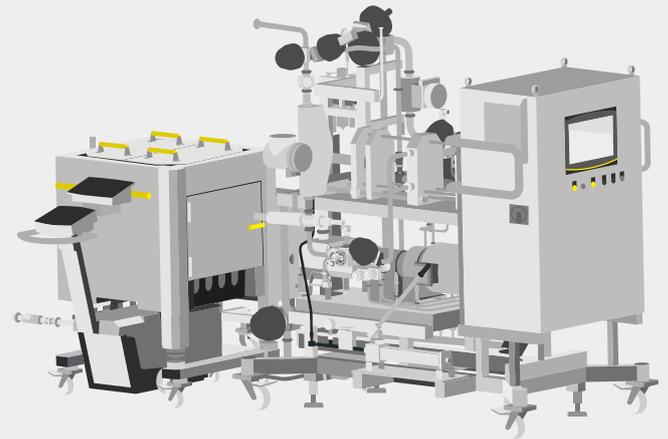


Sartoflow[®] MU TFF Systems

Fully Automated Multi-Use
Systems for Pilot- and
Commercial-Scale
Processing



Product Information

The scalable Sartoflow[®] Multi-Use (MU) System platform delivers advanced Tangential Flow Filtration (TFF) for efficient ultrafiltration and diafiltration. With optional stainless-steel or single-use recirculation vessels, it supports applications requiring precise control and high throughput. Compatible with Sartocube[®] and Sartoflow[®] TFF cassettes, it offers flexibility in membrane selection and scalability from pilot to production scale. The robust design ensures reliable operation, while the automation system enables user-friendly control and data management. Engineered for hygiene compliance, Sartoflow[®] MU systems support a range of biopharmaceutical applications. Available as Sartoflow[®] 5000 MU, and 10,000 MU, with customization on request.

Features and Benefits

- Bioburden control: Designed for optional steam-in-place operation
- Flexible: Compatible with stainless-steel or single-use recirculation tanks
- High performance: Enables optimal use of ECO-screen, Q-screen, and E-screen TFF cassettes for enhanced filtration efficiency.

Introduction

Relevant Applications

- Vaccines
- Monoclonal antibodies
- Recombinant proteins

Relevant Process Steps

- Ultrafiltration
- Microfiltration
- Diafiltration

The Sartoflow® MU TFF platform offers state-of-the-art TFF systems designed to meet the demanding needs of the biopharmaceutical industry. With its optional 200 L stainless-steel or single-use recirculation vessels, the systems are engineered for high-performance ultrafiltration and diafiltration processes. The optional steam-in-place (SIP) system configuration was designed for optimal steamability.

The robust system design ensures reliable operation, while its advanced automation system, based on Siemens S7 PLC and WinCC, provides intuitive control and comprehensive data management. The Sartoflow® 5000 MU and Sartoflow® 10,000 MU are built to meet the high hygiene standards, adhering to cGMP and ASME BPE guidelines. This makes the platform an ideal choice for applications such as protein concentration, buffer exchange, and virus purification. Its versatile design and efficient operation make it a valuable asset in any biopharmaceutical production facility.

Technical Specifications

System Specification

	Sartoflow® 5000 MU	Sartoflow® 10,000 MU
Holder size	Standard holder	<ul style="list-style-type: none"> ▪ Standard holder ▪ Extended holder ▪ Large holder
Filter holder specifications	<ul style="list-style-type: none"> ▪ Filter holder for up to 7 m² ▪ Torque adjustment via hydraulic pump information with specifications not included in material and component specification section. 	<ul style="list-style-type: none"> ▪ Standard holder*: up to 14 m² filtration area ▪ Extended holder*: up to 21 m² filtration area ▪ Large holder*: up to 28 m² filtration area ▪ *Torque adjustment via hydraulic pump
Number of cassettes Sartococon®	1 - 10	<ul style="list-style-type: none"> ▪ Standard holder: 2 - 20 ▪ Extended holder: 2 - 30 ▪ Large holder: 4 - 40
Number of cassettes Sartocube®	1 - 2	<ul style="list-style-type: none"> ▪ Standard holder: 2 - 4 ▪ Extended holder: 2 - 6 ▪ Large holder: 4 - 8
Recirculation pump	<ul style="list-style-type: none"> ▪ Lobe pump ▪ Tri-clamp 1.5" 1.5" Vertical port ▪ Ra ≤ 0.4 μm, e-polished ▪ Up to 5 m³/hr @ 4 barg ▪ Power rating: ~3 kW ▪ IP rating: IP66 	<ul style="list-style-type: none"> ▪ Lobe pump ▪ Tri-clamp 2" 2" vertical port ▪ Ra ≤ 0.4 μm, e-polished ▪ Up to 10 m³/hr @ 4 barg ▪ Power rating: ~5.5 kW ▪ IP rating: IP66

