

## Mobius® iFlex Bioreactor

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

Biopharmaceutical molecule pipelines are diversifying, with an increasing number of candidates and new modalities. To keep up with this evolution, cell culture processes are evolving to deliver higher productivity, while increasing the speed to market with reduced risk. To achieve higher outputs, process engineers need to be ready to work on upstream process intensification and perfusion without forgetting traditional fed-batch, from seed train to the production bioreactor. Therefore, the equipment required needs to offer flexibility in manufacturing modes. Efficiently implementing process intensification requires a combination of several different technologies, namely bioreactors capable of supporting the high cell densities that can be achieved via intensified upstream processing.

The Mobius® 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 fed-batch 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® iFlex Bioreactor enables your transition into the automated biomanufacturing facility of the future. Single-use bags constructed with high-strength Ultimus® film meet the demands of both fed-batch and intensified processes, and perfusion capabilities are within reach with the Cellicon® filter assemblies for perfusion. With best-in-class process analytical technology (PAT) capabilities, the Mobius® 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 coefficients ( $k_{La} > 50 \text{ hr}^{-1}$ ) and characterized bubble sizes, to accommodate cell densities of up to 200 e6 cells/mL (estimated based on average cellular oxygen consumption rate of 5 pmol/cell\*day) and 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; 250:1 turn-down ratio), allowing for a broad range of flow rates suiting both traditional and intensified need.
- Optional fully integrated perfusion tower for complete monitoring and control of perfusion processes, with feedback loops for bioreactor and Cellicon® 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 ( $N_p$ ) 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® 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<sub>2</sub> 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<sub>2</sub>, O<sub>2</sub> and CO<sub>2</sub>).

**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 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 high-performance spargers, with flexibility to direct any MFC to any outlet

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

**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 comfort for operators to work with the bioreactor

**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

**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® 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® 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 days



## 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® assembly for the Mobius® iFlex Bioreactor is designed for maximum operational flexibility, ergonomic usability, and operational safety. The bag is made of Ultimus® 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® 168 free contact layer and a low extractable profile, Ultimus® 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 30-day duration and a wide range of flow rate

### Perfusion-ready:

Standard bags include AseptiQuik® connectors for smooth connection to cell retention devices



### Port for ProCellics™

#### Raman Analyzer:

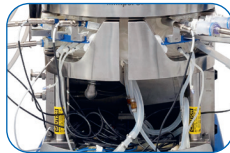
Ports are incorporated in all standard bags for seamless sensor integration



### Effortless

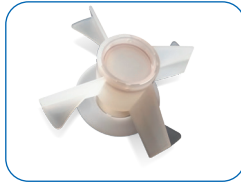
#### process sampling:

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 ( $k_L a$ ):

All bags integrate an open pipe and two drilled-hole spargers with different pore sizes, achieving  $k_L a > 50 \text{ hr}^{-1}$

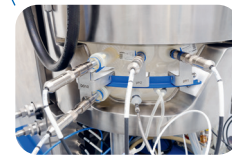


### Safe operation with primary and back-up connectors for vent filters:

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 single-use 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 events 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® 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  $\mu\text{m}$ , enables maximum  $k_L a$ , while a second mid-range drilled-hole sparger, with pore sizes of 150  $\mu\text{m}$ , creates larger bubbles for intermediate  $k_L a$  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

While innovation on sparger design is essential to meet the demands of intensified processes, further optimization of mixing capabilities is also required to maximize oxygenation performance. Typically, higher power inputs are required to enhance sparger benefits in supporting higher oxygen demands, while reducing mixing times and minimizing cell shear effects across all scales.

