

# UNICORN™ 6 control software

UNICORN system control software provides built-in knowledge for planning, controlling, and analyzing chromatography systems and results. UNICORN is used on all ÄKTA™ design systems and can be used throughout all stages of process development from the lab bench to full-scale production.

UNICORN 6 control software has been specially developed for use with ÄKTA avant liquid chromatography system. ÄKTA avant, together with UNICORN 6, enables you to achieve fast and secure process development. UNICORN 6 features a user friendly graphical user interface (GUI), an improved **Method Editor**, and an integrated **Design of Experiments (DoE)** tool (Fig 1).

## Key features:

- **Method Editor:** simple, intuitive, and flexible method creation using predefined phases from the **Phase Library**
- **DoE:** integrated tool for experimental design provides more precise information in fewer experiments for cost efficiency and time savings
- **Column Logbook:** valuable tool to keep track of individual column and run data for traceability and operational security
- **BufferPro:** automatic on-line buffer preparation for quick method optimization includes several buffer systems and an improved algorithm
- **Database storage:** robust data storage allows easy access to data, data security, and data integrity
- **FDA 21 CFR Part 11 compliance:** protection of maintained records, signature manifestation, electronic audit trails, and more



**Fig 1.** UNICORN 6 has an improved graphical interface with a task bar, customizable docking windows, and object navigators.

## Description

UNICORN control system is based on an integrated controller and an intuitive computer-based GUI. For easy usability, the GUI uses a familiar windows environment with a task bar, customizable docking windows, drag-and-drop object handling, and object navigators. The chromatography run sequence is fully determined by the end-user for maximum control of the purification process. By selecting column type, programming code (e.g., of run parameters) is automatically generated by UNICORN, although conventional line programming may be performed by advanced users.

UNICORN 6 control software consists of four modules: **Administration**, **Method Editor**, **System Control**, and **Evaluation**. The **Administration** module is used to set up user access, and methods are generated in the **Method Editor**. The run is performed using **System Control**, while data analysis is performed in the **Evaluation** module. Integrated tools such as **DoE**, **Column Handling**, and **BufferPro** extend across the different modules, enabling increased productivity. UNICORN contains the tools needed for beginners and advanced users to perform all types of chromatography, from setting up and running a method to evaluating the data.



## Administration

The **Administration** module shows the system logs and system properties, and allows database management and user setup. In previous UNICORN versions, data storage was file-based. In UNICORN 6, data is stored in an SQL-based database, which provides a secure and robust form of data storage where data can be easily accessed, archived, and searched. The SQL Server Express software is included in the UNICORN installation program, and information is available about the possibility of upgrading to the full Microsoft SQL Server.

**Administration** features:

- Advanced user and system administration
- **Archive/Retrieve** and **Backup/Restore** functions for database handling such as archiving of data and scheduled backups

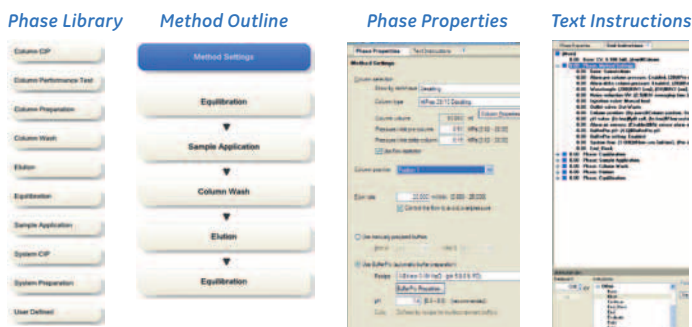
## Regulatory support

UNICORN is suitable for use in a regulated environment in a manner complying with 21 CFR Part 11. 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 active processes can be locked for unattended operation without risk of unauthorized interference.

All maintained records are stored in a single, unalterable database, including results and extended run documentation. Additional validation support includes comprehensive documentation on control system validation and Installation Qualification and Operational Qualification services.

