Sartorius T-Cell Autologous Manufacturing Solution

Data Sheet Collection

SARTORIUS

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Simplifying Progress

Engineered for Life –

Biostat® RM TX with Flexsafe® RM TX

for Culturing Consistent Quality Cellular Products

SARTORIUS

Our Competence in Cell and Gene Therapy

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

Solutions for Cellular Immunotherapies

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

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

Biostat® RM TX Bioreactor System and Flexsafe® RM TX Bags

The Ideal Combination for Your Cells

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

You Can Rely on:

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

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

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

Lead scientist in major cell therapy company

The Right Solution for Your Needs

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

Optimize Cell Growth

Minimize Impact of Single-Use Material

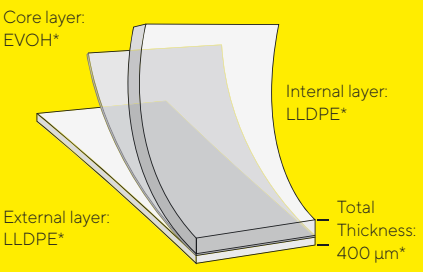
Flexsafe® RM TX bags were introduced in June 2014 and have been used with continuing success ever since by major global biopharma and cell therapy customers. The complete control of our raw materials, the extrusion process and the bag assembly, provides lot-to-lot product consistency. In collaboration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

Zero Slipping Agents & Nontoxic Mechanical Antiblocking
⟶ No risk of interference due to these agents*

Protect Your Cell Product

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

Structure of the S80 Film



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

* Independent labs have confirmed that Flexsafe® bags are free of cytotoxic leachables. No bDtBPP is identified in WFI extracts of Flexsafe® bags
** Fenge et al. 2014. Consistently Superior Cell Growth: Achieved with New Polyethylene Film Formulation. Bioprocess International, Volume 12 Suppl 5.

Efficient Cell Processing

Maximize Cell Yield

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

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

Robust & Consistent Manufacturing

Our Biostat® B control unit is ideal for walk-away automated analysis and control of high cell density perfusion cultures.

Benefit from:

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

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

* Patent pending.

Single | Twin Configuration
One controller can run up to two Biostat® RM TX completely independently to save valuable lab space.

Biostat® RM TX

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

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

12" Touch Screen
Easy-to-use and reliable operation of your Biostat® RM TX system due to intuitive design of human-machine interface and advanced touch-screen technology – even while wearing laboratory gloves. Integrated flush housing ensures liquid protection.

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

Safety Bellow
Protects operator & tubing from mechanical hazards of moving tray.

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

Configurable Control Tower
Contains aeration, pumps and temperature control modules for various application needs. The BioPAT® MFCS multi fermenter control system ensures reliable data management and automation.

Connectivity to Supervisory Systems
The BioPAT® MFCS multi fermenter control system or third party SCADA system integration (DeltaV™) ensures reliable data management and automation.

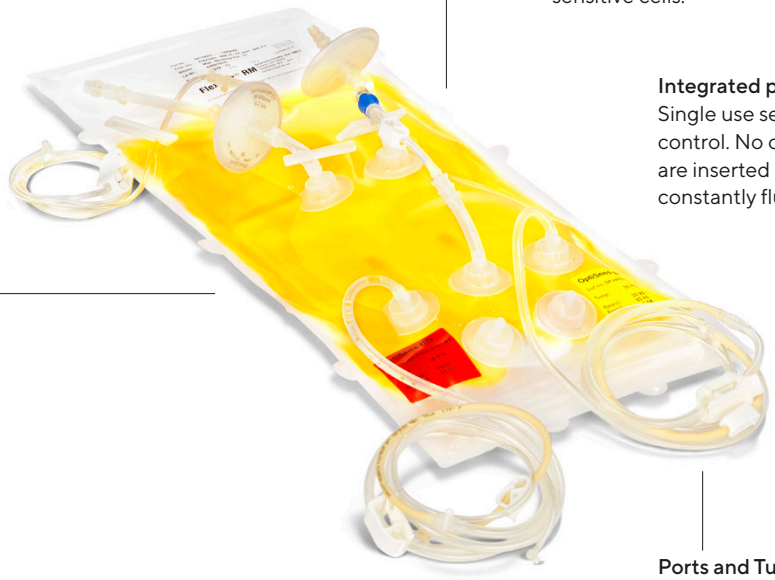
Flexsafe® RM TX Bags

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

BioPAT® ViaMass
Integrated sensor for online biomass determination and reduced sampling need.*

Vent Filters
Sartopore® Air filters are 100% integrity tested before gamma irradiation for improved process safety.

