ClearLine®

Portable Steam Sterilizer

Instructions for use

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 682 622 (option 1)

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

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

Model.

Serial Number.

Date of purchase.

UK CA 0086

bsi ISO 13485:2016

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

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Registered in England
Reg No. 2826793

Contents

Please read these instructions carefully before using the autoclave.

Section 1: Introduction

Thank you for choosing the Prestige Medical T-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.

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

Note: this instruction for use is applicable to users of all models of T-Classic.

Intended Purpose / Use

The autoclave is designed for sterilization of medical and surgical goods such as unwrapped-solid, and media used in health care facilities (e.g., medical, and dental offices), podiatry, and laboratories.

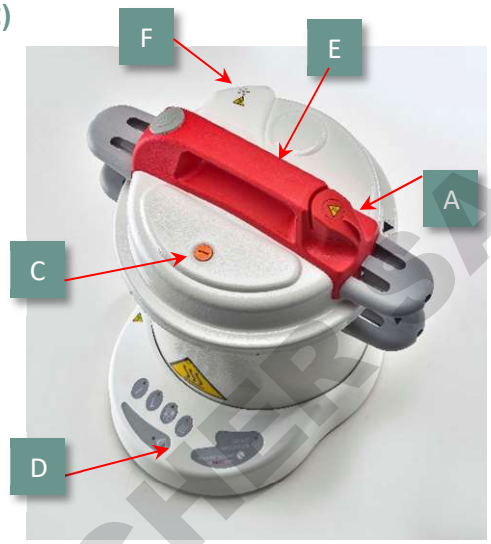
The intended use of the T-classic range of autoclaves is to sterilise unwrapped-solid, and media which may be used within in medical context. The sterilisation process which the T-Classic range of autoclaves uses to sterilise items Is high pressure, high-temperature steam.

No specialized facilities, specialized training or qualifications are required for the device user. The product only requires basic training in use, which will be provided by your installation engineer.

Section 2: Operating Symbols, Displays and Controls

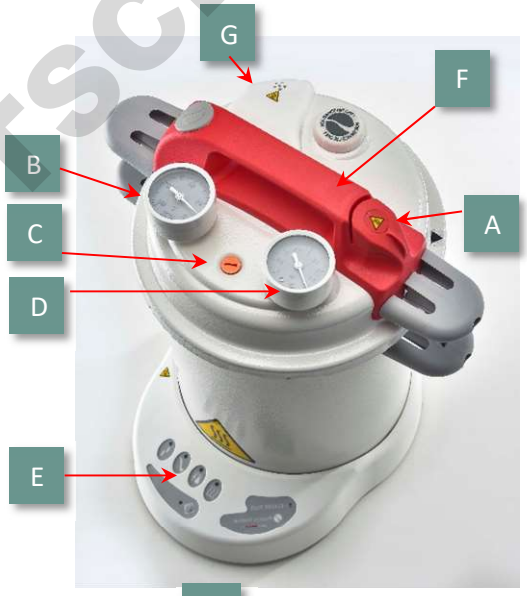
The following descriptions refer to the pictures of the controls, display lights and operating symbols opposite. The following will vary depending on the model you have purchased.

T-Classic One (210001) and T-Classic Podiaclave (210052)



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!

T-Classic Plus (210004)



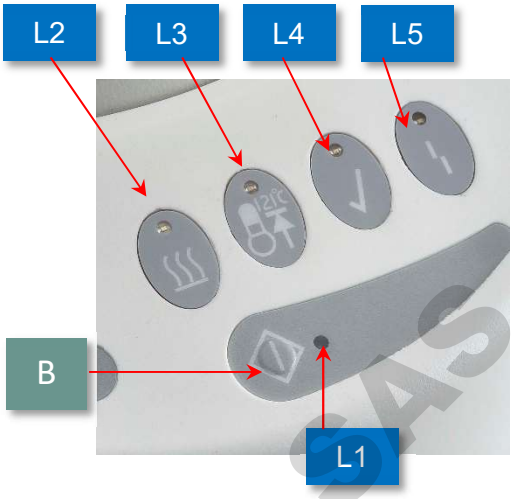
Controls:
A Depressurization Valve
B Pressure gauge
C Pressure Rise Indicator
D Temperature gauge
E Control panel
F Top handle
Do not touch the top handle immediately after the cycle has finished as it may be hot.
G Steam Duct - **WARNING HOT PART!** Do not cover!
H Cycle start button

T-Classic Media (210048)

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!
G Interlock Mechanism

All models

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



All models

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”.

IMPORTANT!
Prestige Medical recommends that your unit is annually serviced & calibrated by a qualified service technician.

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. Water quality between <55µm.

WARNING. Do not use tap water or overfill the unit.
Check water level after every cycle.

