

User's manual



Electrotherapy device

BioStim 2.2

BioStim 2.1

BioStim 2.0

BioStim 1.0

Instructions for use & Technical description

Please read these instructions 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 only by qualified physiotherapists and midwives.

In the event of a failure or, if misunderstanding this manual, please contact your distributor (see stamp on 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 within 15 days of installation or acceptance.



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1 Introduction

This user and maintenance manual has been published to help you get to grips with your BioStim, from the initial acceptance phase, through commissioning, to successive stages of use and maintenance.

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

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

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

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

Only personnel who have been informed of the contents of this document may operate the device. Non-compliance with any of the instructions contained in this document releases Électronique du Mazet and its authorized distributors from liability for the consequences of accidents or damage to personnel or third parties (including patients).

2 Symbols used



Warning: this logo draws your attention to a specific point.



Operating instructions: this logo informs you that the operating instructions must be read for safe use of the device.



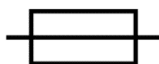
Type BF applied part: applied part in contact with the patient



Recycling: this device must be disposed of at an appropriate recycling facility. Consult the manufacturer.



Protective earth



Fuse



Caution: Switching the unit off and on



Alternating current



Serial number



Manufacturer



Date of manufacture



Product number



Unique identifier



Medical device

3 Device presentation

3.1 Device description

Biostim is an electrotherapy device designed to support physiotherapists and midwives in perineal rehabilitation.

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

The device's pre-set programs can be used for most perineal rehabilitation treatments, in both urogynecological and anorectal fields.

The main programs available are :

- Urogynecological biofeedback, EMG or Pressure
- Urogynecological stimulation
- Combined urogynecological programs, which combine biofeedback and stimulation
- Analgesia for urogynecology
- Stimulation and anorectal biofeedback programs

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

3.2 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 pathologies (stress, urge or mixed; detrusor inhibition)
- Treatment of anal incontinence pathologies
- Treatment of pelvic static disorders: muscle relaxation and strengthening.
- Analgesic treatment
- Treatment of genito-sexual pathologies (including erectile dysfunction)

Expected benefits :

Today, based on European and French recommendations and the results of studies carried out by health specialists, the device makes it possible to offer pre-established, specific programs for pathologies requiring treatment by physiotherapists or midwives. The expected benefits are a significant reduction in urinary or anal leakage, with contraction or relaxation of the pelvic floor muscles, improved muscular endurance with increased perineal contraction strength, reduced pain with an analgesic effect, and improved quality of life.

3.3 Intended use

The device is 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 prolapses: muscle-strengthening and relaxation treatments.
- 4- Pain management: analgesic treatments.
- 5- Management of genitosexual disorders: erectile dysfunction.

Currents are applied locally to the treated body part, stimulating or relaxing muscles, or reducing pain.

3.4 Application

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

3.5 User profile

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

This equipment must be used by trained medical personnel who are not disabled in any way (motor, mental, cognitive or psychic). The user must be aware of all the safety precautions, operating procedures and maintenance instructions provided in this user manual.

3.6 Target population

The device is designed for use by women and men over the age of 5. It should be noted that pelvic floor rehabilitation is particularly indicated for post-partum women.

3.7 Major contraindications

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

- During pregnancy
- Presence of a pacemaker
- Presence of cardiac arrhythmia
- Presence of a bladder stimulator
- Perineal hypoesthesia
- Urinary and vaginal infections
- Recent abdominal surgery
- Intrapelvic tumors
- Do not apply to the carotid sinus



3.8 Side effects

To date, medical literature does not mention any significant side effects of electrotherapy.

3.9 Technical specifications

3.9.1 General features

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

3.9.2 Technical specifications

- Case dimensions: **33.7 x 28 x 6.7 cm**
- Case weight: **3.1 Kg**
- Case color: **white**
- Power supply: **110-230VAC - 50-60Hz**
- Power consumption: **55VA**
- Fuses: 2x size 5x20mm - **T1.25AH-250V**
- **Class I** electrical appliance
- Medical **Class IIa** equipment.
- **Type BF** applied part
- Liquid protection type **IPX0**.
- PC communication: optically isolated **USB**.
- Green LED on front panel indicates power on.
- Stimulation can be stopped by an emergency stop bulb.
- 1 or 2 Electro channels. Each channel features the following functions:
 - Current generator :
 - Output currents of each generator adjustable from **0 to 100mA** (+/-10%)
 - With a load impedance of 1kΩ (or more), at max current, the voltage is **limited to 100V**
 - 20%/+10% (peak value).
 - With a load impedance of less than 1kΩ, the voltage level is limited according to the impedance (10volts for 100Ω, 50volts for 500Ω).
 - If the impedance is too high (above 10 kΩ), the current can be cut off: **unstuck electrode** function
 - ⇒ Rectangular-shaped signals are biphasic (symmetrical pulses with zero mean value), pulse width is adjustable from **100μs to 10ms**, frequency is adjustable from **1Hz to 5kHz**.
 - ⇒ The generators are electrically independent (no current flows between the 2 electrodes of the 2 generators).
 - ⇒ Yellow LED indicates output activation status.
 - Biofeedback activity measurement: Full-scale sensitivity: 2mV (peak-peak)
- 0, 1 or 2 Biofeedback pressure channels

⇒ sensitivity range: **400 mBar**

If the current is not perceived at 10 or 15mA, stop treatment and check that the probe or electrode is correctly positioned, using lubricant without excess.

3.9.3 Different versions of the device

The functionalities 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.

3.9.4 Accessories

This device is supplied with the following accessories as standard:

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

3.9.5 Applied parts

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

List of compatible products :

- Dura-Stick Plus Stimulation Electrodes (DJO Global) CE 0473
- Vaginal probe type Saint-Cloud classic or higher with banana or DIN plugs (Optima, OVA, Periform, Perisize...).
- Perifit or Fizimed CE Bluetooth connection probe
- Rectal pressure probe such as RectoMax or vaginal pressure probe such as Aerolys
- Axtim anal probe 201-B0-1-S
- Blueback physio (Blueback SAS)
- BioMoov (Electronique du Mazet)

The use of products not recommended by the manufacturer does not incur the manufacturer's liability

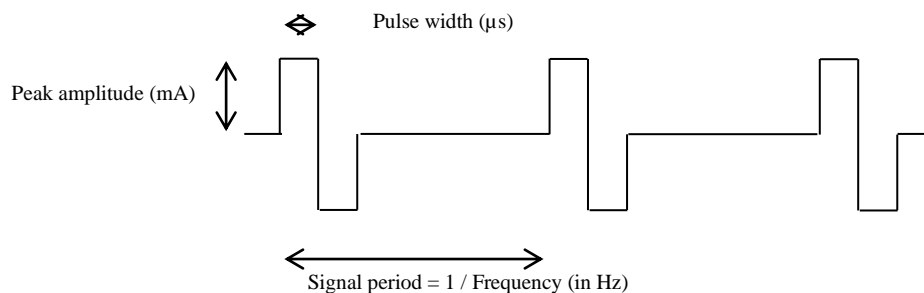
Be sure to observe the hygiene conditions recommended by the manufacturer of the applied part.

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

3.9.6 Current shape

Two-phase rectangular pulses

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

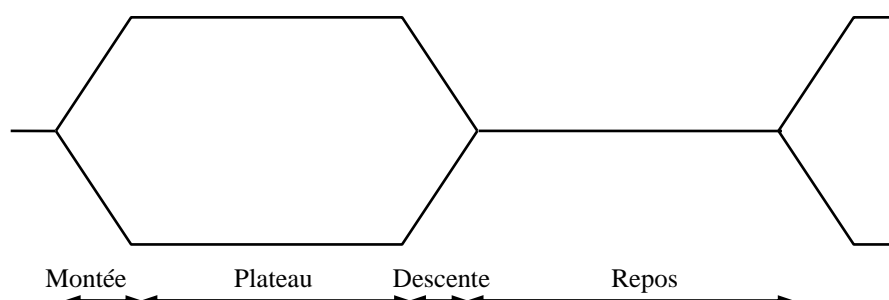


The waveform is constant current and does not depend on the value of the load.
Pulse width is adjustable from **100µs to 10ms**, frequency is adjustable from **1Hz to 5kHz**.
LF modulation (1Hz to 500 Hz) of the signal is possible.

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. In particular, this standard limits the intensities delivered and the power per pulse.

Envelope generation :

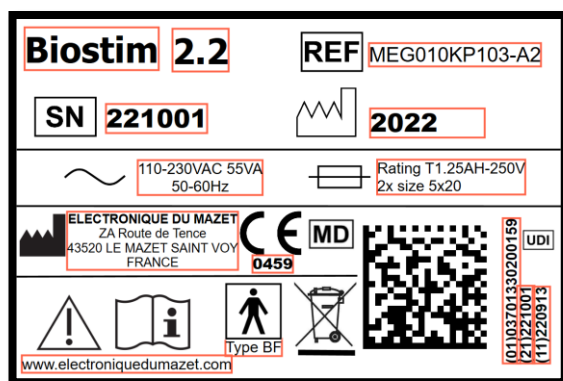
The pulse signal is enclosed in an envelope that allows the current to be applied and removed progressively.



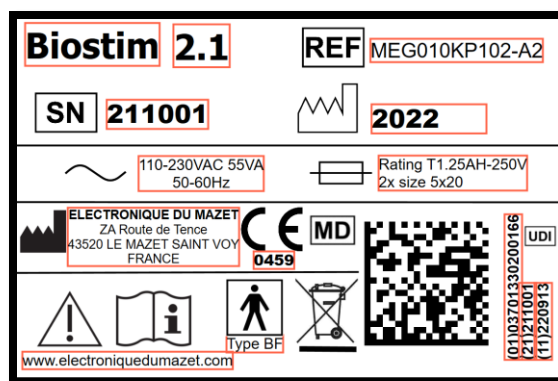
3.10 Identification label

Information and specifications are given on a label on the back of each unit.

