Enbio S
Enbio PRO

Product Manual

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CE 2274

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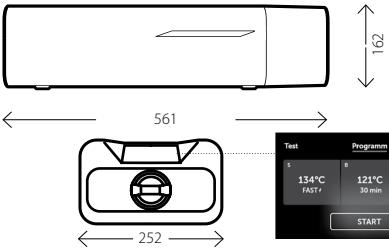
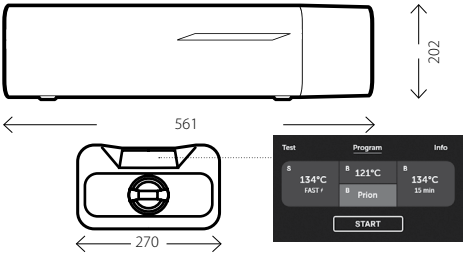
enbio

GENERAL VIEW

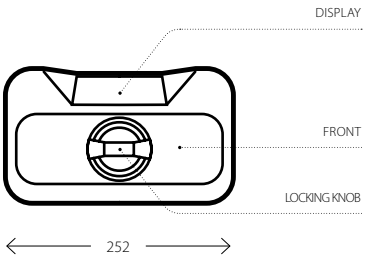
Enbio S



Enbio PRO

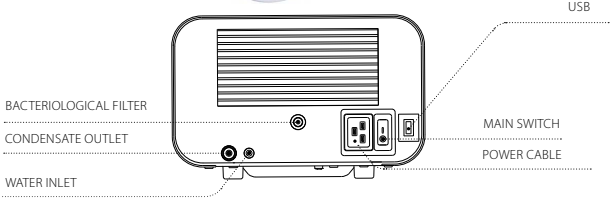


FRONT VIEW



REAR VIEW

NOTE: Enbio S & Enbio PRO come with AUS Standard 3-Pin Plug



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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 steriliser and ensure:

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

1.2 Applicable legal acts

The ENBIO S / ENBIO PRO meet the following legal requirements:

- The sterilisers have been designed and manufactured in accordance with the EN 13060 standard.
- The sterilisers meet the essential requirements of Directive 93/42/EEC and the Medical Products act and have the status of medical product.
- DIRECTIVE 2012/19/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 on waste electrical and electronic equipment (WEEE)

1.3 Purpose of the device

The ENBIO S / ENBIO PRO is a small class B and S steam sterilisers according to standard EN 13060, classified as a class IIb medical product according to annex IX to Directive 93/42/EEC on medical products, and the Regulation of the Minister of Health dated 5 November 2010 on classification of medical products.

According to the classification under standard 13060, the ENBIO device can sterilise the following medical products: 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.**

ENBIO S / ENBIO PRO can be used in primary healthcare practices, dentistic practices, and in operating rooms.

In addition, the Enbio PRO autoclave has a dedicated PRION program as one of the stages of decontamination of items that have or may have had contact with diseased prion proteins (e.g. 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 steriliser is suitable for use in the vicinity of other powered medical products.

The ENBIO S / ENBIO PRO may not be used to sterilise liquids, biomedical waste or pharmaceutical products. The device is intended for professional use by properly trained staff only.

Extra-medical applications:

The ENBIO S / ENBIO PRO can also be used for extra-medical applications, such as beautician and biological regeneration studios, and in veterinary practices, tattoo artist and piercing studios, hair stylist salons.

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

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

1.4 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.

1.5 Precautions, requirements and recommendations

– 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 steriliser is not intended for sterilising liquids, biomedical waste or pharmaceutical products.
– The steriliser 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 sterilisation.
– 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 grid.
– Servicing may only be performed by trained service personnel and using original replacement parts.

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, commissioning, 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 war-

ranty 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 steriliser 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 sterilisers
2. Water and condensate connection cables, rubber plugs for water/condensate containers
3. USB drive
4. Operating Manual
5. HEPA filter
6. TÜV Certificate
7. Validation report
8. Certificate

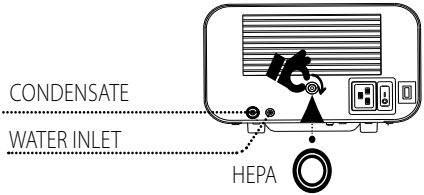
DIRECTIVE 2012/19/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 on waste electrical and electronic equipment (WEEE), collection point registered with the General Inspectorate of Environmental Protection; this unit handles selective waste collection.

