# **Instructional Documentation**



USD 3193a

# Allegro<sup>TM</sup> Cubical LevMixer® and Magnetic Mixer Tanks Instructions For Use



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# 1 Safety Symbols and Statements

#### 1.1 Types of Safety Symbols

All safety symbols: warning, prohibition, mandatory and Globally Harmonized System (GHS) can / will be accompanied by additional text and signs to explain the reason for the warning, explain the nature of the prohibition, and explain the reason for the action.

Table 1

ISO 7010 safety signs and symbols

Color	Meaning / Purpose	Example	Description	Instruction and Information
Red	Prohibition / Danger		Red ring and diagonal bar with black symbol on white background	Specifies behavior that is prohibited because it would result in an immediate or potential risk of personal injury or threat to health / life.
Yellow	Warning / Caution	4	Yellow triangle with black border and black symbol	Warns of hazards which could result in personal injury or threat to health.
Blue	Mandatory / Information		Blue circle with white symbol	Specifies an action required or informs of information to safeguard personal health and / or avoid risk of personal injury.
Red	GHS Hazards	$\Diamond$	Red diamond, white background with a black symbol	Classifies the hazards of chemical products and communicates health and safety information.

## 1.2 Safety Messages

## Table 2

Safety signs and symbols within this document

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Symbol

#### Instruction and Information

Prior to operating, the instructions must be read in entirety.

#### Highlights important information regarding instructions for use.

If the unit is transported or stored in temperatures colder than the operating environment it is necessary to wait 1-2 hours to equalize the internal temperatures of the unit before powering on.



Keep the supplied magnetic shields on mixing biocontainers, magnetic chargers, and impellers when not in use. More than one person is required to move the tank.

The tank should only be moved using the tank handle, and only with the tank/mixing biocontainer empty and the drive detached.



#### Identifies a dangerous situation that may result in personal injury.

Do not attempt to move the tank by pulling/pushing the handle of the installed drive unit.

Do not use this equipment in any manner inconsistent with these operating instructions or under any conditions that exceed the environmental specifications stated.



Persons who have pace makers and implanted medical devices should not operate the equipment.



Caution should be taken. Potential risk to equipment. For technical assistance contact your Pall representative.



#### **Electrical Safety**

The control box should remain closed whist the unit is plugged in. Contact your Pall representative for any electrical faults.



Strong Magnetic field. Take caution when in close proximity to the impeller.

### 2 Introduction

The following procedure is provided for the installation of Pall single-use mixing biocontainers with capacities of 50 L, 100 L, 200 L, 400 L, 650 L and 1000 L in the corresponding stainless steel cubical mixing tanks. (For 2000 L installation procedures refer to Pall document reference USD3197). Pall cubical mixing tanks must be used in accordance with this manual. The instructions contained in the product documentation should be read thoroughly because they contain valuable information gained by extensive experience. It is very important that all instructions in this document are carefully followed and, where appropriate, they should be incorporated into the user's standard operating procedures. If some of the procedures do not suit your needs, please consult Pall or your local distributor before finalizing your system. Use of this product in a manner other than in accordance with Pall's current recommendations may lead to injury or product loss. Pall cannot accept liability for such injury or loss.

# 3 Specifications

All specifications are valid for standard mixing tanks only. Refer to customer approved drawings and specification for custom mixing tanks, which may deviate from what is stated in this manual.

Standard mixing tanks described in this manual are designed for use with the LevMixer and Magnetic Mixer single-use mixing biocontainers.

The standard mixing tanks have 4 available configurations:

- 1. Standard
- 2. Standard with load cells
- 3. Standard jacketed
- 4. Standard jacketed with load cells

All tanks have a push handle on the docking side of the tank.

All tanks, except for the 50 L tanks, have a window door for easy mixing biocontainer installation. 650 L and 1000 L tanks have a double door.

All tanks, except for the 50 L tanks, have an insert plate for front and bottom tubing. As of 200 L, two bottom insert plates are included, one closed and one drain insert plate.

Additional options include probe supports, powder port supports, powder bag lifts and closed-loop heater/chillers for temperature control.

