Data Sheet

# Cogent® M1 TMP Control Tangential Flow Filtration System

## A benchtop TFF system with automatic TMP control suited for process development and scaling studies, as well as clinical trials and small-scale production

Benefiting from decades of bioprocess knowledge and expertise, the Cogent® M1 unit incorporates innovative and intelligent design features that not only enhance performance, but enable an extremely low hold-up volume for maximum volume concentration and optimal product recovery.

Equipped with a 10 liter tank with embedded balance, the Cogent® M1 system can run in fed-batch or diafiltration mode using an optional transfer pump, which enables the system to process up to 100 liters or more based on product and membrane filter characteristics.

In addition, the proprietary membrane filter holder is designed with integrated sensors and sanitary connections, greatly contributing to a low minimum working volume. According to flow characteristics, the system can run up to five Pellicon® 2 mini (0.1 $m^2$) cassettes or up to five 0.11 $m^2$ Pellicon® 3 cassettes. These cassettes support a membrane area from 0.1 $m^2$ up to several $m^2$ with an optional Labscale™ holder.

## Benefits

- Extremely low hold up volume for maximum product recovery
- Enhanced productivity
- Easy-to-use
- Can process up to 100 liters or more
- Automatic TMP/ΔP control

# The optimal choice for all of your application and processing needs

## APPLICATIONS

- Monoclonal antibody
- Vaccine
- Protein
- Plasmid
- Plasma
- Colloidal suspension
- Buffer depyrogenation
- Desalting and buffer exchange
- Cell harvesting and concentration
- Nanoparticules

## PROCESSING

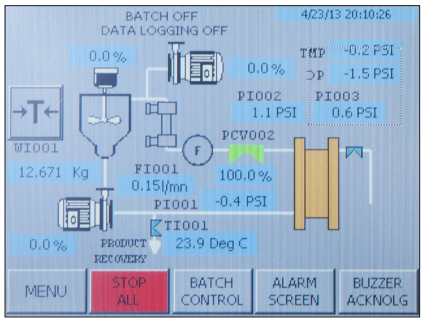
- Clarification
- Concentration
- Purification
- Diafiltration
- Fed batch

## Easy-to-Use System

An intuitive, multilingual display and touch screen interface makes the Cogent® M1 TFF system easy to operate, and the user-configurable alarm setpoints, automated data acquisition and comprehensive safety features 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, as well as imported into standard spreadsheet programs such as Microsoft® Excel®.

Figure 1.

The Cogent® M1 system P&ID screen provides real-time monitoring of your TFF process.




Transmembrane pressure (TMP) can be set with the help of an automated pressure control valve, and controlled through the touch screen interface along with set point operation for constant pump speed or constant ΔP.

Also included are alarm setpoints for feed and retentate pressure, ΔP, and TMP, as well as four settings that 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 includes an E-stop that will immediately shut down the process if needed.

Figure 2.

The innovative automated Pressure Control Valve (PCV) allows smooth and accurate TMP.

The process & instrumentation diagram (P&ID) screen monitors all active parameters including: pump speed, mixer speed, feed and retentate pressures, temperature, feed flow rate, ΔP and TMP, providing an effortless way to monitor your process in real time. Through a separate trend screen, you can quickly see how key process parameters have changed over the course of a run, facilitating process development.

## Models Full Scale Production

The Cogent® M1 system utilizes components usually reserved for industrial production equipment such as a diaphragm pump and 316 L stainless steel fluid path components. By emulating the design of production equipment at the bench scale, you are able to conduct scale-down studies and secure your scale-up in reproducing shear. Moreover, for small manufacturing purposes, a record of data compliant with CFR 21 Part 11 is possible through an optional data recorder.

## Cleanability

The Cogent® M1 system is completely drainable and designed for clean-in-place (CIP). The smooth stainless steel surfaces and zero dead space provide enhanced cleanability using standard cleaning agents.

## Precise Retentate Flow Measurement

For critical applications that require assurance beyond the included pressure flow curves, the Cogent® M1 system can be fitted with an optional electromagnetic retentate flow meter that directly measures retentate flow with a high degree of accuracy. The stainless steel housing offers high sanitary safety and the PFA lining is fully compatible with high process temperatures, and with CIP cleaning processes.