Some available validation support documentation includes:

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



**Fig 2.** In the **Method Editor**, methods may be created using predefined methods, or by dragging predefined phases from the **Phase Library** into the **Method Outline**. Parameters are set in the **Phase Properties** pane, and the instructions for the run are automatically programmed in the **Text Instructions** pane.

## Method Editor

The **Method Editor** module contains all the instructions used for controlling the chromatographic run (Fig 2). The **Method Editor** provides built-in application support, and the GUI provides for easy viewing and editing of the run properties. In UNICORN 6, methods are built by using phases. Each phase reflects a step in the chromatography run, such as sample application or wash phases (see **Method Outline**; Fig 2). For convenience, the **Method Editor** contains predefined methods for different chromatography techniques and maintenance procedures, as well as 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** into the **Method Outline**.

Column parameters (e.g., flow rate and pressure limits) are automatically programmed into the method by selecting the column type in the **Phase Properties** pane. Other important parameters are easily set in the **Phase Properties** pane, or for added flexibility, advanced users may 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**.

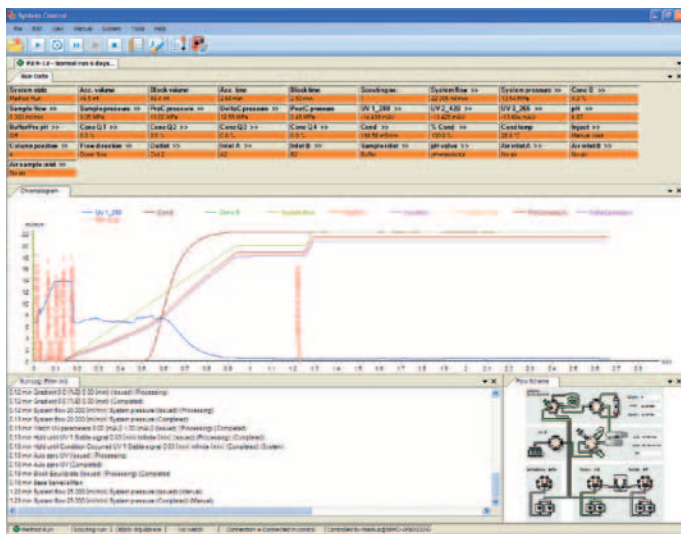


Fig 3. In **System Control**, the view and layout of the docking windows can be customized by the user by dragging-and-dropping each window.

## System Control

The **System Control** module is used to start, monitor, and control a run. The **System Control** window has customizable and dockable panes showing the chromatogram, current run data values, run log, and actual flow scheme. Users have the flexibility to choose which docking panes are viewed and can customize the layout to suit their needs (Fig 3).

The extensive UNICORN **Watch** function enables you to control your processes with regard to monitor signals such as UV, conductivity, pH, and pressure. In a **Watch** instruction, an action specified by the user is executed when a certain condition is met. For example, a **Watch** instruction can be used to continue column equilibration until 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, saving time and material, and automating entire runs.

Individual **Alarms** can be set 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.

**System Control** features:

- Manual system interaction
- Real-time flow scheme shows the current flow path, valve positions, and monitor values (Fig 4)
- Detailed help text by right clicking on the flow scheme or run data
- Control of up to three instruments simultaneously, with an individual layout for each system
- **Start Protocol** function for conveniently starting a run
- **Notes** tab allows the user to add free text notes about the run

