



Cogent® Process-Scale Tangential Flow Filtration Systems

Fully automated, configurable systems for biopharmaceutical manufacturing and cGMP process scale applications

The Cogent® TFF systems are designed to achieve optimum separation and purification of monoclonal antibodies, vaccines, plasma, and therapeutic proteins. The systems support rapid scale-up and are ideally suited for pilot and process scale.

The Cogent® Process Scale systems are designed based on 50 years of process knowledge and engineering expertise to provide a configurable, intuitive process-scale purification solution. Cogent® Process Scale system A, B and C sizes have an extended flow rate span and has a very low hold-up volume. It enables maximum volume concentration and optimal product recovery, thus enhancing process performance. The Cogent® Process Scale C (240 Lpm) covers higher scales and allows to scale-up directly from Cogent® Process Scale B (120 Lpm) and Cogent® Process Scale A (50 Lpm).

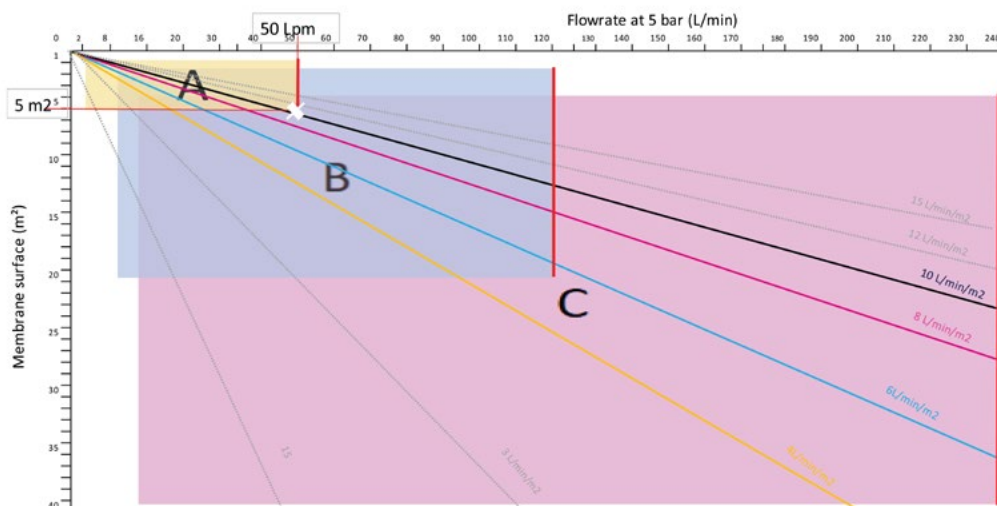
Benefits

- Scalability with 3 flow rate ranges:
 1. Cogent® Process Scale Size A (50 Lpm) up to 5 m² filtration surface with 2 x 2,5m² Pellicon® 2 cassettes | 4,56m² with 4 x 1,14m² Pellicon® 3
 2. Cogent® Process Scale Size B (120 Lpm) up to 20 m² filtration surface with 8 x 2,5m² Pellicon® 2 cassettes | 20,5m² with 18 x 1.14m² Pellicon® 3
 3. Cogent® Process Scale Size C (240 Lpm) up to 40 m² filtration surface with 16 x 2,5m² Pellicon® 2 cassettes | 41m² with 36 x 1,14m² Pellicon® 3
- Optimized design and component integration of NovAseptic® valves and TFF cassettes holders result in a low minimum working volume and ensure maximum product recovery.
- Designed to maximize TFF performances in different modes: fed-batch, concentration, total recycle or single pass for flushing and cleaning.
- Comprehensive services ensure rapid implementation and optimized performance.



