

User Manual



Electrotherapy Device
Biostim 2.2 / 2.2 +
BioStim 2.1 / 2.1+
BioStim 2.0 / 2.0 +
Biostim 1.0

Instructions for Use & Technical Description

**Please read this entire 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 device was designed and manufactured for
therapeutic use.**

**Only physiotherapy professionals and midwives with
proper training are authorised to use this device.**

**In the event of a breakdown, or if you have questions that are not
answered in this manual, please contact your distributor (see stamp on
last page) or Électronique du Mazet at:**

Tel.: (+33) (0)4 71 65 02 16 - Fax: (+33) (0)4 71 65 06 55

**Please complete the warranty certificate within the 15 days following
installation or reception.**

1. Device Presentation

The Biostim is an electrotherapy device that physiotherapists and midwives employ in perineal re-education.

Biostim's computerized technology and user-friendly menus make it very easy to use.

The device's pre-set programmes allow you to perform most perineal re-education treatments, and treatments in the urogynaecological and anorectal fields.

The main pre-set programmes are:

- Urogynaecological biofeedback, EMG or Pressure
- Urogynaecological stimulation
- Urogynaecological programmes that combine biofeedback and stimulation
- Analgesia for use in urogynaecology
- Programmes for anorectal stimulation and biofeedback

The device also allows you to track each patient individually by recording the sessions carried out and their results, letting you add comments, and providing links to tracking forms.

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2. Description and Technical Information

- This manual was written to facilitate the use and maintenance of your Biostim device, from reception, to commissioning, to the successive stages of use, to maintenance. If you have questions that are not answered in this manual, please contact the manufacturer, Électronique du Mazet, or your dealer or distributor.
- This document must be kept in a safe place, protected from the elements, where it will not be damaged.
- This document ensures that the devices and their documentation are up-to-date technically at the time of sale. However, we reserve the right to make changes to the device and its documentation, without obligation to update the present documents.
- In the event that the device is transferred to a third part, you must provide Électronique du Mazet with the contact details of the device's new owner. It is imperative that you provide the new owner with all of the device's documents, accessories, and packaging.
- Only personnel who have read the present document are authorised to use this device. Non-compliance with any of the instructions contained in this document exempts Électronique du Mazet and its authorized distributors from the consequences of accidents or injury to personnel or third parts (for example, patients).

2.1 Symbols Used



Warning: This symbol draws your attention to a specific point.



Operating Instructions: This symbol informs you that the operating instructions must be read in order to use the device safely.



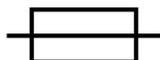
Applied Part, Type B: Applied part that comes in contact with the patient and can be earthed.



Recycling: This device must be disposed of at an appropriate recovery and recycling facility. Contact the manufacturer.



Protective Earth



Fuse



Warning: Device Stop / Start



Alternating current



Serial number



Manufacturer



Date of manufacture



Country of manufacture



Product reference

2.2 Technical Specifications

2.2.1 General Characteristics

- Operating temperature: 0°C to 40°C.
- Storage temperature: -40°C to 70°C.
- Operating relative humidity: 30% to 75%.
- Operating altitude: < 2000 metres

2.2.2 Technical Specifications of the Device

- Dimensions of housing: **33.7 x 28 x 6.7 cm**
 - Weight of housing: **3.1 kg**
 - Housing colour: **white**

 - Electrical power supply: **110-230 VAC – 50-60 Hz**
 - Absorbed power: **40VA max (230VAC)**
 - Fuses: **2x size 5x20mm - T1.6AH-250V**
 - **Class I** electrical device
 - **Class IIa** medical device
 - Type **BF** Applied Part
 - Liquid Ingress Protection Rating: **IPX0**
 - Communication with computer: Optically isolated **USB**
 - Green "ON" indicator light on front panel.
 - It is possible to connect a handheld emergency stop that stops stimulation.

 - 2 stimulation tracks (A and B)
 - Current generator:
 - The output currents for each generator are adjustable from **0 to 100 mA** (+/-10%)
 - Under a load impedance of 1k Ω (or more), at the max. current, the tension is **limited to 100V** +10%-20% (peak value)
 - Under a load impedance inferior of 1k Ω , the tension level is limited according to the impedance (10 Volts for 100 Ω , 50 Volts for 500 Ω)
 - In the case of a too high impedance (above 10k Ω), the current can be cut of: function electrode removed
- ⇒ Rectangular signals are biphasic (mean-zero symmetric impulsions), the impulsion width is adjustable from **15 μ s à 10ms**, the frequency is adjustable from **1Hz to 5kHz**.
- ⇒ The two generators are electrically independent, no current passes between the two electrodes of the two generators.
- ⇒ Yellow LED indicates the output's activation state
- 2 biofeedback tracks (A and B).
 - Full-scale sensitivity: 2mVcc
 - 0, 1 or 2 Biofeedback pressure track
 - Sensibility range: **400mBar**

2.2.3 Biostim different versions

The functionalities of the different versions of the Biostim are the following:

	Number of EMG tracks	Number of pressure tracks
Biostim 1.0	1	0
Biostim 2.0	2	0
Biostim 2.1	2	1
Biostim 2.2	2	2

Each version (except the version 1.0) can have the optional functionalities of the software (+ version). Those functions are described in the section 7.3.

To activate the + version, enter the activation key in the debug page (click on the monkey wrench in the configuration page).

2.2.4 Accessories

The standard version of this device comes with the following accessories:

- MEG010EN601 cable for A and B tracks Biostim
- MEG010EN603 Handheld emergency stop Biostim
- MEG010EN605 Blue pressure kit Biostim (option)
- MEG010EN606 Red pressure kit Biostim (option)
- EM6055KP504 Infrared remote control (option)
- USB2-102B USB cable 2m blue or grey
- USB KEY 2.0 1 Go (PC Software / Drivers USB)
- Power cord
- User manual

2.2.5 Applied Parts

Applied parts include vaginal probes, rectal probes, and electrodes. They are not supplied with the device.

The following products are compatible with the device:

- Dura-Stick® Plus Self-Adhesive Electrodes for stimulation (DJO Global) CE 0473
- Saint-Cloud Classic vaginal probe (DJO Global) CE 0473
- PINK Perifit probe (Perifit)
- Emy probe (Fizimed)

The use of products not recommended by the manufacturer exempts the manufacturer from liability.

Make sure to respect the hygiene conditions recommended by the applied parts manufacturer.

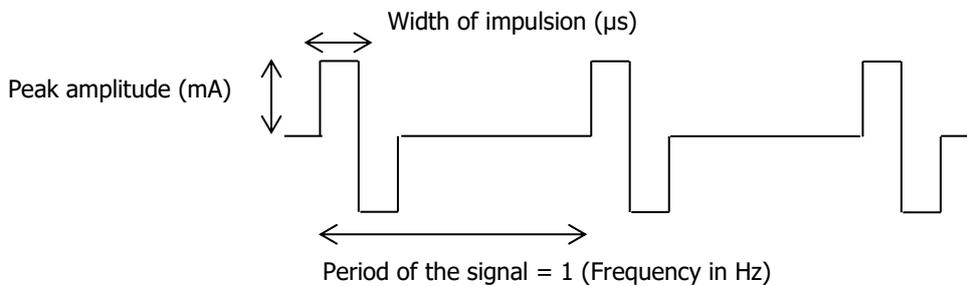
The user must be careful and adapt the size of the electrodes to the zone to treat.

2.2.6 The currents form

Rectangular biphasic impulsions

The current is mean-zero biphasic symmetric:

- the positive and negative impulsions have the same width and time



Frequency of the impulsions	Peak amplitude maximum
≤ 400Hz	50mA
> 400Hz to ≤ 1500Hz	80mA
> 1500Hz	100mA

(Amplitude values assured for an impedance span from 200Ω à 2kΩ)

The form of the wave is a constant current and it does not depend on the value of the load.

