



sartorius stedim  
biotech

## Engineered for Life – BIOSTAT® RM TX with Flexsafe® RM TX for Culturing Consistent Quality Cellular Products



turning science into solutions

# Our Competence in Cell and Gene Therapy

Sartorius Stedim Biotech is a global solution provider to the biologics industry and is well positioned to support regenerative medicine companies with our tried and trusted technologies for applications in this sector. Utilizing our strong expertise in single-use technology and biopharmaceutical automation, Sartorius supports the development, analysis and manufacture of various types of regenerative medicines, including cellular immunotherapies.

## Solutions for Cellular Immunotherapies

The fight against cancer has taken a dramatic step forward in recent years with the development of cellular immunotherapies such as CAR-T cells. To produce these cells to a consistent quality, manufacturers face issues including: maintaining product sterility, protecting the cell product from adverse stress or environment and maximizing cell yield with efficient processing. These can be achieved with gentle expansion and harvesting techniques, in process controls and the use of bioanalytics to ensure lot-to-lot consistency, characterize the cellular product, as well as utilizing rapid and robust lot release testing methods.

Sartorius provides a wide range of platforms to address the unique challenges around the production of both allogeneic and autologous cells.



# BIOSTAT<sup>®</sup> RM TX bioreactor system and Flexsafe<sup>®</sup> RM TX bags – The Ideal Combination for Your Cells

The BIOSTAT<sup>®</sup> RM TX and Flexsafe<sup>®</sup> RM TX bag combination provides you with an automated, wave-mixed and closed environment suitable for optimal growth of cell products in working volumes up to 5 L.

The BIOSTAT<sup>®</sup> RM TX system consists of an automated control unit (based on our well-established BIOSTAT<sup>®</sup> B) and a rocking platform, for gently agitating a single-use Flexsafe<sup>®</sup> RM TX bag. Enabling the ex vivo expansion of patient-specific T cells or other types of immune cells, the BIOSTAT<sup>®</sup> RM TX is suitable for process development, as well as for the expansion of relevant cell numbers. Fed-batch, perfusion processes or a combination of culture modes are all possible with this system.

## You Can Rely on:

- Proven industry leading Flexsafe<sup>®</sup> RM TX film that supports consistent cell growth
- Closed system for minimal contamination risk
- Unique gravity harvesting for maximizing cell recovery
- Advanced, automated system for walk-away monitoring and control of the cell culture including online biomass
- Proven rocking motion platform for optimal cell growth



BIOSTAT<sup>®</sup> RM TX and Flexsafe<sup>®</sup> RM TX bags are for research use or further manufacturing use only – not for use in therapeutic or diagnostic procedures. They are not CE marked for in vitro diagnostic use nor are they medical devices. Drug manufacturers and clinicians are responsible for obtaining the appropriate IND | BLA | NDA approvals for clinical applications.



"Sartorius' perfusion filters turned out to be most solid and robust compared to other technologies we tested."

Lead scientist in major cell therapy company



## The Right Solution for Your Needs

At Sartorius, we help you develop a scalable, cost-effective process and combine this with the security of our worldwide supply chain and manufacturing capabilities. Product development in close cooperation with external industry partners guarantees the reliability of your equipment. Our expertise and experience allow us to provide you with a proven product portfolio to support early stage process development and establish scalable processes.

### Optimize Cell Growth

#### Minimize Impact of Single-Use Material

Flexsafe® RM TX bags were introduced in June 2014 and have been used with continuing success ever since by major global biopharma and cell therapy customers. The complete control of our raw materials, the extrusion process and the bag assembly, provides lot-to-lot product consistency. In collaboration with our resin and film suppliers, we have optimized the resin and minimized the additives in our Flexsafe® film technology\* ensuring excellent, reproducible batch-to-batch culture performance of even the most sensitive cells.\*\*

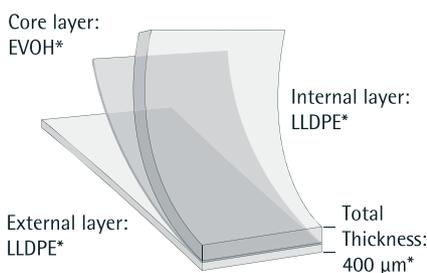
#### Zero Slipping Agents & Nontoxic Mechanical Antiblocking

