

Mobius® TFF 20 System

Single-use Tangential Flow Filtration Solution, Designed for Optimal Performance

The Mobius® TFF 20 system is a flexible solution for concentration, ultrafiltration and diafiltration of monoclonal antibodies, antibody drug conjugates, viral vectors, vaccines or mRNA in a single use process. The system maximizes the production yield and enables the achievement of high concentration factors, minimizing unrecoverable volume. Its single-use flow path offers the flexibility to operate in traditional, functionally or fully closed mode.

Flexibility with no compromise on quality

- 50 L, 100 L and 200 L tanks, with up to 20 L/min diaphragm pump for gentle processing of biologics
- Holder for filter area from 0.5 to 5 m² with Pellicon® cassettes and 0.5 to 4.5 m² with single-use Pellicon® capsule manifolds
- Traditional and closed mode of operation are possible with specifically designed flow path and consumables, allowing to reduce contamination risk while increasing flexibility and operator safety.

Designed for optimized yield and product recovery

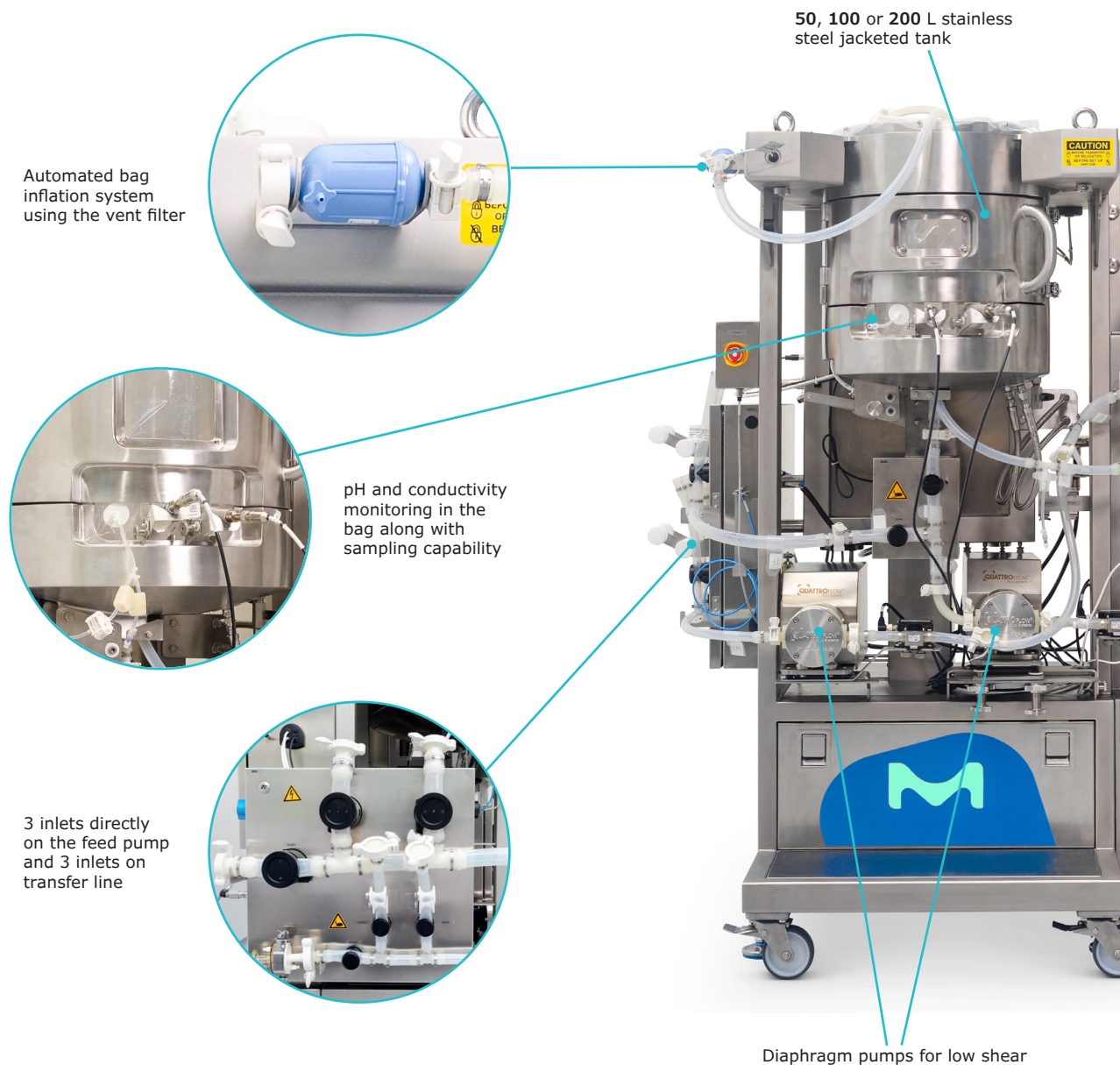
- Tank geometry, bag design and mixing technology ensure product homogeneity, key for product quality during concentration and diafiltration
- Large tank volume to minimum working volume ratio for high concentration factor
- Overmolded flow path and valve position ensure no dead leg is created
- Highly drainable system for maximum recovery of product



