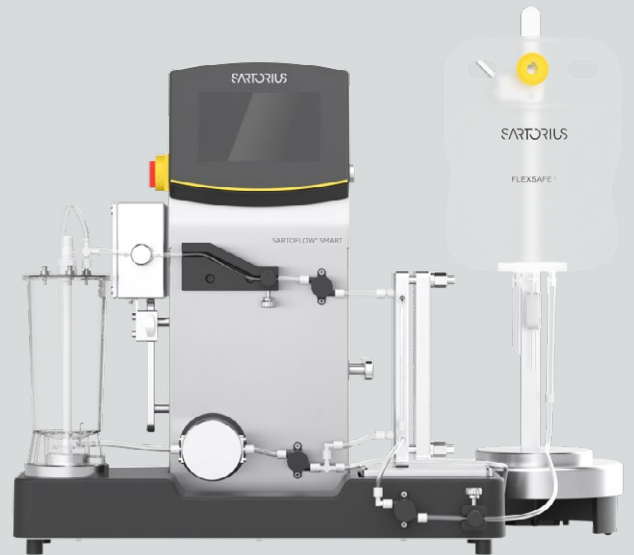


Sartoflow[®] Smart

Smart and Easy – The
Crossflow System For
Process Development



Product Information

The Sartoflow[®] Smart is a modular and flexible small scale benchtop crossflow system optimized for ultrafiltration and diafiltration applications used in many downstream processes, such as purification of vaccines, monoclonal antibodies and recombinant proteins. The system is suitable for use in laboratory environments for process development and clinical trials as well as for cGMP environments.

Features and Benefits

- Excellent Flexibility
Ideal for membrane surface areas from 50 cm² to as much as 0.14 m²
- Intuitive and Comfortable
User-friendly through high level of automation with automatic retentate valve and external feeding pump
- Highest Product Yields
Low recirculation volume at 20 mL and low shear four-piston membrane pump

Introduction

Description

The Sartoflow® Smart system includes a Sartocon® Slice 200 filter cassette holder that can accommodate cassette areas from 200 cm² to 0.14 m² membrane area, 1 L graduated recirculation vessel made of transparent PSU with a self-sealing lid, vortex breaker and magnetic stir bar for effective mixing. The tank is located on top of a load cell for level control. Three pressure sensors, each in the feed, retentate and permeate line for operating the system at user-defined set points. Interactive prompts for easy guidance through entire sequences that support the daily operation are displayed conveniently on a 7" touch panel. When the optional automated retentate valve is included, the system can be run at stable retentate pressure or transmembrane pressure (TMP) values. One external peristaltic pump is optionally available, making it possible to load product or buffer as a discrete process step for feeding or buffer exchange. An electronic balance is connected to the Sartoflow® Smart for monitoring the quantitative collection of filtrate and its collection rate. A low shear four-piston membrane pump provides a wide range of flow rates making it possible to use membrane areas from 50 cm² to as much as 0.14 m².

A variety of options are available making it possible to customize the system to your specific requirements e.g. conductivity-, pH- or a temperature probe can be installed into the recirculation vessel.

The Sartoflow® Smart can also be configured with further options like bag stands for the retentate or permeate balance. This crossflow system is equipped with our intuitive DCU-4 control unit that readily communicates with Sartorius Stedim Biotech's BioPAT® Scada, MFCS-4 software for data logging and export to excel.

The Sartoflow® Smart can be configured to accept either Sartocon® Slice 200 or Sartocon® Slice Eco UF cassettes. An optional holding device for 50 cm² filtration modules e.g. Sartocon® Slice 50 is available. As a result, this gives you an exceptionally wide working range of membrane surface areas. Since all Sartocon® crossflow cassettes have the same hydrodynamic flow path length, the Sartoflow® Smart can be used for scale up and scale down experiments.

Its unique compact design has an ultra-low loop volume of ~20 mL, making it possible to concentrate even small process batches. The Sartoflow® Smart can be run in demanding production environments. Moreover, the unit and its touch screen is built to withstand continuous use in both laboratory and production conditions.

Recirculation Module

The recirculation tank utilizes a load cell for level control and can be replaced by a recirculation bag stand with Flexboy® bag. All control functions are fully operable whether you run the system with a polysulfone (PSU) tank or a single-use bag.

Control Functions

All control and alarm functions are set and displayed on the 7" touch screen. The screen displays all signal readouts, set point controllers and trend curves, ensuring user-friendly operation. It enables immediate process control, even when you change parameters on the fly. Active controllers and alarms are visualized on the main display. The logbook function stores alarms, set points and user logs. All logbook inputs can be read into the optional MFCS | win Scada software program and can be personalized using three-level password protection.

