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.

Table of contents

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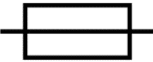
- This document must be kept in a safe place, protected from atmospheric agents, where it cannot be damaged.

- 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

Symbol	Beschreibung
⚠️	**Warnung:** Dieses Symbol weist Sie auf einen bestimmten Punkt hin.
📖	**Bedienungsanleitung:** Dieses Symbol weist Sie darauf hin, dass die Bedienungsanleitung gelesen werden muss, um das Gerät sicher zu verwenden.
🧍	**Angewandter Teil vom Typ BF:** Angewandter Teil, der mit dem Patienten in Berührung kommt.
🗑️	**Recycling:** Dieses Gerät muss in einer geeigneten Rücknahme- und Recyclingeinrichtung entsorgt werden. Wenden Sie sich an den Hersteller.
⏚	**Schutzerdung**
⎓	**Sicherung**
O / I	**Achtung:** Ausschalten / Einschalten des Geräts
∿	Wechselstrom
SN	Seriennummer
🏭	Hersteller
🏭	Herstellungsdatum
REF	Produktreferenz
UDI	Eindeutige Kennung
MD	Medizinisches Gerät

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 1kΩ (or more), at max current, the voltage is **limited to 100V** -20%/+10% (peak value).
    -Under a load impedance of less than 1kΩ, the voltage level is limited according to the impedance (10volts for 100Ω, 50volts for 500Ω)
    -If the impedance is too high (above 10 kΩ), 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 **50µs 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
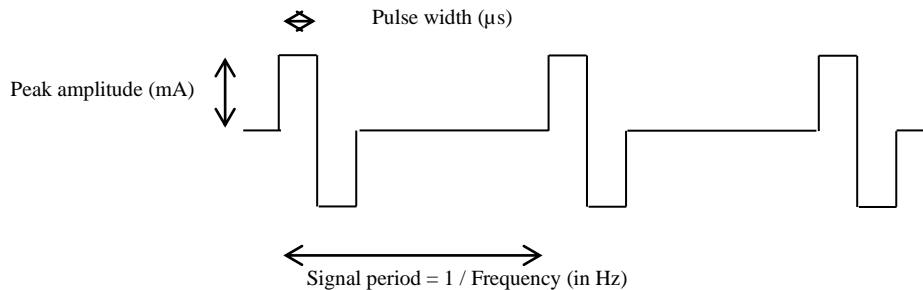
The waveform is constant current and does not depend on the value of the load.
The pulse width is adjustable from **15µs to 10ms**, the frequency is adjustable from **1Hz to 5kHz**.
LF modulation (1Hz to 500 Hz) of the signal is possible.

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
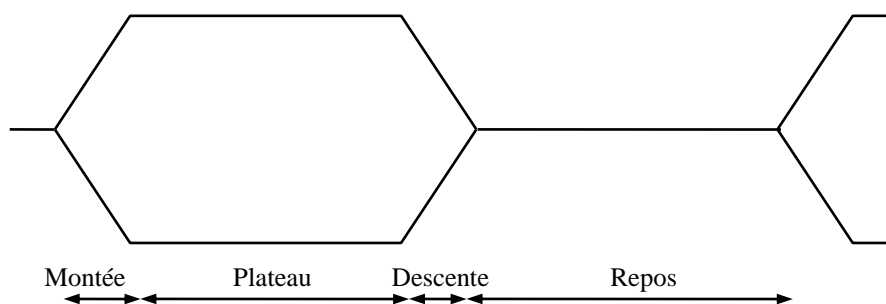
2.3 *Nameplate label*

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

Label for "Biostim 2.2+" :
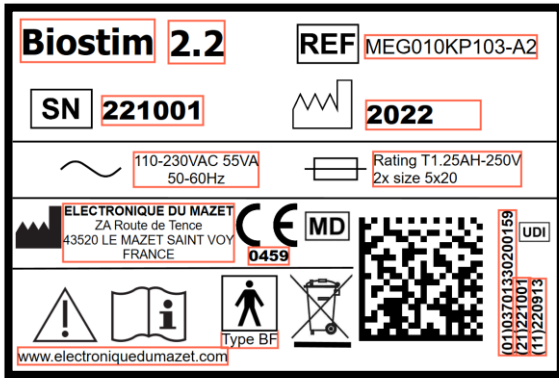
Label for "Biostim 2.1 / 2.1+".
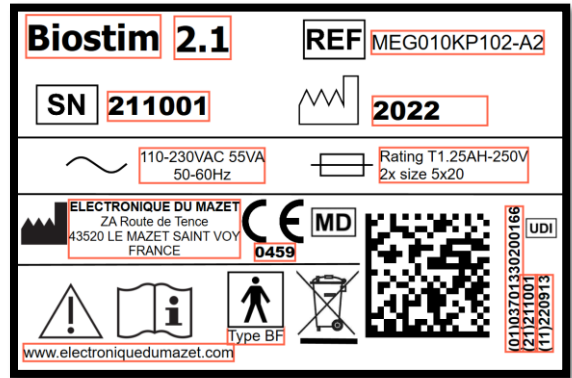
Biostim 2.0" label
or "Biostim 2.0+":
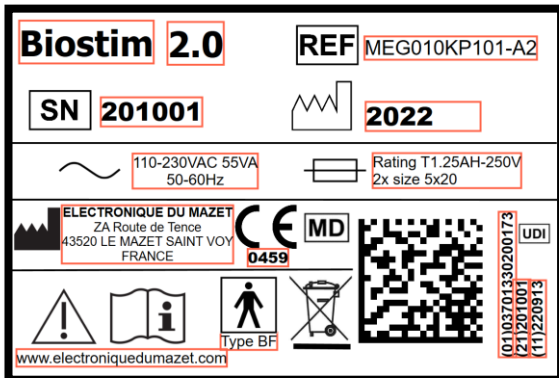
Biostim 1.0" label
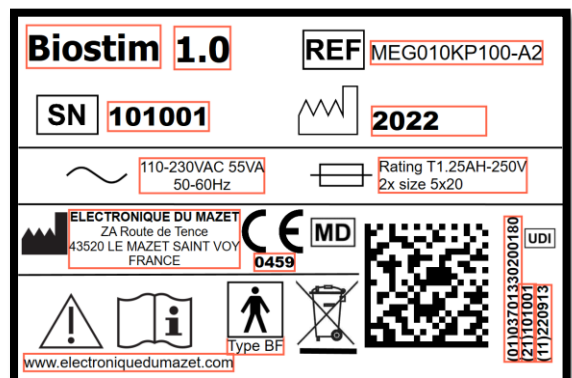
2.4 *Warnings*

ACHTUNG: Es sind keine Veränderungen am Gerät erlaubt. Es ist strengstens verboten, das Gehäuse des Geräts zu öffnen.

ACHTUNG: Der Betrieb in unmittelbarer Nähe (z. B.:1 m) eines EM-GERÄTS für Kurzwellen- oder Mikrowellentherapie kann zu Schwankungen der Ausgangsleistung des STIMULATORS führen.

ACHTUNG: Stellen Sie das Gerät auf einer ebenen und stabilen Fläche auf. Blockieren Sie die Belüftungsöffnungen nicht (keine Gegenstände im Abstand von weniger als 4 cm).

ACHTUNG: Die Mehrfachsteckdosenleisten dürfen nicht auf dem Boden liegen. Es dürfen keine anderen elektrischen Geräte oder Steckdosenleisten an die Steckdosenleiste des Geräts angeschlossen werden.

ACHTUNG: Das Gerät muss an eine Steckdose mit Erdungsanschluss angeschlossen werden (Elektrogerät der Klasse I).

ACHTUNG: Das Gerät muss so positioniert werden, dass im Notfall der Zugang zum Netzkabel frei bleibt.

ACHTUNG: Ziehen Sie im Notfall das Netzkabel direkt vom Gerät ab.

