USD 3188

PALL Life Sciences

Instructions For Use

PadMixer™ 1000 Premium 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 PadMixer 1000 Premium. 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.

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.

3. Assembly and commissioning

It is not permitted to move the machine when a tank and/or mixing biocontainer is connected to it. To move the machine push it from the backside.

⚠ Do not attempt to move the machine by pushing/pulling the mixing head.

Required facilities:

Electricity:	The system 701024 can be used on a single phase net of 220V. The system 701039 can be used on a single phase net of 110V. The fuse present in the local power supply cabinet has to be minimum 16Ampère, with a curve C or curve D. In case a differential switch is present in the local power supply cabinet, it has to be type A or type B.
Compressed air:	Min. 3 bar, max. 8 bar. Use of nitrogen is permitted. The connection of the system to the compressed air system is effected by connecting a 6 mm ID compressed air hose to the compressed air coupling closest to the rear of the machine. A compressed air cable is provided on the coupling closest to the front of the machine with a fast coupling to be connected to the mixing biocontainer. The outgoing pressure (to the mixing biocontainer) can be adjusted by means of the manometer underneath the mixing head cover plate. This pressure is preset to a maximum of 500 mbar.

The machine is ready for use as soon as the electricity is connected. Connection of the air supply is not necessary for the functioning of the machine, only for the inflation.
Voltage is applied to the machine by means of the main switch fitted on the door of the electrical cabinet. All other controls are effected using the Touch Screen.

4. Touch screen operation

4.1. General

All items (text & symbols) with a light blue background fulfil a certain function and can be touched to perform the underlying function or to change the underlying adjustment. Also the start, pause and stop symbols can be touched to perform their function.

The following symbol appears in the top left corner on different screens and can be used to return to the previous screen and finally to the main menu: 

4.2. Start-up screen

A screen saver appears when the main power switch is switched on. The main screen is shown when the screen is touched.

4.3. Main screen – main menu

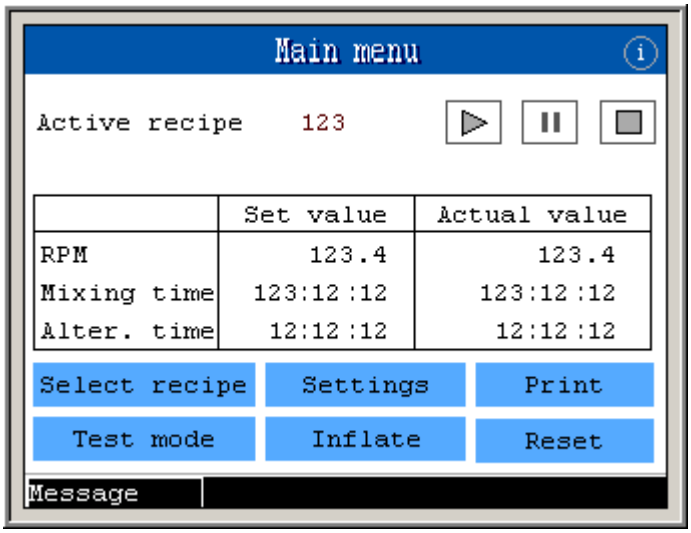

Figure 1: Main Menu

The main screen consists of the following fields:

- **Control buttons**: Start - Pause - Stop 
- **Table with Set and Actual process parameters**
  - RPM: Mixing speed expressed in revolutions per minute
  - Mixing time: expressed in hours : minutes : seconds
  - Alternation time: expressed in hours : minutes : seconds

- **Function buttons**
  - Select recipe
  - Test mode
  - Settings
  - Inflate
  - Print
  - Reset

The operation of the machine is controlled by this main menu only. The active recipe is executed by pushing the Start button. This starts the mixer (see the set acceleration & deceleration times) until it reaches the set rpm and the mixing and alternation time start running. As soon as the alternation time is reached the mixer changes the direction of revolution. The mixer stops when the mixing time has elapsed. If so set, the data are printed out on the printer.

If during mixing the Pause button is pushed the mixer decelerates in accordance with the set deceleration time. The actual data remain valid so that the recipe can be continued with the remaining actual values when the Start button is pushed again.

If the Stop button is pushed the mixer decelerates and the actual values are deleted.

In both cases the mixer always returns to the zero position. This is the position where connecting the mixing biocontainer to or disconnecting the mixing biocontainer from the system is effected most easily (with the paddle pointing towards the back of the mixing tank).

If the mixing cycle is interrupted by an emergency stop the mixer will immediately stop and the actual data will be deleted. The mixer will not stop in the zero position, but in this case the mixing head can easily be manually turned to the zero position in order to disconnect the mixing biocontainer.

4.3.1. Select recipe

Pressing Select recipe shows a screen on which a (different) recipe may be selected. No password is required.

Figure 2: Menu "Select recipe"

The operator can call this screen only if the active recipe is completed (or has been interrupted). The following message will appear if another recipe is in progress or paused.

Figure 3: Message "stop current recipe"

The number of the recipe that is ready for activation appears on top. It may be changed by keying the number. A small numeric keypad appears with which a number may be entered. To enter a number via the numerical keypad first push CLR (clear) to delete the old value, then enter the new value. Alternatively the recipe number can be increased or decreased by 1 using the up and down arrows. The data of the selected recipe are shown under the recipe number.

Pushing the "Confirm" button activates this recipe number and the main screen appears again. This recipe number then appears on the main screen as active recipe number.

4.3.2. Test Mode

In the Test Mode screen the setting values of the active recipe can be changed during mixing. This requires a password.

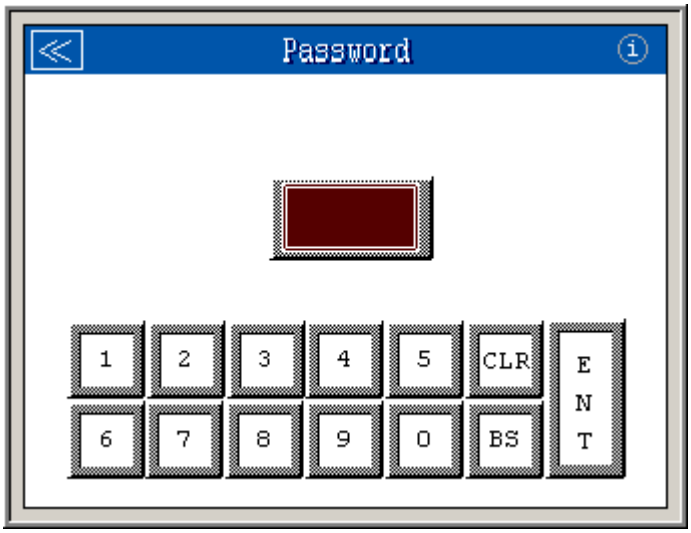

Figure 4: Screen to enter password

If the password you entered is incorrect the following screen appears with an error message.

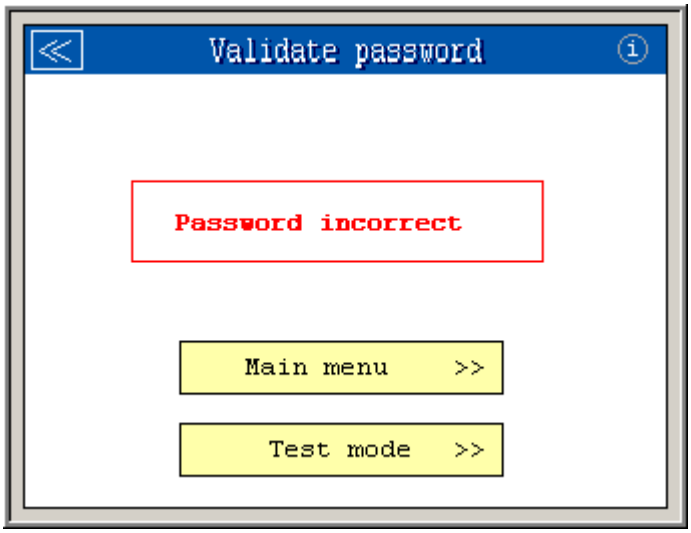

Figure 5: Message when incorrect password entered

By pushing the “Main menu” button the main menu appears again. When the “Test mode” button is pushed, a new password can be entered. If the password is correct the Test Mode menu appears.