Film
Industry leading proprietary Flexsafe® film for optimal cell growth of most sensitive cells.



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

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

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

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

Process

Flexsafe® 2D Bags
- Single-use Flexsafe® bags for media storage coupled with Flexsafe® pre-designed solutions for sterile filtration, storage and transfer of media and buffers
- Proven integrity to enhance process and product safety by reducing risks of contamination of valuable cell products

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

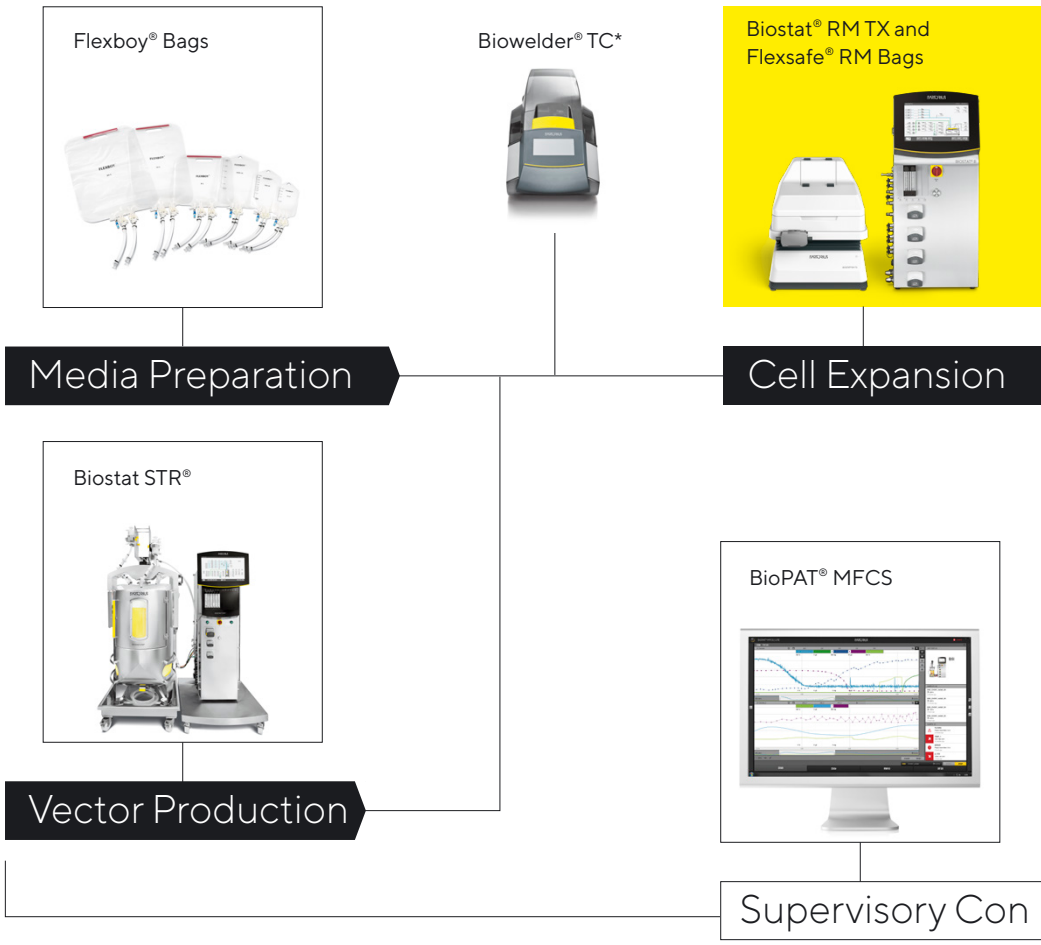
Biostat STR®
- Scalable, single-use bioreactor family based on stirred-tank design
- Wide range of sizes (12.5 L to 2000 L working volume) and process regimes for flexible manufacturing