- No risk of interference due to these agents\*

#### Protect Your Cell Product

- A perfusion membrane (PES, 1.2 µm) is fixed at the bottom of the bag, forming a compartment for removal of cell free media during the perfusion process – for minimal loss or damage to the cells
- Single-use sensors for pH, DO and viable biomass enable sophisticated process control with reduced sampling need
- 100% integrity tested, gamma-irradiatable and fully validated Sartopore® Air sterile filters continuously protect the culture from contamination
- Industry standard tubing option (DEHP free PVC) for seamless connection to up- & downstream processes

#### Structure of the S80 Film



\*LLDPE: Linear Low Density Polyethylene  
\*EVOH: Ethylene Vinyl Alcohol

\* Independent labs have confirmed that Flexsafe® bags are free of cytotoxic leachables. No bDtBPP is identified in WFI extracts of Flexsafe® bags

\*\* Fenge et al. 2014. Consistently Superior Cell Growth: Achieved with New Polyethylene Film Formulation. Bioprocess International, Volume 12 Suppl 5.

## Efficient Cell Processing

### Maximize Cell Yield

Conventional harvesting procedures mostly use pumping which can reduce the number of live cells and affect cell viability. Since cell yield is critical for autologous cell therapies, we have designed our Flexsafe<sup>®</sup> RM TX bags with a special port for hands-free gravity harvesting. This unique gravity harvesting concept in combination with the Flexsafe<sup>®</sup> RM TX Harvest Device allows the safe recovery of as many cells as possible by reducing shear stress on these delicate cells and minimizes contamination risks from manual handling.



Viable biomass sensor (BioPAT<sup>®</sup> ViaMass) integrated in the Flexsafe<sup>®</sup> RM bag – connection to the hardware component



### Robust & Consistent Manufacturing

Our BIOSTAT<sup>®</sup> B control unit is ideal for walk-away automated analysis and control of high cell density perfusion cultures.

Benefit from:

- Advanced control and monitoring of gas mixture and flow rate, filling volume and substrate addition; parallel activation of multiple controllers provides maximum flexibility
- On-line viable biomass analysis with culture volumes greater than 500 mL
- Up to 4 internal pumps can be integrated into control loops for ease of operation without the need to constantly change the pumps' function.
- Easy connection to industry standard Distributed Control (DCS) or Supervisory Control and Data Acquisition (SCADA) systems such as BioPAT<sup>®</sup> MFCS, Siemens PCS 7 or Emerson DeltaV<sup>™</sup>. Straightforward integration into existing automation and single-use infrastructure for data and process consistency throughout
- Complete qualification of the system for GMP use to support regulatory compliance

Flexsafe<sup>®</sup> RM TX Harvest Device for hands-free gravity harvest of the cell culture with maximum recovery.

\* Patent pending.



# BIOSTAT<sup>®</sup> RM TX

The BIOSTAT<sup>®</sup> RM TX system in combination with Flexsafe<sup>®</sup> RM TX bags support the culturing of consistent quality cells and is perfect for small volume autologous processes with multi-parallel scale out needs. Using this system, one Flexsafe<sup>®</sup> RM TX bag can be controlled and monitored via the BIOSTAT<sup>®</sup> B control unit. For scale-out, two Flexsafe<sup>®</sup> RM TX bags and two separate rocking platforms can be attached to a twin BIOSTAT<sup>®</sup> B control unit.

## Single | Twin Configuration

One controller can run up to two BIOSTAT<sup>®</sup> RM TX completely independently to save valuable lab space.

## Easy to Use

Two flap door magnetic lid concept for convenient access to bag and filters. Handles allow for easy transport. Status LED – full control via DCU tower.

## 12" Touch Screen

Easy-to-use and reliable operation of your BIOSTAT<sup>®</sup> RM TX system due to intuitive design of human-machine interface and advanced touch-screen technology – even while wearing laboratory gloves. Integrated flush housing ensures liquid protection.

## Temperature Control

Together with the control tower the integrated temperature control is optimized for small working volumes and perfusion membrane bags.

## Safety Bellows

Protects operator & tubing from mechanical hazards of moving tray.

## Load Cells

The integrated precise load cells are ideal for small volume perfusion processes.

## Configurable Control Tower

Contains aeration, pumps and temperature control modules for various application needs. The BioPAT<sup>®</sup> MFCS multi fermenter control system ensures reliable data management and automation.

## Connectivity to Supervisory Systems

The BioPAT<sup>®</sup> MFCS multi fermenter control system or third party SCADA system integration (DeltaV<sup>™</sup>) ensures reliable data management and automation.