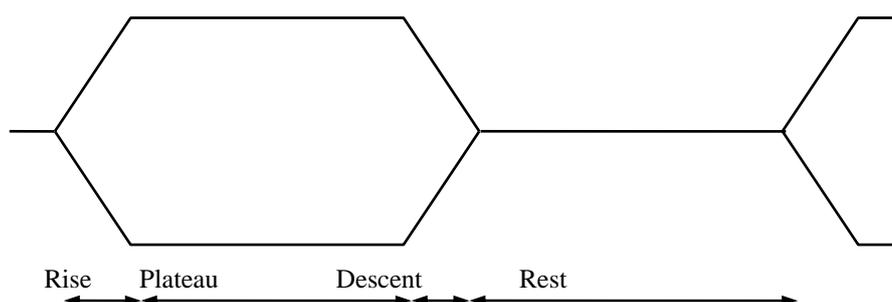
The width of the impulsion is adjustable from **15µs to 10ms**, the frequency is adjustable from **1Hz to 5kHz**.

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

The current I_{RMS} (in mA) = I_{peak} (in mA) × 2 × the width of impulsion (in s) × frequency (in Hz)

Generation of the envelopes:

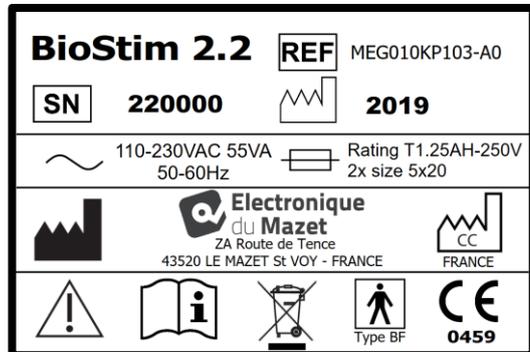
The impulse signal is included in an envelope that make an application and a progressive stop of the current.



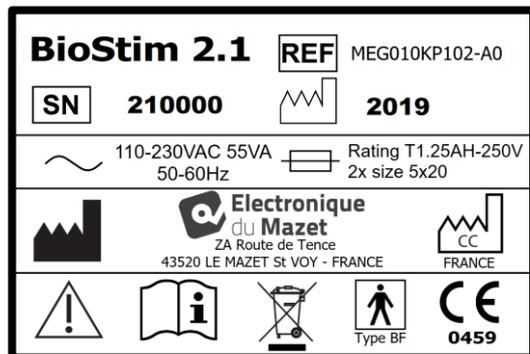
2.3 Nameplate Label

The nameplate label on the back of each device provides information and characteristics.

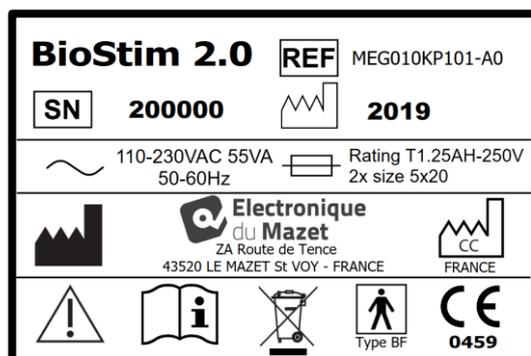
Label of the "Biostim 2.2" or "Biostim 2.2+":



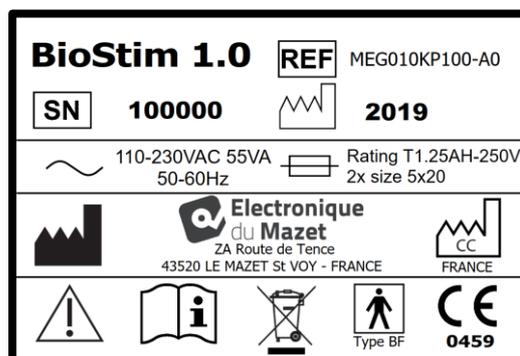
Label of the "Biostim 2.1" or "Biostim 2.1+":



Label of the "Biostim 2.0" or "Biostim 2.0+":



Label of the "Biostim 1.0"



3. Warnings



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



WARNING: The multi-socket power strips must not be laid on the ground. No other electrical device, nor another power strip, may be connected to the device's power strip.



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



WARNING: The device must be positioned in such a way as to ensure that the power cable remains accessible in the event of an emergency.



WARNING: In the event of an emergency, unplug the power cable directly from the device.



WARNING: No modification of the device is authorised. Opening the device's housing is expressly prohibited.



WARNING: This device complies with applicable electromagnetic compatibility standards. If you notice that your device malfunctions in the presence of another device, due to interference or otherwise, contact Électronique du Mazet or your distributor for advice on how to avoid or minimize potential problems.



WARNING: Using the device with a close proximity (ex: 1m) from an EM DEVICE of short-waves or micro-waves can cause instabilities of the STIMULATOR output power.



WARNING: The patient using the device must not be using other devices (monitoring or diagnosis equipment) during the treatment. Those devices could be perturbed. The simultaneous connection of a PATIENT to an EM DEVICE of high-frequency surgery can cause burns at the contact points of the electrodes connected to the STIMULATOR, and the STIMULATOR can be damaged.



WARNING: This device must be used with the accessories supplied by the manufacturer.



WARNING: If the PATIENT has an electronic implanted equipment (ex: a cardiac pacemaker), using the stimulation mode of the device must OBLIGATORY be subjected to a medical AUTHORIZATION before.



WARNING: Using electrodes between the thorax and the upper back (side of the heart), on both sides of the head, directly on the eyes, on the mouth, on the neck (particularly the carotid sinus), can increase the risk of cardiac fibrillation.



WARNING: In some conditions, the efficient value of the impulses of stimulation can exceed 10mA and 10V. Please scrupulously respect the information given in this manual.



WARNING: The user must lend a particular attention and adapt the size of the electrodes to the zone to treat.



WARNING: It is important to verify the size of the electrodes. The relative gravity of the current must be inferior to 2mA rms/cm².



WARNING: The output signals of the device are mean-zero biphasic symmetric and do not have continuous component. Every unpleasant sensation (irritation, heating), from the lower intensities can mean that the device is defective. Do not use the device without the opinion of the MANUFACTURER.



WARNING: This device must not be accessible to the patient. It must not be placed in contact with the patient.



WARNING: If the computer used is not approved as a medical device, the electrotherapy device must under no circumstances be located in a place that is accessible to the patient.



WARNING: The circular connector put on the back side of the device is dedicated to the diagnosis and the maintenance. It must not be connected to a power supply or to another device not recommended by the manufacturer.

4. Potential Risks

In the event of a power failure, or if the control computer malfunctions, be sure to disconnect the cables in order to avoid the risk of burning or tetanisation.

Applied parts that are too old or of poor quality can affect the quality of the contact with the patient and cause discomfort. Be sure to replace them regularly.

Microbes and/or viruses can be transmitted from one patient to another via the applied parts. Be sure to follow the instructions for proper hygiene conditions recommended by the manufacturer of the applied part.

If water gets into the device, it could malfunction. If water gets into the device, disconnect the device and the cables. In any case, avoid having water in close proximity to the device.

5. Device Installation

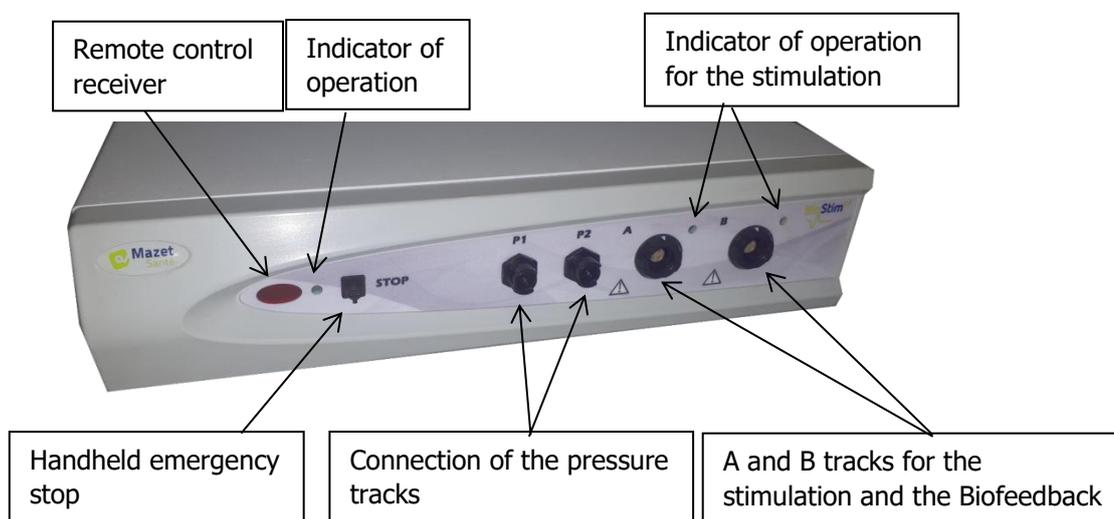
Open the cardboard packaging, remove the accessories and the device.
Check the contents of the box by looking at the packing list included with the documentation.

