

Cogent® Lab Systems

A family of modular and flexible systems for TFF at process development scale

When developing a tangential flow filtration (TFF) step at small scale, using a model representative of large-scale performance is essential. It not only allows for the successful transfer from laboratory scale to larger volumes, but also maintains consistent process parameters.

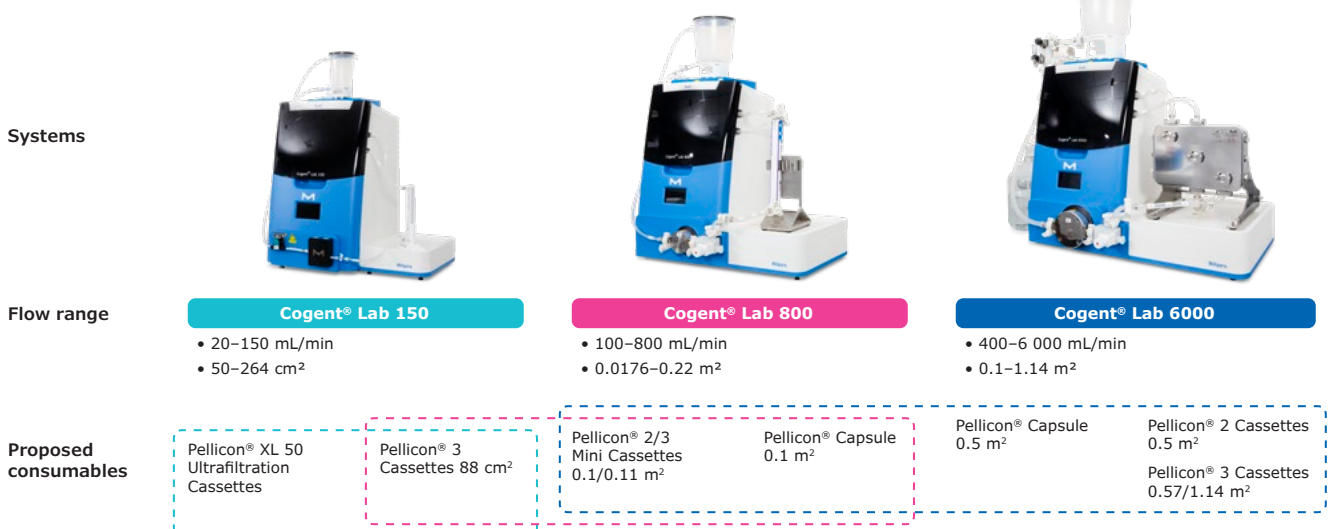
Our family of Cogent® Lab systems uses similar design, sensing technologies, and accessories as our manufacturing-scale equipment. With a homogeneous design and flow range from 20 to 6000 mL/min, our Cogent® Lab systems have been specifically created to simplify process development. These systems offer linear performance and a uniform and intuitive software experience, reducing training requirements and ensuring smooth scale-up and scale-down.

The Cogent® Lab 150, 800, and 6000 systems are optimized for high product recovery and drainability, ensuring successful small-scale TFF operations. With the ability to operate in concentration/diafiltration, microfiltration, and single pass tangential flow filtration (SPTFF) modes, our systems can accommodate a wide range of operating parameters (volume, temperature, flow), increasing flexibility and reducing CAPEX. While the base configuration meets the majority of process development pre-requisites, the modularity allows the systems to be tailored to specific requirements.

Benefits

- **One family** of TFF systems with harmonized design and linear performance ensures successful and seamless scale-up or scale-down
- User-friendly **Bio4C® Control Software** offers pre-defined recipe steps, real-time data visualization and export capabilities assuring reliable and reproducible results
- Cogent® Lab systems can be tailored to your specific process with an **extensive list of options**
- **Flexibly** operates in TFF or SPTFF mode and across a wide range of parameters
- Ideally paired with **Pellicon® cassettes and capsules**