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

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

Cellular Immunotherapy Processes

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



Analytics

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

iQue® Screener PLUS Platform | Virus Counter® 3100 | BioPAT® Trace

BioPAT® ViaMass

Biowelder® TC*

kSep® Centrifuge

Cell Harvest

*Alternative:
Sartorius Transfer Sets

trol and Data Acquisition

BioPAT® ViaMass

Microsart® ATMP Mycoplasma and Bacteria Kits

BioOutsource

Characterization & Cell Banking Services

Analytics

iQue® Screener PLUS Platform

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

Virus Counter® 3100

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

Microsart® ATMP Mycoplasma and Bacteria Kits

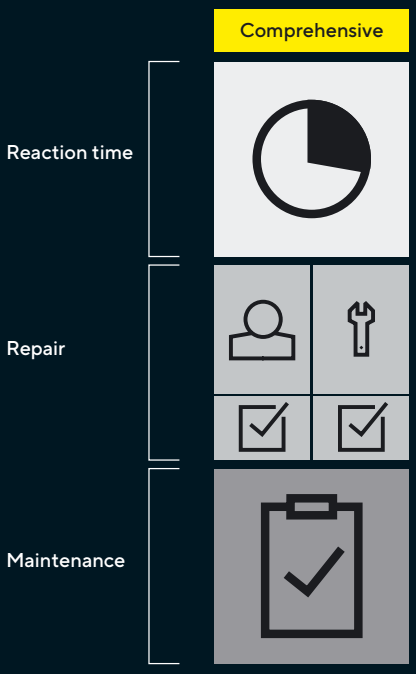
- PCR-based, easy and fast detection of mycoplasma or bacteria
- Results are available within 3 hours (rather than days) resulting in a better ability to keep cell-based therapeutics contamination-free

Characterization Services for Biologics

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

BioPAT® Tools

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



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

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

Reaction Time Commitment:

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

Your Benefits

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

Read more
Broch_Bioprocess-Service-Program_S-1546-e

Sartorius as Your Partner for Cell and Gene Therapy Manufacturing

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

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

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

Technical Specifications Biostat® RM TX

Applicable Bag Sizes and Designs

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

Facility and Utility Requirements

Power Supply (Country Specific) | Frequency | Electricity Consumption | Protection Class	
Rocker platform	230 V | 50 Hz | 1.3 A | IP23 or 120 V | 60 Hz | 2.5 A | IP23
Control tower	230 V | 50 Hz | 10 A | IP21 or 120 V | 60 Hz | 12 A | IP21
Load cells	Integrated in rocker
Gas Supply via Biostat® B Tower	
Inlet pressure (barg)	1.5
Connection hose coupling, external	Hose barb for tubing with 6 mm ID
Gas Specification According to ISO 8573-1: dry, free of oil and dust	
Particle size: < 0.1 mm	☐
Max. amount 0.1 mg/m^3 (class 1)	☐
Condensate: dew point < 3°C (class 4)	☐
Oil < 0.01 mg/m^3 (class 1)	☐
Germs (class 0)	☐
Operative Environment	
Ambient temperature of between	5 – 40°C
Relative humidity [%]	< 80% for temperatures up to 31 °C (87.8 °F), decreasing linearly < 50% at 40 °C (104 °F)

* Bags with sensors might require higher minimum working volumes depending on rocking rate and angle. We recommend using 20 % of the total volume as the minimum working volume.
** incl. Sartopore® Air Midisart vent filters, harvest port for gravity harvest, Press-In Plugs, PVC or C-Flex tubing

System Characteristics

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

Process Control

Temperature Module	
Temperature control	Heating only – electrical heating plates
Temperature control range	Ambient temperature + 5°C to 40°C (min. set point 15°C , min. controllable temp = ambient temp. + 15°C)
Temperature measurement	2°C to 50°C
Temperature control accuracy (excl. measurement error)	±0.2°C
Heating capacity	1 × 120 W (24 VDC)
Over temperature protection	☐
Gassing Module Control Tower	4-Gas mix (O_2, N_2, CO_2, air) with headspace outlet
MFC ▪ flow rates ▪ accuracy	max. 4 0.003 lpm – 5 lpm ± 1% full scale
Advanced DO controller	☐
Sensors & Measurement	
Temperature probe Pt 100 ▪ temperature range Pt 100 ▪ display resolution ▪ amplifiers	☐ 0 – 99°C 0.1°C 1 (single) | 2 (twin)
pH single use ▪ measurement range ▪ display resolution ▪ amplifiers ▪ recalibration function	☐ 6.5 – 8.5 0.1 pH 1 (single) | 2 (twin) ☐
DO single-use ▪ measurement range ▪ display resolution ▪ amplifiers ▪ recalibration function	☐ 0 – 250% 0.1% 1 (single) | 2 (twin) ☐

