

Spett.le
Ospedale Pediatrico Bambino Gesù
Piazza S. Onofrio n. 4 00165 Roma
Pec:funzione.legale-contratti@pec.opbg.net

OGGETTO: DETERMINA A CONTRARRE PER L'ESPLETAMENTO DI UNA PROCEDURA NEGOZIATA SENZA PREVIA PUBBLICAZIONE DI UN BANDO DI GARA AI SENSI DELL'ART. 76, COMMA 2, LETT. B), PUNTO 2 DEL D. LGS. 36/2023 PER L'AFFIDAMENTO DELLA FORNITURA DI N. 3 BIOREATTORI SARTORIUS, MODELLI: BIOSTAT® B TWIN CC - UNIVESSEL® SU 2L; BIOSTAT® RM 20 L; BIOSTAT STR® 50L; PIATTAFORMA MFCS 4, NELL'AMBITO DEL PROGETTO "CREAZIONE DI UN CENTRO NAZIONALE PER TERAPIA RNA E TERAPIA GENICA" - CUP E83C22003170001.

Riscontro lettera d'invito con offerta economica

Il sottoscritto Paolo Truzzi Codice fiscale TRZPLA70L31L020I residente a Barberino Tavernelle (FI), in via di Tignano n. 63 in qualità di rappresentante legale della società Sartorius Stedim Italy Srl codice fiscale/Partita IVA 01820860482, numero matricola aziendale INPS 3009429162e INAIL 4281222, con sede sociale in via A. Meucci n. 4 50012 Bagno a Ripoli - Grassina (FI), posta elettronica certificata cs.sartorius@pec.it; iscritta al n.01820860482 del Registro delle Imprese di Firenze; costituita in data 01/07/1981; capitale sociale deliberato, capitale sociale sottoscritto, capitale sociale versato 873.600,00 euro;

avente ha ad oggetto sociale:

commercio all'ingrosso, sviluppo, import-export, produzione ed assistenza pre e post-vendita di prodotti per la filtrazione a membrana e tecnologie affini in campo chimico, microbiologico, farmaceutico, dal 01/07/1981;

Sartorius Stedim Italy S.r.l.
Via A. Meucci, 4
50012 Grassina-Bagno a Ripoli (FI),
Italy

Tel. +39.055.6340500
Fax +39.055.6340526
www.sartorius-stedim.com

PREMESSO

che l'importo a base d'asta dell'appalto è pari ad

Euro 699.408,32 (seicentonovantanovemilaquattrocentotto/32) oltre IVA, ove dovuta;

Cap. Soc. € 873.600 i.v.
R.E.A. 307529
N. Iscrizione Registro Imprese di FI,
Cod. Fiscale e Partita IVA
IT01820860482

Società unipersonale

Società soggetta all'attività di direzione e coordinamento di Sartorius Stedim Biotech GmbH (Goettingen, Germania)
Amministratore Delegato: Paolo Truzzi

DICHIARA

sotto la propria responsabilità ai sensi e per gli effetti degli artt. 46 e 47 del DPR n. 445 del 28.12.2000, consapevole delle responsabilità e delle conseguenze civili e penali a cui può andare incontro in caso di false attestazioni, dichiarazioni mendaci e/o formazione o uso di atti falsi, nonché in caso di esibizione di atti contenenti dati non più corrispondenti a verità ai sensi dell'articolo 76 del DPR n. 445 del 28.12.2000 e degli artt. 483, 495 e 496 del Codice penale:

- 1) di partecipare alla procedura per l'affidamento diretto di materiali consumabili, ai sensi dell'art.50, comma 1, lett. b) del d. lgs. 36/2023, e impegnarsi a fornire i beni indicati nel Capitolato tecnico, al prezzo di Euro 620.000,00 (seicentoventimila/00) oltre IVA, ove dovuta;
- 2) che la presente offerta è irrevocabile ed impegnativa sino al 90 (novantesimo) giorno successivo al termine fissato per la presentazione della stessa;
- 3) che la presente offerta non vincolerà in alcun modo l'Ospedale Pediatrico Bambino Gesù;
- 4) ai fini della tracciabilità dei flussi finanziari (Legge 13/08/2010, n.136) gli estremi identificativi del conto corrente bancario/postale dedicato, anche non in via esclusiva, per le commesse pubbliche è il/i seguente/i IBAN IT441031040280000000820414, che le generalità e il codice fiscale delle persone delegate ad operare sul C/C indicato sono:

Emanuele GUERRA codice fiscale GRRMNL36A30A515Y nato ii 30/01/1936 ad Avezzano (AQ) e residente a Firenze in Piazza Niccolo Tommaseo n°4

Paolo TRUZZI codice fiscale TRZPLA70L31L020I nato ii 31/07/1970 a Suzzara (MN) e residente a Barberino Val D'Elsa (FI) Via di Tignano n°63

Le Man TRUONG codice fiscale 02 38 786 231 019 nata ii 08/10/1977 a Cholon (Vietnam) residente in 166 Boulevard des Acacias - Le Castellet (Francia)

Isabelle LIGUORI codice fiscale 05 32 991116 231 nata ii 17/01/1967 a Paris 13e (Francia) residente in 119 Rue Jules Mou let -13006 Marseille (Francia)

Magali DEGIOANNI codice fiscale 16 33 553 400 353 nata ii 24/05/1981 a Aubagne (Francia) residente in 273 Chemin de Valmejjane -13360 Roquevaire (Francia)

SARTORIUS

Antonella COLIN Codice fiscale 18 94 439 809 311 nata il 11/10/1982 a Ollioules 83 (Francia) Residente in 467 Chemin de la Courtine 83190 OLLIOULES (Francia)

- 5) di assumere tutti gli obblighi previsti nell'art.3 della legge 136/2010, pena la nullità assoluta dell'atto conclusivo.

Firenze, 15/05/2024

Il legale rappresentante
Paolo Truzzi

Documento sottoscritto con firma digitale ai sensi del d.lgs. 7 marzo 2005, n. 82 e del D.P.C.M. 22 febbraio 2013 e ss.mm.ii.

Quotation

No. 2402-GIM-5047-6s

(Please mention with each correspondence)

Biostat® B-Twin 2L SU + Biostat® RM 20/50L + Biostat STR®50L + MFCS 4

To:	OSPEDALE BAMBINO GESU' Michele Veneruso Piazza Sant'Onofrio 4 00165 ROMA Italy Email: michele.veneruso@opbg.net
From:	Sartorius Stedim Italy S.r.l. Via A. Meucci n.4 50012 Grassina - Bagno a Ripoli (Florence) Italy Phone: +39.055.63.40.41 Fax: +39.055.63.40.526
Contact person:	Ms. Daniela Bartocci Phone: 055634041 Email: Daniela.Bartocci@Sartorius.com
Date:	28.02.2024

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Products

Pos 1 1 x Biostat® B Twin CC - UniVessel® SU 2L / 2L 230V



The shown picture is just a product example.

The Biostat® B is a fermenter | bioreactor which has been developed specifically for the varied requirements of biotechnological and biopharmaceutical research and development. With several thousand installations worldwide, Biostat® B is the most successful laboratory fermenter system in its class and is now available in the fourth generation. Various configurations are available for animal, plant and insect cell culture plus microbial fermentation. The system can control one or two vessels, or rocking motion bioreactors completely independent of each other. The controller unit can be combined with our stirred glass vessels (UniVessel® Glass), single-use vessels (UniVessel SU®), or Biostat® RM rockers for use with single use bags. The volumes for our UniVessel® range from 1 L through to 2 L and 5 L up to 10 L. The UniVessel SU® is available as a 2 L polycarbonate vessel. Bags of various sizes for the rocker allow cultivation volumes between 0.1 L to 100 L

The system is tailored towards the specific needs of animal, insect and plant cell cultivation. Impeller and sparger designs of the glass vessels assure an effective gas supply with gentle mixing even for shear sensitive organisms.

Pos 1.1 Scope without optional functions

Basic unit

1 x Control- & Supply Tower Biostat® B, Twin

The benchtop system with easy to clean stainless steel housing features a 12" touch screen for comfortable operation and navigation. The control unit may be controlled locally or via SCADA system.

General set-up:

- Connection of two culture vessels
- IP- class: IP21
- Certified according to CE, UL, CSA, RoHS
- Supervisory control connection via ethernet

Internal features:

- USB port
- Ethernet
- 2 motor connections incl. cable for 200W motor (Univessel® Glass, UniVessel® SU)
- Electrical bond
- Potential free alarm contact for connection to external alarm system, M12
- Check Valve and security valve for gas supply to culture vessel (1 barg for Univessel® Glass and UniVessel® SU, 100 mbarg for RM Rocker)
- Pressure regulator 1,0 barg for utility water inlet (for temperature module, heating/cooling)

1 x Storage Dish

- Placed on top of control tower housing
- Magnetic Connection for quick & easy cleaning

1 x Power cord Type E I/3/16, IP65

Art. no. BB-8847887

- Cable length: 2.5 m

1 x Software Biostat® B

The 5 main menu sections MAIN, TREND, CALIBRATION; CONTROLLER and ALARM provide easy navigation and control of the process.

MAIN

- Overview for all system critical parameters
- Detail view for culture vessel 1 and 2 for Twin systems
- Shortcut to controllers of single system parameters

TREND

Overview on process parameter course. Up to 8 process parameters may be displayed at the same time. Display ranges can be adjusted individually. The displayed range can be defined in 1 h steps between 1 and 72 h. All parameters are displayed in a different colour or easy overview and navigation. BioPAT® MFCS software for data logging of the complete batch is available additionally.

CALIBRATION

The user is graphically guided through the entire calibration routine for pH and DO sensors. Furthermore, totalizer set-ups for rotameters, pumps and mass flow controllers can be adjusted. A re-calibration function enables the user to re-calibrate the pH and DO sensor during the fermentation run.

CONTROLLER

Measurement and control capabilities feature temperature, stirrer speed, rocking rate, rocking angle, pH and DO. Additional options such as gasmix, gas flow control, foam control, level control as well as various possibilities for substrate addition and control for fed batch and continuous processes can be integrated based on the chosen configuration. All controller outputs may be limited and setpoints can be combined with an alarm function. PID settings may be adjusted by the user as well.

ALARM

- for process parameters
- for setpoint overshoots
- Listing of all occurred alarms
- potential free alarm output for external alarm systems

Additional Features:

- Security shut down for heating system in case of overheating
- Password protection for all controller outputs
- Manual control of all controller outputs
- Control via external remote PC
- Shutdown function for all process controllers

Please note:

The software package is configured according to the delivered hardware set-up, this may cause deviations to the description above.

