USD 3185

Magnetic Mixer

Single-Use Mixing System

OPERATOR MANUAL

DU005-US, DU006-EU, DU006-UK, DU006-SW, DU006-JP, DU006-AU

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Filtration.Separation.Solution is a service mark of Pall Corporation.

Safeguards and Precautions

1. Read and follow all instructions in this manual carefully, and retain this manual for future reference. Operation manual can be provided electronically in alternate languages upon request.

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

3. Do not plug the drive unit of the mixer in before verifying voltage configuration.

4. Use caution when lifting the equipment: Hold equipment by the frame and not by the motor. Lifting may require more than one person.

5. Prior to servicing the drive unit, always turn the power off using the ON/OFF switch on the front of the unit. Unplug and remove power cord to avoid tangling or breaking.

6. Do not attempt to open or repair the drive. Removal or destruction of the housing voids any warranty, explicit or implied. Consult the manufacturer or distributor for qualified technical service assistance.

7. Each mixing bag contains a magnetic impeller, which is the source of a strong magnetic field in close vicinity (12 inches) of the impeller. PEOPLE USING ANY ELECTRONIC MEDICAL DEVISES, SUCH AS PACEMAKERS, SHOULD NOT BE INVLOVED IN THE CLOSE HANDLING OF MIXING BAGS, IMPELLERS OR TEST IMPELLERS and should also be cautious when in close vicinity to the mixing head of the drive unit.

8. Keep supplied magnetic shells on bags, magnetic shields on magnetic chargers, and on impellers when not in use

9. DO NOT attempt to mix in empty or dry bags - it may result in to damage of the film of the bag.

DO NOT	**submerge drive unit in water**
DO NOT	**cut ground plug**
CAUTION	**Disconnect all power before servicing**
WARNING	**Risk of Electric Shock**

CAUTION **Disconnection of the Protective Earth Connector may impair the protection provided by the system**

ATTENTION **Mains outlet used to power the equipment must be within 3 meters of the device and easily accessible**

EXPLANATION OF SYMBOLS

WEEE: Waste of Electrical and Electronic Equipment

HIGH VOLTAGE

CAUTION

PROTECTIVE EARTH: Ground

MAIN POWER SWITCH

CE CERTIFIED **(230V UNITS ONLY)**

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2. SPECIFICATIONS

Power:	Single Phase 115/230V AC 50/60 Hz, full load current 2.0/1.0 A
Input Wattage:	Less than 180 Watts at maximum speed
Speed Range	0-300 RPM
Degree of Protection:	NEMA 4X, IP 65
Altitude	Up to 1000 m (3280 ft.)
Ambient Temperature:	0-40^{o}C
Max Humidity:	85% (non-condensing), *avoid condensation, * for indoor use
Vibration:	Not subject to continuous vibration or excessive impact. In conformance with JIS C 60068-2-6, “Sine-Wave Vibration Test”
Voltage fluctuation:	MAIN supply voltage fluctuations up to $\pm$ 10% of the nominal voltage
Drive Unit Footprint:	33 in x 16 in (84 cm x 41 cm)
Drive Unit Height:	41 in (104 cm), to top of handle
Drive Unit Weight:	55 lb (25 kg)

3. INTRODUCTION & PRINCIPLE OF OPERATION

The Magnetic Mixer disposable bag 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 drive unit and proprietary magnetic impeller based mixing bags fitted into retaining tanks on either a universal portable dolly (30L – 500L) or a floor mounted tank support (500L – 2,000L). The magnetic Drive 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 bag. The coupling of the in-bag impeller with the Drive Motor is accomplished by magnetic forces only, therefore no dynamic seals or shaft penetration inside the bag is required. The Drive 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 Motor.

