B-One

STEAM STERILIZER

English user manual

B-One

STEAM STERILIZER

User manual

Dear Doctor,

We would like first and foremost to thank you for having selected a **B-One** autoclave.

Please note that the manufacturer is at your disposal for any further information and explanations regarding this equipment.
We also would like to remind you that this manual must be read carefully before any equipment use to ensure proper autoclave use.
Our products comply with current general safety norms and do not create hazards for operators if used according to provided instructions.

Finally, we wish you success with your work and remind you that the reproduction of this manual is strictly prohibited and that, due to our continued research and technological developments, technical features of this equipment could be modified without prior notice.

Smeg Instruments

READ THE INSTRUCTION MANUAL CAREFULLY

Failure to read this manual or any misunderstandings or erred interpretations of the instructions contained within can cause damage to the equipment and could become sources of danger for operators and notably reduce machine performance levels.

The manufacturer declines all responsibility for any use of this equipment differing from uses described within this manual.

Any installation, maintenance and repair operations must be performed solely by authorised Smeg personnel.

The warranty shall be forfeited any time the machine is employed in a manner which has not be authorised by the manufacturer.

The machine must only be used by specifically trained person. It is Smeg task to train the designated users when the machine is installed. Smeg declines all liability for malfunctioning or accidents due to the machine having been used by untrained persons.

MANUAL CONTENTS

The purpose of this manual is to supply instructions for:

- correct installation
- safe and efficient equipment use
- continued and regular maintenance

Dimensions indicated in this manual are not binding.

INDEX

GENERAL NOTES ON DELIVERY

Verify that packaging has not been damaged upon receipt of equipment.

Wait for a Service Assistance technician to open packaging and verify that supply complies with order specifications and that there are no clear signs of damage. Promptly inform Smeg S.p.A. or area representatives of any damage or missing parts. Do not proceed with installation in case of said damage or missing parts.

The user is responsible for legal obligations related to correct installation and operation. Smeg S.p.A. declines all responsibility for any failure or damage to third parties derived from erred installation, improper use or lack of maintenance.

PACKAGING DIMENSIONS AND WEIGHT

The autoclave is delivered in packaging with the indicated dimensions and weight

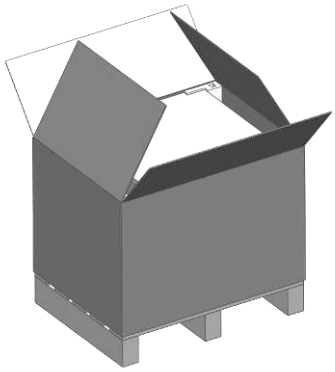


fig. 1 – autoclave packaging, open bottom box which extraction from top

Approx. 52 x 60 x 70 [cm] – respectively width, height, depth

Net weight approx. 52 kg - Gross weight approx. 60 kg

TRANSPORT

B-ONE is supplied with packaging compliant with transport norms and with markings with respect to product conservation and transport safety. We recommend keeping packaging for any future equipment transfers or shipping.

1 PROPER USE

B-One is a steam autoclave which can be used for the sterilization of medical and dental instruments, in health or beauty centres and in veterinary practices.
As a small autoclave, this device is categorised as a class IIA medical device (according to directive CE/93/42 classification criteria).

B-One carries out class "B" sterilization cycles, meaning cycles whose aim is to sterilize packaged and unpackaged products, solids, products with a type A[1] hollow bodies and porous products.
The fast cycle, named “FAST”, is dedicated solely to solid, unbagged instruments - this cycle is not suitable for hollow bodies.
Test cycles to verify proper pneumatic system sealing and product operation efficiency are also present.

Inner architecture

B-One has been designed with an innovative inner architecture: the sterilization chamber is wound by an external chamber. The compartment between the two form a jacket in which steam is present. This jacket is the essential element for autoclave performance and efficiency.
B-One is also equipped with a steam generator connected directly to the jacket. A heating element is housed in the generator.
Steam is produced by the generator and fills the jacket, therefore winding the sterilization chamber and creating maximised temperature uniformity and stability conditions.

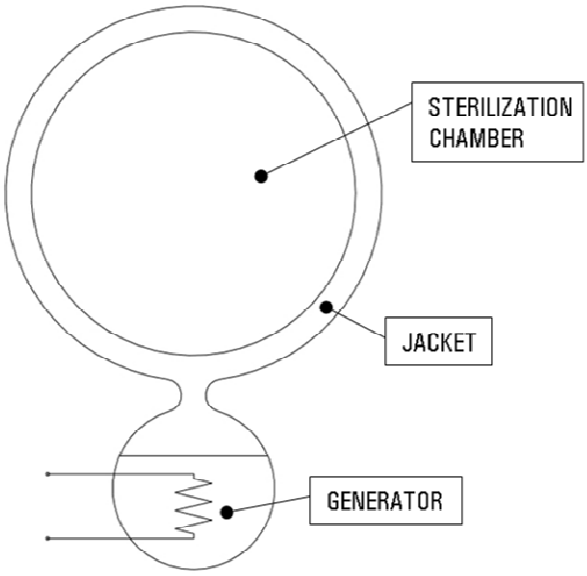


fig. 2 – Inner architecture: sterilization chamber, jacket, generator

[1] Ref. NORM UNI EN13060: hollow bodies type "A" are intended as an open space with one end where the ratio between length and diameter of the cavity is larger or equal to 1 and less or equal to 750 - or rather, a body with a length L on diameter D ratio so that: $1 \leq (L/D) \leq 750$ (or analogous open cavity at both ends such so that $2 \leq L / D \leq 1500$).

2 TECHNICAL FEATURES

Manufacturer	Smeg S.p.A. Via Leonardo da Vinci, 4 42016 Guastalla RE - Tel. +39 0522 8211
Supply voltage	230V
Frequency	50 Hz
Max power input	1500W
Fuses on power input	2x10A 5x20 mm
Printer setup	RS-232 serial port
Operating cycles	3 sterilization cycles 1 special prion cycle Vacuum seal test and B&D test
Air filter	Bacteriologic - porosity 0.3µm
Sterilization chamber dimensions	240 x 340 mm
External dimensions	48 x 44 x 60 cm (L x A x P)
Electrical resistance	1300W
Chamber capacity	4 standard trays (284x183x17)
Net weight	52 kg
Max weight (filled reservoirs and maximum load in chamber)	62,5 kg
Net weight - Max weight (N/feet)	128 - 153 N/feet
Temperature range	from 10℃ to 40℃
Humidity	80% for temperatures up to 31℃ with linear decrease up to 50% at temperatures of 40℃
Altitude	max 1000m
Max Noise emissions	66 db
Chamber – max pressure	2.6 bar
Generator and jacket – max pressure	2.6 bar

REFERENCE NORMS

Product norm
UNI EN 13060

Safety norm
UNI EN 61010-1; UNI EN 61010-2-041

Directives
DIRECTIVE 93/42/CE “MEDICAL DEVICES”
DIRECTIVE 2004/108/CE “ELECTROMAGNETIC COMPATIBILITY”

3 INSTALLATION

3.1 INSTALLATION AND ELECTRICAL CONNECTION

B-ONE is factory tested.
Product installation and maintenance must be performed by authorised Smeg technical personnel.
Smeg declines all responsibility in the event of installation or maintenance performed by unauthorised personnel.

Set **B-One** on a flat surface.
In addition to the external autoclave dimensions, consider an extra bulk in depth for connections located on the rear side, approx. 6cm.

In the event of built-in installation, leave a suitable space on the sides and rear to allow for equipment aeration, if possible leaving the rear part of the cabinet open. Do not set equipment in areas with insufficient ventilation.

