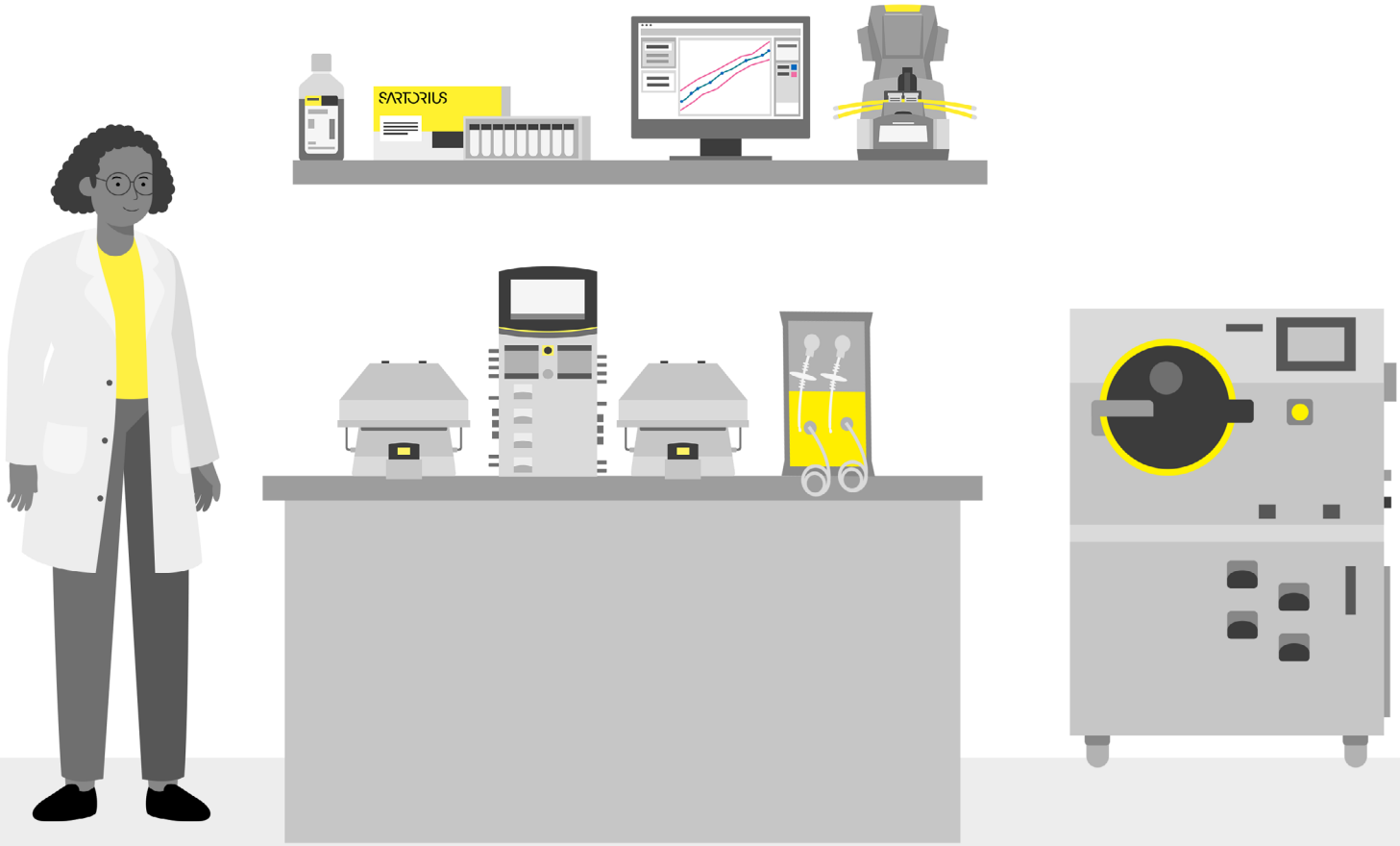

Sartorius T-Cell Allogeneic Manufacturing Solution

Data Sheet Collection

SARTORIUS

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Biostat® RM and Flexsafe® RM

For Seed Production and Small-Scale Protein Supply

Simplifying Progress

SARTORIUS

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,* T-cells and stem cells.

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

Process Step
- Protein and cell supply for preclinical purposes
- Seed production for large bioreactors
- Suitable for GMP use

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

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 or T-cells

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

Fully configurable control tower Biostat® B for various application needs

Flexsafe® RM bags with integrated single-use sensors (pH, DO, BioPAT® ViaMass*) for full process control

Load cells to enable more demanding processes, e.g. perfusion cultivation

* Manufactured under license from HAMILTON.

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|CO_2 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

Biostat® B with RM 200 Rocker

The Biostat® B with RM 200 Rocker is a single-use, rocking motion bioreactor for large-scale. Flexsafe® RM 100 L and 200 L bags are also available with a bag integrated perfusion filter. This solution is ideal for intensified seed supply without the need for an external cell retention device, e.g. ATF.

- 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

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 equiped with single-use pH, DO and 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.

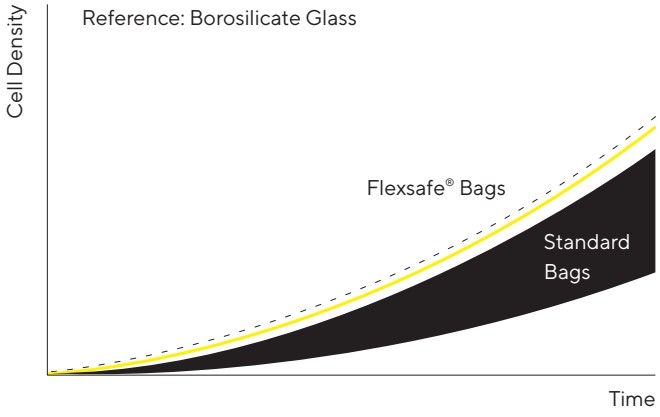
Watch Video
www.sartorius.com/video-biostat-b

The Flexsafe® Bag Family

Use our Flexsafe® RM bags in your seed train and scale-up to our Biostat STR® single-use stirred tank bioreactors equiped 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 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 bioprocessing 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.

- 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

Designs

The Flexsafe® RM bags are available in 1 L, 2 L, 10 L, 20 L, 50 L, 100 L and 200 L size.
They come in different configurations – basic, optical and two different perfusion options.

Basic Bags

Basic bags are designed for use in seed train and production applications without pH and DO control.

Optical Bags

Optical bags feature integrated single-use opto-chemical pH and DO sensors, which are already precalibrated. Used together with the Biostat® RM control tower, they allow high end cultivation with full process automation. Basic and optical bags up to 50 L size are also available with screw caps (Ø 38 mm). The screw cap can be used for the insertion | removal of larger objects inside a laminar flow cabinet, e.g. microcarriers.

Perfusion Bags

Perfusion bags are available in two versions:

- With an integrated 1.2 µm perfusion membrane (PES). The membrane is fixed at the bottom of the bag, forming a compartment for removal of cell free media. The wave created by the agitation moves over the surface of the membrane, thereby flushing the membrane with every rocking motion. This innovative and patented design ensures low fouling and long cultivation times.
- ATF perfusion bags are designed for the convenient connection to an external cell retention device via OPTA connector.

Flexsafe® RM bags are supplied gamma irradiated and ready to use. The Flexsafe® RM bag is mounted on the bag holder of the rocker easily and secured on both sides through fixation clamps.

	Basic Bag	Optical Bag	Perfusion Bag
For cultivation under constant conditions without pH and DO control	■		
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	■		

BioPAT® ViaMass

Single-Use Biomass Sensor

2–200 L rocking motion bags are available with an integrated single use biomass sensor: BioPAT® ViaMass. It measures the viable cell volume using the principle of biocapacitance, which is selective to viable cells only.

BioPAT® ViaMass is fully integrated in the Sartorius advanced control system and feedback loops can easily be implemented.

- 24 | 7 monitoring of viable cell volume | viable cell mass
- Can be used to calculate the viable cell density
- Automated feeding based on biocapacitance
- Viral processes: Determination of infection and harvest time point
- Cell therapy: Process monitoring without contamination risk and volume reduction
- Intensified processing: Automated cell bleed control based on biocapacitance

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 Screw Cap	Sampling Fill | harvest with dip tube Acid | Base Screw Cap	Sampling Fill | harvest with dip tube Acid | Base Perfusion feed | harvest Screw Cap
Sensors	Single-use viable biomass (BioPAT® ViaMass) 10 – 200 L	Optical chemical pH Optical chemical DO Single-use viable biomass (BioPAT® ViaMass)	Optical chemical pH Optical chemical DO Single-use viable biomass (BioPAT® ViaMass)
Perfusion	–	–	Perfusion membrane PES 1.2 µm | Opta aseptic connector to ATF** System
Tubing material	LDPE, PVC, Natvar TPE, C-Flex®***, Silicone, PharMed®***		
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.
** 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 1.2 µm Perfusion ViaMass	Perfusion ATF Perfusion ATF ViaMass
1 L	DFB001L –	– –	– –	– –	– –
2 L	DFB002L –	DFB002L----01SC DFO002L----01SC	DFO002L DFO002L--VM	DFP002L--SM DFP002L--SMVM	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 DFB100L----VM	– –	DFO100L DFO100L----VM	– DFP100L--SMVM	DFP100L--AT DFP100L--ATVM
200 L	DFB200L DFB200L----VM	– –	DFO200L DFO200L----VM	– DFP200L--SMVM	DFP200L--AT DFP200L--ATVM

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 – 7 lpm	0.016 lpm – 7 lpm
▪ accuracy		± 5% full scale	± 5% full scale
MFC	–	max. 4	max. 4
▪ flow rates		0.003 lpm – 5 lpm	0.06 lpm – 7 lpm
▪ accuracy		± 1% full scale	± 1% full scale
4-stage DO cascade	–	■	■
Advanced DO controller	–	(■)	(■)

* alternative dimension – 740 × 720 mm – suitable for competitor rockers
() – optional, needs to be ordered separately

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 static | ± 30 g dynamic	max 30 kg | ± 10 g static | ± 30 g dynamic	max 120 kg | ± 100 g static | ± 300 g dynamic
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

Process Control

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/mi
▪ 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

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	Ø 4 mm	(Ø 6 mm)	(Ø 6 mm)
Connection hose coupling, external	–	Ø 6 mm	Ø 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/m³ (class 1)	■	■	■
Condensate: dew point < 3°C (class 4)	■	■	■
Oil < 0.01 mg/m³ (class 1)	■	■	■
Germs (class 0)	■	■	■
Water			
Water supply pressure (barg)	–	2 – 8	2 – 8
Connection hose coupling, external	–	Ø 10 mm	Ø 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)		

() – optional, needs to be ordered separately

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 × 613 × 500 mm 30 × 24 × 20 in	30 kg 66 lb	Stainless steel, ABS
Bag holder 20	763 × 597 × 60 mm 30 × 24 × 2.4 in	5.5 kg 12 lb	Stainless steel, ABS
Lid 20	761 × 597 × 252 mm 30 × 24 × 10 in	2.5 kg 5.5 lb	ABS
Biostat® RM 50 Rocker complete	1085 × 625 × 500 mm 43 × 24 × 20 in	31.3 kg 69 lb	Stainless steel, ABS
Bag holder 50	1085 × 598 × 60 mm 43 × 24 × 2.4 in	7.8 kg 17 lb	Stainless steel, ABS
Lid 50	1083 × 576 × 252 mm 43 × 23 × 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

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 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 Controler	■		■		–
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	–		–		■

() – optional, needs to be ordered separately

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SARTORIUS

Product Datasheet

Flexsafe® RM

Disposable Cultivation Chambers for Rocking Motion Bioreactors

Product Information

The Flexsafe® RM is a single use bioreactor bag available in multiple sizes and configurations depending on customer requirements. The control of the complete manufacturing process, from the resin to the final bag, ensures consistent and reproducible quality of the Flexsafe® bioprocessing bags.

Applications

Our Biostat® RM bioreactors use rocking motion mixing technology which is ideal for cell cultivation with low shear stress. Easy to use, it is hassle free and applicable to all cell types, including

- Mammalian cells
- Plant cells
- Insect cells
- Microbial cells
- Stem cells and
- T-cells.

Flexibility and Configurations

The Flexsafe® RM bags are available in 1 L, 2 L, 10 L, 20 L, 50 L, 100 L and 200 L size. Bags are available as basic, optical and perfusion configurations.

Basic bags are designed for use in seed train and production applications without pH and DO control.

Optical bags feature integrated single use opto-chemical pH and DO sensors, which are already pre-calibrated. Used together with the Biostat® RM control tower, they allow high end cultivation with full process automation.

Basic and optical bags up to 50 L size are also available with screw caps (38 mm diameter). The screw cap can be used for the insertion | removal of larger objects inside a laminar flow cabinet, e.g. microcarriers.

Perfusion bags are available in two versions:
A) With an integrated 1.2 µm perfusion membrane (PES). The membrane is fixed at the bottom of the bag, forming a compartment for removal of cell free media. The wave created by the agitation moves over the surface of the membrane, thereby flushing the membrane with every rocking motion. This innovative and patented design* ensures low fouling and long cultivation times.
B) ATF perfusion bags are designed for the convenient conne

Easy Implementation

Flexsafe® RM Bags are supplied gamma irradiated and ready to use. The Flexsafe® RM bag is mounted on the bag holder of the rocker easily and secured on both sides through fixation clamps.

Sensors

Precise and reliable single-use sensors for pH and DO come pre-installed and sterilized with the bag. The sensors are pre-calibrated and the calibration data is supplied together with the bag.

2 L to 200 L bags are also available with integrated sensors for measurement of viable biomass (Viamass). All 2nd generation Biostat® B with RM systems can be equipped with the BioPAT® Viamass electronics. Please contact your local Sartorius Stedim Biotech representative for further information.

Figure 1: *Viable Biomass Sensor (BioPAT® Viamass) Integrated in the Flexsafe® RM Bag – Connection to the Hardware Component.*

Working Volumes and Surface Areas of Flexsafe® RM Standard Bags

Bag Size (Total Volume)	Min. Working Volume* [L]	Max. Working Volume [L]	Surface Area [mm²]**
1 L	0.1	0.5	127296
2 L	0.2	1	172260
10 L	1	5	303360
20 L	2	10	633080
50 L	5	25	985320
100 L	10	50	1421724
200 L	20	100	2777064

Validation and Extractable Testing

Flexsafe® RM Bags have been qualified applying the most complex and innovative test regimes. Biological, chemical and physical tests combined with extractable testing prove lowest extractable and leachable levels and excellent compatibility to the relevant pharmacopoeias and guidelines. For more information, please refer to our Validation Guide and Extractable Guide.

Quality Assurance

All relevant materials are selected following applicable regulations and standards such as FDA, CFR's, cGMPs and in-house guidelines. Finished Flexsafe® RM bags undergo final product quality control which is certified with a Quality Assurance certificate.

* Perfusion bag design protected by Sartorius patents US 9,017,977 B2 and EP2268788B1

Technical Data

Flexsafe® RM Bag Sizes and Available Components

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 & optical with screw cap		■	■	■	■		
Optical		■	■	■	■	■	■
Perfusion with integrated membrane		■	■	■	■		
Perfusion with connection to ATF module		■	■	■	■	■	■
Basic, optical, perfusion & perfusion ATF with Viamass		■	■	■	■	■	■

Main Components	Basic	Optical	Perfusion
Connectors	Female | Male Luer Female | Male MPC Clave® connector	Female | Male Luer Female | Male MPC Clave® connector	Female | Male Luer Female | Male MPC Clave® connector Opta® connector
Filters	Air Inlet | Air Outlet	Air Inlet | Air Outlet	Air Inlet | Air Outlet
Ports	Sampling Fill | harvest with dip tube Acid | Base Screw Cap	Sampling Fill | harvest with dip tube Acid | Base Screw Cap	Sampling Fill | harvest with dip tube Acid | Base Perfusion feed | harvest Screw Cap
Sensors	Single-use viable biomass (BioPAT® Viamass) 10 – 50 L	Optical chemical pH Optical chemical DO Single-use viable biomass (BioPAT® Viamass)***	Optical chemical pH Optical chemical DO Single-use viable biomass (BioPAT® Viamass)***
Perfusion	–	–	Perfusion membrane PES 1.2 µm | Opta aseptic connector to ATF system
Tubing material	LDPE, Silicone, PVC, C-Flex®, PharMed®, Natvar TPE		

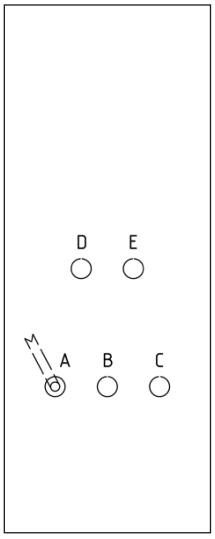
** Bags with sensors might require higher minimum working volumes depending on rocking rate and angle. We recommend using 20% of the total as the minimum working volume.
*** Manufactured under license from HAMILTON.

