

# **Mobius® iFlex Bioreactor**

The next generation of high performance single-use modular bioreactors for fed-batch and perfusion processes

The Mobius<sup>®</sup> iFlex Bioreactor is a scalable family of single-use bioreactors, ranging from 50 L to 2000 L and suitable for process development and commercial manufacturing.

With optional and configurable modules designed to adapt to a variety of control strategies, biopharmaceutical manufacturers can switch from fedbatch to perfusion and be highly responsive to market demand, uncertainty, or a change in strategy. As a skid ready to integrate into your preferred automation platform, the Mobius<sup>®</sup> iFlex Bioreactor enables your transition into the automated biomanufacturing facility of the future.

Single-use bags constructed with high-strength Ultimus<sup>®</sup> film meet the demands of both fed-batch and intensified processes, and perfusion capabilities are within reach with the Cellicon<sup>®</sup> filter assemblies for perfusion.

With best-in-class process analytical technology (PAT) capabilities, the Mobius<sup>®</sup> iFlex Bioreactor integrates all the sensors your upstream process requires for monitoring and control of critical process parameters. Additionally, the system is ready to connect to Raman analyzers and autosamplers for streamlined analytics for advanced process monitoring and control.



## **Benefits**

- High performance with enhanced mixing and oxygen transfer.
- Flexibility to fulfill batch, fed-batch and perfusion processes.
- Scalability from 50 L to 2000 L.



## **Features**

# Enhanced bioreactor performance to meet the requirements of the most demanding upstream processes

- The single-use bag incorporates three spargers, providing a wide range of oxygen mass transfer coefficient  $(k_L a > 50 \text{ hr}^1)$  and characterized bubble sizes, to accommodate unique gassing strategies while minimizing bubble shear.
- The optimized bottom-mounted impeller design leads to fast mixing times and higher power density (P/V up to 100 W/m<sup>3</sup>) while minimizing tip speed and mechanical shear.
- The internal X-baffle allows for fast homogeneous mixing, while preventing the formation of a vortex.

# Flexible design to fit highly diverse operational strategies, balancing today's needs with tomorrow's expectations

- Fed-batch tower with up to five peristaltic pumps and up to seven mass flow controllers (MFC), allowing for a broad range of flow rates suiting both traditional and intensified needs.
- Optional fully integrated perfusion tower for complete monitoring and control of perfusion processes, with feedback loops for bioreactor and Cellicon<sup>®</sup> filter assemblies.
- Multiple addition lines at the top, side, and bottom of the single-use bag with a variety of tubing dimensions for welding, providing versatility for sterile connections.
- Double-jacketed vessel on load cells, with electrical cabinet incorporating connectors for single-use and multi-use sensors to meet advanced control and operational strategies.

# Designed with scalability engineering principles in mind, to facilitate both scale up and down

- Consistent geometry across all sizes.
- Spargers scaled by open sparger area to achieve constant gas velocity (m/s) at maximum sparger flow rate.
- Impellers scaled by keeping consistent power number ( $N_{\rm p}$ ) with <2.2 m/s tip speed, achieving mixing times <35 seconds.
- Demonstrated engineering performance from 50 L to 2000 L.

## **System Components**

#### Fed-batch hardware configuration

The constantly increasing complexity of process strategies in the biopharmaceutical industry demands a scalable single-use bioreactor that can operate in the widest range of process conditions. The Mobius<sup>®</sup> iFlex Bioreactor is designed to meet this need. In its fed-batch configuration, the system is composed of a bioreactor vessel, a fed-batch tower, and a control station.

The vessel is provided on load cells and has a door for easy bag installation, with a viewing window for visual inspection of your cell culture. The electrical box incorporates connections for the sensors you need to enable monitoring and automated control of process parameters, such as pH, DO,  $pCO_2$  and VCD.

The fed-batch tower can be configured to suit your process requirements, with options available at the time the system is purchased. This tower includes 3–5 peristaltic pumps for liquid additions and 4–7 mass flow controllers for gases (air,  $N_2$ ,  $O_2$  and  $CO_2$ ).

Connection for headspace: Any MFC of choice can be directed to the headspace

Vibrant M: Indicates system status (green: no alarms, yellow: non-critical alarms, and red: critical alarms)

> Mass flow controllers: 4-7 MFCs with up to 250:1 turn-down ratio for versatility around gassing strategies

#### Peristaltic pumps:

Variety of pump sizes enables wide range of flow rates to cover needs for all process steps. Blinking LEDs show flow direction when pump is running



Connections for spargers: Open pipe, drilled-hole, and highperformance spargers, with flexibility to direct any MFC to any outlet

#### Vessel on load cells: Feedback loop uses weight of vessel content for process control



Connections for sensors: Monitor and control pH, DO, temperature, viable cell density and pCO<sub>2</sub>, throughout the duration of the cell culture process

#### Vent filter heaters:

Support for Aervent® filters that allow up to 80 SLPM of exhaust gassing per vent filter

Door: for easy bag installation

Viewing window: For visual inspection of your cell culture



Control station for DeltaV™ control platform (optional): 18.5" touch screen HMI, allowing for easy visualization of your process P&ID

#### Shelf with adjustable height for keyboard:

Provides additional ergonomy and comfort for operators to work with the bioreactor



**Openings for lines and sensors:** Side addition lines and aseptic connection for cell retention devices are available, as well as single-use sensors and AseptiQuik® connectors for multi-use sensors

#### **Perfusion hardware configuration**

Fully integrating scalable cell retention devices into your new or existing Mobius® iFlex Bioreactor has now become a reality. Developed as a modular platform, users of the fed-batch Mobius® iFlex Bioreactor can easily transition to a perfusion process, simply by adding a perfusion tower. The robustness and reliability of our Cellicon<sup>®</sup> filter assembly enables perfusion processes with the unparalleled design of a single-use bioreactor that can support ultra-high cell densities.