If the device was stored in a cold environment and there was a risk of condensation, allow the device to rest at room temperature, approx. 20°C, for at least 4 hours.
Install the device on a support that is at working height.

5.1 General positioning of the installation

Put the Biostim on a table outside the environment of the patient.
Put the PC on the same table and connect them together with the USB cable at the back side of the device.
Plug the power cord at the back side of the device.

The practitioner places himself between the patient and the device.
The patient is laid down on a massage table, or sat down on a chair next to the practitioner.

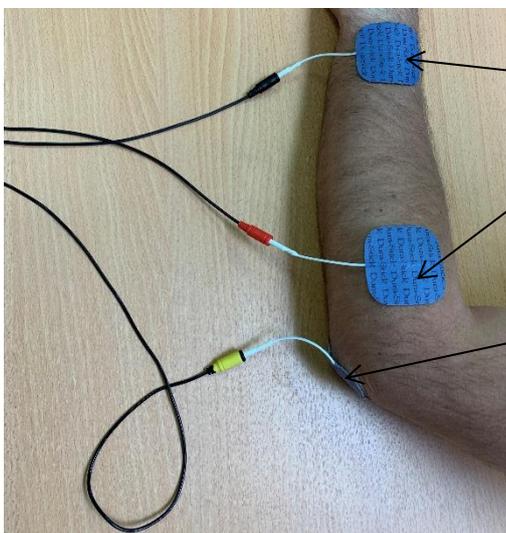


5.2 Connection of the accessories

Connect the handheld emergency stop on the front side.



Connect the cable(s) of stimulation on the track(s) A (and B) according to your use.



Put the electrodes on the muscle we want to work on.

To do Biofeedback, put the 3rd electrode (yellow connector) on a bone (not necessary for the stimulation)

To use the pressure tracks, connect the pressure kit on the tracks.



Next the probe is directly connected on the back of the tap.



6. Commissioning the Software

6.1 Configuration

The device will connect to a computer with at least the following minimum requirements:

- Windows 7, 8, or 10
- Intel Core i3
- 4 GB RAM
- Recommended resolution: at least 1366*768 (minimum 1280 * 720)
- To use Bluetooth accessories (Blueback, BioMoov, Emy or Perifit), it is necessary to have a PC under Windows 10 or 11 and equipped with a Bluetooth card

6.2 Required pieces of software

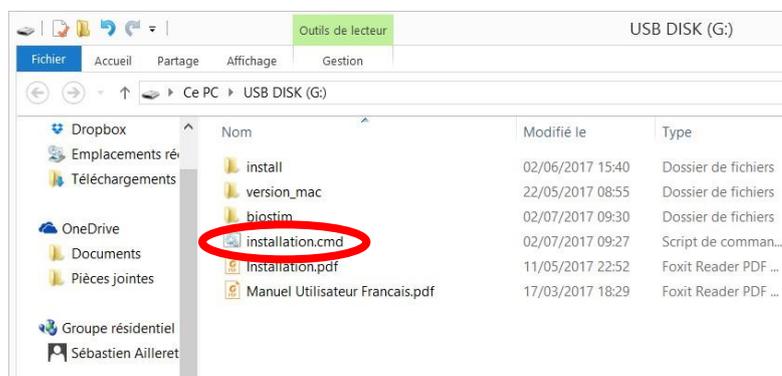
The following pieces of software must be installed on the computer:

- Java 8 64 bits (<https://www.java.com/fr/download/>)
- FTDI Driver (installation by CDM21228_Setup.exe given with the software)
- Foxit PDF Reader

If they were not already installed on the computer, the installation files are available on the USB key in the folder named « install ».

6.3 Installation

Install the programme on the desktop with a double click on the software **installation.cmd** (at the root of the key).



This operation creates a folder named biostim on the desktop (which will contain all the patient data), as well as a shortcut biostim.exe.

6.4 Start-up

Position the on/off switch on the rear of the device to ON "1".

Check that the green ON indicator light on the front of the device is lit.

Run the Biostim.exe program on the computer.



6.5 Check of the connection

Check that the connection has been established: the Home button will turn green.



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

- ✓ The module is powered on, the green indicator light on the front of the device is lit.
- ✓ The USB cable is properly connected to both the device and the computer.
- ✓ The FTDI driver is correctly installed (CDM21228_Setup.exe).

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

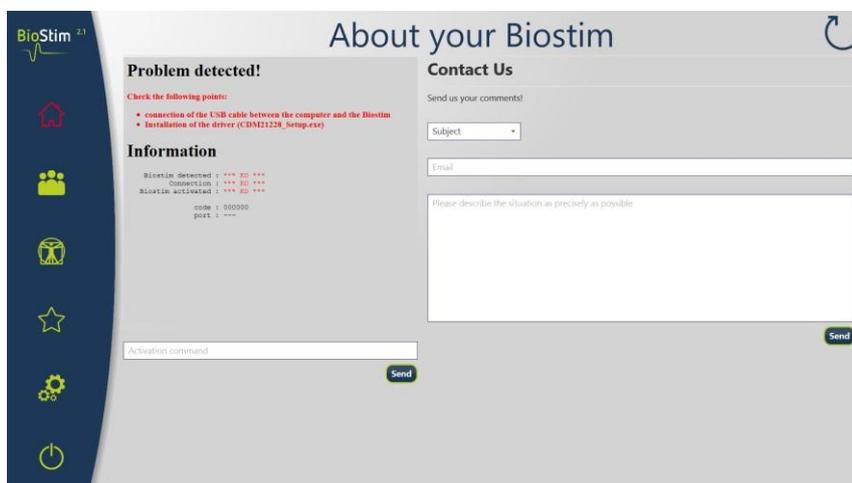
- ✓ Check that the emergency handheld stop is connected
- ✓ If the emergency stop has been used, the Biostim must be restarted (on/off switch on the back side of the device)

In case of problem

Go to the page "About your Biostim" (through the configuration page)



This page gives information on the problem. Problems can be escalated, and suggestions can be done by email in this page.



6.6 Switch off your device

First disconnect the patient from the applied parts.

Exit the programme Biostim on the PC (symbol ).



Switch off the device using the button on the back side (put it on OFF "O").