Sensors & Measurement	
Single-use viable biomass (BioPAT® ViaMass)	Optional
Integrated load cells	☐
Media weight control range	0 to 5 kg
▪ Scale, absolute accuracy	Static: ± (10 + 0% of load) g Dynamic: ± (25 + 0% of load) g
▪ Scale, relative accuracy	Static: ±3 g Dynamic: ±5 g*
Resolution (DCU)	1 g
External signal input	max. 2 0 – 10 V or 4 – 20 mA
Pump Module | Built-in Pumps	
Watson Marlow 114, fast load pump head	
Fixed Speed for Base Addition | pH Control	
▪ Speed 5 rpm Flow rate (tubing wall thickness 1.6 mm)	ID: 0.5 mm: 0 – 0.1 ml/min ID: 0.8 mm: 0.05 – 2.4 ml/min ID: 1.6 mm: 0.01 – 0.7 ml/min ID: 2.4 mm: 0.03 – 1.5 ml/min ID: 3.2 mm: 0.05 – 2.4 ml/min ID: 4.8 mm: 0.09 – 4.3 ml/min
Speed Controlled for Feed Addition	
▪ 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

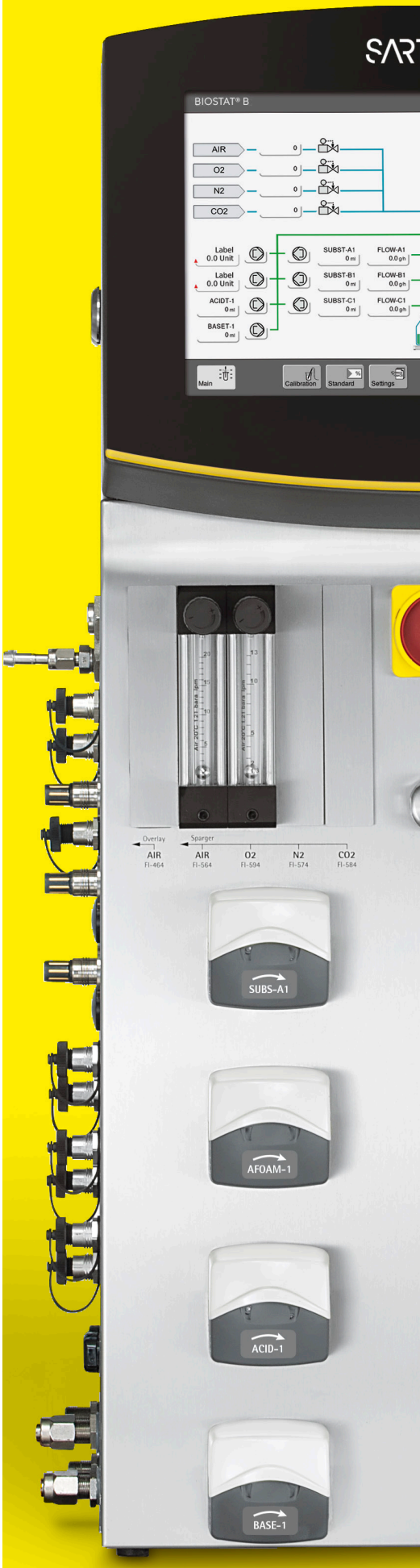
* Dynamic weight measurement (while rocking) can be influenced by cables and tubing and interferences caused by the same.

Communication

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

Technical Data

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



Read more
Data_Flexsafe-RM_SBT2013-e

Read more
Broch_Biostat-RM-Bibliography_SBI1111-e

Sales and Service Contacts

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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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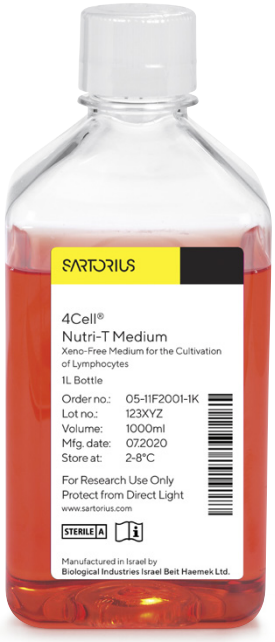
Product Datasheet

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.

