midmark™

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

B18, S18 & N18
B23, S23 & N23

CE 0051

Code: STD070024

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0. TABLE OF CONTENTS

1. GENERAL WARNINGS

Use of the autoclave is strictly prohibited to people under the influence of alcohol, drugs and/or medicines that may alter the person's state of alert. Misuse of or failure to follow the instructions in this manual can cause danger to the user and persons around the device.

1.1 WARNINGS

→Please read this instruction manual carefully before starting to use the device, in order to perform the required operations correctly: **DO NOT** therefore, perform operations other than those described in this booklet. The manufacturer disclaims any liability for direct or indirect damage or injury to property, persons or animals caused by improper use of the equipment.

→The machine should only be used by responsible adult personnel.

→Position the machine in a place that cannot be accessed by children.

→Install the device so that it is easy to access the plug.

→Do not use the machine near flammable or explosive sources.

→Use the machine in a dry, protected place.

→Check the condition of the power cord periodically: do not operate the device if the cable is not fully intact.

→Do not perform maintenance while the machine is operating or plugged in.

→Do not approach the machine holding flammable material.

→Always wear personal protective equipment, complying with applicable directives.

→Read the paragraph on technical specifications carefully before operating the device.

→For your safety, we ask you to pay close attention to the instructions below.

→The sterilizer must be used in a controlled environment and by trained personnel.

→Do not perform maintenance or cleaning operations while the machine is operating or plugged in.

→Do not stand in front of the sterilizer when in use.

→The sterilizer has not been designed to sterilize food products. Do not insert food.

1.2 INTENDED USE

Dear Customer,

This autoclave is designed to sterilise small tools and equipment for medical, dental and veterinary purposes using water vapour.

It is used in outpatient, general practitioners', dentistry and veterinary clinics. It is also used to sterilise materials and equipment designed to come into contact with blood or physiological fluids, where sterilisation loads are extremely specific.

Therefore, the characteristics must be diversified based on the required sterilisation cycles.

For this reason, this device must be used by professional and trained personnel.

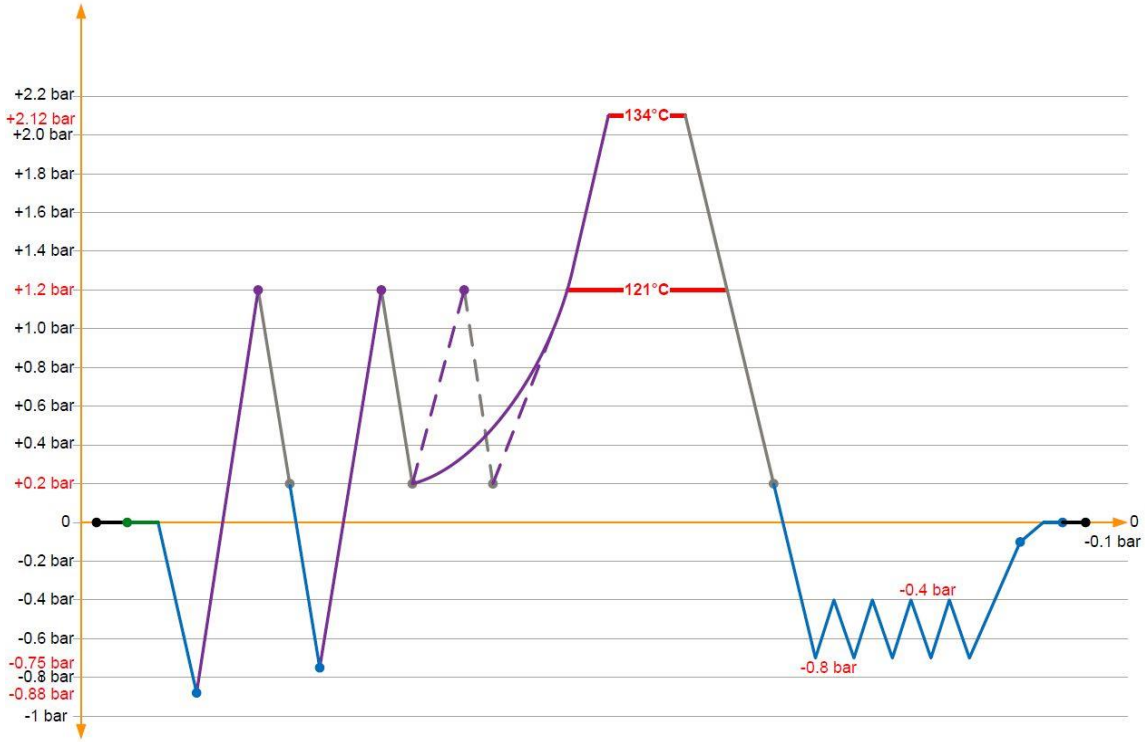
The sterilizer and its equipment must only be used to sterilize the type of products for which they have been designed. We invite you to read the Declaration of Conformity for this device.

In chapt. 11 – *Sterilization Tables* - you will find all the information necessary in order to determine what kinds of cycle you should use to sterilize all your instruments.

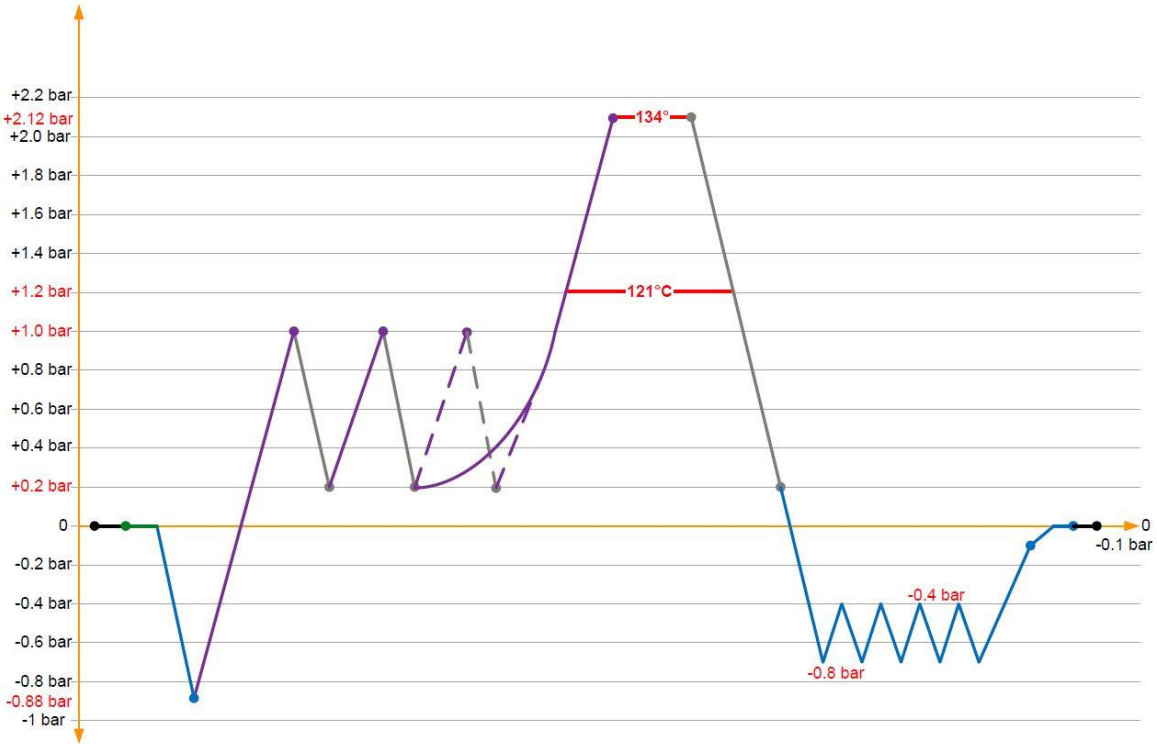
1.3 GRAPHIC EXAMPLE OF VARIOUS TYPES OF CYCLES

The autoclave you have purchased has several sterilization cycles so that you can choose the best possible one based on the type and volume of the load you are going to sterilize. Below are summarised examples of the various available cycles.

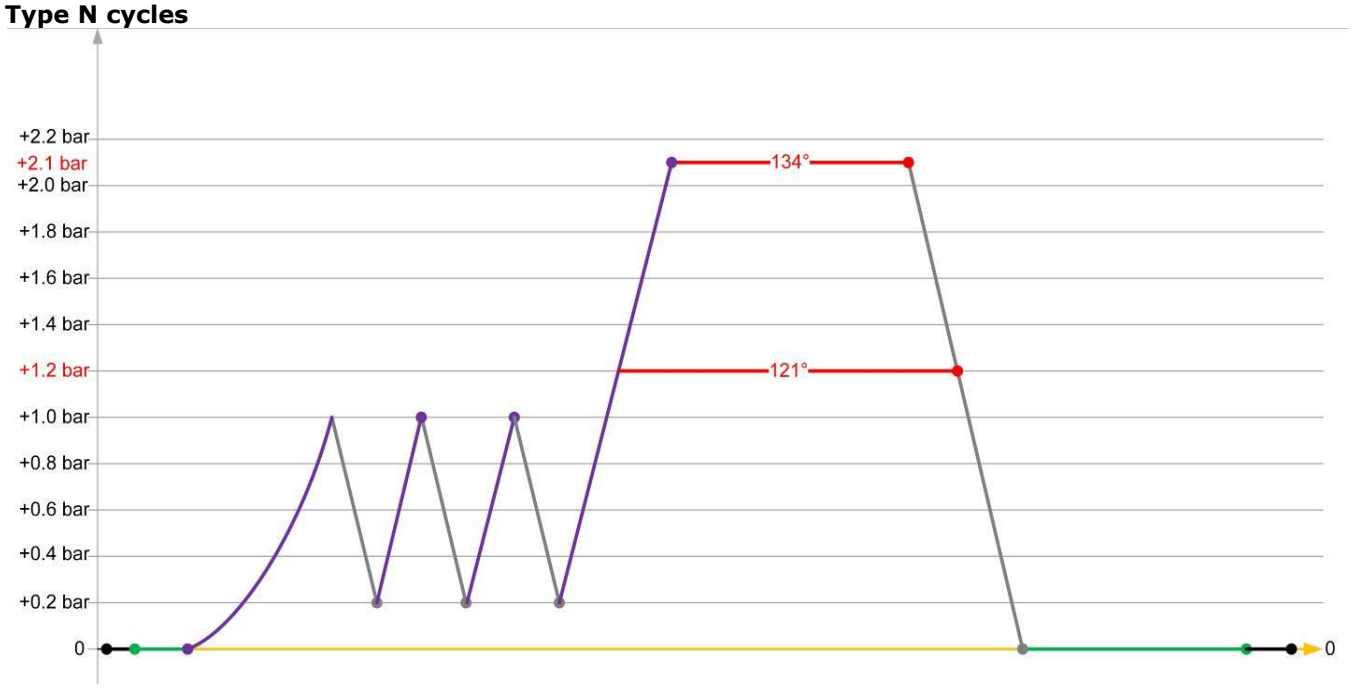
Type B cycles



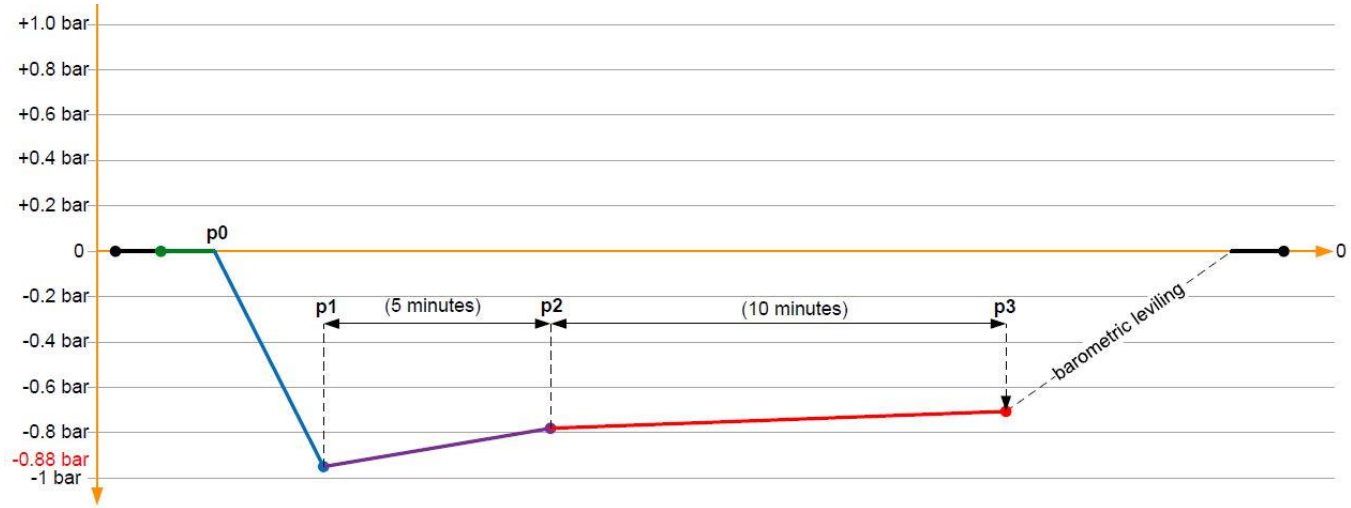
Type S cycles



Type N cycles

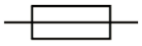


Vacuum Test



2. SAFETY

2.1 SYMBOLS USED

	Indicates the manufacturer of the medical device as defined in Directive 93/42/EEC		Indicates the date of manufacture of the medical device
	Indicates the serial number of the specific medical device		Indicates that the instructions for use must be consulted
	Indicates that the user should refer to the instructions for use for important precautionary information that cannot be reported on the medical device.		MIN and MAX permitted temperature range
	CE marking	**0051** **2399**	Identification number of the notified body that issued the EC product certificate of the medical device (0051) and / or of the pressure equipment (2399), if applicable
	Fuses (chapt.16)		Earth connection
	Indicates surfaces at high temperature		Indicates that the user must pay special attention to the instructions shown in the user manual
	Indicates a danger of crushing		Indicates the risk of electric shock due to the presence of voltages
	Maximum permitted load for each sterilisation cycle, expressed in kilograms (Kg)		Cycle suitable for sterilising packaged material
	Indicates a button to be pressed one or more times		Material subject to Directive 2002/96/EC for Waste Electrical or Electronic Equipment
For the meaning of the control panel symbols, see chap. 6			

2.2 SAFETY DEVICES

The safety devices envisaged are as follows:

→Door control micro-switches and automatic coupling system are independent of one another and ensure the door system is closed and locked correctly. In the event of a problem, an alarm alerts the user that the cycle cannot start. If the cycle is already running and a problem is detected, the microprocessor interrupts the process and immediately discharges the machine pressure.

→Different mechanical temperature thermostats ensure that the temperature of the various components does not accidentally exceed the required temperature. The thermostats are reset manually.

→Electronic temperature sensors continuously monitor all critical points of the machine, preventing overheating errors during the work process.

→A safety valve against overpressure eliminates the risk of explosion. Safety valve inspection is reserved for Regulatory authorities and/or authorized technicians and is governed by specific law, in force in the country of installation. Please refer to the user manual of the valve provided.

→An electronic pressure transducer monitors all the solenoid valves and opens them in case of overpressure.

→Two fuses, positioned inside the autoclave.

→Tests have been carried out on the container under pressure, which is an integral part of the machine, in accordance with that required by directive 2014/68/UE.