ACHTUNG: Das Gerät darf nur mit dem vom Hersteller gelieferten Zubehör verwendet werden.

ACHTUNG: Das Gerät darf für den Patienten nicht zugänglich sein. Es darf nicht mit dem Patienten in Berührung gebracht werden.

ACHTUNG: Der an das Gerät angeschlossene Patient darf während der Behandlung nicht an andere Geräte (Überwachungs- oder Diagnosegeräte) angeschlossen werden. Diese Nebengeräte könnten gestört werden. Wenn ein PATIENT gleichzeitig an ein EM-GERÄT für Hochfrequenzchirurgie angeschlossen wird, kann es zu Verbrennungen an den Kontaktstellen der Elektroden des STIMULATORS kommen, und der STIMULATOR kann eventuell beschädigt werden.

ACHTUNG: Wenn der PATIENT mit einem implantierten elektronischen Gerät (z. B. einem Herzschrittmacher) ausgestattet ist, darf das Gerät im Stimulationsmodus UNBEDINGT nur nach vorheriger ärztlicher GENEHMIGUNG verwendet werden.

ACHTUNG: Das Anbringen von Elektroden zwischen Brustkorb und oberem Rücken (Herzbahn), auf beiden Seiten des Kopfes, direkt über den Augen, dem Mund, der Vorderseite des Halses (insbesondere dem Karotissinus) kann das Risiko von Herzflimmern erhöhen.

ACHTUNG: Unter bestimmten Bedingungen kann der Effektivwert der Stimulationsimpulse 10 mA und 10 V überschreiten. Bitte halten Sie sich genau an die in dieser Anleitung gegebenen Informationen.

ACHTUNG: Der Benutzer muss besonders vorsichtig sein und die Größe der Elektroden an den zu behandelnden Bereich anpassen.

⚠️	**ACHTUNG:** Es ist wichtig, die Größe der verwendeten Elektroden zu überprüfen. Die Stromdichte muss weniger als 2 mA rms/cm² betragen.
⚠️	**ACHTUNG:** Die Ausgangssignale des Geräts sind zweiphasige, symmetrische Nulldurchschnittssignale und enthalten keine Gleichstromkomponente. Jede unangenehme Empfindung (Reizung, Erwärmung) bereits bei niedrigen Stromstärken könnte einen Gerätedefekt bedeuten. Verwenden Sie das Gerät nicht ohne den Rat des HERSTELLERS.
⚠️	**ACHTUNG:** Wenn der verwendete Computer nicht als Medizinprodukt zugelassen ist, darf sich der Computer auf keinen Fall in einem für den Patienten zugänglichen Bereich befinden.

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
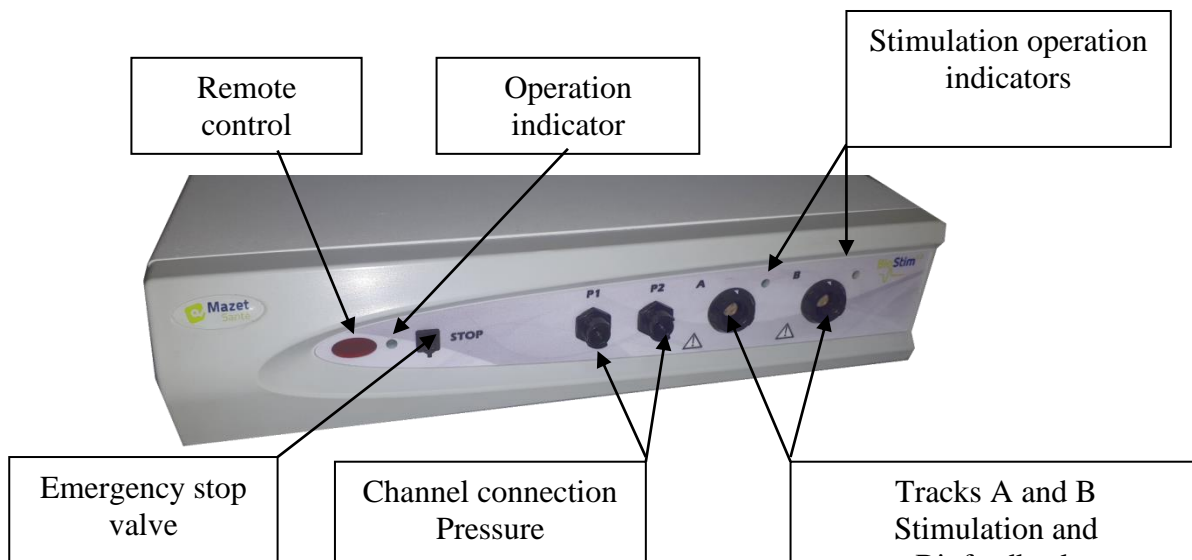
3.2 Connection of accessories

Connect the emergency stop bulb to the front panel.

Connect the pacing lead(s) to channel(s) A (and B) according to your application.
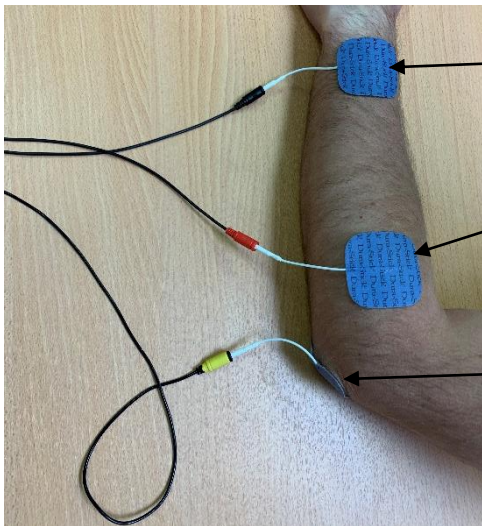
Place the electrodes or probe on the muscle you wish to work with, using the red and black connectors

To do BFB, place the $3^{ème}$ electrode (yellow tip) on a bony part (useless for stimulation)
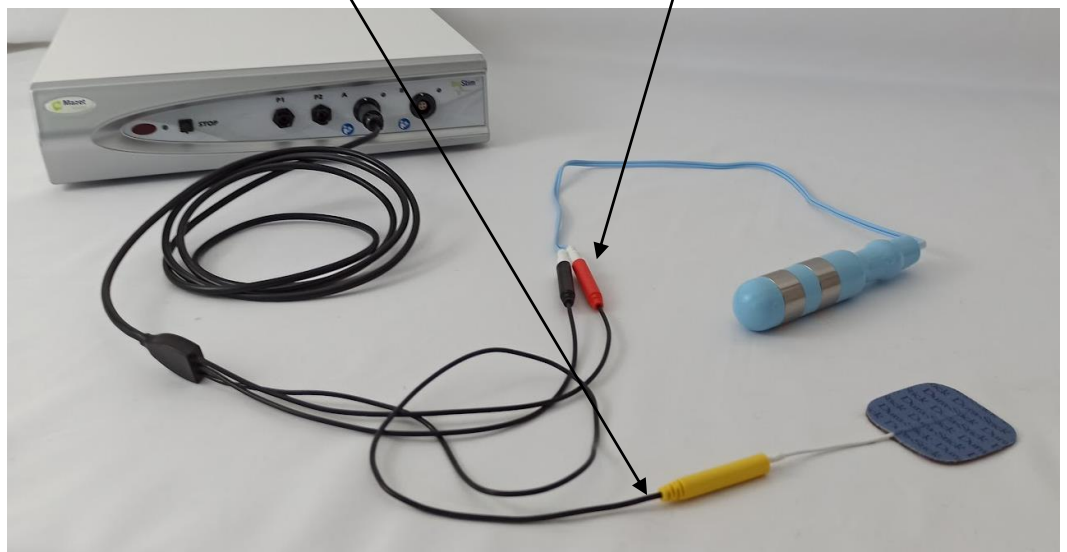
To use the pressure channels, connect the pressure kit to the pressure channels.

