

FlexiPro™ Chromatography

- GMP system scalable from small-pilot to commercial scale
- One instrument; Four FlowKits covering 0.6 – 560 LPH range
- FlowKit installation in >15 minutes
- High precision gradient and dilution
- User-friendly software
- 21 CFR Part11 and USP VI Compliant
- Complete documentation for regulatory submission

Scalable single-use chromatography system for process development, clinical trials and GMP manufacturing

The FlexiPro™ Chromatography single-use system can easily be configured to perform a wide range of chromatography processes. The system supports multiple applications without the risk of contamination (Figure 1).

The system works in combination with adaptor sets and four disposable FlowKit sizes, providing a flow rate range from 0.6 – 560 LPH within a single system. Each FlowKit is pre-assembled, including the pump heads, sensors and valves, for quick and easy installation in less than 15 minutes.



Figure 1. FlexiPro™ Chromatography offers single-use flexibility with four FlowKit options

FlowKit Recommended Ranges			
	Column Diameter (cm)	Monolith Volume (mL)	Flow Range (LPH)
ULFK	2.5-10	8-80	0.6-6.6
VLFK	5-25	8-800	1.0-30
LFK	10-45	80-4000	5.0-150
HFK	20-100	400-8000	20-560

FlowKits

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

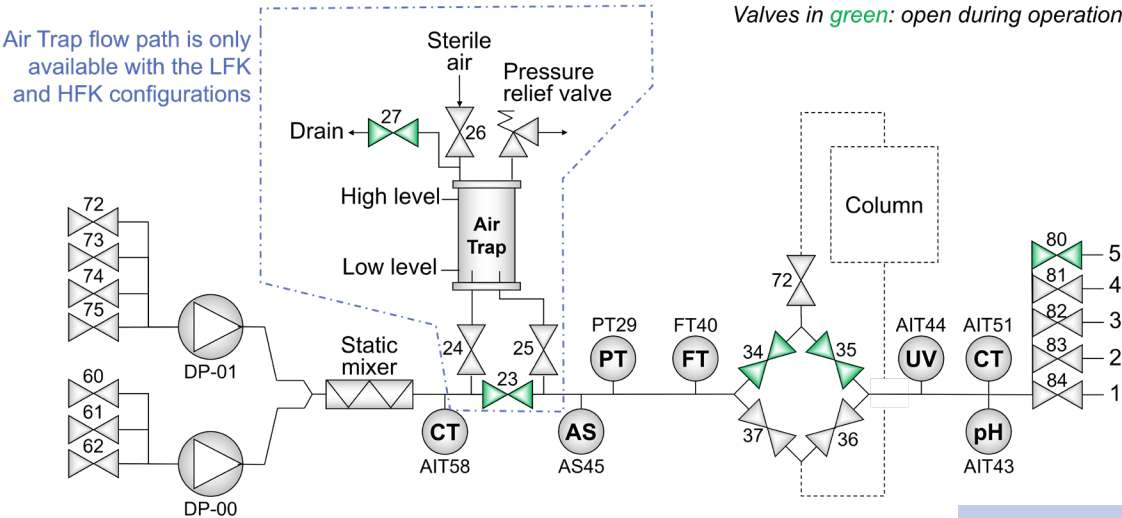


Figure 2. Piping and Instrumentation Diagram (P&ID) of the installation

Compact footprint

The FlexiPro™ Chromatography system is a compact self-contained system that integrates all necessary hardware components. A laptop PC with SCADA software provides 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 routing channels by a transparent door and flow-path channel locks. If the benchtop system needs to be easily moved, Verdot offers a specifically designed cart to securely hold the FlexiPro Chrom system and drawers to hold extra FlowKits and adaptation sets.

High precision gradient and inline dilution

Inline dilution or gradient of aqueous buffers can be performed with the FlexiPro™ Chromatography system. Only the most precise and robust sensors are used in order to monitor the process and control the flow rate and dilution.

- Linear or step gradient up to 500 mS/cm at constant flow (see Figure 3)
- Narrow linear gradients (e.g., 6-20 mS) are easily achievable with precise conductivity control
- High precision inline dilution using a four-electrode conductivity probe

