

Biostat[®] B

The Multi-Talented Bioreactor for Research and Development

Simplifying Progress



Biostat[®] B at a Glance

Our Biostat[®] B is the ideal benchtop bioreactor for your lab. The multi-talented control tower opens up a new world of flexibility for your changing requirements. Use it as single or twin configuration, choose your cultivation chamber from our proven range of options (pictures below):

- Conventional stirred-tank Univessel® Glass in a max working volume range from 1 L to 10 L
- Single-use stirred-tank Universel[®] SU



Univessel[®] Glass

Univessel[®] SU

Proven Technology

With several thousand installations in over 50 countries, Biostat® B is the most successful benchtop bioreactor in the world. Benefit from our experience and collaboration with customers worldwide.

Configurable Design

Contact your Sartorius representative and configure your Biostat® B bioreactor solution matching your specific needs. Benefit from our flexible and scalable options.

Reliable Quality

Every Biostat[®] B is thoroughly tested before it leaves our production facilities in Germany. Benefit from our global service and application specialist network for professional installation and training.





reddot design award

Applications

- Process development, optimization and characterization
- Scale-up and scale-down studies
- Seed expansion and small scale production
- Cell bank production
- Protein supply
- Stem cell expansion

Cells

- Mammalian
- Insect
- Microbial
- Yeast
- Fungi
- Plant

Industries

- Biopharmaceuticals
- Vaccines
- Cell therapies
- Industrial
- biotechnology
- Basic research
- Education

Process Modes

- Batch
- Fed-batch
- Continuous
- Perfusion



Biostat[®] B—The Universa



Univessel® Glass

Our proven autoclavable borosilicate glass culture vessel is available in four different volumes: 1 L, 2 L, 5 L and 10 L for all kinds of cell culture and microbial applications.

Benefits -

- Classic stirred-tank design simplifies your scale-up and scale-down studies
- Extensive performance and engineering data package available
- Save additional investment and use our special design for small autoclaves

Fully interchangeable glass and single-use stirred-tank culture vessels.

Univessel® SU _

Our single-use 2 L stirred-tank vessel for cell culture applications combines scalable design with all the benefits of disposable solutions. No more worries about challenging timelines, workload or cross-contamination. Get started within minutes.



Benefits -

- Fully single-use vessel, DO and pH sensors
- Proven, scalable stirred-tank design
- Connection kit to upgrade existing bioreactor controllers

al Controller for Your Lab



Biostat[®] B-Configurable Flexibility

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Designed to meet your specific needs, Biostat[®] B covers a wide range of applications, extending from use as a flexible basic unit for preclinical research to a fully qualified system that complies with the requirements of a validated GMP environment.

12" Touch Screen

with closed frame; protected against water splashes and dust deposits. Easy-to-use and reliable operation of your Biostat® B due to intuitive design of human-machineinterface and advanced touch-screen technology even while wearing laboratory gloves.

Control Tower

The control tower contains both the aeration, pump and temperature control modules, saving valuable bench space in your lab.

New Standards for Interference-Free Measurements

All inlets and ports for, e.g. cooling water, process gasses, electricity, ethernet and potential-free alarm contact are located on the rear panel of the control tower. An equipotential bonding conductor shields the bioreactor against electromagnetic current and ensures interference-free measurements during your processes.

Single | Twin Control Tower

One Biostat[®] B control tower can control up to two vessels completely independently to save valuable lab space.





Connections for Sensors and External Accessories

Quick-connect couplings make it easy to attach all cables and supplies to the culture vessels. All connections are clearly marked with the same names used on the rear control tower panel and in the local control software menu for fast, error proof identification.

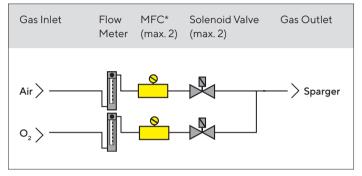
Fast Load Peristaltic Pumps

Insert the tubing in seconds: Open, insert tube, close, done! No more pinched fingers or torn gloves. Up to four internal pumps can be selected per vessel. Choose between speed-controlled pumps and fixed-speed pumps for feed and corrective agent addition.