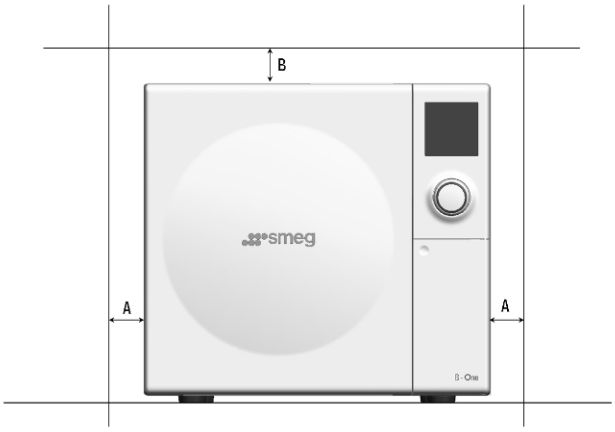


fig. 3 – Recommended values: A ≥ 1 cm, B ≥ 1cm

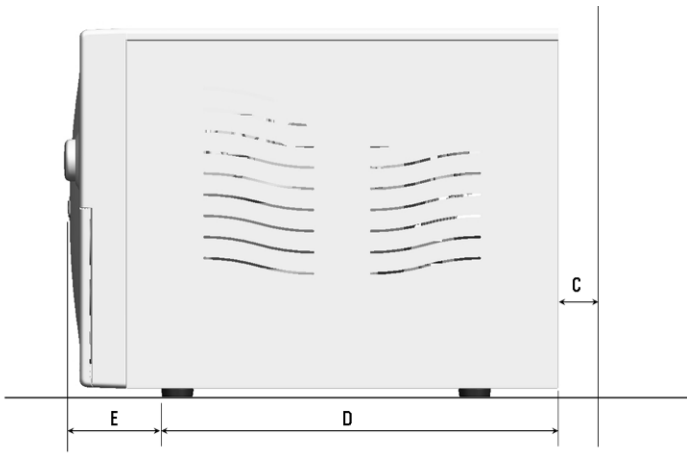


fig. 4 – D = 48 cm, E = 12cm. Recommended value: C ≥ 6 cm

Do not install **B-One** next to sinks or other sources of humidity. Contacts with water can generate short circuits and damage to electrical and electronic parts.

Keep equipment away from heat sources.

Make sure that the **power supply cable** is not bent and that nothing has been placed on top of it and that the electrical socket can be easily reached. The cable is equipped with a "schuko" type plug: **do not use reducers or multiple sockets as they can cause overheating.**

The autoclave must be connected via **protective switch** to a system supplied with earthing in compliance with current norm IEC 64-4. Make sure that the electrical capacity of the system and electric connections are suitable for autoclave power. If necessary, request a system check from qualified technicians.

Upstream installation a **differential switch** with the following is essential: rated current 10A; differential sensitivity 0.03A.

EN 61010-1 installation category (Class II)

Degree of pollution: 2

3.2 SAFETY WARNINGS

Do not use **B-One** in the presence of potentially explosive gas or vapours.

Do not pour water or other liquids on the equipment except in special connections for demineralised water filling.
B-One carries out sterilization cycles during function, bringing B-One metal parts near the chamber to high temperatures: **be careful to prevent direct contact with the trays and with other metal parts, use special supplied pliers.**

Check that the power supply has been disconnected before any maintenance or control intervention. If this is not impossible, disconnect the external network switch signalling maintenance operations with a special sign in accordance with legal requirements regarding safety in the workplace.

Do not tamper with labels or other identification signs on the equipment.

Smeg S.p.A. declines all responsibility for damage to property or persons derived from a failure to observe the aforementioned instructions, in particular for a failure to verify the suitability of the electrical system or any improper management of said system.

4 PRESENTATION

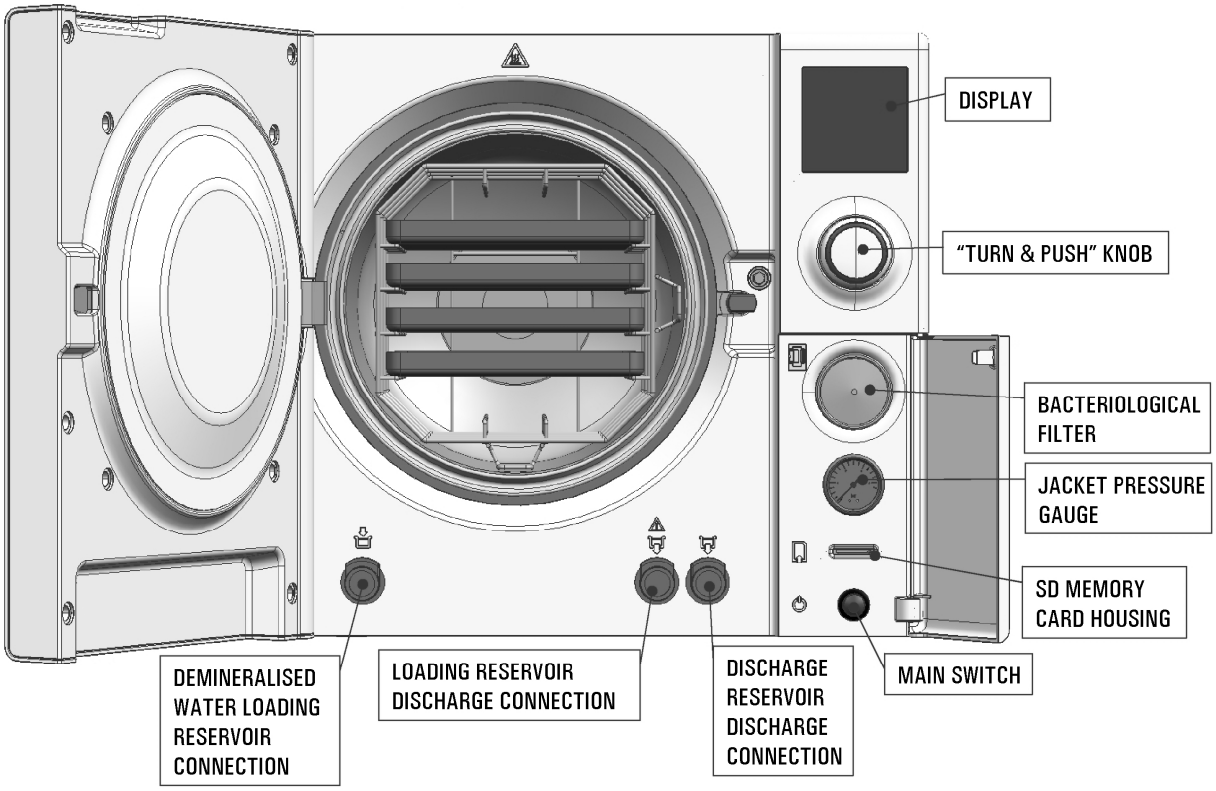


fig. 5 - Front view of the autoclave, door open

4.1 FRONT DEVICES – CONTROL PANEL

Components on the control panel, located on the front right part of the machine

1. **Display** – communication component between the autoclave and user
2. **"Turn and push" knob -** to select and confirm selections
3. **Bacteriologic filter** from input air, replaceable
4. **Analog gauge** signals pressure present in the jacket winding around the chamber.
5. **"Memory card" housing** – if the "memory card" ("SD" type) is present, information related to sterilization cycles is registered on it
6. **Main switch** – equipment power supply.

4.2 FRONT HYDRAULIC CONNECTIONS

The three front hydraulic connections are accessible only when the door is open

1. **Load connection** demineralised water tank

2. **Discharge connection** used water collection tank

3. **Demineralised water tank discharge connection** – said connection is utilised when the loading tank needs to be emptied: in the event of maintenance or tank emptying, if the tank has been filled with low quality water which is not suitable for sterilization.

4.3 DEVICES ON THE REAR PANEL

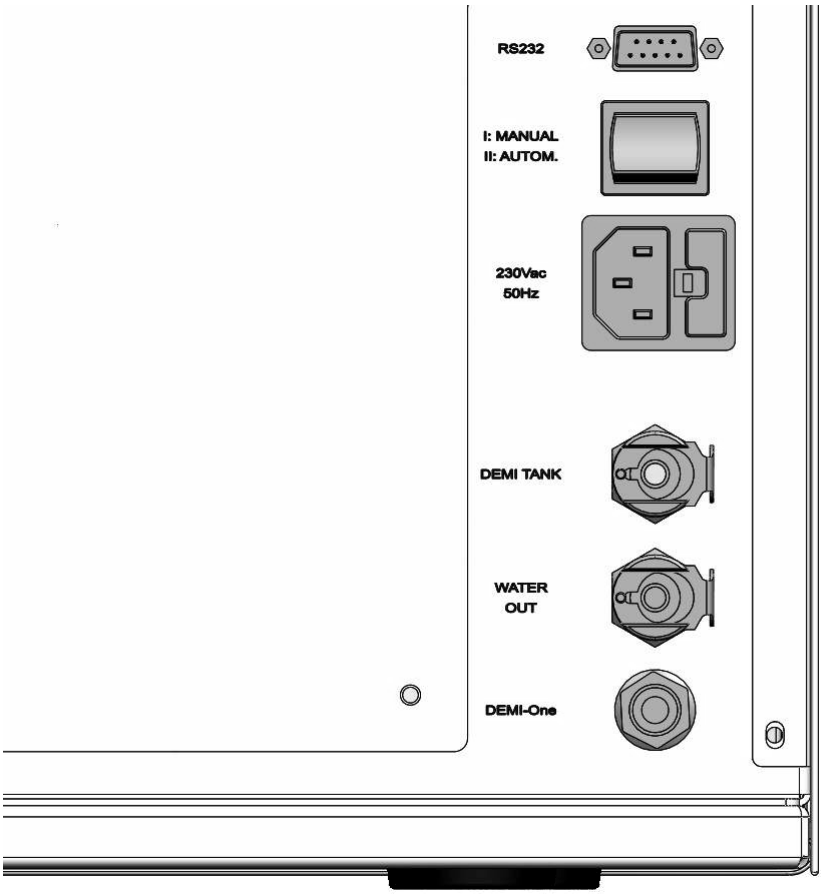


fig. 6 - Rear view of the autoclave, lower right corner

In order, from top to bottom:

1. **RS 232 port** (printer or PC connection)

2. **Switch for water purifier supply** manual supply - standard: automatic – can be set only by authorised technical personnel)

3. **Power supply input cable**

4. **Quick connect for tank loading** demineralised water from can (can only be set by authorised technical personnel)

5. **Quick connect for tank discharge** of used water

6. **Quick connect for DEMI-One** water purifier loading

5 MACHINE OPERATION

5.1 GENERAL USER INTERFACE

fig. 7 – Display and knob selection – on the upper right of the machine

The **graphics display** is the means by which the machine communicates with the user.

