



# COMBIMED 4000

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



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## INFORMATION ON THIS 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 information for the installation and proper use of the apparatus for combined therapy COMBIMED 4000, bringing together in a single container the modules of Electrotherapy, Ultrasound therapy and LLLT Lasertherapy.

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 user 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 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.

**NOTE:** The Therapy Application Manual is available upon request.

### WRITING CONVENTIONS

Certain sections of the manual have been underlined in order to highlight their importance.

#### NOTE

These contain important information and useful tips for operating the equipment

#### CAUTIONS

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

#### ! WARNING !

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

## WARRANTY

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;
- unauthorized opening of the outer casing;
- tampering or unauthorized 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.
- The selection of the USB memory is possible only if the USB key is previously inserted into the slot.
- To prevent erasure or formatting of USB, confirmation is required.
- YOU MUST ENTER A SECURITY CODE TO START THE MACHINE. The default security code is 12345: to ensure the security of access to the machine it is advisable to change the code and to mark it as a reminder in a safe place to avoid losing it or make it available to unauthorized personnel. The new code must be made of 5 numeric characters.
- 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.
- It's advisable to switch periodically the polarity according to the way it is connected to the applicator plates: the exchange will increase its durability.

## CAUTIONS

### PRELIMINARY NOTES

- The customer is liable for all damage caused by inadequate packaging of the material. Keep the original packaging of the unit: it will be needed if the unit is returned to the company.
- Do not use the equipment in places where it might get wet.
- Before operating the machine carefully check the correctness of the connections according to the instructions.
- To avoid the risk of electric shock, this device must only be connected to power supply networks with protective earth.

- Do not use accessories other than the ones provided: they might damage the unit, causing the warranty to become void. In case you have any problems or difficulties with installation, contact EME srl technical support.
- If using the same extension for the unit and other units, make sure that the total current being absorbed by the connected units, does not exceed the max current allowed for that type of cable and that, however, it does not exceed 15 A.
- The therapeutic suggestions are stored in the permanent memory of the machine. These protocols can be edited but not possible to save any changes.
- The protocols of therapeutic suggestion preloaded on the machine cannot be deleted.
- It is not possible to define a number of sessions suggested to evaluate the effectiveness of the treatment, since they are related to the power delivered to the patient undergoing treatment. It is task of the physician to decide the number of therapy sessions which subject the patient according to the specific requirements of the case, in order to ensure to the patient himself the execution of an effective treatment in time and place in conditions of absolute safety.
- Always control sometimes the integrity of the cable and of the probe/applicator connector: they must not be damaged or worn.
- The laser radiation that outgoings from the device is dangerous: always use the appropriate glasses, always avoid the exposition of the eyes to the direct or reflected laser beam.
- **Before beginning any treatment both operator and patient must wear the PROTECTIVE GLASSES.**
- Before starting up the machine to perform treatment with LASER module, make sure it is inserted the key INTERLOCK that allows it to start.
- CLASS A device suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
- Do not use the machine near HF SURGERY DEVICES and rooms with an RF shield of an EM system for magnetic resonance, in which the intensity of the EM DISORDERS is high
- No modification of this device is allowed.
- The use of accessories, transducers and cables, other than those specified or supplied by EME srl, could lead to higher electromagnetic emissions or a decrease in the level of electromagnetic immunity of the appliance, with consequent incorrect operation.

#### USE

- 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.
- USB option is visible (and therefore selectable) only if the USB key is properly inserted in its slot. In case of lacked insertion of the USB key in its slot or improper insertion, the option button USB 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 USB key (due to its lack or to an improper insertion in its slot) is the only support of available memory to load customized programs.

- Never swap ultrasound probes of the same or different devices, because each probe emits at specific frequencies that are different from any other probe. These frequency are previously set in the channel where the probe shall be used.
- The COMBIMED 4000 device in the MODULE FOR ULTRASOUND THERAPY automatically recognise the probe plugged to the output connector. For the probes supplied with the device, this operation is **not executed** because the frequencies specific of the supplied probe are set in the factory, during the testing phase of the device.
  - Avoid application across or through the head, directly on the eyes, covering the mouth, on the front of the neck, (especially the carotid sinus), or from electrodes placed on the chest and the upper back or crossing over the heart.
- In order to ensure successful treatment with the ULTRASOUND MODULE, it is very important that the transmitting head adheres perfectly to the treatment area, in order to avoid the temporary or permanent appearance of air bubbles as much as possible. Bubbles would reflect part of the radiated Energy and cause overheating of the skin in the areas of poor contact.
- **When treating in the ULTRASOUND module and in the CONTINUOUS modality, the power must be set at a lower level in order to avoid the painful feeling due to the administration of energy concentrated in a single spot.** The negative phenomena, connected to an excessive thermal effect, can be eliminated using a pulsed emission treatment, that delivers adequate peak power. without provoking overheating in the treated area.
- During the delivery of a treatment by using a standard protocol of treatment or more than one treatment, the modified parameters will be saved directly by creating a personalized treatment.
- The machine when saving a custom protocol performs a check on your name and notifies the user if this has already been used. Close the warning window click Yes to continue.
- When creating the patient card is required enter the field name or the last name field. The lack of inclusion will bring up an information window that indicates the need to include such data in order to save the card.
- After saving the patient card, all fields (including first name and surname) may be modified.
- The device when inserting a card control on patient name and notifies the user if this has already been used. Close the warning window click Yes to continue.
- Changing PATIENT CARD by clicking the button saves the new data will be saved on the selected card by erasing and overwriting old ones that are no longer recoverable.
- 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;

- Contact the manufacturer or local technician for assistance.
- Portable and mobile radiocommunication devices can affect the operation of the device.
- transportable RF communication equipment (including peripherals such as antenna cables and external antennas) should be used at a distance not less than 30 cm (12 inches) from any part of the device, including the specified cables. Otherwise, the performance of this device may be degraded

#### MAINTENANCE

- Use the probes/applicators with care: any misuse may affect their performance and features.
  - Under no circumstances technicians not authorized by EME srl are allowed to open and/or disassemble the probe/applicator: such tampering, besides damaging its characteristics, immediately invalidate the right to 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, aggressive solutions or flammable liquids to clean the external parts of the unit and accessories. Using these substances, or misusing the accessories, will cause the immediate voiding of all warranty rights, as well as irreparably damaging the unit and the accessories.
  - 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.
  - For a correct replacement of the installed fuses, observe the following indications:
    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 recommended to perform periodic maintenance **every two years**, in order to check:
    - emission levels;
    - the intensity of any leakage current;
    - the continuity and thus the integrity, of the ground conductor;
    - the correctness of the value of insulation resistance;
- in order to ensure the electrical safety of the device, and ensure that it is operating according to guaranteed safety conditions. For this kind of intervention you should contact EME srl or one of its authorized service centers.

#### WORKING PROBLEMS

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

## ! WARNING !

#### PRELIMINARY NOTES

- The correct position while moving the machine: the apparatus has to be moved exclusively by gripping it with both hands on the curved profiles of the lid.
- The perfect functionality of the device is guaranteed in accordance with the rules of installation and of use included, only with original accessories and spare parts.
- If there are problems or 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.
- Patients with implanted electronic devices (i.e. pacemakers should not be subjected to electrotherapy without the consent of the physician.
- The application of electrodes in the chest area may increase the risk of cardiac fibrillation.
- Avoid use in areas where there are ongoing inflammatory processes.
- Simultaneous connection of a patient to a unit of high frequency electro-surgery can lead to burns and damage the unit supplied with electrotherapy module.
- Operate in close proximity to shortwave or microwave devices can produce instability in output for use with electrotherapy and ultrasound module.
- If you want to install an external Interlock circuit, contact exclusively qualified technicians and supply them the scheme correspondent to the room used for the emission of the treatment. A bad installation of the device can generate serious ocular lesions.
- 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 manufacturer is held responsible for the fundamental safety, reliability and performance of the device only if:
  - The electrical system of the premises complies with the appropriate regulations;
  - The device is used in accordance with the instructions for use.

**USE**

- In order to ensure the functioning of the machine in conditions of absolute safety for the patient, the operator must pay attention to the necessity of a periodic maintenance (every 2 years) of the equipment. EME srl authorized personnel should carry out such operations.
- It is 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 draw the attention of the operator to the necessity of verifying the correctness of the device's electric installation before activating the supply switch.
- It is advisable to suspend the therapeutic treatment if it were to appear some disturbances during its emission.
- It's strongly advised not to hold the device on in state of start without using the probe, it could overheat.
- If you want to proceed with the software update and upgrade of the application but do not have to connect the USB port with the source that contains the updates, the machine quit anyway from the main program and enters the update procedure remaining pending USB connection. Displays a screen that indicates the non-realization of the connection.
- In order to avoid the contamination of the environment where the machines are working and/or the people involved in its use, do not apply to patients electrodes already used in other appliances.
- In order to avoid increases in the level of current delivered out of control, the software monitors the current circulation, the patient circuit is then monitored and in the event of removal from the electrodes' connection, the therapeutic treatment is interrupted.
- The electrotherapy treatments, laser-therapy should be provided under the strict control of the operator, to "conscious" patients, who are able to interact with the operator in the face of the stresses transmitted by the machine. In the event of non-compliance to the designation given, EME srl shall not be responsible for any accidents.
- Some electro-therapy treatments have a high average value current, which make the treatment inherently dangerous as it may occur temporary redness and muscle blocks.
- The advanced termination of a therapy session should be done only by the key STOP. Do not remove the plug from the wall outlet 230V, do not unplug the power cord or using the bipolar switch ON/OFF.
- Moreover it is necessary to remove first the electrodes from the patient's body and then you can proceed with the turning off.
- Use special care in the arrangement of electrodes and in the delivered current when associated to a continuous component ( Ionophoresis ).
- Use particular attention in the arrangement of electrodes with a current density superior to 2mA/cm<sup>2</sup>(right value for efficacy. When using galvanic currents ( Ionophoresis) do not exceeded for any electrode current density of 0,2mA/cm<sup>2</sup>.
- Do not use electrodes in direct contact with the skin, use special moistened sponges.
- Communicate to the patient to alert the operator in case of the intensity of the supplied current causes discomfort.
- In order for the ultrasound probe to be perfectly recognized by the device, make sure you connect/disconnect it while there is no treatment emission going on.
- The use of the controls or regulations or the execution of different procedures from those specified in this user manual can cause the exposition to dangerous radiation
- The operator has the responsibility to verify that the issuing head of laser probe remains well in contact to the zone of treatment, to avoid the emission of the laser in different zones from those to be treated.
- As the laser radiation that escapes from the laser-probes for the emission of the laser-therapy treatments is invisible, the probes foresee on board the assemblage of two diodes led, of red colour.
- The two pointer LED diodes, of red colour, delimit the action area of the spot relative to the laser emission. Use the spots of the pointer-diodes as reference drive for the revealing of the position of the spot of the laser beam.
- The red led-diodes light on with the activation of the laser emission from the operator, and everyone of them they emits a pointer beam.
- The pointer-beams produce some red spot on the point of impact, and they delimit the region where it will revert the spot of the laser beam, that is invisible to human eye.
- The laser beam is always found to the centre of the axis of symmetry of the two red spots.
- The laser radiation that outgoings from the device is dangerous: always use the appropriate glasses. Always avoid the exposition of the eyes to the direct or reflected laser beam.
- It is important that the operator ensures the machine's correct electrical installation before turning on the device. It is recommended not to start the emission of treatment if the device isn't in perfect mechanical conditions.
- **THE PROBE MUST NEVER BE DIRECTED TO AREAS OF BODY SENSITIVE TO THE LASER RADIATION, FOR EXAMPLE THE EYES.**
- **ALWAYS AVOID THE EXPOSITION OF THE EYE TO THE DIRECT OR REFLECTED LASER BEAM.**
- 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 COMBIMED 4000 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.

**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 probes/applicators. In particular:
  - **Every two years** submit to calibration/adjustment all the programmable accessories, such as probes/applicators, supplied with the dispositive. For this kind of intervention please contact EME srl technical support service.

- Check **every week** the treatment head of the probes, in particular of the ultrasound probes, in order to reveal eventual cracks which could lead to the entrance of conductor liquid.
- **Before every treatment therapy** check the integrity of the cable and connector of probes/applicators.
- Before every treatment, it is recommended to clean with caution all of the accessories and the parts of the equipment that have been in contact with 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.
- **Before every treatment therapy** control the integrity of the electric cable and of the probe/applicator connecting cable applied to the patient: they must not be damaged or worn.
- Before delivering the ultrasonic treatment, check the integrity of the emitting head by carefully checking the absence of cracks that could allow the entry of conductive fluids.
- It is advised that personnel with technical preparation substitute the fuses, to perform the operation in safety conditions.
- Do not open the device: inside there are high voltages that may be hazardous.
- 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.
- The electrode is considered a commodity . It is necessary to replace electrodes periodically every 2-3 months in conditions of normal use : an electrode has a duration of hundreds of milliamperes/hour.
- The use of depleted electrodes reduces the performance of the machine and can cause burns.
- As the emission of ultrasound in the CONTINUOUS operating mode is continuous, the operator is responsible for checking that the emitting probe head is adhering well to the treatment area in all its parts, in order to avoid that air bubbles form or stay in area, thus causing the partial reflection of emitted energy and consequently causing an overheating effect.

#### WORKING PROBLEMS

- Do NOT OPEN the unity, as HIGH VOLTAGE ELECTRICITY is present and may prove VERY DANGEROUS.
- When an electromagnetic compatibility disturbance occurs, the device may interrupt therapy delivery, the display continues to function properly, giving the opportunity to pause and restart therapy. If this happens, you must pause and then switch the device off and on again.
- Upon the occurrence of an electromagnetic compatibility disturbance, the device may interrupt the supply despite the display operating; it is only possible to pause and stop the therapy, all the other touch keys lose their functionality. If this happens, you must pause, stop the therapy delivery and then switch the device off and on again.

## INTRODUCTION OF THE TECNOLOGY

### ELECTROTHERAPY

Electrotherapy is used in order to stimulate denervated muscle, to reduce the hypotrophy due to the non-use of the muscle normal-innervated, to maintain the muscular trophism of the denervated muscle or partially innervated, to strengthen the innervated muscle.

Electrotherapy uses the biological effects obtained by electrical Energy for therapeutic purposes and consists of electric currents which are passed through the part of the body concerned, taking care to choose them with certain characteristics suitable to the aims to be achieved. The electric currents can be continuous or variable.

The continuous current (or Galvanic current) is generated by the uniform movement of electric charges in the same direction. Therefore it has constant intensity over time.

Any action produced on an organism by this type of current is effectively linked to the electrochemical effect. If you immerse the electrodes of a galvanic current generator into an electrolyte solution, the ions will flow towards the poles of the opposite sign.

From the point of view of electricity, the human body behaves like an electrolyte solution: ions naturally present in the organism 'migrate' in the presence of an electric field.

Their distribution in cellular and extracellular spaces is variable, and so the potential and permeability of cell walls change.

These phenomenon give rise to a series of effects that can be summarised as follows :

- vasomotor: strong hyperthermia may be felt in the area where the current is applied, even after a brief treatment session;
- trophic: improvement in cellular 'breathing' due to greater blood flow that stimulates the metabolic processes;
- anti-oedematogenous and anti-inflammatory: linked to the reabsorption of exudatives and inflammatory substances;
- nervous: the excitability is increased near the negative pole, and lessened near the positive pole ('polar' effect of the current).

This phenomenon regards the resting electric potential of the membrane that surrounds the nervous fibre. The external surface of the membrane is positively charged with respect to the internal surface.

Contact with the negative pole leads to depolarisation of the membrane, while the positive pole is hyperpolarised.

Even the conductivity of the nerve is changed during passage of the direct current. Temporary neuropraxia may occur at the positive pole.

It is quite difficult to correctly interpret the effects caused by the direct current however since the mechanisms that determine them are not fully understood.

This kind of current serves best as a transcutaneous carrier of medicines or cosmetically active substances.

Variable currents are generally meant to denote all those currents where the intensity is not constant over time.

Alternating current belongs to this category: it varies in intensity, and also periodically alternates in direction: the classic sinusoidal current belongs to the category and the time that the current takes to make a complete sinusoid is called the period. The space covered during the period is the wavelength.

The number of periods made by the current in a second defines the frequency and its unit of measurement is the Hertz [Hz]. We can distinguish between low (0 - 800Hz), medium (800 - 60.000Hz), and high frequency currents (above the 100.000Hz), and for physiotherapy purposes.

All these currents have some properties in common as regards their application effects: the most important biological effect is definitely the motor neuronal excitability effect.

In order to avoid the risk of possible muscular adjustment during contraction, some equipment can supply currents that automatically vary their frequency at regular intervals.

