

# 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 for the life of the product.**

**This device was designed and manufactured for  
therapeutic use.**

**Only professionals of physiotherapy 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.

# Table of Contents

1. Device Presentation .....	3
2. Description and Technical Information .....	5
2.1 Symbols Used.....	6
2.2 Technical Specifications.....	7
2.3 Nameplate Label.....	10
3. Warnings.....	11
4. Potential Risks .....	13
5. Device Installation .....	13
5.1 General position of the installation .....	13
5.2 Connection of the accessories.....	14
6. Commissioning the Software.....	16
6.1 Configuration.....	16
6.2 Required pieces of software .....	16
6.3 Installation .....	16
6.4 Start-up .....	16
6.5 Check of the connection.....	17
In case of problem.....	18
6.6 Switch off your device.....	18
7. User Manual .....	19
7.1 Home Page .....	19
7.2 Program Selection and Customisation Page .....	19
7.3 Specific programs to the + version .....	20
7.4 Launching a Programme .....	22
7.5 Favourite Programmes .....	26
7.6 Anatomical Charts.....	27
7.7 Select a Patient .....	27
7.8 Patient Records .....	28
7.9 Biostim Cloud .....	30
7.10 Configuration Page .....	30
8. Clinical Guide.....	32
8.1 Target Population .....	32
8.2 Expected Performance .....	32
8.3 Major Contraindications.....	32
8.4 Side Effects .....	32
9. Maintenance, Servicing.....	33
9.1 Housing and Accessories .....	33
9.2 Sterilization .....	33
10. Malfunction .....	33
11. After-sales Service and Warranty .....	35
12. Scrapping.....	35
13. Transportation and Storage .....	35
14. EC Declaration of Conformity .....	36
15. Manufacturer.....	36
16. EMC Scorecard .....	37

## **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.



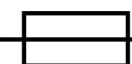
**Applied Part, Type B:** Applied part that comes in contact with the patient and can be earthed.



**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 1kΩ (or more), at the max. current, the tension is **limited to 100V** +10%-20% (peak value)
    - Under a load impedance inferior of 1kΩ, the tension level is limited according to the impedance (10 Volts for 100Ω, 50 Volts for 500Ω)
    - In the case of a too high impedance (above 10kΩ), the current can be cut of: function electrode removed
- ⇒ Rectangular signals are biphasic (mean-zero symmetric impulsions), the impulsion width is adjustable from **15µs 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
<b>Biostim 1.0</b>	<b>1</b>	<b>0</b>
<b>Biostim 2.0</b>	<b>2</b>	<b>0</b>
<b>Biostim 2.1</b>	<b>2</b>	<b>1</b>
<b>Biostim 2.2</b>	<b>2</b>	<b>2</b>

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
- MEG010EN604 Adaptor cable DIN 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.**

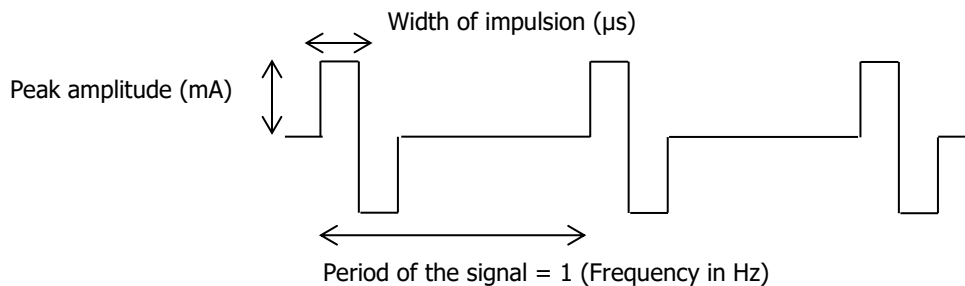


## 2.2.6 The currents form

### 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
$\leq 400\text{Hz}$	50mA
$> 400\text{Hz to } \leq 1500\text{Hz}$	80mA
$> 1500\text{Hz}$	100mA

(Amplitude values assured for an impedance span from  $200\Omega$  à  $2\text{k}\Omega$ )

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

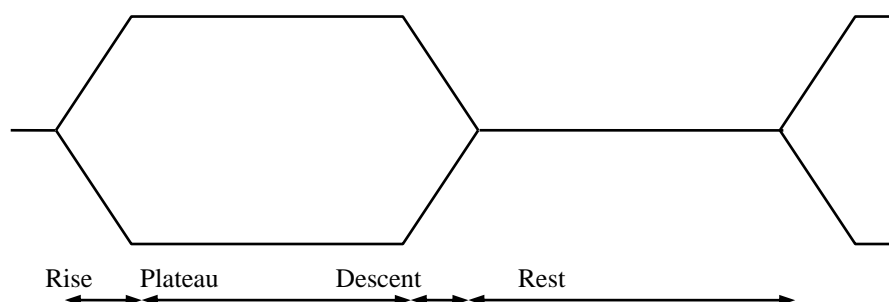
The width of the impulse is adjustable from **15µs to 10ms**, the frequency is adjustable from **1Hz to 5kHz**.

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

The current  $I_{\text{RMS}}$  (in mA) =  $I_{\text{peak}}$  (in mA)  $\times 2 \times$  the width of impulse (in s)  $\times$  frequency (in Hz)

### Generation of the envelopes:

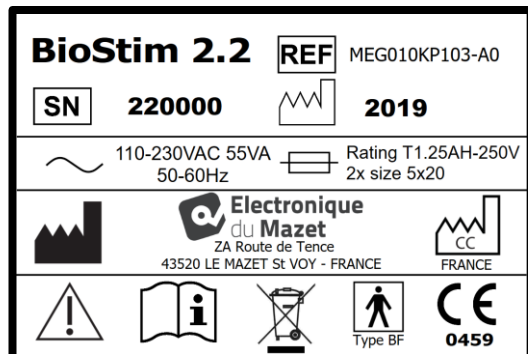
The impulse signal is included in an envelope that make an application and a progressive stop of the current.



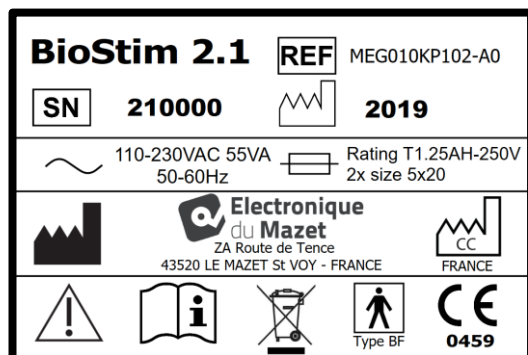
## 2.3 Nameplate Label

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

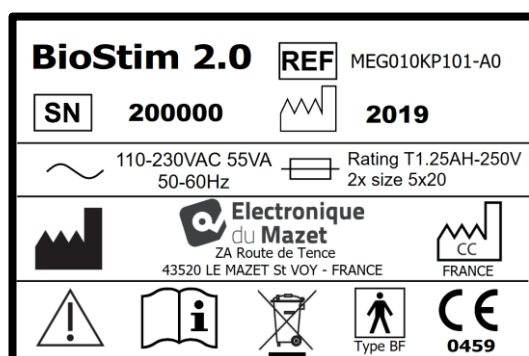
Label of the "Biostim 2.2" or "Biostim 2.2+":



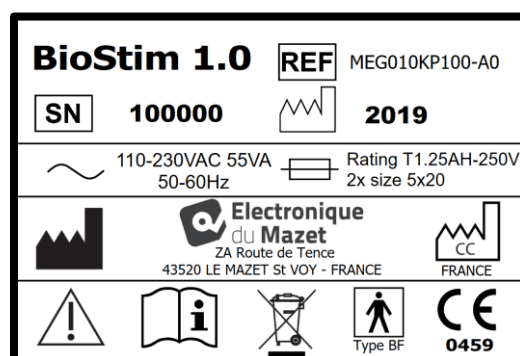
Label of the "Biostim 2.1" or "Biostim 2.1+":



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/cm<sup>2</sup>.



