VERSAflux

VERSAflux is an easy-to-use, manual benchtop cross flow filtration system that is well suited for process development as well as small-scale biopharmaceutical production (Fig 1).

As a high-quality, durable system, VERSAflux is optimized for GE Healthcare Life Sciences hollow fiber cartridges. This makes it suitable for microfiltration applications, such as cell harvesting and clarification as well as for protein concentration and purification. The advanced system can also be configured to support ultrafiltration cassettes through an optional manual cassette holder for ultrafiltration and diafiltration applications.

- Effective performance
- Convenient usage
- Robust design for reliable operations
- Increased return of investment (ROI)

Effective performance

Designed to meet the demanding requirements of real-world process development, VERSAflux filtration system consists of a four-piston diaphragm pump, which provides a continuous and uniform fluid flow.

The system also incorporates an optimized flow path resulting in low void volume. VERSAflux utilizes silicone hoses and polypropylene tubing that resists pressures up to 3 bar, enabling users to perform inline integrity tests of hollow fiber cartridges.

In addition, GE Healthcare Life Sciences hollow fiber cartridges provide robust processing across a wide range of cross flow applications. This helps ensure consistent productivity over a long period of time.

Convenient usage

The VERSAflux system includes an intuitive display and touch screen interface, which provide the user with an effortless way to monitor process parameters and control pump speed. In addition, the system's compact footprint makes it portable.

Fig 1. VERSAflux system (benchtop).

Robust design for reliable operations

VERSAflux comprises high-quality components that can help ensure reliability and productivity in operations. Its robust design allows the system to be used within a wide range of operating conditions, with the added benefit of reduced facility expenditure.

VERSAflux also incorporates comprehensive safety features, such as a two-level alarm monitor – one level to give a warning message and the other to give a critical alarm to enable immediate suspension of the filtration process.

Industrially designed with an E-stop switch, indicator, and a reset (software) button for handling emergencies, the system embodies GE Healthcare Life Sciences' uncompromised commitment to quality.

Table 1. System specifications

General specifications	
Supported membranes	
Hollow fiber cartridges	3M, 3 x 2M, 4M, 4 x 2M, 5, 6, 8, 9
Cassettes	Kvick Lab SCU
Maximum operating flow rate, feed pump (lpm)	13[1]
Minimum operating flow rate, feed pump (lpm)	0.15
Maximum operating pressure (bar)	3.0
Minimum working volume (without HF cartridge) (mL)	180
Hold-up volume (installed with HF 5 cartridge) (mL)	50
Ambient temperature range (°C)	2 to 25
Process temperature range (°C)	2 to 60
Footprint W × D × H (mm)	697 × 440 × 1013
Weight (kg)	40
Materials of construction	
Piping	Polypropylene
Gaskets	EPDM
Frame, cabinet and supports	304 SS
Other specifications	
Protection class IP	
Cabinet	IP 54
Field mounted instruments	IP 54
Power supply system	L-N-PE, 115/230 VAC, 50 to 60 Hz

[1]Maximum operating flow rate valid for water at 25°C with 3 bar g back pressure

Increased ROI

The focused functionality of VERSAflux, its effective performance, convenient usage, and a high degree of reliability can enable users to experience better asset utilization and productivity, which can translate into an increased ROI in comparison to traditional manual cross flow filtration systems.

System specifications

The P&ID of the system is shown in Figure 2 and the system specifications are listed in Table 1.

System performance

The cross flow filtration performance of VERSAflux (benchtop) system was verified by performing several microfiltration, ultrafiltration, and diafiltration experiments on both a fermentation broth of *E. coli*, expressing green fluorescent protein (GFP), as well as a GFP solution by using GE Healthcare Life Sciences hollow fiber cartridges and ultrafiltration cassettes. The results from the experiments are presented in Figure 3A-D.