The display is 128 horizontal x 128 vertical pixels - it is monochromatic white and blue and backlit.

The selectable items and icons on the display appear chromatically "inverted" when selected to distinguish them from those which have not been selected.

fig. 8 - Stop" icon for a forced cycle stop, selected and unselected

The **"turn-and-push" knob** is the means by which the user communicates with the machine: turn the knob to select items shown on the display, press to confirm selection.

A **lit ring** is housed on the knob. It shows different colours for different status (off, flashing, fixed) depending on the current machine condition:

- **Fixed blue ring**: machine ready for use
- **Flashing blue ring**: cycle in progress
- **Fixed red ring**: alarm compromising cycle implementation
- **Fixed violet ring**: warning, operator intervention required (tank filling/emptying, memory card insertion)
- **Ring off**: machine off

5.2 TURN-ON

The autoclave switches on when the ON/OFF button (blue general switch) is pressed. The SMEG logo appears on the display and a BEEP sound will be activated.
The autoclave carries out a *routine* initial check. Any irregularities will be shown on the display.

fig. 9 – Start-up screen – Smeg logo

Immediately following the initial check, the **preheating** phase starts. The main cycle selection screen will appear on the display (see the following "preheating" paragraph for further details).

fig. 10 – Main screen – cycle selection

It is also possible to select and confirm sterilization cycles during the preheating phase. The machine will automatically manage the initial wait (approx. 15 min) and cycle start-up.

The **vacuum test** cycle does not need to wait until the end of the preheating phase to be turned on.

5.3 STERILIZATION CYCLE SELECTION AND START-UP

Select the desired cycle from the main screen by turning the knob. Press the knob to confirm cycle.

fig. 11 – Main screen

Once the desired cycle has been selected, the interface will request confirmation to proceed.

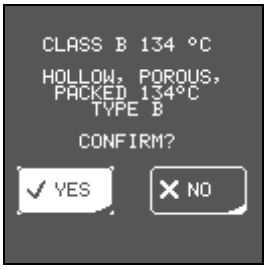


fig. 12 – Confirmation screen for selected cycle.

If the wrong cycle is selected, press "NO" on the display and you will return to the main menu.

When "YES" is selected on the display, the machine will proceed and the user will be asked to set the door for closing ("CLOSE DOOR" - see par. 5.9).

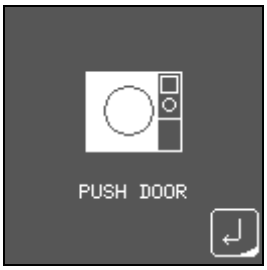


fig. 13 – Door closing request screen

It is still possible at this point to return to the main screen by selecting the "escape" icon

fig. 14 – "escape" icon– on the lower right of the display, this allows the user to return to the previous screen.

If the door is set for closing, **B-One** proceeds with automatic closing.

The display will read "cycle in progress".
In the event that the machine has not completed its preheating phase, the same screen will however appear, but the preheating icon will appear flashing.

fig. 15 – "Cycle in progress" screen

The following information will be shown on the **"cycle in progress" screen**:

- ✓ Completed cycle sequence number (ex. “CYCLE N. 00029” image);
- ✓ current cycle name (ex. “CLASS B 134 ℃”);
- ✓ chamber temperature (ex. “56.1 ℃”)
- ✓ chamber pressure (ex. “1.01 bar”);
- ✓ instantaneous progress graphic with indication of time elapsed;
- ✓ “lock” icon indicating the door status, locked:
- ✓ preheating icon (if the icon image is not present, preheating has been completed);
- ✓ “STOP” icon, for forced cycle interruption

5.4 AVAILABLE CYCLES – STERILIZATION AND TESTS

Available sterilization cycles:

- Class B 134℃
- Class B 121℃
- Fast 134℃
- Prion 134℃

2 test cycles:

- Vacuum test (auto vacuum seal test)
- B&D / helix test (class B auto-test)

The following table summarises sterilization cycle features.

Cycle	Number of vacuums	Sterilization temperature	Sterilization time	Drying time	Description
CLASS B	4	121℃	16:00	9:00	Cycle for sterilization of turbines, handpieces, hollow bodies, porous, double bagged
		134℃	4:00		
FAST	3	134℃	4:00	2:00	Cycle for sterilization of solid, unbagged instruments, not suitable for hollow bodies, type N
PRION	4	134℃	22:00	9:00	Prion cycle

Vacuum test: cycle for autoclave pneumatic seal verification (duration approx. 16 min). A vacuum and electronic controls verify pneumatic seal efficiency in the sterilization chamber.

B&D / Helix test: cycle for sterilization efficiency verification, cycle parameters analogous to those used in the “CLASS B 134℃” cycle but with 3.5 minutes of sterilization time and limited drying. To be performed together with related system tests.

5.5 PREHEATING

Preheating requires that the machine be brought to a useful temperature range for starting a sterilization cycle.
In this phase, the heater in the steam generator is activated.
Once useful conditions are reached, resistance start-up is modulated to keep the machine ready for use for a period of approx. 1 hour.

The preheating phase is immediately active upon machine turn-on (the turn-on time, or "wake", can also be programmed - see the "SETTINGS-WAKE" paragraph).

It is possible to turn on a sterilization cycle (or test) even if preheating has not been completed. In this case, sterilization will require additional preheating time, managing the wait time automatically.

fig. 16 – “"preheating" icon

The "preheating" icon appears on the lower right side of the display to indicate preheating status

- ✓ If the **icon is flashing**, preheating is in progress.
- ✓ If the **icon does not appear**, the machine is ready and jacket temperature has reached a suitable level for immediate cycle turn-on.

After a certain period without use, approximately 1 hour, the machine will enter into **energy saving** or “stand-by” mode. In this phase, the heater will not be activated. The chamber, jacket and generator temperatures will gradually decrease over time.

It is possible to select and activate a sterilization cycle even from the stand-by mode. The machine will then restart preheating and will autonomously manage cycle turn-on.

5.6 SHUTDOWN

Machine shutdown is carried out when the user presses the blue **main switch** found under the flap on the right.

This switch is lit up when the machine is one and is off when the machine is switched off.

Do not switch off the machine during a cycle. The sterilization process in progress will be invalid when this happens. When the machine is restarted after a sudden shutdown, once the cycle in progress is completed, the machine will behave in the same way as if it had been shut down suddenly due to a black-out (see the following paragraph).

Also when interrupting a sterilization process in progress is necessary, we recommend proceeding with a forced interruption (see the following "cycle interruption" paragraph).

5.7 RECOVERY AFTER A SUDDEN BLACK-OUT

In the event of a power failure during any sterilization cycle phase, when the machine is turned back on, it will complete the end of the preceding cycle in progress, discharging the pressure in the chamber and drying.

Sterilization should **not** be considered valid, the machine will enter into safe conditions and the interface will guide the user through procedures to return to initial conditions with the door open.

Once procedure resetting has been completed, the machine will be ready for a new sterilization cycle to be turned on.

