Allegro™ 50 L

MIXING SYSTEMS

Allegro™ 50 L single-use mixers are designed for high performance, ease of use, and manual to fully automated solution preparation between 2 and 50 L.

Mixing is a critical operation within many biopharmaceutical processes, for applications ranging from buffer and media preparation, in-process unit operations, such as low pH viral inactivation, to final formulation. The Allegro 50 L single-use mixer is part of our range of products and services providing integrated process solutions throughout the drug production process. Allegro mixers combine critical requirements for single-use technologies, such as ease-of-use, with established engineering design principles and criteria for robust mixer design to deliver exceptional mixing performance. The 50 L mixer features an advanced impeller design to facilitate low-volume mixing down to 2 L.

The standard model of the Allegro 50 L mixer incorporates a plastic tote. The mixer is also available in a jacketed stainless steel tote format, and can incorporate sensors (e.g. pH, conductivity and temperature) for on-line monitoring and control.

Sensor signals can be displayed locally on the mixer, or alternatively can be connected to an automated Allegro MVP system. With the added capability of a weighing platform option, the Allegro mixer can be integrated to the Allegro MVP automated single-use system, providing complete automated process monitoring and control solutions for applications that require mixing (e.g. of pH adjustment for buffers and virus inactivation).

Fig 1. Allegro 50 L standard mixer and weigh platform.

Applications

The Allegro 50 L mixer is designed to provide exceptional mixing performance for a wide range of applications, from upstream through downstream processes to formulation and filling. Due to its efficient mixing and high turn down ratio, this mixer is especially suited to small-volume formulation applications where fast, reproducible results are required.

Potential applications include:

- Upstream media preparation for cell culture
- Downstream pH adjustment, virus inactivation and buffer preparation
- Final formulation mixing

Allegro mixers can be combined with the Allegro MVP system to fully automate mixing and filtration processes, including fluid transfer to and from the mixers. These high-performance mixers lend themselves especially well to difficult mixing applications (such as mixing dense powders or high viscosities), applications requiring repeatable, fast mixing performance, or where biologicals sensitive to shear are being mixed.

Fig 2. Allegro 50 L mixer motor and UCI.

Fig 3. Allegro 50 L mixer.

Fig 4. Allegro 50 L mixer user control interface (UCI).

Features and benefits

Features	Benefits	
Four pitch blade low-volume impeller	Efficient low-shear general purpose mixing over a wide range of applications. Capable of mixing down to 2 L.	
Impeller rotation in clockwise or counterclockwise direction	Flexibility to perform both upflow and downflow for floating (low-density) and settling (high-density) fluid or solids	
Inflation of the mixer bag	Provides mixing envelope for consistent performance from 2 to 50 L and the ability to have a gas blanket in operation	
Jacketed tote	Temperature control in appropriate applications	
Plastic tote with see-through door	Excellent visibility of mixing process	
Sensor integration	In-process monitoring and control with local display and/or integration with automated Allegro MVP systems	
Weighing trolley option	Accurate control of fluid and powder additions during operation (can also link to the Allegro MVP system for automation)	
Contoured floor (plastic tote version)	Extremely high fluid recovery – 50 mL hold-up volume following draining (tested with water)	

Validation

The robustness of the Allegro 50 L mixer has been validated by the series of tests listed below:

- Biological safety (USP <87> and <88>)
- Physico-chemical tests (USP <661>)
- Particulate matter in injections (USP <788>)
- USP <85> LAL endotoxin (compared to limit for WFI)
- Extractables testing (water and ethanol)
- Gamma resistance
- Leak tests
- Drainage/product recovery
- Tubing connection robustness
- Shelf life studies

Contact us for a comprehensive validation guide.

Quality standards

Allegro single-use mixer biocontainers are leak tested at manufacture.

Allegro biocontainers, including the mixer, are manufactured in a controlled environment (Class 10 000) certified to ISO 13485 and ISO9001.

The materials of construction of the Allegro mixer biocontainer meet:

- USP <88> biological reactivity test *in vivo* for Class VI - 50°C Plastics
- USP <87> biological reactivity tests *in vitro*, Cytotoxicity
- ISO 10993 biological evaluation of medical devices
- USP <661> physico-chemical testing for plastics
- European Pharmacopeia (section 3.1.5)
- Japanese Pharmacopeia (section 61 Part 1)

Allegro mixer totes are manufactured under a quality management system certified to ISO 9001 and ISO 14001 and are in conformity with the requirements of the European Directive 2004/108/EC (Electromagnetic Compatibility) and European Directive 2006/95/EC (Low Voltage Safety).

Performance

Allegro mixers have been tested on a wide range of applications that represent a broad range of biopharmaceutical operations where mixing is required. The applications summary table lists the applications tested and the mixing performance achieved.

