⚠ Read this User Manual before using the device

CONTENTS

MI-BIOSTIM-UK Revision 1.5 – October 2018
SW. 4.0.x

1. INTRODUCTION

1.1 What BIOSTIM is and how it works

BIOSTIM system is a Bone Growth Stimulation (BGS), which uses Pulsed Electromagnetic Fields.
BIOSTIM is a therapeutic aid and must be used with a medical prescription.
The system basically consists of an electromagnetic field generator pulsated at low frequency and consists of an impulse signal at a frequency of 75 Hz, with a 10% duty cycle, that is, an activation time of approx. 1.33 milliseconds.
This electromagnetic field has the capacity of inducing an average electrical field of 0.04mV/cm into the bone tissue, which consists in the active component of the signal, able to boost osteoblasts activity.
The electrical field is concentrated at the point to be treated by means of coils of suitable shape.
The coil applied to the area requiring therapy, forms a homogeneous magnetic field and does not therefore have to be placed at the very center of the area in need of treatment; the patient is able to apply the coil himself without the aid of a doctor or nurse.
The generator is controlled by a microprocessor that constantly monitors the correct operation of the patient reporting any anomalies or malfunctions which may occur during therapy and for this purpose it is equipped with visual and acoustic simple and effective.

1.2 Who can use BIOSTIM

BIOSTIM must be used by people who understand and put into effect independently the instructions provided in this manual: otherwise, and if used on children, BIOSTIM can be used only under the supervision of people able to understand and put into effect the instructions provided in this manual.

1.3 Therapeutic treatments can be performed with BIOSTIM

BIOSTIM is used mainly in orthopaedics and traumatology fields for the treatment of:

- Non-union
- Recent fracture
- Osteotomy
- Necrosis
- Painful prosthesis
- Complex fracture and risk fracture
- Osteoporosis fracture
- Revision prosthesis
- Skin wound healing
- Bone grafts

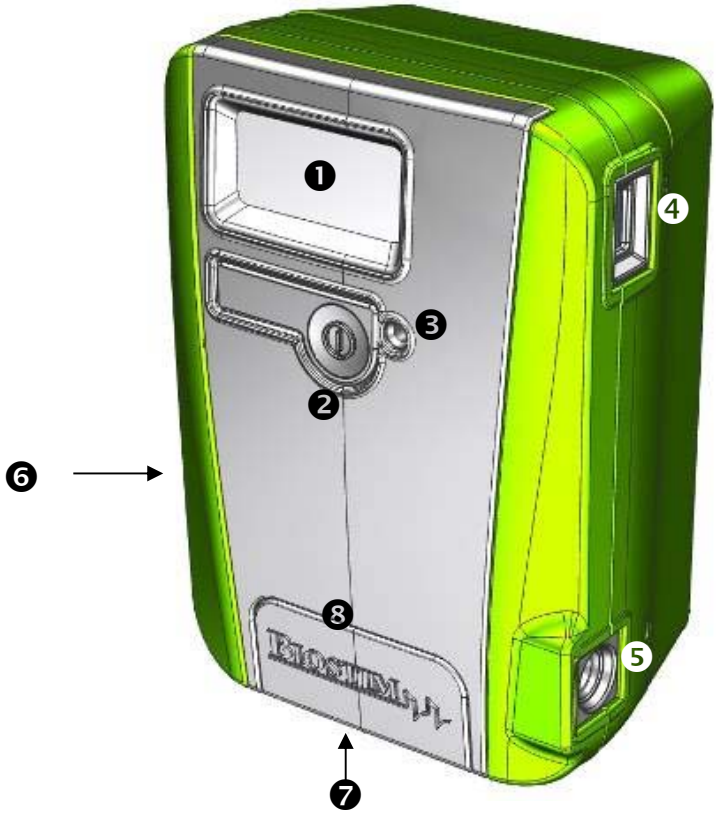
2. BIOSTIM SYSTEM COMPONENTS

BIOSTIM system features three main components:
- the signal generator ❶ already connected with a rechargeable battery;
- the coil ❷, applied part of the device ;
- the power supply ❸, whose specifications are given in Chapter 8.

The system also comprises an elastic strap ❹ used to hold the coil in the correct position during therapy.

2.1 Generator

The generator is equipped with:



- A display ❶ on which messages are shown that indicate the system status.
- An on/off button ❷ marked "⏻".
- A led light ❸ that changes color or flashes depending upon system status and in combination with the displayed messages.
- A socket for connecting the coil to the generator ❹, marked ⊖→.
- A socket for connecting the generator to power supply ❺, marked ⎓.
- A reset button ❻ that resets the system when pressed. Use a sharp pointed implement to press the button. The system shuts down after the reset button is pressed; press on/off button to re-start.
- A hole, in the bottom of the device ❼ that houses the screw for connecting the battery.
- A cover ❽ marked with the name "BIOSTIM" that have to only be opened by IGEA's operators, during maintenance operations.
- A clip, at rear, for attaching the device to a belt or other position convenient for the user.

3. SYSTEM PREPARATION

3.1 Battery recharging

The battery must be charged upon receipt of the system before the therapy, using the external power supply.

Insert the connector of the power supply [❶] in the relevant socket on the right-hand side of the generator. Connect the plug of the power supply to a mains socket.

