

LASER THERAPY

I TECHLA500

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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 machine;
- 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 in order to highlight their importance.

NOTE

These contain important information and useful tips for operating 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.

WARRANTY

IACER srl guarantees the quality of its products for a period of 24 months from the date of purchase, when information contained in this manual regarding installation, use and maintenance is strictly adhered. For professional user warranty is for a period of 12 months from the date of purchase.

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 T.U.S. 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 in order to facilitate the technical department's intervention and save time on repair.

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.

CAUTIONS

PRELIMINARY NOTES

- 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 the machine carefully check 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 I.A.C.E.R. srl technical support.
- 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 max current allowed for that type of cable and that, however, it does not exceed 15 A.
- The protocols of therapeutic suggestion preloaded on the machine cannot be deleted.
- It is not possible to define a number of sessions suggested to evaluate the effectiveness of the treatment, since they are related to the power delivered to the patient undergoing treatment. It is task of the physician to decide the number of therapy sessions which subject the patient according to the specific requirements of the case, in order to ensure to the patient himself the execution of an effective treatment in time and place in conditions of absolute safety.
- Always control sometimes the integrity of the cable and of the probe/applicator connector: they must not be damaged or worn.

USE

- The laser radiation that outgoings 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.
- Because of security reasons, the only specific software must be loaded into each machine. In case of exchange of software, the machine may immediately stop all its functions, requiring the intervention of I.A.C.E.R. srl technical assistance.

! WARNINGS!

- The perfect functionality of the device is guaranteed in accordance with the rules of installation and of use included, only with original accessories and spare parts.
- If there are problems or installation difficulties, please contact the I.A.C.E.R. srl technical assistance department.
- The correct position while moving the machine: the apparatus has to 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 to generate serious ocular lesions.
- Before connecting the cable to the mains plug, check that the equipment wasn't damaged during transport. Ensure that the power supply specifications on the mains 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 connector on the unit, make sure it is plugged out from the mains 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, I.A.C.E.R. 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 zones from those to be treated.
- The laser radiation that outgoings from the device is dangerous: always use the appropriate glasses. Always avoid the exposition of the eyes to the direct or reflected laser beam.
- 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 specifications table).
- 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 operator must pay attention to the necessity of a periodic maintenance (every 2 years) of the probes/applicators. IACER srl authorised personnel should carry out such operations.
- It is absolutely forbidden in presence of anaesthetic inflammable substances and in full oxygen environment. I.A.C.E.R. 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, I.A.C.E.R.Srl 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.

INTRODUCTION OF THE TECNOLOGY

The evolution of light

The new Laser I-TECH LA 500 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 oedema in acute pathologies, and in the rapid resolution of painful articular, muscular, neurogenal 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 orthopaedic, 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.

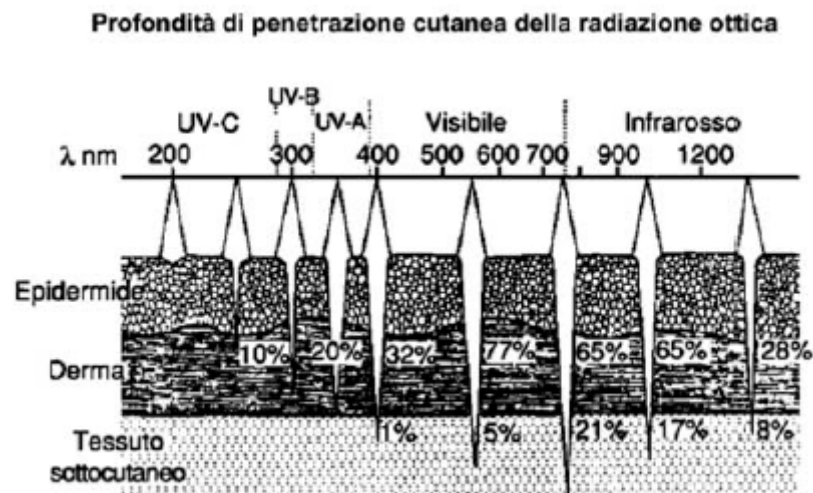
The applications of the I-TECH LA500 laser produce a number of effects on the treated tissues:

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.