	Sartoflow® 5000 MU	Sartoflow® 10,000 MU
Vessel fed batch buffer pump	<ul style="list-style-type: none"> ▪ Watson Marlow 630 UN R peristaltic pump with endless tubing ▪ Up to 1080 LPH ▪ Power: 100 – 120 V 220 – 230 V, 50 60 Hz, 1 ph 	<ul style="list-style-type: none"> ▪ Watson Marlow 630 UN R peristaltic pump with endless tubing ▪ Up to 1080 LPH ▪ Power: 100 – 120 V 220 – 230 V, 50 60 Hz, 1 ph
Magnetic drive stirrer (tank)	Ra ≤0.4 μm, e-polished	Ra ≤0.4 μm, e-polished
Over-pressure protection	Yes	Yes
System frame and cabinet materials of construction	304	304
Process air supply [bar(g)]	2 – 4	2 – 4
Instrument air supply [bar(g)]	6 – 8	6 – 8
WFI [bar(g)]	2 – 3	2 – 3
CIP supply [bar(g)]	2 – 3	2 – 3
Clean steam [bar(g)]	2 – 3	2 – 3
Chilled water supply [°C]	~8	~8
Chilled water return [°C]	~12	~12
Power	<ul style="list-style-type: none"> ▪ 400 VAC, 50 Hz, 32 A, ▪ 3 phases + N + PE (EU) ▪ 1Ph, 220 V 3Ph, 415 V, 50 Hz 	<ul style="list-style-type: none"> ▪ 400 VAC, 50 Hz, 32 A, ▪ 3 phases + N + PE (EU) ▪ 1Ph, 220 V 3 Ph, 415 V, 50 Hz
Main control equipment	<ul style="list-style-type: none"> ▪ WinCC V7.5 Runtime ▪ Siemens CPU S7-1516-3PN DP incl. memory card ▪ Siemens Mirobox PC IPC427E with Siemens IFP 19-inch touch screen 	<ul style="list-style-type: none"> ▪ WinCC V7.5 Runtime ▪ Siemens CPU S7-1516-3PN DP incl. memory card ▪ Siemens Mirobox PC IPC427E with Siemens IFP 19-inch touch screen

Component Specification

	Sartoflow® 5000 MU	Sartoflow® 10,000 MU
Recirculation pump	Up to 5 m ³ /hr @ 4 bar(g)	Up to 10 m ³ /hr @ 4 bar(g)
Vessel fed batch buffer pump	Up to 1,080 LPH	Up to 1,080 LPH
Magnetic flow meter (retentate)	<ul style="list-style-type: none"> ▪ Accuracy: 0.5% of measured value ▪ Range: Up to 5,000 L/hr 	<ul style="list-style-type: none"> ▪ Accuracy: 0.5% of measured value ▪ Range: Up to 10,000 L/hr
TMP control valves	Retentate and permeate	Retentate and permeate
Permeate flow measurement (mass)	<ul style="list-style-type: none"> ▪ Accuracy: 0.15% of measured value ▪ Range: Up to 2,000 L/hr 	<ul style="list-style-type: none"> ▪ Accuracy: 0.15% of measured value ▪ Range: Up to 4,000 L/hr
Pressure transducer	<ul style="list-style-type: none"> ▪ Accuracy: ±0.5% of full scale ▪ Range: -1 to +5 bar(g) 	<ul style="list-style-type: none"> ▪ Accuracy: ±0.5% of full scale ▪ Range: -1 to +5 bar(g)

