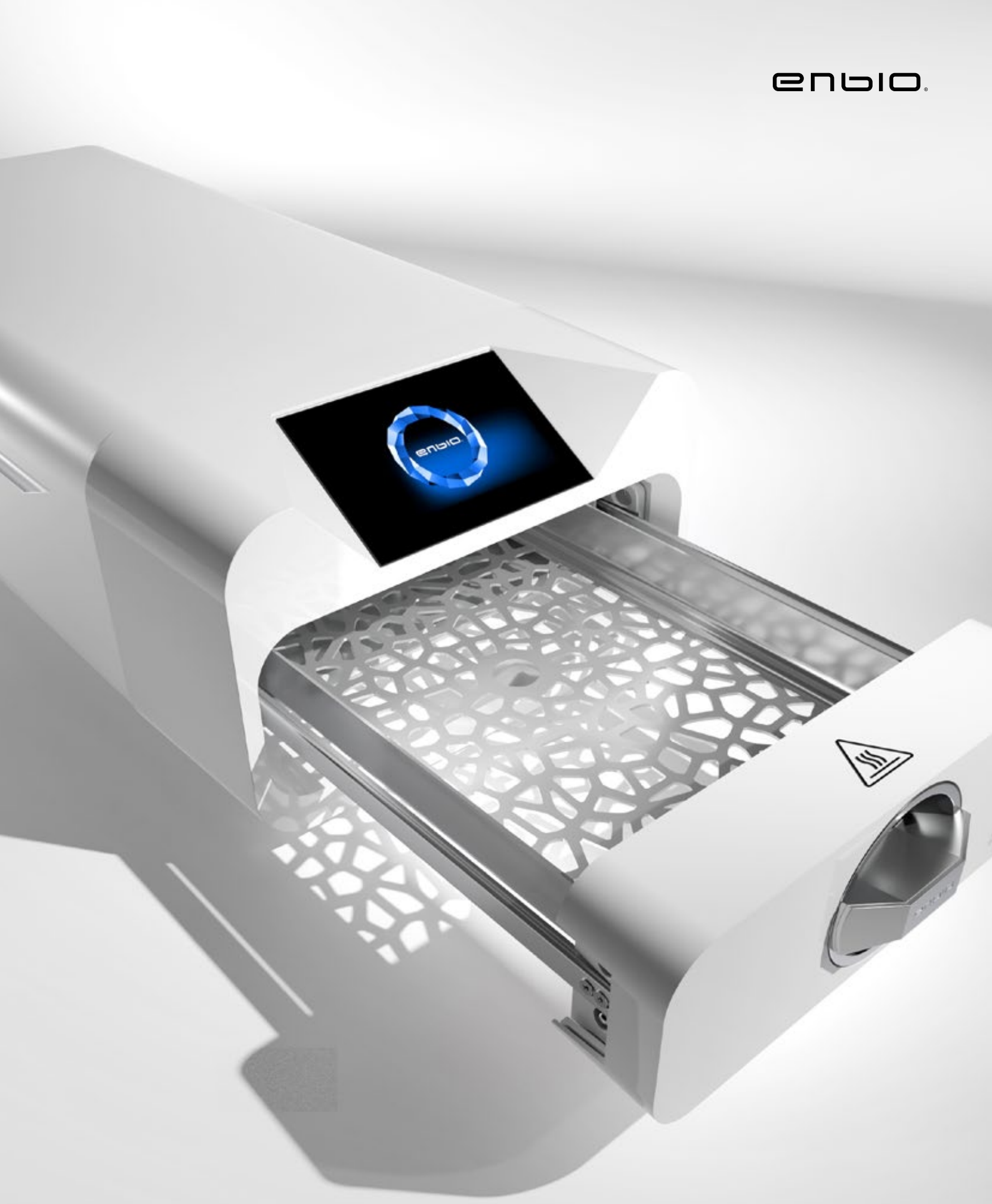


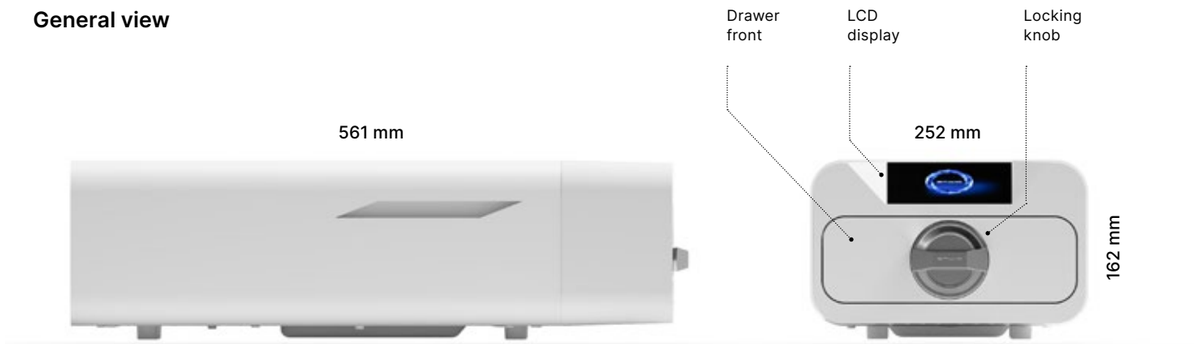
2022.10.04

Enbio S
User Manual USA

Designed
in Switzerland

Enbio S

General view



Rear view

Table of Contents

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

1. Introduction

1.1 Purpose

The purpose of this user manual is to provide information about the ENBIO sterilizer and ensure:

- proper installation and setup,
- optimum use,
- safe and reliable operation,
- regular and correct maintenance and servicing in accordance with requirements.

The sterilizers confirmed to UL 61010-1:2012 Ed.3+R:19Jul2019, CAN/CSA C22.2 NO. 61010-1-12 (R2017), UL 61010-2-040:2016 Ed.2, CSA C22.2#61010-2-040:2016 Ed.2

1.2 Indications for Use

The Enbio S is an air-removal (pre-vacuum) table-top steam sterilizer intended for use by a health care provider to sterilize medical products by means of pressurized steam. It is suitable for the sterilization of dental and medical instruments that are validated to be sterilized by steam. The Enbio S has not been designed to sterilize liquid loads, bio-medical waste or materials not compatible with steam sterilization. The processing of such loads may result in incomplete sterilization and/or damage to the autoclave. Please refer to the table below for program name, load description, sterilization temperature, exposure time, drying time and maximum load.

Enbio S

Program name	Load description	Sterilization temperature	Sterilization time	Drying time maximum load	Maximum load
134˚C	solid objects, small porous objects, simple objects recessed, narrow-clearance items, dental handpieces, and textiles; wrapped and unwrapped	134˚C (273˚F)	4:05 minutes	3 minutes	0.5 Kg /1.1 lbs
121°C	solid objects, small porous objects, simple objects recessed, narrow-clearance items, dental handpieces, textiles, and plastics; wrapped and unwrapped	121°C (250˚F)	30 minutes	5:30 minutes	0.5 Kg /1.1 lbs
134°C FAST*	solid objects, non-porous objects, simple instruments (such as scissors, handles, pliers, chisels, probes, etc.), and dental handpieces; unwrapped	134˚C (273˚F)	4:10 minutes	N/A	0.5 Kg /1.1 lbs

* - Immediate Use Steam Sterilization cycle

The sterilizer is suitable for use in the vicinity of other powered medical products.

The ENBIO device may not be used to sterilize liquids, biomedical waste or pharmaceutical products.

The device is intended for professional use by properly trained staff only.

1.3 Symbols used on the device

	This symbol is located on the front of the device, on the upper part of the drawer front. It is recommended to maintain caution due to high temperature within and around the operating chamber.
	This symbol is located on the device's rating plate and indicates the serial number.
	This symbol is located on the device's rating plate and indicates compliance with EC guidelines.
	This symbol is located on the device's rating plate and indicates the device's date of production.
	This symbol is located on the device's rating plate and indicates the device's manufacturer.
	This symbol is located in the user manual and indicates reading the information provided in the user manual.
	DIRECTIVE 2012/19/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 on waste electrical and electronic equipment (WEEE) , collection point registered with the General Inspectorate of Environmental Protection; this unit handles selective waste collection.

1.4 Indications for Use

- Enbio S complies with IEC 60601-1-2:2014 (Edition 4.0)
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally. Max power cord length is 160 cm.
- Use of accessories and cables other than those specified or provided by Enbio could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Enbio S, including cables specified by Enbio. Otherwise, degradation of the performance of this equipment could result.
- The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- The user is responsible for the installation, correct operation and maintenance of the device in accordance with instructions provided in this user manual. If needed, contact the service or the supplier of the device.
- The sterilizer is not intended for sterilizing liquids, biomedical waste or pharmaceutical products.
- The sterilizer must not be used if explosive gases or vapours are present in the air.
- After the cycle is completed, the load is hot. Remove tools or packs from the chamber using appropriate thermal gloves or equipment that prevents burns.
- Do not remove the rating plate or any other elements of labelling from the device.
- Follow guidelines for preparing tools for sterilization.
- Pouring water or other liquids on the device may cause a short-circuit.
- Prior to inspection, maintenance or servicing, turn off the device and disconnect it from the power source.
- Servicing may only be performed by trained service personnel and using original replacement parts.
- The device is intended for indoor use only.
- Max working high elevation of the device is 2,000 m above sea level.
- Pollution Degree 2: Normally only nonconductive pollution occurs. Temporary conductivity caused by condensation is to be expected.
- Overvoltage Category II.
- If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.
- Use only detachable cord that rated equal or greater to the equipment electrical ratings.

