

Magnetic Mixer Drive Unit for Single Use Mixing Systems

Instructions For Use



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1 Safeguards and precautions






This is the original instructions for use for the Drive Unit. Read and follow all instructions in this manual and retain for future reference. The standard Drive Unit is supplied with the original instruction in English. The local translation will be supplied electronically in alternate languages by the local Pall sales team.

If the Drive Unit is used in a manner inconsistent with the original instructions, the protection provided by the equipment may be impaired.

1.1 Safety signs and symbols in this document

Table 1






Safety signs and symbols within this document

Symbol	Instruction and Information
	Prior to operating, the instructions must be read in entirety.
	Mandatory information for use
	Prohibited actions
	Do not use if you have a Pacemaker
	Do not sit or step
	Calls attention to a hazard or unsafe practice which might result in personal injury or damage to the equipment.
	Strong magnetic field
	Risk of electrocution.
	Hot Surface
	Protective Earth (ground)

1.2 Safety Messages

Table 2

Safety messages

Symbol	Safety Message
	<ul style="list-style-type: none"> - Prior to operating, the instructions must be read in entirety. - The Drive Unit should only be used in accordance with these instructions.
	<ul style="list-style-type: none"> - For technical assistance contact your local Pal sales team or Pall directly. - Only use the detachable power cord supplied by Pall - Drive unit should be turned off prior to cleaning - Only use water and isopropyl alcohol to clean - To transport roll on a flat surface - Intended for indoor use in an atmosphere not containing corrosive substances - Always put the protective shield back on the biocontainer impeller prior to disposal - Must be placed on a levelled floor
	<p>Do not:</p> <ul style="list-style-type: none"> - Use flammable liquids / substances - Use in a hazardous atmosphere - Lift during normal operation - Open the machine or control box whilst plugged in - Submerge in water - Obstruct access to the power outlet - Attempt to move the tank while the Drive Unit is docked - Use in a manner not specified within this instruction
	<ul style="list-style-type: none"> - Do not use if you have a Pacemaker
	<ul style="list-style-type: none"> -Do not sit or step on the equipment



- Calls attention to a hazard or unsafe practice which might result in personal injury or damage to the equipment.
- If stored or transported at a temperature lower than the operating environment wait 1-2 hours to equalize the internal temperature prior to powering on the unit



- Keep the supplied magnetic shields on biocontainers and impellers when not in use.



- Using a power cord not supplied by Pall can impair the protection provided by the equipment.
- Turn power off during cleaning, service, and maintenance.
- The power supply shall match the requirements indicated on the tag plate
- Ensure the mains power switch is easily accessible
- Mains outlet must be within 3 meters of the device



- Surfaces may be hot



- In compliance with CE marking a ground connection shall be established.

2 System Overview

2.1 Introduction

The Magnetic Mixer disposable biocontainer mixing system is based on a single use mixing bag containing a bottom mounted disposable magnetic impeller on a disposable bearing. The single-use magnetic impeller includes a proprietary bearing assembly designed and composed to control particulate generation. All the materials of the impeller/bearing assembly contacting the fluid are non-metallic USP Class VI and ADCF. The Magnetic Mixer disposable mixing system consists of an interchangeable Magnetic Mixer Drive Unit and proprietary magnetic impeller based mixing bags fitted into retaining tanks on either a universal portable dolly (30 L – 350 L) or a floor mounted tank support (50 L – 2,000 L). The Magnetic Mixer Drive Unit motor is coupled with the mixing bag through a proprietary interface. The activation of the motor induces rotation of the in-bag impeller (0-300 RPM) resulting in the mixing action inside a hermetically sealed biocontainer. The coupling of the in-bag impeller with the Drive Unit motor is accomplished by magnetic forces only, therefore no dynamic seals or shaft penetration inside the bag is required. The Drive Unit motor is mounted on a portable cart that can be easily disconnected from the bag and reconnected to another mixing bag thereby allowing mixing in multiple bags of various sizes with a single Drive Unit.

The system hardware has 4 major components:

1. Drive motor with control boxes and rotational speed display
2. Stainless-Steel Dolly or Stainless-Steel Tank with docking structure on them.
3. Plastic/Steel retaining tank for use on a dolly/stand
4. Accessory kit for interfacing the drive with the tank and biocontainer

The Magnetic Mixer reusable system can accommodate a variety of standard and custom-designed disposable bags and tanks available from Pall® Biotech with a capacity range from 30 L to 2000 L.

2.2 Magnetic Mixer System Components

Figure 1

Main components of the Magnetic Mixer disposable mixing system (shown with 1000 L tank).

1000 L Stainless Steel Tank

Magnetic Mixer Drive Unit

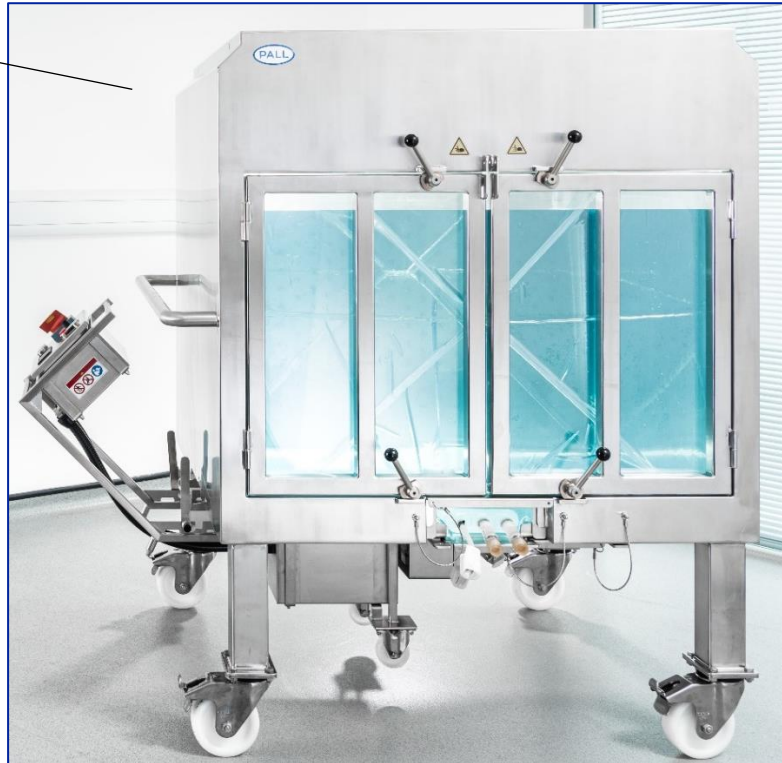


Figure 2

Magnetic Mixer disposable mixing system and universal portable dolly (shown with 200 L round plastic tank).