The rectangular currents that operate at 50 Hz frequency with 1msec pulse duration are of special importance as they produce analgesic effects.

The so called "ionic acceleration" is also beneficial as it involves an overlapping of galvanic current with a rectangular current. This device allows us to obtain parallel muscular stimulation during the iontophoretic delivery (normally done by applying the current with constant intensity).

Treatment time is markedly reduced when this method is used.

The different types of currents can be summarised according to their specific actions (or biological effects) :

- Currents at IONTOPHORETIC action = continuous current (at constant intensity);
- Currents at EXCITO-MOTOR action = sinusoidal currents, rectangular exponential currents, pulse train, triangular
- Currents at ANTALGIC action = rectangular pulses of low frequency (50Hz) and pulse time 1msec.
- Currents at TROFIC and VASCULARISING = continuous currents; straightened currents.

## IONOPHORESIS

Current thinking confirms that ionophoresis is an effective way of administering different substances when localised action is required.

Actually, the percutaneous application of medicinal substances is notably affected by the barrier function of the corneal stratum. Methods generally used to neutralise this effect are not always effective.

Overcoming the cutaneous "barrier" stratum is not easy even when direct current is used, since substances generally prefer to enter via the glandular ducts and hair channels.

In addition, the substances can only reach a few millimetres depth.

Excluding the cases where a localised surface effect only is required, the effectiveness and distinctiveness of ionophoresis lies in the fact that the substances introduced in this fashion seem to bind more stably with proteins that normally form part of surface tissue. The substance is therefore reabsorbed into the general cycle more slowly than it would have been if administered hypodermically.

The general effect is however linked with the type of substance used: direct current only functions as a medium.

Therefore medicinal ionophoresis refers to substances introduced that have pharmacological effects.

The substances that can be used are all those with the following properties: a constant percentage of ionic disassociation in water, stability in solution and in contact with electric currents.

However, certain basic rules must be remembered :

- any *water* used to put the substance into solution must be *distilled* to avoid preferential transport of parasite ions;
- *sponges and electrodes* must always be kept perfectly clean and they must be washed well in distilled water;
- if an active substance solution must be prepared on the spot, the concentration of solution must be correctly chosen and measured (remember that it is unnecessary to use high concentrations: generally 1% in weight is easily enough for most substances);
- if products contained in vials are used (for parenteral use) ensure that there are no products incompatible with the technique among the excipients. If it is a freeze-dried product, ensure that the solvent is not a physiological solution: in that case use distilled water if possible;
- avoid including other substances unless you are sure that they are perfectly compatible: if you consider the substance to be essential, ensure that it has the same polarity;
- the correct *electrode* arrangement is essential for diffusion of the substance, especially if the molecular weight is low;

If you have to introduce a positive ion, it must be put with a positive electrode and vice versa for negative ions (in the case of complex molecules on the other hand, it seems that electro-osmosis (and also electrophoresis) takes priority: therefore the concept of polarity loses meaning, and penetration is more effective if done at anode level; the polarities of the most commonly used medicinal substances are described in another section).

Even though the dosage of medicine to introduce is significant from a theoretical point of view, it is actually related to too many factors (skin resistance, ion size, electrode placement) to make even an approximate calculation.

The use of galvanic current to the introduction of substances, when the parameters of current intensity and duration of application are respected, does not give rise to undesirable effects on the skin.

Localized redness may occur occasionally, and even burns, but only when these parameters are not met, or there is a lack of maintenance or improvement of electrodes. Chemical burns at the points of contact of the skin with the electrodes,

due to concentrations of chlorine ions and/or sodium (for formation of caustics substances with water ) may occur when using water source.

There is the possibility of local allergic reactions, although relatively uncommon : in any case, events are mild.

## **ULTRASOUND - THERAPY**

### **THE PHYSICS OF ULTRASOUND**

Ultrasounds are elevated frequency sound waves (of more than 16,000 cycles/sec), not perceptible to the human ear, that exist within nature (for example in the cries of bats, diapasons, etc.). Such waves can also be artificially produced in numerous different ways, although in the medical field this is done by means of the inverse "Curie" effect.

They are propagated under the form of longitudinal compression waves in the presence of a means capable of being compressed; the movement of the particles in the compressed means takes place parallelly to the wave or propagation, meaning that the sound cannot be transmitted through empty space.

The fundamental characteristics of sound waves are:

- the length of the wave,
- the speed of propagation,
- the frequency measured in cycles (the cycle or period measures the number of sound oscillations in 1 second).

In the medical field ultrasonic vibrations are obtained through maniples that take advantage of the piezoelectricity and the reciprocal piezoelectric effect of quartz. This effect lies in the characteristic property of quartz crystals that produce electrical charges when subject to depression and traction forces.

The simplest piezoelectric generator consists of a plate made of quartz (or other piezoelectric material) onto whose surfaces an alternative potential difference, with a frequency able to take the crystal into resonance, is applied.

Ultrasonic vibrations propagate themselves in different ways according to the means within which they travel, in relation to the facility and speed with which the means itself can be deformed.

This depends on a physical characteristic, known as the **acoustic impedance**, of each material. The greater the difference of acoustic impedance between two materials, the greater the quantity of rays that will be reflected, that is to say, not transmitted.

The sound waves travel quicker in materials with greater specific acoustic impedance; therefore, they propagate easily in metals, quite easily in water and yet with great difficulty in air where acoustic impedance is very low.

In the human body ultrasound beams are diffused in all directions thanks to small reflectors, such as, for example, erythrocytes, that behave like elastic points of diffusion and vibrate at the incident sound frequency diffusing energy in all directions.

There is, however, a certain difference between propagation in water and that through human tissues, to the disadvantage of the latter. Therefore, in order for ultrasounds to have the same biological effect in water treatments it is necessary to decrease the frequency and length of application, with the biological effect of the ultrasounds being slightly quicker.

It is, however, obvious that applications in water should only be carried out on suitable parts of the body (such as hands and feet) as it is not easy to carry out ultrasound treatment on a knee in water!

Substance	Propagation speed cm/sec	Specific acoustic impedance*** gr/cm <sup>2</sup> /sec.
Air	331	43
Carbon dioxide	260	51,5
Hydrogen	1260	11,5
Distilled water 19°	1461	146.100
Ice	2100	190.000
Iron	5000	3.900.000
Glass	5400	1.350.000

Table1: Values of propagation and specific acoustic impedance of ultrasounds in given substances.  
\*\*\* the specific acoustic impedance derives from the relationship between the density of the fluid times its propagation speed ( $I = D \times V$ ) and is specific to individual substances.

Ultrasound intensity is expressed in Watt/cm<sup>2</sup>, it refers to the average intensity of the field, and is got by measuring the total output of the treatment (Watts) from the handpiece probe and dividing by the radiating surface area of the applicator.

$$I = Wu / s$$

Where: Wu = output in watts, s= applicator surface.

Ultrasound emitting units used in physiotherapy are manufactured on the above referred to principles and feature:

- an alternate current generator with a frequency of between 500 KHz and 3 MHz; this should be aligned with the quartz frequency to ensure maximum power dissipation. More advanced units, such as those in our Ultrasonic range, operate in both continuous and pulsated (100-120 Hz pulsation frequency) modes; some units have, however, been designed to work in pulsated mode at a frequency of 16-48 Hz. This frequency is important as a number of studies seem to suggest that the kick start system, which plays an important role in the regeneration of bone tissue, is activated and stimulated by ultrasounds at a frequency of 16Hz and multiples of the same;

- a high tension shielded cable that connects the generator to the head and which supplies it with the high frequency produced by the generator;

- an emitting head housing the quartz (nowadays replaced by various materials such as barium titanite) onto whose surfaces an alternative potential difference with a frequency able to take the crystal into resonance is applied. The size of the emitting head can vary between 1cm<sup>2</sup> and 10 cm<sup>2</sup>. The irradiation proprieties of each head therefore depend upon its diameter and the length of the wave, with the sound irradiation produced by the transducer penetrating the tissues in a conical form. In order to have a therapeutic effect on in-depth human tissues, the emitting head must be able to produce an average intensity of 3watt/cm<sup>2</sup>. A head with a radiating surface of 10 cm<sup>2</sup> should have a maximum total output of between 30 watts. The heads of our ultrasound units feature a non-contact luminous indicator that informs the user as to incorrect contact between tissues and the emitting head, and these heads are self-calibrating meaning that they do not need to be reset at any time.

The units POLYTER EVO, supplying both continuous and pulsated ultrasounds, have a duty cycle adjustment feature that significantly decreases the diathermic effect as heat is dispersed in the interval between one impulse and the next.

In addition, pulsated emissions offer the technical advantage of reducing the probability of transducer overheating and allow for the use of greater intensities.

## PHYSIOLOGY AND EFFECTS ON HUMAN TISSUES

The application of ultrasounds on human tissues translates into a high frequency cellular and intercellular massage action. The tissues irradiated with ultrasounds start, in turn, to vibrate resulting in the use of energy and production of heat.

The biological effects of ultrasounds, that is to say, the mechanical and diathermic effects, can be seen in these manifestations.

The MECHANICAL effect develops by means of rhythmic tissue compression and decompression. The particles of a tissue subjected to the vibrating beam are all alternately excited at the same level of speed and acceleration.

The ultrasonic radiation penetrating into the tissues undergoes a progressive weakening in terms of intensity. In the point of passage from the transducer to the skin there is the first limit layer effect, that is to say, the first phenomenon of energy dispersion and re-absorption. The effects of the limit layer become more noticeable at greater depths, particularly at the point of passage between the soft tissues and bone, where the difference in resistance between the two means in contact causes particularly elevated reflection.

The bone tissue, nevertheless, does not completely reflect the ultrasonic beam but rather absorbs a fraction of it, while a rather significant fraction is absorbed by the periosteum which notably overheats with consequential painful sensations that may be provoked by excessively long or high-powered application.

The DIATHERMIC mechanism with assumable biological effects starts to become possible at energies of 1 watt/cm<sup>2</sup>. As the sound propagates through the tissues it is absorbed and converted into heat.

The distribution of the temperature produced by ultrasounds in the tissues is unique in terms of forms of deep heating: in fact, it causes a relatively small increase in temperature on tissue surfaces and has a greater probability of penetrating into the musculature and soft tissues compared to the diathermy produced with microwaves or short waves.

The temperature of articulations covered with heavy masses of soft tissue, such as, for example, the hip, can be increased to therapeutic levels and levels of tolerance that have no detrimental effects on other tissues.

Endotissular hyperthermia manifests itself quite rapidly and is followed by the establishment of a state of thermic balance determined by the dispersion provoked by the blood flow.

Further effects, in addition to these two main effects, are chemical and neural effects.

The CHEMICAL effect seems to be linked to a characteristic phenomenon induced by ultrasounds, known as “cavitation”, that can be seen when the small gaseous bubbles in the liquid components of tissues increase in size translating into oxidization, polymerisation and macro-molecule destruction processes, etc.

Therefore, ultrasounds, at non-detrimental doses, increase exchange favouring diffusion processes and humoral exchanges through the cellular walls.

The NEURAL effect is linked to the influence of ultrasounds on the neuro-vegetative system. Different tissues absorb ultrasounds in different ways: soft tissues at a frequency of 1 MHz attenuate radiation of 1 db/cm, that is to say that in between 15 and 30 mm of tissue only half the energy will be absorbed and the intensity will be reduced to approximately 1/2 of the initial value.

The penetration depth of ultrasonic energy in the muscle is particularly marked: at a depth of approximately 3 cm the intensity is still approximately half that measured at the muscle surface.

A number of scientific experiments have shown how the absorption of ultrasound energy greatly increases the extensibility of connective tissues leading to significant applications in the treatment of scar tissue, superficial articular capsules and cases of tendinitis.

### Applications techniques

Correct ultrasound application requires perfect contact between the emitting head and the tissue in so far as the interposition of layers of air reduces the penetration capacity of the radiation.

Sometimes the area to be treated has an uneven surface making correct direct contact application impossible, although this can be remedied by placing a synthetic rubber pad (filled with oil, anhydrous petrol, degassed water or conductive gel) slightly larger in size than the emitting head, between the transducer and the skin.

A range of different application methods can be used.

The DIRECT and MOBILE CONTACT treatment is the most widely used form of treatment. A greasy cream, Vaseline or conductive gel is spread over the area to be treated in order to allow for better skin ultrasonic wave transmission. The emitter head is directed using circular or up and down movements.

In the DIRECT and FIXED CONTACT treatment, the head can also be held in a fixed position on the part to be treated, spread with a transmitting substance, for the whole length of the session, although in this case it is necessary to lower the power emitted in order to avoid creating patient discomfort (pain is caused by the excessive absorption of ultrasonic energy, for example, in articular and periosteum treatments) or to carry out the treatment using the pulsed mode.

The INDIRECT SUBAQUEOUS CONTACT treatment involves immersing the body part to be treated in a water bath; the emitter head is immersed in the water a short distance from the part to be treated and is moved parallel to the latter.

The emitting maniples of COMBIMED 4000 unit are specially designed for this type of treatment. The part to be treated is immersed in a recipient (better in metal because it is more reflective) containing water together with the emitting head which is positioned at a maximum distance of 2-3 cm from the body surface in order to avoid an excessive dispersion of the ultrasonic beam with a related decrease in therapeutic effects. The ultrasonic vibration is transmitted in a relatively uniform manner in the liquid and homogeneously enters the immersed segment of the body. This method is recommended when it is necessary to treat irregularly-shaped parts of the body (elbows, malleoli, hands, feet, etc), ulcerated areas or hyperesthetic skin zones that cannot withstand pressure. It is a useful method to employ when the surfaces to be treated are particularly small or irregular, or when the area is too painful to permit direct contact.

In the COMBINED treatment (bipolar technique) the specially designed unit, through its metallic head surfaces, emits ultrasounds and impulsive low and medium frequency antalgic-effect currents, or infrared radiation laser energy, contemporaneously.

The SONOPHORESIS involves the localised administration of pharmacologically active substances applied, in place of the gel, in the form of products designed for local use.

## **LASERTHERAPY LLLT**

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

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

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

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

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

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

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

## **COMPONENTS OF LASER SYSTEM**

In general, lasers comprise four structural units:

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

and obviously a mechanical support structure.

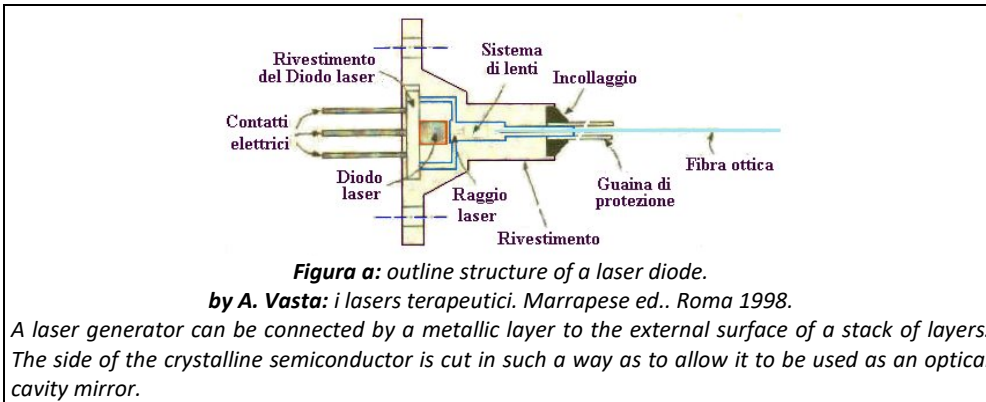
Diode lasers are all made of semiconductor material and have the typical electrical properties of electric diodes.

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

The most common technique is by the p-n junction. The p-n junction refers to a p type semiconductor attached to an n type. This junction conducts electricity in a preferred direction. When the positive pole of the generator is connected to the p side of the p-n junction, and the negative pole of the generator is connected to the n side, a current runs through the p-n junction changing the population of the energy

band. The layers of semiconductor material are placed in such a way so as to create an active region in the p-n junction where photons are generated by a recombination process.

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



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.

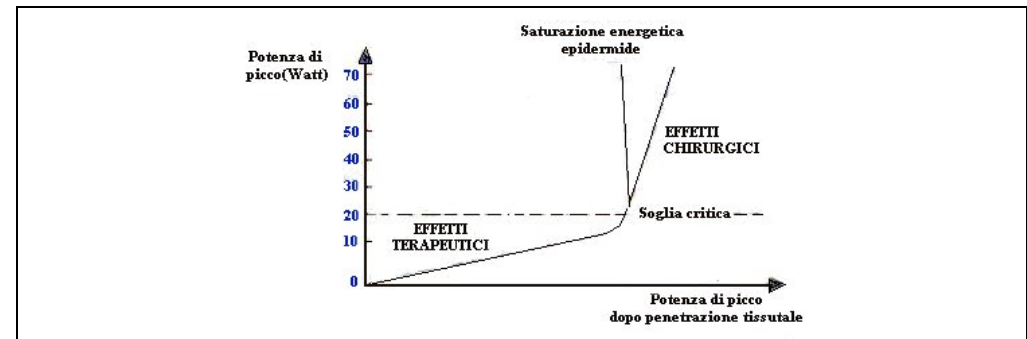
**3. Average power (Pm):** this is a function that varies according to the size, the duration and the frequency of the pulse.