Bag Configurations – Flexsafe® RM Basic Bags

Flexsafe® RM 1 L basic

DFB001L

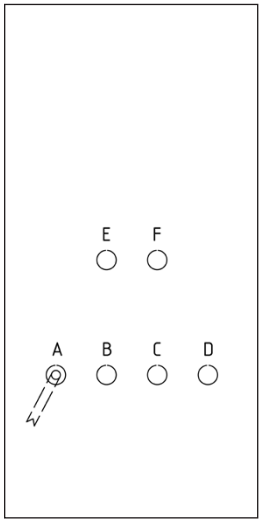
Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port B	Septum for needle-free sampling, FM-Luer
Port C	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer
Port D	Gas Outlet Filter with Check Valve, M-Luer
Port E	Gas Inlet Filter ¼" Hose barb



Flexsafe® RM 2 L basic

DFB002L

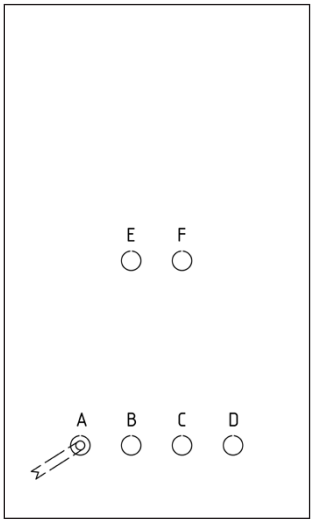
Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port B	Septum for needle-free sampling, FM-Luer
Port C; D	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer
Port E	Gas Outlet Filter with Check Valve, M-Luer
Port F	Gas Inlet Filter ¼" Hose barb



Flexsafe® RM 10 L basic

DFB010L

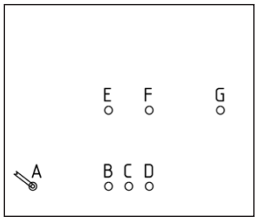
Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port C	Septum for needle-free sampling, FM-Luer
Port D	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer
Port E	Gas Outlet Filter with Check Valve, M-Luer
Port F	Gas Inlet Filter ¼" Hose barb



Flexsafe® RM 20 L basic

DFB020L

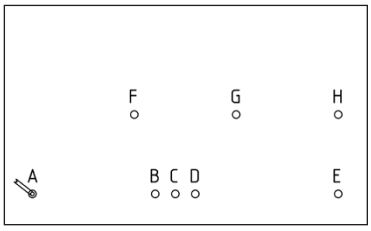
Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port C	Septum for needle-free sampling, FM-Luer
Port D; G	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer
Port E	Gas Outlet Filter with Check Valve, M-Luer
Port F	Gas Inlet Filter ¼" Hose barb



Flexsafe® RM 50 L basic

DFB050L

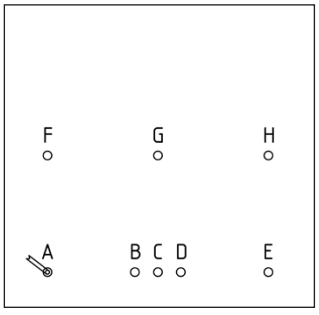
Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port C	Septum for needle-free sampling, FM-Luer
Port D; H	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer
Port E	C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), M-MPC
Port F	Gas Outlet Filter with Check Valve, M-Luer
Port G	Gas Inlet Filter ¼" Hose barb



Flexsafe® RM 50 L basic (US)

DFB050L----01US

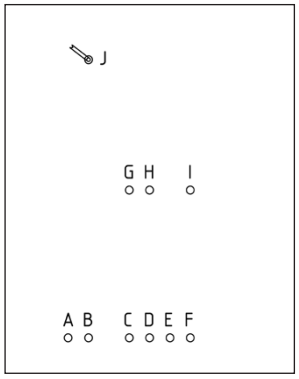
Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port C	Septum for needle-free sampling, FM-Luer
Port D; H	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer
Port E	C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), M-MPC
Port F	Gas Outlet Filter with Check Valve, M-Luer
Port G	Gas Inlet Filter ¼" Hose barb



Flexsafe® RM 100 L basic

DFB100L

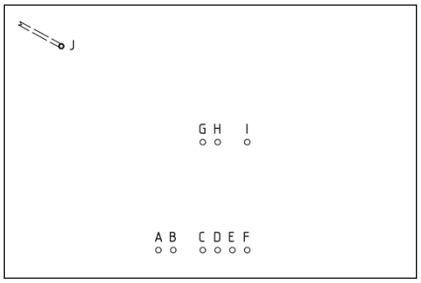
Ports	
Port A; C	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer
Port B	C-Flex® 374 tubing 3⁄8" × 5⁄8" (1000 mm), M-MPC
Port D; E	Septum for needle-free sampling, FM-Luer
Port F	C-Flex® 374 tubing 1⁄8" × 1⁄4" (1000 mm), FM-Luer
Port G	Gas Outlet Filter, M-Luer
Port H; I	Gas Inlet | Outlet Filter 1⁄4" Hose barb
Port J	Dip Tube Silicone, C-Flex® 374 tubing 3⁄8" × 5⁄8" (1000 mm), M-MPC



Flexsafe® RM 200 L basic

DFB200L

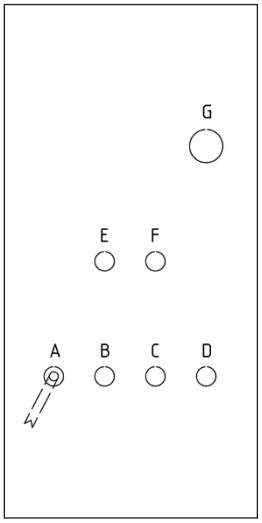
Ports	
Port A; C	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer
Port B	C-Flex® 374 tubing 3⁄8" × 5⁄8" (1000 mm), M-MPC
Port D; E	Septum for needle-free sampling, FM-Luer
Port F	C-Flex® 374 tubing 1⁄8" × 1⁄4" (1000 mm), FM-Luer
Port G	Gas Outlet Filter, M-Luer
Port H; I	Gas Inlet | Outlet Filter 1⁄4" Hose barb
Port J	Dip Tube Silicone, C-Flex® 374 tubing 3⁄8" × 5⁄8" (1000 mm), M-MPC



Flexsafe® RM 2 L basic Screw Cap

DFB002L----01SC

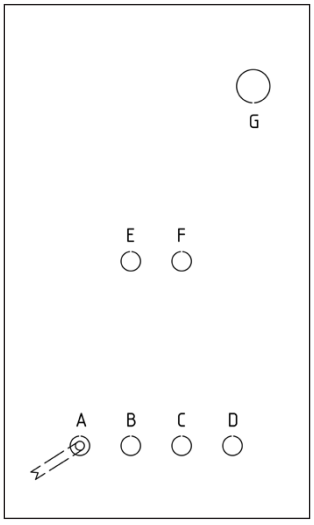
Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing 1⁄8" × 1⁄4" (1000 mm), FM-Luer
Port B	Septum for needle-free sampling, FM-Luer
Port C; D	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer
Port E	Gas Outlet Filter with Check Valve, M-Luer
Port F	Gas Inlet Filter 1⁄4" Hose barb
Port G	Screw Cap 38 mm



Flexsafe® RM 10 L basic Screw Cap

DFB010L----01SC

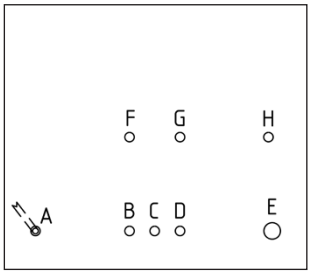
Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port C	Septum for needle-free sampling, FM-Luer
Port D	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer
Port E	Gas Outlet Filter with Check Valve, M-Luer
Port F	Gas Inlet Filter ¼" Hose barb
Port G	Screw Cap 38 mm



Flexsafe® RM 20 L basic Screw Cap

DFB020L----01SC

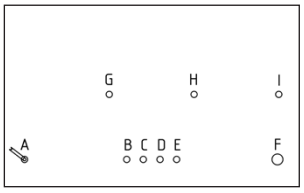
Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port C	Septum for needle-free sampling, FM-Luer
Port D; H	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer
Port E	Screw Cap 38 mm
Port F	Gas Outlet Filter with Check Valve, M-Luer
Port G	Gas Inlet Filter ¼" Hose barb



Flexsafe® RM 50 L basic Screw Cap

DFB050L----01SC

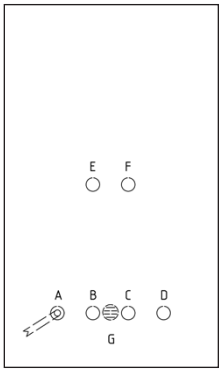
Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port C	Septum for needle-free sampling, FM-Luer
Port D; I	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer
Port E	C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), M-MPC
Port F	Screw Cap 38 mm
Port G	Gas Outlet Filter with Check Valve, M-Luer
Port H	Gas Inlet Filter ¼" Hose barb



Flexsafe® RM 10 L basic Viamass

DFB010L----VM

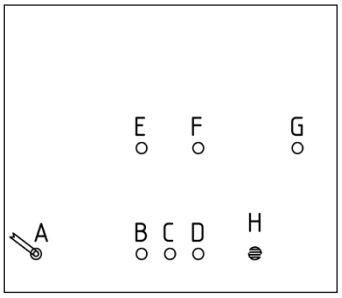
Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port C	Septum for needle-free sampling, FM-Luer
Port D	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer
Port E	Gas Outlet Filter with Check Valve, M-Luer
Port F	Gas Inlet Filter ¼" Hose barb
Port G	BioPAT® Viamass sensor



Flexsafe® RM 20 L basic Viamass

DFB020L----VM

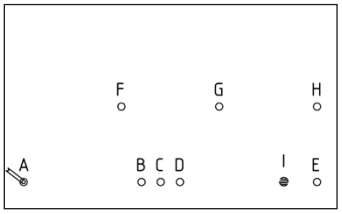
Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port C	Septum for needle-free sampling, FM-Luer
Port D; G	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer
Port E	Gas Outlet Filter with Check Valve, M-Luer
Port F	Gas Inlet Filter ¼" Hose barb
Port H	BioPAT® Viamass sensor



Flexsafe® RM 50 L basic Viamass

DFB050L----VM

Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port C	Septum for needle-free sampling, FM-Luer
Port D; H	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer
Port E	C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), M-MPC
Port F	Gas Outlet Filter with Check Valve, M-Luer
Port H	Gas Inlet Filter ¼" Hose barb
Port I	BioPAT® Viamass sensor

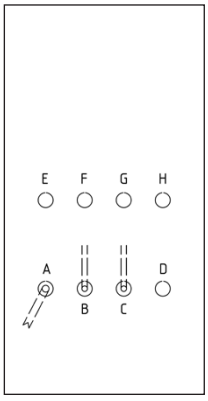


Bag Configurations — Flexsafe® RM Optical Bags

Flexsafe® RM 2 L optical

DFO002L

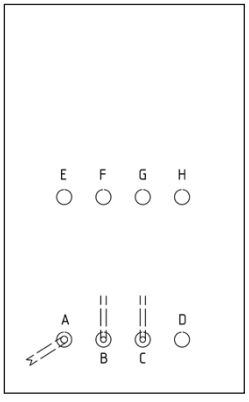
Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port B	DO sensor
Port C	pH sensor
Port D	Septum for needle-free sampling, FM-Luer
Port E; H	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer
Port F	Gas Outlet Filter with Check Valve, M-Luer
Port G	Gas Inlet Filter ¼" Hose barb



Flexsafe® RM 10 L optical

DFO010L

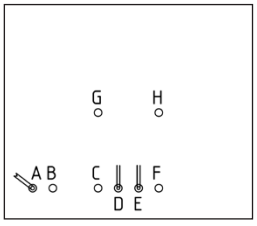
Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), FM-MPC
Port B	DO sensor
Port C	pH sensor
Port D	Septum for needle-free sampling, FM-Luer
Port E	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port F	Gas Outlet Filter with Check Valve, M-Luer
Port G	Gas Inlet Filter ¼" Hose barb
Port H	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer



Flexsafe® RM 20 L optical

DFO020L

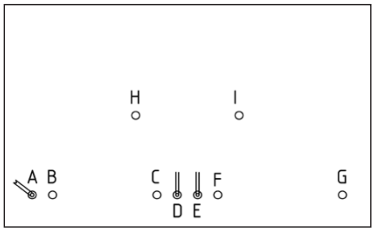
Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port C	Septum for needle-free sampling, FM-Luer
Port D	DO sensor
Port E	pH sensor
Port F	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer
Port G	Gas Outlet Filter with Check Valve, M-Luer
Port H	Gas Inlet Filter ¼" Hose barb



Flexsafe® RM 50 L optical

DFO050L

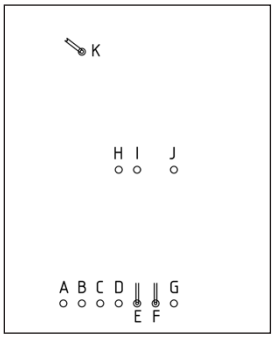
Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port C	Septum for needle-free sampling, FM-Luer
Port D	DO sensor
Port E	pH sensor
Port F	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer
Port G	C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), M-Luer
Port H	Gas Outlet Filter with Check Valve, M-Luer
Port I	Gas Inlet Filter ¼" Hose barb



Flexsafe® RM 100 L optical

DFO100L

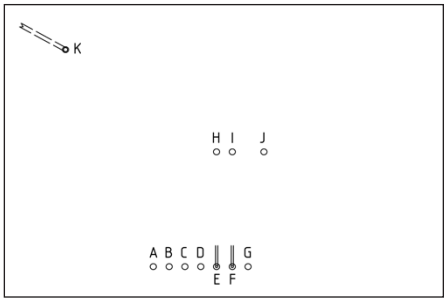
Ports	
Port A	C-Flex® 374 tubing ⅜" × ⅝" (1000 mm), M-MPC
Port B	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer
Port C; D	Septum for needle-free sampling, FM-Luer
Port E	DO sensor
Port F	pH sensor
Port G	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port H	Gas Outlet Filter, M-Luer
Port I; J	Gas Inlet | Outlet Filter ¼" Hose barb
Port K	Dip Tube Silicone, C-Flex® 374 tubing ⅜" × ⅝" (1000 mm), M-MPC



Flexsafe® RM 200 L optical

DFO200L

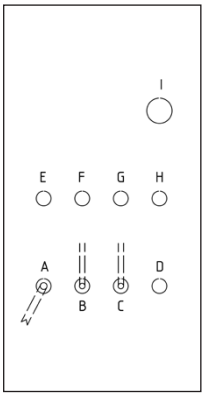
Ports	
Port A	C-Flex® 374 tubing ⅜" × ⅝" (1000 mm), M-MPC
Port B	Silicone tubing ³⁄₁₆" × ⁵⁄₁₆" (50 mm), FM-Luer
Port C; D	Septum for needle-free sampling, FM-Luer
Port E	DO sensor
Port F	pH sensor
Port G	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port H	Gas Outlet Filter, M-Luer
Port I; J	Gas Inlet | Outlet Filter ¼" Hose barb
Port K	Dip Tube Silicone, C-Flex® 374 tubing ⅜" × ⅝" (1000 mm), M-MPC



Flexsafe® RM 2 L optical Screw Cap

DFO002L----01SC

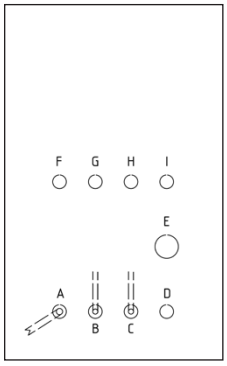
Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port B	DO sensor
Port C	pH sensor
Port D	Septum for needle-free sampling, FM-Luer
Port E; H	Silicone tubing ³⁄₁₆" × ⁵⁄₁₆" (50 mm), FM-Luer
Port F	Gas Outlet Filter with Check Valve, M-Luer
Port G	Gas Inlet Filter ¼" Hose barb
Port I	Screw Cap 38 mm



Flexsafe® RM 10 L optical Screw Cap

DFO010L----01SC

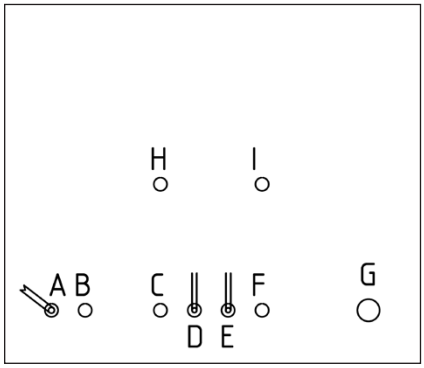
Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), FM-MPC
Port B	DO sensor
Port C	pH sensor
Port D	Septum for needle-free sampling, FM-Luer
Port E	Screw Cap 38 mm
Port F	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port G	Gas Outlet Filter with Check Valve, M-Luer
Port H	Gas Inlet Filter ¼" Hose barb
Port I	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer
Port K	Dip Tube Silicone, C-Flex® 374 tubing ⅜" × ⅝" (1000 mm), M-MPC



Flexsafe® RM 20 L optical Screw Cap

DFO020L----01SC

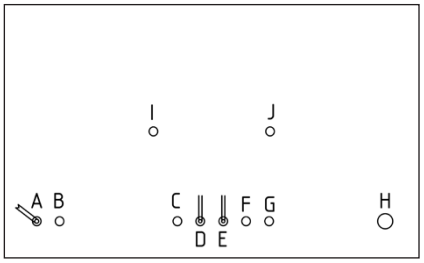
Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port C	Septum for needle-free sampling, FM-Luer
Port D	DO sensor
Port E	pH sensor
Port F	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer
Port G	Screw Cap 38 mm
Port H	Gas Outlet Filter with Check Valve, M-Luer
Port I	Gas Inlet Filter ¼" Hose barb



Flexsafe® RM 50 L optical Screw Cap

DFO050L----01SC

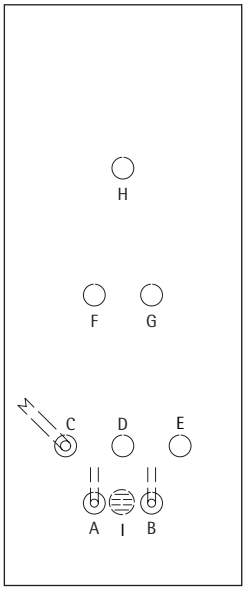
Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port C	Septum for needle-free sampling, FM-Luer
Port D	DO sensor
Port E	pH sensor
Port F	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer
Port G	C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), M-MPC
Port H	Screw Cap 38 mm
Port I	Gas Outlet Filter with Check Valve, M-Luer
Port J	Gas Inlet Filter ¼" Hose barb



Flexsafe® RM 2 L optical Viamass

DFO002L--VM

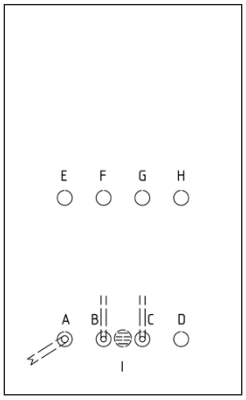
Ports	
Port A	DO sensor
Port B	pH sensor
Port C	Dip Tube Silicone, C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), FM-Luer
Port D	Septum for needle-free sampling, FM-Luer
Port E	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer
Port F	Gas Outlet Filter with Check Valve, M-Luer
Port G	Gas Inlet Filter ¼" Hose barb
Port H	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer
Port I	BioPAT® Viamass sensor