The generator starts charging the battery within 30 seconds:

- the generator beeps twice; the display switches on and displays a moving sequence of symbols indicating that the battery is charging properly:  . The moving sequence continues to be displayed until the battery is fully charged.
- an empty battery takes around 5 hours to recharge.
- the heating of the battery case during the charging is a normal condition.
- after recharging has finished, the screen indicates that the battery is fully charged  : disconnect the Power supply from the generator and mains socket.

NOTE: if the battery is charged in an environment with a temperature over 40°C, it may not charge fully and thus not guarantee the 8 hours of autonomy for the next treatment.

To prevent this inconvenience, **BIOSTIM must be charged in environments with a temperature of less than 40°C.**

To recharge the battery, ever use only the power supply provided. The use of different devices could cause damage to the system or the user for which the manufacturer declines all responsibility.

IMPORTANT NOTE

- It is not possible to recharge the battery during the therapy.
- If the device is not used for long periods, the battery may have discharged and have not enough residual energy to complete the treatment. It is therefore advisable to recharge the battery before starting it.
- Under special conditions, such as after long periods of storage or long periods without being uses, the battery may be completely flat and the device may not be able to turn on; in these cases:
  1. Connect the external power supply to the generator and wait for up to 30 seconds; the battery charge should start as described in paragraph 3.1
  2. If after 30 seconds the battery charging does not start, leave the power supply connected to the generator and press the RESET button on the left side of the generator for 2 seconds (ref.❻ paragraph 2.1): the battery charging should start. Charge the generator completely before using the device.
  3. If after pressing the RESET button for 2 seconds, the battery charge does not start, contact the IGEA Technical Assistance.

3.2 Coil connection to generator

Insert the coil connector into the socket, on the right side of the generator, pressing on it until you hear a "click".

4. EXECUTION OF THERAPY

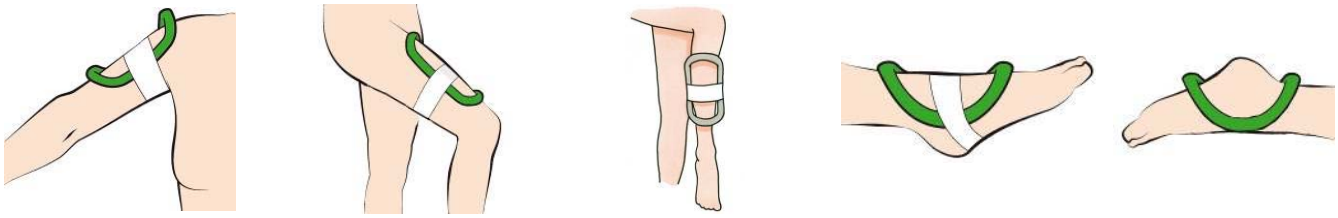
4.1 Application of coil on area for treatment

Place the coil ensuring that the part requiring treatment is at the center of the coil; **it is recommended to always place the coil over light clothes.**

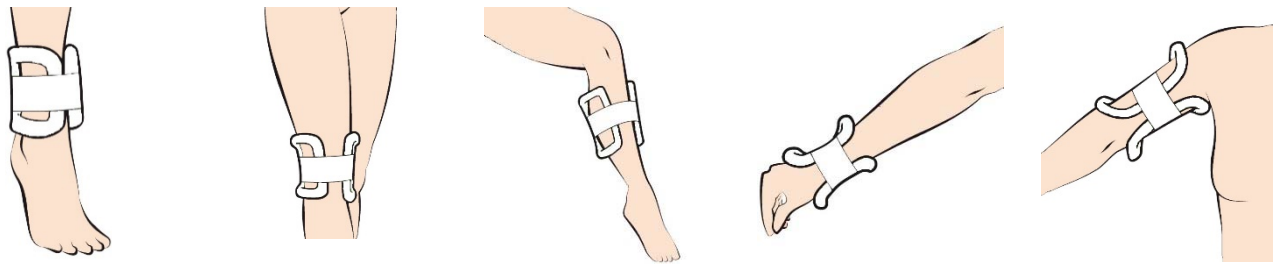
The double coils should be positioned in opposite, if possible laterally, making sure that the treatment area is located between the two solenoids. In the double coils the correct placement is facilitated by the double color of the coils**. It is very important to keep the color matching of the faces of the coils**, if possible by placing the two green faces inwards.

Fasten the coil with the provided strap or other suitable item, without squeezing or force the contact between the coil and the site of treatment. Use the flaps on the coil to facilitate the fixing of the elastic strap.

Below are some examples of positioning.