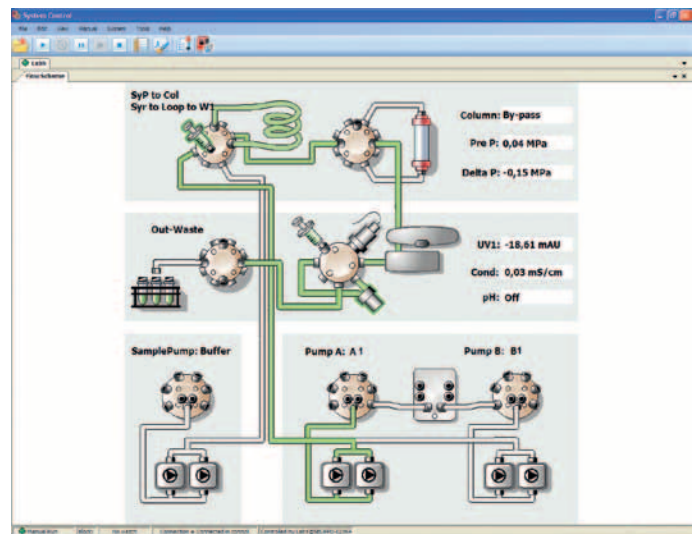


Fig 4. The real-time flow scheme shows the current flow path and valve positions.

- Improved **Method Queues** function for unattended operation
- Pressure control regulates flow rate so that it does not exceed the set pressure limit

## Evaluation

The **Evaluation** module allows for automatic, semi-automatic, or manual data processing. UNICORN offers extensive data evaluation, including peak integration and height equivalent to a theoretical plate (HETP) determination. The **Multiresult Peak Compare** function makes it easy to compare data from different runs and scouting schemes, simplifying for example, method reproducibility studies.

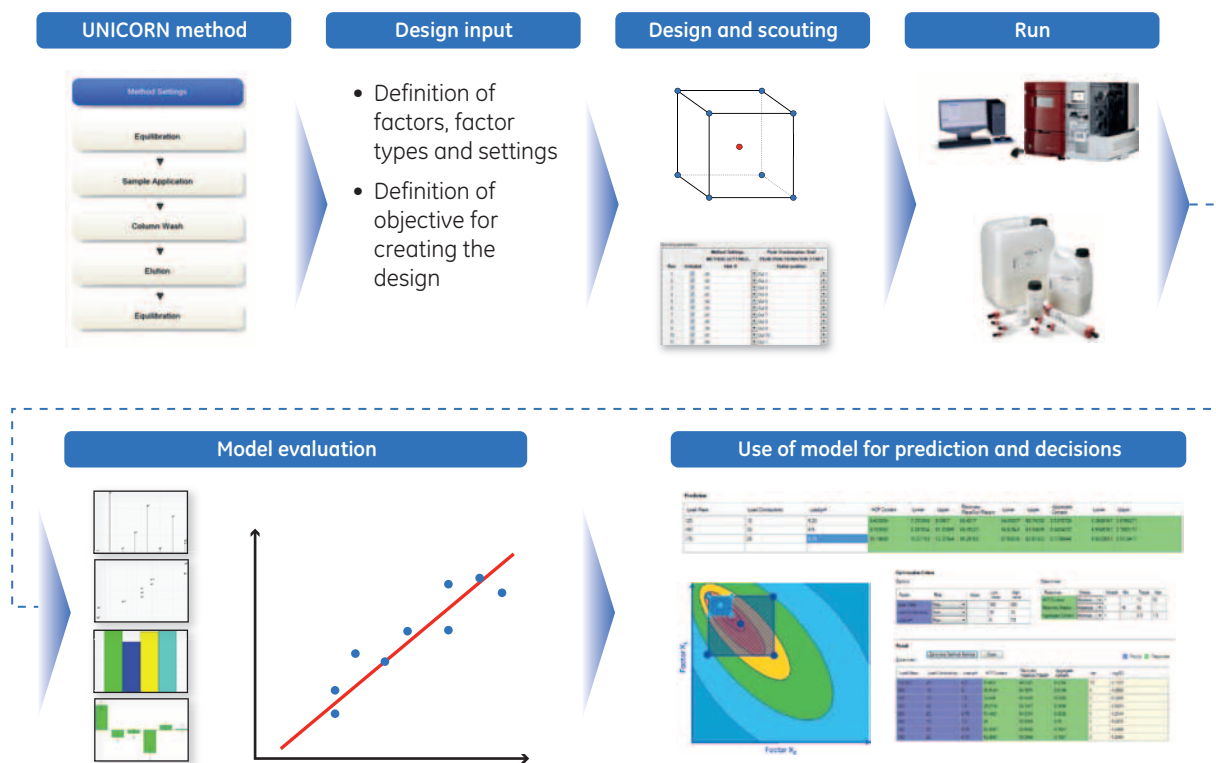
**Evaluation** features:

