

# Allegro™ Fully Automated, Single-Use Chromatography System

For control, flexibility  
and ease of use  
in manufacturing

## Benefits

- Intuitive Process Step Editor control software
- Easy system set up and installation of manifolds
- Single-use sensor options for process monitoring and control
- Designed for all typical biochromatography applications



## Product Information

The Allegro single-use chromatography system is a flexible system designed for pilot scale, clinical production batches and commercial production. The flexible modular system design enables column operation with isocratic or gradient set up options.

Unique pinch valve blocks enable the system to accommodate both  $\frac{3}{8}$  in. (0.95 cm) internal diameter (ID) and  $\frac{1}{2}$  in. (1.27 cm) ID manifolds, conferring maximum flow rates of 500 and 900 L/h respectively. The column operation range is 10–60 cm diameter pre-packed or conventional and membrane chromatography capsules.

## System Concept

The Allegro single-use chromatography system offers a combination of hardware, control automation and single-use assemblies designed to work perfectly together. Clever system design ensures ease of use in running fully automated chromatography process sequences, with simplified single-use assemblies, incorporating all of the critical sensor and instrumentation technologies. Flexibility is a key requirement for single-use system design. The system offers the end user a choice of single-use sensors for isocratic, gradient, filter | bubble-trap, column and outlet manifolds. A range of single-use bags is available for product loading, product eluate and buffers.

Weigh scales and Sartorius mixer technologies can also be offered with the Allegro single-use chromatography system to suit individual process requirements.

A review of your specific process needs with our application specialists or Integrated Solutions engineers will ensure a solution is offered to meet exactly all of the process requirements. This might be achieved with our standard platform design for the Allegro single-use chromatography system, along with standard totes and mixers. Or it might lead to the creation of a custom design. The custom designs will still retain the core components that we have validated for use in the Allegro single-use chromatography system.

Sartorius has the flexibility to integrate our systems with other plant equipment and plant control systems. The system design gives full consideration to ease of use in system set up and processing, while ensuring use of components and instruments that can achieve the performance requirements for chromatography processes.

Adopting single-use technologies can have many potential benefits in a process. Cost of Goods (CoG) studies have shown significant savings in capital, materials, labor and facility operating costs.

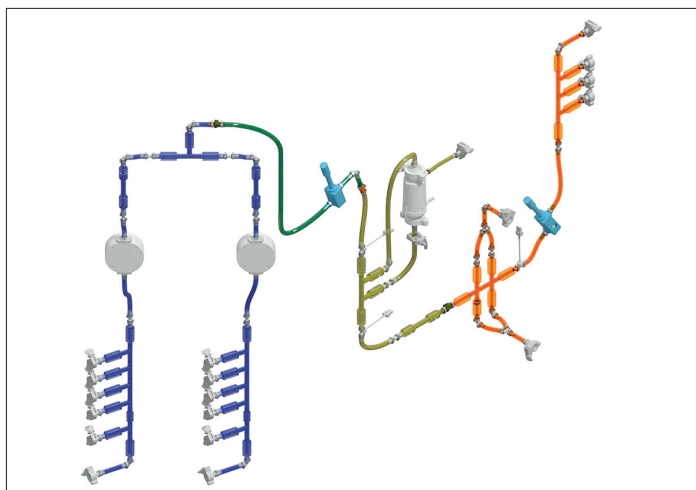


Figure 1: Single-use gradient manifold

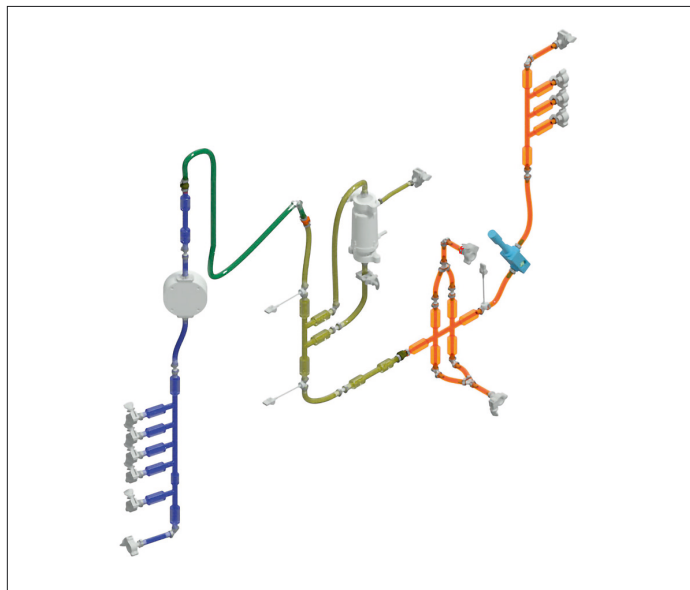


Figure 2: Single-use isocratic manifold

## Control System

The Process Step Editor is PLC (programmable logic controller) based automation enabling process robustness in manufacturing environments and complies with CFR21 Part11 and Current Good Manufacturing Practice (cGMP) guidelines.



