⚠ Only use the device after reading this manual.

CONTENTS

MI-IONE-EN Revision 1.5 - April 2024

SW Rev. from 1.7

1. INTRODUCTION

1.1 What is the I-ONE and how does it work?

The I-ONE is a medical device for the treatment of inflammatory and degenerative tissue diseases using low-frequency electromagnetic fields.
The I-ONE 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 pulse width (trigger time) of approximately 1.0 millisecond.
This electromagnetic field is capable of inducing an average electric field of 0.04 mV/cm in the 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 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 I-ONE?

The I-ONE 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 I-ONE 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 the joints and the stimulation of osteogenesis. In particular, the **I-ONE** device, model **CBA04** is indicated for:

- ***Treatment of inflammatory and degenerative tissue diseases***

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 produces a specific effect on the receptors that control inflammation. The effect on inflammation, which is related to the agonist activity of adenosine for A2A receptors, justifies the indication for use in various tissues.

1.5 Treatments that can be carried out with I-ONE Therapy

The main **indications** for which the I-ONE is used are:

- Ligament reconstruction
- Microfractures of the subchondral bone
- Joint fractures
- Joint inflammatory processes
- Oedema
- Autologous chondrocyte grafts
- Osteochondral grafts
- Early stages of arthrosis
- Meniscectomy
- Algodystrophy
- Knee prosthesis
- Femoro-rotulea syndrome

The coil to be applied to the treatment site has a homogeneous field and does not require a perfectly centred application on the site to be treated; for this reason the patient is able to perform the application independently, without the need for medical or nursing supervision. The device operates on a rechargeable battery with an external power supply.

1.6 Expected clinical benefits

The expected clinical benefits of using the **I-ONE CBA04** pulsed electromagnetic field generator are**:**

- Chondroprotection,
- pain relief,
- functional recovery,
- a better quality of life.

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

2. I-ONE DEVICE COMPONENTS

The I-ONE device consists of the following components:

① The generator that incorporates the rechargeable battery

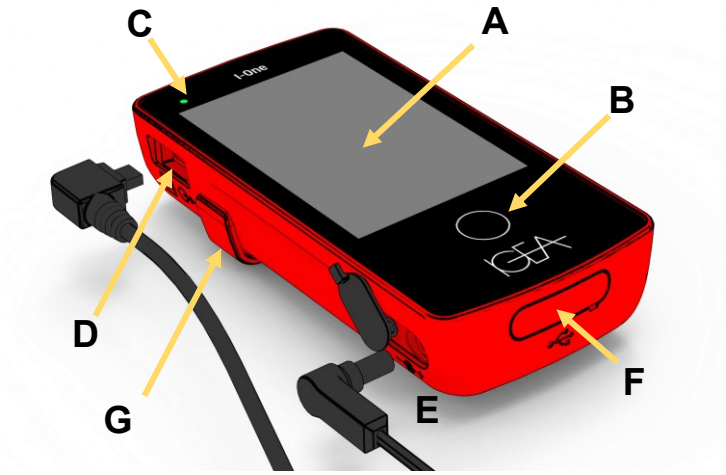
② The coil, the applied part of the device

③ The external power supply unit

④ An elastic band to keep the coil in the correct position during the treatment

2.1 Generator

The generator is equipped with:



(A) A display with a touch-screen function that shows the status of the device and allows certain functions to be activated by pressing the button shown on the display

(B) A multifunctional button for switching the device on/off/reset

(C) A multi-coloured LED whose activation and colour indicates the status of the device in addition to the messages on the display.