The mixing system can accommodate a variety of standard and custom-designed single-use mixing biocontainers available from Pall Life Sciences.

These tanks are not designed to be compatible with other mixing technologies nor with biocontainers supplied by other manufacturers. Modification of these tanks without prior authorization from Pall will immediately void the warranty

**Table 3**Specifications

Part Number	Dimensions, mm (inches) W x D x H	Weight, kg (lbs)
LEV50NC	836 x 830 x 938 (32.9 x 32.7 x 36.9)	57 (125)
LEVI00NC	933 x 964 x 1054 (36.7 x 37.9 x 41.5)	81 (179)
LEV200NC	861 x 895 x 1162 (33.9 x 35.2 x 45.7)	106 (234)
LEV400NC	1079 x 1164 x 1273 (42.5 x 45.8 x 50.1)	151 (333)
LEV650NC	1154 x 1273 x 1442 (45.4 x 50.1 x 56.8)	182 (402)
LEV1000NC	1241 × 1409 × 1597 (48.9 × 55.5 × 62.9)	234 (516)
LEV50JC	818 x 807 x 941 (32.2 x 31.8 x 37.0)	126 (278)
LEV100JC	887 x 894 x 1056 (34.9 x 35.2 x 41.6)	114 (252)
LEV200JC	864 x 847 x 1160 (34.0 x 33.3 x 45.7)	160 (353)
LEV400JC	1060 x 1157 x 1275 (41.7 x 45.5 x 50.2)	230 (507)
LEV650JC	1197 x 1249 x 1444 (47.1 x 49.2 x 56.8)	320 (706)
LEV1000JC	1291 x 1387 x 1599 (50.8 x 54.6 x 62.9)	403 (889)
LEV50NC420SLC	889 x 855 x 1410 (35.0 x 33.7 x 55.5)	70 (155)
LEVI00NC420SLC	1238 x 1070 x 1596 (48.7 x 42.1 x 62.8)	165 (364)
LEV200NC420SLC	1231 x 1071 x 1596 (48.5 x 42.2 x 62.8)	188 (415)
LEV400NC420SLC	1266 x 923 x 1595 (49.8 x 36.3 x 62.8)	224 (494)
LEV650NC420SLC	1564 x 1140 x 1562 (61.6 x 44.9 x 61.0)	274 (605)
LEVI000NC420SLC	1615 x 1190 x 1597 (63.6 x 46.9 x 62.9)	324 (715)
LEV50JC420SLC	888 x 862 x 941 (35.0 x 33.9 x 37.0)	147 (325)
LEV100JC420SLC	1239 x 1070 x 1596 (48.8 x42.0 x 62.8)	202 (446)
LEV200JC420SLC	1224 x 1070 x 1596 (48.2 x 42.1 x 62.8)	246 (542)
LEV400JC420SLC	1351 x 983 x 1596 (53.2 x 38.7 x 62.8)	317 (699)
LEV650JC420SLC	1564 x 1109 x 1562 (61.6 x 43.7 x 61.0)	408 (900)
LEV1000JC420SLC	1518 x 1334 x 1598 (59.8 x 52.5 x 62.9)	505 (1114)
Material and Finish		
Tank, framing and cabinet material	304L stainless steel	
Surface finish	Glass bead blasted: Ra ~ 1.2 pm (47 pin) Bag contact surface: Ra ~ 0.89 pm (35 pin)	

Wheels	4 x locking swivel, except for 50 L tanks on load cells: 2 X locking swivel and 2 X swivel			
Wheel material	Polyamide	Polyamide		
Wheel bracket material	304L stainless steel			
Jacketed Models				
Jacket type	Dimpled, insulated			
Operating range	Max. 6.2 bar @ -5/90 °C / Max.	90 psig @ 23/194 °F		
Jacket connectors	Threaded female 1 in. gas			
Jacketed sides	50 L: front, right, left, back 100 L – 1000 L: right, left, back			
Models with Load Cells				
Number of load cells	3			
Operator interface type	LCD display, membrane keypad			
Control box ingress rating	IP 65			
Voltage	100-230 VAC			
Maximum humidity	85%, avoid condensation			
Ambient temperature	4-40 °C			
Power cord length	600 cm (20 ft.)			
Power cord plug options	US, EU, Australia, Switzerland, UK			
Signal type(s) for remote output	4-20 mA			
Load cell accuracy	0.3% of the nominal volume			
	50 L	0.15 kg (0.33 lbs)		
	100 L	0.3 kg (0.66 lbs)		
	200 L	0.6 kg (1.32 lbs)		
	400 L	1.2 kg (2.65 lbs)		
	650 L	1.95 kg (4.30 lbs)		
	1000 L	3 kg (6.61 lbs)		