Read this Operating Manual carefully before using this device. Install and operate the device strictly as specified herein. Comply with all safety requirements for the device. This will ensure proper and safe operation of this device. Any other application, inconsistent with this manual, may lead to dangerous accidents. Restrict unauthorised personnel access to the device and train the personnel handling the device. An operator of this device is any person who, by training, experience and knowledge of applicable reference standards, manuals and occupational health and safety regulations has been authorised for the essential operation with the device and who is capable of identifying and avoiding the hazards related to operation of this product.

Always append this Operating Manual with the device if transferred to a new owner. The Operating Manual contains detailed information about assembly, installation, initial start-up, use, repairs and maintenance of the device. If the device is used as intended, this Manual will provide sufficient guidance to qualified personnel. Keep this Operating Manual close to the device and easily accessible at all times. As required by continuous improvement of the product, the manufacturer has the right to amend this Manual or make

changes to the device without prior notice. Enbio Group AG shall not be liable for damage incurred during the wait for warranty service, any damage to the Customer's property other than this device, or errors caused by improper installation and/or improper operation of the device.

Detailed recommendations, coutnerindications and warnings are described in the relevant sections.

2. Scope of delivery and unpacking of the Device.

2.1 Unpacking of the device

If the sterilizer was transported or stored at a temperature or humidity different than that at the location of installation, wait for 60 min. When moved from a cold room to a warm one, the device may contain moisture that, by negatively affecting the device's electrical components, may cause damage to it after startup.

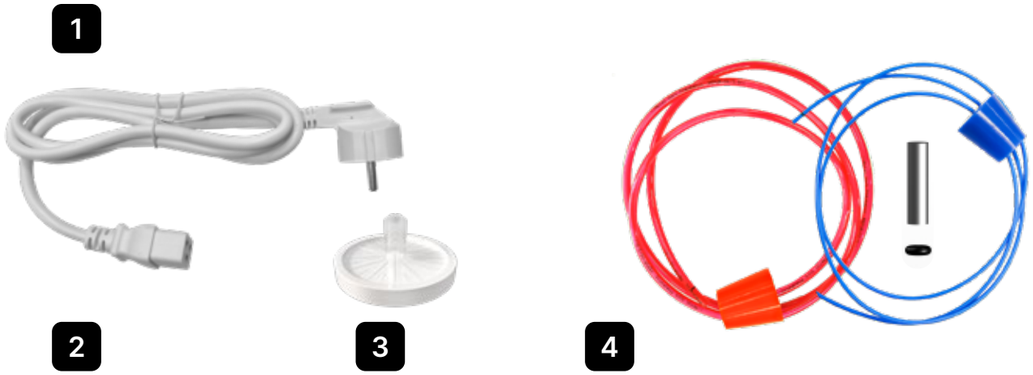
Remove the device from its packaging carefully.

Attention! Check the packaging and its contents for external damage. If damage is found, contact the seller or the transport enterprise to prepare a damage report.

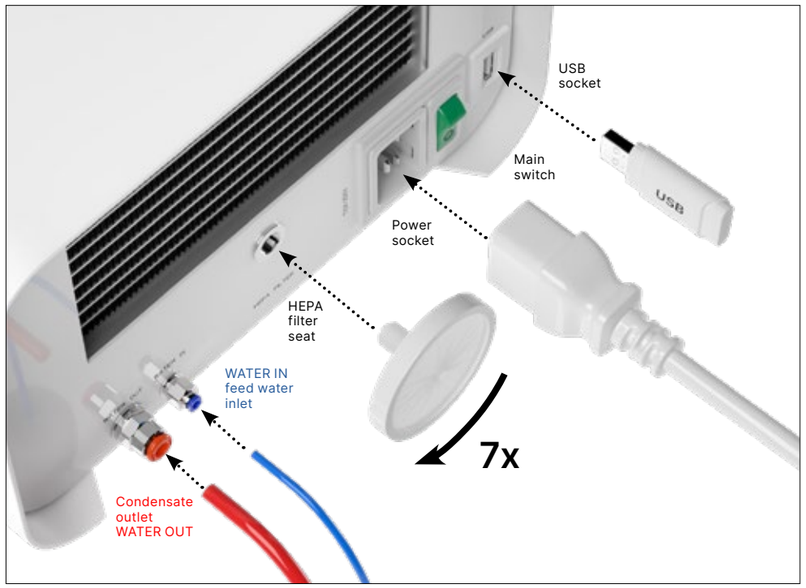
It is recommended to leave the carton for possible autoclave transport.

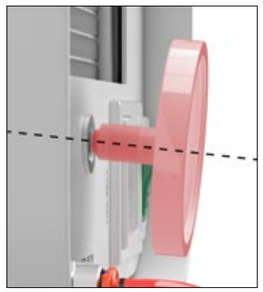
2.2 Standard equipment

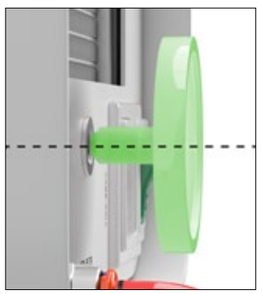
Verify the contents of the packaging in which the device has been delivered prior to installing it. The delivery packaging should contain:
1. ENBIO S sterilizer
2. Power cord
3. HEPA filter
4. Water and condensate connection cables, rubber plugs for water/condensate containers
5. USB drive
6. Operating Manual (PDF, on USB drive)
7. Validation report
8. FDA Approval
9. Warranty
10. Enbio Data Viewer software

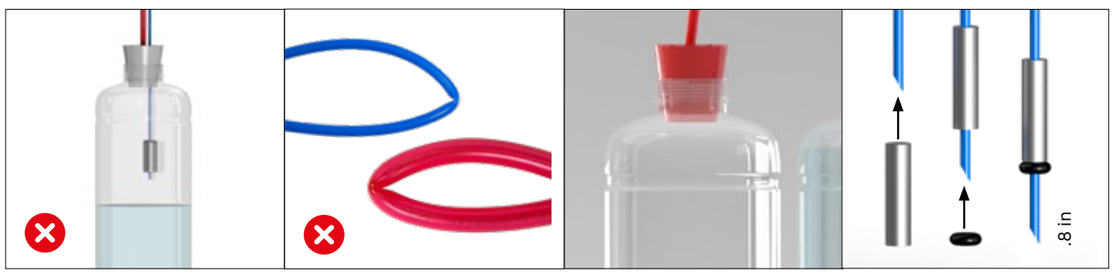


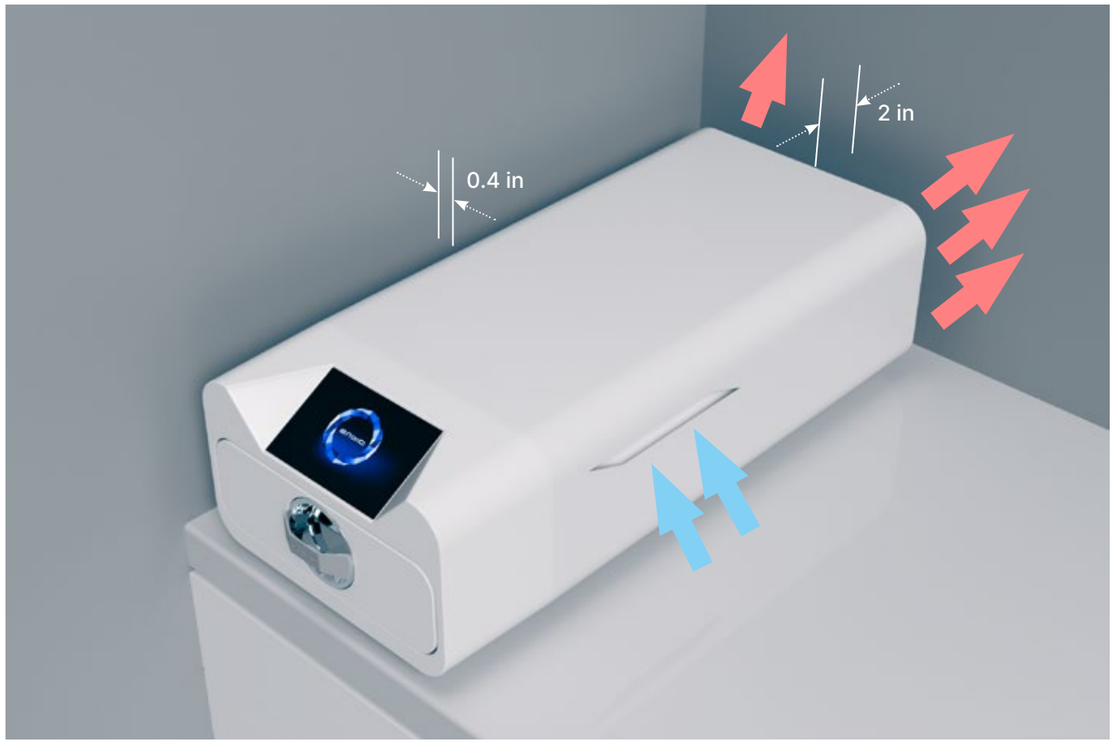
Accoprding to Directive 2012/19/EU of the European Parliament and of the Council of July 4th, 2012 on waste electrical and electronic equipment (WEEE) must not be disposed of or stored with household waste. Take the waste device to the nearest WEEE collection point registered with the General Inspectorate of Environmental Protection; this unit handles selective waste collection.











