I-TECH
MEDICAL DIVISION

# USER MANUAL

# I-TECH LA8000
# I-TECH LA10000


**I.A.C.E.R. Srl**
Via S. Pertini 24/A - 30030 Martellago (VE) - Italy
Tel.: (+39) 041/5401356 - Fax: (+39) 041/5402684 - Email: iacer@iacer.it - PEC: iacer@pec.it - Web: www.itechmedicaldivision.com
Vat Number: IT00185480274 - R.E.A.: VE N. 120250 - M. VE001767 - Share Capital: € 110.000,00 i.v.

# INDEX

## Information on the user manual

This manual is addressed to:

- machine user;
- owner;
- managers;
- handling personnel;
- installers;
- users;
- maintenance personnel.

It contains general information on the operation, precautionary practices, and maintenance information of the device I-TECH LA8000/10000
The user manual has to be considered as part of the device and it must be stored for future references until its disposal. The user manual must be always kept at hand for quick reference and correctly stored.
The manufacturer declines all responsibility for:

- improper use of the device;
- use contrary to specific national laws;
- incorrect installation;
- defective power supply;
- improper maintenance;
- unauthorized modifications and interventions;
- use of material or spare parts that are not specific for the model;
- partial or complete non-observance of the instructions supplied;
- exceptional events.

To get further information, consult the fabricant.

**WRITING CONVENTIONS**
Certain sections of the manual have been underlined to highlight their importance.

| **NOTE** |
|---|

These contain important information and useful tips for the utilization of the equipment.

| **CAUTIONS** |
|---|

The CAUTION message appears before operations, which, if not correctly performed, may cause damage to the machine and/or its accessories.

**!WARNING!**

This signals operations or situations, which, if unknown to the operator, or incorrectly carried out, may harm the operator.

## Manufacturer

**I.A.C.E.R. S.r.l.**

Via S. Pertini, 24/a • 30030 Martellago (VE)

Tel. 041.5401356 • Fax 041.5402684

IACER Srl. is an Italian manufacturer of medical devices (certified CE no. 0068/QCO-DM/232-2020 from the Notified Body no. 0068 MTIC InterCert S.r.l.).

## Declaration of conformity

**I.A.C.E.R. S.r.l**

Via S.Pertini 24/A – 30030 Martellago (Ve), Italia

herewith declares under its own responsibility, that the products

**I-TECH LA8000**

**I-TECH LA10000**

UMDNS Code**: 12299**

have been designed and manufactured according to the European Medical Device Directive 93/4/EEC (transposed in Italy by the D.Lgs. 46/97), as modified by the Directive 2007/47/EC (D.Lgs.37/2010) and further modifications/integrations.

The products have been assigned to class IIb, according to Annex IX, rule 9 of the Directive 93/42/EEC (and further modifications/integrations) and bear the mark

CE 0068

Compliance of the concerned products with the Directive 93/42/EEC has been assessed and certified by the Notified Body

**0068 – MTIC InterCert S.r.l.**
**Via G. Leopardi 14, Milano (MI) 20123**
Certificate no.: 0068/QCO-DM/232-2020
following the certification procedure according to Annex II (excluding point 4) of the Directive 93/42/EEC.

Martellago, 19/06/2020 — MASSIMO MARCON
*Place, date* — *Legal Representative*

## Classification

The I-TECH LA8000 e LA10000 has the following classification:

- class IIb (Directive 93/42/EEC, Annex IX, rule 9, 10 and further amendments);
- class I with B type applied part (classification EN 60601-1);
- class 4 laser (classification EN 60825-1);
- equipment unsuitable for use in presence of a flammable anesthetic mixture containing air, oxygen and nitrous oxide;
- equipment suitable for continuous operation;
- equipment unsuitable for outdoors use.

## Purpose and scope

| | |
|---|---|
| Clinical intended use: | Therapeutic |
| Environmental intended use: | Ambulatory and in hospital |

I-TECH LA8000/10000 is an electro-medical device that delivers treatments of laser-therapy, with the help of power laser up to 8000mW (10000mW for the LA10000 model) for the provision of treatment though a specific probe.
I-TECH LA8000/10000 is an active therapeutic device, not invasive, used especially by physiotherapists, physicians and pain therapists.

The use of I-TECH LA8000/10000 is reserved to those professionals, who can guarantee thanks to their training a proper and completely safe use of the device.
In fact, the operator must be properly qualified and must pass an adequate training course or he/she must operate under the guidance of a qualified

physician in order to use the device in complete safe condition for the patient under treatment.
The device can be used both in hospitals and in clinics (on adult patients of both sexes, of age unless otherwise indicated by medical doctors), unless the operator is qualified to use such equipment and the conformity to the statements declared in the manual is respected.

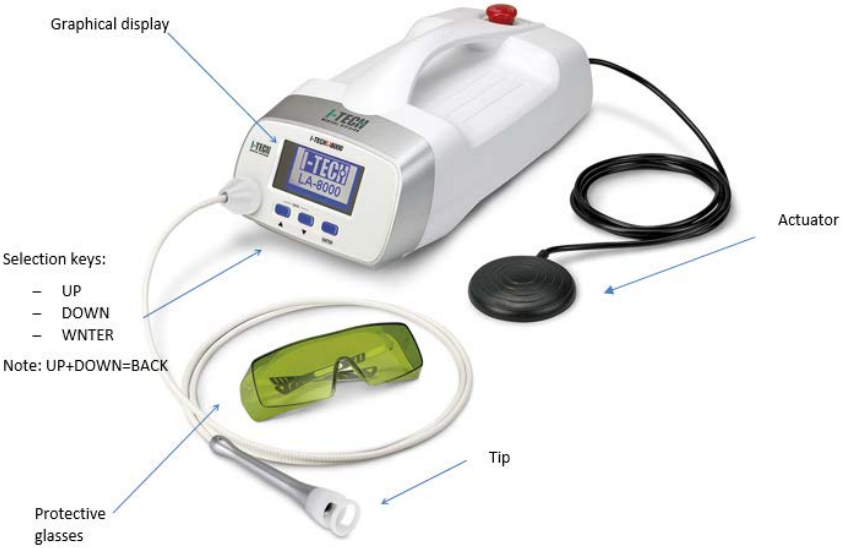
## Technical features

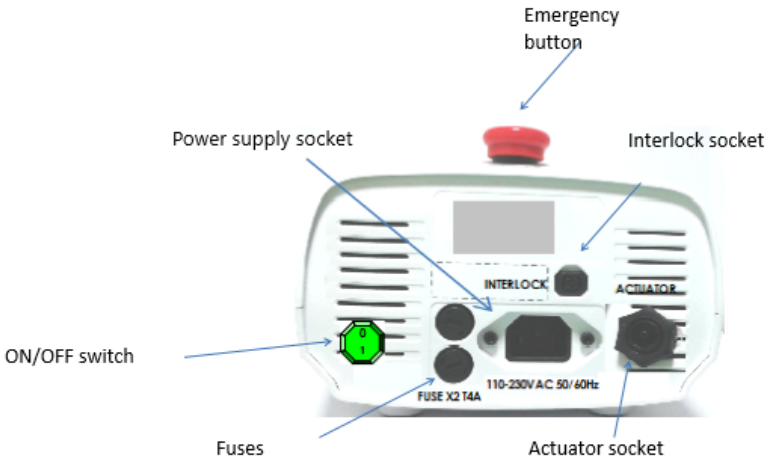
| Characteristic | | Specification |
|---|---|---|
| Mains power supply | | AC 230V; 50Hz |
| Maximum power consumption | | 40 Watt |
| Two delayed type fuses (T) | | T2.5A |
| Backlit LCD display | | 128x64 pixel graphic display |
| Power | | Settable from 1W to 8W (10W) ±3% |
| Emission wavelength of laser diode | | 974nm (±3nm) |
| Laser classification (IEC 60825-1) | | Class IV |
| DNRO (m) | | 24m ±3% |
| Dimensions of the SPOT with extended spacer | | 10mm$^2$ ±3% |
| Divergence of the beam | | 20x30 milliradians ±3% |
| Modulation | | From 10Hz to 10000Hz |
| Duty-Cycle (Modulation) | | From 10% to 90% (ON) |
| Mode | Trigger Point | From 1 to 9 points |
| | Scanning (massage) | From 25 to 200cm$^2$ |
| Classification according to Directive 93/42/EEC | | IIB |
| Output channels | | 1 - SMA panel socket |
| Classification according to EN 60601-1 | | Class I type B |
| Degree of protection against the penetration of fluids according to EN 60601-1 | | IP20 |
| Treatment activation control | | External pneumatic actuator |
| Saved protocols | | 30 |
| Programmable treatment time | | Between 1 second and 30min |