Flexsafe® RM 10 L optical Viamass

DFO010L----VM

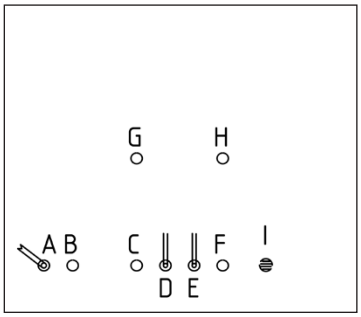
Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), FM-MPC
Port B	DO sensor
Port C	pH sensor
Port D	Septum for needle-free sampling, FM-Luer
Port E	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port F	Gas Outlet Filter with Check Valve, M-Luer
Port G	Gas Inlet Filter ¼" Hose barb
Port H	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer
Port I	BioPAT® Viamass sensor



Flexsafe® RM 20 L optical Viamass

DFO020L----VM

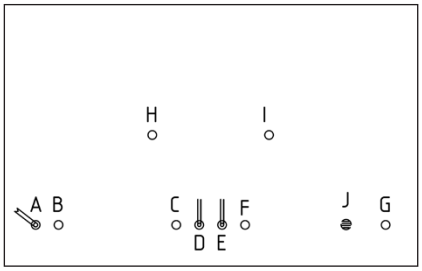
Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port C	Septum for needle-free sampling, FM-Luer
Port D	DO sensor
Port E	pH sensor
Port F	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer
Port G	Gas Outlet Filter with Check Valve, M-Luer
Port H	Gas Inlet Filter ¼" Hose barb
Port I	BioPAT® Viamass sensor



Flexsafe® RM 50 L optical Viamass

DFO050L----VM

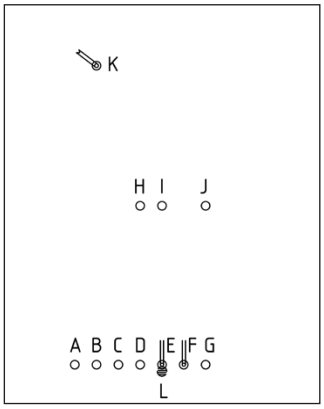
Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port C	Septum for needle-free sampling, FM-Luer
Port D	DO sensor
Port E	pH sensor
Port F	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer
Port G	C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), M-MPC
Port H	Gas Outlet Filter with Check Valve, M-Luer
Port I	Gas Inlet Filter ¼" Hose barb
Port J	BioPAT® Viamass sensor



Flexsafe® RM 100 L optical Viamass

DFO100L----VM

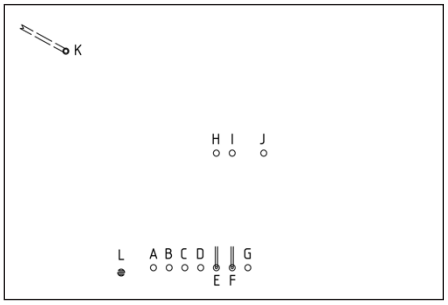
Ports	
Port A	C-Flex® 374 tubing ⅜" × ⅝" (1000 mm), M-MPC
Port B	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer
Port C; D	Septum for needle-free sampling, FM-Luer
Port E	DO sensor
Port F	pH sensor
Port G	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port H	Gas Outlet Filter, M-Luer
Port I; J	Gas Inlet | Outlet Filter ¼" Hose barb
Port K	Dip Tube Silicone, C-Flex® 374 tubing ⅜" × ⅝" (1000 mm), M-MPC
Port L	BioPAT® Viamass sensor



Flexsafe® RM 200 L optical Viamass

DFO200L----VM

Ports	
Port A	C-Flex® 374 tubing ⅜" × ⅝" (1000 mm), M-MPC
Port B	Silicone tubing ³⁄₁₆" × ⁵⁄₁₆" (50 mm), FM-Luer
Port C; D	Septum for needle-free sampling, FM-Luer
Port E	DO sensor
Port F	pH sensor
Port G	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port H	Gas Outlet Filter, M-Luer
Port I; J	Gas Inlet | Outlet Filter ¼" Hose barb
Port K	Dip Tube Silicone, C-Flex® 374 tubing ⅜" × ⅝" (1000 mm), M-MPC
Port L	BioPAT® Viamass sensor

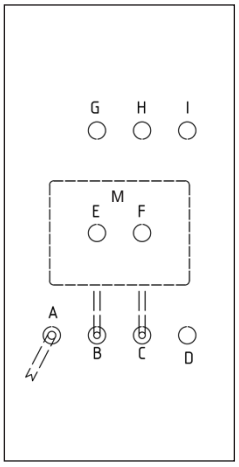


Bag Configurations — Flexsafe® RM Perfusion Membrane Bags

Flexsafe® RM 2 L perfusion

DFP002L--SM

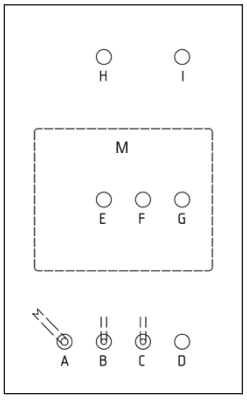
Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ⅛" × ¼" (1000 mm), PharMed® 1/16" × 3/16" (300 mm), FM-Luer (Perfusion Feed)
Port B	DO sensor
Port C	pH sensor
Port D	Septum for needle-free sampling, FM-Luer
Port E	Gas Outlet Filter with Check Valve, M-Luer
Port F	Gas Inlet Filter ¼" Hose barb
Port G	Silicone tubing 3/16" × 5/16" (50 mm), FM-Luer
Port H	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port I	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), PharMed® 1/16" × 3/16" (300 mm), FM-Luer (Perfusion Harvest)
M	Perfusion membrane, PES 1.2 µm, fixed at the bottom of the bag



Flexsafe® RM 10 L perfusion

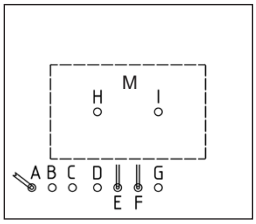
DFP010L--SM

Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ¼" × 7/16" (1000 mm), FM-MPC
Port B	DO sensor
Port C	pH sensor
Port D	Septum for needle-free sampling, FM-Luer
Port E	Gas Outlet Filter with Check Valve, M-Luer
Port F	Gas Inlet Filter ¼" Hose barb
Port G	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), PharMed® 1/16" × 3/16" (300 mm), FM-Luer (Perfusion Feed)
Port H	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port I	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), PharMed® 1/16" × 3/16" (300 mm), FM-Luer (Perfusion Harvest)
M	Perfusion membrane, PES 1.2 µm, fixed at the bottom of the bag



Flexsafe® RM 20 L perfusion

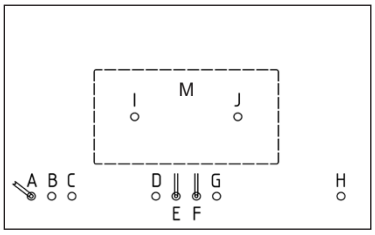
DFP020L--SM



Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port C	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), PharMed® ⅛" × ¼" (300 mm), FM-Luer (Perfusion Feed)
Port D	Septum for needle-free sampling, FM-Luer
Port E	DO sensor
Port F	pH sensor
Port G	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), PharMed® ⅛" × ¼" (300 mm), FM-Luer (Perfusion Harvest)
Port H	Gas Outlet Filter with Check Valve, M-Luer
Port I	Gas Inlet Filter ¼" Hose barb
M	Perfusion membrane, PES 1.2 µm, fixed at the bottom of the bag

Flexsafe® RM 50 L perfusion

DFP050L--SM

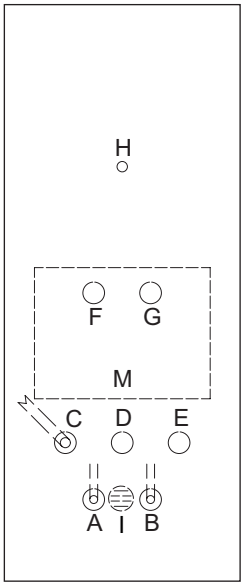


Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port C	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), PharMed® ⅛" × ¼" (300 mm), FM-Luer (Perfusion Feed)
Port D	Septum for needle-free sampling, FM-Luer
Port E	DO sensor
Port F	pH sensor
Port G	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), PharMed® ⅛" × ¼" (300 mm), FM-Luer (Perfusion Harvest)
Port H	C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), M-MPC
Port I	Gas Outlet Filter with Check Valve, M-Luer
Port J	Gas Inlet Filter ¼" Hose barb
M	Perfusion membrane, PES 1.2 µm, fixed at the bottom of the bag

Flexsafe® RM TX 2 L perfusion Viamass, TPE

DFT002L--SMVM1

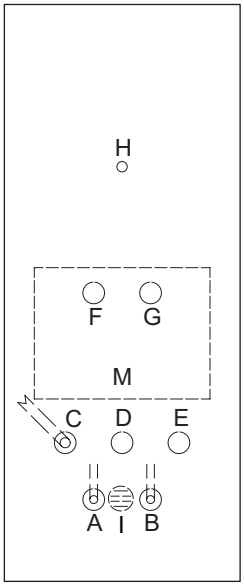
Ports	
Port A	DO sensor
Port B	pH sensor
Port C	Dip Tube Silicone, C-Flex® 374 tubing ⅛" × ¼" (1000 mm), PharMed® 1/16" × 3/16" (300 mm), C-Flex® 374 ⅛" × ¼" (500 mm) press-in plug (Perfusion Feed)
Port D	Septum for needle-free sampling, FM-Luer
Port E	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), PharMed® 1/16" × 3/16" (300 mm), C-Flex® 374 ⅛" × ¼" (500 mm), press-in plug (Perfusion Harvest)
Port F	Gas Outlet Filter, Sartopore® Air Midisart with Check Valve, M-Luer
Port G	Gas Inlet Filter, Sartopore® Air Midisart
Port H	Harvest port: C-Flex® 374 tubing ⅛" × ¼" (1000 mm)
Port I	BioPAT® Viamass sensor
M	Perfusion membrane, PES 1.2 µm, fixed at the bottom of the bag



Flexsafe® RM TX 2 L perfusion Viamass, PVC

DFT002L--SMVM2

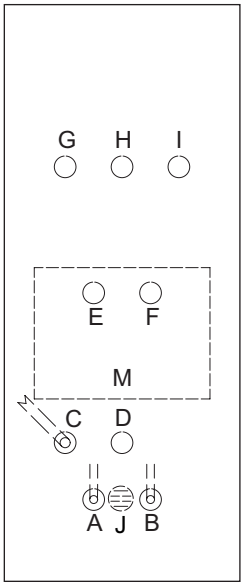
Ports	
Port A	DO sensor
Port B	pH sensor
Port C	Dip Tube Silicone, C-Flex® 374 tubing ⅛" × ¼" (1000 mm), PharMed® 1/16" × 3/16" (300 mm), Tygon 3/32" × 5/32" (500 mm), press-in plug (Perfusion Feed)
Port D	Septum for needle-free sampling, FM-Luer
Port E	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), PharMed® 1/16" × 3/16" (300 mm), Tygon 3/32" × 5/32" (500 mm), press-in plug (Perfusion Harvest)
Port F	Gas Outlet Filter, Sartopore® Air Midisart with Check Valve, M-Luer
Port G	Gas Inlet Filter, Sartopore® Air Midisart
Port H	Harvest port: Silicone tubing ⅛" × ¼" (50 mm), Tygon 3/32" × 5/32" (1000 mm), press-in plug
Port I	BioPAT® Viamass sensor
M	Perfusion membrane, PES 1.2 µm, fixed at the bottom of the bag



Flexsafe® RM 2 L perfusion Viamass

DFP002L--SMVM

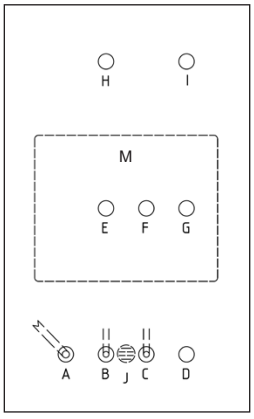
Ports	
Port A	DO sensor
Port B	pH sensor
Port C	Dip Tube Silicone, C-Flex® 374 tubing ⅛" × ¼" (1000 mm), PharMed® 1⁄16" × 3⁄16" (300 mm), FM-Luer (Perfusion Feed)
Port D	Septum for needle-free sampling, FM-Luer
Port E	Gas Outlet Filter with Check Valve, M-Luer
Port F	Gas Inlet Filter ¼" Hose barb
Port G	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer
Port H	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port I	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), PharMed® 1⁄16" × 3⁄16" (300 mm), FM-Luer (Perfusion Harvest)
Port J	BioPAT® Viamass sensor
M	Perfusion membrane, PES 1.2 µm, fixed at the bottom of the bag



Flexsafe® RM 10 L perfusion Viamass

DFP010L--SMVM

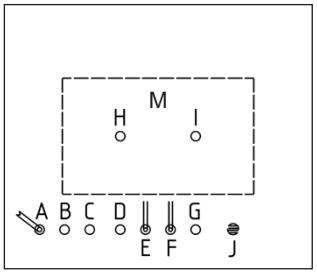
Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), FM-MPC
Port B	DO sensor
Port C	pH sensor
Port D	Septum for needle-free sampling, FM-Luer
Port E	Gas Outlet Filter with Check Valve, M-Luer
Port F	Gas Inlet Filter ¼" Hose barb
Port G	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), PharMed® 1⁄16" × 3⁄16" (300 mm), FM-Luer (Perfusion Feed)
Port H	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port I	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), PharMed® 1⁄16" × 3⁄16" (300 mm), FM-Luer (Perfusion Harvest)
Port J	BioPAT® Viamass sensor
M	Perfusion membrane, PES 1.2 µm, fixed at the bottom of the bag



Flexsafe® RM 20 L perfusion Viamass

DFP020L--SMVM

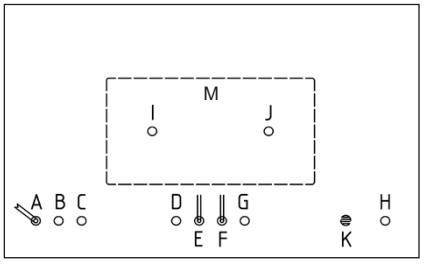
Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port C	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), PharMed® ⅛" × ¼" (300 mm), FM-Luer (Perfusion Feed)
Port D	Septum for needle-free sampling, FM-Luer
Port E	DO sensor
Port F	pH sensor
Port G	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), PharMed® ⅛" × ¼" (300 mm), FM-Luer (Perfusion Harvest)
Port H	Gas Outlet Filter with Check Valve, M-Luer
Port I	Gas Inlet Filter ¼" Hose barb
Port J	BioPAT® Viamass sensor
M	Perfusion membrane, PES 1.2 µm, fixed at the bottom of the bag



Flexsafe® RM 50 L perfusion Viamass

DFP050L--SMVM

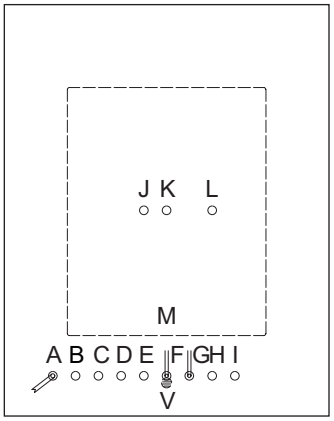
Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port C	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), PharMed® ⅛" × ¼" (300 mm), FM-Luer (Perfusion Feed)
Port D	Septum for needle-free sampling, FM-Luer
Port E	DO sensor
Port F	pH sensor
Port G	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), PharMed® ⅛" × ¼" (300 mm), FM-Luer (Perfusion Harvest)
Port H	C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), M-MPC
Port I	Gas Outlet Filter with Check Valve, M-Luer
Port J	Gas Inlet Filter ¼" Hose barb
Port K	BioPAT® Viamass sensor
M	Perfusion membrane, PES 1.2 µm, fixed at the bottom of the bag



Flexsafe® RM 100 L perfusion Viamass

DFP100L--SMVM

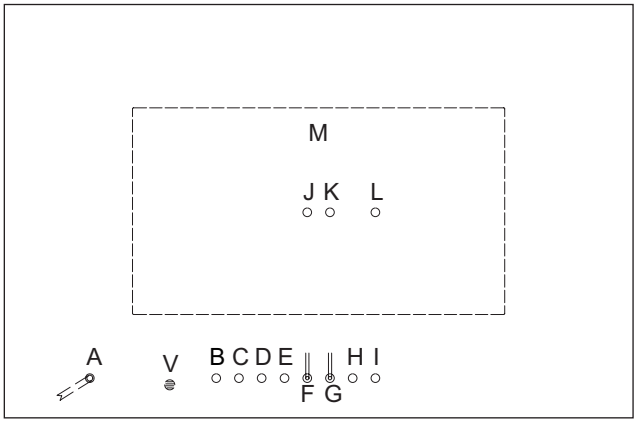
Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ⅜" × ⅝" (1000 mm), M-MPC
Port B	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port C	C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), PharMed® 3⁄16" × 5⁄16" (300 mm), FM-Luer (Perfusion Feed)
Port D	C-Flex® 374 tubing ⅜" × ⅝" (1000 mm), M-MPC
Port E	Septum for needle-free sampling, FM-Luer
Port F	DO sensor
Port G	pH sensor
Port H	C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), PharMed® 3⁄16" × 5⁄16" (300 mm), FM-Luer (Perfusion Harvest)
Port I	Septum for needle-free sampling, FM-Luer
Port J	Gas Outlet Filter, M-Luer, ¼" Hose barb
Port K	Gas Inlet | Outlet Filter, ¼" Hose barb
Port L	Gas Inlet, ¼" Hose barb
Port V	BioPAT® Viamass sensor
M	Perfusion membrane, PES 1.2 µm, fixed at the bottom of the bag



