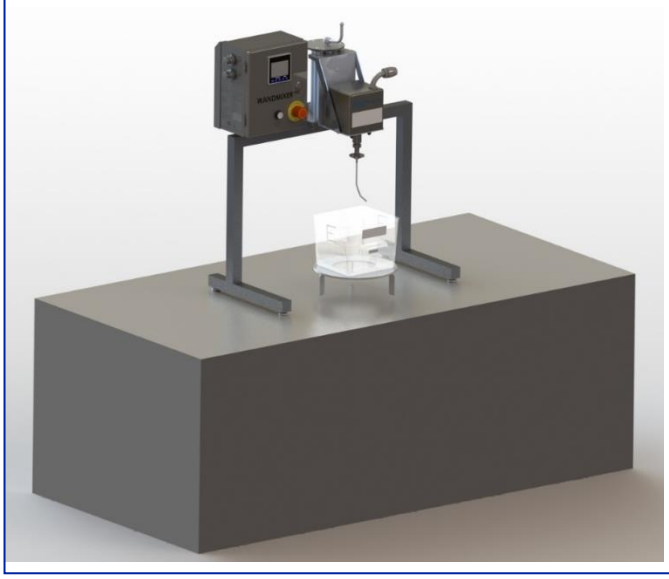
BIOTECH

Instructions For Use

USD 3557

Wand Mixer Single-Use Mixing System

Model: RDUA007BT



Model: RDUA008FB

Contents

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		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		Red diamond, white background with a black symbol	Classifies the hazards of chemical products and communicates health and safety information.

1.2 Safety Symbols Within This IFU

Table 2

Safety signs and symbols within this document.

Symbol	Definition / Meaning
	Prior to operating, the instructions must be read in entirety.
	Highlights important information regarding instructions for use.
	Protected earth; Ground.
	Identifies a dangerous prohibited situation that may result in personal injury or death.
	Caution should be taken. Potential risk to equipment. Refer to instructional text.
	Caution possibility of electric shock.
	Caution risk of entanglement.

1.3 Safety Messages

Prior to operating the product all instructions and safety messages must be read.

Safety is the responsibility of the individual installing, using or maintaining the equipment and any others who may be involved in the operation. It is important that the safety instructions are read and followed.

Table 3

Safety messages.

Symbol	Safety Messages
	WARNING! May lead to severe injuries or death. - Do not use this instrument in any manner inconsistent with these operating instructions or under any conditions that exceed the environmental specifications stated. - Do not attempt to service or reposition the drive unit while shaft/shaft adaptor is rotating. - 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. - Do not use flammable liquids / substances. - Do not use non-Pall rotational wands or heavy-duty frames.
	Do not - Submerge drive unit in water - Cut ground plug - Disconnect the protective earth connector
	- Do not allow loose clothing or parts of the body to come near the rotating drive unit shaft/shaft adaptor.
	- Power supplied to this instrument must match the specifications indicated on the control box. - 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. - For full compliance with CE specifications, be sure the appropriate ground connection is made - Mains outlet used to power the equipment must be within 3 meters of the device and easily accessible
	- Hold equipment by the frame and not by the motor or motor positioner. Lifting may require more than one person - Only Pall rotational wands and heavy-duty frames are to be used.
	- Disconnect all power before servicing.

2 Specifications

2.1 RDUA007BT

Table 4

RDUA007BT specifications.

Specification	Details
Dimensions (H x W x D)	92 cm x 79 cm x 41 cm; 36.3 in. x 30.9 in. x 16.1 in.
Control box, frame, & motor enclosure material	304L Stainless Steel
Control box and frame surface finish	At least 35 µin. Ra / 0.89 µm Ra
Control box and motor enclosure ingress rating	IP 65, NEMA 4X
Voltage	100-230 VAC, 50/60 Hz
Input Wattage	Less than 150 W
Amperage	100 V 1.6 A; 110 V 1.5 A ; 230 V 0.7 A
Voltage fluctuation	± 10%
Altitude rating	1000 m (3280 ft)
Maximum humidity	85%, avoid condensation
Ambient temperature	4-40 °C (39-104 °F)
Motor horsepower	1/8 hp
Power cord length	600 cm (20 ft)
Power cord plug options	US, Continental Europe, Swiss, Australia, Japan, UK
E-stop (present, yes/no, location)	Yes, face of control box
Minimum and maximum speed	0 to 250 RPM
Connections for remote output/control	TURCK RSFPV61, RSFPV579
Functions available from remote control panel	Motor - start, stop. Speed – adjustment, indication. Alarm – indication. Mode of control (remote/local) – indication
Signal type(s) for remote output/control	Wand speed out 4-20 mA, motor control in 0-10 VDC, discrete I/O signals relay contact type
Alarms generated	Motor failure, speed off-range failure, E-stop activation
Method for RPM measurement	Direct measurement of motor shaft speed
Recipe storage	Yes. Up to 10 can be stored. Up to ten instructions in each recipe are executed sequentially. Each instruction contains individual programmable parameters: mixing time, pause time, and speed
Password protection	Operator level: access to protected function - start recipe run. Supervisor level: access to protected functions - Recipe Editor, Pause or Abort Recipe run, Switch of Control between Local to Remote, adjustment of set up for reduced set of parameters. Maintenance level: access to protected functions – Program Setup parameters, System parameters and includes Supervisor level of access.

2.2 RDUA008FB

Table 5

RDUA008FB specifications.

Specification	Details
Dimensions (H x W x D)	164 cm x 95 cm x 75 cm; 64.5 in. x 37.3 in. x 29.5 in.
Control box, frame, & motor enclosure material	304L Stainless Steel
Control box and frame surface finish	At least 35 µin. Ra / 0.89 µm Ra
Control box and motor enclosure ingress rating	IP 65, NEMA 4X
Voltage	100-230 VAC, 50/60 Hz
Input Wattage	Less than 150 W
Amperage	100 V 1.6 A; 110 V 1.5 A ; 230 V 0.7 A
Voltage fluctuation	± 10%
Altitude rating	1000 m (3280 ft)
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Signal type(s) for remote output/control	Wand speed out 4-20 mA, motor control in 0-10 VDC, discrete I/O signals relay contact type
Alarms generated	Motor failure, speed off-range failure, E-stop activation
Method for RPM measurement	Direct measurement of motor shaft speed
Casters	4X swivel with brakes
Wheel material	Nylon
Recipe storage	Yes. Up to 10 can be stored. Up to ten instructions in each recipe are executed sequentially. Each instruction contains individual programmable parameters: mixing time, pause time, and speed.
Password protection	Operator level: access to protected function – start recipe run. Supervisor level: access to protected functions – Recipe Editor, Pause or Abort Recipe run, Switch of Control between Local to Remote, adjustment of set up for reduced set of parameters. Maintenance level: access to protected functions – Program Setup parameters, System parameters and includes Supervisor level of access.

3 Overview

The Wand Mixer single-use technology (SUT) biocontainer mixing system is a revolutionary mixer that provides efficient mixing utilizing a patented rotational wand technology in a sterile, closed SUT biocontainer. The Wand Mixer system can mix in sterile single-use hermetically sealed SUT biocontainers ranging in nominal volume from 5 L to 200 L.

The Wand Mixer system consists of a bench top or floor-based drive, a plastic or stainless-steel tank to support the SUT biocontainers, a rotating stainless-steel wand for mixing and a coupling assembly to connect the wand to the drive and SUT biocontainer.

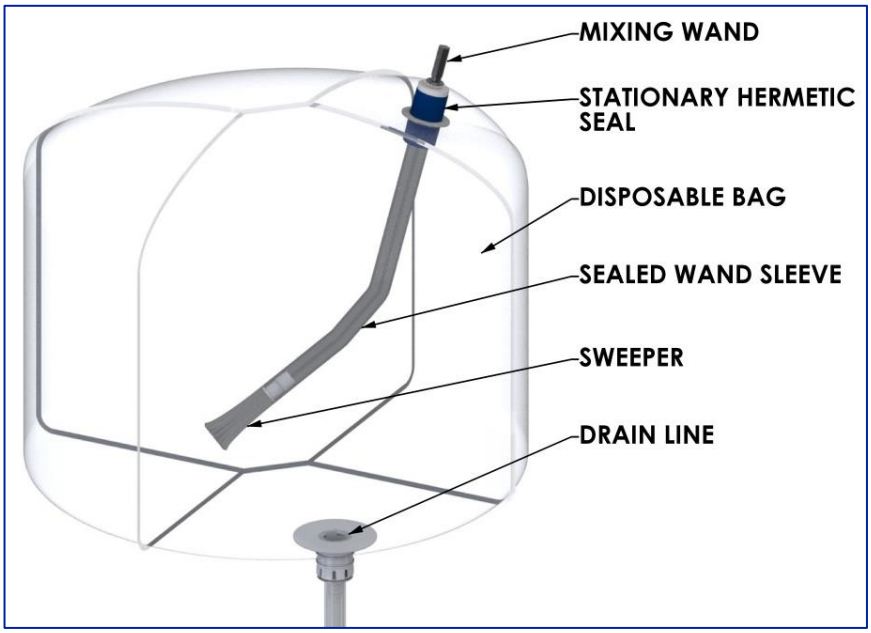
The Wand Mixer can accommodate a variety of standard and custom-designed single-use mixing biocontainers available from Pall Corporation.

