SARTURIUS

Biostat STR® Microbial and Flexsafe STR® Microbial Bags

Engineered for
High Demanding
Microbial Processes



Benefits

- Designed for all types of high demanding microbial processes
- Suited for pDNA production
- Qualified Flexsafe microbial bag for GMP processes
- Improve productivity and ease of use
- Achieve superior process control

Product Information

Biostat STR® Microbial is a high performing single-use fermenter in Sartorius's classical stirred-tank design. The system includes the bag holder hardware, the control tower featuring Biobrain® for industrial GMP processes and advanced automation, and the Flexsafe STR® bag designed specifically for microbial processes. The unique control tower concept allows highest flexibility, easy configuration switch-over and stand-alone GMP process supervision. With 40 L working volume the system allows easy transfer from stainless steel processes to single-use fermentation equipment or scaling from Ambr® 250 microbial processes.

Technical Specifications

Bag Holder with TCU

| | Biostat STR® Microbial | |
|---|---------------------------|--|
| Material | AISI 304L stainless steel | |
| Dimensions | 815 × 1,175 × 1,951 mm | |
| $W \times D \times H$ | 32.1 × 46.3 × 76,8 in | |
| Footprint | 0.86 m² 9.26 ft² | |
| Weight | 335 kg 738.5 lb | |
| Packaging | 1,450 × 1,150 × 2,200 mm | |
| Dimensions | 57.1 × 45.3 × 82.7 in | |
| Installed on Skid | | |
| Double Wall | | |
| Electro-Polished | | |
| Single Front Door | | |
| Holder for Gas Filters | | |
| Viewing Window | 1 | |
| Lateral Window for Sensors and Ports | 2 | |
| Top Drive Motor | | |

lacktriangleq Available — Not available \Box Optional



Biostat STR® 50 Microbial

Control Tower

| Specifications for All Biostat STR® Models and Sizes | | | | |
|--|--|--|--|--|
| Material | AISI 304 stainless steel | | | |
| Dimensions (W × D × H) | 800 × 850 × 1,820 mm 31.5 × 33.5 × 71.7 in | | | |
| Footprint | 0.68 m² 7.32 ft² | | | |
| Weight | 240 kg 529 lb | | | |
| Packaging Dimension | 1,000 × 1,050 × 2,100 mm 39.4 × 41.3 × 82.7 in | | | |
| Single Version | | | | |
| Installed on Skid | | | | |
| Color Touch Screen | 22" | | | |
| Safety Measurement and Shut-Off | | | | |
| Different User Level Login | | | | |
| Standalone GMP Functionality | | | | |

Facility and Utility Requirements

■ Available

Not available

| | Biostat STR® Microbial |
|--|---|
| Power Supply Power Frequency Consumption | |
| 208 VAC 60 Hz 19 A | |
| 400 VAC 50 Hz 13 A | |
| Gas Supply | Gas specification according to ISO 8573-1: dry, free of oil and dust |
| Compressed Air (bar) | 4 |
| Gas Pressure O ₂ , N ₂ (bar) | 4 |
| Water Supply | |
| Cooling Water - Supply Pressure (bar) | 1.5 bar/15 Lpm (recommended) |
| Drain for Water | 25 Lpm |
| Temperature | min. 8 °C min. 46°F |
| Degree of Hardness | 0.7-1.5 mmol/L alkaline earth ions |
| Environmental Requirements | |
| Ambient Temperature | 5 - 40 °C 41 - 104°F |
| Relative Humidity Range | < 80% till 31 °C < 50% linear decreasing for temperature of 31 – 40 °C |

