

Sartoflow[®] 4500^{*}

Single-use Tangential Flow Filtration System



Product Information

The Sartoflow[®] 4500 single-use tangential flow filtration (SUTFF) system offers all of the controls and instrumentation for running fully automated UF | DF processes for batch volumes of 200 to 2,000 L (1 to 15 kg). The system is compact, has low hold-up volume, and the capacity to run cassette surface areas from 3 to 10 m².

Benefits

- Designed for efficiency in SUTFF applications
- High level of operation-based automation
- User-friendly and quick set-up time

Relevant Processes

- Vaccines
- Monoclonal antibodies
- Recombinant proteins

Relevant Process Steps

- Ultrafiltration
- Diafiltration

Related Process Scale

- Large scale manufacturing

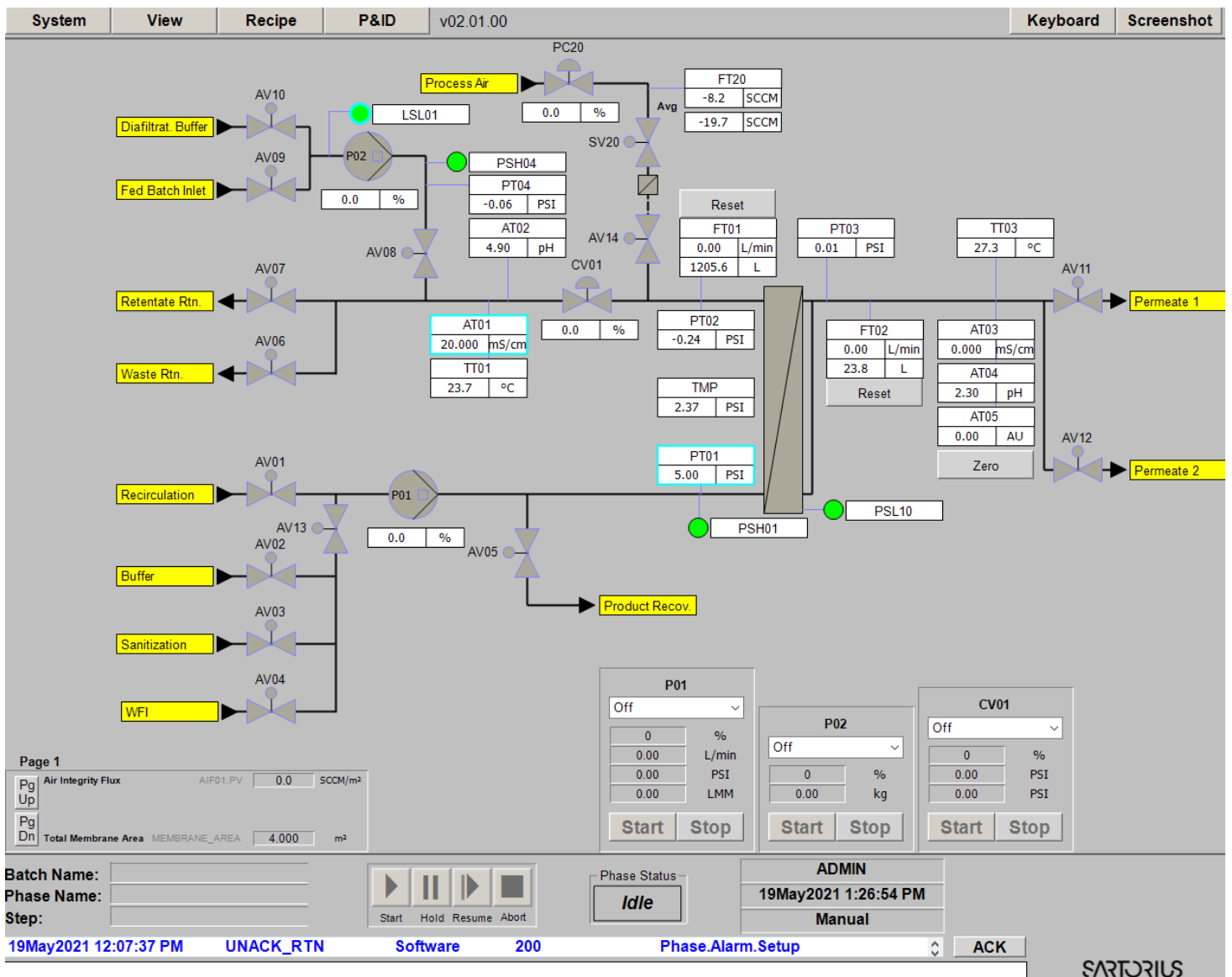
^{*} The Allegro™ CS4500 product name has been changed to Sartoflow[®] 4500 as part of the product integration into the Sartorius TFF portfolio. Both product names will be equivalents until the successful harmonization of all collaterals towards Sartoflow[®] 4500.

