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DynaChrom Single-Use Chromatography System

The latest in single-use downstream purification technology—from process development to manufacturing

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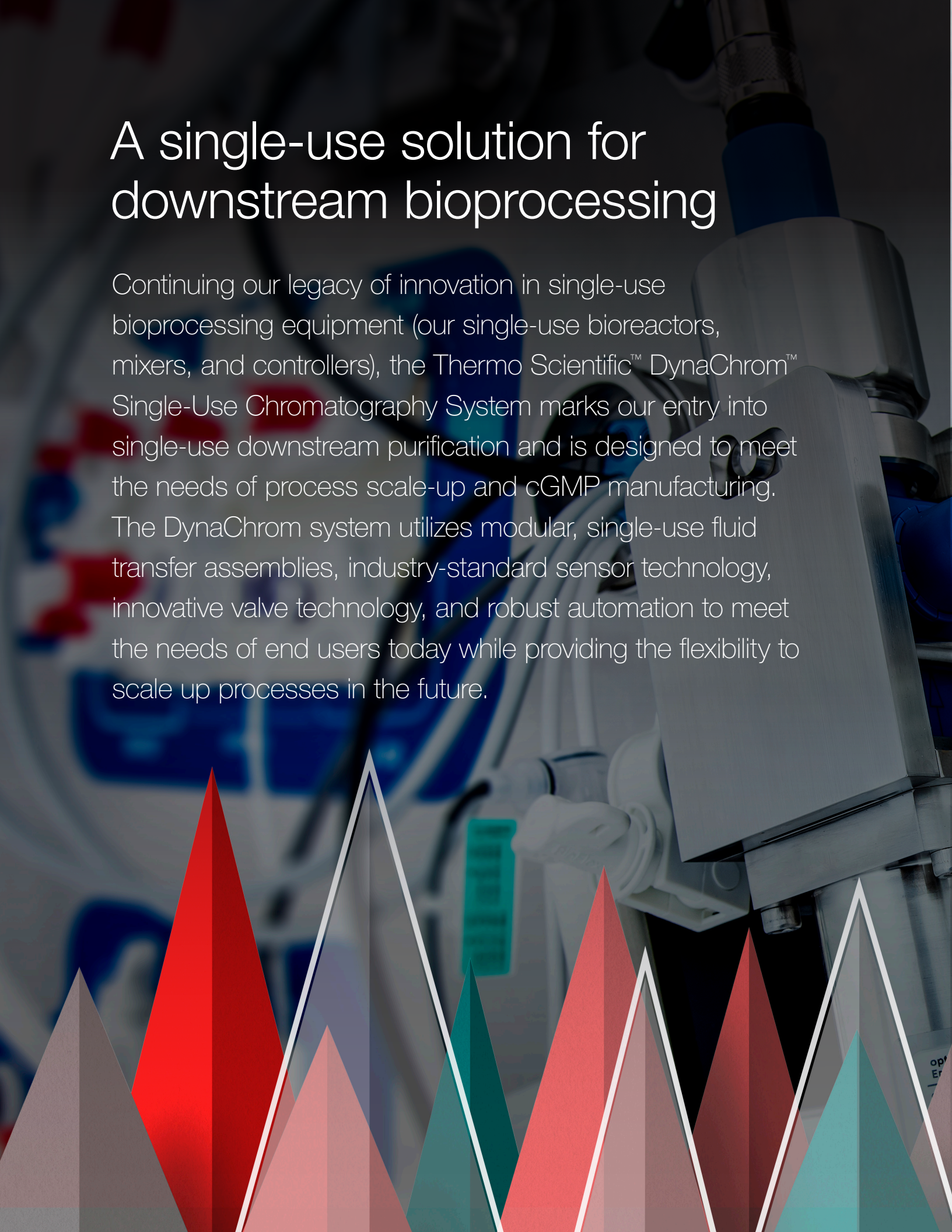

A single-use solution for downstream bioprocessing

Continuing our legacy of innovation in single-use bioprocessing equipment (our single-use bioreactors, mixers, and controllers), the Thermo Scientific™ DynaChrom™ Single-Use Chromatography System marks our entry into single-use downstream purification and is designed to meet the needs of process scale-up and cGMP manufacturing. The DynaChrom system utilizes modular, single-use fluid transfer assemblies, industry-standard sensor technology, innovative valve technology, and robust automation to meet the needs of end users today while providing the flexibility to scale up processes in the future.


