PEOPLE HAVE PRIORITY

User Manual

Water Steam Sterilizer

CE 0051

Lisa MB17/22

LISA MB17/22 201 10 AEN REV. 9

SUMMARY

RECOMMENDATIONS – SAFETY

The purpose of this user manual is to provide you with all the information you need in order to ensure:

- ☞ A proper installation and set-up.
- ☞ Optimal use.
- ☞ A safe and reliable operation.
- ☞ A regular and correct servicing requirements.

DECLARATION OF CONFORMITY

The Lisa sterilizer MB 17/22 is a Medical device class IIb, in accordance with rule 15 - Appendix IX of the European Directive 93/42/CEE.

The sterilizer has been developed, produced and tested in accordance with the new European Norm relative to small water steam sterilizers : EN 13060, and with the applicable safety norms (see appendix 1).

You will find enclosed a declaration of conformity and a warranty card specific to your sterilizer.

CONFORM USE:

The sterilizer must be used only for the purpose for which it was intended: the steam sterilization of solids, textiles and hollow items unwrapped, single or double wrapped.

This symbol draws attention to the user manual.
To disregard the instruction given in this manual, the incorrect use and the unauthorised disassembly of the sterilizer clears the manufacturer, W&H | STERILIZATION of responsibility for warranty and any other claim.

This symbol is visible on the front of the device under the door handle.

It recommends attention be paid to the high temperatures associated with the chamber, the door and the area around the door handle.

We reserve the right to modify the sterilizer in pursuit of our aim to improve our equipment and keep abreast of technology.

GENERAL RECOMMENDATIONS – SAFETY

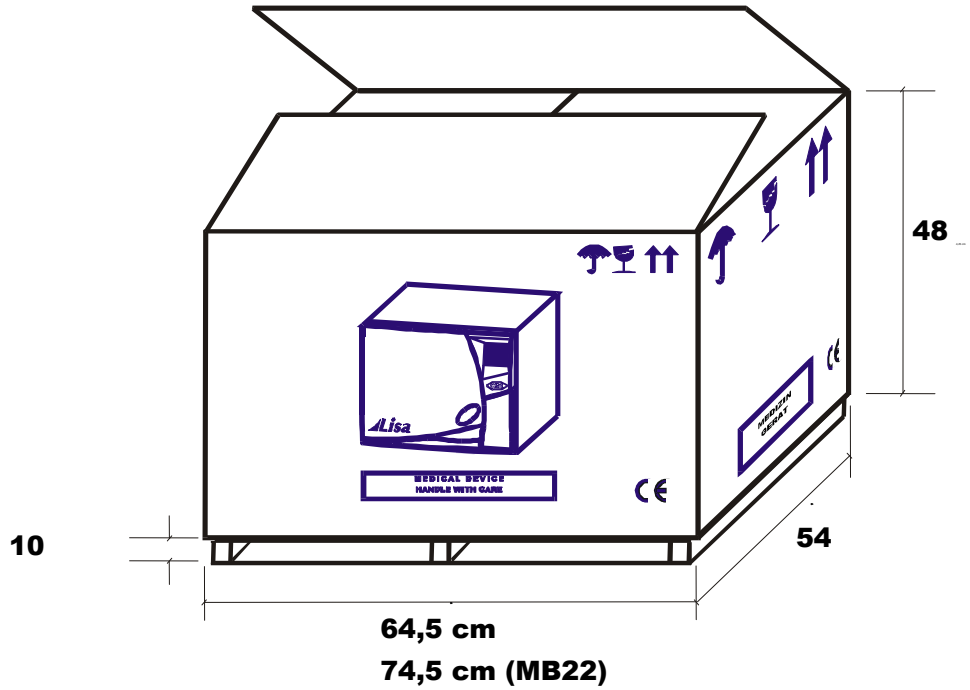
- The user is responsible for operating and servicing the sterilizer in accordance with the instructions listed in this manual.
- The sterilizer has not been designed for the sterilisation of liquids.
- The sterilizer has not been designed to operate in the presence of gas or explosive vapours.
- The chamber is automatically heated to 110°C as soon as the sterilizer is switched on.
- The trays and the load will still be hot at the end of each cycle. Use the tray holder to remove each tray from the chamber.
- Comply with the maximum weight specified, having been tested and validated for each load type (see § 4.6.1.) by **W&H** l **STERILIZATION** in order to ensure smooth operation and effective sterilization.
- Do not remove the instruction plate or any label from the sterilizer.
- Do not pour water or any other liquid over the sterilizer.
- Unplug the mains lead before inspecting or servicing the machine.
- Repairs and maintenance must only be carried out by an approved technician using only original spare parts.
- In case of transport, drain both water tanks completely (§ 4.3 and 4.4), allow the sterilization chamber to cool down and preferably use the original packaging.

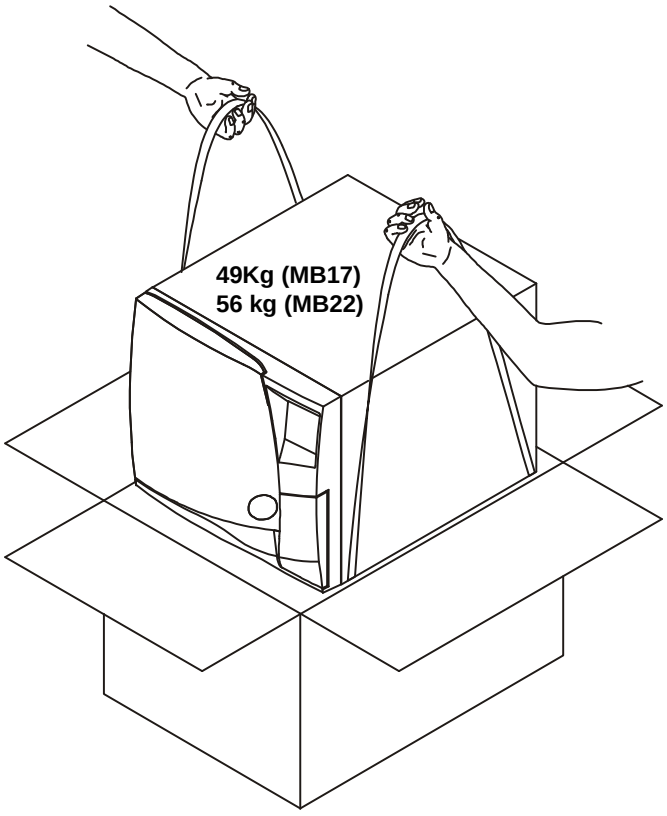
Compliance with the instructions in this manual ensures safe operation.

1. UNPACKING

The sterilizer, the accessories, the user manual and the warranty card are supplied in a sturdy box.
Check the condition of the packaging on receipt. Contact the carrier immediately and inform your supplier if the outer packaging is damaged.

1.1. UNPACKING THE STERILIZER

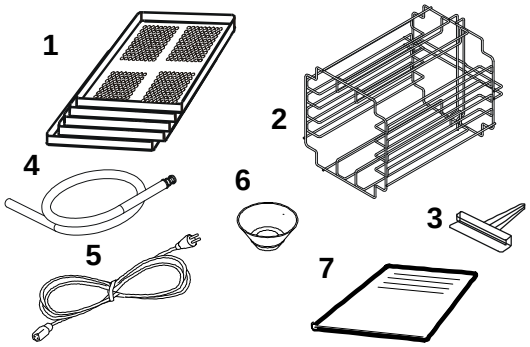




1.2. UNPACKING THE ACCESSORIES

- Open the door and remove the accessories from the sterilization chamber.
- Check the contents:

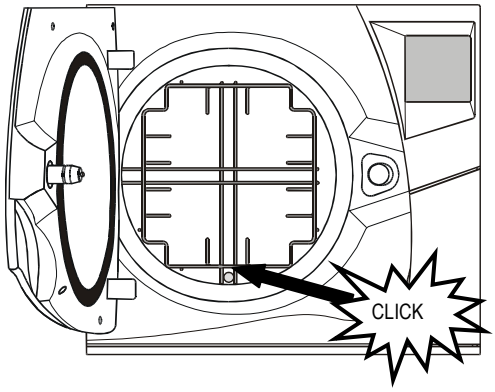
① 5 anodised aluminium trays
② Reversible rack for 3/5 trays
③ Tray holder
④ Drain tube
⑤ Mains cable
⑥ Funnel
⑦ User manual and warranty card
Declaration of conformity CE



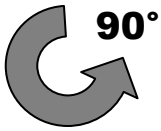
- Insert the rack into the sterilization chamber and click it into position.

The rack is reversible and can be positioned to take either:

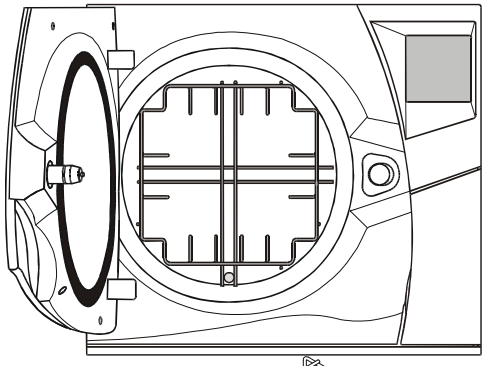
5 trays horizontally / 3 cassettes vertically



or



3 trays / cassettes horizontally.

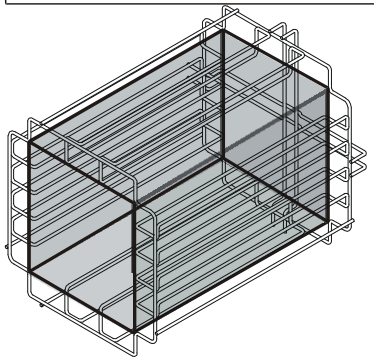


Usable space:

This equates to the usable volume of the chamber accommodating the sterilizable load.

This volume is equivalent to a parallel pipe with the following dimensions:
L: 195 mm, H: 205 mm, W: 300 mm, i.e. 12 litres (MB17)
L: 195 mm, H: 205 mm, W: 400 mm, i.e. 16 litres (MB22).

This volume is identical for all cycles and all types of load.

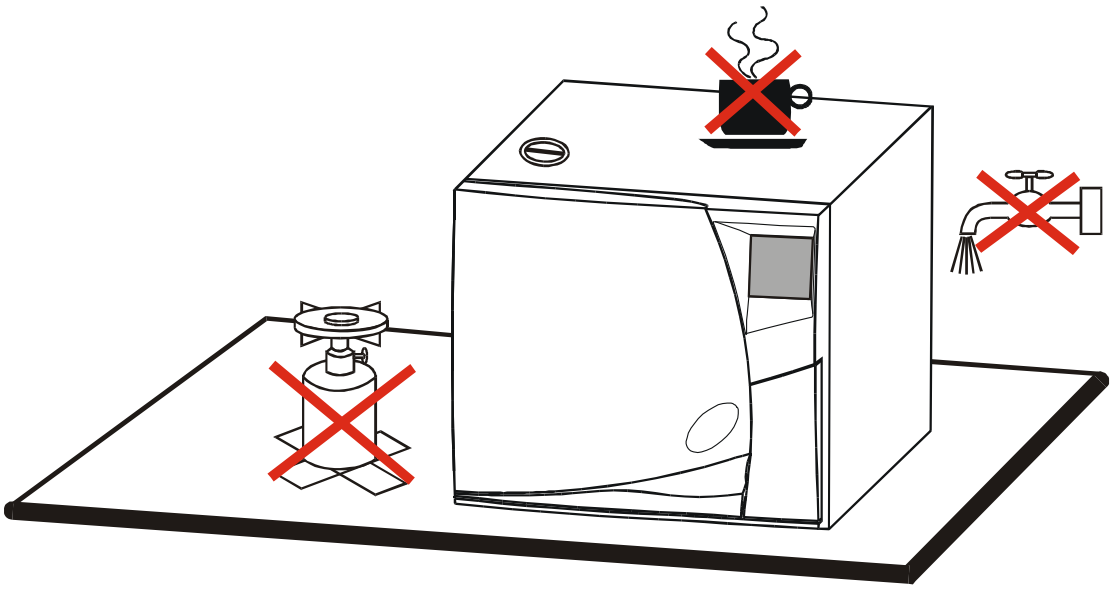


2. SET-UP

2.1. INSTALLATION

The sterilizer has been calibrated and tested in the factory. It does not require calibration during installation.

Working temperature range: 10°C to 40°C / Humidity : 0 to 90%.
Storage temperature range : -20°C to 60°C / Humidity : 0 to 90% (Water tanks empty).



Install the sterilizer as outlined below:

- ☞ Install the sterilizer on a flat and level surface.
- ☞ The maximum weight of the sterilizer with the main water tank full and the chamber fully loaded is:
  57,0 kg, 129.4 N/m², 140 N/foot (MB17)
  66.5 kg, 177.3 N/m², 160 N/foot (MB22)
- ☞ Leave a gap of 5 cm at the back and 2 cm on each side of the sterilizer to ensure adequate ventilation.
- ☞ Do not place the sterilizer near a sink or in a location where it is likely to be splashed.
- ☞ Install the sterilizer in a well ventilated room.
- ☞ Keep away from all sources of heat.

2.2. ELECTRICITY SUPPLY

The electrical installation must comply with the current standards in the country.

☞ The electricity supply must be single phase 230 volts ±10%, 50/60Hz, 10A.

☞ Installation category / Mains overload category = II

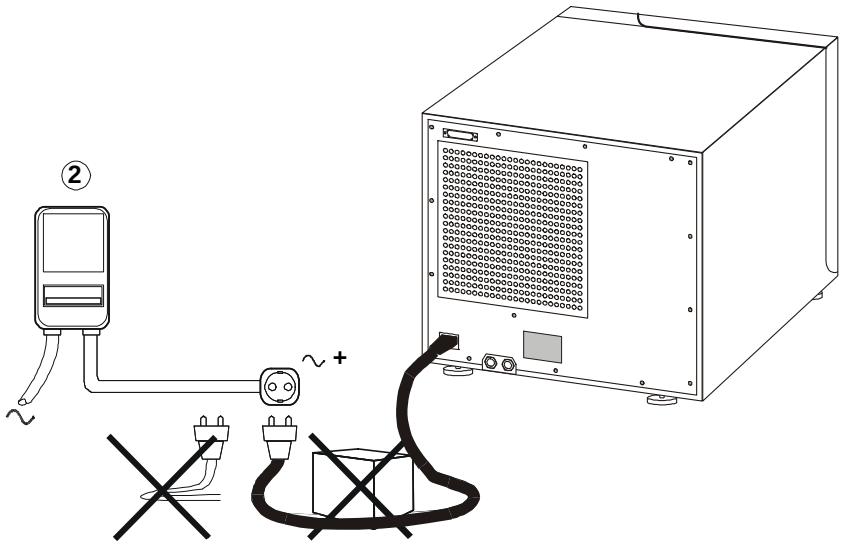
☞ An earth connection is essential.

The sterilizer must be connected to an electrically earthed plug.
Use only the mains cable delivered with the sterilizer.

The maximum absorbed power of the sterilizer is 2100 W (9,2A).

The installation must include:

- an earthed plug.
- a 10A differential circuit breaker with a sensitivity of 30mA (2).



Plug in the mains cable to the back of the sterilizer.

