

# Sartoflow<sup>®</sup> 4500

## Single-use Tangential Flow Filtration System



### Product Information

The Sartoflow<sup>®</sup> 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 m<sup>2</sup> and hollow fiber modules of 2.69 and 5 m<sup>2</sup> filtration area.

### 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

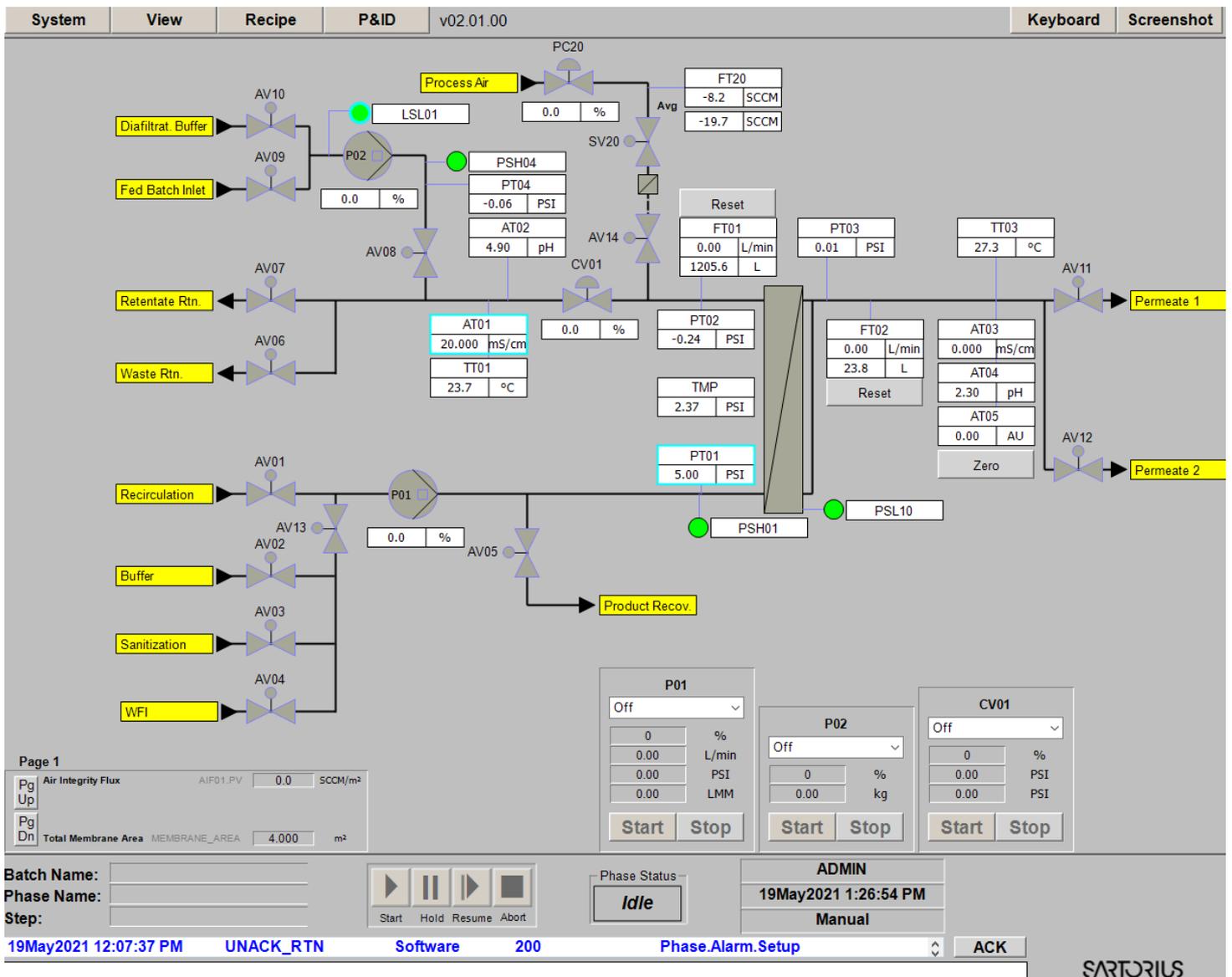
- Large scale manufacturing

# 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

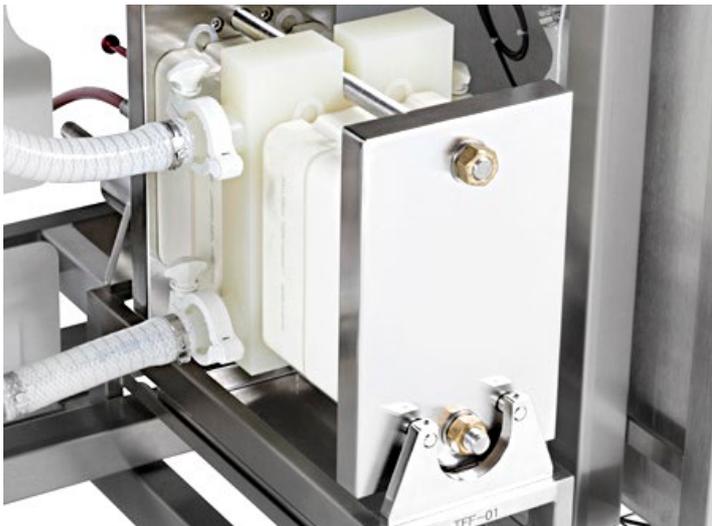
### System

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:

