Chromatography

HyPeak Chromatography System

Continuing the tradition of innovation in single-use bioprocessing equipment

The Thermo Scientific™ HyPeak™ Chromatography System is designed to meet the needs of process scale-up and cGMP manufacturing. The HyPeak Chromatography System utilizes modular single-use fluid transfer assemblies, industry-standard sensor technology, innovative valve technology, and robust automation designed with customer needs in mind and provides the flexibility to scale up their processes in the future.

The HyPeak Chromatography System provides a complete single-use solution for chromatographic purification—a principal unit operation in viral vector production and downstream bioprocessing of recombinant proteins such as monoclonal antibodies. Pre-engineered system options and modular flow kit designs allow selection of suitable tools and technology for each application. The HyPeak Chromatography System can be used for multiple chromatography steps, and with the automation package, the platform can provide consistently high-performing purification.

Key features

- Wide operational flow ranging from 1 L/hr to 1,980 L/hr enabled by up to three pump combinations and four fluid transfer assembly sizes
- Meets the demands of modern downstream bioprocessing with isocratic and gradient elution support as well as in-line dilution (ILD) processing capability
- Zero dead leg/ring flush valve design eliminates residual fluid in the fluid transfer assemblies
- Valve design provides advantages for scaling flow path processes—the same block or locking mechanism can accommodate different fluid transfer assembly sizes
- Works with any alternately sourced column (pre-packed or self-packed) within the design specification of the system
- Ergonomic, space-saving design provides ease of access for system operation and maintenance, including fluid assembly transfer installation, and a user interface for monitoring and control
- Built on the industry-leading Emerson™ DeltaV™ Distributed Control Platform, and packaged with Thermo Scientific™ TruChrom™ automation software
- Simplified recipe structure of TruChrom software provides an enhanced user experience

Advantages of the HyPeak Chromatography System

- The unique prism hardware design of the HyPeak Chromatography System allows easy access to connections for supporting equipment
- Casters and ergonomic handles provide easier system maneuverability
- Swing-out arm with dual touchscreen displays can be positioned to the needs of the user
- Ability to be leveled and fixed to the floor

HyPeak Chromatography System components

- Specialized manifold design to allow easy and precise fluid transfer assembly insertion and a no-pinch valve design for the process fluid path
- Wide operational flow range controlled by two or three QuattroFlow™ pumps
- Zero dead-leg flush valves—previous phase liquids are instantly flushed at the start of next phase
- TruChrom 3.0 automation software powered on the DeltaV Distributed Control Platform

Design elements of the HyPeak Chromatography System*

1. Fluid transfer assemblies and single-use valve manifold (7)
2. Bubble trap
3. Alarm light
4. Adjustable monitor arm
5. Dual monitors
6. Pre-column sensor pack
7. Flow meter
8. UV sensor control pad
9. Post-column sensor pack with UV sensor
10. Large handle
11. Positive displacement pumps (up to 3)
12. 304 stainless steel
13. Tubing management arm
14. Casters (4)
15. Leveling feet (4)