Aeration Strategies

A series of flexible aeration options turns the Biostat[®] B into a multi-talented bioreactor for a wide range of different applications, including high-cell density microbial fermentation requiring considerable amounts of oxygen to high-cell density cell culture applications requiring removal of excess carbon dioxide.

Microbial Applications in Combination with Univessel® Glass

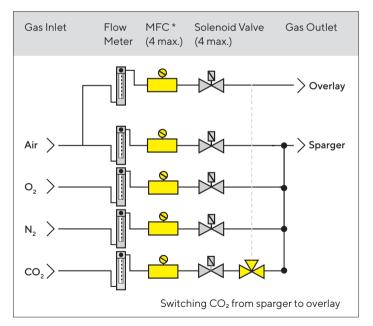


*MFC = mass flow controller

Various controller and hardware configurations enable aeration strategies using air or oxygen or classical O_2 enrichment of air. For anaerobic processes, the air inlet can be used for nitrogen. The standard built-in solenoid valves in combination with a flow meter ensure reliable gas supply for simple applications. Optional mass flow controllers provide exact flow rate control of individual gases.

In combination with BioPAT® Xgas off-gas analysis, this allows mass balancing of consumed and produced gases.

Cell Culture and Multi-Purpose Applications in Combination with Universel® Glass and Universel® SU



Five different gas lines (with flow meters) are equipped with solenoid valves and | or up to four optional mass flow controllers deliver ultimate flexibility and accuracy.

The Biostat[®] B allows you to optionally switch between sparger and overlay supply of CO_2 for pH control. In addition, a constant air | CO_2 mixture can be created in the overlay line to reproduce conditions set in a CO_2 incubator.

*MFC = mass flow controller

Scalability

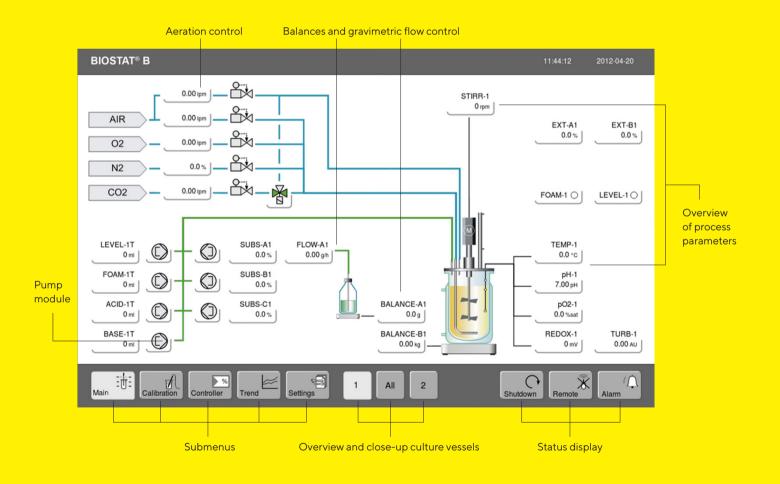
You can configure your Biostat[®] B aeration system in a similar way to your Biostat STR[®] single-use stirred tank bioreactor. Get ready for seamless scale-up and -down, from laboratory scale to large scale single-use production.



BioPAT[®] DCU – Local Control

Since we introduced the first DCU-controlled bioreactors back in the late 80's, we have installed thousands of such bioreactors to date at leading companies in the pharmaceutical and biotech industry worldwide. We have continuously improved our robust, intuitive-use and industryproven DCU control technology, available in its fourth generation. It is our standard local control platform for our Biostat[®] benchtop bioreactors and Sartoflow[®] crossflow filtration units.