Flexsafe® RM 200 L perfusion Viamass

DFP200L--SMVM

Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ⅜" × ⅝" (1000 mm), M-MPC
Port B	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), Silicone, FM-Luer
Port C	C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), PharMed® 3⁄16" × 5⁄16" (300 mm), FM-Luer (Perfusion Feed)
Port D	C-Flex® 374 tubing ⅜" × ⅝" (1000 mm), M-MPC
Port E	Septum for needle-free sampling, FM-Luer
Port F	DO sensor
Port G	pH sensor
Port H	Septum for needle-free sampling, FM-Luer
Port I	C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), PharMed® 3⁄16" × 5⁄16" (300 mm), FM-Luer (Perfusion Harvest)
Port J	Gas Outlet Filter, M-Luer, ¼" Hose barb
Port K	Gas Inlet | Outlet Filter, ¼" Hose barb
Port L	Gas Inlet Filter ¼" Hose barb
Port V	BioPAT® Viamass sensor
M	Perfusion membrane, PES 1.2 µm, fixed at the bottom of the bag

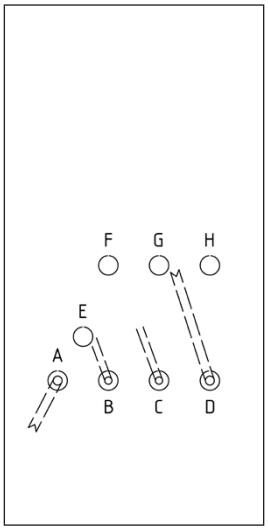


Bag Configurations – Flexsafe® RM Perfusion ATF Bags

Flexsafe® RM 2 L perfusion ATF

DFP002L--AT

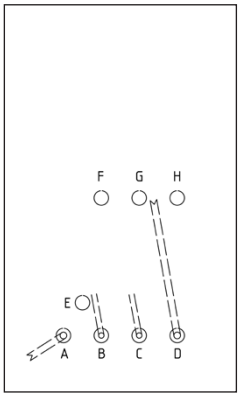
Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port B	DO sensor
Port C	pH sensor
Port D	Dip Tube Silicone, Silicone tubing ⅜" × ⅝" (80 mm), M-Opta SFT-D to connect ATF system
Port E	Septum for needle-free sampling, FM-Luer
Port F	Gas Outlet Filter with Check Valve, M-Luer
Port G	Gas Inlet Filter ¼" Hose barb
Port H	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer



Flexsafe® RM 10 L perfusion ATF

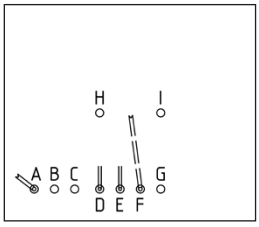
DFP010L--AT

Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), FM-MPC
Port B	DO sensor
Port C	pH sensor
Port D	Dip Tube Silicone, Silicone tubing ⅜" × ⅝" (80 mm), M-Opta SFT-D to connect ATF system
Port E	Septum for needle-free sampling, FM-Luer
Port F	Gas Outlet Filter with Check Valve, M-Luer
Port G	Gas Inlet Filter ¼" Hose barb
Port H	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer



Flexsafe® RM 20 L perfusion ATF

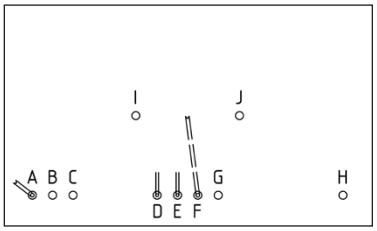
DFP020L--AT



Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port C	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer
Port D	DO sensor
Port E	pH sensor
Port F	Dip Tube Silicone, Silicone tubing ⅜" × ⅝" (80 mm), M-Opta SFT-D to connect ATF system
Port G	Septum for needle-free sampling, FM-Luer
Port H	Gas Outlet Filter with Check Valve, M-Luer
Port I	Gas Inlet Filter ¼" Hose barb

Flexsafe® RM 50 L perfusion ATF

DFP050L--AT

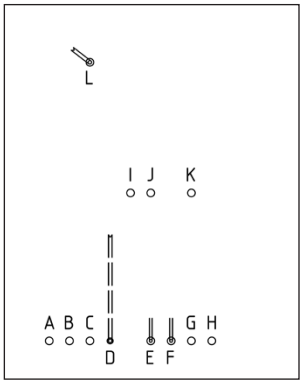


Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port C	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer
Port D	DO sensor
Port E	pH sensor
Port F	Dip Tube Silicone, Silicone tubing ⅜" × ⅝" (80 mm), M-Opta SFT-D to connect ATF system
Port G	Septum for needle-free sampling, FM-Luer
Port H	C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), M-MPC
Port I	Gas Outlet Filter with Check Valve, M-Luer
Port J	Gas Inlet Filter ¼" Hose barb

Flexsafe® RM 100 L perfusion ATF

DFP100L--AT

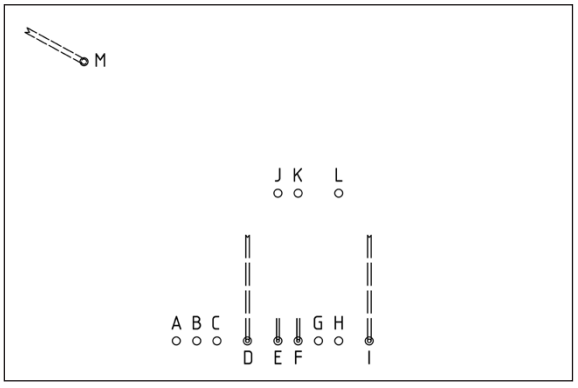
Ports	
Port A	C-Flex® 374 tubing ⅜" × ⅝" (1000 mm), M-MPC
Port B	Silicone tubing 3/16" × 5/16" (50 mm), FM-Luer
Port C	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port D	Dip Tube Silicone, Silicone tubing ½" × ¾" (150 mm), M-Opta SFT-I to connect ATF system
Port E	DO sensor
Port F	pH sensor
Port G; H	Septum for needle-free sampling, FM-Luer
Port I	Gas Outlet Filter, M-Luer
Port J; K	Gas Inlet | Outlet Filter ¼" Hose barb
Port L	Dip Tube Silicone, C-Flex® 374 tubing ⅜" × ⅝" (1000 mm), M-MPC



Flexsafe® RM 200 L perfusion ATF

DFP200L--AT

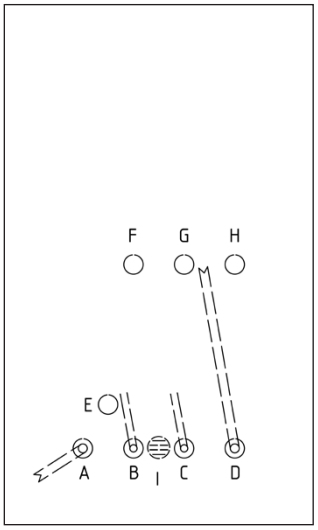
Ports	
Port A	C-Flex® 374 tubing ⅜" × ⅝" (1000 mm), M-MPC
Port B	Silicone tubing 3/16" × 5/16" (50 mm), FM-Luer
Port C	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port D; I	Dip Tube Silicone, Silicone tubing ½" × ¾" (150 mm), M-Opta SFT-I to connect ATF system
Port E	DO sensor
Port F	pH sensor
Port G; H	Septum for needle-free sampling, FM-Luer
Port J	Gas Outlet Filter, M-Luer
Port K; L	Gas Inlet Filter ¼" Hose barb
Port M	Dip Tube Silicone, C-Flex® 374 tubing ⅜" × ⅝" (1000 mm), M-MPC



Flexsafe® RM 10 L ATF Viamass

DFP010L--ATVM

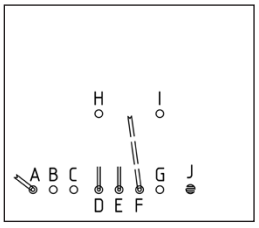
Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), FM-MPC
Port B	DO sensor
Port C	pH sensor
Port D	Dip Tube Silicone, Silicone tubing ⅜" × ⅝" (80 mm), M-Opta SFT-D to connect ATF system
Port E	Septum for needle-free sampling, FM-Luer
Port F	Gas Outlet Filter with Check Valve, M-Luer
Port G	Gas Inlet Filter ¼" Hose barb
Port H	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port I	BioPAT® Viamass sensor



Flexsafe® RM 20 L ATF Viamass

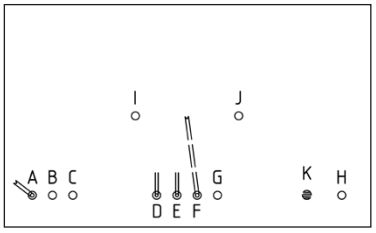
DFP020L--ATVM

Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port C	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer
Port D	DO sensor
Port E	pH sensor
Port F	Dip Tube Silicone, Silicone tubing ⅜" × ⅝" (80 mm), M-Opta SFT-D to connect ATF system
Port G	Septum for needle-free sampling, FM-Luer
Port H	Gas Outlet Filter with Check Valve, M-Luer
Port I	Gas Inlet Filter ¼" Hose barb
Port J	BioPAT® Viamass sensor



Flexsafe® RM 50 L ATF Viamass

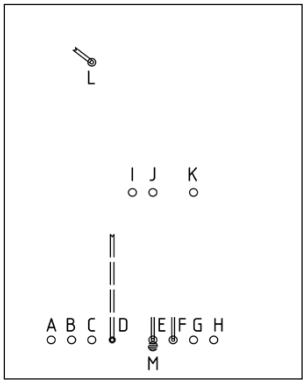
DFP050L--ATVM



Ports	
Port A	Dip Tube Silicone, C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port C	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer
Port D	DO sensor
Port E	pH sensor
Port F	Dip Tube Silicone, Silicone tubing ⅜" × ⅝" (80 mm), M-Opta SFT-D to connect ATF system
Port G	Septum for needle-free sampling, FM-Luer
Port H	C-Flex® 374 tubing ¼" × 7⁄16" (1000 mm), M-MPC
Port I	Gas Outlet Filter with Check Valve, M-Luer
Port J	Gas Inlet Filter ¼" Hose barb
Port K	BioPAT® Viamass sensor

Flexsafe® RM 100 L ATF Viamass

DFP100L--ATVM

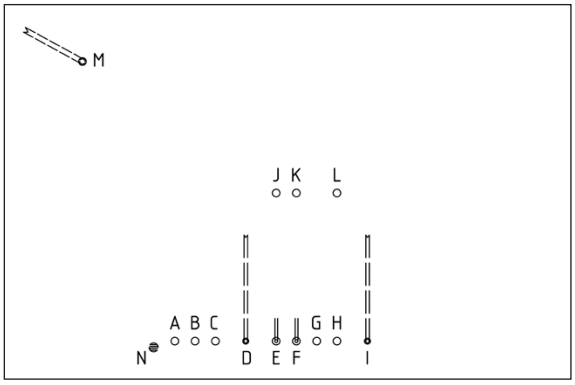


Ports	
Port A	C-Flex® 374 tubing ⅜" × ⅝" (1000 mm), M-MPC
Port B	Silicone tubing 3⁄16" × 5⁄16" (50 mm), FM-Luer
Port C	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port D	Dip Tube Silicone, Silicone tubing ½" × ¾" (150 mm), M-Opta SFT-I to connect ATF system
Port E	DO sensor
Port F	pH sensor
Port G; H	Septum for needle-free sampling, FM-Luer
Port I	Gas Outlet Filter, M-Luer
Port J; K	Gas Inlet | Outlet Filter ¼" Hose barb
Port L	Dip Tube Silicone, C-Flex® 374 tubing ⅜" × ⅝" (1000 mm), M-MPC
Port M	BioPAT® Viamass sensor

Flexsafe® RM 200 L ATF Viamass

DFP200L--ATVM

Ports	
Port A	C-Flex® 374 tubing ⅜" × ⅝" (1000 mm), M-MPC
Port B	Silicone tubing ³⁄₁₆" × ⁵⁄₁₆" (50 mm), FM-Luer
Port C	C-Flex® 374 tubing ⅛" × ¼" (1000 mm), FM-Luer
Port D; I	Dip Tube Silicone, Silicone tubing ½" × ¾" (150 mm), M-Opta SFT-I to connect ATF system
Port E	DO sensor
Port F	pH sensor
Port G; H	Septum for needle-free sampling, FM-Luer
Port J	Gas Outlet Filter, M-Luer
Port K; L	Gas Inlet Filter ¼" Hose barb
Port M	Dip Tube Silicone, C-Flex® 374 tubing ⅜" × ⅝" (1000 mm), M-MPC
Port N	BioPAT® Viamass sensor



Ordering Information

Bag Accessories

Order Code	Description
DS-------GF	Light conductor cable for Flexsafe® RM optical and perfusion (1 piece)
DS-------CGF	Clamp for fiber optic cable fixation (1 piece)
DS-------CV	Check valves for outlet filter of Flexsafe® RM (50 pcs)
DZ-----R2FH	Exhaust filter heater Flexsafe® RM
DZ-----R3FH	Exhaust filter heater Flexsafe® RM, type Midisart
DZ-------BH1	Flexsafe® RM Harvest Device for gravimetric harvesting

Minimum Order Quantities

Article Number	Product Description	Quantity per Order Code Bags per Box	Min. Order Quantity Number of Bags	Min. Order Quantity Number of Boxes
Flexsafe® RM Basic Bags				
DFB001L	Flexsafe® RM 1 L basic	5	10	2
DFB002L	Flexsafe® RM 2 L basic	5	5	1
DFB002L----01SC	Flexsafe® RM 2 L basic SC	5	10	2
DFB010L	Flexsafe® RM 10 L basic	5	5	1
DFB010L----01SC	Flexsafe® RM 10 L basic SC	5	10	2
DFB020L	Flexsafe® RM 20 L basic	5	5	1
DFB020L----01SC	Flexsafe® RM 20 L basic SC	5	10	2
DFB050L	Flexsafe® RM 50 L basic	5	5	1
DFB050L----01SC	Flexsafe® RM 50 L basic screw cap	5	10	2
DFB050L----01US	Flexsafe® RM 50 L basic US rocker	5	5	1
DFB100L	Flexsafe® RM 100 L basic	2	4	2
DFB200L	Flexsafe® RM 200 L basic	2	4	2
Flexsafe® RM Optical Bags				
DFO002L	Flexsafe® RM 2 L optical	5	5	1
DFO002L----01SC	Flexsafe® RM 2 L optical SC	5	10	2
DFO010L	Flexsafe® RM 10 L optical	5	5	1
DFO010L----01SC	Flexsafe® RM 10 L optical SC	5	10	2
DFO020L	Flexsafe® RM 20 L optical	5	5	1
DFO020L----01SC	Flexsafe® RM 20 L optical SC	5	10	2
DFO050L	Flexsafe® RM 50 L optical	5	5	1
DFO050L----01SC	Flexsafe® RM 50 L optical SC	5	10	2
DFO100L	Flexsafe® RM 100 L optical	2	4	2
DFO200L	Flexsafe® RM 200 L optical	2	4	2

Article Number	Product Description	Quantity per Order Code Bags per Box	Min. Order Quantity Number of Bags	Min. Order Quantity Number of Boxes
Flexsafe® RM Perfusion Bags				
DFP002L--SM	Flexsafe® RM 2 L perfusion 1.2 µm	3	3	1
DFP010L--SM	Flexsafe® RM 10 L perfusion 1.2 µm	3	3	1
DFP020L--SM	Flexsafe® RM 20 L perfusion 1.2 µm	3	3	1
DFP050L--SM	Flexsafe® RM 50 L perfusion 1.2 µm	3	3	1
DFP002L--AT	Flexsafe® RM 2 L perfusion ATF	3	3	1
DFP010L--AT	Flexsafe® RM 10 L perfusion ATF	3	3	1
DFP020L--AT	Flexsafe® RM 20 L perfusion ATF	3	3	1
DFP050L--AT	Flexsafe® RM 50 L perfusion ATF	3	3	1
DFP100L--AT	Flexsafe® RM 100 L perfusion ATF	2	4	2
DFP200L--AT	Flexsafe® RM 200 L perfusion ATF	2	4	2
Flexsafe® RM with integrated Viamass Sensor				
DFB010L----VM	Flexsafe® RM 10 L basic Viamass	5	5	1
DFB020L----VM	Flexsafe® RM 20 L basic Viamass	5	5	1
DFB050L----VM	Flexsafe® RM 50 L basic Viamass	5	5	1
DFO002L--VM	Flexsafe® RM 2 L optical Viamass	3	3	1
DFO010L----VM	Flexsafe® RM 10 L optical Viamass	5	5	1
DFO020L----VM	Flexsafe® RM 20 L optical Viamass	5	5	1
DFO050L----VM	Flexsafe® RM 50 L optical Viamass	5	5	1
DFO100L----VM	Flexsafe® RM 100 L opt Viamass	2	4	2
DFO200L----VM	Flexsafe® RM 200 L opt Viamass	2	4	2
DFT002L--SMVM1	Flexsafe® RM TX 2 L perf. Viamass, TPE	3	3	1
DFT002L--SMVM2	Flexsafe® RM TX 2 L perf. Viamass, PVC	3	3	1
DFP002L--SMVM	Flexsafe® RM 2 L perfusion Viamass	3	3	1
DFP010L--SMVM	Flexsafe® RM 10 L perfusion Viamass	3	3	1
DFP020L--SMVM	Flexsafe® RM 20 L perfusion Viamass	3	3	1
DFP050L--SMVM	Flexsafe® RM 50 L perfusion Viamass	3	3	1
DFP100L--SMVM	Flexsafe® RM 100 L perfusion Viamass	2	2	1
DFP200L--SMVM	Flexsafe® RM 200 L perfusion Viamass	2	2	1
DFP010L--ATVM	Flexsafe® RM 10 L ATF Viamass	3	3	1
DFP020L--ATVM	Flexsafe® RM 20 L ATF Viamass	3	3	1
DFP050L--ATVM	Flexsafe® RM 50 L ATF Viamass	3	3	1
DFP100L--ATVM	Flexsafe® RM 100 L ATF Viamass	2	4	2
DFP200L--ATVM	Flexsafe® RM 200 L ATF Viamass	2	4	2

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SARTORIUS

Product Datasheet

BioPAT® Viamass

Standardized Online Biomass Measurement in Single-Use Fermentation

Product Information

One of the most requested parameters in industrial cell cultivation is the monitoring of biomass. The knowledge of the biomass progress during a fermentation process gives deeper process knowledge and understanding. Therefore it enables the control of the biomass and helps to define feeding, harvest or infection points.