**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 position of the installation

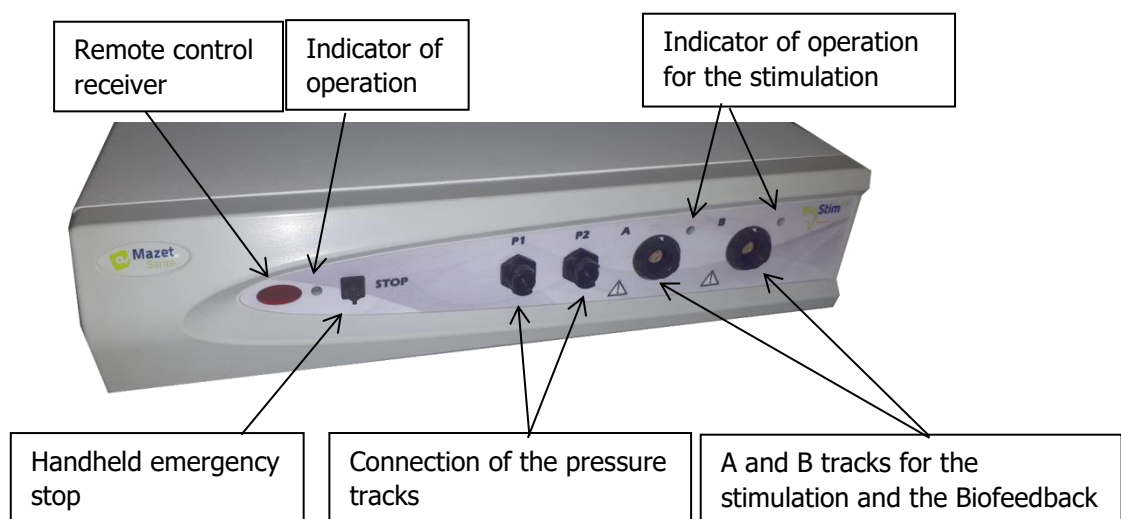
Put the Biostim on a table outside the environment of the patient.

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.

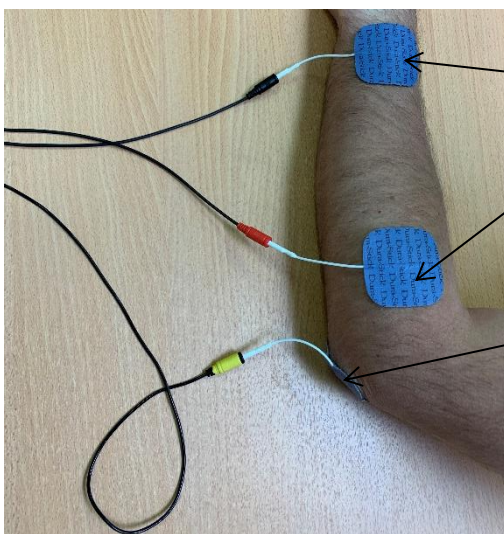


## **5.2 Connection of the accessories**

Connect the handheld emergency stop on the front side.



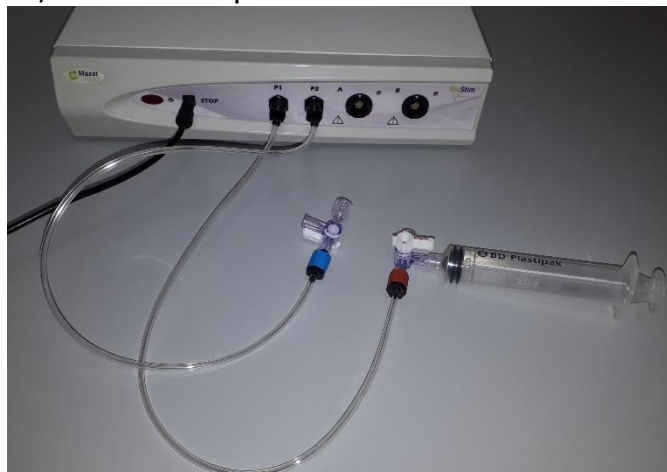
Connect the cable(s) of stimulation on the track(s) A (and B) according to your use.



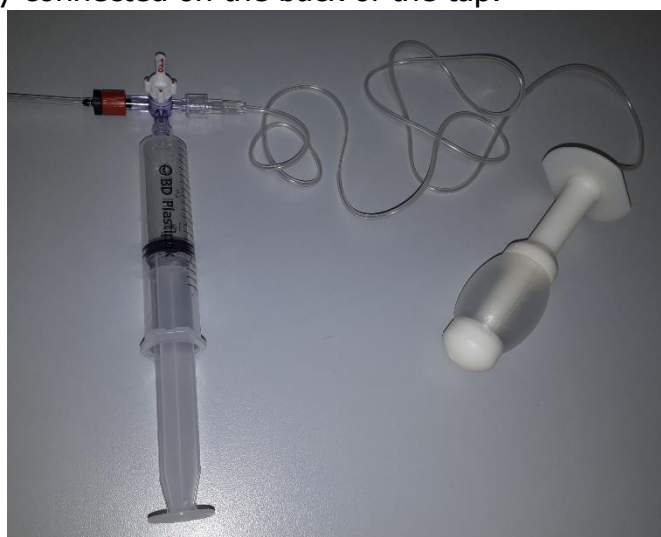
Put the electrodes on the muscle we want to work on.

To do Biofeedback, put the 3<sup>rd</sup> 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 a Bluetooth probe (Emy or Perifit), it is necessary to have a PC under Windows 10 and equipped with a Bluetooth card

### 6.2 Required pieces of software

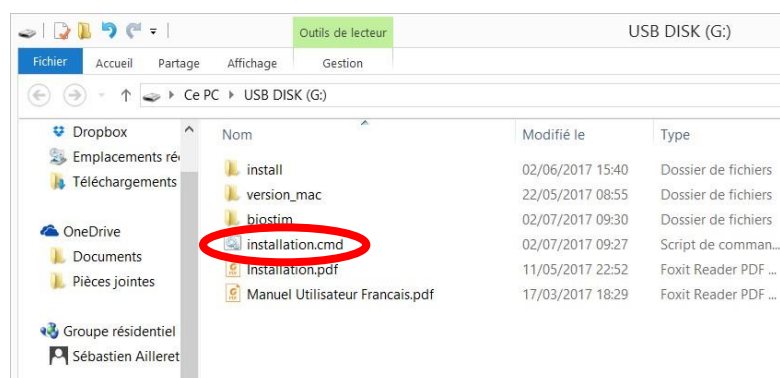
The following pieces of software must be installed on the computer:

- Java 8 ( <https://www.java.com/fr/download/> )
- FTDI Driver (installation by CDM v2.10.00.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.



If the Home button is **red**, this indicates that there is a communication problem between the computer 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 (CDM v2.10.00.exe).

