Section 8: Additional Information

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 given and may adversely affect the performance and safety of the unit.

Accessories

A range of accessories are available for your autoclave as described below.

Please contact your supplier for further details.

1. 219500 – Green Silicone Sealing Gasket

2. 219277 - 126°C TST Indicator Strips

- 3. 259277 121°C/134°C TST Indicator Strips
- 4. 219258 Cord Set UK
- 5. 219297 Cord Set Euro
- 6. 219294 Lifting Device
- 7. 219708 9ltr Basket / 219720 12ltr Basket
- 8. 219291 Cassette Box / 219706 Cassette Rack
- 9. 219740 Cassette Ring
- 10. 219706 3 Cassettes & Cassette Carrier

Warranty

Prestige Medical shall, in the first 12 months from the date of purchase, repair or replace free of charge any parts which prove to be defective in workmanship and/or materials. **Prestige Medical shall not be so 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 also result in the protection provided by the equipment being impaired.

This warranty **excludes** the gasket, all internal furniture and consumables. Consumer's statutory rights are not affected.

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).



Approvals

Note: Please ask for details of approvals specific to your model.

- ASME VIII Division 1 Pressure Vessel
- Medical Devices Directive MDD 93/42/EEC
- Pressure Equipment Directive PED 2014/68/EU
- BS EN 61010-1 Safety standard for electrical equipment
 BS EN 61010-2-040 Safety requirements for electrical equipment for measurement, control and laboratory use.
 BS EN 61326-1:2013 Electromagnetic compatibility *Electromagnetic environment:*

The Classic autoclave is conceived for use in the following environments; laboratory, residential & medical practices. The device should be located at least 1.5 m away (radius) from any patient treatment areas. The classic unit is a class B Group 1, according to CISPR11 standard

Cleaning materials

- Mild washing up liquid
- Non-abrasive cream cleaner
- Disinfectant diluted in water non chlorine base

Packaging

All packaging materials used are recyclable, please dispose of accordingly.

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.

Disposal

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.



Classic User Manual

Portable Steam Sterilizer





Prestige Medical Integrated Decontamination Solutions



Page 2 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.

UK Customer care line: 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.

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

Model No.

Date of purchase.

Serial No.



Overseas Customers

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

> Prestige Medical, East House, Duttons Way, Shadsworth Business Park,

> > Breda, The Netherlands

Blackburn, BB1 2QR, England Tuttnauer Europe b.v., Hoeksteen 11.

4815 PR Breda, P.O. Box 7191, 4800 GD



Contents

Introduction

& controls

Getting Started

Continued Operation

Care & Maintenance

Technical Specification

Additional Information

Trouble shooting

Operating symbols, displays

Section

1

2

3

4

5

6

7

8

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 Registered in England Reg No. 2826793

In the unlikely event that something should go wrong, we have incorporated a number of safety features to ensure that your autoclave remains safe at all times. Safety features

1. Located to the rear of the lid, beneath the cover, is a spring called the Gasket Offset Device (GOD Spring), This has been designed to prevent pressure building up if the lid has been incorrectly fitted.

DO NOT TAMPER WITH THIS SAFETY DEVICE

2. If for any reason, the temperature falls below the minimum required sterilizing temperature, the Fault Light (L5) will be illuminated. Switch the unit off and leave to cool down. Then switch back on. Check gasket, water level and refill if necessary. Run another cycle and if the fault persists arrange an engineer to visit.

3. If there is an electrical or electronic failure resulting in a build-up of pressure - in excess of normal operating pressure - one or all of the following safety features will be activated.

i) Depressurization Valve (A) will loudly and rapidly "Vent" steam. The overpressure Safety Valve located underneath the handle (E) will loudly and rapidly vent steam allowing its exit via the Steam Duct (F)

ii) The gasket will "extrude" through the slot in the rear of the lid rapidly releasing excess pressure and steam.

iii) An automatically resetting thermal trip is located in the base of the unit. This will activate automatically if a fault was to occur with the unit.

NOTE: Once the machine has cooled down sufficiently the thermal trip will reset. This will allow for an immediate service following this.

Should any of the devices listed activate, please observe the following steps:

- a) Do not touch the unit.
- b) Switch off at the wall socket and un-plug
- e) Arrange for an immediate service.

