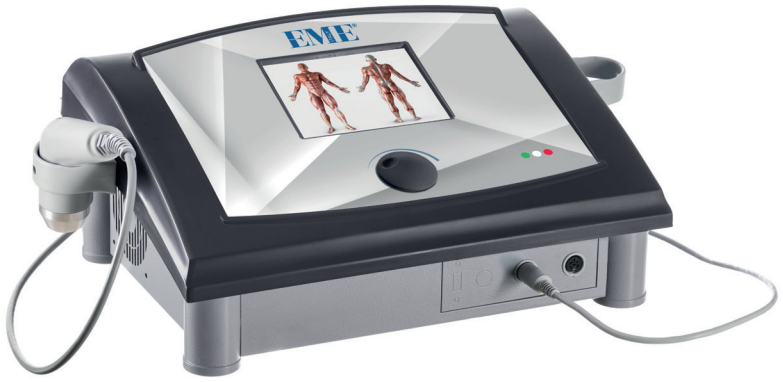
EME ITALY

LASERMED 2200

Manuale d'uso | User's manual | Mode d'emploi
Gebrauchsanleitungen | Manual de instrucciones
Руководство по эксплуатации



Italian manufacturer of physiotherapy equipment since 1983

CE 0476

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INFORMATIONS ON THE MANUAL

This manual is addressed to:

- user of the machine;

- owner;

- responsible;

-people in charge of moving;

- installers;

- users;

- people in charge of maintenance.

This document provides valuable information regarding the installation, set up and use of LASERMED.

It is a useful and essential reference guide for the user: read the contents of the manual carefully before installing the equipment and keep it on hand at all times for future reference.

It is of vital importance that you strictly adhere to the recommendations contained within the manual in order to avoid malfunction, which may cause damage to the equipment and consequent annulment of the validity of the warranty.

Furthermore, in order to obtain the highly efficient technical service available from the manufacturer, it is essential that any handling of the equipment be in accordance with the instructions provided.

The limits of this manual are:

- the user manual cannot replace proper experience;

- the instruction manual, for particularly difficult operations, can only be a reminder of the main operations.

The manual is to be considered part of the equipment and must be preserved for future reference until the decommissioning of equipment. The operating instructions must be available for consultation in the vicinity of the machine and properly stored.

This manual reflects the state of the art at the time of sale and cannot be considered inadequate because later updated based on new information. The manufacturer has the right to update products and manuals without necessarily updating preceding products or manuals unless these have no implications for the safety of the device.

The company will not assume any responsibility for any major cases:

- improper use of the machine;

- use against to specific national regulations;

- incorrect installation;

- defects in power;

- serious shortcomings in maintenance;

- changes and unauthorized interventions;

- use of parts or materials not specific to the model;

- total or partial non-observance of the instructions;

- exceptional events.

If you would like any further information, please get directly in touch with the company EME srl, to stay up to date on the best ways to use these machines and to receive the necessary assistance.

N.B. The Therapy Application Manual is available upon request.

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

EMEsrl 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 to and the warranty coupon is returned within 15 days of purchase.

The guarantee covers the replacement of faulty parts.

The warranty does not however, include the replacement of the equipment.

The warranty does not cover any malfunction or damage caused by:

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

EMEsrl registered offices provide the warranty.

Should you need to return the goods then please note the packing instructions as follows. Enclose a copy of the purchasing receipt.

You should insure the postal package.

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.

A simple call to EMEsrl technical department may prove to be the solution to the problem .

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.

USE

- Each time you click the START button or the STOP button the machine will emit a long confirmation beep.
- Each time you select the SMART-CARD will take a few seconds to allow the machine to recognize and load the card: meanwhile it shows the message PLEASE WAIT.
- The selection of the SMART-CARD is possible only if previously inserted into the slot.
- To prevent erasure or formatting of SMART CARD, confirmation is required.
- To navigate the software it is necessary to use the encoder knob that can: rotate (both clockwise and anticlockwise) by moving the selection of an option, or confirm the selection by pressing the knob itself.
- The keys shown on the display are touch.

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 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.
- To avoid the risk of electric shock, this device must only be connected to power supply networks with protective earth.

- IT'S NECESSARY TO INSERT A SAFETY CODE TO START THE DEVICE UP. The safety code is **1234**, to guarantee the safety of access to the device we suggest to change such code and to note it in a safe place to avoid to lose it or to make it available to not authorized personnel. The new code will be 4 numeric characters.
- The device is not available to the activation of some functions before having carried out some safety procedures; during this phase the pressure of any key is not considered.
- In the event of a blockage due to the intelock connector, after reconnecting the interlock in the appropriate connector, press the START key only after taking the handpiece in hand and repositioning it on the application part.
- 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.
- Check the integrity of the cable set and the cables connecting the handpiece/applicator at frequent intervals: they should never be damaged or display signs of wear and tear.
- Before operating the machine carefully check the correctness of the connections according to the instructions.
- Do not use different accessories from those provided : they could damage the unit and cause the warranty to lapse. If there are problems or installation difficulties, please contact the EME srl technical assistance department.
- If an extension lead is used with this equipment and other equipment, make sure that the total ampere absorption of all the devices together does not exceed that consented for that type of cable, and in any case does not exceed 15A.
- The therapeutic suggestions are stored in the internal memory of the device and not in user memories, the operator cannot modify this memory . The protocols of therapeutic suggestion pre loaded cannot be eliminated.
- The protocols of therapeutic suggestion preloaded on the machine cannot be deleted.
- It is not possible to define for the devices LASERMED a number of suggested sessions for to evaluate the effectiveness of the generic treatment, since they are tied up to the power emitted to the patient submitted to the treatment. The medician must to decide the number of therapeutic sessions which to submit the patient depending on the specific cases , with the purpose to guarantee to the patient the execution of an effective treatment in the time and developed under 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.
- **CLASS A device (EN 61000-3-2)** suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
- Do not use the machine near HF SURGERY DEVICES and rooms with an RF shield of an EM system for magnetic resonance, in which the intensity of the EM DISORDERS is high.
- No modification of this device is allowed.
- The use of accessories, transducers and cables, other than those specified or supplied by EME srl, could lead to higher electromagnetic emissions or a decrease in the level of electromagnetic immunity of the appliance, with consequent incorrect operation.

USE

- The Smart Card has to be introduced keeping the golden chip facing up.
- A new ***Smart- Card*** has to be initialized using **FORMATTING** before being used. (see section MEMORY).
- In case of selection of this type of memory if the card is introduced in wrong way or is not formatted or results not correct, a warning window will appear with the information about the error. Close the window clicking OK to continue.
- SMART-CARD option is visible (and therefore selectable) only if the smart-card is properly inserted in its slot. In case of lacked insertion of the Smart-card in its slot or Improper insertion, the option button SMART CARD is not visible, for which a possible selection does not involve any action.
- The selection of programs to be loaded takes place by default in the user memory, that in cases of non-presence of the Smart-card (due to its lack or to an improper insertion in its slot) is the only support of available memory to load customized programs.
- On request we can provide the user manual in electronic form.
- 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 EME srl technical assistance.
- The appliance or the system must not be used near other equipment and, if it is necessary to use it near other equipment, the medical electrical equipment must be observed to check normal operation in the configuration in which it is used.
- If the electro-medical device, interacting with another device, causes or receives detectable interferences, the user is invited to limit the interference by adopting one or more of the following measures:
    - Reorient or reposition the receiving device;
    - Increase the distance between the devices;
    - Connect the equipment to a scale of a circuit different from or to devices that cause interference;
    - Contact the manufacturer or local technician for assistance.
- Portable and mobile radiocomunication devices can affect the operation of the device.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) must not be used at a distance less than 30 cm (12 inches) from any part of the device, including the cables specified by the manufacturer. Otherwise, the performance of this equipment may be degraded

MAINTENANCE

- Handle with care the probe-applicator: rough handling can negatively affect the performance and the features.
- Not authorized EME srl personnel is never allowed to open and/or to dismantle the handful/applicator: this tampering damages the features of the probe and immediately lapse the warranty.
- The equipment should never be disassembled for cleaning or inspection purposes : the units does not have to be cleaned internally, and if for some reason the unit must be opened, it should only be done by specialized technicians authorized by EME srl .

- Do not use thinners, detergents, acid solutions, harsh solutions or flammable liquids to clean the outside of the unit and its accessories. The use of these substances, with the improper use of accessories, irreparably damages the equipment and the warranty will lapse.
- For optimal use of the apparatus and to ensure its optimum performances it is recommended to perform properly within the time and in the manner recommended maintenance actions.
- In order to make a correct substitution of the fuses housed in LASERMED unit , please follow these instructions :
    1. disconnect the power supply and open the fuse box using a screwdriver, makingsure you insert the screwdriver in the slot on the fuse box and levering up outwards;
    2. insert a screwdriver into the two side holes for fuse expulsion
    3. remove the old fuses
    4. insert a new fuse at a time by using a slight pressure to the left, with a finger
    5. push the box back to fit into the slot.
- It is advisable to carry out periodic maintenance every two years, making sure :
    - the intensity of any leakage currents
    - the emission level
    - the continuity/integrity ground wire
    - the correctness of the value of insulation resistance
    - the characteristics of the laser emission

perform such audits ensures electrical safety of LASERMED unit , ensuring that the unit operates under security conditions guaranteed, and allows you to verify the correctness of the calibration of laser diodes.

WORKING PROBLEMS

- Only technicians authorized by the manufacturer may access the interior of the unit.
- You should contact EME srl or its authorized service centres for any repair work or further information.

! WARNINGS !

PRELIMINARY NOTES

- 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.
- The device of target pointing of the probe supplied to the device is characterized by two drive-lights (led diodes), what they have a driving function, in conformity to the EN 60601-2-22 standard.
- 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.
- 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 installationdifficulties, please contact the EME srl technical assistance department.
- 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 connecter 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.**
- If using extension cords verify the presence and the integrity of the protective conductor to earth.
- 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.
- The manufacturer is held responsible for the fundamental safety, reliability and performance of the device only if:
    - The electrical system of the premises complies with the appropriate regulations;
    - The device is used in accordance with the instructions for use.

