UNICORN 6.4.1 control software

CHROMATOGRAPHY CONTROL SYSTEMS

UNICORN™ system control software provides built-in knowledge for planning, controlling, and analyzing results from various types of systems, including bioreactors, chromatography and filtration systems. UNICORN is a unified platform for your systems and suitable to use from research at the lab bench to full scale production.

UNICORN 6.4 has been developed with a focus on the user experience. Advanced capabilities can be accessed in a very easy and seamless manner.

When operating an ÄKTA™ avant or ÄKTA pure system, it also features 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 (only for ÄKTA avant and ÄKTA pure)
- **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 (only for ÄKTA avant)
- **Database storage:** robust data storage allows easy access to data, data security, and data integrity
- **Regulatory compliance:** protection of maintained records, signature manifestation, electronic audit trails, and more. Developed according to Good Automated Manufacturing Practice (GAMP) 5.
- **Advanced users and system administration:** users can logon using Active directories (LDAP). Users and workstation access to individual systems is controllable.

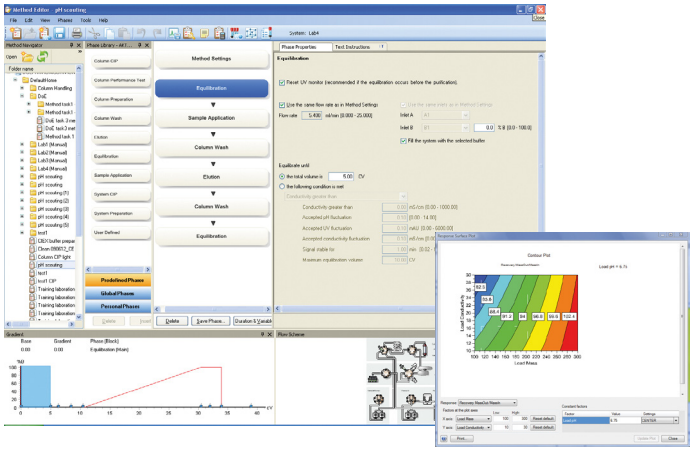

Fig 1. UNICORN 6.4 has an improved graphical interface with a task bar, customizable docking windows, and object navigators.

Description

UNICORN control system is based on an integrated controller and an intuitive computer-based interface. For easy usability, the interface 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 process. A graphical interface helps the user to create the process sequence, although conventional line programming may be performed by advanced users.

UNICORN contains the tools needed for beginners and advanced users to perform all types of experiments and processes, from setting up and running a method to evaluating the data. UNICORN 6.4 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.

Administration

The ***Administration*** module shows the system logs and system properties, and allows database management and user setup. In previous versions of UNICORN, data storage was file-based. In UNICORN 6.4, 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 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 **(LDAP authentification supported)**
- ***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 manner that complies with 21 CFR Part 11 and is developed according to GAMP 5 guidelines. UNICORN features a system audit trial, 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

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 interface provides for easy viewing and editing of the run properties. In UNICORN 6.4, 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, when using ÄKTA avant or ÄKTA pure systems, 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***.

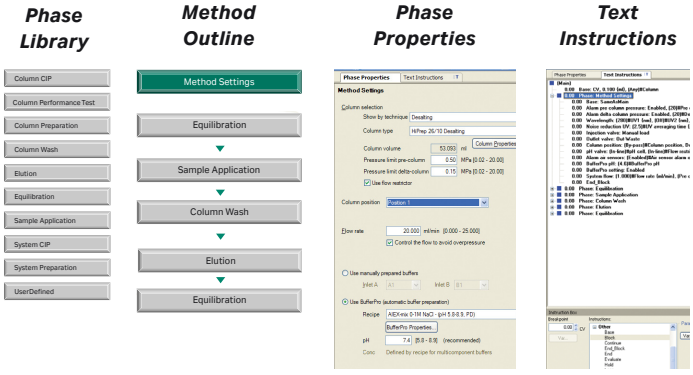

Fig 2. In the ***Method Editor,*** methods may be created using predefined methods, or by dragging predefined phases from the ***Phase Library*** into the ***Method Outline***. Parameters are set in the ***Phase Properties*** pane, and the instructions for the run are automatically programmed in the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

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 curve chart, 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).

