FlexiPro™ TFF

VERDOT

- **Multi-purpose processing:**

  Ultrafiltration (concentration, diafiltration) and microfiltration

- **GMP system scalable from small-pilot to commercial scale**
- **One instrument, four Flow Kits covering 1.0 – 3,500 L/h range**
- **Flow Kit installation in <15 minutes**
- **High precision pressure regulation**
- **Low shear**
- **>95% product recovery**
- **User-friendly software**
- **21 CFR Part 11 and USP VI Compliant**
- **Complete documentation for regulatory submission**

A scalable single-use tangential flow filtration system for process development, clinical trials, and GMP manufacturing

The FlexiPro™ TFF single-use system can easily be configured to perform a wide range of filtration processes for ultrafiltration (i.e., concentration, diafiltration, enrichment) and microfiltration (clarification). It is compatible with all filter (e.g., membranes, cassettes or hollow fibers) formats from most manufacturers (Figure 1).

The FlexiPro TFF works in combination with adaptation sets and four single-use Flow Kit sizes, providing the largest flow rate range (1.0 – 3,500 L/h) on the market within a single system. Each Flow Kit is pre-assembled, including the pump heads, sensors and valves, for quick and easy installation in less than 15 minutes.

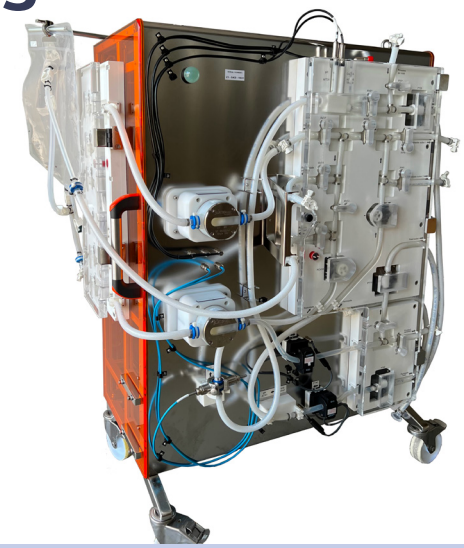

Figure 1. FlexiPro™ TFF offers single-use flexibility with four Flow Kit options

	Flow Kit Recommended Ranges		
	Sample Volume (L)	**Membrane S.A. (m^2)**	**Flow Range (LPH)**
VLFK	0.20-10	0.002-0.06	1.0-30
LFK	1-53	0.007-1.0	5.0-170
HFK	5-190	0.05-5.1	25-1150
VHFK	10-1600	0.16-34.0	100-3500*

* Higher flow can be achieved if TMP >0.7 bar

Flow Kits

Flow Kits are double-bagged and sealed in an ISO 7 clean room, with instructions and full traceability file. The Flow Kits are available in both non-gamma irradiated and gamma irradiated (>25 kGy) versions.

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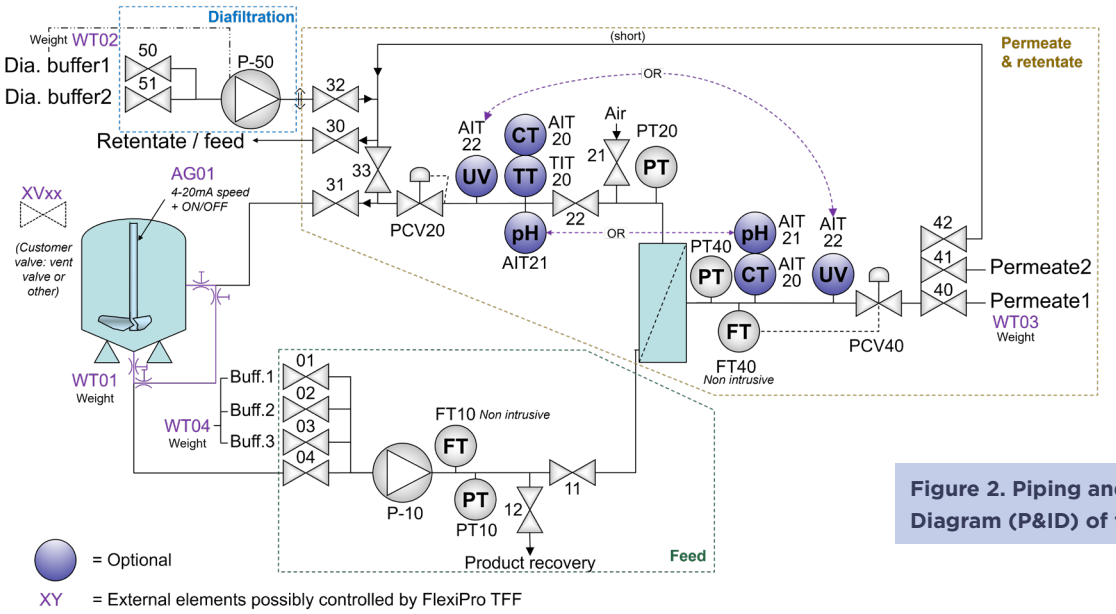

Figure 2. Piping and Instrumentation Diagram (P&ID) of the system

Compact footprint

The FlexiPro TFF is a compact system that integrates all hardware components commonly used in filtration processes. A laptop PC with SCADA software, providing the interface to communicate with the PLC. Configuration for DCS integration can be proposed upon request.

