User's Manual

bruxoff

The Holter for the monitoring of Bruxism

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⚠ **Read this manual carefully before using Bruxoff.**

CE 0476 This product is manufactured in compliance with the CE European Medical Device Directive and later directives and additions (2007/47 directive) and according to the reference norms **CEI EN 60601-1, 60601-1-2, 60601-1-11, 60601-2- 40, 60601-1-6, CEI IEC 62304, Directive 2002/96/CEE**

SYMBOLS USED

The graphic symbols used on this device and on this manual refer to the UNI EN ISO 980 Law, CEI EN 60601-1, RAEE Law and 2002/96/ECC Directive.

SYMBOL	DESCRIPTION
	Serial Number
	Device with BF parts.
	Class II device
	Warning, read the instructions before using the device. This symbol could also be used as a "Warning" symbol
	Read the instructions of use
	Manufacturer
	Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary following the 2002/96/EC Law of the European Parliament and Council of the European Union about the disposal of e-waste.

The Bruxoff device has been tested in reference to the EN 60601-1 and the EN 60601-1-2 Law. If the user connects the Bruxoff device to any other unauthorized device following the EN 606011 and EN 60601-1-2 Laws, he/she has to ensure that the combined use of the two devices follows the laws above mentioned.

Otherwise Spes Medica S.r.l shall not be held liable for accidents and/or injuries to persons or damage. For the features of the software, read the Software Manual.

1. INDEX

2. GENERAL DESCRIPTION

The *BruxOff device* is a three-canals Holter. This system has been designed to detect the surface electromyography signal (sEMG) from the two masseter muscles trough the use of the concentric electrodes called CoDe, in addition to the heart rate detected with three surface electrodes inside the chest belt.
The information detected from the electrodes is then saved on a non-removable Micro SD card inside the device. The Bruxoff system works with a software called Bruxmeter in order to display and process the data. This software is part of the Bruxoff system and it is also possible to download it free on the website www.bruxoff.com in the Downloads section.

3. INTENDED USE

BruxOff has been designed to be used as an electromyography Holter to monitor Bruxism.

⚠ **The device is not intended to be used near inflammable anaesthetics.**

⚠ **The device is not intended to be used for an electrocardiographic exam.**

4. PLACE OF USE

BruxOff is intended to be used as a home device and a hospital device: as a home device, the patient uses the device at home during the night and as a hospital device the operator uses the information detected from it in order to make a diagnosis.

5. THE USER

USER: Patient

a) Age : >15 years-old

b) Weight: not important

c) Health: no heart problems or pacemakers

d) Nationality: not important

e)Patient status: able to understand the use of Bruxoff, with Bruxism problems

Education level: High school

Knowledge: Minimum. Basic notions about the human body

Languages: Italian and/or English

Experience: Minimum . Minimum training about the device use

Handicaps:

- maximum reduction of the hearing of 40% with residual hearing at 60%;
- maximum sight reduction of 40% with residual sight at 60%

5. SAFETY CAUTIONS AND WARNINGS

The use of Bruxoff is forbidden in the following conditions:

- Simultaneous use of electro surgery systems, shortwave or microwave therapy or near these type of devices;
- Unsound mind patient;
- the device is damaged;
- Near inflammable anaesthetics with air, oxygen or nitrous oxide.
- To make an electrocardiographic exam
- Pacemaker users

These warnings must be followed:

- Contact immediately the manufacturer if foreign materials (liquids, etc.) come into contact with the device.
- If the device falls in to the ground or something similar happens, check that the device is undamaged. In case of doubt, contact the manufacturer.

- The Bruxoff device could be sensitive to electromagnetic interferences of other devices that could alter its electromyography measurements and consequently the physiological variables calculated on the basis of the information detected. For this reason, do not use it near devices that could cause the problems described above, for example mobile phones, instruments with power transformer, etc.

- The operator must be sure that the battery of the device is completely charged following what is indicated in this User's Manual before to give the device to the patient.

