

Istruzioni per l'uso
Instructions for use
Mode d'emploi
Bedienungsanleitung
Instrucciones de uso

Europa B evo

Europa B evo 24

ITALIANO
ENGLISH
FRANCAIS
ESPAÑOL
DEUTCH



Costruito da / The Manufacturer / Fabriqué
par / Fabricado por / Hersteller:

MEDILINE ITALIA s.r.l.

Via 8 marzo, 4
43025 Corte Tegge – Cavriago (RE)
ITALY

Dear Client,

Thank you for having chosen our autoclave, we know how to exchange your fidelity, with maximum attention and service definitely corresponding to your expectations.

The autoclave you have chosen is the maximum expression of applied technology. It guarantees safe sterilization of all types of instruments and materials: solids, hollows, porous, free and packaged.

Before using this autoclave, we invite you to read with maximum attention the user's manual and then keep it in a place accessible to all operators in charge of sterilization.

The autoclave must be used only and exclusively for the uses foreseen by the constructor.

For installation, maintenance and assistance **ask exclusively** for a technician authorized. We invite you to use and ask for **exclusively** original spare parts.

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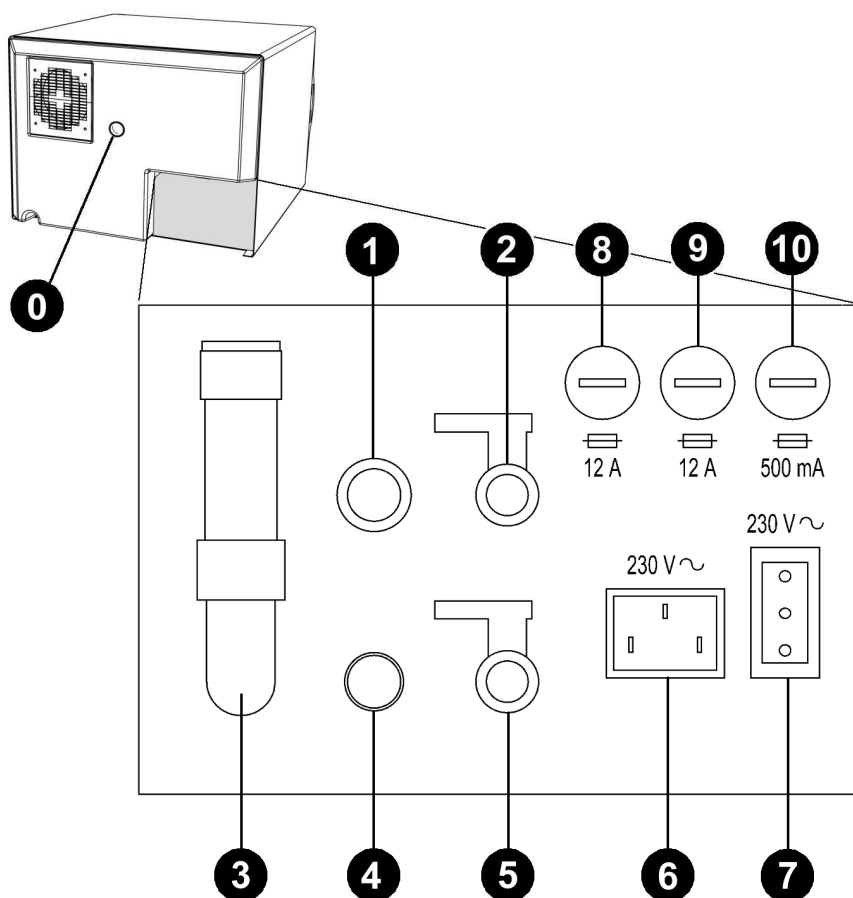
17. PROCEDURES FOR SERVICE AND ASSISTANCE

18. GUARANTEE

VACUUM	Pressure below atmospheric pressure
CHAMBER	Cylindrical steel body that, during the cycle, is filled with
FILTER	Device for retaining particles
TRAY	Drawer for holding the load to be sterilized
TRAY HOLDER	Structure for holding the trays in the sterilization chamber
DEMINERALIZER	Device for eliminating mineral salts in mains water
HELIX TEST	Test for checking the penetration of steam in a hollow object
BOWIE - DICK TEST	Test for checking the penetration of steam in a porous object
VACUUM TEST	Test for checking that the degree of vacuum in the chamber is maintained
BACTERIOLOGICAL FILTER	Device for retaining particles in suspension in the air larger than 0.3 µm.
OVER PRESSURE	Pressure higher than the standard one for the cycle considered
OVER TEMPERATURE	Temperature higher than the standard one for the cycle
RESINES	Replaceable component (cartridge) of the demineralizer that

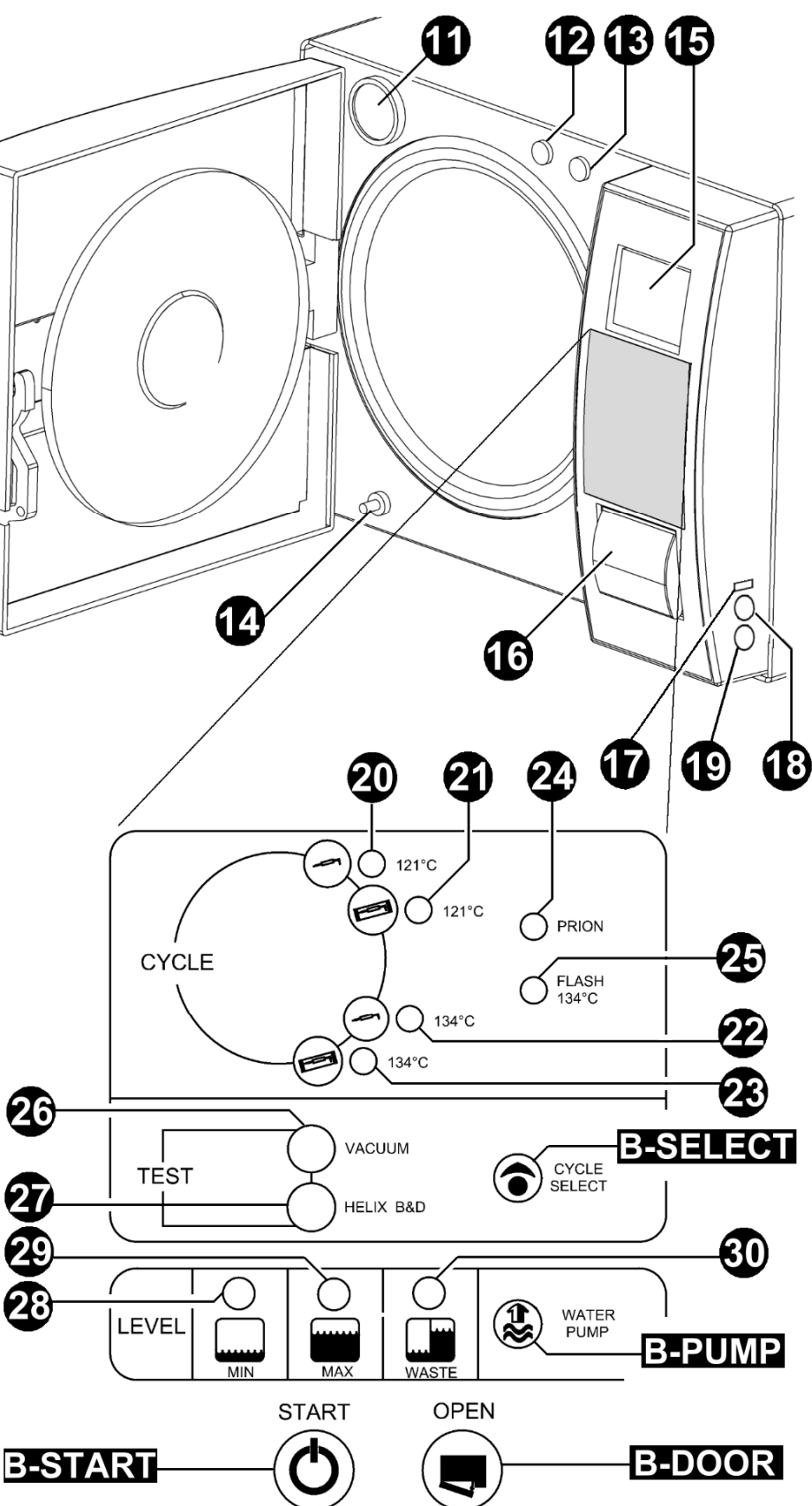
	WARNING: Instruction to follow to avoid damaging property or compromising the successful result of the cycle
	DANGER: Safety instruction to avoid injury
	HAZARDOUS VOLTAGE
 ATTENZIONE TOGLIERE TENSIONE PRIMA DI RIMUOVERE IL COPERCHIO  WARNING DISCONNECT THE MAINS SUPPLY BEFORE REMOVING THIS COVER	DISCONNECT THE POWER BEFORE REMOVING THE LID
 ATTENZIONE ATTENTION ACHTUNG ALTA TEMPERATURA HIGH TEMPERATURES TEMPERATURES ELEVÉES HOHE TEMPERATUR	HIGH TEMPERATURE
	EARTHING

