



# PR 999 500mW-4W-8W

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



 Italian manufacturer of physiotherapy equipment since 1983

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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 laser therapy scanning equipment PR999 series.

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.

## 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

EME 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 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.

EME srl 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 EME srl 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.**
- To avoid the risk of electric shock, this device must only be connected to power supply networks with protective earth.
- Before switching the device on, be sure that the INTERLOCK key, that allows to start up the machine, is connected.

- 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 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.
- 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.
- You can only load therapy programmes among the preset ones stored in the unit's memory in the SCANNING LASER section. The EXTERNAL PROBE (optional) only works with the Free Procedure.
- It is not possible to define for the devices PR999 series 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 external probe/applicator connector (optional): they must not be damaged or worn.
- 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.
- 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.
- It's a class B machine in terms of emission. The EM device is suitable to be used in every environment, including those directly connected to a public network power of low voltage which supplies buildings used for domestic purposes.
- 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:
  - o Reorient or reposition the receiving device;
  - o Increase the distance between the devices;
  - o Connect the equipment to a scale of a circuit different from or to devices that cause interference;
  - o Contact the manufacturer or local technician for assistance.
- Portable and mobile radiocommunication 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 external 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 external probe/applicator: this tampering damages the features of the probe (optional) 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-series unit , please follow these instructions :

1. disconnect the power supply and open the fuse box using a screwdriver, making sure 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 :
    - o the intensity of any leakage currents
    - o the continuity/integrity ground wire
    - o the correctness of the value of insulation resistance
    - o the emission level
- perform such audits ensures electrical safety of PR999-series 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.
- The equipment contains IR LASER SOURCES that emit dangerous radiation.
- You should contact EME srl or its authorized service centers 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.
- We advise to use the equipment in the suggested environmental conditions, in order to prevent any malfunctions.
- 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 transport position of the equipment is when the device is moved only along the X direction, holding with both hands the curved profiles of the cover.
- We advice to move the equipment of the series PR999 following the indicated modalities, in order to avoid the unbalancing of the device caused by the weight of the laser arm, placed on the rear side of the equipment.
- To avoid tripping over of the device, close tightly the joints of the laser arm, after you set the right distance between the laser head and the patient body.
- To avoid potential malfunction problems, the PR999-series devices have been engineered, taking into account the following aspects:
  - Applying air slits on the side and rear walls of the case, in a safe position.
  - Placing the electronic component in the upper part of the cart and not on the bottom.

In case any problems arise or to get more information, get in contact with EME srl or with its authorised service centers.

- 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 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 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.**
- 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:
  - o The electrical system of the premises complies with the appropriate regulations;
  - o The device is used in accordance with the instructions for use.

#### USE

- We recommend the operator and the patient to wear the eye protection goggles against laser radiations and to put them on before starting the therapeutic treatment.
- We advise the operator to warn the patient not to move their body (if possible) during the treatment emission, to make sure the right body part is treatment and the treatment is effective.
- 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 .
- 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 color, 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.
- We suggest not to start the treatment emission if the device does not have perfect mechanical conditions or if the characteristics of the laser emission do not comply with the purpose (read the technical characteristics chart).
- DO NOT LOOK AT THE BEAM WITH YOUR NAKED EYE OR WITH ANY OPTICAL INSTRUMENTS.
- DO NOT EXPOSE THE BEAM UNLESS IT IS BEING STRICTLY MONITORED.
- Avoid direct exposure to radiation as it may harmful effects: the damage will be directly proportional to the power emitted.
- The geometric size of the scan, amplitude and speed given refer to a fixed distance between the laser opening and the part of the patient to be treated.
- 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 the use environment for PR999-series 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.
- We advice the operator to follow thoroughly the preliminary procedure before the laser session. Only by doing so, the risk of possible dangers associated with an incorrect placing of the scanner will be reduced to minimum.
- 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 absolutely forbidden the use of the device in the presence of a flammable anesthetic mixture and oxygen-rich environments. In case of non-compliance with this indication, EME srl will not be 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.
- We strictly prohibit using the PR999 series equipment if both the operator and patient do not put on the eye protection goggles against the laser radiation before starting the treatment. In case of such indication is not followed, EME srl will not be responsible for any incidents that might occur.
- 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.
- If the button OK is pressed to confirm the software updating before having connected the USB-port to the source containing the software updating, the device goes out from the

main program and enters in the updating routine waiting for the USB connection. A screen indicates the missed connection. If the support to connect to carry out the updating is not available, it is necessary to switch off the device and turn it on again through the general switch to restart the device with the available software

#### 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.
- The cleaning and disinfection must be done systematically before the therapeutic treatment which subject the patient.
- 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 prove VERY 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 prove VERY 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 color 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;

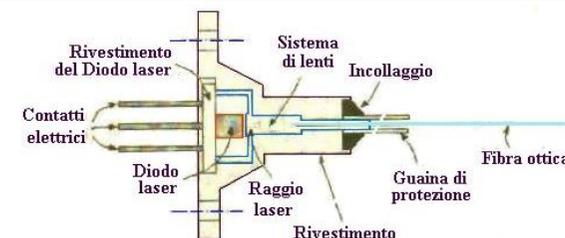
and obviously a mechanical support structure.

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

### Parameters of the laser beam

**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.

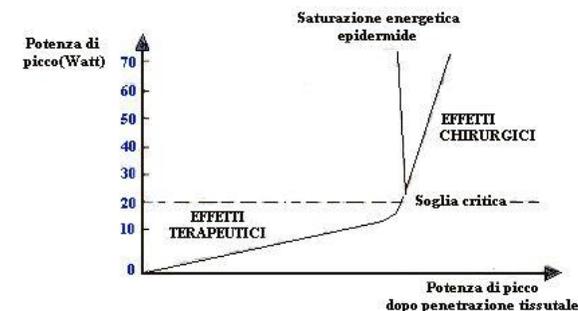
**3. Average power (Pm):** this is a function that varies according to the size, the duration and the frequency of the pulse.

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.

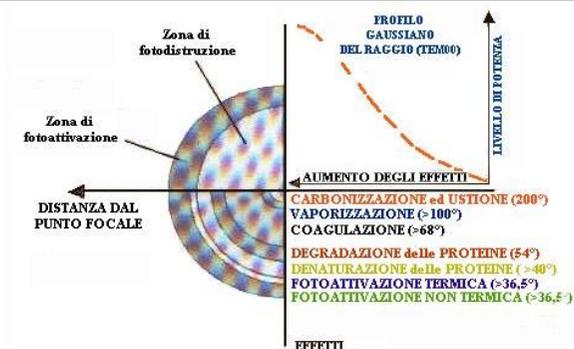
The power of laser beams (both therapeutic and surgical) is higher at the centre of the beam and falls off towards the edges in a bell shaped curve (Gaussian showed in fig.c). The power weakens towards the edges of the beam with lesser effects on the tissue hit. This phenomenon is called the alfa effect. 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<sup>2</sup>) or through an area that covers more than a few cm<sup>2</sup> 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 PR999-series equipment is of the highest quality.

The equipment PR999-series were planned and built in manner that their 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.

PR999-series is a machine produced according to the Directive MED 93/42/EEC concerning medical devices.

## INTENDED USE

The PR999-series unit are medical devices that emits treatments of laser-therapy, both in modality "scanning", through a laser heading, or in modality "with probes", through the aid of mono-diode and multi-diode probes for the emission of the treatment.

