

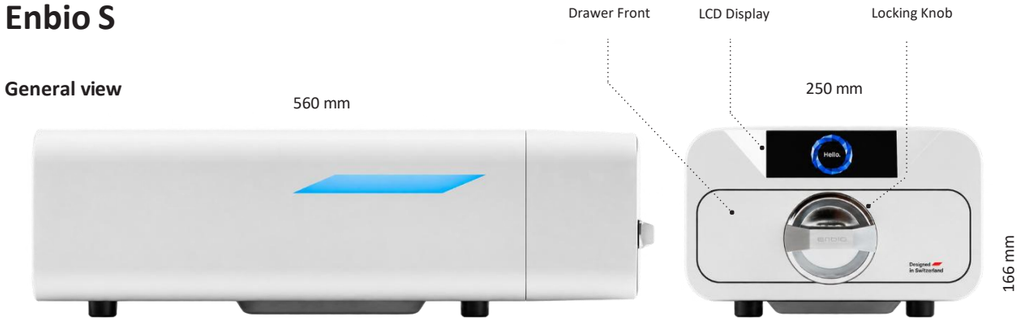
2026.10.30 The latest version of the manual is available at www.enbio.com

Enbio S / Enbio PRO
User Manual EN

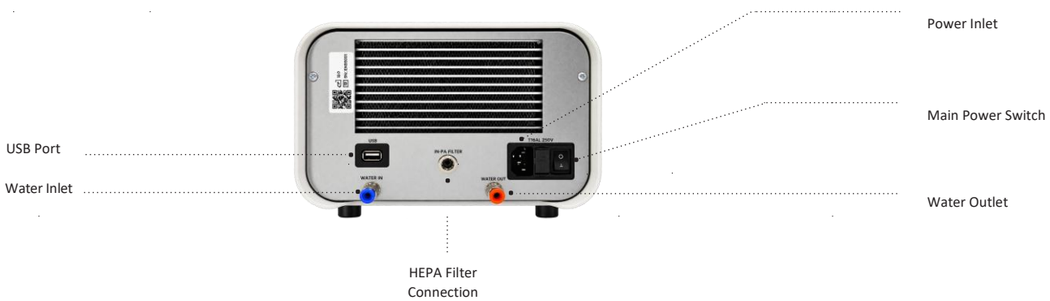
Designed in Switzerland

Enbio S

General view

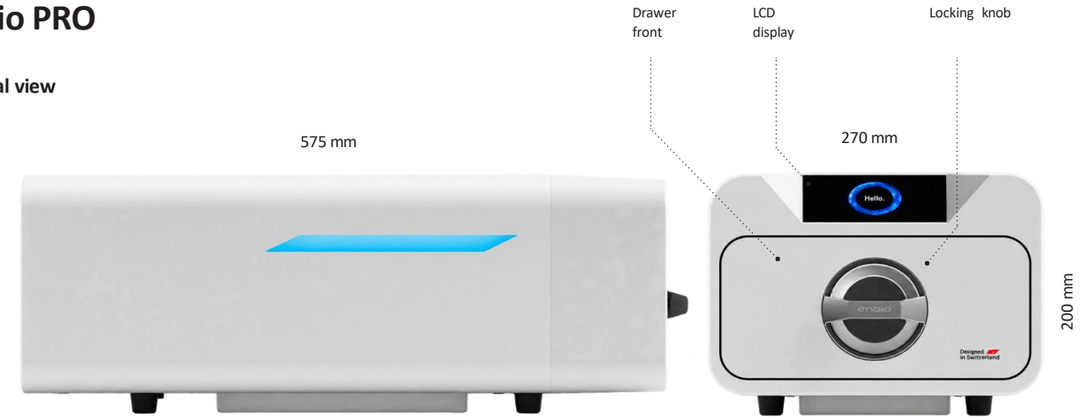


Rear view



Enbio PRO

General view



Rear view

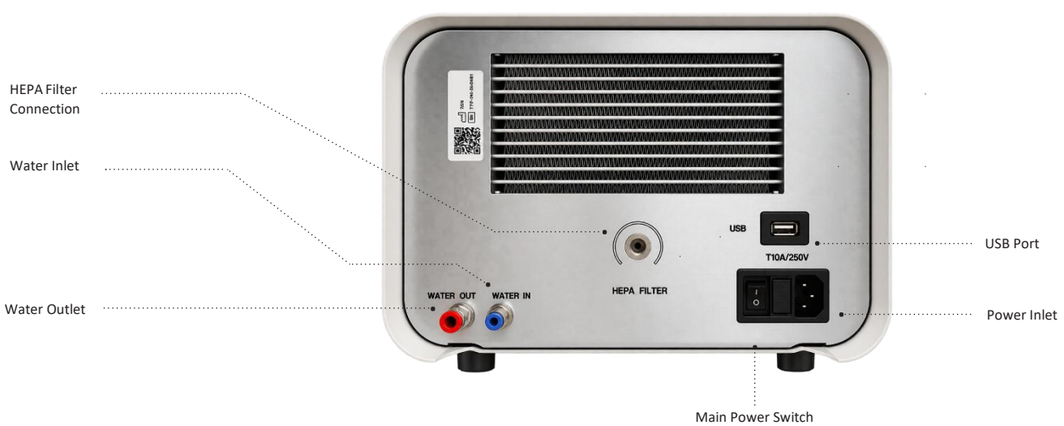


Table of Contents

1. Introduction **2**
1.1 Purpose and scope 2
1.2 Applicable legislation 2
1.3 General description of the device 2
1.4 Purpose of the device 3
1.5 Enbio S sterilization parameters 4
1.6 Enbio PRO sterilization parameters 6
1.7 Symbols used on the device 8
1.8 Precautions, requirements, recommendations 8
1.9 Reasonably foreseeable misuse 10
2. Scope of delivery and unpacking **12**
2.1 Unpacking the device 12
2.2 Equipment of the sterilizer 13
3. Installation and preparation for operation **14**
3.1 HEPA filter installation 14
3.2 Feed water quality 15
3.3 Installing the Chamber Drain Filter (only Enbio Pro) 15
3.4 Connection with water recycling 16
3.4.1 Connecting the supply water (WATER IN) 16
3.4.2 Connecting the wastewater (WATER OUT) 16
3.5 Setting up the device 19
3.6 Connecting the device to the power supply 19
4. Preparation and loading of instruments **20**
4.1 Preparation of packages 20
4.2 Arranging packs on sterilizer tray (sterilizing packaged loads) 21
4.3 Arranging instruments on the sterilizer tray (sterilization of loads without packaging) 21
5. Operating the device **24**
5.1. First run 22
5.2 Program selection 22
5.3 Process summary 25
5.4 Test programs 26
5.5 Info menu 31
5.5.1 LED lighting 32
5.5.2 Counters 32
5.5.3 User identification 34
5.5.4 Auto test plan 37
5.6 Restart 39
6. Service inspections **41**
6.1 Product shelf-life 41
7. Device maintenance **42**
7.1 Regular operation 42
7.2 Cleaning the tray
7.3 Consumable parts 43
7.4 Replacing the Enbio Magic Filter 44
8. Data archiving **45**
9. The my.enbio.com application **46**
9.1 How to get started with the my.enbio.com app 46
10. Warning messages and codes **48**
10.1 Warning messages 48
10.2 Information messages 48
10.3 Codes 49
11. Complaints procedure **53**
12. Warranty conditions **53**
13. Technical data **54**
14. EU declaration of conformity **56**

1. Introduction

1.1 Purpose and scope

The purpose of these operating instructions is to provide information on the ENBIO S and ENBIO PRO sterilizer. In particular information concerning:

- Intended use
- Correct installation and settings
- Correct use and operation
- Safe and reliable operation
- Regular and proper maintenance and servicing

1.2 Applicable legislation

The ENBIO S and ENBIO PRO sterilizers are designed and manufactured to meet the following requirements:

- EN 13060 standard "Small Steam Sterilizers" and related documents
- Regulation (EU) 2017/745 on medical devices
- Directive 2012/19 / EU on waste electrical and electronic equipment (WEEE)
- The Restriction of Hazardous Substances Directive 2002/95/EC
- Law on Medical Devices (Dz. U. 2022 poz. 974)

1.3. General description of the device

ENBIO S and ENBIO PRO are compact steam sterilizers designed to sterilize medical devices using steam. They feature a hermetically sealed, heated chamber. The load to be sterilized is placed inside the chamber on a specially designed perforated tray.

After closing the chamber, the user selects and starts the appropriate sterilization program via the touchscreen.

The sterilization process begins with a pre-vacuum phase, which consists of one pre-vacuum pulse for the FAST program and three pre-vacuum pulses for the other Class B programs.

The steam generator produces steam and introduces it into the chamber, where it transfers heat to the load. Inside the chamber, the required temperature and pressure are maintained for a specified period, depending on the selected sterilization cycle.

After the sterilization exposure phase, steam is removed from the chamber. For programs that include drying, the drying phase then begins. The 134°C FAST program does not include a drying phase.

Once the cycle is complete, the device displays a summary and the result of the sterilization process on the touchscreen.

1.4. Intended use of the device

The Enbio S and Enbio PRO are a small class B steam sterilizers according to standard EN 13060.
They are classified as class IIa medical devices in accordance with Annex VIII of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (rule 16). According to the classification of the EN 13060 standard, the following medical devices can be sterilized in the Enbio S and Enbio PRO devices, for which the manufacturer has provided for steam sterilization: solid charges, small porous objects, small porous charges, full porous charges, simple recessed items, items with a narrow gap, multiple use packs that may be non-packaged or packaged (in one or more layers). The 134 FAST process is dedicated to solid, non-porous, simple instruments and dental tools (eg scissors, handles, pliers, chisels, probes, etc.) exclusively unpacked, not textile, for immediate use.

In addition, the Enbio PRO autoclave has a dedicated 134 PRION program for items that have or may have had contact with diseased prion proteins (e.g. causing Creutzfeld-Jacob disease, BSE, etc.): solid loads, small porous items, small porous ripples, full porous loads, simple hollow items, items with narrow clearance, multiple packages that may be unpackaged or wrapped (single and multi-layer).

The Enbio S and Enbio PRO devices can be used in primary healthcare practices, dental practices, and in operating rooms. They can also be used in beautician and biological regeneration studios, in veterinary practices, tattoo artist and piercing studios, hair stylist salons.

The Enbio S and Enbio PRO devices cannot be used to sterilize liquids, biomedical waste or pharmaceutical products.

Meeting the requirements of the EN 13060 and EN 61326-1 standards, Enbio S and Enbio PRO sterilizers are adapted to work in the vicinity of other electrical medical devices.

The devices are intended for professional use by properly trained staff only.

However, the manufacturer has also provided for the possibility of use by laypersons (i.e. individuals who do not perform sterilization as part of a business activity). In such cases, it is essential to comply with so-called good decontamination practices, including: wet mechanical cleaning, chemical disinfection, drying, and steam sterilization (with or without packaging). In each of the above-mentioned cases, the user is required to familiarize themselves with the contents of these instructions for use and to comply with all of the guidelines contained therein.

1.5. Enbio S sterilization parameters

The table below, which presents the characteristics of the individual sterilization programs in the Enbio S device, should be read in detail. It is the user's responsibility to select the program appropriate to the type of load and not to exceed the maximum weight of the sterilized load. Failure to comply with the following rules may endanger the health of patients and the operation of the device.

Enbio S

Program name	Description of the load	Sterilization temperature	Sterilization time	Drying time	Max. load weight	Number of pre-vacuums	Total process time (for a load of specified weight)*	Max. water consumption	Sterilization process class
134˚ C	solid loads, small porous objects, small porous loads, full porous loads, simple dimpled objects, narrow clearance objects, multiple packages that may be unpackaged or packaged (single or multiple layers)	134˚C	4 min.	3 min.	500 g	3	load of 100 g ≈ 13 minutes	115 ml	B
121°C	solid loads, small porous objects, small porous loads, full porous loads, simple dimpled objects, narrow clearance objects, multiple packages that may be unpackaged or packaged (single or multiple layers)	121°C	15 min.	5 min.	500 g	3	load of 100 g ≈ 26 minutes	110 ml	B
134°C FAST **	solid, non-porous, simple dental instruments and appliances (e.g. scissors, handles, pliers, chisels, probes, etc.) only unpackaged, non-textile	134˚C	3.5 min.	no drying	500 g	1	load of 100 g ≈ 7 minutes	105 ml	S

* Ambient temperature can have an effect on increasing the total process time.
* The total duration of the first process may be longer due to the need for the appliance chamber to warm up.
** After sterilization at 134°C FAST the loads are wet. It is recommended to leave the drawer ajar in order to evaporate the remaining water and to lower the temperature of the instruments.
** After sterilization in the 134°C FAST program, the instruments are intended for immediate use.