Left side of control tower

Connectivity to cultivation chamber

1 x Connection to UniVessel® SU culture vessel for cell culture applications

- Connection to UniVessel® SU culture vessel
- The system is specifically suited for mammalian, insect or plant cell culture

DO control

General

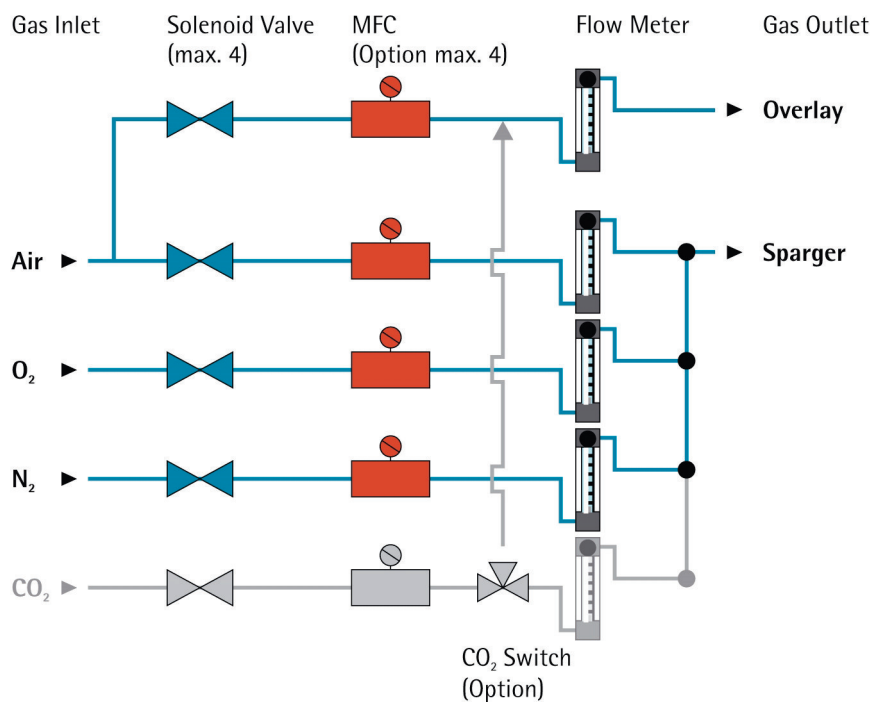
1 x DO Control ADVANCED - cell culture

- DO control with parallel control of multiple actuators
- Up to 5 actuators can be activated at the same time
- Individual flow rate control of each actuator based on DO controller output
- Individual setting of min and max controller output for each actuator

1 x Optical DO measurement UniVessel SU

- Display of the optical measured DO value in controller menu
- communication with UniVessel SU optical holder via serial interface

1 x Gassing Module Additive Flow 5-gas



Picture shows all possible options. Depending on the specific configuration, the amount of massflow controllers and solenoid valves may be reduced. Please check the details below for the actual system configuration.

- Gassing module designed for mammalian, plant- and insect cell culture, as well as microbial fermentation
- Check Valve and Shut-off valve
- Automatic gasmix via DO Controller

1 x 3/2 way solenoid valve CO₂

- Re-direction of CO₂ flow from sparger to overlay
- Activation on demand via touch key

Air Overlay

1 x Flow meter 0.16 – 1.6 lpm (l/min), Scale 65 mm
Art. no. BB-8847703

- Calibrated with air (standard conditions, 1.21 bara)
- precision control valve

1 x Mass flow controller II, 0.03–1.5 slpm (Air/N₂) 24 V
Art. no. BB-8847739

- Thermal flow measurement
- Calibrated for Air/N₂

Air Sparger

1 x Flow meter 33 – 333 ccm (ml/min), Scale 65 mm
Art. no. BB-8847690

- Calibrated with air (standard conditions, 1.21 bara)
- precision control valve

1 x Mass flow controller II, 6–300 sccm (Air/N₂)
Art. no. BB-8804106

- Thermal flow measurement
- Calibrated for Air/N₂

O₂ Sparger

1 x Flow meter 16 – 166 ccm (ml/min), Scale 65 mm
Art. no. BB-8847681

- Calibrated with air (standard conditions, 1.21 bara)
- precision control valve

1 x Mass flow controller II, 2–100 sccm (O₂)
Art. no. BB-8804134

- Thermal flow measurement
- Calibrated for O₂

N₂ Sparger

1 x Flow meter 33 – 333 ccm (ml/min), Scale 65 mm
Art. no. BB-8847690

- Calibrated with air (standard conditions, 1.21 bara)
- precision control valve

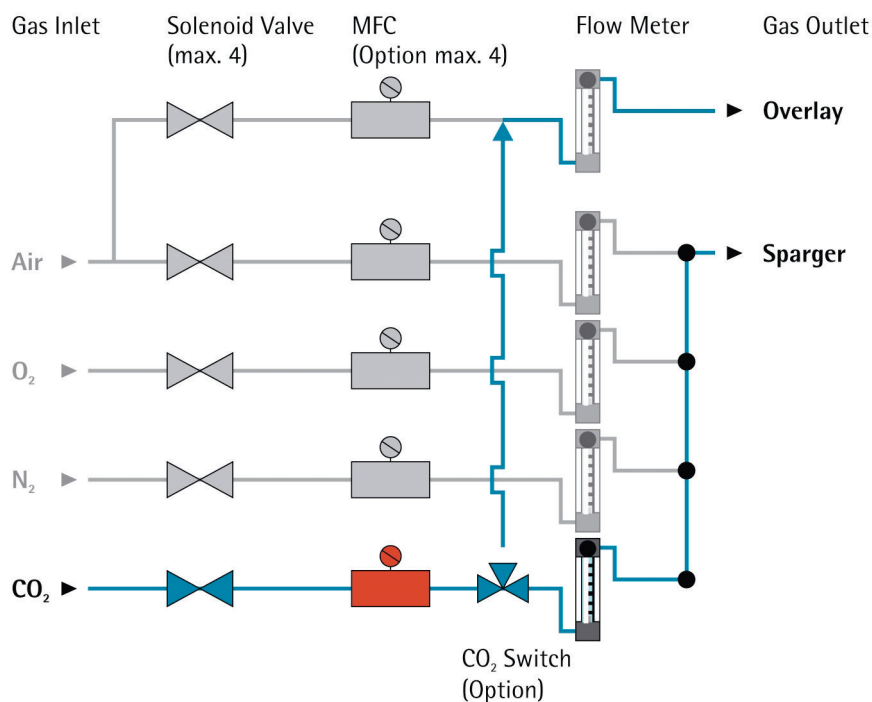
1 x Solenoid Valve N₂ Sparger

- for pulsed gas supply to sparger
- controlled by DO controller

pH control

General

1 x pH Control CO₂ / Base



Picture shows all possible options. Depending on the specific configuration, the amount of massflow controllers and solenoid valves may be reduced. Please check the details below for the actual system configuration.

- pH control via base addition with peristaltic pump and CO₂ gassing with solenoid valve or optional mass flow controller
- Measurement range pH 2 - 12 (optical sensors pH 6.5 - 8.5)

1 x Optical pH measurement UniVessel SU

- Display of the optical measured pH value in controller menu
- communication with UniVessel SU optical holder via serial interface

Base

1 x Integrated Pump WM114, 44 rpm

- Fixed speed (on/off controlled)

1 x Storage bottle 250 ml

Art. no. BB-8823600

Autoclavable

Consist of:

- glass bottle
- head piece with two hose connectors for 3.2 x 1.6 mm tubing
- screw cap with silicone gasket
- aeration filter 0.2 µm
- PTFE-tubing

CO₂ Sparger

1 x Flow meter 16 - 166 ccm (ml/min), Scale 65 mm

Art. no. BB-8847681

- Calibrated with air (standard conditions, 1.21 bara)
- precision control valve

1 x Mass flow controller II, 2-100 sccm (CO₂)

Art. no. BB-8804164

- Thermal flow measurement
- Calibrated for CO₂

Feed 1

1 x Substrate Addition via pump

- Substrate controller
- Addition via speed controlled peristaltic pump
- Totalizer
- Time-based setpoint profiles for substrate controller
- Rotation speed of pump is entered in % based on controller output

1 x Integrated pump WM114, 0.15-5 rpm

- speed controlled

1 x Storage bottle 250 ml

Art. no. BB-8823600

Autoclavable

Consist of:

- glass bottle
- head piece with two hose connectors for 3.2 x 1.6 mm tubing
- screw cap with silicone gasket
- aeration filter 0.2 µm
- PTFE-tubing

Feed 2

1 x Substrate Addition via pump

- Substrate controller
- Addition via speed controlled peristaltic pump
- Totalizer
- Time-based setpoint profiles for substrate controller
- Rotation speed of pump is entered in % based on controller output

1 x Integrated pump WM114, 0.15-5 rpm

- speed controlled

1 x Storage bottle 250 ml

Art. no. BB-8823600

Autoclavable

Consist of:

- glass bottle
- head piece with two hose connectors for 3.2 x 1.6 mm tubing
- screw cap with silicone gasket
- aeration filter 0.2 µm
- PTFE-tubing

Level control

1 x Weight Measurement Culture Vessel

- Measurement and display of weight on control unit touch screen

1 x Sartorius Balance System 60 kg for DCU (IE11172)

Art. no. BB-8843513

- Weight indication on balance display and DCU display
- Taring in bioreactor control system (taring via balance deactivated)
- Max. load: 60 kg
- Resolution: 10 g
- Stainless steel platform
- Platform dimensions: 400 x 300 mm
- Incl. connection cable

Tempering

1 x Temperature module for UniVessel®

- Electrical heater
- Cooling water control valve for optional cooling finger
- Connections for optional cooling finger
- Connections for exhaust cooler

Mixing

1 x Agitation Motor Direct Coupling

- Agitation Drive with integrated controller
- * Maintenance free
- * 200 Watt
- for culture vessel with direct coupling

External Signals

1 x Two External Signal Inputs 0-10V

- For connection of external measurement devices
- Range 0-100%
- Display of signal in controller menu

1 x Two External Signal Inputs 4-20mA

- For connection of external measurement devices
- Range 0-100%
- Display of signal in controller menu

Right side of control tower

Connectivity to cultivation chamber

1 x Connection to UniVessel® SU culture vessel for cell culture applications

- Connection to UniVessel® SU culture vessel
- The system is specifically suited for mammalian, insect or plant cell culture