The intuitive touch screen on the control tower is used to locally operate the Biostat® B:



Automatic Feed Control and Continuous Processing

Design your process strategy or select different options. Configure your Biostat[®] B with gravimetric feed control, gravimetric level control or substrate addition profiles. This enables you to run your Biostat[®] B in batch, fed-batch, continuous or perfusion mode.

Automatic pH Control

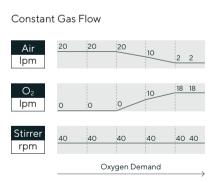
Control the pH of your culture by automatic acid and base addition or by CO_2 aeration and base addition. If you want to use your Biostat[®] B for both microbial and cell culture you can configure your bioreactor system with the option of either CO_2 aeration or acid addition for pH (acid) control.

Automatic DO Control

Besides classic DO cascade control, we have developed the unique advanced DO controller that gives you more flexibility to develop and optimize your DO control strategy.

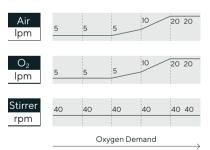
The advanced DO controller supports parallel adjustment of all DO affecting parameter settings like stirrer speed and gas flow rates of air and pure oxygen, automatically and simultaneously to control the DO set point. Optionally, you can keep the total gas flow rate constant and the ratio of pure oxygen in the gas mixture is increased automatically to match the oxygen consumption of the culture.

This gives you ultimate flexibility to adapt your aeration strategy to your process requirements.



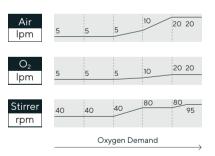
Constant gas flow decreases the flow of air and simultaneously increases oxygen flow keeping the total gas flow constant.





Constant gas ratio, increases both air and oxygen flows at the same rate keeping the ratio constant

Bubble Size Optimization



Bubble size optimization enables fine tuning of the oxygen percentage and gas-liquid interface area

BioPAT[®] MFCS Software – Monitoring, Control and Automation of Bioprocesses

BioPAT[®] MFCS is a "plug-and-play" solution, ideally suited for capturing, storing and visualizing process data of the Biostat[®] B Control Tower.

BioPAT® MFCS offers a range of scalable features to meet your supervisory needs:

- ANSI | ISA-88 Recipe Management
- Connectivity for up to 32 process units including 3rd party instrument support
- Remote Alarming
- 21 CFR Part 11 compatibility
- Connectivity to SIMCA[®] | SIMCA[®]-Online
- Connectivity to 3rd party systems such as PCS7 or OSIpi
- User Management





Learn more about the new BioPAT[®] MFCS: www.sartorius.com/sartorius/en/EUR/biopat-mfcs

SIMCA[®] and SIMCA[®]-Online – Process Analysis and Monitoring Software

SIMCA® and SIMCA®-online connect to MFCS through a SimApi. SIMCA®-online uses multivariate data analysis (MVDA) to provide real-time process monitoring for better process understanding and control. MVDA models, which use multiple parameters and their correlation patterns are created in SIMCA®. The entire process can be visualized in just a few charts and helps to:

- Spot important trends, clusters, and "hidden gems" in the data
- Improve product yield and throughput
- Ensure consistent product quality

With SIMCA[®]-online it is easy to predict, monitor and control.





Maximized Process Security

To keep your biopharmaceutical process robust and reliable, we provide a comprehensive range of services to ensure the highest reliability and uptime of your Biostat[®] B, regulatory compliance and best quality of results.

From installation and qualification to regular preventative maintenance: Our service team will be happy to assist you on site and will be with you quickly thanks to our worldwide service network.