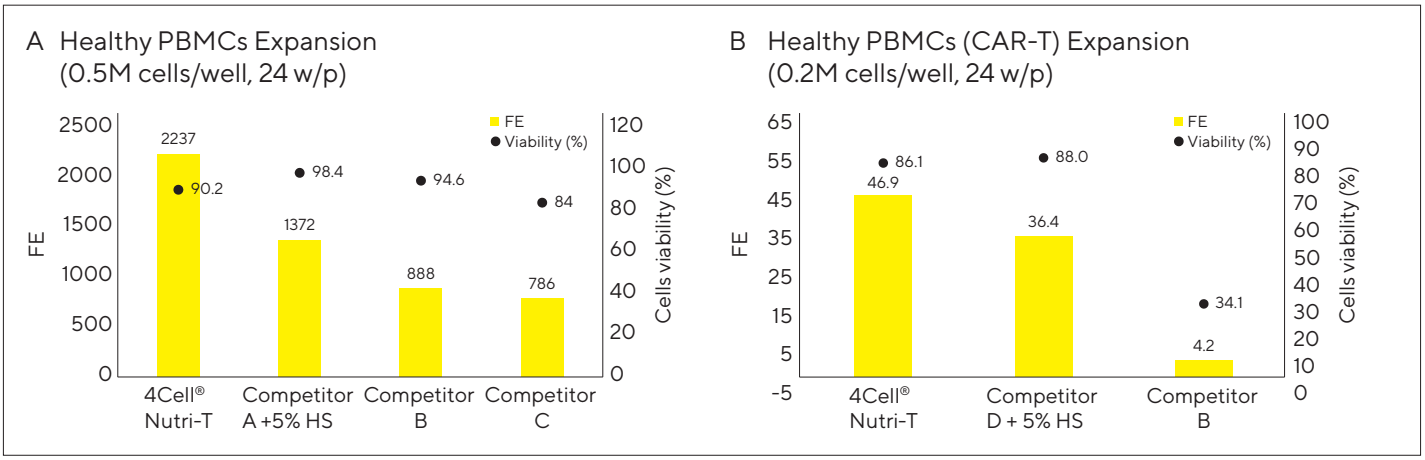
Product Snapshot

- 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



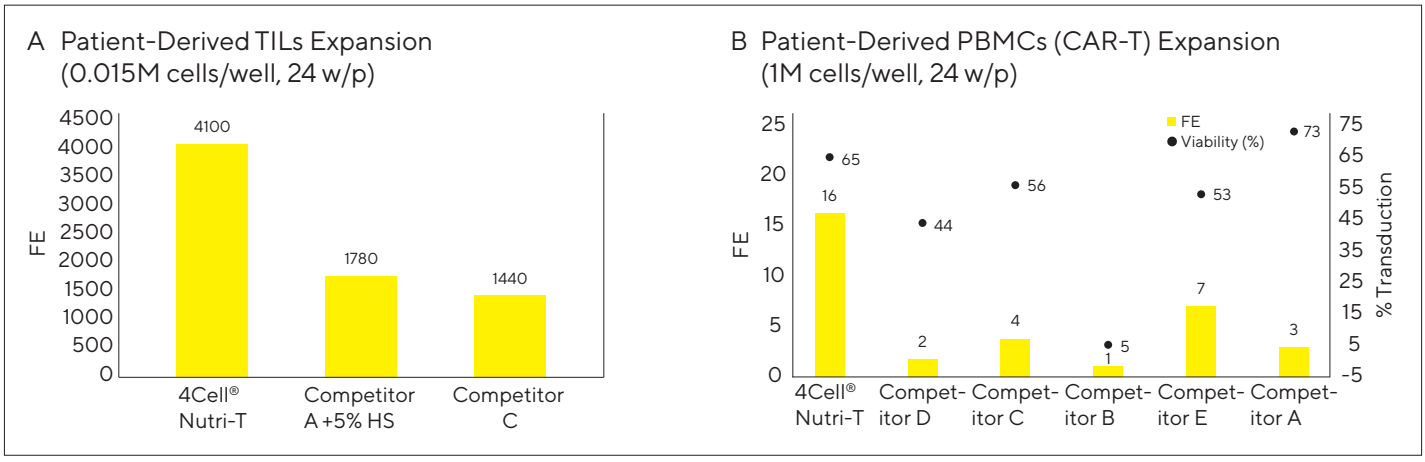
(A) 0.5M healthy donor PBMCs were seeded in 24w plates (2 ml media/well). Cells were activated with TransAct 1:100 and 600 IU/ml IL-2. Cells were split and media renewed every 2 – 3 days. Fold expansion (FE) and cell viability were measured at Day 11.