	Sartoflow® 5000 MU	Sartoflow® 10,000 MU
Temperature measurement [°C]	0 – 150	0 – 150
Conductivity (permeate) [µS/cm]	0.1 – 200	0.1 – 200
UV (optional)	<ul style="list-style-type: none"> ▪ Measurement range: 0 – 3 AU ▪ Wavelength: 280 nm ▪ Optical path length: 20 mm 	<ul style="list-style-type: none"> ▪ Measurement range: 0 – 3 AU ▪ Wavelength: 280 nm ▪ Optical path length: 20 mm

Components in Fluid Contact

Material of Construction

	Sartoflow® 5000 MU	Sartoflow® 10,000 MU
Product recirculation pump	<ul style="list-style-type: none"> ▪ Multilobe ▪ Single-mechanical seal SIC SIC EPDM ▪ Vertical port orientation ▪ EPDM, FDA CFR 21, 177.2600 & USP Class VI 	<ul style="list-style-type: none"> ▪ Multilobe ▪ Single-mechanical seal SIC SIC EPDM ▪ Vertical port orientation ▪ EPDM, FDA CFR 21, 177.2600 & USP Class VI
Filter holder	<ul style="list-style-type: none"> ▪ 1.4404 ▪ Ra ≤ 0.4 µm, e-polished 	<ul style="list-style-type: none"> ▪ 1.4404 ▪ Ra ≤ 0.4 µm, e-polished
Magnetic flow meter	SS 316 L	SS 316 L
Level switch	SS 316 L	SS 316 L
Connectors and fittings		
Sensors:	SS 316 L	SS 316 L
▪ Pressure	SS 316 L	SS 316 L
▪ UV	SS 316 L	SS 316 L
▪ Temperature	SS 316 L	SS 316 L
▪ Flow	SS 316 L	SS 316 L
▪ Conductivity	SS 316 L	SS 316 L
Sanitary fittings	SS 316 L	SS 316 L
TC gaskets	EPDM	EPDM
Diaphragm valves	SS 316 L	SS 316 L
Pneumatic diaphragm valves	SS 316 L	SS 316 L
Electrical diaphragm valves	SS 316 L	SS 316 L
Angle seat valves	SS 316 L	SS 316 L
Ball valves	SS 316 L	SS 316 L

Feed Line

The feed line connects the outlet of a recirculation containment, such as a stainless-steel vessel or single-use bag, to the stainless-steel filter holder(s). It includes the recirculation pump, protected by a level switch against dry run. A pressure sensor before the filter holder(s) automatically shuts off the pump if pressure exceeds 3.5 bar(g) to prevent filter membrane damage. The main components of the feed line are listed in the following table.

Components	Sartoflow® 5000 MU	Sartoflow® 10,000 MU
Diaphragm pressure sensor	■	■
Rotary lobe pump	■	■
Level switch	■	■

Retentate Line

The retentate line connects the filter holder(s) to the recirculation containment and includes a pressure sensor for transmembrane pressure (TMP) adjustment and a flow meter. The main components are listed in the following table.

Components	Sartoflow® 5000 MU	Sartoflow® 10,000 MU
Diaphragm pressure sensor	■	■
Diaphragm pressure control valve, pneumatically actuated	■	■
Flow meter (magnetic)	■	■

Permeate Line

The permeate line connects the filter holder(s) to the permeate interface for collection or drain, featuring a pressure sensor for TMP adjustment, a flow meter, conductivity sensor, and optional UV sensor. The main components are listed in the following table.