# Flexsafe<sup>®</sup> RM TX Bags

Different sizes of Flexsafe<sup>®</sup> RM bags: 1 L, 2 L and 10 L total volume can be used with the BIOSTAT<sup>®</sup> RM TX rocking platform, providing a working volume of up to 5 L. The Flexsafe<sup>®</sup> RM TX bag has been intelligently designed with features including a special port for gravity harvesting and an internal cell retention membrane, making it ideal for perfusion culture of cellular products such as CAR-T cells.



## BioPAT<sup>®</sup> ViaMass

Integrated sensor for online biomass determination and reduced sampling need.\*

## Vent Filters

Sartopore<sup>®</sup> Air filters are 100% integrity tested before gamma irradiation for improved process safety.

## Film

Industry leading proprietary Flexsafe<sup>®</sup> film for optimal cell growth of most sensitive cells.



## Perfusion Membrane

Integrated 1.2 membrane for secure cell retention during perfusion processes. No fouling and reduced shear as wave constantly flushes over the bottom fixed filter\*.

## Ports and Tubing

Special harvest port for hands-free gravity harvesting. PVC tubing for seamless connectability to upstream and downstream processes.

## Integrated pH & DO Sensors

Single use sensors for advanced process control. No cell accumulation as sensors are inserted from top into the liquid and constantly flushed.

\* perfusion bag design protected by patents US 9 017 997 B2 and EP 2 268 788 B1

## Process

### Flexsafe® 2D Bags

- Single-use Flexsafe® bags for media storage coupled with Flexsafe® pre-designed solutions for sterile filtration, storage and transfer of media and buffers
- Proven integrity to enhance process and product safety by reducing risks of contamination of valuable cell products

### BioPAT® MFCS

- World standard for supervisory process control with GAMP category 4 software package

### BIOSTAT STR®

- Scalable, single-use bioreactor family based on stirred-tank design
- Wide range of sizes (12.5 L to 2000 L working volume) and process regimes for flexible manufacturing

### kSep® Centrifuge

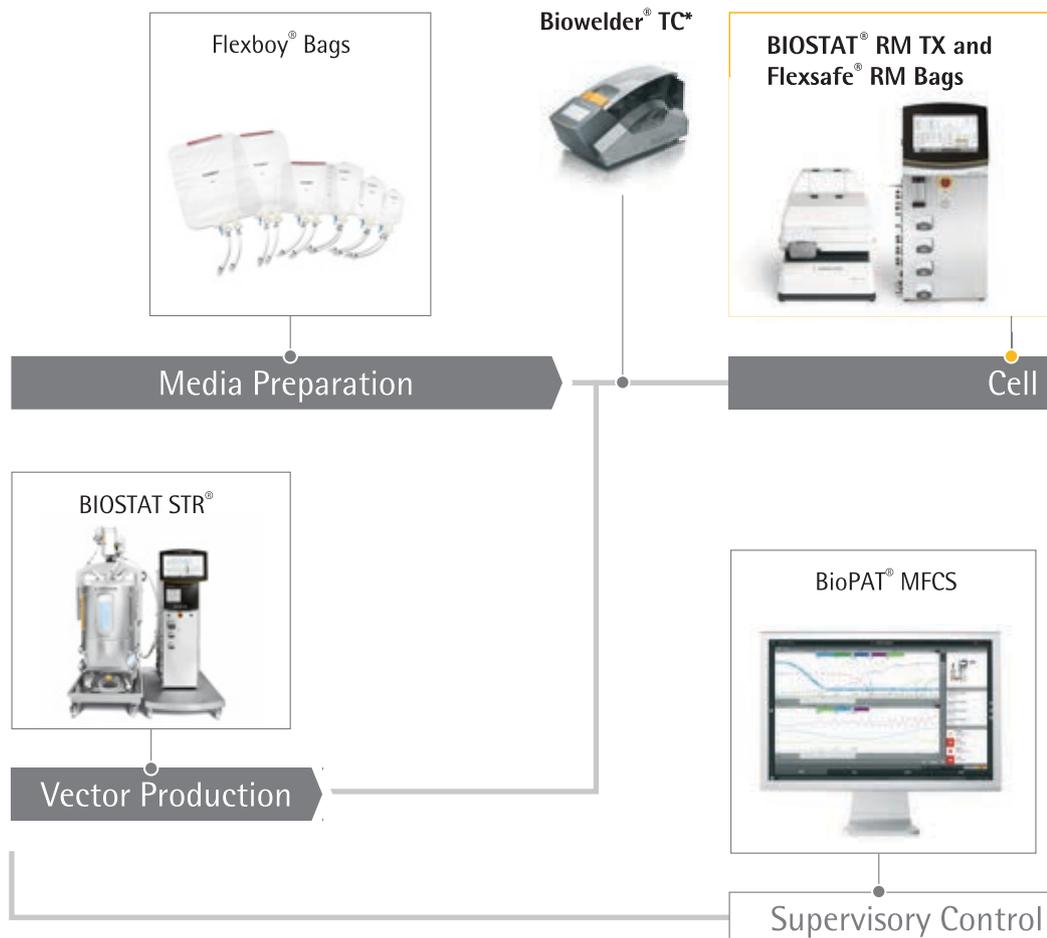
- Closed seal-less single-use fluidized bed centrifugation platform
- The opposing centrifugal and fluid flow mechanism provides low shear force which is ideal for wash & harvest of sensitive cells