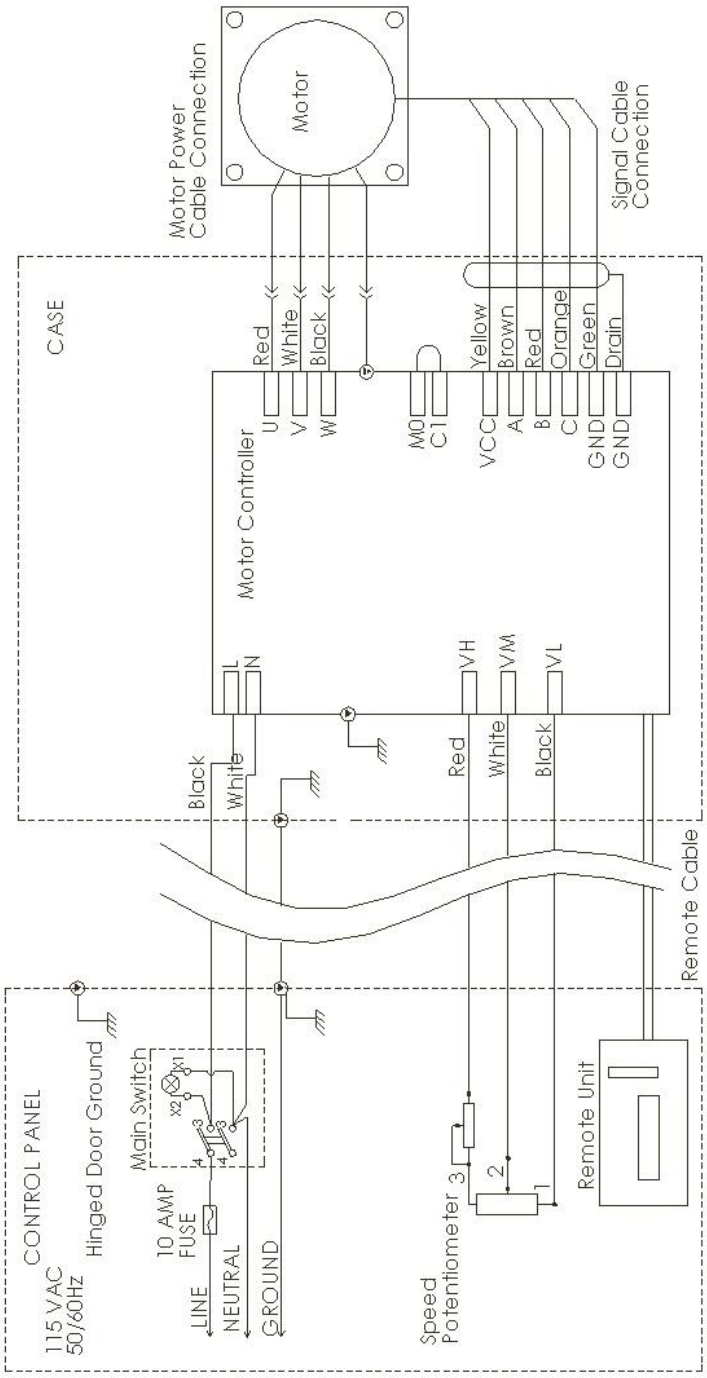
The system hardware has 4 major components:

1. Drive motor with control box and rotational speed display
2. Stainless Steel Dolly/platform for supporting the tank and interfacing with the drive
3. Plastic/Steel retaining tank for use on a dolly/stand
4. Accessory kit for interfacing the drive with the tank and bag

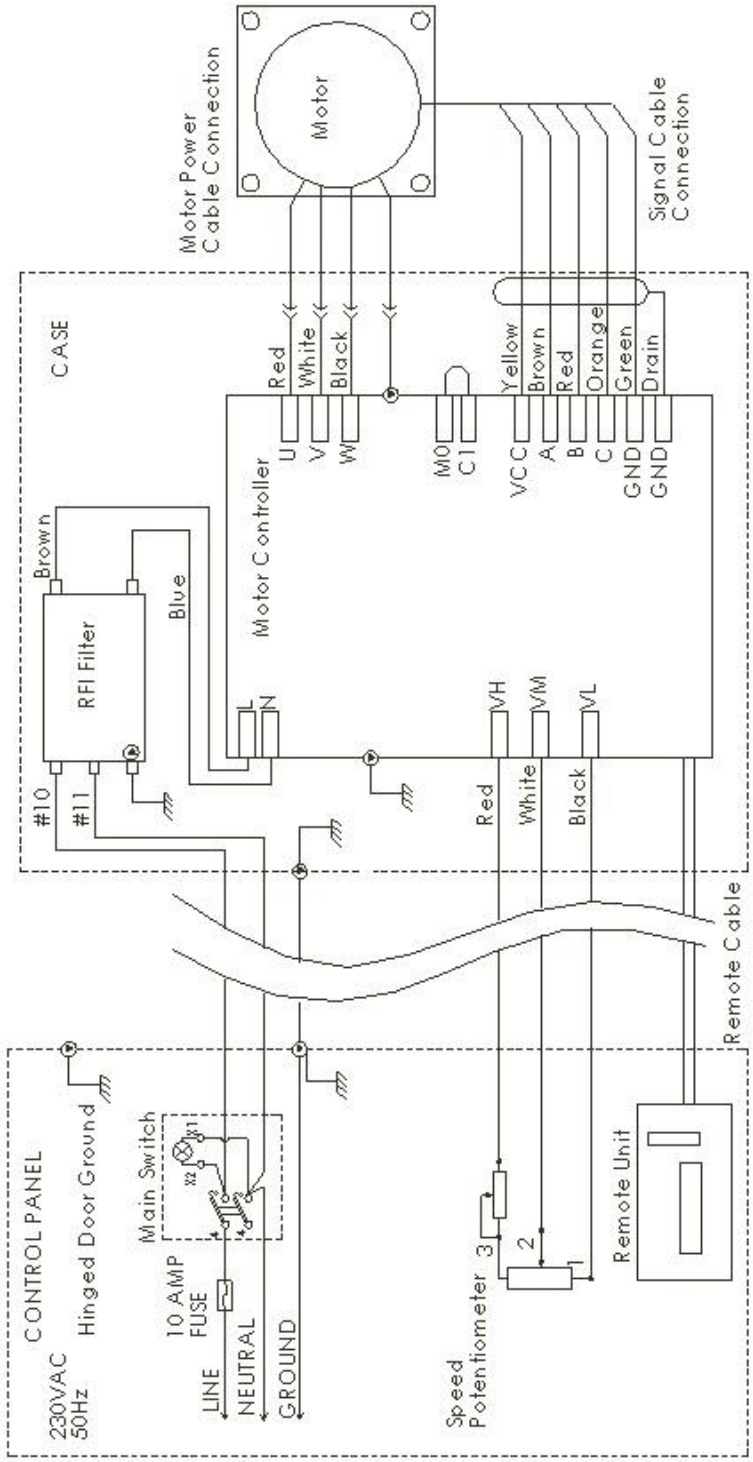
The Magnetic Mixer reusable system can accommodate a variety of standard and custom-designed disposable bags and tanks available from Pall® Lifesciences with a capacity range from 30L to 2000L.