#### Peristaltic pumps:

Variety of pump sizes enables wide range of flow rates to cover needs for all process steps. Blinking LEDs show flow direction when pump is running:

- Small addition pump (optional)
- Cell bleed pump (optional)
- Perfusion media inlet
- Perfusate pump

Supports for single-use flowmeters: Reduce footprint by eliminating the need for floor scales. SU flowmeters included in single-use assembly for perfusate and media in flow control

Connectors for single-use feed, retentate, and perfusate pressure sensors: Complete process monitoring and control to ensure robust perfusion filter performance

#### Holder for Cellicon<sup>®</sup> Perfusion Filter:

Integrate our ready-to-use assembly for perfusion processes and benefit from the ease of use, reproducibility and scalability of Cellicon® filter assemblies

Non-invasive clamp-on feed flowmeter: Operate feed pump by rpm or flow rate



Low shear levitating pump: Gentle on cells, high cell densities can be produced within davs

# **Bioreactor Flexware® Assemblies**

Existing single-use bioreactor bags have limited ports for sensors and a small number of lines for additions, making them poorly suited for the complex feeding strategies of today's biologics manufacturing processes. Additionally, they have limited operating conditions because they use spargers suited to either low or high oxygen demanding processes and cannot adapt to gassing strategies for intensified processes.

The Flexware<sup>®</sup> assembly for the Mobius<sup>®</sup> iFlex Bioreactor is designed for maximum operational flexibility, ergonomic usability, and operational safety. The bag is made of Ultimus<sup>®</sup> film, a damage-resistant, single-use film that is resilient for the toughest bioprocessing applications. It contains a woven nylon layer that provides a protective barrier against abrasion, impact damage, tears, and material fatigue. With an Irgafos<sup>®</sup> 168 free contact layer and a low extractable profile, Ultimus<sup>®</sup> film offers cell growth comparable to glass without the need for clean-in-place (CIP) and steam-in-place (SIP) operations.

**Designed for flexibility and long durability:** Multiple weldable, labeled lines, precisely selected to enable 40-day duration and a wide range of flow rates

#### Perfusion-ready:

Standard bags include AseptiQuik<sup>®</sup> connectors for smooth connection to cell retention devices

Port for ProCellics™ Raman Analyzer: Ports are incorporated in all

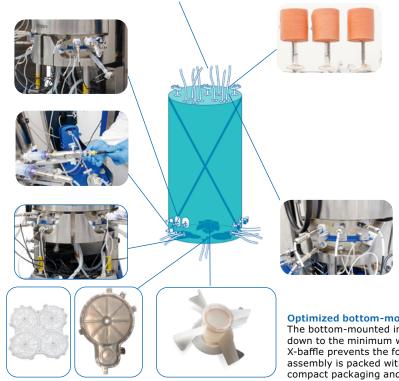
standard bags for seamless sensor integration

#### Effortless

process sampling: Options available for manual sampling using luer lock connector or via welding. Bag is ready to connect to MAST® Autosampling Solution

#### Wide range of mass

transfer of oxygen ( $k_La$ ): All bags integrate an open pipe and two drilled-hole spargers with different pore sizes, achieving  $k_La > 50$  hr<sup>1</sup>



#### Safe operation with primary and back-up connectors for vent filters:

Lynx® S2S sterile connectors for vent filter assemblies comprised of the hydrophobic Opticap® XL5 capsule with hydrophobic Aervent® filters. All bags integrate a single-use pressure sensor, that in conjunction with a safety interlock prohibits overpressurizing the singleuse bioreactor bag, ensuring a safe operation at all times

Process control and monitoring enabled by variety of sensors: Single-use pH, DO and VCD sensors are available, as well as ports with sterile connectors for multi-use sensors

**Optimized bottom-mounted impeller design:** The bottom-mounted impeller ensures gentle agitation down to the minimum working volume and the internal X-baffle prevents the formation of a vortex. The bag assembly is packed with folding patterns, allowing for compact packaging and easy installation

#### **Unparalleled oxygen transfer**

A common challenge of modern, intensified upstream processes is meeting the increased oxygen demand when targeting higher cell densities without working at the maximum capabilities of your single-use bioreactor. It is therefore critical to deliver the appropriate mass transfer while simultaneously managing cell shear and foaming.

With these challenges in mind, we have developed new single-use spargers that offer best-in-class performance to support a wide range of viable cell densities, by balancing high oxygen transfer while minimizing cell bubble shear. We have developed an innovative new sparging strategy, adding two laser drilled hole spargers on Ultimus<sup>®</sup> film and a novel air distribution method that ensures consistent gas bubble sizes across all scales. A high performance sparger, an average pore size of 25 µm, enables maximum  $k_La$ , while a second mid-range drilled-hole sparger, with pore sizes of 150 µm, creates larger bubbles for intermediate  $k_La$  needs. Lastly, the traditional open pipe sparger is efficient at delivering macro-bubbles and can be used on its own for gas supply or in combination with other spargers. This approach provides increased process control capabilities, such as addition of carbon dioxide for pH regulation or as a tool to strip excess carbon dioxide. All three spargers are included in our standard single-use bags, enabling operators to execute different gassing strategies, by using any or all three spargers simultaneously. This flexibility reduces the need for bag customizations and for large stocks of several different bag configurations.

### **Advanced mixing performance**

Our bioreactor bags include a bottom-mounted, 15° off-centered 4-blade impeller, with a fin provided on each blade for maximum impeller stability at high rpm. To simplify scalability, impeller power number is kept constant across scales. The internal X-baffle prevents the formation of a vortex during mixing and allows the bottom-mounted impeller to deliver mixing times of under 35 seconds. By eliminating a shaft, our bags are delivered collapsed in a compact packaging, which ultimately reduces the transportation and storage costs and the environmental impact of packaging, while making bag installation easier for upstream operators.