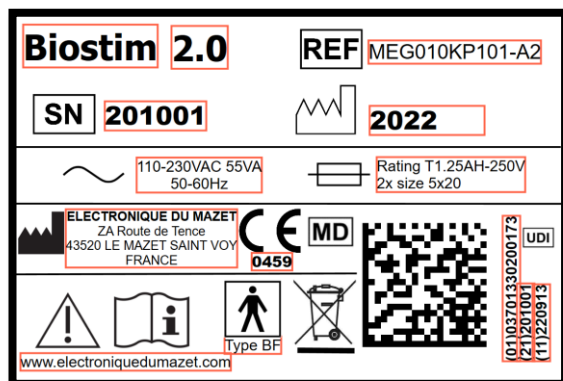
Biostim 2.2+" label:



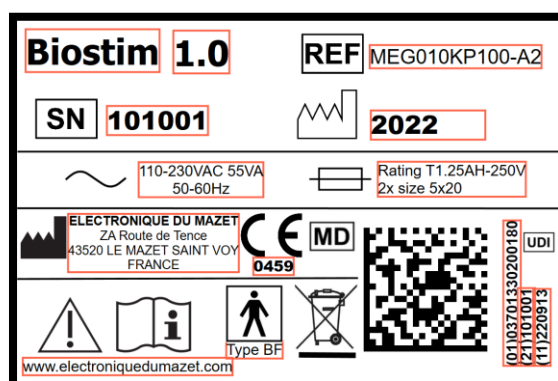
Biostim 2.1 / 2.1+" label



Biostim 2.0" label
or "Biostim 2.0+"



Biostim 1.0" label



3.11 Warnings



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



CAUTION: Multi-socket outlets must not be placed on the floor. No other electrical appliance or power strip may be connected to the power strip.



CAUTION: The device must be plugged into an earthed socket (Class I electrical appliance).



CAUTION: The unit must be positioned so as to allow free access to the mains cable in the event of an emergency.



CAUTION: In an emergency, disconnect the mains cable directly from the unit.



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



CAUTION: This device complies with applicable electromagnetic compatibility standards. If you notice any malfunction due to interference or otherwise in the presence of another device, contact Électronique du Mazet or the distributor, who will give you advice on how to avoid or minimize possible problems.



CAUTION: Operation in the immediate vicinity (e.g. 1 m) of a short-wave or microwave EM therapy DEVICE may cause instabilities in the STIMULATOR's output power.



CAUTION: The patient connected to the device must not be connected to other equipment (monitoring or diagnostic equipment) during treatment. Such ancillary equipment could 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 eventually be damaged.



ATTENTION: The appliance must be used with the accessories supplied by the manufacturer.



WARNING: If the PATIENT is equipped with an implanted electronic device (e.g. pacemaker), use of the device in stimulation mode is IMPERATIVELY subject to prior medical AUTHORIZATION.



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



CAUTION: Under certain conditions, the RMS value of stimulation pulses may exceed 10 mA and 10 V. Please adhere strictly to the information given in this manual.



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



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



CAUTION: The output signals from the device are symmetrical two-phase with zero mean value, and have no DC component. Any unpleasant sensation (irritation, overheating) at low intensities could mean equipment failure. Do not use the device without the advice of the MANUFACTURER.



CAUTION: The device must not be accessible to the patient. It must not be placed in contact with the patient.



CAUTION: If the computer used is not approved as a medical device, the computer must never be located in an area accessible to the patient.

4 Precautions

4.1 Environment

This device is intended for professional use only

This device is designed for indoor use only. Do not use in damp or potentially explosive environments

This device is not intended for domestic use.

4.2 Risks residual

4.2.1 Mains failure

To avoid any risk of burns or tetanization, be sure to disconnect the cables in the event of a power cut or of a malfunction on the control computer.

4.2.2 Applied parts

Old or poor-quality applied parts can alter the quality of contact with the patient and cause discomfort. Make sure you change them regularly.

4.2.3 Operating environment

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

4.2.4 Water ingress

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

5 Patient data confidentiality

The device collects data from the computer to which it is connected. No data is stored in the device. It is the responsibility of the practitioner to apply and comply with the European Parliament's General Data Protection Regulation 2016/679. When returning to the After Sales Service, if the computer is returned with the device, the practitioner must delete the patient data so that it is not disclosed. The practitioner has the option of making a backup copy of this data by saving it on an external medium before deleting it."

6 Cybersecurity

As the Biostim device and software are computerized systems that form part of a wider information systems, certain rules and best practices must be observed to ensure the safety of patients and users.

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

6.1 Best practices for IT security

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

6.2 Technical information

- Biostim software is a Java program
- Software configurations and the database are saved 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.
- Software uses proprietary USB driver to communicate with device

6.3 Network communications

- The device does not require a network connection to operate.
- Data may be sent to the Electronique du Mazet servers on a regular basis.
 - All data is anonymized
 - They are only collected for statistical purposes, or to facilitate remote assistance.
- The device can also communicate with the Electronique du Mazet servers, to find out if updates are available, and if so, update the software.
- All exchanges use a secure protocol (https)

7 Installation

7.1 Unpacking the unit

Open the package, remove the accessories and the unit.

Verify that the contents of the package fit the packing list included with the documentation.

If the unit has been stored in a cold place and there is a risk of condensation, leave it to stand for at least 4 hours at room temperature (approx. 20°C).

Install the unit on a support at working height.

7.2 Getting started

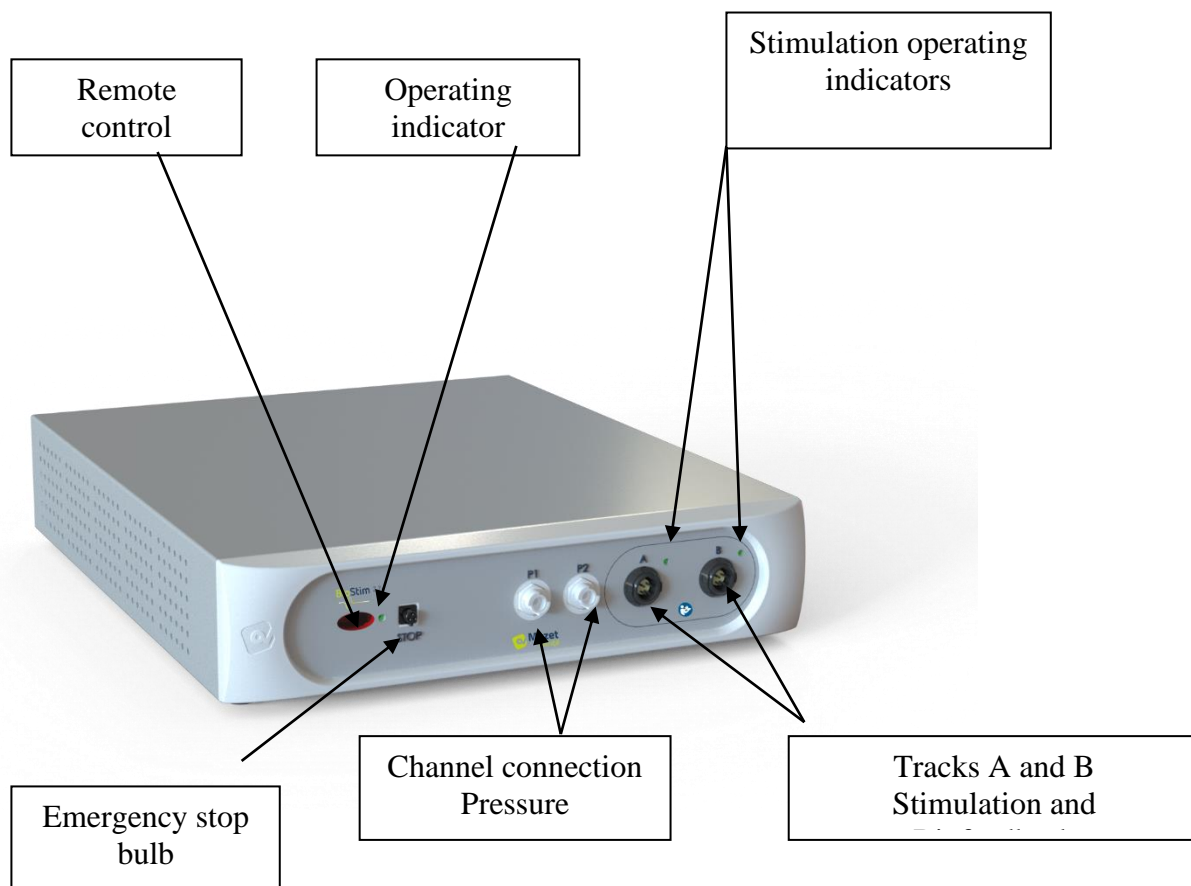
Place the Biostim on a table away from the patient's environment.

Place the PC on the same table and connect them using the USB cable. Connect one USB plug to the computer and the other USB plug to the back of the device.

Connect the power cord to the rear of the unit.

The practitioner positions himself between the patient and the device.

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

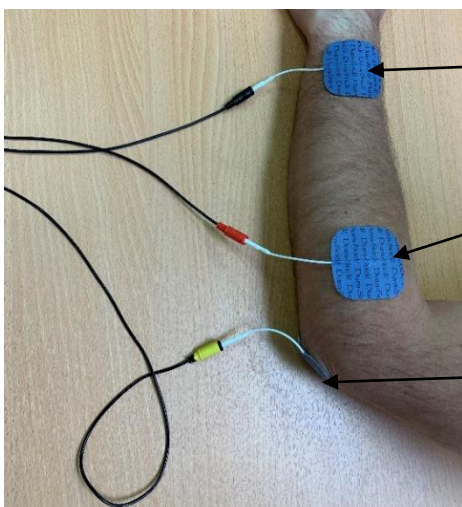


7.3 Connecting accessories

Connect the emergency stop bulb to the front panel.

