

User manual

BioPod

MEG021KP101



Biofeedback Device

Instructions for Use & Technical Description

Please read this manual carefully before using your new device!
This manual is an integral part of the device and must be kept until it is destroyed.
Use is restricted to professionals who have undergone appropriate training.

In the event of a breakdown or if you have any questions about this manual, please contact your distributor (see stamp on the last page) or Électronique du Mazet at:

Tel: (33) 4 71 65 02 16 - Fax: (33) 4 71 65 06 55

Please return the warranty certificate on the last page of this manual within 15 days of installation or receipt.



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1 Introduction

This manual has been designed to assist you in getting started with and using your **BioPod**, from receipt to commissioning, daily use and maintenance.

If you have any difficulty understanding this document or have any questions about it, please contact Électronique du Mazet, your retailer or your distributor.














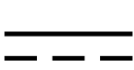

Keep this manual in a safe place, away from moisture, heat and any source of damage.

This document reflects the technical status of the device and its documentation at the time of sale. However, Électronique du Mazet reserves the right to make changes without any obligation to update this manual.

If the device is transferred to a third party, Électronique du Mazet must be informed of the new owner's contact details. It is essential that the new owner is provided with all documents, accessories and packaging relating to the device.

Important: Only users who have read this document are authorised to use the **BioPod**. Failure to follow the instructions may result in risks for the practitioner, patients or third parties. In this case, Électronique du Mazet and its authorised distributors cannot be held liable.

1.1 Symbols used

	<u>Warning</u> : this logo draws your attention to a specific point
	<u>Operating instructions</u> : this logo informs you that the operating instructions must be read in order to use the device safely
	<u>Type BF applied part</u> : applied part in contact with the patient
	<u>Recycling</u> : this device must be disposed of at an appropriate recovery and recycling facility. Consult the manufacturer.
	Serial number
	Manufacturer
	Date of manufacture
	Product reference
	CE marking
	Non-ionising electromagnetic radiation
	UDI (Unique Device Identifier)
	Temperature limit
	Operating instructions
	Direct current
	Medical device

2 Presentation of the device

2.1 Description of the biofeedback device

BioPod is a biofeedback device designed for pelvic floor muscle rehabilitation.

2.2 Expected performance

The main clinical performance of the **BIOPOD** biofeedback device in combination with a perineal rehabilitation programme (PFMT*) is an increase in perineal muscle strength measured by EMG in adults with disorders related to pelvic floor dysfunction.

2.3 Intended use

The **BIOPOD** device is indicated for use in rehabilitation programmes for the management of functional pelvic floor disorders, in particular urogynaecological disorders (stress urinary incontinence, urge urinary incontinence, mixed urinary incontinence, prolapse), as well as anorectal disorders (anal incontinence, dyschezia, dyssynergy) in accordance with protocols defined by a healthcare professional trained in this technique.

2.4 Applications

The **BIOPOD** device does not come into contact with the body. However, it is used with accessories (see §Accessories) that come into contact with the body, particularly the abdominal area (electrodes), perineal area (electrodes and vaginal probes) and rectal area (electrodes and anal probes).

These are dependent devices that can be used in combination with other devices (see §Accessories).

2.5 User profile

The **BIOPOD** device must be used in hospitals, rehabilitation centres or healthcare practices by midwives and physiotherapists.

It must be used by trained medical personnel who do not have any disabilities (motor, mental, cognitive or psychological) and who are recognised as healthcare professionals (physiotherapists or midwives). The user must be informed of all safety precautions, operating procedures and maintenance instructions provided in the user manual.

2.6 Target population

The **BIOPOD** device is not suitable for home use.

The **BIOPOD** device is intended for use exclusively by adults, regardless of gender or weight. It is indicated for patients with disorders related to pelvic floor dysfunction.

2.7 contraindications

This device **must not be used** in the following cases:

- Current pregnancy
- Presence of a pacemaker
- Presence of cardiac arrhythmia
- Presence of a bladder stimulator
- Perineal hypoaesthesia
- Urinary and vaginal infection
- Recent abdominal surgery
- Intrapelvic tumours
- Do not apply to the carotid sinus

2.8 Side effects

To date, the medical literature does not mention any significant side effects associated with biofeedback.

2.9 Technical characteristics

2.9.1 General characteristics

- Operating temperature: 15°C to 35°C.
- Storage temperature: -20°C to 60°C.
- Operating relative humidity: 30% to 65%.
- Operating altitude: < 2000 metres
- Atmospheric pressure: > 80 kPa.

2.9.2 BioPod technical specifications

- Case dimensions: 120 mm x 80 mm x 25 mm
- Case weight: 110g
- Case colour: White
- Power supply: 5Vdc-500mA
- Power consumption: 1W
- Low voltage electrical appliance
- Bluetooth function: BLE 2.4GHz
- Class I medical equipment.
- Type BF applied part

Protection against electric shock is provided by a 2MOPP DC/DC converter and certified to IEC/EN 60601-1.

2.9.3 Accessories

This device comes standard with the following accessories:

USB charging cable



2 x 1-channel electrode cables



A Velcro belt



2.9.4 Accessories

Accessories not supplied with the device , charger , USB C to A adapter, probes, or electrodes. Probes and electrodes are applied parts.

List of products compatible with the device:

- Dura-Stick Plus Self-Adhesive Stimulation Electrodes (DJO Global) CE 0473
- Saint-Cloud Classic vaginal probe (DJO Global)
- Optima 3 Probe (Sugar)
- Axtim Anal Probe 201-B0-1-S

The manufacturer cannot be held liable for the use of products not recommended by them. Be sure to follow the hygiene guidelines recommended by the accessory manufacturer. The user must take particular care and adapt the size of the electrodes to the area to be treated.

2.10 Identification label

The information and specifications are listed on the back of each device on an identification label.

2.10.1 BioPod identification label



3 Warnings



CAUTION: Place the device on a flat, stable surface or on the dedicated belt, then fasten the belt around your waist.



CAUTION: No modifications to the device are permitted. It is strictly forbidden to open the device casing.



CAUTION: The device complies with applicable electromagnetic compatibility standards. In the event of malfunction caused by interference or the presence of another device, please contact Électronique du Mazet or your distributor. They will be able to advise you on how to prevent or reduce any problems.



CAUTION: Operating altitude below 2000m. The performance of the device decreases with altitude.



CAUTION: The device must be used with the accessories and associated devices supplied by the manufacturer.



CAUTION: The device is not designed for use with creams, essential oils or any other product that may cause premature wear.



CAUTION: The device must be cleaned with a soft, dry cloth.



CAUTION: The user must replace accessories as soon as they appear to be damaged.



CAUTION: The user must not place anything on top of the device.



CAUTION: The device is not waterproof.



CAUTION: The battery may only be replaced by Électronique du Mazet's technicians or their distributors.

4 Precautions

4.1 Environment

This device is intended for professional use only.

This biofeedback device is designed for indoor use only.

Do not use this appliance in damp locations or locations where there is a risk of explosion.

This device is not intended for domestic use.

4.2 Residual risks

4.2.1 Areas treated

The areas treated by the device are the pelvic floor muscles.

4.2.2 Applied parts

The use of worn or poor-quality **applied parts** may compromise proper contact with the patient and cause discomfort. It is therefore recommended that they be replaced regularly.