USE

- In the indicated temperature range, during normal use, laser handpieces can reach temperatures of 53 ° without endangering patient health.
- 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, EME 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 of the laser in different zones from those to be treated.
- As the laser radiation that escapes from the laser-probes for the emission of the laser-therapy treatments is invisible, the probes foresee on board the assemblage of two diodes led, of red colour.
- The two pointer LED diodes, of red colour, delimit the action area of the spot relative to the laser emission. Use the spots of the pointer-diodes as reference drive for the revealing of the position of the spot of the laser beam.
- The red led-diodes light on with the activation of the laser emission from the operator, and everyone of them they emits a pointer beam.
- The pointer-beams produce some red spot on the point of impact, and they delimit the region where it will revert the spot of the laser beam, that is invisible to human eye.
- The laser beam is always found to the centre of the axis of symmetry of the two red spots.
- 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 important that the operator ensures the machine's correct electrical installation before turning on the device. It is recommended not to start the emission of treatment if the device isn't in perfect mechanical conditions.
- During the supply the probe has to be positioned in contact with the part to treat, avoid that after the activation of the probe through the contact with the plates, this is moved 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.
- Use different names for each customized protocol, if the same name is used for two different customized protocols, the two different treatments will be saved with the same name
- Not to leave the device on and unattended, it always has to be switched off after the use.
- To avoid contamination of th use environment for LASERMED unit and/or persons involved in its use, do not apply to contact with patients laser probes that have not been thoroughly cleaned and disinfected at the end of the previous treatment.
- With the purpose to guarantee the operation of the device under conditions of absolute safety for the patient, we recommend to submit the device to a cycle of periodic verifications (lilt at least 2 years), because the device contains some parts submitted to an electric degrade or aging, as the laser source if is constantly used under conditions by maximum power.
- It is absolutely forbidden the use in presence of flammable anaesthetic mixtures. in the event of default, EME srl shall not be consider responsible for any accidents.
- 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, EME 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 be damaged.

MAINTENANCE

- For safety reasons before carrying out any maintenance or cleaning the unit, **YOU MUST** turn off the equipment with the power switch at the back and unplug the socket connected to the mains.
- Before every treatment, it is recommended to clean with caution all of the accessories and the parts of the equipment that have been to contact with the patient, particularly the ferrule of the laser probes.
- The operator must pay attention to the necessity of a periodic maintenance of the probes/ applicators, EME srl authorised personnel should carry out such operations
- The cleaning and disinfection must be done systematically before the therapeutic treatment which subject the patient.
- Do not use thinners, detergents, acid solutions, harsh solutions or flammable liquids to clean the outside of the unit and its accessories. The use of these substances, with the improper use of accessories, irreparably damages the equipment and the warranty will lapse.
- Control the integrity of the cable and of the probe/applicator connector.
- It is advised that personnel with technical preparation substitute the fuses, to perform the operation in safety conditions.
- Do NOT OPEN the unity, as HIGH VOLTAGE ELECTRICITY is present and may proveVERY DANGEROUS.
- Only personnel authorized by the manufacturer may access the internal components. For repairs and further information please contact EME srl or its authorized service centers.

WORKING PROBLEMS

- Do NOT OPEN the unity, as HIGH VOLTAGE ELECTRICITY is present and may proveVERY DANGEROUS.

INTRODUCTION TO THE TECNOLOGY

We will start by explaining the physical properties of laser in order to provide a better understanding of how it works in a medical context.

Basically, laser is a system whereby energy contained in some substances is transformed into electromagnetic radiation when stimulated electrically.

The laser radiation has some properties that do not exist in other types of electromagnetic radiation:

1) Mono-chromaticity: the laser has only one wavelength, and therefore only one vibration frequency. It also has only one colour defined by the active medium that produces it.

2) Coherency: is the property whereby all the photons emitted vibrate in phase concordance. Laser radiation is composed of waves with the same wavelength that leave at the same time and keep their phases constant in the direction of propagation.

3) Collimation: radiation is emitted from the laser in one direction only, and is diffused with a definite angle of divergence. The angular diffusion of a laser beam is very small if compared to other sources of electromagnetic radiation, since the divergence is in the order of milli-radians. The beam is practically always parallel and laser radiation can propagate for very long distances.

4) Brilliance: is the power emitted per surface unit. This equipment gives the highest intensity possible per space unit. The space can be as small as a few microns.

COMPONENTS OF LASER SYSTEM

In general, lasers comprise four structural units:

1. an active laser medium,

2. an excitation mechanism (source of energy, called "pump" source),
3. an optical cavity, comprising two mirrors and the space in between them;
4. an output mechanism;

and obviously a mechanical support structure.

Diode lasers are all made of semiconductor material and have the typical electrical properties of electric diodes.

The semiconductors can be used as a small and highly effective source of photons which can be pumped using a variety of techniques. They include pumping with other optical sources (photo-pumping), pumping with an electron beam, or pumping with a pn junction.

The most common technique is by the p-n junction. The p-n junction refers to a p type semiconductor attached to an n type. This junction conducts electricity in a preferred direction. When the positive pole of the generator is connected to the p side of the p-n junction, and the negative pole of the generator is connected to the n side, a current runs through the p-n junction changing the population of the energy band. The layers of semiconductor material are placed in such a way so as to create an active region in the p-n junction where photons are generated by a recombination process.

The base structure of a simple laser diode is shown in the following figure:

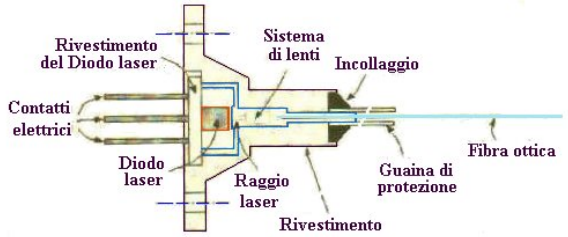


Figura a: *outline structure of a laser diode.*
by A. Vasta: *i lasers terapeutici. Marrapese ed.. Roma 1998.*
A laser generator can be connected by a metallic layer to the external surface of a stack of layers. The side of the crystalline semiconductor is cut in such a way as to allow it to be used as an optical cavity mirror.

The voltage is applied to the metal on the external layers of the semiconductor.

Since the laser diode is so small, it has a special covering that means it can be easily handled. There are different types of covering, but the standard one is similar to transistor containers. It incorporates a collimated lens that is essential for the creation of a usable beam (see figure a).

Special types of laser diodes have been developed to get high power laser diodes.

These special diodes emit synchronised radiation: an output power of a few Watts can therefore be obtained.

Diode lasers have numerous advantages:

- highly effective (more than 20 % of the input energy is emitted as laser radiation)
- high reliability and safety
- long lasting (about 100 years estimated in continuous operation)
- low cost (laser diodes are manufactured using mass production techniques in the electronics industry)
- ability to carry out direct modulation of the emitted radiation, and control the electric current that passes through the p-n junction.

FEATURES OF THE LASER RADIATION

Prameters of the laser bean

1. Frequency: this determines the average power of the laser and therefore the capacity of therapeutic lasers to penetrate tissue.
The higher the frequency, is obtained a greater penetration energy density. Clearly therefore, choosing low frequencies for analgesic purposes and high frequencies for anti-inflammatory purposes does not make scientific sense.

2. Pulse duration: the laser emission can take place in two modes:

- continuous: radiation produced by lasers is emitted without any pauses between the pulses;
- pulsed.

3. Average power (Pm): this is a function that varies according to the size, the duration and the frequency of the pulse.
The evolution towards pulse lasers is very favourable from the therapeutic point of view and for the average power, since laser penetration into the body is improved.

4. Peak power: is the maximum power that a single laser pulse can reach.
Above a certain value of between 10 and 20 W, the increase in peak power exceeds the critical energy threshold, saturates the superficial layer of the epidermal tissue, and causes burning of the skin (thermic effect), see fig.b.
The power of laser beams (both therapeutic and surgical) is higher at the centre of the beam and falls off towards the edges in a bell shaped curve (Gaussian showed in fig.c).

The power weakens towards the edges of the beam with lesser effects on the tissue hit. This phenomenon is called the alfa effect. Therefore the low power part of the beam is the reason that there is less pain and inflammation in the injuries.

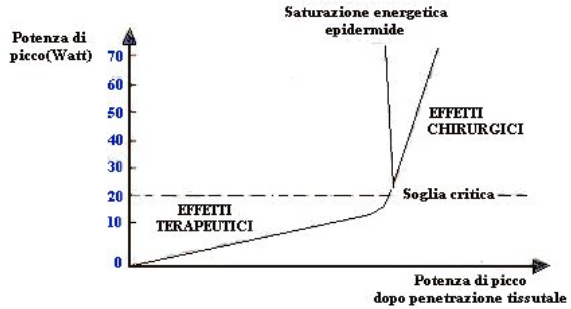


***Figure b:** : peak power and critical threshold of power in the therapeutic laser effects.*
***Da A. Vasta:** i lasers terapeutici. Marrapese Ed. . Roma,1998.*
Skin becomes saturated with energy above the critical threshold and can only be permeated at lower peak power. If power higher than 20 Watts is used, it can lead to photothermal effects which give rise to skin burning.

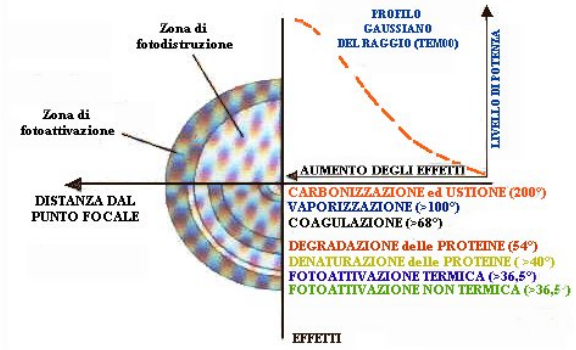


***Figure c**: illustration of a typical Gaussian distribution of laser beam power. The energy density is high at the centre of the beam (surgical laser) and decreases gradually towards the edges (therapeutic effects).*
***Da: A.Vasta:** I lasers terapeutici. Marrapese editore. Roma,1998.*

5. quantity of radiation (energy density): the quantity of radiation is the most important parameter in low power laser therapy. It is even more important than the type of laser used (visible or invisible, pulsed or continuous)**.**
The quantity of radiation means the amount of the energy that is transmitted into the tissue. It is very important to know if this energy is going to be transmitted through a small area (lets say 1 mm^2) or through an area that covers more than a few cm^2 of tissue.
In order to gain optimal therapeutic benefits in laser therapy, are also essential the following concepts:

1. For best bio-stimulation effects (in treatment of sores, burns, bruises, etc.) the radiation dose has minimum and maximum limits.