3. Device installation

We recommend reading this user manual carefully before using the ENBIO S device. Follow all applicable safety guidelines and ROHS regulations when operating the device.

Mounting the HEPA filter. For reasons of transport safety, the HEPA filter has not been installed in the device. Remove it from the bag placed in the carton and tighten it yourself in a specially designated place on the back of the device. The filter should be screwed in manually until resistance is felt.

a. The device should be positioned on a flat, even surface. Do not use the device if it is inclined.
b. The device should be connected to a power supply that is grounded, equipped with fuses and has the same voltage rating as that indicated on the device.
c. Demineralized or distilled water can be used in the device. Under no circumstances should tap water be used.
d. Connect the connection tube included with the device to the water supply quick-release coupling on the device's rear panel, marked as WATER IN. Submerge the other end of the tube in the water supply container. The device is equipped with a water suction pump, there is no need to position the water container above or on the same level as the device. In order to secure the water supply tube, use the plug included in the delivery and place the plug in the opening of the water supply container. To prevent the hose from coiling in the water tank, install the included weight with a rubber ring at 0.8 in from the end of the hose.
e. The wastewater formed after the water is turned into steam during the sterilization process can be removed using the tube provided, which should be connected to the port at the device's rear panel, marked as WATER OUT. The wastewater can be removed directly to the sewerage or to a special container intended for wastewater. If using container, place the tube end inside the container and secure the inlet with the plug provided. The tube must not be submerged in the wastewater.
f. The wastewater container or the sewege drain must be located below the device.
g. If using wastewater containers, we recommend using containers of the same volume as those used for the deionised water. Emptying them concurrently with replacing/filling the deionised water containers will prevent overflow.

Correct positioning of tubes in the water supply and wastewater containers.

h. Leave 5 cm (2 in) of space behind the device and 1 cm (0.4 in) on each side from walls or other elements in order to ensure sufficient ventilation.
i. The device should be positioned in a way that ensures easy access to the main switch located on the rear panel of the device.
j. Do not position the device near to washbasins or other places where it could be poured with water - possible short-circuit.
k. Install the device in a well-ventilated room, away from heat sources and rooms where mixtures of gases or liquids, and other hazardous agents may form.
l. Ensure the following environment conditions: operating temperature range +5°C to +40°C (+41°F to +104°F) / relative humidity 0–90%, storage temperature

Enbio S device is designed for self-assembly by the end user and do not require any special installation at the place of use. The user is responsible for the correct installation of the device on spot, according to this manual.

3.1 Water quality

ENBIO S sterilizers use demineralized or distilled water to form steam during the sterilization process. The total mineral content in the water used for sterilization must be lower than 10 ppm, or for conductance measurements, lower than 15 µS/cm. Standard tap water has hardness within the 2–3 mmol/l range and must not exceed 5 mmol/l according to current regulations, making it unsuitable for use in ENBIO S sterilizers. Therefore tap water cannot be used as feed water for ENBIO S sterilizers. The table below presents the hardness and conductance parameters of water used in steam sterilization according to EN 13060.

Acceptable parameters of water used for sterilization

Hardness	< 0.02 mmol/l
Conductance (at 20°C/68°F)	< 15 µS/cm
Chemical additives	No chemical agents or additives must be added to the water used in the sterilization process, even if they are intended specifically for use in steam generators, or for use as additives in sterilization, disinfection, cleaning or corrosion protection.

Water conductance above 50 µS/cm may have a major impact on the sterilization process and cause serious damage to the sterilizer, and constitute ground for voiding the warranty. Use of water with impurities level exceeding the levels specified in the EN 13060 standard in the steam generator can significantly shorten the sterilizer's lifetime.

The distilled water in the supply tank should be replaced at least once every three months due to the increasing conductivity due to prolonged contact with air. If the tank was contaminated, it should also be changed to a new one. The tank should be closed with the attached cap. Then the water does not change its properties so quickly.

The manufacturer's warranty expires when the autoclave has been used with water services of a quality not compliant with the recommended one.

4. Tool preparation and loading

Only clean and dry tools may be sterilized. For this reason, before loading tools on the tray, clean and disinfect the tools in accordance with current regulations. Residue of agents used or solid particles may prevent the sterilization process from completing successfully. Furthermore, sterilization of tools not subjected earlier to pre-cleaning may cause damage to both the tools and the sterilizer.
During 134°C FAST program do not use packages or wrapping.
If the tools were covered in grease, remove its excess.
Optimum method of positioning tools to be sterilized on the tray:

- For non-packaged tools – place the tools on the tray in such a manner so they do not contact each other directly. This will accelerate the drying process.
- For packed tools – position them on the tray in disposable sleeves as recommended by the pack manufacturer. Position packages with either the paper or film sides facing each other. Otherwise the packages may cement with each other during the sterilization.

4.1. Tool pack preparation
4.1.1 Characteristics of a sterilization pack

It is recommended to use sterilization packages that meet the requirements of the standards EN ISO 11607-1:2019, EN 868-2-10:2017-3. A suitable pack is characterised by:

- good permeation of the sterilization agent to the inside of the pack – resistance to damage during the sterilization process,
- ensuring tight, durable sealing of the contents and their safe removal for further use,
- forming a barrier for microorganisms and undesired substances such as adhesive, ink from the label or a chemical test.

4.1.2 Rules for arranging tools on a tray

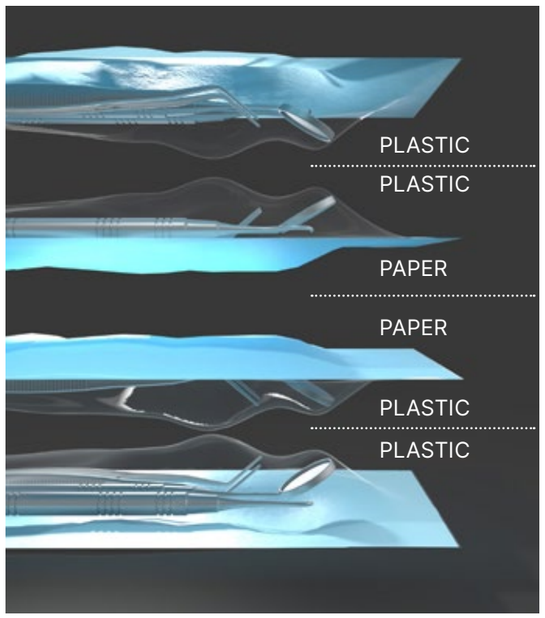
Sterilized instruments should not protrude beyond the outline of the sterilization tray, special attention should be paid to sterilized instruments without packages. The tools must be positioned in such a way that no part of them falls into the holes of the tray, and does not rest on the edge of the sterilization tray or protrudes above the tray outline. Failure to comply with the above recommendations may damage the sterilization chamber phase, which will cause a chamber leak.

- Sterilized instruments in packages: Arrange in a tray so that the package does not come into contact with the door seal and the phase of the sterilization chamber. Failure to comply may result in a lack of tightness in the device.
- Do not exceed a maximum weight of 500 g (1.10 lb) for ENBIO S.
- Special attention should be paid so that the ends of the packs do not protrude out of the sterilizer tray, which may cause the pack to jam during closing and lead to leakage of the sterilizer working chamber
- It is recommended that when the working chamber is significantly loaded, the first packages should be directed with the foil side to the bottom of the tray. This guarantees faster and more efficient drying of packets.
- **Do not use packages or wrapping in the 134˚C FAST program.**
- **Items sterilized using 134˚C FAST program are intended for immediate use only and cannot be stored or held for future**

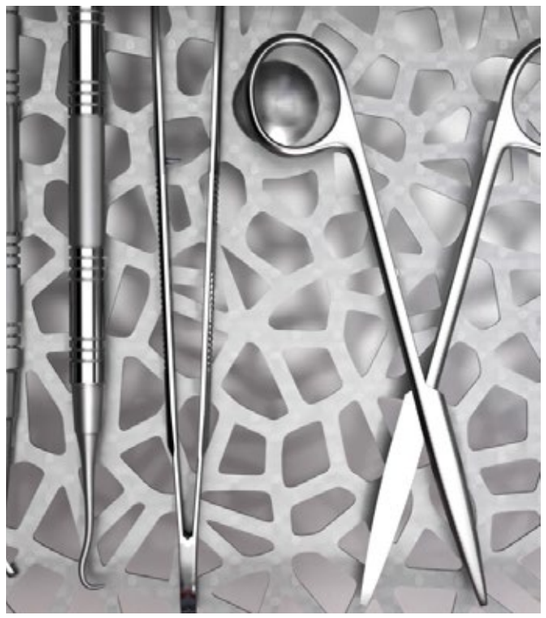
Not following the manufacturer's instructions will be associated with the loss of warranty on the device.

