

User Manual



Electrotherapy device
BioStim 2.2+
BioStim 2.1 / 2.1+
BioStim 2.0 / 2.0+
BioStim 1.0

Instructions for use & Technical description

Please read these instructions carefully before using your new device!

This manual is an integral part of the device and must be kept until it is destroyed.

This equipment has been designed and manufactured for therapeutic use.

The device is intended to be used only by physiotherapy professionals and qualified midwives.

If you have a problem or do not understand this manual, please contact your distributor (see stamp on the last page) or contact Électronique du Mazet at :

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

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

1 Presentation of the device

The Biostim is an electrotherapy device that helps physiotherapists and midwives in perineal rehabilitation.

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

The programmes, predefined in the device, allow most perineal rehabilitation treatments to be carried out in the urogynaecological and anorectal fields.

The main programmes available are

- Urogynaecological biofeedback, EMG or Pressure
- Urogynaecological stimulation
- Combined urogynaecological programmes, which combine biofeedback and stimulation
- Analgesia for urogynaecology
- Stimulation and anorectal biofeedback programmes

The device also allows individual follow-up of each patient, by memorising the sessions carried out and their results, as well as by adding any comments or links to follow-up forms.

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2 Description and technical information

- This user and maintenance manual is published to facilitate the handling of your BioStim from the initial reception phase, through commissioning, to the successive stages of use and maintenance.

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

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

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

- In the case of transfer of the device to a third party, it is obligatory to inform Électronique du Mazet of the details of the new owner of the device. It is imperative to provide the new owner with all documents, accessories and packaging relating to the appliance.

- Only personnel who have been informed of the contents of this document may use the equipment. Failure to comply with any of the instructions contained in this document will release Électronique du Mazet and its authorised distributors from the consequences of accidents or damage to personnel or third parties (including patients).

2.1 Symbols used



Warning: this logo draws your attention to a specific point



Operating instructions: This logo informs you that the operating instructions must be read for safe use of the appliance



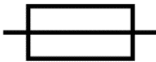
Type BF applied part: applied part in contact with the patient.



Recycling: This appliance should be disposed of at an appropriate collection and recycling facility. Consult the manufacturer.



Protective earth



Fuse



Caution: Switching the appliance off and on



Alternating current



Serial number



Manufacturer



Date of manufacture



Product reference



Unique identifier



Medical device

2.2 Technical specifications

2.2.1 General characteristics

- Operating temperature: 15°C to 35°C.
- Storage temperature: -20°C to 70°C.
- Operating relative humidity: 30% to 75%.
- Operating altitude: < 2000 metres

2.2.2 Technical characteristics of the device

- Case dimensions: **33.7 x 28 x 6.7 cm**
- Case weight: **3.1 Kg**
- Housing colour: **white**

- Power supply: **110-230VAC - 50-60Hz**
- Power consumption: **55VA** max
- Fuses: 2x size 5x20mm - **T1.25AH-250V**
- **Class I** electrical equipment
- Medical **Class IIa** equipment.
- Applied part **type BF**
- Liquid protection type **IPX0**.
- Communication with the PC: Optically isolated **USB**.
- Power on indication by a green light on the front panel.
- Possibility to stop the stimulation by an emergency stop bulb.

- 1 or 2 Electro channels. Each channel has the following features:
 - Current generator :
 - Output currents of each generator adjustable from **0 to 100mA** (+/-10%).
 - Under a load impedance of 1k Ω (or more), at max current, the voltage is **limited to 100V** -20%/+10% (peak value).
 - Under a load impedance of less than 1k Ω , the voltage level is limited according to the impedance (10volts for 100 Ω , 50volts for 500 Ω)
 - If the impedance is too high (above 10 k Ω), the current can be cut off: **unstuck electrode** function
 - ⇒ The rectangular shaped signals are biphasic (symmetrical pulses with zero average), the pulse width is adjustable from **50 μ s to 10ms**, the frequency is adjustable from **1Hz to 5kHz**.
 - ⇒ The generators are electrically independent (no current flows between the 2 electrodes of the 2 generators).
 - ⇒ Indication of the activation status of the output by a yellow LED.
- Biofeedback activity measurement: Full scale sensitivity: 2mV (peak-to-peak)
- 0, 1 or 2 channel Biofeedback pressure
 - ⇒ sensitivity range: **400 mBar**

2.2.3 Different versions of the device

The functionality of the different versions of the device is as follows:

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

Each version (except version 1.0) may have additional optional software features (version +). These functions are described in section 7.3.

2.2.4 Accessories

This device is delivered with the following accessories as standard:

- MEG010EN601 Biostim electrode lead
- MEG010EN603 Biostim emergency stop bulb
- MEG010EN605 Blue Biostim pressure kit (optional)
- MEG010EN606 Red Biostim pressure kit (optional)
- EM6055KP504 IR REMOTE CONTROL (optional)
- 2m USB cable
- USB CLE (PC software / USB drivers)
- POWER CABLE

2.2.5 Applied parts

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

List of products compatible with the device :

- Dura-Stick Plus Stimulation Electrodes (DJO Global) CE 0473
- Vaginal probe Saint-Cloud Classic (DJO Global) or Optima 3 (Sugar)
- Perifit or Fizimed CE probe.
- RectoMax rectal or Aerolys vaginal pressure probe
- Blueback (Blueback SAS)
- BioMoov (Electronique du Mazet)

The use of products not recommended by the manufacturer does not engage his responsibility

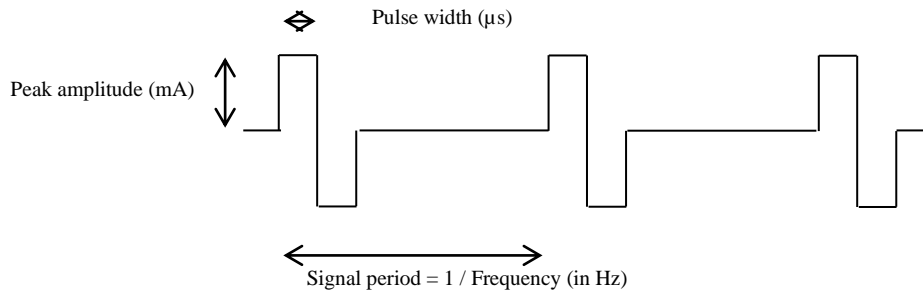
Make sure that the hygiene conditions recommended by the manufacturer of the applied part are observed.

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

2.2.6 Form of the currents

Two-phase rectangular pulses

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



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

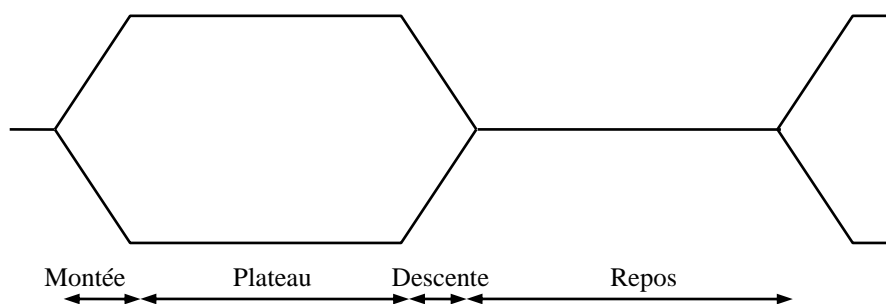
The pulse width is adjustable from **15µs to 10ms**, the frequency is adjustable from **1Hz to 5kHz**.

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

The device complies with standard 60601-2-10: Medical electrical equipment: special requirements for basic safety and essential performance of nerve and muscle stimulators. In particular, this standard limits the delivered intensities as well as the powers per pulse.

Envelope generation :

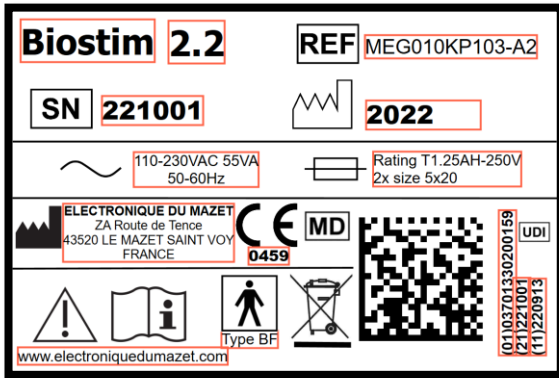
The pulse signal is included in an envelope allowing a progressive application and cut-off of the current



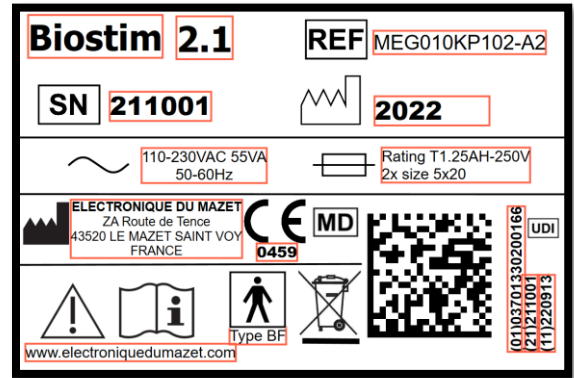
2.3 Nameplate label

The information and characteristics are given on the back of each appliance on a label

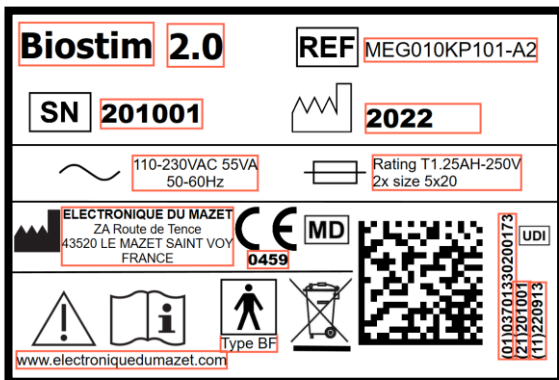
Label for "Biostim 2.2+" :



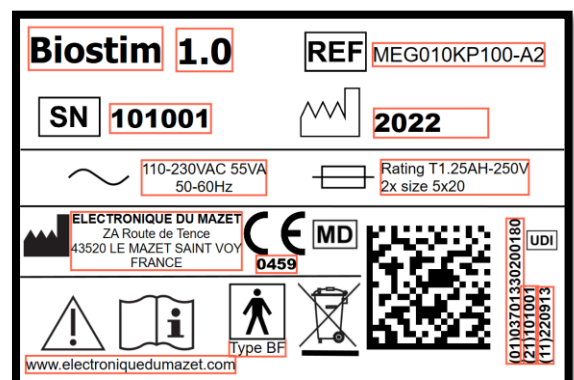
Label for "Biostim 2.1 / 2.1+".