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

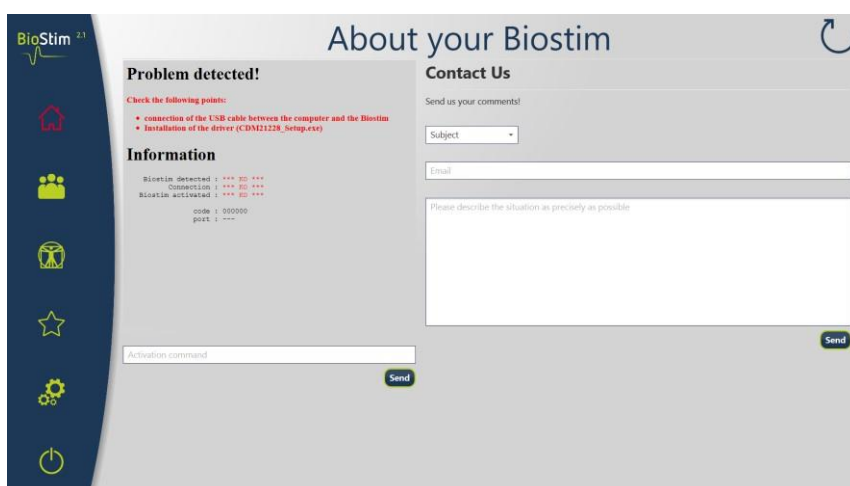
- ✓ Check that the handheld emergency stop is connected
- ✓ Si the emergency stop has been used, the Biostim has to be restarted (on/off button on the back side of the device)

## 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").

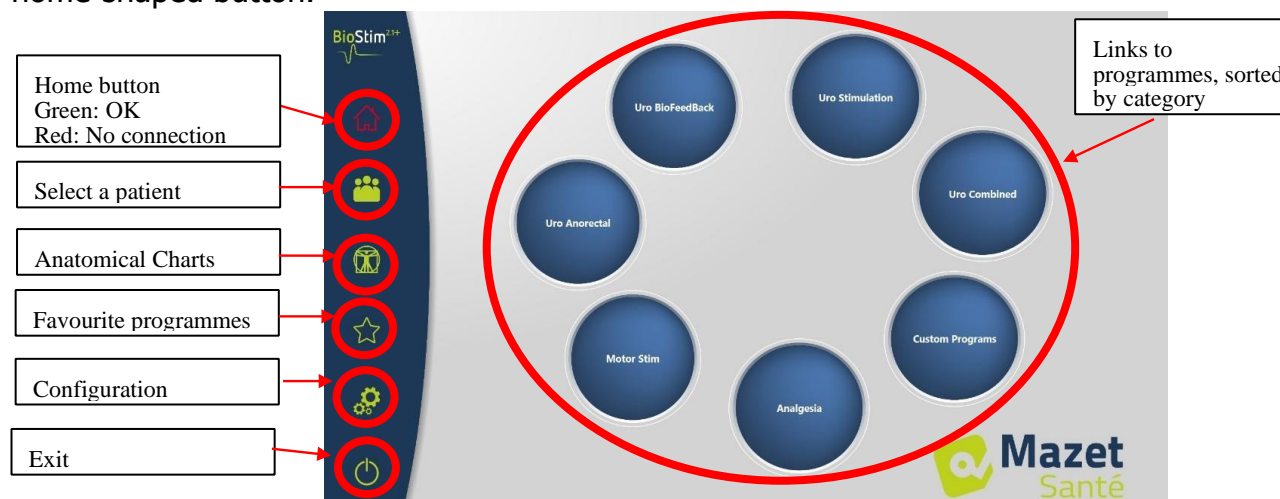
If the version is well activated, the button "Custom Programs" appears on the Home page.

## 7. User Manual

### 7.1 Home Page

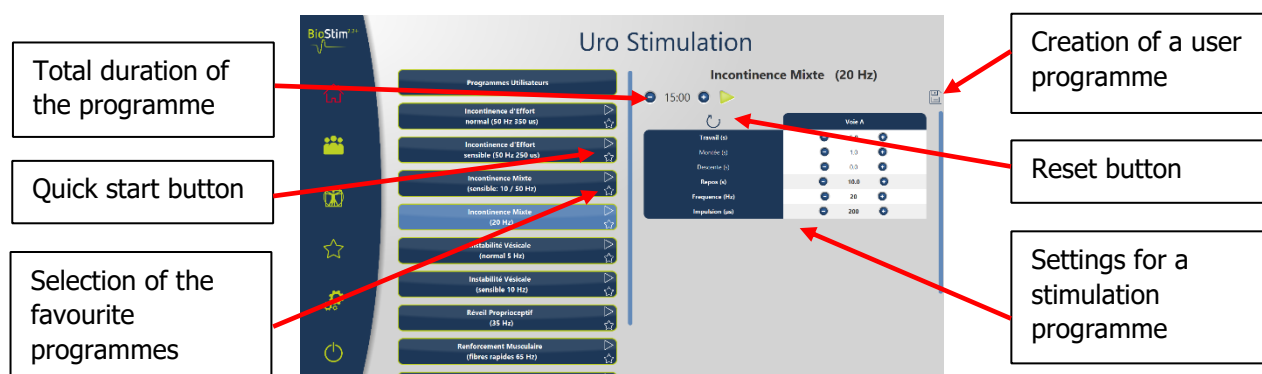
Upon launch, the software opens to the Home page, where all of the device's features can be accessed.

To return to the Home page from any of the other pages in the application, simply press the home-shaped button.



### 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

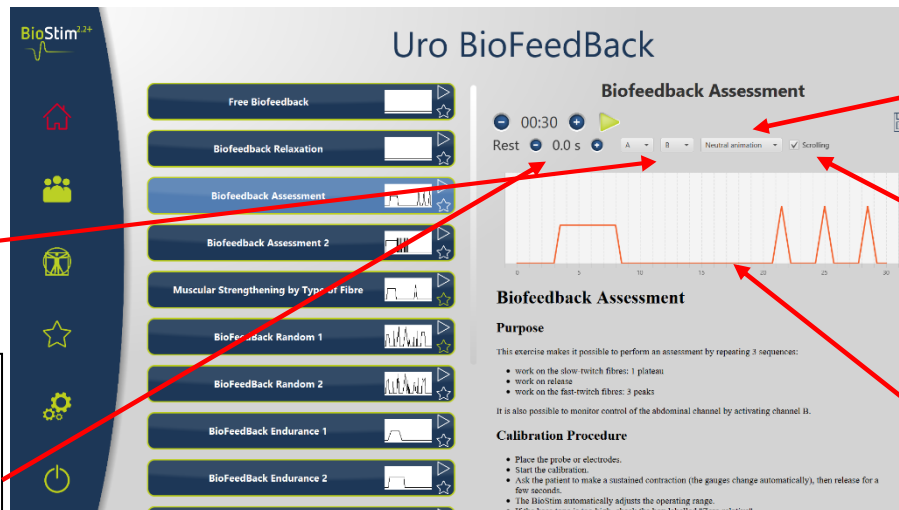
Descriptions of stimulation programmes also feature the parameters of the applied current.

Biofeedback programme descriptions include:

- 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 tracks to use for the principal one and for the secondary one. It is possible to mix an EMG track and a pressure one.



Configuration of the rest time between each profile. This time can be adjusted during the exercise




Choice of the animation to use.

To choose if it is the cursor that move or the background image

Visualisation of the exercise profile.

The programmes' parameters can be adjusted using  and  buttons.

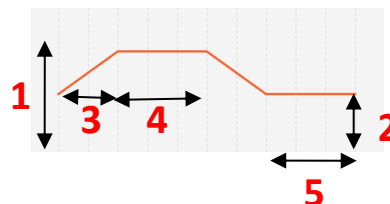
Once you have customised the programme as desired, it can be saved by clicking the  button.