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.

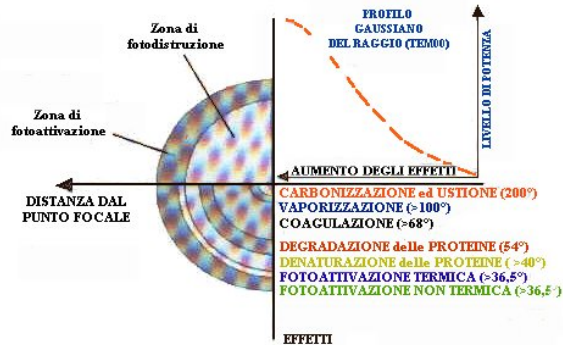
The power of laser beams (both therapeutic and surgical) is higher at the centre of the beam and falls off towards the edges in a bell shaped curve (Gaussian showed in fig.c). The power weakens towards the edges of the beam with lesser effects on the tissue hit. This phenomenon is called the alfa effect. 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.

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. The result is a compact unit, easily transportable, equipped with a modern and essential line, which offers an extremely logical operative sequence supported by a clearly legible display.

Simple and intuitive software is designed using all graphic and functional capabilities of the latest operating systems.

The presence of HELP ONLINE provides a guide to therapy with treatment indications and electrode placement and / or handpieces applicators for each protocol.

The new concept of modularity **MEC system** (Modular Electronic Concept) has allowed us to minimize the footprint of the current electronic forms and allowed to group together in a single container forms of electrotherapy, ultrasound therapy and laser therapy LLLT.

A wide range of therapeutic applications, and guaranteed patient and therapist safety ensure that COMBIMED 4000 is an equipment of the highest quality.

The equipment 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.

## INTENDED USE

COMBIMED 4000 is an electro-medical device for combined therapy capable of delivering therapeutic treatments of Electrotherapy, Ultrasound therapy and Lasertherapy.

In particular, the device may:

- provide electrotherapy treatments by applying conductive electrodes to the patient, regarding the form of electro-therapy;
- delivering ultrasound energy through the use of probe/applicators with integrated contact sensors, with regard to the form of ultrasound-therapy;
- delivering laser energy by means of mono-diodic and multi-diodic probes, with regard to the form of laser-therapy;
- delivering therapeutic treatments combined Electrotherapy and Ultrasound.

The use of COMBIMED 4000 is reserved for operators, such as physiatrists, physical therapists and pain therapists, that, by their training, provide assurance of proper use and safe for the patient.

In fact, the operator must be appropriately qualified and he carefully studied the contents of the user manual in order to use the device; or, he 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.

COMBIMED 4000 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.

COMBIMED 4000 is a machine produced according to the Directive MED 93/42/EEC concerning medical devices.

## INDICATIONS

### **ELECTROTHERAPY:**

Main effects of electrostimulation:

1. Training of the neuromuscular system to respond appropriately during the voluntary and involuntary effort providing an active contraction (isometric, concentric and eccentric ) and the resulting joint movements allowing a proprioceptive feedback;
2. Modulation of pain by the gate control mechanism or mechanisms of descending inhibition;
3. Control or reduction of spasticity by agonist stimulation (contraction/relaxation), antagonists (reciprocal inhibition) or motor inhibition sense;
4. provide to the trans-dermal release of medicinal substances into the skin (Ionophoresis );
5. Improve or maintain joint mobility through mechanical stretching of muscles or connective tissue or reduction of the impediment of movement caused by neuromuscular dysfunction, pain or swelling;
6. Promote wound healing by increasing local circulation, providing a bactericidal effect or alternating electric charges in the injured area.
7. Delay or resolving edema through muscle pump or the effect of electric charges on the interstitial proteins (phenomenon of magnetic fields).

### **ULTRASOUND-THERAPY:**

1. Algia temporomandibular joint;
2. Periarticular calcifications;
3. Adhesive shoulder capsulitis;
4. Scars with keloid evolution;
5. Myofascial pain;
6. Epicondylitis;
7. Low back pain;
8. Knee osteoarthritis;

9. Shoulder periarthritis;
10. Carpal tunnel syndrome;
11. Varicose ulcers (healing is much faster) with 3MHz ultrasound by treating the edge of the ulcer with a commercial gel as a means of coupling (sonophoresis), or by underwater application.

### **LASERTHERAPY:**

Laser therapy treatments are applied under the following conditions:

1. 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
2. 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.
3. Bruises: are treated with laser those with sequelae, the most serious or that you want to solve as soon as possible.
4. 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.

5. Neurology: carpal tunnel syndrome, muscle-intensive headache, phantom limb or facial causalgia and neuralgia.
6. Laser acupuncture: different acupuncturists have become enthusiastic about the use of low-power laser in the stimulation of acupuncture points. The idea of applying the laser in this way has an obvious interest since the treatment is painless, and cost-effective in children or in those who are afraid of needles and also because there is no risk of infection or other (bleeding, fainting, seizures, anatomical damage). At the level of the acupuncture points of the semiconductor laser seem more effective and suitable for their emission mode, more easily modulable.

## CONTRA-INDICATIONS

### ELECTROTHERAPY:

1. Applications on thoracic region in patients with : arrhythmias, congestive heart failure, recent myocardial infarction or other cardiac abnormalities;
2. Application in any region of the body in people with active implantable devices
3. Application on the area of carotid sinus ( the bifurcation of the common carotid artery);, as it may interfere with the normal regulation of the pressure blood flow and cardiac contractily;
4. Trans brain applications, because it can affect neural function (however in some situations the micro-currents are today applied in the trans-brain way )
5. Application on pregnant uterus;
6. Application on cancer tissues ( malignant);
7. High width application directly above areas where it is localized the bone tissue on surface , a sit can cause periosteal pain;
8. Application in damaged area or irritated skin because the current preferentially penetrates through the irritated area causing discomfort ( however some types of E-stim are used to promote the healing of wounds);
9. Application with electrodes near or touching protruding metal, such as surgical staples or sutures;
10. Application on patient who reacts negatively to the procedure;

11. Application on patients who cannot provide with a suitable reaction on stimulation level ( Children, children with mental disorders ).

### **Relative contra-indications:**

12. On areas of excessive fatty tissue when the high level of stimulation, required to activate the deep structures can cause pain or independent reactions;
13. on the phrenic nerve region or on urinary bladder as the stimulus can interfere with the normal function of there structures;
14. on scars because the scar tissue has an increased electrical resistance ;
15. The current acts preferencely around the scar causing an increase of current density at the scars' edges with possible creation of burnings.

### ULTRASOUND-THERAPY:

The ultrasound treatment cannot be provided in the event of:

1. Tumours (Peripheral expansive proliferative stimulation);
2. Osteoporosis (may worsen decalcification phenomena). While this is not an absolute contra-indication, it is advisable to use low frequency pulsed modes (16-48 Hz);
3. Hematomas, risk of re-bleeding;
4. Articulations with epiphysis in the bone-growing phase;
5. Venous vascular affections with thrombosis or thrombophlebitis in the area to be treated in the acute phase;
6. Avoid irradiating near to glands and the cardiac aia, even in healthy patients, (modification of action potentials and contractile proprieties);
7. Avoid using on or close to the eyes (as the fluid means cavitation effect may lead to irreversible damage) due to a risk of hemorrhages and retinal detachment;
8. Avoid carrying out treatments on abdominal or lumbar areas during menstrual cycles and during pregnancy;
9. Avoid carrying out treatments in cases of cutaneous lesions and alterartions of sensitiveness (especially in diabetics with neuropathic complications);
10. Patients with active implantable devices or metal implants;

**Collateral effects:**

The therapeutic treatment with ultrasound has not generally contra-indications if it is made in compliance to the normal modalities.

It is pointed out that after the first-second session of treatment is possible to have an increase of the pain, that will disappear after 5-6 hours.

At maximum dosages of 2-3 W and in case of continuous emission for a duration greater than 12 minutes, it will appear a focused pain in the treatment's area and it is possible to have sick's sensation that could disappear reducing the power .

However, these phenomena are temporary.

**LASERTHERAPY:**

1. 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.
2. 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.
3. 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.
4. Thyroid: laser must never be used over the thyroid.
5. Haemorrhages: indirect laser vaso-dilatation may worsen the haemorrhaging.
6. Immunosuppressive therapy: do not use laser therapy on patients undergoing this type of pharmacological treatment.
7. 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.
8. 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.

9. 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.

10. Coagulation problems.

11. Epilepsy.

**PRELIMINARY NOTES****UNPACKING**

The equipment COMBIMED 4000 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 electrotherapy cable complete circular connector and pin;
- n.4 conductive rubber electrodes 6x8.5 cm;
- n.4 conductive rubber electrodes 5x5 cm;
- n.4 sponge for medium electrodes 6x8.5 cm;
- n.4 sponge for small electrodes 5x5 cm;
- n.2 elastic bands 1000x50mm;
- n.2 elastic bands 600x50mm;
- n.1 multi-frequency probe 1/3MHz, 5cm<sup>2</sup>;
- n.1 ultrasound gel 260 ml
- n.1 laser probe MLA1/100mW, 905nm;

- n.1 pair of safety goggles, OLV model;
- n.1 Interlock.

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

### SETTING UP

The installation of the apparatus for combined therapy COMBIMED 4000 does not require special care, so simple and immediate.

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)

### ACCESSORIES

The COMBIMED 4000 is equipped with power cable, and is compatible with the following accessory kit supplied in accordance with the form for your device:

COMBIMED 4000 description	Supplied	Optional
Power cable plug shuko	1	
Spare FUSES (see technical specifications)	1	
User manual	1	
ELECTROTHERAPY description	Supplied	Optional
Output cables for electrotherapy with banana cables of 2mm	1	
Small conductive rubber electrodes 50x50mm	4	
Big conductive rubber electrodes 60x85mm	4	
Sponge for electrodes 50x50mm	4	
Sponge for electrodes 60x85mm	4	
Short elastic bands (60x5cm)	2	
Long elastic bands (100x5cm)	2	
Output cables for electrotherapy ET module		X
Conductive rubber electrodes 50x50mm (2mm)		X
Conductive rubber electrodes 60x85mm (2mm)		X
Conductive rubber electrodes 80x120mm (2mm)		X
Sponge for electrodes 50x50mm		X
Sponge for electrodes 60x85mm		X

Sponge for electrodes 80x120mm		X
Short elastic bands (60x5cm)		X
Long elastic bands (100x5cm)		X
Probe for manual stimulation		X
Kit of n.4 disposable electrodes 45x35mm (2mm)		X
Kit of n.4 disposable electrodes 46x47mm (2mm)		X
Kit of n.4 disposable electrodes 45x80mm (2mm)		X
Kit of n.4 disposable electrodes 45x98mm (2mm)		X
Kit of n.4 disposable electrodes of diameter 75mm (2mm)		X
Kit of n.4 disposable electrodes of diameter 32mm (2mm)		X
Kit of n.4 disposable electrodes of diameter 50mm (2mm)		X
ULTRASOUNDS MODULE description	Supplied	Optional
TV5 ultrasound probe 1/3 MHz with a 5 cm <sup>2</sup> emitting surface	1	
Ultrasound gel bottle 260ml	1	
TV1 ultrasound probe 1/3 MHz, a 1 cm <sup>2</sup> emitting surface		X
TV3 ultrasound probe 1/3 MHz, a 3 cm <sup>2</sup> emitting surface		X
TV8 ultrasound probe 1/3 MHz, a 8 cm <sup>2</sup> emitting surface		X
Ultrasound gel bottle 260ml		X
Ultrasound gel bottle 1000ml		X
Ultrasound gel soft pack 5000MI		X
LASER MODULE description	Supplied	Optional
Laser probe 905nm with touch sensor: guide light+ 1 diode 100 mW	1	
Safety laser goggles, OLV model	2	
Interlock	1	
Laser probe 905nm with touch sensor: guide light+ 1 diode 25 mW		X
Laser probe 905nm with touch sensor: guide light+ 1 diode 100 mW		X
Laser probe 905nm with touch sensor. guide light+ 3 diode 25 mW (75mW total)		X
Laser probe 905nm with touch sensor: guide light+ 3 diode 100 mW (300mW total)		X
Laser probe 905nm with touch sensor: guide light+ 5 diode 25 mW (125mW total)		X
Laser probe 905nm with touch sensor: guide light+ 5 diode 100 mW (500mW total)		X

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

Two poles cable for connecting electrodes. The cable length must be less than 3m.

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

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

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

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

The accessory assembling is simple and intuitive: each cable for the electrotherapy ET, that allows the connection of two output channels, is equipped with a multi-polar connector to be inserted in the plug on the front panel of the device and with two pairs of pins ( red for the positive electrode and black for the negative one) for connection to the plates of conductive rubber of each channel.

The plate holder sponge's pockets have different sizes, each suitable to accommodate the corresponding electrode of conductive rubber.

Be sure of the proper insertion of the electrode into the sponge's pocket.

Along the side of each electrode in conductive rubber, there is a coupling plug in which the banana cable for electrotherapy coming from the equipment must be connected.

For the connection of any ultrasound probe and laser probe, insert the multipolar connector into the corresponding sockets on the front panel of the device.

The device COMBIMED 4000 is supplied with a security key (interlock) that consists of a special DIN pin to be inserted in the appropriate DIN socket on the rear panel of the device.

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.

Contact authorized dealers EME srl for problems or difficulty installation.

## CONNECTIONS

The power entry module can be found on the back of the unit, with the USB connector, 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.

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 is turned on correctly.

