PodiaClave+© User Manual

Vacuum & Non-Vacuum Autoclave

Prestige Medical©

Integrated decontamination solutions

304265B

Instructions for use

Please read these instructions before using the autoclave.

Keep these "Instructions for use" in a safe place close by the unit for future reference.

Service Helpline: Telephone: 01254 844 116

e.mail: customerservice@prestigemedical.co.uk

The Prestige Medical Customer Service Team is available to provide advice and assistance during normal office hours. To avoid delays when making contact, please have the unit's Model and Serial Numbers at hand. These can be found on the rating plate located at the rear of the unit or on the bezel inside the door.

For additional information visit www.prestigemedical.co.uk

UK Customers

Prestige Medical Limited
East House, Duttons Way,
Shadsworth Business Park,
Blackburn BB1 2QR

Tel : +44 (0) 1254 682 622
Fax : +44 (0) 1254 682 606

www.prestigemedical.co.uk
sales@prestigemedical.co.uk

Overseas Customers

Contact your local distributor. In case of doubt contact Prestige Medical.

Contents.

Destination Kit

Date of purchase

Model no.

Vessel rating plate (duplicate)

Serial no.

Prestige Medical©
Integrated decontamination solutions

CE 0086

BS EN ISO 9001:2000 Cert No. FM31988 | ISO 13485:2003 Cert No. FM79156

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Registered in England
Reg No. 2826793

Section 1: Introduction

Thank you for choosing the Prestige Medical PodiaClave+.

Before unpacking, refer to the “Manual Handling” section on page 12.

Whilst unpacking, check the unit for transit damage. If damage is found, please report this to the shipping agent immediately, in writing and then notify your dealer.

Product contents will contain the following:

- Autoclave with internal furniture.
- Handbook and warranty card.
- Performance Test Certificate and Certificate of Conformance for pressure vessel (all UK models).
- Bowie Dick Test Pack.
- Waste water container.

Types of load and loading.

This autoclave has been qualified to sterilize loads as defined by prEN13060. The door will remain closed during the drying cycle.

An “Auto-cycle start” option is included which allows the user to programme the time of day at which the selected cycle should start.

Cycles P1 & P2 – Wrapped, pouched, solid, hollow instruments (length to diameter ratio 750:1 Length may be doubled for tubes that are open at both ends) and porous items.

Cycles P3 – Unwrapped, solid, hollow instruments (length to diameter ratio 750:1 Length may be doubled for tubes that are open at both ends). This is also a “Process Challenge Device cycle” (Bowie Dick Test Pack or Helix). To be used for validation of cycles P1 and P2.

Cycles P4 – Unwrapped solid instruments only.

WARNING!
Refer to the instrument manufacturer about their suitability for autoclaving and the maximum temperature that the instruments can withstand.

- A “responsible person” must qualify other loads as suitable. Refer to “Additional Information”.
- Refer to “Technical Specifications” for the maximum instrument load for the autoclave.
- All instruments must be cleaned prior to sterilizing.
- Wrapped or pouched loads should not touch adjacent loads when placed in the rack. Pouches must be used for only one item.
- When placing on a tray, ensure items are placed on the ribs of the tray (to aid drainage), they do not touch each other and the load does not touch the other trays or chamber in any way.
- Always use the lifting device when removing trays from the autoclave, as they may be hot. Long trays should be supported at their rear as they become free of the tray carrier. Do not use an unprotected hand to hold hot trays.

Section 2: Operating Symbols, Displays and Controls

Pouched instruments should be placed on pouch trays for best drying results

Do not use an unprotected hand to hold hot trays.

IMPORTANT: Read Operating Instructions before use.

Hot parts. Do Not Touch.

Fill water tank when LED illuminated (Maximum fill level is S3 opposite).

Do not use tap water (S2 opposite).

For acceptable water quality refer to Section 13.

The following descriptions refer to the symbols, controls and displays shown on this page.

Symbols:

S1 IMPORTANT: Read Operating Instructions before use.

S2 Do not use tap water.

S3 Maximum water fill line.

S4 Fill water tank.

S5 Hot parts (behind) Do Not Touch. Also behind door (L).

General Controls / Operations:

Note: The function is selected when the LED adjacent to the button is illuminated.

A Standby / Ready button.

B Cycle start button.

C Door open button.

D Select time/date/cycle counter.

E Adjustment time/date settings.

F Accept button time/date/settings.

G Select vacuum cycles.

H Select Non-vacuum cycle.