1.6. Enbio PRO sterilization parameters

The table below shows the characteristics of each sterilization program in Enbio PRO. It is the user's responsibility to select a program suitable for the type of load and not to exceed the maximum weight of the sterilized load. Failure to observe the following precautions may compromise patient health and device operation.

Enbio PRO

Program name	Description of the load	Sterilization temperature	Sterilization time	Drying time	Max. load weight	Number of pre-vacuums	Total process time (for a load of specified weight)*	Max. water consumption	Sterilization process class
134˚ C	solid loads, small porous objects, small porous loads, full porous loads, simple dimpled objects, narrow clearance objects, multiple packages that may be unpackaged or packaged (single or multiple layers)	134˚ C	4 min	4 min	800 g	3	load of 200 grams ≈ 18 minutes	190 ml	B
121°C	solid loads, small porous objects, small porous loads, full porous loads, simple dimpled objects, narrow clearance objects, multiple packages that may be unpackaged or packaged (single or multiple layers)	121°C	15 min	5 min	800 g	3	load of 200 grams ≈ 31 minutes	180 ml	B
134 ° C FAST **	solid, non-porous, simple dental instruments and appliances (e.g. scissors, handles, pliers, chisels, probes, etc.) only unpackaged, non-textile	134˚ C	4 min	no drying	800 g	1	load of 100 grams ≈ 10 minutes	140 ml	S
134 ° C PRION ***	solid loads, small porous objects, small porous loads, full porous loads, simple dimpled objects, narrow clearance objects, multiple packages that may be unpackaged or packaged (single or multiple layers)	134˚ C	18 min	3 min	800 g	3	load of 800 grams ≈ 45 minutes	230 ml	B

* Ambient temperature can have an effect on increasing the total process time.
* The total duration of the first process may be longer due to the need for the appliance chamber to warm up.
** After sterilization at 134°C FAST the loads are wet. It is recommended to leave the drawer ajar in order to evaporate the remaining water and to lower the temperature of the instruments.
** After sterilization in the 134°C FAST program, the instruments are intended for immediate use.
*** The PRION program is available only in selected versions of the Enbio PRO device.

1.7. Symbols used on the device

	This symbol is located on the front of the appliance, on top of the drawer front, and advises extreme caution due to the high temperature of the compartment and its immediate surroundings.
	This symbol is located on the unit's rating plate and identifies its individual serial number.
	This symbol appears on the unit's rating plate and identifies the Notified Body involved in the conformity assessment process for Regulation 2017/745.
	This symbol is located on the unit's rating plate and identifies the year the unit was manufactured.
	This symbol is located on the equipment rating plate and identifies the equipment manufacturer.
	This symbol can be found on the unit's rating plate and requires the user to read and follow the information in this manual.
	This symbol is located on the unit's rating plate and identifies the Authorized Representative.

1.8. Precautions, requirements, recommendations

- The user is responsible for the correct installation, proper use and maintenance of the unit in accordance with the guidelines in this document. If necessary, contact the service department or your device supplier.
- The sterilizer must not be used in the presence of flammable gases or explosive vapors in the ambient air.
- At the end of each sterilization cycle, the load is hot. Instruments or packages should be removed from the chamber using appropriate protective gloves or other equipment to prevent burns.
- Do not remove the rating plate or other markings from the unit - otherwise the warranty will be void.
- Do not disassemble the unit's housing or other parts - otherwise the warranty will be void.
- Follow the local guidelines for preparing instruments for sterilization.
- Flooding the device with water or other liquids may cause a short circuit and threaten the user's safety.
- Turn off the unit and disconnect the power supply before inspecting, performing maintenance, or servicing.
- Inspection and servicing of the device may be carried out only by trained service technicians using original spare parts.

- After sterilization at 134°C FAST the loads are wet. It is recommended to leave the drawer ajar to evaporate the remaining water and to lower the temperature of the instruments.
- ** After sterilization in the 134 ° C FAST program, the instruments are intended for immediate use.
- The correct and safe operation of the device is based on a thorough reading and observance of this document, on the installation and use of the device in accordance with the descriptions given therein and on the observance of all safety conditions. Any other use, not complying with this manual, may lead to dangerous accidents, for which the manufacturer will not be held responsible.
- Access to the device must be restricted to unauthorized persons and the operating personnel must be trained. Operating personnel are understood to be persons who, as a result of their training, experience and knowledge of the relevant standards, documentation and local regulations relating to safety and working conditions, are authorized to carry out sterilization and who can recognize possible dangers and avoid them.
- This document must be supplied with the appliance; it contains detailed information on assembly and installation as well as commissioning, use, repair and maintenance. If the appliance is operated as intended, this manual contains sufficient information necessary for qualified personnel.
- This document should always be kept near the device and easily accessible.
- The manufacturer reserves the right to make changes that do not affect the safety of operation and maintenance of the device, without notice to users.
- The manufacturer shall not be liable for damages during the period of waiting for service, inspections and warranty repairs, or any other damage to the Customer's property other than the device, in particular for errors resulting from improper installation or incorrect operation of the device.
- Failure to follow the instructions in this document may endanger the safety of the device user and patients.
- The user must follow all unpacking, installation and operation guidelines - otherwise the warranty is void.
- In particular, the user must ensure the availability of water of adequate quality - under the pain of losing the warranty.
- It is unacceptable to use any liquids, solutions, chemicals in the sterilization process - the device can be powered only with water of appropriate quality (see: 3.2 Feed water quality). The use of water of incorrect quality or solutions other than water will void the warranty.
- It is the user's responsibility to perform timely maintenance and inspections of the device - under penalty of losing the warranty.
- It is the user's responsibility to select a program appropriate to the type of load and not to exceed the maximum weight of the load to be sterilized.
- Any serious medical incident relating to a device should be notified by the user to the manufacturer and to the competent authority of the Member State in which the user or patient is resident

1.9 Reasonably foreseeable misuse

Reasonably foreseeable misuse of Enbio S and Enbio PRO	Risk	Prevention
Sterilization of products not intended for steam (moist heat) sterilization. Sterilization of liquids, biomedical waste, and pharmaceutical products	risk of damage to the sterilizer and / or sterilized load, risk of non-sterile load	check 1.3 General description of the device and 1.4 Purpose of the device
Incorrect selection of the sterilization process for the sterilized load	risk of damage to the sterilizer and / or sterilized load, risk of non-sterile load	check 1.4 Purpose of the device
Incorrect packaging of the sterilized load	risk of damage to the sterilizer and / or sterilized load, risk of non-sterile load	check 4. Preparation and loading of instruments
Using water with parameters inconsistent with the guidelines of the user's manual. Using any liquids, solutions, chemicals other than water in the sterilization process, with parameters inconsistent with the guidelines of the user manual	risk of damage to the sterilizer and / or sterilized load, risk of non-sterile load, risk of losing the warranty on the device	check 3.2. Feed water quality
The use of a loads with a weight exceeding the maximum allowable weight of the sterilized load	risk of damage to the sterilizer and / or sterilized load, risk of non-sterile load, risk of losing the warranty on the device	check 1.5. Enbio S sterilization parameters and 1.6. Enbio PRO sterilization parameters
Incorrect installation of the device	risk of damage to the sterilizer and / or sterilized load, risk of non-sterile load, risk of losing the warranty on the device, danger to life or health of the operator	check 3. Installation and preparation for operation and 13. Technical data
Incorrect preparation of tools for sterilization	risk of damage to the sterilizer and / or sterilized load, risk of non-sterile load, risk of losing the warranty on the device	check 4. Preparation and loading of instruments
Incorrect maintenance of the device	risk of damage to the sterilizer and / or sterilized load, risk of non-sterile load, risk of losing the warranty on the device	check 6. Service inspections and 7. Device maintenance
Not using the USB memory while the device is running	no archiving of tests and sterilization processes	check 8. Data archiving
Ignorance of the content of warning messages and error codes	risk of damage to the sterilizer and / or sterilized load, risk of non-sterile load	check 10. Warning messages and error codes

2. Scope of delivery and unpacking the device

2.1. Unpacking the device

⚠	If the sterilizer has been transported or stored at a temperature and humidity different from that in the place of installation, wait at least 60 minutes after delivery. If the device is moved from a cold to a warm place, it may contain humidity which, by adversely affecting the electrical components of the device, may damage it when it is turned on.
⚠	Carefully unpack the device from its packaging.
🛈	The packaging and its contents should be checked for external damage. In the event of damage, immediately contact the seller or the transport company to write a damage report. Do not use the device.
🛈	It is recommended to leave the carton for possible transportation of the autoclave.
♻	Used electrical and electronic equipment must not be placed, thrown away or stored with other waste. Used equipment should be delivered to a local collection point for used electrical equipment, which is registered with the respective environmental protection office and conducts selective waste collection.

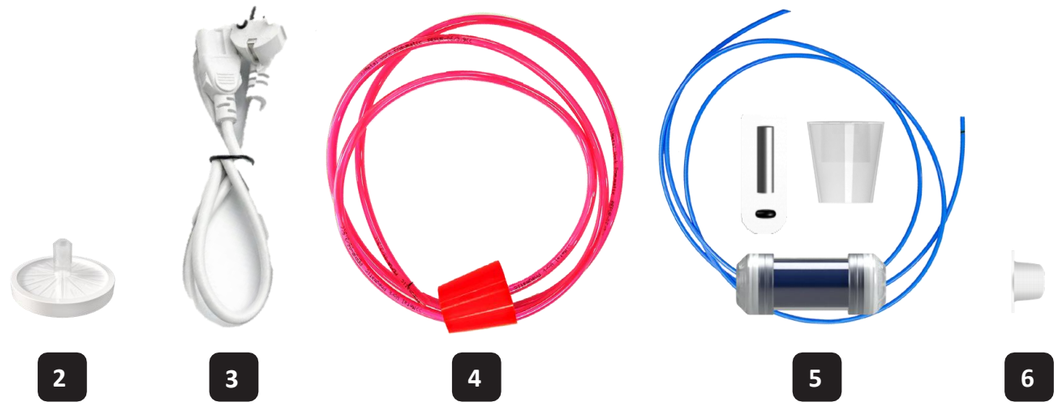
2.2. Equipment of the sterilizer

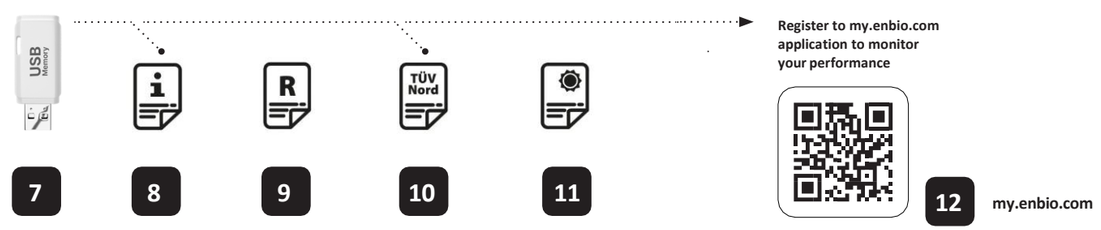
Before starting the installation, it is recommended to check the contents of the package.
The following items should be included in the package:

1. Enbio S / Enbio PRO sterilizer
2. HEPA filter (inside the chamber of the device)
3. Power cord
4. Condensate connection hose with rubber sealing cap
5. Enbio Magic Filter with water connection hose and rubber sealing cap
6. Chamber drain filter
7. USB flash drive
8. User manual*
9. Device validation report
10. TÜV certificate*
11. Warranty*
12. my.enbio.com*

