⚠ Only use the device after reading this manual.

CONTENTS

MI-BIOSTIM-EN Revision 1.6 - April 2024
SW Rev. from 1.7

1. INTRODUCTION

1.1 What is the BIOSTIM and how does it work?

The BIOSTIM is an electrical osteogenesis stimulator using electromagnetic fields.
The BIOSTIM is a therapeutic aid and must be used under a doctor's prescription.
The device consists of a low-frequency pulsed electromagnetic field generator characterised by a pulse signal at a frequency of 75 Hz, with a duty cycle of 10%, i.e. an activation time of approximately 1.3 milliseconds.
This electromagnetic field is capable of inducing an average electric field of 0.04 mV/cm in the bone tissue, which represents the active component of the signal and is capable of increasing osteoblast activity.
The electric field focusses on the site to be treated by means of appropriately shaped coils.
The coils, or the applied part to be applied to the site requiring treatment, have an extremely homogeneous field and therefore do not require a perfectly centred application; for this reason the patient is able to perform the application themselves, without the need for medical or nursing supervision.
The generator is controlled by a microprocessor that constantly monitors the correct functioning of the device, promptly signalling any anomalies or malfunctions to the patient that may occur during the treatment; to this end, it is equipped with simple and effective visual and acoustic alarms.

1.2 Who can use the BIOSTIM?

The BIOSTIM must be used by people who are capable of independently understanding and implementing the instructions provided in this manual; otherwise, and if it is being used on children, the BIOSTIM may only be used under the supervision of people who are capable of understanding and implementing the instructions provided in this manual.

1.3 Intended Use

The intended use of the low-frequency pulsed electromagnetic field generator for therapeutic use is the treatment of inflammatory and degenerative tissue diseases, with particular reference to joints and the stimulation of osteogenesis. In particular, the **BIOSTIMBB02** device is indicated for the:

- ***Stimulation of osteogenesis***

1.4 Device performance characteristics

The device performance characteristics are:

- the ability to generate an electrical signal with the specified characteristics capable of driving a coil and producing a pulsed electromagnetic field that provides the expected clinical benefits;
- the device must allow the user to activate/deactivate the signal delivery and check the time the treatment is performed at.

More specifically, the time-varying electromagnetic field generated with a specific profile produces a stimulating effect on osteoblasts and a consequent increase in bone tissue-generating activity.

1.5 Therapeutic treatments that can be performed with the BIOSTIM

The main areas in which the BIOSTIM is used in orthopaedics and traumatology are:

- Delayed union and pseudarthrosis
- Recent fractures
- Osteotomy

- Necrosis
- Painful prosthetic implantation
- Complex and/or risk fractures
- Osteoporosis fractures
- Revision prostheses
- Bone grafts
- Healing skin wounds

1.6 Expected clinical benefits

The expected clinical benefits of using the **BIOSIM BB02** pulsed electromagnetic field generator are:

- The stimulation of osteogenesis,
- the healing of fractures,
- soft tissue healing,
- pain relief,
- health-related quality of life.

These clinical benefits and claims of product performance are reported in multiple scientific articles and confirmed by sufficient clinical trials.

2. DEVICE COMPONENTS

The BIOSTIM consists of the following elements:

- the signal generator ❶ that the rechargeable battery is connected to
- the coil ❷, the applied part of the device
- the power supply ❸, the specifications of which can be found in section 10.

The device also has an elastic band to keep the coil in the correct position during the treatment.

2.1 Generator

The generator is equipped with:

An LCD display ❶ with touch function which displays messages indicating the status of the device.

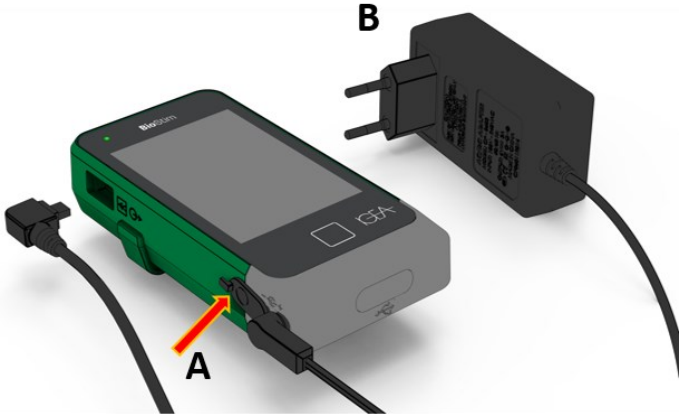
- A button ❷ used to switch on/off and reset the generator.
- An LED ❸ which indicates the status of the device, together with the messages shown on the display.
- A coil ❹ connection socket, marked with the symbol .
- A socket ❺ for connection to the external power supply, marked with the symbol .
- A USB socket at the bottom of the generator ❻, covered by a protective cap and reserved for the IGEA technical service.
- A removable attachment clip ❼ that the user can use to carry the generator on a belt and perform the treatment on the move.

3. DEVICE PREPARATION

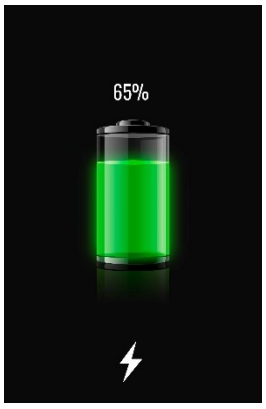
3.1 Initial battery charge

Upon receipt, the battery must be charged before treatment using the external power supply**.**

Connect the power supply to the generator by inserting connector **[A]** into the socket on the bottom left of the generator. Then connect power supply plug **[B]** to the mains socket.



Within a few seconds, the device will start to charge the battery:



- The generator beeps, the display lights up and shows a progressively filling battery symbol to indicate that the battery is charging. The charge percentage also appears below the battery symbol.
- Charging a completely empty battery can take up to 4 hours
- It is a normal for the device to heat up when charging.
- When charging is complete, the display shows the battery charge symbol
- Disconnect the power supply unit from the generator and the mains socket.

NOTE: if the BIOSTIM is charged in an environment with a temperature above 30°C, the battery may take longer than 4 hours to fully charge.

To avoid this, the BIOSTIM should be charged in an environment with a temperature that does not exceed 30°C.

IMPORTANT NOTES

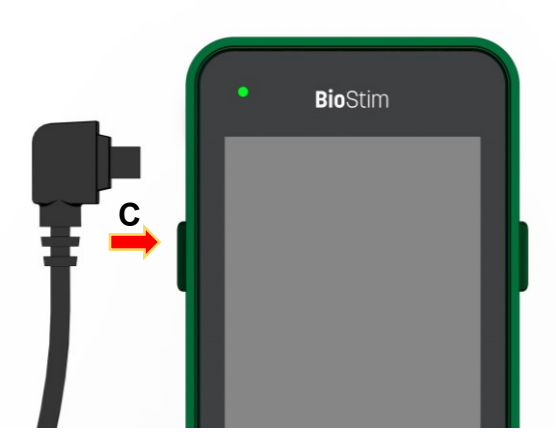
Only use the supplied power supply unit for charging. The use of other devices may cause damage to the device or the user and the manufacturer will accept no liability for this.

- If the device is not used for long periods, the battery may go flat or may not have enough energy left to complete the treatment; it is therefore recommended to charge the battery before each use.
- If the device comes from a place with a different temperature (e.g. due to transportation or storage), wait about 10 minutes for it to adjust to the room temperature before using it.