## **Mobius® iFlex Bioreactor Services**

To help you navigate the highly regulated and challenging environment of the pharmaceutical and biotechnology industry, we offer a wide range of services that can help you save time, lower costs, and comply with your specific requirements of performance and quality. For peace of mind, all our services are performed by our global experts who have an intimate knowledge of our equipment backed by decades of experience.



## **Qualification Services**

Our qualification services are designed to make the integration of our system into your process as seamless as possible and to ensure your equipment is properly installed and functioning per your pre-defined requirements. These services are aligned with the ASTM E2500 guideline, ensuring consistency and efficiency in our qualification strategy.

- Factory acceptance test (FAT)
- Installation qualification/operational qualification (IQ/OQ)
- Performance qualification support (PQ)

### **Training Services**

Our training offering has been designed to make your staff more autonomous in managing your system and your process while saving time and money. Our training services cover system use with interactive hands-on sessions including:

- Installing the Flexware® assemblies
- Designing and scaling your process
- Troubleshooting
- Process recommendations

These trainings can be delivered either at your site or in our M Lab<sup>™</sup> Collaboration Centers. Please contact your local representative or email ilearn@milliporesigma.com to discuss our training offering.

### **System Service Reliance Plans**

To support you in ensuring optimum equipment uptime and regulatory compliance while mitigating risks, we have developed a complete range of services for your systems and equipment: System Service Reliance Plans. These comprehensive packages offer priority access to a wide range of services and support, ensuring your equipment is properly maintained and allowing you to select a coverage level that best fits your needs. For additional details, please refer to the System Service Reliance Plans Data Sheet (DS7881EN).

## **Spare Parts & Repair Services**

#### **Repair services**

In the unlikely case your system does experience a problem, our worldwide engineering organization will provide on-site technical support to get you back up and running as quickly as possible.

#### Spare parts

Purchasing spare parts directly from us is the only way we can guarantee that you get the right parts every time, with the same level of performance as the original. For details and ordering information, please check the illustrated spare parts list (AD12083EN).

Learn more on our systems services at SigmaAldrich.com/services-plans

# **Specifications**

# System and Flexware® Assembly Specifications

### **General System Specifications**

Mobius <sup>®</sup> iFlex Bioreactor	200 L	2000 L
Working Volume (L)	40-200	400-2000
Total bioreactor volume (L)	240	2400
Total Height-to-Diameter Ratio	2:1	2:1
Vessel Diameter	54.6 cm (21.3 in.)	115.8 cm (45.6 in.)
Impeller Position	Bottom mounted	d 15° from center
Impeller Diameter	21 cm (8.3 in.)	40.6 cm (16 in.)
Impeller Geometry	Down-pumping pitc	ched blade (4 blades)
Impeller Power Number	3.6	3.7
Internal Baffle	X-b	paffle

## Mechanical Specifications Mobius® iFlex Bioreactor 200 L

	Bioreactor vessel	Fed-batch tower	Perfusion tower	Control station		
*Dimensions (W × D × H)	806 mm × 1100 mm × 1746 mm, max 2142 mm with vent heaters (31.7 in. × 43.3 in. × 68.7 in., max 84.3 in. with vent heaters)	400 mm × 533 mm × 1574 mm (15.8 in. × 20.9 in. × 61.9 in.)	450 mm × 964 mm × 1598 mm (17.8 in. × 37.9 in. × 62.9 in.)	With shelf: 620 mm × 660 mm × 1547 mm (24.4 in. × 26.0 in. × 60.9 in. Without shelf: 620 mm × 530 mm × 1547 mm (24.4 in. × 20.9 in. × 60.9 in.)		
Net weight (empty)	460 kg (1014 lbs)	230 kg (507 lbs)	170 kg (375 lbs)	120 kg (265 lbs)		
Wheels including levelling feet	4 wheels, with integrated leveling feet		4 wheels, with 2 brakes			
Materials of construction		Stainless steel 304 minimum				

\*Tolerances are provided on the mechanical drawing

## Mechanical Specifications Mobius® iFlex Bioreactor 2000 L

	Bioreactor vessel	Fed-batch tower	Perfusion tower	Control station		
*Dimensions (W × D × H)	1648 mm $\times$ 2447 mm $\times$ 3116 mm, max 3453 mm with vent heaters (64.9 in. x 96.5 in. $\times$ 122.7 max 135.9 in. with vent heaters)	450 mm × 700 mm x 1833 mm (17.8 in. × 27.6 in. × 72.2 in.)	700 mm × 1064 mm × 1788 mm (27.6 in. × 41.9 in. × 70.4 in.)	With shelf: 620 mm × 660 mm × 1547 mm (24.4 in. × 26.0 in. × 60.9 in.) Without shelf: 620 mm × 530 mm × 1547 mm (24.4 in. × 20.9 in. × 60.9 in.)		
Net weight (empty)	1805 kg (3980 lbs)	310 kg (683 lbs)	265 kg (584 lbs)	120 kg (265 lbs)		
Wheels including levelling feet	None (except drawer (×4))		4 wheels, with 2 brakes			
Materials of construction	Stainless steel 304 minimum					

\*Tolerances are provided on the mechanical drawing

### **Operating Specifications**

Mobius <sup>®</sup> iFlex Bioreactor	200 L	2000 L			
Power Supply Voltage System supplied with 5 m power cord (no plug). Permanent connection recommended due to high residual voltage. Cord & plug solution possible but with appropriate instructions to disconnect power from the equipment	IEC 3× 380-400 VAC (6.5 A) IEC 3× 200-220 VAC (9 A) UL 3× 208 VAC (8.5 A)	IEC 3× 380-400 VAC (11 A) IEC 3× 200-220 VAC (19.5 A) UL 3× 208 VAC (19 A)			
System operating temperature	Ambient temperature (15–30 °C)				
Altitude	0 to 2500 m				
Process duration	Validated for 40 days				

