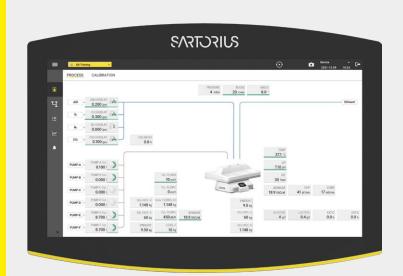


SARTURIUS

Biobrain®

Integrating Biobrain®-Powered Products Into Higher Level Systems



Product Information

Biobrain® is the automation platform powering Sartorius process units for up- and downstream processing tailored for regulated manufacturing environments.

Features and Benefits

- Flexible and scalable integration to DCS, SCADA, MES, Historian and IT infrastructure
- Powerful and reliable interfaces like OPC UA server
- Intuitive interface documentation

Introduction

Customer Challenge

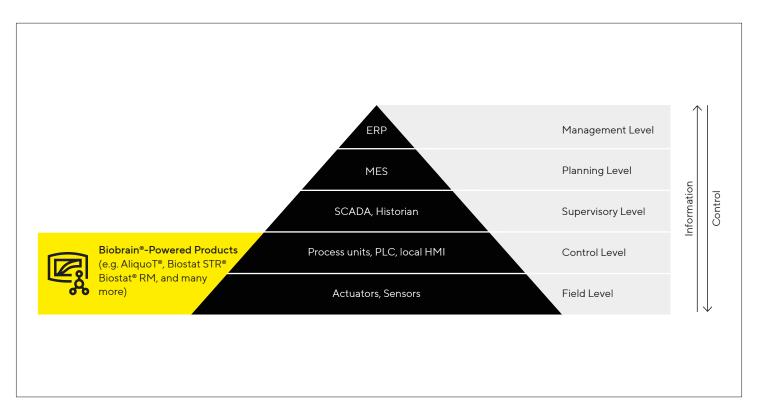
As digitalization and analytics are transforming the biopharmaceutical industry, a connected plant is becoming a necessity. Manufacturers often struggle to integrate process units into the plant's higher-level systems, such as DCS, MES, and IT infrastructure, because engineering and configuration are complex and time-consuming (Figure 1). Biobrain® integration functionality coupled with our Interface Consulting Service can help you overcome the integration challenges by reducing risk and effort while enhancing your success and accelerating time to market.

Biobrain® Automation Solution for Process Units

Biobrain® is a modular automation platform tailored to the needs of different process units in up- and downstream processing and fluid management. In the coming years, Biobrain® will become the standard solution for new and upgraded product releases in the regulated environment. The uniform user experience across our portfolio will lead to reduced training efforts, improved service quality, a richer functional scope, and seamless integration possibilities.

More detailed information about Biobrain® is available in our Biobrain® general datasheet.

Figure 1: Typical Enterprise and Automation Infrastructure at Biopharmaceutical Production Facilities

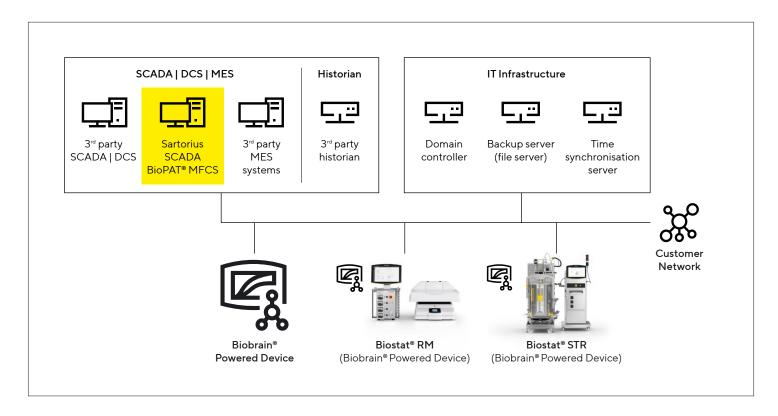


Connect and Integrate

Integration into diverse environments with multiple integration layers and increasing numbers of endpoints is key for state-of-the-art (bio)pharmaceutical production environments. Consequently, Biobrain®-powered products provide a variety of integration possibilities to satisfy the diverse needs of the industry (Figure 2). These opportunities cover typical SCADA | DCS and MES and also consider data historization solutions. A powerful OPC UA interface is provided for these applications. IT infrastructural aspects like centralized access management, domain integration, file exchange and time synchronization are available out-of-the-box for the variety of Biobrain®-powered products.