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 at full volume and 100 W/m<sup>3</sup> and allows the bottom-mounted impeller to deliver mixing times of under 35 seconds up to 2000 L. 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™ Collaboration Centers. Please contact your local representative or email [ilearn@merckgroup.com](mailto:ilearn@merckgroup.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](https://SigmaAldrich.com/services-plans)

## Specifications

### System and Flexware® Assembly Specifications

#### General System Specifications

Mobius® 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 Motor Speed Operating Range	0–144 rpm	0–102 rpm
Impeller Position	Bottom mounted 15° from center	
Impeller Diameter	21 cm (8.3 in.)	40.6 cm (16 in.)
Impeller Geometry	Down-pumping pitched blade (4 blades)	
Impeller Power Number	3.6	3.7
Internal Baffle	X-baffle	

#### 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	4 wheels, with 2 brakes	4 wheels, with 2 brakes
Materials of construction	Stainless steel 304 minimum	Stainless steel 304 minimum	Stainless steel 304 minimum	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 × 2447 mm × 3116 mm, max 3453 mm with vent heaters (64.9 in. × 96.5 in. × 122.7 max 135.9 in. with vent heaters)	450 mm × 700 mm × 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	4 wheels, with 2 brakes	4 wheels, with 2 brakes
Materials of construction	Stainless steel 304 minimum	Stainless steel 304 minimum	Stainless steel 304 minimum	Stainless steel 304 minimum

#### Operating Specifications

Mobius® 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 Mobius® iFlex Bioreactor 200 L

Tag	Type	Instrument Range	Operating Process Range	Accuracy on Process Range	Notes
AT001 AT002	Multi-use pH sensor	0.00–14.00	6.00–8.00 (ability to measure 4.00)	± 0.10 post <i>in situ</i> calibration	Initial 2-point calibration (refer to Hamilton technical documentation) is required. <i>In situ</i> calibration is required. For information: drift per day max ± 0.06
	Single-use pH sensor	3.00–10.00	6.00–8.00 (ability to measure 4.00)	± 0.10 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 is required. For information: drift per day max ± 0.06
AT003 AT004	Multi-use dissolved oxygen sensor	0–300% air saturation	20–60% air saturation	± 10% of measured value post <i>in situ</i> calibration	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	0–300% air saturation	20–60% air saturation	± 10% of measured value 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.
AT005	Multi-use partial pressure of carbon dioxide sensor	0.5–100% volume	0.5–30% volume	Please refer to Hamilton technical documentation: ± 5% of Measured Value (>100 mbar)	Initial 2-point calibration (refer to Hamilton technical documentation) is required. <i>In situ</i> product calibration can be done additionally (refer to Hamilton technical documentation)
AT006	Multi-use viable cell density sensor	0–700 pF/cm	0–700 pF/cm	Please refer to Hamilton technical documentation. Accuracy at 25 °C: Conductivity (at 0 pF): ± 25 µS or ± 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	0–700 pF/cm	0–700 pF/cm	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
FE001 FE102	Single-use flow sensor	0–0.8 LPM	0.035–0.500 LPM	n/a	For indication: accuracy +/- 10% of measured value with fluid at 37 °C and water like fluid viscosity. Zero adjustment after priming of the lines, with pumps stopped, is required
FT101	Non-intrusive clamp-on flow sensor	0–20 LPM	1.0–6.0 LPM	n/a	For indication: accuracy +/- 10% of measured value with C-Flex 374 tubing, fluid at 37 °C, viscosity < 3 Cp. Zero adjustment after priming of the lines, with pumps stopped, is required
FC100 FC200 FC300	Mass flow controllers	0.2–50 SLPM	1–50 SLPM	Control range: 0.2–50 SLPM Metrology range: 1–10 SLPM +/- 0.09 SLPM >10–50 SLPM +/- 5% of setpoint	Zeroing of the MFC after warming up by pressing the “zero button” is recommended. Maximum flow range are given for N <sub>2</sub> equivalent (which also applies 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>
FC400 FC500 FC600 FC700	Mass flow controllers	0.2–50 SLPM or 0.08–20 SLPM or 0.04–10 SLPM or 0.02–5 SLPM	1–50 SLPM or 0.4–20 SLPM or 0.2–10 SLPM or 0.1–5 SLPM	Please contact your sales representative for accuracy	Zeroing of the MFC after warming up by pressing the “zero button” is recommended. Maximum flow range are given for N <sub>2</sub> equivalent (which also applies 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>
PE001	Bioreactor bag single-use pressure sensor	0 to 6 psi	0 to 0.5 psi	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 (detection +/- 0.05 psi)