2.3 OPERATOR TRAINING

The operators in charge of using the autoclave must be properly educated and trained.
In particular, the RESPONSIBLE AUTHORITY (that is, *the individual or group responsible for the use and maintenance of the machine*) must ensure that all personnel who use the autoclave have been trained to use it correctly and safely. The responsible authority must also ensure ongoing training for all operator personnel through training courses. Operator attendance at must courses must be recorded and these attendance reports must be archived. The operators must demonstrate a correct understanding of the information presented during the training courses.

2.4 SAFETY PROCEDURES FOR POTENTIALLY DANGEROUS OPERATIONS

The operator must use proper personal protection equipment to remove materials from the sterilisation chamber (such as thermally-insulated gloves provided by the manufacturer). The materials inside the sterilisation chamber must always be considered dangerous since they can reach high temperatures and any time and may become possible sources of burn hazards. The sterilisation chamber and the door can reach very high temperatures and; therefore, may represent potential burn hazards. Steam or hot liquids may be present inside the sterilisation chamber. THE RESPONSIBLE AUTHORITY must properly educate operators so they wear suitable personal protection equipment when using the autoclave and especially when removing sterilised materials from the sterilisation chamber.

ATTENTION:
opening the steriliser door can cause contact between the final user and high temperature steam. Contact your doctor immediately in the event of a burn.

3. STORAGE AND PACKAGING

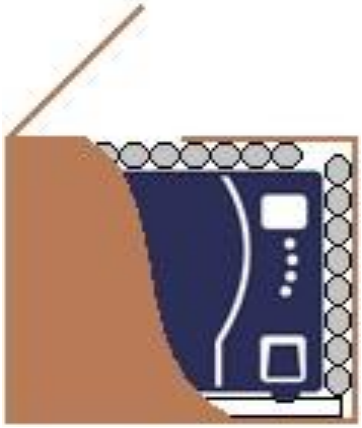
3.1 STORAGE

→Upon receipt of the product, check packaging conditions prior to storage. In case of damage, immediately contact your dealer, the shipper and the carrier who performed transport.

→The autoclave is a delicate device, and must therefore be transported without excessive knocks, without impact and WITHOUT OVERTURNING IT.

→Store the product still in its packaging in dry and protected areas at a temperature approximately between 5°C and 30°C. Variations within ± 30% should not cause damage to the product. In any case, during the first commissioning (chapter 9), special attention should be paid especially to the water pumps.

3.2 PACKAGING



→The sterilizer is placed inside the cardboard box with a polyethylene protective bag. To protect it from accidental impact, it is packed surrounded by polystyrene, cardboard, polyurethane or other materials suitable for the purpose.

→Customers are advised to keep packaging throughout the warranty period: any repairs without the original packaging will be charged for new packaging at the time of return.

→The cardboard packaging used to transport the autoclave IS NOT STERILE.

3.2.1 Unpacking and installing the autoclave

Unpacking and positioning of the machine must be done by at least two people together, following the instructions below.

→Remove the top adhesive tape and cut the strapping holding the cardboard box to the wooden pallet (if present).
→Remove the metal fastening points to avoid scratching or cutting during machine unpacking. →Open the cardboard box and lift the machine.
→Remove the machine from its cardboard box, picking it up from the side without creating stress on the plastic parts.
→Connect the plug to an earthed socket (chapt. 16).
- →Do not replace the original plug with Others.
- →Do not use additional connections.
- →Do not connect to a power strip or similar.
- →Make sure that the system to which the sterilizer is connected is in compliance with the law and can support the required load (point 16).

→Turn on the machine via the main switch on the side of the control panel.
→Open the door by pressing the DOOR button.
→Remove the accessories kit and turn off the machine.
→**Read the user instructions.**

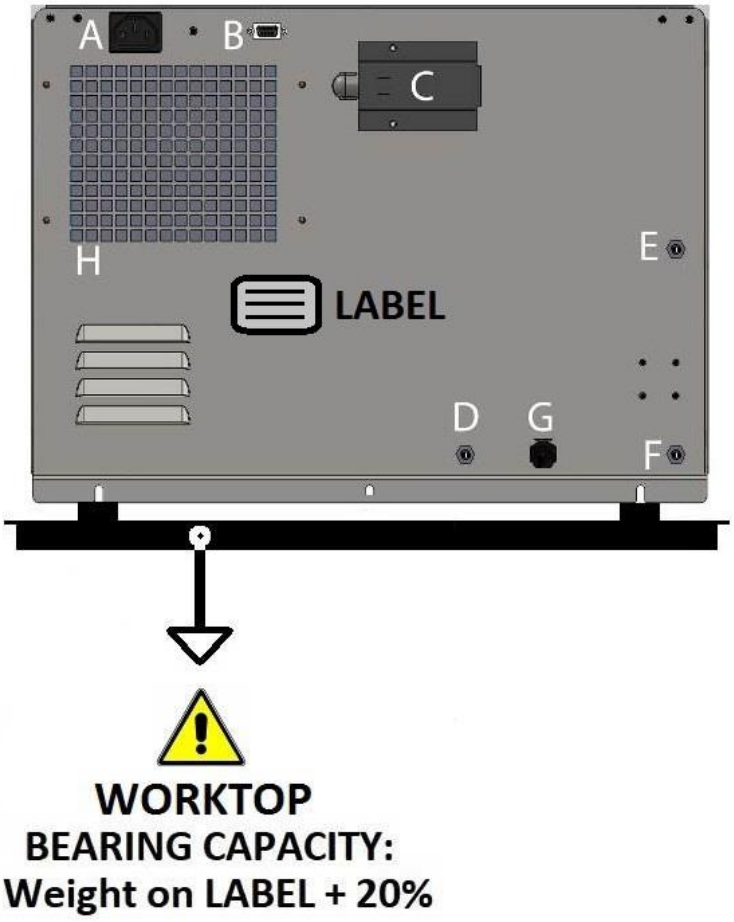
4. INITIAL INSTALLATION

It is vital that the autoclave be correctly installed for its proper operation. Below are the instructions for correct installation:

→ Remove the autoclave from the packing box as described in chapter 3.2.1.
→ Install the machine in a laboratory where only authorised personnel can access it.
→ The work environment must be adequately lit and sufficiently ventilated.
→ The autoclave is supplied already levelled. The sterilisation chamber is slightly inclined towards the rear. Unscrew the front feet only if the supporting surface is not regular.
→ Leave at least 5 cm of free space between the wall and the back of the autoclave.
→ Place the autoclave so that the sterilisation chamber can be inspected.
→ Do not install the machine next to heat sources (other autoclaves, ovens, etc.).
→ To avoid damage to people, animals or things, place the machine in a way to allow the possible outflow from the safety valve in a safe place.

4.1 HYDRAULIC CONNECTIONS

The hydraulic connections of the machine are of primary importance to its proper operation. Carefully read chapter 10 to understand what options are available, take note of the legend below, and finally proceed with the connections as described later in this chapter.

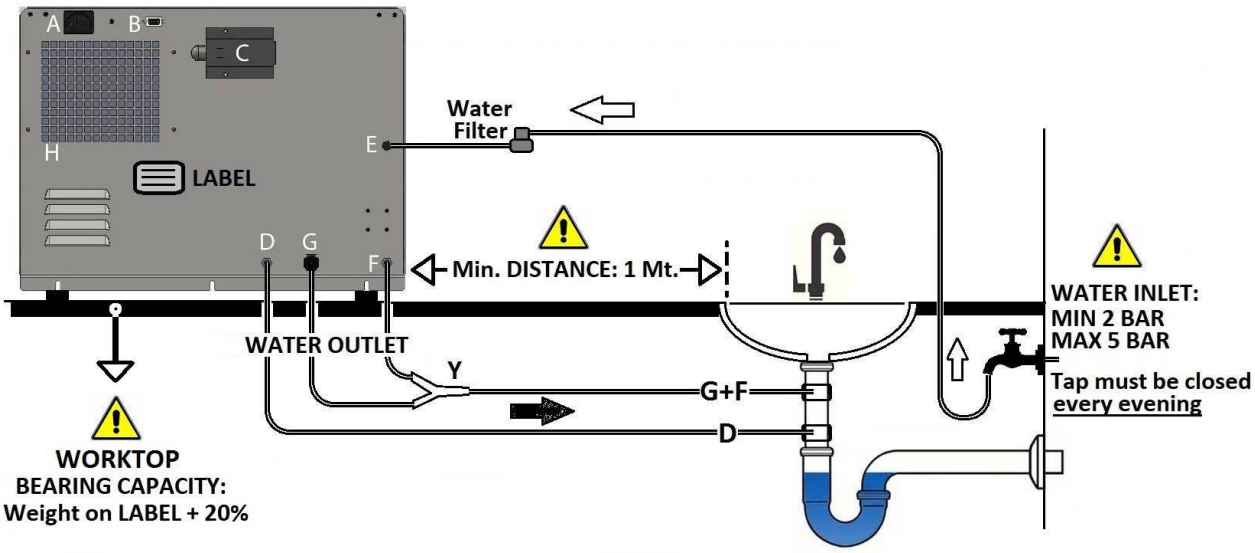


KEY:
A - Socket to which the provided power cord is connected.
B - RS232 serial connection: do not connect any PC to this socket. 5V on pin 9.
C - Safety valve (chapt.15.4).
D - Vent for condensation and safety from overflow.
E - Fitting for inlet of purified water from a resin system or reverse osmosis (MAX 5 Bar).
F - Fitting for discharge of water eliminated from the osmosis system (optional).
G - Discharge fitting for water used for sterilization.
H - Ventilation grille. Always leave at least 5 cm of space to allow for rear ventilation.

4.1.1 Autoclave with ROSI system on board

The autoclave equipped with the optional ROSI system is supplied with the software already programmed.
For the correct operation of the machine, the hydraulic connections must be made according to the following diagram.

It is mandatory to comply with all the instructions provided in the hydraulic connection diagram.



NOTE: The G and F outlets can be unified using the "Y" fitting supplied in the ROSI kit.

FILLING PROCEDURE (**<u>responsibility of the Installer technician</u>**):

→ Open the left side of the autoclave and turn the blue tap to the OPEN position.
→ Switch on the autoclave and wait a few seconds: the water will begin to enter into the filter cartridge. The eliminated water will exit from the rear pipe, going toward the drain.
→ At this point, wait 60 to 120 seconds then slowly rotate the tap to the CLOSED position.

OPEN

CLOSED

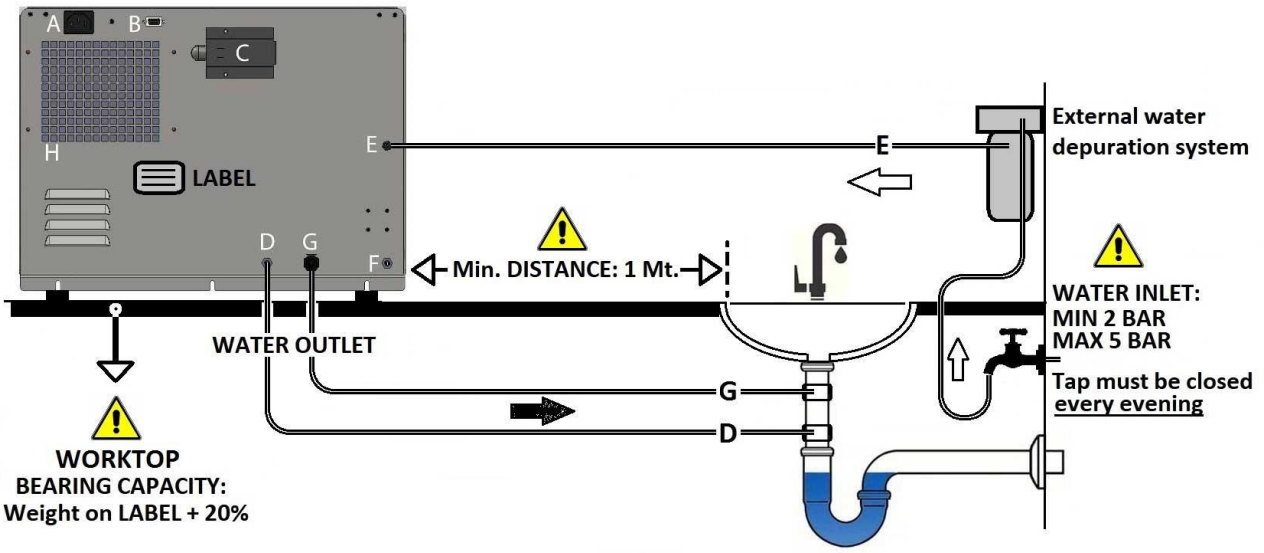
Slow tank filling will begin from this point. The whole process can be long (15-20 minutes) and may become blocked automatically by the software even if the Max Lev. has not been reached). **Make sure there are no water droplets leaking from fittings, pipes, connections or plastic cartridges.**

After completing the hydraulic connections, make sure that there is no water leakage during tank filling.
The manufacturer denies all responsibility for any problems arising from installations and connections not in accordance with the operating instructions and/or performed by unauthorized personnel.

4.1.2 Autoclave connected to an external purification system

When the autoclave is connected to an external purification system, the autoclave software must be programmed following the instructions given in chapter 8.1. The connections are described in the diagram given below.

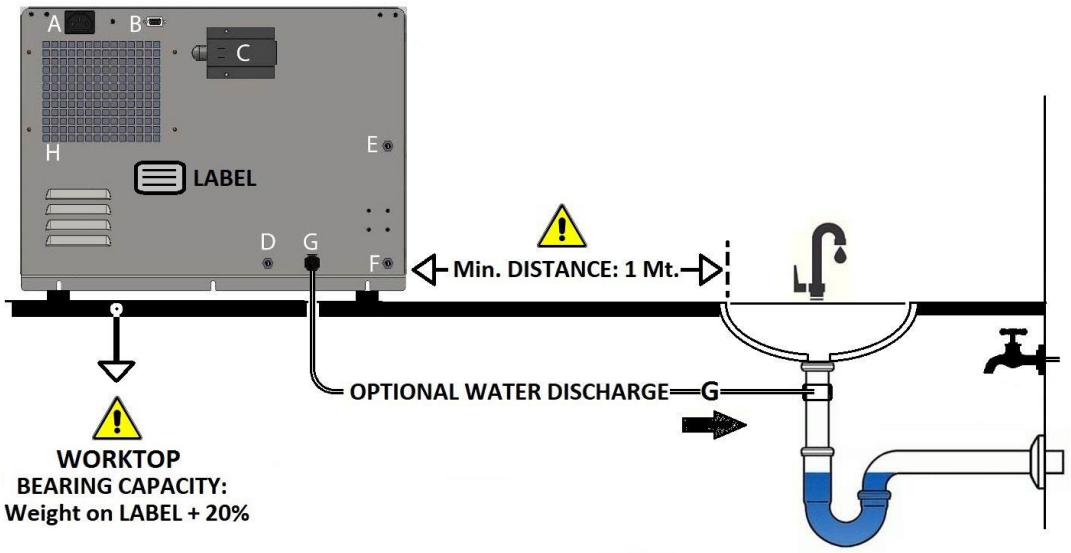
It is mandatory to comply with all the instructions provided in the hydraulic connection diagram.



After completing the hydraulic connections, make sure that there is no water leakage during tank filling.
The manufacturer denies all responsibility for any problems arising from installations and connections not in accordance with the operating instructions and/or performed by unauthorized personnel.

4.1.3 Autoclave standard (not connected to a purification system)

The standard autoclave does not require any software control or mandatory water connection. However, to speed up the customer's work, the G fitting (water drain) can be combined with the siphon drain. In this way, the discharge of the used water is automatic and the customer no longer has to perform any manual operations.