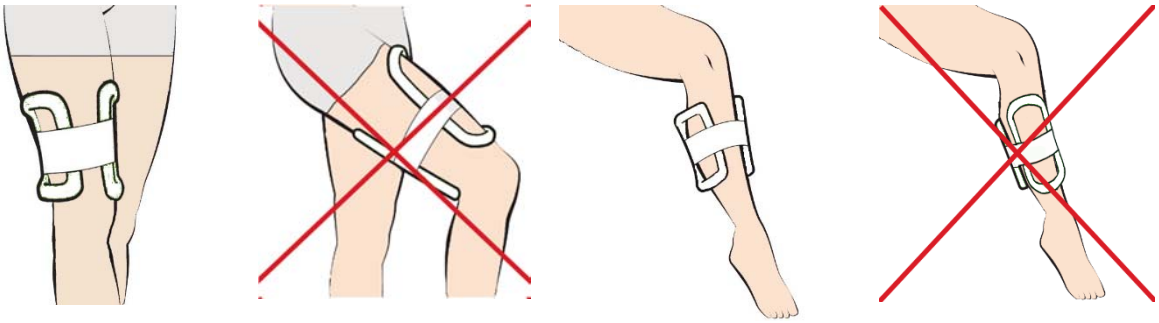
Single coil – examples of positioning



Double coil – examples of positioning

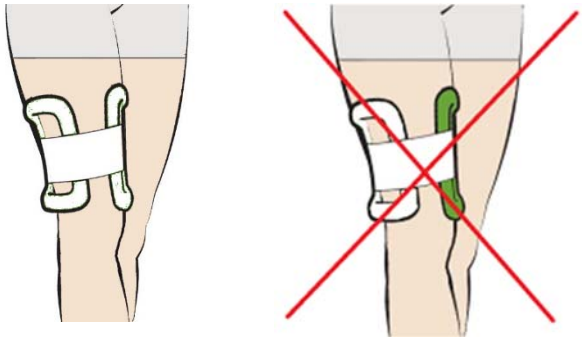
4.2 Recommendations for the correct use of the coil

- The coil does not have to be applied directly on the skin. For hygiene purposes, **it is recommended to always place the coil over light clothes**, which cannot affect treatment in any way. In particular if the coil is to be applied on injured skin, wear a light item of clothing that covers the area; if this is not possible, disinfect the coil with disinfectant before applying it to the injured skin.
- For effective treatment is sufficient to fix the coil on the treatment site using the provided strap; **do not force the contact with the coil.**
- Double coils should be placed in opposed way, laterally if possible, so that the treatment area is between the two coils.



YES NO YES NO

- To ensure the effectiveness of the treatment, **double coils must be positioned maintaining the color matching of the faces of the coils**, if possible by placing the two green faces inwards.



YES NO

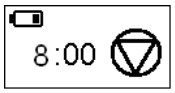
- Do not use the coil if the cable connecting it to the generator shows obvious sign of wear or damage.
- The use of the coil under heavy blankets limits heat dispersion and can lead to overheating of the coil surface; in case of excessive overheating, discover the coil. In any case, the generator and the power supply must not be covered during the operation, to allow its aeration.
- Before cleaning the coil make sure to switched off the generator and disconnect the coil from the generator. The coil can be cleaned using neutral detergents, never use aggressive detergents or solvents for cleaning it. Regularly disinfect the coil, particularly in the case of prolonged use or direct contact with the skin.

4.3 Switching on the generator

After charging the battery and connecting the coil, switch on the generator by pressing the “on/off” button for **at least 2 seconds** until you hear a beep, confirming the generator has switched on. **Then release the button**.

Once the generator is on, the led switches on, displaying a steady green light. The display shows the message “IGEA”, and the message “BIOSTIM”; the generator performs a test to detect presence of the coil and automatically sets the correct parameters as a function of the coil applied. After a few seconds therapy can begin:

The green light **starts flashing** and the display shows this message whereby 00:00 is the timer displaying the hours and minutes of executed therapy; the timer updates after each minute of therapy. This message is displayed until daily therapy is over (8 hours).



After the daily therapy session is over, the system beeps three times and stops therapy, the **green** light becomes **steady** and the display shows this message whereby the “stop” symbol indicates that the system has stopped providing therapy and the **flashing** timer stops at the time specified for the duration of therapy (8 hours).

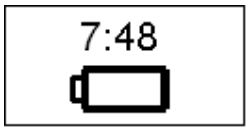
The system remains in this position (standby) without switching off. The user can switch off the device by pressing the “on/off” button for at least a second until it beeps once. If the user does not switch off the system, the device switches itself off when the battery finally runs flat.

- After the daily session, remove the coil from the area of application. In the interest of convenience, the coil can always remain connected to the generator.
- The timer always resets to zero upon start-up.
- If the user has to interrupt treatment before completion of the daily therapy session simply press the “on/off” button for at least a second, until you hear a beep. To re-start therapy, simply press the button; the generator re-starts with the timer back at zero.
- When the battery is fully charged provides up to 8 continuous hours of treatment, which is why **it is recommended to recharge the system at the end of the daily treatment** according to par. 4.4, so that it is able to perform the entire subsequent therapy.
- If the user connects the power supply during therapy, the system stops the therapy and starts to charge the battery.
- If the power supply is connected to the generator, it is not possible to start the therapy. The treatment stops immediately if it is plugged while the device is on.

4.4 Battery monitoring and recharging

The system can monitor battery status during treatment. The battery symbol, displayed in the top left corner of the screen, features three bars each of which symbolizes 1/3 of **total battery power**; the bars disappear one at a time as the battery power is consumed during treatment.

After the third bar has disappeared (indicating low battery), this message appears, reminding the user to recharge the battery:



- the screen displays the timer and empty battery symbol.
- the device beeps twice every minute.
- the **flashing green led** indicates that the system is still providing therapy.

If the battery is not recharged, therapy continues until the battery is fully empty. In which case:

- The **empty battery symbol** flashes on the screen and the timer stops because the system is no longer providing therapy.
- The **led switches off** and the device beeps every second. If the battery is not recharged within 30 seconds, the system switches off automatically.