Biostim 2.0" label
or "Biostim 2.0+":



Biostim 1.0" label



2.4 Warnings



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



CAUTION: Power strips must not be placed on the floor. No other electrical appliance or power strip should be connected to the power strip.



CAUTION: The appliance must be connected to an outlet with a grounding terminal (Class I electrical appliance)



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



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



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



CAUTION: This equipment complies with applicable electromagnetic compatibility standards. If you experience interference or other problems with another device, contact Électronique du Mazet or the distributor for advice on how to avoid or minimize the problem.



CAUTION: Operation in close proximity (e.g., 1 m) to shortwave or microwave therapy EM equipment may cause instabilities in the output power of the STIMULATOR.



CAUTION: The patient connected to the device must not be connected to other equipment (monitoring or diagnostic equipment) during treatment. This may cause interference with the ancillary equipment.

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



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



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



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



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



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



ATTENTION:

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



CAUTION: The output signals of the device are biphasic symmetrical with zero average and do not include a DC component. Any unpleasant sensation (irritation, overheating) at low intensities could mean a defect in the equipment.
Do not use the device without the advice of the MANUFACTURER.



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



CAUTION: If the computer used is not approved as a medical device, the computer must not be located in a space accessible to the patient

2.5 Risks residual

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

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

Microbes or viruses can be transmitted from one patient to another via the applied parts. Make sure that the hygiene conditions recommended by the manufacturer of the applied part are observed.

If water enters the unit, it may not function properly. In this case, unplug the unit and disconnect the cables. In any case, avoid the presence of water in the vicinity of the device.

2.6 Confidentiality of patient data

The device collects data from the computer to which it is connected. No data is stored in the device.

It is the responsibility of the practitioner to apply and comply with the European Parliament's General Data Protection Regulation 2016/679.

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

2.7 Cybersecurity

As the device and its software Biostim are computerised systems integrated into larger information systems, certain rules and good practices must be put in place to ensure the safety of patients and users.

Électronique du Mazet does not supply or have control over the operating environment of its products, it is therefore the responsibility of the practitioner to ensure that the following recommendations are respected.

2.7.1 Good practices for IT security

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

2.7.2 Technical information

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

2.7.3 Network communications

- The device does not require a network connection to operate
- If the user agrees (by checking the BiostimCloud option), data can be sent regularly to the Electronique du Mazet servers
 - All these data are anonymised
 - They are only collected for statistical purposes, or to facilitate remote assistance
- The device can also communicate with the Electronique du Mazet servers, to find out if updates are available, and if so, to update.
- All exchanges use a secure protocol (https)

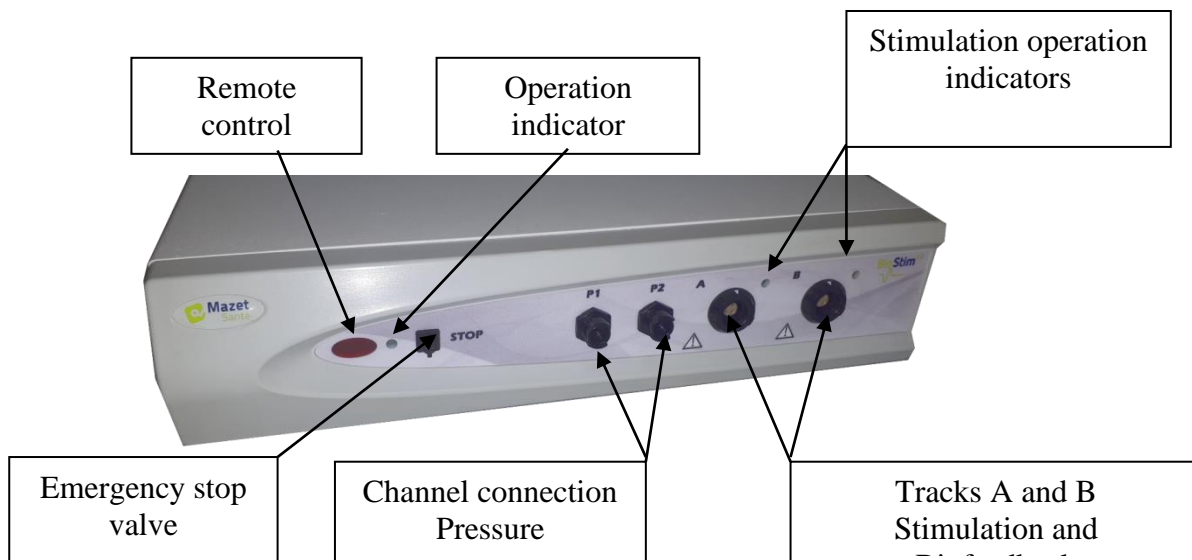
3 Installation of the appliance

Open the carton, remove the accessories and the appliance.
Check the contents of the box against the packing list included with the documentation.
If the appliance was stored in a cold place and there was a risk of condensation, leave the appliance to stand for at least 4 hours at room temperature, about 20°C.
Install the unit on a stand at working height.

3.1 General positioning of the installation

Place the Biostim on a table outside the patient's environment.
Place the PC on the same table and connect them via USB to the back of the unit
Connect the power cord to the back of the unit

The practitioner positions himself between the patient and the device
The patient lies on a massage table, or sits on a chair next to the practitioner

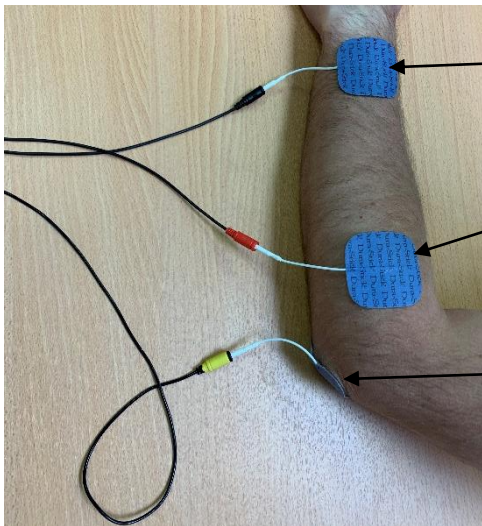


3.2 Connection of accessories

Connect the emergency stop bulb to the front panel.

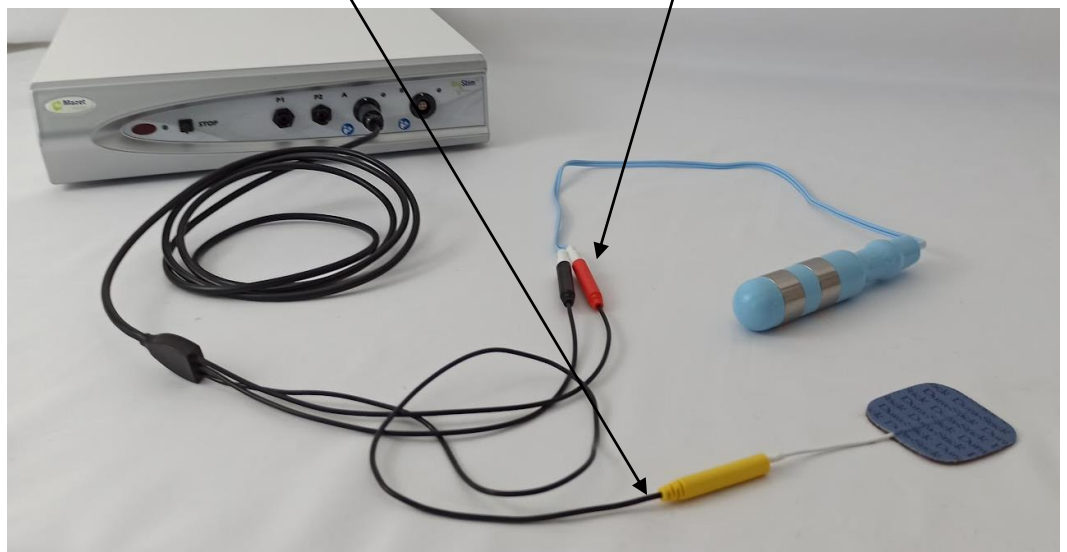


Connect the pacing lead(s) to channel(s) A (and B) according to your application.



