Data Sheet

Cogent® Process-Scale Tangential Flow Filtration System

A fully-automated, configurable, TFF system suited for manufacturing of biopharmaceuticals and cGMP process-scale applications

The fully automated Cogent® TFF system is 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.

Benefiting from our leading bioprocess knowledge and engineering expertise, the Cogent® Process Scale System is the culmination of 25 years of custom system design and incorporates many unique, innovative and intelligent design features. This system has a very low hold-up volume for maximum volume concentration and optimal product recovery, thus enhancing process performance.

Benefits:

- Modular standard options allow the unique system configuration that best matches process requirements while minimizingupfront investment.
- Full process automation eases the consistent production of preclinical and clinical scale quantities of high-value drug products to cGMP standard.
- Optimized design and component integration of NovAseptic® valves and TFF cassette holders result in a low minimum working volume and ensure maximum product recovery.
- Designed to maximize TFF performances in fed-batch, concentration, total recycle or single pass mode.
- Comprehensive services ensure rapid implementation and optimized performance.

Configure your system according to your process needs...

Option 1: Tank (50, 100, 200L)

Jacketed for temperature regulation

Option 7: Filtrate conductivity

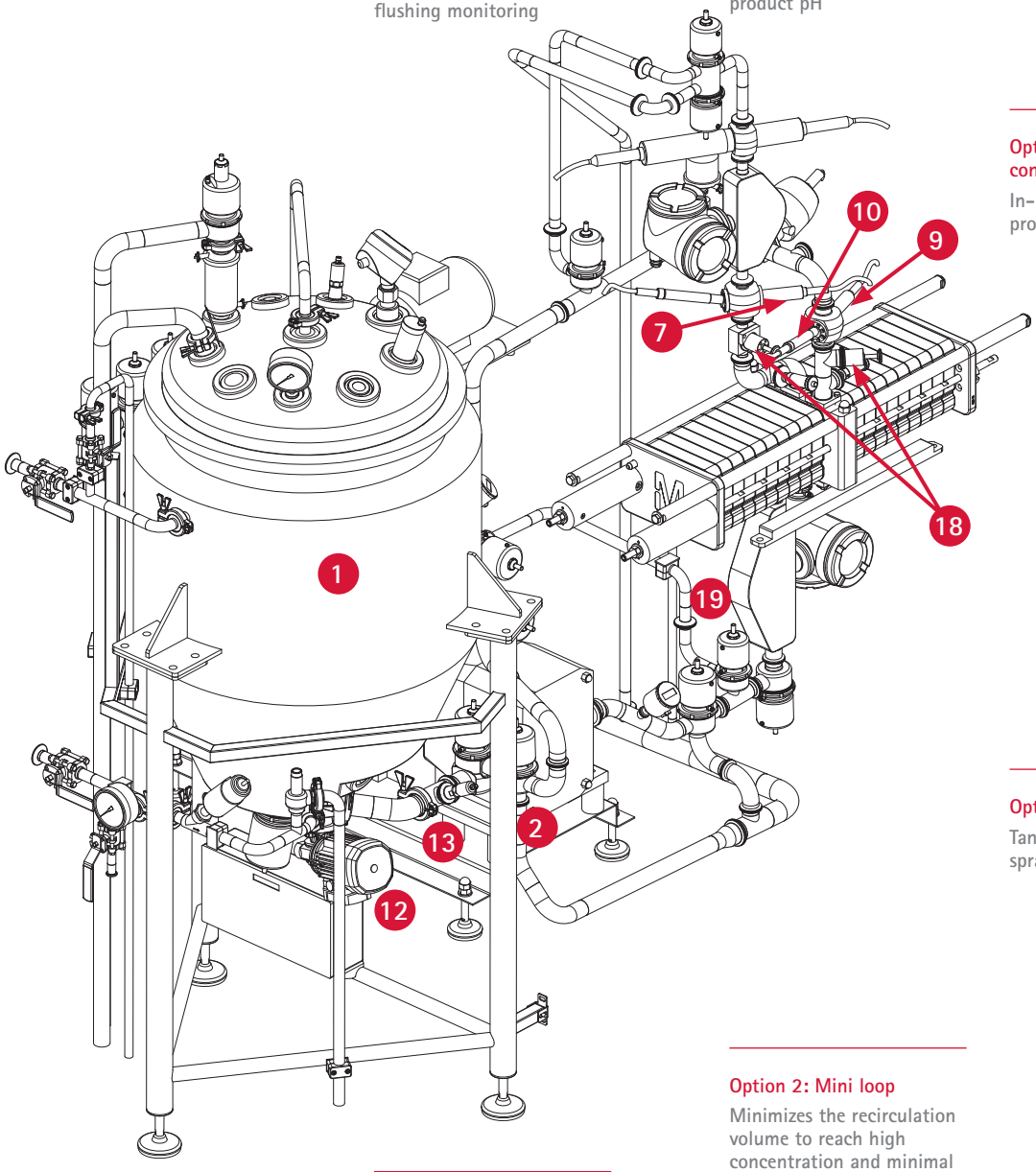
Measurement of a wide range of products (WFI, buffer solutions, protein solutions) or post CIP flushing monitoring