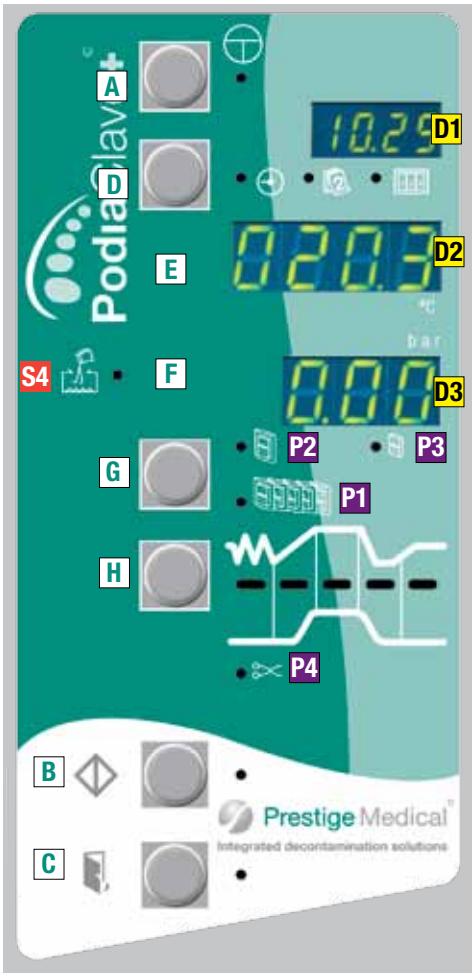
I Door moulding.

J Fuses (located behind access panel).

K Printer

L Fresh water tank drain.

M Fresh water tank fill



Cycle controls.

Press G to select the **vacuum** cycles these are as follows:

P1: 134°C/3min.20sec Vacuum cycle for porous loads, wrapped, pouched, solid / hollow instruments, with 10 minutes drying.

P2: 134°C /3min.20sec. Vacuum cycle for porous loads, wrapped, pouched, solid / hollow instruments with 5 minutes drying.

P3: 134°C /3min.20sec. Vacuum cycle for unwrapped, solid / hollow instruments without drying. Also Process challenge device cycle.

Press H to select **non-vacuum** cycles.

P4: 134°C /3min.20sec. Non vacuum cycle for unwrapped, solid instruments without drying.

AFTER EVERY CYCLE, THE UNIT RETURNS TO THE DEFAULT CYCLE P1.

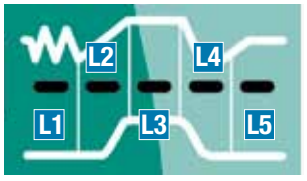
Display Options.

D1 Display for “Time” “Date” & “Cycle counter”. *The normal display mode is time. The date or cycle counter can be selected by pressing the button D adjacent to the display. The selection is valid until a cycle is completed or until the unit is returned to standby mode, at which point the display will revert to the current time.*

D2 Display for “Temperature”

D3 Display for “Pressure”.

The following show the cycle status: (Vacuum unit)



L1 Cycle started.

L2 Heating and air bleed.

L3 Sterilizing.

L4 Depressurisation / drying.

L5 Cycle complete.

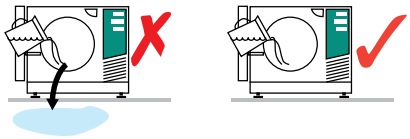
Section 3: Operation

Please take time to read these instructions before using the autoclave. It is essential that the operator is correctly trained and a “Responsible Person” has been assigned for the management of the autoclave. By following these simple step-by-step instructions you can ensure your instruments are correctly sterilized every time.

1. Installation.

Ensure the unit is placed on a strong, flat and level surface.

To check if the unit is level, pour half a cup of water into the chamber. The water should flow towards the rear of the chamber, not out of the front.



WARNING!
The autoclave is heavy; at least two people will be needed to lift it.

2. Connection.

Plug the unit into the mains outlet socket of the correct type & rating. Refer to the duplicate rating plate located inside the printer door (K).

After a few seconds the LED next to button (B) illuminates.

WARNING!
The mains outlet MUST BE EARTHED (GROUNDED).
The mains plug should always be easily accessible as it is to be relied upon as “the means of disconnection”.

3. Single Use Water System.

This unit has a “single use” water system designed to prevent the recycling of any contaminants, which may be present on the instruments being sterilized.

Ensure the waste water container is checked regularly to prevent overflowing. The container should be emptied when the waste water reaches the “Max” line.

To empty the container, undo the screw cap and carefully remove the steam-condensing coil, which passes through the cap.

Place on a heat resistant surface whilst emptying the container.

Use the carry handle to support the container when emptying.

Replace the steam-condensing coil and cap, ensuring it is screwed on securely.

Note: Before using for the first time and after emptying, always add water until the level reaches the minimum level mark.

The waste water container can be located in any appropriate place, although care should be taken that it cannot be knocked over.

WARNING!
Waste water and steam condensing coil may be hot.
Care should betaken at all times.

4. Setting Date and Time.

Date and time are set in the following sequence.

Note: The 24 hour clock is used.

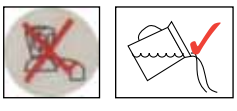
Year (tens): Year (hundreds): Month: Day: Minutes: Hours.