The stainless-steel cabinet is IP65 rated provides protection from liquid ingress. On the outside of the system, fluid paths and sensors are secured in the routing channels by a transparent door and flow-path pinch valves. Lockable caster wheels help prevent the system from moving during use.

Gain precision with Verdot's patented pressure control valves

Precise regulation of the pressure control valves is critical to ensure constant transmembrane pressure (TMP). VERDOT® has developed and patented a unique technology using a high-precision pressure actuator which provides maximum precision over a wide pressure range, up to the maximum system pressure (4 bar). The pressure control value is compatible with, and provides identical pressure stability with all four available Flow Kits. The same level of precision is found on the permeate side to regulate flux.

Configurable to your process

Depending on the scale, complexity and type of separation, the need for instrumentation may vary for each application: vessel weighing or flowmeter, in-line control of conductivity, pH or UV, etc. The FlexiPro TFF system is designed with a base set of instrumentation (2 flowmeters, 3 pressures) and optional ones (UV, conductivity, pH), and can be interfaced with the 0-10V/4-20 mA output of 4 electronic scales for circulation, buffer, permeate, and diafiltration vessels (Figure 2). The permeate and retentate Flow Kits are custom built with several options to meet the application need:

- Option I: UV probe on the retentate or permeate section
- Option II: Conductivity, temperature and pH on the retentate section
- Option III: Conductivity, temperature and pH on the permeate section

An adaptation set matching the required Flow Kit may need to be installed, if transitioning to other flow ranges. It can easily be changed within 15 minutes and comprises of the pump head supports, the pressure control valve rollers and supports, and the clamp-on flowmeters (Figure 3).

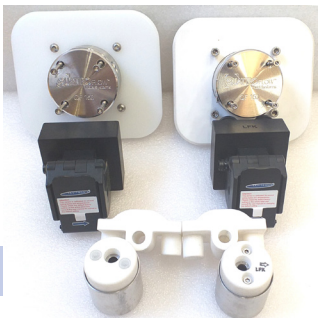

Figure 3. Adaptation set for the Low Flow Kit (LFK)

Confidence in process pressure / flow parameters no matter the application

Through the use of our patented pressure control valve, high-precision pressure and flow regulation can be achieved as demonstrated in Figure 4. The data shows that the target flow rate is smoothly reached in less than 2 minutes as the target pressure or TMP set point is obtained in less than 30 seconds with less than 2% error.

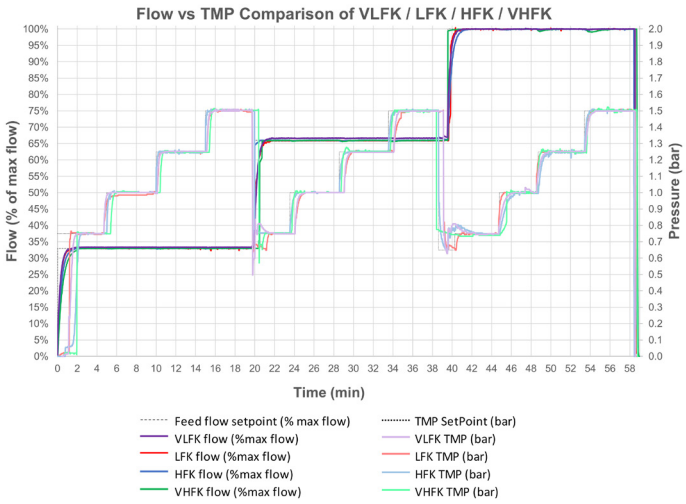

Figure 4. TMP vs. flow comparison across Flow Kit options

Air inlet for integrity tests and >95% product recovery

The FlexiPro TFF system hardware includes a low pressure air inlet on the retentate that can be used for integrity testing using the pressure decay method, before and after the filtration. It can also be used for product recovery, by pushing air through the recirculation loop.

Maintain low shear stress for critical processes

The FlexiPro TFF system hardware, including the pressure regulating valves, pumps and fluid path were specifically selected to ensure low-shear stress conditions required to maintain adenovirus, lentiviral and mRNA product integrity. An internal study with liposomes demonstrated that low shear stress can be maintained even under maximum flow and TMP (Figures 5 and 6).

