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

Fully scalable, the UNICORN platform is suitable for use within small-scale research all the way to full-scale manufacturing. UNICORN can be used for a wide range of applications, including protein purification as well as cell culture and preparation.

Trusted for more than 20 years by researchers in academia and industry, UNICORN continues to evolve, based on requirements and inputs from our users. UNICORN 7 retains 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 easy 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 data is secure through robust database handling.

Description

UNICORN is based on an integrated controller and an intuitive computer-based interface. For easy usability and minimized 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. Conventional line programming can be performed by advanced users.

UNICORN contains the tools needed to perform almost any type of experiment and process at different scales, from setting up and running a method to evaluating the data.

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 inbuilt SQL Server® database

Integrated tools such as **Design of Experiments (DoE)**, **Column Handling***, and **BufferPro†** extend across the different modules, enabling increased productivity.

* Use of the DoE and Column Handling tools 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.

When using AKTA avant or AKTA pure 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).

**System Control**

The System Control module is used to 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 viewed, and can customize the layout to suit your needs (Fig 3).

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.

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.

**Phase Library**

**Method Outline**

**Phase Properties**

**Text Instructions**

Fig 2. The different parts of the Method Editor.

UNICORN includes a library of predefined GE Healthcare Life Sciences’ 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** features include:
- Full control during manual or programmed runs. Parameters can be changed at any time and are included in the run log.
- Real-time flow scheme showing 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 for unattended operation

**Evaluation**

With UNICORN 7, 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 include:
- 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
The user experience is greatly improved compared to previous versions of UNICORN. Some of these improvements include:

- 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 perform 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 include:

- 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 allows database management and user setup. Starting from UNICORN 6.0, data is stored in a SQL-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 best operation.

Administration features include:

- 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.

Integrated tools in UNICORN 7
DoE for chromatography systems
When used in connection with ÄKTA avant or ÄKTA pure, UNICORN 7 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.

In the traditional approach, optimal conditions can 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, might be missed. 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 7A). Furthermore, DoE allows variability and noise to be analyzed as well, providing 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. It provides guidance, without requiring statistical expertise. The runs are performed automatically on an ÄKTA system.

* Use of the Evaluation Classic module requires an additional e-license.
The outcome can be directly used in the form of
- 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

By tracking individual columns, information is recorded for each run regarding column type, production lot, column ID, type of medium, 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 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 fresh on-line. BufferPro includes an improved algorithm and more buffer systems than its predecessor BufferPrep. BufferPro provides data showing the actual mixing ratios used for 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.
Regulatory support
UNICORN is technically compatible with the relevant sections of FDA 21 CFR Part 11 and is developed according to 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 active processes can be locked for unattended operation without risk of unauthorized interference.

All records are maintained and stored in a single, un-alterable database, including results and extended run documentation. Additional validation support includes comprehensive documentation on control system validation, installation qualification, and operational qualification services.

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 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, in order to take advantage of the evaluation capabilities within UNICORN. For more details about this extension, see the OPC Import UNICORN extension data file, 29088592.

Networking capabilities
UNICORN can be deployed in several different ways, to better take advantage of the functionality available in a networked configuration (Fig 9).

Advantages of network setup include:
- Remote control
- Data sharing
- Floating licenses for optimized usage
- Centralized administration

Requirements
Operating system: Windows 10 (64-bit) or Windows 7* (Professional with SP1 installed, 32-bit or 64-bit).

Database: UNICORN 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 GE representative for full technical specifications.

* UNICORN 7 is tested using an English operating system. Using other language versions might cause errors.
Support and service

UNICORN comes with a variety of service support documentation, including service agreements. Please contact your local GE Healthcare sales or service representative for more details.

Related products

- AKTA avant 25
- AKTA avant 150
- Computer with Windows OS*
- AKTApilot™
- ReadyToProcess WAVE 25 Rocker
- AKTA pure 25 L
- AKTA pure 25 M
- AKTA pure 25 M1
- AKTA pure 25 M2
- AKTA pure 150 L
- AKTA pure 150 M
- AKTA pure 150 M3
- AKTApurify

* 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.

Discontinued products supported by UNICORN 7

- AKTexplorer
- AKTApurifier

Related literature

- Validation Support File UNICORN software, data file
- AKTA avant, data file
- AKTApilot, data file
- AKTA pure, data file
- ReadyToProcess WAVE 25, data file
- OPC Import UNICORN Extension, data file
- Purification and immobilization of a transaminase for the preparation of an enzyme bioreactor, application note

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