If the amount is too low, the treatment may not be effective, if the amount is too high the treatment may be either ineffective, or provoke negative effects.

2. the bio-stimulating effect is cumulative: suitable, repeated amounts given at relatively frequent intervals give a cumulative effect.

Small, repeated amounts given at 1-7 day intervals provide as powerful an effect as if the same amount of radiation was given in one treatment session only.

EFFECTS OF DIODE LASERS ON HUMAN TISSUES

1.Anti-inflammatory effect
Numerous studies have shown that laser treatment, acting on a number of different cellular and biochemical components of an inflammation, can have a significant effect on the histological, biological and clinical inflammation parameters in patients with such reactions.

2.Effects on peripheral nervous system (antalgic and regenerative effect)
Numerous studies carried out both on patients and in test tubes have shown that low energy laser irradiation can have biological effects on the central and peripheral nervous system and on its functions: increasing neuronal metabolism, re-establishing normal neuro-physiological activity, preventing neuronal degeneration and stimulating the repairing and functioning capacity of the spinal cord and peripheral nerves.

3.Bio-stimulant and tissular regeneration effect
Recent studies have demonstrated significant stimulation effects on both connective tissue and on the general mechanisms involved in tissular regeneration. The primary biological effect of He-Ne lasers on connective tissue is the rapid proliferation of fibroblasts in cellular cultures irradiated with He-Ne lasers with myo-fibroblasts being formed from fibroblasts.

4. Effect on microcirculation and blood vessels
Lasers induce improvements in local microcirculation that include relief from local spasms of the arteriolar and venular vessels (that occur, for example, after a trauma or inflammation), the intensification of blood flow in the nutritional capillaries, the opening of anastomoses and the activation of neo-angiogenesis processes.

5. Immuno-modulating effect

The human immune system activates a defense mechanism against esogenes or endogenes, such as bacteria and viruses, which are potentially dangerous for the body.

6. Enzymatic photo-activation effect
A photon can activate an enzymatic molecule that, in turn, can activate a biological process.

7. Placebo effect
It should be underlined that a number of studies have concluded that the use of infrared lasers in pain treatment may produce a significant placebo response that is worth taking into consideration.

IN GENERAL

EME srl has recently developed a complete series of apparatus, accessories and equipment, designed and manufactured according to the highest standards of quality, making use of the latest technology and fully adhering to current directives and norms.

Particular attention has been paid to the design, easy operation, function and safety of the equipment and the final result is this modern, compact unit, which offers an extremely logical operative sequence supported by a clearly legible display .

A wide range of therapeutic applications, and guaranteed patient and therapist safety ensure that LASERMED equipment is of the highest quality.

The equipment LASERMED was planned and built in manner that its use, if it happens at the conditions indicated, doesn't compromise the health and safety of the patients, of the users and of third, taking into consideration the benefit to the patient.

Such equipment are not bound to diagnosis, prevention, monitoring, compensation of injury or handicap, substitution or modification of the anatomy, control of the conception, support/vital support of functions but allow to treat special pathologies and to reduce the illness.

A special intervention is not required in the event of failure of the medical device, but just a normal maintenance/repair.

INTENDED USE

The LASERMED 2200 unit is an electro-medical device that deliver laser-therapy treatments, with the help of mono-diode and multi-diode probes for the provision of treatment.

Lasertherapy devices are non-invasive therapeutic active devices, used mainly by physiatrists, physiotherapists, and pain therapists.

The use of these equipments is reserved, under the supervision and responsibility of an expert in the problems of the laser radiation, for operators that, by their training, provide assurance of proper use and safe for the patient.

In fact, the operator must be appropriately qualified and he carefully studied the contents of the user manual in order to use the device; or, it must operate under the supervision of a health professional adequately qualified to use the machine, able to understand the benefits and the limits of therapy and to work in conditions of safety for the person undergoing treatment.

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

LASERMED is a machine produced according to the Directive MED 93/42/EEC concerning medical devices.

INDICATIONS

Laser therapy treatments are applied under the following conditions:

- Rheumatology: beneficial effects of laser radiation have been reported in the case of rheumatoid arthritis, rheumatic and degenerative diseases. About the Bechterew's disease, that mainly affects the spine, the laser takes a therapeutic significance in the early stages of the disease, when it has not yet come to the fibrosis and ankylosis of the affected joints
- Orthopedic: analgesic effects in the case of radial and ulnar epicondylitis, analgesic action in case of tendinitis of the rotator cuff, significant pain improvement in lumbago, discal syndromes and radiculitis. In case of pain syndromes of the shoulder, the laser should be made only after a careful diagnosis, and it is effective only in the musculoskeletal forms and not in joint forms (biceps tenosynovitis, muscle trauma or local fibromiopatie) and articular (inflammatory, degenerative, traumatic). On the other side, neurovascular forms are indicated for laser treatment such as radiculitis, carpal tunnel syndrome, cervical brachialgia. All other forms should avoid laser treatment because not effective.
- Bruises: are treated with laser those with sequelae, the most serious or that you want to solve as soon as possible.

- Dermatology: in the case of pressure ulcers and diabetic, the laser accelerates and promotes the healing process, inhibits the presence of microbial superinfections, has a hyper-emetogenic with improved wound cleansing. The positive influence of low-power laser therapy on the healing time and healing itself is significantly positive both on the healing of venous stasis, that pain on edema and hyperemia of the skin. The irradiation with the laser decreases the itching sensation in the case of atopic dermatitis, improves skin rashes, decreases in epidermal cells the biological reactions of the disease. The laser would intervene on the pathogenesis of hypertrophic scar by inhibiting the inflammatory response continues, which causes increased production of connective tissue, and reducing the tension of the skin edges.
- Neurology: Neurology: carpal tunnel syndrome, muscle-intensive headache, phantom limb or facial causalgia and neuralgia.
- Laser acupuncture: different acupuncturists have become enthusiastic about the use of low-power laser in the stimulation of acupuncture points. The idea of applying the laser in this way has an obvious interest since the treatment is painless, and cost-effective in children or in those who are afraid of needles and also because there is no risk of infection or other (bleeding, fainting, seizures, anatomical damage). At the level of the acupuncture points of the semiconductor laser seem more effective and suitable for their emission mode, more easily modulable.

CONTRA-INDICATIONS

- Direct eye radiation: class 3B lasers are potentially harmful to the retina, although retina damage is extremely improbable. The special safety goggles (supplied) must always be worn by both the patient and the operator.
- Pregnancy: the laser should not be used over a pregnant woman's uterus. It can be used on pregnant women on condition that there is no radiation over the abdomen.
- Neoplasy**:** do not use the laser over primary or secondary wounds that have not been diagnosed. Laser treatment may be used to relieve pain in the final stages of the illness. It should only be performed with full patient consent.
- Thyroid**:** laser must never be used over the thyroid.
- Haemorrhages**:** indirect laser vaso-dilatation may worsen the haemorrhaging.
- Immunosuppressive therapy: do not use laser therapy on patients undergoing this type of pharmacological treatment.
- Treatment over the sympathetic nervous system, the vagus nerve and the heart area in patients with heart disease: laser therapy can significantly modify neural functions and should not be used over these areas of the body in patients with heart disease.
- Photosensitive reactions: patients who use certain types of medicine can display photosensitive reactions. It is not fully understood how the combination of laser and medicine trigger these reactions. Patients who may be at risks for allergies, or who have a history of these reactions, should first be "tested" by applying treatment for a minimal time period.
- Means of attachment, metallic or plastic plates CAN be used with lasers, and patients with metallic and plastic implants, stitches can safely avail of laser treatment.
- Coagulation problems.
- Epilepsy.

PRELIMINARY NOTES

UNPACKING

The equipment is specially packaged for transport in a single pack complete with filling which has been specifically studied for safe transportation and storage.

To remove the equipment from the pack, place the box on a smooth, flat surface. Open the top of the box and remove the polystyrene filling. Be very careful when removing the contents of the pack.

The unit and accessories are wrapped in transparent sheets of polyethylene protection and contains the following:

- the User Manual;
- n.1 mains power supply cable;
- n.2 spare fuses (see technical specifications);
- n.1 laser probe;
- n.1 interlock;
- n.1 pairs of safety goggles;

Check the contents of the package and should any of the items be missing then contact your local authorized EME srl dealer.

SETTING UP

Installation of the laser therapy equipment is fast and simple.

The following environmental conditions are ideal when installing the equipment:

- room temperature: from +10° to +40°C;
- humidity level: from 10% to 80% without condensation;
- avoid direct exposure to sunlight, chemical products and vibrations
- avoid using RF wireless communication devices in proximity (<0.30m).

If the device is used at an ambient temperature above 35 °, it is not possible to use the device by setting the maximum power value since the laser handpiece can reach temperatures of 53 °. In this case, set a power value equal to 50% of the maximum allowed value.

If the client requires an external safety interlock is necessary to expect a twisted pair cabling of diameter 0.6mm minimum and 20mm maximum, with screen connected to ground.

At the side safety circuit it necessary to plan the creation of a micro-switch to a via normally closed .

Such circuit is an external safety accessory: it allows to interrupt the laser therapy treatments if the door of the treatment room has been opened .

