

User Manual
BioStim 2.2
BioStim 2.1
BioStim 2.0
BioStim 1.0



Electrotherapy 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.**

**This equipment has been designed and manufactured for
therapeutic use.
It is intended for use by professionals who have undergone
appropriate training. .**

**In the event of a malfunction 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

**Please return the warranty certificate within 15 days of installation or
receipt.**



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1 Introduction

This user and maintenance manual has been published to help you get started with your **BioStim device**, from the initial delivery and commissioning stages through to the subsequent stages of use and maintenance.

If you have any difficulty understanding this manual, please contact the manufacturer, Électronique du Mazet, your retailer or distributor.






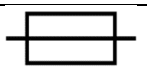

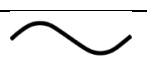







This document must be kept in a safe place, protected from atmospheric agents, where it cannot be damaged.

This document guarantees that the devices and their documentation are technically up to date at the time of sale. However, we reserve the right to make changes to the device and its documentation without any obligation to update these documents.

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

Only personnel who are familiar with the contents of this document may be authorised to use the device . Failure to comply with any of the instructions contained in this document releases Électronique du Mazet and its authorised distributors from liability for accidents or damage to personnel or third parties (including patients).

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.
	<u>Protective earth</u>
	<u>Fuse</u>
	<u>Caution:</u> Switching the device off/on
	Alternating current
	Serial number
	Manufacturer
	Date of manufacture
	Product reference
	CE marking
	UDI (Unique Device Identifier)
	Medical device

2 Device overview

2.1 Description of the device

The BioStim device is an electrotherapy device that assists physiotherapists and midwives in perineal rehabilitation.

The computerised technology used in the BioStim device makes it very easy to use and navigate through the menus.

The programmes, which are predefined in the device, can be used to perform most perineal rehabilitation treatments in the urogynaecological and anorectal fields.

The main programmes available are:

- Urogynaecological biofeedback, EMG or Pressure
- Urogynaecological stimulation
- Combined uro-gynaecological programmes, which combine biofeedback and stimulation
- Pain relief for uro-gynaecology
- Anorectal stimulation and biofeedback programmes

The device also allows individual monitoring of each patient, storing the sessions performed and their results, as well as adding any comments or links to follow-up forms.

2.2 Medical use

2.2.1 Expected performance

Through the use of different electrical currents and a biofeedback function, the device is intended for use in the following applications:

- Prevention and treatment of urinary incontinence (stress, urge or mixed incontinence; detrusor inhibition)
- Treatment of anal incontinence disorders
- Treatment of pelvic floor disorders Muscle relaxation and strengthening
- Pain relief treatment
- Treatment of genitosexual disorders (including erectile dysfunction)
-

Expected benefits:

Based on European and French recommendations and the results of studies conducted by health specialists, the device now offers pre-established, specific programmes for conditions requiring physiotherapy or midwifery care. The expected benefits are a significant reduction in urinary or anal leakage with contraction or relaxation of the pelvic floor muscles, improved muscle endurance with increased perineal contraction strength, pain reduction with an analgesic effect, and improved quality of life.

2.2.2 Intended use

The devices are intended for:

- 1- Management of urinary incontinence: stress, urge or mixed incontinence, and bladder inhibition.
- 2- Management of anal incontinence.
- 3- Management of contractures and prolapse: muscle strengthening and relaxation treatments.
- 4- Management of pain: analgesic treatments.
- 5- Treatment of genitosexual disorders: erectile dysfunction.

Electrical currents are applied locally to the treated area of the body to stimulate or relax the muscles, or to reduce pain.

2.2.3 Application

The device does not come into contact with the body. However, it is used with accessories (see §applied parts) that come into contact with the body, particularly the abdominal, perineal and rectal areas.

2.2.4 User profile

The user must be a recognised healthcare professional. These devices are intended for use by physiotherapists or midwives.

This device must be used by trained medical personnel who do not have any disabilities (motor, mental, cognitive or psychological). The user must be informed of all safety precautions, operating procedures and maintenance instructions provided in this user manual.

2.2.5 Target population

The device is intended for use by individuals over the age of 5, both male and female. It should be noted that pelvic floor rehabilitation is particularly recommended for women after childbirth.

2.2.6 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

The contraindications are not exhaustive and we advise users to seek further information if in doubt.

2.2.7 Side effects

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

3 Technical characteristics

3.1.1 General characteristics

- Operating temperature: 15°C to 35°C.
- Storage temperature: -20°C to 70°C.
- Relative operating humidity: 30% to 65%.
- Operating altitude: < 2000 metres

3.1.2 Technical specifications of the BioStim

- Case dimensions: **33.7 x 28 x 6.7 cm**
- Case weight: **3.1 kg**
- Case colour: **white**
- Power supply: **110-230VAC – 50-60Hz**
- Power consumption: **55VA max**
- Fuses: 2x size 5x20mm – **T1.25AH-250V**
- **Class I** electrical appliance
- **Class IIa** medical equipment.
- **Type BF** applied part
- Liquid protection type **IPX0**.
- Communication with PC: optically isolated **USB**.
- Power-on indication by a green LED on the front panel.
- Stimulation can be stopped using an emergency stop button.
- 1 or 2 Electro channels. Each channel has the following features:
 - Current generator:
 - Output currents for each generator adjustable from **0 to 100mA** (+/-10%).
 - Under a load impedance of 1kΩ (or more), at maximum current, the voltage is **limited to 100V** -20%/+10% (peak value).
 - Under a load impedance of less than 1kΩ, the voltage level is limited according to the impedance (10 volts for 100Ω, 50 volts for 500Ω)
 - In the event of excessive impedance (above 10 kΩ), the current may be cut off: **electrode lift-off** function.
 - ⇒ The rectangular signals are biphasic (symmetrical pulses with zero average), the pulse width is adjustable from **100μs to 10ms**, and the frequency is adjustable from **1Hz to 5kHz**.
 - ⇒ The generators are electrically independent (no current flows between the two electrodes of the two generators).
 - ⇒ Yellow LED indicates output activation status.
 - Biofeedback activity measurement: Full-scale sensitivity: 2mV (peak-to-peak)
- 0, 1 or 2 pressure biofeedback channels
 - ⇒ Sensitivity range: **400 mBar**

If no current is detected at 10 or 15mA, stop treatment and check that the probe or electrode is correctly positioned and that there is sufficient lubricant.

3.1.3 Different versions of the device

The features of the different versions of the device are as follows:

	Number of Electro channels	Number of pressure channels
Biostim 1.0	1	0
Biostim 2.0	2	0
Biostim 2.1	2	1
Biostim 2.2	2	2

Each version (except version 1.0) has additional software functions (version +). These functions are described in section 9.3.

3.1.4 Accessories

This device comes with the following accessories as standard:

- MEG010EN601 Biostim electrode cable
- MEG010EN603 Biostim emergency stop bulb
- MEG010EN605 Biostim Blue pressure kit (optional)
- MEG010EN606 Biostim red pressure kit (optional)
- EM6055KP504 Infrared remote control (optional)
- 2m USB cable
- USB key (PC software/USB drivers)
- Mains cable

3.1.5 Applied parts

Applied parts, type BF, are vaginal probes, rectal probes or electrodes. They are not supplied with the device.

List of products compatible with the device:

- Dura-Stick Plus adhesive electrodes for stimulation (DJO Global) CE 0473
- Vaginal probe with banana plugs or DIN plugs (with adapter) (Saint Cloud, Optima, etc.)
- Perifit or Fizimed Bluetooth connection probe CE
- RectoMax rectal pressure probe or Aerolys vaginal pressure probe
- Axtim anal probe 201-B0-1-S
- Blueback Physio (Blueback SAS)
- BioMoov (Electronique du Mazet)
- BioPod (Electronique du Mazet)

The manufacturer cannot be held liable for the use of products not recommended by them.

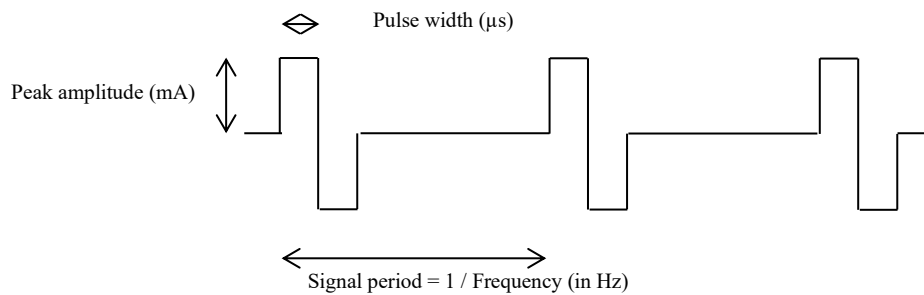
Ensure that you comply with the hygiene conditions recommended by the manufacturer of the applied part.

The user must take particular care and adapt the size of the electrodes to the area to be treated.

3.1.6 Current shape

Biphasic rectangular pulses

The current is symmetrical biphasic with a zero average: the positive and negative pulses are of the same amplitude and duration.



The waveform is constant current and does not depend on the load value.

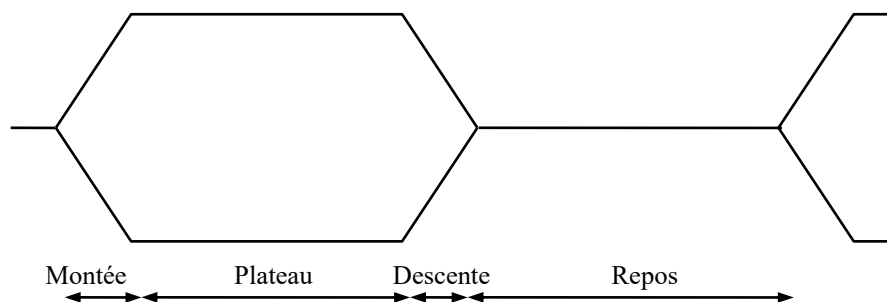
The pulse width is adjustable from **100µs to 10ms**, the frequency is adjustable from **1Hz to 5kHz**.

AF modulation (1Hz to 500 Hz) of the signal is possible.

The device complies with standard 60601-2-10: Medical electrical equipment: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators. This standard limits in particular the intensities delivered and the power per pulse.

Envelope generation:

The pulse signal is enclosed in an envelope allowing for gradual application and cut-off of the current.