Fig 5. Allegro 50 L mixer showing installed system and support frame.

Applications summary table

Mixing type	Application	Solution	Time to mix
Liquid – liquid	Final formulation and filling	1% (v/v) acetone	< 1 minute
		1.25% (v/v) polysorbate 80	4.5 minutes
	Conductivity adjustment	200 g/L > 10 g/L NaCl	< 1 minute
Solid – liquid	Conductivity adjustment	1 M NaCl	5.5 minutes
	Media preparation	5.36 g/L DMEM	4 minutes
		47.6 g/L terrific broth	3 minutes
	Vaccine formulation	1.4 g/L aluminum hydroxide	< 10 minutes
	Final formulation and filling	0.04 g/L allura red dye in 250 cP corn syrup	3.5 minutes
	Buffer preparation	9.6 g/L PBS	< 2 minutes
		1 M ammonium sulfate	4.5 minutes
		21 g/L citrate buffer	2 minutes
	Dye test	0.05 g/L allura red dye	2.5 minutes

Contact us for full details of tests performed.

Technical specifications

	Allegro 50 L standard mixer	Allegro 50 L jacketed mixer	Allegro 50 L standard mixer and weigh platform	Allegro 50 L jacketed mixer and weigh platform
230 VAC PN	**LGRMXTTE50L230A**	**LGRMXJTTE50L230A**	**LGRMXWTTE50L230A**	**LGRMXJWTTE50L230A**
120 VAC PN	**LGRMXTTE50L120A**	**LGRMXJTTE50L120A**	**LGRMXWTTE50L120A**	**LGRMXJWTTE50L120A**
Min/max volume (L)	2 to 50			
Current (A)	5.1 (230 VAC) 9.2 (120 VAC)			
Frequency (Hz)	50 to 60			
Motor power (kW)	0.18			
Impeller speed (%)	0 to 100			
Gas supply (barg/psi)	2 to 6 / 30 to 90			
Weight (empty) (kg)	94	133	103	142
Weight (full) (kg)	144	186.5	153	195.5
Footprint (L x W) (mm/in.)	883 × 654 / 35 × 26	883 × 654 / 35 × 26	964 × 654 / 40 × 26	964 × 654 / 40 × 26
Height (mm/in.)	1286 / 51	1286 / 51	1364 / 54	1364 / 54
IP rating	65/Nema 4	65/Nema 4	65/Nema 4	65/Nema 4
Weighing platform accuracy (g)	N/A		20	
Materials of construction				
Tote	Plastic (acrylic)	304 stainless steel	Plastic (acrylic)	304 stainless steel
Frame	304 stainless steel			
Wheels	Nylon/stainless steel			

*Height does not include installed system height or the optional powder bag/tubing support frame

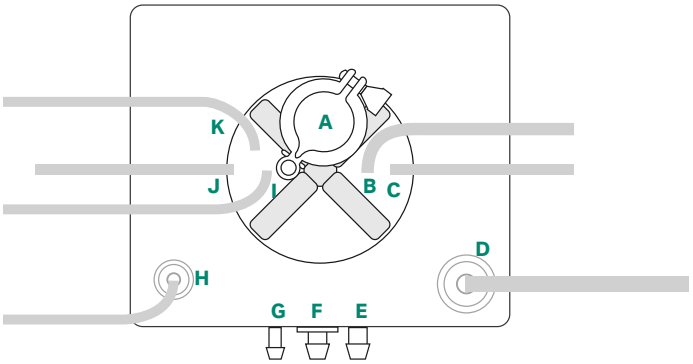
Ordering information

Standard hardware and options

	Allegro 50 L standard mixer	Allegro 50 L jacketed mixer	Allegro 50 L standard mixer and weigh platform	Allegro 50 L jacketed mixer and weigh platform
	System shown: LGRMXTTE50L01 with LGRMX125COND LGRMX225PH	System shown: LGRMXTTE50L07	System shown: LGRMXWTTE50L230A	
				
230 VAC	LGRMXTTE50L230A	LGRMXJTTE50L230A	LGRMXWTTE50L230A	LGRMXJWTTE50L230A
120 VAC	LGRMXTTE50L120A	LGRMXJTTE50L120A	LGRMXWTTE50L120A	LGRMXJWTTE50L120A
230 VAC with pH/cond transmitter	LGRMXTTE50L01	LGRMXTTE50L05	LGRMXTTE50L09	LGRMXTTE50L13
120 VAC with pH/cond t ransmitter	LGRMXTTE50L02	LGRMXTTE50L06	LGRMXTTE50L10	LGRMXTTE50L14
230 VAC with temperature transmitter	LGRMXTTE50L03	LGRMXTTE50L07	LGRMXTTE50L11	LGRMXTTE50L15
120 VAC with temperature transmitter	LGRMXTTE50L04	LGRMXTTE50L08	LGRMXTTE50L12	LGRMXTTE50L16
125 mm conductivity sensor	LGRMX125COND			
125 mm pH sensor	LGRMX125PH			
225 mm pH sensor	LGRMX225PH			
PT100 temperature sensor	LGRMXTEMP			
Powder bag/tubing support frame	LGRMX50LSF			
Funnel support	LGRMX50LFS			
Tubing support	LGRMX50LTBS			
FAT	LGRMXTTE50L-FAT	LGRMXJTTE50L-FAT	LGRMXWTTE50L-FAT	LGRMXJWTTE50L-FAT

