

# Mobius<sup>®</sup> FlexReady Solution for TFF

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



Part of the Mobius FlexReady family of application-specific solutions, the Mobius FlexReady Solution for Tangential Flow Filtration (TFF) is an easy-to-use system featuring an optimized single-use flowpath, and is designed to fully support your TFF needs. The system uses Millipore's leading Pellicon<sup>®</sup> cassettes, which are ideally suited for purification or concentration/diafiltration of monoclonal antibodies, vaccines and therapeutic proteins.

The Mobius FlexReady Solution for TFF consists of single-use Flexware<sup>®</sup> 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. Accompanied by extensive Millipore support and services, the Mobius FlexReady Solution for TFF 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 for TFF 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 filters and containers, right where you need them. The modular, interlocking multi-cart design lets you easily and safely move your system from one space to another. 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.

## TWO SYSTEMS FOR OPTIMUM SCALABILITY

The TF-1 system contains a 10L retentate recycle container and, in typical conditions, will use Pellicon cassettes of up to 0.5 m<sup>2</sup> filtration area. The TF-2 system is designed with a 50L retentate recycle container and, in typical conditions, will use Pellicon cassettes of up to 2.5 m<sup>2</sup> filtration area.

- Designed for minimum working volume and high recovery of protein at high concentrations
- Novel retentate recycle container with levitating magnetic impeller, retentate divertor, and vortex breaker for efficient mixing
- Retentate recycle tank mounted on load cells and integrated transfer pump to enable fed batch and constant volume diafiltration operations
- Innovative low dead volume t-connectors, enabling the use of traditional pressure transducers
- Flexware assemblies designed to fit the hardware and install quickly and easily
- Constant  $\Delta P$  and constant feed flow (calculated) operation
- Ease of operation with an intuitive touch screen interface and user-defined process and alarm set points

## Tank Designed for Efficient Mixing

The retentate recycle tank is specifically designed for efficient concentration and diafiltration of proteins. An innovative single-use process container design incorporates a magnetically coupled levitating impeller, ensuring efficient mixing at high tank levels.

The Mobius FlexReady Solution for TFF provides maximum adaptability to your changing process needs, such as varying volume levels. The low-point retentate return with patented retentate diverter plate and vortex breaker on the container outlet, reduces air entrapment and ensures efficient mixing at low tank levels. The retentate recycle tank is mounted on load cells to enable fed-batch operation, diafiltration and final concentration based on set-point input.



Figure 3. A pivoting retentate recycle tank design facilitates container loading.

## Low Dead Volume T-connector

The Mobius FlexReady Solution for TFF features our innovative low dead volume t-connector built into the flowpath which is 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 4. The innovative low dead volume t-connector prevents pressure sensor contact with the fluid path.

## Pellicon® Cassettes

Pellicon cassettes are the optimum tangential flow filtration (TFF) devices for solutions containing monoclonal antibodies, therapeutic proteins, albumin, hormones, vaccines and growth factors. These advanced, high-performance cassettes are ideal for today's higher titer therapeutic antibodies as well as the more demanding filtration processes that require greater operating pressures and temperatures.



Figure 5. Pellicon Cassettes are ideal for higher titers and more demanding filtration processes.

## Easy and Intuitive Operation

An intuitive, touch screen interface, makes the Mobius FlexReady Solution for TFF easy to operate. The system uses a combination of configurable process alarm set points and automated data acquisition. Transmembrane pressure (TMP) can be set with the help of an automated pressure control valve, and controlled through the touch screen interface along with set point operation for constant pump speed or constant  $\Delta P$ .

The system features a user-configurable set point for controlling tank volume during fed batch processing and diafiltration, as well as a final tank volume end point during ultrafiltration. The TMP value is calculated and shown on the main piping and instrumentation diagram (P&ID) on the interface screen.

The onscreen P&ID provides an easy way to monitor your process in real time, including pump speed, mixer speed, feed, retentate and filtrate pressures, tank temperature, calculated feed flow rate,  $\Delta P$ , TMP, calculated filtrate flow rate, and totalized filtrate weight (requires optional weigh scale). A separate screen shows key process parameter changes over the course of the run.



Figure 6. The Automated Pressure Control Valve (PCV) features a clear outer door enabling a clear view during operation. If the door is opened during operation, the valve automatically shuts off ensuring operator safety.