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

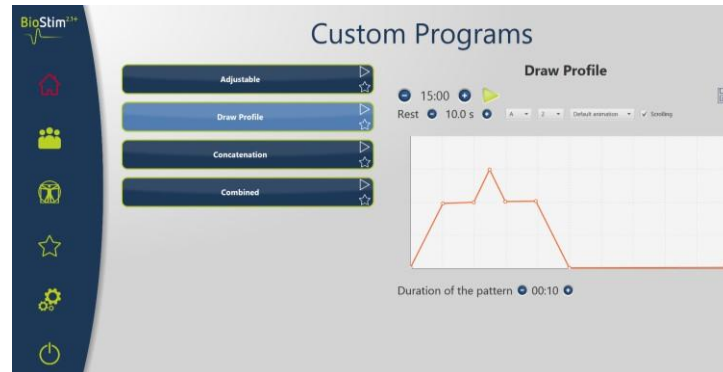
### 7.3.1 2.1+ Version: Adjustable profile

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

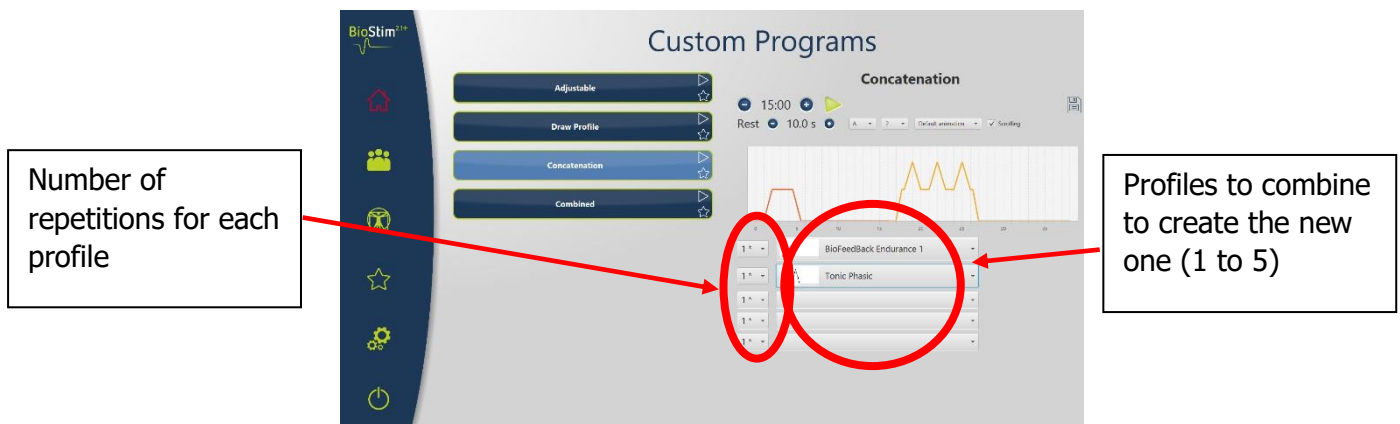


### 7.3.2 + Version: Draw Profile

Permits to draw a profile clicking with the mouse on the drawing area.  
A click in the drawing area adds a point in the curve.  
To delete a point, click on it.

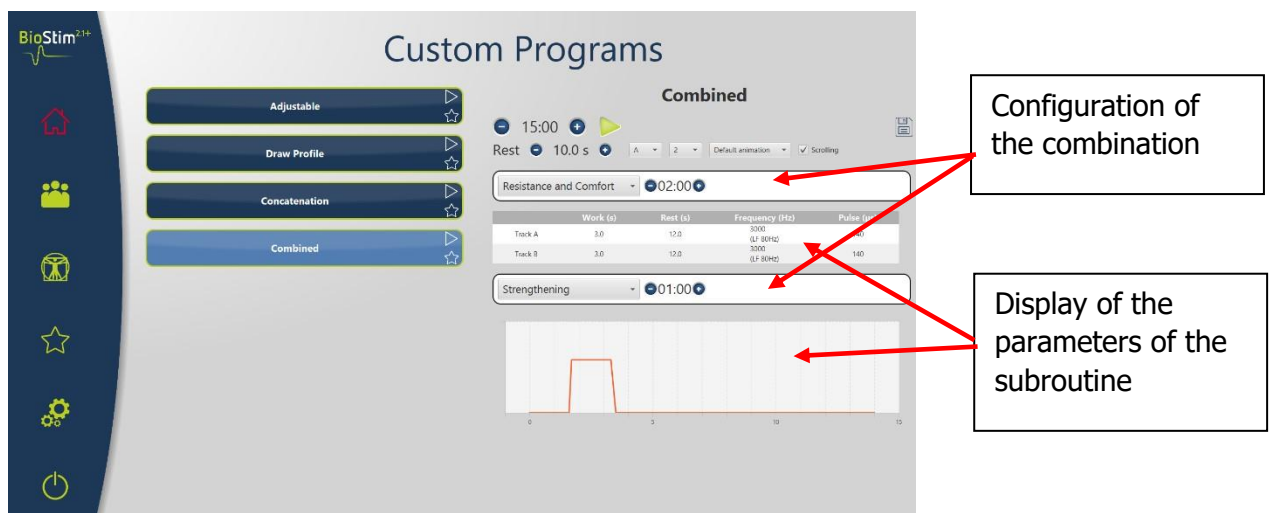


### 7.3.3 + Version: Concatenation





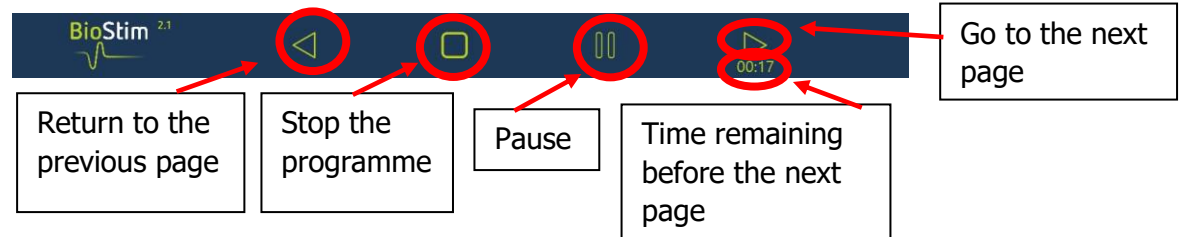
### 7.3.4 + Version: Combined

The combined mode is made to create your own programs, integrating stimulation and BFB, a succession of two 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.



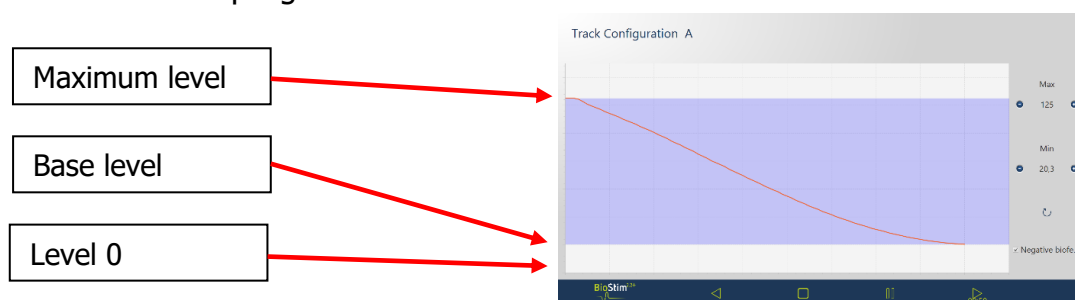
The programme can also be stopped with the handheld emergency stop.

### 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.

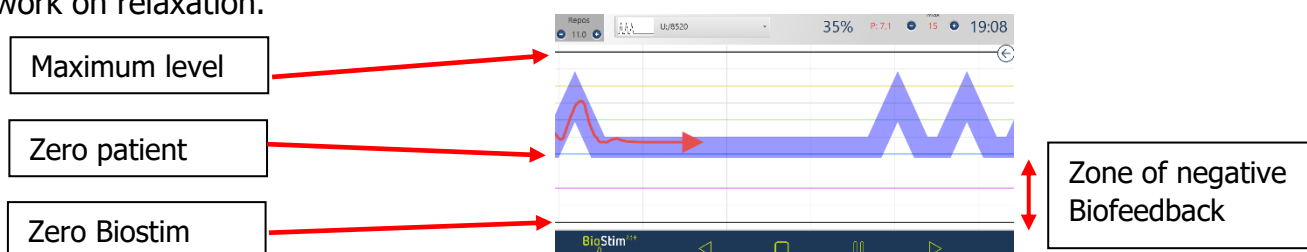
#### Calibration Procedure

- 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 calibration 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.

