



BioPAT® MFCS/win

Supervisory Control and Data Acquisition (SCADA)
Software for Cross-Flow Applications

Product Information

- Proven performance, high functionality and professional service & support
- Easy graphical recipe programming to realize customized purification strategies
- One software from lab-scale to manufacturing and single-use to reusable applications
- Design of Experiments (DoE) for rapid optimization of cross-flow performance
- 21 CFR Part 11 compliance with audit trails, user management and reports based on templates



Introduction

BioPAT® MFCS/win is the world standard software for supervisory bioprocess control and data acquisition. Based on over 25 years of experience and more than 3,000 installations, the latest release of BioPAT® MFCS/win provides various solutions to meet your particular requirements.

MFCS is part of the BioPAT® automation platform and provided in two versions. The new BioPAT® MFCS 4 is our most recent software development for reliable data acquisition, effective trend monitoring and supervisory control of all Sartorius BIOSTAT® Sartoflow® instruments.

In contrast the proven BioPAT® MFCS/win is a feature rich, fully 21 CFR-11 compliant software package with preconfigured modules enabling plug-and-play setup of advanced SCADA functionalities.

Software modularity enables customization

Besides the core functionality of a real SCADA system for reusable and single-use bioprocess applications, BioPAT® MFCS/win offers a number of additional modules for adaptation to individual requirements.

- Cross-flow optimization with DoE
- Recipe control according to ANSI/ISA-88.01
- 21 CFR Part 11 compliance
- Secure integration to corporate networks
- Flexible device connectivity using OPC
- Enhanced data logging & historical archiving
- Distributed alarming & transmission to multimedia devices
- ...

BioPAT® MFCS/win and additional modules were strictly developed according to the software technology.

DCU and MFCS – a valuable combination

Our key platform to automation of fermentation and filtration systems is based on the use of the flexible Digital Control Unit (DCU), which is specifically tailored for bioprocess applications. When combined with BioPAT® MFCS/win this solution provides the most cost-effective and flexible platform for small to medium scale research and pilot plant applications.

The DCU provides local user interfaces that allow operators to manipulate the process locally. BioPAT® MFCS/win is positioned on top of the DCU and used to control and document the cross-flow process by logging all kind of process data and information around the process. Data collection and control at the supervisory level allows supervisory decisions that may be required to adjust or override normal DCU controls.