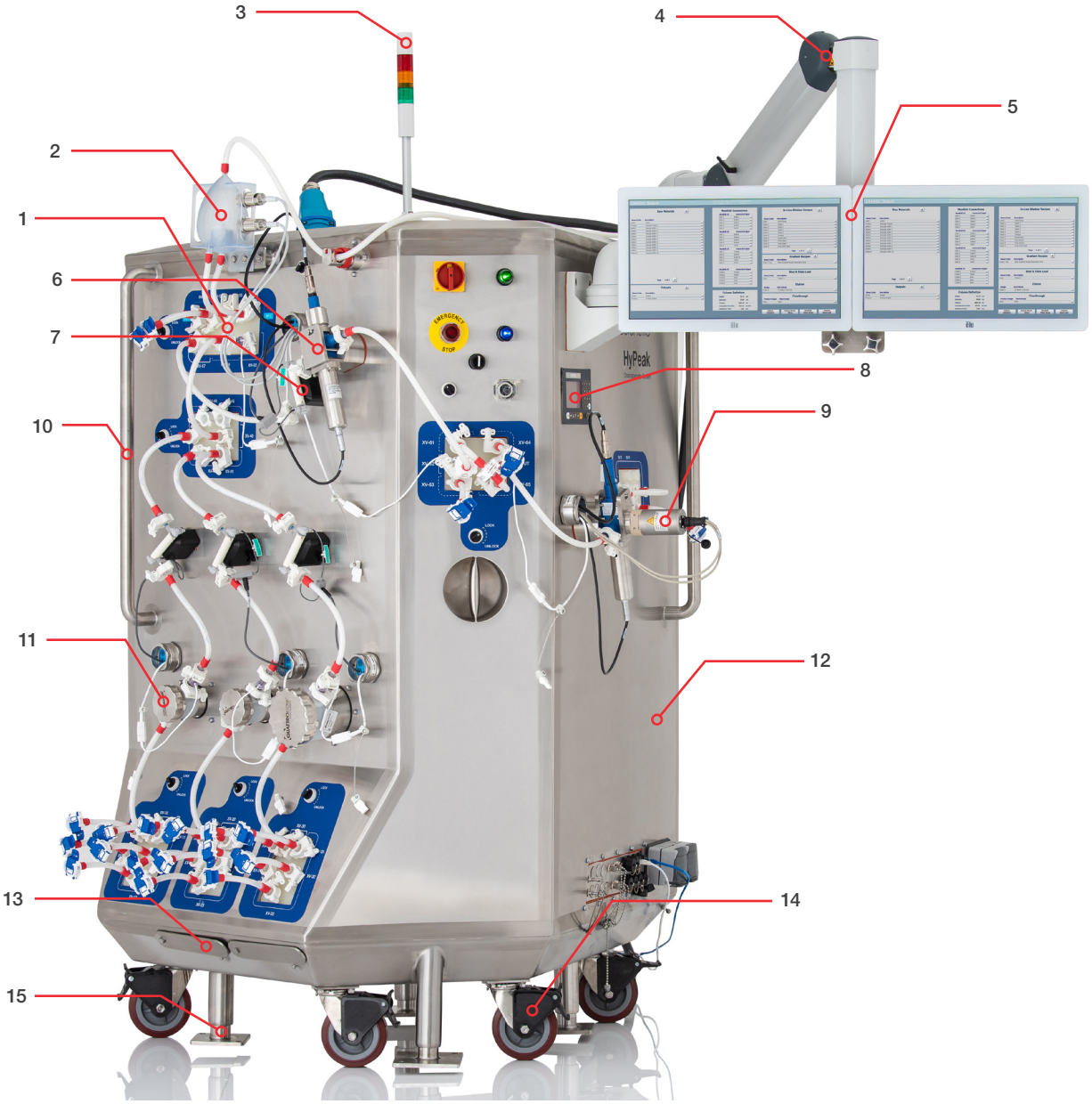

Figure 1. Design elements of the HyPeak Chromatography System.

