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Instructions manual

E9 Next



CE 0051

Euronda®

надежный поставщик стоматологического оборудования
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Dear Sir or Madam,

*first of all we would like to thank you for purchasing our **E9 NEXT** steriliser.*

Please feel free to contact us if you require any further information or have any queries concerning the operation and use of this equipment.

We strongly recommend, however, that you first read this manual with care to ensure correct use of the product. Our devices comply with all the applicable safety regulations in force and present no danger to the operator when used according to the instructions. Please also note that Euronda S.p.A. declines all liability for incorrect or insufficient interpretations of the translations of this manual: in the event of a dispute, only the manual written in the Italian language shall apply.

While wishing you success in your work, we remind you that the reproduction of this manual is forbidden and that the technical components may be changed without notice due to our ongoing technical research.

EURONDA S.p.A.

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CONTENTS

CHAPTER 1 ..... **5**
1.1 WARRANTY 5

CHAPTER 2 ..... **6**
2.1 REFERENCE STANDARDS 6
2.2 STAFF REQUIREMENTS 6
2.3 USING AND STORING THE MANUAL 6
2.4 READING THE MANUAL: SYMBOLS AND CONVENTIONS 7
2.5 HOW TO OBTAIN A NEW COPY OF THE MANUAL 7

CHAPTER 3 ..... **8**
3.1 GENERAL SAFETY WARNINGS 8
3.2 INTENDED USE 9
3.3 SAFETY DEVICES 9
3.4 RESIDUAL RISKS 11
3.5 SAFETY SIGNS ON THE UNIT 11
3.6 PERSONAL PROTECTIVE EQUIPMENT (PPE) 11

CHAPTER 4 ..... **12**
4.1 WEIGHT AND DIMENSIONS OF PACKAGING 12
4.2 RECEIPT AND HANDLING 12
4.3 DESCRIPTION OF CONTENTS 12
4.3.1 Optional devices (also see Appendix 10) 12

CHAPTER 5 ..... **13**
5.1 DESCRIPTION OF UNIT 13
5.1.1 Front elements 13
5.1.2 Rear elements 13
5.1.3 Upper elements 14
5.2 OVERALL SPACE REQUIRED 15
5.3 TECHNICAL DATA AND NOISE 16
5.3.1 Rating plate 17
5.3.2 Noise level 18
5.4 OPTIONAL PRINTER (INTEGRATED OR EXTERNAL) 18
5.4.1 Integrated label printer 18

CHAPTER 6 ..... **20**
6.1 WORK ENVIRONMENT: POSITIONING 20
6.2 INSTALLING THE UNIT 21
6.3 ELECTRICAL CONNECTIONS 22
6.4 FIRST START-UP 23
6.5 HOW TO USE THE CONTROL PANEL 23
6.5.1 How to use the control panel 23
6.6 INSTALLATION MENU 24
6.7 TANKS: INSTRUCTIONS FOR FILLING AND DRAINING 24

CHAPTER 7 ..... **28**
7.1 PROGRAM MENU 28
7.2 SELECTING A STERILIZATION CYCLE 30
7.2.1 Start-up, execution and end of a cycle 31
7.2.2 Information on process parameters 33
7.2.3 How to unlock the Personal cycles 34

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7.3 SELECTING A TEST 35
7.3.1 Start-up, execution and end of a test 36
7.4 MANUALLY STOPPING A CYCLE OR A TEST 37
7.4.1 Manually stopping a cycle before or during the sterilization phase 37
7.4.2 Manually stopping a cycle after the sterilization phase 38
7.5 POWER BLACKOUTS 38
7.6 RESETTING THE UNIT AFTER AN INTERRUPTION CAUSED BY AN ALARM 38
7.7 SETTINGS 38
7.7.1 Date and time set up 39
7.7.2 Expiry days and label number set up 39
7.7.3 User set up 39
7.7.4 Printer and printer type set up 42

7.7.5 Label reprinting management 43
7.7.6 Language set up 43
7.7.7 Aquafilter setup 44
7.7.8 Release of the load through the identification of the user 45
7.7.9 Ethernet connection set up 46
7.7.10 Planning set up 47
7.9 LONG PERIODS OF INACTIVITY 49

CHAPTER 8 50
8.1 E-MEMORY SOFTWARE 50
8.1.1 Minimum system requirements 50
8.1.2 Installing the E-Memory software 50
8.1.3 User interface 51
8.1.4 General warnings 52
8.2 SOFTWARE CONFIGURATION 53
8.2.1 User management 53
8.3 INSERTING AND REMOVING THE SD CARD 54

CHAPTER 9 56
9.1 SAFETY WARNINGS 56
9.2 ORDINARY MAINTENANCE 56
9.2.1 Periodic maintenance 60
9.2.2 Adjustment of the closing mechanism 61
9.3 EXTRAORDINARY MAINTENANCE 62
9.3.1 Rusting 63

CHAPTER 10 64
10.1 INSTRUCTIONS FOR DISPOSAL 64
10.2 RESALE 64

APPENDIX 1 65
Preparing the instruments for sterilization 65

APPENDIX 2 66
Packaging 66

APPENDIX 3 67
Positioning the load 67

APPENDIX 4 68
Unloading and preserving sterilized instruments 68

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APPENDIX 5 ..... **69**
Description of programs 69

APPENDIX 6 ..... **71**
Description of Tests 71

APPENDIX 7 ..... **74**
Validating the cycles 74

APPENDIX 8 ..... **75**
Quality of process water 75

APPENDIX 9 ..... **76**
Troubleshooting 76

APPENDIX 10 ..... **83**
Description of optional devices 83

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CHAPTER 1

1.1 WARRANTY

Euronda guarantees the quality of its equipment, if used in accordance with the instructions supplied in this manual, and according to the conditions printed on the warranty certificate.

The warranty is valid from the date of purchase by the client and the details can be found by registering on www.euronda.com/myeuronda

In the case of dispute, the date indicated on the purchase invoice, showing the serial number of the unit, will be considered as valid.

NOTE 1: please retain the original packaging and use it each time the unit needs to be transported. The use of different packaging could damage the product during transportation.

NOTE 2: in order to release the *Personal Functions*, the user must complete the registration at the www.euronda.com/myeuronda portal, where an information document can be found, required to take advantage of the Light and Light & Stock cycles (for further specifications refer to page 16 of the above Manual).

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CHAPTER 2

2.1 REFERENCE STANDARDS

Steam sterilizer E9 NEXT.
The saturated steam sterilizer complies with the essential requirements of Council Directives:
Medical devices 93/42/EEC of 14/06/93 and 2007/47/EC, class IIb - CE 0051

It also complies with the national standards in their harmonized versions:
EN 13060
EN 61010-2-040
EN 61326

Boiler
The boiler complies with the following standards:
EN 13445

It also complies with the essential requirements of Council Directives:
Pressure vessels 2014/68/UE del 15/05/2014 - Category II–D1 - CE 0497

2.2 STAFF REQUIREMENTS

The staff authorized to use and service the equipment must possess the following requirements:
- sufficient general culture to understand the contents of this manual;
- knowledge of the unit and its place of installation;
- knowledge of health, accident prevention, and technical regulations.

The main figures who operate and service the unit are shown below.

The **OPERATOR** is the person who physically uses the unit for the purpose for which it has been designed.

The **RESPONSIBLE AUTHORITY** is the person or group responsible for the use and routine maintenance of the unit and for operator training.
The responsible authority is legally responsible for the installation, operation and use of the unit.

2.3 USING AND STORING THE MANUAL

This manual refers to the following series and models of appliance:

Series	Model
E9 NEXT	E9 NEXT 18L
	E9 NEXT 24L

This manual is an integral part of the product and must be kept near the unit for quick and easy consultation.
The purpose of this manual is to give instructions on:
- correct installation;
- the safe and efficient use of the unit;
- routine maintenance.

The unit must be used according to the procedures contained in the manual and only for the purpose for which it was designed. The occupational health and safety directives in force in the Country of destination of the unit must be known and applied in the place of use.
The manual must be kept in a safe place, easily accessible to all personnel; it must also be handled with care. It is forbidden to remove, rewrite, or modify the contents of this manual in any way.
The drawings and any other documents delivered with the unit may not be divulged to third parties in that Euronda S.p.A. is the sole owner and reserves all rights to them.
Reproduction of the text and illustrations, in full or in part, is strictly forbidden.

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Euronda S.p.A. reserves the right to make modifications or improvements to the manual or unit without notice and without being obliged to update previous products and manuals. The information contained in this manual refers to the unit the characteristics of which are specified in chap. 5.3.1 “Rating plate”.
If the unit is resold, it must be delivered to the new owner together with this manual. In this case, the maker must be informed of the new owner (see chap. 11.2 “Resale”).

2.4 READING THE MANUAL: SYMBOLS AND CONVENTIONS

In this manual, symbols are placed beside certain descriptions, notes, etc..
These symbols are used to attract the attention of readers to a particular note or piece of information. Their meanings are explained below.

SYMBOL	DESCRIPTION
	**IMPORTANT SAFETY INFORMATION** **This symbol is used to draw the reader's attention to particularly important notions for operator safety.**
	**INFORMATION AND PRECAUTIONS** **This symbol refers to general indications and advice.**
	**STRICTLY FORBIDDEN** **This symbol means it is strictly forbidden to perform the operation in question. Failure to observe this prohibition may cause serious harm to the operator or damage to the unit.**

The manual is divided into chapters and sub-chapters; the figures are numbered with the chapter to which they refer, with the addition of a progressive number. E.g. Fig. 3.4-1 (figure No. 1 relative to chap. 3.4).

2.5 HOW TO OBTAIN A NEW COPY OF THE MANUAL

If the manual is lost or destroyed, ask Euronda S.p.A. for a new copy. Provide the following information:
- model and serial number of the unit;
- name and address where the manual should be sent.

Send your request to the following address:

EURONDA SPA
Via dell’Artigianato, 7
I - 36030 Montecchio Precalcino
Vicenza - Italy
Tel. 0039 (0)445 329811
Fax 0039 (0)445 865246
E-mail info@euronda.com

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CHAPTER 3

3.1 GENERAL SAFETY WARNINGS



Carefully read the safety information before using the unit. Non-observance could cause accidents or damage to the machine.

- Before using the unit, operators must have perfectly understood the meanings and functions of all the controls.
- Operators must be aware of and know how to apply the safety regulations governing the use of the unit.
- Operators must know and correctly interpret all indications contained in this manual and those applied to the unit.
- Operators must not perform operations on their own initiative or operations that are not part of their job.
- The responsible authority must instruct and train the operator to use and service the unit safely; in particular, it must ensure that the information contained in this documents are correctly understood. Particular attention must be paid to the emergency procedure concerning pathogenic materials released into the atmosphere. This must be written in a special guide stored near the unit.
- In the event of malfunctions or potentially dangerous situations, operators MUST immediately report the situation to the responsible authority.
- It is strictly forbidden to use or neutralize the safety devices.
- Make sure the unit is powered at the correct voltage.
- Make sure the unit is earthed and conforms to the standards applicable in the country of installation.
- Never dismantle the unit.
- Do not remove the outer guard before disconnecting the power supply: the unit contains live parts, fans and heaters that could activate without warning.
- The internal high voltages are dangerous.
- If it is not possible to disconnect the power supply, disconnect the mains supply. If this is distant or not visible by the person carrying out the maintenance work, turn the switch to "OFF" and secure it with a padlock or, alternatively, lock the electrical cabinet and keep the key; always make sure the voltage is effectively absent.
- Keep the area around the unit clean and dry.
- Do not use solvents on plastic parts or labels.
- Do not remove the labels on the unit. If necessary, ask for new ones.
- Clean the unit with a damp cloth after checking that the power cord is not connected (remove any traces of moisture before using the unit again).
- Do not pour water or any other liquids onto the unit that could cause short circuits or corrosion.
- Do not touch the unit with wet hands or if the unit is wet; always follow the precautions required for the use of electrical equipment.
- The unit was not designed for use in the presence of gas or explosive vapours.
- Do not expose the unit to excessive mechanical stress such as impacts or strong vibrations.
- Do not lean over or stand in front of the door when opening it as there is a risk of scalding from escaping steam (see **chap. 3.4 "Residue risks"**).
- The used water in the discharge tank, or the parts in contact with the material to sterilise may contain contaminated residues; it is therefore advisable to use protective rubber gloves during draining and handling, in order to prevent the risk of pathogenic contamination (see **chap. 6.7 "Tanks: instructions for filling and draining"** and **chap. 3.4 "Residual risks"**).
- Before transporting the machine, drain both water tanks. Use the supplied drain tube and follow the instructions for draining (see chap. **6.7 "Tanks: instructions for filling and draining"**).
- Before being sterilised, all the materials must be treated as required by current law.
- Do not try to open the door in case of blackout during a sterilization cycle (see 3.4 "Residual Risks").

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3.2 INTENDED USE

EN NEXT water steam steriliser: unit designed and developed for the sterilisation of instruments used in medical, dental, veterinary and podology surgeries, and tattoo shops, that can be sterilised by steam between 121°C and 134°C.

The unit is designed for use by professional, qualified persons only. The unit must only be used for the purpose it was designed for.

The manufacturer cannot be held responsible for any breakage, damage or malfunctioning of the unit if the machine has not been used correctly, been used inappropriately or not adequately maintained.

3.3 SAFETY DEVICES

Electrical safety

Description	Effect
Double-pole thermal protection circuit breaker for protection against short-circuit.	Disconnects main electrical power supply
Protection of the electronic card against short-circuit: both the transformer and the entire low-voltage circuit are self-protected.	Disconnects one or more low-voltage circuits

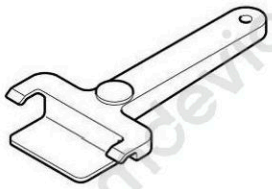
Thermal protection

Description	Effect
Thermal protection of the unit: if anomalous overheating occurs, the unit turns off.	The unit cannot be switched on until the manually resettable thermostat on the front panel is reset.
The vacuum pump is protected by a automatically resettable thermostat.	Temporary cut-off to permit cooling
The vibration pump is protected by a thermal fuse.	Interruption of electrical circuit, replace the thermal fuse.
Manually resettable thermostat protecting the steam generator	Interruption of power input to the steam generator until the thermostat on the generator is reset.
Safety valve, complying with the PED 97/23/EC standards, for protecting the unit from over-pressure	Discharge of steam and re-balancing of pressure to safety values

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Mechanical safety devices

Description	Effect
Door safety micro-switch: it ensures correct closure of the door	Message indicating wrong door position
Door-lock micro-switch: it detects the correct position of the locking system	Indication that the door is not locked
Door lock: electro-mechanical device that prevents the door from being opened accidentally	It prevents the door from being opened while the unit is in operation. Attempting to open the door with the door safety device applied **may seriously damage the closing system**
Extractor tool. Used to avoid touching the inner parts of the unit. 	Prevents burns while removing the trays containing the sterilized instruments

Control devices

Description	Effect
Pressure levelling: restores the system to its normal pressure values, in the event of manual stops or alarms and/or warnings during the cycle.	Automatic pressure re-balancing inside the sterilization chamber.
System for evaluating process parameters, managed entirely by the microprocessor	In the event of faults during the cycle, the program in progress is stopped immediately and alarms are generated
Constant monitoring of the device: the steriliser components are constantly monitored during operation.	Generation of alarm messages and/or warnings in the event of faults

It is forbidden to remove, modify, tamper with or neutralize the safety devices in any way. Euronda S.p.A. declines all liability for accidents to people or damage or malfunctions to the unit if the above instruction is not observed.

Periodically check the safety systems (see chap. 10 “Maintenance”).

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3.4 RESIDUAL RISKS

During the normal work cycle, the operator is exposed to certain risks that cannot be completely eliminated due to the nature of the unit.

- **Danger of contamination.**
  In case of unsuccessful sterilisation or a possible fault, the used water and any parts directly or indirectly in contact with the load may contain contaminating residues.
  The responsible authority must teach the operator how to use the unit safely.

- **Danger of burns.**
  1. When the steriliser finishes the sterilization cycle and the door is opened to remove the sterilized instruments, the inner parts of the boiler and door are still very hot. Do not touch these directly in order to avoid getting burnt (Fig. 3.4-1). Use the relative extractor tool (chap. 3.3 “Safety devices”).
  2. When opening the door, do not stand over or in front of it as you may be scalded by the steam (Fig. 3.4-2).
  3. In case of blackout during a sterilization cycle, every try to open the door is absolutely forbidden. A potential residual pressure could cause burns due to steam leak.

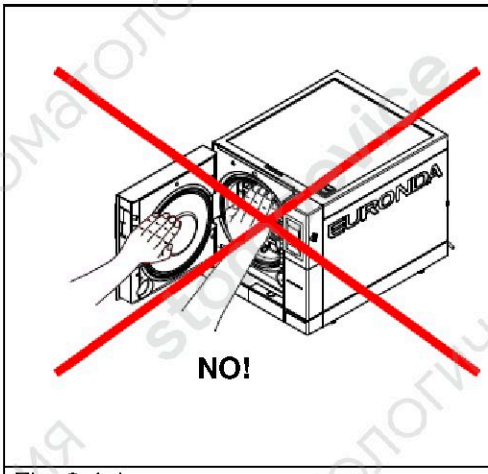


Fig. 3.4-1

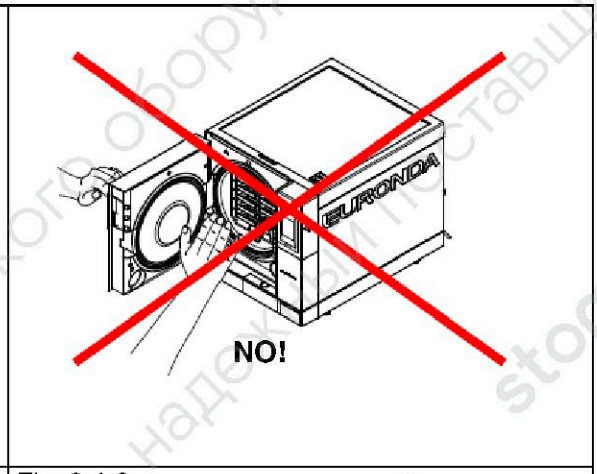


Fig. 3.4-2

- **Danger of contamination.**
  The water used by the discharge tank may contain contaminated residues: during the draining operations use latex safety gloves (see chap. 3.6).

- **Danger of injury to hands**. Even if the unit is not performing a cycle, it may power mechanical, heating or live elements. **Do not remove the outer safety guard before disconnecting power supply.**

- **Danger of electrocution**. Always disconnect the power supply before starting work on the unit . Use the personal protective equipment indicated in chap. 3.3 “Safety devices”.

3.5 SAFETY SIGNS ON THE UNIT

Safety signs on the unit:

	**CAUTION**: DISCONNECT FROM THE POWER SUPPLY BEFORE OPENING THE SAFETY GUARD
	**CAUTION**: HOT SURFACE

These signs must not be removed, covered or damaged.

3.6 PERSONAL PROTECTIVE EQUIPMENT (PPE)

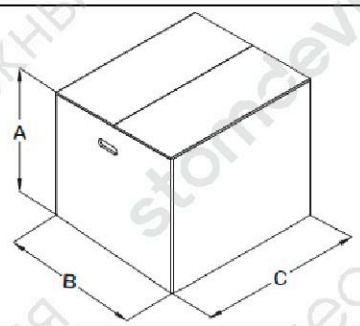
- Latex safety gloves.

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CHAPTER 4

4.1 WEIGHT AND DIMENSIONS OF PACKAGING



Overall dimensions of packaging:	
A = 545 mm	
B = 560 mm	
C = 745 mm	
Total weight of packaging:	
E9 NEXT 18L	E9 NEXT 24L
50 kg	54 kg

Fig. 4.1-1

4.2 RECEIPT AND HANDLING

On receipt of the machine, check that the packaging is intact (keep it for future despatches).
Open the packaging and check that:
- the supply meets the technical specifications (chap. 4.3 “Description of contents”);
- there are no obvious signs of damage.

If any damage or missing parts are discovered, inform the hauler, wholesaler or Euronda S.p.A immediately, providing all details.
Handle the packed unit as described in chap. 6.1 “Work environment: positioning” (Fig. 6.1-1).

4.3 DESCRIPTION OF CONTENTS

Description	Specifications	Quantity
Steam sterilizer E9 NEXT	Steriliser 18L - Steriliser 24L	1
Tray	Anodized aluminium perforated tray	5
Tray carrier	Support with 5 compartments in stainless steel	1
Extractor pincer	Pincers for extracting trays	1
Door adjustment lever	Stainless steel lever for adjusting the door gasket	1
Water drainage tube	Transparent PVC tube with quick fit attachment	1
Overfill draining tube	Transparent PVC tube	1
Instructions manual	This manual	1
Warranty certificate		1
Quick start sheet		1
Installation sheet		1
Test Report		1
Declaration of conformity	Steriliser: CE 0051	1
	Boiler: CE 0497	1

4.3.1 Optional devices (also see Appendix 10)

Description	Specifications	Quantity
Aquafilter	External deioniser for the automatic supply of water	1
Integrated printer	Thermal paper printer	1
Integrated printer	Label Printer	1
External printer	Label Printer	1

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CHAPTER 5

5.1 DESCRIPTION OF UNIT

E9 NEXT: totally automatic steam sterilizer for sterilizing instruments both loose and packed in bags.

5.1.1 Front elements

1. Touch screen: used to set, visualize and control all the functions of the unit. The functions of the various buttons are explained in chap. 6.5 “How to use the control panel”.
2. Door handle inserted in the chamber.
3. General switch door: accesses the general switch and a service serial port.
4. SD card slot: the SD card, which stores the machine cycle data, is housed in this slot.
5. Optional thermal printer cover (see chap. 5.4 “Integrated printer”).

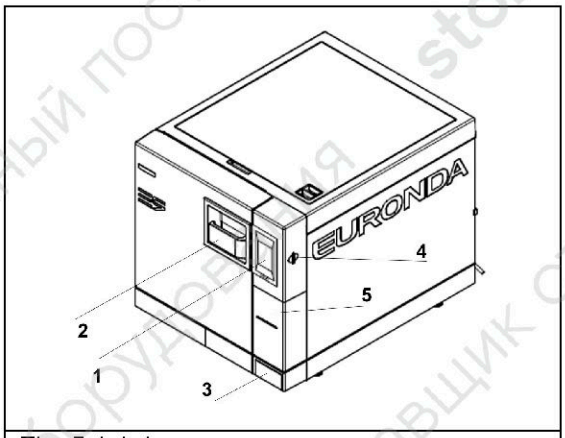


Fig. 5.1.1-1

Devices on the front of the unit with the door open

1. Door gasket.
2. Gasket.
3. Bacteriological filter.
4. Connector for draining used water.
5. Closing mechanism block with electromagnetic pin and internal safety micro-switches.
6. Connector for draining clean water.
7. Screw cap for the safety thermostat switch.

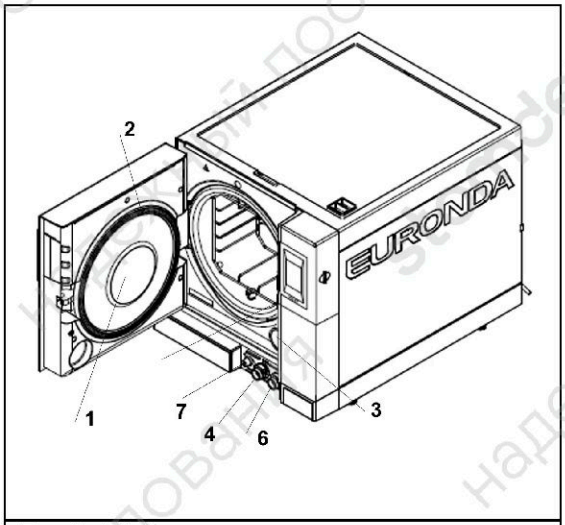


Fig. 5.1.1-2

5.1.2 Rear elements

1. Used water and overflow drain.
2. Power cord socket.
3. Electric connection for deionizer.
4. Safety valve.
5. Rear serial socket.
6. External water inlet from the deioniser.
7. Ethernet socket.

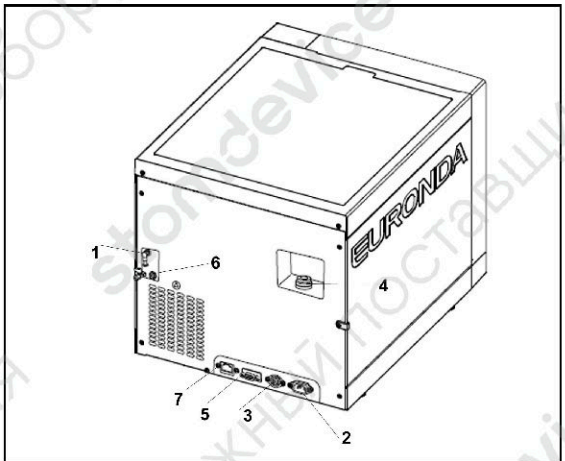


Fig. 5.1.2-1

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5.1.3 Upper elements

1. Clean water tank.
2. Dirty water tank.
3. Filters.
4. Max clean water and max dirty water sensor.
5. Minimum clean water level/conductivity meter sensor.