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

To do BFB, place the 3^{ème} electrode (yellow tip) on a bony part (useless for stimulation)



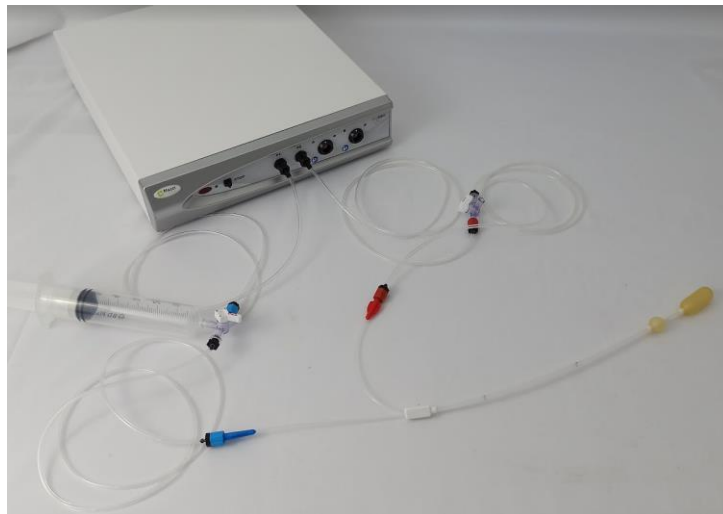
To use the pressure channels, connect the pressure kit to the pressure channels.

A single balloon catheter (vaginal or anal) is then connected directly behind the tap to the P1 line.



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

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



4 Software commissioning

4.1 Configuration

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

- Windows 8, 10 or 11, or MacOS
- Intel Core i3
- 4 GB RAM
- Recommended resolution: at least 1366*768
- To use an accessory (Blueback, BioMoov, Emy or Perifit), it is necessary to have a PC running **Windows 10 or 11** equipped with a BlueTooth card

4.2 Software requirements

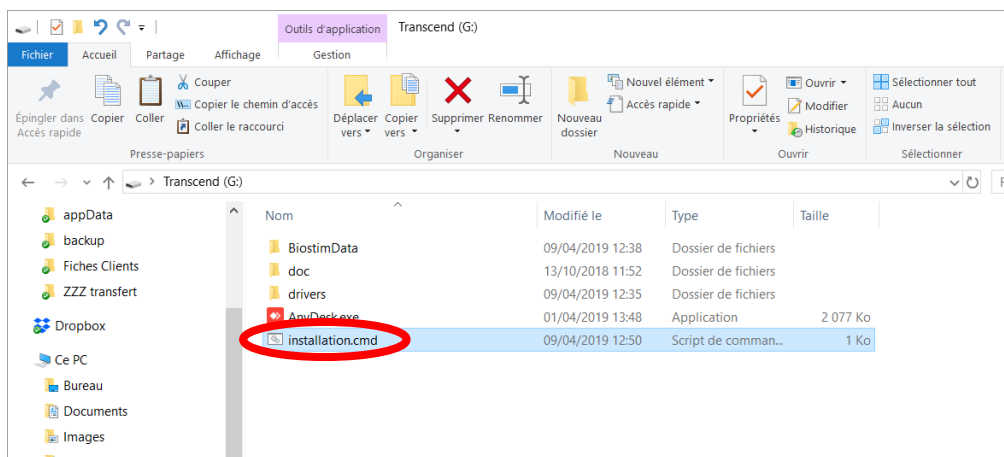
The following software must be installed on the computer:

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

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

4.3 Installation

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



This creates a BiostimData directory on the desktop (which will contain all patient data), as well as a Biostim shortcut (or Biostim.exe).

4.4 Start-up

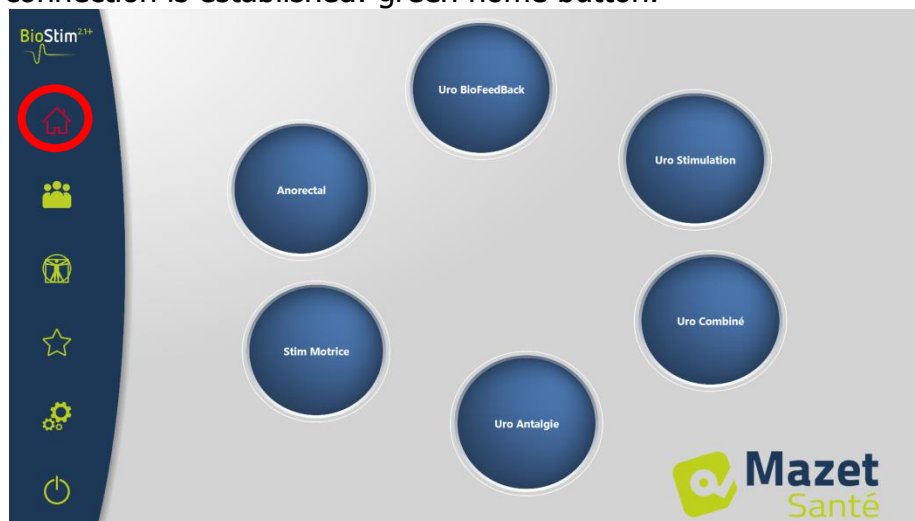
Turn the on/off switch on the back of the unit to ON "1".
Check that the green power indicator light on the front of the unit is on.

Run the Biostim program on the PC



4.5 Checking the connection

Check that the connection is established: green home button.



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 up, the green light on the front panel is on.
- The USB cable is properly connected to the device and the PC.
- The FTDI driver is correctly installed (CDM21228_Setup.exe)

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

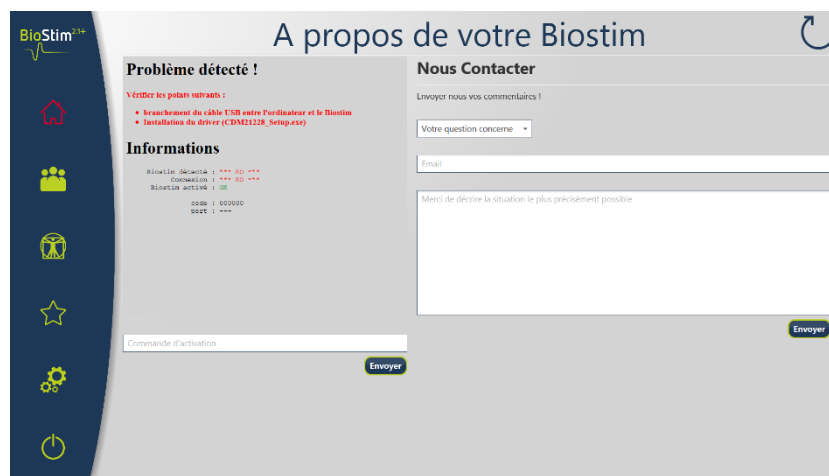
- Check that the emergency stop valve is connected
- If the emergency stop has been activated, the BioStim must be restarted (on/off switch at the back of the device)

4.6 *In case of problems*

Go to the "About your Biostim" page (via the configuration menu)



This page gives information about the problem and also allows you to report problems or suggestions by e-mail.



4.7 *Switching off the device*

Disconnect the patient from the applied parts beforehand.
Exit the Biostim program on the PC (symbol)



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

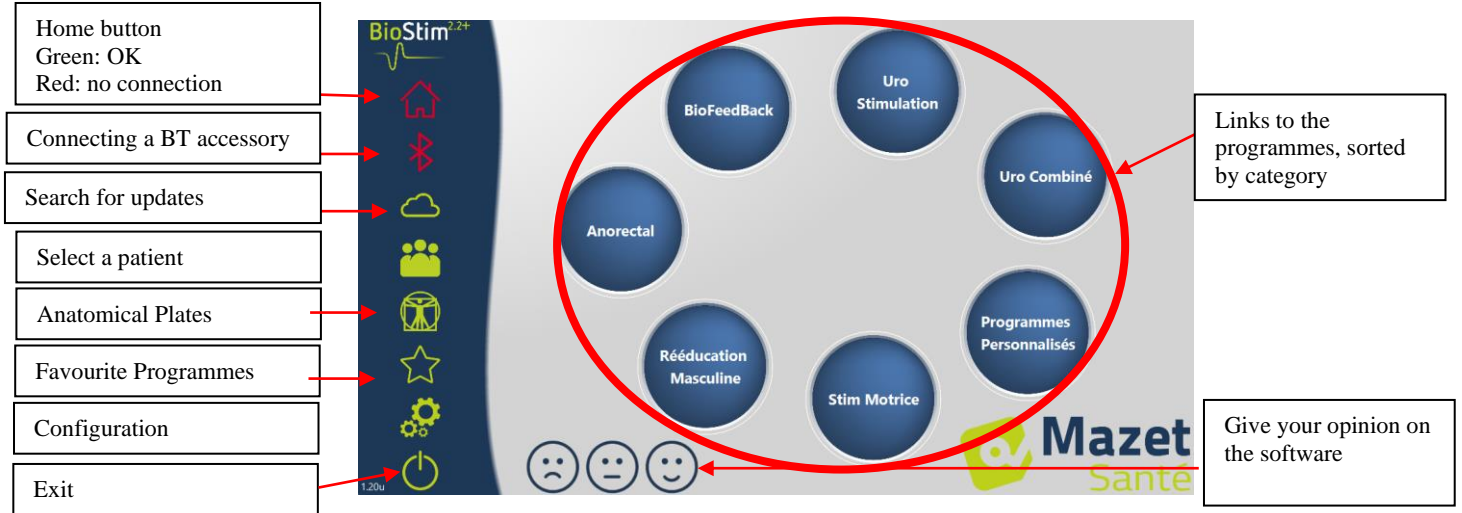


5 User's manual

5.1 Home page

On launch, the software opens to the home page, which provides access to all the device's features.

From any page of the application, pressing the home button will take you back to this page.