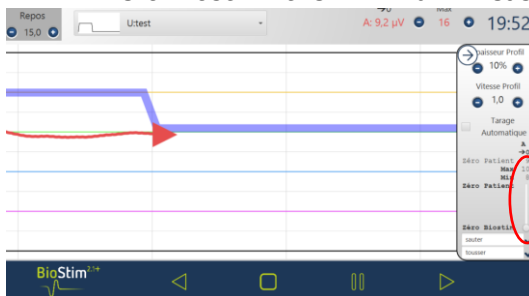


In the "+" version, it is possible to adjust the negative Biofeedback level to show during the exercise with the slider in the panel on the right:

- 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

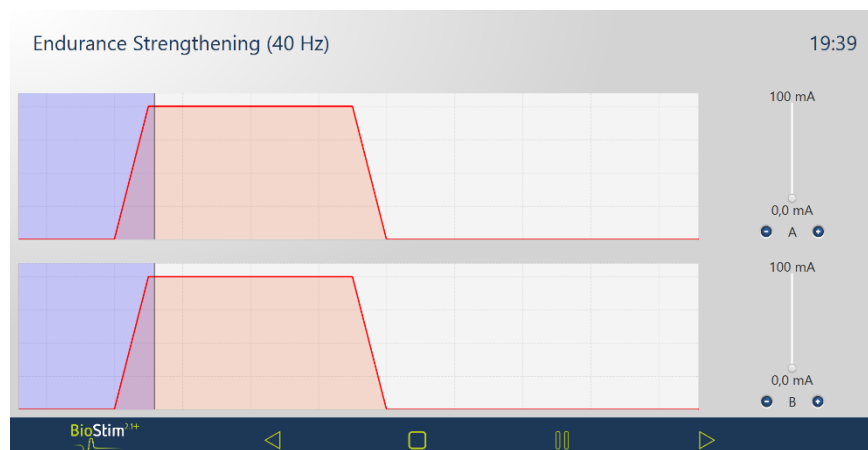


- It is also possible to choose middle values:



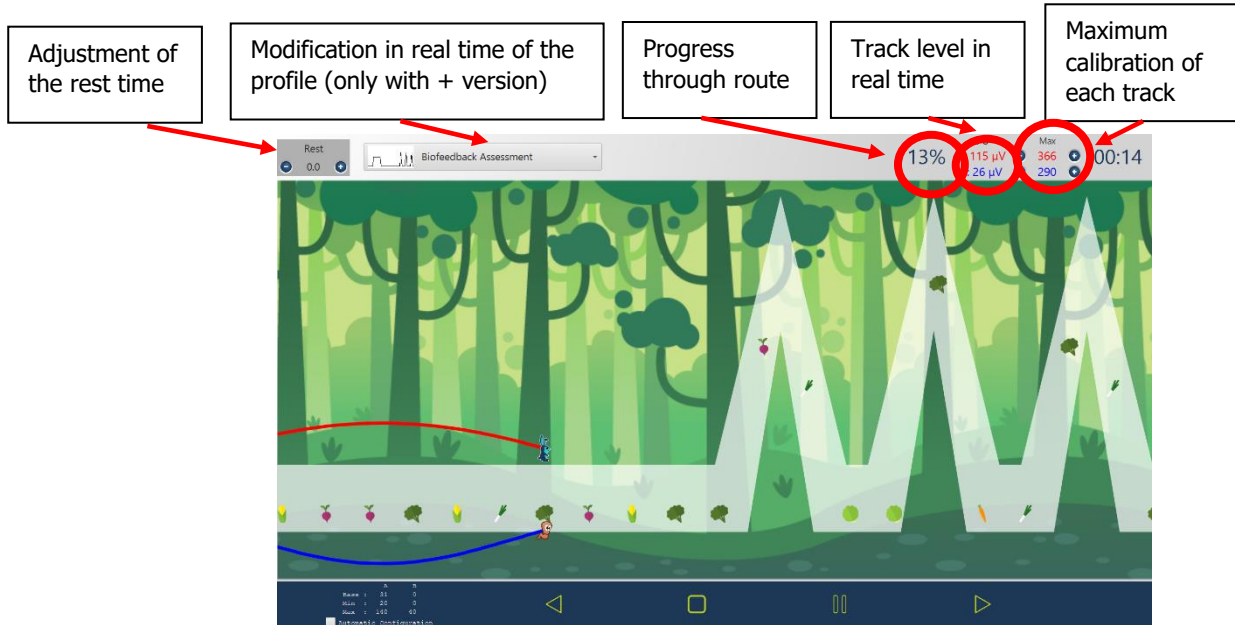
## 7.4.2 Stimulation

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

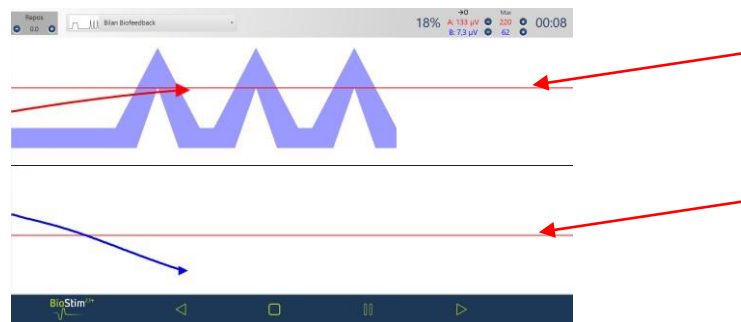




### 7.4.3 Biofeedback

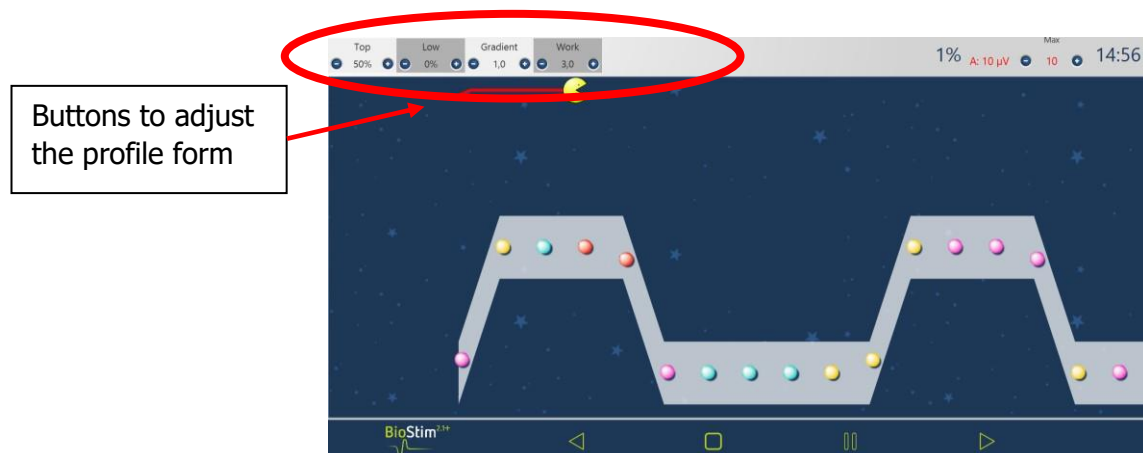


Thanks to a right click on the page, a landmark line is added at the location wanted.