To charge the battery: switch off the generator, connect the power supply to the relevant socket of the generator, then to a mains socket. The generator starts charging the battery within 30 seconds:

- the generator switches on and beeps twice, the display switches on and displays a moving sequence of symbols until the battery is fully charged (an empty battery takes around 5 hours to be recharged).
- after recharging has finished, the screen indicates that the battery is fully charged : disconnect the power supply from the generator and mains socket.

If, while charging the battery, the generator is switched on by pressing the power button, the system doesn't start to deliver therapy because the user can't perform the therapy while charging of the battery.

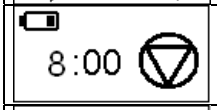
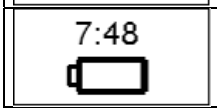
As it is normal for the battery to heat up during charging, it is recommended not to put the generator in direct contact with the skin while charging the battery.

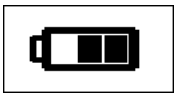
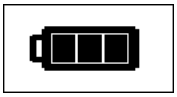
4.5 Efficiency of the battery

The efficiency of the battery is based on its correct use on the normal wear and tear of same. In case the battery is not able to feed the generator for the daily 8 hour therapy, try again to charge the battery. If the problem persists, contact IGEA Assistance Service.

If the battery is not effective, you can replace it with a new battery to be asked at the assistance service: the battery should be replaced according to paragraph 5.2 and fully recharged before the therapy.

4.6 Device status indications

Generator switched on during therapy		
Screen	**Led and acoustic signals**	**Device status**
	**Flashing** green light	Therapy in progress
	**Steady** green light	Daily therapy has ended (you can switch off the device)
	**Flashing** green light One beep a minute	Therapy is in progress but the battery must be recharged as soon as possible.

Generator switched off during battery recharging		
Screen	**Led and acoustic signals**	**Device status**
	led switched off	The battery is charging. In this operative mode it is not possible to start the therapy.
	led switched off	The battery has fully recharged (the Power supply have to be disconnected to start the therapy).

4.7 Therapy times

The user must perform therapy for number of days specified by the doctor who prescribed the therapy.

Therapy with BIOSTIM SPT is performed for about 6 - 8 hours a day.

Daily therapy should preferably all be in one session; if you prefer to split daily therapy time into several parts, continuous periods should be of **no less than 2 hours.** As there are no adverse side effects, therapy can also be carried out during sleeping hours.

4.8 Advice

- Leave the battery and coil connected to the generator for ease of use; this cannot harm the system and saves having to constantly reconnect the components.
- It is advisable to recharge the battery **after each daily therapy** session in order to perform the entire subsequent therapy;
- Use the backup battery (optional) only when necessary: the battery must be charged before use.
- The parts of the device that may come into contact with the skin usually do not cause any allergic reaction. Although the coating material of the coil is non-allergenic and biocompatible it is advisable not to place the coil in direct contact with the skin, but to place it over light clothes, which cannot affect treatment in any way, in particular if a slight rash or irritation arises in the area of application.
- Clean the coil regularly, with neutral detergent; make sure to disconnect the coil from the generator before cleaning.
- The wear of the coating of the coil, due to the use, does not affect the effectiveness of the therapy. In case of loss of integrity of the coating, the coil must be replaced.
- Use of the coil under heavy bed covers could cause it to overheat: it is therefore advisable to execute therapy during the day, without covering the coil with blankets. In any case, do not cover the generator to allow aeration during operation.
- It is recommended not to use the system in environments where the temperature is above 30 °C, to avoid overheating of the surface of the coil. If this is not possible, and the coil temperature does cause discomfort, it is advisable to split the daily time of therapy in multiple sessions lasting no less than two hours each.
- As it is normal for the battery to heat up during charging, we recommend you do not put the generator directly on the body while charging the battery.
- The elastic strap is machine washable.

4.9 Device cleaning

The device must be used in compliance with the normal rules of hygiene, and should be cleaned regularly. The presence in the environment of use of hair, hair, dust and exposure to direct sunlight, even if it does not cause malfunction of the device, should be avoided.

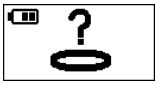
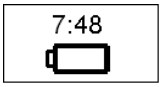
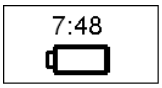
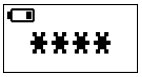
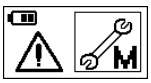
Switch off the generator **and disconnect the power supply** before cleaning: clean the generator with a slightly damp cloth using water or a neutral detergent. do not use aggressive solvents or detergents.

Clean regularly the coil with neutral detergents: make sure to disconnect the coil from the generator before cleaning.

5. TROUBLE SHOOTING

5.1 Error messages

The system can detect and signal any conditions preventing correct operation. The table describes the system messages and actions to restore correct operation.