4.1.3 Principles of packing tools for sterilization

Sterilization pack type	Principles of packing tools
Disposable paper and film packages	• bags should be filled only to 3/4 volume to allow proper sealing and minimize the risk of breakage • a distance of 30 mm (1.2 in) should be kept between the welding and sterilized equipment • protect sharp edges to avoid damage to the packaging • the packaging material must not be laid loosely or stretched so that it does not affect pressure changes during sterilization • the equipment should be stacked so that the paper side contacts the paper side as the sterilizing agent penetrates and air exchange can only take place through paper • a label should be placed on the packaging with information about the content of the packaging, the code of the packer, date of sterilization and expiry date and sterilization parameters • it is recommended to insert a sterilization strip into each process that discolours as a result of the correct sterilization cycle



Sample placing of sterilization packages.

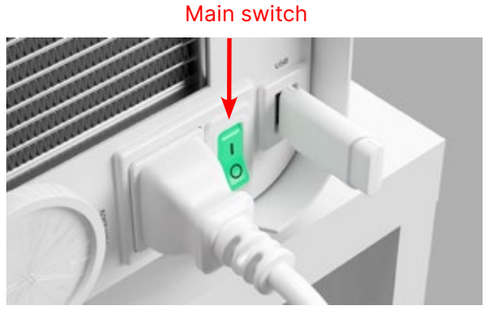


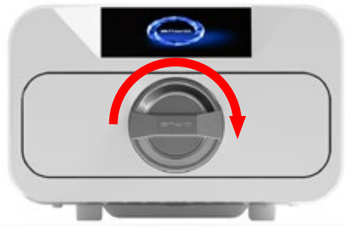
Example of solid load.

5. Starting the device

5.1 Initial Start-Up

Before initiating the sterilization cycle, turn the device on using the main switch located on the rear panel of the device. Make sure that water supply and wastewater tubes are connected correctly, and that water is present in the water supply container, while the wastewater tank is empty, in order to prevent overflow. Monitor the water level in the tank regularly, depending on how frequently you perform your processes. Place tools or materials in the working chamber tray and close the chamber and turn the knob locking the front of the device clockwise.





5.2 Program selection

Depending on the type of load to be sterilized, the user is responsible for selecting the appropriate program dedicated for the given type of load, in accordance with the manufacturer's recommendations for sterilization. **After the process in 134°C FAST program, tools are wet and hot.**

Enbio S program	**134°C FAST**	**134°C**	**121°C**
Type of load	Unwrapped instruments only	Wrapped or unwrapped instruments	Wrapped or unwrapped instruments
Process temperature	134°C	134°C	121°C
Pre-vacuum number	1	3	3
Sterilization duration	4:05 min	4:10 min	30 min
Drying duration	-	3 min	5:30 min
Total process duration*	100g: 7 min	100g: 13 min	100g: 45 min
Class	S	B	B

* - Ambient temperature can affect the process extension.
* - The duration of the first process may be longer due to the need for the device to heat up.

The 134°C program is recommended for the majority of sterilized materials due to the short duration of the entire program. The 121°C should be used to sterilize all other materials that cannot be subjected to sterilization at the temperature of 134°C. Do not exceed a maximum weight of 500 g (1.10 lb) for ENBIO S.

After switching on the device, the start screen appears on the display. To go to the next screen, press the screen once with your finger (anywhere).

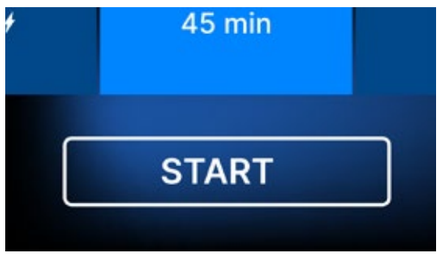
This screen only appears on first run, before the first process is performed.

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

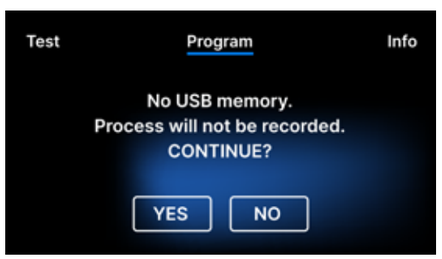
From here you can execute the **Program**, go to the Test, Information menu, and the COUNTERS menu. In the Program menu, you can choose the 121°C, 134°C temperature programs.

Selection of sterilization programs

When the chamber is opened, the **DOOR OPEN** symbol blinks.

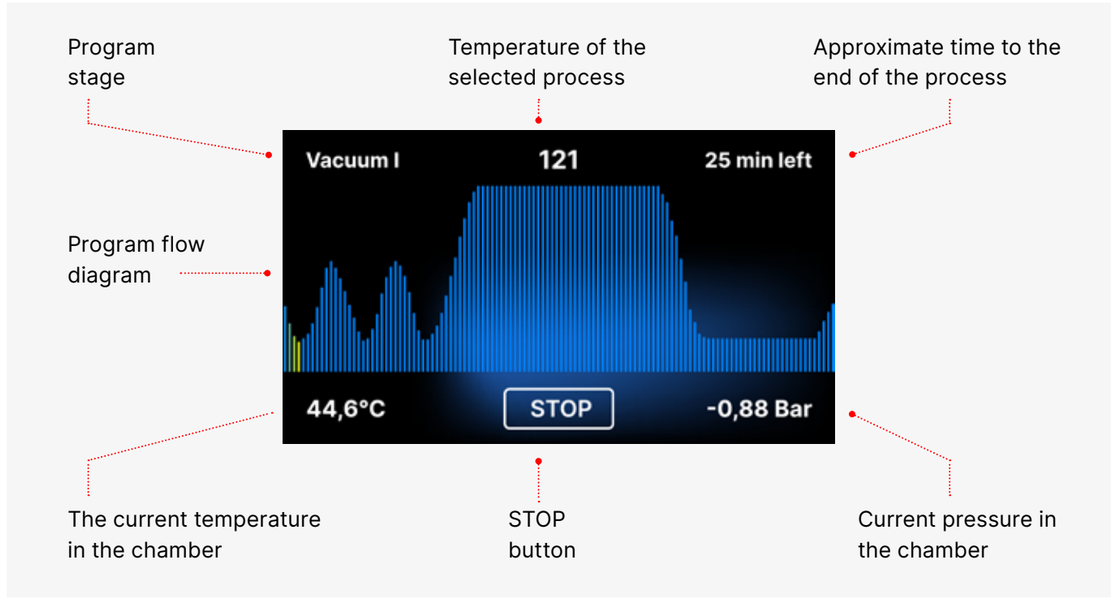


When the chamber is locked by turning the lock knob clockwise, the display will show the **START** symbol, indicating the chamber has been closed correctly. Now you can select the program by pressing the symbol of the temperature you want to perform the sterilization for example in 121°C or ???? The selected program is initiated by pressing the corresponding **START** symbol.



If the USB drive has not been inserted in the device, the USB symbol is **not** displayed in the bottom right corner of the screen, and a message about the missing USB drive is displayed. The program data will not be saved. You can continue working without saving the data on the USB drive by pressing the **YES** field or stop working by selecting the **NO** field to insert the drive in the port and start the program from the beginning.

If you decide to continue working or the **START** field has been selected, the screen will display a chart of pressure during the entire process, with the current stage of the program indicated, while information on subsequent stages is displayed in the upper left corner of the screen.



When a program is being run, the screen displays the temperature of the selected sterilization program **121°C** or **134°C**, the current temperature of the process chamber in the bottom left corner **44,6°C**, the pressure currently in the chamber in the bottom right corner **-0.88 Bar**, while the process duration left is displayed in the upper right corner of the screen **25 min left**. This is the expected time, which may be extended due to the mass and type of charge.

During the process, the **STOP** field is displayed instead of the **START** field, enabling you to stop the process at any time. The upper left corner of the screen displays the status of individual subsequent program stages, e.g. – **Vacuum I / Chamber lock / Process chamber heating**.