(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

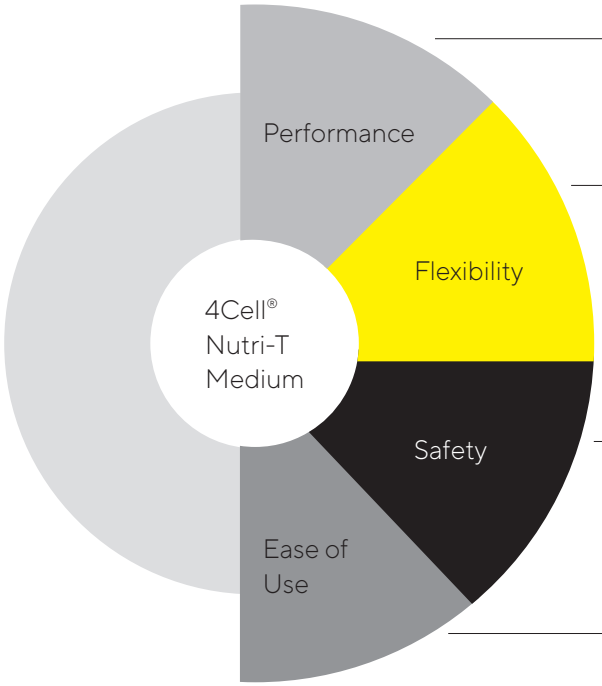
When working with a patient's cells, the materials used and the time from cell isolation to patient administration with the final product are critical. You cannot afford to waste time as a result of production or shipment delays.

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

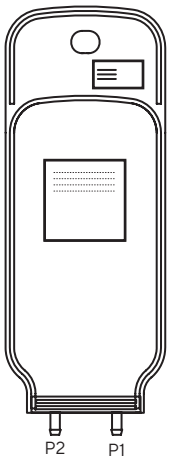
Supply Chain

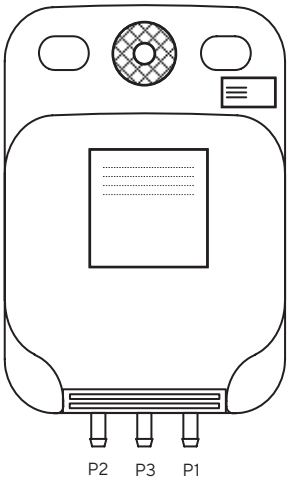
Configurable Flexsafe® 2D Bags are available as configured to order products. Pre-configured products based on application knowledge allow savings on engineering time and production preparation, thus providing reduced lead-times compared to classical fully customized processes.