The use of this device is reserved for operators such as physiatrists, physiotherapists and pain therapists who by virtue of their professional training offer the guarantee of adequate use and total safety 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.

### Scanner or laser probe positioning

Both with the application through the laser-head to scanning or with the probes (mono and multidiodic), the scanner and the probe must be applied so that the laser beam perpendicularly reaches the region to treat.

To apply in fact the head of the scanner and the probe with an angling always perpendicular (90°) in comparison to the tissue zone to treat.

An inclination excessive or partial of the laser probe allows that the angle of incidence of the laser radiation becomes too much great in such way that, when you overcome the 10°, is had the total reflection of the beam.

The probe must be applied to direct contact ; the head of the scanner must be applied to a distance from the zone or region to be treated. The power of the laser decreases with the square of the distance.

There are no dangers if you observe the behavioral rules to perform during a laser session.

### Preliminary modalities to be performed before the session

- *To carefully clean the skin* in correspondence of the tissue to treat removing in such way the layer of fat, the possible makeup and the impurities that physiologically cover it in way to avoid the possible reflection of the laser beam (up to 70%). This preliminary cleaning can be effected with etilic alcohol (preferable), ether, or through soap. It is possible to apply topical substances during the laser session only if are endowed with precise characteristics; for example it is possible to use a solution of red eosin to 3% (constituted by 60% of denatured alcohol, 37% of water, 3% of red pigment of eosin) to the purpose to decrease the reflection and to make the skin to treat as a filter partially red to obtain a best penetration of the red and infrared lasers
- *Not to move the laser probe* during the treatment once you have chosen the point to treat, both for the danger of a possible dangerous reflection of the laser beam, or for a loss of energy during the move.
- *To maintain the laser probe possibly to direct contact with the skin* so that to reduce to the minimum the losses of energy. Clearly, this isn't effected in the treatment of wounds or pathological alterations of the skin for the danger of infections or to dirty the probe; in every case, nevertheless, we recommend you to hold here also the probe the more possible next to the treated zone. In the use of the scanning laser, even though it is endowed with slow focalising that allow the treatment to a certain distance, you must care attention not to overcome the 35 cms of distance from the skin.
- *To daily clean to every application the part of the diode* that is to contact with the skin of the patient, to avoid the occlusion and the defilement of the surface of the diode and also the possibility to communicate infections. The cleaning of the output of the diode can quietly be effected with a cotton wad soaked of etilic alcohol or ether.
- *To always use for all the during of the treatment the special glasses of filter protection* and to estrange from the work environment every metallic object or surface that could accidentally reflect the laser beam, all of the extraneous people to the treatment that however, if present, they have to also wear them the special glasses of protection.
- *To remove the personal jewels of the patient* : clocks, rings act as reflectors. When you enter in the laser room you must to remove every object that can favor the risk of reflection. It needs to observe such rule both in case of use of low-power laser that in case of high-power laser systems and to get used to this indication

## Applications points

Some important indications are brought for the operator, relatively to the points of application of the therapeutic treatment and the modalities to be followed for preparing the point to treat.

1. to directly apply on the zone or region to treat :
  - a) to a predetermined distance from the cutaneous surface, in the case of treatment with the laser scanning
  - b) or to direct contact of the tissues and on the aching points reported by the patient, in the case of treatment with the probe
2. to subjectively apply on the aching and sensitive points to the palpation ("tender point")
3. to apply on the reflected points or stings "trigger" ("trigger point") : it deals with circumscribed areas and well you topographically defined, located and in the muscles (generally in the muscular abdomen), on which the digital pressure evokes violent pain that in some cases it radiates him in areas well delineated, said target areas ("target area"); these points (great less than 1 cm) usually show one decreased cutaneous resistance if compared with the surrounding tissues and it has been verified that the laser irradiation increases the pattern of resistance of the treated points (Snyder Mackler L, 1988). The laser can be used under different muscle-skeletal pathological conditions for disarming the trigger points.
4. *On the points of acupuncture.* Uniquely treatment with probe (monodioidic) with use of the ferrule of acupuncture supplied. The probe must perpendicularly be applied to the body surface to treat and it must not be moved during the application.

## INDICATIONS

- 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 fibromiopathie) 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 (NOTE: Acupuncture treatments are not covered by medical CE marking).

## 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.
- Neoplasia: 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 interlock;
- n.2 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 scanning equipment is fast and simple.

Once positioned the device lock the wheels with the appropriate brake to prevent involuntary movements.

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 72°. 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, 20m max, 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 :

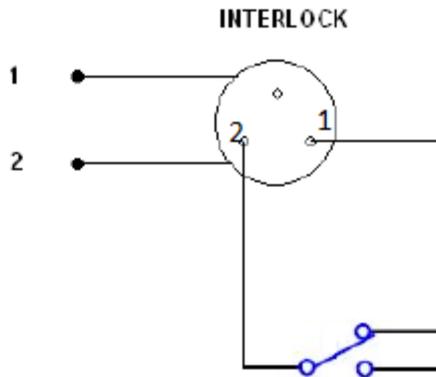


Figure d

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

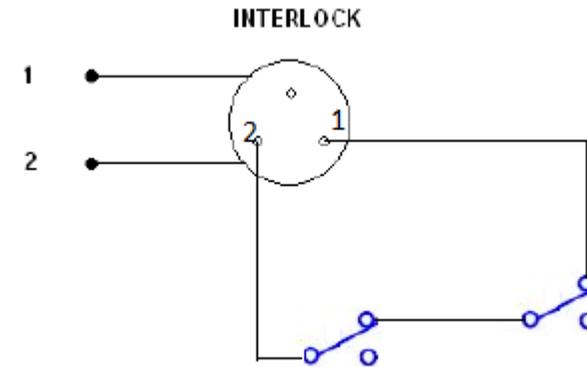


Figure e

## ACCESSORIES

The devices PR999 500mW, PR999 4W (2W+2W), PR999 8W can be used with the following accessories :

Description	PR999 500mW	PR999 4W	PR999 8W
Power cable supply	1	1	1
Spare FUSES (see technical specifications)	1	1	1
User manual	1	1	1
Interlock	1	1	1
OLV safety laser goggles	2		
YG3 safety laser goggles for operator		2	2
Smart-Card	x	x	x
MLA1/100 Laser probe 905nm with touch sensor: guide light+ 1 diode 100 mW	x	x	x
MLA3/300 Laser probe 905nm with touch sensor: guide light+ 3 diode 100 mW (300mW total) automatic sensor.	x	x	x
MLA5/500 Laser probe 905nm with touch sensor: guide light+ 5 diode 100 mW (500mW total). automatic sensor	x	x	x
Probe holder	x	x	x

**LEGEND:** number=supplied accessory, x=optional

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 patient safety glasses must possess are the following:

- Wavelength: 808-905 nm
- Gradation number: 5
- Optical class: 1
- Densità ottica ( $\lambda=808\text{nm}$ ): 3.523
- Densità ottica ( $\lambda=905\text{nm}$ ): 4.456
- CE marking

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

- CE marking
- 808-840 DI LB4
- 950 -1080 D LB6 +I LB7
- 840-950 DI LB5

The accessory installing is simple and intuitive: each cable for the therapy is equipped with a multi-pin connector to be inserted into the socket on the rear panel of the device.

Contact authorised dealers 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.

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.

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 external probe/applicator (optional) is simple: you need to connect your cable to the device, inserting it into the connector on the rear panel.