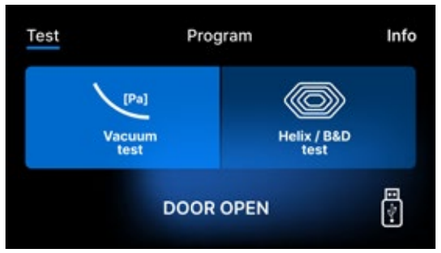
If the process was completed successfully, the display will alternately show information that the process has been completed and the load is sterile, and that the chamber may be opened.

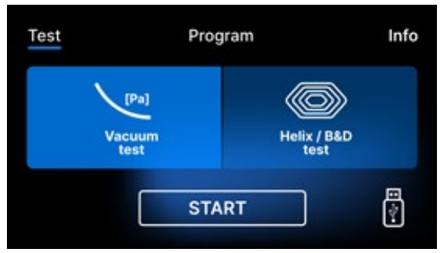
By pressing the **FINISH** field, you return to the start screen.

ATTENTION! When the process is completed, the chamber, the tray and the load are hot. Maintain particular care and use protective gloves to remove the load, or wait until it cools.

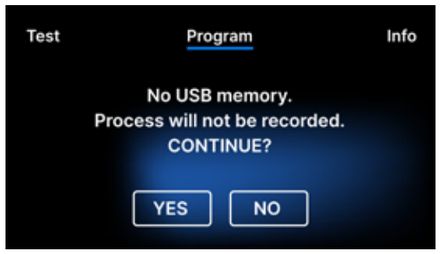
Performing the sterilization process in the ENBIO S device does not affect material biocompatibility. All components of the device that are in direct contact with the sterilized load have no toxic, sensitising or irritating effects.

5.3 Test programs





By pressing the **Test** field, you can go to the test program menu. From here you can select the vacuum leak test program and the Helix/B&D test program. Select the appropriate program by pressing the relevant field on the display. When the process chamber is closed, the **DOOR OPEN** information changes to **START** and by pressing this field you launch the selected test program.



If the USB drive has not been inserted in the device, the USB symbol is not displayed in the bottom right corner of the screen, and a message about the missing USB drive is displayed. The test program data will not be saved. You can continue working without saving the data on the USB drive by pressing the **YES** field or stop working by selecting the **NO** field to insert the drive in the port and start the test program from the beginning.

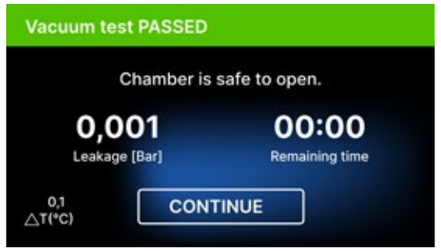
Enbio S	Bowie & Dick / Helix	Vacuum test
Process temperature	134°C	–
Number of pre-vacuums	3	1
Sterilization time	3.5 min	–
Drying time	3 min	–
Total process time	15 min	20 min

Vacuum leak test

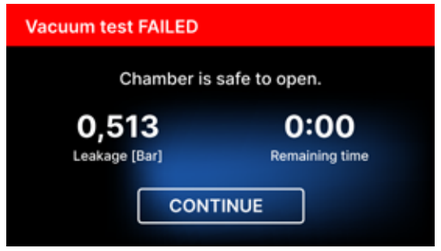
The vacuum leak test may only be performed on a cold device, before work is commenced. The vacuum leak test enables testing the autoclave for the presence of leaks. The following are checked during the test:
- Vacuum pump performance.
- Pneumatic system sealing.

When the vacuum leak test program is selected and launched with the **START** button, the vacuum leak test progress screen is displayed. Information on pressure loss in the process chamber, and the test duration are displayed.

When the test program is completed, the following screens are displayed alternately.



When the test program was completed successfully.



When the test program was not completed successfully.

After pressing the **CONTINUE** field, the start screen is displayed.

The process chamber must be completely dry and cold during the vacuum leak test. Otherwise, the vacuum leak test results may not be fully reliable, even if the sterilizer is fully functional. When the test is completed, a message with the results will be displayed. If the result is negative, check, clean or replace the seal, clean the front edge of the chamber and repeat the test. If the device fails the test again, contact your supplier or the manufacturer.

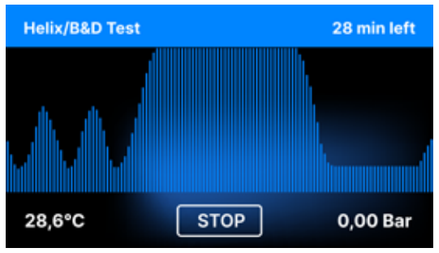
Bowie&Dick test

Perform the Bowie&Dick test daily before commencing work, in order to verify that the device performs sterilization correctly. The Bowie&Dick test, also known as the steam penetration test, imitates a small, highly porous load. It contains sheets of paper packaged in a small pack containing a chemical indicator (a physicochemical test). This test assesses the device's performance in sterilizing charges composed of porous objects:

- Pre-vacuum performance and steam penetration.
- Saturated steam temperature and pressure, reached for a specific time.

How to perform the test:

- Perform the test with an empty chamber, as per the EN 13060 standard.
- Place the Bowie-Dick test pack in the chamber, in the middle of the tray.



When the Helix/B&D test program is selected and launched with the **START** button, the program progress screen is displayed. Process parameter information is displayed. The Helix/ B&D test program can be stopped at any time by pressing the **STOP** field.

When the test program is completed, the following screens are displayed alternately.

You can safely open the sterilizer's process chamber. When the process chamber is opened, the start screen is displayed.

- Remove the test pack.

WARNING! The package will be hot.

In order to interpret the test correctly, read the instruction provided by the test pack manufacturer.

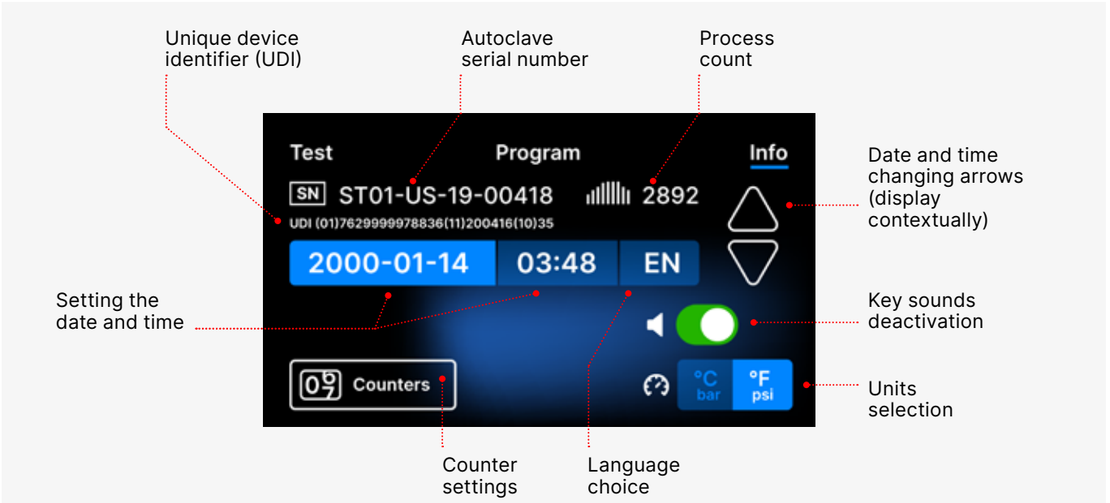
- Open the pack and remove the chemical indicator from inside.

Positive result
Vhemical indicator has changed color on a dark uniform over the entire surface.

Negative result
The middle of the test field remains clear because of the residual air in the middle of the device under test.

Any change of color, uneven coloring of the test, indicates the presence of air during the test cycle, caused by faulty operation of the sterilizer.

5.4 Information menu



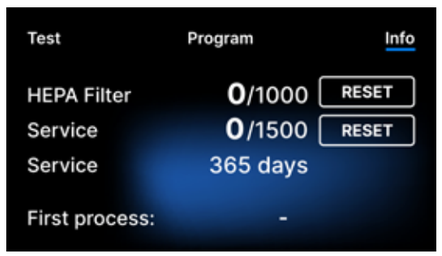
The information menu can be accessed by pressing the **INFO** field. Here, information about the device type, serial number, number of performed processes, amount of free memory available on the USB drive for saving process data, and the service menu **COUNTERS** with the process counters for HEPA filter and the next service inspection can be displayed. You can also change the date and time.
In order to set the date or time, touch the digits on the display. When a field is selected, it starts to blink and arrows used to change values are displayed, up and down.
This way you can correctly set the date and time. Pressing the number again confirms it, and you can change another parameter. The user can choose the language the same way by clicking on the shortcut.

5.4.1 Counters

The ENBIO S sterilizer counts the number of performed processes and uses it to notify you about the recommended dates of replacing elements subject to wearing down, and about required service inspections.