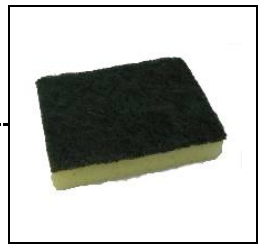


5. SUPPLIED ACCESSORIES

At least 4 trays and the accessories contained below are provided together with the tray holders.

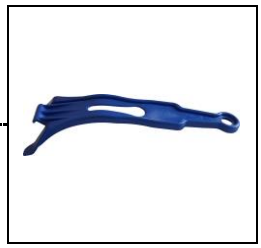
CLEANING SPONGE

The sponge must be used as described in chapt.15.



TRAYS REMOVAL HANDLE

Use the handle to remove hot trays from the machine.



1 LOADING TUBE

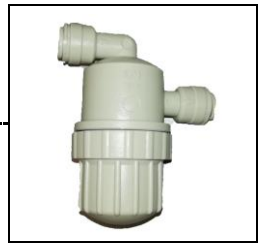
The loading tube is a normal silicone hose without any connector on its end.
Insert one end of the tube into the water vessel and connect the other end to the hose connection at the top left of the boiler edge: start loading via the PUMP/WATER button. See chapt.10.

1 DISCHARGE TUBE:

The discharge tube is easily identifiable as it has a plastic fitting on one of its ends.
The discharge tube should be used as described in chapt.10 for the manual discharge of used water (black fitting on the front of the machine).
The tube can also be used to automate the discharge of dirty water as described in chapt .10. In this case, it must be connected to the black fitting at the rear of the machine (chapt.4.1).
For maintenance and/or transport purposes, the same tube can be used to drain water from the clean water tank (white fitting on the front of the machine).
In any case, read the instructions in chapts. 4 and 10.

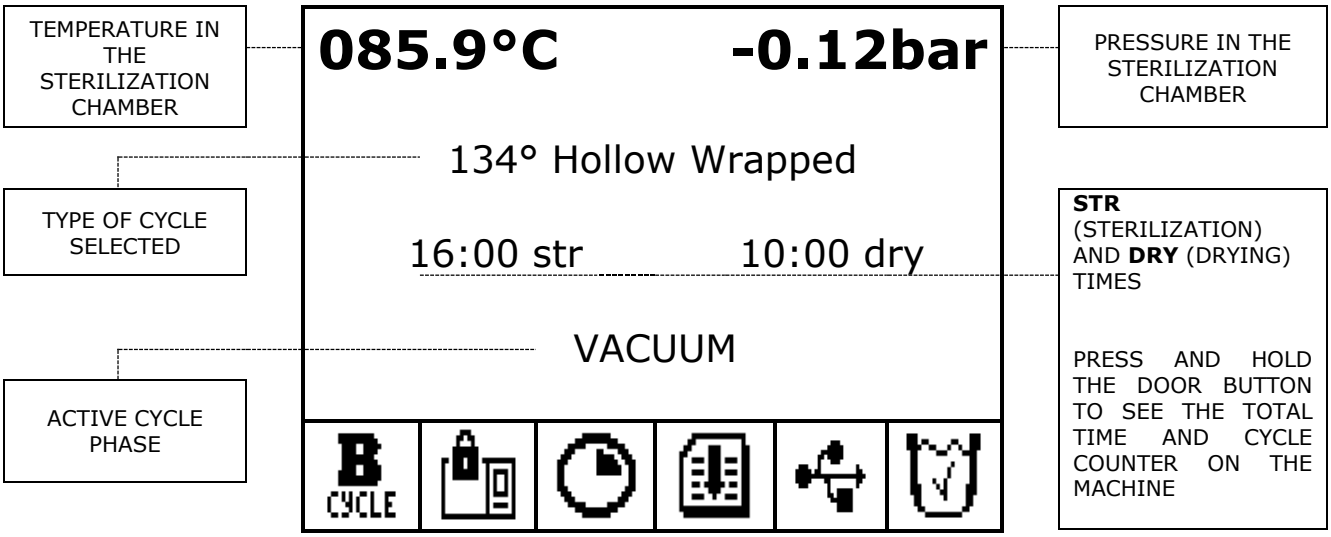
ROSI PROTECTION FILTER

The ROSI protection filter is supplied only when the autoclave is purchased with the built-in osmosis system. The installer technician must place the protection filter between the fitting **E** and the water tap (read instruction in chapter 4).



6. CONTROL PANEL

6.1 DISPLAY



SERVICE ICON (point 6.3)

6.2 KEYPAD

DOOR

Used to open the door of the machine at the end of a cycle.
Press and hold this button to view the total STR+DRY time and the machine cycle counter.

SELECT

Use this key to select the cycle type to be used. It also provides access to the user menu (chapt.8)

PUMP WATER

Is used to fill water in the tank.

In autoclaves provided with an optional water quality reading system, if pressed after a "BAD WATER" message, reactivates automatic tank filling (chapt.10).

START STOP

Starts the cycle.
If pressed for more than 1 second when a cycle is running, the cycle is interrupted.

Press and hold with the door open for at least 10 seconds to RESET the BACT. FILTER message (chapt.14.2).

6.3 SERVICE ICONS

	Type of cycle selected: B, S or N type (see chapt.1.3).
	This icon appears when the machine door has been closed and locked.
	The presence of this icon indicates that the cycle is in progress: you can also see the rotating movement of the triangle.
	This icon signals there is no paper in the printer, or that the door of the printer is not properly closed. However, the machine can run cycles without causing any damage.
	Autoclaves are equipped with work software that can communicate and write on a USB flash drive. Sterilizers have a USB port already on-board the machine. When the USB pen drive is inserted into its connector, the icon appears on the display. Care must be taken to read the relevant attached operating instructions also to prevent data rescue errors. DATA SAVING ONLY BEGINS IF THE PEN DRIVE HAS BEEN INSERTED INTO ITS CONNECTOR BEFORE THE CYCLE IS STARTED.
	This icon warns that the clean water has reached the minimum level: a new cycle cannot be started. Fill the clean water tank before starting a new cycle (chapt.10).
	The autoclave is filling the clean water tank. When the colour of the icon changes from white to black, it means that the minimum level has been reached and that you can now start a new sterilization cycle.
	The clean water tank is full. If you press the PUMP/WATER button again, the display will warn you that you cannot load more water.
	If this cycle is present, no cycle can be started and you must empty the dirty water tank. Allow the water to drain completely before closing the drain tap (chapt.10).

7. PRINTER

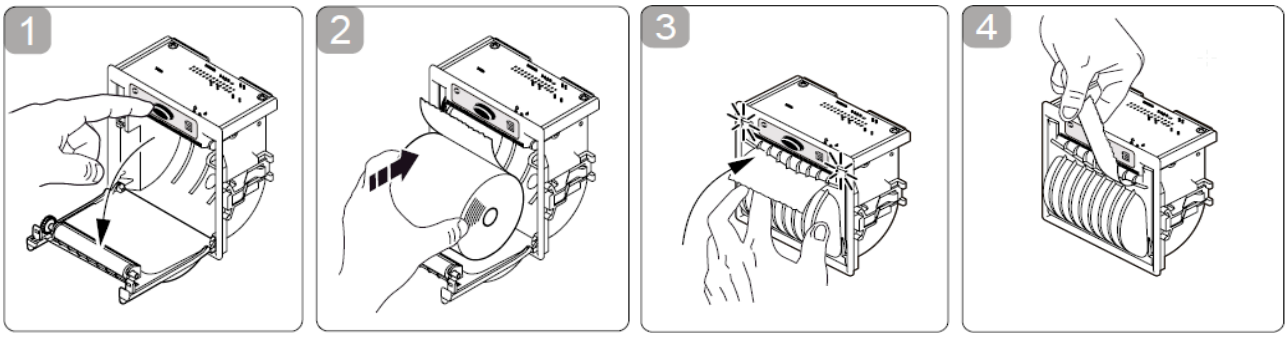
When starting any cycle, the autoclave starts a printing strip that reports all the values of the selected cycle type, model, and serial number of the machine (chapt.7.3). At the end of the cycle, the autoclave also terminates the printing strip: cut the note by pulling it upward (doing so using the built-in cutter).

If the door has not been correctly closed or if paper is low, the user will be notified with a service icon that will appear on the display (chapt.6.3).

Refer to local AUSL instructions for printing strip archiving.
Correct and long-lasting preservation of the printing strip requires its storage in a place away from sources of light and heat.

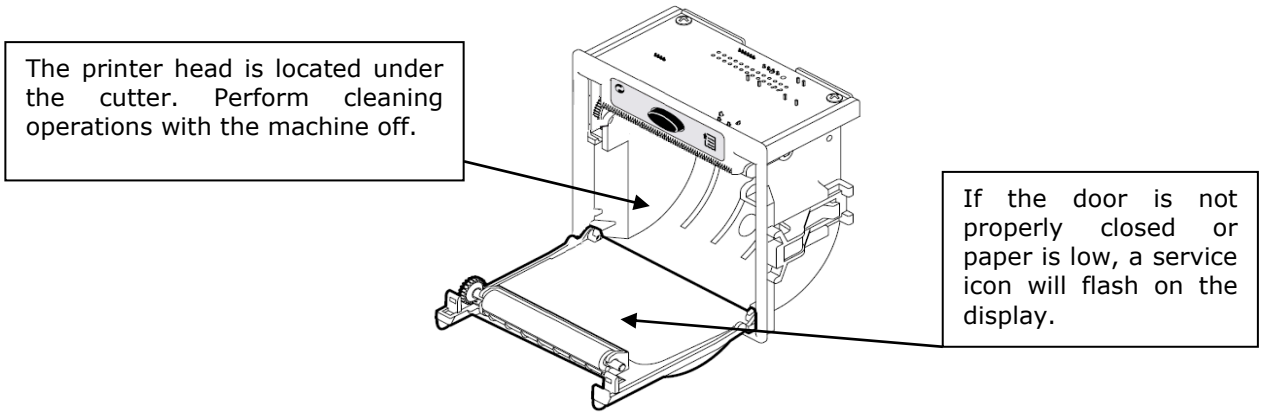
7.1 REPLACING THE ROLL IN THE PRINTER

To replace the printer roll: open the door, insert a thermal paper roll (with maximum width 57 mm) in the corresponding compartment, having the paper over the door roller come out while closing it. Use thermal paper only. Position the thermal paper in the correct direction: printing strip paper will be blank if assembled upside down.



7.2 CLEANING THE PRINTING HEAD

Printing may sometimes be hard to read: clean the printer head, blowing away dust released by the thermal paper rolls. It rarely occurs that you have to repeat the operation: in that case, use a cloth wet with isopropyl alcohol (not denatured alcohol), open the printer door, remove the roll of paper, and clean the head (see points highlighted in the photo).



7.3. PRINTING STRIP

7.3.1 Example of a normal sterilization cycle

Reading and correct interpretation of printing strip data for a normal sterilization cycle.

	::::::::::::::::::::::::::::::::::::	
Brand	STAR	
Model	STARCLAVE B23	
Software version	RELEASE: SPS 7.00	
Device serial number	S/N: BD2QHG1520	
Cycle start date	DATE: 05:08:2017	
Number of started cycle	C/N: 00016	
Water quality	Water: GOOD	
Type of started cycle	CYCLE: "B"	
Name of started cycle	HOLLOW WRAPPED	
Characteristics of started cycle	134°C 2.06bar 15.00min	
	START	Cycle start
	hh:mm:ss °C bar	
	08:45:19 029.5 -0,047	
	08:53:08 045.8 -0,882	Time, temperature and pressure values during the preliminary phase of the cycle
	08:58:15 120.3 1,214	
	08:58:45 105.0 0,169	
	09:01:37 088.2 -0,751	
	09:05:55 122.3 1,220	
	09:06:56 105.1 0,175	
	STERILIZATION	Sterilization phase start
	09:11:44 135.1 2,160	
	09:12:44 135.2 2,171	
	09:13:44 135.3 2,199	Time, temperature and pressure values during the sterilization phase
	09:14:44 135.6 2,222	
	09:15:44 135.3 2,200	
	09:16:44 135.5 2,228	
Minimum and Maximum temperature and pressure values during sterilization	Min. Max. °C 135.0 135.8 bar 2,160 2,251	
	DRYING	Drying phase start
	09:16:50 135.4 2,227	
	09:17:50 116.7 0,757	
	09:18:50 109.9 0,006	
	09:19:50 108.4 -0,441	
	09:20:50 104.4 -0,605	
	09:21:50 100.2 -0,723	
	09:22:50 093.8 -0,541	Time, temperature and pressure values during the drying phase
	09:23:50 092.3 -0,766	
	09:24:50 090.1 -0,710	
	09:25:50 088.4 -0,611	
	09:26:50 086.7 -0,798	
	09:27:50 085.5 -0,757	
	09:28:50 084.4 -0,681	
	09:29:50 083.4 -0,594	
	09:30:50 082.3 -0,612	
	09:31:50 085.5 -0,152	
End result of the cycle	END CYCLE: OK	
	OPERATOR :	Space for operator signature
	::::::::::::::::::::::::::::::::::::	

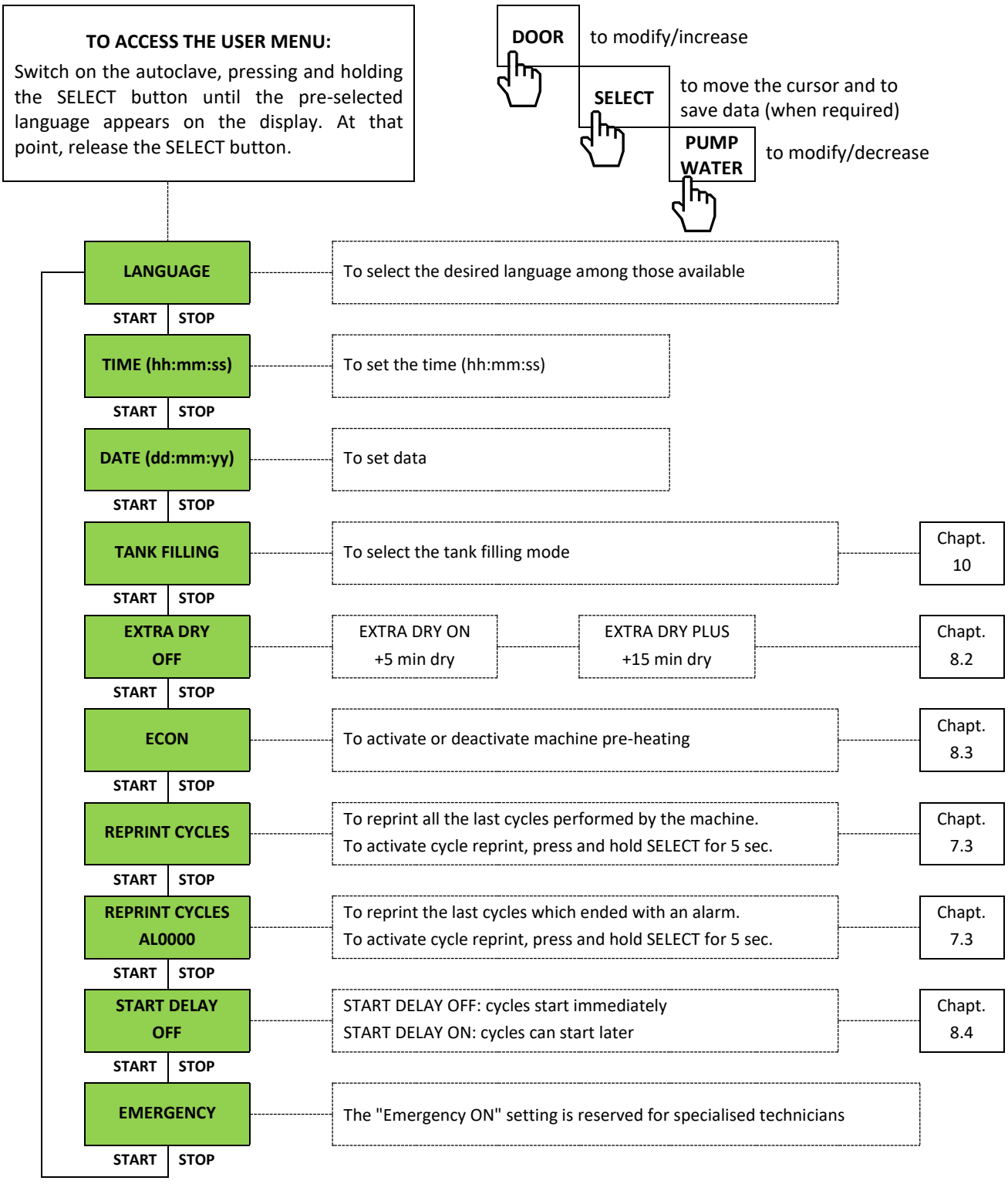
7.3.2 Example of a Vacuum Test cycle

Reading and correct interpretation of printing strip data for a Vacuum Test cycle.