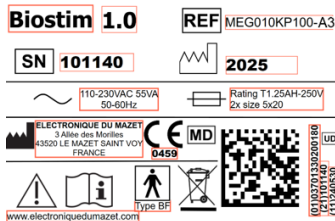


3.2 Identification label

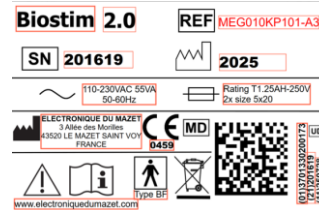
The information and specifications are listed on a label on the back of each device.

3.2.1 BioStim device identification label

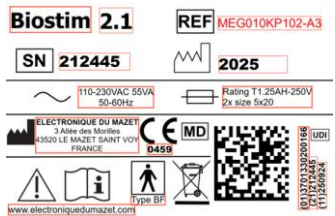
Biostim 1.0



Biostim 2.0



Biostim 2.1



Biostim 2.2



4 Warnings



CAUTION: Install the device on a flat, stable surface. Do not obstruct the ventilation openings (no objects within 4 cm).



CAUTION: Multi-socket power strips must not be placed on the floor. No other electrical device or power strip may be connected to the device's power strip.



CAUTION: The device must be plugged into a socket with an earth terminal (Class I electrical device).



CAUTION: The appliance must be positioned so that the mains cable is accessible in case of emergency.



CAUTION: In an emergency, unplug the power cord directly from the appliance.



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



CAUTION: The device complies with applicable electromagnetic compatibility standards. If you notice a malfunction due to interference or other issues in the presence of another device, contact Électronique du Mazet or your distributor for advice on how to avoid or minimise potential problems.



CAUTION: Operating in close proximity (e.g., 1 m) to a shortwave or microwave therapy device may cause instability in the output power of the STIMULATOR.



CAUTION: Patients connected to the device must not be connected to other devices (monitoring or diagnostic equipment) during treatment. These ancillary devices may be disrupted.

Simultaneous connection of a PATIENT to a high-frequency surgical EM DEVICE may cause burns at the contact points of the STIMULATOR electrodes, and the STIMULATOR may be damaged.



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



CAUTION: If the PATIENT has an implanted electronic device (e.g., a pacemaker), use of the device in stimulation mode is subject to prior medical AUTHORISATION.



CAUTION: Applying electrodes between the chest and upper back (heart pathway), on either side of the head, directly on the eyes, mouth, or front of the neck (especially the carotid sinus) may increase the risk of cardiac fibrillation.



CAUTION: Under certain conditions, the effective value of the stimulation pulses may exceed 10 mA and 10 V. Please follow the information in this manual carefully.



CAUTION: The user must pay particular attention and adapt the size of the electrodes to the area to be treated.



CAUTION: It is important to check the size of the electrodes used. The current density must be less than 2mA rms/cm².



CAUTION: The device's output signals are symmetrical biphasic with zero mean and do not contain any continuous component. Any unpleasant sensation (irritation, heating) at low intensities could indicate a fault in the equipment. Do not use the device without consulting the MANUFACTURER.



CAUTION: The device must not be accessible to the patient.
It must not come into contact with the patient.



CAUTION: If the computer used is not approved as a medical device, it must not be located in an area accessible to the patient under any circumstances.

5 Precautions

5.1 ***Environment***

This device is intended for professional use only.

This device is designed for indoor use only; do not use it in a damp location or in an area where there is a risk of explosion.

This device is not intended for domestic use.

5.2 ***Residual electrical hazards***

5.2.1 Power cut

To avoid the risk of burns or paralysis, be sure to disconnect the cables in the event of a power failure or malfunction of the control PC.

5.2.2 Applied parts

Auxiliary parts that are too old or of poor quality may impair the quality of contact with the patient and cause discomfort. Be sure to replace them regularly.

5.2.3 Operating environment

There is a risk of bacteria or viruses being transmitted from one patient to another the applied parts. Be sure to follow the hygiene conditions recommended by the manufacturer of the applied part.

5.2.4 Water ingress

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

6 Patient data confidentiality

The device collects data on the computer 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 computer 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.

7 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.

7.1 Best practices for IT security

- 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

7.2 Technical information

- The Biostim software is a Java programme
- The software configurations and database are stored in the biostimdata folder in the user folder (e.g. C:\Users\romain\biostimdata).
- The software uses port 61976 of the local loop (localhost / 127.0.0.1) to check that there are not several instances of the software running at the same time.
- The software uses a proprietary USB driver to communicate with the device

7.3 Network communications

- The device does not require a network connection to operate.
- Data can 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)

8 Installing the device

8.1 Unpacking the device

Open the packaging box and remove the accessories and the device.

Check the contents of the box against the packing list included with the documentation.

If the device has been stored in cold conditions and there is a risk of condensation, leave the device to rest for at least 4 hours at room temperature, approximately 20°C.

Place the device on a stable surface at working height and away from the patient.

8.2 Getting started with the device

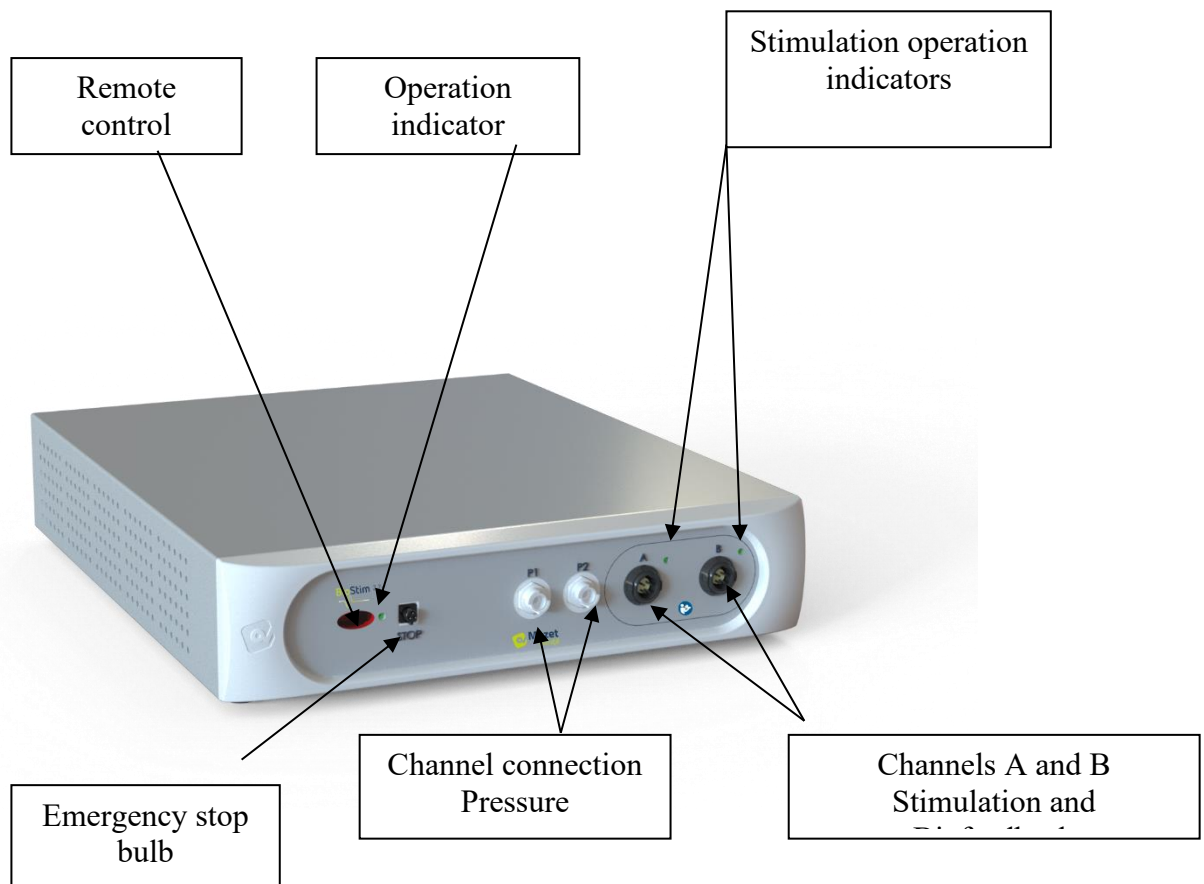
Place the Biostim on a table outside the patient's environment.

Place the PC on the same table and connect them using the USB cable. Plug one end of the USB cable into the computer and the other end into the back of the device.

Plug the power cord into the back of the device.

The practitioner positions themselves between the patient and the device.

The patient lies down on a massage table or sits on a chair next to the practitioner.



8.2.1 Powering up

Connect the power cord as follows:

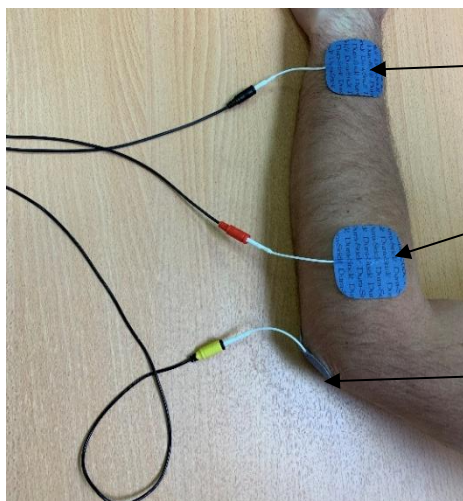
- Connect the mains cable to the mains socket on the device.
- Plug the mains lead into the mains socket.

8.3 Connecting accessories

Connect the emergency stop button to the front panel.

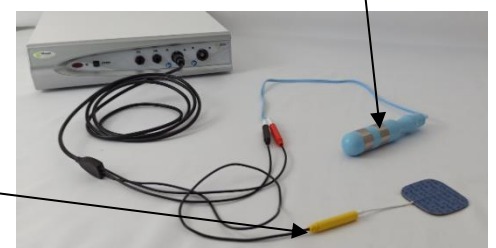


Connect the stimulation cord(s) to channel(s) A (and B) depending on your application.



Place the electrodes or probe on the muscle you wish to work on, using the red and black connectors.

To perform BFB, place the 3rd electrode (yellow tip) on a bony part of the body (not needed for stimulation).



To use the pressure channels, connect the pressure kit to the pressure channels.

A single balloon probe (vaginal or anal) is then connected directly behind the valve, on channel P1.



For a double balloon anal probe, such as a rectoMax, connect the large balloon to channel P2 (blue kit) and the small balloon to channel P1 (red kit)

On a Biostim 2.1 (or 2.1+), which only has one pressure channel, connect only the small balloon to channel P1 on the device.