	Pursuant to DIRECTIVE 2002/96/EC, this symbol shows that the product must not be disposed of as urban waste at the end of its operating life.
	Alternate current
	Warning: high voltage. Risk of electrocution!
	Fuse
	Read with attention the manual use
	Manufactured the -- / -- / --
	Unwrapped Material
	Wrapped Material
	Clean water maximum level
	Clean water minimum level
	Used water maximum level
pos.	Position (number identifying a component in the figures or diagrams).
Pict.	Picture
Ω	Ohm (Electric Resistance unit)
s	Seconds (time unit)
kW	kilowatt (power unit)
Hz	Hertz (Frequency unit)
mm	Millimeters (Length unit)
A	Ampere (Electric Current unit)
V	Volt (Electric Voltage unit)
°C	Degrees Centigrade (Temperature unit)
kg	Kilograms (Weight unit)



PICT.1

0	Spacer
1	Clean water overflow
2	Clean water drain tap-Demineralizer tap
3	Safety Valve
4	Used water overflow - condensate drain
5	Used water drain tap
6	Main power supply
7	ONLY DEMINERALIZER electrical socket
8	Fuse 12A
9	Fuse 12A
10	Fuse 500mA



PICT.2

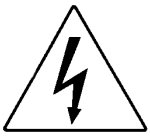
11	Bacteriological filter
12	Manual water filling with funnel
13	Water filling with pump
14	Used water draining
15	Display
16	Printer
17	Connector RS232
18	Connector B-test (incubator) (<i>paragraph 2.3</i>)
19	General switch (MAINS)
20	121°C cycle unwrapped indicator
21	121°C cycle wrapped indicator
22	134°C cycle unwrapped indicator
23	134°C cycle wrapped indicator
24	Cycle Prion
25	Cycle 134°C Flash
26	Vacuum Test
27	Led Helix – B&D Test
28	Clean Water Minimum Level
29	Clean Water Maximum Level
30	Used Water Maximum Level
B-START	Start of cycle selection button
B-PUMP	Button for water filling with pump
B-SELECT	Cycle selection button
B-DOOR	Door opening button

02

SAFETY

2.1

Safety Marking



HAZARDOUS VOLTAGE



ATTENZIONE
TOGLIERE TENSIONE
PRIMA DI RIMUOVERE
IL COPERCHIO

DISCONNECT THE POWER BEFORE REMOVING THE
LID



WARNING
DISCONNECT THE
MAINS SUPPLY BEFORE
REMOVING THIS COVER



ATTENZIONE
ATTENTION
ATTENTION
ACHTUNG

HIGH TEMPERATURE

ALTA TEMPERATURA
HIGH TEMPERATURES
TEMPERATURES ELEVÉES
HOHE TEMPERATUR



EARTH CONNECTION

2.2

Safety Devices

The following Safety Devices are installed:

- Safety valve set at 2.4 bar 0/+10%
- Electromagnetic lock to prevent the door from opening while the cycle is running
- Resistance over temperature thermostats

2.3

Safety Notes

- The manufacturer is liable for the marketed product in accordance with current regulations.

The manufacturer's liability will expire when operations are carried out on the device, or a part of it, by unskilled personnel or using non-original spare parts.

- There should be no potential risk of explosion and/or fire in the room where the autoclave is installed.

- The autoclave should be installed in a special well-ventilated room.

The incubator's connector (PICT.1 pos **18**), should be used only for the B-TEST.

The 230 V a.c. connection is independent by the **MAINS**, don't touch the connector with wet hands and protect by the water.

This product is subject to Directive 2002/96/EC of the European Parliament and the Council of the European Union on Waste of Electrical and Electronic Equipment (WEEE) and, in jurisdictions adopting that Directive, is marked as being put on the market after August 13, 2005, and should not be disposed of as unsorted public waste. Please utilise your local WEEE collection facilities in the disposition and otherwise observe all applicable requirements.

The autoclave is able to sterilize the three types of load provided for by the standard EN13060, especially:

METAL OR SOLID MATERIALS	Instruments with no cavities and no obstacles to the penetration of steam
POROUS OBJECTS	Simple or composite materials that can absorb fluids (fabrics, gowns, surgical gauzes, dressings, etc)
HOLLOW OBJECTS	Materials or devices with cavities, obstructions, etc. These are subdivided into two types, classified according to the length and diameter of the cavity. Approximately: TYPE B: cannulas, tubes or devices with large passages. TYPE A: turbines, hand pieces and devices with blind or small holes.

The autoclave must be used, solely and exclusively, for the sterilization of instruments and materials compatible with the steam sterilization system.

This equipment can be used in the dental, medical, aesthetic fields and, generally, in all the fields where the sterilization of the instruments and materials is made

This device has been certified for the sterilization of the following materials *:

	EUROPA B EVO	EUROPA B EVO 24
Wrapped and unwrapped solid materials for a maximum load of	kg. 5,00	kg. 7,00
Type A/B hollow materials for a maximum load of	kg. 5,00	kg. 7,00
Porous materials for a maximum load of	kg. 1,50	kg. 2,0

* Only for european countries



Always make sure the loads undergoing sterilization can withstand the temperatures of the selected cycle

04
TECHNICAL DATA
4.1 Mechanical Data

	EUROPA B EVO	EUROPA B EVO 24
<i>Working temperature</i>	+5°C ÷ +40°C	
<i>Maximum altitude</i>	2.000 m	
<i>MAX relative humidity at 30°C</i>	80%	
<i>MAX relative humidity at 40°C</i>	50%	
<i>Dimensions of space occupied (L x H x P)</i>	510 X 390 X 590 mm	510 X 390 X 730 mm
<i>Space occupied with open door</i>	300 mm	
<i>Weight (tank empty)</i>	54 kg	58 kg
<i>Weight (tank full)</i>	63 kg	67 kg
<i>Weight of area of support</i>	2058 N/m ²	2058 N/m ²
<i>Volume</i>	0.12 m ³	0.15 m ³
<i>Potential sound level</i>	< 70 db A	

4.2 Electrical Data

	EUROPA B EVO	EUROPA B EVO 24
<i>Power voltage</i>	230 V a.c. +/-10 % single phase	
<i>Power</i>	1,7 kW	2.0 kW
<i>Frequency</i>	50 / 60 Hz	
<i>Power cord</i>	2 + 1 x 1mm ²	
<i>Fuses</i>	6.3 x 32 - 12 A	
<i>Heat transmitted</i>	3.6 E +6 J / hour	

4.3 Chamber

	EUROPA B EVO	EUROPA B EVO 24
<i>MAX working pressure</i>	2.4 bar (relative)	
<i>MAX empty</i>	- 0.9 bar (relative)	
<i>MAX Temperature</i>	138 °C	
<i>Material</i>	Inox AISI 304	
<i>Size</i>	Ø 245 x 318 mm	Ø 245 x 500 mm

4.4 Clean Water tank

	EUROPA B EVO	EUROPA B EVO 24	
		With Demineralizer	Without Demineralizer
<i>Volume</i>	4,5 l		
<i>Usable cycles</i>	4	Read demineralizer instruction	2
<i>Material</i>	polyethylene		

4.5 Used Water tank

	EUROPA B EVO	EUROPA B EVO 24
<i>Volume</i>	4,5 l	
<i>Usable cycles</i>	4	2
<i>Material</i>	polyethylene	
<i>Max temperature used water</i>	50°C	

4.6 Bacteriological filter

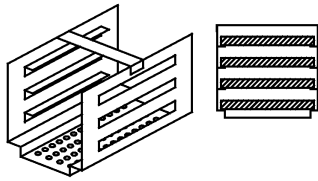
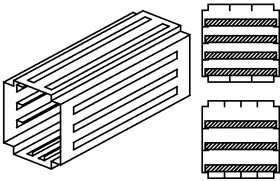
	EUROPA B EVO	EUROPA B EVO 24
<i>Diameter</i>	56 mm	
<i>Filtering capacity</i>	0.3 µm	

05
ACCESSORIES

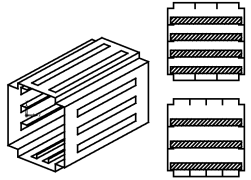
Autoclave is sold and delivered complete of all accessories, which are included in the original packaging.