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.
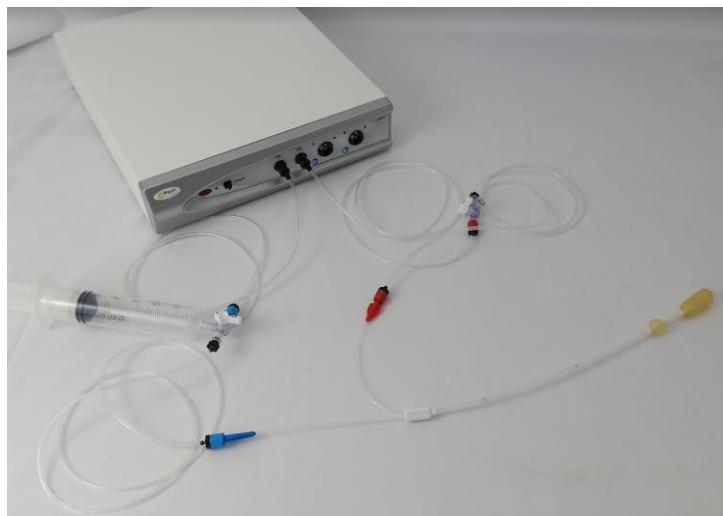
4 Software commissioning

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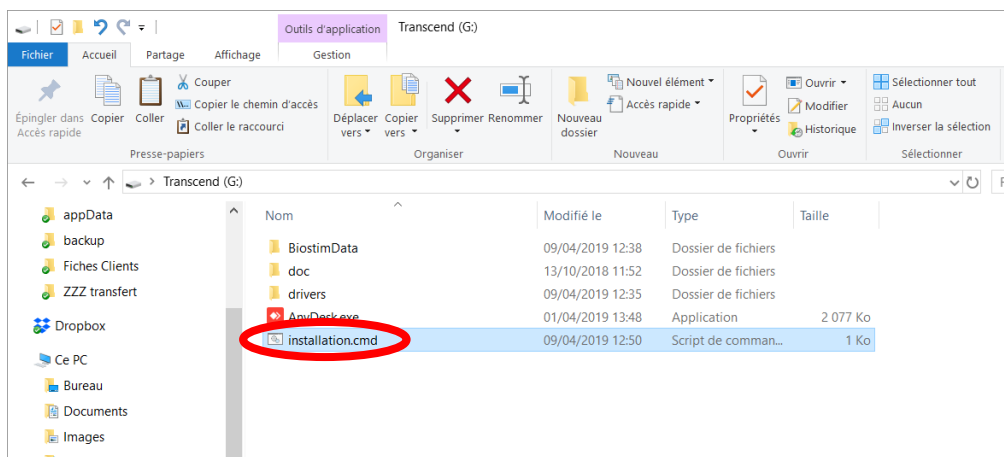
This creates a BiostimData directory on the desktop (which will contain all patient data), as well as a Biostim shortcut (or Biostim.exe).

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

Biostim

4.5 *Checking the connection*

Check that the connection is established: green home button.
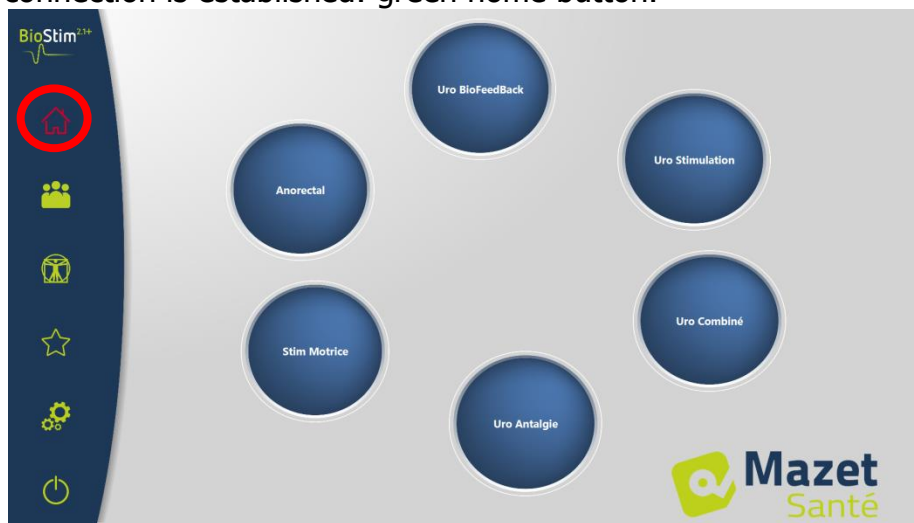
The **red** home button indicates a communication problem between the PC and the device. In this case, check the following points:
- The module is powered up, the green light on the front panel is on.
- The USB cable is properly connected to the device and the PC.
- The FTDI driver is correctly installed (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.
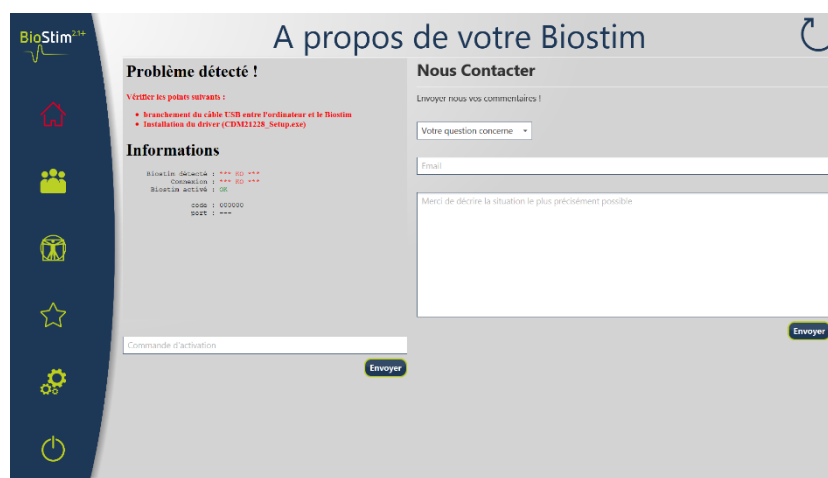
4.7 *Switching off the device*

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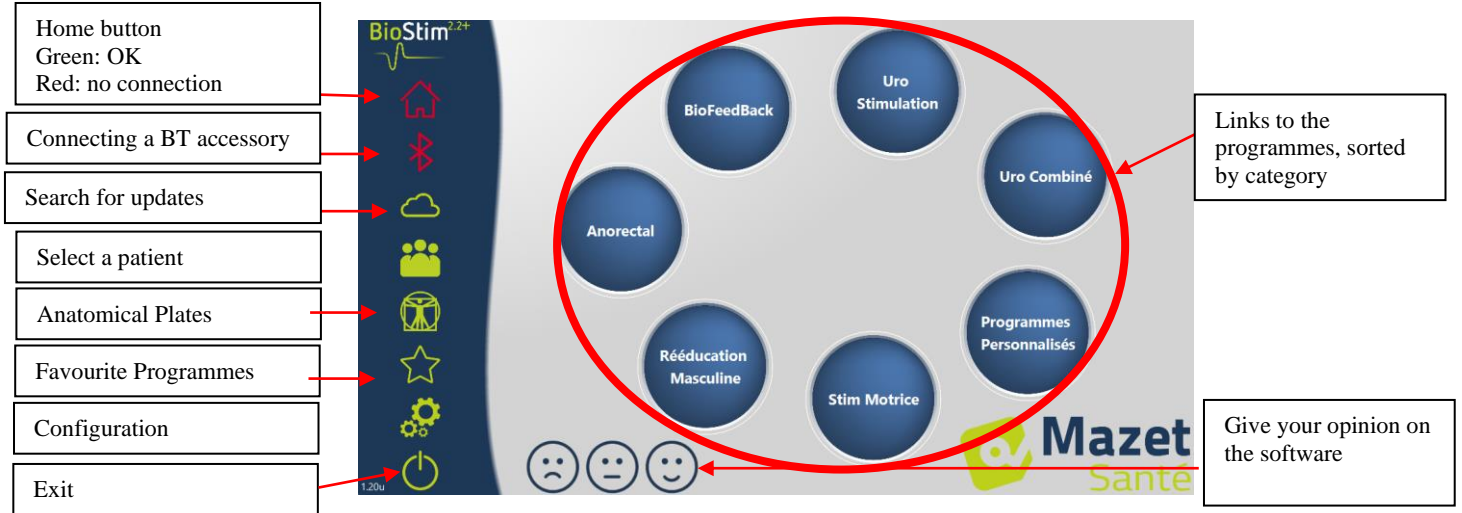
It is possible to rename a category by right-clicking on the desired category.