# Instrument Specifications for Mobius<sup>®</sup> iFlex Bioreactors

Туре	Тад		Instrument Range	Operating Process Range	Accuracy on Process Range	Notes		
Multi-use pH sensor			0.00–14.00	_ 6.00-8.00	± 0.10 post <i>in situ</i>	Initial 2-point calibration is required (refer to Hamilton technical documentation). In situ calibration is required. For information: drift per day max ± 0.06		
Single-use pH sensor	AT001 AT002		3.00-10.00	(ability to measure 4.00)	calibration	Factory calibration data provided with the single-use element is required and should be entered into the Arc Module. <i>In situ</i> calibration is required. For information: drift per day max ± 0.06		
Multi-use dissolved oxygen sensor	AT003		0-300% air	20-60% air	± 10% of measured value	Initial 2-point calibration is recommended (refer to Hamilton technical documentation). <i>In situ</i> calibration with 100% Air sat. in cell culture media is required. For information: drift per day max ± 2% Air sat.		
Single-use dissolved oxygen sensor	lissolved		saturation	saturation	post <i>in situ</i> calibration	Factory calibration data provided with the single-use element is required and should be entered into the Arc Module. <i>In situ</i> calibration with 100% Air sat. in cell culture media is required. For information: drift per day max ± 2 % Air sat.		
Multi-use partial pressure of carbon dioxide sensor	AT005		0.5–100% volume	0.5–30% volume	Please refer to Hamilton technical documentation: ± 5% of measured value (> 100 mbar)	Initial 2-point calibration is required (refer to Hamilton technical documentation). In situ product calibration can be done additionally (refer to Hamilton technical documentation)		
Multi-use viable cell density sensor	AT006		viable cell		0-700 pF/cm	0-700 pF/cm	Please refer to Hamilton technical documentation. Accuracy at 25 °C: Conductivity (at 0 pF): $\pm$ 25 µS or $\pm$ 1%, whichever value is greater over the entire measuring range	Factory calibration only. Mark zero (zero adjustment) is required before inoculation
Single-use viable cell density sensor					Please refer to Hamilton technical documentation. Accuracy at 25 °C: Conductivity (at 0 pF): ± 5%	Factory calibration data provided in the User Guide is required and should be entered into the Arc Module. Mark zero (zero adjustment) is required before inoculation		
Single-use	Mobius® iFlex 200 L Bioreactor	FE001 FE102	0-0.8 LPM	0.035-0.500 LPM		For indication: accuracy ± 10% of measured value with C-Flex 374 tubing, fluid at 37 °C and water like		
flow sensor	Mobius® iFlex 2000 L Bioreactor	FE001 FE102 FE104	0-8 LPM	0.35-4.16 LPM	n/a	fluid viscosity. Zero adjustment after priming of the lines, with pumps stopped, is required		
Non-intrusive clamp-on flow	Mobius <sup>®</sup> iFlex 200 L Bioreactor	FT101	0-20 LPM	1-6 LPM	n/a	For indication: accuracy ± 10% of measured value with C-Flex 374 tubing, fluid at 37 °C, viscosity <3		
sensor	Mobius® iFlex 2000 L Bioreactor	FT101 FT103	0-80 LPM	20-30 LPM		Cp. Zero adjustment after priming of the lines, with pumps stopped, is required		

# Instrument Specifications for Mobius® iFlex Bioreactors (continued)

Туре	Тад		Instrument Range	Operating Process Range	Accuracy on Process Range	Notes
	Mobius® iFlex 200 L Bioreactor Mobius® iFlex 2000 L Bioreactor	FC100 FC200 FC300 FC300	- 0.2-50 SLPM	1-50 SLPM	1–10 SLPM: ± 0.09 SLPM > 10–50 SLPM: ± 5% of setpoint	
					50 SLPM: 1–10 SLPM: ± 0.09 SLPM > 10–50 SLPM: ± 5% of setpoint	
	Mobius®	FC400 FC500	0.2–50 SLPM or 0.08–20 SLPM	1-50 SLPM or 0.4-20 SLPM	20 SLPM: 0.4-4 SLPM: ±0.036 SLPM > 4-20 SLPM: ± 5% of Setpoint	Zeroing of the MFC after warming up by pressing
Mass flow controllers	iFlex 200 L Bioreactor	FC600 FC700	or 0.04–10 SLPM or 0.02–5 SLPM	or 0.2–10 SLPM or 0.1–5 SLPM	10 SLPM: 0.2-2 SLPM: ±0.018 SLPM > 2-10 SLPM: ± 5% of Setpoint	the "zero button" is recommended. Maximum flow range are given for $N_2$ equivalent (which also applies
					5 SLPM: 0.10-1 SLPM: ± 0.009 SLPM > 1-5 SLPM: ± 5% of Setpoint	to Air and Oxygen) and will be limited in case of CO <sub>2</sub> . Refer to the configurator for maximum flow range with CO <sub>2</sub>
-	Mobius® iFlex 2000 L Bioreactor	FC100 FC200	16.7-200 SLPM	100-200 SLPM	100–200 SLPM: ± 5% of Setpoint	
	Mobius® iFlex 2000 L Bioreactor	FC400 FC500 FC600 FC700	0.2–50 SLPM or 0.08–20 SLPM	1–50 SLPM or 0.4–20 SLPM	50 SLPM: 1-10 SLPM: ± 0.09 SLPM > 10-50 SLPM: ± 5% of setpoint 20 SLPM: 0.4-4 SLPM: ± 0.036 SLPM > 4-20 SLPM: ± 5% of	
Bioreactor bag single- use pressure sensor	PE001		0-6 psi	0-0.5 psi (200 L) 0-0.4 psi (2000 L)	Setpoint n/a	Zero adjustment (offset) of the pressure sensor has to happen when the Flexware® assembly is at atmospheric pressure. Bag pressure interlock value to stop MFCs is set to 0.5 psi for 200 L and 0.4 for 2000 L (detection ± 0.05 psi)
Cellicon® Filter Assembly single-use pressure sensors	PE101 PE102 PE103 (also PE104, P PE106 in Mobiu 2000 L Biorea	is <sup>®</sup> iFlex	-10 to 10 psi	-10 to 10 psi	± 5% of measured value	Zero adjusment (offset) of the pressure sensor has to happen when the Flexware <sup>®</sup> assembly is at atmospheric pressure
Non-intrusive temperature sensor	TE001		-50 to 150 °C	4-40 °C	± 0.2 °C	
Load cells	WE001 WE002		200 L: 0-240 kg	0-240 kg	± 0.6 kg	-
	WE003		2000 L: 0-2400 kg	0-2400 kg	± 6 kg	
Mixer	M201		200 L: 0-350 rpm	0–144 rpm	- n/a	For indication: speed feedback accuracy ± 5% of reading.
			2000 L: 0-140 rpm	27–102 rpm		Mixer is used with a single-use impeller