System selection tool

Actual Mapping of the Cogent® Process Scale (P2 cassettes example)



Guidelines:

- Feed velocity: max 2,2 m/s |
- Pump speed: max 500 RPM

Legend:

- 4 L/min/m²
- 6 L/min/m²
- 8 L/min/m²
- 10 L/min/m²

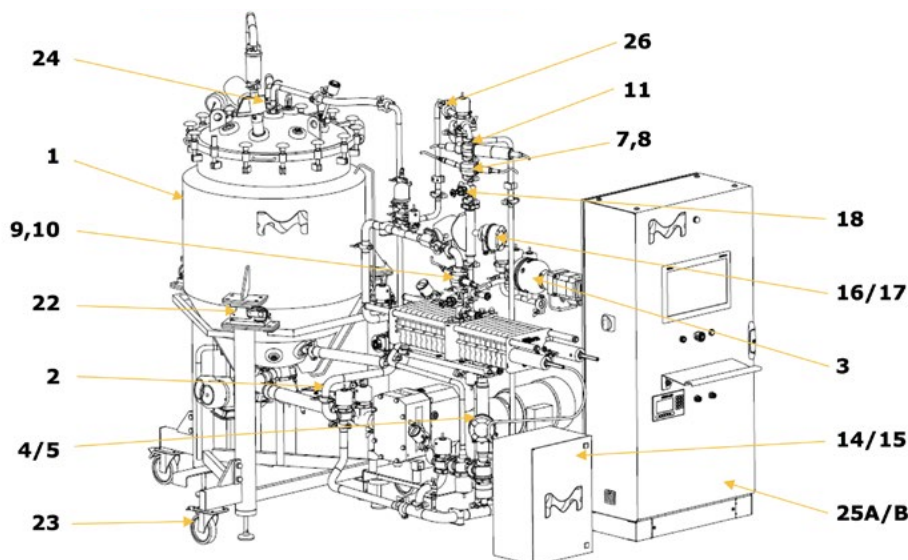
Example:

- Inputs: Flowrate = 50 Lpm; Crossflow = 10L/min/m²
→ Size A; or Size B if potential further upscale needed

Configure to best meet your purification requirements ...

To best meet your unique tangential flow filtration processing requirements, you can select options to add to the Cogent® Process Scale base platform (see options below). Some of the options have been included in the Cogent® Process Scale base system to better meet customer needs, see table 1 for details.

Cogent® Process Scale System Size B



The Cogent® Process Scale B base platform includes: Lobe feed pump, low level switch on pump inlet, pressure transmitter and pressure switch on pump outlet, Pellicon Holder with manual closure, pressure transmitters on the feed, the retentate and the filtrate, integrity test port, pressure control valve on the retentate, process air inlet with Opticap® Aervent filter, product inlet valve on the recirculation loop, filtrate flowpath to drain, filtrate flowpath to tank, filtrate outlet, product outlet, system drain line, electrical enclosure, and pressurized air supply block.

Option 1: Jacketed process vessel (from 50 to 1000L)

- NovAseptic® Valves, Mixer compliant with cGMP Design Qualification criteria for aseptic processing
- NovAseptic® connector ensures no dead legs and maximum product recovery with zero hold up volume.
- Comply with the most stringent cleaning requirements
- Level and temperature sensor to monitor the product volume and temperature during different process steps.
- Vent valve and Opticap® Aervent filter
- Manometer
- Light glass and sight glass
- Ball valves on double jacket inlet and outlet to fill and drain

Option 2: Low volume by pass

- Minimizes the recirculation volume to reach high concentration and minimal product volume

Option 3: Diaphragm Transfer Pump

- Transfer of product / buffers into the feed tank from any other tank.
- Allows fed-batch mode, and diafiltration.
- CIP manifold for cleaning the entire system in CIP, from one single inlet to one single outlet

Option 4: Feed magnetic flowmeter

- One magnetic flowmeter is set up between the pump and the holder for monitoring and regulation of the feed flow.
- The performance of the flowmeter is dependent on the conductivity of the product. Product conductivity must be greater than 5 $\mu\text{S}/\text{cm}$ for liquids, in general, and greater than 10 $\mu\text{S}/\text{cm}$ for demineralized water.

Option 5: Feed massic flowmeter

- One mass flowmeter is set up between the pump and the holder for monitoring and regulation of the feed flow.

Option 7: Filtrate conductivity

- A conductivity sensor (with temperature compensation) is integrated in the filtrate line.
- Measurement of a wide range of products (WFI, buffer solutions, protein solutions) or post CIP flushing monitoring

Option 8: Filtrate pH

- pH monitoring during cleaning and sanitization procedures

Option 9: Retentate conductivity

- A conductivity sensor (with temperature compensation) is integrated in the retentate line.
- In-process monitoring of product conductivity

Option 10: Retentate pH

- A pH sensor is integrated in the retentate line.
- In-process monitoring of product pH

Option 11: Filtrate UV

- In-process monitoring of protein content in filtrate during ultrafiltration

Option 14/15: Process scale holder hand pump

- Hydraulic closure can be done with a hand pump or with an automated hydraulic box (3 pressure level).