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

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

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

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

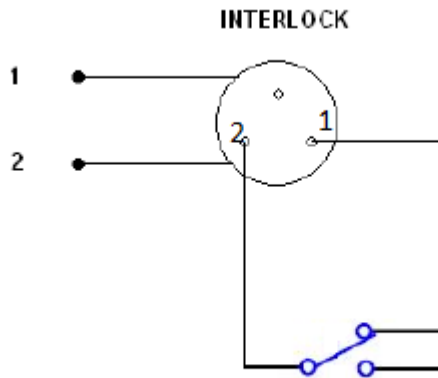


Figure d

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

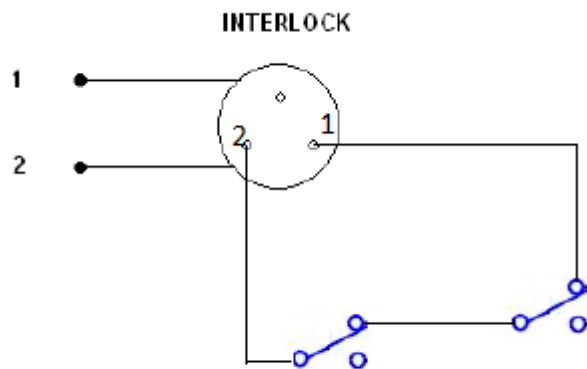
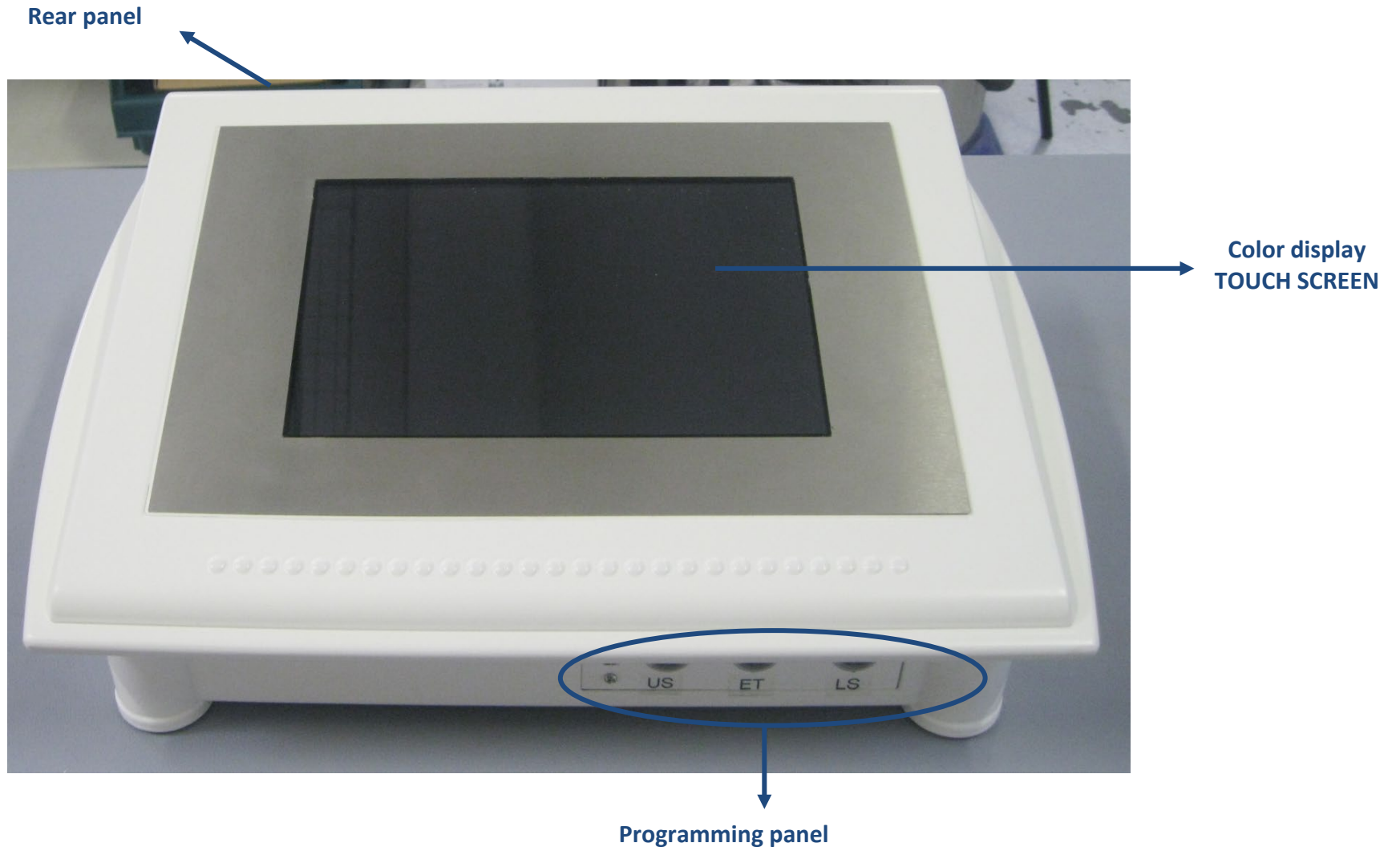
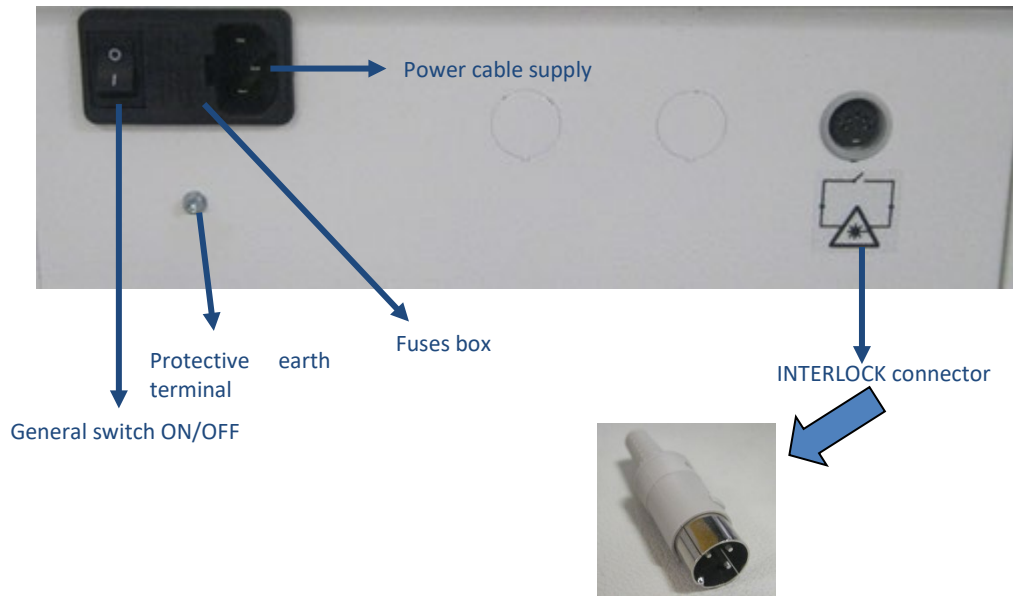


Figure e

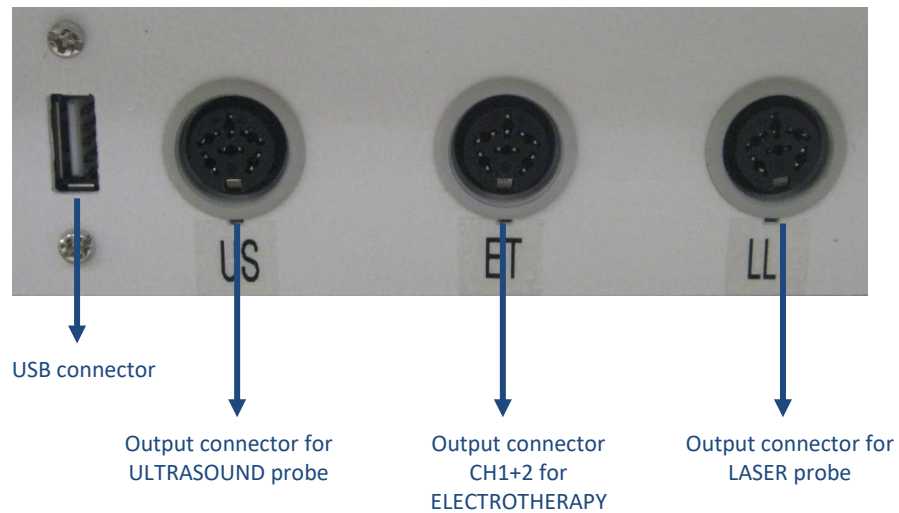
DESCRIPTION OF THE EQUIPMENT



**REAR PANEL**



**PROGRAMMING PANEL**



**ACCESSORIES**

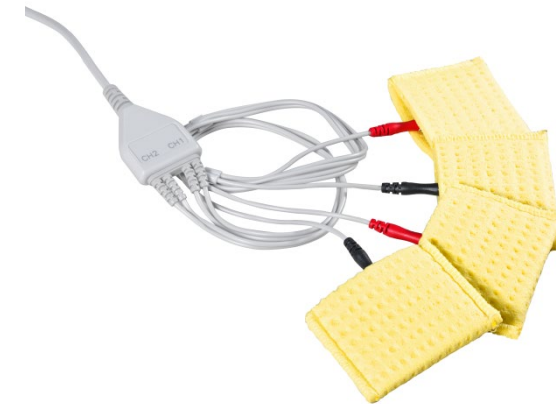
**ULTRASOUNDS PROBE**



**LASER PROBE**



**ELECTRODES**



## HOW TO USE OF THE DEVICE

This chapter provides important information about the right uses of the device for combined therapy COMBIMED 4000, that groups in a single container the modules of Electrotherapy, Ultrasound-therapy and LLLT Lasertherapy.

All the control functions and the overall functional structure of the device are managed by a microprocessor (o MAIN BOARD): this allows access to the stored application programs, and ensures optimal and safe use of the equipment as decided by the operator.

The dialog interface with the user is done by a large and clear Color TOUCH-SCREEN DISPLAY: it displays all operating messages of interest to the user, the functional state of the machine during normal activity, any error messages and HELP ONLINE.

The following sections will explain how the operator should use the equipment for best performance, in addition to illustrating the capacity and the technical features of COMBIMED 4000.

The different choices available are explained; from the selection of a pre-stored program to apply specific treatment, to the evaluation of the correct work parameters needed to apply “customized” application.

### BEST USE

After having installed and correctly positioned the machine as per the instructions described in the previous sections, and you apply the cable (s) for the connection of the electrodes applicators and ultrasound and laser probes in the appropriate connectors, plug the power plug into the outlet wall (230 Vac) and activate the device by bringing in the "ON" the main ON / OFF switch on the rear panel.

This sets the machine to operate, resulting turning on of the DISPLAY, which indicates the condition of equipment ready to work.

With the first start up of the device it is possible to set and choose the language of the seven available. Then click directly on the flag representing the language of interest. Selected language will be maintained for all subsequent switching of the device.

**PLEASE NOTE:** to change the language it is necessary to RESTORE THE FACTORY SETTINGS (see part RESTORE THE FACTORY SETTINGS of user manual).

For the first 20 times when device is switched on is displayed REMINDER for EME PREMIUM SERVICE where we remember the operator the possibility to extend 6-month warranty completely free of charge, only by registering at the site [www.emesrl.com/premium-service](http://www.emesrl.com/premium-service).

After some seconds the DISPLAY will show the logo and a screen to INSERT THE PASSWORD:

1. Enter the PASSWORD
  - o in case of wrong password will appear warning information for user to enter password again
2. once you enter correct password it leads to the main screen where you can select the desired operating mode between the four available.

The password is set by default to 12345: It is sufficient to press in sequence 5 numeric buttons and then ENTER button. By entering the correct code prepares COMBIMED 4000 for the operation.

This code is modified by the user (see part SETTINGS – GENERAL SETTINGS– PASSWORD SETTING).

On main screen you can enter sections :

- **FREE PROCEDURE**
- **PATHOLOGIES** (wizard)
- **PATIENT’S CARD**
- **SETTINGS**

By pressing the button on screen. Here below there is the detailed description of each button.

COMBIMED 4000 gives you the ability to save custom programs and patients cards in two different storage media:

- one internal called INTERNAL MEMORY
- one external called USB MEMORY

where can be managed custom protocols and patients cards.

The both memories can be FORMATTED at any time to be usable with new patients or other compatible devices.

It is possible to use these units to save custom protocols and patients cards, to load and run these programs or to eliminate treatments no longer in use.

The standard protocols of therapeutic suggestion are saved in the internal memory further down the device. This memory is not managed by the user, the data can not be eliminated or formatted, to make available any changes made need to store them on one of the alternative media by creating a custom protocol.

To turn off the device bring in the "OFF" position the main ON / OFF switch on the rear panel.

## FREE PROCEDURE

By pressing the button FREE PROCEDURE in main menu you can enter the screen to select the therapy module.

The buttons that can be pressed are:

- ✓ ELECTROTHERAPY
- ✓ ULTRASOUND
- ✓ COMBINED
- ✓ LASER

After selecting the desired therapy module, a screen will appear to:

- Modify the data of treatment, by acting as described in section **MODIFY**;
- Save the new parameters, following the instructions of section **SAVE**;
- Start the treatment, as described in **START** procedure;
- Load a program by choosing one of the customized ones, created by the operator, as described in the section **LOAD**;
- Open the screen to select the module by pressing the button **BACK**;
- Open the main menu by pressing **HOME**.

In the FREE PROCEDURE the tool called **HELP** online, or the help function to therapy with treatment indications and electrode and / or probes applicators placement, is not applicable.

## ELECTROTHERAPY

In main menu of ELECTROTHERAPY module, it is also necessary to select the channel of treatment, that can be: **CH1** e **CH2**.

To enable the synchronization of output channels, that is to allow the emission of same treatment on both channels, press on button **CH1+2**.

### MODIFY

In this section it is possible to modify quickly and arbitrarily the selected wave forms and the values of therapy parameters of wave forms to use them for a customized program.

To change the wave form:

1. Press the button on the name of wave form;
2. Scroll the list of all wave forms by using the selection arrows on screen;
3. After choosing the desired wave form, press on **CONFIRM** to enter the main screen of the selected wave form with its parameters;
  - Otherwise, to cancel the operation to cancel the modification of the wave form press on **BACK**; the main screen will appear.

Once the wave form has been selected it is possible to modify the values of its parameters, as described here below:

1. If necessary scroll the list of parameters up or down (as shown by the arrow on right side of screen);
2. Press on the parameter to modify;
3. As for parameters **TIME**, **RISE TIME**, **DECAY TIME**, **ACTION TIME**, **PAUSE TIME**, **PHASE DURATION**, **DIPHASE DURATION**, **MIN. HOLD TIME**, **MAX. HOLD TIME** (in seconds) increase or decrease the time with the buttons + or – or scrolling the cursor to the desired value;
4. As for parameters **FREQUENCY**, **MIN. MODULATED FREQUENCY**, **MAX MODULATED FREQUENCY**, **MODULATION FREQUENCY**, **CARRIER FREQUENCY**, **BURST FREQUENCY** (in Hz) increase or decrease the frequency with the buttons + or – or scrolling the cursor to the desired value;

5. As for parameters **POLARITY**, **½ TIME INVERSION**, **WORK MODE**, **DENSITY CONTROL**, **ROTATION (A/M)** press the buttons R+/R-, ON/OFF, CV/CC, ON/OFF and AUTO/MAN in the middle of screen;
6. As for parameters **PULSE DURATION**, **PULSE PAUSE** it is necessary to choose the unit of measurement by pressing the button **µs** or **ms** or **sec** (where necessary), then increase or decrease the duration by using the buttons + or – or scrolling the cursor to the desired value;
7. As for parameter **ELECTRODES SURFACE** (in cmq) increase or decrease the surface of electrodes by using the buttons + or – or scrolling the cursor to the desired value;
8. Press on **CONFIRM** to confirm the modification of parameter; the main screen will appear and the modified value will be in green color highlighted;
  - Otherwise, to cancel the operation press on **BACK**; the main screen will appear.

### SAVE

To save the modification of parameters and save the customized therapeutic program:

1. Press on **SAVE**;
2. A window will appear to select the memory to save the customized program (INTERNAL MEMORY or USB MEMORY);
3. Insert the name of the created program with the virtual keyboard;
4. Press on **OK** to save the program;
  - Otherwise press on **CANCEL**, the program will not be saved and the screen with the modified parameters will appear;
5. A window will appear, then select by using the flag (on the left of the name) one or more anatomical zones to set the created program;
  - Press on flag if you do not want to select the anatomical zone;
6. Press on **OK** to confirm the selection of the anatomical zone and save the program;

- Otherwise press on **CANCEL** to delete the selection of the anatomical zone and not to save the program, in this case the screen with modified parameters will appear;

7. A window will appear to inform the operator that the program has been saved;
8. To start the customized program proceed as described in section START.

When a new customized program is saved, the software controls the programs of database.

If the program has a name already created for another program it will not be possible to save the data with the same name, unless the operator wants to overwrite the therapy:

- Press on **YES** to overwrite the therapy ;
- Press on **NO** to cancel the procedure and insert a new name for the just created program.

### START

To start the emission of an electrotherapy treatment:

1. Position the electrodes on the area to be treated ;
2. Select the channel (**CH1**, **CH2** or **CH1+2**);
  - In screen on the left the name of selected channel appears.
3. Press on **START**, a beep will confirm that the treatment has been started ;
4. A window appears and it shows:
  - the timer with the time left to the end of treatment, with the animation of wave form;
  - The used channel in red color;
  - The emission intensity (mA or V) is on zero as default.
5. Then press on **INTENSITY** and increase or decrease the values by using buttons + or – or scrolling the cursor on right or left;
  - If the selected channel is **CH1+2** and in section ELECTROTHERAPY SETTINGS the synchronization of both channels is on, it will be necessary to set only one **INTENSITY** parameter;

- If the selected channel is **CH1+2** and in section ELECTROTHERAPY SETTINGS the synchronization of both channels is off, it will be necessary to set the parameters **INTENSITY 1** and **INTENSITY 2**;
  - Other parameters that can be personalized during the treatment are in blue color and on the right of the screen. To change them follow the instructions as per section MODIFY;
6. To stop temporarily the emission of treatment on selected channel press on button **PAUSE**;
- It is possible to pause the treatment in one channel and start the emission on another channel by pressing on button **CH1** or **CH2**.
  - This option is not possible if the selected channel is **CH1+2**.
7. The timer stops and a window showing the PAUSE appears, in this window:
- The channel used for the emission in yellow color;
  - The intensity of emission (mA or V) is on zero.
8. To start again emission of treatment press on button **START** and set the value of parameter **INTENSITY**;
- If the emission channel is **CH1+2** and in section ELECTROTHERAPY SETTINGS the synchronization of both channels is on, it will be necessary to set only one **INTENSITY** parameter;
  - If the selected channel is **CH1+2** and in section ELECTROTHERAPY SETTINGS the synchronization of both channels is off, it will be necessary to set the parameters **INTENSITY 1** and **INTENSITY 2**;
9. To stop definitively the emission of electrotherapy treatment press on button **STOP**;
10. A window will appear, then select:
- **YES** to stop the treatment
  - **NO** to continue the treatment .
11. To confirm the stop of treatment on selected channel press on **OK**.