### Biowelder® TC

- Automated welder for sterile connection of dry or liquid filled thermoplastic tubing to support a functionally closed process

# Cellular Immunotherapy Processes

Sartorius provides a wide range of single-use technologies. Our portfolio supports viral vector transduction, cell expansion and downstream processing steps including harvest, wash and concentration of cells.



## Analytics

Sartorius provides various analytical technologies that monitor and control your product during the entire manufacturing process.



iQue® Screener PLUS Platform

Virus Counter® 3100

BioPAT® Trace



## Analytics

### iQue® Screener PLUS Platform

- Flow cytometry-based instrument, software and reagent system enables high content, multiplexed analysis of cells and beads in suspension
- Immune cell assessment including immunopheno-typing, immune cell function and cytokine profiling

### Virus Counter® 3100

- Rapid quantification of intact virus particles, providing results in minutes
- Multiple reagents allow specific detection of a wide range of viruses and VLPs
- Enables real-time monitoring and optimization of cell and gene therapy processes

### Microsart® ATMP Mycoplasma and Bacteria Kits

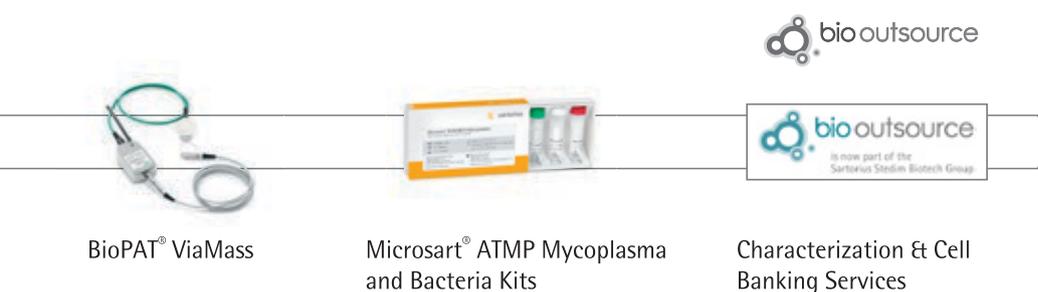
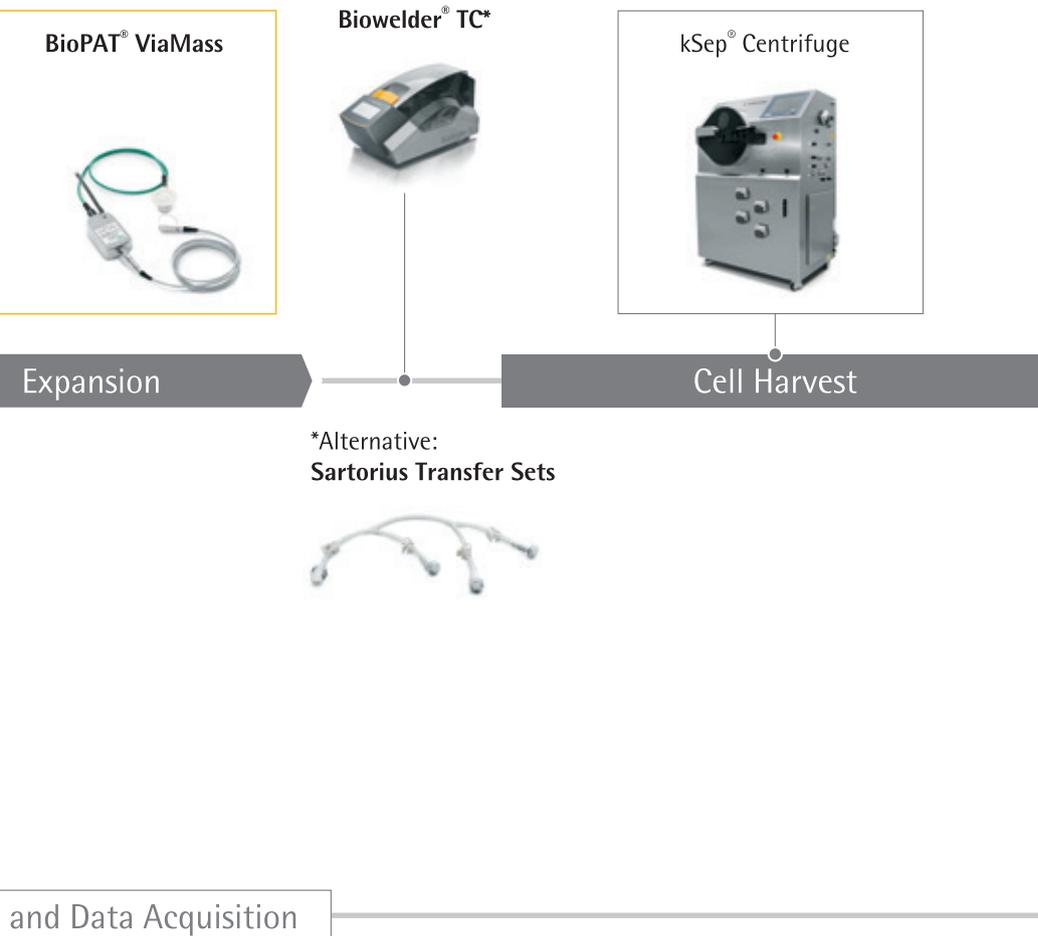
- PCR-based, easy and fast detection of mycoplasma or bacteria
- Results are available within 3 hours (rather than days) resulting in a better ability to keep cell-based therapeutics contamination-free