Fully automated and user friendly

- Full automation with step edition CCP® Software or user programmable system delivered with automation documentation package to enable smooth DCS integration
- Easy flow path installation with adaptable support and connection labelling
- Transparent clamshell design allowing visual monitoring of process fluids within the flow path

System Components



Automated bag inflation system using the vent filter

pH and conductivity monitoring in the bag along with sampling capability

3 inlets directly on the feed pump and 3 inlets on transfer line

50, 100 or 200 L stainless steel jacketed tank

Diaphragm pumps for low shear

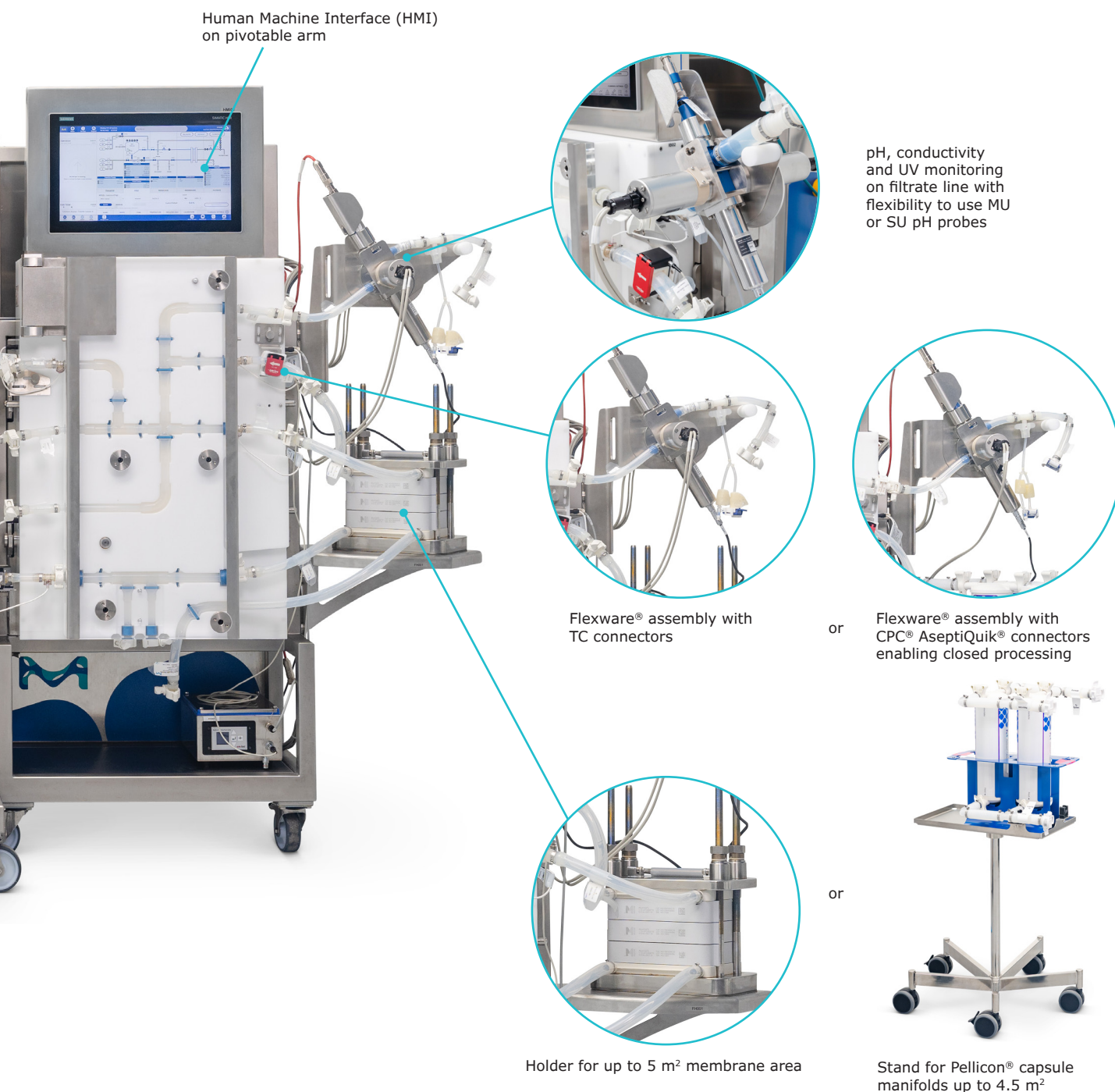
Instrumentation

All Mobius® TFF 20 systems come with flow measurement on feed and filtrate lines, UV, pH and conductivity single use cell on filtrate line and temperature, pH and conductivity monitoring capabilities in the tank. An optional flowmeter can be added on the transfer line.

On the bag and filtrate line pH can be monitored with a single-use probe pre-installed and irradiated as part of the Flexware® assembly or multi-use pH probe.

Tank and pump cart

The tank is an integral part of the system. Its design and location minimize the recirculation loop volume, maximize drainability and allow to reach low end volumes. Our efficient mixing technology paired with the vortex breaker and diverter plate in the feed bag ensure product homogeneity during concentration and diafiltration steps.



Base cart

The base cart is a modular piece of equipment common to Mobius® Chrom and Mobius® TFF 80 systems. It hosts the clamshell carved to support the overmolded tubing, enabling valve closure with no dead leg and avoiding long tubing installation in multiple pinch valves.

