

УСТАНОВКИ MOBIUS FLEXREADY BMF



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Mobius® FlexReady Solution for Buffer and Media Preparation

**Fast setup. Maximum adaptability.
Pre-designed and optimized.**



Part of the Mobius FlexReady family of application-specific solutions, the Mobius FlexReady Solution for Buffer and Media Preparation is an easy-to-use system featuring an optimized single-use flowpath designed to fully support your needs. It features a choice of Millipore Express® PES or Durapore® filters which are ideally suited for buffer preparation and cell culture media filtration.

The Mobius FlexReady Solution for Buffer and Media Preparation consists of single-use Flexware™ assemblies, innovative separation devices and process-ready hardware systems to deliver optimal operational flexibility, from process development to clinical production to small-scale commercial manufacturing. The self-contained and disposable nature of the system eliminates maintenance as well as cleaning validation requirements. Accompanied by extensive Millipore support and services, the Mobius FlexReady Solution for Buffer and Media Preparation can help you maximize resource productivity and reduce risk.

- Fast setup of hardware with easy installation of optimally designed Flexware assemblies
- Maximum adaptability to your changing operational needs with single-use flowpaths
- Pre-designed and optimized solution for buffer and media preparation to give you confidence and peace of mind

MODULAR, OPTIMIZED DESIGN

Mobius FlexReady Solutions are ergonomically designed for fast setup, maximum adaptability to changing process needs and reduced operator error. Specially designed hardware conveniently holds pumps, filters and containers, right where you need them. A modular, interlocking multi-cart system offers maximum mobility. The filter end cart is designed to work with all Mobius FlexReady Solutions, leveraging your investment in capital equipment and maximizing resource utilization.



Figure 1. The filter end cart works with all Mobius FlexReady Solutions for optimum equipment utilization.

SCALABLE PROCESS FLUID PREPARATION

The Mobius FlexReady Solution for Buffer and Media Preparation is a single hardware system with scalable Flexware assemblies to process from 100 L to 500 L of solution. The system offers:

- Presized sterilizing-grade filter and product collection assembly
- Optional prefilter for cell culture media filtration
- Innovative low dead volume t-connectors, enabling the use of traditional pressure transducers
- Peristaltic pump with preset constant flowrate
- High-pressure cut-off switch ensures operator safety
- Flexware assemblies designed to fit the hardware and install quickly and easily

NOVEL INTEGRATED TECHNOLOGIES

Opticap® XL Capsules with Millipore Express (Sterile High-Retention) SHR with

Prefilter 0.1 µm Membranes

- For sterilizing-grade performance and mycoplasma removal
- Provides high sterility assurance, broad chemical compatibility, high flow rates and extended throughput for superior process efficiency and economy
- Applications: cell culture media, media additives



Figure 2. Scalable, Reliable Filtration Products

Opticap XL Capsules with Millipore Express (Sterile High-Capacity) SHC 0.05/0.2 µm Membranes

- Provides sterility assurance, broad chemical compatibility and exceptionally high capacity
- Applications: sterile filtration of high-fouling solutions including serum-free media, biologicals, buffers and process intermediates

Opticap XL Capsules with Millipore Express (Sterile High-Flux) SHF 0.2 µm Membranes

- Provides sterility assurance, broad chemical compatibility and exceptionally high flow rates
- Applications: buffers, pH adjusters

Low Dead Volume T-connector

Mobius FlexReady Solutions feature our innovative low dead volume t-connectors that are designed for use with traditional pressure transducers. A LLDPE septum provides the barrier between the process fluid and the transducer thereby eliminating the risk of contamination.



Figure 3. The innovative low dead volume t-connector protects the process fluid from contamination.

Simple Fit with Mobius Single-use Mixing Systems

The Mobius FlexReady Solution for Buffer and Media Preparation easily connects with Mobius Single-use Mixing Systems. Available in 100 L, 200 L and 500 L, the Mobius mixers include an electronic drive unit, and a single-use

Mobius process container with an integral magnetically-driven, levitating impeller. See datasheet DS1175EN00 for more information.

