PALL Life Sciences

Instructions For Use

Jet Mixer

Filtration. Separation. Solution.SM

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1. Introduction

The purpose of this manual is to inform the users about the safe and correct use of the Jet Mixer. This includes all persons who have the task of installing, commissioning, adjusting, maintaining, cleaning, repairing, transporting or scrapping the machine.
Before using this machine all persons involved should thoroughly read and understand the user manual. All safety precautions and safety provisions in use in the company must be known and respected.

The Jet Mixer is a mixing system that contains of stainless steel jacketed and non-jacketed tanks, with a holder for a magnetic driver and a controller, that are used as biocontainerholder for various sizes of Jet Mixer biocontainers (50L, 200L, 500L and 1000L). Underneath the tank the driver is installed inside a tray and at the tank side, the controller is placed in a holder.

This user manual must always be available near the machine. It is very important that all instructions 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 your Pall 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.

2. Safety warnings

⚠ Operation outside the specifications defined in this manual may cause personal injury and result in damage to the equipment.

⚠ No operations (cleaning, maintenance, ...) may be performed on the machine if the machine is not switched off. Protections around moving parts may not be removed.

⚠ The system must be operated indoor, in a clean industrial environment within a temperature range as mentioned in § 7.4 Temperature

⚠ The power cable of the machine should always be plugged into an earthed electrical network.

⚠ The system should always be moved on a clean, flat, even, step less floor surface.

⚠ Never position yourself between the tank and any obstacles in the moving direction of the tank when moving it. With a full biocontainer the tanks momentum could easily crush whatever gets in between.

3. Assembly and commissioning

3.1. General

When transporting system it is recommended that the drive unit and control unit be disassembled from the system to avoid damage due to vibrations.

For limited on-site transportation this is not required and the control unit and drive unit may remain on the tank.

Required electrical utility:

- The Telemodul 700827 can be used on a single phase net of 220V.
- The Telemodul 700828 can be used on a single phase net of 110V.

3.2. System components

Table 1 describes the different components of the Jet Mixer mixing system. Figure 1 - Figure 4 show the main components.

Table 1: Jet Mixer system components

Component	Description	Function
Bag tank	Stainless steel tank with drain opening on the base plate	Holder for the disposable mixing biocontainers
Drive unit tray	Stainless steel support tray on which the magnetic drive unit is positioned	Aligns the drive unit in the correct position underneath the tank
Control unit holder	Stainless steel holder in which the control unit is placed	Houses the control unit
Drive unit	Thermo Scientific VARIOMAG® Mobil 200 magnetic stirring platform	When correctly housed in the drive unit support, the drive unit aligns with the magnetic turbine inside the mixing biocontainer and provides the turning force to the turbine
Control unit	Thermo Scientific VARIOMAG® Telemodul 80M magnetic stirring controller	Controls the magnetic drive unit (on/off, speed and time settings)

Figure 1: Drive unit tray

Figure 2: Control unit holder

Figure 3: Drive unit

Figure 4: Control unit

3.3. Control unit

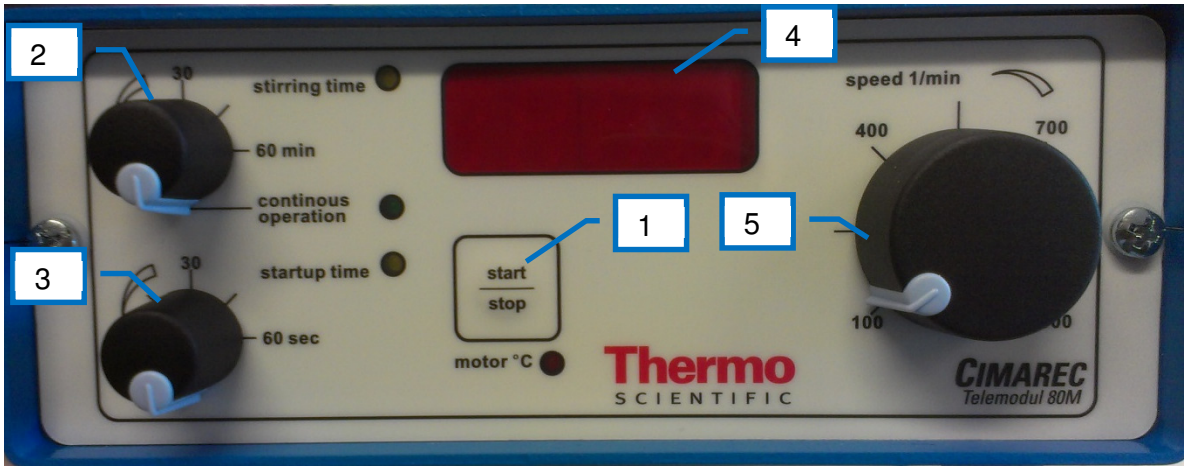

Figure 5: Front of control unit

1. Start/Stop button
2. Stirring time button
3. Startup time button
4. Display
5. Speed set point button

Figure 6: Back of control unit

6. Master power On/Off button
7. Power cable female socket
8. Communication cable female socket

3.4. Assembly

To assemble the equipment, follow the next steps:

- Lock the wheel brakes of the tank
- Open the drive unit holder underneath the bottom plate of the tank by releasing the 2 screws and by pulling the holding plate out. The holding plate will rotate downwards.

Figure 7: Open drive unit tray

- Insert the MOBIL 200 drive unit into the drive unit holder with the cable on the open end

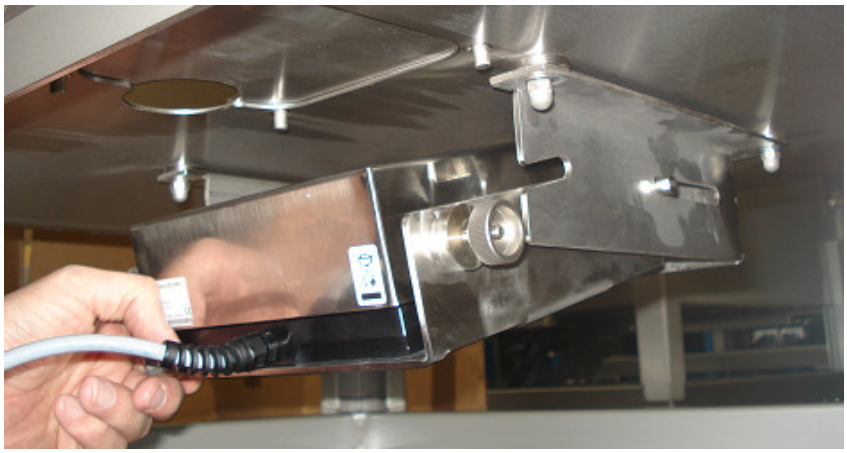

Figure 8: Inserted drive unit

- The driver has 4 rubber stoppers at the bottom that fit into the 4 square openings of the holding plate. Insert the driver as far as possible to the back (until the hard stop).
- Lift up the holding plate with driver

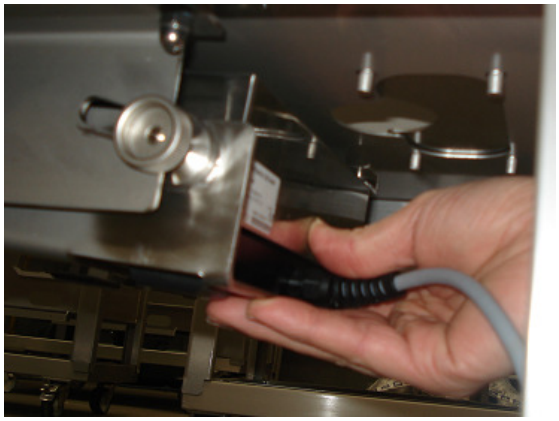

Figure 9: Inserted drive unit

- Push the driver into a horizontal position

Figure 10: Correctly installed drive unit

- Lock the 2 screws to fixate the system.

Figure 11: Locking screws

Figure 12: Correctly installed drive unit in final position

- Place the TELEMODUL control unit holder on the side of the tank. As the non-jacketed and jacketed tanks have a different edge design, the holder has a positioning tool. The 2 discs on the side of the holder can be rotated. In this way the drive unit can always be positioned vertical.

Figure 13: Control unit holder on a jacketed tank

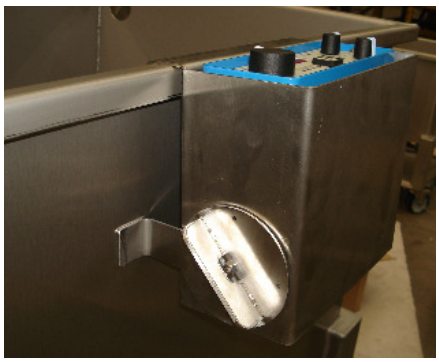

Figure 14: Control unit holder on a non-jacketed tank

- Insert the control unit into the control unit holder.

Figure 15: Installed control unit

- Connect the communication cable from the drive unit to the control unit and connect the power cable.

Figure 16: Connected power and communication cable

- Plug the power cable into the mains electricity and switch on the control unit with the ON/OFF button at the back side.

