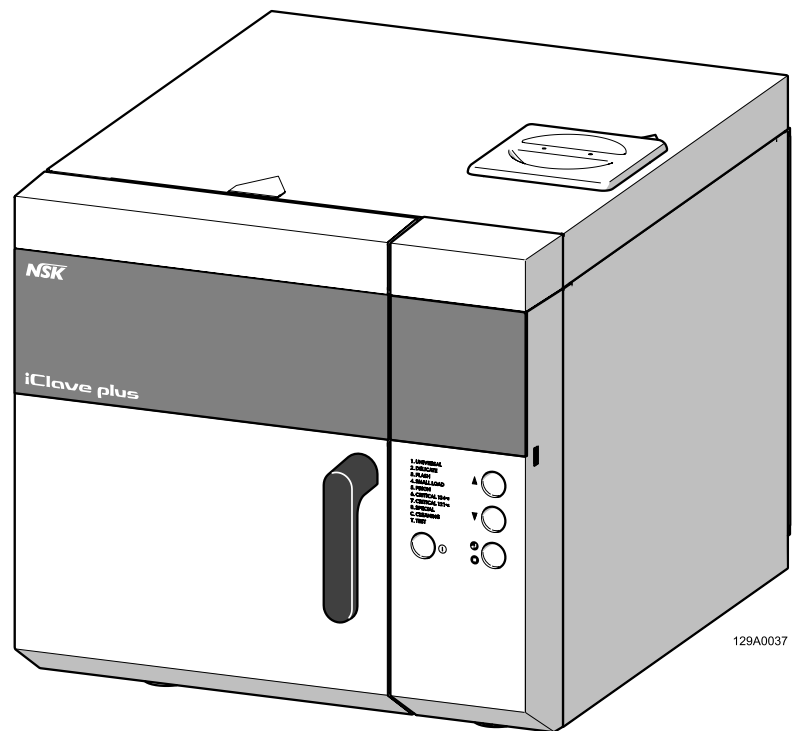


# iClave plus



# OPERATOR MANUAL



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**1 GENERAL INFORMATION**

**1-1 Purpose of the manual**

This operator manual was issued by NSK to provide the operator with the necessary information for:

- proper installation
- appropriate and safe use
- careful maintenance

The manual is an integral part of the iClave plus steam sterilizer, hereafter referred to in this manual as the "sterilizer" or, more simply, the "device", and must always remain with it, even when sold.

It should always be kept close to the device, in an easily accessible place, and protected from environmental agents that could affect its integrity and durability. It should readily be at hand for immediate consultation at any time by operators and maintainers.

Read the manual carefully and understand it fully before installing the device and putting it into service, particularly the instructions given in the chapter on "Safety information", which are aimed at preventing potential risks that could cause injuries to the operator or damage to the device.

The company that uses the devices is responsible for always ensuring that all operators fully understand the operating instructions.

NSK declines any liability for failure to observe the safety and prevention rules described in the various sections of this manual and for damages caused by improper installation and use of the device.

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This publication may not be reproduced, transmitted, transcribed, stored in computer systems or translated into another language or computer language, even partially, in any form or by any means without prior written permission from NSK.

NSK reserves the right to make changes to the technical characteristics of the product described in this manual at any time, with no obligation of prior notice or communication.



**1-2 Criteria for use of the manual and finding information**

The information and instructions are collected and organized into chapters and paragraphs, and can be easily found by searching the index.

Information preceded by a warning sign must be read carefully.

Basic information for the health and safety of operators/maintenance personnel is contained in a box marked with warning signs on a grey background, as illustrated below.

**Safety instructions are classified as follows, in accordance with the seriousness of the risk:**

Classification	Risk level
<b>NOTE</b>	Information on general product specifications highlighted to prevent malfunctions and loss of product performance.
 <b>CAUTION</b>	Indicates cases where failure to follow the safety instructions may lead to minor or considerable injury to people or damage to the device.
 <b>WARNING</b>	Indicates cases where failure to follow the safety instructions may lead to serious injury to people or damage to the device.

### 1-3 Professional user profiles

European regulations on safety and the sterilization process describe the following professional roles:

**OPERATOR** a person who uses the device for the intended purpose on a daily basis  
**MAINTENANCE TECHNICIAN** a person assigned to the ordinary maintenance of the device on a daily basis  
Note: the operator and maintenance technician may also be the same person.

**RESPONSIBLE AUTHORITY:** an individual (often the employer) or group of people responsible for the use and maintenance of the device, who ensures that:

- the operator and maintenance technician are adequately trained to use the device in full safety;
- regular training is provided for all personnel regarding the operation and maintenance of the device, including emergency procedures in the event of emission of toxic, flammable, explosive or pathogenic material into the environment;
- registration documents for attendance of the training are preserved and its full understanding is verified;
- a written, electronic or paper record is kept of the sterilization procedures carried out from the moment the device is installed.

### 1-4 Conformity to European Directives

The IClave plus sterilizer produced by NSK Dental Italy satisfies the essential requirements of the Directive 93/42/EEC for medical devices, European Standard EN 13060 and Directive 2014/68/EC for pressure equipment (PED). This NSK product has been designed and manufactured with high quality materials and parts that can be recycled and reused.



Separate disposal of electrical and electronic equipment, in accordance with Directive 2012/19/UE (WEEE). The equipment belongs to Category 8 (medical equipment). In force in the nations of the European Union, Norway and Switzerland.



CE Mark and Notified Body number. The CE mark indicates that the device satisfies the essential requirements of the Medical Devices Directive 93/42/EEC.  
Notified Body: IMQ S.p.A., Via Quintiliano, 443, 20138 Milan (Italy), Identification N. 0051.

### 1-5 Warranty

NSK products are guaranteed against manufacturing errors and defective materials. NSK reserves the right to examine and determine the cause of any problem. The warranty will be void if the product has not been used properly or for its intended use, if it has been tampered with by unqualified personnel or fitted with non-original NSK parts. Replacement parts are available for ten years after production of the model has ceased.

Failure to follow the guidelines given below will void the warranty and/or make the device dangerous to operate.

- In the event of faults and/or malfunction, follow the guidelines given in *paragraph 6.2 "Warning messages"* and *paragraph 6.3 "List of alarms"*. If the problem persists, do not attempt to operate the device but contact the NSK technical support.
- Do not operate the device until the necessary repairs have been made to restore its proper operation.
- Do not attempt to disassemble the device, replace faulty or damaged components and/or have it adjusted or repaired by personnel without proper training and authorization from NSK.
- Faulty or damaged components should only be replaced with original NSK parts.

## **2 SAFETY INFORMATION**

### **2-1 General safety information**

To maintain a maximum level of device safety for patients and specialized professional operators, it is essential that:

- the operators and maintenance technicians have read and understood the instructions for installation and use of the device
- the periodic maintenance operations described in the chapter 7 “Maintenance” are carried out
- the following safety instructions are observed:

#### **WARNING**

- Ensure that the device is connected to a power socket with an earth connection.
- Keep the plug in the socket until the sterilization is finished and do not use the socket for other devices at the same time.
- Use only original NSK cables, as other cables can cause electric shock, fires or damage to the device.
- Do not turn the power on or off unless strictly necessary, as this may trip the fuse.
- Do not touch the power cord with wet hands as this may cause electric shock.
- Install the product with sufficient space to allow immediate removal of the electrical plug.
- Turn off the power switch and disconnect the power cord before performing any maintenance.
- Do not connect non-original NSK accessories or equipment to the device.
- Keep explosive substances and flammable materials far from the device.
- If the device overheats or emits a bad smell, turn off the power switch immediately, remove the plug from the electrical socket and contact technical support.
- Do not allow water or disinfectant liquid to enter the inside of the device as it may cause a short circuit and electrical shock.
- Avoid inadvertently touching the door or the area around the chamber while the device is in operation or immediately after stopping the product, as these reach high temperatures and can cause burns.
- Do not obstruct or cover the steam outlet on the product with other objects. In addition, avoid inadvertently placing your face or hands near the steam outlet, as this can cause burns.
- Only use original NSK components and spare parts.

#### **CAUTION**

- The device must only be installed in enclosed environments.
- Install the machine on a flat surface.
- Do not sterilize liquids or objects other than medical instruments reported in the intended use.
- Avoid any impact on the device. Do not drop the device.
- Wash and dry objects before sterilization. Chemical detergent residues in the chamber can cause corrosion or leave bad odours on sterilized objects.
- Insert the objects to be sterilized using the racks. Directly inserting objects into the chamber may cause sterilization problems, discolouration or even damage to the objects.
- Ensure that any water has been drained before moving the device.
- Use a container or case for sterilizing fine-pointed objects, as these may protrude from the bottom of the rack.
- Sterilize the instruments in accordance with the parameters recommended by the manufacturer or retailer.
- If any irregularities are noticed during use, stop the sterilization cycle and contact technical support.
- Conduct periodic diagnostic checks and routine maintenance operations.
- If the device has not been used for a long time, check that it is working properly before use.
- Portable and mobile RF communication devices can interfere with the device.
- The device must not be used near or above another device. If this is not possible, ensure that all devices work properly.
- The device may malfunction if used near electromagnetic interference. Do not install the device near other equipment that emits magnetic waves. Turn off the power if an ultrasonic oscillation or electrosurgery device is located near the site of use.

### 2-2 Safety and protection features on the device

The sterilizer has several devices, listed below, that ensure the total safety of operators.

#### 2-2-1 Soft-close door with double safety

An electromechanical device allows the door to be opened only under the following conditions:

- device plugged in and switched on
- no alarms activated
- internal pressure not hazardous to the operator

For additional safety, the Start/Stop button must be pressed to unlock the door at the end of a cycle.



**If the device is switched off with the door open, do not try to close the door by forcing the handle. To close the door, simply turn the device on again using the main switch.**

#### 2-2-2 Overpressure protection - safety valve and pressure relief valve

##### Safety valve

This is a valve located on the back of the device that is triggered when the pressure inside the chamber exceeds 2.55 bar. To check that valve is working properly, switch the device off and allow it to cool down, then unscrew the black cap, pull it slightly until a "click" is heard and then check that it moves freely. The safety valve requires no adjustment or maintenance.

##### Pressure relief valve

This is triggered when the pressure inside the sterilization chamber exceeds 2.4 bar; an acoustic signal alerts the operator and the message ALARM 16 appears on the display.

#### 2-2-3 Blackout protection

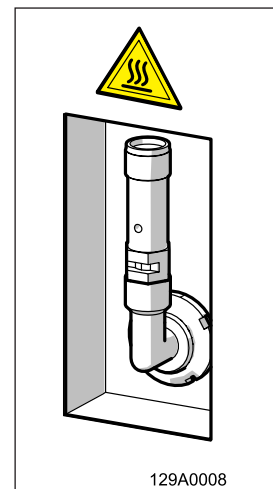
In the event of a power supply failure during the sterilization cycle, the pressure in the chamber is completely released and brought down to ambience level. When the power supply returns, the message BLACK OUT appears on the display.

#### 2-2-4 Overheating protection

The temperature inside the sterilization chamber is programmed to not exceed a limit of 142 °C; in the event of failure, additional protection is provided to prevent the temperature from rising above 150 °C.

#### 2-2-5 Automatic power off

Thirty minutes after the end of the cycle, unless the door has been opened or a button pressed on the front panel, the device automatically switches off.



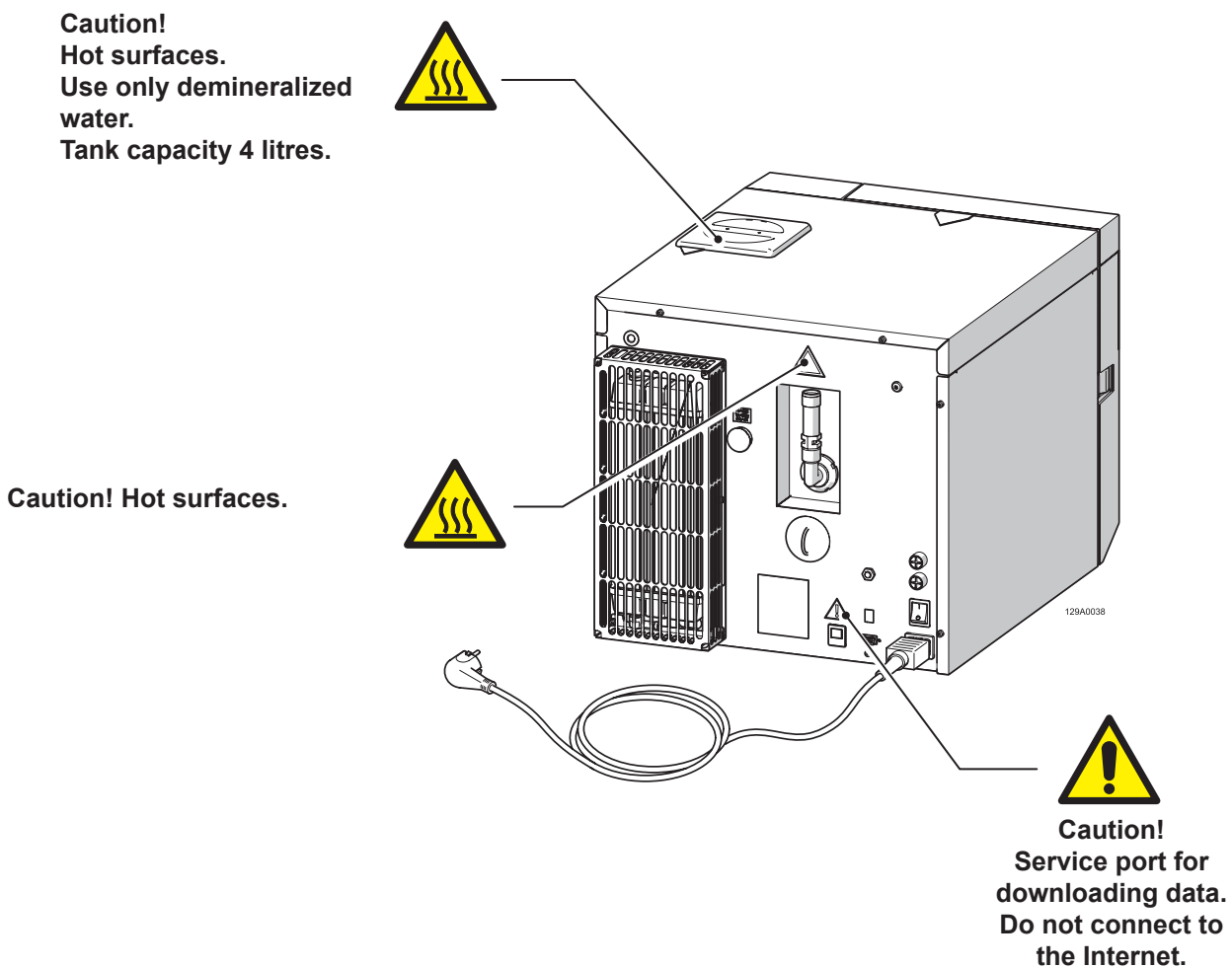
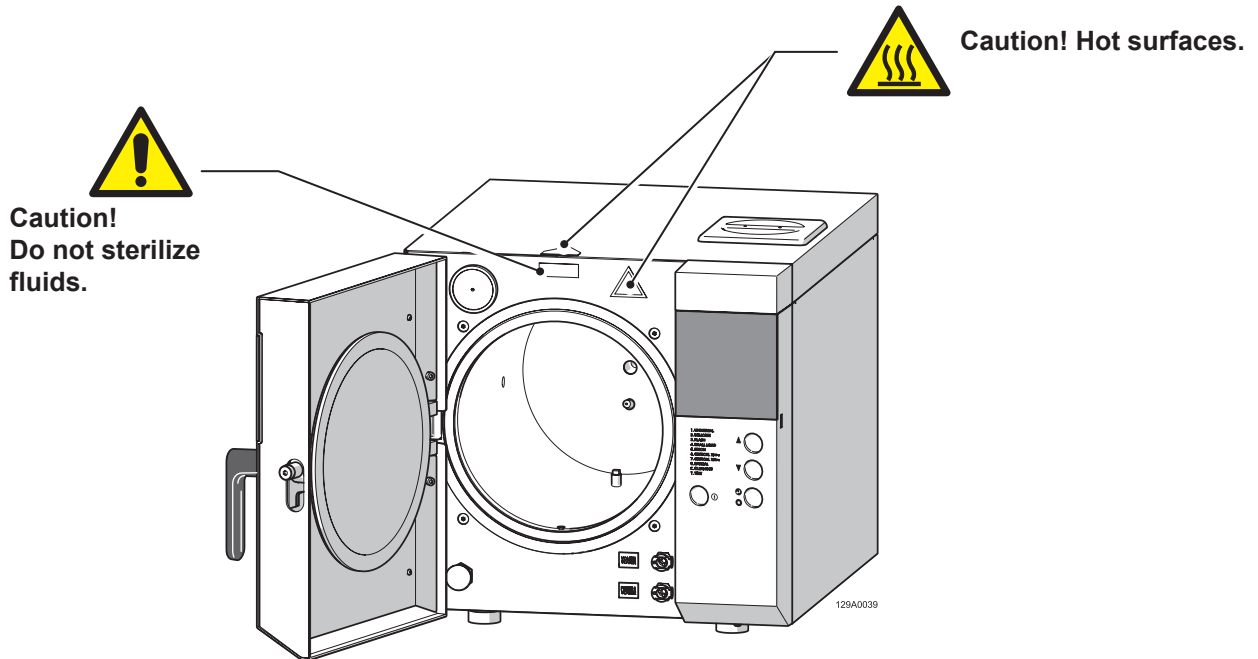
#### NOTE

This function is not implemented if no sterilization cycle has been run.