 \square Optional

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Process Control

| | Biostat STR® Microbial | | | | |
|---|---|--|--|--|--|
| Agitation Module | | | | | |
| Max. Stirrer Speed | 500 rpm | | | | |
| Temperature Control Unit | | | | | |
| Туре | Heating Cooling | | | | |
| Heating kW Cooling HP | | | | | |
| Temperature control, double wall | 8 °C (46°F) above cooling water up to 40 °C (104°F) | | | | |
| Over-Temperature Protection | | | | | |
| Connection to Pressure-Rated Cooling Water up to 6 bar | | | | | |
| Aeration Module | 3-gas mix (O ₂ , N ₂ , air) with 1 outlet | | | | |
| Mass Flow Controllers (MFC) | | | | | |
| ■ Number of MFCs | 3 | | | | |
| ■ Accuracy of MFC | ±1% full-scale | | | | |
| For Sparger Line | Ring sparger (O ₂ , N ₂ , air) | | | | |
| ■ Flow Rates (Lpm) | (0.38-60) | | | | |
| Advanced DO Controller | | | | | |
| Max. Total Gassing Rate | 1.5 vvm | | | | |
| Pump Module | | | | | |
| Three Internal Pumps Installed | | | | | |
| WM314 Speed-Controlled | 1 | | | | |
| WM314 Fixed-Speed | 2 | | | | |
| External Pumps | | | | | |
| At the Tower Speed-Controlled | up to 8 | | | | |
| | | | | | |
| ■ Available — Not available | ☐ Optional | | | | |

Process Control (continued)

| | Biostat STR® Microbial | | | |
|--|---|--|--|--|
| Sensors and Measurement | | | | |
| Temperature Probe Pt100 | | | | |
| ■ Measurement Range | 0 - 150 °C 32 - 302°F | | | |
| pH, Electro-Chemical, Multiuse and Single-Use | • | | | |
| ■ Measurement Range | 4 - 10 | | | |
| DO, Single-Use | | | | |
| ■ Measurement Range | 0 - 110% | | | |
| ■ Recalibration Function | | | | |
| DO Optical or Polarographic, Reusable | | | | |
| ■ Measurement Range | 0 - 100% | | | |
| Load Cells | | | | |
| Balance Substrate | (up to 4) | | | |
| Accessories | | | | |
| Filter Line IN | | | | |
| Filter Line OUT | | | | |
| SU Exhaust Cooler | ■ (required) | | | |
| Holder for Conventional Probes | | | | |
| Trace (MFCS) | | | | |
| Transfer Set | ■ (required to connect two exhaust filters) | | | |

Communication | Control Tower Interface

| | Biostat STR® Microbial | |
|---------------------|------------------------|--|
| OPC UA | | |
| OPC DA (convertor) | | |
| RS232 | up to 4 | |
| Industrial Ethernet | | |
| Analog IN | 4 | |
| Analog OUT | 4 | |

| — A :1.1.1 | A1 1 21 1 1 | |
|-------------------|-----------------------------------|------------|
| Available | Not available | □ Optional |

Flexsafe STR® Bags

Geometrical Data of Flexsafe STR® Bags

| Flexsafe STR® | Microbial |
|---|---|
| Total Volume [L] | 68 |
| Max. Working Volume [L] | 40 |
| Min. Working Volume [L] | 11 |
| Turndown Ratio | 1:3.6 |
| Bag Diameter, d, [mm] | 370 |
| Bag Height, h ₁ [mm] | 666 |
| Ratio, h ₁ /d ₁ | 1.8 |
| Liquid Height, h₂ [mm] | 428 |
| Ratio, h ₂ /d ₁ | 1.2 |
| Impeller Diameter, d ₂ [mm] | 143 |
| Ratio, d ₂ /d ₁ | 0.38 |
| Distance Between Impellers [mm] | 186 |
| Volume Bottom Impeller Fully Immersed V ₁ [L] | 10 |
| Volume Top Impeller Does Not Touch Surface V₂ [L] | 25 |
| Volume Top Impeller, Fully Immersed V ₃ [L]* | 28 |
| Bag Packaging Dimensions W × D × H (mm in) | 395 × 395 × 1,170 15.5 × 15.5 × 46 |