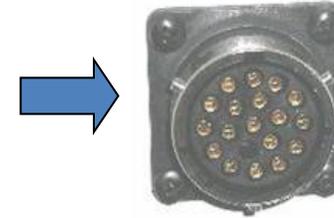
To set the laser head to work conditions you have to connect the scan cable to the connector placed in the back of the device (see appendix C).

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

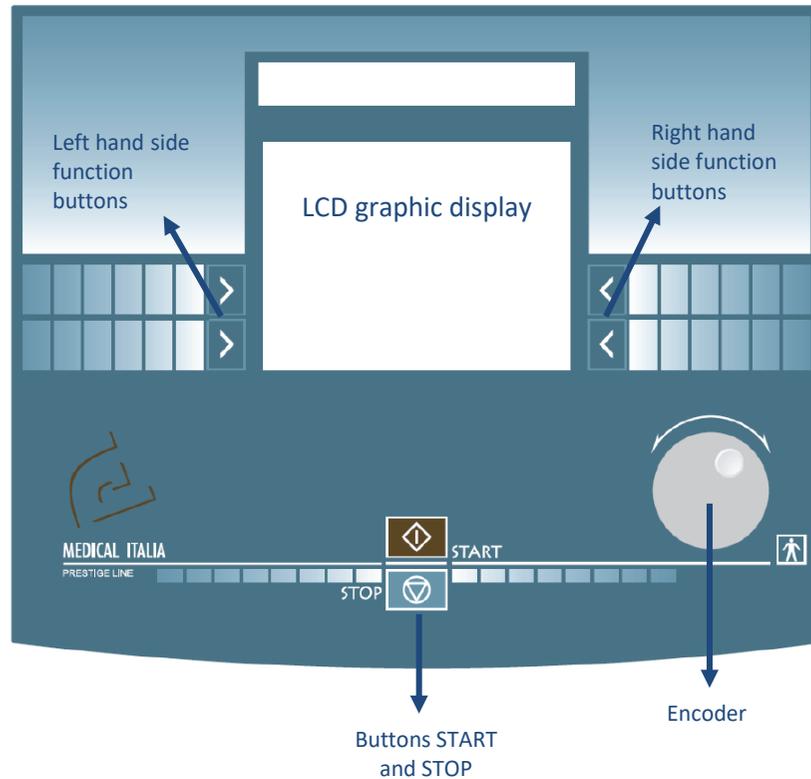


Head connector  
(on the back of the machine)



Models PR999	PR999 500mW	PR999 4W (2W+2W)	PR999 8W
Hallmarks of unit			
N. laser sources	1	2	1
Wavelength	808nm	808nm e 940nm	940nm
Total power	500mW	4W	8W

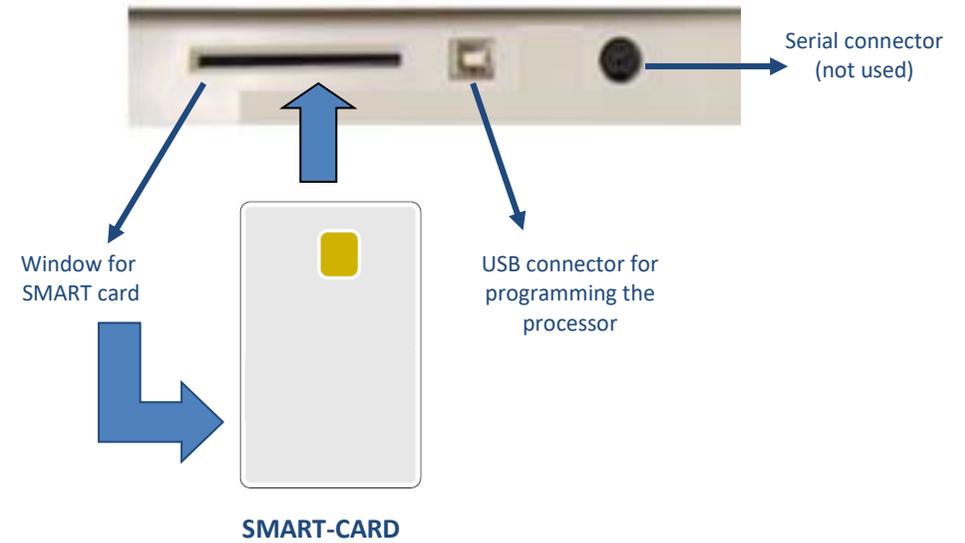
**FRONTAL PANEL**



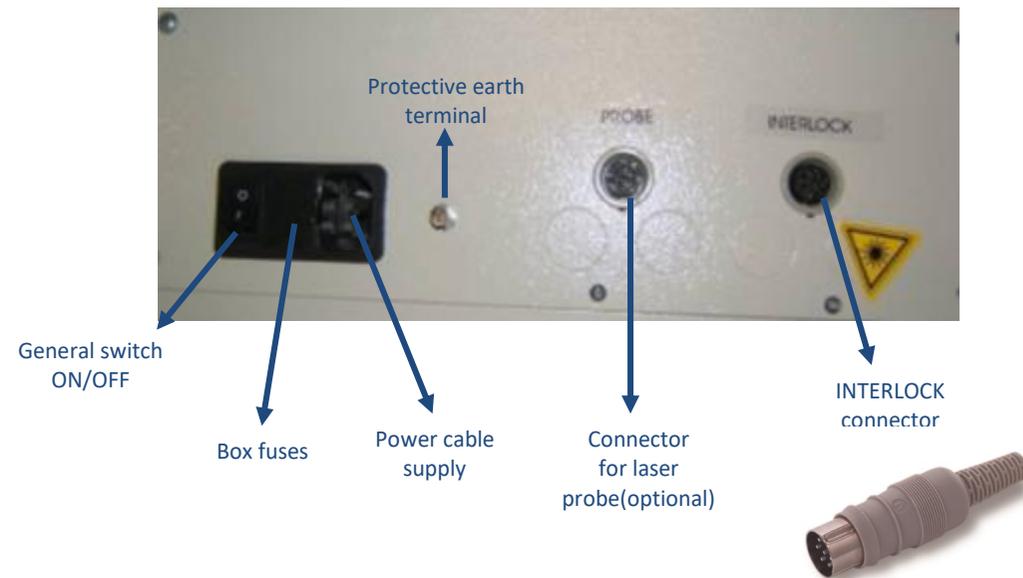
**ACCESSORIES**

The optional available probes for these equipments are with automatically touch sensor, i.e. when the lens is close to the skin start delivery, and can be single diode or multi diode and can develop maximum power of 800 mW.

**PROGRAMMING PANEL**



**POWER SUPPLY BOARD AND OUTPUTS**



## 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 scanning PR999 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 PR999-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, plug the power plug into the mains socket (230 Vac) and turn on the equipment by switching the ON/OFF switch on the back panel to “ON”.

This operation prepare the device to work, it turns on the LCD display LCD, that shows the device is ready to work.

When the LCD display will turn on, it will light up and a logo will appear (see Fig.1), then on the screen a request for the access code will appear.

This code has been set with the default number of 1234: then press in sequence the function buttons near the number on the video (see Figure 2). This code can not be changed by the user, and its typing prepares PR999 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.

Once you entered the access code, appears a screen that allows you to select between four operating modes (Fig.3) by tapping the corresponding button on the screen.