- Set the autoclave in “Ready Mode” by pressing ready button (A). The LED next to button (A) will then go out.
- Press and hold button (D) for 5 seconds.
- Set year (tens) by pressing button (D) up and (E) down. Press button (F) to accept.
- Set year (hundreds); Month; Day; Minutes; hours; by pressing button (D) up and (E) down. Press button (F) to accept.
- The unit returns to “Ready Mode” when the hours are accepted.

5. Ready.

Press button (A) to set the autoclave into “Ready Mode”. The LED next to button (A) will go out.
Note: When in “Ready Mode”, the boiler and chamber are kept warm.

6. Water fill – DO NOT USE TAP WATER.



Before using the autoclave for the first time fill with water.

Press button (C) to open the door. Pour water into the fill spout (M) until it reaches the “Maximum line” (S3). The water capacity is 3.7 litres.

When the low water indicator illuminates (S4), top up with water.
Always use de-ionised, distilled or sterile water as recommended. Never use tap water.

7. Loading.

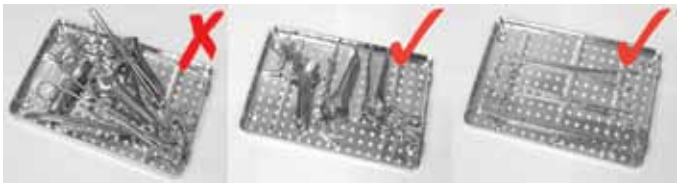
Refer to “Type of load and loading” on page 3 “Specifications” on page 14 for the maximum permissible load.

Failure to follow instructions may cause the unit to malfunction and result in an unsuccessful cycle.

Before loading, ensure instruments are cleaned and rinsed.

Always use the instrument trays or racks, which are supplied.

Load instruments so that they do not touch other instruments or the chamber and are resting on the ribs of the tray.



Only one item should be placed in a pouch.

Linen loads should be formed into a cube of size

150mm.x 120mm. x 100mm. (maximum), weighing no more than 1 kg. Place on an instrument tray in the middle of the chamber.

Linen loads should not be sterilized in combination with other loads.

8. Door closing.

Once the trays are in place close the door by pushing until a “click” is heard. The LED next to the door open button (C) illuminates.

9. Cycle Options.

After each cycle the unit returns to the default cycle “P1” 134ºC /3min.20secs. Vacuum cycle for porous loads, wrapped, pouched, solid / hollow instruments with drying.

Cycle options are:

Press G to select the **vacuum** cycles these are: -	
	134ºC /3min.20scs. Vacuum cycle for porous loads, wrapped, pouched, solid / hollow instruments with 10 minutes drying.
	134ºC /3min.20sec. Vacuum cycle for porous loads, wrapped, pouched, solid / hollow instruments with 5 minutes drying.
	134ºC /3min.20sec. Vacuum cycle for unwrapped, solid / hollow instruments without drying. Also Process challenge device cycle.
Press H to select **non-vacuum** cycles.	
	134ºC /3min.20sec. Non Vacuum cycle for unwrapped, solid instruments without drying.

10. Start Cycle.

Press button (B) to start a fully automatic cycle. A visual display shows the stages of the cycle:

Stage 1	Cycle started (L1)
Stage 2	Heating and air bleed (L2)
Stage 3	Sterilizing (L3)
Stage 4	Depressurisation / drying (L4)
Stage 5	Cycle completed (L5)

11. Opening door.

At the end of a cycle a buzzer sounds 3 times. Press button (C) to open the door, allowing access to the load.

Additional Operations.

Steam Penetration Test.

The “Steam penetration test” should be performed on a daily basis to confirm that the unit is operating correctly.

A Bowie Dick Test Pack or a Test Helix MUST be used with this test. The Pack or Helix should be placed on an instrument tray in the middle of the chamber towards the front.

Albert Brown Test Helix

Bowie Dick Test Pack

For the steam penetration test run the P3.

Following this test, the Test Pack or Helix TST should change to a uniform purple colour. If the TST is not a uniform purple colour check the door gasket and vessel. Repeat the test.

If the test fails again seek technical assistance.

Vacuum system leak test.

The “vacuum system leak test” checks the integrity of the vacuum system. NB. A printer MUST be fitted.

The test MUST be undertaken when the unit is cold and dry (before any other cycle has been run).

Set the autoclave in “Standby Mode” by pressing ready button (A). The LED next to button (A) will illuminate.

Press and hold button (G) for 6 seconds. The display (D1) will begin to count down. Hold button (G) until the countdown reaches zero. The test will then start.

During the test, the segments of the cycle status graphic (S6) will flash. The test will take between 15 to 30 minutes. On completion the print out will advise if the unit has passed or failed the test.

If a fail occurs clean the gasket and the chamber rim before repeating the test. If the unit repeatedly fails contact Prestige Medical or your dealer.

Auto-cycle start.

The unit can be programmed to enable any cycle to be started at any time of the day when the unit is unattended. This option is recommended particularly when the operator performs “Air leak detection test”.