Installation & Commissioning Safe and proper operation of your equipment right from the start



system

Qualification (IQ | QQ) Compliance with GMP requirements, easy integration into your quality management



Operator Training

Quality through greater experience: Sartorius trains the personnel operating your equipment

Installation Phase



Repairs & Spare Parts

In the event of service requests, we are quickly at your side with the necessary spare parts worldwide



Maintenance & Contracts

Optimal equipment operation and protection against potential downtimes



Calibration

Accurate results in the long term and compliance with regulatory requirements

Service Contracts for the Entire System Lifecycle

With our Bioprocess Service Program, Sartorius offers service contracts to protect your equipment through its entire lifetime. Based on your specific risk assessment and requirements, you can choose between three Service Level Agreements: Essential, Advanced and Comprehensive. Protect your Biostat[®] B by choosing the appropriate service contract. For maximum productivity and minimum downtimes.

Essential

You benefit from:

- A plannable annual maintenance
- A fast support at the technical helpdesk within one business day and priority on-site-response
- In case of repair: A discount on all time and material based cost elements

Advanced

You benefit from:

- A plannable annual maintenance
- Technical helpdesk reaction time within 8 hours and 72 hours
- on-site response
- In case of repair: Labor and travel costs are covered, a discount of 10% on spare parts

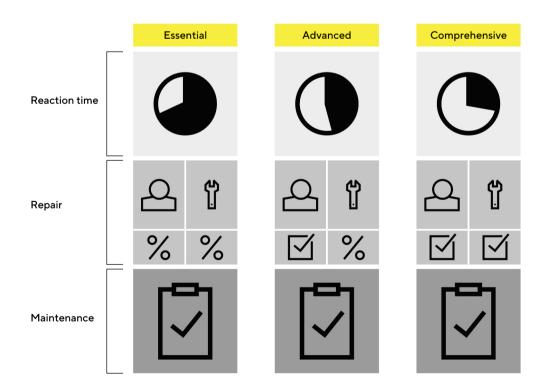
Comprehensive

You benefit from:

- A plannable annual maintenance
- Technical helpdesk reaction time within 4 hours and 48 hours on-site response
- In case of repair: All costs are covered



- Process stability and minimized downtime
- Maximized system uptime, higher profitability
- Optimized total cost of ownership



For further details and the dedicated datasheets, please have a look at our website: www.sartorius.com/services

Technical Specifications

Biostat® B

Control Tower Weight	
Single Twin	~ 40 55 kg (88 121 lbs.)
Control Tower Dimensions ($W \times H \times D$)	
Single Twin	350×822×430 mm (14"×32"×17")
Utility Connections	
Power supply	 230 V (±10%), 50 Hz, max. power consumption 10 A 120 V (±10%), 60 Hz, max. power consumption 12 A Potential equalisation
International protection rating	IP21
Gases	 Gas supply pressure, 1.5 barg Dry, oil and dust-free Hose barb for tubing, external diameter = 6 mm
Water	 Water supply pressure, 2-4 barg Flow rate up to 20 lpm Temperature min. = 4 °C Discharge pressure-less Hose barb for tubing, external diameter = 10 mm Degree of hardness: max. 12° dH
Control Tower	
Housing	Stainless steel, AISI 304
Display	Touch screen, 12″, glass, capacitive
Resolution	125 dpi
SCADA communication	Industrial Ethernet
Potential-free (common) alarm contact	
Safety valve gas pressure	1 bar (14.5 psi) for Univessel® Glass and SU
Water inlet pressure reduction	1.5 bar (22 psi), integrated pressure control
Motor Drive (Univessel® Glass SU)	
Maintenance-free, quiet direct drive	Power: 200 W
Maintenance-free top drive with magnetic motor coupling	Power: 200 W
Rotation speed motor, direct coupling	1 L: 20 - 2,000 rpm 2 L: 20 - 2,000 rpm 5 L: 20 - 1,500 rpm 10 L: 20 - 800 rpm 2 L SU: 20 - 400 rpm