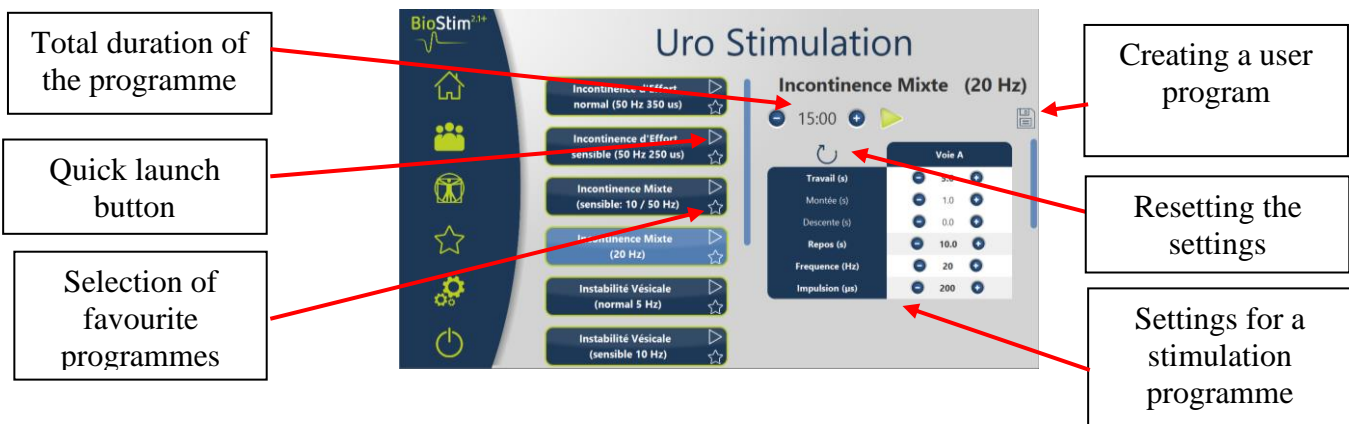


It is possible to rename a category by right-clicking on the desired category.

5.2 Programme selection and customisation page

Clicking on a programme category opens the programme selection page.

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



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

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

In the case of a stimulation programme, the current parameters are also included

In the case of a biofeedback programme, this includes

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


Choice of channels to be used for the primary and secondary pathways. It is possible to mix

Choice of the type of animation to be

Allows you to choose whether the cursor or the background image

Viewing the exercise profile

It is possible to adjust the parameters of the programmes using the buttons **+** and **-**.

Once the programme has been customised as desired, it can be saved using the  button. Registered programmes are recognisable because their name starts with "U:". They are placed at the top of the programme list.

5.3 Programs specific to the + version

5.3.1 Version+: Adjustable Profile

Allows you to define profile settings and adjust them in real time during exercise.

Programmes Personnalisés

Ajustable

Repos: 15:00
Repos: 10.0 s
Animation par défaut: Lyon

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

5

1 2 3 4 5

5.3.2 Version + : Free Drawing



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.

5.3.3 Version +: Drawing 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.

5.3.4 Version + : Chains



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

5.3.5 Version +: Random programmes





The random mode allows you to create a random programme. Each time it is started, a new profile is created by combining all the selected elementary patterns

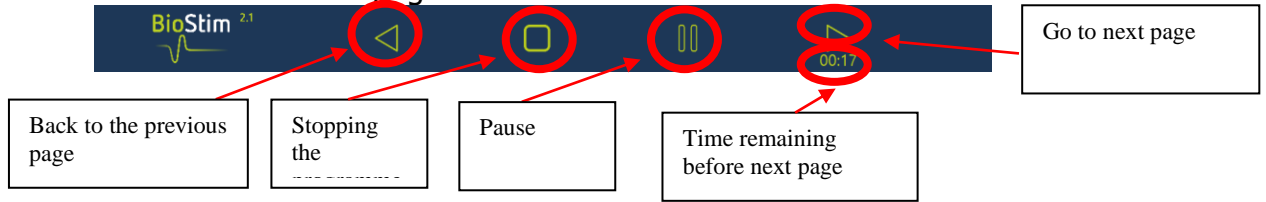
5.3.6 Version +: Combined Programmes



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



5.4 Launching a programme

From the program selection page, a program can be started by clicking on the  button in the program description section, or on the  icon in the upper right corner of the program name. A programme is composed of one or more pages that are linked after a predefined time or by an action on the lower menu of the page.



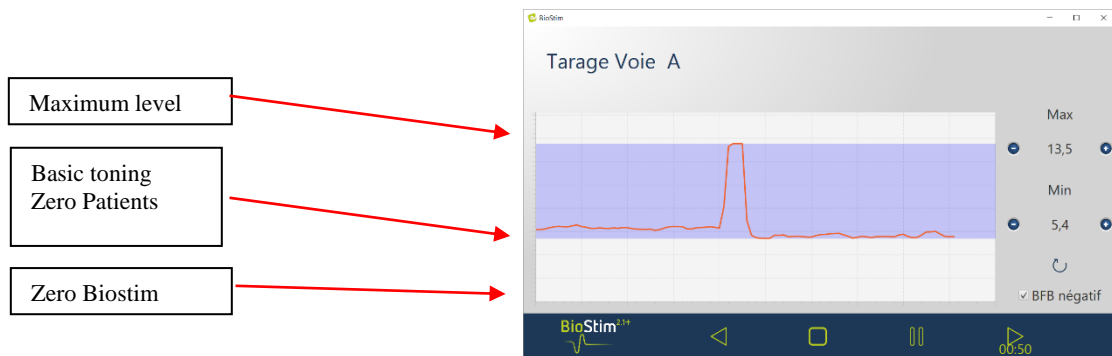
It is also possible to stop the programme using the emergency stop bulb

5.4.1 Taring Biofeedback

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

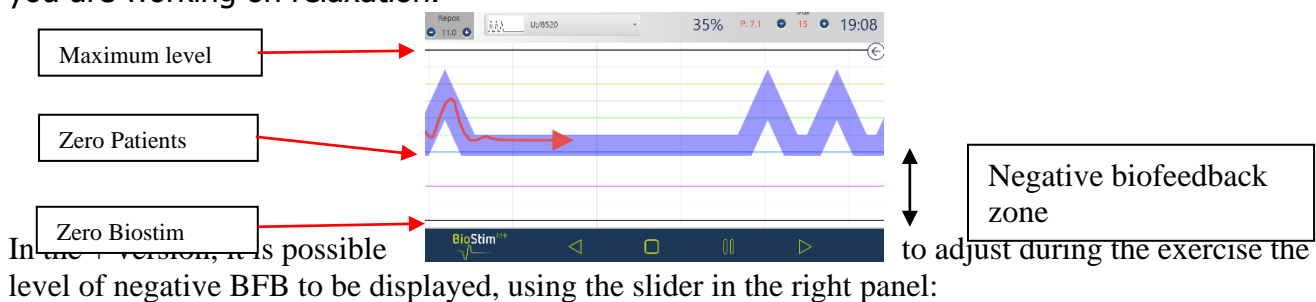
Procedure for taring

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



It is possible for each channel to enable or disable negative biofeedback, either in the configuration page or during taring.

If the option is enabled, you can see the work below the base level. This is particularly useful if you are working on relaxation.



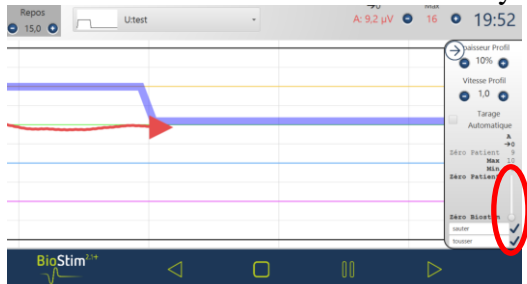
In the previous version, it is possible to adjust during the exercise the level of negative BFB to be displayed, using the slider in the right panel:

- Zero Patient: the bottom of the screen corresponds to the minimum reached by the patient during taring

This setting allows the basic tone to be erased.



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

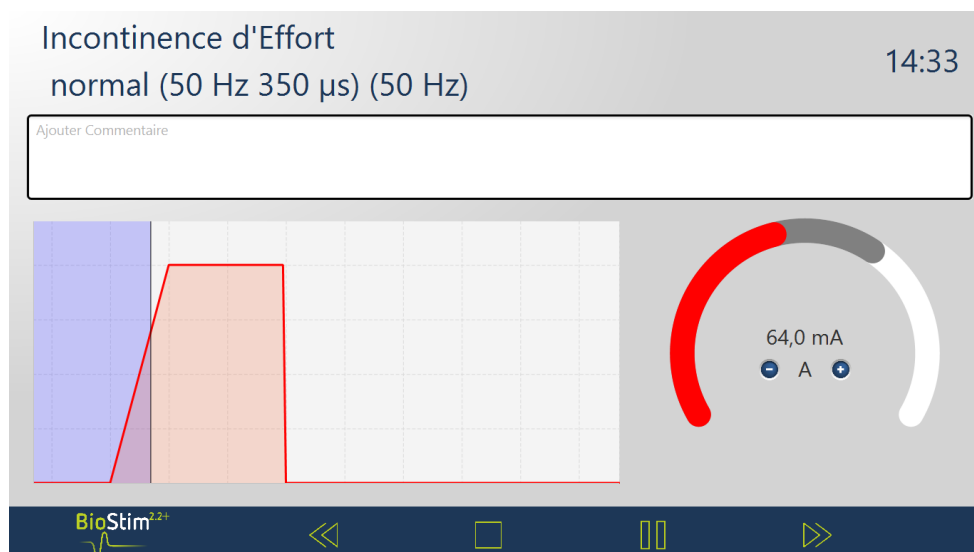


- It is also possible to choose intermediate values:



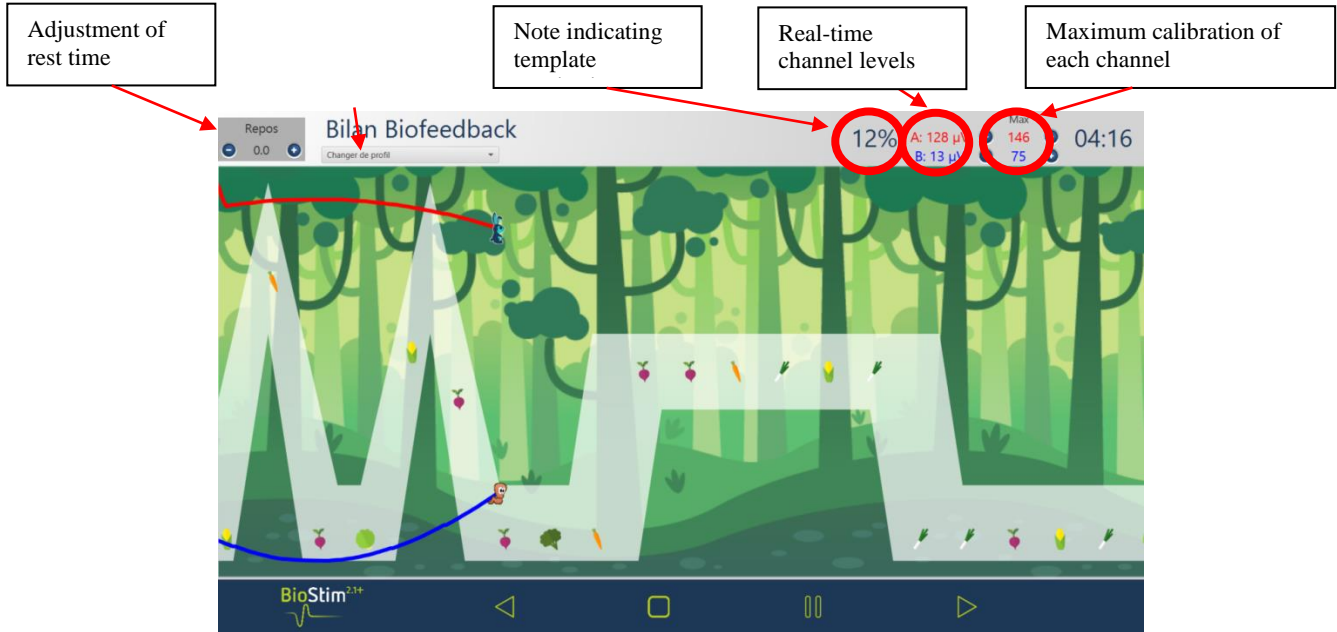
5.4.2 Stimulation

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

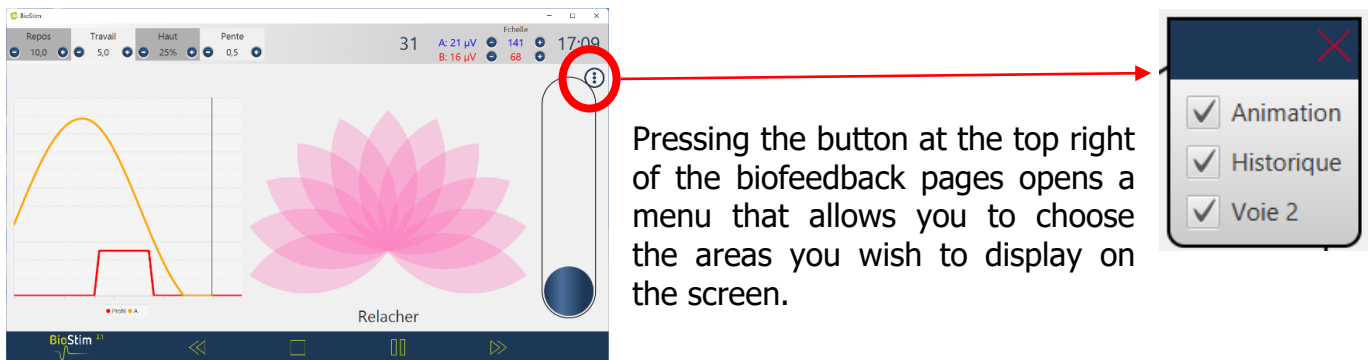


5.4.3 Biofeedback

Real-time modification of the profile (only version +)

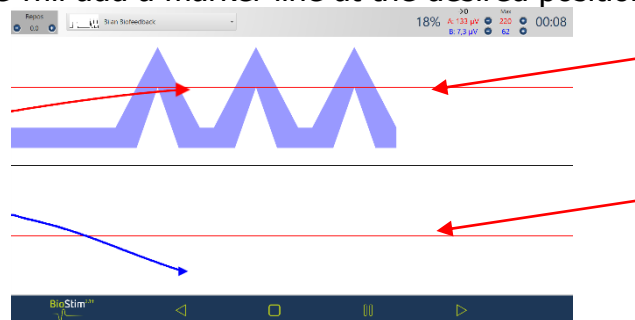


5.4.3.1 Menu for selecting the areas to be displayed



5.4.3.2 Version +: Position markers

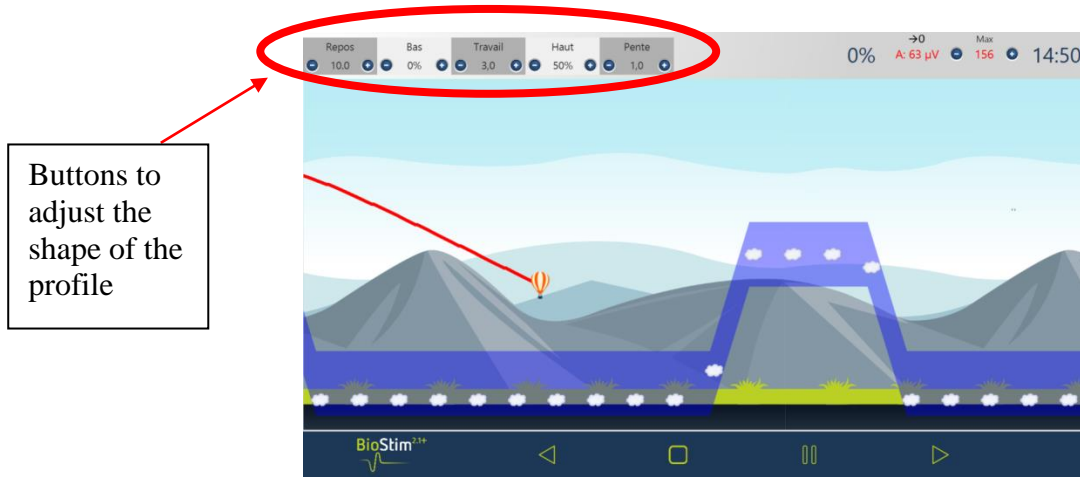
A mouse click on the page will add a marker line at the desired position:



Right click on the screen to add a time marker or an object to the screen (choice to be made in the configuration menu)

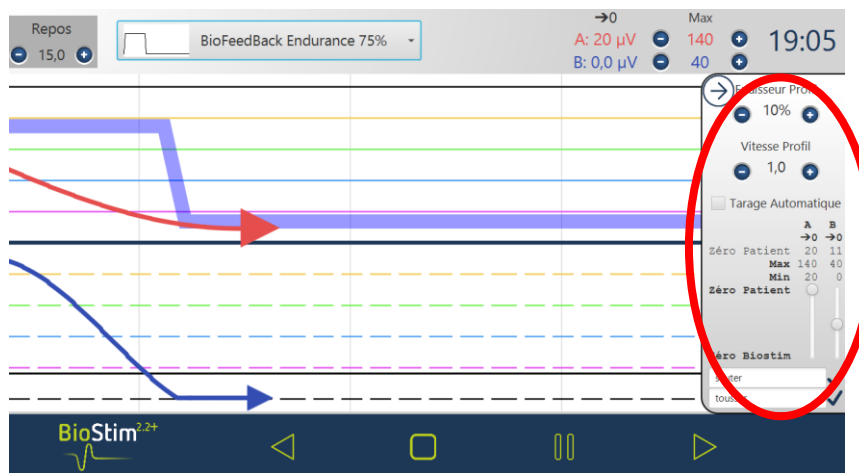
5.4.3.3 Version + : adjustable mode

When the biofeedback has been created in adjustable mode, it is possible to change the shape of the curve during the exercise using the buttons at the top left of the page.



Buttons to adjust the shape of the profile

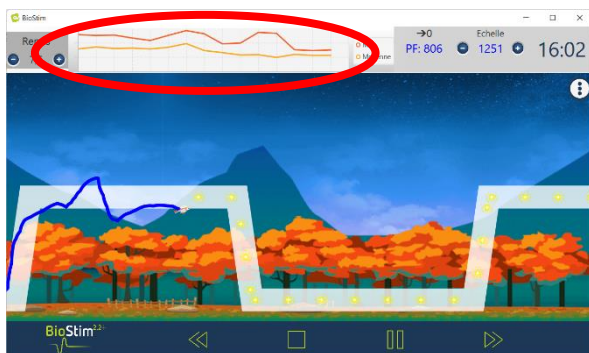
5.4.3.4 Version + : Side Panel



This panel allows you to set :

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





5.4.3.5 Version +: Trend line



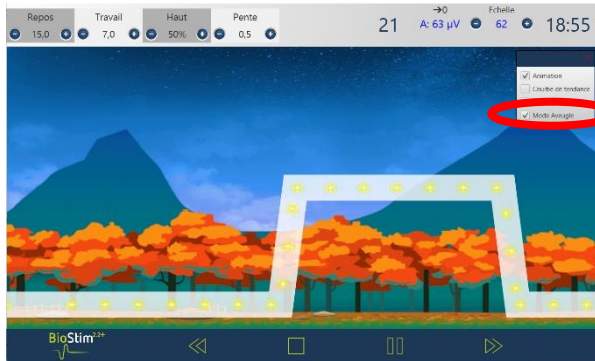
A trend line can be displayed by going through the zone selection menu.