DO control

General

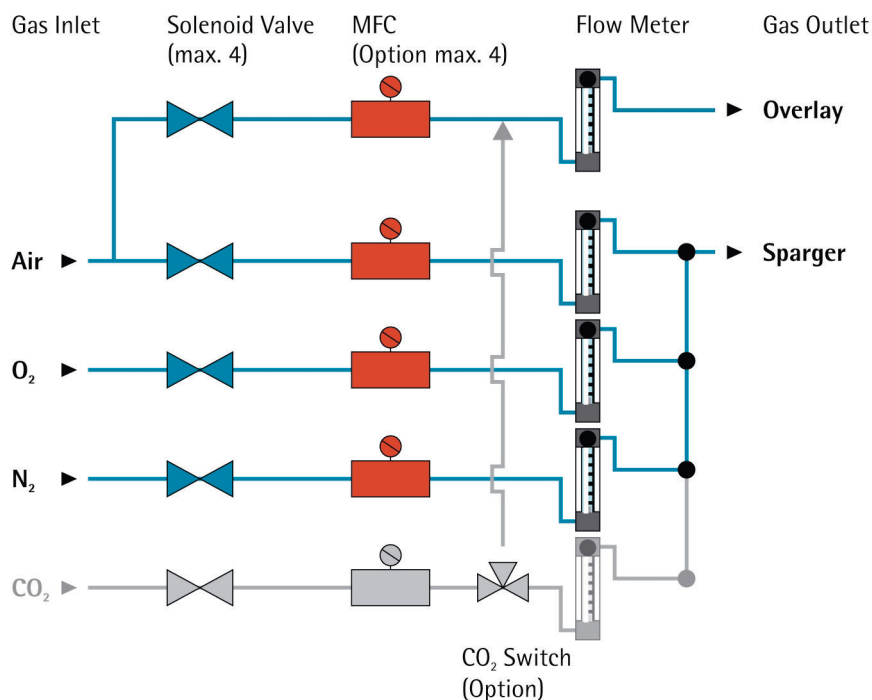
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- Individual setting of min and max controller output for each actuator

1 x Optical DO measurement UniVessel SU

- Display of the optical measured DO value in controller menu
- communication with UniVessel SU optical holder via serial interface

1 x Gassing Module Additive Flow 5-gas



Picture shows all possible options. Depending on the specific configuration, the amount of massflow controllers and solenoid valves may be reduced. Please check the details below for the actual system configuration.

- Gassing module designed for mammalian, plant- and insect cell culture, as well as microbial fermentation
- Check Valve and Shut-off valve
- Automatic gasmix via DO Controller

1 x 3/2 way solenoid valve CO₂

- Re-direction of CO₂ flow from sparger to overlay
- Activation on demand via touch key

Air Overlay

1 x Flow meter 0.16 - 1.6 lpm (l/min), Scale 65 mm Art. no. BB-8847703

- Calibrated with air (standard conditions, 1.21 bara)
- precision control valve

1 x Mass flow controller II, 0.03-1.5 slpm (Air/N₂) 24 V Art. no. BB-8847739

- Thermal flow measurement
- Calibrated for Air/N₂

Air Sparger

1 x Flow meter 33 - 333 ccm (ml/min), Scale 65 mm Art. no. BB-8847690

- Calibrated with air (standard conditions, 1.21 bara)
- precision control valve

1 x Mass flow controller II, 6-300 sccm (Air/N₂) Art. no. BB-8804106

- Thermal flow measurement
- Calibrated for Air/N₂

O₂ Sparger

1 x Flow meter 16 - 166 ccm (ml/min), Scale 65 mm Art. no. BB-8847681

- Calibrated with air (standard conditions, 1.21 bara)
- precision control valve

1 x Mass flow controller II, 2-100 sccm (O₂) Art. no. BB-8804134

- Thermal flow measurement
- Calibrated for O₂

N₂ Sparger

1 x Flow meter 33 - 333 ccm (ml/min), Scale 65 mm Art. no. BB-8847690

- Calibrated with air (standard conditions, 1.21 bara)
- precision control valve

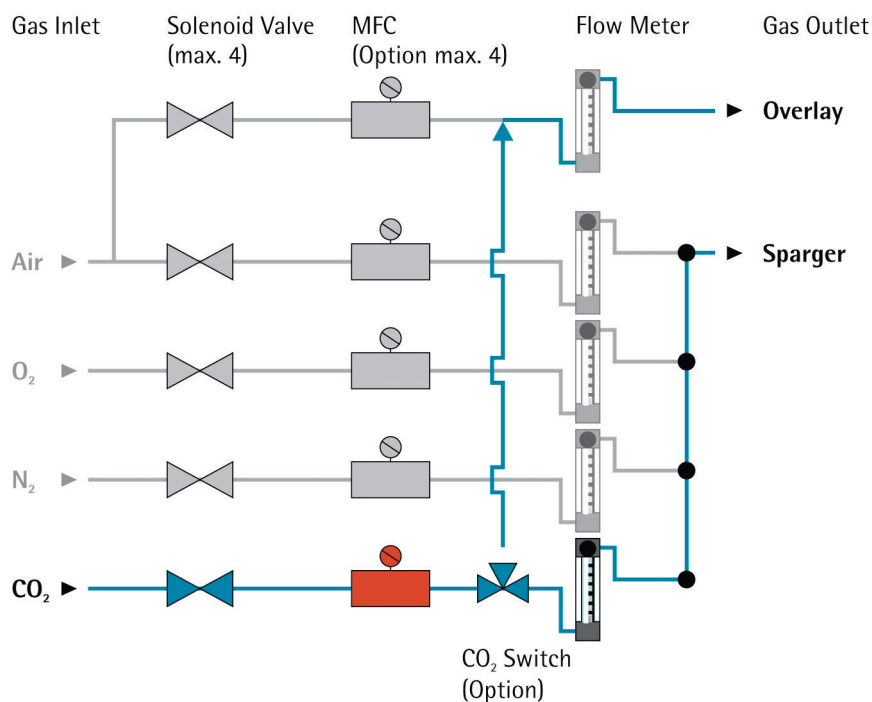
1 x Solenoid Valve N₂ Sparger

- for pulsed gas supply to sparger
- controlled by DO controller

pH control

General

1 x pH Control CO₂ / Base



Picture shows all possible options. Depending on the specific configuration, the amount of massflow controllers and solenoid valves may be reduced. Please check the details below for the actual system configuration.

- pH control via base addition with peristaltic pump and CO₂ gassing with solenoid valve or optional mass flow controller
- Measurement range pH 2 - 12 (optical sensors pH 6.5 - 8.5)

1 x Optical pH measurement UniVessel SU

- Display of the optical measured pH value in controller menu
- communication with UniVessel SU optical holder via serial interface

Base

1 x Integrated Pump WM114, 44 rpm

- Fixed speed (on/off controlled)

1 x Storage bottle 250 ml

Art. no. BB-8823600

Autoclavable

Consist of:

- glass bottle
- head piece with two hose connectors for 3.2 x 1.6 mm tubing
- screw cap with silicone gasket
- aeration filter 0.2 µm
- PTFE-tubing

CO₂ Sparger

1 x Flow meter 16 - 166 ccm (ml/min), Scale 65 mm

Art. no. BB-8847681

- Calibrated with air (standard conditions, 1.21 bara)
- precision control valve

1 x Mass flow controller II, 2-100 sccm (CO₂)

Art. no. BB-8804164

- Thermal flow measurement
- Calibrated for CO₂

Feed 1

1 x Substrate Addition via pump

- Substrate controller
- Addition via speed controlled peristaltic pump
- Totalizer
- Time-based setpoint profiles for substrate controller
- Rotation speed of pump is entered in % based on controller output

1 x Integrated pump WM114, 0.15-5 rpm

- speed controlled

1 x Storage bottle 250 ml

Art. no. BB-8823600

Autoclavable

Consist of:

- glass bottle
- head piece with two hose connectors for 3.2 x 1.6 mm tubing
- screw cap with silicone gasket
- aeration filter 0.2 µm
- PTFE-tubing

Feed 2

1 x Substrate Addition via pump

- Substrate controller
- Addition via speed controlled peristaltic pump
- Totalizer
- Time-based setpoint profiles for substrate controller
- Rotation speed of pump is entered in % based on controller output

1 x Integrated pump WM114, 0.15-5 rpm

- speed controlled

1 x Storage bottle 250 ml

Art. no. BB-8823600

Autoclavable

Consist of:

- glass bottle
- head piece with two hose connectors for 3.2 x 1.6 mm tubing
- screw cap with silicone gasket
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Level control

1 x Weight Measurement Culture Vessel

- Measurement and display of weight on control unit touch screen

1 x Sartorius Balance System 60 kg for DCU (IE11172)

Art. no. BB-8843513

- Weight indication on balance display and DCU display
- Taring in bioreactor control system (taring via balance deactivated)
- Max. load: 60 kg
- Resolution: 10 g
- Stainless steel platform
- Platform dimensions: 400 x 300 mm
- Incl. connection cable

Tempering

1 x Temperature module for UniVessel®

- Electrical heater
- Cooling water control valve for optional cooling finger
- Connections for optional cooling finger
- Connections for exhaust cooler

Mixing

1 x Agitation Motor Direct Coupling

- Agitation Drive with integrated controller
- * Maintenance free
- * 200 Watt
- for culture vessel with direct coupling

External Signals

1 x Two External Signal Inputs 0-10V

- For connection of external measurement devices
- Range 0-100%
- Display of signal in controller menu

1 x Two External Signal Inputs 4-20mA

- For connection of external measurement devices
- Range 0-100%
- Display of signal in controller menu

Cultivation chamber

1 x left: UniVessel® SU 2L



The shown picture is just a product example.

The UniVessel® SU is a single-use bioreactor available with a working volume range of 0.6 to 2L. It is assembled, irradiated and shipped ready-to-use. Moreover, it comes with single-use pH and DO sensors that further reduce the preparation time required to an absolute minimum; for more runs with your available lab resources in process validation, process optimization and process development.

General

1 x UniVessel® SU 2L, CC 2, (2 pieces)
Art. no. DU0002LL-SS01--V

Single use bioreactor for cell cultivation.