- Set the autoclave in “Standby Mode” by pressing ready button (A). The LED next to button (A) will illuminate.
- Press and hold button (D) for 6 seconds and release. The time display (D1) will flash with the default time of 06.30 being displayed.
- Press (F) to accept. If another time is required for the auto-cycle start, change minutes then hours; by pressing button (D) up and (E) down. Accept by pressing button (F).
- The unit returns to “Ready Mode” and the LED to the left of the clock symbol continues to flash.
- Select the required sterilizing cycle using buttons (G), (H).
- Press the start button (B). The door LED (C) and the start LED (B) both flash. The clock symbol LED is still flashing.
- The selected cycle will start when the programmed start time is reached. The clock symbol LED flashes until the cycle is completed.
- To abort a timed cycle (before the cycle starts) press the “Standby button”

Note:
If the unit is used in a very cold environment, water vapour may be seen coming from the cooling fan. This is normal and will only last a few minutes.

Section 4: Essential Information

To ensure the autoclave continues to operate correctly it is important to follow the following points and to carry out the necessary care and maintenance procedures as specified.

Do ensure that.....

…you read and follow these operating instructions.

…the load is suitable for sterilizing and the cycle selected.

…the load can be sterilized at the selected temperature.

…the load has been cleaned.

…the load has been rinsed thoroughly in clean water prior to sterilization to avoid any chemical residues left after cleaning contaminating the autoclave.

This product is not a washing / cleaning machine.

…when placing instruments on trays, ensure that they are placed on the ribs of the tray (to help drainage), they must not touch each other and must not interfere with other trays or the chamber above.

…only distilled, de-ionised or sterile water is used (as recommended).

…the autoclave is in a draught free area.

…the autoclave cooling fan outlet is at least 100mm. from any nearby surface. If the nearby surface is cold, then condensation may occur.

…the autoclave is not installed in an enclosed cupboard space.

…all other exterior product panels are 50mm. clear of adjoining surfaces to allow air circulation.

…the door is left ajar when not in use.

…you quote model/serial number (which are located inside the printer door) and date of purchase in all correspondence.

…only qualified personnel service the autoclave.

It is recommended that a Chemical Indicator strip be used every cycle to verify that the sterilizing cycle is effective. If the Chemical Indicator strip fails to change colour repeat the cycle. If it still fails to change colour then arrange for a service.

Do not....

…lose this handbook.

…add any chemicals whatsoever to the water.

…attempt to sterilize volatile substances, toxic materials or other unsuitable loads. Refer to your “Responsible Person” for advice.

…place the autoclave in direct sunlight.

…place the autoclave on heat sensitive surfaces.

…use inappropriate cleaning materials.

…drop or abuse the autoclave.

…use in areas of risk associated with flammable materials or gases.

…remove the casing or attempt to service or repair the autoclave.

Section 5: Routine Care and Maintenance

WARNING!

Disconnect the autoclave from the mains power supply before cleaning.

Daily Maintenance

Gasket

THE GASKET MUST BE CLEANED ON A DAILY BASIS, BEFORE USING THE AUTOCLAVE.

Wipe exposed surface of the gasket and the surface of the vessel with warm soapy water using a lint free damp cloth.

Wipe both the gasket and the vessel again with water using a lint free damp cloth to remove any residual soap.

EVERY 250 CYCLES.

Clean the autoclave using Autoclave cleaning kit (Part No. 289138A).

WARNING

Failure to perform these procedures may result in the unit showing UOD1 on the display (UOD1 indicates that the unit may have been contaminated and could fail to operate correctly).

EVERY 500 CYCLES.

Change the air filter situated at the front of the autoclave.

Gently unscrew the air filter and remove.

Exterior surfaces (as required).

Exterior surfaces should be cleaned with warm soapy water using a damp cloth.

For persistent marks, use a gentle cream cleaner.

Fresh water tank / Waste water container.

On a monthly basis, fully drain the water tank and leave overnight (use Autoclave cleaning kit Part No. 289138). Drain, then refill with fresh water. Repeat this operation twice more to remove any residue.

Always use de-ionised, distilled or sterile water as recommended. NEVER USE TAP WATER.

Routine Maintenance.

Every three months check the calibration – refer to the service manual.

Annually replace the water filters.

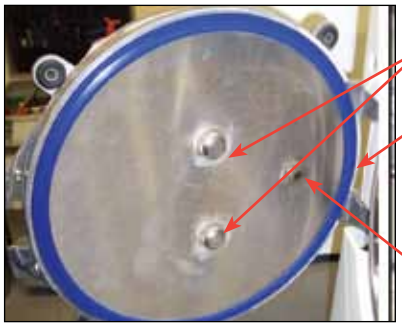
Gasket Replacement

Should the gasket develop a persistent leak it should be removed, cleaned thoroughly in warm soapy water and shaken dry. Wiping with a lint-free cloth is acceptable (Other materials may lead to contamination of the gasket with fibres).