Option 10: Retentate pH

In-process monitoring of product pH

Option 9: Retentate conductivity

In-process monitoring of product conductivity



Option 18: Retentate and Filtrate NovaSeptum® Sampling port

In-process sterile sampling of product

Option 19: Spray ball valve

Tank cleaning using the spray ball

Option 2: Mini loop

Minimizes the recirculation volume to reach high concentration and minimal product volume

Option 12: Tank NovAseptic® GMP mixer

Ensures product homogeneity, specially important during diafiltration step. Aseptic design, minimized shearing

Option 13: Tank Outlet Level Switch

Allows to stop the feed pump when air reaches this sensor. E.g: In Mini loop concentration mode, detects the end of the step (tank fully empty).

Option 3: Transfer Pump

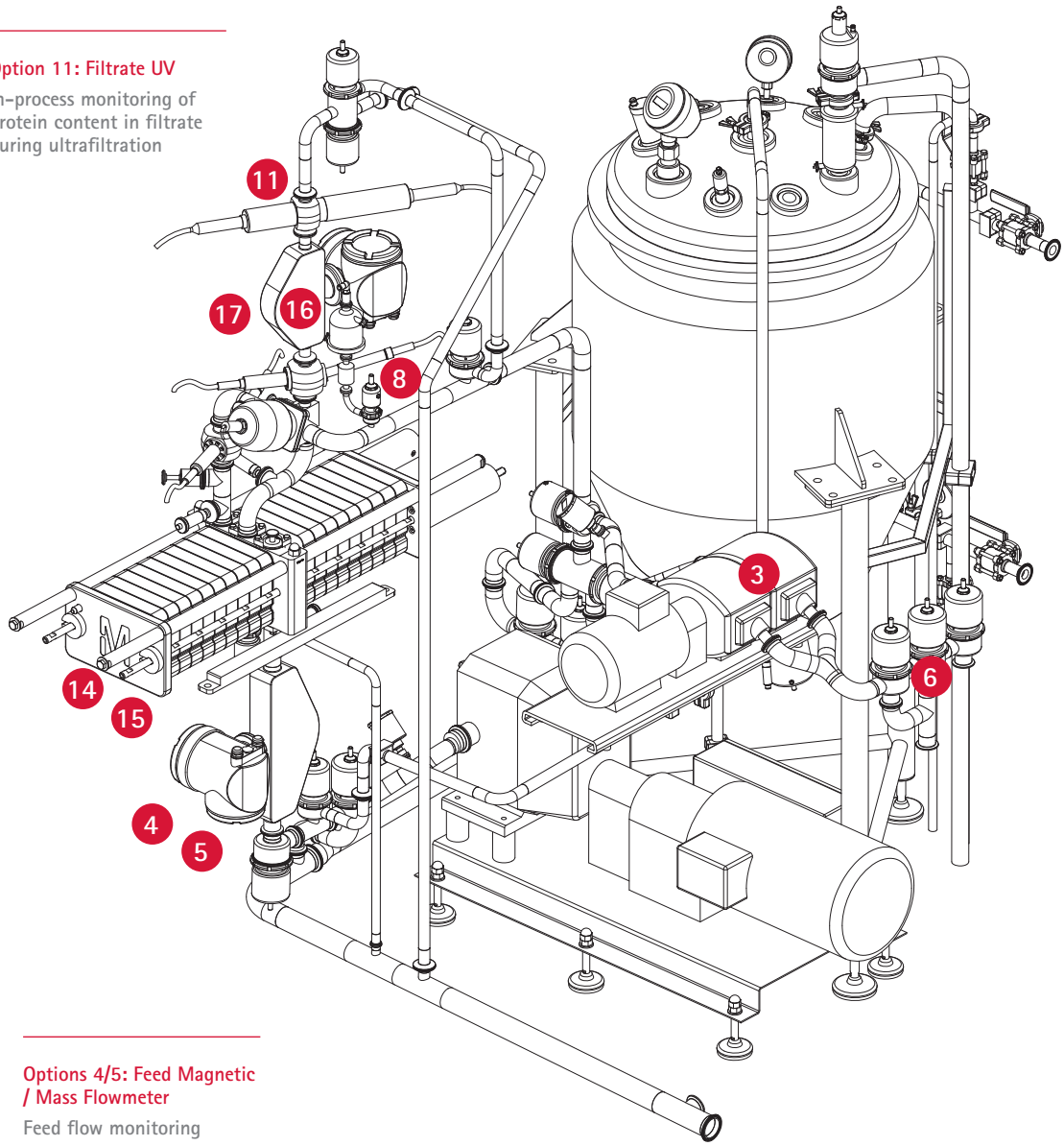
Transfer of product / buffers into the feed tank from any other tank. Allows fed-batch mode, and diafiltration.