Offline methods like visual cell counting or semi-automated systems still dominate the biomass measurement in industrial cell cultivation. But these offline methods based on taking a representative sample cannot monitor the process continuously.

The radio frequency (RF) impedance method for online in-situ detection of viable biomass has already become well established in biopharmaceutical applications using traditional reusable fermenter equipment. But industrial cell cultivation tends more and more to single-use (SU) fermentation solutions.

In order to follow these, an easy-to-use online biomass monitoring system is a basic necessity. BioPAT® Viamass is the first standardized online biomass measurement solution for single-use fermenter systems which is fully integrated into the standard fermenter control system and tailored to the single-use fermentation bags such as the Flexsafe® RM, and soon to be launched in Flexsafe STR®.

Biostat® B With RM | Flexsafe® RM – Use in Rocking Motion Fermentation Systems

The rocking motion of the fermentation system causes signal fluctuations of the measurement signal due to the variation of the liquid level over the sensor. For this reason, appropriate optimization filters are implemented in the sensor's electronics including different rocking motion parameters. Using these filters enables the biomass evolution monitoring continuously in rocking motion cell cultivation.

Configuration of the System

A complete BioPAT® Viamass system consists of:

1. The BioPAT® Viamass Electronics for signal generation and evaluation (Art.No. BPV0001). This includes a lightweight pre-amplifier with an integral sensor disc connector.
2. A connection cable
   a) A connection cable to the DCU or
   b) A connection cable to the Connection Hub for service and manual configuration – the Connection Hub is mandatory for the use of the analog output via 4 – 20 mA, the Connection Hub connects the electronics to a PC
3. A BioPAT® Viamass Signal Simulator Set (Art.No. BPV0011) for functionality validation
4. The single-use sensor disc, which is welded in a Flexsafe® RM or Flexsafe STR® bag

Validation and Extractable Testing

BioPAT® Viamass sensor discs have been qualified applying the most complex and innovative test regimes. Biological, chemical and physical tests combined with extractable testing prove lowest extractable and leachable levels and excellent compatibility to the relevant pharmacopoeias and guidelines. For more information, please refer to our Validation Guide and Extractable Guide. A leachable testing service is also available. Please contact your local Sartorius representative for further information.

Quality Assurance

All relevant materials are selected following applicable regulations and standards such as FDA, CFRs, cGMPs and in-house guidelines. This includes the terms of delivery and acceptance of our purchasing department. Finished Flexsafe® RM | Flexsafe STR® bags undergo final product quality control which is certified with the Quality Assurance certificate included with every bag.

Electromagnetic Compatibility

A Declaration of Conformity is available from Sartorius.

Technical Specifications

BioPAT® Viamass Electronics – Technical Data

Frequency Range	50 KHz to 20 MHz
Measuring Ranges	
Capacitance	0.0 to 400 pF/cm
Conductivity	1.0 to 40 mS/cm
Cell Concentration Range	Depends on cell sizes but typically: ▪ Yeast (6 µm): 10^6 cells/ml to 10^{10} cells/ml ▪ Bacteria (1 µm): 10^9 cells/ml to 10^{13} cells/ml ▪ Animal Cell (12 µm): 10^5 cells/ml to 10^9 cells/ml ▪ Plant Cell (50 µm): 10^3 cells/ml to 10^7 cells/ml
Power Supply	▪ Power is provided by the control tower in standard configurations ▪ For service and manual configuration power is supplied by a connection hub running on 110 V AC to 240 V AC mains
Environmental	▪ IP41 rated ▪ Safe ambient operating temperature range: 5°C to 40°C
Dimensions of Housing	
Main Enclosure	▪ Height × Width × Depth (approx): 30 mm × 135 mm × 64 mm ▪ Weight (approx): 211 g
Remote Enclosure	▪ Height × Width × Depth (approx.) 28 mm × 95 mm × 34 mm ▪ Weight (approx): 81 g

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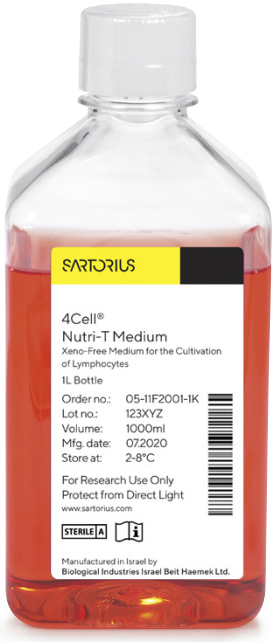
Publication No.: SLL2010-e | Order No.: 85037-541-14 | Status: 06 | 24 | 2021

SARTORIUS

Product Datasheet

4Cell® Nutri-T Medium

A Xeno-Free, Serum-Free Medium for the Cultivation of Lymphocytes Offering Superior Performance and Flexibility



Product Information

4Cell® Nutri-T Medium: A Solution Without Serum
Cell-based immunotherapy is at the forefront of advanced cancer treatments. The most common cell-based immuno-therapies to date are T cell therapies (mainly CAR-Ts and TILs). Cells being used for immunotherapy are commonly cultured in media supplemented with human serum. The use of serum introduces further variability into the process due to donor-to-donor variation, which leads to inconsistent cell growth and characteristics. Eliminating serum simplifies the process, lowers the regulatory risk, and reduces the associated logistical burden. Nutri-T eliminates this need for serum addition by substituting serum's critical components with specific proteins, lipids, and other small molecules.

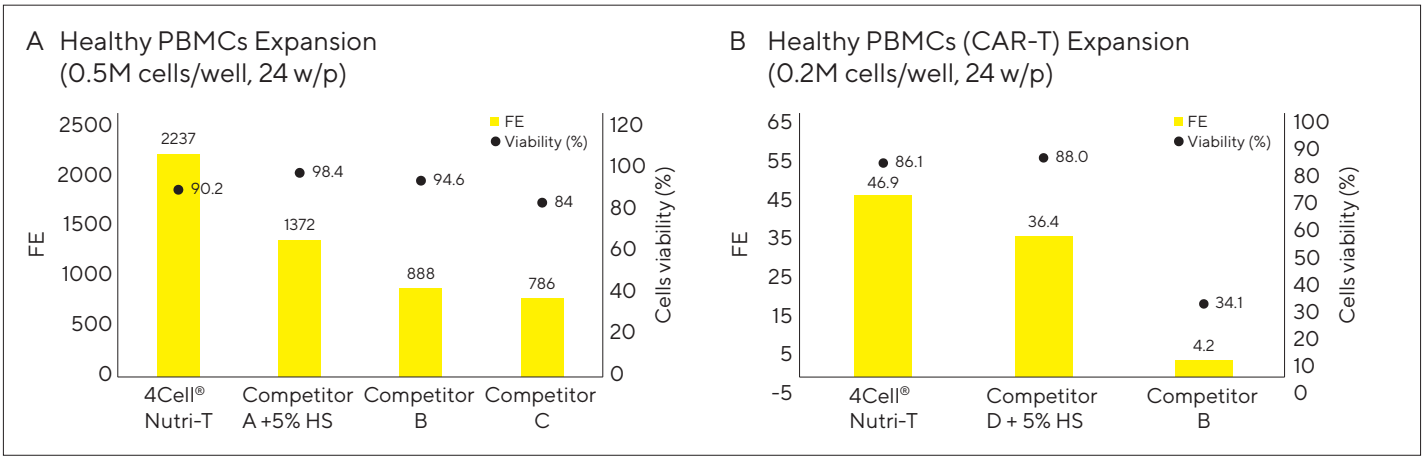
Product Snapshot

- Xeno-free
- Serum-free. No need to add serum
- ISO13408 Regulatory Compliance
- Research use only
- Developed using actual cancer patient cells
- Excellent performance for PBMCs, TILs, CAR-T
- Excellent performance at low initial seeding densities

4Cell® Nuti-T Cell Medium: Advancing Research and Clinical Applications

4Cell® Nutri-T is the ideal medium to use in the development and scale-up of cell-based therapeutic applications in the field of immune-oncology. Nutri-T is a xeno-free formulation demonstrating consistent and accurate results for both healthy donors (Fig. 1) and patient-derived (Fig. 2) T cells, without serum supplementation.

Figure 1: Nutri-T is Superior to Competitor Media in Expansion of Healthy PBMCs (With and Without CAR-T Transduction) at Multiple Seeding Densities



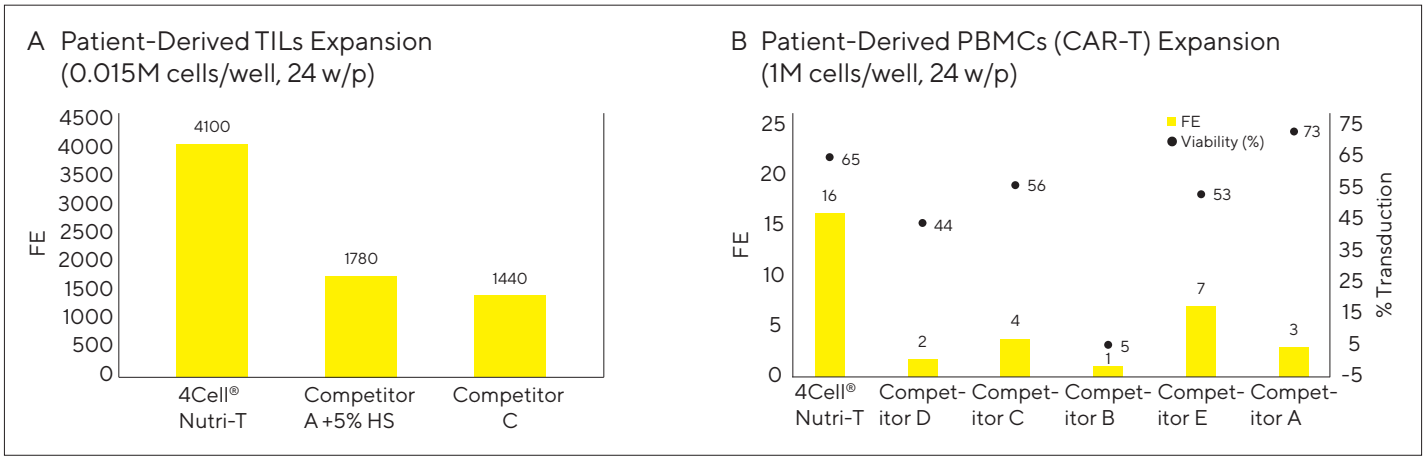
(A) 0.5M healthy donor PBMCs were seeded in 24w plates (2 ml media/well). Cells were activated with TransAct 1:100 and 600 IU/ml IL-2. Cells were split and media renewed every 2 – 3 days. Fold expansion (FE) and cell viability were measured at Day 11.

(B) 0.2M PBMCs from healthy donors were seeded in 24w plates (2 ml media/well). Cells were activated with TransAct 1:100 and 600 IU/ml IL-2. 24 h. After seeding cells were transduced with a lentiviral vector expressing an EGFR-CAR-T. Cells were split and media renewed every 2 – 3 days. FE and cell viability were measured at Day 11.

4Cell® Nutri-T Medium: Excellent Performance With Patient-Derived Cancer T Cells

Most of the currently available xeno-free media for T cells have been validated only on cells isolated from healthy donor derived PBMCs, or healthy CAR-T manipulated cells. 4Cell® Nutri-T was developed in collaboration with the highly accredited Ella Lemelbaum Institute for Immuno-Oncology at Sheba Medical Center, Israel. The Sheba partnership allows Sartorius access to clinical, patient-derived TILs and T cells. This unique development platform resulted in 4Cell® Nutri-T medium exhibiting excellent performance even with clinical condition cells at low initial seeding concentrations (Fig. 2).

Figure 2: Nutri-T is Superior to Competitor Media in Expansion of Patient-Derived Cancer Cells for Both TILs and CAR-T Processes



(A) TILs were isolated from a melanoma patient. 15,000 cells were seeded in a 24 well plate (2 ml/well) with PBMCs (1:100). Cells were activated with IL-2 (3,000 IU/ml) and OKT-3 (50 ng/ml). 2 ml and 4 ml of fresh medium + IL2 were added at days 5 and 7 respectively (total volume of 8 ml). Fold expansion was measured at 14 days. Inherent variations among primary T lymphocyte donor populations may result in varying outcomes.

(B) PBMCs were separated from peripheral blood of a lymphoma patient. Tested mediums were supplemented with 50 ng/ml OKT3 and 300 IU/ml IL2. At day 2 post seeding, 2 – 3M cells for the G-Rex24 were transduced with a CD19-CAR lentiviral vector in 6w/p pre-coated with RTN. Post transduction the cells were collected and reseeded. At day 4, 4 ml fresh medium +IL2 were added and at day 6, 50% medium was replaced with fresh medium + IL2. At day 9 transduction efficiency was evaluated and at day 10 Fold expansion was measured.

4Cell® Nutri-T Cell Medium: Sartorius is Your Reliable Supply Partner

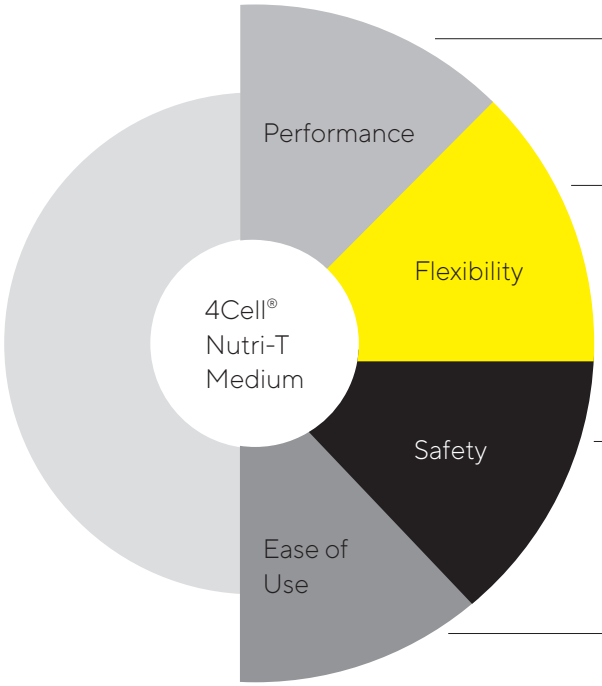
When working with a patient's cells, the materials used and the time from cell isolation to patient administration with the final product are critical. You cannot afford to waste time as a result of production or shipment delays.

Sartorius is your trusted partner. With multiple distribution sites and a robust supply chain, we can guarantee your media is on time, lot-to-lot consistent, and of the highest quality.

Ordering Information

Product Description	Size & Package	Storage	Cat. No.
4Cell® Nutri-T medium	1L Bottle (Liquid)	2 – 8 °C	05-11F2001-1K

Your Benefits at a Glance



- Superior fold expansion
- Excellent % viability and % of CD8+ expression
- High transduction efficiency % for CAR-T applications

- Superior performance for healthy PBMC, TIL, and CAR-T applications
- Superior performance with cancer patient-derived cells
- Excellent performance with low initial seeding concentrations

- No serum means elimination of serum-associated risk
- Manufactured in accordance with ISO 13408 guidelines
- Robust release testing

- No need to source, store, or purchase serum
- Low lead-time as Nutri-T is on-shelf at global Sartorius sites
- Sartorius technical support and complementary products

Sales and Service Contacts

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Status: 12 | 21 | 2020

SARTORIUS

Product Datasheet

Configurable Flexsafe® 2D

Bags From 20 mL to 50 L

Product Information

Flexsafe® 2D Bags are designed for the preparation, storage and transport of biopharmaceutical solutions, intermediates and final bulk products.

Configurable Flexsafe® 2D Bags are designed from a database of pre-qualified components and proven functionalities using a web-based and interactive product configurator tool.

Description

The user friendly product configurator tool provides the flexibility needed for the application-based single-use configuration whilst improving design and quotation turnaround times, manufacturing lead times, security of supply and product reliability, safety and robustness.

They provide a single-use alternative to traditional glass, stainless steel and rigid plastic carboys in a large variety of applications. The broad chemical compatibility of Flexsafe® 2D Bags ensures the safe processing of a wide range of biopharmaceutical fluids in a variety of applications.

Applications

The multi-layer, PE and EVOH based S80 film provides a strong structure with low gas permeability and high chemical resistance, for the safe processing of a wide range of biopharmaceutical fluids in a variety of applications such as:

- Buffers and media sterile
- Filtration and storage
- Bulk harvest
- Product pooling
- Fraction collection
- Sample collection
- Bulk intermediate hold
- Final product handling

Flexibility

Configurable Flexsafe® 2D Bags are configured from pre-qualified components and proven functionalities including a variety of tubing, connectors, filter and sampling methods for a streamlined incorporation into your process. Multiple configurations are available with bag volumes from 20 mL to 50 L with TPE tubing, compatible with Biowelder® and Biosealer® for aseptic connection | disconnections, silicone Tuflux® tubing compatible with Clipster® Aseptic Disconnector and qualified for peristaltic pumping and TPE tubing for RF sealing with Vante™ Sealers. Sartopore® 2 Gamma Midicaps® are proposed with an optional flush bag. Needle free sampling port or sampling bag may be used for easy and convenient sampling. Quick couplers, triclamps, Luer® fittings, Steamthru™ valves and sterile-to-sterile connectors are provided for optimal connection compatibility flexibility in a production environment.

Easy Implementation

Configurable Flexsafe® 2D Bags are available in bag chamber volumes between 20 mL and 50 L. They are supplied, sterilized and ready to use. This allows an easy and convenient process implementation. A series of associated systems such as trays and racks facilitate an easy bag handling. Sartorius Stedim Biotech supports users already at the design and implementation phase of a new production facility, with the most comprehensive support program that ensures successful design implementation of Single-Use Manufacturing.