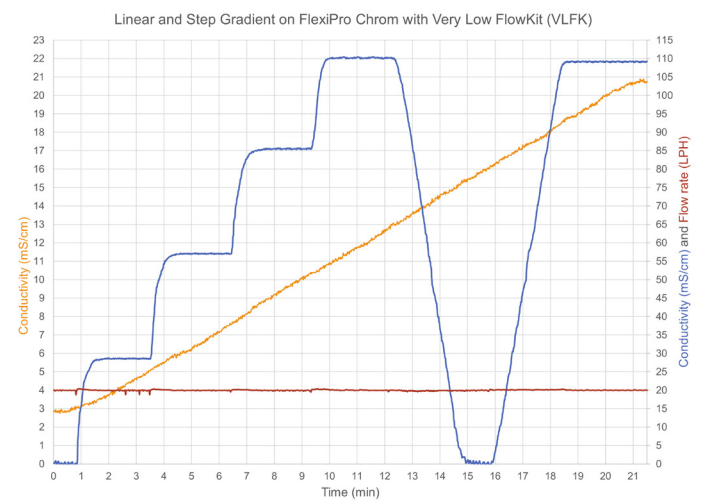
Figure 3. Linear and step gradient example illustrates system precision

Configurable to your process

The system offers process flexibility with a flow rate range from 0.6 – 560 LPH within a single instrument (Figure 2). Additionally, the system can be configured to accommodate specific process needs, including:

- Flow monitoring based on pressure and flow set points with lower of the two numbers being the constraint
- Linear gradient based on pH
- Additional inlets and outlets; FlowKit extension required
- High precision UV monitoring (down to 3 mAU) for low titer applications

An adaptation set matching the required FlowKit may need to be installed, if transitioning flow ranges. It can easily be changed within 15 minutes and comprises of the pump head supports, the air trap support, and spacers for holding the Very Low and Ultra Low FlowKits.



User-friendly software

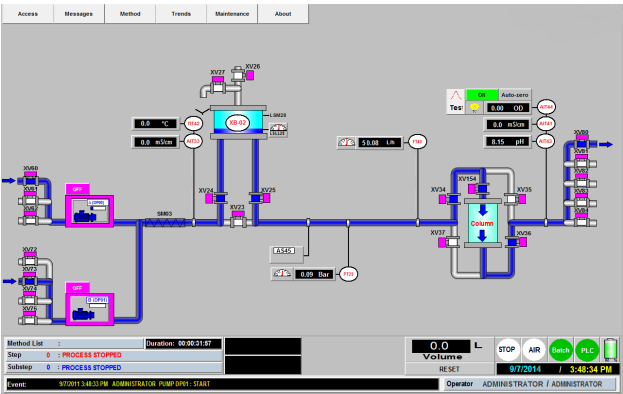


Figure 4. System Controller software

The system controller uses a simple, user-friendly interface for data input and programming commands (Figure 4). The process skid is password protected (with customizable access levels), and all events and actions are recorded in accordance with cGMP compliance guidelines.

The FlexiPro Chromatography system can be operated in manual or automated mode through the software. The automated mode includes:

- Multiple step programming;
- Configurable fluid path for each step;
- Valve control;
- Wide choice of end step conditions;
- Sensor alarm options;
- U.S. FDA 21 CFR Part 11 compliance.

Full trend review, printing and data export are standard options within the software.

Pre-programmed procedure for testing and calculating Asymmetry and HETP values is included.

Key data can be monitored remotely through OPC UA.

Configuration for DCS integration can be proposed upon request.

Specifications

FlowKit	ULFK	VLFK	LFK	HFK
Tubing ID	1/16"	1/8"	1/4"	3/8"
	1.6 mm	3.2 mm	6.4 mm	9.5 mm
Operating Pressure	4 bar at column inlet			
Flowmeter Accuracy	± 2% of the full range			
Dilution Accuracy	± 4% of the measured value			
Viscosity	1-3 cP			
Temperature Range	2-30°C (up to 60°C during CIP)			
Pump Technology	ULFK/VLFK: peristaltic LFK/HFK: membrane pump			
Flowmeter	Levitronix® LEVIFLOW® LFS-SU			
UV	Pendotech single use, A280 nm, 0-2 AU Dual wavelength available, 0-3 AU			
Conductivity	1 uS/cm - 500 mS/cm			
pH Range	3-10 pH. Hamilton OneFerm VP120			
Bubble Trap	Included on LFK and HFK configurations: Two level capacitive sensors Drain and air injection value (≤ 0.4 bar)			
Valves	Pneumatic pinch valves (6 bar)			
Air Sensor	Non-invasive			
Tubing Material	Silicone or silicone-braided USP Class VI			
Material of Wetted Parts	Plastic parts: PP, PSU, PVDF, Silicone Elastomers: EPDM Blubble trap: glass or PMMA			
	Note: all wetted parts are BSE/TSE free and USP Class VI compliant			
Dimensions (HxWxD) without FlowKit	1100 x 1280 x 670 mm			
Weight	250 Kg			
Power	220V AC 50/60Hz, 1 phase 115V AC 50/60Hz, 1 phase			
Air Supply	6 bar			
Control	PLC: OMRON with OPC UA SCADA: iFix 5.8			
PC	Microsoft Windows® laptop (industrial touch panel upon request)			