Process Sequences

You can use predefined parameters to automatically run customized sequences for concentration, diafiltration (UF | DF), rinsing, filling, draining, flushing steps and tare functions. All Sartoflow® Smart units are equipped with feed pressure and level controllers for operating the system at user-defined set points. With the optional automated retentate valve (also available as an retrofittable upgrade) processes can also be executed with constant process value for retentate pressure and TMP. The level controller controls the peristaltic pump to keep the volume in the recirculation vessel or bag constant.

cGMP Production Environment

Optionally validated MFCS | win software can be upgraded with our 21 CFR Part 11 and S88 recipe options. The BioPAT® MFCS | win OPC specifies the communication of real-time data between control devices from different manufacturers. This convenient option offers you the possibility of connecting the Sartoflow® Smart to other process control systems.

Features	Benefits
Low shear four-piston membrane pump	The system is ideally suited for both scaling studies and low volume UF DF work over a very wide range of surface areas from 50 cm ² to as much as 0.14 m ² .
Qualifiable system	Ready to be used in production and cGMP environments.
DCU4 HMI	Easy-to-use in any research, production or lab environment. The DCU-4 touch screen offers a full view and control of the critical process parameters.
Preprogrammed sequences	The system can be set-up to run a process to a redefined recipe
Scalability with Sartorius TFF portfolio	Similar predefined sequences on all TFF systems and universal Sartocan [®] cassette design enable scalability throughout the Sartorius TFF portfolio.

Data Acquisition

Data collection software can be installed on your PC and connected to the Sartoflow[®] Smart system over an ethernet interface. You can easily integrate this system into existing MFCS networks with Sartorius DCU-4 based systems.

Service

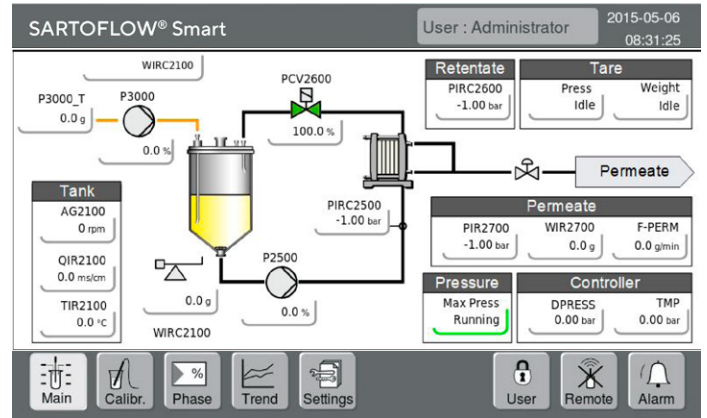
Reliability and smooth operation of equipment are ensured through proper installation | configuration and regular maintenance by our Sartorius service experts.

Service offering includes:

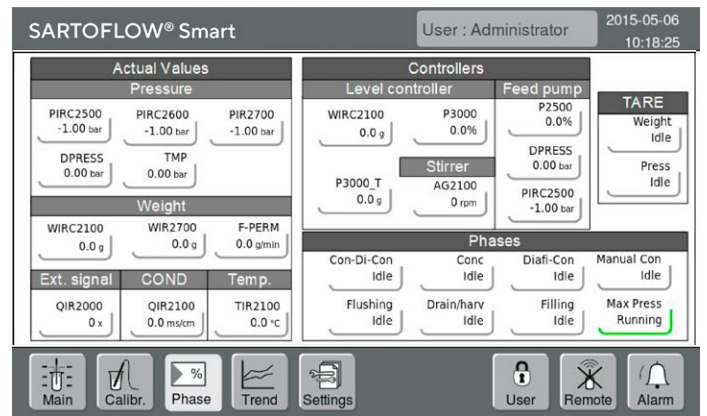
- Installation
- Site Acceptance Test (SAT)
- Extended warranty
- Preventive maintenance contracts

Benefits:

- Perfectly operating and protected equipment
- SAT and complete documentation for GMP compliance
- Maximum system up time
- Cost-efficient, reliable budget planning



DCU-4 Touch Screen



Process Sequences

The following production sequences are provided with the system

Con-Di-Con	Used to concentrate the product to a predefined level and to diafilter the product subsequently - followed by concentration to a final level.
Concentration	Used to concentrate the product to a predefined final level.
Diafi-Conc	Diafiltration of the product. At the end of this phase, the product is concentrated to a predefined volume.
Flushing	Used to rinse the system by flushing the pipework and tank with WFI, acidic or alkaline solutions.
Drain harv	Used to drain or harvest the product from the system.
Filling	Used to fill the tank or bag with the product.
Weight	Automatically zeros the load cell.
Pressure	Automatically zeros all pressure sensors.

Just select and start the phases on the control panel and the DCU-4 will then execute the steps automatically. Interactions or process end will be indicated by text messages.