8.4 Software commissioning

8.4.1 Configuration

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

- Windows 10 or 11, or MacOS Monterey (version 12) or newer
- Intel i3 for Windows versions
- Intel i5 or M1 chip for MacOS versions
- 8 GB RAM
- Recommended resolution: at least 1600*900
- To use a Bluetooth accessory (BioMoov, BioPod, BlueBack, Emy or Perifit), you must have a PC running **Windows 10 or 11** equipped with a Bluetooth card, or MacOS

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

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

8.4.2 Required software

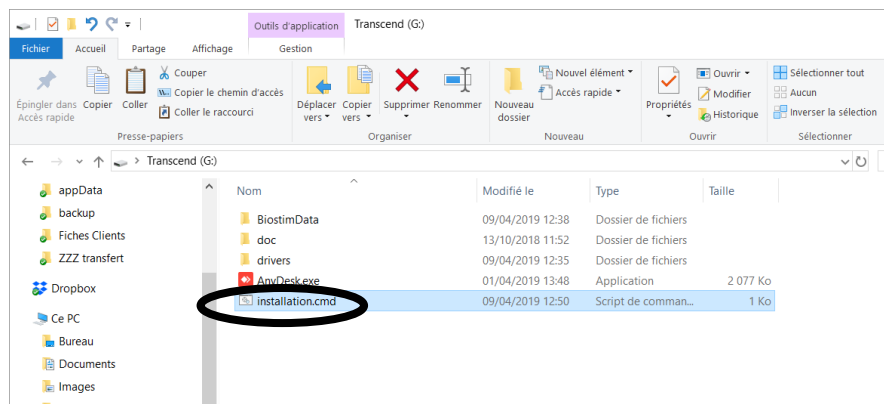
The following software must be installed on the computer:

- FTDI Driver (installation via CDM212xxx_Setup.exe supplied with the software)
- Foxit PDF Reader

If they are not already present on the computer, the installation files are available on the USB stick in the "drivers" directory.

8.4.3 Installation

Install the programme on the desktop by double-clicking on the **installation** utility (or **installation.cmd**) at the root of the USB key.



This operation creates a BiostimData folder in the user folder (which will contain all patient data), as well as a shortcut on the desktop.

8.4.4 Mac OS

Launch the Biostim_Installer.pkg programme.

This operation creates a BiostimData directory in the user directory (which will contain all patient data), as well as a shortcut on the desktop.

8.4.5 Start

Set the on/off switch located on the back of the device to ON "1".

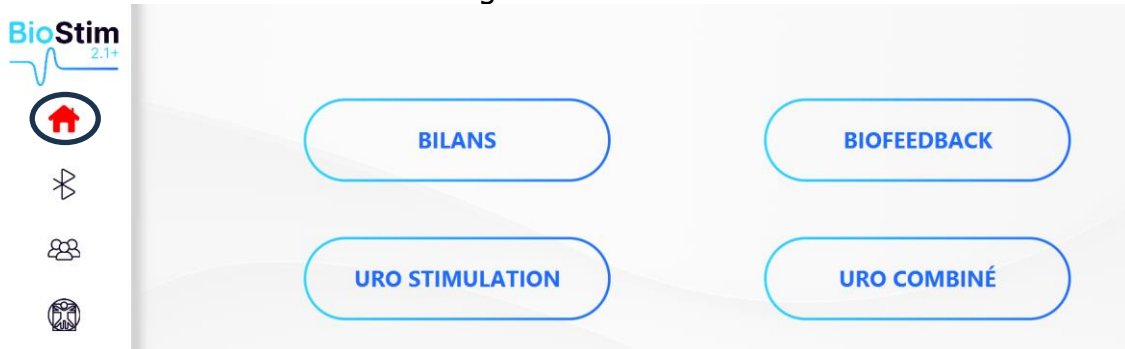
Check that the green power indicator light on the front of the device comes on.

Launch the Biostim programme on the computer.



8.4.6 Checking the connection

Check that the connection is established: green home button.



A **red** Home button indicates a communication problem between the computer and the device.

In this case, check the following points:

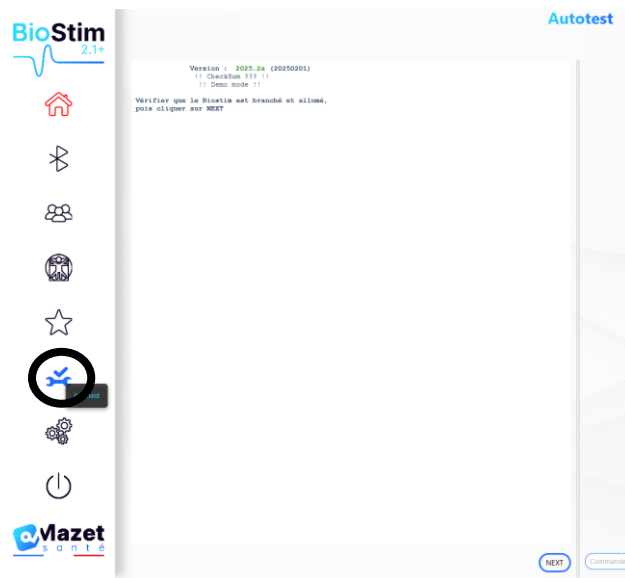
- The module is powered on, the green light on the front panel is lit.
- The USB cable is properly connected to the device and the computer.
- The FTDI driver is correctly installed (CDM212xxx_Setup.exe).

The **orange** home button indicates a problem with the emergency stop button:

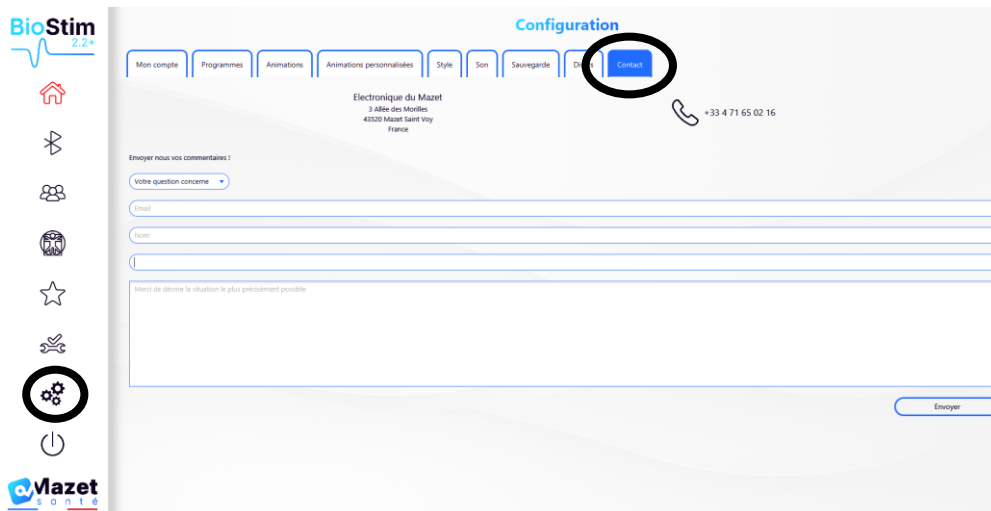
- Check that the emergency stop button is connected.
- If the emergency stop has been activated, restart the BioStim (on/off switch on the back of the device).

8.5 In case of a problem

Go to the Self-test tab. If a problem is detected, it will be indicated in red. Follow the advice provided. If there is no internet connection, the self-test logo will be red.



If this is not sufficient, go to the Contact tab on the configuration page, which allows you to report problems or make suggestions by email.



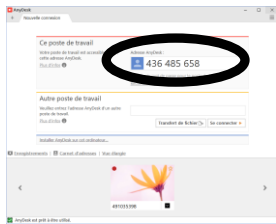
8.6 Remote control

During installation, the AnyDesk software was installed on the PC. It allows remote control of the PC for after-sales service.

A shortcut is available on the desktop.



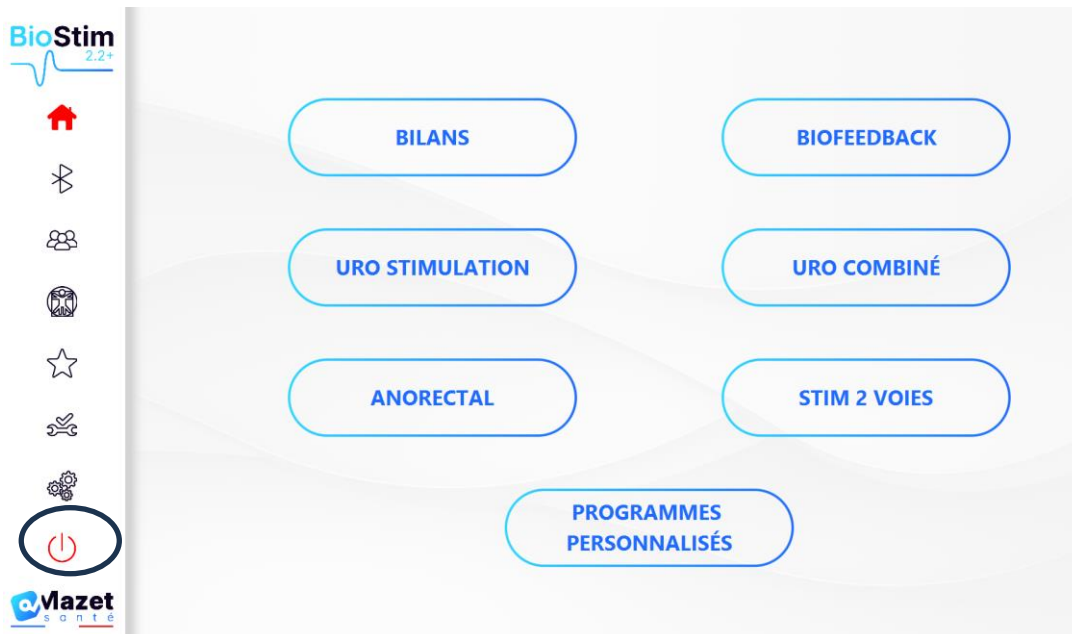
To allow a technician to take control, you must provide them with the username and password that appear in the window after launching the software.



8.7 Shutting down the device

First disconnect the patient from the applied parts.

