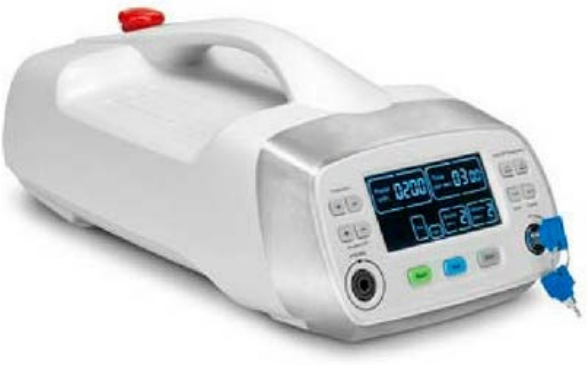
I-TECH
MEDICAL DIVISION

USER MANUAL

I TECH LA500



I.A.C.E.R. Srl

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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 LA500.
This is an essential reference guide for users. It is essential to read the manual carefully before installing and using the device and to keep it at hand for quick reference.
The manufacturer declines all responsibility for:

- improper use of the device;
- use contrary to specific national laws;
- incorrect installation;
- defective power supply;
- improper maintenance;
- unauthorised 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 product

I-TECH LA500

UMDNS Code**:** 12299

has been designed and manufactured according to the European Medical Device Directive 93/42/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 product has been assigned to class IIa, according to Annex IX, rule 9 of the Directive 93/42/EEC (and further modifications/integrations) and bears the mark

CE 0068

Compliance of the concerned product 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, Italia

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 — *Signature*

Classification

The I-TECH LA500 has the following classification:

- class IIa (Directive 93/42/EEC, Annex IX, rule 9, 10 and further amendments);
- class I with B type applied part (classification EN 60601-1);
- class 3B 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 hospitals

I-TECH LA500 is an electro-medical device that delivers treatments of laser-therapy, with the help of power laser up to 500mW for the provision of treatment though a specific probe.
I-TECH LA500 is an active therapeutic device, not invasive, used especially by physiotherapists, physicians and pain therapists.
The use of I-TECH LA500 is indicated for professional user in clinics/hospitals.
In order to guarantee the safety and security of the user, it is mandatory to strictly follow the instructions in this manual.

The device can be used both in hospitals and in clinics (on adult patients of both sexes, adults unless otherwise indicated by doctors), unless the operator is qualified to use such equipment and the conformity to the statements declared in the manual is respected.

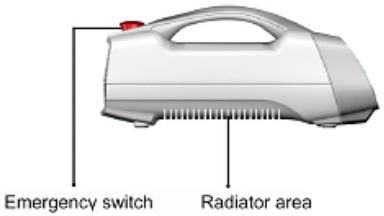
Technical features

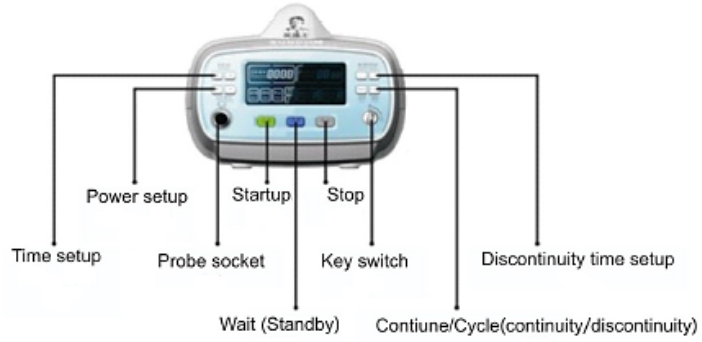
Characteristic	Specification
Power supply	AC 230V, 50-60Hz, ±10%
Protection fuse	1.5A
Maximum absorbed power	30VA
LCD display	Icons
Maximum Power	500mW ± 20%, spot diam. ≤10mm
Laser diode wavelength	810 ± 30nm
Laser classification	3B
DNRO (m)	2,3
Divergence	260mrad
Impulse duration	Set
Emission	CONTINUOUS
Adjustable percentage of emitted power	0% - 100%
Emission frequency	Set
Pulsed mode	ON/OFF (sec)
Pointing led	Red light 650nm±30nm
Classification in compliance with the directive 93/42/EEC	IIa
Output channels	1