### 2-3 Safety signs on the device

The following warning and hazard signs are located on the sterilizer in the positions indicated.

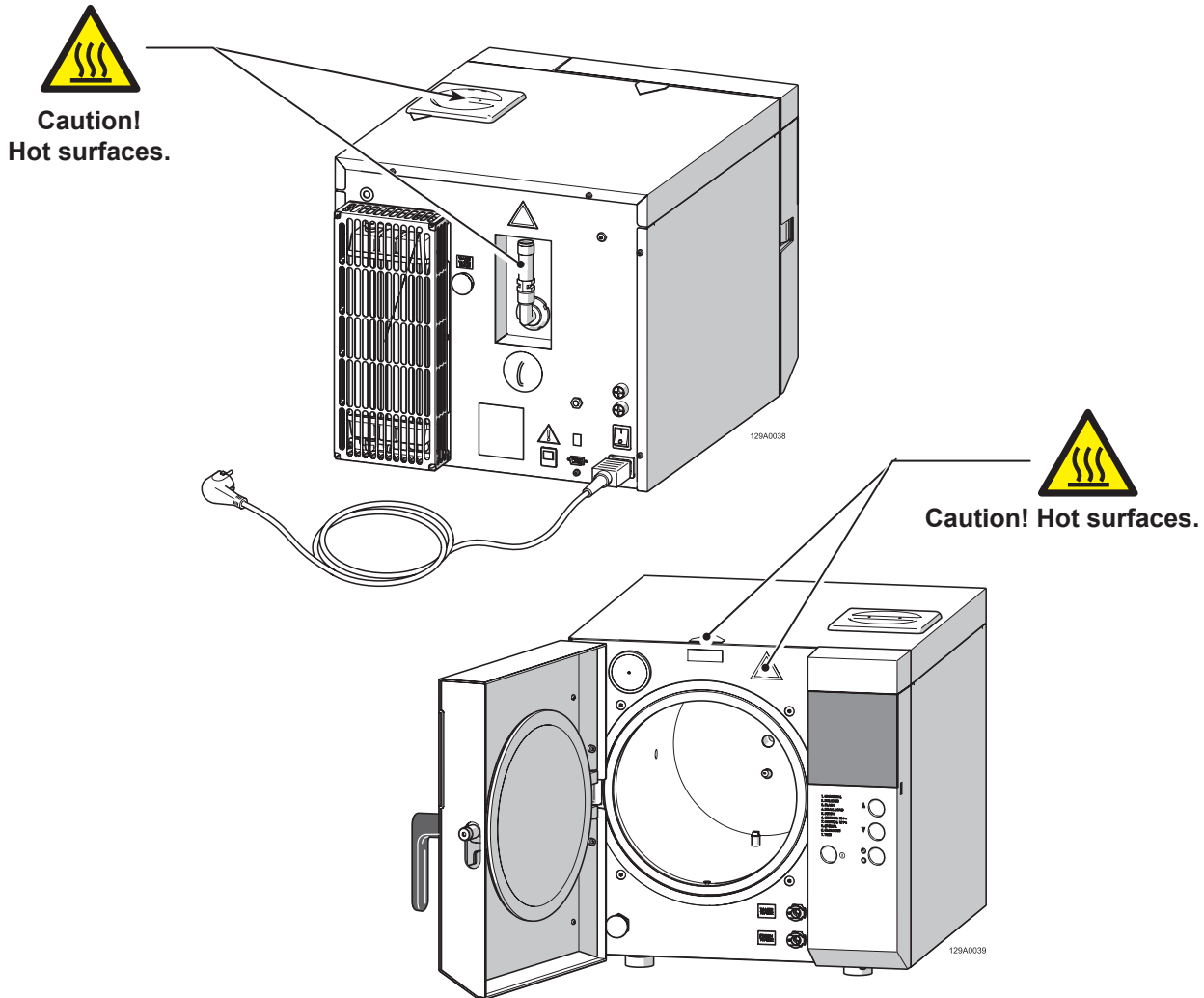


## 2-4 Residual risks

The sterilization process works by means of pressurized steam at high temperature. When removing a load from the sterilization chamber, always use suitable tools and personal protective equipment for handling the hot racks and tools.

When opening the sterilizer door, particularly during a cycle failure, a small quantity of steam or hot condensate may be released; open the door with caution.

 **WARNING** During normal daily use of the device, residual heat risks persist in the areas marked with special warning signs, as shown in the figure. Avoid direct contact of body parts with these surfaces.



## 2-5 Bacteriological risks

- If the sterilization cycle is not completed, the load, the trays and their restraint system, as well as the inside of the chamber, should always be considered as potentially contaminated until a subsequent sterilization cycle has been successfully completed.
- The water in the recovery tank should be considered as contaminated, therefore necessary precaution should be taken when emptying the tank. Check the integrity of the drain hose before using it.
- To avoid cross-contamination, wear a new pair of sterile gloves for each task. Take particular care to replace the sterile gloves when loading or unloading instruments from the sterilization chamber and during maintenance operations.

**3 CHARACTERISTICS**

**3-1 Description of the sterilizer**

The IClave plus is a table-top steam sterilizer designed for the sterilization of dental and medical products and equipment, in accordance with the requirements of standard ISO EN 13060. It consists of an airtight copper sterilization chamber accessed through a front door; it is protected by an external shock-resistant moulded plastic body and equipped with protective devices that allow operators to use it in full safety. The sterilization cycles are started from the operator panel on the front of the device, beside the door. A detailed description of the units that make up the sterilizer and the components supplied is given in the following paragraphs.

**3-2 Intended use**

The steam sterilizer is intended for the sterilization of reusable medical devices suited to steam sterilization in a range of temperatures from 121 °C to 135 °C.

The types of sterilization include:


**Class B sterilization**

Sterilization of all wrapped and unwrapped solid material, porous products as represented by the test loads and type A and B hollow loads.

**Class S sterilization**

Sterilization of products as specified by the manufacturer of the sterilizer, including unwrapped solid products and at least one of the following:

- Porous products (fabrics)
- Small porous items
- Fluid loading or unloading products with type A and B hollows
- Single-wrapped products
- Products with multiple-layer wrapping

 <b>WARNING</b>	<p><b>Sterilizing instruments unsuitable for this process may expose the operator to risk, cause damage to the sterilizer and compromise its safety devices. Always check the manufacturer's label to ensure that products are suitable for sterilization.</b></p> <p><b>The device is not suitable for the sterilization of liquids and flammable materials. Do not use the device in the presence of anaesthetic or flammable gases.</b></p>
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<b>NOTE</b>	<p>The room where the device is installed should be adequately ventilated to prevent excessive humidity.</p>
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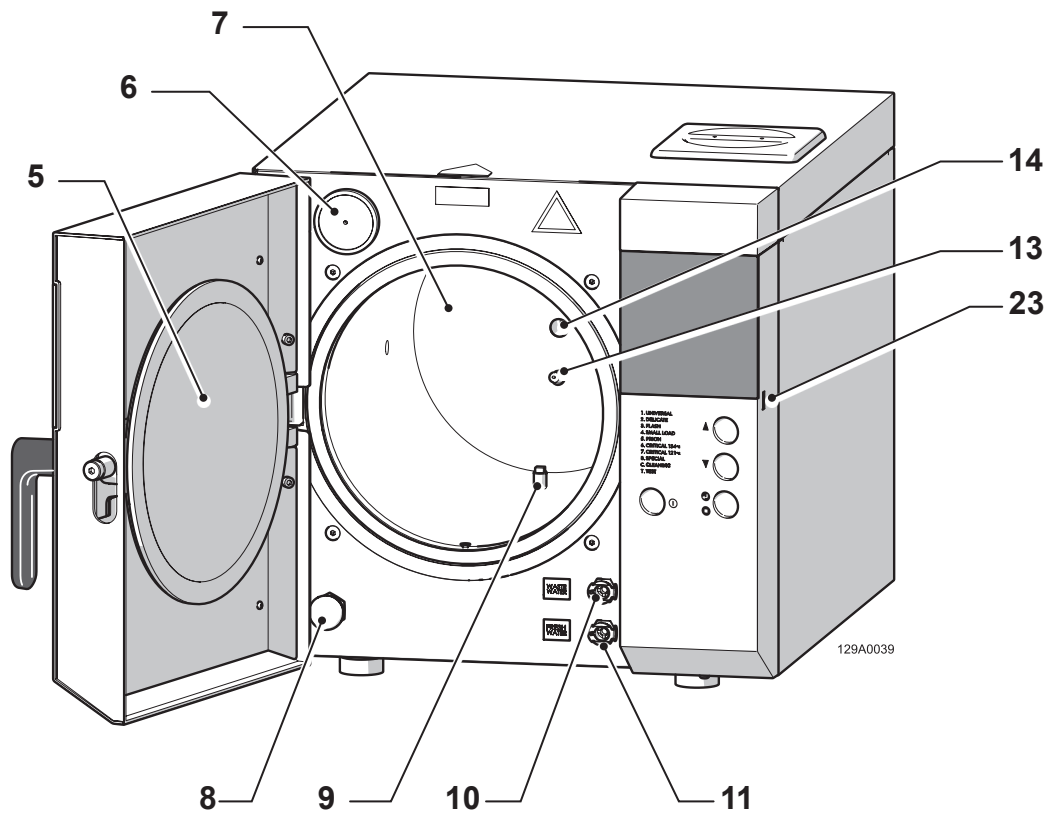
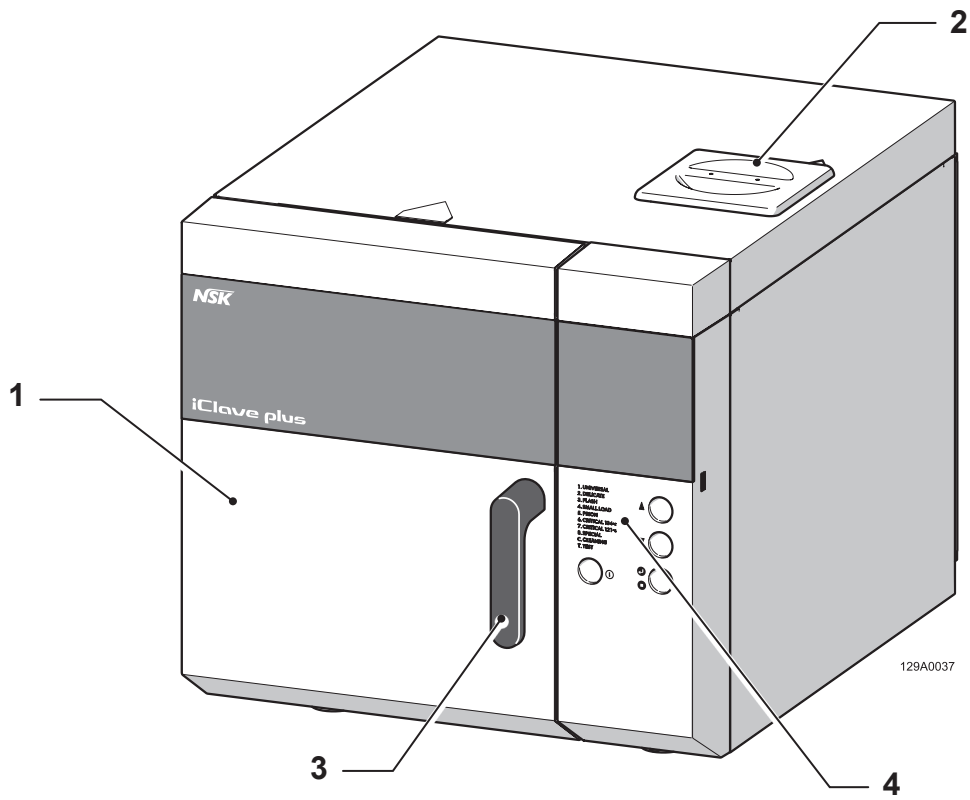
**3-3 Environmental conditions**

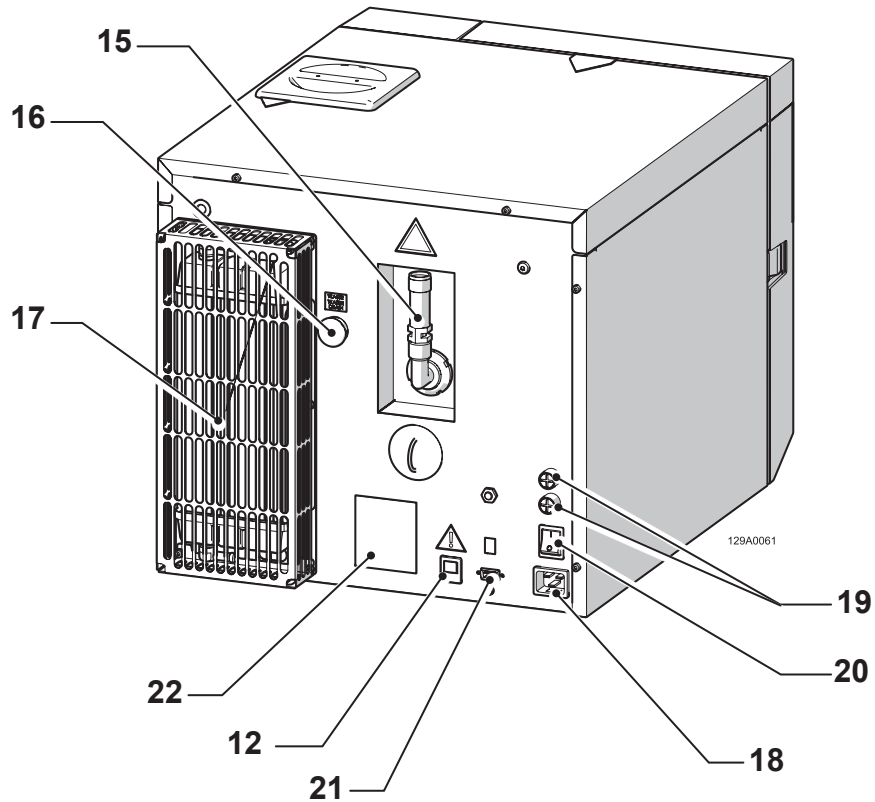
The sterilizer is designed to operate in environments with:

- temperatures between 10°C and 40°C.
- relative humidity between 20% and 85%.
- air pressure between 750 mBar and 1050 mBar
- an altitude between 0 and 2000 above sea level.