Exit the Biostim programme on the PC: symbol 



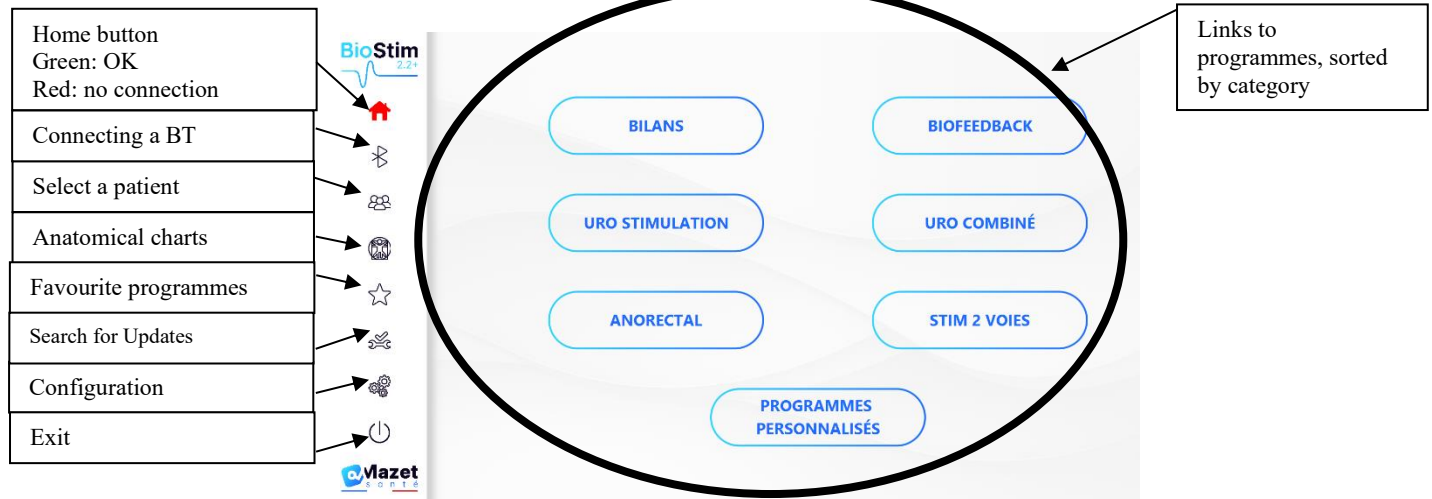
Set the on/off switch on the back of the device to OFF "O".

9 User manual

9.1 Home page

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

From any page in the application, press the home button (house) to return to this page.



You can rename a category by right-clicking on the desired category.

9.2 Programme selection and customisation page

When you click on a programme category, the programme selection page opens.

This page displays a list of all programmes in a category.



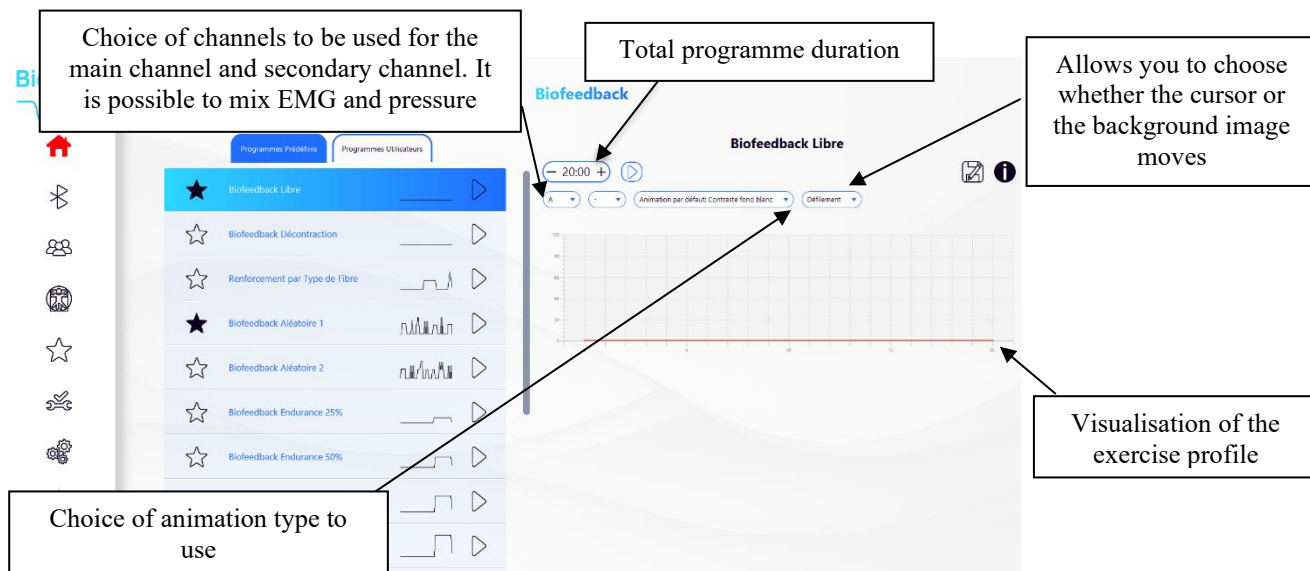
The selected programme button is highlighted and its description is displayed on the right-hand side of the page. This description contains:

- The name of the programme
- The duration of the programme
- A brief description


In the case of a stimulation programme, the current settings are also displayed

In the case of a biofeedback programme, the following are also displayed

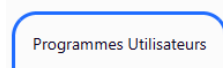
- the biofeedback profile
- the choice of animation
- the option to also display the channels that will be used (1 or 2)



You can adjust the programme settings using the buttons $+$, and $-$.

Once the programme has been customised as desired, it can be saved using the button . Saved programmes can be recognised by their names beginning with "U:". They are placed at

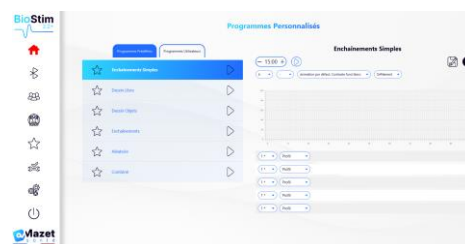
the top of the programme list.



9.3 Custom programmes (except versions 1.0 and 2.0)

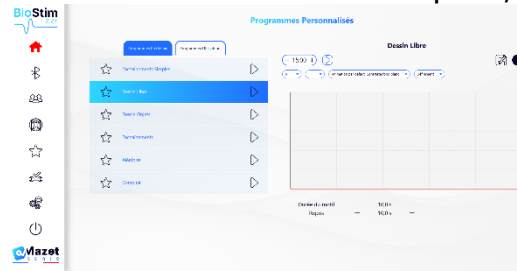
9.3.1 Simple sequences

This mode allows you to create a programme that combines simple shapes (peaks or plateaus) and stimulation.



9.3.2 Freehand Drawing

Allows you to draw a profile by clicking with the mouse on the drawing area. Clicking in the drawing area adds a point to the curve. To delete a point, simply click on it.



9.3.3 Draw Objects

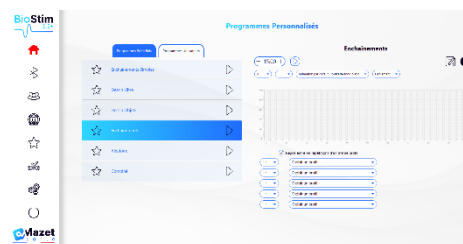
Allows you to draw an exercise using only images positioned on the screen, without having to follow a profile.

The objects can be chosen by the user or linked to the animation used.



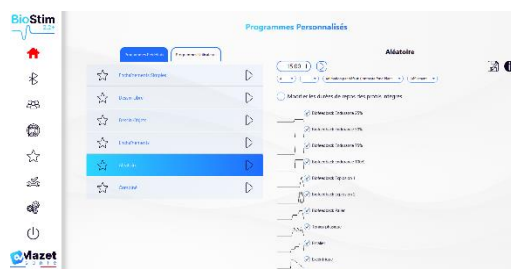
9.3.4 Sequences

Sequence mode allows you to create a programme by combining other programmes. A profile is defined based on other existing programmes (predefined or saved by the user).



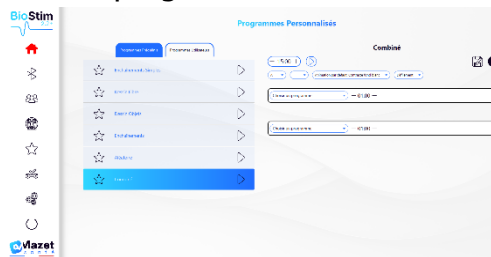
9.3.5 Random programmes

Random mode allows you to create a random programme. Each time it is launched, a new profile is created by combining all the selected basic patterns.



9.3.6 Combined programmes

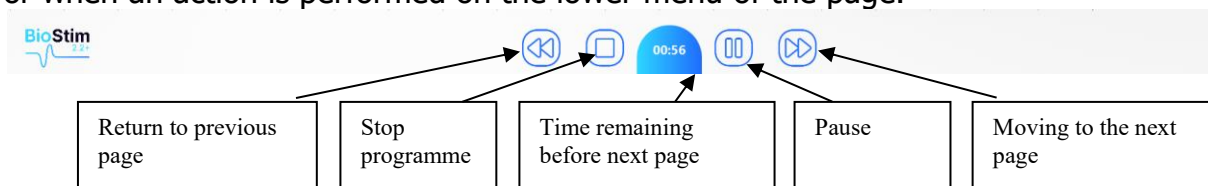
Combined mode allows you to create your own programmes incorporating stimulation and BFB by combining two other programmes.



9.4 Launching a programme

From the programme selection page, you can launch a programme by clicking on the '▶' button in the programme description section, or on the '▶' icon at the top right of the programme name.

A programme consists of one or more pages that follow one another after a predefined period of time or when an action is performed on the lower menu of the page.