Characteristic		Specification
Class of isolation/parts applied according to the rule EN 60601-1		I B
Protection level against liquid's penetrations according to the rule EN 60601-1		IPX0
Minimum optical density (protection factors of the glasses required at the minimum distance indicated)		N.D.dnr
Command of execution of the treatment		Button
Configuration of the laser probe		Diode probe
		Defocused
		Connection specific for the device
Adjustable treatment time		0-30 minutes
Dimensions (Length * Height * Depth)		30x15x12cm
Weight main body		5.2Kg
Conditions of use	Environmental temperature	+5 - +40°C
	Relative humidity	< 80 % without condensation
Storage/transport conditions	Environmental temperature	-10 - +55°C
	Relative humidity	<93% without condensation
	Atmospheric pressure	700-1060hPa

The useful life of the device is 5 years.

Device and command description





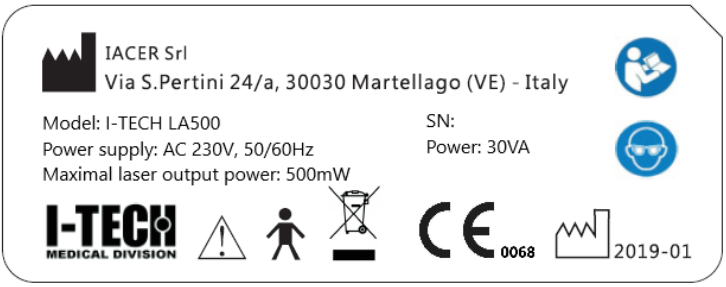
Probe

Probe cover

Electric power cable

Protective glasses
(Wear before operations)

Labels

<table>
<tr><th colspan="2">Label</th></tr>
<tr><td colspan="2"> 

It resumes the principal information of the device plus the sybols, whose meaning is reported below.</td></tr>
<tr><td> 

Warning label regarding the laser beam, placed on the back of the device.</td><td> 

Closse to the exit laser beam.</td></tr>
<tr><td> 

Close to the emergency button, it indicates the emergency stop.</td><td> 
On the back of the device, warning of the beam.</td></tr>
</table>

Symbol	Meaning
	Warning, see document in attachment with the product.
	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 information.
	Manufactured date (YYYY-MM).
	The product must be disposed as "electronic waste", in accordance to WEEE Directive on waste electrical and electronic equipment.
	Read instructions for use.
	Wear protection glasses.

Package content

The I-TECH LA500 box contains:

- N°1 mainframe;
- N°2 safety keys;
- N°1 probe;
- N°1 power cable;
- N°1 user manual;
- N°1 protective goggle.

Notes

PRELIMINARY NOTES

- The installation of the device does not require any special care, is therefore simple and immediate.

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 Laser I-TECH LA500 is equipped with a new probe that allows beam laser application directly to the treatment area. Thus, you can make sure that the laser performs its therapeutic action as an impressive regenerative stimulation in chronic pathologies, in the acceleration of the inflammation resolution and of the edema in acute pathologies, and in the rapid resolution of painful articular, muscular, neurogenic and soft tissues syndromes, both acute and chronic.
I-TECH LA500 allows an immediate improvement in the symptoms of inflammatory and degenerative pathologies in the orthopedic, neurologic, dermatologic domain and a reduction of recovery times and presents itself as an indispensable therapy, especially in Sports Medicine, since it allows rapid recovery for many sportsmen, for whom time is a determining factor in their career.

The advantages of Laser therapy

Laser therapy is not based on the generation of heat, but on photochemical and photo-biological effects on cells and tissues. Observations have shown that if the laser light is supplied in the right quantities, you will obtain a stimulation of certain cellular functions, especially in the presence of cells with functional deficiencies. The biological action in using the Laser therapy produces a series of effects on the cells in function of a “stimulating” action on mitochondrial functions with a higher production of ATP.
The applications of the I-TECH LA500 laser produce several effects on the treated tissues:

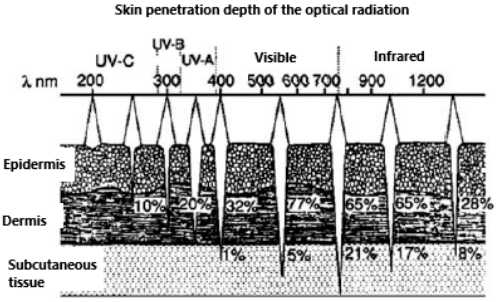
1. increase in hematic flow: vasodilatation of capillaries and arteries
2. biostimulation: tissue regeneration, stimulation of the protein synthesis, stimulation of the production of ATP, stimulation of the fibroblast mitosis, increase in collagen and elastin;
3. anti-inflammatory effect;
4. anti-edematous effect, with stimulation of the lymphatic system;

5. analgesic effect: increase in the perception threshold of nerve endings.