Consists of:

- 2 x Single wall vessel with torospherical bottom, self standing
- Lid with tube holders
- Stirrer shaft with lip seal and bearings
- 2 x 3-blade segment impeller (down flow)

Lid ports:

- 3 x Sensor port pG 13.5, removable blind plugs with O-ring sealing
- Head space aeration, silicon tubing with Midisart® BV 0.2 µm sterile filter
- Aeration tube with L-Sparger, silicon tubing with Midisart® BV 0.2 µm sterile filter
- Exhaust port, C-flex® with Y-piece and 2 x silicon tubing with Midisart® BV 0.2 µm sterile filter
- Sampling tube with needle free sampling system
- Addition port 1: C-flex®, 1/8" x 1/4", 900 mm, Male Luer Lock 1/8"
- Addition port 2: C-flex®, 1/4" x 7/16", 900 mm, Female MPC Lock 1/4"
- Addition port 3: C-flex®, 1/8" x 1/4", 900 mm, Female Luer Lock 1/8"
- Dip tube 1: C-flex®, 1/8" x 1/4", 900 mm, Female Male Luer Lock 1/8"
- Dip tube/ Harvest 2: C-flex®, 1/4" x 7/16", 900 mm, Male MPC Lock 1/4"
- Dip tube 3: C-flex®, 1/8" x 1/4", 900 mm, Male Luer Lock 1/8"
- thermowell for insertion of a temperature sensor

Bottom:

- Single use pH-sensor patch
- Single use DO-sensor patch

Items per unit: 2 x UniVessel® SU, irradiated, single removable

1 x UniVessel® SU holder, optical
Art. no. DZ-----VHC

- vessel holder for optimal stability of UniVessel® SU during operation
- integrated opto-electronic for optical pH and DO measurement
- incl. connection cable

1 x UniVessel® SU holder adaptor ring 2L
Art. no. DZ002L---VHI-01

1 x Motor adaptor UniVessel® SU
Art. no. DZ-----MB

- Applicable for Biostat® B (since 2012), Bplus, B-DCU, B-DCU II

1 x Pressure relief unit, UniVessel® SU
Art. no. DZ-----VE2

- Bench top unit for safe operation of the UniVessel® SU
- 1 x safety valve for overlay
- 1 x safety valve for sparger
- Set pressure safety valves: 0.5 barg
- Connection: 6 mm OD hose barb

1 x Heating blanket UniVessel® SU 2L

Art. no. BB-8840341

- Heat output: 200 W
- Insulation material: silicone
- Overheat protection
- Plug: Amphenol eco|mate 6-pol +PE
- Connection cable: 1 m

1 x Filter heater UniVessel® SU, Size 1

Art. no. DZ-----FH1

- Filter heater for heating the exhaust filter, Midisart
- including support for optimal fixation of the exhaust line
- including multi-voltage power supply

6 mm port accessories

1 x Pt100 with thermowell (pocket), 211/6-M12-1m

Art. no. BB-8848649

- Pt100 temperature sensor with pocket
- Sensor length: 211 mm
- Connector: M12
- Connection cable: 1 m

1 x right: UniVessel® SU 2L



The shown picture is just a product example.

The UniVessel® SU is a single-use bioreactor available with a working volume range of 0.6 to 2L. It is assembled, irradiated and shipped ready-to-use. Moreover, it comes with single-use pH and DO sensors that further reduce the preparation time required to an absolute minimum; for more runs with your available lab resources in process validation, process optimization and process development.

General

1 x UniVessel® SU 2L, CC 2, (2 pieces)
Art. no. DU0002LL-SS01--V

Single use bioreactor for cell cultivation.

Consists of:

- 2 x Single wall vessel with torospherical bottom, self standing
- Lid with tube holders
- Stirrer shaft with lip seal and bearings
- 2 x 3-blade segment impeller (down flow)

Lid ports:

- 3 x Sensor port pG 13.5, removable blind plugs with O-ring sealing
- Head space aeration, silicon tubing with Midisart® BV 0.2 µm sterile filter
- Aeration tube with L-Sparger, silicon tubing with Midisart® BV 0.2 µm sterile filter
- Exhaust port, C-flex® with Y-piece and 2 x silicon tubing with Midisart® BV 0.2 µm sterile filter
- Sampling tube with needle free sampling system
- Addition port 1: C-flex®, 1/8" x 1/4", 900 mm, Male Luer Lock 1/8"
- Addition port 2: C-flex®, 1/4" x 7/16", 900 mm, Female MPC Lock 1/4"
- Addition port 3: C-flex®, 1/8" x 1/4", 900 mm, Female Luer Lock 1/8"
- Dip tube 1: C-flex®, 1/8" x 1/4", 900 mm, Female Male Luer Lock 1/8"
- Dip tube/ Harvest 2: C-flex®, 1/4" x 7/16", 900 mm, Male MPC Lock 1/4"
- Dip tube 3: C-flex®, 1/8" x 1/4", 900 mm, Male Luer Lock 1/8"
- thermowell for insertion of a temperature sensor

Bottom:

- Single use pH-sensor patch
- Single use DO-sensor patch

Items per unit: 2 x UniVessel® SU, irradiated, single removable

1 x UniVessel® SU holder, optical
Art. no. DZ-----VHC

- vessel holder for optimal stability of UniVessel® SU during operation
- integrated opto-electronic for optical pH and DO measurement
- incl. connection cable

1 x UniVessel® SU holder adaptor ring 2L
Art. no. DZ002L---VHI-01

1 x Motor adaptor UniVessel® SU
Art. no. DZ-----MB

- Applicable for Biostat® B (since 2012), Bplus, B-DCU, B-DCU II

1 x Pressure relief unit, UniVessel® SU
Art. no. DZ-----VE2

- Bench top unit for safe operation of the UniVessel® SU
- 1 x safety valve for overlay
- 1 x safety valve for sparger
- Set pressure safety valves: 0.5 barg
- Connection: 6 mm OD hose barb

1 x Heating blanket UniVessel® SU 2L

Art. no. BB-8840341

- Heat output: 200 W
- Insulation material: silicone
- Overheat protection
- Plug: Amphenol eco|mate 6-pol +PE
- Connection cable: 1 m

1 x Filter heater UniVessel® SU, Size 1

Art. no. DZ-----FH1

- Filter heater for heating the exhaust filter, Midisart
- including support for optimal fixation of the exhaust line
- including multi-voltage power supply

6 mm port accessories

1 x Pt100 with thermowell (pocket), 211/6-M12-1m

Art. no. BB-8848649

- Pt100 temperature sensor with pocket
- Sensor length: 211 mm
- Connector: M12
- Connection cable: 1 m

Documentation/Qualification

1 x Documentation package Biostat® B (Level 0)

Documentation binder, containing one hard copy each of:

- Operating Manual
- CE Declaration of Conformity / NRTL certificate
- Quality Assurance Certificate
- Consumable list

Electronic documentation (on CD/DVD), comprising

- Operating Manual
- CE Declaration of Conformity
- Quality assurance certificate
- Consumable list

1 x Level 1 Qualification Biostat® B Twin

Extended "as built" documentation package

Documents are supplied either as hardcopy or on CD

Including:

- Training certificates of tester
- P&I diagram
- Wiring diagram
- Major component list

Utility requirements and power supply

1 x Mains Connection 230V

for BIOSTAT® B

1 x Gasses: regulated 1,5 barg (oil- and particle- free, dry)

1 x Water: regulated 2 - 4 barg (12 dH), gravity drain at ambient pressure

Advanced Services

1 x Advanced Order Execution for 1 Biostat® B

Advanced order execution service with dedicated project coordinator as primary contact person for internal organization, coordination, scheduling, monitoring and commercial handling.

Advanced Order Execution

1 x Advanced Order Execution Service - on request

Advanced Order Execution is not included in delivery. On request, we would be glad to submit a separate offer. Please address to your sales representative.

Frequently requested optional extras for Biostat® B Twin CC - UniVessel® SU 2L / 2L 230V

A demonstration or trial is available upon request.
Please contact your local account manager for more details.

<https://www.sartorius.com/en/products/process-analytical-technology/sensors-analyzers>



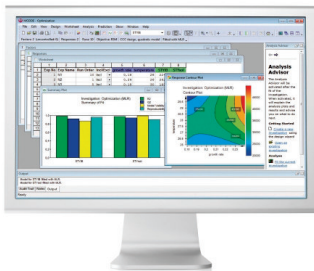
Automated Glucose feed control

Measurement & control of key nutrients during cell culture growth



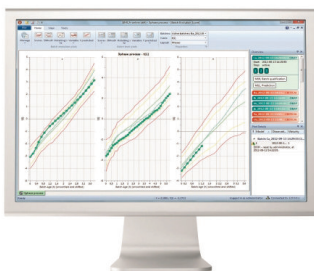
Advanced Metabolic respiration control

Measurement & control of cell activity based on exhaust gas analysis



DoE screening with advanced process analytics for cell culture

Linking key performance parameters to critical quality attributes through designed experiments



Academic software packages

Discounted price for Universities on Chemometrics packages for higher process understanding

Pos 2 1 x Installation in Italy for 1 Biostat® B

The reliability and the service life of your equipment significantly depend on its installation and configuration according to the specifications. Installation and commissioning by our service professionals will ensure that your system successfully operates right from the start.

Pos 2.1 Scope without optional functions

Installation

1 x Installation, Biostat® B Twin

Art. no. S8759INSTP

Installation by a qualified technician

Scope of service:

Unpacking and Verification of Contents

System assembly and utilities connection

Start-up test

Brief operator instruction

Note:

Package Price, all expenses e.g. for travelling and charges are included.

With several units the package price is valid only if the systems are installed at the same time and at a common site.

Pos 3 1 x Biostat® RM 20 230V



The shown picture is just a product example.

The Biostat® RM is the new industrial platform that includes Biobrain® based control tower and rocking motion bioreactor. The Biostat® RM is a bioreactor which has been developed specifically for the varied requirements of biotechnological and biopharmaceutical research and development, as well as seed train expansion needs in the commercial manufacturing area. Various configurations are available for fed-batch, N-1 perfusion and intensified processes. It can be configured as a single unit (1 control tower and 1 rocker) with single bag configuration. The controller unit can be combined with our RM 20|50 or RM 200 rocker. The working volume spans between 0.1 L and 100 L. Various additional peripherals can be added to the system to get better control of the cultivation process.

Pos 3.1 Scope without optional functions

Basic Unit

1 x Biostat® RM Control Tower

The system with easy to clean stainless steel housing features a 17" touch screen for comfortable operation and navigation. The control tower may be operated locally through the Biobrain® platform or via SCADA system.