*digital form only





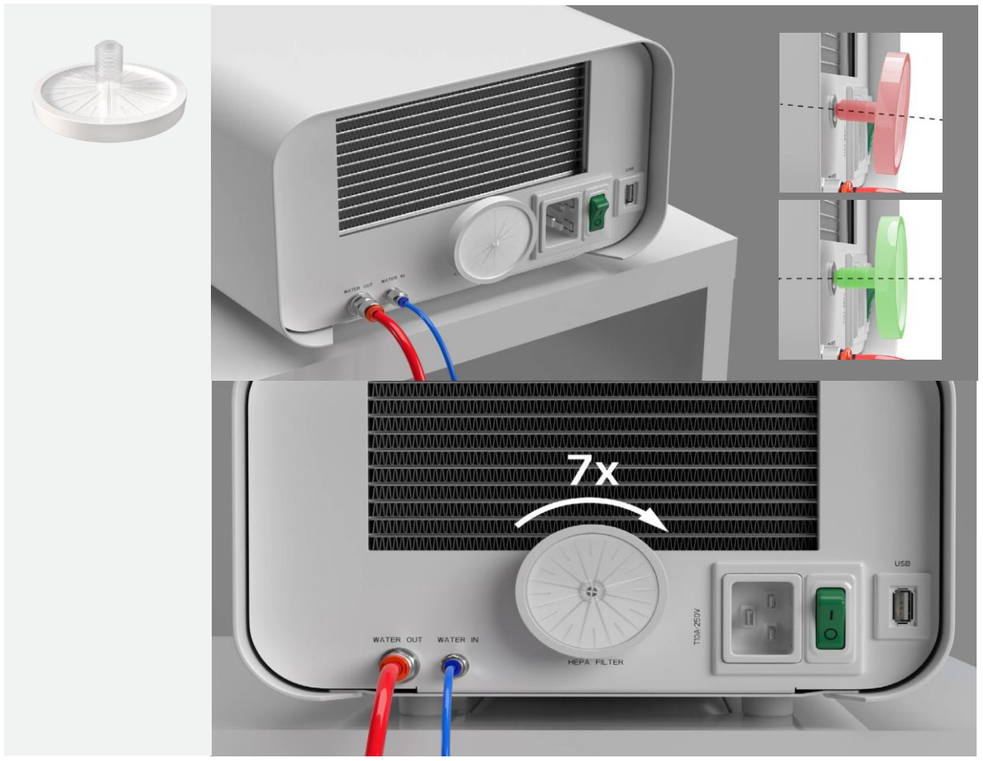


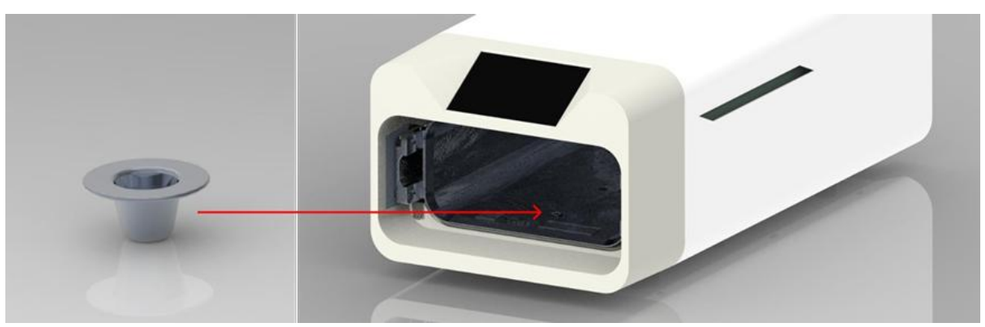
3. Installation and preparation for operation

Please read these operating instructions carefully before using the ENBIO S or ENBIO PRO. During operation, observe the guidelines in these instructions as well as the applicable local health and safety rules. The ENBIO S and ENBIO PRO units are designed for self-assembly by the user and do not require specialized installation on site. The user is responsible for proper installation of the unit on site in accordance with these instructions.

3.1. HEPA filter installation.

To protect the component during transport, a HEPA filter is not installed in the device. It was placed inside the chamber, on a tray. Take it out of the chamber, take it out of the bag and by yourself, carefully screw it into the slot provided for this purpose (see fig.). The filter should be screwed in by hand (approx. 7 turns) until resistance is felt - further screwing in will damage the filter and immobilize the sterilizer.





Feed water quality

It is unacceptable to use any liquids, solutions, chemicals, additives to the feed water - the device may be powered only with demineralized or distilled water of appropriate quality.
No chemicals or additives must be added to the sterilization water, even if they are specifically intended for use in steam generators, steam production or for use as additives in sterilization, disinfection, cleaning or corrosion protection.
The use of incorrect quality water or solutions other than water reduces the effectiveness of sterilization and leads to damage to the device and loss of warranty.
The total mineral content of the sterilization water must be less than 10 ppm or, in the case of conductivity measurement, it must be less than 15 µS/cm - therefore tap water cannot be used as feed water for the device.
The table below shows recommended water hardness and conductivity parameters for Enbio S and Enbio PRO sterilizers.

Permissible parameters of water used for sterilization

- hardness <0.02 mmol / l
- conductivity (at 20 ° C) <15 µS / cm
- pH - from 5 to 7.5
- chemical additives - none

The use of water with an impurity content in excess of the above levels will damage the device and will void the warranty.

The water in the supply tank should be replaced at least every three months (due to increased conductivity due to prolonged contact with air). If the tank is dirty, also change it to a new one. The tank should be closed with the attached stopper so that water does not deteriorate its chemical composition as a result of contact with air.

The guarantee granted by the manufacturer becomes void if the autoclave has been used with water of a quality inconsistent with the recommended

---

If the autoclave is operated in a water recycling system using the Enbio Magic Filter, the filter must be replaced with a new one every 6 months or less when the resin has completely discolored to an amber color. As long as the blue color is visible, the resin has still water-purifying properties, i.e. water hardness <0.02 mmol / l and conductivity <15 µS / cm. In order to ensure the correct parameters of the water supplying the device, it is recommended to check the water tank at least quarterly. In the event of contamination, the tank should be emptied, cleaned and filled with new demineralized water. Failure to comply with these obligations may disrupt the sterilization process and will void the warranty on the sterilizer.

3.3. Installing the Chamber Drain Filter

To protect the component during transport, the chamber drain filter has not been installed in the device. It has been placed in the separate small bag. Remove it from the bag and insert it into the designated chamber drain opening.

Installation: Remove the filter from its packaging and insert it into the designated opening inside the chamber, as shown in the illustration on the left.

3.4. Connection with water recycling (Enbio Magic Filter)

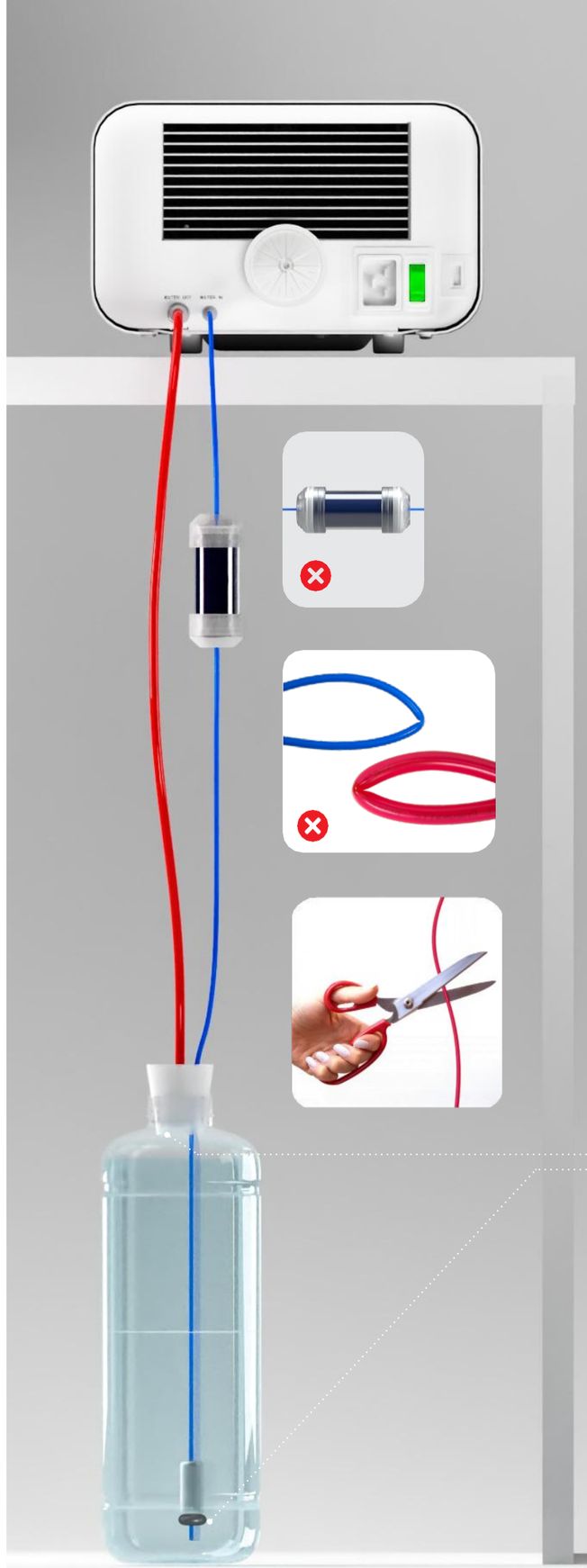
Enbio Magic Filter is a filter for recycling water used in the sterilizer. The ion-exchange resin contained in Enbio Magic Filter allows you to purify wastewater to the level of deionized water in accordance with the requirements of EN 13060 - that is, water which is recommended and approved for use with Enbio autoclaves. You only need 1 water tank to use Enbio autoclave with filter.

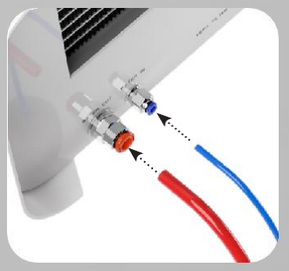
3.4.1 Connecting the supply water (WATER IN) with Enbio Magic Filter

- Connect the shorter part of the blue Enbio Magic Filter connection hose to the blue water supply connection, which is marked on the rear panel of the WATER IN device. The tubing should be inserted into the connector, to the depth of the black line (placed on the tubing).
- Submerge the longer part of the blue Enbio Magic Filter hose into the feed water tank. The unit is equipped with a water intake pump, so there is no need to place the water tank above or at the same level as the unit
- To ensure proper operation, Enbio Magic Filter must always be placed in a vertical position
- To prevent the hose from coiling in the water tank, install the included weight with a rubber ring at 2 cm from the end of the hose (fig.)
- To secure and immobilize the water supply hose to the machine, use the plug supplied with the Enbio Magic Filter and insert the plug into the opening of the water tank. An unsecured tubing may jump out of the water and cause sterilization errors.
- The minimum water load in the tank is 300 ml.
- Remember to make sure that the blue tube is always immersed in the water.
- Check the water level in the tank on a regular basis, depending on the frequency of the processes.
- The hose should be trimmed with scissors, at a point that prevents it from bending.

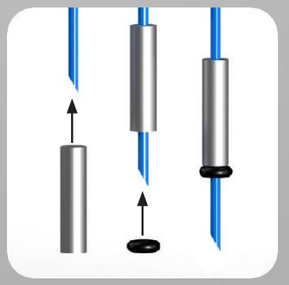
3.4.2 Connecting the wastewater (WATER OUT) with Enbio Magic FIlter

- Connect the red wastewater hose to the orange wastewater connector that is marked on the rear panel of the WATER OUT device. The tubing should be inserted into the connector, to the depth of the black line (placed on the tubing).
- Wastewater should be drained into a water tank. To secure and immobilize the water drain hose from the unit, use the plug supplied with Enbio Magic Filter and insert the plug into the opening of the water tank. The unsecured tubing may jump out of the tank and flood the room.
- Make sure that the red tube is never immersed in water, otherwise the water will not drain properly, causing sterilization errors.
- The water tank must always be located below the unit.
- The hose should be trimmed with scissors, at a point that prevents it from bending.





Correct connection of the hoses to the feed and wastewater connections



Correct installation of the weight with the securing ring

Correct positioning of the hoses in the water tank



3.5. Setting up the device

- The unit should be placed on a flat, level surface. Do not use the unit if it is at an angle.
- Only demineralized or distilled water should be used in the devices. The use of incorrectly specified water (see "3.2. Feed water quality") reduces may compromise sterilization effectiveness and cause damage to the device that is not covered by the warranty.
- Leave at least a 5 cm gap at the rear and sides of the unit from walls or other objects to ensure proper ventilation and access to fresh air.
- An overly tight enclosure may cause malfunctions in the unit. It is recommended that the front, top and one of the sides of the autoclave are not adjacent to the surface of other furniture or walls, leaving at least 15 cm of free space.
- The unit should be located to provide easy access to the main switch located on the rear panel of the unit.
- Do not place the unit near a sink with water or other places where the unit could be flooded - danger of short circuit.
- The device should be installed in a well-ventilated room, far from heat sources and rooms where mixtures of gases or liquids or other dangerous factors may arise.

The following conditions must be ensured for safe and efficient operation of the device:

- ambient temperature from +5°C to +25°C,
- relative humidity from 0 to 90%,
- storage temperature from +5°C to + 60°C.

3.6. Connecting the device to the power supply

Connect the appliance only to power sources that are grounded and equipped with residual current protection, and that have the same voltage rating as the appliance (see "12. Technical Data").

It is unacceptable to use extension cords to connect the device to the power source. Connecting the device to an incorrect power source may damage it and void the warranty.

4. Preparation and loading of instruments

The devices are suitable for sterilization of loads for which steam sterilization is stipulated. The instruments must be sterilized only if they are clean and dry. Therefore they must be washed and disinfected before being loaded onto the tray in accordance with applicable regulations. Residues of used chemicals or other solid particles may render the sterilization process impossible or even damage the device. In addition, sterilization of instruments that have not been previously cleaned and disinfected is a biological hazard and can lead to damage (both to the instruments and to the sterilizer). For instruments that must be lubricated, use steam sterilization lubricants. Excess lubricant must also always be removed

- The 134 ° C FAST program is intended only for sterilization of unwrapped instruments (see "1.5 Enbio S Sterilization Parameters" and / or "1.6 Enbio PRO Sterilization Parameters").
- After sterilization with 134°C FAST the instruments are moist - it is recommended to leave the drawer open for a few minutes to evaporate excess moisture.
- After sterilization of unpackaged loads, they are intended for immediate use.
- Tools that require oiling should always be packed in a pouch before being placed in the sterilization chamber. Their use without packaging may lead to contamination of the device and, consequently, damage.