The timer and the emission continue until:

- The time ends: a beep confirms the operator that the time is ended;

- The button **STOP** is pressed and the end of therapy is confirmed: the end is confirmed by a beep.

Now it is possible:

- Press on button **BACK** to go to main screen of ELECTROTHERAPY module;
- Press on button **HOME** to enter the main menu.

### **LOAD**

In this section it is possible to load a PROGRAM by choosing one of the customized ones following the instructions here below:

1. Select **LOAD**;
2. Press on **INTERNAL** or **USB** depending on the memory to load the customized program;
3. If necessary, scroll the list of therapies by lateral scroll bar;
4. Select the desired customized program from the list of therapies to open its screen;
  - Otherwise press on button **BACK** to enter the main screen of ELECTROTHERAPY menu.

Now it is possible:

- modify the data of treatment, as per instructions in **MODIFY**;
- save the new parameters as indicated in section **SAVE**;
- start the treatment, as per instructions in **START**;
- press **BACK** button to go back to the selection screen of the form of therapy;
- press on **HOME** to enter the screen of main menu.

## ULTRASOUNDS

### MODIFY

In this section it is possible to modify the values of default parameters to create customized programs.

1. Select the parameter to be modified;
2. As for parameters **TIME(s)**, **POWER (W/cm<sup>2</sup>)**, **DUTY-CYCLE (%)** and **PULSE FREQUENCY (Hz)** increase or decrease the value with buttons + or – scrolling the cursor to the desired value;
  - If the value of DUTY-CYCLE is between 0%-60% the POWER can be modified from 0.1W/cm<sup>2</sup> to 3W/cm<sup>2</sup>;
  - If the value of DUTY-CYCLE is over than 60% the POWER can be modified from 0.1W/cm<sup>2</sup> to 2W/cm<sup>2</sup>;
3. As for parameter **FREQUENCY (MHz)** press on button 1MHz/3MHz in the middle of screen;
4. As for parameter **WORK MODE** press on button AUTO/CONTINUOUS in the middle of screen
5. Differently from the continuous mode, the automatic work mode starts when the probe, that has a contact sensor, detects that the area to be treated is near or in contact, through the gel, with the probe. Moreover, if the set frequency is 3 MHz, you can only use the continuous mode while at a frequency of 1 MHz you can use both continuous and automatic.
6. Press on **CONFIRM** to confirm the modification of the parameter; in this way the main screen of ULTRASOUND with the modified parameter appears;
  - Otherwise press on **CANCEL** to delete the modification of the parameter, in this case the main screen of ULTRASOUND and the parameter will not be modified.

**PLEASE NOTE:** the % value that defines the DUTY-CYCLE represents the percentage of time of action in respect of the entire duration of the operative cycle (1/100 seconds). The 100% means continuous action, 50% gives equal time value to the action phase and to the following pause.

### SAVE

To save the modification of parameters and save the customized therapeutic program:

1. Press on **SAVE**;
2. A window will appear to select the memory to save the customized program (INTERNAL MEMORY or USB MEMORY);
3. Insert the name of the created program with the virtual keyboard;
4. Press on **OK** to save the program;
  - Otherwise press on **CANCEL**, the program will not be saved and the screen with the modified parameters will appear;
5. A window will appear, then select by using the flag (on the left of the name) one or more anatomical zones to set the created program;
  - Press on flag if you do not want to select the anatomical zone;
6. Press on **OK** to confirm the selection of the anatomical zone and save the program;
  - Otherwise press on **CANCEL** to delete the selection of the anatomical zone and not to save the program, in this case the screen with modified parameters will appear;
7. A window will appear to inform the operator that the program has been saved;
8. To start the customized program proceed as described in section START.

When a new customized program is saved, the software controls the programs of database.

If the program has a name already created for another program it will not be possible to save the data with the same name, unless the operator wants to overwrite the therapy:

- Press on **YES** to overwrite the therapy ;
- Press on **NO** to cancel the procedure and insert a new name for the just created program.

**START**

To start the emission of a treatment for ultrasound therapy:

1. Connect the ultrasound probe to the connector on front panel of device;
2. Press on **START** to start the treatment, a beep confirms that the emission starts;
3. If work mode is CONTINUOUS the us probe connected is working immediately, that means that emission starts immediately even if there is no contact with the skin; the led on probe turns on (red color);
  - Otherwise if work mode is AUTOMATIC the probe starts emission only when contact sensor is in contact with the area; in this moment the led on probe (red color) turns on.
4. A window appears that shows:
  - The timer with time left to the end of treatment;
  - The parameters **POWER**, **DUTY-CYCLE** and **PULSE FREQUENCY**, it will be possible to change them during the treatment as described in section MODIFY.
5. To stop temporarily the emission of treatment in CONTINUOUS mode press on button **PAUSE** and the connected probe will be in pause;
  - Otherwise, in AUTOMATIC work mode, to stop temporarily the emission it is necessary to distance the probe from the treated area and it will be in CONTACT PAUSE .
6. The led on probe turns off;
7. The timer stops and a PAUSE screen appears;
8. To start the treatment again press on START button and follow instructions as from point 2;
9. To stop the emission of ultrasound treatment press on **STOP**;
10. The led on probe turns off;
11. A window will appear then press:
  - **YES** to stop the treatment
  - **NO** to continue the treatment.

12. To confirm the end of therapy press on **OK**.

The timer and emission go on until when :

- The selected time ends: a beep confirms the operator that the time is ended;
- The button **STOP** is pressed and the end of therapy is confirmed: the end is confirmed by a beep.

Now it is possible:

- Press on button **BACK** to go to main screen of ULTRASOUNDS module;
- Press on button **HOME** to enter the main menu.

**LOAD**

In this section it is possible to load a PROGRAM by choosing one of the customized ones following the instructions here below:

1. Select **LOAD**;
2. Press on **INTERNAL** or **USB** depending on the memory to load the customized program;
3. If necessary, scroll the list of therapies by lateral scroll bar;
4. Select the desired customized program from the list of therapies to open its screen;
  - Otherwise press on button **BACK** to enter the main screen of ULTRASOUND menu.

Now it is possible:

- modify the data of treatment, as per instructions in **MODIFY**;
- save the new parameters as indicated in section **SAVE**;
- start the treatment, as per instructions in **START**;
- press **BACK** button to go back to the selection screen of the form of therapy;
- press on **HOME** to enter the screen of main menu.

## COMBINED

The COMBINED ELECTROTHERAPY and ULTRASOUND mode allows delivering combined treatments of electrotherapy at constant voltage (CV) and ultrasound-therapy CONTINUE, corresponding to the channel CH1 of ELECTROTHERAPY module.

To perform a treatment in COMBINED ELECTROTHERAPY and ULTRASOUND mode should be applied on the patient only the positive electrode of channel 1 (CH1) of the electrotherapy and the ultrasound applicator probe, because the ultrasound applicator probe is negative electrode of the channel 1 (CH1) of the electrotherapy.

This connection allows to replace to an hardware level the negative electrode of the channel 1 of the electrotherapy with the ultrasound probe.

On the main screen of COMBINED mode, after selecting the Electrotherapy module and / or ULTRASOUND module, it is possible:

- modify data processing of the available modules, proceeding as indicated in section **ELECTROTHERAPY - MODIFY** and / or **ULTRASOUND - MODIFY**;
- start the combined treatment ELECTROTHERAPY + ULTRASOUND, following the procedure described in section **ELECTROTHERAPY - START** and / or **ULTRASOUND - START**;
- return to the selection screen of module therapy by clicking on **BACK**;
- return to the screen of main menu by clicking on **HOME**.

When LASER module is selected, a window to visualize/modify the treatment area.

After modifying/confirming the dimension of treated area (cm<sup>2</sup>), as described in section **MODIFY**, it will be possible to proceed as described in FREE PROCEDURE.

### MODIFY

In this section it is possible to modify the values of default parameters to create customized programs.

1. Press on parameter to modify;
2. As for parameters **TREATED AREA** (cm<sup>2</sup>), **TIME** (s), **FREQUENCY** (Hz) and **DUTY-CYCLE** (%) increase or decrease the value by using buttons + or – or scrolling the cursor until the required value;

- When TIME is changed (this parameter can be modified) from the default value the values **ENERGY DENSITY** (J/cm<sup>2</sup>) and **ENERGY TO BE EMITTED** (J) vary;
- When FREQUENCY (this parameter can be modified) is changed, the **POWER** (mW) is automatically modified;
- when TIME, TREATED AREA and DUTY-CYCLE (these parameters can be modified) also **ENERGY DENSITY** (J/cm<sup>2</sup>) and **ENERGY TO BE EMITTED** (J) are modified;
- when TIME, TREATED AREA and DUTY-CYCLE and FREQUENCY (these parameters can be modified) **POWER**(mW), **ENERGY DENSITY** (J/cm<sup>2</sup>) and **ENERGY TO BE EMITTED** (J) are modified;

The parameters are connected each other.

**PLEASE NOTE:** the 2 parameters **EMITTED ENERGY**(J) and **REMAINING ENERGY** (J), can be modified only after having connected the probe and started the program.

3. For parameter **WORK MODE** press on button AUTO/CONTINUOUS in the middle of screen
  - Differently from the continuous mode, the automatic work mode starts when the probe, that has a contact sensor, detects that the area to be treated is near or in contact, through the gel, with the probe.
4. Press on **CONFIRM** to confirm that the parameter has to be modified; the main screen of LASER appears and the parameter is in orange color;
  - Otherwise press on **CANCEL** to delete the modification of the parameter, in this case the main screen of LASER and the parameter will not be modified.

### SAVE

To save the modification of parameters and save the customized therapeutic program:

- 1 Press on **SAVE**;
- 2 A window will appear to select the memory to save the customized program (INTERNAL MEMORY or USB MEMORY);

- 3 Insert the name of the created program with the virtual keyboard;
- 4 Press on **OK** to save the program;
  - Otherwise press on **CANCEL**, the program will not be saved and the screen with the modified parameters will appear;
- 5 A window will appear, then select by using the flag (on the left of the name) one or more anatomical zones to set the created program;
  - Press on flag if you do not want to select the anatomical zone;
- 6 Press on **OK** to confirm the selection of the anatomical zone and save the program;
  - Otherwise press on **CANCEL** to delete the selection of the anatomical zone and not to save the program, in this case the screen with modified parameters will appear;
- 7 A window will appear to inform the operator that the program has been saved;
- 8 To start the customized program proceed as described in section **START**.

When a new customized program is saved, the software controls the programs of database.

If the program has a name already created for another program it will not be possible to save the data with the same name, unless the operator wants to overwrite the therapy:

- Press on **YES** to overwrite the therapy ;
- Press on **NO** to cancel the procedure and insert a new name for the just created program.

### **START**

To start the treatment:

1. Connect the applicator/applicators in connectors on front panel of device;
2. Select the dimension of the area to treat by using the parameter **TREATED AREA** (cm<sup>2</sup>) as described in **FREE PROCEDURE– LASER - MODIFY**;
3. Press on **START** , a beep confirms that the treatment has been started;

4. If work mode is **CONTINUOUS** the us probe connected is working immediately, that means that emission starts immediately even if there is no contact with the skin; the led on probe turns on (red color);
  - Otherwise if work mode is **AUTOMATIC** the probe starts emission only when contact sensor is in contact with the area; in this moment the led on probe (red color) turns on.
5. A window appears that shows:
  - The timer with time left to the end of treatment;
  - The parameters **EMITTED ENERGY** (J) and **REMAINING ENERGY RESIDUA** (J) start to vary:
    - The **EMITTED ENERGY** increases until it reaches the value of **ENERGY TO BE EMITTED**;
    - The **Remaining ENERGY** decreases until it reaches 0,0 J.
6. If necessary vary the value of parameters **FREQUENCY** and **DUTY-CYCLE** during the treatment:
  - Press on parameter to modify and increase or decrease the value by using buttons + or – or scrolling the cursor until the desired value.
7. To stop temporarily the emission in continuous mode press on button **PAUSE** and the probe will be in pause;
  - Otherwise, in **AUTOMATIC** work mode, to stop temporarily the emission it is necessary to distance the probe from the treated area and it will be in **CONTACT PAUSE**.
8. The led on laser probe turn off;
9. The timer stops and a **PAUSE** window appears:
  - The counter of parameters **EMITTED ENERGY** and **REMAINING ENERGY** is stopped ;
10. To start the treatment again press on **START** button and follow instructions as from point 3;
11. To stop the emission of laser treatment press on **STOP**;
12. The led on laser probe turn off;

13. A window will appear then press:

- **YES** to stop the treatment
- **NO** to continue the treatment.

14. To confirm the end of therapy press on **OK**.

The timer and emission go on until when::

- The selected time ends : a beep confirms the operator that the time is ended;
- The button **STOP** is pressed and the end of therapy is confirmed: the end is confirmed by a beep.

Now it is possible:

- press the button **BACK** to enter the main screen of LASER module;
- press on **HOME** to enter the screen of main menu.

### **LOAD**

In this section it is possible to load a PROGRAM by choosing one of the customized ones following the instructions here below:

- 1 Select **LOAD**;
- 2 Press on **INTERNAL** or **USB** depending on the memory to load the customized program;
- 3 If necessary, scroll the list of therapies;
- 4 Select the desired customized program from the list of therapies to open its screen;
  - Otherwise press on button **BACK** to enter the main screen of LASER menu.

Now it is possible:

- Modify the data of treatment, as per instructions in **MODIFY**;
- save the new parameters as indicated in section **SAVE**;
- start the treatment, as per instructions in **START**;
- press **BACK** button to go back to the selection screen of the form of therapy;
- press on **HOME** to enter the screen of main menu.

## **PATHOLOGIES**

By pressing the button **PATHOLOGIES** in main screen you can enter the menu to select the anatomical regions to treat.

You can select one of six anatomical regions (delimited by horizontal lines) of the human body shown in the display.

The anatomical regions are:

- ✓ HEAD (FRONT and BACK)
- ✓ CHEST
- ✓ BACK
- ✓ UPPER LIMBS (FRONT and BACK)
- ✓ HANDS (FRONT and BACK)
- ✓ PUBIS
- ✓ LOWER LIMBS (FRONT and BACK)
- ✓ FEET (FRONT and BACK)

By selecting an anatomical region the list of possible pathologies for the selected region is shown and you can load the therapeutic suggested protocol.

This is a list of pathologies with **preloaded programs** on the internal memory of the device and **customized programs** created by the operator and saved on the internal memory.

To select an anatomical region and load its list of pathologies, proceed as follows:

1. Select the button **PATHOLOGIES**;
2. Enter **THERAPIES** to visualize all suggested therapeutic protocols for each anatomical region, divided by therapy module (that is ET,US and LASER);
  - Otherwise click **COMBINED THERAPY** if you want to view the protocols of therapeutic suggestion be performed by combining the ELECTROTHERAPY and ULTRASOUND modules.
  - Otherwise press **MULTI THERAPY** to visualize the suggested therapeutic protocols, for each anatomical zone, that can be executed in succession of two or more therapy modules (as for example ET-US-LASER, ET-US, ET-LASER, US-LASER).
3. Select the anatomical region to treat in picture of body shown on display;

4. On the display a window with the zoom of the selected area to be treated appears, it shows the possible anatomical zones;
5. Select the anatomical region by pressing the blue spot;
6. The list of therapeutic protocols available for that area appears;
  - If the button **THERAPIES** was selected, each therapeutic protocol of the list is shown in different color depending on the module of treatment (light blue for ET, blue for US and yellow for LASER);
  - Otherwise, if the button **MULTI THERAPIES** was selected, each therapeutic protocol of the list is associated to all modules of treatment.
7. Scroll the list of pathologies up or down (as shown by the arrow on the right of display);
8. Select the desired pathology;
9. The screen of the selected pathology appears with all the data of treatment.

In case of **THERAPIES** it's possible:

- MODIFY the data of treatment, as described in section MODIFY of each therapy module;
- SAVE the modified parameters, as described in section SAVE of each therapy module;
- LOAD customized programs, as described in section LOAD of each therapy module;
- START the treatment as described in section START of each therapy module.
- CONSULT HELP ONLINE.

In case of **COMBINED THERAPY** it's possible :

- MODIFY treatment data, proceeding as shown in the section MODIFY of ELECTROTHERAPY and ULTRASOUND module;
- START treatment proceeding as shown in the section START of ELECTROTHERAPY and ULTRASOUND module;
- CONSULT HELP ONLINE.

In both cases to consult HELP online, which constitute a guide to therapy by providing indications of treatment and placement of the electrodes and / or applicators probes, occurs:

1. Select the **HELP** button at the screen of the selected pathology;
2. On the screen of HELP online that appears is described :
  - Type of pathology;
  - Mode of treatment to be performer;
  - Ideal positioning of electrodes and / or applicators probes during execution of the treatment (as shown in the imagine on the left of the screen);
  - The number of suggestion sessions;
  - Possible combinations with other technologies in the treatment of the disease.
3. Click on **CLOSE** to exit from the HELP online screen and return to the screen of the selected pathology.

