



sartorius stedim
biotech

BIOSTAT[®] RM and Flexsafe[®] RM for Seed Production and Small-scale Protein Supply



turning science **into solutions**

BIOSTAT[®] RM and Flexsafe[®] RM Bags

The BIOSTAT[®] RM, a fully GMP compliant, single-use, wave-mixed bioreactor and Flexsafe[®] bags are proven for a broad range of different cell lines incl. CHO, NS0, SF9, E.coli and mesenchymal stem cells.

Benefit from our excellent global application support and technical service and get started right away.



► Process Step

- Protein and cell supply for preclinical purposes
- Seed production for large bioreactors
- GMP production

► Cells

- Mammalian, insect and plant cells
- Suspension cells and adherent cells on microcarriers
- Low to medium density microbial cultures
- Shear sensitive cells such as stem cells

► Purpose

- Scale-up from shake or T-flasks
- Rapid material supply for pre-clinical trials
- Expansion and differentiation of stem cells
- Production of recombinant proteins, mAbs and vaccines
- Continuous cultures with reported cell densities of 150 million cells/mL

► Volumes

- 100 mL to 100 L culture volume
- Two rocker sizes: 20/50 and 200



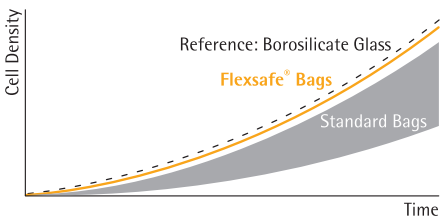
- ▶ Excellent Cell Growth and Robustness
- ▶ Security of Supply & Consistent Quality
- ▶ Easy-to-use Rocker with Advanced Control Capabilities

New Flexsafe® Bag Family

Use our Flexsafe® RM bags in your seed train and scale-up to our BIOSTAT STR® single-use stirred tank bioreactors equipped with Flexsafe STR® bags. Benefit from the same polyethylene film material across all your cell culture steps. Our Flexsafe® RM bags fit on rocking motion bioreactors from several manufacturers. Benefit from excellent cell growth, robustness and unprecedented assurance of supply.

Cell Growth

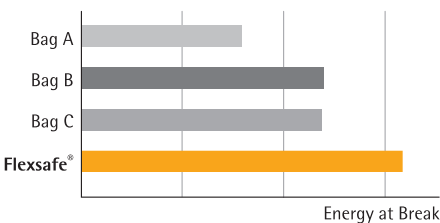
Flexsafe® ensures an excellent and reproducible growth behavior with the most sensitive production cell lines. The complete control of our raw materials, the extrusion process and the bag assembling guarantees consistent lot to lot cell growth performance.



To ensure consistent cell growth performance, we optimized the resin and minimized the additive package in collaboration with our resin and film suppliers.

The bags are proven to be free of cytotoxic leachables by independent labs. No bDtbPP identified in WFI extract of Flexsafe® bags.

Robustness



The thickness, strength and flexibility of the new polyethylene film enhances the mechanical robustness of Flexsafe®, making it ideal for all bio-processing applications. The strength of Flexsafe® significantly reduces the risk of accidental damage to the bag due to inappropriate handling. Its flexibility enables convenient installation and self-deployment of the bag in its container.

Assurance of Supply

Flexsafe® provides you with an unprecedented assurance of supply and enables robust business continuity plans. Our strategic partnership with resin and film suppliers ensures full traceability of raw materials and control over the entire manufacturing process from the resins to the final assembled bags.