| Characteristic | | Specification |
|---|---|---|
| Free memory | | 10 |
| External dimensions (width x height x depth) | | 18x18x35cm |
| Weight of the body of the machine | | 2Kg |
| Distance between the laser emission point and the skin | | Around 38 mm |
| Spot area | | Around 10mm$^2$ ±3% |
| Operating conditions | environmental temperature | From +10°C to +40°C |
| | relative humidity | From 15 to 93% without condensation. |
| | atmospheric pressure | 500-1060 hPa |
| Conditions for storage/transport with the device in the packaging provided by the company | environmental temperature | From +5 to +40 °C |
| | relative humidity | From 15 to 93% without condensation. |
| | atmospheric pressure | 500-1060 hPa |

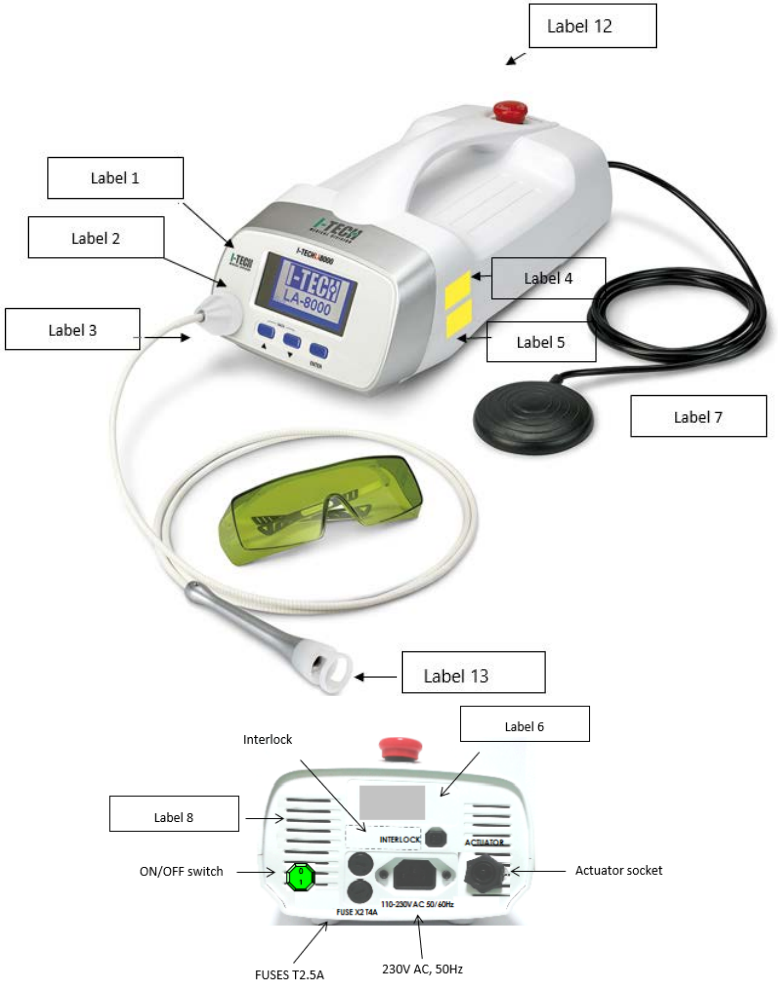
The useful life of the device is 10 years.

## Device and command description



## Labels


Label 12
Label 1
Label 2
Label 3
Label 4
Label 5
Label 7
Label 13
Label 6
Interlock
Label 8
ON/OFF switch
Actuator socket
FUSES T2.5A
230V AC, 50Hz
INTERLOCK
ACTUATOR
FUSE X2 T4A
110-230V A.C. 50/60Hz

<table>
<tr><th>Label<br>Meaning</th><th>Label<br>Meaning</th></tr>
<tr><td>LABEL 1<br>  <br>Placed on one side of the device, it indicates “Warning, laser beam”.</td><td>LABEL 2<br>I-TECH Batch n..... Date:.....<br>Probe LA8000 - LA10000<br>Placed on the connector’s tip, it indicates batch number and date.</td></tr>
<tr><td>LABEL 3<br>PROBE<br>Placed on the laser, under the fiber optics connector.</td><td>LABEL 4<br>CAUTION<br>INVISIBLE LASER RADIATION<br>AVOID EYE OR SKIN EXPOSITION TO THE DIRECT OR WIDESPREAD RADIATION<br>CLASS 4 DEVICE<br>Placed on one side of the device, in warns on the danger of the laser radiation.</td></tr>
<tr><td>LABEL 5<br>POWER: 1÷8<br>EMISSION: CONTINUE OR PULSED (10÷10000Hz)<br>DUTY CYCLE: 10÷90%<br>WAVE LENGTH: 974nm<br>Placed on one side of the device.</td><td>LABEL 6<br>Model: I-TECH LA10000<br>SN:<br>Input: AC 230V, 0.4A max, 50Hz, 40W<br>LASER CLASS 4 (EN 60825-1:2014)<br>0068<br>I-TECH MEDICAL DIVISION<br>I.A.C.E.R. S.r.l.<br>Via S.Pertini 24/A<br>30030 Martellago (VE)<br>ITALY<br>Placed on the back of the device, it resumes the principal information of the device.</td></tr>
<tr><td>LABEL 7<br>I-TECH<br>Actuator LA8000 - LA10000<br>Placed on the cable, indicates the cable.</td><td>LABEL 8<br>  <br>Placed on the back of the device, laser exit at the end of the fiber optics.</td></tr>
</table>

| Label<br>Meaning | Label<br>Meaning |
|---|---|
| LABEL 9<br>FUSES T2.5A<br>It indicates the position of the safety fuses. | LABEL 10<br>230V AC, 50Hz<br>It indicates the power supply. |
| LABEL 11<br>INTERLOCK<br>It indicates the interlock socket. | LABEL 12<br>  <br>It indicates the emergency stop button. |
| LABEL 13<br>  <br>It indicates the position of the laser aperture. | |

| Symbol | Meaning |
|---|---|
|  | Manufacturer's logo. |
|  | CE product mark released by the Notification Body no. 0068. |
|  | Class of isolation I with applied part type B according to EN 60601-1 ed. III^. |
|  | Manufacturer's information. |
|  | Manufactured date (YYYY-MM). |
|  | Consult the instructions for use. |

| Symbol | Meaning |
|---|---|
|  | The product must be disposed as “electronic waste”, in accordance to WEEE Directive on waste electrical and electronic equipment. |
| **SN** | Serial number. |
|  | Protective ground according to EN 60601-1 ed. III^. |
| **IP20** | Degree of protection against the infiltration of solids and liquids (device protected against external bodies having a diameter ≥12,5mm and against the vertical falling of water drops). |
|  | Obligation to wear protective glasses. |

### Packaging content

The I-TECH LA8000/LA10000 box contains:

- n.1 user manual,
- n.1 power supply cable, shuko plug;
- n.2 spare fuses (see table *Technical features*);
- n.1 handpiece;
- n.1 pedal;
- n.1 interlock key;
- n.1 smart-card;
- n.1 protective glasses;
- n.1 case for transportation.