- The device must be kept out of reach of children or unsound mind patient
- Do not clean the device using acetone, ether, freon, oil products or any other solvent
- Do not use soap or water on the connector pin
- Do not clean Bruxoff or connection cables with water, in autoclave or steam cleaning

 The device must not be used in any other way than indicated in these instructions

6. CONTENT OF THE BRUXOFF KIT

ACCESSORIES AND DOCUMENTS			
REF	Description	Features	
CUSB01	USB connection cable: battery charge and PC connection	**NON-STERILE**	**REUSABLE**
CPAT01	Connection cable for the recording electrodes	**NON STERILE**	**RIUSABILE**
BRUXBELT000	Chest belt with device	**NON STERILE**	**RIUSABILE**
BRUXMETERSW	CD – ROM with Bruxmeter software	**NA**	**NA**
BRUXMAN0001	User's Bruxoff	**NA**	**NA**
BRUXMANSW	**Bruxmeter software manual**	**NA**	**NA**

⚠ **The accessories of the machine indicated above are to be considered as part of the device itself, so they are not subject to CE marking.**

ACCESSORIES NEEDED BUT NOT INCLUDED IN THE STANDARD EQUIPMENT			
REF	Description	STERILE	SINGLE-USE
KITBRUX002	**KIT contains the following codes:**		
CODEXX1500	**CoDe® adhesive concentric electrode with 15 cm cable and two-pin plug**	**NO**	**YES**
CDESBRUX24	Array of self-adhesive surface electrodes for the detection of the heart rate	**NO**	**YES**

⚠ **Use of the equipment accessories and/or CE** accessories of the Spes Medica s.r.l to be used for the detection of the electromyography signals.

7. DETAILED DESCRIPTION

Controls, indicators and connectors of the Bruxoff system are shown in Fig. 1 and described in the following sections.

