

Sartorius MSC Pilot Solution

Data Sheet Collection

SARTORIUS

Table of Contents

Univessel® Glass Platform Cultivation Vessel	3
Biostat® B Universal Controller	43
MSC NutriStem® XF Medium	67
Flexsafe® 2D Single-Use Storage Bag	69
SoloHill® Microcarrier Products	77
PLTGold® Human Platelet Lysate	82
ACF Recombinant Trypsin	84
Ksep® Single-Use Centrifugation System	86
Biosealer® TC Sterile Disconnection Device	90
BioWelder® TC Sterile Connection Device	94
MSCgo™ Differentiation Media	98
Incucyte® SX5 Live-Cell Analysis System	100
iQue 3® Advanced High-Throughput Flow Cytometry	102
Microsart® ATMP Mycoplasma Rapid Detection Kit	104
Microsart® ATMP Bacteria/Fungi Rapid Detection Kit	106
NutriFreez® D10 Cryopreservation Medium	110
SIMCA® Multivariate Data Analysis	111



Univessel[®] Glass

Reliability and Continuity

Simplifying Progress

SARTORIUS

One For All

The Univessel® Glass is our platform cultivation vessel for all Biostat® benchtop bioreactors. It is available in 1 L, 2 L, 5 L and 10 L working volume. Benefit from the new design and the backward compatibility – all existing probes, dip tubes, spargers and impellers fit also into the new Univessel® Glass.

Get in contact with your local Sartorius representative and learn more about the new features – e.g. dishwasher proof stirrer shaft, ring sparger with bores facing downwards or the glass vessel fixation for cleaning.



Benefits

Reliability

Decades of experience made the Univessel® Glass the most reliable autoclavable cultivation vessel on the market.

Continuity

Compatible with all Biostat® benchtop bioreactors dating back to 2004. Dimensions and characteristics are untouched compared to the predecessor Univessel® Glass.

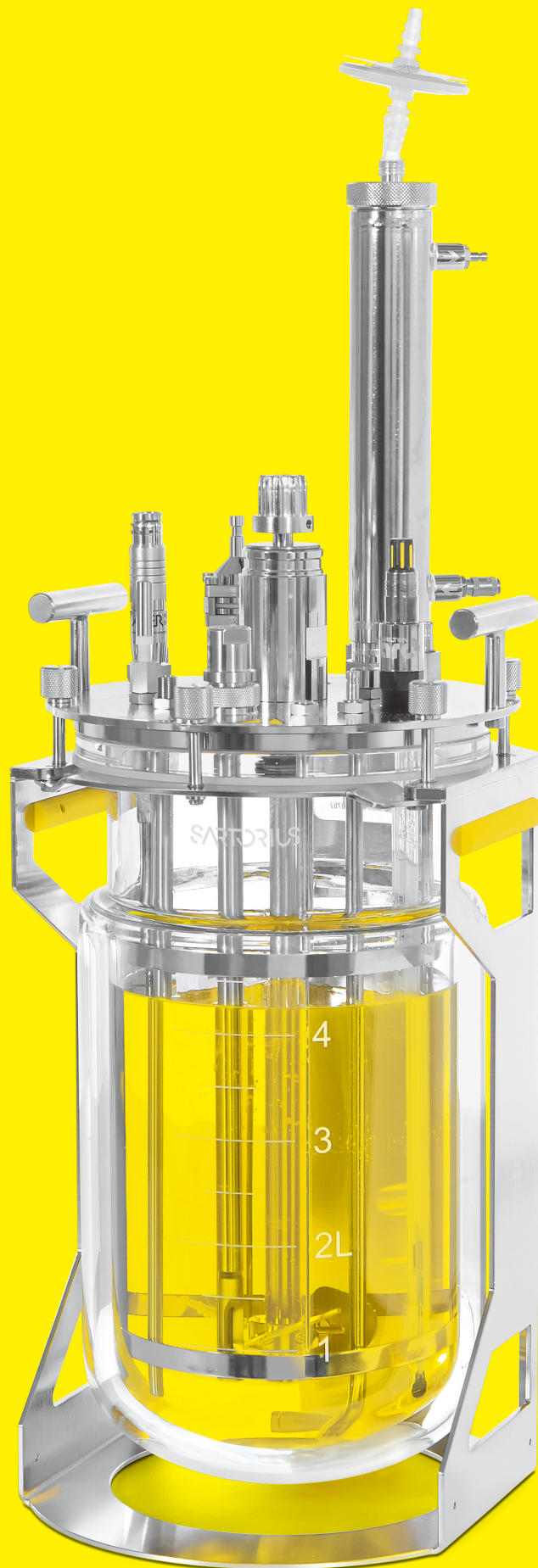
Ease of Use

Speed up cleaning with the dishwasher proof stirrer shaft and benefit from the new handling concept.

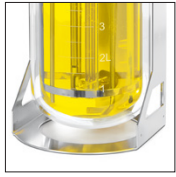
Configurability

More options for more flexibility in process development and characterization. The Univessel® Glass creates a greater design space for you.





New Features



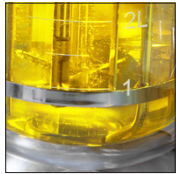
Stability

The round shaped bottom of the stand provides a maximum of sturdiness to the Univessel® Glass.



Ease of Cleaning

The complete dish-washer proof stirrer enables cleaning of the head plate in a dishwasher without removing the stirrer shaft.



More Sparging Options

Now available: a ring sparger with holes facing downwards. Easy to clean and no dead volumes.



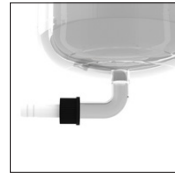
Ease of Handling

The additional, integrated handles make the Univessel® Glass more ergonomic and easier to carry – especially for 5 and 10 L vessels.



No More Damaged Glass Vessel

New fixation for cleaning to secure the glass vessel during the whole cleaning procedure. It only takes 5 seconds to protect your glass vessel.



Bottom Drain Outlet

The special bottom drain version makes it ideal for ATF and TFF based intensified processes.

Less Weight

Eliminating unnecessary weight, makes the Univessel® Glass lighter than ever without losing stability or risking sterility.

Documentation for Qualification

The documentation of our Univessel® Glass is designed to allow for full qualification as typically needed in a regulated environment. Request our comprehensive documentation package of manufacturer and material component certificates.

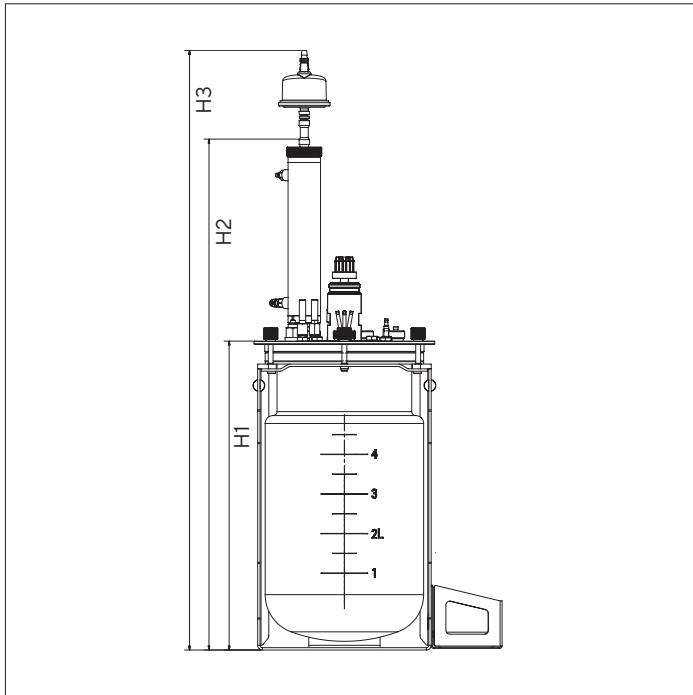
Technical Specifications

General

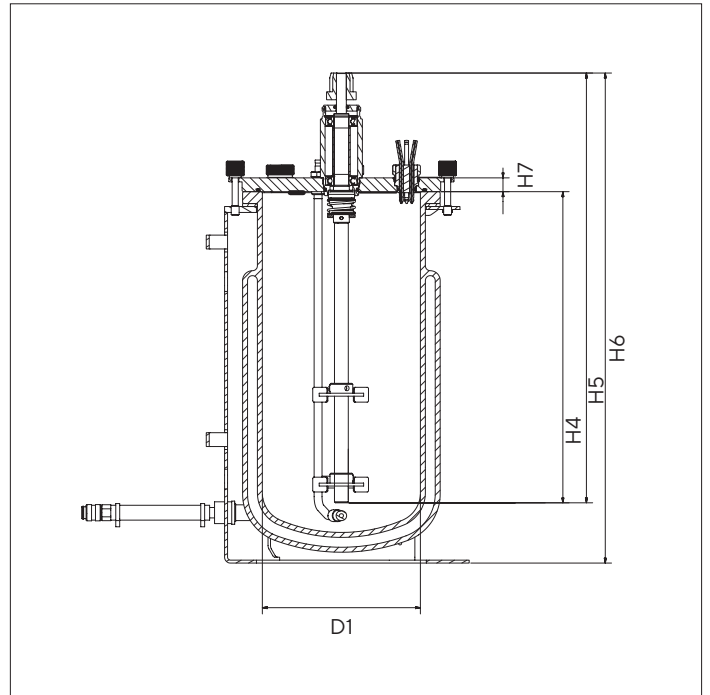
	Univessel® Glass 1 L single-wall (SW)	Univessel® Glass 1 L double-wall (DW)	Univessel® Glass 2 L single-wall (SW)	Univessel® Glass 2 L double-wall (DW)	Univessel® Glass 5 L single-wall (SW)	Univessel® Glass 5 L double-wall (DW)	Univessel® Glass 10 L single-wall (SW)	Univessel® Glass 10 L double-wall (DW)
Materials of major product wetted parts	Borosilicate glass, stainless steel AISI 316L, EPDM							
Weight without medium and accessories (stand, glass vessel, head plate, stirrer)	4.4 kg 9.4 lbs	5.3 kg 11.7 lbs	5.9 kg 13.0 lbs	6.9 kg 15.2 lbs	10.5 kg 23.1 lbs	12.6 kg 27.8 lbs	14.9 kg 32.8 lbs	18.5 kg 40.8 lbs
Top ports 19 mm 12 mm 6 mm	3 2 6	3 2 6	3 2 9 (3 3 8 for head plate with extra PG 13.5 port)	3 2 9 (3 3 8 for head plate with extra PG 13.5 port)	3 3 8	3 3 8	5 2 9	5 2 9

Outside Dimensions

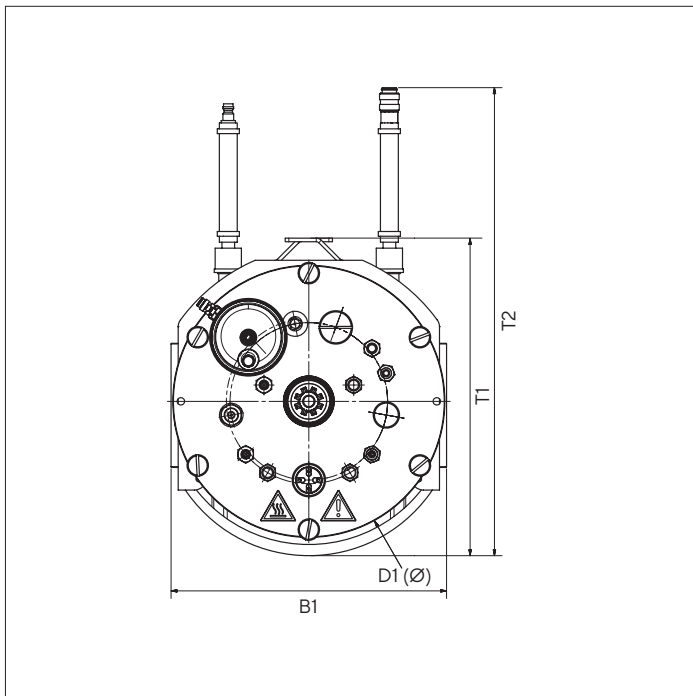
Pos.	Unit	Univessel® Glass 1 L	Univessel® Glass 2 L	Univessel® Glass 5 L	Univessel® Glass 10 L
		Value	Value	Value	Value
D1	mm	110.0	130.0	160.0	190.0
H1	mm	224.0	285.0	390.0	512.0
H2	mm	446.0	507.0	645.0	767.0
H3	mm	558.0	619.0	757.0	879.0
H4	mm	158.0	220.0	315.0	421.0
H5	mm	278.0	340.0	435.0	541.0
H6	mm	330.0	391.0	496.0	618.0
H7	mm	14.0	14.0	14.0	14.0
B1	mm	156.0	176.0	231.0	281.0
B2	mm	239.0	262.0	314.5	364.5
D1	mm	172.0	198.0	228.0	270.0
T1	mm	196.0	216.5	266.0	306.0
T2	mm	319.0	332.0	392.0	433.0
T3	mm	234.5	234.5	285.0	285.0
T4	mm	353.0	342.0	409.8	433.4



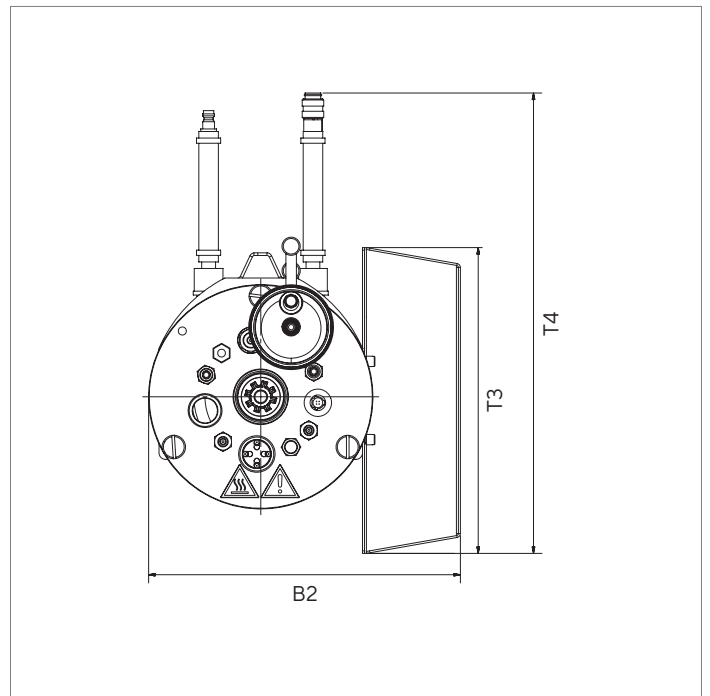
Univessel® Glass 5 L with exhaust cooler (example)



Univessel® Glass 5 L (DW) without exhaust cooler (example)



Univessel® Glass 5 L (DW) without bottle support (example)



Univessel® Glass 1 L (DW) with bottle support (example)

Dimensions for Autoclaving

		Univessel® Glass 1 L (DW)	Univessel® Glass 1 L (SW)	Univessel® Glass 2 L (DW)	Univessel® Glass 2 L (SW)	Univessel® Glass 5 L (DW)	Univessel® Glass 5 L (SW)	Univessel® Glass 10 L (DW)	Univessel® Glass 10 L (SW)
Unit	Value	Value	Value	Value	Value	Value	Value	Value	Value
Space requirement in the autoclave without flexible adapter for exhaust cooler									
Diameter	mm	320.0	200.0	335.0	220.0	395.0	270.0	435.0	310.0
Height	mm	446.0	446.0	507.0	507.0	645.0	645.0	767.0	767.0
Space requirement in the autoclave with flexible adapter for exhaust cooler									
Diameter	mm	450.0	450.0	490.0	490.0	570.0	570.0	600.0	600.0
Height	mm	330.0	330.0	391.0	391.0	496.0	496.0	618.0	618.0

Inside Dimensions

	Univessel® Glass 1 L	Univessel® Glass 2 L	Univessel® Glass 5 L	Univessel® Glass 10 L
Total volume [L]	1.6	3	7	13
Max. working volume [L]	1	2	5	10
Min. working volume [L]	0.35	0.4	0.6	1.5
Vessel diameter d_v [mm]	110	130	160	190
Vessel height h [mm]	180	240	345	470
Ratio $h d_v$	1.6	1.8	2.2	2.5
Liquid height h_l [mm]	110	180	280	360
Ratio $h_l d_v$	1	1.4	1.8	1.9
Diameter 6-blade disc impeller d_{i_1} [mm]	45	53	64	75
Diameter 3-blade segment impeller d_{i_2} [mm]	48	54	70	78
Ratio $d_{i_1} d_v$ (6-blade)	0.44	0.42	0.41	0.41
Ratio $d_{i_2} d_v$ (3-blade)	0.41	0.41	0.44	0.39



Flexible Adapter for Exhaust Cooler

Typically, the exhaust cooler and its fittings are at the highest point of the culture vessel. They have to be arranged vertically to enable condensate to flow back into the vessel. However, in the case of small autoclaves, the height of the fully equipped Univessel® Glass can be challenging.

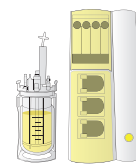
Using a flexible adapter reduces height requirements in an autoclave. The adapter is installed between the exhaust cooler and its top plate port at the culture vessel.

Impeller Angle Tool

Helps to adjust easily the angle of the impeller blades to 30°.

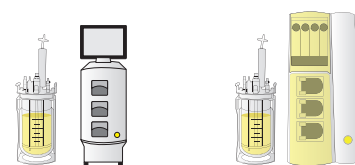


Univessel® Glass 1L

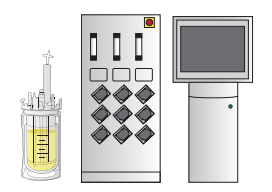
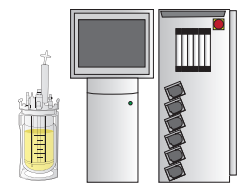
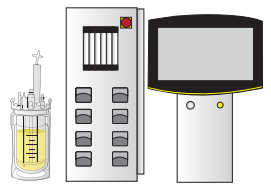
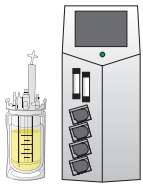
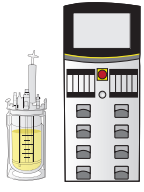


	Article number	Biostat® A (2014)	Biostat® Aplus
Univessel® Glass			
Univessel® Glass 1L, double wall (stand, reaction vessel, head plate)	UNIVESSEL-00001		
Univessel® Glass 1L, single wall (stand, reaction vessel, head plate)	UNIVESSEL-00005	■	■
Reaction vessel double wall	SB-18-14-0001		
Reaction vessel single wall	SB-18-14-0005	■	■
Head plate	SB-18-14-0009	■	■
Stand (incl. support bracket)	SB-18-14-0013	■	■
Silicone support ring Ø 140 mm	SB-18-14-0017	■	■
O-Ring for head plate	SB-80-01-0037	■	■
Stirrer shaft			
Stirrer shaft, single mechanical seal	SB-18-14-0022	■	■
Standard direct coupling	SB-18-14-0026	■	
Biostat® Aplus direct coupling	BB-39240983		■
Biostat® Qplus direct coupling	BB-8841221		
Standard magnetic coupling	SB-18-14-0031		
Mixing			
6-blade disc impeller	BB-8846359	■	■
3-blade segment impeller	BB-8846367	■	■
Baffle cage	BB-8846375	■	■
Aeration			
Ring sparger (bores downwards)	UNIVESSEL-00011	■	■
Ring sparger (bores upwards)	BB-8846383	■	■
Micro sparger	UNIVESSEL-00055	■	■
Aeration basket	BB-8846405	■	■
Biostat® B, B-DCU II, B-DCU (2016) exhaust cooler	UNIVESSEL-00025		
Biostat® Aplus, Bplus, Qplus exhaust cooler	BB-8846871		■
Biostat® A exhaust cooler	BB-8822009	■	
Flexible adapter for exhaust cooler	BB-8844593	■	■
Biostat® A exhaust for filter heater	BB-34164267	■	
Biostat® A filter heater for Univessel® Glass SU	BB-8822023	■	
Air inlet exhaust filter, Midisart® 2000 (12 pc.)	17805-----E	■	■
Air inlet exhaust filter Sartofluor® Capsule	5181307T5--OO--D	■	■
Filterkit (1 × Midisart® 2000 8" MNPT, 3 × Midisart® 2000 Hose Barb, 5 × Minisart® SRP15)	UNIVESSEL-KIT1	■	■

Univessel® Glass 1L



	Article number	Biostat® A (2014)	Biostat® Aplus
Dip tubes			
Dip tube; straight, height-adjustable, ID 4 mm	BB-8848637	■	■
Dip tube; straight, fixed, ID 4 mm	BB-8848629	■	■
Dip tube; straight, height-adjustable, ID 2 mm	UNIVESSEL-00015	■	■
Dip tube; bended, height-adjustable, ID 4 mm	BB-8848633	■	■
Dip tube; for ATF connection, straight, height-adjustable, ID 10 mm	UNIVESSEL-00036	■	■
Cooling fingers and tubing set for chiller			
Standard cooling finger	UNIVESSEL-00021		
Biostat® Aplus, Qplus cooling finger	BB-8846456		■
Biostat® A cooling finger	BB-8822024	■	
Tube connection set Biostat® A chiller	BB-8822027	■	
Foam disc			
Foam disc 74 10	BB-8844465	■	■
pH sensors			
Standard pH sensor, Hamilton EasyFerm Plus, 160 mm	BB-8848655		
Digital pH sensor, Hamilton EasyFerm Bio Arc, 160 mm	UZE---0001		
Standard pH sensor, Mettler, 150 mm	BB-8848691		
Biostat® A sensor package (pH and DO), E+H, 160 mm	BB-8822010	■	
Biostat® Aplus pH sensor, Hamilton, 160 mm	BB-34090811		■
Biostat® Aplus pH sensor, Mettler, 150 mm	BB-34099264		■
Biostat® Bplus pH sensor, Hamilton, 160 mm	BB-8837241		
Biostat® Qplus pH sensor, Hamilton, 160 mm	BB-8837239		
pH & Redox sensor, Hamilton EasyFerm Plus, 160 mm	BB-8844201		
pH & Redox sensor, Mettler, 150 mm	BB-8844211		
DO sensors			
Standard DO sensor, optical, Hamilton VisiFerm DO, 160 mm (Arc and analog)	BB-8848669		
Standard DO sensor, electrochemical, Hamilton OxyFerm DO, 160 mm	BB-8848662		
Standard DO sensor, electrochemical, Mettler, 150 mm	BB-8848675		
Biostat® A sensor package (pH and DO), E+H, 160 mm	BB-8822010	■	
Biostat® Aplus DO sensor, electrochemical, Hamilton, 160 mm	BB-34090821		■
Biostat® Bplus DO sensor, electrochemical, Hamilton, 160 mm	BB-8837231		
Biostat® Qplus DO sensor, electrochemical, Hamilton, 160 mm	BB-8837235		