Global SUPPLY GUARANTEE

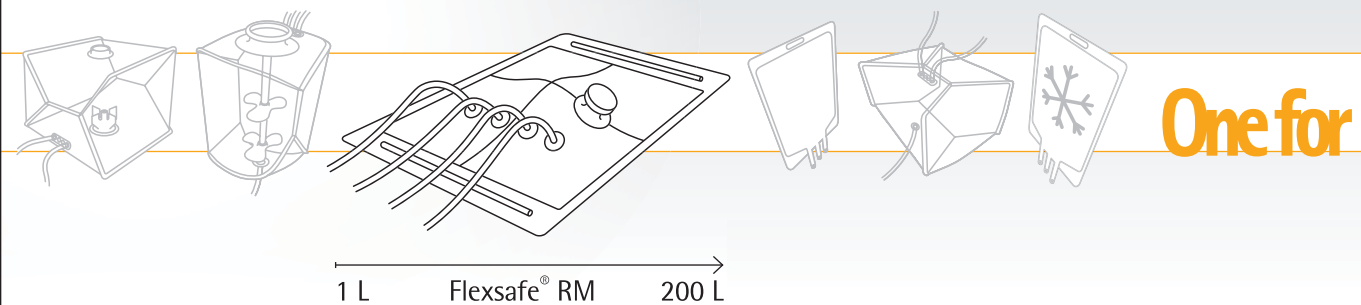
- 10-year contract with the film manufacturer
- Last time buy option for minimum of 2 years resin demand
- Up to 2 years safety stock of film
- Multiple manufacturing sites

Watch Video: www.sartorius.com/video-flexsafe ◀



New Bag Family





One for



Designs

The bags come in 7 different sizes supporting working volumes from 100 mL up to 100 L. Standard designs are available from stock.

	Basic Bag	Optical Bag	Perfusion Bag
For cultivation under constant conditions without pH and DO control for seed train	•		
With single-use pH and DO sensors installed in bag for advanced applications		•	•
With integrated perfusion membrane, fixed at the bottom of the bag, for continuous processing with low membrane fouling and long cultivation times			•
With single-use viable biomass sensors (BioPAT® ViaMass)	•	•	•
Available with screw caps for bulk additions	•	•	•
Customized bag designs	•	•	•
Can be used on competitor systems	•		



BIOSTAT® RM 20 | 50 Basic

The BIOSTAT® RM 20 | 50 basic is a perfectly sized, stand-alone bioreactor for bench-top use. It features an exchangeable bag holder to fit bags from 1 L to 50 L total volume. The BIOSTAT® RM basic rocker with integrated local controller, Air|CO₂ mixing module and load cells is the optimal choice for straight forward applications such as seed generation.

- Space-saving, individual control of two bags on the same platform
- Advanced alarming and safety features for safe cultivation
- Reduced manual handling via automated sampling function



Advanced Control System

Do you want to run fully automated and controlled batch, fed-batch or high cell density perfusion cultures? Combine your basic rocker with our BIOSTAT® B control tower and use Flexsafe® RM bags equipped with single-use pH, DO and now also viable biomass probes.

- Advanced control of gas mixture and flow rate, filling volume and substrate addition
- Extra small space requirement with TWIN configuration – two culture systems controlled by one controller at the same time

Your BIOSTAT® B controller is designed to work with a conventional glass vessel, the single-use UniVessel® SU and the RM rocker, making it a real multi talent. It allows you to use the same controller platform for research purposes, process development and preclinical supply.

Watch Video:

www.sartorius.com/video-biostat-b ◀



NEW

BioPAT® ViaMass* – single-use biomass sensor

for non-invasive measurement of viable biomass. BIOSTAT® RM is the only rocking motion bioreactor with inline single-use biomass monitoring.

- Reduce your contamination risk by using inline single use cell growth monitoring, e.g. in cell therapy or other critical applications



* Manufactured under license from HAMILTON.

BIOSTAT[®] B with RM 200 Rocker

The system consists of the BIOSTAT[®] RM 200 Rocker, BIOSTAT[®] B control tower on lab-cart and Flexsafe[®] RM cultivation bag. It is your choice for larger scale seed expansion and production of material for preclinical and clinical studies. It supports working volumes from 10 L up to 100 L. Together with our proven BIOSTAT[®] B control tower, flexible process strategies can be enabled.

- Low consumable costs compared to stirred single-use bioreactors
- Reliable single-use probes for measurement of pH, DO and viable biomass
- Designed for automated batch, fed-batch and perfusion processes using an external cell retention unit
- Flexible arrangement of control tower and rocker unit on individual trolleys