Section 7: Technical Specification

the unit to re-power up. It is advised that you arrange

- c) Allow temperature and pressure to drop before touching the unit or removing your instruments
- d) Do not attempt to re-start the unit

Technical Specifications	9 litre	12 litre
Height	335mm	420mm
Width	340mm	340mm
Net Weight	3.6 Kg	4.5 Kg
Capacity	9 Litres	12 Litres
Internal Chamber Dimensions (d/h)	210/230mm	210/270mm
Max' Instrument length	228mm	268mm
Max' Load Weight	3 Kg	4 Kg

Mains plug fuse (User replaceable), F13A to BS1362 - UK ONLY.

Rating - Models are rated continuously for intermittent use.

Body - Deep drawn aluminium.

Lid – Stainless Steel

Heater - Externally surface mounted mechanically fixed electric element.

Temperature cut out - Thermal trip.

Pressure - Calibrated pressure release valve.

Max. Single Fault Temperature - 133.3°C

Over Voltage Category - Group II

Environment conditions - indoor use - temperature 5°C to 40°C - altitude up to 2000m - maximum relative humidity 80% for temperatures up to 31°C decreasing linearly to 50% relative humidity at 40°C. -mains supply voltage fluctuations not to exceed +10% of the nominal voltage input Connections - Mains inlet socket 'hot' format conforming to IEC 302.

Safety shut down - See 'Temperature Cut Out'.

Packaging - All packaging materials are recyclable









Page

3

3

Λ

5

6

6

7

8

Section 5: Daily Care & Maintenance

WARNING! Disconnect the autoclave from the mains power supply before cleaning.

Green sealing gasket

- Remove the gasket from inside the lid and clean with warm, soapy water.
- Rinse thoroughly, shake dry, do not wipe.
- Replace the gasket, carefully placing it under the location lugs. Please ensure that gasket sits against the Gasket Offset Device as shown in the image below. Please note that the gasket may appear slightly wrinkled until the unit has been used.
- Replace gasket when it begins to show visible signs of degradation and leakage.



Autoclave

- If a new gasket leaks, or a persistent leak develops, gently clean the sealing surface of both the lid and body of the unit with a light nylon pan scourer, making sure you do not remove any metal. Rinse both surfaces but do not dry.
- Clean both interior and exterior with warm, soapy water ensuring the electrical parts are kept dry.
- Monitor the first cycle of the day to check the Air Bleed Device, which is located inside the lid, audibly "clicks" shut.
- Lubricate underside of body lugs with "Vaseline" if the lid becomes stiff.

DO NOT LUBRICATE THE GASKET

Section 6: Trouble Shooting

In the event of a fault occurring during any stage of the units operation, identify the fault by referring to the descriptions below. The fault can be rectified by following the Fault Remedy applicable to the problem encountered.

Fault indication/Description/Remedy

Fault 1: No power to unit Light: L1 fails to illuminate. Blown fuse / Defective Socket / Mains not connected Ensure mains lead is connected. Check / replace fuse, check power to socket

Fault 2: Boil dry error.

Light: L5 flashes RED i) Check water level – allow unit to cool before refilling to correct water level. ii) Check & ensure de-pressurization valve is closed. iii) Clean gasket & vessel rim. Please arrange for a service engineer visit if the fault repeats after checking and carrying out the above.

Fault 3: Sterilization failed to be achieved.

Light: L4 fails to illuminate GREEN. Disconnect from mains then reconnect and repeat cycle. If the fault repeats arrange for a service engineer to visit.

Fault 4: Incomplete sterilization cycle

TST strip fails to change / completely change colour. Check expiry date of TST strips. Disconnect from mains then reconnect and repeat cycle. If the fault repeats arrange for a service engineer to visit.

Fault 5: Steam or water leaks from under the lid i) Worn or dirty gasket.

Wash gasket and sealing surfaces on the body and lid as described under "Care and Maintenance". If the fault persists, replace with a new gasket. ii) Incorrectly closed lid.

Ensure the unit is fully depressurized by opening Depressurization Valve (A). Remove lid and re-fit carefully. Disconnect from mains, reconnect and repeat cycle.

Fault 6: Excessive steam or water leaking from depressurization valve (A). Depressurization valve (A) in "OPEN" position, close

depressurization valve (A).