Features	Benefits
Pre-qualified component database and proven functionalities	Quality by design for improved product reliability
Standard components and manufacturing methods	Save on development and engineering costs
Instant design with a web-based product configurator	Shorten lead time for drawing and quotes
CTO dedicated supply chain and manufacturing capability	Shorten lead-time for products
Offer a large range of standardized configurable products	Reduce complexity and risks by standardization
Product configurator tool with preconfigured options and functionalities	Flexibility for optimal design tailored to the application needs
Most commonly used components and solutions in the market	Compatibility with end user process requirements

Robust Performance and Assurance of Supply

Flexsafe® 2D bags are designed for safe storage and shipping of biopharmaceutical solutions. Flexsafe® bags ensure consistent cell growth robustness and ease of use and are extensively validated for all process steps, from cell culture and downstream purification of drug substance to final formulation and filling of drug product. Characterization of resins and establishing supply contracts for the resins and the film ensure compliance, reliable assurance of supply and change control.

Validation

Flexsafe® 2D Bags have been qualified applying the most comprehensive and innovative test regimes. Biological, chemical and physical tests combined with extensive extractable testing provide users of configurable Flexsafe® 2D Bags with data representing the widest range of process fluids in a variety of processing conditions. Full compliance with ISO 11137 allows for a validated claim of sterility on all Sartorius Stedim Biotech single-use products with a sterility assurance level of 10^{-6} over the shelf life.

Quality Assurance

Sartorius Stedim Biotech Quality Systems for single-use products follow applicable ISO and FDA regulations. Design, manufacture and sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements.

Flexsafe® 2D Bags are tested for compliance to:
- USP <85>: Bacterial endotoxins test
- USP <87>: Biological reactivity tests, in Vitro
- USP <88>: Biological reactivity tests, in Vivo
- USP <661>: Tests for plastic
- USP <788> and E.P. 2.9.19: Particulates
- ISO 11737: Bioburden
- ISO 11137: Sterilization of medical devices

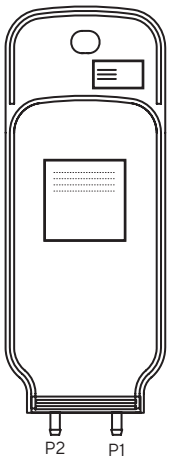
Supply Chain

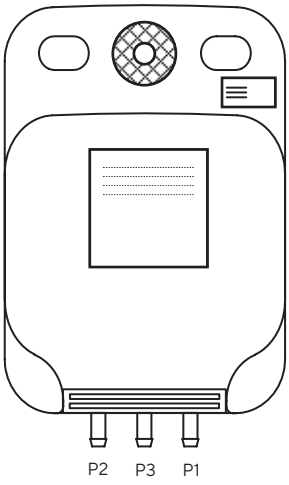
Configurable Flexsafe® 2D Bags are available as configured to order products. Pre-configured products based on application knowledge allow savings on engineering time and production preparation, thus providing reduced lead-times compared to classical fully customized processes.

Configurable Transfer Line

Bag chamber	Multiple layer film, including EVOH gas barrier layer and TPE contact layer S80 film
Volumes	20 mL – 50 L
Tubing	Silicone Tuflux® or Silicone (Pt) compatible with Clipster® Aseptic Disconnector, TPE compatible with Biowelder® and Biosealer®
End connectors	Quick couplers Triclamp and mini-triclamp Luer® locks Steamthru™ valves for SIP connections Sterile-to-sterile connectors, including Opta® sterile connector
Filters	Sartopore® 2 0.2 µm Gamma Midicaps® size 4 Sartopore® 2 0.2 µm Gamma Midicaps® size 7 Sartopore® Platinum 0.2 µm Gamma Midicaps® size 7 Sartopore® Platinum 0.2 µm Gamma Midicaps® size 4 Sartopore® XLM 0.1 µm size 7 with optional flush bag for volume 1 L to 50 L
Sampling	Needleless sampling site Sampling with bag
Number of lines	2 lines for bags from 20 mL to 500 mL 3 lines for bags from 1 L to 50 L

Technical Data





Functionalities

- Storage application

Specifications

Volume

20 mL, 50 mL, 150 mL, 250 mL, 500 mL,
1 L, 3 L, 5 L, 10 L, 20 L, 50 L

Number of Ports | Lines

- Three lines where P1 is assimilated to the filling line, P2 to the draining line or sampling line and P3 to the sampling line

Tubing Diameters

ID × OD = ¼" × 7⁄16" for P1, P2, P3
¼" × ⅜" for P1, P2, P3
⅜" × ⅝" for P1, P2

Tubing Materials

Silicone tubing, Silicone Tuflux®, TPE tubing,
Silicone Tuflux® + TPE tubing, Silicone + TPE tubing

Tubing Lengths

150 mm, 300 mm, 500 mm, 1000 mm, 1500 mm,
2000 mm, no tubing

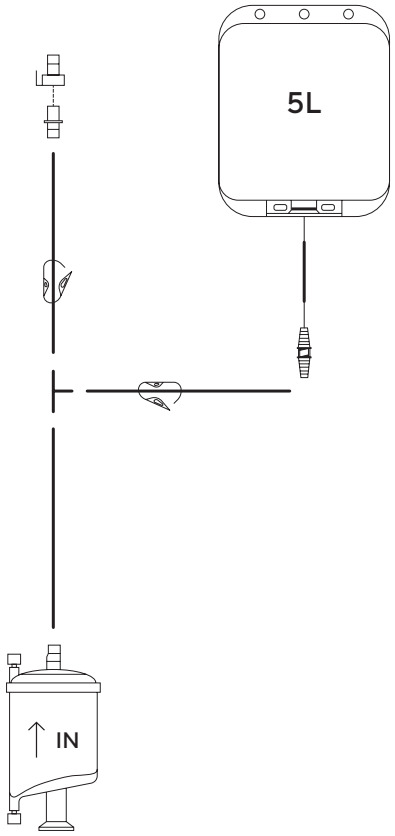
Type of Lines

Port	P1	P2	P3
Line	Line 1	Line 2	Line 3
Function	Fill	Drain | Sampling	Sampling
Normal Flow Rate with Filter	■		
High Flow Rate with Filter	■		
Normal Flow Rate	■	■	
High Flow Rate	■ (1)	■ (1)	
Sampling		■	■
Not Used		■ (1)	■ (2)

(1) For Flexsafe® 2D from 3 L to 50 L
(2) For Flexsafe® 2D from 20 mL to 500 mL

Line Type Normal Flow Rate With Filter and High Flow Rate With Filter: Port 1

Generic Description



Specifications

Tubing Diameters
ID × OD = ¼" × 7⁄16" (6.4 mm × 11.1 mm)
or ⅜" × ⅝" (9.5 mm × 15.8 mm)

Tubing Materials
- Silicone Tuflux® or Si(Pt)
  (filter removal with CPC Quick Coupler
  or no filter disconnection)
- TPE tubing (filter removal with tube sealing)

Tubing Lengths
- 150 mm
- No tubing

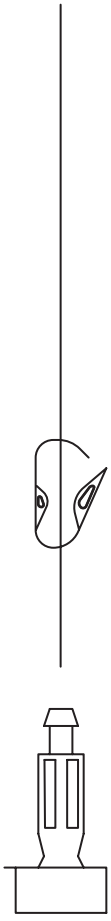
Type of Filters
- Sartopore® 2 0.2 µm Gamma Midicaps® size 4
- Sartopore® 2 0.2 µm Gamma Midicaps® size 7
- Sartopore® Platinum 0.2 µm Gamma Midicaps® size 4
- Sartopore® Platinum 0.2 µm Gamma Midicaps® size 7
- Sartopore® XLM 0.1 µm size 7

Options
- No flush bag for volume 20 mL to 1 L
- 1 L Flexboy® Flush Bag (only with normal flow rate)
- 5 L Flexboy® Flush Bag

Functionalities
- Filling through a sterilizing grade filter
- Optional filter flush bag only for volume > 1 L
- Optional filter disconnection with a Quick Coupler
  or with tube sealing (TPE)

Line Type Normal Flow Rate: Port 1 and 2 and High Flow Rate: Port 1 and 2

Generic Description



Functionalities
- Bag filling or bag drainage
- Transfer with a peristaltic pump or by gravity
- Tube to tube welding
- Tube sealing
- Aseptic connection
- Generic connection with a TriClamp or a Quick Coupler

Specifications

Tubing Diameters
ID × OD = ¼" × 7⁄16" (6.4 mm × 11.1 mm)
or ¼" × ⅜" (9.5 mm × 15.8 mm)
or ⅜" × ⅝" (9.5 mm × 15.8 mm)

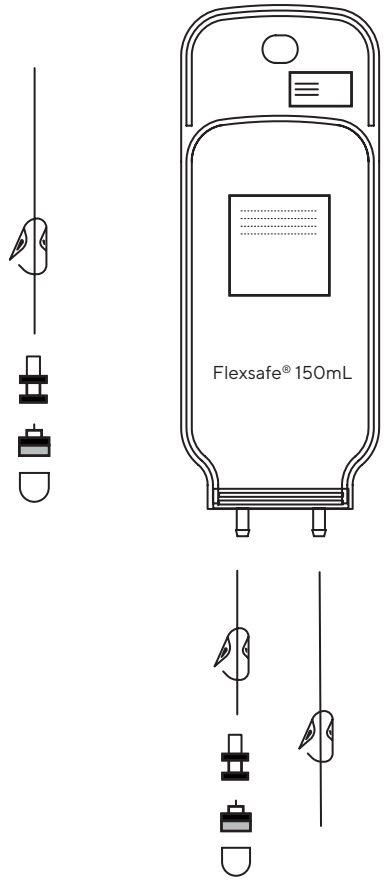
Tubing Materials
- Silicone Tuflux® or Si(Pt) for 10 hr maximum operation with a peristaltic pump
- TPE (thermoplastic tubing) for tube sealing and welding operations
- Silicone Tuflux® or Si(Pt) with a TPE extension for 10 hr maximum operation with a peristaltic pump and for tube sealing and welding applications

Tubing Lengths
- 150 mm (6") for Si(Pt) Tuflux® or Si(Pt)
- 300 mm (12") for Si(Pt) Tuflux® or Si(Pt)
- 500 mm (20") for Si(Pt) Tuflux®, Si(Pt) or TPE tubing
- 1,000 mm (39") total line length: 500 mm (20") Si(Pt) Tuflux® or Si(Pt) + 500 mm (20") TPE for Silicone with a TPE extension
- 1,500 mm (59") total line length: 1,000 mm (39") Si(Pt) Tuflux® or Si(Pt) + 500 mm (20") TPE for Silicone with a TPE extension
- 2,000 mm (79") total line length: 1,500 mm (59") Si(Pt) Tuflux® or Si(Pt) + 500 mm (20") TPE for Silicone with a TPE extension

Distal Connectors
- SSB Triclamp (1-½" or ¾" flange) with optional triclamp cap, plug, gasket and union
- Quick Coupler with plug – MPC (male or female)
- MPC PSU (male or female)
- OPTA® SFT – aseptic connection (male or female)
- STC I – CPC Steamthru™ connection (¾" × ¾" triclamp flanges)
- STC II - CPC Steamthru™ connection (¾" × ¾" triclamp flanges)
- KPC HT – male or female
- Luer® male or female with cap (only with normal flow rate)
- AseptiQuik® Genderless
- Lynx Valve ST ¼" or ⅜"

Line Type “Sampling” P2 - P3[1] Normal Flow Rate

Generic Description



Functionalities (Sampling)
- Clave connector
- Sampling bag

[1] P2 For volume 20 mL to 500 mL
P3 for volume 1 L to 50 L

Specifications

Tubing Diameters
ID × OD = ¼" × 7⁄16" (6.4 mm × 11.1 mm)

Tubing Materials
- Silicone Tuflux® or Si(Pt) for needleless sampling port
- TPE (thermoplastic tubing) for welding and sealing operations (sampling bag disconnection)

Tubing Lengths
- 150 mm

Connector
- Clave

Sampling Bag
- Flexsafe® 2D bag 150 mL

Line Type “Not Used” P2 – P3[2]

Functionality
- Not used
- Obstructed port

[2] P2 only for volumes > 1 L

Functionalities of the Flexsafe® 2D Bag From 20 mL to 50 L

	Normal Flow Rate with Filter or High Flow Rate with Filter	Normal Flow Rate	High Flow Rate	Sampling | Transfer
Function	Sterile Fill	Fill Drain Addition	Fill Drain Addition	Sampling
Port	P1	P1 – P2	P1 – P2	P2 – P3
Tube Dim.	¼" × 7⁄16" (6.4 mm × 11.1 mm) ⅜" × ⅝" (9.5 mm × 15.8 mm)	¼" × 7⁄16" (6.4 mm × 11.1 mm)	⅜" × ⅝" (9.5 mm × 15.8 mm)	¼" × 7⁄16" (6.4 mm × 11.1 mm)
Tube Length mm	150 (6")	150 (6") 300 (12") 500 (20") 1,000 (39") 1,500 (59") 2,000 (79")	150 (6") 300 (12") 500 (20") 1,000 (39") 1,500 (59") 2,000 (79")	150 (6")
Tubing Materials	Si(Pt) Tuflux® Si(Pt) TPE	Si(Pt) Tuflux® Si(Pt) TPE Si(Pt) + TPE Si(Pt) Tuflux® + TPE	Si(Pt) Tuflux® Si(Pt) TPE Si(Pt) Tuflux® + TPE Si(Pt) + TPE	Si(Pt) Tuflux® Si(Pt) TPE
Standard Connectors		Luer® M-F SSB TC 1½" or ¾" w/wo cap, plug, gasket, union Quick Coupling MPC-M/F Quick Coupling PSU-M/F	Luer® M-F SSB TC 1½" or ¾" w/wo cap, plug, gasket, union Quick Coupling MPC-M/F Quick Coupling PSU-M/F	Clave
Aseptic Connectors		Opta® SFT-M/F AseptiQuik® Genderless	Opta® SFT-M/F AseptiQuik® Genderless STC I ¾" × ¾" STC II ¾" × ¾"	
Other Connectors		KPC HT-M/F Lynx ST ¼"	KPC HT-M/F Lynx ST ⅜"	
Filters	Sartopore® 2 0.2 µm Gamma Midicaps® size 4 Sartopore® 2 0.2 µm Gamma Midicaps® size 7 Sartopore® Platinum 0.2 µm Gamma Midicaps® size 7 Sartopore® Platinum 0.2 µm Gamma Midicaps® size 4 Sartopore® XLM 0.1 µm size 7			
Flush Bag	Flexboy® 1 or 5 L[1]			
Sampling Bags				Flexsafe® 2D Bag Bags 1 × 150 mL[2]

[1] Only for volume > 1 L
[2] Only for volume 1 L to 50 L

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SARTORIUS

Product Datasheet

Microsart® ATMP Mycoplasma

Rapid Real-time PCR Mycoplasma Detection Kit for testing ATMPs

Benefits

- 3 hours time-to-result
- Designed for ATMP testing
- Easy handling and highest level of security

Product Information

A standard DNA extraction followed by a TaqMan® probe real-time qPCR is used for the detection of Mycoplasma DNA. 200 µL sample volume can be used as starting material for DNA preparation. The isolated DNA is amplified in a qPCR cycler and the evaluation can be performed with the standard cycler software.

Introduction
Microsart® ATMP Mycoplasma utilizes quantitative, real-time PCR (qPCR) as the method of choice for sensitive and robust detection of Mycoplasma contaminations. The Microsart® ATMP Mycoplasma kit was validated according EP 2.6.7 in combination with EP 2.6.21 with respect to detection limit for all listed Mycoplasma species, specificity and robustness for cell cultures and autologous cell transplants (e.g. chondrocytes).

Applications
The Microsart® ATMP Mycoplasma real-time PCR kit is especially designed for all hospitals, institutions and companies which are involved in testing Mycoplasma contamination according to EP 2.6.7 in cell-based therapeutics.

High Performance
The Microsart® ATMP Mycoplasma kit was developed for EP compliant Mycoplasma testing. A detection limit of less than 10 cfu/mL for all Mycoplasma species mentioned in the European Pharmacopoeia fulfills the requirements for sensitivity and specificity.

Fast Result
The Microsart® ATMP Mycoplasma kit is a fast and easy to use real-time PCR kit. The total procedure from DNA extraction to the PCR result takes only a few hours.

TaqMan® Probes
The application of TaqMan® probes adds specificity to the PCR detection system. Highly specific results are already generated during the cycling process – no subsequent melting curve analysis is needed.

Contamination Prevention
The kit contains dUTP instead of dTTP, so the option is available to degrade amplicons from previous analyses by using uracil-DNA glycosylase (UNG). Thus, the occurrence of false-positive results can be minimized. UNG is not included in the kit.

Summary
The Microsart® ATMP Mycoplasma kit is the perfect solution for all QC labs which perform Mycoplasma testing of cell-based therapeutics.

Technical Specifications

Each kit contains all required reagents for 25 reactions including polymerase as part of the Mycoplasma Mix. The expiry date of the unopened package is specified on the package label. The kit components are stored at +2 to +8°C. After opening and rehydration the kit components need to be stored below -18°C. The LOT specific Certificate of Analysis can be downloaded from the manufacturer's website (www.minerva-biolabs.com).

Kit Component	25 Reactions
Order No.	SMB95-1003
Mycoplasma Mix	1 × lyophilized
Rehydration Buffer	1 × 1.0 mL
Positive Control	1 × lyophilized
Internal Control	1 × lyophilized
PCR grade Water	1 × 1.5 mL

Ordering Information

Mycoplasma Kits

Description	Quantity	Order No.
Microsart® ATMP Mycoplasma	25	SMB95-1003

Accessories

Description	Quantity	Order No.
Microsart® AMP Extraktion	50 extractions	SMB95-2003

Related Products

Description	Quantity	Order No.
Microsart® AMP Mycoplasma	25	SMB95-1001
Microsart® Research Mycoplasma	25	SMB95-1005

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Status: 09 | 2021

SARTORIUS

Product Datasheet

Microsart® ATMP Bacteria | Fungi | Sterile Release Microsart® Research Bacteria | Fungi

Rapid Detection of Total Fungi in ATMPs Prior Treatment

Benefits

- All critical bacterial and fungal contaminents detected in one test
- 3h-result: prior to treatment
- Specific TaqMan® probes reduce false-positives
- Non-infectious validation standards
- Less pipetting: controls already included

Product Information

Microsart® ATMP: Contaminated ATMPs pose life-threatening risks for immunocompromised patients. Microbial release test results prior to treatment are critical to patient safety. Microsart® ATMP Bacteria and Fungi or combined Microsart® ATMP Sterile Release that is ready prepared for single samples, enable the detection of bacterial and fungal contamination within 3 hours validated according to EP 5.1.6 and EP 2.6.27. During kit validation sensitivity (5 to 99 CFU/ml) was proven for 19 bacterial and 7 fungal species including 6 standard USP and EP strains. Comparability to the compendial method was demonstrated. The kit is not suitable to replace sterility testing according EP 2.6.1 or USP <71> yet. The Microsart® ATMP kits should be used as precheck test to get rapid QC results for ATMPs.