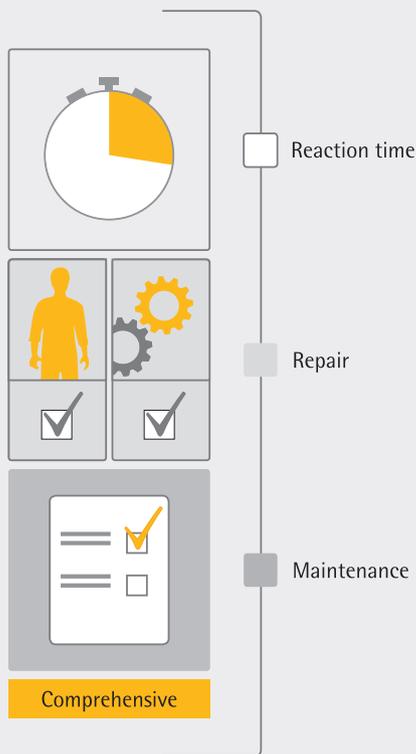
### Characterization Services for Biologics

- The BioOutsource® analytical testing package combines physicochemical and biological analysis for in-depth characterization and comparability studies

### BioPAT® Tools

- In-line monitoring and control of biomass and glucose | lactate helps you define and automate feeding and harvest regimes (including perfusion) for optimal cell growth and minimized process risk





## Service Level Agreement: All-Inclusive Coverage for Maximum Process Security

Our Comprehensive Service Level Agreement offers the highest level of protection for your critical process equipment. Experience our worry-free contract support including our quickest reaction times and full cost coverage, in addition to the planned preventative maintenance. Benefit from our technical helpdesk response within 4 hours and on-site response within 48 hours.

### Reaction Time Commitment:

Technical helpdesk response within 4 hours and on-site response within 48 hours



Read more:  
[Broch\\_Bioprocess-Service-Program\\_S--1546-e](#)

## Sartorius as Your Partner for Cell and Gene Therapy Manufacturing

We are working closely with customers to fully understand their needs, so we can help them address these during the early phase of their process development.

We apply innovative design approaches to new product developments and test early so there is the opportunity to influence and adjust the scope.

We hear what our customers tell us and are committed to serve their needs in the best possible way from start to end of the manufacturing process.