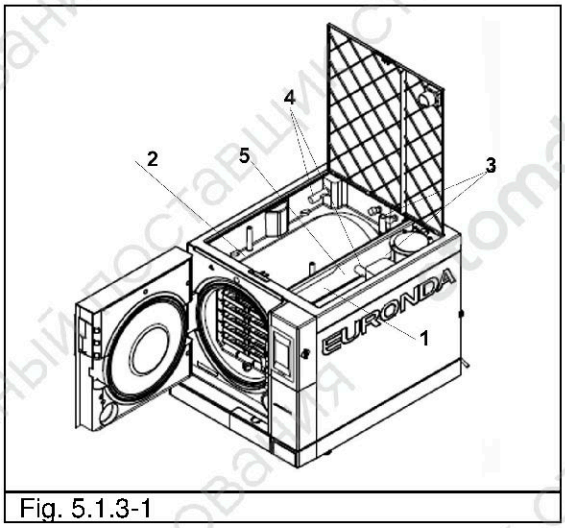
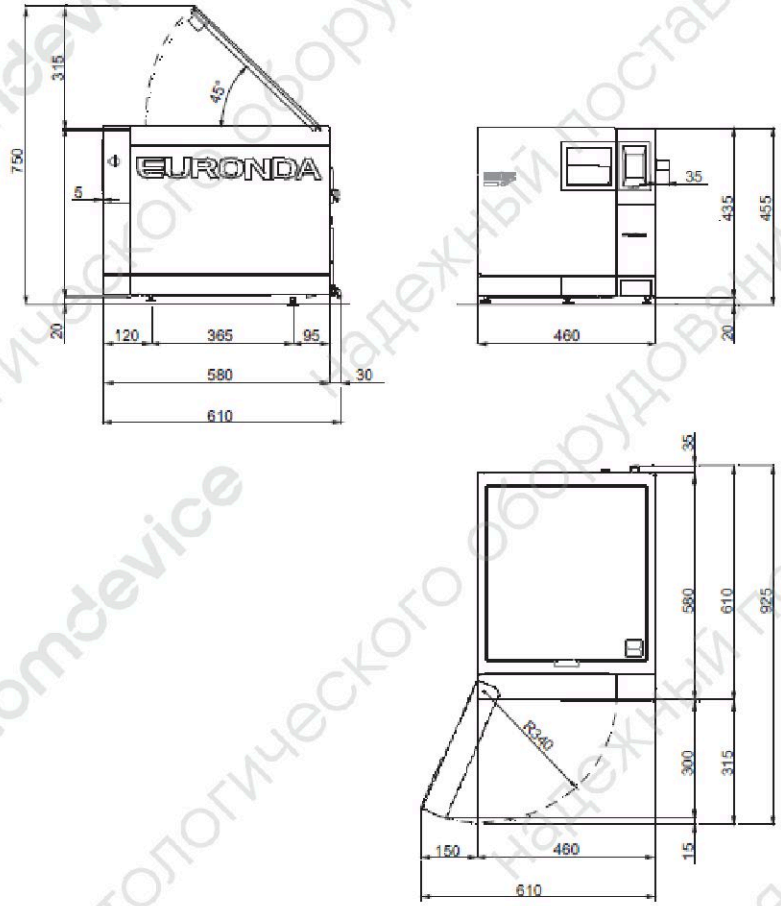


Fig. 5.1.3-1

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5.2 OVERALL SPACE REQUIRED



Overall dimensions of the machine with door closed (fig. 5.2-1):	
E9 NEXT 18L	**E9 NEXT 24L**
L = 460 mm H = 455 mm D = 615 mm	
Overall dimensions of the machine with door open (fig.5.2-1):	
E9 NEXT 18L	**E9 NEXT 24L**
L = 610 mm H = 455 mm D = 930 mm	
Weight of the machine:	
E9 NEXT 18L	**E9 NEXT 24L**

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Empty: 44 kg. Maximum weight with full tank and maximum load: 58 kg	Empty: 47.5 kg. Maximum weight with full tank and maximum load: 61.5 kg

5.3 TECHNICAL DATA AND NOISE

CHARACTERISTICS	E9 NEXT 18L	E9 NEXT 24L
Power supply voltage	230 V	
Mains frequency	50 / 60 Hz	
Power output	2300 W	
Absorbed current	10A	
Insulation class	I	
Protection class	IPX0	
Sterilisation cycles	5 sterilisation cycles	
Control cycles	Vacuum test - Bowie & Dick test - Helix test	
Personal Functions	2 LIGHT* cycles (N134, N121), 2 LIGHT & STOCK* cycles (S134, S121), 2 NGV cycles *to enable the *Personal Functions* complete the registration in the www.euronda.com/myeuronda portal	
Additional test cycles	Pressure hold - activation of safety valve	
Range of environmental conditions in which the unit was designed to operate	- Indoor use - Altitude up to 2,000 m a.s.l. - Temperature: +5 - +40°C - Max. relative humidity 85% - Max variation in mains voltage: ±10% - Installation category (overvoltage category) II - Degree of pollution: 2 - Temporary overvoltage for long time 230V + 1200V up to 5 s - Temporary overvoltage for short time 230V + 250V for more than 5s	
Maximum pressure *	250 kPa (2.5 bar)	
Dimensions of sterilisation chamber	Diameter: 250 mm Depth: 340 mm	Diameter: 250 mm Depth: 440 mm
Usable space** of chamber	180 x 160 x 280 mm (LxHxD)	180 x 160 x 380 mm (LxHxD)
Usable capacity of chamber	8.12 litres	11 litres
Capacity of water tanks	4 litres	
Weight for support area (full tank and chamber with maximum weight)	3.07 kg/cm^2 (301210 N/m^2)	3.21 kg/cm^2 (315384N/m^2)
Operation control	Microprocessor	
Printer	Optional (thermal, labels, external labels)	
Bacteriological filter	Yes	

* **Note**: in this manual, the word “pressure” always refers to “relative pressure”.

****Usable space**
This is the internal capacity of the sterilization chamber available for material to sterilize (fig. 5.3-1).

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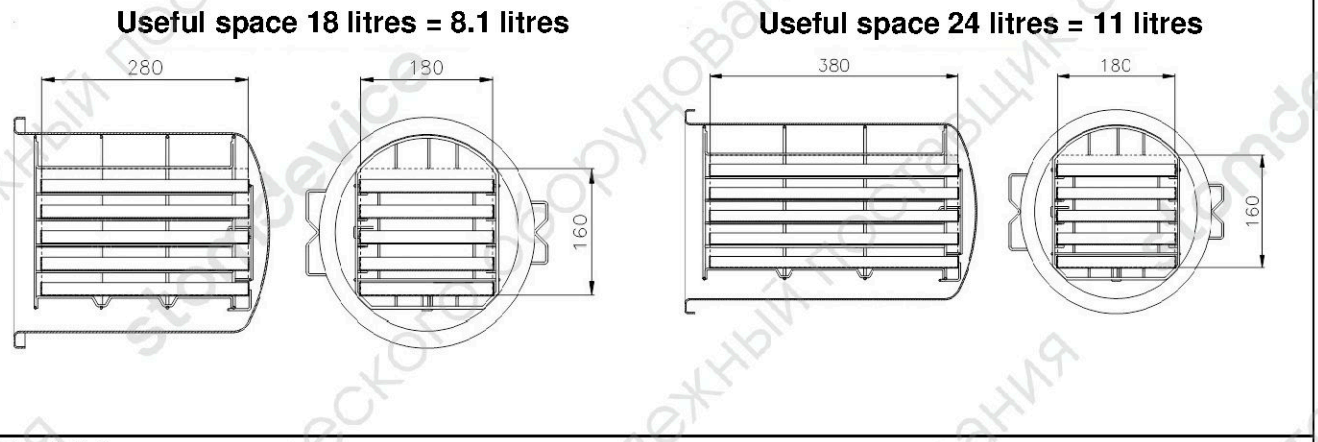


Fig. 5.3-1

5.3.1 Rating plate

The rating plate (Fig. 5.3.1-1) lists the main data and characteristics of the unit, the information required to identify it when ordering spare parts, and/or when requesting information. The information shown in the following figure is subject to change.

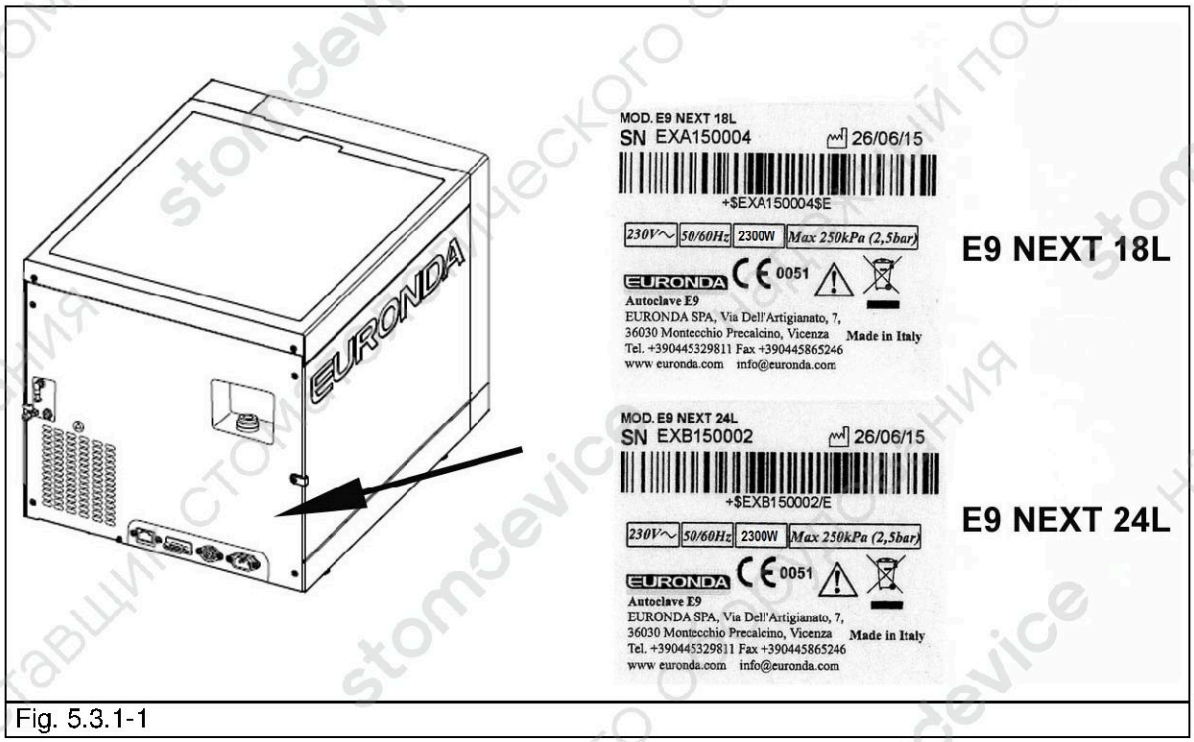
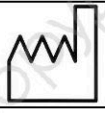


Fig. 5.3.1-1

The label of the unit bears symbols the meaning of which is shown below.

SYMBOL	DESCRIPTION
SN	**"SERIAL NUMBER"** The symbol must be followed by the manufacturer's serial number. The serial number must be adjacent to the symbol.
	**"PRODUCTION DATE"** The symbol must be accompanied by the year. The year must be composed of four digits.

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	**"WARNING, READ THE INSTRUCTIONS MANUAL"**
	"RECYCLING SYMBOL" The symbol means that at the end of the life of the equipment must be disposed of at appropriate collection points, and not with standard household waste (European Union only).

5.3.2 Noise level

The unit has been designed and built to reduce the maximum noise levels, which are lower than 64 dB(A).

5.4 OPTIONAL PRINTER (INTEGRATED OR EXTERNAL)

5.4.1 Integrated label printer

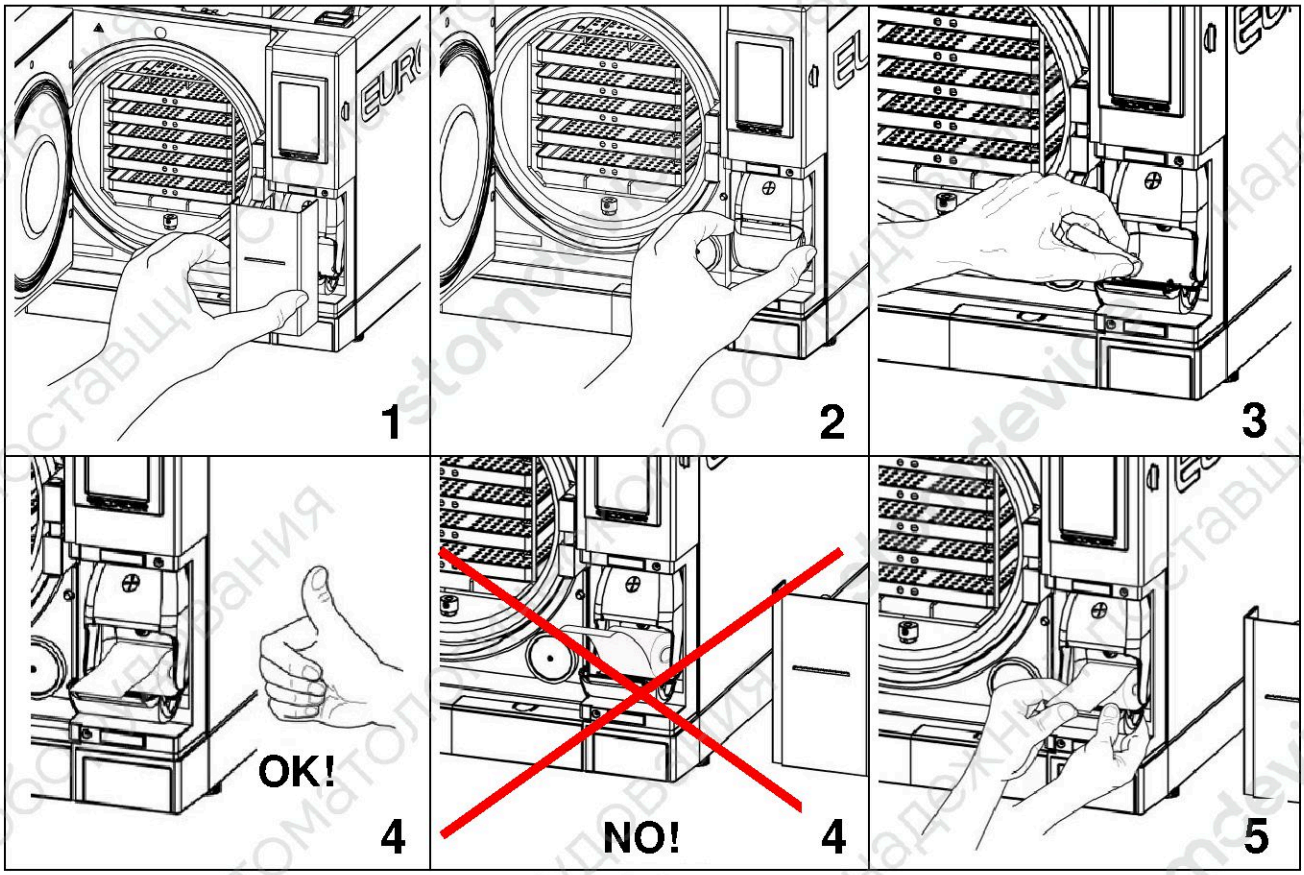
With the printer set using the settings menu, upon completion of each cycle, the printer shows the results of the cycle, both if it was successful or unsuccessful, or if it has been stopped manually, or caused an alarm.

- The printer only works if the label roll is inserted.
- If no label roll is inserted, the printer does not work.

To fit a new label roll:

1. Open the main door and remove the magnetic door at the front.
2. Open the label roll housing cover by holding the sides with your fingers and pulling it down slightly.
3. Remove the used roll, if present.
4. Fit the new roll of labels as shown in the figure; make sure the paper leaves the roll in the right direction.
5. Pull the paper, close the cover and tear off the excess paper
6. Reposition the magnetic door at the front.

Only use original Euronda labels.



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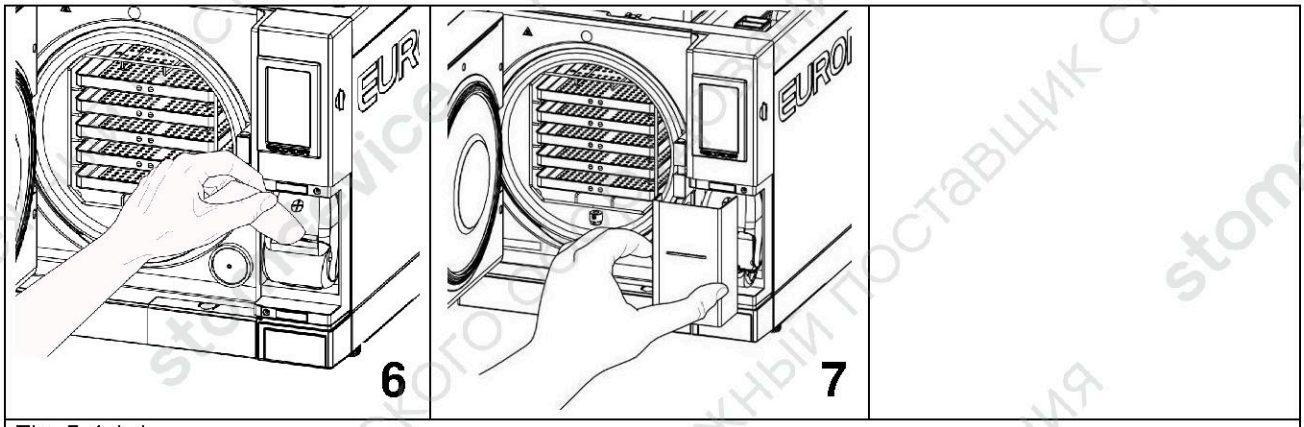


Fig. 5.4.1-1

Paper roll integrated printer

- The printer only works if the paper roll is inserted.
- If no paper roll is inserted, the printer does not work.
- The button on the printer is used to feed the paper.
- Press the button once to feed the paper by one line.
- Hold down the button to feed the paper continuously.

To fit a new roll of paper:
1. Open the paper roll housing cover by holding the sides with your fingers and pulling it slightly.
2. Remove the empty roll, if present.
3. Fit the new paper roll as shown in the figure; make sure the paper leaves the roll in the right direction.
4. Pull out a small quantity of paper and close the cover.
5. Tear off the excess paper.

Use rolls of thermal printer paper with the following characteristics:
width: 57 - 58 mm
maximum diameter: 40 mm

Do not expose thermal printer paper, both before and after use, to direct sunlight, heat or humidity.

Avoid direct contact with materials in polyvinyl, as well as solvents and various derivatives (filing envelopes in PVC, acrylics and paper treated with ammonia vapours).

Rolls should be kept in a dry place with humidity of no more than 70% and direct temperature lower than 35° centigrade.

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CHAPTER 6

6.1 WORK ENVIRONMENT: POSITIONING

The unit is packed in the following way: on pallet, protected by totally recyclable mouldings in foamed polyethylene, and placed inside a corrugated cardboard box, certified for transportation by sea. The box is secured to the pallet with screws.

Lift the unit with care and do not turn it upside down.

The packaging and the equipment are fragile, handle with care. Transport as fragile. THE HANDLES ON THE PACKAGING (1 of Fig. 6.1-1) MUST ONLY BE USED FOR VERTICAL LIFTING. Keep in a dry and protected place. **The packaging must be kept for the whole guarantee period.**

NOTE: please retain the **original packaging** and use it each time the unit needs to be transported. The use of different packaging could damage the product during transportation.

Two people are required to lift the unit:

- Remove staples closing the top of the cardboard packaging (Fig. 6.1-1).
- Open the top of the cardboard packaging.
- Make sure there is no evident damage and that all the parts are present.
- Use the relative belts to lift the unit (two people required) taking care to always keep it vertical.
- Do not grip the plastic parts of the appliance.
- Place the unit on the work surface, and then remove the straps by lifting it up slightly.

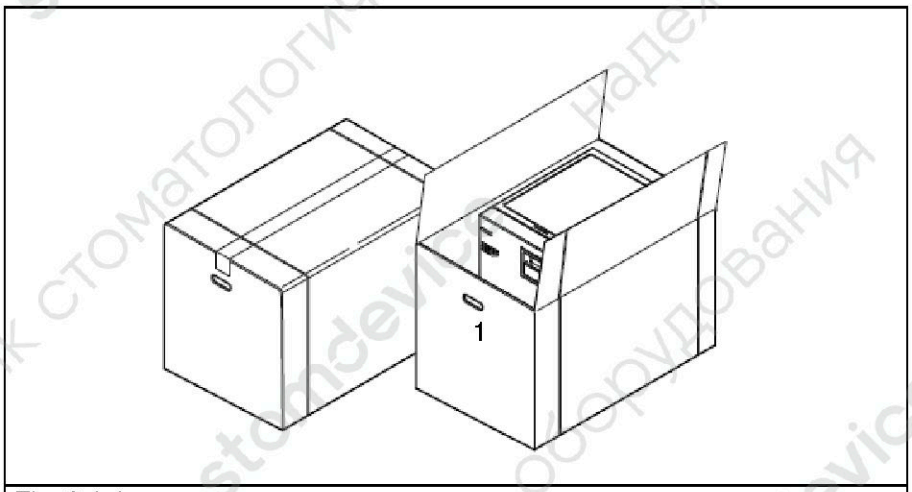


Fig. 6.1-1

- The unit should be installed inside a laboratory, which is accessible only to authorised personnel.
- Position the unit on a flat and horizontal surface (Fig. 6.1-3).
- Leave a space of at least 8 cm on the back, and 3 cm on the sides, for air circulation and heat dispersion (Fig. 6.1-3).
- Do not place the unit near sources of steam or where it could be splashed by water, which could damage the internal electronic circuits.
- Do not install the unit where there is poor air circulation (Fig. 6.1-4).
- Do not place the unit near sources of heat (Fig. 6.1-4).
- The area where the unit is placed must be lit in accordance with standard UNI 12464-1.
- Acceptable environmental conditions:
  temperature from 5 to 40°C - max. humidity 85% without condensation - max. altitude 2,000 m a.s.l.

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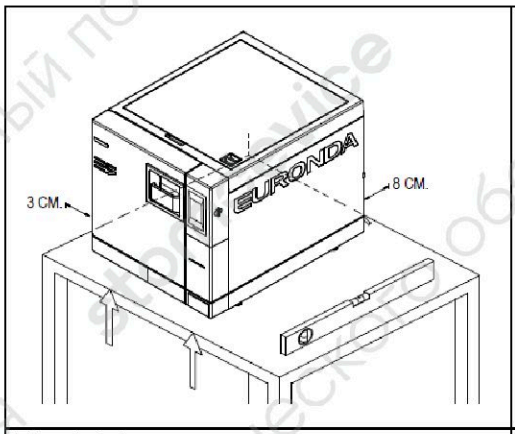


Fig. 6.1-3

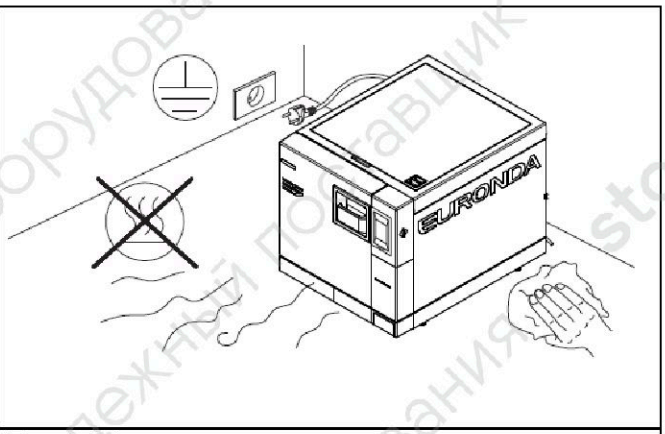


Fig. 6.1-4

6.2 INSTALLING THE UNIT

Installation is a fundamental operation for the subsequent use and correct functioning of the unit.

CAUTION: the unit MUST be installed by specialised technicians.

After installing the unit, always fill out the installation sheet.

Machine installation and start-up should be performed with the door open in order to measure ambient pressure.

This unit has been designed for use in a normal environment (see chap. 5.3 “Technical data”); it is necessary, however, to follow the instructions given below.

- Before installation, make sure to remove the kit of accessories from inside the unit.
- Install the unit so that the power lead does not kink or become squashed, but has a free run to the socket.
- The unit must be placed so that the plug is accessible.
- Place the unit at a height that will allow the user to inspect the entire sterilization chamber and clean it with ease.
- Connect the overflow connector (1 of Fig. 5.1.2-1) to allow the autoclave to drain any excess water formed due to faults.
- Do not place trays, newspapers, containers of liquids, etc. on the unit.
- Do not lean on the door when it is open.
- When emptying the discharge tank directly into the waste pipes, position the unit at a height above the drains.

Once installed and connected to an electrical power point, the unit is ready to use.

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6.3 ELECTRICAL CONNECTIONS

CAUTION: Electrical connections MUST be made by specialised technicians.

- Check that the power supply voltage indicated on the rear label (Fig. 5.3.1-1) corresponds to that available at the point of installation.
- The unit must be connected with an overload cut-out switch to a system fitted with an adequate earth system that conforms to the standards applicable in the country of installation.
- The system must be connected according to current standards.
- Max variation in mains voltage: ±10%.
- A differential switch with the following characteristics must be installed upstream the power socket of the unit:
  nominal current: 16 A.
  differential sensitivity: 0.03 A.
- Connect the supplied cable to the rear of the unit.
- Position the unit so that the plug is accessible.

Do not allow the lead to bend tightly and do not place any object on it.

Do not use extension cords.

Only use the original lead.
ONLY USE ORIGINAL SPARE PARTS.

If the unit does not function correctly, please refer to Appendix 9 “Troubleshooting” of this manual for possible causes. For further information or repairs, please contact your supplier or the technical department of Euronda S.p.A.

WARNING. The unit conforms to the electrical safety requirements of the Standards Institute and comes supplied with a double-pole plug that ensures the unit is earthed.
A fundamental safety requirement is to check that the electric system is appropriately connected to the earth, and that the ratings of both system and sockets are suitable for the power of the unit, which is shown on the rating plate (see chap. 5.3.1 “Rating plate”). **Have the system checked by qualified personnel.**

EURONDA S.p.A DECLINES ALL LIABILITY IF THE ABOVE IS NOT OBSERVED.

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6.4 FIRST START-UP

The unit is packed with the door closed.

- Take out the accessories inside the sterilisation chamber and remove the packaging.
- Connect the unit to the power socket following the safety instructions in chap. 6.3 “Electrical connections”.
- After opening the door (3 of Fig. 5.1.1-1) that provides access to the general switch, and to a service serial port, switch the unit on using the ON-OFF switch.

6.5 HOW TO USE THE CONTROL PANEL

6.5.1 How to use the control panel

The E9 NEXT steam steriliser features a touch screen user interface (1 of Fig. 6.5.1-1) which integrated the control bar at the bottom.

The buttons on the display are used to perform all the programming, use and maintenance functions of the unit. Their operation depends directly on what appears on the screen: press the key corresponding to the desired function, based on the desired action, as per the example below.