Microsart® Research Bacteria and Fungi are used for fast and reliable direct detection of microbial contamination in cell cultures, cell culture supernatants and cell media components in research and development or whenever there is no need for regulation conform testing (i.e. according to EP/USP/JP).

Kit Components and Storage

Each kit contains all required reagents for the qPCR reaction. Due to lyophilization they are less temperature sensitive and ensure highest performance stability. Color-coded tubes with master mix, buffers, positive control and negative control, make the handling as simple as possible. For details, see kit components table on page 2.

The expiry date and the storage conditions of the unopened package are noted on the package label. The kit components are stored until use at +2° C to +8° C and must be stored after rehydration or opening at < -18° C. Please note: The master mix, also called Bacteria | Fungi Mix, should be protected from light all the time.

Test Principle

Microsart® ATMP | Research utilizes real-time PCR. The detection procedure can be performed within 3 hours, including less than 1 hour hands-on time. In contrast to the detection by cell cultivation method, samples do not need to contain vital bacteria.

The assay can be performed with any type of real-time PCR cycler able to detect the fluorescence dyes FAM™ and ROX™.

Bacteria or fungi are specifically detected by amplifying a highly conserved 16S|18S rRNA coding region in the bacterial | fungal genome. The amplification is detected at 520 nm (FAM™ channel). The kit includes primer and FAM™ labeled TaqMan® probes which allow the specific detection of more than 95% of all known bacterial and fungal species so far described as contaminants of cell cultures and media components. Eukaryotic DNA is not amplified by this primer | probe system.

False negative results due to PCR inhibitors or improper DNA extraction are detected by the internal amplification control which is part of the PCR master mix. The amplification of the internal amplification control is detected at 610 nm (ROX™ channel).

Product Versions

a. Microsart® ATMP Sterile Release – contains all reagents for testing 10 patient samples for bacterial and fungal contamination including DNA extraction
b. Microsart® ATMP Bacteria – contains all reagents for 100 qPCR reactions to test for bacterial contamination without DNA extraction
c. Microsart® ATMP Fungi – contains all reagents for 100 qPCR reactions to test for fungal contamination without DNA extraction
d. Microsart® Research Bacteria – contains all reagents for 25 | 100 qPCR reactions to test for bacterial contamination without need of DNA extraction
e. Microsart® Research Fungi – contains all reagents for 25 | 100 qPCR reactions to test for fungal contamination without need of DNA extraction

The lot specific Certificate of Analysis can be downloaded from the manufacturer's website (www.minerva-biolabs.com).

Kit Components

Order No.	Cap color	Microsart® ATMP Sterile Release SMB95-1007 (10 patient samples)	Microsart® ATMP Bacteria SMB95-1008 (100 rxn)	Microsart® ATMP Fungi SMB95-1012 (100 rxn)	Microsart® Research Bacteria (25|100) SMB95-1009 (25 rxn) SMB95-1010 (100 rxn)	Microsart® Research Fungi (25|100) SMB95-1014 (25 rxn) SMB95-1013 (100 rxn)
ATMP Bacteria Mix	red	10 × lyophilized	4 × lyophilized	–	4 × lyophilized	–
ATMP Fungi Mix	orange	10 × lyophilized	–	4 × lyophilized	–	4 × lyophilized
Rehydration Buffer	blue	10 × 0.3 ml	4 × 0.5 ml	4 × 0.5 ml	4 × 0.5 ml	4 × 0.5 ml
Positive Control DNA	green	10 × lyophilized	1 × lyophilized	1 × lyophilized	1 × lyophilized	1 × lyophilized
Internal Control DNA	yellow	10 × lyophilized	4 × lyophilized	4 × lyophilized	4 × lyophilized	4 × lyophilized
PCR grade Water	white	20 × 0.3 ml	5 × 1.5 ml	5 × 1.5 ml	5 × 1.5 ml	5 × 1.5 ml
Lysis Buffer	transparent	10 × 1.8 ml	–	–	–	–
Suspension Buffer	violet	10 × 0.4 ml	–	–	–	–
Processing Tubes	–	10 × 3	-	-	-	-

Related Products

DNA Extraction Kit		
Order No.	**Description**	**Quantity**
SMB95-2001	Microsart® ATMP Extraction	Reagents for 50 extractions
SMB95-2003	Microsart® AMP Extraction (only for Mycoplasma qPCR)	Reagents for 50 extractions

Mycoplasma Detection Kits for qPCR		
Order No.	**Description**	**Quantity**
SMB95-1001|1002	Microsart® AMP Mycoplasma	25 | 100 reactions
SMB95-1003|1004	Microsart® ATMP Mycoplasma	25 | 100 reactions
SMB95-1005|1006	Microsart® Research Mycoplasma	25 | 100 reactions

Microsart® Validation Standard according to EP 2.6.7 and USP <63> for Mycoplasma species and EP 2.6.1, EP 2.6.27 and USP <71> for other bacteria and fungi

3 vials with 10 CFU/vial for Mycoplasma species and 6 vials with 99 CFU/vial for other bacteria and all fungi

Order No.	Description
SMB95-2005	*Bacillus subtilis*
SMB95-2006	*Pseudomonas aeruginosa*
SMB95-2007	*Kocuria rhizophila*
SMB95-2008	*Clostridium sporogenes*
SMB95-2009	*Bacteroides vulgatus*
SMB95-2010	*Staphylococcus aureus*
SMB95-2011	*Mycoplasma arginini*
SMB95-2012	*Mycoplasma orale*
SMB95-2013	*Mycoplasma gallisepticum*
SMB95-2014	*Mycoplasma pneumoniae*
SMB95-2015	*Mycoplasma synoviae*
SMB95-2016	*Mycoplasma fermentans*
SMB95-2017	*Mycoplasma hyorhinis*
SMB95-2018	*Acholeplasma laidlawii*
SMB95-2019	*Spiroplasma citri*
SMB95-2020	*Mycoplasma salivarium*
SMB95-2037	*Candida albicans*
SMB95-2038	*Aspergillus brasiliensis*
SMB95-2039	*Aspergillus fumigatus*
SMB95-2040	*Penicillium chrysogenum*
SMB95-2041	*Candida glabrata*
SMB95-2042	*Candida krusei*
SMB95-2043	*Candida tropicalis*

Microsart® Calibration Reagent

1 vial, 10^8 genomes/vial for all bacteria and 10^6 genomes/vial for all fungi

Order No.	Description
SMB95-2021	*Mycoplasma arginini*
SMB95-2022	*Mycoplasma orale*
SMB95-2023	*Mycoplasma gallisepticum*
SMB95-2024	*Mycoplasma pneumoniae*
SMB95-2025	*Mycoplasma synoviae*
SMB95-2026	*Mycoplasma fermentans*
SMB95-2027	*Mycoplasma hyorhinis*
SMB95-2028	*Acholeplasma laidlawii*
SMB95-2029	*Spiroplasma citri*
SMB95-2030	*Bacillus subtilis*
SMB95-2031	*Pseudomonas aeruginosa*
SMB95-2032	*Kocuria rhizophila*
SMB95-2033	*Clostridium sporogenes*
SMB95-2034	*Bacteroides vulgatus*
SMB95-2035	*Staphylococcus aureus*
SMB95-2036	*Mycoplasma salivarium*
SMB95-2044	*Candida albicans*
SMB95-2045	*Aspergillus brasiliensis*
SMB95-2046	*Aspergillus fumigatus*
SMB95-2047	*Penicillium chrysogenum*
SMB95-2048	*Candida glabrata*
SMB95-2049	*Candida krusei*
SMB95-2050	*Candida tropicalis*

User-Supplied Equipment and Material

- For DNA extraction we recommend the DNA-free Microsart® ATMP Extraction kit, Order No. SMB95-2001
- DNA-free PCR reaction tubes for the specific qPCR device
- Microcentrifuge for 1.5 ml reaction tubes, i.e. Centrisart A-14, Order No. A-14-1EU
- Pipettes with DNA-free filter tips (10, 100 and 1000 µl)
- qPCR device with filter sets for the detection of the fluorescence dyes FAM™ and ROX™ and suitable for 25 µl reaction volume

For PCR support and recommendation please contact **PCR@Sartorius.com**.

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Status: 03 | 2021

SARTORIUS

Product Datasheet

Ksep® Systems

Advanced, Scalable, Single-Use Automated Centrifugation Systems

Introduction

Sartorius Ksep® systems provide robust, single-use bioprocessing solutions in the areas of recombinant therapeutics, cell therapy, vaccine manufacturing, and blood processing. As per your process requirements, our fully-automated systems are optimized to recover supernatant or solids (cells | particles) in a continuous manner.

Ksep® systems solve the problems of traditional centrifugation and filtration based technologies by handling very high cell densities while providing high recoveries and product quality.

Description

Patented Ksep® systems technology is the only current technology that provides significant advantages for users that want to either harvest cells as product or discard cells as by-product during manufacturing.

Through the balance of centrifugal and fluid flow forces, the Ksep® retains particles such as cells or microcarriers, as a concentrated fluidized bed under a continuous flow of media or buffer. These are the only bowl centrifuges that do not stop rotating while discharging. The system can be operated under sterile conditions and all consumables are delivered pre-sterilized.

Benefits

Smart Bioprocessing

- Integrates and | or reduces processing steps and time
- Improves recoveries of both solids and liquids
- Provides option to selectively remove small particulate impurities, e.g. plastic generated, cell debris, extracellular viruses
- Built-in scalability (4 – 6 fold) for development and manufacturing using the same system
- Automated with option to run in complete manual mode
- No hardware change for different applications
- Handles low to high cell density cultures (>150 million cells/mL) equally well

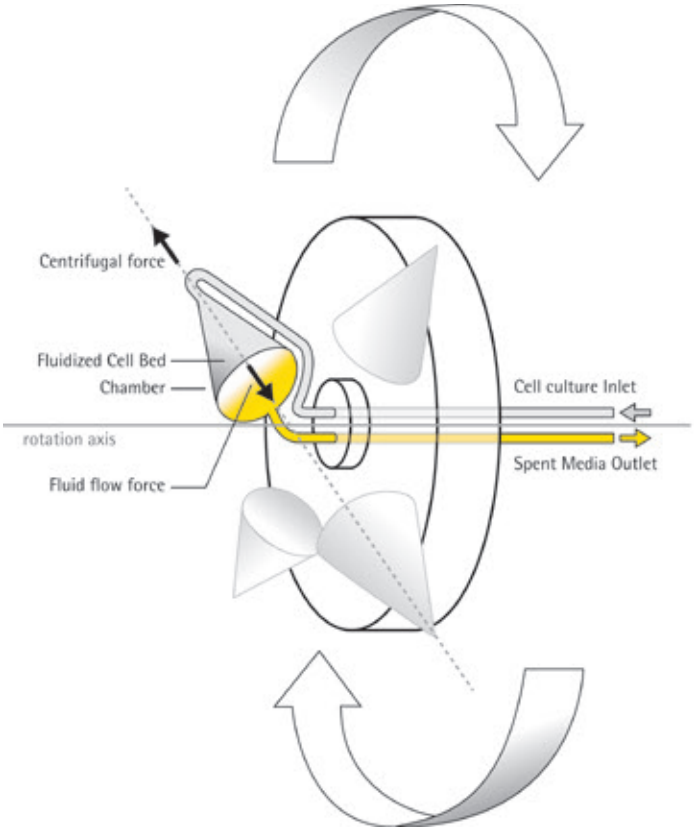
Advanced Cell Handling

- Imparts low shear on cells and keeps the cells intact
- Maintains a healthy environment to sustain cell viability
- Complete supernatant product recovery from slurry without dilution
- Reduces intracellular protein contamination for harvest applications by keeping the cells intact

Ensures cGMP Manufacturing

- Closed system with single-use class VI product contact surfaces
- Simple, robust, and scalable
- One software for all systems
- Clog-free and continuous operation

Ksep® Centrifuge Function Principle



Applications

- Harvest | Clarification
- Cell Therapy
- Vaccine Manufacturing
- Blood Processing

Concentrate-Wash-Harvest

Ksep® systems concentrate cells with high recovery while maintaining high viability. Additionally, Ksep® systems can remove cell debris, light particulate impurities, all while significantly reducing any aggregation of cells. Ksep® systems do not contain any rotary seals (providing completely closed system) or filters (for reduced issues from clogging). These features are critical for cell therapy manufacturing. Once captured and concentrated, the cells can efficiently be washed, manipulated, and harvested. Ksep® is a breakthrough for applications requiring maintenance of cellular integrity during processing. This automated sequence is currently being used for cell therapy manufacturing, perfusion, cell banking, and vaccine manufacturing processes. This is the only perfusion technology where the bleeding of cells does not cause loss of recovery.

Harvest Clarification

Ksep® systems are the first single-use centrifugation systems that are completely closed. These systems are fully-automated and designed to recover >97% of product by efficient product displacement from slurry. This process is independent of cell density. In addition, low-shear process ensures reduced downstream contamination (due to cellular debris or proteolytic enzymes) and high product quality.

Additional Applications

We are continually working with clients and have developed a wide range of additional applications including microcarrier separation and coating, blood separation, infection, and transfection.

Technical Specifications

	Ksep®400	**Ksep®6000S**
Functional		
Max g-force	1,000 g	2,000 g
Max Flow Rate	114 L/hr	720 L/hr
Volume	400 mL (4 × 100 mL)	6000 mL (6 × 1,000 mL)
Cell Capacity per Cycle (CHO)	Up to 80 Billion	Up to 1200 Billion
Processing Volumes	0.1 – 500 L	10 – 2,000 L

Physical		
Height	140 cm	179 cm
Length	107.5 cm	225 cm
Width	72 cm	106 cm
Weight	350 kg	2141 kg

	Ksep®400	Ksep®6000S
Process Connections		
All	⅜″ × ¼″ C-Flex®	⅝″ × ⅜″ C-Flex®

Utility Requirements		
Voltage	208 – 240 V 1 Ph	208 – 240 V 3 Ph (US) | 400 V 3 Ph (EU)
Current	20 A	60 A
Process Air	Not required	90 psi – ½″ NPT
Connection	NEMA L6 – 20	Customer supplied
Chilled Water (Optional)	½″ NPT	¾″ NPT

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Order No.: 85037-556-14
Status: 11 | 2020

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Product Datasheet

Biosealer® TC

For Robust and Consistent Sealing

Applications

The Biosealer® TC is used to disconnect thermoplastic tubing (TPE) such as Tuflux® TPE, C-Flex® 374, AdvantaFlex®, SaniPure™ BDF™ and Pharmed® BPT, on disposable assemblies used in biopharmaceutical manufacturing processes. Individual components of assemblies can be disconnected in a non-sterile environment while maintaining sterility of the product.

Product Information

The Biosealer® TC is a fully automated device for disconnecting thermoplastic tubing in a sterile sealing operation. This proven technology allows for sterile disconnection of tubing from ¼" up to 1" outer diameter.

Feature	Benefit
Sealing of dry or liquid filled tubing from ¼" to 1" OD without the need for accessories	One device to seal all tubing sizes under different process conditions
Larger sealing area with cutting guide	Increased sealing robustness and safer disconnection
Fully automated portable device without accessory required	Repeatable and easy to use
Standard programs for TPE tubings	Ready to use for Tuflux® TPE (except ½" × ¾", ¾" × 1"), C-Flex® 374, AdvantaFlex®, SaniPure™ BDF™ (except ¾" × 1") and PharMed® BPT
New design	Ergonomic Operator friendly Easy to use

C-Flex®, Sani-Pure™ and PharMed® are registered trademarks of Saint-Gobain Performance Plastics Corporation.

Simple Operating Principle

The inserted dry or liquid filled tubing is compressed between two heating elements. The heat and the compression force generate a homogeneous sealing of the tubing section. The resulting sealing can be cut through the embedded guideline using scissors.

Flexibility

The Biosealer® TC device is capable of sealing TPE tubing, either gamma-irradiated or autoclaved, from ¼" up to 1" OD. Sealing parameters for all tubing dimensions and materials are pre-installed on the system and simple to select. Disconnections can be performed on dry, wet or liquid filled tubing. Due to its weight and small dimensions the unit is portable and can be easily used in a variety of locations.

Ease of Use

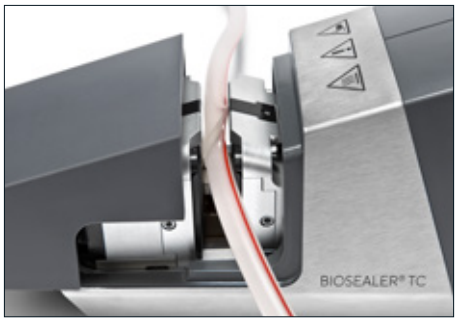
A LCD touch screen guides the user through the operator menu which is aligned with Biowelder® TC. Each step of the sealing process can be easily followed and monitored by the information provided on the display. The Biosealer® TC is equipped with an SD Card slot to allow loading and printing of the sealing cycle data via a computer. A kit is available as accessory for purchase to allow user to verify the temperature of the device.

Process Time

Depending on the tubing size and TPE material the sealing process time is between 2 to 4 minutes.

Summary table of validated tubing materials and sizes which can be sealed on Biosealer® TC.
These parameter sets have been validated at room temperature.