4. Operation of the control unit

The main functions of the drive unit and control unit are:

- rotation speed control with digital rotation speed indication (0-1000RPM)
- start and stop button
- adjustable startup time (0 – 60sec)
- continuous operation or timed operation (0 – 60min)

It is advised to use the function of the start-up time, especially when high speed is used. A gentle acceleration of the RPM will ensure a stable coupling and will prevent decoupling of the magnet.

For further functional information of the driver and controller in specific, we refer to the operating manual of the Variomag Mobil200 and Telemodul 80M.

5. Installation and use of the mixing biocontainer

5.1 Installing the mixing biocontainer

Remove the mixing biocontainer from the packaging bags.

Insert the drain tubing through the opening in the bottom plate of the tank.

If the tubing is too large to fit through the hole, or if the tubing has large items such as y-pieces or filters, the small drain cover plate around the drain hole can be removed.

If the mixing biocontainer incorporates an EZ Drain fitment, position it in the drain port cutout, install the drain insert plate, and then snap the EZ Drain clip over the fitment OUTSIDE the tank (Figure 17).

Figure 17: EZ Drain clip installation

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).

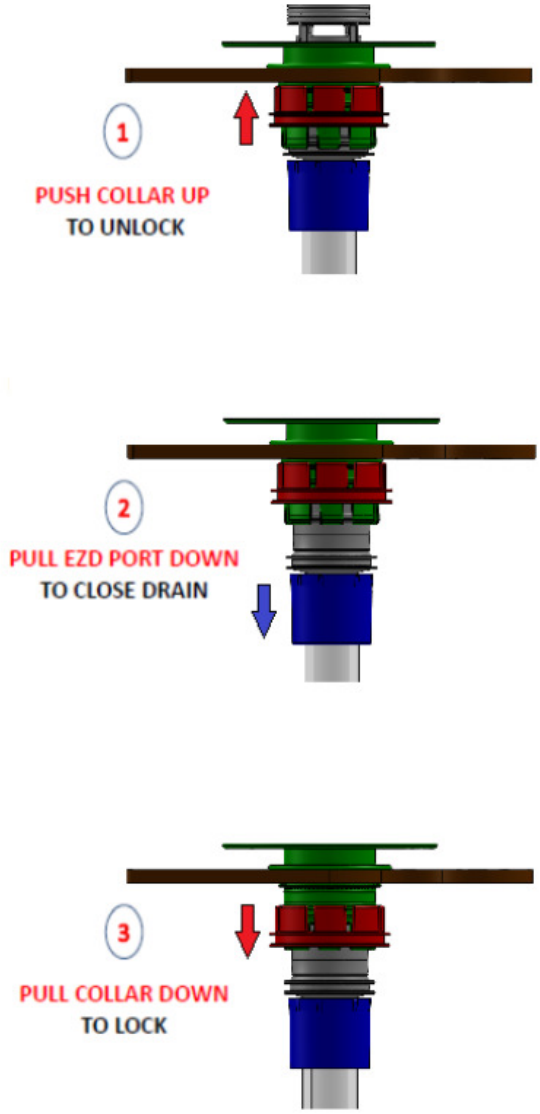

Figure 18: Moving from open to closed (stops fluid flow)

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.

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.

5.2 Filling the mixing biocontainer

Make sure that the clamp on the drain tubing is closed and that the clamps on the filling tubing are open. Connect the filling tube to the liquid supply and start filling.

It is important that the filling of the first liters of liquid happens gently to be able to position the bottom square of the mixing biocontainer correctly, without too many wrinkles and stresses on the film.

When the liquid inside the biocontainer is approximately 3cm high, the mixing can be started.

⚠ Do not start the mixing when the biocontainer is still dry! This will lead to a high friction of the impeller to its bearing and can cause the plastic of the impeller to overheat. This can cause impeller deformation and even blocking.

5.7 Starting the mixing cycle

It is advised that the mixing is tested when the biocontainer is only filled with a few centimeters of liquid. In case the biocontainer was not properly centered in the tank, the coupling of the magnet might not be OK, and the impeller will not rotate correctly. If this is observed at this stage one can still gently manipulate and reposition the biocontainer.

When activating the impeller, start at low speed and gently increase the speed, or use the start-up time function.

If the impeller is rotating properly, the biocontainer can further be filled.

5.8 Emptying the mixing biocontainer

After the mixing process is completed, the mixing biocontainer's 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.

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 19).