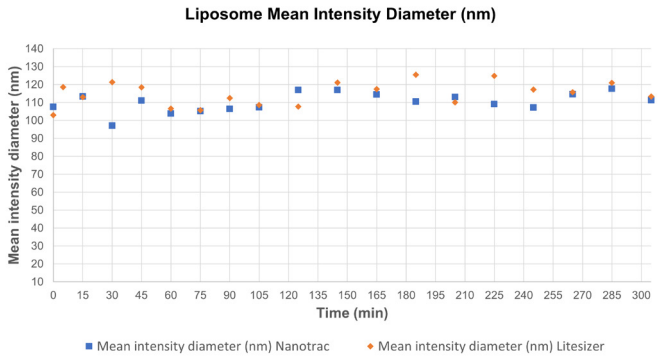

Figure 5. FlexiPro TFF system demonstrates particle size integrity over 5 hour period of circulation at 1.4 bar TMP

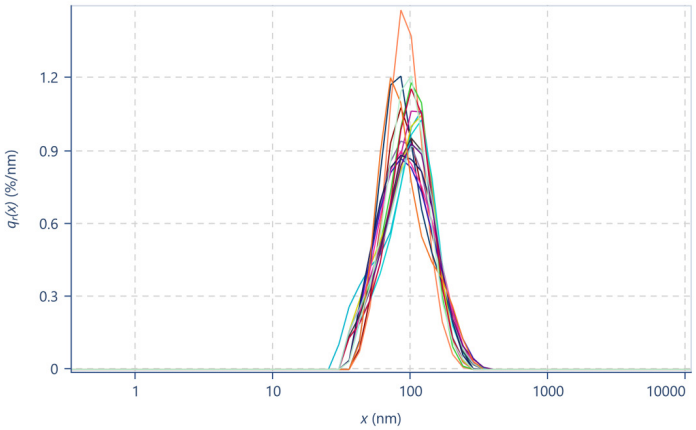

Figure 6. Stable liposome size distribution over 5 hour of circulation at 1.4 bar TMP

User-friendly software

The system control software uses a simple, user-friendly interface for data input and programming commands. The software is password protected (with customizable access levels), and all events and actions are recorded in accordance with 21 CFR Part 11 compliance guidelines.

The software allows for manual or automated mode of operation. The automated mode includes:

- Multiple step programming;
- Configurable fluid path for each step;
- Wide choice of end step conditions: weight, volume, conductivity, UV, pH, permeate flow, diafiltration volume number;
- Regulation of the pressure control valve based on % opening, feed pressure, retentate pressure or transmembrane pressure;
- Regulation of the circulation pump based on fixed speed, flow, cross flow or ΔP;
- Regulation of the flux with permeate regulating valve;
- Control of external agitation with a %speed set point and on/off command;
- Sensor alarm options;
- U.S. FDA 21 CFR Part 11 compliance;
- Configurable fluid paths.

Full trend review, printing and data export are standard options within the software. Configuration for DCS integration can be proposed upon request.

Specifications

Flow Kit	VLFK	LFK	HFK	VHFK
Tubing ID	1/8" 3.2 mm	1/4" 6.4 mm	1/2" 12.7 mm	3/4" & 7/8" 19.1 mm & 22.1 mm
Recirculation Pump (Quattroflow®)**	QF30SU	QF150SU	QF1200SU	QF2500SU*
Void Volume†	49 mL	190 mL	767 mL	2240 mL
Maximum Pressure	4 bar			
Temperature Range	2-40°C			
pH Range	3-10 pH. Hamilton OneFerm VP120 Error ± 1.2% FS			
UV (optional)	Kemtrak single use, 0-4.5 AU Two wavelengths, Error ± 0.2% FS			
Conductivity and Temperature (optional)	0-500mS/cm 0-100°C, Error ± 4% MV			
Flowmeters (non-product contact)	Levitronix® ultrasonic Error ± 5% MV			
Pressure Probes (non-product contact)	Endress + Hauser Error ± 0.3% FS			
Tubing Material	Silicone or silicone-braided USP Class VI			
Dimensions (HxWxD) without Flow Kit	1770 x 1370 x 805 mm			
Power	208-240 VAC, 50/60 Hz 1 or 3 phase available			
Control	PLC: OMRON with OPC UA SCADA: iFix 2023			
PC	Microsoft Windows© laptop			

* Flow >2500 LPH with QF2500SU can be obtained by running two pumps in parallel. Flow >3500 LPH can be obtained if TMP is > 0.7 bar.

** Levitronix® LeviFlow® pumps can be substituted for Quattroflow®

† >95% of the void volume can be recovered through air inlet flush.