



SARTOFLOW® Alpha plus SU

Outstanding crossflow filtration performance and efficient single-use technology combined

Product Information

The SARTOFLOW® Alpha plus SU combines innovative single-use technology with excellence in Crossflow performance – to meet your process needs and to supply you with an easy to use solution. Bag Loop assemblies for the SARTOFLOW® Alpha plus SU are supplied sterile and ready to use.



Description

The SARTOFLOW® Alpha plus SU is a benchtop Crossflow system for micro- and ultrafiltration applications.

All product wetted parts of the System are supplied sterile, made from single-use components and pre-assembled. Each assembly is optimized for ultrafiltration and diafiltration (UF| DF) applications used in many downstream processes like purification of vaccines, monoclonal antibodies or recombinant proteins.

The system is suitable for use in cGMP environments for process development, clinical trials and for small-scale production batches.

The system is an ideal choice for Contract Manufacturers, research and development applications and all companies with multi-product through-put.

The SARTOFLOW® Alpha plus SU is equipped with a gamma pre-sterilized loop consisting of a self contained UF unit, pump tubing pressure domes, flow meters, valves, bags and tubing.

This Crossflow system control unit is equipped with our DCU4 control unit that can communicate with Sartorius Stedim Biotech BioPAT® MFCS/win SCADA software. The Crossflow filter holder is specially designed for Sartorius' Sartocan® Slice Self Contained unit with membrane areas up to 0.42 m².

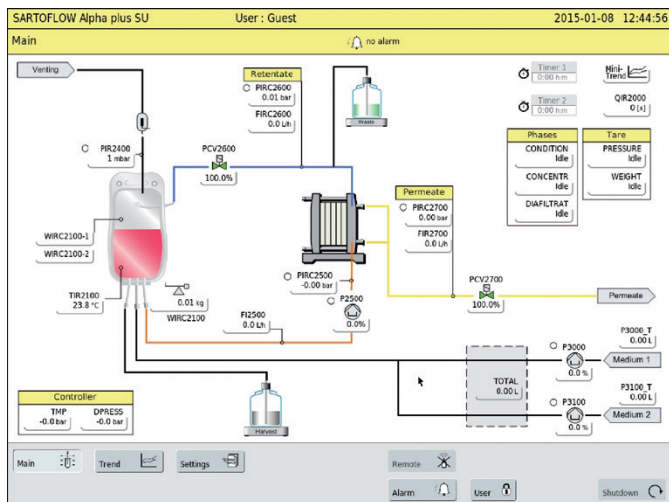
The cassette is designed with the same hydrodynamic flow path as our larger production scale filter cassettes, enabling linear scale-up to larger filter areas. The unique compact design allows small volumes to be run on a laboratory bench even under aseptic conditions.

The pump and control unit, the whole system, including control unit, can be run in harsh production environments. The unit and its touch screen are splash-proof and can withstand continuous use in both laboratory and production conditions.

The system is easy to install in the production area. The control unit and filtration module are separate components, to make handling more convenient.

Filtration Module

Filtration Module includes a Sartocan Slice Holder – optional hydraulic closure – for Sartocan® Slice Self Contained operation, a bag holder, TMP control, delta P control, four pressure transmitters, two flow transmitters, two positioning actuators for the back pressure control valves, overpressure protection, peristaltic recirculation pump (0.3 m³/h vs. 3 bar), a temperature transmitter and level control.



DCU-4 touch screen

SARTOFLOW® Alpha plus Tower

DCU4 control includes a 15" Siemens Touch Panel. Two peristaltic feed pumps are integrated in to the control tower making it possible to load product and buffer as discrete process steps.

Bag Loop with Sartoco® Slice Self Contained

For single-use processing the SARTOFLOW® Alpha plus SU is supplied with a gamma sterilized loop consisting of a PESU Self Contained Filter Unit, four pressure domes, retentate and permeate flow meters, two valve bodies for back pressure control in either the retentate or permeate lines, and a 10 l recirculation bag with vent filter and tubing.



The Sartoco® Slice Self Contained – available from 0.1 m² to 0.42 m² membrane area – is part of the gamma sterilized loop assembly. The system is suitable for use in laboratory and cGMP environments. Bag Loop Assemblies are available in various configurations. Opta® sterile connectors with colored tags make it easy to connect to the bag loop while maintaining the sterile envelope.

The single-use pressure domes are located in feed, retentate, permeate line and for over pressure protection of the recirculation bag. The pressure domes are simply snapped on to the reusable pressure transducer. SARTOFLOW® Alpha plus SU features flow meters in the permeate and retentate line.

Bag Stand

A bag stand for the SARTOFLOW® Alpha plus SU is designed for Crossflow operations. During process the slope of the bag can be changed to optimize the recirculation volume. The stand is mounted on to a load cell for accurate level control.

