Millipore®

Preparation, Separation,
Filtration & Monitoring Products

Bio4C ACE™ Software

Remote control and automation software optimized for bioprocess

There is a growing need in biomanufacturing for control software that automates manual tasks, enables remote monitoring of critical process parameters, supplies advanced process control, and facilitates regulatory compliance. Bio4C ACE™ application control software meets these needs with robust monitoring and control of bioprocess unit operation. Designed to be intuitive and secure, it allows users to run their processes in either manual or automated modes.

Figure 1. Interactive P&ID allows monitoring and control of process.

Recipe-driven automation eliminates manual operations, increases reproducibility, and minimizes the risk of errors. An interactive piping and instrumentation diagram (P&ID) allows users to visually monitor their process and control each component (e.g., pumps, sensors) in the unit operation's Human Machine Interface (HMI) or from anywhere through a browser-based application.

Key Benefits:

- **Complete control:** interactive P&ID allows you to switch modes, change setpoints, and control actuators, enabling you to proactively identify potential issues and automatically take corrective actions.
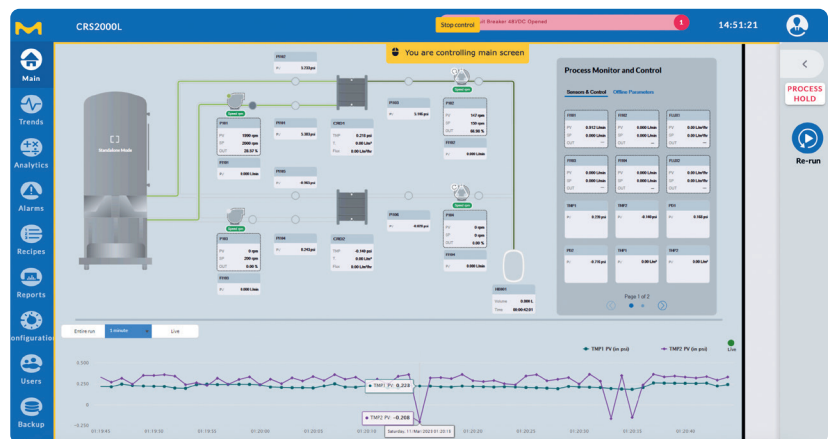
- **Remote control:** in addition to the system's HMI, the software has a browser-based interface, allowing you to control your unit operations from anywhere.

- **Visual insights:** understand your process status at a glance with real-time, critical process parameters trending.

- **Simplified Monitoring:** alarms and instrument status are easily accessible.

- **Data Integrity:** simple data backup and restore, and audit trails ensure data integrity.

- **Process Automation:** recipes automate execution of instructions on the system and thereby reduce manual tasks and human errors.

The Life Science business of Merck operates as MilliporeSigma in the U.S. and Canada.

Merck

Data Management and Regulatory Compliance

Bio4C ACE™ software is designed to facilitate 21 CFR Part 11 and EudraLex Volume 4 Annex 11 compliance for electronic records and signatures, including time-stamped audit trails for verification. It is developed according to GAMP® 5 guidelines for automation software and securely acquires, stores, and manages the system's data.

P&ID

The main screen displays the system-specific P&ID. From here, users can visualize each component (e.g., sensors, pumps, devices) in the system's layout. Important information such as component status, active alarms, and process values is also displayed. Through the P&ID, users can assign manual or automatic control for each component, adjust setpoints and ranges, change settings, and adjust process alarms. Additionally, control loops are provided or can be configured to take action in response to different component or process conditions.

