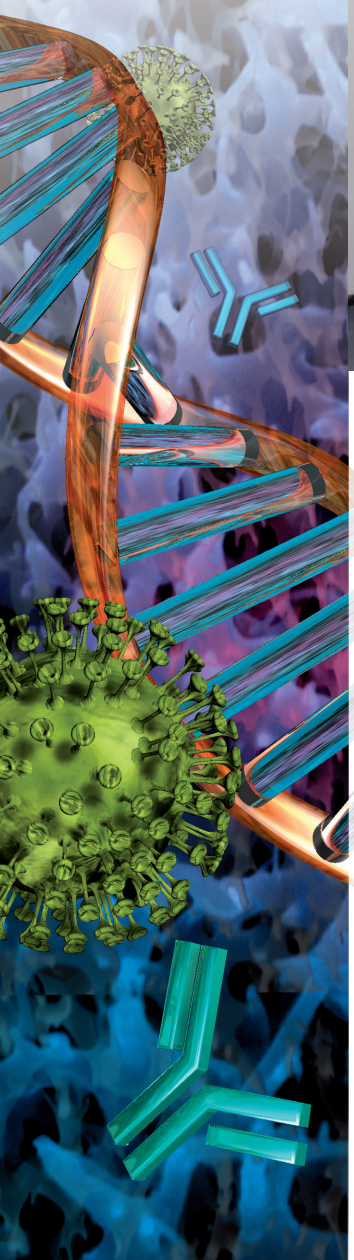
PALL Life Sciences

USD2745c[1]

Allegro™ Single-Use Mixers



High performance, easy-to-use mixers for manual to fully automated solution preparation

Mixing is a critical operation within biopharmaceutical processes for many applications, ranging from buffer and media preparation, in-process unit operations such as low pH viral inactivation, to final formulation. The Allegro single-use mixers are part of Pall's expanding range of Allegro products and services providing integrated process solutions throughout the drug production process. The Allegro mixers combine critical requirements for single-use technologies, such as extreme ease-of-use, with established engineering principles and criteria for robust mixer design to deliver the ultimate in mixing performance.

The Allegro mixers are available in 200 L, 500 L and 1000 L sizes, in both standard and jacketed stainless steel tote formats, and can incorporate sensors (e.g. pH, conductivity and temperature) for on-line monitoring and control. Sensor signals can be handled locally on the mixer, or alternatively, can be fed directly to an existing Distributed Control System (DCS) or to an Automated Pall MVP single-use system. With the added capability of load cell integration, the Allegro mixers from Pall can be fully integrated to the Allegro MVP automated single-use systems, providing complete automated process monitoring and control solutions for all applications that require mixing (e.g pH adjustment for buffers and virus inactivation).

AllegroSystems™
The Single-Use Solution

Filtration. Separation. Solution.SM

Applications

The Allegro mixers are designed to provide exceptional mixing performance for a wide range of applications from upstream through the downstream process to formulation and filling. With jacketed and standard totes that can integrate on-line sensor technologies and load cells, potential applications include:

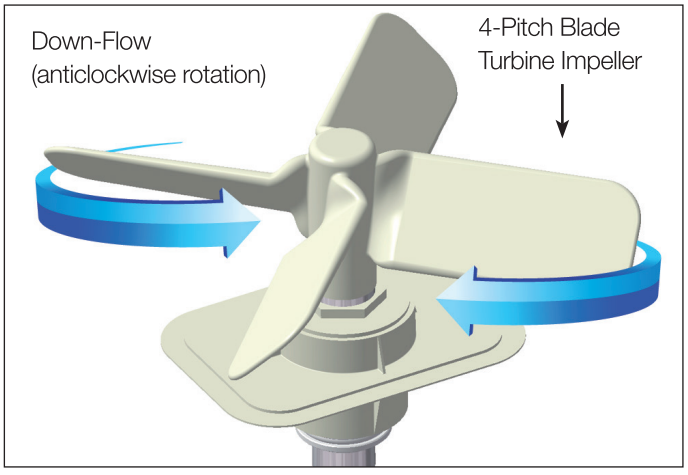
- Upstream media preparation for cell culture
- Downstream pH adjustment, virus inactivation and buffer preparation
- Final formulation mixing

In addition to the mixers, Pall also offers a wide range of complimentary technologies within the Allegro single-use platform (such as filters incorporating state-of-the-art membranes and sterile connection and disconnection devices) providing fully validated, integrated processing solutions from upstream to final formulation and filling. The Allegro mixers can be combined with the Pall MVP system to fully automate mixing and filtration processes, including fluid transfer to and from the mixers. The high performance mixer lends itself especially well to difficult mixing applications (mixing dense powders or high viscosities), applications requiring repeatable, fast mixing performance, or where biologicals sensitive to shear are being mixed.