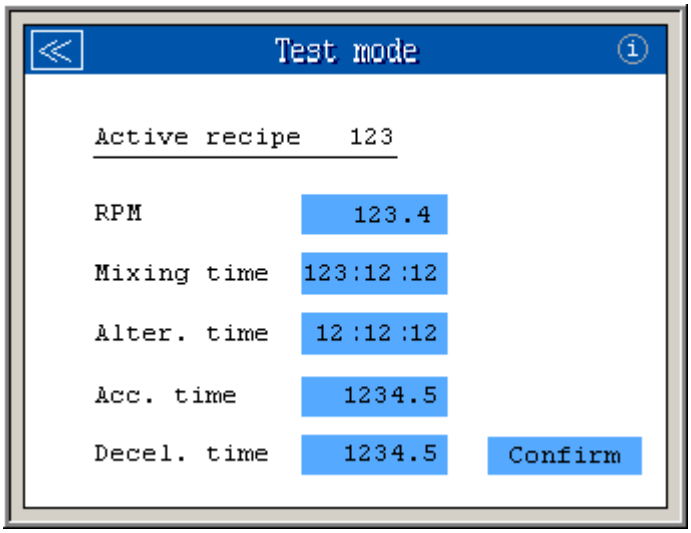

Figure 6: Menu "Test mode"

On this screen all current settings can be changed during mixing. Pushing the "Confirm" button copies all the values of this screen to the setting values of the active recipe and the new values are immediately executed. The executed changes will only apply during this "test mode". The initial values of the recipe will not be changed.

4.3.3. Settings

This shows the menu in which the different mixing parameters can be changed.

Here again a password is required. The following screen with the adjustable parameters appears upon correct entry of the password.

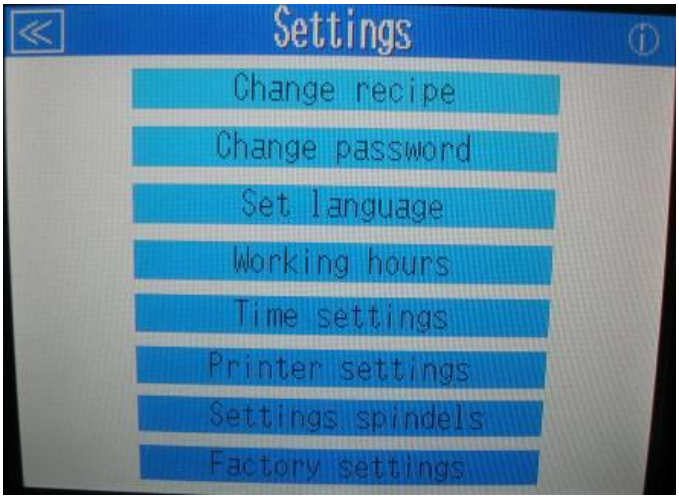

Figure 7: Menu " Settings"

Pushing a button shows the corresponding settings.

4.3.3.1 Change recipe

The setting values of all recipes (from number 1 to 999) can be changed on this screen.

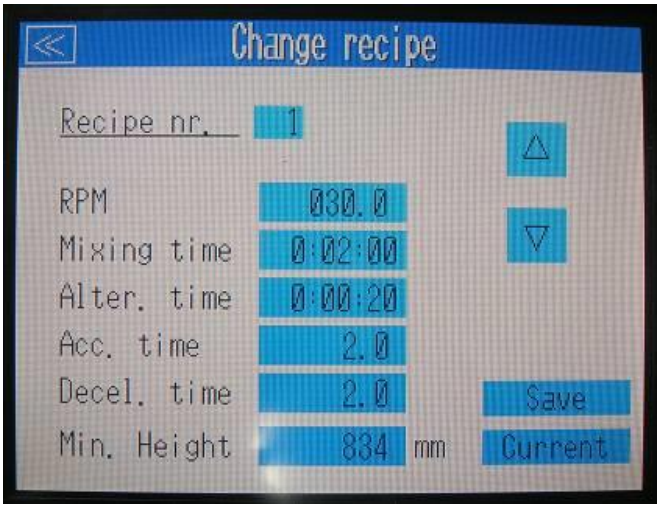

Figure 8: Screen to change the recipe settings

The recipe number can be changed by keying the number. A small numerical keypad appears with which a number can be entered. Alternatively the recipe number can be increased or decreased using the up and down arrows.

The recipe settings can be changed by pressing them, calling up a numerical keypad with which the setting value may be entered.

The desired height of the connection mixing biocontainer-to-system (distance to the floor) depends on the type of mixing tank and mixing biocontainer used. This height should be determined when a recipe is created. The mixing system will not be able to start unless the system is installed at its correct height (to avoid a too high or too low position). The “min. Height” value can be entered in 2 ways: either by entering the value in mm, or by placing physically installing the mixing system at the desired height, followed by pressing the “current” key. In this way the recipe will take the current height as value.

After all values of the recipe have been entered they can be saved using the “Save” button. At the same time this recipe number from the “Select recipe” menu (see above) is set to match this recipe number.

4.3.3.2 Change password

The password requested when choosing the “Test mode” and “Settings” options can be changed here.

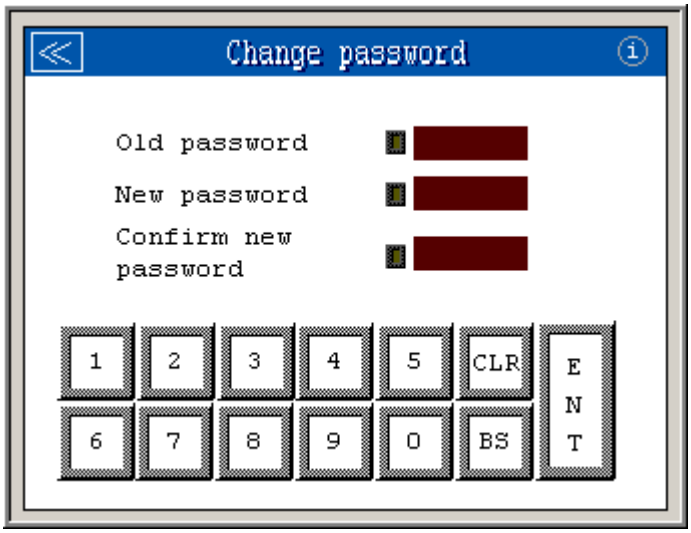

Figure 9: Screen to change the password

First the existing (or old) password is requested, then the new password and the confirmation thereof. If the old password is incorrect the following screen appears with the error message:

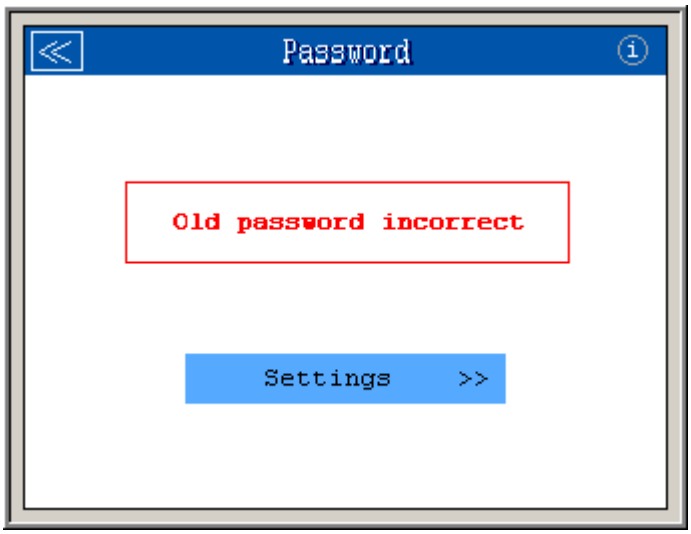

Figure 10: Message when incorrect password

By pushing the “Settings” button the settings menu appears again. The following screen appears with an error message if the new password does not correspond with its confirmation:

Figure 11: Message when incorrect password confirmation

Pushing the “Settings” button returns to the settings menu. The following screen appears if both the entries for the existing password and the new password are correct:

Figure 12: Message when new password is activated

If this screen appears the new password is activated. Pushing the “Settings” button returns the user to the settings menu.

The default password that is installed on new systems is 0000 or 1234.

The „master“ password to enter all menus, including the Factory settings is a 5 digit password. Contact your Pall distributor for more information.

4.3.3.3 Language setting

The language of all words and texts appearing anywhere on the screen can be changed here. Pushing the button for a language immediately activates that language on all screens.

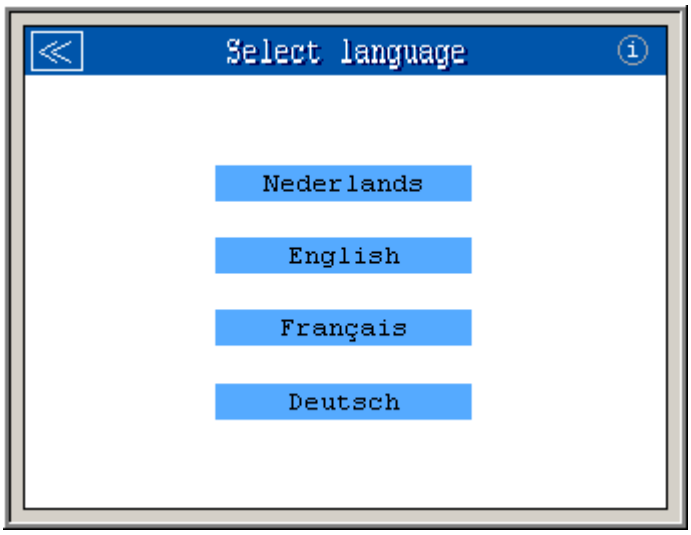

Figure 13: Screen to select language

4.3.3.4 Working hours

The machine working hours are given here for information. The indication of the total working hours (top row) cannot be reset, in other words the total counter from the first moment that the machine was started. The indication of the working hours since the last reset (bottom row) can be reset by pushing the button situated on the right.

