User Manual

Only begin using OSEOBIT after having read this User Manual

MI - OSTEOBIT-UK Rev 2.6 january 2021
software 1.x

1. INTRODUCTION

1.1 What is OSTEOBIT and how it works

OSTEOBIT is a therapeutic aid and must be used with a medical prescription.
OSTEOBIT is an electrical bone growth stimulator, which use electrical fields.
OSTEOBIT is a portable medical appliance with a very low energy consumption which used an alternating signal at a frequency of approx. 60 KHz in order to pilot a pair of electrodes of specified dimensions thereby creating a low intensity electrical current on the zone to be treated (approx. 1 mA) with an average density between 15 and 30 $\mu A/cm^2$.
Such a current density at the specified frequency causes acceleration in the proliferation of the osteoblasts thereby stimulating the osteo-genetic activity speeding up healing times.
The correct signal to the area to be treated is ensured by the application of pre-gelled adhesive electrodes. These electrodes are specifically designed, thus recommended, in order to obtain the proper current density values, which come within the field of therapeutic validity.
Electrode application is simple and does not require any assistance by medical or nursing staff, the patient can apply the electrodes by himself.
The system is powered by a rechargeable battery, which should be recharged using an external power supply provided with the system.
The generator is controlled by a microprocessor, which constantly controls the correct function of the device. In case of anomalies or faults of the device during the therapy, simple and highly effective visual and acoustic signals immediately alert the patient.
Thanks to its compact weight and dimensions, together with battery-operated feature, the device is fully portable, and the patient can undergo treatment even while moving, providing that the actual medical condition permits it.

OSTEOBIT PLUS is a system configuration in which the signal amplitude drives larger electrodes for the treatment, for example, of lower limbs.

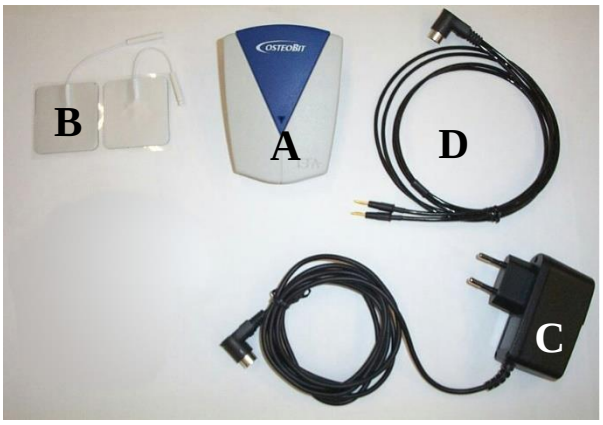
1.2 Possible therapeutic treatments with *OSTEOBIT*

OSTEOBIT is mainly used in orthopaedics to treat:

- Fractures
- Recent fractures
- Stress related fractures
- Pseudoarthrosis
- Edema
- Non-unions

2. SYSTEM COMPONENTS

OSTEOBIT systems are made up of four components.

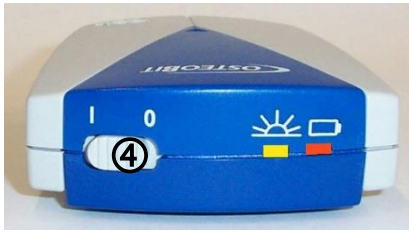


- The **signal generator** for electrode piloting (A)
- The **electrodes** (B) that should be used in pairs
- The **battery charger** (C). IGEA can provide different models of charger approved for use in the system.
- The **cable** for connection between generator and electrodes (D).

2.1 Signal Generator

Inside the generator it is the rechargeable battery. The generator is equipped with:

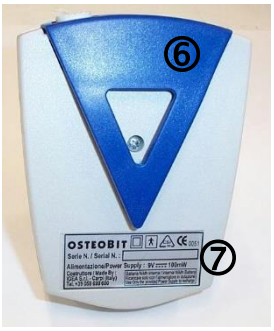
- ① A **yellow indicator** light "☼" which indicates the system operation conditions and the treatment undertaken.
- ② A **red indicator** "▭" which comes on either in a continuous or flashing form which indicates the power battery charge/recharging status.
- ③ An **internal acoustic signal** or buzzer used together with the yellow and/or red indicators to signal conditions of particular importance in the use of the device. The ignition combinations of these signalling devices inform the user of all the possible conditions of the system; which are described in detail in par. 3.4.
- ④ A **Sliding on/off switch** positioned on the top part of the stimulator and marked with symbols "0" = off and "I" = on.
- ⑤ A **connection plug**, marked with the symbol "⚠" positioned on the side of the stimulator and used for the alternative and exclusive connection with external devices such as the electrodes used for treatment or the external battery charger.



