Automated Engineering Services, Inc.

TECHNICAL BROCHURE

Precision Benchtop Tangential Flow Filtration Unit

PRODUCT SUMMARY

The Precision Benchtop Tangential Flow Filtration (TFF) Unit is a highly efficient and flexible solution designed to streamline the TFF process. The skid incorporates a comprehensive control system that ensures seamless operation and precise control over critical process parameters. Leveraging advanced automation technology, the control system offers intuitive user interfaces, real-time monitoring, and data logging capabilities, empowering operators to optimize the filtration process easily. With the control system's robust integration and compatibility with industry-standard protocols, our TFF Skid enables effortless integration into existing bioprocessing infrastructures, enhancing downstream processes. Benefit from enhanced process control, improved efficiency, and reliable performance with our TFF Units's cutting-edge control system.

APPLICATIONS:

Our TFF Unit is meticulously designed to excel in various bioprocessing applications, offering efficient and reliable filtration solutions. Its adaptability and advanced features facilitate seamless integration into diverse processes, ensuring optimal performance and consistently high-quality outcomes. Noteworthy applications where our TFF Unit demonstrates exceptional performance encompass:

- Ultrafiltration and Diafiltration Process Steps
- Facilitating Monoclonal Antibodies (mAb) Production
- Enabling Vaccines Filtration
- Supporting Recombinant Proteins Processing
- Conducting Filtration of liposomes, exosomes, and viruses
- Aiding in Process Development

BENEFITS OF THE AES PRECISION TFF UNIT:

- Delivers consistent, efficient filtration across various bioprocessing applications, reducing fouling and enhancing productivity.
- Advanced TMP control automatically regulates flow and pressure, optimizing filtration conditions for peak performance.
- Continuously monitors air presence during filtration with an innovative ultrasonic bubble detection system, preventing air from entering the system. This ensures a stable fluid stream, minimizes disruptions, and maximizes product yield.
- Boosts operational efficiency and reliability with real-time monitoring, data logging, and seamless integration.
- Standard integration with Rockwell, with options for stand-alone systems or your preferred DCS.

AUTOMATED PROCESS MONITORING & REMOTE CONTROL:

Users can configure alerts and set points, tailoring them to their application requirements. They can monitor trend reports for these crucial process values, gaining valuable insights into their system performance. Additionally, users are equipped to create, edit, and save methods, enabling them to optimize purification protocols according to their unique needs. This comprehensive suite of features empowers operators to effectively manage their operations, providing them with the tools needed to identify deviations from the defined purification parameters swiftly.

DESIGNED FOR A REGULATED ENVIRONMENT:

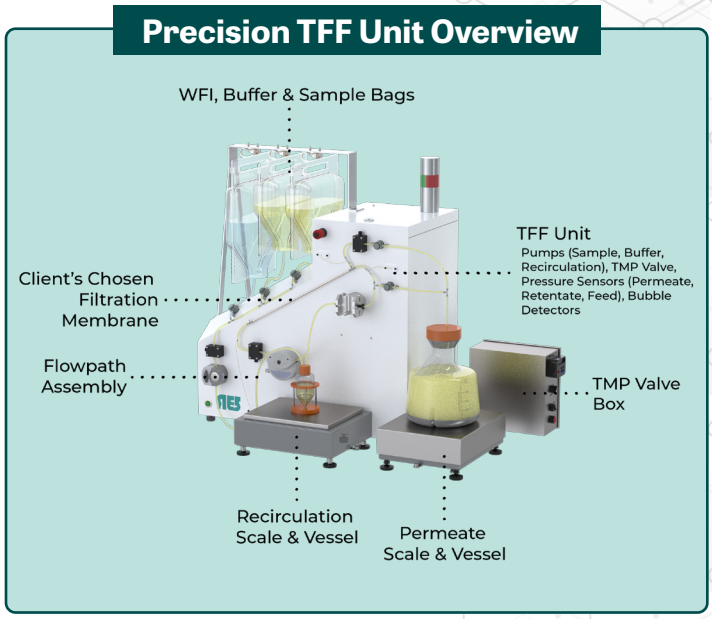
This TFF unit can be designed to meet a regulated environment's rigorous demands and standards if required. In addition, the TFF unit is GMP compliant and can be incorporated to meet 21 CFR Part 11 compliance regulations.

