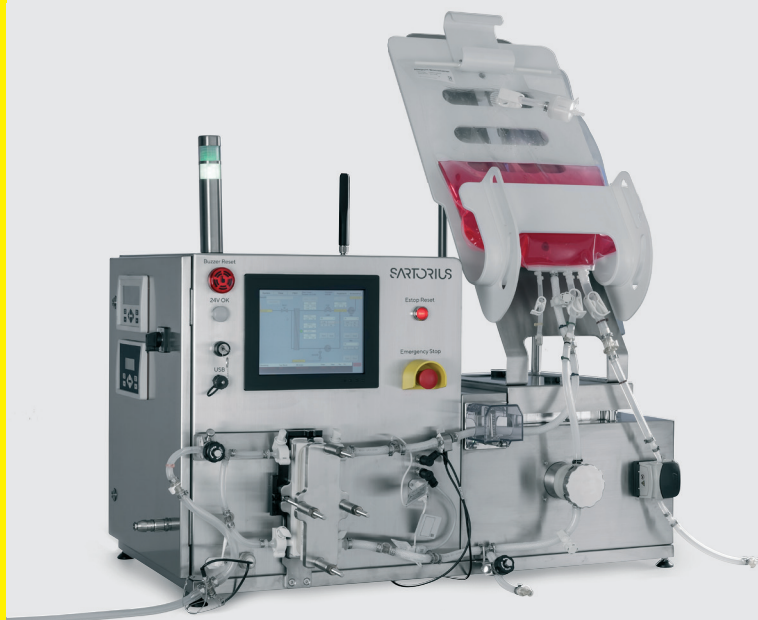


# Sartoflow<sup>®</sup> 150<sup>\*</sup>

## Single-use Tangential Flow Filtration System



### Product Information

The Sartoflow<sup>®</sup> 150 single-use tangential flow filtration (SUTFF) system is easy to use and offers all the critical sensors for running ultrafiltration (UF) and diafiltration (DF) processes for 2 – 20 L batch volumes. The system layout is optimized for a minimum recirculation loop to ensure final target volumes and achieve excellent product recovery.

### Benefits

- Designed for efficiency in SUTFF applications
- Suitable for low-shear applications
- Excellent product recovery
- Low hold-up volume, approximately 100 mL
- Single-use sensors: Pressure, flow, conductivity, temperature, UV
- 0.1 - 0.4 m<sup>2</sup> filtration area

### Relevant Processes

- Vaccines
- Monoclonal antibodies
- Recombinant proteins

### Relevant Process Steps

- Ultrafiltration
- Diafiltration

### Related Process Scale

- Process Development | Preclinical scale

\* The Allegro™ CM150 SUTFF product name has been changed to Sartoflow<sup>®</sup> 150 as part of the product integration into the Sartorius TFF Portfolio. Both product names will be equivalents until the successful harmonization of all collaterals towards Sartoflow<sup>®</sup> 150.

# System Concept

The Sartoflow® 150 SUTFF system is an automated TFF system with the advantages of fully disposable single-use flow kits and includes automated features such as diafiltration and TMP control. The system provides a touch screen interface with password control and data logging | data transfer functionality. The system is designed to accommodate 3/8" ID single-use flow kits. All process-wetted flow paths comprised of tubing, pump chamber, measuring instruments, bags, etc., are constructed from single-use components.

- The system has the flexibility to run various types of TFF modules and cassettes.
- The system is designed to generate scalable data for use in small-scale production and process development.
- Continuity of single-use component and design approach across the system range provides reliable scale-up from the Sartoflow® 150 to larger scale SUTFF systems.

# Control System

The Sartoflow® 150 offers essentially automated control of TFF processes. The programmable, logiccontroller-based (PLC) control system ensures easy operation and monitoring of UF applications, constant volume diafiltration, and real-time trending and data-logging capabilities.

The control software is designed for flexible and user-friendly control of TFF processes, and provides the following key features:

- P&ID-based user interface with dynamic flow path
- Retentate bag weight controller
- TMP Control
- Full security access to configuration settings screens
- Real-time trending Data logging with data transfer to Excel or similar in CSV format
- Three-level user login, user administration, and password control