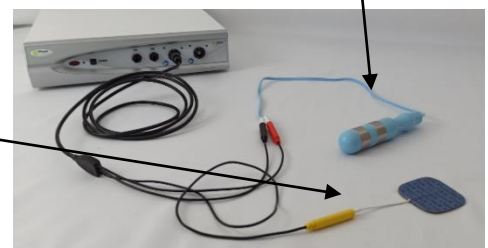


Connect the stimulation lead(s) to channel(s) A (and B) depending on the intended use.



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

For BFB, place the 3rd electrode (yellow tip) on a bony part (useless for stimulation).



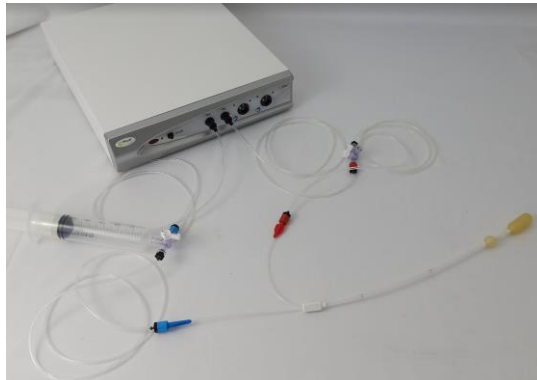
To use the pressure ports, connect the pressure kit to the pressure ports.

A single balloon probe (vaginal or anal) is then connected directly behind the tap, to the P1 port.



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

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



8 Software commissioning

8.1 Configuration

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

- Windows 10 or 11, or MacOS Monterey (version 12) or later
- 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, BlueBack, Emy or Perifit), you need a PC running **Windows 10 or 11** equipped with a BlueTooth card, or MacOS

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

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

8.2 Software requirements

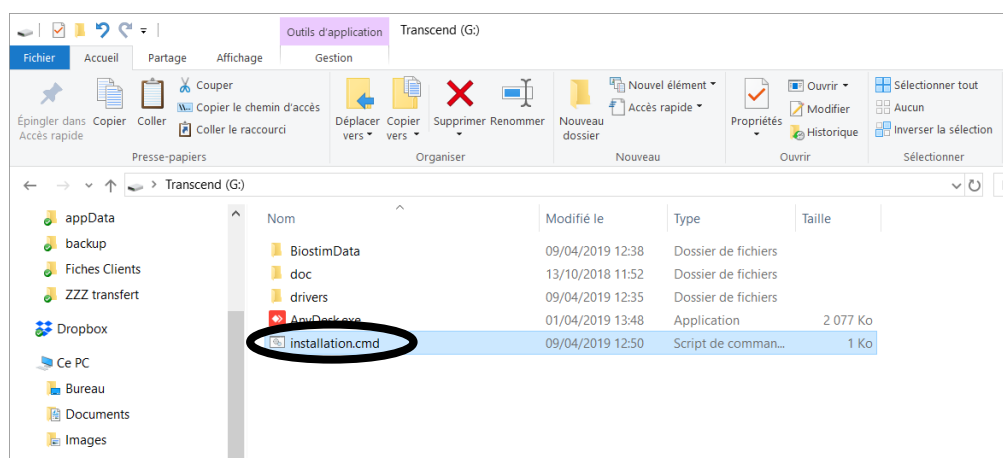
The following software must be installed on your computer:

- FTDI Driver (installation via CDM212xxx_Setup.exe supplied with 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.

8.3 Installation

Install the program on the desktop by double-clicking on the **installation** utility (or **installation.cmd**) available on the provided USB stick.



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

8.4 Mac OS

Run the Biostim_Installer.pkg program.

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

8.5 Start

Set the ON/OFF switch on the rear of the unit to ON "1".

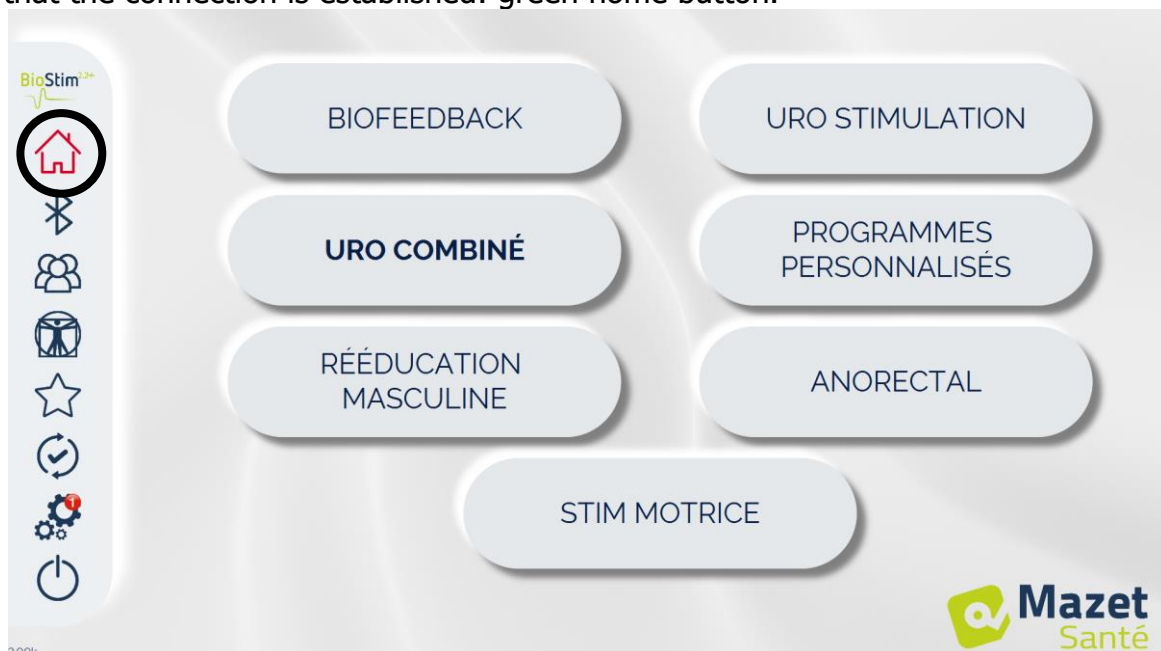
Check that the green power indicator light on the front of the unit is on.

Run the Biostim program on your computer.



8.6 Connection check

Check that the connection is established: green home button.



The **red** home button indicates a communication problem between the computer and the device. In this case, check the following points:

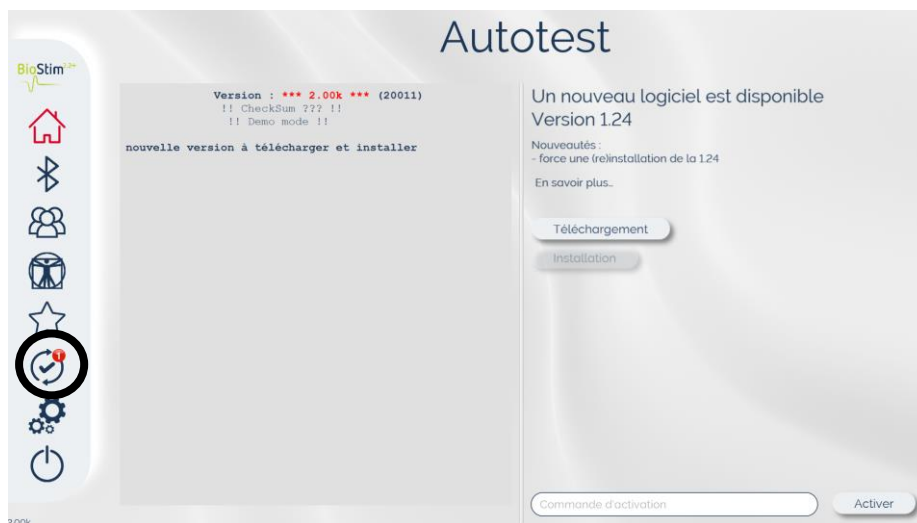
- The module is powered up, the green LED on the front panel is lit.
- The USB cable is properly connected to both the device and the computer.
- FTDI driver correctly installed (CDM212xxx_Setup.exe)

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

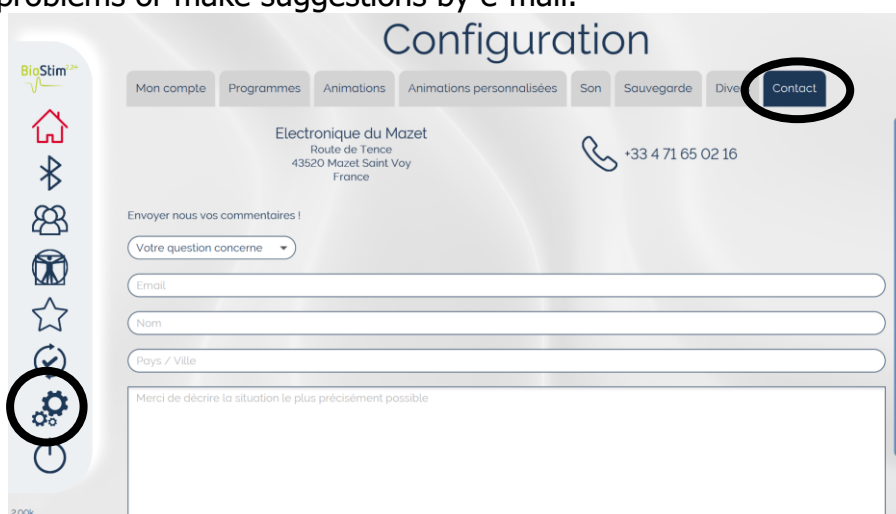
- Check that the emergency stop bulb is connected
- If the emergency stop has been activated, the BioStim must be restarted (on/off switch at the back of the unit).

8.7 In the event of a problem

Go to the Autotest tab. If a problem is detected, it will be indicated in red. If there is no internet connection, the autotest logo will be red.



If you need more assistance, go to the Contact tab on the configuration page, where you can report problems or make suggestions by e-mail.