#### 7.4.3.1 + Version: adjustable profile

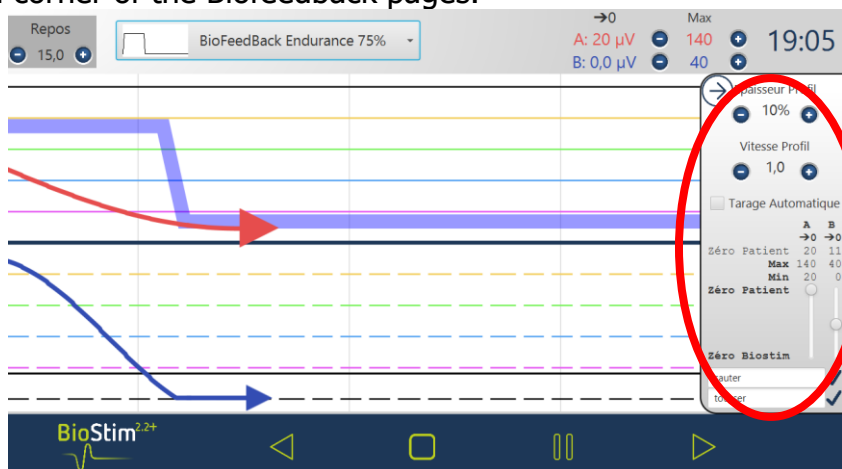
Once the Biofeedback has been created in adjustable profile, the form of the curve can be modified during the exercise thanks to the buttons situated in the top-left corner.





### 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.

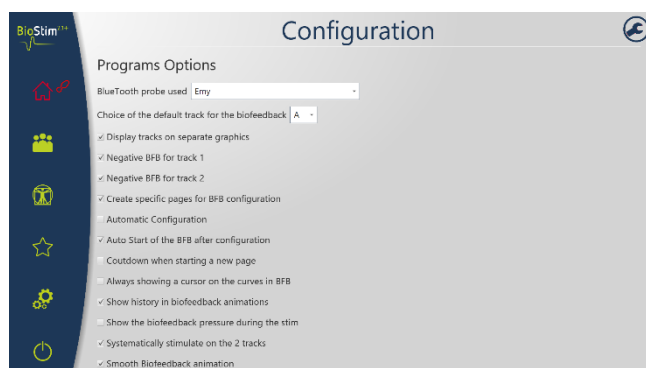
### 7.4.3.3 Review mode

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.

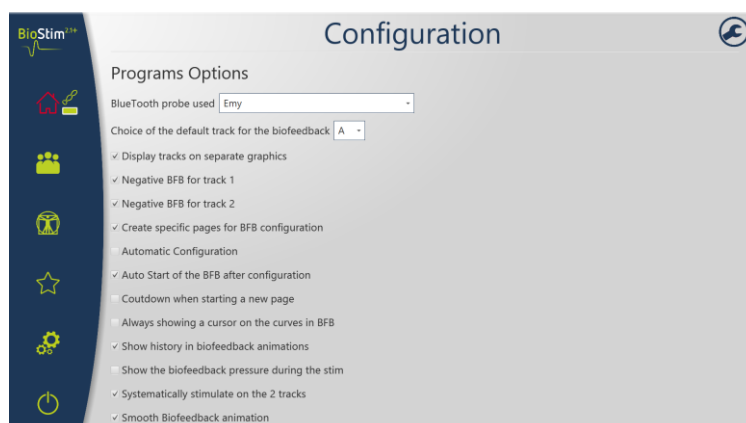


### 7.4.4 Using a Bluetooth probe (Emy or Perifit)

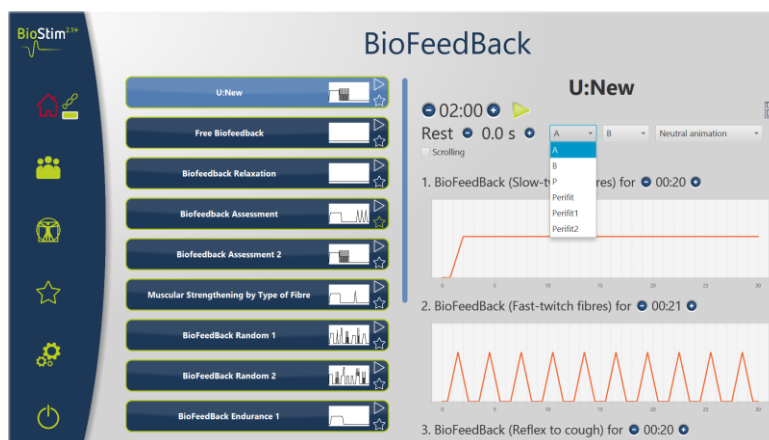
The Biostim is compatible with the probes Emy and Perifit.  
This function is available only if the corresponding option has been bought.  
To use the probes, choose the type of probe you want to use in the configuration page. Next, the probe appears next to the home (on the left menu).



To work with a probe, switch it on (button on the white part of the Perifit, or shake the Emy probe), and click on the probe icon (on the right of the home). When the probe is connected, the icon becomes green and a bargraph indicates the level of the battery.



Then use the probe like the other ones, selecting the track corresponding to the probe in the Biofeedback menu.




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

## 7.5 Favourite Programmes

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.

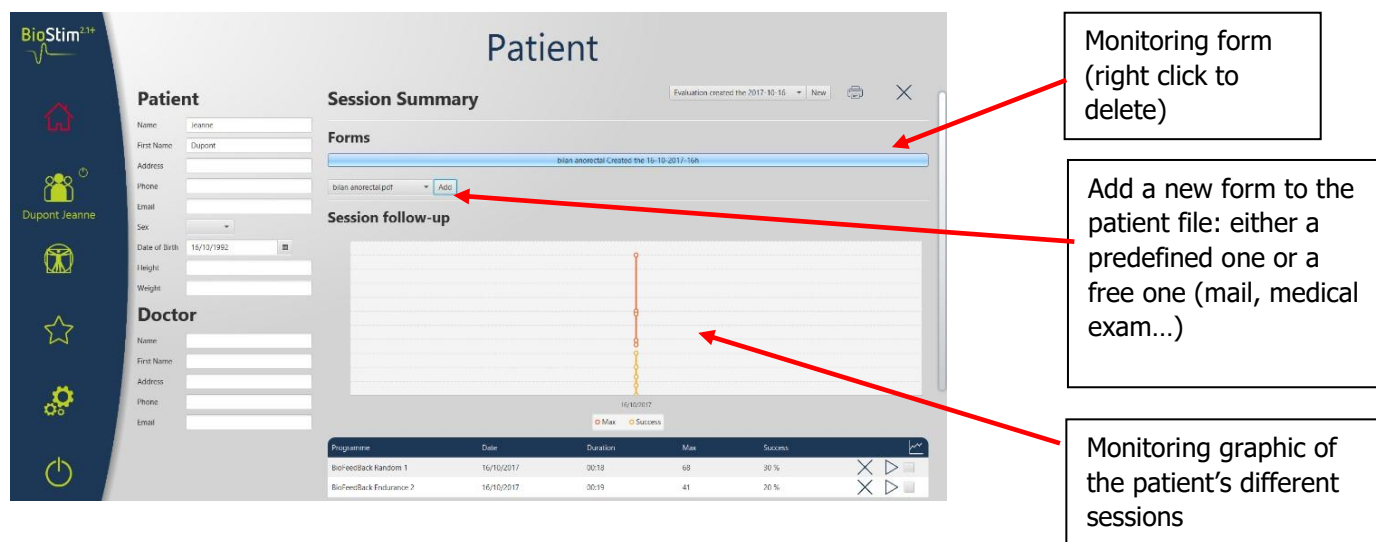


## 7.8 Patient Records

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.



