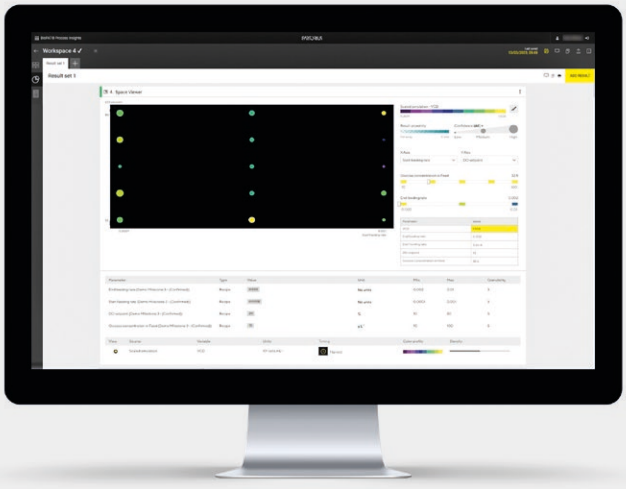
SARTORIUS

Product Datasheet

BioPAT® Process Insights Release 2



Product Information

BioPAT® Process Insights (Release 2) is a software application aimed at simplifying and optimizing scale-up | scale-down across Sartorius bioreactors. Designed for bioprocess scientists and engineers, Process Insights complements Sartorius' expert know-how with an intuitive user interface. Release 2 includes an additional Recipe Scaling module to evaluate process scalability, encouraging in silico exploration and investigation to achieve operational goals.

Process Insights is an Insights Application and part of a toolbox of DIY digital solutions to help users improve scaling and reduce development times and costs.

Insights Applications: BioPAT® Process Insights, Cell Insights by Umetrics® Studio

Features and Benefits

- Offers exclusive and extensively characterized bioreactor data of supported Sartorius bioreactors in one place
- Predicts and de-risks process transfer early on in a development workflow
- Encourages in silico exploration and discovery, considering risk, uncertainty, and variability of the recipe, environment, and cell behavior when scaling to a Sartorius bioreactor

Introduction

Relevant Applications

- Process Insights is a scaling software designed for process development, cell line selection, process characterization, and transfer to manufacturing for supported Sartorius bioreactors.
- Process Insights Release 2 supports CHO protein-based therapies and some HEK-based viral vector cultures depending on the process conditions. Note that only suspension cultures are supported.
- More applications and cell lines may be supported in future releases. Please check with your local Sartorius representative for more information.

Sartorius Supported Bioreactors in Release 2

- Ambr® 15 cell culture vessel
- Ambr® 250 HT and Modular cell culture vessels (standard and baffleless)
- Univessel® SU 2 L
- Univessel® Glass 2 L, 5 L, and 10 L (2 × 3 and 3 + 6 impeller, ring and micro sparger), cell culture only
- Biostat STR® 50 L, 200 L, 500 L, 1,000 L, and 2,000 L (2 × 3 and 3 + 6 impeller, ring and micro sparger), cell culture only

Coming later in Release 2 (for the Point Scaling Module only and subject to change):

- Ambr® 250 HT and Modular microbial (MO) vessels (standard and 30 mm)
- Biostat STR® 50 MO

Relevant Process Steps

- BioPAT® Process Insights Release 2 is a standalone software application for bioreactor scaling across supported Sartorius bioreactors.
- Users can optionally use Process Insights and Cell Insights by Umetrics® Studio together for a more robust scaling approach.
- Process Insights can simulate the physical environment within the target bioreactor (in silico) to optimize scaling based on empirical models, a candidate recipe, and a user-defined cell model.
- Cell Insights by Umetrics® Studio can then be used to simulate cellular metabolic behavior in silico, independent of the hardware. Advanced mechanistic cell models included within Cell Insights can help optimize cultures by providing users with a better understanding of the biological performance.
- Additional insights and knowledge gained from Cell Insights can be applied to Process Insights to better reflect the actual cell behavior when transferring the process to the target Sartorius bioreactor.
- Alternatively, start with the cell modelling in Cell Insights and then optimize the process for scale-up using Process Insights.
- Process and Cell Insights are one of many Digital Solutions from Sartorius to help increase knowledge and ability and to improve decision making. This toolbox of DIY solutions helps to reduce timelines and costs to achieve efficient and fast process development.