Example of Flexsafe STR® Microbial Configuration

| Position | Designation | Tubing Material | Tubing Termination | Remarks |
|----------|-----------------------|------------------------|----------------------------------|-----------------------------------|
| A | Pressure | Si(Pt) | Opta connector | Without spare port |
| В | Substrate line 1 | Si(Pt), TPE (C-Flex®)* | Clave connector | |
| С | Substrate line 2 | Si(Pt), TPE (C-Flex®)* | MPC quick coupling | |
| D | Sparger aeration | Si(Pt) | Opta connector | Without spare port |
| E | Substrate 3-4 | Si(Pt), TPE (C-Flex®)* | MPC quick coupling | Two lines via Y, dip tube |
| F | Base addition | Si(Pt), TPE (C-Flex®)* | Clave connector | |
| G | Antifoam addition | Si(Pt), TPE (C-Flex®)* | Clave connector | |
| Н | Gas out (exhaust) | Si(Pt) | Opta connector | |
| X | Condensate return | Si(Pt) | Opta connector For exhaust coole | |
| I | Temperature sensor | Si(Pt) | N/A Reusable sensor (F | |
| L | DO sensor | N/A | N/A | Optical single-use sensor |
| JIU | pH sensor | N/A | N/A | Electrochemical single-use sensor |
| OIT | Multi-use sensors | Si(Pt) | KPC female | |
| N | Small-volume sampling | Si(Pt), TPE (C-Flex®)* | Clave connector | |
| M | Bottom-drain harvest | Si(Pt), TPE (C-Flex®)* | MPC quick coupling | |

 $^{{}^*\}text{C-Flex}{}^{\otimes}\text{ is a registered trademark of Saint-Gobain Performance Plastics Corporation}.$

Ordering Information

| Description | Order No. |
|-------------|-----------|
| | |

Biostat STR® Bioreactor System

System will be configured according to process requirements based on broad choice of configuration options. Please contact your sales representative.

Flexsafe STR® Single-Use Bioreactor Bag

Standard Design

| Bag reference | Impeller configuration | Sparger | Sampling line | Temp. | Optical DO (single-use) | pH electrode (single-use) | KPC port (for multi-use electrodes) | Sterile connector |
|---------------|---------------------------|---------|---------------|-------|----------------------------|------------------------------|---|----------------------|
| FRS313532 | 2x Rushton | Ring | 1x | 1x | 2x | 1x | - | Opta® |
| FRS313533 | 2x Rushton | Ring | 1x | 1x | 2x | - | 4x | Opta® |
| FRS313534 | 2x Rushton | Ring | 1x | 1x | 2x | 2x | 2x | Opta® |
| FRS313536 | 2x Rushton | Ring | 1x | 1x | 2x | 1x | - | AseptiQuik® |
| FRS313537 | 2x Rushton | Ring | 1x | 1x | 2x | - | 4x | AseptiQuik® |
| FRS313538 | 2x Rushton | Ring | 1x | 1x | 2x | 2x | 2x | AseptiQuik® |
| | | | 1 | | | | | |

Customer-specific designs: please contact your sales representative.

Bag Tester Fleece

| Biostat STR® 50 L | DZ050L-S2SIT |
|-------------------|--------------|
| | |

| Description | Order No. | |
|---|--------------|--|
| Accessories | | |
| Filter Line IN 500 1,000 L Microbial | DS001K-SBFLI | |
| Filter Line OUT 500 1,000 L Microbial | DS001K-SBFLO | |
| Lab Cart | 1ZG0032 | |
| Autoclave Tray for Reusable Probes | 1ZG0034 | |

| Single-Use Exhaust Cooler | | Additional information |
|--|-----------|--|
| SU Exhaust Cooler STR® 500 1,000 L Microbial | DS001KEC | For use with Biostat STR® Microbial, with OPTA® connectors |
| Transfer Set OPTA® OPTA® Exhaust | FBT312258 | |
| SU Exhaust Cooler STR® 500 1,000 L Microbial ASQ | DS001KECA | For use with Biostat STR® Microbial, with AseptiQuik® connectors |
| Transfer Set AseptiQuik® AseptiQuik® Exhaust | FBT312260 | |

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