



Allegro™ MVP Single-use System



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

Key Attributes

- ▶ Good engineering design provides reliability, robust operation and minimizes risk of operator error
- ▶ High degree of automation enables precise and consistent operation, control of key parameters, and minimizes 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 fully automated addition of acid & base stock solutions. Allegro mixers can be used with the MVP 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 pre-filters when selecting a flowpath ensures the manifold is completely suited to your process application.

No other system offers 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	



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

- ▶ Different capsule types
- ▶ Filter combination
- ▶ Filters in series / parallel

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 cm to 10.5 cm (up to 30 in. Pall 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.

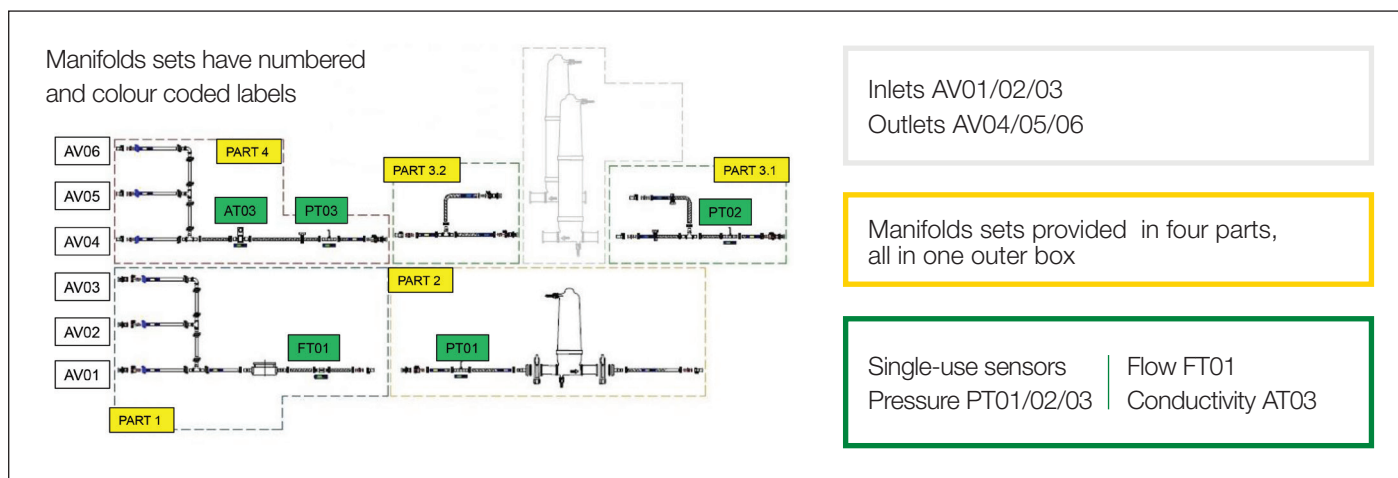
The acid and base stock solutions are located in the two 20 L trays.

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 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

Unique, intuitive, labelling on the Allegro MVP manifolds ensures quick and easy installation of flowpaths and filters in the correct location.



Application Areas for Allegro MVP System

pH measurement



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

Media/buffer prep & sterile filtration



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

Virus filtration



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



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

Virus inactivation



- ▶ Acid and base stock solutions held in 20 L bags
- ▶ High accuracy dosing using automated sequences

Membrane chromatography



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

Product Validation

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

- ▶ EMC 89/336/EEC
- ▶ Good Automated Manufacturing Practice (GAMP) current version
- ▶ CFR21 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.

System Description and Components

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

Technical and Validation Support

Pall can provide a high level of process validation support, through our Scientific and Laboratory Services (SLS) group. Pall places its extensive technical resources at the disposal of its customers in the form of world-wide 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.