4 Principle of Operation

The Wand Mixer single-use biocontainer mixing technology provides non-invasive mixing inside sterile plastic biocontainers. The technology is based on rotating a rod of predetermined shape introduced in the sleeve of the mixing biocontainer. The rod is separated from the processed sterile fluid by a sleeve that is hermetically sealed on one end. Rotation of the rod induces the rotational motion of the sleeve due to flexural shape changes. The flexural rotational motion of the sleeve results in efficient mixing inside the biocontainer.

Figure 1

Rotational wand.



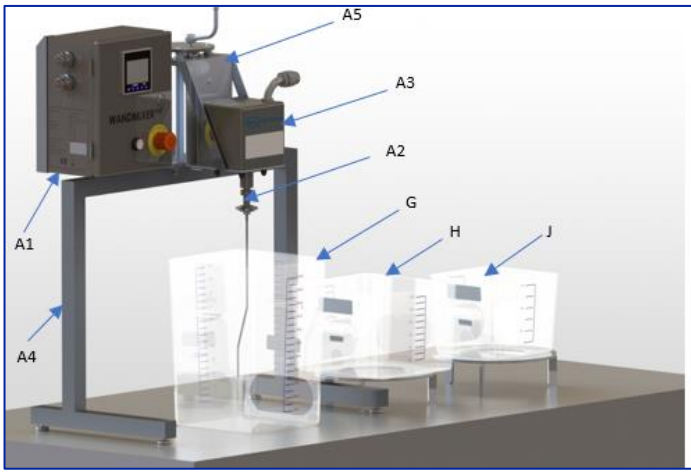
Once rotation of the wand is activated by external drive, sleeve performs rotational motion based on its flexing. The mixing procedure is non-invasive leaving the processed fluid contained in sealed biocontainer.

5 Wand Mixer Components and Accessories

5.1 RDUA007BT

Figure 2

Bench top Wand Mixer drive unit.



ITEM	DESCRIPTION
A	WAND MIXER
A1	CONTROL BOX
A2	COUPLING SYSTEM
A3	DRIVE MOTOR
A4	FRAME
A5	HEIGHT ADJUSTMENT ASSEMBLY
G	20L PLASTIC, CUBICAL TANK
H	10L PLASTIC, CUBICAL TANK
J	5L PLASTIC, CUBICAL TANK

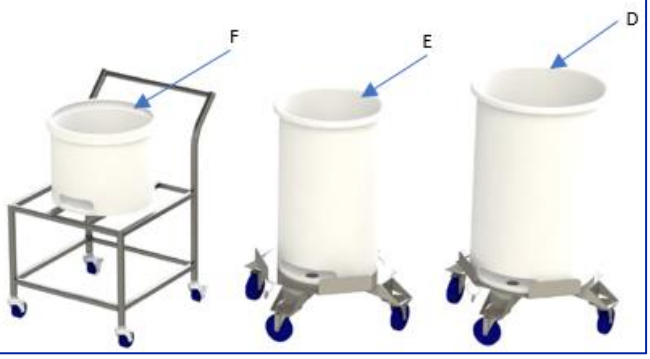
The above image shows the 5 L, 10 L, and 20 L containers. Both the 5 L and 10 L containers are on stand RESA003A.

5.2 RDUA008FB

Figure 3

Floor based Wand Mixer drive unit.

ITEM	DESCRIPTION
B	WAND MIXER
B1	CONTROL BOX
B2	COUPLING SYSTEM
B3	DRIVE MOTOR
B4	FRAME
B5	HEIGHT ADJUSTMENT ASSEMBLY
D	200L PLASTIC, ROUND TANK
E	100L PLASTIC, ROUND TANK
F	50L PLASTIC, ROUND TANK

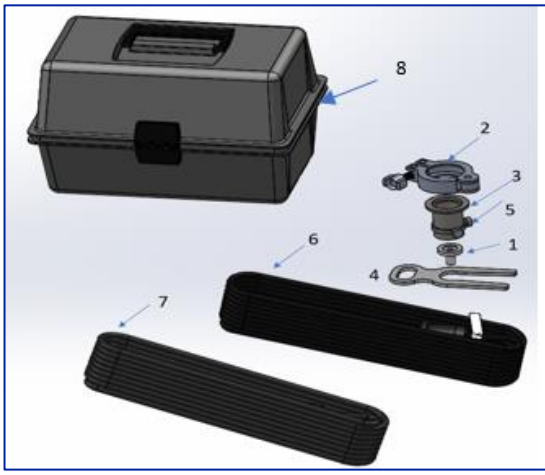


The above image shows the 200 L container on a stainless-steel dolly RDOC2005

5.3 Wand Mixer Toolbox

Figure 4

Toolbox and contents (215-18520-00).



ITEM	DESCRIPTION
1	BUSHING, WAND HDPE
2	QUICKCLAMP TUB EFITTING WINGNUT CLAMP
3	COUPLER, WAND, SST
4	PLATE, CLIP FOR 1" DRAIN VALVE
5	KNURLED HEAD THUMB SCREW
6	ASSY, EU POWER CORD
7	ASSY, US POWER CORD
8	TOOLBOX

5.4 Wands

The rotational wands provide the rotational motion of the mixing sleeve inside the biocontainer. The wand is introduced in the open end of the sleeve, while its hexagonal head is received by motor shaft adaptor. It is very important to only use each wand with its designated nominal biocontainer size. Failure to use the proper wand can result in damage to the biocontainer and/or the equipment. See Table 6 for each wand's designated biocontainer size.

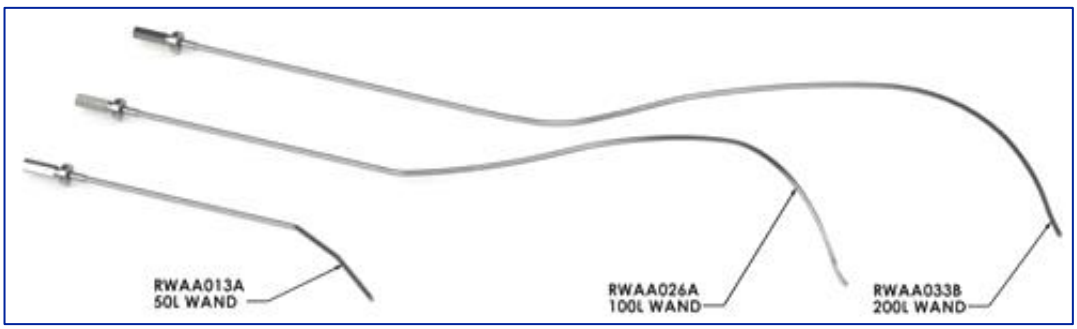
Table 6

Wand part numbers and nominal biocontainer volume.

Part Number	Nominal Biocontainer Volume (L)
RWAA005A	5
RWAA006A	10
RWAA014A	20
RWAA013A	50
RWAA026A	100
RWAA033B	200

Figure 5

Rotational wands.



6 Operator Interface and Control

The Wand Mixer is sealed for water/spray resistance.

Note: The Wand Mixer is sealed for water/spray resistance.

The controls are located on the face panel of the control box. They include: a touchscreen controller, quick adjustment keys, power switch, and emergency stop push button. In addition, connections for remote control are available on the left side panel of the control box as shown in Figure 6.

Most control functionality is provided to the user through the touchscreen interface including activation of functions, display of system information, and alarm status. The Wand Mixer can be operated in one of three modes selected by the operator from the Main Menu: Manual Mode, Automatic Mode, and Remote Mode. Each mode includes a specific set of functions to support processing requirements.

In case of emergency the operator can stop rotation of the motor by pressing the E-Stop button on the face panel. This can be done during any mode of operation. Doing so halts motor rotation and activates the system Failure mode while leaving other functions of the drive unit in operation. To reset the unit, release the E-stop button by pulling it up until it clicks, then acknowledge the alarm on the touchscreen.

Upon returning the unit to operation after reset of interruption and/or power cycling there is no rotation initiated until intentional action of the operator.

Figure 6

Overview of the control box.