**Patient**

Name: [blank]  
First Name: Dupont  
Address: [blank]  
Phone: [blank]  
Email: [blank]  
Sex: [blank]  
Date of Birth: 16/10/1992  
Height: [blank]  
Weight: [blank]

**Doctor**

Name: [blank]  
First Name: [blank]  
Address: [blank]  
Phone: [blank]  
Email: [blank]

**Session Summary**

Forms

biplan anorectal Created the 16-10-2017-16h

biplan anorectal pot Add

**Session follow-up**

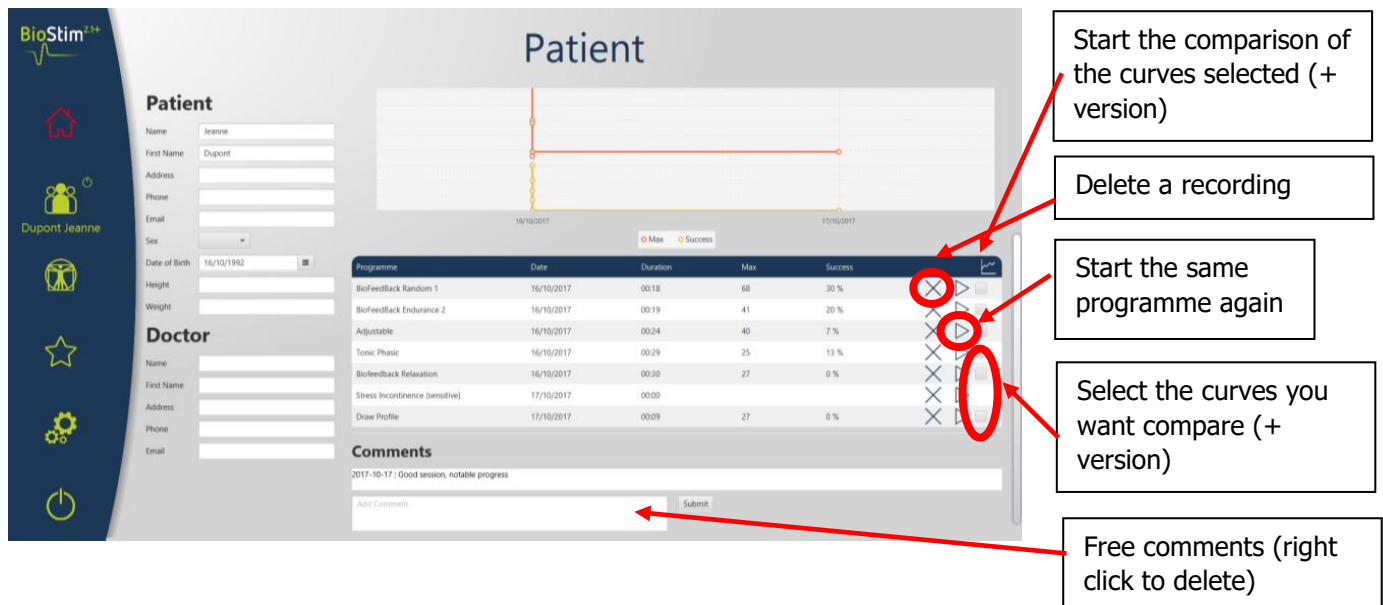
Monitoring form (right click to delete)

Add a new form to the patient file: either a predefined one or a free one (mail, medical exam...)

Monitoring graphic of the patient's different sessions

Programme	Date	Duration	Max	Success
biofeedback random 1	16/10/2017	30:10	69	96 %
BioFeedback Endurance 2	16/10/2017	30:15	41	76 %

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**

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 Incontinence (sensitive)	17/10/2017	00:00		0 %
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.



**Comparison Interface:**

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

**Comparison Table:**

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%

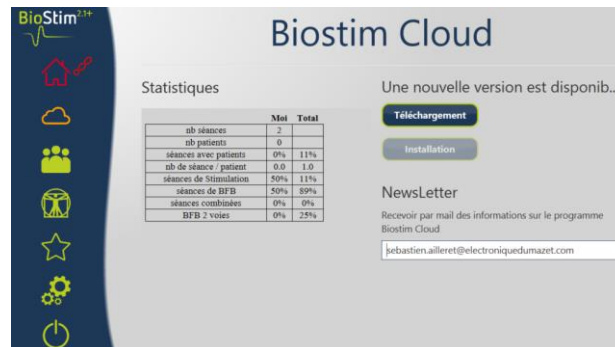
**Legend:**

- 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

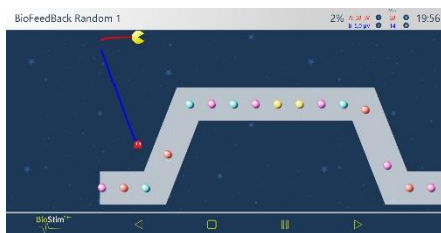


## 7.10 Configuration Page

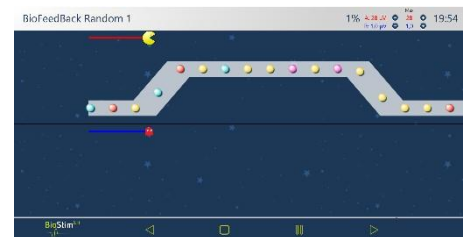
The configuration page allows you to configure the software's settings:

- Scrolling speed: permits to accelerate or to brake the Biofeedback scrolling
- Default track for the BFB (A, B or P)
- Show the tracks on two separate graphics

Inactivated:

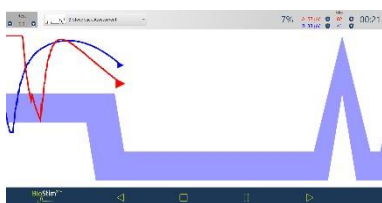


Activated:

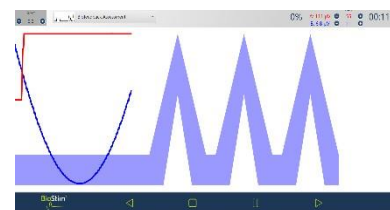


- Possibility to activate or deactivate the negative BFB for each track
- Automatically launch the BFB after the calibration: if this option is not activated, the cursor will not move and wait for a click on the start button at the beginning of the BFB: no movement before a click on this button.
- Obligation to show the cursor on the curves:

Activated:

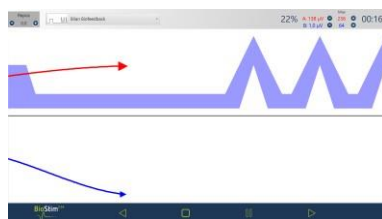


Deactivated:

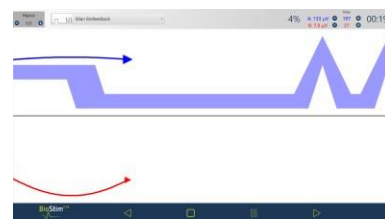


- Invert the colour of the tracks (A= red and B= blue, or the other):

Normal:

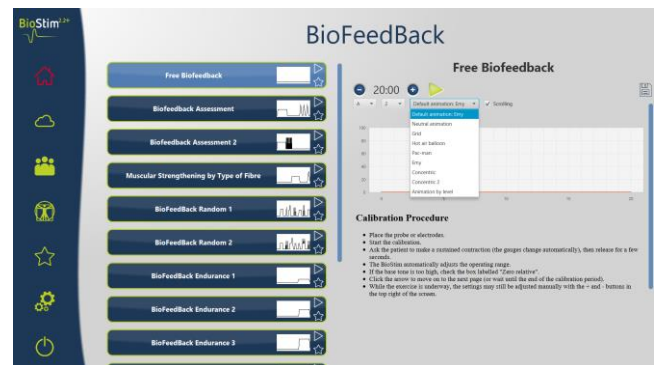
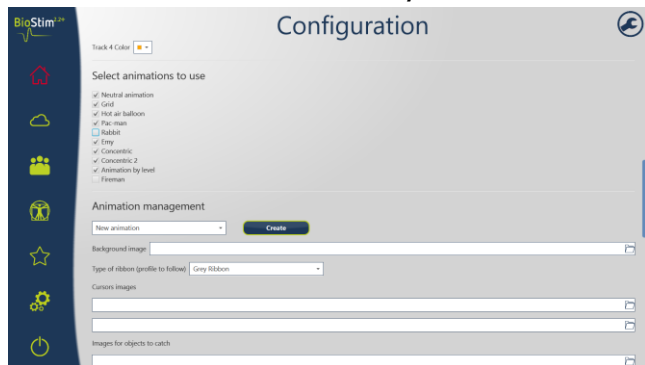


Opposite:





- Selection of the animations: it is possible to choose the animations we want to use. The ones which are deselected will not be shown in the presentation page of the programmes. The custom animations are always shown.