Process Automation with S88 Recipes

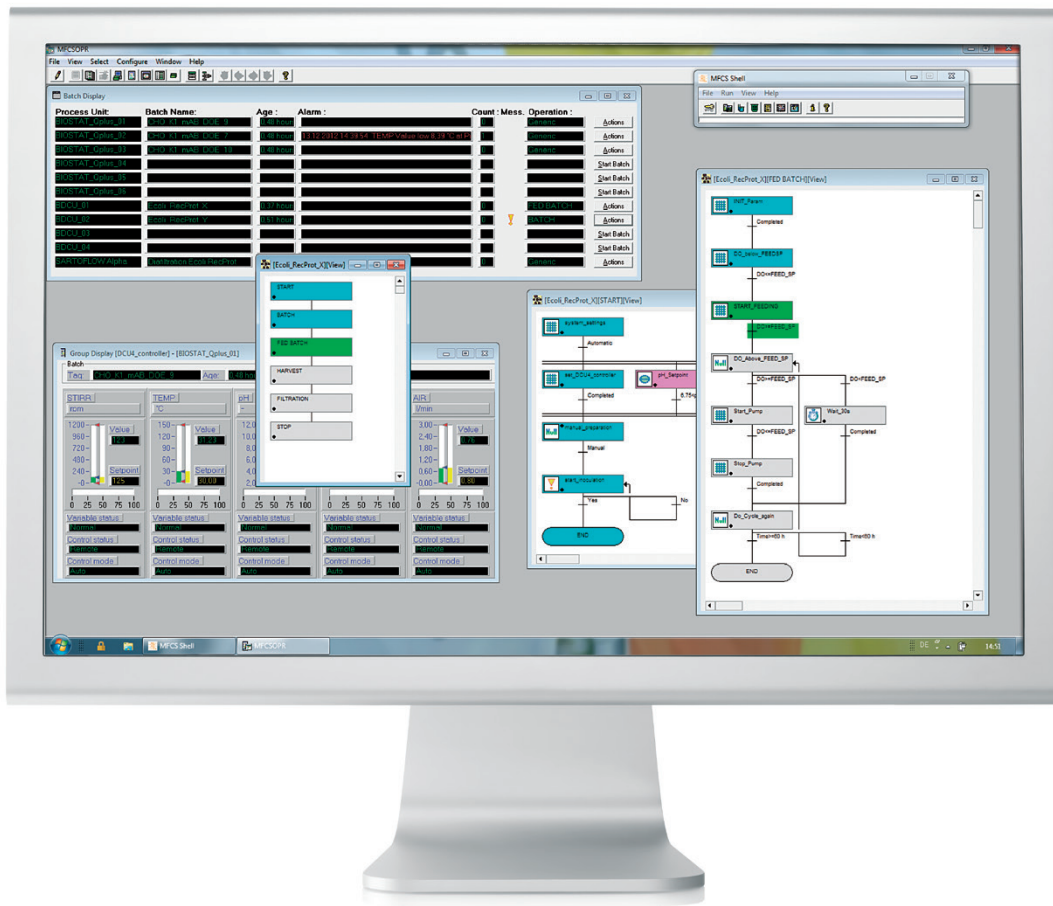
The american ANSI/ISA-88.01 standard and its international equivalent IEC-65112 are industrial standards for the control of all kinds of batch processes. The BioPAT® MFCS/win Recipe Control (S88) Module follows these standards and contains all functions and models that are of use for biopharmaceutical up- and down-stream processes.

BioPAT® MFCS/win and the Recipe Control (S88) Module support industrial users as well as researchers in universities and institutes to realize customized automation strategies for cross-flow processes, even in-line with QbD principles. With its conditional logic and the direct translation of biopharmaceutical unit operations into S88 phases the Recipe Control Module supports diverse automation strategies to reduce variability and increase run-to-run consistency.

The recipe editor permits graphics-based process automation with loops and jumps, facilitating application-oriented automation even in-line with QbD principles. Semi or fully-automatic operations and pre-defined phases with state or time-dependent transitions enable an organized and structured batch processing as well as flexible manufacturing.

In order to achieve a reproducible and fully automated cross-flow process, BioPAT® MFCS/win recipes are designed to trigger different actions automatically by events.

- Automatic stop of diafiltration, e.g. based on conductivity measurement
- Optimization of cross-flow performance, e.g. by periodic adjustment of differential pressure



Furthermore BioPAT® MFCS/win recipes can be used to customize sequences which cannot be mapped in the DCU. That means that you can automatically apply different parameter settings without manual interaction for a process, e.g. consisting of

1. Membrane conditioning
2. Ultrafiltration 1
3. Diafiltration 1
4. Ultrafiltration 2
5. Diafiltration 2
6. Ultrafiltration 3
7. Product recovery

It is, of course, possible to save different types of processes as master recipe and, if required, to change parameters of the control recipe manually during the run.

cGMP Production Environment

The FDA rule relating to electronic records and signatures is a significant legislation. Where validation is required, SCADA systems must comply with 21 CFR Part 11.

BioPAT® MFCS/win supports all requirements to achieve full compliance. That means that your process can be evaluated, reviewed, approved and archived without a single sheet of paper and without the possibility to falsify process data and signatures. However, if required, all information can be printed and signed handwritten.

- Creation and modification of electronic records
- Audits trails for all electronic records
- Unique electronic signatures for approvals and as identification for changes
- Export in FDA accepted electronic format
- Human readability during a defined retention period
- User Management for individual rights on a functional level
- cGMP compliant batch and configuration audit trail report

Efficient optimization with DoE

A key benefit of applying QbD is the ability to identify critical quality attributes and process parameters. The correlation can be made in a cost effective and statistically significant manner by using Design of Experiments (DoE).