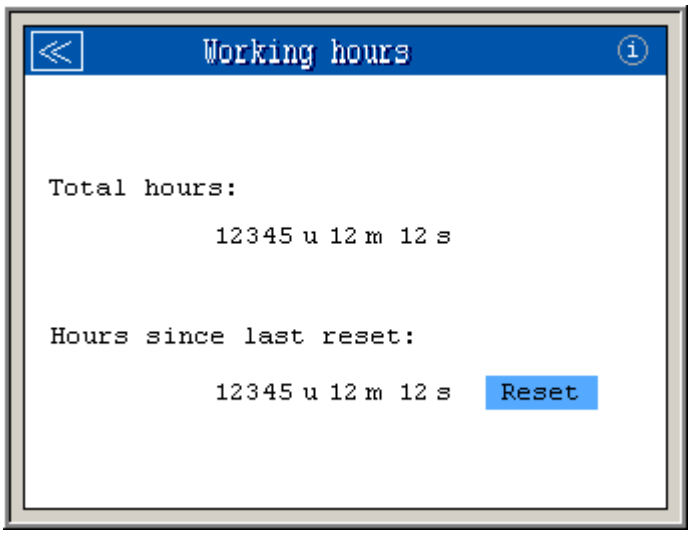

Figure 14: Screen to view and reset the Working hours

The working hours indicate the period of time during which the mixer is working, in other words the period of time during which the start button on the main screen is active.

4.3.3.5 Time settings

As mentioned for the main screen it is possible to show the current time values of the active menu in increasing or decreasing order. The choice between the two can be made on this screen.

Also the time and date can be set.

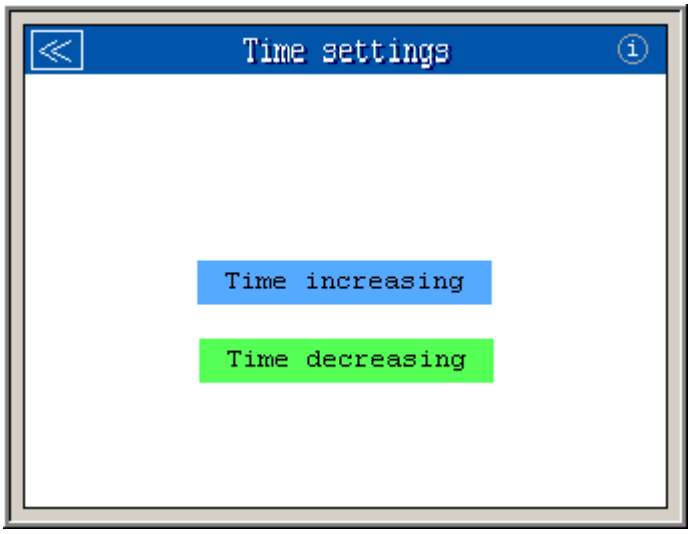

Figure 15: Screen to change the Time settings

4.3.3.6 Printer setting

The data for the completed recipe can be printed out on the printer. On the following screen the choice can be made to print out the data on completion of each recipe automatically or not. Note that the data for the last completed recipe remain available for reprinting, if necessary, by pushing the “Printer” button on the main screen.

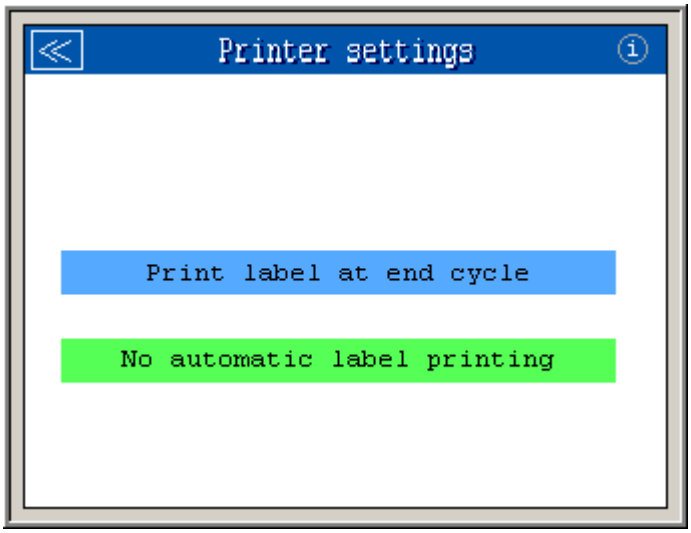

Figure 16: Screen to change the Printer settings

4.3.3.7 Spindle settings

The system contains 2 pairs of spindles. One pair that has a 300mm stroke and one pair with a 500mm stroke. In this menu one can view the height of the pairs of spindles and the total height, being the distance of the mixing head to the floor.

After a number of up-and-down movements, the system will automatically give a warning message that the height measurement through the spindles need to be calibrated.

By pressing the “calibrate spindles” button, the system will go to its lowest possible position (typically 675mm) and will reset itself.

It is at any time possible to perform an additional calibration in case the system height mentioned on the display does not match with the actual height.

Figure 17: Screen to view the spindle location, settings and to calibrate

Note: as the system will automatically move down, no object should be present. The display will mention following warning message. Press OK to carry out the calibration.

Figure 18: Warning message for calibration

4.3.3.8 Factory settings

Certain settings are set by the manufacturer in accordance with the type of machine. These data are intended solely for the technician who commissions the machine and are thus not applicable for the operator. Entering the menu of the Factory settings is not possible with the first level password. A master password is required (5 digits). Contact your Pall distributor for more information. Figure 19: Screen to change the Factory settings shows these factory settings.

In the lower right hand corner of the screen one can see the current active password.

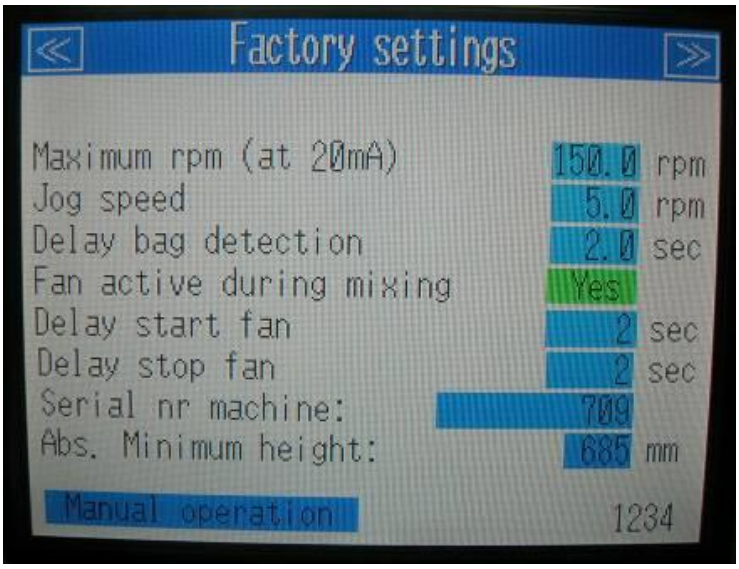

Figure 19: Screen to change the Factory settings

When pressing the „right" arrow one can modify some additional parameters related to an alarm that the system can give when during mixing the actual RPM deviates from the set value.

One can define the time before checking the actual versus set RPM. This is set default at 60 seconds to avoid false alarms during the acceleration phase.

One can define the delay time for actually displaying the „out of range" message. This is set default at 30 seconds.

One can define the maximum RPM deviation allowed. This is set default at 20 RPM.

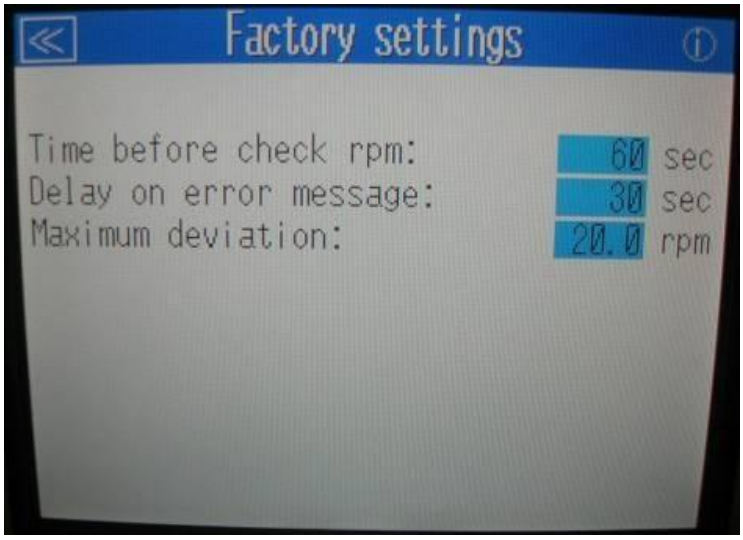

Figure 20: Screen to change additional Factory settings

4.3.4. Inflate

This function is used to inflate the mixing biocontainer with compressed air or nitrogen. When activated the icon turns green and the compressed air valve is activated.

