

BioPAT® MFCS

ANSI-88 Compliant Batch Control for Robust Process Automation



Benefits

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

Product Information

BioPAT® MFCS is the standard software for monitoring, control, and automation of bioprocesses. Relying on

more than 5,000 installations worldwide and 30 years of experience, BioPAT® MFCS is the solution for stable and robust upstream and downstream processes.

Besides the core functionality of a true SCADA system for reusable and single-use bioprocess applications, BioPAT® MFCS offers a number of additional modules for adaptation to individual requirements. The unique Recipe Control (S88) Module allows bioprocess operators to implement automation strategies for batch, fed-batch, and continuous processes in line with Quality by Design (QbD) principles.

Turn Advanced Process Strategies Into Reality

BioPAT® MFCS fulfills Recipe Standards

The American ANSI/ISA-88.01 standard and its international Equivalent, IEC-65112, are industrial standards for the control of batch processes. The BioPAT® MFCS Recipe Control (S88) Module follows these standards and provides all the functions and models useful for biopharmaceutical upstream and downstream processes.

Minimize run-to-run variability

The BioPAT® MFCS software package and Recipe Control (S88) Module support industrial users and academic researchers. Industrial users may need a well-structured system that can be validated. Researchers need a flexible, open system. The Recipe Control (S88) Module considers both aspects. In order to achieve a reproducible and fully automated batch process, BioPAT® MFCS recipes are designed to trigger different actions automatically in response to events. Examples include initialization of substrate feed control after automatic detection of batch end and automatic harvesting start after a specific cell concentration has been reached.

Adapt to evolving recipes

The S88 recipe structure adapts perfectly to constantly evolving recipes in pilot plant development. It provides a common language for process design and specification. An early recipe development enables the implementation of an operator-independent process control strategy for both development and commercial manufacturing. The advanced use of Process Analytical Technologies (PAT), whether in development to gain process understanding or manufacturing to monitor Critical Process Parameters (CPPs), enables implementation of enhanced control strategies. With its conditional logic and direct translation of biopharmaceutical unit operations into S88 phases, the Recipe Control Module supports automation strategies to reduce variability and increase batch-to-batch consistency.

Technical Features of Recipe Control Module

- Drag and drop for quick positioning of operations and phases
- Pre-defined phase types for set points, feeding profiles, and timers
- Sequential, parallel, alternative path, and repeated execution of phases
- Configurable transition conditions to realize state- and time-dependent process strategies
- Quick identification of errors in recipes via intelligent syntax checking
- Automatic checking of process unit compatibility before recipe execution
- Visually traceable progress of recipes currently running
- Direct interaction with recipe phases and transitions currently running
- Overview function to monitor the progress of multiple recipes at one time
- Complete set of advanced action control enabled through recipe phases:
- Alarm parametrization through recipe parameter phases (change alarm settings through different recipe steps)
- DCU sequence



Applications

Improving Upstream and Downstream Processes

BioPAT® MFCS provides connectivity for upstream and downstream devices. The Recipe Control (S88) Module is widely used to establish a sophisticated control strategy across both areas and even link systems for integrated bioprocessing. This can optimize yield and improve production cost-effectiveness.

Enhance event detection through the identification of process states based on online measurements.

- Automatic batch-end detection, e.g., based on pO_2 | off-gas measurements
- Initialization of feed and induction, e.g., based on substrate or biomass measurement
- Just-in-time harvest, e.g., based on (by-) product measurement
- Automatic diafiltration stop, e.g., based on conductivity measurement

Realize the implementation of advanced feeding strategies for fed-batch bioreactors.

