

Chromatography



DynaChrom Single-Use Chromatography System

Continuing the tradition of innovation in single-use bioprocessing equipment

Advantages

- Designed for scalability with configurable pump combinations and UV wavelengths
- A wide operational flow ranging from 6 L/hr to 1,980 L/hr can greatly enhance the flexibility and versatility of a skid system, enabled by up to three pump combinations and four fluid transfer assembly sizes
- Valve manifold design leverages zero static valves with minimal dead leg; design compliant with ASME BPE 2022
- Built on the industry-leading Emerson™ DeltaV™ Distributed Control Platform, and packaged with Thermo Scientific™ TruChrom™ automation software

The Thermo Scientific™ DynaChrom™ Single-Use Chromatography System is designed to meet the needs of process scale-up and CGMP manufacturing. The DynaChrom Single-Use 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 DynaChrom Single-Use Chromatography System provides a complete single-use solution for chromatographic purification—a critical 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 DynaChrom Single-Use Chromatography System can be used for key chromatography steps, and with the automation package, the platform can support consistently high-performing purification.

Keywords

DynaChrom, TruChrom 3.0, chromatography, bioprocessing, single-use, fluid transfer assembly, purification, automation, bioprocessing

Key features

- The hardware design of the DynaChrom Single-Use Chromatography System allows easy access to connections for supporting equipment
- Supports the demands of modern downstream bioprocessing with isocratic and gradient elution support, as well as in-line dilution (ILD) processing capability
- Casters and ergonomic handles allow easier system maneuverability
- Valve design supports advantages for scaling flow path processes—the same skid can accommodate fluid transfer assembly sizes from 1/4 in. to 3/4 in.
- Works with columns (pre-packed or self-packed) within the design specification of the system
- Ergonomic, space-saving design enables ease of access for system operation and maintenance, including fluid assembly transfer installation, and a user interface for monitoring and control, and is compliant with OSHA 5(a) 1
- Swing-out arm with dual touchscreen displays can be positioned according to the needs of the user
- Simplified and highly configurable structure of TruChrom software enables an enhanced user experience and is fully ISA-88 compliant as of time of the datasheet publication
- Fluid transfer assemblies without pinch valves provide a robust solution capable of long contact time with harsh chemicals
- Ability to be leveled and fixed to the floor

DynaChrom Single-Use 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
- Liquids from the previous phase are quickly flushed at the start of next phase
- Minimized flow path volume that is compliant with ASME BPE 2022



Design elements of the DynaChrom Single-Use Chromatography System

1. Fluid transfer assembly (shown with 3 pumps, 7 valve manifolds, and sensors)
2. Bubble trap with high- and low-level sensors
3. Alarm light
4. Adjustable monitor arm
5. Dual monitors
6. Pre-column sensor pack (pH, conductivity, and temperature)
7. Flow meter
8. UV sensor control pad
9. Post-column sensor pack with UV sensor (pH, conductivity, temperature, and dual UV)
10. Dual-purpose large handle and filter mount
11. Positive displacement pumps (up to 3)
12. 304 stainless steel
13. Tubing holder
14. Casters (4)
15. Leveling feet (4)
16. Spare analog, pneumatic, and digital communication ports