General set-up:

- Connection of one rocking motion system
- IP-class: IP54
- Certified according to CE, UL (EN 61010, EN 60204), CSA, RoHS
- Automation through Siemens ET200 IO
- Supervisory control connection via ethernet

Internal features:

- USB port
- Ethernet
- Potential free alarm contact for connection to external alarm system, M12

Temperature

- Temperature module RM Rocker, heating only
- Electrical heating mat for temperatures up to 40°C

Gassing Module Additive Flow 4-Gas

- Gassing module for mammalian, plant and insect cell culture or microbial fermentation for RM Rocker
- Check valves and security valve (100 mbar for RM Rocker) for gas supply to rocking motion system
- 4 Mass flow controllers (Air, N₂, O₂, CO₂) with 1:200 flow ranges
- Automatic gas mixing via pO₂- and pH- controllers

DO Control Advanced

- DO control with parallel control of multiple actuators
- Up to 4 actuators (Air-, O₂-, N₂-overlay and Rocks) can be activated at the same time. The Rock Controller can be controlled by rocking rate and angle.
- Individual flow rate control of each actuator based on DO controller output
- Individual setting of min and max controller output for each actuator

Optical DO measurement RM Bag

- Measurement of DO value using the optical DO sensors integrated in the bag
- Display of the optically measured DO value on the Control Tower display
- Calibration of the probes
- Inline recalibration
- Measurement range 0 - 250% | 0.1%

pH Control

- Measurement of pH value using the optical pH sensors integrated in the bag
- Display of the optically measured pH value in the display
- Calibration of the probes
- Inline recalibration

Single-use pH measurement RM Bag

- Measurement range: 4.0 - 10.0 pH | 0.1 pH

- Recommended working range: 6.0 - 8.0 pH | 0.1 pH

External Signals

- Two external signal inputs 4-20 mA and two external signal inputs 0-10 V
- For connection of external measurement devices
- Range 0.0-100.0%
- Display of signal in controller menu

1 x Two Internal Pumps

- Speed controlled peristaltic pumps WM114
- Speed range: 0.15-200 rpm
- Rotation speed of pump is entered in % based on controller output
- Clockwise (CW) and Counterclockwise (CCW) rotation

If the internal pumps are used for substrate addition, then:

- Totalizer
- Time-based setpoint profiles for substrate controller

1 x Biobrain® GMP Expert

This option provides required functionalities to support execution in a GMP environment as a stand-alone system, including:

- user management (local or domain connectivity)
- audit trail
- up to one year data historization
- archiving of process data, audit trail, alarms
- creation and export of batch report from Biobrain® including audit trail
- approval workflow for excuted batch (support e-signature for both review and approval of batch reports)

1 x Back-up and Restore Software for Biobrain®

The SIMATIC IPC Image & Partition software powered by Siemens provides the capability to create back-ups of one Biobrain® instrument and restore this image in case of failure.

Delivery includes:

- Delivery of SIMATIC IPC Image & Partition software on a USB stick
- Software license is limited to one Biobrain® installation
- No possibility to install the software on the server
- User manual

Feed | Harvest | Bleed

1 x Interface for BioPAT® Viamass Measurement - Viable Cell Volume Measurement

- Display of output parameters on control tower screen: Biomass, Capacitance, Conductivity
- All software drivers and interfaces are integrated in Biobrain® platform

Gas Supply - via Overlay

Air Overlay

1 x Mass flow controller Air, 0.015 - 3 lpm

- Thermal flow measurement
- Calibrated for air

O₂ Overlay

1 x Mass flow controller O₂, 0.015 - 3 lpm

- Thermal flow measurement
- Calibrated for O₂

N₂ Overlay

1 x Mass flow controller N₂, 0.015 - 3 lpm

- Thermal flow measurement
- Calibrated for N₂

CO₂ Overlay

1 x Mass flow controller CO₂, 0.005 - 1 lpm

- Thermal flow measurement
- Calibrated for CO₂

External Hardware

BioPAT® Viamass

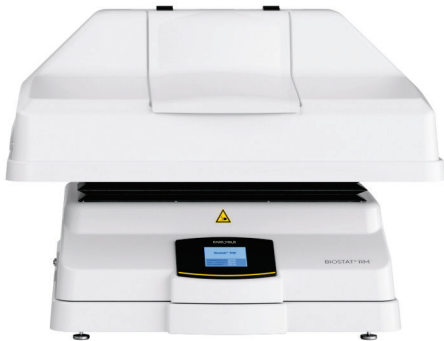
1 x BioPAT® Viamass - Viable Cell Volume Measurement - Hardware for Biostat® RM

- BioPAT® Viamass electronic for single-user bioreactors
- Incl. cable adapter for connection to control tower, electronics holder and electrical grounding

1 x Signal Simulator kit for BioPAT® Viamass

Signal Simulator Set with 2 different values: 0 pF/0 mS/cm and 100 pF/40 mS/cm

Rocker Platform



The shown picture is just a product example.

1 x Biostat® RM 20 Rocker, Including Load Cells

- Dimensions:
 - * W x H x D: 756 x 562 x 662 mm (29.8 x 22.1 x 26.1 inch)
 - * Weight: 39 kg
- Rocking rate|angle
 - * Rocking angle: 4 - 10 degrees
 - * Rocking rate: 8 - 42 rocks/min
- Temperature control system for temperature up to 40°C
- Use of only 1 bag per rocking motion system
- Weight control of the vessel via load cells

- 1 x Filter heater for Flexsafe® RM exhaust filter
 - * Material: polycarbonate
 - * 24 V | 8 W
 - * Magnetic closure

- LED-Screen
- 1 x Pt100 surface temperature sensor for RM
- Power supply: 120V - 230 V | 50-60 Hz
- Color coded plugs
- Country specific power cord

Documentation/Qualification

1 x Standard Documentation Package (Level 0+1)

Documents are supplied either as hardcopy or on CD.

Including:

- Operating Manual
- CE Declaration of Conformity / NRTL certificate
- Quality Assurance Certificate
- Consumable list
- P&I diagram
- Wiring diagram
- Major component list
- Certificates of mass flow controllers

Advanced Services

Advanced Order Execution

1 x Advanced Order Execution for 1 Biostat® RM

Advanced order execution service with dedicated project coordinator as primary contact person for internal organization, coordination, scheduling, monitoring and commercial handling.

Advanced Order Execution

1 x Advanced Order Execution Service - on request

Advanced Order Execution is not included in delivery. On request, we would be glad to submit a separate offer. Please address to your sales representative.

Pos 4 1 x Installation in Italy for 1 Biostat® RM

The reliability and the service life of your equipment significantly depend on its installation and configuration according to the specifications. Installation and commissioning by our service professionals will ensure that your system successfully operates right from the start.

Pos 4.1 Scope without optional functions

Installation

1 x Installation, Biostat® RM 20/50 Biobrain
Art. no. S874UINSTP

Installation by a qualified technician

Scope of service:

Unpacking and Verification of Contents
System assembly and utilities connection
Start-up test
Brief operator instruction

Note:

The system must be unpacked and set in final position by client, witnessed by Sartorius Stedim Engineer.
Package Price, all expenses e.g. for travelling and charges are included.
With several units the package price is valid only if the systems are installed at the same time and at a common site.

Pos 5 Accessories

In Section Accessories any component, independent from a product configuration, can be added to the quotation.

Accessories will be quoted independently from a product configuration. These parts will be delivered separately, without integration into a system.

Pos 5.1	1 x White lid for Bag Holder 50 Art. no. DS050L-R2WL	1.360,00 EUR
Pos 5.2	1 x Bag Holder 50 Art. no. DZ050L-R2BH For 50 L RM Rocker or WB Bags	2.770,00 EUR

Pos 6 1 x Biostat STR® Generation 3 CC Single 50L 400V



The shown picture is just a product example.

The Biostat STR® is a fully scalable, single-use bioreactor based on a conventional stirred-tank design, specially configured for cell culture applications in process development and clinical or commercial manufacturing for e.g. antibodies, recombinant proteins or vaccines.

The system consists of a stainless steel bag holder, a single-use STR® cultivation bag and a control tower for local control via touch screen. The bag holder and the control tower are both separate mobile skids for flexible arrangement in your lab. In order to organize your production and lab environment we offer the Media Control Hub which comes with additional organizational tools. The concerted contribution of new automation platform and hardware design leads to the highest level of flexibility and modularity for PD and commercial manufacturing systems.

The integrated, automatically-controlled gas mixing system provides an advanced sparger and overlay aeration. You choose whether you would like to work with single-use or conventional pH and DO sensors.

The Biostat STR® control system runs on Biobrain®, an industrial automation platform, based on Siemens components, which fully conforms to ANSI-88 industrial standards. Biobrain® includes an integrated native OPC-UA server, which provides a standard interface for connectivity to superordinate systems (such as OSI-PI).

As a turn-key SCADA solution, BioPAT® MFCS software can also monitor and control your Biostat STR® bioreactors extending your system with recipe control, sample management and historization capabilities.

The design of the Biostat STR® and Flexsafe STR® single-use bioreactor bags supports applications ranging from simple Batch processes to Fed-Batch and Intensified Perfusion.

Pos 6.1 Scope without optional functions

BASIC UNIT

1 x Control tower Biostat STR® with Biobrain® Soft PLC

The Biostat STR® Control Tower with Biobrain® automation has an easy to clean stainless steel housing and features a 22" touch screen for comfortable operation and navigation. The design is independent of bagholder size, improving facility flexibility. The control unit follows ANSI-88 principles with a user friendly HMI that can be controlled locally and via our own MFCS SCADA system. Furthermore a native OPC-UA interface allows integration into DCS systems and data transfer to historian systems.

Set-up:

- Main switch
- Siemens Soft PLC SIMATIC IPC
- Installed on mobile skid
- Connection of one culture vessel (bagholder)
- Design is independent of bagholder size allowing for interchangeable connection to different bagholders (additional bagholders can be purchased as retrofit)
- Certified according to CE, NRTL (UL/CSA) , RoHS
- Supervisory control connection via ethernet
- Communication with balances or printer via RS232 connection
- Three internal pumps at front of cabinet always included (2x digital, 1x analog)
- Connectors for sensors and process I/O cables
- All transmitters and interfaces are on board. Exception: pH single-use optical transmitter is optional. 2nd optical pH and DO transmitters are optional.
- Dimensions WxHxD: 800 x 1980 x 850 [mm]
- Weight: max. 240 kg

1 x Document Tray for Biostat STR®

Stainless steel panel to attach to the Biostat STR® Control Tower horizontal systems rails. Can act as a document shelf or storage depending on position of attachment. It is possible to use 2 panels side by side to increase storage area.

1 x Biobrain® GMP Basic

This option provides a set of functionalities to support execution in a GMP environment such as user management (local or domain based), audit trail and archiving. Connection to superordinate systems such as BioPAT® MFCS is required for full GMP functionalities such as batch report and approval.