*** This unit is only a prototype. Design is subject to change.**

HyPeak Chromatography System specifications

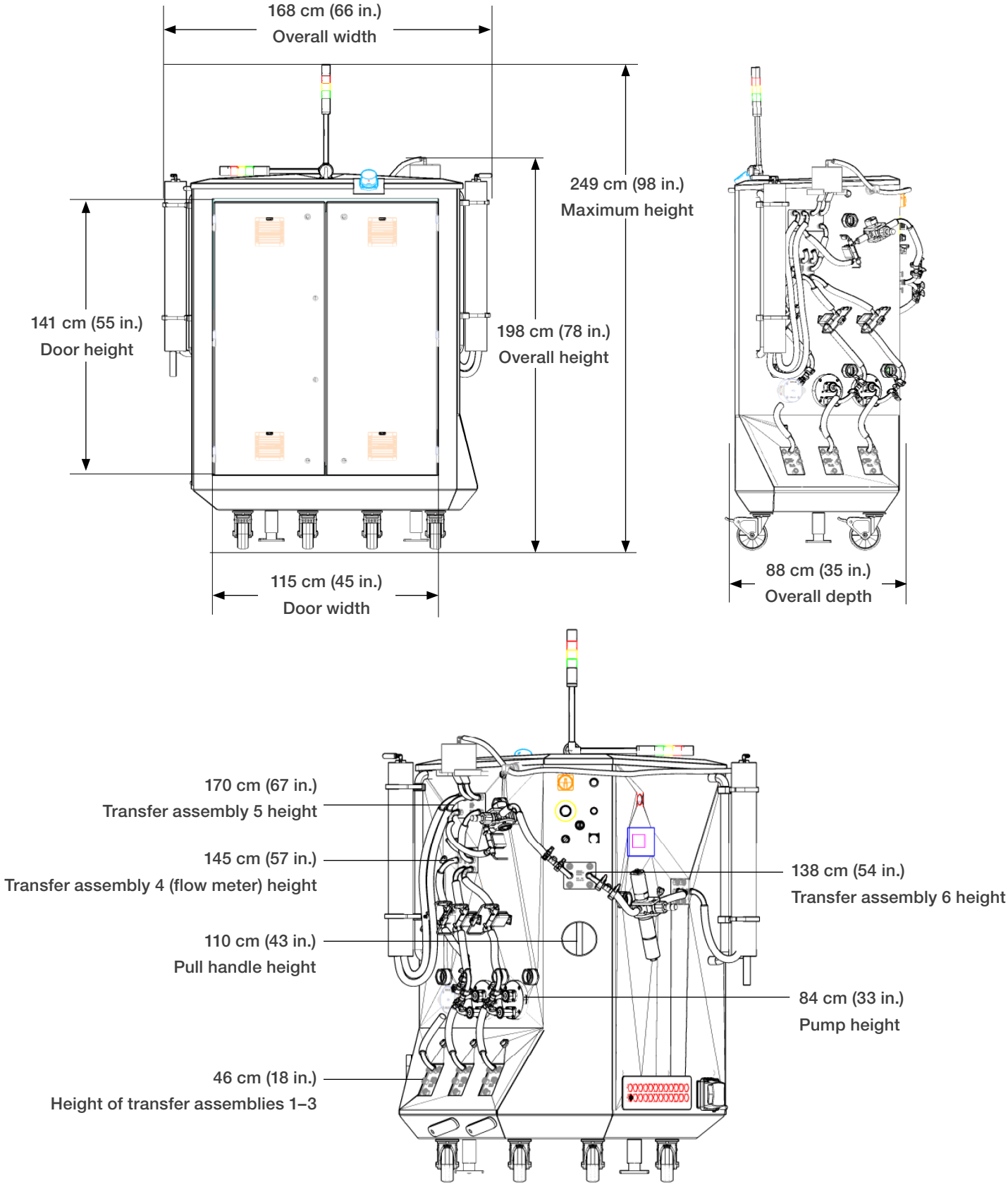

Figure 2. HyPeak Chromatography System specifications.

Table 1. HyPeak Chromatography System specifications.

