Biostat STR® Generation 3 and Biobrain® Automation Platform

Commercial Manufacturing
Engineered for Quality and Precision

The Biostat STR® Generation 3 single-use bioreactors are powered by the GMP compliant automation platform Biobrain® and come with a comprehensive suite of analytical tools. Ready for process intensification through integrated Repligen XCell ATF® Technology, the Biostat STR® can help enhance productivity, reduce footprint and lower COGs of your facility. The system can be used fully standalone or easily integrates into existing automation infrastructures and consistently delivers outstanding performance, quality, and productivity – supporting manufacturers as they bring safe, effective, and affordable life-changing biopharmaceuticals to market.

Maximize Quality and Consistency

The Biostat STR® system simplifies technology transfer between production scales and ensures consistent quality without surprises and re-optimization. Process transfer can be further enhanced with BioPAT® Process Insights, a software application that enables simplified, predictive and low risk transfer between supported Sartorius bioreactor scales.

The Flexsafe STR® bags with optimized resin formulation and minimized additive package lead to increased cell viability and higher cell densities. The complete control of the raw materials, the extrusion process and the bag assembly guarantee consistent lot-to-lot cell growth performance.

The thickness, strength and flexibility of the polyethylene film enhances the mechanical robustness of Flexsafe® bags, making it ideal for all bioprocessing applications.

Together with advanced process monitoring through BioPAT® sensors, the standalone GMP automation platform Biobrain® powers the Biostat STR® bioreactor for superior process control to deliver quality product to the market.

- Stay flexible and optimize space
- Reduce operating expenses
- Minimize risk
- Achieve superior process control
- Improve productivity and ease of use
- Increase facility throughput

<table>
<thead>
<tr>
<th>BioPAT® ViaMass</th>
<th>In-line monitoring of viable biomass and automated cell bleed control</th>
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<tbody>
<tr>
<td>BioPAT® Trace</td>
<td>On-line monitoring of glucose and lactate and automated feed control</td>
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<tr>
<td>BioPAT® Foam</td>
<td>Monitoring of foam level with alarming and interlock functionalities</td>
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<tr>
<td>BioPAT® Xgas</td>
<td>Oxygen–carbon dioxide sensor featuring automatic compensation of humidity and pressure</td>
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Flex Your Production

The Biostat STR® system with a working volume from 12.5 L to 2,000 L and Biobrain® automation platform provides you the flexibility and power to adapt on-demand.

The Generation 3 control tower is a universal design, running the fully configurable Biobrain® software. This allows for use of one control tower interchangeably with any bag holder size. The advanced user interface and improved connectivity make bioreactor operation more streamlined.

Furthermore, the Media Control Hub is an elegant tool with organization and connectivity to simplify complex setups and maintain an orderly suite.

With Biostat STR® Generation 3 Single-Use Bioreactor System, process intensification is faster, easier and more efficient through fully integrated Repligen XCell ATF® Technology for perfusion processes, coupled with BioPAT® Viamass cell bleed control and BioPAT® Trace glucose control.

Everything is managed through Biobrain®, the automation platform with standalone GMP functionality, helping to significantly increase facility throughput.

Attain Operational Excellence

The Biostat STR® 3 runs on Biobrain®, a GMP-compliant automation platform enabling advanced process monitoring and control.

- Comply with industry standards GAMP 5, ISA 88 and OPC UA
- Be GMP-ready with one year of data storage, archiving, audit trail and batch reporting
- Execute automated processes with local recipe control based on ANSI-88 compliant process automation
- Benefit from native connectivity to BioPAT® MFCS4 for enhanced process automation and control
- Interface with your data historian, external SCADA, or DCS systems
- Enjoy ease-of-use with the modern, intuitive Biobrain® HMI

Find out more
For more information, please visit www.sartorius.com/biostat-str
Biostat STR® Generation 3 Configurations

Our commercial manufacturing solutions have been predesigned into two configuration packages with flexible options and easy upgrades. Select the configuration that best fits your current needs and can conveniently adapt to any future requirements.

### Features

<table>
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<tr>
<th>Essential</th>
<th>Performance</th>
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<tbody>
<tr>
<td>Integrated Repligen Xcell ATF® Technology</td>
<td>☐</td>
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<tr>
<td>Media Control Hub for organizing pumps, balances, and feeds</td>
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<tr>
<td>Bagholder Surface Ra &lt;1.2 µm, improved over previous model</td>
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<tr>
<td>pH and DO Sensor Redundancy (up to 4×pH + 4×DO)</td>
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### Process Analytical Technologies (PAT) Toolbox

- BioPAT® Trace glucose | lactate sensor | ☐ |
- BioPAT® Viamass sensor for real-time viable cell density | ☐ |

### Advanced Process Control

- Vessel Level Control | ☒ |
- Gravimetric Feeds | 2 up to 5 |
- Viamass Cell Bleed | Feed Control | ☐ |

### Automation

- Meets GMP standards GAMP 5, ISA 88 and OPC UA | ☒ |
- Local Data Archive, Historical Trending and Batch Reporting | ☒ |
- User Management and Audit Trail | ☒ |

### Safety

- IP Rating: IP65/NEMA 4x (Tower); IP54/NEMA 12 (Bagholder) | ☒ |
- BioPAT® Foam single-use sensor with High Foam Alarm | ☐ |
- Bag Lifting & Installation Device for 500 L, 1,000 L, and 2,000 L | ☐ |
- Sartocheck® bag tester | ☐ |

Specifications subject to change without notice.

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