# Instrument Specifications for Mobius® iFlex Bioreactors (continued)

Туре	Тад		Instrument Range	Operating Process Range	Accuracy on Process Range	Notes
	300 series	oumps	_			
	Mobius® iFlex 200 L Bioreactor	P001 P002 P003 P006 P007 P008 P102	8–408 rpm	15–200 rpm		
	Mobius® iFlex 2000 L Bioreactor	P001 P002 P003 P006				
	500 series	oumps				Pump is used with a
Peristaltic pumps	Mobius <sup>®</sup> iFlex 200 L Bioreactor	P004	0–220 rpm	15–110 rpm	n/a	single-use element (tubing). Accuracy of speed feedback depends on SW calibration of the analog signal (offset
	Mobius® iFlex 2000 L Bioreactor	P007 P102 P104				and slope)
	600 series	pumps	_			
	Mobius <sup>®</sup> iFlex 200 L Bioreactor	P005	0–282 rpm	15–150 rpm		
	Mobius® iFlex 2000 L Bioreactor	P004 P008	-			
	700 series ( Mobius® iFlex Bioreactor:	2000 L	8-360 rpm	15–180 rpm		
Centrifugal pump	P101 (also P Mobius® iFlex Bioreact	2000 L	200 L: 0-7000 rpm 2000 L: 0-8000 rpm	0-4000 rpm	n/a	Pump is used with a single-use element
	Mobius® iFle Bioreactor: ` VH002, VI	VH001,				Recommended temperature
Vent heaters	Mobius® iFlex Bioreactor: VH002, VH003 VH005, VH	VH001, 8, VH004,	- 0−90 °C	0-60 °C	n/a	Recommended temperature setpoint: 55 °C

# Flexware<sup>®</sup> Specifications

Flexware <sup>®</sup> Assembly	2	.00 L			
	Filter	Millipak <sup>®</sup> filters with 0.22 µm hydrophobic Durapore <sup>®</sup> membrane			
Gas Lines (headspace, open pipe, drilled-hole —	Open pipe diameter (1 hole)	7.4 mm			
and high performance spargers) —	High performance sparger pore size	25 $\mu$ m drilled holes in Ultimus <sup>®</sup> film			
	Mid-range drilled-hole pore size	150 µm drilled holes in Ultimus® film			
Compline	Lines with luer lock	2			
Sampling —	Weldable lines for sterile sampling	2			
	MU assembly	7 × ports for MU instruments			
Probes configuration	SU assembly	2 × single-use pH probes, 2 × single-use DC probes, 1 × single-use VCD probe and 3 × ports for MU instruments			
Dimensions of Flexware <sup>®</sup> Box (L $\times$ W $\times$ H)	90.8 cm × 60.3 cm × 26.0 ci	m (35.8 in. × 23.8 in. × 10.3 in.)			
Weight of Box with Flexware <sup>®</sup>	11.2 kg	) (24.7 lbs)			
Weight of Bag Assembly	7.4 kg	(16.1 lbs)			
Flexware <sup>®</sup> Assembly	20	000 L			
	Filter	Millipak <sup>®</sup> filters with 0.22 µm hydrophobic Durapore <sup>®</sup> membrane			
Gas Lines (headspace, open pipe, drilled-hole —	Open pipe diameter (2 holes)	10.4 mm			
and high performance spargers) —	High performance sparger pore size	25 $\mu$ m drilled holes in Ultimus® film			
	Mid-range drilled-hole pore size	150 µm drilled holes in Ultimus® film			
Sampling —	Lines with luer lock	2			
Sampling	Weldable lines for sterile sampling	2			
_	MU assembly	$7 \times \text{ports}$ for MU instruments			
Probes configuration	SU assembly	$2 \times \text{single-use pH}$ probes, $2 \times \text{single-use DC}$ probes, $1 \times \text{single-use VCD}$ probe and $3 \times \text{ports}$ for MU instruments			
Dimensions of Flexware <sup>®</sup> Box (L $\times$ W $\times$ H)	118.1 cm × 77.5 cm × 34.3 c	m (46.5 in. × 30.5 in. × 13.5 in.)			
Weight of Box with Flexware <sup>®</sup>	24.9 kg	a (55.0 lbs)			
Weight of Bag Assembly	18.6 kg	g (41.0 lbs)			
	Mobius <sup>®</sup> Vent Filter Assembly				
Sterile filter	Opticap <sup>®</sup> XL5 capsule with	n Aervent <sup>®</sup> 0.2 µm membrane			
Connector	Male Lynx <sup>®</sup> Co	onnector 1/2" HB			
Dimensions of Assembly Box (L $\times$ W $\times$ H)	43 cm × 19 cm × 13 cm (16.9 in. × 7.5 in. × 5.1 in.)				
Weight of Box with Assembly	0.31 k	g (0.68 lb)			
	Perfusion Media Addition Line				
	BRXPERFB102 (200L)	BRXPERFB105 (2000L)			
	89.5 cm × 59.7 cm × 31.8 cm	89.5 cm × 59.1 cm × 41.9 cm (35.3 in. × 23.3 in. × 16.5 in.)			