Control Unit

All control and alarm functions are set and displayed on the 15" touch screen. The screen displays all signal readouts, set point controllers and trend curves to ensure user friendly operation. It enables immediate process control even when you change parameters on the fly. Active controllers and alarms are visualized in the main display.

The logbook function stores alarms, set points and user logs. All logbook entries are transferable to the optional BioPAT® MFCS/win SCADA software and can be personalized with three-level password protection.

Process Sequences

Predefined sequences provide operation for membrane conditioning, Concentration, Diafiltration (UF | DF), Rinsing and CIP steps using predefined parameters.

All SARTOFLOW® Alpha plus SU units are equipped with a feed pressure and level controllers for running the system at user defined set points. The feed pressure controller keeps the feed pressure constant by controlling the pump speed (feed pressure is the defined value). Delta P and the retentate flow are controlled by the recirculation pump speed.

The TMP option permits control of the retentate and the permeate pressure at predefined set points using the valves electrically driven positioning actuators.

The retentate flow option enables the user to run processes at specified retentate flow rates by adjusting the feed pump speed. The level controller can run two integrated peristaltic pumps to keep the volume in the recirculation bag constant. The systems' software architecture is designed to allow one to conduct optimization trials at constant recirculation flow rates and TMP values.

- DCU4-Touchscreen
- Stand with recirculation bag
- Step by step TMP and Feed Flow rate

Optimization trials can be customized using our BioPAT® MFCS/win SCADA software.

Data Acquisition

Data acquisition is accomplished using an external PC connected to the system over an ethernet interface. BioPAT® MFCS/win SCADA software for data acquisition, batch management and visualization is included in the package. The system can be easily integrated into existing MFCS networks with Sartorius Stedim Biotech fermentors and incubation shakers.

cGMP Production Environment

Optional, validated MFCS/win software can be upgraded with the 21 CFR Part 11 and S88 recipe option.



Stand with recirculation bag

Technical Data

Specifications

Pump output	300 L/h @ 3 bar (43 psi)
PESU and Hydrosart® Sartocoon® Slice Self Contained	up to 0.42 m ² membrane area
Level control via load cell	0 – 100 kg
Max. inlet pressure	3 bar (43 psi) sterile Opta® connectors with colored tags
Dimensions (H × L × W)	1,100 mm × 800 mm × 960 mm
Weight approx.	150 kg
Electrical requirements	230 VAC 60 Hz 120 VAC 50 Hz

SARTOFLOW® Alpha plus SU modules	Filtration module with standard filter holder	Filtration module with hydraulic filter holder
DCU4 Tower	230 VAC 60 Hz	120 VAC 50 Hz

Ordering Information

Consumables

Components of bag assembly: 10 L recirculation bag, pressure domes, flow meter, valve bodies, Opta® connectors and tubing with color code.

Cut off	Membrane	Channel Configuration	0.14 m ²	0.28 m ²	0.42 m ²
10 kD	Polyethersulfone	ECO-Screen	SFA-SUM1463901	SFA-SUM1463921	SFA-SUM1463931
10 kD	Hydrosart®	ECO-Screen	SFA-SUM1443901	SFA-SUM1443921	SFA-SUM1443931
30 kD	Polyethersulfone	ECO-Screen	SFA-SUM1465901	SFA-SUM1465921	SFA-SUM1465931
30 kD	Hydrosart®	ECO-Screen	SFA-SUM1445901	SFA-SUM1445921	SFA-SUM1445931
100 kD	Polyethersulfone	ECO-Screen	SFA-SUM1466801	SFA-SUM1466821	SFA-SUM1466831
100 kD	Hydrosart®	ECO-Screen	SFA-SUM1446801	SFA-SUM1446821	SFA-SUM1446831
300 kD	Polyethersulfone	ECO-Screen	SFA-SUM1467901	SFA-SUM1467921	SFA-SUM1467931

Cut off	Membrane	Channel Configuration	0.1 m ²	0.2 m ²	0.3 m ²
10 kD	Polyethersulfone	E-Screen	SFA-SU-1463901	SFA-SU-1463921	SFA-SU-1463931
30 kD	Polyethersulfone	E-Screen	SFA-SU-1465901	SFA-SU-1465921	SFA-SU-1465931
0.1 µm	Polyethersulfone	W-Screen	SFA-SU-1545801	SFA-SU-1545821	SFA-SU-1545831



Sartocin® Slice Self Contained Bag Loop Assembly

Data acquisition

- BioPAT® MFCS/win SCADA Standard Software Package
- Recipe Control (S88) Software Module
- 21 CFR part 11 Software Module

Abbreviations

- $\Delta d = P_{\text{feed}} - P_{\text{retentate}}$
- MFCS: Multi Function Control Software
- DCU4: Digital control unit
- cGMP: current Good Manufacturing Practice
- $TMP = \left(\frac{P_{\text{feed}} + P_{\text{retentate}}}{2} \right) - P_{\text{permeate}}$
(TMP: Trans Membrane Pressure)

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