4.2.3 Environment of use

There is a risk of bacteria or viruses being transmitted from one patient to another via the applied parts. Ensure that you comply with the hygiene conditions recommended by the manufacturer of the applied part.

4.2.4 Water ingress

If water penetrates the device, it may malfunction. In this case, switch off the device and disconnect the cables. In all cases, avoid the presence of water in the vicinity of the device.

5 Data confidentiality patient s

The device collects data from the Biostim software to which it is connected. No data is stored in the device. It is the practitioner's responsibility to apply and comply with the European Parliament's General Data Protection Regulation 2016/679.

When returning the device to the After-Sales Service, if the software is returned with the device, the practitioner must delete patient data so that it is not disclosed. The practitioner has the option of making a backup copy of this data by saving it to an external medium before deleting it.

6 cybersecurity

As the device and its Biostim software are computerised systems that are integrated into larger information systems, certain rules and best practices must be implemented to ensure the safety of patients and users.

Électronique du Mazet does not provide and has no control over the operating environment of its products, so it is the practitioner's responsibility to ensure compliance with the following recommendations.

6.1 Minimum configuration (for Biostim software)

The software connects to a computer with at least the following specifications:

- Windows 10 or 11, or MacOS Monterey (version 12) or newer . A PC running **Windows 10 or 11** equipped with a Bluetooth card, or MacOS
- Intel i3 for Windows versions
- Intel i5 or M1 chip for MacOS versions
- 8 GB RAM
- Recommended resolution: at least 1600*900

Please note that the software **does not work** with:

- Windows 10S or 11S
- PCs with an ARM chip
- Tablets or smartphones (Android or iOS)
- Chromebooks

6.2 Best practices for IT security (relating to Biostim software)

- Keep your software up to date, including the operating system (Windows or MacOS)
- Use operating system accounts to prioritise access.
- Use strong passwords to access accounts
- Lock your computer when not in use
- Back up the Biostim database regularly
- Verify the authenticity of any third-party software you install
- Use antivirus software and a firewall
- Regularly check the Cloud menu for available updates

6.3 Network communications (relating to the Biostim software)

- The device does not require a network connection to operate. However, when connecting the BioPod device to the software for the first time, an internet connection is required
- Data may be sent regularly to Mazet Electronics servers
 - All this data is anonymised

- It is collected for statistical purposes only, or to facilitate remote assistance.
- The device can also communicate with Electronique du Mazet servers to check for available updates and, if necessary, perform the update.
- All exchanges use a secure protocol (https).

7 Installing the device

7.1 Unpacking the device

Open the packaging box and remove the **BioPod** device.

Check that the contents of the box are not damaged. If you have any doubts about the integrity of the device or its accessories and whether the device will function properly, contact Électronique du Mazet.

If the device has been stored in a cold environment and there is a risk of condensation, **leave the device to rest for at least 2 hours at room temperature** before switching it on.

Keep the original packaging to ensure the device can be transported for maintenance or after-sales service (see § After-sales service and warranty).

Before using the device for the first time, it is advisable to clean the device and its accessories (see § **Care and Maintenance**).

Install the device on a stable support at working height and away from the patient's environment .

7.2 Getting started with the device



REAR view

1- USB-C port



Front view

2- On/Off button

3 - Electrode cable connectors

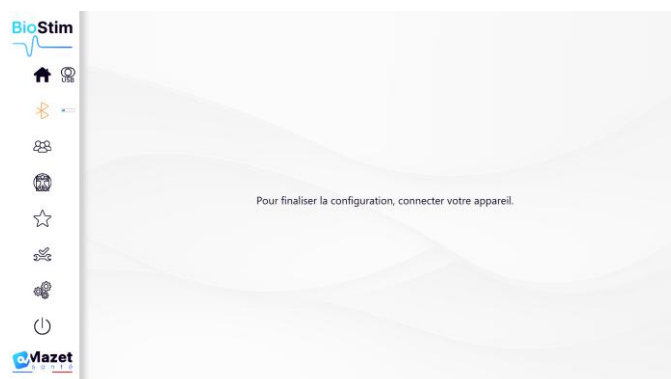
7.2.1 First use

Switch on the device by pressing the push button on the top of the device.



The button will light up blue. When the device is switched on, it will automatically connect to the Biostim software via Bluetooth. It is therefore necessary to launch the Biostim software at the same time as switching on the device.

When you launch the software for the first time, the following screen will appear:



Connect your BioPod device to access the various menus.

Note: *If the connection is not established within 2 minutes, the BioPod will automatically switch off.*

7.3 Connecting accessories

Connect one electrode cable per channel to the connectors. If only one electrode cable is required, connect only one cable.



To connect the electrode to the cable, see the photo below



To charge the **BioPod**, connect the supplied USB-C cable to the USB-C port. When the **BioPod** is charging, the indicator light will turn green.



To attach the strap to the **BioPod** case, see photos below.



Fitting the strap to the patient: the strap is secured around the abdomen



7.4 BioPod status

LED colour/status	Meaning
Solid green	Battery 100% charged and Bluetooth disconnected
Flashing green (pulsing)	Charging and Bluetooth disconnected
Flashing orange	Low battery, device will shut down in 4 seconds.
Blue flashing	Searching for pairing
Solid blue	Bluetooth Low Energy pairing established

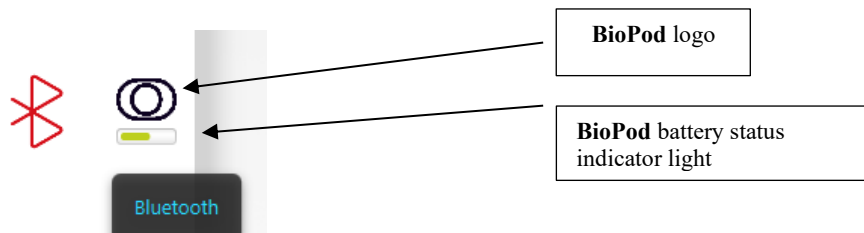
7.5 Using the device

7.5.1 Start-up

Turn on the device using the button on the top of the case. The button will flash blue to indicate that it is on and searching for a Bluetooth connection. At the same time, start the BioStim software and click on the Bluetooth logo to search for nearby devices.

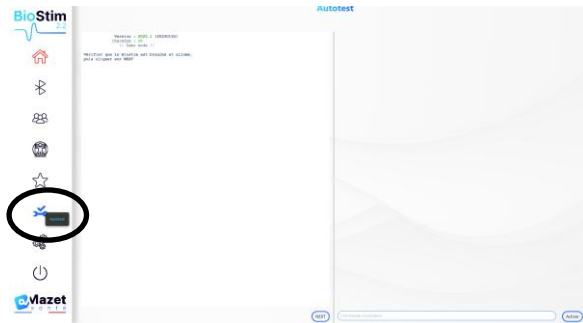
Once connected, the **BioPod** button light will turn solid blue to indicate that it is paired, and the **BioPod** logo will appear next to the Bluetooth symbol.

The gauge below the **BioPod** logo indicates the remaining battery life.



7.5.2 Update

If the computer is connected to a network, check for updates in the "Self-Test" tab of the BioStim software.



Updates are performed in two steps:

1	Download the update
2	Install the update

The download may take between 10 and 30 minutes, depending on your Internet connection speed.