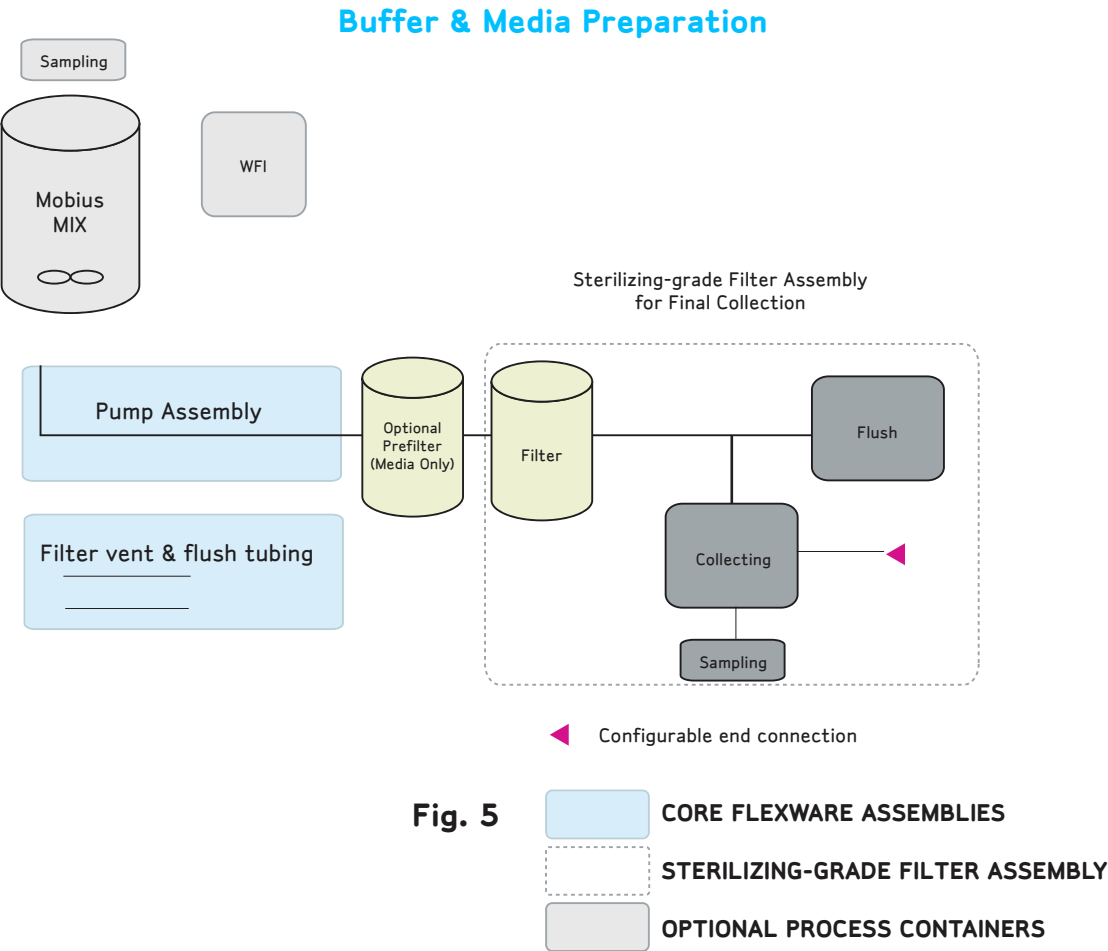


Figure 4. Scalable Single-use Mixing Systems

STANDARDIZED CONFIGURATIONS FOR RELIABLE RESULTS

The flowpath has been carefully designed and tested by our design and applications engineers, resulting in a consistent, standardized flowpath. The Flexware assemblies are gamma-irradiated for low bioburden operations and include a sterilizing-grade filter for final product collection to safeguard product quality. The flowpath (See Fig. 5) consists of:

- Core Flexware assemblies which includes pump tubing assembly, filter vent and flush tubing
- Optional process container for WFI and Mobius Disposable Mixing Assembly
- Sterilizing-grade filter assembly for final collection with sampling container and NovaSeal™ Crimping Sleeve for sterile disconnect
- Choice of TC clamp, quick disconnect couplings, or Lynx® S2S sterile connectors to integrate your final product into your next process step



Select from Standard Flowpath Configurations for Each System

	Buffer Preparation	Media Preparation
Mobius Disposable Mixing Assembly	100 L, 200 L, 500 L	100 L, 200 L, 500 L
Process container for sampling from the Mobius Disposable Mixing System	50 mL, 100 mL, 250 mL, 1 L	50 mL, 100 mL, 250 mL, 1 L
Prefilter	n/a	Opticap XL or XLT capsule with Millipore Express SHC or Durapore membrane
Process container for WFI	20 L, 50 L	20 L, 50 L
Sterilizing-grade Filter Assembly for Final Collection	100 L, 200 L, or 500 L process container and Opticap XL or XLT capsule with Millipore Express SHC, SHF or Durapore membrane	100 L, 200 L, or 500 L process container and Opticap XL or XLT capsule with Millipore Express SHR or Durapore membrane
End connection	Lynx S2S connector, TC Clamp, Quick disconnects (MPC or MPU series)	Lynx S2S, TC Clamp, Quick disconnects (MPC or MPU series)

SPECIFICATIONS

Mobius FlexReady System: BMF

Recommended Operating Parameters	
Fluid Operating Temperature	4 to 40 °C
Max. Operating Pressure	1.7 bar (25 psi)
Feed Flowrate	2 - 10 L/min
Environmental Requirements	4-25 °C, Relative humidity 10-90% (non condensing)

ELECTRICAL REQUIREMENTS		
Supply voltage	100-110 VAC, 50/60 Hz, 1 phase	230 VAC, 50/60 Hz, 1 phase

INSTRUMENTATION	
High pressure switch	Sanitary diaphragm pressure transducer located at the feed pump outlet

WEIGHT (Approx.)	
Pump cart	105 kg (231.5 lbs)
Filter cart	120 kg (264.6 lbs)
Filter support kit	7 kg (15.4 lbs)

DIMENSIONS (H x W x D)	
Pump Cart	1500 x 870 x 800 mm (59.0 x 34.3 x 31.5 in.)
Filter Cart	1050 x 1100 x 800 mm (41.3 x 43.3 x 31.5 in.)

MATERIALS OF CONSTRUCTION (PRODUCT CONTACT)	
Process containers	ULDPE film (PureFlex™ Film)
Tubing	Platinum-cured silicone
Fittings	Polypropylene, polysulfone, polycarbonate, polyvinylidene difluoride
Lynx S2S connector	Polysulfone (connector), silicone (o-ring)
Low dead volume t-connector	LLDPE film (septum), polysulfone (body nut), LLDPE (gauge protector), silicone (o-ring)
TC gaskets	Silicone
SmartSite® valve on sampling process container (optional)	Polyurethane, silicone, acrylic
Filtration devices	See individual filter datasheets

MATERIALS OF CONSTRUCTION (NON-PRODUCT CONTACT)	
Frame	Stainless steel 304 L
Panels	Stainless steel 304 L, Epoxy coating PMS Cool Gray 7
Drip Tray	Stainless steel 304 L
Non-painted exposed surfaces, e.g. shelves, installation bar, installation support, handle bars	Stainless steel 304 L polished 220 grit
Bench	Laminated glass (tempered)
Trays/bins	Polyethylene
Wheels	Nylon non-marking wheels with brakes on 2
Filter supports	Stainless steel 304 L/316 L, POM
Low dead volume t-connector	Polysulfone (nut), nylon (washer), PVC (plug)
Pinch valves	Polypropylene, glass-reinforced nylon
NovaSeal Crimp	Nickel-coated brass
Clips, Clamps	Nylon, borosilicate reinforced nylon, polypropylene, polysulfone, polyester, stainless steel 304

FLEXWARE ASSEMBLIES	
Mobius Bronze Certification: Each assembly is exposed to a gamma irradiation level of 25-40 kGy. Component materials meet criteria for USP<88> Biological Reactivity Test, Class VI Plastics. Assemblies are compliant with EMEA410/01 Rev.2.	