## Simple Data Management

The system automatically captures time-stamped data for the active parameters and separately logs the alarm and event history. These tab delimited/CSV files can be uploaded directly to your computer. The standard design includes a Profibus card allowing data export to a DCS. The data can also be exported to meet 21CFR Part 11 compliance. An option is available to allow data export through an Ethernet IP protocol.

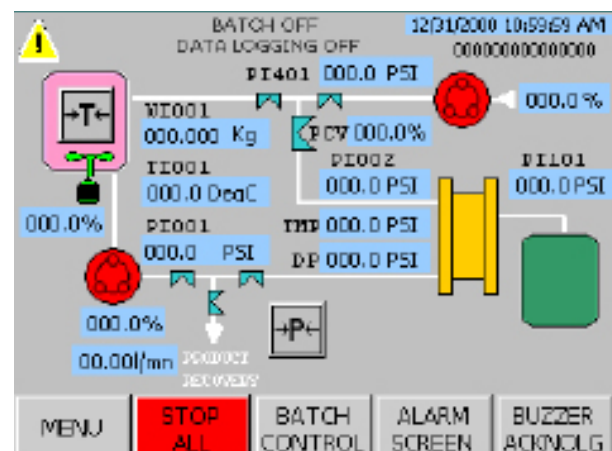


Figure 7. The P&ID provides real-time display of all active parameters.

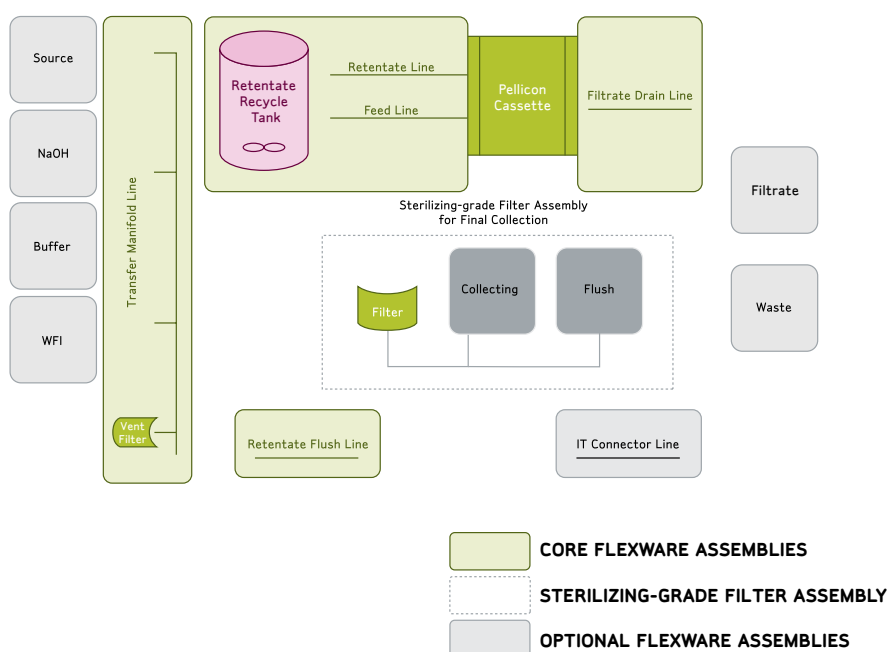
## Standardized Configurations for Reliable Results

The flowpath has been carefully designed and tested by our design and applications engineers, resulting in a consistent, standardized flowpath. You are guaranteed that the flowpath is designed to fit the system and your TFF needs. The flowpath (See Fig. 8) consists of:

- Core Flexware assemblies which includes the transfer manifold line and vent filter, retentate recycle container, retentate and feed lines, retentate flush line, and filtrate drain line

- Sterilizing-grade filter assembly for final collection with sampling bag and NovaSeal™ Crimping Sleeve for sterile disconnect
- Optional Flexware assemblies including process containers for source, NaOH, buffer, WFI, filtrate, and waste, and integrity tester (IT) connector line
- Pellicon cassettes