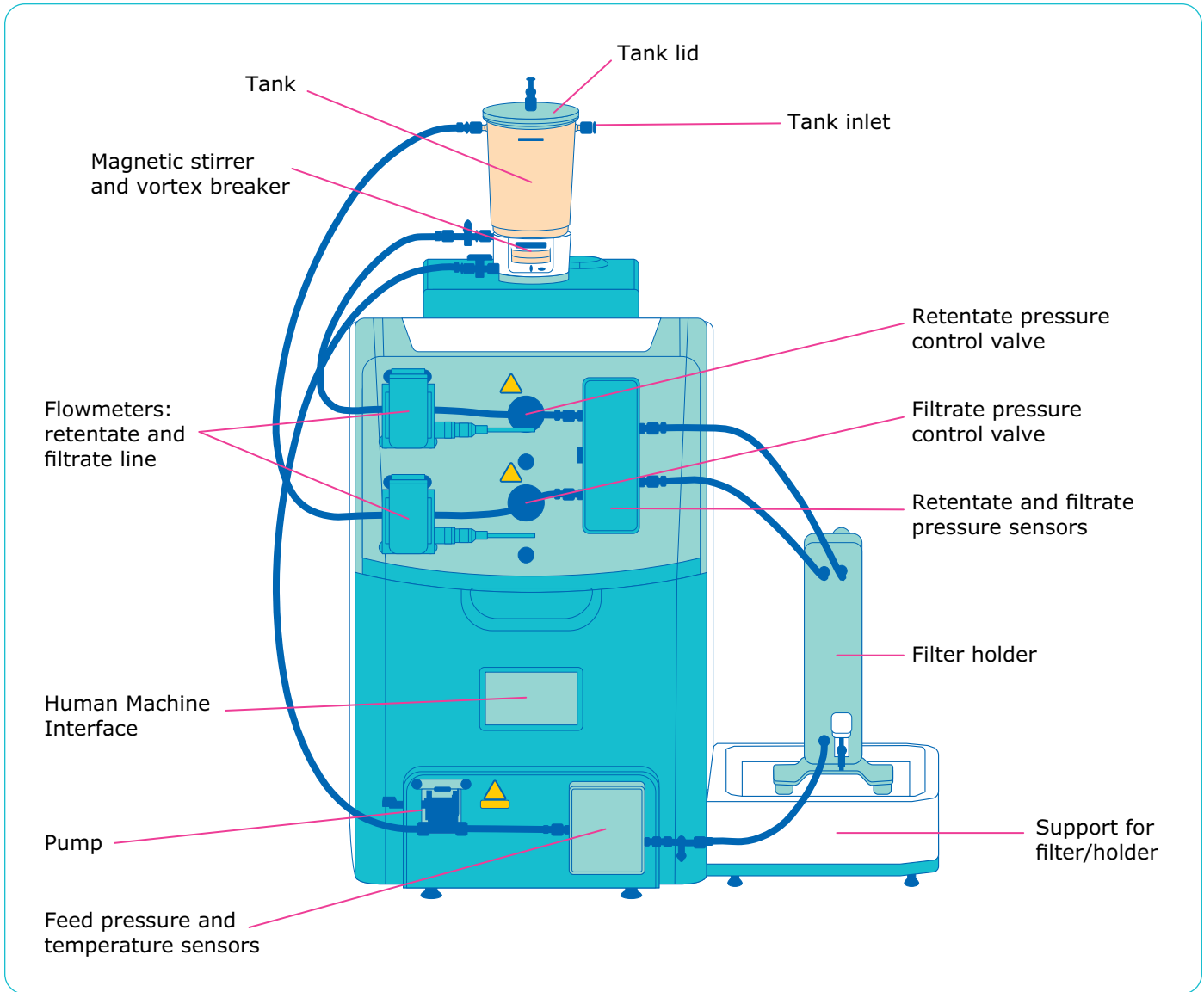
Overlapping flow range for seamless linear scalability



System Components

All Cogent® Lab systems include a tank with a magnetic stirrer and vortex breaker, diaphragm feed pump, automated pressure control valve on retentate line, pressure sensors on feed and retentate, as well as an Human Machine Interface (HMI) on the system. The browser-based Bio4C® Control Software allows control of Cogent® Lab systems from a customer supplied laptop.

Cogent® Lab 150



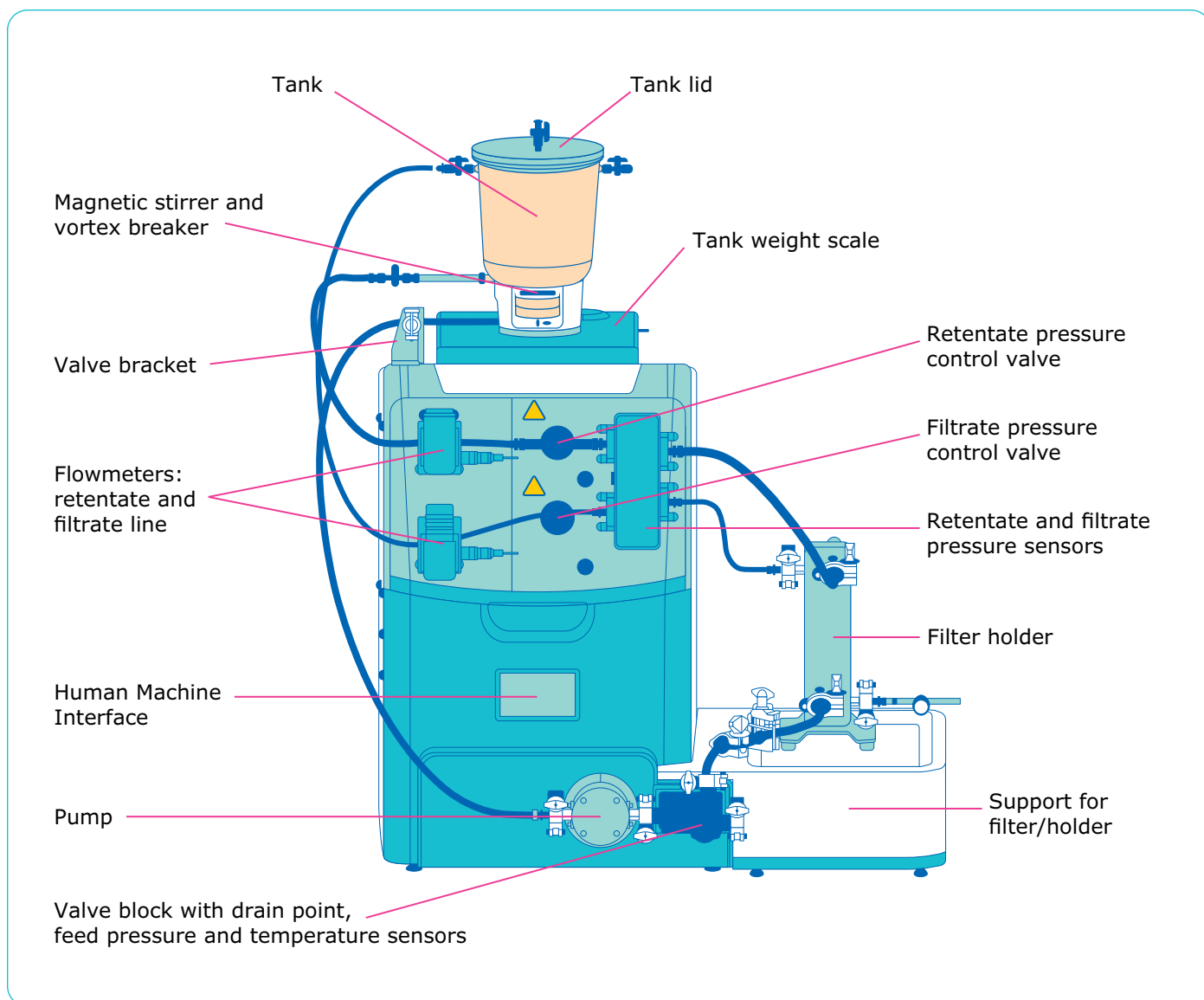
Note: equipment presented in total recirculation mode

