



Data Sheet

Mobius® FlexReady Solution for Clarification

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



Part of the Mobius FlexReady family of application-specific solutions, the Mobius FlexReady Solution for Clarification is an easy-to-use system featuring an optimized single-use flowpath designed to fully support your clarification needs. It features Millipore's innovative, high-performance Millistak+® Pod disposable depth filters which are ideally suited for primary and secondary clarification.

The Mobius FlexReady Solution for Clarification 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 Clarification 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 Clarification to give you confidence and peace of mind

MOBIUS[®]
byMILLIPORE

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, instrumentation, 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.



Figure 2. Hardware system components move and connect easily for maximum mobility.

EFFICIENT PROCESSING FROM LAB TO PILOT

The Mobius FlexReady Solution for Clarification is designed to process up to 250 liters of high cell density, low viability mammalian cell culture using Millistak+ Pod disposable depth filters without centrifugation. Processing volumes can range up to 500L or even higher, depending upon the feed quality and the use of the centrifuge. The Mobius solution enables clarification operations across a membrane area range of 0.054 m² to 5.5 m². The CL-1 system is designed for lab scale processing, and the CL-2 system efficiently manages pilot scale processing.

- CL-2 system features an ergonomic cart that supports pilot scale Pod filters
- Innovative low dead volume t-connectors, enabling the use of traditional pressure transducers
- Peristaltic pump with preset pressure controls
- High-pressure cut-off switch ensures operator safety
- Presized sterilizing-grade filter and product collection assembly
- Flexware assemblies designed to fit the hardware and install quickly and easily

NOVEL INTEGRATED TECHNOLOGIES

Low Dead Volume T-connectors

Mobius FlexReady Systems feature Millipore's innovative low dead volume t-connector built into the flowpath which is specifically designed for use with traditional pressure transducers. A LLDPE septum provides the barrier between the process fluid and the transducer that eliminates the need to clean sensors while eliminating the risk of contamination.



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

Millistak+ Pod Disposable Depth Filter System

Millistak+ depth filter media is offered in a scalable, single-use format, the Pod Filter System. The Millistak+ Pod system is ideal for a wide variety of primary and secondary clarification applications, including cell cultures, yeast and *E. coli* lysates post centrifuge, *E. coli* refolds, media, vaccines, plasma proteins and sera.

Millistak+ Pod filters are available in three distinct series of media grades in order to meet your specific application needs. Millistak+ DE, CE and HC media deliver optimal performance through a gradient density matrix as well as positive surface charge properties.

Although the Mobius FlexReady Solutions for clarification are designed to accommodate applications from lab to pilot, the Pod depth filter system is also scalable to process scale applications. See datasheet DS0217EN00 to learn more about Pod for process scale applications.



SAFE AND EASY LOADING OF PILOT SCALE POD FILTERS

The Mobius FlexReady Solution, CL-2, for pilot scale processing is uniquely designed with user safety and utility in mind. The Pod cart includes a Pod holder and extension kit, and is ergonomically designed at a convenient height to load pilot scale Pod filters. This cart also includes an easy to clean drip tray, and convenient drawer for supply storage.



Figure 4. Ergonomic cart for easy loading of pilot scale Pod depth filters.



Figure 5. Easy to clean drip tray.

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. 6) consists of:

- Core Flexware assemblies which includes pump tubing assembly, Pod drain & sampling assembly, filter drain line, and Pod vent line
- Sterilizing-grade filter assembly for final collection with sampling containers and NovaSeal™ Crimping Sleeve for sterile disconnect
- Optional process containers for source, buffer, WFI, waste and sampling
- Millistak+ Pod Disposable Depth Filter