Biostat® B

Biostat® Bplus

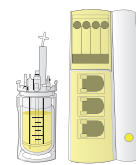
Biostat® B-DCU
(2016)

Biostat® B-DCU II

Biostat® Qplus

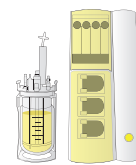
	Biostat® B	Biostat® Bplus	Biostat® B-DCU (2016)	Biostat® B-DCU II	Biostat® Qplus
	■	■	■	■	■
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Univessel® Glass 1L



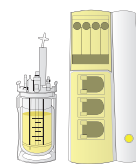
	Article number	Biostat® A (2014)	Biostat® Aplus
Turbidity sensors (connected to tower of bioreactor)			
BioPAT® Fundalux, Ø 12 mm, optical path length 1 mm	BPF1L01		
BioPAT® Fundalux, Ø 12 mm, optical path length 5 mm	BPF1L05		
BioPAT® Fundalux, Ø 12 mm, optical path length 10 mm	BPF1L10		
Trace probes (connected to BioPAT® Trace)			
BioPAT® Trace dialysis probe, 165 mm	BPT0015	■	■
BioPAT® Trace membranes for dialysis probes (Glc Lac) standard, 5 pc.	BPT0024	■	■
BioPAT® Trace membranes for dialysis probes (Glc Lac) cellulase stable, 5 pc.	BPT0040	■	■
BioPAT® Trace membranes for dialysis probe (EtOH MeOH), 5 pc.	BPT0047	■	■
Biomass sensors			
BioPAT® Viamass multiuse ABER sensor, 128 mm	BPVOM1L		
Temperature sensor			
Standard Pt100 with thermowell (pocket), 151 mm	BB-8848648		
Biostat® Aplus Pt100, 151 mm	BB-33197105		■
Biostat® Bplus, Qplus Pt100, 151 mm	BB-33197024		
Level and foam sensors			
Standard level sensor, 150 mm, clip (6 mm port)	BB-8844490	■	
Biostat® Aplus, Bplus, Qplus level sensor, 150 mm, incl. cable (6 mm port)	BB-8844488		■
Standard foam sensor, 80 mm, clip (6 mm port)	BB-8844463		
Pressure sensor 0.0 - 1.0 barg, autoclavable (M26×1)	BB-8804060		
Sensor cables			
DO sensor connection cable, VP8-VP8, 1 m	BB-8848685		
pH sensor connection cable, VP8-VP8, 1 m	BB-8848681		
pH DO Arc sensor cable, M12-VP8, 1 m	UZE---0005		
Level foam sensor connection cable, clip-M12, 1 m	BB-8848684	■	
Level foam sensor connection cable, clip-clip, 1 m	SB-38125129		■
Foam sensor connection cable, clip-M12, 1 m	BB-8848683		
Pressure sensor connection cable, M12-M12, 2 m	BB-34147287		

Univessel® Glass 1 L

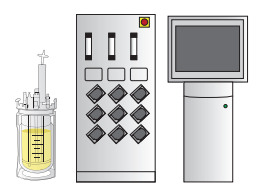
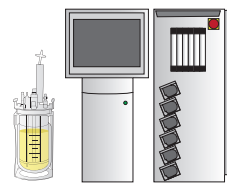
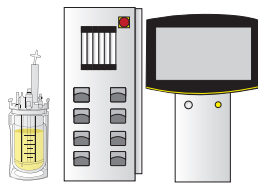
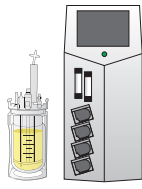
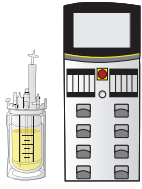


	Article number	Biostat® A (2014)	Biostat® Aplus
Heating blankets			
Standard heating blanket 120 230 V	BB-8842191		
Biostat® A Heating blanket, 48 VDC	BB-8822028	■	
Biostat® Aplus, Bplus heating blanket, 120 VAC	BB-8807501		■
Biostat® Aplus, Bplus heating blanket, 230 VAC	BB-8807502		■
Handling			
Reaction vessel fixation for cleaning	UNIVESSEL-00049	■	■
Tool and accessory kit	UNIVESSEL-00045	■	■
Bottle support for 250 mL bottles	UNIVESSEL-00019	■	■
Integrated handle bar	UNIVESSEL-00033	■	■
Handle for installation on the head plate	UNIVESSEL-00044	■	■
Impeller angle tool	UNIVESSEL-00059	■	■

Univessel® Glass 2 L



	Article number	Biostat® A (2014)	Biostat® Aplus
Univessel® Glass			
Univessel® Glass 2 L, double wall (stand, reaction vessel, head plate)	UNIVESSEL-00002		
Univessel® Glass 2 L, single wall (stand, reaction vessel, head plate)	UNIVESSEL-00006	■	■
Reaction vessel double wall	SB-18-14-0002		
Reaction vessel single wall	SB-18-14-0006	■	■
Univessel® Glass 2 L, single wall with extra PG 13.5 port, w/o accessories	UNIVESSEL-00065		
Univessel® Glass 2 L, double wall with extra PG 13.5 port, w/o accessories	UNIVESSEL-00066		
Kit Univessel® Glass w/ bottom drain 2 L single wall	UNIVESSEL-00077		
Kit Univessel® Glass w/ bottom drain 2 L double wall	UNIVESSEL-00080		
Head plate	SB-18-14-0010	■	■
Stand (incl. support bracket)	SB-18-14-0014	■	■
Silicone support ring Ø 160 mm	SB-18-14-0018	■	■
O-Ring for head plate	SB-80-01-0035	■	■
Stirrer shaft			
Stirrer shaft, single mechanical seal	SB-18-14-0023	■	■
Standard direct coupling	SB-18-14-0026	■	
Biostat® Aplus direct coupling	BB-39240983		■
Standard magnetic coupling	SB-18-14-0031		



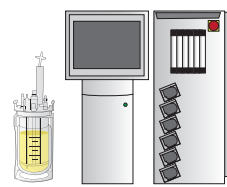
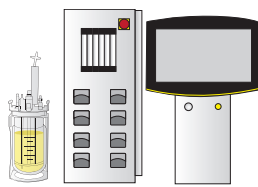
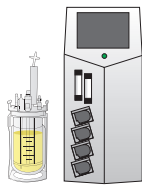
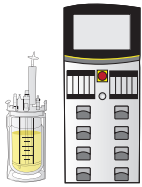
Biostat® B

Biostat® Bplus

Biostat® B-DCU
(2016)

Biostat® B-DCU II

Biostat® Qplus



Biostat® B

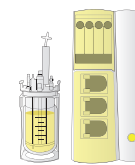
Biostat® Bplus

Biostat® B-DCU
(2016)

Biostat® B-DCU II

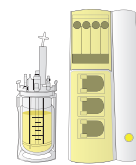


Univessel® Glass 2 L

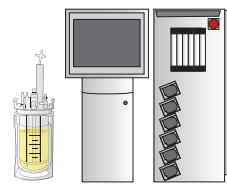
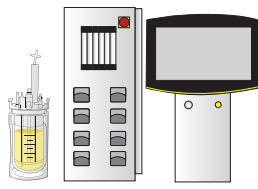
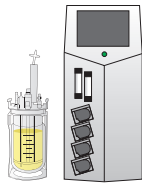
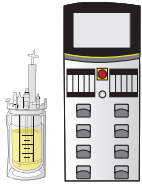


	Article number	Biostat® A (2014)	Biostat® Aplus
Mixing			
6-blade disc impeller	BB-8846804	■	■
3-blade segment impeller	BB-8847398	■	■
Baffle cage	BB-8846812	■	■
Aeration			
Ring sparger (bores downwards)	UNIVESSEL-00012	■	■
Ring sparger (bores upwards)	BB-8846847	■	■
Micro sparger	UNIVESSEL-00056	■	■
Aeration basket	BB-8848009	■	■
Biostat® B, B-DCU II, B-DCU (2016) exhaust cooler	UNIVESSEL-00025		
Biostat® Aplus, Bplus, Qplus exhaust cooler	BB-8846871		■
Biostat® A exhaust cooler	BB-8822009	■	
Flexible adapter for exhaust cooler	BB-8844593	■	■
Biostat® A exhaust line for filter heater	BB-34164267	■	
Biostat® A filter heater for Univessel® Glass SU	BB-8822023	■	
Air inlet exhaust filter, Midisart® 2000 (12 pc.)	17805-----E	■	■
Air inlet exhaust filter, Sartofluor® Capsule	5181307T5--OO--D	■	■
Filterkit (1 × Midisart® 2000 8" MNPT, 3 × Midisart® 2000 Hose Barb, 5 × Minisart® SRP15)	UNIVESSEL-KIT1	■	■
Spinfilter			
Spinfilter 10 µm	BB-8847447	■	■
Spinfilter 20 µm	BB-8808309	■	■
Spinfilter 75 µm	BB-8808325	■	■
Draft tube	BB-8840539	■	■
Dip tubes			
Dip tube; straight, height-adjustable, ID 4 mm	BB-8807884	■	■
Dip tube; straight, fixed, ID 4 mm	BB-8807850	■	■
Dip tube; straight, for spinfilter, ID 4 mm	BB-8808260	■	■
Dip tube; straight, height-adjustable, ID 2 mm	UNIVESSEL-00016	■	■
Dip tube; bended, height-adjustable, ID 4 mm	BB-8848634	■	■
Dip tube; for ATF connection, straight, height-adjustable, ID 10 mm	UNIVESSEL-00037	■	■
Cooling fingers and tubing set for chiller			
Standard cooling finger	UNIVESSEL-00022		
Biostat® Aplus cooling finger	BB-8847819		■
Biostat® A cooling finger	BB-8822025	■	
Tube connection set Biostat® A chiller	BB-8822027	■	

Univessel® Glass 2 L



	Article number	Biostat® A (2014)	Biostat® Aplus
Foam disc			
Foam disc 84 10	BB-8844466	■	■
pH sensors			
Standard pH sensor, Hamilton EasyFerm Plus, 225 mm	BB-8848656		
Standard pH sensor, Mettler, 220 mm	BB-8848692		
Digital pH sensor, Hamilton EasyFerm Bio Arc, 225 mm	UZE---0002		
Biostat® A sensor package (pH and DO), E+H, 225 mm	BB-8822011	■	
Biostat® Aplus pH sensor, Hamilton, 200 mm	BB-34090812		■
Biostat® Aplus pH sensor, Mettler, 200 mm	BB-33182582		■
Biostat® Bplus pH sensor, Hamilton, 200 mm	BB-8837242		
pH & Redox sensor, Hamilton EasyFerm Plus, 225 mm	BB-8844202		
pH & Redox sensor, Mettler, 220 mm	BB-8844212		
DO sensors			
Standard DO sensor, optical, Hamilton VisiFerm DO, 225 mm (Arc and analog)	BB-8848670		
Standard DO sensor, electrochemical, Hamilton OxyFerm DO, 225 mm	BB-8848663		
Standard DO sensor, electrochemical, Mettler, 220 mm	BB-8848676		
Biostat® A sensor package (pH and DO), E+H, 225 mm	BB-8822011	■	
Biostat® Aplus DO sensor, electrochemical, Hamilton, 215 mm	BB-34090822		■
Biostat® Bplus DO sensor, electrochemical, Hamilton, 215 mm	BB-8837232		
Turbidity sensors (connected to tower of bioreactor)			
BioPAT® Fundalux, Ø 12 mm, optical path length 1 mm	BPF2L01		
BioPAT® Fundalux, Ø 12 mm, optical path length 5 mm	BPF2L05		
BioPAT® Fundalux, Ø 12 mm, optical path length 10 mm	BPF2L10		
Trace probes (connected to BioPAT® Trace)			
BioPAT® Trace dialysis probe, 212 mm	BPT0016	■	■
BioPAT® Trace membranes for dialysis probes (Glc Lac) Standard, 5 pc.	BPT0024	■	■
BioPAT® Trace membranes for dialysis probes (Glc Lac) cellulase stable, 5 pc.	BPT0040	■	■
BioPAT® Trace membranes for dialysis probe (Eth Met), 5 pc.	BPT0047	■	■
Biomass sensors			
BioPAT® Viamass multiuse ABER sensor, 228 mm	BPV0M2L		



Biostat® B

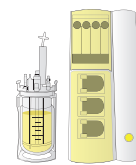
Biostat® Bplus

Biostat® B-DCU
(2016)

Biostat® B-DCU II

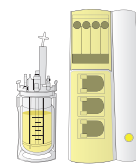
Biostat® B	Biostat® Bplus	Biostat® B-DCU (2016)	Biostat® B-DCU II
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Univessel® Glass 2 L



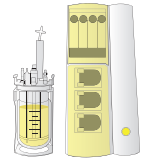
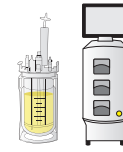
	Article number	Biostat® A (2014)	Biostat® Aplus
Temperature sensor			
Standard Pt100 with thermowell (pocket), 211 mm	BB-8848649		
Biostat® Aplus Pt100, 211 mm	BB-33197083		■
Biostat® Bplus Pt100, 211 mm	BB-33197032		
Level and foam sensors			
Standard level sensor, 150 mm, clip (6 mm port)	BB-8844490	■	
Standard foam sensor, 80 mm, clip (6 mm port)	BB-8844463		
Biostat® Aplus, Bplus foam sensor, 80 mm, incl. cable (6 mm port)	BB-8844461		■
Pressure sensor 0.0–1.0 barg, autoclavable (M26×1)	BB-8804060		
Sensor cables			
DO sensor connection cable, VP8-VP8, 1 m	BB-8848685		
pH sensor connection cable, VP8-VP8, 1 m	BB-8848681		
pH DO Arc sensor cable, M12-VP8, 1 m	UZE---0005		
Level foam sensor connection cable, clip-M12, 1 m	BB-8848684	■	
Level foam sensor connection cable, clip-clip, 1 m	SB-38125129		■
Foam sensor connection cable, clip-M12, 1 m	BB-8848683		
Pressure sensor connection cable, M12-M12, 2 m	BB-34147287		
Heating blankets			
Standard heating blanket 120 230 V	UNIVESSEL-00075		
Biostat® A heating blanket, 48 VDC	UNIVESSEL-00074	■	
Biostat® Aplus, Bplus heating blanket, 120 VAC	BB-8807541		■
Biostat® Aplus, Bplus heating blanket, 230 VAC	BB-8807542		■
Handling			
Reaction vessel fixation for cleaning	UNIVESSEL-00050	■	■
Tool and accessory kit	UNIVESSEL-00046	■	■
Bottle support for 250 mL bottles	UNIVESSEL-00019	■	■
Integrated handle bar	UNIVESSEL-00033	■	■
Handle for installation on the head plate	UNIVESSEL-00044	■	■
Impeller angle tool	UNIVESSEL-00060	■	■

Univessel® Glass 5 L



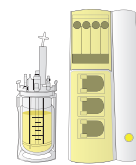
	Article number	Biostat® A (2014)	Biostat® Aplus
Univessel® Glass			
Univessel® Glass 5 L, double wall (stand, reaction vessel, head plate)	UNIVESSEL-00003		
Univessel® Glass 5 L, single wall (stand, reaction vessel, head plate)	UNIVESSEL-00007	■	■
Reaction vessel double wall	SB-18-14-0003		
Reaction vessel single wall	SB-18-14-0007	■	■
Kit Univessel® Glass w/ bottom drain 5 L single wall	UNIVESSEL-00078		
Kit Univessel® Glass w/ bottom drain 5 L double wall	UNIVESSEL-00081		
Head plate	SB-18-14-0011	■	■
Stand (incl. support bracket)	SB-18-14-0015	■	■
Silicone support ring Ø 200 mm	SB-18-14-0019	■	■
O-Ring for head plate	SB-80-01-0032	■	■
Stirrer shaft			
Stirrer shaft, single mechanical seal	SB-18-14-0024	■	■
Standard direct coupling	SB-18-14-0026	■	
Biostat® Aplus direct coupling	BB-39240983		■
Standard magnetic coupling	SB-18-14-0031		
Mixing			
6-blade disc impeller	BB-8847371	■	■
3-blade segment impeller	BB-8847401	■	■
Baffle cage	BB-8846820	■	■
Aeration			
Ring sparger (bores downwards)	UNIVESSEL-00013	■	■
Ring sparger (bores upwards)	BB-8846855	■	■
Micro sparger	UNIVESSEL-00057	■	■
Aeration basket	BB-8848017	■	■
Biostat® B, B-DCU II, B-DCU (2016) exhaust cooler	UNIVESSEL-00009		
Biostat® Aplus, Bplus exhaust cooler	BB-8846880		■
Biostat® A exhaust cooler	BB-8822009	■	
Flexible adapter for exhaust cooler	BB-8844593	■	■
Biostat® A exhaust line for filter heater	BB-34164267	■	
Biostat® A filter heater for Univessel® Glass SU	BB-8822023	■	
Air inlet exhaust filter, Midisart® 2000 (12 pc.)	17805-----E	■	■
Air inlet exhaust filter, Sartofluor® Capsule	5181307T5--OO--D	■	■
Filterkit (1 × Sartofluor® Capsule, 1 × Midisart® 2000 8" MNPT, 3 × Midisart® 2000 Hose Barb, 5 × Minisart® SRP15)	UNIVESSEL-KIT2	■	■

Univessel® Glass 5 L

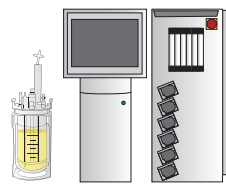
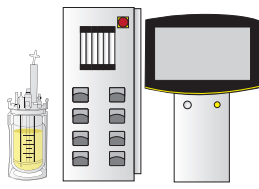
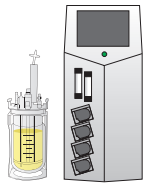
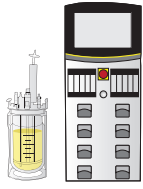


	Article number	Biostat® A (2014)	Biostat® Aplus
Spinfilter			
Spinfilter 10 µm	BB-8847448	■	■
Spinfilter 20 µm	BB-8847452	■	■
Spinfilter 75 µm	BB-8847487	■	■
Draft tube	BB-8840660	■	■
Dip tubes			
Dip tube; straight, height-adjustable, ID 4 mm	BB-8807892	■	■
Dip tube; straight, fixed, ID 4 mm	BB-8807868	■	■
Dip tube; straight, for spinfilter, ID 4 mm	BB-8808279	■	■
Dip tube; straight, height-adjustable, ID 2 mm	UNIVESSEL-00017	■	■
Dip tube; bended, height-adjustable, ID 4 mm	BB-8848635	■	■
Dip tube; for ATF connection, straight, height-adjustable, ID 12 mm	UNIVESSEL-00038	■	■
Cooling fingers and tubing set for chiller			
Standard cooling finger	UNIVESSEL-00023		
Biostat® Aplus cooling finger	BB-8847827		■
Biostat® A cooling finger	BB-8822026	■	
Tube Connection Set Biostat® A Chiller	BB-8822027	■	
Foam disc			
Foam disc 96 14	BB-8844467	■	■
pH sensors			
Standard pH sensor, Hamilton EasyFerm Plus, 325 mm	BB-8848657		
Standard pH sensor, Mettler, 325 mm	BB-8848693		
Digital pH sensor, Hamilton EasyFerm Bio Arc, 325 mm	UZE---0003		
Biostat® A sensor package (pH and DO), E+H, 325 mm	BB-8822012	■	
Biostat® Aplus pH sensor, Hamilton, 325 mm	BB-34090813		■
Biostat® Aplus pH sensor, Mettler, 325 mm	BB-33182574		■
Biostat® Bplus pH sensor, Hamilton, 325 mm	BB-8837243		
pH & Redox sensor, Hamilton EasyFerm Plus, 325 mm	BB-8844203		
pH & Redox sensor, Mettler, 325 mm	BB-8844213		