Accessories

Bag hook holds a single-use bag in place of feed tank

Low range pressure sensor provides the level of accuracy needed in microfiltration

Cogent® Lab 800



Note: equipment presented in total recirculation mode

Accessories

Bag hook holds a single-use bag in place of feed tank

Transfer pump enables fed-batch or buffer addition in diafiltration step

Filtrate pH/conductivity enables monitoring of flush or buffer exchange efficiency

Filtrate UV allows to detect and prevent protein loss

Low range pressure sensors provide the level of accuracy needed in microfiltration

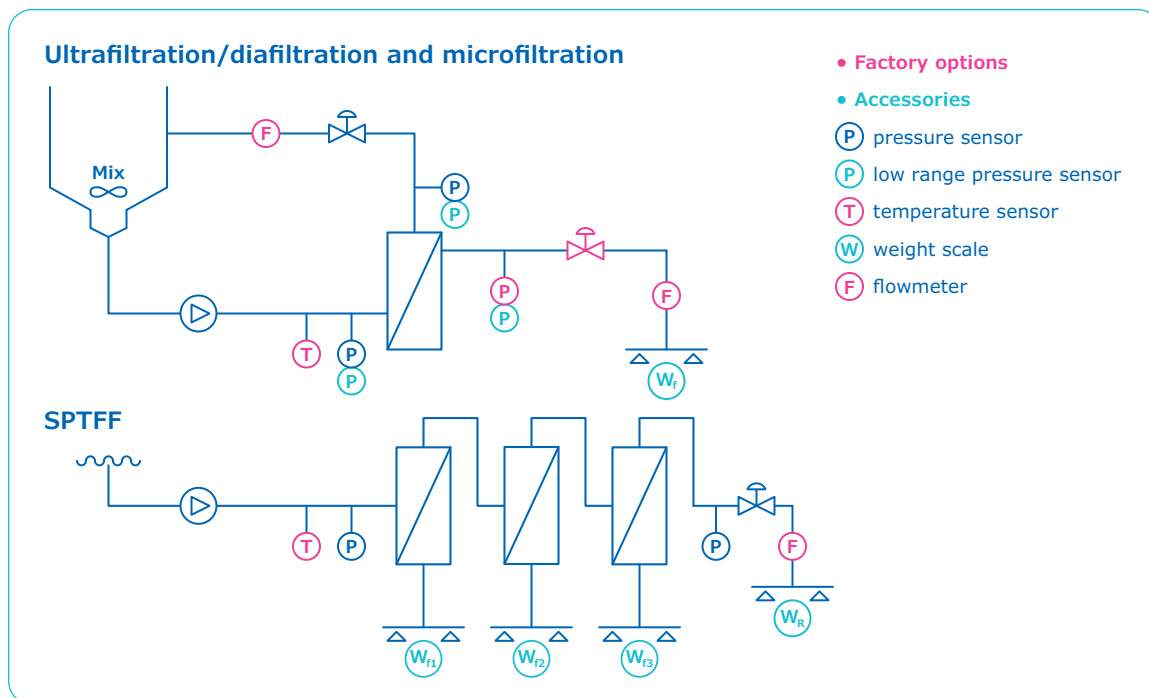
Temperature control unit maintains product temperature or warms up a cleaning solution

Note: The Cogent® Lab 6000 system has the same components as the Cogent® Lab 800 system. For additional details, please refer to the configuration table.