⚠ **Important:** It is important to note that the generator uses a single connector for the applied part and battery charger. This aspect is of particular relevance in terms of the electrical safety of the device, as it **can never be connected to a mains socket** (by means of external battery charger) **and the patient** (by means of cable leading to the electrodes) **at the same time.**

The generator is complete with:

- ⑥ A **plastic clip**, which can be used to clip the device to one's belt.
- ⑦ A **data plate** which indicates the main technical data of the device and information useful to the user as the model or the serial number of the device.



2.2 The electrodes (applied part)

The device is set up for the generation of a specific output signal according to the dimensions of the electrode supplied; **the user should use only the electrodes provided by IGEA.**

A correct therapy requires always the electrodes placed in direct contact with the skin; they cannot be placed on any other type of material (clothing, plaster, etc).

The materials that make up the electrode are anti-allergic and of proven biocompatibility; the electrode can therefore be directly placed in contact with the skin without causing any kind of problem.

3. APPLICATION AND USE OF THE STIMULATOR

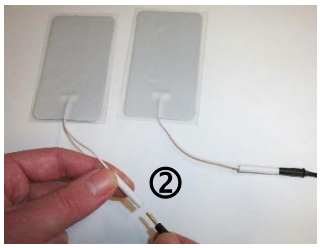
3.1 Initial charging

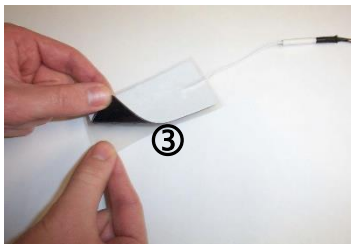
On receipt **it is necessary to recharge the battery for about 10/12 hours** before using the system, following the instruction of chapter 3.6:

3.2 Therapy execution

After charging the battery, use the stimulator as described below:

- ① Insert the connector of the connection cable to the generator using the special socket marked with "⚠" symbol.
- ② Insert the two terminal pins of the connection cable into the inlets on the electrode cables.
- ③ Detach each single electrode from its rigid transparent film before applying it to the treatment area.

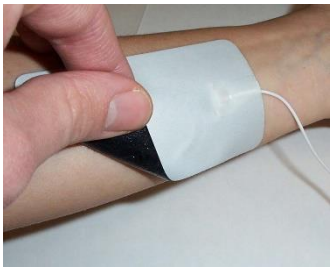


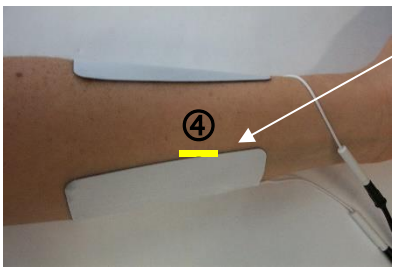


- **Preserve this transparent film**, as the electrodes may be used for up to 3-4 times before needing to be replaced; therefore at the end of the treatment session replace the electrode on the transparent protective film.
- Position the adhesive part of each individual electrode in the vicinity of the treatment area (④), ensuring that:

the electrodes do not come into direct contact with each other.

the area to be treated is in the middle of the two applied electrodes.





LESION

- Switch on the generator, moving the switch to position "I".

At the start both the yellow "☼" and red "▭"indicators will come on, and the buzzer will emit a short buzz indicating that the system is on; the device will then take a few seconds in order to check that the electrodes are present and correctly applied to the body (continuous yellow indicator light on) and once this test is completed the treatment starts (flashing yellow light).

The **correct operating condition is indicated by the flashing yellow led** "☼"; the flashing yellow light indicates the correct therapy mode.