**Table 4**Recommended working volumes

Tank Description	Minimum Working Volume	Maximum Working Volume	
50 L Cubical	15 L	50 L	
100 L Cubical	20 L	100 L	
200 L Cubical	35 L	200 L	
400 L Cubical	57 L	400 L	
650 L Cubical	76 L	650 L	
1000 L Cubical	98 L	1000 L	

<sup>\*</sup>Top of impeller exposed. Some mixing effect at smaller volumes.

# 4 Unpacking and Setup for First Time Use



Take caution when preparing load cells for use.

The tank ships in a wooden crate. Carefully open the crate, unlock the two front brakes, wheel the tank out of the crate, and position it in the desired working location. The crate should be retained for use if the tank must be shipped in the future.

Tanks fitted with a heating/cooling jacket may be connected to an external supply of heating/cooling fluid. Available connection types are female 1 in. gas.

Mobile tanks fitted with integral load cell systems incorporate three (3) load cell assemblies and a weight indicator unit. These tanks should be located on a level surface and have their wheels locked prior to use.

Each load cell assembly must be prepared and inspected to ensure correct weighing performance. The following steps are required in preparation for first use (NOTE: exact load cell and mounting kit design and orientation may vary from those shown – consult the documentation provided with your tank for details of your configuration):

- 1. Use a hex key, size 3 (≤ 400 L tanks) or 4 (≥ 650 L tanks), to remove the shipping plate from each of the load cell assemblies (Figure 1). The plates and bolts should be retained for use if the tank must be shipped in the future.
- 2. Use a wrench, size 13 (≤ 400 L tanks) or 24 (≥ 650 L tanks) to fully retract the jack bolt (Figure 2, left image). Confirm that, after retraction, there is a visible gap between the head of the jack bolt and the opposing mounting plate (Figure 2 and Figure 3, right images) and that the load cell sits securely in its recess without any looseness or play.
- 3. Verify by hand that each anti-liftoff plate and rod end bearings (heim/rose joint) freely (Figure 4). Binding in these assemblies can cause inconsistent weight readings or problems with return to zero.
- 4. Connect the power cord and secure with the threaded collar (Figure 5).
- 5. Plug the power cord into the appropriate power outlet. Verify that the load cell indicator responds to applied loads as expected, and that it returns to zero consistently. Refer to supplied load cell manual for detailed instructions.

6. Each load cell is supplied pre-calibrated with a certificate. Following installation, calibration should be confirmed or repeated according to user organization requirements. Repeat calibration service is available directly from the load cell supplier. Contact Pall for details.

Figure 1
Removing load cell shipping plate



Figure 2

Jack bolt adjustment and inspection



Figure 3
Section view of locked position for transport (left) and open position for use (right)

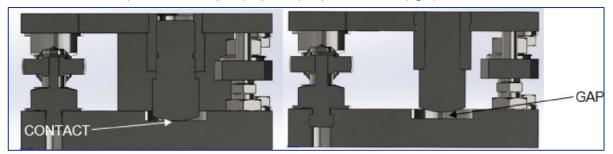


Figure 4
Anti-Liftoff plate and rod end bearing



Figure 5
Attaching the load cell power cord



# 5 Mixing Biocontainer Installation



The procedure described below is intended for LevMixer and Magnetic Mixer single-use mixing systems and mixing biocontainers only.