Figure 8. TFF Flowpath



### Select from Standard Flowpath Configurations for Each System

	TF-1	TF-2
Core Flexware Assemblies	10L retentate recycle container	50L retentate recycle container
Sterilizing-grade filter assembly for final collection	5L or 10L collecting container featuring Opticap® XL 600 capsule with Millipore Express® SHC membrane	10L or 20L collecting container featuring Opticap® XL 600 capsule with Millipore Express® SHC membrane
Process container for source	10L, 20L, 50L	50L, 250L
Process container for NaOH	10L, 20L, 50L	250L, 500L, 1,000L
Process container for buffer	10L, 20L, 50L	250L, 500L, 1,000L
Process container for WFI	10L, 20L, 50L, 250L	250L, 500L, 1,000L
Process container for filtrate	10L, 20L, 50L	250L (accommodates up to 2 process containers for filtrate)
Process container for waste	250L	1,000L
Pellicon 2 cassettes	0.1 m <sup>2</sup> (1-5 cassettes)	0.5 m <sup>2</sup> (1-5 cassettes) 2.5 m <sup>2</sup> (1 cassette)
Pellicon 3 cassettes	0.11 m <sup>2</sup> (1-4 cassettes)	0.56 m <sup>2</sup> (1-4 cassettes) 1.14 m <sup>2</sup> (1-2 cassettes)

## SPECIFICATIONS

	TF-1	TF-2
<b>Recommended Operating Parameters</b>		
Retentate recycle tank	10L	50L
Flowrate	0.4 - 4.0 L/min	2 - 18 L/min
Surface area Pellicon 2	0.1 - 0.5 m <sup>2</sup>	0.5 - 2.5 m <sup>2</sup>
Surface area Pellicon 3	0.11 - 0.44 m <sup>2</sup>	0.56 - 2.28 m <sup>2</sup>
Min. working volume (based on feed flow of 8 L/min/m <sup>2</sup> ) <i>Min. working volume is the volume in the retentate recycle container, feed line, Pellicon filters, and retentate line.</i> <i>Min. working volume is a function of the membrane surface area and the feed flowrate.</i>	320 mL @ 0.1 m <sup>2</sup> 490 mL @ 0.5 m <sup>2</sup>	1,350 mL @ 0.5 m <sup>2</sup> 2,400 mL @ 2.5 m <sup>2</sup>
Fluid operating temperature	20 - 45 °C (68 - 113 °F)	
Max. operation pressure	50 psi (3.45 bar)	
Environmental Requirements	20-25 °C, (68 - 113 °F) Relative humidity 10-90% (non condensing)	

<b>Utilities</b>				
Supply voltage	100 - 110 VAC, 50/60 Hz, 1 phase	230 VAC, 50/60 Hz, 1 phase	200 - 208 VAC, 50/60 Hz, 3 phase	400 VAC, 50/60 Hz, 3 phase
Compressed Air/N <sub>2</sub>	Clean, dry air or nitrogen source at 3.5 to 6.0 bar (50 - 90 psi) for connecting to Integritest® 4 and for bag inflation			

<b>Instrumentation</b>		
Filtrate weigh scale (optional)	up to 60 kg (132.3 lbs)	up to 600 kg (1,328 lbs)
Pressure transducer	Sanitary diaphragm pressure transducer located at retentate and filtrate lines	
High pressure cut-off switch	Sanitary diaphragm pressure transducer located at feed and transfer pump outlet	
Temperature sensor	Located at retentate recycle container outlet	
Weight load cells	Located at retentate recycle tank (qty. of 4)	

### Control Modes: Operations will be supervised by alarm setpoints

Set point	Details
Constant $\Delta P$ ( $P_{\text{feed}} - P_{\text{retentate}}$ )	Operate at constant $\Delta P$ or calculated constant feed flow rate
Constant TMP $\frac{(P_{\text{feed}} + P_{\text{retentate}})}{2} - P_{\text{filtrate}}$	Operate at constant TMP or retentate pressure
Constant retentate tank weight	For fed batch concentration, for constant-volume diafiltration
Cumulative filtrate	For concentration or diafiltration endpoint determination volume/weight

### Languages Supported

English

<b>Weight (Approx.)</b>		
Filter support kit	10 kg (22 lbs)	30 kg (66.1 lbs)
Pump cart	330 kg (727.5 lbs)	
Filter cart	150 kg (330.7 lbs)	
Manifold plate	5 kg (11 lbs)	

<b>Dimensions (H x W x D)</b>		
Pump cart	1910 x 1250 x 800 mm (75.1 x 49.2 x 31.5 in.)	
Filter cart	1050 x 1100 x 800 mm (41.3 x 43.3 x 31.5 in.)	