4. ELECTRICAL SCHEMATIC

115 VAC:



230 VAC:

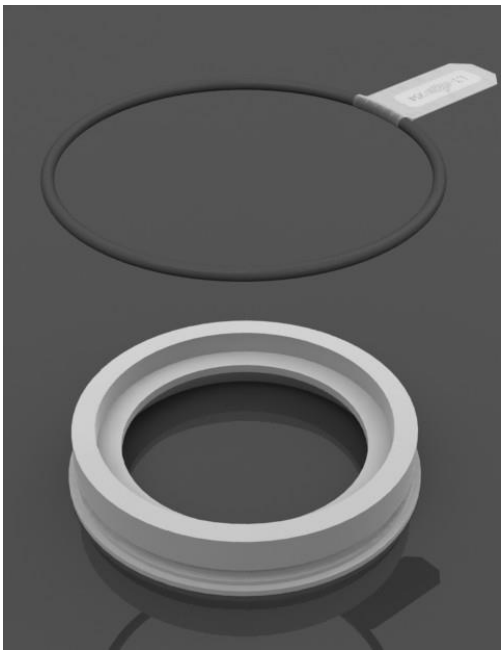

Motor
Motor Power Cable Connection
Signal Cable Connection
CASE
Red
White
Black
Yellow
Brown
Red
Orange
Green
Drain
U
V
W
M0
C1
VCC
A
B
C
GND
GND
Motor Controller
Brown
Blue
RFI Filter
L
N
VH
VM
VL
#10
#11
Red
White
Black
Remote Cable
CONTROL PANEL
230VAC
50Hz
Hinged Door Ground
Main Switch
10 AMP
FUSE
LINE
NEUTRAL
GROUND
Speed
Potentiometer
3
2
1
Remote Unit

MAGNETIC MIXER SYSTEM COMPONENTS

Figure 1: Main components of the Magnetic Mixer disposable mixing system (shown with 500L tank).

5. MAGNETIC MIXER SYSTEM ACCESSORIES

6.1 Interface with O-ring: The Interface provides mechanical interfacing of the drive unit with the impeller inside the bag.



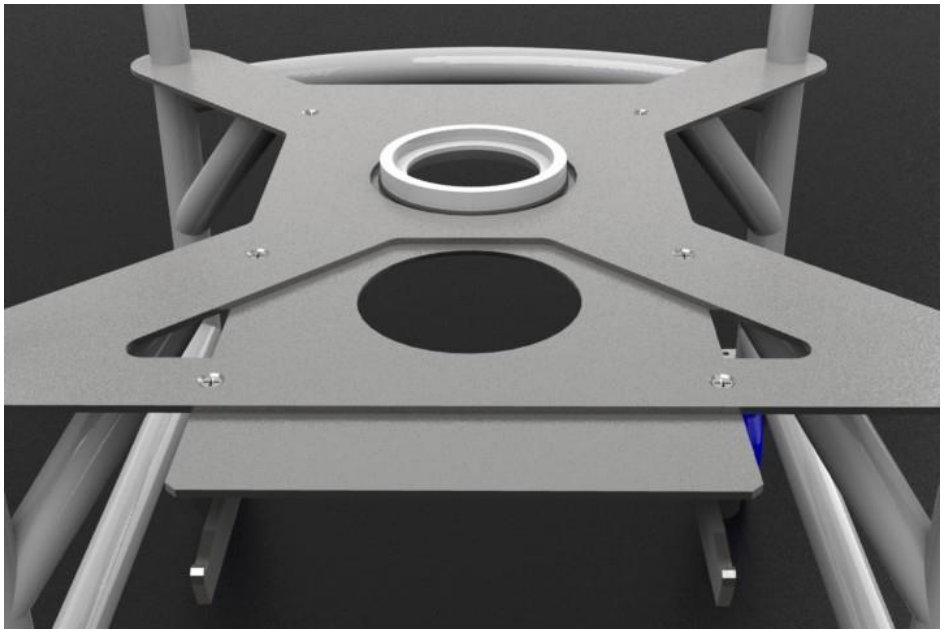


Figure 2: Top: Drive-bag interface and O-ring.
Bottom: Interface is installed in the railed port of the dolly (locked by the O-ring).

6.2 Centering Aligner and Magnetic Clamp: The Centering Aligner maintains centered position of the impeller with respect to the interface. The Magnetic clamp provides holding function for the bag in the tank before the fluid is put inside the bag. After the fluid is filled to at least a level of 3", the magnetic clamp can be removed as the hydrostatic pressure from fluid will hold the bag in place.

