



# BioPAT® MFCS

The Standard in Bioprocess  
Data Management  
and Automation

Simplifying Progress

SARTORIUS

# Developed for the Process – Designed for You!

BioPAT® MFCS enables you to incorporate a new standard in bioprocess data management and automation. Its reliable data acquisition, efficient trend monitoring, and advanced recipe control make it an ideal tool for all upstream and downstream processes, no matter if you prefer single-use or reusable systems. The new BioPAT® MFCS is your solution for robust and reproducible processes in R & D and GMP environments – all backed by our expertise since 1986.



reddot award 2019  
winner

**Focus on Essential:** Get the right focus for a fast and clear operation with our award-winning UI.

**Quick Overview:** Support of up to 32 process units and get all relevant information at a glance.

**Connectivity:** Integrate PAT sensors and analyzers as well as third-party instruments via OPC for enhanced process knowledge and control.

**Process Safety:** Let the alarm management system take care of process limits.

**Advanced Charting:** Display real-time monitoring of 12 process values and benefit from batch analysis.

**Calculation Capabilities:** Calculate important bioprocess parameters and non-direct measurable variables with the calculation module.

**Full Process Control:** ANSI-88-compliant batch control for robust process automation

**Data Integrity and Security:** High-quality data collection for on- and offline process data, in a fast, powerful, and searchable SQL-database.

**Compliance:** Technical features ensure compliance with common regulations like 21 CFR Part 11 or EU Annex 11.

# Compliant and Reliable Operation

BioPAT® MFCS gives you audit-safety. Its functionality to support GMP, EU Annex 11 and 21 CFR Part 11 regulations brings the highest degree of data integrity and data security from research to production scale.



## Traceability

The comprehensive automatically generated audit trail records all system changes and batch-related activities.



## Data Integrity and Security

Data integrity & security of your data over the whole retention period is ensured by a Microsoft SQL database.



## Electronic Record Management

Benefit from using compliant digital batch records and electronic signatures to streamline documentation and review processes.



## Access Control

The advanced role-based user management system, capable of integration with LDAP, allows controlled access based on your organizational rules.

## Confident Service

Sartorius support with planning and implementation during all phases of the installation and validation. From assistance with writing the functional design specification over the installation and configuration up to the execution of FAT/SAT.

As your BioPAT® MFCS SCADA system is a critical component for your bioprocess, it is important to have confidence that your software is up-to-date and properly supported. Our Service and Support Agreements providing regular product updates and dedicated expert support.



# Turn Advanced Process Strategies into Reality

## Recipe Automation

- Intuitive, graphically guided configuration
- Drag-and-drop operations and phases
- Sequential, parallel, and repeated execution of phases
- State and time-dependent transitions
- Pre-defined phase types for set-points, feeding profiles, or timers