Figure 3: Fully maneuverable touchscreen human machine interface (HMI)

The user can select the transition points which move the process from one phase step to the next. This can be done by selection of one or several process parameters (with an "and" or "or" logic) such as conductivity, column volume, pH, volume, and biocontainer weight. Further flexibility is added as the system allows the configuration and use of loop and jump functions, making selective step repetitions feasible. Upon the operator's selection batch reports will be generated automatically at the end of a batch for each single step. The content of the batch report is predefined.

Supervisory control and data acquisition (SCADA) process data is captured using the integrated analytical tool soft-

ware module via open platform communications (OPC) and saved to a discrete database. Data can be displayed in customized charts and historical trend analysis can also be carried out for comparison of batches. Calculation of and reporting of critical process indicators such as transition analysis, peak asymmetry and height equivalent to a theoretical plate (HETP) is made easily with the analytical tool.

### Key System Features

- Isocratic or gradient set up options
- System utilizes 3/8 in. (0.95 cm) ID and 1/2 in. (1.27 cm) ID manifolds
- Utilizes new pinch valve block technology – easy manifold installation
- No calibration of single-use sensors
- cGMP compliant design and documentation
- Compact system footprint with maneuverable HMI
- Suitable for both resin and membrane chromatography
- Intuitive Process Step Editor automation platform
- Reliable, robust operation
- Ethernet network capability
- Full security access to configuration
- Data and event logging
- Audit trail

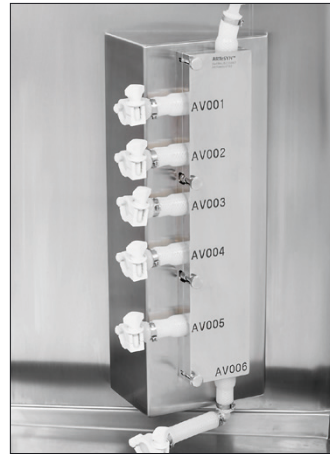


Figure 4: Pinch valve buffer inlet block (left); compact single-use flow cell (right)

### Automated Single-Use Downstream Operations

Both the Allegro chromatography system and Allegro TFF systems are well-designed single-use automated systems for downstream processing. Both utilize the Process Step Editor automation control software platform. The common software platform simplifies standard operating practices (SOPs) and operator training, and provides robust and reliable operation of key DSP operations.



Figure 5: Allegro single-use downstream processing technologies platform, showing Allegro single-use TFF system (left) and Allegro single-use chromatography system (right).

# Technical Data

System Capacity	¾ in. Manifolds	½ in. Manifolds
Volumetric flow	10 to 500 L/h	20 to 900 L/h
Column diameter	10 – 60 cm	10 – 60 cm
Tubing ID	¾ in. (0.95 cm)	½ in. (1.27 cm)
Hold-up volume	0.5 L	1.0 L
Pressure rating	0 to 4 bar	0 to 4 bar
System pump	Up to × 2 diaphragm (single-use)	Up to × 2 diaphragm (single-use)
Inlets	6 per pump	6 per pump
Outlets	4	4

Instruments	Location	Range and Accuracy
Air sensor	Pre column (integrated into flow sensor)	Ultrasonic (0 to 100%)
Level sensor	Bubble trap (filter)	Capacitive (0 to 100%)
Pressure sensor	Post pump, pre column, post column	-0.5 to 4 bar
Conductivity sensor	Pre column (optional), post column	0 to 150 mS/cm (± 2% ± 0.4 µS/cm)
Temperature sensor	Part of conductivity sensor	5 to 40 °C (≤ 0.8% of measured value)
pH sensor	Pre column (optional), post column	± 0.1 pH unit
UV detector	Post column	0 to 3 AU @ 280 nm, ± 0.5%
Flow meter	Pre column, post pump (optional)	0 – 500 or 0-1000 L/h ± 3% of reading or 3% of full range (whichever is greater)

## System Dimensions and Weight

Dimensions (W × D × H)	186 × 80 × 180 cm (73 × 31.6 × 71 in.)
Weight (Net)	550 kg (1213 lb)

## Sales and Service Contacts

For further contacts, visit  
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