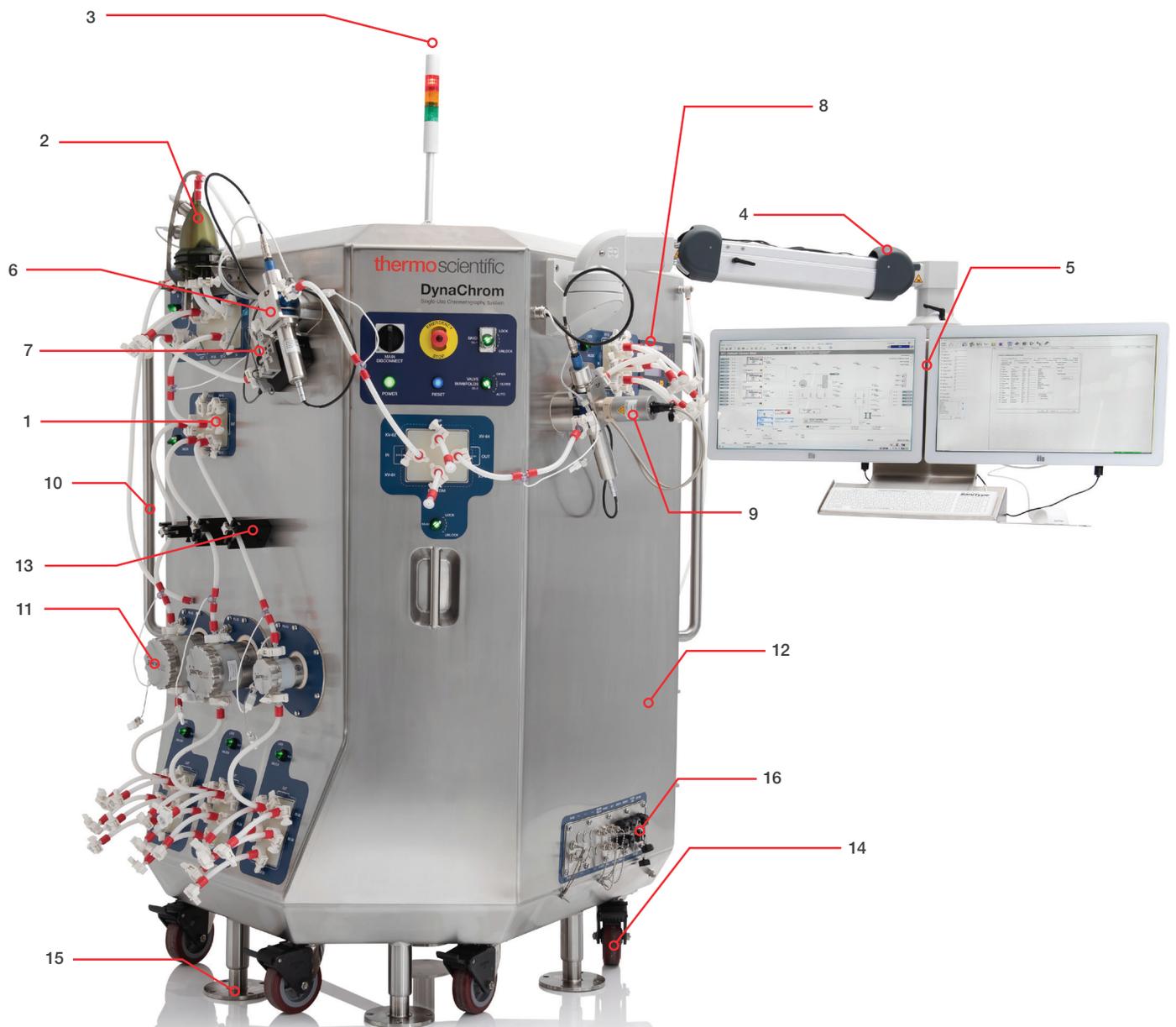


Figure 1. Design elements of the DynaChrom Single-Use Chromatography System.