Once the treatment session is over, the patient should simply switch off the generator moving the switch in "O" position; all the indicator lights will be off.

3.3 Recommendations for the correct use of the electrodes

1. ⚠ Use only electrodes of **type and dimensions as those supplied with** the appliances; the manufacturer guarantees the efficient functioning of the device only if used with its original electrodes and no others.
2. The electrodes should be placed directly on the skin, ensuring that the part of the body to be treated is roughly in the middle of the two applied electrodes.
3. Before positioning the electrodes clean the skin using a normal detergent (soap and water or neutral soap) and then dry.
4. Never apply the electrodes on damp skin; otherwise there is a risk that it will not adhere sufficiently.
5. **Never apply the electrodes to damaged skin**; in the event of any damaged skin in the area, move the electrodes so as to avoid contact between the electrode and the damaged skin; in the event of extensive skin damage seek medical advice.
6. It is important to avoid pulling or stretching the cable, which comes out the electrode, as there is a risk of irreparable damage to the electrode itself.
7. Do not use the electrodes should they, or the cables which come out of them and to which the generator is connected, show obvious signs of wear or damage; electrodes worn or lacking in good adhesion to the skin may limit the effectiveness of the treatment.
8. The electrodes can be re-used for subsequent treatment sessions, generally a further 3-4 sessions: the possibility of use however always depends on the actual application area and the typical skin characteristics of each individual undergoing treatment, therefore the number of subsequent sessions for which it can be re-used will vary from one person to the next.
9. The system is provided with a number of electrodes corresponding to the average demand for treatment; to receive more electrodes contact the manufacturer or an authorized service centre.
10. Do not to re-use the electrodes in the event that the adhesive potential is visibly diminished. The electrodes must firmly and thoroughly adhere to the skin.
11. When possible it is advisable the use of a cotton or rubber belt or any other suitable mean in order to allow the electrodes to firmly and thoroughly adhere to the skin.
12. The electrodes and the parts of the device that may come into contact with the skin usually do not cause any allergic reaction. in case of irritation in the area of use please consult your doctor.
13. The electrodes package shows the expiring date of the same. Do not use electrodes after the expiration date printed on the package.

3.4 System conditions indications

During operation different situations may occur, indicated by the combination of indicators and buzzer described below.

STIMULATOR CONDITION	INDICATORS AND BUZZER	
Stimulator on and searching for signal, the electrodes neither yet applied to the patient nor connected to the generator. When switch on the generator it takes a few seconds to check that the electrodes are present and applied on the body, then the treatment signal starts.	Yellow indicator	**Continuous light on**
	Red indicator	Off
	Buzzer	Emits an **intermittent sound** until the problem is resolved
Stimulator on with electrodes connected and in **correct operational stage.**	Yellow indicator	**On and flashing**
	Red indicator	Off
	Buzzer	Off
Low Battery. The stimulator is on and works correctly, but the battery is almost flat, from the signal alarm the appliance has got some working hours.	Yellow indicator	**On and flashing**
	Red indicator	**On and flashing**
	Buzzer	**Buzzes for a second** and then switches off
Flat Battery. The stimulator is on and in operation but the battery is totally flat and can no longer power the circuit. The battery needs charging in order to resume therapy.	Yellow indicator	**On and flashing**
	Red indicator	**Continuous light on**
	Buzzer	Emits **a "beep" every 5 sec for a total of 30 seconds** after which the generator switches off.
Battery recharging in progress. The stimulator is connected to the external battery charger and the battery is charging. The red light goes out whenever the generator is disconnected from the battery charger.	Yellow indicator	Off
	Red indicator	**On** and **flashing** for the whole recharging time. At the end of charging, continuous light remains on.
	Buzzer	Off
Short-circuited electrodes or cables. The stimulator is on but there is a functional anomaly due to a **direct contact of the electrodes** or to a **short-circuiting of the cables**. Check that the electrodes or their connecting cables are not in direct contact with each other.	Yellow indicator	**Continuous light on**
	Red indicator	Off
	Buzzer	Off
Maintenance required. The stimulator founds irregular parameters and it fails to maintain the normal functioning signals. In this case the maintenance service is required.	Yellow indicator	**Continuous light on**
	Red indicator	**Continuous light on**
	Buzzer	Emits **a "beep" every 5 sec for a total of 30 seconds** after which the generator switches off. In the event of switching on again it repeats the same signal.