Control the content of the package. If some element is missing, please contact immediately the authorized vendor.

### Note

**PRELIMINARY NOTES**

- The laser therapy equipment can be installed quickly and with ease.
  The environmental conditions for installation are as follows:
  - ambient temperature: +10 to +40°C;

- relative humidity: 15% to 93% without condensation;
- avoid direct exposure to sunlight, chemical products and vibrations.

**MAINTENANCE**

– For an optimal use of the device and to guarantee its maximum performance, it is recommended to perform maintenance at the correct time and suggested ways.

## Introduction to the technology

**The evolution of light**

The new I-TECH LA8000/10000 laser with tip permits the direct application of the laser beam to the affected area with the utmost precision. In this way, laser therapy can be carried out to effectively stimulate regeneration in the case of chronic diseases, and reduce inflammation and the edemas of acute diseases, as well as quickly alleviate joint, muscular and neurogenic pain and acute and chronic pain in soft tissue.
The I-TECH LA8000/10000, therefore, permits immediate alleviation of the symptoms of inflammation and degeneration in the fields of orthopedics, neurology and dermatology, and reduces healing time; it is also a valid form of therapy especially in the field of Sports Medicine because it permits quick recovery and healing for many professional sports-people for whom time is of the essence.

**The benefits of Laser therapy**

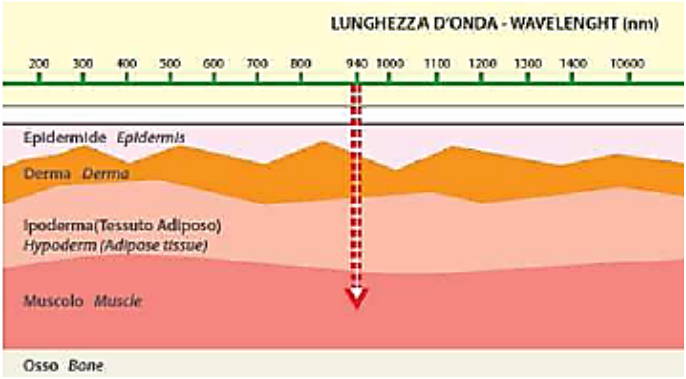
Laser therapy is based not on the development of heat but on the photochemical and photobiological effects on cells and tissue. It has been observed that the administration of the correct amount of laser light can stimulate certain cellular functions, especially in the case of cells with functional deficits. The biological action of laser therapy stimulates the cells, causing an increase in mitochondrial products such as ATP.
The I-TECH LA8000/10000 laser has various effects on treated tissue:

1. increase in blood flow: vasodilation of the capillary veins and arteries;
2. biostimulation: regeneration of tissue, stimulation of protein synthesis, stimulation of the production of ATP, stimulation of the mitosis of fibroblasts, increase in collagen and elastin;
3. anti-inflammatory effect;
4. anti-edematous effect, with stimulation of the lymphatic system;
5. analgesic effect: increase of the threshold of perception of the nerve endings.

The I-TECH LA8000/10000 is, therefore, a laser with the following characteristics:

- a power rating of up to 8000mW, in the case of the LA8000, or 10000mW, in the case of the LA10000, and a wavelength of 980nm, permitting the deep stimulation of tissue for rapid and uniform cell regeneration;
- the I-TECH LA8000/10000 permits deep stimulation for treating internal tissue and structures (like the articulation of the femur) and chronic conditions like arthritis;
- it can be used in various fields like sports medicine, orthopedics, neurology, dermatology, rheumatology, dentistry (conservative periodontics, implantology, oral pathology, surgery, scaling) and acupuncture;
- it permits recovery from acute, chronic and degenerative inflammation such as osteoarthritis.

The I-TECH LA8000/10000 can be used to effectively stimulate regeneration in the case of chronic diseases, and reduce inflammation and the edemas of acute diseases, as well as quickly alleviate joint, muscular and neurogenic pain and acute and chronic pain in soft tissue.




## Indications

The fields of application of the I-TECH LA8000/10000 laser therapy equipment are:

1. Sports traumatology
   Strained or pulled muscles, sprained joints, epicondylitis, tendinitis and enthesitis, bruising, hematomas and skin hemorrhages, bursitis.

2. Rheumatic disorders
   Arthritis, sciatica, scapular-humeral periarthritis, arthropathies of hands and feet, epicondylitis, hip arthrosis in the early stage, gonalgia with or without effusion, myogenic stiff neck, lumbago, myositis, etc
3. Rehabilitative therapy
   Articular motor rehabilitation after removing plaster casts or after orthopaedic surgical operations.
4. General medicine and dermatology
   Decubitus ulcers, cheloids, torpid sores treated thanks to its well-known biostimulating and anti-infective effects.

## Contraindications

- Direct exposure to eyes: class 4 lasers are potentially harmful to the retina; although the likelihood of damage to the retina is extremely low. The operator must, however, wear the special safety glasses (provided).
- Pregnancy: the laser must not be used above a pregnant uterus. The laser can, however, be used for pregnant women providing it is not directed at the abdomen.
- Neoplasia: do not use the laser on an undiagnosed primary or secondary lesion. Laser treatment can be used to alleviate pain during the final stage of a disease, but we recommend that this be done only with the full consent of the patient.
- Thyroid: the laser must not, for any reason, be used above this gland.
- Hemorrhages: it is possible that vasodilation caused by the laser could worsen the hemorrhage.
- Immuno-suppressive therapy: laser therapy is not recommended for patients subjected to this type of pharmacological therapy.
- In the case of suspect skin lesions: strictly avoid exposing black marks or suspect lesions on the skin to the laser.
- Treatments over the sympathetic ganglia, the vagus nerve and the heart region in patients with heart disease: laser therapy can affect the neural function to a significant degree and is, therefore, counter indicated in this region of the body in patients with heart disease.

Other contraindications:

- Atopic dermatitis and acute eczema.

- Inflammatory processes in the area to be treated.
- Cuts or scratches.
- Photoallergies.
- Photodermatitis.
- Recent surgical operations or cryotherapy in the skin areas to be treated.

### Side effects

**!Warning!**

- Photosensitivity reactions: some kind of drugs are well-known to be a potential cause of photosensibilization reactions in patients who take them. However, it is not clear how the combination of laser and drugs triggers this response. It is recommended that patients at allergic risk, or patients with a history of such reactions are "tested" with a minimum time of treatment.
- Means of fixation, metal plates, plastic DO NOT constitute contraindication to the use of lasers, which can be safely used on metallic implants, sutures and plastics.