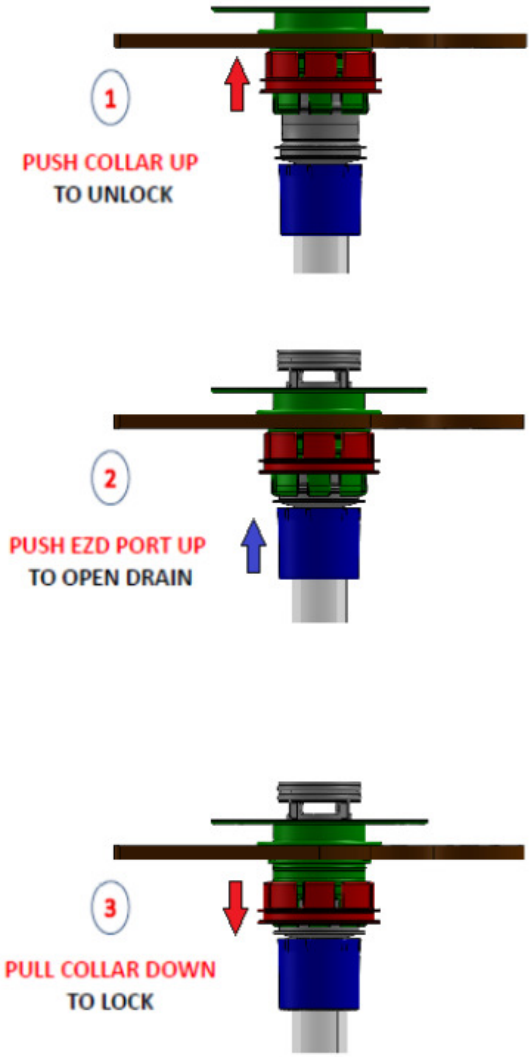

Figure 19: Moving from closed to open (allows fluid flow)

After the mixing biocontainer has drained, any residual liquid can be recovered by gently lifting the mixing biocontainer so as to direct the residual liquid to the drain.

Close all clamps and detach the mixing biocontainer from all external connections. Remove the EZ Drain clip (if used) then carefully lift the empty mixing biocontainer out of the tank.

Dispose of the mixing biocontainer according to applicable EH&S policies and regulations.

6 Cleaning, maintenance and inspection activities

6.1 Cleaning

The tank and supports are made of 304 stainless steel and may be cleaned with water, isopropyl alcohol, acetone or other solvents typically used for the cleaning of stainless steel. The control unit and driver should be cleaned with a damp cloth with water or isopropyl alcohol (but not with acetone or other corrosive products). It is recommended that the system be dried thoroughly after cleaning or spills.

The system should be inspected on cleanliness after every biocontainer process termination or after a set period of time (e.g. weekly). In the event the system is found not clean anymore, corrective actions must be taken to ensure the system is clean when restarting a new process. Therefore the system must be cleaned after every spill and after every biocontainer changeover.

6.2 Maintenance and inspection

The equipment is maintenance-free and must be cleaned as mentioned in 6.1.

For additional cleaning and maintenance considerations of the drive unit (Mobil 200- Thermo Scientific) and control unit (Telemodul 80 - Thermo Scientific), please consult the Operating Manual of these systems.

6.3 Transport

The tank castors supplied are intended for use on smooth clean room floors. In order to prevent wheel damage, do not transport tanks across rough industrial floors where possible. If this is unavoidable (for example during transport to final location) it is recommended that the wheel surface are taped or the tank transported on a device such as a pallet jack.

Before moving the tanks please make sure the power cable is unplugged and stored to prevent tripping on it.

6.4 Storage

When storing the system for periods longer than one month, it is recommended that the drive unit and power supply be disassembled from the tank and that all parts are cleaned and dried with a lint-free cloth.

The system must be stored in a heated room within a temperature range of 0oC to 40oC protected against all weather conditions and dust.

Before reinstating the system after a longer period of storing, the Instructions and protocols as mentioned in the equipment manuals must be followed again and the system should be visually check on damages.

7 General machine specifications

7.1 Materials

Plate material (outside plate surfaces)	Stainless steel AISI 304L Brushed surface finish Surface roughness <1.2 µm Ra / 47 µin Ra
Wheels (castors)	White polyamide
Drive unit	Stainless steel housing
Control unit	Blue coated steel housing

7.2 Capacity

The control unit and driver are designed to work with biocontainers and tanks of sizes 50L, 200L, 500L and 1000L.

7.3 Noise level

The system generates negligible noise.

7.4 Operating temperature

The operating temperature range is 0°C to 60°C at max 80% humidity.

For more details, please consult the specific equipment manuals. (doc ref 020-17473-00)

8 Service

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

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

For information about applicable patents, visit www.pall.com/patents

9 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.

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