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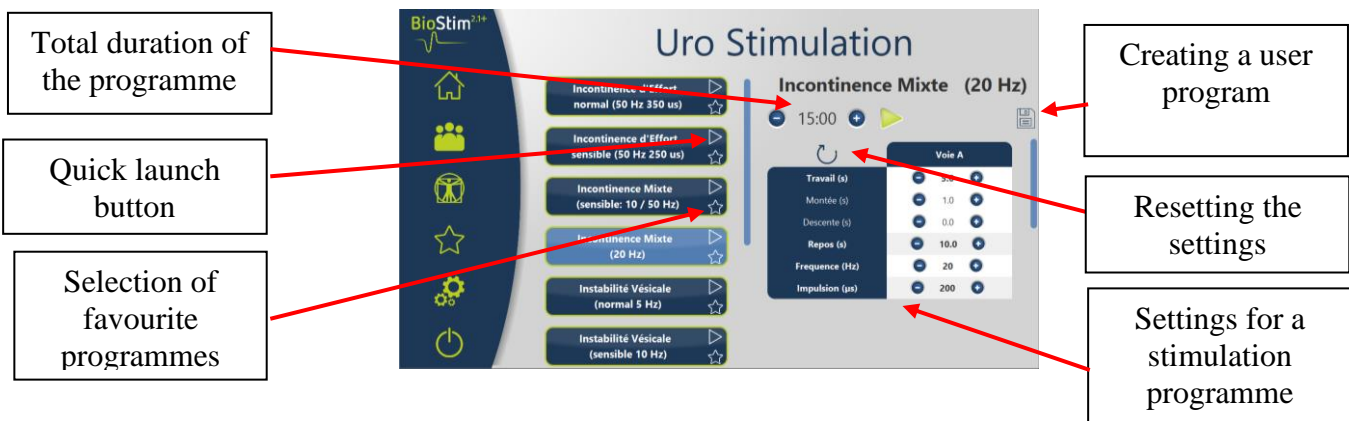
The button of the selected programme is highlighted and its description is displayed on the right side of the page. This description contains :

- 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.
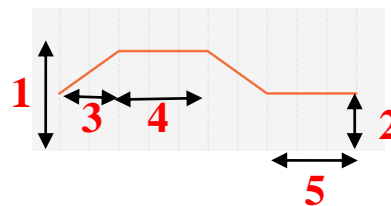
5.3.2 Version + : Free Drawing

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
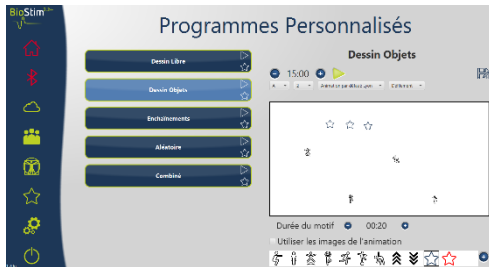
Allows you to draw an exercise only with images positioned on the screen, without having a profile to follow.
The objects can be objects chosen by the user, or objects related to the animation used.

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.

Back to the previous page

Stopping the programme

Pause

Time remaining before next page

Go to next page

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

5.4.1 Taring Biofeedback

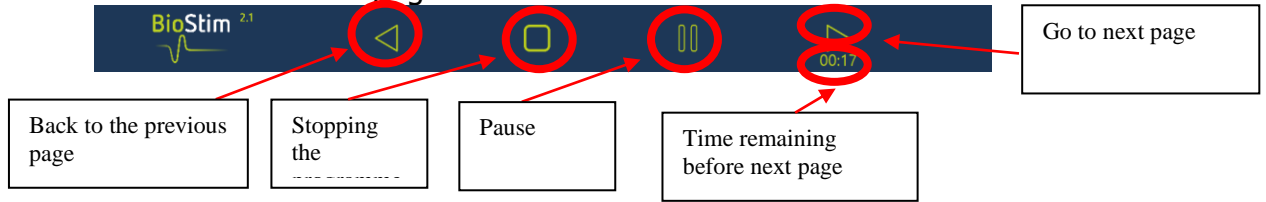Taring works automatically. However, it is possible to adjust the parameters calculated by the machine with the buttons ⊕ and ⊖ .

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

Maximum level

Basic toning
Zero Patients

Zero Biostim
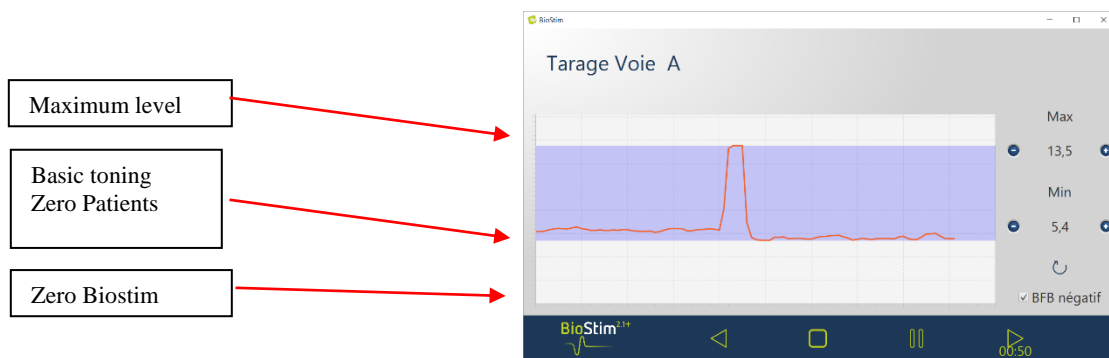
It is possible for each channel to enable or disable negative biofeedback, either in the configuration page or during taring.
If the option is enabled, you can see the work below the base level. This is particularly useful if you are working on relaxation.

