

# **BIOMOOV Manual**



Proprioception sensor



# 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 use in a therapeutic setting.

Use is reserved for professionals who have undergone the appropriate training.

If you have any problems 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 located on the last page of this manual within 15 days of installation or receipt.





# 1 Presentation of the device

BioMoov is a proprioception sensor. The sensor has no therapeutic claims.

Equipped with a software, the BioMoov allows, through a Bluetooth connection to the Biostim, to transcribe the patient's activities on a proprioception board.

The BioMoov is provided in a pouch, with a USB cord to recharge it, and a scratch to fix it on a proprioception tray.



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## 2 Description and technical information

-This user and maintenance manual is published to facilitate the handling of your BioMoov from the initial reception phase, then the 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 mandatory 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 related to the device.
- -Only personnel who have been informed of the contents of this document may operate the device. Failure to comply with any of the instructions contained in this document will relieve Électronique du Mazet and its authorized distributors of 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 device
	Recycling: This device should be disposed of at an appropriate collection and recycling facility. Consult the manufacturer.
	Manufacturer
	Date of manufacture
REF	Country of manufacture
LOT	Lot number
	Direct current
(((•)))	Non-ionizing electromagnetic radiation
MD	Medical device
IUD	UDI
<u></u>	Deposit
i	Operating instructions
CE	CE marking (European Conformity)



# 2.2 <u>Technical specifications</u>

#### 2.2.1 General characteristics

• Operating temperature: 0°C to 40°C.

Storage temperature: -40°C to 70°C.
Operating relative humidity: 30% to 75%.

• Operating altitude: < 2000 meters

#### 2.2.2 Technical characteristics of BioMoov

• Housing dimensions: 5.8 x 5.8 x 1.9 mm

Case weight: 159,425Case color: black

• Medical Class I equipment.

• Applied part type BF



#### 2.2.3 Accessories

This device is delivered with the following accessories as standard:

- USB cable
- Scratch

Accessories are for personal use only.

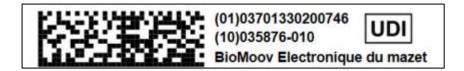
The BioMoov is not in contact with the patient. Indeed, it is intended to be fixed only on a proprioception tray.

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

#### 2.3 <u>Identification label</u>

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

#### 2.3.1 BioMoov's identification label







## 3 Warnings



<u>CAUTION</u>: Install the unit on a flat, stable surface. Do not block the rear ventilation openings (no objects closer than 4 cm).



<u>CAUTION</u>: The appliance must be plugged into an outlet with a grounding terminal (Class I electrical appliance).



<u>CAUTION</u>: In case of emergency, disconnect the power cable directly from the unit.



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



<u>CAUTION</u>: This device 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: Operating altitude below 2000m.

The performance of the device decreases with altitude.



<u>CAUTION</u>: The device must be used with the accessories supplied by the manufacturer



#### 4 Precautions

#### 4.1 Risks residual

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

#### 5 Installation of the device

Open the package, remove the accessories and the BioMoov device.

Check the contents against the **packing list** included with the documentation.

Check that the contents of the box are not damaged; if you have any doubts about the integrity of the device or its accessories and that the proper functioning of the device could be questioned, contact Électronique du Mazet

If the unit was stored in a cold place and there was a risk of condensation, let the unit rest for at least 2 hours at room temperature before turning it on.

Before the first use, a cleaning of the device and its accessories is recommended see § maintenance



# 6 User's manual

# 6.1 Handling the device

## 6.1.1 Powering up / starting up

Turn on the device with the on/off button located on the device. The BioMoov turns on and a LED flashes.

#### 6.1.2 Use of Bluetooth

See setting specification.

#### 6.1.3 Warning screen

When the BioMoov device is connected to the Biostim, a logo is displayed on the Biostim screen.



#### 6.2 Choice of treatment

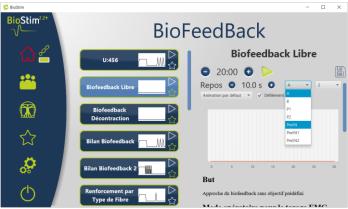
Refer to the Biostim user manual.

#### 6.3 Setting the parameters

Turn on the device and 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

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The accessory is then used like the other probes, by choosing the channel to be used that corresponds to the probe in the BFB menu.



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

When accessing the treatment, and before launching it, it is necessary to set up the tray: Clicking on the tray logo to the right of the Bluetooth symbol opens the configuration page.

This page allows you to configure the tray type:

2 axis tray (ball type) Or 1 axis (support on a bar)

Then, the calibration is done by putting the device in the right stop, then before, and by clicking on the adjustment logo for each





Note: During adjustment, the movement of the dot on the target may be reversed. After adjustment, the movement of the stage should cause the dot on the target to move in a consistent manner.



#### 6.4 Run a treatment

#### 6.4.1 Start the treatment

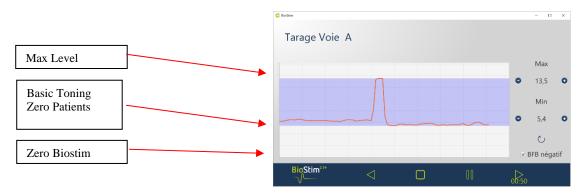
Use the BioFeedBack exercise module.

#### **Reminder: Taring Biofeedback**

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

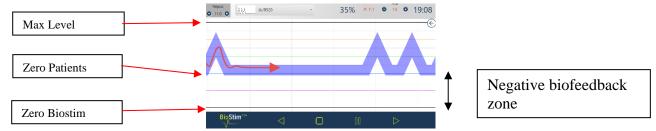
#### Procedure for taring

- 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 always 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 activate or not the negative biofeedback, either in the configuration page or during the 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.