INTENDED USE

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 through 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 and for home users in home environment.

The operator, in fact, should be qualified to be able to use such equipment, and he should have passed an adapted training, or should operate under the control of a medical adequately qualified to the use of the equipment, in order to guarantee safety conditions to the patient.

Such equipment can be used in hospital environment outpatient, nevertheless, it is important to know that the user follows the medical instructions to use the equipment or that he follows the indications present in the user's manual.

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 peri-arthritis, 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 orthopaedic surgical operations.

3. General medicine and dermatology

Decubitus ulcers, cheloids, torpid sores for its well-known bio-stimulating and anti-infectious effects.

CONTRA-INDICATIONS

- direct radiation in the eye: the human eye is extremely sensitive to laser radiation and can be permanently damaged from direct or reflected laser beams. The special safety glasses must be worn by both patient by 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 stage of disease, it is recommended that this be performed only with the full consent of the patient.
- thyroid: the laser should not be used in any case above the gland.
- bleeding: vasodilatation 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 radiation on angiomas, black points or injuries suspects on the skin.
- treatments over the sympathetic ganglia, the vagus nerve and region of the heart in patients with heart disease: laser therapy can significantly alter the function neural, and is therefore contraindicated in this regions body patients with heart disease.

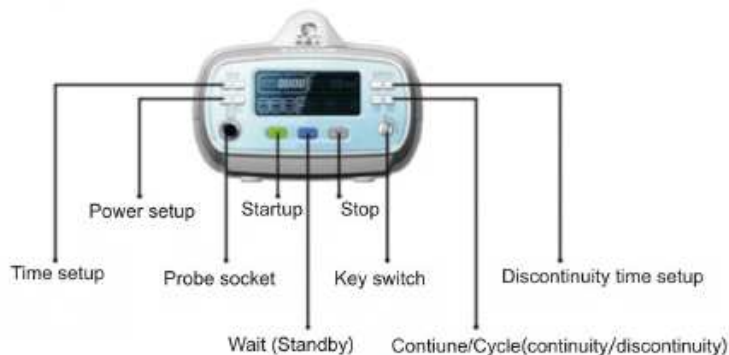
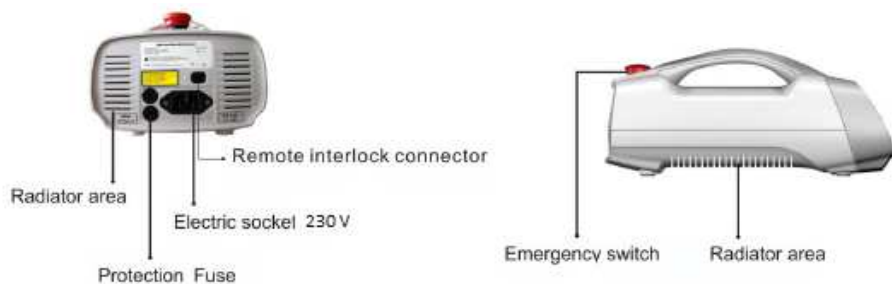
Other:

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

WARNING

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

DEVICE DESCRIPTION



Probe



Probe cover



Electric power cable



Protective glasses
(Wear before operations)

PATIENTS PREPARATION

Before applying the laser therapy, is necessary to prepare the skin of the patient. This will allow to the laser light to reach better the zones to be treated and to reduce the risk of skin irritation.

For preparing 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.

HOW TO USE IT

CONNECTORS

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 plug 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 chapters, plug the power cable into the wall socket (230 Vac) 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 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.



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

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.



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).

After the set-up of the power 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 the 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.

MAINTENANCE

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.

To guarantee the best operation of the device in safety condition for the patient, we suggest to send the machine to the manufacturer for a check-up every two years.

The check-up of the system must be done only by technicians authorized by the manufacturer because specific machines are needed.

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

All the liquids used for the cleaning of 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.