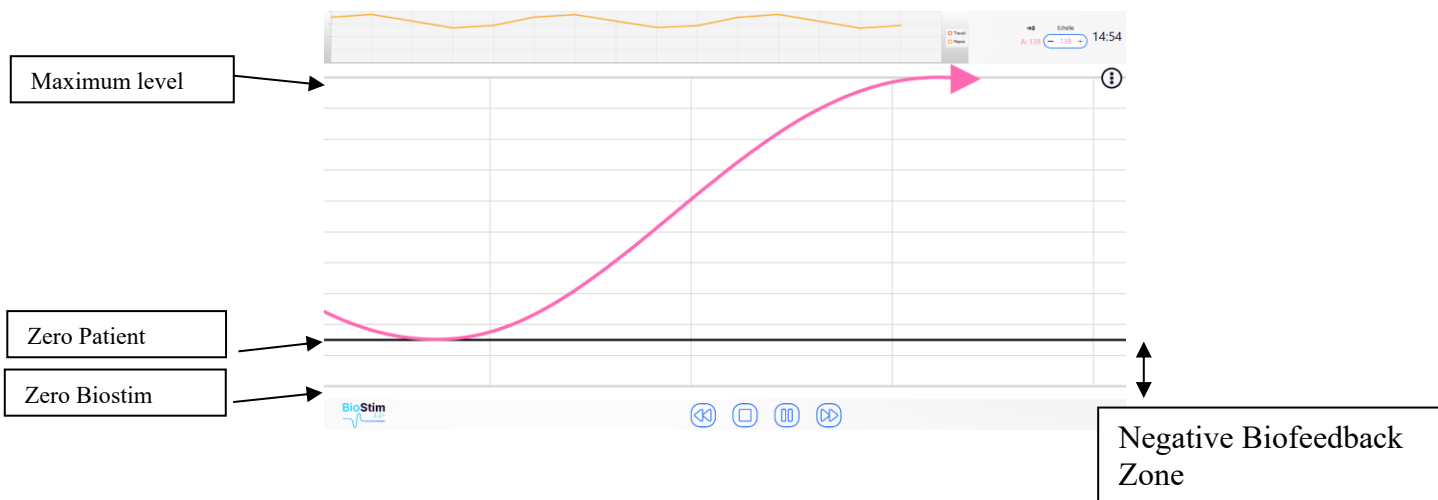
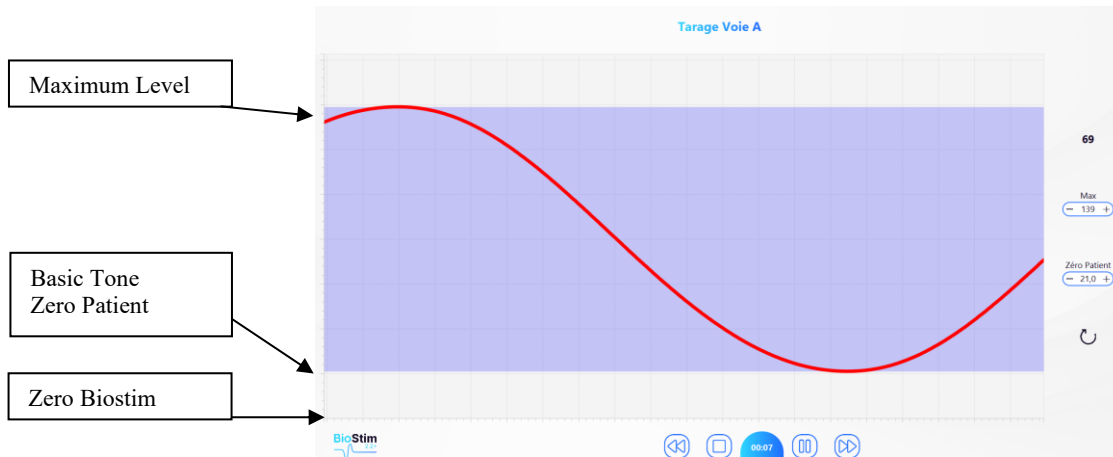
It is also possible to stop the programme using the emergency stop button

9.5 Biofeedback calibration

Calibration is automatic. However, it is possible to adjust the parameters calculated by the machine using the "+" and "-" buttons.

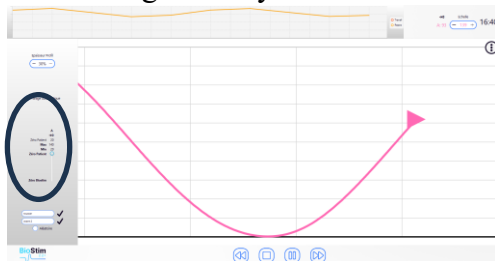
Calibration procedure

- Place the probe or electrodes
- Start calibration
- Ask the patient to maintain a contraction (the calibres change automatically), then 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

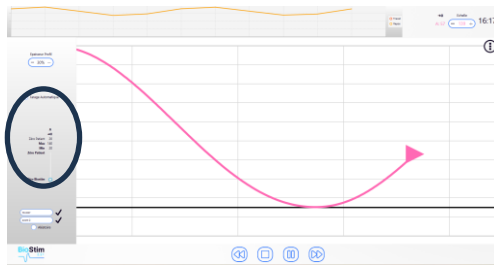


In the + version, it is possible to adjust the negative BFB level to be displayed during exercise using the slider in the right-hand panel:

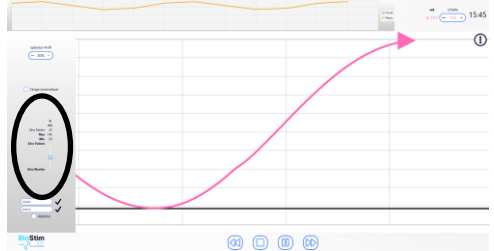
- Zero Patient: the bottom of the screen corresponds to the minimum reached by the patient during calibration
This setting allows you to clear the baseline tone.



- Zero Biostim: minimum measurable by the device: for working in negative BFB



- It is also possible to choose intermediate values:

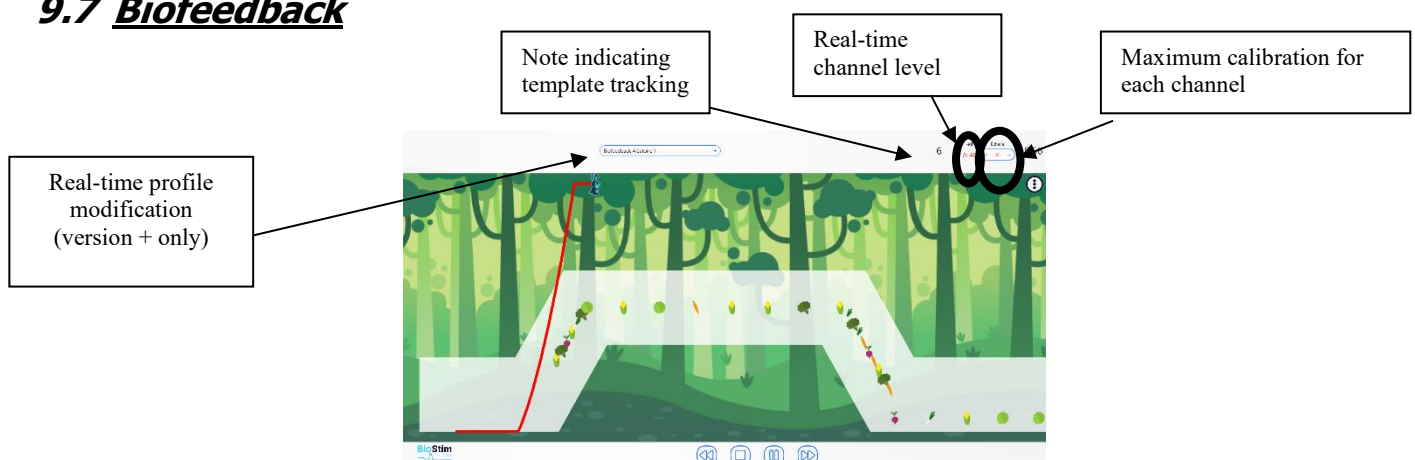


9.6 Stimulation

The stimulation level is adjusted channel by channel during programme execution. It can only be adjusted upwards during the working phases.

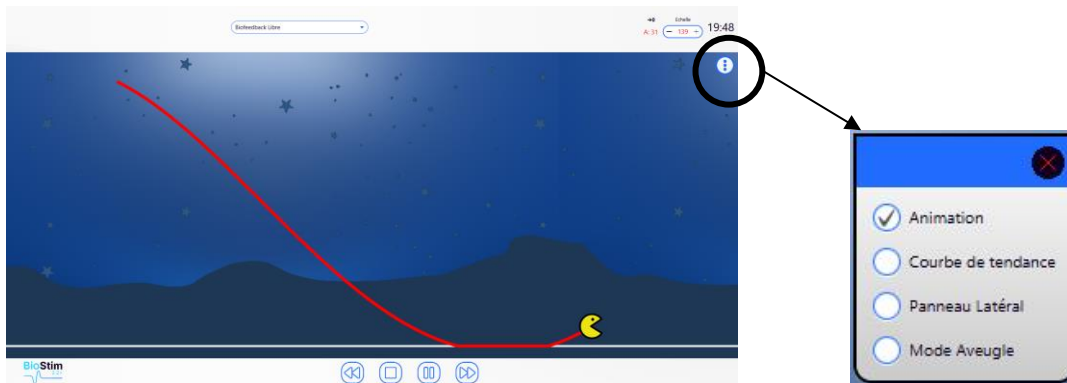


9.7 Biofeedback



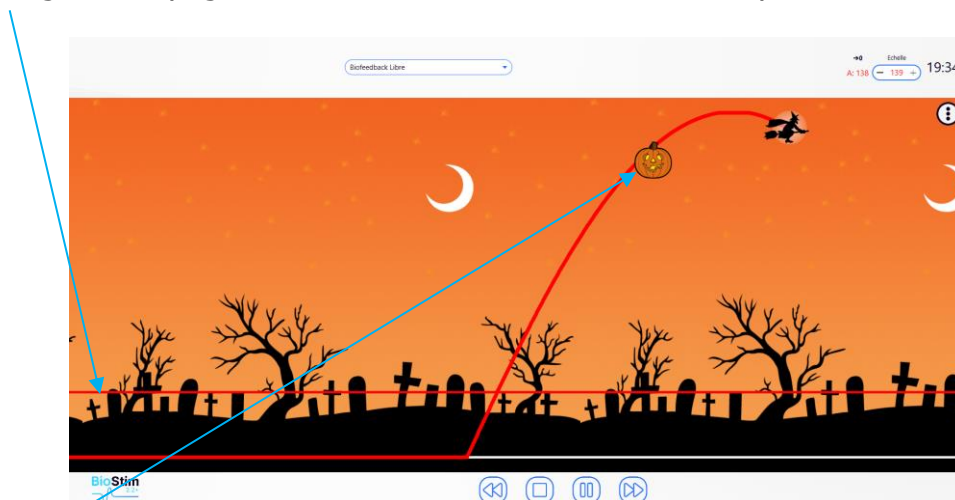
9.7.1 Menu for selecting areas to display

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.