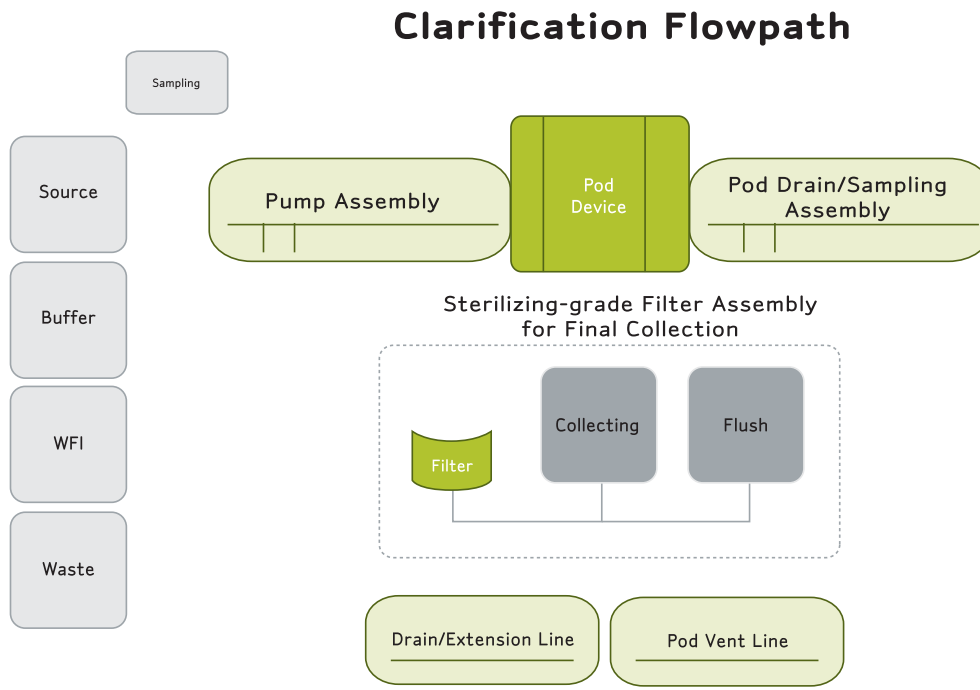

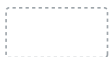
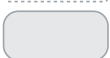


Fig. 6  **CORE FLOWPATH**
 **STERILIZING-GRADE FILTER ASSEMBLY**
 **OPTIONAL PROCESS CONTAINERS**

Select from Standard Flowpath Configurations for Each System

	CL-1	CL-2
Sterilizing-grade filter assembly for final collection	20L process container and Opticap®XL 300 or 600 Capsule with Millipore Express® SHC membrane	250L or 500L process container and Opticap®XL or XLT capsule with Millipore Express® SHC membrane or Durapore® media
Process container for source	20L	100L, 250L, 500L
Process container for buffer	20L, 50L	100L, 250L, 500L
Process container for WFI	20L, 50L	20L, 50L
Process container for waste	20L, 50L	100L, 250L, 500L
Millistak+ Pod Depth Filters (ordered separately)	0.054 m ² (up to 0.11 m ²)	0.11 m ² (up to 5.5 m ²)
Process container for turbidity sampling with SmartSite® sampling port	50 mL, 100 mL, 250 mL, 1L	50 mL, 100 mL, 250 mL, 1L

SPECIFICATIONS

	CL-1	CL-2
Recommended Operating Parameters		
Filtration Area	0.054 m ² - 0.11 m ²	0.11 m ² - 5.5 m ²
Filtrate weight	0 - 50 kg	0 - 600 kg
Fluid Operating Temperature	4 to 25 °C	
Max. Operating Pressure	1.7 bar (25 psi)	
Flowrate	50-100 LMH for filtration, 300 LMH for flushing	
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
		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	
Pressure gauge	Sanitary diaphragm pressure gauge located at depth filter outlet	
Weight		
Pump cart	approx. 90 kg (198.4 lbs)	approx. 110 kg (242.5 lbs)
Pod cart with Pod holder	n/a	approx. 220 kg (485.0 lbs)
Filter cart	approx. 120 kg (264.6 lbs)	approx. 120 kg (264.6 lbs)
Manifold plate	2.5 kg (5.5 lbs)	
Filter support kit	7 kg (15.4 lbs)	10 kg (22.0 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.)	
Pod cart	n/a	1100 x 1070 x 800 mm (43.3 x 42.1 x 31.5 in.)
Materials of Construction (product contact)		
Tubing	Platinum-cured Silicone	Platinum-cured Silicone, Bioprene® TPE tubing for pump
Process containers	ULDPE film (PureFlex™ Film)	
Low dead volume t-connector	LLDPE film (septum), Polysulfone (body nut), LLDPE (Gauge Protector), Silicone (o-ring)	
Fittings	Polypropylene, polysulfone, polycarbonate, polyvinylidene difluoride	
TC Gaskets	Silicone	
SmartSite port on sampling process container (optional)	Silicone, Acrylic, Polyurethane	
Filtration devices	See individual filter datasheets	