- ✓ Check that the serviceable voltage specified on the name plate located on the back of the sterilizer corresponds to the supplied mains voltage.
- ✓ The overall electrical safety of the sterilizer is only guaranteed if the sterilizer is appropriately earthed.
- ✓ If unclear, have the installation checked by a qualified electrician.
- ✓ Do not plug other equipment into the same socket.
- ✓ Do not bend or twist the mains cable.

W&H | STERILIZATION does not accept any responsibility if these instructions are not complied with.

2.3. PRINTER CONNECTION (OPTIONAL)

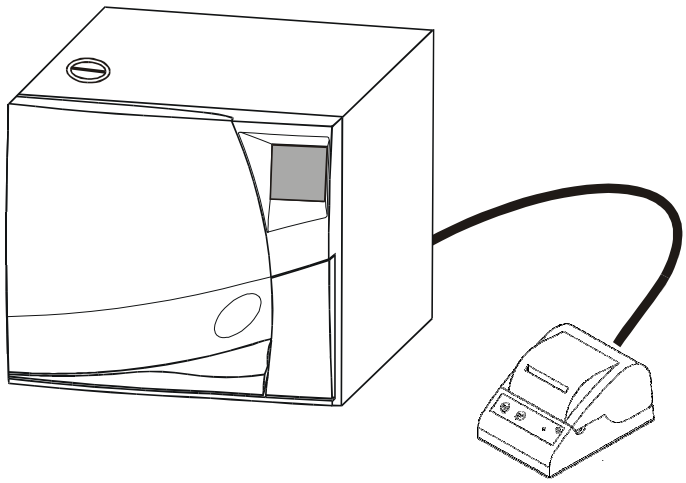
Attention !

We recommend to use the following printer:

- Custom DP40H.

It has been tested and is perfectly compatible with the sterilizer and its software.

The use of another printer is undertaken with the full responsability of the user, clearing the manufacturer, W&H | STERILIZATION of responsability for warranty and any other claim.



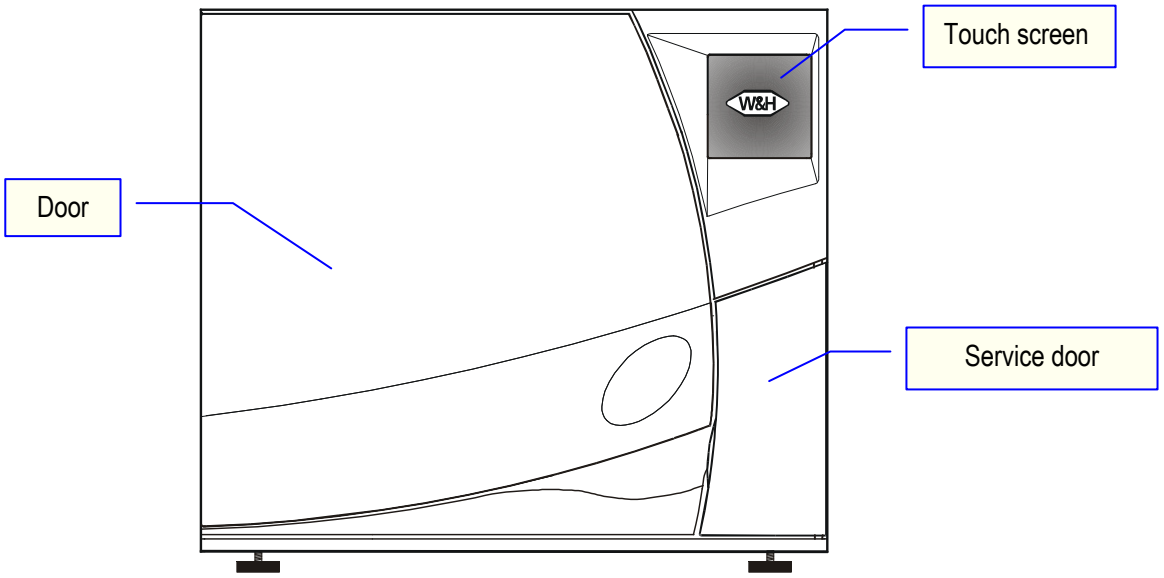
- ❑ Connect the printer cable to the 25 pin parallel port socket at the back of the sterilizer. Cable length should not exceed 2 metres.
- ❑ Plug in the printer mains cable.
- ❑ Switch ON the printer.
- ❑ Switch ON the sterilizer.
- ❑ Select the printer type (§ 4.5.4.).

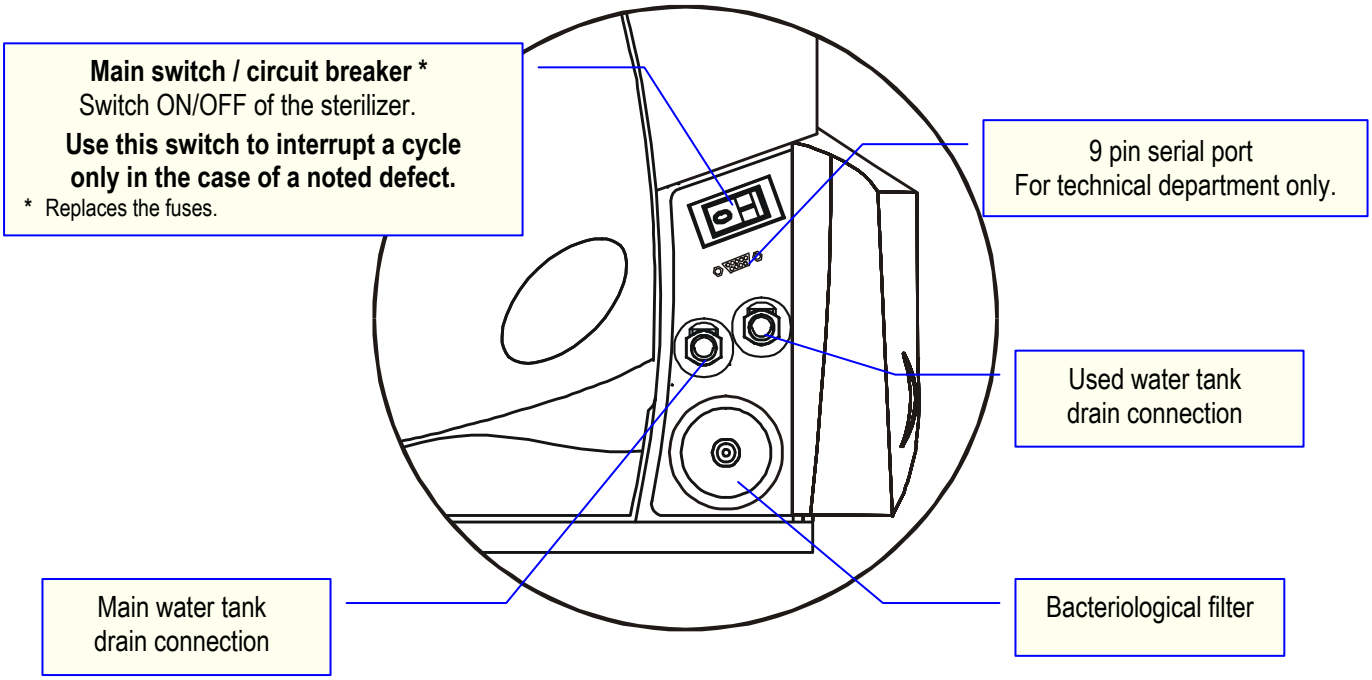
All the information needed to document the sterilization cycles is printed:

- The name of the Doctor / surgery (§ 4.5.2.).
- The serial number of the sterilizer.
- The chronological number of the cycle.
- The date and time at the beginning and at the end of the cycle.
- The cycle selected.
- The duration, temperature and pressure of the various phases.
- Comments on cycle efficiency.

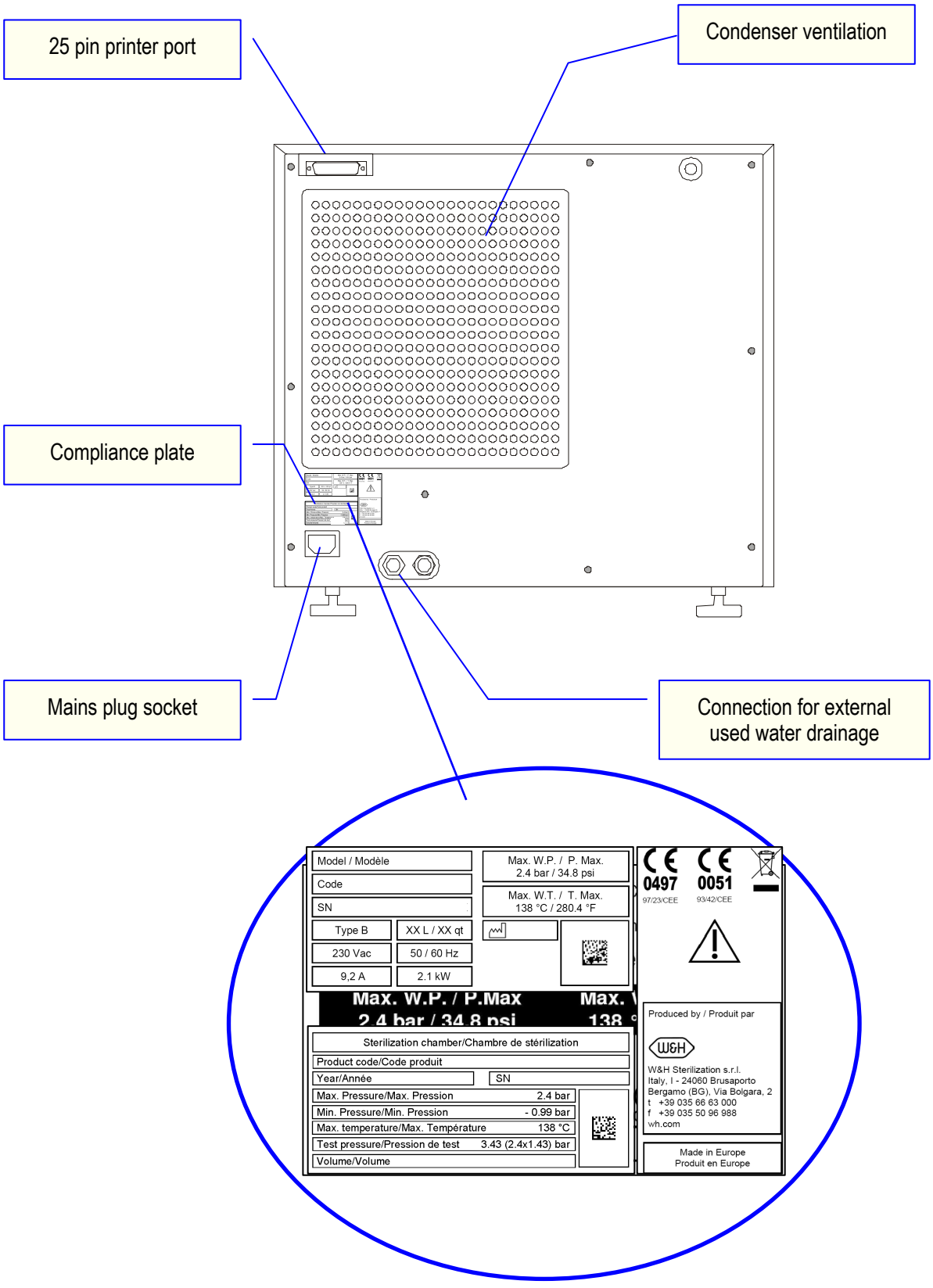
3. DESCRIPTION

3.1. FRONT VIEW OF THE STERILIZER





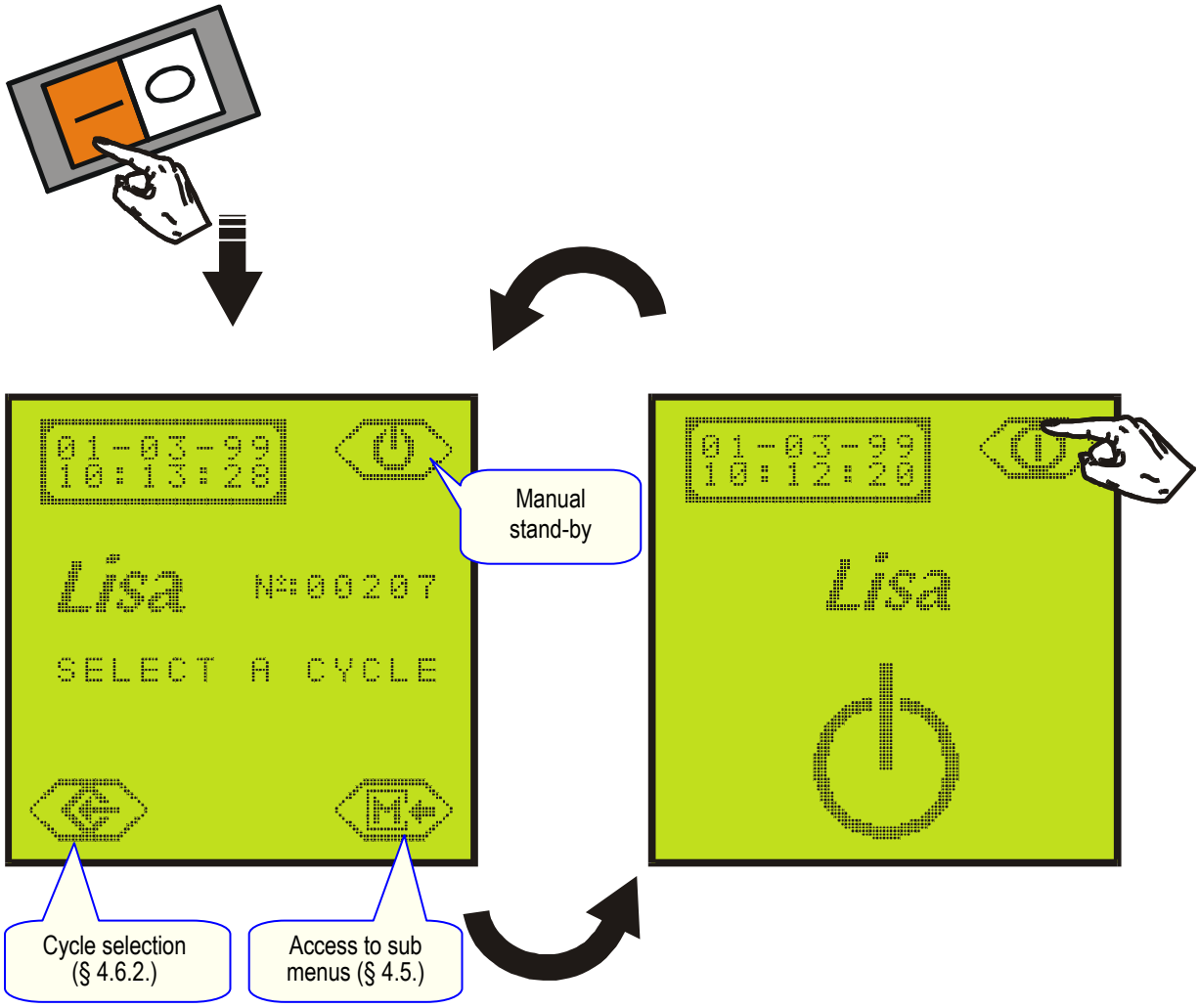
3.2. REAR VIEW OF THE STERILIZER



4. USE

4.1. MAIN MENU

Activate the mains switch, the selection screen appears.



If the sterilizer is not used for a certain period of time, it will automatically go into stand-by mode.
Stand-by mode time is programmable (§ 4.5.6.).