Technical Specifications

Flexsafe® RM Bags

Total Volume (L)	1	2	10	20	50	100	200
Working volume (L)*	0.1–0.5	0.2–1	1–5	2–10	5–25	10–50	20–100
Bag Types							
Basic	•	•	•	•	•	•	•
Basic and optical with screw cap		•	•	•	•		
Optical		•	•	•	•	•	•
Perfusion with integrated membrane		•	•	•	•		
Perfusion with connection to ATF** System		•	•	•	•	•	•
Basic, optical, perfusion & perfusion ATF with ViaMass			•	•	•		
Main Components		Basic		Optical		Perfusion	
Connectors	Female Male Luer Female Male MPC		Female Male Luer Female Male MPC		Female Male Luer Female Male MPC		
Filters	Air Inlet Air Outlet		Air Inlet Air Outlet		Air Inlet Air Outlet		
Ports	Sampling Fill harvest with dip tube Acid Base		Sampling Fill harvest with dip tube Acid Base		Sampling Fill harvest with dip tube Acid Base Perfusion feed harvest		
Sensors	–		Optical chemical pH Optical chemical DO Single-use viable biomass		Optical chemical pH Optical chemical DO Single-use viable biomass		
Perfusion	–		–		Perfusion membrane PES 1.2 µm Opta aseptic connector to ATF** System		
Tubing material	C-Flex**** 374, Silicone, PharMed**** Natvar ABL-1222 TPE						
Material of the bag	Contact layer: LLDPE gas barrier: EVOH outer layer: LLDPE						
Production conditions	Cleanroom environment of at least ISO 8						
Biological reactivity	USP for plastics Class VI						
Sterility	ISO 11137 – sterility assurance level (SAL) of 10 ⁻⁶						
TSE/BSE status	Compliant to EMA410/01/rev.3 guideline						
Endotoxin	USP<85> for sterile water for injection; < 0.25 EU/ml						
Irradiated	25–40 kGy						

* Bags with sensors might require higher minimum working volumes depending on rocking rate and angle.

() – optional, needs to be ordered separately

** ATF cell retention system from Repligen

**** C-Flex® and PharMed® are registered trademarks of Saint-Gobain Performance Plastics Corporation.

Ordering Information

Flexsafe® RM	Basic Basic ViaMass	Basic screw cap Optical screw cap	Optical Optical ViaMass	Perfusion Perfusion ViaMass	Perfusion ATF Perfusion ATF ViaMass
1 L	DFB001L –	– –	– –	– –	– –
2 L	DFB002L –	DFB002L----01SC DFO002L----01SC	DFO002L –	DFP002L--SM –	DFP002L--AT –
10 L	DFB010L DFB010L----VM	DFB010L----01SC DFO010L----01SC	DFO010L DFO010L----VM	DFP010L--SM DFP010L--SMVM	DFP010L--AT DF010L--ATVM
20 L	DFB020L DFB020L----VM	DFB020L----01SC DFO020L----01SC	DFO020L DFO020L----VM	DFP020L--SM DFP020L--SMVM	DFP020L--AT DFP020L--ATVM
50 L	DFB050L DFB050L----VM	DFB050L----01SC DFO050L----01SC	DFO050L DFO050L----VM	DFP050L--SM DFP050L--SMVM	DFP050L--AT DFP050L--ATVM
50 L *	DFB050L----01US	–	–	–	–
100 L	DFB100L –	– –	DFO100L –	– –	DFP100L--AT –
200 L	DFB200L –	– –	DFO200L –	– –	DFP200L--AT –

* alternative dimension – 740 × 720 mm – suitable for competitor rockers

Technical Specifications

Facility and Utility Requirements

	BIOSTAT® RM 20 50 Basic	BIOSTAT® B with RM 20 50 Rocker	BIOSTAT® B with RM 200 Rocker
Power Supply (Country Specific) Frequency Electricity Consumption Protection Class			
Rocker platform	100 (240 V) 60 (50) Hz 600 W IP23	100 (240 V) 60 (50) Hz 600 W IP23	120 (230 V) 60 (50) Hz 10 (5.2) A 1200 W IP21
Control Tower	–	230 V 50 Hz 10 A IP21 or 120 V 60 Hz 12 A IP21	230 V 50 Hz 10 A IP21 or 120 V 60 Hz 12 A IP21
Load cells	100–240 V 15 W	100–240 V 15 W	
Gas Supply			
Inlet pressure (barg)	1.0–1.5	1.0–1.5	1.0–1.5
Quick coupling for gas tubes, Festo Type	∅ 4 mm	(∅ 6 mm)	(∅ 6 mm)
Connection hose coupling, external	–	∅ 6 mm	∅ 6 mm
Gas Specification According to ISO 8573-1: dry, free of oil and dust			
Particle size: <0.1 mm	•	•	•
Max. amount 0.1 mg/m ³ (class 1)	•	•	•
Condensate: dew point <3°C (class 4)	•	•	•
Oil <0.01 mg/m ³ (class 1)	•	•	•
Germs (class 0)	•	•	•
Water			
Water supply pressure (barg)	–	2–8	2–8
Connection hose coupling, external	–	∅ 10 mm	∅ 10 mm
Cooling water (for heating cooling system only)	–	(•)	(•)
Temperature	–	min. 4°	min. 4°
Degree of hardness	–	max. 12 dH	max. 12 dH
Operative Environment			
Ambient temperature	5–40°C		
Relative humidity range	50% (40°C) – 80% (31°C)		