5.8 TANK MANAGEMENT

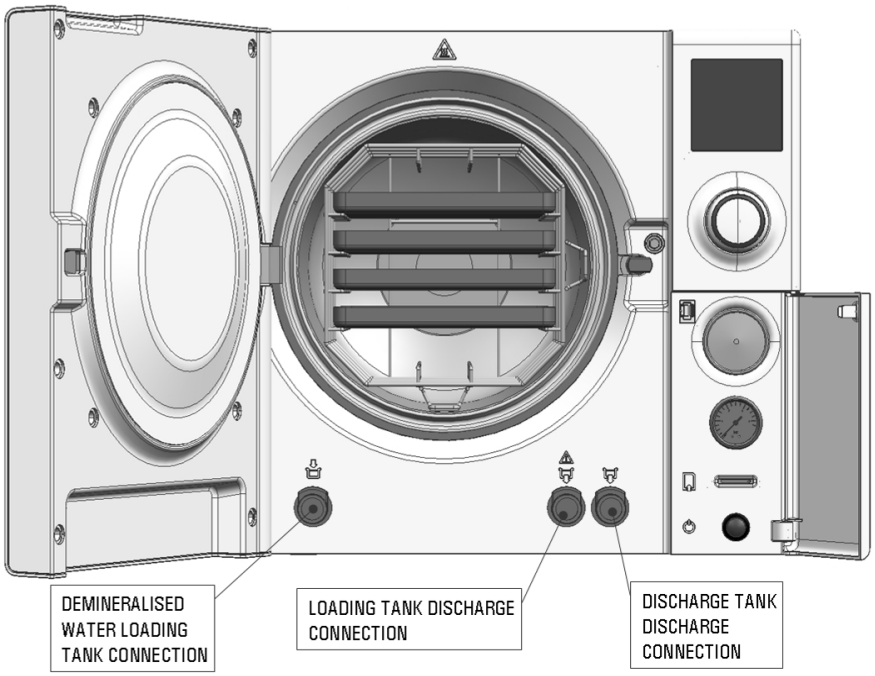


fig. 17 – front connections for water load/discharge

The **B-One** sterilizer is equipped with **two tanks**:

1. **Loading tank - demi**: for demineralised water input. This tank contains water which is slowly withdrawn for sterilization cycle needs. A minimum level sensor in the tank permits interface to warn the user when the water supply must be topped up.
2. **Discharge tank**: for used water. The discharge tank collects water used for sterilization. A maximum level sensor in the tank permits interface to warn the user when the discharge tank must be emptied.

5.8.1 LOADING TANK FILLING - DEMI

When the loading tank level goes below the minimum, it will no longer be possible to proceed with any sterilization cycles.

The operator is warned by means of a message (“LOADING TANK EMPTY") and demineralised water must be added.

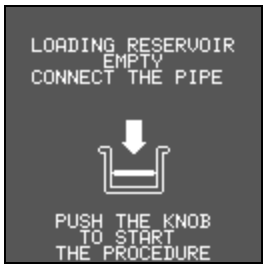


fig. 18 – "LOADING TANK EMPTY" warning screen

Use the supplied tube to refill the tank.

1. Enter the tube into the end connection in the corresponding outlet (blue, found on the lower left front of the machine)
2. Properly plunge the other end of the tube in a demineralised water can. The end must be positioned so that it is completed immersed in water. Any tube blockages must be prevented: these can compromise the loading process and, in the long run, compromise the successful operation of the machine loading device itself.
3. Press the knob as requested on the display
4. Wait for loading to be completed.

In the event of any special needs, water loading can be stopped at any time by pressing the knob.
This is recommended if, for example, a limited quantity of demineralised water is available. when the machine has completed the loading of available water, it is best to interrupt the process to prevent that pumps work "dry" and thus become damaged.

Cycles cannot be turned on if the tank water level does not reach the minimum.

The autoclave is set with two **rear automatic loading attachments** for water, to be used with a water purifier or external can, using supplied fittings. In this case, accessories configuration and installation must be performed by an authorised technician.

In case of serious emergencies - loading system malfunctions and sterilization requirements - it is possible to top up the tank via the auxiliary input located under the top level (sheet metal plate cover, as seen in the following image).

Report the loading system malfunction to Smeg technical assistance before carrying out the procedure described below.

1. Switch off the machine and disconnect the power supply cable connected at the rear of the equipment.
2. Remove the sheet metal cover, holding it at the rear and pulling upward. The cover is fastened with inserts which lock and unlock when pressed. Two tanks are housed under the cover. These tanks have blue rubber covers, do not remove them.
3. A white plastic cap, 4 cm diameter, identifies the auxiliary emergency input.
4. Remove the white cap and slowly pour demineralised water into the hole (**max 2 litres**), taking care that none leaks (the electrical and electronic components on the machine could become damaged)
5. Reposition the white plastic cap
6. Reposition the sheet metal cover.

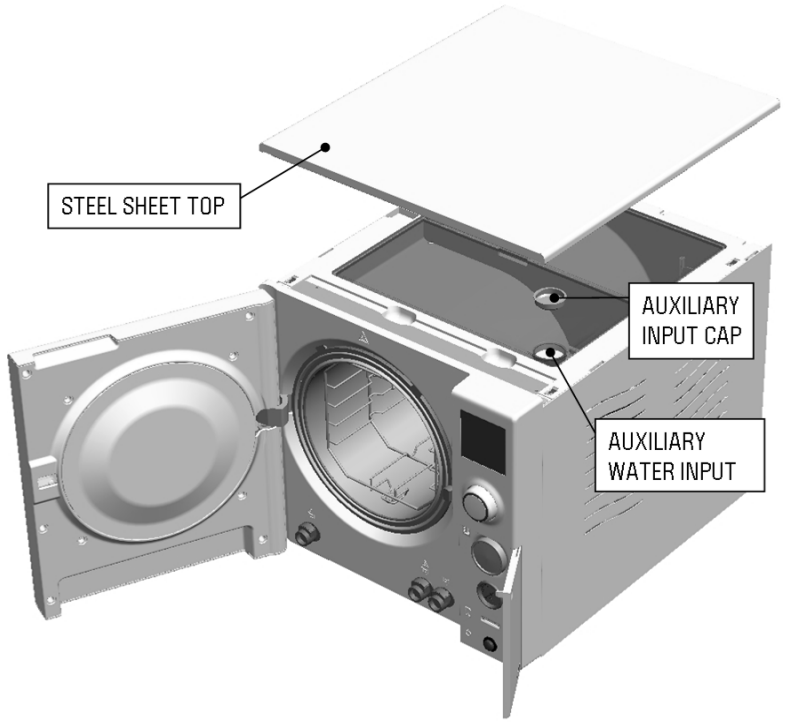


fig. 19 – Top cover removed for auxiliary water input use - only for emergencies

5.8.2 DEMINERALISED WATER QUALITY CONTROL

The **B-One** autoclave is supplied with an integrated system for input water conductivity verification.

Each time demineralised water is loaded, the autoclave verifies if loaded water is suitable for use.
The user will be notified if water is not suitable: the corresponding icon on the display signals that the loaded water does not have suitable features for sterilization, and the lit ring on the knob will turn violet.

fig. 20 – icon signalling unsuitable quality of loaded water

This same icon is also located over the front outlet which allows loading tank draining.
When this icon appears, the user should empty the tank and top up with suitable quality demineralised water.

The user can decide at his/her own risk to proceed with sterilization.

5.8.3 SUPPLY WATER QUALITY

Only optimal quality demineralised water should be used.

The use of municipal water line water compromises **B-One** function, causing calcium build-up, energy dissipation and system malfunction.
The manufacturer declines all responsibility derived from a failure to use quality water.

See the following table for recommended supply water values (ref. “APPENDIX C” norm UNI EN 13060).

RECOMMENDED SUPPLY WATER FEATURES	
DRY RESIDUE	≤ 10 mg / l
SILICON OXIDE SiO_2	≤ 1 mg / l
IRON	≤ 0.2 mg / l
CADMIUM	≤ 0.005 mg / l
LEAD	≤ 0.05 mg / l
HEAVY METAL	≤ 0.1 mg / l

RECOMMENDED SUPPLY WATER FEATURES	
RESIDUES (EXCEPT IRON, CADMIUM, LEAD)	
CHLORIDES	≤ 2 mg / l
PHOSPHATES	≤ 0.5 mg / l
CONDUCTIVITY AT 20°C	≤ 15 µS/cm
pH LEVEL	From 5 to 7.5
APPEARANCE	Colourless, transparent, without sediments
HARDNESS	≤ 0.02 mmol / l

5.8.4 MANUAL DRAINING OF LOADING TANK WATER

The loading tank can be drained manually for transport and maintenance needs and any other time that input water quality is indicated as unsuitable for sterilization.

Manual draining procedure:

1. Set the free end of the supplied tube in a large container for the water to be drained into, set underneath the autoclave.

2. Connect the end with the tube connection on the corresponding quick couple (gray) on the front part of the equipment (the second quick couple from the right). Position the tube in such a way to prevent any blockages. The quick connect is indicated with an icon similar to the "unsuitable quality" icon for supply water.

