Data Sheet

Cogent® µScale TFF System

Easy-to-use, semi-automated bench top TFF system for both micro-scale process development and everyday low-volume ultrafiltration/diafiltration work.

The Cogent µScale tangential flow filtration (TFF) system is an easy-to-use, semi-automated bench top solution that has been designed to fully support TFF process development at the "micro-scale" using up to three Pellicon® 3 88 cm^2 cassettes (264 cm^2). It is also an excellent tool for streamlining everyday low volume ultrafiltration/concentration and diafiltration (UF/DF) work in the biopharmaceutical research environment.

With a low minimum working volume (16 mL*), the ability to operate at feed pressures up to 80 psi (5.5 bar) and low pulsation (≤3 psi), the Cogent µScale TFF system enables both scaling studies and low volume UF/DF work using Pellicon 3 88 cm^2 TFF cassettes. It can also be configured to run up to three Pellicon XL 50 TFF devices (150 cm^2), and is ideally suited for purifying and concentrating your monoclonal antibodies, recombinant proteins, vaccines, gene therapy constructs, blood serum products, and other cell derived components.

- **Versatile system—ideally suited for both scaling studies and low volume UF/DF work**
- **Enhanced productivity—User-configurable alarm set points and automated data acquisition**
- **Easy-to-use—Intuitive, multilingual display and touch screen interface**

* Reference minimum working volume specification

DESIGNED FOR EVERYDAY USE

An intuitive, multilingual display and touch screen interface makes the Cogent µScale TFF system easy to operate, and the user-configurable alarm set-points and automated data acquisition enable you to be more productive. Time-stamped data for all operational parameters, including alarm and event history are automatically captured by the system and can be easily uploaded in a tab delimited/CSV file format directly to your PC, and imported into standard spreadsheet programs such as Microsoft® Excel® software.

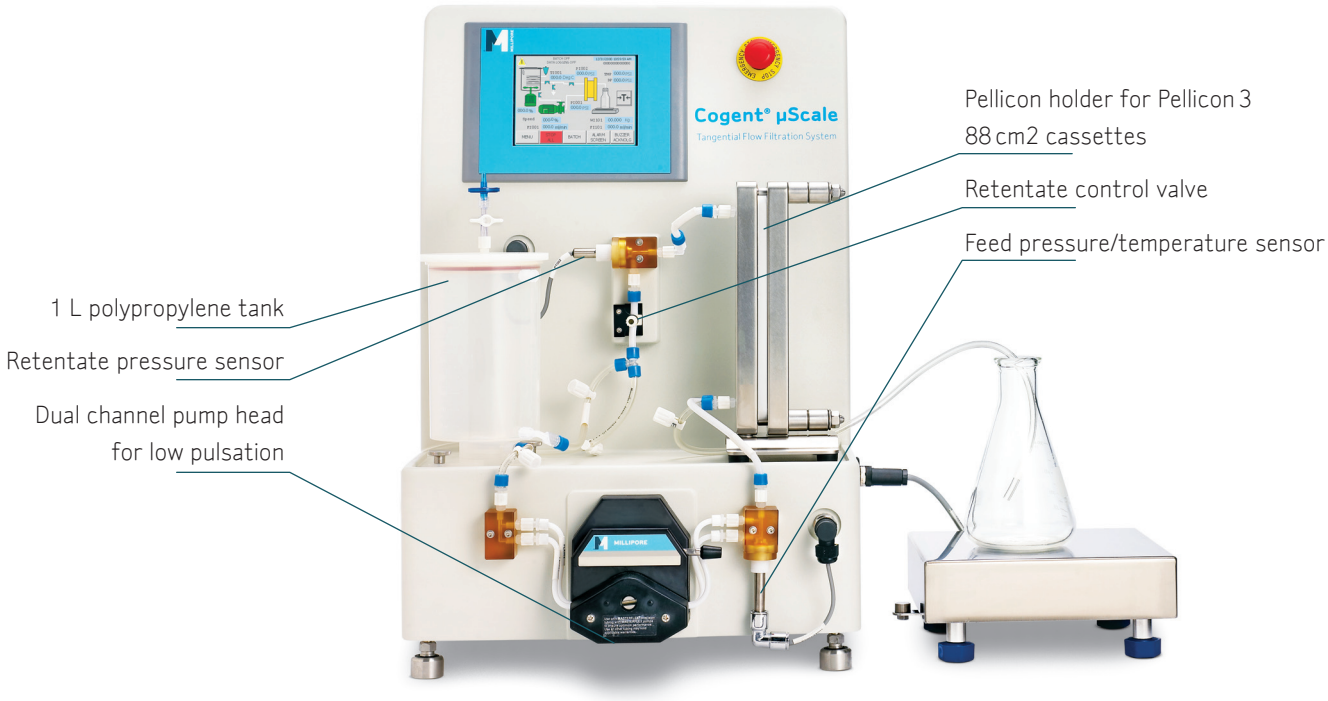
The semi-automated system can be run at either a fixed pump speed or at a set DeltaP via an automated control loop. Alarm set-points for feed and retentate pressure, DeltaP, TMP, and filtrate flow/weight (present only with filtrate weight scale option) include four settings that either "alert" you to changing conditions (Hi/Lo settings), or "shut down" the process (HiHi/LoLo settings) if desired. When an alarm condition is triggered, a message appears on the touch screen display. An audible alarm can also be activated. The system also includes an E-stop that will immediately shut down the process if needed.