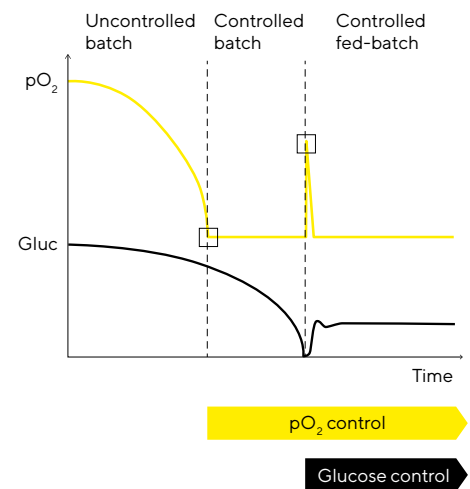
## Benefits

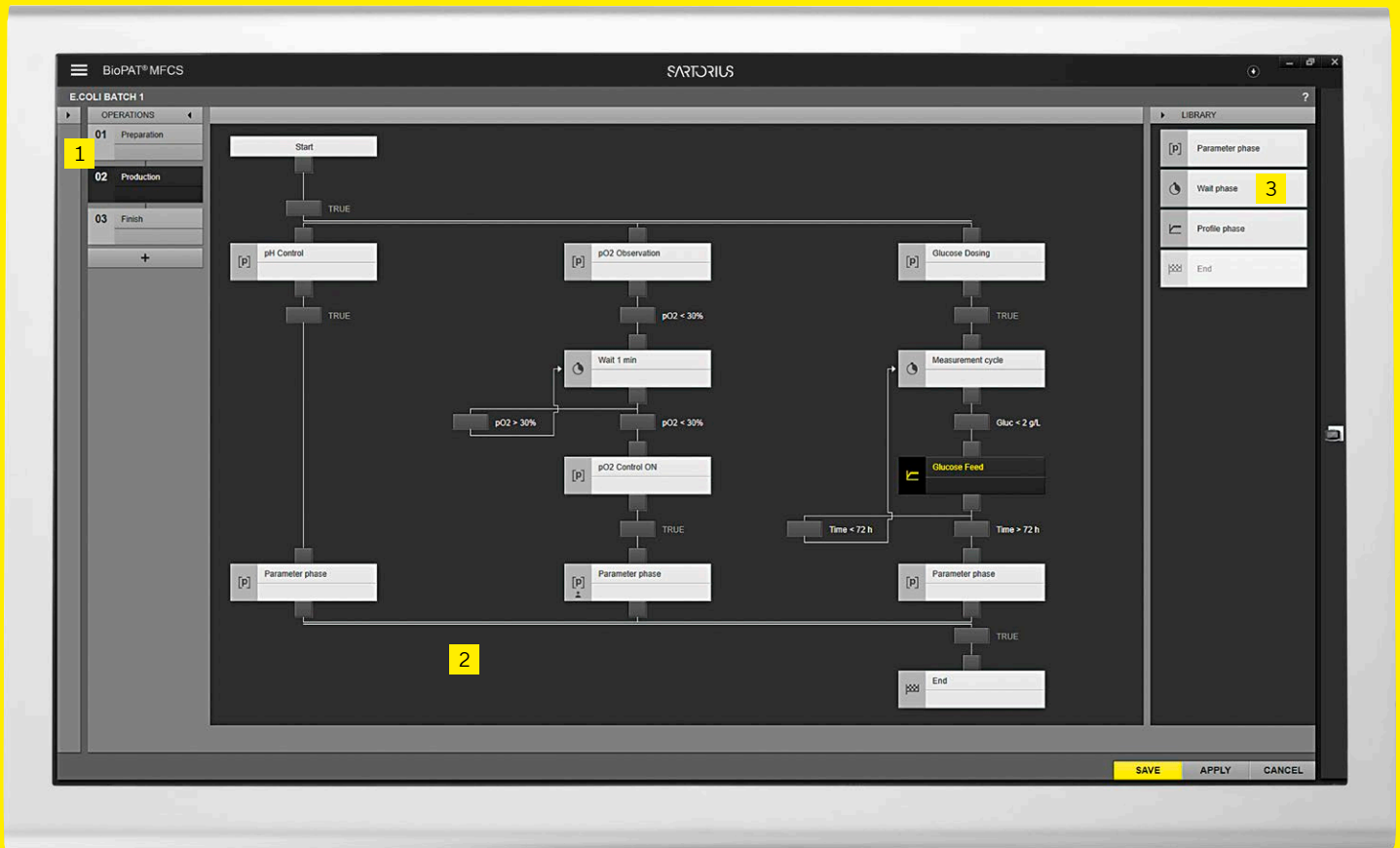
- Improved batch-to-batch consistency
- Decreased risk of errors
- Minimized number of rejected lots
- Automated processing to free up operator time
- ANSI-88-compliant, standardized automation

## Application Example

- Event-based activation of control loops
- Automatic batch end detection, e.g., based on  $pO_2$  | off gas measurements
- Implement advanced feeding strategies for fed-batch processes
- Control complex perfusion processes with predefined perfusion recipes

### Automatically Switch Between Process Phases





BioPAT® MFCS Recipe Control Module

### 1: Easy Configuration

Get started immediately, and implement your process strategies.