Message	Led & acoustic signals	Problem and solution
	**Flashing red** light + a beep each second	**Problem with the coil** - Check if coil's connector is properly connected to the generator (par. 3.2). If the coil is not connected within 30 seconds, the device switches off. - If the coil is properly connected and the signals persist, the coil is damaged and must be replaced. Use only coils provided by IGEA.
	**Flashing green** light + a beep each minute	**Low battery** The system is operating correctly but the battery must be recharged as soon as possible (par. 4.4).
	**No light** Flashing battery symbol and an intermittent beep every 30 sec	**Flat battery** The battery is flat; therapy can no longer be dispensed. Recharge the battery, following par. 4.4.
	**Intermitted green and red** light + intermittent beeps for 30 sec	**Maintenance required** The system needs to be sent to the manufacturer for maintenance.
	**Flashing red** light + intermitted beeps for 30 sec	There is a problem with the memory; switch off and re-start the system, and normal operation will resume.
Problem		**Solution**
Battery fully charged does not allow to make a 8 hour treatment		Try again to fully charge the battery. - If the battery is charged in an environment with a temperature over 40°C, it may not charge fully and thus not guarantee the 8 hours of autonomy: charge the battery in environments with a temperature of less than 40°C. - The battery must be replaced with a new one.
Problem & Solution		
If the device is **left for long period unused**, the battery may discharge completely. It is then necessary recharge the battery before the treatment.		

Problem & Solution

Under special conditions, such as after long periods of storage or long periods without being uses, the battery may be completely flat and the device may not be able to turn on; in these cases:

- Connect the external power supply to the generator and wait for up to 30 seconds; the battery charge should start as described in paragraph 3.1
- If after 30 seconds the battery charging does not start, leave the power supply connected to the generator and press the RESET button on the left side of the generator for 2 seconds (ref.❻ paragraph 2.1): the battery charging should start. Charge the generator completely before using the device.

If after pressing the RESET button for 2 seconds, the battery charge does not start, contact the IGEA Technical Assistance.

Electrostatic discharge.

The device is sensitive to electrostatic discharge; discharges with> 8kV potential could cause a device lock (the device is not be able to turn on) or permanent failure. In the event of a lock, press the reset button on the left side of the generator, using a pointed object, to restore normal operation. If the lock does not resolve it may be necessary to disconnect and reconnect the battery. In the event of a permanent fault, contact IGEA Technical Assistance for the replacement of the device.

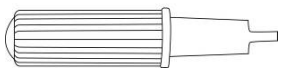
⚠ **The device technical assistance is exclusive pertinency of Manufacturer IGEA S.p.A.** In case of failure, or in any case where repairs is necessary, the user should contact a service centre authorized by IGEA S.p.A.

IGEA S.p.A. - Via Parmenide 10/A - 41012 Carpi (MO) - ITALY
Tel. +39 059 699 600 Fax. + 39 059 695 778 e-mail: info@igeamedical.com

5.2 Battery replacement

Only if necessary, replace the battery following the instructions below. The replacement battery is not included with the device.

Use the supplied screwdriver to unscrew the screw located on the underside of the generator.



- Move away the 2 parts of the system and disconnect the connector

To connect the new battery,

- Place the battery near the generator (side connector) and connect the connector. Be sure to insert the cable, in excess, in its slot.
- Bring the two parts closer until they are in complete contact and fix the contact using on of the screw and the screwdriver supplied
- **Screw without forcing**; this way the battery and generator become a single body. Once connection has been made, it is advisable to keep the generator connected to the battery even when the therapy is finished and the system off.

6. SAFETY INSTRUCTIONS

6.1 Warnings and Recommendations

Closely follow these instructions to ensure optimal and safe operation of the device:

- Make sure you read the instruction manual before using the device
- BIOSTIM must be used by people who understand and put into effect independently the instructions provided in this manual: otherwise, and if used on children, BIOSTIM can be used only under the supervision of people able to understand and put into effect the instructions provided in this manual.
- Keep the device away from children and pets, if any.
- Attention, connecting cables could cause strangulation hazard if incorrectly used; do not allow the cables to pass around the neck and pay attention to the placement of cables if you use the device during sleep. The adult supervision is recommended if the device is used by children.
- Do not use the device in the presence of inflammable gases.
- Do not keep the device or its applied part close to breathing system or devices that use oxygen because in case of leaks, an environment rich of oxygen might create in such cases flammable materials may become more likely to be ignited by sparks that could develop when an electrical connection is made or removed.
- BIOSTIM should not be used near-Pace Maker or other implanted devices (other than internal fixation mean) unless it has been tested for compatibility.
- Do not handle any of the system components with wet hands, especially when connecting the power supply to the mains.
- Do not dip or splash any of the system's components with water or any other type of liquid. **In the event of the accidental immersion of the generator in liquids it must no longer be used** and must be returned to an authorized assistance centre or manufacturer for checking/repairs. Immersion in liquids can compromise the safety of battery and of the power supply.
- Do not connect any part of unit to other equipment or devices.
- Do not connect to BIOSTIM any part not intended for use and not supplied by the Manufacturer.
- Do not cover the generator, for example with blankets, during the use or the charge, to allow aeration and avoid overheating of the device.
- Using the coil under heavy blankets, you may experience an overheating of the coil surface: in this case, perform the therapy without covering the coil.
- Do not put the generator directly on the body during the charging of the battery, because its surface may become warmer and this may create discomfort or skin irritation.
- Clean regularly the coil to prevent accumulation of dirt and prevent skin irritation or infection. Use neutral detergents; do not use aggressive solvents or detergents. Make sure to disconnect the coil from the generator before cleaning. The coil is single patient.
- Clean the generator with a slightly damp cloth using water or a neutral detergent; do not use spray or flammable liquids. Switch off the device and disconnect the power supply before cleaning.