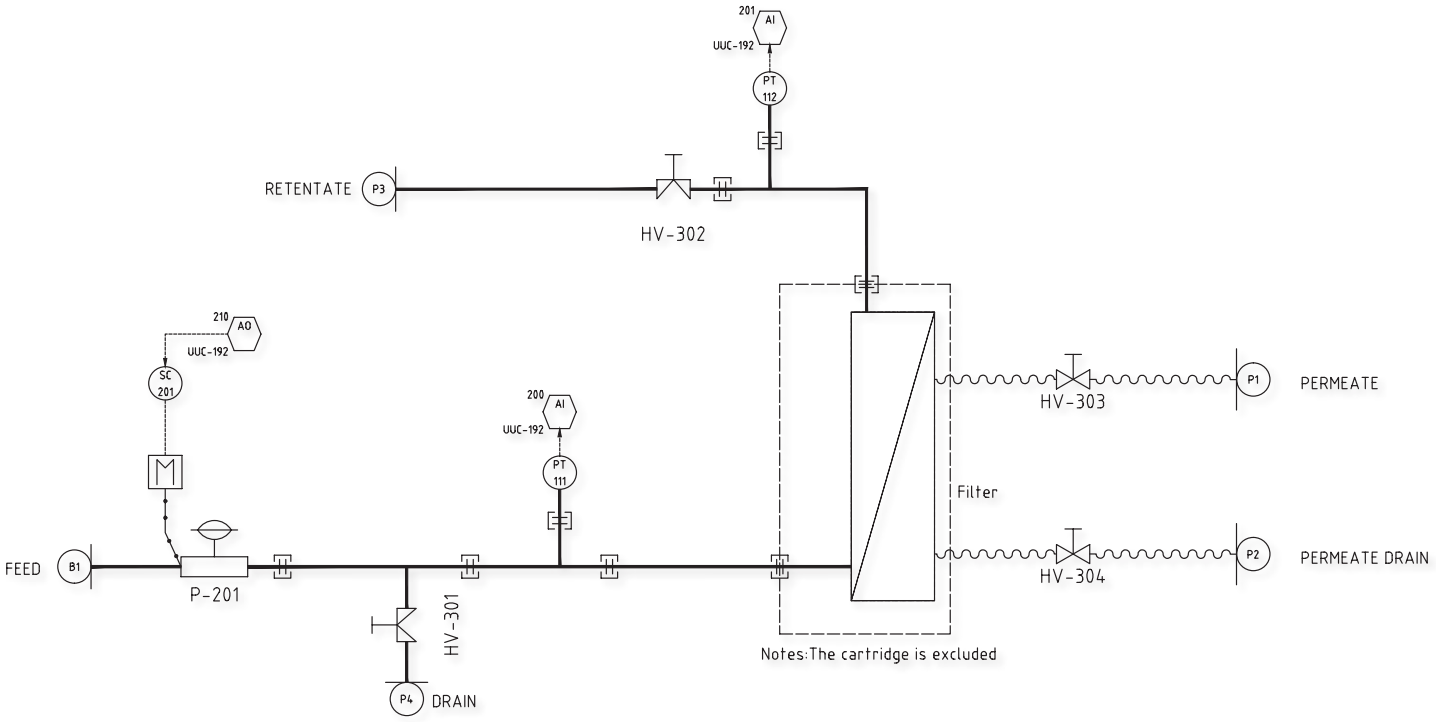
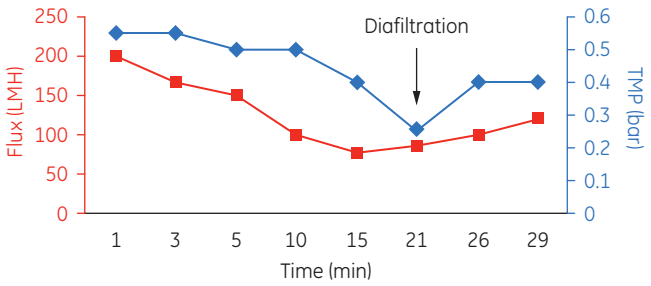
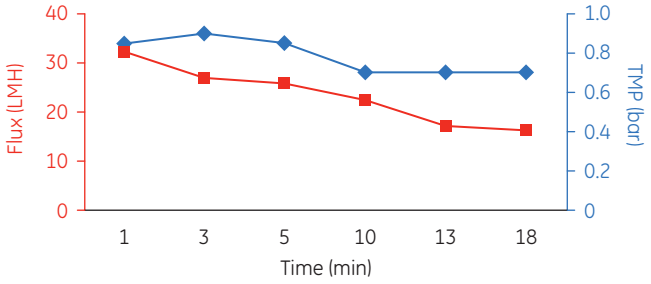


Fig 2. Piping and Instrument Diagram (P&ID) of the system.