In the following pages, we explain the capabilities of the OPC UA interface for connecting to higher-level systems and IT infrastructure. Examples of integration scenarios are provided for Siemens SIMATIC PCS 7, Emerson DeltaV™, and Rockwell PlantPAx®.

Figure 2: Flexibility of the Biobrain® Infrastructure



Technical Specifications

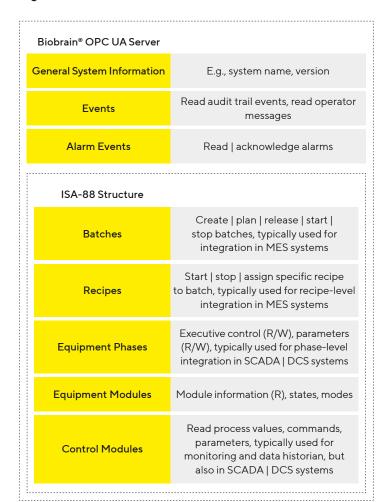
Flexible Integration Into SCADA | DCS | MES | Historian Solutions

What is OPC UA?

OPC Unified Architecture (OPC UA) is a powerful communication protocol that enables secure and standardized data exchange in industrial automation and manufacturing. Its flexibility, scalability, and interoperability make it an ideal choice for connecting machines, systems, and applications in diverse industrial environments, including pharmaceutical production.

Biobrain®-powered products are equipped with a powerful OPC UA interface, providing various layers of information and enabling different integration opportunities. Figure 3 provides a schematic overview of the OPC UA-enabled capabilities of Biobrain®.

Figure 3: OPC UA Server Structure



Remote Supervision of Process Values

Connect with Historian solutions or any other higher-level software via OPC UA to relevant control-module nodes providing process and setpoint values, alarm ranges, parameter settings, and many more. Values are updated on change with a maximum frequency of 1/s.

Alarms and Events

Subscribe to system and process value alarms via OPC for global alarm management solutions, but also MES, DCS, SCADA or historian software. Biobrain®-powered devices provide the capabilities, to remotely read and acknowledge alarms as well as reading created audit trail messages.

Batch | Recipe Level Integration

Typically used by MES systems, Biobrain® powered products provide extensive integration capabilities to manage and control local unit batches and recipes. Batches can be remotely planned, released, started and stopped; current batch status can be monitored online. Similarly, end-to-end supervision and control of unit recipes is enabled via OPC UA. Use the protocol to select and assign recipes to a batch, start, and stop the execution of a recipe, as well read the execution status.

Phase-Level Integration

Equipment phases are the elements triggered for execution within recipes steps but can also be accessed directly via OPC UA. Such scenario, known as phase-level integration, is typically applied when a connection to a SCADA or DCS system is envisioned. All available Biobrain® equipment phases expose their full ISA-88 compliant state model (e.g. start, hold, pause, suspend, stop, abort) on the OPC UA server, including allocation and arbitration mechanisms. Phase parameter can be adapted, alarms set, start and hold conditions can be monitored. Using Phase-level integration a in-depth precise and exact control of the system is possible.

OPC UA – Secure and Reliable

OPC UA is evolving as the de facto standard for industrial automation, as it is inherently designed to provide secure and reliable communication for automation environments. The protocol uses encryption to protect data in transit, ensuring it cannot be intercepted or tampered with by unauthorized parties.

The OPC UA server of Biobrain®-powered products supports multiple authentication mechanisms, including username | password, X.509 certificates, and Kerberos, which help ensure that only authorized users can access the system. In the case of network outages, the Biobrain® serversided interface automatically buffers values for up to 10 minutes and pushes the missed values after connection re-establishment. Historical data can be obtained by supporting clients using the historical data access (HDA) standard.

Key Features

- Secure connection (certificates, encryption, username | password)
- Browsable interface
- Data buffering on the interface for connection breaks
 10 min
- Historical data access (HDA)

Integration Into Diverse IT Infrastructures

Given their deployment in diverse IT landscapes, Biobrain®-powered products are designed to offer interfaces that meet a variety of needs.

Centralized User Authentication and Domain

Biobrain®-powered products are ready for connection to domain servers to obtain domain policies (e.g., auto-logout settings) and support centralized access management by connecting to name servers. As a result, user authentication can be managed centrally, ensuring secure and coordinated access to the device. In such a setup, configurable user roles on the Biobrain®-enabled product can be mapped to domain user groups to permit different access levels for users with different needs (e.g., operators, supervisors, engineers, and administrators).

