

# Sartoflow<sup>®</sup> 1000<sup>\*</sup>

## Single-use Tangential Flow Filtration System



### Product Information

The Sartoflow<sup>®</sup> 1000 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 20 to 500 L (200 g to 2.5 kg). The system is compact, has low hold-up volume and has the capacity to run cassette surface areas from 0.5 to 2.5 m<sup>2</sup>.

### Benefits

- Designed for efficiency in SUTFF applications
- High level of operation-based automation
- Quick single-use flow kit change out, and cleanability, maximizes batch turnaround

### Relevant Processes

- Vaccines
- Monoclonal antibodies
- Recombinant proteins

### Relevant Process Steps

- Ultrafiltration
- Diafiltration

### Related Process Scale

- Pilot- | large scale manufacturing

\* The Allegro™ CS1000 product name has been changed to Sartoflow<sup>®</sup> 1000 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<sup>®</sup> 1000.

# System Concept

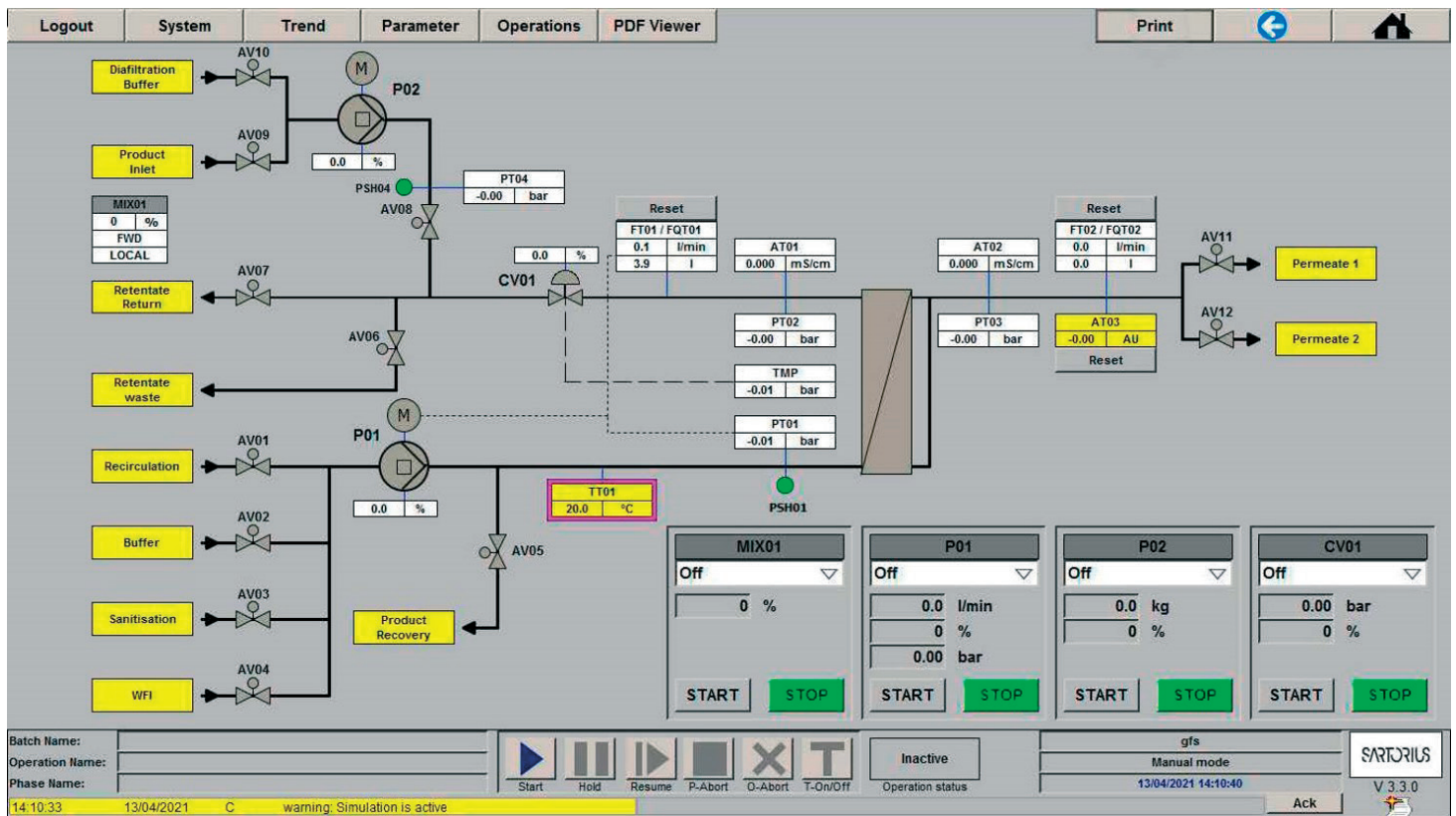
The SUTFF system offers a combination of hardware, control system and single-use flow kits designed to work together perfectly. A smart system design ensures ease of use when running fully automated TFF process sequences with complete single-use flow kits incorporating all critical sensor and instrumentation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