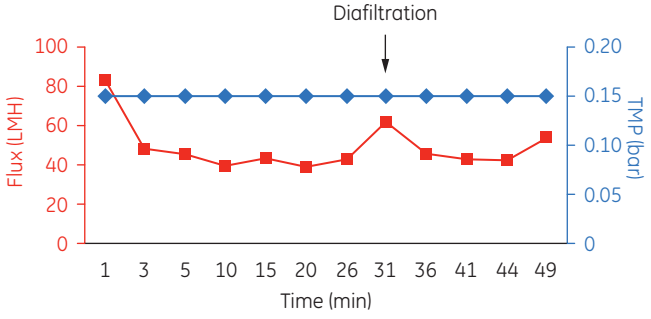
A) Experiment 1: 9.3X concentration and 3 DV diafiltration using 750kD, #5 HF Cartridge



B) Experiment 2: 9X concentration using 5kD, #4X2M HF Cartridge



C) Experiment 3: 5X concentration and 4 DV diafiltration using 0.1 µm, #4M HF Cartridge



D) Experiment 4: 4.3X concentration using 5kD, Kvick Lab SCU cassette

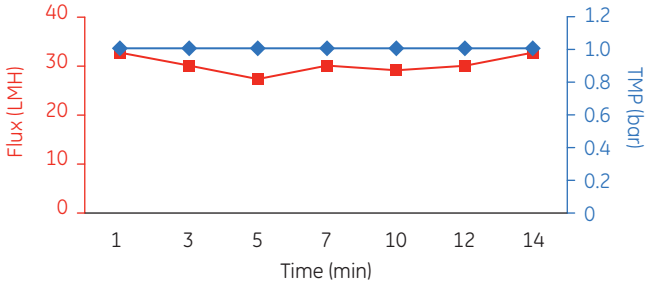


Fig 3. Cross flow performance of VERSAflux system.

Target yield and purity were achieved in all four experiments. The cross flow filtration performance (flux decay and maintenance of process trans-membrane pressure) was shown to be in accordance with expectations.

Quality and regulatory considerations

As with all GE Healthcare Life Sciences equipment, the VERSAflux (benchtop) system is designed to fulfill the highest expectations in terms of quality. The wetted materials used in the system fulfill FDA 21 CFR Part 177 guidelines. Additionally, two levels of documentation are available to help fulfill the requirements set by the regulatory authorities:

- Basic: Includes product specification, assembly drawing, general specification, bill of material (equipment list), piping and instrument diagram, spare part list, user manual, and certificate of conformity. These documents come standard with the purchase of the system.
- Advanced: Includes input/output list, layout and interconnection, electrical schematics, wiring table, cable diagram, functional test records, calibration certificates, configuration of programmable devices record, material certificates, and installation test records. These documents can be purchased at an additional cost.

Validation documentation, such as Installation and Operational Qualification (IQ/OQ) documents, as well as a service to perform actual qualification of the system on-site upon installation, can be ordered separately. These services help towards satisfying the increasingly strict demands posed by regulatory authorities who expect manufacturers of pharmaceuticals to qualify equipment before using in production.

Typical applications where the system can be used

- Monoclonal antibody clarification and concentration
- Mammalian cell harvesting, cell washing, and cell clarification
- Bacterial cell harvesting and cell clarification
- Yeast cell harvesting and cell clarification
- Hybridoma cell culture clarification
- Protein concentration and diafiltration
- Vaccine concentration and diafiltration
- Plasmid concentration and diafiltration
- Virus clarification, concentration, and purification
- Purification of blood substitutes
- Lysate clarification

Summary

VERSAflux is an easy-to-use, modular benchtop cross flow filtration system that is well suited for process development as well as small-scale biopharmaceutical production. The system offers many advantages over traditionally available manual cross flow filtration systems, such as effective performance, convenient usage, and reliability in operations all of which can translate into an increased return on income (ROI) for the user.

Ordering information

To order VERSAflux, please contact your regional sales representative.

For local office contact information, visit
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29-0432-61 AA 02/2013