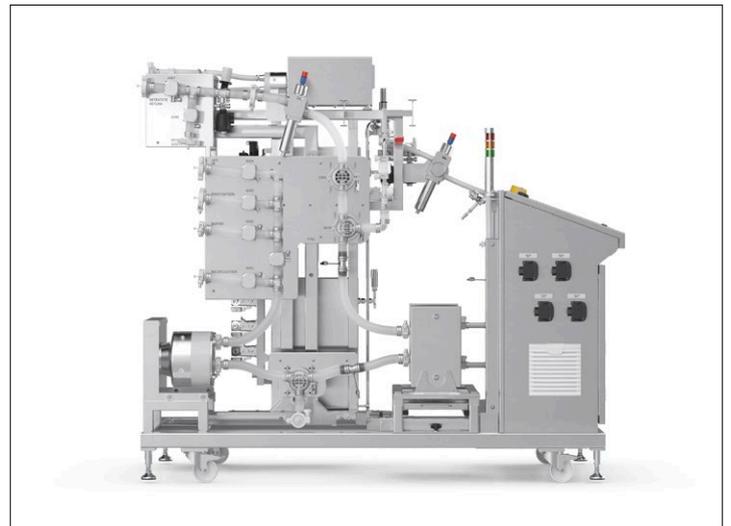
- Good automated manufacturing practice (GAMP) current version
- Code of Federal Regulations 21 – Good manufacturing practice (GMP) for finished pharmaceuticals
- 2004/108/EC - Software complies with CFR21Part11 for electronic records, signature and audit trail
- The quality management system is ISO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

### 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



Sartoflow® 4500 Cassette Holder 3 to 10 m<sup>2</sup>



Single-use Flow Kits

# Technical Specifications

## System Specifications

Filtration area	Flat sheet cassettes 3 – 10 m <sup>2</sup>	
Hollow fiber modules	2.69 and 5 m <sup>2</sup>	
Recirculation pump	Quattroflow™* 5050SU 4-piston diaphragm pump 100 – 4,500 L/hr	
Fed batch   buffer pump	Quattroflow™ 1200SU 4-piston diaphragm pump 20 to 900 L/hr	
Over pressure protection	Yes	
Maximum pressure	4 bar   58 psi	
Volume in 1" feed and retentate lines without cassettes	2.8 L	
Non recoverable volume	<100 mL in QUT (system flow kit, not including the retentate vessel)	
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/hr
Fed batch   buffer pump	20 – 900 L/hr
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/hr accuracy ± 10% of reading)
Permeate flow measurement	± 6% of full scale (1,000 L/hr)
Pressure measurement	± 0.15 bar   ± 2 psi of reading  ± 3% from 0 – 0.41 bar ± 5% from 0.41 – 2.07 bar ± 7% from 2.07 – 4.14 bar
Temperature measurement	2 – 50°C ± 0.5 °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)

\*Quattroflow™ is a trademark of Dover Company.

Component Specification									
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	<table border="0"> <tr> <td>EMEA   Asia:</td> <td>US:</td> </tr> <tr> <td>0 – 12,500 sccm</td> <td>0 – 20,000 sccm</td> </tr> <tr> <td>± 0.18% of FS (&lt; 20% FS)</td> <td>± 0.18% of FS (&lt; 20% FS)</td> </tr> <tr> <td>± 0.9% of S.P. (20 – 100% FS)</td> <td>± 0.9% of S.P. (20 – 100% FS)</td> </tr> </table>	EMEA   Asia:	US:	0 – 12,500 sccm	0 – 20,000 sccm	± 0.18% of FS (< 20% FS)	± 0.18% of FS (< 20% FS)	± 0.9% of S.P. (20 – 100% FS)	± 0.9% of S.P. (20 – 100% FS)
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Mass measurement	Appropriate size load cell will be defined for each process								

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>▪ Flow</li> <li>▪ Conductivity (incl. temperature)</li> </ul>	<ul style="list-style-type: none"> <li>▪ Polysulfone</li> <li>▪ PVDF with ruby bearing</li> <li>▪ Polysulfone with stainless steel 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.

# Ordering Information

## Preconfigured Sartoflow® 4500 System

	EMEA and APAC	US
Configuration code	LGRTFF4500SPPUTX	WH3SUTFFSTD-1IN
System components	Quattroflow™ 5050SU recirculation pump (600 – 4500 L/hr) and Quattroflow™ 1200SU buffer pump	
	Pneumatic pinch valves: <ul style="list-style-type: none"><li>▪ SU diaphragm control valve</li><li>▪ SU diaphragm recovery valve</li></ul>	
	Single sensors: Pressure, UV, temperature, flow, conductivity	
	Multi sensor cell: <ul style="list-style-type: none"><li>▪ Temperature   conductivity   pH   UV</li><li>▪ Flow, TMP and bag weight controller</li></ul>	

## Single-Use Flow Kits for Flat Sheet TFF Cassettes

Description	Sensors	Order Codes EMEA and Asia	Order Codes US
Sartoflow® STD 4500 1" - Feed	Pressure	7444-0653J	8444-0687K
Sartoflow® STD 4500 1" - Diafiltration	Pressure	7444-0653G	8444-0734H
Sartoflow® STD 4500 1" - Buffer & WFI	-	7444-0653H	8444-0687J
Sartoflow® STD 4500 1" - Retentate	Pressure, conductivity, temp.	7444-0653K	8444-0687L
Sartoflow® STD 4500 ½" - Permeate	Pressure, flow, conductivity, UV, pH, temp.	7444-0653L	8444-0734J
Sartoflow® STD 4500 - Pump Head	-	7444-0653M	7444-0653M

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