ISTRUZIONI D'USO
INSTRUCTION MANUAL
MODE D'EMPLOI
MANUAL DE USO
BETRIEBSANLEITUNG

B - Rev.4.17 - 2014.06.04

CE 0051

SUPERIOR B23
MEDICLAVE

Dear Customer,

The autoclave is a device designed for water steam sterilization of small sized tools and professional equipment, and is widely used for medical purposes by general practitioners and dentists, in salons that deal with personal hygiene and body care and also in veterinary surgeries. It is also used for sterilizing materials and equipment that come into contact with blood or physiological liquids, such as instruments used by beauticians, tattoo artists, piercers and hairdressers. The very specific sterilization loads used in these sectors of applications require different performance features for the sterilization cycles. It is, therefore, advisable that this device is used by professional personnel duly trained.

It is of fundamental importance for the sterilizer and the respective equipment to be used solely for the type of product for which they were designed. We therefore request you to consult the Declaration of Conformity of this appliance: the Class to which the appliance belongs is indicated in the "Category" box. The" Sterilization Table" (Chap. 11) gives all the information necessary for establishing the type of cycle to be used for sterilizing the various instruments.

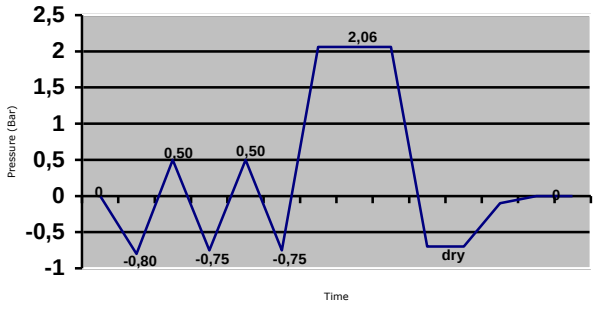
INFORMATION TABLE (Annex D - EN13060)

REQUIREMENTS	B	S	N
Dynamic steriliser chamber pressure	X	X	X
Air outlet	X	X	
Empty chamber	X	X	X
Solid load	X	X	X
Small porous objects	X		
Small porous loads	X		
Full porous load	X		
B type hollow load	X		
A type hollow load	X		
Multiple wrap	X		
Drying, solid load	X	X	X
Drying, porous load	X	X	
Residual air			X

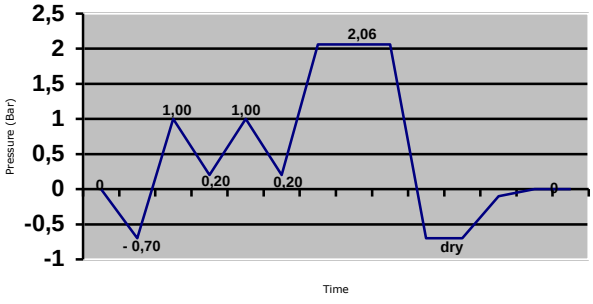
X = available

GRAPHIC EXAMPLE OF VARIOUS TYPES OF CYCLE

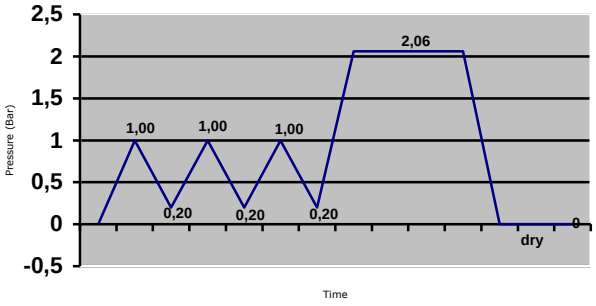
B type



S type



N type



GENERAL WARNINGS

- **We recommend** that you read the Instruction Manual carefully before beginning to use the device, to ensure that the operations required are carried out correctly: **DO NOT** carry out operations other than those described in this booklet. The Manufacturer declines all responsibility for direct or indirect damage to objects, persons or animals deriving from improper use of the appliance.
- The machine must be used by responsible adults only.
- Position the machine in a place where it is not accessible to children.
- Install the machine in a position where it is easy to reach the plug.
- Do not use the machine near inflammable or explosive sources.
- Use the machine in dry protected areas.
- Check the condition of the power cable periodically: do not use the appliance if the power cable is not perfectly intact.
- Do not carry out maintenance with the machine running or if it is plugged into the power socket.
- Do not approach the machine with inflammable material.
- Always use personal protection devices, in compliance with the applicable directives.
- Do not use the appliance for purposes other than those mentioned in this Instruction Manual.
- Read the paragraph concerning the technical features carefully before starting up the appliance.
- For your safety, make sure you pay <u>great attention</u> to the instructions given below.

ATTENTION

IT IS STRICTLY FORBIDDEN THE USE OF THE AUTOCLAVE UNDER THE EFFECT OF MEDICINALS, DRUGS OR ALCOHOL

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2. SAFETY

2.1 SAFETY SIMBOLS

	ATTENTION: READ CAREFULLY THE INSTRUCTIONS OF THE USER'S MANUAL
	VOLTAGE
	ATTENTION HIGH TEMPERATURE
	EARTH CONNECTION

2.2 SAFETY DEVICES

This equipment includes the following safety devices:

1. Three micro-switches controlling the door and the automatic locking system: they are independent of each other and ensure that the door is closed and properly locked. If problems arise, the user is warned by an alarm and the next cycle cannot start. If any problem arises while the cycle is running, the microprocessor stops the process and immediately reduces the machine pressure level.

2. Two different mechanical thermostats ensure that the temperature of the various components does not accidentally exceed the preset value. Thermostats are manually reset.

3. Four electronic temperature sensors continually monitor all critical points on the machine, to prevent over temperature errors during the operating process.

4. A pressure relief safety valve protects against the risk of explosion.

5. An electronic pressure transducer checks all the solenoid valves and opens them if an overpressure is detected.

3. PACKAGING, STORAGE AND DISPOSAL

The cardboard packaging used for transporting the autoclave IS NOT STERILE.

The autoclave is fragile and should therefore be transported with extreme care.
DO NOT TURN UPSIDE DOWN.

The sterilizer is packed with all accessories placed inside the chamber. It is wrapped in a protective polyethylene bag and then placed inside a cardboard box. To protect it against accidental impact, it is also padded with polystyrene or cardboard.

Keep in a dry and protected area at a temperature of 5-30°C.

The user is recommended to retain the packaging for the period of the warranty: if the equipment is returned for repair without the original packaging, the user will be charged for a new packaging at time of reshipment.

Unpacking and locating the autoclave

At least two people are required to remove the equipment from the box, following the instructions given below:

- Open the box and remove the staples to avoid getting scratched or cut while removing the equipment.
- Carefully read the instructions for use.
- Remove the machine from its box by taking hold of the sides, without putting strain on parts made of plastic.
- Place the machine on a perfectly horizontal level surface with a load capacity of at least 70 kg.
- Connect the plug to a Schuko plug with safety ground.

  Do not replace the original plug with other types.

  Do not make additional connections.

  Do not connect to multiple plugs or similar: ensure that the installation to which the sterilizer is connected complies with all relevant legislation and can sustain the specified load (paragraph 16).

- Open the door by pushing the DOOR button.
- Take the accessory kit out of the box and switch the equipment off.
- CAREFULLY READ PARAGRAPHS 4 AND 4.1 BEFORE STARTING NORMAL OPERATION.

DISPOSAL AND/OR SCRAPING

For the disposal and/or scraping of any component (packaging, water, complete machine…) strictly refer to the norms in force in the country where the operation is carried out.