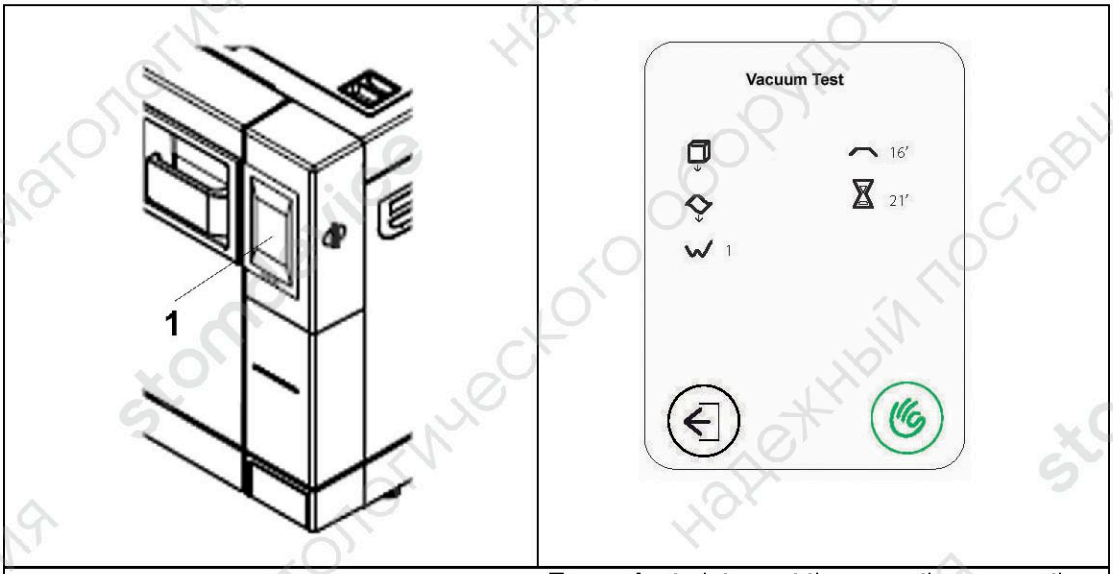


Fig. 6.5.1-1

Example: to interrupt the operation, press the **arrow** button, to confirm, press the **green (hand)** button.

For specific uses, see chapter 7.

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6.6 INSTALLATION MENU

The first time that the unit is turned on using the ON-OFF button, the LCD screen comes on and shows the following welcome message. This message stays on the screen for a few seconds, until the machine is ready to be used. After a few seconds, required to load the process controller, the language selection screen will appear. After selecting the language, the installation screen will appear.







	Touch this icon to confirm the installation of the unit, the date and the time displayed on the screen.
	Touch this icon to exit the unit installation procedure. The installation screen will appear again the next time the unit is switched on.

6.7 TANKS: INSTRUCTIONS FOR FILLING AND DRAINING

The unit features **two separate tanks**: one for the clean water required for the cycles, and one for the used water that is collected at the end of the cycles. Both tanks are connected with drain valves.

Filling with distilled water for the first time

1. If a cycle is run and the water in the clean water tank does not reach the minimum level, the following icon appears on the display:



2. Open the plug in the upper cover, fit the supplied funnel into the hole (1 in Fig. 6.8-1) and pour in a quantity of distilled water as indicated in chap. 5.3 “Technical data”; never exceed the level indicated with the word MAX in the water filling hole. Water can also be poured in through the deionizer (optional, Appendix 10). To install this optional, consult the respective “Aquafilter” instruction manual supplied with the deionizer.

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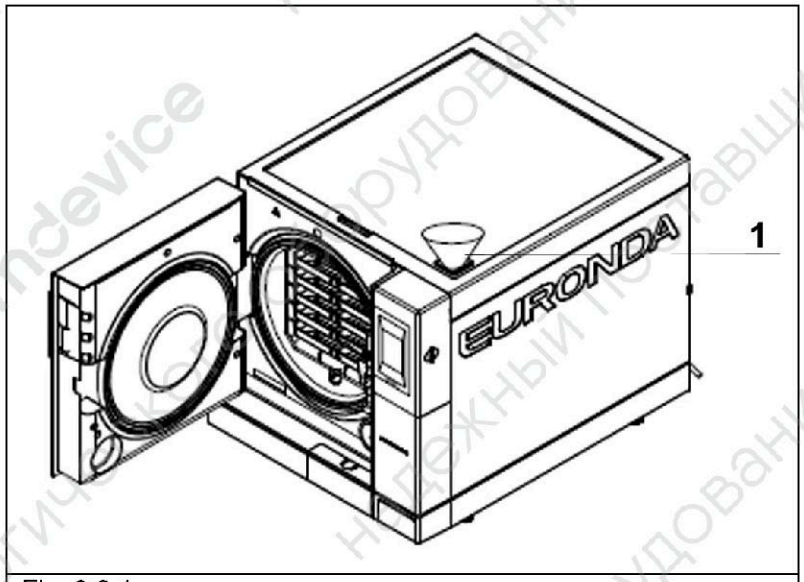


Fig. 6.8-1

Later, when using the unit, whenever the water reaches the MIN level, the “MIN” message will appear and, until the water tank is filled, it will not be possible to perform any work cycle and certain tests.

Adding clean water

1. Empty the inner tank for collecting used water as described below in the par. “Emptying used water”.
2. Fill the clean water tank with fresh clean water (1 di Fig. 6.8-1).

WARNING: always use good quality clean water (Appendix 8 “Quality of process water”). To ensure correct machine operation it is fundamental to use distilled water only.

CAUTION: before transporting the unit, **drain both water tanks**. Use the supplied tube.
To empty the clean water tank, remove the discharge section cover (3 of Fig. 6.8-2) and fit the end of the tube with the connector to the connector with the light blue button at the bottom of the front panel (1 of Fig. 6.8-2), and place the other end into an empty container.

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Emptying used water

If the **used water tank** is full, the following icon appears on the LCD display of the control panel:



In these cases, **it is not possible to perform sterilisation cycles**. The capacity of the clean water tank is sufficient for about 8 cycles for the 18L model, and for about 7 cycles for the 24L model.

1. Empty the internal used water collection tank:

CAUTION: DANGER OF CONTAMINATION. The used water in the discharge tank may contain contaminated residues: it is advisable to wear latex safety gloves when draining (chap. 3.4 “Residual risks”).

NEVER REUTILISE USED WATER.

Get hold of an empty tank, fit the clear tube supplied with the unit, after removing the discharge section cover (3 of Fig. 6.8-2) to the connector with the grey button at the bottom of the front panel (2 of Fig. 6.8-2). At the end of the draining operation, remove the tube from the connector by pressing on the clip.

CAUTION: this operation is fundamental for the correct operation of the unit.

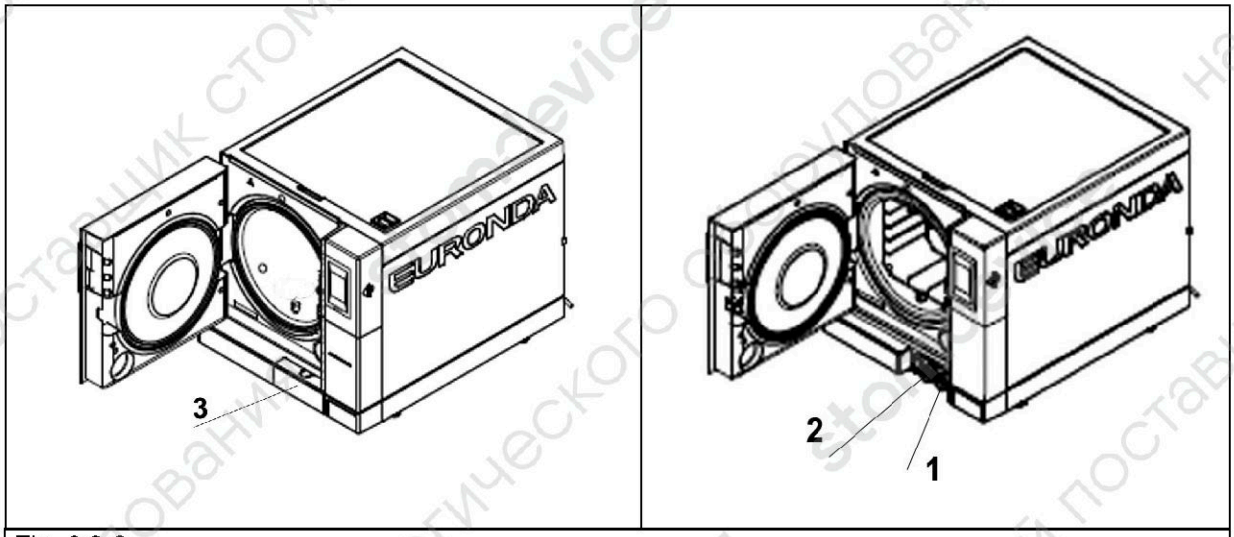


Fig. 6.8-2

Used water can easily be continuously drained by means of the draining connector situated on the rear part of the unit (3 of Fig. 6.8-3). After connecting the tube (Fig. 6.8-4), make sure it never exceeds the height of the connector on the steriliser during its journey to the drain, otherwise the water will not flow (Fig. 6.8-5).

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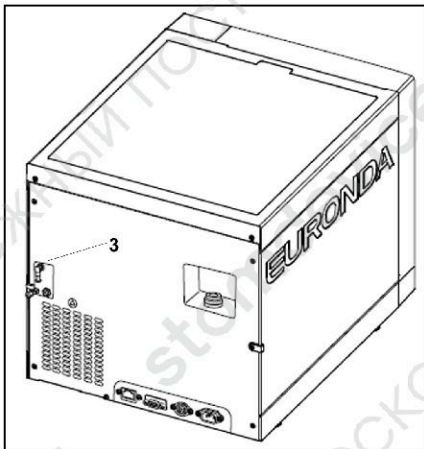


Fig. 6.8-3

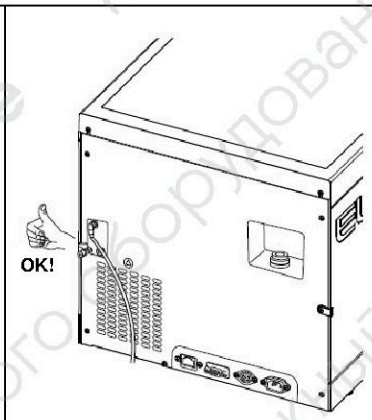


Fig. 6.8-4

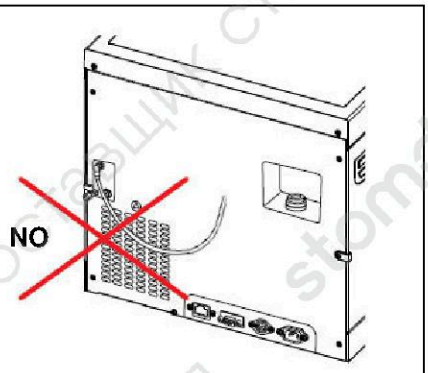


Fig. 6.8-5

Maximum load

Never exceed the max. load specified in Appendix 5 “Description of Programs”.

- Always observe the maximum load limit, established and set by Euronda S.p.A. for each solid material to sterilise.
- The maximum sterilisable load of the unit is indicated in Annex 5.
- The unit is tested and only provides the indicated performance levels if the internal load does not exceed the above values for the maximum load.

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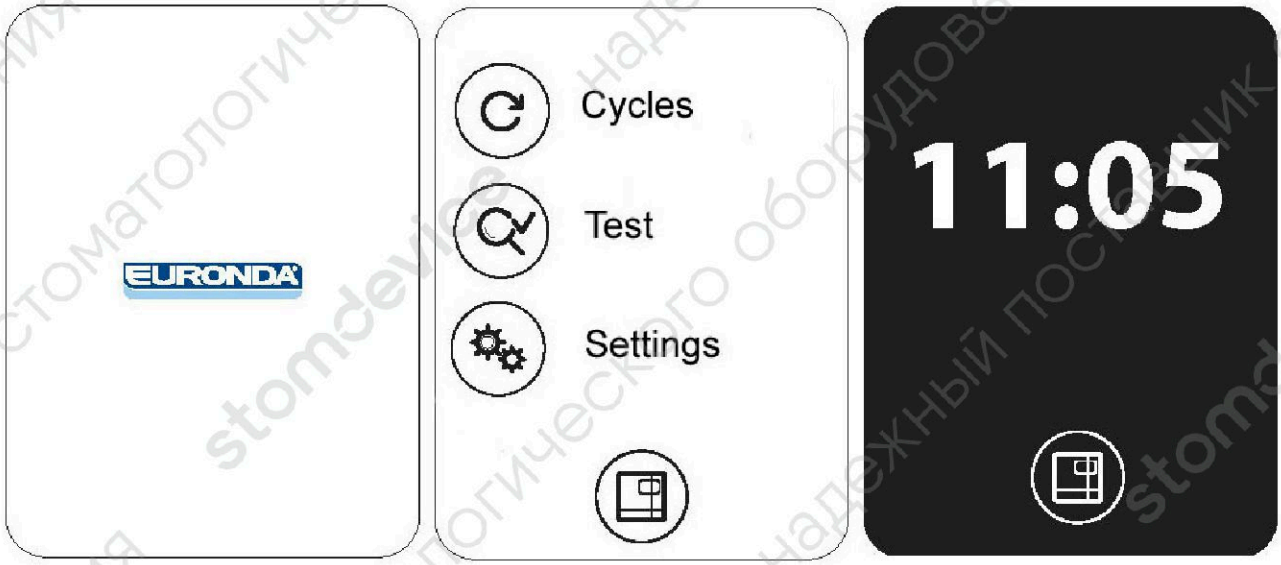
CHAPTER 7

7.1 PROGRAM MENU

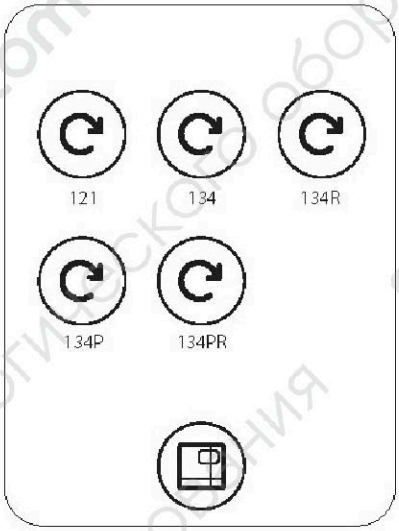
Before beginning to operate the unit, carefully read all the warnings indicated in this manual, especially chap. 3 “Safety”.

During the sterilisation cycle NEVER OPEN the cover of the tank.

Once the installation procedure has been completed (chap. 6.6 “Installation menu”), the next time the unit is switched on, using the ON-OFF button, the following welcome screen appears:



After a few seconds, this is replaced by the HOME screen. If no activity is performed on the autoclave for a minute, the home screen is replaced by the black screensaver.
From the HOME screen it is possible to select the sterilisation cycle, access test procedures, or sub-menus. To select the cycles, simply select CYCLES. for the sub-menus select SETTINGS, and for the tests TEST. If the bottom icon is selected, a screen with the currently active settings appears. Press CYCLES to access the following screen, where the desired cycle can be selected.



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Before starting the selected cycle, load the material to sterilize into the unit:

1. Open the door (Fig. 7.1-1).

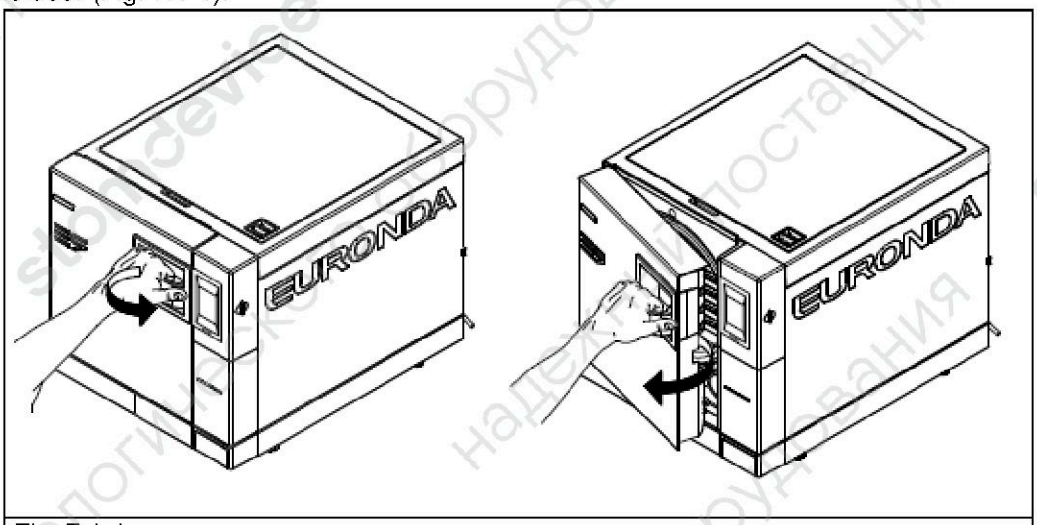


Fig. 7.1-1

2. Place the trays with the material to sterilise inside the unit.

In order to load the material to sterilize correctly, carefully read all the instructions given in Appendix 1 "Preparing the instruments for sterilization", Appendix 2 "Packaging" and Appendix 3 "Positioning the load".

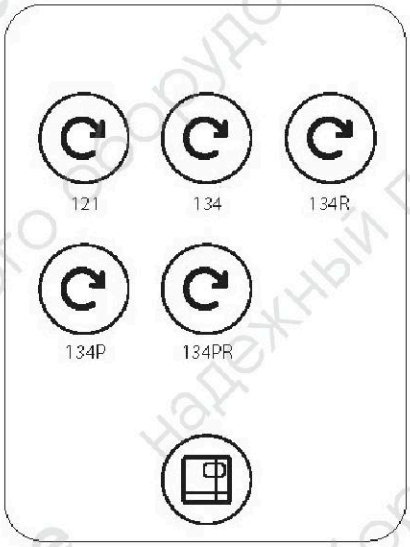
3. Close the door: pull the handle towards you while pushing the door in, and then turn the handle back towards the unit.
4. Select the cycle type following the instructions given in chap. 7.2.

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7.2 SELECTING A STERILIZATION CYCLE

To select a sterilisation system, press one of the five available cycle buttons on the CYCLES screen:



After the cycle has been selected, this screen appears:



This screen summarises the main characteristics of the chosen cycle:

- at the top, the cycle name (B 134 in this case);
- next to the cube image, the maximum admissible solid load (4.5/6 kg in this case);
- next to the wave image, the maximum admissible porous load (1.5/2 kg in this case);
- next to the zig-zag line, the number of pre-vacuum cycles for removing the air required by the cycle (3 in this case);
- next to the flat line, the sterilisation time (4 minutes in this case);
- next to the hour glass, the average cycle duration (48 minutes in this case).

At the bottom, the green hand for running the cycle and the arrow-left icon for returning to the previous screen.

For loads not exceeding 0.6 kg, of solid and 0.2 kg of porous, placed on the same tray, it is possible to perform a rapid cycle allowing the load to be sterilised in an average time of 30 minutes. The RAPID cycle has a shorter drying time that dries the load in any case, even if it is placed in bags.

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Important: set the load to sterilise in the highest possible position of the tray support.

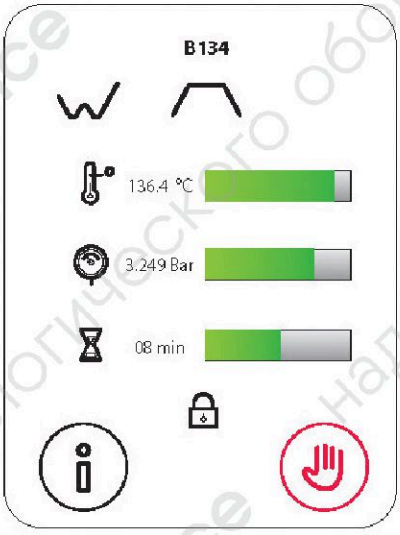
For enveloped loads over the indicated weight it is not guaranteed a correct drying.

7.2.1 Start-up, execution and end of a cycle

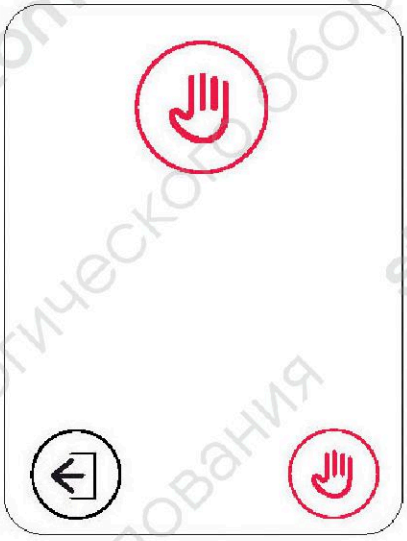
While the steriliser is performing a sterilisation or test cycle, the following screen appears on the display. This shows:

- at the top the cycle name (B 134 in this case);
- below, an indicator of the cycle stage: pre-vacuums, sterilisation, drying;
- below, the instantaneous temperature value in °C, of the pressure in bars, an hourglass with an approximate estimate of the time left to the end of the cycle, and the padlock symbol, to indicate that the door is locked

At the bottom, the hand icon for manually stopping the cycle and the "i" icon for accessing the menus giving detailed information on the values read by the probes.



If the icon is touched when a cycle is being run the following screen appears requesting confirmation of the manual stop. Touching the hand icon again will confirm the intention to stop the machine, and the machine will therefore start the manual stop procedure. If the left-arrow icon is touched the previous screen appears.



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When the cycle is completed normally, the sterile load is dried, and the door is released. The following screen confirms that the process has been completed.



CAUTION: when the sterilizer is turned off, be sure that the door is either open (**a**) or completely closed (**b**). It is important to avoid the situation shown in **c**, which is closing the door with handle not completely hooked.

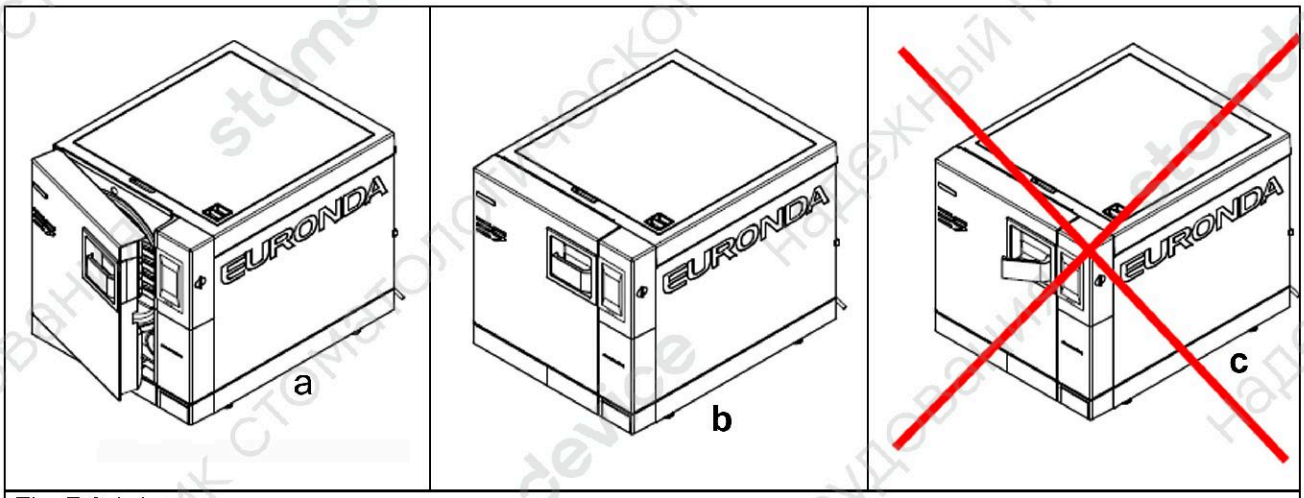


Fig. 7.2.1-1

CAUTION: **DANGER OF BURNS.** When the unit finishes the sterilization cycle and the door is opened to remove the sterilized instruments, the inner parts of the boiler and door are still very hot. These must not be touched directly in order to avoid getting burnt (chap. 3.4 “Residual risks”). Use the relative extractor tool.

CAUTION: **DANGER OF BURNS.** Do not lean over or stand in front of the door when opening it as there is a risk of scalding from escaping steam (chap. 3.4 “Residual risks”). Use the relative extractor tool.

If the sterilization cycle has not been successful, an error message will be displayed indicating the cause of the problem (**Appendix 9 “Troubleshooting”**).

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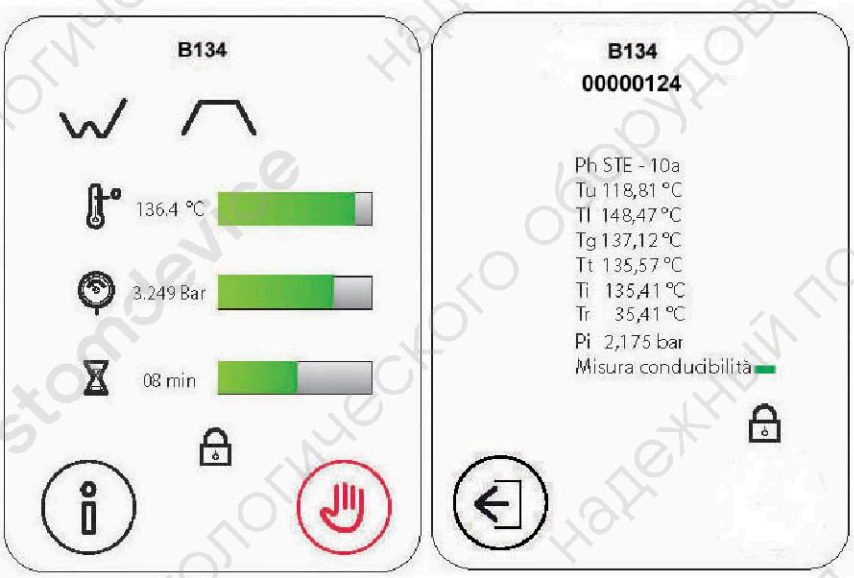
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Door release

ATTENTION: A safety pin automatically locks the door when the cycle starts. The pin only returns to its seat at the end of the cycle. **Attempting to open the door with the door safety device applied may seriously damage the closing system. Always wait for the end of cycle signal on the LCD display** before opening the door.
In the event of an alarm, the door can only be opened after giving consent by touching the screen (see 7.6).
CAUTION: LOAD NOT STERILE, HANDLE WITH CARE.

7.2.2 Information on process parameters

Additional information on the parameters of the currently running cycle can be obtained by pressing "i" on the **Cycle in progress** screen.