- 1. Prior to mixing biocontainer installation, inspect the mixing biocontainer-contact surfaces of the tank to ensure they are clean, dry and free from material or defects that might damage the mixing biocontainer surface.
- 2. If a LevMixer or Magnetic Mixer drive unit is coupled to the tank, remove the drive unit before proceeding.
- 3. Apply the caster locks to ensure the tank will not move during mixing biocontainer installation.
- 4. If appropriate, open the chamber access door(s) to allow operators access to the tank interior.
- 5. Ensure that a drive-biocontainer interface (Figure 6) is installed in the drive port hole on the bottom of the tank. If not, install the interface by inserting it from the bottom and securing it in place using the supplied O-ring. Ensure that the interface is fully engaged in the drive port and that the O-ring is completely installed in the corresponding O-ring channel on the side of the interface (Figure 7).

**Figure 6**Drive-Biocontainer interface and O-ring

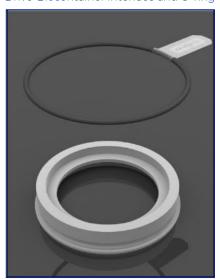
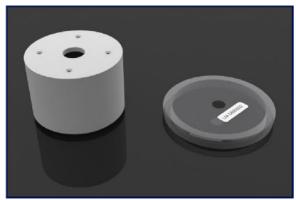


Figure 7
Interface installation in a drive port

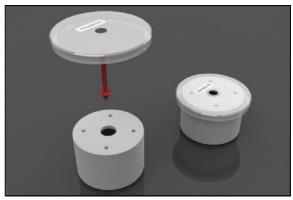


6. Locate the magnetic clamp and centering aligner (Figure 8). These parts are required for proper mixing biocontainer installation and alignment. Inspect the centering aligner for damage; if the center hole is deformed, torn or not concentric, discard and replace with an undamaged centering aligner. Assemble the clamp and aligner as shown in (Figure 9).

Figure 8
Magnetic clamp (left) and centering aligner (right)



**Figure 9**Magnetic clamp assembled with centering aligner

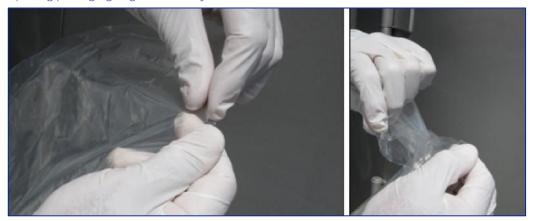




Mixing Biocontainer and drive Units are not interchangeable. Do not use scissors or other cutting implements

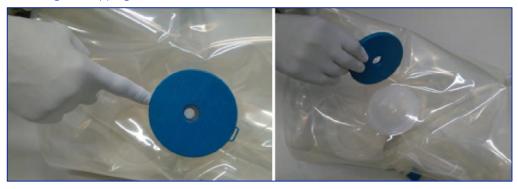
7. Select a LevMixer or Magnetic Mixer single-use mixing biocontainer according to the drive type you plan to use. Verify the correct article code and expiration data. Remove the outer and inner packaging by tearing open at the Easy Tear notch (Figure 10). Retain the label from the inner packaging according to the user organization's Quality policies

**Figure 10**Opening packaging bags via the Easy tear notch

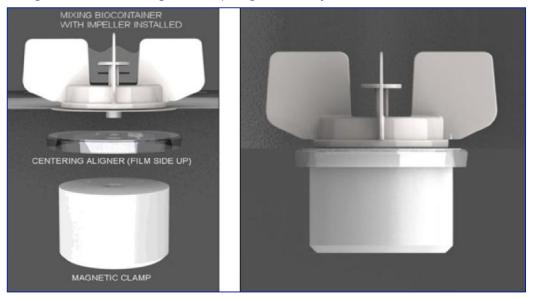


- 8. Visually inspect the mixing biocontainer for shipping damage or imperfections; cuts, tears, or punctures; film cracks that are externally rough / sharp to the touch (note: white creases that are not sharp to the touch are typically not a cause for concern); impeller detached from impeller seat/post; kinked tubing that cannot be unkinked; damaged, missing or detached subcomponents. If any such imperfections are discovered, contact Pall or the user organization's Quality group for advice on whether the mixing biocontainer should be used.
- 9. A blue shipping disc is magnetically attached to the outside of the mixing biocontainer, over the impeller seat. Remove the blue shipping disc (Figure 11) (retain this item; it will be used to secure the impeller during subsequent mixing biocontainer disposal). Place the magnetic clamp / centering aligner assembly over the impeller seat, ensuring the hole in the centering aligner lines up with the post on the seat. The clamp will be magnetically attracted to the impeller and will secure the assembly to the impeller seat when properly installed (Figure 12).