If the treatment room has only one door, the referring diagram is the following one :

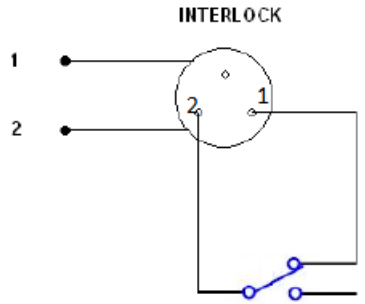


Figure d

If the treatment room has more than one door, the referring diagram is the following one :

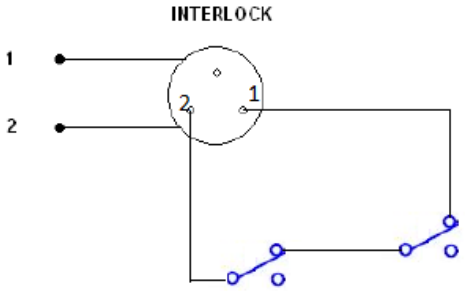


Figure e

ACCESSORIES

The devices can be used with the following accessories:

Description	Supplied	Optional
Power cable supply	**1**	
Spare FUSES (see technical specifications)	**2**	
Interlock	**1**	
User manual	**1**	
OLV safety goggles	**1**	
Laser probe 905 nm - 1 diode 100 mW	**1**	
Probe holder	**1**	
Screw	**1**	
OLV safety goggles		x
Orthostatic arm		x
Laser probe 905 nm - 3 diode 300 mW (300 mW total)		x
Laser probe 905 nm - 5 diode 500 mW (500 mW total)		x
Smart Card		x
LEGENDA: x=optional, NUMERO=quantità fornita in dotazione		

The ACCESSORIES that can be replaced by the RESPONSIBLE ORGANIZATION and that can influence the conformity of the EM EQUIPMENT:

Shielded cable for handpiece connection. The cable length must be less than 3m.

The main features that the operator / patient safety glasses must possess are the following:

- Wavelength: 808-905 nm
- Gradation number: 5
- Optical class: 1
- Densità ottica (λ=808nm): 3.523
- Densità ottica (λ=905nm): 4.456
- CE marking

The accessory installing is simple and intuitive: each cable for the therapy, that allows the connection with the outlet channel, is equipped with a multi-pin connector to be inserted into the socket on the front panel of the device.

Contact authorised dealears EME srl for problems or difficulty installation.

The device is supplied with a security key (interlock) consists of a special DIN pin to be inserted in the appropriate DIN socket on the back of the equipment. You must use a 1-way micro-switch that is normally turned off, for the safety interlock.

The unit DOES NOT WORK WITHOUT THE INTERLOCK SAFETY KEY.

The presence of such socket allows also to remote the safety contacts; particularly the safety key works by cutting off both the invisible laser emission, and the power of the leds pointing red.

In the event of a blockage due to the intelock connector, after reconnecting the interlock in the appropriate connector, press the START key only after taking the handpiece in hand and repositioning it on the application part.

The smart-card is provided to the “personalization” of the user programs. The device should be used with only smart-card supplied.

CONNECTIONS

The power entry module can be found on the back of the unit and consists of a three-pole socket for the cable set, an extractible fuse box with two fuses (see technical specifications) and the main switch. Plug the power supply cable three-pin plug into the integrated board and ensure that it is correctly plugged into the connector.

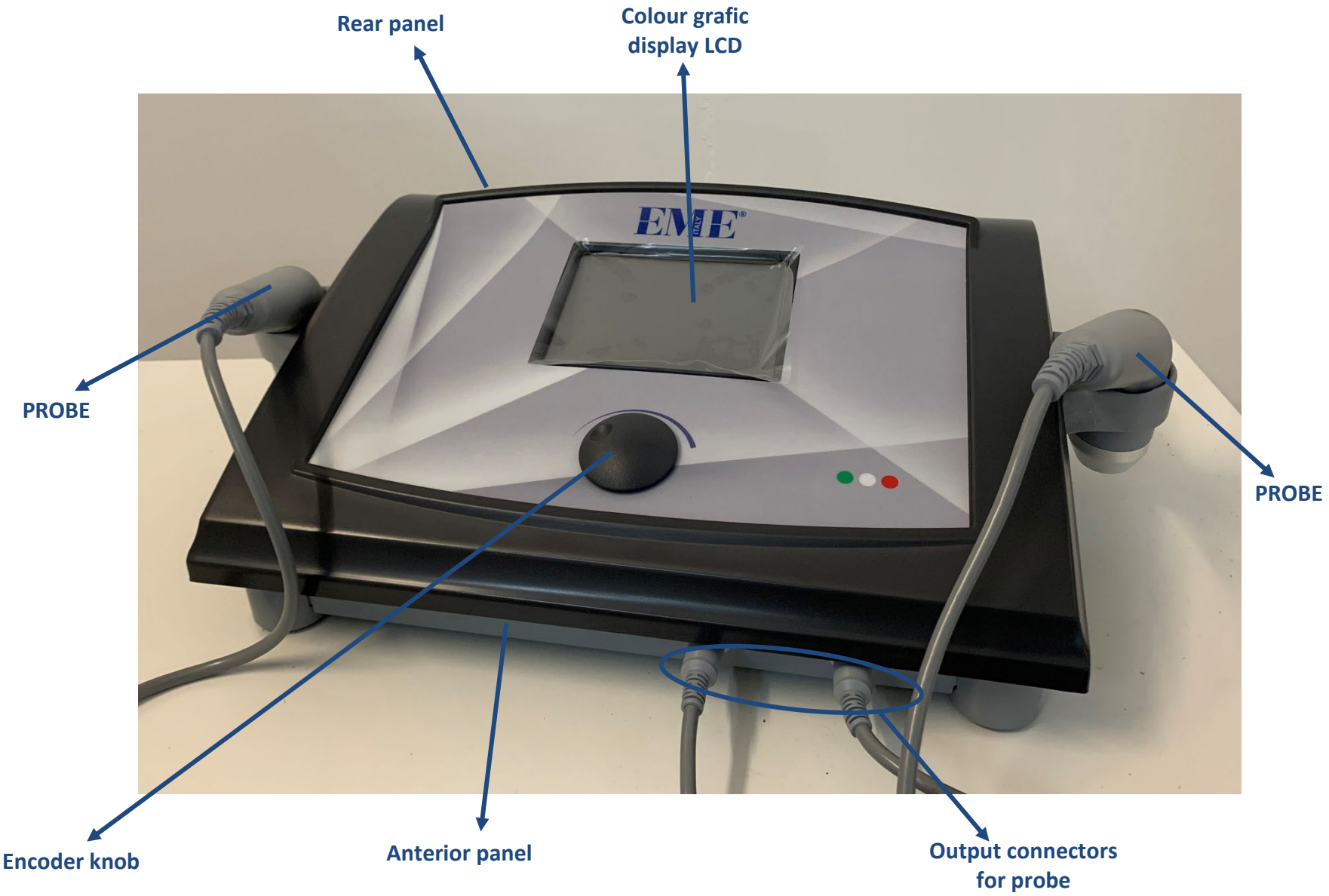
Insert the key into the INTERLOCK connector in the back panel of the device.When using an extension lead, make sure that it has been earthed.

Failure to comply with the above instructions may lead to dangerous electrical discharge causing machine damage and harm to persons.

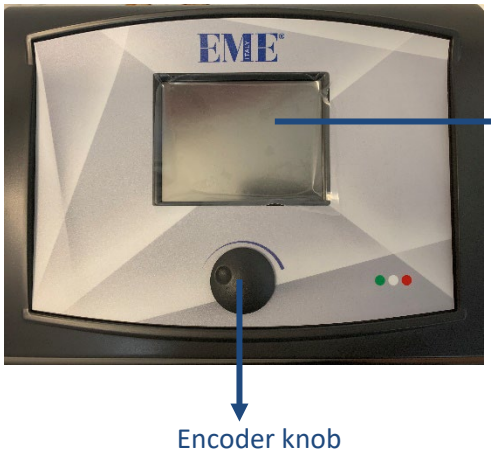
The connection of the probe/applicator is simple: you need to connect your cable to the device, inserting it into the connector on the anterior panel.

Once you have checked that installation and assembly have been carried out according to instructions provided up to this point in the manual, switch on the machine making sure that the display screen is turned on correctly.

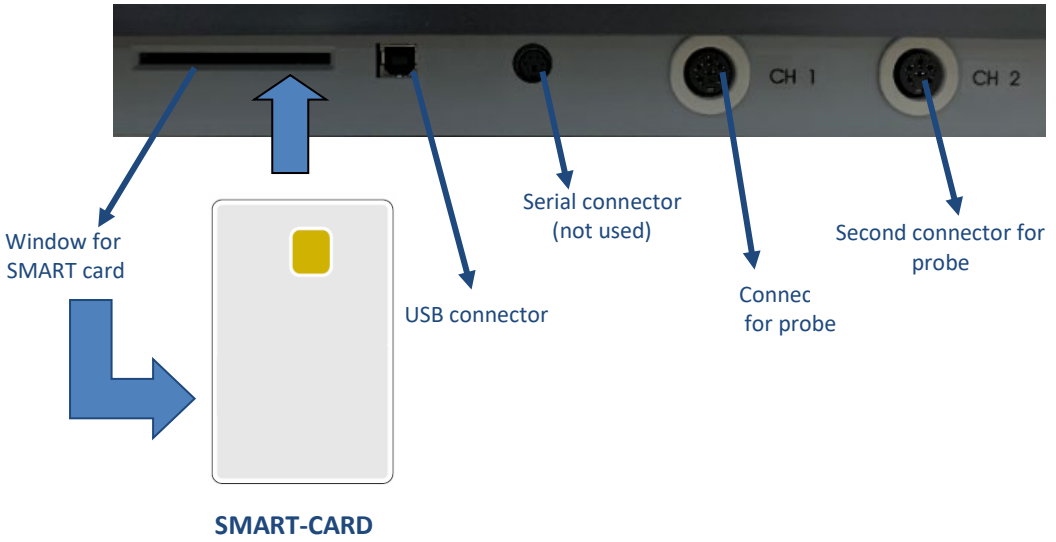
DESCRIPTION OF EQUIPMENT



FRONT PANEL



ANTERIOR PANEL

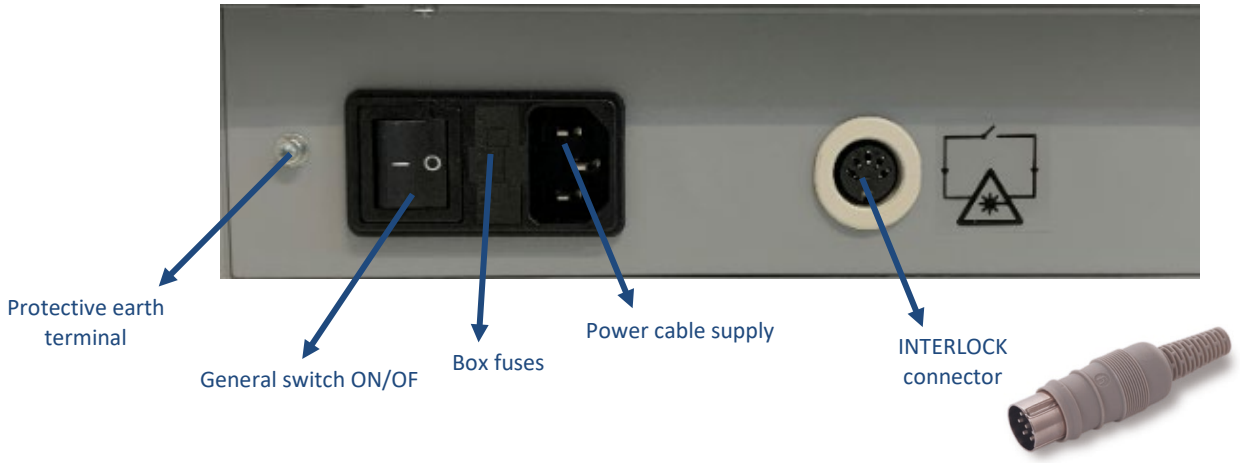


ACCESSORIES

The probe supplied with the device is with automatically touch sensor: when the lens is close to the skin start delivery.