4. FIRST INSTALLATION

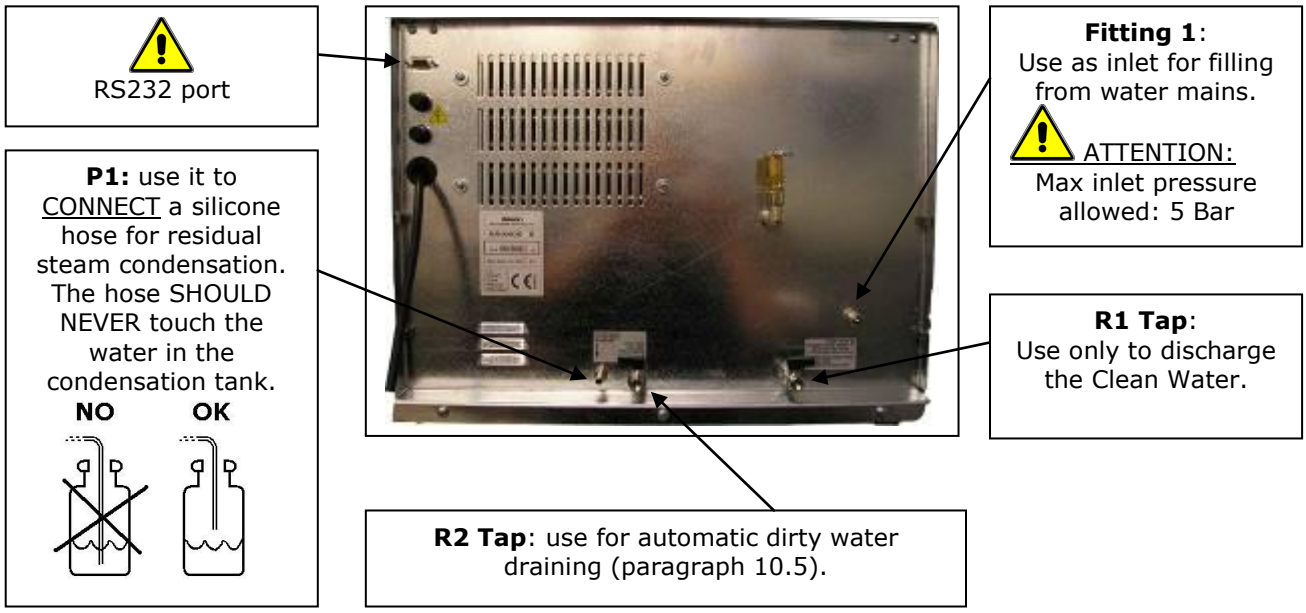
Correct installation of the autoclave is key to ensuring its proper operation. Below is an installation checklist:

1. The device must be installed in a laboratory accessible only to authorised personnel.
2. The working environment must be properly lit and adequately ventilated.
3. Position the equipment on a perfectly flat and horizontal surface with a minimum load capacity of 70 kg. The autoclave is supplied already levelled. The sterilisation chamber is slightly inclined to the rear of the equipment. Leave at least 5 cm between the wall and the back of the autoclave.
4. Position the autoclave so as to leave sufficient room for inspecting and cleaning the sterilisation chamber.
5. Do not install the autoclave close to washbasins or taps: the cover of this equipment is not watertight.
6. Do not install the equipment close to heat sources (i.e. other autoclaves, ovens or similar).
7. In order to avoid any damage to people, things or animals, the machine must be put in a position allowing the flow coming from the safety valve to flow in a safe place.

4.1 WATER CONNECTIONS

The equipment water connections are of primary importance for its correct operation (see the photo for details):

1. ***Follow instructions as detailed in the photo***.
2. If it is present, remove the silicone hose on "**P1**".
3. To use the automatic dirty water discharge, the "**R2 Tap**" must be leaves always open.
4. "**Fitting 1**" is of nut type, for use with a 4/6mm hose.
5. NEVER connect "**R2 Tap**" to "**P1**" on the same terminal: always use two separate hoses.
6. To leave at least 5 cm between the autoclave and the wall.



ATTENTION:

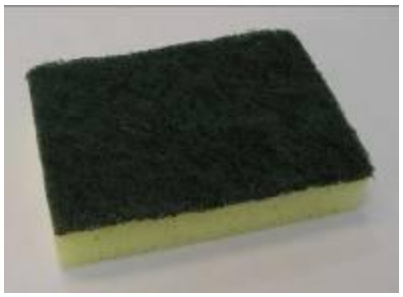
If the automatic water filling system (FILLING FROM WATER MAINS) is used, it is COMPULSORY to connect the condensate drainage pipe (**P1**) to a sewer line and not to the condensate container.

5. ACCESSORIES

The tray holder is supplied together with four trays and the following accessories.

TOOL FOR TRAY EXTRACTION

Use the right side to extract the hot trays.



CLEANING SPONGE

Use the sponge as indicated in paragraph 15.

FILL HOSE (1x)

Install the filter in the water container and secure the other end to the hose connection at the top, left-hand side of the chamber rim: press the PUMP / WATER button to start filling.

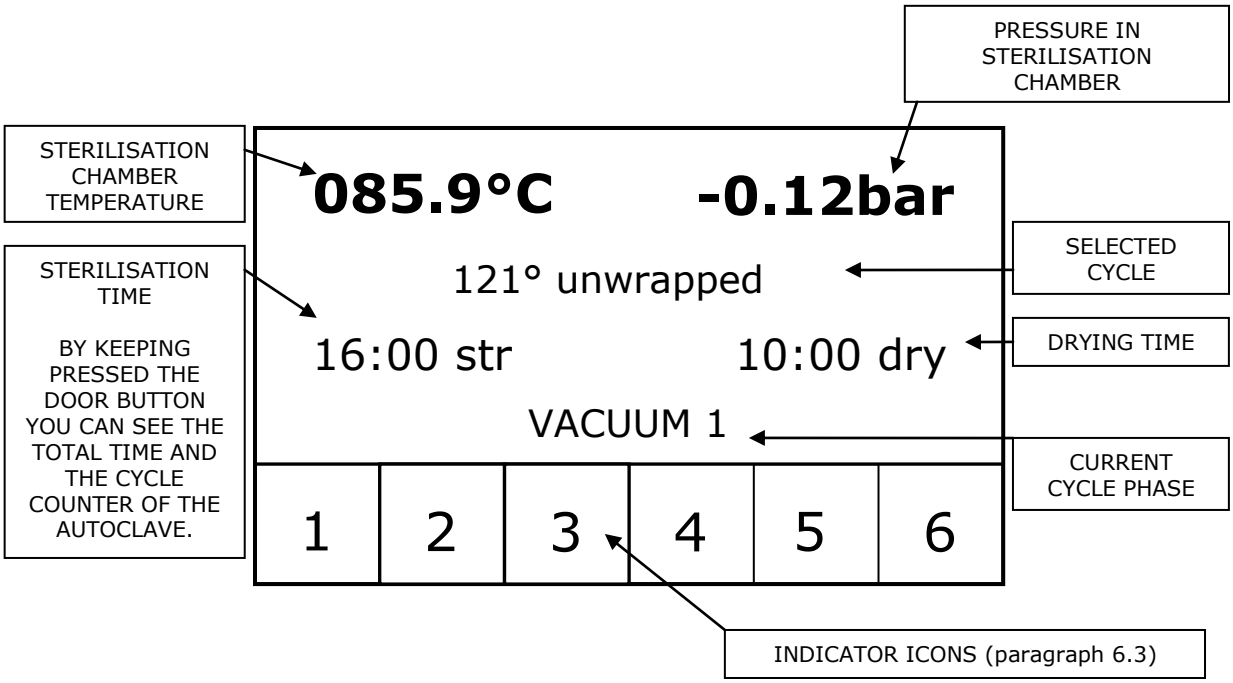
DRAIN TUBES (2x)

Use one tube as described in paragraph 10.3, to drain the used water.
The second tube should be connected to the hose connection "B", as described in paragraph 4.1.