200 L Round Plastic Tank

Magnetic Mixer Drive Unit



2.3 Magnetic Mixer Drive Unit Accessories

Figure 3 A - B

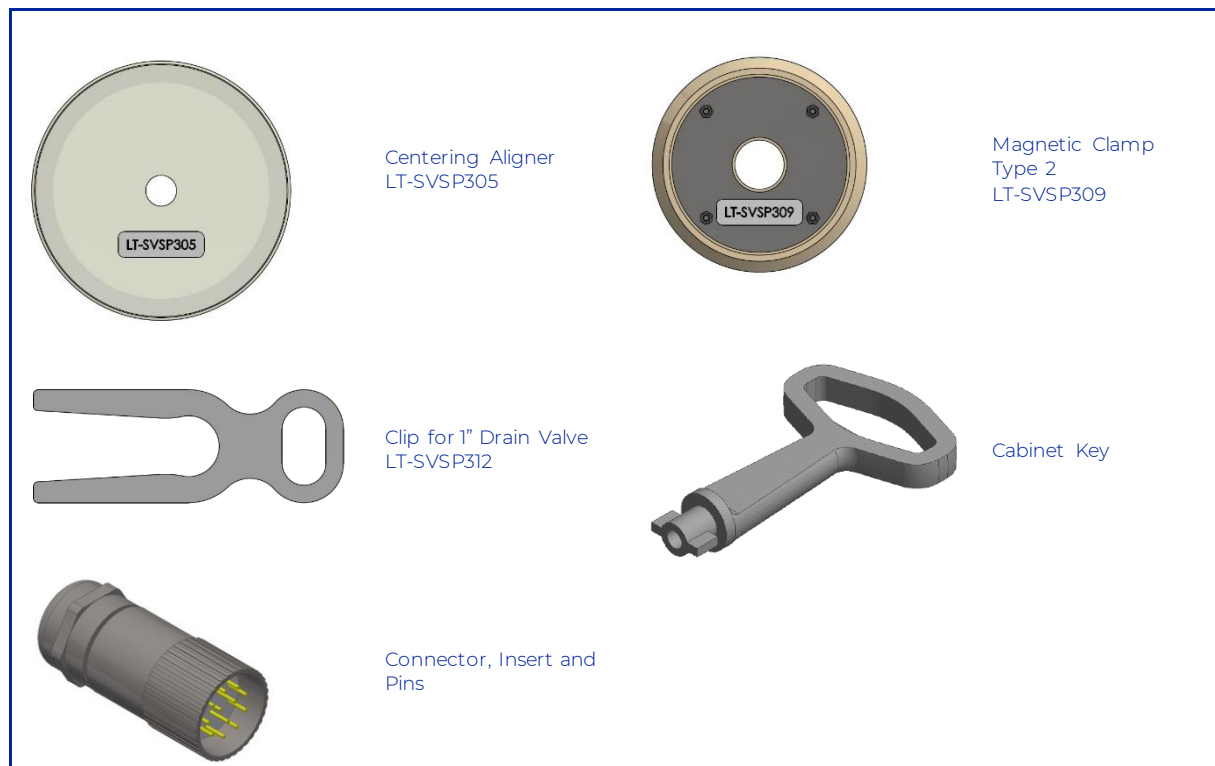
Magnetic Mixer Drive Unit Toolbox (supplied with the Drive Unit).

A



B

Components included inside the toolbox.



3 Installation of the Magnetic Mixer System Hardware

3.1 Receiving and unpacking the Magnetic Mixer Drive Unit

Inspect the crate and, if applicable, the tilt and shock indicators to ensure the crate and Drive Unit have not been damaged during shipping. All crates are designed so they can be moved to the desired location with a forklift or pallet truck.

- The Drive Unit is shipped in a reusable wooden crate with the dimensions and weights as per table below.
- The crate has foam inserts to protect the Drive Unit during transport.
- The Drive Unit accessories are placed inside a toolbox that is supplied in the Drive Unit crate. Make sure to store the toolbox in the vicinity of the Drive Unit.
- The crate should be retained in case the Drive Unit has to be shipped in the future.
- Only use the original packaging for shipping the Drive Unit.
- Remove any foam and protective packaging from the Drive Unit before first use.

Table 3

Approximate weight and dimensions of the crated and separated Drive Units.

<u>Crated Weight</u>	<u>Crate Dimensions</u>	<u>DU010 Weight</u>	<u>DU010 Dimensions</u>	<u>DU011 Weight</u>	<u>DU011 Dimensions</u>
134 kg; [~295.4 lbs]	1390x710x1080; [~54.7x27.9x42.5]	32.2 kg; [~70.9 lbs]	1245x426x888; [~49.0x16.8x34.9]	32.4 kg; [~71.4 lbs]	1245x426x888; [~49.0x16.8x34.9]

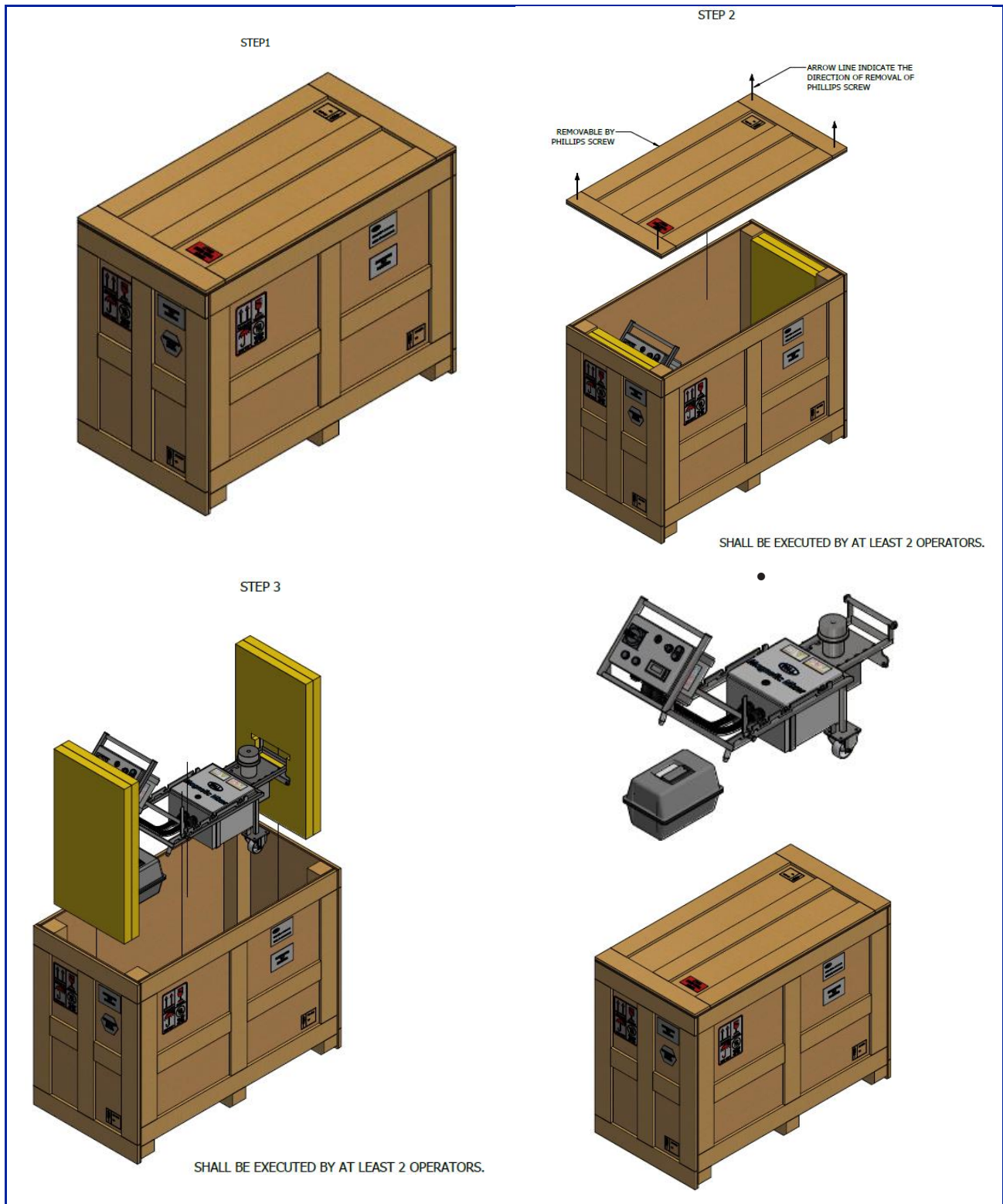
3.2 Uncrating of the Magnetic Mixer Drive Unit

To un-crate, follow the next steps:

1. Place the Magnetic Mixer Drive Unit crate in an area with a minimum of 1 m all around the crate.
2. Remove the top panel fixation screws and use 2 operators to remove the crate top panel.
3. Lift the Drive Unit and foam from both ends simultaneously.
4. Place the Drive Unit and toolbox in the desired location. Store the protection foam inside the crate and re-mount the top panel on the crate.

Figure 4

Uncrating of the Magnetic Mixer Drive Unit.