# Technical Specifications

## BIOSTAT<sup>®</sup> RM TX

### Applicable Bag Sizes and Designs

Total Volume	1 L	2 L	10 L
Working volume [L]*	0.1 – 0.5	0.2 – 1	1 – 5
Basic Bags for cultivations under constant conditions	•	•	•
Optical Bags with SU pH & DO sensors		•	•
Perfusion Membrane Bags with SU pH & DO		•	•
Integrated Viamass Sensor*		•	•
Flexsafe RM TX Design**		•	

### Facility and Utility Requirements

#### Power Supply (Country Specific) | Frequency | Electricity Consumption | Protection Class

Rocker platform	230 V   50 Hz   1.3 A   IP23 or 120 V   60 Hz   2.5 A   IP23
Control tower	230 V   50 Hz   10 A   IP21 or 120 V   60 Hz   12 A   IP21
Load cells	Integrated in rocker

#### Gas Supply via BIOSTAT B Tower

Inlet pressure (barg)	1.5
Connection hose coupling, external	Hose barb for tubing with 6 mm ID

#### Gas Specification According to ISO 8573-1: dry, free of oil and dust

Particle size: < 0.1 mm	•
Max. amount 0.1 mg/m <sup>3</sup> (class 1)	•
Condensate: dew point < 3°C (class 4)	•
Oil < 0.01 mg/m <sup>3</sup> (class 1)	•
Germs (class 0)	•

#### Operative Environment

Ambient temperature of between	5–40°C
Relative humidity [%]	< 80% for temperatures up to 31 °C (87.8 °F), decreasing linearly < 50% at 40 °C (104 °F)

\* Bags with sensors might require higher minimum working volumes depending on rocking rate and angle. We recommend using 20 % of the total volume as the minimum working volume.

\*\* incl. Sartopore Air Midisart vent filters, harvest port for gravity harvest, Press-In Plugs, PVC or C-Flex tubing



## System Characteristics

	Dimensions W + D + H	Weight	Material
BIOSTAT® B control Tower Single   Twin	410×520×810 mm 16×20×32 in	40   55 kg 88   121 lbs	Stainless steel AISI 304
BIOSTAT® RM TX Rocker complete	439×602×561 mm 17×24×22 in	35 kg 77 lbs	Stainless steel, ABS
Bag holder TX	430×602×86 mm 17×24×3.4 in	5.5 kg 12.1 lbs	Stainless steel, ABS
Lid TX	430×602×495 mm 17×24×20 in	2.5 kg 5.5 lbs	ABS
Lab-cart (optional)	800×800×900 mm 32×32×36 in	88 kg 194 lbs	Stainless steel

## Process Control

### Temperature Module

Temperature control	Heating only – electrical heating plates
Temperature control range	ambient temperature + 5°C to 40°C (min. set point 15°C, min. controllable temp = ambient temp. + 15°C)
Temperature measurement	2°C to 50°C
Temperature control accuracy (excl. measurement error)	±0.2°C
Heating capacity	1 × 120 W (24 VDC)
Over temperature protection	•

### Gassing Module Control Tower

MFC	max. 4
– flow rates	0.003 lpm – 5 lpm
– accuracy	± 1% full scale
Advanced DO controller	•

### Sensors & Measurement

Temperature probe Pt 100	•
– temperature range Pt 100	0–99°C
– display resolution	0.1°C
– amplifiers	1 (single)   2 (twin)
pH single use	•
– measurement range	6.5–8.5
– display resolution	0.1 pH
– amplifiers	1 (single)   2 (twin)
– recalibration function	•
DO single-use	•
– measurement range	0–250%
– display resolution	0.1%
– amplifiers	1 (single)   2 (twin)
– recalibration function	•



## Sensors & Measurement

Single-use viable biomass (BioPAT® ViaMass)	Optional
Integrated load cells	•
Media weight control range	0 to 5 kg
- Scale, absolute accuracy	Static: ± (10 + 0% of load) g Dynamic: ± (25 + 0% of load) g
- Scale, relative accuracy	Static: ±3 g Dynamic: ±5 g*
Resolution (DCU)	1 g
External signal input	max. 2 0–10 V or 4–20 mA

## Pump Module | Built-in Pumps

Watson Marlow 114, fast load pump head

### Fixed Speed for Base Addition / pH Control

- Speed 5 rpm	ID: 0.5 mm: 0–0.1 ml/min
Flow rate (tubing wall thickness 1.6 mm)	ID: 0.8 mm: 0.05–2.4 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