1. Under special conditions, e.g. after long periods of storage or inactivity, the battery may be completely flat and **the device may not be able to switch on**; in this case, connect the external power supply to the generator and wait up to 30 seconds; the battery should begin to charge as described in section 3.1.
2. Leave the generator on charge until it is fully charged before using the device.
3. The power supply battery contained in the device **cannot be removed/replaced by the user**. If necessary, the battery may only be replaced by the manufacturer or by the manufacturer's authorised service department.

3.2 Connecting the coil to the generator

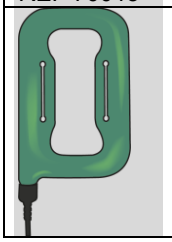
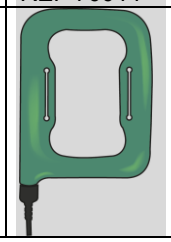
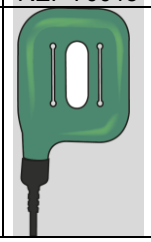
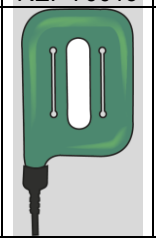
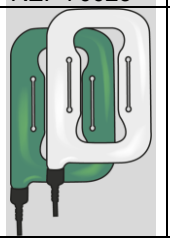
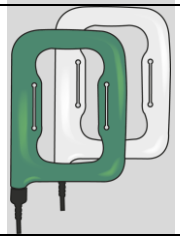
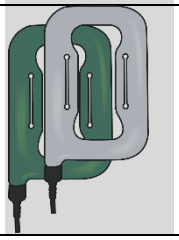
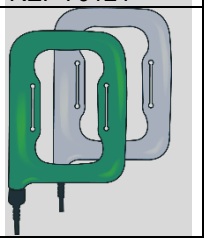
Insert the coil connector into the coil socket on the left side of the generator (**C**), pressing down until you hear a 'click'.



The BIOSTIM can be used with different coils, single or double coils with different shapes and sizes, so that it can be adapted to any parts of the body requiring treatment.

The table below shows all coils that can be used with the BIOSTIM, each identified by their reference code.

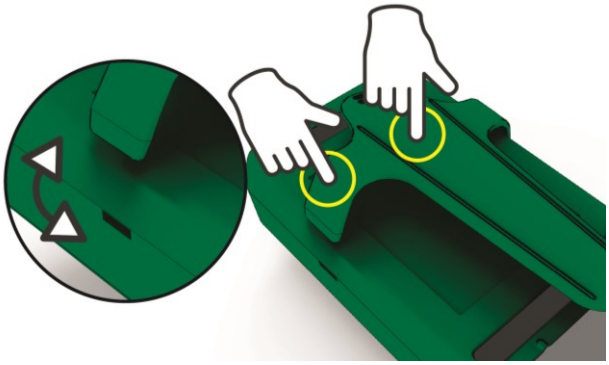
Coils that can be used with the BIOSTIM BB02

REF 70013	REF 70014	REF 70015	REF 70016	REF 70023	REF 70024	REF 70123	REF 70124
							

4. CLIP ATTACHMENT AND REMOVAL

If necessary, the generator can be clipped onto the belt using the supplied clip, so that the treatment can also be carried out on the move.

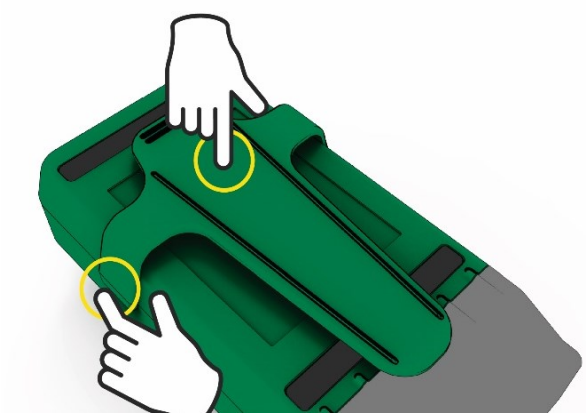
To fit the clip, engage one side notch in the slot provided and apply light pressure to the centre of the clip until the second notch is also fully engaged.

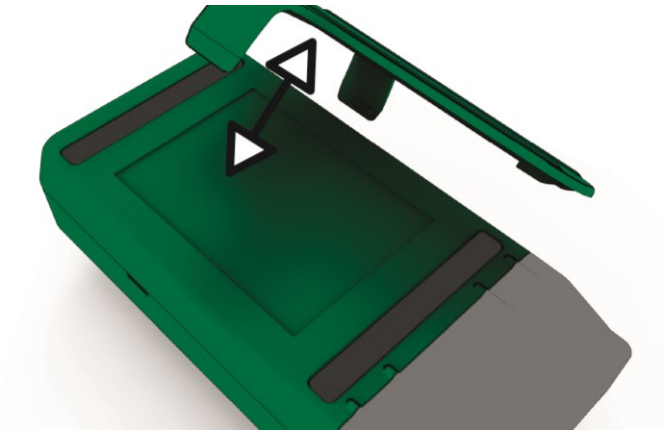


The generator can now be attached to the belt.

To remove the clip, press gently in the centre to release the first side tooth

from its housing and then the second one. Now lift the clip and remove it.





5. ADMINISTERING THE TREATMENT

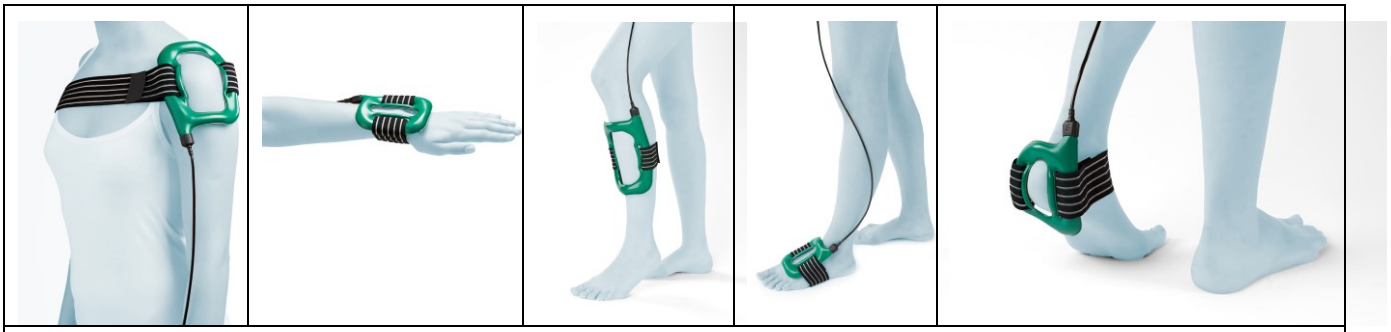
5.1 Coil positioning

Position the coil so that the site to be treated is in the centre of the coil; positioning it on a garment or washcloth is recommended.