Components	Sartoflow® 5000 MU	Sartoflow® 10,000 MU
Diaphragm pressure sensor	■	■
Diaphragm pressure control valve, pneumatically actuated	■	■
Flow meter (mass)	■	■
Conductivity sensor	■	■
UV sensor (optional)	□	□

■ included

□ optional

Pumps and Sensors

The recirculation pump, situated between the recirculation vessel outlet and the filter holder in the feed line is a stainless-steel self-draining, non-self-priming positive displacement pump. It provides the necessary filtration pressure and flow rate, with speed regulated by a frequency drive. A dry running sensor ensures protection against dry runs.

Recirculation Vessel Options

The system can be ordered without recirculation tank, with 200 L stainless steel recirculation vessel or with a 200 L Palletank® container for single use recirculation bags.

Vessel	Option 1 Without Recirculation Tank	Option 2 MU Tank (CIP)	Option 3 MU Tank (CIP + SIP)	Option 4 SU Tank (Palletank®)
Working Volume (L)	-	200	200	200
Recirculation vessel	-	Operating pressure-vessel: 0–3 bar(g)	Operating pressure-vessel: 0–3 bar(g)	Depends on single use bag
Concept	-	<ul style="list-style-type: none"> ▪ Open loop jacket bottom jacketed, entire shell coverage up to working volume ▪ Flat top lid flanged vessel head ▪ J tube facing vessel wall (product buffer addition) and dip tube for retentate line. 		Palletank® container supports the use of single use recirculation bags
Component specification	-	Operating pressure-vessel: 0–3 bar(g)		
Material of construction	-	<ul style="list-style-type: none"> ▪ SS 316 Ti, static type and removable ▪ Chloride-free ceramic wool SS 304 		

Quality Concept

- Quality Management System: The system is designed and manufactured in accordance with ISO 9001-2015 standards, ensuring consistent quality and reliability in production processes.
- Current Good Manufacturing Practices (cGMP): The system adheres to cGMP guidelines, which are critical for ensuring the safety and efficacy of biopharmaceutical products.
- Design and Safety Standards: Compliance with EN ISO 12100:2010 for machinery safety and EN 60204-1 for electrical equipment, ensuring safe and reliable operation.
- Piping Standards: The system follows ASME BPE 2022 standards for piping, which are essential for maintaining hygiene and process integrity in biopharmaceutical applications.
- These standards and guidelines reflect the commitment to delivering high-quality, reliable, and safe equipment for the biopharmaceutical industry, ensuring that the system meets the rigorous demands of modern production environments.

Automation System

PLC: Siemens S7-1516-3PN|DP

HMI: Siemens IPC427E with 19-inch touch screen

The automation of the system is based on Siemens S7 series PLC and WinCC, providing the basic Siemens features. It consists of a full-featured package unit, including HMI, process control, and data storage. No additional computer system is required to run the process.

Sartorius develops the application software for the PLC and the SCADA system and provides all the necessary documentation for supporting the qualification.

The application software is made with Siemens WinCC and Siemens STEP7 (TIA-Portal), and based on a standard Sartorius module library, structured according to the ISA-S88 standard into the following modules:

- Control modules
- Equipment modules
- Phases
- Recipe editor (Sartorius does not create a recipe for user-specific processes. The user must create a recipe fitting to his process requirements)

Besides the HMI functionality, which is used for visualization and operation of the plant, additional functionality is provided. For example:

- Management of user permissions (Microsoft™ Windows™ user management and SIMATIC logon)
- Storage of process data
- Generation of reports
- Alarming of process values and device alarms (alarm and warning limits can be adjusted directly on the control module or automatically in predefined process phases)
- Interlocks that provide a certain process safety
- Reaction to emergencies, including HOLD logic
- Embedded 21 CFR part 11 compliant audit trailing (with SIMATIC logon. No electronic signatures.)
- Calibration routines for transmitters without an external interface