The optional available probes for these equipments can be single diode or multi diode and can develop maximum power of 500 mW.

REAR PANEL



HOW TO USE OF THE DEVICE

This section provides important information and instructions on how to make the best use of the equipments for laser therapy LASERMED series.

All the control functions and the machine itself are handled and co-ordinated by a microprocessor: apart from making pre-memorised programmes available for application, the microprocessor ensures that the machine can be personalised and operated in a highly safe and efficient manner.

Interfacing allows for the operator to communicate with the unit by means of a large, clear graphic backlit liquid crystal display screen (LCD) through which all operational messages required by the operator, work status during operation, and errors are visualised.

The following paragraphs illustrate the procedures to be carried out and the technical specifications of the LASERMED series unit . They also deal with the different options available, from the selection of a pre-memorised programme for use in specific treatments as well as how to determine the correct working parameters for “personalised” application”.

BEST USE

After having installed and correctly positioned the machine as per the instructions described in the previous sections and connecting the laser applicator correctly, plug the machine into a 230Vac wall socket and switch on using the ON/OFF main switch on the back panel of the unit.

Once turned on, the LCD display lights up and LASERMED series unit is ready for use.

With the first turn on of the device, you can set the language from the six available. Turn the encoder to select the desired language and press it to confirm the selection. Then press the SAVE button to save the changes. A confirmation message will inform you of any modification.

When turning, the user will be prompted to enter an access code. This code has been set with the default number of 1234: then press in sequence the four numberic buttons on the screen (see Figure 1). This code can not be changed by the user, and its typing prepares LASERMED for operation. A double beep will inform the user that the code has been entered correctly, so you can continue with the lighting of the device.

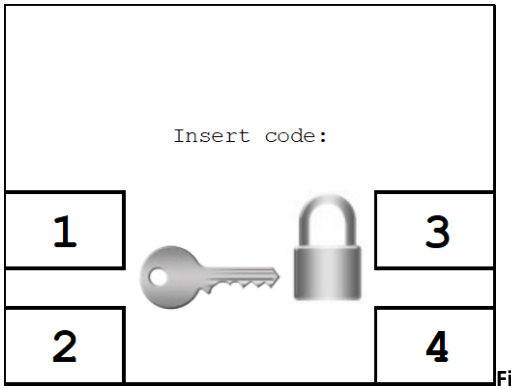


Fig.1

The LCD display will light up showing the logo (see Fig.2), and appears a screen that allows you to select between four operating modes (Fig.3) by tapping the corresponding button on the screen.

Fig.2

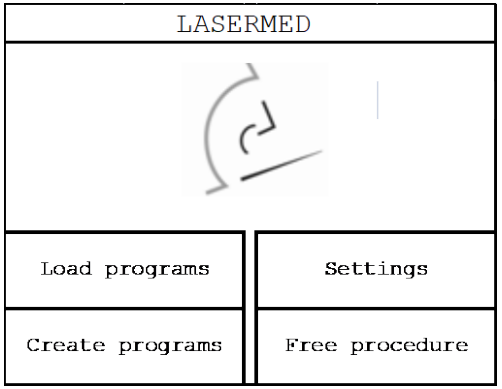


Fig.3

If you want to use the Smart-Card to create new customised programmes or to run those already stored, insert it as shown in the following figure, with the chip facing upward:

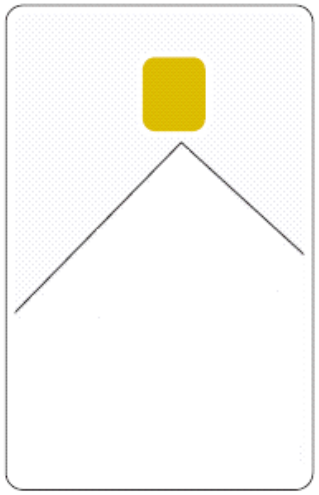


Fig.4 – SMART-CARD

SETTINGS

Pressing on the screen the button SETUP, appears the screen of the fig.5.

Turn the encoder you select the settings that you want to change, then pressing this knob confirms the choice.

The screen displays also the version of the software and of firmware modules installed on the lasertherapy machine, and contacts of the company. Moreover are indicated also the tensions of the internal adapter.

Pressing the button EXIT, to return to the screen of the fig.3.

VARIOUS

In this section, it's possible customize or turn off the acoustic signal to suit operator preferences.

Pressing the encoder knob on the BUZZER menu, it's possible to alternate the screen A with the fig. B of the figure 6.

Pressing the SAVE button, stores the desired sound settings. Instead, pressing the EXIT taste will cancel the operation. In both cases, it returns to the screen in fig.5.

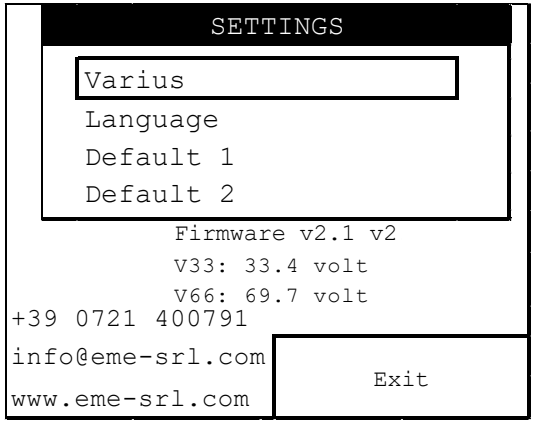
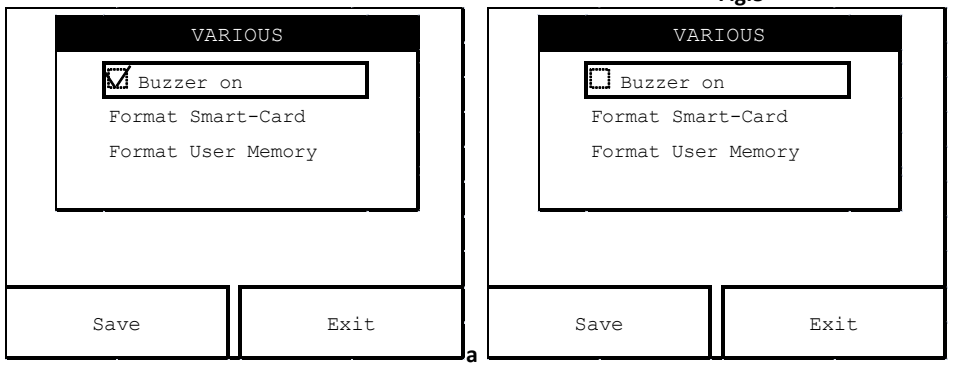


Fig.5



a

b

Fig.6

The Smart-Card and the user memory can be formatted.

All new cards that have never been previously used must be formatted. You can also use the "FORMAT SMART-CARD" function to delete it completely. If you do this it can be used on a different unit. In order to avoid accidental deletion, you are asked to confirm the operation (see fig.7).

Pressing the FORMAT button, the formatting operation of the selected support memory is executed. When formatting is completed, a screen will appear showing that the operation is completed (see fig.8). If you proceed with the formatting of Smart-Card but this support is not entered, the operator is informed by an error message.

Pressing the EXIT button to cancel the format operation of the selected memory support and returns to the screen in fig.5. Pressing the EXIT button to return to the screen in fig.3.

LANGUAGE

To choise the language in which you wish to have all the commands and messages, rotate the encoder knob then press this knob at the LANGUAGE menu (see fig.5).

For to choose the desired language, rotate the encoder knob until to reach the correspondent language, then push this knob for to confirm the choice.

Finally, press the SAVE button for to train the device to work with the selected language. Otherwise, press the EXIT button to cancel the operation. In both cases, it returns to the screen in fig.5.

Pressing the EXIT button to return to the screen in fig.3.

After a short wait for the loading of the new dictionary, you will see the menu with the new language.To change the language back, you can repeat this procedure at any time.

DEFAULT

This section allows to set the parameters of a standard therapy that can be immediately used with the FREE PROCEDURE function

At the screen in fig.5 rotate and then press the encoder knob at the DEFAULT1 or DEFAULT2 menu to access this section.

Fig.9 screen appears where you can configure the default program by changing parameters such as duration, frequency, duty cycle and area. These parameters are selected by turning the encoder knob and then pressing it to highlight the selected parameter.

Then turn the knob (clockwise for increasing values or counterclockwise for decreasing values) until you reach the desired value for the parameter; then press the knob to exit the procedure.

Pressing the button for the function SAVE, you return to the screen of the fig 5.

Pressing the function key for the button AUTOMATIC EMISSION you can toggle between automatic emission and the continuous emission.

Pressing the EXIT button instead, we go back to the main screen of the SETTINGS menu (Figure 5) without having made any changes.