Fault 7: Settings Issue. Light L1 flashes continuously, arrange an engineer visit.

Section 1: Introduction

Thank you for choosing the Prestige Medical Classic Autoclave designed to sterilize solid unwrapped instruments.

After removing from the box, please check for any transit damage, if damage to the box is found, please contact your supplier immediately.

Section 2: Operating Symbols, Displays and Controls

The following descriptions refer to the pictures of the controls, display lights and operating symbols opposite.

Controls:

A Depressurization Valve B Start Cycle Button C Pressure Rise Indicator D Display Panel E Top Handle Do not touch the top handle immediately after the cycle has finished as it may be hot. F Steam Duct - WARNING HOT PART! Do not cover!

Display lights:

L1 Power [©]On" light illuminates GREEN L2 Heating light illuminates ORANGE L3 Sterilizing light illuminates YELLOW L4 Sterilizing complete light illuminates GREEN L5 Fault light illuminates RED

Warning symbols:

W1 Caution, electric shock hazard W2 Warning, read manual before using the autoclave W3 Warning, unit must be earthed/grounded W4 Warning, heat hazard

WARNING!

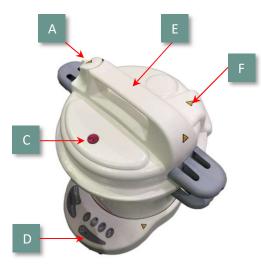
Do not touch the body or lid as these parts become hot when the autoclave is in operation.

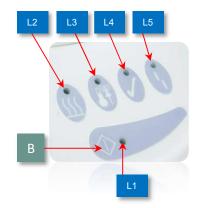
WARNING!

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".

Together with this unit and operating manual, you will find the following:

- Instrument furniture
- Electrical mains cord
- Spare fuses x2 (230v models only)
- Certificate of Compliance (230V Models Only)
- Performance test certificate





Section 3: Getting Started

Before using the autoclave for the first time please take time to read the following pages to familiarise yourself with the operation of the unit.

We strongly recommend that all users of the autoclave are trained in its operation.

The autoclave is very easy to use. By following this simple operating sequence in conjunction with the pictures of the autoclave, its controls, display panel and operating symbols (page 3), you will be able to ensure your instruments are correctly sterilized every time.

3.1 Water

Fill the unit to the water level line on the inside of the chamber with 0.75l of distilled or de-ionised water.

DO NOT USE TAP WATER OR OVERFILL

CHECK WATER LEVEL AFTER EVERY CYCLE

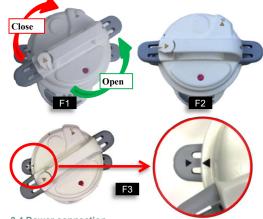
3.2 Loading

Place UNWRAPPED and WASHED instruments ONLY plus a TST strip into the instrument basket or cassettes, and place in the unit. TST strips (available as an accessory) should be placed as near to the centre of the load as possible.

Please see section 7 – Technical specification for loading capacities

3.3 Closing

Always place the lid on the autoclave with the Depressurization Valve (A) open. Align the two black triangles on the lid and body as shown in (F3) and turn in a clockwise direction(F1) ensuring the lid is completely closed (F2). Close the Depressurization Valve (A) so it is aligned with the top handle on the lid. Never leave the autoclave in the position as shown in F1.



3.4 Power connection

Attach the cable supplied to the rear of the unit and plug into an EARTHED mains electrical socket of the CORRECT voltage. Lights: L1 illuminates GREEN. If this flashes continuously then there is a fault and you should arrange an engineer visit.

3.5 Starting

Start the sterilizing cycle by pressing button (B).

Lights: L1 illuminates GREEN L2 illuminates ORANGE

As the temperature rises, air will be displaced by steam through the Air Bleed Device located in the lid, until it closes with an audible "click", sealing the unit.

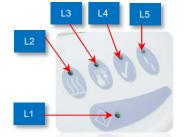
The Pressure rise Indicator (C) will rise indicating the unit is now pressurised.