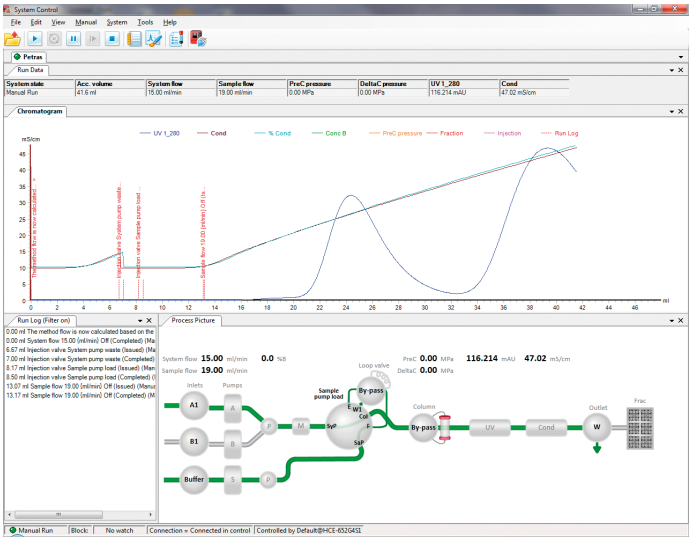

Fig 3. In ***System Control***, the view and layout of the docking windows can be customized by the user by dragging-and-dropping each window.

The extensive UNICORN ***Watch*** function enables you to control your processes with regard to monitor signals depending on the system that is being controlled. 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, ending a concentration step, stopping the media feed in a bioreactor (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 showing the current flow path, valve positions, and monitor values (Fig 4)
- Detailed help text accessed 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 allowing the user to add free text notes about the run
- Improved ***Method Queues*** function for unattended operation
- Pressure control regulating flow rate so that it does not exceed the set pressure limit

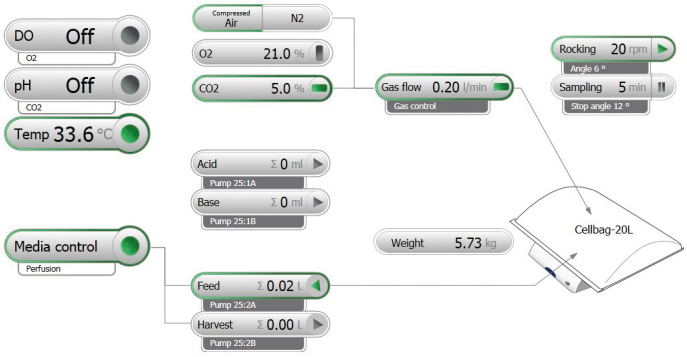

Fig 4. Example of UNICORN 6.4 interface to a ReadyToProcess™ WAVE™25 system with interactive display and buttons.

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
- An ***Import/Export*** function to move results to another UNICORN database
- Data migration from UNICORN 5

Integrated tools in UNICORN 6.4

Design of Experiments (DoE)

When used in connection with ÄKTA avant or ÄKTA pure, UNICORN 6.4 features a functionality called DoE, a powerful tool that allows a maximum amount of information to be obtained from a minimum number of experiments, thus reaching the required level of understanding of a process or an experiment faster, saving both time and money.

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. DoE is an organized, statistical approach that varies multiple factors simultaneously to significantly reduce the number of required experiments. The effect of all parameters and their interactions are detected and described in a validated statistical model (Fig 6A). Furthermore, DoE allows variability and noise to be analyzed as well, providing a way to discriminate meaningful values from non-significant values.

DoE 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 adjusting different factors affects a process

DoE is well integrated into UNICORN 6.4, guiding the user without requiring statistical expertise. The runs are performed automatically on the ÄKTA system.