PURIFICATION WORKFLOW:

Our TFF unit seamlessly integrates into purification protocols, working with our Chromatography unit to deliver comprehensive and efficient bioprocessing workflows. The TFF unit is designed to be compatible with various unit operations, including chromatography performed on our Chromatography systems and clarification steps downstream of upstream processes such as microbial fermentation or cell culture. Our team of application specialists is available to provide valuable expertise and guidance on process design, ensuring optimal integration and efficiency throughout your bioprocessing workflow. Our TFF unit and Chromatography unit offer a powerful solution for your purification needs, enabling streamlined and robust processes to achieve high-quality results.

SYSTEM OVERVIEW

The Precision Benchtop TFF Unit is a versatile and compact solution meticulously designed to facilitate the seamless execution of the entire TFF process. Equipped with manual, semi-automated, or fully automated operating modes, the skid integrates an enclosure that houses crucial hardware and instrumentation. It encompasses valves, pumps, pressure sensors, and bubble detectors, working in unison to deliver exceptional performance, reliability, and adaptability. The system includes two benchtop scales, ensuring precise weight measurement of the recirculation vessel and permeate collection. In addition, an external control box allows effortless configuration and comprehensive control of key process parameters.



LIQUID MANAGEMENT:

This TFF unit features essential pumps for precise fluid handling during filtration, ensuring optimal flow control and efficiency. Engineered with robust construction and precise mechanisms, these pumps work harmoniously to ensure reliable fluid handling and accurate flow control. They enable accurate flow control throughout filtration, with adjustable speeds for fine-tuning flow rates according to process needs. Bi-directional stepper motors integrated into the pumps allow seamless control for various filtration operations. The unit maintains contamination-free fluid handling, streamlining tube loading and maintenance for efficiency. Through adjustable pump speeds, bi-directional control, and precise stepper motor fluid control, our TFF unit offers efficient purification throughout the purification process.

Recirculation Pump:

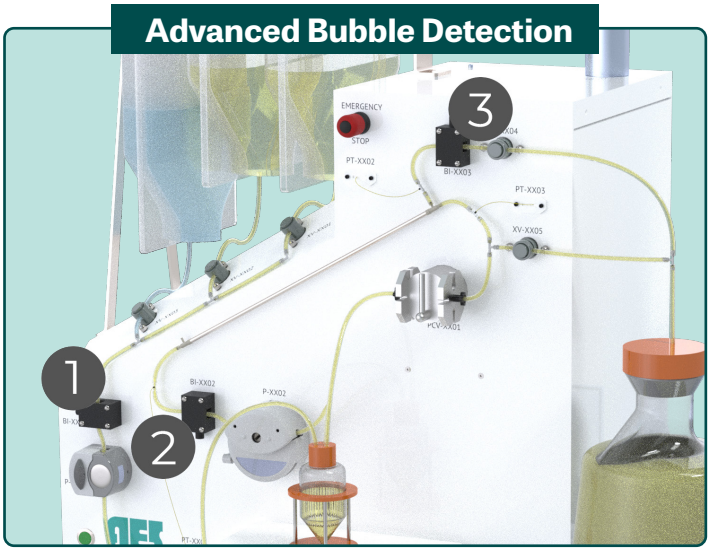
The recirculation pump maintains a continuous flow of the retentate fluid within the system. It enables the recirculation of the retentate back into the TFF system, ensuring consistent and uniform filtration conditions. The recirculation pump offers reliable performance, delivering the necessary pressure and flow rates to sustain the filtration process. With its robust design and precise control capabilities, the recirculation pump ensures steady-state operation, minimizing the risk of fouling or disrupting the filtration process.

Feed Pump:

The feed pump is designed to accurately and consistently control the delivery of a range of process fluids, including Water for Injection (WFI), buffers, and samples. This pump's precision extends to its capacity for regulating flow rates, ensuring a controlled and meticulous introduction of these fluids into the TFF system. By presenting configurable control options, the feed pump's

adaptability extends to managing various process parameters, encompassing flow rates and dosing volumes. The feed pump's advanced control features harmoniously interact with upstream and downstream processes. This seamless integration becomes evident as the pump maintains a steadfast feed pressure set according to user-defined parameters. This pivotal control optimizes filtration, enhancing fluid delivery's role within the broader purification workflow.