The next screen shows the type of cycle currently running, and the number of cycles completed. Below is the instantaneous reading of the probes on the steriliser and the name of the current phase (at the top). Below that, is the icon with the left arrow, to return to the previous screen.
* If Aquafilter is set to ON, the conductivity measure appears.

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7.2.3 How to unlock the Personal cycles

N.B: To receive the password and unlock the Personal Light and Light&Stock cycles, register your E9 Next at www.myeuronda.com.



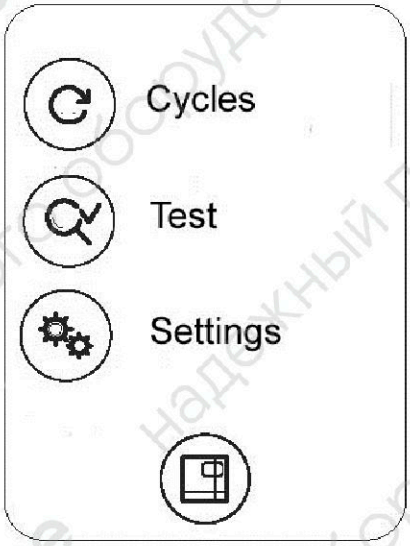
ATTENTION: these sterilization programs can be used only for solid loads. They cannot be used for hollow loads, or double wrapped loads. Read carefully the program description, appendix 5.

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7.3 SELECTING A TEST

In order to constantly monitor the efficiency of the unit, it is extremely important to perform certain tests, at the times recommended in Appendix 6 “Description of tests”.



Select the TEST icon to return to the test cycle menu.



From this screen, the steriliser test cycles can be run by touching the corresponding icons.

1. pressure gauge icon: this runs the vacuum test;
2. PCD helix icon (central): this runs the helix test;
3. sheet icon (left): this launches the Bowie and Dick test

Below is the icon that takes to the home screen (cycles, test, settings).

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7.3.1 Start-up, execution and end of a test

CAUTION: the VACUUM TEST can only be activated with the machine cold, i.e. WITHIN 3 MINUTES FROM SWITCHING ON THE UNIT, in that once this time has elapsed, the unit starts pre-heating (see "Appendix 6"). It will no longer be possible to perform the test.

If the unit is pre-heating and you switch it off and then switch it back on again, it still will not be possible to perform the vacuum test in that the steriliser must be cold.
If, however, the test is completed with positive results, the following screen appears:



At this point, the door release symbol indicates that the door can be opened, and the display goes back to the Test Selection screen.

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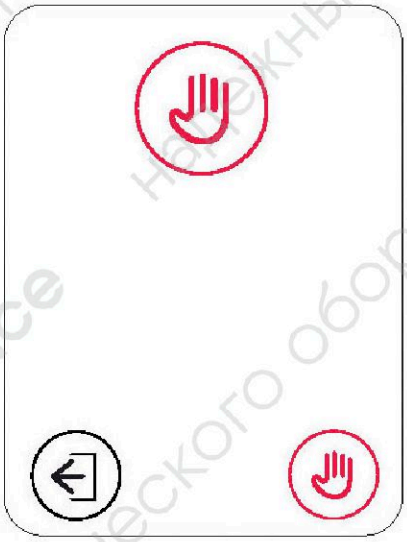
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7.4 MANUALLY STOPPING A CYCLE OR A TEST

A sterilisation or test cycle can be manually stopped at any time.

DO NOT INTERRUPT THE CYCLE BY SWITCHING OFF THE POWER SUPPLY TO THE UNIT as this may cause damage. Always use the manual stop procedure indicated in this paragraph.

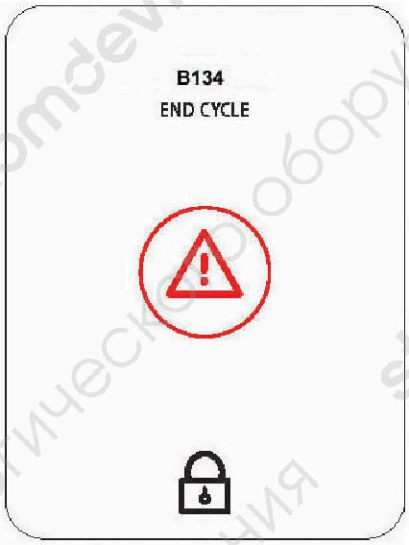
To perform a manual stop, press the **RED HAND** button in the Cycle in Progress screen, and then the **RED HAND** button in the next screen. This procedure applies to all sterilisation and test cycles.



At this point, the steriliser will start a sequence of operations allowing the steam to be safely discharged and return the boiler pressure to the external level.

7.4.1 Manually stopping a cycle before or during the sterilization phase

If a cycle is stopped before the sterilisation phase has terminated, the load in the boiler must be considered as NOT STERILE. After the manual stopping operations, an error screen appears on the LCD display. The door is locked. Touch the screen to release it.



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7.4.2 Manually stopping a cycle after the sterilization phase

If a cycle is stopped after completion of the sterilisation phase but before the end of the drying phase, the load in the boiler is to be considered as STERILE BUT WET. As the load has not been dried correctly, it is not possible to preserve it and it must therefore be considered as being for IMMEDIATE USE. The sterile but wet load screen appears on the display. The door is locked. Touch the screen to release it.



7.5 POWER BLACKOUTS

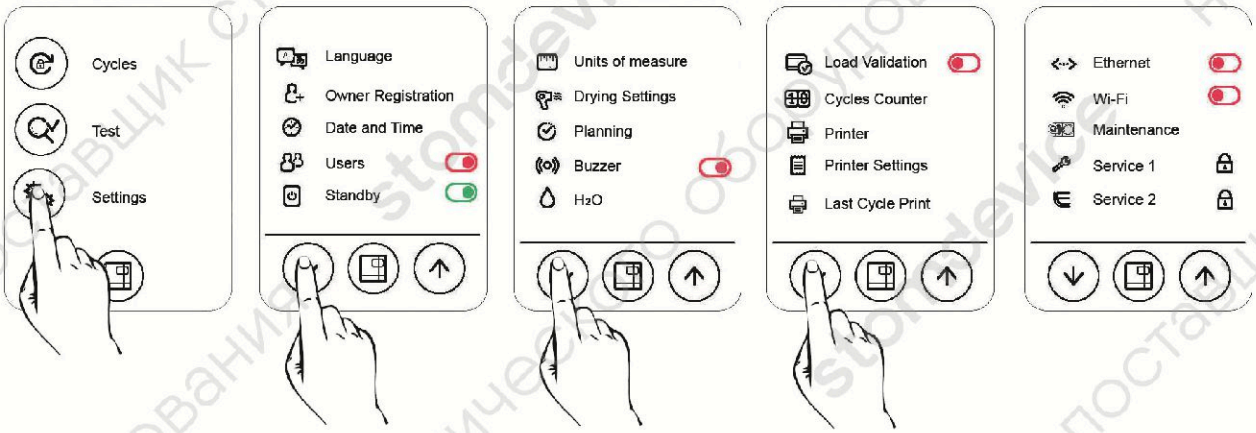
Power cuts may occur during the operation of the unit, caused by the electricity provider. In this case, the E 02 alarm message appears (see “Appendix 9 Troubleshooting”).

7.6 RESETTING THE UNIT AFTER AN INTERRUPTION CAUSED BY AN ALARM

To recover the unit after an interruption caused by an alarm, touch the screen to release the door and return to the Home screen. For further information, consult “Appendix 9 Troubleshooting”.

7.7 SETTINGS

In the HOME screen, touch SETTINGS to access the settings menu.

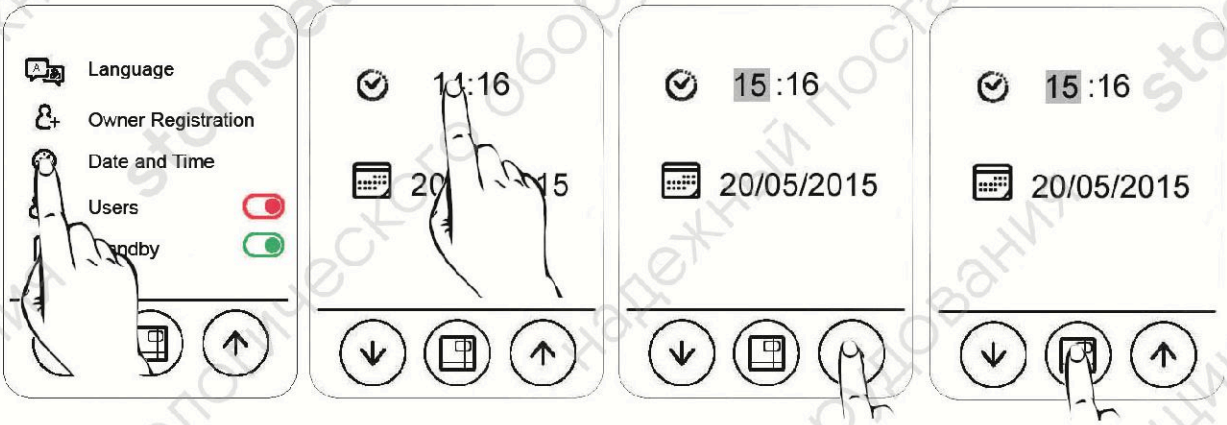


Touch the arrows to scroll through the settings menu. Touch the central icon to return to the start screen. This menu can be used to set the various operating parameters of the steriliser.

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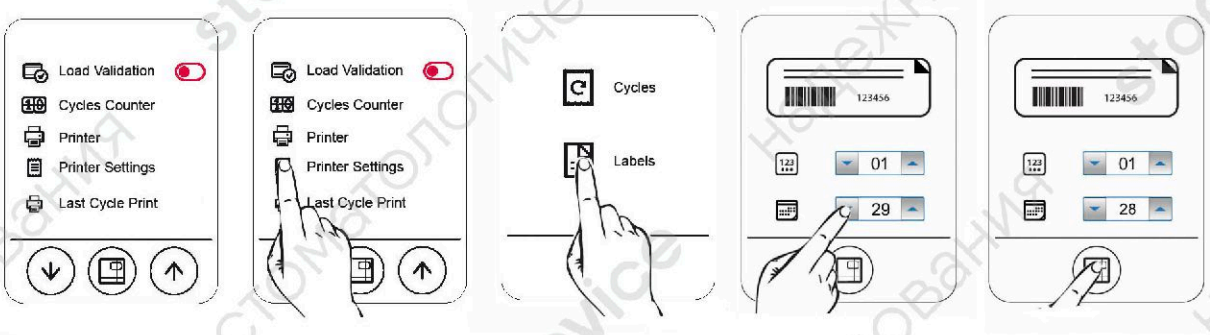
7.7.1 Date and time set up

To change the date and time simply touch the field to change, which will turn grey, and change the value using the up and down arrows. The various changes made will become active once confirmed by pressing the central key, therefore leaving the specific screen.



7.7.2 Expiry days and label number set up

In label printing mode, the unit prints the sterile condition expiry days on the labels.
By default the unit assigns an expiry of 30 days, and the number of labels to print to 0.
In order to change the number of labels, simply select/touch the upper field, and change the value using the up and down arrows. Use the lower field to change the expiry days. The various changes made will become active once confirmed by pressing the central key, therefore leaving the specific screen.

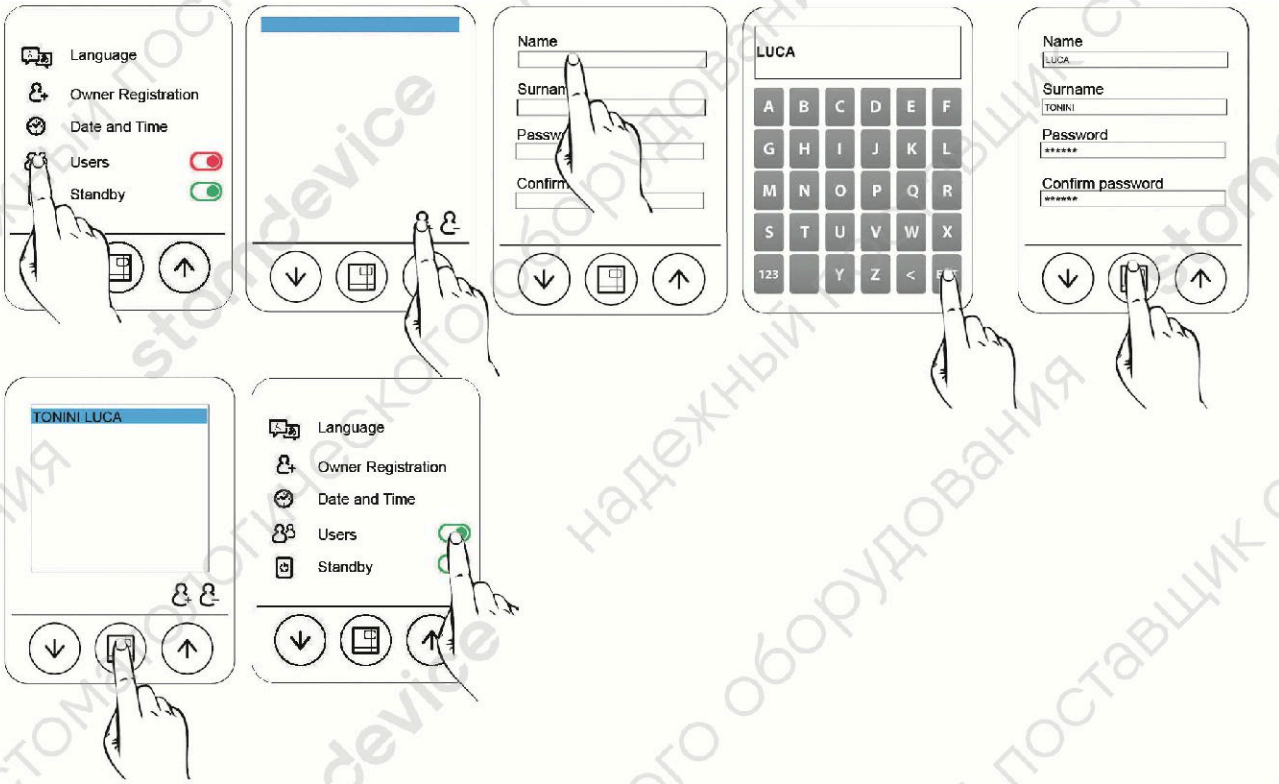


7.7.3 User set up

The unit gives the possibility of associating each sterilisation cycle to the user launching it. By default, this function is not enabled. To enable it, simply touch the Users icon. Enter a list of users, with the name and surname of each one of them. Each user must be allocated a password. Once all users have been entered, the user list can be activated by touching the icon on the right, which will turn green.

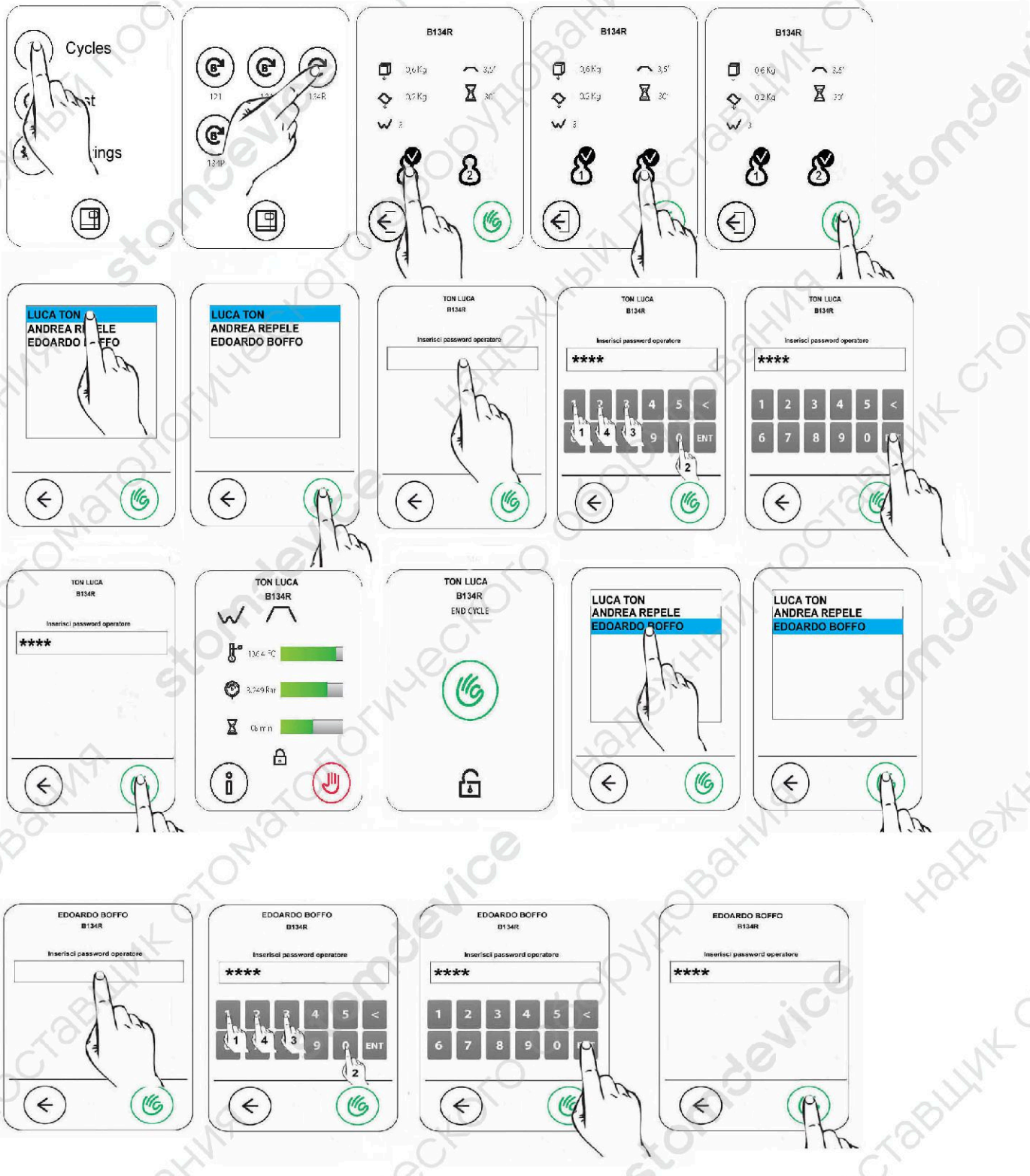
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When the cycle is launched, the user will be able to select the user name on the list of generic users (OPERATOR 1, OPERATOR 2, etc.).

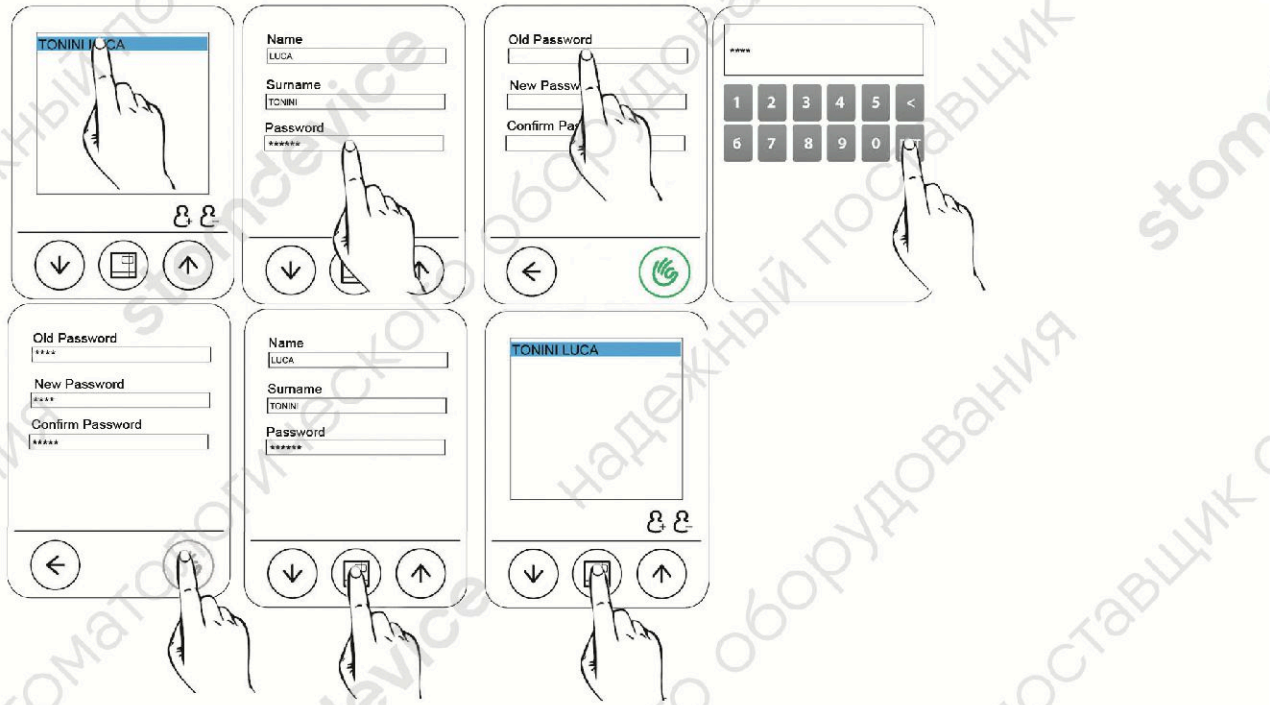
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The user password can also be changed at a later stage.
To change the password, enter the Users menu, select the user whose password must be changed, and select the password field.
A new screen will appear, where it will be sufficient to enter the old password, the new password, and the confirmation of the new password.

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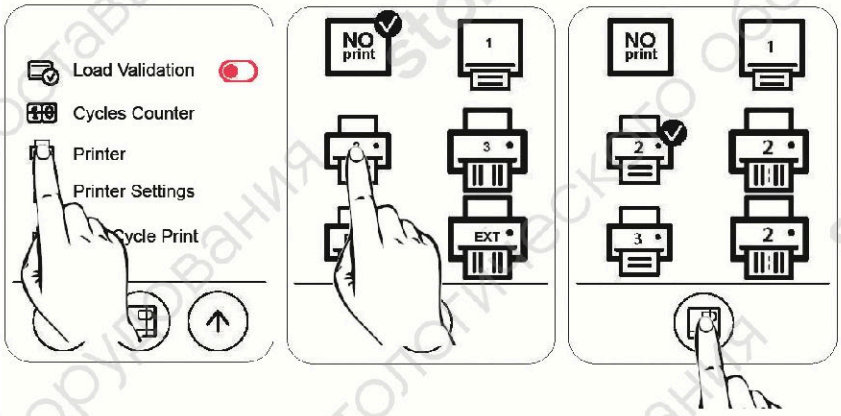
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7.7.4 Printer and printer type set up

The unit can have 3 optional printer types (integrated thermal printer, integrated label thermal printer, and external label thermal printer). By default, the machine uses the printing off mode. After electrically and mechanically connecting the desired printer, for interfacing it with the autoclave proceed as follows. The following printer selection options are available:

1 = integrated thermal printer
2 = integrated label printer
2 - larger icon = integrated barcode label printer
EXT = external label printer
EXT - larger icon = external barcode label printer



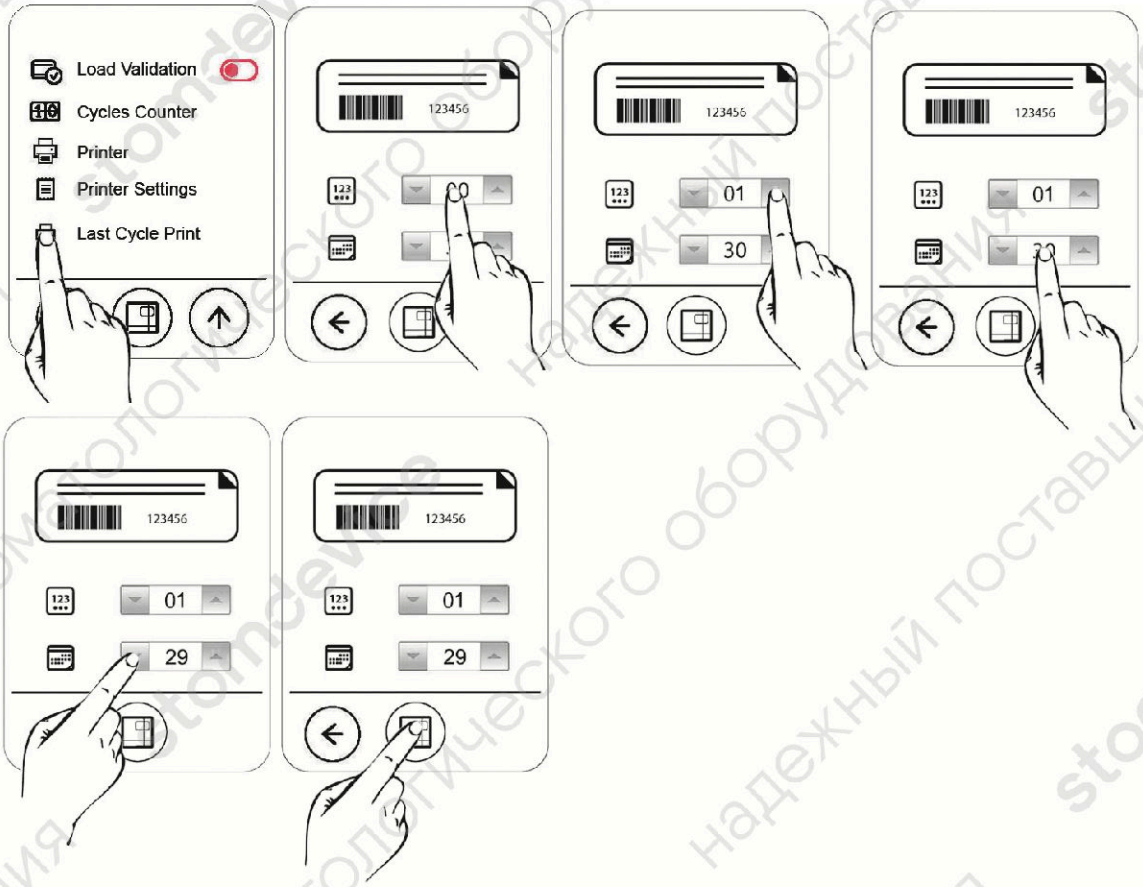
Once the printer has been selected, at the end of each cycle the same will print the receipt and the number of labels set, plus one "status transfer" label, to confirm the end of the cycle.