- The SUTFF system facilitates the automated processing of batch volumes from 20 to 500 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

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



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

# 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

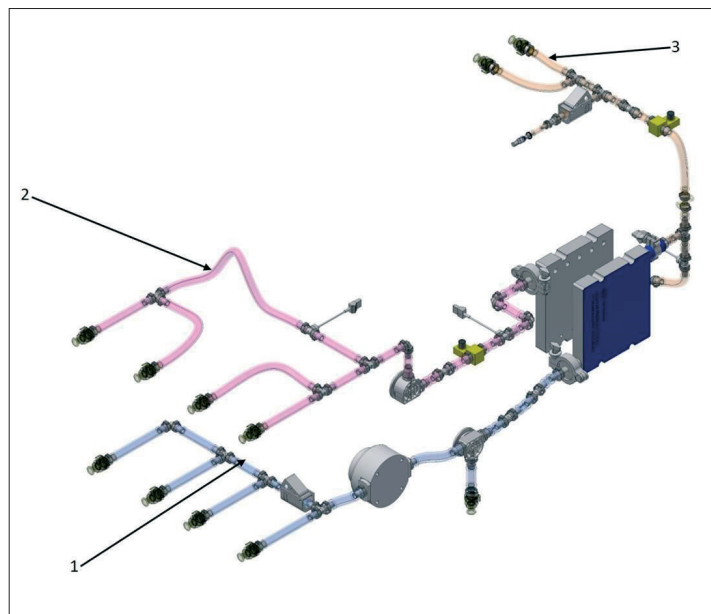
The quality management system of the manufacturing is certified according to DIN EN ISO9001.

## 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



Cassette Holder



Single-use Flow Kit including feed (1), retentate (2) and permeate (3) Flow Kit.

# Technical Specifications

System Specifications		
Membrane area	0.5 – 2.5 m <sup>2</sup>	
Recirculation pump	Quattroflow™* 1200SU, 4-piston diaphragm pump 20 to 1,000 L/h	
Fed batch   buffer pump	Ismatec Flowmaster™** FMT300 peristaltic pump, ISM Drive 6 – 600 L/h with 12.7 mm element	
Over pressure protection	Yes	
Maximum pressure	4 barg   58 psig for reinforced flow kit sections 1 barg   14.5 psig for permeate and medium pressure flow kit sections	
Holdup volume in feed and retentate lines	650 mL	
Operating temperature range	4 – 40°C	
System frame and cabinet materials of construction	304 stainless steel	
Weight of empty system	350 kg	
Pneumatic supply	6 bar   90 psi	
System dimensions (length × depth × height)	EMEA   Asia: 1,920 × 1,000 × 1,718 mm (nominal)	US: 2,050 × 1,200 × 1,750 mm (nominal)
Power	EMEA   Asia: 230 VAC 1-phase 50 Hz	US: 120 VAC, 1-phase 60 Hz

Component Specification	
Recirculation pump	Flow range 20-1,000 L/h
Fed batch   buffer pump	6-600 L/h with 12.7 mm element
Pneumatic pinch valves	For use with ½" tubing
Control valve	Single-use diaphragm valve body with positioner
Recovery valve	Single-use diaphragm valve body
Retentate flow measurement	20-1,200 L/h ± 60 L/h
Permeate flow measurement	20-1,200 L/h ± 60 L/h
Pressure measurement	-0.48 – 5.2 bar ± 0.15 bar   -7 – 75 psi ± 2 psi
Temperature measurement	0-70 °C ±1 °C
Conductivity	± 0.5 mS/cm from 0 –10 mS/cm ± 2 mS/cm from 10 – 100 mS/cm ± 4 mS/cm from 100 – 200 mS/cm
UV	0-2 AU ± 0.06 AU
Mass measurement	0-150 kg ± ≤1% of reading

\*Quattroflow™ is a trademark of Dover Company

\*\*Ismatec FLowmaster™ is a trademark of Cole-Parmer GmbH

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"> <li>▪ Pressure, UV</li> <li>▪ Temperature</li> <li>▪ Flow</li> <li>▪ Conductivity</li> </ul>	<ul style="list-style-type: none"> <li>▪ Polysulfone</li> <li>▪ Polysulfone with stainless sensor and silicon ring</li> <li>▪ PVDF with ruby bearing</li> <li>▪ Polysulfone with gold electrode</li> </ul>
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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