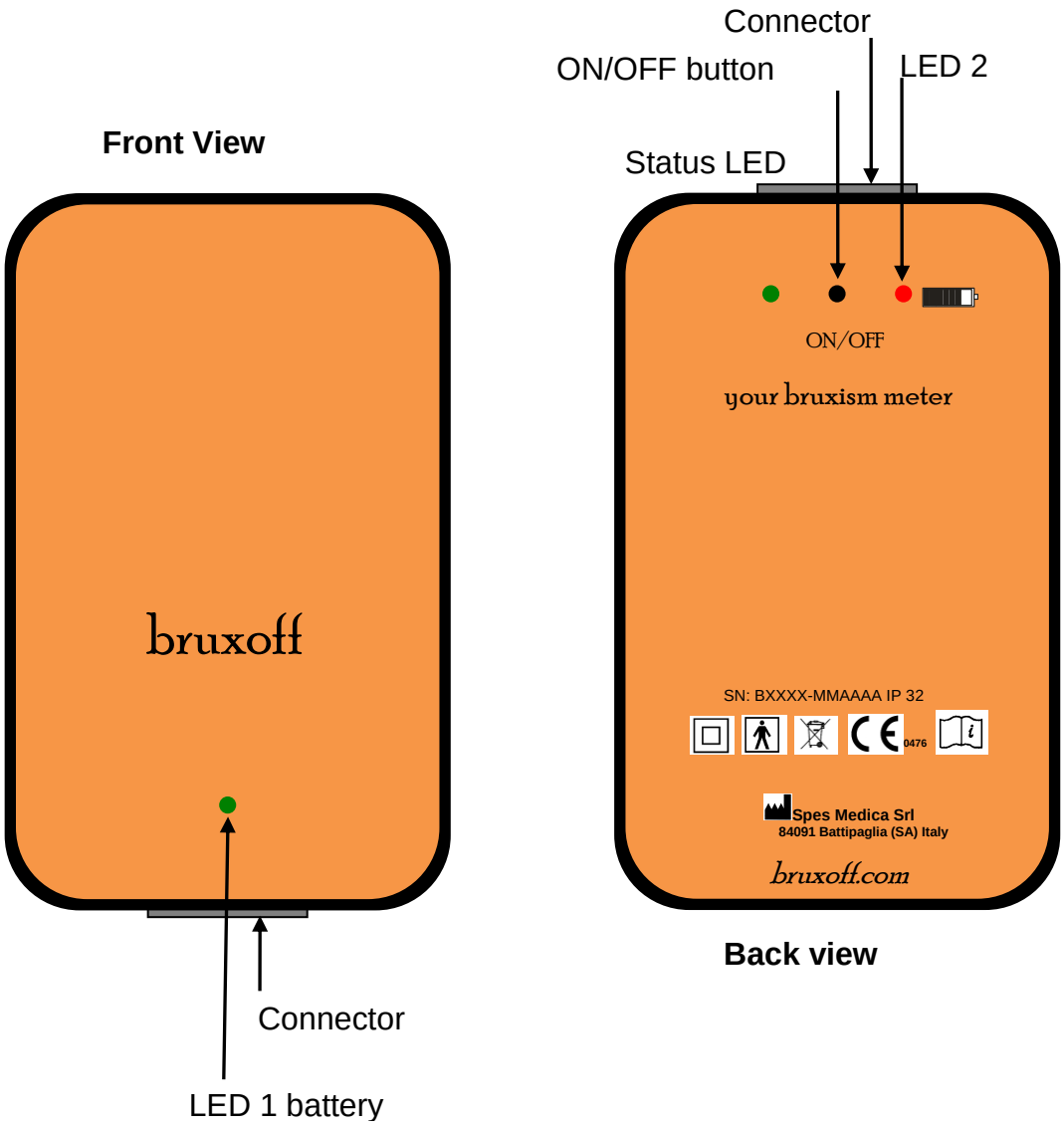

Fig. 1: *Front view and Back view of the Bruxoff system*

Description of controls, indicators and connectors shown in fig.1:

- **Power/ Electrodes Connector:** It is the connector to which the adapter should be connected for the detection of the signals and charge battery/ download data connector.

⚠ **To switch on the device the patient cable connector must be connected to the device**

- LED 1 battery: This is the only LED on the front side of the Bruxoff. This LED flashes (on and off) when in charge and the light stays on green when the battery is 100% charged or when the device is on charge and connected to the PC

- LED 2 battery: This LED is on the right side of the back of the Bruxoff. It is identified by the symbol of the battery. This LED is normally turned off when the battery level is enough to allow the recording of the exam, while when it starts to flash red means that it is possible to record one last exam, when the LED light stays on red the system is not recording anymore.

⚠ **When the battery LED on the right side of the back of the Bruxoff (identified by the battery symbol) stays on red light, the device is not recording anymore. In that case contact the operator so that he/she can charge the battery before making another exam.**

- Status LED: This LED is on the left side of the back of the Bruxoff and it stays on green light when the Bruxoff device is in stand-by. This LED starts flashing after pushing the ON/OFF button to confirm that the device is on and detecting signals.

- **ON/OFF button:** Pushing this button with a pen or something similar it is possible to start and stop the data capture.

⚠ **If after pushing the ON/OFF button the Status LED is not flashing, the data capture did not started. Push the ON/OFF button again. If the problem persists, contact the manufacturer.**

In fig. 2 it is shown how the Bruxoff system should be worn by the patient.

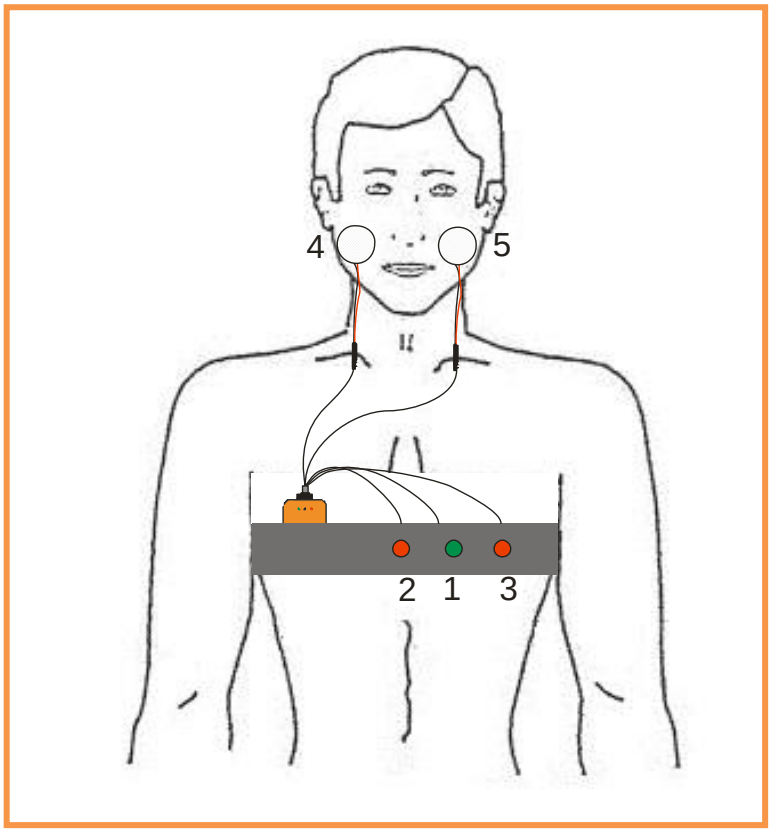

Fig. 2: *Patient wearing the Bruxoff system*

Patient Cable: to detect the electromyography signals produced by the masseter muscles and the heart rate the Bruxoff needs the cable for the connection of the electrodes. This cable is shown in fig. 3