3. DEVICE INSTALLATION

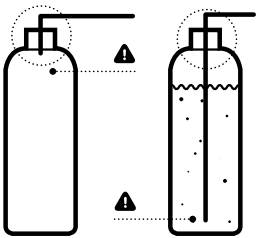
We recommend reading this user manual carefully before using the ENBIO device. Follow all applicable safety guidelines and OHS regulations when operating the device.

⚠ **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 ENBIO S / ENBIO PRO 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 earthed, equipped with fuses and has the same voltage rating as that indicated on the device.
c. Demineralised 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. The minimum water load in the tank is 300 ml. Make sure that the blue hose of the inlet water is always immersed in the water.



e. The wastewater formed after the water is turned into steam during the sterilisation 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 sewerage 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 cables in the water supply and wastewater containers.**

h. Leave 5 cm of space behind the device and 1 cm on each side from walls or other elements in order to ensure sufficient ventilation.

i. The device should be positions 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/ relative humidity 0–90%, storage temperature range from -20°C to +60°C/ relative humidity 0–90%.

Enbio S and Enbio PRO devices are 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 sterilisers use demineralised or distilled water to form steam during the sterilisation process. The total mineral content in the water used for sterilisation 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 sterilisers.

The table below presents the hardness and conductance parameters of

water used in steam sterilisation according to EN 13060.

Acceptable parameters of water used for sterilisation	
Hardness	< 0,02 mmol/l
Conductance (at 20°C)	< 15 µS/cm
Chemical additives	No chemical agents or additives must be added to the water used in the sterilisation process, even if they are intended specifically for use in steam generators, steam generation or for use as additives in sterilisation, disinfection, cleaning or corrosion protection.

⚠ **Use of water with conductance exceeding 15 µS/cm may affect the sterilisation process and cause damage to the steriliser.**

⚠

Water conductance above 50 µS/cm may have a major impact on the sterilisation process and cause serious damage to the steriliser, 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 steriliser's lifetime.

⚠ **The warranty granted by the manufacturer is void if the autoclave has been operated using water containing impurities or exceeding the chemical content levels listed in the table above.**

4. TOOL PREPARATION AND LOADING

Only clean and dry tools may be sterilised. 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 sterilisation process from completing successfully. Furthermore, sterilisation of tools not subjected earlier to pre-cleaning may cause damage to both the tools and the steriliser.

If the tools were covered in grease, remove its excess.

Optimum method of positioning tools to be sterilised 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 sterilisation.

4.1. Tool pack preparation

4.1.1 Characteristics of a sterilisation pack

It is recommended to use sterilisation 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 sterilisation agent to the inside of the pack – resistance to damage during the sterilisation 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 result in the sterilizer being sealed.

- 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 for ENBIO S and 800 g for ENBIO PRO.
- Special attention should be paid so that the ends of the packets do not protrude out of the sterilizer tray, which may cause the packet 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.
- We do not use packages in the 134 C FAST program. Unpackaged sterilized instruments are intended for immediate use.

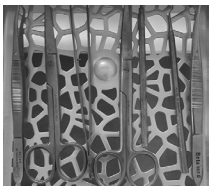
⚠

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 sterilisation

Sterilisation 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 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 sterilisation packages.

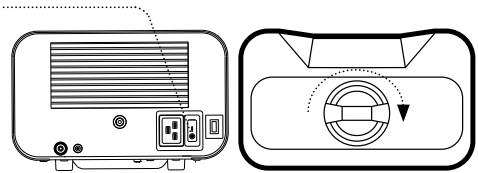


5. STARTING THE DEVICE

5.1 Commissioning

Before initiating the sterilisation cycle, turn the device on using the main switch located on the rear panel of the device. Make sure that water supply and wastewater cables 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.

MAIN SWITCH



5.2 Program selection

Depending on the type of load to be sterilised, the user is responsible for selecting the appropriate program dedicated for the given type of load, in accordance with the manufacturer's recommendations for sterilisation.