Univessel® Glass 5 L



	Article number	Biostat® A (2014)	Biostat® Aplus
DO sensors			
Standard DO sensor, optical, Hamilton VisiFerm DO, 325 mm (Arc and analog)	BB-8848671		
Standard DO sensor, electrochemical, Hamilton OxyFerm DO, 325 mm	BB-8848664		
Standard DO sensor, electrochemical, Mettler, 320 mm	BB-8848677		
Biostat® A sensor package (pH and DO), E+H, 325 mm	BB-8822012	■	
Biostat® Aplus DO sensor, electrochemical, Hamilton, 325 mm	BB-34090823		■
Biostat® Bplus DO sensor, electrochemical, Hamilton, 325 mm	BB-8837233		
Turbidity sensors (connected to tower of bioreactor)			
BioPAT® Fundalux, Ø 12 mm, optical path length 1 mm	BPF5L01		
BioPAT® Fundalux, Ø 12 mm, optical path length 5 mm	BPF5L05		
BioPAT® Fundalux, Ø 12 mm, optical path length 10 mm	BPF5L10		
Trace probes (connected to BioPAT® Trace)			
BioPAT® Trace dialysis probe, 332 mm	BPT0018	■	■
BioPAT® Trace membranes for dialysis probes (Glc Lac) Standard, 5 pc.	BPT0024	■	■
BioPAT® Trace membranes for dialysis probes (Glc Lac) cellulase stable, 5 pc.	BPT0040	■	■
BioPAT® Trace membranes for dialysis probe (Eth Met), 5 pc.	BPT0047	■	■
Biomass sensors			
BioPAT® Viamass multiuse ABER sensor, 325 mm	BPV0M5L		
Temperature sensor			
Standard Pt100 with thermowell (pocket), 316 mm	BB-8848650		
Biostat® Aplus Pt100, 316 mm	BB-33197091		■
Biostat® Bplus Pt100, 316 mm	BB-33197040		
Level and foam sensors			
Standard level sensor, 150 mm, clip (6 mm port)	BB-8844490	■	
Standard level sensor, 300 mm, clip (6 mm port)	BB-8844491		
Standard foam sensor, 80 mm, clip (6 mm port)	BB-8844463		
Biostat® Aplus, Bplus foam sensor, 80 mm, incl. cable (6 mm port)	BB-8844461		■
Pressure sensor 0.0 – 1.0 barg, autoclavable (M26×1)	BB-8804060		



Biostat® B

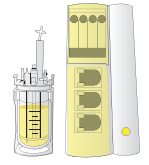
Biostat® Bplus

Biostat® B-DCU
(2016)

Biostat® B-DCU II

Biostat® B	Biostat® Bplus	Biostat® B-DCU (2016)	Biostat® B-DCU II
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Univessel® Glass 5 L



	Article number	Biostat® A (2014)	Biostat® Aplus
Sensor cables			
DO sensor connection cable, VP8-VP8, 1m	BB-8848685		
pH sensor connection cable, VP8-VP8, 1m	BB-8848681		
pH DO Arc sensor cable, M12-VP8, 1m	UZE---0005		
Level foam sensor connection cable, clip-M12, 1m	BB-8848684	■	
Level foam sensor connection cable, clip-clip, 1m	SB-38125129		■
Foam sensor connection cable, clip-M12, 1m	BB-8848683		
Pressure sensor connection cable, M12-M12, 2m	BB-34147287		
Heating blankets			
Standard heating blanket 120 230 V	BB-8842193		
Biostat® A heating blanket, 48 VDC	BB-8822030	■	
Biostat® Aplus, Bplus heating blanket, 120 VAC	BB-8807551		■
Biostat® Aplus, Bplus heating blanket, 230 VAC	BB-8807552		■
Handling			
Reaction vessel fixation for cleaning	UNIVESSEL-00051	■	■
Tool- and accessory kit	UNIVESSEL-00047	■	■
Bottle support for 500 mL bottles	UNIVESSEL-00020	■	■
Integrated handle bar	UNIVESSEL-00034	■	■
Handle for installation on the head plate	UNIVESSEL-00044	■	■
Impeller angle tool	UNIVESSEL-00061	■	■

Univessel® Glass 10 L

	Article number
Univessel® Glass	
Univessel® Glass 10 L, double wall (stand, reaction vessel, head plate)	UNIVESSEL-00004
Univessel® Glass 10 L, single wall (stand, reaction vessel, head plate)	UNIVESSEL-00008
Reaction vessel double wall	SB-18-14-0004
Reaction vessel single wall	SB-18-14-0008
Kit Univessel® Glass w/ bottom drain 10 L single wall	UNIVESSEL-00079
Kit Univessel® Glass w/ bottom drain 10 L double wall	UNIVESSEL-00082
Head plate	SB-18-14-0012
Stand (incl. support bracket)	SB-18-14-0016
Silicone support ring d 230 mm	SB-18-14-0020
O-Ring for head plate	SB-80-01-0030
Stirrer shaft	
Stirrer shaft, single mechanical seal	SB-18-14-0025
Standard direct coupling	SB-18-14-0026
Standard magnetic coupling	SB-18-14-0031
Mixing	
6-blade disc impeller	BB-8847380
3-blade segment impeller	BB-8847410
Baffle cage	UNIVESSEL-00010
Single baffle (old version)	BB-8846839
Aeration	
Ring sparger (bores downwards)	UNIVESSEL-00014
Ring sparger (bores upwards) with baffle	BB-8846863
Ring sparger (bores upwards)	BB-8807752
Micro sparger	UNIVESSEL-00058
Aeration basket	BB-8848025
Biostat® B, B-DCU II, B-DCU (2016) exhaust cooler	UNIVESSEL-00009
Biostat® Bplus exhaust cooler	BB-8846880
Flexible adapter for exhaust cooler	BB-8844593
Air inlet exhaust filter, Midisart® 2000 (12 pc.)	17805-----E
Air inlet exhaust filter, Sartofluor® Capsule	5181307T5--OO--D
Filterkit (1 × Sartofluor® Capsule, 1 × Midisart® 2000 8" MNPT, 3 × Midisart® 2000 Hose Barb, 5 × Minisart® SRP15)	UNIVESSEL-KIT2
Spinfilter	
Spinfilter 10 µm	BB-8847449
Spinfilter 20 µm	BB-8847991
Spinfilter 75 µm	BB-8847495
Draft tube	BB-8840580

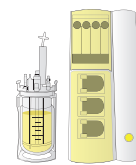
Univessel® Glass 10 L

	Article number
Dip tubes	
Dip tube; straight, height-adjustable, ID 4 mm	BB-8807906
Dip tube; straight, fixed, ID 4 mm	BB-8807876
Dip tube; straight, for spinfilter, ID 4 mm	BB-8840598
Dip tube; straight, height-adjustable, ID 2 mm	UNIVESSEL-00018
Dip tube; bended, height-adjustable, ID 4 mm	BB-8848636
Dip tube; for ATF connection, straight, height-adjustable, ID 12 mm	UNIVESSEL-00039
Cooling fingers	
Standard cooling finger	UNIVESSEL-00024
Foam disc	
Foam disc 96 16	BB-8844468
pH sensors	
Standard pH sensor, Hamilton EasyFerm Plus, 425 mm	BB-8848658
Standard pH sensor, Mettler, 425 mm	BB-8848694
Digital pH sensor, Hamilton EasyFerm Bio Arc, 425 mm	UZE---0004
Biostat® Bplus pH sensor, Hamilton, 425 mm	BB-8837244
pH & Redox sensor, Hamilton EasyFerm Plus, 425 mm	BB-8844204
pH & Redox sensor, Mettler, 425 mm	BB-8844214
DO sensors	
Standard DO sensor, optical, Hamilton VisiFerm DO, 425 mm (Arc and analog)	BB-8848672
Standard DO sensor, electrochemical, Hamilton OxyFerm DO, 425 mm	BB-8848665
Standard DO sensor, electrochemical, Mettler, 425 mm	BB-8848678
Biostat® Bplus DO sensor, electrochemical, Hamilton, 425 mm	BB-8837234
Turbidity sensors (connected to tower of bioreactor)	
BioPAT® Fundalux, Ø 12 mm, optical path length 1 mm	BPF5L01
BioPAT® Fundalux, Ø 12 mm, optical path length 5 mm	BPF5L05
BioPAT® Fundalux, Ø 12 mm, optical path length 10 mm	BPF5L10
Trace probes (connected to BioPAT® Trace)	
BioPAT® Trace dialysis probe, 432 mm	BPT0020
BioPAT® Trace membranes for dialysis probes (Glc Lac) Standard, 5 pc.	BPT0024
BioPAT® Trace membranes for dialysis probes (Glc Lac) cellulase stable, 5 pc.	BPT0040
BioPAT® Trace membranes for dialysis probe (Eth Met), 5 pc.	BPT0047

Univessel® Glass 10 L

	Article number
Biomass sensors	
BioPAT® Viamass multiuse ABER sensor, 425 mm	BPVOMXL
Temperature sensor	
Standard Pt100 with thermowell (pocket), 418 mm	BB-8848651
Biostat® Bplus Pt100, 418 mm	BB-33197059
Level and foam sensors	
Standard level sensor, 150 mm, clip (6 mm port)	BB-8844490
Standard level sensor, 300 mm, clip (6 mm port)	BB-8844491
Standard foam sensor, 80 mm, clip (6 mm port)	BB-8844463
Biostat® Bplus foam sensor, 80 mm, incl. cable (6 mm port)	BB-8844461
Pressure sensor 0.0 - 1.0 bar, autoclavable (M26×1)	BB-8804060
Sensor cables	
DO sensor connection cable, VP8-VP8, 1m	BB-8848685
pH sensor connection cable, VP8-VP8, 1m	BB-8848681
pH DO Arc sensor cable, M12-VP8, 1m	UZE---0005
Level foam sensor connection cable, clip-M12, 1m	BB-8848684
Level foam sensor connection cable, clip-clip, 1m	SB-38125129
Foam sensor connection cable, clip-M12, 1m	BB-8848683
Pressure sensor connection cable, M12-M12, 2 m	BB-34147287
Heating blankets	
Standard heating blanket 120 230 V	BB-8842194
Biostat® Bplus heating blanket, 120 VAC	BB-8807533
Biostat® Bplus heating blanket, 230 VAC	BB-8807534
Handling	
Reaction vessel fixation for cleaning	UNIVESSEL-00052
Tool and accessory kit	UNIVESSEL-00048
Bottle support for 500 mL bottles	UNIVESSEL-00020
Integrated handle bar	UNIVESSEL-00034
Handle for installation on the head plate	UNIVESSEL-00044
Impeller angle tool	UNIVESSEL-00062

General Accessories – Volume Independent




	Article number	Biostat® A (2014)	Biostat® Aplus
Sampling			
Single-use sampling solution with needle-free septum, 10 pc.	BNCHSSBF0003	■	■
Manual sampler	BB-8844623	■	■
Bypass sampler	BB-8844348	■	■
Port accessories			
Universal adapter 3.2 mm (6 mm port)	BB-8807809	■	■
4-way addition fitting, ID 0.8 mm (M26×1, 19 mm)	BB-8844313	■	■
4-way addition fitting, ID 2 mm (M26×1, 19 mm)	UNIVESSEL-00053	■	■
3-way addition fitting, ID 2 mm (PG 13.5, 12 mm)	BB-8841226	■	■
Inoculation port 6 mm (6 mm port)	BB-8844631	■	■
Inoculation port 19 mm (M26×1, 19 mm)	BB-8840601	■	■
1-channel inoculation kit (M26×1, 19 mm)	BB-8840610	■	■
Adapter M26×1 PG 13.5, standard (M26×1, 19 mm)	BB-8848630	■	■
Compression fitting for 12 mm sensors (PG 13.5, 12 mm)	UNIVESSEL-00054	■	■
Compression fitting for 12 mm sensors (M26×1, 19 mm)	BB-8891281	■	■
Burst protection complete, incl. 2 burst discs, 1 bar (M26×1, 19 mm)	UNIVESSEL-00026	■	■
Spare burst disc, 1 bar	SB-18-14-0000	■	■
Adapter M26×1 PG 13.5 - only for burst protection! (M26×1, 19 mm)	UNIVESSEL-00027	■	■
Blind plug 6 mm	BB-8807957	■	■
Blind plug PG 13.5, 12 mm	BB-8807949	■	■
Blind plug M26×1, 19 mm	BB-8807930	■	■
Miscellaneous			
Knurled head screw	SB-18-14-0021	■	■
Warning signs	SB-18-14-0027	■	■
Rubber bench pad	SB-18-14-0032	■	■
Buffer solution pH 9, 250 mL bottle	SB-34090366	■	■
Buffer solution pH 4, 250 mL bottle	SB-34090367	■	■
Buffer solution pH 7, 250 mL bottle	SB-34090368	■	■
Storage bottle 250 mL	BB-8823600	■	■
Storage bottle 500 mL	BB-8823618	■	■
Storage bottle 1 L	BB-8823675	■	■
Biostat® B motor adaptor Applikon vessel 1-7 L	UNIVESSEL-00063		
Biostat® B-DCU II, B-DCU (2016) motor adaptor Applikon vessel 1-7 L	BB-8890358		
Torque wrench for knurled head screw	UNIVESSEL-00064	■	■

Germany

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 For further contacts, visit
www.sartorius.com



Biostat[®] B

The Multi-Talented
Bioreactor for Research
and Development

Simplifying Progress

SARTORIUS

Biostat® B at a Glance

Our Biostat® B is the ideal benchtop bioreactor for your lab. The multi-talented control tower opens up a new world of flexibility for your changing requirements. Use it as single or twin configuration, choose your cultivation chamber from our proven range of options (pictures below):

- Conventional stirred-tank Univessel® Glass
- Single-use stirred-tank Univessel® SU
- Wave-mixed RM Rocker with Flexsafe® RM bags



Univessel® Glass



Univessel® SU



RM Rocker

Proven Technology

With several thousand installations in over 50 countries, Biostat® B is the most successful benchtop bioreactor in the world. Benefit from our experience and collaboration with customers worldwide.

Configurable Design

Contact your Sartorius representative and configure your Biostat® B bioreactor solution matching your specific needs. Benefit from our flexible and scalable options.

Reliable Quality

Every Biostat® B is thoroughly tested before it leaves our production facilities in Germany. Benefit from our global service and application specialist network for professional installation and training.



Applications

- Process development, optimization and characterization
- Scale-up and scale-down studies
- Seed expansion and small scale production
- Cell bank production
- Protein supply
- Stem cell expansion and production (RM rocker)

Cells

- Mammalian
- Insect
- Microbial
- Yeast
- Fungi
- Plant

Industries

- Biopharmaceuticals
- Vaccines
- Cell therapies
- Industrial biotechnology
- Basic research
- Education

Process Modes

- Batch
- Fed-batch
- Continuous
- Perfusion

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

Biostat® B – The Universal



Univessel® Glass

Our proven autoclavable borosilicate glass culture vessel is available in four different volumes: 1 L, 2 L, 5 L and 10 L for all kinds of cell culture and microbial applications.

Fully interchangeable glass and single-use stirred-tank culture vessels.

Univessel® SU

Our single-use 2 L stirred-tank vessel for cell culture applications combines scalable design with all the benefits of disposable solutions. No more worries about challenging timelines, workload or cross-contamination. Get started within minutes.



Benefits

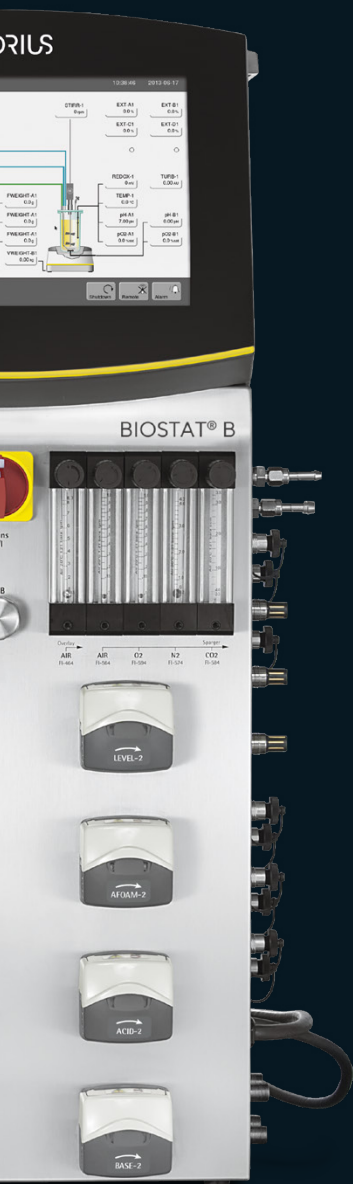
- Classic stirred-tank design simplifies your scale-up and scale-down studies
- Extensive performance and engineering data package available
- Save additional investment and use our special design for small autoclaves

Benefits

- Fully single-use vessel, DO and pH sensors
- Proven, scalable stirred-tank design
- Connection kit to upgrade existing bioreactor controllers



Controller for Your Lab



Benefits

- Easy-to-use rocker with advanced alarms and safety features for reliable cultivation
- Space-saving, individual control of two RM bags on the same rocker platform
- Inline viable biomass measurement for reduced sampling need and contamination risk



RM Rocker

Our proven wave-mixed bioreactor consists of a rocker unit with bag holder and pillow-shaped Flexsafe® RM single-use bags for culture volumes from 100 mL to 25 L. Use it as basic system or in combination with the Biostat® B control tower and single-use optical pH and DO sensors to enable advanced control strategies for batch, fed-batch and continuous perfusion.

New Flexsafe® Bag Family

Cell Growth

Excellent & reproducible growth behavior.

Assurance of Supply

Guaranteed consistent quality & continuous supply.

Robustness

Superior strength & flexibility of material.

One for All

No matter what size or process step.

 **Watch Video:**
www.sartorius.com/sartorius/en/EUR/flexsafe

Biostat® B – Configurable Flexibility

Designed to meet your specific needs, Biostat® B covers a wide range of applications, extending from use as a flexible basic unit for preclinical research to a fully qualified system that complies with the requirements of a validated GMP environment.

12" Touch Screen

with closed frame; protected against water splashes and dust deposits. Easy-to-use and reliable operation of your Biostat® B due to intuitive design of human-machineinterface and advanced touch-screen technology – even while wearing laboratory gloves.

Control Tower

The control tower contains both the aeration, pump and temperature control modules, saving valuable bench space in your lab.

New Standards for Interference-Free Measurements

All inlets and ports for, e.g. cooling water, process gasses, electricity, ethernet and potential-free alarm contact are located on the rear panel of the control tower. An equipotential bonding conductor shields the bioreactor against electromagnetic current and ensures interference-free measurements during your processes.



Single | Twin Control Tower

One Biostat® B control tower can control up to two vessels completely independently to save valuable lab space.



Storage Tray

A storage tray for accessories helps you organize your workplace.

Connections for Sensors and External Accessories

Quick-connect couplings make it easy to attach all cables and supplies to the culture vessels. All connections are clearly marked with the same names used on the rear control tower panel and in the local control software menu for fast, error proof identification.

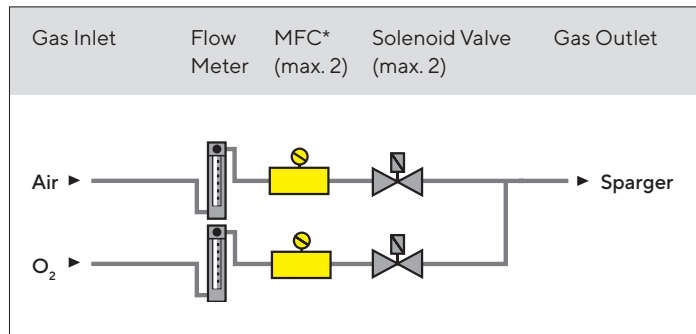
Fast Load Peristaltic Pumps

Insert the tubing in seconds: Open, insert tube, close, done! No more pinched fingers or torn gloves. Up to four internal pumps can be selected per vessel. Choose between speed-controlled pumps and fixed-speed pumps for feed and corrective agent addition.

Aeration Strategies

A series of flexible aeration options turns the Biostat® B into a multi-talented bioreactor for a wide range of different applications, including high-cell density microbial fermentation requiring considerable amounts of oxygen to high-cell density cell culture applications requiring removal of excess carbon dioxide.

Microbial Applications in Combination with Univessel® Glas

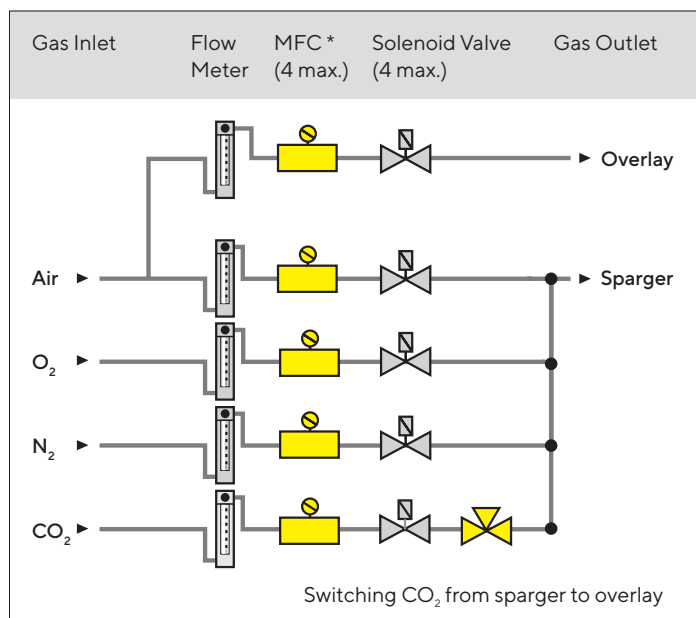


*MFC = mass flow controller

Various controller and hardware configurations enable aeration strategies using air or oxygen or classical O₂ enrichment of air. For anaerobic processes, the air inlet can be used for nitrogen. The standard built-in solenoid valves in combination with a flow meter ensure reliable gas supply for simple applications. Optional mass flow controllers provide exact flow rate control of individual gases.

In combination with BioPAT® Xgas off-gas analysis, this allows mass balancing of consumed and produced gases.

Cell Culture and Multi-Purpose Applications in Combination with Univessel® Glass and Univessel® SU

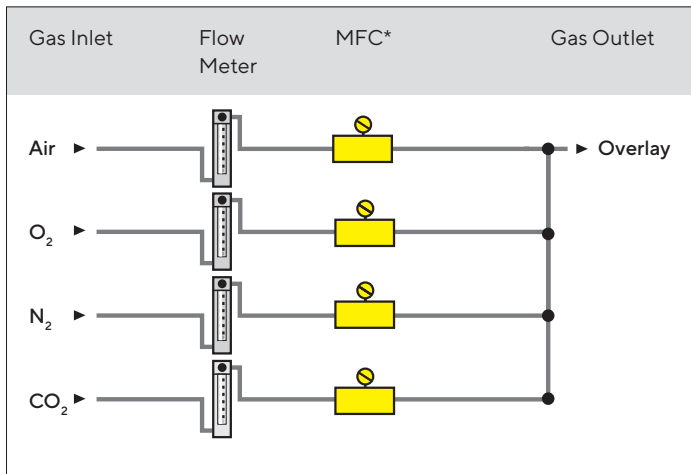


Five different gas lines (with flow meters) are equipped with solenoid valves and | or up to four optional mass flow controllers deliver ultimate flexibility and accuracy.