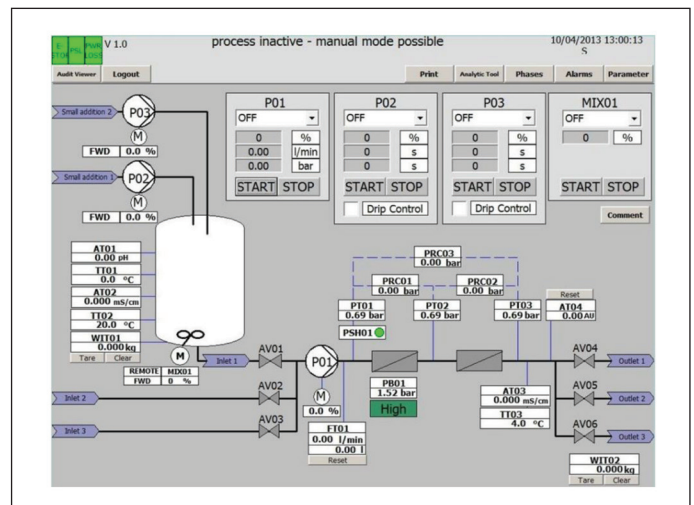


The Single Use Flowpaths:

- ▶ Are assembled in a dedicated Class 10000 (Grade C) Clean Room, to ISO standards 9001:2008 and 14001:2004 using validated assembly methods.
- ▶ 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

Operating Conditions

Pressure	0 – 4 bar
Feed pump flow	0.06 - 2220 L/hr
Temperature	4 – 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 PLC



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 cm 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/hr +/- 5% >180 L/hr

Additional Components for Advanced System¹

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

¹Advanced 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 – 1080 L/hour
Watson Marlow 720 DuN double headed peristaltic pump	For low pressure, high volume unit operations 0.06 – 2220 L/hr

Product Contact Components

Components

Tubing
Diaphragm pump head
Manifold connectors
Fittings
Pressure sensor
Flow sensor
UV sensor
Conductivity sensor
Triclamp gaskets

Materials

Platinum cured silicone, C-Flex®
Head – polypropylene; diaphragm - EPDM; valves - EPDM
Polysulfone, silicone
Polypropylene
Polysulfone
PVDF with ruby bearing
Polysulfone
Polypropylene
Silicone

Hardware

Part Numbers	Description
LGRMVPB230	Basic system 230 V
LGRMVPA230	Advanced system 230 V
LGRMVPB	Basic system 120 V
LGRMVPA	Advanced system 120 V

Delivery Pump Options

Part Numbers	Description
LGRMVPP	Allegro MVP system peristaltic pump WM720 (dual voltage motor)
LGRMVDP230	Allegro MVP diaphragm pump Q1200 (230 V fan)
LGRMVDP120	Allegro MVP diaphragm pump Q1200 (110 V fan)

To discuss your process needs and the full range of manifold options for this system, please contact your local Pall Specialist.



Life Sciences

Corporate Headquarters

Port Washington, NY, USA
+1.800.717.7255 toll free (USA)
+1.516.484.5400 phone
biopharm@pall.com e-mail

European Headquarters

Fribourg, Switzerland
+41 (0)26 350 53 00 phone
LifeSciences.EU@pall.com e-mail

Asia-Pacific Headquarters

Singapore
+65 6389 6500 phone
sgcustomerservice@pall.com e-mail

Filtration. Separation. Solution.sm



Visit us on the Web at www.pall.com/allegro

E-mail us at allegro@pall.com

International Offices

Pall Corporation has offices and plants throughout the world in locations such as: Argentina, Australia, Austria, Belgium, Brazil, Canada, China, France, Germany, India, Indonesia, Ireland, Italy, Japan, Korea, Malaysia, Mexico, the Netherlands, New Zealand, Norway, Poland, Puerto Rico, Russia, Singapore, South Africa, Spain, Sweden, Switzerland, Taiwan, Thailand, the United Kingdom, the United States, and Venezuela. Distributors in all major industrial areas of the world. To locate the Pall office or distributor nearest you, visit www.pall.com/contact.

The information provided in this literature was reviewed for accuracy at the time of publication. Product data may be subject to change without notice. For current information consult your local Pall distributor or contact Pall directly.

© 2013, Pall Corporation. Pall, Allegro, the Allegro design, Kleepak and Stax are trademarks of Pall Corporation. ® indicates a trademark registered in the USA and TM indicates a common law trademark.

Filtration.Separation.Solution.sm is a service mark of Pall Corporation. C-Flex is a trademark of Saint-Gobain Performance Plastics.