DynaChrom Single-Use Chromatography System specifications

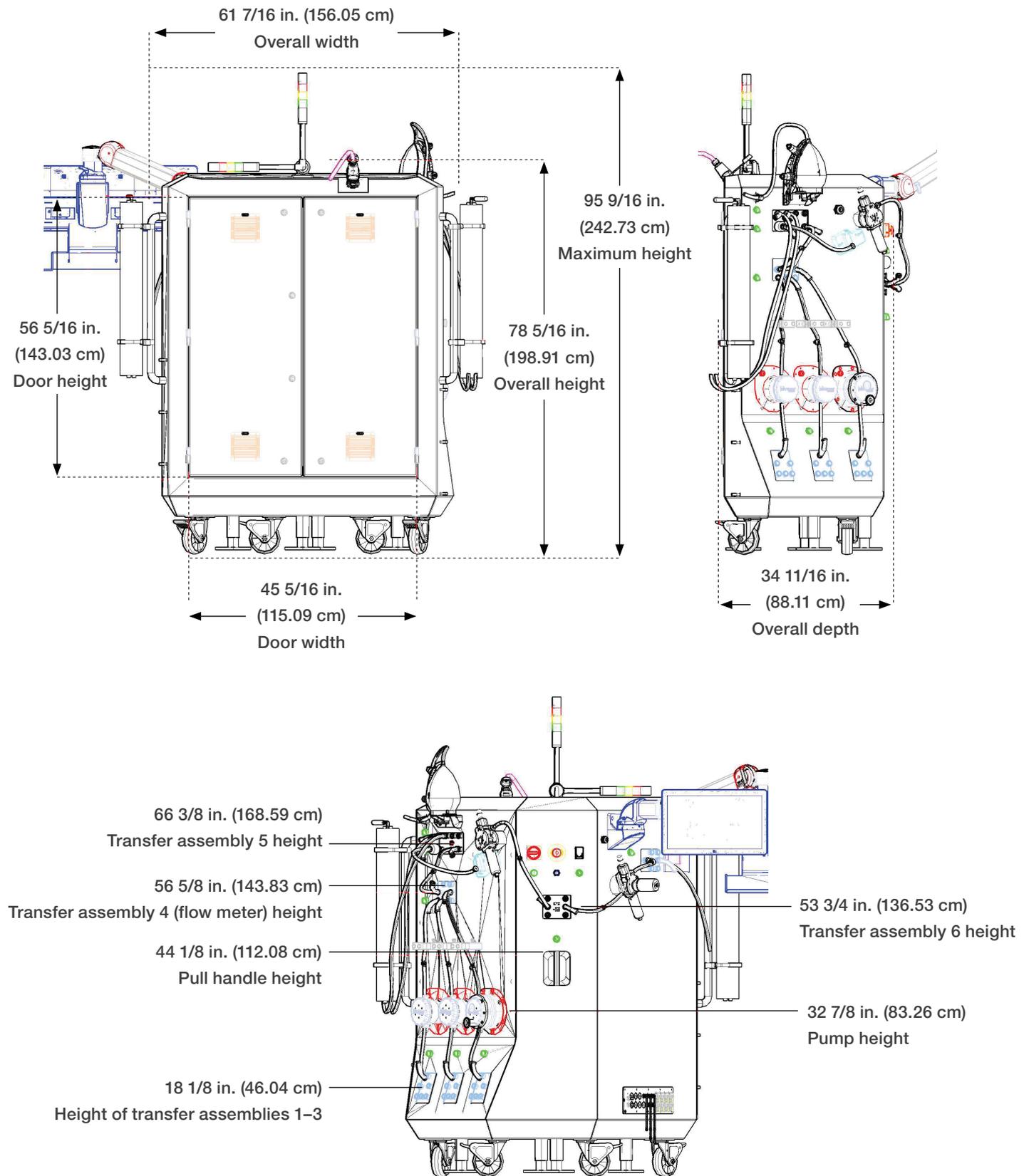


Figure 2. DynaChrom Single-Use Chromatography System dimensions.

Table 1. DynaChrom Single-Use Chromatography System specifications.

