

Sartoflow[®] 1000

Single-use Tangential Flow Filtration System



Product Information

The Sartoflow[®] 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 200 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 0.6 to 2.8 m² and hollow fiber modules from 0.13 to 2.5 m² filtration area (usable filter area is depending on filter type and process parameters).

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

Introduction

System Concept

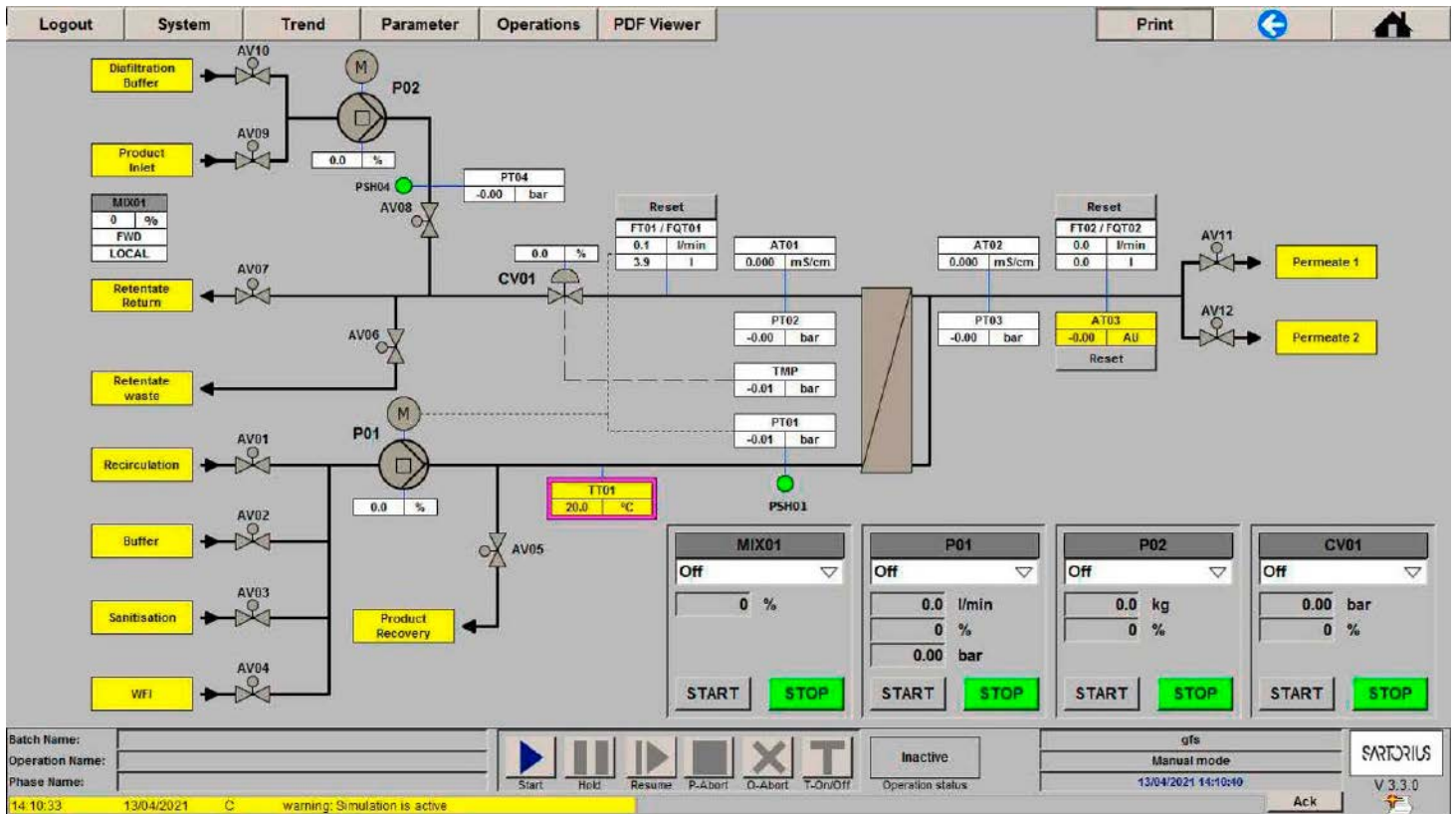
The SUTFF system offers a combination of hardware, control system and single-use flow kits designed to work together perfectly. A smart system design ensures ease of use when running fully automated TFF process sequences with complete single-use flow kits incorporating all critical sensor and instrumentation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

- The SUTFF system facilitates the automated processing of batch volumes from 20 to 200 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:

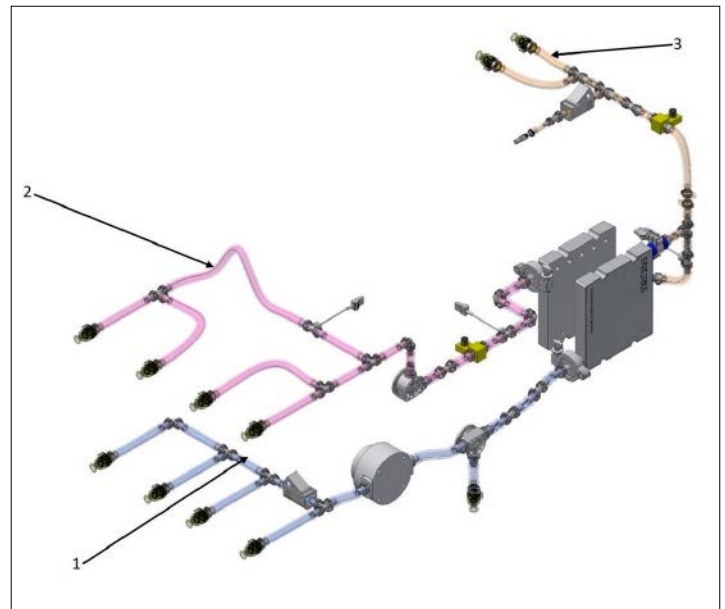
- Good automated manufacturing practice (GAMP) current version
- Code of Federal Regulations 21 – Good manufacturing practice (GMP) for finished pharmaceuticals
- 2004/108/EC - Software complies with CFR21Part11 for electronic records, signature and audit trail
- The quality management system is ISO 9001 complaint

Single-use Flow Kits for Flat Sheet Cassettes

- Manufactured in a controlled environment (Class 7 in operation according to ISO 14644)
- Feature components tested for biocompatibility and certified according to USP<88>
- Components are compliant with EMA410/01 Rev3 requirements with regards to TSE | BSE
- Manufactured according to a validated assembly process
- Supplied double-bagged and irradiated with a minimum dose of 25 kGy
- The quality management system is ISO 9001 compliant



Cassette Holder



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

Technical Specifications

System Specifications

Membrane area	0.6 – 2.8 m ² (usable filter area is depending on filter type and process parameters)	
Hollow fiber modules	0.13 and 2.5 m ² (suggested modules, further combinations are technically possible)	
Recirculation pump	Quattroflow™* 1200SU, 4-piston diaphragm pump 20 to 900 L/h	
Fed batch buffer pump	Ismatec Flowmaster™** FMT300 peristaltic pump, ISM Drive 6 – 600 L/h	
Over pressure protection	Yes	
Maximum pressure	4 bar 58 psi for reinforced flow kit sections 1 bar 14.5 psi for permeate and medium pressure flow kit sections	
Volume in ½" feed and retentate lines without cassettes	<650 mL	
Non recoverable volume with ½" ID tubing 20 L bag	<100 mL	
Non recoverable volume	<100 mL	
Holdup volume in ½" ID feed and retentate lines without cassettes	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 – 900 L/h
Fed batch buffer pump	6 – 600 L/h
Pneumatic pinch valves	For use with ½" ID tubing
Control valve	Single-use diaphragm valve body with positioner
Recovery valve	Single-use diaphragm valve body
Retentate flow measurement	30 – 1,200 L/h ± 10% of reading from 180 – 360 L/h ± 5% of reading from 360 – 720 L/h ± 10% of reading from 720 – 1,200 L/h
Permeate flow measurement	30 – 1,200 L/h ± 10% of reading from 180 – 360 L/h ± 5% of reading from 360 – 720 L/h ± 10% of reading from 720 – 1,200 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"> ▪ Pressure, UV ▪ Temperature ▪ Flow ▪ Conductivity 	<ul style="list-style-type: none"> ▪ Polysulfone ▪ Polysulfone with stainless sensor and silicon ring ▪ PVDF with ruby bearing ▪ Polysulfone with gold electrode
Sanitary fittings	Polypropylene
TC gaskets	Silicone
Diaphragm valves	Body polypropylene, diaphragm TPE
Distribution plate	Polypropylene

Ordering Information

Single-Use Flow Kits for Flat Sheet TFF Cassettes With Round Hole Ports** and Options

Description	Sensors	EMEA & APAC Order Code	North America Order Code
Sartoflow® STD 1000 ½" - Feed	Pressure, temp.	7443-0965Z	809-03D
Sartoflow® STD 1000 ½" - Retentate	Pressure, conductivity, flow	7443-0966A	809-03F
Sartoflow® STD 1000 ½" - Permeate	Pressure, flow, conductivity, UV	7443-0966B	809-02F
Sartoflow® 1000 – 10 L Recirculation Bag	-	7443-0972H	809-02H
Sartoflow® 1000 – 20 L Recirculation Bag	-	7443-0972G	809-02J
Sartoflow® 1000 – 100 L Recirculation Bag	-	7443-0971H	809-02K
Integrity test flow kit	Sterile air filter	FBT312862	FBT312861

*Santoprene™ is a trademark of Exxon Mobil Corporation.

**Please reach out to our application specialists for additional support on cassette installation and flow kit options for the Sartoflow® 1000 system.

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