Fig.1

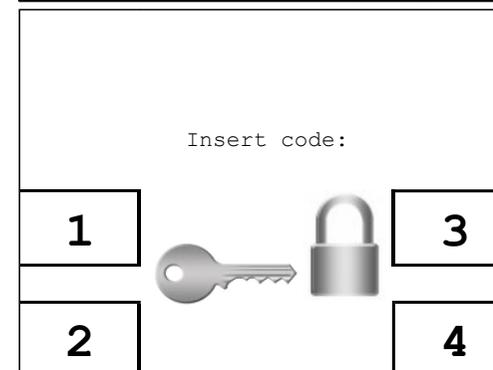


Fig.2

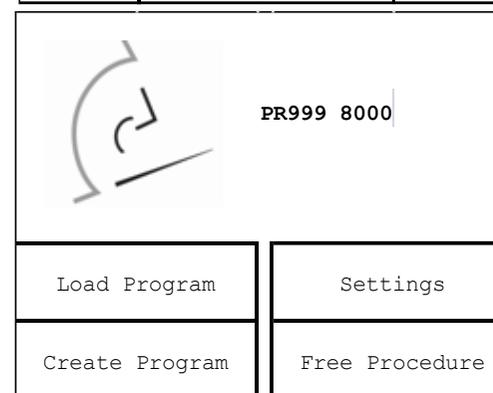


Fig.3

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:

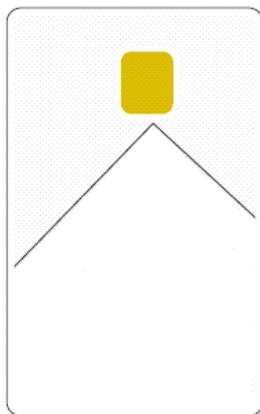


Fig.4 – SMART-CARD

**NOTE:** In order to increase the level of safety of the equipment, the unit has an EMERGENCY STOP SWITCH on a shelf on the front of the housing.

When it is pressed, the unit turns off automatically and it cannot be turned on again until the switch is reset by raising it.

The EMERGENCY STOP SWITCH should be raised in order to start up the unit.

## SETTINGS

This enables the basic settings to be memorised and saved within the machine memory and will automatically be called up each time the machine is turned on.

1. push the function taste relative to the SETTINGS button in correspondence of the screen of fig. 3 ; it appears the main screen of the SETTINGS button ( see fig. 5)
2. Rotate the encoder knob until to position the cursor on the menu of the function that you want to select among those available ( display, various, language )
3. press the encoder knob for to confirm the choice
4. otherwise, push the function taste relative to the EXIT button ; the operation of configuration is aborted and you return to the screen of fig. 3.

## DISPLAY

1. Rotate the encoder knob in correspondence of the main screen of the SETTINGS button until to position the cursor on the DISPLAY menu ( see fig. 5 )
2. press the encoder knob ; it appears a screen where is possible to modify the visibility settings, luminosity and contrast respectively
3. Rotate the encoder knob until to position the cursor on the menu that you want to customize
4. Press the encoder knob on the selected menu for to enable the routine for the menu customization
5. Rotate the encoder knob ( in clockwise way for increasing values, in counter-clockwise way for decreasing values ) until to reach the desired value
6. Press the encoder knob for to confirm the choice
7. repeat the step from 3 to 6 for every menu that you want to customize
8. for to memorize the combination that better he suits for the conditions of visibility of the environment, press the function taste related to the SAVE button; it appears to video the message "saved settings! ", that confirms that the settings are saved, then you return to the main screen of SETTINGS menu
9. otherwise press the function taste related to the EXIT button ; you return to the main screen of SETTINGS menu.

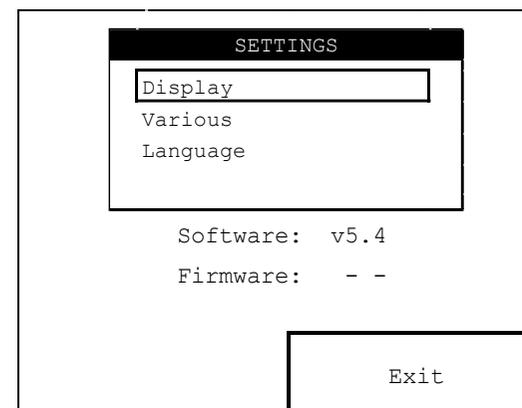


Fig.5

## **VARIOUS**

Enable or turn off the acoustic warning tone (Buzzer) according to operator preferences.

It allows besides to perform the formatting of the Smart-Card and User Memory.

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.

1. Rotate the encoder knob in correspondence of the main screen of the SETTINGS button until to position the cursor on the VARIOUS menu (see fig 5)
2. press the encoder knob; it appears a screen where is possible to select the operation to execute among those available ( training of the buzzer, formatting of the smart-card, formatting of the user-memory)

To enable the "Buzzer on" function, so that for to activate the buzzer

1. rotate the encoder knob until to position the cursor on the "Buzzer on" check-box;
2. press the encoder knob until it appears a check sign in the check-box; this action allows the training of the buzzer in the device;
3. to memorize the configuration setted, press the function taste related to the SAVE button ; it appears to video the message "saved settings! ", that confirms that the settings are saved, then you return to the main screen of SETTINGS menu;
4. otherwise press the function taste related to the EXIT button ; you return to the main screen of SETTINGS menu

To format the User Memory:

1. position the cursor on the "Format User Memory" menu, in correspondence of the main screen of the VARIOUS menu
2. press the encoder knob ; this action allows the appearing of a screen, containing:

- the message to video "Proceed to format ?", where it asks to the operator to obtain the confirmation of the formatting operation to execute
  - the FORMAT and EXIT virtual buttons
3. pushing the EXIT virtual button in correspondence of the screen indicated to the step 2, the formatting operation is aborted and you return to the main screen of the VARIOUS menu;
  4. pushing the FORMAT virtual button in correspondence of the screen indicated to the step 2, the formatting operation is confirmed ; it appears to video a progression bar, that shows the evolution running in the formatting operation, and at the end of this operation ( it needs some seconds ) it appears to video the "Format completed!" message, then you return to the main screen of the VARIOUS menu

To format the Smart-Card:

1. position the cursor on the "Format Smart-Card" menu, in correspondence of the main screen of the VARIOUS menu;
2. press the encoder knob ; this action allows the appearing of a screen, containing:
  - the message to video "Proceed to format ?", where it asks to the operator to obtain the confirmation of the formatting operation to execute
  - the FORMAT and EXIT virtual buttons
3. pushing the EXIT virtual button in correspondence of the screen indicated to the step 2, the formatting operation is aborted and you return to the main screen of the VARIOUS menu
4. pushing the FORMAT virtual button in correspondence of the screen indicated to the step 2, the formatting operation is confirmed; it appears to video a progression bar, that shows the evolution running in the formatting operation, and at the end of this operation ( it needs some seconds ) it appears to video the "Format completed!" message, then you return to the main screen of the VARIOUS menu.

In case of wrong insertion of the smart-card in its slot, the pression of the function taste relative to the FORMAT button in correspondence of the screen indicated at the

step 6 enable the appearing to video of the "Warning ! smart-card not inserted !" message.

To memorize the configuration setted, press the function taste related to the SAVE button ; it appears to video the message "saved settings! ", that confirms that the settings are saved, then you return to the main screen of SETTINGS menu. Otherwise, press the function taste related to the EXIT button; you return to the main screen of SETTINGS menu.

## LANGUAGE

It allows to choose the language where will be written all of the commands and messages of the device.