(D) A coil connection socket, marked with the symbol

(E) A socket for connection to the external power supply, marked with the symbol

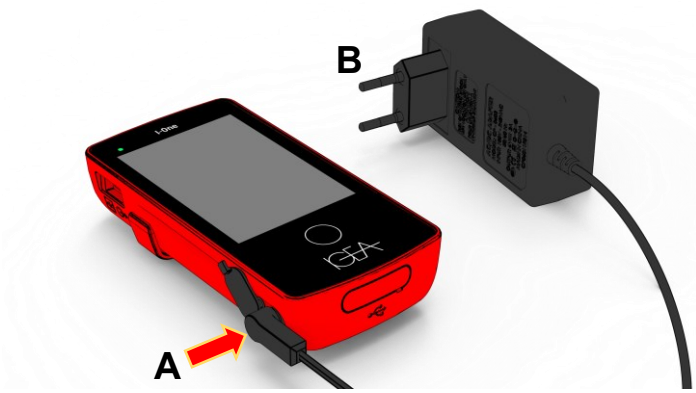
(F) *A service socket at the bottom of the generator which is* ***reserved for technical support****.*

(G) A removable attachment clip 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

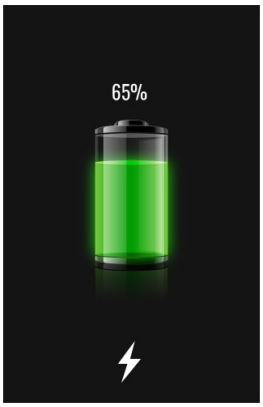
Upon receipt, the battery must be charged before treatment using the external power supply.



With the generator switched off, connect the power supply to the generator by inserting connector **[A]** into the socket on the bottom left of the generator. Then connect external 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 above the battery symbol.

- charging a completely empty battery can take up to 3 hours

- it is a normal for the device to heat up when charging and it should not be cause for concern

- when charging is complete, the display shows the battery charged symbol.

Disconnect the power supply unit from the generator and the mains socket.

NOTE on the room temperature: *if the I-ONE is charged in an environment with a temperature above 30 °C, the battery may take longer than 3 hours to fully charge*.

To avoid this, the I-ONE should be charged in an environment with a temperature that does not exceed 30 °C, where possible.

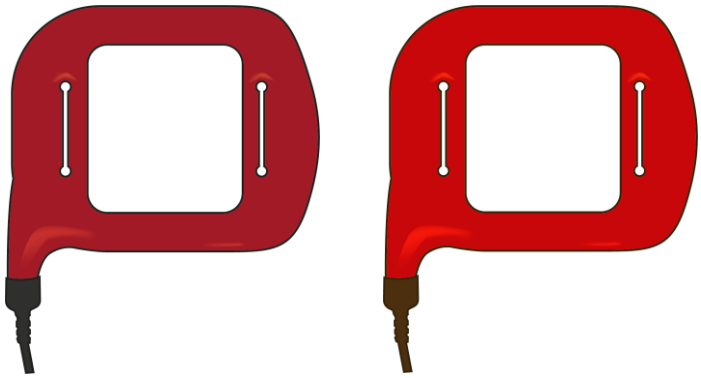
IMPORTANT

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 waives any liability for this.
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. 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**. 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. The battery may only be replaced, if necessary, by the manufacturer or by the manufacturer's authorised technical support.

3.2 Connecting the coil to the generator

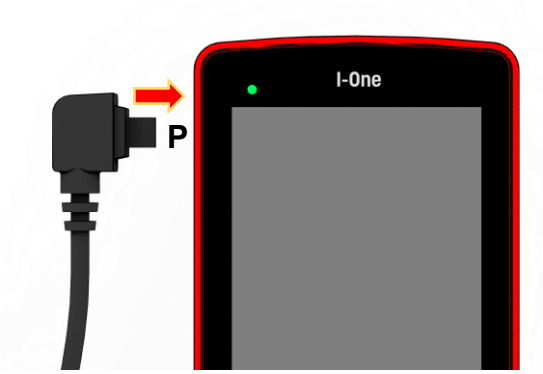
The coil that is compatible with the I-ONE is shown in the figure below, identified by its code:

REF. 70010 **REF. 70110**



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

When switched on, the device will automatically recognise the connected coil and emit the required alarm level.