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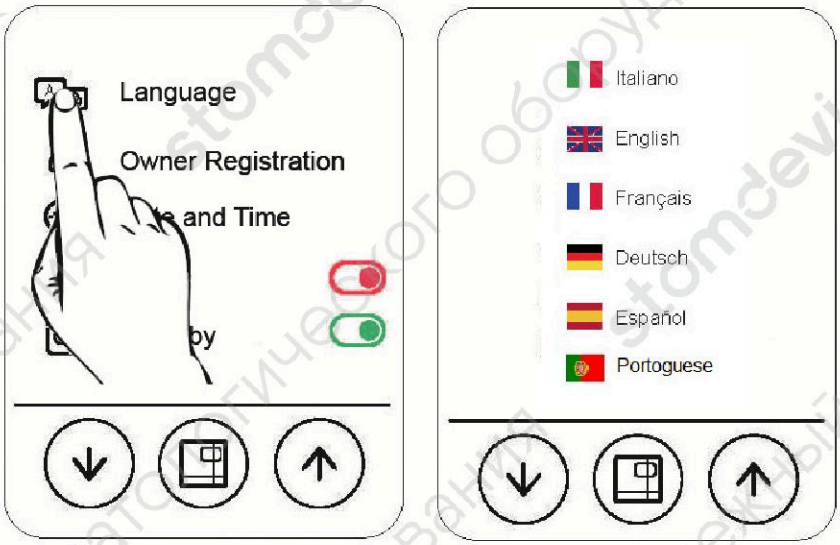
7.7.5 Label reprinting management

If a label roll is exhausted during printing, the unit gives the possibility of reprinting the labels. The cycle will complete normally without printing the labels. In this case, enter the settings menu and touch the Last Print Cycle icon. Then set the number of labels and the expiry.



7.7.6 Language set up

To set the language of the steriliser, simply touch the appropriate flag and check that the ticking mark appears.

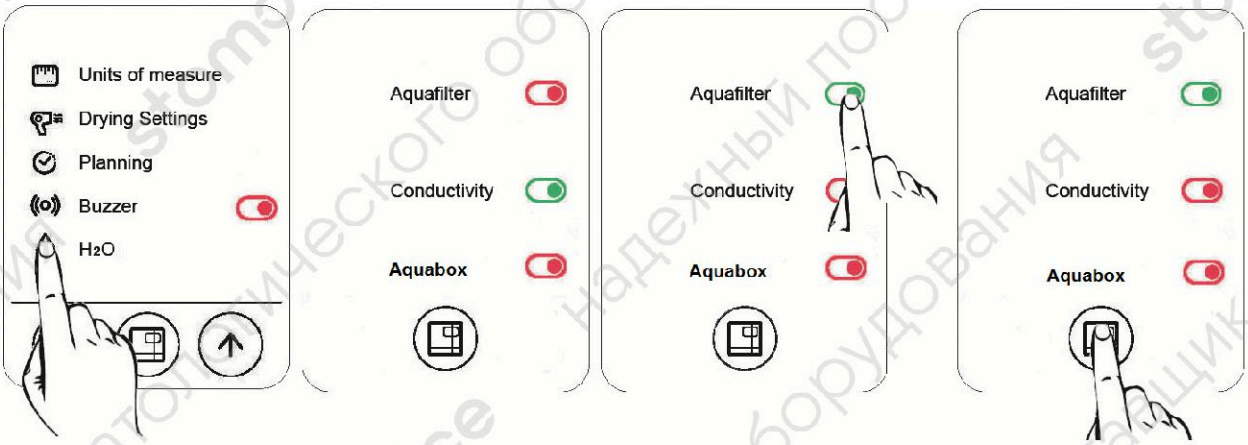


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7.7.7 Aquafilter setup

An acquafilter can be installed on the autoclave. This is a device giving the possibility of automatically obtaining the water required for the operation of the steriliser through direct connection to the water mains. After completing the required hydraulic connections, select aquafilter in the settings menu. Proceed as shown below

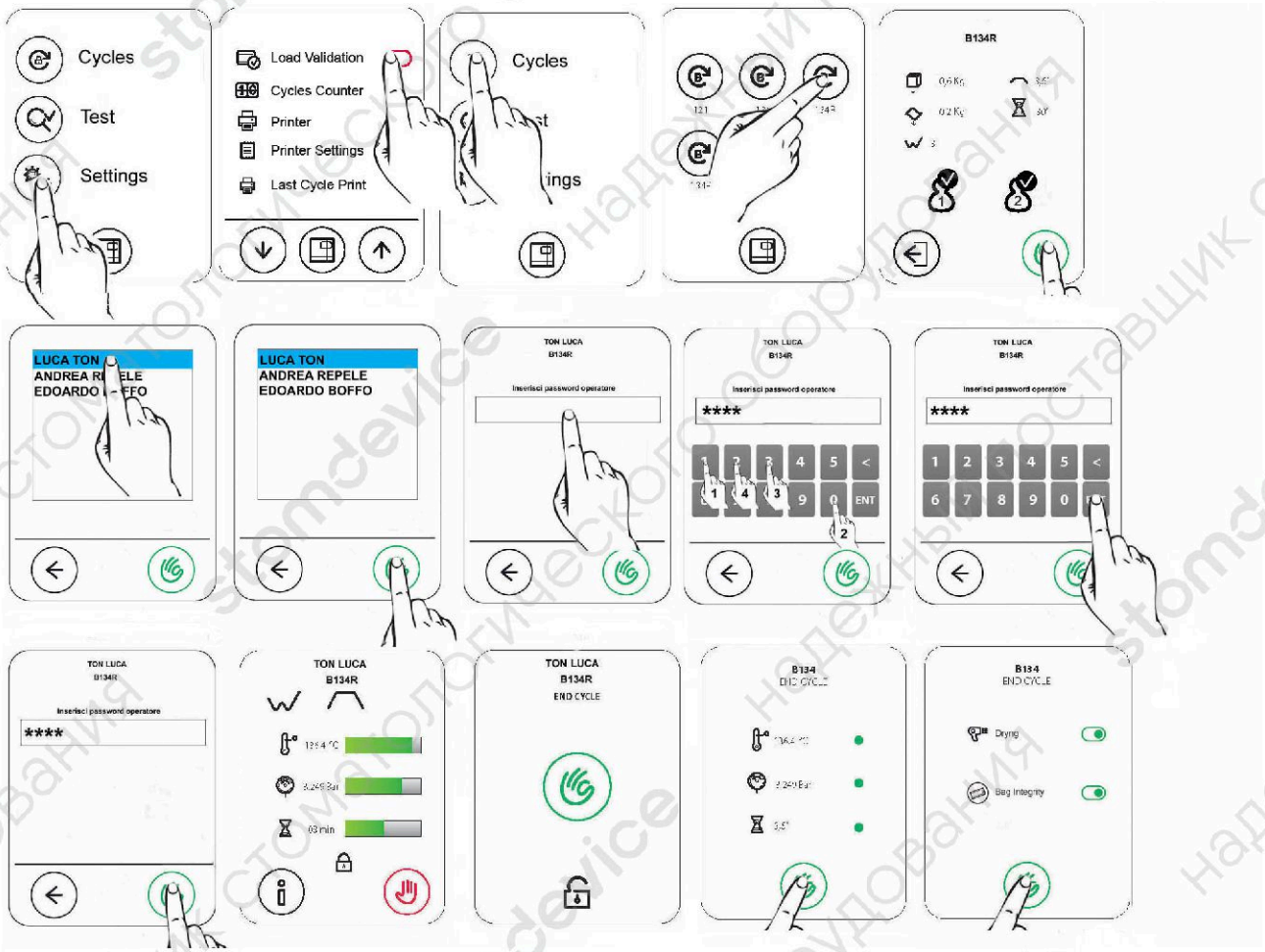


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7.7.8 Release of the load through the identification of the user

Once the list of users has been entered, if the load release function is activated using the settings menu, also load release through the user identification function is activated. While this function is active, when the door is opened at the end of the cycle, if the load is sterile the autoclave asks users to identify themselves by selecting their names in the user list. The user can then decide if to release the load, reject it, or accept it for immediate use. Once accepted, if the unit is connected to a label printer, at the end of the operation the labels will be printed. The unit will also record the decision.

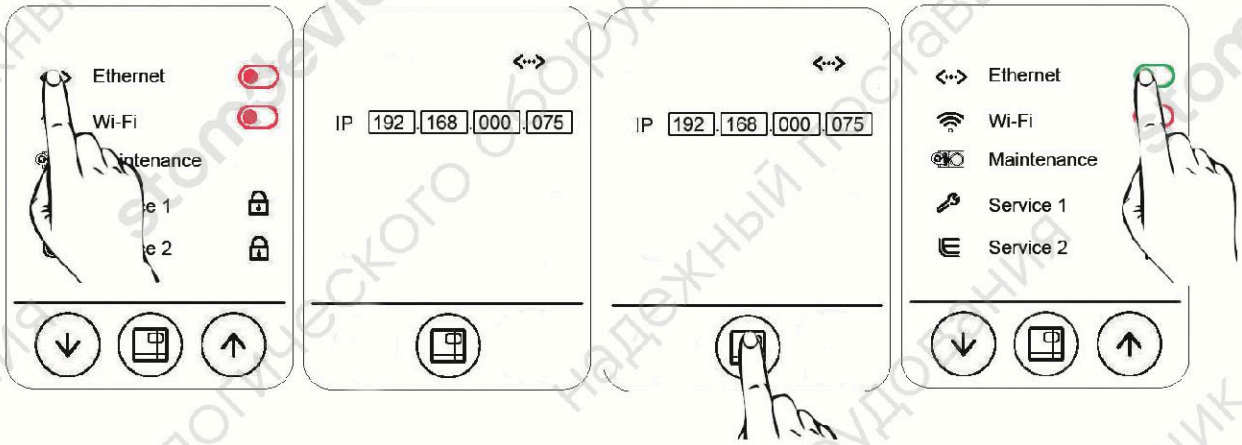


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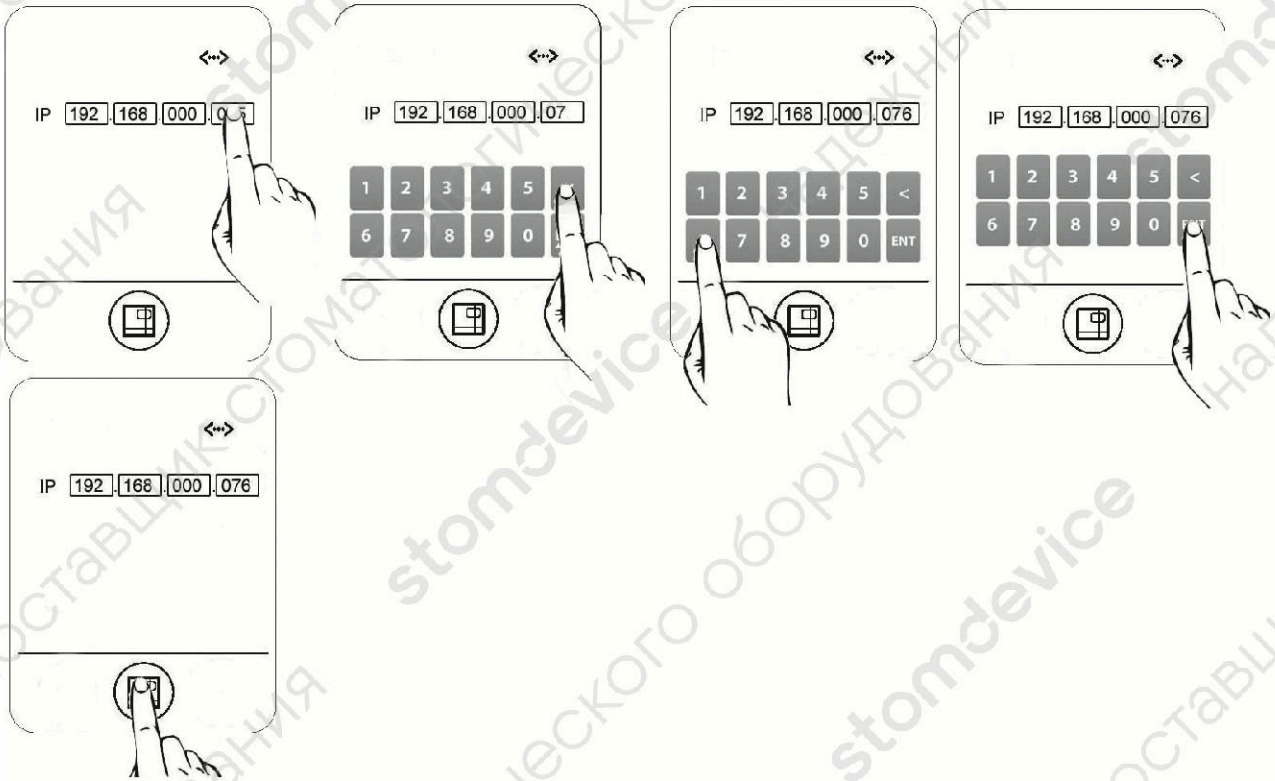
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7.7.9 Ethernet connection set up

To activate the autoclave Ethernet connection proceed as shown in the figure.



The default IP address is 192.168.0.75. This can be changed for adaptation to the own network.



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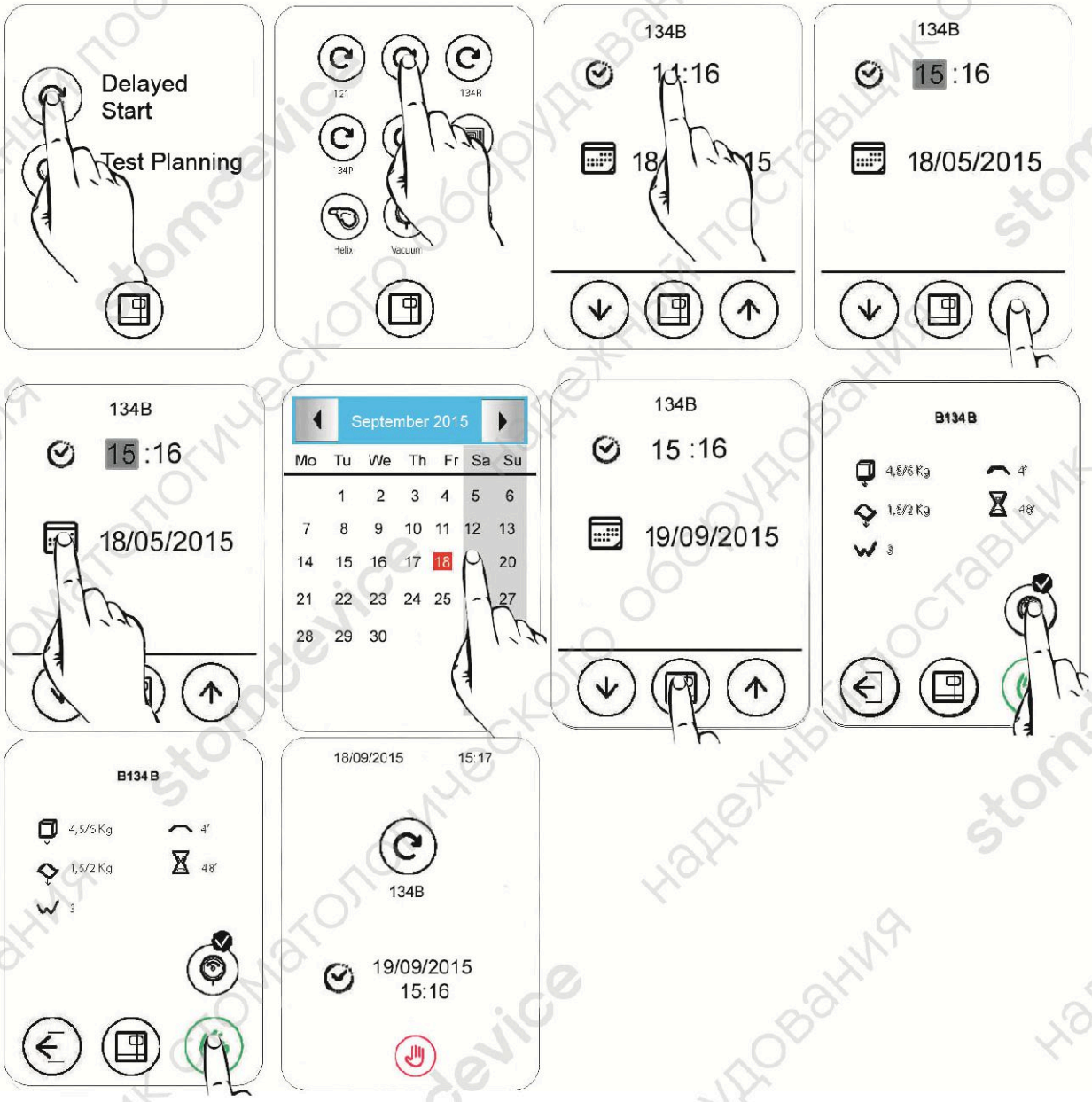
7.7.10 Planning set up

Select the "**Planning**" icon. This will give the following two possibilities:
a) Delayed start
b) Test planning

a) Delayed start

It is possible to plan the start of a cycle or a test for a precise day and time.
The delayed start occurs if the autoclave is left on, with the door closed, and the water level above the minimum.
On the set day and time, the autoclave automatically starts the planned cycle and/or test.
The following combinations are possible:
-Vacuum Test
-Bowie & Dick
-Helix Test
- Vacuum Test followed by the cycle
- Cycle
- Vacuum Test followed by Helix Test
- Vacuum Test followed by Bowie & Dick Test
If a Vacuum Test is planned, the autoclave only completes it if the machine is not hot. The next planned cycle will only start if the Vacuum Test is successful.
To plan a delayed start follow the instructions in the figure:

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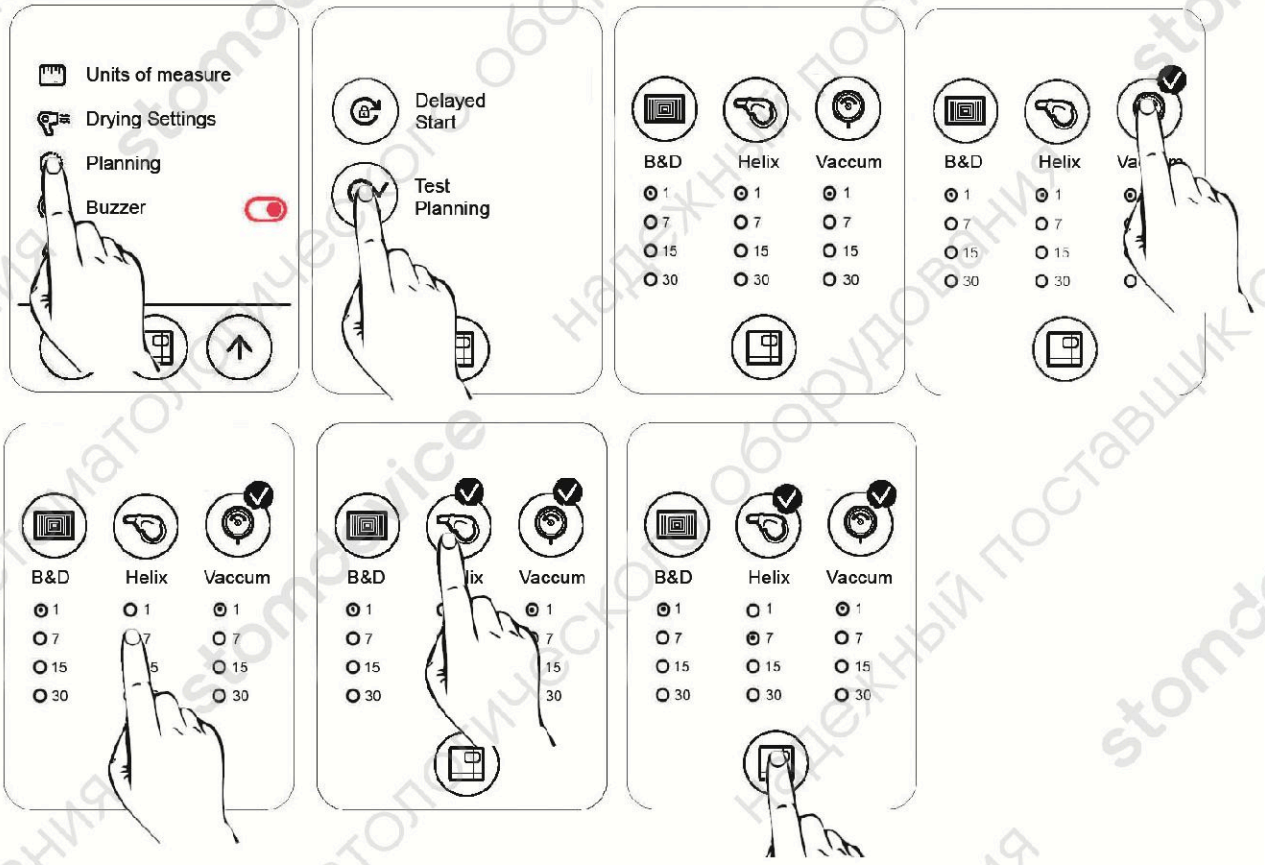
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b) Test planning

It gives the possibility of setting test execution intervals (Bowie & Dick, Helix, Vacuum).

After the expiry of the set interval, when the autoclave is switched on, the user is reminded to execute the required test.

To activate this function proceed as indicated in the figure



7.9 LONG PERIODS OF INACTIVITY

1. Disconnect the unit from the mains supply.
2. Empty the tanks (chap. 6.7 "Tanks: Instructions for filling and draining").
3. Leave the door ajar.
4. Cover the unit with the polyethylene hood supplied with the unit, to protect it from humidity and dust.

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CHAPTER 8

8.1 E-MEMORY SOFTWARE

The E-memory software is used to manage the data saved to the SD card by copying it to a PC database.

8.1.1 Minimum system requirements

- Operating system: Windows 98 SE, Windows NT, Windows 2000, Windows XP.
- Processor: Intel® Pentium® III, 600 MHz or higher.
- Microsoft® Internet Explorer® 5.0 or higher.
- 150 Mbyte of Hard Disk.
- RAM: minimum 128 Mbyte, recommended 256 Mbyte or higher.
- Display resolution 800x600 or higher and 65000 colours or higher.
- Peripherals: CD ROM or DVD ROM.
- Keyboard and mouse.
- Printer.
- SD card reader or USB interface.

8.1.2 Installing the E-Memory software

Make sure that the specifications of the computer and operating system are compatible with the requirements of the E-memory Software (see "MINIMUM SYSTEM REQUIREMENTS").
Make sure no other applications are running during the installation procedure.
N.B.: in the example, the letter "D:\" is used to indicate the letter assigned to the CD-ROM drive: this may differ from system to system.
Insert the CD-ROM into the CD-ROM drive; the E-Memory Software Installer programme will start automatically.
If this does not happen, proceed as follows:

a) click on "Start" and select "Run"
b) type [D:\setup\setup.exe] (where D: is the CD-ROM drive) and click on Next to run the installation programme.
   Click on Next to continue installation.
   Note: the default installation folder is [C:\Programmes\memory]. Click on "Browse" to change folder.

CAUTION: at the beginning of the installation procedure the programme looks for all the components required for installation: if one or more components are not found, the installation programme will install it and will then ask the user to reboot the system.
After rebooting the PC, perform the above operation.

The programme will search for Microsoft Access 2000 Runtime or Microsoft Office 2000 or later releases.
If it fails to find one of these two components, the Access 2000 Run time installation screen will appear: installation will take a few minutes after which the computer will have to be rebooted.
After rebooting, run the setup.exe file once again.
N.B. if, after failing to find Access 2000 Runtime or Microsoft Office 2000, the system does not run the Runtime installation programme automatically, consult the "TROUBLESHOOTING" paragraph.

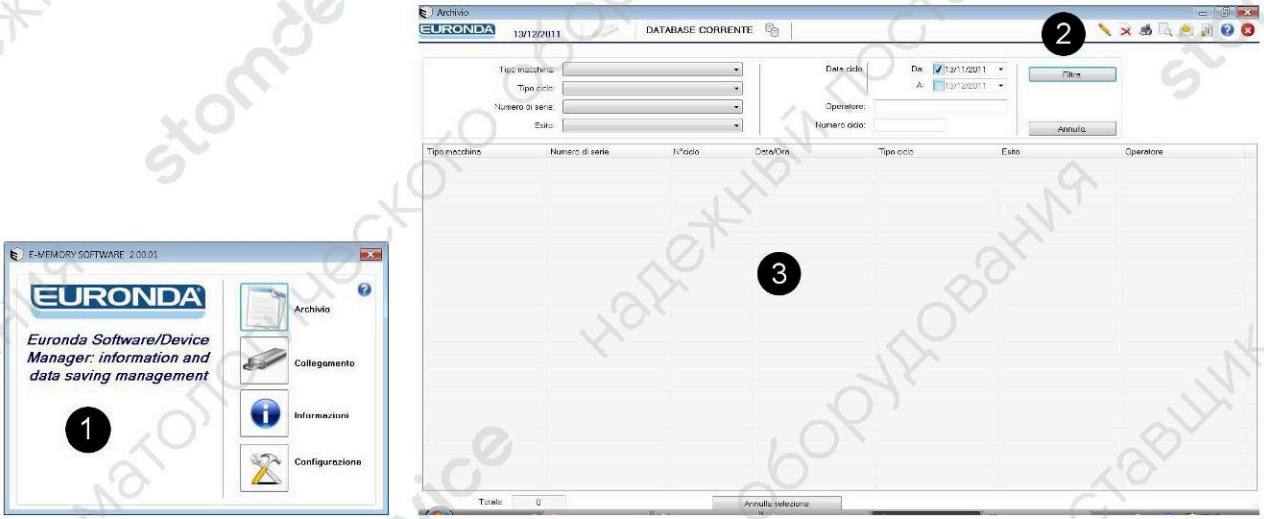
If E-Memory Software is installed to Windows 98SE, they memory drivers will be installed first.
Afterwards, run the setup.exe file again.