## Warnings

Recommendations:

- Read the entire operating manual.
- The customer is held responsible for any damage due to inadequate packaging. Keep the original packaging from the machine: you will need this in the event of a return.
- Do not use the equipment near or on top of other equipment. If this is not avoidable, the operator must monitor the correct operation of the equipment.
- Do not use the equipment in the vicinity of flammable materials, solutions or gases, or in oxygen-rich environments, in order to avoid the risk of FIRE AND/OR EXPLOSION. Do not use the equipment in areas where it could get wet.
- Assess and avoid the use of accessories or of any other parts that, during normal operation, could contain elements that might explode/ignite (e.g. absorbent cotton saturated with oxygen) on contact with the laser beam.
- CAUTION: to avoid the risk of electrocution, connect this equipment to

an earthed power supply system. Check the connections carefully with reference to the instructions provided, before turning on the machine. If using the same extension for the machine and other equipment, check that the total power consumption of the connected devices does not exceed the maximum permitted current for the type of cable, which should in any case not exceed 15 A.

- Even though no particular measures are required when installing the device, carefully insert the fiber optic in the socket of the panel of the I-TECH LA8000, making sure not to touch the end of the fiber with your fingers as this could dirty the laser input and prevent the correct flow of the laser beam, causing power losses and overheating between the connection of the tip and the I-TECH LA8000.
- After carefully inserting the fiber optic in the socket, turn the locking ring clockwise to the end of its stroke without forcing it. In any case, turn the locking ring to bring the reference mark on this parallel with the one on the socket of the fiber optic.
- If the laser tip of the I-TECH LA8000 needs to be disconnected, put the protective caps back on the tip of the fiber optic and on the panel socket of the device. This is very important to protect the delicate optical parts from dust and other dirt.
- It is not possible to recommend a specific number of sessions for an efficient treatment because this depends on the amount of power used to treat the patient. The doctor must decide on the number of sessions for the patient according to the specific requirements involved, in order to guarantee effective treatment over time and conditions of absolute safety.
- Assess the quantity and type of pigment of the skin of the patient.

**USE**

- The laser radiation produced by the equipment is intrinsically dangerous: always wear protective glasses, do not direct the beam at unprotected eyes or at any optical instruments, and avoid exposing eyes to direct or diffused radiation. **Before starting any treatment, the operator must put on PROTECTIVE GLASSES.**
- Insert the INTERLOCK key in order to run the machine.
- Do not use accessories other than the original ones provided: non-original ones can damage the machine and render the warranty null and void. If any problems or difficulties arise during installation, please

contact the technical assistance service at IACER srl.

- Suggestions concerning therapy are saved on the hard drive of the machine. These cannot be deleted or modified, but the parameters can be customized in the programs available in the "Libero" (Free) section.

## Patient preparation

The skin of the patient must first be prepared for laser therapy. This is to ensure that the laser reaches the affected areas in the best possible manner, while also reducing the risk of skin irritation.
Prepare the patient's skin for therapy as follows:

1. clean the skin with care where the head of the laser is to be positioned, using either water and soap or alcohol.
2. dry the skin thoroughly.

Cleaning and disinfection must be carried out systematically before treating the patient.

## Instructions for use

### !Warning!

**PRELIMINARY NOTES**

- Use a different name for each personalized protocol, using the same name for two different personalized protocols the two different treatments with the same name will be saved.
- Before connecting the cable to the mains plug, check that the equipment isn't damaged during transport. Ensure that the power supply specifications on the main socket correspond with the information on the label attached to the back of the unit.
- Prima di iniziare qualsiasi trattamento è molto importante collegare il MANIPOLO che si desidera utilizzare nell'apposito connettore del pannello frontale.

**USE**

- DURING TREATMENT IN CONTINUOUS MODE, **IT IS FORBIDDEN TO HOLD THE HANDPIECE STILL IN ONE POSITION. IT IS ESSENTIAL TO MOVE THE HANDPIECE TO SCAN THE TREATED AREA.**
- Laser treatments must be carried out under the close supervision of the operator and with the patient fully conscious and able to provide feedback on the effects of the machine. IACER Srl cannot be held

responsible for accidents due to a failure to observe this requirement.

- USE OF THE CONTROLS, ADJUSTMENTS AND PROCEDURES OTHER THAN THOSE SPECIFIED IN THIS OPERATING MANUAL CAN CAUSE EXPOSURE TO HAZARDOUS RADIATION.
- The operator is responsible for checking that the emission head remains in contact with the affected area, in order to prevent emission of the laser into areas other than those to be treated.
- It is advisable to carry out treatment only when the machine is in perfect mechanical working order and the laser specifications are suited to the purpose (refer to the table of technical specifications).
- The device is intended to be used exclusively with the tip at 1cm distant from the skin, in order to ensure the correct distance and dimensions of the laser beam and compliance with the energy settings configured on the display. **For this reason, keep the handpiece 1cm away from the affected area during the emission of the laser**. After activating the handpiece by means of contact with the plates, avoid moving it towards or directing it at other areas. NEVER DIRECT THE HANDPIECE AT PARTS OF THE BODY THAT ARE SENSITIVE TO LASER BEAMS, LIKE THE EYES. DO NOT LOOK INTO THE BEAM OF THE HANDPIECE OR THE ONE DIRECTED OR REFLECTED DURING TREATMENT.
- Never leave the device running unattended and always turn it off after use.
- In order to avoid contamination of the work environment and/or of the people involved in its use, only use laser handpieces cleaned and disinfected with care after the previous treatment.
- It is strictly forbidden to use the device in the presence of flammable anesthetic mixtures and in environments that are rich in oxygen. IACER Srl cannot be held responsible for accidents due to a failure to observe this requirement.
- **NEVER COVER THE AIR VENTS**: THIS COULD AFFECT THE SAFETY OF THE MACHINE WHEN RUNNING. IACER SRL CANNOT BE HELD RESPONSIBLE FOR ACCIDENTS DUE TO A FAILURE TO OBSERVE THIS REQUIREMENT.
- The operator is urged to check the installation of the electrical system for the equipment before turning on the power switch.
- It is advisable to suspend therapeutic treatment if any problems arise during use.
- It is strongly recommended to turn off the machine when the

handpiece is not actively in use, in order to avoid overheating.

**WORKING PROBLEMS**

- DO NOT OPEN the unit, in it there are HIGH ELECTRIC VOLTAGE, which can be very DENGEROUS.

## Connections

At the back of the machine is an integrated power supply module. This features a three-pole connector for the power cord, a removable fuse-holder that holds two fuses (refer to *Technical features* paragraph) and a two-way main switch.
Insert the female three-pole plug of the power cord in the integrated module, making sure to fit it perfectly inside the connector.
Insert the interlock key in the dedicated connector.
Connect the pedal, inserting the connector in the relative socket on the rear panel.
Connect the handpiece in the relative socket on the front panel, fastening carefully the connector so that the mark on the connector of the handpiece will be aligned with the mark on the front panel of the device.
**ATTENTION: do not strain the connection and screw only to its limit. A wrong connection or a forced connection could damage the optical fiber of the handpiece.**
Routinely check the condition of the power cord and the cable connected to the handpiece/applicator: these must be neither damaged nor worn.

## Start-up and protection password

After installing and positioning the machine as instructed above and fitting the cable of the handpiece in the relative connector, plug the machine into the (230 Vac) mains socket and turn on the main ON/OFF switch on the rear panel.
The user interface of the device is represented by the LCD display: here are displayed the error messages, the operation messages and the functioning status of the device during the therapy treatment. Turning the device on powers the I-TECH LA8000/10000 and the backlit LCD display lights up, indicating that the equipment is ready to start.
First, the device will ask to enter the PIN (default password set to 0000); after inserting the correct PIN the display will show the main menu.