4.1. Preparation of packages

It is recommended to use sterilization packaging that meets the requirements of EN ISO 11607-1: 2020 and EN 868-2: 2017. Appropriate packaging should:

- Ensure good penetration of the sterilizing agent into the inside of the package,
- Provide resistance to damage during the sterilization process,
- Ensure tight and durable sealing of contents and safe removal for use,
- Provide a barrier to microorganisms and unwanted substances and contaminants,
- Use disposable sterilization sleeves (intended for steam sterilization) as recommended by their manufacturer
- Sleeves should only be filled to about 3/4 full to allow for proper sealing and minimize the risk of damage to the package
- A distance of at least 30 mm should be maintained between the seals and the sterilized load.
- The sharp edges of the load should be protected to avoid damaging the packaging
- The packaging material must not be placed too loosely or be tightly stretched so as not to affect pressure variations during sterilization
- A label with information about the contents of the package, the code of the packer, date of sterilization and use-by date as well as parameters of the sterilization process should be placed on the package



Example of a wrapped load.



Example of an unwrapped load.

4.2. Arranging pouches on sterilizer tray (sterilizing wrapped loads)

- Pouches on the tray should be placed so that the paper side touches the paper side, because penetration of the sterilizing agent and air exchange can only take place through the paper.
- The pouches must be placed on the tray so that they do not come into contact with the door seal or the walls of the sterilization chamber. Failure to follow this instruction may prevent the chamber from sealing properly. If the chamber is not properly sealed, the sterilization cycle will not start or proceed. As a result, the instruments will not be sterilized.
- The edges of the packs must not protrude beyond the sterilizer tray.
- If the sterilizer chamber is heavily loaded, the first packs must face the foil side towards the bottom of the tray (this ensures faster and more efficient drying of the packs).

4.3. Arranging instruments on the sterilizer tray (sterilization of loads without packaging)

- In the case of sterilization without packages - the instruments must be placed in such a way that they do not have direct contact with each other, no element of them falls into the openings of the tray, and does not rest against the edge of the tray or protrude beyond its outline.
- Failure to follow the above recommendations may cause permanent and irreversible damage to the sterilization chamber or door seal, which will result in the lack of tightness of the sterilizer and loss of warranty.

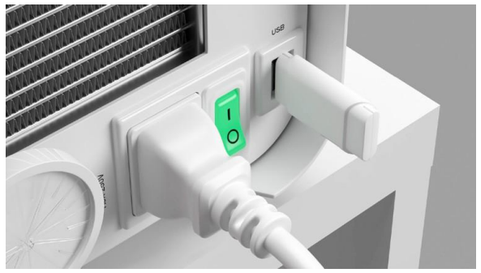


Do not exceed the maximum load weight: 500 g for Enbio S and 800 g for Enbio PRO. To monitor the sterilization process, it is recommended to place a chemical indicator in the chamber during each cycle. The indicator changes color when exposed to the specified sterilization conditions. However, a color change alone does not confirm that sterilization has been successfully completed.

5. Operating the device

5.1. First run

Turn on the device using the main switch located on the rear panel of the device. Make sure that the supply and wastewater hoses are connected correctly, and that there is water in the supply tank/bottle. Place the load on the tray, slide the drawer in and lock it, i.e. turn the knob clockwise. The sterilizer provides audible information about changes and the completion of the process.

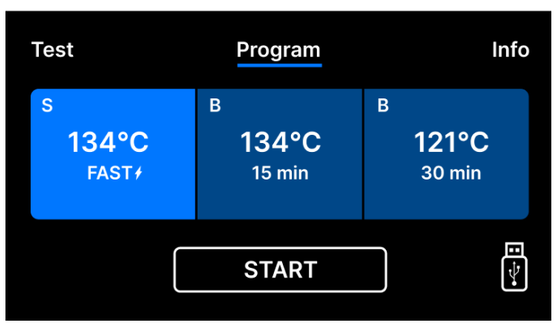




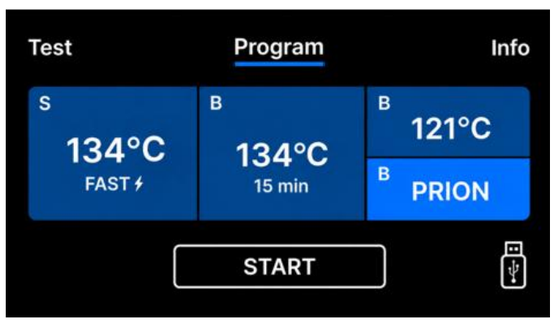
5.2 Program selection

Depending on the type of load to be sterilized, the user must select the appropriate program - in accordance with the instructions of the sterilizer manufacturer (see sections: "1.4 Intended use of the device", "1.5 Enbio S sterilization parameters" and "1.6 Enbio PRO sterilization parameters") and the load manufacturer's recommendations.

- Carrying out sterilization processes for which the manufacturer recommends steam sterilization in the ENBIO S / ENBIO PRO device does not affect the biocompatibility of the materials.
- All device components that come into direct contact with the sterilized load do not cause toxicity, sensitization or irritation.



Process selection screen **Enbio S**

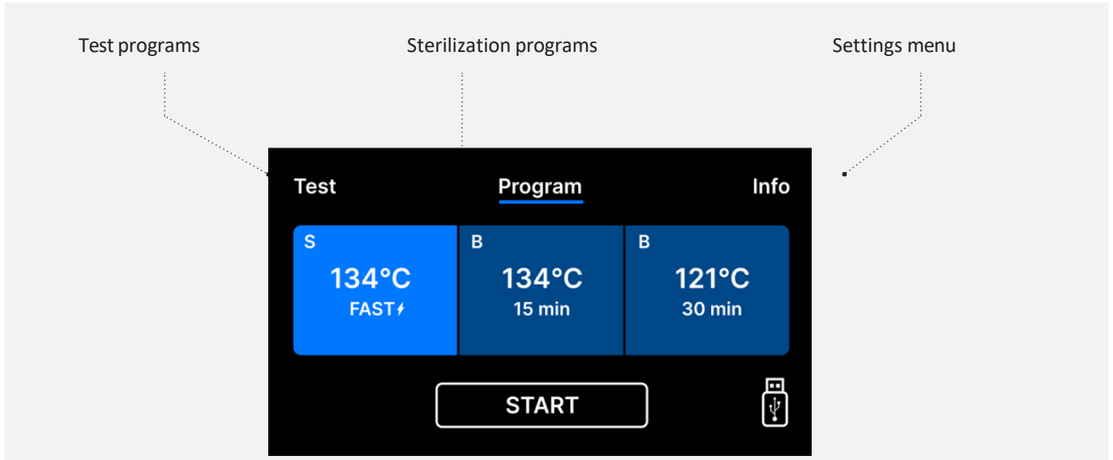


Process selection screen **Enbio PRO**

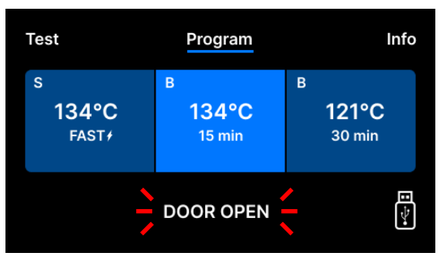


Each time the device is switched on, the welcome screen appears in the display. To go to the next screen, press the screen once with your finger (anywhere).

On the next screen, we can go to sterilization, test the device or open the information menu. The following sterilization programs can be selected from the main menu: 121 ° C, 134 ° C, 134 ° C FAST and 134 ° C PRION (Enbio PRO only).



Selection of sterilization programs

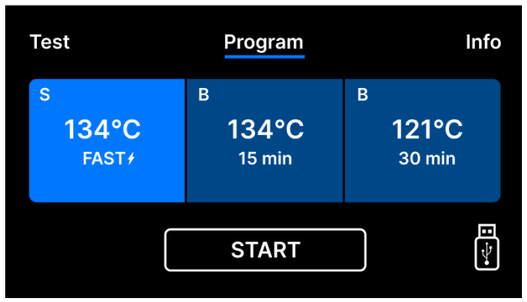


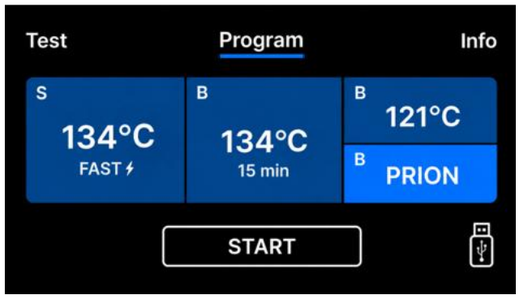
When the chamber is opened, the DOOR OPEN symbol flashes.

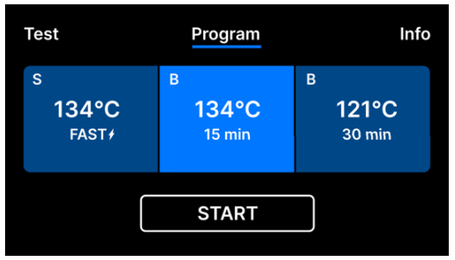


When the chamber is closed by turning the locking knob clockwise, the START symbol appears on the display, which informs that the chamber is properly closed.

Now we can select the program by pressing the appropriate symbol of the temperature in which we want to sterilize 121 ° C, 134 ° C, 134 ° C FAST or 134 ° C PRION, which will highlight the selected program. The selected program is started by pressing the START symbol.







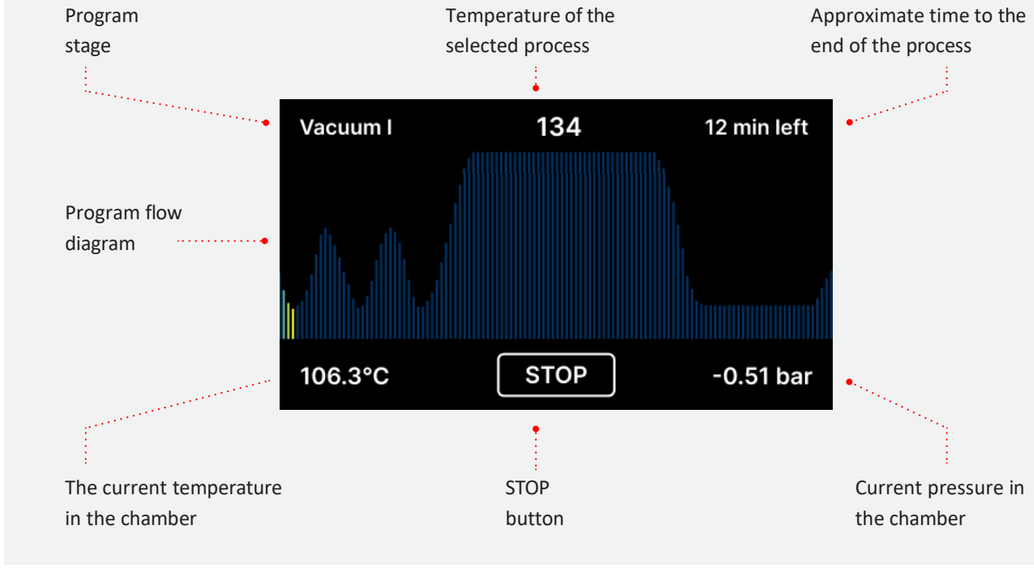
If the USB memory is not inserted in the device, the USB disk symbol is not displayed in the lower right corner of the screen.



A message appears that USB memory is missing. The program data will not be saved. We can continue working without saving data to the USB memory stick by pressing the YES box, or abort the work by selecting the NO box to place the stick in the port and start the program steps from the beginning.

It is recommended to use a USB drive with each of the processes. The data stored on it will allow you to print reports from selected processes.

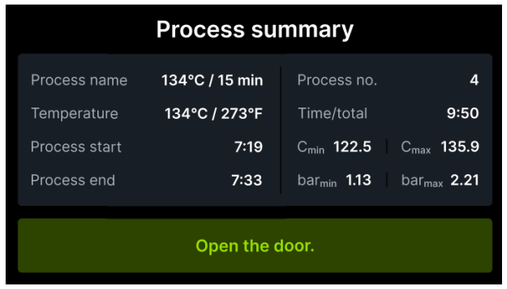
If work continues or the START field has been selected, a symbolic pressure diagram of the entire process is displayed on the screen with the current program progress highlighted against a background and information on the next process steps in the upper left corner of the screen. During the program run, the screen displays the temperature of the selected sterilization program or the current temperature in the process chamber in the lower left corner, the current pressure in the chamber in the lower right corner, and the time remaining until the end of the process in the upper right corner of the screen. This is an estimated time, which may be increased due to the weight and type of the load.