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8.1.3 User interface

Use the following path to run the E-Memory Software:
"Start" → Programmes → E-Memory Software → E-Memory
or click twice on the desktop icon.
The following screen appears (you may have to wait a few seconds):



For ease of use, this screen is split into three areas:
1 • task bar **2 • control bar** **3 • work area**

1 - **Task bar**
This is divided into four sections:
File: this is the E-Memory Software home page which manages the device cycles.
Link: this screen shows the status of the device connected to the PC (SD card memory) and all the autoclaves (models and serial numbers) present in the software file.
Information: gives information on the software and database releases.
Setup: all programm settings are made here: language, user personal data entry, password entry and personal data transfer from the E-Memory Software to the device and vice-versa.

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2 • Control bar

 This button is used to display the name of the operator, if set, and enter the lot number (if you wish to associate the test with the relative cycle).

 Deletes the selected cycle: enter the password to delete the cycle.

 Directly prints all selected cycle data.

 Provides a print preview of the selected cycle.

 Sends one or more selected cycles by e-mail. An e-mail client (MS Outlook, Becky, FoxMail, ThunderBird, etc.) must be installed on the PC.

 Generates the certificate for the selected cycles.

 Opens the on-line guide.

3 - Work area

This screen displays all the cycles acquired by the E-Memory Software; you may use the “Filter” option to make selective cycle searches by result, date, type, cycle number or device serial number. To select multiple cycles, hold down CTRL or SHIFT (CTRL to select cycles one by one or SHIFT to select them sequentially) and click on the required cycles with the left-hand mouse button. Press “Cancel selection” to deselect the selected cycles.

Note: The “Print preview” function is not available for multiple cycles.

8.1.4 General warnings

Never delete memory files from “Explorer” as they would be completely irretrievable.

Manage the data in the SD card memory only and exclusively from the E-memory Software.

Periodically back up your data by copying the MEM_DB.MDB file to the application installation folder C:\Programmes\memory



The maker declines all liability for the loss of any data from the memory or PC if it is used incorrectly or inappropriately.

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8.2 SOFTWARE CONFIGURATION



1 - Programme language, click on modify to change the interface language:

2 - User data entry: this data then appears on the cycle print header. The “Read from machine” function allows you to import data from the device (if previously entered) while the “Write into machine” function allows you to export data from this screen to the device.

3 - User logo can be used to enter a small drawing or photo. This photo appears in the header of the cycle print page near the user data. Operator name, instead, can be used for reasons of traceability to indicate the name of the person performing sterilisation operations.

4 - Setting the password: the password is requested whenever you attempt to delete one or more cycles from the file screen, delete the external memory or modify the password. When entering the password, you are asked to confirm it by typing it in again. The predefined password is “certificate”.

5 - Default e-mail: you may enter a predefined e-mail address in order to e-mail cycle data to a previously entered address.

6 - Totally deletes the cycles in the SD Card memory.

NOTE: All modifications must be saved before they have any effect: after making a modification, hold the cursor over any field and click on the button.

8.2.1 User management

To personalise the list of available users, once the SD card is placed in the PC, enter the configuration menu, select board 2, then click "User Management".
At this point a table will be displayed, on which a list of personalised users can be entered. When clicking “Write in E-memory” the list will be saved on the SD card and then detected by the sterilizer.
The steriliser can store up to 5 different users.

Turn the steriliser off and then on again so it detects the new user list.

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8.3 INSERTING AND REMOVING THE SD CARD

Turn off the steriliser before removing the SD memory card. Put the SD memory card back in before turning the unit on again. The absence of the SD memory card during operation may cause errors.

Do not perform cycles if the SD memory card is not inserted: if cycles are performed without the SD memory card, or if the card is removed during the cycle, the corresponding cycle data will be lost.

To insert and remove the SD memory card into/from the slot, simply push it in (ensuring that the pin faces the front of the autoclave) until it clicks in position.

If the SD card enters the slot with difficulty, do not force the mechanism and check it was inserted in the right direction.

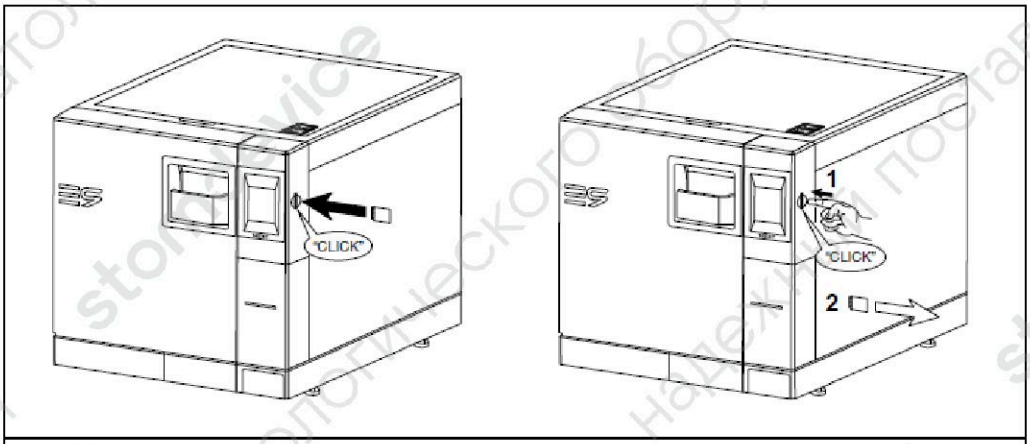
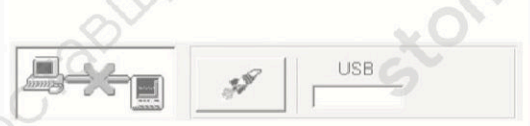


Fig. 8.3-1

You may check is the PC recognises the external memory correctly by seeing if it appears as a “Removable disk” in “Explorer”.
The E-memory Software indicates the state of the device in the Links page; the following conditions may occur:

	• USB device not connected. • USB device not found. • USB device found but MEMORY.DAT marker file missing. • USB box empty.
	• USB device found but SETUP.DAT machine description file missing or incorrect. The USB box indicates the hard disk.
	• OK, sterilisation cycles being loaded.

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	• OK, but there are no new cycles to load.
	• Cycle read errors **(red LED on the left).**

Note: "USB device" means the SD memory card, whether it is connected directly to the PC or via the SD card-USB adaptor.

Rapid data acquisition button : the application normally acquires the data in slowly so as to minimise the use of PC resources. To accelerate acquisition (e.g.: if the SD memory card contains many cycles) click on this button. The function is automatically disabled following acquisition.

Safe removal of the SD memory card: to remove the card use the **Windows Safely Remove Hardware** procedure which ensures that all the operations are completed on the device. This procedure can also be accessed from the **Connection** section of the E-memory Software by clicking on the button.
The system asks whether you wish to continue with the procedure and, if so, it terminates the programme after running the Windows procedure.

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CHAPTER 9

9.1 SAFETY WARNINGS



Before performing any maintenance operations, carefully read the following safety instructions and, especially, chap. 3 "Safety".



CAUTION: when replacing components that directly or indirectly affect **safety**, it is essential to only use **ORIGINAL SPARE PARTS.**



HAZARD: HIGH INTERNAL VOLTAGES.

CAUTION: DISCONNECT THE POWER SUPPLY BEFORE STARTING WORK. Non-observance may cause serious injury to people or may seriously damage the unit.

ALL MAINTENANCE OPERATIONS MAY ONLY BE PERFORMED BY THE RESPONSIBLE AUTHORITY OR BY THE TECHNICIANS AUTHORISED BY THE ASSISTANCE SERVICE OF EURONDA S.p.A.

- Observe the intervals prescribed or indicated in this manual.
- It is forbidden to remove the safety devices installed on the machine (see chap. 3.3 "Safety devices"). Check them at regular intervals.
- If an effective danger situation arises, press the ON-OFF button (4 of Fig. 5.1.1-1) immediately.
- Unauthorised people must stay at a safe distance from the machine during maintenance operations.

9.2 ORDINARY MAINTENANCE

Just like all electric units, this unit must be correctly used, serviced, and checked at regular intervals. These precautions will ensure continuous, safe, and efficient use of the unit.
To prevent operator hazards, the unit must be subject to regular checks and servicing by the technical assistance service.

- For good preservation of the unit, periodically clean all external parts with a soft cloth damped with normal neutral detergent (do not use corrosive or abrasive products).
- Do not use abrasive cloths, pads or metal brushes (or anything abrasive) to clean the metal.
- Before starting each cycle, clean the door seals carefully using a damp cloth.
- The formation of white stains on the base of the chamber shows that the demineralised water used is of poor quality.

Maintenance programme

FREQUENCY	OPERATION
DAILY	Cleaning of the door seal. General cleaning of the external surfaces. General cleaning of the internal surfaces.
WEEKLY	Cleaning of the sterilization chamber. Cleaning of the trays and the support.
ANNUALLY	Maintenance of the safety valve.
EVERY 500 cycles	Replacement of the bacteriological filter
EVERY 1000 cycles	Replacement of the seals
EVERY 1000 cycles/2 years	1000 cycle maintenance kit replacement
EVERY 1500 cycles/3 years	Replacing the bacteria filter and the seals.
EVERY 2000 cycles/4 years	2000 cycle maintenance kit replacement

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EVERY 2500 cycles/5 years	Replacing the bacteria filter and the seals.
EVERY 3000 cycles/6 years	3000 cycle maintenance kit replacement
EVERY 3500 cycles/7 years	Replacing the bacteria filter and the seals.
EVERY 4000 cycles/8 years	4000 cycle maintenance kit replacement
AFTER 10 YEARS	Request a structural check of the chamber.
WHEN NECESSARY	Adjustment of the closing mechanism.

Cleaning the sterilization chamber, accessories, door and seal

Sterilization chamber

Clean the sterilisation chamber thoroughly (Fig. 9.2-1), after having removed the tray support, using a non-abrasive damp cloth.

To dampen the cloth, use only and exclusively distilled or demineralised water. Follow the same procedure for cleaning the trays and their support. Cleaning the sterilization chamber is important for eliminating deposits that could compromise the good working order of the machine. To remove the tray support: remove the support from the chamber (Fig. 9.2-2) and, after finishing cleaning, refit it following the same procedure in the reverse order.

CAUTION: DISCONNECT THE POWER SUPPLY BEFORE STARTING WORK. Non-observance may cause serious injury to people or may seriously damage the unit.

CAUTION: take care not to damage the probe at the bottom of the chamber.

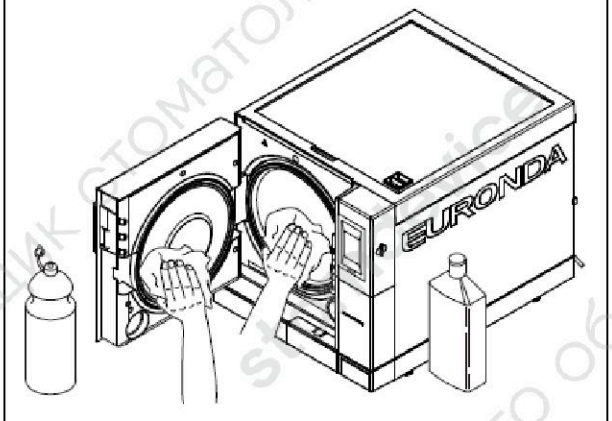


Fig. 9.2-1

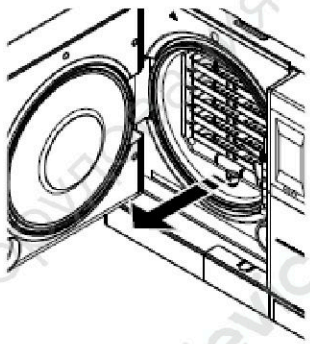


Fig. 9.2-2

Do **NOT** use disinfecting substances to clean the chamber.

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Seal and door

Clean the seal and the door with a damp cloth (Fig. 9.2-3), dampened with water or vinegar, to eliminate traces of lime-scale. Cleaning should be carried out to remove any impurities that could cause a lack of pressure in the sterilisation chamber and possible cuts in the seal.

ATTENTION: do not allow residues of lime-scale or dirt to accumulate on the seal, since these can damage or break it over time.

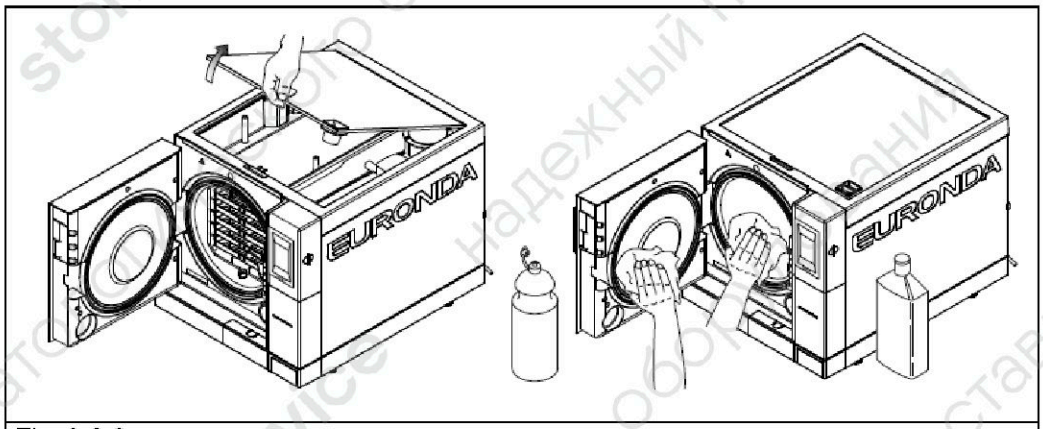


Fig. 9.2-3

To maintain the unit in good working order, periodically clean all the external parts using a soft cloth and normal neutral detergents or just water (do not use abrasive products).

DO NOT use solvents that could damage the external plastic components of the unit.

DO NOT wash the unit with direct sprays or high-pressure jets or water, since any infiltration into the electrical components could prejudice the working of the machine and the safety systems.

Emptying and cleaning the tanks

CAUTION: DISCONNECT POWER SUPPLY. Non-observance may cause serious injury to people or may seriously damage the unit.

ATTENTION: if the unit is not used for more than three days, both tanks should be emptied to prevent deposits from forming.

1. Empty the clean water tank: fit the end of the tube with the connector into the connector at the bottom of the front panel (1 of Fig. 9.2-4), and the other end into an empty container.
2. Empty the internal tank for collecting used water: fit the end of the transparent tube into the connector at the bottom of the front of the unit (2 of Fig. 9.2-4) and the other end into an empty container.
3. At the end of the draining operation, remove the tube from the connector by pressing its button.

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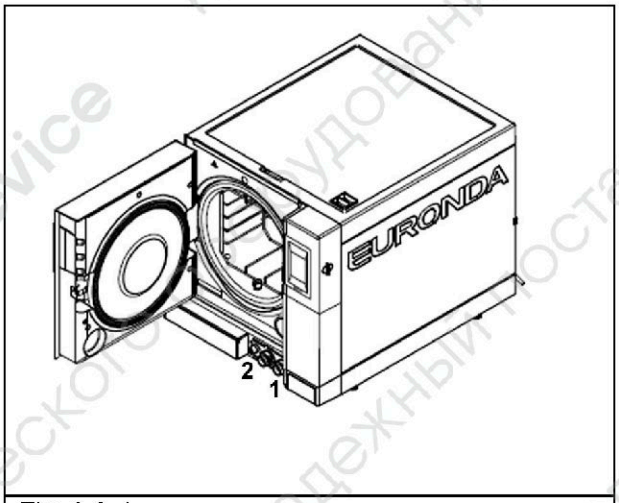


Fig. 9.2-4

4. Remove the cover in order to access the tanks:
   - lift the cover by 45° (Fig. 9.2-5) and pull it towards you (Fig. 9.2-6).

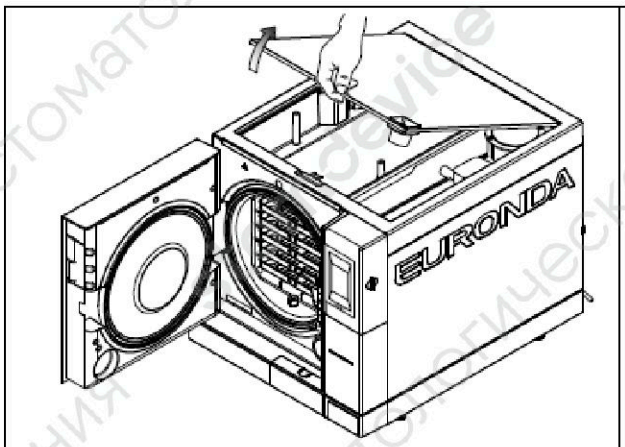


Fig. 9.2-5

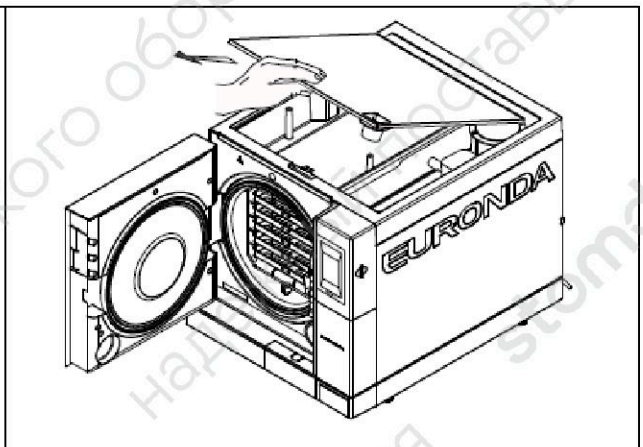


Fig. 9.2-6

5. Carefully clean the tanks with the sponge supplied and water. Use the soft side of the sponge, not the abrasive side. Clean with care, paying particular attention to any dirt that may have deposited in the corners.
6. Remove the filters of the clean and dirty water tank (Fig. 9.2-7), rinse away any deposits under running water and then reinstall them in the tank, taking care to position them correctly.

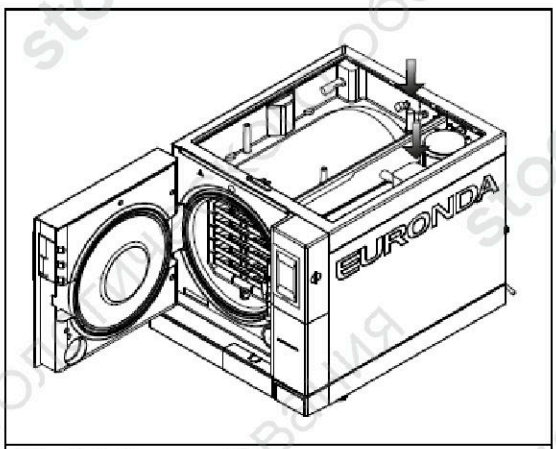


Fig. 9.2-7

7. **Rinse thoroughly** and empty the water used for this operation.

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8. Run a sterilization cycle without loading the unit.

ATTENTION: While performing all cleaning operations, **be careful not to damage the floating level sensors** situated in the tanks.

9.2.1 Periodic maintenance

CAUTION: DISCONNECT THE POWER SUPPLY BEFORE STARTING WORK. Non-observance may cause serious injury to people or may seriously damage the unit.

Drain pipe
Periodically check this for damage and replace if necessary.

Servicing the safety valve

CAUTION: HIGH TEMPERATURE. Only perform this operation when the machine is cold.

CAUTION: DISCONNECT THE POWER SUPPLY BEFORE STARTING WORK. Non-observance may cause serious injury to people or may seriously damage the unit.

1. Access the safety valve mounted at the rear of the machine.
2. Turn the plug (Fig. 9.2.1-1) located on the upper part of the valve anti-clockwise until it reaches the end of the thread and turns loose.
3. Return the plug to its original position, screw it back on and repeat the operation from the beginning at least a couple of times.

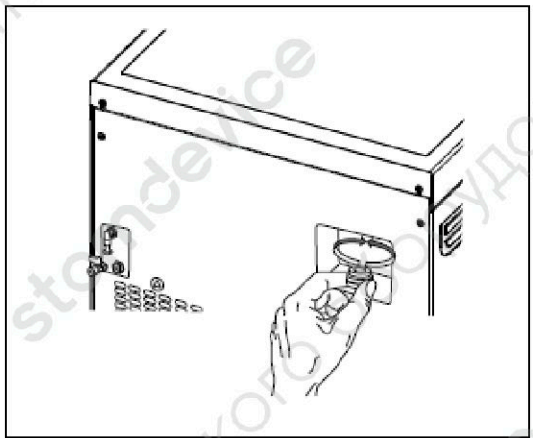


Fig. 9.2.1-1

CAUTION: this operation ensures the safety valve works correctly over time. Make sure the plug is properly closed afterwards.

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9.2.2 Adjustment of the closing mechanism

CAUTION: HIGH TEMPERATURE. Only perform this operation when the machine is cold.

The closing mechanism of the unit occasionally requires adjusting due to normal settling of mechanical parts and wear on the seal gasket. This is particularly important as a poor seal may prevent the pressure from increasing to the level set for the selected program and therefore jeopardise the result of the cycle. Proceed as follows:

1. Open the door. **Always work with the unit cold.**
2. Fit the supplied adjustment lever (Fig. 9.2.2-1) into the slot under the door (Fig. 9.2.2-2).

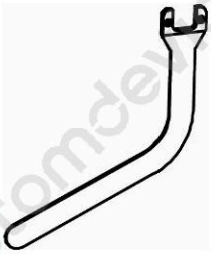


Fig. 9.2.2-1

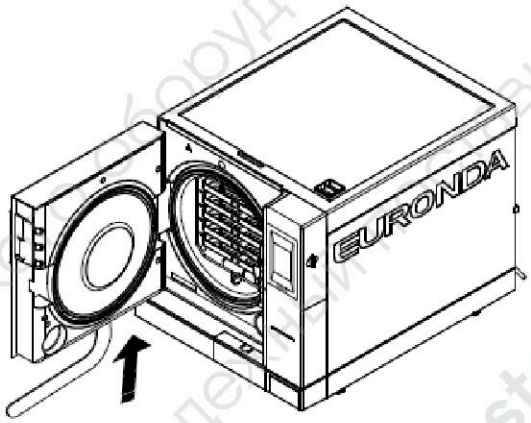


Fig. 9.2.2-2

3. Look through the slot of the door hook to make sure the lever has engaged the adjustment pin. (Fig. 9.2.2-3).

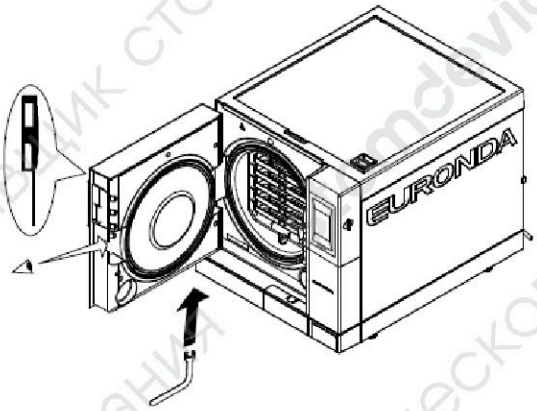


Fig. 9.2.2-3

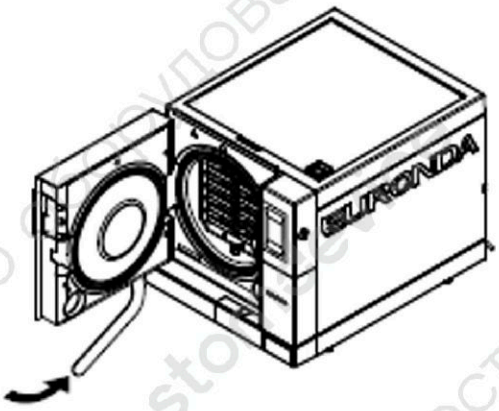


Fig. 9.2.2-4

4. Turn the adjustment pin anticlockwise, looking at the door gasket, by 1/4 of a turn (to close) (Fig. 9.2.2-4).
5. Check that the door closes properly. If the handle is too hard to close, turn a little in the opposite direction (clockwise).
6. Carry out a test cycle to check it is correctly adjusted.

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9.3 EXTRAORDINARY MAINTENANCE

Any jobs not mentioned above are considered as extraordinary maintenance. In these cases, contact specialists authorised by Euronda S.p.A.

CAUTION: extraordinary maintenance must be performed by qualified staff only.

The bacteriological filter and the gasket are components that are not covered by the guarantee.

Service maintenance

After 1000 cycles or after two years from installation it is necessary to carry out a general overhaul of the unit. This can only be performed by specialists authorised by Euronda S.p.A.

ATTENTION: extraordinary maintenance must only be performed by specialists authorised by Euronda S.p.A..

Replacing the bacteriological filter

- Unscrew the bacteriological filter (7 of Fig. 5.1.1-2) by turning it anticlockwise
- Screw on the new filter by turning it clockwise until it is tight.

Replacing the door seal

- Grip the lip of the seal with two fingers and remove it;
- Clean the seat of the seal with a cloth soaked in alcohol;
- Fit the new seal into the seat located in the door and distribute it evenly around the circumference by applying the same pressure on the entire gasket with your fingers. Then lift up the lip of the gasket to make sure no points have been badly fitted.
- Switch on the steriliser, close the door making sure the correct closing force is required; if necessary, adjust the closing force with the relative adjustment wrench.

To simplify insertion of the new gasket in the slot use neutral soap diluted 1 to 10 with water.

Cleaning the drain filter

When necessary, clean the drain filter at the front of the boiler; unscrew the filter as shown in the figure (fig. 9.3-1), rinse it under running water and then screw back in place.

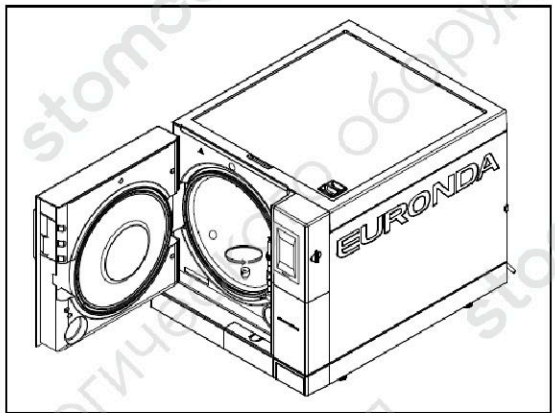


Fig. 9.3-1

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9.3.1 Rusting

The formation of rust on the surfaces of the unit or instruments is caused by the introduction of rusty instruments, even if made from stainless steel, or of instruments in normal steel that cause galvanisation to take place.
The introduction of a single instrument with a rust stain is often sufficient to form and develop rust on the instruments and in the unit itself.
Another factor that causes the formation of rust in the steriliser is the use of water containing chlorine, such as drinking water, sea water or water containing disinfectants or detergents. **Only use good quality distilled water.**



CAUTION: DISCONNECT THE POWER SUPPLY BEFORE STARTING WORK. Non-observance may cause serious injury to people or may seriously damage the unit.