Figure 1: *Complementing Expert Know-How With "Do-It-Yourself" Solutions*

Cell Insights by Umetrics® Studio

- Take advantage of advanced in silico models to generate knowledge about cell growth, death, cytotoxicity and metabolism
- Contains out of the box mechanistic models

BioPAT® Process Insights

- Improve bioreactor scaling design whilst considering risk, uncertainty and variability of the process
- Encourages in silico discovery and exploration of processes for scaling

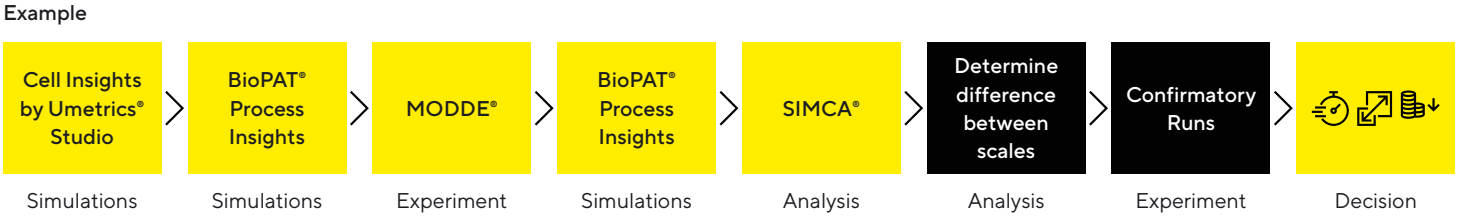
MODDE® and SIMCA®

- DOE | Define experimental approach
- MVDA | Refine down scale model and ensure scales match closely

Enabling Digital Solutions

Knowledge and quality as foundation → **improve decision-making** through in silico simulation → **save time and money** → **accelerate your research**

Figure 2: *Reduce Development Time and Costs With Complementary Tools for Scaling*



Technical Specifications

Software Features

Attribute	BioPAT® Process Insights Release 2 (Current Release)	Cell Insights by Umetrics® Studio (Complementary Insights Application)	BioPAT® Process Insights Release 1 (Previous Release)
Focus of Software Application	Focuses on the evolution of the **process** (recipe and cells) for bioreactor scaling.	Focuses on in silico **mechanistic cell modeling** utilizing propriety models based on Monod growth kinetics.	Focuses on bioreactor point scaling
	Contains modules for: **Recipe Scaling** In silico batch evolution (time-series) simulation of the process, considering the bioreactor instructions (recipe), the cell behavior, and environmental variables **Point Scaling** Non-time series simulation of scaling parameters at a specific point(s), enabling a risk-based, multi-parameter, and multi-scale approach to bioreactor scaling.	Contains out-of-the-box **mechanistic cell models** to generate knowledge about cell growth, death, and metabolism, enabling users to explore new cell culture modes through simulations and pose what-if scenarios. Supports a variety of cell-culture development use cases such as cell line selection (in fed batch or perfusion mode) and optimization of process parameters and intensified feeding protocols.	Contains a **point scaling module** for non-time series simulation of scaling parameters at a specific point(s) in time of a process, enabling a risk-based, multi-parameter, and multi-scale approach to bioreactor scaling.
Target User	Bioprocess scientists and process engineers	Bioprocess scientists and process engineers	Bioprocess scientists and process engineers
Key Functionality and Components	**In Silico Recipe Scaling** **Workspaces** containing: ▪ **Recipe Builder** ▪ **Cell Model Builder** To create basic user-defined cell models (no cell models included) ▪ **Process Data** ▪ **Simulations** ▪ Insights (objectives of scaling scenario and assessment) ▪ **Optimizations** (optimize recipe and cell model parameters to improve Insights) ▪ **Results and Calculations** **Point Scaling** (see Release 1 details)	**In Silico Cell Modeling** **Mechanistic Cell Models** included **Simulation Workflows:** ▪ **Perfusion Cell Line Selection** Narrow down cell line clones based on qualitative differences ▪ **Virtual Bioreactor** Explore how process events impact growth kinetics and productivity (bioreactor-agnostic)	**Bioreactor Point Scaling** **Guided Workspace Templates:** ▪ Scale between Bioreactors ▪ Convert bioprocess parameters to bioreactor parameter ▪ Find operational space ▪ Create custom workspaces