Additionally, the Enbio PRO autoclave has a PRION program dedicated as one of the stages of decontamination of objects which are suspected to have had or may have had contact with pathologically altered prion proteins (e.g. Creutzfeldt-Jakob disease, BSE, etc.). Detailed information and recommendations on the control of transmissible spongiform encephalopathies are presented in the document "WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies - Report of a WHO consultation. (Geneva, Switzerland, 23-26 March 1999)". It is the responsibility of the user of the device to comply with the above guidelines.

PROGRAM	134°C FAST	134°C	121°C	PRION**
Type of load	Unpacked instru-ments	Packaged and non-pack-aged tools	Packaged and non-pack-aged tools	Packaged and non-pack-aged tools
Process temperature	134°C	134°C	121°C	134°C
Pre-vacuum number	1	3	3	3
Sterilisation duration	3,5 min	4 min	15 min	18 min
Drying duration	-	3 min 4 min **ENBIO PRO**	5 min 5 min **ENBIO PRO**	5 min
Total process duration	100g: 7 min 100g: 10min **ENBIO PRO**	100g: 13 min 200g:18 min **ENBIO PRO**	100g: 26 min 200g: 31 min **ENBIO PRO**	800g: 43 min
Max. water consumption	105 ml 140 ml **ENBIO PRO**	115 ml 190 ml **ENBIO PRO**	110 ml 180 ml **ENBIO PRO**	230 ml
Class	S	B	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

**PRION program is available only in ENBIO PRO.

The 134°C program is recommended for the majority of sterilised materials due to the short duration of the entire program. The 121°C should be used to sterilise all other materials that cannot be subjected to sterilisation at the temperature of 134°C. Do not exceed a maximum weight of 500 g for ENBIO S and 800 g for ENBIO PRO. The displayed time is approximate. The pre-vacuum time is updating and depends on the form and weight of the charge.

When the device is turned on and the display shows the start screen, press the screen to go to the device menu. From here you can execute the Program, go to the Test, Information menu, and the COUNTERS menu. Temperature programs with 121°C, 134°C and 134°C PRION for unpacked and packaged loads and the 134°C FAST program for unpacked loads can be selected via the program menu.

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 sterilisation in **121°C** or **134°C**.

The selected program is initiated by pressing the corresponding symbol **START**.

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 pro-

cess, with the current stage of the program indicated, while information on subsequent stages is displayed in the upper left corner of the screen.

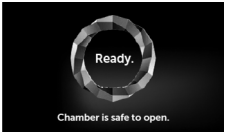
When a program is being run, the screen displays the temperature of the selected sterilisation program **121°C** or **134°C** the current temperature of the process chamber in the bottom left corner **116,7°C** the pressure currently in the chamber in the bottom right corner **0,30 Bar** while the process duration left is displayed in the upper right corner of the screen **12 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.

– Chamber lock **Locking door.**

– Process chamber heating
Heating up



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.
In the 134C FAST program, instruments are hot and wet after sterilization.

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 sterilisation process in the ENBIO device does not affect

material biocompatibility. All components of the device that are in direct contact with the sterilised load have no toxic, sensitising or irritating effects.

Type text here

5.3 Test programs

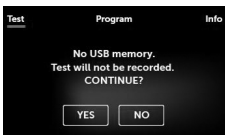
By pressing the **Test** field, you can go to the test program menu.

The **DOOR OPEN** message blinks on the display.

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.

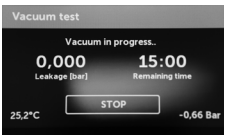
Program ENBIO S / ENBIO PRO	Bowie & Dick / Helix	Vacuum leak test
Process temperature	134°C	–
Pre-vacuum number	3	1
Sterilisation duration	4 min	–
Drying duration	3 min	–
Total process duration	15 min	16 min

Vacuum leak test

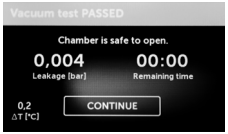
The vacuum leak test may only be performed on a cold device, before work is commenced. The vacuum leak test enables testing the autoclave for the presence of leaks. The following are checked during the test:

- Vacuum pump performance.
- Pneumatic system sealing.

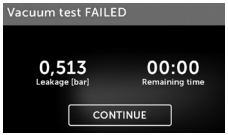
When the vacuum leak test program is selected and launched with the **START** button, the vacuum leak test progress screen is displayed.



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 steriliser 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 sterilisation 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).