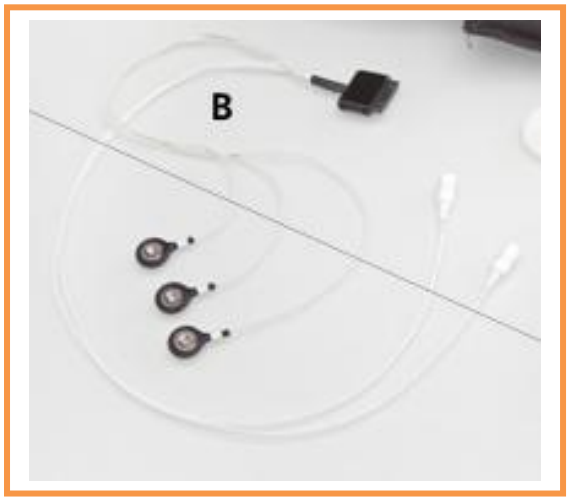

Fig. 3: *Patient Cable B*

An end of this cable ends with a multipolar connector; the other end is divided in 5 different cables: every cable ends with the following connector:

- A female clip identified with the number 1 to be used to connect the reference connector that will be placed inside the chest belt in the position identified with number 1.
- two female clips identified with numbers 2 and 3 to be used to connect the adhesive chest belt and that will be placed inside the chest belt in the positions identified with numbers 2 and 3: they will detect the heart rate;
- Two concentric connector identified with numbers 4 and 5 to be used to connect the CoDe concentric electrodes for the detection of the EMG signals from the masseter muscles.

CoDe Electrodes (*Concentric Detection*)

The Bruxoff system uses two concentric electrodes for the detection of the electromyography signals from the masseter muscles called Code. In fig. 4, an image of the CoDe concentric electrode.

Fig. 4: *CoDe® Electrodes*

Application of the CoDe® Electrodes (*Concentric Detection*)

Apply the CoDe electrodes as shown in fig. 5.

Fig. 5: *Application of the CoDe® electrodes*

Array of electrodes for the detection of the heart rate (REF: CDESBRUX24)

The Bruxoff system uses an array of 3 surface adhesive electrodes for the detection of the heart rate. In fig. 6, an image of the array.

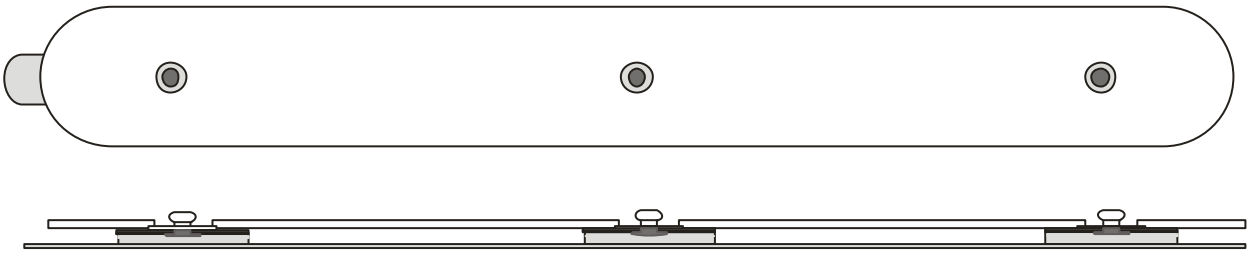

Fig. 6: *Array of adhesive electrodes for the detection of the heart rate*

⚠ **Avoid contact between the electrodes connected to the device but not applied yet and the conductor parts connected to the ground connection.**

Application of the Array of electrodes for the detection of the heart rate.