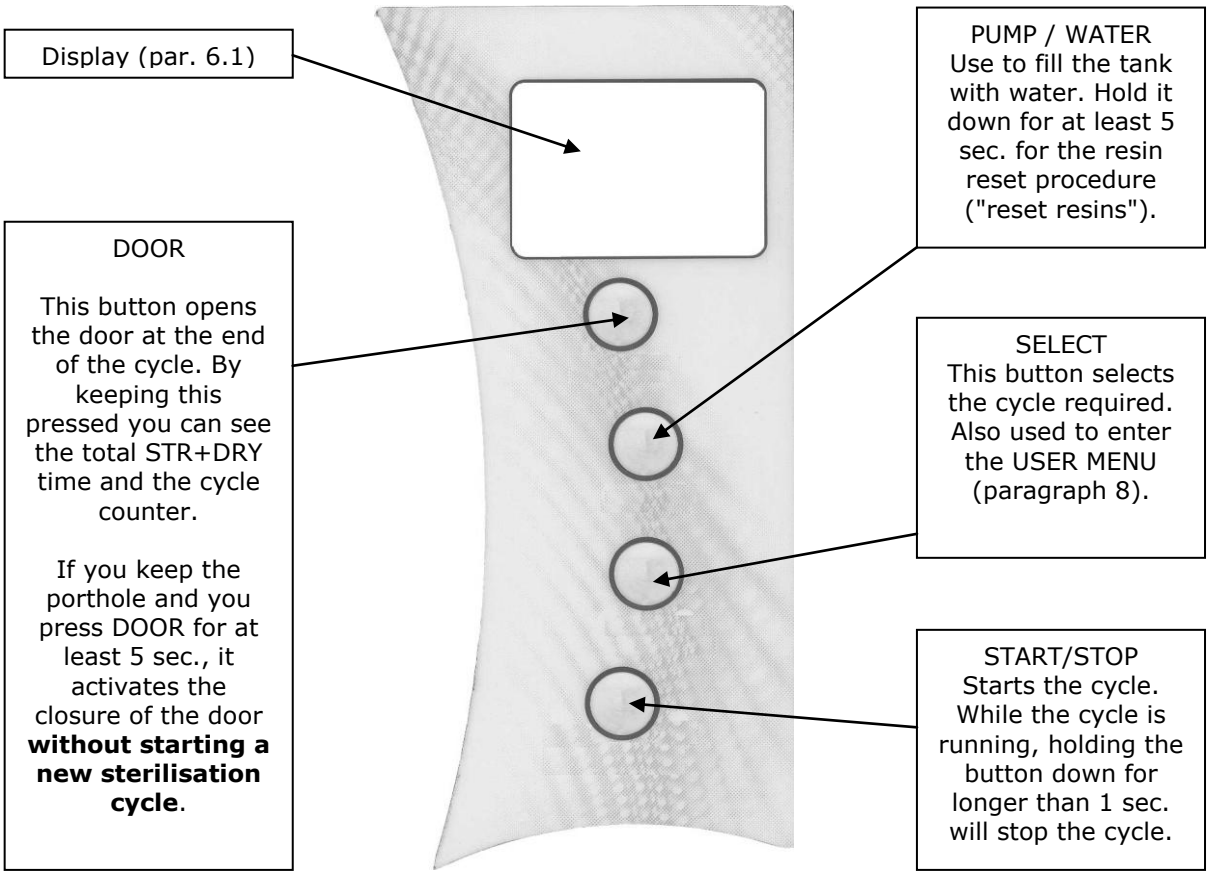
6. CONTROL PANEL

In order to understand and use the controls correctly, please refer to paragraphs 6.1, 6.2 and 6.3.

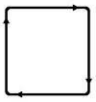
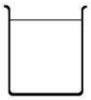
6.1 DISPLAY



6.2 KEYBOARD



6.3 INDICATOR ICONS

	This icon is displayed shortly after a cycle has started and indicates that the machine door is locked.
	This icon indicates that a cycle is running: you will see the arrows spinning around.
	Icon #3 warns that printer is out of paper, or the that printer cover is not properly closed. The machine can execute its cycle without any risk.
B	Kind of cycle selected: B, S or N type (see Table on Page 1).
	The autoclaves are equipped with software which is able to communicate and to write data onto a USB key. Some sterilisers have a USB connector already on board the machine; others require the STS-Datalogger system which must be connected to the RS232 serial port: both systems are OPTIONAL. When the USB key is inserted in the connector (or on the Datalogger), the USB icon appears on the display. With the USB, on board the machine or with the Datalogger system, it is always necessary to read the specific enclosed manual carefully to prevent data saving errors. DATA SAVING BEGINS AND ENDS ONLY AND EXCLUSIVELY IF THE USB KEY IS ALREADY INSERTED IN THE CONNECTOR BEFORE THE CYCLE IS STARTED.
	This icon warns the user that clean water is at its minimum level: it is not possible to start a new cycle. Fill the machine with water before starting other cycles.
	The clean water tank is full. If the PUMP/WATER button is pressed again, the display will show that it is not possible to continue filling the tank with water.
	While this icon is displayed, no cycle can start: the dirty water tank should be completely drained. Allow all water to drain out before closing the draining tap.

7. PRINTER

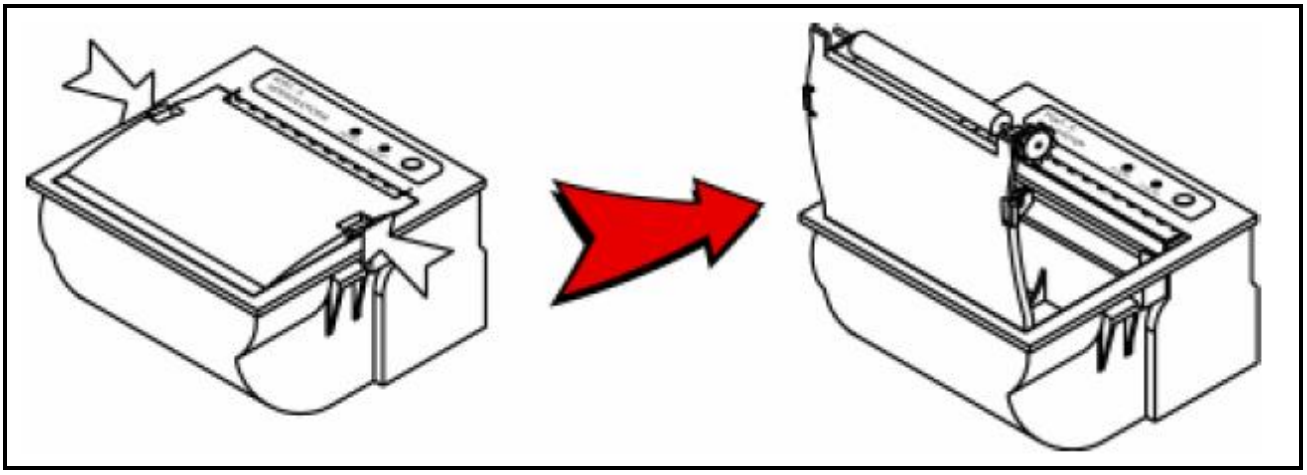
On starting any cycle, the autoclave starts printing all values concerning the selected cycle, plus the machine model and serial number (paragraph 7.3). When the autoclave cycle is completed, the printer stops printing: cut off the printout by using the built-in cutter (simply pull the paper upward).
If the cover is not properly closed, or if the printer is out of paper, the relevant indicator icon will be displayed to warn the user (paragraph 6.3).

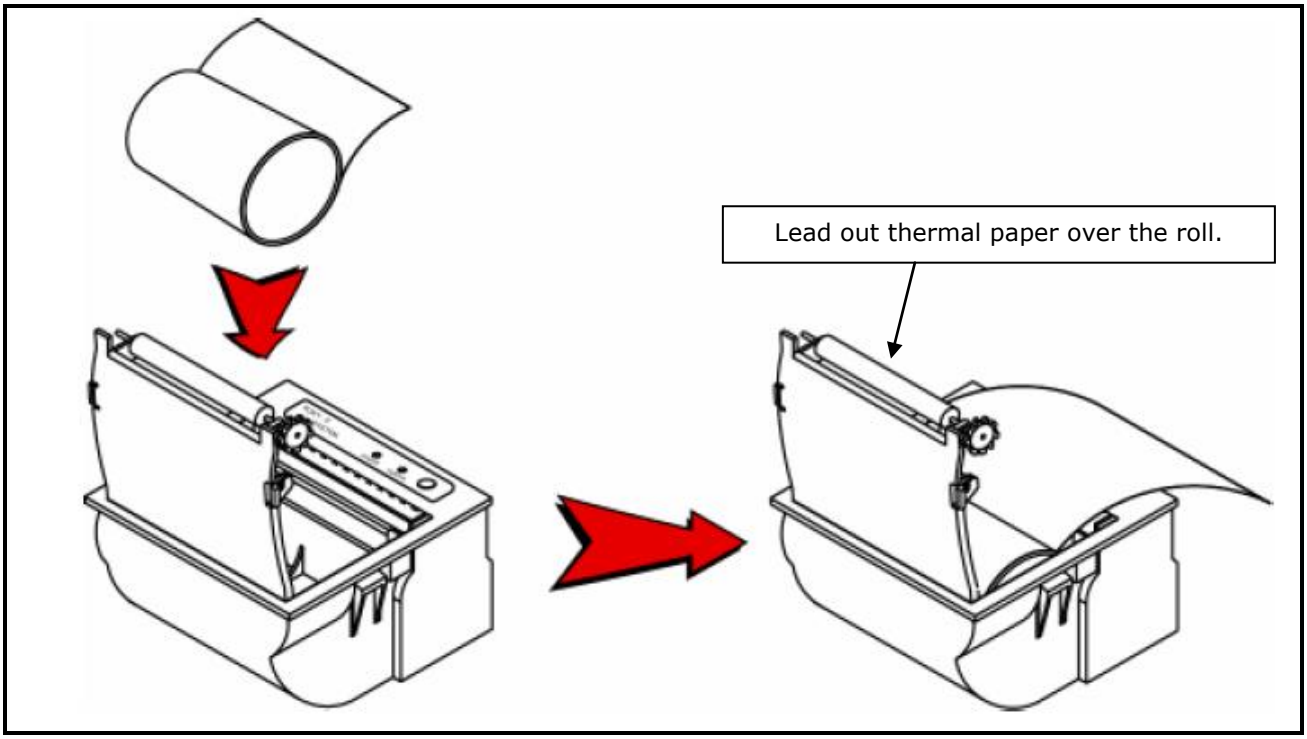
Refer to the instructions provided by the local health authority for printout-filing.

