

STERILIZERS

THE TECHNICAL SIDE OF THE STANDARDS

Performance testing.
Tracking

Enbio Sterilisers
World's fastest Class "B"

Is a rule enacted by the European Commission in order to define the classification of sterilization loads.

The regulation classifies sterilization loads into three classes: B, S, N.

EN 13060 regulation provides for more than 420 technical normative points.

The classification of sterilisation loads

DEFINITIONS

Solid or ferrous materials: All Metal Instruments

Porous bodies: All fabrics are divided in two classes:

- Type B: Gauzes or small tissue devices or porous material in general.
- Type A: Gowns or other porous material or devices.

Hollow Instruments: All instruments or devices that are hollow or with holes are divided into two classes:

- Type B: cannula, tubes or devices equipped with considerable passages.
- Type A: turbines, handles, and devices with blind holes or small sized.

Sterilization cycle. **What you should know about it.**

Instruments turning yellow: Chemical residue has been left on the instruments and “cooked on”. The instruments have not been rinsed or dried correctly.

Yellow spots on the autoclave chamber: Possible residual chemical left after cleaning. Proper rinsing has not been done.

White spots on instruments: Rinsing has been done with hard water and the instruments have not been rinsed or dried properly.

Instruments turning black: These instruments obviously contain a high carbon content . This is an indication of a lesser quality instrument.

If at the end of the sterilization cycle instruments are not completely dried:

“Wet Packs” indicate a malfunction with the Sterilizer. Do not use and contact the Service Contractor

Phases of the The Sterilization Cycle.

1. VACUUM

2. PRE-HEATING

3. EXPOSURE TIME

4. DRYING

1. VACUUM

WHY HAVE A VACUUM?

When the autoclave is started and the sterilization process begins, some pockets of air with a temperature of 20-25C are inevitably incorporated in the chamber.

When the pre-heating process commences, the steam produced does not absorb the air pockets because of their different physical characteristics (elasticity). As a result, these air pockets remain “cold” and disturb the sterilization cycle. It is crucial to expel all air pockets from the chamber, in order to guarantee the efficacy of the process.

This air expulsion is achieved by using a vacuum system. The most efficient is a forced vacuum with mechanical pumps.

Different types of vacuum generation: Thermodynamic vacuum “N”

Vacuum with pump “S” Cycle

Fractionated vacuum with pump “B”

Hollow Load A

Bowie Dick Helix Test – Hollow Load A

The Bowie Dick Helix Test is an obligatory test for class B Bench Top Steam sterilizers as per EN 13060 - 2010

Sterintech is one of the world's leading producers of sterilization process challenge devices (PCD). They are produced to conform to European Standards ISO 11140 – 1 Type 2 – EN 867 part 5, class B.

Sterintech Bowie Dick Devices are an accurate test for the effectiveness of all Class “B” Sterilizers.

The BDHT consists out of a Chemical Indicator Holder in Teflon connected to a 1,5 mtr long tube.

This type of Bowie Dick Test will detect failures during the Bowie Dick Test cycles as it detects smaller volumes of trapped air etc.

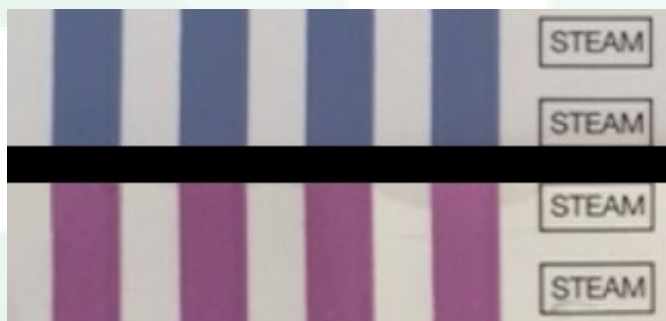
Failures which are picked-up by the BDHT are:

- Sterilization temperature too low
- Sterilization holding time too short
- Insufficient vacuum in depth and in number of vacuum pulses.
- Insufficient air removal from hollow devices
- Insufficient steam penetration in hollow devices
- Leakage of piping / valves / door seals
- Detection of presence of small volume inert gases in steam supply.
- Detection of excessive amounts of condensate.

Bowie Dick Helix Test for hollow load “A”

The EN 285 : 2009 are specifying the Helix test (Hollow A) to be used as Bowie Dick Test as well as Batch Monitoring when hospitals are sterilizing Hollow Loads.