	::::::::::::::::::::::::::::::::::::	
Brand	STAR	
Model	STARCLAVE B23	
Software version	RELEASE: SPS 7.00	
Device serial number	S/N: BD2QHG1520	
Cycle start date	DATE: 05:08:2017	
Number of started cycle	C/N: 00017	
Water quality	Water: GOOD	
Type of started cycle	CYCLE:	
Name of started cycle	VACUUM TEST	
	START	Cycle start
	hh:mm:ss °C bar	
	08:25:04 024.7 0,007	Values at cycle start and stabilisation phase start
	STABILISATION	
	P1 = -0.887 bar	
	10:28:04 027.1 -0,887	
	10:29:04 027.8 -0,886	Time, temperature and pressure values during the preliminary phase of the cycle
	10:30:04 028.1 -0,883	
	10:31:04 028.1 -0,882	
	10:32:04 028.1 -0,882	
Start values of maintenance phase	MAINTAIN. DATA	Maintenance phase start
	P2 = -0.882 bar	
	10:33:04 028.1 -0,882	
	10:34:04 028.1 -0,880	
Time, temperature and pressure values during the maintenance phase	10:35:04 028.1 -0,880	
	10:36:04 028.1 -0,880	
	10:37:04 028.1 -0,879	
	10:38:04 028.1 -0,879	
	10:39:04 028.1 -0,879	
	10:40:04 028.1 -0,879	
	10:41:04 028.1 -0,879	
	10:42:04 028.1 -0,878	
	10:43:02 028.1 -0,878	
Final maintenance value	+ -0,878 bar	
	P3-P2: 0,004 bar	Difference between P2 and P3
Loss gradient	GRAD: 00.4 mbar/min	
	END CYCLE: OK	End result of the cycle
	OPERATOR :	Space for operator signature
	::::::::::::::::::::::::::::::::::::	

8. USER MENU

8.1 USER MENU STRUCTURE



8.2 EXTRA DRY

The EXTRA DRY function is useful when sterilizing large volumes of wrapped and/or porous materials. It is usually activated when the load drying quality is not sufficient. There are 3 different configurations depending on the type of load to be sterilized and then dried:

EXTRA DRY	CHANGE MADE	EXTRA HEATING
OFF	No change	No change
ON	Drying times increased by 5 minutes	No change
PLUS	Drying times increased by 15 minutes	Heating boosted during the dry phase

Once the ON or PLUS function has been set, the machine memorises data and sets all subsequent cycles considering the pre-selected mode. To return to the factory default configuration, set EXTRA DRY OFF.

8.3 ECON

The ECON function is used to activate or deactivate machine pre-heating. In fact, upon start-up, the machine starts heating the sterilization chamber to speed up the work cycles. Pre-heating is automatically active on all cycles except for the Vacuum Test cycle. For pre-heating to work, ECON must be on OFF and there must be water in the clean water tank. The ECON ON function interrupts any type of pre-heating outside of the cycle (when the machine is switched on but not in operation, no significant energy absorption will occur except that related to the display and basic functions).

ECON	CHANGE MADE
OFF	The machine performs pre-heating already upon first ignition. Then it maintains the chamber temperature at the factory default setting values until it goes into stand-by.
ON	The machine does not perform any pre-heating, also creating energy savings. At the end of a cycle, the machine cools down without maintaining any pre-set temperature.

8.4 START DELAY

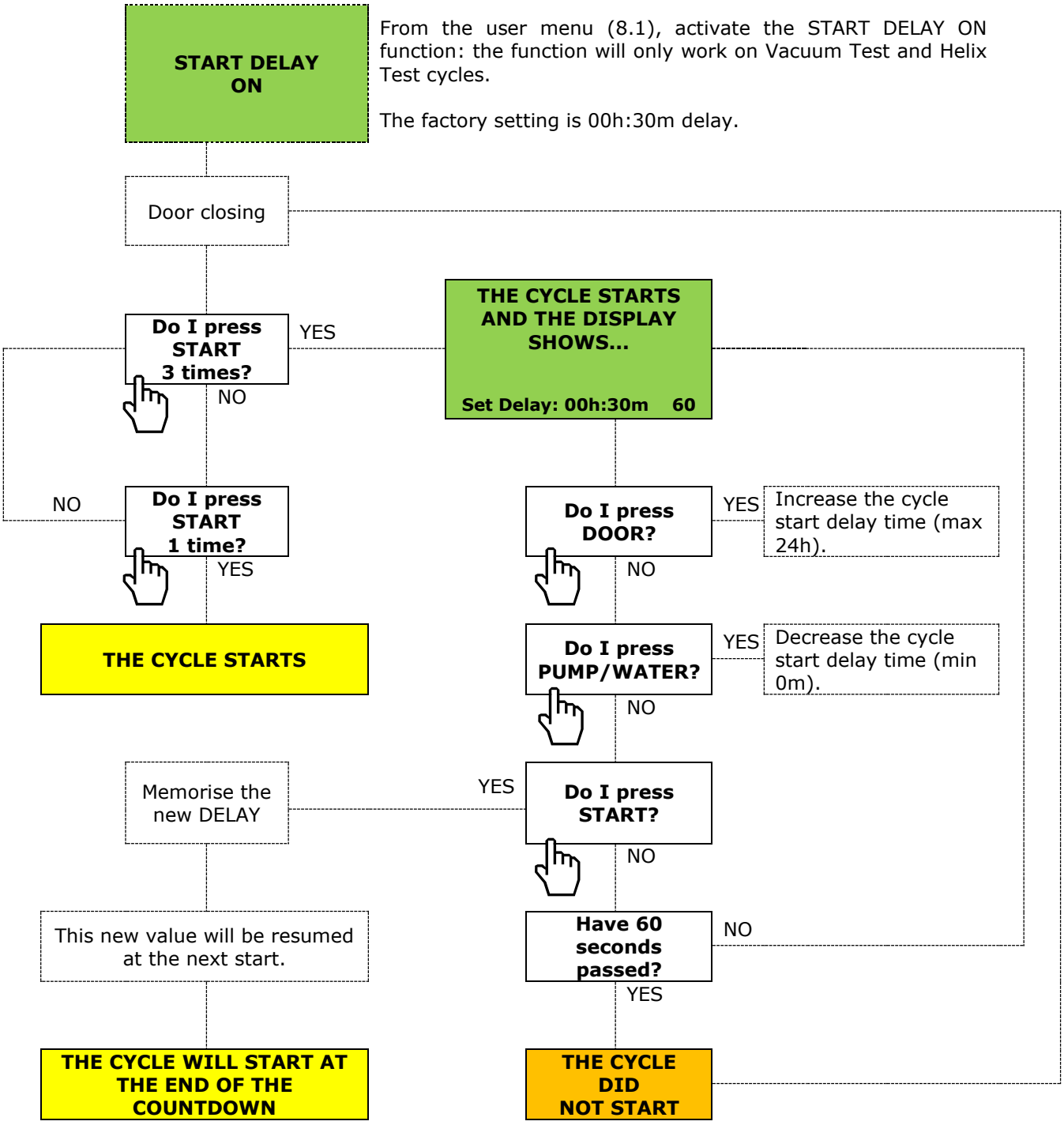
The START DELAY function allows for delayed cycle start-up. It is activated from the user menu (chapt.8.1). It is usually used to perform morning tests, where required, having the machine start the evening before and setting a delay to complete the cycle shortly before returning to the office the following morning. To have the cycle start at a pre-set time:
- Activate the START DELAY ON function from the user menu (chapt.8.1).
- Start up a test cycle (Helix or Vacuum), pressing the START/STOP button 3 times in rapid sequence.

See both the following table and the subsequent flow chart to fully understand the START DELAY mode.

START DELAY	CYCLE START TIME	SET DELAY	ACTUAL CYCLE START TIME
OFF	08h:12m:56s	00h:00m	08h:12m
OFF	22h:59m:47s	00h:00m	22h:59m
ON	08h:12m:56s	00h:30m	08h:42m
ON	08h:12m:56s	08h:30m	16h:42m
ON	22h:59m:47s	00h:30m	23h:29m
ON	22h:59m:47s	08h:30m	07h:29m

The delay can be set from 0 minutes (m) to 24 hours (h) at intervals of 30 minutes (m).

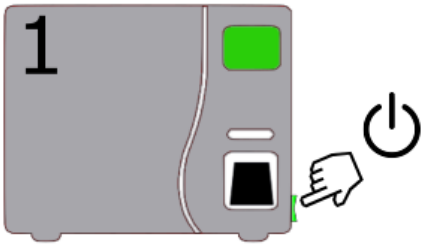
8.4.1 Start Delay flowchart



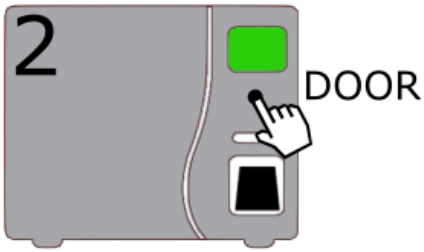
9. PUTTING INTO SERVICE FOR THE FIRST TIME

9.1 HOW TO OPEN THE DOOR

After positioning the autoclave (chapter 3) and completing the water and electrical connections (chapter 4):

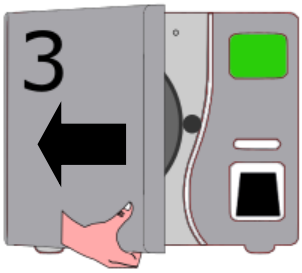


Switch on the machine using the ON/OFF switch (**1**).



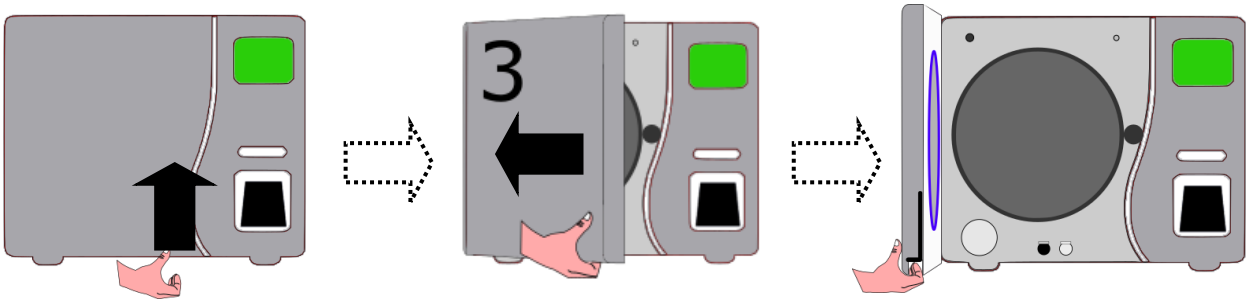
Press the DOOR button (**2**).

The internal motor will slowly release the door automatically.



After a few seconds, the motor finishes its operation and the door (3) can be opened. Then, with your hand, you may open it completely.

Note: in some models, the handle must be raised in order to unlock the door, as shown in the diagram below.



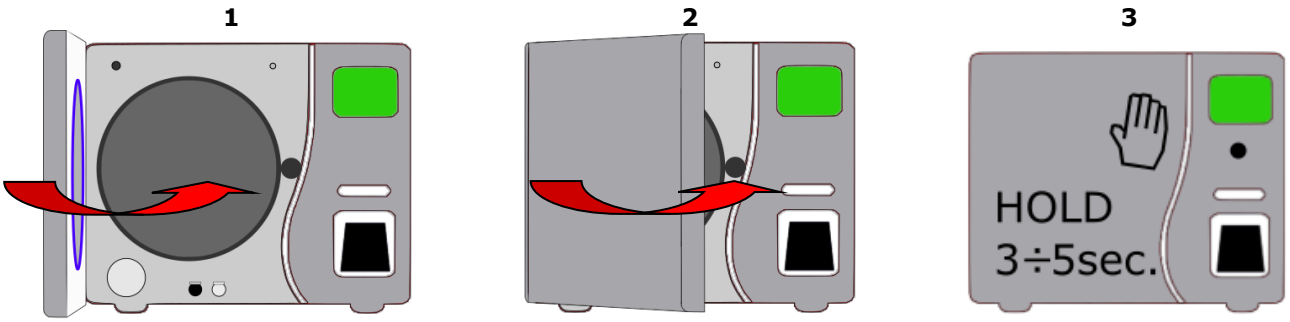
After step (**2**), raise the handle…

…open the door by hand…

...until it is completely open. Then, release the handle

The autoclave will not allow the door to open if there are any risks present due to residual pressure.

9.2 HOW TO CLOSE THE DOOR

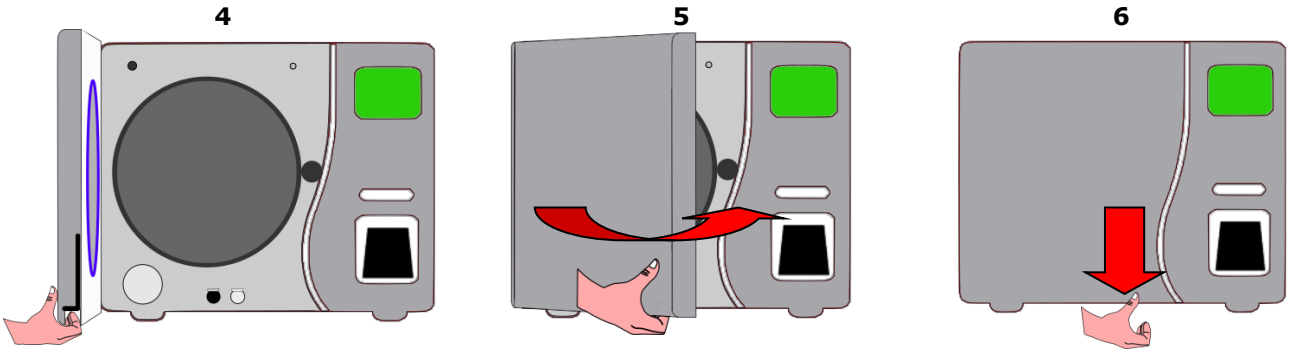


Close the door, using your hand gently (**1**) (**2**), then keep the door pressed for about 3-5 seconds (**3**). Automatic closing will be activated: you can now release the door. The internal motor will complete the closure.

	If the door is released earlier than expected, the automatic system will reverse the closing process and return to the door-open position. Wait a few seconds and repeat the closing operation.

	The door is only closed and locked when the door icon appears on the display.
	DO NOT press the START button to close the door. Pressing the START button starts the sterilisation cycle.