Option 16/17: Filtrate massic/magnetic flowmeter

- Filtrate flow and total volume monitoring in diafiltration mode

Option 18: Retentate & filtrate Novaseptum® sampling port

- In-process sterile sampling of product

Option 22: Tank load cells

- Load cells can be provided as an alternative to the level sensor.

Option 23: Wheels on tank

- To transport the tank without forklift
- These removable wheels facilitate the movement of empty tank.
- It is designed in such a way that it facilitates the installation of the tank in front of the filtration skid.
- Once the tank installed, the wheels can be removed.

Option 24: Burst disc detection

- This option gives the status of the burst disc integrity - Alarm and record when burst disc breaks

Option 25A/25B: Internal/External UPS

- UPS (Uninterruptible Power Supply) option:
- The purpose of this option is to have a specific EXTERNAL (from customer) secured power supply (ie without power outage) which feeds components (remote control, PC, PLC, I/O's).
- In case of main power supply failure, relevant data are not lost.
- All the power components like pumps, mixer, etc remain connected to the main power supply, during 15min, the time for operator to safely turn off the system.

Option 26: Filtrate PCV

- Upon request, a PCV valve can be added on the filtrate line
- The sizing of this valve will be done depending on expected filtrate flow range.

Option 27: Improved surface finish

- Product contact surface finish <0.51 µm electropolished
- Vessel external surface finish <1.2 µm mechanically polished

Cogent® Process Scale	Cogent® Process Scale size A	Cogent® Process Scale size B	Cogent® Process Scale size C
Total options	22 options	22 options	22 options
Option 1: Jacketed process vessel	50 or 100L	200 or 300L	500, 600, 800 or 1000L
Option 2: Low volume by pass	Yes	Yes	Yes
Option 3: Diaphragm Transfer Pump	Yes	Yes	Yes
Option 4: Feed magnetic flowmeter	Yes	Yes	Yes
Option 5: Feed massic flowmeter	Yes	Yes	Yes
Option 7: Filtrate conductivity	Yes	Yes	Yes
Option 8: Filtrate pH	Yes	Yes	Yes
Option 9: Retentate conductivity	Yes	Yes	Yes
Option 10: Retentate pH	Yes	Yes	Yes
Option 11: Filtrate UV	Yes	Yes	Yes
Option 14: Process scale holder hand pump	Yes	Yes	Yes
Option 15: Process scale holder control box	Yes	Yes	Yes
Option 16: Filtrate massic flowmeter	Yes	Yes	Yes
Option 17: Filtrate magnetic flowmeter	Yes	Yes	Yes
Option 18: Retentate & filtrate Novaseptum sampling port	Yes	Yes	Yes
Option 22: Tank load cells	Yes	Yes	Yes
Option 23: Wheels on tank	Yes	Yes	Yes
Option 24: Burst disc detection	Yes	Yes	Yes
Option 25A: Internal UPS	Yes	Yes	Yes
Option 25B: Connection to customer UPS	Yes	Yes	Yes
Option 26: Filtrate control valve	Yes	Yes	Yes
Option 27: Improved surface finish	Yes	Yes	Yes

Table 1: Options for all Cogent® Process Scale system sizes.

Total Process Control and Connectivity

Common Control Platform® Software (CCP®) for Multiple Unit Operations

From bioreactors to clarification, chromatography, tangential flow filtration and virus filtration systems, our CCP® software can provide you with one familiar interface that simplifies software management and reduces the learning curve for new operators. This software package is available to support all application sizes, accelerating tech transfer and process scale-up.

Monitors Processes and Enables Batch Reporting

The latest version of CCP® software is powerful, intuitive and graphical. It provides real-time monitoring and total in-depth control of your TFF platform.

Create process operations using the recipe editor, monitor the process from the home screen and create reports for the batch using the configurable report generator.