The Biostat® B allows you to optionally switch between sparger and overlay supply of CO₂ for pH control. In addition, a constant air | CO₂ mixture can be created in the overlay line to reproduce conditions set in a CO₂ incubator.

*MFC = mass flow controller

Cell Culture Applications in Combination with Our Rocking-Motion Bioreactor



The wave generated in the RM bags due to the rocking motion ensures effective gas exchange through the gas-liquid interface. Four different gas lines for air, O₂, N₂ and CO₂ are equipped with flow meters and four high-precision mass flow controllers. An integrated pressure sensor continuously measures the pressure inside the bag. To ensure process safety, aeration is switched off when an upper threshold is reached.

*MFC = mass flow controller

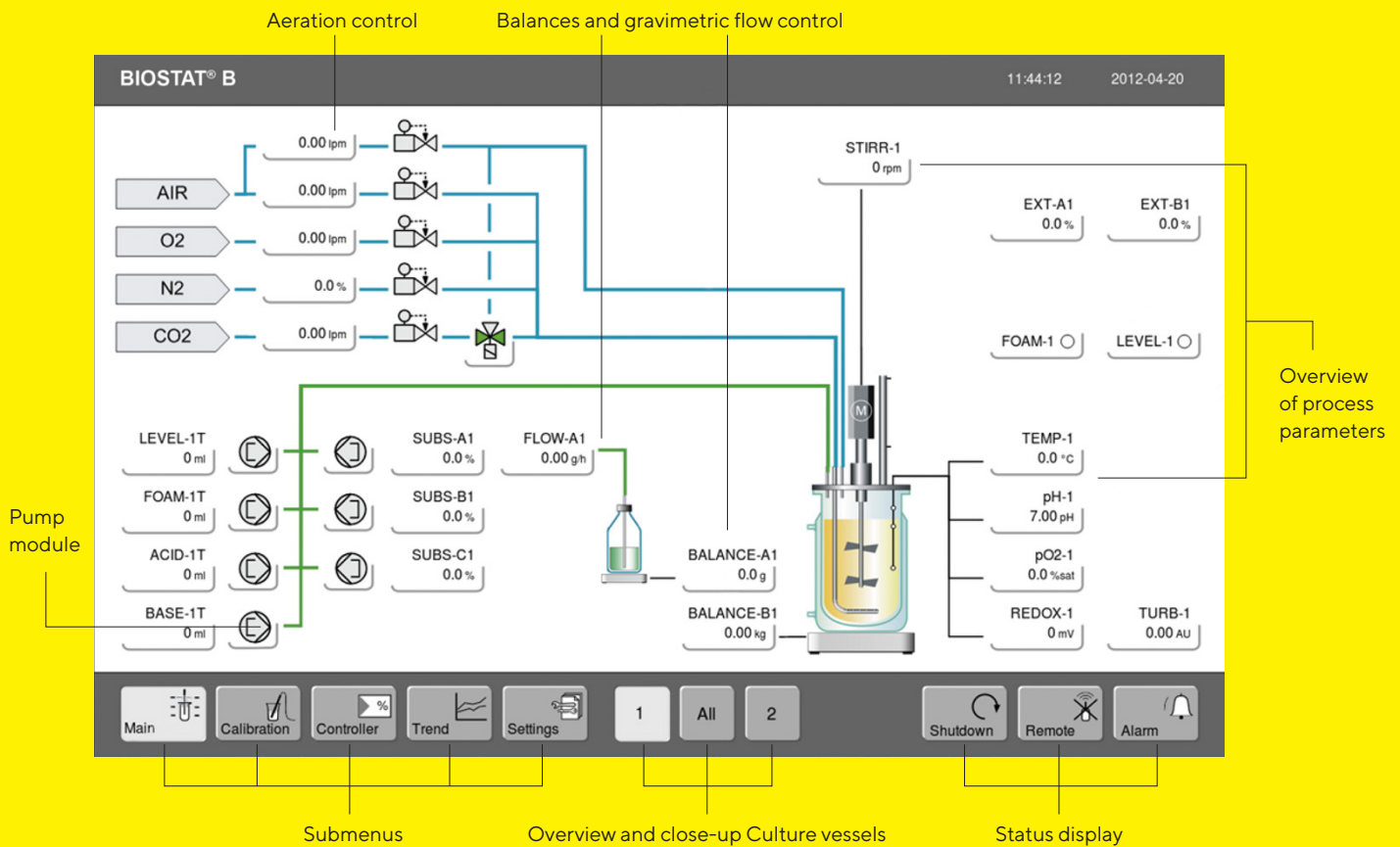


You can configure your Biostat® B aeration system in a similar way to your Biostat STR® single-use stirred tank bioreactor. Get ready for seamless scale-up and -down, from laboratory scale to large scale single-use production.

BioPAT[®] DCU – Local Control

Since we introduced the first DCU-controlled bioreactors back in the late 80's, we have installed thousands of such bioreactors to date at leading companies in the pharmaceutical and biotech industry worldwide. We have continuously improved our robust, intuitive-use and industry-proven DCU control technology, now available in its fourth generation. It is our standard local control platform for our Biostat[®] bioreactors, Sartoflow[®] crossflow filtration units and Flexact[®] configurable systems available for a large number of unit operations.

The intuitive touch screen on the control tower is used to locally operate the Biostat[®] B:



Automatic Feed Control and Continuous Processing

Design your process strategy or select different options. Configure your Biostat® B with gravimetric feed control, gravimetric level control or substrate addition profiles. This enables you to run your Biostat® B in batch, fed-batch, continuous or perfusion mode.

Automatic pH Control

Control the pH of your culture by automatic acid and base addition or by CO₂ aeration and base addition. If you want to use your Biostat® B for both microbial and cell culture you can configure your bioreactor system with the option of either CO₂ aeration or acid addition for pH (acid) control.

Automatic DO Control

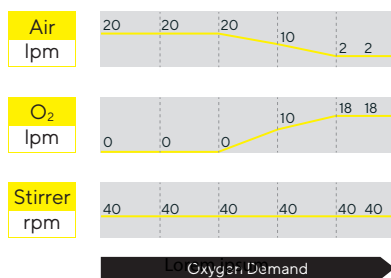
Besides classic DO cascade control, we have developed the unique advanced DO controller that gives you more flexibility to develop and optimize your DO control strategy.

The advanced DO controller supports parallel adjustment of all DO affecting parameter settings like stirrer speed and gas flow rates of air and pure oxygen, automatically and

simultaneously to control the DO set point. Optionally, you can keep the total gas flow rate constant and the ratio of pure oxygen in the gas mixture is increased automatically to match the oxygen consumption of the culture.

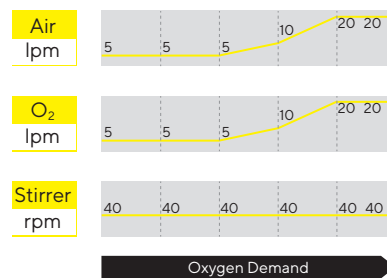
This gives you ultimate flexibility to adapt your aeration strategy to your process requirements.

Constant Gas Flow



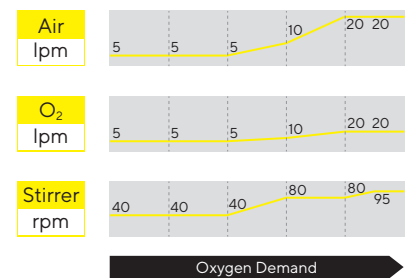
Constant gas flow decreases the flow of air and simultaneously increases oxygen flow keeping the total gas flow constant.

Constant Gas Ratio



Constant gas ratio, increases both air and oxygen flows at the same rate keeping the ratio constant

Bubble Size Optimization



Bubble size optimization enables fine tuning of the oxygen percentage and gas-liquid interface area

BioPAT® MFCS – The Bioprocess SCADA System

BioPAT® MFCS is our SCADA software for supervisory bioprocess control and data acquisition to ensure process reliability, when used in combination with the advanced Biostat® B Control Tower for local process control. It is ideal for efficient data acquisition and trend monitoring.

The optional advanced version; BioPAT® MFCS win includes modules such as:

- Multi-user network access for up to 16 process units
- Automation with recipes according to ANSI | ISA 88.01
- 21 CFR, Part 11 compatibility



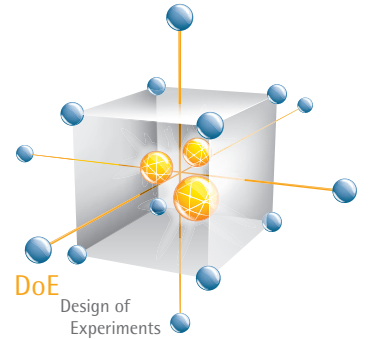
Learn more about the new BioPAT® MFCS:
www.sartorius.com/sartorius/en/EUR/biopat-mfcs

BioPAT[®] MODDE for Increased Process Understanding

BioPAT[®] MODDE is a state-of-the-art DoE software package which helps to understand complex processes and products.

The BioPAT[®] MFCS/win DoE module delivers a simple introduction into Design of Experiments, supported by a user-friendly design wizard providing step by step guidance for the experimental design and interpretation of results.

Automatic transfer of the experimental design parameters into an existing recipe allows for reliable and seamless integration into existing control strategies.



Maximized Process Security

To keep your biopharmaceutical process robust and reliable, we provide a comprehensive range of services to ensure the highest reliability and uptime of your Biostat® B, regulatory compliance and best quality of results.

From installation and qualification to regular preventative maintenance: Our service team will be happy to assist you on site and will be with you quickly thanks to our worldwide service network.



Installation & Commissioning

Safe and proper operation of your equipment right from the start



Qualification (IQ|QQ)

Compliance with GMP requirements, easy integration into your quality management system



Operator Training

Quality through greater experience: Sartorius trains the personnel operating your equipment

Installation Phase

Utilization Phase



Repairs & Spare Parts

In the event of service requests, we are quickly at your side with the necessary spare parts – worldwide



Maintenance & Contracts

Optimal equipment operation and protection against potential downtimes



Calibration

Accurate results in the long term and compliance with regulatory requirements



Service Contracts for the Entire System Lifecycle

With our Bioprocess Service Program, Sartorius offers service contracts to protect your equipment through its entire lifetime. Based on your specific risk assessment and requirements, you can choose between three Service Level Agreements: Essential, Advanced and Comprehensive. Protect your Biostat® B by choosing the appropriate service contract. For maximum productivity and minimum downtimes.

Essential

You benefit from:

- A plannable annual maintenance
- A fast support at the technical helpdesk within one business day and priority on-site-response
- In case of repair: A discount on all time and material based cost elements

Advanced

You benefit from:

- A plannable annual maintenance
- Technical helpdesk reaction time within 8 hours and 72 hours on-site response
- In case of repair: Labor and travel costs are covered, a discount of 10% on spare parts



















Comprehensive


You benefit from:

- A plannable annual maintenance
- Technical helpdesk reaction time within 4 hours and 48 hours on-site response
- In case of repair: All costs are covered

Your Benefits

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

	Essential	Advanced	Comprehensive
Reaction time			
Repair	 	 	 
	 	 	 
Maintenance			

 For further details and the dedicated datasheets, please have a look at our website: www.sartorius.com/service

Technical Specifications

Biostat® B

Control Tower Weight

Single | Twin ~ 40 | 55 kg (88 | 121 lbs.)

Control Tower Dimensions (W × H × D)

Single | Twin 350 × 822 × 430 mm (14" × 32" × 17")

Utility Connections

Power supply

- 230 V (± 10%), 50 Hz, max. power consumption 10 A
- 120 V (± 10%), 60 Hz, max. power consumption 12 A
- Potential equalisation

International protection rating IP21

Gases

- Gas supply pressure, 1.5 barg
- Dry, oil and dust-free
- Hose barb for tubing, external diameter = 6 mm

Water

- Water supply pressure, 2–4 barg
- Flow rate up to 20 lpm
- Temperature min. = 4°C
- Discharge pressure-less
- Hose barb for tubing, external diameter = 10 mm
- Degree of hardness: max. 12° dH

Control Tower

Housing Stainless steel, AISI 304

Display Touch screen, 12", glass, capacitive

Resolution 125 dpi

SCADA communication Industrial Ethernet

Potential-free (common) alarm contact

-

Safety valve gas pressure 1 bar (14.5 psi) for Univessel® Glass and SU | 100 mbar for RM Rocker

Water inlet pressure reduction 1.5 bar (22 psi), integrated pressure control

Motor Drive (Univessel® Glass | SU)

Maintenance-free, quiet direct drive Power: 200 W

Maintenance-free top drive with magnetic motor coupling Power: 200 W

Rotation speed motor, direct coupling

- 1L: 20–2,000 rpm
- 2L: 20–2,000 rpm
- 5L: 20–1,500 rpm
- 10L: 20–800 rpm
- 2L SU: 20–400 rpm

RM Rocker 20 | 50

Power supply	<ul style="list-style-type: none"> ▪ 240 V (± 10%), 50 Hz, power consumption 10 A ▪ 100 V (± 10%), 60 Hz, power consumption 12 A
Power consumption	600 W
International protection rating	IP23
Rocking speed	8–42 ± 1 (r/min)
Rocking angle	4–10 ± 0.3 (°)
Load cells	100–240 V 15 W

Process Control | Sensors

	Sensor Measurement Range Display Accuracy	Univessel® Glass	Univessel® SU	RM Rocker 20 50
Temperature	Pt100 0–150°C (temperature control 0–80°C) 0.1°C	▪	▪	▪
Dissolved oxygen, reusable	Polarographic or optical 0–100% 0.1%	▪	▪	
Dissolved oxygen, single-use	0–100% 0.1%		▪	▪
pH, reusable	Combined measuring electrode 2–12 pH 0.01 pH	▪	▪	
pH, single-use	6.5–8.5 pH 0.1 pH		▪	▪
Foam control	Electrical conductive sensor, stainless steel, ceramic insulated	▪		
Level	Electrical conductive sensor, stainless steel, ceramic insulated	▪		
Turbidity	1-channel NIR absorption sensor 0–6 AU 0.01 AU	▪		
Redox	Combined measurement with pH sensor –1,000–1,000 mV 1 mV	▪	▪	
Balance substrate	7 kg max. 1 g 60 kg max. 10 g 300 kg max. 100 g	▪	▪	▪
Gravimetric Flow Controller	Accuracy for 7 kg balance: 5 g/h Accuracy for 60 kg balance: 50 g/h Accuracy for 300 kg balance: 500 g/h	▪	▪	▪
Balance culture vessel	60 kg max. 10 g	▪	▪	
RM load cells	30 kg max. 10 g Weight: 9 kg Dimensions: 609 536 60–68 mm			▪
External signal input	0–10 V or 4–20 mA Univessel® Glass SU: 4 max. RM Rocker: 2 max.	▪	▪	▪

Aeration Module

Outlet to culture vessel bag	Hose coupling Ø external = 6 mm
Univessel® Glass MO (Microbial)	Two-gas mixing with sparger outlet
Air with O ₂ Enrichment or Gas Flow Ratio mixing along with anaerobic fermentation; for further information, please see page on “Aeration Strategies”	
Max. total flow	Up to 20 L/min total volume flow
Flow meters	2
▪ Flow Range	Various models available: 0.1 – 20 liters per min. [lpm] (sparger)
▪ Accuracy	± 5% full scale
Mass flow controllers (optional)	2 max.
▪ Flow rate	Various models available: 0.03 – 20 lpm (sparger)
▪ Accuracy	± 1% full scale
Univessel® Glass CC (Cell Culture) Univessel® SU	Four-gas mixing with sparger and headspace outlet
Additive flow, 4-gas (Air, O ₂ , N ₂ , CO ₂) mixture; for further information, please see page on “Aeration Strategies”	
Max. total flow	Up to 13 L/min total volume flow
Flow meters	5
▪ Flow Range	Various models available: 3.3 ccm – 1.6 lpm (sparger) 0.16 lpm – 13 lpm (headspace)
▪ Accuracy	± 5% full scale
Mass flow controllers (optional)	4 max.
▪ Flow rate	Various models available: 1 ccm – 1.5 lpm (sparger) 0.03 lpm – 10 lpm (headspace)
▪ Accuracy	± 1% full scale
Univessel® Glass, Dual Use	Four-gas mixing with sparger and headspace outlet
Additive flow, 4-gas (Air, O ₂ , N ₂ , CO ₂) mixture; for further information, please see page on “Aeration Strategies”	
Max. total flow	Up to 20 L/min total volume flow
Flow meters	5
▪ Flow Range	Various models available: 3.3 ccm – 20 lpm (sparger) 50 ccm – 20 lpm (headspace)
▪ Accuracy	± 5% full scale
Mass flow controllers (optional)	4 max.
▪ Flow rate	Various models available: 0.6 ccm – 20 lpm (sparger) 10 ccm – 20 lpm (headspace)
▪ Accuracy	± 1% full scale

RM Rocker 20 50	Four-gas mixing with sparger and headspace outlet
Additive flow, 4-gas (Air, O ₂ , N ₂ , CO ₂) mixture; for further information, please see page on "Aeration Strategies"	
Flow meters	4
▪ Flow Range	Various models available: 16 ccm – 7 lpm (headspace)
▪ Accuracy	± 5% full scale
Mass flow controllers (optional)	4 max.
▪ Flow rate	Various models available: 3 ccm – 5 lpm (headspace)
▪ Accuracy	± 1% full scale

Pump Module

Built-in Pumps	
Fixed speed (on off controlled)	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 – 0.2 ml/min ID: 1.6 mm: 0.01 – 0.7 ml/min ID: 2.4 mm: 0.03 – 1.5 ml/min ID: 3.2 mm: 0.05 – 2.4 ml/min ID: 4.8 mm: 0.09 – 4.3 ml/min
▪ Speed 44 rpm Flow rate (tubing wall thickness 1.6 mm)	ID: 0.5 mm: 0.02 – 0.9 ml/min ID: 0.8 mm: 0.04 – 1.8 ml/min ID: 1.6 mm: 0.12 – 6.2 ml/min ID: 2.4 mm: 0.26 – 12.8 ml/min ID: 3.2 mm: 0.41 – 20.7 ml/min ID: 4.8 mm: 0.75 – 37.4 ml/min
Speed-controlled	Watson Marlow 114, Fast Load pump head
▪ Speed 0.15 – 5 rpm Flow rate (tubing wall thickness 1.6 mm)	ID: 0.5 mm: 0 – 0.1 ml/min ID: 0.8 mm: 0.01 – 0.2 ml/min ID: 1.6 mm: 0.02 – 0.7 ml/min ID: 2.4 mm: 0.04 – 1.5 ml/min ID: 3.2 mm: 0.07 – 2.4 ml/min ID: 4.8 mm: 0.13 – 4.3 ml/min
▪ Speed 5 – 150 rpm Flow rate (tubing wall thickness 1.6 mm)	ID: 0.5 mm: 0.1 – 3 ml/min ID: 0.8 mm: 0.2 – 6 ml/min ID: 1.6 mm: 0.7 – 21 ml/min ID: 2.4 mm: 1.45 – 43.5 ml/min ID: 3.2 mm: 2.35 – 70.5 ml/min ID: 4.8 mm: 4.25 – 127.5 ml/min
External Pumps	
Speed-controlled	Watson Marlow 120, Fast Load pump head, up to 200 rpm

Temperature Control Module

	Heating and Cooling	Heating Only
For Univessel® Glass Single-wall Culture Vessels	Electrical heating system and automatic cooling water valve; connection to heating blanket and cooling finger	-
	Temperature control of 8°C above cooling-water inlet temperature up to 60°C	-
	Heating blanket capacities 1 L 2 L 5 L 10 L: 100 170 400 780 W	-
For Univessel® Glass Double-wall (Jacketed) Culture Vessels	Open thermostat system with recirculation pump and automatic cooling water valve	-
	Temperature control of 8°C above cooling-water inlet temperature of up to 80°C	-
	Heating capacity: 600 W	-
For Univessel® SU Single-use Culture Vessels	Open thermostat system with recirculation pump and automatic cooling water valve; connection to heating cooling jacket	Electrical heating blanket
	Temperature control up to 50°C	Temperature control up to 50°C Heating capacity 2 L: 200 W
For RM Rocker 20 50	Open thermostat system with recirculation pump and automatic cooling water valve	Electrical heating plates
	Temperature control of 8°C above cooling-water inlet temperature of up to 40°C	Temperature control from room temperature up to 40°C
	Heating capacity: 600 W	Heating plates: 2 × 140 W

Culture Vessel Univessel® Glass

Autoclavable Single-wall or Double-wall (Jacketed) Glass Vessel	1 L	2 L	5 L	10 L
Material	Borosilicate glass, stainless steel AISI 316L, EPDM			
Sizes [L]	1	2	5	10
Total volume [L]	1.6	3	6.6	13
Working volume [L]	0.35–1	0.6–2	0.6–5	1.5 5–10
Top port 19 mm 12 mm 6 mm	3 2 6	3 2 9	3 3 8	5 2 9
Univessel® Glass, Single-wall	1 L	2 L	5 L	10 L
Weight ¹ [kg]	4.4	5.9	10.5	14.9
Space requirements in autoclave [diameter × height mm]	200 × 446	220 × 507	270 × 645	310 × 767
Space requirements in autoclave, reduced ² [diameter × height mm]	450 × 330	490 × 391	570 × 496	600 × 618
Univessel® Glass, Double-wall	1 L	2 L	5 L	10 L
Weight ¹ [kg]	5.3	6.9	12.6	18.5
Space requirements in autoclave [diameter × height mm]	320 × 446	335 × 507	395 × 645	435 × 767
Space requirements in autoclave, reduced ² [diameter × height mm]	450 × 330	490 × 391	570 × 496	600 × 618

¹ With tripod and head plate, without medium

² Adapter for exhaust cooler to reduce height in the autoclave optionally available

Culture Vessel Univessel® SU

Single-use vessel made of pre-sterilized polycarbonate for cell culture applications

Total volume [L]	2.6
Working volume [L]	0.6–2
Max. temperature	50°C
Operating pressure	< 0.5 barg

Basic Configurations for Univessel® Glass

The Biostat® B is a highly flexible and modular system that can be individually adapted to the requirements of your application. Below you will find an overview of the basic equipment which you can extend with diverse options.