The compressed air remains active until one of the following points:

- The function is cancelled by touching the INFLATE icon on the touch screen again
- The mixing biocontainer is inflated to the point that it presses against the mixing biocontainer detection. However, if the mixing biocontainer is emptied and the detection is released the compressed air will reactivate after a delay of three seconds
- The emergency stop is pressed
- The protective front cover is opened.

4.3.5. Print

This prints out the data for the last finished recipe. To print the last recipe, make sure the mixing system has completely stopped rotating.

Note: the total mixing time stated on the label may be a few seconds shorter than the difference between the start and finish times. The reason is that the last deceleration time is not included in the calculation of the total mixing time, but the finish time is not determined until the mixer has come to a complete standstill.

4.3.6. Reset

This resets all error messages, for example after using the emergency stop.

4.4 Troubleshooting

When touching the top left corner of the main menu a screen appears with the status of all digital inputs. In the event of a malfunction a quick and easy check can be run to see which inputs are working and which may be defective. This function is intended solely for the technician carrying out troubleshooting on the machine.

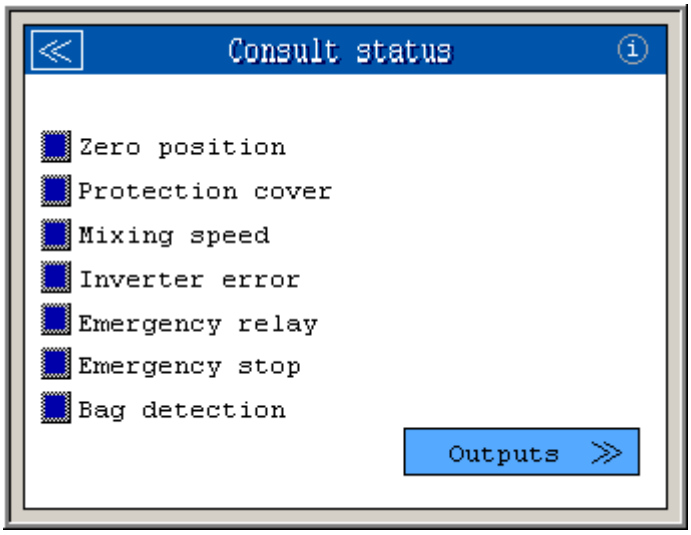

Figure 21: Screen to consult the status of the machine inputs

When pushing the “Outputs” button a menu appears that displays the status of the outputs (inflation valve, fan, …).

If the technician has activated the “Manual operation” feature in the “factory settings” screen, a “Manual” button will appear at the bottom of this menu. The following screen appears if this button is pushed.

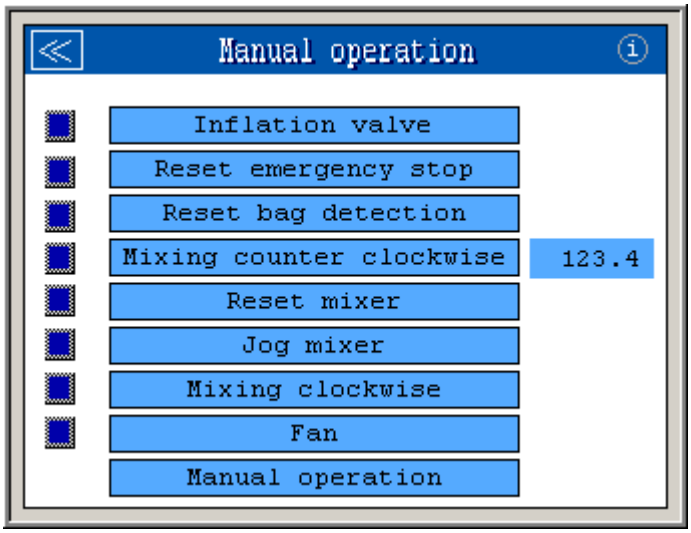

Figure 22: Screen to manually modify machine status

All outputs can be controlled from this screen. This may be useful in order to detect a malfunction in the event that a given function is not working at all or not working correctly.

4.5 Error Messages

At the very bottom of the main menu appears a bar showing the error messages (if active). Pushing this bar shows the complete list of error messages.

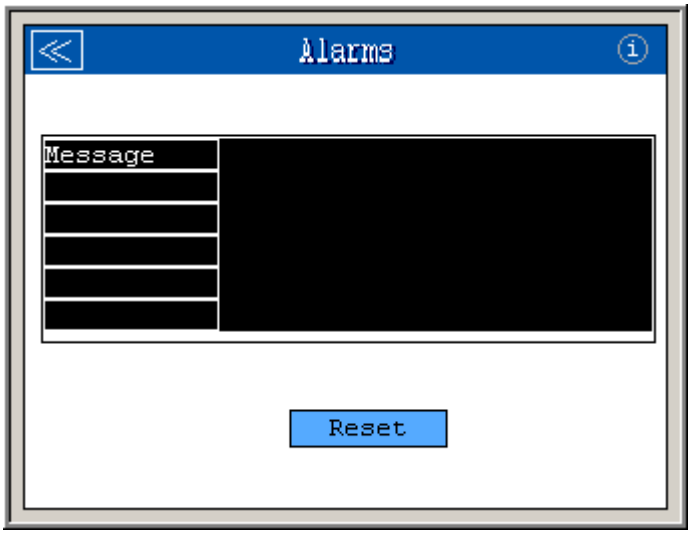

Figure 23: Screen to consult and reset alarms

The error messages can be reset by pushing the reset button in the main menu or, alternatively, by pushing the reset button in the list of error messages.

The following malfunctions & corresponding error messages may occur:

- Protective front cover is open
- Frequency regulator error
- Emergency stop module error
- Emergency stop button is pressed

4.6 Information

As mentioned earlier, contact information about Pall can be consulted by touching the information icon situated in the top right-hand corner of most screens.

Figure 24: Supplier contact information

5 Installation and use of mixing biocontainer

5.1 Installing the mixing biocontainer

A standard powder/liquid mixing biocontainer will have one drain tube, one filling tube, one inflation tube and one powder port. In case of a liquid/liquid mixing biocontainer the powder port is replaced by a second filling tube.

The mixing biocontainers are packed under vacuum and folded in such a way that the drain port is the lowest point of the mixing biocontainer.

Figure 25: Drain port and vacuum folded mixing biocontainer

The drain tube, is introduced through the opening in the bottom plate of the mixing tank.

Figure 26: Installation of a 50L PadMixer biocontainer in the mixing 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 (see above, Figure 15), and then snap the EZ Drain clip over the fitment OUTSIDE the tank (Figure 27 and Figure 28).

Figure 27: EZ Drain clip installation

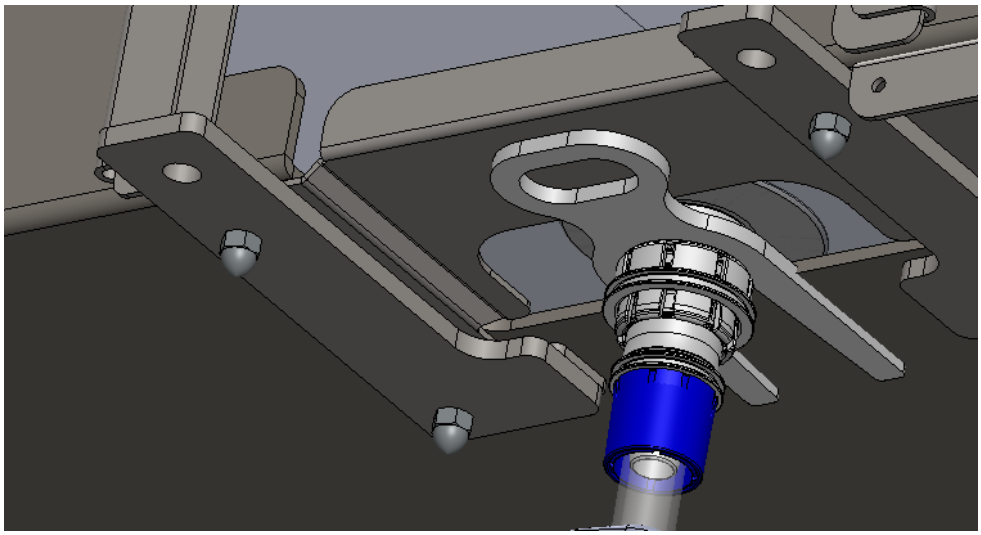

Figure 28: EZ Drain clip installed outside the tank

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 29).