### 2: Intuitive Use

Clear workflows for maximum productivity.

### 3: Quick Access

Pre-defined functions are right where you need them.

## Extend the Possibilities of BioPAT® MFCS



**Recipe Control Module**  
ANSI-88-compliant batch control for robust process automation



**OPC Server Module**  
Connect BioPAT® MFCS process data and alarms to your historian or MES systems (e.g. SIM API)



**User Management**  
Centralized user management with domain connectivity and flexible permission rights configurations



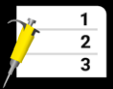
**OPC UA Client Module**  
Connect to Biobrain® and additional equipment, e.g., BioPAT® Trace, BioPAT® Xgas



**Calculation Module**  
Create soft sensors to monitor non-directly-measurable quantities, e.g., OUR, RQ



**Multi User Option**  
Monitor and control your process from up to 30 BioPAT® MFCS clients simultaneously (RDP supported)



**Sample Data Module**  
Integrate and manage off-line sample data



**21 CFR Part 11 Module**  
Capabilities to ensure compliance with 21 CFR Part 11 or EU Annex 11 regulations

# Engineering Recipe Services For BioPAT® MFCS

Creating recipes can be a time-consuming and tedious task, especially when complex automation strategies must be implemented. Leverage the experience of the Sartorius MFCS engineers, which can create customized BioPAT® MFCS recipes based on your requirements:

The BioPAT® MFCS Customized Recipe Service includes the creation of a recipe template which is easy to import, comprehensive documentation and optional available qualification services.

The BioPAT® MFCS Perfusion Recipe Service provides a ready-to-use BioPAT® MFCS recipe template for perfusion and concentrated fed-batch cell cultivation guided by on-screen instructions for Biostat STR® 50 L, and Biostat® B-DCU 2 L, 5 L or 10 L.

## Interface Consulting (IC)

Based on standard system capabilities, the Interface Consulting Service decreases the effort and the risk to integrate BioPAT® MFCS into manufacturing IT answering the customer need for support for system integration.

## Advanced Order Execution (AOE)

Advanced Order Execution provide a dedicated project coordinator (remotely) for order of BioPAT® MFCS including scheduling and monitoring of order progress, order related questions and early access to all available documentation.

Learn more about BioPAT® MFCS by downloading the demo version. Stay up to date about the latest product and security updates by visiting the BioPAT® MFCS website for more information.

 Visit the BioPAT® MFCS website:  
[www.sartorius.com/biopatmfcs](http://www.sartorius.com/biopatmfcs)



# Ordering Information

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## Software

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BioPAT® MFCS          Core Software

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## Additional Software Modules and Options for BioPAT® MFCS

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21 CFR Part 11 Module

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Recipe Control Module

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OPC Client Module

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OPC Server Module

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Sample Data Module

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Calculation Module

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Charting Module

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Multi-User Option (small and large size)

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User Management Module

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Microsoft® SQL Server 2019 Standard run time (Server, 64-bit) | University

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Remote Alarming Package

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## Services for BioPAT® MFCS

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Perfusion Recipe

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Customized Recipes (simple, medium, and complex size)

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System Qualification

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Basic User Training (remote and on-site)

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Administrator Training (remote and on-site)

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Recipe Training (remote and on-site)

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Crossflow Training (remote and on-site)

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BioPAT® MFCS Support Package

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BioPAT® MFCS Lifecycle Agreement

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Advanced Order Execution (AOE)

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Interface Consulting (IC)

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BioPAT® MFCS is available for up to 32 Units.

Please contact your local sales representative regarding a license for more than 1 unit.

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