During the program, the START button is replaced by the STOP button, allowing the user to stop the process at any time. The names of the individual program stages are displayed sequentially in the upper-left corner of the screen, e.g., chamber locking, heating.

5.3 Process summary

If the process has been completed successfully, the display alternately shows information screens indicating the end of the process and the sterility of the load, as well as the possibility of opening the device chamber.

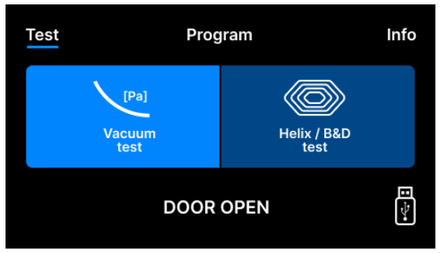


WARNING! After the process, the chamber, tray and load are hot. Be especially careful and use protective gloves to remove the load or wait until it cools down. In the 134C FAST program, instruments are hot and wet after sterilization.

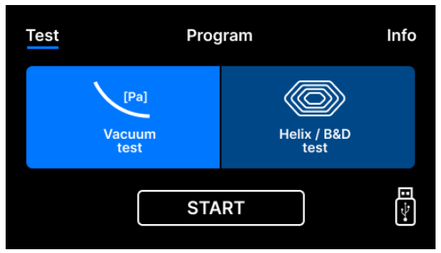
5.4 Test programs

The devices are equipped with special test programs to verify the correct operation of the sterilizer.

Enbio S / Enbio PRO	Bowie & Dick / Helix	Vacuum test
Process temperature	134°C	–
Number of pre-vacuums	3	1
Sterilization time	3.5 min	–
Drying time	3 min (S), 4 min (Pro)	–
Total process time	15 min	16 min



By pressing the Test field you go to the test programs menu. From this screen, we can choose between the Vacuum test and Helix / B&D test programs. We select the appropriate program by pressing the required field on the display.



When the device chamber is closed, the word DOOR OPEN changes to START and by pressing this field the selected test program is started.

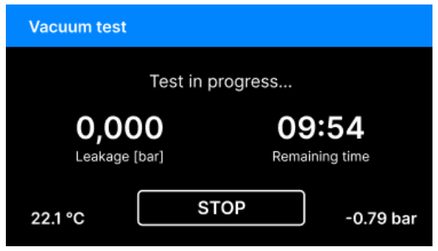


If a USB flash drive has not been inserted into the unit, the USB symbol is not displayed in the lower right corner of the screen and a message indicating no USB flash drive is displayed. The test program data will not be saved. We can continue without writing data to the USB flash drive by pressing the YES box or abort by selecting the NO box to place the USB flash drive in the port and start the program from the beginning.

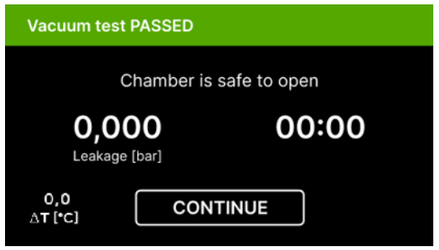
Vacuum test

The vacuum test should only be performed on a cold device before starting work. During the test, the device verifies:

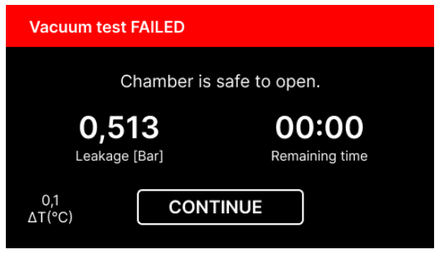
- vacuum pump capacity.
- tightness of the pneumatic system.



After selecting a vacuum test program and starting it with the button, the vacuum test program run screen is displayed, with Information about loss of pressure in the working chamber and the duration of the test.



[Vacuum test PASSED]
When the test program ran successfully.



[Vacuum test FAILED]
When the test program did not run successfully.



After pressing the CONTINUE field, the welcome screen is displayed.

During the vacuum test the sterilizer chamber must be completely dry and cold. If not, the vacuum test may not be reliable even if the sterilizer is fully operational. When the test is complete a message indicating the result will appear on the display. If the result is negative check, clean or replace the seal, clean the front edge of the chamber and repeat the test. If the Vacuum test fails again, contact the supplier or manufacturer.

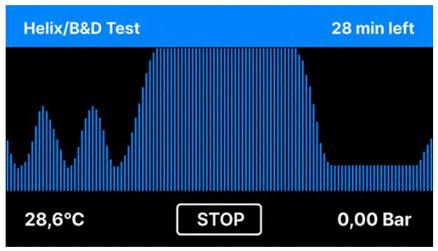
Bowie & Dick test

The Bowie & Dick test, also known as the steam penetration test, simulates a small, highly porous load. To perform the test it is necessary to have a special test packet and placed inside the chamber. The package is not an accessory of the device, the user should purchase it on their own.
This test evaluates the device's performance in sterilizing loads of porous objects:

- Pre-vacuum performance and steam penetration.
- Temperature and pressure of saturated steam reached for a certain period of time.

How to run the test:

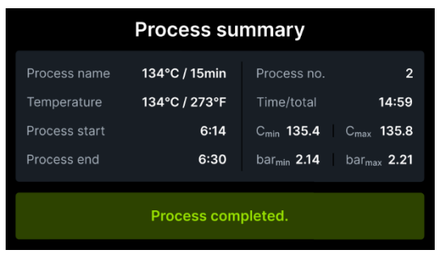
- The test must be carried out with an empty chamber in accordance with EN 13060.
- Place the Bowie-Dick test package in the chamber in the center of the tray.

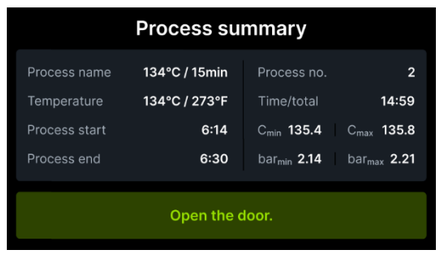


After selecting the Helix / B & D test program and starting it with the START button, the program sequence screen is displayed.
Information about the process parameters is displayed.

The Helix / B&D test program can be stopped at any time by pressing the STOP button. Stopping the program before completion will result in an invalid test. The test indicator used in the interrupted cycle must not be reused and should be replaced with a new one before repeating the test.

When the test program is complete, alternating screens are displayed: Test complete / Open door.
The process chamber of the sterilizer can be safely opened.







After opening the process chamber, the welcome screen is displayed.

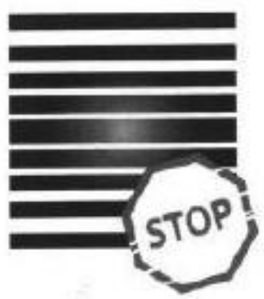
The control test should be removed.

WARNING! The package will be hot.

To correctly interpret the test, refer to the instructions provided by the test manufacturer.
Open the package and remove the indicator chemical from the center of the package.



Positive result
The chemical indicator turned a uniform dark color over the entire surface.



Negative result
A bright field remained in the middle of the test because of the remaining air inside the tested device.

Any color change, uneven coloring of the test, indicates the presence of air during the test cycle due to a malfunction of the sterilizer. If the test result is abnormal, check the expiration date of the test pack and repeat the test.

Helix test

The Helix test corresponds to the sterilization of instruments with A-holes in accordance with EN 13060. It consists of a 1500 mm long tube open on one side and a closed test capsule on the other side. The indicator strip is inside the test capsule.



Helix test kit

This test is used to evaluate the efficiency of the device in the sterilization of hollow and porous loads, in particular:

- Pre-vacuum performance and speed and uniformity of steam penetration.
- Saturated steam temperatures and pressures reached for a certain period of time.

How to run the test:

- The test must be carried out with an empty chamber in accordance with EN 13060
- Follow the test manufacturer's guidelines
- Place the test in the center of the tray in the chamber.
- At the end of the cycle, open the sterilizer and remove the test.

WARNING! The test kit will be hot.



Positive result
all areas of the indicator strip have turned dark



Negative result
Part of the indicator strip did not turn dark due to the presence of air inside the capsule.

To correctly interpret the test, refer to the instructions provided by the test manufacturer. Open the capsule and remove the test strip.

Insufficient color change of the indicator strip fields indicates the presence of air during the test cycle due to a malfunction of the sterilizer. If the test result is incorrect, check the expiration date of the test pack, additionally check that the tubing is not clogged and obstructed, and repeat the test.

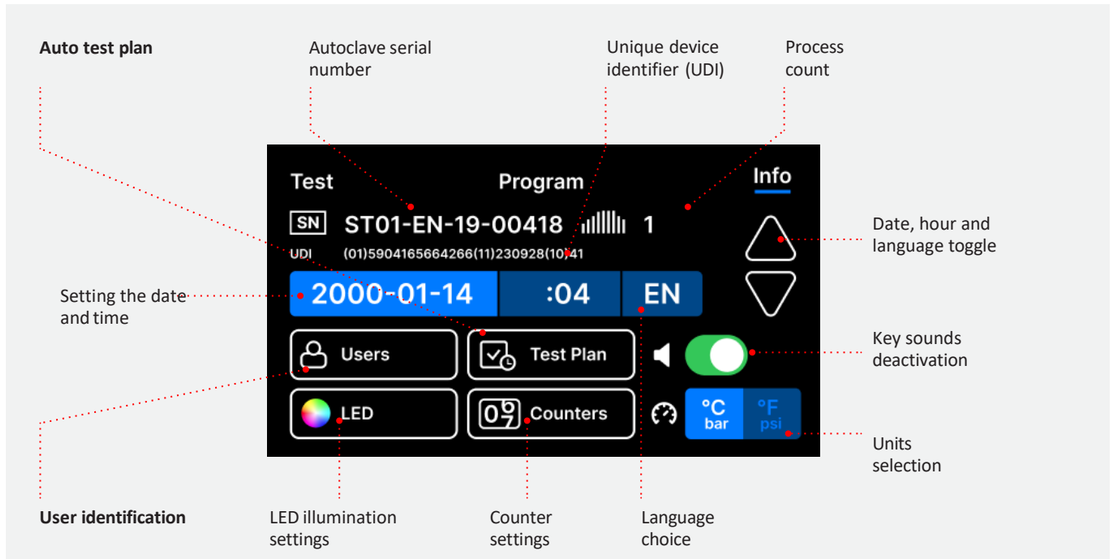
5.5 Info menu

The info menu is accessible by pressing the **Info**. button.
This screen displays information about the unit type, serial number, number of processes performed, as well as the **COUNTERS** service menu - process counters for filter changes. It is also possible to change the date and time. To set the date or time touch the digits on the display. When a certain field is selected, it starts flashing and the arrows for changing the value up or down are displayed. This allows to set the date and time. Pressing the field again confirms it and you can move on to changing the settings of the next parameter. In the same way, you can select the language by clicking on its abbreviation.

LED lights - Clicking the **LED** button launches the lights on the sides of the device.

Sound - Tapping a **green switch** turns off and on the button sounds.

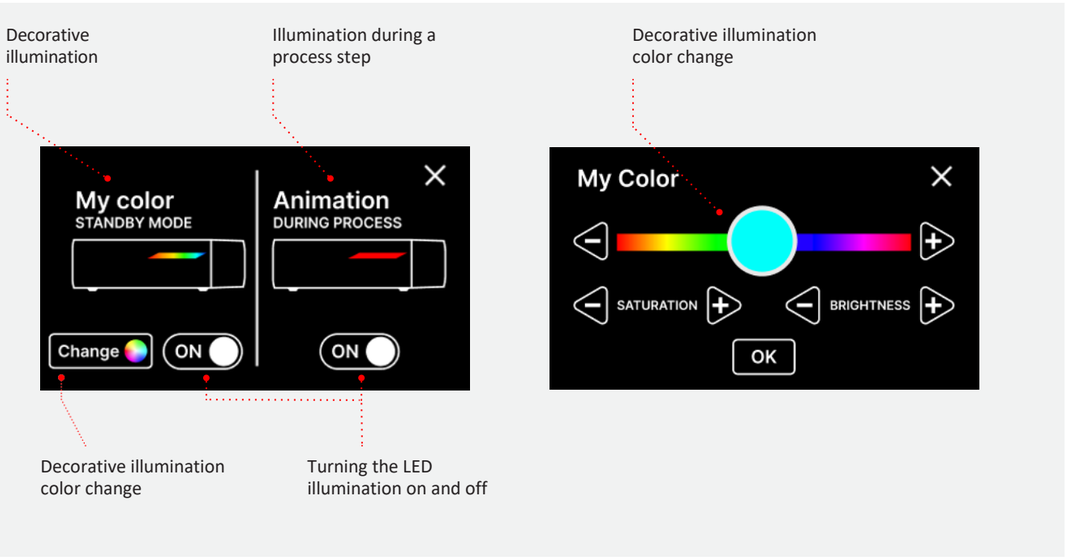
Users – Tapping the **Users** button opens the user management menu, where users can be added or removed.