For a correct and long-lasting storage of the paper printouts, it is necessary to keep them away from light and heat sources.

7.1 CHANGING THE PRINTER ROLL

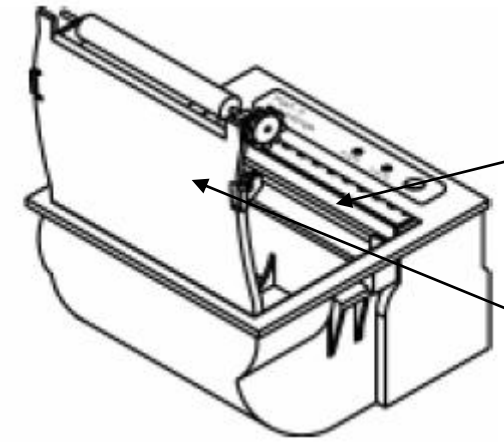
To change the printer roll: open the cover, insert a new thermal paper roll (maximum width should be 57 mm) in the space provided and lead out the paper over the cover roll while closing the cover. Use only thermal paper. Make sure the thermal paper is correctly oriented: if the paper is inserted the wrong way up, the printouts will be blank.





7.2 PRINT HEAD CLEANING

If printouts are difficult to read, the print head should be cleaned using a moistened soaked in alcohol: open the printer cover, remove the paper roll and clean the head (see points shown in the picture). Use compressed air to clear dust from the interior of the printer.

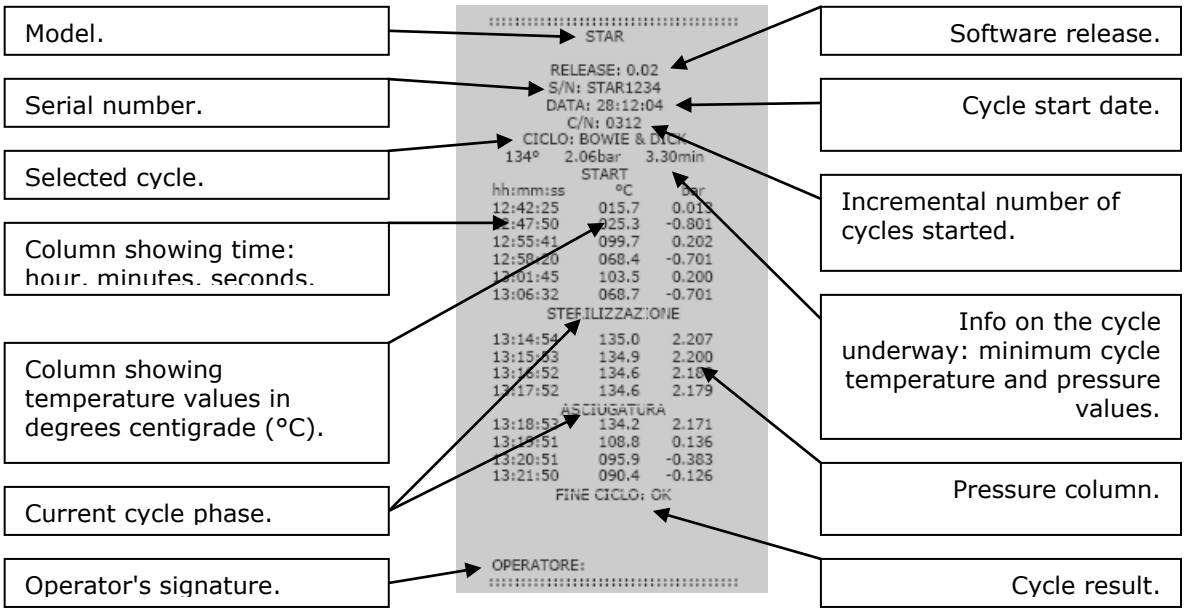


the print head is below the cutter. Cleaning should be carried out with the machine OFF.

If the cover is not properly closed, or if printer is out of paper, the relevant indicator icon will flash on the display.

7.3 PRINTOUTS

How to read and interpret the information provided in the printouts.



8. USER MENU

To access the user menu, proceed as described below:

- Switch-OFF the autoclave.
- Keep SELECT pressed and switch-ON the autoclave: release the SELECT button only when the preset language (e.g.: ENGLISH) appears on the display.

Within the user menu, the pushbuttons are used in the following manner:

- START = proceed to the next page.
- DOOR and PUMP = used to modify the settings in the pages.
- SELECT = when pressed until the confirmation sound is given, it saves the pre-selected value (not all the pages need to save the pre-selected value).

8.1 ENGLISH

use DOOR and PUMP buttons to select the required language. Press the START/STOP button to move on to...

8.2 TIME: hh mm ss

This page allows you to set the time. Press the DOOR button to increase the value and the PUMP button to decrease it; use the SELECT button to move the cursor to the value to be changed. Press the START/STOP button to move on to...

8.3 DATE: dd mm yy

This page allows you to set the date. Press the DOOR button to increase the value and the PUMP button to decrease it; use the SELECT button to move the cursor to the value to be changed. Press the START/STOP button to move on to...

8.4 atm PRESSURE

_ . _ _ _ bar

The machine automatically sets the correct atmospheric pressure. It is recommended not to change this setting to avoid damaging the equipment. Press the START/STOP button to move on to...

8.5 CHARGE WATER BY…

This page is used to select the water filling mode. If external filling mode is used (demineralizer), set the desired values with the DOOR and PUMP buttons, then hold the SELECT button down for 5 sec. (until the system emits a beep), to save the setting. Press the START/STOP button to move on to...

8.6 CYCLES RE-PRINT

This function allows you to save the last cycles executed by the machine with a single action. These cycles can be either printed from the internal or external printer by holding down the SELECT button for 5 sec. Press the START/STOP button to move on to...

8.7 EMERGENCY ON/OFF

The "Emergency ON" setting is reserved for specialised technical personnel. Press the START/STOP button to move on to...

8.8 DISCHARGE H2O

Do not carry out this operation if the sterilizer is connected to an external water supply (demineralizer): disconnect all inlet water connections before proceeding (paragraph 4.1).

Press the START/STOP button to return to the language setting page; hold it down to quit the user menu. You can exit the USER MENU at any time by holding down the START/STOP button.

9. FIRST TIME START-UP

USING THE SYSTEM FOR THE FIRST TIME

After installing the autoclave (as per paragraphs 4 and 4.1), make sure that all water connections are watertight. Proceed as detailed below:

1. Start the equipment using the main switch.
2. Enter the USER MENU (paragraph 8) and configure the system in accordance with the selected filling mode (if water filling is from the water mains, check that inlet water connections are as per paragraph 4.1).
3. Fill the tanks with water: once the clean water MAX. LEVEL icon is displayed, the test cycle can start.
4. Insert at least the tray holder and start the cycle by using the START button: the autoclave will run automatically until the end of the cycle, when a warning sound will be heard and the display will show "END CYCLE".
5. Carry out the test cycle.

9.1 CLOSURE OF THE DOOR

When switching on the machine, the display shows the manufacturer logo, the model of autoclave and the software version in use. This software version can determine a different procedure for closing the door. The various possibilities are described below:

STANDARD SOFTWARE (e.g. 2.01): keep the door pushed in and press the DOOR button for at least 5 seconds: only release the door when the display shows the door locked icon (point 6.3). With this software version, it is possible to start the sterilisation cycle by simply pressing the START button instead of the DOOR button.

EVOLUTION SOFTWARE (e.g. E.2.1a): keep the door pushed in until the display shows the door locked icon (point 6.3). To close the door, it is NOT necessary to press the START button as the motor starts automatically. To start the cycle, press the START button once the door is closed.

To open the door, it is necessary to press the DOOR button. If there is a small amount of residual pressure inside the steriliser, in order to guarantee maximum operator safety the autoclave will first of all discharge the pressure and will not open the door. In this case, simply press the DOOR button again.

9.2 TEST CYCLE

The purpose of the test cycle is to ensure that the autoclave is in working order, has not suffered any damage during transport and is not subject to any operational faults due to technical causes. It is recommended that this test is based on BOWIE & DICK cycle.