HANDLES CLEANING

The laser handle is very weak and it needs a daily cleaning.

The following advices are absolutely important to not damage 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

Do not twist the handle's cable.

Don't let any liquid penetrate into 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 start 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 I.A.C.E.R. technicians.

WORKING PROBLEM

In case of working problems, we recommend to consult the table at the paragraph TROUBLESHOOTING CHART before contacting the manufacturer .

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 into the device;
- The device has been exposed to the rain.

ELECTROMAGNETIC INTERFERENCES

The I-TECH LA500 equipment has been designed and manufactured according to the ELECTROMAGNETIC COMPATIBILITY DIRECTIVE 2004/108/CE with the aim of providing adequate protection from harmful interference when installed in homes and health establishments.

The I-TECH.AR 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 said equipment complies with the ELECTROMAGNETIC COMPATIBILITY directive.

In any case, in order to avoid any interference problems, we recommend that you operate the therapy equipment far enough away from critical equipment for monitoring vital patient functions, and that you be careful when applying therapy to patients with pacemakers.

TROUBLESHOOTING CHART

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 srl service centre.

The LCD display in the frontal panel does not turn on.	Defective components in the control electric board.	Contact IACER srl service centre.
Some controls on the front control panel do not work properly.	Faulty keys or buttons.	Contact IACER srl service centre.
	Control electronic circuit failure.	
The device does not emit the therapy.	Parameters are not setted correctly.	Check that the parameters have been setted correctly.
	Laser sources not working or depleted.	Check laser source emission mode.
	Faulty components in the control electronic circuit.	Contact IACER srl assistance centre.
	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 centre.
	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.

TECHNICAL FEATURES

Power supply:	230 Vac, 50-60 Hz, ±10%	
Maximum absorbed power	20 VA	
Double protection fuse on power supply (T):	1,5 A-T - 5 X 20 mm	
LCD display	Icons	
Maximum Power	500 mW ± 20%	
Laser diode wavelength	810 nm	
Laser classification	3B	
DNRO (m)	2,3	
Divergence	260 mrad	
Impulse duration	set	
Emission	CONTINUOUS	
Adjustable percentage of emitted power	0% - 100%	
Emission frequency	set	
Pulsed mode	ON/OFF (sec)	
Pointing led	Red light	
Classification in compliance with the directive 93/42/CEE	IIB	
Output channels	1	
Class of isolation / parts applied according to the rule EN 60601-1	I / BF	
Protection level against the liquids penetrations according to the rule EN 60601-1	IPX0	
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	
Diameter of the spot on the skin of the patient	< 10 mm	
Dimensions (Length * Height * Depth) :	30x15x12 cm	
Weight main body:	5,2 Kg	
Conditions of use	temperature environment	(+5 : +40) ° C
	relative humidity	< 80 % without condensation
Storage / transport conditions	temperature environment	(+5 : +40) ° C
	relative humidity	<93% without condensation
	Atmospheric pressure	(500 : 1060) hPa

APPENDICES

Appendix A – ENVIROMENTAL PROTECTION

The devices I-TECH LA500, were designed and engineered to have minimal negative environmental impact, in consideration of their operational and safety requirements.

Rigorous standards were followed in order to minimize the amount of waste, use of toxic materials, noise, non-required radiation and energy consumption.

A thorough research was carried out to design the unit so as to optimize power consumption in accordance with energy saving principles.



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

The user must dispose of scrap equipment by taking it to a recognized centre of recycling of electrical and electronic equipment.