Feature	Benefit
Design principles based on existing Allegro 3D tote format for ease-of-use	Very easy and quick to install and remove the single-use systems pre and post-use

Product Features and Benefits

Feature	Benefit
4 pitch blade impeller	Efficient, low shear general purpose mixing over a wide range of applications and shear sensitive soluitons
Impeller rotation in clockwise or counter-clockwise direction	Flexibility to perform both up-flow and down-flow for floating (low density) and settling (high density) fluid or solids



Feature	Benefit
Inflation of the mixer bag	Provides mixing envelope for consistent performance from 50 - 1000 L and the ability to have a gas blanket in operation and mix a range of volumes

Mixer Size	200 L	500 L	1000 L
			
Minimum Volume (L)*	50	100	155
Maximum Volume (L)	200	500	1000

** minimum volume also covers on-line sensors*

Feature	Benefit
Jacketed Totes	Temperature control in appropriate applications

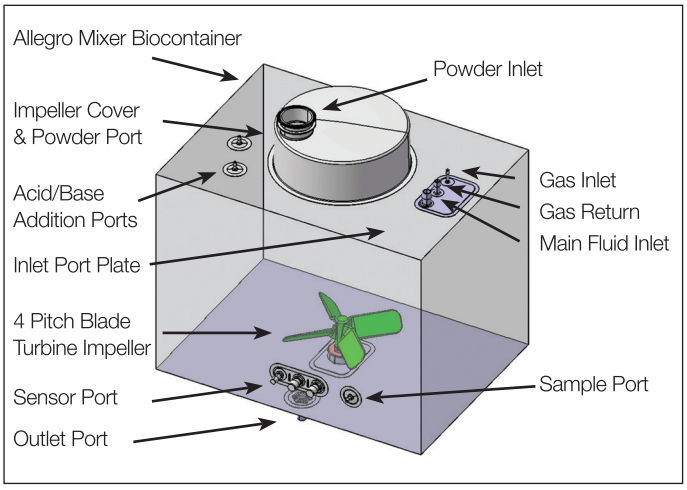
Feature	Benefit
Sensor integration	Allows in-process monitoring and control through integration with automated Allegro MVP systems

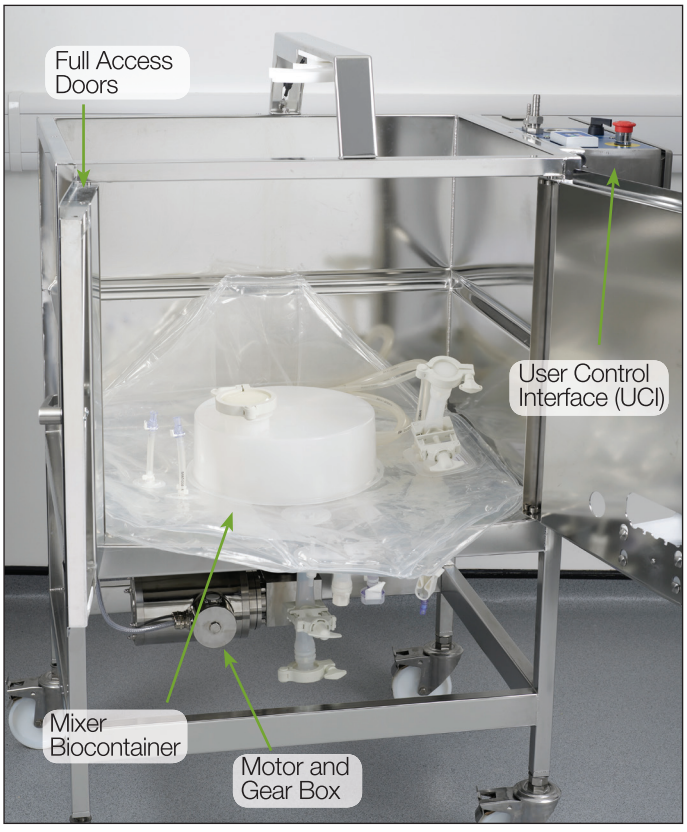
Feature	Benefit
Uses existing Allegro film with high clarity and ultra-low extractables	Material/validation consistency across all Allegro biocontainer based systems