When the sterilizer is switched ON, the chamber is automatically heated to 110°C.

Pre-heating starts from room temperature and takes approximately 10 minutes.
It is nevertheless possible to select and start a cycle before the end of pre-heating.

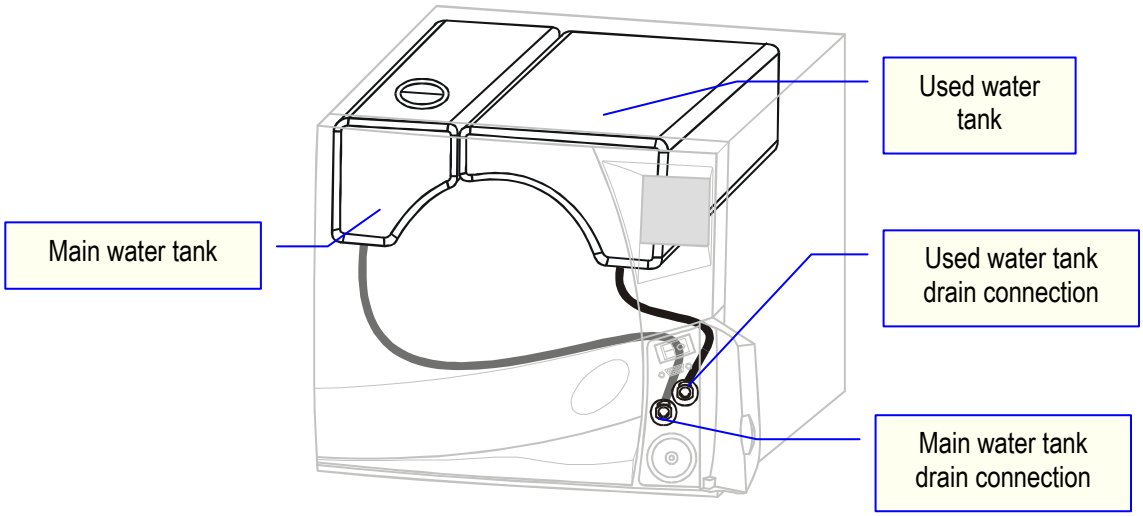
4.2. DESCRIPTION OF THE WATER TANK

The sterilizer is equipped with 2 independent water tanks of equal volume - 3.5 litres (MB17) or 4,5 litres (MB22).

The left tank also called the "**main tank**" contains the distilled or demineralized water required for each cycle.
It is fitted with 2 level sensors, minimum (0.5 l) and maximum (3.5 l on MB17 or 4.5 l on MB22).

The right tank called the "**used water tank**" contains the used water collected at the end of each cycles.
It is fitted with a maximum level sensor (3.5 l on MB17 or 4.5 l on MB22).

The 2 tanks are connected to drain connections located behind the service door.



The water consumption per cycle varies depending on the type and mass of the sterilized load.

The sterilizer will run for at least 8 cycles before the main tank needs refilling.

The following message is displayed on the screen when the minimum water level is reached in the main tank:

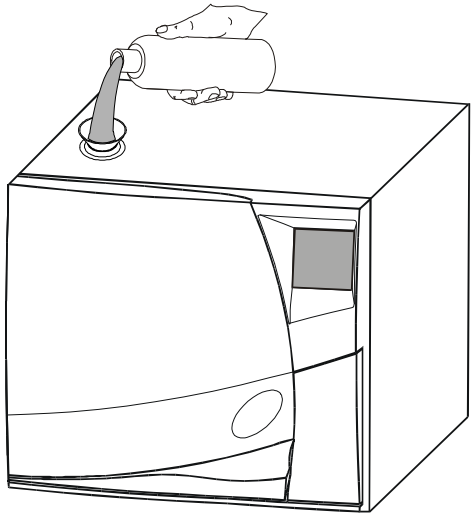
While the message is displayed, it is impossible to run another cycle.
The selection button has disappeared !

4.3. FILLING OF THE MAIN WATER TANK

Attention !

Use only high quality distilled or demineralized water (see Annex 7).

Remove the main water tank cap located on the top of the sterilizer …



…Fill the tank with approx. 3 litres on MB17 (or 4 litres on MB22) of water...

…Once the tank is almost full, an audible tone will be heard.

When you hear the tone proceed carefully. You must stop filling as soon as the water level reaches the lower edge of the opening to the water tank.

The water from the main tank (3 litres on MB17 or 4 litres on MB22) has been used for a series of cycles.

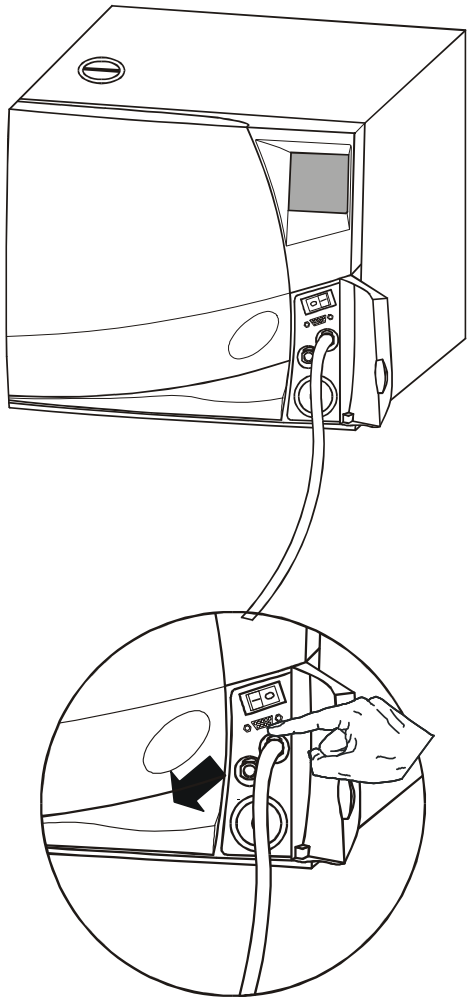
This water has been drained off and stored in the used water tank which will be full.

While the main tank is re-filled, the used water tank must be drained in the meantime (see § 4.4.).

If the sterilizer is not used for more than 3 days, both water tanks must be completely drained in order to avoid alga growth or any other deposits.

4.4. DRAINING OF THE USED WATER TANK

When the used water tank is full, it is impossible to run another cycle. The following message appears:



- Open the service door.
- Insert the drain tube into the quick coupling drain connection of the used water tank (right) as shown in the diagram.
- Allow the entire contents of the tank to empty and discard the used water.

NEVER RE-USE THE USED WATER !

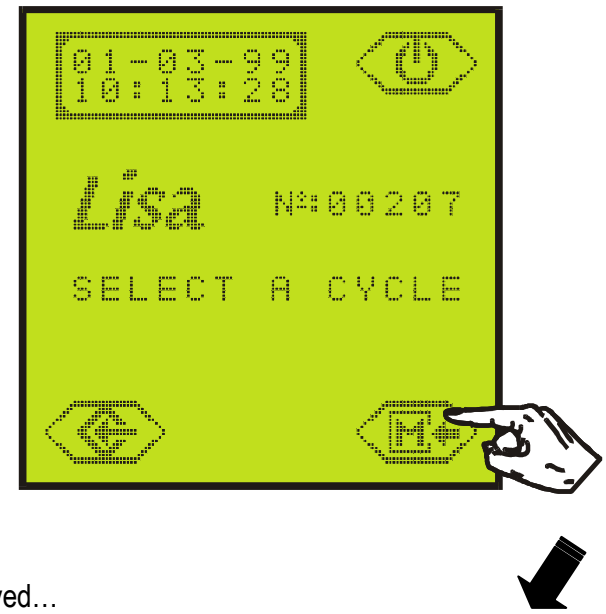
Disconnect the drain tube by pressing the push button on the drain connection.

In the meantime, while the used water tank is drained, the main tank can be re-filled.

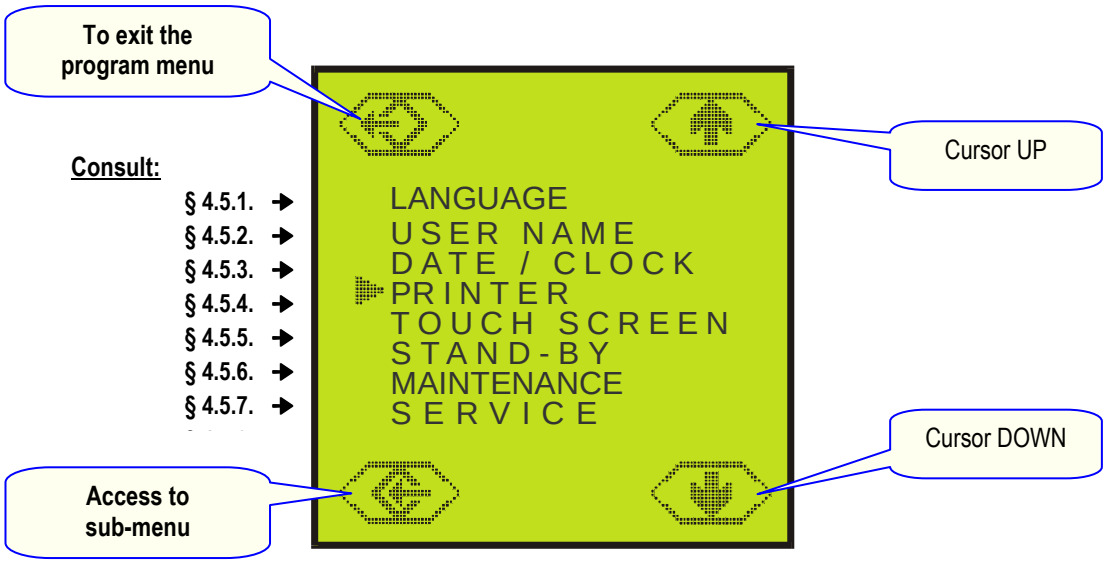
If the sterilizer is not used for more than 3 days, both water tanks must be completely drained in order to avoid alga growth or any other deposits.

4.5. PROGRAMMING

Press the "**M**" key on the selection screen…



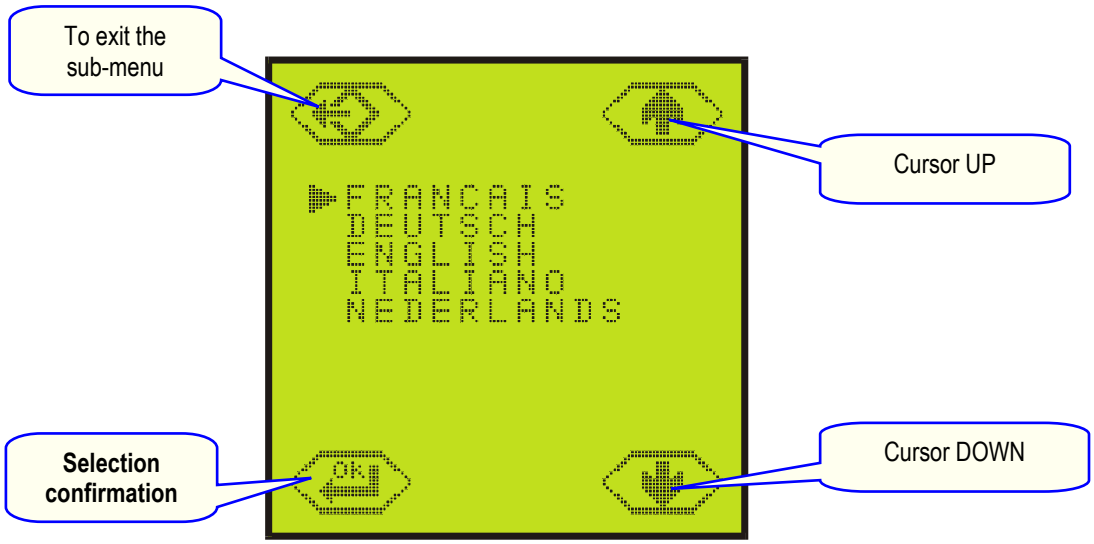
…The program menu is displayed…



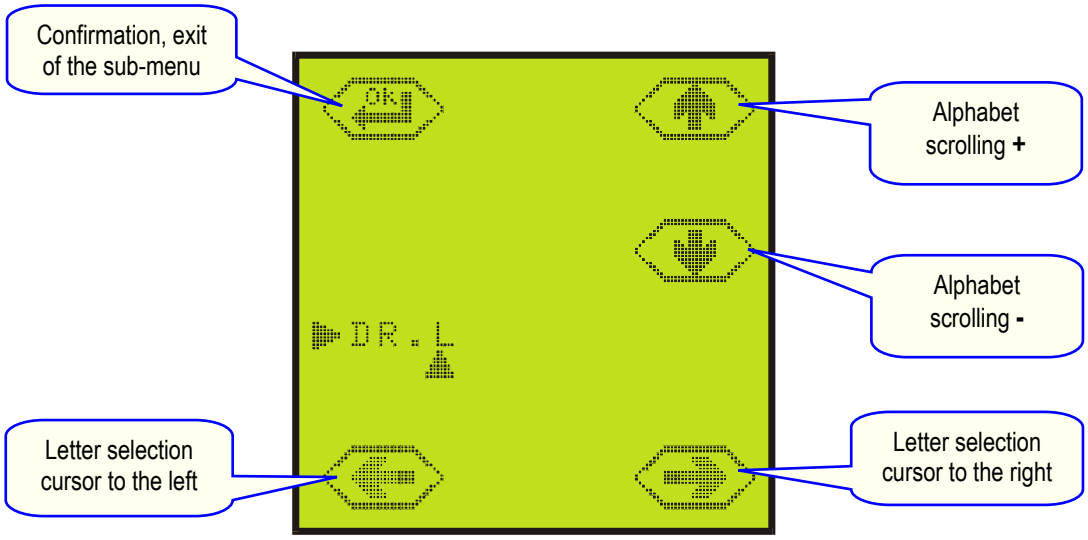
… Place the cursor "**>**" in front of the desired sub-menu using the "UP" and "DOWN" keys.
Confirm the selection by pressing the sub-menu access key.

Refer to the relevant chapter for the sub-menu selected.