Storage conditions: temperature -10°C 50°C, humidity without condensation 10-95%, atmospheric pressure 500-1060 mBar.

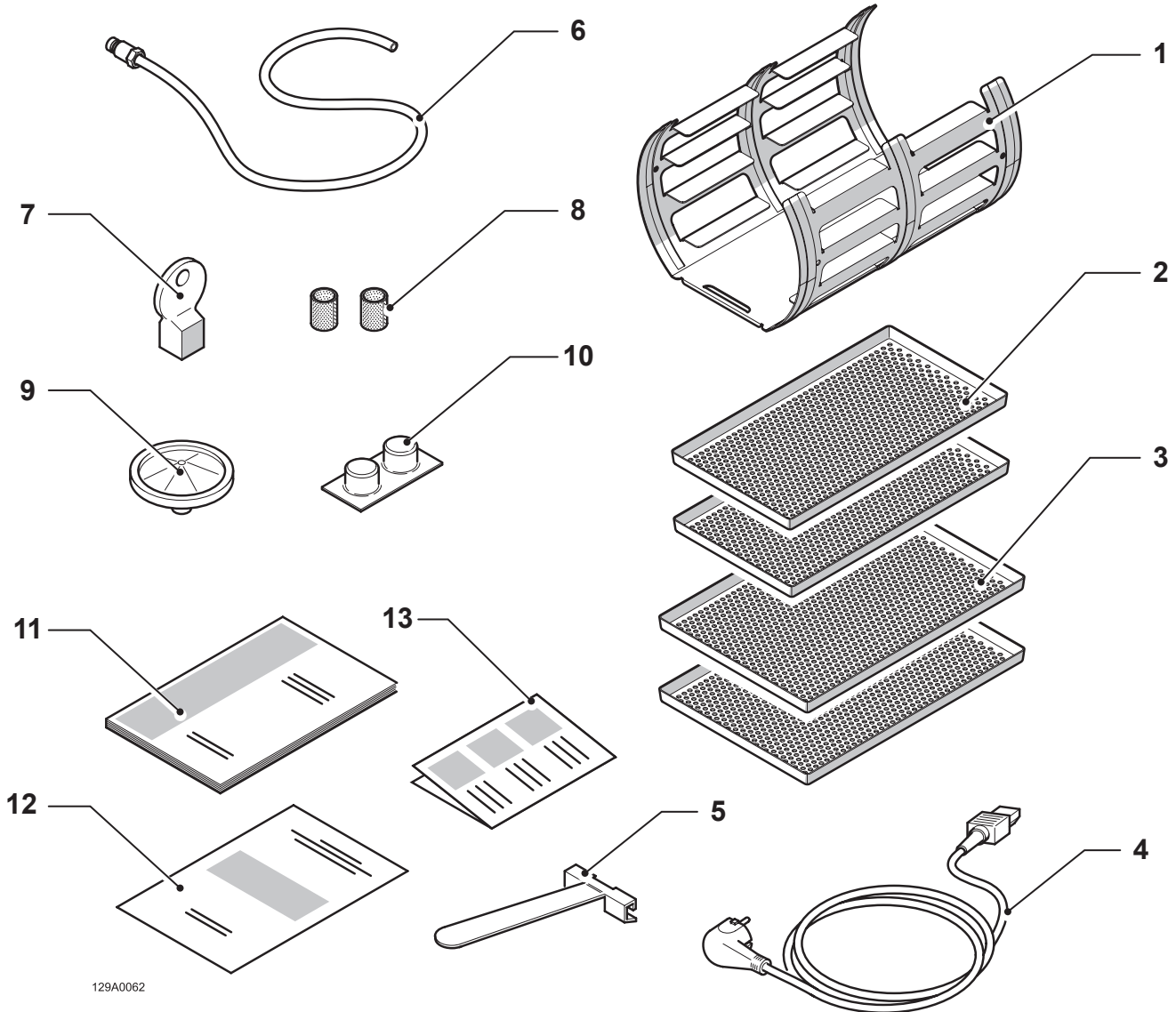
3-4 Units that make up the sterilizer





Position	Description
1	Door
2	Clean demineralized water tank input
3	Handle
4	Operator panel
5	Steel sterilizing chamber closure disc
6	Bacteriological filter
7	Sterilization chamber
8	Clean demineralized water tank filter
9	Drain filter
10	Quick coupling for draining contaminated water tank
11	Quick coupling for draining demineralized water tank
12	Network port for technical support service data
13	Temperature sensor
14	Safety valve connection
15	Sterilization chamber maximum pressure safety valve
16	Automatic contaminated water recovery tank outlet for the Purity device (optional)
17	Condenser protection grid
18	Electrical supply input socket
19	Electrical protection fuses
20	Main switch
21	External printer port (optional)
22	Regulatory label
23	USB port

3-5 Components supplied with the sterilizer



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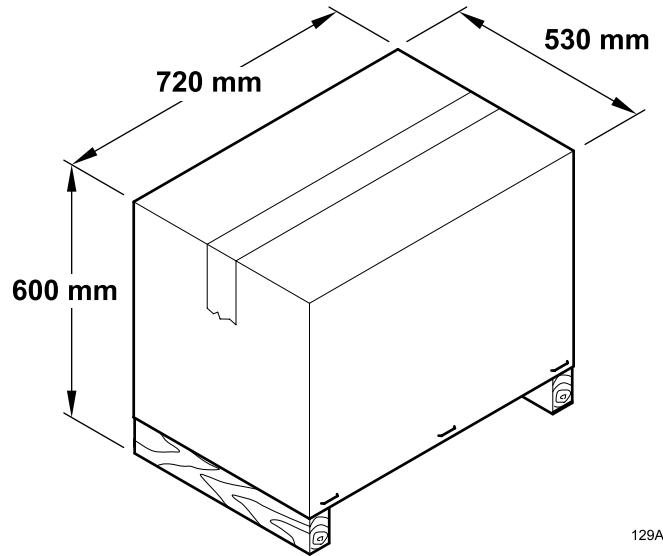
Position	Description	Code
1	Tray rack	105078
2	Small tray (2 pieces)	105076
3	Large tray (2 pieces)	105077
4	Power cord	
5	Rack insertion and extraction clamp	105619
6	Rubber hose with quick coupling for draining water	119001
7	Water filter extraction key	105228
8	Water filter (2 pieces)	105320
9	Bacteriological filter	021008
10	Sterilization chamber cleaning tablets (2 pieces)	0230050
11	Operator manual	
12	Warranty certificate	
13	Quick guide	

**3-6 Size and weight of package**

Packaging size: 720 x 600 x 530 (L x H x D)

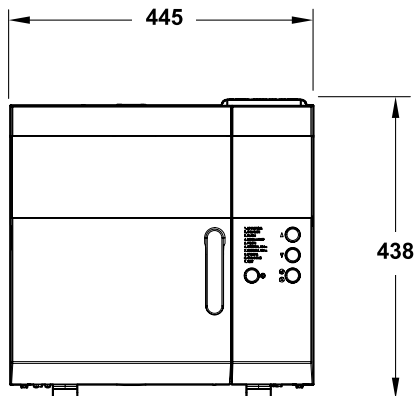
Total weight of package: 55 kg

<b>NOTE</b>	Keep the original packaging intact
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**3-7 Size and weight of sterilizer**



**STERILIZER**

Net unladen weight: 45 kg

Weight with full load: 57 kg

**STERILIZATION CHAMBER**

Diameter: 240 mm

Depth: 384 mm

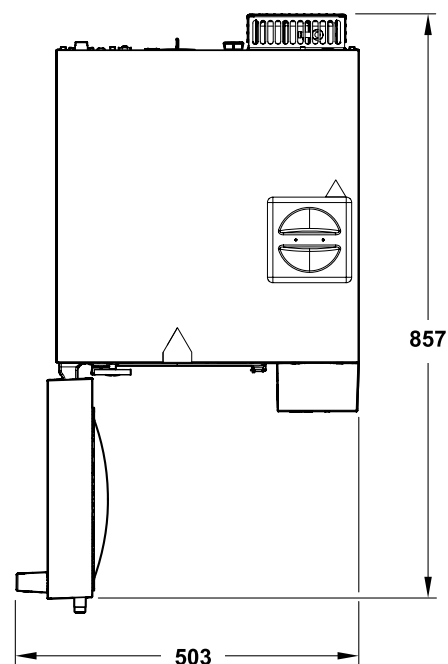
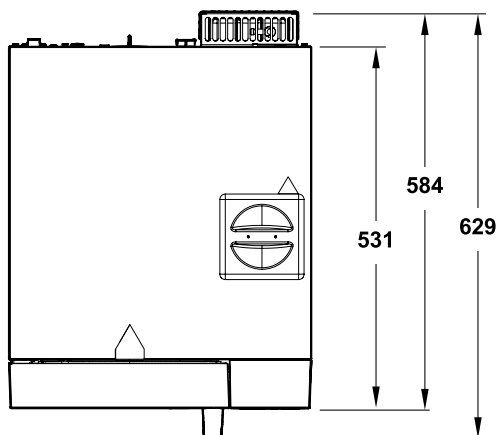
Volume: 17.5 litres

**TRAYS**

Usable large tray space: 315x214 mm (x 2)

Usable small tray space: 315x168 mm (x 2)

Usable volume on trays: 10 litres



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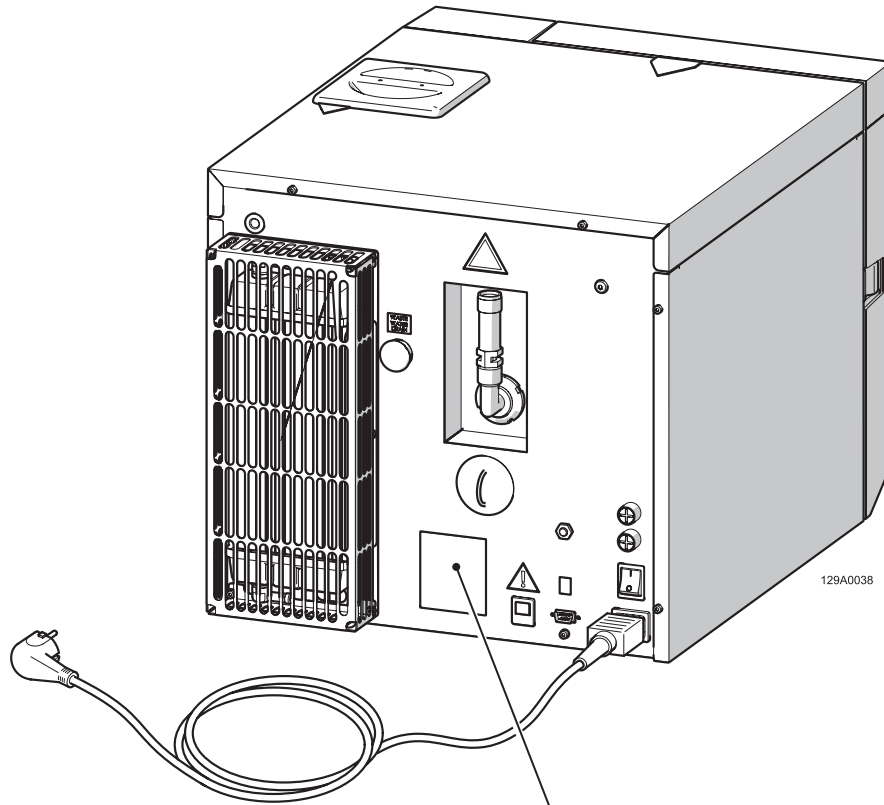
3-8 Technical specifications

Chamber dimensions	Ø = 240 mm D = 384 mm
Chamber volume	17.5 l
Maximum load	4 kg (solid instruments) 1.5 kg (porous instruments)
Heating time	20' from room temperature 10' with preheated chamber
Sterilization time	From 3' to 90' depending on the cycle
Drying time	From 3' to 14' depending on the cycle
External dimensions	445 x 438 x 629 mm (L x H x D)
Net weight	45 kg
Mains voltage	230 VAC
Frequency	50/60 Hz
Maximum power consumption	1920 W
Average consumption	600 W
Standby consumption	12 W (20 W printer version)
Fuses	2 x FF 10A (type 6.3 x 32 H 500V)
Clock battery	Internal, not replaceable by the operator: CR2032
Automatic used-water drain rate (optional)	Max 0.5 l/min, T max 70 °C
Auto-off	after 30' of inactivity at the end of the cycle
Double water tank	4 l each
"Average" water consumption for standard cycles 134°C - 121°C - 3 vacuum	584 cc - 627 cc
Vacuum pump	20 l/min - 0.96 bar
Bacteriological filter	0.3 µm at 99.97 %
IP rating (in accordance with EN 60529)	IP31
Noise level	53 db
Differentiated heating system	DHS
Heat transmitted to the environment at 23° C	2.16MJ
Operating cycle	continuous
Pollution level	2
Transient overvoltage	II
Water conductivity control	H <sub>2</sub> O GOOD / H <sub>2</sub> O HARD (in reference to a value of 15 microsiemens)
Available volume on trays	10 l
Maximum chamber temperature	135°C (-0+2°C)
Safety valve intervention pressure	2.55 bar
Pressurized container conforming to Directive 2014/68/UE (PED)	

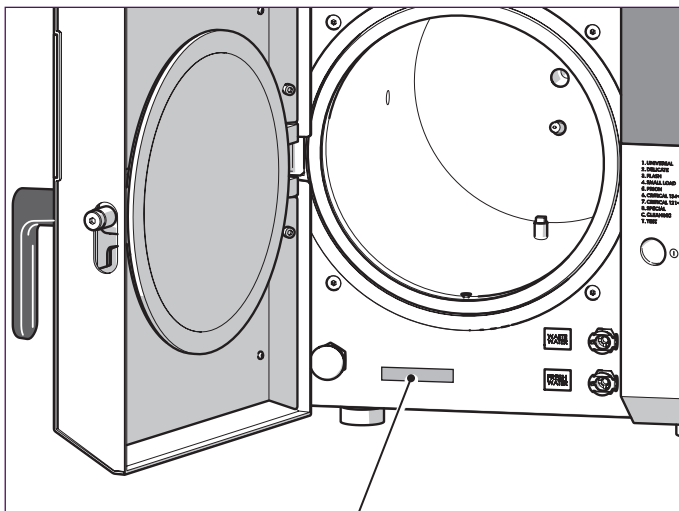


**3-9 Sterilizer regulatory label**

The regulatory label is fixed on the back of the sterilizer and displays the CE marking together with important data for operation, already given in the technical specifications table, and the serial number. For convenience, the device serial number is also displayed on an adhesive label on the lower section of the internal front panel, visible when the sterilization chamber door is open.










