

Allegro™ MVP

SINGLE-USE SYSTEM

An automated bioprocessing system, providing flexibility and improved productivity in upstream and downstream single-use processing

Single-use technology continues to be adopted across many areas of bioprocessing. The use of automation provides additional benefits in manufacture such as consistency in product quality, reduced labor costs and reduction of operator errors.

The Allegro™ MVP system is designed for use across a range of bioprocessing activities such as:

- Sterile filtration
- Bioburden reduction
- Depth filtration
- Virus filtration
- Media and buffer preparation
- Membrane chromatography
- pH adjustment
- Virus inactivation
- Final formulation and filling

The Allegro MVP system uses disposable flowpaths, and incorporates single-use sensors for control and monitoring of key parameters. This enables processing to be conducted at optimum conditions, using automated process sequences.



Fig 1. Allegro MVP single-use system.

Key attributes

- Good engineering design provides reliability and robust operation, and reduces risk of operator error
- High degree of automation enables precise and consistent operation, control of key parameters, and decreases operator contact
- High degree of flexibility to run many different processes

Optimized design

The system was designed to perform the pH adjustment steps needed in media preparation and virus inactivation, with the automated addition of acid and base stock solutions. Allegro mixers can be used with the system, to ensure rapid dispersal of the added fluids during these process steps.

A large selection of pre-designed manifolds is available, with a specially designed manifold selection tool to help identify the most suitable manifold for your application.

A choice of sensors, connectors, tubing type, filters and prefilters when selecting a flowpath enables the manifold to be suited to your process application.

It is one of the few systems to offer such a wide range of preconfigured standard manifold options.

The system is designed to automatically monitor multiple parameters and the following sensors can be selected:

- Pressure (inlet, between filters, outlet single-use sensors)
- pH (reusable probe in mixer)
- Flow (inlet single-use sensors)
- Conductivity (reusable probe in mixer or single-use sensor on outlet)
- UV (outlet single-use sensors)
- Mass (via load cell connection)

Easy configuration

The sensors being used in any given process can be easily selected or deselected on the configuration screen. Sensors not being used are not shown on the main operating screen.

The phase editor in the control system allows the generation and configuration of customer-specific processes in a simple and user-friendly way. This facilitates reliable, automated control of processing at optimum conditions.

Allegro MVP system capabilities

Final formulation and filling	Membrane chromatography
Sterile filtration	pH adjustment
Bioburden reduction	Media and buffer preparation (mixing, pH adjust, filtration)
Depth filtration	
Virus filtration and inactivation	



Fig 2. Allegro MVP system configured for filtration.



Fig 3. A universal clamp can be used to support capsules with diameter 5 to 10.5 cm.

The Allegro MVP system can accommodate a variety of capsule styles, sizes and configurations. The vertical brackets can be moved horizontally to give flexibility with any manifold design.

Depending on the process application and the flow range required, either a diaphragm or a peristaltic feed pump can be used with the Allegro MVP system.

Capsules with a diameter 5 to 10.5 cm (up to 30 in. Kleenpak™ Nova filter or equivalent) are supported, on the Allegro MVP system, with universal clamps fixed to vertical brackets. This allows for different filter combinations and running filters in series or parallel.

Stax™ depth modules (up to 20 m²) can be positioned next to the Allegro MVP system, with connections running between the units.

Automated pH adjustment

The Allegro MVP system has two small pumps which add acid / base as programmed by the software.

The acid and base stock solutions are located in the two 20 L trays.

Mixing is required for virus inactivation and media preparation. An Allegro mixer bag with acid/base ports and pH probe access point can be used with this system. The mixer can be controlled from the HMI on the Allegro MVP system.

A reusable, autoclavable, pH probe in the mixing bag will continually monitor the pH, so that the end point can be accurately determined.

Intuitive flowpath installation

Intuitive labeling on the Allegro MVP manifolds supports quick and easy installation of flowpaths and filters in the correct location.



Fig 4. Capsules are supported on the Allegro MVP system with universal clamps.

Fig 5. Integral trays containing process fluids.