BUBBLE DETECTION:
Our TFF unit features an innovative bubble detection system based on cutting-edge ultrasonic technology. This system excels in real-time monitoring and detecting air presence during the TFF process. Enabled by non-invasive clip-on bubble detectors, this capability promptly addresses issues for optimal filtration and productivity. The non-invasive design seamlessly integrates into existing process lines, avoiding costly modifications. Integrated into the control system, this enhances process control and assures a bubble-free fluid stream, maintaining filtrate quality and product purity.



1. Supply Bubble Detector Connection 2. Recirculation Bubble Detector Connection 3. Permeate Bubble Detector Connection

PRESSURE CONTROL:
Incorporating cutting-edge technology, our TFF unit integrates an advanced Transmembrane Pressure (TMP) Valve and a comprehensive Pressure Sensor System, together revolutionizing the control and precision of the entire TFF process. The TMP Valve's automated pressure control and flow regulation, guided by three pressure sensors, ensure optimal conditions and peak filtration performance. Strategically positioned, these sensors monitor and control pressure at key points, guaranteeing unwavering performance and enhancing operator control. This integrated approach underscores our commitment to reliability, control, and precision, shaping desired filtration outcomes with exceptional accuracy.

TMP Valve:
Our advanced TMP Valve distinguishes itself through its automated pressure control capabilities and exceptional flow regulation. This valve operates seamlessly due to an automated TMP calculation method employing data from the three pressure sensors. This automated design is pivotal in establishing and maintaining optimized process conditions, ensuring precise liquid flow adjustment and accurate pressure control. The TMP Valve's dependable operation guarantees peak filtration performance, giving operators unparalleled reliability, control, and precision, essential for achieving the desired filtration outcomes. Notably, this valve enables automatic throttling of liquid flow and precise pressure regulation upstream, further enhancing operator mastery over the TFF process.

Pressure Sensors:
A comprehensive Pressure Sensor System, strategically embeds three key sensors within the setup, enabling precise monitoring and control of pressure parameters throughout the entire TFF process. These pressure sensors maintain optimal operating conditions and achieve meticulous filtration outcomes. The Inlet Filter Pressure Sensor is strategically positioned in the recirculation system, which continuously oversees the pressure ahead of the filter. Concurrently, the Retentate Pressure Sensor meticulously tracks the pressure in the retentate line, a pivotal factor in calculating delta P and Transmembrane Pressure (TMP). This automated feedback control mechanism meticulously upholds delta P at the defined set point, guaranteeing unwavering performance and ideal filtration conditions. Notably, this control mechanism employs data from the Permeate Pressure Sensor, positioned within the permeate line, to enhance TMP calculations and ensure precise pressure control. This dual role further exemplifies the synergy of our Pressure Sensor System, which empowers operators with exceptional control and insight throughout the TFF process.

WEIGHT MEASUREMENT:
Accurate weight measurement is integral to our TFF unit, providing precise monitoring throughout filtration. The system incorporates advanced weight measurement capabilities to enable real-time monitoring of key components. It includes a dedicated permeate scale for accurately measuring the permeate weight. Additionally, a dedicated recirculation vessel scale ensures accurate control and monitoring of the fluid level within the vessel. These weight measurement features provide valuable insights into the filtration process, allowing operators to optimize and monitor the process effectively.

RECIRCULATION VESSEL:
Including a recirculation vessel in our system offers several advantages for efficient and controlled filtration processes. The recirculation vessel is a dedicated TFF system chamber designed to collect and recirculate the retentate fluid. A recirculation vessel enables continuous flow and maintains a consistent retentate volume during filtration. This ensures optimal conditions for filtration, allowing for thorough and efficient purification while minimizing the risk of fouling or clogging. Additionally, the recirculation vessel provides the flexibility to adjust and fine-tune the process parameters, such as flow rates and transmembrane pressure (TMP), leading to enhanced control over the filtration process and improved overall performance. With the recirculation vessel as a key component of our system, users can achieve reliable and reproducible results, streamline their filtration operations, and optimize the efficiency of their bioprocessing workflows.

FLOWPATH & CONSUMABLES:
Our TFF unit supports efficient, sterile filtration with a complete set of consumables tailored to your bioprocess needs. From the tubing and sample bag to various specialized buffer and permeate bags, our consumables simplify setup and ensure reliable, consistent filtration performance.