Maximum level

Zero Patients

Zero Biostim

Negative biofeedback zone
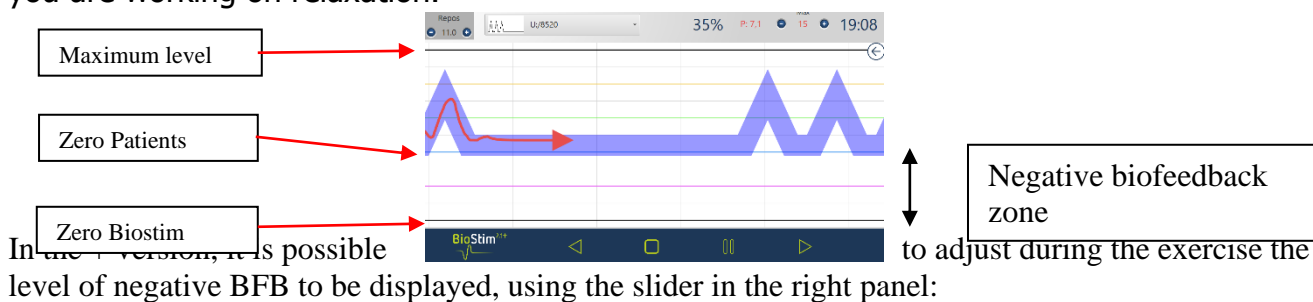
In the 1 version, it is possible to adjust during the exercise the level of negative BFB to be displayed, using the slider in the right panel:

- 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
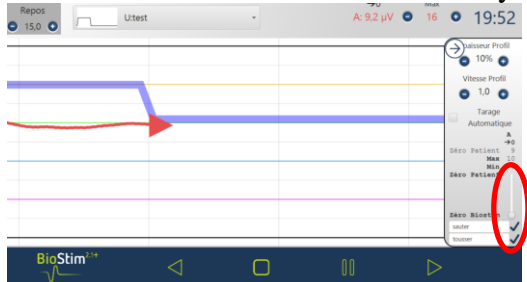
- It is also possible to choose intermediate values:

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.
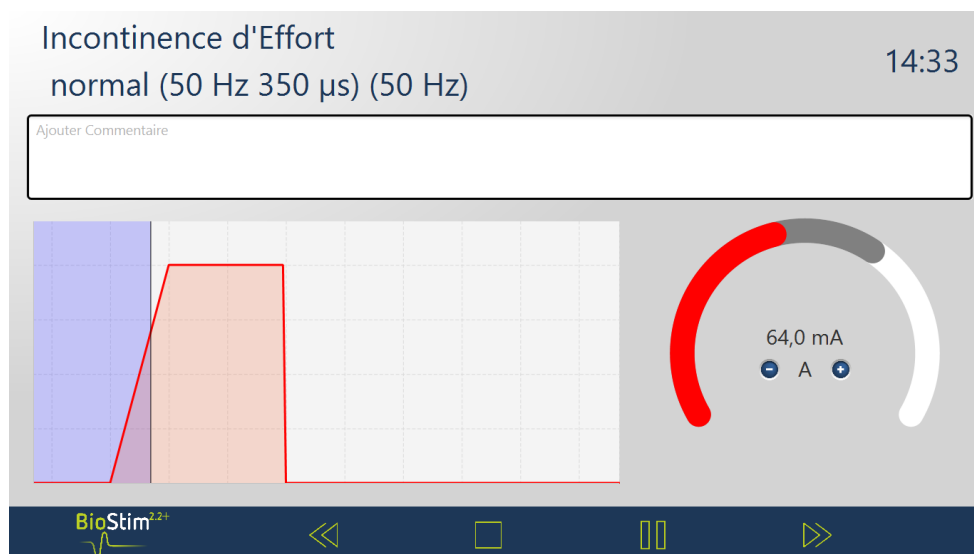
5.4.3 Biofeedback

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

Adjustment of rest time

Note indicating template

Real-time channel levels

Maximum calibration of each channel
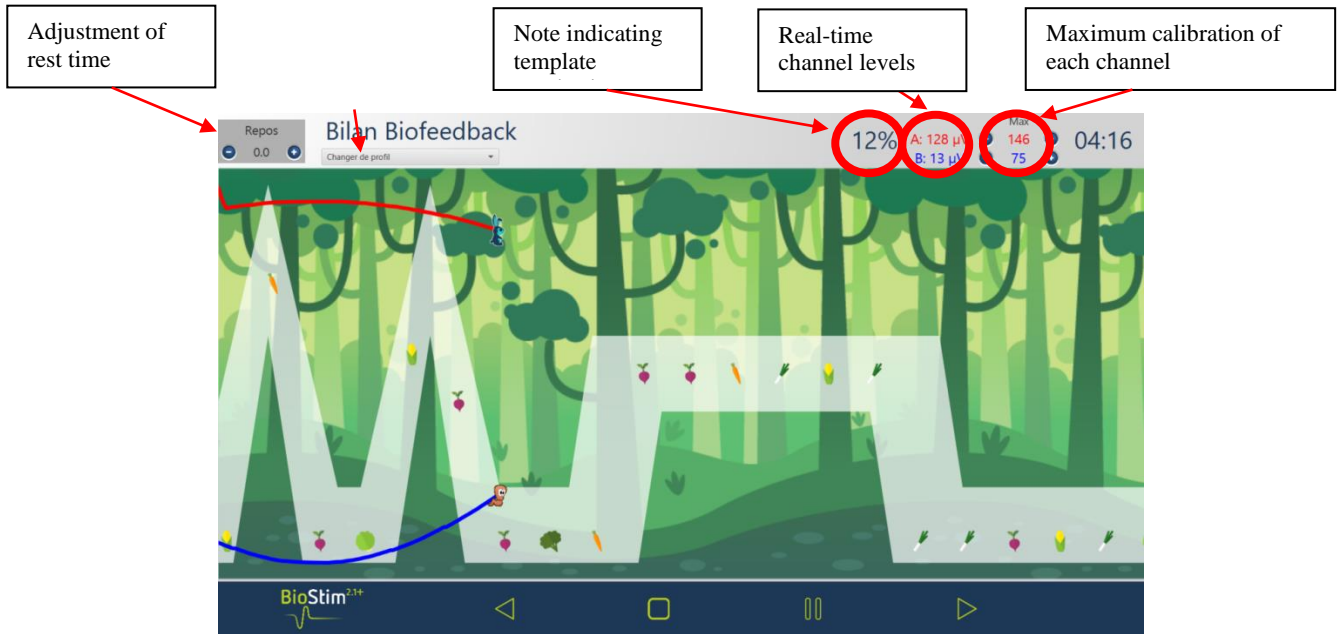
5.4.3.1 Menu for selecting the areas to be displayed

Pressing the button at the top right of the biofeedback pages opens a menu that allows you to choose the areas you wish to display on the screen.
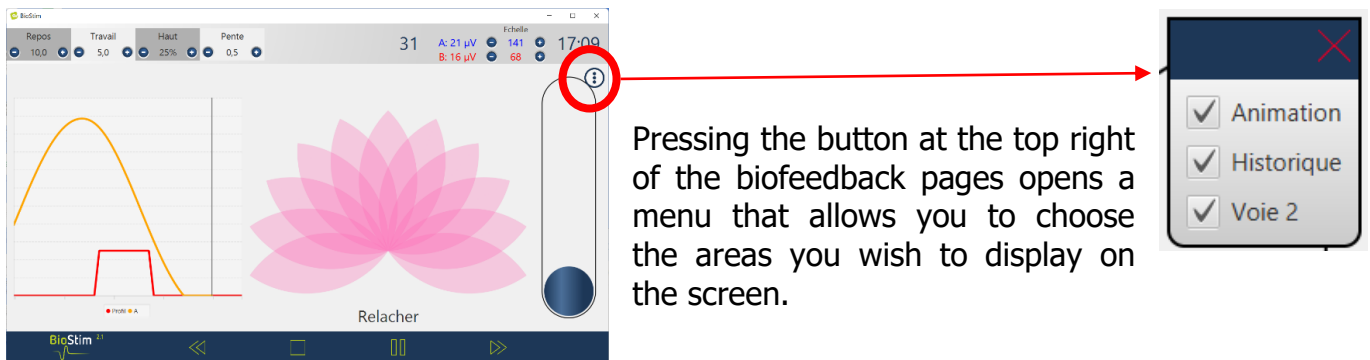
5.4.3.2 Version +: Position markers

A mouse click on the page will add a marker line at the desired position:
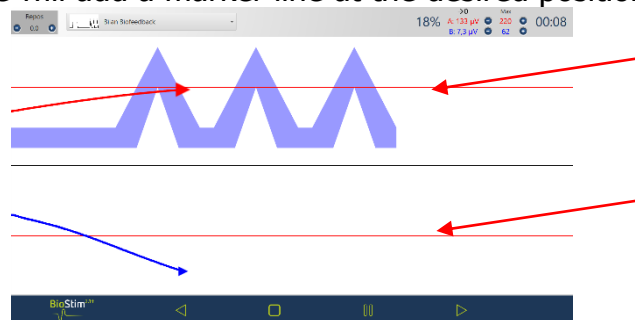
Right click on the screen to add a time marker or an object to the screen (choice to be made in the configuration menu)