## Efficient and Effective Cleaning

An optional rotating spray ball kit will efficiently and effectively clean the 10 L tank. The kit can be installed quickly and easily by the user.

## Heat Exchanger

Maintaining temperature in every tangential flow filtration process is often critical during cleaning steps and when biomolecules are sensitive to temperature variation. Process temperature can be maintained from 4 °C to 50 °C with an optional heat exchanger fully controlled by embedded software. The optional heat exchanger kit is quick and easy to install.

## Air Integrity Test

In order to ensure that the cassette has been installed properly and has not sustained any damage during storage and handling, integrity testing all TFF assemblies prior to start up and after each post-use cleaning is recommended. Air Integrity Test accessories consist of a set of air pressure regulators and fittings, including an assembly procedure to guarantee an easy plug and play solution.

## Comprehensive Services

Proper and expedient installation through validation is the first step towards minimizing risk and improving your time to market. To cater to these needs, the Cogent® M1 system comes equipped with a complete documentation package including a user manual, safety instruction guide, factory test results and material certificates to assist you in the start up, commissioning and qualification of your system. Developed by our team of technical experts who understand cGMP and regulation requirements, it will ensure that your equipment is installed, validated and fully operational.

To ensure optimum performance, our service offering also provides scheduled preventive maintenance as well as corrective maintenance upon request. Preventive maintenance is a cost-effective approach to ensuring trouble free operation. Our Field Service engineers will not only check sensor calibration and replace gaskets, pumps and valve diaphragms but will also test the PLC batteries. Every operation is documented in a cGMP report and given to you prior to the completion of our services.