Flowpath Assembly:
The flowpath assembly—comprising the sample manifold and sample bag—is pre-assembled and sterilized to ensure easy integration with the TFF unit. Designed for optimal fluid transfer and compatibility, it supports a range of filtration applications, including protein purification and viral concentration, enabling seamless and efficient operation.

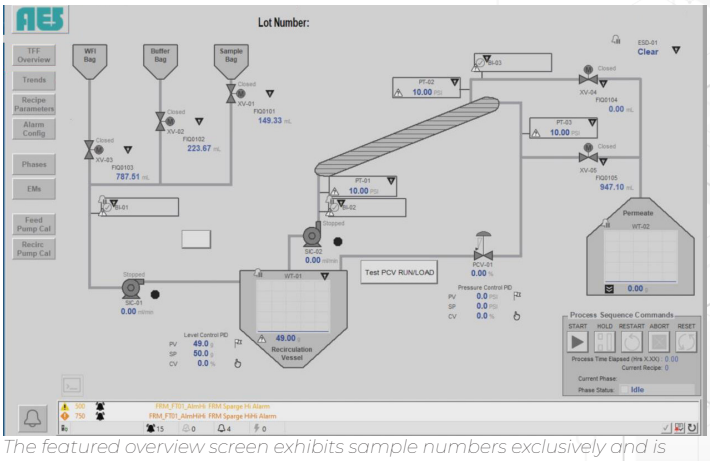
Bags:
We offer a variety of sterilized, ready-to-use bags to support your filtration process:

- WFI Bags: For reliable water-for-injection handling and storage.
- Buffer Bags: Designed for buffer exchange to maintain consistency in your filtration process.
- Permeate Bags: Ensure secure and efficient collection of permeate during filtration.

Together, these components streamline your workflow, providing a comprehensive, easy-to-use solution for your filtration needs.

AUTOMATION & CONTROL SYSTEMS:
The Precision TFF Benchtop Unit's automation and control software offers flexible integration into your setup, supporting PC laptop control and Ethernet communication standards. The standard offering for the controller is Rockwell™, providing real-time data acquisition and enabling accurate process control. Convenient trend analysis further enhances the capabilities of this controller. With streamlined tech transfer, scale-up, and recipe sharing, the Basic Bioprocess Controller simplifies research and facilitates seamless automation across different stages of the product development process.

DATA & COMMUNICATION:
The Precision TFF Benchtop Unit is an innovative piece of lab equipment that provides precise data and control functions. The user-friendly interface displays real-time and historical data and can meet the specific needs of each experiment. Additionally, the platform includes advanced features such as remote monitoring and control, data logging, and alarm notifications, allowing for efficient and reliable operation.



The featured overview screen exhibits sample numbers exclusively and is subject to variation based upon the client's operational process workflow.

TECHNICAL SPECIFICATIONS

Enclosure Specifications	
Enclosure Footprint (H x W x D)	35.9 in x 31.1 in x 18.1 in
Power Requirements	120 - 230 VAC, 50/60 Hz, 1200 Watts
E-Stop	Yes
Equipment & Instrumentation Specificiations	
Attributes	
Membrane Area	155 cm^2
Max Pressure	20 psig
Filter Type	Disposable Hollow Fiber Filter
Recirculation Control Valve	
Pressure Control	0 - 100% control for 75 - 0 psi
Liquid Control	
Onboard Pumps	(2) pumps with Bi-Directional Stepper Motors
Pump Head Type	Peristaltic, Flip-Top Pump Heads
Pump Speed Range	0.2 - 200 RPM
Pump Capacity / Flow Capacity	340mL/min
Max Tubing Size	L/S #25
Max Tubing Inside Diameter	4.8 mm (~3/16 in)

Process Analytics	
Inline Pressure Sensors	(3) Single-Use Pressure Sensors
Pressure Range	0 – 30 psi ± 0.15 psi
Overpressure Protection	Yes
Inline Bubble Detectors	(3) Clamp-on Bubble Detectors
Weight Measurement	
Permeate Scale	15 kg ± 0.01 Readability, Ethernet/IP
Recirculation Vessel Scale	3 kg ± 0.01 Readability, Ethernet/IP
Automation & Control Software	
Standard Offering	AES Library Rockwell™