I-TECH LA500 is therefore a laser with the following characteristics:

- thanks to the power adjustable up to 500mW and to the 810 nm wavelength, it allows the stimulation of the deepest layers of the treated tissue, thus favoring a rapid and diffused cellular re-generation;
- with I-TECH LA500 it is possible to obtain a deep tissue stimulation and this makes possible to treat the most internal tissues and structures (such as the femoral joint) and chronic pathologies such as arthrosis;
- it may be used in many fields such as sports medicine, orthopedics, neurology, dermatology, rheumatology, odontology (conservative parodontology, medical treatment by implants, oral pathology, surgery, removal of tartar with pain) and acupuncture;
- crucial in acute, chronic and degenerative inflammations such as knee arthritis.

I-TECH LA500 carries out an important therapeutic action for the regeneration of chronic pathologies, for the acceleration of the healing process in the acute pathology of edema inflammation. Furthermore, it is very effective in the fast resolution of painful articular, muscle, neurogenic syndromes and soft tissues.



Indications

The application fields that can profit from using the laser-therapy I-TECH LA500 are the following:

1. Arthro-rheumatic pathology
   Arthrosis, sciatica, scapular and humeral periarthritis, arthropathy of hands and feet, epicondylitis, hip arthrosis at its initial stage, gonalgia with or without effusion, myogenic stiff neck, lumbago, myositis, chronic and acute pathologies etc.
2. Rehabilitative therapy
   Articular motor rehabilitation after removing plaster apparatuses or after orthopedic surgical operations.
3. General medicine and dermatology
   Decubitus ulcers, keloid, torpid sores for its well-known bio-stimulating and anti-infectious effects.

Contraindications

Laser therapy is contraindicated in the following cases:

- Direct radiation in the eyes: the human eye is extremely sensitive to laser radiation and can be permanently damaged from direct or reflected laser beams. The special safety glasses (supplied) must be worn by both patient and the operator.
- Pregnancy: the laser is contraindicated for use over the pregnant uterus. It can still be used in pregnant women with the foresight to not radiate over the abdomen.
- Neoplasms: you must not use the laser on a primary lesion or secondary non-diagnosed. Laser treatment may be granted to relieve pain during the terminal stages of the disease, but it is recommended to be performed only with the full consent of the patient.
- Thyroid: the laser should not be used in any case above this gland.
- Bleeding: vasodilatation due to laser effect may worsen the bleeding.
- Immuno-suppressive therapy: laser therapy is contraindicated in patients who have undergone such type of drug therapy.
- In the skin and injuries suspects: never laser radiate on angiomas, black points or injuries suspects on the skin.

- Treatments over the sympathetic ganglia, the vagus nerve and among the heart in patients with heart disease: laser therapy can significantly affect the heart neural functions; therefore it is contraindicated to be used on this area in patients with heart disease.

Other:

- Atopic dermatitis and eczema in the acute phase.
- Inflammatory processes in place at the site to be treated.
- Abrasions or bruises.
- Photoallergy.
- Photodermaititis.
- Recent surgery or cryotherapy in cutaneous sites to treat.

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:

- The customer is liable for all damage caused by inadequate packaging of the material. Keep the original packaging of the unit: it will be needed if the unit is returned to the company.
- Do not use the equipment in places where it might get wet.
- Before operating, check carefully the correctness of the connections according to the instructions.
- Do not use accessories other than the ones provided: they might damage the unit, causing the warranty to become void. In case you have any problems or difficulties with installation, contact

IACER Srl technical support. The perfect functionality of the appliance is guaranteed in compliance with the installation and use standards indicated, only with original accessories and spare parts.

- Always control the integrity of the cable and of the probe/applicator connector: they must not be damaged or worn.