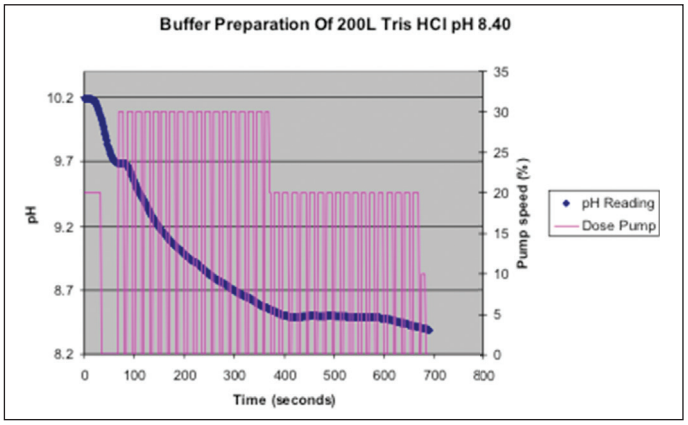
Feature	Benefit
Optional baffles available	To assist in reducing air entrapment at high rotation speed for sensitive molecules

Single-Use Mixer Design

The Allegro single-use mixer design is based on proven engineering principles used to develop efficient and appropriate mixing in a wide range of biopharmaceutical applications. Aspects of power input, impeller geometry and position, flow characteristics, flow pattern, pumping and shear were all considered as part of the design process.







pH target of 8.40 to an accuracy of ± 0.06 pH units achieved after 36.5 doses in <12 minutes.

High Performance Mixing

The Allegro mixers have been tested on a wide range of applications representing a broad range of biopharmaceutical operations where mixing is required. The Applications Summary Table summarizes the applications tested and the mixing performance achieved.

Allegro single-use mixers have been tested to demonstrate capability to mix a wide variety of liquid-liquid, solid-liquid, and high viscosity solutions. For further details on mixing performance, please refer to the Application note, document reference: USD2744.

Quality Standards and Validation

The Allegro single-use mixer biocontainers are 100% leak tested at manufacture.

All 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)

The mixer totes are manufactured under a Quality Management System Certified to ISO 9001 and ISO 14001 and is in conformity with the requirements of the European Directive 2004/108/EC (Electromagnetic Compatibility) and European Directive 2006/95/EC (Low Voltage Safety).

Application Summary

Type of Mixing	Solution	200 L	500 L (150 rpm)	1000 L (150rpm)
Solid – Liquid	Allura Red Dye (.05 g/L)	5 seconds (75 rpm)	2 min	5 min
	DMEM Media (5.36 g/L)	< 7 min (150 rpm)	6 min	11 min
	PBS Buffer (9.6 g/L)	< 5 min (150 rpm)	4 min	7 min
	NaCl (1 M) (58.44 g/L)	< 1 min (150 rpm)	7 min	12 min
Liquid – Liquid	NaCl (200 g/L → 10 g/L)	< 1 min	4 min	6 min

Product Validation

As part of our rigorous approach to product validation, Pall has conducted a wide range of tests in addition to the general performance tests to prove the robustness of the Allegro mixer. A summary of key validation tests are summarized 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 (Maximum 50 kGy)
- Leak tests
- Drainage/product recovery
- Tubing connection robustness

Technical Specifications

	Standard Mixer	Jacketed Mixer
Mixer Tote Part Number	LGRMXTTE200L230B LGRMXTTE200L120B	LGRMXJTTE200L230B LGRMXJTTE200L120B
Mixing volume – Max (L)	200	200
Voltage (Vac)	230 120	
Current (A)	5.1 9.2	
Frequency (Hz)	50 60	
Motor power (kW)	0.37	
Impeller range (rpm)	50 - 150	
Mixing volume - Covering impeller (L)	40	40
Mixing volume - Covering sensors/sample port (L)	46	46
Gas supply (barg/psig)	4 - 6 / 60 - 90	
Gas connections	SUPPLY & CABINET VENT: 10 mm Pneumatic tubing outside diameter BAG VENT: 12 mm Pneumatic tubing outside diameter	
Weight - empty (kg)	120	195
Weight - full (kg)	340	421
Footprint* (L x W) (mm)	785 x 615	785 x 615
Height (mm)	1401	1401