## Instrument Specifications Mobius® iFlex Bioreactor 200 L (continued)

Tag	Type	Instrument Range	Operating Process Range	Accuracy on Process Range	Notes
PE102 PE103	Cellicon® Filter Assembly single-use pressure sensors	(-10) to 10 psi	(-10) to 10 psi	± 5% of measured value	Zero adjustment (offset) of the pressure sensor has to happen when the Flexware® assembly is at atmospheric pressure
TE001	Non-intrusive temperature sensor	(-50) to 150 °C	4–40 °C	± 0.2 °C	
WE001 WE002 WE003	Load cells	0–240 kg	0–240 kg	± 0.6 kg	
M201	Mixer	0–350 rpm	0–144 rpm	n/a	For indication: speed feedback accuracy +/- 5% of reading. Mixer is used with a single-use impeller
P001 P002 P003 P006 P007	Peristaltic pump	8–408 rpm	15–200 rpm	n/a	Pump is used with a single-use element (tubing). Accuracy of speed feedback depends on SW calibration of the analog signal (offset and slope)
P004	Peristaltic pump	0–220 rpm	15–110 rpm	n/a	Pump is used with a single-use element (tubing). Accuracy of speed feedback depends on SW calibration of the analog signal (offset and slope)
P005	Peristaltic pump	0–282 rpm	15–150 rpm	n/a	Pump is used with a single-use element (tubing). Accuracy of speed feedback depends on SW calibration of the analog signal (offset and slope)
P008 P102	Peristaltic pump	8–408 rpm	15–200 rpm	n/a	Pump is used with a single-use element (tubing). Accuracy of speed feedback depends on SW calibration of the analog signal (offset and slope)
P101	Centrifugal pump	0–7000 rpm	0–4000 rpm	n/a	Pump is used with a single-use element
VH001 VH002 VH003	Vent Heaters	0.0–90.0 °C	0.0–60.0 °C	n/a	Recommended temperature setpoint: 55 °C

**Note:** SU: single-use; MU: multi-use

## Instrument Specifications Mobius® iFlex Bioreactor 2000 L

Tag	Type	Instrument Range	Operating Process Range	Accuracy on Process Range	Notes
AT001 AT002	Multi-use pH sensor	0.00–14.00	6.00–8.00 (ability to measure 4.00)	± 0.10 post <i>in situ</i> calibration	Initial 2-point calibration (refer to Hamilton technical documentation) is required. <i>In situ</i> calibration is required. For information: drift per day max ± 0.06
	Single-use pH sensor	3.00–10.00	6.00–8.00 (ability to measure 4.00)	± 0.10 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 is required. For information: drift per day max ± 0.06
AT003 AT004	Multi-use dissolved oxygen sensor	0–300% air saturation	20–60% air saturation	± 10% of measured value post <i>in situ</i> calibration	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	0–300% air saturation	20–60% air saturation	± 10% of measured value post <i>in situ</i> calibration	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.
AT005	Multi-use partial pressure of carbon dioxide sensor	0.5–100% volume	0.5–30% volume	Please refer to Hamilton technical documentation: ± 5% of Measured Value (>100 mbar)	Initial 2-point calibration (refer to Hamilton technical documentation) is required. <i>In situ</i> product calibration can be done additionally (refer to Hamilton technical documentation)