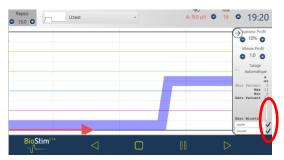


In the + version, it is possible to adjust the level of negative BFB to be displayed during the exercise, using the slider in the right-hand panel:

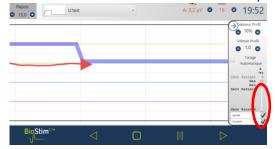
Zero Patient: the bottom of the screen corresponds to the minimum reached by the patient during the taring

This setting allows you to erase the basic tone.

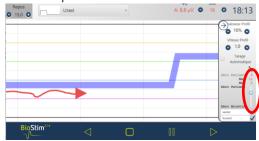




• Zero Biostim: minimum measurable by the device: to work in negative BFB



• It is also possible to choose intermediate values:



#### 6.4.2 **During treatment**

All parameters can be changed during processing by selection on the screen or by pressing the buttons on the remote control (optional).

The treatment can be stopped or restarted by selection on the touch screen or by pressing the keys on the remote control.

#### 6.4.3 End of treatment

Refer to the Biostim user manual

#### 6.5 Saving a treatment

Refer to the Biostim user manual

## 6.6 <u>Technical Information, Configuration & Settings</u>

Refer to the Biostim user manual



#### 7 Clinical Guide

## 7.1 <u>Target population</u>

BioMoov is intended for anyone over 5 years of age, regardless of gender, in combination with the BioStim device, it cannot work alone. The clinical part is detailed in the Biostim user manual

## 7.2 Side effects

As the device has no therapeutic claims, there are no side effects.

# 8 Maintenance, upkeep

The BioMoov device is designed to last 5 years.

To guarantee the preservation of the device's performance throughout its life, it is necessary to have the device checked by Electronique du Mazet's technicians every 2 years.

#### 8.1 Housing

The case only requires normal and periodic cleaning of its external surface which could be dirty. The same applies to the USB cable, ....

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



## 8.2 Sterilization:

This device is not sterile, Accessories are not sterile

#### 9 Malfunction

If you notice a malfunction that is not commented on in the documents accompanying the device, please inform your distributor or the manufacturer.

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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 unit.
- Set up the different elements.
- Make sure the package is properly closed.

#### Shipping address:

Electronique du Mazet ZA Route de Tence 43520 Le Mazet St Voy

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

Email: sav@electroniquedumazet.com

#### Possible operating anomalies:

Description of the anomaly	Possible causes	Actions
No connection to Biostim	Bluetooth connection problem	-Check that the Biomoov is charged -Switching the Biomoov off and on -Click on the Bluetooth logo (under the house).
No charging of the device	USB cord problem	Make sure the cord is not damaged
Flat trace in biofeedback windows	<ul><li>loss of communication with the module.</li><li>no sensor on the considered input</li></ul>	- exit the current treatment and return to the main office check the path used

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.



# 10 After-sales service and warranty

This device is warranted 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 device must be carried out by Électronique du Mazet or its authorized distributors for these operations.
- The work environment meets all regulatory and legal requirements.
- The device may only be used by competent and qualified personnel. Use must be in accordance with the instructions in this user's manual.
- Treatments should be used only for the applications for which they are intended and which are described in this manual.
- The device must be regularly maintained according to the manufacturer's instructions.
- All legal requirements for the use of this device are met.
- The device uses only the consumables or semi-consumables supplied or specified by the manufacturer.
- Machine parts and spare parts must not be replaced by the user.

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

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

The warranty is 24 months from the date of delivery of the device.

The accessories are guaranteed for 6 months from the date of delivery of the device.

Consumables and semi-consumables are not guaranteed.

Shipping and handling costs are not included in the warranty.

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

# 11 Disposal

#### 11.1 Accessories

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

#### 11.2 Electronics

If the BioMoov device should fail or become unusable, it is requested to return it to the manufacturer or to deposit it in a Recylum collection point.

Indeed, as part of its commitment to the environment, Électronique du Mazet finances the Recylum recycling network 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.recylum.com).





## 12 Transport and storage

The device 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

#### 13 CE declaration

ÉLECTRONIQUE DU MAZET makes available on request the CE declaration of this device.

The first affixing of the medical CE on this device took place on 18/05/2022.

## 14 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 devices (uro rehabilitation).

For any additional information, please contact us.

SAS Électronique du Mazet ZA Route de Tence 43520 Le Mazet St Voy Tel : +33 (0)4 71 65 02 16

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



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# **ELECTRONIQUE DU MAZET**

# ZA ROUTE DE TENCE 43520 LE MAZET SAINT VOY

Tél: +33 4 71 65 02 16

Mail: sav@electroniquedumazet.com

Your dealer / distributor :		



# 15 Certificate of guarantee

# **Certificate of Guarantee**

This form must be returned to Electronique du Mazet within 15 days of installation or receipt of equipment.

i, the undersigned,					
Organization:					
Address:					
Declares to have received the <b>Biomoov</b> device n° in working order.					
I have received all the necessary instructions for its use, maintenance, care, etc					
I have read the instruction manual and I have noted the warranty and service conditions.					
In the event that Electronique du Mazet or its distributors do not receive this form duly completed and signed within one month of delivery, Electronique du Mazet will be relieved of all responsibility with regard to the warranty and after-sales service, or any other consequence due to misuse of the device.					
Done at on					
Signature User:  Your distributor:					

#### To be returned to:

Electronics of the Mazet Z.A. Route de Tence 43520 Le Mazet St Voy