Please contact your Sartorius Stedim Field Representative or Application Specialist for additional information.

Microbial Packages

Volume: 1 L, 2 L, 5 L or 10 L

Digital controller, color display with touch screen

Control temperature, pH, DO, stirrer speed

Maintenance-free, quiet motor

Storage tray for accessories

Aeration module with 2 solenoid valves

2 flow rate controllers for manual flow rate control
(Air | N₂, O₂)

Software configured for microbial applications

4-stage DO cascade

2 integrated pumps for pH control (acid | base)

Temperature control module for double-wall vessels

2 external signals 0–10 V

Standard test and documentation

Installation set for the gas and water connections

Power cable

Double-wall culture vessel

Stirrer shaft with single-mechanical seal and direct coupling

2 addition bottles for correction agents

Exhaust cooler

Aeration filters

Rushton impellers

Ring sparger

4-way addition port

Inoculation port

Harvest pipe, height-adjustable

Manual sampler

Tool set for disassembly of vessel

Pt100 temperature sensor

pH sensor

DO sensor, amperometric

Cell Culture Packages

Volume: 1 L, 2 L, 5 L or 10 L

Digital controller, color display with touch screen

Control temperature, pH, DO, stirrer speed

Maintenance-free, quiet motor

Storage tray for accessories

Aeration module with 4 solenoid valves

5 flow rate controllers for manual flow rate control
(Air Overlay, Air sparger, N₂, O₂, CO₂)

Software configured for cell culture applications

4-stage DO cascade

1 integrated pump for pH control (base)

Temperature control module for single-wall vessels

2 external signals 0–10 V

Standard test and documentation

Installation set for the gas and water connections

Power cable

Single-wall culture vessel

Heating blanket 120 | 230 V

Stirrer shaft with single mechanical seal and direct coupling

1 addition bottle for correction agent

Exhaust cooler

Aeration filters

3-blade segment impeller

Microsparger

4-way addition port

Harvest pipe, height-adjustable

Manual sampler

Tool set for vessel dismantling

Pt100 temperature sensor

pH sensor

DO sensor, amperometric

Options

Control System

Advanced DO controller

Flexible switching CO₂ from sparger to headspace

Software for dual use MO | CC

Mass flow controller

Antifoam control via sensor

Mechanical foam destroyer (MO applications)

Level control via sensor

Weight measurement substrates | culture vessel

Gravimetric feed | level control

Substrate addition via time profile

Redox (ORP) measurement

BioPAT® Fundalux turbidity measurement

BioPAT® Xgas O₂ | CO₂ off-gas analysis

System IQ | OQ

BioPAT® MFCS SCADA system

Univessel® Glass

Double-wall culture vessel

Magnetic coupling for drive motor

STT connectors for safe inoculation and media transfer

Cooling finger (single-wall culture vessels)

Spin filter for perfusion mode

Aeration basket for organisms sensitive to shear stress

Rushton impellers | 3-blade segment impellers

Baffles

Bottle holder

Adapter for height reduction of exhaust cooler for the autoclave

Inoculation port

3-way addition port

Universal adapter ID 3.2 mm

Harvest pipe bent for complete draining

Port adapter 19 mm - 12 mm


Set of consumables

Germany

Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen
Phone +49 551 308 0

USA

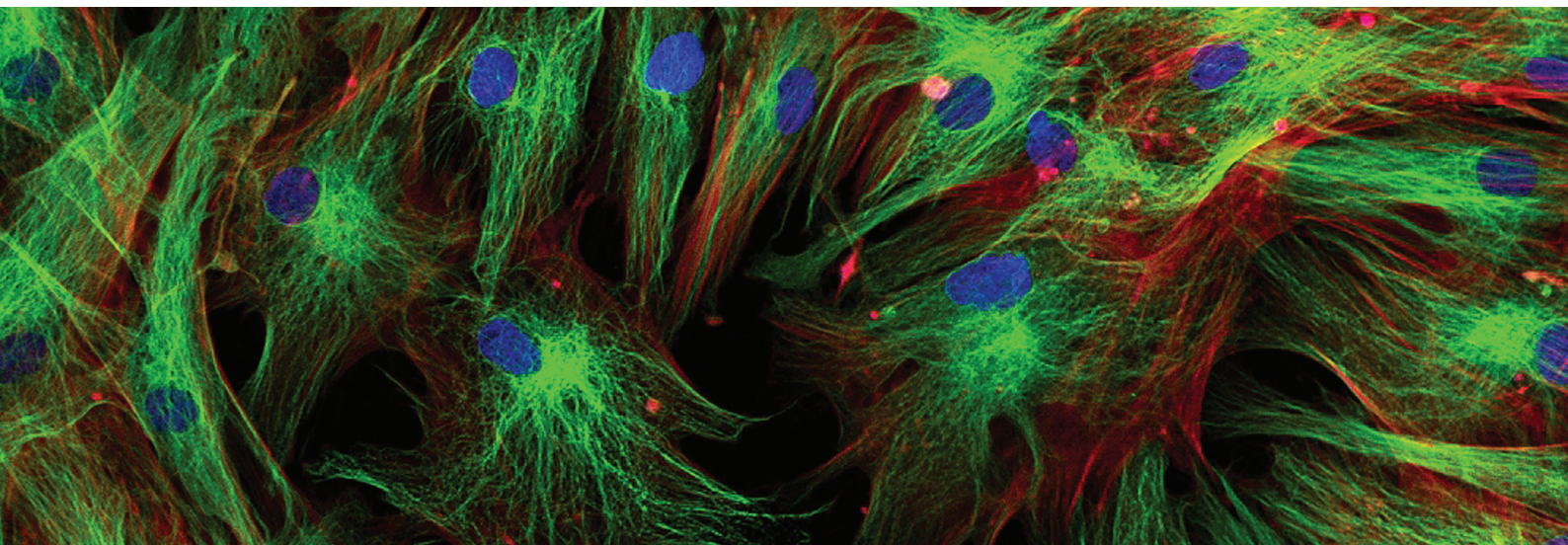
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NutriStem® MSC Culture System

A complete xeno-free, serum-free system for the growth and expansion of hMSCs



- **Defined, xeno-free, serum-free medium**
- **Superior proliferation of hMSCs**
- **Supports long-term growth and differentiation potential**
- **FDA Drug Master File**

Redefining stem cell excellence and advancing clinical applications

Defined, serum-free, xeno-free reagents are essential tools for all human mesenchymal stem cell (hMSC) research having potential clinical applications. The NutriStem® MSC Culture System includes defined reagents ideal for translational research use. hMSCs cultured in serum-free, xeno-free NutriStem® MSC XF Medium show superior proliferation and self-renewal potential in comparison to serum-containing media and other serum-free media. In addition, hMSCs maintain their proper fibroblast-like cell morphology, tri-lineage differentiation potential, and demonstrate normal hMSC marker profiles and karyotypic stability over long-term culture.

NutriStem® MSC XF Medium is designed for optimal growth and expansion of hMSCs derived from a variety of sources, including bone marrow (BM-hMSC), adipose tissue (AT-hMSC), Wharton's jelly (WJ-hMSC), placental tissue (PT-MSC), and umbilical cord matrix (UC-hMSC).

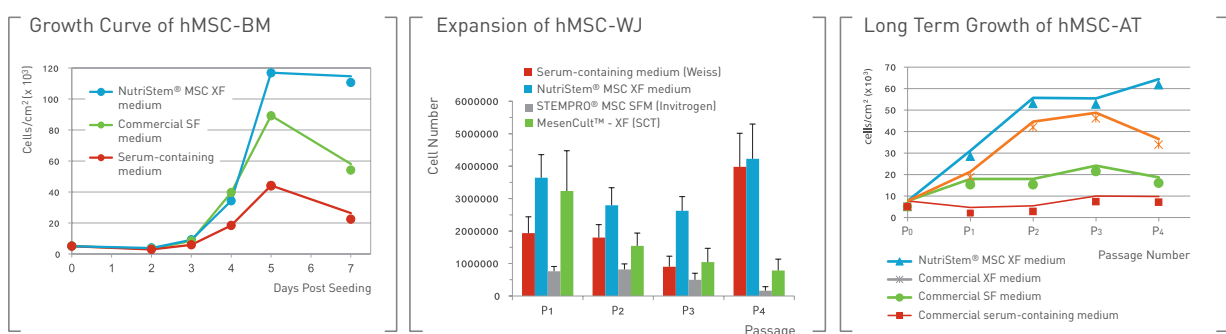
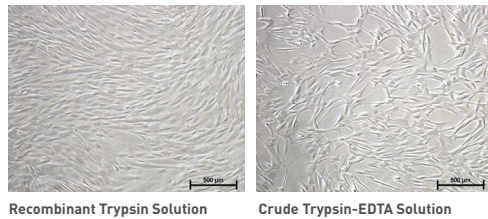


Figure 1: NutriStem® MSC XF Medium promotes superior proliferation and expansion of hMSCs over time as compared to other serum-free and serum-containing media.

MSC Attachment Solutions

- Xeno-free, purified human fibronectin/human fibrinogen
- Optimized for serum-free cultures
- For hMSC proliferation and differentiation



MSC Dissociation Solutions

- Ready-to-use, defined
- Recombinant trypsin solutions

NutriFreez™ D10 Cryopreservation Solution

- Chemically defined, animal component-free, protein-free
- Excellent cell attachment and viability

Figure 2: MSC Dissociation Solutions.

Recovery of BM-hMSC after dissociation with either Recombinant Trypsin Solution or Recombinant Trypsin-EDTA Solution and re-seeding on plates pre-coated with the MSC Attachment Solution and cultured in NutriStem® MSC XF Medium. Images were taken on Day 5 post-dissociation (100X).

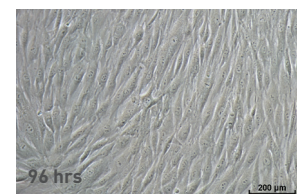
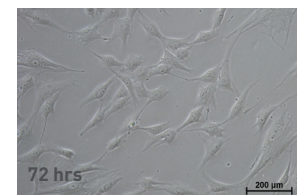
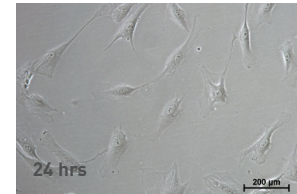
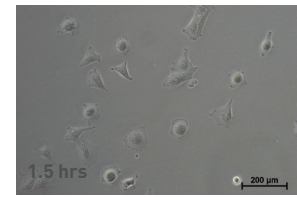


Figure 3: NutriFreez™ D10 Cryopreservation Medium. Images show the recovery of BM-hMSC after thawing. Cells were frozen using NutriFreez™ D10 Cryopreservation Medium, thawed, and re-seeded in NutriStem® MSC Medium. Images were taken at the indicated time points post-thawing (200X).

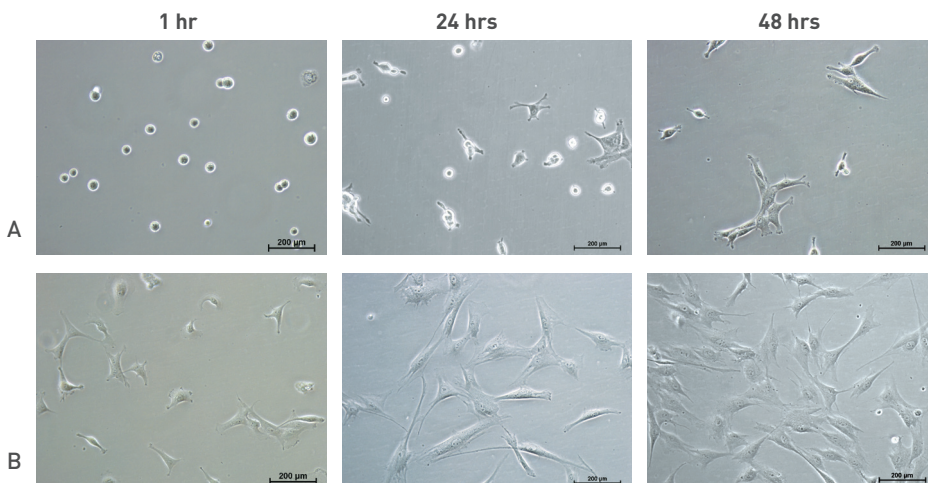


Figure 4: MSC Attachment Solutions. The use of MSC Attachment Solution greatly enhances BM-hMSC attachment and growth in culture. Cells in panel A images were cultured without MSC Attachment Solution. Cells in panel B were cultured with MSC Attachment Solution. Images were taken at the indicated time points post-seeding (200X).

Ordering Information

Cat. #	Product
05-200-1	MSC NutriStem® XF Basal Medium
05-201-1	MSC NutriStem® XF Supplement Mix
05-760-1	NutriCoat™ Attachment Solution
05-752-1	MSC Attachment Solution
05-713-1	NutriFreez™ D10 Cryopreservation Medium
03-078-1	Recombinant Trypsin Solution
03-079-1	Recombinant Trypsin-EDTA Solution
PLTGOLD100R	PLTGold® Human Platelet Lysate (Research-grade)
PLTGOLD100GMP	PLTGold® Human Platelet Lysate (Clinical-grade)
PLTGOLD100GMP-PI	PLTGold® Human Platelet Lysate (Pathogen Inactivated)
PLTMAX100R	PLTMax® Human Platelet Lysate (Research-grade)
PLTMAX100GMP	PLTMax® Human Platelet Lysate (Clinical-grade)

ALSO AVAILABLE

MSCgo™ Differentiation Media

A unique line of complete, serum-free, and xeno-free media for efficient and reproducible differentiation of hMSCs.

- MSCgo™ Osteogenic XF Medium
- MSCgo™ Rapid Osteogenic XF Medium
- MSCgo™ Chondrogenic XF Kit
- MSCgo™ Adipogenic XF Kit

How to Order

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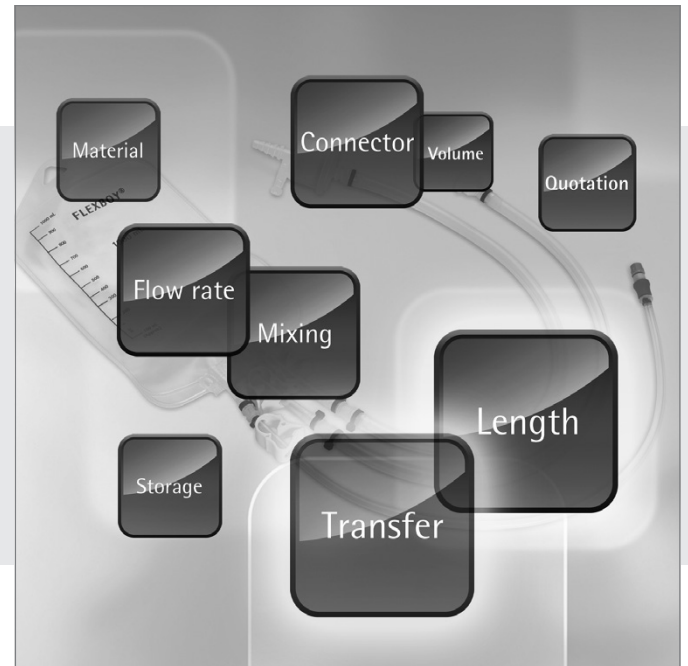
Configurable Flexsafe® 2D

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 assures 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 & 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 Disconnecter 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, Steam thru™ 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 & 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 & manufacturing methods	Save on development and engineering costs
Instant design with a web-based Product Configurator	Shorten lead time for drawing & 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 & 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.

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 Disconnecter, TPE compatible with BioWelder® and BioSealer®
End Connectors	Quick Couplers Triclamp and Mini-Triclamp Luer® Locks Steam thru™ 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

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 ISO11137 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.

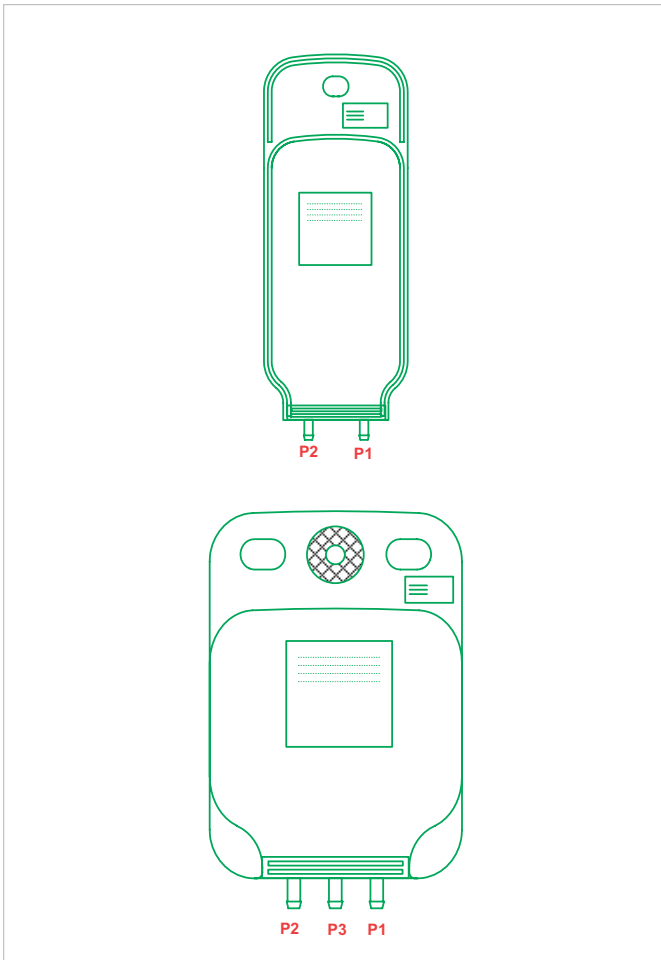
Flexsafe® 2D Bags are tested for compliance to:

- 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.

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

– 3 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 = 1/4" × 7/16" for P1, P2, P3
1/4" × 3/8" for P1, P2, P3
3/8" × 5/8" 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

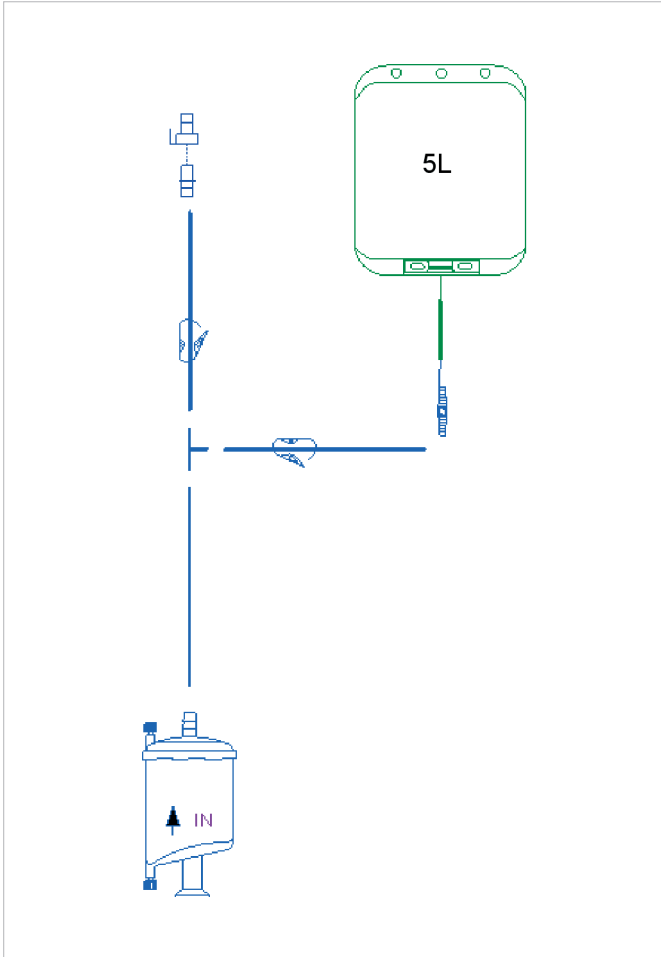
Port	P1	P2	P3
Line	Line 1	Line 2	Line 3
Function	Fill	Drain Sampling	Sampling
Normal Flow Rate with Filter	●		
High Flow Rate with Filter	●		
Normal Flow Rate	●	●	
High Flow Rate	● ⁽¹⁾	● ⁽¹⁾	
Sampling		●	●
Not Used		● ⁽¹⁾	● ⁽²⁾

⁽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 = 1/4" × 7/16" (6.4 mm × 11.1 mm)
or 3/8" × 5/8" (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