The outcome of DoE is directly usable by the user in the form of

- response contour plots that graphically show the interactions between parameters (Fig 6B)
- a predictor chart, which calculates the predicted responses for a set of input parameters values
- an optimizer chart, which proposes parameters values that will ensure reached the desired target responses

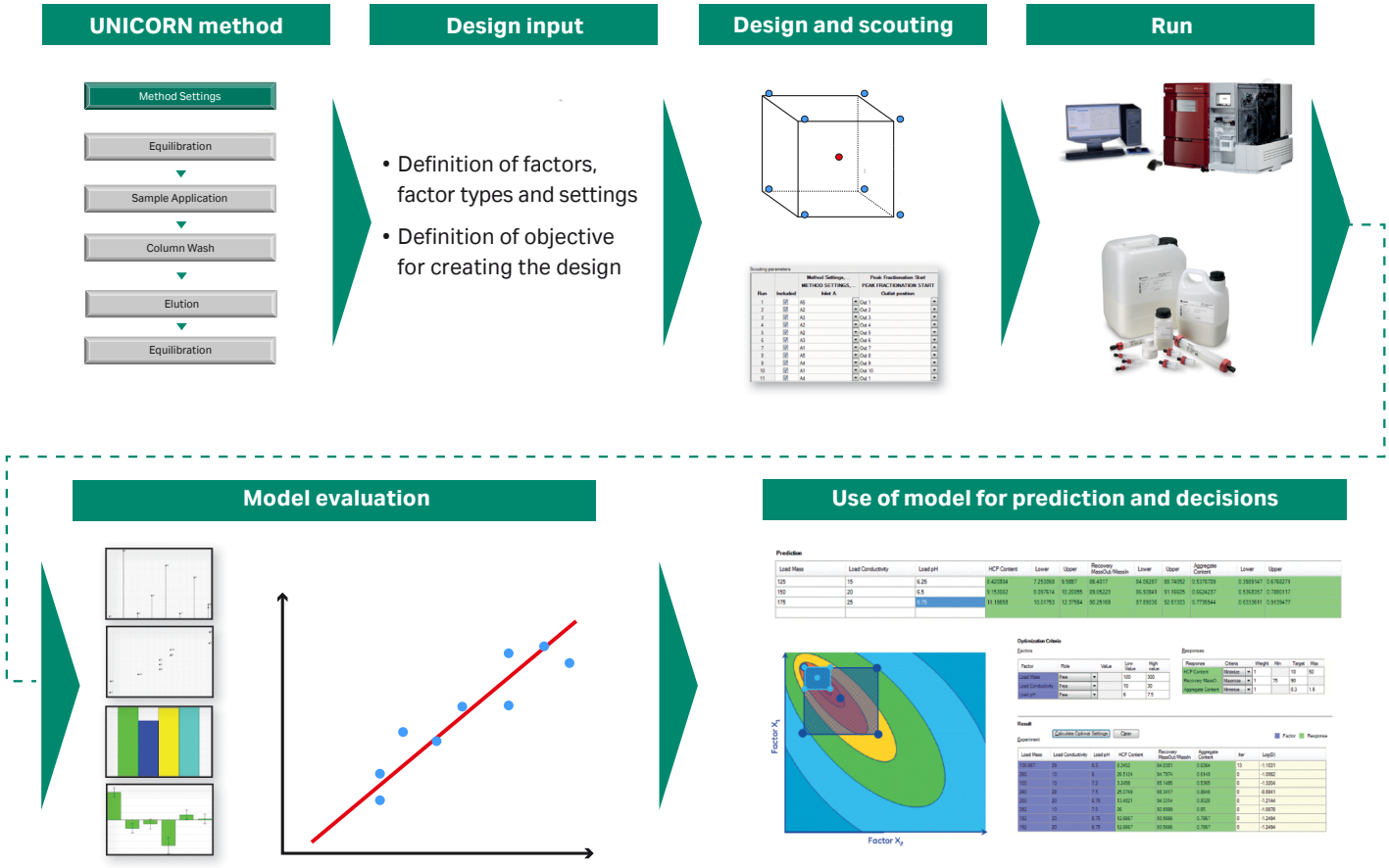

Fig 5. In ***DoE***, multiple factors are varied simultaneously and the resulting data is used to generate a statistical model. The model is validated and used to produce maps that support decision making.