- Close the door as described in point 9.1 then, with the door closed, press the START button.
- BOWIE & DICK:
  While the cycle is running, the display will show the temperature – pressure– time remaining– selected cycle number – type of cycle - current cycle phase - any warning icons. Insert the tray holder and the trays inside the machine as indicated at paragraph 12.1. The vacuum pump starts removing air from the chamber until the preset value is reached (VACUUM 1), after which the rise phase will start (PREHEATING). During this phase a slight buzz coming from the water injection pump (used to inject steam into the chamber) can be heard. Once the preset vacuum degree is reached the EXHAUST phase will start; on completion, another two vacuum phases and two preheating phases will be carried out until the cycle preset values are reached (paragraph 11). The STERILISATION phase will now start. during the exposure period, pressure and temperature will be continually software-controlled to ensure that the sterilisation is successful. Alarms will trip in the event of problems (see paragraphs 14 and 14.1). On completion of the sterilisation phase, the DRYING phase will begin: pressure inside the chamber will be released and the final vacuum phase will start (the pump will suck any steam to considerably improve the final drying of the sterilised instruments). The door can only be opened when the display shows END CYCLE. In the event of residual positive or negative pressure, the door lock system will not open (proceed as indicated in paragraph 6.2). Remove the instruments by using the special handle supplied with the equipment: **use protective gloves to avoid getting burnt**.

10. WATER TANK FILLING AND DRAINING

10.1 AUTOMATIC TANK FILLING WITH CLEAN WATER

The total capacity of the clean water tank is 4.5 litres. In order to fill the tank, connect the supplied hose (paragraph 5) to the hose connection fitting, at top, left-hand side of the chamber and press the PUMP button: the filling pump will run for a maximum of 220 sec. When the icon signalling the maximum level (paragraph 6.3) lights up on the display, the water supply will continue for a further 5 sec., after which the pump will stop automatically. The filling operation can be stopped at any time by pressing the PUMP button. If the water is at minimum level, as indicated by the relevant icon on the display, the cycle cannot start.

10.2 FILLING FROM THE WATER SUPPLY MAINS (Demineralizer) or BY OSMOSIS SYSTEM

If a water purification system (Demineralizer or OSMOSIS system) is present, the water connections as described at point 4.1 must be used and the software must be programmed with the pre-selected setting. Proceed as described below:

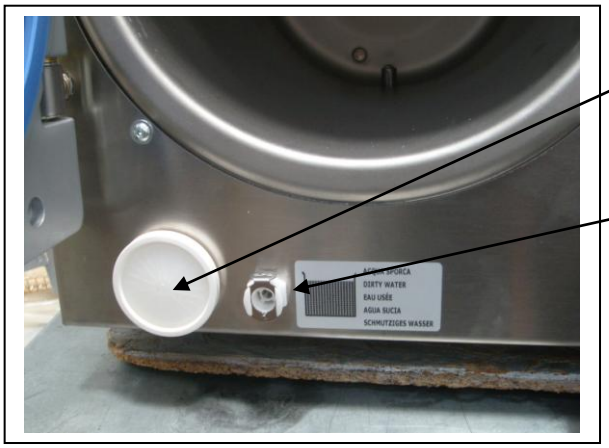
- Switch-OFF the autoclave.
- Keep SELECT pressed and switch-ON the autoclave: release the SELECT button only when the preset language (e.g.: ENGLISH) appears on the display.
- Press START to reach the page in which it is possible to select the clean water tank filling mode. The various possibilities are:
  - **FILLING BY WATER PUMP** (the autoclave takes in the water from the front: point 10.1).
  - **FILLING FROM THE WATER MAINS** (the steriliser requires a purification system by resins).
  - **OSMOSIS** (the machine needs an osmotic purification system).
- Set the mode pressing PUMP, then keep SELECT pressed for 5 seconds: the long sound confirms the value is saved in the software. Switch OFF the sterilizer.
-  **Read and comply with the instructions of the purification system you are installing.**

Once the installation of the purification system is completed, turn the machine on and verify all the hydraulic connections while the tank is being filled.

 **THE MANUFACTURER DECLINES ALL RESPONSIBILITY FOR PROBLEMS DERIVING FROM INSTALLATION AND CONNECTIONS CARRIED OUT BY UNAUTHORIZED PERSONNEL.**

10.3 MANUAL DRAINING OF THE DIRTY WATER TANK

The capacity of the dirty water tank is 4.5 litres. To empty the tank, use the silicon tube supplied with the machine, by connecting it into the discharge joint (see photo). Push the joint towards the autoclave and wait for all the water to go out before disconnecting the tube. Pull the joint and disconnect the tube. Dirty water may contain contaminated residues and it is therefore recommended that protective gloves are used while draining water from the equipment.



Bacterial filter: replace after approx. 300 cycles or every three months at the latest.

Joint for water discharge: use the silicon tube supplied with the machine, by connecting it into the discharge joint. Push the joint towards the autoclave and wait for all the water to go out before disconnecting the tube.

REMOVE TUBE AFTER DRAINING.

10.4 AUTOMATIC DRAINING OF THE DIRTY WATER TANK

To eliminate the need to empty the dirty water tank manually, use the tap at the rear of the autoclave. Connect a hose to the tap, secure it with a metal hose clamp, and insert then the other end of the hose into a container or connect it directly to a water drain (paragraph 4.1). Leave the tap open: the dirty water will be drained automatically into the collection container or into the direct drain.

10.5 DRAINING AND CLEANING THE CLEAN WATER TANK

In order to empty the tank and gain access for cleaning purposes, proceed as indicated in paragraph 8.8. This operation should be performed only after disconnecting the water supply line from the mains (if the sterilizer is connected to an external water purifier).

10.6 WATER QUALITY TABLE (UNI EN 13060)

UNI EN 13060 – annex C	**Maximum value**
Evaporation 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 residues (except iron, cadmium and lead)	0.1 mg/l
Chloride	2 mg/l
Phosphate	0.5 mg/l
Conductivity (at 20°C)	15 µs/cm
pH value	5 to 7
Look	colourless, clean, without sediment
Hardness	0.02 mmol/l

NOTE: The use of water containing contaminants at concentrations exceeding those given in the table can considerably shorten the operating life of the equipment, seriously damaging its components, in particular way to the vaporizer, and invalidating the manufacturer's warranty.

11. STERILISATION TABLE

Sharp surgical instruments must be wrapped to ensure they are sterile at time of use. Data shown in table are only approximate: the type of sterilisation cycle selected should be based on data supplied by the manufacturer of the items to be sterilised. This autoclave is not suitable for the sterilisation of liquids. The overall cycle time can change due to various factors (e.g. weight and type of load, etc.).

Please, to consult the Declaration of Conformity of this appliance: the Class to which the appliance belongs is indicated in the "Category" box.

11.1 "**B**" TYPE AUTOCLAVE

Type and total duration of cycle	Cycle type	Steriliz. (min.)	Drying (Min.)	Pressure	Vacuum phase #	Maximum load	Materials and instruments to be sterilised
Helix /B&D test 35 min.	Test	3.30	4.00	2.06	3	Pack test only	Test cycle
Vacuum test 15 min.	Test	/	/	-0.80	1	Empty	Test cycle
121° hollow wrapped 43 min.	B	18.00	10.00	1.06	3	2.5 kg	Fragile hollow, stainless hollow and turbines (wrapped)
134° hollow wrapped 40 min.	B	5.00	10.00	2.06	3	2.5 kg	Stainless hollow and turbines (wrapped)
121° wrapped solids 43 min.	S	18.00	10.00	1.06	1	2.5 kg	Rubber and fragile solids (wrapped)
134° wrapped solids 35 min.	S	5.00	10.00	2.06	1	2.5 kg	Rubber and metal solids (wrapped)
PRION (134°) 51 min.	B	20.00	10.00	2.06	3	2.5 kg	Stainless hollow and metal instruments (wrapped)
121° Porous 55 min.	B	18.00	15.00	1.06	3	1 kg	Porous material (**not wrapped**)
134° Porous 55 min.	B	5.00	15.00	2.06	3	1 kg	Porous loads (wrapped)
121° Fast 33 min.	S	18.00	4.00	1.06	1	4 kg	Rubber and fragile solids (**not wrapped**)
134° Fast 25 min.	S	5.00	4.00	2.06	1	4 kg	Rubber and metal solids (**not wrapped**)
134° hollow open 30 min	B	5.00	4.00	2.06	3	4 kg	Stainless hollow and turbines (**not wrapped**)

ATTENTION: for the 23 Lts. models	1.	The duration of the drying is 5 minutes longer in every cycle.
	2.	The total times must be lengthened of about 15-20 minutes.
	3.	The tolerable load can increase of around 1 kg (0.5 kg on "Porous" cycles).

THIS AUTOCLAVE IS NOT CONCEIVED FOR THE STERILISATION OF LIQUIDS

11.2 NIGHT CYCLE

If the autoclave is not in use, it will switch to energy-saving mode with only the display background lit. Pressing any key (except the START/STOP button), the display will show the result of the last operation carried out (e.g. END CYCLE). Any cycle can be made a "Night cycle".