3. Let the water flow entirely into the container

5.8.5 WATER SUPPLY TANK DRAINING

During sterilization, used water is collected in a suitable tank ("discharge tank").

If the level exceeds the maximum allowed level, the machine will warn the operator with a message (“DISCHARGE TANK FULL").

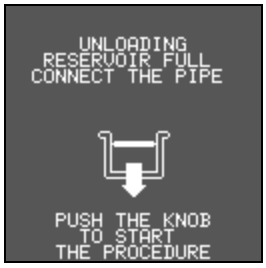


fig. 21 – “DISCHARGE TANK FULL” warning screen

The machine will not allow any new sterilization cycles to be carried out until the tank is drained.

To drain the tank:

1. Set the free end of the supplied tube in a large container for the water to be drained into, set underneath the autoclave.
2. Connect the end with the tube connection on the corresponding gray quick couple on the front part of the equipment (the second quick couple from the right). The quick connect is indicated with an icon similar to the "discharge tank full" icon.
3. Press the knob
4. Let the water flow entirely into the container.

If necessary, tank draining can be interrupted by pressing the knob a second time.

5.8.6 AUTOMATIC DRAINING

When a free discharge connection is set near the machine, **authorised Smeg technical personnel can configure discharge in such a way that it is carried out automatically**, without the user needing to manually manage operations.

The hydraulic system connection for used water discharge must be set at a height which is lower than the autoclave support level and must not allow for any water reflux to the machine.

The maximum allowed distance from the hydraulic connection to the connection set on the machine is 1.5m.

5.8.7 WATER PURIFIER WATER SUPPLY

The Smeg **DEMI-One** water purifier is an optional accessory for the autoclave.
DEMI-One is designed to produce quality demineralised water.

DEMI-One connection to the autoclave must be carried out by authorised Smeg technical personnel.

DEMI-One can operate in two modes: automatic and semi-automatic.

Automatic mode: autoclave tank top up is managed completely automatically by the equipment itself.

Semi-automatic mode: the user is requested confirmation for tank top up via the display. Simply press the knob for top up.

In both modes, **B-One** manages its water supply via a connection located at the rear.

5.8.8 AUTOMATIC SUPPLY FROM AN EXTERNAL CAN

Authorised Smeg technical personnel can configure the B-One in such a way that supply water is withdrawn from an external can.

In this case, the user does not need to worry about manual management of loading tube connection on the front connection. A hydraulic connection located at the rear is in fact utilised and a fixed connection between the autoclave and can is set.

Tank supply can operate in two modes: automatic and semi-automatic.

Automatic mode: autoclave tank top up is managed completely automatically by the equipment itself.

Semi-automatic mode: the user is requested confirmation for tank top up via the display. Simply press the knob for top up.

Note
The connection tube between the can and water purifier must not be longer than 1.5 metres.
The can should be positioned on the same level or higher than the autoclave support level. Any incorrect positioning can compromise **B-One** loading pump operation.

5.9 DOOR CLOSING

Door closing is possible if the type of cycle to be started has been confirmed (see “Sterilization cycle selection and start-up" paragraph).

Automatic closing is activated when the door is set for closing.

Close the door pressing it on the central right part.

fig. 22 – closed door – closing is aided if the user presses on the central right part of the door itself

A corresponding icon will appear on the display whenever the door is locked.

fig. 23 – "lock" icon for door opening

The door can be opened during the preheating phase by selecting the "lock" icon and confirming the selection by means of the knob.

The door icon flashes during the door opening phase. The icon is not visible when the door is open.

5.10 CYCLE INTERRUPTION

The "stop" icon appears on the lower right of the display during the cycle. select this icon to interrupt the cycle in progress.

fig. 24 – "STOP" icon for forced cycle interruption

Once the icon has been selected, the user will be however be asked for cycle interruption confirmation.

fig. 25 – "STOP" icon for forced cycle interruption

Select "YES" to activate forced stop procedure.
Said procedure interrupts the cycle and brings the system to safe conditions and may take a few minutes.

Once the procedure has been completed, a message indicating successful forced process interruption will appear on the display.
("CYCLE INTERRUPTED, LOAD NOT STERILE").

fig. 26 – "cycle interrupted" screen

5.11 CYCLE COMPLETED

If the cycle has been completed successfully, the screen will read "CYCLE COMPLETED SUCCESSFULLY."

The door will open automatically after the knob is pressed once.
Once the door has been opened, the display will return to the start-up screen from where a new process can be turned on.

If the SD (memory card) is connected to the cycle report, all information will be saved on the card.
The total number of completed cycles can be seen by activating the "Cycle Archives" (see 6.1 Cycles archive).

5.12 PRINTER CONNECTION

The printer can be connected to the RS232 port located at the rear. The machine recognises installation and immediately activates printing of the cycle in progress.

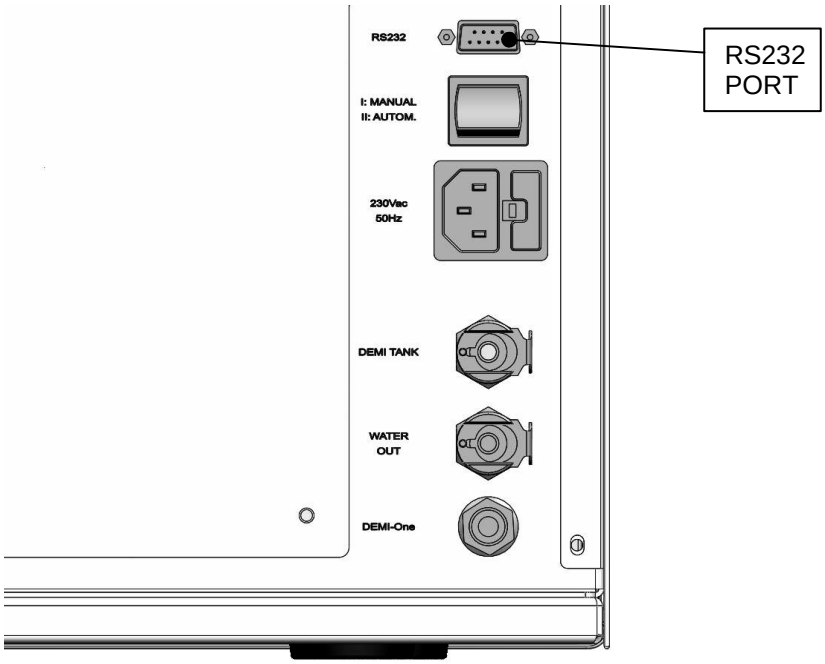


fig. 27 – machine rear

5.13 FORCED INTERRUPTION

The “STOP” icon allows the user to interrupt equipment function during sterilization or test cycles.

The autoclave will behave differently depending on the status in which it is found at the time of interruption.

During the initial vacuum phase
As no steam has yet been entered into the chamber, the autoclave will reset the atmospheric pressure and refill air at forced interruption and resetting will take place quickly.

During later phases (fractioned vacuums– increased pressure/temperature – sterilization)
The autoclave has entered steam (in pressure and temperature) in the chamber and must be brought to safe conditions.
Pressure present is discharged, drying takes place and then resetting of the atmospheric pressure. These operations will last for a few minutes.

The same situations will be undergone in the event of a BLACK-OUT during the aforementioned phases.

Sterilization cycles interrupted by means of the "STOP" icon or due to a black-out are not to be considered valid. material in the chamber is not sterile.

5.14 USER RECOGNITION

The autoclave is equipped with a system for recognising the user which does not allow use by unidentified persons.
This identification system is not active when using the autoclave for the first time, therefore anyone can use it.
To activate this option, the autoclave operator must activate the corresponding function (see following "SETTINGS-PASSWORD" menu paragraph). 6.6).
When the user identification system is active, a password will be requested upon autoclave start-up. Only one correct password can be used to access machine use.

5.15 PASSWORD ENTRY PROCEDURE

fig. 28 – administrator password request screen

The procedure for password entry is the same both for regular users and the administrator.

Procedure:

1. Rotate the knob and position the cursor on the first space of the password line (space at the far left)
2. Press the knob to enter into "modify character" mode
3. Turn the knob to select the alphanumeric character
4. Press the knob to confirm the character
5. Turn the knob and position the cursor on the next password character
6. Repeat this aforementioned procedure for each character making up the password
7. Once password entry has been completed, use the knob to confirm by selecting the icon at the lower right.