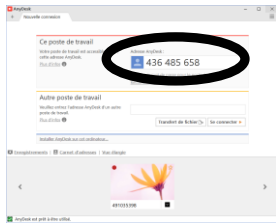
8.8 Remote control

During installation, AnyDesk software will be installed on the PC. It enables us to take remote control of the PC to manage an after-sales service.


A shortcut is available on the desktop



To authorize a technician to take control, you need to give him the login and password that appear in the window after launching the software.



8.9 Switching the device off

Disconnect the applied parts from the patient beforehand.
Quit the Biostim program on the PC: symbol 

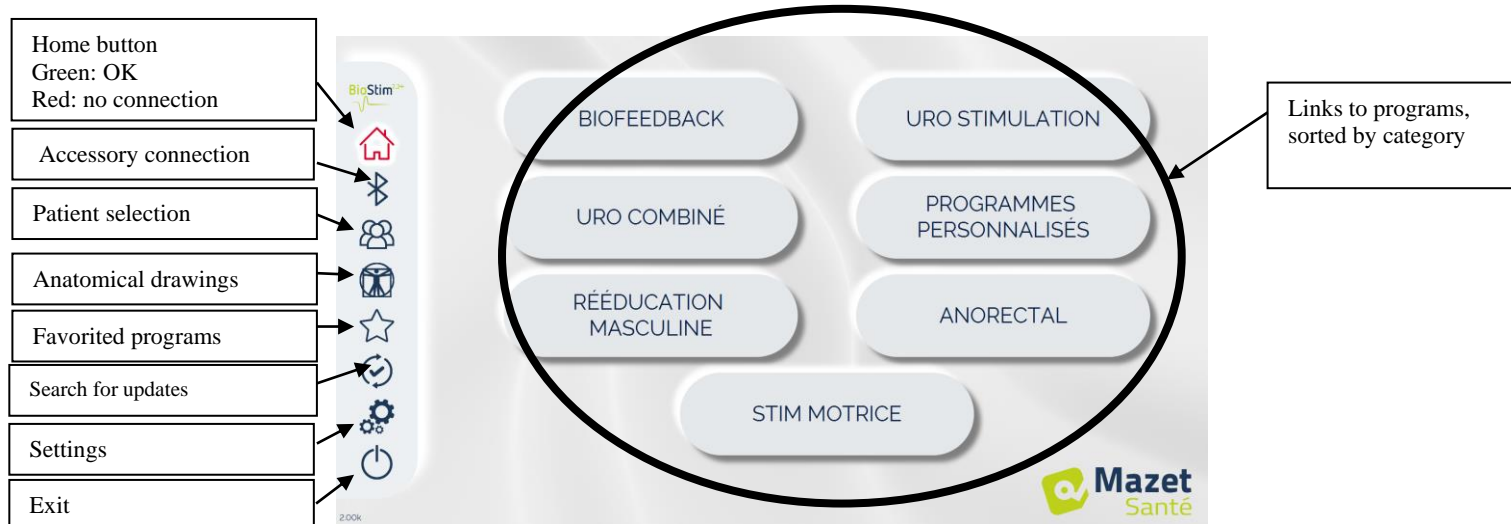


Set the on/off switch on the back of the unit to OFF "O".

9 User's manual

9.1 Home page

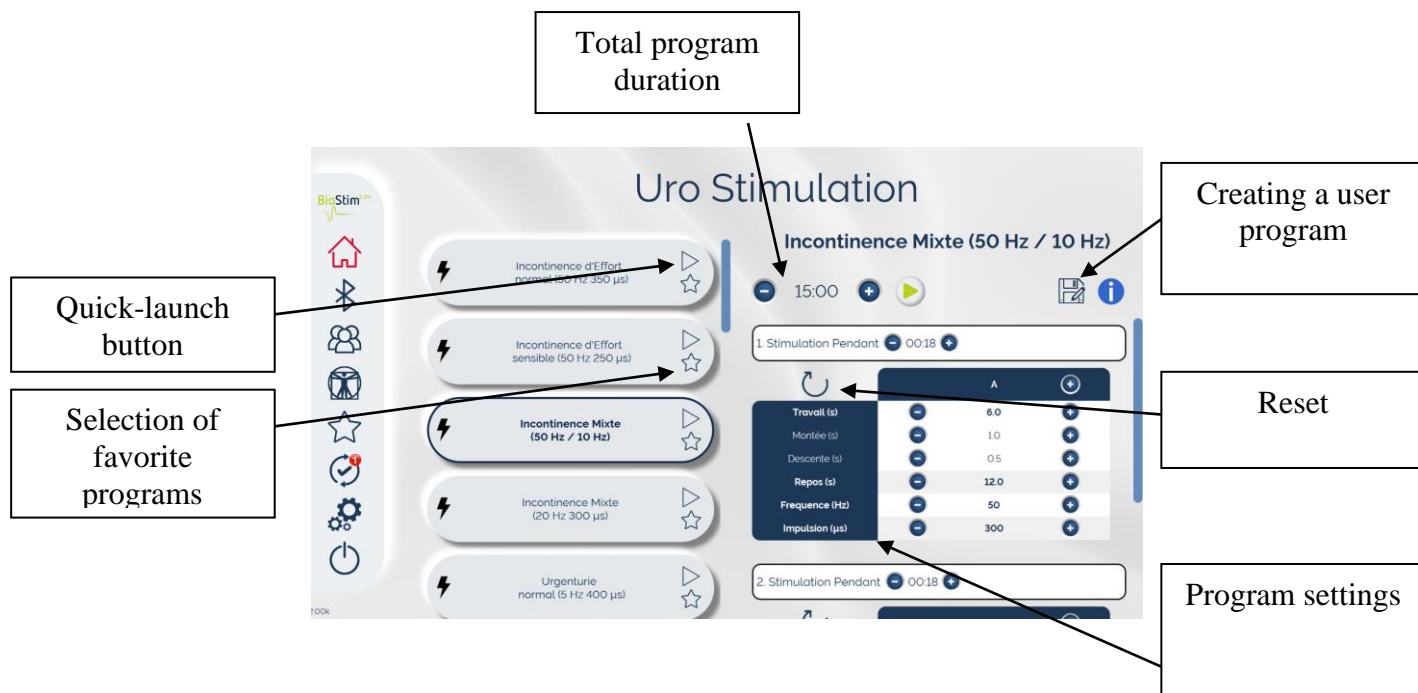
On launch, the software opens on the home page, giving access to all the device's functions.
From anywhere in the application, press the home button to return to this page.



You can rename a category by right-clicking on it.

9.2 Program selection and customization page

Clicking on a program category opens the program selection page.
This page displays a list of all the programs in a category.



The selected program is highlighted, and its description appears on the right-hand side of the page. This description contains :

- Program name
- Program duration
- A brief description

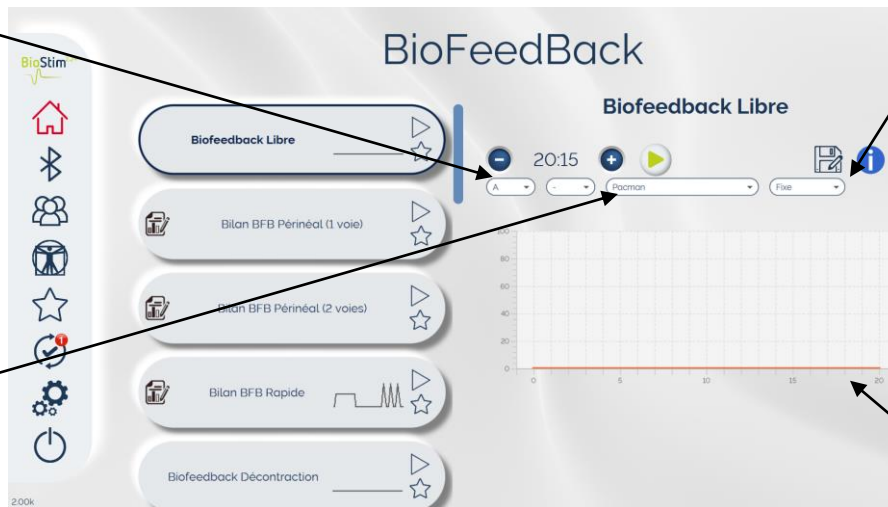
In the case of a stimulation program, the power parameters are also included.

In the case of a biofeedback program, these include

- biofeedback profile
- the choice of animation
- the option of displaying which channels will be used (1 or 2)

Choice of channels to be used for the primary and secondary pathways. EMG and pressure can be mixed


Choosing the type of animation to use



Selects whether the cursor or the background image moves

View exercise profile

Program settings can be adjusted using the  and  buttons.

Once the program has been customized as required, it can be saved using the  button. Saved programs can be recognized by their name, which begins with "U:". They are placed at the top of the program list.

9.3 Custom programs (except versions 1.0 and 2.0)

9.3.1 Simple sequences

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



9.3.2 Free Drawing

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



9.3.3 Drawing Objects

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

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



9.3.4 Chains

The chaining mode allows you to create a program by combining other programs. A profile is defined from other existing programs (predefined or saved by the user).



9.3.5 Random programs

Random mode creates a random program. Each time it is launched, a new profile is created by combining all the selected elementary patterns.





9.3.6 Combined programs

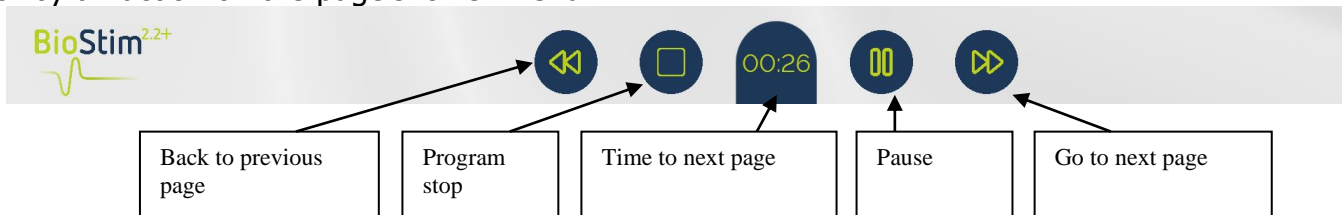
Combined mode lets you create your own programs integrating stimulation and BFB, in sequence with 2 other programs.



