



STANDARD OPERATING PROCEDURE

SOP NUMBER FSN-004-01	SOP TITLE OPERATING PROCEDURE FOR RODWELL 60 – MP25 AUTOCLAVE
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PART 1

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PART 2

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PART 3

Authoriser	Date of Issue:
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PART 4 (To be filled in by OOS, QSU or RSSD)

<input type="checkbox"/> This procedure has been revised and is no longer valid as from: (Write date)	<input type="checkbox"/> Date of NEXT REVISION is extended until: (Max. 4 years)	<input type="checkbox"/> SOP rendered obsolete on: (Write date)
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1. Reason for revision

- 1.1. Not applicable. New SOP

2. Purpose and scope

- 2.1. The SOP is intended to provide a guideline to the proper use of the autoclave together with any safety precautions that need to be observed during its operation and maintenance. However it is imperative to note that in no way does this procedure replace either the manufacturer's detailed User Operating Manual (which should also be readily accessible in the lab) or a proper on-site training by qualified staff on how to operate the autoclave.
- 2.2. Within the scope of implementation of this SOP are all laboratory personnel authorized and trained to use the autoclave.

3. Definitions

- 3.1. SOP – Standard Operating Procedure
- 3.2. ppm – parts per million

4. Responsibilities

4.1. User's Responsibilities

The user is responsible for ensuring that:

- The load contents will be compatible with the materials used to construct this vessel.
- The chamber is free from stress corrosion cracking; this is foreseen by the use of excessive sodium chlorides, from the load or from the water used to fill the vessel.
- The operator carries out routine maintenance checks as stated in this manual.
- The operator is fully trained before using this equipment.
- Any service interventions (both preventive and corrective) are properly recorded.
- The contents of the autoclave are correctly sterilized before releasing the door.
- All necessary precautions are taken to prevent the possible release of harmful pathogens or chemicals into the environment both through the atmosphere and through any discharge to the waste system
- Any leaks or operational malfunctions are reported immediately and rectified before using.
- A record is immediately entered in the Log Book each time the autoclave is used or any intervention is made on it.

5. Health and Safety Requirements

- 5.1. Operators must wear a visor, heat protective gauntlets, a laboratory coat with sleeves, suitable closed footwear and a heavy apron before opening the door or unloading the autoclave.
- 5.2. It is imperative that in the event of a breakdown (and hence prior to any service intervention) or spillage of any waste liquid, a dry cycle is completed to ensure the chamber is sterilized and free from any hazardous pathogens.
- 5.3. The table below lists potential hazards related to the operational use of the autoclave and possible preventive measures:

HAZARDS	COMMENTS
Burns and scolds from liquid loads	Protective Clothing must be worn.
Back injury through loading and unloading	Use Loading Hoist or Loading Trolley.
Burns and scolds from opening the autoclave before cycle is complete	Locks fitted. However care should always be taken.
Damage to Load Probe(s) or any damage to the autoclave.	Do Not use the autoclave. Fit new Load Probe.
Liquid Spillage when loading or unloading.	Clean Up and Dry.
Burns and Scolds from opening manual drain valves.	Ensure there is no pressure in the chamber and the temperature is below 80°C before opening any manual valves
Burns and Scolds from failing to close manual drain valves.	Ensure all manual valves are securely closed after servicing or maintenance