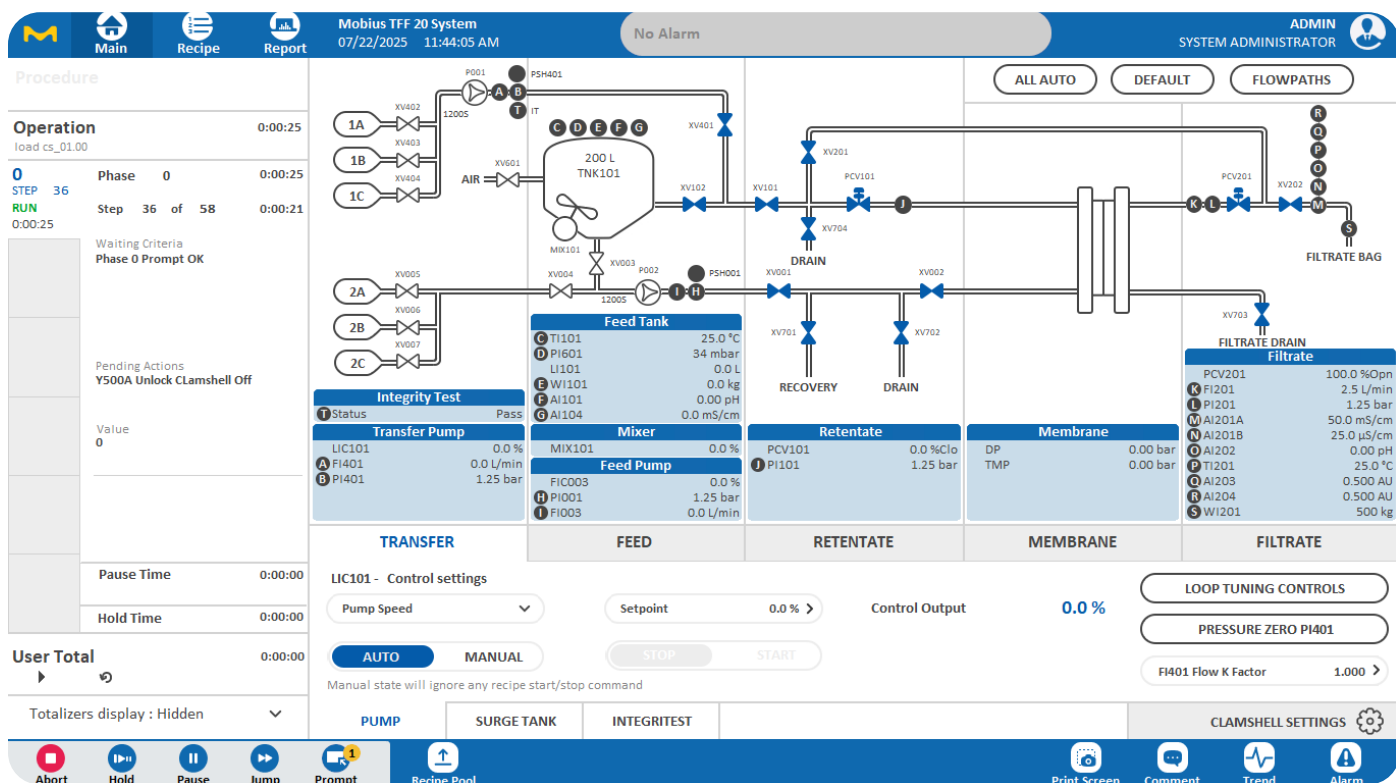
Holder and stand

Each system comes with a holder or a stand to support Pellicon® cassettes or Pellicon® capsules from 0.5 up to 5 m².

Functionally and fully closed modes

All modes of operation are enabled with specifically designed flow path, allowing to reduce contamination risk and protect operators. Fully closed flowpath design ensures flowpath closure is maintained during all process steps such as sensor calibration, sampling, pre and post run IT testing.

Common Control Platform® (CCP®) Software



CCP® software provides a single control platform across our portfolio of automated systems for a familiar look and feel at each step of your process that helps reduce training time for operators.

The software offers recipe driven processing that eliminates manual operation, reduces process variability, and minimizes risk of errors. Process operations are easily created and managed using the recipe editor, each aspect of your process is monitored

from the HMI (Human Machine Interface), and the report generator allows you to create state-of-the-art batch reports.

The software is designed for GMP facilities, is in line with GAMP® 5 recommendations for automation software, and fulfills FDA guideline 21 CFR Part 11 requirements for electronic records and signatures and includes an accessible audit trail for verification.

Related products to support your TFF process