4.5.1. SELECTING THE LANGUAGE



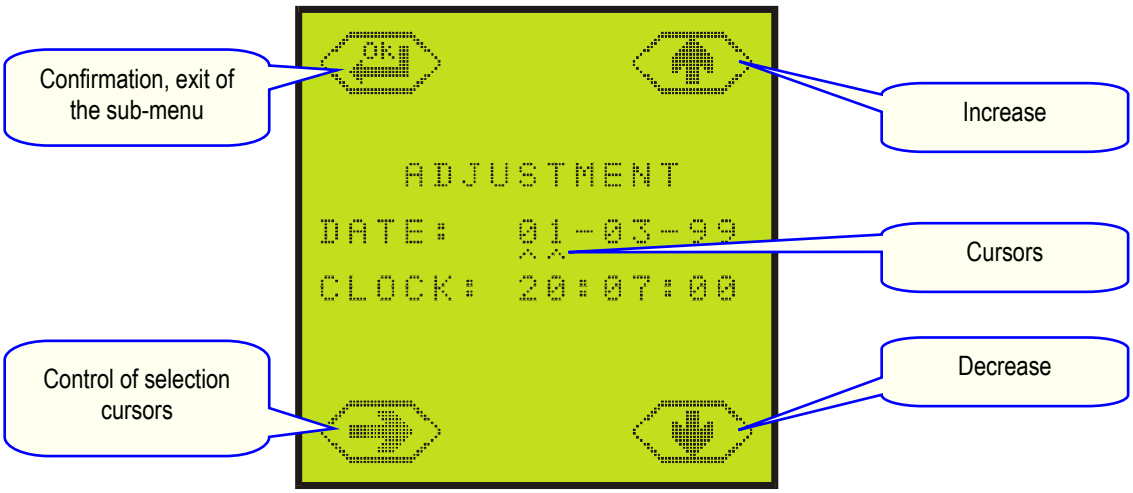
4.5.2. PROGRAMMING THE NAME OF THE DOCTOR / SURGERY



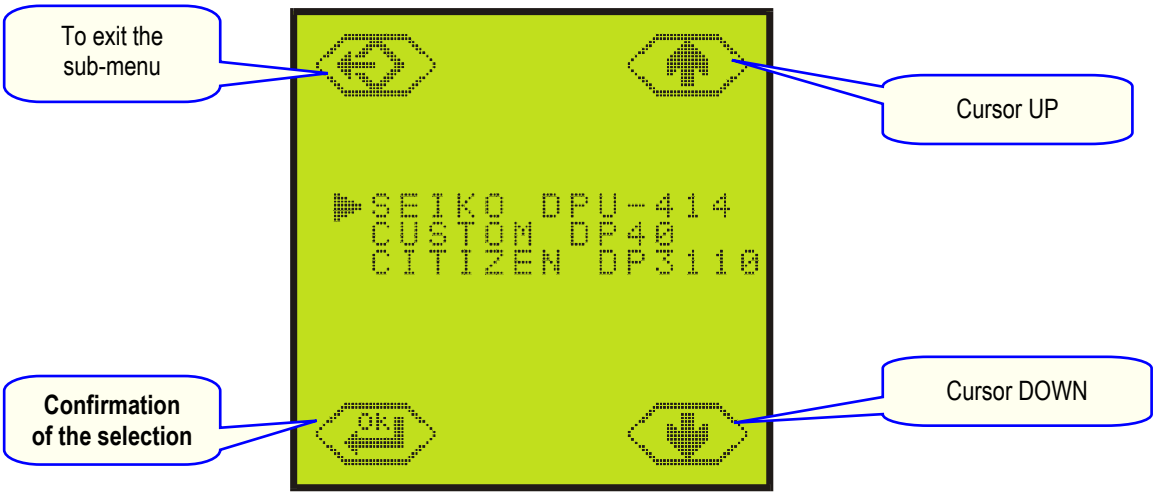
4.5.3. PROGRAMMING THE DATE AND TIME

It is essential to adjust the date and time especially if the sterilizer is connected to a printer. These parameters are systematically printed at the beginning and at the end of the cycle report.

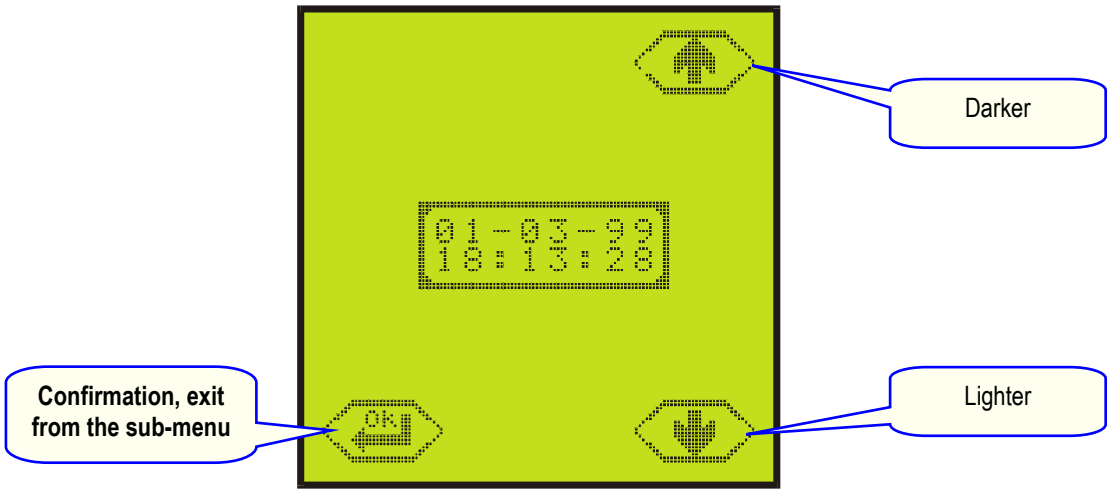
Place the selection cursors under the data that is to be adjusted. Increase or decrease its value, move the cursors under the next value and repeat operation. Confirm the adjustment by pressing the "Ok" key.



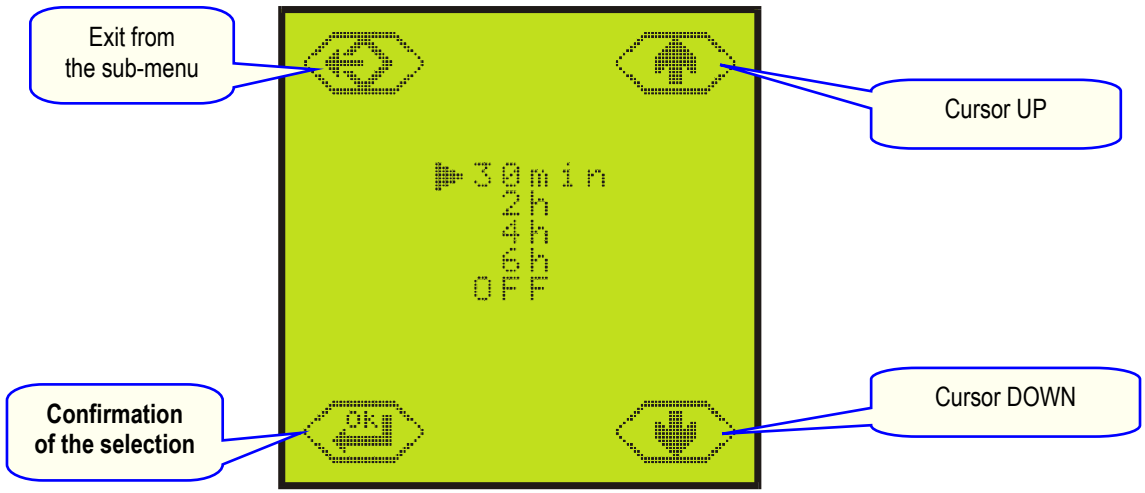
4.5.4. PROGRAMMING THE PRINTER



4.5.5. PROGRAMMING THE BRIGHTNESS OF THE TOUCH SCREEN

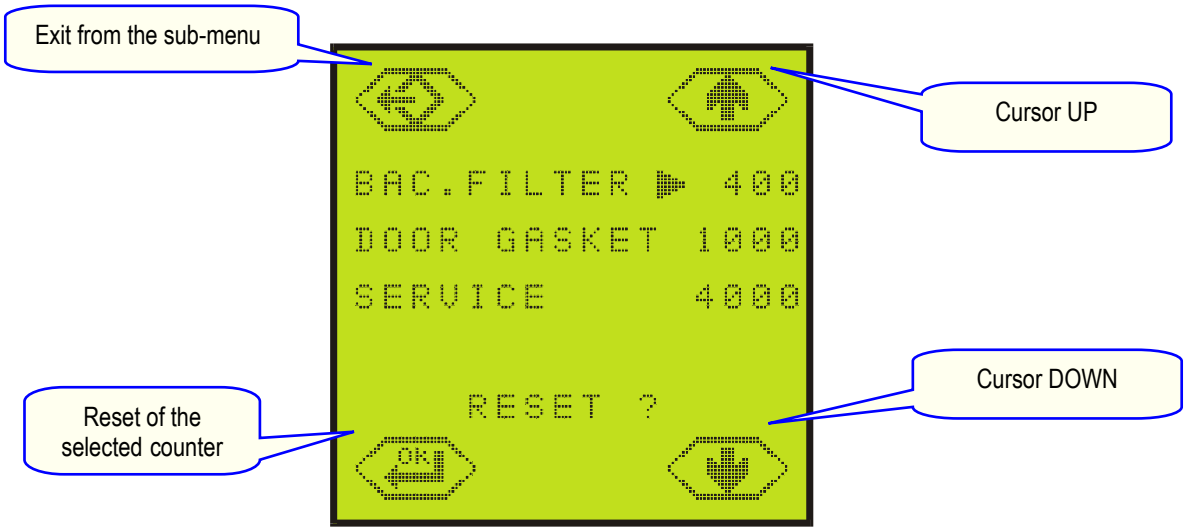


4.5.6. PROGRAMMING THE STAND-BY MODE



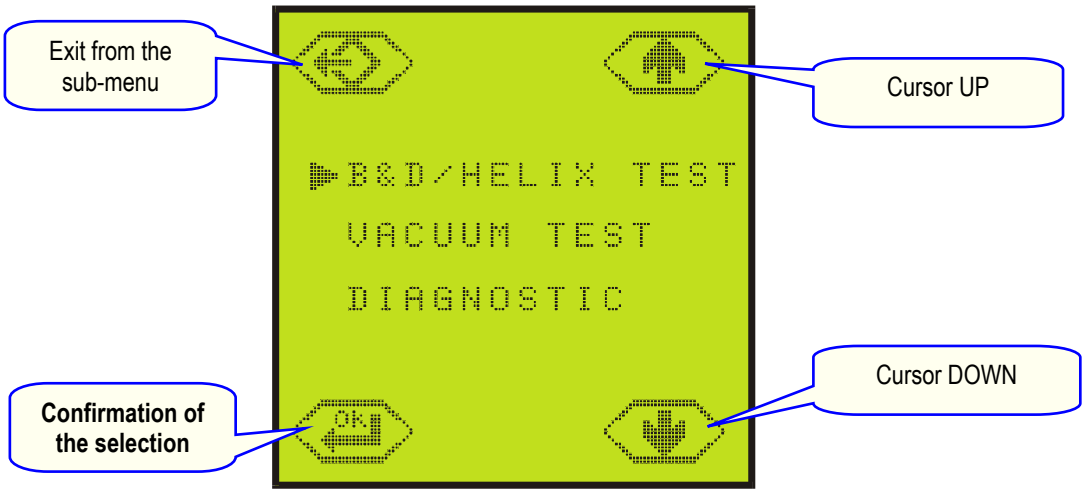
4.5.7. MAINTENANCE PROGRAM

This screen shows the number of cycles remaining before replacement of the bacteriological filter (400), the door seal (1000) as well as when general servicing (4000) is required. The three counters are decreased in value after each cycle.
When one of the counters reaches 0 a corresponding message appears at the bottom of the selection screen.
It is not possible to run a new cycle (the selection button will disappear) unless the reading of the message has been confirmed by pushing the Ok icon. The counter is then automatically reset.
If one of the three operations is completed before the respective counter has reached 0 it is necessary to reset the counter manually. Place the cursor in front of the operation with the icons UP and DOWN and reset it by pushing the Ok icon.



4.5.8. SERVICE PROGRAM

In this sub-menu it is possible to select and run the Bowie & Dick, Helix and air leakage/vacuum test cycles.
The diagnostic function is reserved for technical service personnel and requires an access code.



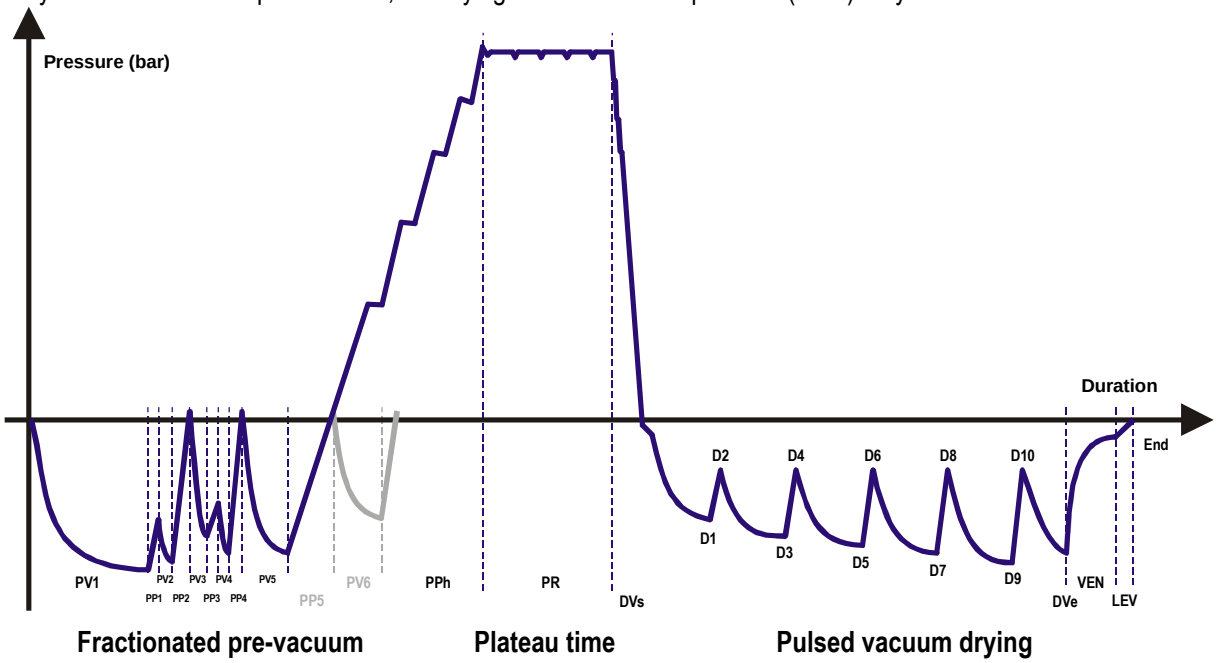
4.6. CYCLE SELECTION

4.6.1. CYCLE TABLE

TYPE OF CYCLE		STERILIZATION CYCLES			TEST CYCLES	
		B CYCLE B-STANDARD 134	**B CYCLE** B-PRION 134	**B CYCLE** B-STANDARD 121	B&D/ HELIX TEST	VACUUM TEST
Temperature		135.5°C	135.5°C	122.5°C	135.5°C	--
Pressure		2.16 bar	2.16 bar	1.16 bar	2.16 bar	-0.85 bar
Duration of the plateau		4'	18'	15'	3'20	16'
Duration of the drying phase		15'	15'	20'	4'	--
Total duration empty – full load		30' - 40' (MB17) 32' - 52' (MB22)	44' – 54' (MB17) 46' - 66' (MB22)	50' – 60' (MB17) 48' - 68' (MB22)	23' (MB17) 26' (MB22)	24' (MB17) 25' (MB22)
TYPE OF LOAD	Full solid (Probes, tweezers, burs,…)	**YES**	**YES**	**YES**	Empty	
	Small porous items (gauze, cotton,…)	**YES**	**YES**	**YES**		
	Full porous : 80% of the usable space.	**YES**	**YES**	**YES**		
	Hollow A (handpieces, forceps, scissors,)	**YES**	**YES**	**YES**		
	Hollow B (vacuum tips,…)	**YES**	**YES**	**YES**		
	Unwr., bagged, single/double wrapped	**YES**	**YES**	**YES**		
	Max mass of the load : Solid / Porous	4.5 / 1.5 kg (MB17) 6.0 / 2.0 kg (MB22)	4.5 / 1.5 kg (MB17) 6.0 / 2.0 kg (MB22)	4.5 / 1.5 kg (MB17) 6.0 / 2.0 kg (MB22)		
Load: The 3 Class B cycles can sterilize and dry all type of loads: full solid, porous, hollow A, hollow B, plastics, rubber, etc. unwrapped, bagged, single and double wrapped, but : ➢ **Instructions given by the respective manufacturers must be followed in each case.** ➢ **For guaranteed sterilization, never exceed the maximum load weight validated by the manufacturer.**					**Test cycles See annex 4, 5 & 6**	

All the cycles have the same profile:

Only the duration of the plateau time, the drying time and the temperature (121°) vary.