Next to that this Bowie Dick Helix Test is an obligatory test for class B Bench Top Steam sterilizers.



Characteristics:

- Conform to ISO 11140 - 1 Type 2 - EN 867 part 5 class B
- Clear transition of color into pink
- Easy to interpret
- Easy to document
- Non-Toxic / Lead Free
- Can be fully recycled
- PCD guaranteed for 500 Cycles (134°C - 3,5 min)

REF: 101.201.0100 Hollow A Helix with 1,5 mtr tube Unit: 100 indicators
REF: 101.201.0250 Hollow A Helix with 1,5 mtr tube Unit: 250 indicators

Reference of color change of BCH test

134°C - 3,5 min
121°C - 15 min

1



2



3



4



5



Explanation of the
color reference

- Position 1: Untreated indicator strip (original chemical indicator color)
- Position 2: Low temperature / short holding time or absence of steam
- Position 3: Typical for vacuum or leakage problem
- Position 4: Typical for inert gas problem
- Position 5: Complete successful color change

Bowie Dick Test Pack Porous Load - Mini

Recommended for daily monitoring of pre-vacuum steam sterilizer and bench-top steam sterilizers (Class B). Based upon the Bowie Dick test result the steam sterilizer is released for usage during the day.

Characteristics:

- ◆ Fulfill requirements of EN 285 and ISO 17665
- ◆ Conform to ISO 11140 - 4 Type 2
- ◆ Performance similar to original Bowie Dick Test Pack
- ◆ Clear blue - violet color change
Easy to interpret
- ◆ Easy to document
- ◆ Non-Toxic / Lead Free
- ◆ Dimensions: 105 x 65 x 6 mm



REF: 102.100.0100 Bowie Dick Test Pack - Mini
Unit: 50 pieces

Sterintech™ Emulator – Type 6 Indicators

The Emulator with a big plus...

Emulators are critical to test the effectiveness of the sterilisation process produced by an autoclave. Infection Control is critical – Every batch its critical.

Characteristics:

Shelf life: 5 years after production.

Steam emulator conform to ISO 11140 – Type 6.

Clear colour transition from Blue into Pink.

Chemical emulator covered with lacquer.

Non-Toxic / Lead Free.

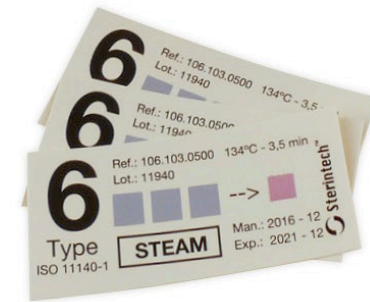
The Emulator with a big plus .

Sterintech™ Emulator – Type 6 Indicators

Effective and successful sterilisation of instruments is critical.... Testing every batch is important. The Sterintech Type 6 Emulator (Indicator) does just this...place it in every load and know what the result is. No more guessing.

The Sterintech™ Sequential Emulators give the operator more information about the sterilization process than the standard class 6 indicator. This is because the one strip has three indicators each calibrated to an individual time/steam combination that will identify any malfunction during the process

Ref: 106.103.0500SA Emulator, 134°C-3,5 min/121°C-15 min, includes Self-Adhesive backing, Box of 500 (Blue to Pink)



Sterin-Trace

The Ultimate Sterilizer Record & Tracking System

The Sterin-Trace Sterilizer Record & Tracking System is designed to provide a simple method of record keeping & “Patient to Process” trace-ability of devices & instruments in the modern office based practice.

Sterin-Trace uses a simple intuitive check list that creates a reliable audit trail & enables the operator to record:

1. Sterilizer cycles
2. Process Expiry Date
3. Steam Penetration Test (Bowie-Dick)
4. Daily Test
5. Registered Authorised Operator
6. Patient
7. Maintenance Records

Sterin-Trace

The Ultimate Sterilizer Record & Tracking System

“IF IT’S NOT RECORDED THEN IT IS NOT DONE”

- Record keeping is the evidence that the practice has performed & monitored all stages of the sterilisation process.
- To comply with, AS/NZS 4187, AS/NZS 4815 & ISO 13683 the practice must maintain “Patient to Process” tracking of instruments & devices.
- Responsibility lies with the practice management to ensure all the cleaning & sterilization processes are performed & recorded.

