

# SARTOFLOW® Smart

Smart and easy – the crossflow system for process development

#### **Features**

#### **Excellent flexibility**

Ideal for membrane surface areas from 50 cm<sup>2</sup> to as much as 0.14 m<sup>2</sup>

#### Intuitive and user-friendly

One operating design and predefined sequences for all SARTOFLOW® systems

#### The highest product yields

Low shear 4-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 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. 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 4-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' 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  $\sim 20$  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 4-piston<br>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 Stedim Biotech DCU-4 based systems.

#### Service

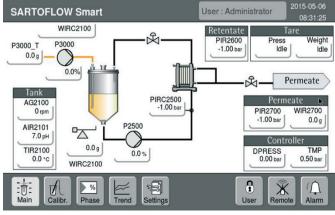
Reliability and smooth operation of equipment are ensured through proper installation | configuration and regular maintenance by our Sartorius Service experts.

#### Service offering includes:

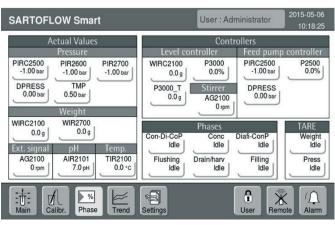
- Installation
- Site Acceptance Test (SAT)
- Extended Warranty
- Preventive Maintenance Contracts

#### 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 system 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 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:

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Standard module

Filtration module 230 V – 50 Hz or 120 V – 60 Hz: Four-piston diaphragm feed pump, Sartocon® 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

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

| Options   |  |  |
|---|--|--|
| Diafiltration pump_SF Smart   |  |  |
| pH sensor_SF Smart  |  |  |
| Conductivity sensor_SF Smart  |  |  |
| Temperature 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                               |  |  |
| Tubing & Connector Set SARTOFLOW® Smart                             |  |  |
| 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                      |  |  |

SARTOFLOW® Smart PP pump head for QF150 with luer connections

SARTOFLOW® Smart Vessel 1L PSU

| 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 cm <sup>2</sup> , 200 or 400 cm <sup>2</sup> up to 0.14 m <sup>2</sup> of membrane area |
| Minimum recirculation volume         | < 20 mL   |
| Max. inlet pressure                  | 3 bar (43.5 psi)  |
| Dimensions (W $\times$ D $\times$ H) | $602 \times 440 \times 610 \text{ mm}$  |
| Weight                               | ~35kg (77 lbs.)   |
| Electrical requirements              | 230 VAC   50 Hz 2 Amp;<br>120 VAC   60 Hz 3 Amp   |
| IP-Standard                          | 33  |
| Tubing connections                   | Luer-Lock   |

# **Ordering Information**

# 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 200 with 0.02 m² membrane area

| Order Code    | Membrane  | MWCO   |
|---------------|-----------|--------|
| 3081460902ESW | PESU      | 1 kD   |
| 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 | 30 kD  |
| 3M81446802ESW | Hydrosart | 100 kD |
| 3M81463902ESW | PESU      | 10 kD  |
| 3M81465902ESW | PESU      | 30 kD  |
| 3M81466802ESW | PESU      | 100 kD |
| 3M81467902ESW | PESU      | 300 kD |

# Sartocon® Slice ECO with 0.14 m<sup>2</sup> 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 |

<sup>\*</sup> For grey silicone cassettes material number ends with "...--SG"

#### Consumables

| Order Code | Crossflow Bag Specification   |
|------------|-------------------------------|
| FFB102643  | Flexboy <sup>®</sup> 150 mL   |
| FFB102670  | Flexboy <sup>®</sup> 500 mL   |
| FFB103547  | Flexboy® 1,000 mL             |
| FFB102812  | Flexboy <sup>®</sup> 3,000 mL |

Sartorius Stedim Biotech GmbH August-Spindler-Strasse 11 37079 Goettingen, Germany

Phone +49.551.308.0 Fax +49.551.308.3289 www.sartorius-stedim.com

USA Toll-Free +1.800.368.7178 UK +44.1372.737159 France +33.442.845600 Italy +39.055.63.40.41

Spain +34.90.2110935 Russian Federation +7.812.327.5.327

Japan +81.3.4331.4300 China +86.21.68782300

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