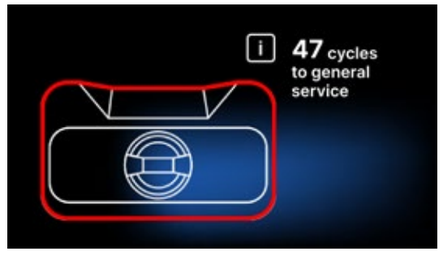
	Warning cycles (yellow)	Warning days (yellow)	**Limit cycles (red)**	**Limit days (red)**
HEPA filter	950	-	1000	after 1000
Service	1450	345	1500	365

By pressing the **COUNTERS** field, you go to the counter display.



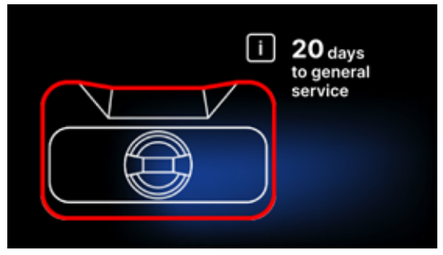
The number of performed processes is on the left and on the right side – the number at which the given element should be replaced or a service inspection performed. After replacing a filter, the values can be reset by the user by pressing the button. The service inspection value can only be reset by an authorised service.
When approaching a value when replacement of an element or a service inspection is recommended, the values will be **highlighted in yellow.** If the limits are exceeded, the value will be **displayed in red.**

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:

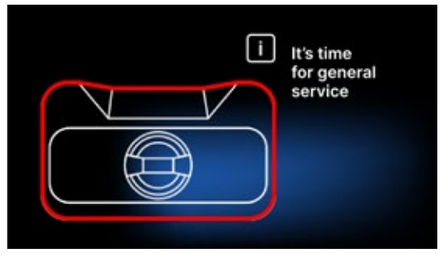


If the process count exceeds 1500, the device informs the operator or user to perform a mandatory periodical service.

20 days before the service due date, the device will inform the operator or user of this via a warning screen and display this value on the counter screen:

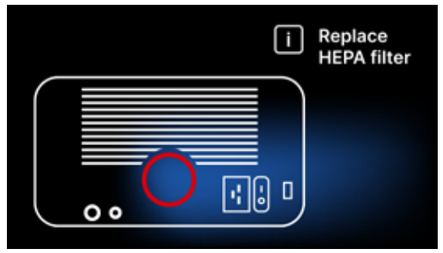


After 12 months of the first process, the device will inform the operator or user about the necessity to perform the service.



If the process count exceeds 950, the device warns the operator or user about upcoming HEPA filter replacement.

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



During regular operation, info screens concerning replacement of individual elements or required service inspection are displayed alternately. Counter values displayed in yellow or red do not prevent the device from operation. However, exceeding the required inspection date may significantly affect the device's operation and the load sterilization process.
For replacing individual elements, please contact the manufacturer or supplier.

5.5. Restarting

Restarting the device is forced when a process is aborted by the user by pressing the **STOP** field, or when power or water supply is lost.

5.5.1 Restarting after user aborted process

If the **STOP** field is selected, the following messages will be alternately displayed, notifying you that the process has been aborted by the user and pressure is being equalised in the process chamber, and a message notifying you that the process has not been completed correctly and the load is not sterile.

When the pressure is equalised in the process chamber, the following messages will be displayed alternately on the screen

You can freely open the device now. The following screen will be displayed when the chamber is opened. By selecting the **RESTART** field, you can return to the start screen.

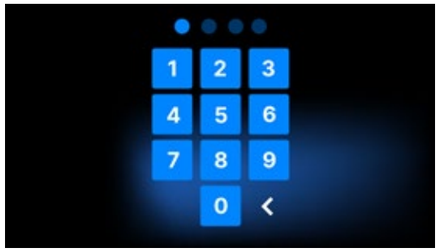
5.5.2 Restarting after error

If the error during process occurs, the following messages will be alternately displayed, notifying you that the process has been aborted and pressure is being equalised in the process chamber, and a message notifying you that the process has not been completed correctly and the load is not sterile.

When the pressure is equalised in the process chamber, the following messages will be displayed alternately on the screen

You can freely open the device now. The following screen will be displayed when the chamber is opened. By selecting the **RESTART** field, you can return to the start screen.

If the restart is forced by process error, before returning to the start screen, you must enter the 4-digit security code **0000**.



If the code is entered incorrectly, a message will be displayed on the screen. Enter the code again. The arrow enables cancelling incorrectly entered digits. When the code is entered correctly, the start screen will be displayed.

6. Maintenance and care

Tray cleaning

Maintaining tray cleanliness aids in maintaining correct functioning of the device. It is recommended to clean the internal part of the tray once a week using a mild, chlorine-free detergent that does not react with aluminium. After cleaning, the tray must be thoroughly washed with water. Dry the tray before reinstalling the tray and push it over the front face pins and push it down gently to lock it.

Cleaning the process chamber

Maintaining the chamber cleanliness aids in maintaining correct functioning of the device. It is recommended to clean the process chamber interior once a week using a mild, chlorine-free detergent. After cleaning, wipe the chamber with a soft cloth until dry. To clean the tray well it must be removed from the front of the device. To do this, lift the tray gently up and pull it away from the front. The mounting studs have notches in which the drawer fits.

Cleaning external surfaces

The external parts of the device should be cleaned using a soft cloth slightly wet with water and a mild detergent (chlorine-free and not reacting with plastics, varnishing coats and aluminum). Do not use strong detergents. Use of mild detergents for maintaining the device does not affect the possibility of hazard related to toxic agents forming in contact with elements of the device.

Cleaning the seal

It is recommended to clean the seal after 100 performed processes. Use warm water and a microfiber cloth (microfiber with silver particles is acceptable) to clean the device. Use of dull or sharp cleaning tools is not acceptable. Cleaning with chemical agents is not acceptable. Perform the cleaning when the device has cooled down, after opening the drawer. Maintain caution and do not bend the drawer. After cleaning, leave the device open until the seal dries. During this time, protect the device from damage. After cleaning and drying the seal, it can be lubricated with a silicone lubricant.

Replacement of elements subject to wearing down

Elements subject to wearing down should be replaced periodically to ensureb failure-free operation of the sterilizer. A message on the screen will notify the user when individual elements should be replaced. During regular operation, info screens concerning replacement of individual elements or required service inspection are displayed alternately. They are described in detail in the „Warning messages and error codes” section.

In order to ensure efficient sterilization and correct operation of the device, it is recommended to observe the replacement dates for elements subject to wearing down.

Cleaning the water container

In order to ensure correct parameters of the water supplying the device, it is recommended to check the water tank at least once per month. If any contamination is found, the tank should be drained, cleaned and refilled with new, fresh and clean deionized or demineralized water.

6.1 Replacement parts

The following table includes elements subject to periodic replacement, and elements subject to natural wear and tear. Replacement parts should be ordered directly from the manufacturer. Use of other replacement parts voids the warranty and does not guarantee correct functioning of the device.

Name	Part no
Front seal	ST1-UL1
Bacteriological filter	DZ0035
Connection/water supply tube	ST1-HW1
Connection/water supply tube	ST1-HW2
Rubber plug for the water container	ST1-KS1
Rubber plug for the condensate container	ST1-KS2

6.2 Periodic inspections

In order to ensure correct functioning of the ENBIO S sterilizer, it is recommended to perform periodic service inspections and replace parts subject to wearing down in accordance with the following schedule, and periodic inspection of individual sterilizer elements in accordance with the following guidelines.

Name	Replacement frequency
HEPA bacteriological filter	Every 1000 cycles or every 12 months
Connection/water removal tube	If damage is observed or once a year
Plugs for water/condensate containers	If damage is observed

Element subject to inspection	Inspection frequency
Front seal	weekly or in the event of incorrect functioning - performed by the user
Bacteriological filter	every week - performed by the user
Connection / water removal tube	weekly or in the event of incorrect operation - performed by the user
Container plugs	weekly - performed by the user

7. Data archiving

The progress of each performed sterilization is automatically saved on a data carrier (USB drive). The data can be used only for archiving, the sterilization process correctness is directly communicated by the device. The USB port is located on the rear panel of the device. It is recommended to periodically archive the data on another carrier, e.g. a desktop PC, laptop.

We strongly recommend using the USB drives supplied together with the device. Nevertheless, if user want to use their own USB drive, it is required to use drives with following specification: minimum 16 GB capacity, FAT32 file system.

It is not possible for the user to upgrade or downgrade the sterilizer's control software - this task can be performed only by Enbio.

8. Enbio Data Viewer

The Enbio Data Viewer software enables viewing and archiving sterilization programs on a computer, and printing them.