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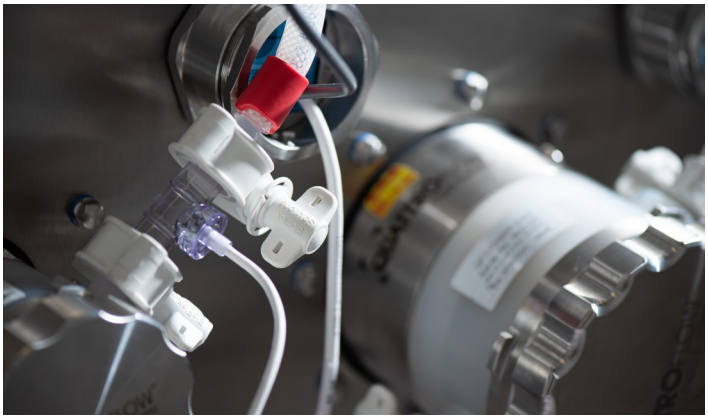


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Applications

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

Key features

- Wide, operational flow ranges are available from 1 L/hr to 1,980 L/hr enabled by pump and fluid transfer assembly combinations: 1/4 in., 3/8 in.*, 1/2 in.*, and 3/4 in. sizes with a maximum operating pressure rating of 4 bars. This offering provides a configurable system with operational flexibility to support the gamut of scales needed from process development to manufacturing.
- The hardware, software, and single-use consumables of the DynaChrom system meet the demands of modern downstream bioprocessing with isocratic and gradient elution support, as well as inline dilution capability. The system can be configured for bind-elute, flow-through, and other modes of operation. (See the Software section for details.)
- The zero dead leg with ring flush valve design eliminates residual fluid in the line sets because the previous phase liquids are instantly flushed at the start of a new phase. This can result in less buffer use, improved peak resolution, and increased product yield.
- The novel, single-use valve manifold removes limitations caused by pinch valves or clamshell-liner designs. Scalable design of the valve block and locking mechanism allows for easy flow path scaling with the various fluid transfer assemblies. The valve manifold also provides easy and precise transfer assembly installation enabling safe operation and quick turnaround time for process operation.
- The DynaChrom system is designed to be column-agnostic so it can work with any end user–selected membrane or resin column (prepacked or self-packed) that adheres to the design specification of the system. The system also has column upflow and downflow capability. Column size recommendations to match the flow rates and line set sizes are provided in the Specifications section. We can also provide consultation for the selection of our chromatography purification products.
- Ergonomic, space-saving design of the system provides ease of access for system operation and maintenance, including line-set installation and operator interface for monitoring and control.
- Thermo Scientific™ TruChrom™ Automation Software, powered by the Emerson™ DeltaV™ Distributed Control System, provides the ability to leverage existing DeltaV network infrastructure and allows ease of tech transfer, data integration, and data storage. (DeltaV v14 is required for other DeltaV versions. Please consult with our technical sales support.)
- The simplified recipe structure of TruChrom software provides an enhanced user experience. Configurable user access, an audit trail, and batch reporting are available as standard features.

* These fluid transfer assembly sizes are not immediately available. Please consult our technical support team.

Hardware

The DynaChrom system hardware is built as a modular system with all the features to run a purification operation included in the base configuration, and with easy options for advanced, custom configurations.

Functionality and scalability

The DynaChrom system is available with the following major components:

Pumps

Two or three low-pulsation, positive-displacement pumps—controlled by servomotors and variable frequency drives—are available to support the wide range of flow rates and they are configurable to meet your application needs. The industry-standard pumps provide nonslip operation with virtually no heat degradation or particle generation.

Valve manifolds

The concept revolves around a single-use manifold with integrated flow paths and valves. The single-use manifolds are part of the single-use fluid transfer assembly set, and are placed into the actuator alcoves and locked in place with a pneumatically operated lever controlled by a local switch. The advantage of this novel design over other available technologies is the inherent scalability. Using the same actuator alcove and valve block, the internal flow path can be varied to match the inner diameter of the tubing portions of the fluid transfer assembly (1/4, 3/8*, 1/2*, or 3/4 in.). The valve manifolds are designed to manage the various flow paths based on their location in the fluid transfer assembly.

- Inlet, outlet, and mixing manifold
- Bubble trap and filter manifold
- Column feed, bypass, and downflow manifold

Sensors and devices

The following inline instruments and devices are available as standard with the chromatography system.

- Conductivity, temperature, pH, flow, motor speed, bubble-trap level, and pressure instruments are provided as standard on the column-supply flow path.
- UV, conductivity, temperature, and pH instruments are provided as standard on the column-output flow path. Available UV options are dual wavelength—280/300 nm and 280/254 nm.
- Single-use ultrasonic flow sensor provided pre-column is used for flow monitoring.
- Bubble trap: A novel, rigid-wall, translucent single-use bubble trap designed to eliminate air bubbles is provided as standard. Two capacitive proximity sensors are used to maintain a level state. The system can be operated in a bubble trap–bypass mode.
- Filter: A filter holder at the column inlet is provided as standard, and an optional single-use filter assembly is available.