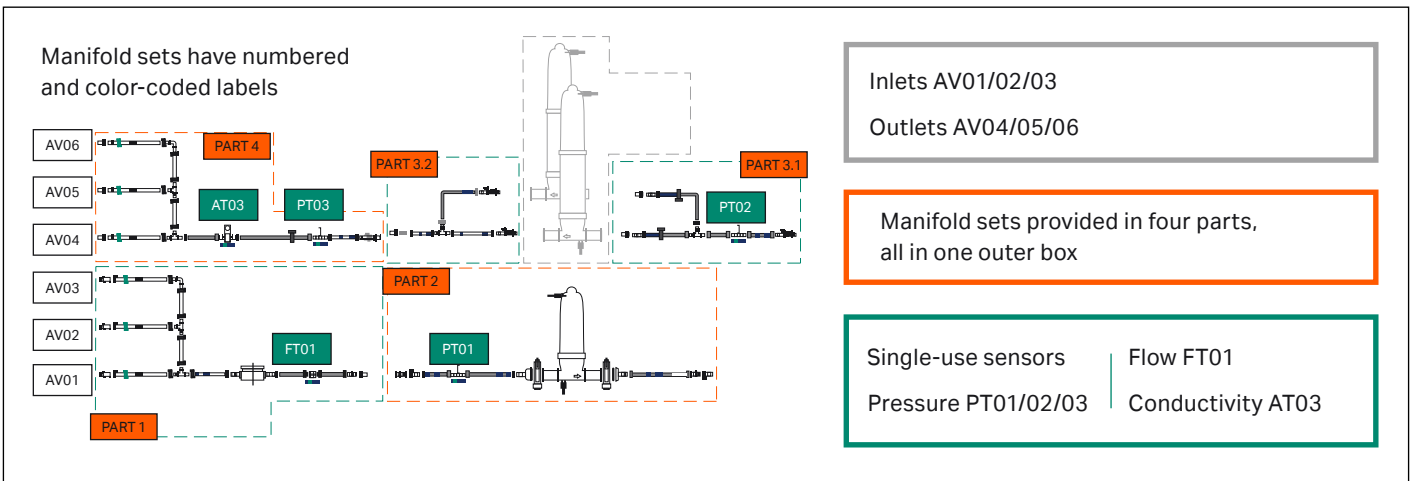


Fig 6. Labeling on the Allegro MVP manifolds.

Application areas for Allegro MVP system

Automated processing provides a batch record for the whole process sequence. Use of automated valves allows more complex process steps to be simplified into an automated sequence.

Virus filtration



- Automated flushing and wetting of membranes
- *In situ* integrity test pre and post-use
- Automated precise and consistent processing

pH measurement



- Can be formed in the mixer bag or off line
- Accurate to 0.1 pH unit

Media/buffer prep and sterile filtration



- Mixer control from system HMI
- Automated acid/base dosing into mixer to reach required pH
- Dosing volume controlled by pump speed and pulse time

Depth filtration



Multiple automated valving allows automation of:

- Pre-flush of depth media
- Operation at constant pump flow, monitoring feed pressure and Delta P
- Recovery flush

Membrane chromatography



- Sanitization and buffer flush to equilibrate the membrane, monitoring pH and conductivity
- Process at required flow and pressure

Virus inactivation



- Acid and base stock solutions held in 20 L bags
- Accurate dosing using automated sequences

Product validation

Cytiva maintains a stringent approach to quality of purchased and manufactured components. The system is designed and built to recognized industry standards, including but not limited to:

- EMC 89/336/EEC.
- Good Automated Manufacturing Practice (GAMP) current version.
- FDA 21 CFR Part 11 for electronic records.
- The rules governing medicinal products in the European Community, Volume IV, and good manufacturing practice for medicinal products, Annex 11, computerized systems.

The single-use flowpaths:

- Are assembled in a dedicated Class 10 000 (Grade C) cleanroom, to ISO standards 9001:2008 and 14001:2004.
- Have components which have been tested for biocompatibility and certified to USP <88> Biological Reactivity Tests, *in vivo*, for Class VI plastics.
- Include components that are certified TSE/BSE free.
- Are supplied double bagged and irradiated at a minimum dose of 25 KGy.

System description and components

System frame	304 stainless steel
230 V system dimensions (L x W x H)	1278 x 957 x 1133 mm
120 V system dimensions (L x W x H)	1321 x 981 x 1185 mm
System weight	Basic system approximately 205 kg Advanced system approximately 220 kg

Operating conditions

Pressure	0 to 4 bar
Feed pump flow	0.06 to 2220 L/h
Temperature	4 to 40°C
Power supply	230 V 1-phase 120 V 1-phase
Compressed air	Air source at 6 bar (for operation of valves)
Software	HMI software with Siemens or Allen Bradley

Technical and validation support

Cytiva can provide a high level of process validation support. We place our technical resources at the disposal of our customers in the form of worldwide technical advice and training. We can provide guidance to select and efficiently size filters that can be run on the Allegro MVP system across the range of applications.