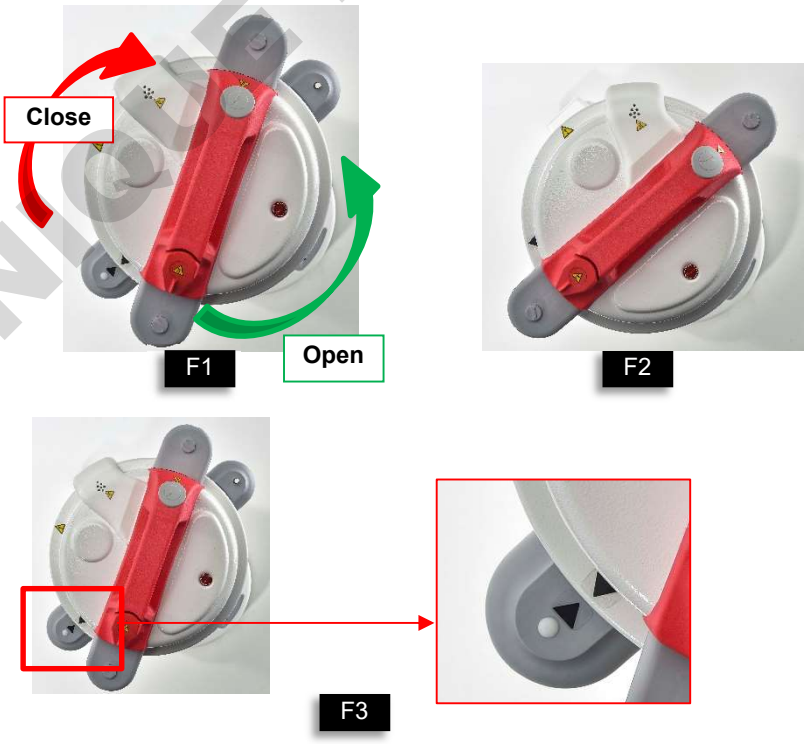
3.2 Loading

Place 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.

For T-Classic Media, place MEDIA ONLY plus a TST strip into the basket and place in the unit. Note: the T-Classic Media cycle is NOT designed for sterilisation of instruments.
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**.



Note: to open the Interlock on the T-Classic Media, the button must be pressed down whilst turning the lid. All other models open and close in in the same way with no buttons to interlock.

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

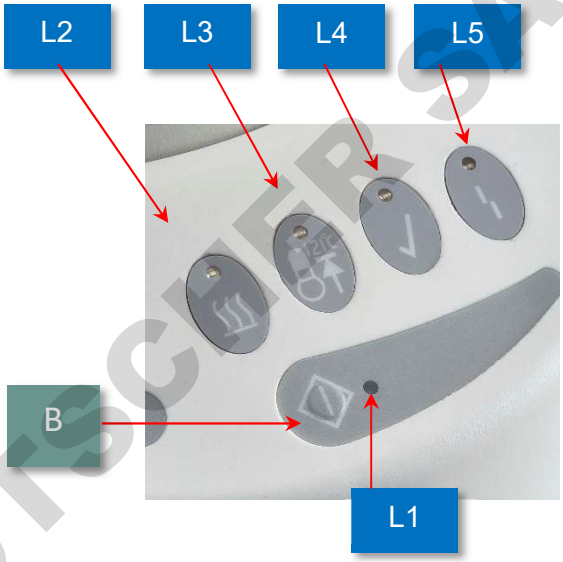
As the temperature rises, air will be displaced by steam through the Air Bleed Device located in the lid, until it closes with an audible “click”, sealing the unit.

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.

If you start a cycle and the sterilizing complete light **(L4)** and the fault light (L5) are illuminated, this means that the unit is too hot to start a cycle. Wait until these are no longer illuminated, you can then start the cycle.

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 will drop once the steam has been released.


Valve Open

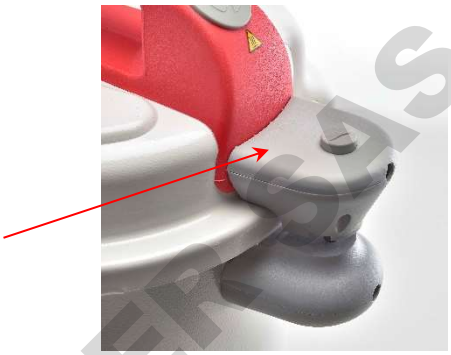

Valve Closed

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**).

For the T-Classic Media 210048, the interlock handle will open in a different way to the other models.



Once the temperature has reached a safe level and is below 80ºC the interlock will release and the lid can be unlocked.

Remove the lid by pressing down on the interlock button and turning the lid in an anti-clockwise direction.

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.

For Media - The basket containing the sterilized media can now be lifted out of the unit with care. Allow 5 minutes for the lid to cool down before replacing.