Pellicon® 2 and Pellicon® 3 Cassettes

These advanced, high-performance cassettes are ideal for high titer therapeutic antibodies, as well as more demanding filtration processes that require higher operating pressures, temperatures, and caustic cleaning regimes. Our Mobius® TFF 20 system can operate with Pellicon® 2 and Pellicon® 3 cassettes up to 5 m².



Mobius® Single-Use Mixing Systems

The Mobius® MIX and Power MIX systems are single-use solutions designed for efficient mixing of pharmaceutical ingredients, buffers, and media from intermediate stages to final drug products. They offer high-performance, easy-to-use technology that enhances operational efficiency and reliably handles even the most challenging biopharmaceutical mixtures.



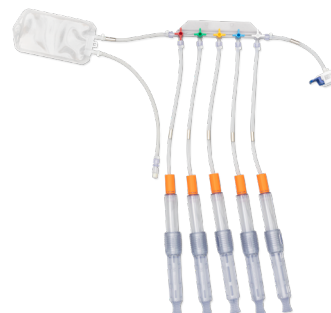
Pellicon® Capsule Manifolds

Our innovative Pellicon® capsules are ideal for processing biopharmaceuticals that require single-use capabilities, including enhanced ease-of-use, process flexibility, rapid product turnaround, and reduced operator exposure. First-of-its-kind, the capsule has a holderless and self-contained design for fast and flexible product changeover. Provided gamma sterilized and with aseptic connectors, Pellicon® Capsule manifolds are ideally paired with our Mobius® TFF 20 system, up to 4.5 m², to offer robust and consistent performance in a closed process for clinical or commercial manufacturing.