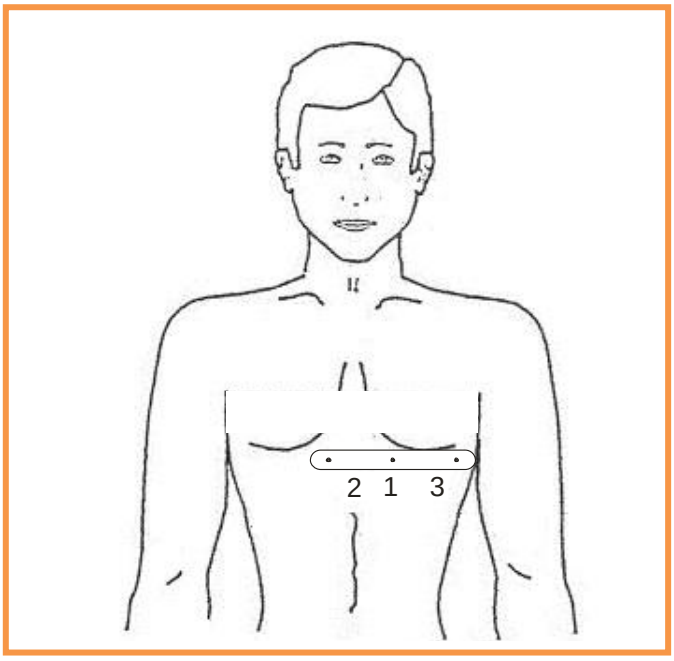

Fig. 7: *Application of the Array of adhesive electrodes*

The chest belt of the Bruxoff device

The Bruxoff device uses a chest belt that includes the system with a belt in the chest belt itself.

This belt overlaps the array of electrodes for the detection of the heart rate in order to ensure a good contact between the electrode and the skin.

Fig. 8: *Chest Belt*

Application of the chest belt of the Bruxoff device

Apply the chest belt of the Bruxoff device as shown in fig. 2 and as described in the section “Application of the Bruxoff system”

USB cable: charge battery and PC connection

The Bruxoff device has an USB cable as shown in fig. 9 and the operator (but not the patient) uses it as a double-function cable. The first function is that of connecting the Bruxoff to a PC so that the software can download and then process the data. The second function is that of charging the battery once connected to a PC.

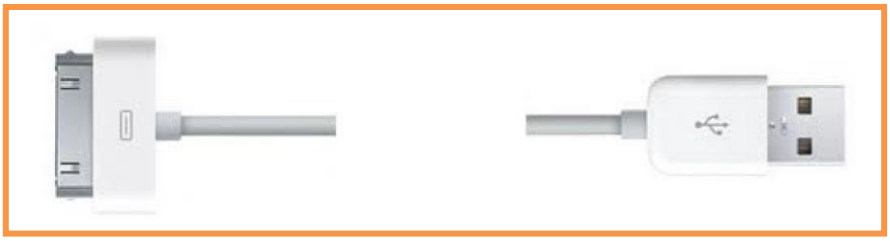

Fig. 9: *Cable for data downloading/ battery charge*

⚠ The connection to the PC and charging of the Bruxoff device is allowed only in the operator office or clinic, not at home. Only the operator can use the USB cable in order to charge the battery: it should not be given to the patient.

System Requirements for PC connection

1. Windows Operating system for PC (Windows XP, Vista, Windows 7)
2. USB port

⚠ **Use the USB cable that you find in the kit.**

Behaviour of the device during battery charge process

During the battery charge process the green LED on the front side of the Bruxoff flashes. When the device is fully charged the LED stays on.

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⚠ **Charge the device for at least 10 hours before to use it.**

Application of the Bruxoff Device

How to apply the Bruxoff system correctly:

- connect the multipolar connector of the patient cable to the multipolar connector on the Bruxoff device;
- take the CoDe electrodes and remove the protective liner, then apply them as shown in fig. 5, that is to say in direct contact with the masseter muscles;
- Without removing the protective liner of the array of electrodes for the detection of the heart rate (REF: CDESBRUX24), place the electrode on a flat surface an lay upon it the chest belt so that the three holes of the chest belt lay upon the three button on the electrode;
- Take the three clips of the patient cable numbered with the numbers 1,2,3 and connect them to the buttons of the Array of adhesive electrodes pushing the cables trough the holes numbered with the number 1,2,3 of the chest belt. Note: the clip number 1 must be connected to the central clip of the Array of electrodes of detection of the heart rate (REF: CDESBRUX24);
- Wear the chest belt and the Array of electrodes as shown in fig.2 and wear it tight enough so that the electrodes previously applied are under the left pectoral muscle and in direct contact with the skin;
- Connect the two concentric connectors numbered with the number 4 and 5 to the respective concentric connectors of the CoDe electrodes;
- Push the ON/OFF button with a pen or something similar to start the recording. Be sure that the status LED is flashing green. If the LED does not flash, go to section 10 of this manual “troubleshooting”.

- Insert the Bruxoff device in the appropriate pocket of the chest belt and get ready to go to sleep;
- Grind the teeth three times with the maximum clenching force and go to sleep. Each clenching should last about two seconds, with five seconds of rest between each clenching.
- When the patient wakes up, push the ON/OFF button again with a pen or something similar to stop the recording;
- Remove the electrodes and disconnect them from the chest belt. Disconnect the patient cable from the Bruxoff device, and then put the device and its accessories (chest belt and patient cable) back in its packaging. Throw away the single-use CoDe electrodes and the electrodes for the detection of the heart rate after use.