Legend:

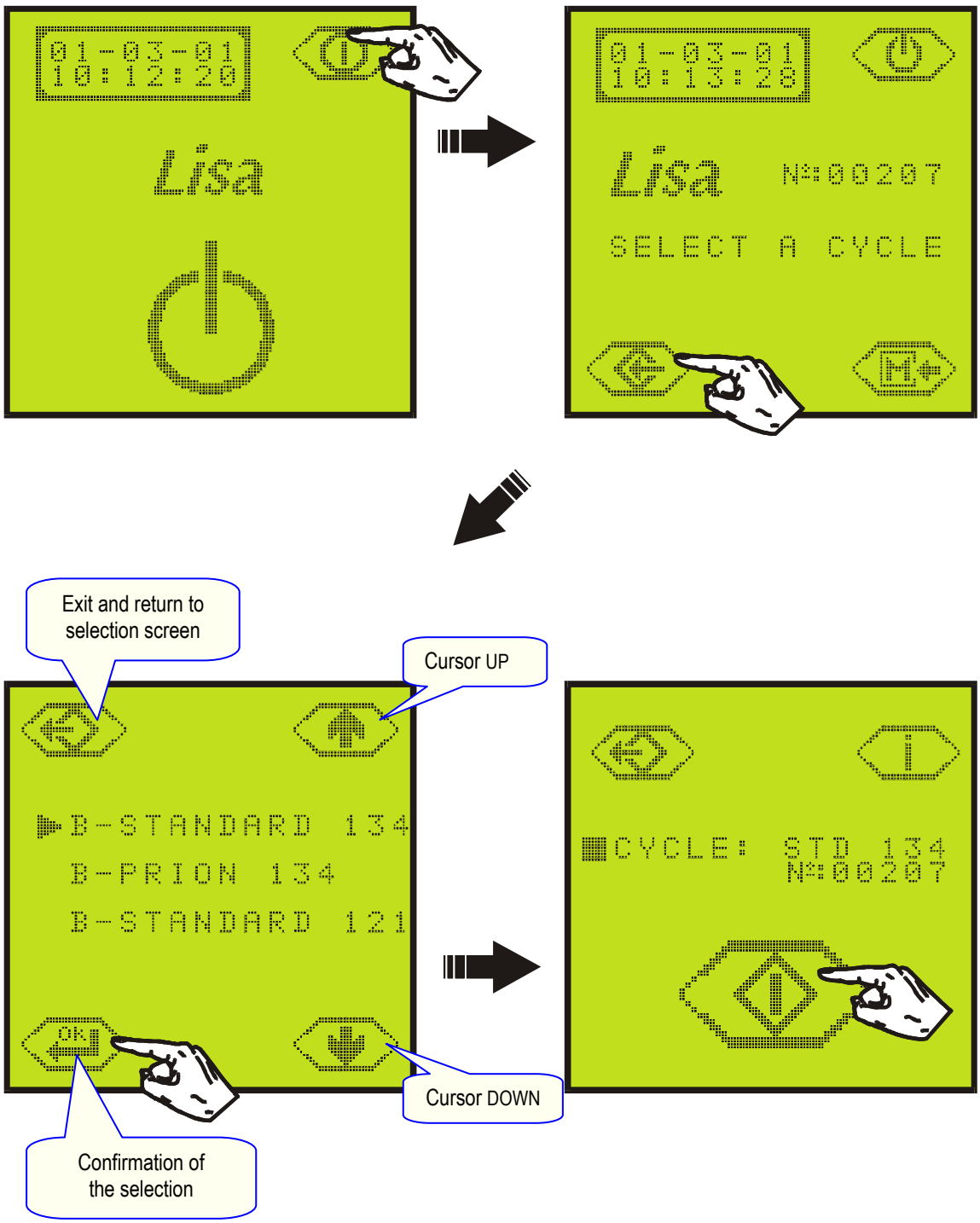
PV1..6 : Vacuum pulse **PP1..5** : Pressure pulse **PPh** : Pressure pulse and heating

PR : Process **DV** : Vacuum drying **VEN** : Ventilation **LEV** : Levelling

4.6.2. SELECTION – START OF THE CYCLE

Exit, if necessary, from the stand-by mode…

…Enter cycle select menu…

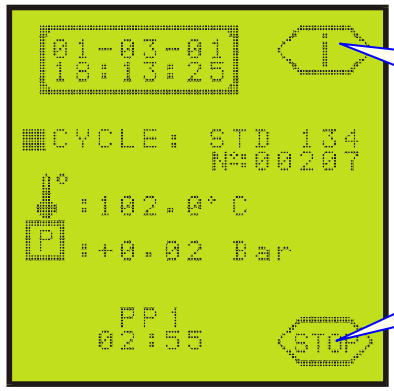


Position the cursor in front of the required cycle.
Confirm your selection by pressing the "OK" key.

Start the selected cycle.

4.6.3. CYCLE PROCEDURE

The following information is displayed during the cycle:



Date
Time

Selected cycle
N° of the cycle

Temperature
Pressure

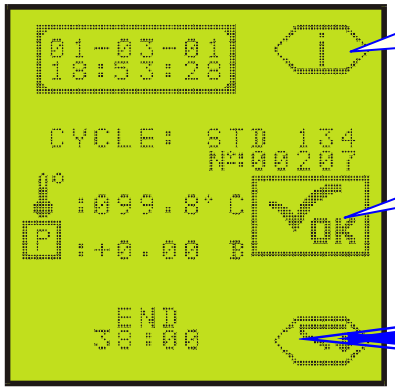
Current phase
Total duration

Access to technical data ⇨ § 4.8

Manual stop ⇨ § 4.7

You can access the technical parameters at any time by pressing the "Info" icon (see § 4.8.).
If needed, the cycle can be interrupted by pressing the "STOP" icon for 2 seconds.
An audible tone will confirm your request.
This is followed by a 2-minute interval necessary to reinitialise the system and revert to atmospheric pressure in the chamber (see § 4.7.).

END OF THE CYCLE



Date
Time

Selected cycle
N° of the cycle

Temperature
Pressure

End of the cycle
Total duration

Reference to cycle data ⇨ § 4.9

"Load sterile"

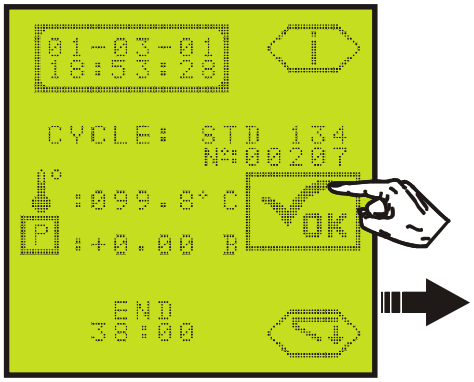
Opening of the door

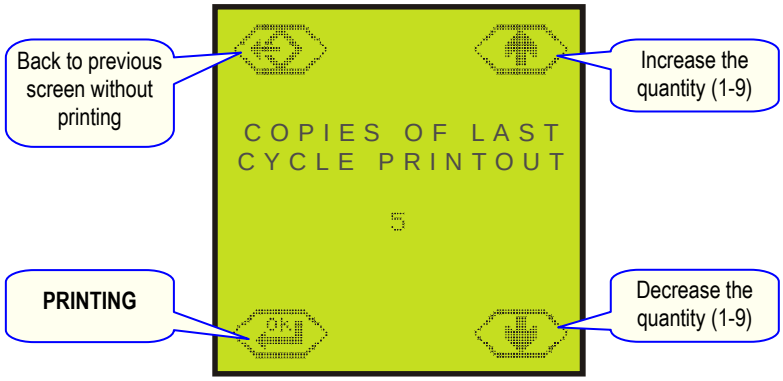
At the end of the cycle, the micro-processor analyses the temperature, pressure and duration of all the phases in order to confirm whether or not sterilization has occurred.
After reading the comment, you can open the door by pressing the corresponding key.

Comment: **If the door remains locked at the end of the cycle, the vacuum pump remains in operation. Every 10 minutes the pump will run for 40 seconds in order to ventilate the chamber and load preventing the build up of moisture. This operation continues until the temperature of the chamber falls below 60°C.**
Before the door is opened, it is possible to access the cycle data by simply pressing the "Info" icon (see § 4.9.).

4.6.4. COPIES OF CYCLE PRINTOUTS

It is possible to get copies of the last cycle printout prior to door opening.



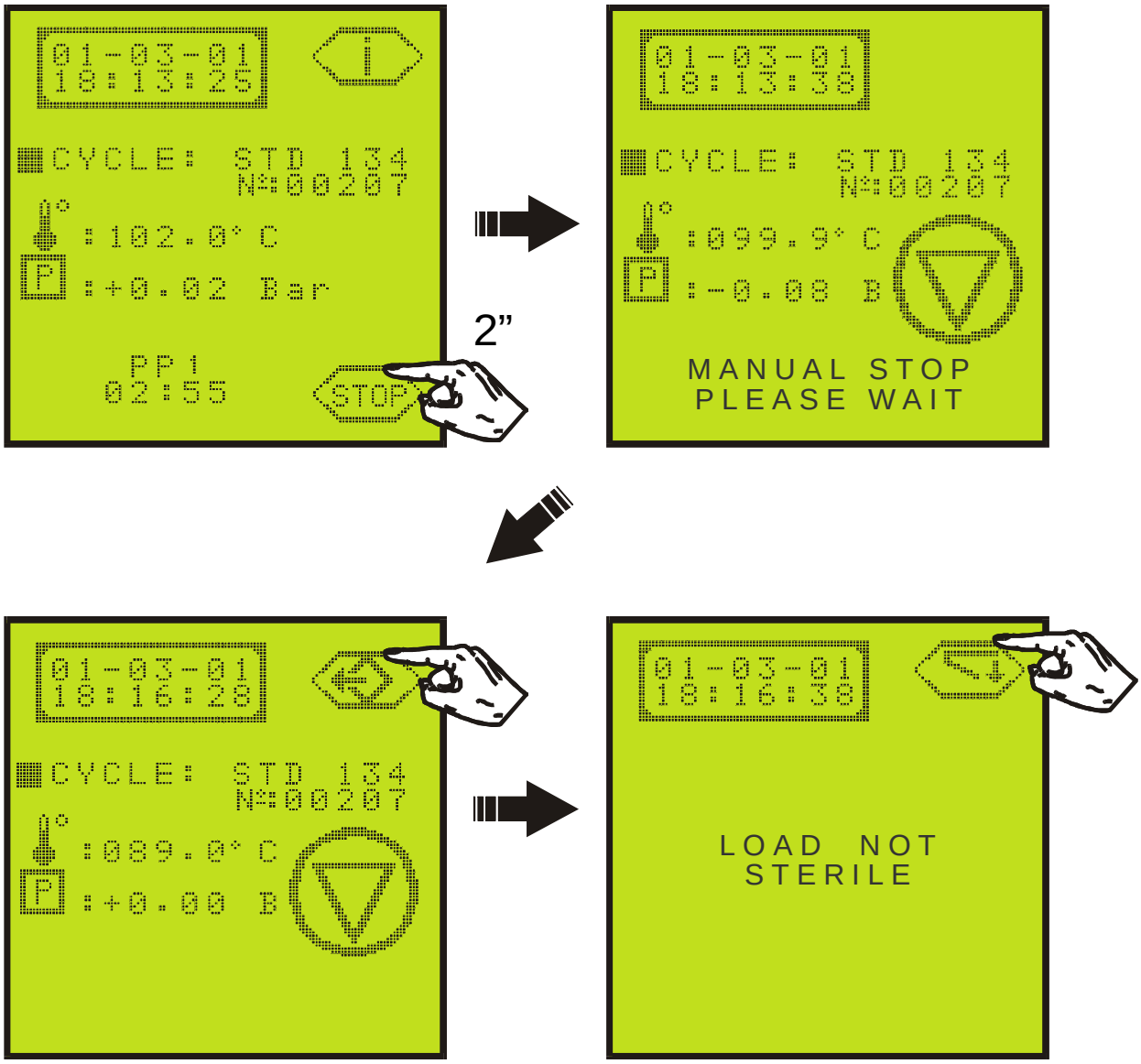


Press … ….Select the quantity needed: 1 to 9,

Print by pressing

4.7. MANUAL STOP

If needed, the cycle can be interrupted at any moment by pressing the "STOP" key for 2 seconds. An audible tone will confirm the request…



…This is followed by a phase of approximately 2 minutes, required to reinitialise the system and return the chamber to atmospheric pressure.

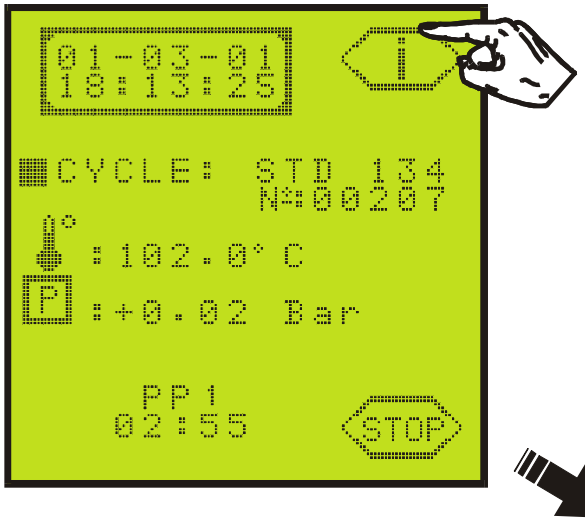
The door can be opened when the "Exit" key appears on the display at the end of this phase.

The load is not sterile and the cycle must be repeated !

If the cycle is interrupted after the PR phase (plateau period), following message will be displayed and printed : !! LOAD STERILIZED, BUT NOT DRIED !!
!! FOR IMMEDIATE USE ONLY !!

4.8. CYCLE DATA INFORMATION

You can access the technical data at any time during the cycle by pressing the "**I**nfo" icon.