Accessories provided and optional accessories:

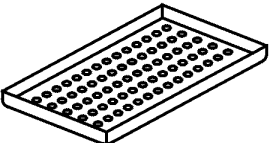
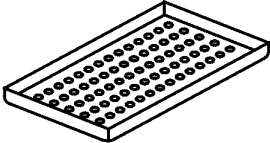
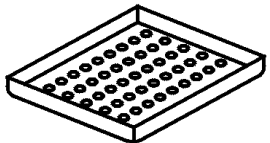
- Tray holder

	EUROPA B EVO	EUROPA B EVO 24
Material	Aluminium anodized	
Size (L x H x P)	192 x 165 x 280 mm	192 x 200 x 470 mm
Picture	 PICT.3	 PICT.4
Envelope standard	1	

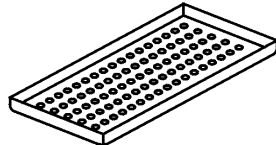
-- Optional Tray holder

	EUROPA B EVO	EUROPA B EVO 24
Material	Aluminium anodized	/
Size (L x H x P)	193 x 200 x 280 mm (200 x 193 x 280) mm	/
Picture	 PICT.5	/
Envelope standard	1	/

- Tray

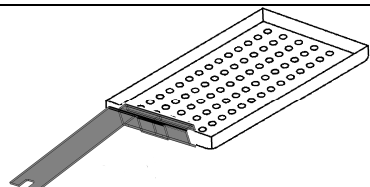
	EUROPA B EVO	EUROPA B EVO 24
Material	Aluminium anodized	
Size (L x H x P)	184 x 17 x 286 mm	184 x 17 x 286 mm + 184 x 17 x 140 mm
Picture	 PICT.6	 +  PICT.7 PICT.8
Envelope standard	4	4 + 4

-- Optional trays

	EUROPA B EVO	EUROPA B EVO 24
Material	/	Aluminium anodized or stainless steel
Size (L x H x P)	/	184 x 17 x 460 mm
Picture	/	 PICT.9
Envelope standard	/	4

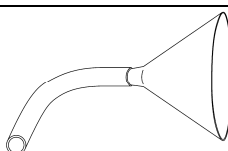
- Tray extraction and door adjustment wrench

Use for extract the trays (*PICT.11*) and for door adjustement (*paragraph 11.4*)

Picture	 PICT.10	 PICT.11
Envelope standard	1	

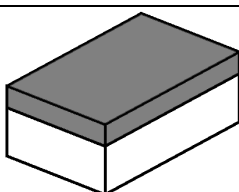
- Plastic funnel with pipe

Use to charge water in manual metod (*paragraph 8.3*)

Picture	 PICT.12
Envelope standard	1

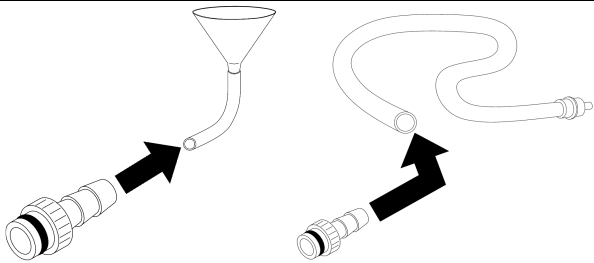
- Chamber and door gasket clearing sponge

Use to clean sterilization chamber and door gasket (*paragraph 11.2-11.3*)

Picture	 PICT.13
Envelope standard	1

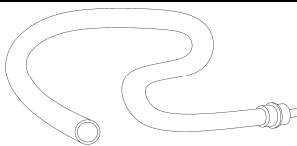
- **Connection for water filling pipe and plastic funnel**

Use with plastic funnel and water filling pipe with filter

Picture	
Envelope standard	PICT.14 1

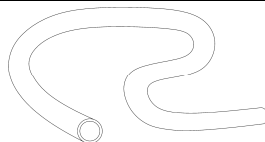
- **Water filling pipe with filter**

Use to charge water with pump (paragraph 8.3)

Picture	
Envelope standard	PICT.15 1

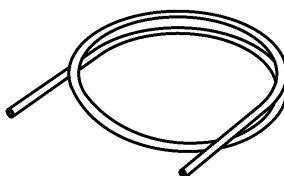
- **Water discharge pipe**

Use to empty used water tank (paragraph 8.9)

Picture	
Envelope standard	PICT.16 1

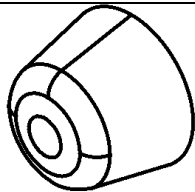
- **Rilsan pipe**

Connect one pipe end into the used water overflow - condensate drain pipe fitting (PICT.1 pos. 4) and put the other end in a tank.

Picture	
Envelope standard	PICT.17 1

- Rear spacer

Put the spacer in the autoclave's back panel (PICT.1 pos. **0**) It's necessary for guarantee a good ventilation if you place the autoclave near a wall.

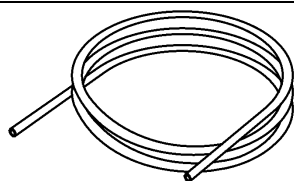
Picture	
Envelope standard	PICT.18 1

- Pipes for discharge utilities

- 1- Pipe for clean water overflow
- 2- Pipe for discharging used water

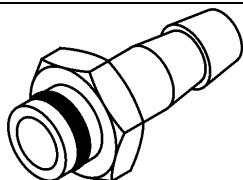
1- Connect one pipe end into the water overflow pipe fitting (PICT.1 pos. **1**) and put the other end in a tank or in the discharge (demineralizer version).

2- Connect one pipe end at the pipe fitting PICT.20 and screw it into the used water tap (PICT.1 pos. **5**) then put the other end in a tank or in the discharge.

Picture	
Envelope standard	PICT.19 2

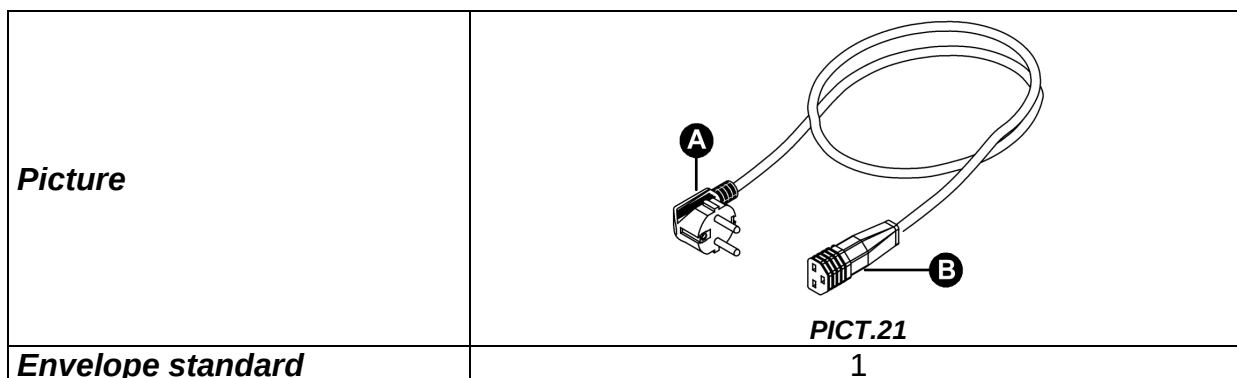
- Pipe fitting for back discharge used water

Connect the pipe for discharging used water into the pipe fitting for back discharge used water PICT.20 and screw into the used water tap (PICT.1 pos. **5**).

Picture	
Envelope standard	PICT.20 1

- Power supply cord

Take the power supply cord provided and insert the female plug (PICT.21 pos. **B**) in the socket of the back panel of the autoclave (PICT.1 pos. **6**). Then insert the male plug (PICT.21 pos. **A**) in the electric plug of the system.



IMPORTANT

Ask for and use only and exclusively original accessories.

The autoclave is shipped in a suitable package to be transported and moved easily and to protect its contents.

The package must not be jostled, it must be moved with care avoiding letting it turn over or fall from a height superior to 16 cm.

In case autonomous handling means are not available handle the packaged autoclave always in two persons.

Autoclave is placed on wooden pallet and packed with corrugated cardboard internal and external application.

For remove the autoclave to its pack please remove first the corrugated cardboard.

For lift the autoclave please use the belts.

For your safety pay attention to weight of the autoclave, for lift or move the autoclave it is necessary at least 2 people.

Use the belts also for move the autoclave

IMPORTANT

Do not lift the autoclave from the inferior part of the door or command panel, this incorrect operation can create problems of a mechanical nature.

Inside the package you will find:

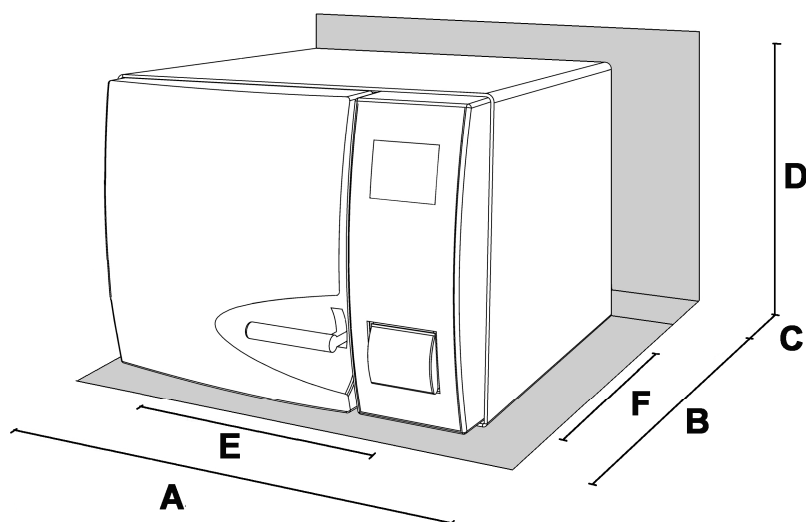
USER'S MANUAL to be read with attention and kept in a place available to all operators assigned to sterilization.

CERTIFICATION which must be conserved

GUARANTEE LABEL which must be completed and send.

ATTENTION

Always conserve original packaging.