3.3 Interface with O-Ring

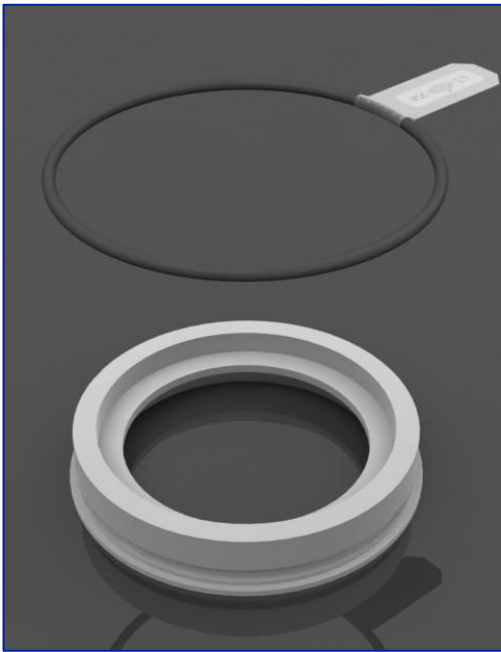
The Interface provides mechanical interfacing of the Drive Unit with the impeller inside the bag.

Figure 5

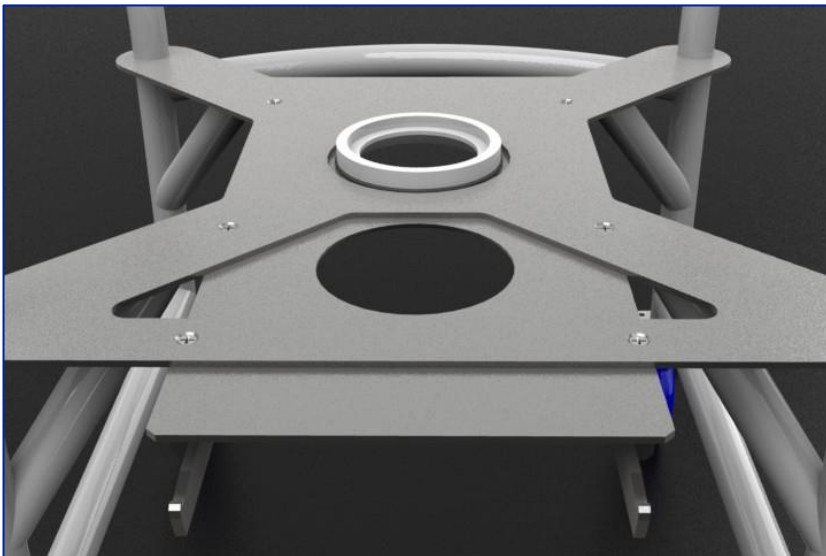
A: Drive-biocontainer interface and O-ring.

B: Interface is installed in the railed port of the dolly (locked by the O-ring).

A



B



3.4 Dolly-Tank Assembly

In case the Drive Unit is used in combination with a plastic tank on dolly, the following procedure(s) should be used for the installation of the tank on the dolly. Larger tanks are constructed in two parts.

1. Both the Dolly and Tank have holes for Drive Unit coupling. Insert the drive/biocontainer Interface into this hole from below and apply the O-ring to secure as shown in Figure 6. It is not necessary to remove or replace the Interface after installation (i.e., after mixing or between batches).
2. Position the plastic tank on the dolly. The bottom of the tank has two holes: a small hole for the biocontainer drain and a larger hole for the drive head. Line up the larger hole with the drive port on the dolly. The tank hole should locate around the Interface.
3. Tanks up to and including 350L use a centrally located impeller and therefore use the central port dolly configuration. See procedure below for changing the dolly port configuration.

Figure 6

Installation of the drive-biocontainer interface on dolly with O-ring

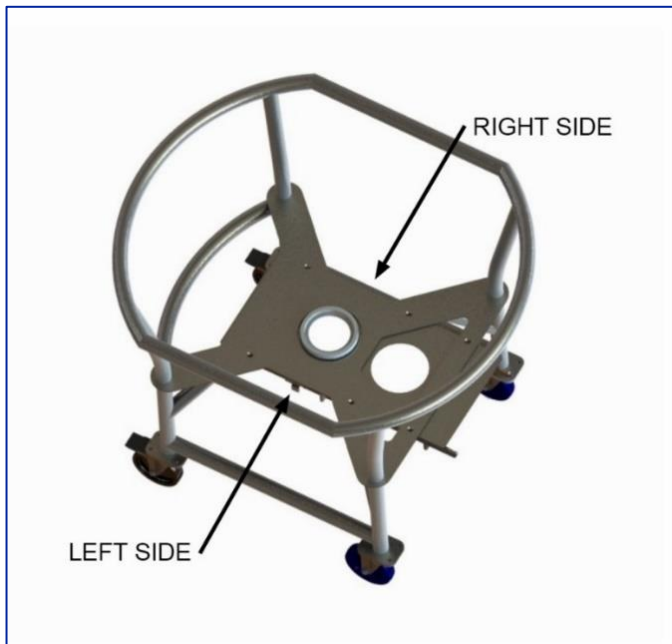


3.5 Changing dolly configuration to center impeller port

Central port configuration is required for tanks sizes 30 – 350L. Each rail of the dual port has an adjuster attached to the rail with two screws. The right adjuster is marked with two dots and the left adjuster is marked with one dot. The right and left rails of the port are also marked with two and one dot respectively, see *images below*. Right adjuster should always be used with the right rail and the left adjuster with the left rail.

Figure 7

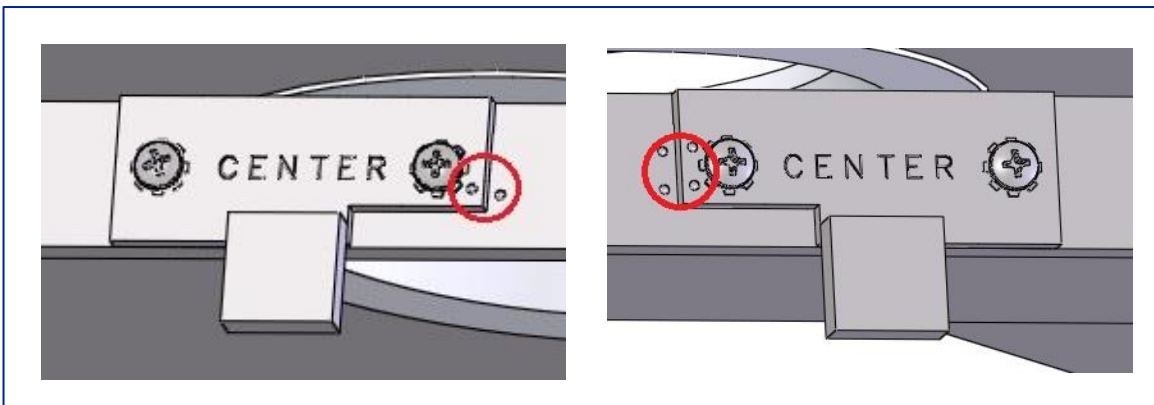
Rail port orientation – Showing left side vs. right



To set the rails for the central port position set the right and left adjusters so that the side with word “CENTER” is visible on both. See Figure 8. Ensure that the two dot marks on the right adjuster are located next to the two dot marks on the rail and single dot mark of the left adjuster is located next to the single dot mark on the left rail. Secure the adjusters with the screws provided.