The door gasket plate must also be cleaned.

If the leak persists you should obtain and fit a new gasket (279011).

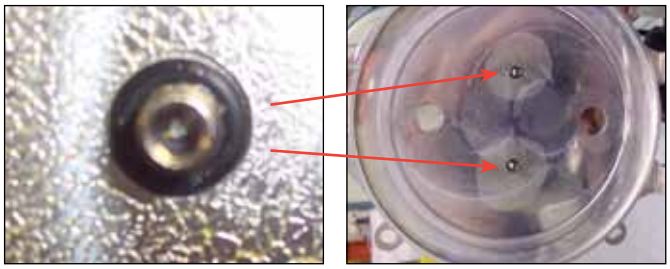
To remove the gasket, undo the two thumb-nuts (279300) in the centre of the gasket plate.



Remove the plate/gasket assembly and then remove the gasket from the plate.

CAUTION: Ensure the gasket is located the right way around on the plate, the lip should face outwards.

During re-assembly, place new black sealing washers (supplied with the gasket) in the machined recesses in the door casting.



Ensure that the entry port plug aligns with the hole in the cast lid.

Prior to tightening the two thumb-nuts ensure that the gasket is correctly seated on the gasket plate and in the door recess.

DO NOT over-tighten the thumb-nuts as this may damage the thread.

Section 6: Trouble Shooting

Should a fault occur a visual and audible indication would be given. The nature of the fault can be determined by reference to the fault guide below. The recovery sequence allows access to any instruments within the autoclave and is the first step when rectifying a fault mode.

User Message	Cause	Remedy.
UOD1 and UOD2	Contamination.	Conduct routine maintenance procedures. Replace gasket. If fault persists Engineer call-out required.
Low water LED (S4)	Insufficient water to run a cycle.	Press button (A) twice. Top up with water to mark (S3).
"door" illuminates on display (D2)	Cycle start button pressed whilst door is open or door micro-switch requires adjustment.	If door closed but door LED (C) not illuminated - push on door to see if LED can be illuminated. If door open, close door and try again. If fault occurs during a cycle – follow Recovery sequence "i"
01	Power failure during a cycle.	Recovery sequence "i" Check power supply – repeat the cycle.
b02	Sterilizing Temperature out of range.	Recovery sequence "i". Clean gasket and chamber face then repeat the cycle. If fault persists Engineer call-out required.
d02	Probe difference out of range.	Recovery sequence "i". Conduct routine maintenance procedures. Clean gasket and chamber face then repeat the cycle. If fault persists Engineer call-out required.
t02	Clock error.	Recovery sequence "i". Check & rest the clock – repeat the cycle. If fault persists Engineer call-out required.
p02	Sterilizing Pressure out of range.	Recovery sequence "i". Clean gasket and chamber face then repeat the cycle. If fault persists Engineer call-out required.
03	Air bleed has not been successful.	Recovery sequence "i". Clean gasket and chamber face then repeat the cycle.
04	Vacuum failure.	Recovery sequence "i". Clean gasket and chamber face then repeat the cycle.
07	Sensor fault – Boiler thermistor.	Recovery Sequence "ii" – Repeat cycle. If fault persists Engineer call-out required.
08	Sensor fault – Pressure transducer.	Recovery Sequence "ii" – Repeat cycle. If fault persists Engineer call-out required.
10	Water in the boiler.	Recovery Sequence "iii" – Repeat cycle.
UOD3	Vacuum failure in drying stage.	Recovery sequence "i". Clean or change gasket. If fault persists Engineer call-out required.
13	Water fill time out.	Recovery sequence "i". Drain water out of the fresh water tank and refill with de-ionised, distilled or sterile water. Repeat the cycle.
14	Sensor fault – Chamber probe.	Recovery Sequence "ii" – Repeat cycle. If fault persists Engineer call-out required.
15	System Leak.	Recovery Sequence "ii" – Clean gasket and chamber face then repeat the cycle. If fault persists Engineer call-out required.
16	Low Induced leak rate (NHS ONLY)	Seek advice from Responsible person.

As non-warranty related calls can be expensive it is advisable to ensure that all consumable items have been replaced or cleaned as appropriate, and that the water quality is as described in Section 13 before contacting Prestige Medical Ltd.

Section 7: Recovery Sequence (allows instruments to be removed from the unit).

Recovery Sequence (allows instruments to be removed from the unit).		
Recovery Sequence "i"	Recovery Sequence "ii"	Recovery Sequence "iii"
Press button (A) Stabilize (no flashing or bleeping) Press button (A) "Recover"	Press button (A) Stabilize (no flashing or bleeping) NB: Cannot proceed. Switch off at mains supply. Service required.	Press button (A) Stabilize (no flashing or bleeping) Press button (A) to enter "Ready Mode"

The Recovery Sequence (depending on where the fault occurs) will flush the water from the boiler and eventually complete the cycle with a continuous bleeping to indicate recovery is completed.