ITEM	DESCRIPTION
A	Operator touch screen interface
B	PLC serial comm connector
C	Quick adjustment keys
D	Power button
E	E-Stop push button
F	Motor cable conduit
G	Discrete I/O remote control connector
H	Analog I/O remote control connector
J	Power entry receptacle
K	Nameplate

7 Pre-Mixing Setup

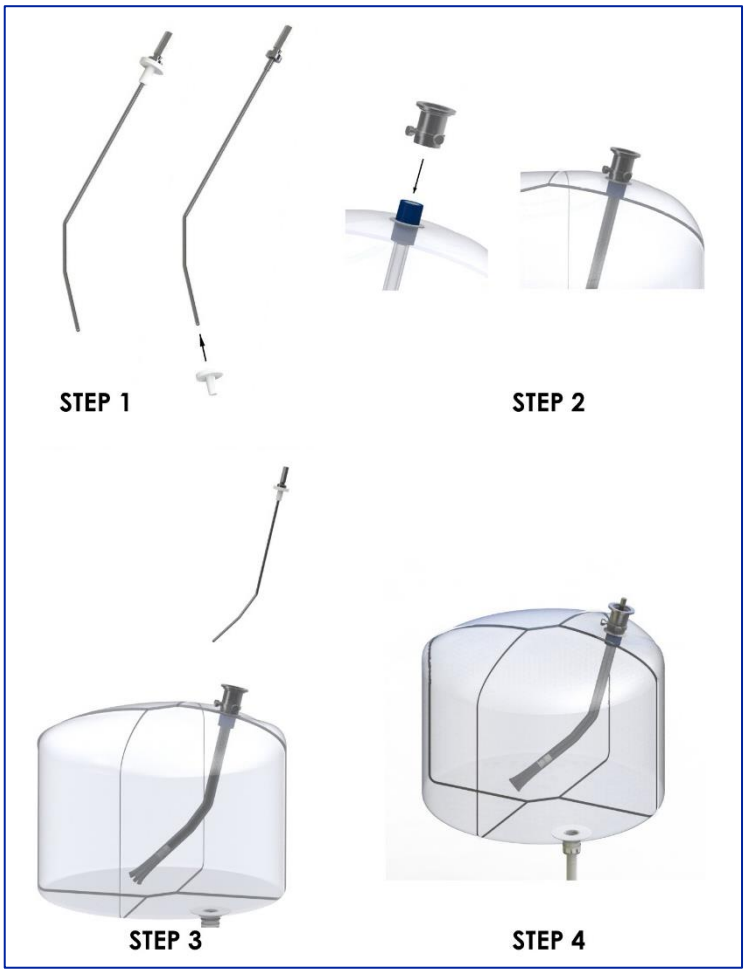
The mixing biocontainer must be assembled properly prior to mixing. The following components are needed to assemble the biocontainer:

- Stainless steel rotational wand.
- Stainless steel coupler – The coupler provides mechanical interface between the biocontainer and the driving motor. It has a hollow bore that receives the sleeve fitting on the biocontainer. The coupler is secured on the sleeve fitting of the biocontainer with two thumb screws. It has a flanged end that mates with the flange of the shaft adaptor.
- Plastic bushing – The plastic wand bushing centres the wand in the sleeve fitting. The wand is inserted into the bushing prior to wand insertion into the biocontainer.
- Shaft adaptor – The shaft adaptor interfaces the coupler and the driving motor. The adaptor receives the hexagonal head of rotational wand. The bearing in the flange of the shaft adaptor decouples the rotation of the shaft from the biocontainer.
- Clamp – The clamp secures the connection between the mating flanges of coupler and shaft adaptor.

Properly assembling the biocontainer starts by placing the mixing biocontainer into appropriate retaining tank and filling it with fluid by using the appropriate tube line. Make sure that retaining tank is compatible with the biocontainer volume. Next, ensure the two thumb screws do not penetrate beyond the inner surface of the coupler. Assemble the coupler with the biocontainer by sliding the coupler over the sleeve fitting all the way down to the film of the biocontainer as shown on the next page in Step 2 of 7. Secure the coupler against the fitting by tightening both thumb screws. The wand part number is stamped on its hexagonal head. Use only the specified wand.Insert the rotational wand into the bushing, and then insert the assembly into the sleeve of the biocontainer as shown in Step 3 of 7.

Figure 7

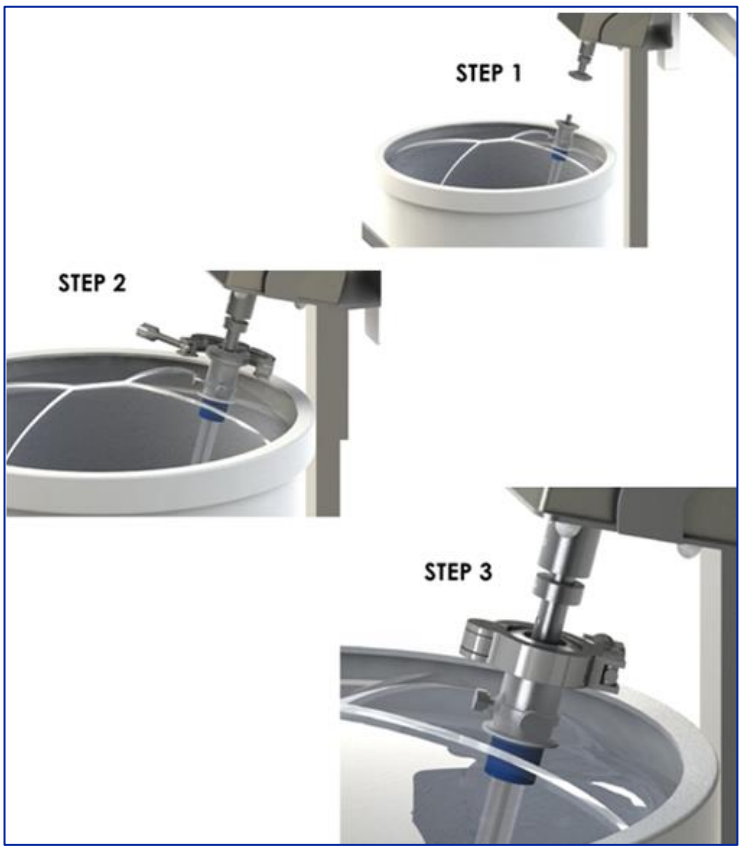
Steps for setting up the mixing biocontainers.



Now that the biocontainer is properly assembled, the biocontainer must be connected properly to the mixer. First position the mixing biocontainer with retaining tank in such a way that the fitting with coupler is located approximately under the shaft adaptor as shown below in Step 1 of 8. Adjust the vertical position of the motor by rotating the handle of the motor positioner until the distance between the coupler and the shaft adaptor is about 50 mm or 2 inches. Hold the coupler and move it toward the shaft adaptor. Insert the hex head of the wand in the receiving hex cavity inside the adaptor. Bring the mating surfaces of two the flanges together and secure the flanges of the coupler and shaft adaptor against each other with the clamp as shown on the next page in Step 2 of 8. Tighten the screws on the clamp. Lastly, increase the motor height slightly up by turning the handle of the motor positioner until noticeable biocontainer tension is developed.

Figure 8

Steps for connecting the biocontainer to the driver.



8 Mixing

Do not attempt to mix in empty or dry biocontainers.

1. On the touchscreen choose the mode of operation and set parameters/recipe for the mixing run
2. Start run
3. For additional instruction on using the operator interface see cleaning and decontamination guide. Section 11.

9 Disconnecting the Biocontainer

After the motor has come to a complete stop, remove the clamp connecting the coupler with shaft adaptor. Push the coupler down away from shaft adaptor by 25-50 mm or 1-2 in. Push the wand down and away from shaft adaptor until the hex head of the wand is released from adaptor. Use the small bearing on wand for better grip. Once the hex head of the wand is released, raise the motor up 25-50 mm, or 1-2 in. by rotating the handle on the top of the motor positioner for a better clearance from the biocontainer. Pull the wand from the sleeve holding the plastic bushing. Loosen thumb screws on the coupler and slide the coupler out of the sleeve fitting. Lastly, remove the plastic bushing out of the coupler. The mixer is now ready to accommodate new mixing biocontainer.

10 Maintenance

Update/restore of software resets the runtime counters and recipe content to zero. 20 RPM.

The Wand Mixer is designed to operate with minimal maintenance. However, to minimize wear it is recommended that the drive be unplugged if it is not in use for more than 24 hours.

Recipes can be transferred between Wand Mixer units, including the whole recipe library, using external media (micro SD card).

If user defined library content needs to be transferred back in the unit after service is done it is recommended to save the recipe library on a micro SD card prior to conducting software service.

10.1 Preventive Maintenance

Periodical maintenance is recommended to keep the drive unit in reliable working condition. Wearing of moving parts can be monitored through the elapsed run time counter in the PLC. Run time information is accessible for viewing on the touchscreen through the setup menu.

Table 7

Preventive maintenance procedures.

Description	Frequency	Spare Parts Involved	Who Performs
Battery replacement	6 years	Li battery	Service

10.2 Troubleshooting

Table 8 lists ways for resolving possible problems. Contact technical service if problems persist.

Table 8

Troubleshooting.

Problem Description	Possible Reason	Corrective Action
Unit does not start when power button is pressed	Main power fuse is burned out	Contact service personnel.
No white light when power is on while unit started	Power button LED is burned out	Contact service personnel.
Low battery notification	Battery low	Elevated risk of memory corruption and unreliable operation. Call for technical service.
Motor failure alarm	Overheating of the controller by frequent starting-stopping of the motor	Reset the motor controller alarm. Pause about 3 min before starting up motor. Avoid frequent starting-stopping of the motor.
Cannot read/write to micro SD card.	Micro card improperly formatted	Format micro SD card.
E-stop ALARM persists after reset	E-stop button is activated	Deactivate E-stop button by pulling it up until it clicks, then reset the alarm.