Figure 8

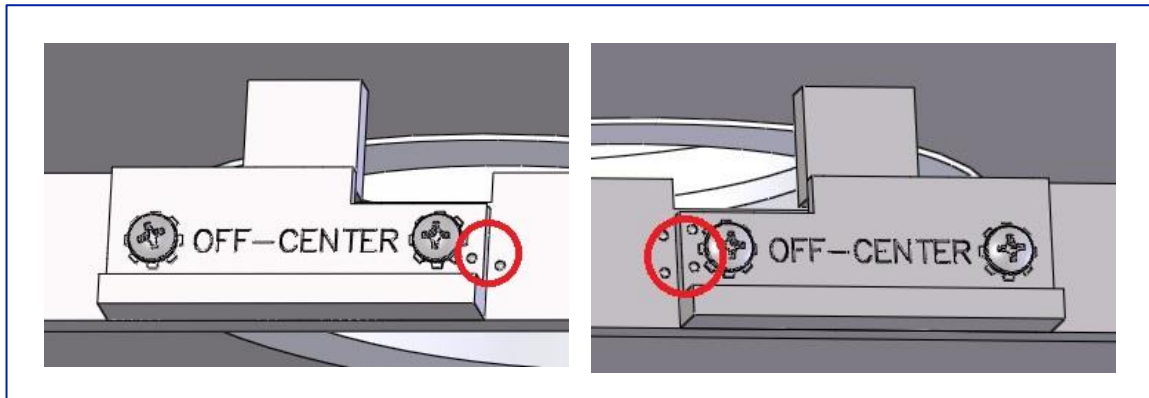
Rail adjustments for central position (left and right side)



To set the rails for the off center port position set the right and left adjusters so that the side with words "OFF-CENTER" is visible on both. See **Error! Reference source not found.**a. Ensure that the two dot marks on the right adjuster are located next to the two dot marks on the rail and single dot mark of the left adjuster is located next to the single dot mark on the left rail. Secure the adjusters with the screws provided.

Figure 9a

Rail adjustments for off-centre position (left and right side)



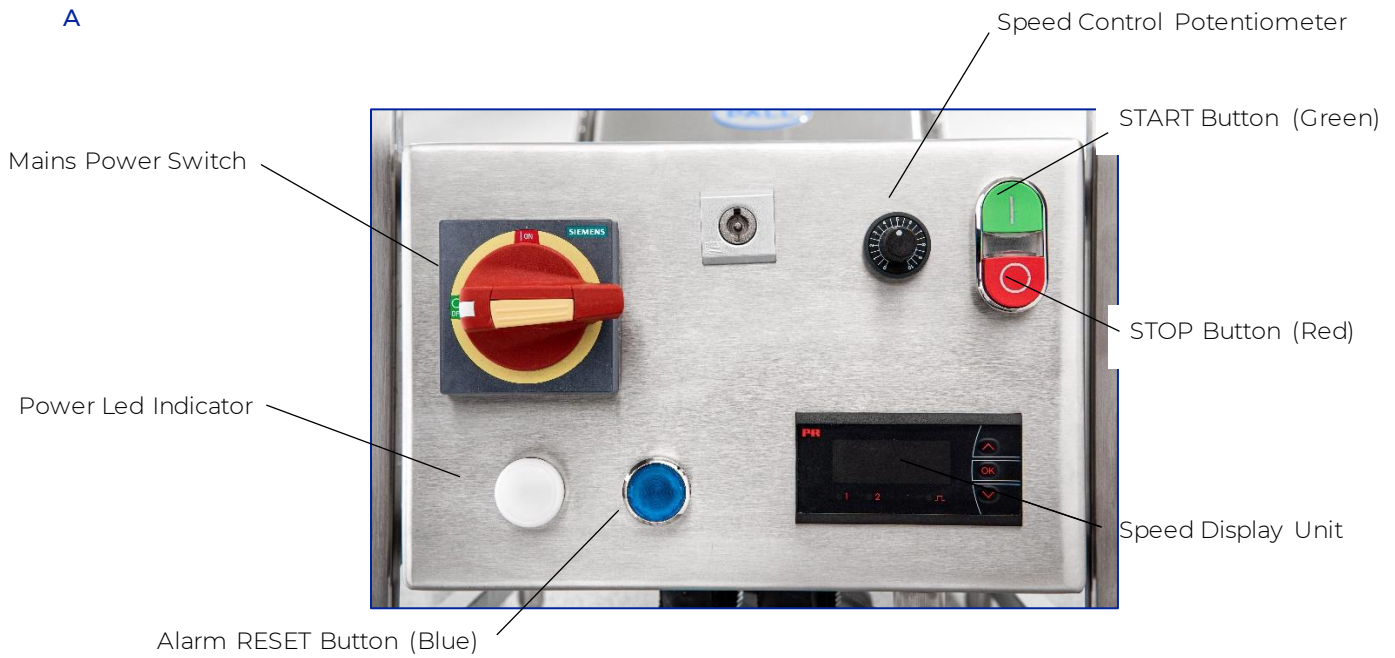
4 HMI Interaction

4.1 User Interface Overview

Figure 10

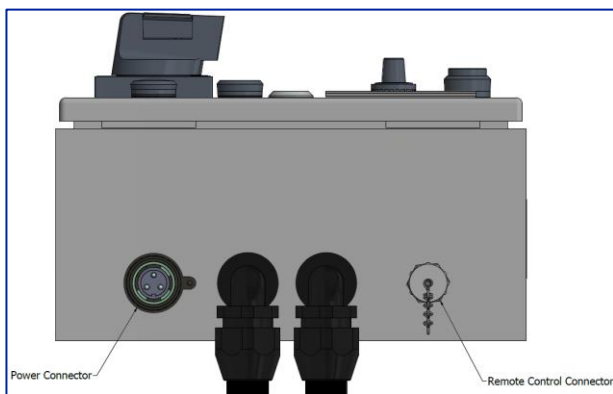
A: Control Box - User Control Interface.

B: Power interface and remote-control connector.

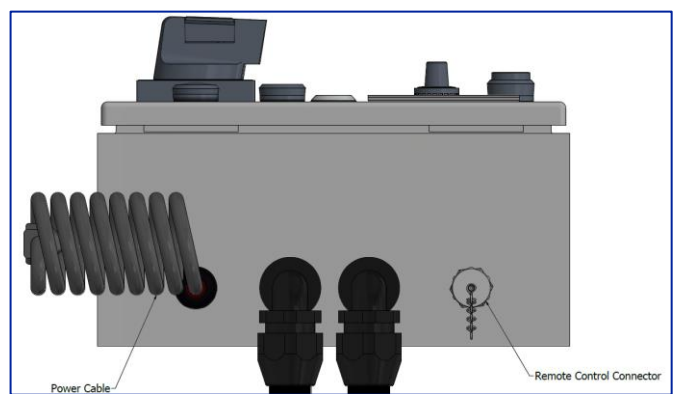


B

DU010



DU011



4.2 Set-up and Operation

1. Plug the power cord into a power supply that matches the requirements indicated on the tag plate of the Drive Unit.
2. Place the knob of the Speed Control Potentiometer in ZERO position by turning it all the way counter clockwise.
3. Turn the mains power switch ON to energize the system (the Power Led Indicator will illuminate).
4. Press the START button (**Green**) on the User Control Interface.
5. Set the speed of the Drive Unit by turning the Speed Control Potentiometer clockwise until the desired speed value is shown on the Speed Display Unit.
6. To stop the motor, press the STOP button (**Red**) on the User Control Interface. Press the START button (**Green**) to resume motor operation at a pre-set speed.

5 Magnetic Mixer System Installation

5.1 Allegro Mixing Container Installation

The below procedure describes the basics of installing an Allegro mixing biocontainer in a tank. For more detailed instructions, please refer to the instructions delivered with the stainless-steel tanks.

1. Locate the magnetic clamp and centering aligner (Figure 11). These parts are required for proper Allegro 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
- 2.
- 3.
4. Figure 12.

Figure 11

Centering aligner (left) and magnetic clamp (right)

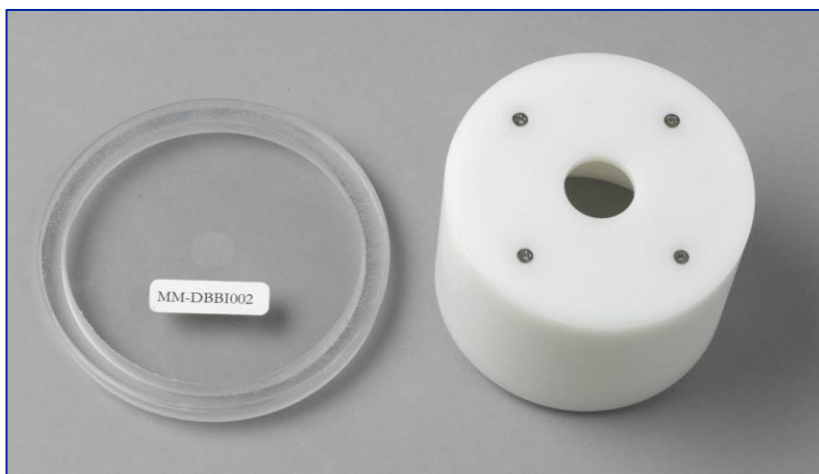


Figure 12

Magnetic clamp assembled with Centering Aligner



5. Verify the correct article code and expiration date on the bag package. Remove the outer and inner packaging bag by tearing open at the Easy Tear notch (Figure 13) - DO NOT USE SCISSORS OR OTHER CUTTING IMPLEMENTS. Retain the label from the inner packaging according to the Quality policies of your organization.