Category	Specifications
Skid	
System dimensions (overall W x H x D)	156 x 243* x 88 cm (61 1/2 x 95 1/2* x 34 3/4 in.)
System weight	544.3 kg (1,200 lb)
Construction materials	Skid frame and cabinet: 304 stainless steel Valve alcoves: anodized aluminum with additional anodal PTFE coating HMI arm: extruded aluminum HMI monitors: medical-grade IP54 touchscreens with built-in speakers
System requirements and capacity	
Volumetric flow (dependent on fluid transfer assembly size and pump type)	6–1,980 L/hr Tubing sizes 1/4 in.: 6 to 230 L/hr 3/8 in.: 6 to 510 L/hr 1/2 in.: 6 to 960 L/hr 3/4 in.: 60 to 1,980 L/hr
Fluid transfer assembly inner diameter (ID)	1/4 in., 3/8 in., 1/2 in., and 3/4 in.
Recommended column sizes**	ID of 10–80 cm
Power specifications	200–240 V, 1-phase or 3-phase, 50/60 Hz, 1,800 VA
Instrument air	6.5 ± 0.3 bar (95 ± 5 psi)
Storage temperature	–25°C to 85°C (–13°F to 185°F)
Operating conditions	
Room operating temperature	5°C to 40°C (41°F to 104°F)
Relative humidity	5% to 95% (noncondensing)
Maximum operating pressure	4 bar
Sensors	
Conductivity sensor	0–200 ± 0.4 mS/cm, or 2.4% of reading
pH measuring range (display range)	3–10 (0–14) with accuracy ±0.15 at pH 7 or ±0.16 at pH 10
UV detector	–0.500 to 3.000 ± 0.035 AU
Temperature sensor (from conductivity sensor)	0°C–50°C ± 0.24°C at 25°C, or ± 0.31°C at 40°C
Flow meter operable range (display range)	0–8, 0–20, or 0–50 L/min, depending on model 1/4 in.: 0.1–3.85 L/min with accuracy 5% of reading (0–8.5 L/min) 3/8 in.: 0.1–8.5 L/min with accuracy 5% of reading (0–8.5 L/min) 1/2 in.: 1–16 L/min with accuracy 5% of reading (0–20 L/min) 3/4 in.: 1–33 L/min with accuracy 5% of reading (0–50 L/min)
Pressure sensor operating range (measured range)	0–4 (0–5.17) ± 0.21 bar, at 4 bar
Pump	
QuattroFlow 150	0–3,000 ± 1 rpm, or 0.2% of reading
QuattroFlow 1200	0–2,400 ± 1 rpm, or 0.2% of reading
QuattroFlow 2500	0–1,750 ± 1 rpm, or 0.2% of reading
Wetted materials	
Fluid transfer assembly tubing	Braided silicone
Tube fittings	Polypropylene (PP) and PVDF
Elbows	PVDF
Valve blocks	PP, TPE
Pressure sensor	Polysulfone
Flow meter	Polypropylene
Bubble trap	Somos® BioClear™ Stereolithography Resin
Conductivity/UV sensor	316 L stainless steel, quartz, EPDM, polyphenylsulfone
pH sensor	Glass, vinyl methyl silicone (VMQ)

* NOTE: Alarm stack light folds to 198.5 cm (78 1/8 in.) in height for easy transport.

** 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 DynaChrom Single-Use Chromatography System is available with the following major components:

- **Fluid transfer assembly (Figure 3)**—flexibility to order preconfigured or in sections with a choice of 1/4 in., 3/8 in., 1/2 in., and 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 and are configurable according to application
- **Sensors and devices (Figures 6, 7)**—the following in-line instruments and devices come with the chromatography system:
 - Bubble trap, air sensor, flow sensor, and sensors for pH, conductivity, temperature, and pressure are located pre-column (Figure 6)
 - Dual UV, pH, conductivity, temperature, and pressure sensors are located post-column (Figure 7)
 - Available UV options are 280/254 nm and 280/300 nm (Figure 7)
- **Bubble trap (Figure 8)**—a novel, rigid, and translucent single-use bubble trap designed to remove air bubbles
- **Filter holder**—a filter holder that is adjustable to hold 10 in.–30 in. filters
- **Electrical and control system**—all electrical and control system hardware components are housed within the DynaChrom Single-Use Chromatography System

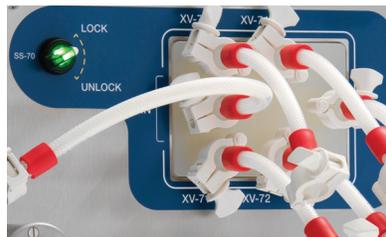


Figure 3. Fluid transfer assemblies attached to valve manifold.

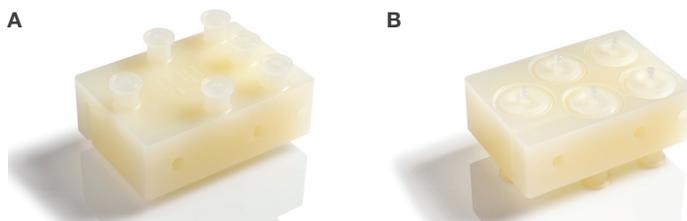


Figure 4. Single-use valve manifold. (A) Top view showing port connections. (B) Bottom view showing diaphragm valves and orientation key way.



Figure 5. Three positive displacement pumps.