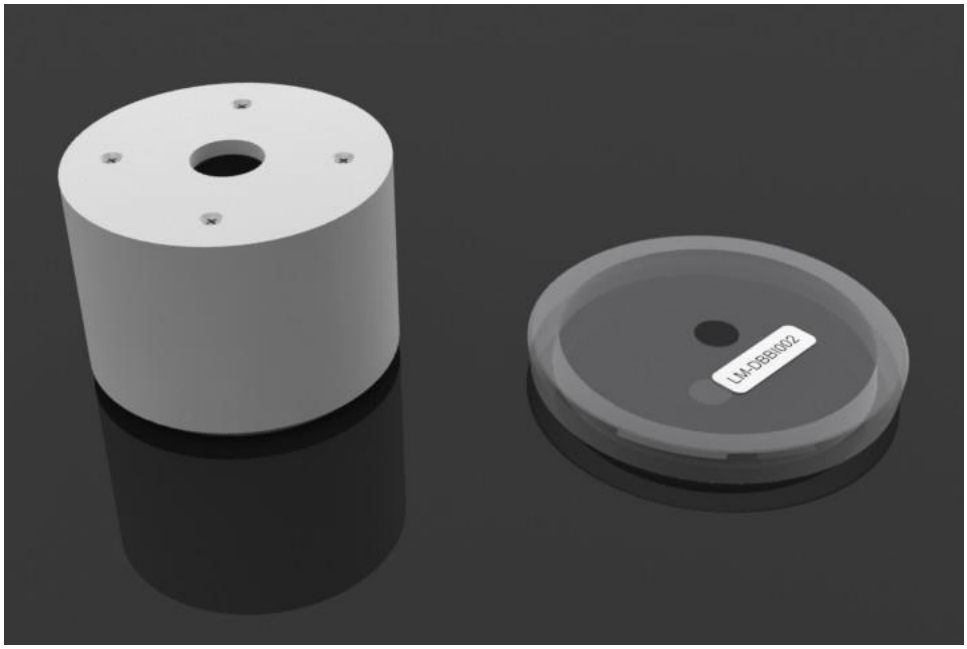


Figure 3: Magnetic clamp (left) and Centering Aligner (right)

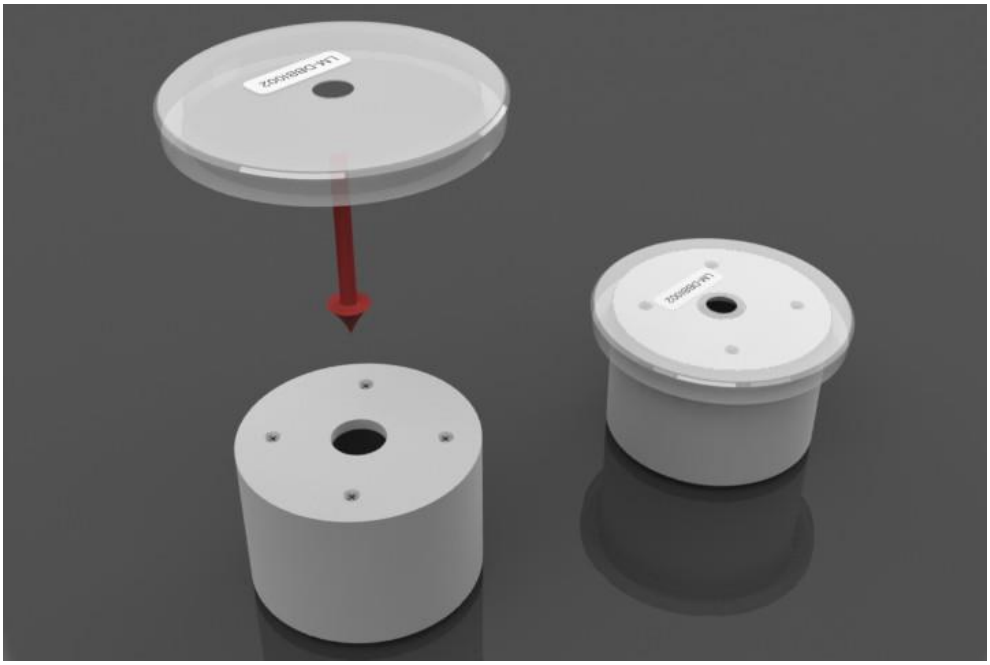


Figure 4: Assembly Magnetic clamp is assembled with the centering aligner prior to attachment to the bag

6. DOLLY - TANK ASSEMBLY

Note: Certain larger tanks (>350L) are constructed in two parts.

7.1. The Dolly has a pre-cut hole over the drive port. Insert the Interface into this hole from below and apply the O-ring as shown (*see* **Figure 2**) to secure. It is not necessary to remove or replace the Interface after mixing or between batches.

7.2 Position the plastic tank on the dolly. The bottom surface of the tank has two pre-cut holes: a small hole for the bag drain and a larger hole for the drive head. Line up the larger hole with the hole in the dolly over the drive port. The larger whole should fit loosely around the Interface.

7. BAG - INTERFACE ASSEMBLY

Figure 5: Assembly of dry bag with interface

8.1 Carefully open the EXTERNAL packaging of the mixing bag. A blue protective shell is magnetically attached to the outside of the bag over the locator. This shell must be removed from the bag before assembling the interface.