3.5 Treatment times

The user should perform the treatment by the number of days specified by the doctor who prescribed the therapy.

OSTEOBIT treatment may be undertaken for about 8 hours a day, preferably continuously. It is possible to divide the daily treatment period provided it lasts not less than 2 hour.
It is possible to undergo the therapy during the night while sleeping, but the therapy is generally advised during daytime, as the device is portable.

3.6 Battery recharging

The battery must be recharged whenever the system indicates that it is necessary, as described in paragraph 3.4; as the battery has a lifetime of about 20 hours: **it is therefore advised to recharge the device every day.**

- ⚠ Warning: It must be used the battery charger supplied only; this charger has been specifically selected and approved for this purpose. The use of other devices differing from those supplied or not specifically provided by the manufacturer, may damage the generator itself, or the power battery or even the be harmful for the user, in such an event the manufacturer declines all responsibility.
- Switch off the generator positioning the switch to "O" position (off).
- Detach the electrode connection cable from the generator.
- Insert the battery charger connector into the generator "⚠" socket (①).
- Connect the battery charger plug (②) to a functional mains socket.

- The circuit begins internal battery recharging and the red indicator "▭" starts flashing.

IMPORTANT: In case the battery should be completely flat, it is possible that the **red light also uses a few hours before turning on**; keep the system charging for 10-12 hours. Then it is possible verify the battery status by disconnecting the charger and turning the device on.

- The charging time is about 5 hours, at the end the red indicator light remains on in a continuous manner; should the battery charger remain connected to the generator for a longer period than that required for complete battery charging the charging operation is suspended once the battery power level is restored and will be resumed only if the battery power level once again falls to below the fixed value (maintenance charge with flashing red light).
- At the end of the charging period disconnect the battery charger from the mains socket and then detach the battery charger from the generator.

  ⚠ **Important**: **Always disconnect the power charger after a maximum of 24 hours of recharging**. In the event the charge exceeds this limit there is a risk of serious battery damage. The manufacturer will not accept responsibility for any damage to the system as the result of an improper use. However there is no other kind of risk as the result of over-charging except damage to the same.

3.7 Generator 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.
Before cleaning the generator **ensure that the device is switched off and disconnected from the battery charge**r: the generator can be cleaned with a damp cloth and neutral detergents, never use any aggressive detergent or solvent agents to clean the generator. Electrodes do not need cleaning and can be used for more treatment sessions.

4. TROUBLE SHOOTING

4.1Error messages

The device notifies the fault conditions; the table below shows the reports provided and the actions required to restore correct operation.

IF	THEN
On positioning the switch to "on" (I) **the yellow "☼" indicator fails to come on.**	The internal power battery may be completely flat, recharge it as described in paragraph 3.6
The stimulator is on with only the yellow "☼"indicator light on in a continuous manner, the buzzer emits an intermittent sound which is continually repeated.	The electrodes have not been applied to the patient or they have become disconnected from the generator. Check the correct positioning and connection. If the message persists, the cable might be broken and must be replaced.
Even if the electrodes are correctly connected, the yellow "☼"indicator light is on in a continuous manner.	Check that electrodes or cables are not in direct contact with each other.
The stimulator is on with yellow "☼" indicator flashing; the buzzer emits a sound and the red "▭"indicator begins flashing.	The stimulator is operating correctly, but the battery is low, from the time of the signal the appliance has a residual autonomy of some hours before running out. The battery must be recharged as soon as possible.
The stimulator is on with yellow "☼" indicator flashing, continuous red "▭" indicator light on and buzzer emitting a "beep" every 5 seconds for a total of 30 seconds; before the device goes off.	The stimulator is on and operational, but the battery is totally flat and can no longer power the circuit. The battery needs to be charged before resuming treatment. This condition is preceded by the condition described above.
The stimulator is on with continuous yellow "☼" and red "▭" lights on and buzzer emitting a "beep" every 5 seconds for a total of 30 seconds; before the device goes off.	The generator founds irregular; the device does not provide any signal and maintenance service is required.
	NOTE: external interferences due to electromagnetic perturbations, high potential electrostatic discharges (> = 8kV) or complete run down of the internal battery might block the device functioning. Restart the device by **pressing the little button placed on the left side of the device**, as shown in the picture, using a pen for instance. If the operation does not resolve the blocking state, disconnect the supply battery (as described in paragraph 4.2) and reconnect it after a few seconds.