Important.
Before restarting a cycle, check that the mains plug is fully inserted into the mains outlet socket and the outlet is of the earthed/grounded type.

Should all power be lost the door cannot be opened until power is restored and pressure returned to ambient.

Should an internal power failure occur, the door cannot be opened until: -

1. The unit has cooled down to atmospheric pressure. Access can then be made using the supplied tool.
2. A service has been carried out.

In the event of failure of an indication device a service will be required to correct the condition.

Should a safety feature operate, unplug the unit and call for a service – do not attempt to correct the fault.

Primary safety features:
Two primary features have been fitted – a pressure release valve and a boiler over temperature safety cut out.

IMPORTANT NOTE ON EMERGENCY DOOR OPENING PROCEDURES.

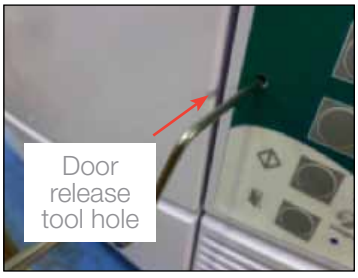
If the door interlock lever does not fully release during door opening and the door led has gone out, light pressure on the door will re-illuminate the door open led. It will then be possible to open the door in the normal manner using the door open button.

Door opening – Power loss.

If the machine has suffered a loss of power and it is essential to open the machine to remove instruments, the following procedure should be followed. This should only be performed by the nominated responsible person: -

1. Disconnect the unit from the mains supply.
2. Allow the machine to cool down to room temperature.
3. Remove the protective white protective cap on the top of the machine.
4. Using the hook on the special tool, release any pressure/vacuum inside the vessel by hooking the ring on the pressure relief valve and pulling this towards you. As shown opposite.
5. Insert the straight end of the special tool into the interlock lever release guide hole and push inwards. If the tool starts to buckle at the preformed strain relief repeat from 3 above.

See Photograph opposite.



DO NOT ATTEMPT TO OPEN THE VESSEL IF PRESSURISED.

ONLY USE THE TOOL PROVIDED AND FOLLOW THE INSTRUCTIONS ABOVE TO GAIN ACCESS TO THE MACHINE.

Section 8: Additional Information

Operator:

The person assigned to use the autoclave.

Responsible Person:

The person who is responsible for the management of the equipment, load assignment, care and maintenance. This person is also responsible for ensuring that all applicable Health & Safety Regulations are applied including those relating to the pressure vessel.

This person must verify that only suitably qualified persons undertake repair and maintenance work other than that described under “Routine Care and Maintenance” within this handbook.

Qualified Person:

A person who is qualified by training or experience to a recognised level in respect of the work to be undertaken.

Service:

Calibration and maintenance as required.

Manual Handling:

Due to the weight of the unit two people are required when unpacking or moving the product.

UNPACKING.
When lifting the unit out of the box ensure there is one person on either side of the unit. Lift out of the box and place on the work surface.

POSITIONING.
Start lifting by holding the unit below the front bezel (large plastic moulding). As clearance is gained, lift at the other corners. Place in position, and release in the reverse order to lifting. NOTE Always drain the water tank before moving. Before moving always allow 30 minutes after use for the unit to cool down.

Cleaning Materials:

Mild washing up liquid. Non-abrasive cream cleaner. Disinfectant diluted in water. Autoclave Cleaning Kit 289138.

Product decontamination.

Should the unit require repair, it must be decontaminated in accordance with a recognised procedure prior to return or on-site repair. A statement of equipment contamination status must be available with the product.

Details of a suitable procedure are available on request from Prestige Medical Ltd.

Approvals:

Approvals are all model specific. However, the following standards apply in whole or part:

- Medical Devices Directive (MDD 93/42/EEC)
- Electro Magnetic Compatibility Directive.
- European Sterilizer Standard (EN13060)
- Pressure vessel to ASME Section 8.
- BS EN 61010 Parts 1 and 2
- UL/CSA 3101

Spares:

Only those spare parts supplied or specified by Prestige Medical should be used in the maintenance of the autoclave. Use of unauthorised parts will invalidate any warranty and may adversely affect the performance or safety of the unit.

Accessories / Consumables

Printer roll (Part No.279505): Ten replacement rolls.

Furniture:
16 litre Pouch tray (Part No.309066):

Optional Furniture
5 Clip tray set (Part No. 309093)

Door tool (Part No.309068):

Door plate thumb screw (Part No.279300):

Sealing gasket x 4 (Part No 219748):
Gasket for a 250mm. diameter chamber.

“O” Ring door (Part No.279100):

Waste Water Container (Part No.279503)
Container for single use water.

Test Pack (Part No.309031):

Prestige Medical Ltd approved TST Helix
available from:

Albert Browne Ltd.
Leicester
LE5 1QZ
UK

Order Code 3781.