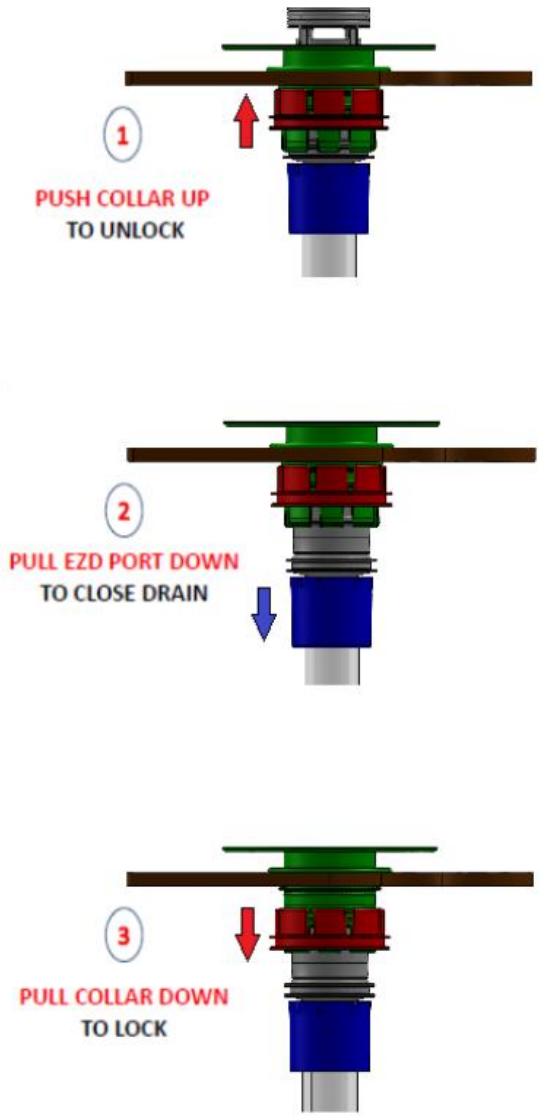

Figure 29: Moving from open to closed (stops fluid flow)

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

The biocontainer can now be filled with liquid and/or powder. This can be done with the mixing tank already under the machine or free-standing (e.g. in a separate room).

In most applications, the following sequence is used:

- filling with liquids
- connecting a powder handling bag to the mixing biocontainer (in case of powder applications)
- partially inflating the mixing biocontainer (in case the bag is less than 80% full)
- connecting the mixing biocontainer to the system
- introducing the powder by opening the powder handling bag
- complete inflating of the mixing biocontainer
- starting of the mixing

However, different applications or processes can have a different mixing biocontainer handling sequence.

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 water happens gently to be able to position the bottom square of the mixing biocontainer correctly, without too many wrinkles and stresses on the film. After the first 10 - 20L the mixing biocontainer can be pulled gently towards the four corners of the mixing tank.

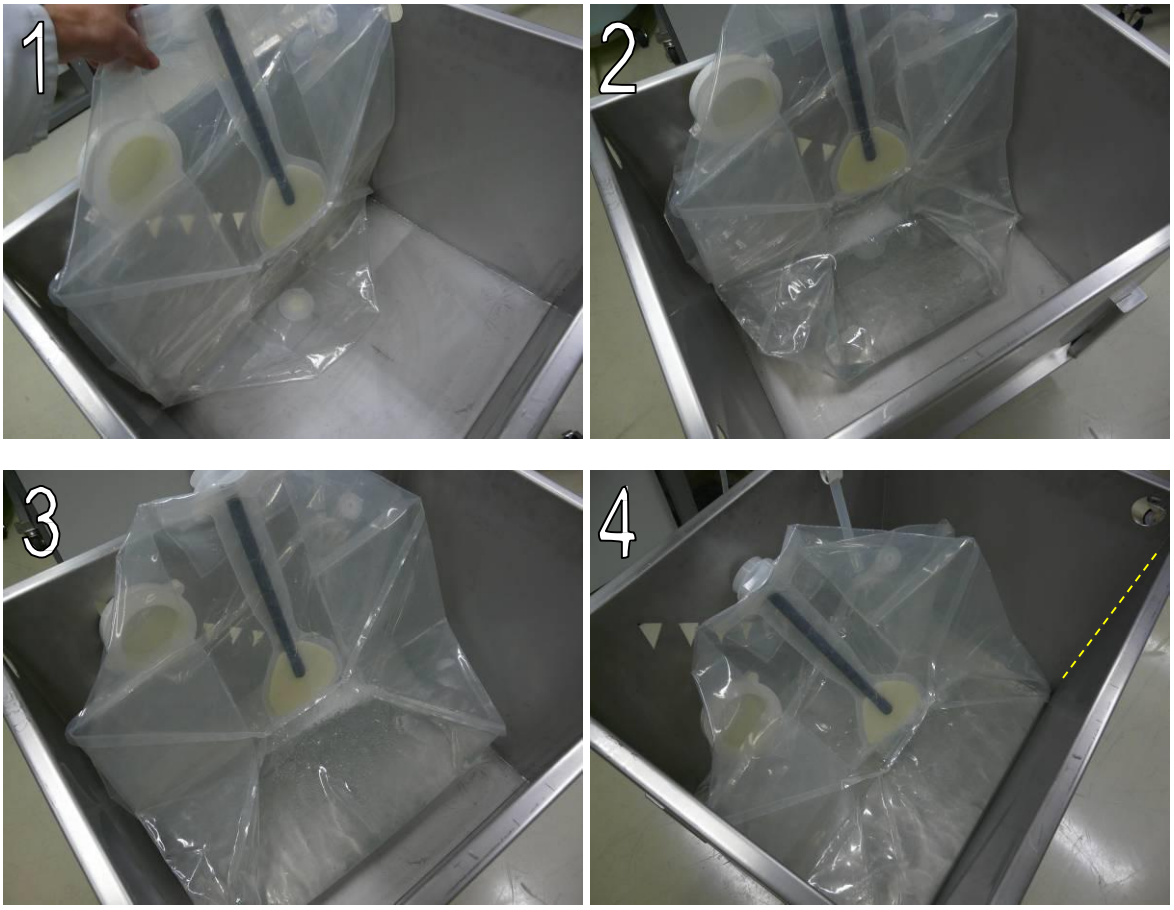

Figure 30: Filling first 10-20L in mixing biocontainer

The following picture shows a mixing biocontainer where the bottom is properly installed. The mixing biocontainer corners are properly positioned in the corners of the mixing tank. From now on the filling speed can be increased and manual manipulation is not required anymore.

Figure 31: Correctly installed mixing biocontatiner, partially filled

5.3 Setting the mixing angle on the drive unit

The angle of the mixing stick can in theory be set between 5 and 25°. It is however not recommended to use an angle above 12.5° in order to avoid damage to the mixing biocontainer while mixing due to high stress on the film.

The angle can be changed by unlocking the 2 fixation pins at the back and by pushing/pulling the mixing head in another angle while keeping the 2 other fixation pins in the front unlocked.

Figure 32: Setting the mixing angle

The life time of a mixing biocontainer will decrease with increasing mixing angle as there are more stresses on the mixing sleeve.

In general an angle of 10 or 12.5° will be more than sufficient to obtain an efficient mixture. Therefore Pall strongly recommends to not use an angle above 12.5°.

5.4 Connecting the mixing biocontainer to the drive unit

Before rolling the mixing tank under the drive unit the stainless steel mixing stick is placed in the hollow rod of the mixing biocontainer. The fork at the end of the stick must slide over the white paddle plate. This can be done by inserting the mixing stick in the hollow tube and slowly rotating the stick until the fork slides over the white plate.

Figure 33: Inserting the mixing stick

The mixing tank can now be rolled under the system. Ensure that the protective front cover is open, that the connection cylinder is in the zero position (pointing towards the front) and that the outer cylinder is open. This cylinder can be turned open manually in the counterclockwise direction.

The mixing tank can now be slowly positioned under the system.

For a 200 and 500L mixing tank use the positioning spacers provided with the drive unit to facilitate the centering of the mixing tanks.

A 1000L does not require spacers as the tank fits in between the frame (left, right and back)

Figure 34: Positioning 200L mixing tank

To avoid possible large (1000L) containers to damage the machine, two PTFE strips are present to stop the mixing tank.

Once the central connector in the mixing biocontainer reaches the machine it must be slightly lifted to ensure fixation.

Figure 35: Lifting of mixing connector

This lifting also allows the stainless steel mixing stick to be inserted in the connection cylinder.