8.2 Assemble the centering aligner and magnetic clamp as shown in Figure 5.

8. INSERTING PLASTIC BAG INTO TANK

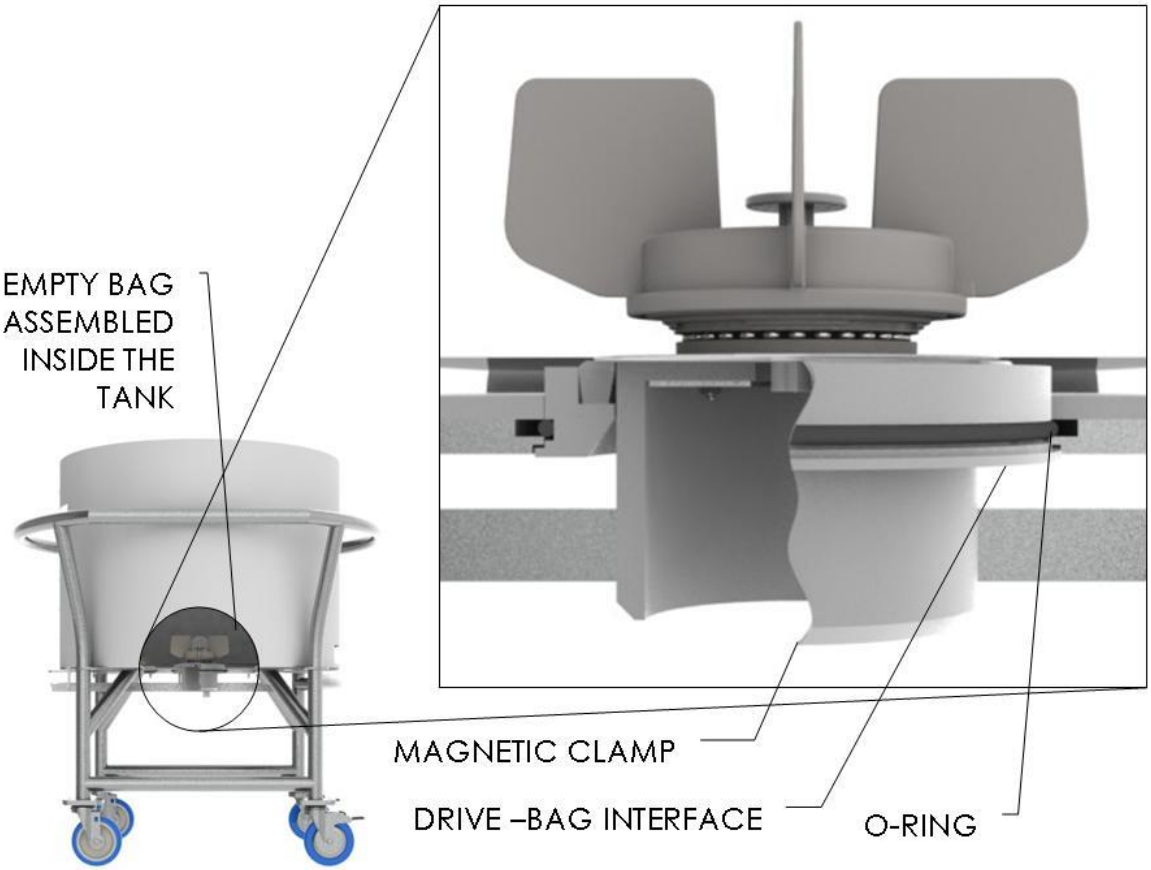


Figure 6: Bag-Tank Assembly

9.1 Place the bag in the plastic tank by aligning magnetic clamp with the large pre-cut port on the bottom surface of the tank and pull the bottom drain tube through the smaller port.

9.2 Insert the magnetic clamp in the appropriate pre-cut port.

9.3 Before filling the bag, ensure that all tubes are clamped, with the exception of the filling tube. Ensure that the bottom drain tube is clamped.

9.4 As bag starts to fill, gently pull the bottom surface of the bag to remove any wrinkles, especially near the impeller.

DO NOT exceed recommended bag capacity
DO NOT alter the tube and/or impeller configuration of bags