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 20 Rocker complete	765×600×510 mm 30×24×16 in	30 kg 66 lb	Stainless steel, ABS
Bag holder 20	765×600×60 mm 30×24×2.4 in	5.5 kg 12 lb	Stainless steel, ABS
Lid 20	765×600×255 mm 30×24×10 in	2.5 kg 5.5 lb	ABS
BIOSTAT® RM 50 Rocker complete	1085×600×510 mm 43×24×18 in	31.3 kg 69 lb	Stainless steel, ABS
Bag holder 50	1085×600×60 mm 43×24×2.4 in	7.8 kg 17 lb	Stainless steel, ABS
Lid 50	1085×600×255 mm 43×24×10 in	3.7 kg 8 lb	ABS
Load cells for BIOSTAT® RM 20 50	609×536×60-68 mm 24×21×2.4-2.7 in	9 kg 20 lb	Stainless steel, ABS
BIOSTAT® RM 200 Rocker in 45° transport position	1940×905×1285 mm 77×36×51 in	197 kg 434 lb	Stainless steel, ABS
BIOSTAT® RM 200 Rocker in horizontal position	1940×1080×1155 mm 76×43×46 in	197 kg 434 lb	Stainless steel, ABS
Lab-cart	800×800×900 mm 32×32×36 in	88 kg 194 lb	Stainless steel



Process Control

	BIOSTAT® RM 20 50 Basic	BIOSTAT® B with RM 20 50 Rocker	BIOSTAT® B with RM 200 Rocker
Temperature Module			
Heating Only – Electrical Heating Plates			
Temperature control	RT-40°C	RT-40°C	RT-40°C
Heating capacity	2 × 140 W (48 V)	2 × 140 W (48 V)	2 × 410 W
Heating Cooling (Option) – Open Thermostat System with Circulation Pump and Automatic Cooling Water Valve			
Temperature control	–	8°C above cooling water up to 40°C	(8°C above cooling water up to 40°C)
Heating capacity	–	1 × 600 W	2 × 600 W
Over temperature protection	•	•	•
Gassing Module Rocker – Optional			
Max. total flow (ml/min) Controlled by MFC	One bag: 1 × 1 lpm Twin bag: 2 × 0.5 lpm	–	–
Fixed CO ₂ gassing (%) measured by IR sensor	0.8 -15 ± 5 %	–	–
Internal air pump	(•)	–	–
Gassing Module Control Tower			
	4-Gas mix (O ₂ , N ₂ , CO ₂ , air) with headspace outlet		
Rotameters	–	max. 4	max. 4
– flow rates		0.016 lpm – 8.3 lpm	0.016 lpm – 13 lpm
– accuracy		± 5% full scale	± 5% full scale
MFC	–	max. 4	max. 4
– flow rates		0.003 lpm – 5 lpm	0.06 lpm – 10 lpm
– accuracy		± 1% full scale	± 1% full scale
4-stage DO cascade	–	•	•
Advanced DO controller	–	(•)	(•)
Sensors & Measurement			
Temperature probe Pt 100	•	•	•
– temperature range	0 – 150°C	0– 150°C	0– 150°C
– display resolution	0.1°C	0.1°C	0.1°C
– amplifiers	2	1 (single) 2 (twin)	2
pH single use	–	•	•
– measurement range		6.5–8.5	6.5–8.5
– display resolution		0.1 pH	0.1 pH
– amplifiers		1 (single) 2 (twin)	2
– recalibration function		•	•
DO single-use	–	•	•
– measurement range		0–250%	0–250%
– display resolution		0.1%	0.1%
– amplifiers		1 (single) 2 (twin)	2
– recalibration function		•	•
Single-use viable biomass (BioPAT® ViaMass)	–	(•)	(•)
Load cells	(•)	(•)	(•)
– weight range accuracy	max. 30 kg 10 g	max. 30 kg 10 g	max. 120 kg 100 g
Balance substrate	–	(up to 2) per side	(up to 2) per side
External signal input	–	max. 2 0–10 V or 4–20 mA	2