Technical Specifications

Sartoflow® Smart is a modular system offering numerous standard and optional features:

Standard Module

Filtration module 230 V – 50 Hz or 120 V – 60 Hz: four-piston diaphragm feed pump, Sartococon® Slice 200 filter holder, three pressure sensors, one load cell, one manual valve in the retentate and permeate line, touch screen, DCU-4

1 L graduated recirculation vessel (transparent PSU) with self-sealing lid, vortex breaker and magnetic stir bar.

Options

Automated retentate valve

External diafiltration pump

pH sensor

Conductivity sensor

Temperature sensor

External permeate balance for up to 64 kg

Sartoflow® Smart recirculation bag holder for Flexboy® bags

Sartoflow® Smart permeate bag holder for Flexboy® bags

Holder for Sartococon® Slice 50 cassette

Sartoflow® Smart replacement pump head for QF150

Sartoflow® Smart replacement vessel 1L PSU

Documentation

Standard documentation package for Sartoflow® Smart

cGMP documentation package for Sartoflow® Smart

Basic Qualification Test documentation package for Sartoflow® Smart

IQ | OQ execution package for Sartoflow® Smart

Replacement Equipment

Sartoflow® Smart replacement pump head for QF150

Sartoflow® Smart replacement vessel 1L PSU

Tubing and connector set for Sartoflow® Smart

Tubing set for automated retentate valve

Optional Software

MFCS | win standard software package

Recipe control (S88) software module

21 CFR part 11 software module

BioPAT® MFCS | win OPC

Specifications

Pump output 1 – 100 L/h @ 3 bar (43.5 psi)

Filter area From 50 cm², 200 or 400 cm² up to 0.14 m² of membrane area

Minimum recirculation volume < 20 mL

Max. inlet pressure 3 bar (43.5 psi)

Dimensions (W × D × H) 602 × 440 × 610 mm

Weight ~35 kg (77 lbs.)

Electrical requirements 230 VAC | 50 Hz 2 Amp;
120 VAC | 60 Hz 3 Amp

IP-Standard 33

Tubing connections Luer-lock

Order Information

Replacement and Maintenance Material

Order Code	Type
179SMARTOP_TUBP	Bioprene® Tubing & Connector Set for Sartoflow® Smart (whole recirculation loop, retentate line for automated retentate valve 179SMARTOP-TUBRET needs to be ordered separately))
179SMARTOP-TUBRET	Tubing for Automated Retentate Valve of Sartoflow® Smart (retentate line only)
179SMARTPPQF150	Sartoflow® Smart replacement pump head for QF150
179SMARTVESSEL	Sartoflow® Smart replacement vessel 1L PSU

Sartocon® Slice 50 With 50 cm² Membrane Area

Order Code	Membrane	MWCO
3D91441950ELLPU	Hydrosart®	2 kD
3D91442950ELLPU	Hydrosart®	5 kD
3D91443950ELLPU	Hydrosart®	10 kD
3D91445950ELLPU	Hydrosart®	30 kD
3D91460950ELLPU	PESU	1 kD
3D91462950ELLPU	PESU	5 kD
3D91463450ELLPU	PESU	8 kD
3D91463950ELLPU	PESU	10 kD
3D91465950ELLPU	PESU	30 kD
3D91465050ELLPU	PESU	50 kD
3D91466850ELLPU	PESU	100 kD
3D91467950ELLPU	PESU	300 kD

Sartocon® Slice Eco With 0.14 m² Membrane Area

Order Code	Membrane	MWCO
3M51463901E--SW	PESU	10 kD
3M51465901E--SW	PESU	30 kD
3M51466801E--SW	PESU	100 kD
3M51443901E--SW	Hydrosart®	10 kD
3M51445901E--SW	Hydrosart®	30 kD
3M51446801E--SW	Hydrosart®	100 kD

Sartocon® Slice 200 With 0.02 m² Membrane Area

Order Code	Membrane	MWCO
3081460902E--SW	PESU	1 kD
3081462902E--SW	PESU	5 kD
3081463402E--SW	PESU	8 kD
3081463902E--SW	PESU	10 kD
3081465902E--SW	PESU	30 kD
3081465002E--SW	PESU	50 kD
3081466802E--SW	PESU	100 kD
3081467902E--SW	PESU	300 kD
3081441902E--SW	Hydrosart®	2 kD
3081442902E--SW	Hydrosart®	5 kD
3081443902E--SW	Hydrosart®	10 kD
3081445902E--SW	Hydrosart®	30 kD
3081446802E--SW	Hydrosart®	100 kD

Sartocon® Slice 200 Eco With 0.02 m² Membrane Area

Order Code	Membrane	MWCO
3M81443902E--SW	Hydrosart®	10 kD
3M81445902E--SW	Hydrosart®	30 kD
3M81446802E--SW	Hydrosart®	100 kD
3M81463902E--SW	PESU	10 kD
3M81465902E--SW	PESU	30 kD
3M81466802E--SW	PESU	100 kD
3M81467902E--SW	PESU	300 kD

Consumables

Order Code	Crossflow Bag Specification
FFB102643	Flexboy® 150 mL
FFB102670	Flexboy® 500 mL
FFB103547	Flexboy® 1,000 mL
FFB102812	Flexboy® 3,000 mL


* For grey silicone cassettes material number ends with "...--"

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