9.4 Launching a program



From the program selection page, you can launch a program by clicking on the  button in the program description section, or on the  icon in the upper right-hand corner of the program name.

A program is made up of one or more pages which are linked together after a predefined time or by an action on the page's lower menu.





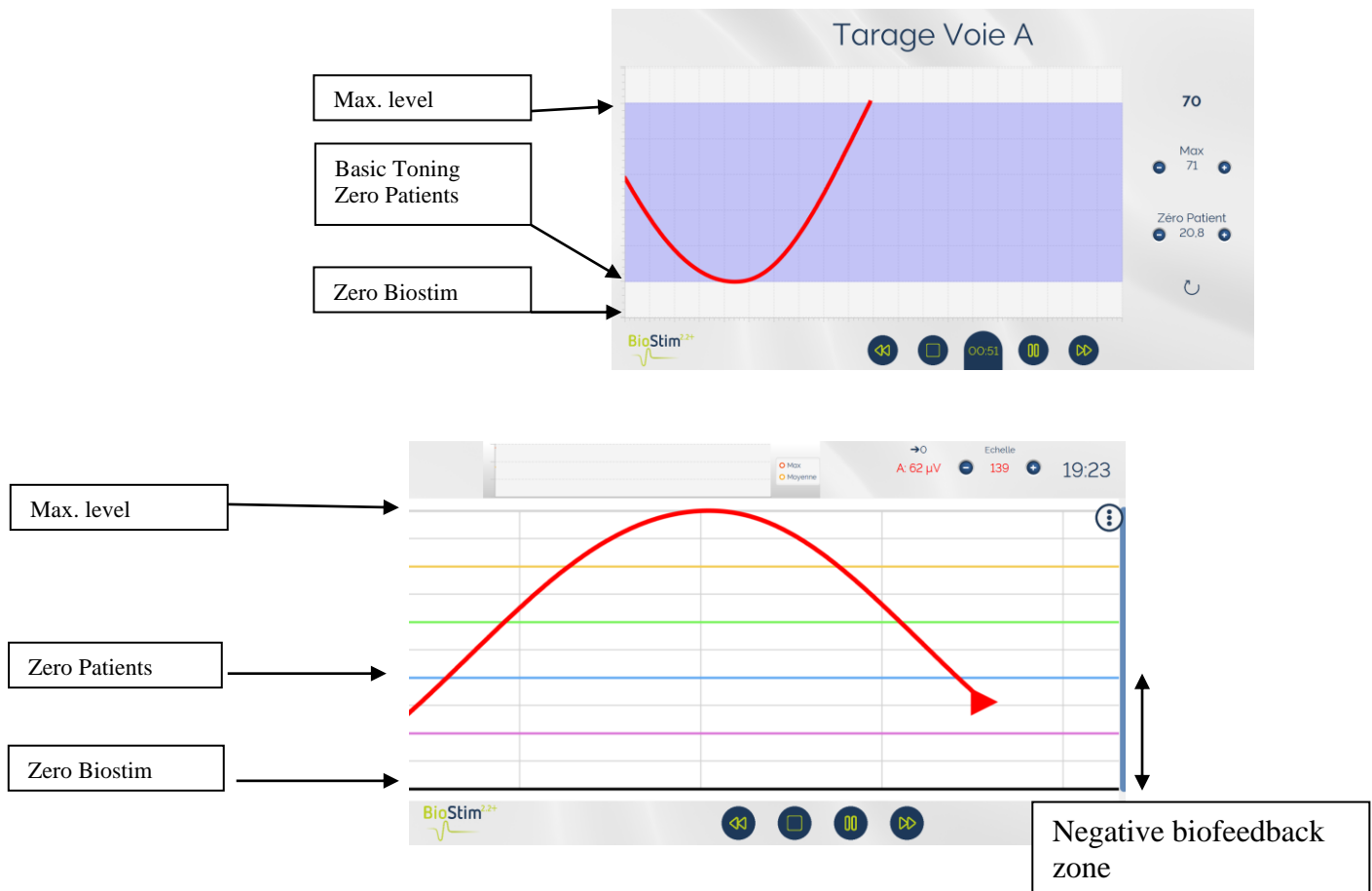
It is also possible to stop the program using the emergency stop bulb.

9.4.1 Taring Biofeedback

Taring works automatically. However, you can adjust the parameters calculated by the machine using the  and  buttons.

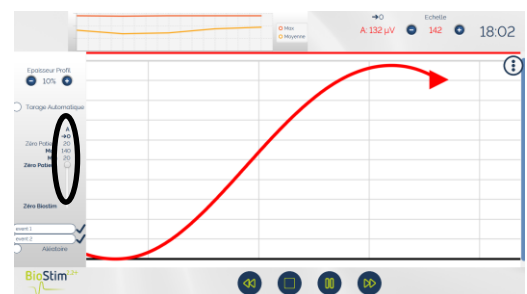
Taring procedure

- Place probe or the electrodes
- Start taring
- Ask the patient to make a sustained contraction (the gauges change automatically), then release the effort for a few seconds.
- BioStim automatically sets the operating range
- Go to next page by pressing arrow (or wait for taring time to end)
- During the exercise, it will still be possible to manually adjust the tare level using the  and  buttons at the top right of the page.



In the + version, you can adjust the level of negative BFB to be displayed during exercise, using the slider in the right-hand panel:

- Patient Zero: the bottom of the screen corresponds to the minimum reached by the patient during taring. This setting allows basic tone deletion.



- Zero Biostim: minimum measurable by the device: to work with negative BFB

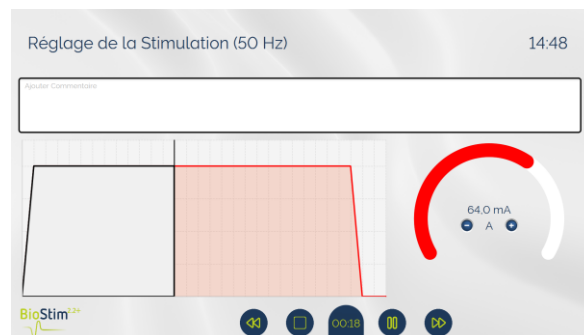


- Intermediate values can also be selected:

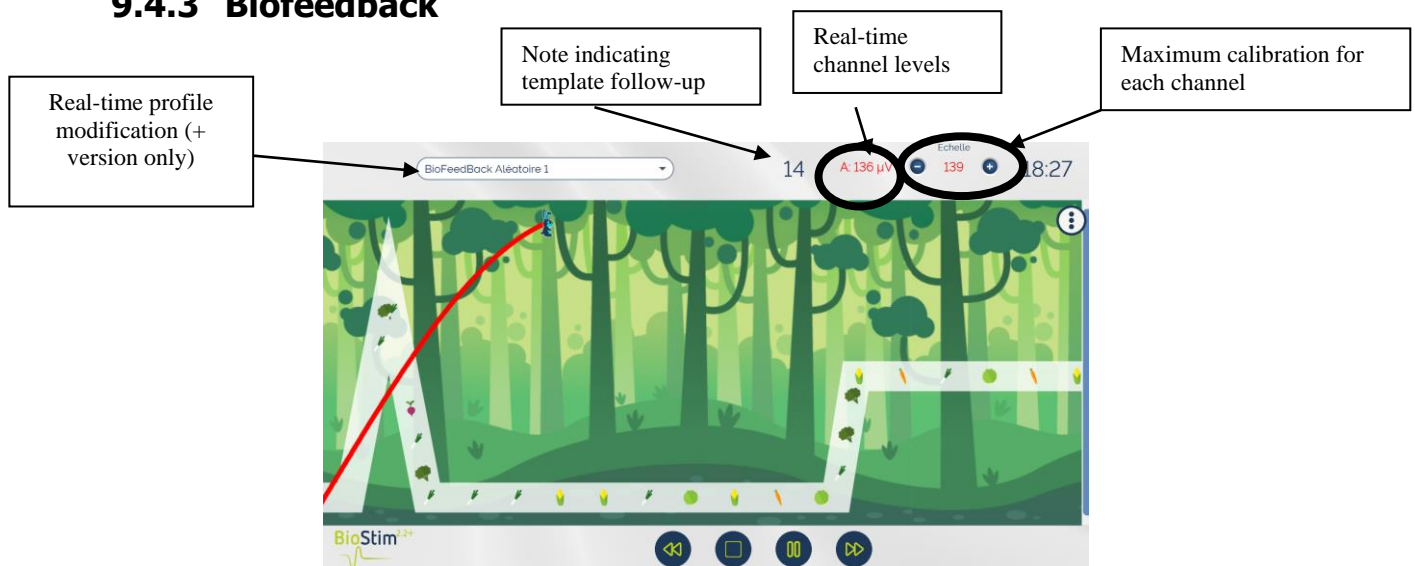


9.4.2 Stimulation

The stimulation level is adjusted channel by channel during program execution. It can only be increased during work phases.