Trends

The trends dashboard displays live and historical trends for the system under control. Users can view trends for selected parameters such as pressure, temperature, flow rate, pump speed, valve position, and calculated parameters specific to the process performance. For control loops, trends can be used to display not only the process values, but also the setpoint and output percent.
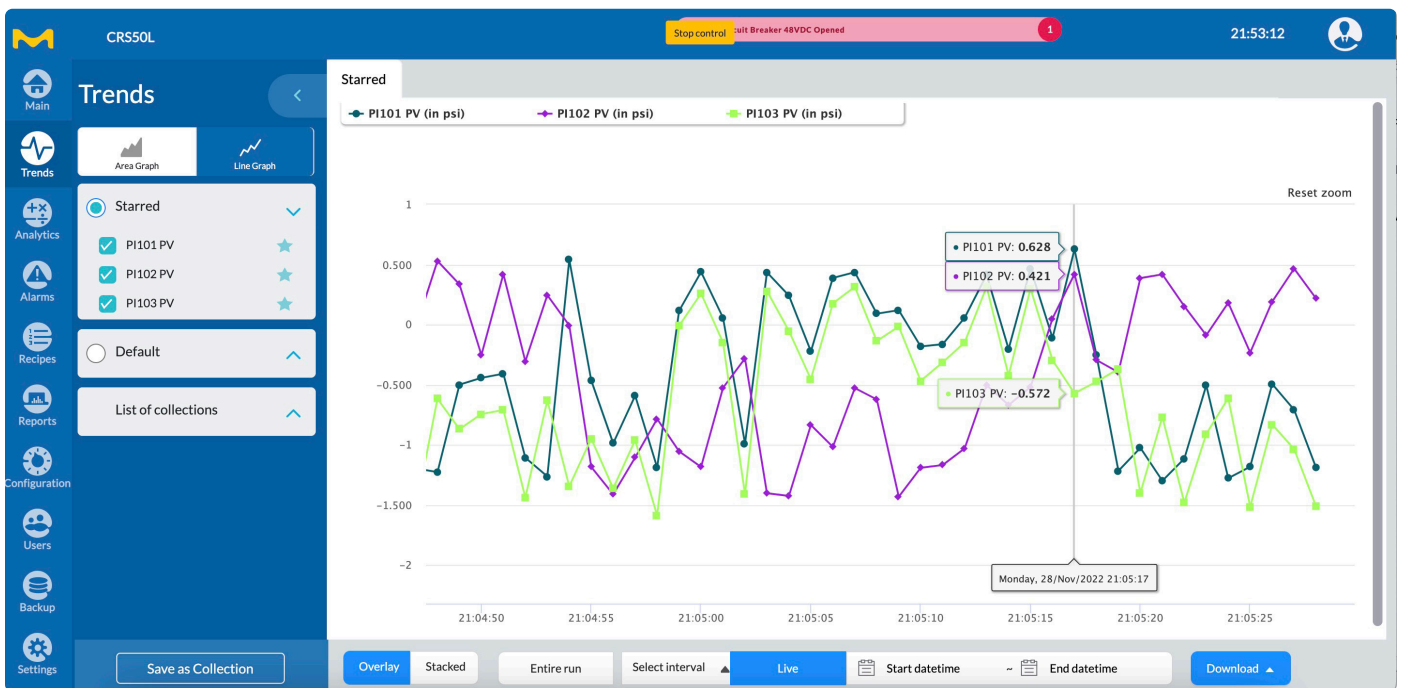

Figure 2. Trends in the form of a line graph or an area graph can be overlaid or stacked.

Analytics

From the Bio4C ACE™ Analytics screen, users can:

- Build relationships between different critical process parameters.
- Build relationships between different process or derived parameters and offline parameters.
- Apply visualizations of these comparisons to better explore them.

Alarms

Robust alarm management allows users to keep track of all alarms in the ongoing run. To grab the attention, active critical and warning alarms are displayed in the alarm banner of every screen until they are acknowledged and no longer active.

Additionally, alarms can be seen from the Alarm dashboard, and can be searched, sorted, and filtered. They are color-coded with critical alarms in red and warnings in orange. The screen displays information about alarm acknowledgement status including date, time, and operator who acknowledged the alarm.