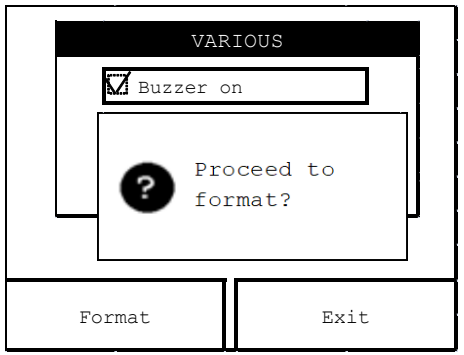


Fig.7

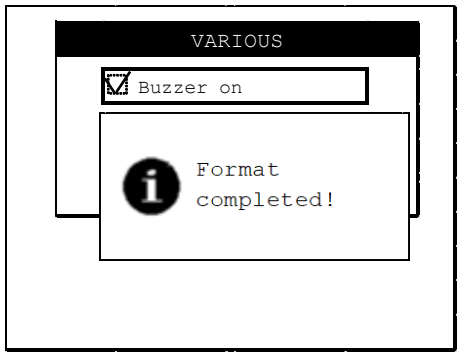


Fig.8

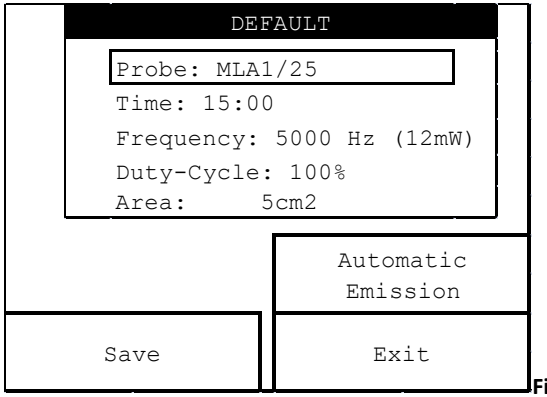


Fig.9

FREE PROCEDURE

Allows you to create customized programs that can be used immediately but not stored.

Pressing the FREE PROCEDURE taste (fig.3), appears the screen of the fig.10.

Before starting treatment you can change the type of handpiece and the treatment parameters Select them rotating the encoder knob and then pressing it on the selected parameter.

Then turn again the knob to modify the value of the parameter and push it again to exit the modification procedure of that parameter.

At the editing stage, the parameters are highlighted in black. You cannot change others or leave the function before you confirm by pressing the knob or waiting a few seconds to let the highlighting disappear.

Note: Duty-cycle (**working cycle time** or **duty cycle time**) is defined as the fraction of time that an entity goes into an active state in proportion to the total time considered.

Pressing the CHANNEL 1 button you can select the output, to switch to channel 2.

By pushing the button related to AUTOMATIC EMISSION you can choose treatment modality: between automatic emission and continuous emission.

Differently from continuous modality, the automatic treatment modality starts when the laser probe gets in touch with the skin surface.

Press the START button to begin the selected treatment: in case of automatic emission the fig.11 screen appears; in case of continuous emission the fig.12 screen appears. In both cases a rotating hourglass shows that the device is emitting, the time parameter shows the remaining treatment time with a countdown.

During treatment delivery, inside the EXIT button in the display shows the output channel highlighted in black; such highlighting becomes red when the delivery of the treatment is suspended.

During treatment delivery, you can change the values of parameters of frequency, duty cycle and area: push the encoder knob for select the parameter and turn it to the right for increasing values or to the left for decreasing values. After a few moments the parameter is cleared.

In the case of automatic emission just remove the laser probe from the skin surface to suspend the treatment, then replace the laser probe to the skin to resume the emission from the point in time when it was interrupted. Pressing the STOP button to return to the fig.10 screen.

On the other hand, in the case of continuous emission, pressing the PAUSE button pauses the emission and a message of PAUSE appears on the screen. By pushing again the button START the emissions resumed from the point where it was interrupted and continues until the set time runs out. Then the system communicates to the operator with a message that the treatment is finished and the software loads back the screen as in fig.10.

While pressing the STOP button the emission finally ends and you return to the screen of the fig 10. Pressing the button for the function EXIT you return to the screen of the fig.3.

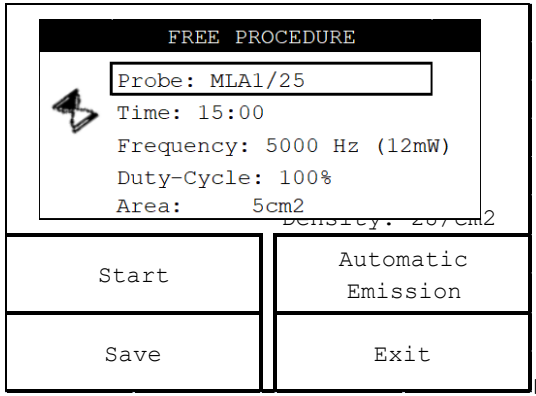


Fig.10

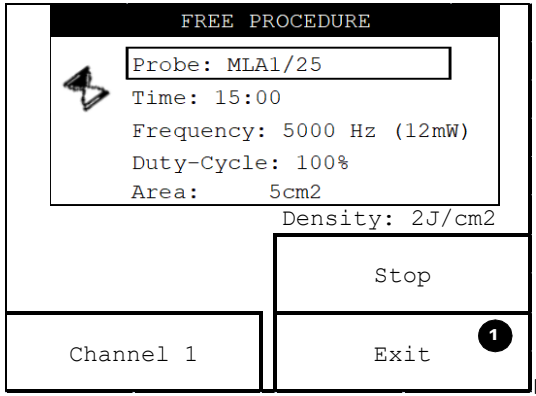


Fig.11

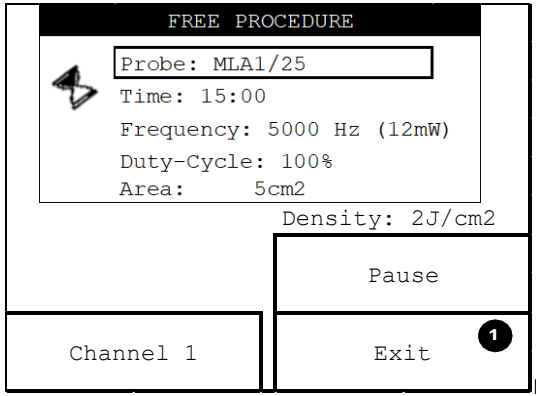


Fig.12

LOADING PROGRAMS

Pressing the LOAD PROGRAM button on the screen (see fig.3), appears the list of therapeutic protocols stored in the main memory (as shown by the frame around the STANDARD PROGRAMS button which is selected by default). These programs cannot be deleted but can be overwrite by changing the parameters of interest without saving.

Instead pressing the USER PROGRAMS button, appear on the screen the numbered sections (with default parameters) that will contain the programs created with the CREATE PROGRAMS function, and you can load programs stored in the user memory.

Finally pressing the SMART-CARD PROGRAMS taste, appear on the screen the numbered sections (with default parameters) that will contain the programs created with the CREATE PROGRAMS function, and you can load customized programs, stored in the smart-card.

NOTE: If you save a program on Smart-Card but the Smart-Card is not inserted, the operator is alerted by an alarm message to the not inclusion of the Smart Card into place and then the inability to be able to continue in the operation of storage programs.

The stored programmes reflect the fruit of many years experience supporting expert professional operators. Appendix **C** shows a list of the programmes available .

Pressing the EXIT button (whatever the memory selected) returns to the screen of the fig.3.

To start the desired treatment, turn the encoder knob to reach the desired protocol, then press it to confirm the selection.Once the display shows the selected program screen, you can go directly to its execution by simply pressing the START button.

Before initiation of therapy, however, you can modify any parameter, as discussed in section FREE PROCEDURE, but the program can neither be stored nor renamed.

CREATE PROGRAMS

This function allows to store “customized” therapeutic programs in the Smart-card or in the user memory, which are the only memory available to save the new programs.

Pressing the CREATE PROGRAMS taste on the screen (see fig.3) to create a program; appears the screen of the fig.13.

Pressing the encoder knob, you can start by default the creation of the program on the user memory (as shown by the frame around the USER PROGRAM button).

Instead, press the SMART-CARD PROGRAMS button to create a program on the smart-card.

NOTE: If you save a program on Smart-Card but the Smart-Card is not inserted, the operator is alerted by an alarm message (see fig.14) to the not inclusion of the Smart Card into place and then the inability to be able to continue in the operation of storage programs.

Once you select the support of memory in which to save the program, press the encoder knob to confirm the selection. The screen in fig.15.

At this screen, to assign a name to the program press the encoder knob: appears a cursor under the first character (see Figure 16), indicating the possibility to switch between the characters that you want to change by turning the knob. Then press the encoder knob at the character to confirm your choice.

Now the selected character is surrounded by two sliders (fig. 17), which means that the character is changed. Rotating the encoder to choose a new character to enter and press the encoder knob to confirm the selection. This exits from the routine to change the selected character.

Repeat the procedure for all the characters that you want to change, then press the OK button to confirm the new name to be entered. You return to the screen of the fig.15, where, however, the program now has a new name.

Before making the save, you can change the parameters of treatment, as described above in the FREE PROCEDURE menu.

Press the button corresponding to the SAVE button to confirm saving the custom program with the new name on the storage support initially selected. The operator will be notified of the rescue, then the screen will appear in fig.18.

After a few moments it returns to the screen in fig.13. Press the EXIT button to return to the fig.3.

MAINTENANCE

The LASERMED devices for laser therapy do not require any particular maintenance operations , but only a periodic maintenance and cleanliness of the laser probes, in order to ensure the better operating conditions, guarantee the effectiveness of the treatment and the safety of the patient. A special intervention is not required in the event of failure of the medical device, but just a normal maintenance / repair .

When cleaning the outer part of the equipment, make sure to use a soft, clean cloth dampened with luke-warm water or very mild non inflammable detergents. The front panel can be cleaned in the same way .

The laser probes, particularly the head of treatment, periodically should be cleaned with water and denatured alcohol.

Store with care the laser probes at the conclusion of every treatment .

Do not place on the equipment any objects that can produce heat or that contains water or other liquids.