9.7.2 Position markers

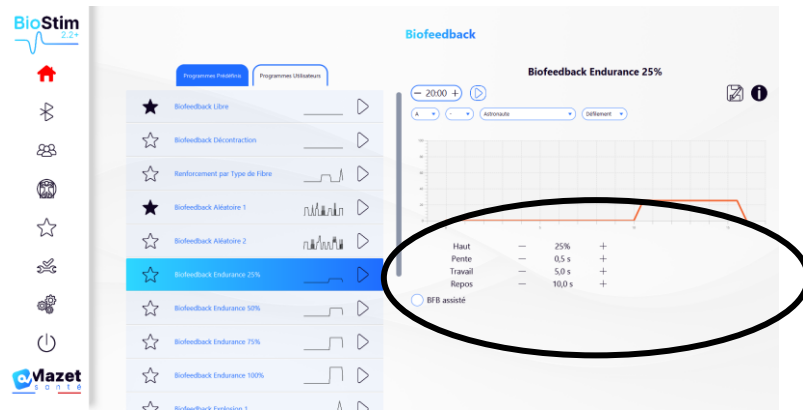
Left-clicking on the page adds a reference line at the desired position:



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)

9.7.3 Adjustable mode

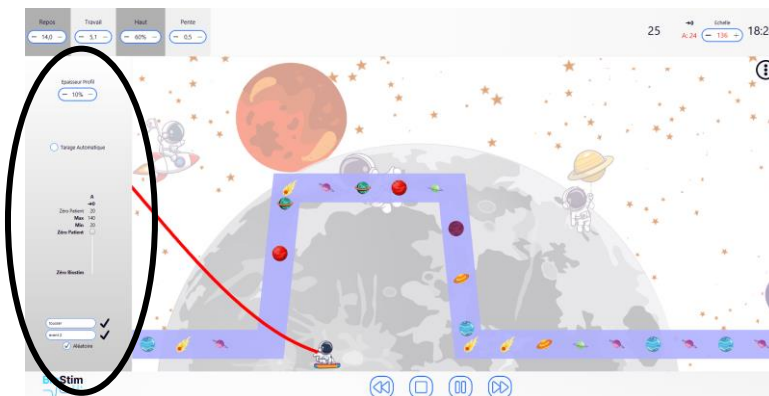
When biofeedback has been created in adjustable mode, you can modify the shape of the curve using the buttons on the right of the screen when selecting the programme. This adjustable function is available in the BioFeedBack Endurance menus.



If you adjust the curve when selecting the programme, the buttons for modifying the curve during the programme will be displayed at the top of the screen.



9.7.4 Side Panel

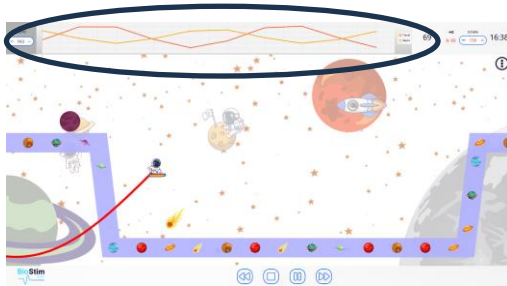


This panel allows you to adjust:

- Profile thickness
- 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 cursors for each channel
- 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.

9.7.5 Trend 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

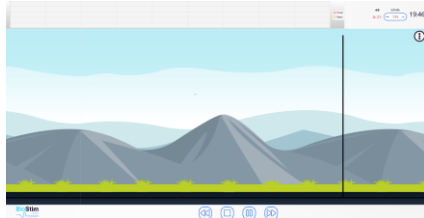


This curve can then be found in the session summary table in the patient file.

	Durée	Max Stim	Amplitude Min - Tonus - Max	Réussite
17/10/25 : Biofeedback Endurance 60%	06:28		20 - 20 - 140	A
				133

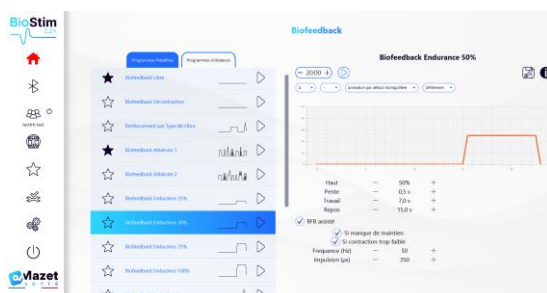
9.7.6 Blind mode

A "blind mode" is available for working without the contractions being displayed on the screen. This mode can be activated during the session in the zone selection menu. The curves are recorded and can be analysed at the end of the session.



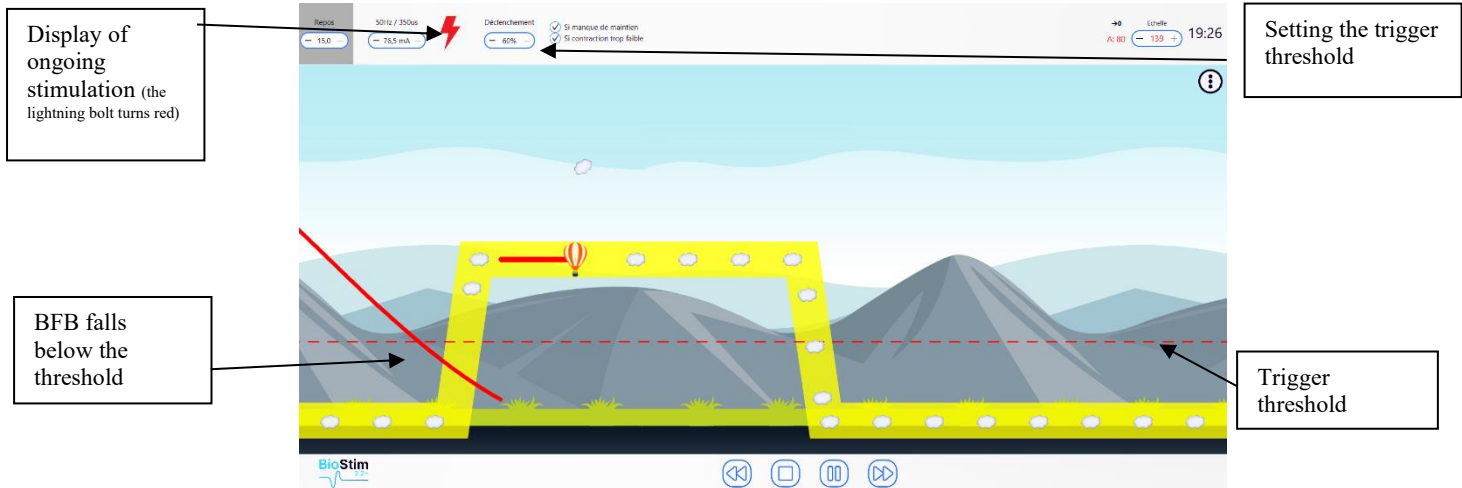
9.7.7 Assisted biofeedback

This mode, available for adjustable programmes, can be activated either before starting the programme or from the side panel.



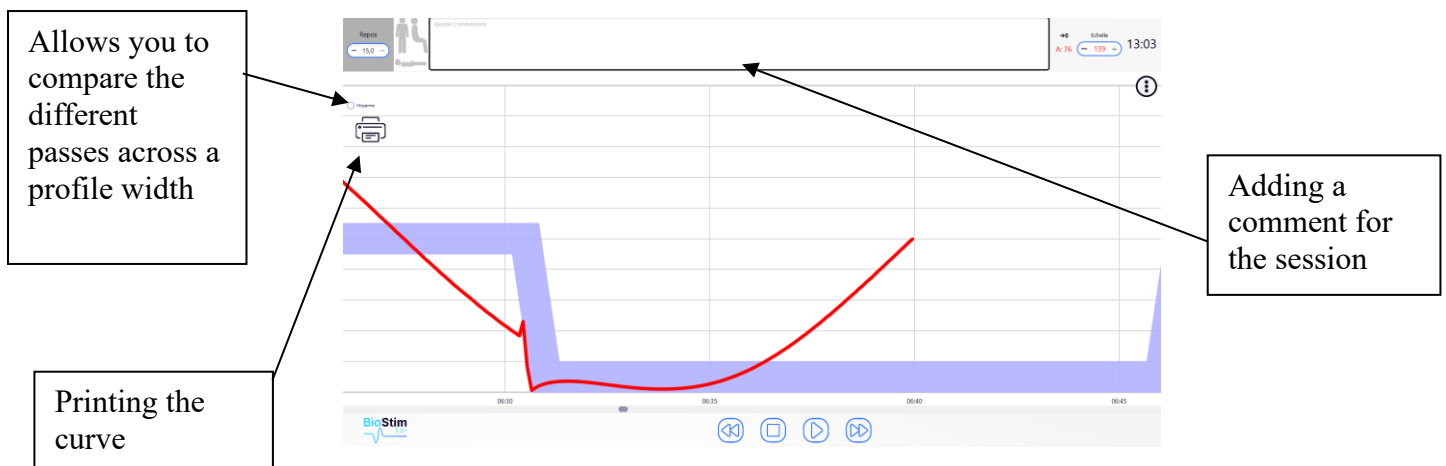
The stimulation then reinforces the muscle work:

- Either in the event of a lack of maintenance: good start to contraction, but insufficient maintenance at the end of the plateau
- Or in the case of insufficient contraction: contraction detected, but insufficient to reach the plateau



9.7.8 Review mode

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



9.7.9 Use of a Bluetooth accessory

Biostim is compatible with many accessories defined in §3.1.4

The BT function is integrated into version 2.2+ and available for purchase for all other versions.

To work with a BT accessory: turn it on (button on the white part of the Perifit, or shake the Emy probe), then click on the Bluetooth logo (under the house). When the accessory is connected, the Bluetooth logo is blue, and the logo of the connected accessory appears on the right with a bar graph indicating the available battery level.



The accessory is then used like the other probes, by selecting the channel to be used that corresponds to the probe in the BFB menu.

If the Biostim is not connected to the PC, the duration of the programmes is limited to 1 minute.



9.8 Favourite programmes

To find frequently used programmes more quickly, you can classify them in the "Favourites" category.