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

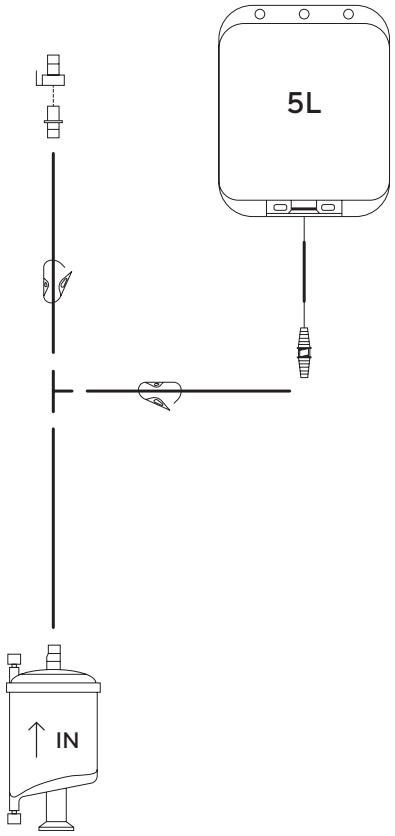
Type of Lines

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

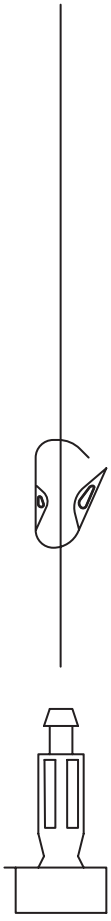
Type of Filters
- Sartopore® 2 0.2 µm Gamma Midicaps® size 4
- Sartopore® 2 0.2 µm Gamma Midicaps® size 7
- Sartopore® Platinum 0.2 µm Gamma Midicaps® size 4
- Sartopore® Platinum 0.2 µm Gamma Midicaps® size 7
- Sartopore® XLM 0.1 µm size 7

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)

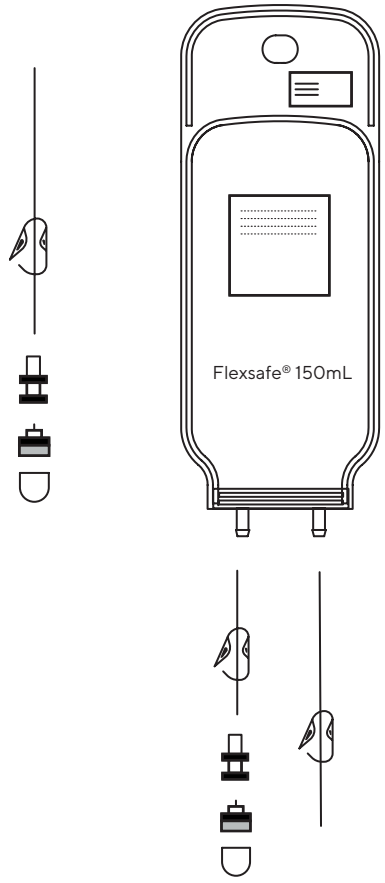
Tubing Materials
- Silicone Tuflux® or Si(Pt) for 10 hr maximum operation with a peristaltic pump
- TPE (thermoplastic tubing) for tube sealing and welding operations
- Silicone Tuflux® or Si(Pt) with a TPE extension for 10 hr maximum operation with a peristaltic pump and for tube sealing and welding 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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Publication No.: SPT2028-e | Order No.: 85037-559-38 | Status: 10 | 11 | 2021

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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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

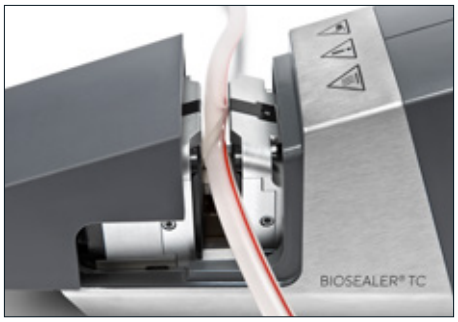
A LCD touch screen guides the user through the operator menu which is aligned with Biowelder® TC. Each step of the sealing process can be easily followed and monitored by the information provided on the display. The Biosealer® TC is equipped with an SD Card slot to allow loading and printing of the sealing 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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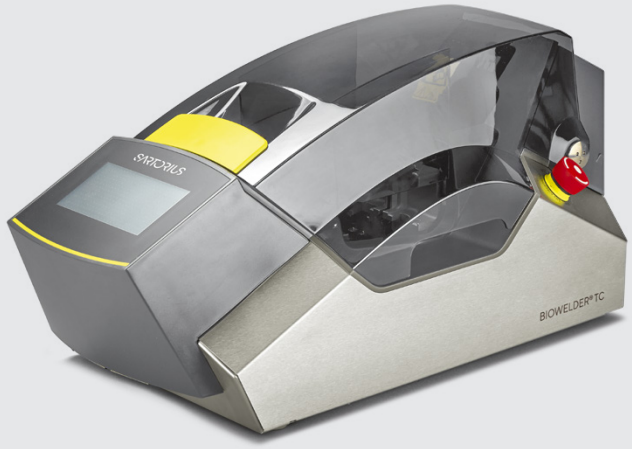
Product Datasheet