Do not place the equipment in proximity of other equipment that can produce electric, magnetic or electro-magnetic fields with high intensity (equipment for diathermy, for X-rays, etc.).

Contact authorised dealers of EME srl for information regarding original spare parts or components.

Do not spray or pour liquid onto the external parts of the LASERMED equipment and onto the laser-probes. Do not immerse the unit in water .

After cleaning the external part of the equipment, make sure to dry it perfectly before turning on the unit.

The unit must under no circumstances be opened or dismantled in order to clean or check inner parts of LASERMED equipment does not require cleaning of inner parts and in all cases, only specialised technicians or EME srl authorised personnel should carry out such operations.

The expected work life of device is 10 years.

TECHNICAL PROBLEMS

LASERMED lasertherapy equipment has been designed and manufactured using highly advanced technology and first class components for reliable and efficient performance.

However, should you meet with any operational problems, we recommended that you consult the following guide before contacting any of our authorised service centres.

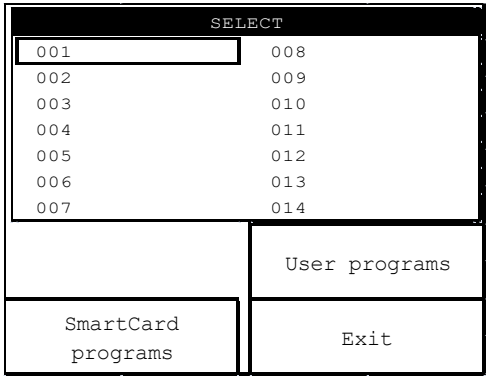


Fig.13

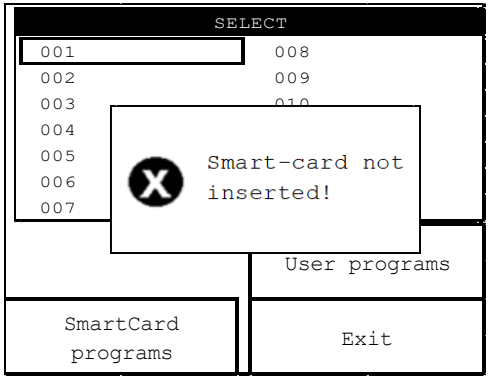


Fig.14

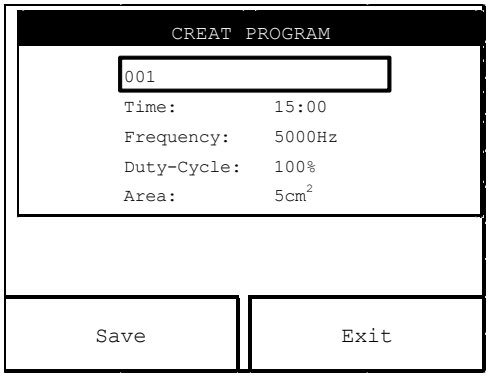


Fig.15

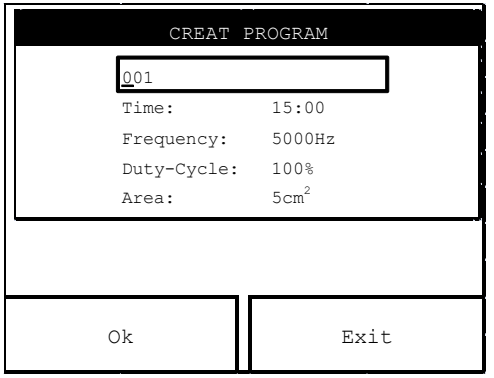


Fig.16

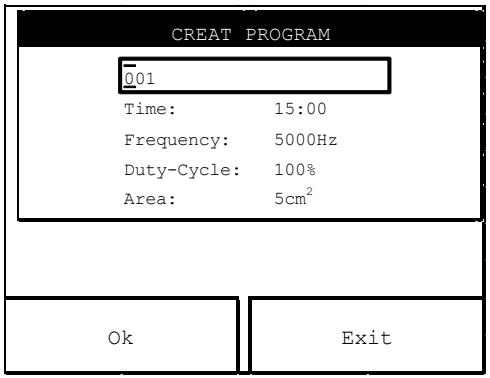


Fig.17

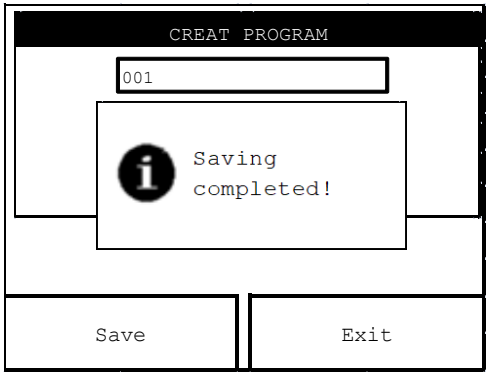


Fig.18

If any of the following situations occur, disconnect the machine and contact EME srl authorised service centres :

- the cable set or rear supply panel show signs of wear and tear or are damaged;
- the liquid has entered the equipment;
- the equipment has been exposed to rain.

ELECTROMAGNETIC INTERFERENCES

LASERMED lasertherapy equipment has been designed and manufactured according to the ELECTROMAGNETIC COMPATIBILITY DIRECTIVE 2014/30/UE with the aim of providing adequate protection from harmful interference when installed in homes and health establishments.

All required measurements and tests have been carried out in EME's internal Testing, Measurement and Inspection laboratory (LPMC), in addition to other external specialised institutes.

The customer, upon prior request, may view the reports relative to EMC measures within the company. The LASERMED unit for lasertherapy 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
LCD display on front panel does not light up.	Plug incorrectly inserted into socket.	Check that the socket is working correctly.
Unit does not function.	Power cable incorrectly inserted into the connector on the rear of the unit	Insert the plug correctly into the socket.
	Cable is worn, damaged or blocked	Replace the worn out or damaged power cable.
	The switch on the rear of the unit is turned off	Turn on the switch
	Fuses missing, blown or blocked.	Replace any missing, blown or interrupted fuses
	Electronic control circuit does not work	Contact EME srl Service centre .
	No power reaching the socket.	
LCD display on front panel does not light up	Presence of faulty components on electronic control card	Contact EME srl Service centre .
Some of the buttons on the front control panel do not function correctly	Faulty keys or buttons.	Contact EME srl Service centre
	Electronic control circuit malfunction	
The unit lights up but does not emit energy	Parameters not set correctly.	Check that the parameters have been set correctly.
	Laser source does not function or has run out.	Check laser source emissionis operating.
	Faulty components on electronic control circuit	Contact EME srl Service centre .
	Faulty supply on laser circuit.	
The unit functions normally but with a significant decrease in efficiency of treatment	Faulty or depleted laser source.	Contact EME srl Service centre .
	Possible break down in power generator circuit of the unit..	
The equipment starts up, or seems to work normally, but there is no emission.	No safety key or the interlock circuit is open.	Insert the DIN safety key into the back socket or reset the safety conditions.

TECHNICAL SPECIFICATIONS

Mains voltage		230 Vac, 50-60 Hz, ±10%
Max. Power absorption		20 VA
Double fuse protection	**230 V**	315 mA Rit. 5 x 20 mm
Interlock socket/Safety key (contacts normally closed)		3 contact DIN socket
Backlit LCD Display, to visualise and control operating parameters:		graphic 320x240 pixel touch screen + encoder
Programmable treatment time:		up to 99 minutes
Diode Laser wave length emission		905 nm
Laser classification according to EN 60825-1		3B
Device class in according to the 93/42/CEE directive		II B
Electrical insulation / applied parts class in according to the UNI EN 60601-1 standard		I/BF
Degree of protection by the liquid access in according to the UNI EN 60601-1 standard		IPX0
OD (Optic density) 25 mW		0.1
OD (Optic density) 100 mW		0.7
Sensor for detecting IR radiation of the external handpiece		On the front
Programmable pulse frequency		(100 - 10.000) Hz
Pulse duration		100 nsec
Pulsed mode		(10 – 100) %
Peak power for single diode		100 W

Total peak power **depends on handpiece-applicator** (See accessories)		
Target pointing device characteristics	Target pointing device in conformity with the UNI EN 60601-2-22 standard	2 light-drive
	Light-drive device	led-diode
	Light-drive color	red
	Light-drive representation on the impact point	spot with red as colour
Typology for emission of the treatment		manual emission
		automatic emission
		continuous emission
Output channels		2 independents
Storable protocols on the smart-card		200
Table container in plastic, external size (width x height x depth)		39 x 14 x 30 cm without probes , 47 x 14 x 30 cm with probes
Unit body weight		3.65 Kg
Use conditions	Room temperature	(+10 : +40) °C
	Relative humidity	(10 : 80) % without condensation
Stocking/transport conditions	Room temperature	(-40 : +70) °C
	Relative humidity	(10 : 100) % without condensation
	Atmospheric pressure	(500 : 1060) hPa

LASER PROBES SPECIFICATION	
MLA1 (100) – pulsed laser diode	
Number of laser diodes	1
Wavelength	905nm
Divergence of the beam	192x436mrad
Duration of the impulse	100 ns
Programmable pulse frequency	100 – 10.000 Hz
Peak power	100W
EMP (Maximum allowed exposure) single pulse	5,14 mJ/m^2
EMP (Maximum allowed exposure) pulse train	2,06 mJ/m^2
EMP (Maximum allowed exposure) average	2,57 mJ/m^2
DNRO (Nominal eye-hazard distance) direct light	251 mm

MLA3 (300) – pulsed laser diode	
Number of laser diodes	3
Wavelength	905nm
Divergence of the beam	192x436mrad
Duration of the impulse	100 ns
Programmable pulse frequency	100 – 10.000 Hz
Peak power	300 W
EMP (Maximum allowed exposure) single pulse	5,14 mJ/m^2
EMP (Maximum allowed exposure) pulse train	2,06 mJ/m^2
EMP (Maximum allowed exposure) average	2,57 mJ/m^2
DNRO (Nominal eye-hazard distance) direct light	251 mm

MLA5 (500)– pulsed laser diode	
Number of laser diodes	5
Wavelength	905nm
Divergence of the beam	192x436mrad
Duration of the impulse	100 ns
Programmable pulse frequency	100 – 10.000 Hz
Peak power	500 W
EMP (Maximum allowed exposure) single pulse	5,14 mJ/m^2
EMP (Maximum allowed exposure) pulse train	2,06 mJ/m^2
EMP (Maximum allowed exposure) average	2,57 mJ/m^2
DNRO (Nominal eye-hazard distance) direct light	251 mm

APPENDICES

Appendix A - ENVIRONMENTAL CONSIDERATIONS

LASERMED-series unit for laser therapy equipment has been designed and manufactured to have minimal negative environmental impact, in line with its operational and safety requirements.