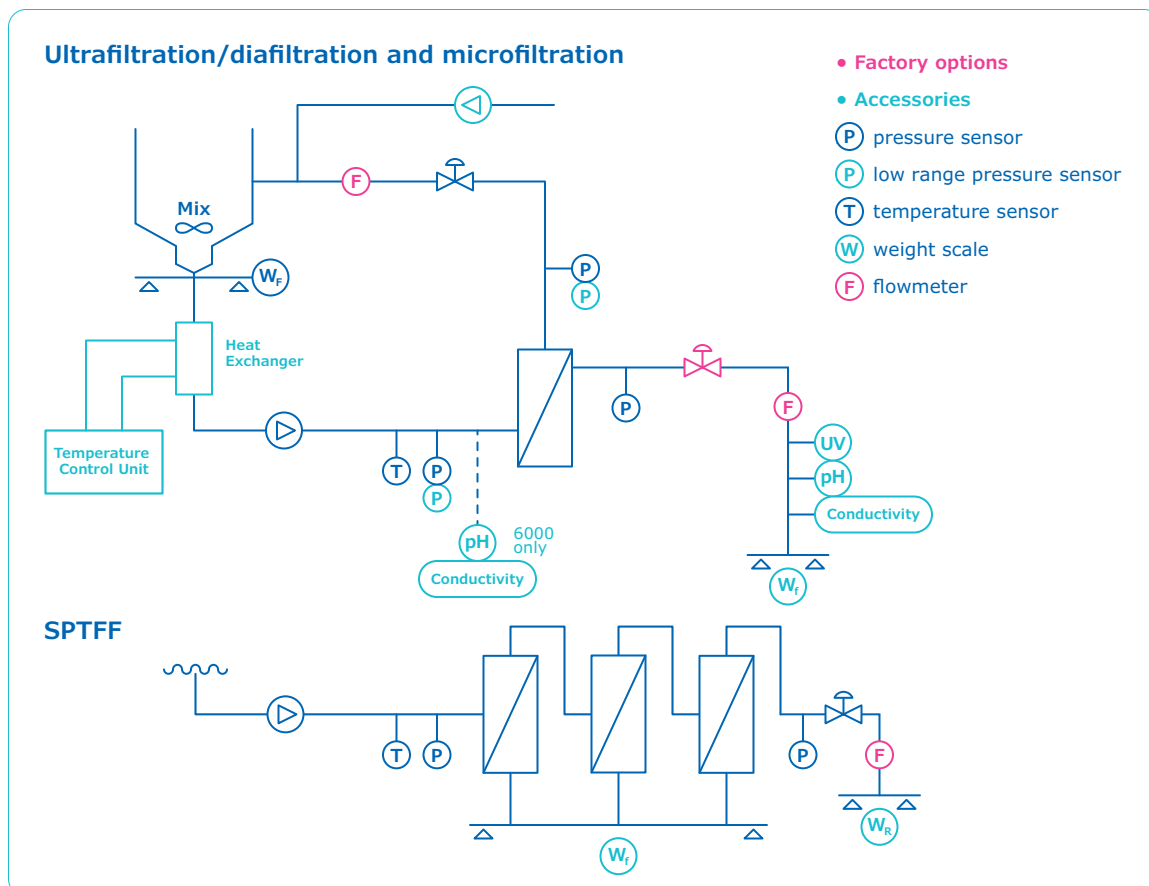
Setups:

Detailed setups for each system can be found below.

Cogent® Lab 150 system setups:



Cogent® Lab 800 and 6000 systems setups:



Bio4C® Control Software for Cogent® Lab Systems

The Bio4C® Control Software provides real-time monitoring and control of all Cogent® Lab System processes.

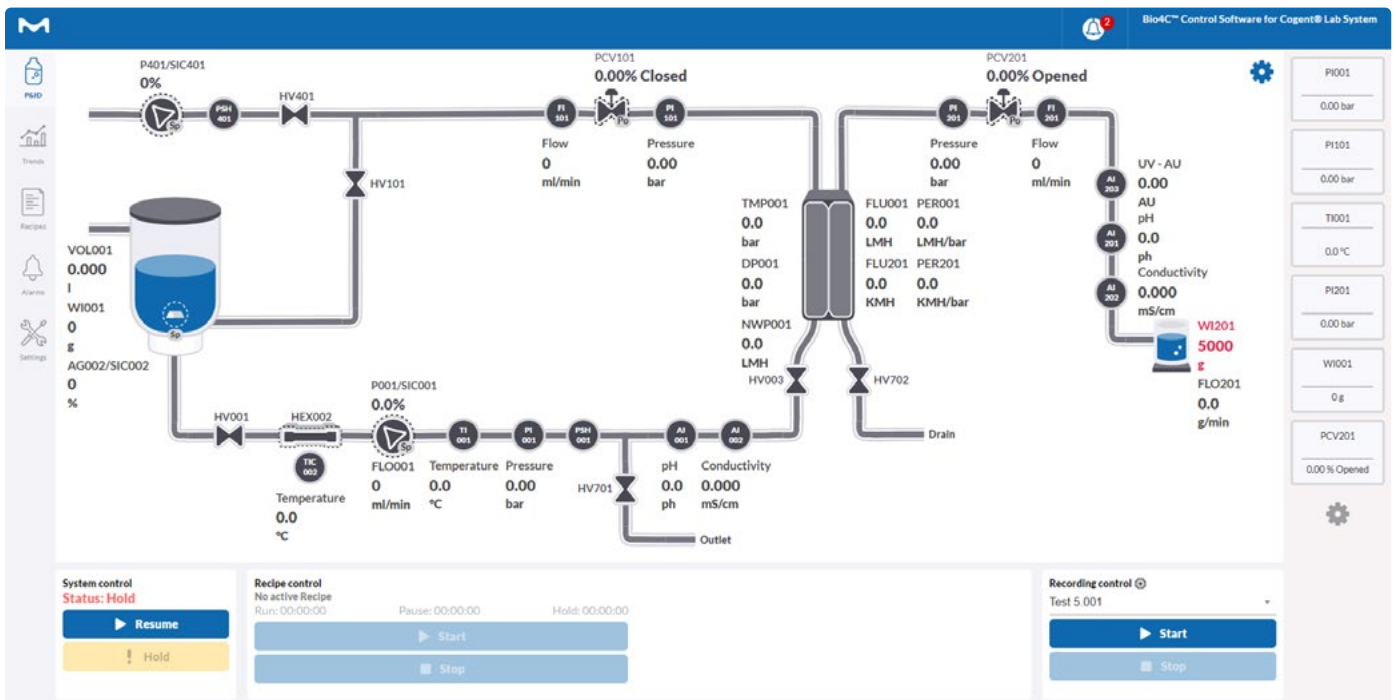
With an intuitive user interface, you can operate the system with minimal training. The home screen provides:

- Persistent left navigation bar for easy access to P&ID, trends, recipes, alarms, and settings
- Top banner with alarms and system information
- Customizable pinned sensors bar with actuator and sensor parameters of interest
- Status bar with current state of the process
- Interactive P&ID schematic of the flow path with icons of actuators, sensors, and virtual sensors
- Update Utility allows you to upload and install the latest version of the Bio4C® Control Software for Cogent® Lab systems

In addition, the Bio4C® Control Software offers the following features to support users in their application runs, from recipe creation and starting a run to monitoring and reporting.

P&ID displays the complete process flow path and provides a snapshot of the system's current state. From the P&ID, a user can directly interact, control, and monitor system components.

The P&ID schematic shows icons of actuators, sensors, and virtual sensors together with information on tags, control mode (manual or automatic), and additional system settings and key parameter values such as setpoints or current speed.



Bio4C® Control Software Home Screen

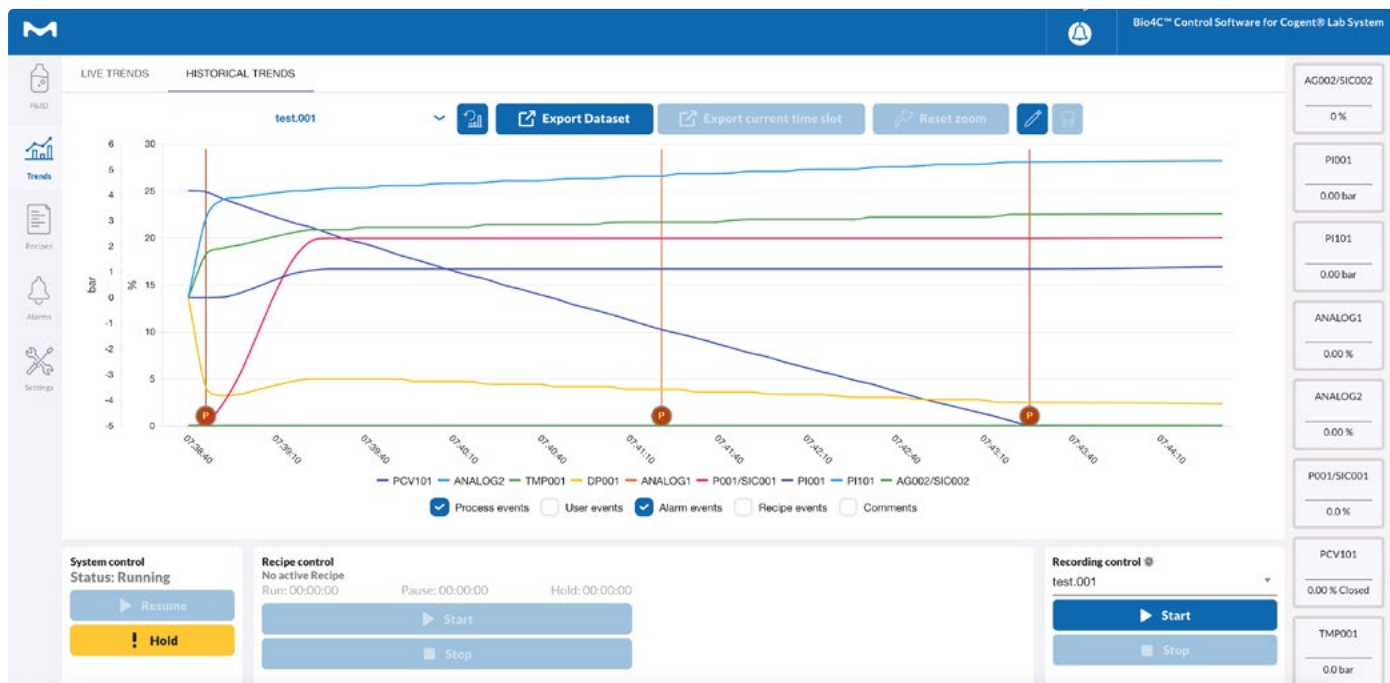
Recipes can be easily created by dragging and dropping preconfigured recipe macro-steps (e.g., diafiltration, concentration) and settings can be customized for each of the macro-step options.