1. Rotate the encoder knob in correspondence of the main screen of the SETTINGS button until to position the cursor on the LANGUAGE menu ( see fig. 5 )
2. press the encoder knob ; it appears a screen where is possible to select the language among those available (Italian, English, French, Spanish, Deutsch, Russian, Hungarian)
3. Rotate the encoder knob until to positioning the cursor on the menu that you want to customize
4. Press the encoder knob on the selected menu for to train the routine for the customization of the menu
5. to enable the loading of the selected language, press the function taste related to the SAVE button; it appears to video the message "saved settings! ", that confirms that the settings are saved, then you return to the main screen of SETTINGS menu

After a short wait while the new dictionary is loading, the menu will appear in the selected language.

6. otherwise, for to abort the procedure for the selection of the language, press the function taste related to the EXIT button ; you return to the main screen of SETTINGS menu

You can repeat the procedure at any time to change the language.

## FREE PROCEDURE

It allows to choose very quickly with this procedure.

1. press the function taste relative to the FREE PROCEDURE button in correspondence of the screen of fig. 3 ; it appears the main screen of the FREE PROCEDURE button ( see fig. 6 ), that contains the informative window for the default treatment emitted with the scanning laser

You can change the parameters before starting the therapy within the range of pre-set intervals: Frequency of the impulses (proportional to the power), Treatment time (duration), Amplitude and Speed according the X coordinate, Amplitude and Speed according to the Y coordinate.

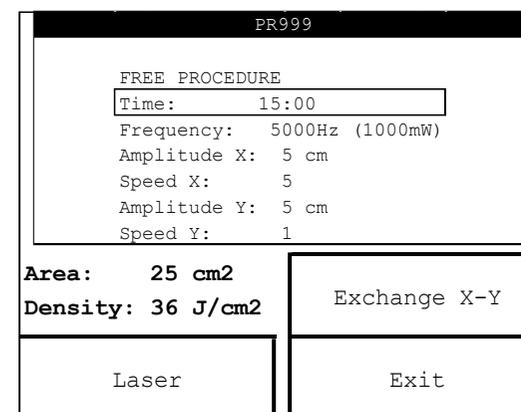


Fig.6

2. Rotate the encoder knob until to positioning the cursor on the menu that you want to customize
3. Press the encoder knob on the selected menu for to train the routine for the customization of the menu
4. Rotate the encoder knob (in clockwise way for increasing values, in counter-clockwise way for decreasing values ) until to reach the desired value
5. Press the encoder knob for to confirm the choice
6. repeat the step from 2 to 5 for every menu that you want to customize
7. To abort the operation of customization and to exit from the "free procedure" modality, press the function taste relative to the EXIT button ; you return to the screen of fig. 3

You can choose the parameters to change by turning the Encoder control knob. You can vary the value by pressing the knob (the function will be disabled if not done within 5 seconds). You confirm the choice by pressing again (or waiting for about 5 seconds after changing the value).

The system automatically calculates the **Area** covered by the scan (which depends on the X and Y amplitudes) and the Energy **Density** (that depends on the Power, the treatment Time (duration) and the area covered).

Using the EXCHANGE X-Y button is possible to reverse the values of the X coordinate with the Y coordinate and vice versa.

The programme cannot be stored during the “Free Procedure” function.

Pressing the function taste relative to the LASER button, you can apply therapy with the PROBE function button using the external probe (optional) at the same time, and independently from the therapy being applied with the SCANNING LASER.

If you press the LASER button the screen will appear (Fig. 7).

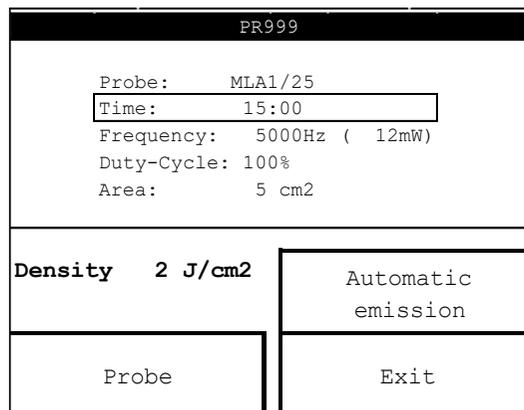


Fig.7

**IMPORTANT:** the power value on the screen shows the emission power of each single diode. For multi-diode probes, each diode emits the indicated power.

You can also change the parameters within the range of pre-set intervals for treatment with the external probe (optional): Type of external probe (MLA1, MLA3, MLA5, MLA8), Frequency of the impulses (proportional to the power), Pulsed (Duty-Cycle), Treatment time (duration).

The percentage value that defines the “Pulsed” mode is the percentage of active time compared to the entire duration of the operative cycle.

So 100% means continuous activity, while 50% means that the active stage and the following pause stage both last for the same amount of time.

1. Rotate the encoder knob until to positioning the cursor on the menu that you want to customize
2. Press the encoder knob on the selected menu for to train the routine for the customization of the menu
3. Rotate the encoder knob ( in clockwise way for increasing values, in counter-clockwise way for decreasing values ) until to reach the desired value
4. Press the encoder knob for to confirm the choice
5. repeat the step from 1 to 4 for every menu that you want to customize
6. For to abort the operation of customization and to exit from the “free procedure” modality, press the function taste relative to the EXIT button ; you return to the screen of fig. 3

To return to the screen that indicates the parameters relative to the scanning laser, you must to push the function taste relative to the LASER button.

Using the AUTOMATIC EMISSION function relatively to the screen of external probe is possible to choose the mode of treatment supplying:

- AUTOMATIC EMISSION: the activation of laser diode take place when it is located at short distance to the skin surface;
- CONTINUOUS EMISSION: the activation of laser diode take place independently from distance to the skin surface

The therapeutic suggestions loaded on the device are related to the emission of the treatment through scanning laser, while the probes allow to emit the treatments in a "free" modality, because they can exclusively act on the treated area and on the duration of the emission.

To use one of the probes supplied for the device, it must to physically connect the probe to the dedicated connector, to set the probe to use and to start the emission of the treatment.

The probes must be used according to the indications supplied inside the user manual.

To start the emission of the default program, press the START button

## TEST LASER

This function lets you check that IR laser radiation is actually emitted from the IR laser emitter diode on the external probe applicator (optional), or from the diodes, if it is a multiple laser head.

For this purpose it is necessary to set the AUTOMATIC EMISSION of the external probe applicator. Then press START button and approach the probe to the surface skin.

Once the probe is located at short distance to the skin surface, the laser diode will turn on automatically, checking the presence of laser emission.

## LOAD PROGRAM

It allows to select the loading program by the main memory ( internal ) or by the secondary memory ( smart-card ) .

1. press the function taste relative to the LOAD PROGRAM button in correspondence of the screen of fig. 3;
2. it appears the main screen of the LOAD PROGRAM button, that contains the list of the pre-setted programs stored in the main memory of the device, the programs stored in the User Memory, the programs stored in the Smart-Card:
  - press the function taste relative to the STANDARD PROGRAM, appears the main screen of the pre-setted programs contained in the main memory of the device; these programs can't be modified or cancelled
  - press the function taste relative to the USER PROGRAM, appears the main screen of the programs loaded on the User Memory, where you can select the customized programs, stored on the User Memory, created with the "Create Program" function
  - press the function taste relative to the SMART-CARD PROGRAM, appears the main screen of the programs loaded on the Smart-Card, where you can select the customized programs, stored on the Smart-Card, created with the "Create Program" function
3. to annul the loading operation of a program, press the function taste relative to the EXIT button ; you return to the screen of fig. 3;

4. once you have selected the memory area among those available (standard pre-setted, User Memory, Smart-Card), so as indicated at the steps 1 and 3, rotate the encoder knob until to position the cursor on the menu of the program that you want to load;
5. press the encoder knob ; it appears the main screen of the selected program;
6. once that the screen relative to the selected program is appeared on the video, you can pass to its execution pushing the START button

It's possible to overwrite a program existing in the User Memory and in the Smart-Card with a new program.