Sterilizing temperature is reached when:

Lights: L1 illuminates GREEN L2 flashes ORANGE L3 illuminates YELLOW

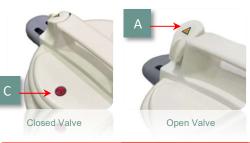
Sterilizing cycle is completed when: L1 illuminates GREEN L4 illuminates GREEN

Note: L4 remains GREEN until a new cycle is started or the unit is disconnected from the mains power.



3.6 Depressurizing

Once the sterilizing cycle has been completed, the unit needs to be depressurized and allowed to cool down before the lid and sterilized instruments can be removed. The time taken to reach the point at which this is safe to do so can be shortened by manually depressurizing the unit. Open the Depressurization Valve (A) by turning slowly in an anti-clockwise direction. The Pressure Rise Indicator (C) will drop once the steam has been released.



WARNING! There will be a visual and audible release of steam from the rear of the Steam Duct.

3.7 Unlocking

Once the pressure has been released the lid may be unlocked. Ensure the Depressurization Valve (A) is open. Remove the lid by turning in an anti-clockwise direction (F1).

3.8 Unloading

Lift off the lid, gently place upside down on a solid work surface and leave to cool. Ensure the Depressurization Valve (A) is in the closed position to avoid damaging it. The unit has completed a successful cycle if the "spot" on the TST Indicator Strip has completely changed colour from yellow to purple.

The basket or cassettes containing the sterilized instruments can now be lifted out of the unit. To avoid damage, replace the lid as described in step "3.3".

3.9 Cycle verification

We recommend the use of a 126°C TST strip with every load to verify the sterilisation cycle. Simply place the indicator strip in with the load. Prestige Medical can supply TST strips.

*Please Note: If the "spot" has not completely changed colour, replace with a new TST strip and start a new cycle. If the "spot" fails to change colour for a second time, do not use the unit until it has been checked by a qualified engineer.

STERILIZATION CYCLE HAS NOT BEEN ACHIEVED

WARNING!

The manufacturers of instruments should be consulted about their suitability for autoclaving and the maximum temperature which the instruments can withstand.

Section 4: Continued Operation

To ensure your autoclave gives you the years of service for which it was designed, it is important to remember a few "do's" and "dont's" with regards to the operation of the unit and to carry out simple care and maintenance procedures.

Do ensure that

- 1.... You read these instructions and always follow the operating sequence.
- **2....** The work surface on which you will place the autoclave is flat, solid and heat resistant.
- 3.... The instruments are designed to withstand the sterilizing temperature, are thoroughly cleaned and rinsed before sterilizing, and are not any longer than the maximum length, or exceed the load weight, specified see "Technical Specification" section.
- 4.... The water level is maintained regularly with clean distilled or deionised water only.
- 5.... The unit is in a "draught free" environment and is positioned not less than 250mm from adjacent walls.

- 6.... You only use the Prestige Medical green high pressure sealing gasket and that it is changed at the end of its life, if visibly damaged, or when shrinkage has occurred, see "Fault mode 5".
- The lid is securely closed when the unit is not in use, to avoid the risk of accidental damage. Never leave in position as shown in F1. (Page 4)
 You quote your model details, serial number and
 - date of purchase when contacting Prestige Medical or your supplier.
- 9.... Change your water on a daily basis

Do not....

- **1....** Touch the unit whilst in operation it gets HOT.
- **2....** Attempt to remove the lid during operation.
- **3....** Lose this operating instruction manual
- **4....** Add any chemicals whatsoever to the water.
- 5.... Attempt to sterilize volatile substances, toxic materials or inappropriate loads.
- **6....** Place the unit on heat sensitive surfaces polished wood or glass.
- 7.... Open the Depressurization Valve (A) during the sterilization cycle.
- Leave the Depressurization Valve (A) in the "open" position when placing the lid upside down on a work surface.
- 9.... Immerse the unit or electrical cord in water when cleaning.
- **10....** Use abrasive materials or lubricants when cleaning.
- 11.... Drop or abuse the unit.
- **12....** Use in areas of risk associated with flammable materials or gases.
- **13....** Attempt to change fuses until the unit has been unplugged from the mains. Only qualified persons should change fuses.
- 14.... Reach over the unit when removing the cover, to do so may cause burns from rising heat and steam.
- **15....** Press the start button once the cycle has been started as this will re-set the cycle timer to zero.