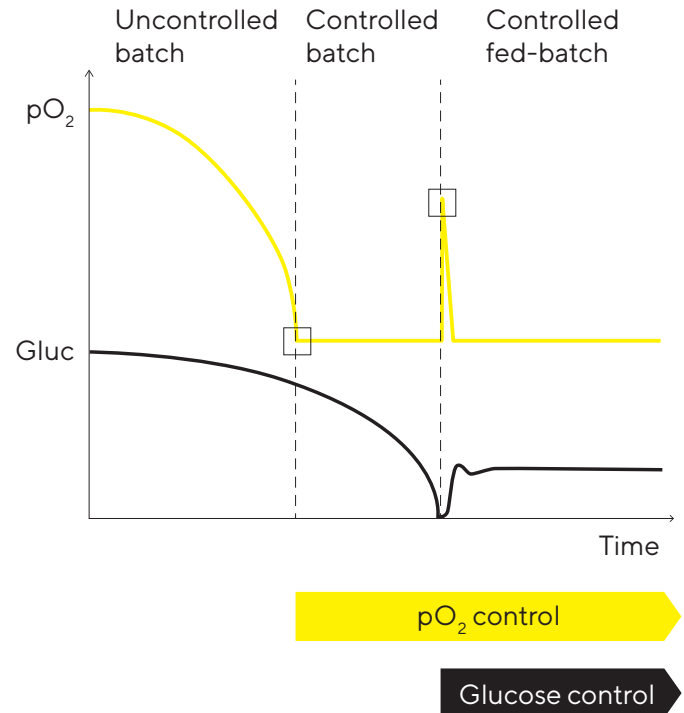
- Linear, exponential, or pulse-wise feeding of growth and production culture media
- DO-stat or adaptive control techniques
- Open- or closed-loop control of cell specific growth rate μ

Recurrent events can be implemented based on loops and jumps.

- Intermittent medium addition or harvesting
- Activation or deactivation of controllers based on user-defined intervals
- Optimization of cross-flow performance by periodic adjustment of differential pressure

Application Example:

- Event-based activation of control loops
- Automatic batch-end detection, e.g., based on pO_2 | off-gas measurements
- Advanced feeding implementation



Perfusion Recipe: Master Intensified Bioprocessing with Embedded Recipe

Benefit from a ready-to-use recipe for perfusion and concentrated fed-batch cell cultivation guided by on-screen instructions for Biostat STR® 50L, and Biostat® B-DCU 2L, 5L or 10L, including:

- S88 operations and phases for bioreactor preparation, cell growth, production, and product harvesting
- Automated algorithms for cell-density-based control of
 - media and feed flow rates
 - cell bleed flow rates
 - mixing, oxygen transfer, and CO₂ stripping
 - antifoam dosing
- Optimized, scale-dependent control parameters
- Predefined alarm settings for early warning and timely mitigation of failure modes

Mandatory requirements for configuration of Biostat STR® and Biostat® B-DCU that are needed to perform the perfusion recipe:

Biostat STR® 50 L

Process Strategy

Number of substrates: 3

Substrate | media addition A (permeate flow):

Gravimetric substrate control

Weighing system: 300 kg

Substrate | media addition B (bleed control):

Gravimetric substrate control

Weighing system: 60 kg (or prepared for Sartorius balance with at least 10 g readability)

Substrate | media addition C (anti-Foam control):

Gravimetric substrate control

Weighing system: prepared for Sartorius Cubis balance with at least 0.1 g readability

Level Control

Level control (main feed):

Gravimetric level control

- Weighing system: 300 kg

pH Control:

pH controller: acid | CO₂-base

Temperature Control:

Filter heater for the exhaust filter of the single-use Biostat STR® 50 | 200

Measurements, Connectivity and Additional Equipment

Recommendation:

BioPAT® Viamass connection –

Viable Cell Volume Measurement

Recommendation:

BioPAT® Trace connection –

Online Glucose|Lactate Measurement

If BioPAT® Viamass is used: Viamass SigSim –

SU Calibration Kit

Biostat® B-DCU 2 L – 10 L

Process Strategy

Number of substrates: 2

Substrate | media addition A (permeate flow):

Gravimetric substrate control

Weighing system:

60 kg (or prepared for Cubis with at least 36 kg weighing capacity)

Substrate | media addition B (bleed control):

Gravimetric substrate control

Weighing system:

7 kg (or prepared for Sartorius balance with at least 0.1 g readability)

Level control

Level control (main feed):

Gravimetric level control

Weighing system:

60 kg (or prepared for Cubis with at least 36 kg weighing capacity)

Anti-Foam Control

Anti-foam control | antifoam addition needs to be configured

PO₂ Control

pH Control

pH controller: acid | CO₂-base

Measurements, Connectivity and Additional Equipment

Recommendation:

BioPAT® Viamass connection –

Viable Cell Volume Measurement

If BioPAT® Viamass is used: Viamass SigSim -

MU Calibration Kit

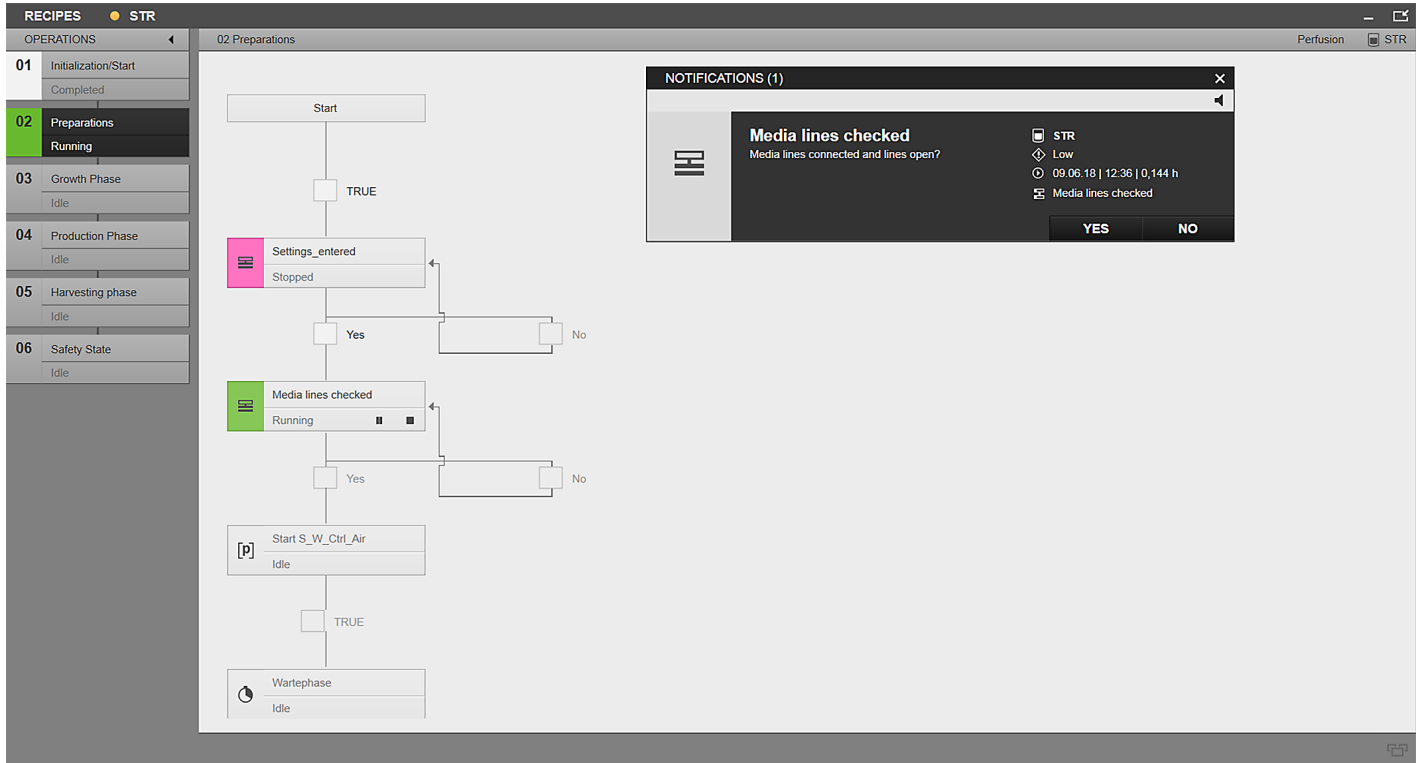
Recommendation:

BioPAT® Trace connection – Online Glucose |

Lactate Measurement

Option:

BioPAT® Xgas connection – Inline Offgas Analysis



Example: Execution of a Perfusion Recipe for Biostat® STR

Customized to Meet Your Needs

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 recipes based on your requirements.

Choose from three customized recipe sizes:

Simple: 5 operations, 25 phases, online calculations excluded

Medium: 10 operations, 80 phases, 5 online calculations

Complex: 30 operations, 400 phases, 512 online calculations

Ordering Information

BioPAT® MFCS Core Software
Recipe Control Module
Perfusion Recipe
Customized Recipes

BioPAT® MFCS is available for up to 24 units. Contact your local sales representative regarding a license for more than one unit.


Learn more about BioPAT® MFCS and download the demo version. Stay up to date about the latest product and security updates by visiting the BioPAT® MFCS website, www.sartorius.com/biopatmfcs.

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