## Instrument Specifications Mobius® iFlex Bioreactor 2000 L (continued)

Tag	Type	Instrument Range	Operating Process Range	Accuracy on Process Range	Notes
AT006	Multi-use viable cell density sensor	0–700 pF/cm	0–700 pF/cm	Please refer to Hamilton technical documentation. Accuracy at 25 °C: Conductivity (at 0 pF): ± 25 µS or ± 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	0–700 pF/cm	0–700 pF/cm	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
FE001 FE102 FE104	Single-use flow sensor	0–8 LPM	0.35–4.16 LPM	n/a	For indication: accuracy +/- 10% of measured value with fluid at 37 °C and water like fluid viscosity. Zero adjustment after priming of the lines, with pumps stopped, is required
FT101 FE103	Non-intrusive clamp-on flow sensor	0–80 LPM	20–30 LPM	n/a	For indication: accuracy +/- 10% of measured value with C-Flex 374 tubing, fluid at 37 °C, viscosity < 3 Cp. Zero adjustment after priming of the lines, with pumps stopped, is required
FC100 FC200	Mass flow controllers	16.7–200 SLPM	100–200 SLPM	Control range: 16.7–200 SLPM Metrology range: 100–200 SLPM: +/- 5% of Setpoint	Zeroing of the MFC after warming up by pressing the “zero button” is recommended. Maximum flow range are given for N <sub>2</sub> equivalent (which also applies 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>
FC300	Mass flow controllers	0.2–50 SLPM	1–50 SLPM	Control range: 0.2–50 SLPM Metrology range: 1–10 SLPM +/- 0.09 SLPM > 10–50 SLPM +/- 5% of setpoint	Zeroing of the MFC after warming up by pressing the “zero button” is recommended. Maximum flow range are given for N <sub>2</sub> equivalent (which also applies 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>
FC400 FC500 FC600 FC700	Mass flow controllers	0.2–50 SLPM or 0.08–20 SLPM	1–50 SLPM or 0.4–20 SLPM	Please contact your sales representative for accuracy	Zeroing of the MFC after warming up by pressing the “zero button” is recommended. Maximum flow range are given for N <sub>2</sub> equivalent (which also applies 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>
PE001	Bioreactor bag single-use pressure sensor	0 to 6 psi	0 to 0.4 psi	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 0.4 psi (detection +/- 0.05 psi)
PE101 PE102 PE103 PE104 PE105 PE106	Cellicon® Filter Assembly single-use pressure sensors	(-10) to 10 psi	(-10) to 10 psi	± 5% of measured value	Zero adjustment (offset) of the pressure sensor has to happen when the Flexware® assembly is at atmospheric pressure
TE001	Non-intrusive temperature sensor	(-50) to 150 °C	4–40 °C	± 0.2 °C	
WE001 WE002 WE003	Load cells	0–2400 kg	0–2400 kg	± 6 kg	
M201	Mixer	0–140 rpm	27–102 rpm	n/a	For indication: speed feedback accuracy +/- 5% of reading. Mixer is used with a single-use impeller
P001 P002 P003 P006	Peristaltic pump	8–408 rpm	15–200 rpm	n/a	Pump is used with a single-use element (tubing). Accuracy of speed feedback depends on SW calibration of the analog signal (offset and slope)

## Instrument Specifications Mobius® iFlex Bioreactor 2000 L (continued)

Tag	Type	Instrument Range	Operating Process Range	Accuracy on Process Range	Notes
P007 P102 P104	Peristaltic pump	0–220 rpm	15–110 rpm	n/a	Pump is used with a single-use element (tubing). Accuracy of speed feedback depends on SW calibration of the analog signal (offset and slope)
P004 P108	Peristaltic pump	0–282 rpm	15–150 rpm	n/a	Pump is used with a single-use element (tubing). Accuracy of speed feedback depends on SW calibration of the analog signal (offset and slope)
P005	Peristaltic pump	8–360 rpm	15–180 rpm	n/a	Pump is used with a single-use element (tubing). Accuracy of speed feedback depends on SW calibration of the analog signal (offset and slope)
P101 P103	Centrifugal pump	0–8000 rpm	0–4000 rpm	n/a	Pump is used with a single-use element
VH001 VH002 VH003 VH004 VH005 VH006	Vent Heaters	0.0–90.0 °C	0.0–60.0 °C	n/a	Recommended temperature setpoint: 55 °C