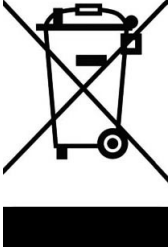
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**SERIAL NUMBER LABEL**

<b>NSK</b> NSK Dental Italy S.r.l. Via dell'Agricoltura, 21 36016 Thiene - VI - Italy Tel. +39 0444 367400 +39 0445 820070		<b>CE</b> 0 0 5 1
Small Steam Sterilizer <b>iClave plus</b>		
<b>SN</b>	<b>IP000000</b>	
<b>REF</b>	<b>IP</b>	
Voltage	230 V	
Power	1920 W	
Frequency	50/60 Hz	
Fuse	6,3x32 FF 10A	
Chamber capacity	17,5 l	
Working pressure	2,35 bar	
Safety valve press. interv.	2,55 bar	
Working temperature	135 °C	
Year of production	2019	
"Attention, consult instructions for use"		
MADE IN ITALY		

	Symbol	Description
1		Symbol for manufacturer. The data given next to this symbol identifies the manufacturer. NOTE: this symbol must be accompanied by the name and address of the manufacturer.
2	NSK Dental Italy S.r.l.	Manufacturer's name
3	Via dell'Agricoltura 21, 36016 Thiene (VI) IT	Manufacturer's address
4		Manufactured for: Logo of the company for which the device is manufactured
5		CE marking in accordance with Dir. 93/42/EEC Medical Devices. The CE marking certifies that the product meets the standards applicable in the EU member states (see declaration of conformity)
6	0051	Identification number of the notified body Notified body IMQ: IMQ S.p.A., Via Quintiliano, 443, 20138 Milan (Italy), Identification number: 0051.
7	Small steam sterilizer	Explanation of use and application of the device
8	MOD.	Name of the device
9		Reference to catalogue Symbol on the equipment: symbol located next to the model number (ref.to catalogue). NOTE The manufacturer's catalogue number shall be after or below the symbol adjacent to it.
10		Serial number
11	Voltage	Type of power supply
12	Power	Maximum power
13	Frequency	Frequency
14	Fuse	Type of fuses
14	Chamber capacity	Chamber capacity
15	Working pressure	Working pressure
16	Safety valve pressure	Safety valve discharge pressure
17	Working temperature	Working temperature
18		Date of manufacture. The date given beside this symbol is the date of manufacture.
19	MADE IN ITALY	This is a merchandise mark indicating that a product is designed, produced and packaged entirely in Italy.

<p>21</p>		<p>Caution, carefully read the instructions for use before using the device.</p>
<p>22</p>		<p>Symbol for separate waste collection of electrical and electronic devices, in conformity with Directive 2012/19/EU (WEEE/RAEE).</p>

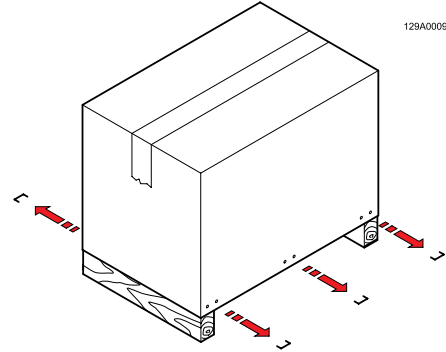
**4** INSTALLATION

**4-1 Unpacking and transportation**

The packaging of the sterilizer consists of a wooden pallet on which the sterilizer is placed, with adequate protective padding and a corrugated cardboard casing fixed to the pallet with metal staples.

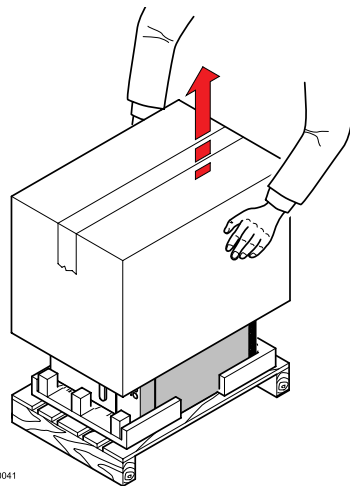
Place the package on a level surface free from clutter to facilitate easy opening and safe extraction of the sterilizer.

- Remove the staples holding the casing to the pallet.

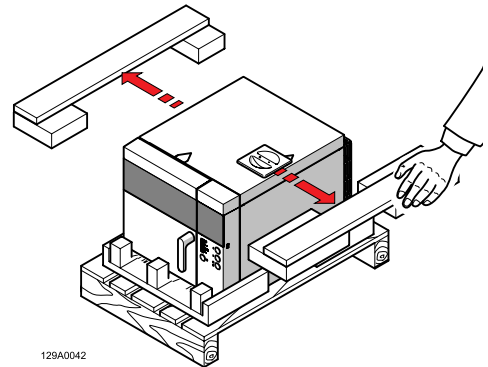


- Remove the cardboard casing.

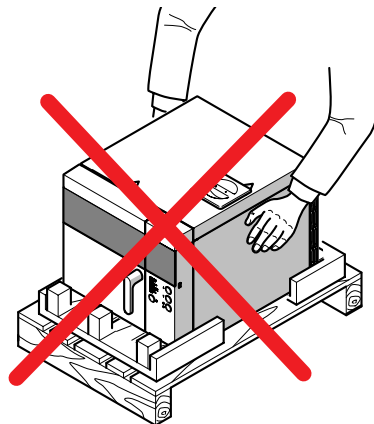
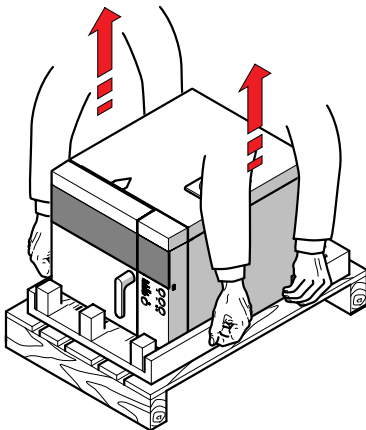
- Remove the corner and edge protection from the sterilizer.



- Lift the sterilizer and position it in the place of installation.



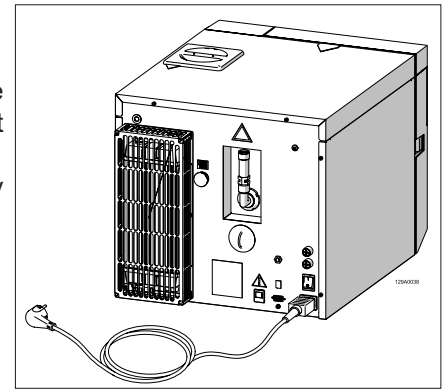
**CAUTION** Lifting, transporting and positioning the sterilizer in the place of installation should be performed by two people.



### 4-2 Positioning

Check that the power supply voltage to the device matches that shown on the regulatory label on the rear panel, that the power outlet is designed to supply at least 16A and that it has an earth connection.

If the installation makes the main power switch inaccessible, a specially dedicated accessible electrical disconnection switch should be provided.

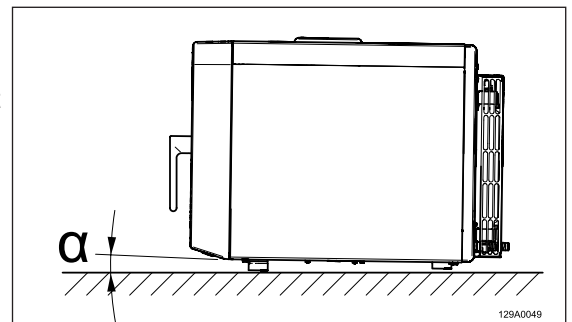


**WARNING**

The manufacturer is not liable for damage to property or persons caused by electrical systems that are unsuitable or have no earth connections.

The device must be installed on a flat surface. If the support surface is perfectly horizontal, the front feet are already adjusted with a slight inclination to facilitate the flow of water during draining.

If the support surface is not perfectly level, adjust the front legs, raising or lowering them to obtain a slight inclination, as shown in the figure.

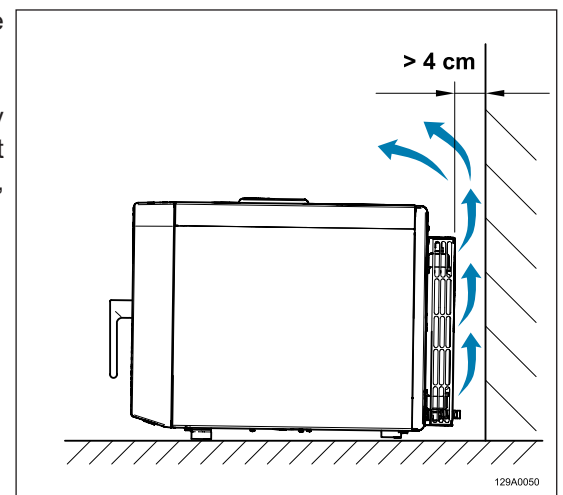


**WARNING**

Do not place the device on a fragile surface that could be damaged or cause fire or smoke if hot objects fall.

For proper operation, leave a free space of at least 4 cm between the rear of the device and any wall.

Do not install the device near heat sources or in damp or poorly ventilated spaces. The room must provide air circulation with at least 10 air changes per hour; a recirculating air ventilation system (e.g., an electric fan) cannot be used as an alternative.

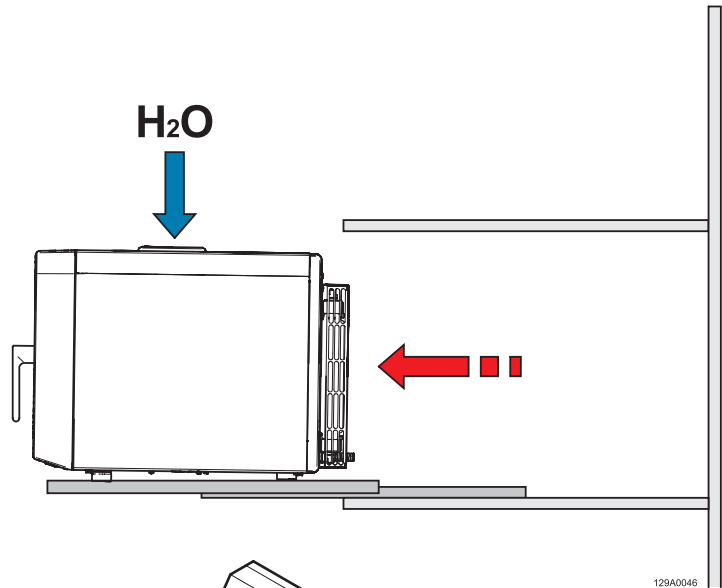
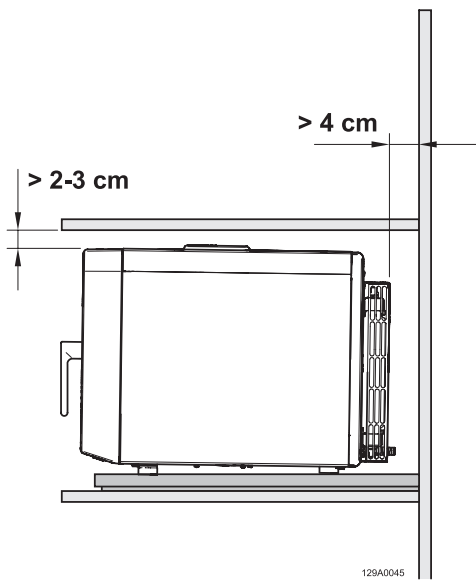


**CAUTION**

The safety valve is on the rear of the device. When triggered by excess pressure, it releases very hot steam into the environment. Position the device to avoid risk of burns to the operator.

In the case of built-in installation with a shelf above the device, a space of at least 2-3 cm should be left between the bottom of the shelf and the top of the device.

Place the device on a mobile shelf with a sliding rail extraction system to allow filling of the deionized water tank, positioned on the top, and access to the main switch at the back of the device.



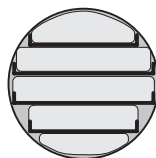
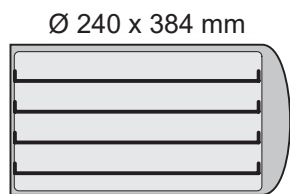
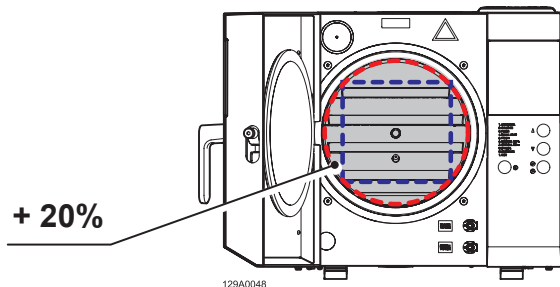
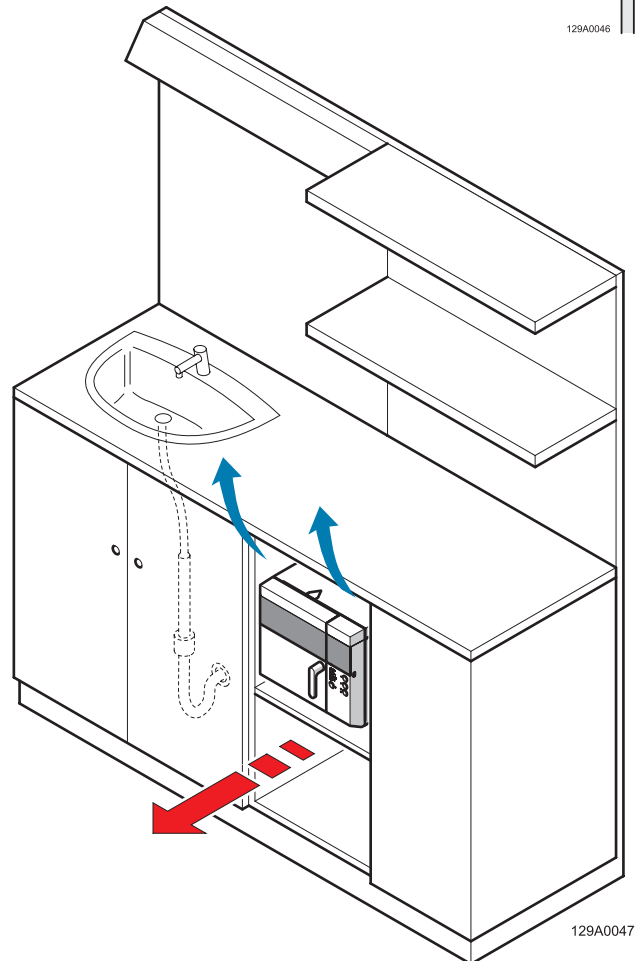
For installation inside a cabinet, leave a ventilation space of at least 2-3 cm between the bottom of the shelf and the top of the device.

Place the device on a mobile shelf with a sliding rail extraction system to allow filling of the deionized water tank, positioned on the top, and access to the main switch at the back of the device.

If the drain pipe under an adjacent sink is used for the drain of the Purity device (optional), place the device at a greater height than the trap to allow proper drainage of the liquids by gravity.