Comprehensive and Secure Data Acquisition

CCP® software was designed to support compliance to 21 CFR part 11 and was developed under GAMP5 guidelines. The software includes an accessible audit trail and electronic signatures for verification. CCP® software is suited for manufacturing equipment from development to large-scale, using industrial computers and controllers for reliability.

Network Integration

Data transfer to the plant control system enables data collected by CCP® software to be centrally stored and managed.

Powerful Recipe Editor Simplifies Generation of Process Specific Separation Protocols

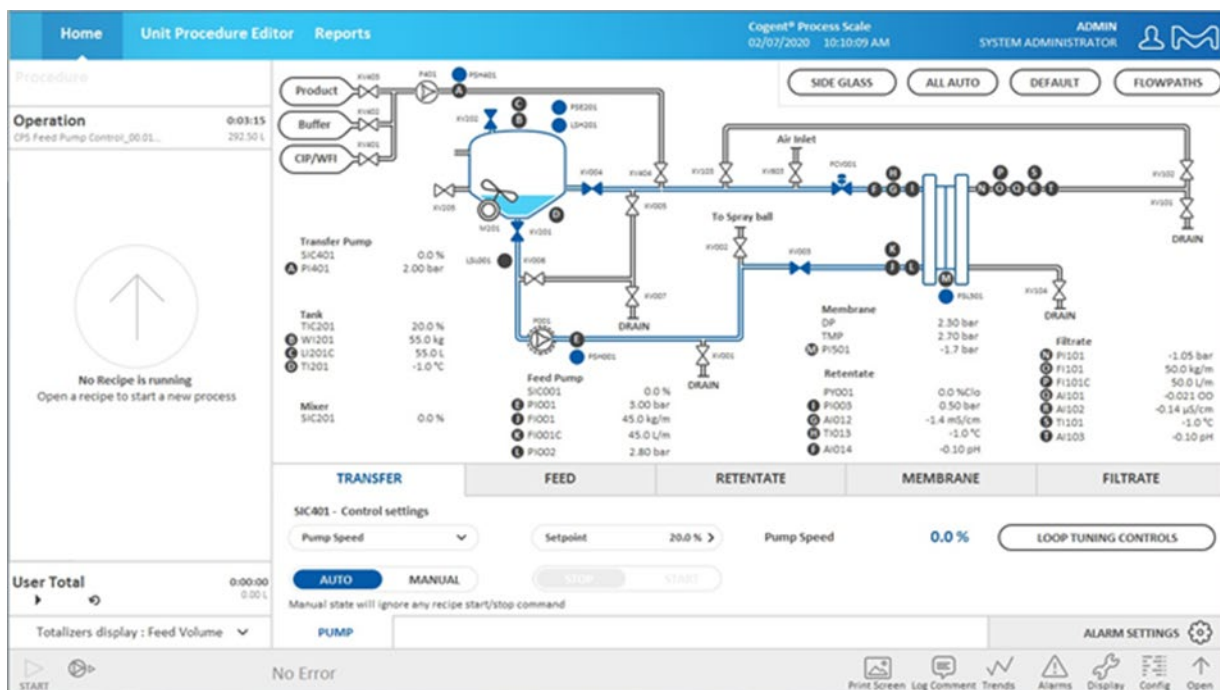
CCP® software monitors and adjusts all process parameters to ensure execution of a preprogrammed method or “recipe” using the Recipe Editor. You can quickly and efficiently configure, modify, test, and ultimately, lock these recipes for initial evaluation, repetitive process investigation, or transfer to production operations. Complex operations are easily constructed without prior programming experience.

Backup and Restoration

Backup and restoration of data can be managed via network integration.

Security Synchronization

Security synchronization allows user accounts to automatically coordinate with the networked plant control system for faster and simpler user account control and editing.



Comprehensive Range of Value-added Services and Support

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 support regulatory compliance. 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.