This curve allows you to see at a glance the evolution during the session of the maximum and average contraction for each profile

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

| | Durée | Max Stim | Amplitude Min/Tonus/M ax | Réussite | |
|---|--------------------------------------|----------|--------------------------|----------|---|
|  | 21/09/22 : U:bfb assist fixe | 01:02 | 20 / 20 / 140 | 25 |  |
|  | 23/09/22 : BioFeedBack Endurance 50% | 05:38 | 379 / 428 / 1437 | 285 |  |

5.4.3.6 Version +: Blind work



A "blind mode" is available to work without the feedback of contractions on the screen. This mode is activated during the session, in the zone selection menu. The curves are recorded, and can be analysed at the end of the session

5.4.3.7 Version +: Assisted Biofeedback

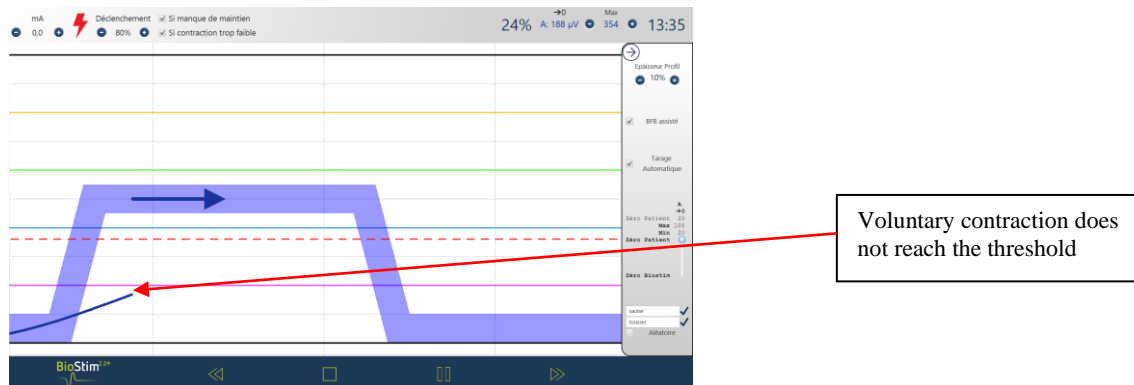
This mode, available for adjustable programmes, is activated either before starting the programme or from the side panel

Stimulation is then used to reinforce the muscular work:

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

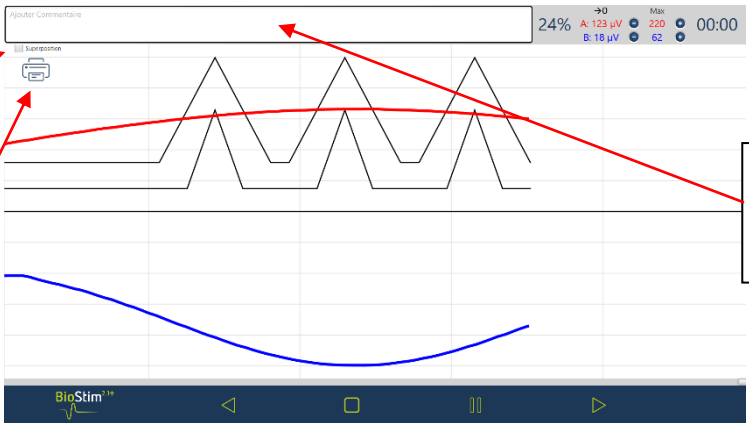


Or on a contraction that is too weak: detection of a contraction, but insufficient to reach the plateau



5.4.3.8 Review mode

At the end of the program (or when the pause button is pressed), the program switches to review mode. In this mode it is possible to save the curve by clicking on the diskette in the upper left-hand corner to print it or display it again later.

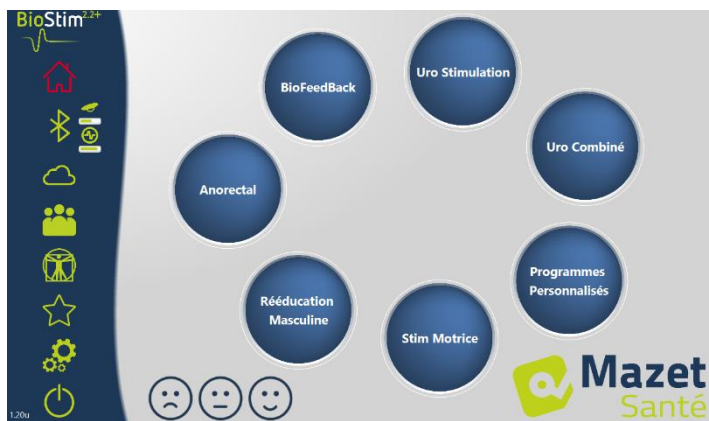


Allows comparison of the different passages on a profile width

Add a comment for the session

Printing the curve

5.4.4 Using a Bluetooth accessory



Biostim is compatible with :

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

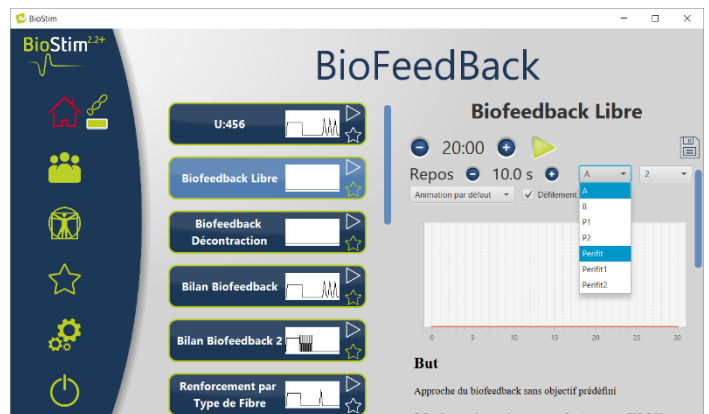
This function is only available if the Bluetooth option has been purchased.

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 in the same way as the other probes, by selecting the channel to be used that corresponds to the probe in the BFB menu.

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



5.5 Favourite Programmes

In order to find frequently used programmes more quickly, they can be classified in the "Favourites" category.

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

5.6 Anatomical Plates


Anatomical plates are available. Clicking on the image opens it in a viewer that allows you to zoom in or out to see the image better.


It is possible to add your own anatomical charts by clicking on the "add chart" button. You can choose image or video files on your computer, or links to videos on the internet (especially YouTube)

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



5.7 Select a patient

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


In order to limit the length of the list, patients can be archived by clicking on the archive icon  to the right of the patient name.

It is possible to display all patients (including archived patients), by activating the "Show archived patients" box.

Archived patients in this case have a green archive icon, while other patients have a blue one. The archiving operation can be reversed by clicking on the archive icon again.



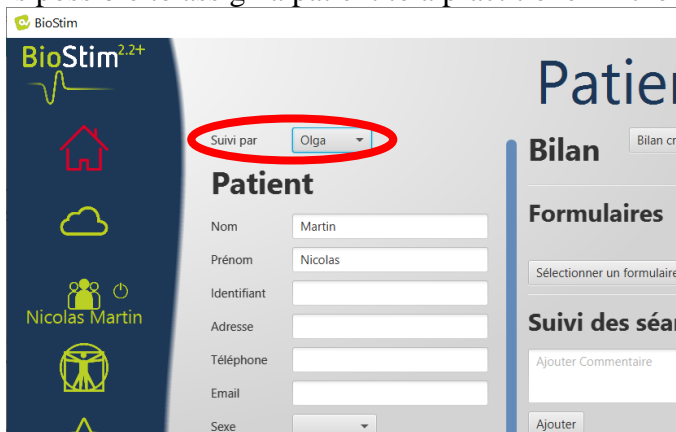
The anonymous display hides the patient's full name, only the initials are visible.

A patient is selected by clicking on his or her name. Once a patient has been selected, his or her name appears in the menu on the left of the page. To disconnect, click on the deselect button to the right of the name  .



5.7.1 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



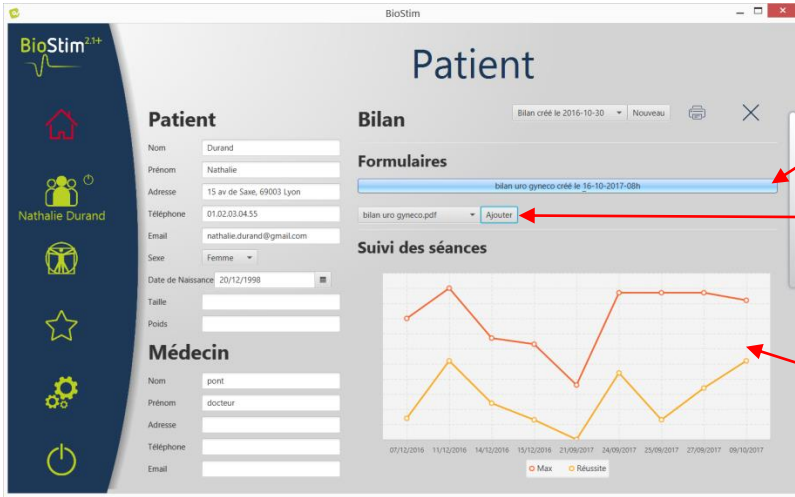
5.8 Patient File

When a patient is selected, the patient's record can be accessed by clicking on the patient's name in the left-hand menu.