ATTENTION:

- After the "night cycle", to the opening of the door, it is normal to find it condenses of water on the gasket of the porthole and on the fund of the sterilization chamber.

- In case of alarms (see paragraph 14) repeat the operation!

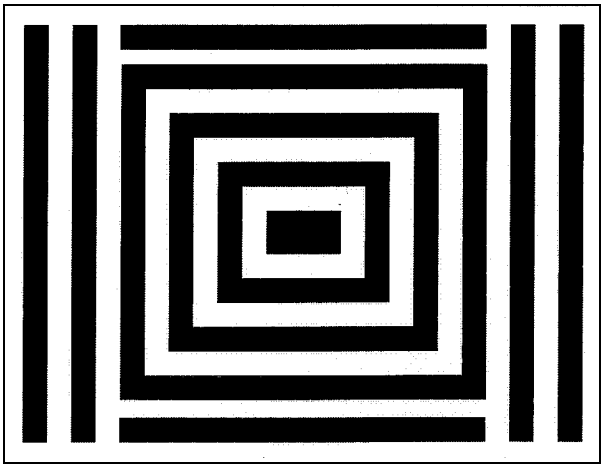
12. TEST CYCLES

12.1 "BOWIE & DICK" CYCLE

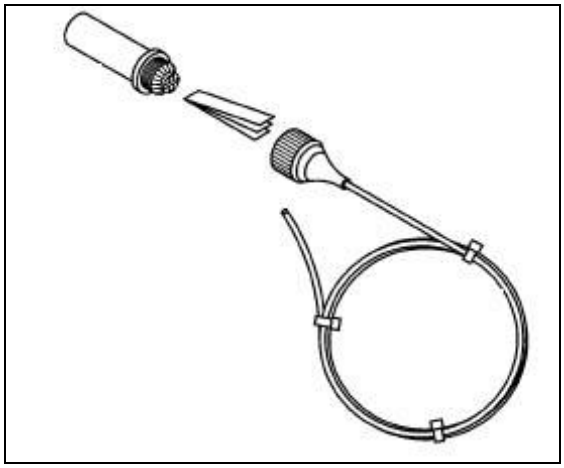
The Bowie & Dick cycle verifies that the steam penetrates properly inside a porous load. Carry out the test cycle after removing all trays from the autoclave chamber but the central one: place the test pack without any other instrument on this tray. Select the "Helix / B&D" cycle and start the cycle. The cycle result is confirmed by the test-pack result.

12.2 "HELIX TEST" CYCLE

This test should be performed to check steam penetration into a hollow load. Carry out the test cycle after removing all trays from the autoclave chamber but the central one: place the "Helix-Indicator System" on this tray (without any other instrument). Select the "Helix / B&D" cycle and start the cycle. The cycle result is confirmed by the test paper included in the test material (see drawing below). **Important: the cycle must be made when the autoclave is warm (immediately after having performed a cycle of work).**



Bowie & Dick Test



Helix test

12.3 VACUUM TEST

The Vacuum Test cycle is used to detect any pressure losses in the sterilisation chamber. This test should be carried out on an empty machine, prior to starting other sterilisation cycles.

The cycle cannot start if the temperature inside the sterilisation temperature is >40°.

Select "Vacuum Test" and start the cycle. The autoclave reaches the selected vacuum degree and will hold it for 15 minutes. The test result is given by the "END CYCLE" message appearing on screen and by the relevant printout. If the machine failed the test (AL0600 or AL0601), the door seal should be checked, cleaned or, if necessary, replaced (paragraph 15.1). Similarly, the sterilisation chamber rim should be checked also. Finally, the test should be repeated. A failed Vacuum Test does not bar the use of the steriliser in the near future. However, it is recommended that you contact a technical support centre as sterilisation cycles may be affected in the long term.

12.4 BIOASSAY

Together with other chemical tests, a bioassay may be required. This assay consists in sterilising one or more vials containing biological spores, together with the normal items to be sterilised. On completion of the cycle, remove the vials and leave them to cool for a few minutes (following the manufacturer's instructions for the control procedure). Sterilised vials should normally be broken using the special tools supplied by the manufacturer and then inserted into a specific incubator: together with these, another vial that has not undergone sterilisation should be added for comparison. After the incubation period, the difference in colour in the sterilised vials will indicate whether the cycle was successful.

13. RECOMMENDATIONS FOR STERILISATION

In order to prolong the life of both autoclave components and instruments, recommended procedures should be followed as well as local health authority instructions. Below is a list of some precautions to be followed.

1. Instruments should be cleaned with appropriate disinfectants immediately after use.
2. Brush the instruments to remove any residue.
3. Rinse the instruments in running water at room temperature.
4. Submit the instruments to ultrasonic bath treatment.
5. Rinse the instruments in demineralised water at room temperature.
6. Dry the instruments thoroughly.
7. Place the instruments on the sterilizer tray, so that the bags do not overlap. If you need to sterilise instruments which are not wrapped in bags, the tray should be covered with suitable napkins, to ensure that each sterilised instrument is perfectly dried. Follow the manufacturers' instructions for each instrument.
8. Instruments such as scissors or forceps should be opened slightly. Mirrors should be positioned face down.
9. Place bags with the paper side up.
10. If empty containers are sterilised, place them upside down to prevent water from accumulating.

The instructions listed above show how important the correct preparation of instruments is to successful sterilisation. Even a single instrument carrying traces of disinfectant placed in the steriliser may cause damage to the sterilisation chamber and the instruments inside. In such a case, the sterilisation process might be adversely affected even if no alarm is triggered.

14. ALARMS AND ERRORS

If alarms are visible on the display (paragraph 14.1), these will prevent any subsequent operation: **in order to reset an alarm press START and SELECT buttons at the same time** until the display temporarily goes out. Alarms are also logged on the printout (see table below). Conversely, errors (paragraph 14.2) do not allow the cycle to restart but indicate that an operation is required before continuing with sterilisation (e.g.: "DRAIN WATER").

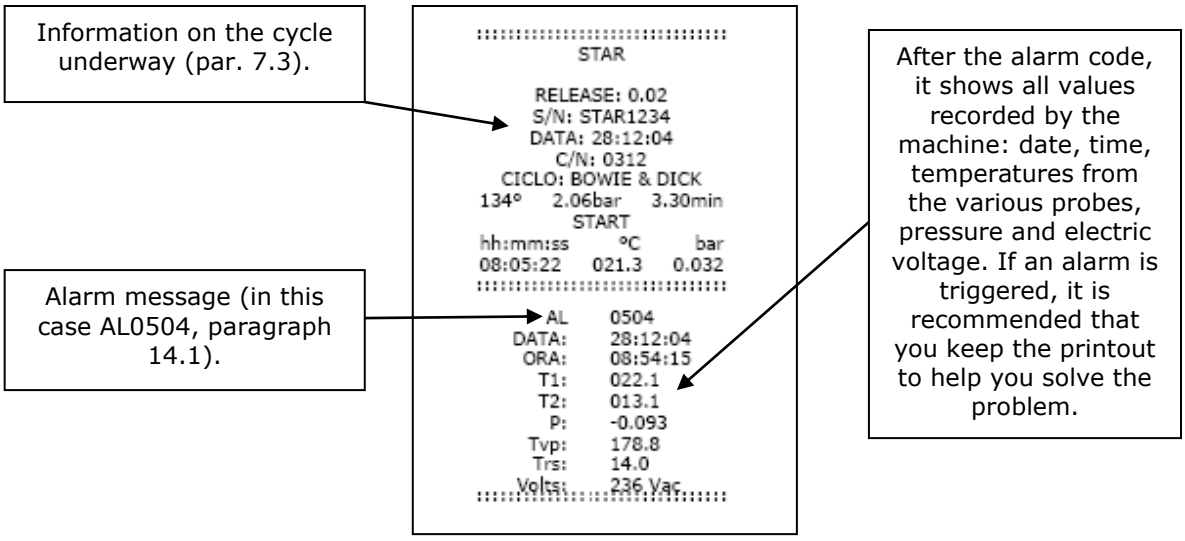
ATTENTION:

Any non-completed cycle means that the instruments are not sterilised: on the display there is a alarm code.

In the event of alarms, the cycle running should be considered invalid

(material not sterilised).