Option

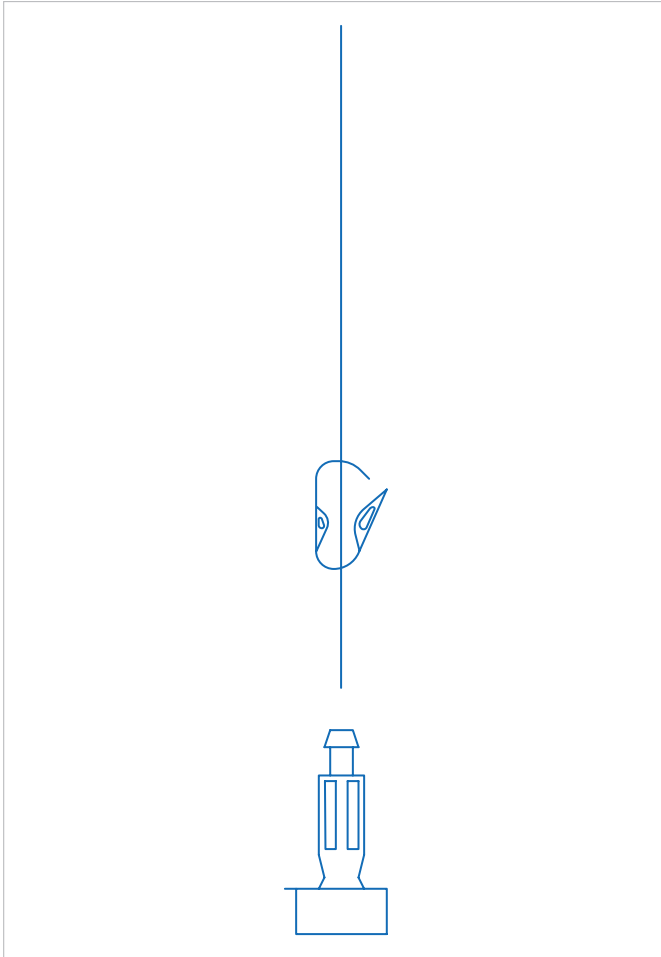
- No flush bag for volume 20 mL to 1 L
- 1 L Flexboy[®] Flush Bag (only with Normal Flow Rate)
- 5 L Flexboy[®] Flush Bag

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 & 2 and High Flow Rate: port 1 & 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 = 1/4" × 7/16" (6.4 mm × 11.1 mm)
- or 1/4" × 3/8" (9.5 mm × 15.8 mm)
- or 3/8" × 5/8" (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

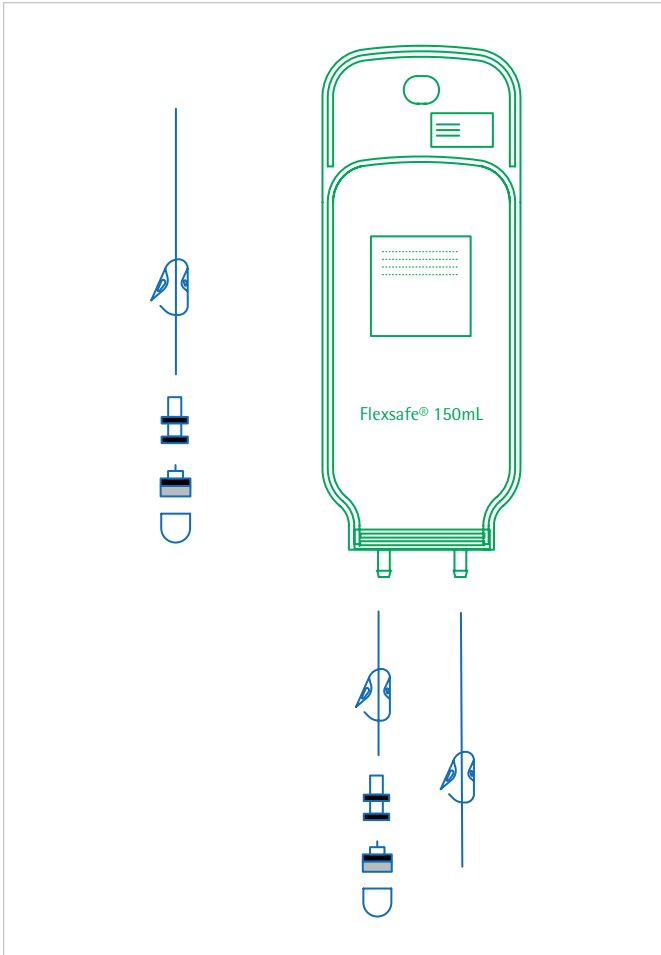
- 150 mm (6") for Si(Pt) TuFlux[®] or Si(Pt)
- 300 mm (12") for Si(Pt) TuFlux[®] or Si(Pt)
- 500 mm (20") for Si(Pt) TuFlux[®], Si(Pt) or TPE tubing
- 1,000 mm (39") total line length: 500 mm (20") Si(Pt) TuFlux[®] or Si(Pt) + 500 mm (20") TPE for Silicone with a TPE extension
- 1,500 mm (59") total 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 (1-1/2" or 3/4" 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 (3/4" × 3/4" triclamp flanges)
- STC II - CPC Steamthru™ connection (3/4" × 3/4" triclamp flanges)
- KPC HT - Male or Female
- Luer Male or Female with cap (only with Normal Flow Rate)
- Aseptiquick genderless
- Lynx Valve ST 1/4" or 3/8"

Line Type "Sampling" P2 – P3⁽¹⁾ Normal Flow Rate

Generic Description



Specifications

Tubing Diameters

ID × OD = 1/4" × 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

Functionalities (Sampling)

- Clave Connector
- Sampling Bag

⁽¹⁾ P2 For volume 20 mL to 500 mL
P3 for volume 1 L to 50 L

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.	1/4" × 7/16" (6.4 mm × 11.1 mm) 3/8" × 5/8" (9.5 mm × 15.8 mm)	1/4" × 7/16" (6.4 mm × 11.1 mm)	3/8" × 5/8" (9.5 mm × 15.8 mm)	1/4" × 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 1 1/2" or 3/4" w/wo cap, plug, gasket, union Quick Coupling MPC-M/F Quick coupling PSU-M/F	Luer M-F SSB TC 1 1/2" or 3/4" 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 3/4" × 3/4" STC II 3/4" × 3/4"	
Other Connectors		KPC HT-M/F Lynx ST 1/4"	KPC HT-M/F Lynx ST 3/8"	
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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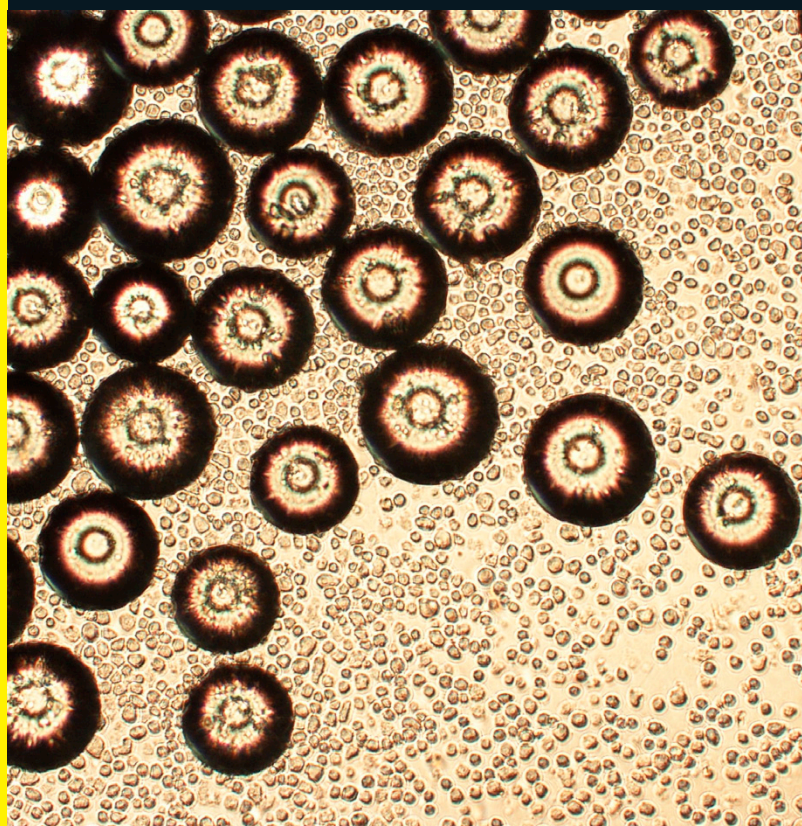
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Microcarrier Products

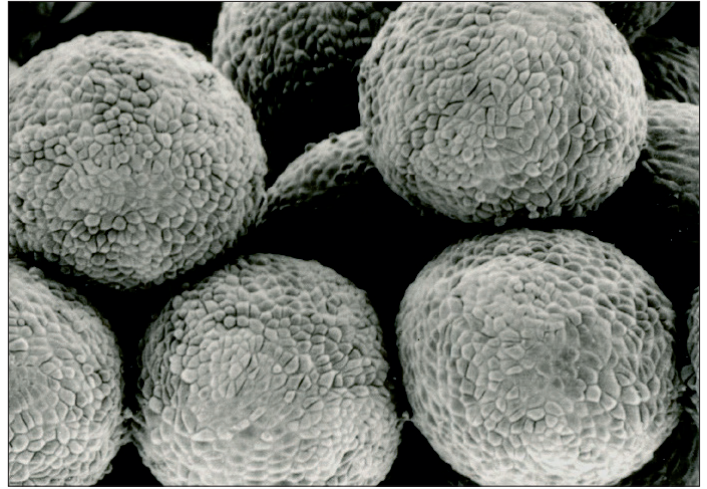
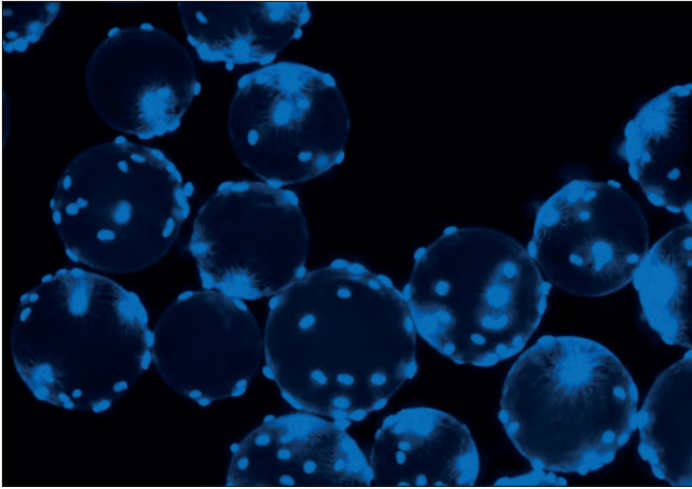
Simplifying adherent,
cell-based research and
manufacturing



Product Information

Since its inception in 1984, SoloHill® has developed an extensive range of commercially available microcarrier products. By successfully combining cutting-edge research with high-quality manufacturing, SoloHill® not only offers excellent products but also provides valuable technical expertise to ensure optimal results. Our talented scientists are available to assist with product selection, process optimization, and technology transfer to end-user laboratories.

Microcarriers are tiny spheres that normally range from 90 to 300 microns in diameter. The relative density of microcarriers is close to water, which facilitates easy suspension in a cell culture medium. Their core material, surface chemistry, and coating promote attachment and growth of anchorage-dependent cells and influences the production of biologics in cell culture processes. A fundamental benefit of microcarriers is that they provide a large effective surface area with a relatively small footprint, allowing large-scale manufacturing of biologics for lower capital investment.



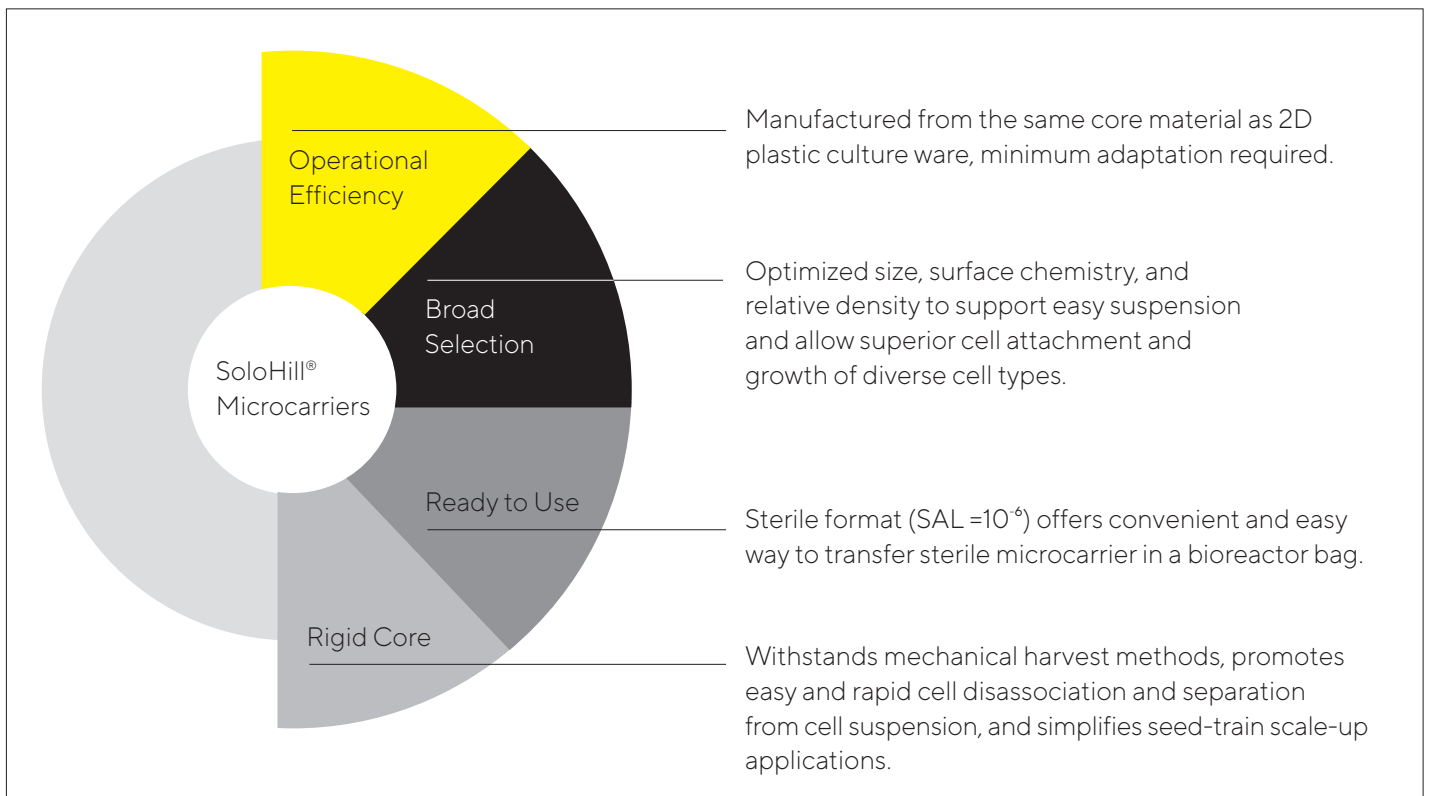
Human mesenchymal stromal/stem cells (hMSCs) growing on SoloHill® Microcarriers

Scanning electron micrograph of Vero cells on SoloHill® Microcarriers

Benefits

Sartorius SoloHill® Microcarrier technology has many advantages for the large-scale production of high-quality, anchorage-dependent cells.

- **Proven Track Record:** Used by the animal and human health industry for over 30 years.
- **Streamlined Solution:** Simply sterilize and use: hydration and pre-swelling steps are not required.
- **Ready-to-Use:** Sterile format with sterility assurance level (SAL) 10^{-6} eliminates sterilization validation and shortens manufacturing process.



Applications

Microcarrier technology provides an efficient, cost-effective tool to scale up various adherent, cell-based biopharmaceutical applications such as advanced cell and gene therapy, vaccines, and biologics production. Historically, microcarrier and stirred-tank bioreactor technologies have been used successfully by the biopharmaceutical industry, and this platform is accepted by regulatory agencies for both animal and human health product manufacturing.

A wide range of commercially available, traditional stainless steel, and single-use stirred-tank bioreactors are used to scale processes up to 3000 m² surface area or greater using microcarrier technology. Additionally, microcarrier-based scale-up performed in controlled bioreactor systems facilitates automated closed system operations, thereby diminishing contamination risks and providing a regulated manufacturing environment for consistent product manufacturing.

Product Specification

SoloHill's diverse microcarrier products are manufactured and handled under ISO 9001 standards. All microcarrier types are offered in standard non-sterile and sterile (gamma-irradiated), ready-to-use formats that facilitate ease of use. Specific cell types have different requirements for attachment, growth, and biologic production, hence the optimal microcarrier should be selected experimentally.

Microcarriers are offered in a convenient starter kit format to accelerate this initial screening and evaluation. Selecting the optimal microcarrier type is key to a successful culture. Sartorius offers a variety of microcarrier types in multiple size formats ranging from 10 grams to 1000 grams, allowing user flexibility during the selection and optimization of manufacturing processes.

Microcarrier Types and Their Properties

Microcarrier type, core material, and surface chemistry	Relative density range	Size (microns)	Surface area (cm ² /g)	Surface charge	Protein-coated	Number of MC per gram
Plastic Cross-linked polystyrene	1.022-1.030	125-212	360	No	No	4.6 × 10 ⁵
	1.022-1.030	90-150	480	No	No	1.0 × 10 ⁶
Plastic Plus Cross-linked polystyrene, cationic-charged	1.022-1.030	125-212	360	Yes	No	4.6 × 10 ⁵
Star-Plus Cross-linked modified polystyrene, cationic-charged	1.022-1.030	125-212	360	Yes	No	4.6 × 10 ⁵
Hillex II® Modified polystyrene, cationic-charged	1.090-1.150	160-200	515	Yes	No	5.5 × 10 ⁵
Collagen Cross-linked polystyrene coated with Type 1 porcine collagen (gelatin)	1.022-1.030	125-212	360	No	Yes	4.6 × 10 ⁵
	1.034-1.046	125-212	360	No	Yes	4.6 × 10 ⁵
	1.022-1.030	90-150	480	No	Yes	1.0 × 10 ⁶
Fact III Cross-linked polystyrene coated with Type 1 porcine collagen (gelatin), cationic-charged	1.022-1.030	125-212	360	Yes	Yes	4.6 × 10 ⁵

Ordering Information

Microcarrier type	Part number	Weight (gram)	Ready to use (Sterile)
Plastic Cross-linked polystyrene	P-221-020	10	No
	P-221-050	100	No
	P-221-070	500	No
	P-221-080	1000	No
	PIR-221-020	10	Yes
	AMDS05PS100	100	Yes
Plastic Plus Cross-linked polystyrene, cationic-charged	PP-221-020	10	No
	PP-221-050	100	No
	PP-221-070	500	No
	PP-221-080	1000	No
	PPIR-221-020	10	Yes
	AMDS05PPS100	100	Yes
Star-Plus Cross-linked modified polystyrene, cationic-charged	SP-221-020	10	No
	SP-221-050	100	No
	SP-221-070	500	No
	SP-221-080	1000	No
	SPIR-221-020	10	Yes
	AMDS05SPS100	100	Yes
Hillex II® Modified polystyrene, cationic-charged	H-170-020	10	No
	H-170-050	100	No
	H-170-070	500	No
	H-170-080	1000	No
	HIR-170-020	10	Yes
	AMDS05HS100	100	Yes
Collagen-coated Cross-linked polystyrene coated with Type 1 porcine collagen (gelatin)	C-221-020	10	No
	C-221-050	100	No
	C-221-070	500	No
	C-221-080	1000	No
	CIR-221-020	10	Yes
	AMDS05CS100	100	Yes
FACT III Cross-linked polystyrene coated with Type 1 porcine collagen (gelatin), cationic-charged	F-221-020	10	No
	F-221-050	100	No
	F-221-070	500	No
	F-221-080	1000	No
	FIR-221-020	10	Yes
	AMDS05FS100	100	Yes
Microcarrier Starter Kit (Plastic, Plastic Plus, Star-Plus, Hillex® II, Collagen-coated, Fact III)	SK102-1521B	10g of each	No


Custom size options are available upon request, contact at microcarriers@sartorius.com.

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PLTGold® Product Insert

About PLTGold®

PLTGold® is a non-xenogeneic, animal serum-free product derived from human platelets. PLTGold® is used as a manufacturing component in the generation of adult stems cells. A Drug Master File for PLTGold® is registered with the FDA and is cross-referenceable. Contact us for more information on the DMF.

Product	Catalog Number	Size
PLTGold® Research Grade	PLTGold27R	27mL
	PLTGold100R	100mL
	PLTGold500R	500mL
PLTGold® Clinical Grade (GMP)	PLTGold27GMP	27mL
	PLTGold100GMP	100mL
	PLTGold500GMP	500mL

Safety Information

All PLTGold® donors have been tested for infectious diseases; however, universal precautions for handling and disposal of biological products should be used when working with PLTGold®.

Using PLTGold®

- Thaw at 37°C or 4°C.
- It is not recommended to expose PLTGold® to repeated temperature changes that could affect the integrity of its components. For that reason, we recommend thawing the product and preparing aliquots as soon as it is received.
- Aliquots can be stored at -20°C or colder. Storage at 4°C is recommended for periods no longer than 2 weeks.
- Complete media can be prepared, aliquoted and stored at -80°C for up to 9 months. Do not store complete media at 4°C for longer than 2 weeks.
- Filtration of PLTGold® or complete media containing PLTGold® is NOT recommended.

Culture Conditions Using PLTGold®

- Cell seeding should be performed following the general guidelines for the specific cell type. For Mesenchymal Stem Cells (MSCs), cells are typically plated at approximately 2×10^3 – 5×10^3 cells per cm^2 .
- For MSCs, PLTGold® can be used at 5% vol/vol in a typical cell culture medium such as DMEM or α -MEM. If the basic media doesn't contain Glutamine, a source of L-Glutamine will need to be added to the media at a final concentration of 2mM. For other types of cells, the concentration of PLTGold® will need to be titrated according to the application (a titration from 2% vol/vol to 10% vol/vol is recommended to establish the percentage of PLTGold® needed for the cell type to use).
- Do not allow primary MSC confluence to exceed 70-80%.

Origin

- PLTGold® was developed to eliminate the need for heparin in hPL. It is an unfractionated product derived from our original hPL, PLTMax® that does not contain or require the addition of heparin. PLTGold® remains clot free and with similar performance to PLTMax®.