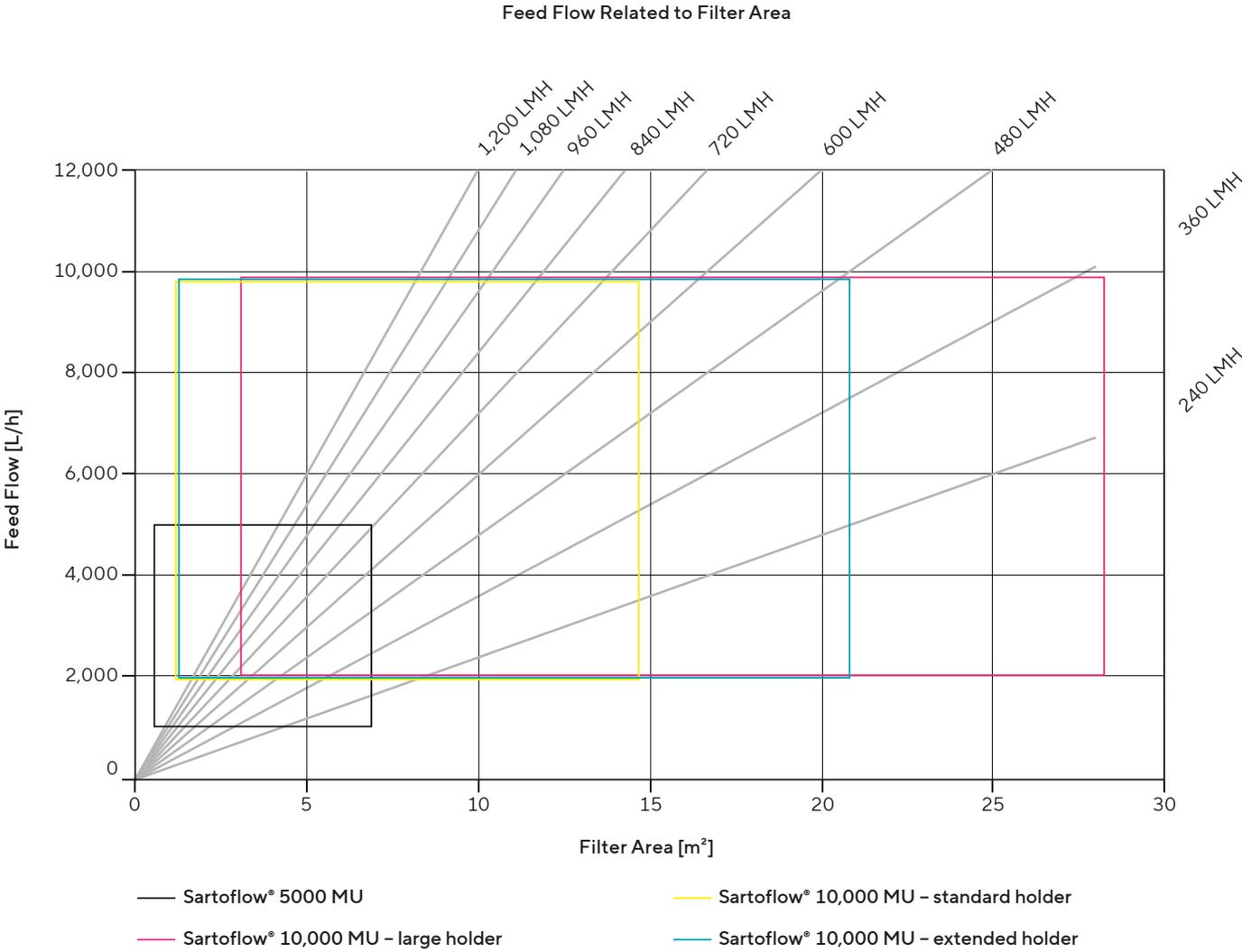
Uninterrupted Power Supply (UPS)

In case of power failure, the system transitions into a safe operating mode (shuts down all operations) and raises an alarm. The operation can be resumed without interruption until a pre-defined time (normally 5 minutes).

After exhaustion of internal UPS (approximately 5 minutes), the system shuts down automatically and must be started again with user interaction. All process data and settings are saved.