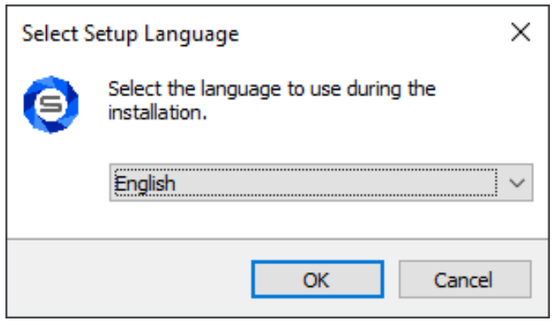
Minimum hardware requirements to install the software:

- Operating system - Windows min. Windows 7 or higher
- Free disk space - min. 100 MB
- Minimum processor requirements - min. 1 GHz
- Minimum operating memory - min. 512 MB Ram
- Screen resolution - min. 1200×720 or higher

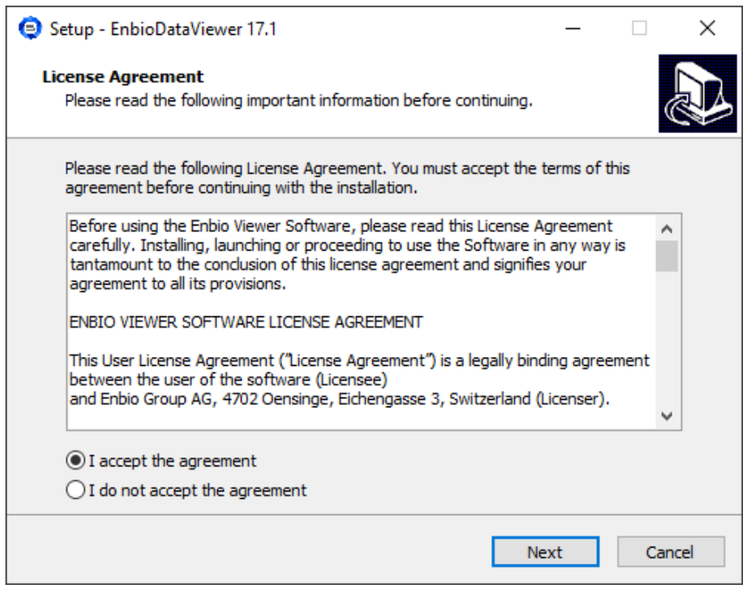
Using up-to-date antivirus software – strongly recommended.

The software is delivered with the device and can be found on a removable disk - the USB flash drive or the latest version can be downloaded from the manufacturer's website https://www.enbio.com/enbio-data-viewer/

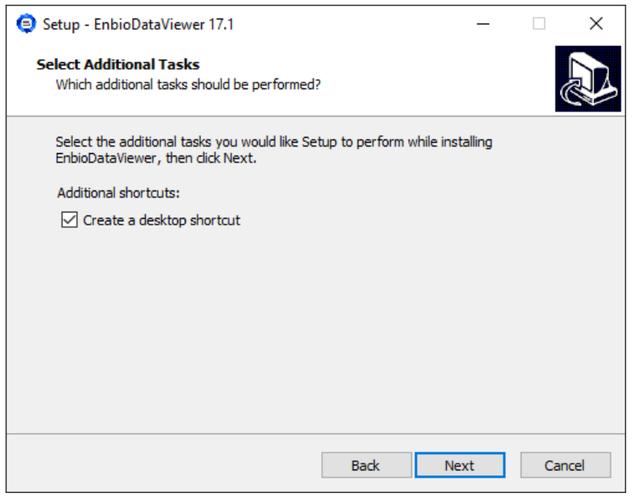
8.1 Software installation



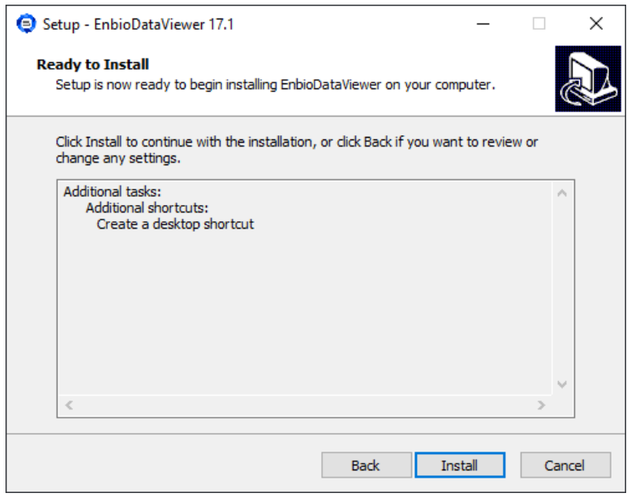
To install the software, double click on the software installation file. After performing this operation, the installation window regarding the language selection will be displayed



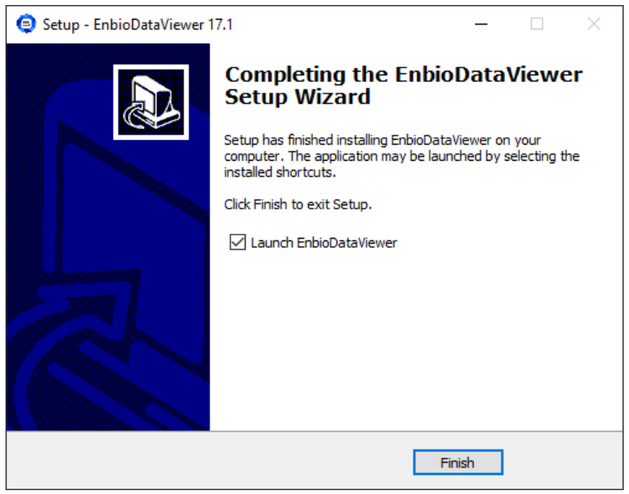
After confirmation, you must accept the license terms for the installed software.



Next, the information about placing the software shortcut on the computer desktop will be displayed.



After making your selection, click „Next". By clicking the Install button you will install the Enbio Data Viewer software.



After installation, the following message is displayed. We can now run the software or finish the installation without running the software by clicking the Finish button.

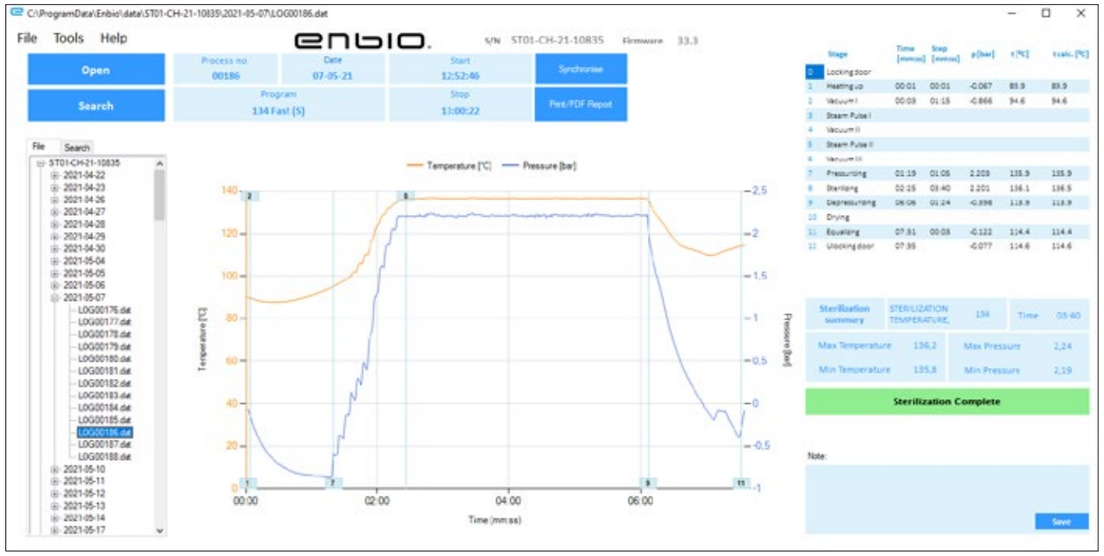
The main program window is displayed.

Enbio Data Viewer updating procedure

1. Run Enbio Data Viewer software.
2. At main screen of Enbio Data Viewer click "Help" button and then "About the program".
3. At new window choose „Check the current software version".
4. The Enbio website will open automatically, from which you should download the latest version of the EnbioDataViewer program – by clicking in "Download" button
5. Unpack downloaded .zip file
6. Double click on the file to start updating the program.
7. Select the language used during the installation and click "OK" button.
8. Read the License Agreement and if you agree, click the "Next" button.
9. Check option „Create a desktop shortcut" if you want to, and click the "Next" button.
10. The summary of the installation will be displayed.
11. Click the "Next" button and the update will be performed automatically.
12. After the installation is complete, a summary will appear.
13. Check option "Launch EnbioDataViewer" if you want to run the program and click "Finish" button.
14. Update is finished. Current version of software can be checked by using "Help" and then "About the program" button.

8.2. Program construction and main functionalities

The main window consists of three main areas



All processes, which have been synchronized from pendrive were sorted by the dates of performance	Temperature and pressure diagram together with the main data regarding autoclave and process (date of completion).	Data on the subsequent stages of the process. The most important parameters of sterilization. The ability to save a note for each process.