Figure 13

Opening packaging bags via the Easy Tear notch



6. Visually inspect the Allegro 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 Allegro mixing biocontainer should be used.
7. A blue shipping disc is magnetically attached to the outside of the Allegro mixing biocontainer, over the impeller seat. Reverse the Allegro mixing biocontainer to have access to the magnetic impeller with the blue disc. Next, remove the blue shipping disc (Figure 14) (retain this item; this will be used to secure the impeller during subsequent Allegro mixing biocontainer disposal).

Figure 14

Removing blue shipping disc from Allegro mixing biocontainer



8. Assemble the centering aligner and magnetic clamp on the impeller on the Allegro mixing biocontainer as shown in Figure 15.

Figure 15

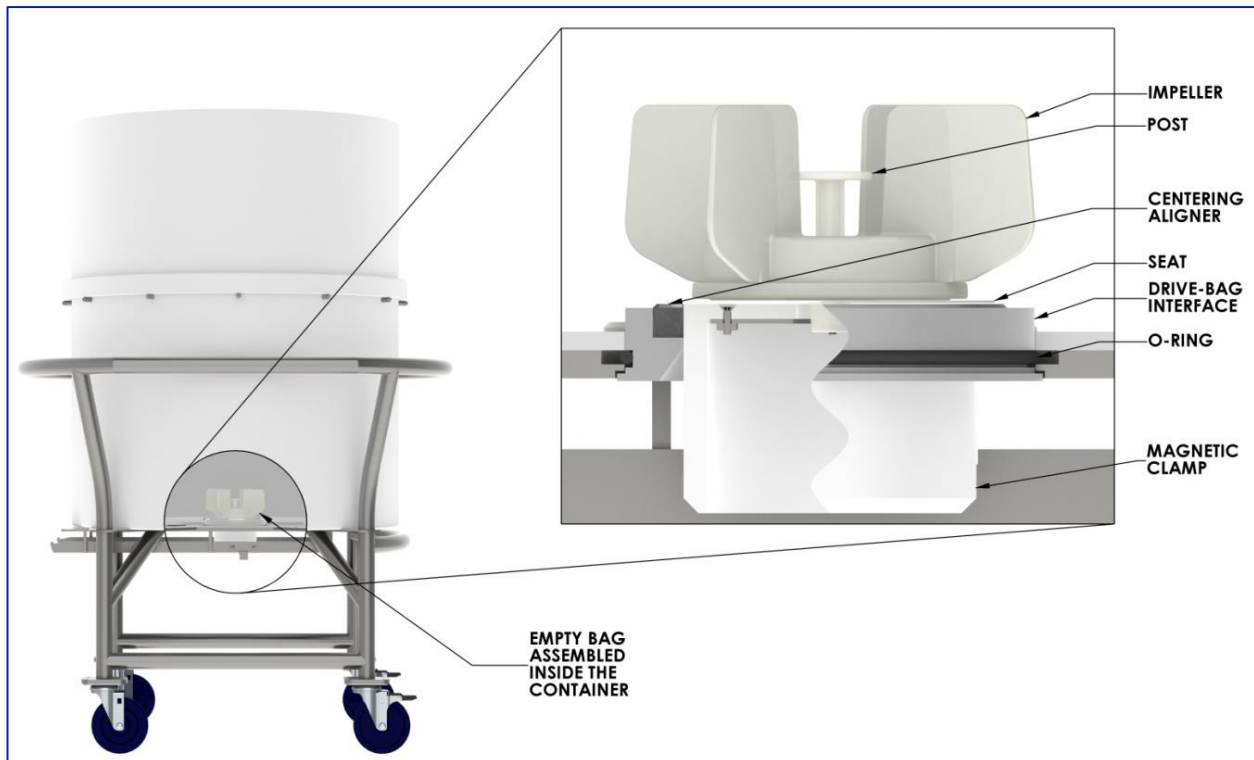
Assembly of Allegro mixing biocontainer with magnetic clamp/aligner assembly



9. Place the Allegro mixing biocontainer in the tank by aligning the magnetic clamp with the large port on the bottom how it is shown in Figure 16.

Figure 16

Biocontainer assembly with round plastic tank



10. For round plastic tanks, gently pull the bottom drain tube through the drain port opening. For other tanks, please refer to the specific instructions delivered with the tank.
11. Before filling the biocontainer, ensure that the bottom drain tube is clamped. If the biocontainer contains an EZ-Drain, ensure the drain is fully closed and clamp the drain in place using the provided plastic drain clip.
12. As the biocontainer starts to fill, gently pull the bottom surface of the biocontainer to remove any wrinkles, especially near the impeller.



Do not:

- Exceed the recommended biocontainer capacity
- Alter the tube and / or impeller configuration

5.2 Docking of the Drive Unit to the Tank and Biocontainer

Do not remove the magnetic clamp until initial quantity of fluid pour in biocontainer enough to hold the bag seat in place without magnetic clamp support. Not following this rule may cause seat to get misaligned with interface and crooked with no possibility to re-install other than after draining out the content.

Remove the Magnetic Clamp from the biocontainer-container assembly before coupling. To remove the magnetic clamp, reach underneath the drive port and carefully pull the magnetic clamp downwards until it is free from the biocontainer-tank assembly (see Figure 17). Return the magnetic clamp to the supplied Accessories Box for future use.

Figure 17

Removal of magnetic clamp



Figure 18

Coupling of Magnetic Mixer Drive Unit with the bag can be accomplished only when the bag is filled with fluid.





No coupling should be attempted with an empty or dry biocontainer.

Do not attempt to move the tank with the Drive Unit handle whilst it is docked.

1. Remove Magnetic Clamp from the biocontainer-tank assembly before coupling. To remove the magnetic clamp, reach underneath the drive port and carefully pull the magnetic clamp until it is free from the biocontainer-tank assembly. Return the magnetic clamp to the supplied Accessories Toolbox for future use.
2. Shift the latch toward the control box slightly.
3. Carefully press down on the drive handle and raise the front wheels off the ground.
4. Align the guide bearings with the guide rails on the drive port (as shown in the first segment of Figure 18).
5. Roll the Drive Unit along the rails all the way until the bearings are caught in the well located at the dead end of the rails.
6. Using the Drive Unit handle, raise the Drive Unit to an upright position.
7. While holding the Drive Unit in this position shift the latch toward the dolly/tank so that the cross-bar rests on the grooves in the guide rails (as shown in the fourth segment of Figure 18).



The tank may differ in appearance than depicted. However, the drive installation procedure remains the same.

5.3 Disconnecting the Drive Unit from Tank

1. When mixing is complete, turn the RPM Regulator to zero (0) and press the STOP button. Firmly hold the Drive Unit handle and raise the Drive Unit slightly to release the latch. Release the latch by pulling it toward the control box.
2. Carefully lower the wheels of the Drive Unit to the floor. Roll the Drive Unit on its wheels away from the dolly.
3. Press down on the Drive Unit handle until the guide bearings are free from the guide rails.
4. Pull the Drive Unit away from the dolly until the guide bearings are free from the rails. Carefully lower the front wheel to the ground.
5. The Magnetic Mixer Drive Unit can now be wheeled to another station for use.