- Evaluation and generation of customizable reports (e.g., PDF format)
- Wide range of curve operations
- Move results to another UNICORN database using the **Import/Export** function
- Data migration from UNICORN 5

## Integrated tools in UNICORN 6

### Design of Experiments (DoE)

UNICORN 6 has an integrated functionality called **DoE**, a powerful tool that allows the maximum amount of information to be obtained from a minimum number of experiments. By improving efficiency, both time and money are saved. Traditionally, optimal conditions may be determined by varying one parameter at a time while the rest of the parameters are kept fixed. Important information, such as interaction data between different parameters, may be missed using this traditional approach.

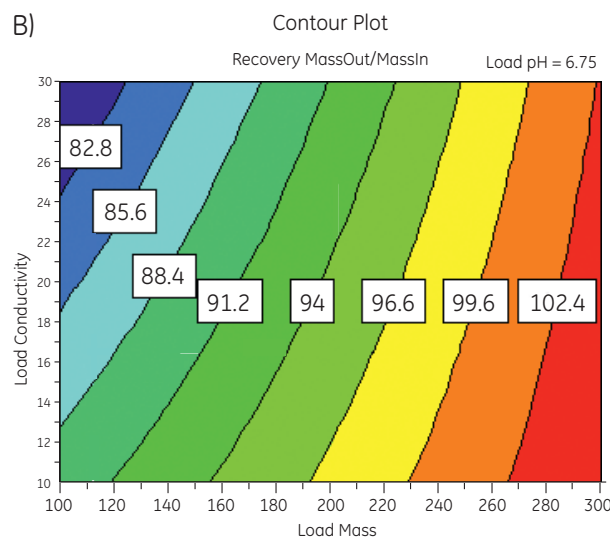
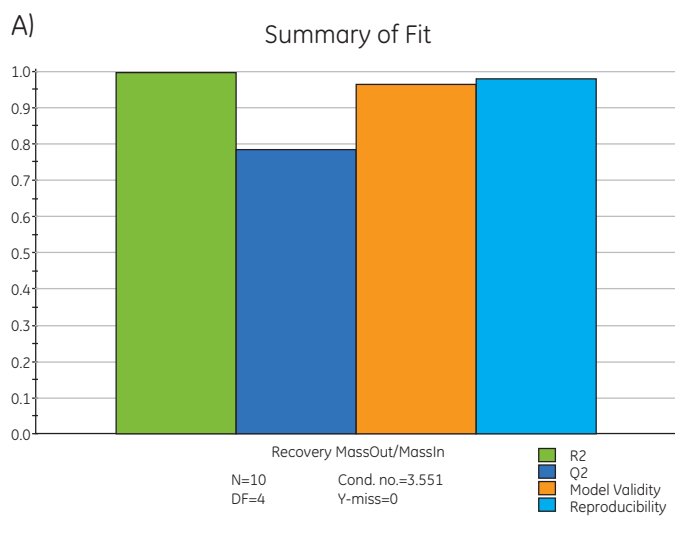


**Fig 5.** In *DoE*, multiple factors are varied simultaneously and the resulting data is used to generate a statistical model. The model is validated and used to produce maps that support decision making.

*DoE* is an organized, statistical approach that varies all factors simultaneously to significantly reduce the number of required experiments. Furthermore, *DoE* allows variability and noise to be analyzed as well as interaction effects between factors. *DoE* is an important step towards automating process development, and the basic workflow is shown in Figure 5.