9.COUPLING THE BAG WITH THE DRIVE UNIT

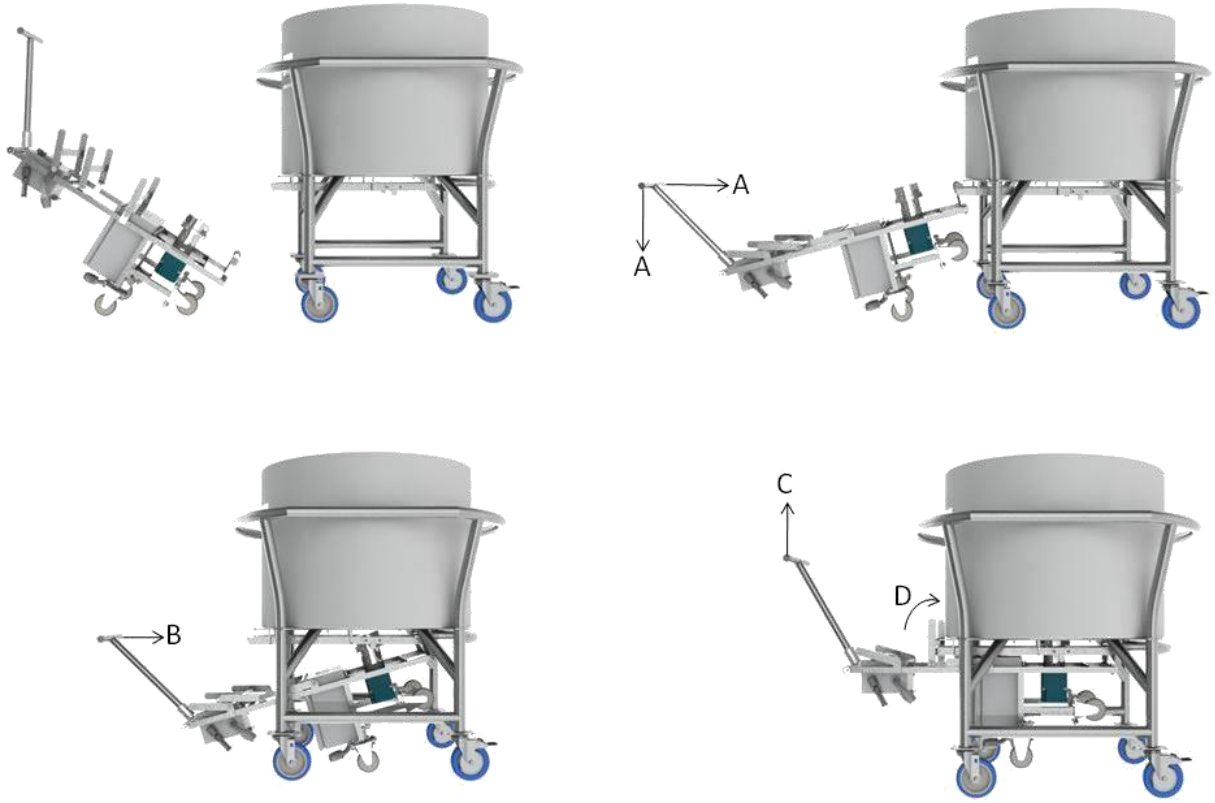


Figure 7: Coupling of magnetic mixer drive with the bag can be accomplished only when the bag is filled with fluid (**No coupling should be attempted with an empty or dry bag**! **The impeller will damage the bag.)**

10.1 Remove Magnetic Clamp from the bag-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 bag-tank assembly. Return the magnetic clamp to the supplied Accessories Box for future use.

10.2 Shift the latch toward the control box slightly, (as shown in the first segment of Figure 7).

10.3 Carefully press down on the drive handle and raise the front wheels off the ground (as shown on the second segment of Figure 7)

10.4 Align the guide bearings with the guide rails on the drive port.

10.5 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.

10.6 Using the drive unit handle, raise the superconductive drive unit to an upright position. 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 forth segment of Figure 7).

DO NOT put fingers under Locking Lever when locking the Drive Unit onto the Dolly
DO NOT **attempt to move the Dolly with the Drive Unit Handle while the system is assembled (doing so might damage the drive unit). Always use the dolly push handle to move the Dolly or Dolly/Drive Unit assembly.**

10. DRIVE MOTOR OPERATION

11.1 Plug the power cord in to the proper power source identified on the nameplate of the system.

11.2 Place the knob of the speed control potentiometer in ZERO position by turning it all the way counterclockwise.

11.3 Depress the round button of the main switch to energize the system (the button will illuminate).

11.4 Press the RUN **(green)** button on the speed readout.

11.5 Set the speed of the mixer by turning the potentiometer clockwise until the desired speed value illuminates on display.

11.6 To stop the motor press the STOP **(red)** button on the speed readout. Press the RUN **(green)** button to resume motor operation at a preset speed. See Figure 8 (below) for details on the control Box.

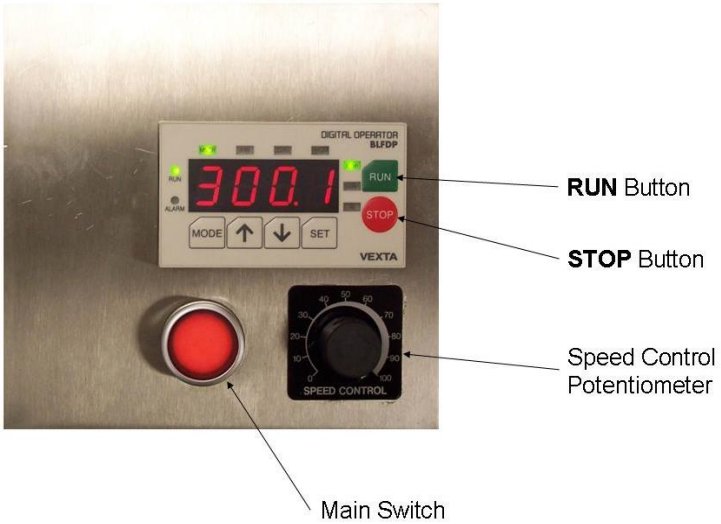


Figure 8: Control Box

11. DISCONNECTING DRIVE UNIT FROM TANK

12.1 When mixing is complete, turn the RPM Regulator to zero (0) and turn the drive switch to the STOP position. (Ensure that electrical power remains connected to the machine when mixing multiple bags consecutively.)