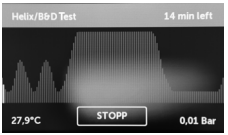
This test assesses the device's performance in sterilising charges composed of porous objects:

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

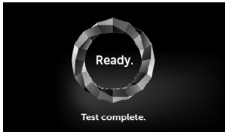
How to perform the test:

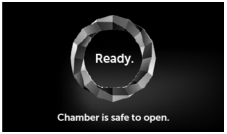
- Perform the test with an empty chamber, as per the EN 13060 standard.
- Place the Bowie-Dick test pack in the chamber, in the middle of the tray.

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.



PThe 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 steriliser'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
chemical indicator has changed color on a dark uniform over the entire surface.

NEGATIVE RESULT
In the middle of the test field remains clear because of the residual air in the middle of the device under test.

Any change of colour, uneven colouring of the test, indicate the presence of air during the test cycle, caused by faulty operation of the steriliser.

Helix test

The Helix test represents sterilisation of tools with A-type holes in accordance with the EN 13060 standard. It consists of a 1500 mm long tube open on one side, and a closed test capsule on the other. The indicator strip is located in the test capsule.

Helix test set

This test is used to assess the device's performance in sterilising recessed and porous charges, in particular:

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

How to perform the test:

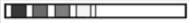
- Perform the test with an empty chamber, as per the EN 13060 standard.
- Place the test strip in the capsule. Read the instruction provided by the test's manufacturer.
- Close the capsule.
- Place the test in the middle of the tray in the chamber.
- After completing the test, open the steriliser and remove the test.

WARNING! The package will be hot.

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

– Open the capsule and remove the test strip.

POSITIVE RESULT
All fields of the indicator strip became dark.



NEGATIVE RESULT
Part of the indicator strip did not change color on the dark due to the presence of air inside the capsule. Part of the indicator strip did not change color on the dark due to the presence of air inside the capsule.

A part of the indicator strip did not change colour to the dark one due to the presence of air in the capsule.

An insufficient change of colour of the indicator strip indicates the presence of air during the test cycle, caused by faulty operation of the steriliser.

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 sealing, 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 2016-02-22 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.

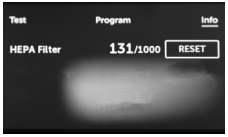
We can choose the language in the same way by clicking on the shortcut. The button marked with the letter B turns off and on the blue backlight in the back of the screen Clicking the LED button launches the backlight control menu, which is located on the sides of the device. LED lighting has two modes:
- Free mode, in which the user (by moving the sliders) sets the colors, intensity and brightness of the light.
-Continuous mode, which indicates the stages of the entire sterilization process with colors
LED lighting is available only in ENBIO S devices with colored housings: Midnight Blue, Dolly Pink, Ashy Stone, Yellow Sunflower.

5.4.1 Counters

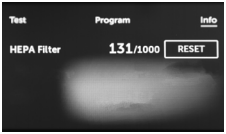
The ENBIO steriliser counts the number of performed processes and uses it to notify you about the recommended dates of replacing elements subject to wearing down, and about required service inspections.

No.	Name	Recommended frequency of replacement (cycles)	Yellow (Nearing the replacement date, number of cycles)	Red (Exceeded replacement date, number of cycles)
1.	HEPA filter	after 1000	from 980	after 1000

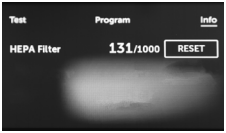
By pressing the COUNTERS field, you go to the counter display.



The number of performed processes is on the left hand side, and on the right hand side – the number at which the given element should be replaced or a service inspection performed 980/1000. After replacing a filter or seal, the values can be reset by the user by pressing the RESET button. The service inspection value can only be reset by an authorised service.



When nearing 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.

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 sterilisation 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.

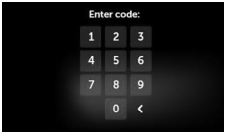
If the STOP field is selected, the following messages will be alternately displayed, notifying you that the process has been aborted by the

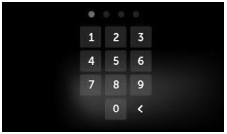
user and pressure is being equalised in the process chamber, and a message notifying you that the process has not been completed correctly and the load is not sterile.

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. However, in order to do so, 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.