Recipes

Bio4C ACE™ software allows for both manual and automated operation of all system actions required for precise process management. During automated operation, the software uses recipes to provide full equipment control. Recipes can be written to control the entire process or only specific parts of the process depending on the application needs, and can prompt the user to take necessary action. By configuring the process to run on its own, recipes help reduce the risks of manual operation and improve run-to-run reproducibility. Users can choose from a list of available criteria and process actions to guide them in their recipe creation.
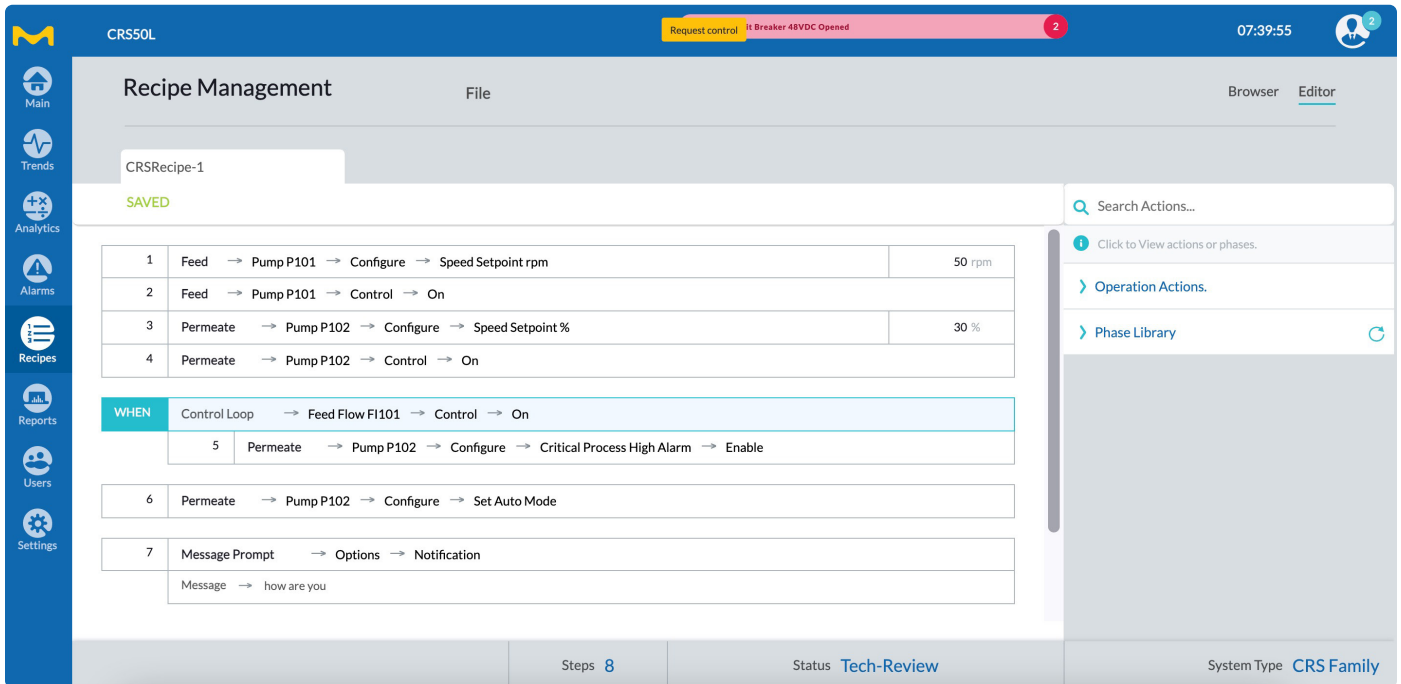

Figure 3. Guided recipe creation prompts for each operation action and parameter value.

Reports

Bio4C ACE™ software provides options to create a report template and approve a report with a e-signature. Users can view, search, and filter all generated reports.

Four types of reports are supported:

- **Run History:** Lists every run for a specified date or date range. Select a run to generate a report.

- **Consolidated:** Creates a report for single or multiple runs.

- **Custom:** Creates a report that includes user selected sections.

- **Audit Trail:** Tracks all user actions that took place during a run.
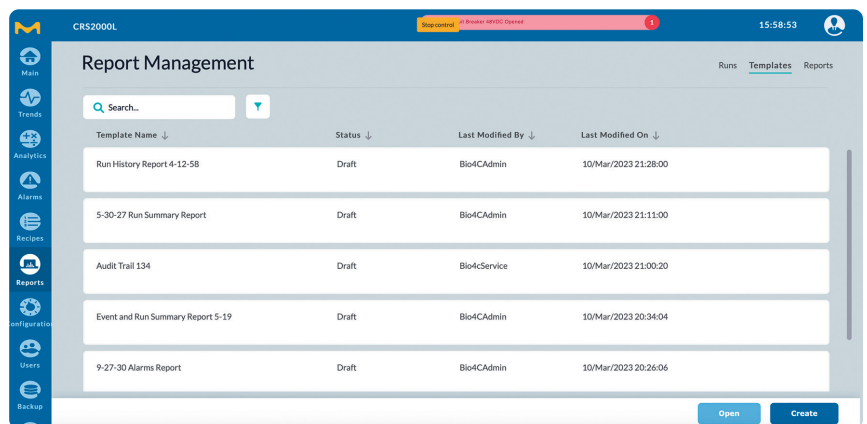

Figure 4. Four types of reports are supported.