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.
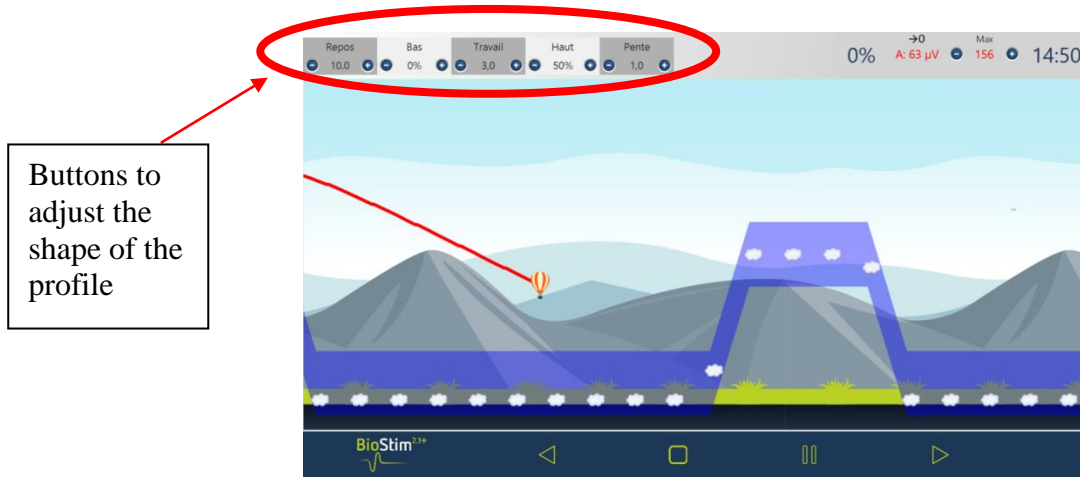
Buttons to adjust the shape of the profile

5.4.3.4 Version + : Side Panel
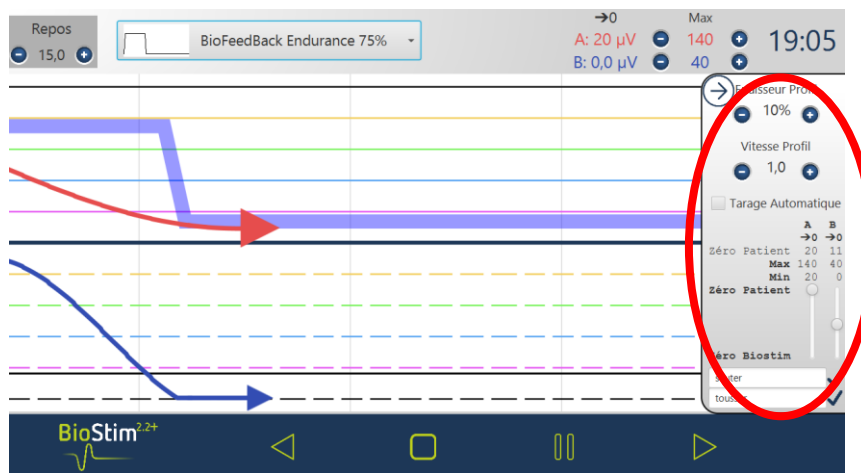
This panel allows you to set :
- Profile thickness
- Automatic taring: adjusts the base and maximum level to the amplitude reached by the patient (allows taring to be adjusted during exercise)
- Setting the "Patient Zero" for each channel ($\rightarrow$ 0)
- The level of the negative BFB, using the sliders 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
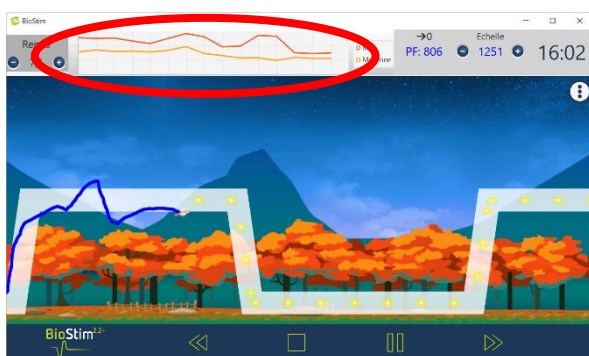
A trend line can be displayed by going through the zone selection menu.
This curve allows you to see at a glance the evolution during the session of the maximum and average contraction for each profile

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

	Durée	Max Stim	Amplitude Min/Tonus/Max	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

Viewing a current stimulus

Setting the trigger threshold

BFB falls below the threshold

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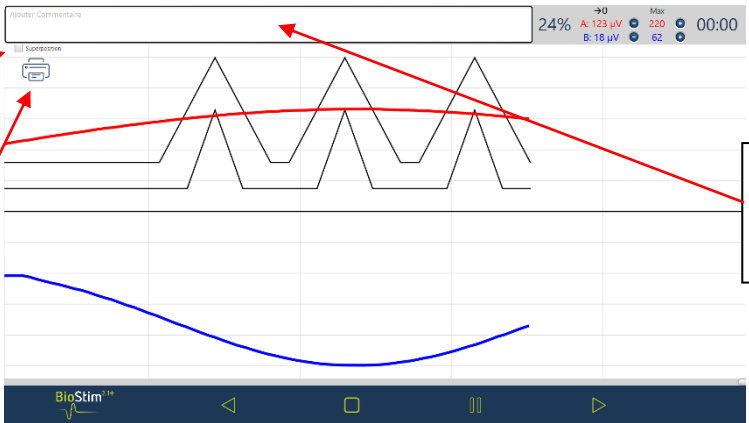
Or on a contraction that is too weak: detection of a contraction, but insufficient to reach the plateau

Voluntary contraction does not reach the threshold

-
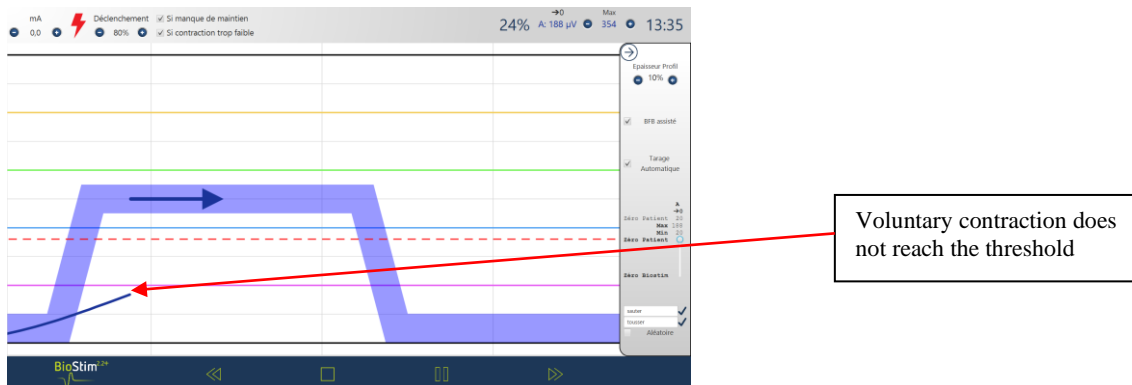
5.4.3.8 Review mode

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

Printing the curve

Add a comment for the session

5.4.4 Using a Bluetooth accessory
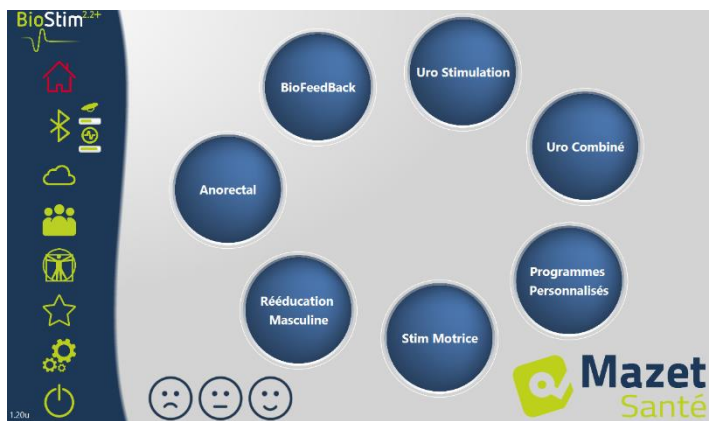
Biostim is compatible with :
- The Emy probe
- The Perifit probe
- The Blueback
- The BioMoov