Macro-Steps	Description	Controlled Actuators*
Concentration	Used for volume reduction (including fed-batch), based on time or VCF	Feed pump, PCV retentate, PCV filtrate, transfer pump
SPTFF Concentration	Used for SPTFF processing, based on feed tank weight threshold	Feed pump, PCV retentate, PCV filtrate
Diafiltration	Used for buffer exchange, with automated diafiltration buffer addition	Feed pump, PCV retentate, PCV filtrate, transfer pump
Total Recirculation	Typically used for final sanitization, buffer equilibration, and TMP/flux excursion experiment	Feed pump, PCV retentate, PCV filtrate
Single Path Flush	Used for cleaning and flow path rining	Feed pump, PCV retentate, PCV filtrate, transfer pump
Tank Emptying	Used for product recovery or changeout	Feed pump
Tank Filling	Used for initial tank filling using the transfer pump	Transfer pump
Stop Equipments	Used to stop all automated components, all pumps, and freeze all PCV in place	Feed pump, transfer pump, PCV

*Control mode and end criteria available depend on configuration and accessories selected

Trends allow you to visualize the live data of the current process in real-time or historical trends of saved data of previous runs. Users can enable or disable the trend curve of interest and can also overlay events on the charts.

Calculated values (math expression and aggregation) can be overlayed on historical data. Historical data can also be exported to a spreadsheet for additional offline analysis.



Historical Trends Display

Specifications

Cogent® Lab Systems and Accessories				
		Cogent® Lab 150 System	Cogent® Lab 800 System	Cogent® Lab 6000 System
Supported Devices	Pellicon® XL 50 cassettes 50 cm ²	Up to 3		
	Pellicon® 3 cassettes 88 cm ²	Up to 3	2 to 5	
	Pellicon® 2 and 3 cassettes 0.1/0.11 m ²		Up to 2	Up to 5
	Pellicon® capsule 0.1 m ²		Up to 2	Up to 5
	Pellicon® capsule 0.5 m ²			Up to 2
	Pellicon® 2 and 3 cassettes 0.5/0.57 m ²			Up to 2
	Pellicon® 3 cassettes 1.14 m ²			Up to 1
Filtration Area		50 to 264 cm ²	176 cm ² to 0.22 m ²	0.1 m ² to 1.14 m ²
Tank Volume		500 mL	2000 mL	5000 mL
Minimum Working Volume	Lowest volume in recirculation loop (mixing off, feed pump on, no air suction)	30 mL	87 mL	283 mL
Unrecoverable Volume	Remaining volume in flowpath after system draining	3 mL	3,5 mL	10 mL
Pump Flow Rate	Feed pump range at 5 bar	20–150 mL/min	100–800 mL/min	400–6000 mL/min
	Feed pump range at 1 bar*	20–250 mL/min	30–1750 mL/min	100–12000 mL/min
	Transfer pump max flow (optional)	N/A	800 mL/min	3000 mL/min
Process Temperature Range		5–40 °C		
System Operating Ambient Temperature		4–30 °C		
Connection to holder		Luer lock	Micro clamp (25 mm ferrule)	Micro clamp (25 mm ferrule)
Maximum Operating Pressure		5 bar		
Language Supported	Chinese, English, French, German, Italian, Japanese, Spanish			
Dimensions	Core system + filter support (width x depth)	600 x 450 mm	715 x 555 mm	805 x 585 mm
	Height without tank (with)	605 mm (800)	670 mm (940)	670 mm (1000)
Weight (nominal)	Core system (+/- 10%)	28 kg	40 kg	55 kg
Power Supply		100 – 240 V~, 50 – 60 Hz with protective earth		
Materials of Construction for All Wetted Parts	Stainless-steel parts	316L		
	Polymers	PP, PVDF, PPSU, PEEK, PC, HDPE, PTFE, EPDM, Santoprene, Silicone platinum cured		
Regulatory Information	<p>All plastic and elastomer parts in contact with the product comply with USP <88> Class VI or USP <87> or FDA title 21 CFR, paragraph 177 or ISO 10993-5 except for Cogent® Lab 150 System feed pump</p> <p>All stainless-steel parts manufactured from 316 L stainless-steel or equivalent in contact with the product complies with material certificate 3.1 following EN 10204.</p> <p>Cogent® Lab Systems are designed and manufactured in application of the following directives:</p> <ul style="list-style-type: none"> • 2014/30/EU relating to electromagnetic compatibility; • 2014/35/EU relating to electrical equipment designed for use within certain voltage limits; • 2011/65/EU relating to the Restriction of the use of certain hazardous substances (RoHS) in electrical and electronic equipment. supplemented by the new Delegated Directive 2015/863/EU. <p>Please review the product's Declaration of Conformity for the most up to date list of standards and directives the systems comply to.</p>			

*According to pump specifications

Cogent® TFF System Services

The pharmaceutical and biotechnology industries are highly regulated. To support you as you navigate this challenging environment, we offer a wide range of services that can help save time and lower costs. All of our services are performed by global experts who have an intimate knowledge of our equipment backed by decades of experience, giving you peace of mind at every step.