Autoclave cleaner (Part No.289138):
For cleaning the autoclave to ensure continued operation.

Air filter (Part No.299052): Replacement air filter.
Replacement air filter.

Section 9: Warranty

Prestige Medical Ltd will, in the first twelve months from the date of purchase (or 18 months from the date of factory despatch – whichever is first), repair or replace free of charge any parts* inclusive of labour which prove to be defective in workmanship and / or materials.

In the following twelve months Prestige Medical Ltd will replace free of charge any parts which prove to be defective in workmanship and / or materials exclusive of labour.

This warranty cover is dependent on authorised servicing of the unit at least every 12 months and that Prestige Medical Ltd received the warranty card within 3 months of installation.

Prestige Medical Ltd will not be liable in the event that the purchaser has failed to adhere to the instructions contained herein or if the autoclave has been abused, interfered with, altered, repaired or serviced by any unauthorised party. This may result in the protection provided by the equipment being impaired.

* This warranty **excludes** the door gasket, all internal furniture and consumables.

Consumer's statutory rights are not affected.

The Prestige Medical Ltd policy is one of continuous development and as such reserves the right to change the specification of the models and items illustrated and described herein at any time.

Disposal

WEEE Statement
(Waste, Electrical and Electronic Equipment)

The WEEE directive places an obligation on all EU-based manufacturers and importers to take-back electronic products at the end of their useful life.

Prestige Medical Limited accepts its responsibility to finance the cost of treatment of redundant WEEE in accordance with the specific recycling requirements.

The symbol (shown below) is present on all Prestige Medical products, which indicates that the product must NOT be disposed of with other waste. Instead it is the user's responsibility to dispose of their waste electrical and electronic equipment by handing it over to an approved reprocessor, or by returning it to Prestige Medical for reprocessing. For more information about where you can send your waste equipment for recycling, please contact your local city office or Prestige Medical.

Section 10: Printer Instruction

Power on procedure

Connect the printer to the power supply and switch on at the mains. The LED light will illuminate on the printer. Connect the printer to the autoclave with the supplied cable. The printer connection at the autoclave is connector J - see page 4

Replacing Paper Roll – Part Number **279505.**

If the paper roll needs replacing, open the paper cup lid and remove the remaining paper using the button, **do not pull paper through the printer mechanism.** Reel off a few centimetres from a new roll and check that the end has a clean straight edge. Slide the leading edge of the paper through the paper entry slot, with the leading edge feeding forwards from the bottom of the roll, until you feel resistance. Press the button and feed paper through the paper exit slot. Sit the new paper in the paper cup and close the lid.

Should the paper become creased or out of line when feeding in a new roll, cut the end off the paper roll, feed out the creased paper using the button, and reload ensuring the paper has a clean straight edge.

Status LED.

The printer incorporates an LED indicator to report its condition. If there is a fault the LED will flash in sequence. The fault can be identified by counting the number of flashes.

LED Indication.	Condition	Solution.
On	Printer On	-
Off	Printer Off or Asleep	-
* * *	Paper Out	Fit new paper
** ** **	Thermal head too hot	Allow head to cool

Place the printer on the worktop at the side of the autoclave.

Do not place the printer on the top of the autoclave.

Make sure the paper is kept away from hot surfaces such as the dump pipe etc.

Store the printouts in folders away from direct or indirect sunlight.

Data Logger Instructions

Refer to the instructions supplied with the data logger for setting up and operating the data logger.

Section 11: Specification

Chamber component materials.

Vessel:	Stainless Steel – 304 –S15
Boiler:	Aluminium – LM25
Lid:	Aluminium – ASME SB26 356.0 T6
Door Plate:	Stainless Steel – 304 –S15

Chamber Capacities	16litre
Overall product width	480mm.
Overall product height	410mm.
Overall product length	440mm.
Unpacked weight	42Kg. (Max)
Chamber Diameter	250mm.
Chamber lengths	330mm.
Tray/rack capacity/length	6@282mm.
Max. Instrument length	300mm.
Max. load non-vacuum Max. load vacuum *Pack size 110x110x50mm.	6 kilo 6 kilo (un-pouched) 2 kilo (pouched) 1 kilo (porous)*
Sterilizing temp/time.	134ºC/3½mins. 134ºC/18mins. 121ºC/15½mins.
Operating pressure (Minimum)	2.05bar (gauge).
Voltage/Wattage	230v. /2200W
Frequency	50 – 60 Hz.

NB. The overall cycle time will increase as the mains supply voltage decreases.

Rating: **All products are rated for intermittent use, continuously.**

Heaters: **Cast into the boiler.**
Internal heater.

Temperature cut out:
Bi-metallic type rated at 170ºC. with manual reset.

Over Voltage category: **Group II**

Pollution Degree: **Group II**

Insulation: **Class I.**

Safety Shutdown:
Refer to “Temperature cut out”. Only a qualified person should reset this.