6 SERVICE MENU - SETTINGS

The SETTINGS menu lists the following headings:

- CYCLES ARCHIVE
- PREHEATING
- LANGUAGE
- DATE AND TIME
- PASSWORD
- DATE AND TIME FORMAT
- DISPLAY
- SD MEMORY
- PRODUCT INFO
- MAINTENANCE
- SERVICE
- DOOR CLOSING

6.1 CYCLES ARCHIVE - INTERNAL AND MEMORY CARD

Once the heading "CYCLES ARCHIVE" has been selected, the screen will show information relative to completed sterilization cycles. Indicated in order are:

- Cycle name
- Cycle number
- Date on which cycle was carried out
- Start time
- Outcome

The autoclave is equipped with a non-volatile internal memory which contains information relative to the last 200 sterilizations.

The internal memory capacity is limited and cycles will eventually be overwritten when memory is full.

In addition to this internal memory, the B-One is equipped with a data back-up system on the "SD" type memory card.

Data back-up on the SD card is carried out automatically if the memory card is present and correctly installed.
The **card is correctly positioned** by simply inserting the card in the corresponding housing until a light click is heard.
Lightly press and pull the memory card to remove it.

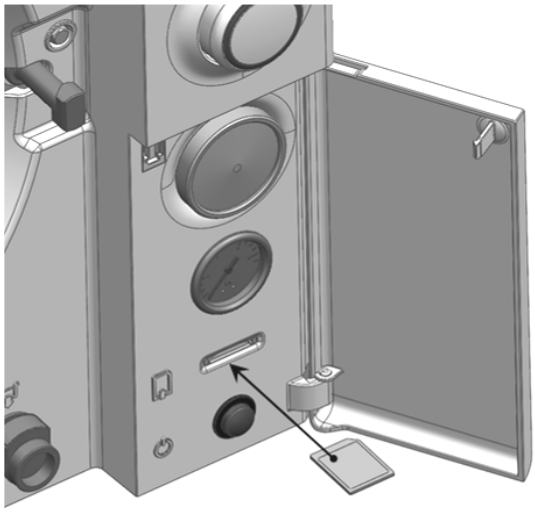


fig. 29 – memory card housing found under the openable door, above the master switch

Do not remove the memory card while an equipment cycle is in progress.

Data can also be downloaded manually onto the SD card by selecting "SD MEMORY", "SAVE CYCLES" from the "SETTINGS" menu (for example if the SD card is not inserted during machine function and the user would like to save completed cycle data).

Data archived on the SD can then be archived on the PC in 2 ways:

1. using the same SD card, if the PC is equipped with the correct inlet
2. using the supplied card reader, connecting the reader to the USB inlet on the PC.

Data on the memory card is already sub-divided in folders (directory) on the basis of sterilization cycle data. Simply copy these folders into a single folder to create a more ordered archive.

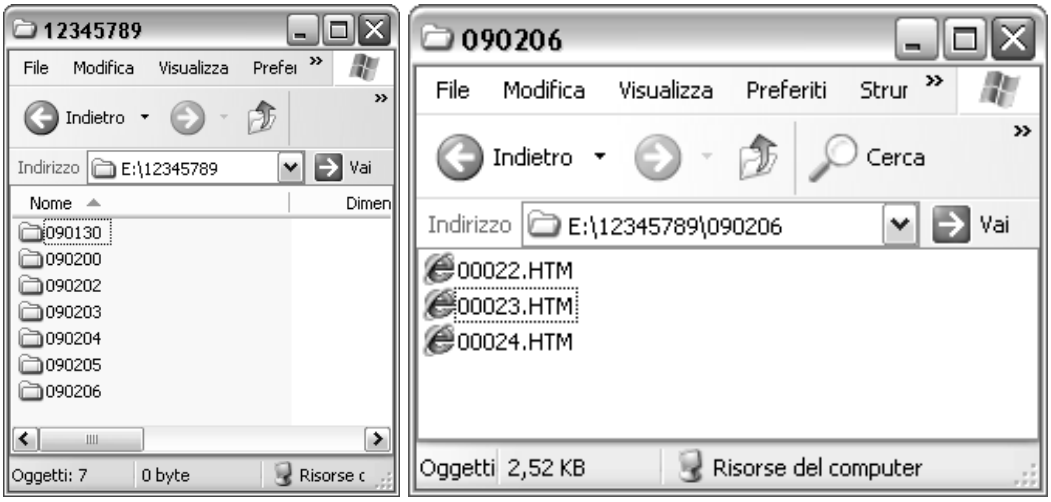


fig. 30 – data is archived already ordered on the SD card (ex: in the image: "12345789" is relative to the equipment series numb., "090130" is the folder relative to cycles performed on 30 January 2009, while "00022" is the 22nd cycle performed on the autoclave)

Finally, it is possible to cancel archives present on the SD card via the PC.

6.2 PREHEATING - WAKE

The machine can be programmed (SETTINGS-PREHEATING menu) to switch on at a preset time.

Programmable elements:

1. wake time
2. wake activation (“ON/OFF”)

The machine activates preheating at the set wake time and begins to bring it to operating temperature to prepare it for use.

The icon located at the lower right corner of the display on the main menu signals the "WAKE" function.

fig. 31 – “wake” icon

Leave the master switch inserted to activate programmed preheating.

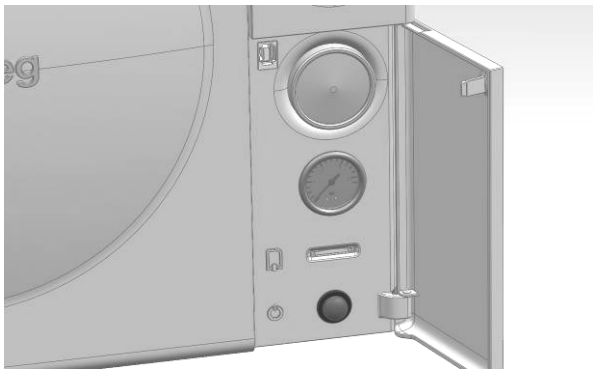


fig. 32 – The master switch is found on the compartment protected by the openable door

6.3 LANGUAGE

Selectable languages are:
Italian - English- French - German - Spanish

6.4 DATE AND TIME

DATE and HOUR display screen.
Using the knob, it is possible to change the following, in order: hours, minutes, month, day and year, pressing once each time to pass to the next setting.
The previous screen will be returned to after the year is modified.

6.5 DATE AND TIME FORMAT

The user will first have to choose from date display options

dd / mm / yyyy (for standard “day/month/year” display)
mm / dd / yyyy (for "month/day/year")

The user will first have to choose from time display options

hh:mm (24h)
hh:mm AM/PM

6.6 PASSWORD

4 password levels are available for limiting access to certain menus/functions.

User level: deals directly with authorised machine function operators (nurses, assistants); this password level allows access to the “PROGRAMME SELECTION" and “SETTINGS” menus except the “SPECIAL MAINTENANCE” and “ASSISTANCE” menus (said access level can be activated if desired by the **administrator**).

Administrator level*:* deals with machine manager (operations manager, chemical engineer, etc.); this level allows access to all user level menus plus the “SPECIAL FUNCTIONS" menu. The administrator can enable/disable password request on the user level.

Superior technical assistance and manufacturer password levels also exist.

The machine is configured with the following base *passwords* for use:

PERSON	PASSWORD
User 1	1
User 2	2
User 3	3
...	...
User 10	10
Administrator	ZZZZZ

The following information is useful with regard to passwords:

- Alphanumeric characters can be used
- Maximum password length is 5 characters

The administrator can enter the name and other identifying information together with the password, and said information will appear in sterilization cycle reports.

Some menu headings for assistance operations require password entry.

6.7 DISPLAY

The contrast and brightness of the display can be adjusted. The temperature which the display is subject to can also be displayed to improve adjustment.

6.8 SD MEMORY

B-One is equipped with an "SD" memory card data archive system.

Select this setting to manually save cycles memorised in the archive on the SD support, or to format the SD card (recommended upon first use on the **B-One** with a new memory card).

Data is automatically archived in folders in the memory.

Protocol for naming folders and files in the archive is as follows:

- Machine registration number (name of "father" folder-directory)
  - Cycle operating data (name of "child" folder-directory)
    - Progressive cycle number (file name with information related to cycle)

6.9 PRODUCT INFO

Read-only display of product information:

1. model name
2. machine serial number
3. software version

6.10 MAINTENANCE

Read-only display of last commands for basic user operations, ex.:

i. Lining: Weekly cleaning with a clean - wet cloth

ii. Sterilization chamber: Cleaning with a clean cloth and hot water every 30 cycles (approximately every 3 weeks)

iii. Water: specifications of recommended water (conductivity threshold 15µS)

iv. Exterior machine cleaning. Disconnect the power supply cable from the autoclave. Clean the machine exterior with a clean cloth moistened with hot water.