The implementation of the Sterin-Trace Quality System within the practice will:

- Provide a legal reference should a challenge occur.
- Reduce the risk to patients.
- Minimize the chance of non sterile items being used.

Sterin-Trace

The Ultimate Sterilizer Record & Tracking System

Features:

- Process Indicators (Steam, FO, EtO, Plasma) conform to ISO
- Clear transition of indicator colour change.
- Easy to use label gun
- Double labels make traceability and documentation, easy.
- Non-Toxic / Lead Free indicators
- Latex free label materials

Two lines ... but it carries all information

REF: 602.002.0001 Two line label gun



Sterin-Trace

The Ultimate Sterilizer Record & Tracking System



Sterin-Trace

INSTRUCTIONS

STERILIZER ID NUMBER: Should the practice have more than one sterilizer, each should be identified by the name & model or number.

CYCLE NUMBER: The cycle number on the “Sterilizer print out” should match the Sterilizer Record Sheet. If the Sterilizer does not have a printer then the operator may create a daily cycle number or a continuous cycle number. This is also recorded on the batch label.

DATE: “The date of Process. Insert the day, month & year. (dd/mm/yy)

PATIENT REF: To keep patient confidentiality a medical record number may be used to trace the patient to this cycle, when the goods are used on that patient only. Where multiple items are processed & used on several patients then the twin layer or “piggy back” Process Label is placed on their notes to trace them back to this cycle.

STERILIZER: _____ PLACE
CYCLE No.: _____ LABEL
DATE: _____ HERE

ITEMS PROCESSED:

LOT / BATCH HELIX TEST - Hollow Instruments as per EN 867-5

PLACE HELIX
INDICATOR HERE

CYCLE RELEASE CHECK LIST

TIME ON	TIME OFF		
STERILIZER TEMP CHECK		PASS <input type="checkbox"/>	FAIL <input type="checkbox"/>
INDICATOR CHECK		PASS <input type="checkbox"/>	FAIL <input type="checkbox"/>

LOAD RELEASED / REJECTED BY:

OPERATOR ID: _____ SIGN: _____

CYCLE RELEASE CHECK LIST:

TIME ON: TIME OFF: Both must match the printout. This establishes a cross check & will identify whether a load has been placed in the sterilizer, & not turned on. Also should the printer malfunction e.g. ink run out, the practice will still maintain a record of time ON & OFF.

OPERATOR ID: Enter the name & ID Number of the person who checks the times. The Practice Manager may need to identify the responsible & accountable operator in the future. An operator ID number may be issued & used on each process label.

STERILIZER TEMP CHECK PASS FAIL

Check the temperature against the print out. Should there not be a printer, check against the temperature gauge.

INDICATOR CHECK PASS FAIL

Check that each pack has a process label attached & that the required colour change has occurred e.g. Autoclave tape or the Sterin-Trace Process Label Purple to Green. A Class 6 indicator is to be used if the sterilizer has no printer. An extra label should be processed each cycle & placed on the sterilizer record sheet. Pack expiry date may also be included.

LOAD RELEASED / REJECTED BY:

OPERATOR ID: _____ **SIGN:** _____

Following inspection **ONLY** release the load if the package is **NOT** damaged, open or wet. These items must be rejected & reprocessed. Draw a line through rejected packs in the "item/s processed list".

The person responsible for checking the process with the cycle, permits the goods to be used.

*PLACE
LABEL
HERE*

The Process Label is placed here with the cycle details, this includes sterilizer number, cycle number, date processed, expiry date and contents (optional).

NOTE: Always use a non-toxic marker pen on the process label or pack. Never use a ball point pen or pencil on packs that are to be sterilized. The Sharpie non-toxic industrial marker pen is recommended & included in the Sterin-Trace system.

STERILIZER PRINT OUT

The cycle "print out" can be detached from the printer & stored on the reverse side of each page directly in alignment with each cycle recorded by using an adhesive or staple.

Label Applicator – Gun (2 lines label)

The Sterintech two line label gun is reliable, easy to use and durable. The applicator is reliable for years of use, even in the busiest of Departments.

Sterintech “piggy back” double labels for two line applicators are available with all types of sterilization indicators as well as a variety of colours. Coloured labels are used to assist FIFO systems. This permits the operator to colour code the items and personalise packs for separate Departments.