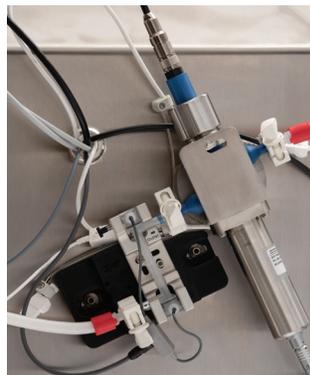


Figure 6. Pre-column sensor pack.



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. The 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 on all single-use transfer assemblies offered for the DynaChrom Single-Use 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 four or five modules of each fluid transfer assembly set flow path to make unpacking and installation easier (Figure 9). 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.*

Chemical solution	Operating time (hr)**
0.3 M sodium phosphate, pH 7.0–7.2	48
20% ethanol	72
8 M urea	18
0.1 M NaOH	72
0.5 M NaOH	10
1 M NaOH	6
1 M acetic acid	4
30% isopropanol	4
30% isopropanol and 1 M NaOH	6
120 mM phosphoric acid, 167 mM acetic acid, and 2.2% benzyl alcohol	50

* Tests were done on a fluid transfer assembly (FTA) containing all subcomponents in the line set design.

** The operating time of the one FTA with 1,500 L/hr per pump at a constant backpressure of 4 bar.

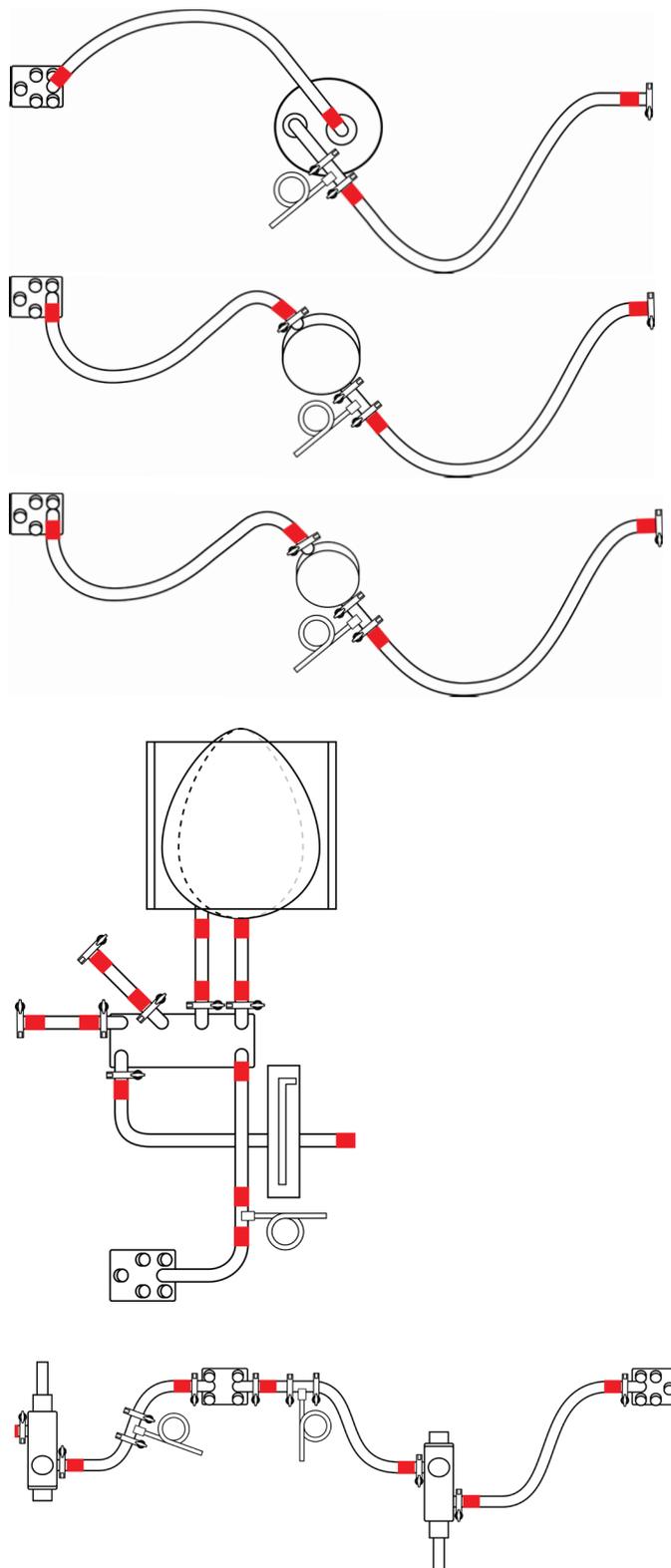


Figure 9. Fluid transfer assemblies.