..The following data will be displayed…

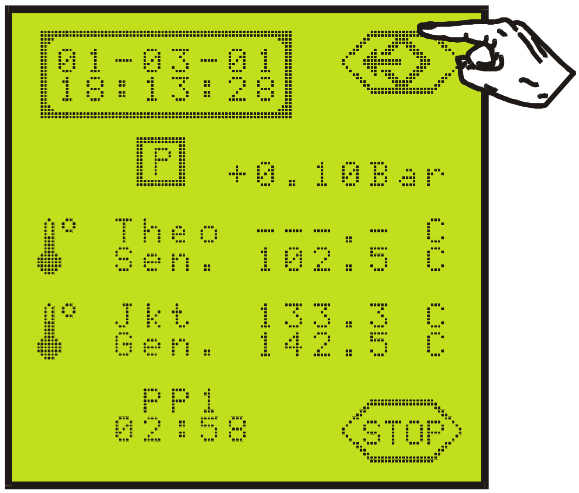
Date
Time

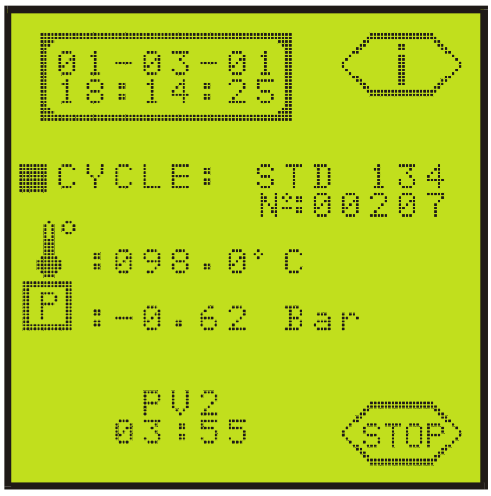
Chamber pressure

T° calculated/Pressure
T° of the steam

T° chamber heater
T° steam generator

Phase in progress
Duration of the phase

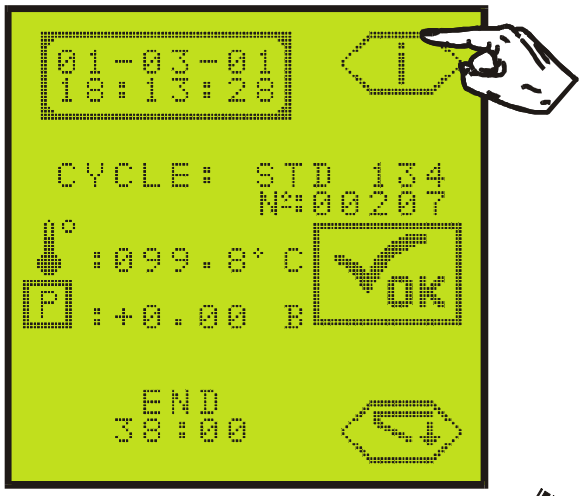




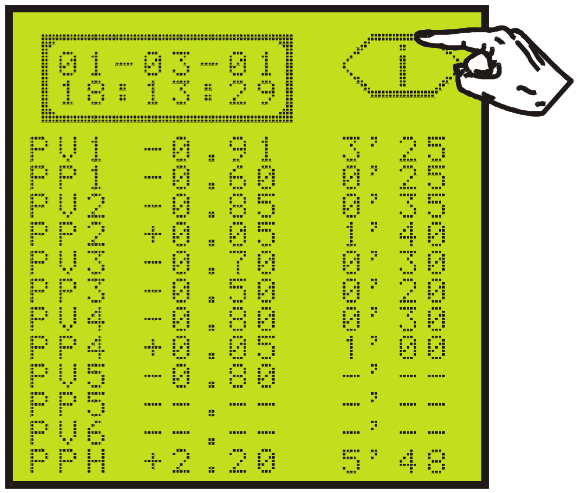
Exit and return to the current cycle screen.

4.9. CYCLE DATA SUMMARY (end of cycle)

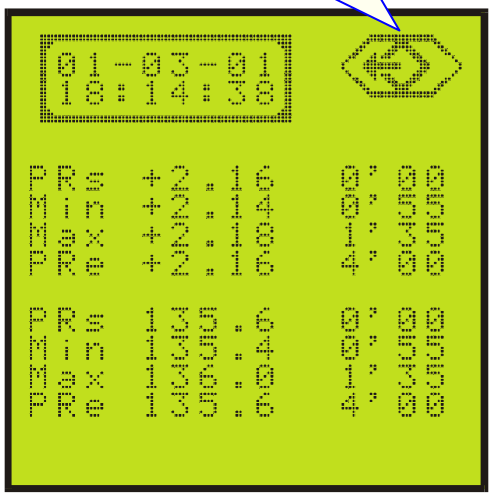
At the end of the cycle, before opening the door, the "Info" icon gives access to the technical data summary of the completed cycle.



The first screen lists the pressure and duration of each phase until the process...
(PV- vacuum pulse / PP- pressure pulse)



Exit and return to "cycle end" screen



…The second screen indicates the temperature and pressure relating to the sterilization phase:

Measured pressures : begin. / end / min. / max.
Measured temperatures: begin. / end / min. / max.

5. MESSAGES

A certain number of messages can appear at the beginning or at the end of the cycle.
This is merely information and not an alarm. The user can continue to operate the sterilizer with complete confidence.

During a cycle, the micro-processor continuously analyses all the parameters. The cycle would be interrupted immediately and an alarm displayed, if there was a concern with the sterilization quality (see § 6).

Message display

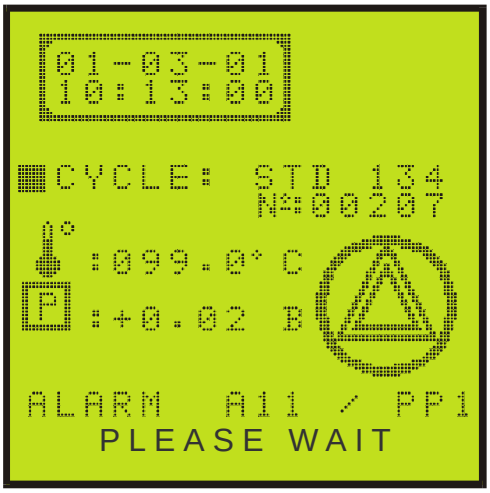
Messages list:

Message	Description	Action
FILL THE WATER TANK	The minimum water level has been reached in the main tank.	Fill the main tank using distilled or demineralised water as described in § 4.3.
DRAIN THE USED WATER TANK	The maximum level of the used water tank has been reached.	Drain the tank described in § 4.4.
CLOSE THE DOOR	The door is not closed properly.	Close the door.
DOOR LOCKING PROBLEM	The door could not be locked properly	Control (clean) the door seal. Monitor. ✎ Service if the message persists.
Ttheo/Tsen DIFF IN STERL. PHASE	During sterilization phase: 2°C difference between measured and theoretical temperatures (deducted from the pressure).	The sterilization grade is satisfactory because, at the beginning of the cycle, the micro-processor evaluates the vacuum level and stops the cycle if it is inadequate. Monitor. ✎ Service if the message persists.
Temp FLUCTUATION IN STERIL. PHASE	During sterilization phase: fluctuation by +/- 1,5°C of the measured and/or the theoretical temperatures (deducted from the pressure).	The sterilization grade is satisfactory because, at the beginning of the cycle, the micro-processor evaluates the vacuum level and stops the cycle if it is inadequate. Monitor. ✎ Service if the message persists.

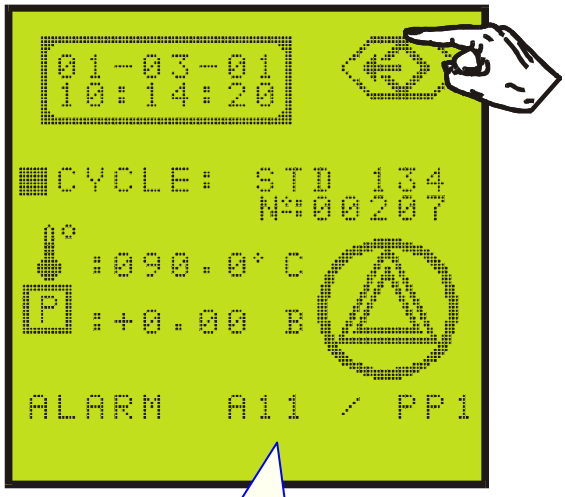
6. ALARMS

The micro-processor continuously analyses all the cycle parameters.
If there is any doubt regarding sterilization efficiency, the cycle is immediately interrupted and an alarm displayed.
This is followed by a phase of approximately 2 minutes required to reinitialise the sterilization system and to return the chamber to atmospheric pressure. **The load is not sterile and the cycle must be repeated !**

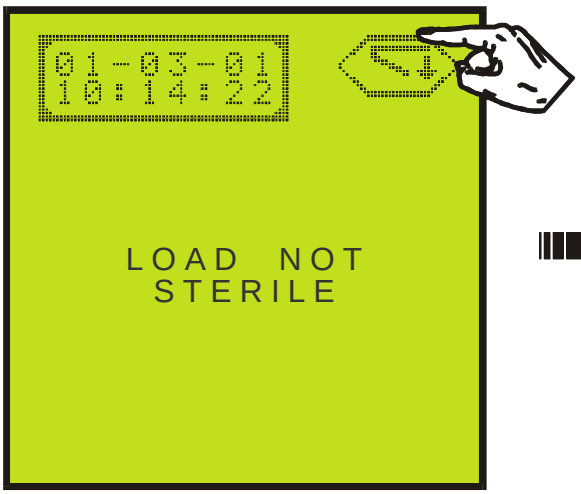
The alarm screen appears…



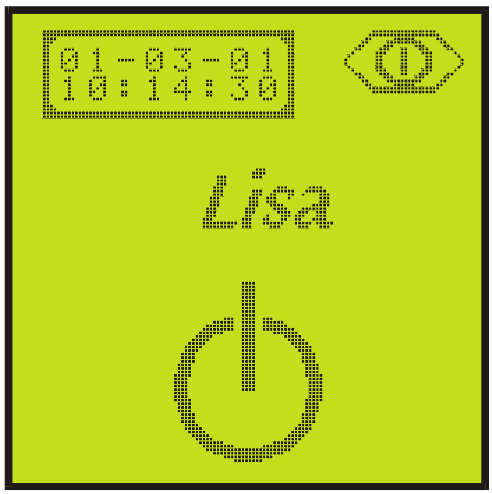
Press the "OK" icon at the end of the re-initialisation phase to confirm the reading of the alarm.



Code of the alarm / interrupted phase see table §6.1.



Opening of the door…



…and return to stand-by mode.

If the cycle is interrupted after the PR phase (plateau period), following message will be displayed and printed :

!! LOAD STERILIZED, BUT NOT DRIED !!
!! FOR IMMEDIATE USE ONLY !!

6.1. DESCRIPTION OF THE ALARMS

N°	Description	Action
Mains		
A01	Mains failure or significant fall in voltage occurred during the cycle.	The load cannot be considered sterile. The cycle must be repeated.
Sterilization chamber		
A10	The time spent to reach the sterilization plateau is too long (overload, leaks, etc.).	Clean the door seal, repeat the cycle. If the problem persists ☎ service.
A11	The temperature of the chamber heating element is above the nominal value.	Repeat the cycle. If the problem persists ☎ service.
A12	The temperature of the chamber heating element is below the nominal value.	Repeat the cycle. If the problem persists ☎ service.
A13	During the sterilization process, the pressure measured in the chamber is above the maximum threshold.	Repeat the cycle. If the problem persists ☎ service.
A14	During the sterilization process, the pressure measured in the chamber is below the minimum threshold.	Repeat the cycle. If the problem persists ☎ service.
A15	During the sterilization phase, the temperature of the steam is below the minimum threshold.	Repeat the cycle. If the problem persists ☎ service.
A16	During the sterilization phase, the temperature of the steam is above the maximum threshold.	Repeat the cycle. If the problem persists ☎ service.
A17	The temperature sensor of the chamber heating element is broken or disconnected.	☎ service
A18	The internal temperature sensor (steam) of the chamber is broken or disconnected.	☎ service
A19	Air Detection system – Leak found in PPH phase	Repeat the cycle. If the problem persists ☎ service.
A20	Air Detection system – A.D. problem	Repeat the cycle. If the problem persists ☎ service.
Steam generator		
A21	The temperature of the steam generator is above the maximum threshold.	Repeat the cycle. If the problem persists ☎ service.
A22	The temperature of the steam generator is below the minimum threshold.	Repeat the cycle. If the problem persists ☎ service.
A23	The temperature sensor of the steam generator is broken or disconnected.	☎ service

DESCRIPTION OF THE ALARMS (continue)

N°	Description	Action
Vacuum pump		
A31	During a vacuum phase, the maximum achieved vacuum is not lower than – 0.20 bar.	Clean and check the door seal (§ 7.2.), repeat the cycle. If the problem persists ☎ service.
A32	During a vacuum phase, the maximum achieved vacuum is not lower than – 0.50 bar.	Clean and check the door seal (§ 7.2.), repeat the cycle. If the problem persists ☎ service.
A33	The global vacuum level obtained after 5 pulses is not sufficient. The calculated additional 6th pulse is impossible to obtain (outside limits).	Clean and check the door seal (§ 7.2.), repeat the cycle. If the problem persists ☎ service.
A34	The last 10 cycles have required a 6th additional vacuum pulse.	Sterilization is guaranteed because the additional 6th pulse ensures the global vacuum level has been obtained, ☎ service for control.
Door locking		
A52	1) The door locking system is blocked during opening and closing phases. 2) The door locking switch is open during the cycle.	☎ service
Electro-valves		
A63	The pressure does not exceed – 0.70 bar, 2 minutes after the end of a vacuum phase.	☎ service

7. USER MAINTENANCE

A distinction must be made between two levels of maintenance, that performed regularly by the user and preventive maintenance carried out by an approved technician (§ 8).

Remove the mains cable before examining the sterilizer.

7.1. MAINTENANCE PROGRAM

Frequency /	N° of cycles	Operation	Spare number	Description
Weekly	50	Cleaning the door seal.	-	§ 7.2.
		Cleaning the chamber, the trays and the rack.	-	§ 7.3.
		Cleaning the external surfaces.	-	§ 7.4.
Every 3 months	400	Replacing the bacteriological filter.	W322400X	§ 7.5.
Every 6 months	1000	Cleaning both water tanks.	-	§ 7.6.
Every year	1000	Replacing the door seal.	F460503X	§ 7.7.
* Every 3 years.	4000	Servicing by an approved technician.	-	§ 8.

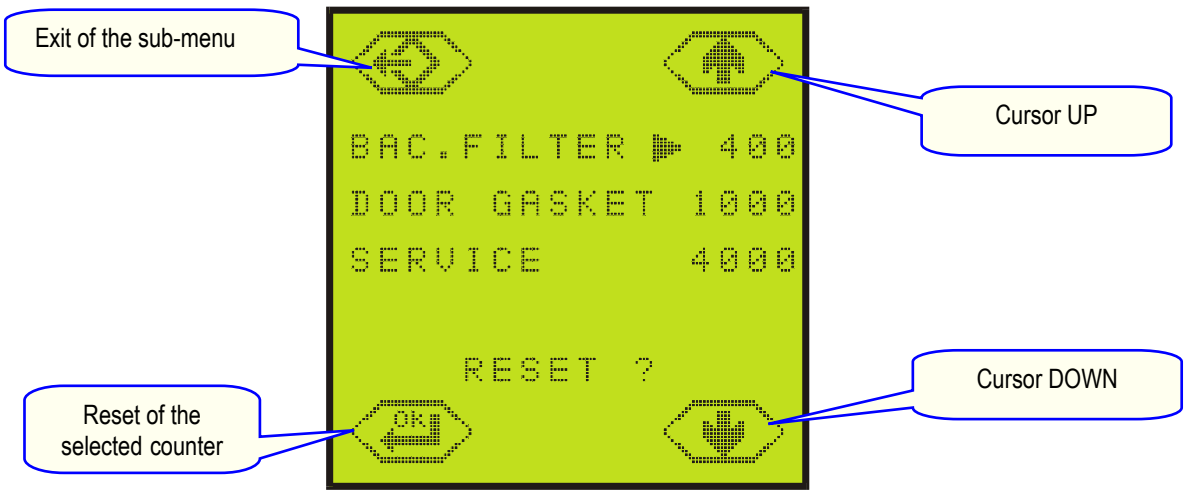
***Refer to the legislation and instructions for each individual country.**

The maintenance sub-menu (§ 4.5.7.) indicates the number of cycles remaining before replacement of the bacteriological filter, the door seal and when general servicing is required. The three counters are decreased in value after each cycle.