1 x Back-up and Restore Software for Biobrain®

The SIMATIC IPC Image & Partition software powered by Siemens provides the capability to create back-ups of one Biobrain® instrument and restore this image in case of failure.

Delivery includes:

- Delivery of SIMATIC IPC Image & Partition software on a USB stick
- Software license is limited to one Biobrain® installation
- No possibility to install the software on the server
- User manual

Left side of control tower

Configuration

1 x Configuration package Performance

Configuration package Performance for advanced process applications - state-of-the-art industrial automation platform

- control tower with traffic light and standard Soft PLC or optional Hard PLC
- NEMA 4X protection level and UL508A certified
- 3 internal pumps (2x digital, 1x analog).
- Interfaces are active for up to 8 external feed pumps, up to 4 balances, and includes 4 gravimetric flow controllers.
- System includes amplifiers for 1 single-use optical DO and 1 electrochemical pH. Additional sensor options allow for up to 4x pH and DO redundancy.
- Optional BioPAT® Foam is a single-use, non-invasive sensor for high foam alarm.
- Optional advanced process analytical technology (PAT) solutions such as BioPAT® Viamass, BioPAT® Trace and BioPAT® Xgas.
- Bag holder with 8x MFC (no rotameter) with load cells for gravimetric level control.

LIQUID HANDLING

Substrat A

1 x Peristaltic pump WM 323 U/D, max. 400 rpm

- Speed range: 3 - 400 rpm
- 150 | 230 V power supply
- Incl. power cord (country specific)

1 x Connection cable external pump WM 323; 3 m

Substrat B

1 x Peristaltic pump WM 530UN/R2, 230V

- Manufacturer: Watson-Marlow
- Speed range: max. 220 1/min, speed controlled
- Drive: 530 UN
- Pump head: 520R2 (for tubing wall thickness 2.4 mm)
- Housing protection class : IP66
- Power cord: 3m
- Power plug: IEC Type L
- Voltage: 200-240 VAC / 50Hz

1 x Connection cable external pump WM 530 / WM 630; 3 m

LEVEL CONTROL

1 x Peristaltic pump WM 530UN/R2, 230V

- Manufacturer: Watson-Marlow
- Speed range: max. 220 1/min, speed controlled
- Drive: 530 UN
- Pump head: 520R2 (for tubing wall thickness 2.4 mm)
- Housing protection class : IP66
- Power cord: 3m
- Power plug: IEC Type L
- Voltage: 200-240 VAC / 50Hz

1 x Connection cable external pump WM 530 / WM 630; 3 m

MEASUREMENT

pH A

1 x Analog pH measurement

- Display of measured pH value in the display
- Calibration and re-calibration of the sensor

pH B

1 x Analog pH measurement

- Display of measured pH value in the display
- Calibration and re-calibration of the sensor

DO C

1 x Optical DO measurement

- Display of the optical measured DO value in controller menu
- Range DO: 0 - 110%

DO D

1 x Optical DO measurement

- Display of the optical measured DO value in controller menu
- Range DO: 0 - 110%

BioPAT® Viamass

1 x BioPAT® Viamass measurement without control

- BioPAT® Viamass measurement without control
- Viamass reading can be displayed on the HMI
- Value displayed as pF signal
- Control functionality can be established through MFCS/SCADA controller function

BAG HOLDER

left: Bag holder STR®

1 x left: Bag holder STR® Generation 3 CC 50L 400V



The shown picture is just a product example.

With the Biostat STR® it is possible to add one or more independent bagholder to an already existing Biostat STR® Generation 3 system. Along with the bagholder hardware an affiliated software configuration needs to be installed. As owner of a Biostat STR® Generation 3 you can add additional bagholders and use them with the already existing control tower. You can configure the bag holder according to your specifications. A new software configuration is generated and will be installed on the control tower to allow your specified functionality running with the new bag holder. In the case a qualified system is needed, the bag holder can be qualified accordingly via a customer-site acceptance test (SAT) to ensure full compatibility with cGMP regulations.

CULTURE VESSEL

1 x Biostat STR® 50 bag holder with load cells

For use with Flexsafe STR® 50 L

- Material: Stainless steel 1.4307/304L, electropolished
- Dimensions WxDxH: 790 x 1070 x 1960 (mm)
- Weight: 310 kg

Consists of:

- Drive motor with magnetic coupling
- Filter holder for max. 6 filter lines
- Fully insulated double wall jacket above the max. filling level, max. 0.5 bar pressure
- One insulated door, with one large viewing window
- Two side openings for access to side ports
- Round bottom with large central opening for harvesting tube
- Cone for drain port - material: POM
- Built-in collection tray with castors and height-adjustable feet
- Tubing and cable management
- Pressure safety valve to monitor bag pressure (70 mbar) and pressure sensor
- Temperature sensor Pt 100, range: 0-150°C

Eight mass flow controllers

Load cells:

- Max. weighing capacity: 375 kg
- Readability: 0.01 kg

TEMPERATURE CONTROL

1 x Temperature Control Unit Biostat STR® 50-200, 400V

A closed thermostat system for connection of jacketed bag holder.

Consists of:

- Heating cartridge: 3.5 kW
- Recirculation pump
- Heating element and cooling water solenoid valve
- Pressure safety valve: 0.5 barg

Utilities:

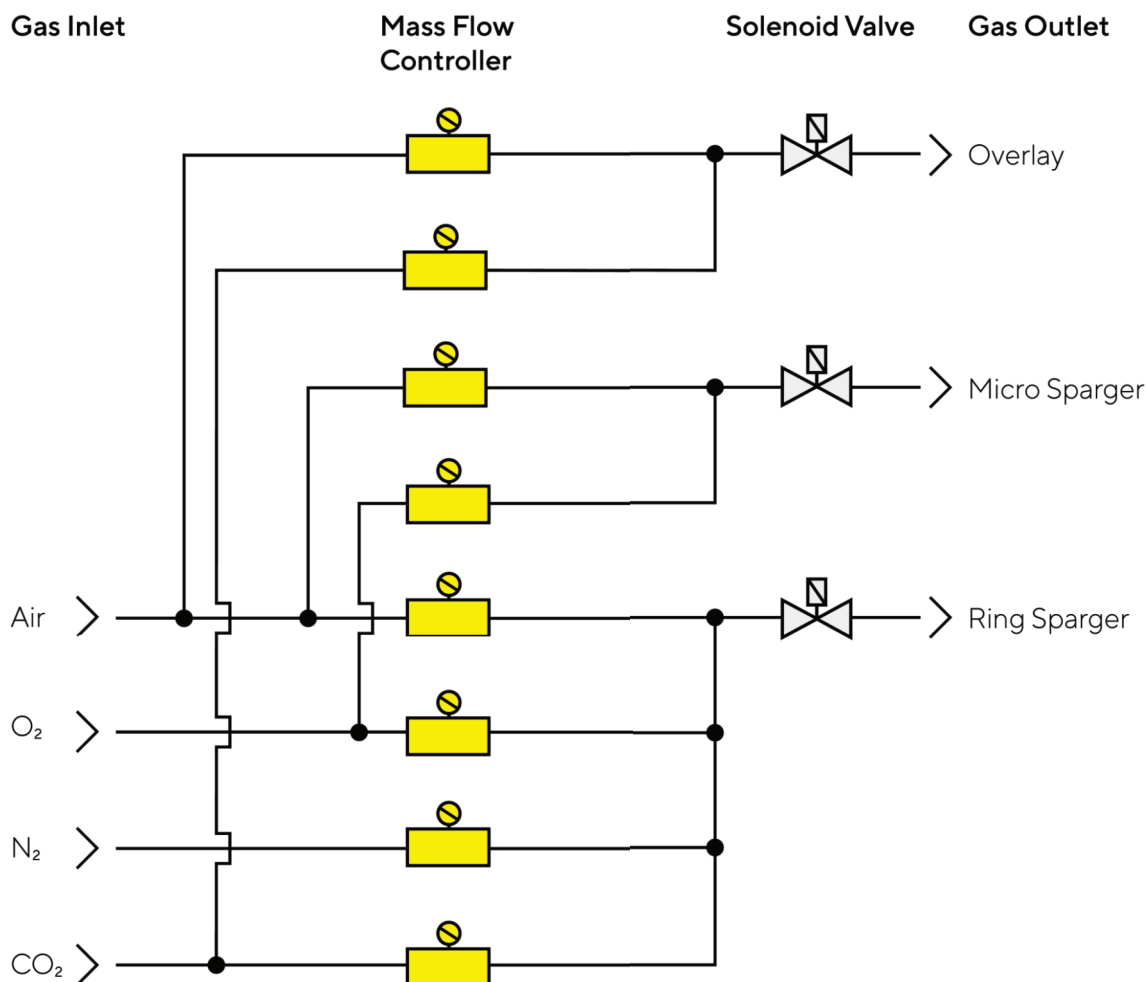
- Water In: Tri clamp connection TC 25 (max. 6.0 barg)
- Water Out: Tri clamp connection TC 25

1 x Filter heater for the exhaust filter of the single-use Biostat STR® 50/200, 24V

DO CONTROL

General

1 x Gassing module « Advanced 8-Gas Additive Flow with 3-Out »



Stainless steel module designed for mammalian and insect cell culture.