If rust forms in the unit, clean the walls of the sterilization chamber and the tray holder using special products for stainless steel, as described previously in the paragraph “Cleaning the sterilization chamber, accessories, door and gasket”.



CAUTION: do not use metal sponges or brushes. Use a damp soft cloth to remove dirt stains.

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CHAPTER 10

10.1 INSTRUCTIONS FOR DISPOSAL

The **E9 NEXT** unit has been manufactured using ferrous materials, electrical components and plastics. To scrap the unit, separate the various components according to the material they are made of in order to simplify reuse or differentiated disposal.
No particular operations are required after scrapping.
Do not dump the unit.
Take it to a disposal company.
Always refer to the specific laws in the country of use when scrapping and disposing of the appliance.

The symbol  on the appliance means that it must be disposed of as “sorted waste”.

The user must therefore send (or instruct other people to send) the unit to one of the sorted waste collection centres set up by the local councils, or send it to the dealer against the purchase of an equivalent unit (European Union only).

Sorted waste collection and the subsequent treatment, recovery and disposal operations facilitate the production of equipment using recycled materials and limit the negative environmental and health effects that may be caused by improper waste management.

Abusive dumping by the user will be punished according to law.

10.2 RESALE

If the unit is sold, hand over all the technical documentation to the new purchaser, inform him/her about any repair work carried out and how to use and service the unit.
Also inform Euronda S.p.A. of the sale and provide it with data about the new purchaser.

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APPENDIX 1	**Preparing the instruments for sterilization**

A correct sterilization depends on the processes described below being carried out correctly; these are all equally important and, therefore, care must be taken while performing them.

1. Preparing the instruments to sterilise
2. Packing
3. Loading
4. Sterilization
5. Preserving the sterilized instruments
6. Routine maintenance of the unit

All the objects must be decontaminated and carefully cleaned and dried before being sterilised. In the case of instruments with parts that are joined to each other, divide the parts or open them as wide apart as possible. In the case of overalls or other reusable fabrics, these must be washed and dried after use and before sterilization, to remove organic material and lengthen the "life" of the fabric, restoring it with its natural water content (i.e. degree of humidity).

The objectives of the initial decontamination procedure are as follows:

a) inactivating bacterial proliferation
b) preventing mutual contamination while handling instruments
c) preventing any products on the instrument from drying
d) protecting personnel

Decontamination is carried out using detergents and, generally, solutions that are active against HIV, HBV and HCV, or by washing at 93°C for ten minutes in thermo-disinfectors. Observe the indications given in the technical data sheets of the products used.

The instruments are cleaned so as to eliminate blood, saliva, dentin and organic substances in general, that may damage the materials to be sterilised, or even the steriliser itself. The use of ultrasound baths is recommended, which offer numerous advantages with respect to traditional cleaning methods, such as efficacy, speed and delicacy on the object being cleaned; always follow the recommendations provided by the respective manufacturers. In general, after ultrasound cleaning with detergent and/or disinfectant, rinsing the instrument is recommended, in that the disinfectant may take on corrosive characteristics as a result of the heat.

Always wipe out any solutions carefully to avoid residues of moisture. Once dry, the instruments to be steam sterilised in the unit must be appropriately packaged, whereas those to be cold sterilised must be immersed in the appropriate chemical solution (glutaraldehyde, paracetic acid, etc.).

It is also important to check the instruments being used: avoid to sterilise instruments showing:

- breaks
- stains
- rust
- single-use devices that cannot be reused

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APPENDIX 2	Packaging

The correct packaging of the materials is essential in ensuring that sterility is maintained. Packaging of the instruments is done so as to maintain the materials sterile until the time of their use.

The way in which the sterilized instruments are packaged, and then stocked, determines the state of preservation of sterilization.

The following can be used as containers: metal containers with lids or perforated bottoms with filters in paper, pouches in paper or polypropylene, Medical Grade paper or trays that are perforated or with grilles. Pouches in paper-polypropylene are excellent packaging systems for steam sterilizing small sets of surgical instruments or individual instruments.



Use materials that comply with **EN ISO 11607-1** for packaging the materials to sterilize.



Do not re-sterilize the pouches in paper-polypropylene and the Medical Grade, in that they undergo a substantial change in their structural characteristics and would no longer guarantee the characteristics of “protective barrier”.

For packaging, observe the following recommendations (for pouches in paper-polypropylene):
1. Contents must not exceed ¾ of the volume of the pouch
2. There must be a space of at least 30 mm between the instrument and the welding strip.
3. The instruments must be positioned so that they can be extracted by their handle
4. The sealing strip on the pouch must be continuous with a height of at least 6 mm (UNI EN 868-5).

Each package prepared must at least indicate the date of sterilization, the type of cycle performed and the date in which the preservation of sterility expires; this latter value must be established considering the length of preservation of sterility as indicated by the manufacturer of the packaging material, the internal procedure used and the stocking conditions of the sterilized material itself.
Instruments packaged in individual pouches have a life (in terms of sterility) of 30 days, those in double pouches of 60, if kept in closed cabinets. These values are, in any case, to be considered indicative, in that the date of preservation is influenced by various factors, such as the environmental microbic level, the granulometry of environmental dusts (that act as carriers of micro-organisms), as well as the temperature, pressure and ambient humidity parameters and the degree of handling of the sterilized material.
Packaging methods that make it possible to avoid partial withdrawals and that allow for mono-patient use are optimum.



CAUTION: use Euronda Eurosteril® sterilization tape rolls to wrap objects or use pouches or rolls marked CE in accordance with Directive 93/42/EEC.

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APPENDIX 3 Positioning the load

The way in which the load to sterilize is arranged is also considerably important to the sterilization process. Always observe the maximum load indicated in this manual, a value that has been tested by the manufacturer and that is therefore valid.

- Always use the tray supports, to facilitate the circulation of steam.
- Do not load trays that are not being used.
- Where it is necessary to sterilise loose instruments, it is advisable to cover the tray with sheets of Tray Paper, to avoid any direct contact of the instruments with the tray.
- Ensure that instruments of different materials are separated and placed on different trays.
- For improved sterilisation results, open instruments such as pincers, scissors, or other composite instruments.
- Position the instruments sufficiently distant from one another that they remain separate for the whole sterilisation cycle.
- Do not overfill the trays with instruments: overloading may compromise the quality of the sterilisation.
- Mirrors should be placed glass side down.
- Do not stack the trays on top of each other, always use the tray supports. It is necessary to leave a space between each tray to allow for the circulation of steam during the sterilization phase and then to facilitate drying.
- Place a chemical sterilisation indicator on each tray.

- *Tubes*
  - After the tubes have been cleaned normally, rinse them using water without pyrogene.
  - Place them on the tray so that the two ends are open and so that they do not bend or twist.

- *Packages*
  - Place the packages upwards, next to each other, do not allow them to come into contact with the sides of the chamber.

- *Material in pouches*
  - When sterilizing material in pouches, do not overlap the pouches on the trays (Fig. A3-1).
  - Place the pouch with the transparent side face down (in contact with the tray) and with the paper face up (Fig. A3-2). Instruments must be put into separate pouches.

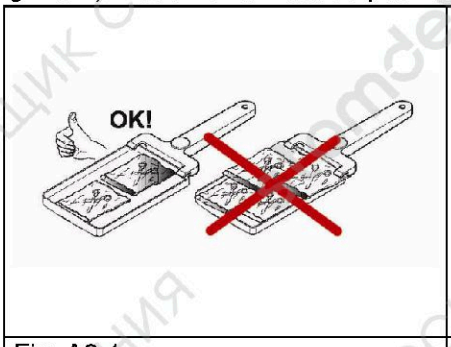


Fig. A3-1

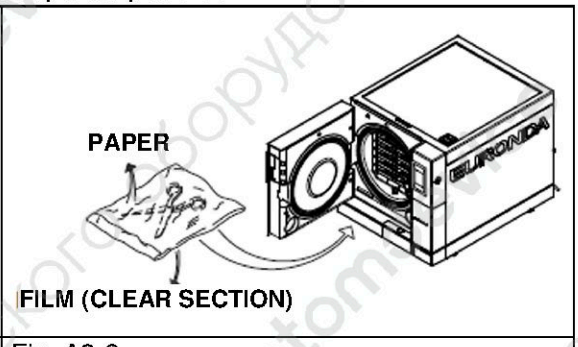


Fig. A3-2

After following the instructions above, put the tray holder and trays into the sterilization chamber.

CAUTION: insert the tray support and the trays, paying particular attention not to damage the door gasket.

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APPENDIX 4	Unloading and preserving sterilized instruments

The material is at the greatest risk of contamination while it is still hot, because the barrier capabilities of the packaging materials are much lower in the presence of residual humidity, compared to an ambient temperature situation. The materials, therefore, should not be stacked once they have been extracted, in order to favour the dispersion of heat.
Wait for the material to drop to room temperature before stocking it: before stocking, make sure that the packages are intact and check the chemical colour change; if the package is broken or torn, the load can only be used immediately, in that preservation of sterility cannot be guaranteed.
The material should be stocked in sealed cabinets, 30 cm away from the floor and 5 cm from the ceiling; if this is not possible, protect the material in nylon bags.



For the duration of the sterile condition refer to the current regulations of the country of use, and to the statements of the manufacturer of the packaging used.

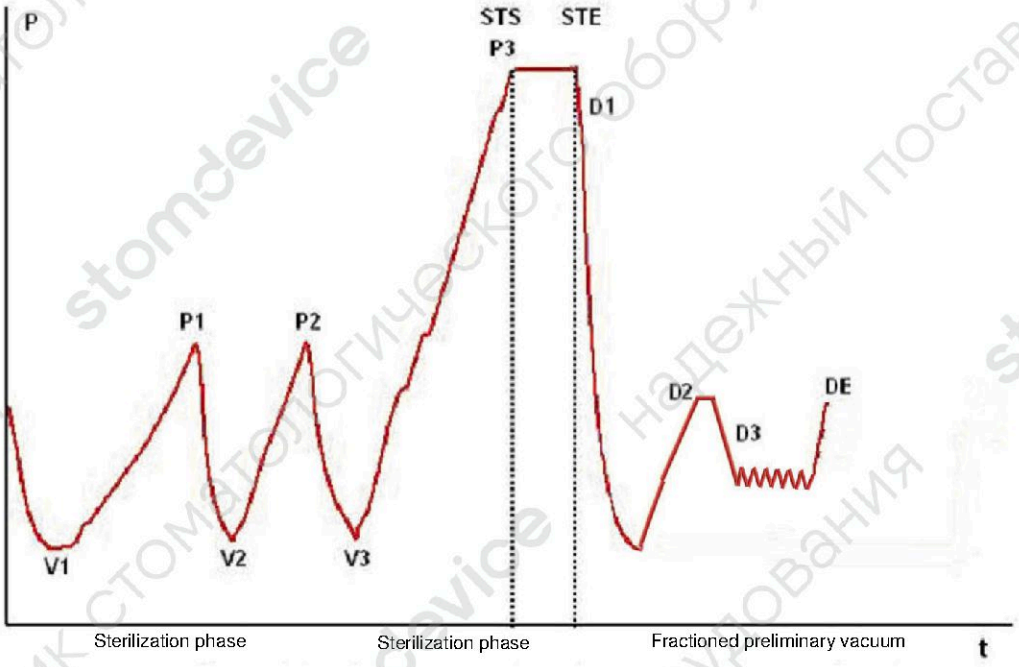
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APPENDIX 5 Description of programs

The E9 NEXT unit can perform three sterilization cycles; the parameters of each cycle are summarised in the table below:

Cycle / Parameters	B134	B134 PRION	B121	B134 RAPIDO / B134 PRION RAPIDO
	NEXT 18/24L	NEXT 18/24L	NEXT 18/24L	NEXT 18/24L
Temperature	135.5°C	135.5°C	121.5°C	135.5°C
Pressure	2.15 bar	2.15 bar	1.15 bar	2.15 bar
Length of sterilization phase (plateau period)	4'	18'	20'	3.5' / 18
Drying time (Auto)	15'	15'	15'	5'
Maximum load (solid/porous)	**4.5/1.5 kg – 6/2 kg**	**4.5/1.5 kg – 6/2 kg**	**4.5/1.5 kg – 6/2 kg**	**0.6/0.2 kg – 0.6/0.2 kg**



The cycle profile may vary from one software version to another.

Fractioned preliminary vacuum	V1	1st vacuum
	P1	1st pressure rise
	V2	2nd vacuum
	P2	2nd pressure rise
	V3	3rd vacuum
	P3	3rd pressure rise
Sterilization phase	STS	Start of sterilization period
	STE	End of sterilization period
Drying	D1	Start of drying phase
	D2	End of swift drying phase
	D3	Start of common drying phase
	DE	End of common drying phase

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The symbols (2b, 3c, etc.) after the code of the phase refer to the software instructions.
The various sterilisation cycles are now described one by one: as they are all B-type cycles, they can sterilise any type of load, whether it be porous, solid or hollow. **In all cases, the recommendations given by the manufacturer regarding sterilization methods and times should be followed.**

Program B 121
This program is used to sterilize objects that are sensitive to temperature, as well as rubber, some articles in plastic and porous materials (cotton, fabrics) in open trays, or appropriate perforated trays.
Hollow instruments and dental instruments such as tubes and similar objects can also be sterilized, after making sure that they have previously been cleaned, disinfected and rinsed. The objects indicated above can also be sterilized without the use of pouches.
This program is particularly suited for sterilizing products in pouches (both single and double pouches), products that will have to be kept sterile for a long period of time.
The length of this cycle depends on the weight of the load, on the type of load and on the temperature in the chamber upon start-up of the cycle.

Program B 134
This program can be used both to sterilize solid instruments and porous materials (cotton, fabrics, etc.) in open trays or using the specific perforated trays. Loads arranged both in single and in double pouches can be sterilized.
Hollow instruments and dental instruments such as tubes and similar objects can also be sterilized, after making sure that they have previously been cleaned, disinfected and rinsed. The objects indicated above can also be sterilized without the use of pouches.
This program is particularly suited for sterilizing boxes of products in pouches, products that will have to be kept sterile for a long period of time.
The length of this cycle depends on the weight of the load, on the type of load and on the temperature in the chamber upon start-up of the cycle.

Program B 134 PRION - B 134 PRION RAPIDO
This program is used to sterilize instruments suspected to have been contaminated by prions. The program makes it possible to sterilize articles, packed in single or in double pouches, in open trays or in specific perforated trays.
Hollow instruments and dental instruments such as tubes and similar objects can also be sterilized, after making sure that they have previously been cleaned, disinfected and rinsed.
The objects indicated above can also be sterilized without the use of pouches.
This program is particularly suited for sterilizing boxes of products in pouches, products that will have to be kept sterile for a long period of time.
The length of the cycle depends on the weight of the load, on the type of load and on the temperature in the chamber upon start-up of the cycle.

Program B 134 RAPIDO
For solid loads not exceeding 0.6 kg and for porous loads not exceeding 0.2 kg is possible to execute a swift cycle that allows to sterilize the load in an average time of 30 minutes. The RAPIDO cycle includes 5 fixed minutes of drying that allows the load to get dried even if put into envelopes.
It is important to remember that the load being sterilised must be placed in the highest available position of the tray support, and that correct drying cannot be guaranteed for loads in pouches exceeding the indicated weight.

Light Program (N121 and 134)
Thanks to this program you can sterilize only solid instruments, not wrapped, and not hollow, till 6 kg. for the 24 lt. version. The 18 lt. model admits a load of maximum 4,5 kg.
Type N cycles cannot be used to sterilize wrapped or hollow instruments: you cannot guarantee steam penetration due to the absence of vacuum phases.
This kind of cycle does not permit storage of instruments.

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Light & Stock Program (S121 and S134)
With this program it is possible to sterilize only solid single wrapped instruments (not hollow).
You can sterilize at maximum 4,5 kg. with the 18 lt. model, and 6 kg. with the 24 lt. version.

APPENDIX 6 Description of Tests

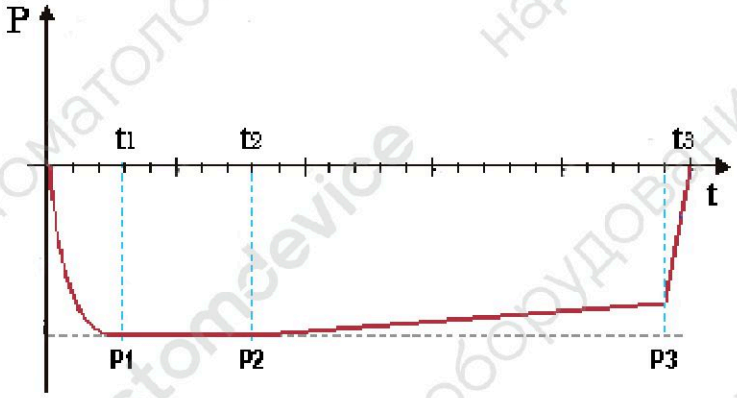
It is important to periodically verify the performance of the unit by performing the appropriate tests; E9 can perform three different ones:

- **B&D test**
- **Vacuum test**
- **Helix test**

The parameters of the respective cycles are as follows:

Parameter Cycles	VACUUM	B&D	HELIX
	NEXT 18/24L	NEXT 18/24L	NEXT 18/24L
Temperature	--------	135.5°C	135.5°C
Pressure	minimum pressure	2.15 bar	2.15 bar
Length of sterilization phase (plateau period)	--------	3'30''	3'30''
Drying time	--------	--------	--------
Total time	21'	26'	26'

Vacuum test



The sole purpose of the diagram is to illustrate the quality performance of the cycle

This test is performed in order to check the performance of the unit, in particular:

- the efficiency of the vacuum pump;
- the seal of the hydraulic circuit.

The cycle is structured as follows:

1. a vacuum is created to the minimum pressure value indicated in the load pre-treatment phase
2. this pressure is maintained for 5 minutes and then measured
3. this pressure is maintained for 11 minutes and then measured

In compliance with EN13060, the test requires a tightness test of less than or equal to 1.3 mbar/min during the 10 minutes of test; if the leakage is greater than this value, the outcome of the test is negative; the seal of the hydraulic circuit of the device must be checked.

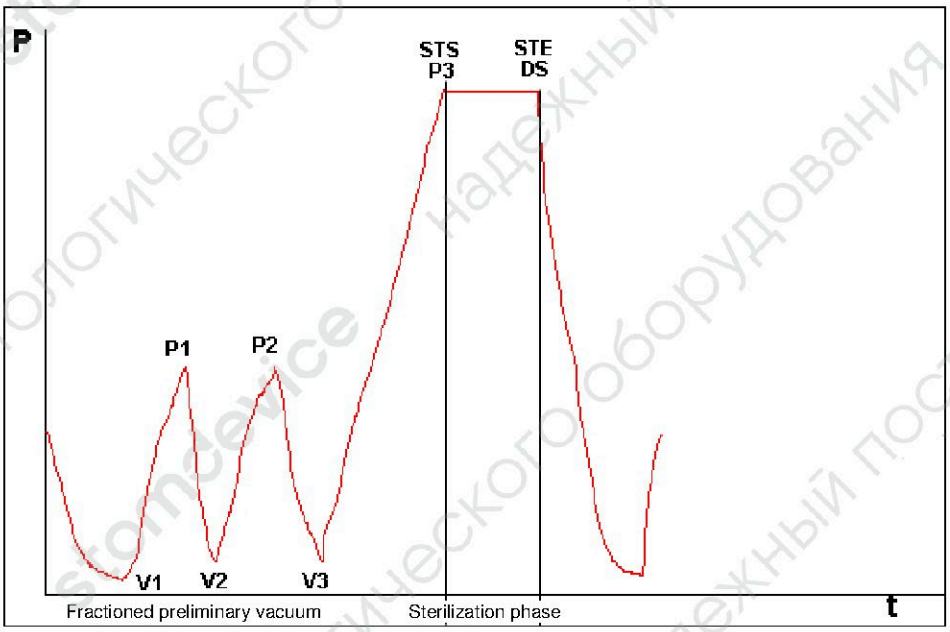
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Bowie & Dick test

This is a chemical-physical test that is also known as the Brown test: the indicator is a heat-sensitive sheet that is placed in the middle of a packet made up of various layers of paper and foam rubber.
The B&D test simulates the performance of the unit with regard to the sterilization of porous loads, in particular:

- the efficiency of the preliminary vacuum and the penetration of steam within the cavities
- the temperature and pressure values of the saturated steam during the sterilization phase



The packet for the B&D test must be inserted on its own, preferably on the lowest tray, with the label facing up. After performing the cycle, specifically the B134 cycle, immediately verify the test. Being careful while handling the packet (it is still hot), remove the indicator sheet and follow the instructions given in the package for evaluating the result of the test.

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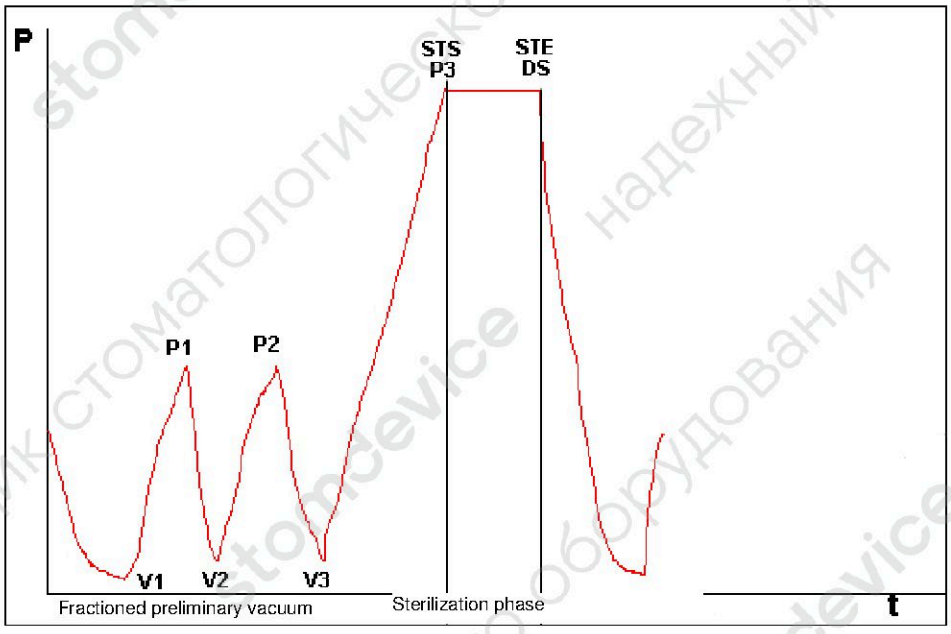
Helix test

The Helix test represents a hollow A-type load, i.e. the load with the most critical characteristics.
The test consists of a 150 mm long PTFE tube with a 2 mm internal diameter.



The Helix test simulates the performance of the unit with respect to the sterilization of hollow loads, in particular:

- the efficiency of the preliminary vacuum and the penetration of steam within the cavities
- the temperature and pressure values of the saturated steam during the sterilization phase



After placing the strip in the capsule, position the tube on the lowest tray inside the sterilization chamber.
At the end of the cycle, take the tube out immediately (with care in that the load is still hot) and verify the result of the test, referring to the indications given on the package.

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APPENDIX 7	Validating the cycles

With reference to standard EN 13060, the following cycles have been validated:

	B134 B134 RAPIDO	B134 PRION B134 PRION RAPIDO	B121
Dynamic pressure of the chamber of the sterilizer	•	•	•
Air leakage	•	•	•
Empty chamber	•	•	•
Solid load	•	•	•
Small porous articles	•	•	•
Light porous loads	•	•	•
Full porous loads	•	•	•
Hollow load B	•	•	•
Hollow load A	•	•	•
Multiple packaging	•	•	•
Dryness, solid load	•	•	•
Dryness, porous load	•	•	•

A number of definitions that are of use in understanding the table above follow:

- Solid load: non-porous article, without notches or other characteristics that may hinder the penetration of steam in an equal or greater amount than those of a hollow load.

- Porous load: material that is capable of absorbing fluids; in particular this regards:
  A. a full porous load when the load occupies 95±5% of the usable space.
  B. a light porous load when the load occupies 20-25% of the usable space.
  C. a small porous load when the load occupies 0.5-5% of the usable space.

- Hollow load **A**: space open at one end in which 1≤L/D≤750, where D is the diameter of the cavity and L the length, with L≤1500mm, or space open at both ends in which 2≤L/D≤1500, with L≤3000mm and that is not hollow load B.

- Hollow load B: space open at one end in which 1≤L/D≤5, where D is the diameter of the cavity and L the length, with D≥5mm, or space open at both ends in which 2≤L/D≤10, with D≥5mm.

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APPENDIX 8 Quality of process water

With reference to standard EN 13060, the table below indicates the recommended limit values (maximum) for contaminating agents, as well as the chemical-physical characteristics of the water used for condensate* and inlet water.

* Condensate is produced by the steam that was formed by the empty chamber of the sterilizer.

	Supply water	Condensate
Dry residue	<10 mg/l	<1 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
Heavy metal residues	≤0.1 mg/l	≤0.1 mg/l
Chlorides	≤2 mg/l	≤0.1 mg/l
Phosphates	≤0.5 mg/l	≤0.1 mg/l
Conductivity at 20°C	≤15 µS/cm	≤3 µS/cm
pH	5-7	5-7
Appearance	colourless, clean, sediment-free	colourless, clean, sediment-free
Hardness	≤0.02 mmol/l	≤0.02 mmol/l

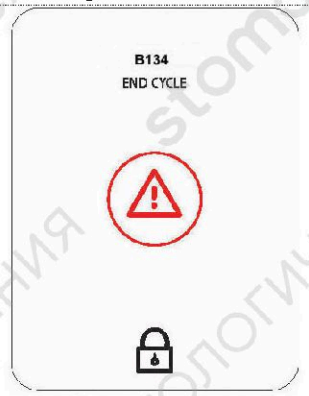
NOTE. The use of water for generating steam containing contaminants at higher levels than those shown in this table may considerably shorten the working life of a sterilizer and may invalidate the maker's guarantee.