PICT.22

	EUROPA B EVO	EUROPA B EVO 24
A	610 mm	
B	590 mm	730 mm
C	50 mm	
D	410 mm	
E	426 mm (front) 455 mm (rear)	403 mm (front) 444 mm (rear)
F	400 mm	431 mm

- 1 - Install the autoclave in an environment suitable for carrying out sterilization procedures.
- 2 - The room must be adequately lit and ventilated, as provided for in the directives in force
- 3 - Install the autoclave away from heat sources and water splashes.
- 4 - Position the autoclave on a surface that is able to bear its weight. The minimum recommended load bearing capacity of the surface is 80 kg.
- 5 - The supporting surface must be perfectly horizontal and must not have inclinations.
- 6 - Place the autoclave at a height that allows the user to inspect and easily clean all parts of the sterilization chamber.
- 7 - Open the door of the autoclave and remove from inside the sterilization chamber all packages which contain the single accessories.

8 - Leave inside the sterilization chamber only the tray carrier with the trays. All other accessories should be positioned in a separate space available to operators.

9 - Never place on the autoclave newspapers, trays, liquid containers, etc.

10 - Do not lean on the door when it is open

11 - Comply with the minimum overall dimensions shown in *PICT.22*. Use the spacer (*PICT.1* pos. **0** – *FIG.18*) for ensure the minum distance to wall.

12 - Connect the overflow connectors to the special drains with the pipes provided.
(*chapter 5*)

13 - Always make sure the electrical system to which the autoclave is to be connected is in conformity with the legislation in force and sized to suit the specifications of the said appliance.

14 - Take the power supply cable supplied and plug the plug on the rear panel of the autoclave into the female socket (*PICT.1* pos. **6**)

15 - Connect the electric plug to the system and make sure the power supply is 230 Vac - 2000 Va minimum

IMPORTANT

Do not make the connections using extensions, reducers or adapters as this could create micro outages with consequent generation of alarm signals.

16 - Turn on the autoclave by pushing the general switch (*PICT.2* pos. **19**) and open the door to the autoclave. Wait a few seconds, there will be two beeps which indicate the reaching of relative parameters for automatic atmospheric alignment, at the same time the display will indicate “door open”.

IMPORTANT

Never select a control before hearing the two acoustic signals: the autoclave will not accept the selected program

17 - Load the pure water tank following the indications in the section entitled USAGE INSTRUCTIONS (*chapter 8*).

Successively run the test cycle, always following the indications expressed in the section USAGE INSTRUCTIONS (*chapter 8*).

18 - If the autoclave is installed with the demineralizer system, follow the instructions contained in the packaging of this device and the *DEMINERALIZER* section (*chapter 14*).

08

USAGE INSTRUCTION

After having installed the autoclave, proceed with preparations and use.

8.1 Turn on the autoclave

Press the general switch (PICT.2 pos. **19**).

8.2 Loading pure water tank

Connect the water filling pipe (provided) with the connection for water filling pipe and plastic funnel PICT.14. Then engage the connection in the charging hole (PICT.2 pos. **13**).

Insert the other end of the pipe with filter in the demineralized or distilled water container.

Press the button **B-PUMP** to start the water loading pump and press it until the countdown start.

The pump loads the tank inside the autoclave. If maximum level is not reached within 180 seconds the pump automatically stops, therefore it is necessary to press the button again.

The pump stops automatically when maximum level is reached.

With connection to a deionizer, if the maximum water level has not been reached, the functioning of the autoclave will be obstructed.

8.3 Manual filling

If you wish to use this method of filling or in the event of malfunctioning of the pump, the filling of the tank can be carried out manually by the operator in the following way:

- Turn on autoclave
- Remove the connection cover of (PICT.2 pos. **12**)
- Insert in this opening the hose connected to the funnel (PICT. **14**)
- Pour distilled water in the funnel, keeping it higher than the loading top
- Add until the led of maximum level turns on (PICT.2 pos. **29**).
- Loading completed, twist on the top

8.4 Characteristics of the water to be used

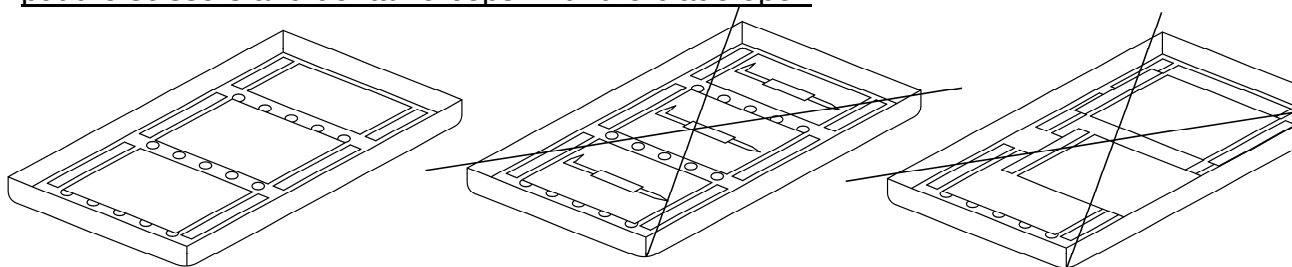
TABLE SHOWING THE QUALITY LEVELS LAID BY THE UNI EN 13060: 2005

CEN STANDARD UNI EN 13060 : 2005			
Evaporation residue	≤	10	mg/l
Silicon oxide	≤	1	mg/l
Iron	≤	0.2	mg/l
Cadmium	≤	0.005	mg/l
Lead	≤	0.05	mg/l
mg/l Remains of heavy metals apart from iron, cadmium, lead	≤	0.1	mg/l
Chloride (Cl')	≤	2	mg/l
Phosphate (P20s)	≤	0.5	mg/l
Conductivity (at 20°C)	≤	15	µs/cm
Ph value (acidity level)	5 + 7,5		
Appearance	Transparent, clear, without deposits		
Hardness (and alkaline earth ions)	≤	0.02	mmol/l

8.5 Loading the material into the autoclave

Place the materials to be sterilized on the trays provided.

- never superpose the materials
- arrange the wrapped instruments, with the paper part facing upwards
- never bring the materials into contact with the sterilization chamber or the closing door
- put the scissors and dental forceps with the blade open



PICT.23

When you have placed all the instruments close the door and you can read DOOR CLOSED on the display.

8.6 Starting the sterilization cycle

Choose sterilization program most adaptable of load prepared and press the button **B-SELECT**.

Each individual pressure changes program selection to the next.

After having chosen the program start the cycle by pressing the button **B-START**, the door will lock automatically and the cycle will begin.

During the cycle, the display will show all parameters and relative information.

8.7 End of cycle

An acoustic signal will warn the operators that the sterilization cycle has been completed. If the cycle is concluded with a positive outcome, the message END OF CYCLE will appear on the display; if, on the other hand, problems arise, an error or alarm code will be displayed.

When the acoustic signal stops, release the door by pressing the **B-DOOR** button. If there is pressure inside the chamber, the button will not activate the release device. Wait until the chamber is completely depressurized, then repeat the operation or, in emergency situations only, simultaneously press **B-DOOR** + **B-PUMP**. When the door is released, pull the door handle to open it.

8.8 Unloading, preserving and storing the sterilized materials

Wear personal protection equipment in accordance with the existing laws.

Extract the trays using the special spanner provided (PICT.10), and place the autoclave load on a clean, dry surface.

Then store the treated instruments in the special, prepared compartments.

8.9 Discharging used water

When the led of used water level (PICT.2 pos. **30**) goes on, proceed with emptying. If not emptied, the autoclave function is inhibited.

Take the pipe provided (PICT.16), and insert it in the used water discharge plug, on the front of the autoclave (PICT.2 pos. **14**), unscrew the metal ring anticlockwise (to execute 2 complete turns), simultaneously place the other end of the pipe in a container, the water will descend into the same container.

IMPORTANT

A – The hose located in the receiving container, must not ever, touch or be immersed in the discharged water, otherwise there will be a situation of sucking up.

B – Always wait until the unloading water is totally emptied. The led of maximum used water level will turn off when there is still water in the tank, therefore do not use as a reference for this operation.

To the term of the drainage to screw the metal ring and remove the tube.

8.10 Interruption of sterilization cycle

A sterilization cycle can be voluntarily interrupted by pressing the button **B-START** for at least 2 seconds.

The autoclave will emit a beep, go into decompression and on the display will appear the message ALLARM 001 (INTERRUPTED CYCLE).

To reset error, maintain pressed simultaneously the buttons below indicated, until the intervention of an acoustic signal:

B-DOOR + **B-PUMP** + **B-SELECT**

ATTENTION:

You can't reset the alarm if the printer works



If an alarm message is displayed (CODE "A") the cycle is to be considered aborted: it will be necessary to repeat all the preparation and sterilization operations.

09

STERILIZATION CYCLES

9.1 Descriptions cycles

The autoclave has three series of cycles:

- A - operation cycles
- B - night cycles
- C - test cycles

9.2 Operation cycles

All operation cycles have a system of fractioned vacuum, which therefore permits sterilization of materials that are hollow, porous, solid, both free and packaged. Temperatures can be selected from 121°C – 134°C.

Normally the cycles of 121°C are used for thermoplastics or sensitive materials, while the 134°C cycles are used for all other materials.

In all cases always follow the indications given by the manufacturer of the instruments or devices to be sterilized.

There are also two special cycles:

- Prion cycle, studied for the **Crutzfeldt-Jacobs** disease (mad cow disease)
- Flash cycle created for rapid sterilization of unpackaged instruments and devices.

9.3 Night cycles

The autoclave is provided with a special economizer device.

This device allows the execution of sterilization cycles without the presence of an operator. At cycle end, if the door is not opened, the autoclave stabilizes and then shuts off automatically.