Option 8: Filtrate pH

pH monitoring during cleaning and sanitization procedures

Option 11: Filtrate UV

In-process monitoring of protein content in filtrate during ultrafiltration



Options 16/17: Filtrate Mass / Magnetic flowmeter

Filtrate flow and total volume monitoring in diafiltration mode

Options 14/15: Process Scale Holder

Can be configured either with manual or hydraulic closure. Hydraulic closure can be done with a hand pump or with an automated hydraulic box.

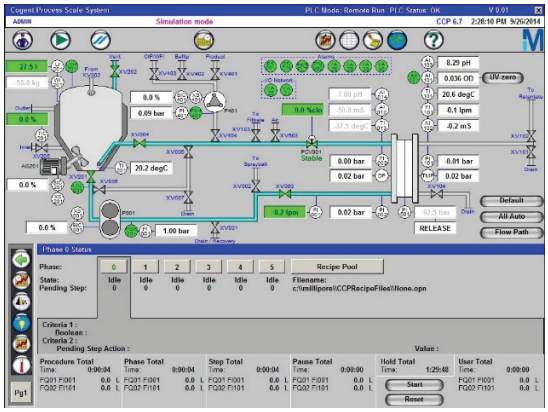
Options 4/5: Feed Magnetic / Mass Flowmeter

Feed flow monitoring

Option 6: Transfer Inlet Manifold

Allows connecting several inlets to the transfer pump head (product/WFI/CIP) at the same time, avoiding many connections / disconnections

...and build a consistent user experience



Total Process Control and Connectivity

The Cogent® Process Scale system is easily controlled via the Common Control Platform® (CCP®) software, a powerful, intuitive and graphical software that provides real-time monitoring and total in-depth control of your TFF process.

Using robust PCs, PLCs, and SCADA® technology, it meets the most stringent standards for connectivity, reliability and ease of use.

Benefits:

- Create process operations using the recipe editor, monitor or control the process in the home screen, and create reports for the batch using the configurable report generator
- Developed under GAMP guidelines and FDA 21 CFR Part 11 compliance-ready, including audit trails and electronic signatures for verification
- Sensor combinations can be adapted to process requirements allowing the maximum confidence in process monitoring
- Utilities to connect all of your separation unit operations to a central network or DCS (e.g. Delta V)
- Used on multiple unit operations CCP® software provides one familiar interface to simplify software management and reduce learning curves

NovAseptic® GMP mixer

Embedded NovAseptic® Valves, Mixer and Connectors

Engineered for optimal performance, reliability, durability and ease of maintenance.

The design and development of each component is based on more than 20 years' experience, focused on aseptic application. This is why we choose to call it "Aseptic by Design."