⚠ 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.

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4.2Rechargeable battery replacement

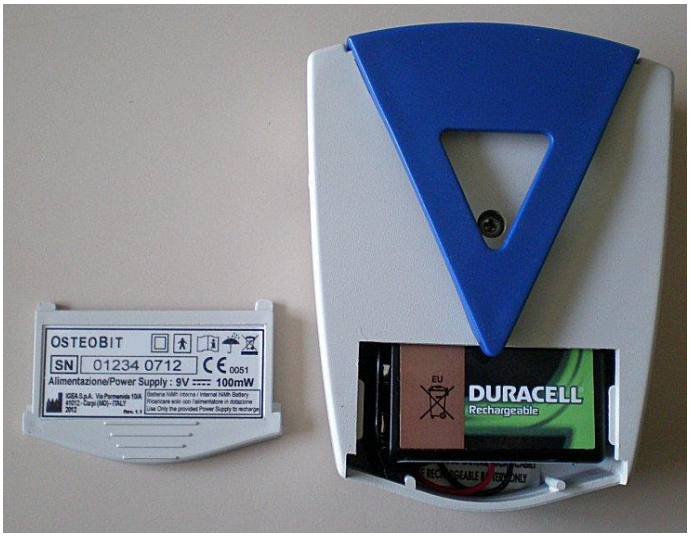
It is allowed to replace the battery with a **rechargeable one** of the same type:

Ni-MH, 9V, 150mAh.

⚠ **Important: use rechargeable battery only and pay great attention to the correct polarity.**

The battery is placed on the rear side of the generator:

- Open the battery compartment by sliding the panel down.
- Remove the battery from its compartment.
- Remove the battery from the connector.
- Connect the new battery to the connector with the correct polarity.
- Insert the new battery in the compartment and close the panel by sliding it upwards.



5. SAFETY INSTRUCTION

5.1 Recommendations

For a safe and correct use of the device it is necessary to carefully follow this advice:

- Only begin using OSTEOBIT after having read this instructions manual
- OSTEOBIT must be used by people who understand and put into effect independently the instructions provided in this manual: otherwise, and if used on children, OSTEOBIT 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 use the appliance in the presence of inflammable gases or rooms in which an explosion risk exists.
- Do not connect any part of unit to other equipment or devices.
- Do not connect to OSTEOBIT any part not intended for use and not supplied by the Manufacturer.
- It is advisable to avoid using this device in the proximity of short wave or microwave treatment appliances, as it may alter the output signals.
- Never handle any components of the system with wet hands, in particular do not connect the external battery charger to the mains power supply.
- Do not use the device in areas or situations where it might get wet. The device remains secure even in the event of penetration of liquids within the container, but may be damaged and no longer be able to deliver therapy.
- Never immerse any of the component parts of the system in water or liquids of any type and never pour any liquids over the same. 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.

- Do not expose the system to heat and do not dispose of in fire, danger of explosion!
- Before using the generator–electrode connection cable always ensure that the electrodes are not visibly damaged; in the event of damaged cable contact an authorized assistance centre.
- Before each treatment session always ensure that the electrodes are in good conditions; should they be damaged contact an authorized assistance centre.
- Avoid excessive pulling or stretching of the connection cable which comes out the electrode and which makes contact with the conductive material of the same, as any cable damage will render the electrode unfit for use.
- Avoid any mechanical shocks or blows to the appliance and its components during transportation and handling.
- The rechargeable battery is classified as polluting substances; it must be disposed of in accordance with the local governmental legislation about pollution.
- 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.
- IGEA recommended a routine maintenance procedure for the operating parameters check at regular intervals not exceeding 24 months of use to ensure reliable performance; ccontact IGEA or an authorized assistance centre.
- The generator can be cleaned with a damp cloth and neutral detergents; before cleaning the generator ensure that the device is switched off and disconnected from the battery charger.