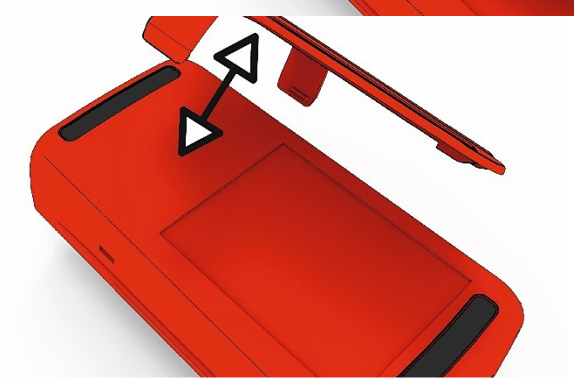
4. CLIP ATTACHMENT AND REMOVAL

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 notch from its socket, followed by the second. Now lift the clip and remove it.



5. ADMINISTERING THE TREATMENT

5.1 Coil positioning

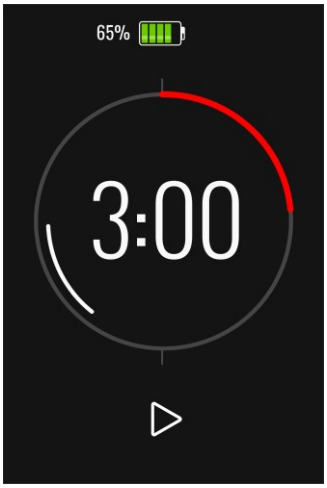
Position the coil so that the place undergoing treatment is in the centre of the coil, then secure it with the supplied band or other suitable means; an example of positioning it on the knee is shown here.

It is not necessary for the coil to come into contact with the skin; **for hygienic reasons, it is always recommended to place the coil on light clothing**, the presence of which does not have an impact on the treatment. 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, clean the coil before each application.

5.2 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 short 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 **I-ONE** suggests a treatment time of **4 hours** every time it is switched on, which is the recommended time in order for the treatment to be effective.

The **LED at the top of the display flashes green** and the timer on the display starts to count down the treatment time.

In the adjacent figure you can see the timer, where **3:00** is the remaining treatment time. The timer updates with every minute of treatment that has been performed until the preset daily treatment time of 4 hours is reached.

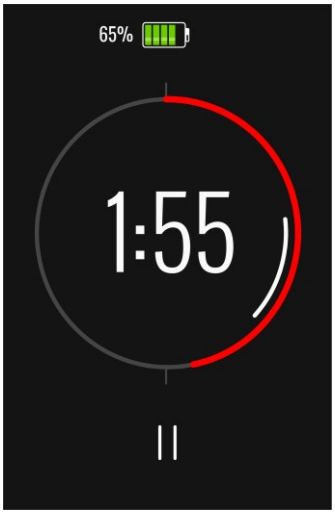
During the treatment phase, it must be remembered that:

After 10 seconds of inactivity, the display lowers its brightness, and after 30 seconds, it switches off to save battery power; **the green LED that continues to flash** informs the patient that **treatment is in progress**.

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:

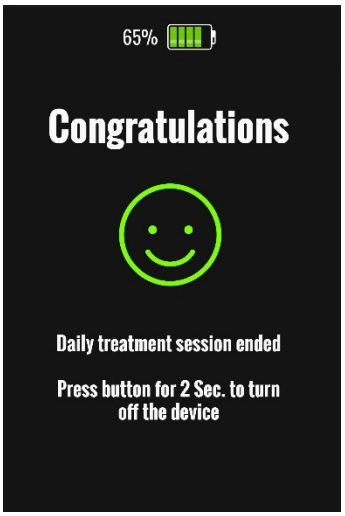
The battery symbol above indicating the percentage of charge remaining; it is normally green and turns red when the battery is low (the battery needs to be charged).