Fig 7. Visual instructions for operators are accessible via the HMI screen..

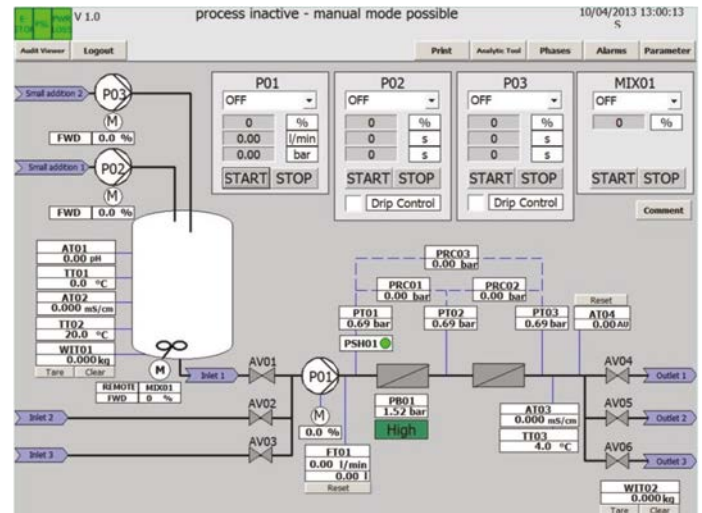


Fig 8. Displaying key processing parameters.

System options

Basic system components

20 L trays	X2 HDPE biocontainer trays	For use with Allegro 2D 20 L biocontainers
Pinch valves	Pneumatic actuated	For use with ½ in. or ¾ in. ID tubing
Valve caps	6 supplied	To cover unused pinch valves
Basket and drip trays	HDPE	For miscellaneous items – pH standards, pinch valve caps
Vertical brackets	4 supplied	To attach filters
Universal clamps	6 supplied	Flexible filter clamps for use with capsule diameters 5.0 to 10.54 cm
Pressure measurement	Single-use with pressure sensitive chip – 3 supplied	-0.48 to 5.2 bar
Flow measurement	Single-use turbine with reusable sensor – 3 supplied	30 to 1200 L/h ± 5% >180 L/h

Additional components for advanced system ⁽¹⁾

Acid and base pumps	Peristaltic dosing pumps – 2 supplied	0 to 180 L/h (9.5 mm tubing) 0.24 to 2.40 L/h (6.4 mm tubing)
pH/temperature probe	Re-usable InPro3253i	0 to 12 pH ± 0.1 pH unit 0 to 100 °C ± 1°C
Conductivity probe	Re-usable InPro7100i	0.02 to 500 mS/cm ± 7% 0 to 100°C ± 1°C
Conductivity in-line	Single-use flow cell	10 to 200 mS/cm, ± 0.25 mS/cm 0 to 100 µS/cm, ± 0.3 µS/cm
Temperature in-line	Single-use flow cell	4 to 50°C ± 0.50°C
UV measurement	Single-use flow cell	0 to 2 AU ± 0.1 AU

⁽¹⁾ Advanced system consists of basic system components plus additional components listed above

Main delivery pump options (pump must be ordered in addition to the base system)

Quattroflow 1200 pump	For high pressure, low pulsation unit operations 30 to 1080 L/h
Watson Marlow 720 DuN double headed peristaltic pump	For low pressure, high volume unit operations 0.06 to 2220 L/h

Product contact components

Components	Materials
Tubing	Platinum cured silicone, C-Flex
Diaphragm pump head	Head – polypropylene; diaphragm – EPDM; valves – EPDM
Manifold connectors	Polysulfone, silicone
Fittings	Polypropylene
Pressure sensor	Polysulfone
Flow sensor	PVDF with ruby bearing
UV sensor	Polysulfone
Conductivity sensor	Polypropylene
Triclamp gaskets	Silicone

Ordering information

Systems

Description	Product code
Advanced Allegro MVP system, 230 V, with Quattroflow pump	LGRMVPAD
Advanced Allegro MVP system, 230 V, with Watson Marlow pump	LGRMVPAP
Advanced Allegro MVP system, 110 V, with Quattroflow pump	LGRMVPADA
Advanced Allegro MVP system, 110 V, with Watson Marlow pump	LGRMVPAPA

Additional pumps

Description	Product code
Quattroflow diaphragm pump 230 V	SUSMVPPD
Watson Marlow pump 230 V	SUSMVPPP
Quattroflow diaphragm pump 110 V	WH305217
Watson Marlow pump 110 V	WH304544

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CY40462-11Dec23-DF