Process Control | Sensors

	Sensor Measurement Range Display Accuracy	Univessel [®] Glass	Univessel [®] SU
Temperature	Pt100 0−150 °C (temperature control 0−80 °C) 0.1 °C		•
Dissolved oxygen, reusable	Polarographic or optical 0 - 100% 0.1%		•
Dissolved oxygen, single-use	0 - 100% 0.1%		•
pH, reusable	Combined measuring electrode 2 - 12 pH 0.01 pH	•	•
pH, single-use	6.5-8.5 pH 0.1 pH		
Foam control	Electrical conductive sensor, stainless steel, ceramic insulated		
Level	Electrical conductive sensor, stainless steel, ceramic insulated		
Turbidity	1-channel NIR absorption sensor 0 - 6 AU 0.01 AU	•	
Redox	Combined measurement with pH sensor -1,000 - 1,000 mV 1 mV	•	
Balance substrate	7 kg max. 1 g 60 kg max. 10 g 300 kg max. 100 g	•	•
Gravimetric Flow Controller	Accuracy for 7 kg balance: 5 g/h Accuracy for 60 kg balance: 50 g/h ■ ■ ■ Accuracy for 300 kg balance: 500 g/h		•
Balance culture vessel	60 kg max. 10 g		
External signal input	al input 0-10 V or 4-20 mA Univessel® Glass SU: 4 max.		•

Aeration Module

Outlet to culture vessel bag	Hose coupling Ø external = 6 mm	
Univessel® Glass MO (Microbial)	Two-gas mixing with sparger outlet	
Air with O₂ Enrichment or Gas Flow Ratio m	ixing along with anaerobic fermentation; for further information, please see page on "Aeration Strategies"	
Max. total flow	Up to 20 L/min total volume flow	
Flow meters	2	
 Flow Range 	Various models available: 0.1–20 liters per min. [Ipm] (sparger)	
 Accuracy 	±5% full scale	
Mass flow controllers (optional)	2 max.	
 Flow rate 	Various models available: 0.03-20 lpm (sparger)	
 Accuracy 	±1% full scale	
Univessel® Glass CC (Cell Culture) Univessel® SU	Four-gas mixing with sparger and headspace outlet	
Additive flow, 4-gas (Air, O₂, N₂, CO₂) mixtu	re; for further information, please see page on "Aeration Strategies"	
Max. total flow	Up to 13 L/min total volume flow	
Flow meters	5	
 Flow Range 	Various models available: 3.3 ccm – 1.6 lpm (sparger) 0.16 lpm – 13 lpm (headspace)	
 Accuracy 	±5% full scale	
Mass flow controllers (optional)	4 max.	
 Flow rate 	Various models available: 1 ccm - 1.5 lpm (sparger) 0.03 lpm - 10 lpm (headspace)	
 Accuracy 	±1% full scale	
Univessel® Glass, Dual Use	Four-gas mixing with sparger and headspace outlet	
Additive flow, 4-gas (Air, O ₂ , N ₂ , CO ₂) mixtu	re; for further information, please see page on "Aeration Strategies"	
Max. total flow	Up to 20 L/min total volume flow	
Flow meters	5	
 Flow Range 	Various models available: 3.3 ccm - 20 lpm (sparger) 50 ccm - 20 lpm (headspace)	
 Accuracy 	±5% full scale	
Mass flow controllers (optional)	4 max.	
 Flow rate 	Various models available: 0.6 ccm - 20 lpm (sparger) 10 ccm - 20 lpm (headspace)	
 Accuracy 	±1% full scale	