In case of **MULTI THERAPIES** it's possible:

- START the treatment depending on the sequence of therapy modules for the selected pathology;
- SKIP one or more therapy modules, by pressing the button **SKIP**, until reaching the desired therapy module to use for treating the pathology.
- CONSULT the HELP ONLINE of each therapy module provided for the treatment of the disease.

To consult HELP online, which constitute a guide to therapy by providing indications of treatment and placement of the electrodes and / or applicators probes, occurs:

1. Select the **HELP** button in correspondence with the screen of the therapy module for the selected pathology;
2. On the screen of HELP online that appears is described :
  - Type of pathology;
  - Mode of treatment to be performer;

- Ideal positioning of electrodes and / or applicators probes during execution of the treatment (as shown in the imagine on the left of the screen);
  - The number of suggestion sessions;
  - Possible combinations with other technologies in the treatment of the disease.
- 3 Click on **CLOSE** to exit from the HELP online screen and return to the screen of the therapy module for the selected pathology.

To start treatment, always proceed as indicated in the START section of each therapy module.

To stop completely the treatment of a therapy module it is necessary to:

1. Press **STOP** button on display of therapy module;
2. Select in window:
  - **YES** to confirm the end of treatment
  - **NO** to cancel the stop of treatment.
3. When the treatment is stopped, it is necessary to confirm or not if the same therapeutic treatment has to be performed with the following therapy module:
  - Select **YES** to go on with the following therapy module
  - Select **NO** to finish the treatment and do not start the following therapy module.
4. When the treatment is finished and all therapies are performed press the button **OK** to confirm that the MULTI THERAPY is finished.

Now it's possible:

- Press the button **BACK** to go to the previous screen;
- Press **HOME** to enter the screen of main menu.

### **SEARCH FOR TEXT**

From the selection screen of anatomical area you can select the treatment of interest from words or portions of text contained in the name of the treatment protocol.

By clicking on the magnifying glass in the upper left corner in the selection screen of the anatomical area opens the screen search for text containing a text box with a keyboard and a list of all treatment protocols in alphabetical order and each highlighted with different colors depending of the type of module which can be used (light blue for ET, blue for US and yellow for LASER).

Typing a text in the box, treatment protocols that contain the text are selected, always highlighted with different colors depending on the module used.

Clicking on the protocol of interest opens the screen of the selected pathology with all treatment data.

### **PATIENT'S CARD**

By pressing the button **PATIENT'S CARD** in main screen it is possible to enter a screen with the list of patient's cards.

When the device is turned on for the first time there is no list of patient's cards, it is possible to create new patient's cards following the procedure described in section "CREAT A CARD".

Then, to search a patient's card it is necessary to select the memory, **INTERNAL** or **USB**, to visualize the correct list of patient's card where to search the required patient's card.

Select the desired patient's card and then it is possible to:

- OPEN THE SAVED PATIENT'S CARD;
- MODIFY the PATIENT'S CARD;
- CANCEL the PATIENT'S CARD.

## CREATE A CARD

1. Select in main menu the button **PATIENT'S CARDS**;
  2. Press the buttons **INTERNAL** or **USB** to choose in which memory save the new PATIENT'S CARD;
  3. Select the button **NEW CARD**;
  4. In the screen complete the following fields:
    - SURNAME (requested field)
    - NAME (requested field)
    - ADDRESS
    - PHONE
    - DATE OF BIRTH
    - PATIENT ANAMNESIS
    - TREATMENT from the therapy list
    - Date of BEGINNING OF THERAPY
    - SESSIONS IN TOTAL
    - SESSIONS CARRIED OUT
    - RESULTS
  5. Press on the field to complete;
  6. Complete the data:
    - Select the fields SURNAME, NAME, ADDRESS, TELEPHONE, PATIENT ANAMNESIS, N. SESSIONS IN TOTAL, N. SESSIONS CARRIED OUT and RESULTS and use the virtual keyboard to insert the required info;
      - To let appear/disappear the virtual keyboard press on keyboard image.
    - Select the fields DATE OF BIRTH and START THERAPY to set the day, month and year by using the selection arrows and confirm by using **SETTING**;
    - Select the field TREATMENT by using the button **SEL** and proceed as described in section PATHOLOGIES;
  7. Press the button **SAVE** to save the new patient's card in selected memory ;
    - By pressing **CANCEL** the new patient's card is not saved.
  8. It appears the screen that displays the patient card with its treatment data:
    - The patient's card is identified tank NAME and SURNAME, if a new card is inserted with name and surname already used it will not be possible to save the data and the existing card will be shown. To save the new card it will be necessary to change one of two parameters.
  9. Press on **BACK** to go the screen with the list of patient's cards.
- Now it is possible:
- Modify the patient's card and treatment data as described in section **CHANGE A CARD**;
  - Start the treatment by selecting **GO TO TREATMENT** and proceeding as described in FREE PROCEDURE, section START depending on the therapy module ;
  - Cancel the patient's card by using the button **CARD DELETION**; it will be possible to select:
    - **YES** to confirm the definitive deletion of patient's card;
    - **NO** to cancel the request of deletion.
- At the end of the treatment of the selected card, the number of MADE SESSIONS used for the patient will be automatically increased.
- Once you reached the indicated sessions number in the patient's card you will see a window that will show COMPLETED TREATMENTS for "patients's name".
- Close the window by the OK button and continue selecting the desired function.
- The card that has completed the number of sessions can no longer perform treatments.
- In order to continue to use it you need to change the number of SESSIONS following the procedure for CHANGE the card's data.

## OPEN A CARD

1. Select the button **PATIENT'S CARD** on screen;
2. Press the buttons **INTERNAL** or **USB** to choose the memory to load the patient's card;
3. Depending on the used memory a window with the list of all patient's cards saved will appear;
4. Touch the patient's card to open it, the words will be highlighted in yellow color;
5. Select **OPEN** to open the patient's card;

Now it is possible:

- Modify the parameters of the patient's card before starting the treatment proceeding as described in CHANGE A CARD ;
- Start the selected treatment by using the button **GO TO TREATMENT** and proceeding as described in FREE PROCEDURE section START of each therapy module;
- Delete the selected patient's card by using the button **DELETE CARD**, it will be possible to select:
  - **YES** to confirm the definitive deletion of patient's card
  - **NO** to cancel the request of deletion.

## CHANGE A CARD

1. Select the button **PATIENT'S CARD** on screen;
2. Press the buttons **INTERNAL** or **USB** to choose the memory to load the patient's card;
3. Depending on the used memory a window with the list of all patient's cards saved will appear;
4. Touch the patient's card to open it, the words will be highlighted in yellow color;
5. Select **OPEN** to open the patient's card;
6. Select **MODIFY**

- It is possible to change following data:
  - SURNAME
  - NAME
  - ADDRESS
  - TELEPHONE
  - DATE OF BIRTH
  - PATIENT'S ANAMNESIS
  - TREATMENT from list of pathologies
  - Date of BEGINNING OF THERAPY
  - N. SESSIONS IN TOTAL
  - N. SESSIONS CARRIED OUT
  - RESULTS

7. Press on the field to modify;

8. Use the keys to modify:

- To modify SURNAME, NAME, ADDRESS, TELEPHONE, PATIENT'S ANAMNESIS, N. SESSIONS IN TOTAL, N. SESSIONS CARRIED OUT and RESULTS use the virtual keyboard to insert the modified data;
- To modify the DATE OF BIRTH and Date of BEGINNING OF THERAPY use the selection arrows to change the day, month and year and then press the button **SET** to confirm:
- To modify the field TREATMENT press the button **SEL** and select a new therapeutic treatment as described in section; PATHOLOGIES;

9. Press the button on **SAVE** to save the modified parameters (the old ones will be overwritten) :

- On screen a message will appear to inform the operator that the patient's card has been modified.

10. After a few seconds will appear the screen of the modified patient card with its treatment data.

Now it is possible:

- Start the treatment by selecting **GO TO TREATMENT** and proceeding as described in FREE PROCEDURE, section START depending on the therapy module;
- Cancel the patient's card by using the button **CARD DELETION**; it will be possible to select:
  - **YES** to confirm the definitive deletion of patient's card
  - **NO** to cancel the request of deletion.
- Press on **BACK** to go the screen with the list of patient's cards.
- Click **HOME** to access to the main menu.

## SETTINGS

By pressing the button **SETTINGS** in main menu it is possible to enter a menu to select:

- ELECTROTHERAPY SETTINGS
- ULTRASOUNDS SETTINGS
- LASER SETTINGS
- GENERAL SETTINGS

## ELECTROTHERAPY SETTINGS

In this section it is possible:

- Enable or disable the synchronization of the currents of the output channels:
  - **SYNCHRONIZATION OUT1-OUT2** in position **ON** means the synchronization of the currents of both output channels if treatment is emitted on channel **CH1+2**;
  - **SYNCHRONIZATION OUT1-OUT2** in position **OFF** means that the currents of output channels are not synchronized, because of this if the treatment is emitted on channel **CH1+2** there will be different **INTENSITY** values.
- Enable or disable electrode contact control:
  - **CONTROL CONTACT ELECTRODES** in **ON** position: in case of failure to connect the electrode appears on the screen an error message;
  - **CONTROL CONTACT ELECTRODES** in **OFF** position: if no connection of the electrodes does not appear any kind of error message.
- Visualize, modify and save in internal memory the basic settings of ELECTROTHERAPY module, these settings will be automatically recalled each time the device is turned on;
- Have info on chronology of executed treatments;
- Have general info on electrotherapy module .

### DEFAULT PROGRAM

By pressing the button **DEFAULT PROGRAM** it is possible to see the default parameters of channels CH1, CH2 and CH1+2 that appear in section FREE PROCEDURE of ELECTROTHERAPY module .

To modify the default parameters and set new ones, it is necessary:

1. Select the emission channel between **CH1**, **CH2** and **CH1+2**;
2. Depending on the selected channel it will be possible to modify the default data;

3. Select the parameter to modify and proceed as described in FREE PROCEDURE – ELECTROTHERAPY - section MODIFY:
  - The default parameters to be changed depend on the selected wave form.
4. Press on **SAVE**;
5. Select **OK** to save the new data as default parameters
  - Otherwise press **CANCEL** if you do not want to save the changes of the default program.

In DEFAULT PROGRAM menu it is possible to load a PROGRAM saved in INTERNAL MEMORY or USB by proceeding as described in FREE PROCEDURE –ELECTROTHERAPY –section.

### TREATMENT CHRONOLOGY

To have the complete chronology of treatments carried out with the ELECTROTHERAPY module:

1. Select **TREATMENT CHRONOLOGY**;
2. Enable the chronology by pressing button **DEACTIVATED**:
  - The button DEACTIVATED will be replaced by button **ACTIVATED**;
  - A window will appear and it will be possible to select:
    - **YES** to enable the chronology of treatments
    - **NO** to disable the chronology of treatments
3. Once the chronology of treatments is, it will be possible to save:
  - The date of therapy;
  - The hour of beginning (START) and finishing (STOP) of the therapy;
  - The duration (min) of therapy;
  - The set time (min);
  - The therapy module used for the therapeutic treatment.
4. Press the button **ACTIVATED** to disable the chronology of treatments:
  - The button ACTIVATED will be replaced by button DEACTIVATED;

- The automatic saving will be deleted but the saved data won't be deleted;
- Select in window:
  - **YES** to disable the chronology of treatments
  - **NO** to not disable the chronology of treatments

Proceed as follows to delete some records from the list of treatment chronology of ELECTROTHERAPY module:

1. Select one or more records to delete: they will be highlighted in blue;
2. Press on **DELETE** button;
3. Select in window:
  - **YES** to confirm the definitive elimination of selected data
  - **NO** to delete the elimination of selected data

Proceed as follows to delete all chronology of treatments of ELECTROTHERAPY module:

1. Press the **DELETE CHRONOLOGY** button;
2. A window will appear, it will be possible to select
  - **YES** to confirm the definitive elimination of all data of saved chronology
  - **NO** to cancel the elimination of all data of saved chronology

Proceed as follows to save the chronology of treatments of ELECTROTHERAPY module in USB key:

1. Insert the USB key into the connector;
2. A window will appear, it will be possible to select:
  - **YES** to save
  - **NO** to cancel the saving
3. Press on button **OK** to confirm that saving of chronology was successful.

Now it is possible:

- Press the button **BACK** to enter the previous screen ;

- Press **HOME** to enter the main screen.

### **INFORMATION**

To visualize the diagnostic information of the ELECTROTHERAPY module press the button **INFORMATION**:

- The most used therapy;
- The total treatment time in minutes;
- The number of slot of electrotherapy module ;
- The HARDWARE version;
- The SOFTWARE version.

The authorized personnel can update the software of the ELECTROTHERAPY module only with the necessary application.

Copy the file, supplied from the manufacturer, in USB key without changing the name of file and without inserting it into;

1. Insert the USB key in the connector;
2. Press the button **SW UPDATE**;
3. A window will appear, it will be possible to select:
  - **YES** to proceed with software update of the electrotherapy module
  - **NO** to cancel the software update procedure
4. Select the file to load;
5. A window will appear, it will be possible to select:
  - **OK** to proceed with software update of the electrotherapy module
  - **CANCEL** to cancel the software update procedure
6. Now follow the instructions on display.

After some seconds COMBIMED 4000 will have the updated software version for ELECTROTHERAPY module.

In case of any problem during software update please contact EME's after sales service.

## **ULTRASOUNDS SETTINGS**

In this section it is possible:

- Visualize, modify and save in internal memory the basic settings of ULTRASOUND module, these settings will be automatically recalled each time the device is turned on;
- Have info on chronology of executed treatments;
- Have general info on ultrasound module.

### **DEFAULT PROGRAM**

By pressing the button **DEFAULT PROGRAM** it is possible to see the default parameters that appear in section FREE PROCEDURE of ULTRASOUND module .

The following parameters can be modified:

TIME (min)

FREQUENCY (MHz)

POWER (W/cm<sup>2</sup>)

DUTY-CYCLE (%)

PULSED FREQUENCY (HZ)

WORK MODE (CONTINUOUS/AUTO)

To modify the default parameters and set new ones, it is necessary:

1. Select the parameter to change and proceed as described in FREE PROCEDURE – ULTRASOUND
2. Press on **SAVE**;
3. A window will appear, select **OK** to save the data as new default values
  - Otherwise **CANCEL** if you do not want to save the changes of the default.

In DEFAULT PROGRAM menu it is possible to load a PROGRAM saved in INTERNAL MEMORY or USB by proceeding as described in FREE PROCEDURE –ELECTROTHERAPY –section LOAD.

## **TREATMENT CHRONOLOGY**

To have the complete chronology of treatments carried out with the ULTRASOUNDS module:

- 1 Select **TREATMENT CHRONOLOGY**;
- 2 Enable the chronology by pressing button **DEACTIVATED**:
  - The button DEACTIVATED will be replaced by button **ACTIVATED**;
  - A window will appear and it will be possible to select:
    - **YES** to enable the chronology of treatments
    - **NO** to disable the chronology of treatments
- 3 Once the chronology of treatments is, it will be possible to save:
  - The date of therapy;
  - The hour of beginning (START) and finishing (STOP) of the therapy;
  - The duration (min) of therapy;
  - The set time (min);
  - The therapy module used for the therapeutic treatment.
- 4 Press the **ACTIVATED** button to disable the chronology of treatments:
  - The ACTIVATED button will be replaced by button DEACTIVATED;
  - The automatic saving will be deleted but the saved data won't be deleted;
  - Select in window:
    - **YES** to disable the chronology of treatments
    - **NO** to not disable the chronology of treatments

Proceed as follows to delete some records from the list of treatment chronology of ULTRASOUNDS module:

1. Select one or more records to delete: they will be highlighted in blue;
2. Press on **DELETE** button;
3. Select in window:

- **YES** to confirm the definitive elimination of selected data
- **NO** to delete the elimination of selected data

Proceed as follows to delete all chronology of treatments of ULTRASOUNDS module:

1. Press the button **DELETE CHRONOLOGY**;
2. A window will appear, it will be possible to select
  - **YES** to confirm the definitive elimination of all data of saved chronology
  - **NO** to cancel the elimination of all data of saved chronology

Proceed as follows to save the chronology of treatments of ULTRASOUNDS module in USB key:

1. Insert the USB key into the connector ;
2. A window will appear, it will be possible to select:
  - **YES** to save
  - **NO** to cancel the saving
3. Press on button **OK** to confirm that saving of chronology was successful.

Now it is possible:

- Press the button **BACK** to enter the previous screen;
- Press **HOME** to enter the main screen.