In the centre of the display, the timer symbol shows the treatment time that is left. Initially, the circle containing the timer is grey and turns red as the patient performs the treatment. The circle will go completely red at the end of the planned 4 hours of treatment (the treatment cycle has been completed).

The **rotating white bar** inside the timer indicates that **treatment is in progress**.

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 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 I-ONE **stops providing the treatment,** the **green light goes out** and the display shows the **end of treatment message**.

The I-ONE remains switched on, without providing the treatment, in standby position. The user can switch it off by pressing the **OFF** button for about two seconds, until there is a beep and a short confirmation vibration.

If not switched off by the user, the I-ONE will switch itself off when the battery is low.

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

Every time it is turned on, the timer will restart at **4:00** hours.

If the user has to interrupt treatment before having completed the set daily treatment time, they can put the I-ONE on **PAUSE** and resume treatment later by pressing the **PLAY** button. This can be done even several hours later. In this case, the treatment counter will restart from the remaining time it showed when it was put on PAUSE.

Alternatively, the patient can switch the I-ONE off by pressing the **ON/OFF** button for about two seconds, until the confirmation beep is heard.

To resume treatment, the patient must switch the I-ONE back on; in this case the treatment timer will reset to the initial 4-hour value.

When the battery is fully charged, it allows up to 4 hours of continuous treatment.

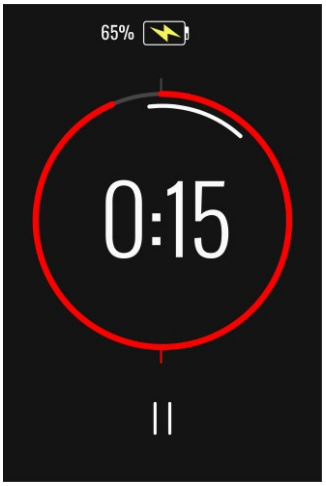
The device should always be charged at the end of the daily treatment so that, the next time it is used, the device is charged and able to provide the full treatment cycle.

NOTE: if the user wants to perform treatment for more than 4 hours each day, when the first 4 hours have been reached and the end of treatment message appears, they must switch the device off and then switch it on again to start a new treatment cycle. However, please note that:

- clinical studies have shown that treatment with the I-ONE is effective when performed for 4 hours a day
- the battery provides up to 4 hours of continuous treatment.

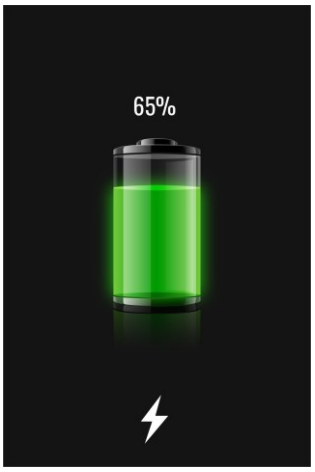
For more than 4 hours, if the battery runs out, the external power supply must be connected while the I-ONE is in operation. This way, the I-ONE **provides the treatment and, at the same time, charges the battery** (see section 5.3). At the end of treatment, leave the I-ONE switched off and connected to the power supply until the battery is fully charged.

5.3 Battery monitoring and charging



The I-ONE can also charge the battery 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 needs charging.
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.

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



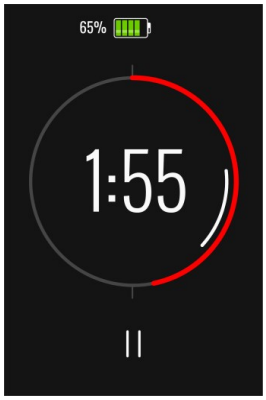
- The display lights up and the generator beeps and vibrates.
- The display shows the animation of the battery being charged and a flash symbol below it
- The animation persists until the charge is complete (full charge may take up to 3 hours)
- When charging is complete, the display shows the battery charge symbol →
- Disconnect the power supply unit from the generator and the mains socket.