Centralized Management

When a machine is part of a domain, it can be managed centrally through the domain controller. This allows for easier administration of user accounts, permissions, and policies.

File Exchange

Recipes, process data, unit batch reports, screenshots, product software updates, and more files can be exchanged from Biobrain®-powered products by accessing a Windows® file server using typical username | password combinations. This eliminates the need for USB mass-store devices in regulated environments, which create a potential security threat

Time Synchronization

Biobrain®-powered products have the native capability to connect to an NTP server to ensure harmonized time recording, e.g., for process data, audit trail events, and alarms. This functionality is critical to ensure data integrity, traceability, and event correlation across different systems and layers. The corresponding settings can be accessed through the Biobrain® user interface.

Support for Integration

Sartorius provides rich documentation regarding the OPC UA interface of Biobrain®-powered products. This documentation package includes:

- an OPC UA interface report listing all relevant node IDs and their functionality
- an OPC UA integration manual describing the generic setup to integrate Biobrain®-powered products via OPC UA into customers' environment.

Need Help?

Our Interface Consulting (IC) service highly reduces effort and risk by supporting customers with virtual consulting and intuitive documents to accelerate integration of Biobrain®-powered products and | or BioPAT® MFCS into Higher Level Systems.

For more information about Biobrain®, visit

sartorius.com/en/products/process-analytical-technology/process-control-automation/biobrain-automation-platform

Examples of Integration Into Higher Level Systems: SIMATIC PCS 7 by Siemens

Supported by the Biobrain® OPC UA server with complete documentation, Biobrain®-powered products such as Biostat® RM or Biostat STR® 3 can be connected to a Siemens SIMATIC PCS 7 (Figure 4). Data acquisition (read and write) from I to Biobrain® in SIMATIC PCS 7 for:

- Visualization
- Supervisory control
- Historization
- Alarms and events
- Alarm acknowledgement
- Recipe execution in SIMATIC PCS 7 via phase-level integration of Biobrain®-powered product equipment phases
- Recipe level integration by triggering recipes in the Biobrain®-powered products via SIMATIC PCS 7

Need Help?

SIMATIC PCS 7 integration is supported by our Interface Consulting (IC) service



Virtual consulting support



Specialized knowledge transfer



Demonstration of typical integration scenarios in a virtual environment



Intuitive integration guide illustrating the configuration of typical integration scenarios as examples

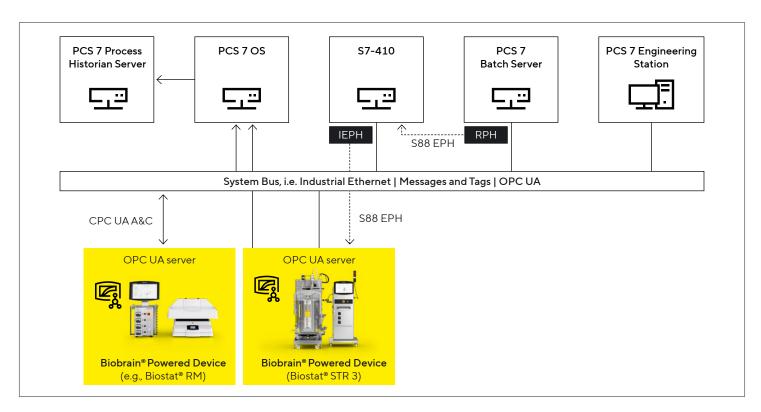


Typical architecture of Biobrain® unit integration into SIMATIC PCS 7



Example SIMATIC PCS 7 project available for Biostat® STR and Biostat® RM: modify as needed

Figure 4: High Level Architecture of Biobrain® Unit Integration Into SIMATIC PCS 7



Examples of Integration Into Higher Level Systems: DeltaV™ by Emerson

Supported by the Biobrain® OPC UA server with complete documentation, Biobrain®-powered products such as Biostat® RM or Biostat STR® 3 can be connected to Emerson's DeltaV™ (Figure 5). Data acquisition (read and write) from | to Biobrain® in Emerson's DeltaV™ for:

- Visualization
- Supervisory control
- Historization
- Alarms
- Recipe execution in DeltaV[™] via phase-level integration of Biobrain®-powered product equipment phases

Need Help?