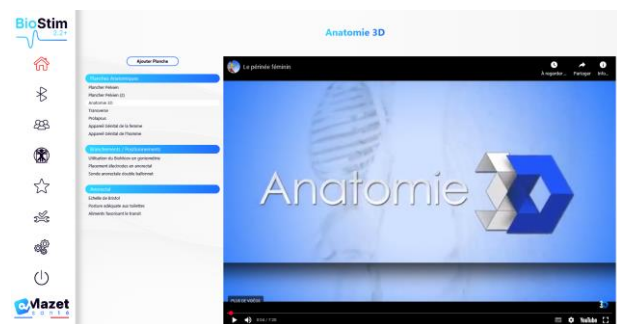
To do this, simply click on the "☆" icon to the left of the programme name.

☆ They can then be accessed by clicking on the "Favourites" button in the left-hand menu on each page.


9.9 Anatomical Plates (except version 1.0)


Anatomical charts are available. Clicking on the image opens it in a viewer that allows you to zoom in or switch to full-screen mode for better visibility.

You can add your own anatomical plates by clicking on the "add plate" button. You can choose image or video files from your computer, or links to videos on the internet (particularly YouTube). We would like to thank the Universities of Lille 2 and Lyon 1 for allowing us to include a link to their 3D anatomical charts.



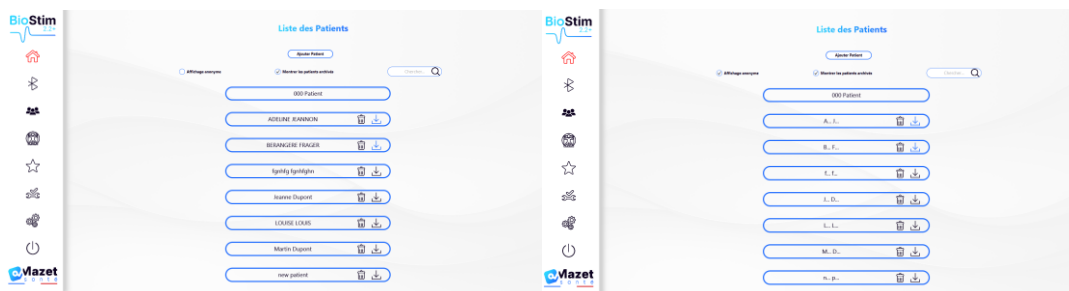
9.10 Select a patient (except version 1.0)

Clicking on the "  " 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.

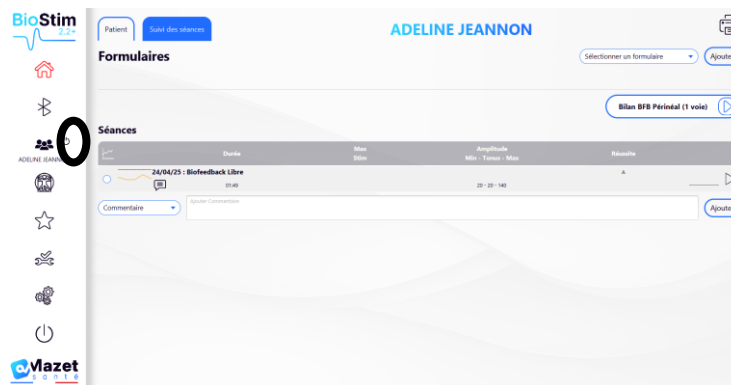
You can display all patients (including archived patients) by selecting the "Show archived patients" checkbox.

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.



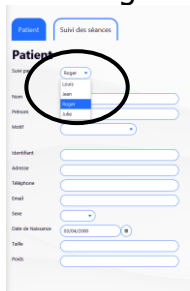
Anonymous display allows you to hide the patient's full name and surname; only the initials will be visible.

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 their name. 



9.10.1 Multi-practitioner mode (except version 1.0)

You can enable multi-practitioner mode on the configuration page. If this mode is enabled, you can assign a patient to a practitioner on the patient assessment page.



On the patient search page, you can add a new practitioner or filter the patient list by selecting a practitioner.



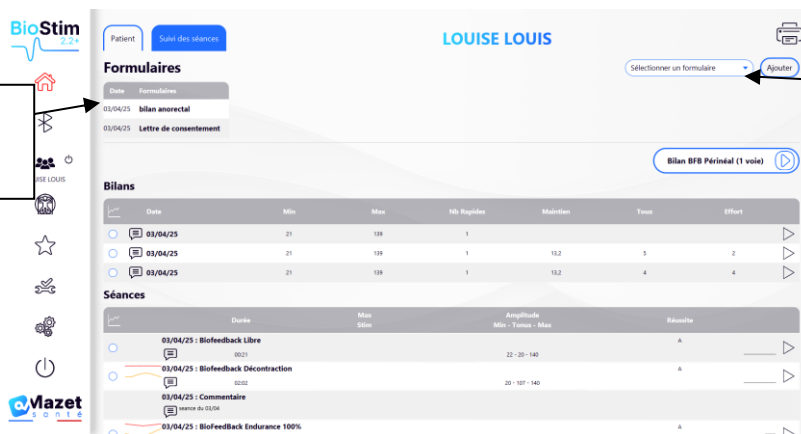
9.11 e Patient File (except version 1.0)

When a patient is selected, their file can be accessed 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
- Standard assessment forms, which will allow you to review the patient's situation.

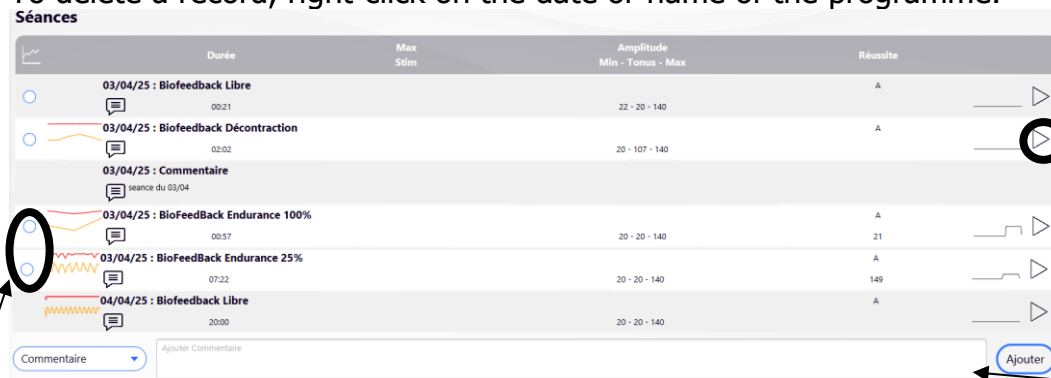


Follow-up form
(right-click on the form
name to delete)

Add a new form to the
patient file: either
predefined or free-
form (letter, medical
examination, etc.)

All sessions are recorded. The results are displayed in graph form for quick viewing, and in a more comprehensive table showing all the session data.

To delete a record, right-click on the date or name of the programme.




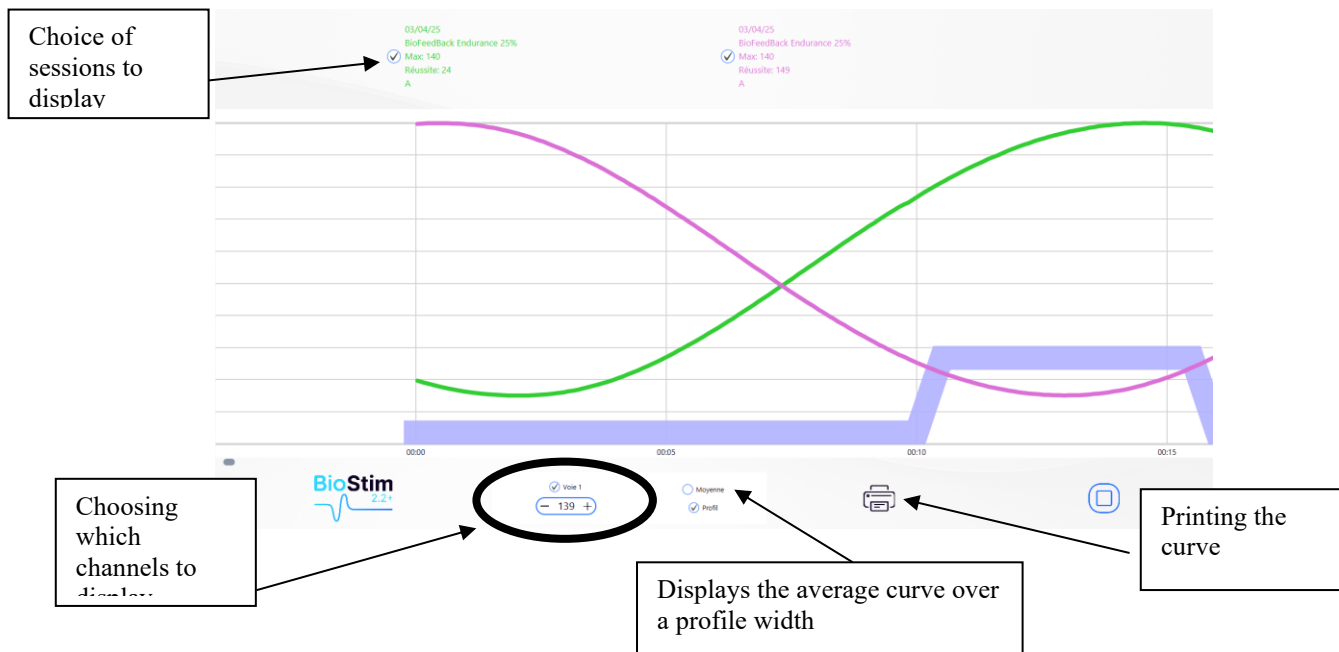
Restarts the same
programme

Free comments
(right-click to delete)

Select the curves you
want to review (version
+)

9.11.1 Curve comparison (version 2.2+)

Clicking on the "  " button in the session table opens the session comparison page (only for version 2.2+).