12.2 Firmly hold the drive unit handle and raise the drive unit slightly to release the locking lever. Release the locking lever by pulling it toward the control box.

12.3 Carefully lower the rear wheels of the drive unit to the floor and roll the drive unit on its rear wheels away from the dolly.

12.4 Press down on the drive unit handle just until the guide bearings are free from the guide rails.

12.5 Pull the drive unit slightly farther away from the dolly and carefully lower the front wheel to the ground.

12.6 The tank can now be wheeled to another station on the elevated dolly. The Superconducting Drive Unit remains ready for mixing.

12.7 To drain fluid from the bag, unclamp the bottom drain tube.

12.8 When the bag is completely drained, remove the bag by carefully pulling the impeller seat and the drain tube out of their respective ports.

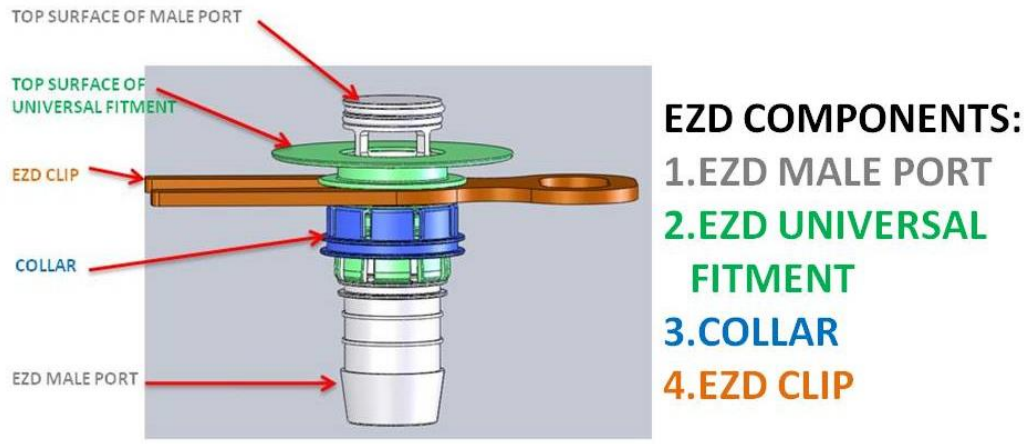
12.9 Remove the centering aligner from the tank and return to the supplied Accessories Box for future use. The Interface should remain in its locked position for future use.

12.10  Always put the protective shell back on the bag before disposal.

12.11 Dispose of plastic bag.

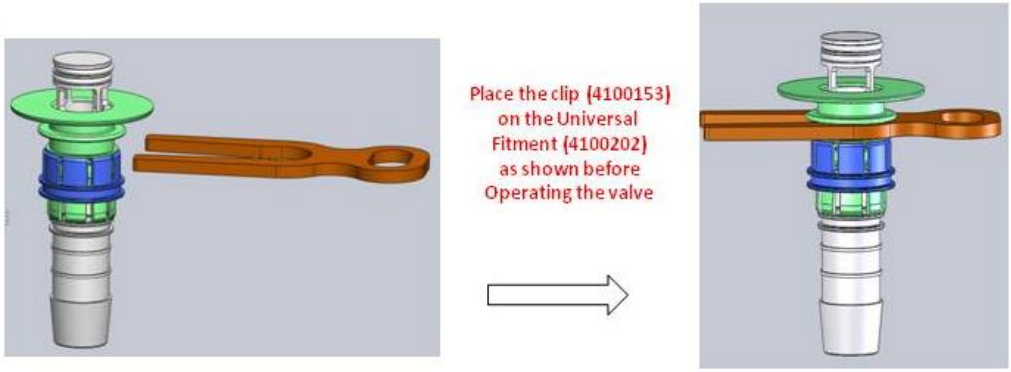
12. EZD OPERATING INSTRUCTIONS

WARNING: EZD Clip (4100153) must be installed on the bag before operating EZD valve or bag can be damaged



EZD stands for Easy Drain meaning a drain that allows easy transfer of fluid to and from the container. The typical applications include draining a container or filling a container with liquid. EZD operation involves relative movement of *EZD Male port* with respect to *EZD Universal Fitment*. The Universal Female fitment always remains stationary and it is only the relative vertical movement of EZD Male port that allows fluid transfer through the port. The EZD is closed to fluid transfer when the top surface of the EZD male port is flush with the top surface of EZD universal fitment. When the EZD male port is pushed into the EZD universal fitment, it is open for fluid transfer. The *Collar* is used to lock the EZD valve in the preferred position (either open or closed) by rolling it over the fingers of the EZD universal fitment. When the collar is over the EZD universal fitment fingers, it prevents movement of the EZD valve and when it is rolled away from the finger region of the universal fitment, it allows the EZD valve to move from a closed to open or open to closed position.

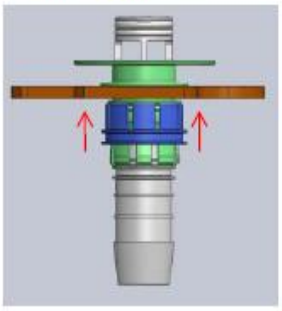
A necessary step to use EZD is that, an EZD CLIP be installed on the EZD universal fitment prior to start using it. The EZD CLIP should be mounted on universal fitment as shown in the image below.