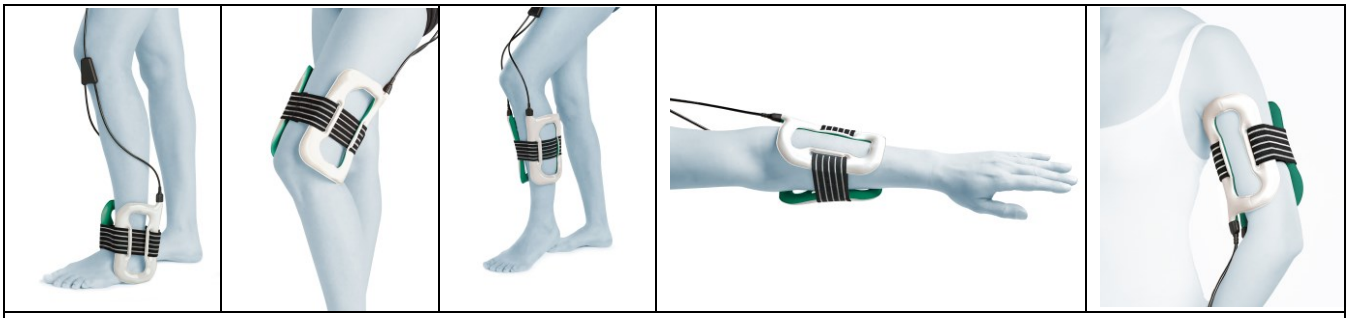
The double coils should be positioned opposite one another, if possible sideways, so that the area to be treated is between the two coils. **IMPORTANT**: **the double coil is correctly positioned by matching the corresponding colours of the coils,** if possible by placing the two green sides inwards.

Secure the coils with the supplied band or other suitable means **without tightening or forcing the contact between the coil and treatment site**; the flaps on the coils can be used to help fix the elastic band.

Below are some positioning examples:



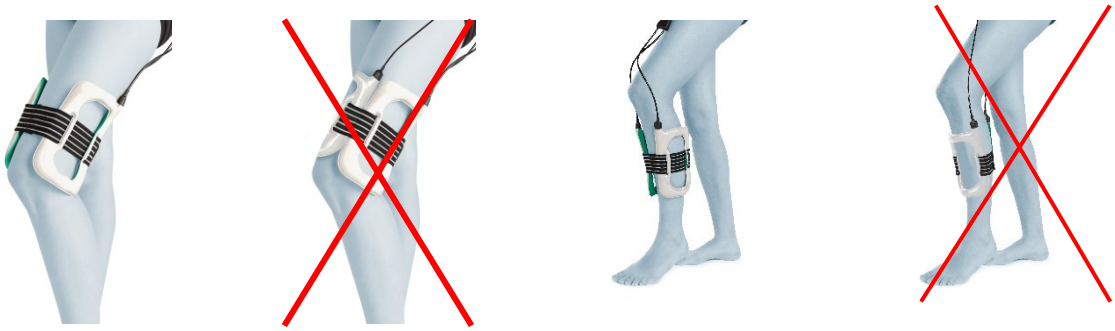
single coil - positioning examples



double coil - positioning examples

5.2 Recommendations on how to use the coil properly

- The coil must not be applied directly to the skin. **For hygiene reasons, the coil should always be placed on light clothing**; treatment will still be effective. Particularly if the skin has lesions in the treatment area, place a light garment between the coil and the skin or, if this is not possible, disinfect the coil before each application.
- To ensure treatment is effective, simply secure the coil on the treatment site with the elastic band provided; do not tighten or force contact between the coil and treatment area so as not to encourage any venous stasis.
- The double coils should be placed opposite each other, sideways where possible, so that the treatment zone is between the two coils.



YES NO YES NO

- To ensure treatment is effective, the double coils must be positioned by matching the colours on the coil, if possible by placing the two green sides inwards.

YES

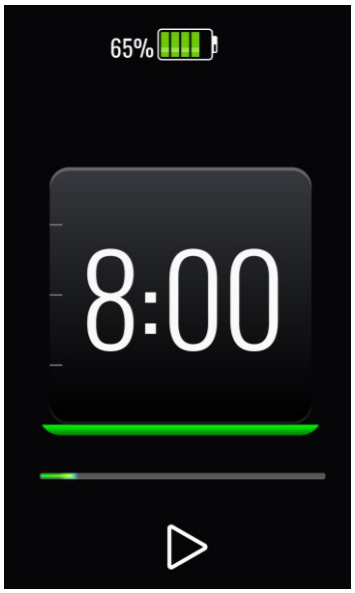
NO

- Do not use the coil if the cable connecting it to the generator is visibly damaged.
- When using the coil under heavy blankets, the coil surface may become overheard. If this is the case, perform the treatment without covering the coil.
- Before cleaning the coil, switch off the generator and disconnect the coil. Clean the coil with a cloth that has been dampened with a neutral detergent; do not use solvents or aggressive cleaning agents. It is advisable to regularly disinfect the coil, particularly if it is used in contact with the skin.

5.3 Turning on the generator

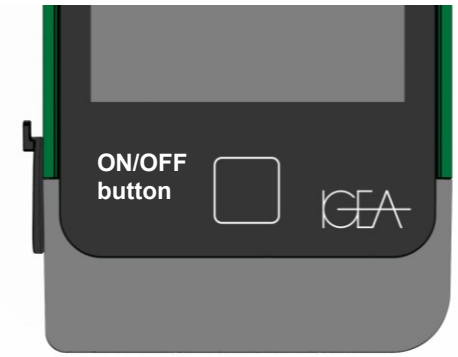
After charging the battery and connecting the coil, **switch on the generator**by pressing the power button for about 2 seconds until you hear a confirmation 'beep' and a small vibration, **then release the button**.

The display lights up and an initial Welcome screen appears. Then the main screen appears with the battery symbol at the top and the timer counting down the treatment time in the middle of the screen. The device immediately starts providing the treatment. Below the timer, the PAUSE button allows the treatment to be paused. ⏸



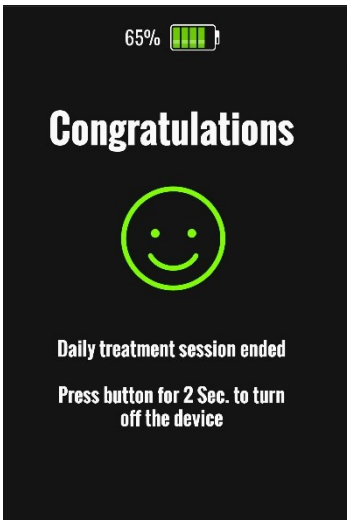
The **LED in the top left above the display flashes green** and the display shows a timer, where '8:00' in the example is the remaining hours and minutes of treatment. The timer updates with every minute of treatment that has been performed until it reaches zero.

- After 10 seconds of inactivity, the display switches off to save battery power; **the green LED that continues to flash** informs the patient that treatment is in underway.
- During treatment, the patient can reactivate the display with a quick press of the ON/OFF button, e.g. to read the treatment time remaining or the remaining battery charge.



When switched on, the display shows:

- The battery symbol above indicating the percentage of charge remaining; it is normally green and turns red when the battery is low (the battery needs to be charged).
- In the centre of the display, the timer symbol counts the treatment time that is left.



- Below the timer is the PAUSE button which, when pressed, pauses the treatment and the PLAY button appears on the screen in its place. Pressing the button again restarts the treatment and the remaining treatment time countdown. Each press of the PLAY/PAUSE button is accompanied by a confirmation beep.

At the end of the daily treatment time of 4 hours, the device **stops providing the treatment,** the **green light goes out** and the display shows the end of treatment message. The stop symbol indicates that the device has finished dispensing the daily treatment.