## Main menu

The I-TECH LA8000/10000 laser therapy equipment can be used in either of two work modes: with emission of the beam in POINT mode or in SCANNING mode.
POINT EMISSION permits the emission of laser points of a specific Power, Duration and Area of Action; the operator can set these data by selecting one of the therapy protocols already saved on the machine or by modifying the parameters directly as required.
SCANNING EMISSION permits manual emission of the laser beam, and in this case the following parameters can be set: *maximum emission time and power*. The OPTICAL FIBRE is used to emit the power; it is very user-friendly and guarantees a high degree of efficiency.
One of the unique features of the I-TECH LA8000/10000 is the HANDPIECE. This special device permits defocusing of the beam for treating areas of tissue of different sizes, from 0.4 to 10 $mm^2$. The equipment works most efficiently with the spacer fully extended, for a laser output of 10$mm^2$. This special HANDPIECE therefore ensures a broader range of action and a higher degree of accuracy for the anatomical area to be treated.
In the “FREE” section the operator can edit the treatment parameters at will. In particular, the parameters in question are:

- number of *Points* (1 to 9) or the *Area* to be treated (5 to 200$cm^2$).
- *Power* of the laser (1W to 8W).
- *Modulation*: continuous or cyclical supply of power; in the latter case, the Duty Cycle can also be set.
- *Density*, i.e. the amount of energy to be emitted per $cm^2$.
- *Time*, i.e. the effective duration of therapy.

Meanwhile in the “PATHOLOGY” section, the I-TECH LA8000/10000 offers the operator a list of therapy protocols that can be used to prepare specific treatments.
The protocols are based on many years of experience in offering assistance to qualified and experienced users. The various protocols are listed at paragraph *Programs’ list*. When a protocol is selected, the work parameters are summarized on the display and the user is prompted to confirm and proceed with execution by simply pressing the ENTER key and following the instructions further on.
The "Free" section on the I-TECH LA8000/10000 offers the possibility of customizing 10 protocols - 5 for "Trigger Point" mode and 5 for "Scanning"

mode; all changes can be saved in the internal memory. This means that the operator can find his/her favorite settings even after a long period of downtime.

### Program selection

Here are reported the instructions regarding selecting the appropriate program related to the pathology:

1. in the main menu, use the UP and DOWN keys to select PATHOLOGIES and press ENTER.
2. The PATHOLOGIEs window appears. Use the UP and DOWN keys to scroll through the list of recommended protocols with the specific parameters.
3. After selecting the pathology, press the ENTER key. In this section it is possible to press the BACK key to return to the main menu, scroll through the protocols (and view the details) using the UP and DOWN keys, and press the ENTER key to confirm the settings. Some of the protocols are divided into two phases; the first is in "trigger point" mode while the second is in "scanning" mode. The operator is free to choose whether to proceed with the second phase or not; the settings of the second phase appear at the end of the first one and the operator is prompted to either continue or end the session.
4. When the ENTER key is pressed, the I-TECH LA8000/10000 prompts the operator to confirm and start treatment. Pressing the ENTER key again starts activation of the laser and calibration of the work parameters. During this phase, it is essential that the fiber optic of the tip is connected to the relative socket on the panel, the interlock is enabled (when applicable) and the actuator is not pressed by anyone or anything. If these requirements are not met, the software does not activate the laser and a message flashes on the screen prompting the operator to connect the tip and check that the actuator has not been pressed. Only when these requirements are met does the I-TECH LA8000/10000 activate the laser and start therapy.
5. The I-TECH LA8000/10000 emits the laser only when the actuator is pressed. To pause the instrument during therapy, simply release the actuator: emission of the laser automatically stops and the countdown timer is paused. To continue emission of the laser,

press the actuator again. In Trigger Point mode, the software automatically calculates the time point by point and triggers three short audible signals when the point changes.

6. It is possible to end the session at any time during treatment by releasing the actuator (to pause the equipment) and pressing the ENTER key; the I-TECH LA8000/10000 automatically disables the laser and returns to the main menu.

**PROGRAMS' LIST**

| N | Name | Watts | Cycle Hz | Duty Cycle % | Timer min. | Punti (p) /Area ($cm^2$) | Joule/ $cm^2$ |
|---|---|---|---|---|---|---|---|
| 1 | Analgesic 1 | 1 | 100 | 50 | 4 | 4p | 120J |
| 2 | Analgesic 2 | 5 | 200 | 60 | 5 | 50$cm^2$ | 18J/$cm^2$ |
| 3 | Neck pain 1 | 1 | 100 | 50 | 4 | 4p | 120J |
| 4 | Neck pain 2 | 5 | 100 | 60 | 5 | 50$cm^2$ | 18J/$cm^2$ |
| 5 | Lower Back Pain 1 | 4 | 200 | 10 | 4 | 4p | 96J/$cm^2$ |
| 6 | Lower Back Pain 2 | 4 | CW | -- | 4 | 50$cm^2$ | 19J/$cm^2$ |
| 7 | Bursitis | 3 | 500 | 60 | 8 | 50$cm^2$ | 17J/$cm^2$ |
| 8 | Baker's Cyst | 3 | 1000 | 10 | 4 | 4p | 72J/$cm^2$ |
| 9 | Cruralgy | 4 | CW | -- | 8 | 100$cm^2$ | 19J/$cm^2$ |
| 10 | De Quervain syndrome | 2 | 100 | 30 | 3 | 5cmq | 21J/$cm^2$ |
| 11 | Sprains/Bruises | 4 | 500 | 50 | 10 | 50$cm^2$ | 24J/$cm^2$ |
| 12 | Acute Pain | 6 | 1000 | 60 | 6 | 50$cm^2$ | 25J/$cm^2$ |
| 13 | Chronic Pain | 6 | 500 | 60 | 10 | 50$cm^2$ | 43J/$cm^2$ |
| 14 | Oedemas | 3 | 500 | 60 | 8 | 50cmq | 17J/$cm^2$ |
| 15 | Hematomas | 3 | 1000 | 60 | 8 | 50$cm^2$ | 17J/$cm^2$ |

| N | Name | Watts | Cycle Hz | Duty Cycle % | Timer min. | Punti (p) /Area ($cm^2$) | Joule/ $cm^2$ |
|---|---|---|---|---|---|---|---|
| 16 | Large Hematomas | 5 | 1000 | 60 | 10 | 100$cm^2$ | 18J/$cm^2$ |
| 17 | Epicondylitis | 4 | 200 | 40 | 5 | 25$cm^2$ | 19J/$cm^2$ |
| 18 | Epitrochleitis | 4 | 200 | 40 | 5 | 25$cm^2$ | 19J/$cm^2$ |
| 19 | Herniated disc | 4 | 100 | 50 | 5 | 25$cm^2$ | 24J/$cm^2$ |
| 20 | Fibromyalgia | 2 | 100 | 20 | 5 | 5p | 120J |
| 21 | Fair Phototype | 4 | CW | -- | 4 | 50$cm^2$ | 19J/$cm^2$ |
| 22 | Dark Phototype | 5 | 200 | 30 | 10 | 50$cm^2$ | 18J/$cm^2$ |
| 23 | Inflammations | 4 | 100 | 20 | 15 | 50$cm^2$ | 14J/$cm^2$ |
| 24 | Ligament injuries | 2 | 100 | 50 | 5 | 25$cm^2$ | 12J/$cm^2$ |
| 25 | Muscle injuries | 4 | 500 | 30 | 5 | 25$cm^2$ | 14J/$cm^2$ |
| 26 | Meniscopathy | 2 | 500 | 50 | 2 | 5$cm^2$ | 24J/$cm^2$ |
| 27 | Sinovitis | 4 | 1000 | 30 | 6 | 25$cm^2$ | 17J/$cm^2$ |
| 28 | Muscle Strain | 6 | 500 | 30 | 10 | 25$cm^2$ | 43J/$cm^2$ |
| 29 | Tendinopathy | 2 | 100 | 40 | 2 | 5$cm^2$ | 19J/$cm^2$ |
| 30 | Carpal tunnel. | 3 | 10 | 50 | 5 | 25$cm^2$ | 18J/$cm^2$ |