5.2 Contraindications and adverse effects

The numerous international studies carried out have not shown there to be any adverse effects as the result of the treatment as a whole, however these precautions are necessary:

- In the event of either suspected or confirmed pregnancy before using the device inform the doctor who has prescribed the therapy, who will decide on whether to continue with the specific treatment or not.
- Those fitted with pace-makers are advised to check the features of their pace-maker device with their cardiologist; and in any case avoid any treatments which involve the application of electrodes in the vicinity of the pace-maker itself;
- In the event of any skin damage or irritation in the zone in which the electrodes are to be positioned, it is necessary to consult the doctor who prescribed the therapy for advice on alternative positioning of the electrodes or the advisability of suspending the actual treatment.
- Therapy should not be performed concurrently with other therapies or applications of medical devices that release energy to the patient body through the use of electrodes, in particular if they use high frequency signals as they may interact with the device and cause harm to the patient or to the device.
- 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.

5.3 Electromagnetic compatibility

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

OSTEOBIT 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:

- *OSTEOBIT* 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;
- *OSTEOBIT* requires special precautions regarding electromagnetic compatibility and must be installed and used in compliance with the electromagnetic compatibility information provided below in this manual;
- *OSTEOBIT* 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 *OSTEOBIT* and cause unwanted changes in the therapeutic signal;
- The use of accessories and cables and electrodes other than those specified and provided directly by the *OSTEOBIT* manufacturer, may result in increased emissions or decreased immunity of *OSTEOBIT* and cause improper operation;.
- 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 *OSTEOBIT* components, including cables. Otherwise the performance of the medical device may deteriorate and the device may report a fault situation. If this situation should occur, the user must interrupt the treatment in progress, place the device and all of its parts at least 1 meter from any possible source of electrical/electronic noise and resume treatment;
- *OSTEOBIT* may be sensitive to electrostatic discharge with a potential > 15kV; It is advisable to use particular care not to subject the device to discharges of this magnitude, which could in the worst case, cause a blockage during the charging phase of the device;

⚠ **Device block**: Electromagnetic interference, such as those due to active cell phones or disturbances to the power supply system, or high potential electrostatic discharge > 8kV, can interfere with the normal functioning of *OSTEOBIT* and cause the device to stop. Should this occur, follow the instructions given in paragraph **Errore. L'origine riferimento non è stata trovata.**. **Be sure to remove the source of the disturbance before continuing treatment.**

⚠ **Caution**: Using the device in the immediate vicinity of a shortwave or microwave therapy device (in operation) may cause disturbances in the output signal which, although it does not pose a risk to the patient, could nullify the therapeutic effect; it may therefore be avoided.

5.4 Biological safety

The electrodes used for the application of the therapeutic signal, which are supplied together with the system, are made of non-allergic materials, which are totally biocompatible; such features being attested by the CE making certificates released by the manufacturer. The methods and type of signal used have been subjected to intensive studies at an international level, which have demonstrated their therapeutic effectiveness and the complete absence of any adverse effects.

6. MANUFACTURER'S RESPONSIBILITY

IGEA considers itself responsible for the safety, reliability and performance of OSTEOBIT providing that:

- The appliance is used in accordance with the instructions for use as indicated in the present manual;
- Any modifications or repairs are made only by personnel authorized by IGEA;
- The appliance is neither opened nor tampered with by the user or unauthorized persons;
- The battery is charged with battery chargers exclusively of models of approved type as those supplied;
- The battery charger is used solely for the charge of the OSTEOBIT battery according to the instructions provided in this manual;
- The electrodes used are solely those supplied or of type and dimensions as specified by the manufacturer.
- The user regularly performs the operating parameters check recommended by IGEA.

For any other information or updates the user may contact the manufacturer itself:

Manufacturer:

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

7. TECHNICAL DETAILS

OSTEOBIT complies with MDD 93/42 EEC and subsequent amendments and is CE 0051 marked under the control of IMQ.
OSTEOBIT has a expected lifetime of five years.