REGULATORY INFORMATION	
The system is manufactured according to the ISO® 9001 quality standard. The system is designed to be compliant with CE and EN 60204.	

ORDERING INFORMATION

Description	Catalogue No.
Core Hardware System	
The core hardware system includes the pumping cart, filter cart with 2 trays (10 L and 50 L), and filter supports.	
100-110VAC 50/60Hz	MBSBA1
230VAC 50/60Hz	MBSBA2
Hardware Accessories	
Collapsible Containers	
250 L bin (holds 100 L or 250 L process container)	MBSACC006U
1,000 L bin (holds 500 L, 750 L, or 1,000 L process container)	MBSACC007U
Containment Trays	
10 L tray (holds 5 L or 10 L process container)	MBSACC005U
50 L tray (holds 20 L or 50 L process container)	MBSACC004U
Services	
Choose from a suite of services, including installation, commissioning validation, training and annual performance review to meet your specific processing requirements. All services are performed by Mobius FlexReady services certified engineers.	
Factory Acceptance Testing (FAT)	SVCMBSEFAT
Installation and Operational Qualification Protocol Performance, Zone* 1	SVCMBSEIQQZ1
Installation and Operational Qualification Protocol Performance, Zone* 2	SVCMBSEIQQZ2
Installation and Operational Qualification Protocol Performance, Zone* 3	SVCMBSEIQQZ3
Installation and Operational Qualification Protocol, BMF	DOCMBSEIQQ
Annual Performance Review, Zone* 1	SVCMBSEAPRZ1
Annual Performance Review, Zone* 2	SVCMBSEAPRZ2
Annual Performance Review, Zone* 3	SVCMBSEAPRZ3

*For Zone and pricing information, contact your local Millipore representative.

Description	Catalogue No.
Flexware Assemblies (Media Prefilter is sold separately)	

For flowpath drawing, see Fig. 5 on pg. 3. Consult with your sales representative to configure your buffer or media preparation flowpath using standard, optimized options.

Each system has a dedicated flowpath, and the flowpath components are not interchangeable between other Mobius FlexReady Solutions.

Recommended Media Prefilter (sold separately)

100L Media Preparation

Opticap Sterile XL05 Millipore Express SHC 0.5 + 0.2 µm 1-1/2 in. TC/TC	KHGES05TT1
Opticap Sterile 4 in. Durapore 0.22 µm 1-1/2 in. TC	KVGLS4TT3

200L Media Preparation

Opticap Sterile XLT10 Millipore Express SHC 0.5 + 0.2 µm 1-1/2 in. TC	KHGES1TTT1
Opticap Sterile XLT10 Durapore 0.22 µm 1-1/2 in. TC	KVGLS1TTT1

500L Media Preparation


Opticap Sterile XLT30 Millipore Express SHC 0.5 + 0.2 µm 1-1/2 in. TC	KHGES3TTT1
Opticap Sterile XLT30 Durapore 0.22 µm 1-1/2 in. TC	KVGLS3TTT1

Mobius Single-use Mixing Systems

Mobius Single-use Mixing Systems must be purchased separately. See datasheet DS1175EN00 for ordering information.

NovaSeal Crimping Solution

The flowpath includes the NovaSeal crimping sleeve for sterile disconnect of sample containers. The NovaSeal crimping tool is sold separately. See datasheet DS1040EN00 Rev. B for ordering information.



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