NovaSeptum® sampling solution

NovaSeptum® SURE single-use sterile sampling assemblies are designed to protect your single-use process from potential cross-contamination ensuring representative samples. This flexible sampling assembly can be easily integrated throughout your single-use manufacturing process via a standard AseptiQuik® connector. The closed assembly ensures your sample will be isolated from point of sample to analysis, reducing the risk of contamination. The NovaSeptum® SURE assemblies come as single or manifold designs in popular formats. They can also be customized to better fit your sampling requirements. Most of the standard assemblies are stocked and ready-to-ship, enabling fast delivery to your site.



Mobius® TFF 20 System Services



The pharmaceutical and biotechnology industries are highly regulated and, to help you navigate this challenging environment, we offer a wide range of services. These services help you save time, lower costs, and comply with regulations. For your 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.

Software Integration

In addition to CCP®, our own automation solution, we support the integration of your own software on our system, with a close collaboration with your automation team.

- Consulting for I/O and P&ID explanations to software developer
- Pairing of Hardware and Software before FAT

Qualification Services

Our qualification services are designed to make the integration of our system into your process as seamless as possible and ensure your equipment is properly installed and functioning per your pre-defined requirements.

- Factory Acceptance Test (FAT)
- Installation Qualification/Operational Qualification (IQ/OQ) with CCP® or customer software
- Full test package: this service is an alternative to standard IQ/OQ for customers who wish to have tests from FAT performed again at their site

For additional information on qualification tests, please contact your local sales representative to get the detailed Test Matrix document (MK_CA11658EN).

Training Services

Appropriate training for users is not only a GMP requirement, but it also ensures your staff has the expertise to operate and manage the system as part of your manufacturing process. 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 and programming with interactive hands-on sessions and, depending on the training you select, may also include:

- Installing the Flexware® assemblies
- Interacting with the Human Machine Interface
- Manual and automatic system operation
- Troubleshooting issues
- Creating and managing your own recipes
- Process recommendations

These trainings can be delivered either at your site or in our M Lab™ Collaboration Centers, or through our Virtual Reality platform which offers flexibility and autonomous training refresh. Please contact your local representative or email ilearn@merckgroup.com to discuss our training offering.

Specialized Services

CCP® Software Recipe Design

Every process is unique and, to ensure that your system is optimized to deliver the best performance, our biomanufacturing engineers will configure your process into your own CCP® software recipe. This allows your system to run fully automatic, resulting in consistency and reduced operator error.

For catalogue numbers, please refer to the ordering information at the end of the document.

System Service Reliance Plans

To help you ensure optimum equipment uptime while mitigating risks, we have developed a wide range of services and support that allow you to select a coverage level that best fits your needs. Our System Service Reliance Plans, a complete range of services for your systems, offer priority access to support while ensuring your equipment is properly maintained.

For additional details, please refer to the System Service Reliance Plans Data Sheet (MK_DS7881EN). Available at [SigmaAldrich.com/services-plans](https://www.sigmaaldrich.com/services-plans)

Repair Services and Spare Parts

Repair Services

In the event your system experiences a problem, our worldwide engineering organization will provide on-site or repair center 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, check the illustrated spare parts list (MK_CA9379EN).