System Concept

The SUTFF system offers a combination of hardware, control system and single-use flow kits designed to work together perfectly. A smart system design ensures ease of use when running fully automated TFF process sequences with complete single-use flow kits incorporating all critical sensor and instrumentation technologies.

- The SUTFF system facilitates the automated processing of batch volumes from 200 to 2,000 L of monoclonal antibodies, recombinant proteins and vaccines processes.
- The single-use sensors provide the means to fully monitor and control the process.

Control System



Main screen with indication of all process signals as well as system | component status

The automation concept is based on the Process Step Editor (PSE), which allows the user to configure automated process sequences (operations) in a very simple and user-friendly way. This is an intuitive control system that is ideally suited for use in the SUTFF system and has an operation editor that allows easy generation and configuration of end-user-specific processes.

- The user can select the transition points that move the process from one step to the next by selecting one or more process parameters (with an “and | or” logic) such as conductivity, retentate volume, permeate volume, bag weight.
- Further flexibility is added as the system allows the configuration and use of loop and jump functions, making selective step repetitions feasible. Once selected by the operator, batch reports are automatically generated for each step at the end of a batch

Quality Standards

System

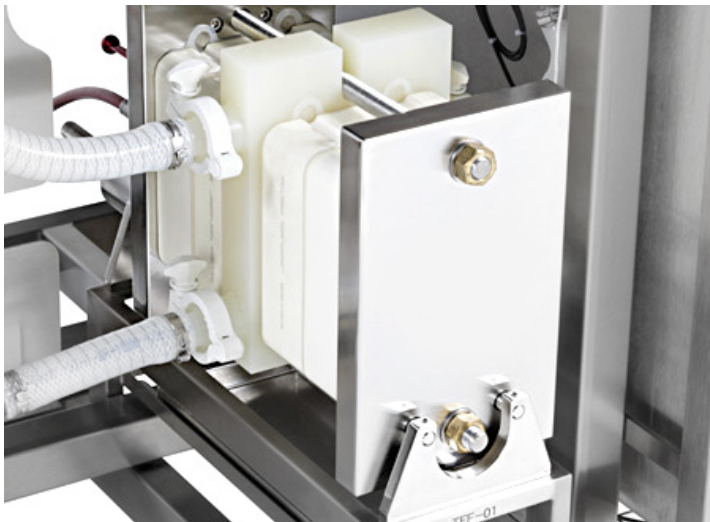
A stringent approach to quality of purchased and manufactured components is maintained. The system hardware is designed and built to well recognized industry standards, including:

- Good automated manufacturing practice (GAMP) current version
- Code of Federal Regulations 21 – Good manufacturing practice (GMP) for finished pharmaceuticals
- 2004/108/EC - Software complies with CFR21Part11 for electronic records, signature and audit trail
- The rules governing medicinal products in the European Community, Volume IV (EMEA | Asia), and Good Manufacturing practice for medicinal products, Annex 11, computerized systems

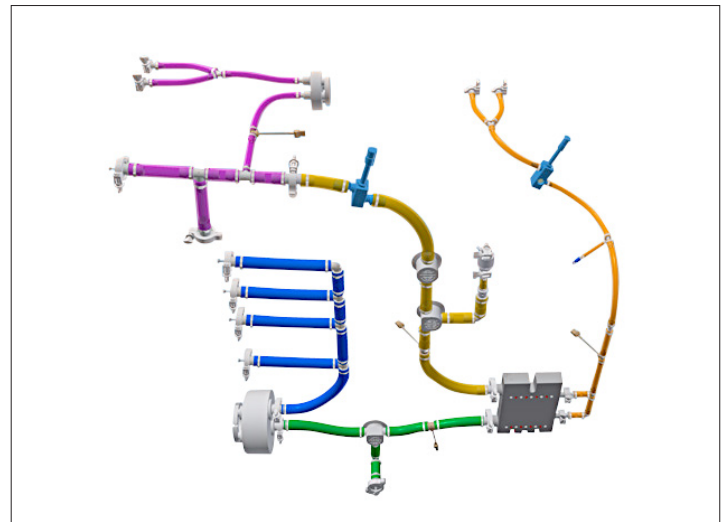
The quality management system of the manufacturing is certified according to DIN EN ISO9001.