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⚠ **The single-use CoDe electrodes and the electrodes for the detection of the heart rate cannot be reused.**

Memory file

Files are saved on the Micro SD Card with a standard name. The name structure is:

BRUXOFFn.BRX

Where n is the number of recordings increasing every time the button ON/OFF is pushed. It can assume values in numbers and values in letters as well: 0, 1, 2... 8, 9, A, B... Z. so that in the system can coexist up to 36 different files. If all the 36 available recordings have been made, Bruxoff does not allow the uploading of new files. The user should copy and delete the files on the Micro Sd Card in order to have new file names to be used again. Every time the device is turned off, that is to say disconnected from the connector, the numbering of the files restart from “BRUXOFF0.BRX”. The Bruxoff device does not have a clock, so the date and the time of the file do not display the moment in which they are saved. Time and date start from 00.00 of the 1st January 2012 and increase of 1 hour with every new recording. The Bruxoff0.brx file will be saved with the date 1/1/2012 and time 00:00, the Bruxoff1.brx will be saved with the date 1/1/2012 and time 01:00 etc... Order the

recording files chronologically in order to have a temporal order of creation of them.

8. TROUBLESHOOTING

This section describes the most common problems that may be found by Bruxoff users.

Problem Description	How to deal with it
After pushing the ON/OFF button the LED 2 (red) stays on.	Memory not available: if the problem persists, contact the manufacturer.
The LED 2 (red) stays on	Low Battery. Charge the battery before using the device.
The LED 2 (red) flashes	Battery almost low but charged enough to record one last exam.
The status LED (green) does not flashes.	The recording did not started. Push the ON/OFF button again. If the problem persists, contact the manufacturer.
No file saved at the end of the recording.	The recording did not started: check that after pushing the ON/OFF button the (green) status LED starts to flash.

9. BRUXOFF MAINTENANCE AND STORAGE

Bruxoff device has to be used, transported and stored in the following conditions:

Temperature:	**from 10°C to +40°C**
Maximum relative humidity:	**from 30% to 75%**
Atmospheric pressure:	**from 700 hPa to 1060 hPa**

It is recommended to turn off the Bruxoff device at the end of every session.
Bruxoff should be stored with all the enclosed accessories on a safe place far from all the conditions described in the section Warnings of this manual. Bruxoff does not need any particular maintenance procedure to work. To maintain the battery efficiency, recharge the device before every use and check regularly the efficiency status of the battery.

⚠ If during the use and after the battery charging the battery lasts less than 3 hours, contact the manufacturer to check the controls of the electrical source itself.

Cleaning the device: At the end of every use clean the Bruxoff with a clean cloth.

- ⚠ Do not clean Bruxoff using acetone, ether, freon, oil products or any other solvent;

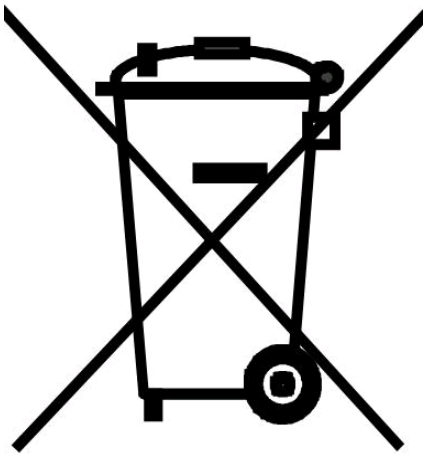
  ⚠ Do not use soap or water on the connectors pin contacts.
- ⚠ Do not clean Bruxoff or its cables with water, in autoclave or with steam cleaning**.**

⚠ **WARNING: clean the electrodes connection cable only with hospital disinfectants before every use to avoid microbial contamination between patients and healthcare professionals.**

Product Disposal

The Bruxoff system contains electronic parts that must be disposed of as e-waste. Dispose the device and the accessories following local regulations. Follow the disposal regulations of your country in order to ensure the correct disposal of the Bruxoff device and its

accessories. For further information about the disposal of this device, contact the Environment Department and local authority.



⚠ **Warning**: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment of necessary, following the 2002/96/EC of the European Parliament and European Council on waste electrical and electronic equipment.
(WEEE). The regulation is not valid in case of corrupted product.

Life span of the device

The Bruxoff system is produced in order to last, if the use and maintenance conditions indicated in this User's manual are followed, but the life span of the device is determined by the life span of the battery (5 years). After this period it is recommended to take the device to the manufacturer every two years.