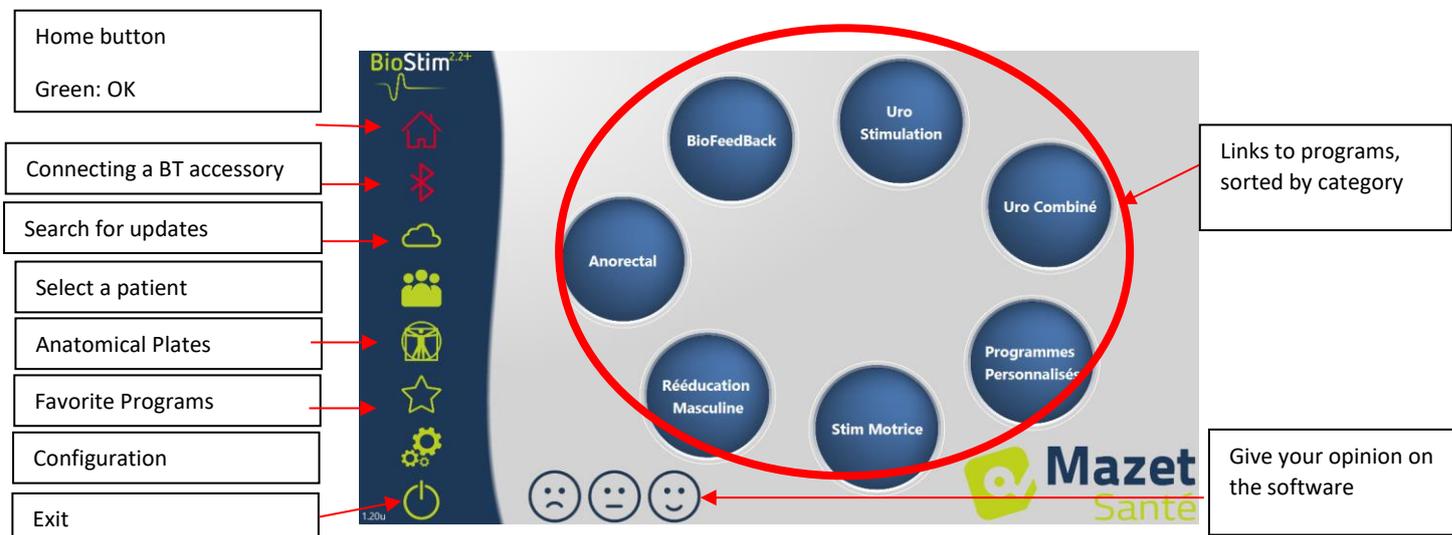
If the version is well activated, the button "Custom Programs" appears on the Home page.

7. User Manual

7.1 Home page

When launched, the software opens on the home page, which gives access to all the features of the device.

From any page of the application, a press on the home button will bring you back to this page.



7.2 Program Selection and Customisation Page

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



Clicking on one of the buttons will select a programme, highlight the selected button, and display its description on the right side of the page. This description contains:

- The programme's name
- The programme's duration
- A brief description

Descriptions of stimulation programmes also feature the parameters of the applied current.

Biofeedback programme description includes:

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

Choice of the channels to be used for the main and the secondary channel. It is possible to mix EMG and pressure

Choice of the type of animation to use

Allows you to choose whether the cursor or the background image moves

Viewing the exercise profile

The programmes' parameters can be adjusted using and buttons.

Once you have customised the programme as desired, it can be saved by clicking the button.

Registered programmes are recognizable because their name begin with "U:". They are at the root of the programmes list.

7.3 Specific programs to the + version

7.3.1 Version +: Adjustable profile

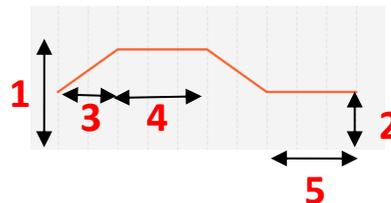
Permits to define the profile's settings and to adjust them in real time during the exercise.

Programmes Personnalisés

Ajustable

Repos: 15:00
Repos: 10.0 s

Haut	50%	1
Bas	0%	2
Pente	1,0 s	3
Travail	3,0 s	4



7.3.2 Version + : Draw Profile

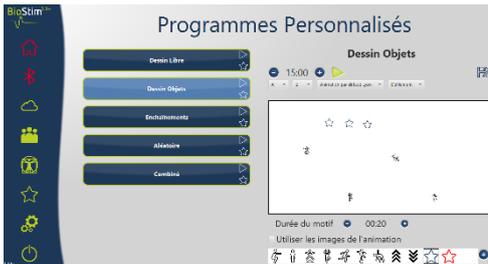


Allows you to draw a profile by clicking with the mouse on the drawing area.

A click in the drawing area adds a point to the curve.

To delete a point, simply click on it.

7.3.3 Version + : Draw Objects



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

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

7.3.4 Version + : Concatenation



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

7.3.5 Version + : Random



The random mode allows to create a random program. At each launch, a new profile is created by combining all the selected elementary patterns

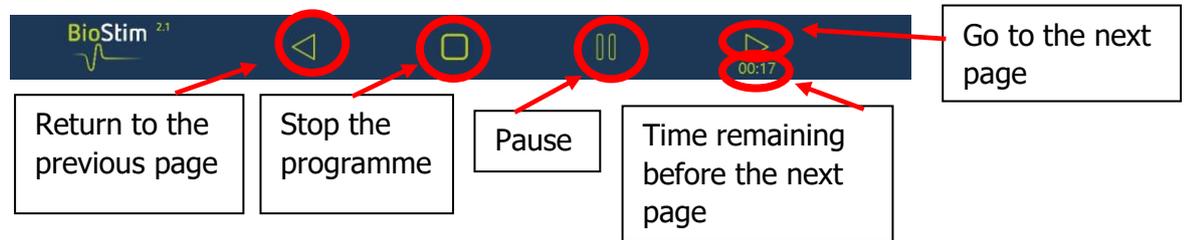
7.3.6 Version + : Combined



The combined mode allows you to create your own programs integrating stimulation and BFB, by chaining 2 other programs.

7.4 Launching a Programme

To launch a programme from the programme selection page, click on the  button in the programme description or on the  icon in the upper-right of the programme's button. A programme is composed of one or more pages that elapse like a slide show, either after a predefined amount of time or by clicking an option in the menu at the bottom of the page.



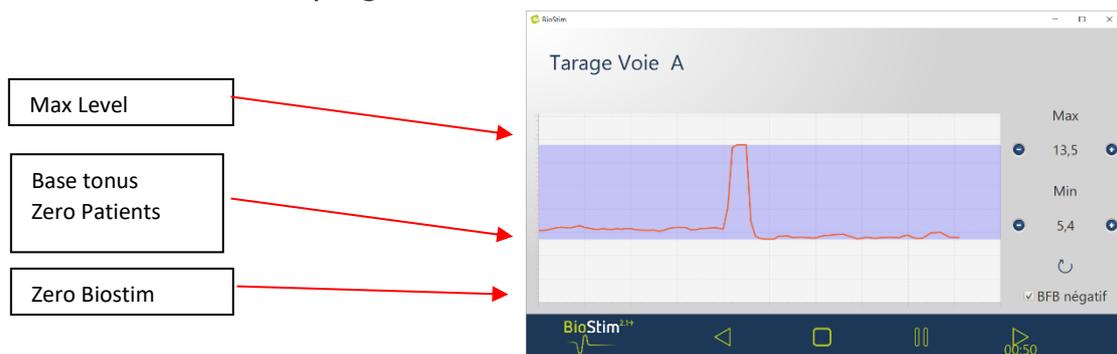
The programme can also be stopped with the handheld emergency stop.

7.4.1 Biofeedback Calibration

Calibration is performed automatically. However, it is possible to adjust the parameters calculated by the machine with the  and  buttons.

Calibration Procedure

- Place the probe or electrodes.
- Start the calibration.
- Ask the patient to make a sustained contraction (the gauges change automatically), then release for a few seconds.
- The BioStim automatically adjusts the operating range.
- Click the arrow to move on to the next page (or wait until the end of the period).
- While the exercise is underway, the settings may still be adjusted manually with the + and - buttons in the top-right of the screen.



It is possible to activate or not the negative Biofeedback for each track, either in the configuration page or in the calibration page. If the option is activated, we can see the effort under the base level. It is particularly useful if we work on relaxation.