NOTE: on some models, you will need to proceed as described below:



Raise the handle (**4**), pull the door closer (**5**) and release the handle (**6**).

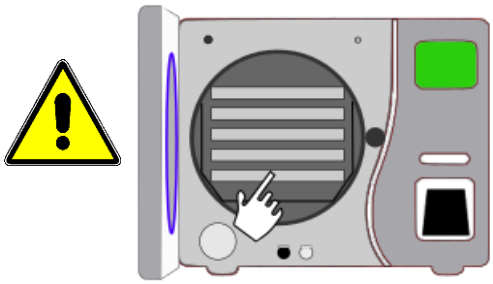
At this point, the internal motor starts to bolt the door closed until it is completely locked.

	Also in these cases, the door is only closed and locked when the door icon appears on the display.
	DO NOT press the START button to close the door. Pressing the START button starts the sterilisation cycle.

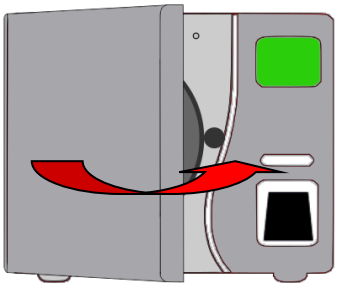
9.3 TEST CYCLE

The test cycle ensures that the autoclave is intact, that it has not been subject to damage during delivery or that, for technical reasons, it does not have any operational problems.

1

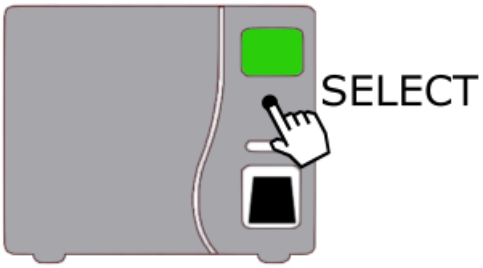


2

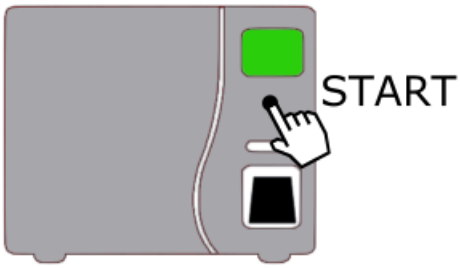


Insert the tray holder and the relative trays inside the sterilisation chamber (**1**), then close the door (**2**) as described in chapter 9.2

3



4



Use the SELECT button (**3**), set the cycle to 134°C, then press START (**4**) to start the test cycle.

Throughout the entire cycle period, the display will show the temperature, pressure, remaining time, no. of the cycle started, type of cycle started, active phase of the cycle and any warning icons.

PRE-HEATING
The autoclave will start a pre-heating phase and then suction the air in the chamber until the pre-set parameter is reached. The climbing phase will begin immediately afterwards. During this phase, you can hear the slight hum of steam entering the sterilisation chamber.
Once the pre-set pressure point has been reached, the discharge phase begins: other air removal and steam injection phases will then be carried out until the values of the chosen cycle are reached (chapter 11).

STERILISATION
The sterilisation phase thus begins: during the minutes of exposure, the pressure and temperature will be constantly monitored by the machine's software to obtain effective sterilisation.

DRYING
The drying phase will begin at the end of the sterilisation phase. The pressure inside the chamber will be discharged and a steam suctioning phase will begin, in order to significantly improve the final drying quality of the sterilised instruments.

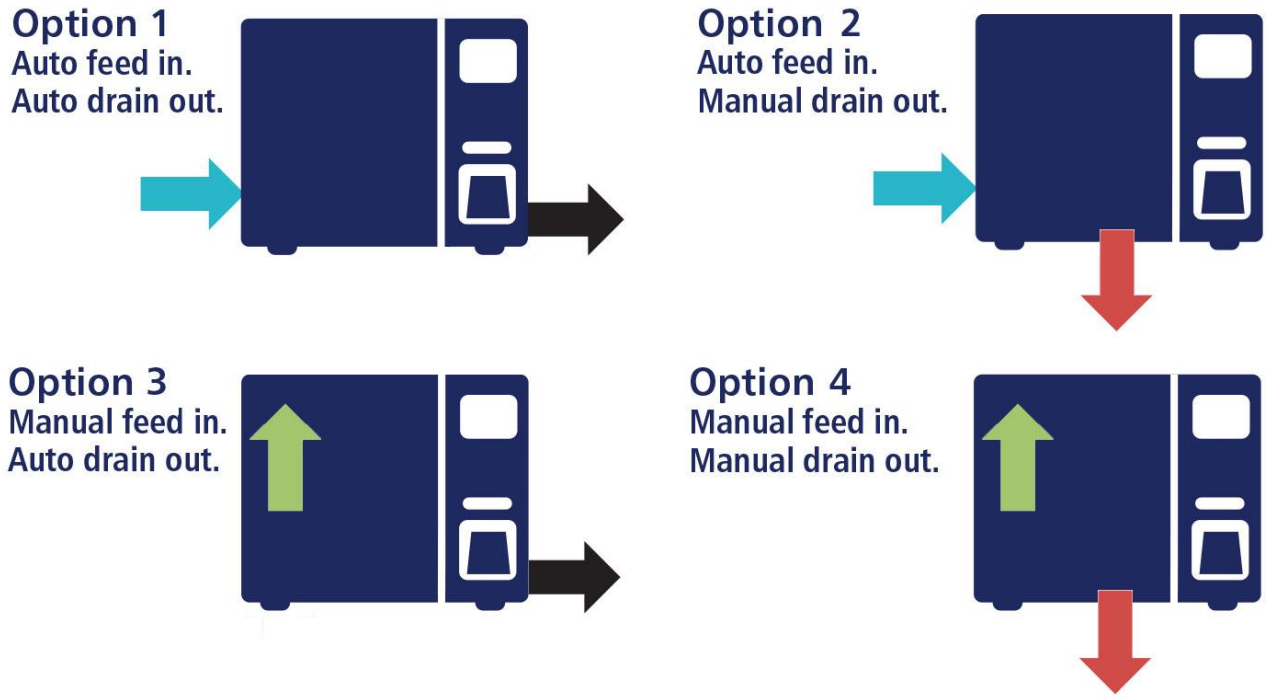
END OF THE CYCLE AND DOOR OPENING (chapter 9.2)
The door can be opened only when "END OF CYCLE" and "OPEN DOOR" appear on the display. Press the DOOR button to start the door release.

	Remove the instruments using the handle provided and use protective gloves to prevent burns.
	If the cycle ends with an error and/or alarm, read Chapters 14.1 and 14.2 and repeat the test cycle.

10. WATER LOADING AND DISCHARGE

10.1 WATER MANAGEMENT OPTIONS

The autoclave is supplied ready to be configured in different ways, depending on different needs. Both clean water inputs and used water discharges can be configured to simplify operator work.



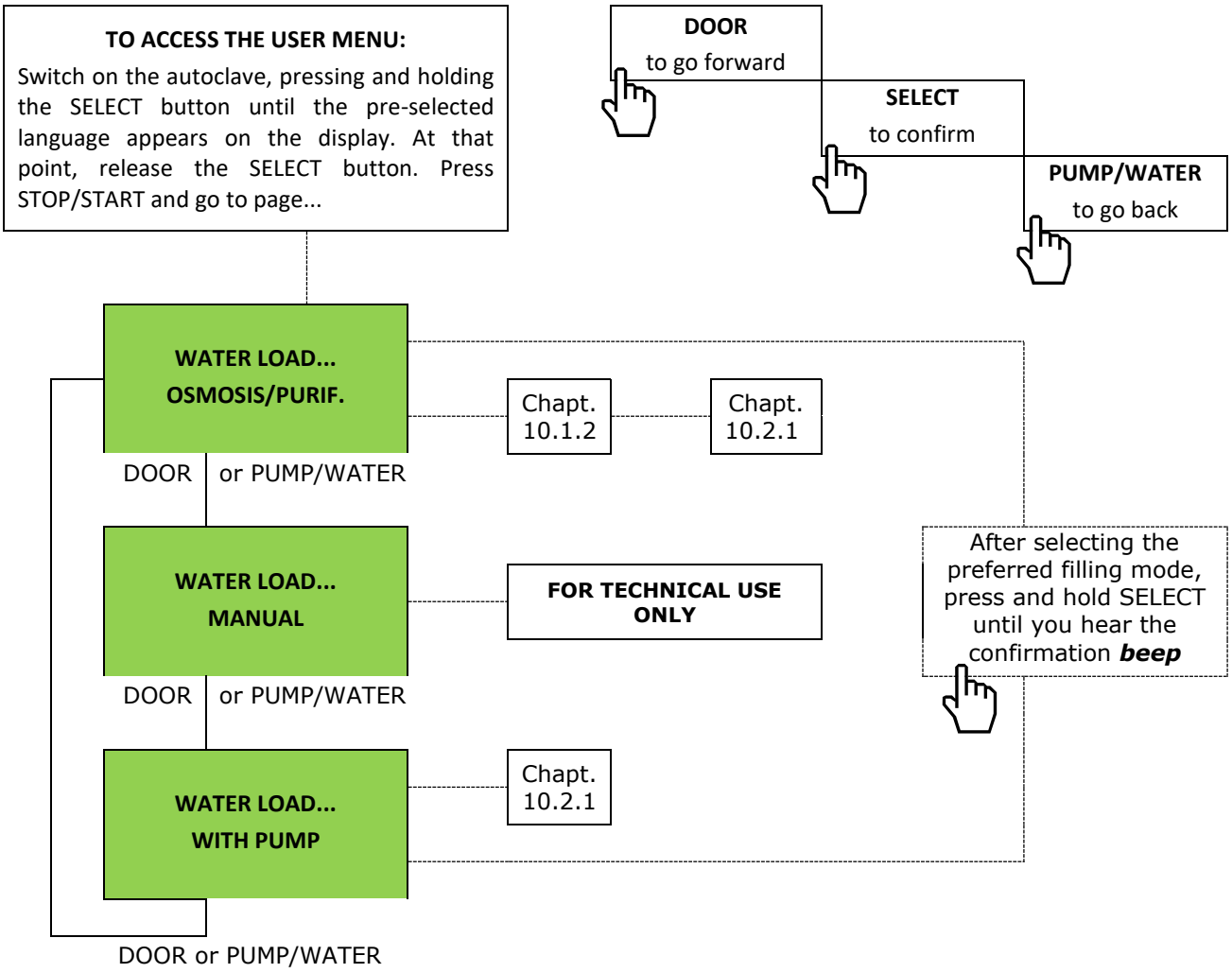
OPTION 1	**Chap.**
Automatic filling of clean water, through ROSI	4.1.1
Automatic draining of dirty water	10.3.2
Or	
Automatic filling of clean water, through an external water purification system	4.1.2 - 10.1.1 10.1.2 - 10.2.1

OPTION 2	**Chap.**
Automatic filling of clean water, through ROSI	4.1.1
Manual draining of dirty water	10.3.1
Or	
Automatic filling of clean water, through an external water purification system	4.1.2 - 10.1.1 10.1.2 - 10.2.1

OPTION 3	**Chap.**
Manual filling of clean water	4.1.3 - 10.2.2
Automatic draining of dirty water	10.3.2

OPTION 4	**Chap.**
Manual filling of clean water	10.2.2
Manual draining of dirty water	10.3.1

10.1.1 Software programming



Press and hold START/STOP for a long time to exit from the user menu. You can exit from the user menu mode at any time by pressing and holding the START/STOP button.

10.1.2 Reverse Osmosis system or Demineralizer?

WATER VALUE AT INLET		RECOMMENDED SYSTEM
< 300 µS/cm	Inlet water has a conductivity value lower than 300µS/cm.	Both a resin purification system and a reverse osmosis system can be used (if approved by the manufacturer).
> 300 µS/cm	Inlet water has a conductivity value higher than 300µS/cm.	A reverse osmosis system must be used (approved by the manufacturer). No resin purification system is permitted.
NOTE:	The autoclave preventively records water quality. The use of unsuitable quality water shall void the product warranty.	

10.2 CLEAN WATER MANAGEMENT

The total clean water tank capacity is 4 liters: in both cases, filling will be electronically stopped when the tank is full.

10.2.1 Automatic filling via external purification system

If a water purification system (demineralizer or reverse osmosis system) is available, hydraulic connections must be used as described in chapt.4.1.3 and software must be programmed with the pre-selected setting, as described in chapt.10.1.1 and in table at chap. 10.1.2.

Read and comply with the instructions of the purification system you are installing. ONLY USE MANUFACTURER-APPROVED PURIFICATION SYSTEMS.

In autoclaves provided with a water quality reading system, water quality is monitored, and various messages can appear on the display during filling via the purification system.

MESSAGE	MEANING	SOLUTION
"**POOR**"	Means that the quality of the water entering into the autoclave tank is at the limits of acceptability. See chapt.10.4.	Acquire water purification system spare parts and replace them as soon as possible to prevent damage to the autoclave (operation intended for a technician).
"**BAD**"	The autoclave has stopped tank filling (even if the MIN. LEV. icon is still present). Means that the quality of the water entering into the autoclave tank is outside the limits of acceptability. See chapt.10.4.	Press the PUMP/WATER button to reactivate automatic filling: After 15 seconds, if water is still not good quality, the autoclave will stop filling once again. After a couple attempts, you must intervene on the purification system, replacing the necessary filters (operation intended for a technician): continued use of unsuitable water will void the warranty on the autoclave.
NOTE:	The autoclave preventively records water quality. The use of unsuitable quality water shall void the product warranty.	

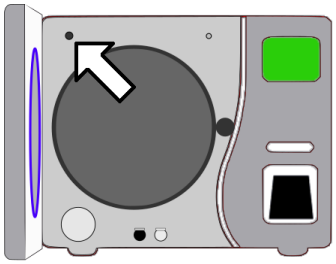
When water filling occurs via a demineralizer or a reverse osmosis system, and any time the device is connected to the water mains, the water supply system must be equipped with a reverse flow prevention device in compliance with IEC 61770.

After having installed the purification system, check all hydraulic connections during tank filling, making sure that no water leaks.
THE MANUFACTURER DENIES ALL LIABILITY FOR ANY PROBLEMS RESULTING FROM INSTALLATIONS AND CONNECTIONS MADE BY UNAUTHORISED PERSONNEL.

10.2.2 Filling via internal pump

The use of water containing concentrations which exceed those indicated in the table in chapt.10.4 may significantly reduce the life of the machine, causing serious danger to its components, particularly the vaporizer, resulting in the voiding of the warranty.

To fill the tank, connect the supplied hose (chapt.5) to the hose connection at the top left of the boiler and press the PUMP/WATER button: the charging pump will activate for a max time of 380".



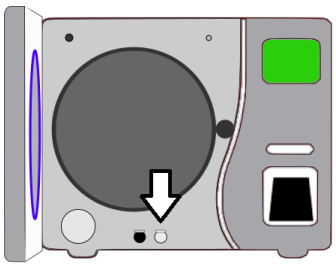
After 380" or when the corresponding icon reaches maximum level (chapt.6.3), the display will light up and the pump will stop automatically. It is possible to stop the filling operation at any time by simply pressing the PUMP/WATER button. Cycle start-up will be inhibited in the event of minimum level as signaled on the display by the corresponding icon (chapt.6.3).

In autoclaves provided with a water quality reading system, water quality is monitored, and various messages can appear on the display during filling.