Only the general switch remains on (PICT.2 pos. **19**).

Upon the operator's arrival it is sufficient to press any button to re-start the autoclave and read the cycle result on the display.

Besides that the printer will have regularly prepared the written report relative to the same cycle.

STERILIZATION TABLE

	EXPOSED TIME T4 (Minutes)	DRYING TIME T5 (Minutes)		PRESSURE WORK MIN AND MAX (relative bar)	TEMPERATURE WORK MIN AND MAX (°C)
		18L	24L		
121°C Unpackaged	18	6	12	1.04 ÷ 1.30	121 ÷ 125
121°C Packaged	18	17	13		
134°C Flash	4	2	4	2.02 ÷ 2.38	134 ÷ 138
134°C Unpackaged	5	6	12		
134°C Packaged	5	17	13		
134°C Prion	20	17	13		

Warmig up time and vacuum fractionation can vary, because of autoclave's conditions, between 25 and 30 minutes. You have to an this time to sterilization's times showed in table. Hall the cycles have three vacuum fases

9.4 Test cycles

- Helix test this test is used to check the capacity of the steam to penetrate a hollow object Place the Helix test system complete with indicator on the central tray in the sterilization chamber, without the presence of a load. Refer to the manufacturer's instructions for correct loading of the indicator.

Carry out the special test cycle. At the end, take out the whole system and check the indicator.

In the event of a negative response, contact and inform an authorized technician.

- Bowie e Dick test this test is used to check the capacity of the steam to penetrate a porous load.

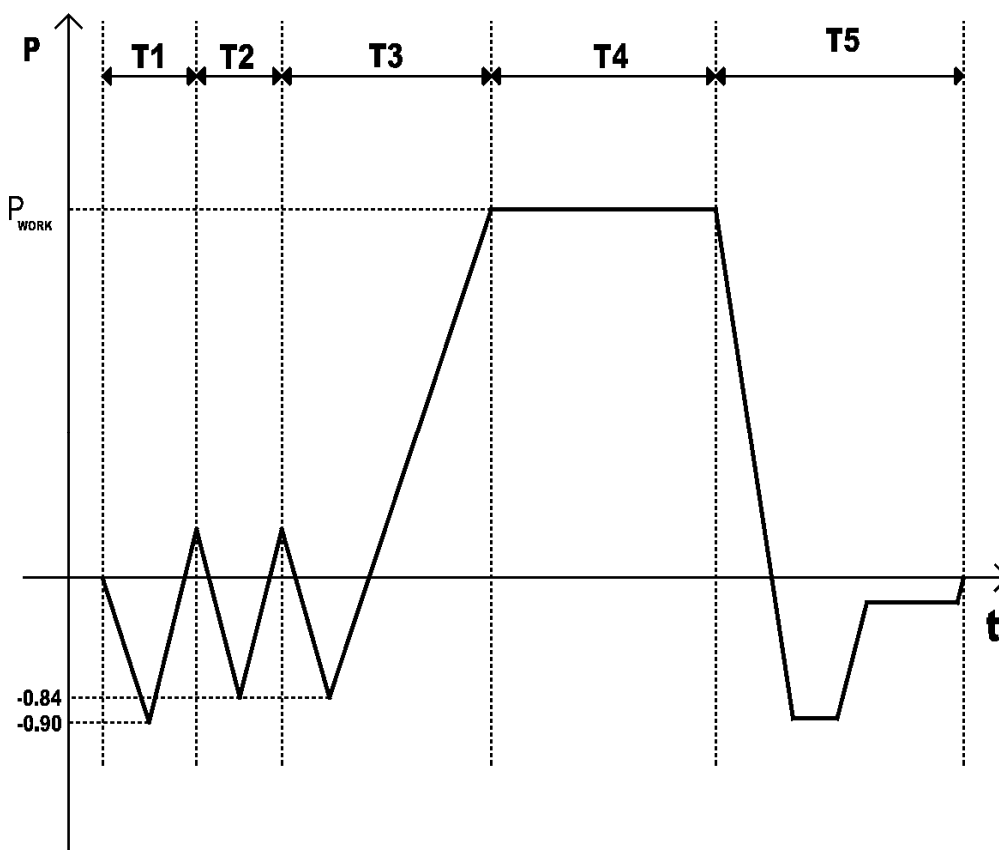
Place the Bowie-Dick test on the central tray in the sterilization chamber, without the presence of a load. Carry out the special test cycle. At the end, take out the packet, open it and check the result by assessing the test sheet in the centre. In the event of a negative response, contact and inform an authorized technician.

- Vacuum test this test is used to check the capacity of the autoclave to maintain the vacuum. The results of this test are printed by the autoclave printer. This test must be carried out with the machine cold. Do not put any type of load into the autoclave. Close the door, select the cycle and start it. At the end, check the result by assessing the ticket issued by the printer connected to the autoclave. In the event of a negative response, contact and inform an authorized technician.

It is preferable to use tests distributed of the manufacturer.

TEST CYCLES TABLE

	STERILIZATION TIME T4 (Minuts)	DRY TIME T5 (Minuts)	PRESSURE WORK MIN AND MAX (relative bar)	TEMPERATURE WORK MIN AND MAX (°C)
134°C Helix/ Bowie&Dick	3.5	4	2.02 ÷ 2.38	134 ÷ 138
Vacuum			-0.9	



PICT.24

T1,T2,T3= pre heater fase and vacuum fases

T4= sterilization

T5= drying

10 MESSAGES OF ERROR OR ALARMS

Messages of error are emphasized through an Alfa-numerical code, consisting in a letter and three numbers.

The “E” CODE is relative to errors of the operator, which can be corrected by same operator.

The “A” CODE is relative to alarms, irregularities of the autoclave, after having carried out the remedy, if the problem persists it is necessary to request telephonic assistance.



If an alarm message is displayed (CODE “A”) the cycle is to be considered aborted: it will be necessary to repeat all the preparation and sterilization operations.

To reset alarms and errors, maintain pressed the buttons here indicated until the intervention of a “BEEP”

B-DOOR + B-PUMP + B-SELECT

10.1 List of error alarm messages

ERROR	CAUSE	REMEDY
E 200	Low water level	Fill tank
E 250	Low level water cleaned up with loading from demineralizer	Fill tank
E 300	Maximum level used water	Empty tank
E 401	Door open	Close door with attention
E 451	Door unlocked	Open door and close again
E 461	High temperature in chamber for vacuum test (above 40°C)	Shut off and wait 10 minutes
A 250	Cycle begins without water	Control demineralizer device
A 001	Interrupted cycle	Reset and restart cycle
A 011	Irregular pc display	Shut off and restart autoclave
A 101	Vacuum not reached in 10' (minutes)	Reset and restart cycle
A 111	Vacuum not maintained for first phase VT	Reset and restart cycle
A 121	Vacuum not maintained for second phase VT	Reset and restart cycle
A 401	Hatch opened during the cycle or problem closing	Check the closing system
A 501	Pressure not maintained	Reset and restart cycle
A 551	Irregular 1° temperature sensor	Reset and restart cycle
A 552	Irregular 2° temperature sensor	Reset and restart cycle
A 641	Overly high pressure	Reset and restart cycle
A 651	Overlay high temperature	Reset and restart cycle
A 661	Irregular temperature comparison	Reset and restart cycle
A 701	Working pressure not reached	Reset and restart cycle
A 751	Low temperature	Reset and restart cycle
A 761	Irregular pressure sensor	Reset and restart cycle

A 801	Irregular unloading pressure	Reset and restart cycle
A 901	Main voltage too low - Temporary lack of electric energy	Reset and restart cycle, Inform electric Energy provider

REPLACE RESINS → Resins IONIC SYSTEM exhaust	Replacement of resins; refer to paragraph 14.3
REPLACE FILTER → Resins OSMOSI SYSTEM exhaust	Replacement of filter; refer to paragraph 14.3

D	The printer's door is not closed	Try to close the printer's door
P	Paper is missing	Insert paper
Lo	There is low voltage on the line	Try to connect the machine to the net electrical worker in an other point; if the problem persists to contact a electrician

IMPORTANT

If after following the remedies, the problem persists, call telephone assistance at MEDLINE ITALIA srl +39 0522 – 94 29 97.

11

MAINTENANCE AND PREVENTION

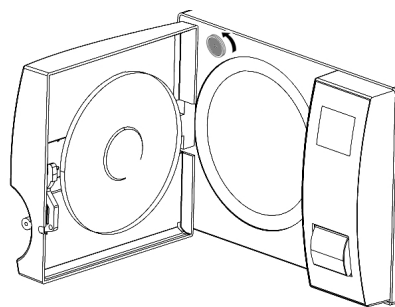
Correct maintenance of the autoclave assures correct functioning of it and a secure saving in terms of time and costs for assistance and maintenance.

11.1 Replacing the bacteriological filter

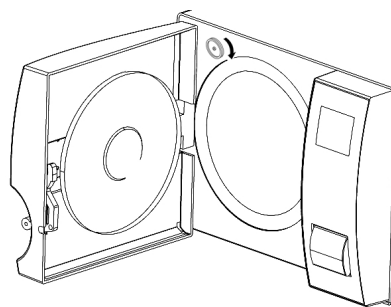
Substitute the bacteriological filter (PICT.2 pos. **11**) maximum every 200 cycles, or as soon as the filter becomes a dark color.