Interpreting ALARM codes:



14.1 ALARMS

Code and meaning	**Problem**	**Solution** Reset alarm = START/STOP+SELECT at least 5 sec.
AL0001 Cycle stopped by user.	Occurs if the START/STOP button is pressed for 1 second or longer	Reset the alarm and repeat the cycle.
AL0002 No mains supply	No mains supply: it is caused by the lack of mains supply.	
AL0003 Door open during cycle	Occurs if a control micro-switch detects an open door while the cycle is running.	Reset the alarm and repeat the cycle. If the problem persists, contact technical support.
AL0004 Timer stopped	The timer will stop when PCB battery power is insufficient.	Reset the time and date again following the instructions in paragraph 8.2 and 8.3. Leave the autoclave ON for at least one hour.
AL0005 High voltage	It is caused by a overload of the mains supply.	Reset the alarm and repeat the cycle.
AL0011 No 1st vacuum	The alarm is triggered only if the first vacuum is not reached.	Reset the alarm, regulate the door following the instructions in par. 15, clean the gasket and repeat the cycle.
AL0012 No 2nd vacuum	The alarm is triggered only if the second vacuum is not reached.	
AL0013 No 3rd vacuum	The alarm is triggered only if the third vacuum is not reached.	
AL0015 No vacuum when drying	Occurs if the preset vacuum degree is not reached during drying. If this alarm is triggered, the machine has already completed the sterilisation.	Reset the alarm and repeat the cycle. Check if the problem persists in the following cycles: in this case contact technical support.
AL0021 No 1st rise	The machine is unable to reach the 1st pressure value set.	Reset the alarm, fill the thank until the maximum icons appears on screen and repeat the cycle: if the problem persists in the following cycles, contact technical support.
AL0022 No 2nd rise	The machine is unable to reach the 2nd pressure value set.	
AL0024 No final rise	The machine is unable to reach the operating pressure.	
AL0031 No 1st pressure release	After reaching the first set pressure, the machine triggers an alarm.	Reset the alarm, remove the tray holder, clean the sterilisation chamber inside and repeat the cycle.
AL0032 No 2nd pressure release	After reaching the second set pressure, the machine triggers an alarm.	
AL0034 No final pressure release	The machine fails to release pressure while drying.	
AL0100 T1 probe encoding error	Alarm due to PCB self-diagnosis.	Reset the alarm, switch the machine off and on: if the problem persists, contact technical support.
AL0101 OPEN T1	System detects that T1 probe is open.	
AL0102 T1 short circuit	System detects short-circuit in T1 probe.	
AL0110 High temp. in T1 probe	T1 probe has exceeded the preset cycle temperature.	Reset the alarm then wait for 10 minutes with the door open. Repeat the cycle: if the problem continues contact the after sales service.
AL0111 Low temp. in T1 probe during sterilisation	Temperature detected by T1 probe during sterilisation is below the minimum set value.	

AL0200 T2 probe encoding error	Alarm due to PCB self-diagnosis.	Reset the alarm, switch the machine off and on: if the problem persists, contact technical support.
AL0201 OPEN T2	System detects that T2 probe is open.	
AL0202 T2 short circuit	System detects short-circuit in T2 probe.	
AL0210 High temp. in T2 probe	T2 probe has exceeded the preset cycle temperature.	Reset the alarm then wait for 10 minutes with the door open. Repeat the cycle: if the problem continues contact the after sales service.
AL0211 Low temp. in T2 probe during sterilisation	T2 probe detects excessively low values during sterilisation.	
AL0300 P probe encoding error	Alarm due to PCB self-diagnosis.	Reset the alarm, switch the machine off and on: if the problem persists, contact technical support.
AL0301 OPEN P	System detects that P probe is open.	
AL0302 P short circuit	System detects short-circuit in P probe.	
AL0310 High pressure during sterilisation	P probe detects excessively high values during sterilisation.	Reset the alarm, remove the tray holder, clean the sterilisation chamber inside and repeat the cycle.
AL0311 Low pressure during sterilisation	P probe detects excessively low values during sterilisation.	Reset the alarm, clean the gasket and repeat the cycle: if the problem continues call the after sales service.
AL0400 TVP probe encoding error	Alarm due to PCB self-diagnosis.	Reset the alarm, switch the machine off and on: if the problem persists, contact technical support.
AL0401 OPEN TVP	System detects that TVP probe is open.	
AL0402 TVP short circuit	System detects short-circuit in TVP probe.	
AL0404 Low temp. in TVP probe	TVP probe does not reach operating temperature.	Reset the alarm and repeat the cycle. If the problem persists, contact technical support.
AL0405 High temp. in TVP probe	TVP probe has reached a temperature higher than operating threshold.	Reset the alarm then wait for 10 minutes with the door open. Repeat the cycle: if the problem continues contact the after sales service.
AL0500 TRS probe encoding error	Alarm due to PCB self-diagnosis.	Reset the alarm, switch the machine off and on: if the problem persists, contact technical support.
AL0501 OPEN TRS	System detects that TRS probe is open.	
AL0502 TRS short circuit	System detects short-circuit in TRS probe.	
AL0504 Low temp. in TRS probe	Temperature does not reach operating temperature.	Reset the alarm and repeat the cycle. If the problem persists, contact technical support.
AL0505 High temp. in TRS probe	TRS probe has reached a temperature higher than operating threshold.	Reset the alarm then wait for 10 minutes with the door open. Repeat the cycle: if the problem continues contact the after sales service.

AL0600 Excessive drop during the VACUUM TEST stabilisation phase	An excessive pressure drop occurred during the first 5 minutes of the stabilisation phase, while performing the VACUUM TEST cycle.	Take the tray holder out: clean and dry thoroughly the sterilisation chamber. Repeat the cycle: if the problem continues you have to do a Vacuum test cycle when the autoclave is cold.
AL0601 Excessive drop during the VACUUM TEST maintenance phase	An excessive pressure drop occurred during the first 10 minutes of the maintenance phase, while performing the VACUUM TEST cycle.	
AL0700 T1/T2 comparison	Conflicting temperature values detected by the two interior sensors during sterilisation.	Reset the alarm, fill the thank until the maximum icons appears on screen and repeat the cycle: if the problem persists in the following cycles, contact technical support.

14.2 ERRORS

The following table contains a list of messages which may appear on display:

MESSAGE	CAUSE	SOLUTION
OPEN THE DOOR	At the time of power-up you are prompted to open the door so that the machine can perform a pressure check-up.	Open the door to allow automatic setting of atmospheric pressure (two beeps).
DOOR OPEN	A cycle has been started with the door open.	Close the door and start the cycle.
DOOR NOT LOCKED	Even though the door is perfectly closed, it is read as "not locked" due to mechanical reasons (if this error persists, contact technical support).	Press the DOOR button, open and close the door, then press the START button to start the cycle.
TO LOAD WATER	A cycle has been started with the clean water minimum level message flashing on the display.	Fill the tank with clean water (paragraph 10.1).
TO DRAIN WATER	A cycle has been started with the dirty water maximum level message flashing on the display.	Drain dirty water from the tank (paragraph 10.4).
FULL WATER RESERVOIR	Attempt to fill the tank with clean water with the full tank icon already present on the display.	Disconnect the water hose. It is now possible to start a new cycle.
DOOR STILL LOCKED	Door lock system fails to open completely when cycle terminates.	Close the door again and start a new cycle: stop the cycle after a few seconds with the START/STOP button (paragraph 6.2), reset the alarm (paragraph 14), then try opening the door with the DOOR button. If the error persists, contact technical support.
CHAMBER TEMP.>40°	Attempt to start a VACUUM TEST cycle with a chamber temperature higher than 40°C; wait for temperatures to drop before starting the test cycle.	Open the door and wait for the temperature reading on the display to fall below 40°C.
REPLACE RESINS	The water treatment system has outlived its effectiveness. After finding the *SOLUTION,* press the PUMP key for 5” (until it makes a sound) to clear the error.	Reset the water treatment system (replacing the cartridges), referring to the instruction manual.
SERVICE	The machine has run an excessively large number of cycles and needs periodic overhauling by a technician.	Contact your dealer as soon as possible and request the services of a technician.

15. MAINTENANCE

Disconnect the equipment from the mains before carrying out any maintenance.

15.1 DAILY MAINTENANCE

Daily maintenance includes keeping the door seals in good working order, cleaning the chamber rim area (very important for a successful test cycle) and check the water levels in the tanks.

- DOOR SEAL: clean the door seal using the soft part of the sponge supplied with the equipment. Cleaning should carry out to remove any impurities which might affect the test cycles.
- CHAMBER RIM: it is the outer rim of the sterilisation chamber with which the seal makes contact. Use the coarse part of the sponge supplied.
- WATER LEVELS (paragraph 6.3): before starting another sterilisation cycle, check the water level in the tanks.
- GENERAL SURFACE CLEANING: use a cloth to remove dust and other deposits from the top of the machine.