Two lines ... but it carries all information

The Sterintech two-line label gun is reliable, easy to use and durable. The applicator is reliable for years of use, even in the busiest of Departments.

Often the combination of a double label gun label and normal tape is a more cost-effective solution than steam tapes only.

Next to that they offer better readable data and prevent writing errors.

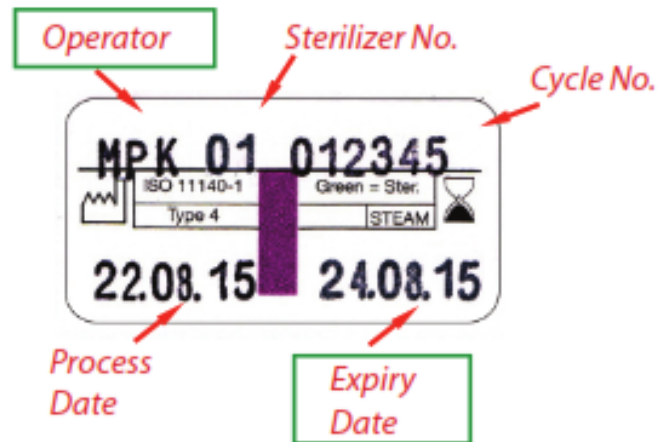
Label Applicator – Gun - (2 lines)

- Easy to use label applicator gun
- Label includes a Type 4 Sterilisation Indicators (Steam, FO, EtO, Plasma) – conform to ISO 11140
- Clear transition of indicator into its end-colour
- Double labels (“PiggyBack”) serve for an easy traceability and documentation
- Non-Toxic / Lead Free labels
- Latex free label materials
- Gun can be fully recycled
- Reference Code 602.002.0001



Sterilisation Tracking – Label Configurations (2 lines)

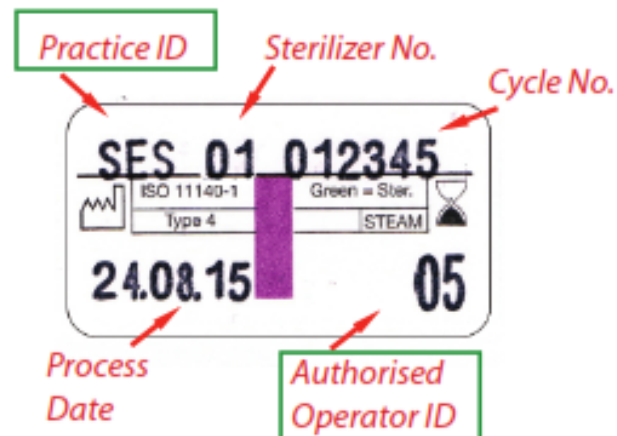
LABEL OPTIONS



Option 1

Operator may be identified using an allocated number or the initials of the person as show opposite.

Expiry Date: Most tracking systems have a provision for two dates on the label, as some Authorities require an expiry date to be displayed, usually 12 months.



Option 2

Practice ID or Department may be identified in this space rather than the Operator as show opposite.

Authorised Operator ID identifies the operator numerically and is recorded by the Practice Manager in the "Register of Authorised Operators" located at the back of the "Sterin-Trace" Steriliser Record Book.

Sterilisation Tracking – Label Applicator (2 lines)



Setting the Print

Move the turning knob to the required position and turn it until the required character is in position. To function properly the white area of the printing position should be visible.

The first three (3) characters of the top line are selected following the table at the front of the printing head label. An example: If you want to print "A" then select "N" in the dialer area. To print "Q" you need to select "D" in the dialer area. For other characters please follow the table below:

A	B	C	D	E	F	G	H	I	J	K	L	M
N	O	P	Q	R	S	T	U	V	W	X	Y	Z

After setting all the characters in the right position for both lines one needs to secure the turning knob in its original position again. In this way the printing is secure.

Sterilisation Tracking – Label Applicator (2 lines)



To be able to load labels into the label gun one should open the bottom of the label gun by pushing both levers at the side backwards. The bottom of the label gun will open itself after which one can push the bottom backwards to have a full access to place the label roll into the gun.



Unroll the label roll partly and **take of about 8 labels**. Push the roll into the label gun as per picture. The labels are pointing toward the top of the label gun.



After closing the bottom of the label gun one takes the backing of the label rolls and fold it backwards into the slot as per picture just behind the metal rolls. By operating the label gun handle a few times the backing material will be pulled in into the label gun. The label gun will align itself into the proper printing position.