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

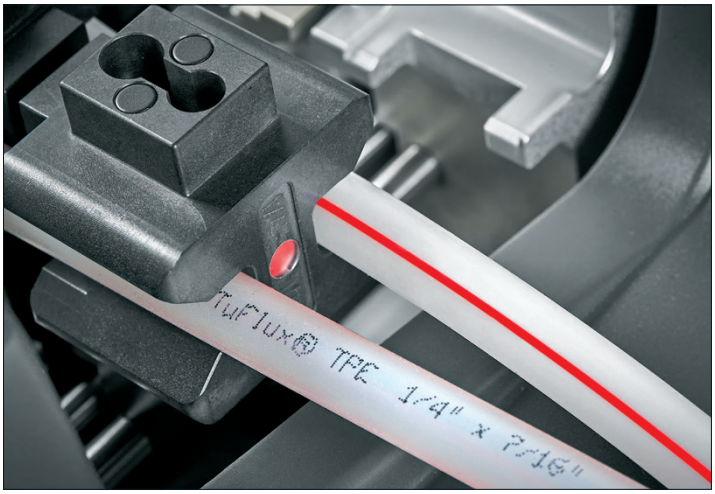
Type designation	**Biowelder® TC, BWTC**
Power connection	100 VAC – 240 VAC
Input frequency	50 | 60 Hz
Power input	300 VA
In and out connections	Device plug C14 max. 250VAC Ethernet jack type RJ45
Power connection of fuse	2 × 3.15 A T (Type FST)
Battery	CR2032
Operating temperature	+5°C – +40°C **
Place 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.

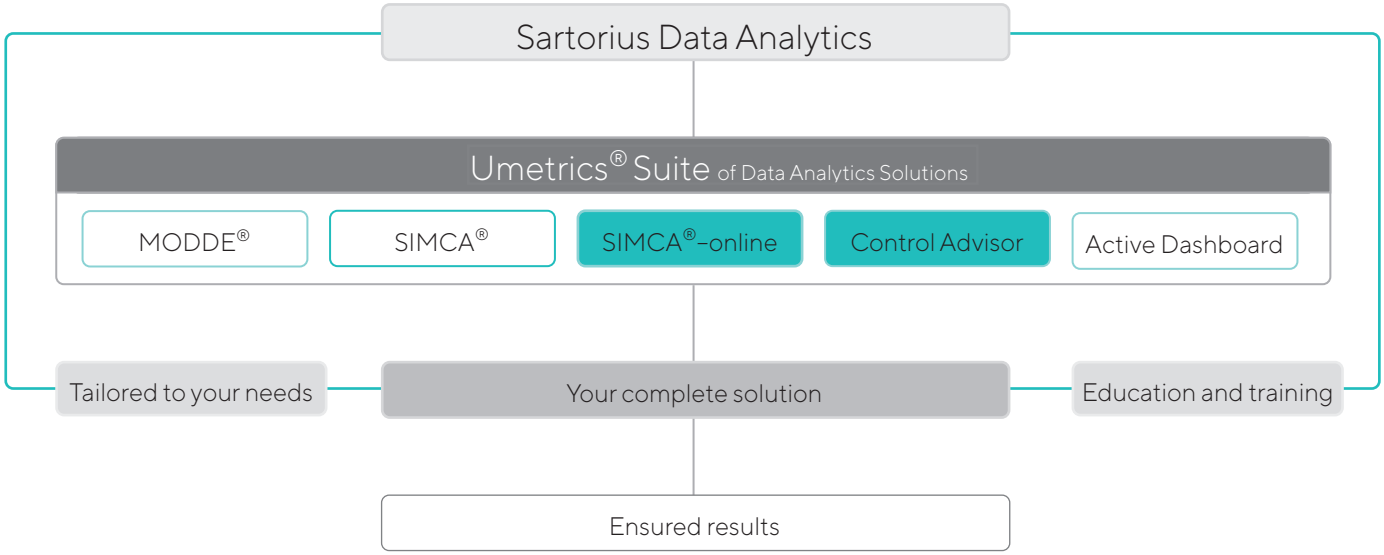
Our customers have seen excellent results in cost savings, efficiency and product quality. For instance:

- 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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