References

- Crespo-Diaz R, Behfar A, Butler GW, et al. **Platelet lysate consisting of a natural repair proteome supports human mesenchymal stem cell proliferation and chromosomal stability.** *Cell Transplant.* 2011;20(6):797-811.
- Burnouf T, Strunk D, Koh MB, et al. **Human platelet lysate: Replacing fetal bovine serum as a gold standard for human cell propagation?** *Biomaterials.* 2016 Jan;76:371-87.
- Alonso-Camino V, Clarke B, Nielsen J, et al. **In vitro expansion of mesenchymal stem cells using media supplemented with unfractionated heparin-free platelet lysate.** Poster presented at: ISCT Annual Meeting. London, UK. 2017 May.
- Bulur P, Wiltshire T, Dudakovic A, et al. **Impact of media supplementation on the secretion of IFN- γ induced indoleamine 2-3 deoxygenase and resultant immune suppression by mesenchymal stromal cells.** Poster presented at: ISCT Annual Meeting. Montreal, Canada. 2018 May.
- Alonso-Camino V, Mirsch W. **In vitro expansion of human primary endothelial cells for clinical use using EndoGo™ XF Medium supplemented with PLTGold® human platelet lysate.** Poster presented at: ISCT Annual Meeting. Montreal, Canada. 2018 May.

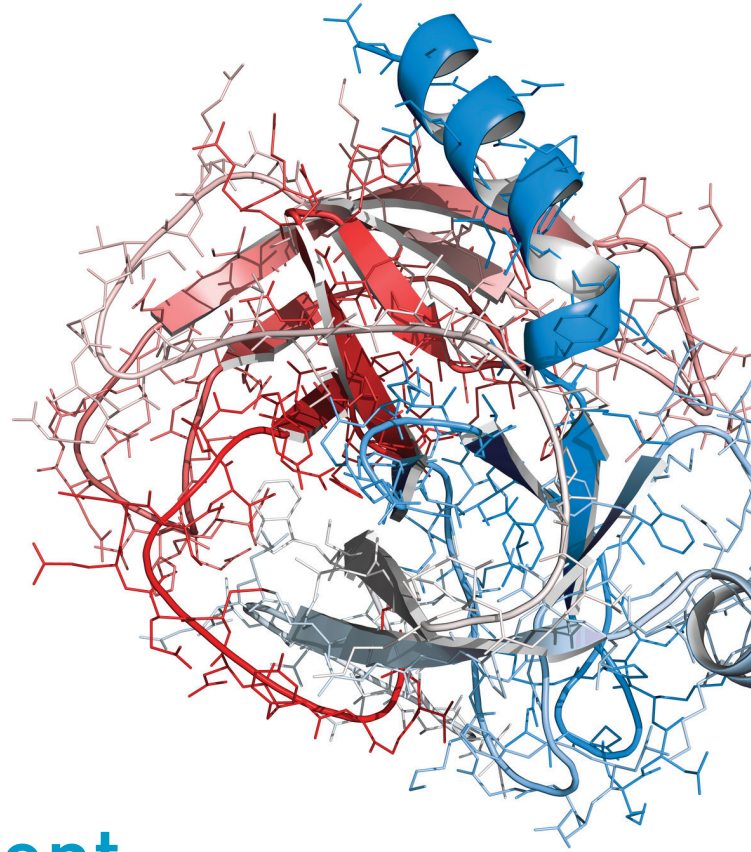
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BI
Biological Industries
Culture of Excellence



Chemical structure of
trypsin enzyme

All the way with animal
component-free solutions

Animal Component- Free (ACF) Recombinant Trypsin Solutions

Alternative to porcine/bovine trypsin

- **Animal Component-Free (ACF)**

Eliminates the risk of viruses or other potential adventitious agents found in animal derived components.

- **High Purity**

- Pure enzyme solutions increase specificity and eliminate contaminating activities found in lower purity enzymes.
- Free of chymotrypsin, carboxypeptidase-A and other protease contaminants.
- Prevents the toxic effects induced by non-desirable proteases.

- **High Activity**

- Maximizes the yield of functionally viable cells.
- Recombinant Trypsin-EDTA Solution (Cat. No. 03-079-1) accelerates the dissociation phase.
- Results in efficient dissociation of adherent cell types (including primary and sensitive cells) from surfaces and tissues.
- Optimized for hMSCs, from a variety of sources, cultured in both serum-free and serum-containing systems.

- **Enzyme Inhibition**

Inactivation with Soybean Trypsin Inhibitor (SBTI, Cat. No. 03-048-1).

- **Ready-to-use**



Comparison of hMSC Dissociation with Various Trypsin Solutions

Recovery of hMSC- Adipose Tissue (AT) cultured in MSC NutriStem XF medium after dissociation with three different dissociation solutions

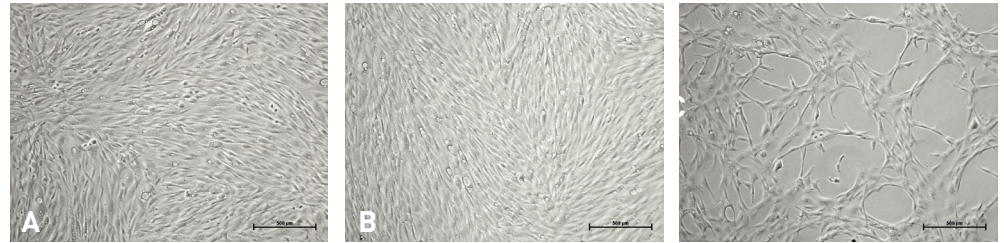


Figure 1.

hMSC-AT, 3 days post split I – Cells were equally seeded (5000cells/cm²) in MSC NutriStem® XF medium. The dissociation procedure was carried out at 37° using:
 A. Recombinant Trypsin Solution, without EDTA (BI's Cat. No. 03-078-1)
 B. Crystalline Trypsin (BI's Cat. No. 03-047-1) (high purity)
 C. Trypsin sol. C (BI's Cat. No. 03-053-1) (crude trypsin)

Rapid and Efficient Dislodging of hMSC with Recombinant Trypsin

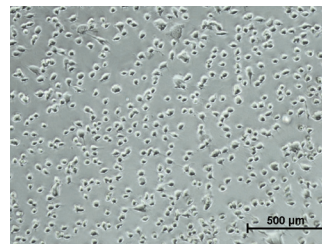
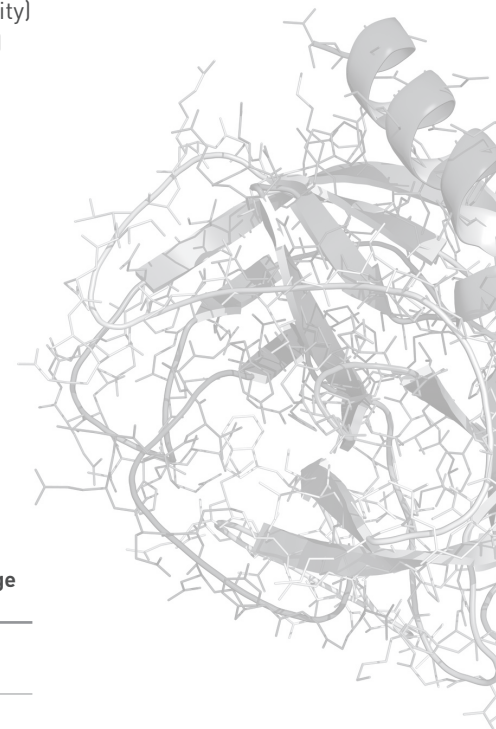


Figure 2.

hMSC-BM cultured in MSC NutriStem® XF medium, were incubated for 2-5 min at 37°. with Recombinant Trypsin Solution (Cat. No. 03-078-1)



Ordering Information

Product Name	Cat. No.	Unit Size	Storage Temp.
Recombinant Trypsin Solution	03-078-1B	100ml	RT
Recombinant Trypsin-EDTA Solution	03-079-1B	100ml	RT
Soybean Trypsin Inhibitor (SBTI) x50	03-048-1C	20ml	-20°C

Source of raw material:

The Recombinant Trypsin is produced by submerged fermentation of *Fusarium Oxysporum*.

It is derived from a production process which does not utilize any raw materials and/or processing aids of animal origin.

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

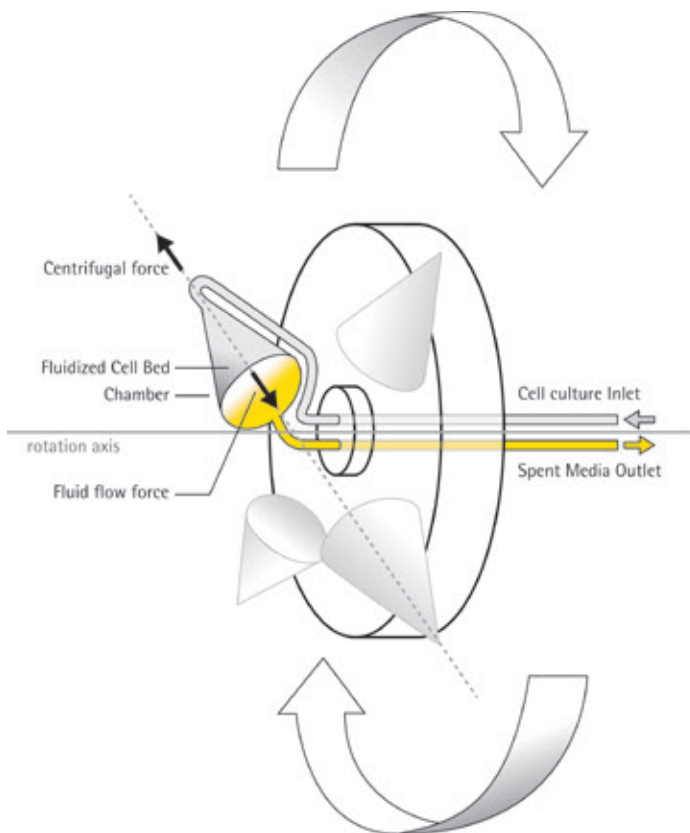
Advanced Cell Handling

- 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	3/8" x 1/4" C-Flex®	5/8" x 3/8" C-Flex®
Utility Requirements		
Voltage	208 – 240 V 1Ph	208 – 240 V 3 Ph (US) 400 V 3 Ph (EU)
Current	20 A	60 A
Process Air	Not required	90 psi – 1/2" NPT
Connection	NEMA L6 – 20	Customer supplied
Chilled Water (Optional)	1/2" NPT	3/4" NPT



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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.

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

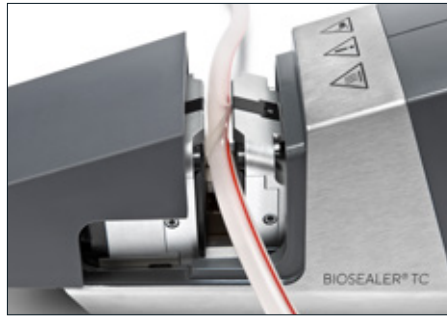
Depending on the tubing size and TPE material the sealing process time is between 2 to 4 minutes.

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" x ¾", ¾" x 1"), C-Flex® 374, AdvantaFlex®, SaniPure™ BDF™ (except ¾" x 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.

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" x ¼"	¼" x ¾"	¼" x 7/8"	¾" x 5/8"	½" x ¾"	¾" x 1"
TuFlux® TPE	TuFlux TPE	A or G	<input type="checkbox"/> (yellow)	<input type="checkbox"/> (orange)	<input type="checkbox"/> (red)	<input type="checkbox"/> (white)		
C-Flex® 374	C-Flex 374	A or G	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
AdvantaFlex®	AdvantaFlex	A or G	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SaniPure™ BDF™	SaniPure	A or G	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Pharmed® BPT	Pharmed	A or G	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



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 3m	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	24VDC
Supply current	6.25A
In and out connections	Device plug, XLR max. 24VDC 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 2000m
Degree of protection	IP20
Weight	Approx. 3kg
Dimension (L×W×H)	391mm×115mm×147mm
Power Supply	
Input Voltage	100VDC – 240VDC
Input frequency (power supply)	47Hz – 63Hz
Input current	2.5A
Power cord	According to local regulations Min. 3×AWG18 or 3×0.75mm² Min. local mains supply voltage

Sealing parameters validation

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


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

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BioWelder[®] Total Containment

Fully automated device for welding dry and liquid filled tubing

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 1/4" up to 1" outer diameter.



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."

Feature	Benefit
Dry or liquid filled tubing from 1/4" 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 5/8" x 7/8" and 3/4" x 1" sizes) and PharMed [®] * (except 1/8" x 1/4" 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

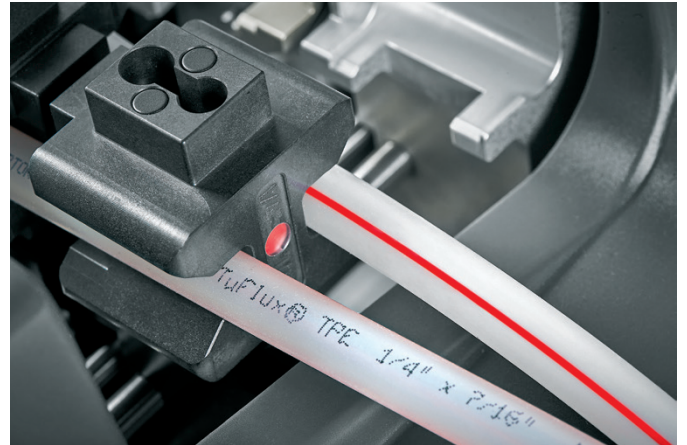
The holders, the blade and the tubes are inserted into the BioWelder[®] TC. The welding process is fully automated and is started via the LCD touch screen. The blade is first heated up for depyrogenation then cooled down to the welding temperature. An infrared sensor monitors and controls the blade temperature 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 1/8" ID x 1/4" OD and 3/4" ID x 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.

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 contract services are available for BioWelder[®] TC.



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 and holders qualified per welding parameters						
				1/8" × 1/4"	1/4" × 3/8"	1/4" × 7/16"	3/8" × 5/8"	1/2" × 3/4"	5/8" × 7/8"	3/4" × 1"
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

Technical Specification

Type designation	BioWelder® TC, BWTC	Power cord	According to local regulations – minimum 3 × AWG18 or 3 × 0.75 mm ² – minimum local mains supply voltage
Power connection	100 VAC – 240 VAC	Tube holder size (ID × OD; color)	1/8" × 1/4"; yellow 1/4" × 3/8"; orange 1/4" × 7/16"; red 3/8" × 5/8"; white 1/2" × 3/4"; grey 5/8" × 7/8"; green 3/4" × 1"; blue
Input frequency	50 60 Hz	Welding Cycle	1 min 30 – 2 min 30 (depending on tube diameters and material)
Power input	300 VA	Standard settings for	TuFlux® TPE, C-Flex® 374*, AdvantaFlex®, PharMed®* BPT, SaniPure™* BDF™
In and out connections	Device plug C14 max. 250VAC Ethernet jack type RJ45	Minimum tubing length	450 mm
Power connection of fuse	2 × 3.15 A T (Type FST)	Max operating pressure validated	1 bar
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		

* 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 1/8" ID × 1/4" OD	2
16389-010	BioWelder® TC Tube Holder 1/4" ID × 3/8" OD	2
16389-011	BioWelder® TC Tube Holder 1/4" ID × 7/16" OD	2
16389-001	BioWelder® TC Tube Holder 3/8" ID × 5/8" OD	2
16389-002	BioWelder® TC Tube Holder 1/2" ID × 3/4" OD	2
16389-003	BioWelder® TC Tube Holder 5/8" ID × 7/8" OD	2
16389-004	BioWelder® TC Tube Holder 3/4" 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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August-Spindler-Strasse 11
37079 Goettingen, Germany
Phone +49.551.308.0
www.sartorius-stedim.com

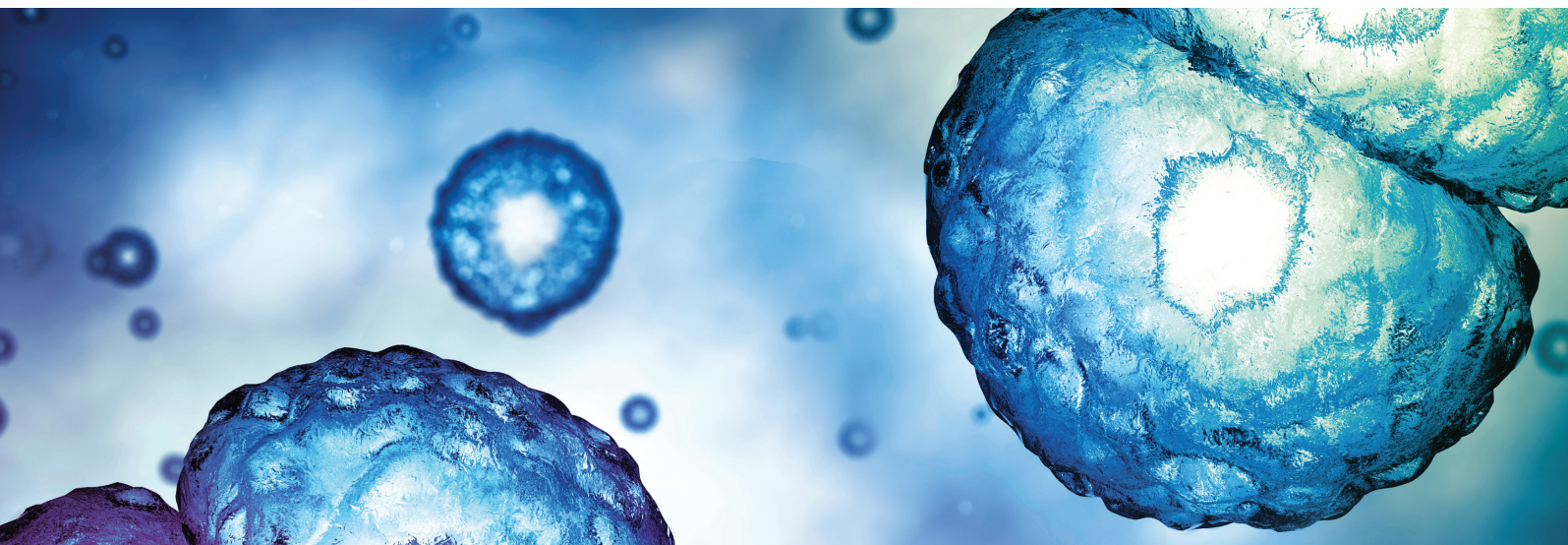
USA Toll-Free +1.800.368.7178
Argentina +54.11.4721.0505
Brazil +55.11.4362.8900
Mexico +52.55.5562.1102
UK +44.1372.737159
France +33.442.845600
Italy +39.055.63.40.41
Spain +34.913.586.098
Russian Federation +7.812.327.53.27
Japan +81.3.4331.4300
China +86.21.6878.2300

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Ver. 05 | 2018



MSCgo™ Differentiation Media

Advanced adipogenesis, osteogenesis, and chondrogenesis from hMSCs



- **Complete, serum-free, xeno-free media**
- **Validated to efficiently differentiate hMSCs from various sources**
- **Simple, efficient protocols**

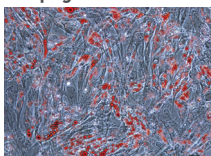
Redefining stem cell excellence

Whether for basic research, drug discovery, or for therapeutic applications, stem cell differentiation requires standardized culture methods to ensure reproducible and reliable results. The unique line of **MSCgo™ Differentiation Media** offers a complete system for multipotency evaluation of human mesenchymal stem cells (hMSCs), designed to efficiently differentiate hMSCs from a variety of sources into mature adipocytes, chondrocytes, and osteocytes/osteoblasts.

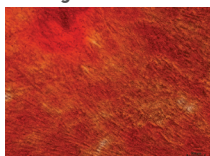
The MSCgo™ Differentiation Media are complete, serum-free, and xeno-free solutions, eliminating the drawbacks of unwanted background differentiation or interruption in cell metabolism, while providing consistent and repeatable results.

Each MSCgo™ Differentiation Medium contains all growth factors and supplements necessary for differentiation to the specified lineage. No adaptation phase is required prior to initiating differentiation when the hMSC's are cultured using NutriStem® MSC XF Medium. The differentiation media are validated with hMSC from a variety of sources, including bone marrow (BM-hMSC), adipose tissue (AT-hMSC), Wharton's jelly (WJ-hMSC), and umbilical cord tissue (CT-hMSC).

Adipogenesis



Osteogenesis



Chondrogenesis



Figure 1: MSCgo™ Differentiation Media is a complete system for multipotency evaluation of hMSCs into mature adipocytes, osteocytes/osteoblasts, and chondrocytes. Images taken of mature differentiated cells from adipose tissue-derived hMSCs.

Adipogenic Differentiation

MSCgo™ Adipogenic Differentiation Medium is a serum-free and xeno-free formulation developed for optimal differentiation of hMSCs to mature adipocytes. Efficient adipogenic differentiation of hMSCs is achieved through cycles in culture with MSCgo™ Adipogenic Differentiation Medium and maintenance medium (NutriStem MSC XF Medium). Oil Red-O solution is then used to stain accumulated intercellular lipid droplets, which are an indication of mature adipocytes.

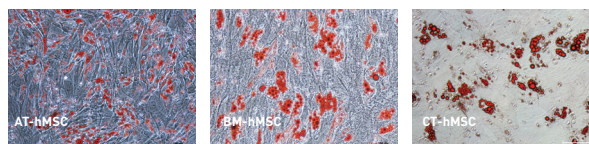


Figure 2: Adipogenesis. After expansion in culture using NutriStem® MSC XF Medium, hMSCs from adipose tissue [AT-hMSC], bone marrow [BM-hMSC], and cord tissue [CT-hMSC] were transferred to a differentiation assay in MSCgo Adipogenic Differentiation Medium. Images were taken after 16 days of adipogenesis and Oil Red-O staining [20X].