# Flexware<sup>®</sup> 200 L Tubing Specifications (BRX0200L101)

Location	Tubing	Tubing Material	Diamet Inner	er (in.) Outer	Tubing Length (in.)	End Connection
	Vent Tubing	Pharma 50	1/2	7/8	3	Female Lynx <sup>®</sup> Connector 1/2" HB
	Vent Tubing	Pharma 50	1/2	7/8	3	Female Lynx <sup>®</sup> Connector 1/2" HB
	Vent Tubing	Pharma 50	1/2	7/8	3	Female Lynx <sup>®</sup> Connector 1/2" HB
						Plug (includes PendoTech® Pressure
	Pressure Sensor	Pharma 50	1/2	7/8	6	Sensor with IP67 connector, 1/2" HE
		Pharma 50	3/8	5/8	72	_
	Medium Addition Tubing	Pharmed	3/8	1/2	24	Plug
		C-Flex-374	1/4	7/16	24	
		Pharma 50	1/4	1/2	6	_
	Small Addition Tubing	Pharma 50	1/8	1/4	60	– Plug
	Small Addition Tubing	Pharmed	1/8	1/4	12	
		C-Flex-374	1/8	1/4	24	
		Pharma 50	1/4	1/2	6	
		Pharma 50	1/8	1/4	60	
	Small Addition Tubing	Pharmed	1/8	1/4	12	– Plug
		C-Flex-374	1/8	1/4	24	_
		Pharma 50	1/4	1/2	6	
		Pharma 50	1/8	1/4	60	—
Тор	Small Addition Tubing	Pharmed	1/8	1/4	12	– Plug
		C-Flex-374	1/8	1/4	24	_
		Pharma 50	1/0	1/4	6	
						_
	Small Addition Tubing	Pharma 50	1/8	1/4	60	– Plug
		Pharmed	1/8	1/4	12	_
		C-Flex-374	1/8	1/4	24	
		Pharma 50	1/4	1/2	6	_
	Small Addition Tubing	Pharma 50	1/8	1/4	60	– Plug
		Pharmed	1/8	1/4	12	_
		C-Flex-374	1/8	1/4	24	
		Pharma 50	1/2	3/4	72	_
	Large Addition Tubing	Pharmed	1/2	3/4	30	– Plug
	Large Addition Tubing - -	C-Flex-374	3/8	5/8	24	Flug
		C-Flex-374	1/4	7/16	24	
	Daufweien Medie Line	Pharma 50	1/4	1/2	12	
	Perfusion Media Line	C-Flex-374	1/4	7/16	60	<ul> <li>AseptiQuik<sup>®</sup> G 1/4" HB</li> </ul>
	Gas Overlay Tubing	Pharma 50	1/4	1/2	24	Millipak <sup>®</sup> Filter Durapore <sup>®</sup> 0.22 $(1/4" HB \times 1/4" HB)$
	·	Pharma 50	1/4	1/2	2	
	Luer sampling	C-Flex-374	1/8	1/4	6	<ul> <li>Needleless sample valve</li> </ul>
		Pharma 50	1/4	1/2	2	
	Luer sampling	C-Flex-374	1/8	1/4	6	<ul> <li>Needleless sample valve</li> </ul>
		Pharma 50	1/4	1/2	2	
	Weldable sampling line	C-Flex-374	1/8	1/4	24	– Plug
		Pharma 50	1/0	1/4	2	
	Weldable sampling line	C-Flex-374	1/4	1/2	24	– Plug
	Tomporatura Droha Dart	Pharma 50	1/0	cannot be		Malaluar
	Temperature Probe Port MU sensor	Molded tubing	1/2	3/4	2.9	Male luer AseptiQuik <sup>®</sup> G 1/2" HB
	MU sensor	(silicone) Molded tubing	1/2	3/4	2.9	AseptiQuik® G 1/2" HB
Lower Front	MU sensor	(silicone) Molded tubing	1/2	3/4	2.9	AseptiQuik® G 1/2 HB
		(silicone)	1/2			
	SU Sensor pH1				n pH 70 NTC (Hamili	
	SU Sensor pH2				n pH 70 NTC (Hamili	ton)
	SU Sensor DO1				Cap S3 (Hamilton)	
	SU Sensor DO2				Cap S3 (Hamilton)	
	SU Sensor VCD			Incy	te-P SU (Hamilton)	
	Cell Retention Device return line	Pharma 50	3/4	1	4	AseptiQuik® G 3/4" HB
	(perfusion return)	Pharma 50	1/4	1/2	12	
						_
	Cell Bleed Line	C-Flex-374	1/4	7/16	24	– Plug
		Pharmed	1/8	1/4	12	_
		C-Flex-374	1/8	1/4	24	

# Flexware<sup>®</sup> 200 L Tubing Specifications continued (BRX0200L101)

Location	Tubing	Tubine Metadal	Diamet	er (in.)	Tubing Length	End Connection
Location	Tubing	Tubing Material	Inner	Outer	(in.)	End Connection
	Open Pipe Tubing	Pharma 50	1/4	1/2	30	Millipak® Filter Durapore® 0.22 (1/4" HB × 1/4" HB), including a non-return valve
	Mid-range Drilled Hole Sparger	Pharma 50	1/4	1/2	30	Millipak® Filter Durapore® 0.22 (1/4" HB × 1/4" HB), including a non-return valve
BottomCe	High Performance Sparger	Pharma 50	1/4	1/2	30	Millipak® Filter Durapore® 0.22 (1/4" HB × 1/4" HB), including a non-return valve
	Cell Retention Device feed line (perfusion outlet)	C-Flex-374	1/2	3/4	48	AseptiQuik® G 1/2" HB
		Pharma 50	1/2	3/4	60	
	Harvest Drain Line	C-Flex-374	1/2	3/4	18	Plug, including a clamp 1.5" TC
	narvest Drain Line	Pharmed	1/2	3/4	30	(between Pharma 50 and C-Flex)
		C-Flex-374	3/8	5/8	18	