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

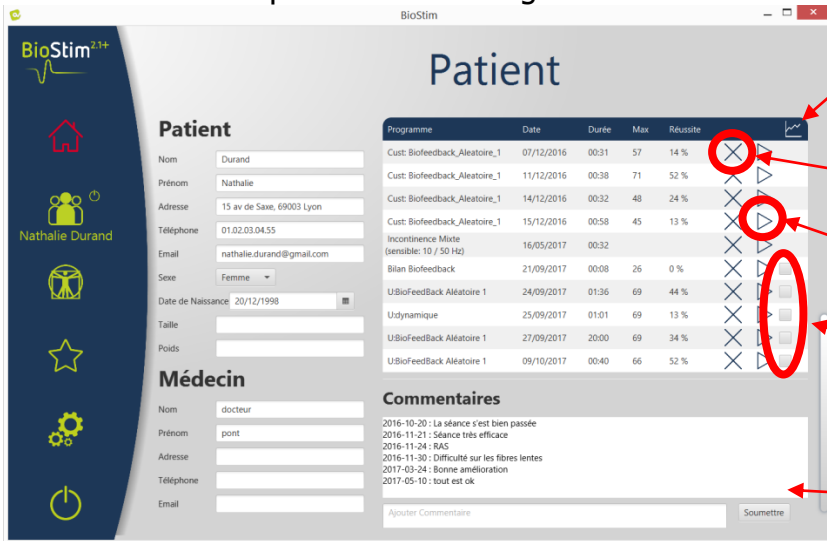
It is also possible to add :

- Textual comments
- Standard assessment forms, which will help to take stock of the patient's situation.



- Follow-up form (right click to delete)
- Addition of a new form to the patient file: either pre-filled or free (mail, medical examination...)
- Graph of the follow-up of the different sessions of the patient

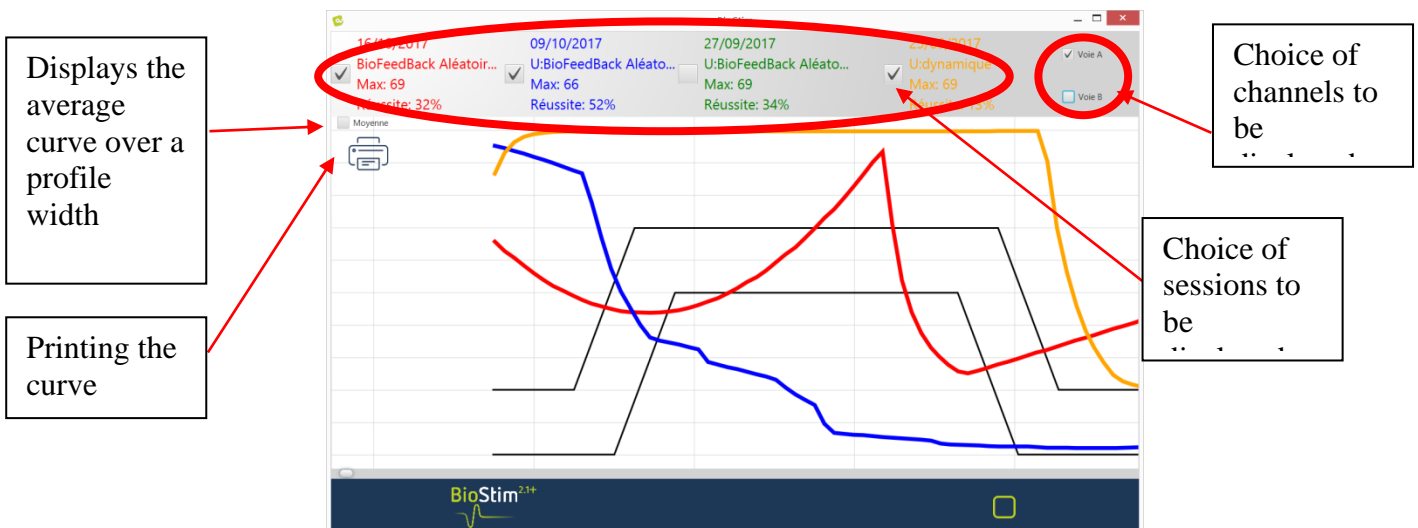
All sessions are recorded. The result is visible in the form of a graph, for a quick visualization, and in a more complete table which gives all the data of the sessions.



- Starts the comparison of the selected curves (+ version)
- Deletes a record
- Relaunch the same program
- Selects the curves to be reviewed (+ version)
- Free comments (right click to delete)

5.8.1 Version +: Comparison of curves

Pressing the button in the session table opens the session comparison page.

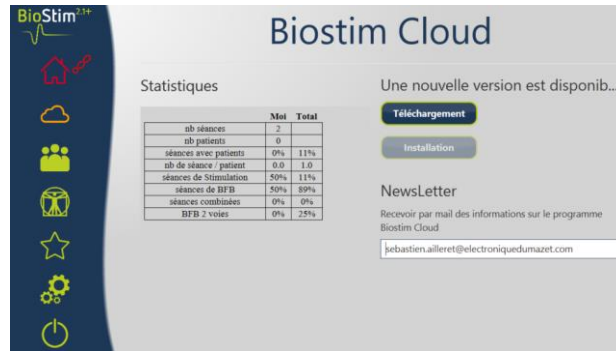


Right click in the drawing area to select a portion of the curve to be printed

5.9 Biostim Cloud

By activating the Biostim Cloud option :

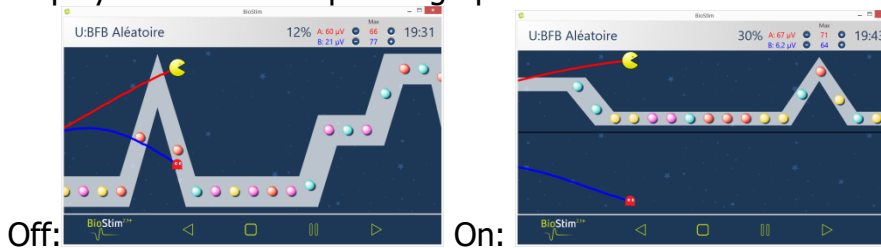
- An anonymised collection of sessions is made
- Access to statistics on the use of the device, as well as the statistics of other participants
- You are notified of new versions and can install them directly from the software



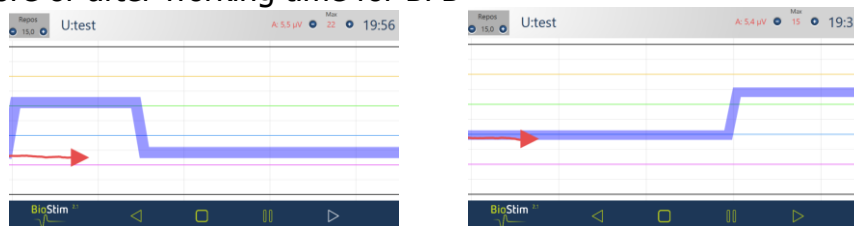
5.10 Configuration page

The configuration page allows you to configure the software. The options available are : Scroll Speed: Allows you to speed up or slow down the biofeedback scroll

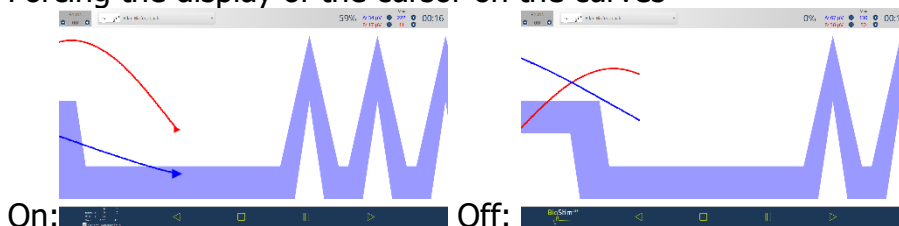
- Default channel for BFB (A, B, or P)
- Display channels on separate graphs



- Rest time before or after working time for BFB



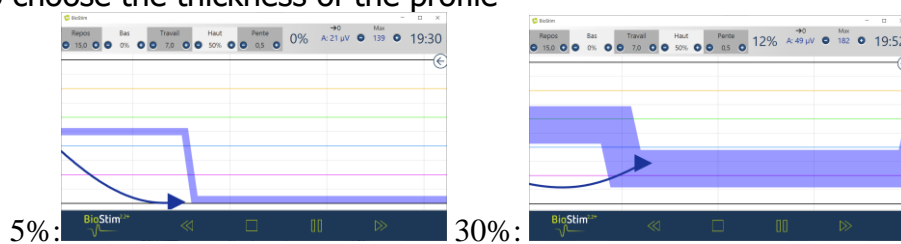
- Automatically start BFB after taring: if this option is not activated, the cursor waits for a press of the start key at the beginning of the BFB: no scrolling until this key is pressed
- Forcing the display of the cursor on the curves



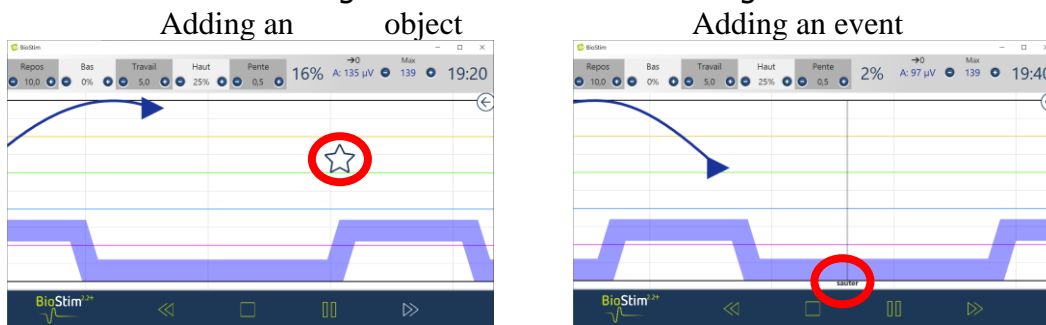
- Selection of animations: it is possible to choose the animations that you wish to use. Those that are unchecked will no longer be visible in the program presentation page. Customised animations are always visible.