Category	Specifications
Skid	
System dimensions (overall W x H x D)	168 x 249 x 88 cm (66 x 98 x 35 in.)
System weight	544.3 kg (1,200 lb.)
Materials of construction	**Skid frame and cabinet:** 304 SST **Valve alcoves:** 316 SST or anodized aluminum **HMI arm:** Extruded aluminum **HMI monitors:** Medical grade IP 54 touchscreens
System requirements and capacity	
Volumetric flow (dependent on fluid transfer assembly size and pump type)*	1–1,980 L/hr
Transfer assembly inner diameter (ID)	1/4 in. or 3/4 in.
Recommended column sizes**	ID of 10–80 cm
Supply voltage power 3–4 kVA depending on model	3 phase 208 V or 380–480 V
Instrument air	60–101 psi
Storage temperature	–25°C to 85°C (–13°F to 158°F)
Operating conditions	
Room operating temperature	2°C to 40°C (41°F to 104°F)
Relative humidity	5% to 95% (noncondensing)
Maximum operating pressure	4 bar
Sensors	
Conductivity sensor	0 µs/cm to 150 ms/cm
pH sensor	3–10 pH
UV detector	0–3 AU at 280 and 300 nm, or 254 and 280 nm depending on model
Temperature sensor	0–50°C (from conductivity sensor)
Flow meter	0–8, 0–20, or 0–50 L/min depending on model
Pressure sensor	0–4 bar
Wetted materials	
Transfer assembly tubing	Silicone
Tube fittings	Polypropylene
Elbows	PVDF
Valve blocks	Polypropylene, TPE, EPDM
Pressure sensor	Polysulfone
Flow meter	Polypropylene
Bubble trap	Bioclear
Conductivity/UV sensor	Stainless steel 1.4435, quartz, EPDM, polyphenylsulfone
pH sensor	Glass/VMQ (silicone elastomer)

* Estimated with no back pressure applied.

** Actual column sizes used may vary depending on processing considerations and requirements (e.g., processing flow rate, column volume, and differential pressure across column).

System options

The HyPeak Chromatography System is available with the following major components:

- **Fluid transfer assembly (Figure 3)**—flexibility with choice of 1/4 in. or 3/4 in. ID
- **Single-use valve manifold (Figure 4)**—part of the single-use fluid transfer assembly; placed into the actuator alcoves and locked in place with a pneumatically operated lever controlled by a local switch
- **Pumps (Figure 5)**—up to three pumps are available to support various flow ranges; configurable for the application at hand
- **Sensors and devices**—the following in-line instruments and devices come with the chromatography system:
  - Bubble trap, flow, and motor speed equipment are located pre-column in the flow path (Figure 6)
  - UV, conductivity, temperature, flow, motor speed, bubble trap, and pH sensor are located on the column output flow path
  - Available UV options: dual wavelength (Figure 7)
- **Bubble trap (Figure 8)**—a novel, rigid, and translucent single-use bubble trap designed to remove air bubbles
- **Filter**—a filter holder at the column inlet is standard; optional single-use filter assembly is available
- **Electrical and control system**—all electrical and control system hardware components are housed within the HyPeak Chromatography System

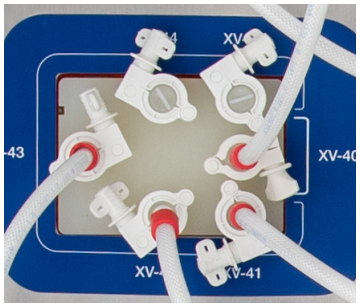

Figure 3. Fluid transfer assemblies attached to valve manifold.

Figure 4. Single-use valve manifold.

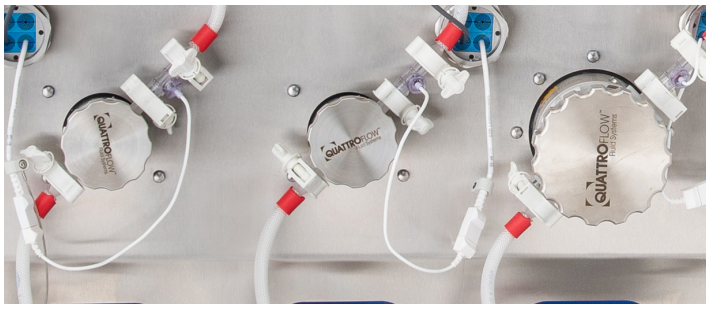

Figure 5. Three positive displacement pumps.

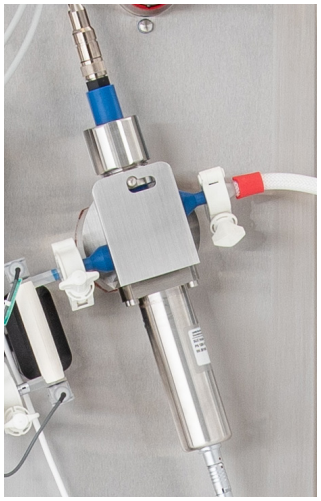

Figure 6. Pre-column sensor pack.