## Selection of free programs

I-TECH LA8000/10000 enables the user to set manually the parameters of the protocols in FREE mode. In fact, the FREE section offers ten customizable spaces for changing the work parameters. The first 5 spaces are for treating patients in conventional "Trigger Point" mode, while numbers 6 to 10 are for treating larger areas in "Scanning" mode. The software prompts the operator to assess each parameter: it is possible to edit the parameters using UP and DOWN keys or just confirm them by pressing the ENTER key. To go back both in the main menu and for the parameters press the BACK key. The various parameters of the I-TECH LA8000/10000 are explained in the table below:

<table>
<tr><th>Free 1 to 5 - Trigger Point</th><th>Free 6 to 10 - Scanning</th></tr>
<tr><td>Points: For setting the number of points to be treated. The software permits configuration of 1 to 9 points. The treatment time is divided by the total number of points to be treated; none of the other parameters modify this value.</td><td>Area: For setting the area to be treated; the operator must move the laser SPOT in a fluid and uniform manner over the required area, simulating a massage. It is possible to set an area of between 5 and 200 cm2; none of the other parameters modify this value.</td></tr>
<tr><td colspan="2">Power: For setting the effective power of the laser beam between 1 and 8 Watts (or 10 Watts, in the case of the LA10000). This parameter does not change in relation to the other parameters.</td></tr>
<tr><td colspan="2">Cycles: For enabling and modulating the laser emission. The first choice is "Continuous", where the emission of the laser is continuous (CW), while the second choice is numerical for setting the emission frequency between 10Hz and 10000Hz. When the latter is selected, a new parameter appears to the right of the set frequency. This is for setting the Duty-Cycle between 10% and 90% of the period. These parameters do not change in relation to the other parameters.</td></tr>
<tr><td>Energy: indicates the energy to be transferred in relation to all the set parameters and is measured in Joules. This value changes whenever</td><td>Fluency: indicates the energy to be transferred per square centimeter of the set area. This value changes whenever an emission parameter is</td></tr>
</table>

| Free 1 to 5 - Trigger Point | Free 6 to 10 - Scanning |
|---|---|
| an emission parameter is modified. Only the therapy timer changes, however, when the software is modified. | modified. Only the therapy timer changes, however, when the software is modified. |
| **Timer**: sets the therapy timer. The value of the timer depends on the "Energy/Fluency" parameter. | |

After setting all the parameters, press ENTER to tell the I-TECH LA8000/10000 that all the parameters have been entered and the software prompts the operator to press ENTER to start therapy. The I-TECH LA8000/10000 then runs as indicated from step 4 in the previous section.

### End of treatment

When the ENTER key and then the actuator are pressed, the LA8000 starts the countdown TIMER. The counter and emission of the laser continue until:

- the counter ends: in the case of a normal session of therapy, the system triggers three long audible signals when the counter ends, disables the laser, and returns to the main menu to await further commands.
- Safety timer: when the I-TECH LA8000/10000 is activated and ready to emit the laser, it permits a pause (with the actuator not pressed) of no more than 3 minutes. After this length of time, the device disables the laser and returns to the main menu.
- ENTER key: during therapy, the operator can end the session at any time by pressing the ENTER key.
- Laser Stop: it is possible to end therapy at any time by pressing the emergency stop button, which shuts down the device completely.

### Last 10 programs

The device stores in its internal memory the last 10 programs used; they can be recall rapidly from the dedicated section in the main menu.

## Setup

From the main menu select SETUP using the UP and DOWN and then ENTER keys. This section allows the operator to:

- CHANGE PASSWORD: following the instructions below, the device permits to change the PIN:
  - showing in the lower part of the display the symbol “>0”, the device requests to:
    - insert the current password;
    - insert the new password;
    - insert the new password again to confirm.

    Use the UP and DOWN keys to select the first number of the PIN and then press ENTER to confirm. Repeat the same operation to change the second, third and fourth number.
  - At last press ENTER key to confirm the new password.
- POINTS MODE: in the TRIGGER POINT work modality the device allows the operator to choose the operational mode: OPERATORE MODE requests the release of the actuator by the user at each point change, meanwhile the AUTOMATIC MODE execute the same operation without the operator’s aid. Select the chosen mode using the ENTER key and BACK to return to the SETUP menu.
- INIZIALIZATION: selecting this operation with the ENTER key, the device checks the connections status.
- LASER LIFE: the device counts the effective therapy time, in order to determine the diode’s lifetime. It is a parameter useful to the manufacturer used for the device electronic problems resolution.

## Maintenance

For safety reasons, ALWAYS turn off the main switch at the back of the equipment and unplug it before carrying out any maintenance or cleaning operations.

For an effective use of the device and to guarantee the optimal performances, it is recommended to follow the maintenance instruction in the specified time and modalities. For this reason, it is advisable to carry out routine annual maintenance, checking:

- the intensity of any dispersion currents;
- the continuity and, therefore, the condition of the earth conductor;
- the accuracy of the insulation resistance value
- the conditions of guaranteed safety, in order to ensure the electrical safety of the equipment. It is advisable to entrust this kind of work to a qualified technical service or to IACER Srl or one of its authorized centers.

In order to guarantee high performance (e.g. in terms of the supply of power, the condition of the optical parts, certification of the IR Spot, the state of the optical coupling device) and the absolute safety of the operator and patient, the LA8000/LA10000 laser must be subjected to a functional test a minimum of once every 12 months, and electrical safety must be assessed in accordance with the latest edition of standard IEC62353 a minimum of once every 24 months. The tests must be entrusted to qualified technicians.

The LA8000/LA10000 laser has a software counter which alerts the need for the above-mentioned tests, when 960 hours of effective use of the laser are reached.

The operator is responsible for checking the correct operation of the buzzer during treatment. The buzzer alerts anyone else in the vicinity that therapy is in progress.

**CLEANING**

No particular detergents are required to clean the equipment. For safety reasons, ALWAYS turn off the main switch at the back of the equipment and unplug it before carrying out any maintenance or cleaning operations.

It is strictly recommended not to use diluents, detergents, acid solutions, aggressive solutions or flammable liquids to clean the external surfaces of

the machine and its accessories. The use of these substances, together with improper use of the accessories, can cause irreparable damage to the equipment and to the electrodes and render the warranty null and void.
Do not use abrasive chemical solvents or detergents for cleaning the handpiece and lens: check the head of the handpiece used for treatment for any cracks that could let liquid in. Always allow the solvents of adhesives and cleaning solvents and disinfectants to evaporate before using the laser device, especially in the case of flammable solutions, to avoid the risk of igniting the endogenous gases.
The handle of the tip can be cleaned with a neutral product. Be careful when cleaning the laser output: do not use any products but remove any impurities with a micro-fiber cloth.
After cleaning the external parts of the box, dry them with care before restarting the equipment.
Do not, for any reason, disassemble the equipment for the purpose of cleaning or inspection: there is no need to clean inside the I-TECH LA8000 machines and, in any case, the machines should be opened only by authorized, specially trained technical staff from IACER Srl.

**HANDEL CLEANING**

The optical fiber laser handpiece is a delicate component which requires suitable daily maintenance.
The following recommendations should be observed to protect the fiber and lens from damage.
IACER's recommendations:

1. use a soft cloth to remove traces of dust;
2. clean the external parts with neutral, non-abrasive products;
3. use a cloth to dry the external parts with care.