10.3 Procedures

10.3.1 Power Cord Replacement

Only use power cords provided by Pall.

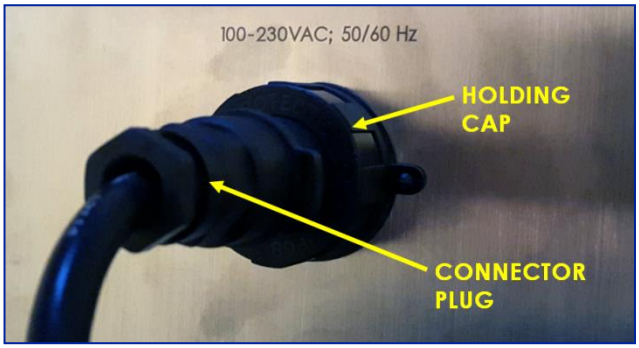
Should you need to replace the power cord with an alternative one with a different type of plug, follow the procedure as described below. Changing the power cord is performed through a power entry connector on the back panel of the control box.

To replace the power cord, follow these steps:

1. Ensure the unit is turned off.
2. Unplug the unit from the external power supply.
3. Disconnect the power cord from the control box by rotating the power connector holding cap counter clockwise then, holding the connector plug, pull it out of the receptacle.
4. Attach the replacement power cord connector plug to the power receptacle on the control box. Make sure the key on the receptacle and keyhole in the plug are aligned and the connector plug is pushed all the way in.
5. Secure the connector holding cap by rotating it clockwise. Tighten the cap firmly to seal the connection.

Figure 9

Power cord replacement.



10.3.2 SD Micro Card Replacement

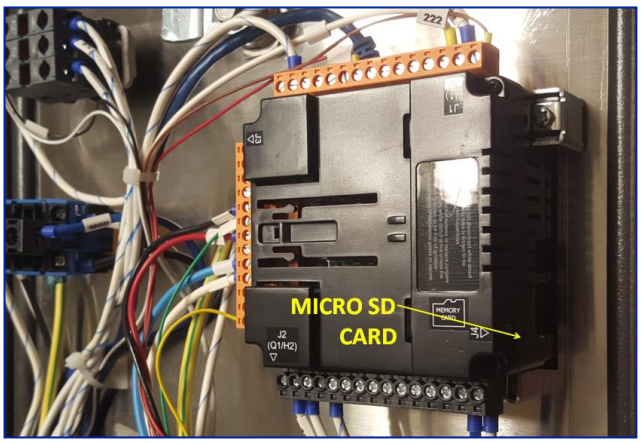
Micro SD cards are compatible with the memory slot. The PLC uses a FAT 32 file system format. The memory slot is equipped with a "push-in, push-out" connector for Micro SD cards insertion.

To change the SD card:

1. Switch the unit off and unplug it from the external power source.
2. Unlock control box by rotating the latch counter clockwise using a flat-head screwdriver.
3. Open the Control Box door and locate the memory slot on the upper side of the PLC (see 10).
4. To insert the SD card:
    a. Align the card so that the 8-pin gold edge connector is facing upwards on the SD card.
    b. Push the Micro SD card in all the way into the memory slot, ensuring that it clicks into place.
5. To remove the Micro SD card:
    a. Push down on the top of the card gently to release the spring. The card will pop up for removal.
6. Close the control box door and lock it by rotating the latch 90º in a clockwise direction using a flat-head screwdriver.

Figure 10

Micro SD card location.



10.3.3 Speed Calibration Verification

Manual mode of operation must be set.

Equipment recommended:

- Reflective tape attached to the mixer head.
- Optical Tachometer: Omega HHT13 or equivalent

1. Set the permanent run speed of rotation to 20 RPM.
2. Press and hold the “Start” button, rotation started. Wait until the mix head accelerates to its nominal speed of rotation.
3. Reading from external tachometer write into the second column of Table 9.
4. Calculate and write down in the third column the difference between set point and measured in c) speed value.
5. Compare the reading recorded in column 2 with corresponding allowable range in the third column of Table 9, then record the result in column 6.
6. RPM Reading from panel screen record into the fourth column of Table 9.
7. Compare the reading recorded in column 4 with corresponding allowable range in column 5, then record the result in column 7.
8. Repeat steps 3 to 7 for each of the RPM set points in the first column.
9. If unsuccessful, call service.

Table 9

Rotational speed calibration test measurements.

1	2	3	4	5	6	7
Set Point (RPM)	External Tachometer Reading (RPM)	External Tachometer Reading Allowable Range (RPM)	Panel Tachometer Reading (RPM)	Panel Reading Allowable Range (RPM)	External Tachometer Maximum Deviation Falls Within Allowable Range (Y/N)	Panel Tachometer Maximum Deviation Falls Within Allowable Range (Y/N)
20		19 - 21		19 - 21		
40		39 - 41		39 - 41		
60		59 - 61		59 - 61		
80		79 - 81		79 - 81		
100		99 - 101		99 - 101		
120		119 - 121		119 - 121		
140		139 - 141		139 - 141		
160		159 - 161		159 - 161		
180		179 - 181		179 - 181		
200		199 - 201		199 - 201		
220		219 - 221		219 - 221		
240		239 - 241		239 - 241		
250		249 - 251		249 - 251		

Calibration verification is successful if all rows in columns 6 and 7 of Table 9 have result Y.

11 Cleaning and Decontamination Guide

The system must be off prior to cleaning.

The steel frame of the machine consists of 304 stainless steel and may be cleaned with water and isopropyl alcohol.

12 Operator Control Interface

12.1 Navigating the Wand Mixer Control Screen

Each screen in the Wand Mixer control software has several common elements.

1. The window bar shows the name and/or status of each screen.
2. To return to the previous screen, press the back button  in the upper right corner of the screen.
3. Screen buttons corresponding to critical commands like START, STOP, PAUSE, etc... are protected from inadvertent activation by a delay function. To activate these commands the operator should press and hold the button until the indicating bar in the top of window completely fills (2-3 sec). A request to hold the command button is shown also indicated as text above the indicating bar.
4. Time is indicated on the operator interface in hh:mm format unless otherwise specified.
5. Each operation mode has its own interactive screen, which is either displayed automatically (failure, power up) or by operator choice from the Main Menu.

12.1.1 User Access Levels

Login function is available through the PW button in the left upper corner of each screen (except informational screens). All passwords are group passwords, with a minimum of six uppercase, lower case or numeric characters. In total, three group logins are available: Operator, Supervisor, and Maintenance. Maintenance login is only available while the system is in power up mode. The login time period is controlled via a program setup parameter. Access is automatically set to the default (common) level upon expiration of a prescribed time period since login.

Access to Wand Mixer control software functions is supported using the following levels.

12.1.2 Common (Default) Functions

1. Use of Manual mode for full access.
2. Use of Failure mode interactive screens for full access
3. Use of Auto mode and Remote mode for view only access
4. No password protection

12.1.3 Operator

This includes all common function with the addition of the below:

1. Use of recipe start access

12.1.4 Supervisor

This includes and common and operator functions with the addition of the below:

1. Use of auto mode and remote mode for full access
2. Access to a limited set of parameters
3. Ability to change the password for the supervisor and operator groups
4. Ability to change the automatic logout time

12.1.5 Maintenance

This includes all supervisor functions, plus full access to system and program parameters and functions.

1. Press **PW** on the top left corner of the screen
2. Select the access level from the **User Login** screen Figure11 then choose **Password** Figure 12 to open the password entry screen.
3. When the keypad entry screen appears, enter the passcode for the desired user access level and then press **Enter** Figure 13.
4. You will now return to the previous screen press **Login.** You are now logged in under the selected user access level.

Figure 11
User login screen.

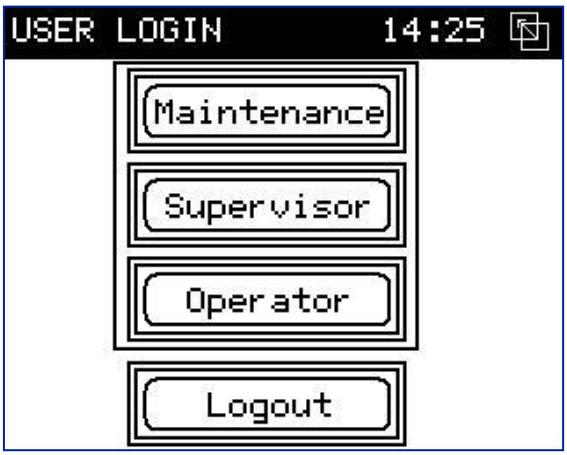


Figure 12
Supervisor user password screen.

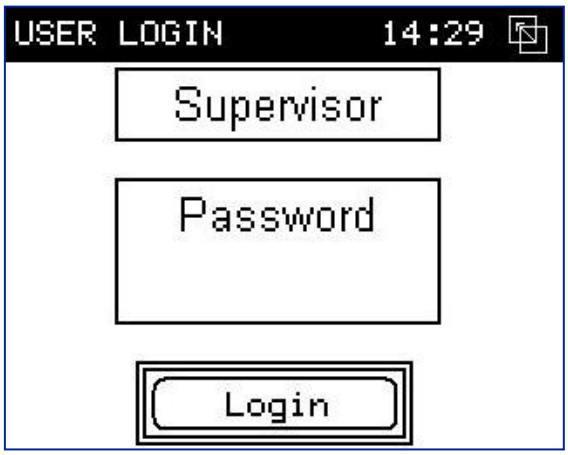


Figure 13
Password entry screen.

