SARTURIUS

Sartoflow® Advanced

Full Flexibility and
Outstanding Crossflow
Filtration Performance
Combined



Description

The system is suitable for flexible use in laboratory environments for process development and clinical trials, as well as for small-scale production batches. Several standardized options are available to enable you to obtain just the right system, exactly tailored to meet your individual requirements. The system can also be upgraded with additional options if your requirements change during process development or production.

Product Information

The Sartoflow® Advanced is a modular benchtop crossflow system optimized for ultrafiltration, microfiltration and diafiltration applications used in many downstream processes, such as purification of vaccines, monoclonal antibodies and recombinant proteins.

This crossflow system is equipped with our proven DCU-4 control unit that readily communicates with BioPAT® MFCS software.

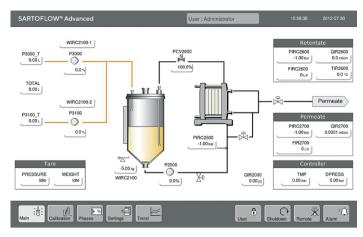
The Sartoflow® Advanced can be configured to accept either Sartocon® Slice or full-sized Sartocon® cassettes. As a result, this gives you an exceptionally wide range of membrane surface areas. Since all Sartocon® crossflow cassettes have the same hydrodynamic flow path length, the Sartoflow® Advanced can be linearly scaled up from 0.1 to 2.1 m² of membrane area. Its unique compact design has an ultra-low loop volume of ~200 ml, making it possible to concentrate even small process batches.

The Sartoflow® Advanced can be run in demanding production environments. Moreover, the unit and its touch screen is built to withstand continuous use in under laboratory and production conditions.

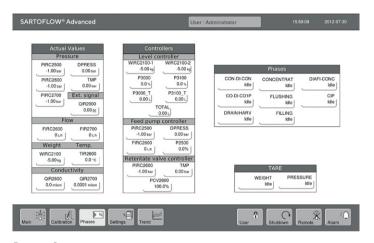
Filtration Module

The filtration module includes a Sartocon® Slice holder – or as an option, a holder for full-sized Sartocon® Eco cassettes – TMP control, delta P control, retentate flow control, three pressure sensors, a flow meter in the permeate line, with one positioning valve in retentate line, a four-piston diaphragm recirculation pump (0.7 m³/h @ 4 bar), a temperature transmitter and a load cell for level control.

The DCU-4 control includes a 12" touch panel. One peristaltic feed pump is located below the touch screen, making it possible to load product or buffer as a discrete process step. A second peristaltic pump is optionally available.



DCU-4 Touch Screen



Process Sequences

Recirculation Module

The recirculation tank utilizes a load cell for level control and can be replaced by a recirculation bag stand with a crossflow bag. All control functions are fully operable whether you run the system with a stainless steel tank or a single-use bag.

A cylindrical 10 L stainless steel tank with a conical base – with or without a sight glass for visual monitoring – and a double-jacketed vessel for cooling, or a bag stand for 5 L, 10 L or 20 L single-use crossflow bags, are available as recirculation modules. Both types of vessel with a sight glass are equipped with a vortex breaker and a dip tube to prevent foaming.

Control Functions

All control and alarm functions are set and displayed on the 12" 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 available BioPAT® MFCS | win Scada software program and can be personalized using three-level password protection.



Tank



Bag

Process Sequences

You can use predefined parameters to automatically run customized sequences for concentration, diafiltration (UF | DF), rinsing, filling, draining, CIP steps and tare functions.

All Sartoflow® Advanced units are equipped with feed pressure and level controllers for operating the system at user-defined set points. The feed pressure controller keeps the feed pressure constant by controlling the pump speed (the 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 feed and retentate pressure at predefined set points using the pump speed and the positioning valve. The retentate flow option lets you run processes at specified retentate flow rates by adjusting the feed pump speed. The level controller can run two peristaltic pumps to keep the volume in the recirculation bag constant. The system's software architecture is designed to enable you to conduct optimization trials at constant recirculation flow rates and TMP values.

Data Acquisition

Data are collected using an external PC (not part of the equipment supplied) connected to the Sartoflow® Advanced system over an ethernet interface. BioPAT® MFCS software for data acquisition and trend monitoring is included in the Sartoflow® Advanced package.

cGMP Production Environment

Optionally validated BioPAT® MFCS | win software can be upgraded with our 21 CFR Part 11 and S88 recipe control modules. The BioPAT® MFCS | win additional software modules based on OPC® technology specify the communication of real-time data between control devices from major third-party products. This convenient option offers you the possibility of connecting the Sartoflow® Advanced to Delta V.