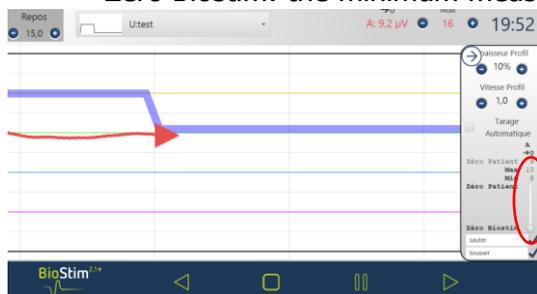


In the "+" version, it is possible to adjust the negative Biofeedback level to show during the exercise with the slider in the panel on the right:

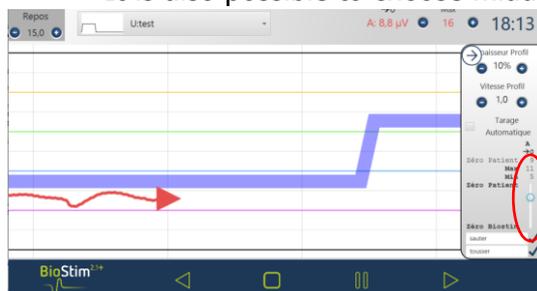
- Zero patient: the bottom of the screen is corresponding to the minimum reached by the patient during the calibration. Thanks this adjustment, the base tonus is deleted.



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

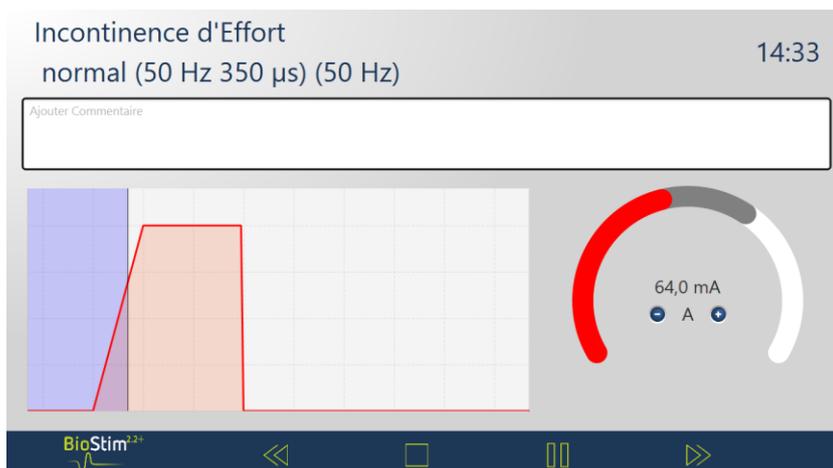


- It is also possible to choose middle values:



7.4.2 Stimulation

The level of stimulation is adjusted track by track while the programme is underway. Levels can only be increased during the work phases.



7.4.3 Biofeedback

Adjustment of the rest time

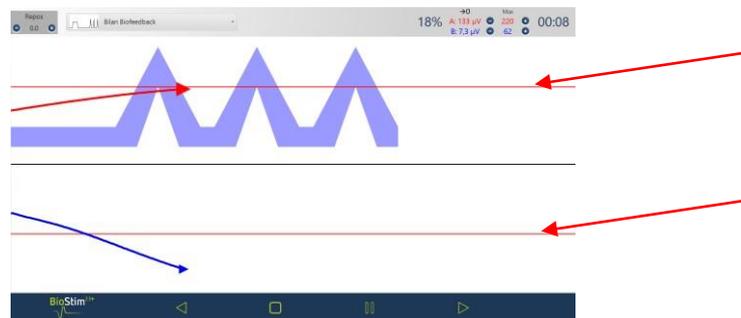
Modification in real time of the profile (only with + version)

Progress through route

Track level in real time

Maximum calibration of each track

Thanks to a right click on the page, a landmark line is added at the location wanted.



7.4.3.1 + Version: adjustable profile

Once the Biofeedback has been created in adjustable profile, the form of the curve can be modified during the exercise thanks to the buttons situated in the top-left corner.

Buttons to adjust the profile form

7.4.3.2 + Version: Side Panel

The side panel enables you to regulate the exercise in time. To open it, click on the icon  in the top right-hand corner of the Biofeedback pages.



Thanks to this panel, you can regulate:

- The profile width
- The profile speed (if we visually increase, we flash up on the screen at the same speed, but the profile curls up, so the peaks come faster one after another)
- The automatic configuration: adjusts the base and the maximum levels to the amplitude achieved by the patient (enables to adjust the configuration during the exercise)
- Regulation of the "Zero Patient" for each track (->0)
- The level of the negative Biofeedback, with the cursors of each voice
- We can add events on the curve (that we will also find in the history). The names are free. It is also possible to add events with a right click on the screen.

7.4.3.3 Version + : Assisted Biofeedback

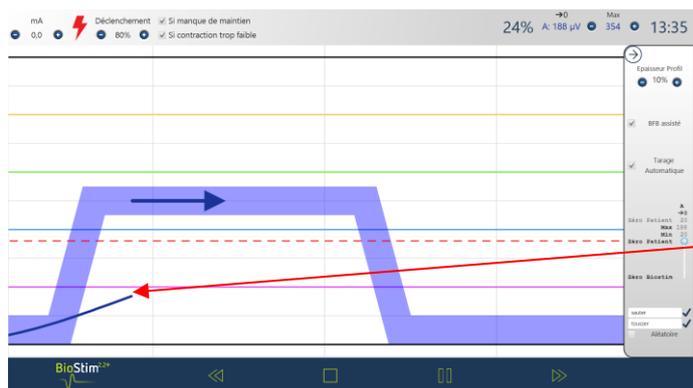
This mode, available for adjustable programs, is activated either before starting the program or from the side panel

Stimulation is then used to reinforce the muscular work:

- Or on a lack of maintenance: good beginning of contraction, but insufficient maintenance at the end of the plateau



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



The voluntary contraction does not reach the plateau

7.4.3.4 Review mode

At the end of the program (or after a click on the pause button), the review mode appears. In this mode, it is possible to register the curve clicking on the diskette button in the top-left to print it or to show it again later.

Allows you to compare the different passages on a profile width

Printing the curve



Add a comment for the session

7.4.4 Using a Bluetooth accessory

Biostim is compatible with :

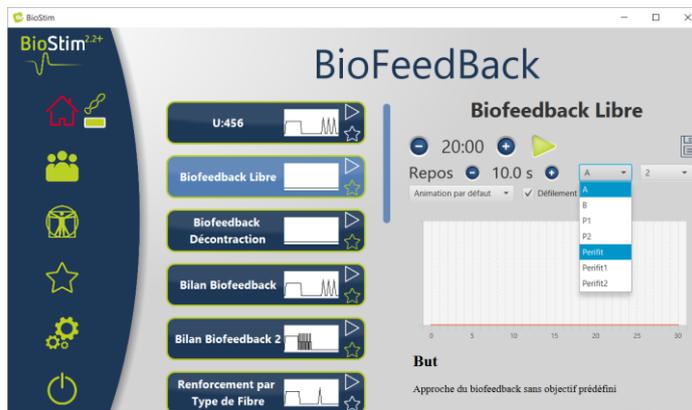
- The Emy probe
- The Perifit probe
- The Blueback
- The BioMoov

This feature is only available if the Bluetooth option has been purchased.



To work with an 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 turns green, 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 choosing 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 programs is limited to 1 minute.

7.5 Favorite Programs

For a quicker access to your most frequently used programmes, you can put them in the "Favourites" category.

To do this, simply click on the  icon in the lower-right of the programme's button. They can then be accessed by clicking on the  button in the left-hand menu on each page.

7.6 Anatomical Charts

Anatomical charts are available. Click on an image to open it in a viewer, where you can zoom in or go to full screen in order to see better the image.

You can add your own anatomical charts clicking on "New Chart". We can choose pictures or videos in the PC, or links from videos on Internet (particularly on YouTube). We would like to the University of Lille 2 and Lyon 1 for the authorization to add the link of their anatomical charts in 3D.



7.7 Select a Patient

Click on the  button to access the patient selection page. This page displays the list of patients.

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

To display all the patients (including archived patients), check the box "Show archived patients".

In this circumstance, archived patients have a green archive icon, and the other ones have a blue archive icon.

Archiving can be reversed by clicking on the archive icon again.