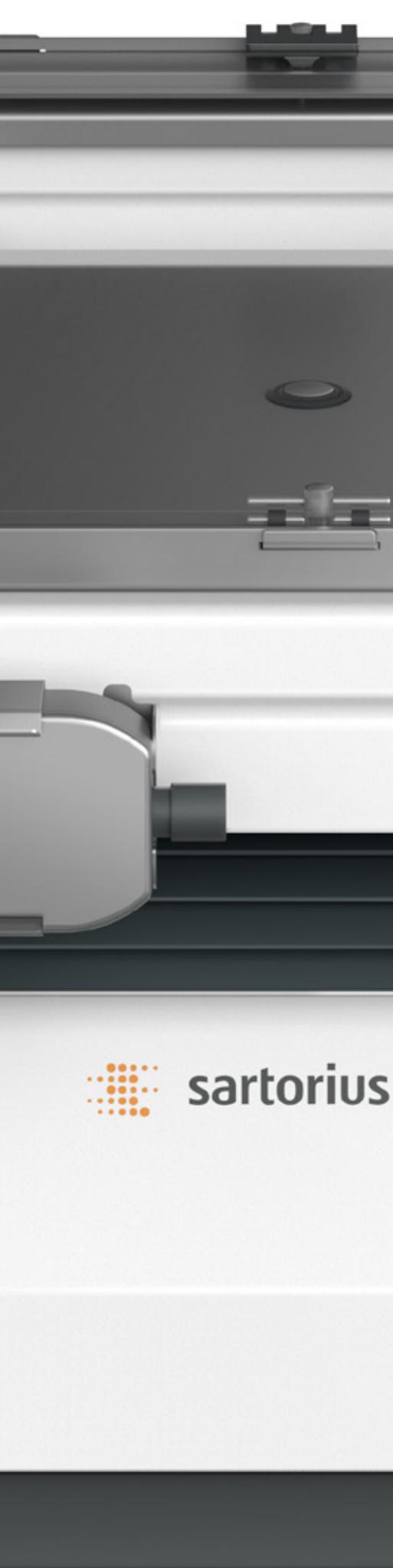
### Speed Controlled for Feed Addition

- 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

\* Dynamic weight measurement (while rocking) can be influenced by cables and tubing and interferences caused by the same.

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## Communication

The BIostat® RM TX system is designed to communicate with industrial SCADA or DCS systems (e.g. DeltaV) through the Modbus TCP/IP protocol.

## Technical Data

### Temperature Module

Max. total volume (L)	10
Max. working volume (L)	5
Rocking speed control range [rpm]	2 – 42 rpm ±1
Rocking angle control range (°)	2 – 12 ± 0.3
Clamping rails for bag fixation	•
Sensor clamps for secure fixation of glass fiber cables	•
Filter heater (2 variants: for std. Hepa filter or for Midisart Sartopore Air)	•
Safety measurement and shut-off	30 mbar
Additional safety valve gasses (mbar)	100 mbar
Water inlet pressure reduction value	1.5 bar, integrated pressure control
Different user level log in	(●)
Logbook function	(●)
Lab-cart for BIostat® B Control Tower	Separately available on request





Read more:  
Data\_Flexsafe-RM\_  
SBT2013-e



Read more:  
Broch\_Biostat-RM-  
Bibliography\_SBI1111-e



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# Sales and Service Contacts

For further contacts, visit [www.sartorius-stedim.com](http://www.sartorius-stedim.com)

## Europe

### Germany

Sartorius Stedim Biotech GmbH  
August-Spindler-Strasse 11  
37079 Goettingen  
Phone +49.551.308.0

Sartorius Stedim Systems GmbH  
Robert-Bosch-Strasse 5-7  
34302 Guxhagen  
Phone +49.5665.407.0

### France

Sartorius Stedim FMT S.A.S.  
ZI des Paluds  
Avenue de Jouques - CS 91051  
13781 Aubagne Cedex  
Phone +33.442.845600

Sartorius Stedim France SAS  
ZI des Paluds  
Avenue de Jouques - CS 71058  
13781 Aubagne Cedex  
Phone +33.442.845600

### Austria

Sartorius Stedim Austria GmbH  
Modecenterstrasse 22  
1030 Vienna  
Phone +43.1.7965763.18

### Belgium

Sartorius Stedim Belgium N.V.  
Rue Colonel Bourg 105  
1030 Bruxelles  
Phone +32.2.756.06.80

### Hungary

Sartorius Stedim Hungária Kft.  
Kagyló u. 5  
2092 Budakeszi  
Phone +36.23.457.227

### Italy

Sartorius Stedim Italy S.r.l.  
Via dell'Antella, 76/A  
50012 Antella-Bagno a Ripoli (FI)  
Phone +39.055.63.40.41