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.
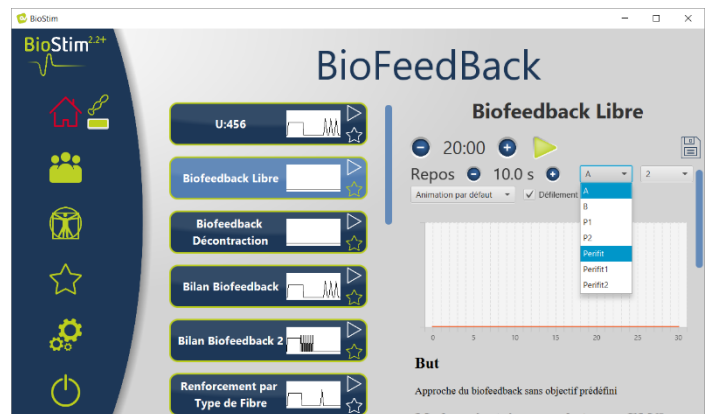
5.5 *Favourite Programmes*

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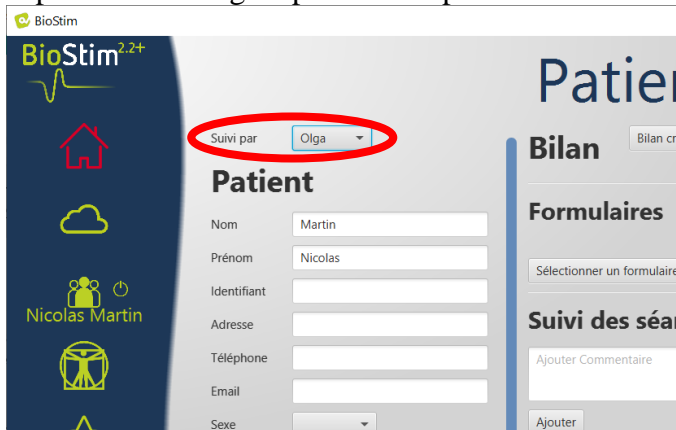
In the patient search page, you can add a new practitioner, or filter the list of patients by selecting a practitioner

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.
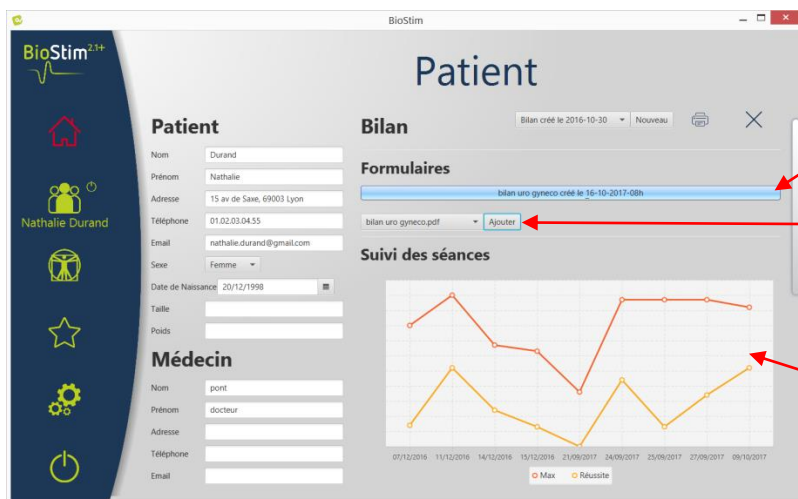
Follow-up form
(right click to delete)

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.
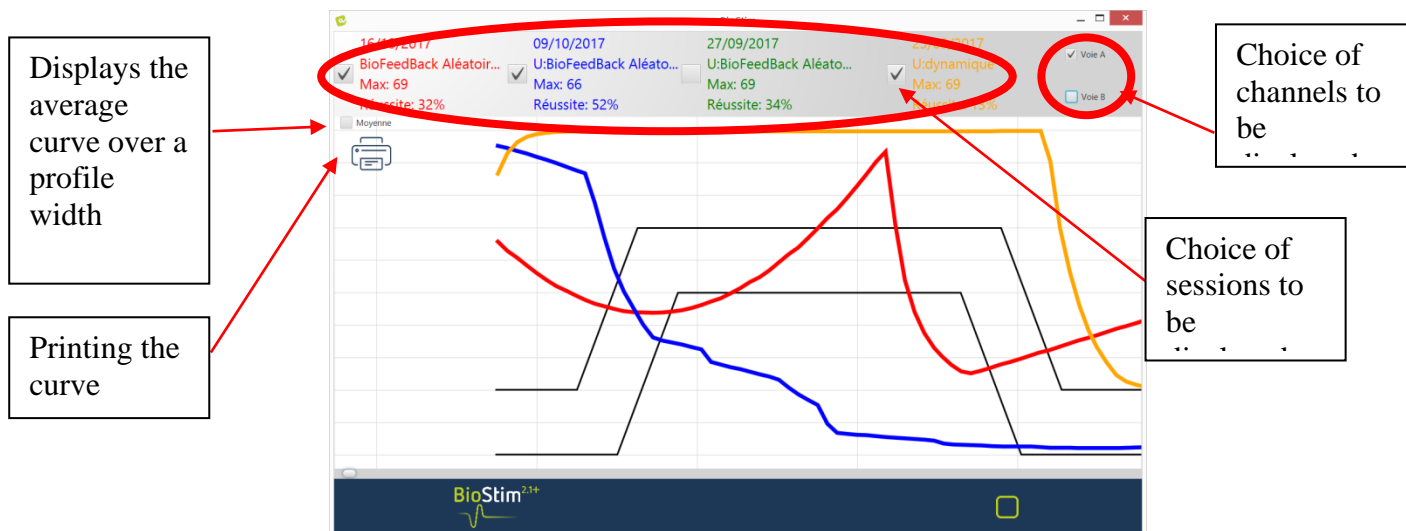
Displays the
average
curve over a
profile
width

Printing the
curve

Choice of
channels to
be

Choice of
sessions to
be

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
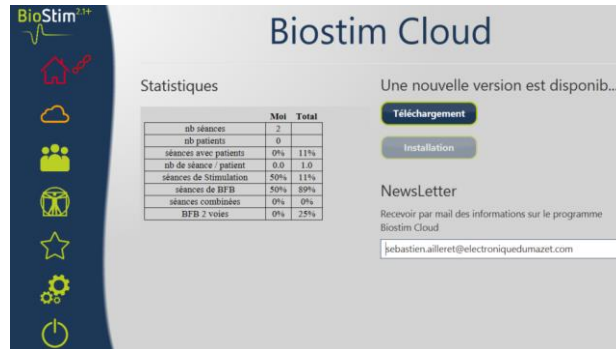
5.10 *Configuration page*