- Inlets for air, O₂, CO₂, and N₂
- Eight MFCs with configurable sizes (3x Air, 2x O₂, 1x N₂, and 2x CO₂)
- Three gas outlets (microsparger, ringsparger and overlay) with non-return valves
- Pressure monitoring with pressure sensor and pressure safety valve
- Solenoid valves for aeration shut-off
- Automatic gas mixing via pO₂ and pH regulation for gas mixing of air, O₂, N₂, CO₂
- Controlled gases require 4 barg
- Quick coupling or hose barb for 12 mm tube connection

Controller

1 x DO control ADVANCED

- DO control with parallel control of multiple actuators
- Up to 4 actuators can be activated at the same time
- Individual flow rate control of each actuator based on DO controller output
- Individual setting of min. and max. controller output for each actuator

Air Overlay

1 x Mass flow controller Air, 0.015 - 3 lpm

- Thermal flow measurement
- Calibrated for air

CO₂ Overlay

1 x Mass flow controller CO₂, 0.015 - 3 lpm

- Thermal flow measurement
- Calibrated for CO₂

Air Micro Sparger

1 x Mass flow controller Air, 0.03 - 5 lpm

- Thermal flow measurement
- Calibrated for air

O₂ Micro sparger

1 x Mass flow controller O₂, 0.03 - 5 lpm

- Thermal flow measurement
- Calibrated for O₂

Air Ring (Macro) Sparger

1 x Mass flow controller Air, 0.03 - 5 lpm

- Thermal flow measurement
- Calibrated for air

O₂ Ring (Macro) Sparger

1 x Mass flow controller O₂, 0.03 - 5 lpm

- Thermal flow measurement
- Calibrated for O₂

N₂ Ring (Macro) Sparger

1 x Mass flow controller N₂, 0.015 - 3 lpm

- Thermal flow measurement
- Calibrated for N₂

CO₂ Ring (Macro) Sparger

1 x Mass flow controller CO₂, 0.008 - 1.5 lpm

- Thermal flow measurement
- Calibrated for CO₂

MEASUREMENT

Probes and accessories

pH A

- 1 x pH probe connection cable
 - Connectors: Double-sided VP6-bushing
 - Cable length: 3 m

pH B

- 1 x pH probe connection cable
 - Connectors: Double-sided VP6-bushing
 - Cable length: 3 m

DO C

- 1 x Optical fibre cable, 2.5 m
 - Optical fibre cable (2.5 m) for optical single-use sensors

DO D

- 1 x Optical fibre cable, 2.5 m
 - Optical fibre cable (2.5 m) for optical single-use sensors

BioPAT® Viamass

- 1 x BioPAT® ViaMass – viable cell volume measurement – Hardware SU for Biostat STR®
 - Display of output parameters on prepared HMI screen: Biomass [mill. cells/ml], Capacitance [pF/cm], Conductivity [mS/cm]
 - ViaMass electronic and signal simulators [0 pF/cm – 0 mS/cm and 100 pF/cm – 40 mS/cm]
 - Cable adapter for connection to control tower – BioPAT® ViaMass electronics holder and electrical grounding
- 1 x Signal Simulator kit for SU BioPAT® ViaMass
 - BioPAT® SU ViaMass Signal Simulator Set (2 values: 0 pF/0 mS/cm and 100 pF/40 mS/cm)
 - Accessories for checking the functionality of the electronic assembly

ORGANIZING

- 3 x Cable manager for Biostat STR®
 - for variable attachment to system rails
 - Flexible swivel arm with contact surface
 - Securing strap for holding tubes in position
- 3 x Cable hook for Biostat STR®
 - Cable hook for arranging the cable channel
 - for variable attachment to system rails

DOCUMENTATION/QUALIFICATION

1 x Standard documentation package Biostat STR® (Level 0+1)

Documents are supplied either as hardcopy or on CD.

Including:

- Operating Manual
- CE Declaration of Conformity / NRTL certificate
- Quality Assurance Certificate
- Spare part list
- P&I diagram
- Wiring diagram
- Major component list
- Certificates of mass flow controllers

Advanced Services

1 x Advanced Order Execution for 1 Biostat STR® Gen.3

Advanced order execution service with dedicated project coordinator as primary contact person for internal organization, coordination, scheduling, monitoring and commercial handling.

Advanced Order Execution

1 x Advanced Order Execution Service - on request

Advanced Order Execution is not included in delivery. On request, we would be glad to submit a separate offer. Please address to your sales representative.

Pos 7 1 x Flexsafe STR® Standard Validation Bag

Pos 7.1 Scope without optional functions

Flexsafe STR®

2 x Flexsafe STR® 50L

8.920,00 EUR

Art. no. FRS132668

Cylindrical Disposable Bioreactor Bag for cell cultivation.
Detailed technical characteristics available on demand.

MAIN CHARACTERISTICS:

- Height: 727 mm; Diameter: 370 mm; Ratio: 1.8:1
- Total Volume: 70L; Working Range: 12,5L-50L
- Multi layer film. Fluid contact layer made of PE

CONFIGURATION:

- 2 x 3-blades impeller and 1 x sparger
- 1 x harvesting line
- 1 x OVERLAY AERATION line
- 1 x SPARGING AERATION line
- 1 x double GAS OUT line
- Multiple FEED lines of different diameters
- 1 x ADDITION BASE line

Lateral connections and side ports:

- 1 x port for reusable PT100 T° sensor
- 1 x Single-use optical pH/DO sensors
- 1 x SMALL VOLUME SAMPLING line

DELIVERED WITH:

- 2 x GAS IN & 1 x GAS OUT sterile filter lines

Pos 8 1 x Installation in Italy for 1 Biostat STR® Gen.3

The reliability and the service life of your equipment significantly depend on its installation and configuration according to the specifications. Installation and commissioning by our service professionals will ensure that your system successfully operates right from the start.

Pos 8.1 Scope without optional functions

Installation

1 x Installation, BIOSTAT STR® 50/200L

Art. no. S874NINSTP

Installation by a qualified technician

Scope of service:

Unpacking and Verification of Contents

System assembly and utilities connection

Start-up test

Brief operator instruction

Note:

The system must be unpacked and set in final position by client, witnessed by Sartorius Stedim Engineer.

Package Price, all expenses e.g. for travelling and charges are included.

With several units the package price is valid only if the systems are installed at the same time and at a common site.

Pos 9 1 x BioPAT® MFCS 4



The shown picture is just a product example.

BioPAT® MFCS enables you to incorporate and benefit from new standards in bioprocess data management. Its reliable data acquisition and effective trend monitoring make it an ideal tool for practically any upstream and downstream process, no matter whether you prefer single-use or reusable systems. BioPAT® MFCS is your solution for efficient processes - all backed by our expertise since 1986.

Standard BioPAT® MFCS delivery includes:

- Delivery of software, manuals and end user license agreement on USB stick
- Delivery of activation keys via e-mail
- 1-year Service & Support Agreement (software updates and technical support) included
- Option to prolong the Service & Support Agreement

It will be necessary for you to register using the provided serial number after installing the software. Once you have successfully registered your software, you will then receive your activation keys.

The following details provided by you has been taken into account for the quotation. We will have the right to correct the price if this given information is not valid.

Information about new BioPAT® MFCS installation

Number process units: 4

Device 1

Product: Biostat® B

Process units: 2

Product serial: new_system

DCU configuration: new_system

DCU firmware version: new_system

Device 2

Product: Biostat® RM

Process units: 1

Product serial: new_system

DCU configuration: not_applicable

DCU firmware version: not_applicable

Device 3

Quotation No. 2402-GIM-5047-6s
Customer: OSPEDALE BAMBINO GESU'
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SARTORIUS

Product: BIostat STR® Generation 3
Process units: 1
Product serial: new_system
DCU configuration: not_applicable
DCU firmware version: not_applicable

Pos 9.1 Scope without optional functions

Software

1 x BioPAT® MFCS 4 Software

Software for bioprocess data acquisition, monitoring, control and automation

- Configuration of up to 32 process units
- Applicable for shakers, bioreactors, crossflow- and FlexAct®-systems
- User-friendly and intuitive graphical user interface
- Opportunity of working in international teams by dynamic language switch
- Unit grouping enables clear process comparisons and universal actions
- Trend-splitview allows synchronization on process events
- User specific templates ensure comfortable and effective working
- Multi-monitoring displays the application on multiple screens
- Event based or equidistant process data storage
- Alarm management according to the ANSI-18.2 standard
- Easy and flexible data exporting as csv-file
- Comprehensive search and filter possibilities with favorite function
- List printouts for system documentation and configuration
- Generate random process values with a simulation device
- Transfer of controller setpoints enables remote operation of devices
- Direct print of charts
- Expanded functionality with additional modules

1 x BioPAT® MFCS 4 Factory Configuration

- System configuration for connected process unit(s)

1 x BioPAT®MFCS Factory Installation

- Installation, configuration and test of the operating system
- Installation of the BioPAT® MFCS software package
- Only in combination with PC hardware from Sartorius

Additional Software Modules

1 x BioPAT® MFCS 4 Calculation Module

Calculation Module estimates non-direct measurable process values

- Online and offline calculation of important bioprocess parameters
 - Configuration assistant guides through the creation of new calculations
 - Syntax check informs in case of errors and ensures correct formula interpretation
 - Individually adjustable calculation cycle allows optimal adaptation to the process behavior
 - Predefined set of mathematical functions, arithmetic operations and relational operators
 - If-then-else statements allow implementation of simple two-state controllers
 - Excellent input support with matching parenthesis highlighting and info tips
 - Preview-function visualizes formulas in fraction style for better readability
 - Realization of feeding strategies by assignment of calculations to controllers
-
- Requires the latest BioPAT® MFCS 4 software
 - Delivery of activation keys via e-mail to activate Calculation Module

1 x BioPAT® MFCS 4 Charting Module

Charting Module for advanced data visualization and inspection

- Common visualization of running and completed processes in one chart
 - Auto-refresh updates the chart content without the need for user intervention
 - Plot up to 12 individually configurable curves in a single chart
 - Adding comments to selectable data points improves process documentation
 - Multifunctional chart legend helps in identifying and editing data series
 - Rectangle zoom for faster inspection of interesting areas
 - Load and save templates for fast and simple chart configuration
 - Multi-monitoring function shows charts & tables on different screens
 - 'Link & synchronize' feature enables easy process comparisons in split-view mode
 - Straight-line representation of exponential data curves in semi-log charts
 - Horizontal and vertical crosshair for detailed readings of measurement values
 - Quick and simple chart design by drag & drop as well as grouping of y-axes
 - Change grid spacing that helps to better visualize and interpret curve characteristics
-
- Requires the latest BioPAT® MFCS 4 software
 - Delivery of activation keys via e-mail to activate Charting Module

1 x BioPAT® MFCS 4 Sample Data Module

Sample Data Module captures offline process data with BioPAT® MFCS 4

- Store results of offline analyses obtained from sampling
 - Assigns automatically the date and process time to the taken sample
 - Common visualization of offline and online data in trends enhances decision-making
 - Snapshot function to simultaneously capture online data when samples are taken
 - Search, sort, and filter functions help to view and manage samples more effectively
 - Export of offline and online data in a shared table facilitates advanced analysis
 - Schedule future samplings for multiple units
 - Attach files or images to sample data entries for consistent traceability
-
- Requires the latest BioPAT® MFCS 4 software
 - Delivery of activation keys via e-mail to activate Sample Data Module

1 x BioPAT® MFCS Recipe (S88) Module

Recipe (S88) Module for advanced process automation with BioPAT® MFCS

- ANSI-88 compliant standardized process automation
- Creation and execution of recipes for reproducible processes
- Intuitive graphically guided configuration
- Drag & drop for quick positioning of operations and phases
- Pre-defined phase types for set points, feeding profiles and timers
- Sequential, parallel and repeated execution of phases
- Definition of conditions to realize state and time-dependent process strategies
- Quick identification of errors in recipes via intelligent syntax checking
- Automatic checking of process unit compatibility
- Visually traceable progress of recipes currently running
- Direct interaction with recipes currently running
- Overview function to monitor the progress of multiple recipes at once
- Requires the latest BioPAT® MFCS software
- Delivery of activation keys via e-mail to activate Recipe Control Module

1 x BioPAT® MFCS 4 OPC Client Module

OPC Client module to connect Biobrain® or additional sensors and analyzers.