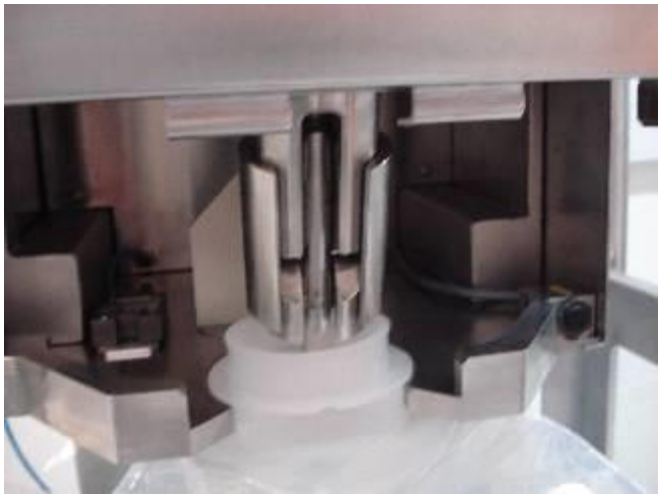

Figure 36: Insertion of mixing stick into connection cylinder

The central connector of the mixing biocontainer must slide under the connector fixation plate at the rear.

Figure 37: Fixation of mixing connector

The outer cylinder can now be turned clockwise to secure the mixing stick in the connection cylinder. The liquid inside the mixing biocontainer might push back the mixing paddle which could make the rotation of the cylinder difficult. In this case, gently push the mixing stick in the cylinder, and close the cylinder. The cylinder must be turned clockwise until one cannot turn further by normal manual force (this is almost one half rotation of 180 degrees).

Figure 38: Inserting the mixing stick in the connection cylinder and closing the cylinder

Position the mixing tank and lock the brakes on the two front wheels of the tank.

Close the protective cover of the drive mixing head and reset the machine. The cover will also fix the front of the central connector to prevent the connector from moving.

Note: A mixing biocontainer is connected to the machine most easily when it is already filled. A completely empty and therefore vacuum mixing biocontainer is more difficult to handle and manipulate. In case the process requires that an empty mixing biocontainer is first coupled to the mixing system, it is recommended that it is inflated first, to facilitate the connection. Note that venting of the air inside the mixing biocontainer will be required when it will be filled with liquid.

5.5 Adding powders

By using a Pall's Powder Handling Bag, powders can be transferred into the mixing biocontainer in a contained manner. The powder handling bag and the mixing biocontainer have the same size HDPE sanitary connector.

Hang the powder handling bag on the steel hook. Install the hook in such a position that the sanitary connector of the powder handling bag and that of the mixing biocontainer are close to each other.

Remove the clamp and end cap from the mixing biocontainer. Leave the silicone gasket on the connector.

Place the sanitary connector of the powder handling bag against the connector of the mixing biocontainer and fix both connectors together with the clamp. Open the clamp on the powder bag to introduce the powder in the mixing biocontainer.

Figure 39: Powder bag arm with hook

5.6 Creating a recipe

Follow the instruction in chapter 4 to create a new recipe and set all desired parameters.

5.6.1 Guidelines to define the correct connection height

The minimum height has to be defined based on the system and mixing tank setup. In general, the correct minimum height is the distance of the mixing tank bottom plate to the floor added to the mixing biocontainer height.

Note: If the mixing tank is not positioned on the floor (e.g. on a floor balance), or if the drive is modified in height, the correct connection height needs to be recalculated.

Note: If the mixing tank is not positioned on the floor (e.g. on a floor balance), or if the drive is modified in height, the correct connection height needs to be recalculated. Also if custom mixing tanks are used, the connection height needs to be redefined. The easiest way to define the connection height is to measure the distance from the floor to the bottom of the tank and to add a certain height depending on the mixing biocontainer size. These values are stated in the table below.

Table 1: Calculation to determing the correct connection height

Nominal biocontainer size (L)	Recommended connection level = Distance between floor to bottom of tank + ... mm
25	270
50	380
200	614
500	725
1000	1098

5.6.2 Mixing speed and mixing angle limitations

The maximum mixing angle that can be installed is 25°. The maximum mixing speed possible is 150RPM. However, when certain combinations are used to achieve a very high mixing turbulence the system will show vibrations. This is mainly the case for the larger volumes. In order to run the system without excessive vibration and hence possible damage to the drive and mixing biocontainer, Pall strongly recommends to use a limited mixing speed and angle combination for the larger mixing biocontainer sizes. An overview with the recommended RPM limits for the different mixing biocontainers is shown in Table 2.

Table 2: Recommended mixing speed and mixing angle limitations for different mixing biocontainers

	Maximum recommended RPM				
Installed mixing angle	***1000L***	***500L***	***200L***	***50L***	***25L***
5°	*100*	*125*	*150*	*150*	*150*
7.5°	*75*	*100*	*125*	*150*	*150*
10°	*75*	*100*	*125*	*150*	*150*
12.5°	*65*	*75*	*100*	*150*	*150*
15°	*Not recommended*			*150*	*150*
17.5°				*150*	*150*
20°				*150*	*150*
22.5°					*150*
25°					*150*

5.6.3 Acceleration and deceleration limitations

In order to prevent excessive vibrating of the system when the system starts or when the alternation is used we recommend to set the acceleration and deceleration times as indicated in the table below.

Table 3: Recommended acceleration and deceleration limitations in function of speed

RPM range	Minimal Acceleration time (sec)	Minimal Deceleration time (sec)
30-70	3	1
70-110	5	3
110-150	10	5

5.7 Height adjustment

Select the recipe that will be used.

As this recipe contains information on the correct height level of the system, the system will not be able to start mixing unless the system is at the correct height.

In the “Select Recipe” menu one can see the desired height (bottom left) and the actual height (bottom right).

Move the system up or down to reach the desired height. The system will automatically stop at the correct height.

Note: Always set the correct height before inflating the mixing biocontainer, in order to avoid bag damage.

5.8 Inflating the mixing biocontainer

Press the reset button to enable the inflation.

If the mixing biocontainer is not completely filled with liquid and the top part of the mixing biocontainer is still empty and under vacuum the residual volume must first be filled with air (or nitrogen).

A fully deployed mixing biocontainer is necessary to prevent the stirring mechanism from rubbing against the side wall during mixing resulting in possible damage to the mixing biocontainer.

Connect the inflation tubing of the mixing biocontainer to the compressed air supply and activate the inflation (via the touch screen).

Figure 40: Connecting the inflation tube to the air supply tube

Once the mixing biocontainer reaches a certain volume the top of the mixing biocontainer will press against the detection sensor and the compressed air supply will be automatically stopped.

This will create an overpressure in the mixing biocontainer of +/- 10mbar. In case this is not desired, it is not required to use the mixing biocontainer detection to stop the inflation. One can also stop the inflation manually (by the touch screen) as soon as the mixing biocontainer is visually sufficiently deployed as shown in Figure 41.

Figure 41: Manually inflated, fully deployed mixing biocontainer

Note: it is advised to check the operation of the mixing biocontainer detection sensor manually each time it is used.

5.9 Starting the mixing cycle

Press the “Start” button and the mixing will start.

5.10 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 42).

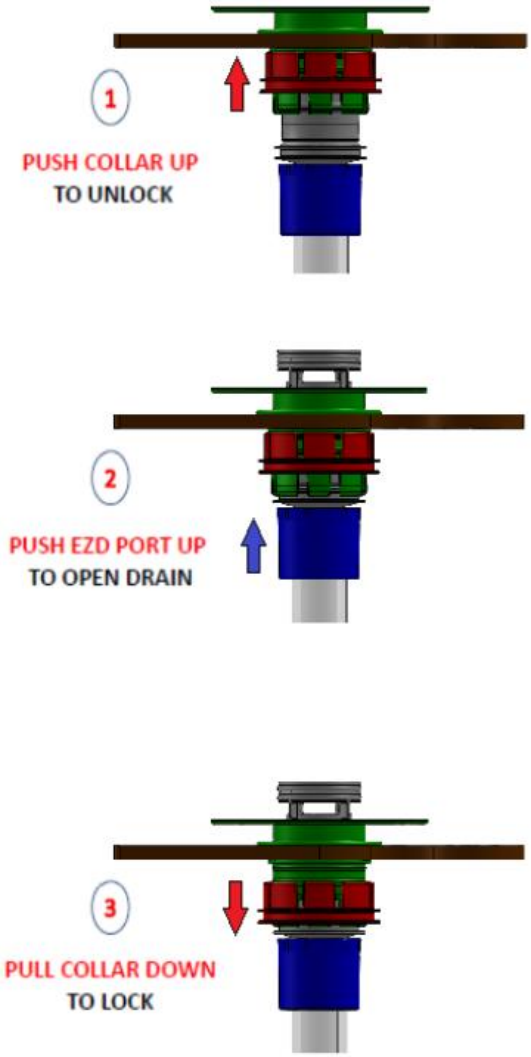

Figure 42: Moving from closed to open (allows fluid flow)

If mixing is required during emptying this can be done by activating the 'Inflate' function so that the mixing bag always retains its three-dimensional shape.