MESSAGE	MEANING	SOLUTION
"**POOR**"	Means that the quality of the water being filled in the autoclave is at the limits of acceptability. See chapt.10.4.	Acquire water with better quantity than the currently used water as soon as possible to avoid damage to the autoclave.
"**BAD**"	The pump stops and tank filling is interrupted, even if the MIN. LEV. icon is still present. Means that the quality of the water being filled in the autoclave is outside of the limits of acceptability. See chapt.10.4.	Using water different from that previously used, press the PUMP/WATER button again: After 15 seconds, if water is still not good quality, the pump will stop once again. After a couple attempts, you must replace water being used with better quality water: continued use of unsuitable water will void the warranty on the autoclave.
NOTE:	The autoclave preventively records water quality. The use of unsuitable quality water shall void the product warranty.	

10.2.3 Manual draining of clean water

If needed or for maintenance servicing, it is possible to empty the clean water tank by connecting the tube to the white fitting on the front of the machine, making sure that all water has been drained before disconnecting the tube.
CAUTION: if the autoclave is connected to an automatic water filling system, perform this operation only after closing the water supply tap.



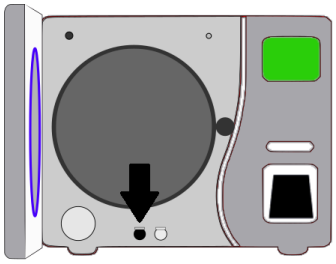
Never re-use discharged water.
Even if it has not come into contact with contaminants, there is a risk that use of this water may reduce the life of the device, causing damage to its components, in particular the vaporizer, resulting in the voiding of the warranty.

10.3 DIRTY WATER MANAGEMENT

The total dirty water tank capacity is 4 litres: in both cases, no new sterilization cycle can be started when the tank is full.

Never use dirty water to sterilize.
Use of this water can reduce the life of the device, causing damage to its components, in particular the vaporizer, resulting in total voiding of the warranty.

10.3.1 Manual draining of the dirty water tank



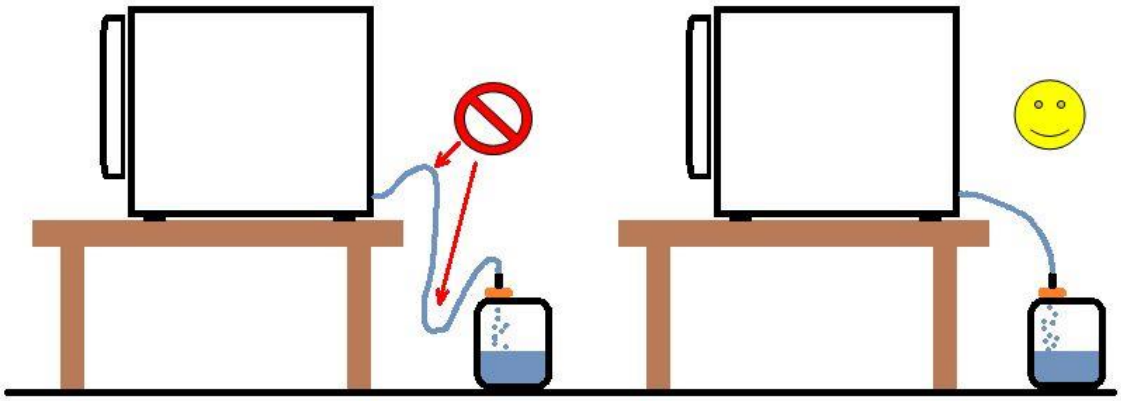
To empty the tank, connect the provided tube (chapt.5) to the black fitting located at the bottom left on the front of the machine.
Let all the water drain out before disconnecting the tube. The dirty water may contain contaminated residues, therefore it is advisable to use protective gloves when draining.

To dispose of waste water from the sterilizer, follow the instructions in the manual under Chapt. 15.5 and the laws in force for waste disposal.

10.3.2 Automatic discharge of the dirty water tank

To completely eliminate the problem of emptying the dirty water tank, you can connect the fitting **G** (chapt.4.1.3) located on the rear panel, connecting it to the drain directly or to a collecting vessel.

If the tube is connected to a collecting vessel, make sure that no siphons are formed or that the tube itself ends below the water level.



10.4 WATER QUALITY TABLE (EN13060, ANNEX C)

The water to be used must be purified or purified by a manufacturer-approved system and must meet the requirements specified in the table. Do not use isopropyl alcohol or unsuitable liquids. Do not add any additives or chemicals to water. Do not reuse the drain water from the tank.

ANNEX C (informative) SUGGESTED MAXIMUM LIMITS OF CONTAMINANTS IN AND SPECIFICATION FOR WATER FOR STEAM STERILIZATION

table C.1 **Contaminants of condensate and feed water**

	Feed water	Condensate
Evaporate residue	≤ 10 mg/l	≤ 1,0 mg/kg
Silicium oxide, SiO_2	≤ 1 mg/l	≤ 0,1 mg/kg
Iron	≤ 0,2 mg/l	≤ 0,1 mg/kg
Cadmium	≤ 0,005 mg/l	≤ 0,005 mg/kg
Lead	≤ 0,05 mg/l	≤ 0,05 mg/kg
Rest of heavy metals, excluding iron, cadmium, lead	≤ 0,1 mg/l	≤ 0,1 mg/kg
Chloride	≤ 2 mg/l	≤ 0,1 mg/kg
Phosphate	≤ 0,5 mg/l	≤ 0,1 mg/kg
Conductivity (at 20 °C)	≤ 15 [A1] µS/cm [A1]	≤3 [A1] µS/cm [A1]
pH value	5 to 7,5	5 to 7
Appearance	Colourless, clean, without sediment	Colourless, clean, without sediment
Hardness	≤ 0,02 mmol/l	≤ 0,02 mmol/l

NOTE 1 The use of water for steam generation with contaminants at levels exceeding those given in this Table can greatly shorten the working life of a sterilizer and can invalidate the manufacturer's warranty of guarantee.
NOTE 2 The condensate is produced from steam that has been taken from the empty sterilizer chamber.

Compliance should be tested in accordance with acknowledged analytical methods.

The use of water containing concentrations which exceed those indicated in the table shown above may significantly reduce the life of the machine, causing serious danger to its components, particularly the vaporizer, resulting in the voiding of the warranty.

11. STERILIZATION TABLES

11.1 GENERAL NOTES

Standard EN13060 determines performance requirements, test methods for small steam sterilizers and sterilization cycle specifications that are used for medical purposes or materials that may come into contact with blood or physiological fluids.

It is the responsibility of the user and the manufacturer of the device to be sterilized to determine the specific cycle suitable for sterilizing a particular device.

The sterilizer and its equipment must only be used to sterilize the type of products for which they have been designed. The choice of sterilization cycle or the quality of the services provided may be inadequate for a particular product. As a result, the suitability of a sterilization procedure for a particular product must be verified by validation (EN ISO 17665-1).

To facilitate selection of the cycle to be used, the manufacturer has indicated the type (B, S or N) of each of them in the cycle tables. In a sterilization process, the nature of microbial inactivation is described by an exponential function. Therefore, the presence of vital microorganisms on any individual element can be expressed in terms of probability. This probability can be reduced to a very low number, but can never be reduced to zero. It is therefore crucial that the choice of the cycle to be used is in line with the product to be sterilized.

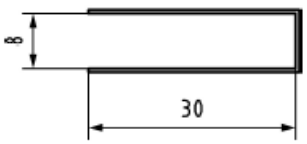
Standard EN13060 proposes these definitions for describing the various types of cycle:

Type of cycle	Description of the intended use
B	Sterilization of all products (as indicated in the Information Table shown below). For products that fall within the specified limits, this includes solid products, porous products and cable devices, wrapped (single layer or multi-layer) or unwrapped.
N	Sterilization of solid unwrapped products.
S	Sterilization of products as specified by the sterilizer manufacturer including unwrapped solid products and at least one of the following: porous products, small porous articles, cable devices, vessels and containers, single wrapped products and multi-layer wrapped products.
Note 1 **Note 2**	The description identifies product ranges and test loads. Unwrapped sterilized instruments are intended for immediate use.

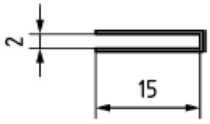
INFORMATION TABLE (Annex D - EN13060)

REQUIREMENTS	B	N	S
Dynamic sterilizer chamber pressure	√	√	√
Air outlet	√		√
Empty chamber	√	√	√
Solid load	√	√	√
Small porous objects	√		
Small sized porous loads	√		√
Full porous load	√		
Simple hollow load (ex Type B) *	√		√
Narrow lumen (ex Type A) **	√		
Multiple casing	√		
Drying, solid load	√	√	√
Drying, porous load	√		√
Residual air		√	

* Simple hollow:
L < 5xØ



** Narrow lumen:
L > 5xØ



√ = present

11.2 AUTOCLAVE B18

This autoclave is not authorized for the sterilization of liquid products and the data in this table is applicable to class B autoclave models with an 18L chamber.

Temp. and name of cycles	Sterilizable loads[1]	Technical specs of the cycles[2]				
			STR	DRY	TOT	Kg
134° **B** Helix - B&D Test	Steam Penetration Test	–	03:30	04:00	~25m	0
- Vacuum Test	Leak Detection Test	–	-	-	~15m	0
121° **B** Hollow Wrapped	Solid load, small porous objects, simple hollow load and narrow lumen, multiple casing	√	18:00	15:00	~50m	2.5
134° **B** Hollow Wrapped		√	05:00	15:00	~39m	2.5
121° **S** Solids Wrapped	Solid load, small porous objects, simple hollow load	√	18:00	10:00	~47m	2.5
134° **S** Solids Wrapped		√	05:00	10:00	~35m	2.5
134° **B** Prion	Load related to the Creutzfeldt-Jakob disease	√	20:00	15:00	~54m	2.5
121° **B** Porous	Full porous load	√	18:00	20:00	~60m	1.0
134° **B** Porous		√	05:00	20:00	~50m	1.0
121° **S** Rapid	Solid load, small porous objects, simple hollow load	–	18:00	04:00	~41m	4.0
134° **S** Rapid		–	05:00	04:00	~30m	4.0
134° **B** Hollow Open	Solid load, simple hollow load and narrow lumen	–	05:00	04:00	~36m	4.0

[1] To select the sterilization cycle, always refer to the indications of the manufacturer of the instrument / load to be sterilized.
[2] Please note that, although the total times indicated in the table have been obtained by trying to simulate the "worst" autoclave conditions, changes to the times indicated are possible: power supply, cycle start temperature, weight of the inserted loads and other factors have an impact on the total duration of the cycle.

– cycle suitable for sterilizing UNWRAPPED MATERIAL only

√ cycle designed to sterilize wrapped material

Instruments intended for invasive use must be wrapped to ensure their sterility at the time of use. The choice of sterilization cycle must be based on the data provided by the manufacturer of the object to be sterilized.

11.3 AUTOCLAVE B23

This autoclave is not authorized for the sterilization of liquid products and the data in this table is applicable to class B autoclave models with a 23L chamber.

Temp. and name of cycles	Sterilizable loads[1]	Technical specs of the cycles[2]				
			STR	DRY	TOT	Kg
134° **B** Helix - B&D Test	Steam Penetration Test	–	03:30	04:00	~35m	0
- Vacuum Test	Leak Detection Test	–	-	-	~15m	0
121° **B** Hollow Wrapped	Solid load, small porous objects, simple hollow load and narrow lumen, multiple casing	√	18:00	15:00	~60m	3.5
134° **B** Hollow Wrapped		√	05:00	15:00	~49m	3.5
121° **S** Solids Wrapped	Solid load, small porous objects, simple hollow load	√	18:00	15:00	~57m	3.5
134° **S** Solids Wrapped		√	05:00	15:00	~45m	3.5
134° **B** Prion	Load related to the Creutzfeldt-Jakob disease	√	20:00	15:00	~64m	3.5
121° **B** Porous	Full porous load	√	18:00	20:00	~70m	1.5
134° **B** Porous		√	05:00	20:00	~60m	1.5
121° **S** Rapid	Solid load, small porous objects, simple hollow load	–	18:00	09:00	~51m	4.5
134° **S** Rapid		–	05:00	09:00	~40m	4.5
134° **B** Hollow Open	Solid load, simple hollow load and narrow lumen	–	05:00	09:00	~46m	4.5

[1] To select the sterilization cycle, always refer to the indications of the manufacturer of the instrument / load to be sterilized.
[2] Please note that, although the total times indicated in the table have been obtained by trying to simulate the "worst" autoclave conditions, changes to the times indicated are possible: power supply, cycle start temperature, weight of the inserted loads and other factors have an impact on the total duration of the cycle.

– cycle suitable for sterilizing UNWRAPPED MATERIAL only

√ cycle designed to sterilize wrapped material

Instruments intended for invasive use must be wrapped to ensure their sterility at the time of use. The choice of sterilization cycle must be based on the data provided by the manufacturer of the object to be sterilized.

11.4 AUTOCLAVE S18

This autoclave is not authorized for the sterilization of liquid products and the data in this table is applicable to class S autoclave models with an 18L chamber.

Temp. and name of cycles	Sterilizable loads[1]	Technical specs of the cycles[2]				
			STR	DRY	TOT	Kg
134° **S** Bowie & Dick Test	Steam Penetration Test	–	03:30	04:00	~28m	0
- Vacuum Test	Leak Detection Test	–	-	-	~15m	0
121° **S** Hollow Wrapped	Solid load, small porous objects, simple hollow load	√	18:00	20:00	~56m	1.5
134° **S** Hollow Wrapped		√	05:00	20:00	~45m	1.5
121° **S** Solids Wrapped	Solid load	√	18:00	15:00	~53m	1.0
134° **S** Solids Wrapped		√	05:00	15:00	~42m	1.0
134° **S** Prion	Load related to the Creutzfeldt-Jakob disease	√	20:00	20:00	~60m	1.5
121° **S** Porous	Small sized porous loads	√	18:00	25:00	~66m	0.5
134° **S** Porous		√	05:00	25:00	~56m	0.5
121° **S** Rapid	Solid load	–	18:00	10:00	~47m	2.5
134° **S** Rapid		–	05:00	05:00	~36m	2.5
134° **S** Hollow Open	Solid load, simple hollow load	–	05:00	10:00	~42m	2.5

[1] To select the sterilization cycle, always refer to the indications of the manufacturer of the instrument / load to be sterilized.
[2] Please note that, although the total times indicated in the table have been obtained by trying to simulate the "worst" autoclave conditions, changes to the times indicated are possible: power supply, cycle start temperature, weight of the inserted loads and other factors have an impact on the total duration of the cycle.

– cycle suitable for sterilizing UNWRAPPED MATERIAL only

√ cycle designed to sterilize wrapped material

Instruments intended for invasive use must be wrapped to ensure their sterility at the time of use. The choice of sterilization cycle must be based on the data provided by the manufacturer of the object to be sterilized.

11.5 AUTOCLAVE S23

This autoclave is not authorized for the sterilization of liquid products and the data in this table is applicable to class S autoclave models with a 23L chamber.

Temp. and name of cycles	Sterilizable loads[1]	Technical specs of the cycles[2]				
			STR	DRY	TOT	Kg
134° **S** Bowie & Dick Test	Steam Penetration Test	–	03:30	04:00	~38m	0
- Vacuum Test	Leak Detection Test	–	-	-	~15m	0
121° **S** Hollow Wrapped	Solid load, small porous objects, simple hollow load	√	18:00	20:00	~66m	2.5
134° **S** Hollow Wrapped		√	05:00	20:00	~55m	2.5
121° **S** Solids Wrapped	Solid load	√	18:00	15:00	~63m	2.0
134° **S** Solids Wrapped		√	05:00	15:00	~52m	2.0
134° **S** Prion	Load related to the Creutzfeldt-Jakob disease	√	20:00	20:00	~60m	2.5
121° **S** Porous	Small sized porous loads	√	18:00	25:00	~76m	0.5
134° **S** Porous		√	05:00	25:00	~66m	0.5
121° **S** Rapid	Solid load	–	18:00	10:00	~57m	3.5
134° **S** Rapid		–	05:00	05:00	~46m	3.5
134° **S** Hollow Open	Solid load, simple hollow load	–	05:00	10:00	~52m	3.5

[1] To select the sterilization cycle, always refer to the indications of the manufacturer of the instrument / load to be sterilized.
[2] Please note that, although the total times indicated in the table have been obtained by trying to simulate the "worst" autoclave conditions, changes to the times indicated are possible: power supply, cycle start temperature, weight of the inserted loads and other factors have an impact on the total duration of the cycle.