# Quality Standards

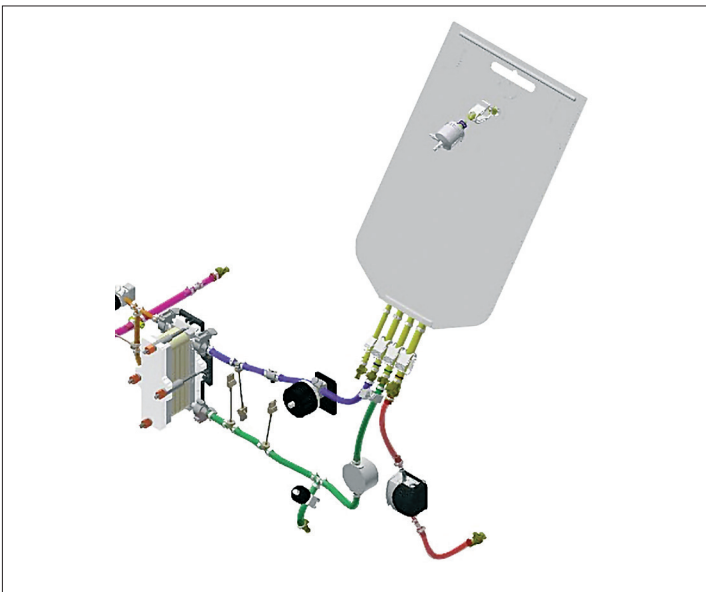
## System

A stringent approach to quality of purchased and manufactured components is maintained. The system hardware is designed and built to well recognized industry standards, including:

- Good automated manufacturing practice (GAMP) current version
- EMC 89/336/EEC
- Software complies with CFR21 Part11 for electronic records

## Single-use Flow Kits

- Manufactured in a controlled environment
  - (Class 7 in operation according to ISO 14644) under a quality system certified according to ISO 9001
  - Feature components tested for biocompatibility and certified according to USP<88>
  - Feature components certified as TSE | BSE-free
  - Manufactured according to a validated assembly process
- Supplied



# Technical Specifications

System Specifications	
Membrane area	0.1 - 0.4 m <sup>2</sup>
Feed and retentate tube ID	3/8" (9.6 mm)
Permeate tube ID	1/4" (6.4 mm)
Recirculation pump	Quattroflow™* - 150SU, 4-piston diaphragm pump 5 to 150 L/h
Fed batch   buffer pump	Watson Marlow Drivesure™** peristaltic pump up to 54 L/h
Over-pressure protection	Yes (on recirculation pump)
Maximum pressure	4 barg   58 psig for reinforced flow kit sections 1 barg   14.5 psig for permeate and medium pressure flow kit sections single-use flow kit 0 barg   0 psig for bags
Operating temperature	4 - 40°C
Dimensions system (W×D×H)	1,079 × 764 × 1,228 mm (nominal)
Weight empty system	115 kg
EU	230V, 1 phase, 50Hz, 13A

Components in Fluid Contact	Materials of Construction
Tubing	Platinum-cured silicone, reinforced in high-pressure sections
Recirculation pump	Head: Polypropylene Diaphragm: EPDM   Polypropylene compound
Connectors	Polysulfone, silicone
Fittings, distribution plates	Polypropylene
Pressure sensor	Polysulfone
Temperature sensor	Polysulfone with stainless steel sensor
Flow sensor	PVDF with ruby bearing
Conductivity sensor	Polysulfone with gold electrode
UV Sensor	Polysulfone and fused silica with silicone O-ring
Sanitary fittings	Connector: polypropylene
(tri-clamp)	Gaskets: silicone

\*Quattroflow™ is a trademark of Dover Company

\*\*Watson Marlow Drivesure™ is a trademark of Watson Marlow Fluid Technology Group

System Hardware	Specifications
Feed pump	Flow range 5 to 150 L/h
Buffer pump	Flow range 0 to 54 L/h (with 4.8 mm bore tubing)
Valves	For use with 3/8 in. ID tubing
Control valve	Automatic TMP control valve $\pm 0.1$ bar   $\pm 1.5$ psi
Recovery valve	For use with 1/4 in. ID tubing

Instrument	Measuring Range   Accuracy
Flow measurement	30 - 1200 L/h $\pm 60$ L/h
Pressure measurement	-0.48 - 5.2 bar $\pm 0.15$ bar -7 - 75 psi $\pm 2$ psi
Temperature measurement	0 to 70°C $\pm 1$ °C
Conductivity measurement	Range: 0.1 to 100 mS/cm 0.1 to 2 mS/cm $\pm 0.1$ mS/cm 2 to 50 mS/cm $\pm 5\%$ of reading; 50 to 100 mS/cm typically $\pm 5\%$ of reading
UV	0 - 2 AU $\pm 0.1$ AU
Mass measurement	0 to 30 kg (in situ readability 0.01 g)

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