User Management

User Management enables the addition of new users, editing of existing users, the creation of custom roles, permissions assignment, and enabling or disabling a user.
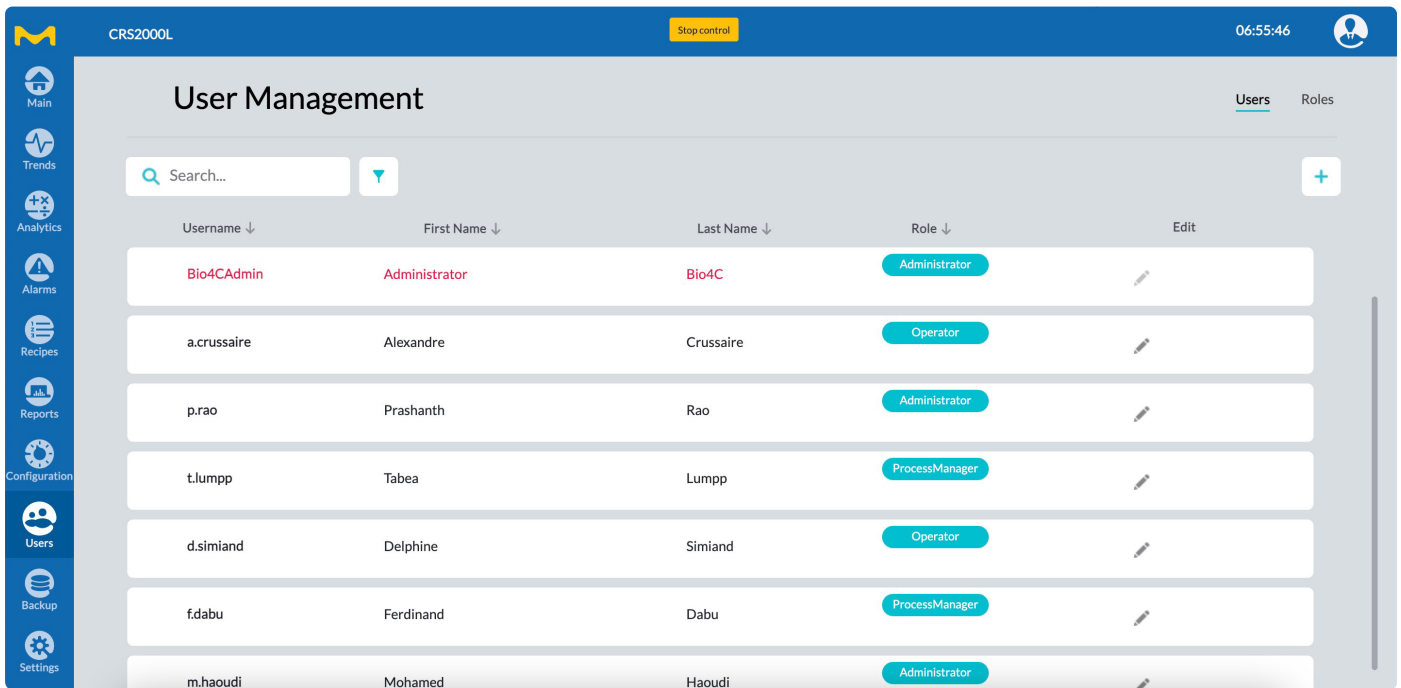

Figure 5. Add new users, edit existing users and create custom roles.

Backup

Data backup creates and stores copies of configurations (e.g., system settings) and batch data (process data, alarms and events, reports, user actions). Backups may be scheduled on a daily, weekly, or monthly basis or run immediately. Data loss can be minimized or prevented by implementing a regular backup schedule.

Bio4C ACE™ Connectivity with Other Systems

Bio4C ACE™ software supports the industry standard protocol EtherNet/IP™ which allows it to connect with other software systems easily.

DCS/SCADA Systems

Bio4C ACE™ software can connect with DCS and SCADA systems, like Emerson DeltaV™ or Siemens Simatic®, using the EtherNet/IP™ protocol. For any other protocol, industry standard gateways can be used to support a connection.

Solution Architecture

Bio4C ACE™ software is built on a scalable architecture which allows for its integration into your organization's network and IT infrastructure.

- Control software is installed on the state-of-the-art industrial computer included with the system.