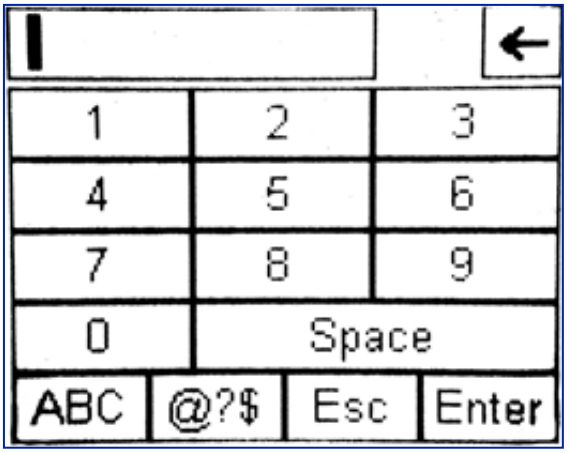


Figure 14
Supervisor login screen.

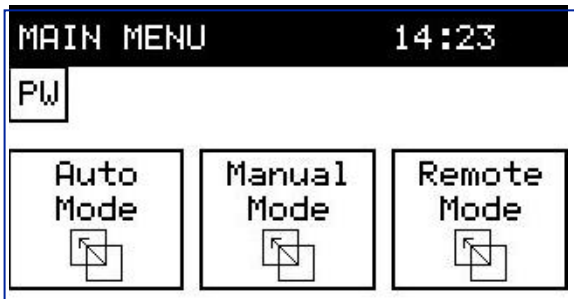
13 Operating the Wand Mixer

To select the mixer's operation mode, press one of the buttons on the Main Menu.

The three mode screens—the Automatic Mode screen, the Manual Mode screen, and the Remote Mode screen—are the locations for setting mixing parameters.

Figure 15

Main Menu screen.



Mode Selection	Operation
Auto mode	Automatic operation mode.
Manual mode	Manual operation mode.
Remote mode	Control the mixer remotely.

13.1 Automatic Mode

Automatic mode is used to run mixing according to recipes; lists of instructions composed by the user to run the mixing process at different speed settings and/or at certain time schedules. The Wand Mixer software includes a library of 10 recipes. Each recipe contains up to 10 instructions executed consecutively during a run. Each instruction consists of 3 user defined parameters: duration of mixing phase, duration of pause phase and speed of rotation. All the recipes have duration of mixing and pause factory pre-installed to values of zero, and speed of rotation set to 20 RPM. Any recipe with all mixing phase durations set to zero considered an "empty" recipe. If the operator tries to run such a recipe a notification is displayed on screen.

To simplify exchange of recipes between drive units a Migration function is available at the Supervisor level. The feature allows Import/Export of the entire library from/to a removable memory card.

Operators can load, start recipe run and view a recipe's instructions. Supervisors and Maintenance can pause/resume or abort recipes as well as edit their contents or change the name under which the recipe is stored. To use the automatic mode to run the mixer according to a recipe, press Auto Mode on the Main Menu. The Automatic Mode screen opens and lists the currently loaded recipe. Status bar indicates "AUTOMATIC MODE"

Figure 16

Supervisor login screen.

Figure 17

Recipe selector screen.

13.2 Loading a Recipe

To load a recipe, follow these steps:

1. On the Automatic Mode scene, press Select. The Recipe Selector screen will open.
2. Use the buttons on the Recipe Selector screen to load recipes and view their contents.
3. At the top of the screen, press the arrow buttons to move through the list of recipes.
4. In the lower right corner of the screen, press the Back and Next buttons to move through the individual instructions in the selected recipe.
5. On the Recipe Selector screen, press the back button  in the upper right corner of the screen to load the selected recipe and return to the Automatic Mode screen.

13.3 Running a Recipe

To run the recipe listed on the Automatic Mode screen, press and hold the Start button. The mixer will start according to the recipe's instructions and "Routine in Progress" will appear in the menu bar. The time remaining in the recipe is listed at the bottom of the screen. The window status bar will show a blinking "Routine in Progress".

Upon finishing the recipe run the screen will show "Successful Finish" with a time stamp, run duration and name of the recipe finished. To resume to the Auto Mode screen press the OK button.

When failure mode is activated during a recipe run the job is paused automatically and can be resumed upon failure reset. "Unscheduled Finish" is displayed with a time stamp, run duration and name of the recipe after finishing the recipe run. To resume to the Auto Mode screen press the OK button.

13.4 Aborting a Recipe

Supervisor and Maintenance user levels can abort running recipes. To abort a recipe that is currently running, press and hold the Abort button. When a routine is aborted the "Unscheduled Finish" screen with a time stamp, name of the recipe aborted and run duration will open. To resume to the Manual Mode screen, press the OK button.

13.5 Pausing and Resuming a Recipe

Supervisor and Maintenance user levels can pause and resume recipes. To a recipe that is currently running, press and hold the Pause button. A blinking "Routine Paused" status is displayed in the status bar. To resume the recipe from where it was paused, press and hold the Resume button.

13.6 Editing a Recipe

Supervisor and maintenance user levels can edit a recipe's instructions. To edit a recipe, follow these steps:

1. Press Select on the Automatic Mode screen. The Recipe Selector screen opens.
2. Use the arrow buttons at the top of the screen to scroll through the list of recipes until you open the one you want to edit.
3. Press Edit. The Recipe Editor screen opens.
4. If needed, press the Back and Next buttons on the right side of the screen to scroll through the list of instructions for that recipe.
5. Each recipe can contain up to 10 instructions.
6. Set the parameters to use for a specific instruction.

7. Press **Pause** to set the length of time the Wand Mixer should pause for that instruction. When the keypad opens, type the length of time to pause and then press **Enter.**

8. Press **Run** to set the length of time the Wand Mixer should run for that instruction. When the keypad opens, type the length of time to run the mixer and then press **Enter.**

9. Press **Speed** to set the RPM set point at which the Wand Mixer should run for that instruction. When the keypad opens, type the RPM set point and then press **Enter.**

10. Press **Save** to save your changes to the recipe. To return to the Automatic Mode screen without saving your changes to the recipe, press **Cancel.**

Figure 18

Recipe editor screen.

To edit the recipe name, follow these steps:

1. Press **Select** on the Automatic Mode screen. The Recipe Selector screen opens.

2. Use the arrow buttons at the top of the screen to scroll through the list of recipes until you find the name you want to edit.

3. Press **Edit**. The Recipe Editor screen opens.

4. If needed, press the **Back** and **Next** buttons on the right side of the screen to scroll through the list of instructions for that recipe.

5. Press the button with the recipe name in it. An entry screen opens.

6. Use the onscreen keyboard and arrows to change the name of the recipe then press enter.

7. Press **Save** to save your changes. To return to the Automatic Mode screen without saving your changes to the recipe, press **Cancel.**

Use the manual mode to run the mixer either continuously or for a specific amount of time at a given RPM. The manual mode is ideal for mixing jobs that have no additional parameters. If the job requires mixing at different speeds use automatic mode instead.

To use the manual mode, press **Manual Mode** on the Main Menu. The Manual Mode screen will open. The status bar will display "MANUAL MODE".

Figure 19
Manual mode parameters screen.

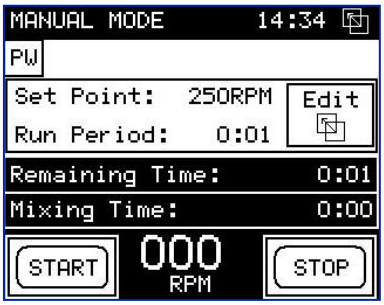
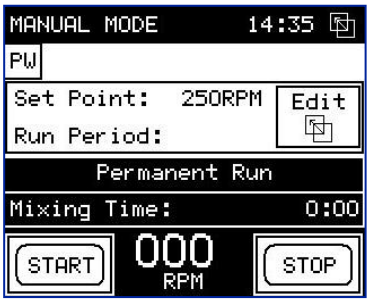


Figure 20
Manual mode permanent screen



13.7 Setting Up a Manual Job

Parameters available for a manual job are speed of rotation of the wand (RPM) and duration of run (hh:mm). Previous settings are remembered until they are changed manually. Quick adjustment of manual job parameters is possible from the PLC face panel with dedicated keys regardless of run status.

To select the parameters to use for the manual job run, follow these steps:

1. On the Manual Mode screen, press Edit. The Manual Setup screen opens
2. Press the **Set Point** box to set the RPM set point.
3. In the Entry screen enter the RPM set point and then press **Enter**.
4. Set the time period for prospective run.
5. The status PERMANENT indicated on a switch means it will run indefinitely until manually stopped.
6. To have manual run stopped automatically, specify the length of run. Press the switch to toggle it to TIMED status to allow time period setting for run.
7. To set the length of time the mixer should run, press the **Run Period** box. When the keypad opens, enter the amount of time and then press **Enter**.
8. Return to the Manual Mode screen. All parameters are indicated in screen areas with white backgrounds.