The programmes that are stored in the unit's memory reflect the fruit of many years experience supporting expert professional operators.

Appendix D shows a list of the programmes available.

## APPLICATION OF THE THERAPY

Once you press the START BUTTON, the SCANNING LASER will be started up when the BLUE Led lights up on the back of the LASER head facing towards the operator.

Once you give the START command by pressing the button, the countdown will start on the TIMER (Fig.8).

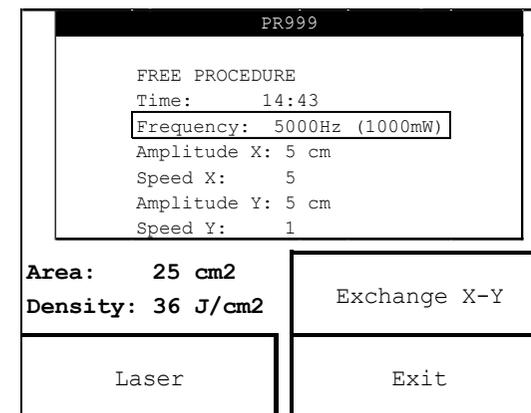


Fig.8

Press the function button LASER to view or set a programme in the external PROBE (optional) channel.

The emission count of the highlighted function (LASER or PROBE) will continue until:

- the set time finishes: when the system will sound intermittent signal tones for about 3 seconds.
- when the STOP button is pressed: the emission cycle will go into Pause mode (Fig.9):
  - o The unit will take up again from the point where it was interrupted when you press the START button;
  - o If you press the STOP button again, the emission will be stopped completely.

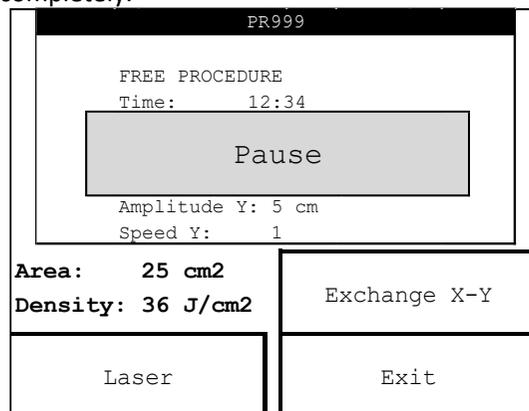


Fig.9

The functioning mode is the same when the external PROBE (optional) function is displayed.

When the LASER function is activated, the equipment prepares for HORIZONTAL scanning; you can reverse the scanning coordinates by exchanging the X and Y coordinates with the EXCHANGE X-Y function key.

During application of the therapy on the LASER channel, you can change the Frequency and the geometric parameters at any time for both the X and the Y coordinates. You can not change the Time (duration) settings.

As previously noted, the PR999-series unit is an IR diode laser beam designed and manufactured in full accordance with national and international safety standards (see Appendix), and it is classified as 3B or 4 LASER CLASS depending on the maximum power (see technical characteristics).

This equipment should always be used with caution in order to reduce any risk (although the risk is contained due to the specific power from IR diode radiation) that may arise from a laser source which is inherently distinguished by mono-chromaticity, collimation, coherency and brilliance.

## CREATE PROGRAM

It allows to create new programs and save them in the User Memory or in the Smart-Card.

1. press the function taste relative to the CREATE PROGRAM button in correspondence of the screen of fig. 3 ;
2. it appears the main screen of the CREATE PROGRAM button that allows to access to the list of programs stored in the User Memory or in the Smart Card:
  - o press the function taste relative to the USER PROGRAM, appears the main screen of the programs loaded on the User Memory, where you can select the customized programs, stored on the User Memory
  - o press the function taste relative to the SMART-CARD PROGRAM, appears the main screen of the programs loaded on the Smart-Card, where you can select the customized programs, stored on the Smart-Card. In case of wrong insertion of the Smart-Card in its slot, the signalling relative to the absence will appear to display, through the appearing to video of the message "warning ! smart-card not inserted!"
3. to annul the operation of creation of a program, push the function taste relative to the EXIT button; you return to the screen of fig. 3;
4. otherwise, ones chosen the memory in which to create the new program (User Memory, Smart-Card), rotate the encoder knob until to position the cursor on a position among the available who you want to save the customized program;
5. if the position selected for to saving the customized program is "free", the program is saved ex-novo ; instead, if the position selected for to saving the customized program is "busy", the customized program overwrites that present in the preceding;
6. press the encoder knob on the selected position for to start the iter for the creation of a program ; this action allows the appearing of the next screen (see Fig.10);
7. to assign a name at the program to create it is necessary to move the cursor in correspondence of the first row, with the rotation of the encoder (Fig.10);
8. press the encoder knob for to train the routine for to rename the customized program ; it appears the position cursor;

- rotate the encoder knob until to move the position cursor in correspondence of the position who you want to insert the character.

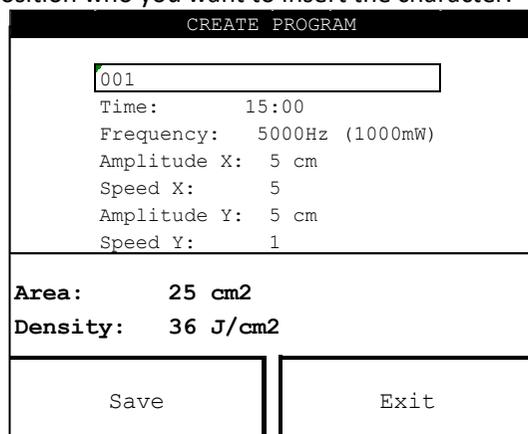


Fig.10

action allows the appearing to video of the message " Saving completed ! ", that it will signal the end of the memorization of the program ; after some seconds, necessary to the saving of the program, you return to the screen containing the list "updated" of the programs saved on smart-card.

You can overwrite a new programme over any existing ones in the memory (User Memory, Smart-Card).

## MAINTENANCE

The PR999-series device for scanning laser therapy does not require any particular maintenance operations.

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 external probes/applicators (optional), particularly the head of treatment, periodically should be cleaned with water and denatured alcohol.

Store with care the probes/applicators at the conclusion of every treatment.

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

Do not spray, nor pour liquids on the external case of the equipment, nor on the air slits.

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 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.

- press the encoder knob; the position cursor is substituted by the selection cursor
- Rotate the encoder knob (in clockwise way for increasing values, in counter-clockwise way for decreasing values) until to select the desired character among those present in the available set;
- press the encoder knob for to confirm the insertion of the selected character in the position chosen ; the selection cursor is substituted by the position cursor
- repeat the steps from 9 to 12 for every of the characters that you want to insert / modify
- when you have completed the typing of the name at the program to create, you must to confirm pushing the function taste relative to the OK button.
- through the rotation of the encoder and then its pression is possible to select the values of the scanning parameters, so that: Frequency, Time, Amplitude and Speed along the X coordinate, Amplitude and Speed along the Y coordinate.
- to modify everyone of the available parameters, please follow the instructions supplied in the preceding paragraphs.
- Once you have assigned the desired name and modified its parameters, it proceeds to the memorization in the memory (User Memory, Smart-Card) through the pressure of the function taste relative to the SAVE button ; this

## TECHNICAL PROBLEMS

PR999-series scanning laser therapy 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 centers.