Qualification Services

Integrating our Cogent® Lab system into your laboratory is seamless and quick, thanks to our qualification services. Our dedicated team ensures your equipment is properly installed and is functioning per your pre-defined requirements.

- Installation qualification/operational qualification (IQ/OQ)

Specialized Services

Application Support

Our experts can help you design your process and scale-up, ensuring smooth operations and an efficient process.

System Service Reliance Plans

To help you ensure optimum equipment uptime while mitigating risks, we have developed a wide range of services and support that allow you to select a coverage level that best fits your needs. Our System Service Reliance Plans, a complete range of services for your systems, offer priority access while ensuring your equipment is properly maintained.

For additional details, please refer to the System Service Reliance Plans Data Sheet (MK_DS7881EN).

Repair Services and Spare Parts

Repair Services

In the event your system experiences a problem, our worldwide engineering organization will provide on-site or repair center technical support to get you back up and running as quickly as possible.

Spare Parts

Purchasing spare parts directly from us is the only way we can guarantee that you get the right parts every time, with the same level of performance as the original.

Learn more about our system services at [MerckMillipore.com/Systems-Services](https://www.merckmillipore.com/Systems-Services)

Related Products

Pellicon® XL 50 Cassettes

With the same flow path and channel height as larger Pellicon® cassettes and the ability to operate with the same pressure drop, flow velocity, and concentration profile, Pellicon® XL 50 cassettes couple our ultrafiltration and microfiltration membranes with the first linearly scalable TFF cassette for processing small volumes. This self-contained device has a filtration area of 50 cm² and is specifically designed for process development.



Pellicon® 2 and Pellicon® 3 Cassettes

These advanced, high-performance cassettes are ideal for high titer therapeutic antibodies, as well as more demanding filtration processes that require higher operating pressures, temperatures, and caustic cleaning regimes. Our family of Cogent® Lab Systems can operate with Pellicon® 2 and Pellicon® 3 cassettes from 88 cm² to 1.14 m², allowing seamless scale-up before implementation into larger systems using the same cassettes.



Pellicon® Capsules

Our TFF capsules are ideal for processing biopharmaceuticals that require single-use capabilities, including enhanced ease-of-use, process flexibility, rapid product turnaround, and reduced operator exposure. First-of-its-kind and gamma sterilized, the capsule has a holderless, self-contained design for fast and flexible product changeover. Our Cogent® Lab Systems paired with Pellicon® 0.1 and 0.5 m² capsules offer robust and consistent performance during process development, ensuring scale-up predictability with our larger systems, including transitioning to closed processing at clinical and manufacturing scale.



Process-Scale TFF Systems

Benefiting from our leading bioprocess knowledge and engineering expertise in tangential flow filtration, we have developed multi-use and single-use systems. Mobius® FlexReady Solution for TFF provides a combination of single-use Flexware® assemblies and process-ready hardware specifically designed for TFF. It is pre-assembled and pre-tested, integrating easily into any process. The multi-use Cogent® Process-Scale TFF System is highly modular and designed to separate and purify monoclonal antibodies, vaccines, plasma, and therapeutic proteins. It is ideally suited for both pilot and production scale applications, thereby supporting rapid scale-up from small- to large-scale operations.



Suggested Configurations and Ordering Information:

Cogent® Lab systems can be used for microfiltration (MF), UF/DF, and SPTFF. Suggested configurations and accessories are highlighted in the tables below.

To tailor the Cogent® Lab system to your needs, choose from:

- A system configuration with factory options (those options cannot be added later)
- A power cord depending on geography (not included with the system, can be added at any time but necessary to start)
- A device holder or stand (not included with the system, can be added at any time but necessary to start)
- Accessories such as sensors, etc. (can be added at any time)
- Further items depending on selected configuration (tubing sets for accessories, etc.)

Cogent® Lab 150	Cogent® Lab 800	Cogent® Lab 6000	Factory options	
			Retentate and filtrate flowmeter	Filtrate PCV
MCLAB150BASE	MCLAB800BASE	MCLAB6000BASE		
MCLAB150FW	MCLAB800FW	MCLAB6000FW	●	
MCLAB1502PCV	MCLAB8002PCV	MCLAB60002PCV		●
MCLAB150FULL	MCLAB800FULL	MCLAB6000FULL	●	●