9.4.3 Biofeedback



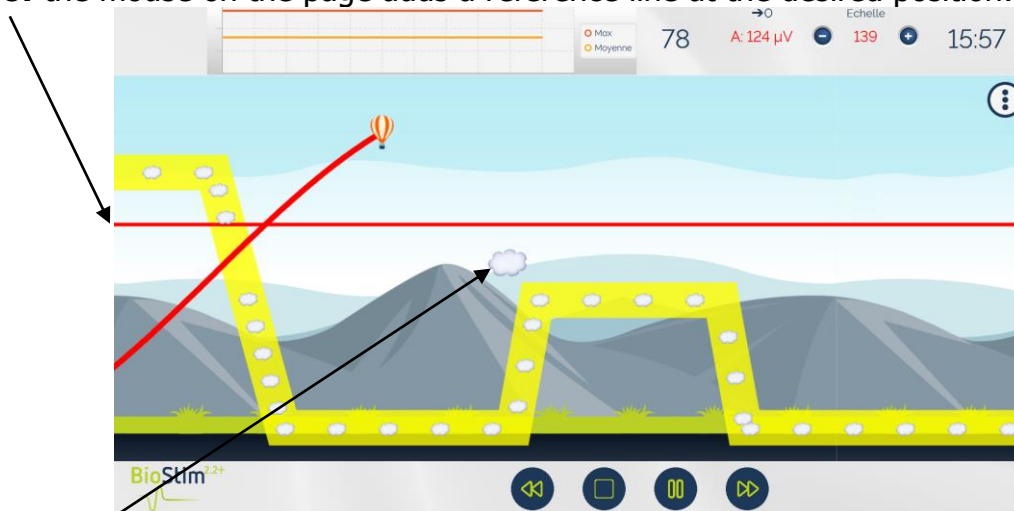
9.4.3.1 Zone selection menu

Pressing the button on the top right of the biofeedback pages opens a menu allowing you to select the zones you wish to display on screen



9.4.3.2 Position markers

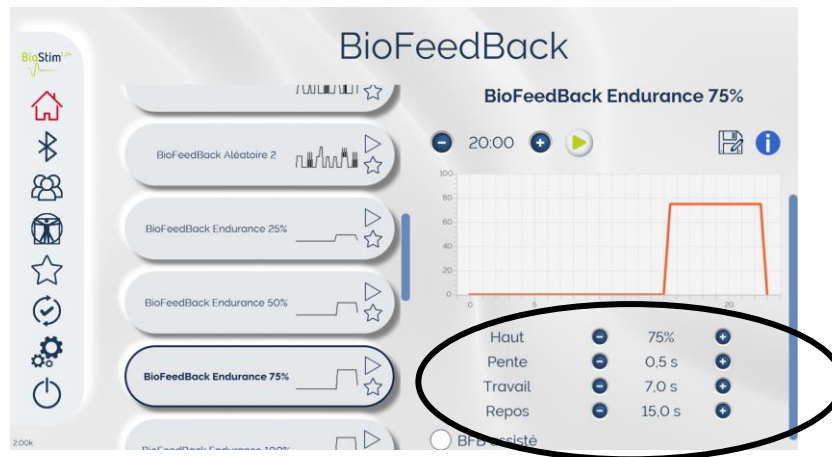
A click of the mouse on the page adds a reference line at the desired position:



Right-click on the screen to add a time marker or an object to the screen (choose from the configuration menu).

9.4.3.3 Adjustable mode

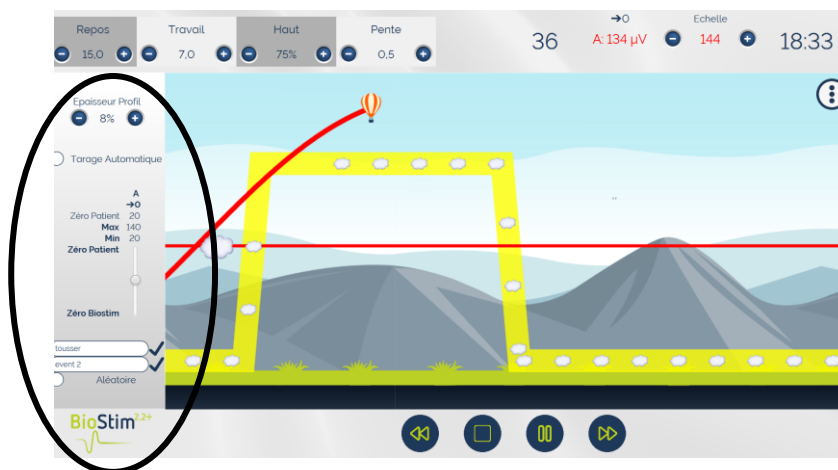
When biofeedback has been created in adjustable mode, it is possible to modify the shape of the curve using the buttons on the right of the screen when selecting the program. This adjustable function is available on the BioFeedBack Endurance menus.



If you adjust the curve when selecting a program, the buttons for modifying the curve during the program will appear at the top of the screen.



9.4.3.4 Side Panel



This panel allows you to set :

- Profile thickness
- Automatic calibration: adjusts the base and maximum levels to the amplitude reached by the patient (allows taring to be adjusted during exercise).
- "Patient zero" setting for each channel (→ 0)
- Negative BFB level, using the sliders on each channel

- You can add events to the curve (which will also appear in the history). You can name the events. You can also add events by right-clicking on the screen.

9.4.3.5 Trend line

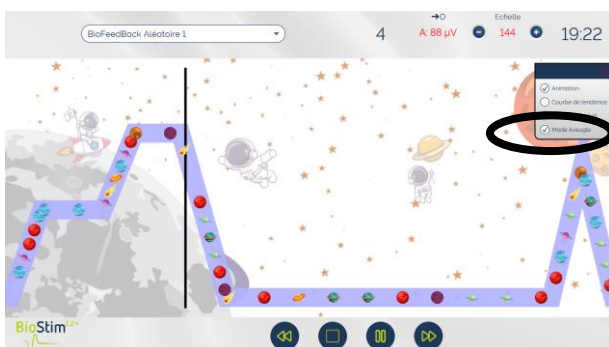


A trend curve can be displayed via the zone selection menu. This curve shows at a glance the evolution over the session of maximum and average contraction for each profile.

Durée	Max Stim	Amplitude Min/Tonus/Max	Réussite
03/04/25 : BioFeedBack Endurance 25%		20 / 20 / 140	60

This curve is then displayed in the session summary table in the patient file.

9.4.3.6 Blind work

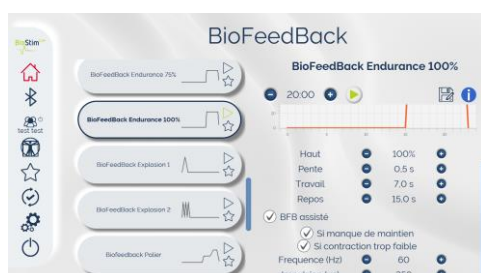


A blind mode is available to work without having the contractions returned to the screen.

This mode is activated during the session, in the zone selection menu. Curves are recorded and can be analyzed at the end of the session.

9.4.3.7 Assisted biofeedback

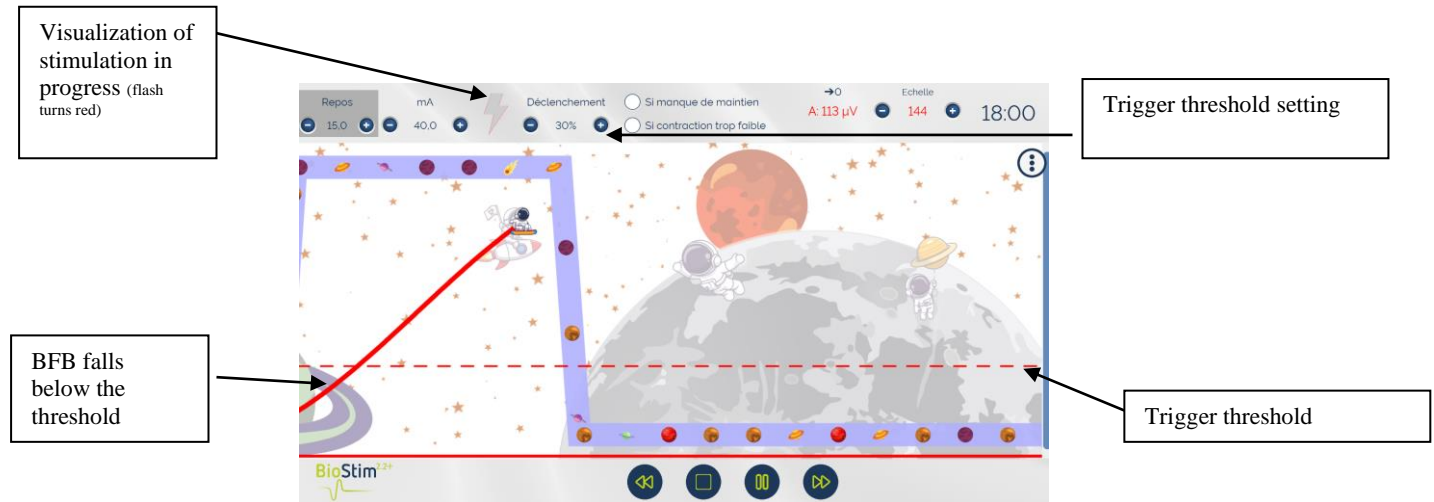
This mode, available for adjustable programs, can be activated either before starting the program, or from the side panel.



The stimulation then reinforces the muscular work:

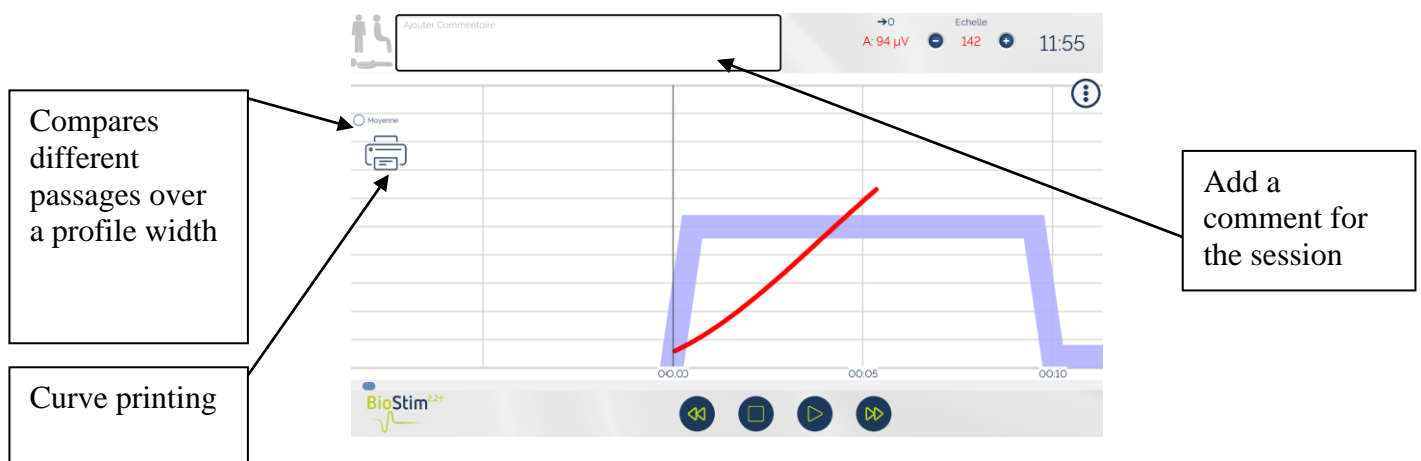
- Either on a lack of support: a good start to the contraction, but insufficient support at the end of the plateau.