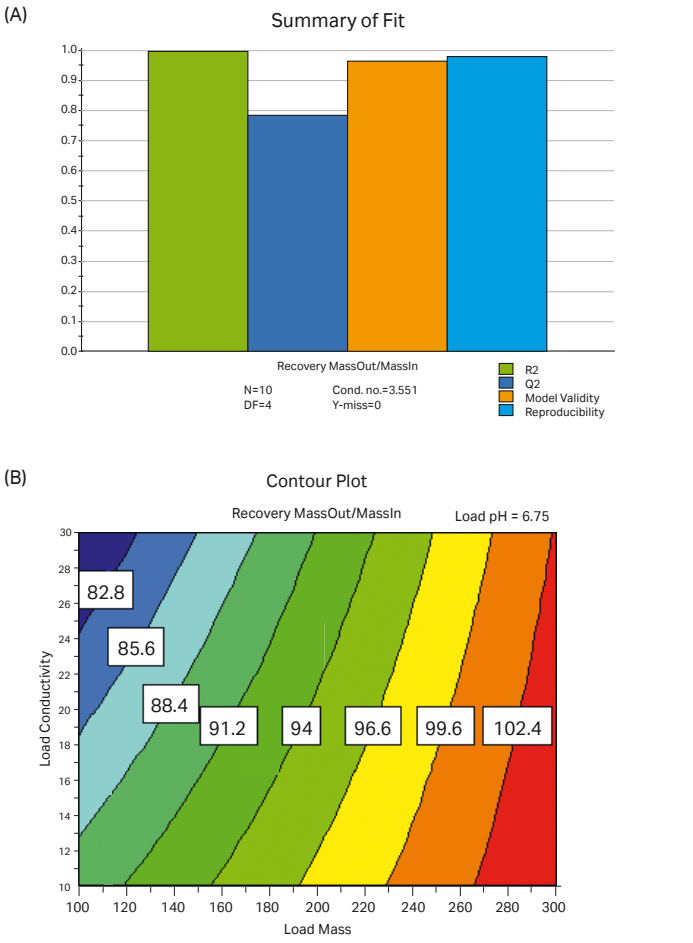

Fig 6. In ***DoE***, (A) a summary of fit plot demonstrates that the model shows a good fit to the data, and (B) a response contour plot shows how process parameters affect the response.

Column Logbook

To increase operational safety, UNICORN 6.4 software features the optional ***Column Logbook***, which provides traceability by keeping track of important column and run data. The ***Column Logbook*** supplies the user with the 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.

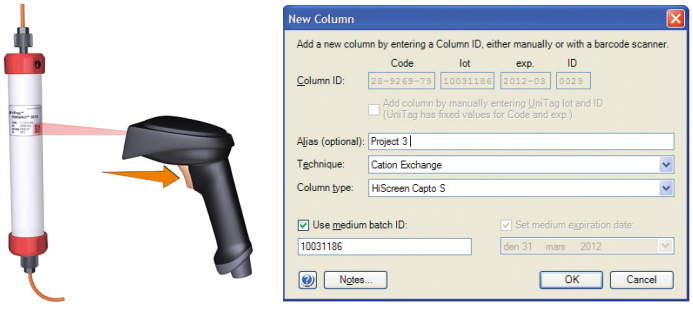

Fig 7. Some prepacked columns are prelabeled with barcodes, allowing each column to have a unique ID. By tracking individual columns, information is recorded for each run regarding the column type, production lot, type of media, run data, and more.

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*** and ÄKTA avant facilitates 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.

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.

UNICORN extension

A UNICORN extension is available to enable data transfer via OPC HDA into UNICORN, in order to take advantage of the advanced evaluation capabilities within UNICORN (e.g., for HETP calculation). This extension is optional and must be ordered in addition to the standard UNICORN licenses. For more details about this extension, see the OPC Import UNICORN extension data file, document number 29-0885-92.