- WAGO PLC bridges the hardware components with the control software.
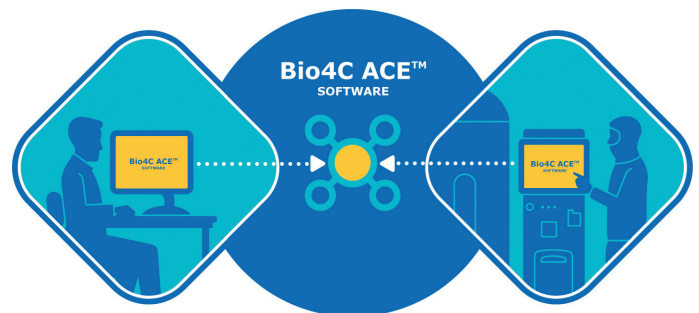
- Backup & Restore
- P&ID
- Recipe Management
- Alarm Management
- Trends
- Analytics
- User Management
- Reporting

Figure 6. Bio4C ACE™ Software Architecture.

Bio4C ACE™ Software Specifications

Bio4C ACE™ Software System Specification	
Supported Languages	English
Security	Compliant with ISA-95 and ISA/IEC 62443-3-3 tailored conformance
Operating System	Windows® Server 2019
SCADA platform	AVEVA System Platform
Data Storage	Stored in read-only database within the PLC
Hardware	
PLC	WAGO 750-8212 PFC200
PC	Advantech MIC 7700 Q
Regulatory	
Data	Facilitates FDA 21 CFR Part 11 and EudraLex Volume 4 Annex 11 requirements for electronic records and signatures
Manufacturing & Development	Developed in-line with GAMP® 5 recommendations

Related Product

Cellicon® Cell Retention Solution

The Cellicon® Cell Retention Solution includes the Cellicon® Filter Assembly and the Mobius® Cell Retention System with Bio4C ACE™ software. The Cellicon® Cell Retention Solution provides simple, robust, and scalable cell retention capabilities that enable perfusion by constantly removing spent media from the cell culture while retaining high numbers of viable cells within the bioreactor vessel.

The filter minimizes cell shear and residence times while maximizing throughput, which when combined with the robust process control of the software achieves consistent, high cell densities and optimum product yield. The unique design of this family of filters and systems, ranging from 50 L to 2000 L, offers an easy-to-use solution and ensures predictable and linear scale-up and scale-down from bench to production.

To learn more, check the datasheet (MK_DS11660EN) available at SigmaAldrich.com/cell-retention.

Figure 7. Mobius® Cell Retention System with Cellicon® Filter Assembly and Bio4C ACE™ software.

Services and Support

To help you navigate the highly regulated and complex biopharmaceutical industry, we offer a wide range of best-in-class, comprehensive services to meet your unique manufacturing requirements.

Bio4C ACE™ Software Data Integration and Domain Integration Services

For a smooth integration of Bio4C ACE™ software, our experts can provide you with customized data and domain integration services as per your network requirements.

Bio4C ACE™ Software Computerized System Validation (CSV)

To verify that the software functions as intended and is reliable, accurate, and secure, our experts will perform industry-standard tests to support your CSV requirements.

Bio4C ACE™ Software Training

Our bioprocess engineers can provide you with specialized training, including hands-on sessions, so that you are able to create and manage your own recipes. This service will help operators to manage the system and process efficiently and independently.

Bio4C ACE™ Software Recipe Design

Our biomanufacturing engineers can provide you with specialized training, including hands-on sessions, so that you are able to create and manage your own recipes. This service will make you more autonomous and able to manage the system and process effectively and independently.

System Service Reliance Plans

To ensure optimum equipment uptime and reduce the risk that the equipment does not meet the validated performance specifications, we have developed System Service Reliance Plans – a complete range of services for your systems and equipment, including the control software. These comprehensive service and support packages allow you to select a coverage level that best fits your needs. For more details, please refer to the System Service Reliance Plans datasheet (MK_DS7881EN) available at SigmaAldrich.com/services-plans.

For more information about our service offerings please contact your local sales representative.

Ordering Information

Bio4C ACE™ Software	Cat. No.
Bio4C ACE™ Software for Mobius® Cell Retention System	BIO4CACE4CRS
Software Service	
Bio4C ACE™ Software – Data integration service at Customer Site	Please contact your local sales representative
Bio4C ACE™ Software – Domain integration service at Customer Site	Please contact your local sales representative
Bio4C ACE™ Software – Computerized System Validation service at Customer Site	Please contact your local sales representative

For additional information, please visit **SigmaAldrich.com/ACE**
To place an order or receive technical assistance, please visit **SigmaAldrich.com/contactAF**