The device remains switched on, without delivering treatment and in standby position (standby); the user can switch the device off by pressing the on/off button for about two seconds, until a 'beep' is heard.

If not switched off by the user, the generator will switch itself off when the battery is completely empty.

At the end of the treatment, remove the coil from the treatment area, keeping the coil connected to the generator for convenience.

Every time it is turned on, the timer will restart at 8:00 hours.

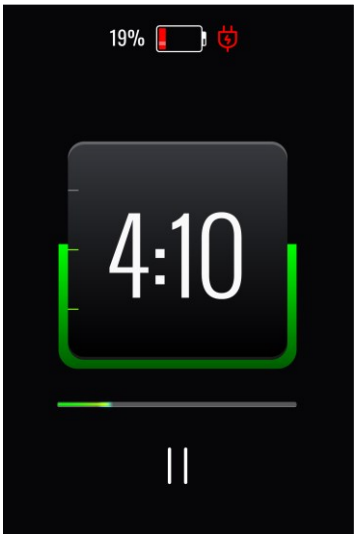
If the user needs to stop treatment before having completed the daily treatment time, simply switch off the generator by pressing the on/off button for about two seconds, until a confirmation 'beep' is heard. To resume treatment, simply switch on the generator: the counter will in any case restart from zero.

When the battery is fully charged it allows up to 8 hours of continuous treatment; therefore it **is recommended to recharge the device at the end of the daily treatment** according to the instructions in paragraph 5.4, so that it is able to perform the next round of treatment.

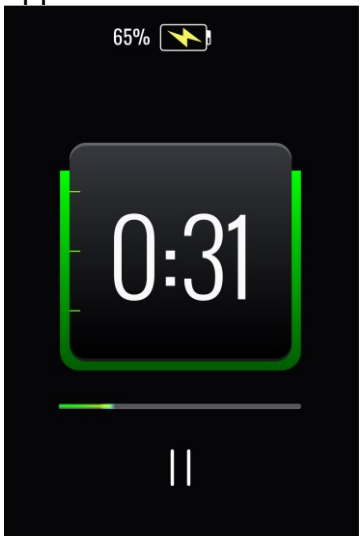
5.4 Battery monitoring and charging

The device monitors the battery charge during treatment.

In the top of the display, the battery symbol is always shown indicating the percentage of remaining charge. The symbol is normally green and turns red when the battery is empty. When the battery is low, a power plug symbol appears next to the battery symbol to warn of the need to recharge the battery.



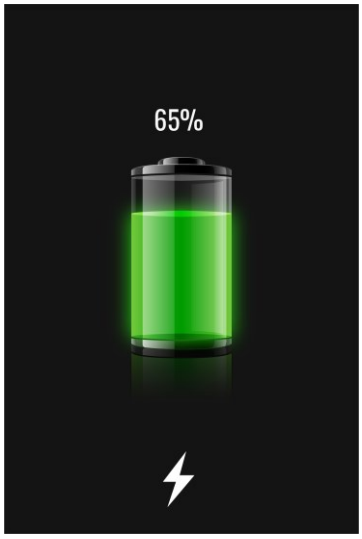
If the external charger is connected during treatment, a flash appears inside the battery symbol to indicate that charging is in progress, and there is a beep as a warning that the power supply is being switched on.



If the device is not charged, the battery is will run even lower and the device can longer deliver the treatment. If this happens:

- the **'empty battery'** symbol **flashes and the counter stops** because the device is no longer delivering treatment,

- the **green LED goes out** and the device beeps every second for 30 seconds after which, if not charged, it will switch off.



With the generator switched off, to charge the battery, connect the power supply first to the generator and then to the mains socket.

- the generator beeps and there is a short vibration, then display lights up showing the icon of the battery being charged until the charge is complete (full charge takes up to 4 hours),
- when charging is complete, the display shows the “battery charged” symbol
- Disconnect the power supply unit from the generator and the mains socket.

It is normal for the battery to heat up when being charged, so it is advisable not to place the generator directly in contact with the body during this time.

5.5 Battery efficiency

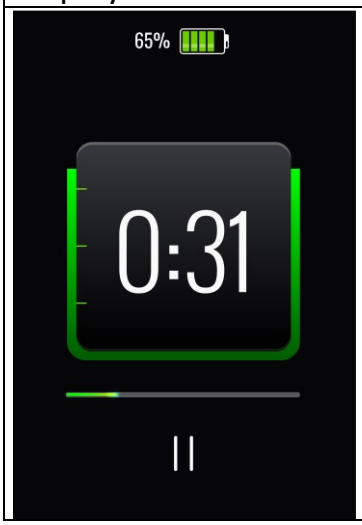
The efficiency of the battery is affected by the correct use and wear of the battery.

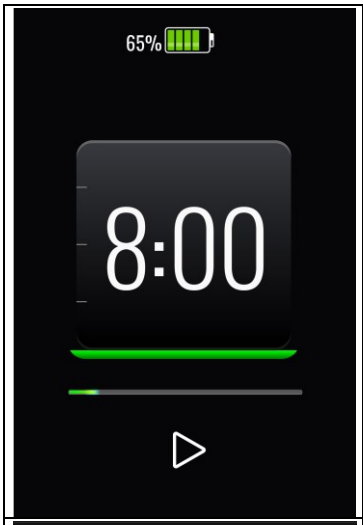
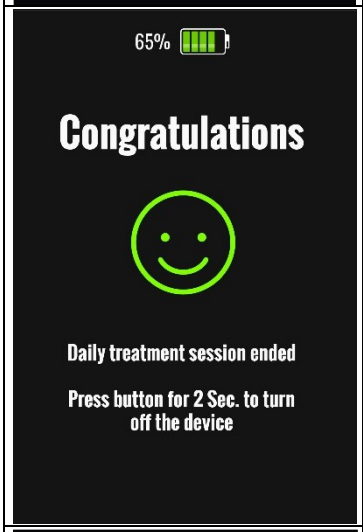
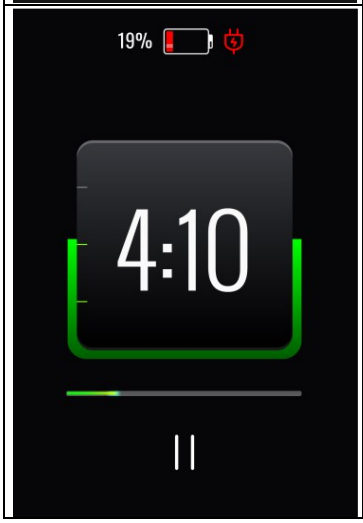
If the battery does not allow 8 consecutive hours of treatment, daily treatment can be performed using the external power supply.
When the display indicates that the battery is running low, the battery symbol turns red and a plug symbol appears next to it. Connect the power supply to the generator and to the mains socket, keeping the generator switched on: the device beeps and vibrates, indicating that the charger has been connected to the generator. The plug symbol disappears and a flash is displayed in its place, indicating that charging is in progress. The device continues to administer the treatment while charging the battery. At the end of the treatment, leave the generator switched off and connected to the power supply until the battery charge is complete.