- Or on a contraction that is too weak: detection of a contraction, but insufficient to reach the plateau.

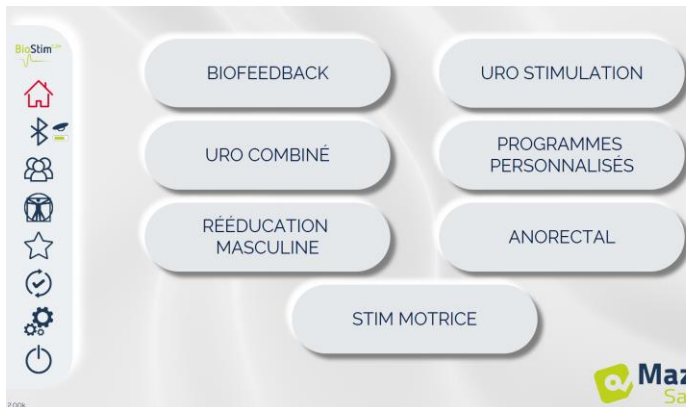


9.4.3.8 Review mode

At the end of the program (or by pressing the pause button), you switch to review mode. In this mode, you can print the curve by clicking on the printer in the top left-hand corner.



9.4.4 Using a Bluetooth accessory



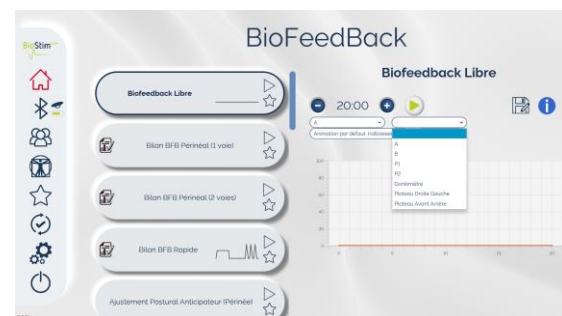
The BT function is integrated in version 2.2+ and available for purchase with all other versions.

Biostim is compatible with many of the accessories defined in §3.9.4.

To work with a BT accessory: switch it on (button on the white part of the Perifit, or shake the Emy probe), then click on the Bluetooth logo (below 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 available battery power.

The accessory is then used in the same way as the other probes, by selecting the channel to be used corresponding to the probe in the BFB menu.

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



9.5 Favorite programs

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

To do this, simply click on the ☆ icon in the lower right-hand corner of the program name.

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

9.6 Anatomical drawings (except version 1.0)


Anatomical drawings are available. Click on the image to open it in a viewer, which can be zoomed in or switched to full-screen mode for better visibility.


You can add your own anatomical boards by clicking on the "add board" button. You can choose image or video files on your computer, or links to videos on the Internet (especially YouTube).

We thank the universities of Lille 2 and Lyon 1 for permission to insert a link to their 3D anatomical plates.



9.7 Select a patient (except version 1.0)

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


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 activating the "Show archived patients" checkbox.

In this case, archived patients have a green archiving icon, while other patients have a blue one.

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

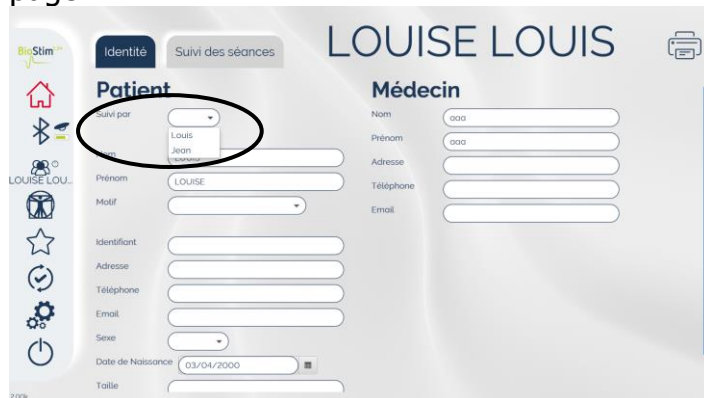


The anonymous display hides the patient's full first and last names; only the initials are visible. Select a patient by clicking on their name. Once a patient has been selected, their name appears in the menu on the left of the page. To disconnect, simply click on the deselect button  to the right of the name.



9.7.1 Multi-practitioner mode (except version 1.0)

Multi-practitioner mode can be activated in the configuration page for version 2.2+ only. If this mode is activated, it is possible to assign a patient to a practitioner in the patient overview page.



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



9.8 Patient file (except version 1.0)

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

This form contains patient data (name, first name...), as well as a graph and table showing the follow-up of all patient sessions.

It is also possible to add :

- Text comments
- Standard assessment forms to help you take stock of your patient's situation.



Follow-up form
(right-click to delete)

Addition of a new
form to the patient file:
either pre-signed or
free (letter, medical
examination, etc.).

All sessions are recorded. The results are displayed in the form of a graph, for quick visualization, and in a more comprehensive table that reproduces all session data. To delete a recording, right-click on the date or program name.




	Durée	Max Stim	Amplitude Min/Tonus/Max	Réussite
03/04/25 : Biofeedback Libre	00:21		22 / 20 / 140	A
03/04/25 : Biofeedback Décontraction	02:02		20 / 107 / 140	A
03/04/25 : Commentaire	seance du 03/04			
03/04/25 : BioFeedBack Endurance 100%	00:57		20 / 20 / 140	A

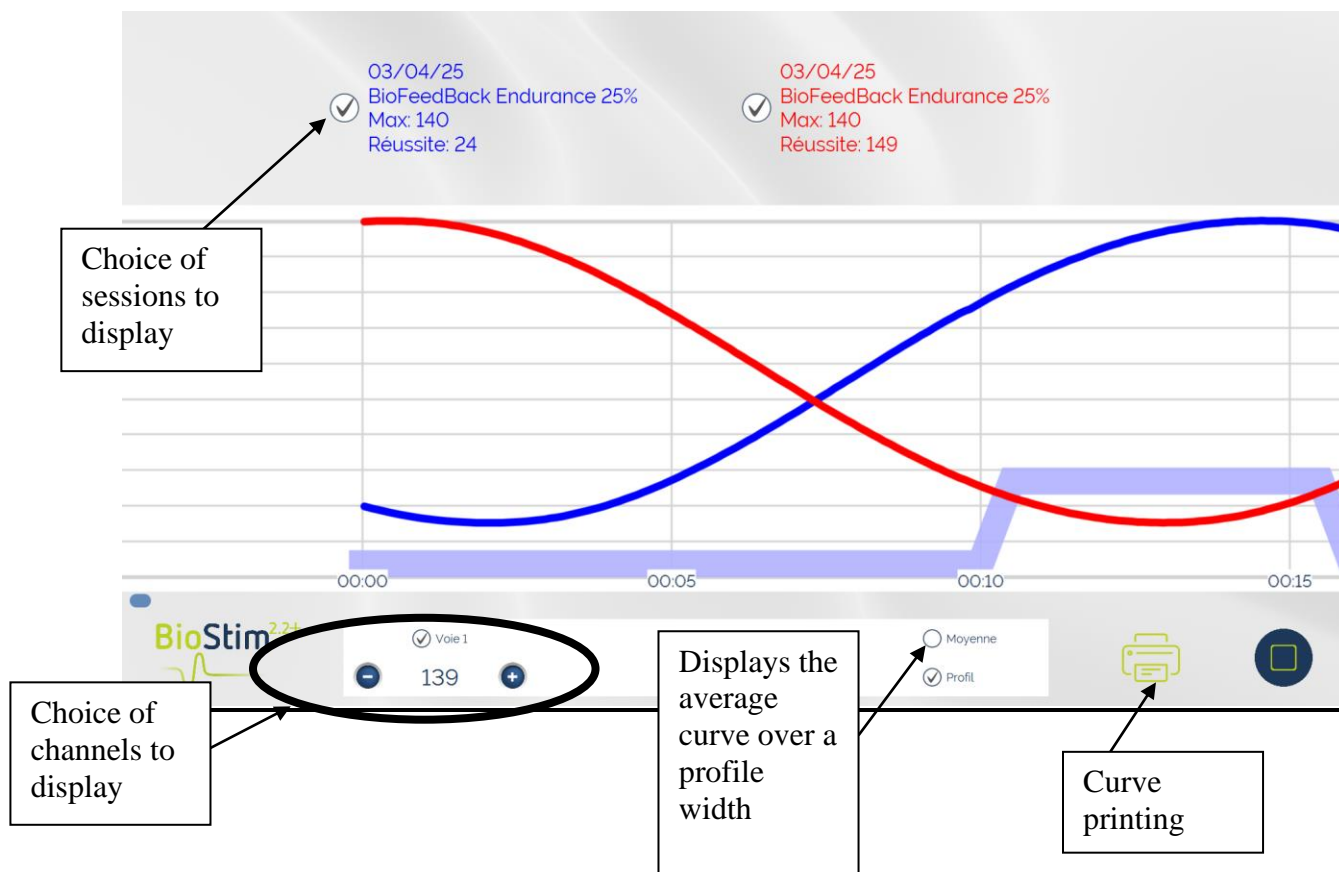
Selects the curves you
wish to review (+
version)

Relaunch the same
program

Free comments
(right-click to delete)

9.8.1 Curve comparison (version 2.2+)

Pressing the  button in the session table opens the session comparison page (version 2.2+ only).