## **INFORMATION**

To visualize the diagnostic information of the ULTRASOUNDS module press the button **INFORMATION**:

- The most used therapy;
- The total treatment time in minutes ;
- The number of slot of electrotherapy module ;
- the HARDWARE version;
- the SOFTWARE version.

The authorized personnel can update the software of the ULTRASOUNDS module only with the necessary application.

Copy the file, supplied from the manufacturer, in USB key without changing the name of file and without inserting it into;

1. Insert the USB key in the connector;
2. Press the button **SW UPDATE**;
3. A window will appear, it will be possible to select:
  - **YES** to proceed with software update of the ultrasounds module
  - **NO** to cancel the software update procedure
4. Select the file to load;
5. A window will appear, it will be possible to select:
  - **OK** to proceed with software update of the ultrasounds module
  - **CANCEL** to cancel the software update procedure
6. Now follow the instructions on display.

After some seconds COMBIMED 4000 will have the updated software version for ULTRASOUNDS module.

In case of any problem during software update please contact EME's after sales service.

## LASER SETTINGS

In this section it is possible:

- Visualize, modify and save in internal memory the basic settings of LASER module, these settings will be automatically recalled each time the device is turned on;
- Have info on chronology of executed treatments;
- Have general info on laser module.

## DEFAULT PROGRAM

By pressing the button **DEFAULT PROGRAM** it is possible to see the default parameters of FREE PROCEDURE of LASER module .

The first screen that appear is the screen to visualize/modify the area of treatment :

1. Increase or decrease the value of the **TREATED AREA** (cm<sup>2</sup>) by using the buttons + or – or scrolling the cursor to right or left until the desired value;
2. Press on **CONFIRM** to confirm the modification of the parameter; the LASER default screen will appear and the changed parameter will be in orange color;
  - otherwise, to cancel the modification of the parameter press on **BACK**; the LASER default screen will appear and the parameter will not be changed.
3. In LASER default screen it is possible to modify the other default parameters.

The default parameters that can be modified are:

TIME (min)

FREQUENCY (Hz)

DUTY-CYCLE (%)

WORK MODE (CONTINUOUS / AUTO)

To change the default parameters and set new ones proceed as below:

1. Select the parameter to change and proceed as described in FREE PROCEDURE – LASER – section MODIFY
2. Press on **SAVE**;
3. Select **OK** to save the new data as new default values
  - Otherwise press **CANCEL**, in this case the default program will not be modified .

In screen DEFAULT PROGRAM it is possible to load a PROGRAM by choosing one of the INTERNAL MEMORY or USB MEMORY; proceed as described in FREE PROCEDURE – LASER –section LOAD.

## TREATMENT CHRONOLOGY

To have the complete chronology of treatments carried out with the LASER module:

- 1 Select **TREATMENT CHRONOLOGY**;
- 2 Enable the chronology by pressing **DEACTIVATED** button:
  - The DEACTIVATED button will be replaced by **ACTIVATED** button;
  - A window will appear and it will be possible to select:
    - **YES** to enable the chronology of treatments
    - **NO** to disable the chronology of treatments
- 3 Once the chronology of treatments is, it will be possible to save:
  - The date of therapy;
  - The hour of beginning (START) and finishing (STOP) of the therapy;
  - The duration (min) of therapy;
  - The set time (min);
  - The therapy module used for the therapeutic treatment.
- 4 Press the **ACTIVATED** button to disable the chronology of treatments:
  - The ACTIVATED button will be replaced by DEACTIVATED button;
  - The automatic saving will be deleted but the saved data won't be deleted;
  - Select in window:
    - **YES** to disable the chronology of treatments
    - **NO** to not disable the chronology of treatments

Proceed as follows to delete some records from the list of treatment chronology of LASER module:

- 1 Select one or more records to delete: they will be highlighted in blue;
- 2 Press on **DELETE** button;
- 3 Select in window:

- **YES** to confirm the definitive elimination of selected data
- **NO** to delete the elimination of selected data

Proceed as follows to delete all chronology of treatments of LASER module:

- 1 Press the button **DELETE CHRONOLOGY**;
- 2 A window will appear, it will be possible to select
  - **YES** to confirm the definitive elimination of all data of saved chronology
  - **NO** to cancel the elimination of all data of saved chronology

Proceed as follows to save the chronology of treatments of LASER module in USB key:

- 1 Insert the USB key into the connector ;
- 2 A window will appear, it will be possible to select:
  - **YES** to save
  - **NO** to cancel the saving
- 3 Press on button **OK** to confirm that saving of chronology was successful.

Now it is possible:

- Press the button **BACK** to enter the previous screen ;
- Press **HOME** to enter the main screen.

## INFORMATION

To visualize the diagnostic information of the LASER module press the button **INFORMATION**:

- The most used therapy;
- The total treatment time in minutes ;
- The number of slot of electrotherapy module ;
- the HARDWARE version;
- the SOFTWARE version.

The authorized personnel can update the software of the LASER module only with the necessary application.

Copy the file, supplied from the manufacturer, in USB key without changing the name of file and without inserting it into;

- 1 Insert the USB key in the connector;
- 2 Press the **SW UPDATE** button;
- 3 A window will appear, it will be possible to select:
  - **YES** to proceed with software update of the laser module
  - **NO** to cancel the software update procedure
- 4 Select the file to load;
- 5 A window will appear, it will be possible to select:
  - **OK** to proceed with software update of the laser module
  - **CANCEL** to cancel the software update procedure
- 6 Now follow the instructions on display.

After some seconds COMBIMED 4000 will have the updated software version for LASER module.

In case of any problem during software update please contact EME's after sales service.

## GENERAL SETTINGS

It is possible to modify and save in the internal memory the general settings that will be automatically loaded when the device is turned on.

A screen will appear by pressing the button **GENERAL SETTINGS** and it will be possible to select:

- SOUND SETTINGS
- MEMORY SETTINGS
- PASSWORD SETTINGS
- SYSTEM SETTINGS

It is also possible to see on screen the **DAYS LEFT FOR SERVICE**.

By pressing the button **RESET COUNTDOWN** it is possible to reset the number of days left for service.

To reset the countdown it is necessary to insert a password and only EME authorized service personnel technical can reset the number of days left for service.

## SOUND MANAGEMENT

In this section it is possible to:

- Select the acoustic setting of the device to confirm the activation of the following functions START TREATMENT, END TREATMENT, ERROR, TREATMENT EMISSION;
- Set the GENERAL VOLUME of the device;
- Enable/disable the KEYBOARD SOUND.

Proceed as described here below:

1. Press the button **SOUND SETTING** ;
2. Enable the **TREATMENT START SOUND** by selecting the desired sound of the list to associate to this function
  - Disable the TRATMENT START SOUND select "No sound" in list;
3. Enable the **TREATMENT END SOUND** by selecting the desired sound of the list to associate to this function
  - Disable the TREATMENT END SOUND select "No sound" in list;
4. Enable the **ERROR SOUND** by selecting the desired sound of the list to associate to this function
  - Disable the **ERROR SOUND** select "No sound" in list;
5. Enable the **WARNING SOUND** by selecting the desired sound of the list to associate to this function
  - Disable the **WARNING SOUND** select "No sound" in list;
6. Enable the **SOUND DURING TREATMENT** by selecting the desired sound of the list to associate to this function
  - Set the intermittent beep of the acoustic sound during treatment using the buttons + and – or scrolling the cursor to right or left until the desired value;
  - Disable the **SOUND DURING TREATMENT** select "No sound" in list;

7. Increase or decrease the **GENERAL VOLUME** of the device using the buttons + and – or scrolling the cursor to right or left until the desired value;
8. Enable / disable the **KEYBOARD SOUND** by pressing alternatively the button **ON / OFF** on display.

Now it is possible :

- Press the button **BACK** to go to the previous screen;
- Press **HOME** to enter the screen of main menu.

### **MEMORIES MANAGEMENT**

By pressing the button **MEMORIES MANAGEMENT** it is possible to format the memories: INTERNAL MEMORY and USB MEMORY. The memories can contain two kinds of data, the PATIENT'S CARDS and the customized PROGRAMS.

To format the INTERNAL MEMORY :

1. Select the button **FORMAT INTERNAL MEMORY**
2. A window will appear, then select:
  - **YES** to format the internal memory
  - **NO** to cancel the formatting of internal memory
3. Press **OK** to confirm the successful INTERNAL MEMORY formatting.

To format the USB MEMORY:

1. Insert the USB key into the connector;
  - If the USB key is not properly inserted, it is not possible to format it.
2. Select the button **FORMAT USB MEMORY**;
3. A window will appear, then select:
  - **YES** to format the USB memory
  - **NO** to cancel the formatting of USB memory
4. Press **OK** to confirm the successful USB MEMORY formatting.

It is necessary to format the USB MEMORY when a NEW USB is inserted or if the USB was never used on this device.

It is also possible to use the function **FORMAT USB MEMORY** to empty the USB key, so that it can be used on another device.

### **PASSWORD MANAGEMENT**

By pressing the button **PASSWORD MANAGEMENT** it is possible to change the access code.

To set the new password proceed as follows:

1. Insert the used password by using the numeric keyboard on screen and press OK;
2. Insert the new access password by using the numeric keyboard on screen and press OK;
3. To confirm the new password type it a second time and press OK;
4. A window will appear to inform the operator that the new password has been properly set;
5. Press the button **BACK** to go the GENERAL SETTING screen.

### **SYSTEM MANAGEMENT**

By pressing the button **SYSTEM MANAGEMENT** a window will appear, and it will be possible:

- See the version of the operational application;
- Update the operational application;
- Recognize the therapy modules;
- Set DATE /TIME;
- Restore factory settings ;
- Enter the section of MAIN BOARD settings .

### **APPLICATION UPDATE**

The authorized personnel can update the operational application only with the specific application.

1. Copy the file, supplied from manufacturer, in USB key without changing the name of file and without inserting it into a directory;
2. Insert the USB key into the connector;

3. Press the button **APPLICATION UPDATE**;
4. A window will appear, then select :
  - **YES** to update the operational application
  - **NO** to cancel the updating procedure
5. Select the file to load ;
6. A window will appear, then select:
  - **OK** to update the operational application
  - **CANCEL** to cancel the updating procedure
7. Now follow the instructions on screen.

After a few seconds COMBIMED 4000 will have loaded the updated operational application version.

In the case of any problem while update contact the EME technical service.

#### NEW CARDS DISCOVERY

By pressing the button **NEW CARDS DISCOVERY** the therapy modules of COMBIMED 4000 are recognized.

After finishing the recognition of the modules the device restarts.

#### DATE AND TIME SETTINGS

To set DATE and TIME on each screen:

1. Press the button **DATE /TIME SETTING**;
2. Select the time zone by scrolling the menu;
3. Select / clear the automatic date and time setting by pressing alternatively the button **ON / OFF**;
4. If the setting is not automatic:
  - Change month, day and year by using the selection arrows
  - Change hour, minutes, AM / PM by using the selection arrows
5. Press the button **NEXT** to confirm the setting and go to screen COMBIMED 4000 APPLICATION SETTING.

Now it is possible:

- Press the button **BACK** to go to the previous screen;
- Press **HOME** to enter the screen of main menu.

#### RESTORE FACTORY SETTINGS

This function allows to reset all values to the default as at the beginning . This allows you to choose different language from the previously set when start the device .

Will be cancelled all customizations including customized protocols and patient's cards.

To enter this section insert the password .

The password has been set by default and is 12345: to insert it is necessary to press the 5 numeric buttons and then OK.

This code can be changed by the operator (see section SETTINGS – GENERAL SETTINGS – PASSWORD MANAGEMENT).

#### MAINBOARD SETTING

By pressing the button **MAINBOARD SETTING** , it is possible to see the diagnostic info of the MAIN BOARD concerning:

- The temperature;
- The HARDWARE version;
- The SOFTWARE version.

The authorized personnel can update the MAIN BOARD software only with the specific application.

1. Copy the file, supplied from manufacturer, in USB key without changing the name of file and without inserting it into a directory;
2. Insert the USB key into the connector;
3. Press the **SW UPDATE** button;
4. A window will appear, then select :
  - **YES** to update MAIN BOARD software
  - **NO** to cancel the software updating procedure
5. Select the file to load;

6. A window will appear, then select:

- **OK** to update MAIN BOARD software
- **CANCEL** to cancel the software updating procedure

7. Now follow the instructions on screen .

After a few seconds COMBIMED 4000 will have loaded the MAIN BOARD updated software application version.

In the case of any problem while update contact the EME technical service.

## MAINTENANCE

The equipment for combined therapy COMBIMED 4000 do not require any particular maintenance operations, but only a periodic maintenance and cleanliness of the probes, in order to ensure the better operating conditions, guarantee the effectiveness of the treatment and the safety of the patient.

In fact, it is recommended to perform periodic maintenance **every two years**, in order to check:

- Emission levels
- the intensity of any eventual leakage current;
- the continuity and thus the integrity, of the ground conductor;
- the correctness of the value of insulation resistance;

in order to ensure the electrical safety of the device and ensure that it is operating according to guaranteed safety conditions. For this kind of intervention you should contact EME srl or one of its authorized service centers.

Moreover, it is necessary to carry out a periodic maintenance of probes/applicators. In particular:

- **Every two years** submit to calibration/adjustment all the programmable accessories, such as probes/applicators, supplied with the dispositive. For this kind of intervention please contact EME srl technical support service.
- Check **every week** the treatment head of the probes, in particular of the ultrasound probes, in order to reveal eventual cracks which could lead to the entrance of conductor liquid

- **Before every treatment therapy** verify the integrity of the cable and connector of probes/applicators.

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

Clean every day with water and denatured alcohol the conductive rubber electrodes , the sponges have to be washed.

Replace the probes / applicators, cables and electrodes with care at the end of each treatment session.

The electrodes in conductive rubber must be periodically replaced as they lose their conductivity with use.

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

Do not spray or pour liquid onto the external parts of the equipment and onto the probes.

Do not immerse the unit in water.

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

The unit must under no circumstances be opened or dismantled in order to clean or check inner parts of 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 life of the device is approximately 10 years.

## TECHNICAL PROBLEMS

The equipment for combined therapy COMBIMED 4000 has been designed and manufactured using highly advanced technology and first class components for reliable and efficient performance.

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

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

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

## ELECTROMAGNETIC INTERFERENCES

The equipment for combined therapy COMBIMED 4000 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 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

COMBIMED 4000		
PROBLEM	POSSIBLE CAUSE	SOLUTION
The display on front panel does not light up: unit does not function.	Plug incorrectly inserted into socket.	Check that the socket is working correctly.
	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
The display on front panel does not light up.	Electronic control circuit does not work.	Contact an EME srl Service centre.
	Presence of faulty components on electronic control card.	Contact an EME srl Service centre.
Some commands on the front control panel are not working properly.	Touch-screen not aligned or not working.	Contact an EME srl Service centre.
	Electronic control circuit does not work.	

ELECTROTHERAPY MODULE		
PROBLEM	POSSIBLE CAUSE	SOLUTION
The display signals that the unit is unable to supply the required output current.	Defective connections in the patient application output circuit.	Check that the output connection is made properly.
	Output cables damaged or bad connected.	
	Output cable worn and/or bad connection.	
	Connectors badly inserted, defective or not connected to the equipment and/or the electrodes.	Check that the output connection is made properly. Replace the cables and/or the defective connectors that show evident signs of wear.
	Electrodes in conductive rubber worn, need to be replaced.	Ensure that the electrodes adhere properly to the patient, replace defective and/or worn electrodes.
	Contact with the patient insufficient, faulty, and/or uncertain.	Contact an EME srl assistance centre.
	Current generator electronic circuit fault.	
The unit works properly but there is a notable reduction in the effectiveness of the treatment.	The output circuit from the patient is not connected properly.	Carry out maintenance operations as described. Install and position the unit as described.
	Uncertain or defective conductive rubber electrode contacts (including the electrode-holder sponge pockets) with the surface to be treated.	Check the condition of the cables, the connectors and the output circuit electrodes. Ensure the electrodes adhere perfectly to the treatment surface.
		Moisten the electrode-holder sponge pockets.
	Possible current generator circuit fault in the equipment.	Contact an EME srl assistance centre.