# Flexware<sup>®</sup> 2000 L Tubing Specifications (BRX2000L101)

		Diameter (in.)		Tubing Length		
ocation	Tubing	Tubing Material	Inner	Outer	(in.)	End Connection
	Vent Tubing	Pharma 50	1/2	7/8	3	Female Lynx <sup>®</sup> Connector 1/2" HB
	Vent Tubing	Pharma 50	1/2	7/8	3	Female Lynx <sup>®</sup> Connector 1/2" HB
	Vent Tubing	Pharma 50	1/2	7/8	3	Female Lynx <sup>®</sup> Connector 1/2" HB
	Vent Tubing	Pharma 50	1/2	7/8	3	Female Lynx <sup>®</sup> Connector 1/2" HB
	Vent Tubing	Pharma 50	1/2	7/8	3	Female Lynx <sup>®</sup> Connector 1/2" HB
	Vent Tubing	Pharma 50	1/2	7/8	3	Female Lynx <sup>®</sup> Connector 1/2" HB
	Pressure Sensor	Pharma 50	1/2	7/8	6	Plug (includes PendoTech® Pressure Sensor with IP67 connector, 1/2" HB
		Pharma 50	5/8	7/8	96	
		Pharmed	5/8	7/8	36	
	Medium Addition Tubing	C-Flex-374	3/8	5/8	36	– Plug
		C-Flex-374	1/4	7/16	36	_
		Pharma 50	1/4	1/2	84	
		Pharmed	1/4	3/8	24	_
	Small Addition Tubing	C-Flex-374	1/4	7/16	36	– Plug
		C-Flex-374	1/8	1/4	36	-
		Pharma 50	1/4	1/2	84	
		Pharmed	1/4	3/8	24	_
	Small Addition Tubing	C-Flex-374	1/4	7/16	36	– Plug
		C-Flex-374	1/8	1/4	36	-
		Pharma 50	1/4	1/2	84	
Тор		Pharmed	1/4	3/8	24	-
•	Small Addition Tubing	C-Flex-374	1/4	7/16	36	– Plug
		C-Flex-374	1/8	1/4	36	_
		Pharma 50	1/4	1/2	84	
		Pharma 50	1/4	3/8	24	_
	Small Addition Tubing	Pharmed	1/4	7/16	36	– Plug
		C-Flex-374	1/8	1/4	36	_
		Pharma 50	1/4	1/2	84	
		Pharma 50	1/4	3/8	24	-
	Small Addition Tubing	Pharmed	1/4	7/16	36	– Plug
		C-Flex-374	1/8	1/4	36	_
		Pharma 50	3/4	1	96	
		Pharmed	3/4	1	48	-
	Large Addition Tubing	C-Flex-374	1/2	3/4	36	– Plug
		C-Flex-374	1/4	7/16	36	_
		Pharma 50	1/2	3/4	24	
	Perfusion Media Line	C-Flex-374	1/2	3/4	60	<ul> <li>AseptiQuik<sup>®</sup> G 1/2" HB</li> </ul>
	Gas Overlay Tubing	Pharma 50	1/2	3/4	84	Opticap <sup>®</sup> XL300 Filters SPG 0.2 (1/2" HB × 1/2" HB)

# Flexware<sup>®</sup> 2000 L Tubing Specifications continued (BRX2000L101)

Location	Tubing	Tubing Material	Diame	ter (in.)	Tubing Length	End Connection
Location	Tubing	Tubing Material	Inner	Outer	(in.)	End Connection
	Lucz compling	Pharma 50	1/4	1/2	2	Needlelees complexister
	Luer sampling	C-Flex-374	1/8	1/4	6	Needleless sample valve
	Luer sampling	Pharma 50	1/4	1/2	2	Needleless sample valve
	Luer sampling	C-Flex-374	1/8	1/4	6	Needleless sample valve
	Weldable sampling line	Pharma 50	1/4	1/2	2	Plug
	weldable sampling line	C-Flex-374	1/8	1/4	24	Fldg
	Weldable sampling line	Pharma 50	1/4	1/2	2	Dive
	weldable sampling line	C-Flex-374	1/8	1/4	24	- Plug
	Temperature Probe Port	Pharma 50		cannot be	welded	Male luer
	MU sensor	Molded tubing (silicone)	1/2	3/4	2.9	AseptiQuik® G 1/2" HB
	MU sensor	Molded tubing (silicone)	1/2	3/4	2.9	AseptiQuik® G 1/2" HB
	MU sensor	Molded tubing (silicone)	1/2	3/4	2.9	AseptiQuik® G 1/2" HB
	SU Sensor pH1			OneFern	n pH 70 NTC (Hamilto	on)
	SU Sensor pH2			OneFern	n pH 70 NTC (Hamilto	on)
_ower Front	SU Sensor DO1			ODC	) Cap S3 (Hamilton)	
	SU Sensor DO2			ODC	) Cap S3 (Hamilton)	
	SU Sensor VCD			Incy	vte-P SU (Hamilton)	
	Cell Retention Device return line (perfusion return)	Pharma 50	1	1 3/8	6	AseptiQuik <sup>®</sup> L 1" HB
	Cell Retention Device return line (perfusion return)	Pharma 50	1	1 3/8	6	AseptiQuik <sup>®</sup> L 1" HB
	Cell Retention Device return line (perfusion return)	Pharma 50	1	1 3/8	6	AseptiQuik <sup>®</sup> L 1" HB
	Cell Retention Device return line (perfusion return)	Pharma 50	1	1 3/8	6	AseptiQuik® L 1" HB
	(Perreserve)	Pharma 50	3/8	5/8	12	
		C-Flex-374	3/8	5/8	48	-
	Cell Bleed Line	Pharmed	3/8	1/2	24	- Plug
		C-Flex-374	1/4	7/16	24	
	Open Pipe Tubing	Pharma 50	1/2	3/4	66	Opticap® XL300 Filters SPG 0. (1/2" HB × 1/2" HB) including non-return valve
	Mid-range Drilled Hole Sparger	Pharma 50	1/2	3/4	66	Opticap® XL300 Filters SPG 0 (1/2" HB × 1/2" HB) including non-return valve
Bottom	High Performance Sparger	Pharma 50	1/2	3/4	66	Opticap® XL300 Filters SPG 0. (1/2" HB × 1/2" HB) including non-return valve
	Cell Retention Device feed line (perfusion outlet)	C-Flex-374	3/4	1	84	AseptiQuik® L 3/4" HB
	Cell Retention Device feed line (perfusion outlet)	C-Flex-374	3/4	1	84	AseptiQuik® L 3/4" HB
	· ·	Pharma 50	3/4	1	72	
		C-Flex-374	3/4	1	24	Plug, including a clamp 1.5" T
	Harvest Drain Line	Pharmed	3/4	1	36	(between Pharma 50 and C-Fle
		C-Flex-374	1/2	3/4	24	-