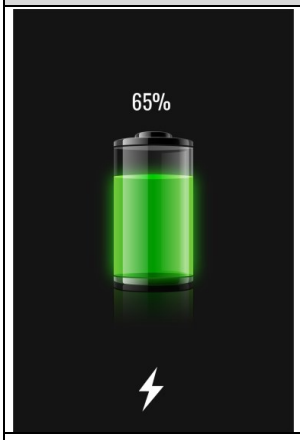
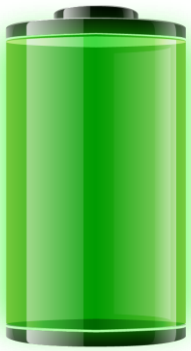
If the battery does not allow 8 consecutive hours of treatment to be delivered, try charging the battery again. If the problem persists, please contact IGEA support centre.

If the battery is no longer efficient, it can be replaced with a new battery. The battery cannot be replaced by the user but must be requested from the service centre, where the user must send the device for replacement.

5.6 Device status

Generator on during treatment		
Display	LED and alarms	Device status
	The LED at the top is ON with a flashing green light The display shows the timer with the treatment time decreasing every minute. Below the timer, the signal symbol can be seen to be moving and below it is the PAUSE symbol.	The device is switched on and is providing the treatment. The battery symbol in the top shows the percentage of charge remaining; it is green up to 20% and red when the capacity is less than 20%.

	The LED at the top is OFF The display shows the timer indicating the remaining treatment time. Below the timer there is no signal (flat line), and the 'PLAY' symbol is visible (restart treatment).	The device is on PAUSE. To resume treatment, press the PLAY symbol on the display.
	The LED at the top is OFF The completed treatment symbol appears on the display. The patient is asked to switch off the generator by pressing the OFF button.	Daily treatment was completed. The device remains on standby and emits no sounds or vibrations so as not to disturb the user if it is on during the night. With a quick press of the On/Off button, the display lights up and the patient is informed that the treatment has finished.
	The LED at the top flashes GREEN. The battery symbol turns red and a power plug symbol appears next to it.	The device is delivering treatment but needs to be charged. **Connect the external power supply and charge the battery.**

Generator switched off during battery charging		
	The generator beeps when connected to the external power supply. The display lights up and shows the image of the battery being charged. The charge percentage appears above the battery symbol.	The device is charging the battery. Charging takes about 4 hours when the battery is completely empty.
	Connected power supply. FULL battery symbol and 100% charge indication.	The battery is charged: **disconnect the power supply**.

5.7 Treatment times

The user must undergo the treatment for the number of days indicated by the prescribing doctor. **Treatment with the BIOSTIM is performed for about 6 to 8 hours a day**. The device is programmed for a daily treatment duration of 8 hours. If the user wishes to undergo less than 8 hours of treatment, simply switch off the generator by pressing the on/off button for about two seconds until a confirmation 'beep' is heard. However, treatment should be no less than 6 hours.

It is good practice to perform the daily treatment in a single session; however, it is possible to split the treatment time into several daily applications of **no less than 2 hours**. The absence of side effects means that the treatment to be carried out even whilst sleeping.

5.8 Useful Tips

- To make using the device easier, it is recommended to leave the coil connected to the generator to avoid having to keep connecting it for each new treatment session.
- It is recommended that the battery be charged every day after the treatment is completed so that the next treatment can be performed.
- The parts of the device that may come into contact with the skin do not normally cause any allergic reaction. Although the coil's covering material is hypoallergenic and biocompatible, it is recommended not to place the coil in direct contact with the skin, but to place it on light clothing, especially if there is any reddening or irritation in the area of application.
- Clean the coil regularly, taking care to disconnect the coil from the generator using neutral detergents.
- Any wear on the coil coating due to use does not affect the effectiveness of the treatment. In the event of a loss of some of the coating, the coil must be replaced.
- When using the coil under heavy blankets, the coil surface may become overheard. If this is the case, perform the treatment without covering the coil.

- The device should not be used in environments where the temperature is above 30°C in order to avoid overheating the coil surface; if this is not possible and the temperature of the coil causes some discomfort, the daily treatment time should be split up into several sessions of no less than two hours each.
- When charging or operating via the mains, it is normal for the battery to get hot; for this reason, the generator should not be placed in direct contact with the body when charging or operating via the mains.
- The elastic band can be washed just like any other garment.

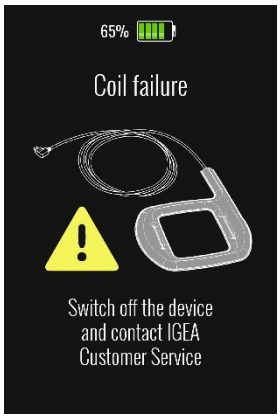
5.9 Cleaning the device

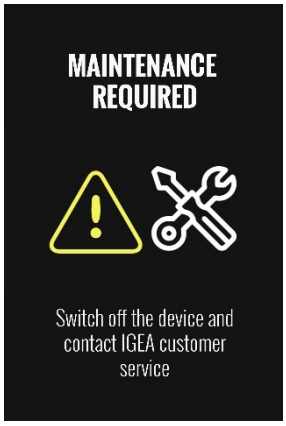
The device must be used in accordance with normal hygiene standards and must be cleaned regularly. The presence near to the device of hair or dust, as well as exposure to direct sunlight, while not causing it to malfunction, should be avoided.
Before cleaning the generator and the battery connected to it, make sure that the generator is **switched off and disconnected from the power supply**; use a cloth that has been slightly dampened with water or a neutral detergent; do not use solvents or harsh detergents.
Clean the coil regularly using neutral detergents, taking care to disconnect the coil from the generator**.**

6. PROBLEM SOLVING

6.1 Error messages

The device recognises and reports any malfunction statuses. Below are the reports it provides and the actions to be taken to restore its operation.

Display	LED alarms	Problem and solution
	The LED turns red. The generator vibrates. There is a rapid sequence of 3 beeps every 3 seconds. In the centre of the display, the image of the coil appears with the warning triangle and the suggestion of what to do to resolve the anomaly.	**'Coil Failure' warning** The coil is connected to the generator but it has no power. Switch off the generator, try removing and reinserting the coil, and switch it on again. If, when switching it back on, the device signals the anomaly again, switch the generator off again and contact IGEA Customer Service for a replacement coil.
	The LED turns YELLOW. The generator vibrates. There is a rapid sequence of 3 beeps every 3 seconds. In the centre of the display, the image of the coil appears with a question mark and the suggestion of what to do to resolve the anomaly.	**'Coil Absent' warning** The device was switched on without connecting the coil The user must **connect the coil to the generator** in order to resolve the anomaly and start/resume treatment. If the coil is not connected to the generator, the device switches off automatically after 30 seconds.

	The LED at the top flashes with an **alternating green and red light**. The device beeps 3 times every 5 seconds The image on the display informs the patient that the device **requires maintenance** and invites them to contact IGEA Customer Service After 1 minute of inactivity, the BIOSTIM shuts down.	The BIOSTIM device has a verification system to ensure it works properly. When this message is displayed, the system detects the need for a standard maintenance check. This check must be agreed upon with the IGEA Customer Service.

6.2 Anomaly when charging and/or switching on

The device will not switch on and will not charge.
External interference or the battery being completely flat (e.g. after prolonged non-use) can block the device, stopping it from working. To unlock it, proceed as follows:
1. Connect the external power supply to the generator and wait for up to 30 seconds; the battery should begin charging as described in section 3.1
2. If charging has not started after 30 seconds, leave the power supply connected to the generator, press and hold the ON/OFF button for at least 10 seconds. This causes the generator to reset. When the button is released, the battery should begin charging.