Appendix B – LABELS


Symbol	Meaning
	Product certification
	Class of the equipment I BF
	Manufacturer
	Manufactured the
	Consult the user manual
	The product must be dispose of as “electronic waste”, not as “domestic waste”

Label Meaning	Label Meaning
<p>Label of “laser warning”, placed on the back side of the machine. Wavelength: 810nm Max emission power: 500mW Invisible laser radiation. Avoid direct exposure to beam. Class 3B laser</p>	<p>Label situated close to the laser aperture.</p>
<p>STOP label for Emergency</p>	<p>“Warning laser beam” label placed on the back of the machine</p>

Appendix C – ELECTRO-MAGNETIC COMPATIBILITY TABLES

Guidance and manufacturer's declaration – electromagnetic emissions FOR ALL ME EQUIPMENT		
The ME EQUIPMENT is intended for use in the electromagnetic environment specified below. The customer or the user of the ME EQUIPMENT should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF Emissions CISPR 11	Group 2	The ME EQUIPMENT must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11	Class A	The ME EQUIPMENT 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 .
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity FOR ALL ME EQUIPMENT			
The ME EQUIPMENT is intended for use in the electromagnetic environment specified below. The customer or the user of the ME EQUIPMENT should assure that it is used in such an environment.			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	- ± 6kV contact	- ± 6kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
	± 8kV air	± 8kV air	
Electrical fast transient/burst 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
	± 8kV for input / output lines	NOT APPLICABLE	
Sovra-tensioni IEC 61000-4-5	- ± 1kV line(s) to line(s)	- ± 1kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment
	± 2kV line(s) to earth	± 2kV line(s) to earth	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U _T (>95% buco in U _T) per 0.5 cicli	<5% U _T per 0.5 cicli	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ME EQUIPMENT requires continued operation during power mains interruptions, it is recommended that the ME EQUIPMENT be powered from an uninterruptible power supply or a battery.
	- <5% UT (>95% dip in UT) for 0.5 cycles	- <5% UT for 0.5 cycles	
	70% UT (30% dip in UT) for 25 cycles	70% UT for 25 cycles	
	<5% UT (>95% dip in UT) for 5 sec	<5% UT for 5 sec	
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A / m	3 A / m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
NOTE : UT is the a.c. mains voltage prior to application of the test level.			

Guidance and MANUFACTURER'S declaration – electromagnetic IMMUNITY – FOR ME EQUIPMENT THAT ARE NOT LIFE-SUPPORTING			
The ME EQUIPMENT is intended for use in the electromagnetic environment specified below. The customer or the user of the ME EQUIPMENT should assure that it is used in such an environment.			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment –guidance
Portable and mobile RF communications equipment should be used no closer to any part of the ME EQUIPMENT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
			Recommended separation distance
Conducted RF IEC 61000-4-6	3V da 150kHz a 80MHz	3V (V ₁)	$d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$
Radiated RF IEC 61000-4-3	3V/m from 80MHz to 2,5GHz	3V/m (E ₁)	$d = \left[\frac{3,5}{E_1} \right] \sqrt{P}$ from 80 to 800MHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ from 800MHz to 2,5GHz
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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,*1 should be less than the compliance level in each frequency range.*2			
Interference may occur in the vicinity of equipment marked with the following symbol : 			
NOTE 1 : At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 : These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
*1: Field strengths 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 ME EQUIPMENT is used exceeds the applicable RF compliance level above, the ME EQUIPMENT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ME EQUIPMENT .			
*2: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the ME EQUIPMENT			
The ME EQUIPMENT is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ME EQUIPMENT can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ME EQUIPMENT 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)		
	150 kHz ÷ 80 MHz	80 MHz ÷ 800 MHz	800 MHz ÷ 2.5 GHz
	$d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$	$d = \left[\frac{3,5}{E_1} \right] \sqrt{P}$	$d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

The logo for I-TECH MEDICAL DIVISION. The word "I-TECH" is in a large, bold, grey sans-serif font. The letter "I" is a solid green vertical bar. The hyphen is a smaller green square. The letter "H" has a green circle with a white outline in the center of its right vertical bar. Below "I-TECH" is the text "MEDICAL DIVISION" in a smaller, bold, black sans-serif font.

I-TECH

MEDICAL DIVISION

Head office and warehouse:

30030 MARTELLAGO (VE) – Via S. Pertini 24/A

Tel. 0039 041 5401356 – Fax 0039 041 5402684

Cod. Fisc./P.IVA IT 00185480274

R.E.A. VE N. 120250 – M. VE001767

e-mail: iacer@iacer.it Internet: www.itechmedicaldivision.com