**REPLACEING THE FUSES**

In order to replace correctly the fuses on the back of the device, follow the instructions below:

- turn off the equipment;
- unplug the equipment;
- use a screwdriver to open the fuse-holder tray, making sure to insert the screwdriver in the slot of the fuse-holder tray and lever it outwards;
- remove the fuse-holder structure, sliding it along the guide;
- remove the fuses and replace them with the same number of new ones;
- insert the fuse-holder structure back in the tray, sliding it along the guide;
- close the plastic cover of the fuse-holder tray and use the tool to fasten the fuse-holder caps.

It is advisable to have the fuses replaced by staff who have received suitable technical training, in the interest of safety.

## General indications for a proper use

- After use, the operator must always turn off and unplug the equipment and check the condition of the optical fiber and the lens of the laser output on the handpiece-applicator. In the event of any damage or impurities, it is recommended to set the device aside and contact the manufacturer.
- Handle the handpiece-applicator with care: rough handling can affect its performance and characteristics. Carry the protected device in the case provided. The handpiece is connected to the device by means of a fiber optic: NEVER bend this sharply and NEVER remove or disconnect it during normal operation, and NEVER tamper with the connection cable of the handpiece. Failure to observe these requirements can result in damage to the fibers or to the beam's optical transmission system and cause injury to the patient or user.
- The technical staff are not authorized, for any reason, to open and/or disassemble the handpiece/applicator: this could result in damage to the handpiece and render the warranty null and void.
- Do not, for any reason, disassemble the equipment for the purpose of cleaning or inspection: there is no need to clean inside the machine and, in any case, the machine should be opened only by the authorized, specially trained technical staff from IACER Srl.

- NEVER allow liquids to enter the cavities. NEVER work in environments that are rich in oxygen. NEVER cover the air vents of the machine, NEVER immerse the machine in water.
- Do not spray or pour liquids on the external case of the equipment, in the air vents, on the LCD display, or in the grate of the fan. If this does occur, make sure the machine is serviced. IACER Srl cannot be held responsible for damage due to use of the machine contrary to the requirements above.
- If the laser point is missing or of reduced intensity, turn off the device and contact the technical assistance service.
- Only authorized technical staff from the manufacturer may access the internal parts of the equipment. Please contact IACER Srl or its authorized service centers for repairs and further information.

## Troubleshooting

The I-TECH LA8000/10000 laser therapy machines were designed and created using state-of-the-art technology and quality components to ensure efficient and reliable performances.
Should any operational issue occur, however, the operator is recommended to consult the guide below before contacting an authorized assistance center.

| PROBLEM | POSSIBLE CAUSE | SOLUTION |
|---|---|---|
| The LCD display on the front panel does not turn on: the equipment does not work. | The plug is not inserted properly in the mains power socket. | Check operation of the socket. |
| | The power cable is not inserted correctly in the connector of the equipment. | Insert the plug properly in the socket and the cable in the connector of the equipment. |
| | The power cable is worn and damaged. | Replace the power cable. |
| | The emergency switch is turned off. | Turn on the emergency switch. |
| | One or more of the fuses are defective or damaged. | Replace the fuse(s) that are missing, defective or damaged. |
| | The electronic control | Contact an IACER Srl |

| PROBLEM | POSSIBLE CAUSE | SOLUTION |
|---|---|---|
| | circuit is defective. | assistance center. |
| The LCD display on the front panel does not turn on. | Some components on the electronic control board are defective. | Contact the manufacturer. |
| Some of the controls on the front panel do not work properly. | Defective keys or buttons. | Contact the manufacturer. |
| | The electronic control circuit is defective. | |
| The equipment turns on, but emission of the laser is not satisfactory. | The parameters have not been set correctly. | Check the correct configuration of the work parameters. |
| | The laser sources do not work or are worn out. | Check the activation of emission of the laser sources. |
| | Some components on the electronic control circuit are defective. | Contact the manufacturer |
| | The power supply sections of the laser sources are defective. | |
| The equipment works properly but there is an evident decrease in the efficiency of treatment. | The laser sources are worn out or defective. | Contact the manufacturer |
| | The current generating circuit in the equipment may be defective. | |
| The equipment does not turn on or appears to work properly but there is no emission. | Loss of pressure in the actuator. | Check air-tightness. |

When any of the following conditions occur, unplug the equipment and contact the IACER Srl technical assistance service:

- the cable or rear integrated power supply module are worn or damaged;
- liquid has entered the equipment;
- the equipment has been exposed to rain.

- Only authorized technical staff from the manufacturer may access the internal parts of the equipment.
- Please contact IACER Srl or its authorized service centers for repairs and further information.

**!CAUTION!**

- DO NOT open the device: the HIGH VOLTAGE inside can be DANGEROUS.

## Disposal

The therapeutic laser devices I-TECH LA8000/LA10000 were designed and engineered to have minimal negative environmental impact, in consideration of their performance and safety requirements, following the disposition given by the European Directive 2012/19/EU, regarding the waste electrical and electronic equipment.
Rigorous standards were followed in order to minimize the amount of waste, use of toxic materials, noise, non-required radiation and energy consumption.
A deep research on the optimization of machine performances guarantees a significant consumption's reduction, in accordance to the saving energy principles.

This symbol means that the product shall not be disposed as domestic waste.

The correct disposal of obsolete equipment, accessories and most of all of batteries contributes in preventing possible negative consequences on human and environmental health.
The user must dispose of scrap equipment by taking it to a recognized center for recycling of electrical and electronic equipment.
For further information on the obsolete equipment disposal please contact the dedicated disposal service or the shop in which the device was bought.

## Warranty

IACER Srl guarantees a warranty period, unless information contained in this manual regarding installation, use and maintenance is strictly adhered, for 12 months from the date of purchase. For more information on the warranty please contact the distributor or vendor, in order to check the norm and standard in force in your Country, or ultimately the manufacturer IACER Srl.

During the warranty period the faulty parts will be replaced or repaired according to company discretion. The warranty does not, however, include the replacement of the equipment.

The warranty does not cover damages resulting from:

- incorrect connection and installation;
- incorrect use due to non-compliance with instructions contained in this manual;
- improper or inadequate maintenance;
- use of the machine in environmental conditions which do not conform with those specified for the product;
- unauthorized opening of the outer casing;
- tampering or unauthorized modifications;
- use of non-original accessories.

The warranty is supplied ex works.

Should you need to return the goods then please note the packing instructions as follows. Enclose a copy of the purchasing receipt. Before sending the machine back for suspected malfunction, we recommend that first you carefully consult sections regarding MAINTENANCE and TROUBLESHOOTING of the manual, as a large part of the problems and faults are usually due to inadequate maintenance or small technical problems which can often be easily solved by the user himself.

When re-packing the equipment for return to the manufacturer, proceed as follows:

1. unplug the machine and any connections, devices, applicators etc.;
2. carefully clean and disinfect all parts of the machine and accessories which have been in contact with patients. Any equipment which the technical department does not consider hygienic (Italian law D.Lgs. 81/2008 on safety in the workplace) will not be accepted;

3. disassemble accessories and any mechanical supports;
4. use original box and packing materials;
5. enclose detailed information regarding the nature of the problem to facilitate the technical department's intervention and save time on repair.