6. When mixing is completed and the biocontainer is completely drained, remove the biocontainer by carefully pulling the impeller seat and the drain tube out of their respective ports.
7. Remove the centering aligner and return to the supplied Accessories Toolbox for future use. The Interface should remain in its locked position for future use.
8. Dispose of plastic biocontainer.



Always put the protective shield back on the biocontainer impeller before disposal.





5.4 Drive Unit Storage when Not in Use

The Drive Unit shall only be stored as shown in the position below.



Do not sit or step on the equipment.

Table 4
Storage positions.

Position	Permission
	<p data-bbox="1082 1016 1155 1041">Correct</p> 
	<p data-bbox="1075 1566 1165 1591">Incorrect</p> 



Incorrect



6 Cleaning Servicing and Maintenance

The Magnetic Mixer Drive Unit is designed to operate with minimal maintenance. The following tools might be required for maintenance or servicing:

- Electrical cabinet key: present inside the supplied toolbox.
- Key for standard M5 hexagonal head acorn nuts: not supplied by Pall.



Turn off the mains power switch, switch off electrical supply and disconnect the mains/power cable before any cleaning or maintenance operation. When finished, make sure all the electrical cabinets are properly locked and all open/detached components placed back and secured in their normal position.

Ensure that the power cable is not plugged in, the mains power switch is turned off and check if the charge indicator led on the driver (inside the electrical cabinet) is turned off before disconnecting the motor connector / cable.

Only qualified, skilled, well-trained, licensed and / or certified personnel may service and perform maintenance on the Magnetic Mixer Drive Unit equipment. All electrical work shall be executed by qualified, licensed and / or certified electrical engineering personnel. Minimal safety precautions: safety shoes and safety glasses.

6.1 Hardware Cleaning



Cleaning solutions containing alcohols are flammable. Care should be taken when using these solutions.

Switch off electrical supply and disconnect the mains/power cable before any cleaning or maintenance operation.

It is recommended that before and after every use, all exposed surfaces of the Drive Unit are cleaned.

A soft, damp cloth moistened with the following recommended cleaning solutions should be used for wiping exposed surfaces of the hardware. Do not use abrasive cleaning agents. Any non-specified cleaning method can result in the nullification of the product warranty.

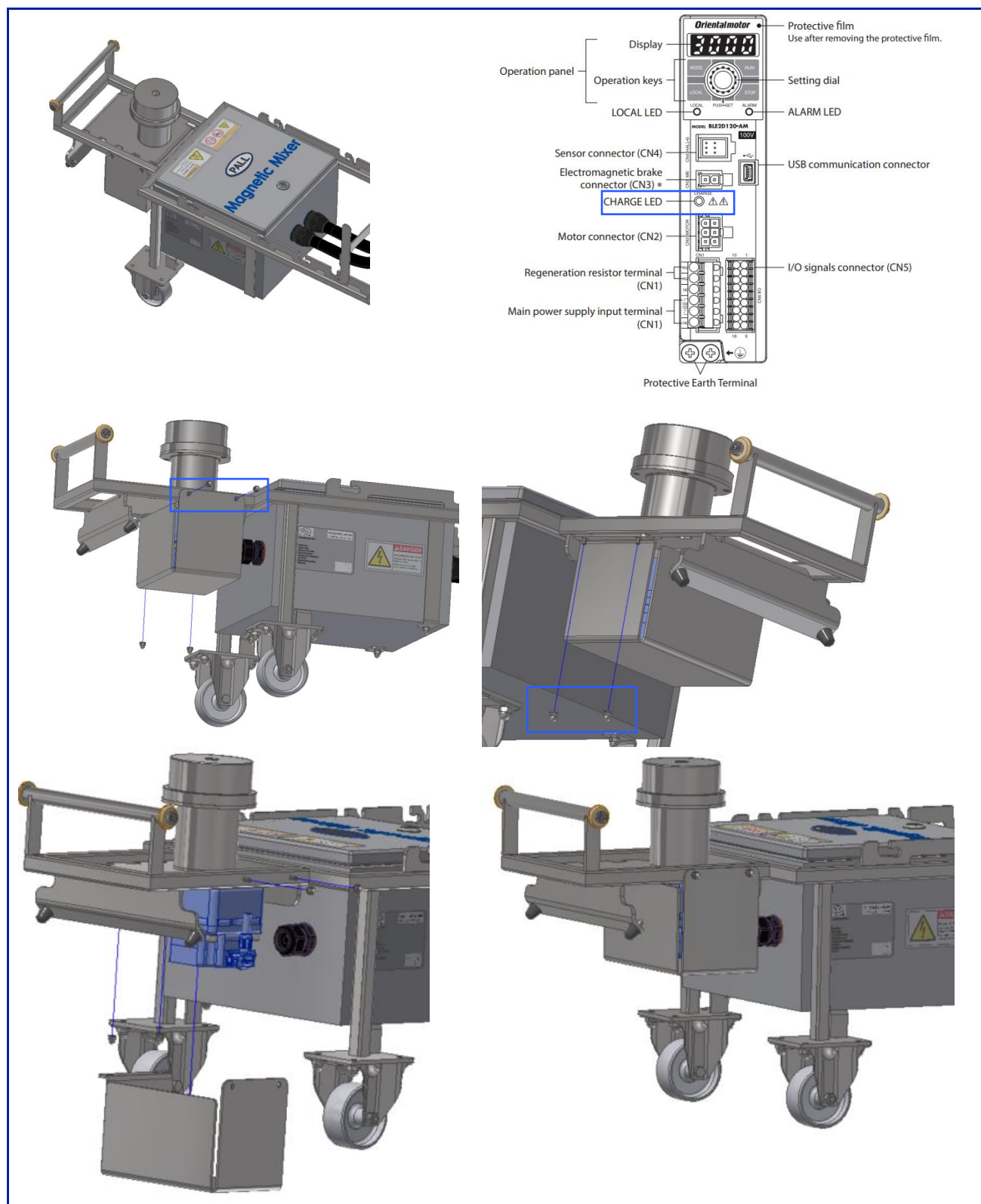
- Water
- 70% IPA

When there is a need to remove the motor cover for cleaning follow these steps:

1. Isolate the Drive Unit before cleaning:
 - Switch off electrical power supply at the mains power switch on the Drive Unit.
 - Switch off electrical power at the plug end and unplug the Drive Unit.
 - The mains power switch on the Drive Unit can be locked. This mains power switch isolates electrical energy sources in the Drive Unit.
2. Open the driver electrical cabinet with the key provided in the toolbox and check if the charge indicator led on the driver is turned off.
3. Remove the 4 fixation acorn nuts and washers.
4. Remove and clean the cover and areas around the motor.
5. Follow the reverse procedure to re-install the cover.

Figure 18

Motor protection cover cleaning.



6.2 Service

The Magnetic Mixer system was developed exclusively for mixing fluids and solids into fluids in Allegro single-use mixing biocontainers. Only use the Magnetic Mixer Drive Unit for these applications to ensure a long service life.

Should your Drive Unit require service, please contact your local Pall sales team.

The following checks should be carried out on a regular basis:

- Inspect power cables to ensure they are intact and undamaged. Do not use the Drive Unit if damage is found.
- Check the operation of the mains power isolation switch.

To isolate the Drive Unit before disconnection or maintenance work:

- Switch off electrical power supply at the main isolating switch on the Drive Unit.
- Switch off electrical power at the plug end and unplug the Drive Unit.

The mains power switch on the Drive Unit can be locked. This switch isolates electrical energy sources in the Drive Unit.

Table 5

Drive Unit inspection intervals and required checks after maintenance /servicing

Tasks	Daily	Weekly	Monthly	Yearly
Drive main functions check (at least OV05) *	-	-	-	X
Remote functions check (at least OV08 – only if the remote functionality is used) *	-	-	-	X
Check if the magnetic mixer roller is rotating smoothly and the play is limited. Replace if excessive play is detected.**	-	-	-	X
Check if the magnetic mixer support stoppers are not excessively worn-out. Replace if excessive wear is detected.**	-	-	-	X

* If applicable, see supplied FAT for detailed procedure on how to perform these checks.