() – optional, needs to be ordered separately

Pump Module	BIOSTAT® B with RM 20 50 Rocker and BIOSTAT® B with RM 200 Rocker
max. 4 internal and 2 external pumps, thereof 3 speed controlled per side	
Built-in Pumps	
Fixed Speed	Watson Marlow 114, Fast Load pump head
- Speed 5 rpm Flow rate (tubing wall thickness 1.6 mm)	ID: 0.5 mm: 0-0.1 ml/min 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 44 rpm Flow rate (tubing wall thickness 1.6 mm)	ID: 0.5 mm: 0.02-0.9 ml/min ID: 0.8 mm: 0.04-1.8 ml/min ID: 1.6 mm: 0.12-6.2 ml/min ID: 2.4 mm: 0.26-12.8 ml/min ID: 3.2 mm: 0.41-20.7 ml/min ID: 4.8 mm: 0.75-37.4 ml/min
Speed Controlled	Watson Marlow 114, Fast Load pump head
- Speed 0.15 – 5 rpm Flow rate (tubing wall thickness 1.6 mm)	ID: 0.5 mm: 0-0.1 ml/min ID: 0.8 mm: 0.01-0.2 ml/min ID: 1.6 mm: 0.02-0.7 ml/min ID: 2.4 mm: 0.04-1.5 ml/min ID: 3.2 mm: 0.07-2.4 ml/min ID: 4.8 mm: 0.13-4.3 ml/min
- Speed 5 – 150 rpm Flow rate (tubing wall thickness 1.6 mm)	ID: 0.5 mm: 0.1-3 ml/min ID: 0.8 mm: 0.2-6 ml/min ID: 1.6 mm: 0.7-21 ml/min ID: 2.4 mm: 1.45-43.5 ml/min ID: 3.2 mm: 2.35-70.5 ml/min ID: 4.8 mm: 4.25-127.5 ml/min
External Pumps	
Speed Controlled	Watson Marlow 520, Fast Load pump head, up to 200 rpm Watson Marlow 323



Communication

	BIOSTAT® RM 20 50 Basic	BIOSTAT® B with RM 20 50 Rocker	BIOSTAT® B with RM 200 Rocker
Industrial Ethernet	1	1	1
Profibus DP	(1)	-	-

The BIOSTAT® RM rocker is designed to communicate with industrial SCADA or DCS systems (e.g. DeltaV) through the standard Modbus RTU or an optional Profibus DP interfaces.



Technical Data

	BIOSTAT® RM 20 50 Basic	BIOSTAT® B with RM 20 50 Rocker	BIOSTAT® B with RM 200 Rocker
Max. total volume (L)	50	50	200
Working volume (L)	0.1–25	0.1–25	10–100
Rocking rate (r/min)	8–42 ± 1	8–42 ± 1	2–20 ± 1
Rocking angle (°)	4–10 ± 0.3	4–10 ± 0.3	2–10 ± 0.3
Clamping rails for bag fixation	•	•	•
Sensor clamps for secure fixation of glass fiber cables	–	2 (single) 4 (twin)	4
Filter heater	2	1 (single) 2 (twin)	2
Integrated Rocker Controller	•	•	–
BIOSTAT® B Control Tower	–	•	•
Color touch screen	•	•	•
Potential-free alarm contact	• (max. 0.5 A)	•	•
Safety measurement and shut-off	30 mbar (in combination with gassing module)	30 mbar	30 mbar
Additional safety valve gasses (mbar)	–	100 mbar	100 mbar
Water inlet pressure reduction value	–	1.5 bar, integrated pressure control	1.5 bar, integrated pressure control
Different user level log in	•	(•)	(•)
Logbook function	–	(•)	(•)
Lab-cart for BIOSTAT® B Control Tower	–	–	•



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