Leave the generator on charge until it is fully charged before using the device.
If, even after the device has been RESET the battery does not start to charge, please contact IGEA Customer Service.
In the event of a permanent failure, contact technical support to repair the device.

6.2.2 The device gets stuck during normal operation

External interference from other electrical and electronic devices in the area of use (modems, mobile phones, cordless devices, etc.) may interfere with the device and cause it to get stuck.
Should the device become stuck and does not respond to normal commands, perform a RESET as described in the previous paragraph.

⚠

Technical support for the device is the sole responsibility of the manufacturer IGEA S.p.A. In the event of a fault or in any case in which the device needs to be serviced, the user must contact the IGEA S.p.A. service centre.

Tel. 059 699 600 - Fax. 059 695 778 e-mail: info@igeamedical.com

7. SAFETY INSTRUCTIONS

7.1 Warnings and Recommendations

For the device to work safely and at its best, the following recommendations must be strictly followed:

- Read this manual before using the BIOSTIM device.
- The BIOSTIM must be used by people who are capable of independently understanding and implementing the instructions provided in this manual; otherwise, and if it is being used on children, the BIOSTIM may only be used under the supervision of people who are capable of understanding and implementing the instructions provided in this manual.
- When the generator is connected to the external power supply, position the device so that the power connector can be easily removed if necessary.
- Keep the device beyond reach of children and pets.
- Caution: connecting cables may cause a strangulation hazard if they are not used correctly.
- Do not use the device in the presence of flammable gases.
- Do not keep the device or its applied part near breathing systems or machines that use oxygen. In the event of any leaks, an oxygen-rich environment can lead to a fire on flammable materials caused by sparks that might develop when an electrical connection is made or removed.
- The BIOSTIM should not be used near to pacemakers or other implanted devices with a power supply (other than internal fixation devices), unless their compatibility has been established.
- Do not handle any parts of the device with wet hands, and more specifically, do not connect the external power supply to the mains to avoid any electric shocks.
- Do not immerse any of the constituent parts of the device in water or liquids of any kind and do not pour liquids on them; **in the event that the generator or the power supply unit accidentally comes into contact with liquids, do not use the** device and return it to the service centre or the manufacturer for inspection/repair. Submerging the device in liquid may compromise the safety of the battery and power supply.
- Do not connect any part of the device to other equipment or devices.
- Do not connect any parts to the BIOSTIM which are not intended for use and not supplied by the manufacturer.
- When using the coil under heavy blankets, the coil's surface may overheat. If the temperature of the coil is uncomfortable to bear, perform the treatment without covering it.
- During use, the display may exceed a temperature of 41°C, but this is in any case below the regulatory limit given the limited patient contact time.
- Clean the coil regularly to prevent dirt from accumulating and to avoid skin irritation or infection. For cleaning, use neutral detergents; do not use solvents or aggressive cleaning agents. Cleaning must be carried out when the coil is disconnected from the generator. The coil is for individual patient use only.
- The generator can be cleaned using a cloth that has been slightly dampened with water or a neutral detergent; do not use sprays or flammable liquids. The generator must be cleaned while the device is switched off.
- Avoid any mechanical shocks to the device during transportation or movement.
- In the event of a collision or fall that causes the device to break and/or open, the device and all its parts must be collected and placed in the transport container and not used for any purpose. If the device is connected to the mains socket, first remove the power supply unit from the mains socket. The user should then contact the manufacturer to return the device and to possibly repair it.
- Before each treatment session, check the integrity of the connection cable between the generator and the coil; if it is damaged, replace the coil with a new, undamaged one.

- Before using the external power supply, check that the casing and cable are undamaged; never use damaged power supply units. If necessary, replace the power supply unit with one supplied by the manufacturer or distributor.
- Do not expose the battery to heat sources and do not throw it into fire as there is a danger of explosion.
- The battery is a polluting waste that must be disposed of according to current disposal regulations.
- In the event of a collision or fall that causes the device to break and/or open, the device and all its parts must be collected and placed in the transport container and not used for any purpose. If the device is connected to the mains socket, first remove the power supply unit from the mains socket. The user should then contact the manufacturer to return the device and to possibly repair it.
- The device is equipped with self-monitoring mechanisms to ensure it is working correctly; any anomalies are signalled by the device and are described in the instruction manual. Any malfunctions therefore do not affect the effectiveness of treatment.
- If the device is left unused for long periods of time, the battery may go completely flat and must be fully charged before starting treatment again.
- ⚠ Caution: only use the power supply unit supplied to charge the battery. The use of other devices could cause damage to the generator, battery or user for which the manufacturer accepts no liability.
- Any serious accident occurring during the use of the medical device and related to it must be reported to the manufacturer by the user, who will notify the competent authority of the member state where the user and/or patient is established.
- The device can be used with implantable medical devices (e.g. joint prostheses of fixation devices) with the CE conformity certification. There are no restrictions on the use of this combination since clinical studies with similar devices indicate that stimulation relieves pain in subjects with mobilised and painful prostheses and no contraindications have emerged.

7.2 Maintenance

The device is assembled by the manufacturer and requires a specific mechanical tool to open it. This is so as to prevent tampering and/or unauthorised repair attempts by the user or third parties.
Any work on the device that requires the generator to be opened must be carried out by the manufacturer or authorised technical service; otherwise the safety of the device is no longer guaranteed.

- In order to ensure a reliable performance, the manufacturer recommends that the device undergoes a routine maintenance procedure and checks on the operating parameters at intervals no greater than 24 months. This maintenance should be requested from the IGEA Customer Service Department.
- The power supply battery contained in the device cannot be removed/replaced by the user. If necessary, the battery may only be replaced by the manufacturer or by the manufacturer's authorised service department.
- The manufacturer recommends repeating the safe tests on the device to check that safety standards are being continuously maintained, at intervals of no greater than 24 months. By agreement with the customer, IGEA can provide the recommended electrical safety inspection service.

7.3 Contraindications and side effects

There are no known contraindications to the use of the BIOSTIM; however, the following precautions must be observed:

- In the case of an established or presumed pregnancy, even though no negative effects related to the therapy have been described, as a precautionary measure, direct treatment of

the pelvic bones should be avoided. In any case, always inform the doctor who prescribed the therapy, who will assess on a case by case basis the need to continue/interrupt therapy.

- The pacemakers currently in use are not susceptible to the action of electromagnetic fields; however, pacemaker wearers are advised to check the characteristics of their device with their cardiologist and not to undergo therapies involving the application of the coil directly on the chest.
- Less than 2 per 1000 of patients report burning and/or redness during treatment. In this case, it is recommended that daily treatment be reduced to 3 hour-long sessions; the treatment should then be gradually increased until the standard regimen is reached. The burning sensation disappears when the treatment is interrupted.
- Although the use of the device does not normally present any contraindications when taken with medication, please advise the prescribing doctor if you are taking anything.
- There are no restrictions on the use of the device with simultaneous implantable medical devices (e.g. joint prostheses or fixation devices), but these must be CE-marked and are not supplied by the manufacturer. Clinical studies with similar devices indicate that stimulation relieves pain in subjects with mobilised and painful prostheses and no contraindications have emerged.

7.4 Electromagnetic Compatibility

The BIOSTIM has been tested and certified as compliant with medical device electromagnetic compatibility standards and declared suitable for use at home.