** See critical spare part list on section 6.2.

6.3 Critical Spare parts

Table 6

Critical Spare Parts

Part Number	Name
PHB0036477	MAGNETIC MIXER TOOLBOX
PHB0034779	MAGNETIC MIXER LATCH
PHB0036020	MAGNETIC MIXER STOPPER
PHB0034787	MAGNETIC MIXER ROLLER
PHB0037357	REMOTE CONTROL CABLE ASSEMBLY
PHB0038145	REMOTE CONTROL CONNECTOR (with 3 m cable)
LT-SVSP366	Power cord EU*
LT-SVSP367	Power cord AU*
LT-SVSP368	Power cord CH*
LT-SVSP369	Power cord UK*
LT-SVSP480	Power cord CN*
LT-SVSP305	Centering Aligner
LT-SVSP309	Magnetic Clamp Type 2
LT-SVSP312	Clip for 1" Drain Valve

6.4 End of Life Disposal

The presence of this WEEE label on a product means that the product contains electrical or electronic materials and therefore must not be disposed of as unsorted waste but instead is treated separately. The presence of these materials may, if not disposed of properly, have potential adverse effects on the environment and human health. Within the European Union, operators are urged to recycle such products when being replaced with a newer version or when they have outlived their useful lives.



Under the Waste Electrical and Electronic Equipment (WEEE) Directive and implementing regulations, when customers buy new electrical and electronic equipment from Pall they are entitled to:

- send old items put on the market in Europe before August 13th, 2005 equipment for recycling on a one-for-one, like-for-like basis (this varies depending on the country)
- send the new equipment back for recycling when this ultimately becomes waste.

Country specific instructions to both customers, and recyclers/treatment facilities wishing to obtain disassembly information, are provided by following the link below.

<https://www.pall.com/en/about-pall/corporate-sustainability/weee-compliance.html>

7 Detailed Specification

7.1 Hardware configuration

The Drive Unit is shipped pre-configured and, in normal circumstances, does not require any configuration changes. Should you require any assistance please contact your local Pall sales team.

The main connection or configurable elements are described below:

Table 6

Remote control connector: Interface pins of the M23 Connector.

Pin	Circuit Description	Signal Type	Logic / Calibration	Diagram
2,4	Speed setpoint input 4-20 mA	0-300 RPM	4mA=0% of range 19.89 mA=100% of range	
1,3	Motor Start/Stop	Logic	Open=Stop; Closed=Start;	
1,5	Local/Remote	Logic	Open= Local; Closed= Remote;	
1,6	Alarm Reset	Logic	Closed= Alarm Reset;	
1,7,10	Alarm Signal Out	Logic	Closed= Alarm Present;	
8,9	Connect Feedback	Logic	24V DC In; 24V DC Out;	
11,12	Speed output 4-20 mA	0-300 RPM	4mA=0% of range 19.89 mA=100% of range	

Figure 19

Dip switches configuration: Setup 4-20 mA to 0-5V

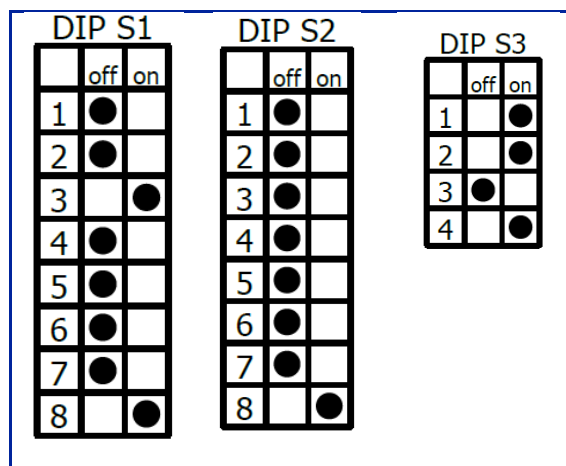


Figure 20

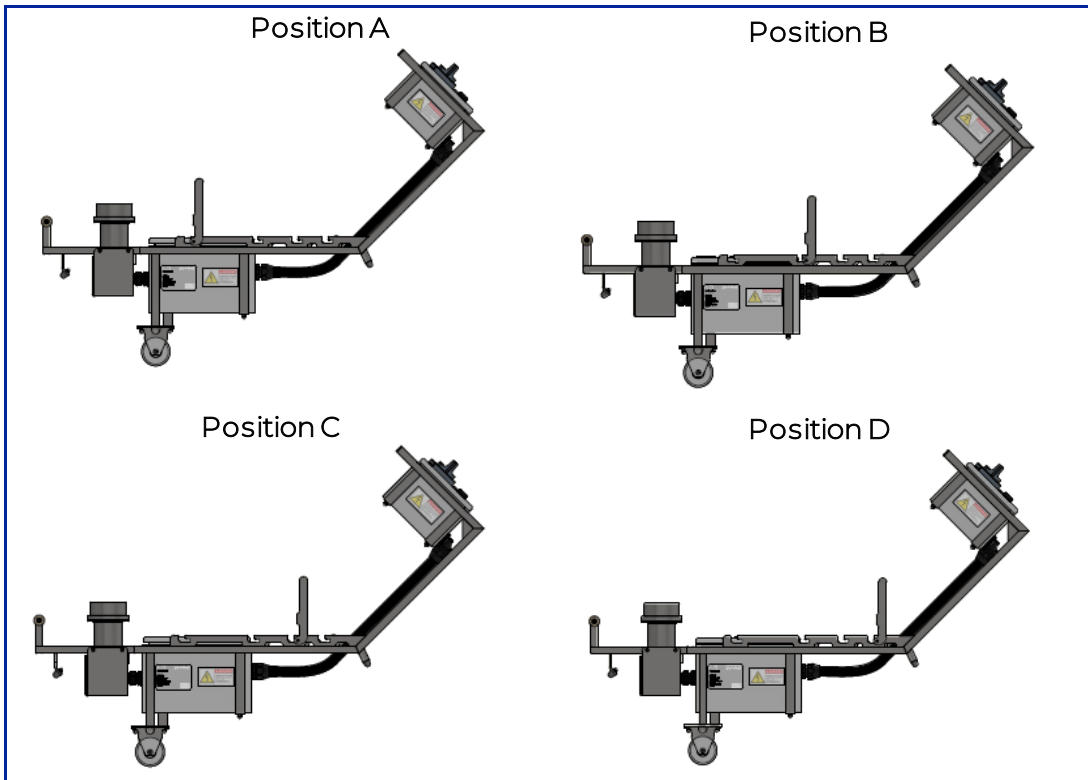
Speed display configuration: setup 4-20 mA output for 0 to 302 rpm.



The device is supplied with password protection. Should you require any assistance please contact your local Pall sales team.

Figure 21

Drive Unit latch position: latch mounting position shall be matched to the tank.



Latch Positions for Cubical Tanks

Latch Position	50L	100L	200L	400L	650L	1000L	1500L	2000L	3000L
A									
B	●	●	●	●					
C									
D					●	●	●	●	●

7.2 Environmental conditions

Table 7

Environmental conditions.