In this section, the user can enter into the SPECIAL PROCEDURES by entering a password for configuration parameters display or to start up system resetting procedures.

6.11 SERVICE

Password entry is requested to access serial number and configuration parameters modification.

Technical assistance can enter a password to access machine operations/calibration parameters.

6.12 DOOR CLOSING

The “door closing" function allows the user to proceed with door closing without having selected any operating cycle.
This function is to be used, for example, for transport needs, if the autoclave door must be closed without the equipment in operation.

fig. 33 – "Settings" screen

When the door closing heading is selected, the user will be asked to set the door for closing

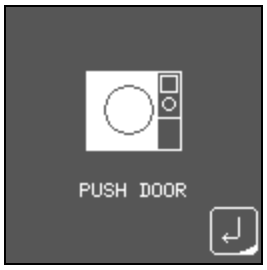


fig. 34 – Screen with door closing request, select the "return" icon to return to the previous screen

Once the door has been set for closing, **B-One** will proceed with automatic closing.

The door can be unlocked by returning to the main screen and selecting the "lock" icon at the lower left of the display.

fig. 35 – Main screen, if the door is locked closed, the "lock" icon is present

7 STEAM STERILIZATION

7.1 RECOMMENDATIONS

Do not insert unsuitable objects into the equipment, for example liquids, bottles, plastic objects, food, etc.

Follow the list below - as long as the instrument manufacturer has also specified that these same items can be steam sterilized in the autoclave.

- Stainless steel instruments
- Stainless steel surgical instruments
- Dynamic instruments (handpieces, turbines, contra-angles, etc.)
- Articles in heat resistant plastic (verify temperatures indicated by each manufacturer)
- Steam sterilizable gloves
- Gauze and fabrics

Any other material marked with the "steam autoclavable" symbol.

7.2 STERILIZATION MONITORING – B&D AND HELIX TESTS

The purpose of these tests is to ascertain sterilization efficiency.
B-One carries out B&D (Bowie-Dick) and Helix tests.

The **B&D test** is performed with a "standard test-pack" (ref. Norm EN 867-5 “Non-biological systems for use in sterilizers”), to be set inside the empty autoclave according to test manufacturer instructions.

The B&D test pack contains an indicator sheet which changes colour (generally from yellow to black) to demonstrate sterilization efficiency.

Read the indicator sheet at the end of the test cycle.
Steam uniformly penetrates the pack and the indicator sheet shows an even colour change if sterilization is efficient.

If on the other hand vacuum conditions are not efficient and area has not been completely removed, the indicator sheet will not show an even colour change.
The presence of a clearer area on the sheet, which could be located near the centre of the indicator sheet, indicates a defect in autoclave function.

The **helix test** is carried out on a certified test cannula (“helix test system”).
One end of the cannula has an open housing where a suitable indicator paper is to be positioned, folded according to manufacturer instructions.
We recommend use of cannulas and paper from the same manufacturer.

The cannula must be positioned inside the autoclave.
The test cycle can now be performed.
At the end of the cycle, the indicator paper colour change (generally from blue to black) will indicate sterilization efficiency.

The indicator papers are generally supplied with an adhesive side for easy archiving.

7.3 PREPARATION OF OBJECTS FOR STERILIZATION

INSTRUMENT CLEANING

Instruments must be cleaned, free from any blood or swab residue, etc.

Use Smeg instrument washers for instrument treatment, or else detergent solutions and distilled water according to instrument manufacturer instructions.

Separate instruments by the type of material they are composed of, avoiding any direct contact between different material instruments.

All instruments must be set in an open position to facilitate steam flow.

Arrange objects, spacing them out from one another.

PACKED

Instruments can be bagged to preserve their sterility, according to indications from the autoclave paper and bag material manufacturers.

Instruments to be sterilized must be set inside the bag material, then bags must be properly sealed.

Bag dimensions must allow for instruments contained within them to be properly spaced out from one another once set on the sterilization tray.

Arrange bags with the plastic part on the bottom and the paper part on the top to facilitate air removal processes in the autoclave. Manufacturer directions for bag material is as follows:

Do not overlap bags.

Rinse tubes with water only and arrange them on a tray without folds or blockages to allow steam to penetrate.

Empty containers should be turned upside down.

Place a chemical indicator test in each tray.

Do not overload or overlap trays. Always use supplied tray supports.

Max recommended naked instruments load: 3.5kg

Max recommended bagged instruments load:1.5kg.

8 ERRORS AND ALARMS

The machine keeps control of alarm conditions during operation.

In the event that any irregularities are verified, the machine emits an acoustic signal and the user is informed of the error / alarm type by means of the display and the colour of the knob ring.

Always note down any errors / alarms signalled.

Some alarms are "not serious" and can be resolved by simply pressing the selector knob.
Sometimes the machine must be switched off and then back on to allow for an electronic reset.

Machine overheating, due to an improper positioning which does not allow for the necessary cooling of sensitive components, can cause transient malfunctions. In these cases, it may be necessary to switch off the machine and then allow it to cool down before restarting operations.
To ensure maximised autoclave operations and preserve its components over time, spaces recommended for positioning must be respected.

The alarm is presented on the display as a "phrase" expressed by 3 groups of alphanumeric characters, as with the following screen:

a. FIRST GROUP = identification of seriousness
b. SECOND GROUP = alarm type
c. THIRD GROUP = indication of the programme phase during which alarm was set off

For example, the message E1-32-015 on the display is to be considered:

a. FIRST GROUP = E1
b. SECOND GROUP = 32
c. THIRD GROUP = 015

Consult the following tables to identify error descriptions from messages.

When an alarm is set off, proceed as follows:

1. Take note of the alarm and conditions on the corresponding manual table. Read the alarm description and possible causes in the following tables.

2. Press the knob to resolve less serious errors / alarms related to electronic system checks of parameters which have been stabilised

3. If the error persists: switch off the machine, wait a few seconds, switch it back on to resolve problems involving an electronic system reset

4. If the error persists: switch off the machine, wait for components to cool down for at least 30 minutes, switch machine back on. Component overheating problems, generally caused by improper equipment use/positioning, can be resolved in this way. We recommend checking autoclave positioning and re-reading manual parts related to proper use.

5. Contact technical assistance if alarms persist.

FIRST GROUP	SECOND GROUP	ALARM DESCRIPTION
E1	1	Sudden shutdown / power loss experienced during wake time programming.
E1	2	Door locking device alarm.
E1	4	Electronic time scanning check of time has failed.
E1	8	Heating resistance problem: electronic feedback not compliant with command given.
E1	16	Vacuum test cycle failed.
E1	32	Timeout during machine operations - said alarm is better specified in the THIRD GROUP of characters (see following table).
E1	64	Steam generator water level too low.
E1	128	Pressure probe generating a value outside of allowed limits.
E2	1	Temperature probe generating a value outside of allowed limits.
E2	2	Electronic problem during writing of parameters of memory.
E5	1	Knob not detected by the programme unit.
E5	2	Interface board – microcontroller communication fault.
E5	3	Interface board – flash memory not programmed
E5	4	Interface board – communication error between the interface and the cpu board.
E5	6	SD card not connected.
E5	7	SD card format not known.
E5	8	SD card full.
E5	10	Cpu board – jumper off
E5	12	Demi switch position not correct

THIRD GROUP	DESCRIPTION
6	Door opening phase: decompression. Error may have been generated by the presence of an object located between the door and lining. In this case, remove object and check that front lining has not been damaged.
7	Door opening phase: recovery of atmospheric pressure. Error may have been generated for banal reasons, such as obstruction or improper positioning of the bacteriological filter (the filter is the round, white component located under the openable door, can be unscrewed by hand for removal)
8	Door opening phase: motor movement, moving away from alignment.
9	Door opening phase: motor movement, closer to alignment.
10	Door closing phase: motor movement, moving away from alignment.
11	Door closing phase: motor movement, closer to alignment.
12	Water load phase into loading tank. The minimum level of water has not been reached in the expected time. Check to see if the demineralised water can is empty and check that the withdrawal tube end is still immersed in the water. Check that loading tube is not blocked.
13	Water draining phase from discharge tank. Check that discharge tube is not blocked.
14	Water load phase into steam generator.
15	Vacuum application phase for B&D/helix test cycles and for vacuum tests.
16	Vacuum maintenance phase in the vacuum test cycle. If the test has been performed with a warm machine, we recommend proceeding with another test after the machine has been cooled down. Vacuum tests are best performed immediately after machines have been started up under cooler conditions.
18	Error during fractioned vacuums - initial cycle phase. Error may have been generated by the presence of an object located between the door and lining. In this case, remove object and check that front lining has not been damaged.
19	Pressure recovery phase during fractioned vacuums. Error may involve function of the machine solenoid valve. Keep in mind that

THIRD GROUP	DESCRIPTION
	solenoid valve malfunction is generally caused by unsuitable water, or water whose parameters are not optimal. See recommended values in this manual.
21	Setpoint application sterilization phase.
22	Sterilization phase.
27	Problems during the hydraulic circuit cleaning phase.
28	Drying decompression phase.
31	Atmospheric balance recovery phase before door opening. Error may involve function of the machine solenoid valve. Keep in mind that solenoid valve malfunction is generally caused by unsuitable water, or water whose parameters are not optimal. See recommended values in this manual.