Cogent® Lab systems references based on factory options included

System major components	Cogent® Lab 150				Cogent® Lab 800				Cogent® Lab 6000			
	MCLAB150BASE	MCLAB150FW ●	MCLAB1502PCV ●	MCLAB150FULL ●	MCLAB800BASE	MCLAB800FW	MCLAB8002PCV ●	MCLAB800FULL ●	MCLAB6000BASE	MCLAB6000FW	MCLAB60002PCV ●	MCLAB6000FULL ●
Tank size	500 mL				2000 mL				5000 mL			
Mixing (stir bar)	●	●	●	●	●	●	●	●	●	●	●	●
Tank weight scale					●	●	●	●	●	●	●	●
Retentate PCV	●	●	●	●	●	●	●	●	●	●	●	●
Feed pressure	●	●	●	●	●	●	●	●	●	●	●	●
Retentate pressure	●	●	●	●	●	●	●	●	●	●	●	●
Filtrate pressure			●	●	●	●	●	●	●	●	●	●
Feed temperature		●		●	●	●	●	●	●	●	●	●
Retentate flowmeter		●		●		●		●		●		●
Filtrate flowmeter		●		●		●		●		●		●
Filtrate PCV			●	●			●	●			●	●
Bio4C® Control Software	●	●	●	●	●	●	●	●	●	●	●	●
Tubing kit for the system	●	●	●	●	●	●	●	●	●	●	●	●

Expert recommended options to run ● MF ● UF/DF ● SPTFF

Power cords for systems and Temperature Control Unit

Note: Power cord is not included the system or the TCU and must be ordered separately.

Geography	Power cord for the system	Power cord for the TCU
Argentina	PWRCORDBULAR	PWRCORDIECAR
Australia / New Zealand	PWRCORDBULAU	PWRCORDIECAU
Brazil	PWRCORDBULBR	PWRCORDIECBR
China	PWRCORDBULCH	PWRCORDIECCH
Europe	PWRCORDBULEU	PWRCORDIECEU
India	PWRCORDBULIN	PWRCORDIECIN
Israel	PWRCORDBULIS	PWRCORDIECIS
Japan / Taiwan	PWRCORDBULJP	PWRCORDIECJP
Switzerland	PWRCORDBULSW	PWRCORDIECSW
Thailand	PWRCORDBULTH	PWRCORDIECTH
United Kingdom/Singapore /Hong Kong	PWRCORDBULUK	PWRCORDIECUK
US / Canada	PWRCORDBULUS	PWRCORDIECUS
South Africa	PWRCORDBULZA	PWRCORDIECZA

Cogent® Lab system accessories references

Description	Cogent® Lab 150	Cogent® Lab 800	Cogent® Lab 6000
Hook for single use bag	C150H00K	C800H00K	C6000H00K
Small weight scale	CWSCALESMALL • • (retentate and/or filtrate)	CWSCALESMALL (retentate)	
Large weight scale		CWSCALELARGE • (filtrate)	CWSCALELARGE • (retentate and/or filtrate)
Transfer pump kit		C800XFERPUMP •	C6000XFERPUMP •
Temperature control kit (heat exchanger and Temperature Control Unit [TCU])		C800TCU	C6000TCU
Filtrate UV kit		CFILTUV	CFILTUV
Filtrate pH/Conductivity kit		CFILTPHC0ND	CFILTPHC0ND
Feed pH/Conductivity kit			CFEEDPHC0ND •
Low range pressure sensors kit	CLOWRANGEPT •	CLOWRANGEPT •	CLOWRANGEPT •
Tubings			
Tubing kit for the system	C150TUB	C800TUB	C6000TUB
Tubing kit for use with Labscale holder on Lab 6000			C6000LABSCALTUB
Tubing kit for the transfer pump		C800XFERTUB •	C6000XFERTUB •
Kit with tubing for connecting TCU or pH/Conductivity or UV sensors		C800MISCTUB	C6000MISCTUB
Holders and stands (1)			
Holders	XX42PMICRO for Pellicon® 3 cassettes 88 cm ²	XX42PMINI short tie rods XX42PMINIX long tie rods • for Pellicon® 2 cassettes 0,1 m ² and Pellicon® 3 cassettes 88 cm ² and 0,11 m ²	XX42PMINI short tie rods XX42PMINIX long tie rods • for Pellicon® 2 cassettes 0,1 m ² and Pellicon® 3 cassettes 0,11 m ² CLABSCALEHLDR Labscale holder for Pellicon® 2 cassettes 0,5 m ² and Pellicon® 3 cassettes 0,57 m ² to 1,14 m ²
Stands	XXPXLSTND for Pellicon® XL 50 ultrafiltration cassettes	PCX001 Pellicon® Capsule Stand	PCX001 Pellicon® Capsule Stand

Expert recommended options to run • MF • UF/DF • SPTFF

(1): Holders and stands are not included with the system and must be ordered separately

Services for Cogent® Lab Systems

Description	Cogent® Lab 150	Cogent® Lab 800	Cogent® Lab 6000
Installation and Operational Qualification (IQ/OQ)	SSVQUAL15	SSVQUAL80	SSVQUAL60
Essential Service Reliance Plan	SSVESPL15	SSVESPL80	SSVESPL60
Advanced Service Reliance Plan	SSVESPL15 + SSVADCL15	SSVESPL80 + SSVADCL80	SSVESPL60 + SSVADCL60
Total Service Reliance Plan	SSVESPL15 + SSVTOCL15	SSVESPL80 + SSVTOCL80	SSVESPL60 + SSVTOCL60
Cogent® Lab Operator Training–On-site	PTRCL01	PTRCL01	PTRCL01
Cogent® Lab Operator Training–Remote	PTRCLR01REM	PTRCLR01REM	PTRCLR01REM

For more information, please visit
sigmaaldrich.com/TFF-systems

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