**STERILIZATION CHAMBER  
LOAD CAPACITY**

The trays of varying widths to fit the circular shape of the sterilization chamber allow an increase of approximately 20% in the loading capacity.



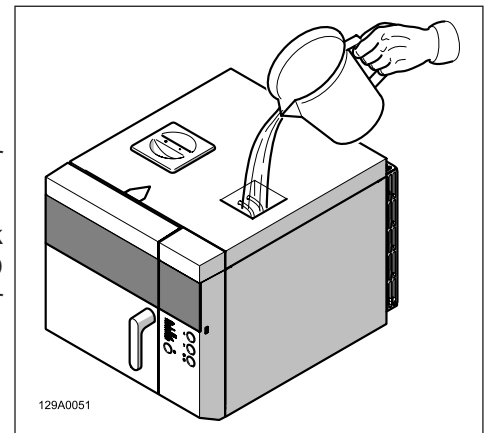
### 4-3 Initial start-up



#### WARNING

The following operations must be carried out by qualified and properly trained personnel. Incorrect procedures and settings can jeopardize the quality of sterilization and cause hazards.

- Check that the power supply has the right voltage and plug the power cord into the outlet.
- Fill the demineralized water tank up to the maximum level. The tank holds approximately 4 litres of water. The minimum water level LED switches off, indicating that the tank is filling. When the full tank indicator lights up, this indicates that the tank has been properly filled.



#### CAUTION

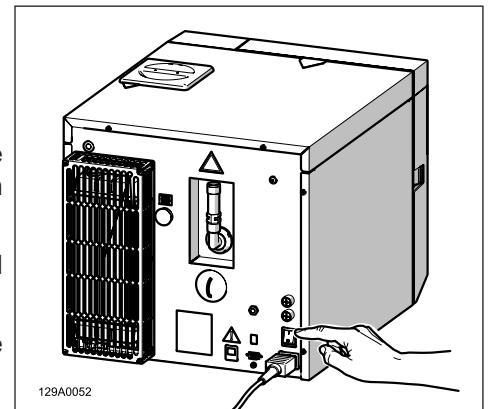
The use of poor quality demineralized water can leave calcium deposits on the instruments, on the inside of the chamber and on the trays. Read the label on the distilled water container carefully. Do not use domestic tap water, even if treated with a filter or water softener.



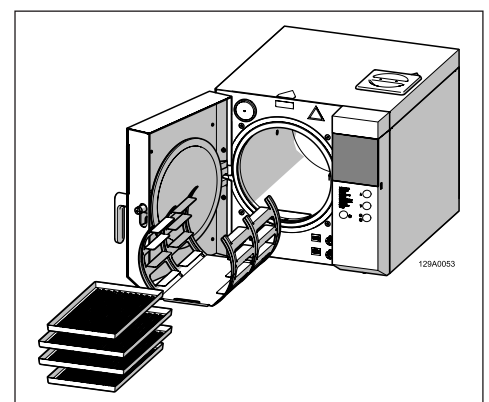
#### WARNING

Do not use battery water or other fluids or additives, as these can cause irreversible damage to the device and hazards to the operator.

- Connect the power.
- Switch the device on by the main switch. For daily inactive periods, the main switch can be left in the ON position, as the power consumption in stand-by is almost nil.
- The display indicates: the current time; the state of the device (OFF) and the date (day-month-year).
- The message **NEED INSTALL** indicates that the initialization procedure is required.



- Remove the rack and trays from the chamber and close the door.



#### NOTE

The door remains locked when the device is switched off; if it is still locked when switched on, turn the device off and then on again.

- Press the ▲ and the ⓘ button at the same time. The message **ALTITUDE** appears on the display, showing the default altitude setting (100 m a.s.l.).
- Using the ▲ or ▼ buttons, adjust the setting to the actual altitude of the installation site (see paragraph on “Compensating for altitude”).
- Press the ⏵ button to confirm the displayed setting and start the automatic initialization procedure for loading the water into the hydraulic system and the chamber. The message **WAIT INSTALL** appears on the display
- At the end of the procedure, the message **END INSTALL** confirms that initialization is complete.
- Open the door and dry the chamber with a clean cloth.

If the initialization procedure is not performed correctly, the display will show one of the following messages:

**DOOR OPEN:** the door was not closed

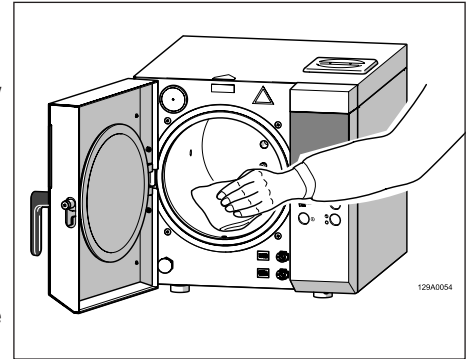
**ADD H2O:** lack of water

**NEED INST:** initialization procedure not performed.

In each case, the procedure must be repeated.

If the initialization procedure is performed correctly, the display will indicate **OFF** and the door will remain locked.

To unlock the door, press the ⓘ button.



**The sterilizer is now ready for use. Entering the MEMORIES menu, under the item INSTALLATION DATE, the display shows the date of installation, which will remain in the memory as information for the support service.**

Place the rack and trays in the chamber and select a sterilization cycle. See the chapter on “Instructions for use”.

### 4-4 Compensating for altitude

In order for the pressure control devices to work properly, the sterilizer has an atmospheric pressure compensation function.

During installation, the altitude value (above sea level) must be set for the location in which the device is used. This procedure must be done every time the device is moved to new locations with different altitudes.

The altitude value set by the manufacturer is 100 metres above sea level and can be left unchanged for altitudes of between 0 and 200 metres as a difference of  $\pm 100$  metres will not affect the proper functioning of the device.

To guarantee proper sterilization, it is important that the difference between the set altitude value and the actual altitude does not exceed 200 metres.

<b>CAUTION</b>	An inaccurate value beyond the tolerated limit can overload the vacuum devices and cause premature or false AL8 or AL5 alarm signals (see the chapter on “Alarms”).
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### 4-5 Setting date and time

To set the current date and time of the device installation location, see the chapter on “Using the sterilizer” and the SET TIME function in the paragraph on “Programming the menu”.

<b>NOTE</b>	The device does not automatically change from daylight-saving time to standard time.
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### 4-6 Setting the language

To set the language for the country where the device is installed, in which the messages will appear on the display and the sterilization cycle reports will be printed, see the chapter on “Using the sterilizer”, and the ADJUST function and “Language” submenu in the “Programming menu” paragraph.



**5 USING THE STERILIZER**

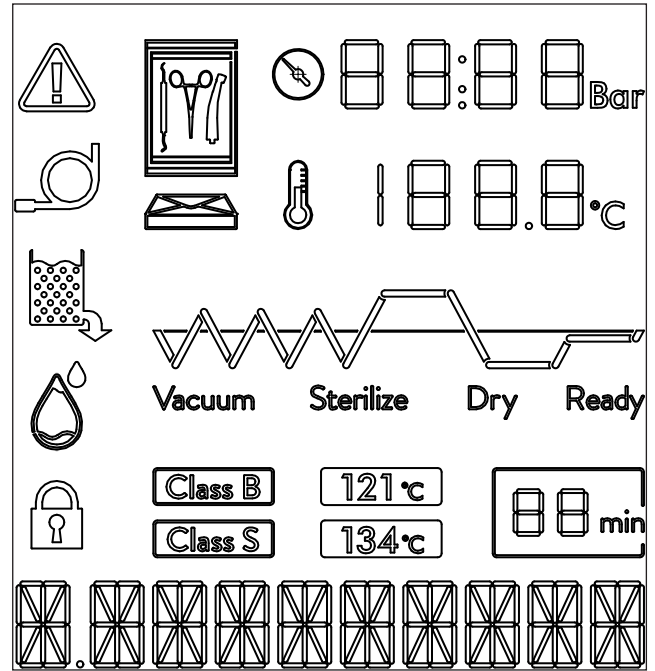
**5-1 Description of the operator panel**

The operator panel, located on the right-hand side of the front panel, allows the operator to receive information and to give all types of commands necessary for proper operation of the sterilizer. It consists of: a liquid-crystal digital display and function buttons, described in detail below.

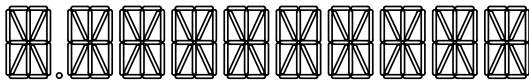
**5-1-1 Display Colouring**

The digital display changes colour to indicate the following operating conditions:

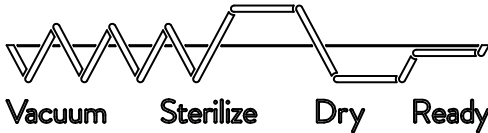
- RED:** alarm state or manual stop
- WHITE:** ready for use
- GREEN:** cycle completed
- YELLOW:** cycle in progress
- PURPLE:** configuration and adjustment
- BLUE:** device heating up



**5-1-2 Display symbols**



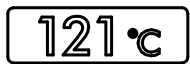
This alphanumeric display gives the name and information for the selected cycle, alarm messages and adjustment menus in real time.



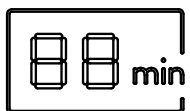
The LEDs on this graphic light up in real time to indicate the respective Vacuum, Sterilize, Dry and Ready phases through which the device passing during any cycle in progress.



These indicators signal the class type (B or S) in which the selected cycle is operating.



These indicators show the operating temperature of the selected cycle, 121°C for cycles 2 and 7 and 134°C for cycles 1, 3, 4, 5, and 6.



This indicator countdowns the time remaining until the end of the current cycle. It is only activated during sterilization.



This indicator acts as a pressure gauge and shows the pressure in bars inside the sterilization chamber in the display at the side.



This indicator acts as a thermometer and shows the temperature in degrees Celsius inside the sterilization chamber in the display at the side.

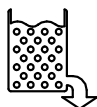
## Chapter 5 - USING THE STERILIZER



This indicator signals an activated alarm; the display shows the ALARM message followed by the specific alarm code (see the chapter on “Alarms”).



This indicator shows that the test program T. is running.



This indicator shows that the contaminated water tank is full and must be emptied immediately (see the paragraph on “Draining the contaminated water recovery tank”).



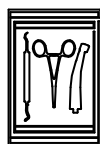
This indicator flashes when the demineralized water tank is full; It remains lit until the quantity of water is sufficient for completion of the program.



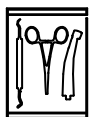
This indicator flashes when the demineralized water tank is empty; it must be filled in order to run the selected program (see the paragraph on “Topping up the demineralized water tank”).



This indicator signals that the door is locked, for example, for the normal running of a program. When it switches off, the door can be opened.



Indicator for loading the instruments in double wrapping.  
This lights up when programs 1, 2, 5, 6, or 7 are selected.



Indicator for loading the instruments in single wrapping.  
This lights up when program 4 is selected.



Indicator for loading the instruments without wrapping.  
This lights up when program 3 is selected.



Indicator for loading the instruments inside a container.  
This lights up when programs 2 or 7 are selected.

### 5-1-3 Function buttons



Power button, for switching the device on and off. When browsing through menus, it allows you to return to the previous menu or to exit from programming.



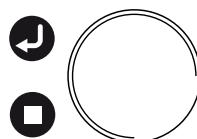
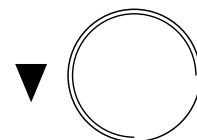
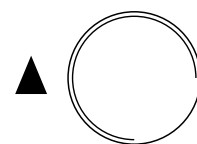
Buttons for selecting programs, menus or functions. These allow you to increase or decrease the values to be set when programming.



Program start/stop button. This confirms the selection made during programming.

**START/STOP**


- 1. UNIVERSAL
- 2. DELICATE
- 3. FLASH
- 4. SMALL LOAD
- 5. PRION
- 6. CRITICAL 134 °C
- 7. CRITICAL 121 °C
- 8. SPECIAL
- C. CLEANING
- T. TEST



## 5-2 Turning the sterilizer on

Turn the sterilizer on using the main switch on the back of the device. The display indicates:

- the current time
- the **OFF** state of the device
- the current day, month and year

Press the  button and wait a few seconds for completion of the automatic self-test. During this time, the parameters of the checked components appear in sequence on the display.

When the self-test is completed, the display shows a series of indications, including:

- pressure;
- temperature;
- the demineralized water tank level;
- whether the door is locked;
- the name of the currently selected program together with its parameters and graphic;
- the type of product that can be sterilized

If the chamber temperature is below 35°C, the message **LOW** appears and the display turns blue. As the temperature increases, it changes colour.

If the contaminated water tank is full, this is indicated on the display.

The microprocessor enables the preheating phase to bring the temperature of the chamber walls to 100°C.

During this phase, the temperature readings on the display are not accurate as there is not yet any steam.

The pre-heating phase keeps the chamber warm in order to speed up the cycles. This function requires greater power consumption in standby; If the device is not used continuously and a high operating speed is not required, the device can be set to ECO MODE, in which the chamber cools down when not needed. This mode has no effect on the performance of the cycle. See the “Programming menu” paragraph.

At this point, the sterilizer is ready to start one of the sterilization cycles (described in the following paragraphs). Arrange the material to be sterilized on the trays, place them in the chamber and close the door.

Check that the water level indicator on the display is above the minimum. If not, fill the main tank with demineralized water until the maximum level is indicated.

## 5-3 Daily tests to check the sterilizer’s performance

During the inspection conducted by the manufacturer, the sterilizer undergoes thorough thorough testing and calibration checks, in accordance with regulations. These tests guarantee the performance of the device, except for in the case of unauthorized repairs, tampering or improper use.

Although the device has an advanced diagnosis and process evaluation system, the operator has the responsibility of ensuring the maintenance of performance standards on a daily basis.


The frequency of these checks is determined regionally and locally by the healthcare protocols of the place of installation.

The manufacturer recommends running the following tests daily, in the morning, before using the sterilizer: **Vacuum, Helix and Bowie&Dick**, described in detail in the following paragraphs.


### 5-3-1 Vacuum test


The purpose of the **Vacuum test** is to ensure that the sterilization chamber is perfectly sealed. The manufacturer recommends running the test at the start of the day, before beginning the daily sterilization cycles.

The **Vacuum test** is activated with the machine unloaded, in standby mode (OFF state shown on the display) and an internal temperature of below 35°C, which are the typical conditions of the state of the device at the start of a working day.

Press and hold the  button; when the button is released the device automatically starts the vacuum test, which lasts for about 15 minutes. The display shows a countdown of the time remaining until the end of the test, the current test phase (e.g.: T0) and the instant pressure value.

If the test result is negative, the message **T3** appears on the Alarms display, indicating that the chamber is insufficiently sealed (see the chapter on “Alarms”).

By pressing and holding the  button for a few seconds, a Vacuum test can be set to start in a few hours. The display shows the message **HOUR DELAY VACUUM TEST** and the ▲ or ▼ buttons can be used to set the delay time in hours for the start of the Test.

Pressing the  button confirms the set delay and exits the procedure.

## Chapter 5 - USING THE STERILIZER

### 5-3-2 Helix test and Bowie & Dick test

The purpose of **Helix test** and **Bowie&Dick test** is to verify the proper penetration of the sterilising steam in the tools contained in the sterilization chamber.

The **Helix test** and **Bowie&Dick test** are activated with the sterilizer switched on.

The manufacturer recommends running these tests at the start of the day, before beginning the daily sterilization cycles, but they can be run at any time, with the sterilizer on.