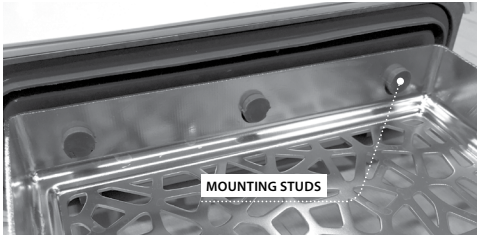
6. MAINTENANCE AND CARE

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 aluminium). 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 microfibre cloth (microfibre 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 ensure failure-free operation of the steriliser.

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.

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 a quarter. If contamination is found, the tank should be drained, cleaned and refilled with new water.

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

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

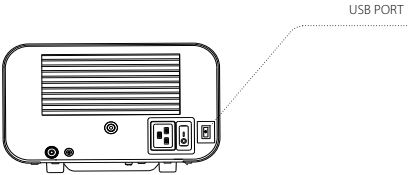
In order to ensure correct functioning of the ENBIO steriliser, it is recommended to perform periodic service inspections and replace parts subject to wearing down in accordance with the following schedule, and periodic inspection of individual steriliser elements in accordance with the following guidelines.

Name	Replacement frequency
Bacteriological filter	every 1000 cycles or every 12 months
Connection/water removal tube	if damage is observed
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	weekly – performed by the user
Connection/water removal tube	weekly or in the event of incorrect functioning – performed by the user
Container plugs	weekly – performed by the user

7. DATA ARCHIVING

The progress of each performed sterilisation is automatically saved on a data carrier (USB drive). The data can be used only for archiving, the sterilisation 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.

8. ENBIODATAVIEWER

The ENBIODATAVIEWER software enables viewing and archiving sterilisation programs on a computer, and printing them.

Minimum requirements for installing the software:

Operating system – Windows – at least Windows 7 or newer

Free disk space – at least 100 MB
Minimum CPU parameters – at least 1 GHz
Minimum RAM – at least 512 MB
Screen resolution – at least 1200 x 720 or more

⚠

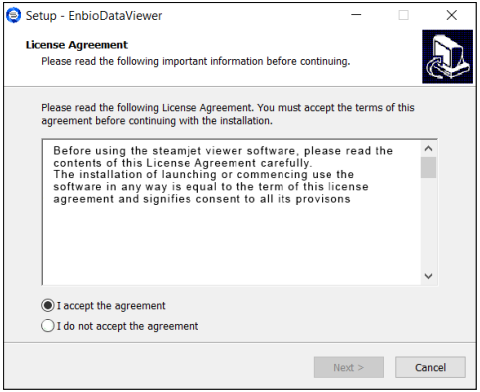
The software is delivered with the device and can be found on a removable disk - the pendrive or the latest version can be downloaded from the manufacturer's website http://enbiogroup.pl/steamjet/steamjet-software-serwis/

8.1 Software installation

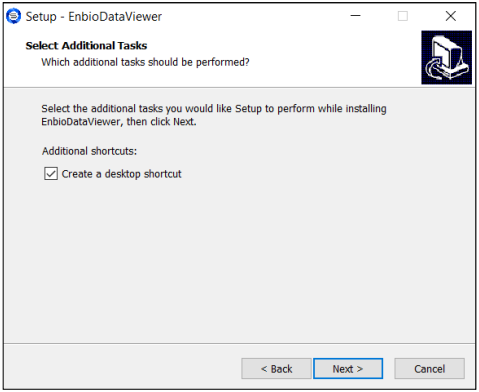
To install the software, double click on the software installation file.

After performing this operation, the installation window regarding the language selection will be displayed.

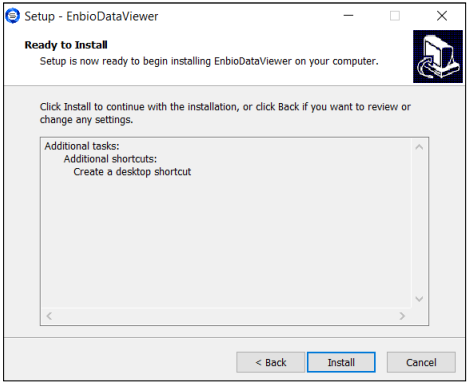
After confirmation, you must accept the license terms for the installed software.