10. TECHNICAL SPECIFICATIONS

The Bruxoff device is a battery system designed following the medical regulations in order to ensure the patient safety.
The signal amplified by the system is saved as a proprietary file on a non-removable MicrdoSdcard inside the system.

In table 1 there are the technical specifications of the Bruxoff system.

Model	BruxOff
Classification	Battery system
Degree of Protection	IP32
Case	Metallic case
Power Supply	3,7V Battery, rechargeable
Battery time	36 Hours (full charge)
Charging time	10 hours
Class	II
Number of Channels	4 of which 3 used
Dynamics	972 μV_{PP}
Band	13 ÷ 400Hz
Input Noise	< 2 μV_{RMS}
Amplification	3.393 V/V (+/- 2%)
Input impedance	> 90 MΩ on the entire bandwith
CMRR	>96 dB
Output Dynamics	0 ÷ 3.3 V
A/D converter resolution	8 bits
Data memory	Micro SD inside the device
Sampling rate	800 Hz
Commands	1 button
Dimensions	59 x 95 x 10 mm
Weight	110g

TAB. 1: *Technical Specifications of the Bruxoff System*

11. APPENDIX

Information from the Manufacturer in reference to the electromagnetic compatibility of the Bruxoff device

EMISSIONS		
The Bruxoff device is designed and made to work in an electromagnetic environment with the following conditions. The Bruxoff user must ensure that it is used in these conditions		
Test of emissions	***Conformity***	***Electromagnetic Environment-guide***
RF Emissions	Gruppo 1	The Bruxoff product uses the RF energy only for its inner functioning, so its RF emissions are very low and most likely it does not cause any interference with the electronic devices in the same environment.
RF Emissions	B Class	The Bruxoff product can be used in every environment, at home and where there is an electrical grid that supplies houses/ buildings
Harmonic Emissions	A Class	
Flicker Emissions	Adequate	

Table 202	**IMMUNITY**		
Immunity Test	***Test level 60601-1-2***	***Conformity level***	***Electromagnetic environment-guide***
Electrostatic charge	± 6 kV contact ± 8 kv air	± 6 kV contact ± 8 kv air	Pavements must be of wood, piling, ceramic. If pavements are of synthetic material, relative humidity must be at least 30%
Transients	± 2 kV phase(i)-ground ± 1 kv phase (i)-phase(i)	± 2 kV common mode ± 1 kv differential mode	The quality of the voltage network should be that of a common hospital/ business environment.
Overvoltages	± 2 kV phase(i)-ground ± 1 kv phase (i)-phase(i)	± 2 kV common mode ± 1 kv differential mode	The quality of the voltage network should be that of a common hospital /business environment.
Voltage interruptions, short interruptions and variations of voltage on the input lines	< 5% Ut (95% of interruption) for 0,5 cycles 40% Ut (60% of interruption) for 5 cycle 70% Ut (30% of interruption) for 25 cycles < 5% Ut (95% of interruption) for 5 seconds	< 5% Ut (95% of interruption) for 0,5 cycles 40% Ut (60% of interruption) for 5 cycles 70% Ut (30% of interruption) for 25 cycles < 5% Ut (95% of interruption) for 5 seconds	The quality of the voltage network should be that of a common home/business environment. If the Bruxoff user calls for a continuative work even during the voltage network interruption, charge Bruxoff with a uninterruptible power source
Mag at the network frequency(50 Hz)	3 A/m	3 A/m	The frequency magnetic field must have home/business environment levels.

Table 202	IMMUNITY		
Immunity Test	***Test Level 60601-1-2***	***Conformity Levels***	***Electromagnetic environment-guide***
Conducted Radio Frequency	3 Veff	3 Veff	$d = 1{,}17 \cdot \sqrt{P}$ Where **P** is the maximum output power of the transmitter in W by the manufacturer of the transmitter and **d** is the distance of separation in metres
Irradiated Radio Frequency	10 V/m (26 MHz÷1 GHz) 3 V/m (1GHz÷2,5GHz)	10 V/m 3 V/m	$d = 0{,}35 \cdot \sqrt{P}$ from 80 MHz to 800 MHz $d = 0{,}7 \cdot \sqrt{P}$ from 800 MHz to 1 GHz $d = 2{,}33 \cdot \sqrt{P}$ from 1 GHz to 2,5 GHz Where **P** is the maximum output power of the transmitter in W by the manufacturer of the transmitter and **d** is the distance of separation in metres

DISTANCE OF SEPARATION RECOMMENDED BETWEEN PORTABLE AND MOVABLE COMUNICATION DEVICES AND THE BRUXOFF DEVICE

Bruxoff is made to work on an electromagnetic environment where the radiofrequency distortions are under control. The Bruxoff user or operator can avoid electromagnetic interferences ensuring a minimum distance between the RF (transmitters) movable and portable communication devices and, as described below, in relation to the maximum output power of the radio communication devices.