5.5.1 LED lighting

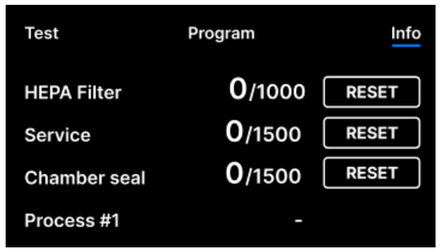
LED lighting has two modes:

- Free mode, where the user (by moving the sliders) freely sets the colors, intensity and brightness of the light to their preference.
- Continuous mode that indicates the stages of the entire sterilization process with colors LED lighting.

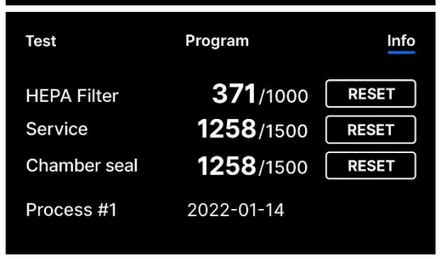


5.5.2 Counters

Enbio S and Enbio PRO sterilizers record the number of processes performed. This lets you know when you need to replace consumable parts and when a service inspection is due. ENBIO sterilizers count down to the required overhaul 12 months or 1500 processes from the time the first process was performed, whichever occurs first.

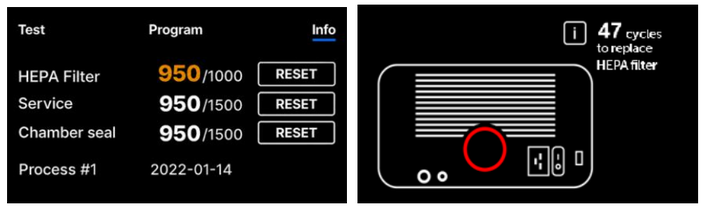


Counter section with the counters reset to zero. The number of processes performed is on the left, while on the right is the number at which the component should be replaced or a service inspection should be performed. After replacing the filter, the user can reset the values by pressing the RESET button. The value for the service check can only be reset by an authorized service technician.

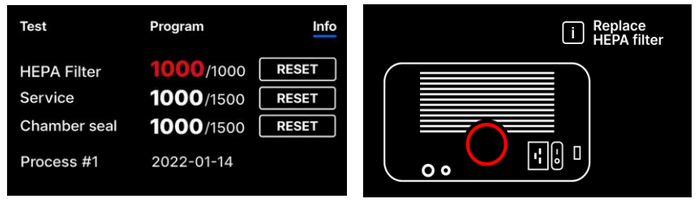


During the first process (Vacuum, Helix, FAST, 134, 121, Prion), the unit will record the current date as the date of the first process (bottom line on the counter screen). The device will count processes and days since the first process.

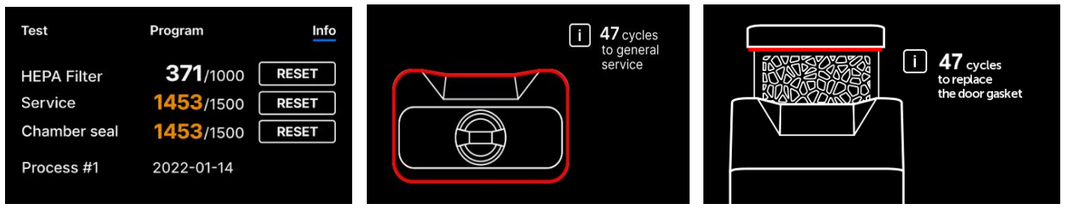
If the process count exceeds 950, the device will inform the operator or user of this via a warning screen and display this value on the counter screen.



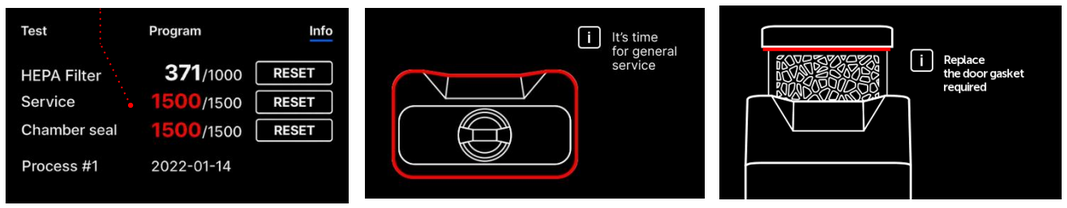
If the process count in exceeds 1000, the device informs the operator or user to replace the HEPA filter.



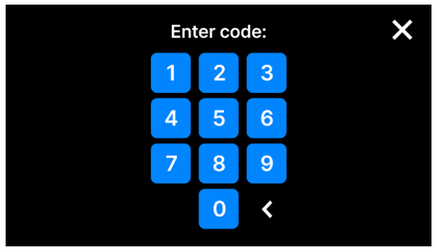
If the process count exceeds 1450, the device will inform the operator or user of this via a warning screen and display this value on the counter screen.

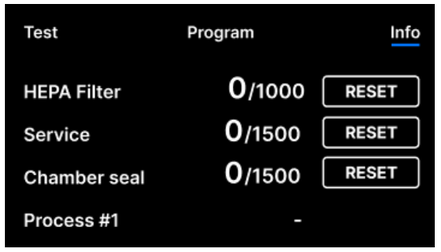


If the process count in exceeds 1500, the device informs the operator or user to perform a periodical service and replace the chamber seal.



The counter can only be reset by Enbio or an authorized external service by selecting the RESET button on the counter screen and entering a unique service code.





Displaying the counter values in yellow or red does not block the operation of the unit. However, exceeding the required replacement time may have a significant impact on the operation of the unit and the sterility of the load. For replacement of individual components, please contact the manufacturer or supplier.

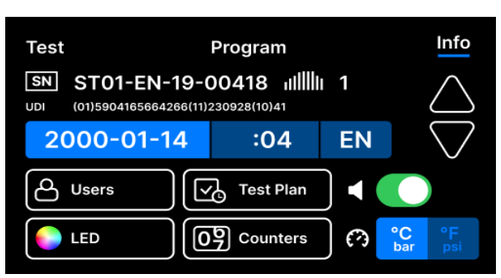
No.	Name	Replacement frequency (cycles)	Yellow Early replacement call (cycles)	Red Replacement after (cycles)
1	**HEPA filter**	1000	950	1000
2	**Door gasket (chamber seal)**	1500	1450	1500
3	**Service**	1500	1450	1500

5.5.3 User identification

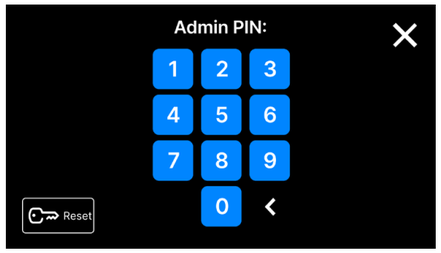
Enbio S and Enbio PRO sterilizers are equipped with user identification, acting as digital signature, allowing to identify the users commencing the sterilization process and approving the sterilized batch for use.

- Only properly trained and qualified users may carry out batch approval
- It is the responsibility of the user carrying out batch approval to follow and adhere to the local guidelines for the qualification of batches after sterilisation.

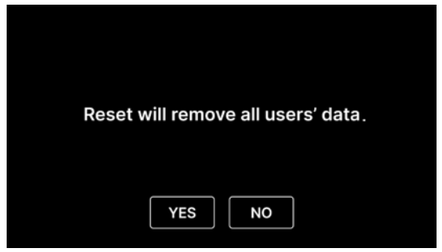
Activating and setting up user identification



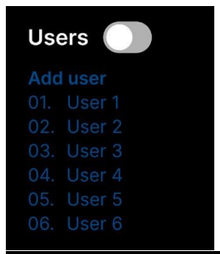
To activate or change user identification settings, tap **Users** button from **Info** menu.

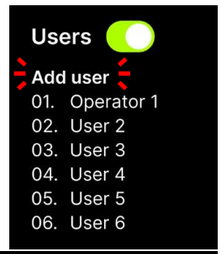


Before activating user identification, 4-digit admin PIN must be set (default admin PIN is set to 0000). The admin user is requested to enter PIN each time any changes are done. If the PIN is lost, the user can use **Reset** button in the lower left corner.

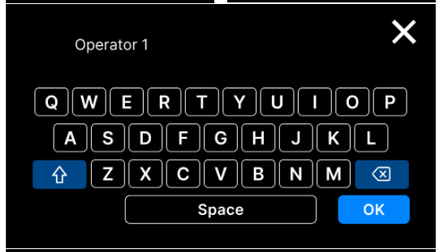


Upon deleting admin PIN, all previously entered users are removed, and admin PIN set to default (0000).

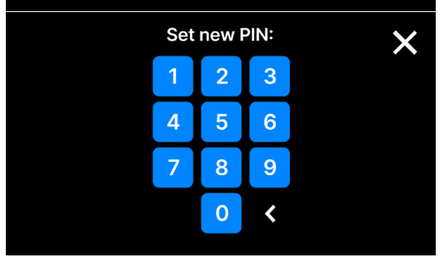




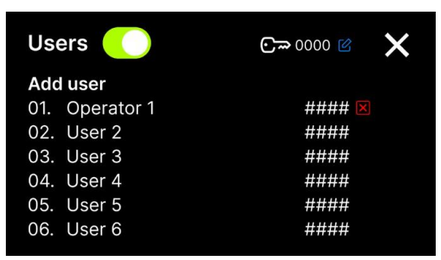
To activate or deactivate user identification feature, tap button next to Users. After activating, list of user fields appears, and **Add user** text blinks. To add new user, tap **Add user** text.



Next, a keyboard with a cursor appears. You can now type in desired user name (letters and numbers). After typing in the name, confirm it with **OK** button.



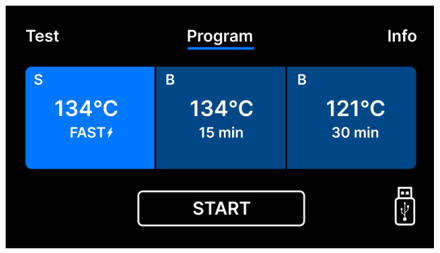
Next, Set new PIN screen appears. Type in 4-digit PIN of your choice.

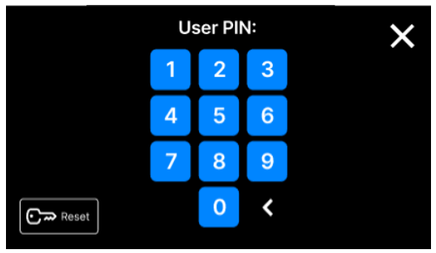


The new user with the PIN is added. You can delete the user by tapping red cross to the right of the PIN. Admin PIN can be changed from this screen, by tapping the small key icon at the top of the screen.

Batch approval

User identification is executed on two levels: identifying the user commencing the process, and identifiyng the user approving the sterilized batch for use (these can be different users). Before using user identification, users with respective PINs must be configured. Names assigned to appropriate user numbers will appear on process report (see: Enbio Data Viewer, p. 50). To read the user data, Enbio Data Viewer must be version 17.3 or newer.





Select the desired program, and tap **START**. The user commencing the process must enter personal PIN. (tap **Skip** to bypass this step).



After the process is completed successfully, the screen with approval options appears. Open the drawer and make visual assesement of the load.



If the chemical indicator was present, tap **PASS** or **FAIL** depending on the result. If the chemical indicator was not present, tap **N/A** (Not Available).



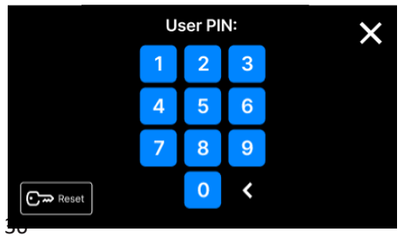




To approve the batch, tap **YES** in Batch approval menu, or **NO** to reject. After selecting this option, **CONFIRM** button appears.



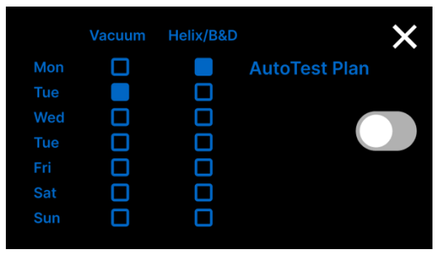




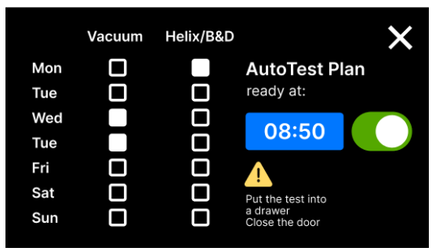
To finish the batch approval for use, user must tap **CONFIRM** button, and enter personal PIN code (tap **Skip** to bypass this step). Then, Hello screen is displayed and the autoclave is ready for the next process.