Sterilisation Tracking – Label Applicator (2 lines)



In case of a rarely misprint one can adjust the printing position manually by loosen this screw and adjust the slide a bit to the back or front. After adjusting one should tight the screw again. The screw can be reached through the backing material.



Now the labels are placed the machine can be operated and labels will be printed and dispensed by the Sterintech 2-line label gun.

After a while the printing will become more grey and a change of the ink roller may be necessary.

Tracking – Labels (2 lines)

Features :

- Easy to use label applicator gun
- Label includes a Type 4 Sterilisation Indicators (Steam, FO, EtO, Plasma) – conform to ISO 11140
- Clear transition of indicator into its end-colour
- Double labels (“PiggyBack”) serve for an easy traceability and documentation
- Non-Toxic / Lead Free labels
- Latex free label materials
- Gun can be fully recycled

Reference Code Unit

602.401.9000 9 000 labels (12 rolls of 750)

602.401.9000 2 250 labels (3 rolls of 750)



PRESENTS

STERILIZERS by

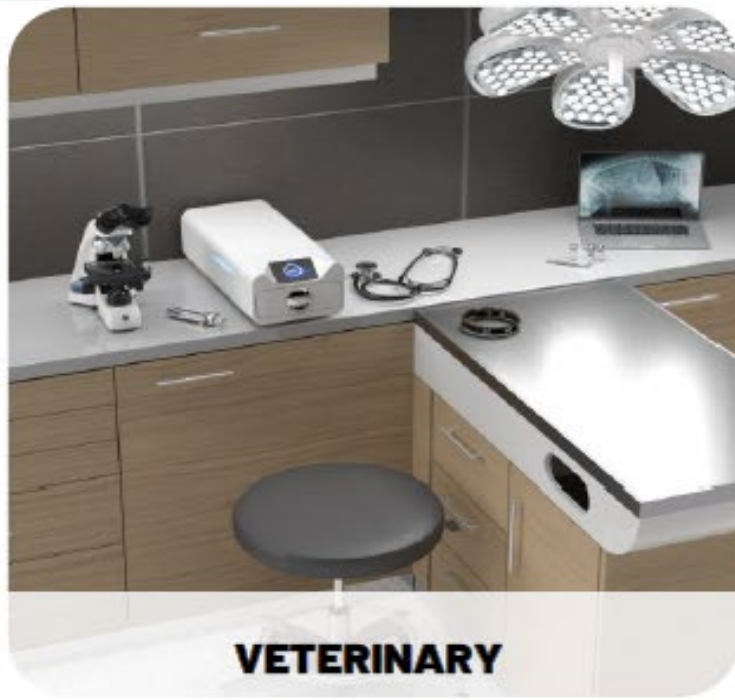
Enbio

**World's fastest “class B”
autoclaves.**

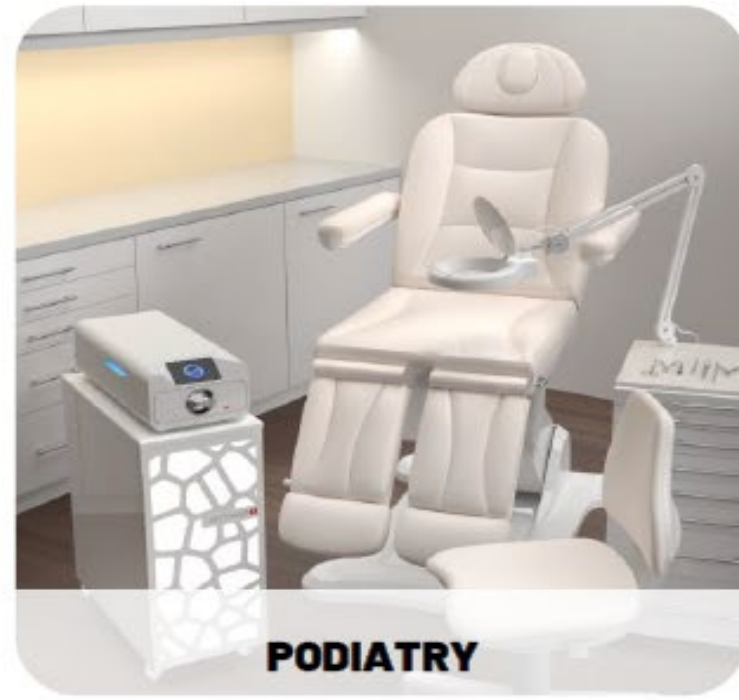




DENTISTRY



VETERINARY



PODIATRY



SURGERY

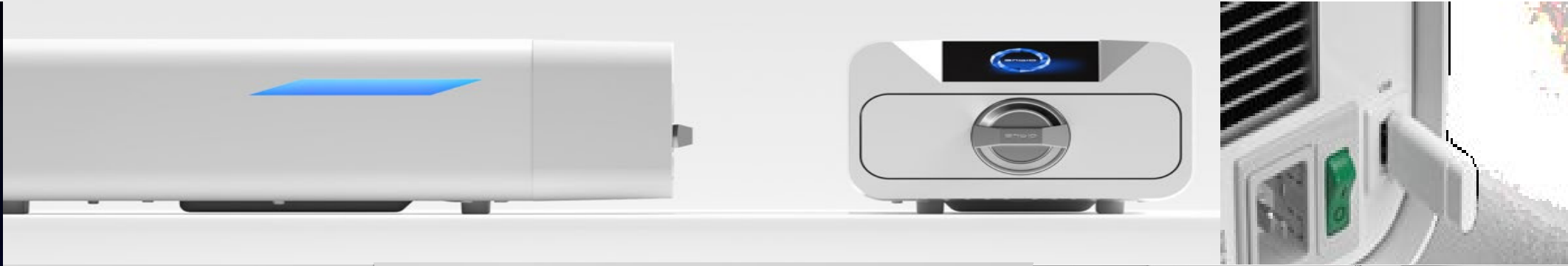


TATTOO

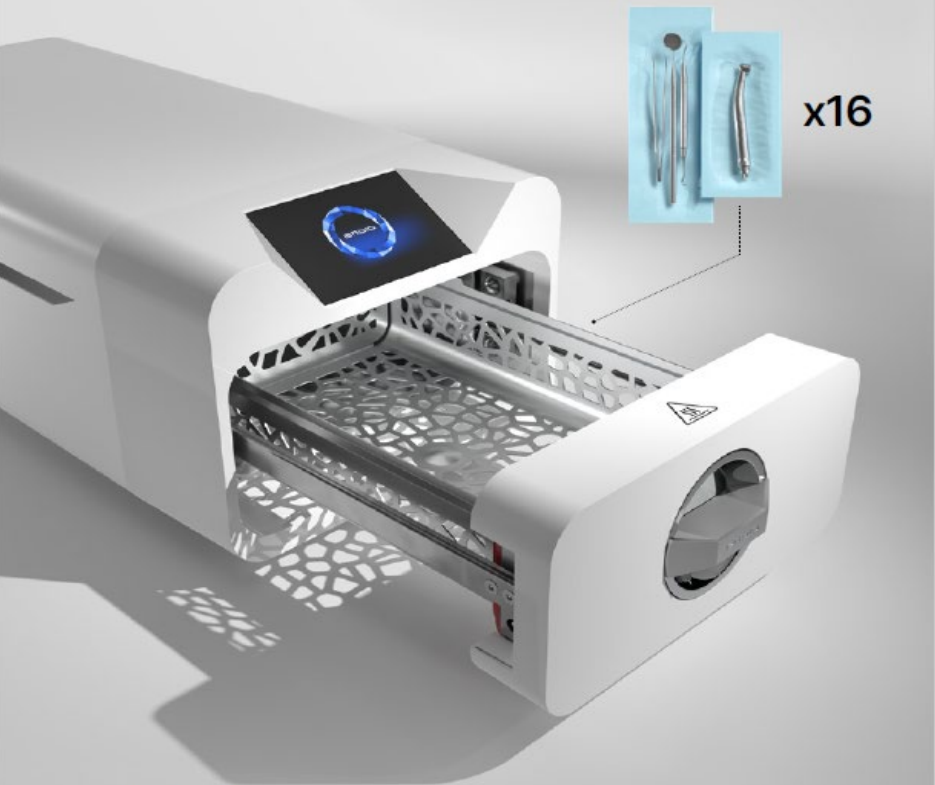


BEAUTY

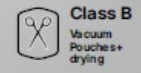




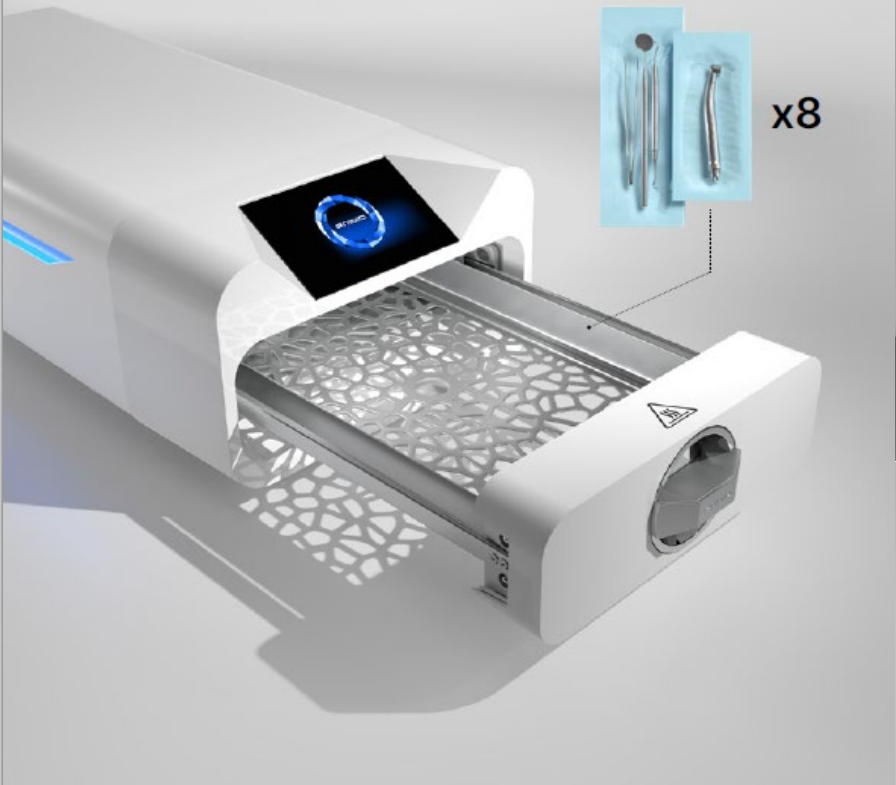
Unwrapped FAST / 134°C	Wrapped Class B / 134°C	Wrapped Class B / 121°C	Wrapped / PRION Class B / 134°C
9 min	18 min	30 min	43 min



Enbio PRO Autoclave
Technical Data



Unwrapped FAST / 134°C	Wrapped Class B / 134°C	Wrapped Class B / 121°C
7 min	15 min	30 min



Enbio^S Autoclave
Technical Data



Enbio Data Viewer Software

The Enbio Data Viewer software allows you to view and archive sterilization data on your computer and print them out.

The software installation file is located on a USB flash drive delivered with the device. You can also download the latest version of the software from the link below.

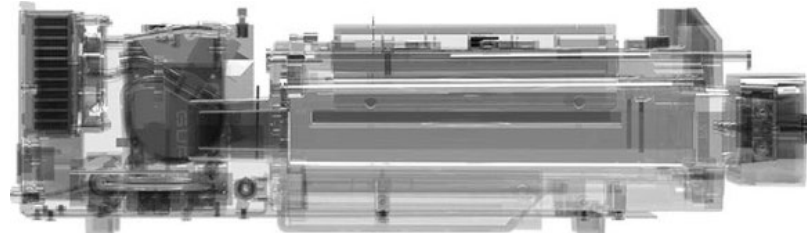
With Enbio Data Viewer you can:

- Loading a saved process from a memory stick or from another location
- Print the saved process
- Save the report as a PDF file
- Export of data to a file in order to send the data to the manufacturer in case of problems
- Synchronisation of all files with saved processes after selecting the memory stick location
- Search for any saved process from the database

Minimum hardware requirements

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

EnbioDataViewer



"Fastest in the world"