**Note:** SU: single-use; MU: multi-use

## Flexware® Specifications

Flexware® Assembly		200 L
Maximum Operating Pressure		0.5 psi (34.5 mbar)
Gas Lines (headspace, open pipe, drilled-hole and high performance Spargers)	Filter	Millipak® filters with 0.22 µm hydrophobic Durapore® membrane
	Open pipe diameter (1 hole)	7.4 mm
	High performance sparger pore size	25 µm drilled holes in Ultimus® film
	Mid-range drilled-hole pore size	150 µm drilled holes in Ultimus® film
Sampling	Lines with luer lock	2
	Weldable lines for sterile sampling	2
Probes configuration	MU assembly	7 × ports for MU instruments
	SU assembly	2 × single-use pH probes, 2 × single-use DO probes, 1 × single-use VCD probe and 3 × ports for multi-use instruments
Dimensions of Flexware® Box		90.5 cm × 26.7 cm × 60.0 cm (35.6 in. × 10.5 in. × 23.6 in.)
Weight of Box with Flexware®		11.2 kg (24.7 lbs)
Weight of Bag Assembly		7.4 kg (16.1 lbs)
Flexware® Assembly		2000 L
Maximum Operating Pressure		0.4 psi (27.6 mbar)
Gas Lines (headspace, open pipe, drilled-hole and high performance Spargers)	Filter	Millipak® filters with 0.22 µm hydrophobic Durapore® membrane
	Open pipe diameter (2 holes)	10.4 mm
	High performance sparger pore size	25 µm drilled holes in Ultimus® film
	Mid-range drilled-hole pore size	150 µm drilled holes in Ultimus® film
Sampling	Lines with luer lock	2
	Weldable lines for sterile sampling	2
Probes configuration	MU assembly	7 × ports for MU instruments
	SU assembly	2 × single-use pH probes, 2 × single-use DO probes, 1 × single-use VCD probe and 3 × ports for multi-use instruments
Dimensions of Flexware® Box		80.0 cm × 34.3 cm × 120.6 cm (47.5 in. × 13.5 in. × 31.5 in.)
Weight of Box with Flexware®		24.9 kg (55.0 lbs)
Weight of Bag Assembly		18.6 kg (41.0 lbs)
Mobius® Vent Filter Assembly		
Sterile filter		Opticap® XL5 capsule with Aervent® 0.2 µm membrane
Connector		Male Lynx® Connector 1/2" HB
Dimensions of Assembly Box (L × W × H)		43 cm × 19 cm × 13 cm (16.9 in. × 7.5 in. × 5.1 in.)
Weight of Box with Assembly		0.31 kg (0.68 lb)