TruChrom 3.0 software

Fully configurable software solution for controlling chromatography functions

TruChrom 3.0 automation software has been developed according to GAMP™ 5 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 give users control of the DynaChrom Single-Use Chromatography System (Figure 10). Please refer to the TruChrom 3.0 software user's guide for additional information.

Advantages of TruChrom 3.0 software

- User-friendly interface
- Preconfigured batch recipes for quick development of customer recipes
- 2 unit procedures, 22 operations, 26 phases
- Ability to run as a stand-alone skid or integrated into a full DeltaV system, allowing it to be used in a variety of configurations
- Easily integrated into existing batch procedures and process trains to aid synchronization of process activities
- The DeltaV PK controller utilizes advanced control algorithms and can operate at very high speeds, making it ideal for applications that require rapid response times
- Interface provides the ability to display pump flow rate, total volume, set point, outputs, and process value (PV) of all connected sensors
- ANSI/ISA 18.2-2009 compliant
- ISA-88 compliant
- Previously defined save and load process parameters
- The ability to quickly change the software to switch between fluid transfer assembly sizes can greatly enhance the flexibility and versatility of a skid system, allowing it to be easily adapted 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

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:
 - Column qualification/efficiency testing
 - Install recipe
 - Flow through
 - Bind and elute
 - Sanitization
- 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™ manufacturing reporting suite module
- The system includes modes for fluid transfer assembly installation and an installation test that checks sensor connection status



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

Ordering information

Product	Cat. No.
DynaChrom Single-Use Chromatography System hardware	
Chromatography, DynaChrom, Automation Pkg: Controller/HMI/DeltaV/InfoBatch, UV: 280 & 300, Pump: 150, 150, 1200	F100-3500-000.000
Chromatography, DynaChrom, Automation Pkg: Controller/HMI/DeltaV/InfoBatch, UV: 280 & 300, Pump: 1200, 1200	F100-3500-000.001
Chromatography, DynaChrom, Automation Pkg: Controller/HMI/DeltaV/InfoBatch, UV: 280 & 300, Pump: 1200, 1200, 150	F100-3500-000.002
Chromatography, DynaChrom, Automation Pkg: Controller/HMI/DeltaV/InfoBatch, UV: 280 & 300, Pump: 1200, 1200, 2500	F100-3500-000.003
Chromatography, DynaChrom, Automation Pkg: Controller/HMI/DeltaV/InfoBatch, UV: 280 & 300, Pump: 150, 150	F100-3500-000.004
Chromatography, DynaChrom, Automation Pkg: Controller/HMI/DeltaV/InfoBatch, UV: 280 & 254, Pump: 150, 150, 1200	F100-3500-000.010
Chromatography, DynaChrom, Automation Pkg: Controller/HMI/DeltaV/InfoBatch, UV: 280 & 254, Pump: 1200, 1200	F100-3500-000.011
Chromatography, DynaChrom, Automation Pkg: Controller/HMI/DeltaV/InfoBatch, UV: 280 & 254, Pump: 1200, 1200, 150	F100-3500-000.012
Chromatography, DynaChrom, Automation Pkg: Controller/HMI/DeltaV/InfoBatch, UV: 280 & 254, Pump: 1200, 1200, 2500	F100-3500-000.013
Chromatography, DynaChrom, Automation Pkg: Controller/HMI/DeltaV/InfoBatch, UV: 280 & 254, Pump: 150, 150	F100-3500-000.014
Chromatography, DynaChrom, w/o Automation Pkg, UV: 280 & 300, Pump: 150, 150, 1200	F100-3500-000.800
Chromatography, DynaChrom, w/o Automation Pkg, UV: 280 & 300, Pump: 1200, 1200	F100-3500-000.801
Chromatography, DynaChrom, w/o Automation Pkg, UV: 280 & 300, Pump: 1200, 1200, 150	F100-3500-000.802
Chromatography, DynaChrom, w/o Automation Pkg, UV: 280 & 300, Pump: 1200, 1200, 2500	F100-3500-000.803
Chromatography, DynaChrom, w/o Automation Pkg, UV: 280 & 300, Pump: 150, 150	F100-3500-000.804
Chromatography, DynaChrom, w/o Automation Pkg, UV: 280 & 254, Pump: 150, 150, 1200	F100-3500-000.810
Chromatography, DynaChrom, w/o Automation Pkg, UV: 280 & 254, Pump: 1200, 1200	F100-3500-000.811
Chromatography, DynaChrom, w/o Automation Pkg, UV: 280 & 254, Pump: 1200, 1200, 150	F100-3500-000.812
Chromatography, DynaChrom, w/o Automation Pkg, UV: 280 & 254, Pump: 1200, 1200, 2500	F100-3500-000.813
Chromatography, DynaChrom, w/o Automation Pkg, UV: 280 & 254, Pump: 150, 150	F100-3500-000.814