When one of the counters reaches 0 a corresponding message appears at the bottom of the selection screen.

It is not possible to run a new cycle (the selection button will disappear) unless the reading of the message has been confirmed by pushing the "OK" icon. The counter is then automatically reset.

If one of the three operations is completed before the respective counter has reached 0 it is necessary to reset the counter manually. Place the cursor in front of the operation with the icons UP and DOWN and reset it by pushing the "OK" icon.



7.2. CLEANING THE DOOR SEAL

- Clean the door seal and the porthole with a lint free cloth saturated with alcohol.
- The porthole can also be cleaned with a non-abrasive detergent.

7.3. CLEANING THE CHAMBER, TRAYS AND TRAY HOLDER

- Remove the trays from the chamber.
- Disconnect and remove the rack.
- Clean the chamber with a damp sponge moistened with a detergent or scouring agent if necessary.
- Rinse with a damp sponge to remove all traces of the cleaning agent.
- Apply the same procedure for the rack, trays (cassettes).

- **Ensure that you clean all around the sterilizer chamber.**
- **Do not bend or damage the temperature sensor at the bottom of the chamber.**
- **Never use disinfectants to clean the chamber.**

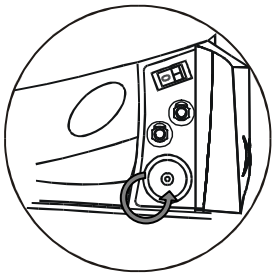
7.4. CLEANING THE EXTERNAL PARTS

- Clean the external parts with a damp cloth and mild detergent.
- Never use scouring agents or highly abrasive products.

- **Do not use copious amounts of water to wash the sterilizer as this may damage the electrical components and safety mechanisms.**
- **Take care not to scratch the plastic film in front of the touch-screen.**

7.5. REPLACEMENT OF THE BACTERIOLOGICAL FILTER

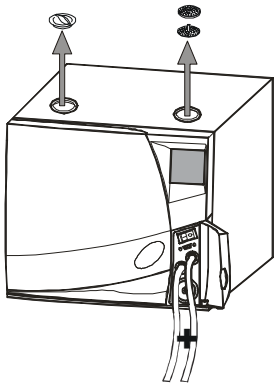
- Open the service door.
- Unscrew the bacteriological filter by hand (anti-clockwise).
- Insert and manually screw the new filter into position



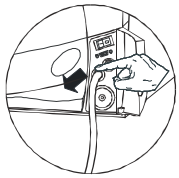
7.6. CLEANING THE WATER TANKS

Completely drain both water tanks (main and used water tank).

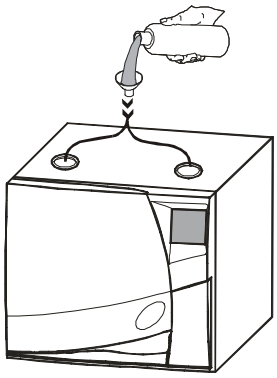
- Open the service door.
- Insert the drain tube into the quick coupling drain connection of the used water tank (right). Allow the entire contents of the tank to empty and discard the used water.
- Disconnect the drainage hose by pressing the push-button on the drain connection.



- Insert the drain tube into the quick coupling drain connection of the main water tank (left). Allow the entire contents of the tank to empty.
- Disconnect the drainage hose by pressing the push-button on the drain connection.

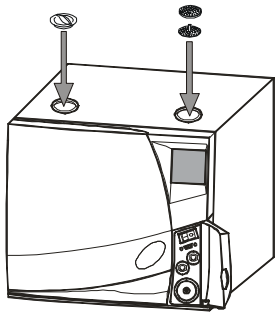


- Fill both reservoirs each with:
  2.8 litres of demineralised water + 0.2 litres of 90% alcohol (MB17)
  3.7 litres of demineralised water + 0.3 litres of 90% alcohol (MB22)



DO NOT RUN A CYCLE !

- **Allow the solution to sit for 30 minutes.**



- Drain both tanks and discard the 3 litres on MB17 (4 litres on MB22) of solution.
- Fill the main tank with 3 litres on MB17 (4 litres on MB22) of distilled or demineralised water.
- Run an empty cycle.

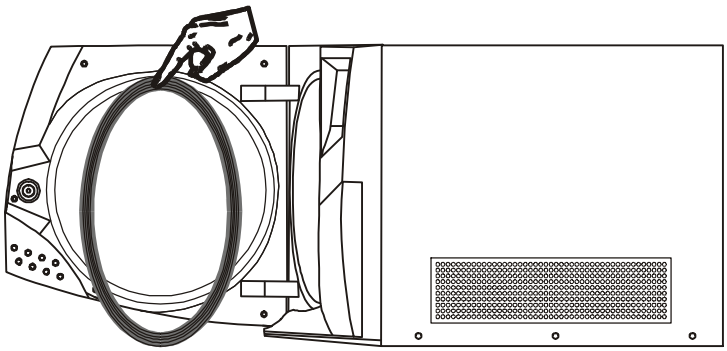
If the sterilizer is not used for more than 3 days, both water tanks must be completely drained in order to avoid alga growth or any other deposits.

7.7. REPLACING THE DOOR SEAL

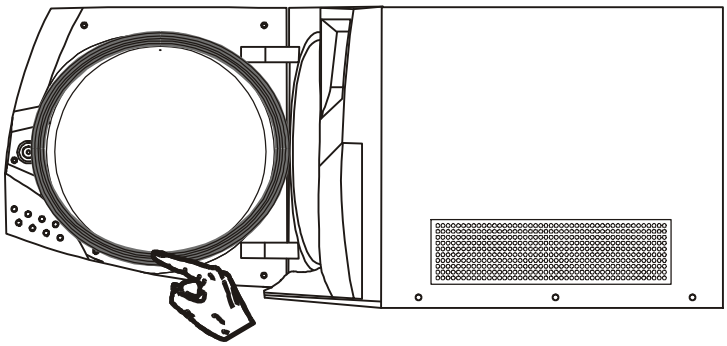
- Fully open the door of the sterilizer.
- Remove the door seal by hand.
- Carefully clean the seal seat with a cotton bud moistened with alcohol.
- Moisten the new seal.
- Insert the seal in the sequence illustrated in the following diagrams:

Insert the seal starting as follows:

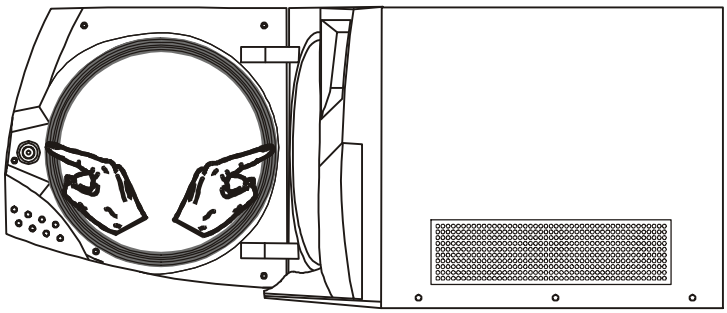
Up



Down



Left and right.



8. SERVICING CONDUCTED BY THE APPROVED TECHNICIAN

Service is essential to continued effective sterilization.
We recommend servicing by an approved technician every 3 years or 4000 cycles.

Check list:

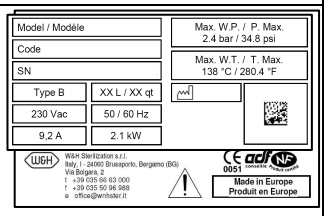
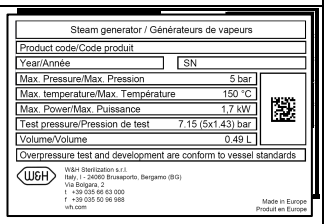
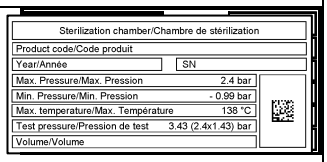
- ✓ Replacement of the 5 Solenoid valves.
- ✓ Replacement of the vacuum pump membrane kit.
- ✓ Replacement of the water filter.
- ✓ Replacement of the steam generator heating element.
- ✓ Cleaning the sterilization chamber.
- ✓ Cleaning the sterilization chamber filter.
- ✓ Cleaning the steam generator filter (EV5).
- ✓ Check of the pneumatic connections.
- ✓ Check the electrical connections.
- ✓ Check the door locking system.
- ✓ Check the 2 pressure safety valves.
- ✓ Check the safety systems.

9. BREAK-DOWN GUIDE

The list below of problems is limited because most defects and incidents are covered in messages (§5) and alarms (§6).

PROBLEMS	POTENTIAL CAUSES	SOLUTIONS
The sterilizer remains switched OFF.	▪ The main switch or network circuit breaker is open (OFF). ▪ No voltage at the socket. ▪ The mains cable is not properly connected.	▪ Activate the main switch or network circuit breaker (ON). ▪ Check the electrical circuit. ▪ Plug in the cable.
Water leaking at the front of the sterilizer.	▪ Leaks via the door seal. ▪ Punctured or disconnected hose.	▪ Clean the door seal (§ 7.2.) ▪ ☎ service for control.
At the end of the cycle, water remains within the chamber and the load is not perfectly dry.	▪ Poorly levelled machine. ▪ Overloaded chamber. ▪ Load incorrectly positioned.	▪ The sterilizer must be installed on a level surface. ▪ Comply with the maximum mass for each type of load (§ 4.6.1.). ▪ Follow the recommendations listed in Annex 2.
Humidity in the packaging or in the load.	▪ Overloaded chamber. ▪ Load incorrectly positioned.	▪ Comply with the maximum load (§ 4.6.1.). ▪ Follow the recommendations listed in Annex 2.
Oxidation or spots on instruments.	▪ Use of poor quality water or water containing chemical substances. ▪ Organic or chemical residues on the instruments. ▪ Contact between various materials. ▪ Calciferous deposits on the chamber.	▪ Drain both water tanks (§ 4.2. / 4.3. / 4.4.). Use good quality water (described in Annex 9). ▪ Clean and rinse all instruments with demineralised water (Annex 2).Remove all traces of disinfectants. ▪ Interleave with tissues. ▪ Clean the chamber.
Instruments turning brown or black.	▪ Incorrect temperature selected.	▪ Consult the table in § 4.6.1. ▪ Follow the instrument manufacturer's instructions.

Annex 1 TECHNICAL CHARACTERISTICS

Electricity supply	Single phase 230 VAC ±10% – 50/60Hz – 10A
Sterilizer:	Name plate situated on the back side: 
Working temperature / Humidity	10°- 40°C / 0-90%.
Storage temperature / Humidity	-20°- 60°C / 0-90% (empty)
Min. atmospheric pressure	0,5 bar
Nominal voltage :	230 V
Max. absorbed power :	2100 W
Max. current :	9,2 A
Dimensions overall :	W : 445mm / H : 410mm / D : 520mm (MB17) – 620mm (MB22)
Max. space required :	W : 485mm / H : 460mm / D : 570mm (MB17) – 670mm (MB22)
Clutter of the door movement :	W : 360mm / H : 400mm / D : 360mm
Weight empty :	49 kg (MB17) or 56 kg (MB22)
Max. mass in working condition fully loaded :	129.4 N/m² (140 N/ foot) for MB17 or 177.3 N/m² (160 N/ foot) for MB22)
Max. heat output :	3000 KJ/hr
Max. noise level :	< 50dB
Steam generator	Name plate on the steam generator: 
Power / Voltage :	1700 W / 230 VAC
Max. pressure / Max. temperature :	4 bar / 150°C
Safety overpressure valve :	5 bar
Sterilization chamber	Name plate on the chamber: 
Power / Voltage :	1000 W / 230 VAC
Max. pressure / Max. temperature :	2,4 bar / 138°C
Safety overpressure valve :	2,4 bar
Total volume :	17 l. Ø:250mm / Depth:350mm (MB17) 21 l. Ø:250mm / Depth:450mm (MB22)
Usable space (identical for all cycles) :	12 l. W:195mm / H:205mm / D:300mm (MB17) 16 l. W:195mm / H:205mm / D:400mm (MB22)
Bacteriological filter :	0.3 µm
Distilled water (or demineralized) :	
Water quality :	Conform to EN 13060 annex C
Min. / Max. consumption :	0,2 l / 0,35 l (full porous load) on MB17 0,3 l / 0,50 l (full porous load) on MB22
Double tank / Autonomy :	Min 8 cycles (full porous load)
Connections	Parallel printer port
Miscellaneous	Fully micro-processor driven and controlled / touch screen Mains filter / 2KV over tension filter. Programmable stand-by mode.

STERILIZER CLASS B conform with following directives and norms :

93/42/EEC	Medical Device Directive (MDD)
97/23/EEC	Pressure Equipment Directive (PED)
EN 13060	Small steam sterilizer.
EN 61010-1	Laboratory equipment – Safety requirements.
EN 61010-2-040	Laboratory equipment – Specific instructions for steam sterilizer
EN 61326	Electrical equipment for measurement, control and laboratory use - EMC requirements

Annex 2. PREPARATION OF THE LOAD

1. Cleaning of the instrument

The instruments to be sterilized must be clean and free from all types of residue such as fragments, dentine and blood, etc. These substances can damage the objects placed in the trays and even the sterilizer itself.

- Clean the instruments immediately after use. Follow the manufacturer's instructions when using an ultrasonic cleaner.
- Remove all traces of disinfectant from the product as this may cause corrosion on heating. Rinse thoroughly, then dry.
- Lubricate in accordance with the manufacturer's instructions.

2. Preparation of the trays

- For each program, do not exceed the maximum load which has been set, tested and validated by the manufacturer and for which a perfect sterilization is guaranteed.
- Always use the rack to allow adequate steam circulation between the trays.
- Do not overload the trays in order to improve sterilization and drying.
- Place the cassettes in the vertical position (if possible) to ensure thorough drying.
- Place the items in such a way so as to allow the steam to circulate properly.
- Empty containers or non perforated trays must be placed upside down to prevent accumulation of water.
- Items made from different materials (stainless steel, carbon, etc.) must be placed on separate trays.
- Where instruments are manufactured from carbon steel, paper should be placed between them and the sterilizer tray.
- Sterilize instruments in the open position, eg. forceps.
- In the case of wrapped items, use porous packaging to facilitate good steam penetration and drying (e.g. nylon/paper sachet for autoclave).

Tubes

- Rinse, drain and dry after washing.
- Place the tubes on a tray allowing the ends to remain open. Do not bend.

Packets

- Place the packets in the vertical position, leaving a space between each one. Do not allow them to come into contact with the walls of the sterilization chamber.

Wrapped material

- Sachets should be placed on trays, leaving a space between each one. Position with paper side upwards.

The sterilizer detects and amplifies errors which occur upstream from sterilization

Annex 3 MAINTENANCE OF DYNAMIC INSTRUMENTATION

1. External disinfecting

This procedure prevents the risk of infection during cleaning and maintenance.

- Wear gloves.
- Dampen the instrument with a non-corrosive disinfectant (pH from 2.5 to 9) or with 70-80% ethyl alcohol.
- Comply with the disinfection reaction times recommended by the manufacturer.