TPE tubing material	Sealing parameter name installed on Biosealer® TC	Sterilization methods of tubing covered by the parameters	Tubing sizes qualified per sealing parameter					
			8" × ¼"	¼" × ⅜"	¼" × 7⁄16"	⅜" × ⅝"	½" × ¾"	¾" × 1"
TuFlux® TPE	TuFlux TPE	A or G	☐ (yellow)	☐ (orange)	☐ (red)	☐ (white)		
C-Flex® 374	C-Flex 374	A or G	☐	☐	☐	☐	☐	☐
AdvantaFlex®	AdvantaFlex	A or G	☐	☐	☐	☐	☐	☐
SaniPure™ BDF™	SaniPure	A or G	☐	☐	☐	☐	☐	
Pharmed® BPT	Pharmed	A or G	☐	☐	☐	☐	☐	☐



Robust Disconnection

The thermal seals produced by the Biosealer® TC ensure an extraordinary level of stability and guarantees sterile disconnections. The sealing parameters have been qualified by stringent and innovative test regimes. Biological, physical and extractables qualification tests were performed and the results are compiled into a validation guide.

Service

The Installation Qualification and Operational Qualification is recommended and should only be performed by Sartorius Service.

Other services are available for Biosealer® TC upon request such as device installation, temperature calibration, preventive maintenance and several levels of maintenance contracts.

Ordering Information

Order Code	Description	Unit / box
16391-000	Biosealer® TC	1
16391-010	Extension cable 3 m	1
16391-011	Temperature validation kit	1

Service

Order Code	Description
S873SINST	Installation, Biosealer® TC
S873SIQOQ	IQOQ, Biosealer® TC

Service and maintenance contract of different levels are available for the Biosealer® TC.

Technical Data

Type designation	**Biosealer® TC**
Input voltage	24 VDC
Supply current	6.25 A
In and out connections	Device plug, XLR max. 24 VDC Ethernet jack type RJ45
Operating temperature	+5°C to 40°C
Place of use	Indoor
Pollution degree	2
Humidity	80% up to 31°C, linearly diminishing to 50% relative humidity at 40°C not condensing
Altitude	Up to 2000 m
Degree of protection	IP20
Weight	Approx. 3 kg
Dimension (L × W × H)	391 mm × 115 mm × 147 mm
Power Supply	
Input Voltage	100 VDC – 240 VDC
Input frequency (power supply)	47 Hz – 63 Hz
Input current	2.5 A
Power cord	According to local regulations Min. 3 × AWG18 or 3 × 0.75 mm² Min. local mains supply voltage

Sealing paremeters validation

The parameter sets have been validated at room temperature (about 22°C) with WFI solution.

It is customer responsibilty to validate the usage of the Biosealer® TC in the process conditions.

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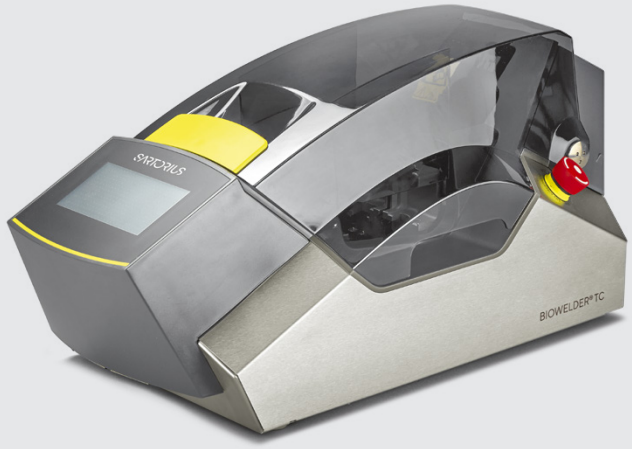
Product Datasheet

Biowelder® Total Containment

Fully Automated Device for Welding Dry And Liquid Filled Tubing



Applications

The Biowelder® TC is used to connect thermoplastic tubing such as Tuflux® TPE, C-Flex® 374*, AdvantaFlex®, SaniPure™* BDF™ and PharMed®* BPT used on disposable bags or bag assemblies within all biopharmaceutical manufacturing processes. Biowelder® TC can weld either dry or liquid-filled tubing in non classified and classified environment while maintaining product sterility.

Tuflux® TPE welding parameters only allow for the cowelding of this tubing material to C-Flex® 374 and to AdvantaFlex®. This unique feature allows one to weld together these 2 different tubing materials to Tuflux® TPE and is supported by a complete validation study."

Product Information

The Biowelder® TC is a fully automated device for connecting thermoplastic tubing in a sterile welding operation. This innovative technology allows for the sterile connection of tubing from ¼" up to 1" outer diameter.

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

Feature	Benefit
Dry or liquid filled tubing from ¼" to 1" OD	Process flexibility & multiple additions via the same tubing line
Fully automated device	Repeatable and easy to use
Standard programs	Ready to use for Tuflux® TPE, C-Flex® 374*, AdvantaFlex®, SaniPure™* (except ⅝" × ⅞" and ¾" × 1" sizes) and PharMed®* (except ⅛" × ¼" size) tubing
New design (device & color coded tube holders)	Ergonomic Operator friendly Easy to use
Extensively qualified	Safe and robust connections
Welding time	Fast connections

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

Simple Operating Principle

The holders, the blade and the tubes are inserted into the Biowelder® TC. The welding process is fully automated and is started via the LCD touch screen. The blade is first heated up for depyrogenation then cooled down to the welding temperature. An infrared sensor monitors and controls the blade temperature throughout the welding process. When the blade reaches the welding temperature, the blade cuts the tubes and the new fluid path is welded together.

Flexibility

The interchangeable and color coded tube holders are available in a variety of sizes between ⅛" × ¼" OD and ¾" ID × 1" OD, which allow a quick and easy adaptation to the process needs. The Biowelder® TC identifies each holder size when installed, which minimizes operator error. The standard Biowelder® TC unit is programmed with parameter sets for Tuflux® TPE, C-Flex® 374*, AdvantaFlex®, PharMed®* BPT and SaniPure™* BDF™.

Ease of Use

A LCD touch screen guides the user through the operator menu. Each process step can easily be followed and monitored by the information provided on the display. The Biowelder® TC is equipped with an SD Card slot to allow loading and printing of the welding cycle data via a computer.

Fast Process Times

The average welding cycle times are between 1 min 30 and 2 min 30 which provides time savings along the process chain.

Summary table of validated TPE tubing materials and sizes which can be welded on Biowelder® TC

TPE tubing material	Welding parameter name installed on Biowelder® TC	Validated welding capabilities	Sterilization methods of tubing covered by the parameters	Tubing sizes qualified per welding parameter						
				⅛" × ¼" (yellow)	¼" × ⅜" (orange)	¼" × 7⁄16" (red)	⅜" × ⅝" (white)	½" × ¾" (grey)	⅝" × ⅞" (green)	¾" × 1" (blue)
Tuflux® TPE	Tuflux® TPE	Tuflux® TPE to Tuflux® TPE	G-G; A-A, G-A	■	■	■	■	■		■
Tuflux® TPE	Tuflux® TPE	Tuflux® TPE to C-Flex® 374	G-G; A-A, G-A	■	■	■	■	■		■
Tuflux® TPE	Tuflux® TPE	Tuflux® TPE to AdvantaFlex®	G-G; A-A, G-A	■	■	■	■	■		■
C-Flex® 374	C-Flex® 374	C-Flex® 374 to C-Flex® 374	G-G; A-A, G-A	■	■	■	■	■	■	■
AdvantaFlex®	AdvantaFlex®	AdvantaFlex® to AdvantaFlex®	G-G; A-A, G-A	■	■	■	■	■	■	■
Pharmed® BPT	Pharmed®	Pharmed® BPT to Pharmed® BPT	G-G; A-A, G-A		■	■	■	■	■	■
SaniPure™ BDF™	SaniPure™	Sanipure® BDF to Sanipure® BDF	G-G; A-A, G-A	■	■	■	■	■		

Note: G = gamma irradiated, A = autoclaved

Ultra Safe Connection

The thermal weld produced by the Biowelder® TC have an extraordinary level of stability and guarantee a sterile connection. The thermal weld has been qualified by applying the most stringent and innovative test regimes. Biological, physical and extractable tests were combined to provide users with data representing a variety of process conditions. Methodologies and equipment are detailed in the validation guide.

Service

All units are individually tested before released to ensure maximum reliability. The Installation Qualification and Operational Qualification is recommended and should only be performed by Sartorius Stedim Biotech Service upon customer request. Calibration and maintenance contrat services are available for Biowelder® TC.

Instrument Services

The Installation Qualification and Operational Qualification is recommended and should only be performed by Sartorius Service.

Other services are available for Biowelder® TC upon request such as device installation, temperature calibration, preventive maintenance and several levels of maintenance contracts.

Please contact us:
www.sartorius.com/en/services/instrument-service

Confidence® Validation Services

An individualized and process specific validation of your welding processes is available by our Validation Services Team. The service includes a thorough integrity check through:

- Mechanical testing
- Microbial testing
- Physico-chemical testing

Please contact us for consultancy and our tailored approach:
www.sartorius.com/en/services/validation-service

Technical Data

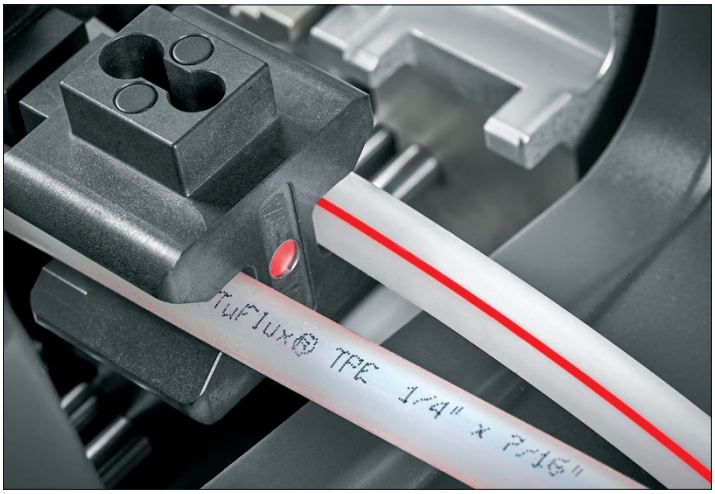
Type designation	**Biowelder® TC, BWTC**
Power connection	100 VAC – 240 VAC
Input frequency	50 | 60 Hz
Power input	300 VA
In and out connections	Device plug C14 max. 250VAC Ethernet jack type RJ45
Power connection of fuse	2 × 3.15 A T (Type FST)
Battery	CR2032
Operating temperature	+5°C – +40°C **
Place of use	Indoor (Laboratory)
Transient overvoltage	Overvoltage category II
Pollution degree	2
Altitude	up to 2000 m
Humidity	80% up to 31°C, linearly diminishing to 50%; relative humidity at 40°C, not condensing
Degree of protection	IP20
Weight	16.4 kg
External size (L × W × H)	555 mm × 261 mm × 269 mm
Power cord	According to local regulations Min. 3 × AWG18 or 3 × 0.75 mm² Min. local mains supply voltage
Tube holder size (ID × OD; color)	⅛" × ¼"; yellow ¼" × ⅜"; orange ¼" × 7⁄16"; red ⅜" × ⅝"; white ½" × ¾"; grey ⅝" × ⅞"; green ¾" × 1"; blue
Welding Cycle	1 min 30 – 2 min 30 (depending on tube diameters and material)
Standard settings for	Tuflux® TPE, C-Flex® 374*, AdvantaFlex®, PharMed®* BPT, SaniPure™* BDF™
Minimum tubing length	450 mm
Max operating pressure validated	1 bar

** The device is programmed with standard parameter sets for welding Tuflux® TPE, C-Flex® 374, AdvantaFlex®, PharMed® BPT and SaniPure™ BDF™.

These parameter sets have been validated at room temperature.

Ordering Information

Order Code	Description	Unit | Box
16389	Biowelder® Total Containment	1
16389-009	Biowelder® TC Tube Holder ⅛" ID × ¼" OD	2
16389-010	Biowelder® TC Tube Holder ¼" ID × ⅜" OD	2
16389-011	Biowelder® TC Tube Holder ¼" ID × 7/16" OD	2
16389-001	Biowelder® TC Tube Holder ⅜" ID × ⅝" OD	2
16389-002	Biowelder® TC Tube Holder ½" ID × ¾" OD	2
16389-003	Biowelder® TC Tube Holder ⅝" ID × ⅞" OD	2
16389-004	Biowelder® TC Tube Holder ¾" ID × 1" OD	2
16389-012	Biowelder® TC Disposable Blades in box (50)	1
16389-013	Biowelder® TC Blade Remover Tool	1
16389-006	Calibration Kit	1
16389-007	SD card	1
16389-008	Carrying case for Biowelder® TC Tube Holder (Max 6 sets)	1



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SIMCA®-online

Ensuring manufacturing success

Simplifying Progress

SARTORIUS

Predicting process problems
Boosting business growth

Every production process follows a strict set of rules. If those rules are broken, you need to know – and the earlier the better. SIMCA®-online from Sartorius Data Analytics monitors your processes in real-time for a continuous snapshot of your operations. You can identify when set parameters change, fix them before they affect production and keep quality consistent. With this level of control, you can maximize efficiency and minimize costs. You will enjoy the confidence of high quality in your product and a real boost to your business growth.

How does SIMCA-online work?

Instead of monitoring each variable, you can concentrate them into one view that is key to your whole process. Easy-to-understand graphics make interpretation simple.

- Monitor in real time and swiftly detect deviations. With SIMCA you can model your ideal process from your collected data. Transferred into SIMCA-online, the model acts as a valuable reference for your current production.
- Predict with confidence. You can predict final quality from the properties of the raw material and the process parameters as well as forecast the final quality.
- Control at a glance. SIMCA-online uses an 'ideal process' model to anticipate the effect of changes and recommend immediate adjustments. This will ensure product performance according to specifications and optimize throughput.

Proven in a wide range of industries

SIMCA-online has been adopted widely in many different industries, including pharma & chemical, pulp & paper and food & beverage.

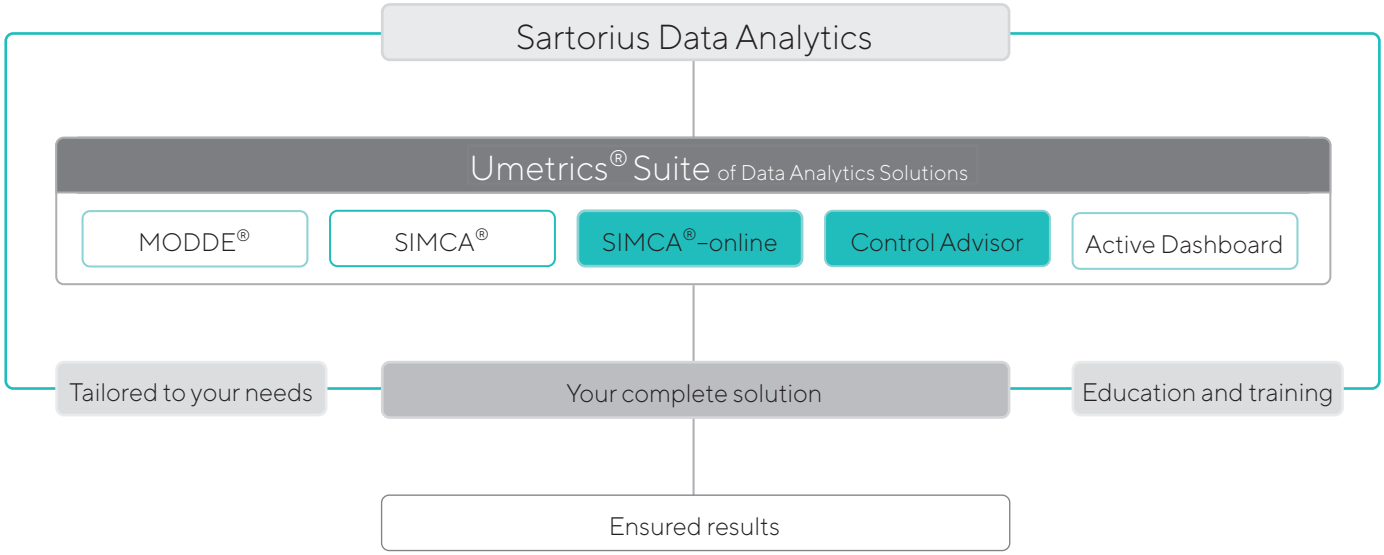
Our customers have seen excellent results in cost savings, efficiency and product quality. For instance:

- A multi-national paper company reduced costs, achieved a more consistent product quality and gained a deeper understanding of their data.
- A major food processing company saved over USD 3 million each year in production costs.
- A pharmaceutical company paid for their investment several-fold in recovered batches alone.

SIMCA-online at a glance:

- Remote predictive monitoring
- Root-cause-analysis
- Predicting final quality attributes
- Soft sensoring
- Real-time supervisory control

More than software



Our complete solution includes everything you need through the whole process and provides results quickly.

As our customer, you'll have access to supporting documents, templates, training and consultation to address your specific business challenges. Our courses and webinars help over a thousand people every year develop expertise and confidence in data analytics.

> "SIMCA-online improves overall understanding of process and equipment

A complete suite for business growth

The Umetrics Suite is a family of proven data analytics solutions that work seamlessly together.
Other software solutions in the Umetrics Suite are:

- MODDE®
  Design of Experiments to get it right from the start
- SIMCA®
  Multivariate Data Analysis Solution to help you see what others don't
- Control Advisor
  Predictive capabilities to be able to forecast the output
- Active Dashboard
  Interactive performance insight

These solutions give you control and confidence in your processes at every stage - from development to manufacturing.

Sartorius Data Analytics

Change a little - Grow a lot

We help organizations grow. The Umetrics® Suite of Data Analytics Solutions helps you harness the wealth of data within your organization. Our expertise in data analytics can help you identify vital elements to improve the results of your research, development and manufacturing processes.
With improved process understanding and more consistent product quality, you'll be able to reduce risk, get to market faster, and grow your business.
Our complete solution encompasses software, training, support and project management. And as part of Sartorius, a global company with more than 7,000 employees, we give you the backing of an international presence.

Experience the benefits for your business today. Find out how our solutions can help your business to grow, whatever industry you are in.

Visit www.sartorius.com/umetrics for details or to download a demo version of SIMCA-online.

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