With *DoE*, the entire experimental space can be explored efficiently by taking into account important process parameters or factors, such as flow velocity and elution pH. The resulting

data or “responses” (e.g., yield and purity) are used to automatically generate a statistical model. The model is validated (Fig 6A), used to predict the response to untested factor settings, and produce maps of the system (response contour plot; Fig 6B) to support decision making (e.g., to determine which process parameters are important for obtaining the optimal yield and purity). Because *DoE* estimates variability and noise as well as interaction effects between the different factors, more precise information is obtained, resulting in more reliable maps and better decision making.



**Fig 6.** In *DoE*, (A) a summary of fit plot demonstrates that the model shows a good fit to the data, and (B) a response contour plot shows how process parameters affect the response.



**Fig 7.** Some prepacked columns are prelabeled with barcodes, allowing each column to have a unique ID. By tracking individual columns, information is recorded for each run regarding the column type, production lot, type of media, run data, and more.

**DoE** features experimental designs for:

- **Screening:** to determine which factors are important in your process
- **Optimization:** to find the optimal factor settings for your process
- **Robustness testing:** to investigate how adjusting different factors affects your process

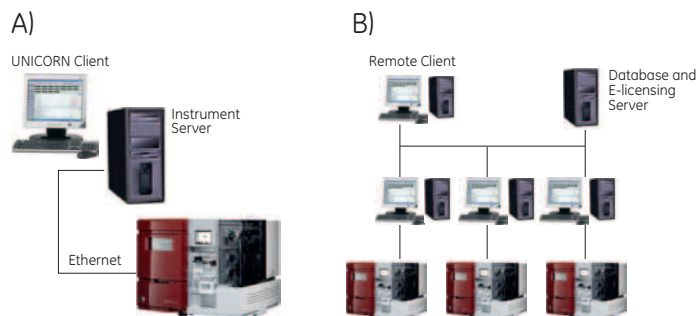
### Column Logbook

To increase operational safety, UNICORN 6 software features the **Column Logbook**, which provides traceability by keeping track of important column and run data. The **Column Logbook** supplies the user with a complete history of an individual column and allows the system to notify the user when it is time for column maintenance. Individual columns are identified using a 2-D barcode scanner, or the information may be entered manually into the system (Fig 7). Some columns, such as HiScreen™ columns, are prelabeled with barcodes (2-D matrix codes). For columns not already labeled with a barcode, UniTag sticker labels containing preprinted barcodes are available.

By tracking individual columns, information is recorded for each run regarding the column type, production lot, column ID, type of media, run data, and more. This information is used to notify the user when it is time for column maintenance. The notification limits are defined by the user, for instance, by defining the number of times the column may be run between cleanings or between column performance tests. Under **Column History**, all results for the column are listed, providing easy access to all run data.

### BufferPro

Automatic buffer preparation with **BufferPro** facilitates the preparation of single buffers as well as screening for optimal buffer compositions. **BufferPro** can be used 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 freshly on-line. **BufferPro** includes an improved algorithm and more buffer systems than its predecessor BufferPrep.



**Fig 8. (A)** Each ÄKTA avant instrument is controlled by a dedicated instrument server. **(B)** In a network with multiple instruments, each ÄKTA avant instrument is connected to its own instrument server and an additional server is used as the database and E-licensing server.

**BufferPro** can be started in just a few easy steps:

1. Select buffer, pH, and buffer concentration.
2. Prepare stock solutions according to the provided instructions.
3. Fill buffer inlets with stock solutions (e.g., water, salt, buffer, and acid/base).