The following phases are provided by 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. |
| CIP | Used to clean the system, including all valves, pipework and tank, by using WFI, acidic or alkaline solutions. |
| 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 before changing to a different phase. |
| Pressure | Automatically zeros all pressure sensors before using a different phase. |

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

Specifications

| Pump output | 700 l/h @ 4 bar (60 psi) | | |
|------------------------------|---|--|--|
| Filter area | 0.1-0.5 m² (optional 0.7 - 2.1 m²) | | |
| Minimum recirculation volume | ~200 ml | | |
| Max. inlet pressure | 4 bar (60 psi) | | |
| Dimensions (H × L × W) | 1,100 mm × 800 mm × 680 mm | | |
| Weight | ~120 kg (~265 lbs.) | | |
| Electrical requirements | 230 VAC 50 Hz 2.5 amp; 120 VAC 60 Hz 4 amp | | |
| IP-Standard | 33 | | |
| Piping connections | Tri-Clamp (½") | | |

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

Modules

- Standard module
 Filtration module 230 V 50 Hz or 115 V- 60 Hz: fourpiston diaphragm feed pump, Sartocon® Slice filter
 holder, three pressure sensors, one flow meter in the
 permeate line, one load cell, one peristaltic pump,
 a temperature sensor in the retentate line, one
 proportional valve in the retentate line, touch
 screen, DCU-4.
- Recirculation modules
- 10 L stainless steel tank
- 10 L stainless steel tank with a sight glass
- 10 L stainless steel double-jacketed tank with a sight glass
- Bag holder

Options

- Flow meter in the retentate line
- Conductivity probe in the retentate line
- Conductivity probe in the permeate line
- 2nd peristaltic pump
- Sartocon® filter holder for up to three full-sized
 Sartocon® Eco cassettes

Optional Software

- BioPAT® MFCS | win standard package
- Recipe Control (S88) module for BioPAT® MFCS | win
- 21 CFR Part 11 Module for BioPAT® MFCS | win
- BioPAT® MFCS | win OPC® modules



Sartoflow® Advanced filtration module and tank module

Consumables

| Order No. | Crossflow Bag Specification | | |
|-----------|-----------------------------|--|--|
| FBB111332 | 5 liters | | |
| FBB111333 | 10 liters | | |
| FBB111334 | 20 liters | | |

Order Information

Sartocon® Eco New Hydrosart® Ultrafiltration Cassettes

Available types and order numbers

| Туре | Filter Area | Cut-off | Order No. |
|---------------------------|-------------|---------|---------------|
| Sartocon® cassettes | 0.7 m² | 10 kD | 3M21443907ESW |
| Sartocon® cassettes | 0.7 m² | 30 kD | 3M21445907ESW |
| Sartocon® cassettes | 0.7 m² | 100 kD | 3M21446807ESW |
| Sartocon® Slice cassettes | 0.14 m² | 10 kD | 3M51443901ESW |
| Sartocon® Slice cassettes | 0.14 m² | 30 kD | 3M51445901ESW |
| Sartocon® Slice | 0.14 m² | 100 kD | 3M51446801ESW |

Sartocon® Slice Cassettes

| | Filter Area | MWCO | Order No. |
|----------------------|--------------------|---------|---------------|
| Ultrafilter Membrane | | | |
| Hydrosart® UF | 0.1 m² | 2 kD | 3051441901ESW |
| Hydrosart® UF | 0.1 m ² | 5 kD | 3051442901ESW |
| Hydrosart® UF | 0.1 m ² | 10 kD | 3051443901ESW |
| Hydrosart® UF | 0.1 m ² | 30 kD | 3051445901ESW |
| Hydrosart® UF | 0.1 m ² | 100 kD | 3051446801ESW |
| | | | |
| PESU UF | 0.1 m² | 1 kD | 3051460901ESW |
| PESU UF | 0.1 m² | 5 kD | 3051462901ESW |
| PESU UF | 0.1 m² | 8 kD | 3051463401ESW |
| PESU UF | 0.1 m² | 10 kD | 3051463901ESW |
| PESU UF | 0.1 m² | 30 kD | 3051465901ESW |
| PESU UF | 0.1 m² | 50 kD | 3051465001ESW |
| PESU UF | 0.1 m² | 100 kD | 3051466801ESW |
| PESU UF | 0.1 m² | 300 kD | 3051467901ESW |
| PESU UF | 0.1 m² | Albumin | 305146AI01KSW |
| | | | |

| Microfilter Membrane | | | | |
|----------------------|--------------------|---------|---------------|--|
| Hydrosart® MF | 0.1 m² | 0.2 µm | 3051860701WSW | |
| Hydrosart® MF | 0.1 m ² | 0.45 μm | 3051860601WSW | |
| PESU MF | 0.1 m² | 0.1 µm | 3051545801WSW | |

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