Figure 21
Manual setup permanent screen.

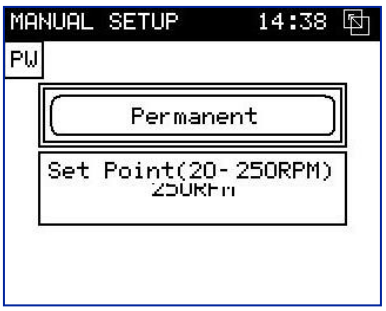


Figure 22
Manual setup times screen.

13.8 Starting a Manual Job

To a manual job press and hold the **Start** button on the Manual Mode screen. The mixer will start, and the current status will show in areas with dark backgrounds: the remaining time (for timed jobs) or the "Permanent Run" (for continuous runs) and net mixing time. The window status bar will have a blinking "Run in Progress".

13.9 Stopping a Manual Mode Job (Permanent Run)

To stop a manual job that is currently running, press and hold the **Stop** button. When a job is stopped the screen will display "Successful Finish" with a time stamp and run duration. To resume to the Manual Mode screen, press the OK button.

When failure mode is activated during run the job is paused automatically and can be resumed upon failure reset. "Unscheduled Finish" is displayed with the time stamp and net mixing time after stopping the run. To resume to the Manual Mode screen, press the OK button.

13.10 Stopping a Manual Mode Job (Timed Run)

Timed runs will automatically stop when the scheduled run time is complete. The screen will display "Successful Finish" with a time stamp and run duration. To resume to the Manual Mode screen, press the OK button.

To stop a timed job that is currently running, press and hold the **Stop** button. When the job stops the screen will display "Unscheduled Finish" with a time stamp and run duration. To resume to the Manual Mode screen, press the OK button.

When failure mode is activated during a run, the job is paused automatically and can be resumed upon failure reset. "Unscheduled Finish" is displayed with a time stamp and net mixing time after manually stopping or automatic finishing of the run. To resume to the Manual Mode screen, press the OK button.

13.11 Pausing and Resuming a Manual Job

Press and hold the **Resume** button.

The remote mode allows you to control the Wand Mixer from external equipment to which the mixer is connected. Supervisor and Maintenance user levels can switch the mixer between remote and local control.

Signal circuits for remote control pass through the control box via two connectors located on the back of the control box. With a remote-control panel, the operator can:

- Start/Stop the motor
- Change the speed of rotation
- Read the speed of rotation
- Read alarms
- Read the unit mode status

While the Wand Mixer is in Remote mode the wand rotation control is available only via the remote-control unit. The Wand Mixer screen indicates speed of motor for local monitoring only. When the control is switched back to local (Wand Mixer) the remote-control unit can only monitor the speed of rotation and alarm status.

When in remote mode the mixer automatically switches to Manual Mode stop status when any alarms are activated.

To use the remote mode:

1. Press Remote Mode on the Main Menu. The Remote Mode screen opens in “Local Control” status indicated in status bar.

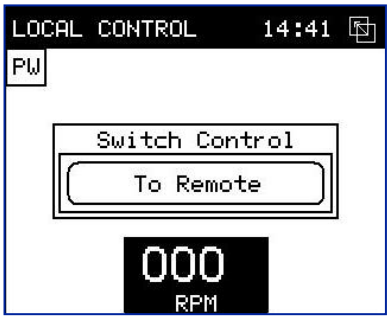
2. To switch control to any remote equipment connected to the mixer, first make sure that the equipment is correctly connected to the Wand Mixer and powered up. Finally, press and hold the Switch Control to Remote button on the Remote Mode screen.

When the control is switched to a remote panel the “Remote Control” status is indicated in the window status bar.

To switch control back to the Wand Mixer, press and hold the Switch Control Back to Local button on the Remote Mode screen. The system will switch to Manual Mode stop status.

Figure 23

Remote mode screen.



14 Failure Detection

If failure happens while any of Editor screen is opened the alarm is generated but notification will not appear on screen until escape from Editor to any of Mode screens.

Failure detected by the system will activate Failure mode while in any mode of operation. Failure mode causes the motor rotation to stop, displays an alarm notification to the operator and generates an alarm output signal for remote control.

The equipment in the mixer will stay powered up but cannot be operated until failure reset is complete. Failure resolution is available only from the Wand Mixer face panel. External control equipment will only receive an alarm signal with no ability to feedback control. Reset of the failure mode is available from the failure detection screen Figure 25 which is opened after pressing the Alarm button.

Figure 24
Alarm screen

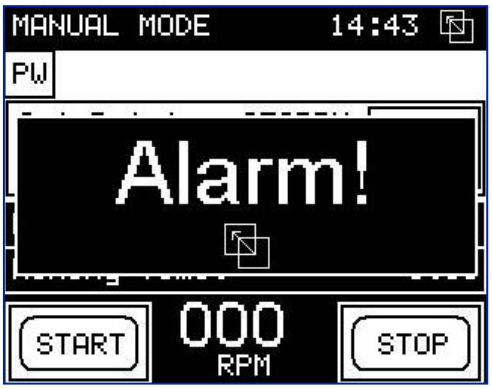
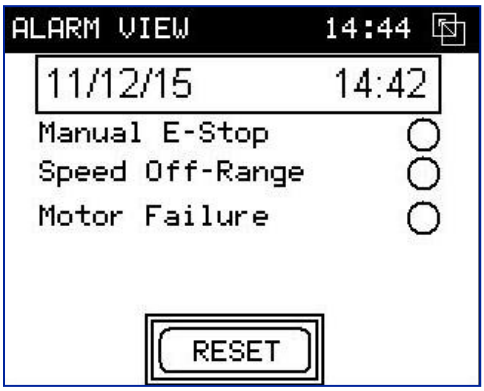


Figure 25
Failure detection screen.



- Manual Mode idle condition: Moment of alarm, the mixer is in Remote mode or idled in Manual mode.
- Manual Mode pause condition: Moment of alarm, the mixer is in Manual mode.
- Automatic mode idle condition: Moment of alarm, the mixer is idled in automatic mode.
- Recipe run pause condition: Moment of alarm, the mixer is in Automatic mode.

Upon returning the unit to operation after reset of interruption and/or power cycling there is no rotation initiated until intentional action of the operator.

14.1 Types of Failure

The three below failures can stop the current job.

14.1.1 Manual E-Stop

When an operator presses the E-Stop button on the Wand Mixer, the motor rotation immediately stops, and the ALARM appears on the screen. To reset the unit, follow the following steps:

- Release the E-stop button by pulling it until it clicks.
- Press the ALARM button. The failure detection screen will then open.
- On the failure detection screen identify the E-stop failure in the blinking bullet. Note: the date and time of the failure event is indicated on this screen.
- Press the RESET button to return the unit to operation.

14.1.2 Speed Off-Range

The Speed Off-Range Alarm is not generated in remote mode of operation. In this case current speed and set point are controlled externally.

If the motor shaft RPM deviates from speed set point outside the ± 5 RPM limits for more than 60 sec, the speed control may be functioning improperly. When this occurs, rotation is *stopped,* and the ALARM appears on the screen. The operator should do the following steps:

- Press the ALARM button. The failure detection screen will then open.
- On the failure detection screen identify the Speed Off-Range failure in the blinking bullet. Note: the date and time of the failure event is indicated on this screen.
- Press the RESET button to return the unit to operation.

14.1.3 Motor Failure

If the mixer's drive motor experiences an error, it signals the PLC. The mixer then stops rotation and displays ALARM on the screen. The operator should do the following steps:

- Press the ALARM button. The failure detection screen will then open.
- On the failure detection screen identify the Motor failure in the blinking bullet. Note: the date and time of the failure event is indicated on this screen.
- Press the RESET button to return the unit to operation. The screen will open with a request to turn off power to reset the failure signal.
- Turn the unit off then turn it back on.

14.1.4 Auxiliary functions

System functionality is controlled with parameters accessible through the setup editor which is available through the Main Menu screen. A Setup button will appear on the screen after a user has logged in at the Supervisor or Maintenance level. The selection of parameters available for adjustment depends on the level of access and is listed in the settings editor for the Supervisor level, which opens after pressing Setup.