The BIOSTIM can be used in conjunction with other electrical or electronic devices if they too conform to current standards without causing interference or receiving interference. However, the following general requirements must be observed:

- The BIOSTIM must not be used adjacent to or on top of other devices. If the BIOSTIM must be used in this way, the medical device must be observed to check it works correctly in the configuration in which it is used;
- The BIOSTIM must be positioned and used in accordance with the EMC information provided later in this manual.
- The BIOSTIM must not be used at the same time as other treatments or applications of electromedical device that involve the release of energy to the patient's body, particularly if they use high-frequency signals, as these signals could interfere with the operation of the BIOSTIM and cause undesirable alterations in the treatment signal.
- The use of accessories, electrodes and cables other than those specified and supplied directly by the BIOSTIM device manufacturer may result in increased emissions or lower immunity for the BIOSTIM and cause it not to work properly.
- The BIOSTIM may be sensitive to electrostatic discharges; the user must take every precaution to avoid discharges to the device which could cause it to freeze or malfunction.
- Portable and mobile RF communication devices, including peripherals such as antenna cables and external antennas, should be kept more than 30 cm away from all BIOSTIM components including cables. Failure to do so could lead to a deterioration in the performance of the medical device.
- Every possible source of proximity magnetic fields, such as wireless chargers, induction hobs, mobile phones, RFDI readers, must be kept at a distance greater than 15 cm from all BIOSTIM components, including the cables and sources of proximity magnetic fields, such as wireless chargers, induction hobs, mobile phones, RFDI readers, must be kept at a distance greater than 15 cm from all BIOSTIM components, including cables.

⚠ **Device blocking**: Electromagnetic interference, in particular electrostatic discharges of a power greater than 8kV, could alter the normal operation of the BIOSTIM and cause the device to become stuck.

If this happens and it is signalled by the BIOSTIM as a fault or interruption in treatment delivery, the device must be switched off and switched on again after a few seconds, using the power button.

If the device does not switch off or does not react when the on/off button is pressed, reset the device to restore normal operation following the instructions in paragraph 6.2.

7.5 Biological safety

The safety of treatment with the BIOSTIM has been extensively verified; all tests showed the absence of adverse treatment effects.

8. MANUFACTURER'S LIABILITY

IGEA S.p.A. is only responsible for the safety, reliability and performance of the BIOSTIM if:

- The device is used in accordance with the operating instructions described in this manual.
- The device is not opened or tampered with in any way by the user or other unauthorised persons.
- The device is operated using only the power supply unit supplied by IGEA.
- The external power supply is used exclusively for the BIOSTIM device as described in this manual.
- Regular inspections, modifications and/or repairs are carried out exclusively by personnel authorised by IGEA.
- The device is subjected to a function parameter check and safe-test at least every 24 months.

Please contact the manufacturer for further information or updates.

Manufacturer:
IGEA S.p.A. Via Parmenide 10/A, 41012 Carpi (MO) ITALY
Tel. 059 699600 Fax. +39 059 695778
e-mail: info@igeamedical.com

9. DEVICE RETURNS

If the device is to be returned to IGEA, the user is requested to use the original packaging complete with all its parts. The adjacent image shows the correct positioning of the various components to ensure that they are adequately protected.

① Place the external power supply in the right-hand rectangular hole with the plug pointing to the left, passing the cable through the space below the hole.
② Insert the elastic band supporting the coil into the housing next to the external power supply.
③ Then insert the BIOSTIM BB02 generator into the hole on the left, pressing slightly to fit it into the housing.
④ Insert the coil into the dedicated central space.

10. TECHNICAL DATA

The BIOSTIM complies with EU Medical Device Regulation 2017/745 and is marked CE 0051 under the control of IMQ.
The BIOSTIM has an expected lifetime of 5 years after being placed on the market.
The applied parts (coils) have an expected lifetime of 12 months after being placed on the market.
The BIOSTIM BB02 generator

Supply voltage	11.4VDC
Maximum current consumption	0.300 A
Maximum input power	4 W
Classification according to EN 60601-1	Class II I BF device

Classification according to MDR 2017/745 EU Class IIa device
Rechargeable battery - Type: Lithium-ion polymer battery 11.4VDC / 2800mAh
Do not expose the battery to heat sources and do not throw it into fire as there is a danger of explosion!
Do not immerse the battery pack in liquids or pour liquids onto it.
The battery is considered a polluting waste that must be disposed of according to current disposal regulations.

External power supply

Model	**ME30A1541B01**	
Brand	SL Power	
Input voltage	230VAC (100-240)	
Network frequency	50-60 Hz	
Max. current input	0.50 A	
Output voltage	15VDC	
Max. output current	2.0A	
Short-circuit protection	Continued	
Insulation class	II	
The power supply model supplied by the manufacturer is approved according to EN60601-1 and EN60601-1-2. Only use the power supply unit supplied by the manufacturer and no others.		

Coil drive signal characteristics and magnetic field strength:
Signal type: triangular signal
Frequency: 75 Hz ± 5%
Pulse width:1.33 ± 0.1 ms
Magnetic field strength produced 10 - 30 Gauss (peak value)
Method of use: Device with internal rechargeable electrical source with specified power supply unit. Device for continuous operation not to be used in the presence of flammable anaesthetic mixtures with air, oxygen or nitrous oxide.
Device with IP22 protection class. The IP22 class offers protection against the entrance of solids with a diameter > 12mm and protection against the entrance of water or rain drops falling at an angle ≤ 15° from the vertical of the device.
Conditions of use of the device:
Room temperature: 5 - 34 °C
Relative humidity: 15% - 90% (free from condensation)
Atmospheric pressure: 700-1060hPa
Transportation and storage conditions:
Room temperature: -25 - +70 °C
Relative humidity: 0% at -25°C to 90% (non-condensing) at 70°C
Atmospheric pressure: 500 - 1060hPa

Storage conditions between one use and the next:
Between one session and the next, the device must be stored in its packaging or in another clean and dry place under the same environmental conditions as when it was intended for use.

Restoration of environmental conditions of use

If the device comes from a place with a different temperature (e.g. due to transportation or storage), wait about 10 minutes for it to adjust to the room temperature before using it.

⚠ Warning! The device must not be used in places where there is a danger of explosion.

End-of-life disposal
The BIOSTIM device and each of its parts cannot be disposed of as municipal waste but are subject to a separate collection according to the procedures established by the local authorities.

10.1 Table of Emission Levels and Electromagnetic Immunity

The BIOSTIM BB02, taking into account the risk analysis associated with electromagnetic interference, meets all test levels and complies with the requirements of EN 60601-1-2.