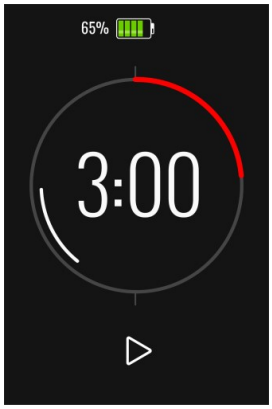
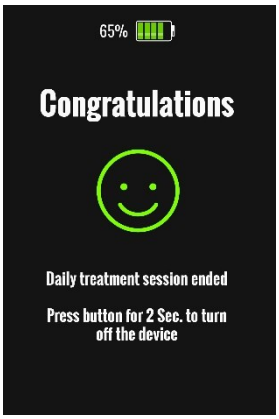
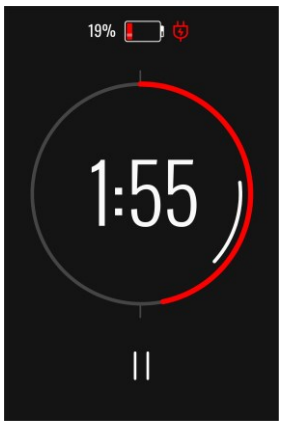
If the I-ONE is switched on during charging, pressing the power button turns on the generator and the user can continue with the treatment whilst the battery is being charged. Under these conditions, the device behaves as described in section 5.2.

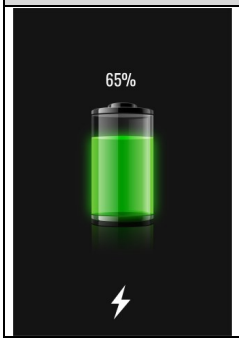
At the end of treatment, leave the I-ONE switched off and connected to the power supply until the battery charge is complete.

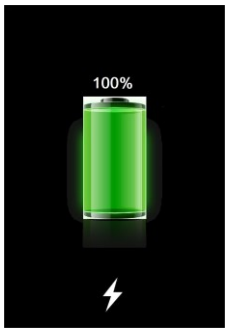
As it is normal for the battery to heat up when charging, if treatment is to be carried out whilst charging, it is recommended not to place the I-ONE in direct contact with the body.

5.4 Status indication of the device

Generator on during treatment		
Display	LED and alarms	Device status
	The LED at the top is **ON with a flashing green light** The timer appears on the display with the treatment time decreasing every minute and the white bar rotates inside the timer. The PAUSE symbol is visible below the timer. Pressing it interrupts the treatment delivery.	The I-ONE **is switched on and is providing the treatment**. The battery symbol in the top centre shows the percentage of charge remaining; it is green up to 20% and red when the capacity is > 20%.

	The **green** LED **stays on** to indicate that the I-ONE is on **PAUSE** The timer with the set treatment time appears on the display and the white bar inside the timer disappears. The **PLAY** symbol is visible below the timer. Pressing it resumes treatment.	The I-ONE **is switched on but is on PAUSE**. To resume treatment, press the **PLAY** symbol on the display. The I-ONE can also be left on PAUSE for several hours, depending on the initial battery status. If the I-ONE is paused and the battery goes low, a LOW BATTERY warning is given.
	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 for about 2 seconds.	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. At this point, the device should be switched off.
	The LED at the top flashes green (the treatment is in progress). **20% battery:** The generator beeps, the **battery symbol turns RED** and a power plug symbol appears next to it. If the battery is not charged: **5% battery:** when the level drops to 5%, the device interrupts the treatment. The battery symbol flashes and the alarm beeps every 5 seconds. **After 60 seconds, the I-ONE shuts down**.	The I-ONE is providing the treatment but the battery is almost empty and needs to be charged. The battery can be charged either during treatment delivery or after switching off the generator. **Connect the external power supply and charge the battery.**

Generator switched off during battery charging		
	When the external power supply is connected, the generator beeps and vibrates. 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. When the battery is completely empty, charging takes 2 to 3 hours depending on the battery's initial status.