Specifications

General specifications		
Maximum fluid pressure	Pressurized flow path and feed pump	0–4 bar
	Non pressurized flow path	0–2 bar
	Feed bag and bags	Atmospheric pressure
Temperature range	System	Ambient (4–30 °C)
	Fluid	4–45 °C
Humidity	Non-condensing	10–90%
Dimensions (H × W × D in cm)	Tank Cart 50 L	170 × 100 × 103
	Tank Cart 100 L	190 × 103 × 105
	Tank cart 200 L	197 × 115 × 112
	Base cart	170 × 112 x 81 (instrumentation included)
	Pellicon® capsule stand	68 × 75 × 75
Weight	Tank cart 50 L	328 kg
	Tank cart 100 L	399 kg
	Tank cart 200 L	445 kg
	Base cart with clamshell	375 kg
Power supply	Base cart	220–240 VAC, 50/60 Hz, 1 phase, 6.5 A, OR 100–120 VAC, 50/60 Hz, 1 phase, 13.6 A, maximum consumption: 1.6 kW
	Tank cart	220–240 VAC, 50/60 Hz, 1 phase, 1.6 A (50 L)/3.5 A (100 L/200 L) OR 100–120 VAC, 50/60 Hz, 1 phase, 3 A (50 L)/8.1 A (100 L/200 L) maximum consumption: 0.38 kW (50 L)/0.97 kW (100 L/200 L)
Pneumatic supply	Compressed air ≥6 bar, ≤10 bar instrument air filtered to ≤5 mm, -20 °C dew point, oil free	
System		
Pump flow rate	Feed pump	2 to 20 L/min
	Transfer pump	2 to 10 L/min
Membrane holder capacity	Pellicon® cassettes	0.5 to 5 m²
	Pellicon® capsules	0.5 to 4.5 m²
Tank volume	Stainless steel jacketed tank	50 L, 100 L, 200 L
Inlets	3 for feed pump, 3 for transfer pump, 1 for IT testing, 1 top inlet for venting/bag inflation, 1 top inlet as spare, 1 Bung port	
Outlets	1 recovery, 1 filtrate, 3 drains (on feed, filtrate and retentate), 1 flush	
Minimum working volume	consult the performance guide to review minimum working volume vs feed flow rate information	
Recirculation loop volume	Volume in feed and retentate line	725 mL for 50, 742 mL for 100 L, 770 mL for 200 L
Unrecoverable volume	After buffer displacement	Virtually zero
Sensors	Process range	Accuracy on process range
Pressure sensors feed, retentate, filtrate	0–4 bar	±0.2 bar
Pressure sensor transfer line	0–2 bar	±0.2 bar
Temperature (tank)	4–45 °C	±1 °C
Weight load cells (tank)	0–50 kg (50 L tank)	±0.15 kg (±0.3%)
	0–100 kg (100 L tank)	±0.3 kg (±0.3%)
	0–200 kg (200 L tank)	±0.6 kg (±0.3%)
Filtrate flowmeter (ultrasonic)	0.2–10 L/min	±5% MV ≥2 L/min, ±120 mL/min <2 L/min
Feed flowmeter (magnetic)	2–20 L/min	±5% MV
Transfer flowmeter (magnetic)	2–10 L/min	±5% MV
Conductivity sensor	0.1–200 mS/cm (process)	±(3% MV + 0.4 mS/cm)
	1–100 µS/cm (cleaning)	±(3% MV + 0.4 µS/cm)
UV sensor (wavelength: 254/280 nm, OPL: 10 mm)	0–2 AU	±0.04 AU (±2% FS)
Single-use pH sensor (tank, filtrate)	3–9 pH	0–18 months: ±0.15 pH After product calibration ±0.10 pH at ±1 pH around calibration point 18–24 months: ±0.20 pH After product calibration ±0.15 pH at ±1 pH around calibration point
Multi-use pH sensor	3–9 pH	±0.15 pH, ±0.10 pH after process calibration at ±1 pH around calibration point

Flow path		
Wetted materials	Tubing (inc. tubing manifolds)	Silicone
	Pump Chambers	EPDM, Santoprene® and Polypropylene
	AseptiQuik® Connectors	Polycarbonate
	TC connectors (and gasket)	HDPE, polypropylene (silicon)
	Magnetic flowmeter	Polysulfone, Hastelloy C22
	Pressure sensor	Polysulfone
	UV, conductivity (SUC)	Polysulfone Quartz, EPDM and Stainless Steel 316L (pins only)
	pH probes	Glass and VMQ (Silicone elastomer)
	Inline sampler	HDPE, Polyethersulfone, Silicon
	Tank bag	Pureflex™ Film, HDPE fittings and polyethylene ports
Regulatory compliance	Liners	Glass Filled Polysulfone
	Single-use Flexware® assemblies	USP <88> or USP <87> or ISO10993-5, animal origin free or compliant with EMA 410/01, USP <85>, USP <788>

Ordering Information

To obtain an integrated solution with Mobius® TFF 20 select:

- A system's configuration based on the tank volume and [option needed for your process](#)
- The accessories and system power cords
- The Flexware® assemblies kits according to your processing mode

Hardware

All Mobius® TFF 20 systems can adapt to open, fully or functionally closed processing mode. For more flexibility additional tank cart can be purchased and seamlessly connected to the base cart.