– cycle suitable for sterilizing UNWRAPPED MATERIAL only

√ cycle designed to sterilize wrapped material

Instruments intended for invasive use must be wrapped to ensure their sterility at the time of use. The choice of sterilization cycle must be based on the data provided by the manufacturer of the object to be sterilized.

11.6 AUTOCLAVE N18

This autoclave is not authorized for the sterilization of liquid products and the data in this table is applicable to class N autoclave models with an 18L chamber.

Temp. and name of cycles	Sterilizable loads[1]	Technical specs of the cycles[2]				
			STR	DRY	TOT	Kg
121° **N** Solids Open	Solid load	–	18:00	15:00	~48m	1.5
134° **N** Solids Open		–	06:00	15:00	~36m	1.5
134° **N** Prion	Solid load related to the Creutzfeldt-Jakob disease	–	20:00	15:00	~50m	1.5
121° **N** Rapid	Solid load	–	18:00	05:00	~38m	3.0
134° **N** Rapid		–	06:00	05:00	~28m	3.0

[1] To select the sterilization cycle, always refer to the indications of the manufacturer of the instrument / load to be sterilized.
[2] Please note that, although the total times indicated in the table have been obtained by trying to simulate the "worst" autoclave conditions, changes to the times indicated are possible: power supply, cycle start temperature, weight of the inserted loads and other factors have an impact on the total duration of the cycle.

– cycle suitable for sterilizing UNWRAPPED MATERIAL only

11.7 AUTOCLAVE N23

This autoclave is not authorized for the sterilization of liquid products and the data in this table is applicable to class N autoclave models with a 23L chamber.

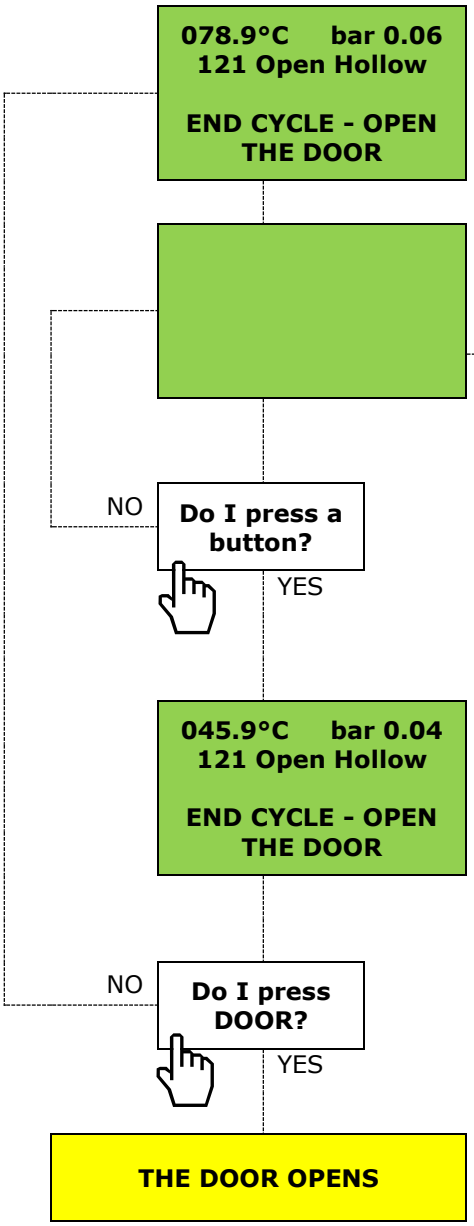
Temp. and name of cycles	Sterilizable loads[1]	Technical specs of the cycles[2]				
			STR	DRY	TOT	Kg
121° **N** Solids Open	Solid load	–	18:00	20:00	~58m	2.5
134° **N** Solids Open		–	06:00	20:00	~46m	2.5
134° **N** Prion	Solid load related to the Creutzfeldt-Jakob disease	–	20:00	20:00	~60m	2.5
121° **N** Rapid	Solid load	–	18:00	10:00	~48m	4.5
134° **N** Rapid		–	06:00	10:00	~38m	4.5

[1] To select the sterilization cycle, always refer to the indications of the manufacturer of the instrument / load to be sterilized.
[2] Please note that, although the total times indicated in the table have been obtained by trying to simulate the "worst" autoclave conditions, changes to the times indicated are possible: power supply, cycle start temperature, weight of the inserted loads and other factors have an impact on the total duration of the cycle.

– cycle suitable for sterilizing UNWRAPPED MATERIAL only

11.8 STAND-BY (NIGHT CYCLE)

The autoclave is equipped with an automatic power-saving system: in addition to the ECON function (chapt.8.3), it also has an automatic stand-by system. This function reduces energy consumption by maintaining only the backlight of the display switched on. It is therefore possible to start any cycle in the late evening and let the machine complete the cycle and enter into stand-by mode automatically (night cycle).



The autoclave has completed the sterilization cycle.

An hour has passed since the end of the cycle and nobody has opened the door: the autoclave enters into stand-by mode. Only the display backlight lights up

CAUTION

During END CYCLE and STAND-BY periods, the vacuum pump removes residual steam from the chamber every 30 minutes.

This automatic operation is used to minimize condensation and better dry the instruments.

It is therefore normal to note that the machine also performs operations outside the sterilization cycle.

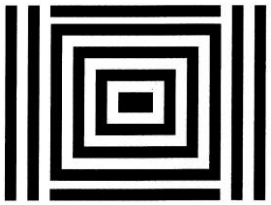
When the door opens, it is normal to find water condensate on the door, on the door gasket and on the bottom of the sterilization chamber.

<u>Work carried out must be repeated</u> in the event of alarms (chapt.14.1).

12. TEST CYCLES

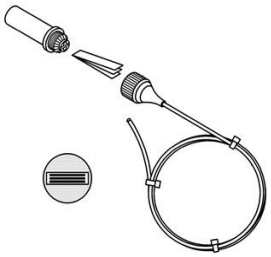
Refer to instructions from local health authorities to determine the appropriate control procedures and relative frequency.

12.1 BOWIE & DICK TEST

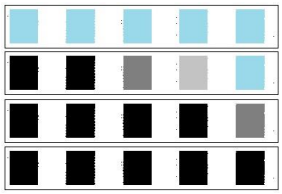


The Bowie & Dick Test verifies the correct penetration of steam into a porous load. Run the test cycle after having removed all the trays from the autoclave chamber, with the exception of the central one, onto which only the test pack without other instruments is positioned. Select the Helix/B&D Test cycle and start the cycle. The outcome of the cycle is validated by the test-pack result.
The Bowie & Dick cycle is present on type B and S autoclaves.

12.2 HELIX TEST

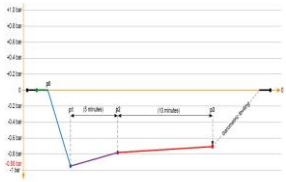


The Helix Test is used to verify steam penetration in a hollow load. Run the test cycle after having removed all the trays from the autoclave chamber, with the exception of the central one, onto which only the test pack is positioned, containing the test paper. Select the Helix/B&D Test cycle and start the cycle. The outcome of the cycle is validated by the result of the paper inserted inside the test device.
Note: the cycle should be carried out with the machine warm.
The Helix Test cycle is present on type B autoclaves.



Test papers can be different colours when new. They are generally light blue, yellow, or another light colour.
When subjected to sterilization, the colour changes (tone) and they become a lighter or darker colour.
A positive outcome (successful sterilization) is shown by a uniform dark colour.
Note: see the test device instructions

12.3 VACUUM TEST



The "Vacuum Test" cycle (chapt.1.3 and 7.3.2) are used to highlight any pressure losses in the sterilization chamber. This test must be carried out with the machine empty before performing any sterilization cycles. The outcome of the test is indicated by the message ""END OF CYCLE" and "OPEN DOOR" that appear on the display and by the relative printing strip.

The Vacuum Test cycle is present on type B and S autoclaves.

→Select the Vacuum Test cycle and start the cycle. The autoclave will reach the set degree of vacuum and will keep it for a total of 15 minutes.

The cycle will not start if the temperature inside the sterilization chamber is >40°. In the event of an alarm AL0600 [(p2-p1) > 0.1(p0-p1)] or AL0601 [(p3-p2)/10 > 1.3 mbar] you must attempt the cycle again after cleaning the door seal and drying the inside of the sterilization chamber (chapt.14.1).

A negative Vacuum Test outcome does not immediately prevent use of the sterilizer. However, contact customer assistance as sterilization cycles may become compromised in the long term.

12.4 BIOLOGICAL TEST

A biological test can be requested together with other chemical tests. This test consists of sterilizing one or more vials containing organic spores together with the normal sterilization load. At the end of the cycle, remove the vials and let them cool for a few minutes (follow the manufacturer's instructions for control procedures). Normally, sterilized vials should be broken, using the tools provided by the manufacturer, and inserted into a special incubator: insert another together with them to act as a comparison, not subjected to the sterilization process. After the incubation period, the colour difference of sterilized vials will determine the outcome of the cycle.

All types of autoclaves are subject to biological verification.

Refer to instructions from <u>local health authorities</u> to determine the appropriate control procedures and relative frequency.

13. STERILIZATION RECOMMENDATIONS

To ensure a long life to your instruments and the components of the autoclave, it is a good idea to follow appropriate procedures (and it is mandatory to refer to the indications provided by the local health authorities). Below are some precautions to follow.

Do not use excessive amount of lubricating oil as it may cause damage to vacuum pump valves and solenoid valves. These types of damage are not covered by the warranty.

→The instruments should be disinfected with appropriate liquids immediately after use.

→Brush the instruments to remove any residue.

→Rinse the instruments under running water at room temperature.

→Subject the instruments to an ultrasonic treatment.

→Rinse the instruments with purified water at room temperature. Thoroughly rinse and clean tools to eliminate possible residues of chemicals or lubrication oils that may damage components of the sterilizer.

→Dry the instruments thoroughly.

→Use the tray holders and trays provided. Do not place tools in direct contact with the chamber. Place the instruments on the sterilizer trays so that bags are not placed on top of one another.

→If you need to sterilize unwrapped instruments, the tray must be covered with the special cloths, in order to ensure each instrument sterilised has been thoroughly dried.

→Instruments such as scissors or pliers should be slightly open. It is advisable to place mirrors facing downwards.

→Arrange the bags with the paper part facing upward.

→If sterilising containers empty containers, these must be placed upside down to prevent accumulation of water.

→At the end of the sterilization cycle, use the removal key provided as trays and tray holders are very hot.

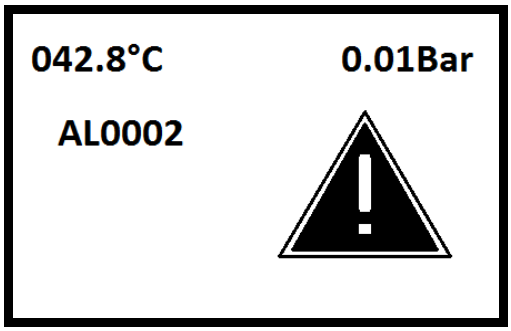
The above highlights the importance of preparing the instruments correctly as regards sterilization. If, for example, a single instrument with traces of disinfectant liquid enters into the sterilizer, this could damage the sterilization chamber and the instruments contained in it. The sterilization process could become compromised even if no alarm code is given.

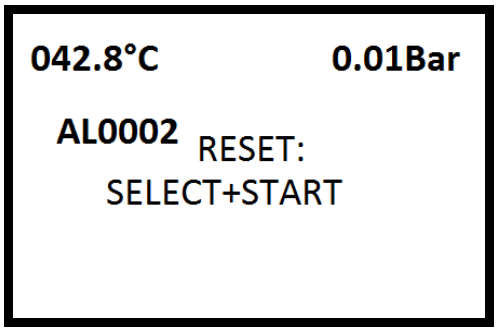
Always use instruments suited to verifying the sterility of the material introduced into the autoclave.

14. ALARMS AND ERRORS

The alarms that appear on the display (chapt.14.1) stop any subsequent operation: **it is necessary to reset the device by pressing the START and SELECT buttons at the same time** until the display goes off for a moment. The alarms are also recorded on the print strip (see table below).
Errors (chapt.14.2) do not allow the start of the cycle and warn that an operation must be carried out before sterilisation can take place.

Each unfinished cycle is considered ineffective: an alarm code (ALxxxx) and its reset instructions are given on the display.
Reset will only occur after safe conditions have been reached: until then the message WAIT PLEASE will be shown.





In the event of an alarm, the cycle performed is to be considered invalid and the material considered not sterile.

Interpreting ALARM codes:

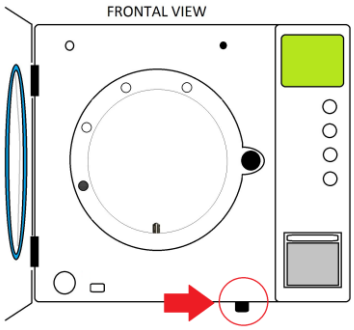
```
::::::::::::::::::::::::::::::::::::

              STAR
         STARCLAVE B23
     RELEASE:   SPS 7.00
         S/N:   BD2QHG1520
        DATE:   05:08:2017
         C/N:   00016
       Water:   GOOD
       CYCLE:   "B"
     HOLLOW WRAPPED
 134°C    2.06bar    15.00min
              START
hh:mm:ss      °C        bar
08:45:19     029.5     -0,047
08:58:15     120.3      1,214
::::::::::::::::::::::::::::::::::::

Alarm signal          AL0504
        DATE:      05:08:2017
        TIME:      09:17:44
Data detected at the
moment of the alarm signal
          T1:      105.4
          T2:      105.3
           P:      0,332
         TVP:      172.4
         TRS:      107.8
       Volts:      232 Vac
::::::::::::::::::::::::::::::::::::
```

All values registered on the machine are shown after an alarm code: date, time, temperature of the various probes, pressure and electrical voltage.

In case of an alarm, it is a good idea to store the printing strip for easy troubleshooting.