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APPENDIX 9	Troubleshooting

Euronda E9 NEXT is equipped with a system for controlling all the components of the unit; when the Process Controller detects a fault either in a component or in the overall behaviour of the machine, an error message appears, preceded by an intermediate “Please wait” screen, necessary for the machine to perform its pressure levelling.



END OF CYCLE AND ERROR SCREEN

This screen appears after a manual stop before the end of the sterilisation cycle, or when an operation error has caused the unit to stop the cycle, and therefore the load is not sterile. The screen shows the name of the cycle at the top and the relative error code at the bottom (in this case) and the door locked icon (padlock). If this screen error appears due to a manual stop by the user, the error code is not used (like in this case).

The door is locked. To release it, touch the central part of the screen. The handle chamber shines red.



LOAD WET END-OF-CYCLE SCREEN

This screen appears when a cycle is interrupted by a manual stop ordered by the user, after the end of the sterilisation phase: the load in the boiler is sterile, but the drying process has not been completed. The load can therefore only be used immediately and cannot be preserved. The door is locked. To release it, touch the central part of the screen.

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The table below lists all the alarm messages with the probable causes of faults; if your steriliser shows any of the following error codes, before contacting the technical support service perform the checks indicated in the table.

CODE	DESCRIPTION	PROBABLE CAUSE	SOLUTION
E01	Anomalous change in input voltage.	Fault in the mains power supply or inadequate input socket.	Make sure the unit is connected to a suitable mains power supply.
E02	Black-out.	1. Temporary black-out. 2. Two-pole thermal safety switch tripped. 3. Safety thermostat tripped.	1. Wait for mains voltage to return. 2. Switch the unit back on. If the problem persists contact the assistance service. 3. Allow the steriliser to cool for a few hours and then reset the safety thermostat at the front of the machine. If the problem persists contact the assistance service.
E19	Excessive pressure during sterilisation in emergency cycles.	Fault during the sterilization phase.	Allow the steriliser to cool and then perform a sterilisation cycle with a small load in the boiler (just one tray). If the problem persists contact the assistance service.
E21	Excessive pressure during sterilisation.	Fault during the sterilization phase.	Allow the steriliser to cool and then perform a sterilisation cycle with a small load in the boiler (just one tray). If the problem persists contact the assistance service.
E22	Insufficient pressure during sterilisation.	Sterilisation phase fault, or overload, or steam loss.	Allow the steriliser to cool and then perform a sterilisation cycle with a small load in the boiler (just one tray). Make sure no water leaks or drips on the front. If the problem persists contact the assistance service.
E23	Excessive temperature during sterilisation.	Fault during the sterilization phase.	Allow the steriliser to cool and then perform a sterilisation cycle with a small load in the boiler (just one tray). If the problem persists contact the assistance service.
E24	Insufficient temperature during sterilisation.	Fault during the sterilisation phase, probably due to a leak during a vacuum phase.	Allow the steriliser to cool and then perform a vacuum test. If this is successful, perform a sterilisation cycle with a small load in the boiler (just one tray). If the problem persists contact the assistance service.

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E25	Unsaturated steam during sterilisation.	Fault during the sterilisation phase, probably due to a leak during a vacuum phase.	Allow the steriliser to cool and then perform a vacuum test. If this is successful, perform a sterilisation cycle with a small load in the boiler (just one tray). If the problem persists contact the assistance service.
E26	Cannot reach the cycle vacuum threshold.	Hydraulic leak during the vacuum phase or overloading.	Allow the steriliser to cool and then perform a vacuum test. If the problem persists contact the assistance service.
E27	Cannot reach the cycle pressure threshold.	Fault in the steam generation system or hydraulic leak or overloading.	Perform a sterilisation cycle with a small load in the boiler (just one tray). If the problem persists contact the assistance service.
E28	Sharp pressure variation.	Excessive heating of the steam or fault in the pressure sensor.	Allow the steriliser to cool and then perform a sterilisation cycle with a small load in the boiler (just one tray). If the problem persists contact the assistance service.
E29	Cannot depressurise the boiler.	Hydraulic circuit obstructed or electrovalve blocked.	Switch off the steriliser, allow to cool for a few hours and then check the drain filter at the front of the boiler. If the problem persists contact the assistance service.
E30	Cannot balance internal pressure with external pressure.	Bacteriological filter clogged.	Make sure the bacteriological filter at the front of the machine is not clogged.
E31	Minimum vacuum not reached during the vacuum test.	Hydraulic leak during vacuum phase.	Allow the steriliser to cool and then perform a vacuum test. If the problem persists contact the assistance service.
E32	Maximum vacuum not reached during the vacuum test.	Hydraulic leak during vacuum phase.	Allow the steriliser to cool and then perform a vacuum test. If the problem persists contact the assistance service.
E33	Leak during the balancing phase of the vacuum test.	Hydraulic leak from a boiler gasket.	Allow the steriliser to cool and then perform a vacuum test. If the problem persists contact the assistance service.
E34	Leak during the maintenance phase of the vacuum test.	Hydraulic leak from a boiler gasket.	Allow the steriliser to cool and then perform a vacuum test. If the problem persists contact the assistance service.
E35	Anomalous temperature during the vacuum test.	Problem in the heating system.	Allow the steriliser to cool and then perform a vacuum test. If the problem persists contact the assistance service.
E41	Steam generator temperature sensor faulty.	Fault in the sensitive element or in the probe connection.	Switch the steriliser off and then back on again. If the problem persists contact the assistance service.
E42	Upper band temperature sensor faulty.	Fault in the sensitive element or in the probe connection.	Switch the steriliser off and then back on again. If the problem persists contact the assistance service.
E43	Lower band temperature sensor faulty.	Fault in the sensitive element or in the probe connection.	Switch the steriliser off and then back on again. If the problem persists contact the assistance service.

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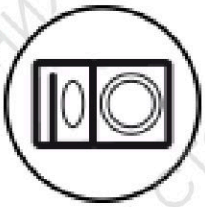
E44	Faulty condensation battery temperature sensor.	Fault in the sensitive element or in the probe connection.	Switch the steriliser off and then back on again. If the problem persists contact the assistance service.
E45	Chamber temperature sensor faulty.	Fault in the sensitive element or in the probe connection.	Switch the steriliser off and then back on again. If the problem persists contact the assistance service.
E46	Pressure sensor faulty.	Fault in the sensitive element or in the probe connection.	Switch the steriliser off and then back on again. If the problem persists contact the assistance service.
E47	Door closed sensor faulty.	Fault in the door closed position switch.	Open and close the door a few times. If the problem persists contact the assistance service.
E48	Door lock sensor faulty.	Fault in the door locked position switch.	Perform a sterilisation cycle. If the problem persists contact the assistance service.
E51	Steam generator inactive.	Fault in the steam generator or electronic board or steam generator safety thermostat tripped.	Contact the assistance service.
E54	Temperature of steam generator too high.	Fault in the electronic board or temperature sensor.	Switch off the steriliser and allow it to cool for a few hours, then perform a sterilisation system. If the problem persists contact the assistance service.
E55	Temperature of upper band too high.	Fault in the electronic board or temperature sensor.	Switch off the steriliser and allow it to cool for a few hours, then perform a sterilisation system. If the problem persists contact the assistance service.
E56	Temperature of lower band too high.	Fault in the electronic board or temperature sensor.	Switch off the steriliser and allow it to cool for a few hours, then perform a sterilisation system. If the problem persists contact the assistance service.
E58	Temperature of lower band heater too high in the pressure maintenance cycle.	Fault in the electronic board or temperature sensor.	Switch off the steriliser and allow it to cool for a few hours, then perform a sterilisation system. If the problem persists contact the assistance service.
E59	Condensation battery temperature too high	Sensor, connection, or fan fault.	Contact the assistance service.
E60	Problems about write on Sd card	SD card inserted after power on or removed during a cycle	Switch off the autoclave and check if the sd card is in the right place. If the problem persists contact the assistance service
E62	Water injections finished.	Boiler overloaded or clogged with scale or water injection pump inefficient.	Perform a sterilisation cycle with a small load in the boiler (just one tray). If the problem persists contact the assistance service.
E81	Water not being supplied by the Aquafilter® deioniser.	Error in the hydraulic or electrical connections with Aquafilter or electronic fault.	Make sure that the Aquafilter connections are correct and that there are no crushed or bent pipes. Make sure the Aquafilter® inlet tap is open. If the problem persists contact the assistance service.
E99	Comunication problem between display board and power board		Switch off the steriliser and after a few seconds turn it on again. If the problem persist contact the assistance service

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E100	Comunication problem between display board and power board		Switch off the steriliser and after a few seconds turn it on again. If the problem persist contact the assistance service

The following table shows the warning messages given by the steriliser using symbols or codes when it detects a problem that prevents a cycle from starting.

CODE	DESCRIPTION	SOLUTION
	Used water at maximum level.	Empty the used water tank.
	Clean water under minimum level.	Fill the clean water tank with distilled or deionized water.
 W41	An attempt was made to start a cycle with the door open.	Before running a cycle, close the door.
 W84	Steriliser too high.	The steriliser temperature is too high for the requested operation. Switch it off and leave it to cool leaving the door open.
	The conductivity read by the Aquafilter® deionizer is out of range and the automatic supply of water is therefore impossible.	Replace the cartridges in the Aquafilter deionizer.

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 W85	The steriliser is not detecting the SD memory card, or the SD card is write-protected.	Check that the SD memory card is present and correctly installed. Switch off the steriliser, remove the SD memory card and check that the safety switch allows writing.
	The conductivity read by the conductivity meter on the autoclave is at the limits of the acceptable values.	Empty the clean water tank as soon as possible, and refill it with demineralised or distilled water of the best quality.
	The conductivity read by the conductivity meter on the autoclave is at the limits of the acceptable values.	Empty the clean water tank, and refill it with demineralised or distilled water of the best quality.
W43	Door lock electromagnet faulty.	Switch the steriliser off and then back on again. If the problem persists contact the assistance service.
W44	Door lock electromagnet out with door open.	Manually move the electromagnet back in by pushing the pin toward the steriliser.
W80	Lower band heater temperature not suitable for cycle start.	Resistance fault.
W81	Upper band heater temperature not suitable for cycle start.	Resistance fault.
W82	Upper band heater temperature not suitable for NGV cycle start.	Resistance fault.
W90	Steam generator temperature sensor faulty.	Switch the steriliser off and then back on again. If the problem persists contact the assistance service.
W91	Upper band temperature sensor faulty.	Switch the steriliser off and then back on again. If the problem persists contact the assistance service.
W92	Lower band temperature sensor faulty.	Switch the steriliser off and then back on again. If the problem persists contact the assistance service.
W93	Faulty condensation battery sensor.	Switch the steriliser off and then back on again. If the problem persists contact the assistance service.
W94	Pressure sensor faulty.	Switch the steriliser off and then back on again. If the problem persists contact the assistance service.
W95	Chamber temperature sensor faulty.	Switch the steriliser off and then back on again. If the problem persists contact the assistance service.

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	Bacteriological filter to be replaced M1	This is not a forcing notice. When it appears, exit pressing the low central icon. Replace the filter with turned off autoclave as soon as possible, or contact the technical assistance.
	Door silicon gasket to be replaced M2	This is not a forcing notice. When it appears, exit pressing the low central icon. Contact the technical assistance in order to do the maintenance.
	Extraordinary maintenance M3	This is not a forcing notice. When it appears, exit pressing the low central icon. Contact the technical assistance in order to do the maintenance.
	Tank cleaning M4	This is not a forcing notice. When it appears, exit pressing the low central icon. Tank cleaning is suggested in order to avoid sediments. Do the cleaning with turned off autoclave.

The following table summarises the errors that can occur during installation and use of the E-Memory software. If the indications are not sufficient to solve the problem, contact the assistance service.

Microsoft Access Runtime does not install automatically.	Open the CD-ROM folder in Explorer, then the ART folder, and click twice on setup.
The data in the SD memory card is not acquired by the E-Memory Software.	Check PC and SD memory card communication in the “connections” page.
The E-Memory Software does not install correctly.	Check the minimum system requirements, in particular the operating system installed on the PC.
The E-Memory Software does not e-mail the cycle data.	Make sure you have installed and enabled an e-mail client on your PC.
Data transfer from the SD memory card to the PC is very slow.	The system the E-Memory Software is installed on is at the limit of the minimum requirements. Click on the rapid acquisition button ( ) in the “Connections” page (see paragraph “PC-SD MEMORY CARD CONNECTION AND DISCONNECTION”).
When the E-Memory software is run, the following message appears: “Protection warning: this file may be dangerous …..Cancel-Open”.	This message is due to the fact that the macro protection in Access 2003 is set to Medium level . Click on “Open”, everything works correctly. To eliminate the initial installation message of Access 2003, the macro protection level can be lowered: run Access 2003 Tools -->Macros-->Protection-->low level and everything will work fine.
If E-Memory Software is run from the desktop icon, the MSACCESS.EXE search screen appears	Problem with the installation of MS Access Runtime. Contact the assistance service.

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APPENDIX 10	Description of optional devices

Aquafilter Deionizer

The Aquafilter Deionizer is a device that makes it possible to obtain water for feeding the tank of the steriliser through direct connection to the water mains. The E9 steriliser-Aquafilter® deionizer interface allows the latter to be directly controlled by the steriliser·

The principle on which the system is based is that of ionic exchange: a synthetic matrix is "charged" with groups that are capable of exchanging hydrogen ions (H^+) and hydroxide ions (OH^-) with the cations and anions present in the water. The deionizer contains a probe used for reading the specific conductivity and is therefore capable of indicating when the characteristics of the water produced are no longer acceptable for the system. The resins are capable of producing approximately 120 litres of water, but this value is strictly dependant on the salinity of the inlet water, i.e. on the region in which the deionizer is installed. When the active sites of the resin are saturated, and the probe detects that the quality of the outlet water has a higher value than a certain pre-set value, a message for replacing the resins will appear on the display of the E9 NEXT steriliser. The quality of the water produced is also indicated by a led on the deionizer; as well as the message on the display of the unit, therefore, the red light in the led also indicates that the quality of the water produced by the deionizer is not suitable.

Aquabox

Aquabox is a device that allows Euronda autoclaves to be connected to an external supply of water that has already been treated. It is ideal for clinics that already have water treatment systems based on osmosis or other methods. It can be installed easily on all Euronda class B autoclave models.

Aquaosmo

Aquaosmo is a system that uses reverse osmosis to produce deionized water. A complex filtering system, containing no fewer than 4 filters and 1 membrane, produces a large amount of water that is suitable for supplying autoclaves and all of the equipment in dental practices, in accordance with the EN 13060 standard (<15 µS/cm). A gun for spraying water manually can be also connected.

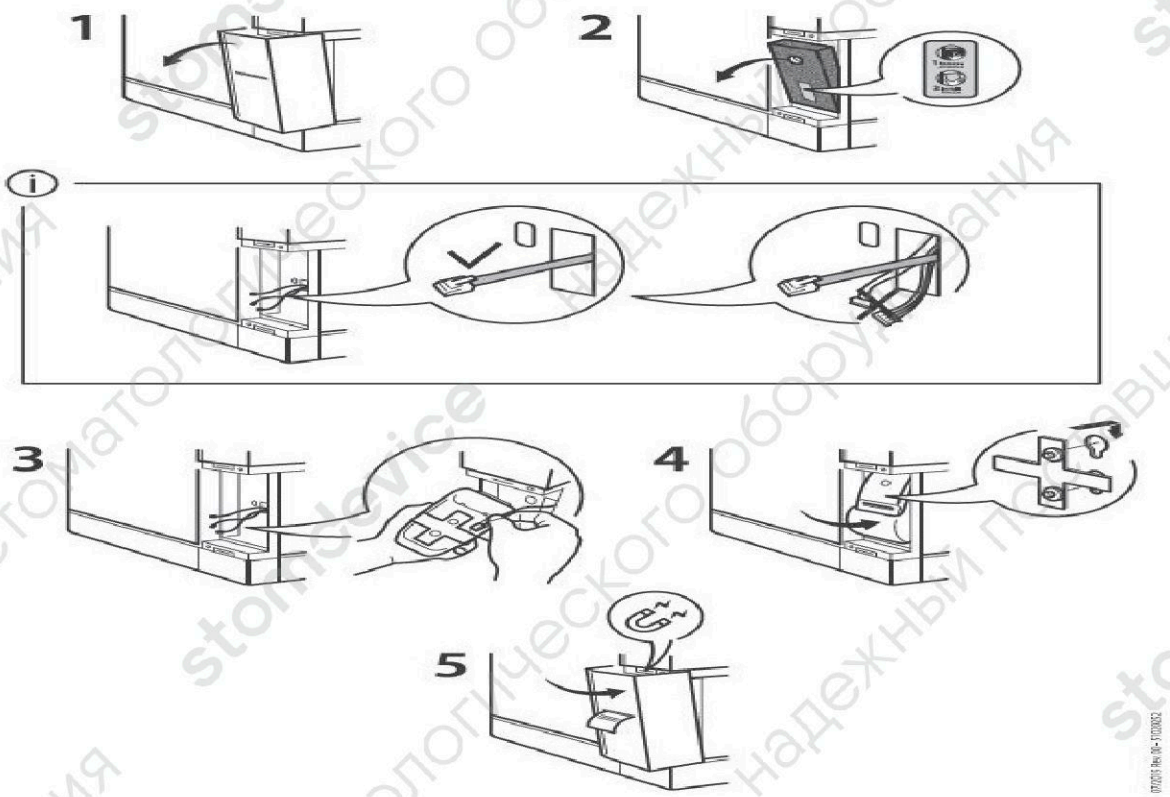
Aquaosmo is designed to be installed together with an Aquabox and connected directly to an autoclave. It can supply up to 4 autoclaves at the same time if it is fitted with the special external accumulator tank kit, which has a capacity of 12 litres. Aquaosmo does not need to be connected to an electrical power supply and it can be installed directly on a work surface or inside a unit.

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Integrated label printer

The integrated label printer is a device that, on completion of each cycle, gives the possibility of expressing the result of such cycle, both if it is successful or unsuccessful, or if it has been stopped manually or caused an alarm. This thermal impact printer gives the possibility of selecting the number of labels to print also using the barcode.

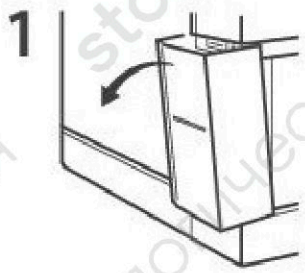


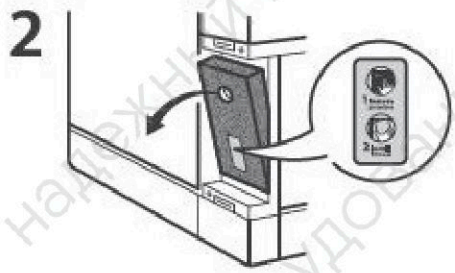
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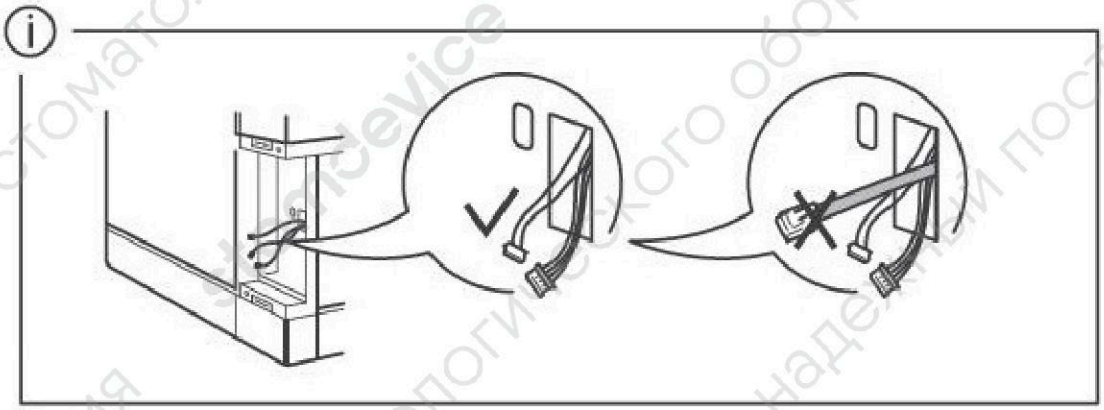
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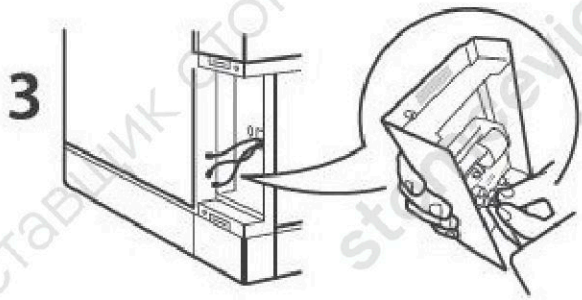
Thermal paper roll integrated printer

The thermal paper roll printer is a device that, on completion of each cycle, gives the possibility of expressing the result of such cycle, both if it is successful or unsuccessful, or if it has been stopped manually or caused an alarm.









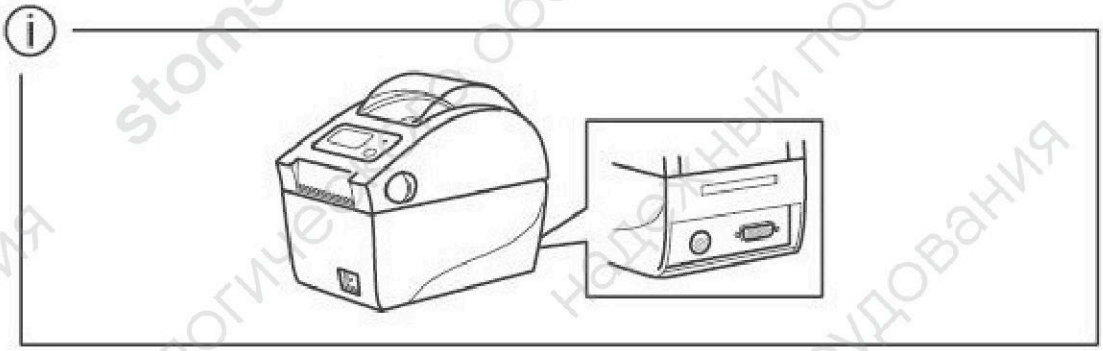


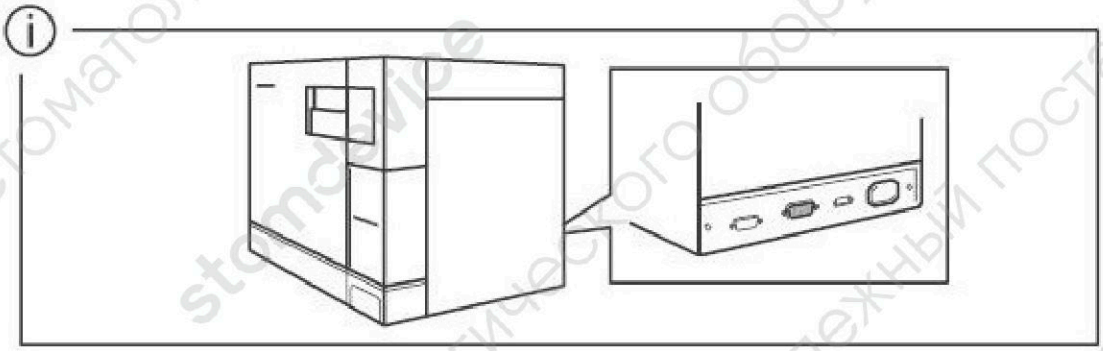
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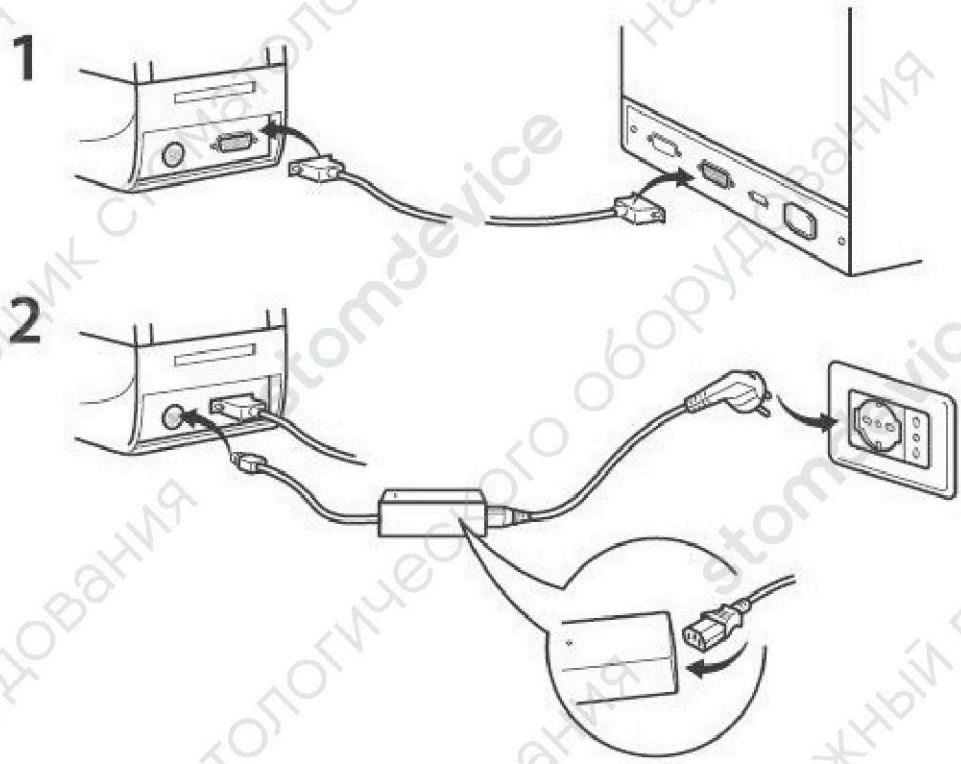
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External label printer

The external label printer (24 Vdc power supply using a power supply unit) is a device that, on completion of each cycle, gives the possibility of expressing the result of such cycle, both if it is successful or unsuccessful, or if it has been stopped manually or caused an alarm. This thermal impact printer gives the possibility of selecting the number of labels to print also using the barcode. As printing is faster than with an integrated printer, it is more appropriate when the printing of a large number of labels is required.







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