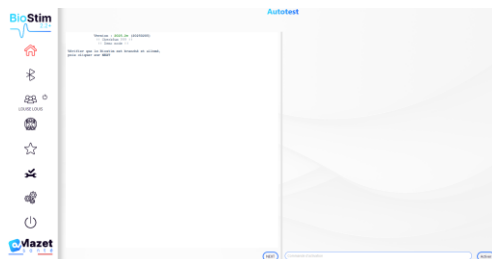


Right-click in the drawing area to select a portion of the curve to print

9.12 Biostim Cloud

If the computer is connected to a network:

- An anonymous collection of sessions is performed
- You are notified of new versions, which can be installed directly from the software



9.13 Configuration page

The configuration page allows you to configure the software. The available options are:

- Scroll speed: allows you to speed up or slow down the biofeedback scroll
- Display channels on separate graphs
- Rest time before or after working time for BFB
- Automatically start BFB after calibration: if this option is not enabled, the cursor waits for the start button to be pressed at the beginning of BFB: no scrolling before this button is pressed
- Force the cursor to be displayed on the curves
- 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. Custom animations are not available in version 1.0
- Display BFB pressure during stimulation (only for pressure probes with electrodes: Sugar International Evolys 3P type)
- Option to choose the thickness of the profile
- Choice of action for a right click on the screen during a BFB (add object/add event)
- Sound management: Choice of end-of-programme music, option to add sound for transitions between BFB and stimulation, audible BFB (for visually impaired patients), audible indication for the start and end of contraction. All these sounds can be configured by the user
- Creation, modification and deletion of a custom animation: requires a background image, an image for tracking each channel, and one or more objects to catch (except for version 1.0).
- Choice of screen display style for the Biostim software.

9.13.1 Networking of multiple devices (except version 1.0)

To network two (or more) devices, they must be on the same network and have a shared common directory (e.g. T:\biostim).

To share the database, simply specify this directory in the "Directory for storing patient data" option.

10 Maintenance

The **Biostim** 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 Electronique du Mazet technicians every 2 years.

Only technicians from Electronique du Mazet or its authorised distributors are authorised to carry out maintenance and repairs on the device.

10.1 Housing and accessories

The case only requires periodic cleaning of its external surface, which may become dirty. The same applies to the accessories.

Only clean the device with a dry or very slightly damp cloth.
Be sure to unplug the power cord before cleaning.

10.2 Associated devices

Associated treatment devices must not come into direct contact with the patient's skin.

Associated treatment devices may be cleaned with a dry or slightly damp cloth.

10.3 Sterilisation:

This device is not sterile.
The accessories are not sterile and are not intended to be sterilised.

11 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 the device needs to be shipped, please follow these instructions:

- Decontaminate and clean the device and its accessories.
- Use the original packaging, including the retaining flanges.
- Include all accessories for the device.
- 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
Green indicator light off	- Electrical network problem - Fuses	- check mains voltage - check and replace fuses
No communication with the PC (home button = red house)	- USB adapter	- check connections - Check that the FTDI driver is correctly installed (CDM21228_Setup.exe)
No stimulation detected but yellow indicators light up.	- poor contact - Faulty cable	- Check connections to the patient. - Swap the cables to check
No stimulation and the yellow indicators do not light up.	- Loss of communication with the module. - The stimulation current settings are inconsistent.	- Exit the current treatment and return to the main office. - Check the settings and modify them.
Flat trace in biofeedback windows	- Loss of communication with the module. - No sensor on the input in question.	- Exit the current treatment and return to the main desktop. - Check the channel used.
Need to increase the stimulation current beyond the usual values with elastomer electrodes.	- Old electrodes. - Insufficient or excessive gel	- Change electrodes. - Add or remove contact gel
Automatic decrease in amplitude slider.	- Old electrodes - insufficient or excessive gel - Pulse width too long.	- Change electrodes. - Add or remove contact gel - Change the programme to a shorter pulse width.
Saturated or very noisy EMG biofeedback signal	- Absence or poor contact of the reference electrode.	- Check that the ^{third} electrode is securely attached. Check the quality of the electrodes and replace them if necessary.
The remote control is not working	- Dead battery - too far away/incorrect orientation	- Replace the battery (CR2450GP/B5 3V) - move closer/position yourself opposite

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

12 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 treatments 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 accessories supplied or specified by the manufacturer.
- The device must only use consumables or semi-consumables supplied or specified by the manufacturer.
- Machine parts and spare parts are not replaced by the user.

Improper 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, etc.

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.

13 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 Récylum collection point.

As part of its commitment to the environment, Électronique du Mazet finances the ecosystem recycling channel 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).

14 Transport and storage

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

Store in a clean, dry place at room temperature.

15 CE declaration

ÉLECTRONIQUE DU MAZET will provide the EC declaration for this device upon request.

The medical CE mark was first affixed to this device on 14/12/2018.

16 Manufactured by nt

Électronique du Mazet is a company based in the heart of the Massif Central. Originally a simple manufacturer of electronic cards, over the years it has developed its own devices, which are marketed under the following brands:



Devices for physiotherapists and midwives

mazetsante.fr



Otological diagnostic devices

echodia.com



Devices for the beauty industry

<https://mazetbeaute.fr/>



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


17 EMC compliance table

EMC compliance according to IEC 60601-1-2 (2014) 4th Edition (EN 60601-1-2: 2015)			
The BIOSTIM is intended for use in the electromagnetic environment specified below. The customer or user of BIOSTIM should ensure that it is used in such an environment.			
Emissions test	Compliance	Electromagnetic environment – guidelines	
RF emissions CISPR 11	Group 1	The BIOSTIM uses RF energy only for its internal functions. Consequently, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.	
RF emissions CISPR 11	Class B	The BIOSTIM is suitable for use in all premises, including domestic premises and those directly connected to the public low-voltage power supply network supplying domestic buildings.	
Harmonic emissions IEC 61000-3-2	Class A		
Voltage fluctuations / Flicker IEC 61000-3-3	Compliant		

EMC compliance according to IEC 60601-1-2 (2014) 4th Edition (EN 60601-1-2: 2015)			
BIOSTIM is intended for use in the electromagnetic environment specified below. The customer or user of BIOSTIM should ensure that it is used in such an environment.			
IMMUNITY TEST	Test level IEC 60601-1-2	Compliance level	Electromagnetic environment – guidelines
Electrostatic discharges (ESD) IEC 61000-4-2	± 8 kV in contact ± 15 kV in air	± 8 kV contact ± 15 kV in air	Floors should be made of wood, concrete or ceramic tiles. If floors are covered with synthetic materials, the relative humidity should be at least 30%.
Transients Fast bursts IEC 61000-4-4	± 2 kV for power lines power supply power ± 1 kV for input/output lines input/output	± 2 kV for power supply power	The quality of the power supply network should be that of a typical commercial or hospital environment.
Transient transient ± 1 kV between phases	± 1 kV between phases ± 2 kV between phase and earth	± 1 kV between phases ± 2 kV between phase and earth	The quality of the power supply network should be that of a typical commercial or hospital environment.
Voltage dips, brief interruptions and voltage variations on input lines supply lines power supply IEC 61000-4-11	0% UT: 0.5 cycle at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0% UT: 1 cycle and 70% UT: 25/30 cycles Single-phase: at 0 degrees 0% UT: 250/300 cycles	0% UT: 0.5 cycle at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0% UT: 1 cycle and 70% UT: 25/30 cycles Single-phase: at 0 degrees 0% UT: 250/300 Cycles	The quality of the power supply network should be that of a typical commercial or hospital environment. If the BIOSTIM user requires continuous operation during power supply network outages, it is recommended that the BIOSTIM be powered by an uninterruptible power supply or a battery. NOTE UT is the AC mains voltage before the test level is applied.
Magnetic field at mains frequency (50/60 Hz) IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50Hz or 60Hz	Magnetic fields at mains frequency should be at levels characteristic of a representative location in a typical commercial or hospital environment.

EMC compliance according to IEC 60601-1-2 (2014) 4th Edition (EN 60601-1-2: 2015)

BIOSTIM is intended for use in the electromagnetic environment specified below. The customer or user of **BIOSTIM** should ensure that it is used in such an environment.

IMMUNITY TEST	Test level IEC 60601-1-2	Compliance level	Electromagnetic environment – guidelines
Conducted RF disturbances IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Veff in ISM bands between 0.15 MHz and 80 MHz 80% AM at 2 Hz	3 Vrms 150 kHz to 80 MHz 6 Veff in ISM bands between 0.15 MHz and 80 MHz 80% AM at 2 Hz	Portable and mobile RF communications equipment RF communications devices should not be used closer to any part of the BIOSTIM , including cables, than the recommended separation distance, calculated from the equation applicable to the frequency of transmitter. Recommended separation distance $d = 1,67 \cdot \sqrt{P}$ $d = 1,67 \cdot \sqrt{P}$ 80MHz-800MHz $d = 2,33 \cdot \sqrt{P}$ 800MHz-2.5GHz Where P is the maximum output power rating of the transmitter in watts (W), as specified by the transmitter manufacturer, and d is the recommended separation distance in metres (m). The field strengths of fixed RF transmitters, as determined by an on-site electromagnetic investigation, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF disturbances IEC 61000-4-3, including clause 8.10, table 9, for proximity to wireless devices	3 V/m 80 MHz to 2.7 GHz 80% AM at 2 Hz including clause 8.10, table 9, for proximity to wireless devices	3 V/m 80 MHz to 2.7 GHz 80% AM at 2 Hz including clause 8.10, Table 9, for proximity to wireless devices	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) The field strengths from fixed transmitters, such as base stations for radiotelephones (cellular/wireless) and land mobile radios, amateur radio, AM and FM radio broadcasting, and TV broadcasting, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an on-site electromagnetic investigation should be considered. If the field strength, measured at the location where the **BIOSTIM** is used, exceeds the applicable RF compliance level above, the **BIOSTIM** should be observed to verify that it is functioning normally. If abnormal performance is observed, additional measures may be necessary, such as reorienting or repositioning the **BIOSTIM**.

b) Beyond the frequency range of 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications devices RF communications and the BIOSTIM

The **BIOSTIM** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the **BIOSTIM** can help prevent electromagnetic interference by maintaining a minimum distance between the portable and mobile RF communications equipment (transmitters) and the **BIOSTIM**, as recommended below, depending on the maximum transmission power of the communications equipment.

Maximum rated output power of transmitter (in W)	Separation distance according to transmitter frequency (in m)		
	150kHz - 80MHz	80MHz - 800MHz	800MHz - 2.5GHz
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.737
1	1.167	1.167	2.330
10	3,690	3,690	7,368
100	11.67	11,67	23,300

For transmitters whose maximum assigned transmission power is not given above, the recommended separation distance in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum transmission power characteristic of the transmitter in watts (W), as specified by the manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects and people.



ELECTRONIQUE DU MAZET

3 Allée des Morilles
43520 LE MAZET SAINT VOY

Tél : +33 4 71 65 02 16
Mail : sav@electroniquedumazet.com

Your dealer/distributor:

A large, empty rounded rectangular box with a thin blue border, intended for the user to write the name of their dealer or distributor.

18 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 declare that I have received the **Biostim** 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