- Check the integrity of the coil cable before each therapy session. If it is damaged, replace with a new coil.
- Before use, always check for visible damage to the power supply case and cable; never use a power supply that is damaged. If there is damage, replace the power supply with a new one supplied by the manufacturer.
- Do not expose the battery to heat sources and do not throw it into fire; danger of explosion!
- The battery is a polluting waste, to be disposed of according to the directives valid for reconversion of waste material.
- Handle and transport the device with absolute care to prevent mechanical shock and damage to the device.
- The device is equipped with self-control mechanisms of the correct functioning; any anomaly that may occur is indicated by the system and is described in the instruction manual. Any malfunctions therefore do not affect therapeutic efficacy.
- ⚠ Warning: to recharge the battery use only the power supply provided ; use of a different device could damage the generator or battery or, worse still, cause harm to the user, for which the manufacturer cannot be held responsible. Other power supply may not assure the same degree of protection against electrical shock.
- IGEA recommended a routine maintenance procedure for the operating parameters check at regular intervals not exceeding 24 months of use to ensure reliable performance; contact IGEA or an authorized assistance centre.
- IGEA recommends to repeat safe test at regular intervals not exceeding 24 months of use, to ensure that safety standards are consistently maintained. IGEA, in agreement with the client, is able to perform the recommended safe test.

6.2 Contraindications and adverse effects

There are no contraindications for use of the BIOSTIM device, although several precautions should be taken:

- If you know or think you are pregnant, it is advisable, as a precaution, to avoid direct treatment of the pelvic bones, even though the therapy has no known negative effects. In any case, always inform the doctor who has prescribed the therapy and he/she will assess the need to continue/interrupt it case by case.
- The pacemaker currently in use are not susceptible to the action of electromagnetic fields, however, if you have a pacemaker it is recommended to check with the cardiologist the characteristics of the pacemakers and, in any case, do not apply the coil directly on the chest.
- Less than 2 $^{0}/_{00}$ of patients suffer burning sensation during treatment. In this case it is advisable therefore to split daily therapy into several one-hour sessions for the first week; and gradually increase therapy to the standard regime. The burning sensation will disappear with the treatment interruption.
- The use of the device at the same time of the use of drugs do not normally presents contraindication. The doctor who prescribes the therapy should be informed by the patient for any medication.

6.3 Electromagnetic compatibility

BIOSTIM has been tested and certified according to the electromagnetic compatibility standards for medical devices and it is declared suitable for the home environment.

BIOSTIM can be used together with other electrical or electronic devices, providing they also conform to current standards, without causing interference or receiving disturbances. However, the following general requirements must be observed:

- BIOSTIM must not be used adjacent or overlapped with other devices. If adjacent or overlapping use is required, the medical device must be observed to verify normal operation in the configuration in which it is used;
- BIOSTIM requires special precautions regarding electromagnetic compatibility and must be installed and used in compliance with the electromagnetic compatibility information provided below in this manual.
- BIOSTIM must not be used at the same time as other therapies or applications of electro-medical devices that release energy to the patient's body, particularly if they use high-frequency signals, as these signals may interact with the operation of BIOSTIM and cause unwanted changes in the therapeutic signal.
- The use of accessories, electrodes and cables other than those specified and provided directly by the BIOSTIM manufacturer, may result in increased emissions or decreased immunity of BIOSTIM and cause improper operation.
- BIOSTIM may be sensitive to electrostatic discharge; the user must take every precaution to avoid discharges to the device that could cause a lock or a malfunction.
- Electrostatic discharge with a potential of more than 8kV may damage the signal generator until it causes a permanent failure; in this case the generator still maintains the basic safety required and does not constitute any danger for the user or for third parties. **In this case the generator will have to be replaced with an efficient one.**
- Portable and mobile RF communications devices, including peripheral devices such as antenna cables and external antennas, should be kept more than 30 cm away from all BIOSTIM components, including cables. Otherwise the performance of the medical device may deteriorate.

⚠ **Device lock**: Electromagnetic interference, in particular electrostatic discharge with a potential higher than 8kV, could alter the normal functioning of BIOSTIM and cause the device to stop. In the event of a lock, indicated by BIOSTIM as a situation of failure or interruption in therapy delivery, the device must be turned off and then on again after a few seconds, using the special power button. If the device does not turn off or does not react when the On / Off button is pressed, press the reset button to restore normal operation.

6.4 Biological safety

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

7. MANUFACTURER'S RESPONSIBILITIES

IGEA S.p.A. is responsible for safety, reliability and performance of BIOSTIM on condition that:

- Regular checks, changes and/or repairs are carried out only by personnel authorized by IGEA.
- The user regularly perform safety tests and check of operational parameters as recommended by IGEA.
- The user or any unauthorized person do not open or tamper with the device in any way.
- The device is used in conformity with user instructions in this manual.
- It is used exclusively power supply supplied by IGEA or authorized distributor.
- The Power supply is used exclusively for powering the BIOSTIM and in accordance with the terms specified in this manual.
- The device is subjected to the control of operating parameters and safe-test every 24 months of operation.

For more information or updates, contact the manufacturer.