## Flexware® 200 L Tubing Specifications (BRX0200L101)

Location	Tubing	Tubing Material	Diameter (in.)		Tubing Length (in.)	End Connection
			Inner	Outer		
Top	Vent Tubing	Pharma 50	1/2	7/8	3	Female Lynx® Connector 1/2" HB
	Vent Tubing	Pharma 50	1/2	7/8	3	Female Lynx® Connector 1/2" HB
	Vent Tubing	Pharma 50	1/2	7/8	3	Female Lynx® Connector 1/2" HB
	Pressure Sensor	Pharma 50	1/2	7/8	3	Plug (includes PendoTech® Pressure Sensor with IP67 connector, 1/2" HB)
	Medium Addition Tubing	Pharma 50	3/8	5/8	72	Plug
		Pharmed	3/8	1/2	24	
		C-Flex-374	1/4	1/2	24	
	Small Addition Tubing	Pharma 50	1/4	1/2	6	Plug
		Pharma 50	1/8	1/4	60	
		Pharmed	1/8	1/4	12	
	Small Addition Tubing	C-Flex-374	1/8	1/4	24	Plug
		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	
	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	
	Small Addition Tubing	Pharma 50	1/4	1/2	6	Plug
		Pharma 50	1/8	1/4	60	
		Pharmed	1/8	1/4	12	
	Small Addition Tubing	C-Flex-374	1/8	1/4	24	Plug
		Pharma 50	1/2	3/4	72	
		Pharmed	1/2	3/4	30	
	Large Addition Tubing	C-Flex-374	3/8	5/8	24	Plug
		C-Flex-374	1/4	1/2	24	
		Pharma 50	1/4	1/2	12	
	Perfusion Media Line	Pharma 50	1/4	1/2	12	AseptiQuik® G 1/4" HB
		C-Flex-374	1/4	1/2	60	
Gas Overlay Tubing	Pharma 50	1/4	1/2	24	Millipak® Filter Durapore® 0.22 (1/4" HB × 1/4" HB)	
Luer sampling	Pharma 50	1/4	1/2	2	Needleless sample valve	
	C-Flex-374	1/8	1/4	6		
Luer sampling	Pharma 50	1/4	1/2	2	Needleless sample valve	
	C-Flex-374	1/8	1/4	6		
Weldable sampling line	Pharma 50	1/4	1/2	2	Plug	
	C-Flex-374	1/8	1/4	24		
Weldable sampling line	Pharma 50	1/4	1/2	2	Plug	
	C-Flex-374	1/8	1/4	24		
Temperature Probe Port	Pharma 50	cannot be welded			Male luer	
Lower Front	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	OneFerm pH 70 NTC (Hamilton)				
	SU Sensor pH2	OneFerm pH 70 NTC (Hamilton)				
	SU Sensor DO1	ODO Cap S3 (Hamilton)				
	SU Sensor DO2	ODO Cap S3 (Hamilton)				
	SU Sensor VCD	Incyte-P SU (Hamilton)				
	CRD return line (perfusion return)	Pharma 50	3/4	1	4	AseptiQuik® G 3/4" HB
	Cell Bleed Line	Pharma 50	1/4	1/2	12	Plug
C-Flex-374		1/4	1/2	24		
Pharmed		1/8	1/4	12		
C-Flex-374		1/8	1/4	24		



## Flexware® 200 L Tubing Specifications continued (BRX0200L101)

Location	Tubing	Tubing Material	Diameter (in.)		Tubing Length (in.)	End Connection	
			Inner	Outer			
Bottom	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	
	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	
	CRD feed line (perfusion outlet)	C-Flex-374	1/2	3/4	48	AseptiQuik® G 1/2" HB	
	Harvest Drain Line		Pharma 50	1/2	3/4	60	Plug, including a clamp 1.5" TC (between Pharma 50 and C-Flex)
			C-Flex-374	1/2	3/4	18	
			Pharmed	1/2	3/4	30	
		C-Flex-374	3/8	5/8	18		