Attention:

- If using the same extension for the unit and other units, make sure that the total current being absorbed by the connected units does not exceed the maximal current allowed for that type of cable and that, however, it does not exceed 15A.
- It is not possible to define a suggested number of sessions to evaluate the effectiveness of the treatment, since they are related to the power delivered to the treated patient. The physician is in charge of the decision on the number of therapy sessions, which will be related to the requirement of the ongoing case, in order to ensure the patient of the treatment effectiveness and its safety conduction

USE

- The laser radiation in output from the device is dangerous: always use the appropriate glasses, always avoid the exposition of the eyes to the direct or reflected laser beam**. Before beginning any treatment both operator and patient must wear the PROTECTIVE GLASSES.**
- Before switching the device on, be sure that the INTERLOCK key that allows to start up the machine is connected.
- For security reasons, the software to be downloaded in the devices are **only** the ones specific to the device in question. In case of wrong software installation, the device could immediately stop its functions, requiring the intervention of IACER Srl technical assistance.

Patient preparation

Before applying the laser therapy, it is necessary to prepare the skin of the patient. This will allow the laser light to reach better the areas to be treated and to reduce the risk of skin irritation.
To prepare the skin of the patient for the therapy, carry out the following operations:

1. wash the skin using soap and mild soap or alcohol where the head of the laser will be positioned;
2. dry well the skin.

We recommend cleaning accurately the probe cover (output lens) using alcohol and a piece of cotton at the end of each treatment to avoid the steamed up (cutaneous sebum and other) and the incrustations of the lens. Pay attention not to pour the liquids into the handle head.

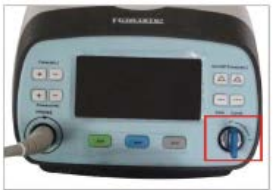
Instruction for use

CONNECTIONS

On the back of the machine is placed the power plug, which is composed of the main plug for the power supply cable and the fuse holder with two fuses (check *Technical information*).
Insert the cable in the power plug, check if the cable is correctly plugged in the power plug.
Connect the interlock to the plug placed on the back of the machine.
Connect the probe laser cable to the proper plug placed on the front of the machine.

STARTING

After the machine has been placed and installed using the instructions given in the previous paragraphs, plug the power cable into the wall socket (230V AC) and switch on the device moving the key button on the “ON” position, which is placed on the front of the machine.
This operation prepares I-TECH LA500 for use, determining the switching on of the LCD display that shows that the equipment is ready to operate. The default program is pre-set on CONTINUOS mode and the treatment time last 3 minutes.




Select the operation mode (CONTINUOS or CYCLE) using the buttons on the right side of the front panel (picture below).

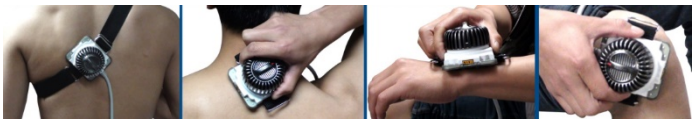

With CYCLE mode it is possible to select the ON time (from 1 to 9 seconds) and the OFF time (from 1 to 9 seconds) using the buttons on the right side of the front panel (next two pictures).


Select the treatment time using the TIME + and TIME – buttons placed on the left side of the front panel of the machine (picture below). You can select the treatment time from 30 seconds to 30 minutes.

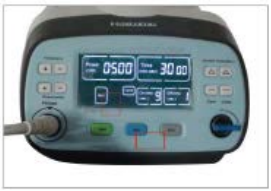
You can set treatment intensity with the POWER + e POWER – buttons placed on the left side of the front panel. The default power is set to 200mW and the range is adjustable from 10mW to 500mW in according to treatment needs.

After the power set-up, place the laser probe on the area to be treated and fasten it with the elastic belt.



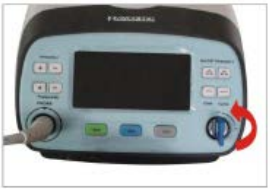


Press the WAIT button to confirm all the adjusted values: at this time, it will be not possible to modify the treatment time and the power. Press the START button to start treatment.




When the treatment will be finished, the machine will emit an intermittent signal. If you need to stop the treatment before the end, press the STOP button and the device will stop immediately the laser emission.

In case of an emergency stop press the red button placed on the back of the machine.



After the treatment switch off the device moving the key switch on the OFF position (upper picture).
Take away the key from the machine to avoid the use by unauthorized personnel.
Please do not switch off the device unplugging the cable from the power socket to avoid any type of damage to the device.

!Warning!