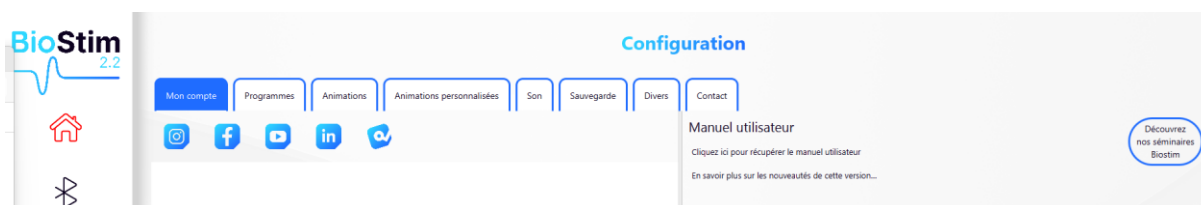
7.5.3 Configuration page

The "configuration" menu allows you to configure the Biostim software. The available options are:

- Scroll speed: allows you to speed up or slow down the biofeedback scroll (animations tab)
- Display channels on separate graphs (animations tab)
- Rest time before or after working time for biofeedback (programmes tab)
- Automatically start biofeedback after calibration: if this option is not enabled, the cursor will wait for the start button to be pressed at the beginning of biofeedback: no scrolling before this button is pressed (programmes tab)
- Force the cursor to be displayed on the curves (Animations tab)
- Animation selection: you can choose which animations you want to use. Those that are unchecked will no longer be visible on the programme overview page. Custom animations are always visible. (Animations tab)
- Option to choose the thickness of the profile (Animations tab)
- Choose the action for a right-click on the screen during biofeedback (add object/add event) (Animations tab)
- Creating, modifying and deleting a custom animation: requires a background image, an image for tracking each channel, and one or more objects to catch. (Custom animations tab)

Important: in the "Configuration" menu, under the "My Account" tab, you will need to register in order to use the software.

The "My Account" tab also allows you to download the latest version of the Biostim user manual .



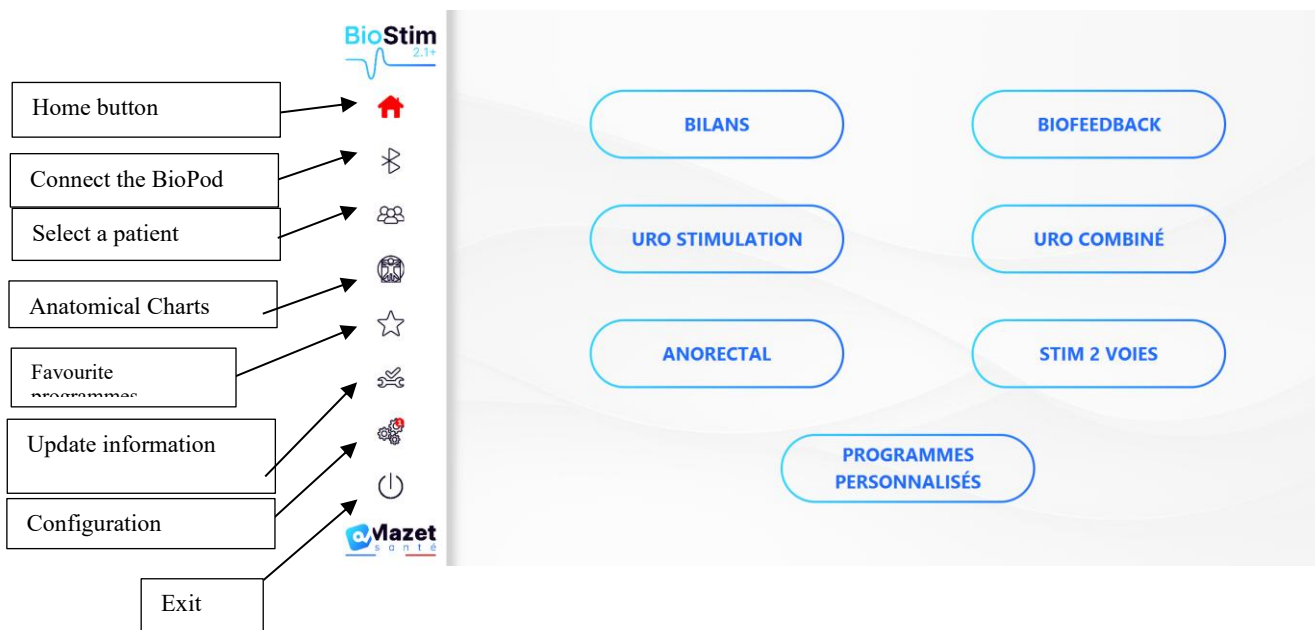
The "Miscellaneous" tab allows you to select the software language.

7.5.4 Main menu

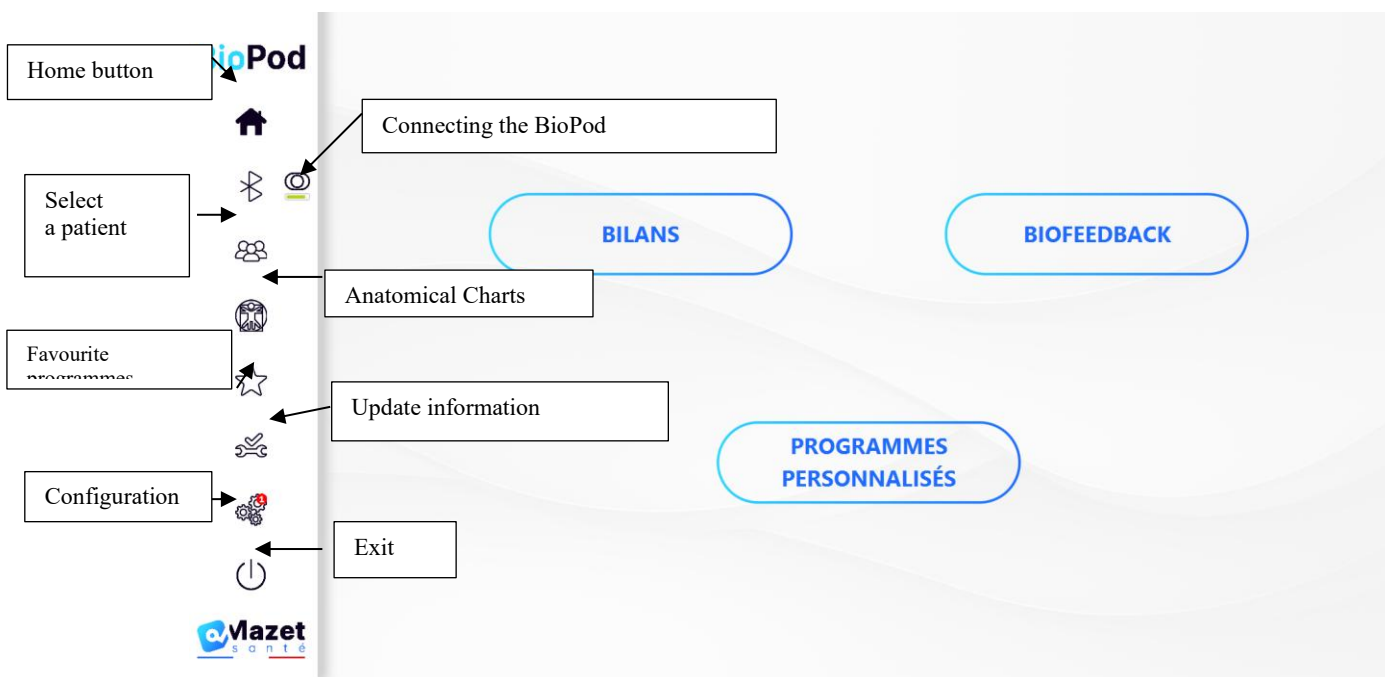
When launched, the Biostim software opens on the home page, which provides access to all the device's features.