Figure 26
Supervisor Main Menu screen

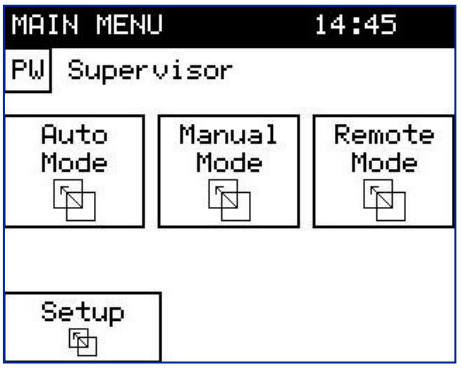
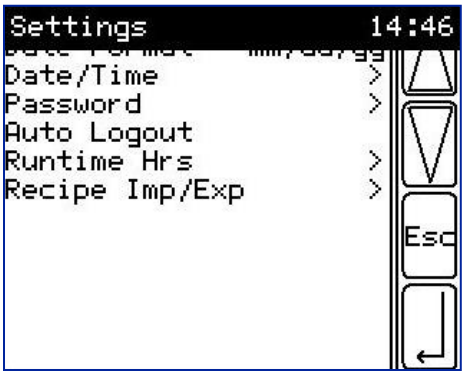


Figure 27
Supervisor Settings screen



Supervisor settings editor allows:

1. **Select the date format for indication on screens: mm:dd:yy or dd:mm:yy**

- Login to system as Supervisor
- Press the setup button on the Main Menu screen
- Select the "Date Format" function using the up and down arrows
- Press the curved arrow to go to the selection screen
- Select the appropriate format using the arrows provided on screen and then press Enter

2. **Adjust the calendar date and clock time**

- Login to system as Supervisor
- Press the setup button on the Main Menu screen
- Select the "Date/Time" function using the up and down arrows
- Press the curved arrow to go to the next screen
- Press the button with the date, adjust the date to current, then press Enter
- Press button with the time, adjust time to current, then press Enter
- Press  to return to the Settings list

3. **Change password for supervisor and operator levels**

- Login to the system as Supervisor
- Press the setup button on the Main Menu screen
- Select the "Password" function using the up and down arrows
- Choose the level of access to which the change of password is required
- Press the curved arrow to go to the next screen
- Press the curved arrow to go to the entry screen

- Enter the new password twice as prompted and press **Change**
- Press  to return to the Settings list

4. **Adjust auto logout time**

- Login to the system as Supervisor
- Press the setup button on the Main Menu screen
- Select the "Auto Logout" function using the up and down arrows
- Press the curved arrow to go to the entry screen
- Enter the time for auto logout then press **Enter**

5. **View runtime counter indicators for System runtime and Motor runtime**

- Login to the system as Supervisor
- Press the setup button on the Main Menu screen
- Select the "Runtime Hrs" function using the up and down arrows
- Press the curved arrow to go to the view screen
- The screen will indicate accumulated runtime separately for both system and motor rotation
- Press  to return to the Settings list

6. **Export of recipe library to memory card**

- Insert a SD card into the Memory slot
- Login to the system as Supervisor
- Press the setup button on the Main Menu screen
- Select the "Recipe Imp/Exp" function using the up and down arrows
- Press the curved arrow to open the next screen
- Press the **File number** button to go to the entry screen
- On the entry screen input the file number (0-9) you wish to export and press **Enter**
- Press the **Export recipes** button and confirm when prompted
- The entire library will be exported to the Micro SD card under filename LIBRARYX.BAK, where X is the file number entered on the previous step.
- A confirmation notice will appear after the file writing is finished (this may take several minutes)
- Acknowledge the notice and press  to return to the Settings list

Figure 28
Import/Export screen.

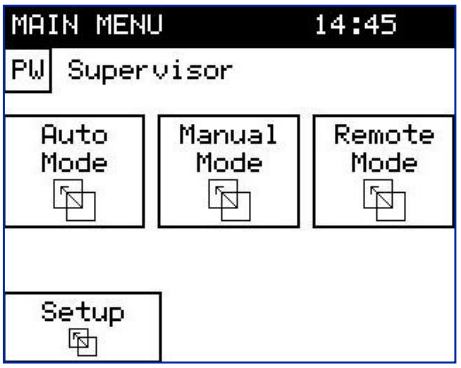
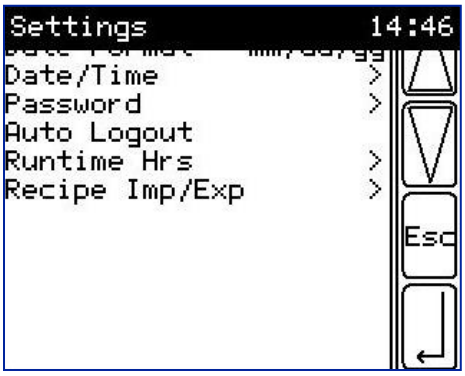


Figure 29
Confirmation screen.



7. Import of recipe library from memory card

- Insert a SD card into the Memory slot
- Login to the system as Supervisor
- Press the setup button on the Main Menu screen
- Select the "Recipe Imp/Exp" function using the up and down arrows
- Press the curved arrow to open the next screen
- Press the **File number** button to go to the entry screen
- On the entry screen input the file number (0-9) you wish to Import, and press **Enter**
- Press the **Import recipes** button and confirm when prompted
- The whole library will be imported from the file on the Micro SD card named LIBRARYX.BAK, where X is the file number entered on the previous step.
- A confirmation notice will appear after the file writing is finished (this may take several minutes)
- Acknowledge the notice and press to return to the Settings list

14.2 Finishing Mixing Run

Each time upon finishing run the notification to operator is exposed on screen. Details of the notification depend on events during process. Possible scenarios are provided in the table below.

Table 10

Finish notification details.

Process Condition		Finish Notice Content	
Started	**During Run**	**Finish Status**	**Duration Shown**
Manual permanent or timed run	Normal process	Unscheduled	Neat mixing time (pause time is not included)
	Paused-resumed		
	Failure-Alarm		
	Stopped (timed run only)		
Recipe run	Normal process	Successful	Actual duration of recipe run time (includes pauses)
	Pause-resumed		
	Failure-Alarm		
	Aborted	Unscheduled	

14.3 Initial Settings

Default settings are the factory preinstalled parameters as listed in Table 11. The parameters can be adjusted through the corresponding editor screens.

Table 11

Default initial settings

Description of Parameter	Units	Factory Setting
Manual mode speed of rotation	RPM	20
Manual mode run duration	Min	0
Recipe mixing phase time duration (in all instructions)	Min	0
Recipe pause phase time duration (in all instructions)	Min	0
Recipe speed of rotation (for all instructions in recipes)	RPM	20
Auto logout time	Min	10
Operator password		123456
Supervisor password		123456
Date format		MM:DD:YY
Calendar date		
Clock time		

15 Spare Parts and Accessories

Table 12

Standard accessories.

Part Number	Description
4100048	Bushing, wand HDPE (Included in tool box)
201487	Quickclamp tube fitting wingnut clamp (included in tool box)
4100049	Coupler, wand, stainless steel (included in tool box)
4100153NS	Plate, clip for 1 in. drain valve (included in tool box)
201489	Knurled head thumb screw (included in tool box)
LT-SVSP366	Assembly, EU power cord (included in tool box)
LT-SVSP365	Assembly, US power cord (included in tool box)
1100025	Shaft adaptor assembly
500-11381-00	Medium acting fuse, 3 A, 5 mm X 20 mm
LT-SVSP367	Assembly, Australian power cord
LT-SVSP368	Assembly, Swiss power cord
LT-SVSP369	Assembly, UK power cord
LT-SVSP480	Assembly, Chinese power cord
LT-SVSP414	White illuminated push button switch, assembled
LT-SVSP415	White LED bulb
CBG401B	Basic Control box CE – optional for DCS/SCADA data transfer
CBG401A	Advanced Control box CE – optional for DCS/SCADA data transfer
CBG402B	Basic Control box UL – optional for DCS/SCADA data transfer
CBG402A	Advanced Control box UL – optional for DCS/SCADA data transfer

16 Electrical Schematic

Figure 30

Electrical schematic.

ITEM	LABEL	DESCRIPTION
1	CBL100	ASSY, US POWER CORD ASSY, EU POWER CORD ASSY, AUSTRALIAN POWER CORD ASSY, SWISS POWER CORD ASSY, UK POWER CORD
2	CBL201	3' PATCH CORD, 24AWG
3	CBL222	MOTOR I/O SIGNAL CABLE
4	CBL226	MOTOR-DRIVER CABLE
5	CBL227	MOTOR-DRIVER CABLE
6	CBL228	MOTOR POWER CABLE
7	CR323	24VDC GENERAL PURPOSE RELAY
8	CR324	24VDC GENERAL PURPOSE RELAY
9	CR326	24VDC GENERAL PURPOSE RELAY
10	FU100	MEDIUM ACTING FUSE, 3A, 5mm X 20mm
11	J201	RJ45 PANEL MOUNTING FRAME RJ45 SOCKET INSERT
12	J231	6 PIN MINIFAST RECEPTACLE, M30 THREAD
13	J235	5 PIN MINIFAST RECEPTACLE, M30 THREAD
14	LF100	6A LINE FILTER
15	LT105	WHITE LED
16	MTR100	BRUSHLESS DC MOTOR AND CONTROLLER
17	P100	3 PIN FRONT FANEL MOUNT CONNECTOR
18	PB100	WHITE ILLUMINATED PUSH BUTTON SWITCH
19	PB204	E-STOP PUSH BUTTON 2X NC CONTACT BLOCK W/ HOLDER 1X NC CONTACT BLOCK
20	PLC200	COMPACT TOUCH SCREEN PLC
21	PW100	24VDC 240W POWER SUPPLY