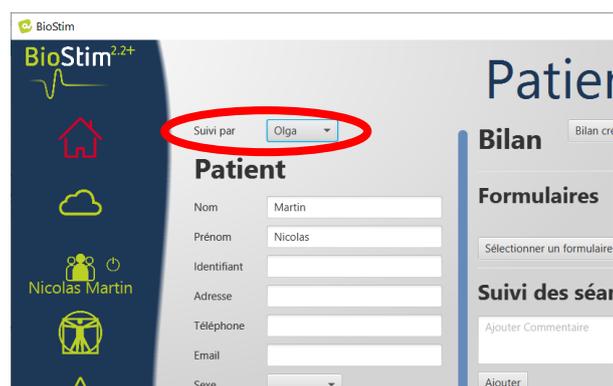
The first name and the name of the patient can be totally masked with the "Anonymous Display" button, only the first letters will be shown.

To select a patient, click on his/her name. Once a patient has been selected, his/her name will appear in the menu on the left side of the screen. To deselect a patient, simply click on the  button to the right of the patient's name.

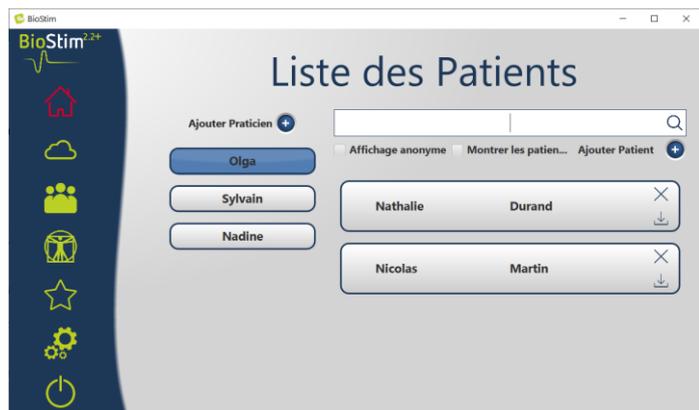


Version + : multi practitioner mode

It is possible to activate the multi-practitioner mode in the configuration page. 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 list of patients by selecting a practitioner

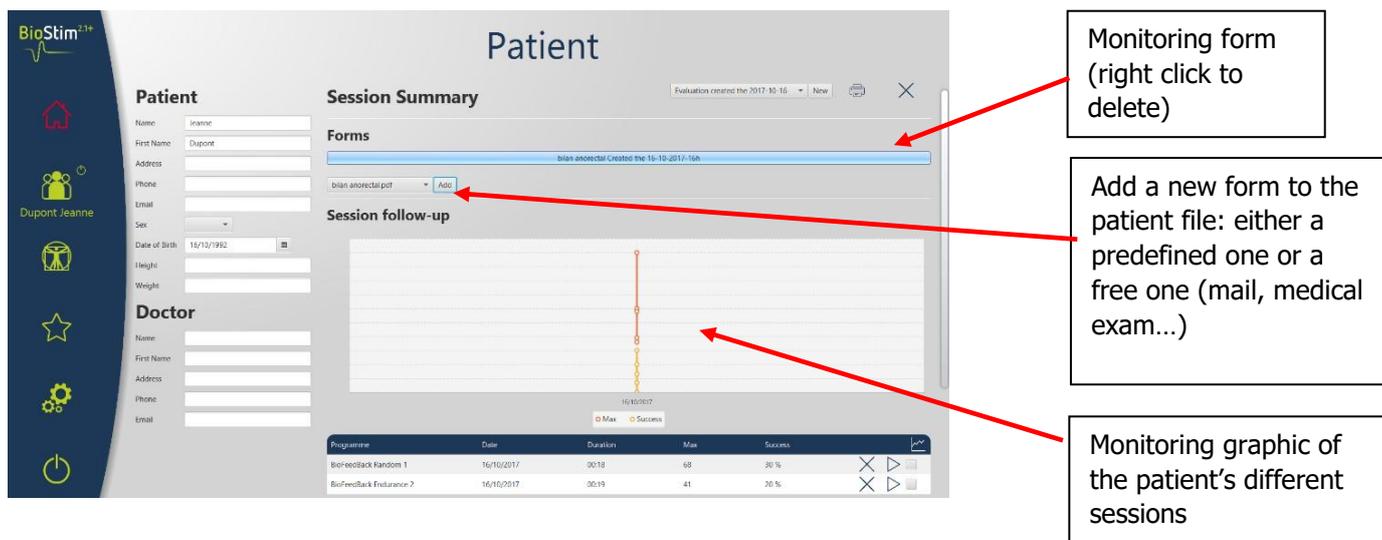


7.8 Patient Records

When a patient has been selected, you can access his/her record by clicking on his/her name in the left-hand menu.

This record contains the patient's data (last name, first name, etc.), as well as the monitoring information from all of the patient's sessions (graphic and table). It is also possible to add:

- Written comments
- Assessment-type forms, which will help you take stock of the patient's condition.



The screenshot shows the 'Patient' record page. On the left is a vertical navigation menu with icons for home, people, a person, a star, settings, and power. The main area is divided into sections: 'Patient' (with fields for Name, First Name, Address, Phone, Email, Sex, Date of Birth, Height, Weight), 'Doctor' (with fields for Name, First Name, Address, Phone, Email), 'Session Summary' (with a dropdown for 'bilan anorectol pot' and an 'Add' button), 'Forms' (with a table of forms), and 'Session follow-up' (with a line graph showing session progress). At the bottom is a table of sessions.

Annotations with red arrows point to specific features:

- Monitoring form (right click to delete)**: Points to a form entry in the 'Forms' section.
- Add a new form to the patient file: either a predefined one or a free one (mail, medical exam...)**: Points to the 'Add' button in the 'Forms' section.
- Monitoring graphic of the patient's different sessions**: Points to the 'Session follow-up' line graph.

Programme	Date	Duration	Max	Success	
BioFeedback Random 1	16/10/2017	30:19	68	30%	X ▶
BioFeedback Endurance 2	16/10/2017	32:19	41	30%	X ▶

All the sessions are registered. The result is visible on a graphic, for a quick viewing, and in a more complete table which restores all the sessions data.

Patient

Name: Jeanne
First Name: Dupont
Address: _____
Phone: _____
Email: _____
Sex: _____
Date of Birth: 16/10/1992
Height: _____
Weight: _____

Doctor

Name: _____
First Name: _____
Address: _____
Phone: _____
Email: _____

Programme	Date	Duration	Max	Success
Biofeedback Random 1	16/10/2017	00:18	68	30 %
Biofeedback Endurance 2	16/10/2017	00:19	41	20 %
Adjustable	16/10/2017	00:24	40	7 %
Tonic Phasic	16/10/2017	00:29	25	13 %
Biofeedback Relaxation	16/10/2017	00:30	27	0 %
Stress Inconvenience (sensitive)	17/10/2017	00:00		
Draw Profile	17/10/2017	00:09	27	0 %

Comments

2017-10-17 : Good session, notable progress

Add Comment: _____ Submit

Annotations:

- Start the comparison of the curves selected (+ version)
- Delete a recording
- Start the same programme again
- Select the curves you want compare (+ version)
- Free comments (right click to delete)

7.8.1 + Version: Curves comparison

A click on the button  in the sessions table open the sessions comparison page.