Manufacturer & Maintenance Service Centre

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

8. TECHNICAL SPECIFICATIONS

BIOSTIM complies with MDD 93/42 EEC and subsequent amendments and is CE marked under the control of IMQ CE 0051.

BIOSTIM has a expected lifetime of five years.

BIOSTIM generator - Model BB-001

Power supply voltage : 11.1 V_{DC} (nominal voltage)
Maximum current assumption : 0.300 A
Maximum input power : 4 W
EN 60601-1 classified : Device of II – BF type class
Classified according to MDD 93/42 EEC : IIa Class device – type BF

Rechargeable battery - Type: Lithium-ion Polymer Battery 11.1V_{DC}/2000mAh

BIOSTIM generator must only be powered with the battery supplied by the manufacturer.

- Do not expose the battery to heat sources and do not throw it into fire – danger of explosion!
- Do not dip the battery system in liquids and do not pour liquids on it.
- The battery is a polluting waste, to be disposed according to requirements specified by local authorities.

External Power Supply

Model*	E2CFMW3 Where "C" is the input plug type. IGEA replaces the plug according to the country of use of the device.	ME30A1541B01
Brand	EGSTOM	SL Power
Input power	100 - 240 V_{AC}	100 - 240 V_{AC}
Mains voltage	50 – 60 Hz	50 - 60 Hz
Max. Input current	620 – 380 mA	1,2A(115Vac) – 0,6A(230Vac)
Output voltage	15 V_{DC}	15 VDC
Max output voltage	2.0 A	2,0 A
Short-circuit protection	Continuous	Continua
Insulation category	II	II
*IGEA reserves the right to provide different models of power supply, tested and approved for the system according to the standards EN60601-1, EN 60601-1-2; use only the power supply provided directly by the manufacturer.		

Characteristics of coil's pilot signal and amplitude of magnetic field

Signal type: Triangular signal
Frequency: 75 Hz ± 5%
Pulse width: 1.33 ± 0.1 ms
Amplitude of magnetic field 20 – 30 G peak value

Instruction for use: Device with internal electrical supply rechargeable with specified power supply. Device for continuous operation not to be used in presence of anesthetic mixes inflammable in contact with air, oxygen and nitrous oxide.

Unit with casing having a degree of protection IP20. (Note: the device remains safe after the test with water drops falling on the enclosure tilted up to 15°).

System conditions:

Ambient temperature: 5 - 40 °C
Relative humidity: 15% - 93% (non-condensing)
Atmospheric pressure: 700 -1060hPa

Environmental conditions for transport and storage

The system can be transported and stored at the following environmental conditions without risk:
Ambient temperature: -25 ÷ +70°C
Relative humidity: from 0 % at -25°C – up to 93% (non condensing) at 70°C

Note: After removing the device from its packaging it is considered that the environmental conditions for use are applicable for transport and storage.

If possible, It's recommended to store the product at a temperature less than 40 °C to reduce premature aging of the battery and it is recommended to store in a 50% charged state.

⚠ **Warning: The system must not be used in explosive environments**

End of Life Disposal

BIOSTIM and all its parts are subject to separate collection in the manner established by local authorities.

8.1 Electromagnetic Compatibility

BIOSTIM, mod. BB-001, taking into account the risk analysis associated with electromagnetic disturbances, complies with all test levels & complies to EN60601-1-2

GUIDE AND DECLARATION OF THE MANUFACTURER - ELECTROMAGNETIC EMISSIONS		
BIOSTIM, mod. BB-001, can be used in the specified electromagnetic environment. The user must ensure that it is used in an electromagnetic environment with the features described below		
Emissions tests	**Compliance**	**Electromagnetic Environment**
RF emissions - CISPR 11	Group 1	BIOSTIM, mod. BB-001, generates RF signals exclusively as a result of the operation of internal electronic circuits. Its RF emissions are very low and hardly cause radio interference in nearby equipment.
RF emissions - CISPR 11	Class B	BIOSTIM, mod. BB-001, is suitable for use in all environments, including domestic environments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions *EN 61000-3-2*	Class A	
Voltage fluctuations / flicker emissions EN 61000-3-3	Compliant	

Guide and declaration of the manufacturer – Electromagnetic Immunity			
Immunity Test	**EN 60601-1-2 Test level**	**Compliance level**	**Electromagnetic Environment**
Electrostatic discharge (ESD) *EN 61000-4-2*	± 8 kV contact ± 15 kV air[1]	IEC 60601-1-2 Test level	All environments, including domestic environment.
Radiated RF *EN 61000-4-3*	10 V/m from 80 MHz to 2,7 GHz	IEC 60601-1-2 Test level	Any environment, including domestic environment with portable and mobile RF equipment kept as far as possible from BIOSTIM, mod.BB-001, including connection cables. Minimum distance 30 cm
Electrical fast transient/burst EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output	IEC 60601-1-2 Test level	All environments, including domestic environment.
Surges EN 61000-4-5	± 1 kV between phases ± 2 kV form phase to ground	IEC 60601-1-2 Test level	All environments, including domestic environment.
Conducted disturbances induced by RF fields *EN 61000-4-6*	3 Vrms from 150 kHz to 80 MHz 6 V - ISM Frequencies and Radio amateur band	IEC 60601-1-2 Test level	Any environment, including domestic environment with portable and mobile RF equipment kept as far as possible from BIOSTIM, mod.BB-001, including connection cables. Minimum distance 30 cm
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	10 ms – 0% a 0°, 45°, 90°, 135°, 180°. 225°, 270°, 315° 20 ms – 0% a 0° 500 ms – 70% a 0° 5 s – 0%	IEC 60601-1-2 Test level	All environments, including domestic environment.
Power frequency (50/60 Hz) magnetic fields EN 61000-4-8	3 A/m	IEC 60601-1-2 Test level	All environments, including domestic environment.