Pump Module

Built-in Pumps	
Fixed speed (on off controlled)	Watson Marlow 114, Fast Load pump head
 Speed 5 rpm 	ID: 0.5 mm: 0 – 0.1 ml/min
Flow rate (tubing wall thickness 1.6 mm)	ID: 0.8 mm: 0 – 0.2 ml/min
	ID: 1.6 mm: 0.01–0.7 ml/min
	ID: 2.4 mm: 0.03–1.5 ml/min
	ID: 3.2 mm: 0.05 – 2.4 ml/min
	ID: 4.8 mm: 0.09-4.3 ml/min
 Speed 44 rpm 	ID: 0.5 mm: 0.02–0.9 ml/min
Flow rate (tubing wall thickness 1.6 mm)	ID: 0.8 mm: 0.04 - 1.8 ml/min
	ID: 1.6 mm: 0.12 – 6.2 ml/min
	ID: 2.4 mm: 0.26–12.8 ml/min
	ID: 3.2 mm: 0.41–20.7 ml/min
	ID: 4.8 mm: 0.75 – 37.4 ml/min
Speed-controlled	Watson Marlow 114, Fast Load pump head
 Speed 0.15 - 5 rpm 	ID: 0.5 mm: 0 – 0.1 ml/min
Flow rate (tubing wall thickness 1.6 mm)	ID: 0.8 mm: 0.01–0.2 ml/min
	ID: 1.6 mm: 0.02 – 0.7 ml/min
	ID: 2.4 mm: 0.04–1.5 ml/min
	ID: 3.2 mm: 0.07–2.4 ml/min
	ID: 4.8 mm: 0.13 – 4.3 ml/min
 Speed 5–150 rpm 	ID: 0.5 mm: 0.1–3 ml/min
Flow rate (tubing wall thickness 1.6 mm)	ID: 0.8 mm: 0.2-6 ml/min
	ID: 1.6 mm: 0.7–21 ml/min
	ID: 2.4 mm: 1.45 – 43.5 ml/min
	ID: 3.2 mm: 2.35 – 70.5 ml/min
	ID: 4.8 mm: 4.25 – 127.5 ml/min
External Pumps	
Speed-controlled	Watson Marlow 120, Fast Load pump head, up to 200 rpm

Temperature Control Module

	Heating and Cooling	Heating Only
For Univessel® Glass Single-wall Culture Vessels	Electrical heating system and automatic cooling water valve; connection to heating blanket and cooling finger	-
	Temperature control of 8 °C above cooling-water inlet temperature up to 60 °C	-
	Heating blanket capacities 1 L 2 L 5 L 10 L: 100 170 400 780 W	-
For Univessel® Glass Double-wall (Jacketed) Culture Vessels	Open thermostat system with recirculation pump and automatic cooling water valve	-
	Temperature control of 8 °C above cooling-water inlet temperature of up to 80 °C	-
	Heating capacity: 600 W	-
For Univessel® SU Single-use Culture Vessels	Open thermostat system with recirculation pump and auto- matic cooling water valve; connection to heating cooling jack	Electrical heating blanket set
	Temperature control up to 50 °C	Temperature control up to 50 °C Heating capacity 2 L: 200 W

Culture Vessel Univessel® Glass

Autoclavable Single-wall or Double-wall (Jacketed) Glass Vessel	1L	2 L	5 L	10 L
Material	Borosilicate glass	, stainless steel AISI 316L	., EPDM	
Sizes [L]	1	2	5	10
Total volume [L]	1.6	3	6.6	13
Working volume [L]	0.35-1	0.6-2	0.6-5	1.5 5 - 10
Top port 19 mm 12 mm 6 mm	3 2 6	3 2 9	3 3 8	5 2 9
Univessel® Glass, Single-wall	1 L	2 L	5 L	10 L
Weight ¹ [kg]	4.4	5.9	10.5	14.9
Space requirements in autoclave [diameter×height mm]	200×446	220×507	270×645	310×767
Space requirements in autoclave, reduced ² [diameter×height mm]	450×330	490×391	570×496	600×618
Univessel® Glass, Double-wall	1 L	2 L	5 L	10 L
Weight' [kg]	5.3	6.9	12.6	18.5
Space requirements in autoclave [diameter×height mm]	320×446	335×507	395×645	435×767
Space requirements in autoclave, reduced ² [diameter×height mm]	450×330	490×391	570×496	600×618

With tripod and head plate, without medium
 Adapter for exhaust cooler to reduce height in the autoclave optionally available

Culture Vessel Univessel® SU

Single-use vessel made of pre-sterilized polycarbonate for cell culture applications		
Total volume [L]	2.6	
Working volume [L]	0.6-2	
Max. temperature	50 °C	
Operating pressure	< 0.5 barg	

Basic Configurations for Univessel® Glass

The Biostat[®] B is a highly flexible and modular system that can be individually adapted to the requirements of your application. Below you will find an overview of the basic equipment which you can extend with diverse options. Please contact your Sartorius Stedim Field Representative or Application Specialist for additional information.