From any page in the application, pressing the "Home" button (house icon) will return you to this page.

Home screen if you have a BioStim device in addition to a BioPod device




Home screen if you only have a BioPod device

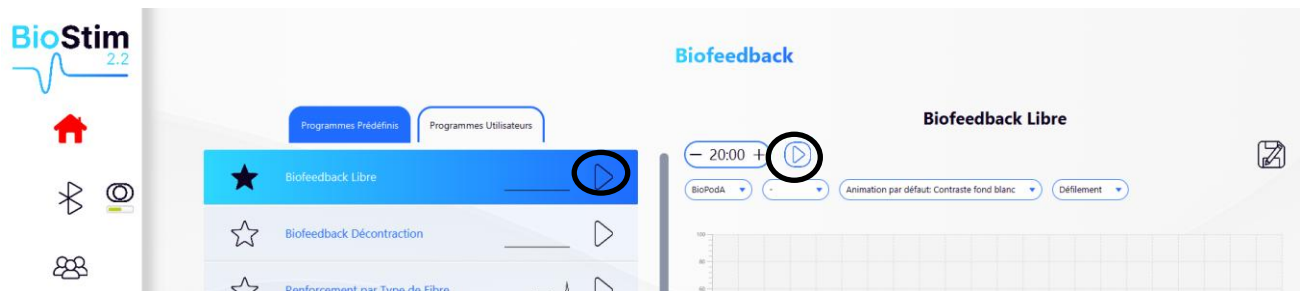


7.6 Choosing a treatment

7.6.1 From the Biofeedback menu

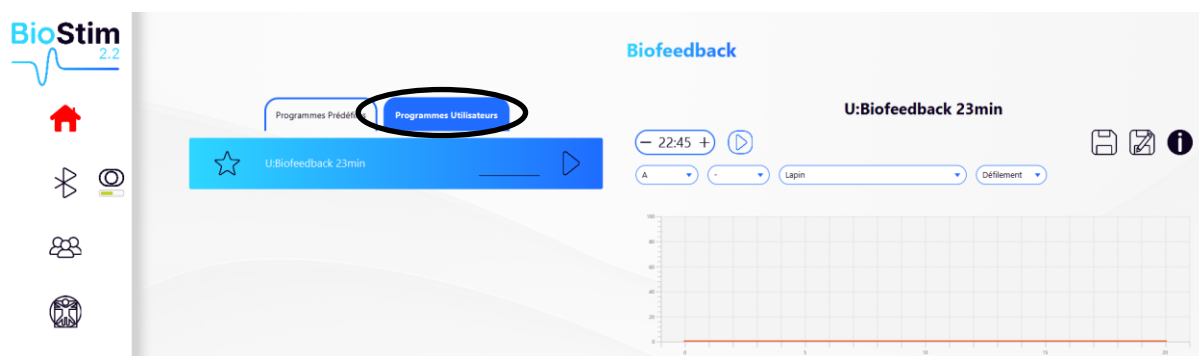
On the home screen, click on "Biofeedback" to open a selection of programmes. These are predefined programmes with pre-set parameters.

Select the desired programme from the left-hand column, then click on the arrow  to launch the programme. The programme will launch automatically using the **BioPod** device.



7.6.2 From the user programmes menu

From the biofeedback menu, the user programmes tab allows you to access programmes saved by the user

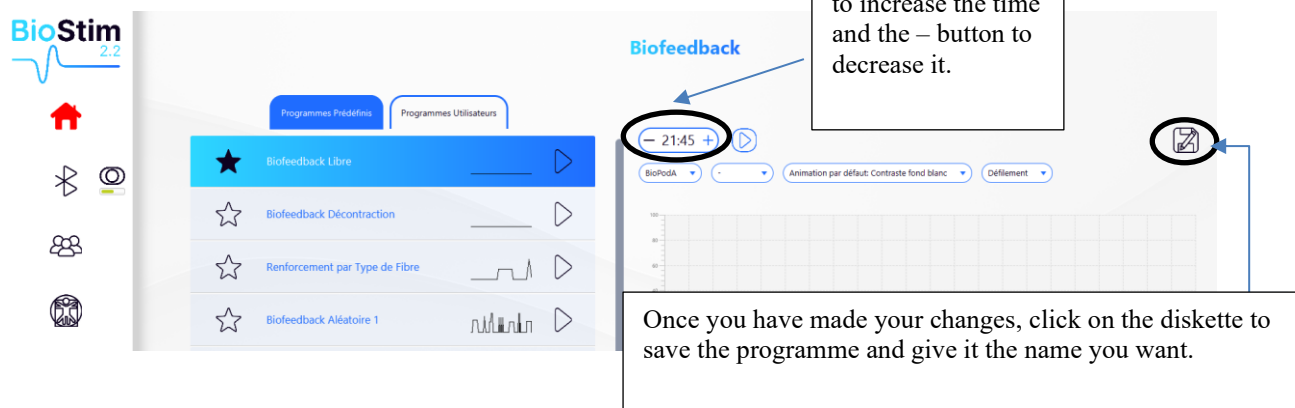


Select the desired programme from the left-hand column, then click on the '▶' arrow to launch the programme.

You can choose between "predefined programmes" and "user programmes".

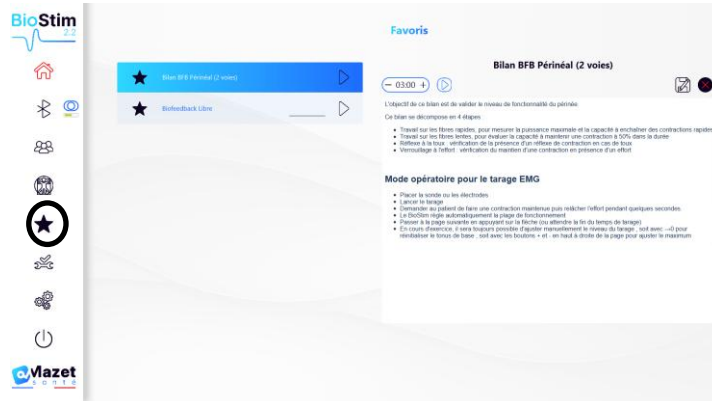
The programme will start automatically using the **BioPod** device.

User programmes are created by modifying the time or another parameter of an existing programme.