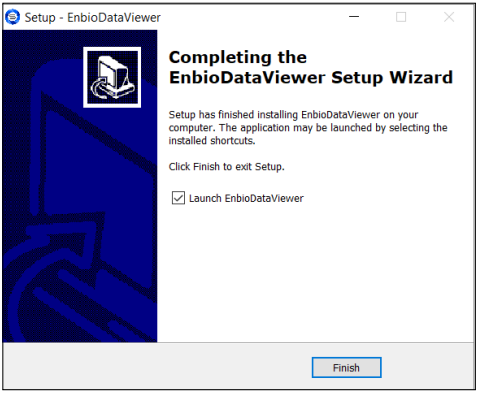
Next, the information about placing the software shortcut on the computer desktop will be displayed.



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

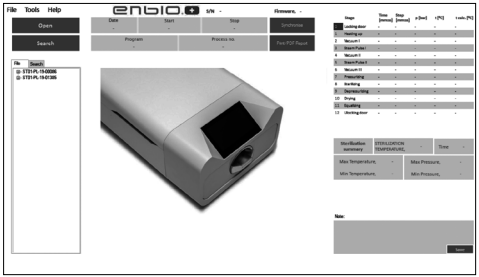


After installation, the following message is displayed.



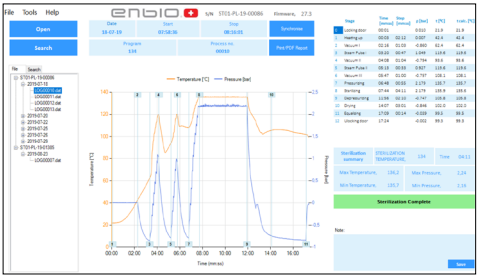
We can now run the software or finish the installation without running the software by clicking the Finish button.

The main program window is displayed.



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 after the dates of performance

Temperature and pressure diagram together with the main data regarding autoclave and process (date of completion).

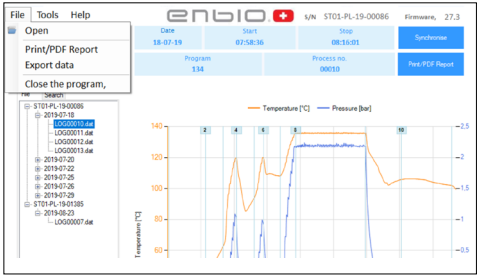
Data on the subsequent stages of the process.

The most important parameters of sterilization.

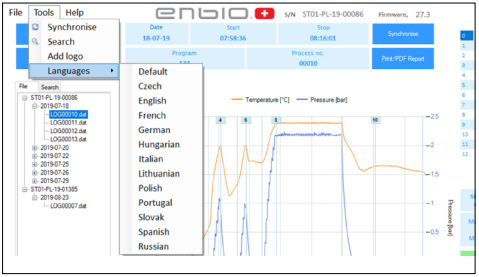
The ability to save a note for each process.

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 pendrive 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 producer
• Exporting data to CSV format
• Closing the program

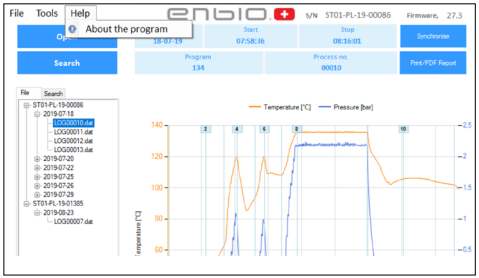


By clicking on the Tools window we have access to the options:
• Synchronization of all files with saved programs from the memory of the pendrive
• Search for any saved process from the database
• Adding your own logo to PDF reports



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

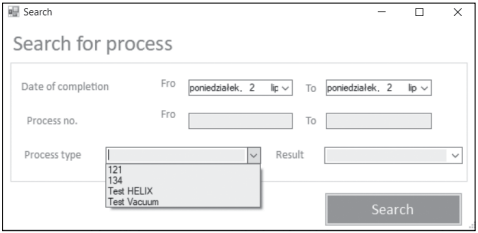
- About program



Search

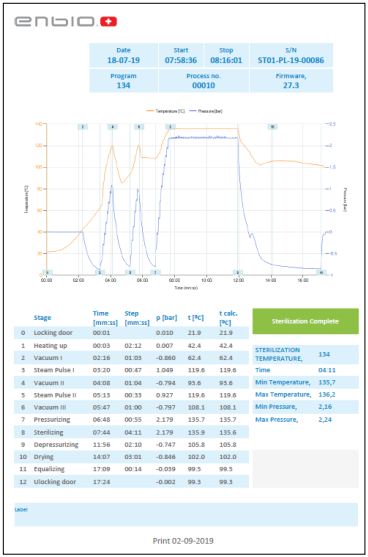
The program allows you to search for processes after:

- 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.