15.2 WEEKLY MAINTENANCE

Weekly maintenance requires a visual check and cleaning of the inside of the sterilisation chamber. Remove the trays and tray holder from the chamber before cleaning.

- CHAMBER INTERIOR: Use the coarse part of the sponge supplied to remove small impurities from the bottom of the chamber. If lime deposits are found, it is advisable to check the quality of water being used.

15.3 QUARTERLY MAINTENANCE

Quarterly maintenance requires lubrication of the door hinges and replacement of the bacterial filter.

- HINGE LUBRICATION: spray the two door hinges with small quantities of silicone oil.
- REPLACE THE BACTERIAL FILTER: replace the filter approximately every 300 cycles (NB: bacterial filter life largely depends on usage rather than time. Notwithstanding this fact, it is recommended that the filter should be changed at least every three months, so as not to reduce the autoclave drying performance). A clogged bacterial filter may lead to some difficulties in opening the door on completion of the sterilisation cycle.

15.4. YEARLY MAINTENANCE

The sterilizer is fundamental to the protection of patient and operator alike: even though the electronic controls of these machines are increasingly reliable, it is good practice to carry out a functional check of the equipment at least once a year. This check should be carried out by authorised service centres only, with calibrated and certified instruments, in order to guarantee the equipment a long life and reliable operation (validation). To establish the proper check procedures, refer to the instructions issued by the relevant health authority.

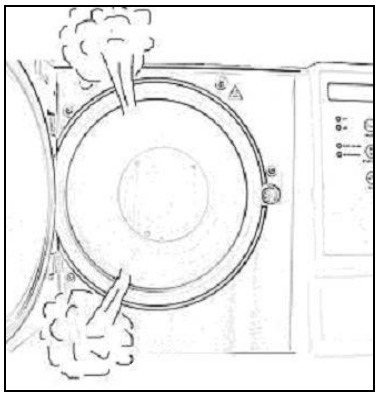
- YEARLY VALIDATION: validation requires the use of instruments calibrated by specialist centres to check the sterilisation cycle parameters. This check includes inspections of pressure and temperature probes and the timer. On request, the manufacturer issues a yearly test certificate for machines returned to its premises for maintenance and checks.

15.5 DOOR REGULATION

ATTENTION:

If the door is not correctly regulated it might create different problems:

- If it is too tight, at the end of the cycle the motor of the door would have problems in opening the door. You have to press many times the DOOR button to open the door.
- If it is too loose, there might be either steam leakages during the cycle or an alarm connected to a vacuum phase.



In case of steam leakage from the upper side see picture 1
In case of steam leakage from the bottom side see picture 2

PICTURE 1

PICTURE 2

Screw only once and start a new cycle

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16. TECHNICAL FEATURES

MECHANICAL SPECIFICATIONS

Operating temperature		+5° +30°C
Max. operating altitude		2.000 m
Max. relative moisture at 30°C		80%
Max. relative moisture at 40°C		50%
Overall dimensions: L x H x D	15 & 18 Lts.	23 Lts.
B type	505 x 400 x 615 mm	505 x 400 x 690 mm
S & N type	445 x 400 x 615 mm	445 x 400 x 690 mm
Weight (with empty tanks)	15 & 18 Lts.	23 Lts.
type	B=45 / S=40 / N=35 Kg	B=50 / S=45 / N=40 Kg
Weight (with full tanks)	15 & 18 Lts.	23 Lts.
type	B=50 / S=45 / N=40 Kg	B=55 / S=50 / N=45 Kg
Overall dimensions (door open)		350 mm
Weight per unit area of support		Max 32.46 N/cm^2
Volume		Max 0.14 m^2
Colour		RAL9002
Material		AISI304 Steel/FeP01 Steel
Noise level at 1 mt distance		53.6 dbA
Noise level in front of the display		62.2 dbA

ELECTRICAL SPECIFICATIONS

Supply voltage	230 VAC (+/-10%)
Power	2400 W
Frequency	50-60 Hz
Supply cable (L 1.5m)	2+1 x 1.5mm^2
Fuses	6.3x32mm – T12A
Max. transmitted heat	5.76 MJ/h (1370 kcal/h)
Insulation class	1

CHAMBER SPECIFICATIONS

Max. operating pressure			2.3 bars (relative)
Max. operating vacuum			-0.90 bars (relative)
Max. operating temperature			140°C
Material			Stainless steel AISI 304
Dimensions: ØxP	15 Lts.	18 Lts.	23 Lts.
	236 x 350 mm	236 x 381,5 mm	236 x 530 mm

CLEAN WATER TANK SPECIFICATIONS

Max. capacity	4.5 litres
Cycles per tankful (before the min. level indicator lights up)	15 Lts.= ~8 18 Lts.= ~6 23 Lts.= ~5
Material	Polyethylene

DIRTY WATER TANK SPECIFICATIONS

Max. capacity	4.5 litres
Cycles per tankful (before the indicator monitoring the max. level of used water lights up)	15 Lts.= ~8 18 Lts.= ~6 23 Lts.= ~5
Material	Polyethylene
Maximum temperature of drained water	50°C

BACTERIAL FILTER DATA

Maximum diameter	56 mm
Max. allowed filtering capacity	0.3 micron
No. of cycles before replacement	~300

TRAY HOLDER SPECIFICATIONS

Material	Stainless steel

TRAY SPECIFICATIONS

Material	Anodised aluminium
No. of trays packaged with unit	4

CLASS OF POLLUTION	**2**

17. WARRANTY

For all defects of conformity existing at the time of delivery of the unit and attributable to actions or omissions by the manufacturer

A. The manufacturer guarantees this product for a period of:

1. 24 months or 1500 cycles on the whole product and
2. 5 years or 5000 cycles on the chamber only.

In both cases (1 and 2) the warranty expires when one of the two aforementioned conditions is met. Labour is excluded from the warranty, if it does not take place at the manufacturer's site.

The warranty period begins on the date the machine is delivered to the customer. In the event of any contestation, the date of delivery is considered valid as evidenced by a document valid for tax purposes (packing slip, invoice, tax receipt or similar) which must contain the name of the seller, the date of delivery, the identification details of the product (serial number and model) and the sales price. The installation documents present inside the product must be completed in full, stamped and signed by both the dealer and the customer and sent to the manufacturer, otherwise the warranty will not be effective.

B. In order for this WARRANTY to be fully valid, the following is necessary:

1. All installation operations must have been carried out strictly following the instructions provided in this USER INSTRUCTION MANUAL.
2. All use and routine maintenance must be carried out according to the USER INSTRUCTIONS.
3. All planned "SERVICE" agreement interventions that the product needs and indicates must be carried out. The interventions necessary once the "SERVICE" agreement expires are always excluded from the warranty.
4. Any repair carried out under the warranty must be performed by authorised personnel and only original spare parts used. Parts replaced under the warranty must be returned to the supplier (or they will be charged for), with the exception of agreements stipulated in advance between the parties.

C. THE FOLLOWING ARE NOT COVERED BY THE WARRANTY:

1. Labour, when this does not take place at the manufacturer's site.
2. Damage resulting from transportation, with the exception of agreements stipulated in advance between the parties.
3. All components that manifest a lack of conformity resulting from incorrect installation of machinery.
4. Damage caused by poor maintenance, neglect or carelessness of usage by the user and failure to comply with what is set out and recommended in the USER INSTRUCTIONS booklet.
5. Damage caused by tampering with the product or product parts.
6. Damage resulting from all other causes not attributable to the manufacturer.
7. All components subject to normal wear and tear (e.g. polycarbonate keypad, tubes supplied, seals, trays, filters etc.) and other accessories if it cannot be proven that it is the result of a manufacturing defect.
8. Costs of delivering spare parts and/or finished products.

D. LIMITATIONS OF THE WARRANTY:

1. The purchaser is not entitled to the replacement of the complete machine if the defect is not reported within two months of the date of purchase.
2. It is at the discretion of the manufacturer whether to repair or replace a component under the warranty. This does not include, however, the cost of labour and travelling expenses for personnel.
3. No compensation is awarded for machine downtime.
4. The warranty is automatically considered null and void if the machine is tampered with, repaired or modified by purchaser or third parties not authorised by the manufacturer. For interventions, the purchaser must contact the dealer or service personnel from the manufacturer only.

The manufacturer disclaims all liability for any damage or injury caused, directly and/or indirectly, to persons, property and animals due to failure to observe the general safety conditions and requirements set out in the USER INSTRUCTIONS MANUAL, in particular concerning the instructions for product installation, use and maintenance.

NOTE:

Manufactured by MAMMOOTH Srl on behalf and solely for **LTE SCIENTIFIC LTD**

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Original Instructions