Unscrew it in an anticlockwise direction (PICT.25). Screw on the new filter in a clockwise direction (PICT.26) until it is seated.

Use only and exclusively original filters from the manufacturer of the autoclave.



PICT.25



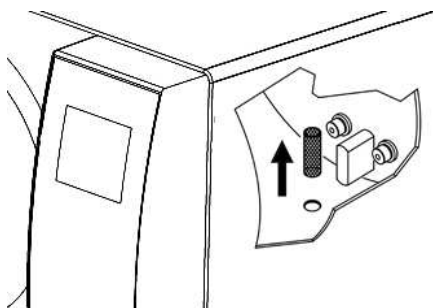
PICT.26

11.2 Cleaning the chamber

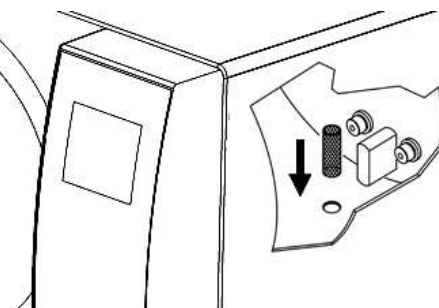
Clean periodically the chamber, remove eventual deposits or debris, thus avoiding the introduction in the discharging circuit of material which can cause obstructions.

For correct cleaning use only demineralized water and the abrasive sponge provided. (PICT.13)

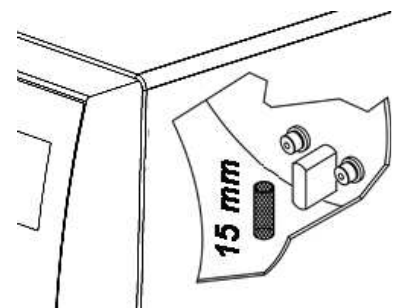
The filter in chamber is fixed about interference. When you extract the filter for the cleaning please you don't damage it (PICT.27). Then, you reposition the filter (PICT.28) and control that protrude about 15mm from the chamber surface (PICT.29).



PICT.27



PICT.28



PICT.29

Never use solvents, detergents, chemical solutions, descaling agents or other similar products.

11.3 Door seal cleaning

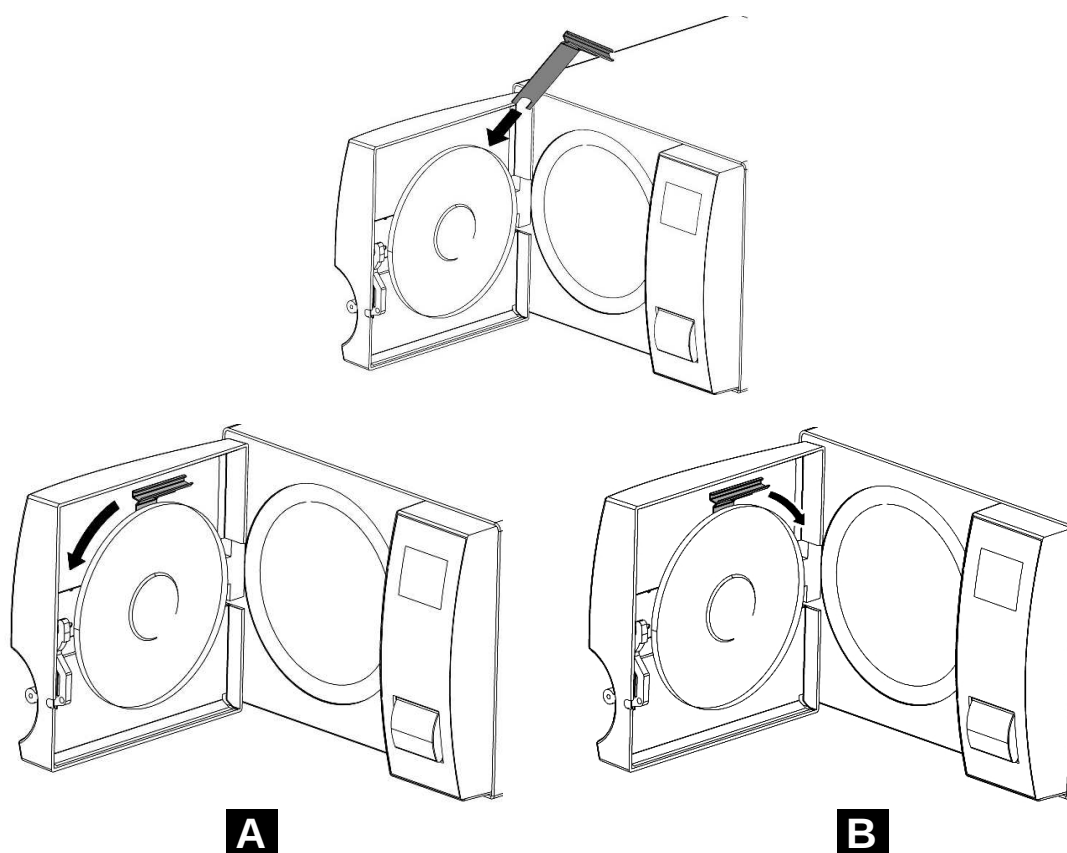
Periodically remove eventual residuals which are deposited on the circumference of the seal using water and the sponge provided (non abrasive side), or else a moistened cloth.

11.4 Door regulation

To regulate the door lock pressure, it is necessary to adjust the regulator of the same door using the double function wrench (extraction tray + wrench) (PICT.10) provided.

Turn anti clockwise (PICT.30 pos. **A**) to increase lock pressure.

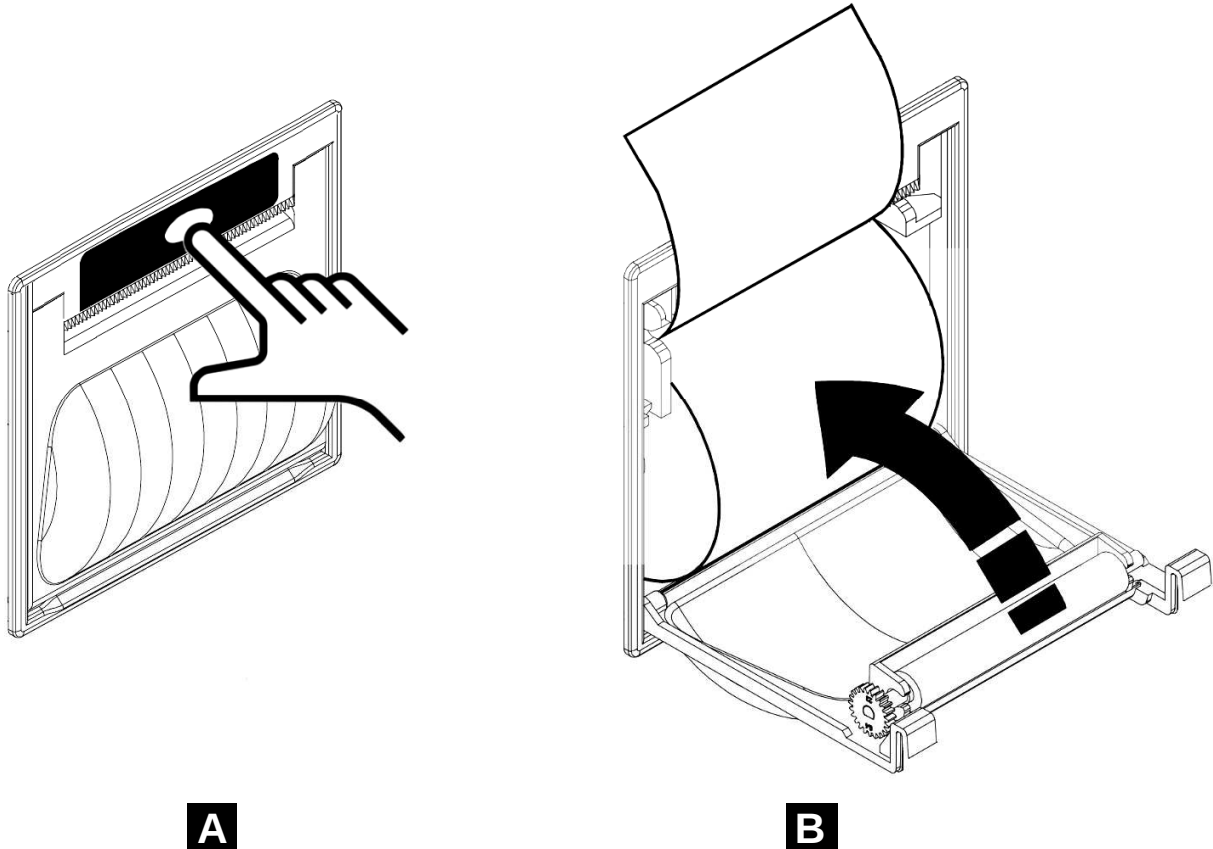
Turn clockwise (PICT.30 pos. **A**) to decrease the lock pressure.



PICT.30

11.5 Substitution printer paper

Thermographic paper roll 57 mm wide. Thermographic paper can be printed on one side only. Open the printer cover by pushing the button (PICT.31 pos. **A**), place the paper roll by paying attention to the rotation direction, pull the paper until it comes out and close the cover (PICT.31 pos. **B**); the printer is ready for printing.