Prepare the sterilizer for a **Helix test** (e.g. HTS100 class 5 cod. 9900051) or a **Bowie&Dick test** (e.g. 3MTM COMPLYTM cod. 1300) in accordance with the requirements of the test procedure regulations.

With machine on, select the **TEST** program **T**. and press and hold the button for a few seconds.

The device automatically starts the test program, with a temperature of 134°C, a sterilization time of 3.5 minutes and 3 vacuum phases.

If a **Helix test** or **Bowie & Dick test** is accidentally started, it can be stopped by pressing the button.

The device deletes the test started unintentionally, automatically initiates a procedure to remove the fluids in circulation and places itself in stand-by, ready for use in a normal working cycle.

## 5-4 Preparing the material before sterilization

### 5-4-1 Preliminary operations

All the material to be prepared for sterilization is normally contaminated.

Before handling or moving contaminated materials or instruments, the following precautions should be taken:

- Wear rubber or latex gloves of suitable thickness and a face mask;
- wash your hands, with the gloves already on, using a germicidal detergent;
- separate the instruments suitable for sterilization from those that are not;
- do not carry contaminated instruments in your hands, but always use a tray suitable for carrying instruments;
- be very careful of instruments with sharp parts that can puncture normal rubber gloves; in such cases, protect your hands with gloves of sufficient strength;
- once the handling and transfer of the contaminated materials is finished, carefully wash your hands while still wearing the gloves.

### 5-4-2 Treatment of materials and instruments before sterilization



Failure to clean and remove organic residues from the instruments to be sterilized can affect the sterilization process and cause damage to the instruments and/or the sterilizer.

Clean and process the materials and instruments to be sterilized as indicated in the following points:

- 1) Rinse the instruments thoroughly under running water immediately after using them.
- 2) Divide metal instruments into groups, according to the type of material of they are made (e.g.: brass, aluminium, stainless steel, carbon steel, chrome-plated metal) in order to avoid electrolytic oxidation.
- 3) Perform a preliminary wash with an ultrasonic device that uses a mixture of water and germicidal solution (follow the manufacturer's instructions) or use a washer-disinfector. For best results, use a special detergent for ultrasonic cleaning, with a neutral pH.



Solutions that contain phenols or quaternary ammonium compounds can cause corrosion to the instruments and the metal parts of the ultrasonic device.

- 4) After instrument cleaning and reprocessing, rinse the instruments and visually check that all residues have been completely removed; if necessary, repeat the ultrasound cleaning or wash the instruments thoroughly by hand.



### CAUTION

To avoid mineral deposits on the instruments to be treated, use demineralized or distilled water for rinsing. If normal hard tap water is used, the instruments should be thoroughly dried.

- 5) When cleaning handpieces, in addition to the steps described above, run a wash cycle using a device specially designed for cleaning handpieces, which performs thorough internal cleansing together with lubrication.
- 6) For sterilization of porous materials, wash and dry the materials thoroughly before sterilization.



### CAUTION

For washing fabrics and porous materials in general, do not use detergent with high concentrations of chlorine and/or phosphates, such as bleach, as it can damage the support and the metal trays inside the chamber during the subsequent sterilization cycle.

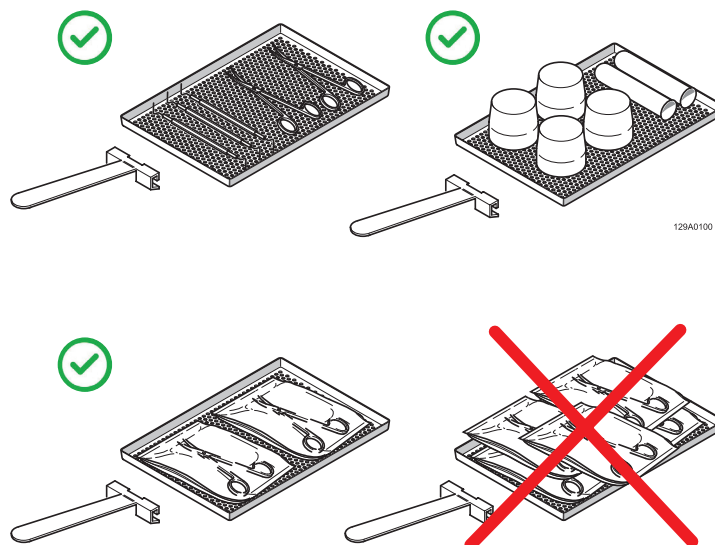
## 5-5 Arranging the material on the trays before sterilization

Follow the guidelines below to obtain optimum effectiveness from the sterilization process and to preserve the life of the materials and instruments.

### NOTE

Place a chemical sterilization indicator on each tray to avoid sterilising the same load twice or using unsterilized material. When sterilising wrapped material, place the chemical indicator inside one of the wraps.

- Arrange instruments of different metals, previously separated, on different trays;
- When sterilising instruments made of metal other than stainless steel, place a sheet of sterilization paper between the tray and the instrument to avoid direct contact between the two materials;
- position cutting instruments so that they do not come into contact during the sterilization cycle; if necessary, isolate them with gauze or cotton cloth;
- arrange receptacles and containers (tubes, cups, glasses, etc.) on their sides or in an inverted position as water accumulation must be avoided;
- do not place more instruments on the trays than they can contain; any overloading must be avoided;
- arrange the instruments with sufficient spacing and ensure that they remain separated throughout the sterilization cycle.
- position articulated instruments, such as scissors, in an open position;
- do not stack the trays one above another or in direct contact with the walls of the chamber; always use the tray support provided with the sterilizer;
- always use the supplied extraction clamp to insert or remove the trays from the sterilization chamber.



### 5-6 Program selection

Various types of programs are available to the operator, depending on the degree of sterilization desired, with a class B or class S sterilization cycle, as described in the program table.


To select the programs, press the ▲ or ▼ buttons and the display will instantly show the program parameters. Programs 1 to 7 are preset by the manufacturer, the **SPECIAL** program 8 can be customized by the operator (see the paragraph on “Setting SPECIAL program 8”).


When the desired program is selected, the displays show the program settings.






**PROGRAM TABLE**

Program	Parameter	Maximum	Cycle	Process values	Maximum Load
<b>1</b> <b>UNIVERSAL</b>	134°C - 5' 3 pre-vacuum phases drying 10' (6' with vacuum + 4' with ventilation)	Solid, porous, hollow type A and B wrapped	Class B	134-137°C 2,04-2,25 bar	4 kg solid or 1.5kg porous
<b>2</b> <b>DELICATE</b>	121°C - 20' 3 pre-vacuum phases drying 12' (7' with vacuum + 5' with ventilation)		Class B	121-124°C 1,04-1,24bar	
<b>3</b> <b>FLASH</b>	134°C - 3' 2 pre-vacuum phases drying 5' (3' with vacuum + 2' with ventilation)	Unwrapped solid instruments	Class S	134-137°C 2,04-2,25 bar	4 kg solid
<b>4</b> <b>SMALL LOAD</b>	134°C - 4' (3 pre-vacuum phases, drying 3'+ 2')	Solid, porous, hollow type A and B wrapped	Class B	134-137°C 2,04-2,25 bar	0,5 kg solid
<b>5</b> <b>PRION</b>	134°C - 18' (3 pre-vacuum phases, drying 6'+ 4')	Solid, porous, hollow type A and B wrapped	Prion Class B	134-137°C 2,04-2,25 bar	4 kg solid or 1.5kg porous
<b>6</b> <b>CRITICAL 134°C</b>	134°C - 5' (4 pre-vacuum phases, drying 8'+ 6')		Class B	134-137°C 2,04-2,25 bar	
<b>7</b> <b>CRITICAL 121°C</b>	121°C - 20' (4 pre-vacuum phases, drying 9'+ 7')		Class B	121-124°C 1,04-1,24bar	
<b>8</b> <b>SPECIAL</b>	Settable parameters Temp: 105 - 135°C Time: 3'- 90' Pre-vacuum phases: 2, 3 or 4 Drying with vacuum + ventilation: 3'+2', 6'+4', 8'+6'	Loading according to the set parameters	According to the set parameters	105-138°C 0,21-2,30 bar	
<b>C</b> <b>CLEANING</b>		Tablet for cleaning the sterilization chamber	Cleaning		Empty chamber
<b>T</b> <b>TEST</b> ( <b>Helix Test</b> <b>Bowie&amp;Dick</b> <b>Test</b> )	134°C - 3' 30" 3 pre-vacuum phases drying 10' (6' with vacuum + 4' with ventilation)	Helix Test  B&D Test	TEST	134-137°C 2,04-2,25 bar	Helix test pack or equivalent  B&D test pack or equivalent
<b>VACUUM TEST</b>	Temperature below 35°C		TEST	< 35°C	Empty chamber

## 5-7 Running the program

Press the  button to run the selected program.

<b>NOTE</b>	The <b>3 FLASH</b> and <b>8 SPECIAL</b> programs do not ensure class B sterilization. To run these program types, press and hold the  button for more than three seconds. For sterilizing non porous and unwrapped products, we recommend using the <b>3 FLASH</b> program. This mode has shorter sterilization times and lower energy consumption.
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<b>NOTE</b>	A <b>delayed cycle start</b> can also be programmed: press and hold the  button for more than 8 seconds: the display will then show the message HOUR DELAY. Press the  or  buttons, select the delay time in hours and then press the  button. The device switches off, indicating the time remaining before the start of the program; the chamber will gradually cool down. This time-delayed start can be cancelled by switching the device on with the  button.
-------------	---

When the program starts, the door is locked and remains locked for the entire duration of the program. The displays show the settings for the selected program for 10 seconds and the device begins to perform the various phases of the sterilization cycle automatically and in sequence. The cycle phases are controlled by the microprocessor and shown in graphic sequence on the display (LED cycle graphics) to allow the operator to follow the respective phases and times in real time.

The indications for the various cycle phases are given below:

- the first LED in the cycle graphic lights up in the VACUUM phase
- the cycle time countdown begins
- The pressure gauge indicates the pressure in the sterilization chamber
- The thermometer indicates the temperature in the sterilization chamber
- The alphanumeric display indicates the current program
- the door lock indicator lights up
- the various indicators light up for the class, cycle temperature and materials introduced
- the tank water level indicators light up.

### Vacuum phase (entry of water into the chamber and pre-vacuum phases)

In this first phase, the vacuum pump is activated and a specific quantity of water is pumped into the chamber. The VACUUM indicator flashes during this phase.

This phase is repeated several times for a total time of between 10 and 20 minutes, depending on the chamber and load conditions. When the pump starts operating there may be a slight noise.

### Sterilization phase

Once the programmed parameter values are reached, the VACUUM indicator switches off and the STERILIZE indicator lights up.

The countdown begins for the time remaining until the end of the sterilization phase and the pressure and temperature indicators show the respective values for the sterilization chamber.

The sterilization phase is followed by the decompression phase and the display shows the pressure falling towards zero. The decompression time countdown is also displayed during this phase.

<b>NOTE</b>	The manufacturer has set intentionally extended decompression times in order to reduce the temperature swing caused by the change in the state of the steam.
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### Drying phase

When decompression is finished, the STERILIZE indicator flashes to signal the end of the sterilization phase and the DRY indicator lights up, signalling the start of the drying phase.

During this phase, the heating elements continue to heat the chamber based on a differentiated logic controlled by the microprocessor, the vacuum pump comes into operation once more to remove residual steam and the display shows the countdown of the remaining time.

This is followed by a phase of forced ventilation through the bacteriological filter, also indicated by a countdown on the display.

### End of cycle

At the end of the drying phase, the DRY indicator switches off and the READY and STERILIZE indicators light up. The device emits a 10-second acoustic signal to alert the operator that the program has ended.

At this point, the heating elements are disabled and remain in a low-power pre-heating state until the door is opened. When the cycle is completed, the total cycle time is shown on the TIME indicator, while the PRESS and TEMP indicators show the current temperature and pressure values for the sterilization chamber.



At the end of cycles **3 or 8**, only the READY indicator lights up, without the STERILIZE indicator, to indicate that the set cycle does not ensure class B sterilization; the display shows the sequence of cycles.


To unlock and open the door, press the  button.

**The sterilization cycle of the selected program is finished and the load can be removed.**



If a printer is connected (optional), the microprocessor sends the most significant cycle data to the printer to provide a detailed printed report that certifies the process carried out.


The displays once more show: the current time and the temperature and pressure of the sterilization chamber. The sterilizer is now ready to run a new program.

The operator can prepare a new load and start a new sterilization cycle with the benefit of a much shorter heating time, as the chamber is already warm, or press the  button to place the device in standby (OFF state).

### NOTE

If the door is not opened or a button pressed within 30 minutes from the end of the program, the device automatically switches to standby mode (OFF state).

If a fault occurs or a parameter deviation is detected during the cycle, the ALARM indicator lights up, the alarm type is shown on the display (see the chapter on “Alarms”) and the door remains locked.


To unlock and open the door, press the  button.




At the end of the sterilization cycle, lubricate the internal mechanisms of any sterilized handpieces with appropriate lubricating oil. This operation helps preserve the life of the instruments.



## 5-8 Interrupting the programme



If necessary, a running program can be aborted at any time by pressing the  button. The message *MANUAL STOP* appears on the display.



- Before opening the door, check that the PRESS display shows a pressure value of 0 (zero). In any case, a safety device prevents the door from being opened while the chamber is pressurized. To unlock the door, press the  button.
- Remove the load with extreme care and check for the presence of water inside the chamber. If the load is wrapped, it is advisable to replace the wraps.
- Before reloading the sterilization chamber, carefully dry the inside of it and wait for 10 minutes to allow evaporation and the complete drainage of water.



## 5-9 Programming menu

The device has a series of menus that allow the operator to set useful configurations and programmes for operating the device.

To access the device's programming menu, press the  and  buttons at the same time.




Pressing the  or  button again allows you to scroll through the following menus described in the paragraphs below:




- **SET TIME**
- **SET SPECIAL CYCLE**
- **MEMORIES**
- **ENERGY**
- **EXP DAYS**
- **ADJUST**




### 5-9-1 SET TIME




In this menu you can set the: year, month, day, hour and minutes




When the display indicates SET TIME, press the  button to enter programming.



The display indicates YEAR SET: select the current year with the  and  buttons and press the  button to confirm.

The display indicates MONT SET: select the current month with the  and  buttons and press the  button to confirm.

The display indicates DAY SET: select the current day with the  and  buttons and press the  button to confirm.

The display indicates HOUR SET: select the current hour with the  and  buttons and press the  button to confirm.

The display indicates MIN SET: select the current minutes with the  and  buttons and press the  button to confirm.

When the procedure is finished, the display once more indicates SET TIME; press the  and  buttons to select other menus.

## Chapter 5 - USING THE STERILIZER

### 5-9-2 SET SPECIAL CYCLE

The **SPECIAL** program 8 is the only one that can be customized by the operator.

To access the setting functions for **SPECIAL** program 8, press the ▲ and ▼ buttons until SET SPECIAL CYCLE appears on the display, then press the button to access programming.

The functions accessed to set this program are described in the following table.