DoE is one of the most important techniques for the systematic planning and execution as well as the statistical evaluation and modeling of experiments. Besides improved process understanding and efficiency, higher product recovery and quality represent the most frequent outcome of a DoE investigation.

BioPAT® MFCS/win provides an easy start into efficient process optimization with Design of Experiments (DoE). Linked to the professional DoE-software BioPAT® MODDE powered by Umetrics™, the BioPAT® MFCS/win DoE module enables you to scout for best process conditions while simultaneously reducing expensive and time-consuming experiments to a minimum. Whether you want to identify Critical Process Parameters (CPPs) or estimate and validate a Design Space, the BioPAT® MFCS/win DoE module bridges the gap between a fast and simultaneously reliable experimental workflow.

BioPAT® MFCS/win recipes and the DoE module support fully automated optimization procedures, not only for concentration or diafiltration but also for clearing filtration and fractionation purposes.

One exemplary application for cross-flow processes is the optimization of

- trans-membrane pressure (TMP),
- pressure difference between feed and retentate (Δp), and
- cross-flow rate

with regards to higher protein yield in the permeate and a short overall process time.

Other examples include factors as membrane area, pore size, membrane material, concentration factor, buffer exchange volume, or temperature.

Professional Service & Support

Genuine value creation becomes feasible when products and services efficiently mesh together. Our team of experienced service engineers has been involved in a number of successful projects world-wide. Expertise gained through long term cooperation with pharmaceutical and biotech companies has been used to develop and refine a comprehensive range of services.

- Validation of MFCS/win Systems
- Installation and Configuration Services
- S88 recipe programming
- Configuration of mimic displays

Sartorius provides different levels of trainings for the BioPAT® MFCS/win system. These training are designed to ensure that each course participant has a proper understanding of the theoretical subject matter and acquires the necessary hands-on, practical skills. The ultimate aim and purpose is to enable technicians and specialists working in R&D or production to perform their work safely and efficiently.

- Basic Course BioPAT® MFCS/win Crossflow
- Basic Course BioPAT® MFCS/win and Design of Experiments (DoE)
- Basic Course DCU User Training
- Individual (in-house) trainings on request

Applications

Features	MFCS 4	MFCS/win 3.1
Windows® 10 (32 bit 64 bit)	●	●
Windows® 8 SP1/8.1 (32 bit 64 bit)	●	●
Windows® 7 SP1 (32 bit 64 bit)	●	●
Windows® Server 2016 (64 bit)	●*	●
Windows® Server 2012 R2 (64 bit)	●*	●
Windows® Server 2008 R2 SP1 (64 bit)	●*	●
Number of supported process units	up to 24	up to 16
Minimum data export interval	0.5 s	1 s
Database management	Microsoft® SQL	Microsoft® Access
User interface languages	EN, DE, ZH, FR, ES, IT	EN
Data acquisition and storage	●	●
Supervisory control	●	●
Process value alarms	●*	●
Process value simulation	●	●
Configuration management	●	●
Sample data management	●	●
Calculations	●	●
Data export to Microsoft® Excel	●	●

Features	MFCS 4	MFCS/win 3.1
Advanced reporting	●*	●
Advanced charting	●	●
Integrated Design of Experiments (DoE)**	●*	●
Integrated Multivariate Data Analysis (MVDA)**	●*	●
Recipe control according to ISA-88.01	●*	●
Replication manager	●*	●
21 CFR Part 11 compliance	●*	●
Multi User Client	●*	●
OPC DA server	●*	●
OPC AE server	●*	●
OPC HDA server	●*	●
OPC DA client	●*	●
Validation support	●*	●
Service & support package	● (1 st year)	●
Training	●*	●

● included ● optionally available * available soon ** powered by Umetrics™, now part of Sartorius Stedim Biotech



Gold Application Development

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