With the optional filtrate weight scale, you can measure filtrate flow and weight. You also have the ability to automatically shut down your process when a target weight/product concentration has been achieved. The P&ID screen monitors all active parameters, including: pump speed, mixer speed, feed and retentate pressures, temperature, calculated feed flow rate, DeltaP, TMP, and calculated filtrate flow and weight (only with weight scale option), providing an easy way to monitor your process in real time. And through a separate trend screen you can quickly see how key process parameters have changed over the course of a run, facilitating process development.

The Cogent µScale TFF system includes a 1 L polypropylene tank with a removable vacuum seal lid that enables vacuum diafiltration/buffer exchange and/or fed batch processing of samples up to 5 L or more. Also included with the system is a filter holder for the Pellicon 3 88 cm^2 cassettes, and a complete high pressure tubing assembly capable of running up to 80 psi (5.5 bar), enabling you to run at higher DeltaP and TMP settings.

Real-world TFF Operations

- Easily create accurate scale down models for process development, membrane screening and process characterization at the micro-scale
  - Enables you to do more with less product
- Feed pressures up to 80 psi
  - Allows higher DeltaP and TMP processing
- Robust design with minimal maintenance requirement



OPTIMIZED FOR PROCESS DEVELOPMENT AND RESEARCH APPLICATIONS

The Cogent µScale TFF system is designed to meet your real-world process development and low volume sample preparation requirements. This system will support all your TFF operations including fed batch, diafiltration and concentration. System set-up is quick and easy and the user interface and user-defined control parameters enable you to execute development work quickly, safely, reliably and reproducibly. The robust flow path supports flow rates from 17 mL/min to 330 mL/min at operating pressures up to 80 psig (5.5 bar) with very low pulsation. The system also has an extremely low minimum recirculation and hold up volume for low volume processing and maximum product recovery, and with a compact footprint, it is easy to use in any research or lab environment.

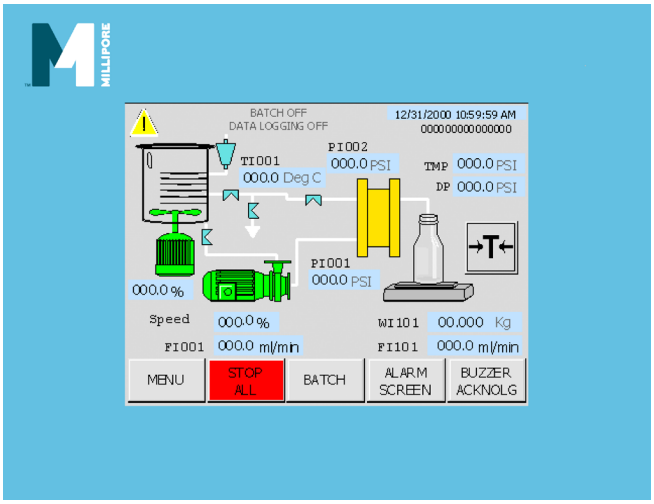
Cleanability

The fluid path is drainable and designed for Clean-in-Place (CIP) using industry standard cleaning agents. If cross contamination is a concern, the tubing assembly and one liter polypropylene tank assembly can be easily replaced in just a few minutes.