### Netherlands

Sartorius Stedim Netherlands B.V.  
Phone +31.30.60.25.080  
[filtratie.nederland@sartorius-stedim.com](mailto:filtratie.nederland@sartorius-stedim.com)

### Poland

Sartorius Stedim Poland Sp. z o.o.  
ul. Wrzesinska 70  
62-025 Kostrzyn  
Phone +48.61.647.38.40

### Russian Federation

LLC "Sartorius Stedim RUS"  
Vasilyevsky Island  
5<sup>th</sup> line 70, Lit. A  
199178 St. Petersburg  
Phone +7.812.327.53.27

### Spain

Sartorius Stedim Spain, S.A.U.  
Avda. de la Industria, 32  
Edificio PAYMA  
28108 Alcobendas (Madrid)  
Phone +34.913.586.098

### Switzerland

Sartorius Stedim Switzerland AG  
Ringstrasse 24 a  
8317 Tagelswangen  
Phone +41.52.354.36.36

### U.K.

Sartorius Stedim UK Ltd.  
Longmead Business Centre  
Blenheim Road, Epsom  
Surrey KT19 9 QQ  
Phone +44.1372.737159

### Ukraine

LLC "Sartorius Stedim RUS"  
Post Box 440 "B"  
01001 Kiev, Ukraine  
Phone +380.44.411.4918

## Americas

### USA

Sartorius Stedim North America Inc.  
5 Orville Drive, Suite 200  
Bohemia, NY 11716  
Toll-Free +1.800.368.7178

### Argentina

Sartorius Argentina S.A.  
Int. A. Ávalos 4251  
B1605ECS Munro  
Buenos Aires  
Phone +54.11.4721.0505

### Brazil

Sartorius do Brasil Ltda  
Avenida Senador Vergueiro 2962  
São Bernardo do Campo  
CEP 09600-000 - SP- Brasil  
Phone +55.11.4362.8900

### Mexico

Sartorius de México, S.A. de C.V.  
Libramiento Norte de Tepotzotlan s/n,  
Colonia Barrio Tlacateco,  
Municipio de Tepotzotlan,  
Estado de México,  
C.P. 54605  
Phone +52.55.5562.1102  
[leadsmex@sartorius.com](mailto:leadsmex@sartorius.com)

## Asia | Pacific

### Australia

Sartorius Stedim Australia Pty. Ltd.  
Unit 5, 7-11 Rodeo Drive  
Dandenong South Vic 3175  
Phone +61.3.8762.1800

### China

Sartorius Stedim (Shanghai)  
Trading Co., Ltd.  
3rd Floor, North Wing, Tower 1  
No. 4560 Jinke Road  
Zhangjiang Hi-Tech Park  
Pudong District  
Shanghai 201210, P.R. China  
Phone +86.21.6878.2300

Sartorius Stedim (Shanghai)  
Trading Co., Ltd.  
Beijing Branch Office  
No. 33 Yu'an Road  
Airport Industrial Park Zone B  
Shunyi District, Beijing 101300  
Phone +86.10.8042.6501

Sartorius Stedim (Shanghai)  
Trading Co., Ltd.  
Guangzhou Branch Office  
Room 1105  
Xing Guang Ying Jing Building  
No. 119, Shui Yin Road  
Yue Xiu District, Guangzhou 510075  
Phone +86.20.3836.4193

### India

Sartorius Stedim India Pvt. Ltd.  
#69/2-69/3, NH 48, Jakkasandra  
Nelamangala Tq  
562 123 Bangalore, India  
Phone +91.80.4350.5250

### Japan

Sartorius Stedim Japan K.K.  
4th Fl., Daiwa Shinagawa North Bldg.  
8-11, Kita-Shinagawa 1-chome  
Shinagawa-ku, Tokyo, 140-0001 Japan  
Phone +81.3.4331.4300

### Malaysia

Sartorius Stedim Malaysia Sdn. Bhd.  
Lot L3-E-3B, Enterprise 4  
Technology Park Malaysia  
Bukit Jalil  
57000 Kuala Lumpur, Malaysia  
Phone +60.3.8996.0622

### Singapore

Sartorius Stedim Singapore Pte. Ltd.  
10 Science Park Rd  
The Alpha #02-13/14  
Singapore Science Park II  
Singapore 117684  
Phone +65.6872.3966

### South Korea

Sartorius Korea Biotech Co., Ltd.  
8th Floor, Solid Space B/D,  
PanGyoYeok-Ro 220, BunDang-Gu  
SeongNam-Si, GyeongGi-Do, 463-400  
Phone +82.31.622.5700



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