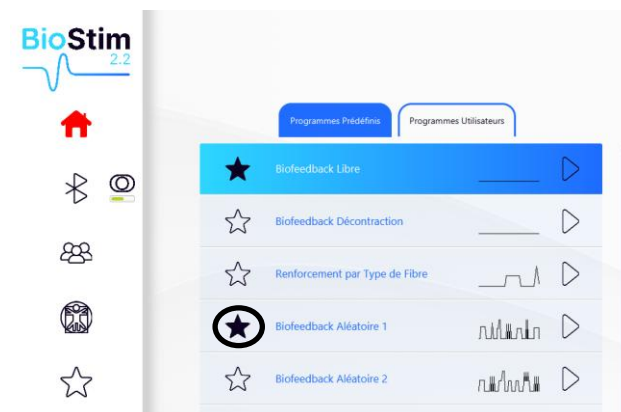


7.6.3 From the "Favourites" menu

In the left-hand menu, clicking on the star icon opens access to programmes saved as favourites

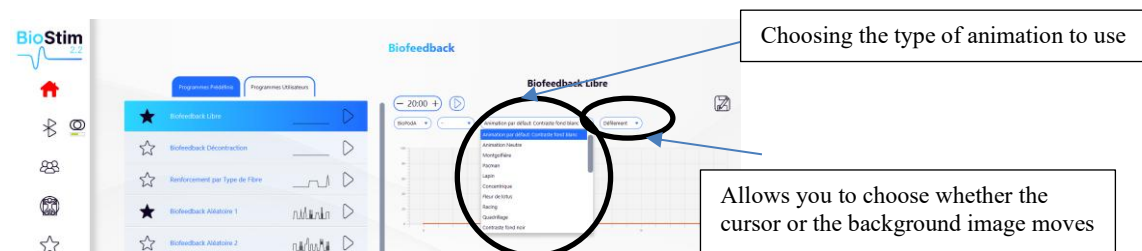


To add a programme to your favourites, click on the star when selecting the programme. The star will turn solid black to indicate that the programme has been saved to your favourites.




7.7 Performing a treatment

7.7.1 Start processing



These two scroll menus allow you to customise the programme before launching it. To

launch the programme, click on the arrow . At the start of the programme, a calibration is performed.



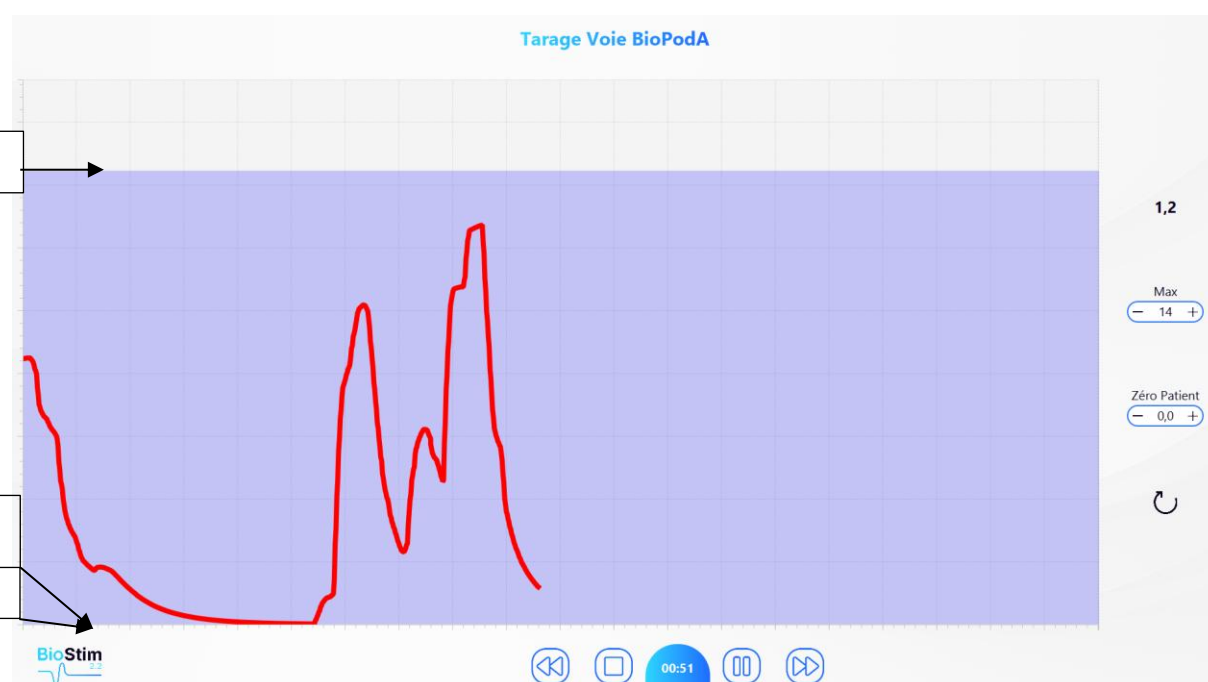
This icon allows you to save programmes.

7.7.2 Biofeedback calibration

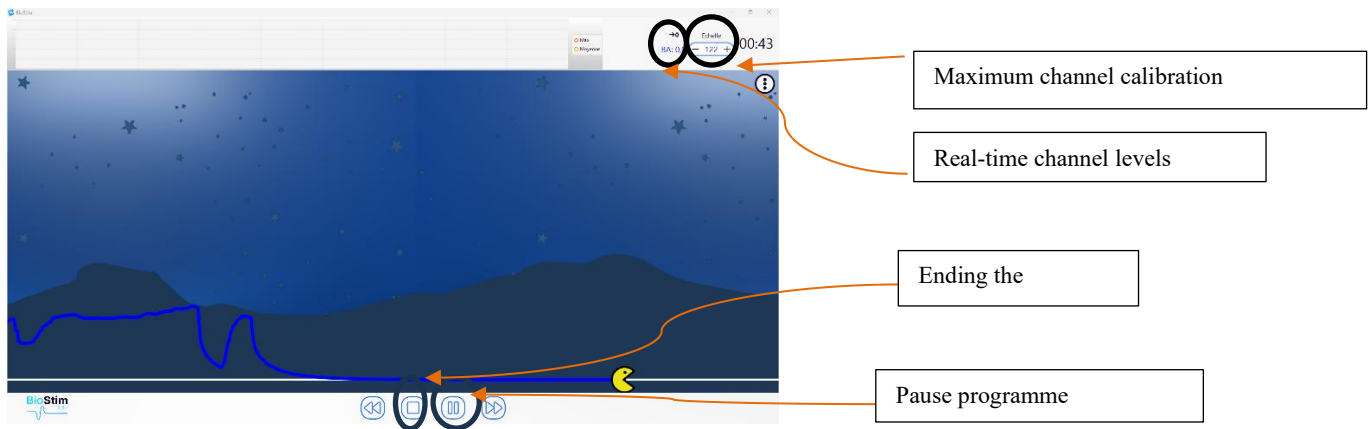
Calibration is performed automatically. However, it is possible to adjust the parameters calculated by the machine using the buttons "+" (Calibrate Biofeedback) and "-" (Calibrate Biofeedback).