Benefits:

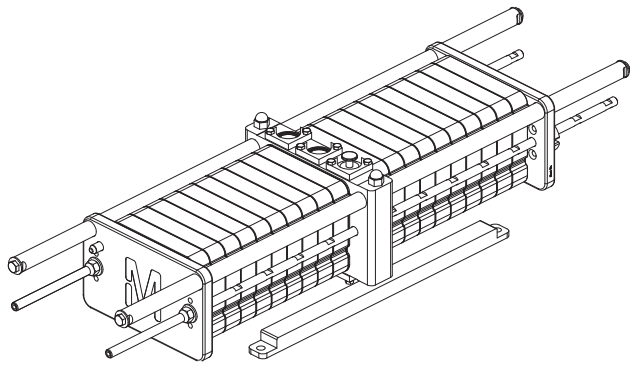
- Comply with cGMP Design Qualification criteria for aseptic processing
- NovAseptic® connector ensures no dead legs and maximum product recovery with zero hold up volume.
- Comply with the most stringent cleaning and sterilization requirements
- Mixer is clean running and is suitable for general mixing, heat transfer and shear sensitive applications.
- Reduced bioburden
- Lower cost of maintenance
- Diamond coated mixer bearings ensure long life and optimum performance.
- Ability to mix the "last drop", ensures complete product recovery

Unparalleled Ultrafiltration

Plug and Play

The Pellicon® Process-scale Holder is uniquely designed to reduce the time required to install and remove TFF cassettes at production scale while keeping the flow path unchanged.

The holder can be configured with a manual or hydraulic closure. Hydraulic closure can be done with a hand pump or with an automated hydraulic box which allows local or distant control.



Benefits:

- Compact footprint
- TFF cassettes can be installed/removed quickly
- Easy to vent and fully drainable, maximizes product recovery
- Easy retrofit from manual to hydraulic closure
- Flow path unchanged, minimizes future re-qualification and validation effort in new process applications

Air Integrity Test

In order to ensure that the cassettes have been installed properly and has not sustained any damage during storage and handling, we recommend integrity testing prior to startup and after each post use cleaning. Air Integrity Test accessories consist of a set of air pressure regulators and fittings including assembly procedure to guarantee an easy plug and play solution.

Pellicon® 3 Ultrafiltration Cassettes

The tangential flow filtration cassette of choice for demanding filtration processes requiring unbeatable performance consistency. For use in applications including: monoclonal antibodies, recombinant and non-recombinant proteins, albumin, hormones, vaccines, and growth factors.

Biomax® membrane

Pellicon® 3 cassettes with Biomax® membranes are designed for the filtration of therapeutic proteins, albumin, hormones, vaccines and growth factors. These advanced, high-performance cassettes are ideal for today's processes that require higher operating pressures, temperatures and higher caustic cleaning regimes.

Ultracel® membrane

Pellicon® 3 Cassettes with Ultracel® membrane are the device of choice for today's higher titer therapeutic antibodies as well as the more demanding filtration processes that require low protein fouling. The new D screen is optimized for applications that require higher viscosity and concentration applications.

Benefits:

- Robust, void-free membranes for optimum product recovery and performance consistency
- All thermoplastic design, protective end cap and integrated gasket provides great process consistency and ease of use
- Predictable and fast process scalability from lab to production scale
- Robust product design ideally suited to filtration processes with higher operating pressures, temperatures and caustic cleaning regimes
- Automated manufacturing delivers unbeatable performance consistency and reliability
- Proven process expertise and technical support to partner with you from development to full scale manufacturing
- Optimized flow path for higher flux and resolution separation capability

Provantage® Bioprocess Consulting Services

Provantage® Bioprocess Consulting Services leverage our core expertise, products, services and technology in downstream production to help solve your business problem or challenge. Our commitment to your project outcomes and timelines is managed with our stage gate approach and a dedicated project manager.

Application Expertise

Our Biomanufacturing Sciences Network (BSN) is a global team of over 85 engineers, scientists and technology specialists who provide expertise and peer-to-peer support in process development and manufacturing. We act as an extension of your team, helping you to minimize potential risk and streamline your operations. With over 3,000 client engagements, our toolkit of best practices will ensure your project is delivered on time and within budget.

Design and Implement

From lab-scale to pilot and manufacturing facility start-up, EMD Millipore is a partner of choice for providing consultative expertise on current best practices to integrate device, hardware and process technology, and process automation. We can provide consultative evaluations for TFF optimization and operating strategies.