Annotations:

- Show the average curve on a profile width
- Printing the curves
- Choice of the tracks to show
- Choice of the sessions to show

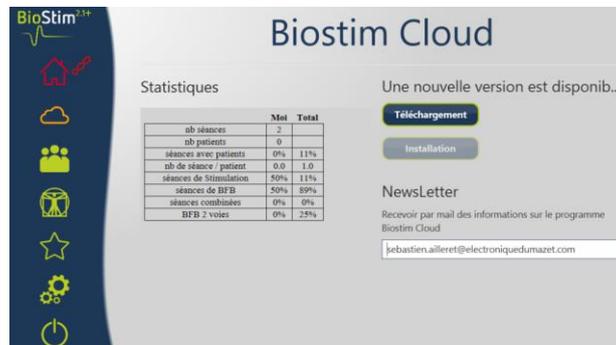
Date	Programme	Max	Success
17/10/2017	Draw Profile	Max: 27	Success: 0%
16/10/2017	Biofeedback Relaxation	Max: 27	Success: 0%
16/10/2017	Tonic Phasic	Max: 25	Success: 13%
16/10/2017	Adjustable	Max: 40	Success: 7%

Tracks: Track A, Track B

7.9 Biostim Cloud

When you activate the option Biostim Cloud:

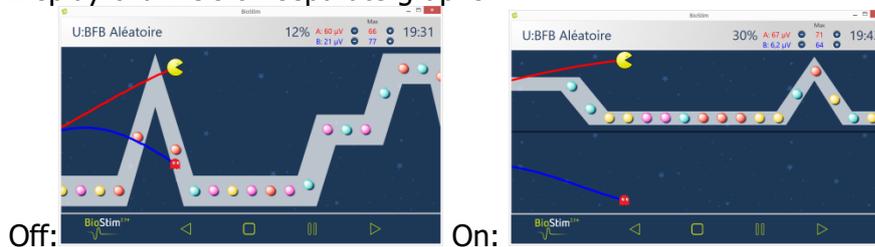
- An anonymous collection of the sessions is done
- We can access to the statistics on the use of the device as well as the statistics of the other users
- We are informed about new versions, and we can install it directly from the software



7.10 Configuration Page

The configuration page allows you to configure the software. The available options are : Scrolling speed: allows you to speed up or slow down the biofeedback scrolling.

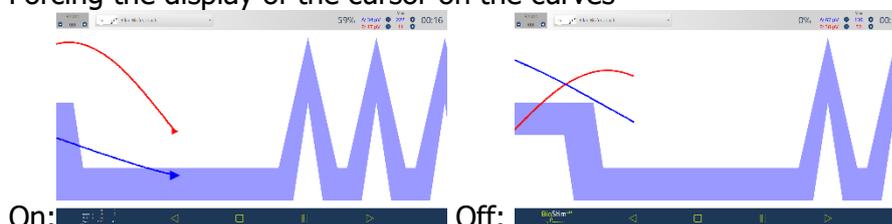
- Default channel for BFB (A, B, or P)
- Display channels on separate graphs



- Rest time before or after working time for BFB



- Possibility to activate or deactivate the negative BFB for each channel
- Automatically start BFB after taring: if this option is not activated, the cursor waits for the start key to be pressed at the beginning of the BFB: no scrolling until this key is pressed
- Forcing the display of the cursor on the curves



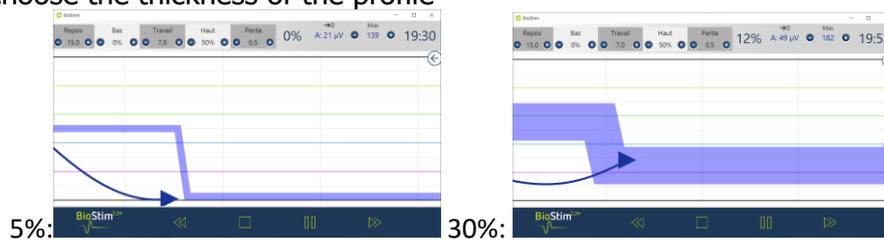
- Selection of animations: it is possible to choose the animations that you want to use. Those that are unchecked will no longer be visible in the program presentation page. Customized animations are always visible.



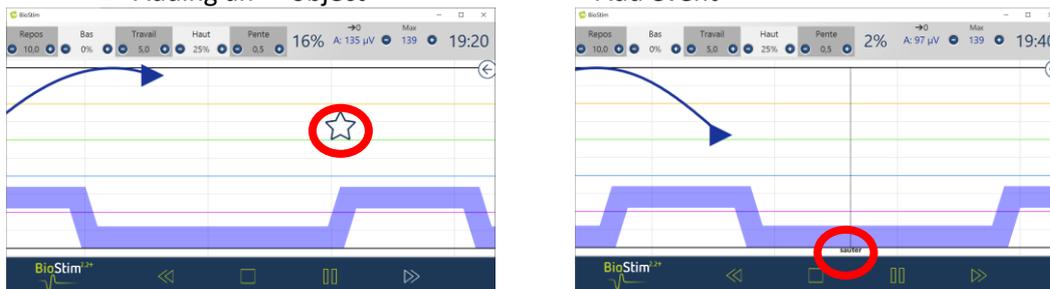
- Show history in animations



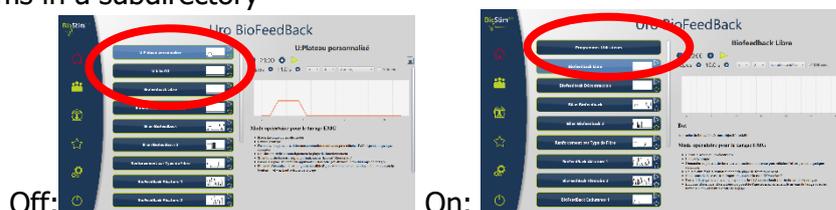
- Display the BFB pressure during stimulation (only for pressure probes with electrodes: type Evolys 3P from Sugar International)
- Possibility to choose the thickness of the profile



- Choice of action for a right click on the screen during a BFB



- Sound management: Choice of music at the end of the program, possibility of adding a sound for the transitions between BFB and stimulation, sound BFB (for visually impaired patients), sound indication for the beginning and end of contractions. All these sounds are configurable by the user
- Creation, modification and deletion of a custom animation: requires a background image, an image for tracking each lane, and one or more objects to catch.
- Put user programs in a subdirectory



7.10.1 Networking several devices

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

To share the base, you just have to indicate this folder in the option "Folder for patient data".

8. Clinical Guide

8.1 Target Population

This device is intended for patients (male or female) aged 5 years or older. Rehabilitation of the pelvic floor is particularly indicated for postpartum women.

8.2 Expected Performance

In keeping with current European and French recommendations as well as the results of studies performed by health specialists, this device has been designed to offer targeted pre-set programmes for pathologies that require treatment from a physiotherapist or midwife.

Its therapeutic uses include:

- 1- Treatment of urinary incontinence: stress incontinence, urge incontinence, or mixed incontinence, and bladder inhibition.
- 2- Treatment of faecal incontinence.
- 3- Treatment of contractures and prolapse: muscle strengthening and relaxation treatments.
- 4- Treating pain: analgesic treatments.

8.3 Major Contraindications

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



- Patient is pregnant
- Has a pace maker
- Has cardiac arrhythmia
- Has a bladder stimulator
- Perineal hypoesthesia
- Urinary and vaginal infections
- Recent abdominal surgery
- Intrapelvic tumours
- Do not apply to the carotid sinus.

These contraindications are not exhaustive. In case of doubt, we recommend that the user research the procedure before proceeding.

8.4 Side Effects

Current medical literature does not note significant side effects involving electrotherapy.

9. Maintenance, Servicing

This device has a lifespan of 5 years.

To ensure peak performance throughout its working life, it is necessary to have the device inspected by Électronique du Mazet every two years.

The technicians of Electronique du Mazet or its distributors certified are authorized to make the maintenance or to repair the device.

9.1 Housing and Accessories

The housing requires only normal, periodic cleaning if its exterior becomes dirty. This applies to the accessories, as well.

Use only a dry or very slightly damp cloth to clean the device.
Be sure to disconnect the power cord before doing any cleaning.

9.2 Sterilization

This device is not sterile.
The accessories are not sterile, nor intended to be sterilized.

10. Malfunction

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

If the device must be shipped, please follow these instructions: ▪
Decontaminate and clean the device and its accessories.

- ✦ Use the original packing, particularly the maintaining flanges.
- ✦ Include all of the device's accessories.
- ✦ Secure the different elements.
- ✦ Ensure that the packaging is properly closed.