Calibration procedure

- Place the probe or electrodes
- Start calibration
- Ask the patient to maintain a contraction (the and values will change automatically), then to relax for a few seconds.
- The BioStim automatically adjusts the operating range
- Proceed to the next page by pressing the arrow (or wait for the calibration time to end)
- During the exercise, it will always be possible to manually adjust the calibration level using the + and - buttons at the top right of the page

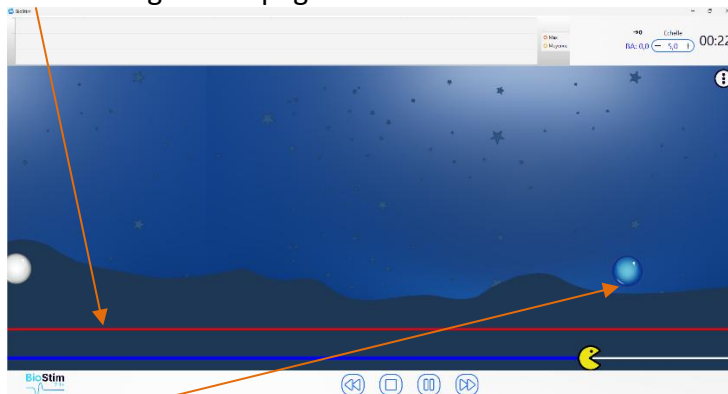


7.7.3 During treatment



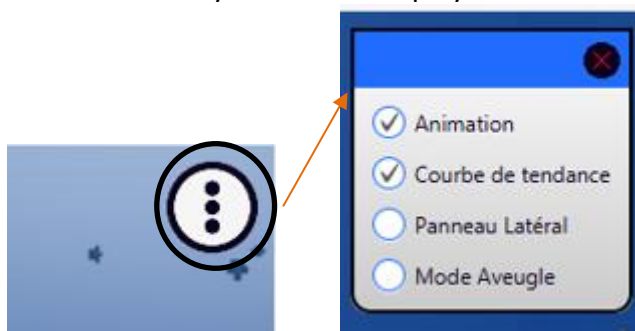
During processing, the programme can be stopped or restarted.

Left-clicking on the page adds a reference line at the desired position:

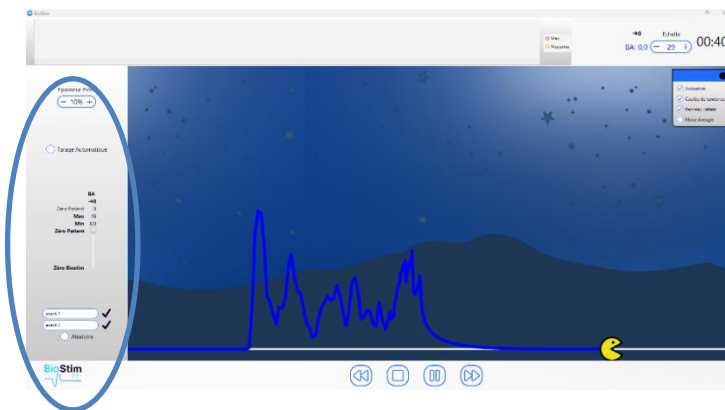


Right-clicking on the screen allows you to add a time marker or an object to the screen (selection to be made in the configuration menu).

Pressing the button at the top right of the biofeedback pages opens a menu that allows you to choose the areas you want to display on the screen.



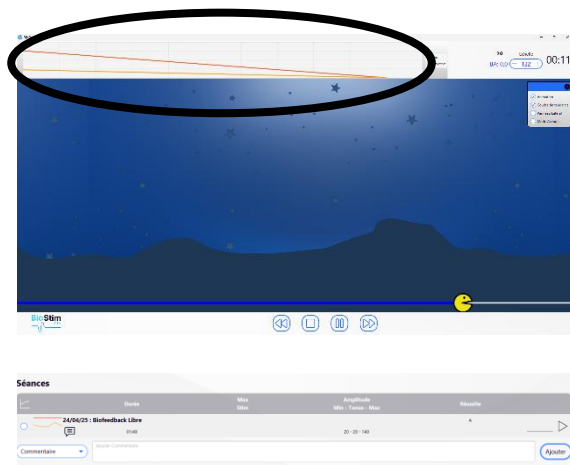
7.7.4 Side panel



This panel allows you to adjust:

- The thickness of the profile
- Automatic calibration: adjusts the base level and maximum to the amplitude reached by the patient (allows calibration to be adjusted during exercise)
- The "Patient Zero" setting for each channel (→ 0)
- The negative BFB level, using the channel sliders
- Events can be added to the curve (which can also be found in the history). The titles are freely definable. It is also possible to add events by right-clicking on the screen.

7.7.5 Trend curve

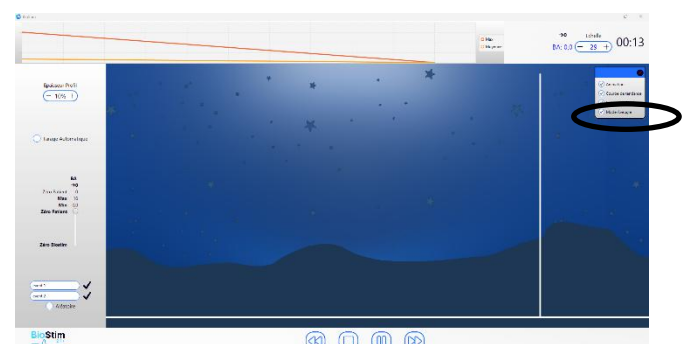


This curve

A trend curve can be displayed via the zone selection menu. This curve allows you to see at a glance the evolution of the maximum and average contraction for each profile during the session

can then be found in the session summary table in the patient file.

7.7.6 Blind mode

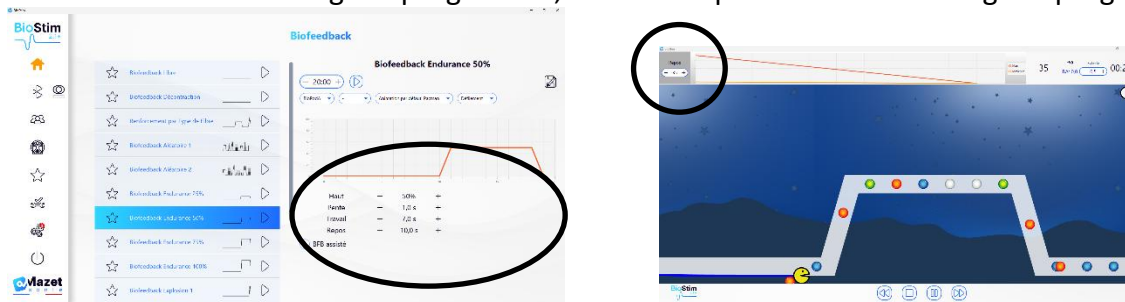


A "blind mode" is available for working without the contractions being displayed on the screen. This mode is activated during the session in the zone selection menu.

The curves are recorded and can be analysed at the end of the session.