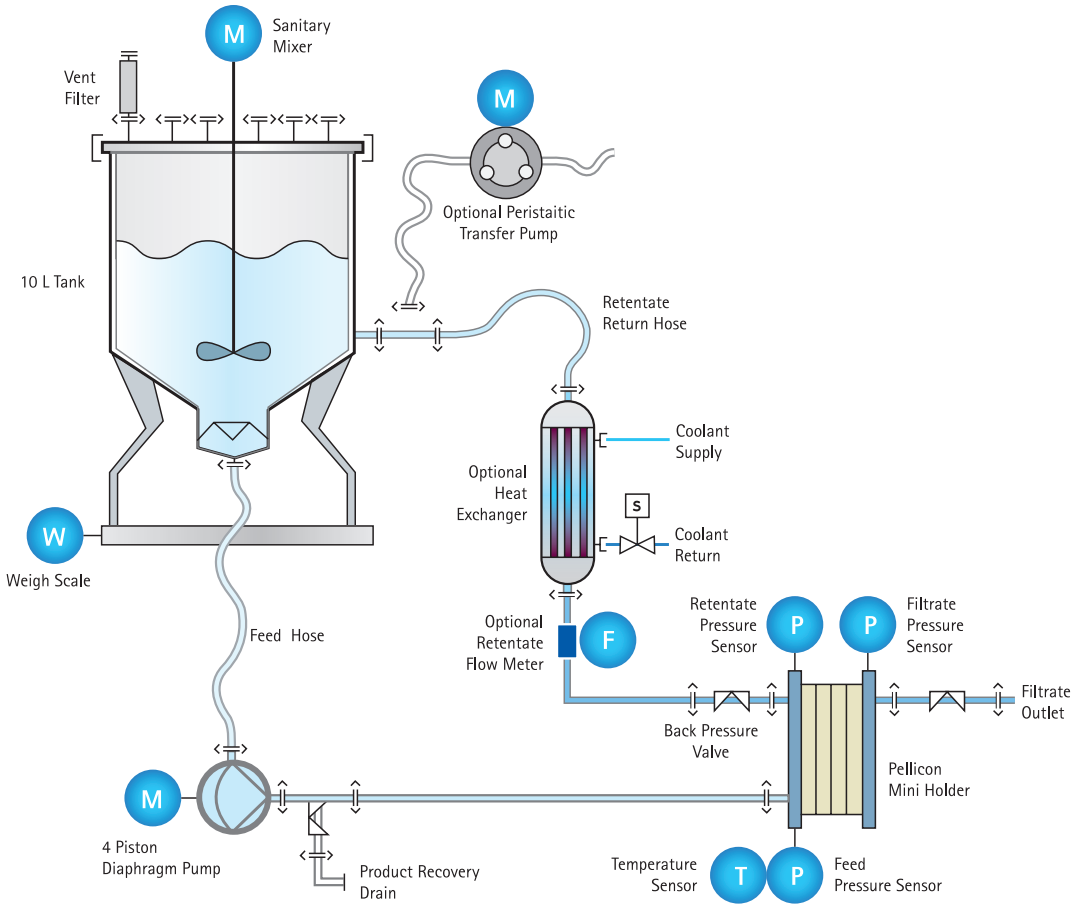



Figure 3.
State-of-the art design.

# Specifications

## Cogent® M1 Tangential Filtration System

**Supported TFF Devices:**

Pellicon® 2 cassettes 0.1 $m^2$: Up to 5 (0.1 $m^2$ to 0.5 $m^2$)
Pellicon® 2 cassettes 0.5 $m^2$: Up to 2 (0.5 $m^2$ to 1.0 $m^2$)*
Pellicon® 3 cassettes 0.11 $m^2$: Up to 4 (0.11 $m^2$ to 0.44 $m^2$)
Pellicon® 3 cassettes 0.57 $m^2$: Up to 2 (0.57 $m^2$ to 1.14 $m^2$)*

**Pellicon® Cassette Holder Included with System:**

Holds up to four 0.11 $m^2$ Pellicon® 3 cassettes
Holds up to five 0.1 $m^2$ Pellicon® 2 cassettes

**Pellicon® Cassette Labscale™ Holder***

Holds up to two 0.57 $m^2$ Pellicon® 3 or
0.5 $m^2$ Pellicon® 2 cassettes

**Filtration Area:**

0.1 $m^2$ to 1.14 $m^2$

**Minimum Working Volume:**

300 mL at 20% feed pump speed

**Starting Volume:**

Tank volume of 10 liters

**Hold up Volume:**

< 10 mL (excluding cassette)

**Process Temperature Range:**

4 °C to 50 °C (39 °F to 122 °F)

**Maximum Feed Flowrate:**

4.5 L/min at 5 bar g (72.5 psi)

**Minimum Feed Flowrate:**

200 mL/min

**Control Modes:**

Constant ΔP ($P_{feed}$ - $P_{retentate}$) : Operate at constant ΔP or calculated constant feed flow rate
Constant TMP ($P_{feed}$ - $P_{retentate}$)/2 - $P_{filtrate}$: Operate at constant TMP or retentate pressure

*The specified items are optional.

Note: Maximum area depends on application fluid and flow characteristic.

**Maximum Operating Pressure:**

5 bar g (72.5 psi)

**Maximum System Pressure:**

6 bar g (86 psi) before pump shut-off

**Optional Transfer Pump Flowrate:**

Tubing dependant (0.16 to 2300 mL/mn)

**Languages Supported:**

English, French, German, Spanish,
Italian, Chinese, and Japanese

**Dimensions:**

Width 76.8 cm (30.23 in.)
Depth 51.2 cm (20.16 in.)
Height 114.7 cm (45.16 in.)
Weight: Approximately 78kg (172 lbs)

**Wetted Materials of Construction:**

Ferrous parts
316L stainless steel (with material certificates)
Polymers (USP Class VI or FDA)
EPDM, Santoprène® elastomer, medical grade epoxy, silicone

**Supply Voltage:**

| | |
|---|---|
| Europe, UK, China: | 220 - 230 VAC, 50 or 60Hz, 1-phase |
| North America, Japan: | 100 - 120 VAC, 50 or 60Hz, 1-phase |

The Cogent® M1 system meets the requirements of the Low Voltage Directive 73/23/EEC and the EMC Directive 89/336/EEC, and is CE marked.