Electrical and control system

All electrical and control system hardware components are housed within the DynaChrom system. The system is rated for IP54 Ingress protection (NEMA 12 equivalent), and maintenance access to the electrical and control system hardware is available through two large doors at the back of the unit. Spares for analog inputs, control loops, and pneumatic outputs are provided.

Interface

The operator interface panel on the system provides switches for on/off, e-stop, reset, valve lock/release as well as system status indication pilot lights.

Controller

The controller configuration allows for stand-alone operation with the included Emerson™ DeltaV™ PK Controller and DeltaV v14 software. The controller can be configured to be integrated into an existing automation layer.

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Design and ergonomics

The unique prism hardware design of the DynaChrom system allows easy access to buffers, the column, and collection containers. With large handles and big casters, this system is effortless to move and easy to maneuver. Other notable, operator-friendly features are:

- The swing-out arm with dual touchscreen displays can be positioned to the needs of the operator and makes monitoring and control easily accessible.
- A tubing-management arm provides routing and keeps the tubing off the floor.

Fluid transfer assemblies

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

Additional features:

- The DynaChrom system uses the Thermo Scientific™ BioTitan™ Retention Device, an innovative tubing retention solution, to address concerns caused by traditional cable ties and other problematic retention technologies. The device is used in all the single-use transfer assemblies offered for the DynaChrom system, enhancing the overall reliability and integrity of the fluid transfer assemblies by minimizing the risk of leaks and failures at connection points.
- Gamma-sterilized, single-use fluid transfer assemblies complete with integrated sensors and robust connections minimize the risk of contamination and enable a functionally closed-system operation.
- There are up to five modules in each fluid transfer assembly set flow path, depending on skid options selected, making unpacking and installation easier. The modules are individually packaged and can be ordered individually, allowing for cost savings.

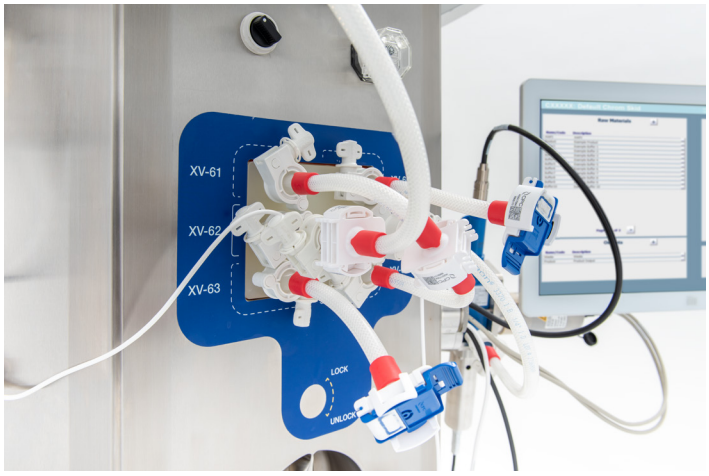
Software

TruChrom software is developed according to GAMP™ 5 methods and conforms to regulatory requirements for use in cGMP-compliant processes as per 21 CFR Part 11. TruChrom software can be configured for either bind-elute or flow-through modes of operation and common types of chromatography such as affinity, ion exchange, and hydrophobic interaction.

Isocratic flow is the default configuration. Inline dilution and linear gradient flow control are available.

Software functionality

- The following logic sequences are configured in the TruChrom software to provide a ready-to-set-up, out-of-the-box user experience: priming, sanitization, equilibrium, load, wash, and elution.
- During single-use line-set installation, the system can be placed in single-use assembly “installation” mode, which will place all actuators in manual mode, stop the pumps, and leave the valves open. Placing the system in single-use assembly “test” mode will verify sensor connection status, valve status, that there is no air entrainment, etc.
- Height equivalent to a theoretical plate and asymmetry factor are typically used to evaluate quality of column packing. These calculations are offered as add-ons for the software.
- The system is capable of running processes in batch mode. When this mode is used, the batch information is retained by the batch reporting system and reports can be generated and issued using the InfoBatch reporting module included as part of the system.



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Knowledgeable and comprehensive technical support

Our global, field-based technical support team is available for local installation and support. A process development team is available for cell culture support, providing expertise on cell growth and troubleshooting. We can also provide you with additional support documentation upon request. All systems are supplied with the following guides:

Comprehensive user guide:

- System installation and setup
- Fluid transfer assembly installation
- Software configuration and use
- Validation guide

Ordering information

Product	Size	Cat. No.
DynaChrom Single-Use Chromatography System		F100-3500-000
DynaChrom Single-Use Chromatography System Fluid Transfer Assemblies	1/4 in.	F100-3600-001
	3/8 in.*	F100-3600-002
	1/2 in.*	F100-3600-003
	3/4 in.	F100-3600-004

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

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