- For communication of BioPAT® MFCS 4 with industrial OPC UA (DA) servers
- For connection of peripheral equipment with OPC Classic DA servers
- Supports OPC V1.0a, V2.05, V3.0
- Requires OPC tunneler if OPC Classic DA server and BioPAT® MFCS 4 are installed on two different computers

Delivery of activation keys via e-mail to activate OPC Client Module.

3rd party modules

1 x Microsoft® SQL Server 2019 Standard Runtime

Microsoft® SQL Server 2019 Standard (Runtime) license for SQL database management system for use with BioPAT® MFCS 4 software.

- Including 1 device CAL (Client Access License)
- Applicable only for BioPAT® MFCS 4 applications

Server Hardware

1 x BioPAT® MFCS Laptop Premium

Technical specifications:

- Dell Mobile Precision Workstation
 - Intel Core processor i7
 - 32 GB RAM
 - NVIDIA graphic card
 - 17.3" FHD, 1920x1080
 - 512 GB Solid-State-Drive
 - 1x RJ-45 10/100/1000 Mbit
 - Operating system: Microsoft Windows® 10 (64-bit) English, Dutch, French, German, Italian
 - Dell wireless mouse
-
- 3 year on-site service by Dell

(Necessary modifications are subject to change without further notice.)

Documentation/Qualification

1 x Level 0: Documentation BioPAT® MFCS

BioPAT® MFCS User Manual

Pos 10 1 x Installation in Italy for 1 BioPAT® MFCS 4

The reliability and the service life of your equipment significantly depend on its installation and configuration according to the specifications. Installation and commissioning by our service professionals will ensure that your system successfully operates right from the start.

Pos 10.1 Scope without optional functions

Installation

1 x On-Site Installation Service for BioPAT® MFCS 4

Art. no. S874MINSTLP

Installation of BioPAT® MFCS 4 with up to 4 process units

BioPAT® MFCS 4 commissioning:

- Installation
- Connection to process units in a prepared IT environment
- Introduction of system functions for the customer
- If additional process units are to be added at a later date - please request an offer from the local Service Organization. On-site installation service does not include connection of non-Sartorius equipment

Prices

1 Biostat® B Twin CC - UniVessel® SU 2L / 2L 230V

1.1 1 x Scope without optional functions 114.174,00 EUR

Price for 1 x Biostat® B Twin CC - UniVessel® SU 2L / 2L 230V 114.174,00 EUR

2 Installation in Italy for 1 Biostat® B

2.1 1 x Scope without optional functions 3.405,00 EUR

Price for 1 x Installation in Italy for 1 Biostat® B 3.405,00 EUR

3 Biostat® RM 20 230V

3.1 1 x Scope without optional functions 117.954,00 EUR

Price for 1 x Biostat® RM 20 230V 117.954,00 EUR

4 Installation in Italy for 1 Biostat® RM

4.1 1 x Scope without optional functions 2.819,00 EUR

Price for 1 x Installation in Italy for 1 Biostat® RM 2.819,00 EUR

5 Accessories

5.1 1 x White lid for Bag Holder 50 1.360,00 EUR

5.2 1 x Bag Holder 50 2.770,00 EUR

Price for 1 x Accessories 4.130,00 EUR

6 Biostat STR® Generation 3 CC Single 50L 400V

6.1 1 x Scope without optional functions 330.000,00 EUR

Price for 1 x Biostat STR® Generation 3 CC Single 50L 400V 330.000,00 EUR

7	Flexsafe STR® Standard Validation Bag	
7.1	1 x Scope without optional functions	8.920,00 EUR
Price for 1 x Flexsafe STR® Standard Validation Bag		8.920,00 EUR

8	Installation in Italy for 1 Biostat STR® Gen.3	
8.1	1 x Scope without optional functions	3.405,00 EUR
Price for 1 x Installation in Italy for 1 Biostat STR® Gen.3		3.405,00 EUR

9	BioPAT® MFCS 4	
9.1	1 x Scope without optional functions	32.814,00 EUR
Price for 1 x BioPAT® MFCS 4		32.814,00 EUR

10	Installation in Italy for 1 BioPAT® MFCS 4	
10.1	1 x Scope without optional functions	2.379,00 EUR
Price for 1 x Installation in Italy for 1 BioPAT® MFCS 4		2.379,00 EUR

Total		
Total Price, net		620.000,00 EUR

Commercial Conditions

Prices & Incoterms

The prices are net excluding the sales tax and any fees.

If costs for packing, shipping, insurance, commissioning (possibly shown as Incoterm costs), installation and training are not expressly offered they are not part of delivery.

Shipments will be DAP (Delivered At Place) Italy according to Incoterms 2020.

Freight and handling charges are prepaid by SELLER and billed to PURCHASER.

The prices are firm for the duration of the contract and not subject to any escalation.

The prices are given based on the current alloy factors for stainless steel. We reserve the right to adjust the prices at the time of order.

Terms of payment

30% after order confirmation due immediately

60% after readiness of shipment due immediately

10% after installation due net 30

Approx. time of delivery ex works (working weeks):

Product	Standard	Qualification Level 1 - 3	Add-ons	Total
Biostat® B Twin CC - UniVessel® SU 2L / 2L 230V	12-14 week(s)	from stock		12-14 week(s)
Installation in Italy for 1 Biostat® B	on request			on request
Biostat® RM 20 230V	12-14 week(s)			12-14 week(s)
Installation in Italy for 1 Biostat® RM	on request			on request
Accessories	on request			on request
Biostat STR® Generation 3 CC Single 50L 400V	12-14 week(s)			12-14 week(s)
Flexsafe STR® Standard Validation Bag	on request			on request
Installation in Italy for 1 Biostat STR® Gen.3	on request			on request
BioPAT® MFCS 4	12-14 week(s)			12-14 week(s)
Installation in Italy for 1 BioPAT® MFCS 4	on request			on request

General information

Delivery times for Accessories are globally defined for 5 weeks, however they can vary individually. More detailed information will be provided case by case on request, or with the order confirmation.

The above mentioned delivery time is an approximate value after receipt of order and based on the current availability of the sub components and raw material and internal capacity.

Standard components (e.g. safety valves, addition valves, bottom valves and stirrers) have been considered for the evaluation of the delivery time.

In case deviating components will be used, especially such to be welded in at the vessel, the delivery time will be extended.

The final delivery time will be checked at the date of the order again and will be confirmed with our order confirmation.

Please note, the delivery might be done via other Sartorius group companies.

Validity of offer

3 months from date of quotation.

Pricing will be confirmed upon order confirmation.

Scope of supply

The scope of supply only includes the described items. If installation, commissioning and training are not expressly offered they are not part of delivery.

Order Reference Code

- Our Product Configurator assigns a unique Order Reference Code (ORC) that is specific to a unique product configuration.
- Any change initiated by customers within the capabilities of our Product Configurator will lead to a new Order Reference Code
- Any change initiated by Sartorius Stedim Biotech will be notified according to our change notification policy

Export control

We explicitly draw your attention to the fact that our products may be subject to international and national export restrictions (e.g. EC Dual-Use regulation No. 428/2009 including latest updates, German Ausfuhrliste, UK Strategic Export Control List, Swiss Güterkontrollverordnung, Indian SCOMET regulation, Singapore Strategic Goods Control List, US Export Administration Regulations (EAR) and US Re-Export regulations according to the EAR. Acceptance and delivery of the order will be done in strict compliance with the appropriate legal provisions and embargo regulations.

The buyer shall comply with all applicable national and international laws and regulations, in particular the applicable export control regulations, embargo regulations and sanction programs. The buyer also agrees not to export, re-export or transfer any hardware, software or technology developed with or using information, software or technology offered by Sartorius, in violation of any applicable laws or regulations

of the competent authorities. Further, the buyer shall neither use any products, information, software and technology offered by Sartorius in or in connection with nuclear technology or weapons of mass destruction (nuclear, biological or chemical) and carriers thereof nor supply military consignees. Acceptance and execution of orders for products requiring approval is subject to the issue of an export license by the Federal Export Office of Economics and Export Control (BAFA), or the relevant authorities of other countries, respectively. In case products require approval, Sartorius requires an appropriate End-Use(r) Certificate from the end user stating the precise use of the products and including an informative company profile.

Our products will be supplied exclusively for civil and peaceful purposes. With the purchase order, the buyer agrees to comply with all applicable laws and to provide all requested information and data in a timely manner to obtain the necessary documents.

As the timely approval of the export license is out of control of Sartorius any delay in shipment due to the pending or rejected approval cannot be seen as a subject to any penalty requirements by the buyer.

Alterations

We reserve the right to incorporate alterations or additions in this specification, if during the manufacturing time of the above items, new technology becomes available, i.e. some parts might be replaced by parts having at least the identical or better operation efficiency.

TERMS AND CONDITIONS OF SALE

This transaction is expressly subject to the Sartorius Terms and Conditions of Sale (Italy), relating to the sale of Goods and Services which can be found at <https://www.sartorius.com/download/618592/3/gtc-sale-final-italy-pdf-data.pdf>.

Such General Terms and Conditions of Sale along with this Quote constitute a legally binding contract ("Contract") between Sartorius and the customer (the "Customer"). These Terms and Conditions shall govern Sartorius' sale to Customer of the products or services specified in the Quote and shall apply to all quotations and any subsequent order, notwithstanding any terms or conditions on any order form, purchase order or other document. Customer shall be deemed to have accepted Sartorius Terms and Conditions of Sale by acceptance of the Quote, or any other performance which, under applicable law, constitutes acceptance, including Customer's failure to object in writing to these Sartorius Terms and Conditions of Sale. Any different, contrary or supplementary terms and conditions which may be presented by the Customer are hereby expressly rejected and deemed excluded and will not be deemed to form part of any contract, even in the event such terms are not excluded by Sartorius in an individual instance.

Please ensure that our quotation number is shown prominently on your purchase order. This helps us to carry out your order promptly and correctly.

If you have questions or require additional information please contact us.

Yours sincerely

Sartorius Stedim Italy S.r.l.

Giacomo.Marino

Daniela.Bartocci