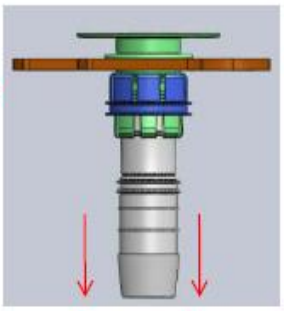
STEP-WISE INSTRUCTIONS FOR EASY OPERATION OF EZD

Moving EZD Valve from Open to Close Position to STOP Fluid Transfer

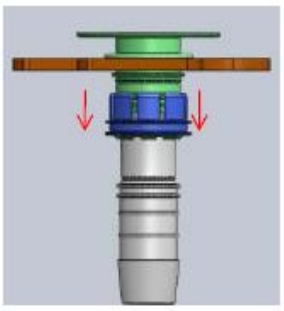
1. PUSH COLLAR UP TO UNLOCK



2. PULL EZD PORT DOWN TO CLOSE DRAIN

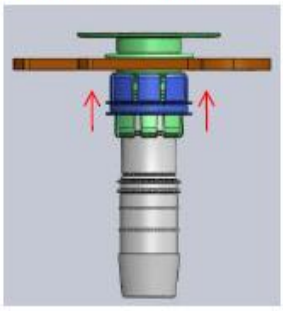


3. PULL COLLAR DOWN TO LOCK

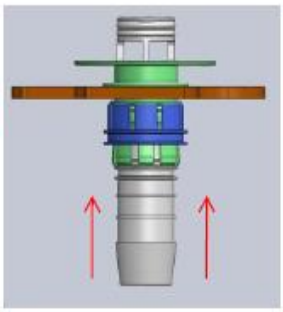


Moving EZD Valve from Close to Open Position to ALLOW Fluid Transfer

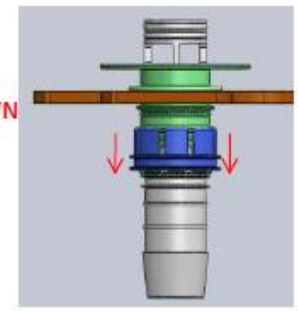
1. PUSH COLLAR UP TO UNLOCK



2. PUSH EZD PORT UP TO OPEN DRAIN



3. PULL COLLAR DOWN TO LOCK



13. Pall® LifeSciences - SERVICE

The Magnetic Mixer system was developed exclusively for mixing fluids and solids into fluids in specially designed disposable bags. Only use the Magnetic Mixer for these applications to ensure a long service life.

Should your Magnetic Mixer require service, contact:

North America:
PALL Life Sciences
20 Walkup Drive
Westborough, MA 01581
E-mail: PASS_Support@pall.com

Europe:
PALL Life Sciences
Reugelstraat 2, B-3320 Hoegaarden, Belgium
Phone: +32 (0) 16.76.61.59
Fax: +32 (0) 16.76.76.25

Magnetic Mixer

Patents:
Pall.com/patents

14. SPARE PARTS

MM-DBBI002	Centering Aligner
MM-DBBI007	Magnetic Clamp
MM-DBBI008	Drive-Bag Interface
MM-DBBI004	O-Ring for use with Drive-Bag Interface
MM-LTOE059	M1 Latch Assembly
MM-LTOE060	M2 Latch Assembly
MM-LTOE061	Magnetic Mixer Rollers
2100024	Fuse

PALL Life Sciences		Released	
		EC DECLARATION OF CONFORMITY IN ACCORDANCE WITH THE MACHINERY DIRECTIVE	
Document #:	FORM-01600	Revision:	3
Originator:	Mairesse, Bastien	Effective Date:	29-apr-2014
Site/Locations:	Europe : Belgium : Brussels	Document Management System:	Quality
Department:	Engineering - Product; R&D	Division:	Life Sciences

EC DECLARATION OF CONFORMITY IN ACCORDANCE WITH THE MACHINERY DIRECTIVE 2006/42/EC, Annex II, Sub. A

The manufacturer, Pall LifeSciences Belgium BVBA.

Reugelstraat 2
3320 Hoegaarden

Name and address of the person (established in the European Community/EEA) authorized to compile the technical file (to the authorities on request):

Steven Vanhamel, Director Research & Development, Pall Life Sciences Belgium BVBA.

Reugelstraat 2

3320 Hoegaarden, Belgium

Hereby declares that the machinery:

Magnetic Mixer Single-Use Mixing System

Models DU006-EU, DU006-UK, DU006-AU, DU006-SW, DU006-JP

is in conformity with the relevant provisions of the Machinery Directive (2006/42/EC) and the regulations transporting it into national law.

is in conformity with the provisions of the following other EC-Directives

- low voltage Directive 2006/95/EU
- EMC Directive 2004/108/EC

And furthermore, we declare that:
the following (parts/clauses of) European harmonized standards have been used :

- EN ISO 12100:2010
- EN 60204-1:2006
- EN 61010-1:2010
- EN55011:2009, Group 1, Class A
- EN61000-6-2:2005

Done at Hoegaarden, Belgium, on October 2014
Signature:

Date of Approval:
17/10/14

PALL Legal representative
Bob Foster, VP operations, PALL Life Sciences Belgium

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