DO NOT USE THE MEDIA IF A COMPLETE STERILIZATION CYCLE HAS NOT BEEN ACHIEVED.

For instruments - 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”.

DO NOT USE THE INSTRUMENTS IF A COMPLETE STERILIZATION CYCLE HAS NOT BEEN ACHIEVED.

3.9 Cycle verification

We recommend the use of a TST strip (121°C, 126°C, 134°C, depending on your device) 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. In this instance the sterilisation has NOT been successful, and instruments should not be used until sterilisation is successful.

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

3.10 Printer Connection (Podiaclave 210052 and Media (210048 ONLY)

Insert the supplied 3,5mm jack plug from the printer into the rear of the autoclave as shown in the image right.

Please refer to the user manual supplied with the printer for further instruction on the correct operation and setup before use.

(see section 9 for part numbers)

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 “don’ts” 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 or grey 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”.
7.... 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)
8.... 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....

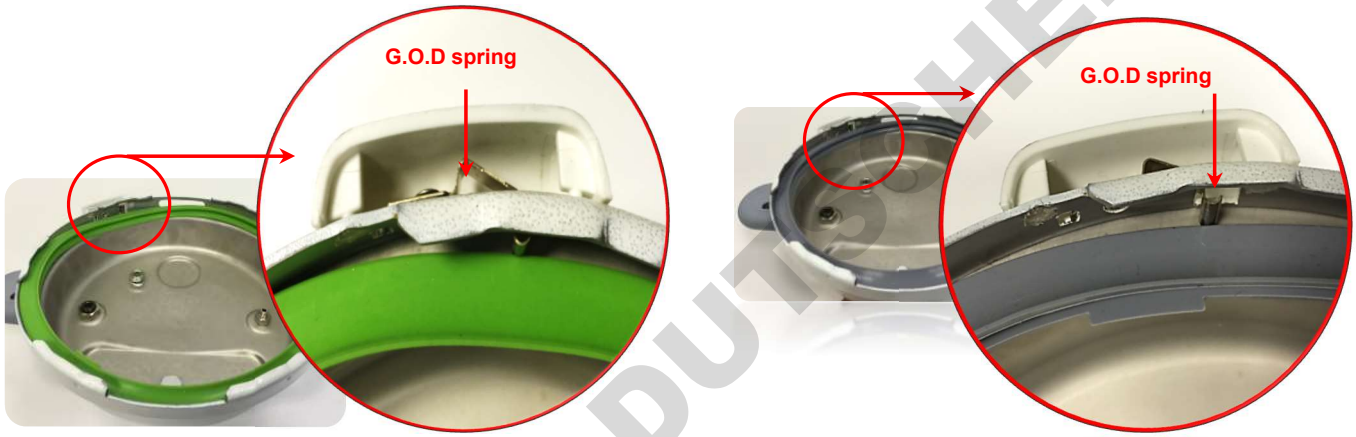
1.... Touch the unit whilst in operation - it gets HOT.
2.... Attempt to remove the lid during operation.
3.... Lose this operating instruction manual.
4.... Add any chemicals whatsoever to the water.
5.... Attempt to sterilize volatile substances, toxic materials, or inappropriate loads.
6.... Place the unit on heat sensitive surfaces polished wood or glass.
7.... Open the Depressurization Valve (**A**) during the sterilization cycle.
8.... 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.

Section 5: Daily Care & Maintenance

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

Green or Grey 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 unit's 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.

Printed Error Codes (Media 210048 and Podiaclave 210052 only):
If the unit enters a fault mode (with a printer connected) due to an operational discrepancy it will automatically print out 1 of 10 fault codes listed below.

Please check the fault codes and carry out the required actions necessary.

01 ERROR_CODE_UNCALIBRATED
ACTION: unit requires recalibrating – Arrange a service engineer.

02 ERROR_CODE_TIME_DATE_INCORRECT
The unit time and date is out-of-range or the back-up battery going low.
ACTION: Arrange a service engineer.

03 ERROR_CODE_VESSEL_OVERTEMP
Autoclave vessel temperature has exceeded maximum working temperature (>150°C).
ACTION: Check water level and fill to line. If error persists, please arrange a service engineer.

04 ERROR_CODE_HEATING_BOIL_DRY
A boil dry condition has been detected in the heating phase.
ACTION: Check water level and fill to line, check and clean both gasket and vessel rim. If error persists, please arrange a service engineer.

05 ERROR_CODE_STERILISATION UNDERTEMP
Sterilisation temperature has dropped below acceptable level.
ACTION: Check water level and fill to line, check for leaks, check and clean both gasket and vessel rim. If error persists, please arrange a service engineer.