Automated Data Capture and Export

The Cogent µScale TFF system automatically captures time-stamped data for the following operational paramaters: Feed Pressure, Retentate Pressure, DeltaP, TMP, Feed Flow, Pump Speed, and Temperature. With the Weight Scale option, Filtrate Flow Rate and Filtrate Weight are captured as well. In addition, alarm history and event history (e.g., user login, calibration changes) are captured in separate time stamped files. These tab delimited/CSV files can then be manually or automatically uploaded directly to a PC for import into standard spreadsheet programs.

Figure 1. Cogent µScale P&ID screen provides real-time-monitoring of your TFF process



SPECIFICATIONS

Supported TFF Devices	
Pellicon 3 88 cm^2 cassettes	Up to 3 (88 cm to 264 cm^2)
Pellicon XL 50 device	Up to 3 (50 cm to 150 cm^2)
Pellicon Cassette Holder Included with system	Holds up to three Pellicon 3 88 cm^2 cassettes
Filtration Area	0.005–0.0264 m^2
Tank Volume	1 L
Minimum Working Volume	16 mL (add 1.5 mL per Pellicon 3 88 cm^2 cassette)
Hold-up Volume	<3 mL (excluding cassette)
Process Temperature	4 to 50 °C
Pump Flow Rate	17–330 mL/min
Sensors	
Feed and retentate pressure	0–5.5 bar (0–80 psig)
Temperature	0–50 °C (32–122 °F)
Retentate Control and Isolation Valves	Manual
Weight Scale	6 kg maximum capacity
Languages Supported	English, French, German, Spanish, Italian, Chinese, and Japanese
Dimensions	
Width	41 cm (16.14 in.)
Depth	48 cm (18.89 in.)
Height	62 cm (24.40 in.)
Weight with holder	30 kg (66 lbs)
Power Supply	100–240 VAC, 50-60 Hz
Wetted Materials of Construction	
Filter holder	316 L stainless steel
Tubing	Silicone (platinum-cured) and GORE STA-PURE® (platinum-cured silicone expanded PTFE) plastic
Luer fittings	Polypropylene
Pressure sensors	Titanium
Flow cells	Polysulfone
Stir bar	PTFE
O-rings	Silicone
Vent valve	Polycarbonate

Wetted Materials

All polymer wetted materials of construction are USP Class VI tested.

Regulatory Information

The Cogent µScale system meets the requirements of the Low Voltage Directive 73/23/EEC and the EMC Directive 89/336/EEC, and is CE marked.

ORDERING INFORMATION

Description	Catalogue No.
Core System and Weight Scale	
Cogent µScale TFF system, 100–240 VAC Includes tank, Pellicon holder, and complete tubing assembly and sensors	CUP0300
Filtrate weight scale	CUP0308
Spare Parts and Accessories	
1 L polypropylene tank subassembly	CUP0301
Tubing subassembly (includes all fittings and pinch valves)	CUP0302
Dual channel peristaltic pump head	CUP0303
Temperature/Pressure sensor subassembly	CUP0304
Pressure sensor subassembly	CUP0305
Retentate valve/manifold subassembly	CUP0306
Set of fuses for main switch	CUP0307
Annual maintenance spare parts kit (PLC battery & O-rings)	CUP0310
PLC battery & media memory card	CMP1415
Vent filters	SLFG025LS
Pellicon 3 88 cm^2 cassette filter holder (includes torque wrench and socket)	XX42PMICRO
Pellicon XL 50 stand	XXPXLSTND
Pellicon XL 50 multi-manifold	XXMULTIMN

TO PLACE AN ORDER OR RECEIVE TECHNICAL ASSISTANCE

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Description	Catalogue No.
Services	
Commissioning with IQ/OQ	
Includes unpacking of system, set-up, testing to verify calibration, and IQ/OQ execution to verify system performance	
Zones*	
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Zone 2 (Travel of more than 50 miles but less than 200 miles from a service office)	SVCBIOQLABZ2
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Annual PM Service Contract	
Includes one (1) annual preventive maintenance visit, travel* expense and labor. Preventive maintenance spare parts (CUP0310) are provided at a discounted rate. Millipore recommends that you order your spare parts when purchasing your preventive maintenance plan.	
Zones*	
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* Contact your sales representative for specific zone information

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