Cogent® M1 Tangential Flow Filtration System

# Ordering Information

## System

| Description | Catalogue No. |
|---|---|
| Cogent® M1 system, 100 – 120VAC, 50 HZ, 60 HZ | CM06100 |
| Cogent® M1 system, 230VAC, 50 HZ | CM06230 |

## Optional Accessories

| Description | Catalogue No. |
|---|---|
| Heat Exchanger with gaskets, clamp and hoses | CMHE1300 |
| Transfer pump (115Vac - 230Vac, 50Hz - 60Hz) | CMP1301A |
| Integrity Test Kit | CMP1303 |
| Retentate Flow Meter Kit | CMP1308 |
| CFR21 part 11 Paperless Recorder | CMP1305 |
| Labscale™ Holder (Cogent® M1 System) | CMP1306 |
| Spray ball assembly for 10 L tank | CMP1310 |

## Spare Parts

| Description | Catalogue No. |
|---|---|
| Tank Assembly (Cogent® M1 System) | CMTK110L |
| Sanitary gaskets | CMP1400 |
| Feed pump diaphragm kit | CMP1401 |
| Valve diaphragm | CMP1405 |
| Feed pressure and temperature sensor kit | CMP1406A |
| Retentate pressure sensor | CMP1407 |
| Filtrate pressure sensor | CMP1408 |
| Flush sanitary clamp, 3/4 in. TC ferrule | CMP0409 |
| Flush sanitary clamp, 1 1/2 in. TC ferrule | CMP0410 |
| Hose pinch clamp | CMP0411 |
| Silicone hose, TC ends | CMP0412 |
| Tank lid clamp | CMP0413 |
| Tank lid seal, 10 in. sanitary gasket | CMP0414 |
| PLC Battery and Media Memory Card | CMP1415 |
| Mixer Blade & Shaft | CMP0416 |
| Mixer Shaft seal | CMP0417 |
| Operating User Guide (Cogent® M1 System) | CMP1418 |
| Mixer motor and harness assembly (Cogent® M1 System) | CMP1420 |
| Scale and harness assembly (Cogent® M1 System) | CMP1421 |
| Annual Maintenance Spares (Cogent® M1 System) | CMP1422 |
| Long tie rods for Pellicon® Mini Cassette Holder | CMP1423 |
| Set of fuses for main switch | CMP1424 |
| Sensor O-ring and stainless steel ring (set of 3) | CMP1429 |
| Touch screen with memory card and software V2.02 | CMP1430 |
| Pressure control valve | CMP1431 |

# Cogent® M1 Services

## System

| Description | Catalogue No. |
|---|---|
| Cogent® M1 On-site Preventive Maintenance with spare parts (protocol included) | SSV OPM CM1 |
| Cogent® M1 Commissioning with IQ, OQ Protocol | DOCCIOQM |
| Cogent® M1 SAT execution (protocol included) | SSV SAT CGM |
| Cogent® M1 SAT and IQOQ execution (protocol included) | SSV IOQ CGM |
| Preventive Maintenance Spare Parts Kit , including:<br>3x EPDM O'ring gasket USP Class VI<br>3x sensor stainless steel ring<br>28x EPDM TC gasket USP Class VI<br>1x EPDM V-seal USP Class VI<br>1x Flange gasket<br>1x PLC battery<br>4x Valve diaphragm<br>1x Pump diaphragm kit<br>1x Neoprene tubing | CMP1422 |

For alternative service options, please contact Technical Service.

## To Place an Order or Receive Technical Assistance

In Europe, please call Customer Service:

**France:** 0825 045 645
**Germany:** 01805 045 645
**Italy:** 848 845 645
**Spain:** 901 516 645 Option 1
**Switzerland:** 0848 645 645
**United Kingdom:** 0870 900 4645

For other countries across Europe, please call: +44 (0) 115 943 0840

Or visit: **www.merckmillipore.com/offices**

For Technical Service visit:
**www.merckmillipore.com/techservice**

MERCK MILLIPORE

**www.merckmillipore.com/offices**