7 Remote	29702882
UNICORN™ 7 Dry	29702884
UNICORN™ 7 DoE License includes Evaluation Classic	29702880
UNICORN™ 7 Column logbook lic	29702892
UNICORN™ 7 StdAlon Evaluation	29702886
UNICORN™ 7 Evaluation Classic	29702888
UNICORN™ 7 DVD pack no license	29128020
OPC Import UNICORN™ extension	29090543

Related products

	Code number
ÄKTA™ avant 25	28930842
ÄKTA™ avant 150	28976337
ÄKTA pilot™ 600S	29274325
ÄKTA pilot™ 600R	29274328
ReadyToProcess WAVE™ 25 Rocker	28988000
ÄKTA go™	29383015
ÄKTA pure™ 25 L	29018224
ÄKTA pure™ 25 L1	29018225
ÄKTA pure™ 25 M	29018226
ÄKTA pure™ 25 M1	29018227
ÄKTA pure™ 25 M2	29018228
ÄKTA pure™ 150 L	29046665
ÄKTA pure™ 150 M	29046694
ÄKTA pure™ 150 M3	29046697
ÄKTA process™ DCS	29692670

Related information	Reference
ÄKTA go™	cytiva.com/aktago
ÄKTA pure™	cytiva.com/aktapure
ÄKTA™ avant	cytiva.com/aktaavant
ÄKTA pilot™ 600	cytiva.com/aktapilot600
ReadyToProcess WAVE™ 25	cytiva.com/wave
Validation Support File UNICORN™ software, data file	28962650
OPC Import UNICORN™ Extension, data file	29088592

Purifying proteins?

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

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

cytiva.com/unicorn

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