### Support

The manufacturer is the one and only allowed to operate with technical assistance. For any technical assistance contact:

**I.A.C.E.R. S.r.l.**
Via S. Pertini, 24/a • 30030 Martellago (VE)
Tel. 041.5401356 • Fax 041.5402684

Technical documentation related to repairable parts could be attached, but only with previous authorization from the manufacturer and only after giving proper training to the staff employed in technical assistance.

### Spare part

The manufacturer makes available at any time the original spare parts for the equipment. Please contact:

**I.A.C.E.R. S.r.l.**
Via S. Pertini, 24/a • 30030 Martellago (VE)
Tel. 041.5401356 • Fax 041.5402684

In order to preserve the warranty, the functionality and the security and safety of the product, it is highly recommended to use exclusively the spare parts given by the manufacturer (see also paragraph *Warnings*).

## Electromagnetic interferences and electromagnetic compatibility tables

The I-TECH LA8000/LA10000 equipment has been designed and manufactured according to the TECHNICAL STANDARD on ELECTROMAGNETIC COMPATIBILITY legislation EN 60601-1-2:2015, with the aim of providing adequate protection from harmful interference when installed in homes and health establishments.
The equipment does not generate significant radio frequency energy and is adequately immune to radiated electromagnetic fields. Therefore, it does

not detrimentally interfere with radio-electric communications, electro-medical equipment for monitoring, diagnosis, therapy and surgery, office electronic devices such as computers, printers, photocopiers, fax machines, etc. or any electric or electronic equipment used in these environments, as long as the equipment complies with the ELECTROMAGNETIC COMPATIBILITY directive.

In any case, in order to avoid any interference problems, it is recommended to use the therapy equipment enough far away from critical equipment for monitoring vital patient functions, and to be careful when applying therapy to patients with pacemakers.

**COMPATIBILITY ELECTROMAGNETIC TABLES**

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – ELECTROMAGNETIC EMISSIONS</th></tr>
<tr><td colspan="3">The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF Emissions<br>CISPR 11</td><td>Group 1</td><td>The device must emit electromagnetic energy at RF in order to perform its intended function. So its RF emissions are very low and therefore it does not affect electronic equipment placed in the surroundings.</td></tr>
<tr><td>RF Emissions<br>CISPR 11</td><td>Class B</td><td rowspan="3">The device is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions<br>EN 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions<br>EN 61000-3-3</td><td>Complies</td></tr>
</table>

| Guidance and manufacturer's declaration – ELECTROMAGNETIC IMMUNITY | | | |
|---|---|---|---|
| The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment. | | | |
| **Immunity test** | **IEC 60601-1-2 Test level** | **Compliance level** | **Electromagnetic environment – guidance** |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±6kV; +8kV a contatto ±8kV; +15kV in aria | ±6kV; ±8kV; a contatto ±8kV; +15kV in aria | Floors should be wood, concrete or ceramic made. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Transistor/Electrical fast transient IEC 61000-4-4 | ± 2kV for power supply lines | ± 2kV per power supply lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Impulses IEC 61000-4-5 | ± 1kV line to line | ± 1kV line to line | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | <5% $U_T$ (>95% dip in $U_T$) for 0,5 cycles<br><br><5% $U_T$ (>95% dip in $U_T$) for 1 cycle | <5% $U_T$ (>95% dip in $U_T$) for 0,5 cycles<br><br><5% $U_T$ (>95% dip in $U_T$) for 1 cycle | Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during |

| Guidance and manufacturer's declaration – ELECTROMAGNETIC IMMUNITY | | | |
|---|---|---|---|
| The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment. | | | |
| **Immunity test** | **IEC 60601-1-2 Test level** | **Compliance level** | **Electromagnetic environment – guidance** |
| | 70% $U_T$ (30% dip in $U_T$) for 25 cycles<br><br><5% $U_T$ (>95% dip in $U_T$) per 5s | 70% $U_T$ (30% dip in $U_T$) for 25 cycles<br><br><5% $U_T$ (>95% dip in $U_T$) per 5s | power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60Hz) magnetic field IEC 61000-4-8 | 30A/m | 30A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment |
| NOTE: $U_T$ is the AC mains voltage prior to application of the test level. | | | |

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – ELECTROMAGNETIC IMMUNITY</th></tr>
<tr><td colspan="4">The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601-1-2 Test level</th><th>Compliance level</th><th>Electromagnetic environment –guidance</th></tr>
<tr><td colspan="4">Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, unless the recommended separation distances calculated from the equation applicable to the frequency of the transmitter are respected.</td></tr>
<tr><td colspan="3"></td><td>Recommended separation distance</td></tr>
<tr><td>Conducted RF<br>IEC 61000-4-6</td><td>3V<sub>rms</sub><br>from 150kHz to 80MHz<br>6V<sub>rms</sub><br>from 150kHz to 80MHz in ISM band</td><td>3V<sub>rms</sub><br>([V<sub>1</sub>] V)<br><br>6V<sub>rms</sub><br>([V<sub>1</sub>] V)</td><td>$d = \left[\frac{3{,}5}{V_1}\right]\sqrt{P} = d = \left[\frac{12}{V_1}\right]\sqrt{P}$<br>for ISM band</td></tr>
<tr><td>Radiated RF<br>IEC 61000-4-3</td><td>3V/m<br>from 80MHz to 2.7GHz</td><td>3V/m<br>[E<sub>1</sub>]V/m</td><td>$d = \left[\frac{12}{E_1}\right]\sqrt{P}$<br>$from\ 80MHz\ to\ 800MHz$<br>$d = \left[\frac{7}{E_1}\right]\sqrt{P}$<br>$from\ 800MHz\ to\ 2.7GHz$</td></tr>
<tr><td>Radiated RF to RF wireless communication equipment<br>IEC 61000-4-3</td><td>3V/m<br>from 80MHz to 6GHz</td><td>3V/m<br>[E<sub>1</sub>]V/m</td><td>$d = \left[\frac{6}{E_1}\right]\sqrt{P}$<br>$from\ 800MHz\ to\ 6GHz$</td></tr>
<tr><td colspan="4">where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, could be less than the compliance level in each frequency range. Interference may occur near equipment marked with the following symbol:  </td></tr>
<tr><td colspan="4">Notes:</td></tr>
</table>

| Guidance and manufacturer's declaration – ELECTROMAGNETIC IMMUNITY | |
|---|---|
| The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment. | |
| (1) | At 80MHz and 800MHz, the higher frequency range applies. |
| (2) | These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. |
| a | Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the I-TECH LA8000 is used exceeds the applicable RF compliance level above, the I-TECH LA8000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the I-TECH LA8000. |
| b | Over the frequency range 150kHz to 80MHz, field strengths should be less than $[V_1]$ V/m. |

**Recommended separation distances between portable and mobile RF communications equipment, not life-supporting machines, and the device I-TECH LA8000**

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

| **Rated maximum output power of transmitter (W)** | **Distanza di separazione alla frequenza del trasmettitore (m)** | | | |
|---|---|---|---|---|
| | $from\ 150kHz\ to\ 800MHz$ | $from\ 150kHz\ to\ 800MHz$ (ISM band) | $from\ 80MHz\ to\ 800MHz$ | $from\ 800MHz\ to\ 6GHz$ (to RF wireless radio communication equipment) |
| 0.01 | 0.12 | 0.2 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.63 | 0.38 | 0.73 |
| 0.2 | – | – | – | – |
| 1 | 1.20 | 2.0 | 1.20 | 2.30 |
| 1.8 | – | – | – | – |
| 2 | – | – | – | – |
| 10 | 3.80 | 6.3 | 3.80 | 7.30 |
| 100 | 12.00 | 20 | 12.00 | 23.00 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance $d$ in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE

(1) At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

(2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.



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