## SPECIFICATIONS

	TF-1	TF-2
<b>Materials of Construction (product contact)</b>		
Pellicon cassette liners	UDEL P-1700	Polysulfone
Process container	ULDPE (PureFlex™ film)	
Low dead volume t-connector	LLDPE film (septum), Polysulfone (body nut), LLDPE (Gauge Protector), Silicone (o-ring)	
Tubing	Nylon-braided silicone, Bioprene®, Platinum-cured silicone tubing	
Fittings	Polypropylene, HDPE, polysulfone, silicone o-rings/gaskets, polyvinylidene difluoride	
Connectors	Polypropylene, silicone	
Filters	See individual datasheets	

<b>Materials of Construction (non-product contact)</b>	
Retentate recycle tank	HDPE
Frame	Stainless steel 304L
Panels	Stainless steel 304L, Epoxy coating PMS233
Drip tray	Stainless steel 304L
Non-painted exposed surfaces, e.g. shelves, installation bar, installation support, handle bars	Stainless steel 304L Polished 220 grid
Bench	Laminated glass
Pellicon holder	Stainless steel 316L
Trays/bins	Polyethylene
NovaSeal crimp	Nickel-coated brass
Wheels	Nylon non-marking wheels with locks
Low dead volume t-connector	Polysulfone (body nut), nylon (washer), PVC (plug)
<b>Manifold Plate</b>	
Plate	Polycarbonate
Supports	Stainless steel 316L
Pinch valves	Glass-reinforced nylon
<b>Filter Support Kit</b>	
Frame	Stainless steel 304L
Support	Stainless steel 304L/316L
Holder nuts	Bronze
Pinch valves	Glass-reinforced nylon
<b>Filtrate Weigh Scale (Optional)</b>	
60 kg (132.3 lbs)	Stainless steel 316TI
600 kg (1,328 lbs)	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.

Flexware 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.
<b>Core Hardware System</b>	
The core hardware system includes the pumping cart, filter cart with 2 trays (10L and 50L), and filter supports.	
<b>Mobius FlexReady System, TF-1 (10L retentate recycle tank)</b>	
100-110VAC 50/60Hz 1 phase (North American)	MBSTA1
230VAC 50/60Hz 1 phase (European)	MBSTA2
<b>Mobius FlexReady System, TF-2 (50L retentate recycle tank)</b>	
200 - 208VAC, 50/60Hz 3 phase (North American)	MBSTB1
400VAC 50/60Hz 3 phase (European)	MBSTB2
<b>Hardware Accessories</b>	
<b>Collapsible Containers</b>	
250L bin (holds 100L or 250L process containers)	MBSACC006U
1,000L bin (holds 500L, 750L, or 1,000L process containers)	MBSACC007U
<b>Containment trays</b>	
10L tray (holds 5 or 10L process containers)	MBSACC005U
50L tray (holds 20L or 50L process container)	MBSACC004U
<b>Filtrate Weigh Scale</b>	
60 kg (132.3 lbs) for TF-1	MBSACC019U
600 kg (1,328 lbs) for TF-2	MBSACC020U

Description	Catalogue No.
<b>Services</b>	
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	SVCMBSTFAT
Installation and Operational Qualification Protocol Performance Zone* 1	SVCMBSTIQQZ1
Installation and Operational Qualification Protocol Performance Zone* 2	SVCMBSTIQQZ2
Installation and Operational Qualification Protocol Performance Zone* 3	SVCMBSTIQQZ3
Installation and Operational Qualification Protocol, TF-1	DOCMBST1IQOQ
Installation and Operational Qualification Protocol, TF-2	DOCMBST2IQOQ
Annual Performance Review Zone* 1	SVCMBSTAPRZ1
Annual Performance Review Zone* 2	SVCMBSTAPRZ2
Annual Performance Review Zone* 3	SVCMBSTAPRZ3

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

### Flexware Assemblies (Pellicon cassettes sold separately)

For flowpath drawing, see Fig. 7 on pg. 4. Consult with your sales representative to configure your TFF flowpath using standard, optimized options.

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

### Pellicon Cassettes

All Pellicon cassettes must be purchased separately. See datasheets DS1324EN00 Rev. B, DS1209EN00 (Pellicon 3) and DS1210EN00 (Pellicon 2) 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](http://www.millipore.com/offices)

Internet: [www.millipore.com](http://www.millipore.com)

Technical Service: [www.millipore.com/techservice](http://www.millipore.com/techservice)



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