**Figure 11**Removing the shipping disc



**Figure 12**Mixing biocontainer with magnetic clamp / aligner assembly



10. Place the mixing biocontainer into the tank, ensuring the magnetic clamp/centering aligner are inserted through the drive-biocontainer interface at the bottom of the tank (Figure 13).

**Figure 13**Aligning metallic clamp with drive-biocontainer interface



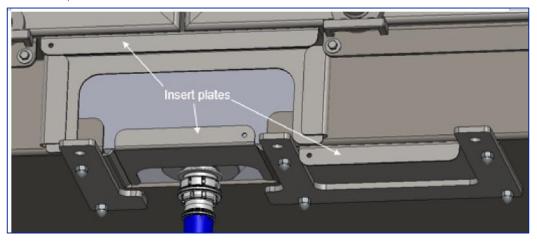
11. Locate the bottom drain hose and pass it through the drain port cut-out of the tank (Figure 14).

**Figure 14**Positioning the mixing biocontainer drain



- 12. Align any side sample ports, sensors and/or tubing with the corresponding port cut-out of the tank, and gently pull the tubing through the cut-out without putting excessive force on the ports. Ensure the ports, sensors and/or tubing are properly aligned for clear access, and that the tubing is not pinched or kinked.
- 13. Install the included tank insert plates in the corresponding port cut-out of the tank (Figure 15).

**Figure 15**Tank insert plates installed

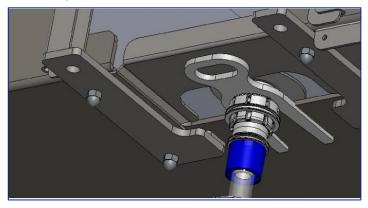


- 14. Before filling the mixing biocontainer, ensure that all tubing clamps on the bottom and side outlets are securely closed.
- 15. If the mixing biocontainer incorporates an EZ Drain fitment, position it in the drain port cut-out, install the drain insert plate (see above, Figure 15), and then snap the EZ Drain clip over the fitment OUTSIDE the tank (Figure 16 and Figure 17).

**Figure 16**EZ drain clip installed

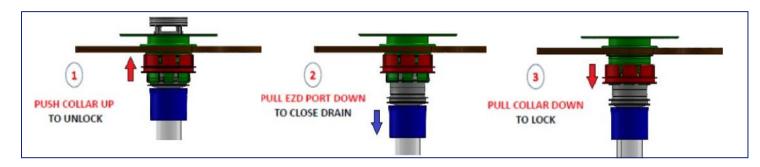


**Figure 17**EZ drain clip installed outside of the tank



16. Confirm that the drain is fully closed by sliding the locking collar up until it clicks, then pulling down firmly on the blue BarbLock" to close the drain, and sliding the locking collar down again to lock it (Figure 18).

Figure 18
Moving from open to closed (stops fluid flow)





In the case of mixing biocontainers being installed in tanks larger than 200 L, the drain fitment may not initially align fully with the drain port cut-out; in such circumstances, carefully guide the drain fitment into position during the filling/inflation step.