Attribute	BioPAT® Process Insights Release 2 (Current Release)	Cell Insights by Umetrics® Studio (Complementary Insights Application)	BioPAT® Process Insights Release 1 (Previous Release)
Data Requirements	Historical process data can be uploaded to the software to refine cell models to better reflect actual behavior and | or be used for comparison against simulated outcomes.	Historical process data is a requirement for simulation.	No process data is needed for import into software, just user-provided info on scaling preferences and constraints.
	Data should be in .csv files following the required template formats included within the software (templates listed below):	Data should be in .csv or Excel format. All datasets must have only one header row containing the variable names, and they need to be unique within the dataset. Each dataset must also have a column with row or batch identifiers.	N/A
	▪ Timeseries (batch evolution process variables data) ▪ Metadata properties (time-independent properties and absolute and relative error measurements) ▪ Metadata liquids (properties on any liquids used in the process)	At a minimum, to perform basic simulations, the following data is needed: ▪ One dataset from a screening experimental design containing sufficient variations in growth ▪ Data should show batch evolution (data over time) Using larger datasets will unlock more advanced simulations and is needed to adapt the models to other mammalian cell lines.	N/A
	Required Variables: Batch ID, time, bioreactor configuration properties, and absolute and relative error measurements. If liquid metadata is included, required variables include inoculum density, buffering capacity, temperature, pH, liquid feeds | media, **Optional Variables:** Process inputs (e.g. DO, pH, temp, fill volume, stir speed, etc.), metabolites (e.g. glucose, lactate, glutamate), product titer, feed and media composition	**Required Variables:** Batch ID, time, viable cell density, viability, and volume **Optional Variables:** Process inputs (e.g. DO, pH, temp), metabolites (e.g. glucose, lactate, glutamate), titer, feed, and media composition	N/A
Application Type	On-premise (private cloud application)	Hosted cloud (SaaS) application	On-premise (private cloud application)
Technical Specifications	Please refer to the latest Technical Specifications document for the on-premise server requirements to run this application. Access to the application, once installed, is via a web browser (Chrome or Edge).	Access to the Hosted Cloud application (provided by Azure) is via a web browser (Chrome, Safari, or Edge). Please contact your Sartorius representative if you need further information on the Sartorius-hosted cloud infrastructure.	Please refer to the latest Technical Specifications document for the on-premise server requirements to run the latest version of this application. Access to the application, once installed, is via a web browser (Chrome or Edge).

Ordering Information

Item	Description	Order Number
BioPAT® Process Insights	First year subscription license for 10 seats	001-1Y01
BioPAT® Process Insights	1 year renewal subscription license for 10 seats (to continue software usage after the first year)	001-1Y02
Cell Insights by Umetrics® Studio	Hosted cloud application subscription (requires Umetrics® Studio viewer seat license in addition)	UT-EPUB-CELL
Umetrics® Studio	Hosted cloud subscription viewer seat license	UT-EPUB-STUDIO

Related Accessories

Ambr® 15
Ambr® 250
Biostat STR®
Univessel® Glass and Univessel® SU
Umetrics® Suite
MODDE®
SIMCA®

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For more information, visit
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www.sartorius.com/biopat-process-insights
www.sartorius.com/umetrics-studio

Specifications subject to change without notice.
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Status: 07 | 2023