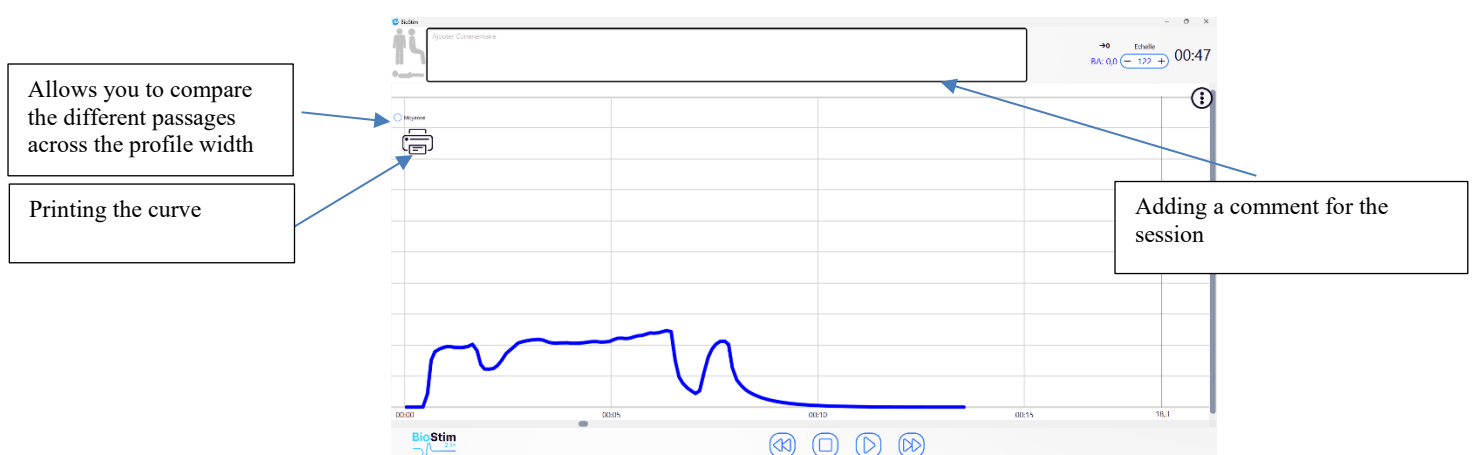
7.7.7 Endurance mode

In endurance mode, you can modify the shape of the curve using the buttons on the right of the screen when selecting the programme, or at the top of the screen during the programme.



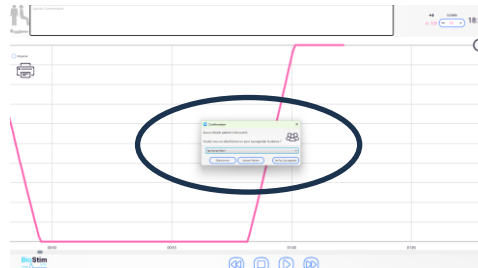
7.7.8 End of treatment

At the end of the programme (or when the pause button is pressed), the device switches to review mode. In this mode, you can print the curve by clicking on the printer icon at the top left.



7.8 Saving a session


At the end of a programme, if no patient has been selected, the software allows you to select an existing patient, create a new one, or not save the session.



7.9 Patient file management



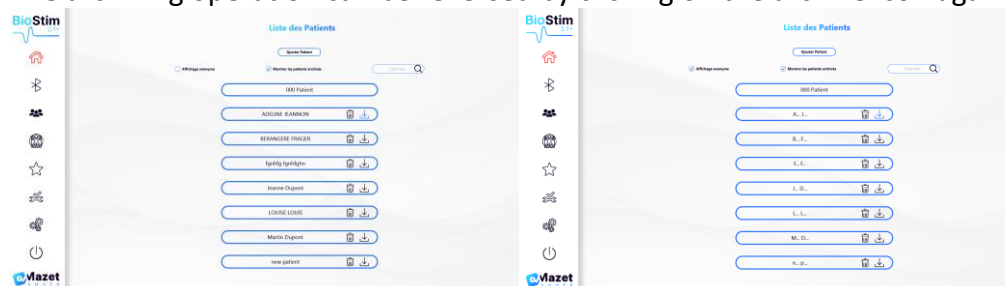
Clicking on the patient button takes you to the patient selection page. This page displays the list of patients.

To limit the length of the list, you can archive patients by clicking on the archive icon  to the right of the patient's name.


You can display all patients (including archived patients) by selecting the "Show archived patients" checkbox.

Archived patients are marked with a blue archive icon, while other patients have a black icon.

The archiving operation can be reversed by clicking on the archive icon again.



Anonymous display allows you to hide the patient's full name and surname; only the initials will be visible.

Select a patient by clicking on their name. Once a patient has been selected, their name appears in the menu on the left-hand side of the page. To disconnect them, simply click on the deselection button to the right of the name .

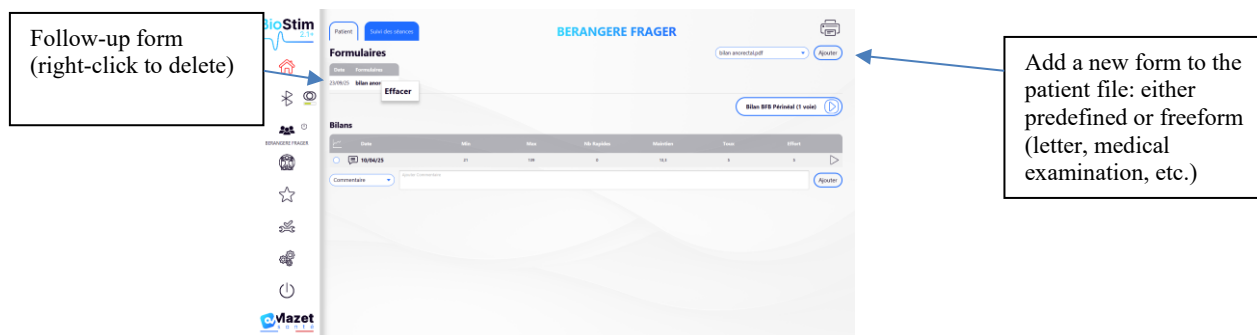


When a patient is selected, you can access their file by clicking on their name in the left-hand menu.

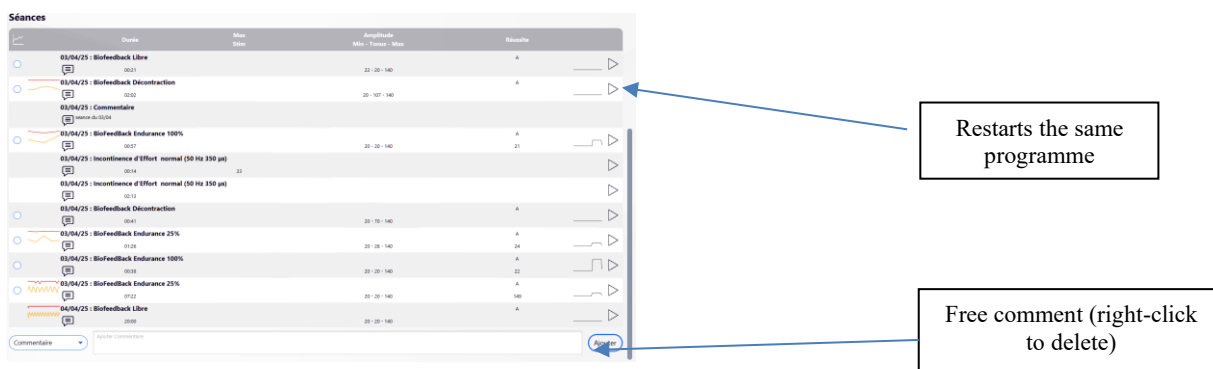
This file contains the patient's details (surname, first name, etc.), as well as a record of all the patient's sessions (graph and table).

It is also possible to add:

- Text comments
- Assessment forms, which will enable you to review the patient's situation.