- 17. OPTIONAL: Prior to filling with liquid, an inert gas or air may be introduced through one of the top ports to pre-inflate the mixing biocontainer. Pre-inflation for a contained or sterile application should be done only via a sterilizing-grade vent filter integral to the mixing biocontainer.
- 18. OPTIONAL: Any sensors (pH, conductivity probe etc.) should be installed before filling the mixing biocontainer. A temperature pt-100 probe can be installed after since it is not fluid contact.
- 19. Start filling the mixing biocontainer per process requirements. If the mixing biocontainer has been preinflated with gas or air, make sure that at least one top port is open to act as a vent for the displaced air to avoid the risk of over-pressurization. Venting for a contained or sterile application should be done only via an adequately sized sterilizing-grade vent filter integral to the mixing biocontainer.
- 20. During the filling process, gentle adjustments to the mixing biocontainer orientation may be made until 20% of maximum volume or 50 L (whichever is smaller) of liquid has been added. Avoid using excessive force during mixing biocontainer adjustment to prevent inadvertently damaging the mixing biocontainer assembly. Minor wrinkles generally do not impact mixer performance.
- 21. In the case of larger tanks with access doors, the doors should be securely latched closed before the liquid level reaches their sills (Figure 19). Appropriate precautions should be taken to ensure the tank doors are not opened while the mixing biocontainer is full.

Figure 19
Liquid Level reaching the door sills





Do not exceed recommended biocontainer capacity.

- 22. Continue filling the mixing biocontainer to the desired level (see Table 4). Stop filling the mixing biocontainer once it appears close to fully inflated. Take care not to over-inflate the mixing biocontainer.
- 23. Once filled, the tank should not be moved, and all four wheels should be in contact with the floor.
- 24. For drainage and disposal guidelines, see section 7.

# 6 Coupling the Drive Unit to the Tank

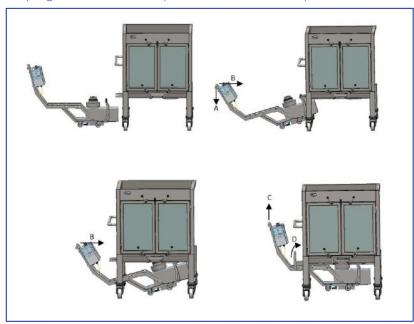
Coupling of the drive unit to the tank should be performed only when the installed mixing biocontainer is filled with fluid to at least the minimum working volume. No coupling should be attempted with an empty or dry mixing biocontainer as the impeller may damage the mixing biocontainer.

- 1. Remove the magnetic clamp (Figure 12) from the mixing biocontainer-tank assembly before coupling the drive. To remove the magnetic clamp, reach underneath the drive port and carefully pull the magnetic clamp downwards until it is free from the mixing biocontainer-tank assembly.
- 2. Make sure that the drive unit has a latch installed in the correct position to match the rail port intended for connection. See the drive user manual for corresponding latch and port positions.
- 3. Carefully press down on the drive handle and raise the front wheels off the ground (direction A as shown on the second step of Figure 20).
- 4. Align the guide bearings on the drive port with the tank guide rails.
- 5. Roll the drive unit along the rails all the way until the bearings rest in the notch located at the end of the rails (direction B).
- 6. Using the drive unit handle, lift the drive unit to a horizontal position (direction C). While holding the drive unit in this position, pivot the latch toward the tank so that the crossbar rests on the hooks in the guide rails (direction D as shown in the fourth step of Figure 20).



Do not move the tank by pulling / pushing the handle of the installed drive unit

Figure 20
Coupling of drive unit to tank (LevMixer drive unit shown)





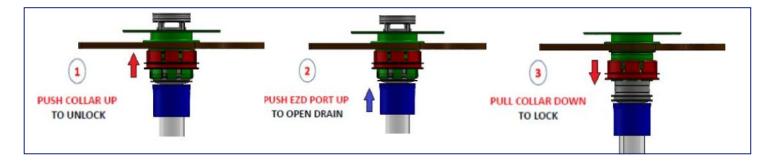
The tank should only be moved using the tank handle, and only with the tank/mixing biocontainer empty and the drive detached.

# 7 Mixing Biocontainer Drainage and Disposal

After the mixing process is completed, the mixing biocontainers contents may be drained and the empty mixing biocontainer responsibly disposed of. The following general guidelines apply and should be used in conjunction with all safety and environmental regulations appropriate for the process and location.

1. To discharge the mixing biocontainer, connect the drain hose to an appropriate receptacle then open the drain tubing clamp. If fitted, the EZ Drain valve should be opened by pushing the locking collar upwards until it clicks, then pushing up on the blue BarbLock to open the drain and pulling the locking collar down again to lock it (Figure 21).