[1] BB-001 is sensitive to electrostatic discharge; potential discharges > 8kV may cause a lock in normal operation or a device failure. In the event of a lock, unlock the device using the Reset button or by disconnecting and reconnecting the supply battery. In case of permanent failure, the generator must be replaced with an efficient one.

8.2 Immunity to proximity fields from RF wireless communication equipment

The 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 at a distance from BIOSTIM, mod. BB-001, 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 communications systems and BIOSTIM, mod. BB-001, using reference the table below.

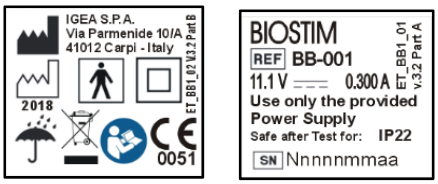
Test Frequency (MHz)	**Band** (MHz)	**Type of service**	**Modulation**	**Maximum power** (W)	**Distance** (m)	**Immunity Test Level** (V/m)
385	380 –390	TETRA 400	Pulse modulation 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0,3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0,3	28
870						
930						
1 720	1700 –1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2400 –2570	Bluetooth, W LAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0,3	28
5 240	5100 –5800	W LAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0,3	9
5 500						
5 785						

The immunity levels shown in the table are respected as long as the device is maintained at a distance of at least 30 cm from any possible source of RF disturbance.

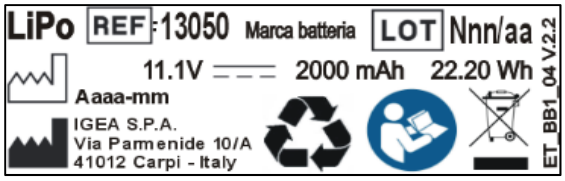
BIOSTIM, mod.BB-001, complies with all test levels with a distance >= 30 cm.

8.3 Data Plate

The following figures show generator and battery data plates, placed in their inner part and not visible when generator and battery are connected.



Generator Data Plates



Battery Data Plate

A third data plate, placed externally on the side of the generator, shows the minimum data essential for the identification of the device.

External data plate

Below are shown the label of the applied parts, located on the cable, near the connector.

Coil label

Note: Further adhesive labels can be applied on the device, on the applied part or on the package; each plate or symbol not described in this manual is to be considered for the exclusive use of the manufacturer (for the internal management of products) but is not intended to provide information to the user.

9. SYMBOLS

SYMBOL	EXPLANATION
	**Class II appliance:** Appliance in which protection against electric shock does not rely on basic insulation only, but includes additional safety precautions such as double insulation.
	**Appliance with BF type applied part:** appliance with a specific degree of protection against electrical hazards, specifically regards admissible leakage current, and with an F type (floating) applied part isolated from the rest of the appliance (coil).
	Continuous current. Symbol on the generator data plate which indicates the type of electrical power supply required for powering of the appliance and also on the power supply plate indicating the type of power provided to the appliance.
	**Alternate Current** (AC): Symbol which appears on the data plate of the power supply and indicates the type of electrical source required.
	**Attention, consult the enclosed documents:** Symbol informing the user to consult the documents supplied with the appliance, as the user manual, for correct understanding and/or use of the part marked with this symbol.
	**Operating Instructions**: refer to the instructions supplied with the device for better use.
	**d collection and recycling of batteries**: the battery cells cannot be disposed of with urban waste but must be disposed of separately for recycling.
	**Manufacturer's** name and address
	**Manufacturing date**: This symbol indicates the year of manufacture
	**Keep dry**: the device is not protected against the penetration of liquids and must be stored and used in dry. Symbol on the generator data plate and on the outer packaging system. (Note: the device remains safe after the test with water drops falling on the enclosure tilted up to 15°).
	**Model:** This symbol, specified on generator's and battery's data plates, indicates the generator's and battery's model.
	**Serial Number**: This symbol, specified on the generator's data plate, indicates the generator's serial number.
	**Lot number:** This symbol, specified on the battery's data plate, indicates the lot number
	**Separated collection**: IGEA devices and their applied parts cannot be disposed of with urban waste but must be disposed of separately according to requirements specified by local authorities.
	**Follow the instructions for use**: This symbol indicates that you must read the instructions before you start using the device.
	**CE symbol** on the device's data plate indicates that the device conforms to European Directive for medical devices 93/42/EEC and its revised version. The CE symbol is followed by the identification number of the notified body that checks conformity to the Essential Requirements of the Directive for applying the mark on the product.
	**Limits of atmospheric pressure for the transport and storage**: symbol on the outer packaging of the system.
	**Limits of relative humidity for the transport and storage**: symbol shown on the external packaging of the system.
	**Temperature limits for the transport and storage**: the symbol found on the outer packaging of the system.
	**Fragile handle with care:** symbol on the outer packaging of the system.