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. To disconnect the biocontainer from the machine the outer connection cylinder must be turned open again (counter clockwise) and the mixing tank can be removed from under the machine. 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.

5.11 Emergency stops

If a problem occurs during mixing the emergency stop button can be pressed and the mixing will immediately stop. Mixing will also immediately stop if the protective front cover is opened during mixing. In both cases the compressed air supply is cut off as well if the „Inflate" function is active at that time.

6 Cleaning, maintenance and inspection activities

6.1 Cleaning

The steel frame of the machine consists of 316 stainless steel and may be cleaned with water, isopropyl alcohol, acetone or other solvents typically used for the cleaning of stainless steel.

The Touch Panel should be cleaned with water or isopropyl alcohol only, preferably with a damp cloth (i.e., not with acetone or other corrosive products).

6.2 Maintenance and inspection

The only preventive maintenance is the oil change. Only changing the oil of the motor reducer is necessary (recommended every 10,000 hours). For detailed information, please consult the technical datasheet of the motor.

It is recommended that the operation of the mixing biocontainer detection sensor is checked before each operation and the operation of the emergency stops once a week (emergency stop button and protective front cover).

It is recommended to perform the spindle calibration when the system displays the message to do so.

With the technical binder, a list of spare parts is supplied. These are mainly parts that are wearing parts, although the wearing is very limited. The changeover time is very much depending on the way the mixing system is used (RPM's, mixing angle used, etc..), so the changeover time is not specified. These parts can be ordered at PALL-Lifesciences.

The cleaning and maintenance of the machine can only be conducted when the machine has been turned off. The power supply must be cut.

6.3 Retrieving a lost password

In case the password is lost or changed by mistake, one can always find the active password back in the menu of the Factory Settings: In the lower right hand corner of the screen one can see the current active password.

6.4 Replacing the printer roll

To replace the printer paper, open the bottom cover plate of the machine.

Remove the white front plastic plate, remove the empty roll, replace by a new roll and replace the plastic plate. Insert the film in the printer as shown on the picture. If the power of the machine is switched on, the printer will automatically pull the paper inside.

Figure 43: Printer with paper roll

If required, press the FEED button to feed the paper in the printer or the PRINT button to print out a test label.

Figure 44: Print and Feed buttons of the printer

6.5 Adjusting the inflation pressure

The outgoing pressure (to the biocontainer) can be adjusted by means of the manometer underneath the mixing head cover plate (an L-shaped plate). This pressure is pre-set to a maximum of 500 mbar.

If however a higher air flow rate is required, this pressure can be adjusted. There is no risk for creating an overpressure inside the bag since the bag detections will stop the inflation in time.

Note however that a too high gas flow might cause issues if certain filters are present on the gas inlet tubing, or if the gas inlet tubing has a very small ID or shows locally diameter reductions.

To change the pressure, the inflation must be switched on and the outlet tubing (towards the bag) must be kept closed. Only then the manometer will indicate the outgoing pressure on the display.

Figure 45: Pressure regulator

6.6 Replacing the motor

To replace the electric motor, first remove the L-shaped plate at the bottom of the machine head. Disassemble the touch screen by unscrewing the four screws positioned at the inside of the head and temporarily disconnect the cables. Remove the full head shield. This shield is mounted with six screws: two are positioned in the head (connector plate) and four are positioned in the inside of the head (gearbox space). Only the emergency stop is still mounted to the head shield. Remove the head shield until the point where also the emergency button can be removed.

Figure 46: View of the head of the machine without the cover

Now there is free access to the gearbox. Disconnect the power supply cable, remove the RPM counter disc and the bracket with the 2 sensors. Disconnect the mixing head from the motor axes and remove the motor from the support plate by means of the 4 screws.

The recommend oil type ISO VG 220.

6.7 Uploading a new PLC code

This chapter explains how a new or modified PLC code can be uploaded onto the systems PLC.

When a new code is uploaded, some old information that is stored in the program will be lost. Therefore note all Recipe settings and Factory settings so that these can be edited when the new code is installed.

Load the new or modified PLC code on a CF-card (Compact Flash).

2 files + 1 folder should be loaded onto the CF-card, so not under another directory or folder. The following type of files and folder should be saved on the CF-card :

Figure 47: Overview of files and folders to be saved on the CF card

Turn off the main power the mixing system.

Open the back of the touch screen box (4 screws). Open the CF-card slot and insert the CF-card.

Figure 48: Inserting the CF card

Close the CF-card slot.

Turn on the main power of the machine.

Wait until the main screen appears (+/-30sec).

Press on the right upper corner and immediately next on the lower left corner. The information screen appears with several buttons at the bottom of the screen.

Press on the button “CF/USB”.

New buttons appear. Press on the button “CF_Start”.

Following screen appears in the language that has been preset:

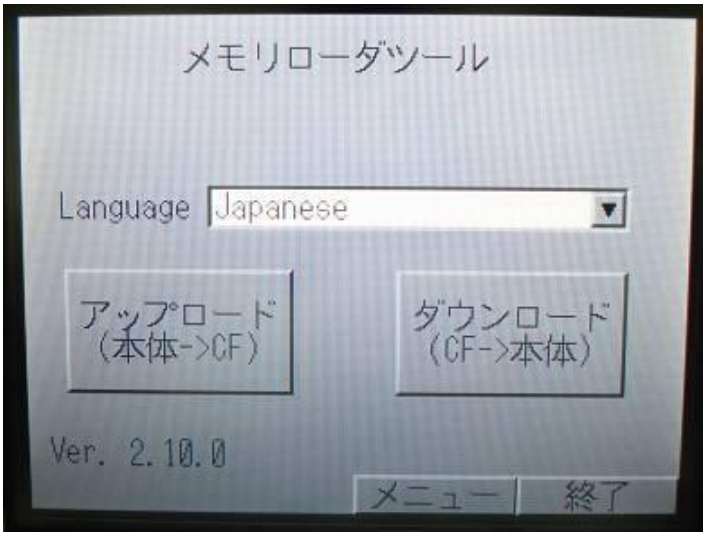

Figure 49: Code Import/Export screen (example when Japanese is selected)

If the screen is not preset to English, select English:

Figure 50: Code Import/Export screen (example when English is selected)

Press on the button “Download CF->Display”. Following screen appears:

Figure 51: Code Import screen

Press on the button “Start”. Following screen appears:

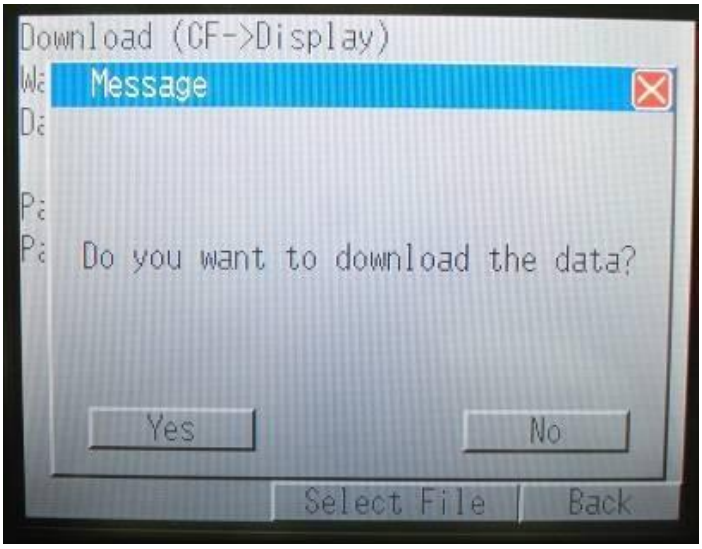

Figure 52: Confirmation screen code import

Press on the button “Yes”. The downloading will start. Following screen appears:

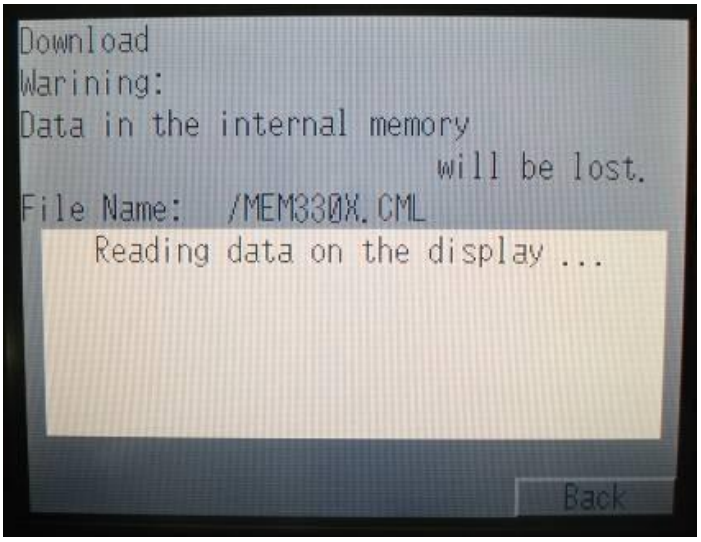

Figure 53: Code import monitoring screen

After a few minutes, the following screen appears:

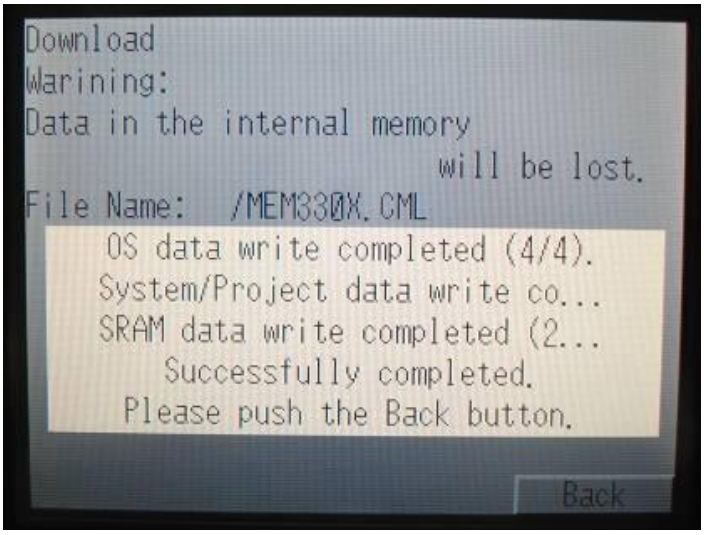

Figure 54: Code import completion screen

Press on the button “Back”
In the next screen press “Back” again.
In the next screen press “Exit”. The following screen appears:

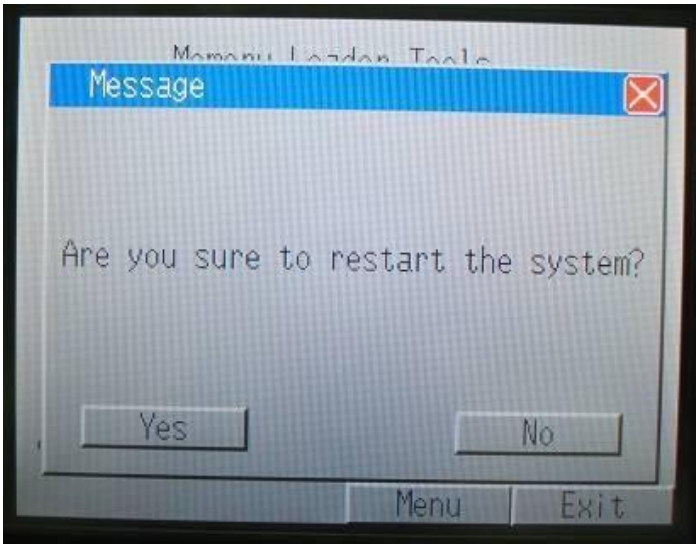

Figure 55: System restart request screen

Press on the button “Yes”. The system will restart. The default password will be now at 0000.

Reinstall the password as desired.

Reinstall all recipe settings.

Reinstall the Factory settings, as shown on following screen:

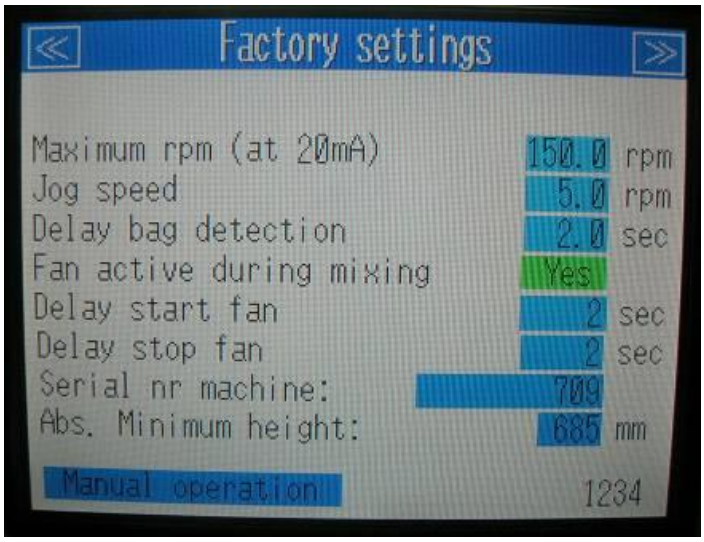

Figure 56: Factory settings

The serial number of the machine can be found on the tag plate of the unit.

Press on the right upper corner to enter a second field of Factory Settings. The following screen shows the preferred standard settings that concern the error message in case of on RPM deviations:

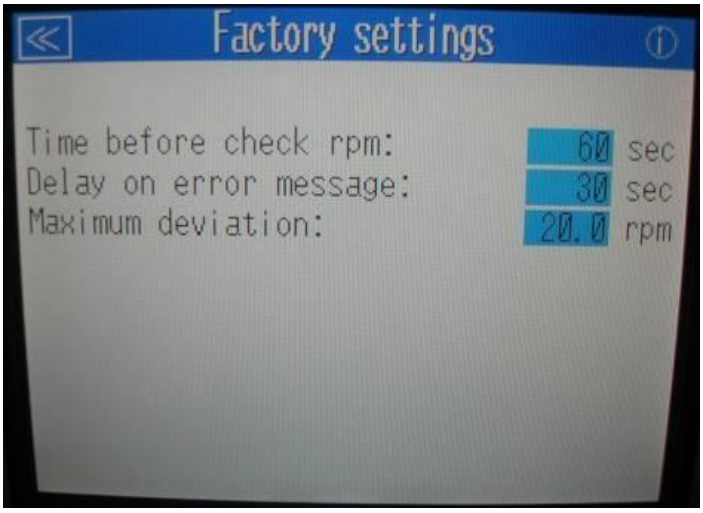

Figure 57: Factory settings

Reinstall the spindle settings, as shown on following screen:

(only the Maximum Height needs to be added).

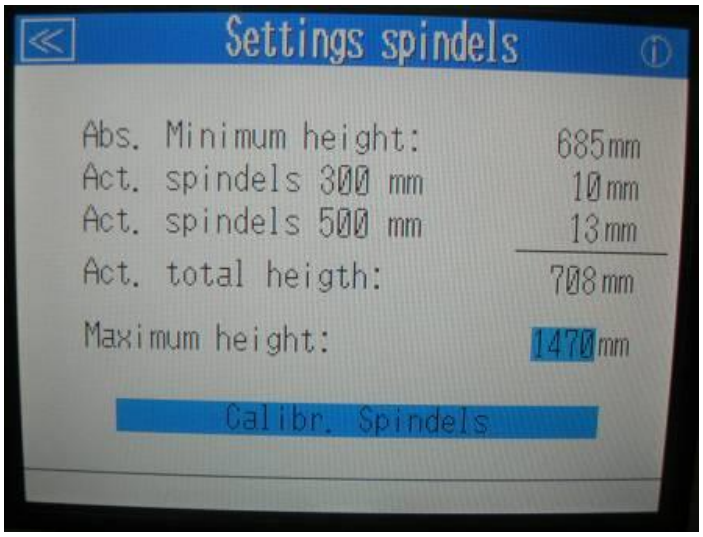

Figure 58: Settings spindles

Perform a calibration of the spindles.

The installation is complete.

Note: Remove the CF-Card from the slot, and close the slot when the system is powered off! Close the back plate of the Touch screen box.

7 General machine specifications

7.1 Materials

Plate material (outside plate surfaces)	Stainless steel 316L Brushed surface finish Surface roughness <1.2 µm Ra / 47 µin Ra
Frame material (inside frame, mixing head bottom plate and handlebar)	Stainless steel 316L Bead blasted surface finish Surface roughness <2 µm Ra / 79 µin Ra
Wheels (castors)	White polyamide
Protection guide and blocks	PTFE
Certain components in the mixing head	PEEK

7.2 Capacity

The machine is designed to work with PadMixer mixing biocontainers of 25, 50, 200, 500 and 1000L.

The minimum mixing speed is set at 30 RPM, the maximum speed is 150 RPM.

7.3 Noise level

The machine generates a noise level of less than 75 dB.

7.4 Operating temperature

The ambient operating temperature is 0°C to 50°C. For more details, consult the equipment specification.

8 Service

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

Should your 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.

PALL Life Sciences

Corporate Headquarters
Port Washington, NY, USA
+1.800.717.7255 toll free (USA)
+1.516.484.5400 phone
biopharm@pall.com e-mail

European Headquarters
Fribourg, Switzerland
+41 (0)26 350 53 00 phone
LifeSciences.EU@pall.com e-mail

Asia-Pacific Headquarters
Singapore
+65 6389 6500 phone
sgcustomerservice@pall.com e-mail

Visit us on the Web at www.pall.com/allegro
E-mail us at allegro@pall.com

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