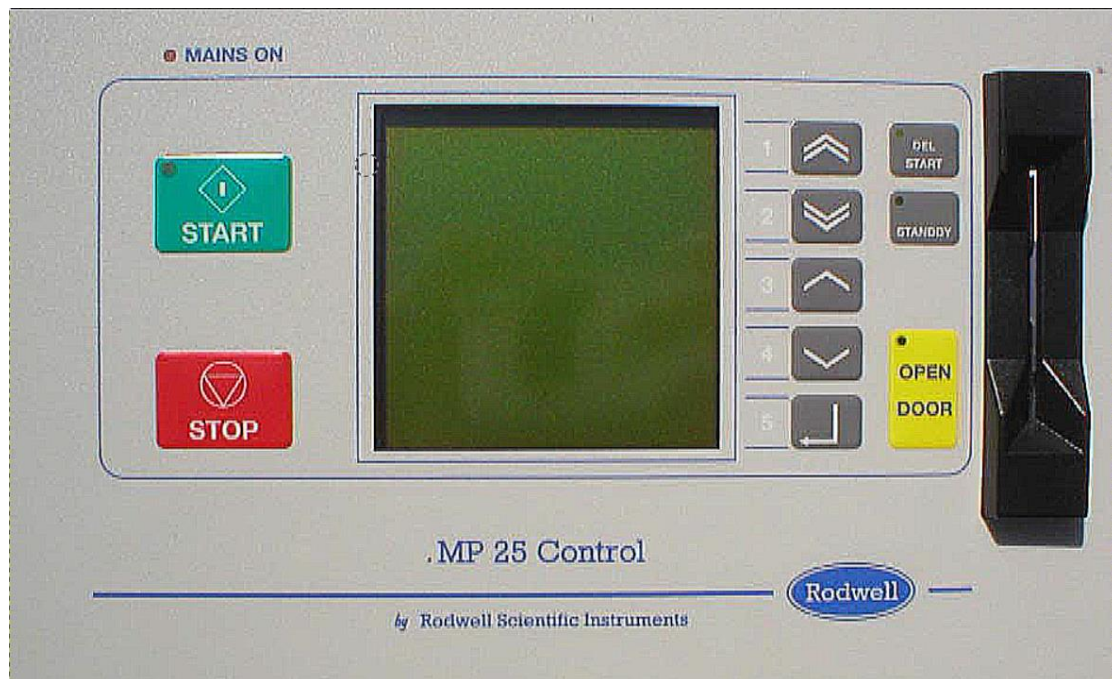
5.3 Safe design operating limits:

- Maximum Working Temp. 138° C.
- Minimum Working Temp. 7° C.
- Maximum Hydraulic Pressure 4.14 Bar.
- Maximum Working Pressure 2.62 Bar.
- Maximum Working Vacuum -1 Bar.
- Sodium Chloride in water supply: Not greater than 1000 ppm
- ELECTRICS: 220 Volts 1 ph 50/60Hz 3kw.

6. Procedure

6.1 Cycle Operation

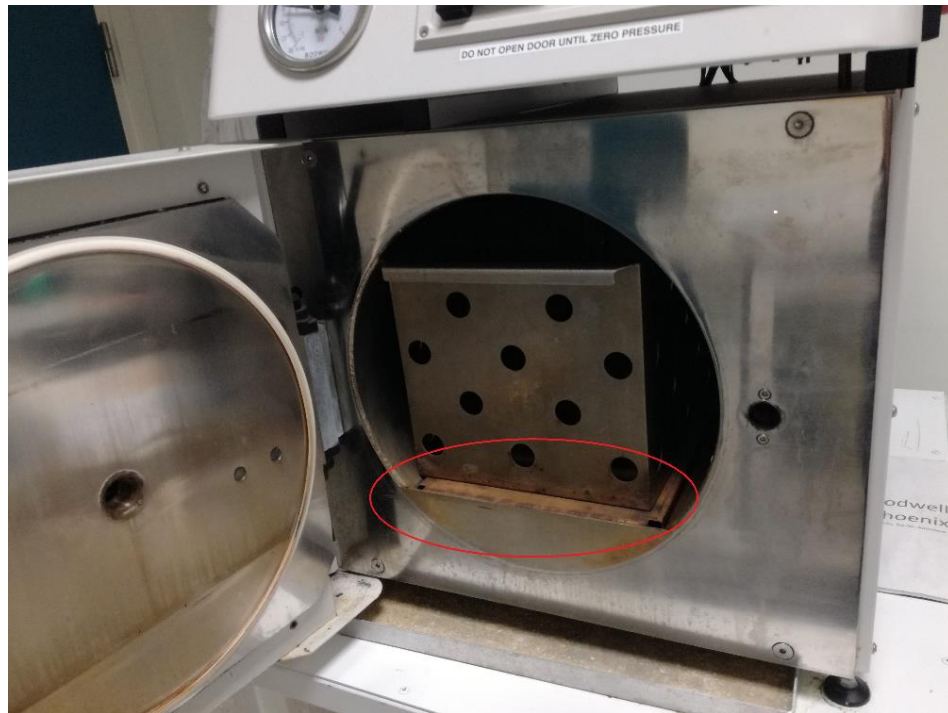
- 6.1.1 The Rodwell 'PHOENIX 60 - MP25' is a bench top loading portable laboratory autoclave with a chamber volume of 60 litres. The controls are simple to use and the instrumentation provides a clear indication of cycle progress.