Maximum Output power of the transmitter (W)	***Distance of separation to the transmitter frequency (m)***			
	From 15 kHz to 80MHz	From 80MHz to 800MHz	From 800MHz to 1GHz	From 1GHz to 2,5GHz
0,01	0,12	0,04	0,07	0,23
0,1	0,37	0,11	0,22	0,74
1	1,17	0,35	0,70	2,33
10	3,69	1,11	2,21	7,38
100	11,67	3,50	7,00	23,33

CUSTOMER SERVICE

Bruxoff has no parts that can be replaced or repaired by the user; contact the distributor for assistance so that he/she can repair or replace the products under warranty.

Maintenance and replacement of parts, modifications and/or reparations made by unauthorized Companies and/or operators by Spes Medica S.r.l will forfeit entitlement to warranty.

Spes Medica S.r.l. denies any and all responsibility for damages caused directly or indirectly as a result of maintenance, replacement of parts, modifications and/or reparations made by Companies and/or operator that are not authorized by the Spes Medica S.r.l.

Bruxoff does not need any prior maintenance.

WARRANTY

Spes Medica S.r.l ensures that every new product has no defects due to materials and labour and will repair and/or replace in warranty products used following the intended use and used in the use conditions described in this manual.

Warranty lasts **2 years** only after filling and signature of the warranty application form that you find below.

Warranty conditions: the obligations of Spes Medica S.r.l following the warranty are limited exclusively to what follows:

- reparation will be made by and no later than 30 work days after the receipt of the product and only after the verification that the malfunctioning is not due to inadequate or inaccurate use, maintenance and /or reparation.

If Spes Medica S.r.l verifies that the malfunctioning is not due to inadequate or inaccurate use or unauthorized maintenance/reparation, the reparation costs (materials and labour) will be invoiced only after acceptation of the budget of reparation by the owner

These warranty conditions substitute all the other warranty conditions, explicit or implicit, included, but not within limits of the general conditions specified in the international sale regulations.
Spes Medica S.r.l reserves the right to refuse the reparation of any products sent by the user for reparation; this refusal will be conveniently explained. The only obligation of Spes Medica S.r.l. is that of returning the product to the user at its own expenses.

BruxOff WARRANTY ACTIVATION FORM

a copy of this module filled and signed by the Costumer must be sent back by e-mail, fax or mail to:

Spes Medica S.r.l. – Via Europa –Zona Industriale –
84091 Battipaglia (SA) – Italy
Tel: +39 (0)828 614191 – fax: +39 (0)828 341788
e-mail: info@spesmedica.com

TO BE FILLED BY THE CUSTOMER

BruxOff Serial Number		*BruxOff Date of Sale*	
Purchase			
Address			
City	*Country*	*ZIP CODE*	
Tel.:	**fax:**	**e-mail:**	

To *be covered by warranty, you must certify that*:

Your BruxOff will be used only according with User's Manual
All unexpected occurrences and malfunction associated with the ***BruxOff*** *will promptly be reported to*
Spes Medica S.r.l. – Via Europa –Zona Industriale – 84091 Battipaglia (SA) – Italy

I declare to have understood and accepted the Warranty terms

Stamp and Signature	*Date*

Spes Medica S.r.l. warrants the BruxOff to be free from defects in material or factory workmanship in the course of normal use and service. The manufacturer's obligation under this warranty is limited to repairing or replacing any defective part, provided that the unit is returned, unmodified, to Spes Medica S.r.l, and that the defect has occurred within one year of the original date of purchase. A handling/postage charge will be at charge of the Customer.
This warranty is void if the purchaser has not returned a copy of this document, signed by the responsible party of the purchaser, and completely executed. Spes Medica S.r.l. expressly disavows any medical liability for the improper use of this device.
This warranty does not apply (is void) to any unit which has been repaired in any way or modified by unauthorized personnel, or which has been subject to misuse, neglect or accident; or which has had the serial number altered or removed

Notes

Manufactured by:

Spes Medica srl

Via Europa (Zona Industriale)

84091 - Battipaglia (Sa) - ITALY

www.spesmedica.com

e-mail: info@spesmedica.com

Designed in collaboration with and Distributed by:

OT Bioelettronica

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