MANUFACTURER'S GUIDANCE AND DECLARATION - ELECTROMAGNETIC EMISSIONS		
The BIOSTIM BB02 is usable in the specified electromagnetic environment. The user must ensure that it is used in an electromagnetic environment with the characteristics described below.		
Emission Test	**Compliance**	**Electromagnetic Environment**
RF emissions - CISPR 11	Group 1	The BIOSTIM BB02 generates radio frequency signals solely as a consequence of the internal electronic circuits. Its radio emissions are very low and are unlikely to cause radio interference with nearby device.
RF emissions - CISPR 11	Class B	The BIOSTIM BB02 is suitable for use in any environment, including households and those directly connected to a low-voltage public mains supply that supplies buildings used for domestic purposes.
Harmonic Emissions *EN 61000-3-2*	Class A	
Voltage fluctuation / flicker emissions *EN 61000-3-3*	Compliant	

Manufacturer's guidance and declaration - electromagnetic immunity			
Proof of Immunity	**Test Level EN 60601-1-2**	**Compliance Level**	**Electromagnetic Environment**
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	Test Level IEC 60601-1-2	Any environment Including at home
Irradiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	Test Level IEC 60601-1-2	Any environment including at home with portable and mobile RF device kept as far away from the BIOSTIM BB02 model as possible, including connecting cables. Minimum distance 30 cm
Fast electrical transients/bursts IEC 61000-4-4	± 2 kV per supply line ± 1 kV per input/output line	Test Level IEC 60601-1-2	Any environment Including at home
Surges IEC 61000-4-5	± 1 kV between phases ± 2 kV between phase and earth	Test Level IEC 60601-1-2	Any environment Including at home
Conducted RF IEC 61000-4-6	3 V eff. 150 kHz to 80 MHz 6 V - ISM frequencies and amateur Radio band	Test Level IEC 60601-1-2	Any environment including at home with portable and mobile RF device kept as far away from the BIOSTIM BB02 model as possible, including connecting cables. Minimum distance 30 cm
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	10 ms - 0% at 0°, 45°, 90°, 135°, 180°. 225°, 270°, 315° 20 ms - 0% at 0° 500 ms - 70% at 0° 5 s - 0%	Test Level IEC 60601-1-2	Any environment Including at home
Magnetic field at mains frequency (50/60 Hz) IEC 61000-4-8	30 A/m	Test Level IEC 60601-1-2	Any environment Including at home

10.2 Immunity to proximity magnetic fields

To avoid any interference between BIOSTIM and any possible source of proximity magnetic fields in the environment of use, such as wireless chargers, induction cooking plates, mobile phones, RFDI readers, the Manufacturer requires the use of the device and all of its parts at a distance of at least 15 cm from such sources of interference.

Test specifications for device immunity to proximity magnetic fields		
Test frequency	**Modulation**	**Immunity test level (A/m)**
30 kHz (a)	CW	8
134,2 kHz	Pulse modulation (b) 2,1 kHz	65 (c)
13,56 MHz	Pulse modulation (b) 50 kHz	7,5 (c)
(a) This test is applicable only to medical equipment and systems intended for use in Home Healthcare Environments. (b) The carrier shall be modulated using a 50% duty cycle square wave signal. (c) r.m.s. before modulation is applied		

10.3 Immunity to proximity fields from RF wireless communication device

Portable or mobile RF communication devices that may be present in the home such as wireless telephones, mobile phones, devices for wireless connection to the internet and similar, must be kept away from the BIOSTIM BB02 to avoid the risk of interference. The recommended minimum separation distance depends on the output power of the RF device and the transmission frequency. The user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication systems and the BIOSTIM BB02 using the table below as a reference.

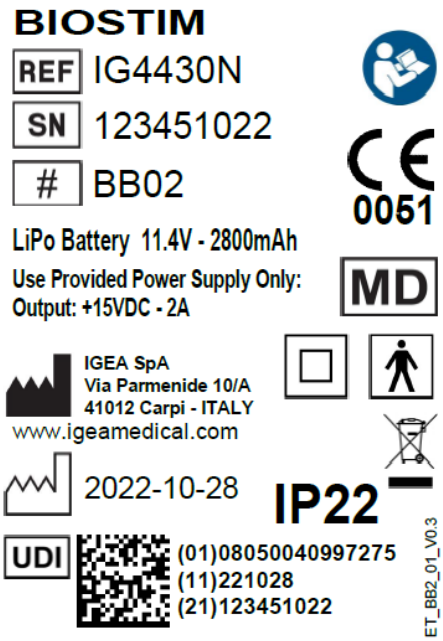
Test Frequency (MHz)	**Band** (MHz)	**Type of Service**	**Modulation**	**Maximum Power** (W)	**Distance** (m)	**Test immunity level** (V/m)
385	+39 380 - 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704 - 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
810 870 930	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
+39 1 720 +39 1 845 +39 1 970	+39 1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
+39 2 450	+39 2400 - 2570	Verdeetooth, W LAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
+39 5 240 +39 5 500 +39 5 785	+39 5100 - 5800	W LAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9

The immunity levels given in the table are met as long as the device is kept at a distance of at least 30 cm from any possible source of RF interference.

The BIOSTIM BB02 complies with all test levels with a distance >= 30 cm.

10.4 Dataplate

Below is an example of a generator dataplate located on the rear of the body containing all the information necessary for the correct identification and use of the device.



Example of generator dataplate

Shown below is the label identifying the coil, an applied part located on the cable near the connector. The identification code of each coil, which will appear in place of "XXXXX", is given in the table in paragraph 3.2

Coil Label

NOTE: Additional labels may be attached to the device, the applied part or the packaging, in addition to the one above. Any plate or symbol not described in this manual is for the exclusive

use of the manufacturer to facilitate internal product handling, but is not intended to provide information to the user.

11. SYMBOLS

	**Class II device:** protection against direct contact consists not only of basic insulation, but also of additional safety measures for double insulation.
	**The device has a BF-type applied part:** the device has a specific degree of protection against electrical hazards, with particular regard to permissible leakage currents, and an F-type applied part (floating) isolated from all other parts of the device (Coil).
	**Direct current:** the symbol shown on the dataplate of the external power supply indicating the type of power supplied to the generator.
	Alternating current: the symbol indicating the type of power supply required from the external power supply.
	**Warning - consult accompanying documentation:** this symbol informs the user that they need to check the documentation supplied with the device, including the user manual, for a correct understanding and/or use of the part marked with the symbol.
	**Follow operating instructions:** this symbol tells the user that the operating instructions must be read before starting to use the device.
	**Name and address of the manufacturer:** Manufacturer's identification details; next to the symbol are the name and address of the manufacturer
	**Date of manufacture:** the year of manufacture is shown next to the symbol
IP22	**IP rating**: this symbol informs the user that the device offers a certain degree of protection against the penetration of dust and liquids.
Mod.	**Model**: this symbol indicates the device model
SN	**Serial number**: this symbol shows the serial number
MD	**Medical Device**: the symbol identifying the device as medical grade
REF	**Catalogue number**: the symbol associated with the product catalogue number assigned by the manufacturer
UDI 	**UDI code**: a two-dimensional code used to enter all the required information in accordance with the UDI (Unique Device Identification) coding system
#	**Model code identifier of a single medical device**
	**Separate collection and recycling of batteries**: the batteries are subject to a separate collection for recycling.
	**Separate collection**: IGEA devices and their applied parts cannot be disposed of as municipal waste but are subject to a separate collection in accordance with the procedures established by the local authorities.
CE 0051	**CE Marking symbol**: the device complies with Medical Device Regulation MDR 2017/745 of the European Union. The number following the CE mark is the identifier of the Notified Body that performs the conformity check with the MDR to enable the mark to be affixed to the product.
	**Atmospheric pressure limits for transportation and storage**: the symbol on the outer packaging of the device.
	**Relative humidity limits for transportation and storage**: the symbol on the outer packaging of the device.
	**Relative temperature limits for transport and storage**: symbol on the outer packaging of the device.
	**Handle with care**: the symbol on the outer packaging of the device.
	**Transportation packaging must be kept out of the rain and in dry conditions**