Display for autoclave

- 6.1.2 Ensure the autoclave is powered **ON** – the welcome message indicating the current time and date should be displayed.
- 6.1.3 After about ten seconds the welcome message will be replaced by the current system status on the top line with the chamber and load temperatures below this. The next two lines display the condition of the machine for example '**Door Open**'. The lower lines display the current program number, sterilizing temperature and period.
- 6.1.4 Place the load to be sterilized inside the machine and the load probe into the center of the load or into the largest flask. (If the load probe is not required place it safely out of the way so that it will not get trapped in the door).
- 6.1.5 If the door is not open press the 'OPEN DOOR' button to release it. If it is safe to open the door then the 'OPEN DOOR' indicator will light and the display shows door is released. Undo the door bolt and open it.
- **DO NOT ATTEMPT TO OPEN THE DOOR UNTIL THE END OF THE CYCLE.**
 - **DO NOT FORCE THE DOOR OR ATTEMPT TO TURN THE BOLTS UNTIL THE OPEN DOOR INDICATOR IS ILLUMINATED**

- 6.1.6 Check that the water level is correct, if the display is showing '**Low water**' then pour water into the chamber until the message clears and the level is just above the base metal platform (as per below picture).



- 6.1.7 Ensure that there is sufficient water in the conical flask containing the temperature probe and that the wire does not get caught between the side of the autoclave and the loading chamber but hangs freely at the back to avoid damage to the same cable.
- 6.1.8 Close the door and secure the bolt. A short beep will be heard as the bolt reaches its limit. Do not over tighten the bolt, it is designed to beep at the point where the safety pins locate, over tightening can result in incorrect operation.
- 6.1.9 Select the correct pre-programmed mode while the machine is in standby (Displaying **Select prog.**) Any changes to a program will be automatically saved whenever these are made. When setting times, these are displayed in minutes except for the sterilizing time which is in hours and minutes.
- Temperature is always in degrees Celsius (°C)
- 6.1.10 With the 'Operator' card (pre-loaded with 4 program cycles) inserted in the front slot, go to the **Select prog** screen and choose the required program number by pressing the up or down buttons (3 & 4), then press the Enter key (5) to return to the **Select prog** screen.
- 6.1.11 If a different program cycle is required other than the 4 pre-programmed ones on the Operator card, please refer the Operating Manual (*Section 3; Pg 9 - Program Set Up*) or seek technical assistance.

6.1.12 When the required program is displayed, press the 'START' button.

- *(Note: If the program start needs to be delayed, refer to Section 6.4).*

6.1.13 If there are no problems during the cycle, the display indicates Heating and the selected Program number, temperature and time.

6.1.14 The machine will work through the various stages of sterilizing, displaying appropriate information on the screen.

- *(Note: If any other messages appear, then press the 'Open Door' button and carry out the required operation before pushing the start button again. Pressing the 'Open Door' or the 'STOP' button will stop the process cycle until the temperature reaches 80°C. Once the temperature is reached, the process cannot be stopped other than by use of the 'STOP' button).*

6.2 Cycle Complete

6.2.1 Once the cycle is completed and the machine has cooled to below 80°C it will display 'Complete' and the sounder will beep every minute. If the cycle completed without any problems the machine will display 'Load is sterile', but if any problems occurred the message will show 'Load not sterile'. If the load is not sterile take any necessary precautions to avoid contamination.

6.2.2 Press the door open button to release the door. The door light will come on and the display will show 'Door is released' and then 'Door is unlocked'.

- if the display shows 'Door lock jammed', then turn the bolt slightly clockwise or anticlockwise to release the bolt, now push the 'Open door' button again.
- if the display shows pressure locked then again move the bolt slightly clockwise or anticlockwise to release the pressure lock.

Once the display indicates door is released undo the bolt and open the door.

- *(Note: the display returns to the **Select prog** whenever the 'Open door' button is pressed. If you do not wish to remove the load at this time but want to stop the sounder operating it is also possible to push the 'Stop' button to return the unit to **Select prog** mode without releasing the door).*

6.2.3 Remove the load - the machine is now ready for further use.

6.3 Lockout

- If during the sterilizing process the system should generate a fault, the autoclave will go into Lockout mode. The screen will indicate what caused the problem and the sounder will beep every minute until the condition is reset.
- The sterilizing cycle will be aborted and the machine cooled down. Once the machine has cooled and the condition reset, it will be possible to open the door but consider any health risks involved as the load may not have been correctly sterilized.

- If the machine consistently locks out then consult your service agent as there may be a problem with the autoclave.
- To unlock the autoclave again:
 - Press button 5 on the display
 - Toggle down using button 4 to '**Reset Lockout**'.
 - Press button 5 again- '**Select**'

Lock out will be removed.