9 MAINTENANCE

B-One requires proper use, careful routine cleaning and regular maintenance by Service Assistance.

Remember to clean all parts with a cloth moistened with water or neutral detergent: non-corrosive and non-abrasive soap. Do not use ethyl alcohol.

Do not use jets of water aimed directly on the machine as they could cause dangerous infiltrations on the electrical equipment, compromising **B-One** functions.

Internal parts in stainless steel, the support and stainless steel trays, can be cleaned with water and normal detergents for stainless steel. Do not use disinfectants or alcohol inside the chamber.

Disconnect the power supply cable before any maintenance operations.

Allow heated parts to cool down before carrying out maintenance operations: inside door, chamber, supports.

9.1 BACTERIOLOGICAL FILTER REPLACEMENT PROCEDURES

Unscrew the filter found under the small door, at the lower right, in a counter-clockwise direction.

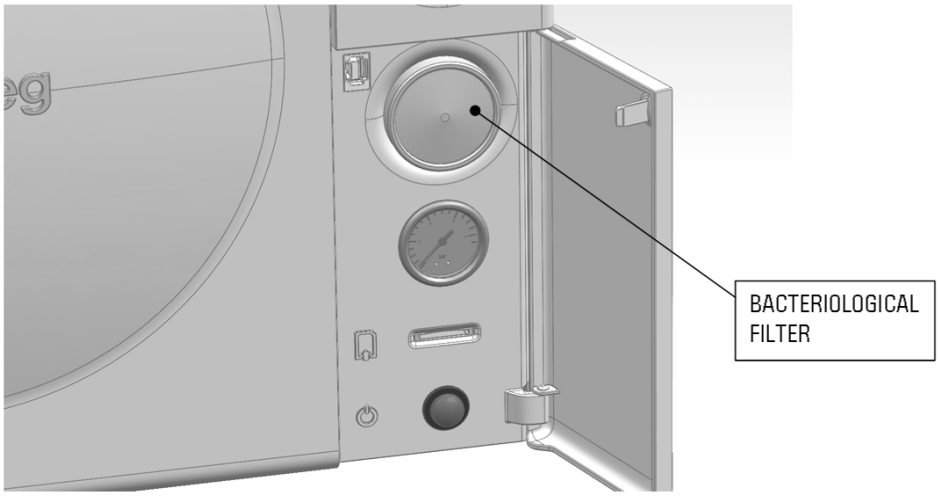
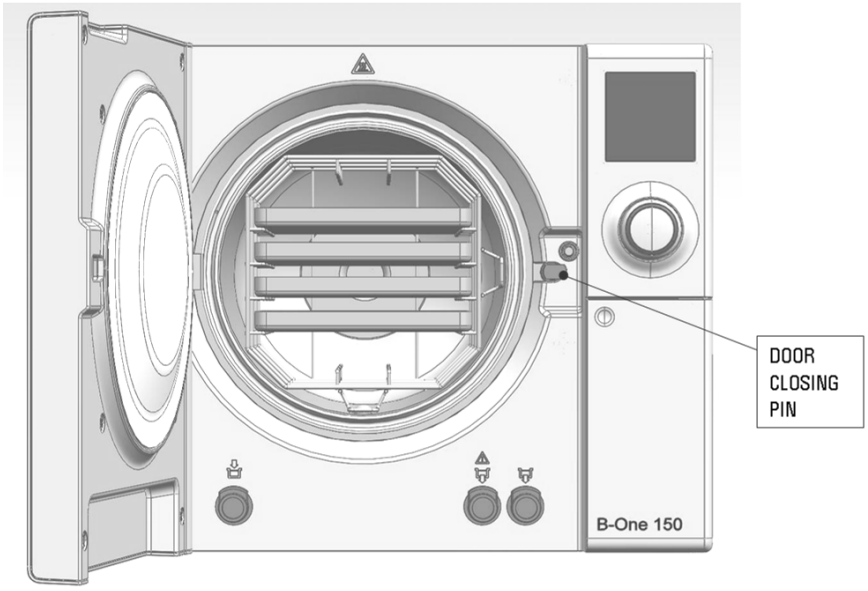


fig. 36 – Replaceable bacteriological filter

Do not user improper instruments which could damage connection elements: unscrew by hand.
Assemble a new filter, screwing it in by hand without forcing.
Filter replacement must be carried out at least every 6 months.

9.2 MECHANICAL PARTS LUBRICATION

Lubricate the door closing pin with a silicone spray, spraying it on a cloth and then carefully applying the silicone. Avoid spraying the silicone directly as it could deposit on the sterilization chamber doors.



Failure to carry out maintenance, interventions by unauthorised personnel, replacements with non-original components can all result in the forfeiture of the official warranty issued by the manufacturer and releases Smeg S.p.A. of any responsibility.

9.3 MAINTENANCE OPERATIONS SUMMARY TABLE

DAILY MAINTENANCE	Clean external and internal surfaces.
WEEKLY MAINTENANCE	Clean sterilization chamber. Clean trays and support, clean and disinfect external surfaces.
MONTHLY MAINTENANCE	Lubricate the door closing pin with silicone oil or a similar lubrication spray.
EVERY 6 MONTHS	Replace bacteriological filter
ANNUAL MAINTENANCE	Revision: contact assistance.

10 ACCESSORIES

10.1 PROVIDED ACCESSORIES

List of accessories

1. N. 1 basket holder support in stainless steel
2. N. 4 mesh baskets in anodised aluminium 284 x 183 x 17 [mm]
3. N. 1 basket extraction pliers
4. N. 2 tubes with quick couple in plastic for water loading/discharge
5. N. 1 bacteriological filter (already mounted in the autoclave)
6. N. 1 power supply cable, schuko plug
7. N. 1 user manual

10.2 OPTIONAL ACCESSORIES UPON REQUEST

a. Wire tray in stainless steel, dimensions 288 x 188 x 18 mm, square mesh 12x12 mm

b. Bacteriological filter (refill)

c. **PRINT-One** countertop thermal printer, RS-232 serial port

d. **DEMI-One** water purifier for autoclave input water

PRESENT ERROR REPORT TABLE

DATE	**ERROR TYPE** (ex. E1-16-16)	**CONDITIONS AT TIME OF ERROR** (type of cycle in progress, number of completed cycles, surrounding conditions)

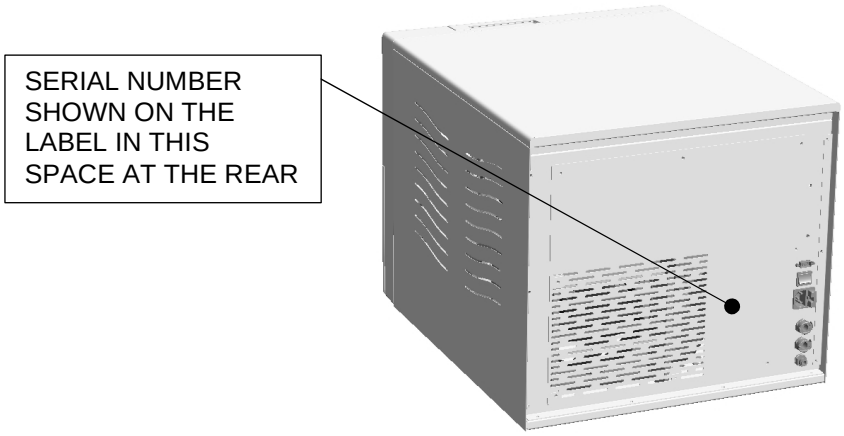
DATE	**ERROR TYPE** (ex. E1-16-16)	**CONDITIONS AT TIME OF ERROR** (type of cycle in progress, number of completed cycles, surrounding conditions)

Information and Assistance for SMEG INSTRUMENTS DIVISION products

Our Sales Office staff can provide you with information on prices and offers.

Our Technical Assistance Office can provide you with information for proper equipment operation and put you in contact with a nearby authorised Assistance Office.

It is important to include the equipment serial number.



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