# SARTURIUS

# Sartoflow® Smart

Smart and Easy – The Crossflow System For Process Development



Benchtop system for cGMP environments

#### **Features**

#### **Excellent Flexibility**

Ideal for membrane surface areas from  $50 \, \text{cm}^2$  to as much as  $0.14 \, \text{m}^2$ 

#### Intuitive and User-Friendly

One operating design and predefined sequences for all Sartoflow® systems

#### The Highest Product Yields

Low shear four-piston membrane pump

## **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.

## Description

The Sartoflow® Smart system includes a Sartocon® Slice 200 filter cassette holder that can accommodate cassette areas from 200 cm<sup>2</sup> to 0.14 m<sup>2</sup> membrane area, 1 L graduated recirculation vessel made of transparent PSU with a selfsealing 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. One peristaltic diafiltration pump is optionally available, making it possible to load product or buffer as a discrete process step. 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 cm<sup>2</sup> to as much as 0.14 m<sup>2</sup>.

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 upgraded with further options should your requirements change e.g. with a buffer | product feed pump or permeate | retentate bag stands. 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. 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 <sup>2</sup> to as much as 0.14 m <sup>2</sup> .
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
One Sartoflow® family design for effortless scalability	All systems equipped with the same functionalities and pre defined sequences.

## 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

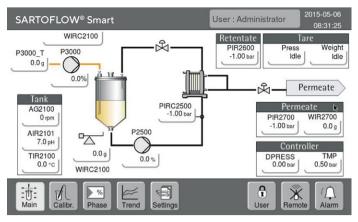
Reliability and smooth operation of equipment are ensured through proper installation | configuration and regular maintenance by our Sartorius service experts.

#### Service offering includes:

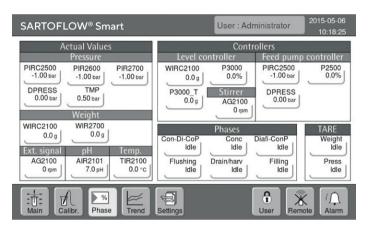
- Installation
- Site Acceptance Test (SAT)
- Extended warranty
- Preventive maintenance contracts

#### 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 Data

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

#### Modules

Standard module

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

#### Recirculation modules

Sartoflow® Smart vessel 1L PSU

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

Options
Diafiltration pump_SF Smart
oH sensor_SF Smart
Conductivity sensor_SF Smart
emperature sensor_SF Smart
External balance perm_SF Smart 64
Sartoflow® Smart recirculation bag holder for Flexboy® bags
Sartoflow® Smart permeate bag holder for Flexboy® bags
Holder for Sartocon® Slice 50 cassette
ubing and connector set Sartoflow® Smart
Standard documentation package for Sartoflow® Smart
GMP documentation package for Sartoflow® Smart
Basic Qualification Test documentation package for Sartoflow® Smart
Q   OQ execution package for Sartoflow® Smart
Sartoflow® Smart PP pump head for QF150 with luer connections

# 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	~35kg (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

# Sartocon® Slice 50 With 50 cm² Membrane Area

Membrane	MWCO
Hydrosart®	2 kD
Hydrosart <sup>®</sup>	5 kD
Hydrosart <sup>®</sup>	10 kD
Hydrosart®	30 kD
PESU	1kD
PESU	5 kD
PESU	8 kD
PESU	10 kD
PESU	30 kD
PESU	50 kD
PESU	100 kD
PESU	300 kD
	Hydrosart® Hydrosart® Hydrosart® Hydrosart® Hydrosart® PESU PESU PESU PESU PESU PESU PESU PESU

# Sartocon<sup>®</sup> Slice 200 With 0.02 m<sup>2</sup> Membrane Area

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

# Sartocon® Slice 200 Eco With 0.02 m² Membrane Area

Order Code	Membrane	MWCO	
3M81443902ESW	Hydrosart®	10 kD	
3M81445902ESW	Hydrosart <sup>®</sup>	30 kD	
3M81446802ESW	Hydrosart <sup>®</sup>	100 kD	
3M81463902ESW	PESU	10 kD	
3M81465902ESW	PESU	30 kD	
3M81466802ESW	PESU	100 kD	
3M81467902ESW	PESU	300 kD	

# Sartocon® Slice Eco With 0.14 m² Membrane Area

Order Code	Membrane	MWCO	
3M51463901ESW	PESU	10 kD	
3M51465901ESW	PESU	30 kD	
3M51466801ESW	PESU	100 kD	
3M51443901ESW	Hydrosart®	10 kD	
3M51445901ESW	Hydrosart®	30 kD	
3M51446801ESW	Hydrosart®	100 kD	

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

## Consumables

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

#### Germany

Sartorius Stedim Biotech GmbH August-Spindler-Strasse 11 37079 Goettingen Phone +49 551 308 0

#### USA

Sartorius Stedim North America Inc. 565 Johnson Avenue Bohemia, NY 11716 Toll-Free +1 800 368 7178

For further contacts, visit www.sartorius.com