The dark blue color has been marked with function keys, e.g. „PDF Report” that will allow you to print a protocol from the process

Drop-down menu:

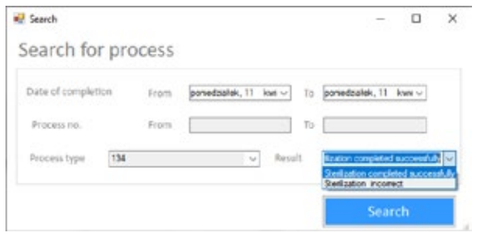
By clicking on the File window we have access to the options:

- Loading the saved process flow from the memory of the USB flash drive or from another location
- Printing a saved program
- Implementation of the report to a PDF file
- Export data to the database to get in case of problems send it to the manufacturer
- Exporting data to CSV format
- Closing the program

By clicking on the Tools window we have access to the options:

- Synchronization of all files with saved programs from the memory of the USB flash drive
- Search for any saved process from the database
- Adding your own logo to PDF reports

By clicking on the Help drop-down menu, you have access to the options:
• About program



Search

The program allows you to search for processes after:

- Range of dates
- Sterilization number
- The type of process
- Result

PDF report

The program allows you to generate a report from every process performed by the autoclave. It contains all necessary process data and the result of sterilization.

9. Warning messages and error codes

If any irregularities in the device's operation occur, the screen will display relevant warning messages and error codes.

9.1 Warning messages

"Aborted by user"	Process aborted by the user. Non-sterile insert 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.
"Vacuum test failed"	Vacuum leak test error	Contact the service
"No USB memory"	No USB drive	Check the USB port and mount the memory. Contact with the service.
"Equalizing pressure"	Pressure during stoppage. Equal to atmospheric pressure	• The message occurs in certain cases as a result of natural processes. • If the message appears frequently, contact the service center.
"Overpressure during standby"	Overpressure in standby mode	The reason for this error is that the hot sterilizer is left with the chamber closed (e.g. overnight). As the sterilizer cools down a vacuum is created in the chamber which causes a startup error. Wait until the device has equalized the pressure automatically - the message will disappear automatically

Sample warning messages are displayed below:

9.2 Error codes

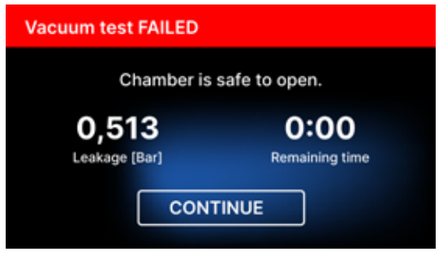
The following table includes the error codes that may be displayed during the use of the sterilizer.

Error code		Description	Recommendations
1	"Chamber over temperature"	Maximum temperature in the chamber exceeded	Contact the service
2	"Steam gen. over temperature"	Excessive steam generator temperature	• Too high weight of sterilized instruments - repeat the process with less instruments (max. 0.5 kg) • Contact the service
3	"Process over temperature"	Excessive process temperature	Contact the service
4	"Overpressure error"	Pressure error	Contact the service
5	"Sterilization pressure too low"	Pressure too low during sterilization	• Check that there is water in the bottle with the blue hose • Correct the position of the blue hose so that the end is completely submerged in water. Add a sinker to eliminate the problem in the future • Check that the water supply hose (blue) is not damaged (After correcting the position / replacing the hose or refilling with water, restart the machine) • Contact the service
6	"Sterilization temp. Too low"	Sterilization temperature too low	• Check the water level in the bottle with the blue hose • Check that the red tube is not pointing up along its entire length, creating the so-called air trap • Contact the service
7	"Too high pressure during drying"	Pressure too high during drying	• Make sure the red drain hose is not immersed in water. The hose must not be kinked, the liquid must flow down by gravity • Check that the weight of the sterilized instruments is not too high • Contact the service
8	"Too many steam pulses / no water"	Too many steam impulses. No water supply.	• Check the water connection to the "water in" connector • Check the distilled water level in the feed water tank (blue plug) • Check that the weight of the load does not exceed the allowable weight. • Contact the service
9	"Drainage error"	Drainage clogged	• Check the level of the wastewater and the connection of the hoses • Check the level of the used water in the bottle with the red cap. If the bottle is full, discard the used water • Check that the red hose is not kinked and that it is pointing downwards along its entire length • Check that there is no debris in the outlet opening (inside the chamber) • Contact the service
10	"Chamber heating error"	Chamber heating error	• Mains voltage too low - consult an electrician for the location where the autoclave is to be installed • Contact the service
11	"Steam generator heating error"	Steam generator error	• Repeat the process • Contact with the service
12	"Prevacuum fail / check outlet"	Vacuum pump / drainage error	• Check the level of used water in the bottle with the red cap and pour out the excess • Check that the red hose is not submerged or kinked • Check that the autoclave setting provides free airflow for cooling the unit • The red hose must point downwards along its entire length, no section may point upwards • Clean the chamber door seal • Contact the service
13	"Power failure"	Momentary voltage loss during operation	• Restart the device and make sure it is properly plugged into the outlet • Consult an electrician competent for the site where the autoclave is installed to check the installation
14	"Pressure during standby"	Overpressure while waiting	• Restart your device • Contact the service
15	"Locking door error"	Door lock error	Contact the service
16	"Unlocking door error"	Door unlock error	• Turn off the autoclave and turn it on again, start the process and stop it after a few seconds. There must be no overpressure in the chamber, i.e. the following information must be displayed: "READY / Chamber is safe to open" • Contact the service
17	"Valve V3 / HEPA filter error"	V3 valve / HEPA filter error	• Replace the HEPA filter • Contact the service
18	"Pressure sensor error"	Pressure sensor error	Contact the service
19	"USB disc error / Change disc"	Writing error on pendrive - damage to medium	Copy the contents from your current flash drive - buy and install a new one
20	Min. Chamber temperature	Chamber temperature too low during the process	Contact the service
21	Chamber temperature sensor failure	Chamber temperature sensor failure	Contact the service
22	Steam gen. Temp. Sensor failure	Steam generator temperature sensor failure	Contact the service
23	Process temp. Sensor failure	Process temperature sensor failure	Contact the service
24	Autoclave has too low temperature	Autoclave temperature too low / temperature sensor error	• Leave the device switched off for 3 hours at room temperature • Contact with the service
31	"Internal flash error"	Internal memory error	Contact the service

Sample error codes are presented below.
Screens displayed alternately: equalising pressure, please stand by.

Process aborted by the user

Screens displayed alternately: equalising pressure, please stand by.
The process has not been completed correctly. The load is not sterile.



Vacuum leak program error.
Error screen: you can continue working.

Error no. 5 - Pressure in the process chamber too low.

The process has not been completed. The load is not sterile. Equalising pressure in the process chamber.

10. Warranty claim handling

In order to report a problem with the device, call to +1 470-323-2234. If the device has been damaged during transport, file your warranty claim with the delivery note and photographic evidence of the damage found.

ATTENTION! The warranty claim process will begin once our Technical Service receives a properly completed Warranty Claim Form.

If you send the device to the Technical Service, clean the chamber and tray, perform decontamination and correctly secure the device for transport. Preferably send the device in the original packaging. If you lack an appropriate packaging, please contact the Technical Service or your supplier.

If the device needs to be transported:

- Disconnect the demineralised water and condensate tubing.
- Wait until the process chamber cools down.
- Use the original or other appropriate packaging with protection lining.

The sender bears complete liability for damage during transport to the Technical Service.

11. Warranty terms and conditions

ENBIO sterilizers are covered by a standard 12-month warranty. Detailed warranty terms and conditions are available from the supplier of this device.

12. Technical data

Technical data	Enbio S
Power supply	110-120 V/60Hz
Installed power	1.6 kW max.
Maximum electric current consumption	15 A
Operating pressure	2.1 bar / 30.5 psi
Maximum pressure	2.45 bar max / 35.53 psi
Maximum process temperature	137°C (278°F)
Process chamber capacity	2.7 l / 0.7 gal
Mass	15 kg / 33 lb
Process chamber dimensions (LxWxH)	292 × 192 × 45 mm / 11.4 × 7.5 × 1.8 in
External device dimensions (LxWxH)	561 × 252 × 162 mm / 22 × 9.8 × 6.3 in
Protection rating	IP20
Noise level	49dB(A)
Process data archiving	USB drive

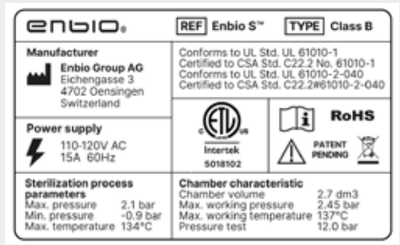
Surrounding conditions

Operating temperature range	from +5°C to +40°C / from +41°F to +104 °F
Relative humidity	0-90%
Storage temperature range	from +5°C do +60°C / from +41°F to +140°F
Relative humidity	0-90%
Surrounding pressure range	900 - 1100 hPa / 26.5 - 32.4 “Hg

Test connector - to be used by authorized service only.
If it is determined that the user has used it, the warranty will be voided.

Rating plate located on the bottom of the device.

Enbio S



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