Figure 7. Post-column sensor pack with UV detector.

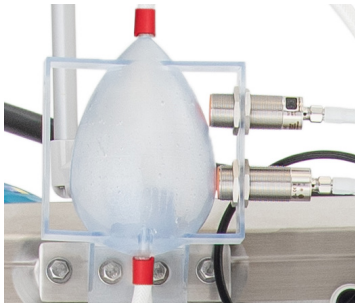

Figure 8. Bubble trap and level sensors.

System options

The flow path designs are optimized to minimize hold-up volume, and the individual fluid transfer assembly sizes are matched to the flow rates with single-use pump heads, single-use valve blocks, and single-use sensors. All wetted materials in the flow path are verified for chemical compatibility and resistance to commonly used solvents and solutions.

- The Thermo Scientific™ BioTitan™ Retention Device is an innovative tubing retention solution developed to address the concerns caused by traditional cable ties and other retention technologies across the single-use bioproduction workflow. The BioTitan Retention Device is included with all the single-use transfer assemblies offered for the HyPeak Chromatography System. The device enhances the overall reliability and integrity of the fluid transfer assemblies by minimizing the risk of leaks and failures at the connection points.
- Gamma-sterilized, single-use fluid transfer assemblies are complete with integrated sensors and robust connections to minimize the risk of contamination.
- There are five modules in each fluid transfer assembly set flow path make unpacking and installation easier. The modules are individually packaged and can be ordered individually, allowing for cost savings.

See Table 2 for chemical compatibility and exposure testing.

Table 2. Chemical exposure testing.

Solutions	Total test time	Requirements
0.3 M sodium phosphate, pH 7–7.2	96 hours	72 hours
6 M guanidine HCl	96 hours	72 hours
4 M sodium chloride	96 hours	72 hours
20% ethanol	96 hours	72 hours
8 M urea	96 hours	72 hours
2.5% acetone	96 hours	72 hours
0.1 M NaOH*	96 hours	72 hours
0.5 M NaOH*	12 hours	8 hours
1 M NaOH*	8 hours	Informational
1% polysorbate 80	96 hours	72 hours
1 M acetic acid	96 hours	72 hours

* Repeated exposure to NaOH will decrease pH sensor performance.