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

- 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

PR999-series scanning laser therapy 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 PR999-series unit for scanning laser therapy 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.	
	Electronic control circuit malfunction	Contact EME srl Service centre.
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 emission is operating.
	Faulty components on electronic control circuit	Contact EME srl Service centre.
	Faulty supply on laser circuit.	

PROBLEM	POSSIBLE CAUSE	SOLUTION
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.

## THECNICAL SPECIFICATIONS

<b>PR999</b> <b>500mW - 4W (2W+2W) - 8W</b>		
Mains voltage	230 Vac, 50-60Hz, ±10%	
Max. mains Power absorption	<b>500 mW</b>	75 VA
	<b>4W</b>	75 VA
	<b>8W</b>	75 VA
Double fuse protection (T)	<b>500 mW</b>	630 mA-T for supply to 230Vac ,
	<b>4W</b>	1.6 A-T for supply to 230Vac ,
	<b>8W</b>	
Interlock socket/Safety key (contacts normally closed)	3 contact DIN socket	
Backlit LCD Display, to visualise and control operating parameters	graphic 320 x 240 pixel, B/N	
Programmable treatment time	Up to 99 minutes	
Diode Laser wave length emission	<b>500 mW</b>	808 nm
	<b>4W</b>	808 nm + 940 nm
	<b>8W</b>	980 nm
<u>Laser classification according to EN 60825-1</u>	<b>500 mW</b>	3B
	<b>4W</b>	4
	<b>8W</b>	4

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	
Programmable pulse frequency	( 200 ÷ 10000 ) Hz	
X scanning amplitude at Z (distance) of 45 cm approx.	( 1 ÷ 20 ) cm	
Y scanning amplitude at Z (distance) of 45 cm approx.	( 1 ÷ 20 ) cm	
Z distance of laser head	45 cm circa	
Area at Z (distance) of 45 cm approx.	( 1 ÷ 400 ) cm <sup>2</sup>	
X scanning speed	Adjustable in 5 steps	
Y scanning speed	Adjustable in 5 steps	
Divergence	<b>500 mW</b>	32°
	<b>4W</b>	32°
Numerical aperture	<b>8W</b>	0.22
Number of diodes in the device	<b>500 mW</b>	1 x 500mW
	<b>4W</b>	2 x 2 W
	<b>8W</b>	1 x 8 W
DNRO (direct light)	<b>500mW</b>	3.7m
	<b>4W</b>	10.5 m for 808 nm
		7.75 m for 940 nm

	<b>8W</b>	2.044 m
Power @ 200 Hz	<b>500mW</b>	12.5 mW
	<b>4W</b>	80 mW
	<b>8W</b>	160 mW
Power @ 10000 Hz (+/- 20%)	<b>500mW</b>	150mW
	<b>4W</b>	4000mW
	<b>8W</b>	8000mW
Power on tissue@ 200 Hz	<b>500mW</b>	3mW
	<b>4W</b>	64mW
	<b>8W</b>	128mW
Power on tissue@ 10000 Hz (+/- 20%)	<b>500mW</b>	120mW
	<b>4W</b>	3200mW
	<b>8W</b>	6400mW
DO (optical density )	<b>500 mW</b>	2.6 (0.1 m of distance)
	<b>4W</b>	3.5 for 808 nm (0.1 m of distance)
		3.3 for 940 nm (0.1 m of distance)
	<b>8W</b>	2.6 (0.1 m of distance)

MPE (CW)	<b>500 mW</b>	16.4 W/m <sup>2</sup>
	<b>4W</b>	16.4 W/m <sup>2</sup> for 808 nm
		30.2 W/m <sup>2</sup> for 940 nm
	<b>8W</b>	36.3 W/m <sup>2</sup>
Typology for emission of the treatment		Pulsed emission Continuous emission (duty-cycle 100%, frequency max)
Output channels independents		2
Pointer		Solid state laser, 3mW 650nm
External probe (optional) sensor for detecting IR radiation		On the front
Storable therapeutic suggestions		200
Characteristics of the target pointing device of the probe	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
	Laser-beam positioning	Always to the centre of the simmetry axis of 2 red spots

Trolley container, external size (width x height x depth)		39 x H168 x 92cm
Unit body weight		35 Kg
<u>Use conditions</u>	<u>Room temperature</u>	(+10 ÷ +40) °C
	<u>Relative humidity</u>	(10 ÷ 80) % without condensation
<u>Stocking / transport conditions</u>	<u>Room temperature</u>	(+10 ÷ +40) °C
	<u>Relative humidity</u>	(10 ÷ 80) % without condensation
	<u>Atmospheric pressure</u>	(500 ÷ 1060) hPa

#### LASER PROBES SPECIFICATION (OPTIONAL)

##### 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 <sup>2</sup>
EMP (Maximum allowed exposure) pulse train	2,06 mJ/m <sup>2</sup>
EMP (Maximum allowed exposure) average	2,57 mJ/m <sup>2</sup>
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 <sup>2</sup>
EMP (Maximum allowed exposure) pulse train	2,06 mJ/m <sup>2</sup>
EMP (Maximum allowed exposure) average	2,57 mJ/m <sup>2</sup>
DNRO (Nominal eye-hazard distance) direct light	251 mm

##### MLA5 (500)– diodo laser pulsato

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 <sup>2</sup>
EMP (Maximum allowed exposure) pulse train	2,06 mJ/m <sup>2</sup>
EMP (Maximum allowed exposure) average	2,57 mJ/m <sup>2</sup>
DNRO (Nominal eye-hazard distance) direct light	251 mm

## APPENDICES

### Appendix A - ENVIRONMENTAL CONSIDERATIONS

PR999-series unit for laser therapy scanning 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 disposed of as “electronic waste”, not as “domestic waste”
	Input characteristics
	Input voltage to the device (mains)
	Fuses 2xT630mAL250V
	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 )
	Output power from the probe
	Temperature range
	Atmospheric pressure range

Symbol	Signification
	Humidity range

Table 1

Label	Signification										
	Label showing devices sensitive to electrostatic charges, placed near the serial connection connector.										
	Label indicating the mandatory reading of instructions, located on the front panel of the device										
	"Laser emission" label , placed near the laser probe connector.										
	"INTERLOCK" label , situed on the rear panel of the device near the interlock connector.										
<b>PROBE</b>	Label "PROBE", applied near the probe connector.										
	<p>"Caution laser beam" labels placed under the laser head (for class 3B and class 4 lasers)</p> <table border="1"> <thead> <tr> <th>Texts on the label</th> <th>Signification</th> </tr> </thead> <tbody> <tr> <td>Warning</td> <td>Warning</td> </tr> <tr> <td>Visible and invisible laser radiation</td> <td>Presence of visible and invisible laser radiation</td> </tr> <tr> <td>Avoid exposure to beam</td> <td>Avoid a direct exposure to laser beam</td> </tr> <tr> <td>Class 3B (4) laser product</td> <td>Product with 3B (4) as laser class</td> </tr> </tbody> </table>	Texts on the label	Signification	Warning	Warning	Visible and invisible laser radiation	Presence of visible and invisible laser radiation	Avoid exposure to beam	Avoid a direct exposure to laser beam	Class 3B (4) laser product	Product with 3B (4) as laser class
Texts on the label	Signification										
Warning	Warning										
Visible and invisible laser radiation	Presence of visible and invisible laser radiation										
Avoid exposure to beam	Avoid a direct exposure to laser beam										
Class 3B (4) laser product	Product with 3B (4) as laser class										
	<table border="1"> <thead> <tr> <th>Texts on the label</th> <th>Meaning</th> </tr> </thead> <tbody> <tr> <td>Maximum output laser radiation (MLA1 – 25): 25W I.R</td> <td>Maximum output laser radiation (MLA1 – 25): 25W I.R</td> </tr> <tr> <td>Maximum output laser radiation (MLA1 – 100): 100W I.R</td> <td>Maximum output laser radiation (MLA1 – 25): 25W I.R</td> </tr> <tr> <td>Maximum output laser radiation (MLA3 – 75): 3x25W I.R</td> <td>Maximum output laser radiation (MLA3 – 75): 3x25W I.R</td> </tr> </tbody> </table>	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		
Texts on the label	Meaning										
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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										