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)
- Site acceptance test (SAT) (combined with IQ/OQ)
- Installation qualification/operational qualification (IQ/OQ) (combined with SAT)
- Performance qualification support (PQ)

	Without Tank	With Tank
All Size	Factory Acceptance Test	
	SSVFATCPS 4 days execution + protocol realization	
	SSVFATCPS2 System quantity = 2, 4 days execution + protocol realization	
	Site Acceptance Test – IQ/OQ	
Size A	CSVQUACTA SAT-IQ/OQ execution incl. protocol & travel	CSVQUACNA SAT-IQ/OQ execution incl. protocol & travel
Size B	CSVQUACTX Cogent® Process Scale size B or C w/o tank SAT-IQ/OQ execution incl. protocol & travel	CSVQUACNX Cogent® Process Scale size B or C w/ tank SAT-IQ/OQ execution incl. protocol & travel
Size C		

Training

Appropriate training for users is not only cGMP requirements, 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.

- 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.

Please contact your local representative or email ilearn@milliporesigma.com to discuss our training offering.

Cat. No.	Description
PTRCPSOP	Cogent Process Scale – Operator training
PTRCPS CCP1	Cogent Process Scale – CCP V.6 training
PTRCPS CCP2	Cogent Process Scale – System use, troubleshooting and CCP V.6
PTRCPS CCP3	Cogent Process Scale – System use, process design, troubleshooting and CCP V.6

CCP® Recipe Creation Service

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.

Services catalogue numbers

Essential Reliance Plan		Advanced Reliance Plan		Total Reliance Plan		
With Tank	Without Tank	With Tank	Without Tank	With Tank	Without Tank	
Size A	CSVESPCTA Cogent® Process Scale size A w/ tank Essential Plan	CSVESPCNA Cogent® Process Scale size A w/o tank Essential Plan	CSVESPCTA Cogent® Process Scale size A w/ tank Essential Plan +	CSVESPCNA Cogent® Process Scale size A w/o tank Essential Plan +	CSVESPCTA Cogent® Process Scale size A w/ tank Essential Plan +	CSVESPCNA Cogent® Process Scale size A w/o tank Essential Plan +
			CSVADCCTA Cogent® Process Scalesize A w/ tank Advanced coverage	CSVADCCNA Cogent® Process Scale size A w/o tank Advanced coverage	CSVTOCCTA Cogent® Process Scale size A w/ tank Total coverage	CSVTOCNA Cogent® Process Scale size A w/o tank Total coverage
Size B	CSVESPCTX Cogent® Process Scale size B or C w/ tank Essential Plan	CSVESPCNX Cogent® Process Scale size B or C w/o tank Essential Plan	CSVESPCTX Cogent® Process Scalesize B or C w/ tank Essential Plan +	CSVESPCNX Cogent® Process Scale size B or C w/o tank Essential Plan +	CSVESPCTX Cogent® Process Scale size B or C w/ tank Essential Plan +	CSVESPCNX Cogent® Process Scale size B or C w/o tank Essential Plan +
	Size C		CSVADCCTX Cogent® Process Scale size B or C w/ tank Advanced coverage	CSVADCCNX Cogent® Process Scale size B or C w/o tank Advanced coverage	CSVTOCCTX Cogent® Process Scale size B or C w/ tank Total coverage	CSVTOCCNX Cogent® Process Scale size B or C w/o tank Total coverage