## Flexware® 2000 L Tubing Specifications (BRX2000L101)

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

## Flexware® 2000 L Tubing Specifications continued (BRX2000L101)

Location	Tubing	Tubing Material	Diameter (in.)		Tubing Length (in.)	End Connection
			Inner	Outer		
Lower Front	Luer sampling	Pharma 50	1/4	1/2	2	Needleless sample valve
		C-Flex-374	1/8	1/4	6	
	Luer sampling	Pharma 50	1/4	1/2	2	Needleless sample valve
		C-Flex-374	1/8	1/4	6	
	Weldable sampling line	Pharma 50	1/4	1/2	2	Plug
		C-Flex-374	1/8	1/4	24	
	Weldable sampling line	Pharma 50	1/4	1/2	2	Plug
		C-Flex-374	1/8	1/4	24	
	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	OneFerm pH 70 NTC (Hamilton)				
	SU Sensor pH2	OneFerm pH 70 NTC (Hamilton)				
	SU Sensor DO1	ODO Cap S3 (Hamilton)				
	SU Sensor DO2	ODO Cap S3 (Hamilton)				
	SU Sensor VCD	Incyte-P SU (Hamilton)				
	CRD return line (perfusion return)	Pharma 50	3/4	1	4	AseptiQuik® G 3/4" HB
	Cell Bleed Line	Pharma 50	1/4	1/2	12	Plug
		C-Flex-374	1/4	1/2	24	
Pharmed		1/8	1/4	12		
C-Flex-374		1/8	1/4	24		
Bottom	Open Pipe Tubing	Pharma 50	1/2	3/4	66	Opticap® XL300 Filters SPG 0.2 including a non-return valve
	Mid-range Drilled Hole Sparger	Pharma 50	1/2	3/4	66	Opticap® XL300 Filters SPG 0.2 including a non-return valve
	High Performance Sparger	Pharma 50	1/2	3/4	66	Opticap® XL300 Filters SPG 0.2 including a non-return valve
	CRD feed line (perfusion outlet)	C-Flex-374	3/4	1	84	AseptiQuik® G 1/2" HB
	Harvest Drain Line	Pharma 50	3/4	1	72	Plug, including a clamp 1.5" TC (between Pharma 50 and C-Flex)
		C-Flex-374	3/4	1	24	
		Pharmed	3/4	1	36	
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
Flow Sensor	Single-use LEVITRONIX flow sensor	
Pump Tubing	BIOPRENE (6.4 mm ID × 11.2 mm OD)	BIOPRENE (12.7 mm ID × 19.1 mm OD)
Additional Tubing	C-Flex-374 1/8" ID × 1/4" OD	C-Flex-374 3/8" ID × 5/8" OD
		C-Flex-374 1/2" ID × 3/4" OD
Connector	AseptiQuik® G 1/4" HB	AseptiQuik® G 1/2" HB

## Ordering Information

Description	Cat. No	
<b>Systems</b>		
Please contact your sales representative for a quotation		
<b>Single-Use Assemblies</b>		
Flexware® Assembly for Mobius® iFlex Bioreactor 200 L – Single-use Sensors	BRX0200L101	
Flexware® Assembly for Mobius® iFlex Bioreactor 200 L – Multi-use Sensors	BRX0200L102	
Flexware® Assembly for Mobius® iFlex Bioreactor 200 L – Perfusion Media Line with Single-Use Flowmeter	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	BRXPERFB105	
Mobius® Bioreactor Vent filter assembly	CRVFL05E01	
Mobius® Bioreactor Clamp Kit	CRCLAMPKIT01	
Mobius® Bioreactor Clamp Kit (4 packs)	CRCLAMPKIT04	
<b>System Services</b>		
<b>Qualification</b>	<b>200 L</b>	<b>2000 L</b>
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
<b>Maintenance and Repair</b>	<b>200 L</b>	<b>2000 L</b>
Mobius® iFlex Bioreactor – Essential Service Reliance Plan	SSVESPIB5	SSVESPIB1
	SSVESPIB5	SSVESPIB1
Mobius® iFlex Bioreactor – Advanced Service Reliance Plan	+	+
	SSVADCIB5	SSVADCIB1
	SSVESPIB5	SSVESPIB1
Mobius® iFlex Bioreactor – Total Service Reliance Plan	+	+
	SSVTOCIB5	SSVTOCIB1
<b>Spare Parts</b>		
Please refer to spare parts list CA12084EN available at <a href="http://SigmaAldrich.com/iFlex">SigmaAldrich.com/iFlex</a>		

## Related resources

Scalability and Performance Guide: PG12163EN.

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

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 MK\_PS9878EN.

Novel gas delivery, distribution, and scalability strategies for meeting increased oxygen demand in intensified bioreactor processes MK\_PS12483EN.

For more information on Mobius® iFlex Bioreactors, including additional documentation, videos and animations, please visit [SigmaAldrich.com/iFlex](https://SigmaAldrich.com/iFlex)

For additional information, please visit  
[SigmaAldrich.com/product-services](https://SigmaAldrich.com/product-services)

To place an order or receive technical assistance, please visit  
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