Materials of Construction	Standard Mixer	Jacketed Mixer

Mixer Tote Part Number	LGRMXTTE200L230B LGRMXTTE200L120B	LGRMXJTTE200L230B LGRMXJTTE200L120B
Mixer tote	304 SS	
Mixer biocontainer (original)	**Biocontainer film; outlet port; inlet manifold & top hat:** Low Density Polyethylene (LDPE); **Impeller:** Polysulfone (PS); **Flush outlet port valve (½ in.):** Polysulfone (PS); **Shaft:** Stainless Steel SS; **O-rings:** Silicone; **Mechanical seals:** Low Density Polyethylene (LDPE)	
Mixer biocontainer (sensor biocontainer)	**Biocontainer film; inlet ports; top hat; hose barb outlet port:** Low Density Polyethylene (LDPE); **Impeller:** Polysulfone (PS); **Shaft:** Stainless Steel SS; **O-ring:** Silicone; **Mechanical seals:** Low Density Polyethylene (LDPE)	

**Leg centre distances*

	Standard Mixer	Jacketed Mixer
Mixer Tote Part Number	LGRMXTTE500L230B LGRMXTTE500L120B	LGRMXJTTE500L230B LGRMXJTTE500L120B
Mixing volume – Max (L)	500	500
Voltage (Vac)	230 120	
Current (A)	5.1 9.2	
Frequency (Hz)	50 60	
Motor power (kW)	0.37	
Impeller range (rpm)	50 - 150	
Mixing volume - Covering impeller (L)	80	80
Mixing volume - Covering sensors/sample port (L)	100	100
Gas supply (barg/psig)	4 - 6 / 60 - 90	
Gas connections	SUPPLY & CABINET VENT: 10 mm Pneumatic tubing outside diameter BAG VENT: 12 mm Pneumatic tubing outside diameter	
Weight - empty (kg)	180	313
Weight - full (kg)	730	878
Footprint* (L x W) (mm)	1170 x 815	1170 x 815
Height (mm)	1470	1470
Materials of Construction		
Mixer tote	304 SS	
Mixer biocontainer (sensor biocontainer)	**Biocontainer film; inlet ports; top hat; hose barb outlet port:** Low Density Polyethylene (LDPE); **Impeller:** Polysulfone (PS); Shaft: Stainless Steel SS; O-ring: Silicone; **Mechanical seals:** Low Density Polyethylene (LDPE)	

**Leg centre distances*

	Standard Mixer	Jacketed Mixer
Mixer Tote Part Number	LGRMXTTE1000L230B LGRMXTTE1000L120B	LGRMXJTTE200L230B LGRMXJTTE200L120B
Mixing volume – Max (L)	1000	1000
Voltage (Vac)	230 120	
Current (A)	5.1 9.2	
Frequency (Hz)	50 60	
Motor power (kW)	0.37	
Impeller range (rpm)	50 - 150	
Mixing volume - Covering impeller (L)	125	125
Mixing volume - Covering sensors/sample port (L)	155	155
Gas supply (barg/psig)	4 - 6 / 60 - 90	
Gas connections	SUPPLY & CABINET VENT: 10 mm Pneumatic tubing outside diameter BAG VENT: 12 mm Pneumatic tubing outside diameter	
Weight - empty (kg)	220	434
Weight - full (kg)	1320	1549
Footprint* (L x W) (mm)	1360 x 1084	1360 x 1084
Height (mm)	1482	1482
Materials of Construction		
Mixer tote	304 SS	
Mixer biocontainer (sensor biocontainer)	**Biocontainer film; inlet ports; top hat; hose barb outlet port:** Low Density Polyethylene (LDPE); **Impeller:** Polysulfone (PS); **Shaft:** Stainless Steel SS; **O-ring:** Silicone; **Mechanical seals:** Low Density Polyethylene (LDPE)	

**Leg centre distances*

Heat Exchange Area Estimation for Jacketed Mixer Totes:

Mixer Capacity (L)	Assumed Minimum Working Volume (L)	Area Available for Heat Exchange @ Min. Working Volume (m^2)	Calculated Maximum Working Volume (L)	Area Available for Heat Exchange @ Max. Working Volume (m^2)
200	46	0.49	200	1.0
500	100	0.93	500	1.8
1000	155	1.37	1000	2.9

Allegro Mixer Standard Single-Use Systems Ordering Information

Scale	Part Number	Description
200 L	LGRMXTTE200L230B	Standard Mixer Tote 230 Volts
200 L	LGRMXJTTE200L230B	Jacketed Mixer Tote 230 Volts
200 L	LGRMXTTE200L120B	Standard Mixer Tote 120 Volts
200 L	LGRMXJTTE200L120B	Jacketed Mixer Tote 120 Volts
200 L	LGRMX20023003	Standard Mixer Tote 230 Volts + Mettler Toledo (pH &/or Cond) Transmitter
200 Lt	LGRMXJ20023004	Jacketed Mixer Tote 230 Volts + Mettler Toledo (pH &/or Cond) Transmitter
200 L	LGRMX20012003	Standard Mixer Tote 120 Volts + Mettler Toledo (pH &/or Cond) Transmitter
200 L	LGRMXJ20012004	Jacketed Mixer Tote 120 Volts + Mettler Toledo (pH &/or Cond) Transmitter
200 L	LGRMXJ20023005	Jacketed Mixer Tote 230 Volts + Status Temp Transmitter & PT100 Sensor
200 L	LGRMXJ20012005	Jacketed Mixer Tote 120 Volts + Status Temp Transmitter & PT100 Sensor
200 L	LGRMXTTE200L-FAT	FAT for Mixer Tote 120 or 230 Volts
200 L	LGRMXW200	Standard tote weighing platform
200 L	LGRMXJW200	Jacketed tote weighing platform
200 L	LGRMX200LIQOQ	IQ/OQ Documentation for 200 L Mixer
500 L	LGRMXTTE500L230B	Standard Mixer Tote 230 Volts
500 L	LGRMXJTTE500L230B	Jacketed Mixer Tote 230 Volts
500 L	LGRMXTTE500L120B	Standard Mixer Tote 120 Volts
500 L	LGRMXJTTE500L120B	Jacketed Mixer Tote 120 Volts
500 L	LGRMX50023003	Standard Mixer Tote 230 Volts + Mettler Toledo (pH &/or Cond) Transmitter
500 L	LGRMXJ50023004	Jacketed Mixer Tote 230 Volts + Mettler Toledo (pH &/or Cond) Transmitter
500 L	LGRMX50012003	Standard Mixer Tote 120 Volts + Mettler Toledo (pH &/or Cond) Transmitter
500 L	LGRMXJ50012004	Jacketed Mixer Tote 120 Volts + Mettler Toledo (pH &/or Cond) Transmitter
500 L	LGRMXJ50023005	Jacketed Mixer Tote 230 Volts + Status Temp Transmitter & PT100 Sensor
500 L	LGRMXJ50012005	Jacketed Mixer Tote 120 Volts + Status Temp Transmitter & PT100 Sensor
500 L	LGRMXTTE500L-FAT	FAT for Mixer Tote 120 or 230 Volts
500 L	LGRMXW500	Standard tote weighing platform
500 L	LGRMXJW500	Jacketed tote weighing platform
500 L	LGRMX500LIQOQ	IQ/OQ Documentation for 500 L Mixer
1000 L	LGRMXTTE1000L230B	Standard Mixer Tote 230 Volts
1000 L	LGRMXJTTE1000L230B	Jacketed Mixer Tote 230 Volts