Press the  button to access the temperature settings	The display shows: <i>SPECIAL TEMPERATURE</i>	Set the sterilization temperature parameter, which can vary from 105°C to 135°C, using the ▲ and ▼ buttons. ▼ Select the value and press the  button to confirm
Press the  button once more to access the process time settings	The display shows: <i>SPECIAL TIME</i>	Set the process time parameter, which can be between 3 and 90 minutes, using the ▲ and ▼ buttons. ▼ Select the value and press the  button to confirm
Press the  button once more to access programming of the vacuum phases	The display shows: <i>VACUUM - SPECIAL</i>	Use the ▲ and ▼ buttons to set the vacuum phases, which can be: 2, 3 or 4. Select the value and press the  button to confirm
Press the  button once more to access programming of the drying time	The display shows: <i>TIME - DRY - SPECIAL</i>	Use the ▲ and ▼ buttons to set the drying time for the vacuum+ventilation combination. Select the value and press the  button to confirm
When the procedure is finished, the display once more indicates SET SPECIAL CYCLE; press the ▲ and ▼ buttons to select other menus.		

<b>CAUTION</b>	<p>The combination of time and temperature parameters set by the operator can lead to cycles that do not ensure sterilization.</p> <p>The effectiveness of the sterilization cycle in the SPECIAL custom program 8 should be verified with appropriate tests.</p> <p>At the end of the SPECIAL program 8, the READY indicator lights up, without the STERILIZE indicator, to indicate that the effectiveness of the cycle set by the operator has not been verified by the manufacturer.</p>
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### 5-9-3 MEMORIES

This menu shows the data stored by the device regarding installation, cycles run and maintenance work performed. This data cannot be edited by the operator.




When the word MEMORIES appears on the display, press the button to access the list of data, and the ▲ and ▼ buttons to scroll through and view the following menu items:

- CYCLES - Cycles counter
- ABORTED CYCLES - Aborted cycles counter
- ALARMS - Codes for the latest alarms
- CLEANING CYCLES - Number of cleaning cycles performed
- INSTALLATION DATE - Date of original installation
- LAST SERVICE DATE - Date of the most recent maintenance work




When you have finished viewing, press the button; the display will indicate MEMORIES once more; press the ▲ and ▼ buttons to select other menus.

**5-9-4 ENERGY**

The power supply mode for the device can be selected from this menu.





When the word ENERGY appears on the display, press the  button to access configuration and the  and  buttons to scroll through and view the following menu items:






- NORM - This uses maximum power in the preheating phase to preheat the sterilization chamber and reduce the waiting time for the cycle start.
- ECO - This stops the heating when it is not strictly necessary.

Press the  button to confirm the chosen configuration; the display will indicate ENERGY once more; press the  and  buttons to select other menus.

**5-9-5 ADJUST**

This menu allows a series of specific adjustments to the device that are not commonly used but are still important for optimal functioning.

When the word ADJUST appears on the display, press the  button to enter and the  and  buttons to scroll through and view the following menu items. Select a submenu and press the  button to access the submenu parameter settings or to return to the initial list.

- PRINTER - this allows functions to be selected for an external printer (optional). This submenu contains three function options:
  - REPORT is used for a standard serial printer that prints a complete report of the cycles like that saved on the USB flash drive;
  - LABEL DYM this is used together with a Dymo LabelWriter SE450 printer (only for this model) to create labels to placed on the packages at the end of the cycle. When this function is selected, the display shows the word LABELS at the end of the cycle; select the number of printouts required using the  and  buttons. Printing starts once the door is open.
  - LABEL CUS this is used together with a Custom branded printer, model S'print (with its specific firmware) to create labels to placed on the packages at the end of the cycle. When this function is selected, the display shows the word LABELS at the end of the cycle; select the number of printouts required using the  and  buttons. Printing starts once the door is open.
- LANGUAGE - this allows you to select the language for messages and displays and for the cycle reports.
- ALTITUDE - this allows you to adjust the altitude settings for the location where the device is installed (required for proper functioning).
- H2O DOSE - this allows you to adjust the quantity of water loaded during the sterilization cycle, to adapt the cycle to different types of loads.
- VACUUM - this allows you to adjust the pre-vacuum level. This adjustment is not normally necessary, although it can be useful for adapting to different local requirements and parameters.
- ADD DRY TIME - this allows you to increase the drying time of the cycles, for better drying in critical load conditions. After selecting the desired value (in minutes) and setting it with the  button, the display shows the following:
 

*DRY MODE select the automatically adjusting vacuum phase, which allows reduction of the drying time when the drying value is acceptable.*
- PRESS-TEM - this displays the readings from the three temperature sensors in the chamber simultaneously. To be used only for technical diagnosis.
- TECH MENU - this allows you to set a secure configuration. This menu can only be used by authorized technical support personnel (password protected).
- FACTORY - This menu can only be used by authorized technical support personnel for predefined adjustments (password protected).

### 5-10 Topping up with demineralized water and draining contaminated water


The sterilizer is fitted with two 4-litre tanks: the main demineralized water tank and the contaminated water recovery tank.


The hydraulic circuit does not allow the reuse of the steam produced during the sterilization cycle, which is collected in the recovery tank and must be periodically drained.

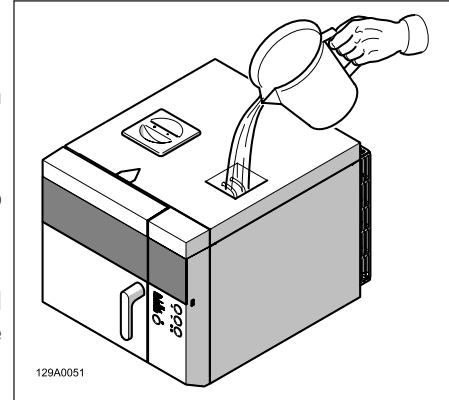
The normal operating cycle therefore involves gradual emptying of the demineralized water tank and filling of the recovery tank.

#### 5-10-1 Topping up the demineralized water tank

The average water consumption for each sterilization cycle is 520 cc, which means that a full tank allows about 7 cycles.

The  indicator lights up (see the “Operator panel description” paragraph) to indicate an insufficient water level in the loading tank.


Top up with demineralized water until the  indicator lights up (accompanied by a 7 beep acoustic signal). However, do not fill beyond the closing grid in the top input opening.



#### WARNING

When removing the cap, avoid coming into contact with hot parts inside the demineralized water tank.

#### 5-10-2 Draining the contaminated water recovery tank

The  indicator (see the “Operator panel description” paragraph) indicates excess water in the contaminated water recovery tank.

Drain the tank as follows:

- 1) Prepare a container of at least 4 litres in capacity;
- 2) Insert the drain hose into the upper quick coupling (waste water);
- 3) Allow the tank to drain completely;
- 4) Remove the drain hose by pushing the coupling ring towards the machine and pulling the hose.

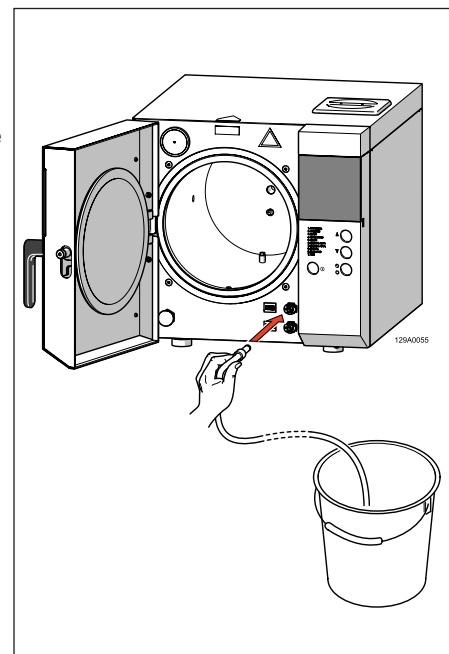


#### WARNING

The water in the dirty water tank should be considered as biologically contaminated, therefore appropriate precautions should be taken if the tank is emptied. Waste water must be disposed of in accordance with local or national regulations.

#### NOTE

The demineralized water tank can also be drained in the same way, if necessary, by connecting the hose to the lower quick coupling (fresh water).



## 5-11 Diagnostics

### 5-11-1 Manual diagnostics

A qualified operator may perform a diagnostic test on the sterilizer at any time.

The test is read-only for the operator and covers the three sensors in the sterilization chamber that measure the internal pressure and temperature at two points in the chamber.

Follow the steps described below to run the diagnostic test.

- Access the device's **programming menu** by pressing the ▲ and ▼ buttons at the same time.
- Press the ▲ or ▼ button again to scroll through the menus to find the **ADJUST** menu.
- Press the ⏴ button to enter and the ▲ and ▼ buttons to scroll through and view the submenus.
- Select the **PRESS-TEM** function (submenu) and press the ⏴ button to view the measurements from the three sensors in the sterilization chamber.
- Press the ⏴ button to exit from the diagnostics function.

#### NOTE

The device cannot be placed in standby during the manual diagnostics phase. You must first exit the diagnostic phase with the ⓘ button and the device can then be placed in standby.

### 5-11-2 Power-on automatic diagnostics

When the device is switched on, a self-test cycle is automatically activated for about 15 seconds.

A 3-beep acoustic signal indicates its completion.

During this phase, all the board components of the device are checked in sequence.

If the test result is positive, the message *CARD GOOD* appears.


Any faults detected are recorded and shown on the display by means of the alarm codes described in the chapter on "Alarms".

To bypass the initial self-test cycle, press any key immediately after switching on.

### 5-11-3 Checking water quality

To prevent accidental use of poor quality demineralized water, the device is equipped with an automatic water quality control system that measures its conductivity. The control system is part of the initial diagnostic tests and starts automatically when the device is switched on, provided it is at room temperature and the demineralized water tank is full.

When the diagnostics are finished, the message *H<sub>2</sub>O GOOD* appears on the display if the conductivity is found to be less than 15 µS, or *H<sub>2</sub>O HARD* if the value is greater than 15 µS.

 <b>CAUTION</b>	A negative result from this check does not prevent use of the sterilizer; however, it is recommended to replace demineralized water of less-than-ideal quality with better quality water.
--	---

The following table shows the recommended minimum parameters for the water to be used

Pollutants	Supply water	Condensate
evaporation residue	≤ 10 mg/l	≤ 1.0 mg/l
silicon oxide	≤ 1 mg/l	≤ 0.1 mg/l
iron	≤ 0.2 mg/l	≤ 0.1 mg/l
cadmium	≤ 0.005 mg/l	≤ 0.005 mg/l
lead	≤ 0.05 mg/l	≤ 0.05 mg/l
residues of heavy metals, excluding iron, cadmium and lead	≤ 0.1 mg/l	≤ 0.1 mg/l
chlorine	≤ 2 mg/l	≤ 0.1 mg/l
phosphates	≤ 0.5 mg/l	≤ 0.1 mg/l
Conductivity (at 20°C)	≤ 15 uS	≤ 3 uS
Ph	from 5 to 7.5	from 5 to 7
appearance	Colourless, clean without sediment	Colourless, clean without sediment
hardness	≤ 0.02 mmol/l	≤ 0.02 mmol/l

## 5-12 Connections

### 5-12-1 Connection to an external printer

The device does not have an integrated printer, but is designed for connection to an external printer, to which the process data is sent in order to document and certify the sterilization.

The use of a printer, which is required in some countries, is destined to become ever more frequent, in order to also ensure the proper sterilization of dental materials from a medical-legal perspective.

The printer cable should not be more than 3 metres in length.

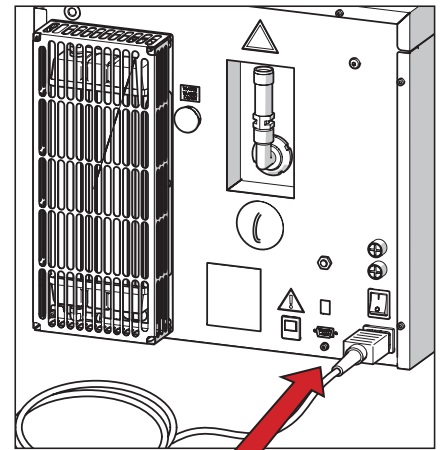
**A printer with an RS232 serial interface can be connected to the serial interface port on the device**

In sequence:

- 1) turn on the printer;
- 2) turn on the sterilizer.

The report is printed automatically during the cycle and will contain the following information:

- date and time of the process
- serial number of the cycle
- cycle and parameters selected
- type of process: sterilization or disinfection
- start and end times of the sterilization phase
- time of completion of the drying phase.



In the case of malfunction or interruption of the cycle, the printer will provide the message *CYCLE ABORTED - NOT STERILE* and will indicate the type of alarm encountered.

At the end of the working day, turn the printer off.

To program the print report language, see the paragraph on “Setting temperature and pressure measurement units and selecting the language”.

The PRINTER port only interfaces directly with the printer.

Facsimile of report with an Alarm

```

CLASS B
-----
iClave plus
Serial no. -----
Date 14.02.06
Prog. 1
134 C 5'
Cycle 001343

START
Time 13:45:34

ABORTED
Time 13:45:35
ALARM NO. 7
    
```

**The procedure described above can also be used for connection to the CUSTOM printer**

The CUSTOM printer is enabled for normal printing of reports on temperature sensitive paper and/or for printing the barcode using a special roll of labels.

The CUSTOM printer operation can be set up from the operator panel through the following steps (see also the submenu “Adjust”, item LABEL CUS, in the paragraph “Programming menu”):

- press the ▲ and ▼ buttons at the same time to enter the menu;
- scroll through the menu with the ▼ button until you see ADJUST;
- press the button to enter the programming submenu;
- the display shows PRINTER, press the button to enter the submenu;
- the display shows REPORT, scroll through the menu pressing the ▼ button till the item LABEL CUS is displayed;
- Confirm the setting with the button;
- press and hold the button to return to the home screen.



### 5-12-2 Connection to a USB log

The sterilizer can be connected to a device that saves the sterilization reports on a USB flash drive instead of printing them on paper.

For connection and use, refer to the user manual for the device.

The port is also used for the diagnostics and technical support system through a dedicated interface, which is supplied to the authorized technical support centres.

The port is protected by a cap to prevent the insertion of foreign objects that could damage the device. Do not remove it if the device is not in use.

Do not connect devices not specified by the manufacturer.

The USB connection enables you to download a report for each cycle performed.

The report is saved in txt format (unformatted plain text) on the USB memory drive connected to the USB port to the right of the display.

Do not insert or remove the memory while the device is performing a cycle; the data is protected but there is a risk of losing some information.

A file is created on the drive for each cycle and the file names match the sequential numbers of the cycles. The file contains the main information for traceability and the most important time, temperature and pressure values.

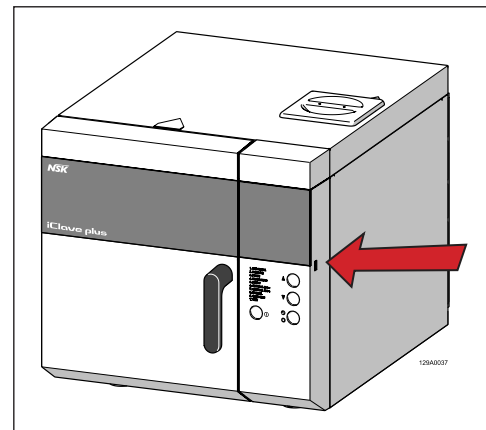
The internal memory stores the information for the 20 previous cycles inside the device (the maximum number depends on the size of the files), allowing this data to be recovered if the USB memory drive is not available or is defective.

The USB drive must be of high quality for the safety of the data, and a backup should be created for all data.

The size of the data is a few kilobytes, therefore a flash drive with a small capacity is sufficient. A large quantity of data stored on the USB drive reduces the access speed, so it is advisable to delete files from the memory drive once a backup copy has been created.