DO NOT :	**Immerse or vaporise the instruments. Do not allow the disinfectant to come into contact with the instrument, poor rinsing, etc.** **Do not use cloths containing chlorhexidine or aldehydes.**

If any traces of disinfectant are left on the instruments, the latter will become corrosive when heated. This may cause extensive damage during sterilization: oxidation, modification to the technical characteristics of seals, rubber, fibre optics, etc.

2. External cleaning

This procedure involves the removal of residues (blood, dentine, etc.) which adhere to critical areas such as spray outlets, fibre optics, etc.

- Use a soft, damp brush and take care not to scratch the surface of the fibre optics.
- Remove from the item all traces of the disinfectant used prior to this cleaning phase. This product must only act over a given time after which it may become aggressive for both instrument and sterilizer.

3. Maintenance

Once the instrument has been disinfected, cleaned and is dry, free from residues, it must be lubricated **before**, not **after** sterilization..

a) Manual lubrication with oil spray

- Check the condition of the O-ring on the spray insert. Replace if necessary.
- Purge the spray tubes by blowing air into the instrument.
- Lubricate using an oil aerosol in accordance with the manufacturer's recommendations.

b) Automatic lubrication with Assistina: a more economical and more effective solution

- Assistina can clean and lubricate dynamic rotating instruments.
- The advantage of this equipment: simplified and effective cleaning and lubricating of the mechanical components.
- Automatic, optimal injected quantity of oil.
- Assistina also cleans and dries the spray tubes, preventing them from clogging.

4. Packaging

In order to preserve sterility, rotating instruments should ideally be wrapped prior to sterilization.

The sterilizer detects and amplifies errors which occur upstream from sterilization

Annex 4: BOWIE & DICK TEST

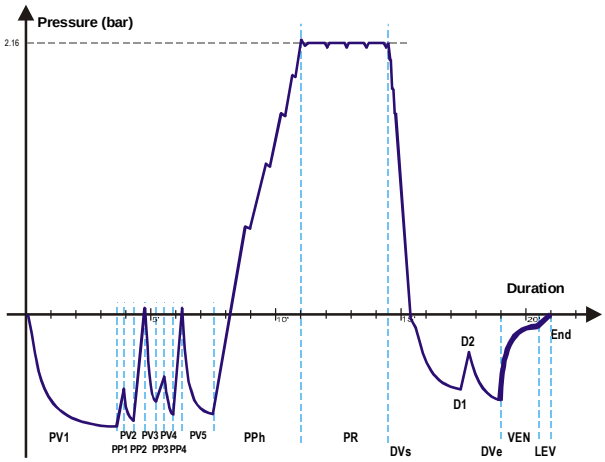
The Bowie & Dick Test, also called the Brown Test, is representative of the small porous type load.
It comprises several sheets of paper and foam wrapped in a small packet in the middle of which there is a chemical heat-sensitive indicator strip (physic-chemical test).

This test is used to validate the equipment performance in terms of textile load sterilization, i.e.:

- ✓ Pre-vacuum efficiency and thus steam penetration.
- ✓ Temperature and pressure parameters of the saturated steam during the holding time.

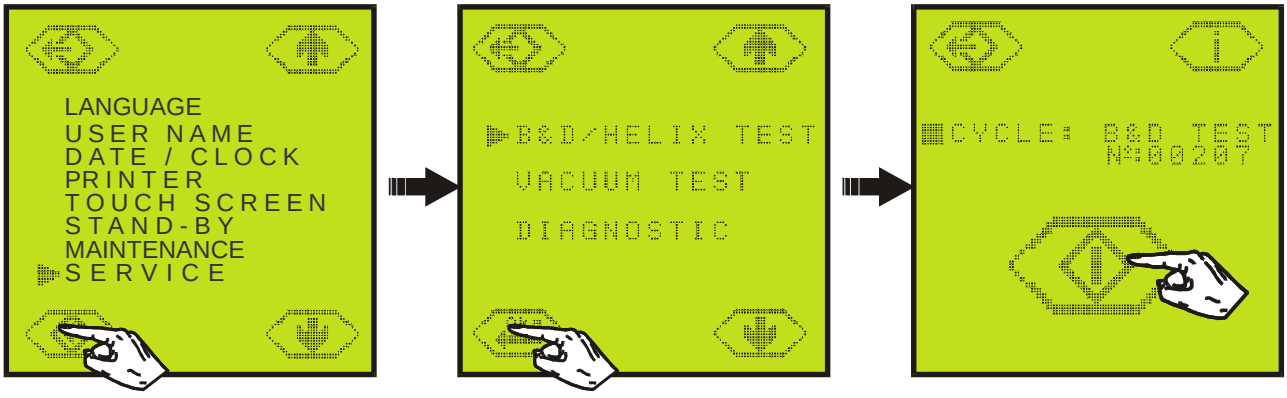
The cycle profile is identical to that of other cycles with:

- ➢ a temperature of 135,5°C .
- ➢ a pressure of 2,16 bar.
- ➢ a sterilization plateau of 3min 20 sec guaranteeing a security margin.
- ➢ a drying time cut to 4 min not to falsify the result.



Carry out the test as follows:

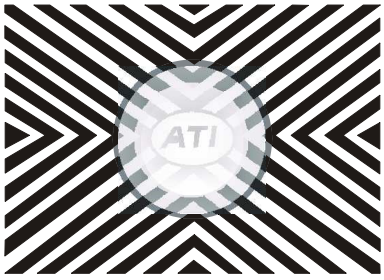
- ♦ Place the Bowie & Dick Test (complete packet) on the lower tray of the chamber, with the label facing upwards.
- ♦ Select and start the **Helix / B&D** cycle from the **"service"** sub-menu.



- ♦ Once the cycle is completed, open the door and remove the test. Caution: the packet will be very hot!
- ♦ Remove the indicator strip from the centre of the packet.

Correct result:
The radial strips have turned black

Incorrect result:
The central part is not the same colour as the edges.



The result is also incorrect, if the indicator is grey or silver (over-exposure, i.e. excessive temperature).

You can enter your name, the date, cycle number and sterilizer number on each test for filing purposes.

Annex 5 HELIX TEST

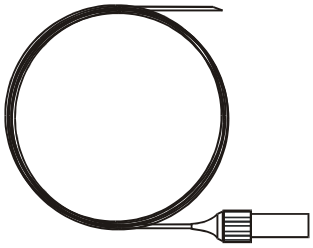
The Helix Test is the most complex representation of a hollow instrument load (type A).

Characteristics:

Length: 150 cm

Internal diameter: 2 mm

Material : PTFE



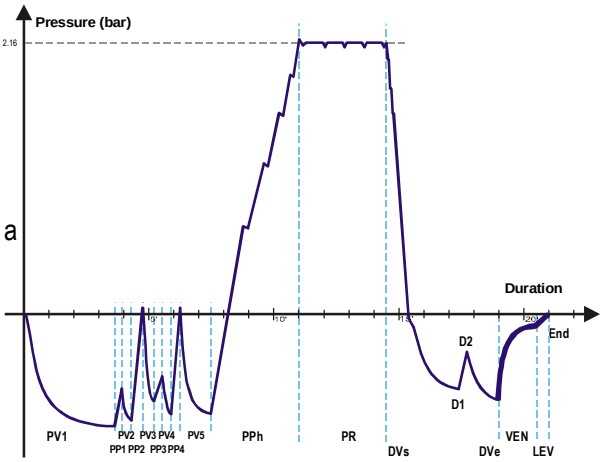
Strip test

This test is used to validate the equipment performance in terms of hollow instruments sterilization, namely:

- ✓ Pre-vacuum efficiency, rapid and uniform steam penetration.
- ✓ Temperature and pressure parameters of saturated steam during the holding time.

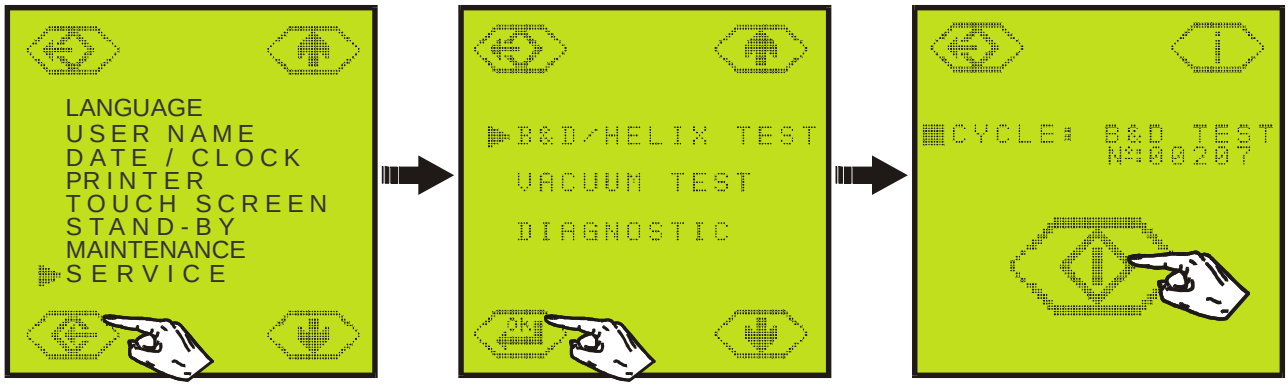
The cycle profile is identical to that of other cycles with:

- ➢ a temperature of 135,5°C
- ➢ a pressure of 2,16 bar.
- ➢ a sterilization plateau of 3 min 20 sec. guaranteeing a security margin.
- ➢ a drying time cut to 4 min not to falsify the result.



Carry out the test as follows:

- ♦ Place a test strip inside the capsule.
- ♦ Close the capsule.
- ♦ Place the test on the lower tray in the chamber.
- ♦ Select and start the **Helix / B&D** cycle from the **"service"** under-menu.



- ♦ Once the cycle is competed, open the door and remove the test.
  Caution the Helix Test will be very hot !
- ♦ Open the capsule and remove the test strip.

Correct result:

The 4 spots on the strip have turned black.

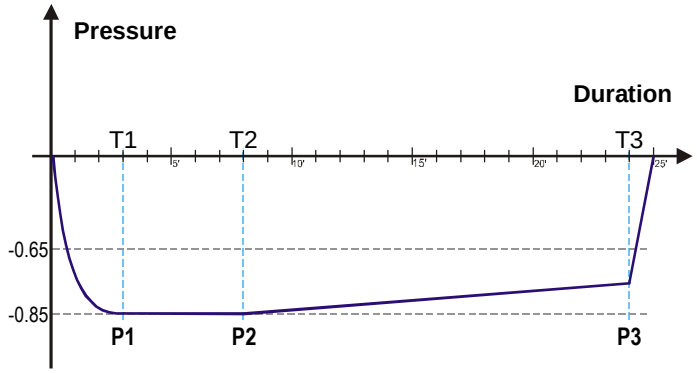
Incorrect result:

Not all the spots have turned black.

Annex 6 VACUUM TEST

This test is used to validate the performance of the sterilizer in terms of leakage:

- ✓ The efficiency of the vacuum pump.
- ✓ The tightness of the pneumatic circuit.

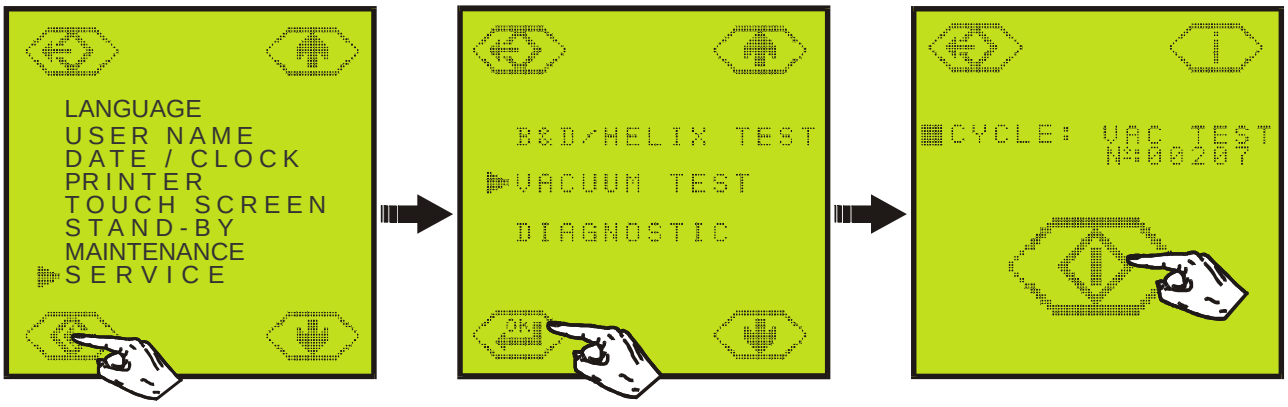


The profile of the cycle, specific for this test includes:

- ➢ A vacuum phase up to P1 = - 0.85 bar.
- ➢ A stabilisation period of 5' => T2. Reading of P2.
- ➢ A testing period of 16' => T3. Reading of P3.

Carry out the test as follows:

- ♦ Select and start the **Vacuum Test** cycle from the **"service"** sub-menu.



- ♦ The micro-processor makes the following calculation: P3 - P2. The result must be less than 0.02 bar *.
- ♦ Comments, positive or negative are displayed at the end of the test.

* **IMPORTANT :** According EN13060 norm, the "AIR LEAKAGE / VACUUM TEST" requires a 13mbar (0,013bar) leak test within a period of 10min. that is to say 1,3 mbar/min. The sterilizer pressure sensor is not 1mbar (0.001bar) but 10mbar (0.01bar) accurate. A leak of 13mbar is therefore not measurable but only a 20mbar (0,02bar) one. The test period has proportionally been increased from 10 to 16min. so that a leak test of 20mbar within 16min. that is to say 1,25 mbar/min is proven.

Annex 7 WATER QUALITY

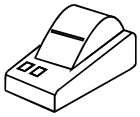
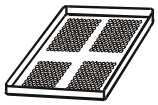
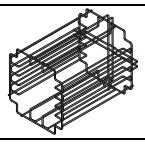
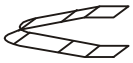
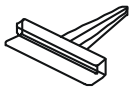
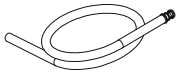
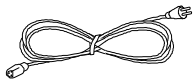
The table below lists the quality of the water to be used for steam sterilization as taken from the new European standard (EN 13060, Annex C)

Table C.1: Contaminants of feed water

	FEED WATER
Evaporate residue	≤ 10 mg/l
Silicium oxide, SiO_2	≤ 1 mg/l
Iron	≤ 0,2 mg/l
Cadmium	≤ 0,005 mg/l
Lead	≤ 0,05 mg/l
Rest of heavy metals, excluding iron, cadmium, 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
Appearance	colourless, clean, without sediment
Hardness	≤ 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 or guarantee.

Annex 8 ACCESSORIES

DESCRIPTION		SPARE NUMBER
Printer: Custom DP40H/cable		A70010XX
Anodised perforated aluminium trays 18,5mm x 28,5mm		T523200X (MB17) T523202X (MB22)
Reversible rack		F523002X (MB17) F523006X (MB17)
Cassette holder		F523000X
Tray holder		F523001X
Drain tubing with quick coupling		S230900X
Mains cable		/
Funnel		F540902X
Bacteriological filter		W322400X
Door seal		F460503X

Manufacturer:

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