SPECIFICATIONS

	CL-1	CL-2
Materials of Construction (non-product contact)		
Pinch valves	Glass-reinforced nylon	
Pilot Scale Holder and extension rods	n/a	Stainless steel 304
Frame	Stainless steel 304L	
Panels	Stainless steel 304L, Epoxy coating PMS 390	
Drip Tray	Stainless steel 304L	
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 locks on 2	
Manifold Plate	Polycarbonate	
Filter supports	Stainless steel 304L/316L, POM	
Low dead volume t-connector	Polysulfone (body nut), nylon (washer), PVC (plug)	
Weigh Scale (Optional), 60 kg (132.3 lbs):	Stainless steel 316TI	
Weigh Scale (Optional), 600 kg (1,328 lbs):	Stainless steel 304	
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	
Mobius FlexReady System, CL-1 The core hardware system includes the pumping cart, filter cart with 2 trays (10L and 50L), and filter supports.	
100-110VAC 50/60Hz	MBSCA1
230VAC 50/60Hz	MBSCA2
Mobius FlexReady System, CL-2 The core hardware system includes the pumping cart, Pod cart with Pod holder and extension rods, filter cart, and filter supports.	
100-110VAC 50/60Hz	MBSCB1
230VAC 50/60Hz	MBSCB2
Hardware Accessories	
Collapsible Containers	
250L bin (holds 100L or 250L process containers)	MBSACC006U
500 - 1,000L bin (holds 500L process container designed for this system)	MBSACC007U
Containment trays	
10L tray (holds 5 or 10L process containers)	MBSACC005U
50L tray (holds 20L or 50L process container)	MBSACC004U
Weigh Scales	
60 kg (132.3 lbs) for CL-1	MBSACC019U
600 kg (1,328 lbs) for CL-2	MBSACC020U
Display 100 -110 VAC 50/60Hz	MBSACC022U
Display 230VAC 50/60Hz	MBSACC023U

Description	Catalogue No.
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	SVCMBSCFAT
Installation and Operational Qualification Protocol Performance Zone* 1	SVCMBSCIQQZ1
Installation and Operational Qualification Protocol Performance Zone* 2	SVCMBSCIQQZ2
Installation and Operational Qualification Protocol Performance Zone* 3	SVCMBSCIQQZ3
Installation and Operational Qualification Protocol, CL-1	DOCMBSC1IQOQ
Installation and Operational Qualification Protocol, CL-2	DOCMBSC2IQOQ
Annual Performance Review Zone* 1	SVCMBSCAPRZ1
Annual Performance Review Zone* 2	SVCMBSCAPRZ2
Annual Performance Review Zone* 3	SVCMBSCAPRZ3

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

Flexware Assemblies (Millistak+ Pod depth filters sold separately)

For flowpath drawing, see Fig. 6 on pg. 4. Consult with your sales representative to configure your Clarification flowpath using standard, optimized options.

Each system has a dedicated flowpath, and the flowpath components are not interchangeable between CL-1 and CL-2. Ensure you order the flowpath for the hardware system you have selected.

Millistak+ Pod Depth Filters

All Millistak + Pod depth filters must be purchased separately. See datasheets DSO217EN00 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.

TO PLACE AN ORDER OR RECEIVE TECHNICAL ASSISTANCE

For additional information call your nearest Millipore office:

In the U.S. and Canada, call toll-free
1-800-MILLIPORE (1-800-645-5476)

In the U.S., Canada and Puerto Rico, fax orders to
1-800-MILLIFX (1-800-645-5439)

Outside of North America contact your local office.

To find the office nearest you: www.millipore.com/offices

Internet: www.millipore.com

Technical Service: www.millipore.com/techservice



www.millipore.com/mobius

ADVANCING LIFE SCIENCE TOGETHER™
Research. Development. Production.

Millipore, Mobius, Millistak+, Durapore, Opticap and Millipore Express are registered trademarks of Millipore Corporation.

ISO is a registered trademark of the International Standards Organization.

Bioprene is a registered trademark of Watson-Marlow Ltd.

SmartSite is a registered trademark of Cardinal Health, Inc.

The M mark and Advancing Life Science Together, FlexReady, Flexware, PureFlex and NovaSeal are trademarks of Millipore Corporation.

Lit. No. DS1065EN00 Rev. B 07/09 DP SBU-09-01811 Printed in U.S.A.

© 2009 Millipore Corporation, Billerica, MA 01821 U.S.A. All rights reserved.