Figure 21
Moving from closed to open (allows fluid flow)



- 2. After the bag has drained, any residual liquid can be recovered by gently lifting the bag so as to direct the residual liquid to the drain.
- 3. Close all clamps and detach the mixing biocontainer from all external connections, detach the mixer drive, remove the EZ Drain clip (if used) then carefully lift the empty mixing biocontainer out of the tank.
- 4. Place the shipping disc (removed during mixing biocontainer installation) over the impeller fitment to secure the impeller and prevent it from being attracted to external steel objects.
- 5. Dispose of the mixing biocontainer according to applicable EH&S policies and regulations. Incineration is a popular method of disposal because the temperatures involved will de-magnetize the impeller and shipping shell.

# 8 Maintenance and Care

Mixing tanks are designed to operate with minimal maintenance.

To clean, wipe down the tank surfaces using water and a mild detergent solution. Standard tanks are constructed from 304-alloy stainless steel, which may be vulnerable to corrosion if exposed to corrosive chemicals or if left in in persistent contact with moisture. Appropriate precautions should be taken to prevent such corrosion. If corrosive conditions are routinely anticipated, end users should consider opting for tank systems constructed from 316-alloy stainless steel (available from Pall upon request).

It is recommended that heating/cooling fluid be drained completely from the jacket (if fitted) before transporting or storing the tank for long periods of time.

Tanks with integral load cell systems should be periodically checked for correct operation in accordance with the user organization's Quality policies.

Return the tank to its original crate, with supplied bracing in place, prior to shipping.

Periodic maintenance is recommended to keep the tank in reliable working condition. Recommended preventive maintenance procedures are listed in Table 5.

Table 5

Preventative maintenance procedures

Description	Frequency	Spare Parts Involved	Responsible
Load cell Calibration	Annually	None	Service or Metrology

#### 8.1 Spare Parts and Standard Accessories

#### Table 6

Spare parts and accessories

Description		Pall Part Number  LT-DBBI009  LT-DBBI004  LT-SVSP304  LT-SVSP309	
Drive-biocontainer interfac	е		
Interface O-ring			
Centering aligner			
Magnetic clamp type 2			
Power Cord:	US EU AU SW UK	LT-SVSP365 LT-SVSP366 LT-SVSP367 LT-SVSP368 LT-SVSP369	
Powder port support:	> 50 L to 1000 L	215-18686-00	
Probe support:	50 L > 50 L to 1000 L	215-18756-00 215-18493-00 or 215-18880-00 (depending on the mixing biocontainer)	
Plate, clip for 1 in. drain valv	e, non-sterile	4100153NS	
Powder bag lifts:	Medium Large	LGRMXPBSM LGRMXPBSL	

# 9 Services

The mixing tank was developed exclusively for mixing fluids, and solids in fluids, in specially designed disposable mixing biocontainers. The tank should only be used for this purpose to ensure a long service life.

Should your tank require service, please contact your local sales team.

# 10 Scientific and Laboratory Services

Pall operates a technical service to assist in the application of all its products. This service is readily available to you and we welcome your questions so that we can help. In addition, a full network of technical representatives is available throughout the world.

# 11 Warranty

Pall warrants that the Allegro systems manufactured by Pall, when properly stored and installed, and operated as per the specifications and design conditions stated in this document will be free from defects in material and workmanship during their shelf life. Pall liability under any warranty is limited solely to replacing or issuing credit for the Allegro systems that may become defective during the warranty period.



#### **Corporate Headquarters**

Port Washington, NY, USA +1-800-717-7255 toll free (USA)

+1-516-484-5400 phone

#### **European Headquarters**

Fribourg, Switzerland +41 (0)26 350 53 00 phone

# **Asia-Pacific Headquarters**

Singapore

+65 6389 6500 phone

#### Visit us on the Web at <a href="https://www.pall.com/Biotech">www.pall.com/Biotech</a> Contact us at <a href="https://www.pall.com/contact">www.pall.com/contact</a>

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IF APPLICABLE Please contact Pall Corporation to verify that the product conforms to your national legislation and/or regional regulatory requirements for water and food contact use.

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