Right-click in the drawing area to select a portion of the curve to be printed.

9.9 Biostim Cloud

If the computer is connected to a network :

- Sessions are collected anonymously
- You are notified of new versions, and can install them directly from the software.



9.10 Configuration page

The configuration page is used to configure the software. The available options are :

- Scroll speed: speeds up or slows down biofeedback scrolling.
- Display channels on separate graphs
- Rest time before or after working hours for BFB
- Automatically start BFB after taring: if this option is not enabled, the cursor waits for the start button to be pressed at the start of BFB: no scrolling until this button is pressed.
- Force cursor display on curves
- Animation selection: you can select the animations you wish to use. Unchecked animations will no longer be visible in the program presentation 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: type Evolys 3P from Sugar International)
- Choice of profile thickness
- Choice of action for right-click on screen during BFB (add object/add event)
- Sound management: choice of end-of-program music, possibility of adding a sound for transitions between BFB and stimulation, sound BFB (for visually impaired patients), sound indication for start and end of contraction. All these sounds are user-configurable.
- Creation, modification and deletion of a custom animation: requires a background image, an image for tracking each track, and one or more objects to catch (except for version 1.0).

9.10.1 Networking multiple devices (except version 1.0)

To network 2 (or more) devices, they must be on the same network, and have a common shared directory (e.g. T:\biostim).

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

10 Maintenance, upkeep

The device is designed to last 5 years.

To ensure that the performance of the device is maintained throughout its lifetime, it is essential to have the device checked by Électronique du Mazet technicians every 2 years.

Only Électronique du Mazet technicians or its authorized distributors are authorized to carry out maintenance and repair operations on the device.

10.1 Housing and accessories

The casing requires only normal, periodic cleaning of its external surface, which may become soiled. The same applies to the accessories.

Clean only with a dry or slightly damp cloth.
Be sure to unplug the power cord before cleaning.

10.2 Associated devices

Associated treatment devices must not be placed in direct contact with the patient's skin.

10.3 Sterilization :

This device is not sterile
Accessories are not sterile, nor are they intended for sterilization.

11 Malfunction

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

When shipping the unit, please observe the following instructions:

- Decontaminate and clean the unit and its accessories.
- Use original packaging, including retaining flanges.
- Include all accessories.
- Set the various elements.
- Make sure the packaging is securely closed.

Shipping address :

**Électronique du Mazet
ZA Route de Tence
43520 Le Mazet St Voy
FRANCE
Tel: (33) 4 71 65 02 16
E-mail: sav@electroniquedumazet.com**

Possible malfunctions :

Anomaly description	Possible causes	Actions
Green indicator light off	- power grid problems - fuses	- check mains voltage - check and replace fuses
No communication with PC (home button = red house)	- USB adapter	- check connections - check that the FTDI driver is correctly installed (CDM21228_Setup.exe)
No stimulation observed, but the yellow LEDs light up.	- bad contact - defective cable	- check patient connections. - swap cables for checking
No stimulation and yellow LEDs do not light up.	- loss of communication with the module. - stimulation current parameters are not consistent.	- exit the current process and return to the main office. - check and modify parameters.
Flat trace in biofeedback windows	- loss of communication with the module. - no sensor on the input in question	- exit the current process and return to the main office. - check the route used
Need to increase stimulation current beyond usual values with elastomer electrodes.	- old electrodes - insufficient gel	- change electrodes. - add contact gel
Automatic decrease of amplitude slider.	- old electrodes - insufficient gel - pulse width too long.	- change electrodes. - add contact gel - change program for lower pulse width.
Saturated or very noisy EMG biofeedback signal	- reference electrode missing or in poor contact	- check that the 3 rd electrode is correctly attached. Check electrode quality, replace if necessary.

In the event of the device being dropped or penetrated by water, it is imperative to have the device inspected by Électronique du Mazet to exclude any risk (patient and user) associated with the use of 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 may be used.
- Any modification, repair, extension, adaptation or adjustment of the device must be carried out by Électronique du Mazet or its authorized distributors.
- The working environment complies with all legal and regulatory requirements.
- The unit may only be operated by competent and qualified personnel. Use must comply with the instructions in this manual.
- Treatments are to be used only for the applications for which they are intended and which are described in this manual.
- The unit must be serviced regularly in accordance with the manufacturer's instructions.
- All legal requirements concerning the use of this device are complied with.
- Accessories used on the Device are only the ones supplied or specified by the manufacturer.
- Machine parts and spare parts must not be replaced by the user.

Inappropriate use of this device or neglect of maintenance releases Électronique du Mazet and its authorized distributors from all liability for defects, breakdowns, malfunctions, damage, injury and the like...

Failure to comply strictly with the operating instructions contained in this manual will invalidate the warranty.

The warranty period is 24 months from the date of delivery.
Accessories have a 6 months warranty from the date of delivery.
Transport and packaging costs are not included in the warranty.

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

13 Disposal

As soon as any deterioration is detected, the product must be cleaned with a broad-spectrum disinfectant and returned to the manufacturer.

If the appliance becomes inoperative or unusable, please return it to the manufacturer or take it to a collection point .[ecosystem](https://www.ecosystem.eco)

As part of its commitment to the environment, Électronique du Mazet finances the [ecosystem](https://www.ecosystem.eco) recycling channel dedicated to WEEE Pro, which takes back free of charge electrical lighting equipment, control and monitoring equipment, and used medical devices (more information at www.ecosystem.eco).



14 Transport and storage

The unit 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 can provide you with the CE declaration for this device on request.

The first affixing of the medical CE to this device took place on 14/12/2018.

16 Manufacturer

Électronique du Mazet is a company located in the heart of the Massif Central. Originally a simple manufacturer of electronic boards, over the years it has developed its own brand of medical devices, mainly for physiotherapy.

Today, EDM designs, develops, manufactures and markets pressotherapy, depressotherapy and electrotherapy (perineal rehabilitation) equipment.

For further information, please do not hesitate to contact us.

***SAS Électronique du Mazet
ZA Route de Tence
43520 Le Mazet St Voy
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www.electroniquedumazet.com

17 EMC compliance table

EMC compliance to IEC 60601-1-2 (2014) 4th Edition (EN 60601-1-2 : 2015)			
BIOSTIM is designed 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. As a result, its RF emissions are very low and unlikely to cause interference in nearby electronic equipment. 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.
RF emissions CISPR 11		Class B	
Harmonic emissions IEC 61000-3-2		Class A	
Voltage fluctuations / Flicker flicker IEC 61000-3-3		Compliant	

EMC compliance 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 discharge (ESD) IEC 61000-4-2	± 8 kV 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 in bursts IEC 61000-4-4	± 2 kV for lines power supply electric ± 1 kV for lines input/output	± 2 kV for lines power supply electric	The quality of the power supply network should be that of a typical commercial or hospital environment.
Surge voltage transitional IEC 61000-4-5	± 1 kV phase-to-phase ± 2 kV phase-to-earth	± 1 kV phase-to-phase ± 2 kV phase-to-earth	The quality of the power supply network should be that of a typical commercial or hospital environment.
Tension dips, short cuts and variations tension on input lines power supply electric 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: 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: 0 degrees 0% UT: 250/300 Cycles	The quality of the power supply should be that of a typical commercial or hospital environment. If the BIOSTIM user requires continuous operation during power cuts, it is recommended to power the BIOSTIM from an uninterruptible power supply or battery. NOTE: UT is the AC mains voltage before the test level is applied.
Magnetic field to the frequency of the power grid (50/60 Hz) IEC 61000-4-8	30 A/m 50Hz or 60Hz	30 A/m 50Hz or 60Hz	Magnetic fields at mains frequency should be at levels typical of a representative location in a typical commercial or hospital environment.

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
RF line 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	Hand-held and mobile devices from RF communications are not used closer to any part of the BIOSTIM , including cables, than the recommended separation distance, calculated from the equation applicable to the frequency of the 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 transmitter's maximum output power characteristic in watts (W), according to the transmitter manufacturer, and d is the recommended separation distance in meters (m). The field strengths of fixed RF transmitters, determined by on-site electromagnetic investigation a, should be below the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF interference IEC 61000-4-3, including clause 8.10, table 9, for proximity of wireless devices	3 V/m 80 MHz to 2.7 GHz 80% AM at 2 Hz including clause 8.10, table 9, for proximity of wireless devices	3 V/m 80 MHz to 2.7 GHz 80% AM at 2 Hz including clause 8.10, table 9, for proximity of wireless devices	
<p>NOTE 1 At 80 MHz and 800 MHz, the highest frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects and people.</p> <p>a) The field strengths of fixed transmitters, such as base stations for radiotelephones (cellular/wireless) and land mobile radios, amateur radio, AM and FM 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 normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or repositioning the BIOSTIM.</p> <p>b) Beyond the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.</p>			

Recommended separation distances between portable and mobile de RF communications andBIOSTIM			
<p>The BIOSTIM is intended for use in an electromagnetic environment in which radiated RF interference is controlled. The customer or user of the BIOSTIM can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BIOSTIM, as recommended below, depending on the maximum emission power of the communications equipment.</p>			
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
<p>For transmitters whose rated maximum transmit power is not given above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the transmitter frequency, where P is the transmitter's maximum transmit power characteristic in watts (W), according to the transmitter manufacturer.</p> <p>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the highest frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects and people.</p>			



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Your dealer / distributor :



[www.facebook.com/MazetSanteFrance/
mazetsante.fr](https://www.facebook.com/MazetSanteFrance/mazetsante.fr)