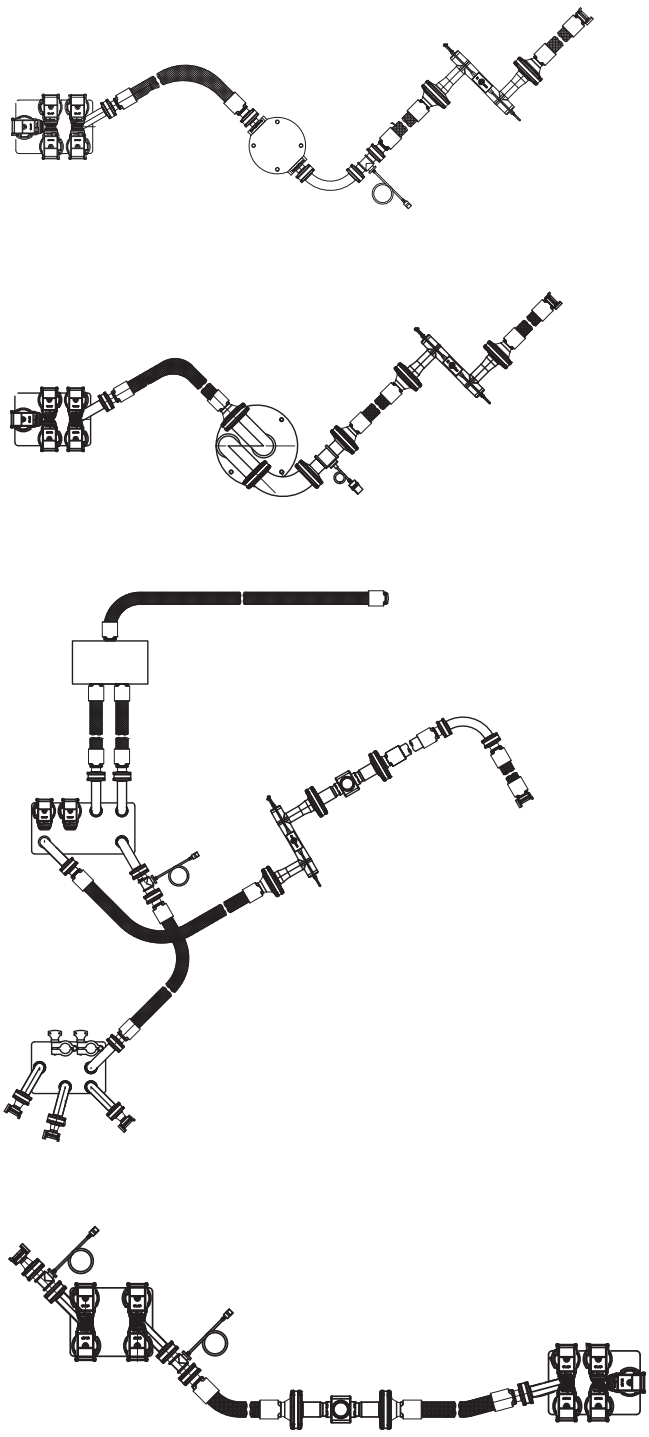

Figure 9. Fluid transfer assemblies.

TruChrom 3.0 Software

Fully configurable software solution for controlling chromatography functions

TruChrom 3.0 automation software has been developed according to GAMP5 methods and conforms to regulatory requirements for use in cGMP-compliant processes per CFR 21 Part 11. TruChrom software can be configured for either bind-elute or flow-through mode and common types of chromatography based on affinity, ion-exchange, and hydrophobic interactions.

TruChrom 3.0 Software is designed to provide the user with the ability to control the HyPeak Chromatography System (Figure 10).

Advantages of TruChrom 3.0 Software

- User-friendly interface
- Pre-configured batch recipes for quick development of customer recipes
- Ability to run as a stand-alone skid or integrated into a full DeltaV system
- Easily integrated into existing batch procedures and process trains to aid synchronization of process activities
- Super-fast DeltaV PK controller to give rapid skid response
- Interface provides the ability to display pump flow rate, total volume, set point, outputs, and process value (PV) of all connected sensors
- Option to save and load previously defined process parameters
- Ability to quickly change the software to switch between fluid transfer assembly sizes to allow easy changeover of skid to different processing requirements
- Integrated batch reporting software and configurable batch report templates
- Easy recovery from skid holds without operator having to recover the process manually
- Ability to easily switch buffer inlet locations and column outlets without having to modify any code

Figure 10. TruChrom 3.0 Software displayed on the dual monitors.

Key features of TruChrom 3.0 Software

- The following logic sequences are configured in TruChrom 3.0 Software to provide a superior, out-of-the-box user experience:
  - Priming
  - Load
  - Sanitization
  - Wash
  - Equilibrium
  - Elution
- The system includes modes for fluid transfer assembly installation and an installation test that checks sensor connection status.
- Height equivalent to a theoretical plate (HETP) and asymmetry factor (As) are typically used to evaluate the quality of column packing.
- Capable of running processes in batch mode. Batch information is retained by the batch reporting system, and reports can be generated and issued using the InfoBatch reporting module.

Ordering information

Product	Cat. No.
HyPeak Chromatography System hardware	F100-3500-000
System options	
HyPeak Chromatography System fluid transfer assembly (1/4 in.)	F100-3500-001
HyPeak Chromatography System fluid transfer assembly (3/4 in.)	F100-3500-004

Find out more at **thermofisher.com/hypeak**