Process reports

Dedicated software for process data reading and

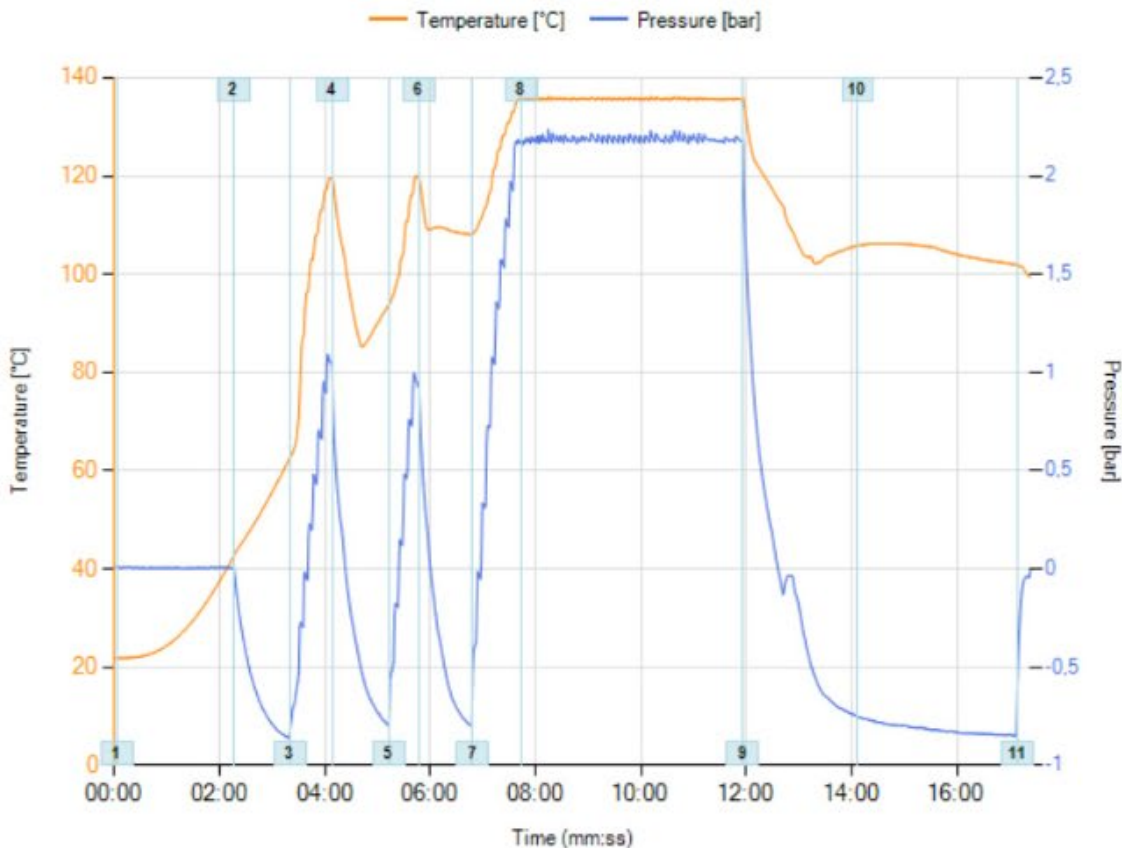
Open

Search

Date 18-07-19	Start 07:58:36	Stop 08:16:01	Synchronise
Program 134		Process no. 00010	Print/PDF Report

File Search

- ST01-PL-19-00086
 - 2019-07-18
 - LOG00010.dat
 - LOG00011.dat
 - LOG00012.dat
 - LOG00013.dat
 - 2019-07-20
 - 2019-07-22
 - 2019-07-25
 - 2019-07-26
 - 2019-07-29
 - ST01-PL-19-01385
 - 2019-08-23
 - LOG00007.dat



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	99.6	99.6
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	-0.039	99.5	99.5
12	Unlocking door	17:24		-0.002	99.3	99.3

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

Sterilization Complete

Note:

Save

A tree of all processes that have been synchronised from the pendrive - they are ordered by execution date

Temperature and pressure graph with main autoclave and process data (date of execution and number).

Data on the duration and achieved parameters of each stage of the process. The most important sterilization parameters. Possibility of saving a note for each process.

<https://majacmedical.com.au/wp-content/uploads/2022/10/Enbio-Sterilisers-presentation.mp4>

<https://majacmedical.com.au/wp-content/uploads/2022/10/Installation-Pro-S-Models.mp4>

<https://majacmedical.com.au/wp-content/uploads/2022/10/Enbio-Pitstop-Precision-Service.mp4>

Enbio

World's fastest “class B” autoclaves.



Thank's your attention

MAJAC HEALTHCARE

Support Continuing Education