Specifications

	Cogent® Process-Scale Tangential Flow Filtration system A	Cogent® Process-Scale Tangential Flow Filtration System B	Cogent® Process-Scale Tangential Flow Filtration System C
Mechanical specifications			
System dimension L × W × H, in mm (Inches)	1606.3×1390×2018 without vessel (63.3" × 54.8" × 79.5")	2026.9×1466.1×2527 without vessel (79.8" × 57.8" × 99.5")	2068.2×1445.3×2292 without vessel (81.5" × 56.9" × 90.3")
	2927.5 ¹ ×1529×2018 with 50L vessel (115.2" × 60.2" × 79.5") ¹ with option 22, 2527.5 without	3416 ¹ ×1689×2537 ² with 200L vessel (134.5" × 66.5" × 99.9") ¹ with option 22, 3015 without ² with option 22, 2527 without	3955.2 ¹ ×2033.8×2820 ² with 500L vessel (155.8" × 80.1" × 111.1") 1 with option 22, 3796.2 without 2 with option 22, 2822 without
	2927.2 ¹ ×1529×2054 ² with 100L vessel (115.2" × 60.2" × 80.9") ¹ with option 22, 2527.2 without ² with option 22, 2042 without	3511 ¹ ×1774×2527 with 300L vessel (138.3" × 69.9" × 99.5") ¹ with option 22, 3158 without	3955.2 ¹ ×2033.8×2927 ² with 600L vessel (155.8" × 80.1" × 115.3") ¹ with option 22, 3796.2 without ² with option 22, 2930 without
			4098.7 ¹ ×2098.4×2565 ² with 800L vessel (161.4" × 82.7" × 101") ¹ with option 22, 3920.7 without ² with option 22, 2568 without
Net Weight	Skid without vessel: 700 kg	Skid without vessel: 1000 kg	Skid without vessel: 1600 kg
	250 kg for 50 L empty tank	450 kg for 200 L empty tank	450 kg for 500 L empty tank 480 kg for 600 L empty tank
	370 kg for 100 L empty tank	550 kg for 300 L empty tank	610 kg for 800 L empty tank 660 kg for 1000 L empty tank
Materials of Construction	Piping: Stainless steel 316 L Elastomer: EPDM in compliance with 21 CFR 177.2600	Piping: Stainless steel 316 L Elastomer: EPDM in compliance with 21 CFR 177.2600	Piping: Stainless steel 316 L Elastomer: EPDM in compliance with 21 CFR 177.2600
Finishing	Product contact surface <0.6 µm electropolished. External surface <1.6µm mechanically polished	Product contact surface <0.6 µm electropolished. External surface <1.6µm mechanically polished	Product contact surface <0.6 µm electropolished. External surface <1.6µm mechanically polished