Develop

With our 35+ year history manufacturing and implementing TFF technologies, EMD Millipore application specialists develop reproducible, scalable and robust TFF processes that meet your specific requirements and your required scale.

Optimize

Starting with a comprehensive technical assessment and characterization of your existing TFF step, EMD Millipore application specialists can recommend and implement TFF enhancements that use best-practice operating conditions and state of the art processes to deliver an optimized and validatable TFF process at your targeted scale, in a timely manner.

Transfer

During the lifecycle of a biopharmaceutical, technical transfers occur at various stages: from research to clinical development to commercial manufacturing, and from one manufacturing facility to another. EMD Millipore leverages experienced technical staff, strong project management, and good documentation practices on both sides throughout the course of transfer activities to ensure a robust and successful transfer.

Troubleshoot

EMD Millipore has extensive experience in troubleshooting and investigating manufacturing, method and process development issues. Our experienced team works together collectively with your technical project team to identify the root cause and to develop a robust, acceptable path forward.

Provantage® implementation services

In the biopharmaceutical industry, implementing new equipment with respect to Quality rules and guidelines can be challenging. To help you stay ahead in today's demanding and competitive production environment, our Provantage® Services group provides unparalleled support for implementation of the Cogent® Process Scale System. With a wide range of comprehensive packages to meet your unique manufacturing requirements, resulting in peace of mind and maximum operational flexibility.

	SAT and IQ/OQ	Operator training	CCP® Software Design	CCP® Software Training	Support for PQ
Qualification package GMP	•	•			•
Single Molecule cGMP package	•	•	•		•
Full cGMP package	•	•	•	•	•

Benefits:

- Qualify your system with our IQ/OQ service protocols and use our qualified Field Service Engineers with years of product experience to ensure your system functions as specified in cGMP environments
- Train your operators with an interactive, hands-on courses for either system operation, or advanced CCP® software recipe creation training by certified trainers
- Get the support of our experienced Biomanufacturing Engineers during your Process Performance Qualification
- Maintain your system with annual preventive maintenance by qualified Field Service Engineers to ensure the lifetime of the system and ultimately reduce your capital expenditures

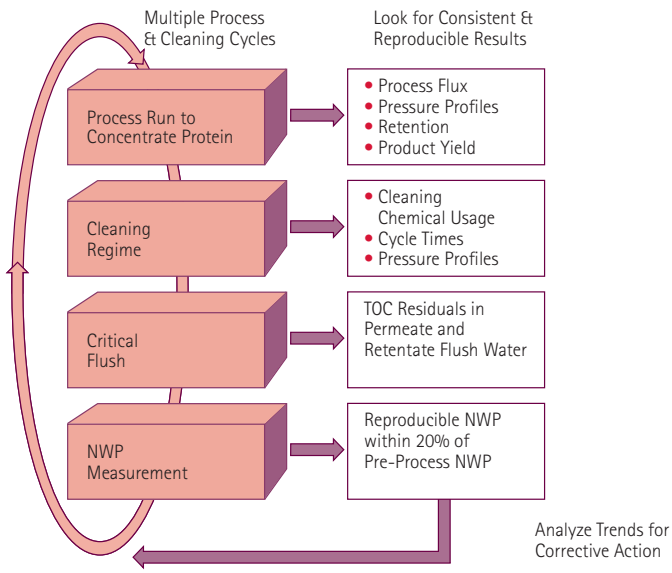
Provantage® Lab Services

Establishing an effective cleaning and sanitization plan for equipment used is a fundamental cGMP requirement necessary to assure the quality and consistency of your drug substance. Effective and consistent membrane cleaning and sanitization after each process cycle is the single most important factor in maintaining system performance.

Cleaning and sanitization after every cycle removes residual foulants and contaminants from the membrane, preventing batch-to-batch carry over, maintaining optimal performance and maximizing the useful life of the filter cassettes.

Effectiveness is measured by the ability to control and eliminate microbial contamination, and to remove process foulants to restore membrane performance such that consistent flux and separation are achieved batch after batch.

Our Provantage® TFF Cleaning Services can help you develop cleaning and sanitization procedures that assure the safety and purity of your product and maximize the useful life of your TFF cassettes.



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