

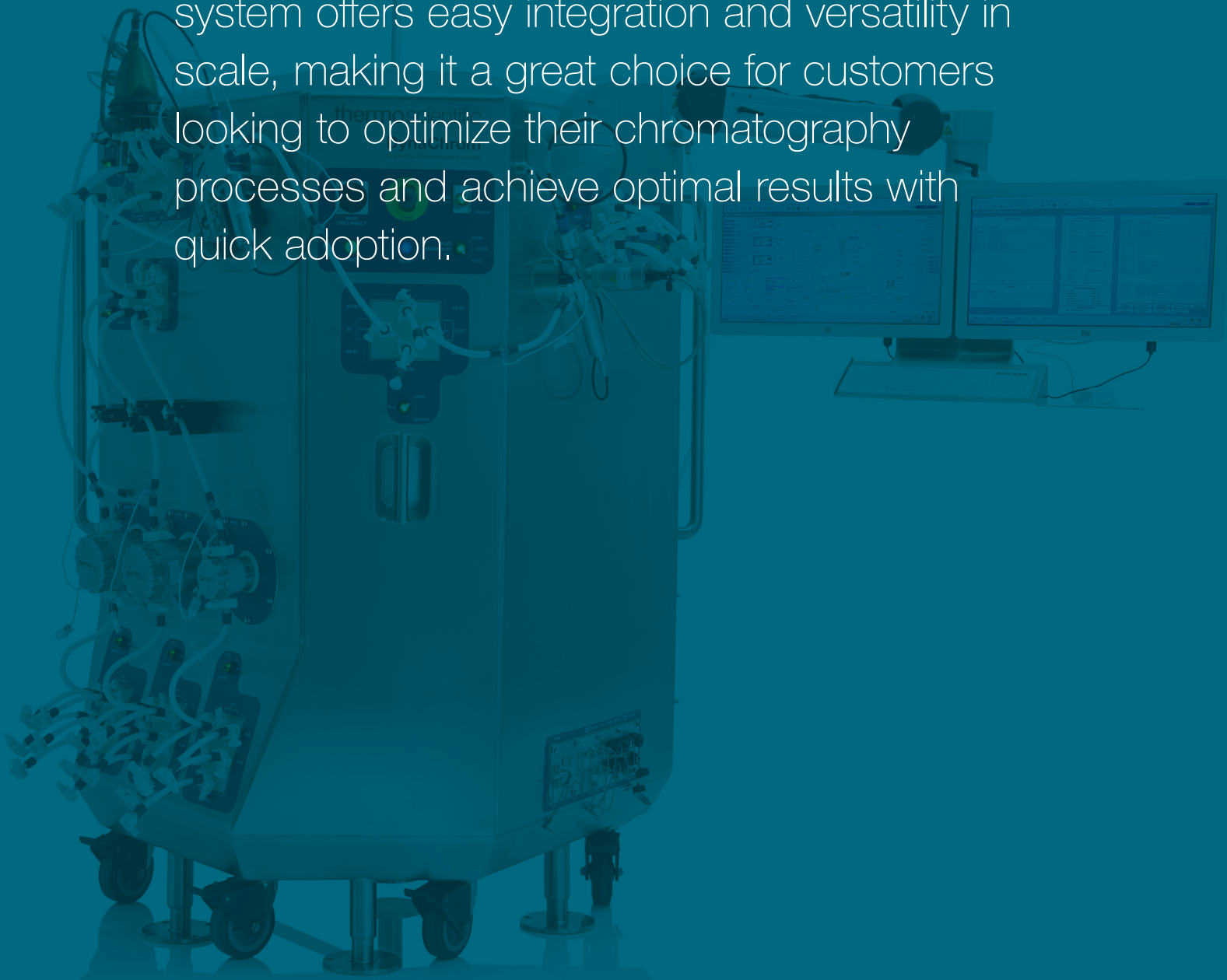
Single-use technologies

Separation made simple

DynaChrom™ Single-Use Chromatography System:
advanced separation for advanced bioprocessing

A single-use solution for downstream bioprocessing

The Thermo Scientific™ DynaChrom™ Single-Use Chromatography System offers a powerful value for CDMOs, CMOs, and those working on pilot to scale-up operations. Whether you're working in a pilot or manufacturing setting, the DynaChrom system offers easy integration and versatility in scale, making it a great choice for customers looking to optimize their chromatography processes and achieve optimal results with quick adoption.



Applications

The DynaChrom system can provide 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 enable the 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, help provide the platform necessary for consistent, high-performing purification.