	Cogent® Process-Scale Tangential Flow Filtration system A	Cogent® Process-Scale Tangential Flow Filtration System B	Cogent® Process-Scale Tangential Flow Filtration System C
Connections			
Feed line pre-pump	TC 2" OD 2"	TC 2" OD 2"	TC 3" OD 3"
Feed line post-pump	TC 1 1/2 OD 1"	TC 1 1/2 OD 1 1/2"	TC 2" OD 2"
Retentate line	TC 1 1/2 OD 1"	TC 1 1/2 OD 1 1/2"	TC 2" OD 2"
Filtrate line	TC 3/4" OD 3/4"	TC 1 1/2 OD 1"	TC 1 1/2 OD 1 1/2"
Inlet lines	TC 1 1/2 OD 1"	TC 1 1/2 OD 1"	TC 1 1/2 OD 1 1/2"
Drain	TC 1 1/2 OD 1 1/2"	TC 2" OD 2"	TC 3" OD 3"
Operating specifications			
Product Temperature Range	+5 to +80 °C	+5 to +80 °C	+5 to +80 °C
System operating Pressure	0 to +5 bar	0 to +5 bar	0 to +5 bar
Vessel operating Pressure	-1 to + 3 bar	-1 to + 3 bar	-1 to + 3 bar
Filtration surface	Cogent® Process Scale Size A (50 Lpm) up to 5 m ² filtration surface with 2 x 2,5m ² Pellicon 2 cassettes 4,56m ² with 4 x 1,14m ² Pellicon 3	Cogent® Process Scale Size B (120 Lpm) up to 20 m ² filtration surface with 8 x 2,5 m ² Pellicon 2 cassettes 20,5 m ² with 18 x 1,14 Pellicon 3	Cogent® Process Scale Size C (240 Lpm) up to 40 m ² filtration surface with 16 x 2,5 m ² Pellicon 2 cassettes 41 m ² with 36 x 1,14 Pellicon 3
Instrument specification and Performances			
Valves			
Pneumatic Valves	Novaseptic diaphragm valves	Novaseptic diaphragm valves	Novaseptic diaphragm valves
Pumps			
Feed Pump P001	WRIGHTFLOW Rotary lobe pump Flow rate: 4 to 60 L/min	WRIGHTFLOW Rotary lobe pump Flow rate: 12 to 180 L/min	WRIGHTFLOW Rotary lobe pump Flow rate: 40 to 310 L/min
Feed Pump P401	Quattroflow® Quaternary diaphragm pump Flow rate: up to 17 L/min Optional	Quattroflow® Quaternary diaphragm pump Flow rate: up to 35 L/min Optional	Quattroflow® Quaternary diaphragm pump Flow rate: up to 75 L/min Optional
Probes			
Flowmeters	Endress+hauser MASS, optional Feed: Range: 4–10 kg/min +/-2% MV Range: 10–90 kg/min +/-1% MV Filtrate: Range: 2–24 kg/min +/-2% MV	Endress+hauser MASS, optional Feed: Range: 10–185 kg/min +/-1% MV Filtrate: Range: 5–90 kg/min +/-1% MV	Endress+hauser MASS, optional Feed: Range: 30–320 kg/min +/-2% MV Filtrate: Range: 5–10 kg/min +/-0.1kg Range: 10–90 kg/min +/-1% MV
	Endress+hauser MAG, optional Feed: Range: 4–100 L/min +/-2% MV Filtrate: Range: 2–24 L/min +/-2% MV	Endress+hauser MAG, optional Feed: Range: 10–185 L/min +/-2% MV Filtrate: Range: 5–90 L/min +/-2% MV	Endress+hauser MAG, optional Feed: Range: 30–320 L/min +/-2% MV Filtrate: Range: 5–10 L/min +/-0.1kg Range: 10–90 L/min +/-1% MV
Conductivity sensors	Optek®, optional Filtrate: 5–10 µS/cm +/-0.2 µS/cm 10–18 µS/cm +/-2% MV 1–10 mS/cm +/-0.2 µS/cm 10–180 mS/cm +/-2% MV	Optek®, optional Filtrate: 5–10 µS/cm +/-0.2 µS/cm 10–18 µS/cm +/-2% MV 1–10 mS/cm +/-0.2 µS/cm 10–180 mS/cm +/-2% MV	Optek®, optional Filtrate: 5–10 µS/cm +/-0.2 µS/cm 10–18 µS/cm +/-2% MV 1–10 mS/cm +/-0.2 µS/cm 10–180 mS/cm +/-2% MV
	Retentate: 5–10 µS/cm +/-0.2 µS/cm 10–84 µS/cm +/-2% MV 1–10 mS/cm +/-0.2 µS/cm 10–180 mS/cm +/-2% MV	Retentate: 5–10 µS/cm +/-0.2 µS/cm 10–84 µS/cm +/-2% MV 1–10 mS/cm +/-0.2 µS/cm 10–180 mS/cm +/-2% MV	Retentate: 5–10 µS/cm +/-0.2 µS/cm 10–84 µS/cm +/-2% MV 1–10 mS/cm +/-0.2 µS/cm 10–180 mS/cm +/-2% MV
pH sensor	Hamilton Range: 0–14 pH +/-0.1	Mettler-Toledo Range: 0–14 pH +/-0.1	Mettler-Toledo Range: 0–14 pH +/-0.1
UV sensor	Optek®, optional Measurement range: 0 to 3 OD adjustable +/- 1% of full scale	Optek®, optional Measurement range: 0 to 3 OD adjustable +/- 1% of full scale	Optek®, optional Measurement range: 0 to 3 OD adjustable +/- 1% of full scale

We offer an extensive portfolio of related product 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.

Air Integrity Test

To ensure that the cassettes have been installed properly and has not sustained any damage during storage and handling, we recommend integrity testing prior to startup and after each post use cleaning. Air Integrity Test accessories consist of a set of air pressure regulators and fittings including assembly procedure to guarantee an easy plug and play solution.

NovAseptic® Valves, Mixer and Connectors

Engineered for optimal performance, reliability, durability and ease of maintenance. The design and development of each component is based on more than 25 years' experience, focused on aseptic application. This is why we choose to call it "Aseptic by Design."

Opticap® Capsules with Aervent® membrane

Our Opticap® single-use capsules embed Aervent® filters with sterilizing-grade 0.2 µm and polytetrafluoroethane (PTFE) hydrophobic membrane designed to provide efficient gas filtration. They are recommended for critical applications requiring a phobic filter with validated bacterial and viral retention capabilities.

To place an order or receive technical assistance

For additional information, please visit: SigmaAldrich.com/TFF-systems

To place an order or receive technical assistance, please visit SigmaAldrich.com/contactAF

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We have built a unique collection of life science brands with unrivalled experience in supporting your scientific advancements.

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