Date	Start	Stop	S/N
18-07-19	07:58:36	08:16:01	ST01-PL-19-00086
Program	Process no.		Firmware,
134	00010		27.3

Temperature [°C] — Pressure [bar]

Temperature [°C] / Pressure [bar] / Time [mm:ss]

	Stage	Time [mm:ss]	Step [mm:ss]	p [bar]	t [°C]	t calc. [°C]
0	Locking door	00:01		0.010	21.9	21.9
1	Heating up	00:03	02:12	0.007	42.4	42.4
2	Vacuum I	02:16	01:03	-0.860	62.4	62.4
3	Steam Pulse I	03:20	00:47	1.049	119.6	119.6
4	Vacuum II	04:08	01:04	-0.794	93.6	93.6
5	Steam Pulse II	05:13	00:33	0.927	119.6	119.6
6	Vacuum III	05:47	01:00	-0.797	108.1	108.1
7	Pressurizing	06:48	00:55	2.179	135.7	135.7
8	Sterilizing	07:44	04:11	2.179	135.9	135.6
9	Depressurizing	11:56	02:10	-0.747	105.8	105.8
10	Drying	14:07	03:01	-0.846	102.0	102.0
11	Equalizing	17:09	00:14	-0.059	99.5	99.5
12	Ulocking door	17:24		-0.002	99.5	99.5

Sterilization Complete

STERILIZATION TEMPERATURE,	134
Time	04:11
Min Temperature,	135,7
Max Temperature,	136,2
Min Pressure,	2,16
Max Pressure,	2,24

Label

Print 02-09-2019

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.

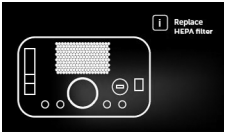
9.1 Warning messages

The warning messages concern the replacement of individual elements subject to wearing down, and the service inspections.

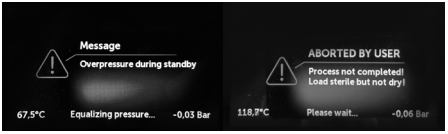
The element subject to replacement is highlighted in red, the screens are displayed alternately.

Screens concerning seal replacement, with the number of processes remaining until replacement.

Screens concerning filter replacement.



9.2 Information codes



Screen for overpressure or underpressure resulting from natural chamber cooling processes.

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

9.3 Error codes

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

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	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 sterilisation	Check water level and connection. Contact the service
6	"Sterilization temp. too low"	Sterilization temperature too low	Check water level and connection. Contact the service
7	"Too high pressure during drying"	Pressure too high during drying	Check if the outlet tube is not submerged in water. Contact the service
8	"Too many steam pulses/no water"	Too many steam impulses. No water supply.	Check water supply level and tubing connections. Contact the service
9	"Drainage error"	Drainage clogged	Check wastewater level and tubing connections. Contact the service
10	"Chamber heating error"	Chamber heating error	Contact the service
11	"Steam generator heating error"	Steam generator error	Contact the service
12	"Prevacuum fail/check condensate outlet"	Vacuum pump/ drainage error	Check wastewater level and tubing connections. Contact the service
13	"Power failure"	Temporary power loss during operation	Confirm error.
14	"Pressure during standby"	Pressure exceeded during standby	Confirm error. Contact the service
15	"Locking door error"	Door lock error	Contact the service
16	"Unlocking door error"	Door unlocking error	Contact the service
17	„Valve V3 / HEPA filter error"	V3 valve / HEPA filter error	Check filter cleanliness/replace filter. Contact the service
18	"Pressure sensor error"	Pressure sensor error	Contact the service
19	"USB disc error / Change disc"	Write error on the pendrive - media damage	Write error on the pendrive - damage to the media. Rip content from the current pendriva - purchase of a new one and use of a new one
31	"Internal flash error"	Memory error	Contact the service
Info			
	„Aborted by user"	Process aborted by the user. Non-sterile insert if interrupted during or before the sterilization process.	
	„Vacuum test failed"	Vacuum leak test error	Contact the service
	„No USB memory"	No USB drive	Check the USB port, insert the drive. Contact the service
	„Equalizing pressure"	Pressure during stoppage. Equal to atmospheric pressure	The message occurs in specific cases as a result of natural processes. In the case of a frequent appearance of a message, contact the service.