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

Off: On:
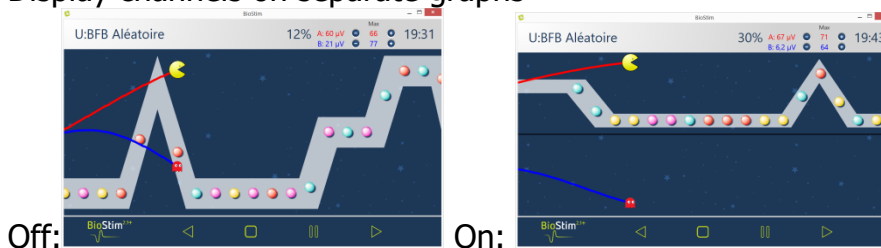
- • Rest time before or after working time for BFB

- • 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

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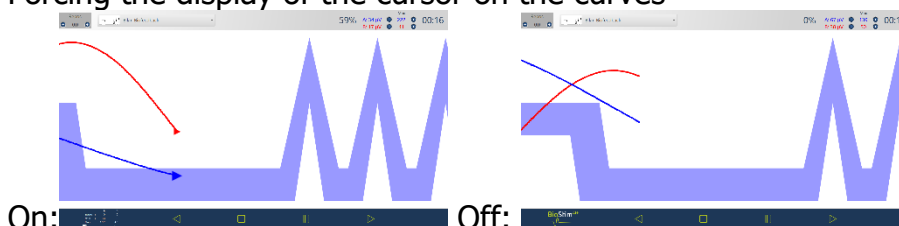
- Selection of animations: it is possible to choose the animations that you wish to use. Those that are unchecked will no longer be visible in the program presentation page. Customised animations are always visible.

- 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

5%:   30%:
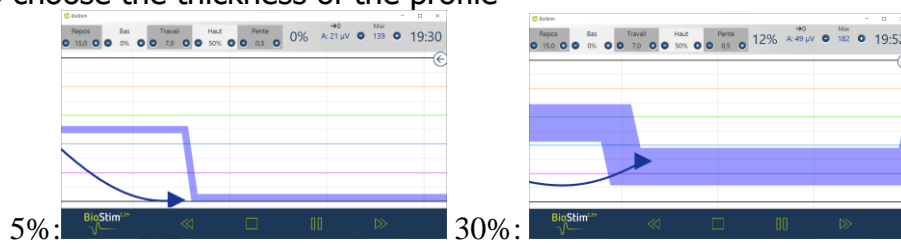
- Choice of action for a right click on the screen during a BFB

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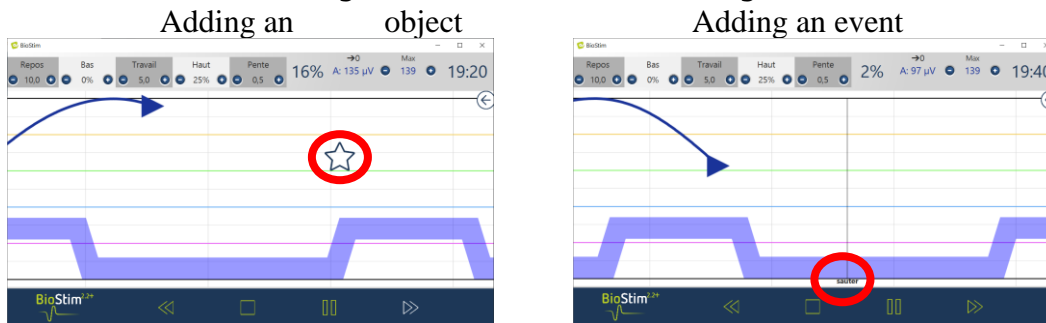
- Sound management: Choice of music at the end of the programme, possibility of adding a sound for transitions between BFB and stimulation, sound BFB (for visually impaired patients), sound indication for the beginning and end of contractions. All these sounds can be configured by the user.
- Creating,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

Off: On:
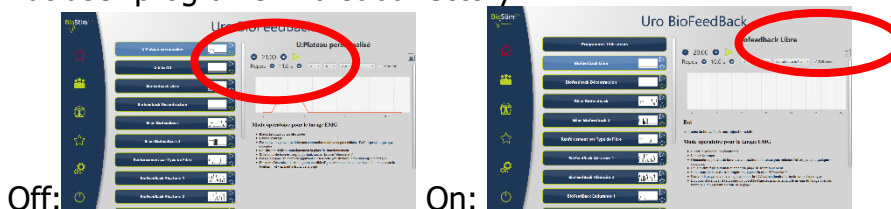
5.10.1 Networking of several devices

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

> Die Kontraindikationen sind nicht erschöpfend und wir empfehlen dem Nutzer, sich im Zweifelsfall zu informieren.

6.4 *Side effects*

Bisher gibt es in der medizinischen Fachliteratur keine Hinweise auf signifikante Nebenwirkungen bei der Anwendung der Elektrotherapie.

7 WARTUNG, PFLEGE

Das Gerät ist für eine Lebensdauer von 5 Jahren ausgelegt. Um sicherzustellen, dass die Leistung des Geräts während seiner gesamten Lebensdauer erhalten bleibt, müssen Sie das Gerät alle 2 Jahre von den Technikern von Electronique du Mazet überprüfen lassen.

7.1 *Housing and accessories*

Das Gehäuse erfordert nur eine normale, regelmäßige Reinigung der Außenfläche, die verschmutzt sein könnte.

Reinigen Sie den Rest des Geräts nur mit einem trockenen oder sehr leicht angefeuchteten Tuch. Achten Sie darauf, dass Sie das Netzkabel aus der Steckdose ziehen, bevor Sie eine Reinigung durchführen.

Der Touchscreen sollte mit einem weichen, trockenen Tuch ohne Reinigungsmittel oder Wasser gereinigt werden.

7.2 *Sterilization :*

Das Gerät und sein Zubehör sind nicht steril und nicht für die Sterilisation vorgesehen.

8 Malfunction

Wenn Sie eine Fehlfunktion feststellen, die nicht in den Begleitdokumenten des Geräts (siehe unten) kommentiert wird, informieren Sie bitte Ihren Händler oder den Hersteller.

Im Falle eines Versands des Geräts beachten Sie bitte die folgenden Anweisungen:
- Dekontaminieren und reinigen Sie das Gerät und das Zubehör.
- Verwenden Sie die Originalverpackung, einschließlich der Halteflansche.
- Legen Sie alle Zubehörteile des Geräts bei.
- Verkeilen Sie die einzelnen Teile.
- Achten Sie darauf, dass die Verpackung gut verschlossen ist.

Versandadresse:

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	- power grid problem - fuses	- check the mains voltage - check and change fuses
No communication with the PC (home button = red house)	- USB adapter	- check the connections - check that the FTDI driver is correctly installed (CDM21228_Setup.exe)
No stimulation is observed but the yellow indicators light up.	- bad contact - defective cable	- check the connections to the patient. - swap cables for verification
No stimulation and the yellow lights do not illuminate.	- loss of communication with the module. - the parameters of the stimulation currents are not consistent.	- exit the current treatment and return to the main office. - check the settings and change them.
Flat trace in biofeedback windows	- loss of communication with the module. - no sensor on the input in question	- exit the current treatment and return to the main office. - check the route used
Need to increase the stimulation current beyond the usual values with elastomer electrodes.	- old electrodes - insufficient frost	- change electrodes. - add contact gel
Automatic decrease of the amplitude slider.	- old electrodes - insufficient frost - pulse width too long.	- change electrodes. - add contact gel - change the programme to a lower pulse width.
Saturated or very noisy EMG biofeedback signal	- missing or poor contact of the reference electrode	- check the correct fixing of the 3ème 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.

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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 the transmitter. **Recommended separation distance** $d = 1{,}67.\sqrt{P}$ $d = 1{,}67.\sqrt{P}$ *80MHz-800MHz* $d = 2{,}33.\sqrt{P}$ *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
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	Interference may occur in the vicinity of the device marked with the following symbol:

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

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

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

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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Your dealer / distributor :

www.facebook.com/MazetSanteFrance/
mazetsante.fr