5.5.4 Auto test plan

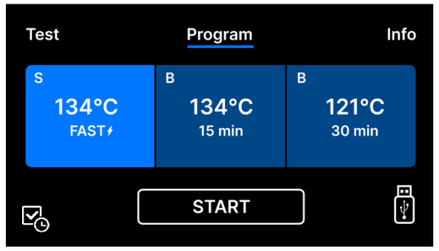
Auto test plan is the feature which allows automatic execution of vacuum or Helix/Bowie&Dick tests at a specified hour and day of the week. The program is prepared so that the tests are already completed at the hour specified on the dial (programs start early in advance). For instance, if you usually begin your work at 9:00, you can set completion time at 8:50, and tests will be completed for that time.



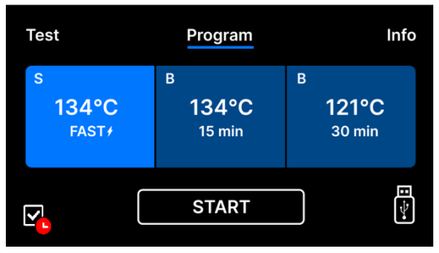
To activate auto test plan, tap toggle switch. Weekly schedule and time dial appears.



Select the desired day of the week for each program, and set the hour at which all tests will be ready.



When auto test plan is active, an icon in the left lower corner of program or test selection screen is displayed.



Red mark on the icon reminds the user about closing the doors before leaving. Auto test will not start when door is open.

Since vacuum test is performed on cold chamber, vacuum test is always executed first.
For successful operation of auto test plan, always remember before leaving your office:

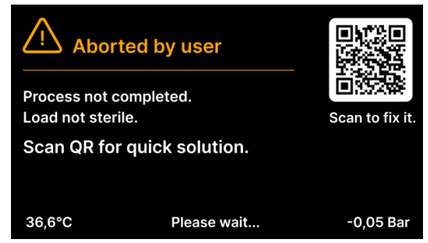
- check whether appropriate tests were placed on the drawer (if Helix/B&D is scheduled).
- close the sterilizer doors, so the red door open icon disappears.

5.6 Restart

The restart of the process is forced when the user stops the process by pressing the STOP field, in the case of a power outage or an error during the process, for example lack of supply water.

If the STOP field is selected, the following messages is displayed: Process not completed. Load not sterile.

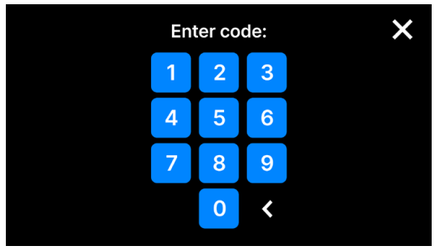


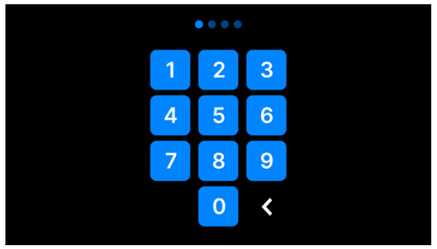


When the pressure in the working chamber is equalized, the following message appear on the display. Now you can open the device freely.

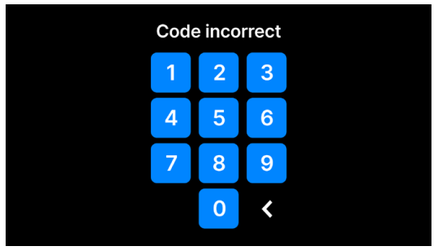


By selecting the field, we can return to the welcome screen. In the event of an error, we must additionally enter the 4-digit security code 0000. Entering this code is tantamount to the operator's declaration that he is aware that the sterilization process has not been carried out properly and that the batch is non-sterile.





If an incorrect code is entered, a message will appear on the display.



Enter the code again. The arrow enables erasing incorrectly entered digits. After entering the correct code, a welcome screen will appear on the display of the device.



6. Service inspections

To ensure proper operation of the device, periodic maintenance and service inspections are recommended in accordance with the values specified in Section 5.5.2.

The device is equipped with a process counter that tracks the number of completed cycles and notifies the user when the recommended cycle-based maintenance interval is approaching.

Service inspections should only be performed by a service center authorized by Enbio. To inquire about inspection costs, please contact us using the contact form available at enbio.com.

A list of authorized service centers is available on the manufacturer's website at www.enbio.com.

6.1 Product shelf-life

The only element determining the shelf life of Enbio S and Enbio PRO sterilizers is the process chamber. In the chambers used in Enbio S and Enbio PRO, no plastic deformations were detected after 20,000 sterilization processes were performed. This number of cycles corresponds to the expected use over 10 years of operation or 20,000 sterilization processes. However, even after exceeding the above-mentioned values, the devices can still be used – if the technical inspections of the device are carried out on time, in accordance with recommendations in this user manual.

7. Device maintenance

7.1 Regular operation

The user must perform at least one complete sterilization cycle every 60 days, even if the device is not in regular use. This helps maintain the proper functioning of internal components, and reduces the risk of malfunctions caused by prolonged inactivity.

7.2 Cleaning

In order to ensure the correct operation of the device, the user is obliged to perform the following maintenance actions.

Cleaning the tray

Keeping the tray clean helps to ensure proper operation of the device. The tray and its technical condition are a good indicator of using the correct water. Limescaled, brown tray indicates the use of poor quality water. It is recommended to clean the inside of the tray on a weekly basis with a mild detergent that does not contain chlorine and does not react with aluminum. After cleaning, the tray requires thorough rinsing with water. In order to clean the tray properly, it should be



Lift the tray up gently and pull away from the front face. The mounting pins have notches into which the drawer fits. Before reinstalling the tray into the unit, drain the tray and slide it over the front face pins and press down gently to lock.

Cleaning the process chamber

Keeping the chamber clean helps to ensure proper operation of the device. It is recommended to clean the inside of the process chamber once a week with a mild detergent without the addition of chlorine. After cleaning, the chamber should be wiped dry with a soft cloth. Cleaning should be performed on a cold chamber.

Cleaning of external surfaces

Cleaning the external parts of the device should be done with a soft cloth moistened with water and a mild detergent (no chlorine added and not reacting with plastics, varnish coatings, aluminum). Strong detergents should not be used. The use of mild detergents to maintain the device does not affect the risk of toxic components coming into contact with device components. Do not clean inside the LED openings or insert any objects into them.

Cleaning the gasket

It is recommended to clean the gasket each time after 100 processes. Use warm, clean water and microfiber to clean the gasket (microfiber with silver particles is allowed). Blunt and sharp cleaning tools are not allowed. Cleaning with chemicals is not allowed. Carry out cleaning on a turn off, cooled down device, after opening the drawer. Be careful not to bend the drawer. After cleaning, leave the device open until the gasket is dry. During this time, protect the device against damage. Any visible mechanical damage is unacceptable and requires the seal to be replaced

7.3 Replacement of consumable parts

The sterilizer is equipped with a high performance sterilization system. A message on the screen informs the user when each component should be replaced. If the sterilizer is in regular operation, alternating replacement screens will appear after the welcome screen has been pressed. The replacement screens are described in detail in section "9. Warning Messages and Error Codes".

Cleaning the water container

In order to ensure the correct parameters of the water supplying the device, it is recommended to check the water tank at least quarterly. If contamination is found, the tank should be emptied, cleaned and refilled with new water.

In order to ensure an efficient sterilization process and the correct functioning of the device, it is recommended to replace consumables in a timely manner.

Consumable parts

The table below contains items subject to periodic replacement and items subject to natural wear. Spare parts must be ordered directly from the manufacturer. The use of other spare parts voids the warranty and does not guarantee the correct functioning of the device.

Name	
HEPA filter Enbio S / PRO	27720A
Enbio S Tray	14738B
Enbio PRO Tray	1191812B
Wastewater set (plug + red hose 1.5 m)	1166667A
Enbio Magic Filter (+plug + blue hose 1.5 m)	1216935EUA
Chamber drain filter	1210748A

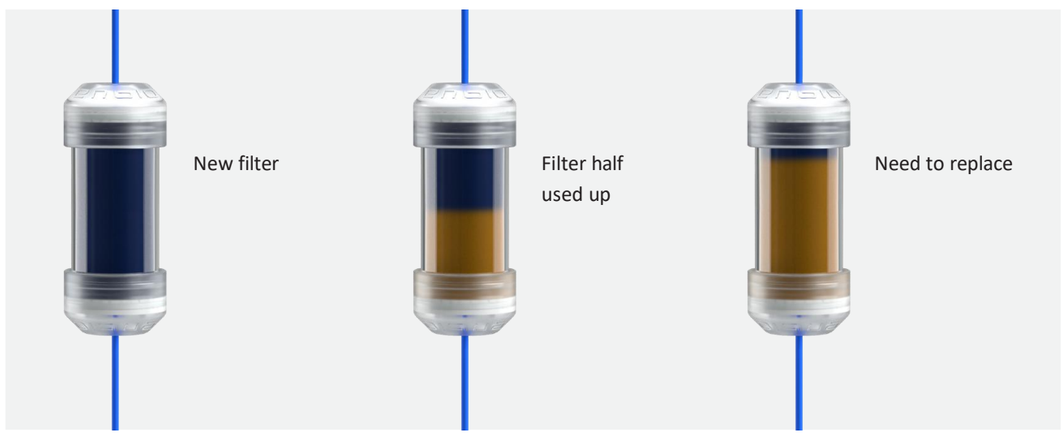
To ensure proper functioning of the Enbio S / Enbio PRO sterilizer, it is recommended that the wearing parts be replaced according to the schedule below. And periodic inspection of the individual components of the sterilizer in accordance with the following guidelines.

Name	Replacement frequency
HEPA bacteriological filter	Every 1000 cycles or every 12 months
Connection / drain hose	If damage is observed or once a year
Plugs for water / condensate containers	If damage is observed
Front drawer with seal	Replacement at mandatory service after 1500 cycles/365 days
Enbio Magic Filter	Replace the filter once every 6 months or sooner when the resin has completely discolored to an amber color

Element to be controlled	Frequency of inspections
Front gasket	weekly or in the event of incorrect operation - performed by the user
Bacteriological filter	weekly - performed by the user
Connection / drain hose	weekly or in the event of incorrect operation - performed by the user
Container stoppers	weekly - performed by the user
Enbio Magic Filter	weekly - performed by the user

7.4 Replacing the Enbio Magic Filter

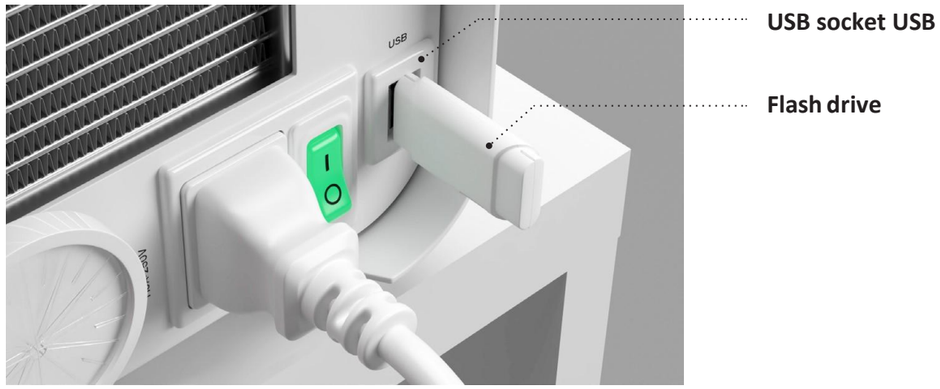
The filter should be replaced with a new one once every 6 months or sooner when the resin has completely discolored to an amber color. Failure to do so may disrupt the sterilization process and will void the sterilizer warranty. Dispose of the used filter according to local guidelines. The filter and all its parts are not recyclable.