PRELIMINARY NOTES

- If there are problems or installation difficulties, please contact the IACER Srl technical assistance department.
- The correct position while moving the machine: the apparatus must be moved exclusively by gripping it with both hands on the curved profiles of the lid.
- If you want to install an extern interlock circuit, contact exclusively qualified technicians and supply them the scheme correspondent to the room used for the emission of the treatment. A bad installation of the device can generate serious ocular lesions.
- 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.
- The electric current that powers the unit is VERY DANGEROUS. Before connecting or disconnecting the power cable from the connecter on the unit, make sure it is plugged out from the main socket. The power cable has an earthed plug for safety reasons. Only use with a mains socket suitable for use with earthed systems. **The equipment should only be connected to electrical systems that fully comply with regulations.**

- Check the integrity and the existence of ground conductor if extensions cables are used.
- Connect the equipment directly to the wall socket without using extensions. Failure to comply with these warnings may result in dangerous electrical discharges that could cause injury operators and compromise the functioning of the unit.

USE

- The laser therapy treatments must be provided, under the strict control of the operator, patients conscious, able to interact with the operator in response to stresses transmitted by the device; in case of default to the indications given, IACER Srl shall not be consider responsible for any accidents.
- THE USE OF THE CONTROLS OR REGULATIONS OR THE EXECUTION OF DIFFERENT PROCEDURES FROM THOSE SPECIFIED IN THIS USER MANUAL CAN CAUSE THE EXPOSITION TO DANGEROUS RADIATION.
- The operator has the responsibility to verify that the issuing head remains well in contact to the zone of treatment, to avoid the emission to different areas from those to be treated.
- It is recommended not to start treatment if the machine is not in perfect mechanical condition or if the laser does not present characteristics of approved for this purpose (see the table in the *Technical Features* paragraph).
- During the delivery the handpiece must be positioned in contact with the part to be treated. After activating the handpiece through the pedal contact, avoid that it moves or is directed to different areas. THE PROBE MUST NEVER BE DIRECTED TO AREAS OF BODY SENSITIVE TO THE LASER RADIATION, FOR EXAMPLE THE EYES. ALWAYS AVOID THE EXPOSITION OF THE EYE TO THE DIRECT OR REFLECTED LASER BEAM.
- Do not leave the device switched on unattended, always switch off after use.
- Use only probes accurately cleaned and disinfected after each treatment in order to avoid environment and users' contamination.
- The use of the device is absolutely forbidden in presence of anesthetic inflammable substances and in full oxygen

environment. IACER will be not responsible if these indications will be not complied.

- It is absolutely forbidden to cover the ventilation slots: such an action may not allow the machine to work in safe conditions. In case of non-compliance with this indication, IACER will not be responsible for any accidents.
- It's important to pay the attention of the operator to the necessity to verify the correctness of the electric installation of device before activating the supply switch.
- It is advisable to suspend the therapeutic treatment if it were to appear some disturbances during its emission.
- It's strongly advised not to hold the device on in state of start without using the probe, it could overheat.

WORKING PROBLEMS

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

Maintenance

To guarantee the device's safest working conditions for the patient, we suggest sending the machine every two years to the manufacturer for a check-up.
The check-up of the system must be done only by technicians authorized by the manufacturer because specific measures machines are needed.
At the end of each treatment carefully store the probe/applicators.

CLEANING

I-TECH LA500 doesn't need any particular maintenance operation. A periodic probe maintenance and cleaning is suggested, in order to guarantee the optimal operating mode and consequently the treatment effectiveness and the patient safety.
The external cleaning of the device must be done only using a wet soft cloth, or not flammable liquid detergents. The frontal panel can be cleaned in the same way.
Unplug the device from the electric socket anytime you decide to clean the machine.
All the liquids used for cleaning the machine must evaporate before starting a new treatment, especially in case of flammable liquids, to avoid any risk of fire caused by endogenous gas.
Store carefully the handles/applicators at the end of each treatment.
Do not twist the handle's cable.
Don't let any liquid penetrate the holes.
Do not use chemical solvents or abrasive detergents.
If you need any kind of information about the original accessories and spare parts, please contact the manufacturer.
Don't sprinkle and spill any kind of liquid into the case or into the air slots placed on back of I-TECH LA500. Please don't immerse the device into the water.
After the cleaning of the box, please dry correctly all the accessories and other parts before starting a new treatment.
It is absolutely forbidden disassemble the device for cleaning or for checking inside: there is no reason for cleaning the inside of the machine I-

TECH LA500, and in any case this operation must be done only by authorized IACER technicians.