PICT. 31

11.6 Printer status

If the cover of the printer is not perfectly closed, on the display the letter “D” appears. Open and close the printer’s cover.

If paper is missing, on the display the letter “P” will appear. Open the cover, insert paper and re-close the cover.

12**PROGRAMMING DISPLAY**

Please, see the PICT.2

12.1 Language selection

Press simultaneously **B-START** and **MAINS** switch. Hold down **B-START** until on the display appears the name of the language programmed.

Press **B-SELECT** to modify the language [forward].

Press to **B-PUMP** modify the language [backwards].

12.2 Hours selection

Press **B-START** the hours appears.

Press **B-SELECT** to modify hour [forward].

Press **B-PUMP** to modify hour [backwards].

12.3 Minuts selection

Press **B-DOOR** minutes appear.

Press **B-SELECT** to modify minutes [forward].

Press **B-PUMP** to modify minutes [backwards].

12.4 Seconds selection

Press **B-DOOR** seconds appear. Do not modify.

12.5 Date selection

Press **B-START** day appears (flashing).

Press **B-SELECT** to modify day [forward].

Press **B-PUMP** to modify day [backwards].

12.6 Month selection

Press **B-DOOR** month appears (flashing).

Press **B-SELECT** to modify month [forward].

Press **B-PUMP** to modify day [backwards].

12.7 Year selection

Press **B-DOOR** year appears.

Press **B-SELECT** to modify year [forward].

Press **B-PUMP** to modify year [backwards].

12.8 Visualize atmospheric pressure

Press **B-START** and compare memorized atmospheric pressure appears.

DO NOT MODIFY!

12.9 Water loading selection

Press and release **B-START** to select next screen until you see setting the water load:

- CHARGING BY PUMP
- IONIC SYSTEM
- OSMOSI SYSTEM

Press **B-SELECT** to modify water supply loading.

Press **B-DOOR** to save the modify and maintain pressed until the sound of the “beep”.

Press **B-START** to exit menu and maintain pressed until the sound of the “beep”.

The data inserted are memorized. Turn off the autoclave using the MAINS switch.

13 SOLUTIONS TO OPERATIONAL PROBLEMS

In many cases some alarms or errors are determined by lack of attention or lack of familiarity with some technical and operational aspects.

Following are listed some cases of irregularity with relative solutions.

13.1 Autoclave does not dry correctly

- a - SUBSTITUTE THE BACTERIOLOGICAL FILTER, with a new original.
- b - ORIGINAL TRAYS HAVE NOT BEEN USED, but other trays without perforations or diverse perforations. Use only original trays, possibly in aluminum. Request additional original trays.
- c - INSTRUMENTS HAVE NOT BEEN ARRANGED CORRECTLY, arrange instruments or packaged materials with the paper turned upwards. Never pile up instruments or materials, arrange them parallel to one another. Never place the instruments or materials in contact with the chamber, they can burn or become deformed.

13.2 Autoclave chamber becomes white

- a - CHANGE IMMEDIATELY THE TYPE OF WATER USED, use demineralized or distilled water, as is specifically indicated in the previous chapter and then proceed with cleaning the chamber.
- b - THE WHITISH COLOR CAN be a consequence of the evaporation of organic materials present on the instruments. Instruments should be cleaned with a detergent action more suitable and thoroughly.
- c - check the demineralizer (IONIC SYSTEM or OSMOSI SYSTEM)

13.3 Autoclave chamber presents blueish green stains

- a - INSTRUMENTS HAVE NOT BEEN CORRECTLY RINSED cleanse and rinse with major attention the instruments. If the stains are evident request telephonic assistance.

13.4 Sterilization cycle interrupts without apparent motive

- a - CONTROL IF AUTOCLAVE IS CONNECTED to the electrical net with extensions, reductions, adapters, if so remove this accessories and connect the autoclave directly to the electric socket.

13.5 Autoclave does not receive commands

- a** - AUTOCLAVE PRE-ARRANGES BAR AUTOMATIC ALIGNMENT wait for the double beep after opening the door, then program the functions.
- b** - PURE WATER TANK is empty, minimum led level is on, fill with pure water
- c** - USED WATER TANK IS FULL. Maximum level led is on, discharge used water.

13.6 Autoclave printer does not print

- a** - PAPER CARRIER COVER IS NOT CLOSED CORRECTLY, on the display appears the letter "D". Open and close the printer cover checking that is correctly closed.
- b** - PAPER MISSING, on the display appears the letter "P". Open the cover and insert the roll of thermo-graphic paper.
- c** - ROLL OF PAPER IS MOUNTED WITH THERMO SIDE TOWARDS INSIDE, open the cover and turn the roll of paper to the correct position.

13.7 Stains on instruments

- a** - INSTRUMENTS BECOME YELLOW, chemical liquid residual has with heat been fixed on the instruments. They were not sufficiently rinsed.
- b** - STERILIZATION CHAMBER PRESENTS YELLOW SPOTS, instruments were introduced in the chamber with chemical liquid which dripped and is fixed due to heat. Rinsing was not sufficient.
- c** - INSTRUMENTS PRESENT WHITE SPOTS, rinsing was done with water with high level of calcium and the instruments were not dried. For last rinse it is advisable to used demineralized water and dry carefully the instruments.
- d** - INSTRUMENTS ARE DARKENED, this is caused by the fact that the instruments have internally a strong component of carbon.

14

DEMINERALIZER

14.1 Set of demineralizer system

Autoclave is already prepared also for plug IONIC SYSTEM or OSMOSI SYSTEM for charging water into the autoclave.

These applications are accessories of autoclave.

These applications have been designed for remove minerals in the water before to charge the autoclave.

First to plug the hydraulic connections it is necessary set the software of autoclave following this instructions:

Switch-on the autoclave with the MAINS (PICT.2 pos. **19**) switch and keep pressed **B-START** (during the switch on) until you see a string reporting the selected language

Press and release **B-START** to select next screen until you setting the water load:

- CHARGING BY PUMP
- IONIC SYSTEM
- OSMOSI SYSTEM

To change this setting use **B-SELECT**.

To save keep pressed **B-DOOR** until you hear a "BEEP".

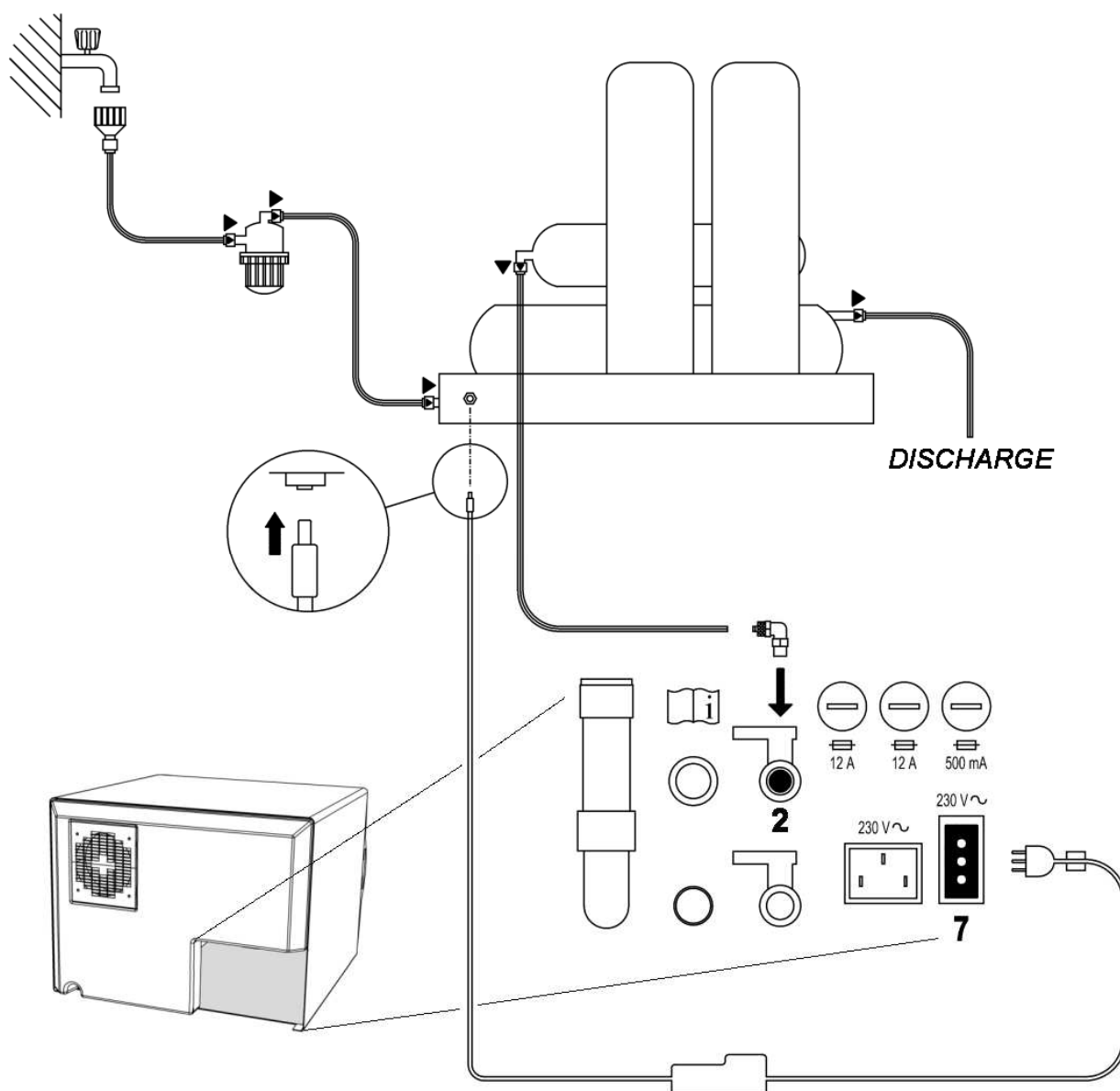
To exit keep pressed **B-START** until you hear a "BEEP".