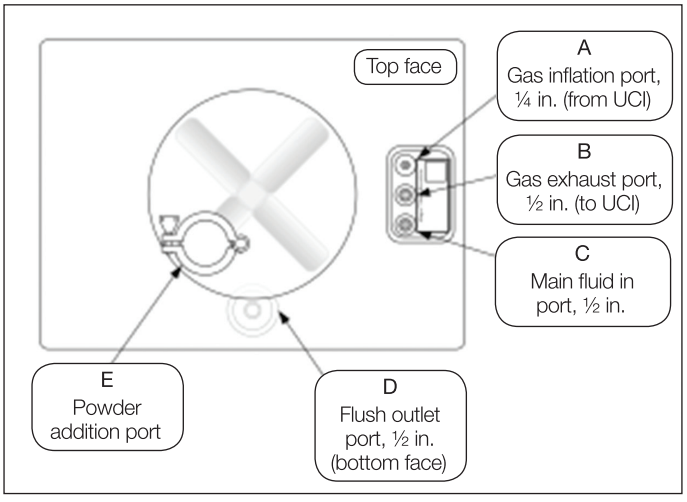
Scale	Part Number	Description
1000 L	LGRMXTTE1000L120B	Standard Mixer Tote 120 Volts
1000 L	LGRMXJTTE1000L120B	Jacketed Mixer Tote 120 Volts
1000 L	LGRMX100023003	Standard Mixer Tote 230 Volts + Mettler Toledo (pH &/or Cond) Transmitter
1000 L	LGRMXJ100023004	Jacketed Mixer Tote 230 Volts + Mettler Toledo (pH &/or Cond) Transmitter
1000 L	LGRMX100012003	Standard Mixer Tote 120 Volts + Mettler Toledo (pH &/or Cond) Transmitter
1000 L	LGRMXJ100012004	Jacketed Mixer Tote 120 Volts + Mettler Toledo (pH &/or Cond) Transmitter
1000 L	LGRMXJ100023005	Jacketed Mixer Tote 230 Volts + Status Temp Transmitter & PT100 Sensor
1000 L	LGRMXJ100012005	Jacketed Mixer Tote 120 Volts + Status Temp Transmitter & PT100 Sensor
1000 L	LGRMXTTE1000L-FAT	FAT for Mixer Tote 120 or 230 Volts
1000 L	LGRMXW1000	Standard tote weighing platform
1000 L	LGRMXJW1000	Jacketed tote weighing platform
1000 L	LGRMX1000LIQOQ	IQ/OQ Documentation for 1000 L Mixer

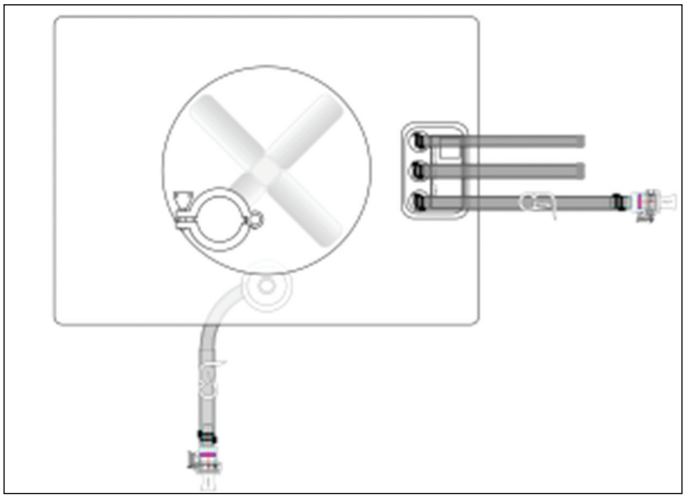
Single-Use Mixer Systems

The following irradiated system exists as off-the-shelf designs for different mixing applications.
Further standard designs are available. Contact Pall for full details.

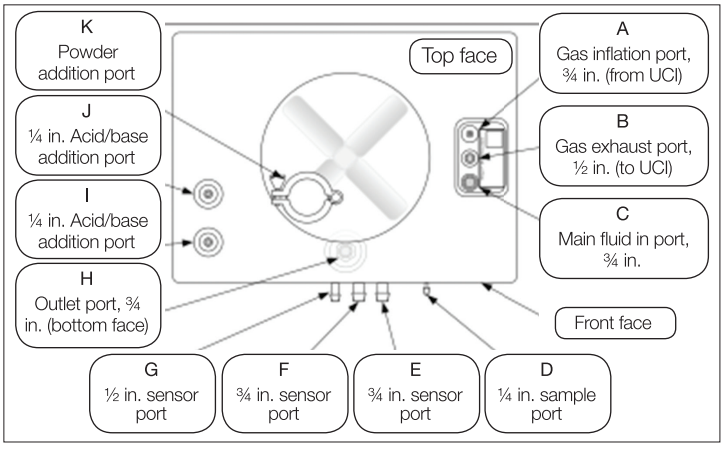
Single-use mixer systems can also be designed according to specific application requirements. For a customized design, please contact your Pall representative with your specific application details.