Osteogenic Differentiation

The MSCgo™ Osteogenic Differentiation Media were developed for differentiation serum-free, xeno-free differentiation of hMSCs to mature osteocytes/osteoblasts with ready-to-use media and simple protocols. Osteogenic differentiation of hMSC results in the formation of a mineralized culture that can be detected and semi-quantified by Alizarin Red S (ARS) staining.

Mature osteocytes are generated between 14 and 21 days with the MSCgo™ Osteogenic Differentiation Medium. Faster osteogenesis is observed with the MSCgo™ Rapid Osteogenic Differentiation Medium, in which mature osteocytes are observed in less than 10 days.

Chondrogenic Differentiation

The MSCgo™ Chondrogenic Differentiation Medium is a complete kit, including basal medium and optimized supplement mix, containing all growth factors and supplements necessary for chondrogenesis of hMSCs from a variety of source tissues. Chondrogenic differentiation of hMSC in 3D spheroid culture results in the formation of cartilage with a typical extracellular matrix rich of Aggrecan, a proteoglycan used as an indicator for cartilage formation and can be detected with Alcian Blue, a dark-blue dye.

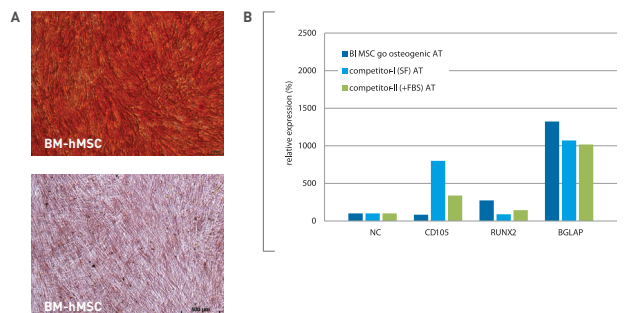


Figure 3: Osteogenic Differentiation. A. BM-hMSCs differentiate into osteoblasts when using serum-free MSCgo Osteogenic Differentiation Medium, detected by ARS staining (top). No osteogenesis is observed when serum-containing medium is used (bottom). B. The MSCgo Osteogenic Differentiation Medium results in the lowest expression of CD105 (hMSC marker), and the highest expression of RUNX2 (osteogenic differentiation marker) and BGLAP (mature osteoblast marker), as compared to other serum-free and serum-containing media.

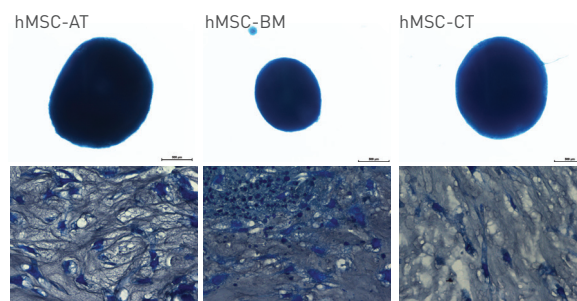


Figure 4: Chondrogenesis. A. Cartilage differentiation from hMSCs after a 21-day assay using MSCgo Chondrogenic Differentiation Medium followed by Alcian Blue staining. B. Histological images of mature chondrocytes surrounded by a cartilage matrix after a 21-day assay using MSCgo Chondrogenic Differentiation Medium followed by Toluidine Blue staining [40X].

Ordering Information

Cat. #	Product	Qty
05-440-1B	MSCgo™ Osteogenic Differentiation Medium	100 mL
05-442-1B	MSCgo™ Rapid Osteogenic Differentiation Medium	100 mL
05-220-1B	MSCgo™ Chondrogenic XF Medium	100 mL
05-221-1D	MSCgo™ Chondrogenic XF Supplement Mix	10 mL
05-330-1B	MSCgo™ Adipogenic XF Medium	100 mL
05-331-1-01	MSCgo™ Adipogenic XF Supplement Mix I	0.1 mL
05-332-1-15	MSCgo™ Adipogenic XF Supplement Mix II	1.5 mL

How to Order

Biological Industries | T. 972-4-996-0595 | F. 972-4-996-8896 | info@bioind.com

Biological Industries USA | T. 860.316.2702 | F. 860.269.0596 | orders@bioindusa.com

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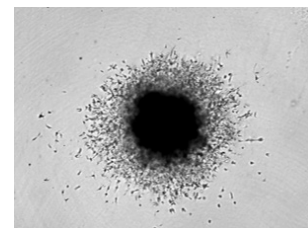
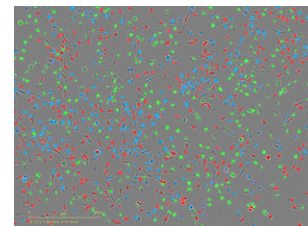
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Neuronal Activity
Angiogenesis

3D Cell Models

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Cell Movement & Morphology

Chemotaxis Migration & Invasion
Scratch Wound Migration & Invasion

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iQue® 3

Faster, Smarter, Flow Cytometry

Advanced High Throughput Flow Cytometry Solution Speeds Up Your Entire Workflow



The iQue® 3 Platform is the most advanced flow cytometry platform—with a focus on speed from setup, to acquisition and analysis. It combines a patented sampling method, which allows for the fastest sample acquisition in the industry. It has the ability to handle 96, 384, or 1536-well plates, and enables continuous plate loading through connection with any automation system. The Enhanced Rinse Station (ERS) provides continuous monitoring of liquid levels to ensure sufficient volumes prior to each run.

When used with the pre-configured iQue® reagent kits, samples can be analyzed instantly through the use of customizable templates following acquisition.

The included iQue Forecyt® Software enables dynamic data visualizations with an ease of use that allows all users to identify samples of interest without having to export to multiple software packages.

The iQue® Advantage

Speed



- Faster plate processing, minutes, not hours
- Mix and read samples
- Faster time to results

Miniaturization



- Consumes less reagents
- Conserves precious cells
- Saves money

Content



- Rich, multiplexed, per-cell content
- Cell and beads together
- Secreted protein analysis

Usability



- Automated workflow
- Validated reagents
- Easiest software you will ever love

Insight



- Link information
- Run scenarios
- Create knowledge
- Make decisions

iQue® 3 Platform

The iQue® 3 Platform is an integrated instrument, software and reagent system that enables rapid, high content, multiplexed analysis of cells and beads in suspension. Our unique, software-assisted automation and experiment-based analyses deliver the deep insight needed to answer complex biological questions.

The iQue® 3 BR (Blue-Red laser configuration) is a phenotypic screening and profiling workhorse that is ideal for applications that require up to 6-color detection, including antibody and biologics discovery, cell health assessment, secreted protein analysis using iQue® Qbead-based assays, and many more applications. Our platform delivers the iQue Forecyt® Software Workflow Advantage: a single data management workflow from input to output, which means you work faster and work smarter—not harder.

Content is king with the iQue® 3 VBR and VYB (Violet-Blue-Red and Violet-Yellow-Blue laser configurations). Three-laser systems offer up to 13-color detection and are ideal for functional and phenotypic applications that demand more choice and flexibility in experimental design. These systems combine high performance multi-color analysis with the iQue Forecyt® Software Workflow Advantage making them hands-down the choice of scientists in immune-based drug discovery, immuno-oncology, and cell therapy applications.

The iQue® 3 HD (Blue-Red laser configuration) provides the ultimate assay miniaturization and is the only high content, per-cell, 1536-well capable suspension screener available.

iQue® 3 Technical Specifications

iQue® 3 Configuration		Blue and Red		Violet, Blue and Red			Violet, Yellow and Blue		
Detectors	Lasers	488 nm	640 nm	405 nm	488 nm	640 nm	405 nm	561 nm	488 nm
	445/45 nm			■			■		
	530/30 nm	■		■	■		■		■
	572/28 nm	■		■	■				
	586/20 nm						■	■	
	615/24 nm			■	■				
	615/20 nm						■	■	■
	660/20 nm						■	■	■
	675/30 nm	■	■	■	■	■			
	780/60 nm	■	■	■	■	■	■	■	
	Forward light scatter (relative size)	■			■			■	
	Side light scatter (relative granularity)	■			■			■	
Optical	Fluorescence sensitivity	FITC < 75 MESF; PE < 50 MESF; APC < 20 MESF							
	Minimum particle size detection	0.5 µm							
	Cell detection rate	Up to 35,000/second							
	Dynamic range of detection*	> 7 decades							
* This wide dynamic range and a Zoom function permit operation of the system without user adjustments of the voltage or gain of the detectors.									
Sampling	Plate compatibility	96-well, 384-well or 384-well, 1536-well (iQue® 3 HD BR)							
	Sampling	Continuous air-gap delimited							
	Minimum assay volume requirements	10 µL							
	Minimum sample aspiration	1 µL							
	Minimum plate sampling time*	< 5 minutes 96 wells				< 20 minutes 384 wells			
	Carryover	< 2% for typical no-wash assays. Actual amounts are cell and assay dependent and are easily managed by including interwell rinses to reduce carryover to < 0.1%							
	Automated plate shaker	Up to 3,000 rpm (Up to 5000 rpm on iQue® 3 HD BR)							
Features	<ul style="list-style-type: none"> ▪ Foil-sealed plate processing ▪ Volumetric cell counting (< 10% CV) 								
* The time required for sampling plates is both sample type and experiment dependent. A range of well-sampling times can be designated from 0.5 seconds–minutes.									
Enhanced Rinse Station	Features	<ul style="list-style-type: none"> ▪ Reduces evaporation ▪ Monitors fluid levels 			<ul style="list-style-type: none"> ▪ Automated QC bead vortexing 				
iQue Forecyt® Software	Features	<ul style="list-style-type: none"> ▪ Auto compensation ▪ Real-time whole-plate data analysis ▪ Dynamic linked gating ▪ Interactive heat maps, profile maps 			<ul style="list-style-type: none"> ▪ Cross plate analysis ▪ Export files in FCS, CSV or iQue Forecyt® formats ▪ Customizable PDF data report ▪ iQue Forecyt® Enterprise Edition compatible 				
Operational	Computer workstation, Windows compatible	Xeon processor, dual 256 GB SSD (RAID 0), 16 GB RAM, 27" monitor 2560 x 1400							
	Weight (less computer)	205 lbs, 93 kg							
	Dimensions	39" W x 25" D x 26" H 99 cm W x 63 cm D x 66 cm H							
	Power requirements	100 115 230 VAC, 50–60 Hz							
	Environment requirements	Temperature: 15–32° C (59–90° F), Relative humidity: 80% maximum							
Features	<ul style="list-style-type: none"> ▪ CE labeled ▪ 21 CFR logging option compatible 			<ul style="list-style-type: none"> ▪ Robotic integration option compatible ▪ iQue® Qmax refill module option compatible 					

iQue® technology is protected by the following patents and other patents pending:

6,890,487, 6,878,556, 7,368,084, 7,842,244, 8,021,872, 8,268,571, 8,637,261, 8,823,943, 9,012,235, D,722,515



Microsart® ATMP Mycoplasma

Rapid Real-time PCR Mycoplasma Detection Kit for testing ATMPs

User Benefits

- Highest Level of Security
- Designed for ATMP Testing
- Easy Handling



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 reliable detection of Mycoplasma contamination in autologous cell transplant culture. The Microsart® ATMP Mycoplasma kit was validated according to 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 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 like autologous chondrocyte transplants (ATMPs – advanced therapy medical products).

High Performance

The Microsart® ATMP Mycoplasma kit has been developed for EP complaint Mycoplasma testing in autologous cell transplants. A detection limit of less than 10 cfu/ml for all Mycoplasma species mentioned in the European Pharmacopoeia fulfills the requirements for the needed 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 PCR result takes only a few hours.

TaqMan® Probes

The use of TaqMan® probes adds specificity to the PCR detection system. The analysis is performed during the cycling process – no 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 use of uracil-DNA glycosylase (UNG). Thus the occurrence of false-positive results can be minimized. UNG is not included in the kit.

Technical Specifications

Each Kit contains all required reagents for 25 or 100 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 to be stored until use at +2 to +8°C and must be stored after opening and rehydration below -18°C. The lot specific Certificate of Analysis can be downloaded from the manufacturer's website (www.minerva-biolabs.com).

Order Information

Description	Quantity	Order No.
Mycoplasma Kits		
Microsart® ATMP Mycoplasma	25	SMB95-1003
Microsart® ATMP Mycoplasma	100	SMB95-1004

Accessories		
Microsart® AMP Extraktion	50 extractions	SMB95-2003

Related Products		
Microsart® AMP Mycoplasma	25	SMB95-1001
Microsart® AMP Mycoplasma	100	SMB95-1002
Microsart® RESEARCH Mycoplasma	25	SMB95-1005
Microsart® RESEARCH Mycoplasma	100	SMB95-1006

Summary

The Microsart® ATMP Mycoplasma kit is the optimal solution for all QC labs which performing Mycoplasma testing of cell-based therapeutics like autologous chondrocyte transplants.

Unlike competitive PCR Detection kits, the Microsart® ATMP Mycoplasma kit is dedicated for the specific application in regard to sample volume, sensitivity, robustness and specificity.

Kit Component	25 Reactions	100 Reactions
Order No.	SMB95-1003	SMB95-1004
Mycoplasma Mix	1 × lyophilized	4 × lyophilized
Rehydration Buffer	1 × 1.0 ml	4 × 0.5 ml
Positive Control	1 × lyophilized	1 × lyophilized
Internal Control	1 × lyophilized	4 × lyophilized
PCR grade Water	1 × 1.5 ml	4 × 1.5 ml

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Italy +39.0362.5557.11
Spain +34.913.586.095
Russian Federation +7.812.327.53.27
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Order No.: 85037-540-16
Ver. 10|2017



Microsart® ATMP Bacteria/Fungi/Sterile Release Microsart® RESEARCH Bacteria/Fungi

Rapid detection of total fungi in ATMPs prior treatment

User Benefits

- All critical bacterial and fungal contaminants 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, enables 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 18 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 pre-check 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 cyclers 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	Microsart® ATMP Bacteria	Microsart® ATMP Fungi	Microsart® RESEARCH Bacteria (25 100)	Microsart® RESEARCH Fungi (25 100)
		SMB95-1007 (10 patient samples)	SMB95-1008 (100 rxn)	SMB95-1012 (100 rxn)	SMB95-1009 (25 rxn) SMB95-1010 (100 rxn)	SMB95-1014 (25 rxn) SMB95-1013 (100 rxn)
ATMP Bacteria Mix	red	10 x lyophilized	4 x lyophilized	-	4 x lyophilized	-
ATMP Fungi Mix	orange	10 x lyophilized	-	4 x lyophilized	-	4 x lyophilized
Rehydration Buffer	blue	10 x 0.5 ml	4 x 0.5 ml	4 x 0.5 ml	4 x 0.5 ml	4 x 0.5 ml
Positive Control DNA	green	10 x lyophilized	1 x lyophilized	1 x lyophilized	1 x lyophilized	1 x lyophilized
Internal Control DNA	yellow	10 x lyophilized	4 x lyophilized	4 x lyophilized	4 x lyophilized	4 x lyophilized
PCR grade Water	white	20 x 1.5 ml	5 x 1.5 ml	5 x 1.5 ml	5 x 1.5 ml	5 x 1.5 ml
Lysis Buffer	transparent	10 x 1.8 ml	-	-	-	-
Suspension Buffer	violet	10 x 1.5 ml	-	-	-	-
Processing Tubes	-	10 x 3	-	-	-	-

Related products

DNA Extraction kits

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

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, 108 genomes/vial for all bacteria and 106 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 Bacteria 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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NutriFreez[®] D10 Cryopreservation Medium

Powerful cryopreservation media optimized for various cells and tissues



NutriFreez[®] D10 Cryopreservation Medium is an optimized freezing solution designed and validated for the cryopreservation of various tissue and cell types, including but not limited to sensitive cell types such as hESCs, iPSCs, and MSCs. NutriFreez[®] D10 Medium maintains defined and animal component-free conditions during cryopreservation, essential to maintaining consistency when culturing cells in a xeno-free system. NutriFreez[®] D10 Medium is ready-to-use and pre-formulated with DMSO, providing a protective environment for cells during the freezing, storage, and thawing process. Cells preserved with NutriFreez[®] D10 Medium show excellent attachment (Figure 1) and maintain proper pluripotency marker expression after thawing, with superior results compared to both serum-containing freezing media, other serum-free solutions, and homebrew formulations¹.

- High recovery post thaw
- Ready-to-use solution
- Serum-free and protein-free
- Chemically-defined
- cGMP-manufactured

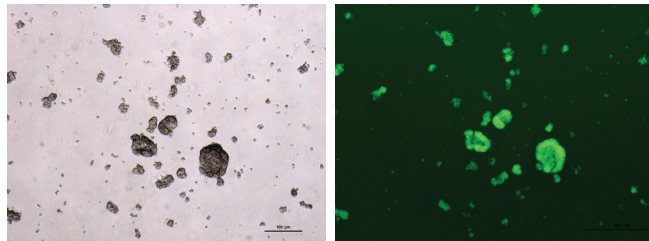


Figure 1: BG01V/hOG cells (an Oct4-GFP reporter hES cell line) frozen in NutriFreez[®] D10 Medium and thawed into NutriStem[®] hPSC Medium on Matrigel. Images taken just 1 hour post-thaw show excellent survival and attachment of the hES cells, with high expression of Oct4 (green).

Applicable Cell Types

- Human Embryonic Stem Cells
- Induced Pluripotent Stem Cells
- Human Mesenchymal Stem Cells
- Peripheral Blood Mononuclear Cells
- Human Endothelial Cells
- T cells, including Chimeric Antigen Receptor (CAR T) Cells and Tumor Infiltrating Lymphocytes (TILs)
- Neuron Cells
- Hybridomas
- CHO Cells
- Vero Cells
- Multiple mammalian cell lines: MRC-5, HEK-293, HepG2, HeLaBSC-1, BGM3T3, MA-10BHK-21

Ordering Information

Cat. #	Product	Qty
05-713-1A	NutriFreez [®] D10 Cryopreservation Medium	500 mL
05-713-1B		100 mL
05-713-1E		50 mL
05-713-1C		20 mL
05-713-1D		10 mL
05-714-1A	NutriFreez [®] D10 Cryopreservation Medium, w/o phenol red	500 mL
05-714-1B		100 mL

1. Nishishita N, et al. An effective freezing/thawing method for human pluripotent stem cells cultured in chemically-defined and feeder-free conditions. *AJSC* 2015;4(1):38-49.

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Turn data into growth

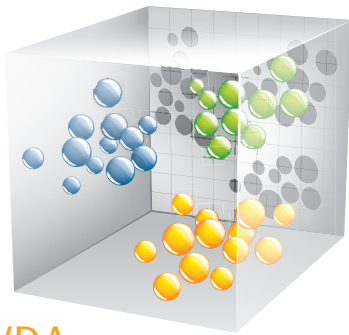
Simplifying Progress

SARTORIUS

SIMCA[®] helps you see what others don't

Every day your business creates a wide variety of data from many different sources. This data holds the key to better performance.

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MVDA
Multivariate
Data Analysis

Who is using SIMCA?

Wherever you create data you can use SIMCA. That's why companies in many different industries have worked with us to help their business grow.

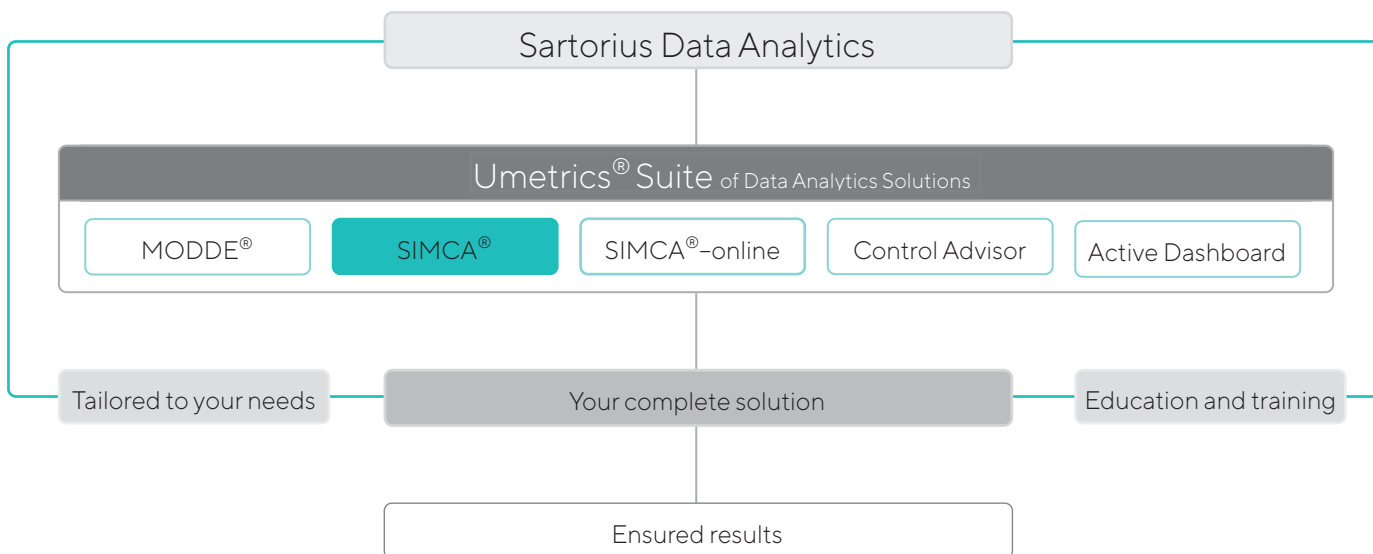
- A major bio-process company improved process yield by 75%, reduced cycle time by 40% and trebled plant output.
- An international food processing company resolved a logistics issue and saved USD 1 million per year in shipping costs.
- A wastewater treatment company used SIMCA to improve their processes for a cleaner, safer environment.



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- Flexibility to handle complex data in many forms
- Powerful multivariate tool
- An easy way to script your workflow
- Seamless model update integration with SIMCA[®]-online

More than Software



“ Using SIMCA to solve problems has saved us millions of dollars over the years.

Timothy Michaelson, Senior Manufacturing Excellence Consultant at International Paper



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