Networking capabilities

UNICORN 6.4 can be deployed in several different ways, to better take advantage of the functionality available in a networked configuration:

- remote control or visualization
- data sharing
- floating licenses for optimized usage
- centralized administration

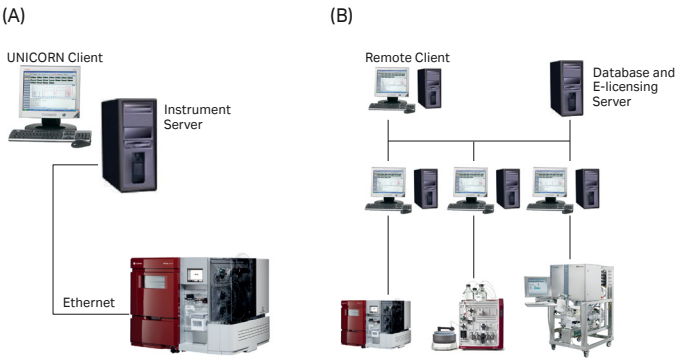

Fig 8. (A) Each ÄKTA instrument is controlled by a dedicated instrument server. (B) In a network with multiple instruments, each ÄKTA instrument is connected to its own instrument server and an additional server is used as the database and E-licensing server.

Requirements

Operating system:

- Windows 7 (Professional with SP1 installed, 32-bit or 64-bit)

Contact your local Cytiva representative for the full technical specifications.

UNICORN 6 eCourse

The online training course for UNICORN 6 helps you to exploit the capabilities of ÄKTA systems with ease and full control (Fig 9). This eCourse is accessed via a 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.

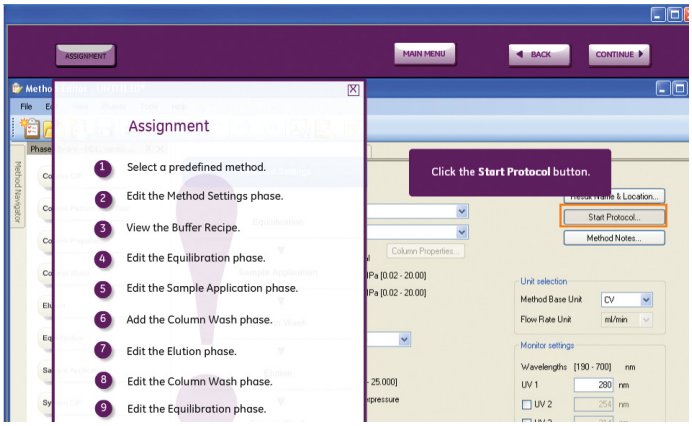

Fig 9. UNICORN 6 eCourse provides interactive, step-by-step tutorials on how to perform different tasks, such as creating a method.

Ordering information

Product	Code number
OPC Import UNICORN extension	29-0905-43
UNICORN 6.4 Manual package	29-0670-74
UNICORN 6.4.1 workstation License pack for ÄKTA avant	29-1102-78
UNICORN 6.4.1 workstation License pack for ÄKTA pure, pilot, process	29-1102-75
UNICORN 6.4 Remote License without DVD	29-0670-44
UNICORN 6.4 Dry License without DVD	29-0670-45
UNICORN 6.4 DoE concurrent license	29-0670-46
UNICORN 6.4 Column logbook, network license	29-0670-47
UNICORN 6.4.1 DVD package	29-1102-68

Related Products	Code number
ÄKTA avant 25	28-9308-42
ÄKTA avant 150	28-9763-37
Computer with Windows XP or Windows 7*	28-9573-31
UNICORN 6 eCourse	28-9500-00
ÄKTApilot™	29-0086-12
ReadyToProcess WAVE 25 Rocker	28-9880-00
ÄKTA pure	N/A†
ÄKTAprocess™	N/A‡
ÄKTApurifier	N/A§
ÄKTAexplorer	N/A§

* For details about the computer, the operating system, and a complete list of the screens, keyboards, printers, and cables available, please contact your local Cytiva representative.
† Various models and configurations are available. Please contact your local Cytiva representative.
‡ Please contact your local Cytiva representative.
§ Discontinued products.

Related Literature	Code number
Validation Support File UNICORN software, Data file	28-9626-50
UNICORN 6 eCourse, Flyer	28-9578-43
ÄKTA avant, Data file	28-9573-45
ÄKTApilot, Data file	18-1167-90
ÄKTApurifier, Data file	18-1119-48
ÄKTAexplorer, Data file	18-1124-09
ÄKTA avant, Brochure	28-9594-86
ÄKTA pure, Data file	29-0211-96
ReadyToProcess WAVE 25, Data file	29-0566-95
OPC Import UNICORN Extension, Data file	29-0885-92
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

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