14.1 ALARMS

Code and meaning	How this occurs	**Solution:** Reset = **SELECT+START** for at least 5 sec.
AL0001 Cycle interrupted voluntarily	This occurs if the START/STOP button is pressed for more than 1 sec.	Reset the alarm then repeat the cycle.
AL0002 No mains power	Caused by a power failure.	
AL0003 Door open	This occurs if one of the door control microswitches detects a "door open during the cycle".	Reset the alarm and then repeat the cycle: if the problem persists, call customer service.
AL0004 Timer stopped	This can occur if the circuit board battery is low.	Re-set the time (chapt.8). Before use leave the autoclave on for at least an hour.
AL0005 High voltage	Caused by an electrical current overload.	Reset the alarm then repeat the cycle.
AL0011 **AL0012** **AL0013** **AL0014** **AL0015** Failed vacuum	This alarm appears if one of the vacuum phases is not reached. AL0015 can only occur during the drying phase.	Reset the alarm, clean the door seal and make sure there are no bags inside the chamber blocking the ducts, then repeat the cycle.
AL0021 **AL0022** **AL0023** **AL0024** Failed ramp	The machine does not reach the set pressure.	Reset the alarm and fill the clean water tank to the maximum level. Repeat the cycle.
AL0031 **AL0032** **AL0033** **AL0034** Failed discharge	The machine does not discharge pressure.	Reset the alarm, remove the tray holder and make sure there are no bags inside the chamber blocking the ducts, clean the inside of the sterilization cycle, then repeat the cycle.
AL0100 **AL0101** **AL0102** Problem on T1	The alarm is the result of self-diagnosis of the circuit board or the T1 probe.	Reset the alarm. Switch the machine off and back on again: if the problem persists, call customer service.
AL0110 **AL0111** T1 in low/high temperature	The T1 probe has exceeded the set cycle temperature limits.	Wait 10 minutes with the door open. Repeat the cycle: if the problem persists, call customer service.
AL0200 **AL0201** **AL0202** Problem on T2	The alarm is the result of self-diagnosis of the circuit board or the T2 probe.	Reset the alarm. Switch the machine off and back on again: if the problem persists, call customer service.
AL0210 **AL0211** T2 in low/high temperature	The T2 probe has exceeded the set cycle temperature limits.	Wait 10 minutes with the door open. Repeat the cycle: if the problem persists, call customer service.
AL0300 **AL0301** **AL0302** Problem on P	The alarm is the result of self-diagnosis of the circuit board or the P probe.	Reset the alarm. Switch the machine off and back on again: if the problem persists, call customer service.
AL0310 **AL0311** P in high/low pressure	The P probe has exceeded the set cycle pressure limits.	Wait 10 minutes with the door open. Repeat the cycle: if the problem persists, call customer service.

Code and meaning	How this occurs	**Solution:** Reset = **SELECT+START** for at least 5 sec.
AL0400 **AL0401** **AL0402** Problem on TVP	The alarm is the result of self-diagnosis of the circuit board or the TVP probe.	Reset the alarm. Switch the machine off and back on again: if the problem persists, call customer service.
AL0404 **AL0405** TVP in low/high temperature	The TVP probe has exceeded the permitted min or max limits for this type of sensor.	Wait 10 minutes with the door open. Repeat the cycle: if the problem persists, call customer service.
AL0500 **AL0501** **AL0502** Problem on TRS	The alarm is the result of self-diagnosis of the circuit board or the TRS probe.	Reset the alarm. Switch the machine off and back on again: if the problem persists, call customer service.
AL0504 TRS in low temperature	The TRS probe has exceeded the permitted min limits for this type of sensor.	Wait 10 minutes with the door open and reset the thermostat like as following picture.  Repeat the cycle: if the problem persists, call customer service.
AL0505 TRS in high temperature	The TRS probe has exceeded the permitted max limits for this type of sensor.	Wait 10 minutes with the door open. Repeat the cycle: if the problem persists, call customer service.
AL0600 **AL0601** Vacuum Test failed	During the 5+10 minutes of the cycle, a loss of pressure has invalidated the Vacuum Test cycle.	Remove the tray holder: clean and thoroughly dry the inside of the sterilization chamber. Repeat the cycle: if the problem persists, perform a sterilization cycle and re-try the Vacuum Test with the machine cooled.
AL0700 T1/T2 comparison	T1 and T2 detect temperatures that are too discordant to each other during the sterilization phase.	Reset the alarm and fill the clean water tank to the maximum level. Repeat the cycle: if the problem persists, call customer service.

In the event of an alarm, the cycle performed is to be considered invalid and the material considered not sterile.

14.2 ERRORS

Code	Meaning and causes	Solution
OPEN DOOR	Upon start-up, door opening is requested to allow the machine to perform a pressure check-up.	Open the door to allow automatic pressure alignment (double beep).
DOOR OPEN	A cycle has been started with the door open.	Close the door correctly then try again.
FAILED	Despite correct closing of the door, the machine reads "unlocked" due to mechanical causes.	Press the DOOR button, open and close the door, start the cycle with the START key. Repetition of this error requires intervention from an experienced technician.
LOAD WATER	The cycle was started when the minimum level of clean water was flashing on the display.	Load clean water in the tank (chapt.10).
WATER DISCHARGE	The cycle was started with the max. level of dirty water flashing on the display.	Load dirty water (chapt.10).
TANK FULL	You are attempting to load clean water in the tank when the tank full icon is already being shown on the display.	Disconnect the water loading tube. You can start a new cycle.
FAILED UNLOCK	The door does not fully open.	Re-close the door (chapt.9.1) and then re-open the door, pressing the DOOR button. Repetition of this error requires intervention from an experienced technician.
CHAMBER TEMP. >40°	A Vacuum Test cycle was started when the chamber temperature was over 40°C.	Wait for the temperature on the display to go down under 40°C, then re-try.
POOR WATER or BAD WATER	The autoclave detects that water quality is just sufficient (POOR) or scarce (BAD).	Carefully read chapt.10.
SERVICE H2O	Potentially unsuitable water with a value greater than 15µS.	Check a small amount of water from the clean water tank (chapt.10). If <15µS, press PUMP/WATER until the message is reset (~10 seconds). If> 15µS, replace the water purification system cartridges.
BACT. FILTER	The autoclave cycle counter invites you to change the bacteriological filter.	Replace the used filter with a new one (chapt.15.2) then, with the open door, press and hold START for at least 10 seconds until you hear a long beep, then the error message will be reset.
SERVICE (1xx - 2xx - 3xx)	The machine has performed a high number of cycles and requires the intervention of a technician for a periodic inspection.	The autoclave can continue to work but you need to carefully follow the instructions contained in chapt.15.3.
SERVICE PM3	The vacuum pump has performed a high number of cycles and requires the intervention of a technician for a periodic inspection.	The autoclave can continue to work. Immediately notify a technician, giving him the information shown here on the side.

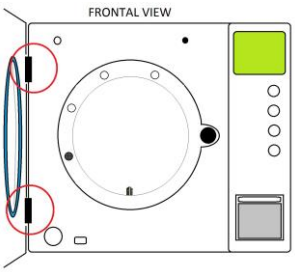
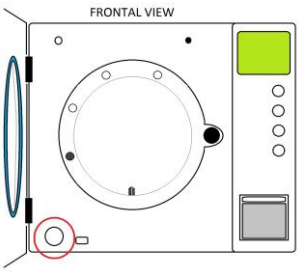
15. MAINTENANCE

The power must be disconnected before performing any maintenance operations.
Make sure that the sterilizer has cooled down before accessing the chamber or parts inside.

15.1 WEEKLY MAINTENANCE

Weekly maintenance is the responsibility of the **end user**.	
DOOR SEAL	Clean the door seal using the soft side of the sponge provided with supply. Cleaning should be performed to remove any impurities that could prevent successful test cycles.
BOILER EDGE	The outer edge of the sterilization chamber where the seal is held. Use the rough part of the sponge provided with supply (chapt.5).
WATER LEVELS	Check water tank levels (chapt.6.3) before starting a new sterilization cycle.
GENERAL SURFACE CLEANING	Use a cloth to remove dust and various deposits from the top of the machine.
CLEANING INSIDE THE CHAMBER	Use the rough part of the sponge provided with supply to remove small impurities on the bottom of the chamber. Check the water you are using if any limestone deposits appear. Do not use disinfectants or sharp objects.

15.2 QUARTERLY MAINTENANCE

Quarterly maintenance is the responsibility of the **end user**.		
LUBRICATION OF HINGES		Use silicone oil, spraying a small quantity of it on the two door hinges (highlighted in the photo).
BACTERIOLOGICAL FILTER REPLACEMENT		Replace the bacteriological filter when required by the autoclave and reset the error message (chapt.14.2). Clogging of the bacteriological filter may cause difficulty in opening the door at the end of the sterilization cycle and worsen instrument drying quality. Remove the used filter, unscrewing it in the counter clockwise direction, and replace it with a new bacteriological filter. Try manual door closing to make sure that the filter is properly tightened in its housing.
WEEKLY MAINTENANCE	Quarterly maintenance involves all weekly maintenance in addition to the information described above (chapt.15.1).	

15.3 SERVICE REQUIRED BY THE AUTOCLAVE

Performing SERVICE required by the autoclave is the responsibility of **specialised technicians**.	
SERVICE (1xx - 2xx - 3xx)	Performing SERVICE required by the machine is mandatory. The autoclave shows a SERVICE message followed by a specific code: 1xx, 2xx, 3xx. Each of these codes must be reported to the specialised technician who will use it to order the parts needed for service resolution.
SERVICE BULLETIN	The specialised technician will have to: →Order Original Spare Parts (together with which he will receive a Service Bulletin) →**Follow the instructions contained in the Service Bulletin** →Use all original spare parts received from the manufacturer or by the manufacturer's representative →Perform the tests indicated in the Service Bulletin using certified instruments →Fill out the Service Bulletin flowchart, signing all parts of it →Have the Service Bulletin signed in the area reserved for customers →LEAVE THE ORIGINAL (OR A COPY OF THE ORIGINAL) WITH THE CUSTOMER

Failure to perform the SERVICE required by the machine will lead to immediate voiding of the warranty.

15.4 ANNUAL MAINTENANCE AND VALIDATION

Annual maintenance and validation are operations that are the responsibility of **specialised technicians**.	
MAINTENANCE VERIFICATION	Sterilizers are essential tools for patient and operator protection: although the electronic controls of these machines are increasingly more reliable, it is best to carry out a functional check of the device at least once a year. This check must be carried out only by authorised and specialised service centres with calibrated and certified instruments in order to guarantee device longevity and reliability (validation). The specialised technician will also need to verify that weekly and quarterly maintenance has been performed.
ANNUAL VALIDATION	Validation involves the use of tools calibrated by specialised service centres for sterilizer cycle parameter checks. In fact, the temperature and pressure probes and the timer of the machine are checked. Upon request, the manufacturer issues an annual test certificate for machines returned for maintenance and inspection.
PRESSURE VESSEL AND SAFETY VALVE MAINTENANCE	In addition to the annual inspection indicated by the sterilizer via its "service light," checks on the following must also be carried out: the closure system, safety seal and valve (for the safety seal, see the operating instructions of the valve itself, delivered together with all autoclave documents). As this is a pressure vessel (assembly), these checks must be carried out by specialised technicians using only original spare parts. Furthermore, perform a visual inspection on the pressure vessel at least every 2000 cycles (corresponding to approximately 20% of the useful life of the device, evaluated as 10,000 cycles) to verify the absence of cracks or other critical issues that compromise safety.

It is the duty of the device user to gather and record all operations performed on the machine. The SERVICE BULLETIN set issued by the specialised technician contributes to the creation of the autoclave technical book.

15.5 DISPOSAL AND/OR DEMOLITION

Disposal and/or demolition of any component (packaging, water, internal machinery, etc.) must strictly observe the current standards in the country in which it is carried out. We recommend that you contact **specialised facilities**.	
	Directive 2002/96/EC (Waste Electrical and Electronic Equipment - WEEE): information to users: this product is compliant pursuant to art. 13 of Legislative Decree of 25 July 2005, No.151 "Implementation of Directives 2002/95/EC, 2002/96/EC and 2003/108/EC on the reduction of the use of hazardous substances in electrical and electronic waste disposal". The crossed-out wheeled bin symbol on equipment or on its packaging indicates that the product must be collected separately from other waste at the end of its useful life. At the end of the equipment's life, the user must therefore give it to appropriate Electrical and Electronic Equipment waste collection centres or return it to the reseller upon the purchase of a new type of equivalent equipment, on a one-to-one basis. The separate collection for the delivery of equipment to recycling, to treatment and environmentally compatible disposal helps avoid possible adverse effects on the environment and health and favours the reuse and/or recycling of materials and equipment. Unlawful disposal of the product by the user involves the application of the administrative sanctions provided for by current legislation.

Do not dispose of the device or its parts in normal waste cycles. Always follow the instructions given by the local authorities.

16. TECHNICAL CHARACTERISTICS

	18 litres	23 litres
MECHANICAL DATA		
Operating temperature	+5° +30° C	
Maximum operating altitude	2000 m	
Relative humidity maximum at 30°C	80%	
Relative humidity maximum at 40°C	50%	
General dimensions (~)	505 x 400 x 615 mm	505 x 400 x 690 mm
Max. weight with empty tanks	52 kg	58 kg
Max. weight with full tanks + ROSI on board	56 kg	62 kg
Overall dimensions of the open door	350mm	
Weight per support area	Max 27.5 N/cm^2	
Volume	Max 0.15 m^3	
Colour	RAL9016	
Material	AISI 304 and/or 316 / S235JR	
Noise at 1 m away	53.6 dbA	
Noise in front of the display	62.2 dbA	
ELECTRICAL DATA		
Supply voltage	230 Vac (+/-10%)	
Power	2400 W	
Frequency	50-60 Hz	
Power cord	3 x 1.5 mm^2	
Fuses	6.3x32mm – 12A/T	
Maximum heat transmitted	9.00 MJ/h (2150 Kcal/h)	
Insulation rating	1	
CHAMBER DATA		
Maximum operating pressure	relative 2.5 bar	
Maximum operating vacuum	relative -0.90 bar	
Maximum operating temperature	140°C	
Material	AISI 304 or 316 Stainless Steel	
Dimensions: Diam.xD	236 x 381.5 mm	236 x 530 mm
CLEAN WATER TANK DATA		
Maximum capacity	4 litres	
Executable cycles	~6	~5
Material	Polyethylene	
DIRTY WATER TANK DATA		
Maximum capacity	4 litres	
Executable cycles	~6	~5
Material	Polyethylene	
Maximum drain water temperature	75°C	
BACTERIOLOGICAL FILTER DATA		
Maximum diameter	56 mm	
Maximum permitted filter capacity	0.03 micron	
Data for filter replacement	Every 250 cycles or every 3 months	
TRAY HOLDER DATA		
Material	Stainless Steel or anodised aluminium	
TRAY DATA		
Material	Anodised aluminium or Stainless steel	

POLLUTION RATING	**2**

The manufacturer reserves the right to amend this product and manual without notice. This manual is the sole property of the manufacturer: it is illegal to reproduce it or transfer it to third parties without written authorisation.

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, the manufacturer guarantees this product as described below:

17.1 LENGTH OF THE WARRANTY

The duration of the warranty is
→24 months or 1500 cycles on the whole product and
→5 years or 5000 cycles on the chamber only.
In both cases, the warranty expires when one of the two aforementioned conditions is met.

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.

17.2 CONDITIONS

In order for this WARRANTY to be fully valid, the following is necessary:
→All installation operations must have been carried out strictly following the instructions provided in this user instruction manual.
→All use and routine maintenance must be carried out per the user instructions.
→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.
→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.

17.3 EXCLUSIONS

The following are not covered by the warranty:
→Labour, when this does not take place at the manufacturer's site.
→Damage resulting from transportation, except for agreements stipulated in advance between the parties.
→All components that manifest a lack of conformity resulting from incorrect installation of machinery.
→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.
→Damage caused by tampering with the product or product parts.
→Damage resulting from all other causes not attributable to the manufacturer.
→All components subject to normal wear (i.e. polycarbonate keyboard, supplied tubes, seals, trays, filters, etc.) and other accessories except when it is proved to be a manufacturing defect.
→Costs of delivering spare parts and/or finished products.

17.4 LIMITATIONS

→The purchaser is not entitled to the replacement of the complete machine if the defect is not reported within 30 days of the date of purchase.
→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.
→No compensation is awarded for machine downtime.
→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 booklet, particularly concerning the instructions for product installation, use and maintenance.

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MADE IN ITALY
Original Instructions

www.midmark.com