OSTEOBIT Generator

Model : OSTEOBIT
Voltage : 9VDC
Max. absorbed current : 0,010 A
Classification according to EN 60601-1 : Class II with Applied Part of Type BF
Classification according to MDD 93/42 EEC : IIa

Method of use: Appliance for continuous function not to be used in the presence of anaesthetic mixtures which are inflammable on contact with air, oxygen and nitrous oxide. Appliance powered by internal electrical power source (rechargeable power battery). Equipment not protected against the penetration of liquids. The device remains safe after the proof required for the degree IP22.

Electrode piloting signal features: Sinusoidal signal with impulse train and activity time of 40 msec followed by a pause time of 40msec

Maximum range : 20 Vpp (effectively 7V)
Maximum electrode output current : 1500µA (effective value)
Therapeutic signal frequency : 59 KHz ± 5%
Electrode piloting frequency : 12,5 Hz (80 msec)
Duty Cycle (operational time) : 50% (40 msec)
Charge Impedance validity field : Min. 500 ohm – Max. 7000 ohm (at nominal frequency)

The impedance validity range indicates the minimum and maximum values of the stimulator charge impedance which does not produce any alterations to the signal parameters of over ± 30% as compared to the nominal values (CEI 62-24 Par.50.2)

Power battery

Ni-MH battery with nominal voltage 9 VDC, Nominal capacity150 mAh, Average battery life with 1/10 C charge > 500 cycles. *The rechargeable battery which powers the device is classified as polluting refuse and must be disposed of in accordance with local current legislation.*

External battery charger

Model*	MENB1020A1840B01	ME20A1840B01
Brand	AULT/SL Power	SL Power
Input power	230VAC (100-240)	230VAC (100-240)
Mains voltage	50-60Hz	50-60Hz
Max. input current	0,100 A	0,100 A
Output voltage	18 VDC	18VDC
Max output voltage	1,0 A	1,0A
Short-circuit protection	Continua	Continua
Insulation category	II	II
** IGEA reserves the right to provide different models of power supply, tested and approved for the system according to EN60601-1, EN 60601-1-2; use only the power supply provided directly by the manufacturer.*		

Environmental condition of use

Atmospheric temperature : 0 - 40°C
Relative humidity : 30% - 75%
Atmospheric pressure : 700-1060hPa

Environmental transportation and storage conditions

Atmospheric temperature : -20 - +70°C
Relative humidity : 10% - 90%
Atmospheric pressure : 500 - 1060hPa

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

⚠ **Warning: This device is not to be used in areas in which an explosion risk exists.**

End of life disposal

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

7.1 Table of Electromagnetic Emission and Immunity Levels

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

OSTEOBIT, 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	*OSTEOBIT*, 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	*OSTEOBIT* 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) [1] EN 61000-4-2	± 8 kV contact ± 15 kV air	IEC 60601-1-2 Test level	All environments, including domestic environment.
Radiated RF ([2]) 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 *OSTEOBIT*, 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 *OSTEOBIT*, 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] OSTEOBIT 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.

[2] OSTEOBIT in the presence of radiofrequencies between 150 and 250Mhz, could present problems during charging; in thiscase OSTEOBIT must be removed from the source of disturbance to eliminate such interference.

7.2 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 *OSTEOBIT*, 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 *OSTEOBIT*, 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,	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,	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.

8. SYMBOLS

	**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:** on the generator data plate indicates the required power supply, on the power supply data plate indicates the provided power supply**.**
	**Alternate Current** (AC): on the power supply data plate indicates the required power supply**.**
	**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.
	**Separated collection and recycling of batteries**: the cells content in the battery cannot be disposed of with urban waste but must be disposed of separately for recycling**.**
	**Manufacturer's name and address:** manufacturer's name and address.
	**Manufacturing date:** manufacturing year of the device.
	**Keep dry**: the device is not protected against the penetration of liquids and must be stored and used in dry.
	**Model:** This symbol, specified on generator and battery data plates, indicates the generator and battery model.
	**Serial Number**: This symbol, specified on the generator's data plate, indicates the generator's serial number.
	**Batch code:** This symbol indicates the battery batch code.
	**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 0051	**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.