	Connected power supply The generator beeps and the 100% FULL battery symbol is displayed.	The battery is charged: **disconnect the power supply**. The device switches OFF when the power supply is disconnected.

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 4 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.

5.6 Treatment times

The user must undergo the treatment for the number of days indicated by the prescribing doctor.

Clinical studies have shown that **the I-ONE treatment is effective if performed for 4 hours a day;** in any case, there are no problems or side effects due to overdosing.

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 can be carried out even whilst sleeping.

5.7 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 fully performed. Please note that it is also possible to carry out the treatment using the mains power by connecting the generator to the external power supply.
- 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 a light garment, 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. However, 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 overheated. If this is the case, perform the treatment without covering the coil.
- In any case, the generator must not be covered to allow ventilation whilst it is in operation.
- Using the device in environments with a temperature above 30°C, although possible, could cause the coil surface to slightly overheat and this may be uncomfortable for the user.
- 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.

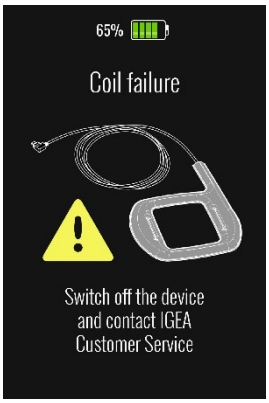
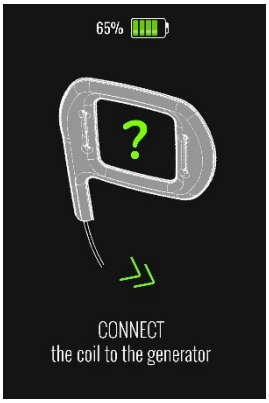
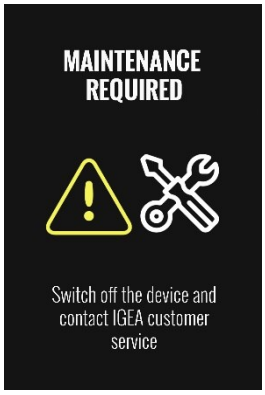
5.8 Cleaning the device

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, make sure it is **switched off and disconnected from the power supply**: the generator can be cleaned with a cloth that has been slightly dampened with neutral detergents. Do not use solvents or aggressive cleaning agents.
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 and alarms	Problem and solution
	**The LED lights up 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 lights up 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 and the PLAY button was pressed, but the coil is not connected to the generator. The user must **connect the coil to the generator** in order to resolve the anomaly and start/resume treatment by pressing the PLAY button on the screen. **NOTE: 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 I-ONE shuts down.**	The I-ONE 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 Anomalies or blocked device

6.2.1 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 as normal.
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 8 seconds.

Continuously pressing the ON/OFF button for 8 seconds causes a generator 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.

6.2.2 Blocked device 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 blocked.
Should the device become blocked and not respond to normal commands, perform a RESET as described in the previous paragraph.

6.2.3 Technical Support

In the event of a permanent failure, contact technical support to repair the device.

⚠

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. support 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 starting to use the device.
- The I-ONE 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, I-ONE 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 away from children and pets, if any.
- 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 connect any part of the device to other equipment or devices.
- Do not connect any parts to the I-ONE which are not intended for use and not supplied by the manufacturer.
- Do not handle any parts of the device with wet hands, and more specifically, do not connect the external power supply to the mains.
- 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 accidentally comes into contact with liquids, do not use the device** and return it to the support centre or the manufacturer for inspection/repair.
- It is recommended not to cover the generator during treatment delivery or charging so as to ensure ventilation.