Microbial Packages

Cell Culture Packages

Volume: 1 L, 2 L, 5 L or 10 L	Volume: 1 L, 2 L, 5 L or 10 L
Digital controller, color display with touch screen	Digital controller, color display with touch screen
Control temperature, pH, DO, stirrer speed	Control temperature, pH, DO, stirrer speed
Maintenance-free, quiet motor	Maintenance-free, quiet motor
Storage tray for accessories	Storage tray for accessories
Aeration module with 2 solenoid valves	Aeration module with 4 solenoid valves
2 flow rate controllers for manual flow rate control (Air N_2 , O_2)	5 flow rate controllers for manual flow rate control (Air Overlay, Air sparger, N_2 , O_2 , CO_2)
Software configured for microbial applications	Software configured for cell culture applications
4-stage DO cascade	4-stage DO cascade
2 integrated pumps for pH control (acid base)	1 integrated pump for pH control (base)
Temperature control module for double-wall vessels	Temperature control module for single-wall vessels
2 external signals 0 - 10 V	2 external signals 0 - 10 V
Standard test and documentation	Standard test and documentation
Installation set for the gas and water connections	Installation set for the gas and water connections
Power cable	Power cable
Double-wall culture vessel	Single-wall culture vessel
Stirrer shaft with single-mechanical seal and direct coupling	Heating blanket 120 230 V
2 addition bottles for correction agents	Stirrer shaft with single mechanical seal and direct coupling
Exhaust cooler	1 addition bottle for correction agent
Aeration filters	Exhaust cooler
Rushton impellers	Aeration filters
Ring sparger	3-blade segment impeller
4-way addition port	Microsparger
Inoculation port	4-way addition port
Harvest pipe, height-adjustable	Harvest pipe, height-adjustable
Manual sampler	Manual sampler
Tool set for disassembly of vessel	Tool set for vessel dismantling
Pt100 temperature sensor	Pt100 temperature sensor
pH sensor	pH sensor
DO sensor, amperometric	DO sensor, amperometric

Options

Control System

Advanced DO controller	Double-wall culture vessel
Flexible switching CO₂ from sparger to headspace	Magnetic coupling for drive motor
Software for dual use MO CC	STT connectors for safe inoculation and media transfer
Mass flow controller	Cooling finger (single-wall culture vessels)
Antifoam control via sensor	Spin filter for perfusion mode
Mechanical foam destroyer (MO applications)	Aeration basket for organisms sensitive to shear stress
Level control via sensor	Rushton impellers 3-blade segment impellers
Weight measurement substrates culture vessel	Baffles
Gravimetric feed level control	Bottle holder
Substrate addition via time profile	Adapter for height reduction of exhaust cooler for the autoclave
Redox (ORP) measurement	Inoculation port
BioPAT® Fundalux turbidity measurement	3-way addition port
BioPAT [®] Xgas $O_2 CO_2$ off-gas analysis	Universal adapter ID 3.2 mm
System IQ OQ	Harvest pipe bent for complete draining
BioPAT® MFCS SCADA system	Port adapter 19 mm - 12 mm
	Set of consumables

Univessel® Glass

Germany

USA

Sartorius Stedim Biotech GmbH August-Spindler-Strasse 11 37079 Goettingen Phone +49 551 308 0 Sartorius Stedim North America Inc. 565 Johnson Avenue Bohemia, NY 11716 Toll-Free +1 800 368 7178

For further contacts, visit www.sartorius.com