Each time the USB drive is connected to the device, the files it contains are compared with those stored in the internal memory and any missing files are copied; this may take a few seconds, during which the keyboard operation is blocked: do not turn off the power during this stage. The last 20 cycles stored in the device are saved on the memory once more; this should be borne in mind when performing a backup.

If an external printer is used, the printed report can be the same as that on the USB drive, or it can be a simplified report with a barcode, if a label printer is used; in any case, the file on the the USB device contains a complete report. The manufacturer assumes no liability for any data lost due to inadequate management of the database or defective USB devices (pens or similar).



#### CAUTION

Do not connect a LAN connection to the service port; this type of connection could cause the machine's microprocessor to malfunction and void the warranty.



## 6 ALARMS

### 6-1 Overview

When the device is switched on and during each sterilization cycle, the characteristic parameters of the various phases of the cycle are constantly monitored, together with the proper functioning and perfect condition of all the components.

Any anomaly or fault is immediately indicated on the display through warning messages and alarm codes, together with an acoustic signal.

The following paragraphs contain tables listing the possible warning messages and alarms.

The tables show:

- in the left-hand column, the message or alarm code that appears on the display;
- in the middle column, the cause of the warning or alarm;
- in the right-hand column, the solution to the problem, which in some cases may be resolved by the operator, while in others technical assistance is necessary.

### 6-2 List of warning messages

MESSAGE DISPLAYED	CAUSE	SOLUTION
<b>OPEN DOOR</b>	The door was not opened at the end of the cycle. command with the door open.	Open the door. Close the door.
<b>FAIL</b>	Failed cycle	See "Alarm code" table.
<b>DRY FAIL</b>	Drying not completed due to manual intervention (the material was removed before the end of the drying phase). Sterilization, however, is completed.	Press the  button. It is possible to run a new cycle.
<b>ADD H2O</b>	Insufficient water level in the loading tank (appears before starting the cycle)	Top up the main tank.
<b>FULL H2O</b>	The used water tank is full (appears before starting the cycle)	Empty the recovery tank.
<b>MANU STOP</b>	The cycle has been stopped manually. Sterilization is not completed.	Dry the chamber, if wet, and restart the cycle.
<b>BLACK OUT</b>	Blackout during the cycle	Press the  button to exit. Check the electrical socket. Dry the chamber and restart the cycle.
<b>NEED CLEANING</b>	60 cycles completed without an automatic cleaning cycle.	Run the automatic cleaning cycle.
<b>NEED SERVICE</b>	A year has passed since the installation date or more than 1500 cycles have been completed without any maintenance by the technical support	The warning message disappears as soon as a cycle is selected, but will appear again at the next switching on. Call for a complete check-up by a qualified technical service; the message will be reset after the servicing.
<b>NEED INST</b>	Request for the installation procedure	Run the installation procedure.
<b>NEED TEST</b>	A preventive alarm has been detected	See "Alarm code" table.
<b>TEST FAIL</b>	Negative Vacuum test results	Clean the door gasket and repeat the test. Call for a technical service.

## 6-3 List of alarms

ALARM CODE	CAUSE	SOLUTION
cd 1	Clogged drain filter.	Clean or replace filter.
cd 2	Slow heating of the upper part of the chamber.	Run a cycle with a smaller load. If the problem persists, contact the technical support service. Check the mains voltage.
cd 3	Slow heating of the lower part of the chamber.	Run a cycle with a smaller load. If the problem persists, contact the technical support service. Check the mains voltage.
cd 4	Blocked water dispenser. Dirty water filter.	Impurities in the water tank. Perform filter maintenance routine. Run an automatic cleaning cycle.
cd 5	Dirty loading solenoid valve.	If the problem occurs more than 3 times consecutively, call the technical service.
cd 6	Clogged bacteriological filter.	Replace the bacteriological filter.
cd 7	Vacuum phase too slow.	Dry the chamber and run an automatic cleaning cycle.
AL 1	Solenoid valve 1 faulty.	Contact the technical support service.
AL 2	Solenoid valve 2 faulty.	Contact the technical support service.
AL 3	Solenoid valve 3 faulty.	Contact the technical support service.
AL 4	Solenoid valve 4 faulty.	Contact the technical support service.
AL 5	The pressure has not increased within the set time.	Excessive load or pressure loss. Run an automatic cleaning cycle.
AL 6	Initial vacuum phase too long.	Run an automatic cleaning cycle.
AL 7	Door not properly locked.	Check that the door is properly closed.
AL 8	Air in the chamber.	Check the door seal. Clean the gasket.
AL 9	Interruption of the countdown for more than 60 seconds during the sterilization phase.	Check the door seal. In necessary, run the automatic cleaning and the Vacuum test.
AL 10	Pressure too high	Contact the technical support service.
AL 11	Pressure too low	Check the door seal. In necessary, run the automatic cleaning and the Vacuum test.
AL 12	Temperature outside the nominal range.	Run the automatic cleaning cycle.
AL 13	Chamber temperature sensor defective	Contact the technical support service.
AL 14	Upper chamber temperature sensor defective	Contact the technical support service.
AL 15	Lower chamber temperature sensor defective	Contact the technical support service.
AL 16	Pressure sensor defective.	Contact the technical support service.
AL 18	Drying interrupted.	Dry the load.
AL 31	Insufficient vacuum.	Excessive load.

# 7 MAINTENANCE

## 7-1 Periodic maintenance

<b>CAUTION</b>	<b>Maintenance of the device must be carried out by suitably trained personnel, who have read and understood all the procedures and information given in this Instruction Manual, particularly in chapter 2 “Safety information”.</b> <b>Always wear sterilized disposable latex gloves.</b>
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The following table shows the routine maintenance that the operator or maintenance technician must perform regularly. It indicates the frequency of the maintenance and describes the type of operation to perform. To see the total number of cycles performed by the sterilizer since the time of installation, press the ▲ and ▼ buttons at the same time and select the MEMORIES menu, which gives the number of cycles actually run (successfully completed) by the sterilizer (see the “Programming Menu” paragraph in the chapter on “Using the sterilizer”). To exit the procedure, press the ⓘ button.

### PERIODIC MAINTENANCE TABLE

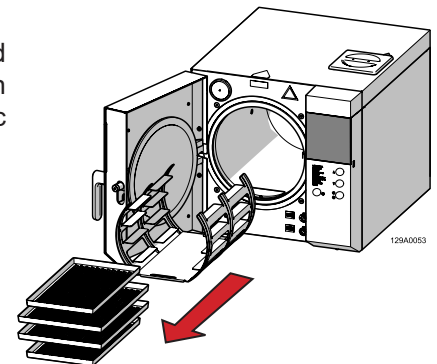
Frequency	Type of operation	Operation procedure
<b>Daily</b>	Manual cleaning of the sterilization chamber. This should be done when the chamber is cold.	Cleaning to be done manually using a cloth moistened with demineralized water
<b>Daily</b>	Manual cleaning of the rubber gasket on the door. This should be done when the chamber is cold.	Cleaning to be done manually using a cloth moistened with demineralized water
<b>Weekly</b>	Cleaning or replacement of the demineralized water filter (code 105320)	See paragraph 7.3
<b>Every 3 weeks, or after 60 cycles</b> or when the display indicates <b>NEED CLEANING</b>	Cleaning of the sterilization chamber by means of the periodic cleaning cycle + Cleaning of the demineralized water filter. This should be done when the chamber is cold.	See paragraph 7.2
<b>Every 6 months, or after 500 cycles</b>	Replacing the bacteriological filter (code 021008)	See paragraph 7.4

## 7-2 Automatic sterilization chamber cleaning cycle

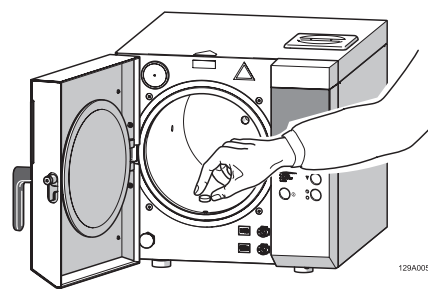
<b>WARNING</b>	<b>Do not use abrasive products.</b> <b>Do not run the automatic cleaning cycle with the trays in the sterilization chamber.</b> <b>Clean the surfaces of the sterilization chamber when the device is cold.</b>
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<b>NOTE</b>	The device must be switched off in order to open the door. When the maintenance is finished, close the door and switch off the device to avoid excessive heating.
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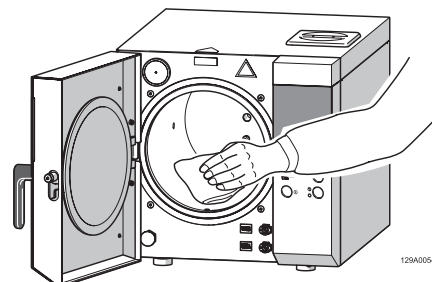
- 1) Remove the rack and the trays from inside the sterilization chamber and wash them with a common neutral detergent. Thoroughly rinse them in running water, dry them and keep them in a dry place during the automatic cleaning cycle.



- 2) Place a cleaning tablet in the sterilization chamber and close the door.
- 3) Select the **CLEANING** program **C**. using the ▲ and ▼ buttons.
- 4) Press the button to start the automatic cleaning cycle. The cycle lasts about 15 minutes.



- 5) At the end of the automatic cleaning cycle, when the **READY** indicator lights up, open the door and clean any residues from the inside of the chamber using a clean cloth lightly dampened with demineralized water. Do not use sponges, brushes, scouring pads or paper.
- 6) Clean the demineralized water filter as described below.

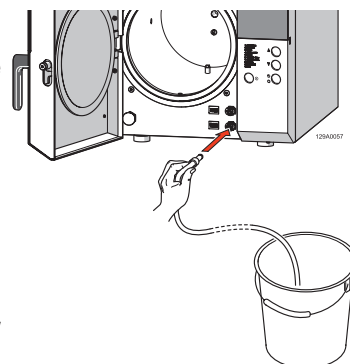


### 7-3 Cleaning or replacement of the demineralized water filter

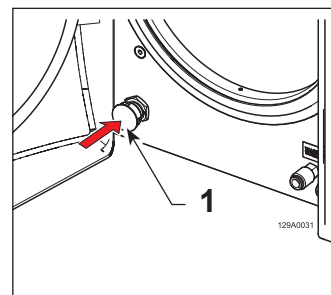
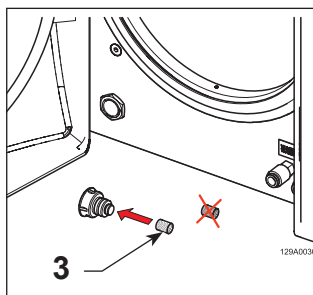
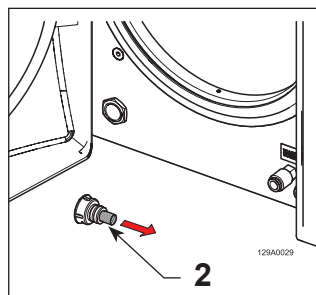
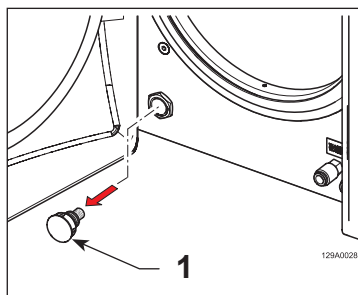
#### NOTE

Clean the demineralized water filter with the sterilization chamber empty after running the automatic cleaning cycle, as described in the previous paragraph.

- 1) Completely drain the demineralized water tank, inserting the silicon hose in the FRESH WATER quick coupling.



- 2) Remove plug **1** of the water filter from its housing, taking care to avoid any outflow of residual water from the internal hoses.
- 3) Remove filter **2**, which is installed directly on the plug.
- 4) Clean the filter with compressed air (or an ultrasonic cleaner), or replace it if damaged with a new filter **3**, and reinstall the filter on the plug.
- 5) Install the plug with the filter in its housing, taking care to ensure that it is properly inserted.

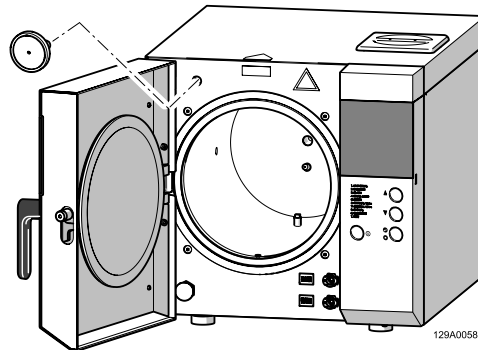


- 6) Fill the main tank with demineralized water as described in the chapter on “Using the sterilizer”.
- 7) With the device in stand-by (OFF on the display), press and hold the ▼ button and press the button. This starts the automatic Initialization procedure, which also requires removal of the residual air filter. At the end of the procedure, the **READY** LED lights up.

## 7-4 Replacing the bacteriological filter

<b>NOTE</b>	Replace the bacteriological filter with the device switched off.
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Unscrew the bacteriological filter and replace it with a new one. Install the filter in its housing, taking care to ensure that it is fully screwed in.



## 7-5 Cleaning the instruments before sterilization

To ensure the maximum duration and reliability of the device, it is advisable to take the utmost care over the cleaning and washing of instruments.

One of the main causes of premature wear of the sterilizer is due to residues from imperfectly cleaned instruments, resulting in the formation of stains, limescale and progressive clogging of filters, solenoid valves and hydraulic circuits.

## 7-6 Scheduled maintenance

<i>Pos</i>	<i>Type of check</i>	<i>Maintenance</i>	<i>Extraordinary maintenance*</i>
<b>1</b>	<b>Door adjustment</b>	1 Year / 1,500 cycles	
	- Gasket replacement	1 Year / 1,500 cycles	
	- Check on door disc play	1 Year / 1,500 cycles	
	- Closing strength check	1 Year / 1,500 cycles	
	- Lubrication of moving parts	1 Year / 1,500 cycles	
	- Check for wear on components	1 Year / 1,500 cycles	
	- Replacement of closure pin		4 Years / 10,000 cycles
	- Replacement of hinge screws		4 Years / 10,000 cycles
	- Tightening of structural screws		4 Years / 10,000 cycles
<b>2</b>	<b>Calibration / Validation</b>	1 Year	
	- Altitude setting check	1 Year / 1,500 cycles	
<b>3</b>	<b>Cleaning / replacement of filters</b>	1 Year / 1,500 cycles	
	- Replacement of bacteriological filter	6 months / 500 cycles	
<b>4</b>	<b>Pump performance check</b>	1 Year / 1,500 cycles	
	- Pump replacement		10,000 cycles
<b>5</b>	<b>Tank cleaning</b>	1 Year / 1,500 cycles	
<b>6</b>	<b>Radiator cleaning</b>	1 Year / 1,500 cycles	
<b>7</b>	<b>Safety valve replacement</b>		4 Years / 10,000 cycles

\*) Extraordinary maintenance must be performed by qualified personnel authorized by Dental X. If the sterilizer needs to be sent back or removed to carry out repairs in a workshop or factory, remember to enclose a photocopy of the sales invoice together with the sterilizer and, in the case of a return, the return merchandise authorization (RMA), which must always be requested in advance from the Dental X customer care office before sending the device.

The purchased sterilizer meets the relevant requirements of current safety standards. The parameters set by the manufacturer are designed to ensure the sterility of the load under the conditions specified in the manual.

Read this manual carefully before using the sterilizer; improper use may terminate or invalidate the warranty conditions applied to the purchase of the device.

NOTE: For any questions, requests or inquiries regarding the device, first contact the dealer who supplied the product.