- Show history in biofeedback animations:



Activated:



Deactivated:

- Show the BFB during the stimulation (only for pressure probes with electrodes: as air/stim from Sugar International)

- Systematically stimulate on the two tracks: it permits to use a 2 tracks probe (ex: Perisize 4), even with the programmes expected for a track only.

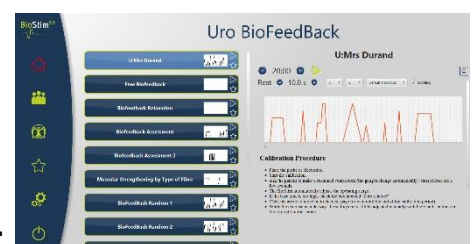
- Sound management: choice of the music played at the end of the programme, possibility to add a sound for transitions between biofeedback and stimulation, sound BFB (for visually impaired person), sound indication for the beginning and the end of a contraction. All those sounds are configurable by the user.

- Creation, modification and deletion of a custom animation: requires a background image, a cursors image and one or several images for objects to catch.

- Put the user programs in a subdirectory:



Activated:



Deactivated:

### 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](mailto:sav@electroniquedumazet.com)**

### Possible malfunctions:

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

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 Récyllum recycling collection point.

As part of its commitment to helping the environment, Électronique du Mazet finances the Récyllum recycling system, which is dedicated to professional WEEE. Récyllum is a free service that takes electrical lighting equipment, control and surveillance equipment, and used medical devices. For more information, go to [www.recyllum.com](http://www.recyllum.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, vacuumobilization, and electrotherapy (urinary re-education). If you would like to find out more, please do not hesitate to contact us.

**SAS 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**




[www.electroniquedumazet.com](http://www.electroniquedumazet.com)

## 16. EMC Scorecard

EMC Compliance according to IEC 60601-1-2 (2014) 4th Edition (EN 60601-1-2 : 2015)			
The <b>BIOSTIM</b> is intended to be used in the electromagnetic environment specified below. The client/user of the <b>BIOSTIM</b> device must ensure that it is used in such an environment.			
Emissions test		Compliance	Electromagnetic Environment - Directives
RF Emissions CISPR 11		Group 1	The <b>BIOSTIM</b> only uses RF energy for its internal functions. As such, it has very low RF emissions, which are not likely to cause interference with neighbouring electronic devices.  The <b>BIOSTIM</b> is suitable for use in all premises, including in homes and premises directly connected to the public lowvoltage power supply network that supplies buildings used for housing.
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 <b>BIOSTIM</b> is intended to be used in the electromagnetic environment specified below. The client/user of the <b>BIOSTIM</b> device must ensure that it is used in such an environment.			
Immunity test	IEC 60601-1-2 Test Level	Level of compliance	Electromagnetic Environment - Directives
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	The floors should be made of wood, concrete or ceramic tiles. If the floors are covered with synthetic materials, relative humidity should be at least 30%.
Electrical fast transient / burst immunity test IEC 61000-4-4	± 2 kV for electrical power supply lines ± 1 kV for input/output lines	± 2 kV for electrical power supply lines	The quality of the electrical power supply network should be typical of a commercial or hospital environment.
Transient overvoltage (surge) 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 electrical power supply network should be typical of a commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines 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-phased: 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% UT: 1 cycle and 70% UT; 25/30 cycles Single-phased: at 0 degree 0 % UT; 250/300 cycles	The quality of the electrical power supply network should be typical of a commercial or hospital environment. If the user of the <b>BIOSTIM</b> requires that the device function continuously during interruptions in the power supply, we recommend powering the <b>BIOSTIM</b> with an uninterruptible power supply or a battery. NOTE: <i>UT</i> is the AC mains voltage prior to application of the test level.
Magnetic field At power frequency (50/60 Hz) IEC 61000-4-8	3 A/m 50Hz or 60Hz	3 A/m 50Hz or 60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic, commercial, or hospital environment.

EMC Compliance according to IEC 60601-1-2 (2014) 4th Edition (EN 60601-1-2 : 2015)			
The <b>BIOSTIM</b> is intended to be used in the electromagnetic environment specified below. The client/user of the BIOSTIM device must ensure that it is used in such an environment.			
Immunity test	IEC 60601-1-2 Test Level	Level of compliance	Electromagnetic Environment - Directives
Conducted RF disturbances IEC 61000-4-6	3 Vrms 150 kHz-80 MHz 6 Veff in the ISM strip between 0,15 MHz and 80 MHz 80 % AM at 2 Hz	3 Vrms 150 kHz-80 MHz 6 Veff in the ISM strip between 0,15 MHz and 80 MHz 80 % AM at 2 Hz	Portable and mobile RF communications equipment should be used no closer to any part of the <b>BIOSTIM</b> , including cables, than the recommended separation distance calculated using the equation applicable to the frequency of the transmitter. <b>Recommended separation distance</b> $d=1,67. \sqrt{P}$  $d=1,67. \sqrt{P} \quad 80\text{MHz}-800\text{MHz}$  $d=2,33. \sqrt{P} \quad 800\text{MHz}-2.5\text{GHz}$
Radiated RF disturbances IEC 61000-4-3, including the clause 8.10, the table 9, for the proximity of the wireless devices	3 V/m 80 MHz-2,7 GHz 80 % AM at 2 Hz including the clause 8.10, the table 9, for the proximity of the wireless devices	3 V/m 80 MHz-2,7 GHz 80 % AM at 2 Hz including the clause 8.10, the table 9, for the proximity of the wireless devices	where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a), should be less than the compliance level in each frequency range (b).  Interference may occur in the vicinity of devices marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcasts and TV broadcasts cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which 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 re-orienting or relocating the BIOSTIM. (b) Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications devices and the BIOSTIM			
The <b>BIOSTIM</b> is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the <b>BIOSTIM</b> can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the <b>BIOSTIM</b> as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (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 rated at a maximum output power not listed 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 output power rating of the transmitter in watts (W) according to the transmitter's manufacturer. NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			





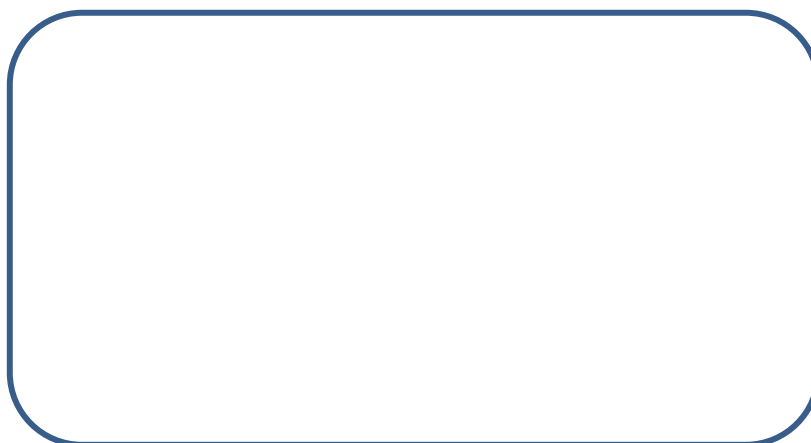
ELECTRONIQUE DU MAZET

ZA ROUTE DE TENCE  
43520 LE MAZET SAINT VOY  
France

Tél: +33 4 71 65 02 16

Mail: [sav@electroniquedumazet.com](mailto:sav@electroniquedumazet.com)

Your dealer / distributor:



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