WARNING

The number you can see on display, under the kind of water system used, it's a counter. It gives you an indication about the number of cycles possible to make until the end of filter (in case of osmosi system) or until the end of resins (in case of ionic system).

When you change the filter or the resins, it's necessary reset the number of the counter after saving of the kind of system used.

For reset the counter it's necessary keep push the button **B-PUMP** until the acoustic signal of the buzzer (it takes about 10 second) in the main page of the menu where you can start the sterilization cycle.



PICT.32

14.2 Connection of demineralizer system

Turn off the autoclave by pressing the General switch (**MAINS**) located on the right side of the autoclave. (PICT.2 pos. **19**)

The operator after having set the autoclave can install the demineralizations system following the indications in the manual attached to the demineralizer apparatus.

Here are indicated the specific connection to the autoclave of the water supply hose and the connection of the electric plug.

1. Turn off the autoclave if it is on;
2. Close the faucet located above the demineralization system;
3. Install the demineralizer as indicated in its manual;
4. Twist the male screw of the connection-hose carrier with Teflon or other component which guarantees the sealing of water;
5. Screw the connection on the Demineralizer tap PICT. 32 pos. **2**;
6. Insert the hose exit of demineralizer to the connection-hose carrier already screwed to the autoclave;
7. Insert the plug of demineralizer to the socket PICT.32 pos. **7** on the back of the autoclave
8. Open the faucet located above the demineralization system;
9. Control that there is no water loss;
10. Turn on the autoclave;
11. Run one or more sterilization cycles to control the functioning of the connection and check above all for leaking.



AT THE END OF EACH DAY ALWAYS CLOSE THE FAUCET LOCATED ABOVE THE DEMINERALIZATION SYSTEM TO PREVENT FLOODING



CONNECT OF DEMINERALIZER ONLY TO PREPROGRAMMED AUTOCLAVE .



IF THE UNIT AT THE BEGINNING OF THE CYCLE SHOWS E250 THEN YOU HAVE TO FILL THE CLEAN WATER TANK UNTIL THE MAXIMUM IS REACHED.

NOTE: FOR THE CONNECTION OF DEMINERALIZATION SYSTEM TO THE AUTOCLAVE TECNO-GAZ REFER TO INDICATIONS IN THE MANUAL.

14.3 Change resins - filter

Autoclave display indicates the state of finishing of the resin with the message "REPLACE THE RESINS" or "REPLACE THE FILTER".

Substitute the resin cartridge as indicated in the demineralizer manual.

After substitution, press button **B-PUMP** until the "beep", to reset the autoclave.

Sterilization means adopting precise operational protocol and applying a system. Autoclave is the final link of this system.

Those who do not follow all of the various phases of the sterilization system will be unsatisfied with the final result.

TECNO-GAZ SpA produces all the devices for each phase of the sterilization cycle. Therefore it is necessary to:

1 - Prepare a precise written operational protocol to distribute to all operators assigned to sterilization.

TECNO-GAZ SpA can provide these personalized protocols.

2 - Follow carefully and with attention all of the sterilization cycle phases:

DISINFECTION obligatory phase, in base of that is obligatory for the operator security, to be done with immersion in chemical liquids or thermo-disinfection.

CLEANING the most important phase which insures the removal of all types of residual, chemical and organic. The most suitable instruments are ultrasound baths.

DRYING essential phase to avoid corrosion of instruments and interference of the sterilization cycle.

PACKAGING essential phase for maintaining sterile the treated instruments.

STERILIZATION final phase of steam sterilization

16**INSTRUCTION FOR AUTOCLAVE SHIPPING**

In case the autoclave must be shipped for repairs, controls, reactivation, revisions, validations follow the obligatory indications below:

- 1- Use the original packaging; if this is no longer in your possession, use adequate packaging. The merchandise travels at risk to the sender.
- 2- Ship only the autoclave, always removing trays and tray carrier.
- 3- Carefully clean the sterilization chamber and autoclave in general before shipping. In case it arrives dirty or with residual the autoclave will be returned without being repaired, or it will be put through a cleansing action and disinfection.
- 4- Always empty the clean water tank through the attachment located on the back of the autoclave (PICT.2 pos. **2**)
- 5- Always empty the used water tank through the attachment located on the back of the autoclave (PICT.2 pos. **5**)
- 6- Indicate by letter and insert in the package a document which indicates precisely the irregularity or service desired.
- 7- Ship at your expense, otherwise you will be billed for shipping.

ATTENTION

All non original packaging which arrives will be disposed of.

**Autoclave will be returned with new and original packing to insure maximum protection for your autoclave during shipping.
Cost of packaging will be charged to client.**

Repairs – Revisions – Assistance – Validation

We consider it important to inform you of the procedures used by our service department.

The service department is the autonomous entity MEDILINE ITALIA SRL (TECNO-GAZ GROUP), which has an articulated and professional structure.

Procedures applied have been explained in our quality manual.

- 1- When the autoclave arrives at MEDILINE ITALIA SRL it is consigned directly to the service center, which codes and creates the technical assistance document.
- 2- Within 48 hours, it is examined by technicians and technical analysis along with cost estimate is prepared for the service requested.
If the autoclave is not delivered as requested in the chapter INSTRUCTIONS FOR SHIPPING, above times can sensibly differ
- 3- Cost estimate will be sent to the distributor client, who will transmit it to the final client for vision and approval.
- 4- After MEDILINE ITALIA SRL receives written acceptance of the cost estimate, the autoclave will be serviced and reshipped according to times indicated on the cost estimate.
- 5- The merchandise will be reshipped in original packaging by the client's shipper.

- 1) DURATION: the product is covered by a 12-month (twelve) guarantee.
- 2) EXCLUSION: the guarantee excludes:
 - a) faults originating from non-performance of scheduled maintenance and due to negligence or improper use of the product by the User;
 - b) periodic checks and maintenance;
 - c) repair or replacement of parts subject to wear that are fragile or have an unpredictable life, unless they prove faulty at the time of their delivery;
 - d) faults caused by personnel or originating from technical personnel transfer and transportation;
 - e) faults or damage originating from improper use or operating errors;
 - f) faults or damage originating from contamination in the water and air infeed systems, extraordinary chemical agents or electrical events;
 - g) faults or damage originating from the use of detergents, disinfecting agents, sterilizing fluids or processes that are not described explicitly in the instruction manual for operation and maintenance;
 - h) natural color change of plastic components.
- 3) INSTALLATION AND TESTING REPORT: an essential prerequisite for guarantee validity is the return of the installation and testing report after all its sections have been filled in by the User and the Fitter. The report must be returned within 15 days after installation, otherwise the guarantee becomes null and void.
- 4) LIMITS: the guarantee entitles its holder to repairs or replacement of faulty components free of charge. The right to replace the entire machine is excluded. As for components either applied or added to TECNO-GAZ products or by third parties, having their own guarantee certificate, the conditions, limits and exclusions indicated in the relevant certificates apply.

Under no circumstances shall carrying out of one or more than one repair during the guarantee term change the guarantee expiry date.
- 5) CLAIMS: in the event of the Purchaser making a claim relating to the application of the guarantee and the quality or conditions of the delivered equipment, the said Purchaser shall in no way suspend and/or delay payments.
- 6) DISPUTES: if a dispute arises on the application and interpretation of this Certificate of guarantee, the Court of PARMA (Italy) shall be the court of jurisdiction, regardless of the location in which the purchase agreement was stipulated.
- 7) DEROGATIONS: any special derogations from the guarantee terms described in this section shall not imply the granting to the Purchaser of any right and shall be considered as granted for a specific case only.
- 8) MISCELLANEOUS: for any other issue, which is not covered by this Certificate of Guarantee, the rules described in the Civil Code and existing relevant Laws in the Republic of Italy apply.

The guarantee becomes null and void in the event that:

- a) the equipment presents damage caused by a fall, exposure to flames, liquid spillage, natural events, bad weather conditions or by any other cause that is not due to manufacturing defects;
- b) installation has not been performed in line with TECNO-GAZ instructions and by authorized personnel;
- c) the equipment is repaired, modified or tampered with by the Purchaser or by non-authorized third parties;
- d) when asking for an intervention under guarantee, the product serial number has been removed, deleted, counterfeited, etc.;
- e) the installation and testing report is not returned suitably filled in and signed within 15 days from installation;
- f) the Purchaser suspends and/or delays payment of amounts due, for any reason whatsoever, relating to the purchase and/or maintenance of the equipment;
- g) scheduled periodic maintenance or any other instruction envisaged in the manual for operation and maintenance is not carried out



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I

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GB

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D

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