Ordering information

Product	Cat. No.
DynaChrom fluid transfer assembly options	
Fluid transfer assembly kit options	
DynaChrom FTA Kit for FAT and SAT (10 1/4 in., 20 1/4 in., 30 3/8 in.); for pump configuration 150, 150, 1200	F100-3500-400
DynaChrom FTA Kit for FAT and SAT (10 1/4 in., 20 1/4 in.); for pump configuration 150, 150, BLANK	F100-3500-401
DynaChrom FTA Kit for FAT and SAT (10 3/8 in., 20 3/8 in.); for pump configuration 1200, 1200, BLANK	F100-3500-402
DynaChrom FTA Kit for FAT and SAT (10 3/4 in., 20 3/4 in., 30 3/4 in.); for pump configuration 1200, 1200, 2500	F100-3500-403
DynaChrom FTA Kit for FAT and SAT (10 3/4 in., 20 3/4 in., 30 1/4 in.); for pump configuration 1200, 1200, 150	F100-3500-404
DynaChrom FTA Kit for FAT and SAT (10 3/8 in., 20 3/8 in., 30 1/4 in.); for pump configuration 1200, 1200, 150	F100-3500-405
DynaChrom FTA Kit for FAT and SAT (10 1/2 in., 20 1/2 in., 30 1/4 in.); for pump configuration 1200, 1200, 150	F100-3500-406
DynaChrom FTA Kit for FAT and SAT (10 1/2 in., 20 1/2 in., 30 3/4 in.); for pump configuration 1200, 1200, 2500	F100-3500-407
Fluid transfer assembly line set options	
DynaChrom FTA, 1/4 in. for 150 pump, section 10	SUT00012
DynaChrom FTA, 1/4 in. for 150 pump, section 30	SUT00013
DynaChrom FTA, 1/4 in. pre-column	SUT00014
DynaChrom FTA, 1/4 in. post-column	SUT00015
DynaChrom FTA, 3/8 in. for 1200 pump, section 10	SUT00016
DynaChrom FTA, 3/8 in. for 1200 pump, section 30	SUT00017
DynaChrom FTA, 3/8 in. pre-column	SUT00018
DynaChrom FTA, 3/8 in. post-column	SUT00019
DynaChrom FTA, 1/2 in. for 1200 pump, section 10	SUT00020
DynaChrom FTA, 1/2 in. for 1200 pump, section 20	SUT00021
DynaChrom FTA, 1/2 in. pre-column	SUT00023
DynaChrom FTA, 1/2 in. post-column	SUT00024
DynaChrom FTA, 3/4 in. for 1200 pump, section 10	SUT00025
DynaChrom FTA, 3/4 in. for 1200 pump, section 20	SUT00026
DynaChrom FTA, 3/4 in. for 2500 pump, section 30	SUT00027
DynaChrom FTA, 3/4 in. pre-column	SUT00028
DynaChrom FTA, 3/4 in. post-column	SUT00029
DynaChrom FTA, 1/4 in. for 150 pump, section 20	SUT00039
DynaChrom FTA, 3/8 in. for 1200 pump, section 20	SUT00040

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