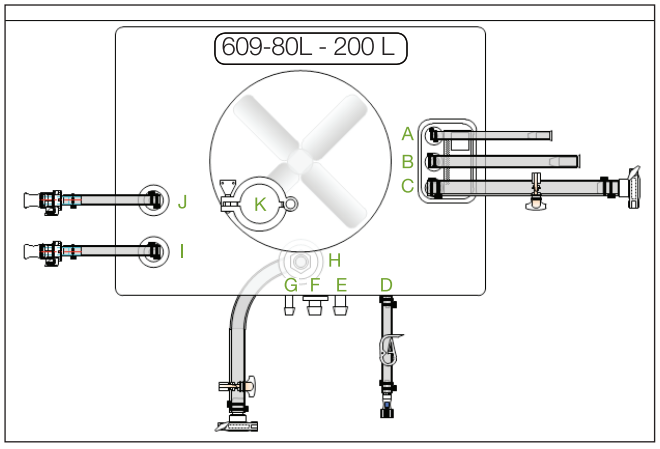
Mixer System Design Number	609-40C 200 L
Port ID	Basic irradiated design for fluid and powder addition
A	¼ in. Thermo-elastomer tubing, welded end
B	½ in. Thermo-elastomer tubing, welded end
C	½ in. Thermo-elastomer tubing (0.2 m), female MPX and plug
D	½ in. Thermo-elastomer tubing (0.2 m), female MPX and plug
E	3 in. Blanked sanitary powder port



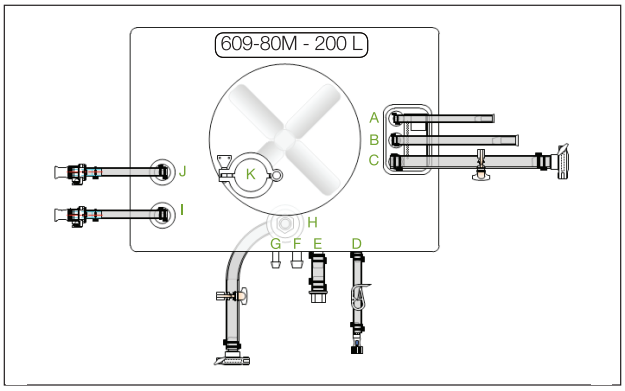


Mixer System Design Number	609-80L 200 L
Port ID	Basic design allows for acid/base adjustment and sampling for off-line analytics/QC (using customers own sensors)
A	¼ in. Platinum cured silicone, plugged
B	½ in. Platinum cured silicone, plugged
C	¾ in. Platinum cured silicone with sanitary fittings
D	¼ in. Platinum cured silicone with swabable Luer fittings
E	Closed
F	Closed
G	Closed
H	¾ in. Platinum cured silicone with sanitary fittings
I	¼ in. Platinum cured silicone with MPC male connector and cap
J	¼ in. Platinum cured silicone with MPC male connector and cap
K	3 in. Powder port with gasket, blank and clamp