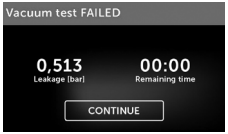
Sample error codes are presented below.
Process aborted by the user.
Screens displayed alternately: equalising pressure, please stand by.

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, fill out the Warranty Claim Form available on the manufacturer's website www.enbio-group.com Our Technical Service will contact you as soon as possible. If the device has been damaged during transport, file your warranty claim with the delivery note and photographic evidence of the damage found. In order to contact us, visit our website, you will find all the information under the link: www.enbio.com

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

12. TECHNICAL INFORMATION

Technical data	ENBIO S	ENBIO PRO
Power supply	230 V/50Hz	230 V/50Hz
Installed power	3,25 kW max	3,25 kW max
Operated Power	1,60 kW	1,60 kW
Maximum electric current consumption	15 A	15 A
Operating pressure	2,1 Bar	2,1 Bar
Maximum pressure	2,3 Bar max	2,3 Bar max
Maximum process temperature	137°C	138°C
Process chamber capacity	2,7 l	5,3 l
Mass	15 kg	20 kg
Process chamber dimensions (LxWxH)	292 x 192 x 45mm	300 x 200 x 90 mm
External device dimensions (LxWxH)	561 x 252 x 162mm	561 x 270 x 202 mm
Protection rating	IP20	IP20
Noise level	49dB(A)	49dB(A)
Process data archiving	USB drive	USB drive

Surrounding conditions:	
Operating temperature range	from +5°C to +25°C
Relative humidity	0-90%
Storage temperature range	from -20°C to +60°C
Relative humidity	0-90%
Surrounding pressure range	900-1100 hPa

Rating plate located on the bottom of the device.

enbio. CE 2274 RoHS

REF Enbio S	TYPE B	SN ST01 - CH - XX -XXXXX	2020

Power supply
220-240 V AC 10A
50/60Hz 2,25 kW max.

Manufacturer
Enbio Group AG
Eichengasse 3
4702 Oensingen
SWITZERLAND

Sterilization chamber

Max. pressure	2,1 bar
Min. pressure	-0,90 bar
Max. temperature	134 °C
Pressure test	9,4 bar
Chamber volume	2,7 dm^3

Maxima

Max. working pressure	2,3 bar
Max. working temp.	137 °C

enbio. CE 2274 RoHS

REF Enbio PRO	TYPE B	SN ST02 - CH - XX -XXXXX	2020

Power supply
220-240 V AC 15A
50/60Hz 3,25 kW max.

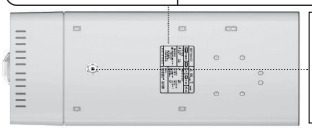
Manufacturer
Enbio Group AG
Eichengasse 3
4702 Oensingen
SWITZERLAND

Sterilization chamber

Max. pressure	2,1 bar
Min. pressure	-0,90 bar
Max. temperature	134 °C
Pressure test	9,4 bar
Chamber volume	5,3 dm^3

Maxima

Max. working pressure	2,3 bar
Max. working temp.	137 °C



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

13. DECLARATION OF CONFORMITY

enbio.

EC Declaration of Conformity

Company: ENBIO GROUP AG, Eichengasse 3 Street, 4702 Oensingen, Switzerland

declares with sole responsibility, that medical devices: **STEAM STERILIZERS**, models:

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

complies with provisions of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (as amended). The device has been classified in Class IIb in accordance with rule 15 of Annex IX of the above mentioned Directive.

Conformity assessment has been carried out in accordance with Annex II without point 4 of the above Regulations.

The conformity assessment has been conducted by the Notified Body No. 2274

TUV Nord Polska Sp. z o.o.
Mickiewicza 29 Street
40-085 Katowice
Poland

CE 2274

Sebastian Magrian

Oensingen
14.01.2021

Managing Director
President of the Board