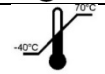
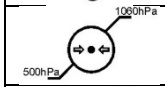
Rigorous standards were followed in order to minimise the amount of waste, use of toxic materials, noise, non-required radiation and energy consumption.

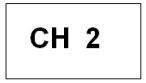
In accordance with careful research, the unit has been designed to optimise power consumption in keeping with energy saving principles.

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

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

Appendix B – LABELS

Symbol	Signification
	This product complies with regulations issued under the certification from a Notified Body
	Applied part BF
	Manufacturer
	Date of manufacture
	Consult instructions for use
	Attention
	The product must be dispose of as “electronic waste”, not as “domestic waste”
	input characteristics
	Input voltage to the device (mains)
	Fuses: 2xT315mAL250V
	Input power of the device (absorbed power)
	Input frequency of the device
	Device model
	Serial number
	Output characteristics of the device
	Output power supply
	Output frequency of the device (laser probe)
	Temperature range
	Atmospheric pressure range
	Humidity range

Label	Signification
	Label showing devices sensitive to electrostatic charges, placed near the serial connection connector
	Label indicating "laser emission" located close to the laser hand connector
	“INTERLOCK” label , situed on the rear panel of the device near the interlock connector
	Label applied near the output channel 1 of the device
	Label applied near the output channel 2 of the device (only for LASERMED 2200)
	Label indicating the mandatory reading of instructions, located on the front panel of the device
	Label indicating "LASER OPENING", placed near the firing part of the laser handpiece.
	Label applied on the applicator handpiece, showing the Manufacturer's name or trade mark and the model or type reference of the laser handpiece.
	"Caution laser beam" label on the back of the device

Texts on the label	Meaning
Warning	Warning
Visible and invisible laser radiation	Visible and invisible laser radiation
Avoid exposure to beam	Visible and invisible laser radiation
Class 3B laser product	Class 3B laser product

Label	Signification
	Label placed on the left side panel of the device, showing the characteristics of the laser handpieces

Texts on the label	Meaning
Maximum output laser radiation (MLA1 – 25): 25W I.R	Maximum output laser radiation (MLA1 – 25): 25W I.R
Maximum output laser radiation (MLA1 – 100): 100W I.R	Maximum output laser radiation (MLA1 – 25): 25W I.R
Maximum output laser radiation (MLA3 – 75): 3x25W I.R	Maximum output laser radiation (MLA3 – 75): 3x25W I.R
Maximum output laser radiation (MLA3 – 300): 3x100 W I.R	Maximum output laser radiation (MLA3 – 300): 3x100 W I.R
Maximum output laser radiation (MLA5 – 125): 5x25 W I.R	Maximum output laser radiation (MLA5 – 125): 5x25 W I.R
Maximum output laser radiation (MLA5 – 500): 5x100 W I.R	Maximum output laser radiation (MLA5 – 500): 5x100 W I.R
Maximum output laser radiation (MLA8 – 200): 8x25 W I.R	Maximum output laser radiation (MLA8 – 200): 8x25 W I.R
Maximum output laser radiation (MLA8 – 800): 8x100 W I.R	Maximum output laser radiation (MLA8 – 800): 8x100 W I.R
PULSE DURATION (ALL PROBES): 100 ns	PULSE DURATION (ALL PROBES): 100 ns
EMITTED WAVE LENGTH (ALL PROBES): 905 nm	EMITTED WAVE LENGTH (ALL PROBES): 905 nm
STANDARD IEC EN 60825-1:2014	STANDARD IEC EN 60825-1:2014

Appendice C – LIST OF THERAPEUTIC SUGGESTIONS

Laser Therapy Treatments	Time (min.)	Frequency (Hz)	Energy density (J/cmq)
Acne	2	5000	2
Temporo-mandibular joint pain	3	5000	2
Phantom limb or causalgia	3	5000	2
Arthritis of the small joints	2	5000	2
Arthritis	2	10000	3
Arthritis hands	3	5000	2
Pre-patellar bursitis	5	5000	4
Patellar candropathy	3	10000	5
Muscle-tension headache	3	10000	5
Neck pain (acute)	2	1000	1
Cervical pain	1	500	1
Cervicoarthrosis 1	1	500	1
Hypertrophic scars	2	10000	3
Contractures	2	5000	2
Myofascial pain	5	5000	4
Back pain	2	10000	3
Recent edema	2	10000	3
Epicondylitis or Tennis Elbow	2	1000	1
Plantar fasciitis	8	10000	12
Gonarthrosis 2	3	10000	5
Herpes Simplex, on the pustules without touching	1	500	1
Laser-acupuncture	2	1000	1
Injury to the flexor tendons (hand)	2	1000	6
Low back pain	3	10000	5
Lumbosciatalgia	2	10000	3
Carpal tunnel syndrome	2	5000	2
Painful shoulder	2	10000	3
Collateral ligament stretch 1	2	5000	2
Supraspinal tendinopathy	2	2000	1
Achilles tendonitis	3	5000	3
De quervain tenosynovitis	5	5000	4
Trigger points	2	5000	2
Leg ulcer	2	1000	1
Diabetic ulcers	1	500	1

The values of energy density given in the table were obtained by considering a MLA1 probe with diode 25mW and area of treatment equal to 1cm^2. The device software automatically updates the parameters based on the selected handpiece while keeping the energy density constant.

NOTE: is not possible to define a number of sessions, depending on the therapeutic suggestion used , as the duration of a session is not uniquely defined but depends on the pathology to be treated, by the patient subjected to special treatment and by the amount of power emitted by the device and absorbed by the patient treated, so the number of sessions required is defined by the medician based on patient's clinical condition and characteristics of the device with which the treatment is emitted.

Appendix D – ELECTRO-MAGNETIC COMPATIBILITY TABLES

Guidance and manufacturer's declaration – electromagnetic emissions		
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 1	The ME EQUIPMENT uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
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	

13.4.1 Guidance and manufacturer's declaration – electromagnetic immunity			
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	± 8kV contact	± 8kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
	± 2; 4; 8; 15 kV air	± 2; 4; 8; 15 kV air	
Electrical fast transient/burst IEC 61000-4-4	± 2kV per power supply lines	± 2kV per power supply lines	Mains power quality should be that of a typical commercial or hospital environment
	± 1kV for input / output lines	± 1kV for input / output lines	
Surge 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	0% U_T for 0,5 cycles	0% U_T for 0,5 cycles	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.
	0% U_T for 1 cycles	0% U_T for 1 cycles	
	70% U_T for 25 cycles	70% U_T for 25 cycles	
	0% U_T for 250 cycles	0% U_T for 250 cycles	
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30A / m	Not applicable, the device does not contain components susceptible to magnetic fields	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.			

Guide and declaration of the manufacturer - electromagnetic immunity				
The ME EQUIPMENT is designed to work in the electromagnetic environment specified below. The client or user of the ME EQUIPMENT should ensure that it is used in this environment Portable and mobile RF communications equipment should not be used closer to any part of, including cables, than the recommended separation distance calculated with the equation applicable to the transmitter frequency.				
Immunity test	Trial level of the IEC 60601		Level of compliance	**Recommended separation distance d:**
Conducted RF IEC 61000-4-6	3 Veff from 150kHz to 80 MHz		3 Veff	**d**= 30 cm
Radiated RF IEC 61000-4-3	3 V/m from 80 MHz to 2,7 GHz		3 V/m	**d**= 30 cm
Immunity to proximity fields from wireless RF communication devices IEC 61000-4-3	TETRA 400 380 – 390 MHz	27 V/m	27 V/m	**d**= 30 cm
	GMRS 460 FRS 460 430 – 170 MHz	28 V/m	28 V/m	
	LTE Band 13, 17 704 – 787 MHz	9 V/m	9 V/m	
	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 800 960 MHz	28 V/m	28 V/m	
	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 5 1700 – 1990 MHz	28 V/m	28 V/m	
	Bluetooth, WLAN, 802.11 b/g/n, RIFD 2450, LTE Band 70 2400 – 2570 MHz	28 V/m	28 V/m	
	WLAN 802.11 a/n 5100 – 5800 MHz	9 V/m	9 V/m	

DICHIARAZIONE DI CONFORMITÀ ALLA DIRETTIVA 93/42/CEE SUI DISPOSITIVI MEDICI

EME ITALY
Aesthetic & Medical Technologies

DECLARATION OF CONFORMITY TO THE 93/42/CEE DIRECTIVE ON MEDICAL DEVICES

Il Fabbricante / *The manufacturer*

EME Srl - Via degli Abeti , 88 / 1 - 61122 PESARO (PU) - ITALY

dichiara sulla sua responsabilità che il prodotto :
declares on its own responsibility that the product :

Apparecchiature per laser terapia /
Equipment for laser therapy :

LASERMED 2200

è conforme alle prescrizioni della direttiva comunitaria 93/42/CEE e successive integrazioni e modifiche (Allegato II eccetto il punto 4), recepita in Italia con D.L. N° 46 del 24 febbraio 1997 e successive integrazioni e modifiche , e la classe di rischio è la IIb secondo la regola 9.

is in compliance with the 93/42/CEE Directive and the following integrations and modifications (Annex II except point 4) , implemented in Italy following the D.L. N° 46 directive issued on 24 february 1997, and the risk class is IIb *according to the rule 9.*

Certificato n. MED – 31009 / *Certificate n. MED – 31009*

La macchina è marcata / *The equipment is marked* :

CE 0476

Organismo Notificato / *Notified Body*
Kiwa Cermet Italia S.p.a.

Pesaro, 14/04/2016

EME srl
L'Amministratore unico / Administrator

Italian manufacturer of physiotherapy equipment since 1983

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