HANDLES CLEANING

The laser handle is very fragile and it needs a daily cleaning.
The following advices are absolutely important to avoid damage to the lens and the laser probe.
It is suggested to:

1. remove the dust using a soft cloth;
2. clean the area using neutral and not-abrasive products;
3. dry it accurately using a cloth.

Troubleshooting

In case of working problems, we recommend consulting the table below before contacting the manufacturer.

PROBLEM	POSSIBLE CAUSE	SOLUTION
The LCD display in the frontal panel does not turn on: the device does not work.	The power plug is inserted not correctly in the socket.	Check that the socket works properly.
	The power cable is not inserted correctly into the connector of the device.	Insert correctly the plug and the cable in the connector of the device.
	The power cable is worn out or interrupted	Replace the power cable.
	The emergency switch is off.	Turn on the emergency switch.
	Fuse/s is/are defective or interrupted.	Replace missing, defective or interrupted fuse/s.
	The control electric circuit is broken.	Contact IACER service center.
The LCD display in the frontal panel does not turn on.	Defective components in the control electric board.	Contact IACER service center.

PROBLEM	POSSIBLE CAUSE	SOLUTION
Some controls on the front control panel do not work properly.	Faulty keys or buttons.	Contact IACER service center.
	Control electronic circuit failure.	
The device does not emit the therapy.	Parameters are not set correctly.	Check that the parameters have been set correctly.
	Laser sources not working or depleted.	Check laser source emission mode.
	Faulty components in the control electronic circuit.	Contact IACER Srl assistance center.
	Faulty supply of laser sources.	
The unit works properly but with a significant decrease in efficiency of the treatment.	Faulty or depleted laser source.	Contact IACER Srl assistance center.
	Possible break down in power generator circuit of the unit.	
The equipment starts up, or seems to work properly, but there is no emission.	No safety key or the interlock circuit is open.	Insert the DIN safety key into the front socket. Reset the safety conditions.

Unplug the device from power socket and contact the manufactures in the following situations:

- the power cable or the plug placed on the back side of the machine are broken or damaged;
- a liquid is penetrated the device;
- the device has been exposed to rain.

Disposal

The therapeutic laser devices I-TECH LA500 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 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. For obvious hygienic reasons, 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 LA500 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.

See the following EMC tables.

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
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
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
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/
flicker emissions
IEC 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	**EN 60601-1-2 Test level**	**Compliance level**	**Electromagnetic environment –guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8kV contact	± 8kV contact	Floors should be wood, concrete or ceramic made. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
	± 15kV air	± 15kV air	
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 for differential mode	± 1kV for differential mode	Mains power quality should be that of a typical commercial or hospital environment.
	± 2Kv for common mode	± 2Kv for common mode	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T per 0.5 cycles, differential angles	0% U_T per 0.5 cycles, differential angles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
	0% U_T per 1 cycle	0% U_T per 1 cycle	
	70% U_T per 25/30 cycles	70% U_T per 25/30 cycles	
	0% U_T per 5s	0% U_T per 5s	
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital

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	**EN 60601-1-2 Test level**	**Compliance level**	**Electromagnetic environment –guidance**
			environment
NOTE: U_T is the ac mains voltage prior to application of the test level.			

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	**EN 60601-1-2 Test level**	**Compliance level**	**Electromagnetic environment –guidance**
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.			
			Recommended separation distance
Conducted RF IEC 61000-4-6	$3V_{rms}$ from 150kHz to 80MHz	$3V_{rms}$ from 150kHz to 80MHz	$d = 1{,}2\sqrt{P}$ $from\ 150kHz\ to\ 800\ MHz$
Radiated RF IEC 61000-4-3	3V/m from 80MHz to 2,7GHz	3V/m from 80MHz to 2,7GHz	$d = 1{,}2\sqrt{P}$ $from\ 80MHz\ to\ 800\ MHz$ $d = 2{,}3\sqrt{P}$ $from\ 800MHz\ to\ 2{,}7GHz$
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: 			

Recommended separation distances between portable and mobile RF communications equipment and the device			
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)	**Separation distance at transmitter frequency (m)**		
	$d = 1{,}2\sqrt{P}$ $from\ 150kHz$ $to\ 800\ MHz$	$d = 1{,}2\sqrt{P}$ $from\ 80MHz$ $to\ 800\ MHz$	$d = 2{,}3\sqrt{P}$ $from\ 800MHz$ $to\ 2{,}7GHz$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
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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I-TECH
MEDICAL DIVISION

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