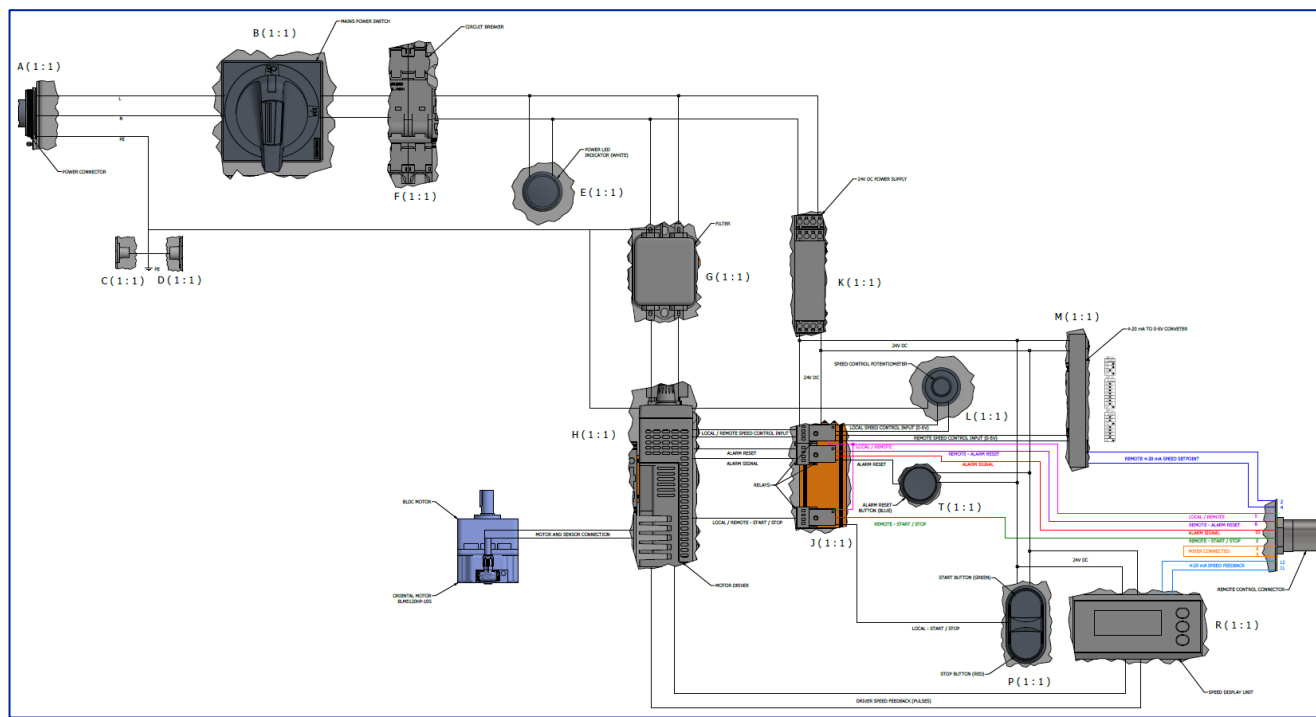
Indoor or Outdoor Use	Indoor
Altitude	Max 2000 m above sea level
Operating temperature	0 to +35°C
Operating relative humidity	20 - 80% (without condensation)
Mains supply voltage fluctuations	+/-10%
Overvoltage category	II
Wet location	No
Pollution Degree of the intended environment	2
Storage temperature	-25 to +55°C
Storage humidity	< 70% RH (Relative Humidity)
Noise level	< 70 dB

7.3 Block diagram

The following block diagram is a simplification, and it is shown for illustration purposes only.

Figure 22

Block Diagram



7.4 EC declaration of conformity

EU 'CE' Declaration of Conformity

This declaration is issued under the sole responsibility of the manufacturer.

Product: *Magnetic mixer Drive Unit for single Use Mixing Systems*
Part No: *DU010*
Manufacturer: *Pall GmbH*
Address: *Philipp-Reis-Straße 6, Dreieich, D-63303, Germany*

The Object of the Declaration (described above) is in conformity with the relevant European Union harmonisation legislation:

2006/42/EC The Machinery Directive
2011/65/EU The Restriction of Hazardous Substances (RoHS) Directive and ROHS3 amendment 2015/863
2014/30/EU The Electromagnetic Compatibility (EMC) Directive

Conformity is shown by compliance with the applicable requirements of the following documents:

Reference & Date	Title
EN 60204-1:2018	Safety of Machinery – Electrical Equipment of Machines – Part 1: General Requirements.
EN 50581:2012	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances.
EN 61000-6-4:2007/A1:2011	Electromagnetic compatibility (EMC) – Part 6-4: Generic standards – Emission standard for industrial environments

Signed for and on behalf of: *Pall GmbH*
Place of issue: *Dreieich, Germany*

Signature:

DocuSigned by:
Massimo Manazza
42F3A5596C8948B...

Name: *Massimo Manazza*
Position: *Global QA Leader Hardware*
Date of issue: *08/09/2021*

The Technical Construction File for the object of the declaration is available from the above address.

*Massimo Manazza
Pall GmbH
Philipp-Reis-Straße 6,
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D-63303
Germany*

7.5 UKCA declaration of conformity

UKCA Declaration of Conformity

This declaration is issued under the sole responsibility of the manufacturer.

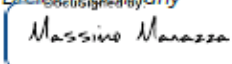
Product: *Magnetic mixer Drive Unit for single Use Mixing Systems*
Part No: *DU010*
Manufacturer: *Pall GmbH*
Address: *Philipp-Reis-Straße 6, Dreieich, D-63303, Germany*

The Object of the Declaration (described above) is in conformity with the following applicable United Kingdom statutory Instruments and their current amendments:

S.I. 2008/1597 The Supply of Machinery (Safety) Regulations 2008 and subsequent amendment 2011
S.I. 2012/3032 The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment 2012 (RoHS)
S.I. 2016/1091 The Electromagnetic Compatibility Regulations 2016 (EMC)

Conformity is shown by compliance with the applicable requirements as given in the following standards:

Reference & Date	Title
EN 60204-1:2018 EN 50581:2012	Safety of Machinery – Electrical Equipment of Machines – Part 1: General Requirements. Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances.
EN 61000-6-4:2007/A1:2011	Electromagnetic compatibility (EMC) – Part 6-4: Generic standards – Emission standard for industrial environments

Signed for and on behalf of: *Pall GmbH*
Place of issue: *Dreieich, Germany*
Signature: 
Name: *Massimo Manazza*
Position: *Global QA Leader Hardware*
Date of issue: *08/09/2021*

Signed for and on behalf of: *Pall Europe Limited*
Place of issue: *Portsmouth, England*
Signature: 
Name: *Ken Turley*
Position: *Quality Assurance Manager*
Date of issue: *08/09/2021*

The Technical Construction File for the object of the declaration is available from the above address for 'place of issue'.

*Ken Turley
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UK*

7.6 Hardware Technical Specification Summary

Table 8

Technical Specifications.

Category	Parameter	Detail
Facility	Dimensions, L x W x H	<ul style="list-style-type: none"> ▪ Docked position: 426 mm x 1245 mm x 888 mm; [16.8" x 49" x 34.9"] ▪ Storage position: 426 mm x 1278 mm x 515 mm; [16.8" x 50.3" x 20.3"]
	Weight	DU010: Approximately 32.2 kg; [~70.9 lbs] DU011: Approximately 32.4 kg; [~71.4 lbs]
	Materials of Construction	Control box, cart & Drive Unit cabinets: 304 Stainless Steel
	Surface finish	Control box, cart & Drive Unit cabinets: Brushed At least 0.89 µm Ra/ 35 µin Ra
	Operational footprint	Approximately 426 mm x 1245 mm; [16.8" x 49.0"]
	IP Rating	Control box: IP54 Drive Unit Enclosure: IP55 Motor: IP66
	Noise (at operator position):	<70dB
	Max humidity	85%, avoid condensation
	Ambient temperature	0 to +35°C
	Utilities	Electrical supply
Amperage		DU010: 1.7A* DU011: 2.7A
Motor power		Less than 180 Watts
Control System	Control architecture	Local: Speed Control Potentiometer and Speed Display Unit. Remote: Speed Control Signal and Speed Feedback Signal.
	Plug type/options	DU010: Bulgin connector (Bulgin power cable available for EU, UK, AU, CN, CH) * DU011: Fixed US power cable
	Remote Control Connector	Hummel M23, 12-pin. Remote/Local; Start/Stop; Speed In: 4-20mA. Speed Out: 4-20mA; Alarm Out.
Mixing	Impeller type	Vertical bladed 'Rushton' type impeller
	Speed range (rpm)	20 to 300 RPM
	DU010 (CE)	EC in accordance with: Machinery Directives: 2006/42/EC EMC Directive: 2014/30/EU
	DU011 (UL)	UL 61010-1: 2012 and 61010-2-051:2019 Standard for Safety Electrical Equipment for Measurement, Control and Laboratory



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