Instrumentation Specification

System Selection Guidance



Ordering Information

Sartoflow® 5000 MU With Standard Holder for up to 10 Sartocan® Cassettes

Configuration Number	SIP Functionality	Recirculation Tank	UV Sensor
SF05K-MUC010-01	No	-	Yes
SF05K-MUC010-02	No	-	No
SF05K-MUC010V01	No	Vessel	Yes
SF05K-MUC010V02	No	Vessel	No
SF05K-MUC010P01	No	Palletank®	Yes
SF05K-MUC010P02	No	Palletank®	No
SF05K-MUS010-01	Yes	-	Yes
SF05K-MUS010-02	Yes	-	No
SF05K-MUS010V01	Yes	Vessel	Yes
SF05K-MUS010V02	Yes	Vessel	No
SF05K-MUS010P01	Yes	Palletank®	Yes
SF05K-MUS010P02	Yes	Palletank®	No

Sartoflow® 10,000 MU With Standard Holder for up to 20 Sartocan® Cassettes

Configuration Number	SIP Functionality	Recirculation Tank	UV Sensor
SF10K-MUC020-01	No	-	Yes
SF10K-MUC020-02	No	-	No
SF10K-MUC020V01	No	Vessel	Yes
SF10K-MUC020V02	No	Vessel	No
SF10K-MUC020P01	No	Palletank®	Yes
SF10K-MUC020P02	No	Palletank®	No
SF10K-MUS020-01	yes	-	Yes
SF10K-MUS020-02	yes	-	No
SF10K-MUS020V01	yes	Vessel	Yes
SF10K-MUS020V02	yes	Vessel	No
SF10K-MUS020P01	yes	Palletank®	Yes
SF10K-MUS020P02	yes	Palletank®	No

Sartoflow® 10,000 MU With Extended Holder for up to 30 Sartocin® Cassettes

Configuration Number	SIP Functionality	Recirculation Tank	UV Sensor
SF10K-MUC030-01	No	-	Yes
SF10K-MUC030-02	No	-	No
SF10K-MUC030V01	No	Vessel	Yes
SF10K-MUC030V02	No	Vessel	No
SF10K-MUC030P01	No	Palletank®	Yes
SF10K-MUC030P02	No	Palletank®	No
SF10K-MUS030-01	yes	-	Yes
SF10K-MUS030-02	yes	-	No
SF10K-MUS030V01	yes	Vessel	Yes
SF10K-MUS030V02	yes	Vessel	No
SF10K-MUS030P01	yes	Palletank®	Yes
SF10K-MUS030P02	yes	Palletank®	No

Sartoflow® 10,000 MU With Large Holder for up to 40 Sartocin® Cassettes

Configuration Number	SIP Functionality	Recirculation Tank	UV Sensor
SF10K-MUC040-01	No	-	Yes
SF10K-MUC040-02	No	-	No
SF10K-MUC040V01	No	Vessel	Yes
SF10K-MUC040V02	No	Vessel	No
SF10K-MUC040P01	No	Palletank®	Yes
SF10K-MUC040P02	No	Palletank®	No
SF10K-MUS040-01	yes	-	Yes
SF10K-MUS040-02	yes	-	No
SF10K-MUS040V01	yes	Vessel	Yes
SF10K-MUS040V02	yes	Vessel	No
SF10K-MUS040P01	yes	Palletank®	Yes
SF10K-MUS040P02	yes	Palletank®	No

Service

Service	Sartoflow® 5000 MU	Sartoflow® 10,000 MU	Description
Installation	S877CINST	S877DINST	Reliable system installation ensures robust performance.
Installation pack (incl. travel exp.)	S877CINSTP	S877DINSTP	
Qualification - SAT	S877CSAT	S877DSAT	Ensures compliance and quality.
Qualification - SAT pack (incl. travel exp.)	S877CSATP	S877DSATP	
Single maintenance	S877CSM	S877DSM	Provides reliability and productivity.
Service level agreement, essential	S877CSLAE	S877DSLAE	Protects equipment stability annually.
Service level agreement, advanced	S877CSLAA	S877DSLAA	Protects equipment stability annually with extended coverage and control.
Service level agreement, comprehensive	S877CSLAC	S877DSLAC	Protects equipment stability annually with maximal protection and support.

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