System part number	Tank size	Transfer flowmeter	Holder for Pellicon® cassettes	Stand for Pellicon® capsules
MTFF20050M3NH	50 L		•	
MTFF20050M3FH		•	•	
MTFF20050M3NS				•
MTFF20050M3FS		•		•
MTFF20100M3NH	100 L		•	
MTFF20100M3FH		•	•	
MTFF20100M3NS				•
MTFF20100M3FS		•		•
MTFF20200M3NH	200 L		•	
MTFF20200M3FH		•	•	
MTFF20200M3NS				•
MTFF20200M3FS		•		•
Tank cart part number				
MBTC050M3TFF20	50 L			
MBTC050M3TFF20	100 L			
MBTC050M3TFF20	200 L			



50 L



100 L



200 L

Holders and Stands

Each system is delivered with a holder or a stand based on the configuration chosen. If you want the flexibility to change filter format you can purchase an additional holder or stand.

Description	Part number	Additional information
Mobius® TFF 20 Cassette holder	MBFILTHDRTFF20	Holder for 0.5 to 5 m ² membrane area of flat sheet devices
Mobius® TFF 20 Capsule stand	MBCAPSTDRTFF20	Stand to support Pellicon® capsule and manifolds from 0.5 to 4.5 m ²
Pellicon® capsule stand	PCX001	Stand for holding 0.5 and 1 m ² Pellicon® capsule (to be bought in addition to MBCAPSTDRTFF20)
Mobius® TFF 20 HF bracket	MBHFBRKTFF20	Bracket for holding hollow fiber with diameter up to 110 mm

Accessories

Description	Part number	Additional information
Clamshell lift 110V	MBCLAMLIFT110V	For use with Mobius® TFF 20, TFF 80 and Mobius® Chrom 2, 10 and 20 systems
Clamshell lift 230V	MBCLAMLIFT230V	For use with Mobius® TFF 20, TFF 80 and Mobius® Chrom 2, 10 and 20 systems
Storage rack for clamshell	MBCLAMSTORE	To store Mobius® TFF and Chrom systems clamshells
Keyboard support	MBSPKBTFF20	-
Maintenance cable	MBCLAMCABLE	Cable used for some maintenance actions on the clamshell
Multi-use pH probe	SPKGENINS012	To be used on filtrate SUC or in the bag
ARC module for SU pH probe	SPKGENINS015	To be used with the single use pH probe pre installed in the bag and filtrate SUC
ARC module for SU conductivity	SPKGENINS041	To be used with the single use patch on the bag
Split nuts	MBSPTNUTHDRTFF20	4 split nuts with associated metric ring jaw spanner to replace original nuts from cassette holder

Power Cord

Description	Part number		
Switzerland	SPKMBPWCCN	China	SPKMBPWCCN
Europe	SPKMBPWCEU	Japan	SPKMBPWCJP
North America	SPKMBPWCNA	Korea	SPKMBPWCKR
United Kingdom	SPKMBPWCUK		

Power cord to connect base cart and tank cart.

Flexware® assemblies kits according to system configuration and processing mode

Pick the bag and kit part number depending on the processing mode and how you want to manage pH monitoring. You have the option to have SU pH probe pre installed and gamma irradiated or to self install a MU pH probe.

Part number	Bag		Open processing kit	
	SU pH probe pre installed in the bag	No pH probe installed*	SU pH probe pre installed in filtrate SUC	No pH probe in filtrate SUC*
MTFF20050M3NH	TFF2050LSMPPH	TFF2050LSMP	FXWTFF2050N1	FXWTFF2050N2
MTFF20050M3NS				
MTFF20050M3FH			FXWTFF2050F1	FXWTFF2050F2
MTFF20050M3FS				
MTFF20100M3NH	TFF20100LSMPPH	TFF20100LSMP	FXWTFF20100N1	FXWTFF20100N2
MTFF20100M3NS				
MTFF20100M3FH			FXWTFF20100F1	FXWTFF20100F2
MTFF20100M3FS				
MTFF20200M3NH	TFF20200LSMPPH	TFF20200LSMP	FXWTFF20200N1	FXWTFF20200N2
MTFF20200M3NS				
MTFF20200M3FH			FXWTFF20200F1	FXWTFF20200F2
MTFF20200M3FS				

* a MU pH probe can be installed by the user (SPKGENINS012)