DeltaV[™] integration is supported by our Interface Consulting (IC) service



Virtual consulting support



Specialized knowledge transfer



Demonstration of typical integration scenarios in a virtual* environment



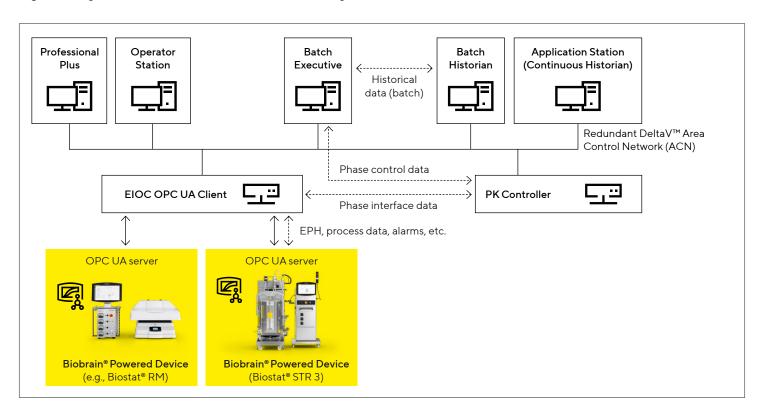
Intuitive integration guide: illustrates configuration of typical integration scenarios as examples



Typical Architecture of Biobrain® unit integration into DeltaV™ DCS

* Planned

Figure 5: High Level Architecture of Biobrain® Unit Integration Into DeltaV™ DCS



Examples of Integration Into Higher Level Systems: PlantPAx® by Rockwell

- Supported by the Biobrain® OPC UA server with complete documentation, Biobrain®-powered products such as Biostat® RM or Biostat STR 3® can be connected to a Rockwell's PlantPAx® (Figure 6). Data Acquisition (read and write) from | to Biobrain® in PlantPAx® for:
- Visualization
- Supervisory Control
- Historization
- Alarms and events
- Alarm acknowledgement
- Recipe execution in PlantPAx® via phase-level Integration of Biobrain®-powered product equipment phases
- Recipe-level integration by triggering recipes in the Biobrain®-powered product via PlantPAx®

Need Help?

PlantPAx® integration is supported by our Interface Consulting (IC) service



Virtual consulting support



Specialized knowledge transfer



Demonstration of typical integration scenarios in a virtual* environment



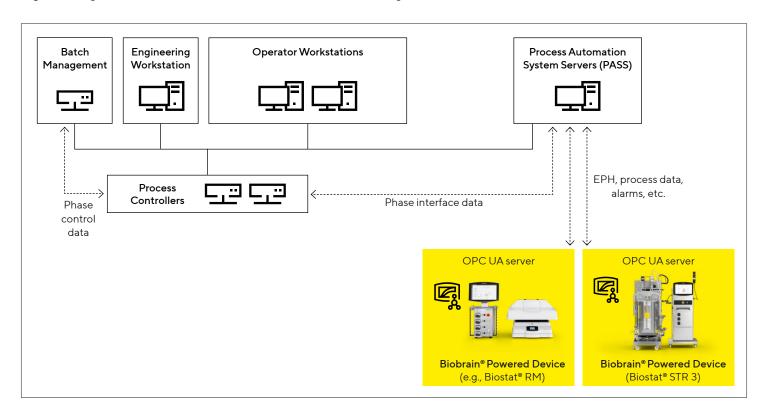
Intuitive integration guide: illustrates configuration of typical integration scenarios as examples



Typical architecture of Biobrain® unit integration into PlantPAx® DCS

* Planned

Figure 6: High Level Software Architecture of Biobrain® Unit Integration Into PlantPAx® DCS



Ordering Information

Biobrain®: Not sold separately but available for supported products

BioPAT® MFCS: View order details here

Interface Consulting Service: Order number: ZB-MB-HA-0044

For more information about Biobrain®, visit

sartorius.com/en/products/process-analytical-technology/process-control-automation/biobrain-automation-platform

Representation about Interface Consulting, download

sartorius.com/resource/static/celum/258659/Interface-Consulting-Flyer-en-B.pdf

Germany

Sartorius Stedim Biotech GmbH August-Spindler-Strasse 11 37079 Goettingen Phone +49 551 308 0



Representation Formation, visit

sartorius.com

USA

Sartorius Stedim North America Inc. 565 Johnson Avenue Bohemia, NY 11716 Toll-Free +1 800 368 7178