Shipping Address:

**Électronique du Mazet
ZA Route de Tence
43520 Le Mazet St Voy
FRANCE**

Tel.: (+33) (0)4 71 65 02 16

Fax: (+33) (0)4 71 65 06 55

E-Mail: sav@electroniquedumazet.com

Possible malfunctions:

Description of the malfunction	Possible causes	Actions
Green indicator light off	<ul style="list-style-type: none"> - problem with the electrical network - fuses 	<ul style="list-style-type: none"> - check the mains voltage - check and change the fuses
No communication with the computer (home button = red house)	<ul style="list-style-type: none"> - USB adapter 	<ul style="list-style-type: none"> - check the connections - check that the FTDI driver is correctly installed (CDM v2.10.00.exe)
No stimulation detected, but the yellow light is lit.	<ul style="list-style-type: none"> - bad contact - faulty cable 	<ul style="list-style-type: none"> - check the connections going to the patient - swap the cables to ensure connections are correct
No stimulation detected and the yellow lights are not lit.	<ul style="list-style-type: none"> - loss of communication with the module - the parameters for the stimulation currents are not consistent 	<ul style="list-style-type: none"> - exit the current treatment and return to the main screen - check the settings, change them if necessary
Flatline in the biofeedback windows	<ul style="list-style-type: none"> - loss of communication with the module - no sensor in the input in question 	<ul style="list-style-type: none"> - exit the current treatment and return to the main screen - check the track being used
Need to increase stimulation current beyond the usual values with elastomeric electrodes.	<ul style="list-style-type: none"> - old electrodes - insufficient gel 	<ul style="list-style-type: none"> - replace electrodes - add contact gel
Automatic reduction of the amplitude cursor.	<ul style="list-style-type: none"> - old electrodes - insufficient gel - pulse width too long 	<ul style="list-style-type: none"> - replace electrodes - add contact gel - change programme for a lower pulse width
EMG biofeedback signal saturated or very noisy.	<ul style="list-style-type: none"> - absence of or bad contact with the reference electrode 	<ul style="list-style-type: none"> - check that the 3rd electrode is properly mounted - check that the electrodes are in good condition, replace if necessary.

If the device falls or water gets into it, it must be checked by Électronique du Mazet to avoid potential hazards (for both patient and practitioner) involved in use of the device.

11. After-sales Service and Warranty

Your supplier provides a warranty for this device under the conditions specified in this document, provided that:

- ✦ Only accessories provided by Électronique du Mazet or its distributors are used.
- ✦ All modifications, repairs, extensions, adaptations and adjustments made to the device are carried out by Électronique du Mazet or its distributors that are authorized to perform these operations.
- ✦ The operating environment meets all regulatory and legal requirements.
- ✦ The device is used only by competent and qualified personnel. Use of the device must comply with the instructions in this user manual.
- ✦ The treatments are used only for the applications for which they are intended, as described in this manual.
- ✦ The device undergoes regular maintenance as per the manufacturer's recommendations.
- ✦ All the legal requirements concerning the use of this device are respected.
- ✦ Only accessories provided by or specified by the manufacturer are used with the device.
- ✦ The parts of the machine and its spare parts are not replaced by the user.

Inappropriate use of this device or negligent maintenance releases Électronique du Mazet and its authorised distributors of any liability in the case of, e.g., faults, failures, malfunctions, damage, injury, etc.

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

The 24-month warranty starts on the date that the device is delivered.

The accessories have a 6-month warranty, which starts when the device is delivered.

Transport and packaging costs are not covered by the warranty.

12. Scrapping

If the device or its accessories are no longer functional or prove unusable, we request that you either return such equipment to the manufacturer or dispose of it in a Réylum recycling collection point.

As part of its commitment to helping the environment, Électronique du Mazet finances the Réylum recycling system, which is dedicated to professional WEEE. Réylum is a free service that takes electrical lighting equipment, control and surveillance equipment, and used medical devices. For more information, go to www.reylum.com.

13. Transportation and Storage

This device must be stored and transported in its original packaging or in a packaging able to protect it from any destructive outside forces.

Store at room temperature in a clean and dry place.

14. EC Declaration of Conformity

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

This device first obtained a medical device CE Mark on 14/12/2018.

15. Manufacturer

Électronique du Mazet is a company located in the heart of the Massif Central. EDM started out as an electronic card maker, and over the years it has developed its own brand of medical devices, primarily intended for use in physiotherapy.

Today, EDM is researching, developing, manufacturing and marketing devices for pressure therapy, vacuomobilization, and electrotherapy (urinary re-education). If you would like to find out more, please do not hesitate to contact us.

SAS Électronique du Mazet
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www.electroniquedumazet.com

16. EMC compliance table

EMC compliance according to IEC 60601-1-2 (2014) 4th Edition (EN 60601-1-2 : 2015)		
The BIOSTIM is designed to be used in the electromagnetic environment specified below. The customer or user of the 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. Therefore, its RF emissions are very low and are not likely to cause interference in any nearby electronic device. 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 buildings for domestic use.
RF emissions CISPR 11	Class B	
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)			
The BIOSTIM is intended to be used 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	Level of compliance	Electromagnetic environment - guidelines
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV in contact ± 15 kV in air	± 8 kV in contact ± 15 kV in air	The floors should be made of wood, concrete or ceramic tiles. If the 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 should be that of a typical commercial or hospital environment.
Surge voltage transitional IEC 61000-4-5	± 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 should be that of a typical commercial or hospital environment.
Tension dips, short cuts and variations of 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% TU: 1 cycle and 70% TU: 25/30 cycles Single-phase: at 0 degree 0% UT: 250/300 cycles	0% UT: 0.5 cycle at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0% TU: 1 cycle and 70% TU: 25/30 cycles Single-phase: at 0 degree 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 outages, it is recommended that the BIOSTIM be powered from an uninterruptible power supply or battery. NOTE UT is the AC system voltage before the test level is applied.
Magnetic field to the frequency of the electrical network (50/60 Hz) IEC 61000-4-8	30 A/m 50Hz or 60Hz	30 A/m 50Hz or 60Hz	Magnetic fields at the power system 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)

The **BIOSTIM** is intended to be used 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	Level of compliance	Electromagnetic environment - guidelines
Conducted RF disturbances IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Veff in the ISM bands between 0.15 MHz and 80 MHz 80% AM at 2 Hz	3 Vrms 150 kHz to 80 MHz 6 Veff in the ISM bands between 0.15 MHz and 80 MHz 80% AM at 2 Hz	It is appropriate that portable and mobile devices of 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
Radiated RF disturbances IEC 61000-4-3, including clause 8.10, Table 9, for the proximity of non-related 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	Where P is the maximum output power characteristic of the transmitter 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, as determined by an on-site electromagnetic investigation a, should be below the compliance level in each frequency range b Interference may occur in the vicinity of the device marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the highest 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.

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**.

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 devices of RF communications and theBIOSTIM

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.

Maximum rated output power of the transmitter (in W)	Separation distance according to the frequency of the transmitter (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 with maximum rated transmit power not given above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum transmit power characteristic of the transmitter in watts (W), according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the highest 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.

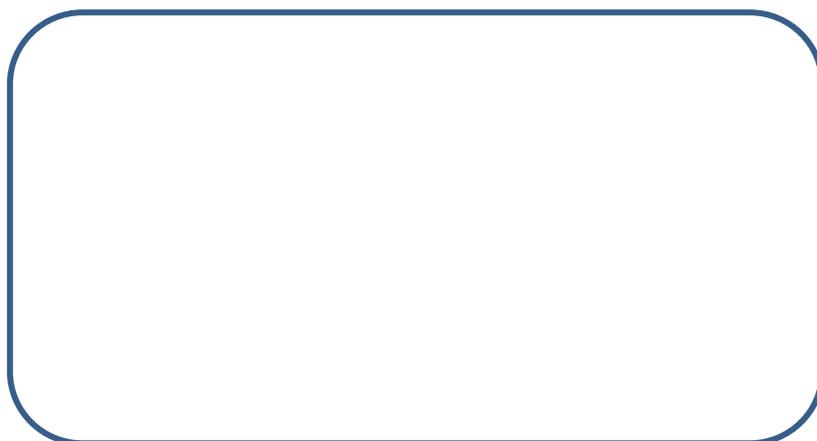


ELECTRONIQUE DU MAZET

ZA ROUTE DE TENCE
43520 LE MAZET SAINT VOY
France

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

Your dealer / distributor:

A large, empty rounded rectangular box with a dark blue border, intended for a signature or stamp.

www.facebook.com/MazetSanteFrance/mazetsante.fr