Environmental conditions:
Indoor use at an altitude of up to 2,000m.
Ambient temperature range +10ºC to +40ºC
Maximum relative humidity 80% for temperatures up to 30ºC, decreasing linearly to 50% at 40ºC.
Mains supply voltage range 207 to 254volts.
Drying performance maybe affected by local environmental conditions.

Maximum Water usage:
Vacuum cycles = 600mls per cycle (typical).
Non-Vacuum cycles = 450mls per cycle (typical).

WARNING

Disconnect the autoclave from the mains power supply before changing fuses.
Only qualified personnel should replace fuses.

Fuses: Located at the rear of the unit under the access panel I.

Mains plug top fuse (user replaceable)
F13A to BS1362 UK only.

Maximum single fault temperature:
143ºC determined by the pressure release valve.

Pressure Release Valve:
Operates at 2.9bar. Accumulation is <10%.

Storage:
When leaving the unit standing idle for any length of time, switch mains off & drain the water tank especially if there is a possibility of the room temperature dropping below freezing point.

Packaging:
Packing materials used have been selected for ease of recycling. Please ensure you use the correct disposal system for disposal of packing materials.

Maximum power used:
1.18kwh

LEQ Sound level = 60db.

The machine is fitted with an automatic thermal reset mechanism. In the event of the boiler overheating (for example due to accidental overload), the unit will power down. After approx. 10 minutes, power will automatically be restored and the display will show Error 01. The load will need to be re-processed, ie start the cycle again.

Section 12: Water Quality

Must be suitable to produce steam in accordance with international standards.

Example specification for clean steam		
Determinant	Value	Recommended test for compliance
Based on Sterilized Water for Injections BP:		
Acid or Alkalinity.	NQ	BP test. Tests for pH are not an acceptable substitute.
Ammonium	0.2mg/litre	BP test or other suitable method
Oxidisable substances.	NQ	BP test.
Calcium and Magnesium.	NQ	BP test. Tests for hardness are not an acceptable substitute.
Heavy Metals.	0.1mg/litre	BP test. Tests for individual elements are not an acceptable substitute.
Chloride	0.5mg/litre	BP test or other suitable method.
Nitrate	0.2mg/litre	BP test or other suitable method.
Sulphate	NQ	BP test.
Residue on evaporation	30mg/litre	BP test. Conductivity measurement is not an acceptable substitute.
Pyrogens	0.25EU/ml	BP test.
Based on EN 285:		
Phosphate	0.1mg/litre	Any suitable method.
Silicate.	0.1mg/litre	Any suitable method.
Routine monitoring only:		
Electrical Conductivity at 25°C	35µS/cm	
NQ = Not Quantified; BP = British Pharmacopeia; EU = Endotoxin unit. (Consideration should be given to single shot type sterilizers, where water is not returned to the reservoir at the end of the cycle).		

USE OF WATER OUTSIDE THE ABOVE SPECIFICATION MAY INVALIDATE THE MACHINE WARRANTY.

Section 13: Loading the Autoclave

Loading has a significant impact on how the autoclave performs.

The maximum permissible loads are as follows: -

6 kg for Non Vacuum Cycles
6 kg for Vacuum cycles (un-pouched)
2 kg for Vacuum cycles (pouched)
1.5 kg for Vacuum cycles (porous load)

Always use the instrument trays provided.

Load instruments so that they do not touch other instruments or the chamber and are resting on the ribs of the tray.

Only one item should be placed in a pouch.

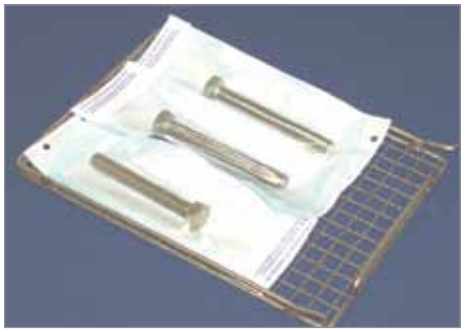
Pouches may be placed on the trays supplied.

Pouches should be arranged so that they do not touch or overlap neighbouring pouches.

Trays should be spaced so that there is a good airflow between them.

When loading the trays into the rack use the top rungs of the rack first and work down.

Pouches should be placed on pouch trays with the paper side down as shown below.



Section 14: Daily Record Sheet

L OAD TYPE. (See KEY below)	CYCLE SELECTED.	DATE	CYCLE NUMBER	PASS OR FAIL *	OPERATOR
KEY FOR LOAD TYPES: -	**B** = Hollow Instruments	**P** = Pouched or bagged Instruments	**U** = Unwrapped Instruments	**M** = Mixed	
*If a cycle fails record the Error Code in the Pass/Fail column					

For Engineer Assistance call the Helpline **01254 844 116** **e-mail: customerservice@prestigemedical.co.uk**
Always quote your Model details, Serial Number and date of purchase when contacting Prestige Medical or your Supplier.

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