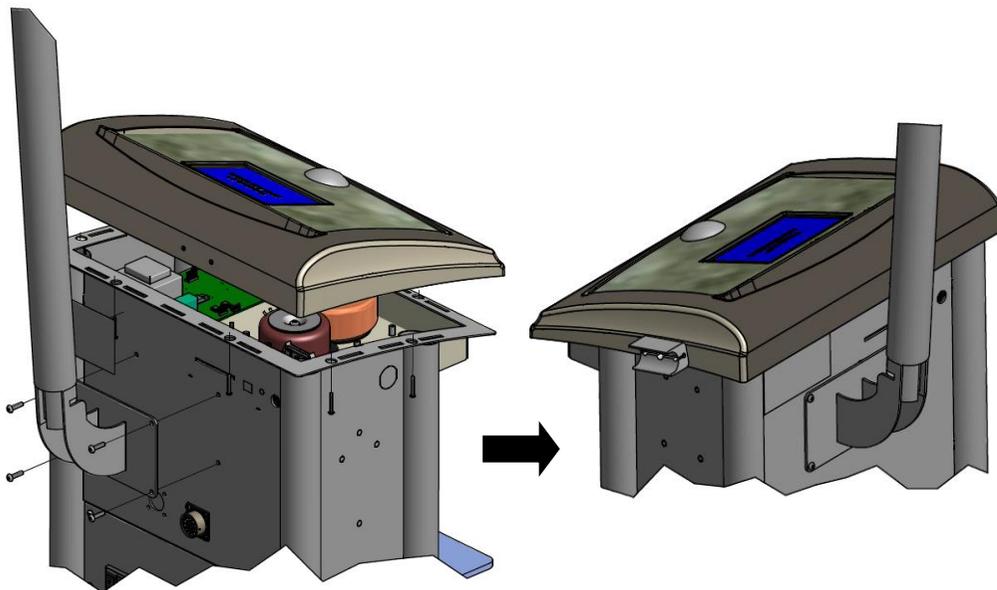
Label	Signification												
	<p>Label placed on the side of the head of the laser arm (where the laser aperture is narrower), containing the characteristics of the laser (IR) and of the guide light (Visible).</p> <table border="1"> <thead> <tr> <th>Texts on the label</th> <th>Signification</th> </tr> </thead> <tbody> <tr> <td>Maximum output</td> <td>Maximum output</td> </tr> <tr> <td>Pulse duration</td> <td>Pulse duration</td> </tr> <tr> <td>Emitted Wavelength</td> <td>Emitted Wavelength</td> </tr> <tr> <td>Classification</td> <td>Reference standard</td> </tr> <tr> <td>Class 3B (4) laser product</td> <td>Product with 3B (4) as laser class</td> </tr> </tbody> </table>	Texts on the label	Signification	Maximum output	Maximum output	Pulse duration	Pulse duration	Emitted Wavelength	Emitted Wavelength	Classification	Reference standard	Class 3B (4) laser product	Product with 3B (4) as laser class
Texts on the label		Signification											
Maximum output		Maximum output											
Pulse duration	Pulse duration												
Emitted Wavelength	Emitted Wavelength												
Classification	Reference standard												
Class 3B (4) laser product	Product with 3B (4) as laser class												
	Labels of "laser aperture" placed on the side of the head of the laser arm (in the point where the laser aperture is narrower), near the opening from which the laser radiation is delivered												
	Labels of " Laser emission stop" applied near the emergency stop button.												
	<p>Label on the back panel of the device, near the connector of the laser handpiece, showing the characteristics of the laser handpieces, as shown in the figure below.</p> <table border="1"> <thead> <tr> <th>Texts on the label</th> <th>Meaning</th> </tr> </thead> <tbody> <tr> <td>Maximum output laser radiation (MLA1 – 25): 25W I.R</td> <td>Maximum output laser radiation (MLA1 – 25): 25W I.R</td> </tr> <tr> <td>Maximum output laser radiation (MLA1 – 100): 100W I.R</td> <td>Maximum output laser radiation (MLA1 – 25): 25W I.R</td> </tr> <tr> <td>Maximum output laser radiation (MLA3 – 75): 3x25W I.R</td> <td>Maximum output laser radiation (MLA3 – 75): 3x25W I.R</td> </tr> </tbody> </table>	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				
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												

Label	Signification	
	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
	Label indicating "Do not push" to be applied in the rear of the cart.	
	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.	

Table 2

## Appendix C – INSTRUCTIONS TO CONNECT THE LASER ARM

1. Place the laser arm as shown in the picture underneath.



2. For the laser head to work, you need to connect the scanner laser to the relative connector in the back of the equipment.

## Appendix D – LIST OF THERAPEUTIC SUGGESTIONS

Laser Therapy Treatments	Time (min.)	Frequency (Hz)	Energy density (J/cm <sup>2</sup> )
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 chondropathy	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

Laser Therapy Treatments	Time (min.)	Frequency (Hz)	Energy density (J/cm <sup>2</sup> )
Trigger points	2	5000	2
Leg ulcer	2	1000	1
Diabetic ulcers	1	500	1

The therapeutic suggestions loaded on the machine relate to the delivery of the treatment through the handpieces while the "scanning" mode allows you to deliver treatments in "free" mode.

**The energy density values shown in the table have been obtained taking into consideration an MLA1 handpiece with a 25mW diode and a treatment surface equal to 1cm<sup>2</sup>. The device software automatically updates the parameters based on the selected handpiece while keeping the energy density constant.**

\* 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 E – 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 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 B	The ME EQUIPMENT is suitable for use in all establishments including 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	± 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	30 A / 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 : $U_T$ 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
	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

**EMME**  
ITALY

Aesthetic & Medical Technologies

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

*The manufacturer*

**EMME 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 :*

**PR999 500mW - PR999 4W - PR 999 8W**

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**

*The machine is marked / The equipment is marked :*

**CE**  
**0476**

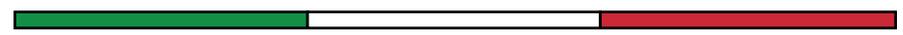
Organismo Notificato / *Notified Body*  
Kiwa Cermet Italia S.p.a.

Pesaro, 20/07/2020

EMME Srl  
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L'Amministratore Unico / *Administrator*

# EME

ITALY



Italian manufacturer of physiotherapy equipment since 1983

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