6.4 **Delayed start**

- If you wish to delay the start of sterilization cycle, a delayed start function is incorporated. Load the machine as described above, close the door and select the required program. **Do not press 'Start'**.
- Press the '**Del. Start**' button. The indicator will light and the screen will display the start time with the hours flashing.
- Press the Increase or Decrease buttons to set the hours to the time that you wish the machine to start. (Use 24 hour format.) Press the right shift button to move to the minutes and set as required.
- Ensure that the correct program has been selected then press the 'Start' key.
- Provided all is correct the machine will display the current time and the message 'Waiting for start'.
- The autoclave will start when the preset time is reached.
- If the delayed start is pressed accidentally, press it again to turn the function off.

6.5 **Standby** (function currently deactivated)

To speed up the heating process it is possible for the autoclave to maintain the water at a preset temperature, in the case of in chamber heated machines the water will be maintained at 40°C.

- This function can be turned on or off for each individual program so that sensitive loads will not be effected by prolonged heat exposure.
- The standby button allows manual override of this function.
- If the Standby indicator is alight then the water will be maintained at this temperature.

6.6 Emergency Stop

- If at any time the machine develops a fault or the cycle has to be aborted for any reason the 'STOP' button will abort the cycle and immediately start cooling. The display will show 'Lockout' mode and 'Emergency stop'.
- Once the machine has cooled the lockout condition can be reset by pressing the reset key (5) and selecting 'Reset lockout' from the menu options (*refer to the Operating Manual: Section 3; Pg 10 – Options Menu*).
- Normally it is best to allow the emergency stop to cool the machine as this be the safest condition however in some circumstances the emergency stop can be pressed a second time, this will shut the control off completely leaving the chamber sealed and possibly under pressure.

6.7 Maintenance

- This autoclave is fitted with several safety interlocks which will require periodic maintenance. It should become standard practice to carry out the routine checks as listed in Appendix 1 – *Recommended Maintenance Schedule*.
- Apart from the daily (if used) and weekly routine schedule, it is recommended that a maintenance check is carried out by a competent engineer approximately every 6 months or 300 cycles (whichever is first) in order to ensure that the equipment is in safe operating condition and that it maintains a satisfactory level of performance.

6.8 Use of instrument logbook

- An equipment log book as per SOP ZRH-OP-002 is to be kept adjacent to the autoclave.
- The type of program used as well as an indication of whether the water level was topped-up is to be indicated in the Description section of the logbook.
- Every time the instrument is used, incident reported or maintenance is carried out, a record should be kept. This is important to keep track of the use, lifetime and maintenance of the equipment for budgeting and upkeep purposes.

7. References

- 7.1. Rodwell Operators Manual "PHOENIX 60-MP25 with Smart Card &USB"; Serial Number 2321 ; issue 28-03-14
- 7.2. SOP-ZRH-OP-002 : Equipment Log Book

8. List of Appendices/Worksheets

- 8.1. Appendix 1 – Recommended Maintenance Schedule

Appendix 1

Recommended maintenance schedule

Daily Maintenance	Weekly Maintenance	6 monthly Maintenance
Ensure that all safety interlocks are operating correctly. In the event of failure, DO NOT use the autoclave. Call a person in authority.	Clean all foreign matter from the chamber. The surface of the chamber should be washed with water containing a mild detergent; the baskets should be cleaned in a similar way. (Materials that will leave deposits such as cotton wool should not be used for cleaning).	Run a cycle with no load (as per the initial check routine) to ensure correct operation.
Check that the Load temperature probe is not damaged or defective. If the probe is damaged the autoclave must NOT be used - call a person in authority).	Check that the door acoustic alarm alarms function correctly.	Check door bolt and hinges for signs of wear.
Check the door seal to ensure that it is in a good condition free from any cuts or abrasions, clean with a damp cloth.	Examine the machine and external pipe work for signs of leaks or damage.	Check that all main electrical connections are firm and show no signs of burning.
Check and empty the door drip tray as required	Lightly lubricate the door bolt with high melting point grease.	Ensure any manual valves are fully operational and that they are securely closed
Keep the autoclave clean and free from dust and dirt.	Scrub out chamber and remove any deposits. Ensure that materials used do not have any ferrous content (Steel wool etc. will leave a contaminated deposit and the chamber will appear to have rusted).	

Note: For a detailed cleaning procedure, refer to Section 6 of the User's Operating Manual (Pg 19)