Key features

- Wide, operational flow ranges are available from 6 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 help 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 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 fluid transfer assembly installation enabling safe operation and quick turnaround time for process operation.
- Valve manifold design leverages zero static valves with minimal dead leg. (Design compliant with ASME BPE 2022) The valves are connected in a ring design that quickly and completely flushes the manifold at the start of a new phase.
- The DynaChrom system is designed to be column-agnostic so it can work with any end user–selected membrane or resin columns (prepacked or self-packed) that adheres to the design specification of the system. The DynaChrom system also has column upflow and downflow capability with automatic column by-pass on air detection. We can also provide consultation for the selection of our chromatography purification products.
- Ergonomic, space-saving design of the system provides accessibility for system operation and maintenance, including easy fluid transfer assembly 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. 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.



Hardware

The 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. This can result in a system that provides exceptional scalability and flexibility to help meet today's need and tomorrow's unknown requests.

Single-use 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 fluid transfer assemblies offered for the DynaChrom system, helping enhance the overall reliability and integrity of the fluid transfer assemblies by minimizing the risk of leaks and failures at connection points.
- No pinch valves enable fluid transfer assemblies a robustness against harsh chemicals, with long exposure times that set new goal posts for the industry.
- 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 to make unpacking and installation easier. The modules are individually packaged and can be ordered individually, allowing for cost savings.

Design and ergonomics

The unique prism hardware design of the DynaChrom system allows easy access to liquid connection ports, the column, and collection containers. This system was designed with large handles and casters, making it easy to move and maneuver.

- Unique prism design provides full view of the entire skid and its' components, and the alarm stack light provides an easy check for system status from across the room.
- The swing-out arm with dual touchscreen displays can be positioned to the needs of the operator and help make monitoring and control easily accessible.
- Valve design provides advantages for scaling flow path processes—the same skid can accommodate line set sizes from 1/4 in to 3/4 in.



Functionality and scalability

The DynaChrom system is available with the following major components:

Pumps

Two or three low-pulsation, positive-displacement pumps—driven by high efficiency/compact servo drive and motor technology—are available to support the wide range of flow rates and they are configurable to help 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 in, 3/8 in, 1/2 in, 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 flow aggregator manifold
- Bubble trap and filter manifold
- Column upflow, downflow and bypass manifold

Sensors and devices

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

- Motor speed and pressure for each pump with hardwired high pressure interlock to the skid's safety circuit.
- Conductivity, temperature, pH, flow, bubble-trap high and low level sensors, air sensor, and pressure instruments are provided as standard on the column-supply flow path.

- Dual 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.
- 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 holder that's adjustable to hold 10inch to 30inch filters.

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 system has several automation packages that include Emerson's PK controller, Licensing, HMI and Batch reporting. The skid can be configured as a stand alone or fully integrated into a site's DeltaV system (v14 required).



Software

TruChrom, the automation layer of the DynaChrom system, is built on Emerson's DeltaV control platform and is fully ISA-88 compliant. It allows for easy batch control and process monitoring, making it a powerful tool for both laboratory and manufacturing settings. The system comes pre-loaded with default recipes and supporting operations that can be easily deployed and modified from the operator graphic depending on a user's security access. This enables users to set up the system quickly and easily, monitor key process parameters, and optimize separation performance. The system is also able to characterize single-use sensors through the use of automated recipe operations that improve the overall performance of the machine.

Software functionality

- Bind and elute and flow through recipes come with default running parameters and use several operations and phases and depending on process needs. TruChrom was designed to be ISA-88 compliant and provides a ready out of the box user experience.
- The system includes a start up recipe that walks the operator through the fluid transfer assembly. During the installation operation sensor verification and pump priming tasks are performed.
- Height equivalent to a theoretical plate and asymmetry factor are typically used to evaluate quality of column packing.
- TruChrom is developed with DeltaV, Emerson enabling batch processing with easy operator use. The batch information is retained by the batch reporting system. Using the InfoBatch reporting module can make generating and reporting easy, which can help improve efficiency. TruChrom is cGMP-compliant.
- The inherent nature of single use components leads to larger manufacturing differences than their stainless counter parts. By digitally communicating to these sensors and pump controllers the system can characterize these single use items automatically. This sensor characterization ability helps improve the that overall performance of the machine.



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As a way of protecting the performance of your equipment throughout its life cycle, we offer our Thermo Scientific™ Bioprocess Integrated Services.

Thermo Fisher Scientific is a trusted partner for your automation and bioprocess equipment needs. We understand the importance of maximizing your operational efficiencies, while minimizing downtime of your bioprocess equipment and automation software throughout your manufacturing processes.

The full range of service solutions, supported by designated service engineers, help to protect your processes against unforeseen downtime, enable productivity, help improve operational costs, and enable your facility to function at maximum operational capacity.

Our service offering includes technical specialists, project management, on-time support, extended warranties, training, repair services, remote support, and preventative maintenance.



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