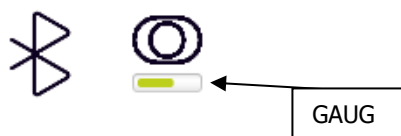


All sessions are recorded.



7.10 BioPod charge

The BioStim software displays the **BioPod** battery status via a gauge



The **BioPod** button flashes ORANGE to indicate that the battery is low. Charge the device using the USB charging cable provided.

Connect the cable to **the BioPod**, then to a computer or a charger compatible with a maximum mains voltage of 250 V, and finally to a mains socket.

During charging, the **BioPod** indicator light will flash GREEN.

Once fully charged, the indicator light will be SOLID GREEN. You can then disconnect the USB cable.

8 Maintenance and servicing

The **BioPod** device is designed for a service life of 5 years.

To ensure that the device continues to perform well throughout its lifetime, it must be checked by Électronique du Mazet technicians every 2 years.

8.1 Cleaning the case

The case requires periodic cleaning with a dry cloth to remove any dirt from its external surface.

Be sure to disconnect the USB cable and electrode cables before cleaning.

8.2 Sterilisation

This device is not sterile.

The accessories are not sterile and are not intended to be sterilised.

9 Malfunction

If you notice a malfunction that is not mentioned in the device's accompanying documents (see below), please inform your distributor or the manufacturer.

If you need to ship the device, please follow these instructions:

- Decontaminate and clean the device and its accessories following the recommendations in §Cleaning the case
- Use the original packaging, with the retaining flanges if possible.
- Include all device accessories.
- Secure the various components.
- Ensure that the packaging is securely closed.

Shipping address:

**Électronique du Mazet
3 Allée des Morilles
43520 Le Mazet St Voy**

Tel: (33) 4 71 65 02 16

Fax: (33) 4 71 65 06 55

Email: sav@electroniquedumazet.com

Possible malfunctions:

Description of the fault	Possible causes	Actions
The button does not light up	Battery dead	Check that the button is pressed, then connect via USB. If there is no light, contact customer service
	Components out of order	Contact customer service
	Update not complete	Contact customer service
Bluetooth connection not working	Temporary connection failure	Close the Biostim software and reopen it, then switch the BioPod off and on again
	Biostim software version without Bluetooth	Check your version of the Biostim software
	Unknown	Contact customer service
Abnormal LED colour	Unknown	Contact customer service
Other anomaly	Unknown	Contact customer service

If the device is dropped or water gets inside it, it must be checked by Électronique du Mazet to rule out any risk (patient , and user) associated with its use.

10 After-sales service and warranty

This device is guaranteed by your supplier under the conditions specified in this document, provided that:

- Only accessories supplied by Électronique du Mazet or its distributors are used.
- Any modification, repair, extension, adaptation and adjustment of the device is carried out by Électronique du Mazet or its authorised distributors for these operations.
- The working environment complies with all regulatory and legal requirements.
- The device is used only by competent and qualified personnel. Use must comply with the instructions in this user manual.
- The devices are used only for the applications for which they are intended and which are described in this manual.
- The device is regularly maintained in accordance with the manufacturer's instructions.
- All legal requirements concerning the use of this device are complied with.
- The device uses only consumables or semi-consumables supplied or specified by the manufacturer.
- Machine parts and spare parts must not be replaced by the user.

Inappropriate use of this device or negligence in maintenance releases Électronique du Mazet and its authorised distributors from any liability in the event of defects, breakdowns, malfunctions, damage, injury, and other issues.

The warranty is void if the instructions for use contained in this manual are not strictly followed.

The warranty is valid for 24 months from the date of delivery of the device.

Accessories are guaranteed for 6 months from the date of delivery of the device.

Consumables and semi-consumables are not covered by the warranty.

Transport and packaging costs are not included in the warranty.

Électronique du Mazet, or its distributor, undertakes to provide the plans, list of spare parts, instructions and tools necessary to repair the device on the sole condition that qualified technical personnel have been trained on this specific product.

11 Disposal

As soon as any damage to an accessory is noticed, the product must be cleaned with a broad-spectrum disinfectant and then returned to the manufacturer.

If the device stops working or proves to be unusable, it must be returned to the manufacturer or taken to a collection point.

As part of its commitment to the environment, Électronique du Mazet finances the ecosystem recycling scheme dedicated to WEEE Pro, which collects electrical lighting equipment, control and monitoring equipment, and used medical devices free of charge (more information at www.ecosystem.eco).



12 Transport and storage

The device must be transported and stored in its original packaging or in packaging that protects it from external damage.

Store the device in a clean, dry place at room temperature.

13 CE declaration

The CE declaration for the device is available on request from **Électronique du Mazet**.

14 Manufacturer

Based in the heart of the Massif Central, **Électronique du Mazet** started out as a manufacturer of electronic cards. Over the years, the company has expanded its expertise and now designs its own devices, which are marketed under various brands.



Devices for physiotherapists and midwives

mazetsante.fr



Otological diagnostic devices

echodia.com



Devices for the aesthetic field

<https://mazetbeaute.fr/>



Electronique du Mazet
3 Allée des Morilles
43520 Le Mazet Saint Voy
Tel: +33 (0)4 71 65 02 16

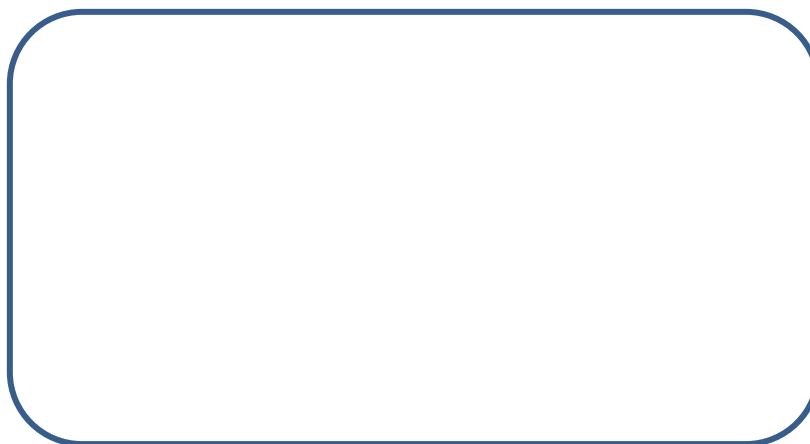


ELECTRONIQUE DU MAZET

3 Allée des Morilles
43520 LE MAZET SAINT VOY

Tel: +33 4 71 65 02 16
Email: sav@electroniquedumazet.com

Your retailer/distributor:



15 Warranty certificate

Warranty Certificate

This form must be returned to Electronique du Mazet within 15 days of installation or receipt of the equipment.

I, the undersigned,

Organisation:

Address:

.....

.....

I hereby declare that I have received the **BioPod** device No. in working order.

I have received all the necessary instructions for its use, maintenance, servicing, etc.

I have read the user manual and have taken note of the warranty and after-sales service conditions.

If Electronique du Mazet or its distributors do not receive this form, duly completed and signed, within one month of delivery, Electronique du Mazet shall be released from all liability with regard to the warranty and after-sales service, or any other consequences resulting from misuse of the device.

Done at on

Signature

User:

Your distributor:

To be returned to:

Electronique du Mazet

3 Allée des Morilles

43520 Le Mazet Saint Voy