Single-use Flow Kits

- Manufactured in a controlled environment (Class 7 in operation according to ISO 14644) under a quality system certified according to ISO 9001
- Feature components tested for biocompatibility and certified according to USP<88>
- Feature components certified as TSE | BSE-free
- Manufactured according to a validated assembly process
- Supplied double-bagged and irradiated with a minimum dose of 25 kGy



Sartoflow® 4500 Cassette Holder 3 to 10 m²



Single-use Flow Kits

Technical Specifications

System Specifications

Membrane area	3 – 10 m ²	
Recirculation pump	Quattroflow™* 5050SU 4-piston diaphragm pump 100 – 4,500 L/h	
Fed batch buffer pump	Quattroflow™ 1200SU 4-piston diaphragm pump 20 to 1,000 L/h	
Over pressure protection	Yes	
Maximum pressure	4 bar 58 psi	
Volume in feed and retentate lines	2.5 L	
Operating temperature range	4 – 40 °C	
Weight of empty system	420 kg	
Pneumatic supply	6 bar 90 psi	
System dimensions (length × depth × height)	EMEA Asia: 1,920 × 1,000 × 1,718 mm (nominal)	US: 1,980 × 1,120 × 1,730 mm (nominal)
Power	EMEA Asia: 400 VAC, 3-phase 50 Hz	US: 480 VAC, 3-phase 60 Hz, 11.1 FLA

Component Specification

Recirculation pump	100 – 4,500 L/h	
Fed batch buffer pump	20 – 1,000 L/h	
Pneumatic pinch valves	For use with 1" ID tubing (feed and retentate)	
Control valve	Single-use diaphragm valve body with positioner	
Recovery valve	Single-use diaphragm valve body	
Retentate flow measurement	Mathematically derived from pump (factory calibration range: 900 – 1,800 L/h accuracy ± 10% of reading)	
Permeate flow measurement	20 – 1,200 L/h ± 60 L/h of reading	
Pressure measurement	–0.48 – 5.2 bar –7 – 75 psi ± 0.15 bar ± 2 psi of reading	
Temperature measurement	2 – 50 °C	
Conductivity	Retentate: 0.0 to 150.0 mS/cm Permeate: 0.0 to 100.0 µS/cm and 0.1 to 150.0 mS/cm ± 0.5 mS/cm from 0 – 10 mS/cm ± 2 mS/cm from 10 – 100 mS/cm ± 4 mS/cm from 100 – 150 mS/cm (dependent of process and ambient temperature being equal)	
UV	0 – 3 AU ± 0.06 AU	
pH	0 – 12 pH ± 0.2 pH	
Level sensor	Presence absence liquid on the product inlet line	
Air flow	EMEA Asia: 0 – 12,500 sccm ± 0.18% of FS (< 20% FS) ± 0.9% of S.P. (20 – 100% FS)	US: 0 – 20,000 sccm ± 0.18% of FS (< 20% FS) ± 0.9% of S.P. (20 – 100% FS)
Mass measurement	Appropriate size load cell will be defined for each process	

*Quattroflow™ is a trademark of Dover Company.

Components in Fluid Contact	Material of Construction
Tubing	Platinum cured silicone, reinforced in high pressure sections
Product recirculation pump	Machined polypropylene head, EPDM valves and O-rings, Santoprene™* diaphragm
Diafiltration fed batch pump	Molded polypropylene head, polypropylene ports, EPDM valves and O-rings, Santoprene™ diaphragm
Connectors and fittings	Polypropylene
Single sensors: <ul style="list-style-type: none"> ▪ Pressure, UV ▪ Flow ▪ Conductivity (incl. temperature) 	<ul style="list-style-type: none"> ▪ Polysulfone ▪ PVDF with ruby bearing ▪ Polysulfone with stainless steel electrode
Multi sensor cell: Temperature conductivity UV	PPSU (electrodes: 316 L, gaskets: EPDM, UV window: quartz)
Sanitary fittings	Polypropylene, gaskets silicone
TC gaskets	Silicone
Diaphragm valves	Body polypropylene, diaphragm TPE
Distribution plate	Polypropylene

*Santoprene™ is a trademark of Exxon Mobil Corporation.

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