8. Data archiving

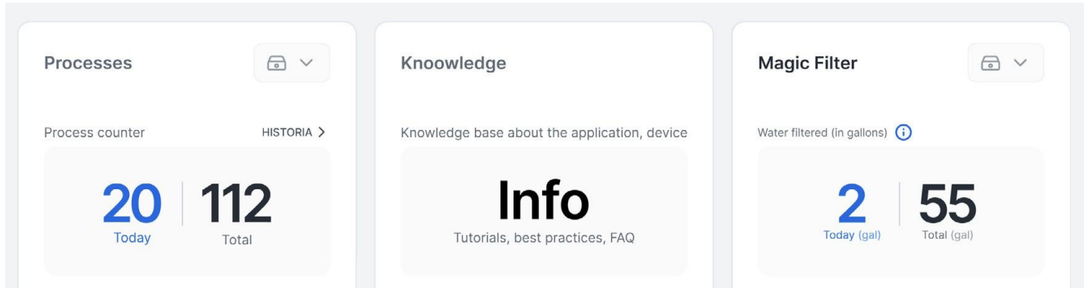
The course of each performed sterilization is automatically saved on a data carrier (USB stick).

- The memory slot is located on the rear panel of the device.
- It is recommended to periodically archive the data on another medium e.g. computer, laptop.
- Do not remove the USB flash drive from the port during the sterilization process.
- The USB flash drive must have a minimum capacity of 8 GB and be formatted with the FAT32 file system.



9. The my.enbio application

The my.enbio application enables effortless review and archiving of sterilization processes, featuring intuitive date-based filtering. It includes a process counter and a water-saving counter powered by the Magic Filter. The app is enriched with a Knowledge section, offering a comprehensive tutorial that guides users step-by-step through the available features. Additionally, it provides instructional videos demonstrating proper device setup and access to the Enbio Academy—a series of educational videos designed to enhance users' understanding of sterilization, tailored specifically to their needs.



9.1 How to get started with the my.enbio app

Go to https://my.enbio.com/register or scan the QR code on the right to begin the registration process.

my.enbio.com

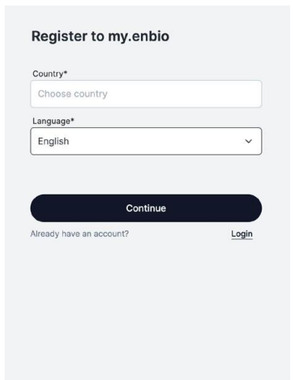
1. Complete the Registration Form
Fill out the required fields in the form and click the "Continue" button.

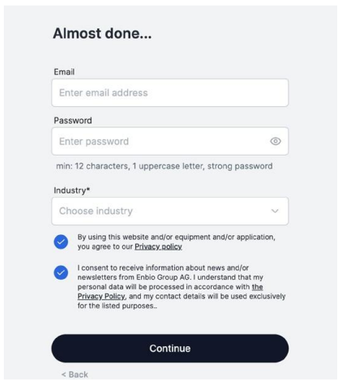
2. Confirm Your Registration

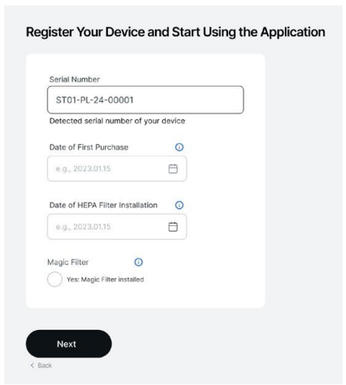
Check your email inbox for a confirmation message. Follow the instructions in the email to verify your registration.

3. Register Your Device
Prepare your device's serial number and purchase date, then complete the device registration process. Once your device

is registered, you can start using the application and enjoy its full functionality.









10. Warning messages and error codes

In the event of a device malfunction, the display shows the relevant information, warning and error codes.

10.1 Warning messages

The warning messages refer to the replacement of individual consumables.
The item to be replaced is highlighted in red.

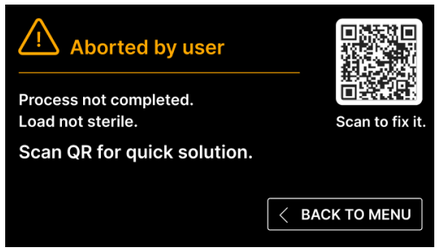


Filter replacement screen

10.2 Information messages



Screen about overpressure or underpressure resulting from the natural processes of cooling the chamber. It can occur immediately after starting the machine.



Message resulting from interruption of the process after the sterilization stage - during drying.

10.3 Warning codes

The table below contains error codes that may appear when working with the ENBIO S / ENBIO PRO sterilizer.

Warning No	Description	Recommendations
1	Maximum chamber temperature exceeded	• Contact technical service.
2	Steam generator temperature too high	• Too high weight of sterilized instruments - repeat the process with less instruments (max. 0.5 kg S, 0.8 kg PRO) • Contact with the service
3	The temperature during the process has exceeded the set limit.	• Contact technical service.
4	The pressure inside the sterilization chamber has exceeded the set limit.	• Contact technical service.
5	Pressure too low during sterilization.	• Make sure the blue tube is submerged in water. • Check the container, tube, and filter. • Restart the autoclave if necessary. • If the problem persists, contact customer service.
6	Sterilization temperature too low	• Make sure the blue tube is submerged in water. • Check the position of the red tube – it must not be placed vertically. • Use only clean distilled or demineralized water. • If the problem persists, contact technical service.
7	The chamber pressure is too high during the drying phase.	• Make sure the red tube is not submerged or kinked. • Check the load weight: max 0.5 kg (S), 0.8 kg (PRO). • If the problem persists, contact technical service.
8	The device attempted to generate steam multiple times without success.	• Check the connection of the blue tube. • Check the water level in the tank. • Check the load weight and the condition of the pump. • If the problem persists, contact an authorized service center.
9	The system has detected a blockage in the drainage system.	• Clean the chamber interior and tray. • Empty the used water tank. • Check the tubing and drain opening for blockages. • If the problem persists, contact technical service.
10	The autoclave did not reach the required temperature on the chamber walls.	• Plug the device directly into a dedicated socket. • Avoid using power strips. • Check the voltage stability. • If the problem persists, contact technical service.
11	The steam generator did not reach the required temperature.	• Try running the cycle again. • Make sure the device is properly connected. • If the problem persists, contact technical service.
12	The device was unable to perform the pre-vacuum phase – possible issues with the gasket, pump, valves, or drainage.	• Clean the door gasket. • Check the used water level. • Check the drain tube and cooling system. • If the problem persists, contact technical service.
13	A temporary power outage or short circuit has occurred.	• Restart the device. • Check the connection to the power outlet. • Consult an electrician about the installation. • If the problem persists, contact technical service.
14	Pressure detected in the chamber during standby.	• Open the chamber and restart the device. • If the problem persists, contact technical service.

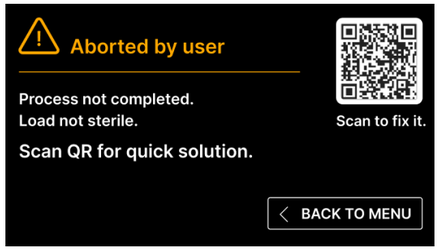
15	Door locking mechanism error detected.	• Turn the device off and on. • Start a cycle and stop it after a few seconds. • Wait for the message Chamber is safe to open. • If the problem persists, contact technical service.
16	The device did not unlock the door after the cycle was completed.	• Turn the device off and on. • Start a cycle and stop it after a few seconds. • Wait for the message Chamber is safe to open. • If the problem persists, contact technical service.
17	A problem occurred during decompression – possible blockage of the V3 valve or HEPA filter.	• Replace the HEPA filter and reset the counter. • If the problem persists, contact technical service.
18	Pressure sensor failure detected – component integrated with the main board.	• Contact technical service.
19	The device cannot save data to the connected USB flash drive – storage media or USB port damage.	• Copy the data from the USB flash drive. • Replace it with a new, empty storage device. • If the problem persists, contact technical service. • Check the USB flash drive's file system format. The device only supports FAT32.
20	The chamber temperature did not reach the minimum level.	• Contact technical service.
21	Chamber temperature sensor failure – sudden or irregular readings detected.	• Contact technical service.
22	Incorrect temperature readings from the steam generator.	• Contact technical service.
23	Temperature reading irregularities detected during the sterilization process.	• Contact technical service.
24	Autoclave temperature too low / temperature sensor error	• Leave the device switched off for at least 3 hours at room temperature. • If the problem persists, contact technical service
31	Flash memory error detected.	• Contact technical service.

Messages

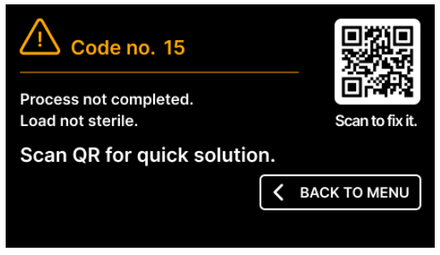
"Aborted by user"	Process interrupted by the user. Non-sterile cartridge if interrupted during or before the sterilization process.	This message appears when the user terminates the process. This does not mean that there is a malfunction. Start a new process.
"No USB memory"	No USB memory stick	Check the USB port and mount the memory. Contact with the service.
"Equalizing pressure"	Pressure when stationary. Equalization of pressure to atmospheric.	• The message occurs in certain cases as a result of natural processes. • If the message appears frequently, contact the service center.

Here are some examples of error codes:
Alternating texts: pressure equalization, please wait.





A QR code is displayed in warning message screens. By scanning this code with a mobile phone with the option of reading QR codes, the user will be redirected to a website containing recommendations on the possibility of eliminating the issue.





Complaints procedure

In order to report a problem with the device, complete the complaint form on the manufacturer's website www.enbio.com or contact the hotline. In the event of transport damage, a claim should be sent along with a bill of lading and a purchase document as well as photos documenting the damage.

If you have any questions, please contact us by e-mail at: **support@enbio.com**

WARNING! The complaint process will be started when the service department receives a correctly completed complaint application.

When returning the device for service, clean the chamber and the tray of the device, carry out the decontamination process and secure it properly during transport. The device should preferably be returned in its original packaging. In the absence of appropriate packaging, please contact the service or supplier.

If you need to transport the device:

- Disconnect the demineralized water and condensate hoses
- Allow the working chamber to cool.
- Use original or suitable packaging with protective inserts.
- It is recommended to remove any residual water from the heat exchanger by performing a vacuum test.

Damage caused during transport to the service due to improper protection of the device is the responsibility of the sender.

12. Warranty conditions

Please refer to “Warranty conditions” document (available on USB stick supplied with the autoclave).

13. Technical data

Device parameters	Enbio S	Enbio PRO
Power supply	220-240V AC 50 Hz	220-240V AC 50 Hz
Installed power	3.25 kW	3.25 kW
Nominal power	1.85 kW	1.85 kW
Maximum current consumption	10A	10A
Working pressure	2.1 bar	2.1 bar
Maximum pressure	2.45 bar	2.45 bar
Maximum process temperature	137°C	137°C
Process chamber volume	2.7 l	5.3 l
Weight	15 kg	20 kg
Process chamber dimensions (LxWxH)	285 x 180 x 33 mm	285x 190 x 70 mm
External dimensions of the device (LxWxH)	560 x 250 x 158 mm	575 x 270 x 200 mm
Degree of protection	IP20	IP20
Noise level	38dB(A)	40dB(A)
Archiving process data	Pendrive	Pendrive

Environmental conditions

Working temperature range	from +5°C to +25°C
Relative humidity	0-90%
Storage temperature range	+5°C to + 60°C
Ambient pressure range	900-1100 hPa



Rating plate located on the bottom of the device.

Enbio Group AG
Eichengasse 3
4702 Oensingen
Switzerland

14. EC declaration of conformity

UE DECLARATION OF CONFORMITY

Date of issue: 17/06/2025

Manufacturer: Enbio Group AG
Eichengasse 3
4702 Oensingen, Switzerland
ID/SRN: CHRN-MF-20001662

declares under its sole responsibility that medical devices:

SMALL STEAM STERILIZERS, REF:

- **Enbio S**
- **Enbio PRO**

Basic UDI-DI code: 7629999sterilizersM2

Product risk class: IIa

EMDN code: Z12011305

Having the intended purpose: *sterilization of medical devices with moist heat*, complies with the content of Regulation (EU) 2017/745 of the European Parliament and of the Council of April 5, 2017 on medical devices and the Act of April 7, 2022 on medical devices (Journal of Laws 2022 item 974). Conformity assessment was carried out in accordance with Annex IX of the above-mentioned Regulation.

The following standards were used in the conformity assessment:

- PN-EN ISO 13485
- PN-EN ISO 14971
- PN-EN 13060
- PN-EN 61010-1
- PN-EN IEC 61010-2-040
- PN-EN IEC 61326-1
- PN-EN ISO 17665-1

In addition, they meet the guidelines of Directive 2012/19/EU on waste electrical and electronic equipment (WEEE) and Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

The following Notified Body No. 2274 participated in the conformity assessment process:

TUV Nord Polska Sp. z o.o.

A. Mickiewicza 29 Street

40-085 Katowice, Poland

CE 2274

Identification of the issued certificate: TNP/MDR/0037/4780/2025

Place and date of the declaration: Oensingen, 17/06/2025

Name and surname and position of the person issuing the declaration: Sebastian Magrian – Chairman of the Board