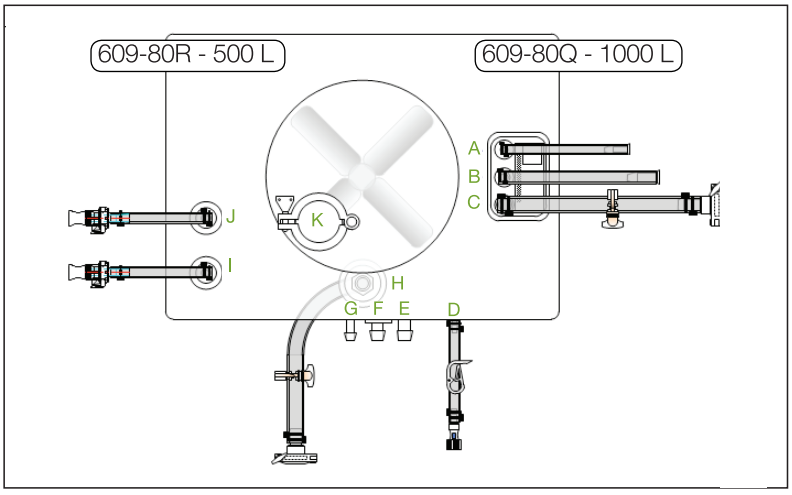


Mixer System Design Number	609-80M 200 L
Port ID	Design allows for 1 non-sterile sensor attachment (pH or Conductivity). Sampling for off-line analytics/QC and acid and base adjustment.
A	¼ in. Platinum cured silicone, plugged
B	½ in. Platinum cured silicone, plugged
C	¾ in. Platinum cured silicone with sanitary fittings
D	¼ in. Platinum cured silicone with swabable Luer fittings
E	¾ in. Platinum cured silicone with sensor screw fitting
F	Closed
G	Closed
H	¾ in. Platinum cured silicone with sanitary fittings
I	¼ in. Platinum cured silicone with MPC male connector and cap
J	¼ in. Platinum cured silicone with MPC male connector and cap
K	3 in. Powder port with gasket, blank and clamp

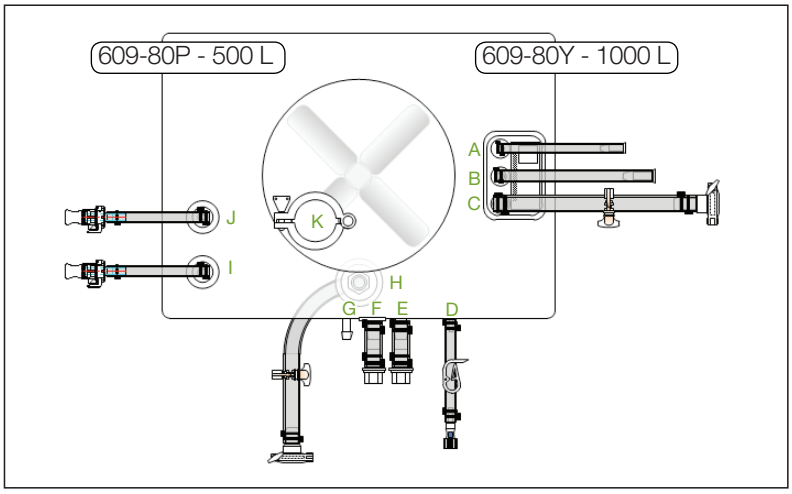


Single-use mixer systems can also be designed according to specific application requirements. Appropriate filters (sterilizing grade/ bioburden/mycoplasma reduction) and Kleenpak sterile connectors for sterile fluid addition can be incorporated into system designs. For a customized design, please contact your Pall representative with your specific application details.

Mixer System Design Number	609-80R – 500 L; 609-80Q – 1000 L
Port ID	**Basic Design: Sample line; Acid/Base addition lines; Main fluid in/out with sanitary ports**
A	¼ in. Platinum Cured Silicone, Plugged
B	½ in. Platinum Cured Silicone, Plugged
C	1 in. Platinum Cured Silicone + Sanitary fittings
D	¼ in. Platinum Cured Silicone + Swabable Luer Fittings
E	¾ in. Closed
F	¾ in. Closed
G	½ in. Closed
H	1 in. Platinum Cured Silicone + Sanitary fittings
I	¼ in. Platinum Cured Silicone + MPC Male Connector and Cap
J	¼ in. Platinum Cured Silicone + MPC Male Connector and Cap
K	3 in. Powder Port with Gasket, Blank and Clamp



Mixer System Design Number	609-80P – 500 L, 609-80Y 1000 L
Port ID	Design allows for 2 non-sterile sensor attachment (pH and/or Conductivity). Sampling for off-line analytics/QC and acid and base adjustment
A	¼ in. Platinum Cured Silicone, Plugged
B	½ in. Platinum Cured Silicone, Plugged
C	1 in. Platinum Cured Silicone + Sanitary fittings
D	¼ in. Platinum Cured Silicone + Swabable Luer Fittings
E	¾ in. Platinum Cured Silicone + Sensor Port/Plug (non-aseptic)
F	¾ in. Platinum Cured Silicone + Sensor Port/Plug (non-aseptic)
G	½ in. Closed
H	1 in. Platinum Cured Silicone + Sanitary fittings
I	¼ in. Platinum Cured Silicone + MPC Male Connector and Cap
J	¼ in. Platinum Cured Silicone + MPC Male Connector and Cap
K	3 in. Powder Port with Gasket, Blank and Clamp



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