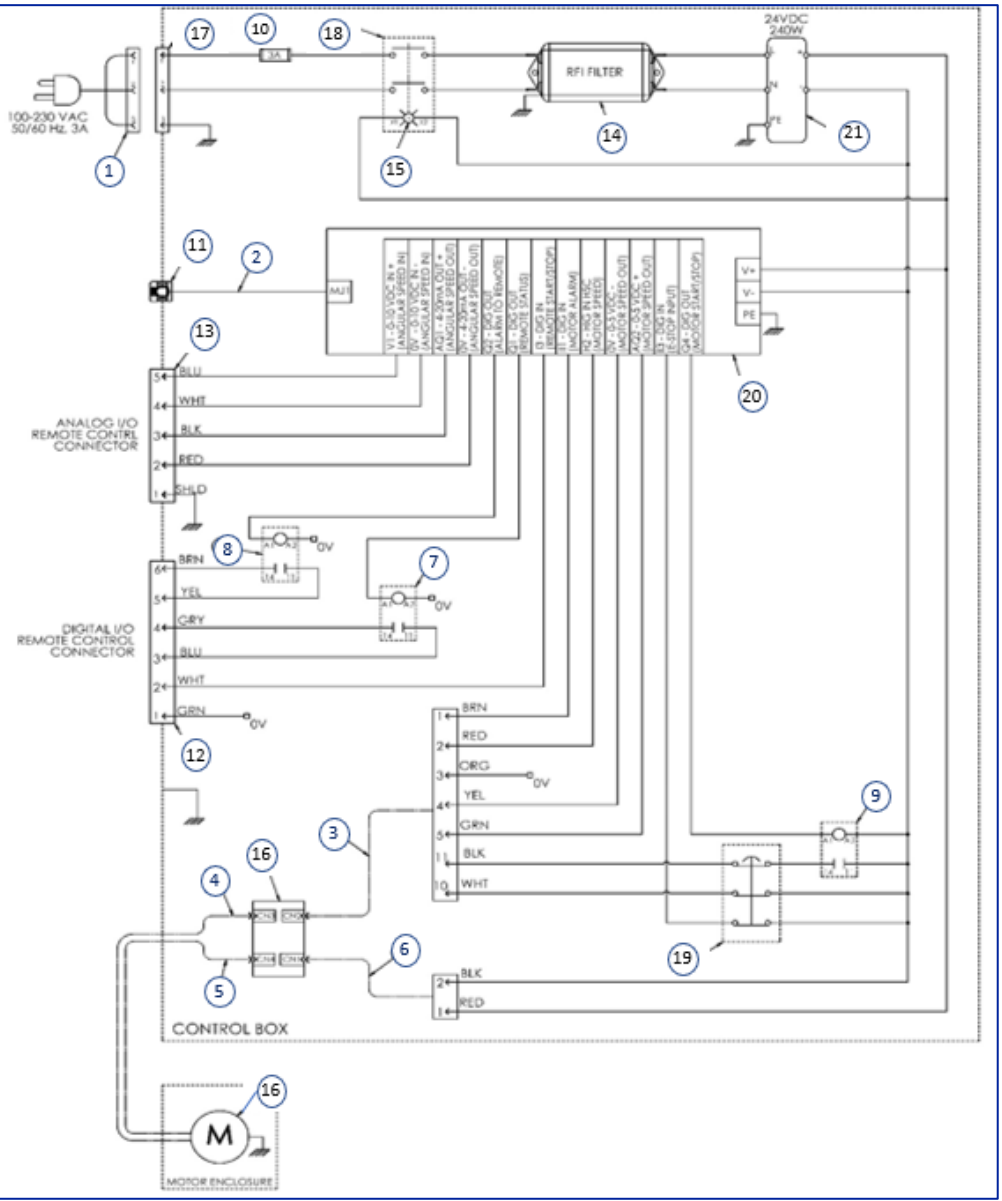


Table 13

Remote control I/O chart.

Analog I/O Connector Circuits				
Pin	**Circuit Description**	**Range**	**Calibration**	
2, 3	Speed output 4-20 mA	0-250 RPM	4 mA=0% of range	20 mA=100% of range
4, 5	Speed set point input 0-10 VDC	0-250 RPM	0 V=0% of range	10 V= 100% of range
Discrete I/O Connector Circuits				
Pin	**Circuit Description**	**Signal Type**	**Logic**	
1, 2	Motor Start/Stop input	Relay contact	Open=Stop	Closed=Run
3, 4	Remote status output	Relay contact	Open=Local Control	Closed=Remote Control
5, 6	Alarm output	Relay contact	Open=No Alarm	Closed=Alarm

The analog speed control input 0-10 V (pins 4 and 5 of analog input connector) has an impedance of 500 kOhm. The safe input voltage range is -0.5 V to +15 V.

For the analog output 4-20 mA (pins 2 and 3 of analog I/O connector) the MAX load resistance should not exceed 500 Ohm.

For equipment safety and to avoid possible excess noise on the speed control input signal (pins 4, 5 of Analog I/O connector) it is recommended to include an Isolation Amplifier in the design of the 0-10 VDC remote control external circuitry.

17 Service

The Wand Mixer system was developed exclusively for mixing fluids and solids in fluids in specially designed biocontainers. The machine should only be used for this purpose to ensure a long service life.

Should your Wand Mixer require service, contact the Equipment Support Hotline.

- **Americas:**

Phone: 1-855-920-PALL (7255)

Hours of Operation: 8AM – 8PM EST, Monday – Friday

- **EMEA:**

Phone: 00800 PALL TECH (7255 8324)

Hours of Operation: 8AM – 5PM CET, Monday – Friday

- **Patents:**

Pall.com/patents

- **Website:**

https://www.pall.com/en/instrument-service-support.html

PALL CORPORATION

EU 'CE' Declaration of Conformity

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

Product: ***Wand Mixer Drive Unit***

Part No: ***RDUA200, RDUA200-A, RDUA007BT, RDUA008FB***

Manufactured for: ***Pall Life Sciences,***

Address: ***Reugelstraat 2, 3320 Hoegaarden, Belgium***

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
2014/35/EU	The Low Voltage Directive (LVD)
2014/53/EU	The Radio Equipment Directive

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

Reference & Date	**Title**
EN60204-1: 2016	Safety of machinery – Electrical equipment of machines
EN 61326-1: 2013	Electrical equipment for measurement, control and laboratory use – EMC requirements – General requirements.
EN 61010-1: 2010	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: general requirements.
EN61010-2-051: 2013	Wide band transmission systems; Data transmission equipment operating in the 2.4 GHz ISM band and using wide band modulation techniques; Harmonised standard covering essential requirements of article 3.2 of the RED (2014/53/EU)

Warning: ***This is a class A product. In a domestic environment this product may cause radio interference in which case the user may be required to take adequate measures.***

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

Signature: DocuSigned by: Massimo Manazza 42F3A5596C894BB...

Name: Massimo Manazza
Position: Global QA Leader, Hardware
Date of issue: 01-Sep-21 | 23:17 PDT

The Technical Construction File for the object of this declaration is available from:

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AUTHORIZATION TO MARK

This authorizes the application of the Certification Mark(s) shown below to the models described in the Product(s) Covered section when made in accordance with the conditions set forth in the Certification Agreement and Listing Report. This authorization also applies to multiple listee model(s) identified on the correlation page of the Listing Report.

This document is the property of Intertek Testing Services and is not transferable. The certification mark(s) may be applied only at the location of the Party Authorized To Apply Mark.

Applicant:	Pall Corporation	**Manufacturer:**	Multisource Manufacturing LLC
Address:	25 Harbor Park Dr. Port Washington, NY 11050	**Address:**	11545 12th Ave S Burnsville, MN 55337
Country:	USA	**Country:**	USA
Contact:	Bill Amsden Lynn Harvey	**Contact:**	Susan Richardson Dan Larson
Phone:	(508) 277-9822 (508) 985-8093	**Phone:**	(952) 314-1233 (952) 882-6211
FAX:	NA	**FAX:**	NA
Email:	bill_amsden@pall.com lynn_harvey@pall.com	**Email:**	srichardson@multisourcemfg.com dlarson@multisourcemfg.com

Party Authorized To Apply Mark: Same as Manufacturer
Report Issuing Office: Intertek Testing Services NA, Inc., Fridley, MN

Control Number: *4008753* **Authorized by:** Charden Jarboe
for L. Matthew Snyder, Certification Manager

This document supersedes all previous Authorizations to Mark for the noted Report Number.

Intertek Testing Services NA Inc.
545 East Algonquin Road, Arlington Heights, IL 60005
Telephone 800-345-3851 or 847-439-5667 Fax 312-283-1672

Standard(s):	Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1: General Requirements>Valid without technical revision: 01Jan2022< [UL 61010-1:2012 Ed.3+R:29Apr2016] Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use Part 1: General Requirements (R2017)>Valid without technical revision: 01Jan2022< [CSA C22.2#61010-1-12:2012 Ed.3+U1;U2]
Product:	Wand mixer
Models:	WMG403 RDUA200 RDUA007BT RDUA008FB

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The information provided in this literature was reviewed for accuracy at the time of publication. Product data may be subject to change without notice. For current information consult your local Pall distributor or contact Pall directly.

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