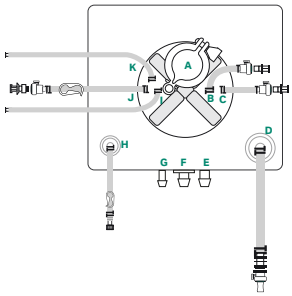
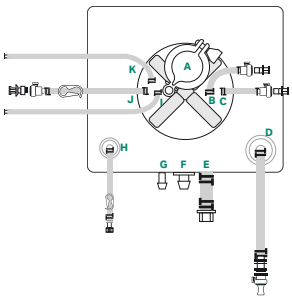
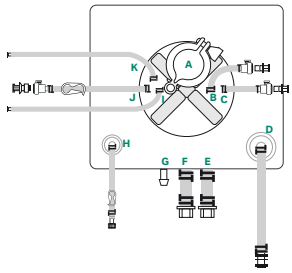
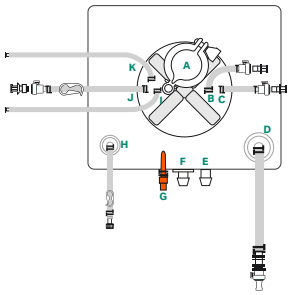
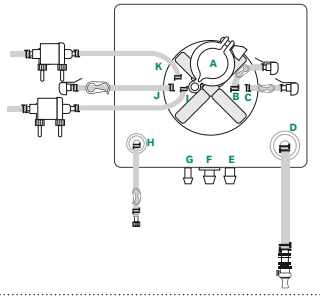
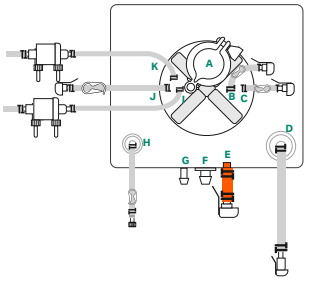
Standard single-use systems

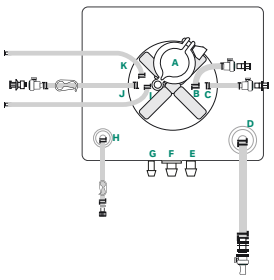
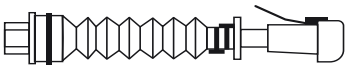
The following systems are standard designs for different mixing applications. Further standard designs are available. Contact us for full details. Single-use mixer systems can also be designed according to specific application requirements. For a customized design, please contact us with specific application details.



A	Powder addition port	3 in.
B	Fluid addition port	¼ in.
C	Fluid addition port	¼ in.
D	Main fluid outlet	½ in.
E	Sensor port	¾ in.
F	Sensor port	¾ in.
G	Sensor port	½ in.
H	Sample port	¼ in.
I	Gas inflation port	¼ in.
J	Main fluid inlet	½ in.
K	Gas exhaust port	½ in.

Fig 6. All systems have the ports shown in common. Left, location of ports; right, definitions and sizes.

Product code	Description	Schematic
609-100Q	• Quick-connect fittings • Flush outlet port • Needleless luer sample port	
609-100R	• Quick-connect fittings • Flush outlet port • Needleless luer sample port • One threaded sensor port (for 125 mm sensors)	
609-100S	• Quick-connect fittings • Flush outlet port • Needleless luer sample port • Two threaded sensor ports (for 125 mm sensors)	
609-100T	• Quick-connect fittings • Flush outlet port • Needleless luer sample port • One thermowell port (for PT100 sensor)	
609-100U	• Kleenpak™ sterile connectors • Flush outlet port • Needleless luer sample port • Sterilizing grade vent filters	
609-100V	• Kleenpak sterile connectors • Flush outlet port • Needleless luer sample port • Sterilizing grade vent filters • One Kleenpak sensor port (for 225 mm pH sensor). Use with bellows assembly (639-80N)	

Product code	Description	Schematic
639-100W	• Quick-connect fittings • Flush outlet port • Needleless luer sample port • Non-irradiated	
639-80N	• Bellows assembly for use with Kleenpak sensor port and 225 mm pH sensor • Non-irradiated	

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