Part number	Bag for fully and functionally closed processing		Functionally closed processing kit		Fully closed processing kit
	With SU pH probe pre installed	With no pH probe installed*	SU pH probe pre installed in filtrate SUC	No pH probe in filtrate SUC*	SU pH probe pre installed in filtrate SUC
MTFF20050M3NH	TFF20FC50LSMPPH	TFF20FC50LSMP	FXWTF20C50N1	FXWTF20C50N2	FXWTF20FC50N1
MTFF20050M3NS					
MTFF20050M3FH			FXWTF20C100F1	FXWTF20C50F2	FXWTF20FC50F1
MTFF20050M3FS					
MTFF20100M3NH	TFF20FC100LSMPPH	TFF20FC100LSMP	FXWTF20C100N1	FXWTF20C100N2	FXWTF20FC100N1
MTFF20100M3NS					
MTFF20100M3FH			FXWTF20C100F1	FXWTF20C100F2	FXWTF20FC100F1
MTFF20100M3FS					
MTFF20200M3NH	TFF20FC200LSMPPH	TFF20FC200LSMP	FXWTF20C200N1	FXWTF20C200N2	FXWTF20FC200N1
MTFF20200M3NS					
MTFF20200M3FH			FXWTF20C200F1	FXWTF20C200F2	FXWTF20FC200F1
MTFF20200M3FS					

* a MU pH probe can be installed by the user (SPKGENINS012)

Services

	With CCP® software	With customer software
Software Integration		
Mobius® Dummy Skids: I/O and P&ID Consulting to Software Developer	N/A	Check with your Merck contact
Mobius® Skid Pairing with Customer software	N/A	
Qualification services		
Mobius® TFF System Factory Acceptance Tests*	SSVFATSFT	Check with your Merck contact
Mobius® TFF 20 IQOQ Installation and Operational Qualifications*	SSVQUAF20	SSVQUAF20DUM
Mobius® TFF 20 Full test package*	SSVFTPF20	N/A
* protocol in english according to the standard scope described in the Test Matrix		
Training services		
Mobius® TFF systems: Operators Training, Hardware & Software overview, system start & use, 0,5 days at customer site	OPTRMOBTFF	
Mobius® TFF systems: Product Training, CCP® SW v.6, 1,5 days at customer site	PTRMOBTFFCCP1	
Mobius® TFF systems: Product Training, CCP® SW v.6, process design, 3 days at customer site	PTRMOBTFFCCP2	
Mobius® TFF systems: Product Training, CCP® SW v.6, process design & troubleshooting, 4,5 days at customer site	PTRMOBTFFCCP3	
VR Training Yearly Subscription – Essential Program for Mobius® TFF systems – System use	VRPTRMBSTFFESS	
VR Training Yearly Subscription – Advanced Program for Mobius® TFF systems – Self Troubleshooting	VRPTRMBSTFFESS + VRPTRMBSTFFADC	
Specialized support		
CCP® Software recipe design (3 recipes)	SSVRPCCPB	
System Service Reliance Plans		
Mobius® TFF System - Essential Reliance Service Plan	SSVESPSFT	
Mobius® TFF System - Advanced Reliance Service Plan	SSVESPSFT + SSVADCSFT	
Mobius® TFF System - Total Reliance Service Plan	SSVESPSFT + SSVTOCSFT	
Mobius® TFF System - Preventive Maintenance, additional to service plan	SSVOPMSFT	

Please refer to spare part list MK_CA9379EN available at **SigmaAldrich.com**
Contact your local representative for repairs.

Flexware® assemblies kits to be purchased prior to maintenance services:

Service Flexware® kits have been designed to fulfill the needs of maintenance services performance. These kits can be reused several times if stored properly and are not suitable for process activities.

Catalogue numbers	PMFXWTFF2050L	PMFXWTFF20100L	PMFXWTFF20200L
Description	Mobius® TFF 20 Flexware® kit for PM performance of 50 L system	Mobius® TFF 20 Flexware® kit for PM performance of 100 L system	Mobius® TFF 20 Flexware® kit for PM performance of 200 L system

Note: Service kits to be ordered separately prior to yearly maintenance services included in the System Service Reliance Plans.



To place an order or receive technical assistance:
SigmaAldrich.com/support



For local contact information:
SigmaAldrich.com/offices

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