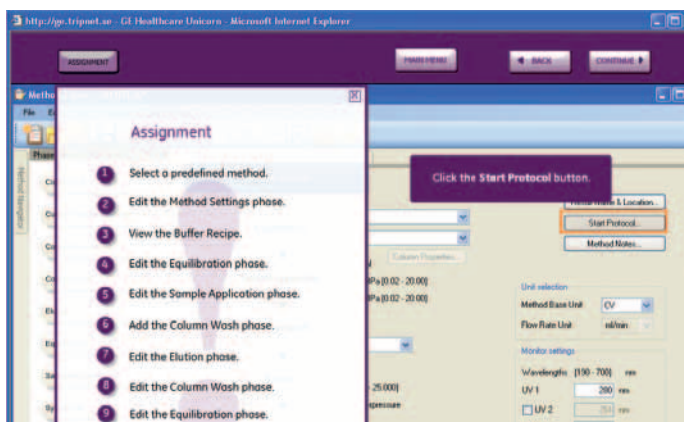
After mixing, **BufferPro** provides data showing the actual mixing ratios used from the stock solutions. During the run, the pH is monitored and **BufferPro** automatically compensates for changes in temperature and salt concentration. The accuracy of pH is crucial in many separations and **BufferPro** gives accurate and highly reproducible data.

### Networking capabilities

UNICORN 6 has an integrated controller that communicates directly with ÄKTA avant instrument hardware via an instrument server. UNICORN operates in Windows™ XP™ and Windows Vista™ environments, and network support allows real-time control from a remote or local PC. Communication is based on Ethernet, and each ÄKTA avant instrument is controlled by a dedicated instrument server (Fig 8A). In a network with multiple instruments, each instrument is connected to its own instrument server and an additional server, which is used as the database and E-licensing server (Fig 8B). Up to three instruments can be controlled simultaneously from one remote UNICORN client. In a network configuration, results are saved locally and then stored on the database server. Because results are saved locally, a run can continue even in the event of a network communication failure.

### Requirements

- Operating system Microsoft™ Windows XP Professional SP3 or Microsoft Windows Vista Business SP1
- 100 Mbit Ethernet LAN
- Two network cards on Instrument server PC
- Dual-Core machine with 3 GB memory



**Fig 9.** UNICORN 6 eCourse provides interactive, step-by-step tutorials on how to perform different tasks, such as creating a method.

## UNICORN 6 eCourse

The online training course for UNICORN 6 helps you to exploit the capabilities of ÄKTA avant protein purification system with ease and full control (Fig 9). This eCourse is accessed via a special Web site where you can complete the training at your own pace over one year. The course is structured into logical modules, and includes interactive step-by-step tutorials on how to perform different tasks, such as creating a method. The course provides an excellent overview for beginners, as well as previous UNICORN users that need to become acquainted with the features offered in UNICORN 6.

## Ordering information

Product	Code no.
UNICORN 6.1 local or remote workstation license with DVD	28-9806-84
UNICORN 6.1 local or remote workstation license without DVD	28-9835-31
UNICORN 6.1 DVD package	28-9806-81

Related products	Code no.
ÄKTA avant 25	28-9308-42
ÄKTA avant 150	28-9763-37
Computer with Windows XP or Windows 7 <sup>1</sup>	28-9573-31
UNICORN 6 eCourse	28-9500-00

Related literature	Code no.
Validation Support File UNICORN software, Data file	28-9626-50
UNICORN 6 eCourse, Flyer	28-9578-43
ÄKTA avant, Data file	28-9573-45
ÄKTA avant, Brochure	28-9594-86
Rapid process development for purification of a MAb using ÄKTA avant 25, Application note	28-9573-47
Rapid method development for native protein purification using ÄKTA avant 25 chromatography system, Application note	28-9623-37
Fast process development of a single-step purification using ÄKTA avant systems, Application note	28-9827-80

<sup>1</sup> For details about the computer, the operating system, and a complete list of the screens, keyboards, printers, and cables available, please contact your local GE Healthcare representative.

For local office contact information, visit  
[www.gelifesciences.com/contact](http://www.gelifesciences.com/contact)

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