- When using the coil under heavy blankets, the coil surface may become overheated: if the temperature of the coil causes discomfort, it is advisable to carry out the therapy without covering the coil.
- In environments where the temperature is above 30°C you may experience warming of the coil surface; if the temperature of the coil causes discomfort, it is advisable to split the daily therapy time into several sessions lasting no less than two hours each.
- Keep the generator away from the body when charging the battery.
- 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, using only 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; the generator must be cleaned when the unit 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 supplied by the manufacturer.
- Before using the external power supply, check that the casing and cable are not damaged; if they are, replace the power supply with one supplied by the manufacturer.
- Do not expose the device 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.
- 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 waives any liability.
- 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 serious accident occurring during the use of the medical device and related to it must be reported by the user to the manufacturer, 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) 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 support; 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 Support.
- 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 technical support.
- The manufacturer recommends repeating the safe tests on the device to check that safety standards are being continuously maintained, at intervals 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 I-ONE and no side effects attributable to the treatment have been observed. However, the following precautions must be taken:

- In the case of an established or presumed pregnancy, although no adverse effects attributable to the treatment have been described, treatment in the pelvic area should be avoided as a precautionary measure. In any case, always inform the doctor who prescribed the treatment, who will assess the need for continuation/interruption on a case-by-case basis.
- Pacemaker recipients may receive treatment with the I-ONE, but they must notify the prescribing doctor, who will assess whether to start/continue the treatment.
- Fewer than 2 in every 1000 patients report heat/burning during treatment. In this case, it is recommended that in the first week of treatment the daily sessions be divided up into several lasting one hour each; the treatment should then be gradually increased until the standard regimen is reached. The burning sensation disappears when the treatment is interrupted.
- While not presenting the use of the device, usually, any contraindications in conjunction with the use of medication, notify the doctor prescribing the therapy of any medications you take.
- There are no restrictions on the use of the device with simultaneous implantable medical devices (e.g. joint prostheses), 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 I-ONE has been tested and certified as compliant with medical device electromagnetic compatibility standards and declared suitable for use at home.

The I-ONE 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 I-ONE must not be used adjacent to or on top of other devices. If the I-ONE must be used in this way, the medical device must be observed to ensure it works correctly in the configuration in which it is used;
- The I-ONE must be positioned and used in accordance with the EMC information provided later in this manual.
- The I-ONE 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 I-ONE and cause undesirable alterations in the treatment signal.
- The use of accessories and cables other than those specified and supplied directly by the I-ONE manufacturer may result in increased emissions or lower immunity for the I-ONE and cause it not to work properly.
- 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 I-ONE components including cables. Failure to do so could lead to a deterioration in the performance of the medical device.
- Any 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 components of the I-ONE, including cables.

  ⚠ **Blocked device**: Electromagnetic interference, in particular electrostatic discharges of a power greater than 8kV, could alter the normal operation of the I-ONE and cause the device to become blocked.

  In the event of a blocked device, or in any case in which 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 section 6.2.

7.5 Biological safety

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

8. MANUFACTURER'S LIABILITY

The manufacturer is only responsible for the safety, reliability and performance of the I-ONE 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.
- Only the power supply unit supplied directly by the manufacturer as a spare should be used.

- The external power supply is used exclusively for the I-ONE device as described in this manual.
- Regular inspections, modifications and/or repairs are carried out 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. 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 rectangular hole on the right 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 I-ONE CBA04 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 I-ONE complies with EU Medical Device Regulation 2017/745 and is marked CE 0051 under the control of IMQ.
The I-ONE 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.

I-ONE Generator - CBA04

Power supply voltage	: 11.1 VDC
Maximum current consumption	: 0.250 A
Maximum input power	: 3 W
Classification according to EN 60601-1	: Class II device - Type BF
Classification according to MDR 2017/745 EU	: Class IIa device

Li-ion 11.1 VDC/1100 mAh or Li-ion 11.1 VDC/1350 mAh rechargeable battery

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 a polluting waste that must be disposed of according to current disposal regulations.