# Perfusion Media Line with Single-Use Flowmeter Specifications

Perfusion Media Line Assembly	200 L: BRXPERFB102	2000 L: BRXPERFB105	
Connector	AseptiQuik <sup>®</sup> G 1/4" HB	AseptiQuik <sup>®</sup> G 1/2" HB	
Pump Tubing	BIOPRENE (6.4 mm ID × 11.2 mm OD)	BIOPRENE (12.7 mm ID × 19.1 mm OD)	
Flow Sensor	Single-use Levitronix <sup>®</sup> flow sensor		
Weldable Tubing	C-Flex-374 1/8" ID × 1/4" OD	C-Flex-374 1/2" ID × 3/4" OD	
		C-Flex-374 3/8" ID × 5/8" OD	

# **Ordering Information**

Description		Cat. No
Systems		
Please contact your sales representative for a quotation		
Single-use Assemblies		
Flexware® Assembly for Mobius® iFlex Bioreactor 200 L – Single-use Sensors		BRX0200L101
Flexware® Assembly for Mobius® iFlex Bioreactor 200 L – Multi-use Sensors	1	BRX0200L102
Flexware® Assembly for Mobius® iFlex Bioreactor 200 L – Perfusion Media Line with single-use Flowmeter	ſ	BRXPERFB102
Flexware® Assembly for Mobius® iFlex Bioreactor 2000 L – Single-use Sensors		BRX2000L101
Flexware® Assembly for Mobius® iFlex Bioreactor 2000 L – Multi-use Sensors	-	BRX2000L102
Flexware® Assembly for Mobius® iFlex Bioreactor 2000 L – Perfusion Media Line with single-use Flowmeter	I	BRXPERFB105
Mobius <sup>®</sup> Bioreactor Vent filter assembly		CRVFL05E01
Mobius <sup>®</sup> Bioreactor Clamp Kit	CF	RCLAMPKIT01
Mobius® Bioreactor Clamp Kit (4 packs)	CF	RCLAMPKIT04
System Services		
Qualification	200 L	2000 L
Mobius® iFlex Bioreactor – Factory Acceptance Test, for fed-batch configuration	SSVFATIF5	SSVFATIF1
Mobius® iFlex Bioreactor – Factory Acceptance Test, for perfusion configuration	SSVFATIP5	SSVFATIP1
Mobius® iFlex Bioreactor – IQ/OQ execution (includes protocol in English and travels), for fed-batch configuration	SSVQUAIF5	SSVQUAIF1
Mobius® iFlex Bioreactor – IQ/OQ execution (includes protocol in English and travels), for perfusion configuration	SSVQUAIP5	SSVQUAIP1
Maintenance and Repair	200 L	2000 L
Mobius® iFlex Bioreactor – Essential Service Reliance Plan	SSVESPIB5	SSVESPIB1
		SSVESPIB1
Mobius <sup>®</sup> iFlex Bioreactor – Advanced Service Reliance Plan	+ SSVADCIB5	+ SSVADCIB1
	SSVESPIB5	SSVESPIB1
Mobius® iFlex Bioreactor – Total Service Reliance Plan	+	+
Spare Parts	SSVTOCIB5	SSVTOCIB1
Spare Parts Please refer to share parts list AD12083EN available at SigmaAldrich com/iElex		

Please refer to spare parts list AD12083EN available at SigmaAldrich.com/iFlex

## **Related resources**

Scalability and Performance Guide: PG12163EN.

Scalability from Mobius<sup>®</sup> 3 L Single-use Bioreactor to 50 L – 2000 L Mobius<sup>®</sup> iFlex Bioreactors to support intensified upstream process development: AN12431EN.

A Comparative Analysis of Mixing Characterization Methods in Stirred Tanks: WP11699EN.

Investigation of increasing poloxamer 188 concentrations on bubble size, volumetric mass transfer, and foam generation to enable intensified bioreactor processes: WP12656EN.

Demonstrated Strength and Durability of Ultimus® Film: TB5661EN.

Cellicon® Cell Retention Solution for Process Scale: DS11660EN.

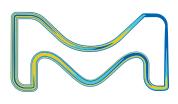
A power number model-based approach for scalable impeller designs to meet oxygenation demands of intensified bioprocesses. PS9878EN.

Novel gas delivery, distribution, and scalability strategies for meeting increased oxygen demand in intensified bioreactor processes. PS12483EN.

For more information on Mobius<sup>®</sup> iFlex Bioreactors, including additional documentation, videos and animations, please visit **SigmaAldrich.com/iFlex** 

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Lit. No. MS\_DS12340EN Ver. 4.0 03/2025