06 ERROR_CODE_STERILISATION_ OVERTEMP
Sterilisation temperature has increased over acceptable maximum sterilisation temperature.
ACTION: Check water level and fill to line. If error persists, please arrange a service engineer.

07 ERROR_CODE_SERIAL_NOT_SET
Product serial code has not been set (default is 00000000).
ACTION: Arrange a service engineer.

08 ERROR_CODE_DWELL_STERILISATION BOIL_DRY
Sterilisation temperature has become unstable.
ACTION: Check water level and fill to line, check and clean both gasket and vessel rim. Replace gasket if worn. If error persists, please arrange a service engineer.

09 ERROR_CODE_DWELL STERILISATION PRE_BOIL_DRY
Sterilisation temperature has become unstable.
ACTION: Check water level and fill to line. If error persists, please arrange a service engineer.

10 ERROR_CODE_JUMPERS_PRODUCT UKNOWN
ACTION: Arrange a service engineer.

Section 7: Technical Specification

	T-Classic One	T-Classic Plus	T-Classic Media	T-Classic Podiaclave
	210001	210004	210048	210052
Sterilization Temp (-0.5/+1°C)	126°C	126°C	121°C	134°C
Sterilization Time (min)	11 minutes	11 minutes	28 minutes	3 minutes
Max Cycle Time (approx.)	22 minutes	22 minutes	70 minutes	20 minutes
Cycle Type	N	N	-	N
Chamber capacity	9 L	12 L	12 L	9 L
Load Weight	3 kg	4 kg	2x 500ml	3 kg
Max Width	340mm	340mm	340mm	340mm
Max Height	335mm	420mm	420mm	335mm
Net Weight	5.4 kg	6.3 kg	6.3 kg	5.4 kg
Electricity Current	1200W AC	1200W AC	1200W AC	1200W AC
Voltage	220-240V	220-240V	220-240V	220-240V
Frequency	50/60Hz	50/60Hz	50/60Hz	50/60Hz
Handle Type	Standard	Standard	Interlocked	Standard
Lid Type	Standard	Gauged	Standard	Standard
Printer	No	No	Yes	Yes
Indication for use	Unwrapped, solid	Unwrapped, solid	Media only	Unwrapped, solid
Industry	Medical, Veterinary, and Dental	Medical, Veterinary, and Dental	Laboratories and Education	Podiatry

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 (210001, 210004 & 210048), 143°C (210052)

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.

Safety features

In the unlikely event that something should go wrong, we have incorporated several safety features to ensure that your autoclave always remains safe.

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 - more than normal operating pressure - one or all the following safety features will be activated.

i) Depressurization Valve will loudly and rapidly “Vent” steam. The overpressure Safety Valve located underneath the handle will loudly and rapidly vent steam allowing its exit via the Steam Duct.

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 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 the unit to re-power up. It is advised that you arrange 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.
c) Allow temperature and pressure to drop before touching the unit or removing your instruments.
d) Do not attempt to re-start the unit.
e) Arrange for an immediate service.

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. Always indicate to the supplier the model number of your device to ensure the correct and appropriate accessories are supplied.

1. 219500 – Green Silicone Sealing Gasket (T-Classic One 210001, T-Classic Plus 210004, and Media 210048 only)
2. 219759 – Grey Silicone Sealing Gasket (Podiaclave 210052 only)
3. 219277 – 126ºC TST Indicator Strips
4. 259277 – 121ºC/134ºC TST Indicator Strips
5. 219258 – Cord Set UK
6. 219297 – Cord Set Euro
7. 219294 – Lifting Device
8. 219708 – 9ltr Basket
9. 219720 – 12ltr Basket
10. 219291 – Cassette Box
11. 219706 – Cassette Rack
12. 219740 – Cassette Ring
13. 219706 – 3 Cassettes & Cassette Carrier
14. 279520 – Printer UK (Podiaclave 210052 and Media 210048 only)
15. 279519 – Printer Euro (Podiaclave 210052 and Media 210048 only)
16. 279505 – Printer Rolls, pack of 10 (Podiaclave 210052 and Media 210048 only)

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 if 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 2019 – Pressure Vessel
- Directive 2014/68/EU Pressure Equipment Directive
- UK MDR 2002 – UK Medical Device Regulations

Standards Compliance

- EN ISO 13485:2016 Quality Management System
- EN ISO 14971:2019 Application of Risk Management to Medical Devices
- BS EN 13060:2014+A1:2018 Small Steam Sterilisers
- BS EN 61010-1:2019 Safety standard for electrical equipment
- BS EN 61010-2-040:2020 Safety requirements for electrical equipment for measurement, control, and laboratory use.
- BS EN 61326-1:2013 Electromagnetic compatibility
- EN ISO 15223-1:2021 Symbols to be used on Medical Device labels, labelling and information to be supplied.

Electromagnetic environment:

The T-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 T-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 re-processor, 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.