External power supply

Model	ME30A1541B01
Brand	SL Power
Input voltage	230 VAC (100-240)
Network frequency	50-60 Hz
Max. current input	0.150 A
Output voltage	15 VDC
Max. output current	2.0 A
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. Exclusively use the power supply unit supplied by the manufacturer.

Coil drive signal characteristics and magnetic field strength:

Signal type : Rectangular signal
Frequency : 75 Hz ± 5%
Pulse width : 1.0 ± 0.1 milliseconds
Magnetic field intensity produced : 10-18 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 > 12 mm 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 uses:

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**.

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

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.

End-of-life disposal

The I-ONE 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 1 - Electromagnetic Emissions

MANUFACTURER'S GUIDANCE AND DECLARATION - ELECTROMAGNETIC EMISSIONS		
The I-ONE - CBA04 model 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 I-ONE - CBA04 model 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 devices.
RF emissions - CISPR 11	Class B	The I-ONE - CBA04 model 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	

10.2 Table 2 - Electromagnetic Immunity

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 devices kept as far away from the I-ONE - CBA04 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 devices kept as far away from the I-ONE - CBA04 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

10.3 Immunity to proximity magnetic fields

To avoid any interference between I-ONE 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 using the device and any its part at a distance of at least 15 cm from such sources of disturbance.

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		

10.4 Immunity to proximity fields from RF wireless communication devices

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 I-ONE device 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 I-ONE 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	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						

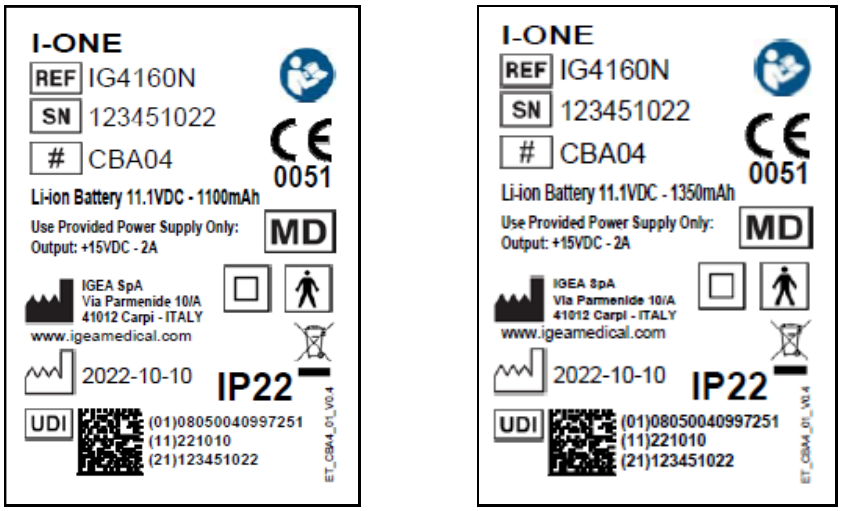
The immunity levels given in the table are met as long as the device is kept at a distance of at least 30 cm from any possible source of RF interference.

The I-ONE - CBA04 complies with all test levels with a distance >= 30 cm.

10.5 Information plate

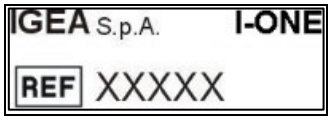
Below is an example of a generator data plate located on the rear of the body containing all the information necessary for the correct identification and use of the device.

NOTE: There can be two data plate attached to the I-ONE CBA04 generator, differing only in the type of power supply battery attached to the device.



Example of generator data plate

Shown below is the label identifying the coil, an applied part located on the cable near the connector. The identification code for each coil is given in reported in section 3.2



Example of Coil Label

N.B.: 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 nameplate 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.
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**: battery elements 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:** the 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**