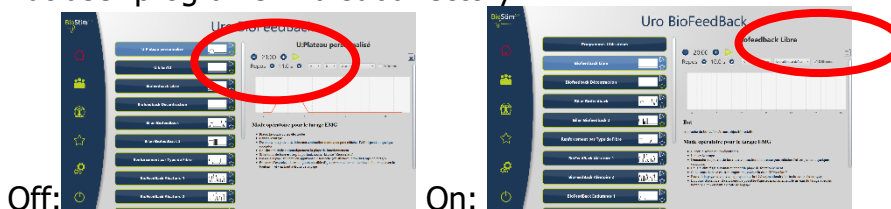
- Display the BFB pressure during stimulation (only for pressure probes with electrodes: type Evolys 3P from Sugar International)
- Possibility to choose the thickness of the profile



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



- Sound management: Choice of music at the end of the programme, possibility of adding a sound for transitions between BFB and stimulation, sound BFB (for visually impaired patients), sound indication for the beginning and end of contractions. All these sounds can be configured by the user.
- Creating, modifying and deleting 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



5.10.1 Networking of several devices

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

To share the database, you only need to indicate this directory in the "Directory for recording patient data" option.

6 Clinical Guide

6.1 Target population

The device is intended for a population over 5 years of age, which can be female or male. It should be noted that pelvic floor rehabilitation is particularly indicated for post-partum women.

6.2 Expected clinical benefits

Today, based on European and French recommendations as well as on the results of studies conducted by health specialists, the device makes it possible to propose pre-established and specific programmes for pathologies requiring physiotherapeutic or midwifery care.

The therapeutic uses are :

- 1- Management of urinary incontinence: stress, urge and mixed incontinence, and bladder inhibition.
- 2- Management of anal incontinence.
- 3- Management of contractures and prolapses: muscle strengthening and relaxation treatments.
- 4- Pain management: analgesic treatments.
- 5- Management of genitosexual disorders: specific muscle strengthening treatments

6.3 Major contraindications

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

- Pregnancy in progress
- Presence of a pace maker
- Presence of cardiac arrhythmia
- Presence of a bladder stimulator
- Perineal hypoesthesia
- Urinary and vaginal infections
- Recent abdominal surgery
- Intrapelvic tumours
- Do not apply to the carotid sinus



The contraindications are not exhaustive and we advise the user to seek advice in case of doubt.

6.4 Side effects

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

7 Maintenance, servicing

The device is designed to last for 5 years.

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

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

7.1 Housing and accessories

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

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

7.2 Sterilization :

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

8 Malfunction

If you notice a malfunction that is not commented on in the documents accompanying the appliance (see below), please inform your dealer or the manufacturer.

In the case of a shipment of the device, please observe the following instructions:

- Decontaminate and clean the unit and its accessories.
- Use the original packaging, including the retaining flanges.
- Attach all accessories to the appliance.
- Set up the various elements.
- Ensure that the packaging is properly sealed.

Shipping address :

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

Possible malfunctions :

| Description of the anomaly | Possible causes | Actions |
|---|--|--|
| Green indicator light off | <ul style="list-style-type: none"> - power grid problem - fuses | <ul style="list-style-type: none"> - check the mains voltage - check and change fuses |
| No communication with the PC (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 (CDM21228_Setup.exe) |
| No stimulation is observed but the yellow indicators light up. | <ul style="list-style-type: none"> - bad contact - defective cable | <ul style="list-style-type: none"> - check the connections to the patient. - swap cables for verification |
| No stimulation and the yellow lights do not illuminate. | <ul style="list-style-type: none"> - loss of communication with the module. - the parameters of the stimulation currents are not consistent. | <ul style="list-style-type: none"> - exit the current treatment and return to the main office. - check the settings and change them. |
| Flat trace in biofeedback windows | <ul style="list-style-type: none"> - loss of communication with the module. - no sensor on the input in question | <ul style="list-style-type: none"> - exit the current treatment and return to the main office. - check the route used |
| Need to increase the stimulation current beyond the usual values with elastomer electrodes. | <ul style="list-style-type: none"> - old electrodes - insufficient frost | <ul style="list-style-type: none"> - change electrodes. - add contact gel |
| Automatic decrease of the amplitude slider. | <ul style="list-style-type: none"> - old electrodes - insufficient frost - pulse width too long. | <ul style="list-style-type: none"> - change electrodes. - add contact gel - change the programme to a lower pulse width. |
| Saturated or very noisy EMG biofeedback signal | <ul style="list-style-type: none"> - missing or poor contact of the reference electrode | <ul style="list-style-type: none"> - check the correct fixing of the 3^{ème} electrode. Check the quality of the electrodes, replace them if necessary. |

If the device is dropped or if water penetrates, it is imperative to have the device checked by Électronique du Mazet to exclude any risk (patient and user) related to the use of the device.

9 After-sales service and warranty

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

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

Inappropriate use of this appliance or neglect of maintenance relieves Électronique du Mazet and its authorised distributors of all responsibility for defects, breakdowns, malfunctions, damage, injuries and the like.

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

**The warranty period is 24 months from the date of delivery of the device.
Accessories are guaranteed for 6 months from the date of delivery of the appliance.
Transport and packaging costs are not included in the guarantee.**

10 Disposal

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

If the appliance becomes inoperative or unusable, it should be returned to the manufacturer or taken to a collection point [ecosystem](#) .

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

11 Transport and storage

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

Store in a clean, dry place at room temperature.

12 CE declaration

ÉLECTRONIQUE DU MAZET can provide the CE declaration for this device on request.

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

13 Manufacturer

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

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

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

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

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www.electroniquedumazet.com


14 EMC compliance table

| 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 the BIOSTIM should ensure that it is used in such an environment. | | |
| Emissions testing | 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. |
| RF emissions CISPR 11 | Class B | The BIOSTIM is suitable for use in all premises, including domestic premises and those directly connected to the public low voltage power supply network supplying buildings for domestic use. |
| 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 for use in the electromagnetic environment specified below. The customer or user of BIOSTIM should ensure that it is used in such an environment. | | | |
| IMMUNITY test | Test level IEC 60601-1-2 | 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 in tension on input lines power supply electric IEC 61000-4-11 | 0% TU: 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 degrees 0% UT; 250/300 cycles | 0% TU: 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 degrees 0% UT; 250/300 Cycles | The quality of the power supply should be that of a typical commercial or hospital environment. If the user of BIOSTIM requires continuous operation during power outages, it is recommended that BIOSTIM be powered from an uninterruptible power supply or battery. NOTE UT is the AC mains voltage before the test level is applied. |
| Magnetic field to the frequency of the power grid (50/60 Hz) IEC 61000-4-8 | 30 A/m 50Hz or 60Hz | 30 A/m 50Hz or 60Hz | Magnetic fields at the frequency of the power system should have 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 for use in the electromagnetic environment specified below. The customer or user of BIOSTIM |

should ensure that it is used in such an environment.

| IMMUNITY test | Test level IEC 60601-1-2 | Level of compliance | Electromagnetic environment - guidelines |
|--|--|--|--|
| RF disturbances conducted 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 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 transmitter. Recommended separation distance $d = 1,67 \cdot \sqrt{P}$ $d = 1,67 \cdot \sqrt{P}$ 80MHz-800MHz $d = 2,33 \cdot \sqrt{P}$ 800MHz-2.5GHz Where P is the maximum output power characteristic of the transmitter in watts (W), according to the transmitter manufacturer and d is the recommended separation distance in metres (m). The field strengths of fixed RF transmitters, as determined by an on-site electromagnetic investigation 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: |
| Radiated RF disturbances IEC 61000-4-3, including clause 8.10, Table 9, for the proximity of devices without a thread | 3 V/m 80 MHz to 2.7 GHz 80% AM at 2 Hz including clause 8.10, Table 9, for proximity to wireless devices | 3 V/m 80 MHz to 2.7 GHz 80% AM at 2 Hz including clause 8.10, Table 9, for proximity to wireless devices |  |

NOTE 1 At 80 MHz and 800 MHz, the 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 required, 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 hand-held and mobile devices of RF communications and BIOSTIM

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 At 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 whose maximum rated transmit power is not given above, the recommended separation distance d in metres (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.

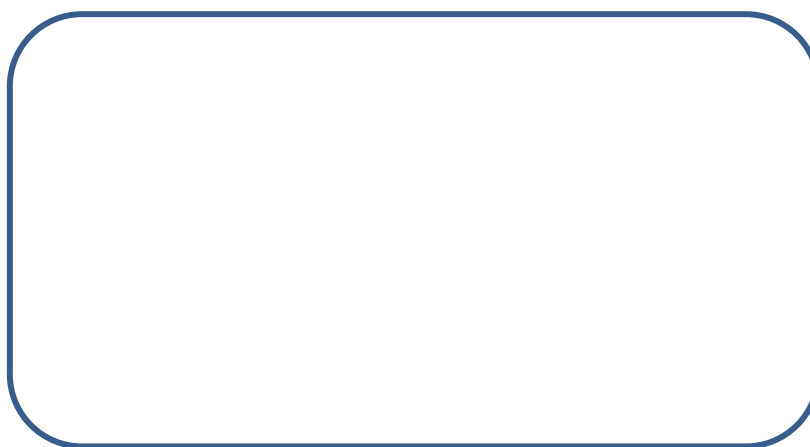


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Mail : sav@electroniquedumazet.com

Your dealer / distributor :



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