ULTRASOUNDS MODULE		
PROBLEM	POSSIBLE CAUSE	SOLUTION
The unit doesn't supply any ultrasound.	Defective connections in the patient application output circuit.	Check that the output connection is made properly.
	Probe cable damaged or incorrectly inserted.	Replace any handpiece probe-applicator that shows evident signs of wear in the supply head or cable.
	Output cable worn and/or faulty connections.	
	Current generator electronic circuit fault.	Contact an EME srl assistance centre.
The unit works properly but there is a notable fall in treatment efficiency.	Handpiece probe-applicator output circuit not connected properly.	Carry out maintenance operations as described.
	Handpiece probe-applicator piezoelectric transducer damaged.	Check the condition of the cable and the handpiece probe/applicator connector.
	Mechanical damage (following a fall or violent impact) of the handpiece probe-applicator, especially on the radiating head.	Ensure that the radiating head adheres perfectly to the treatment surface.
	Loss of electric insulation of the piezoelectric transducer inside the handpiece probe following non authorised opening of the radiating head.	Use the acoustic conductor gel.
	Electronic circuit of the ultrasound generator not perfectly calibrated. Possible current generator circuit fault in the equipment.	Contact the EME srl assistance centre.

LASER MODULE		
PROBLEM	POSSIBLE CAUSE	SOLUTION
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 an EME srl Service centre.
	Faulty supply on laser circuit	
The unit works properly but there is a notable fall in treatment efficiency.	The front lens of probe is dirty.	Carefully clean the front lens of probe.
	Faulty or depleted laser source.	Contact an EME srl Service centre.
	Possible break down in power generator circuit of the unit	
The emission does not start.	No safety key or the interlock circuit is open.	Insert the DIN safety key into the back socket or reset the safety conditions.

## TECHNICAL FEATURES

COMBIMED 4000		
Power supply:		230 Vac, 50-60 Hz, ±10%
Double protection fuse on power supply (T):	<b>230 Vac</b>	1.6 A-T
Max power absorption:		65 VA
Display		Color TOUCH SCREEN, 10.1"
Working Mode		N ° 01 / technology module each time, with the exception of COMBINED ET+US mode
Class of isolation / parts applied according to the rule EN 60601-1		I / BF
Classification in compliance with the directive 93/42/CEE		II B
Degree of protection against input of liquids according to EN 60601-1 standard		IPX0
Table container in ABS, external dimensions (Width x Depth x Height):		61x37x23H cm
Weight of the device body:		8,05 Kg
Use conditions	<u>Room temperature</u>	<u>(+10 : +40) °C</u>
	<u>Relative humidity</u>	<u>(10 : 80) % without condensation</u>
Stocking/transport conditions	<u>Room temperature</u>	<u>(-40 : +70) °C</u>
	<u>Relative humidity</u>	<u>(10 : 100) % without condensation</u>
	<u>Atmospheric pressure</u>	<u>(500 : 1060) hPa</u>

\*upon request

## ELECTROTHERAPY MODULE

Programmable treatment time		Up to 99 minutes
Emission frequency:		All low and medium frequency currents , 32 Waveforms total number
Functioning:		Constant Voltage (CV) Constant Current (CC)
Peak current (Load resistance 1KOhm)	Pulse currents	100 mA
	Diadynamic currents	70 mA
	Continuous currents	50 mA
Peak voltage (Load resistance 1KOhm)	Pulse currents	100 V
	Diadynamic currents	70 V
	Continuous currents	50V
Output channels		2 independents
Storable protocols in the user memory:		---
Storable patient's cards in the user memory:		---
Storable protocols in the USB key:		---
Storable patient's cards in the USB key:		---
Help ONLINE		Guide to the electrode positioning

ULTRASOUND MODULE		
Programmable treatment time	Up to 30 minutes	
Emission	CONTINUOUS / PULSED	
Emission frequency:	1 MHz e 3 MHz $\pm$ 15%	
Adjustable Duty Cycle:	( 10 – 100 ) %	
Adjustable Duty Cycle of frequency:	( 10 – 100 ) Hz	
Continuos peak power	2 W/cm <sup>2</sup> $\pm$ 20%	
Pulsed peak power	3 W/cm <sup>2</sup> $\pm$ 20%	
Output channels	1	
ERA (Effective Radiating Area)	TV1	1.0 cm <sup>2</sup>
	TV3	3.0 cm <sup>2</sup>
	TV5	5.0 cm <sup>2</sup>
	TV8	8.0 cm <sup>2</sup>
BNR (Beam Non-Uniformity Ratio)	TV1	Max 5:1
	TV3	Max 5:1
	TV5	Max 5:1
	TV8	Max 5:1
Storable protocols in the user memory:	---	
Storable patient's cards in the user memory:	---	
Storable protocols in the USB key:	---	
Storable patient's cards in the USB key:	---	
Help ONLINE	Guide to the probe positioning	
COMBINED MODE: ET + US		
Programmable treatment time	Up to 30 minutes	
Functioning Electrotherapy	Constant voltage (CV)	
Working Ultrasound Mode	Continuos	
Current type	Low frequency	
	Medium frequency	
Frequency Emission	See section ELECTROTHERAPY MODULE and ULTRASOUND MODULE	

Adjustable Duty Cycle	See section ULTRASOUND MODULE
Continuous peak power	See section ULTRASOUND MODULE
Pulsed peak power	See section ULTRASOUND MODULE
Output channels	1

LASER MODULE		
Programmable treatment time	Up to 99 minutes	
Interlock socket/Safety key (contacts normally closed)	3 contact DIN socket	
Diode Laser wave length emission	905 nm	
<u>Laser classification according to EN 60825-1</u>	<u>3B</u>	
OD (Optic density) 25 mW	0.1	
OD (Optic density) 100 mW	0.7	
Programmable pulse frequency	(100 - 10.000) Hz	
Pulse duration	100 nsec	
Pulsed mode	(10 – 100 ) %	
Peak power for single diode	25 W	
	100 W	
Total peak power <b>depends on handpiece-applicator</b> (See accessories)		
Target pointing device characteristics	<u>Target pointing device in conformity with the UNI EN 60601-2-22 standard</u>	<u>Light-drive</u>
	<u>Light-drive device</u>	<u>Led-diode</u>
	<u>Light-drive color</u>	<u>Red</u>
	<u>Light-drive representation on the impact point</u>	<u>Spot with red as colour</u>
Typology for emission of the treatment	Automatic emission	
	Continuous emission	
Output channels	1	

Storable protocols in the user memory:	---
Storable patient's cards in the user memory:	---
Storable protocols in the USB key:	---
Storable patient's cards in the USB key:	---

<b>LASER PROBES SPECIFICATION</b>	
<b>MLA1 (25) – pulsed laser diode</b>	
Number of laser diodes	1
Wavelength	905nm
Divergence of the beam	192x436mrad
Duration of the impulse	100ns
Programmable pulse frequency	100 – 10.000 Hz
Peak power	25 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	116.3 mm

<b>MLA1 (100) – pulsed laser diode</b>	
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

<b>MLA3 (300) – pulsed laser diode</b>	
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

<b>MLA5 (500)– diodo laser pulsato</b>	
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

The equipment for combined therapy COMBIMED 4000, 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	Meaning
	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: 2xT1.6AL250V
	Input power of the device (absorbed power)
	Input frequency of the device
<b>REF</b>	Device model
<b>SN</b>	Serial number
	Output characteristics of the device
	Output voltage of the device
	Output current of the device
	Output frequency of the device
	Output power supply

Symbol	Meaning
	Duty-cycle step
	Temperature range
	Atmospheric pressure range
	Humidity range

Table 1






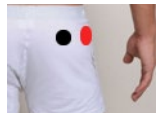
Labels	Meaning
	Label showing devices sensitivity to electrostatic charges, placed near the USB connector used to program the equipment.
<b>US</b>	Label placed near the connector of the output channel of ultrasound-therapy.
<b>ET</b>	Label placed near the connector of the output channels 1 and 2 of electro-therapy.
<b>LL</b>	Label placed near the connector of the output channel of laser therapy.
   	Labels on the handpiece probes of ultrasounds module, with properties.

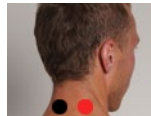
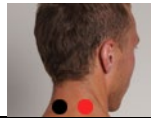
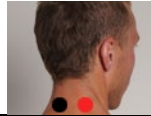


	<p>"INTERLOCK" label , placed on the rear panel of the device near the interlock connector.</p>																				
	<p>Label indicating "laser emission" placed near the connector of the laser probe.</p>																				
<p>             MAXIMUM OUTPUT LASER RADIATION (MLA1-25): 25W I.R.              MAXIMUM OUTPUT LASER RADIATION (MLA1-100): 100W I.R.              MAXIMUM OUTPUT LASER RADIATION (MLA3-75): 3x25W I.R.              MAXIMUM OUTPUT LASER RADIATION (MLA3-300): 3x100W I.R.              MAXIMUM OUTPUT LASER RADIATION (MLA5-125): 5x25W I.R.              MAXIMUM OUTPUT LASER RADIATION (MLA5-500): 5x100W I.R.              PULSE DURATION (ALL PROBES): 100ns              EMITTED WAVELENGTH (ALL PROBES): 905nm              STANDARD IEC EN 60825-1:2014         </p>	<p>Label on the left side panel, showing the characteristics of the laser probe :</p> <table border="1" data-bbox="584 555 1066 1337"> <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 – 100): 100W 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> <tr> <td>Maximum output laser radiation (MLA3 – 300): 3x100 W I.R</td> <td>Maximum output laser radiation (MLA3 – 300): 3x100 W I.R</td> </tr> <tr> <td>Maximum output laser radiation (MLA5 – 125): 5x25 W I.R</td> <td>Maximum output laser radiation (MLA5 – 125): 5x25 W I.R</td> </tr> <tr> <td>Maximum output laser radiation (MLA5 – 500): 5x100 W I.R</td> <td>Maximum output laser radiation (MLA5 – 500): 5x100 W I.R</td> </tr> <tr> <td>PULSE DURATION (ALL PROBES): 100 ns</td> <td>PULSE DURATION (ALL PROBES): 100 ns</td> </tr> <tr> <td>EMITTED WAVELENGTH (ALL PROBES): 905 nm</td> <td>EMITTED WAVELENGTH (ALL PROBES): 905 nm</td> </tr> <tr> <td>STANDARD IEC EN 60825-1:2014</td> <td>Reference standard</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 – 100): 100W I.R	Maximum output laser radiation (MLA3 – 75): 3x25W I.R	Maximum output laser radiation (MLA3 – 75): 3x25W I.R	Maximum output laser radiation (MLA3 – 300): 3x100 W I.R	Maximum output laser radiation (MLA3 – 300): 3x100 W I.R	Maximum output laser radiation (MLA5 – 125): 5x25 W I.R	Maximum output laser radiation (MLA5 – 125): 5x25 W I.R	Maximum output laser radiation (MLA5 – 500): 5x100 W I.R	Maximum output laser radiation (MLA5 – 500): 5x100 W I.R	PULSE DURATION (ALL PROBES): 100 ns	PULSE DURATION (ALL PROBES): 100 ns	EMITTED WAVELENGTH (ALL PROBES): 905 nm	EMITTED WAVELENGTH (ALL PROBES): 905 nm	STANDARD IEC EN 60825-1:2014	Reference standard
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 – 100): 100W I.R																				
Maximum output laser radiation (MLA3 – 75): 3x25W I.R	Maximum output laser radiation (MLA3 – 75): 3x25W I.R																				
Maximum output laser radiation (MLA3 – 300): 3x100 W I.R	Maximum output laser radiation (MLA3 – 300): 3x100 W I.R																				
Maximum output laser radiation (MLA5 – 125): 5x25 W I.R	Maximum output laser radiation (MLA5 – 125): 5x25 W I.R																				
Maximum output laser radiation (MLA5 – 500): 5x100 W I.R	Maximum output laser radiation (MLA5 – 500): 5x100 W I.R																				
PULSE DURATION (ALL PROBES): 100 ns	PULSE DURATION (ALL PROBES): 100 ns																				
EMITTED WAVELENGTH (ALL PROBES): 905 nm	EMITTED WAVELENGTH (ALL PROBES): 905 nm																				
STANDARD IEC EN 60825-1:2014	Reference standard																				





	<p>Label places on the laser probe:</p>											
<table border="1"> <thead> <tr> <th>Texts on the label</th> <th>Meaning</th> </tr> </thead> <tbody> <tr> <td>Warning</td> <td>Warning</td> </tr> <tr> <td>Invisible laser radiation</td> <td>Presence of invisible laser radiation</td> </tr> <tr> <td>Avoid unnecessary exposure</td> <td>Avoid a direct exposure to laser beam</td> </tr> <tr> <td>Class 3B laser product</td> <td>Product with 3B as laser class</td> </tr> </tbody> </table>	Texts on the label	Meaning	Warning	Warning	Invisible laser radiation	Presence of invisible laser radiation	Avoid unnecessary exposure	Avoid a direct exposure to laser beam	Class 3B laser product	Product with 3B as laser class		
Texts on the label	Meaning											
Warning	Warning											
Invisible laser radiation	Presence of invisible laser radiation											
Avoid unnecessary exposure	Avoid a direct exposure to laser beam											
Class 3B laser product	Product with 3B as laser class											
	<p>Label indicating "LASER OPENING", placed near the firing part of the laser probe.</p>											
	<p>Label indicating mandatory reading of instructions, located on the front panel of the device or near the output connectors.</p>											





Table 2







## Appendix C – LIST OF ELECTROTHERAPY THERAPEUTIC SUGGESTIONS

Reference SW	Electrotherapy treatment	Waveform associated	Time length (min)	Pulse length	Action time (sec)	Pause time (sec)	Modulation (Hz)		Frequency (Hz)	Electrodes positioning	N°of sessions
							Minima	Maxma			
PATHOLOGY01	Local dermal anesthesia (Fentanyl)	Galvanic	10 min * the treatment time depends on the desired dose							Variable positioning of the electrodes cannot be defined a priori.	1
PATHOLOGY02	Local dermal anesthesia (Lydoc.)	Galvanic	10 min * the treatment time depends on the desired dose							Variable positioning of the electrodes cannot be defined a priori.	1
PATHOLOGY 03	Arthritis (wrists and hands)	Modulated Phradic	15	1 ms	1 s	0 s			70		15
PATHOLOGY 04	Knee Rheumatoid Arthritis (Dexamethasone)	Galvanic	20 the treatment time depends on the desired dose								1
PATHOLOGY 05	Arthritis in the extremities	TENS S/A/R Random	30	50 µs	1	0			10	Variable positioning of the electrodes cannot be defined a priori.	3
PATHOLOGY 06	Cervical arthritis	TENS S/A/R Random	30	50 µs	1	0			10		3
PATHOLOGY 07	Arthrosis of the acromioclavicular joint	TENS S/A/R Random	20	150 µs	1	0			100		12
PATHOLOGY 08	Muscle atrophy (only on Paraplegics)	Modulated Phradic	10	300 µs	5	5			40	Variable positioning of the electrodes cannot be defined a priori..	20
PATHOLOGY 09	Calcifications of the hand	Galvanic	20								12
PATHOLOGY 10	Pain in the hip	Tens S/A/R Random	30	200 µs	1	0			100		10

Reference SW	Electrotherapy treatment	Waveform associated	Time length (min)	Pulse length	Action time (sec)	Pause time (sec)	Modulation (Hz)		Frequency (Hz)	Electrodes positioning	N°of sessions
							Minima	Maxma			
PATHOLOGY 11	Myofascial cervical pain 1	Bifasica asimmetrica	20	250 $\mu$ s		0	100	100			20
PATHOLOGY 12	Myofascial cervical pain 2	Interpherenial	20			0	100	100	4000		20
PATHOLOGY 13	Neck pain	Tens S/A/R	30	150 $\mu$ s		0	80	80			15
PATHOLOGY 14	Chronic pain	Tens S/A/R	20	200 $\mu$ s		0	2	2		Variable positioning of the electrodes cannot be defined a priori.	15
PATHOLOGY 15	Pain Phantom limb	Tens Random	30	50 $\mu$ s	1	0			10	Variable positioning of the electrodes cannot be defined a priori.	3
PATHOLOGY 16	Causal Pain	Tens Random	30	50 $\mu$ s	1	0			10	Variable positioning of the electrodes cannot be defined a priori.	3
PATHOLOGY 17	Atypical facial pain	Tens Random	30	50 $\mu$ s					10	Variable positioning of the electrodes cannot be defined a priori.	3
PATHOLOGY 18	Knee pain	Kotz	20		1	10	5000	40			20
PATHOLOGY 19	Myofascial pain (jaw)	Tens S/A/R	15	0.5 ms		0	50	50			10
PATHOLOGY 20	Wrist and hand pain	Synchoped Diphase	30		1	0			100	Variable positioning of the electrodes cannot be defined a priori.	20
PATHOLOGY 21	Post-surgical pain 1	Tens Random	30	50 $\mu$ s	1	0			10	Variable positioning of the electrodes cannot be defined a priori.	3

Reference SW	Electrotherapy treatment	Waveform associated	Time length (min)	Pulse length	Action time (sec)	Pause time (sec)	Modulation (Hz)		Frequency (Hz)	Electrodes positioning	N° of sessions
							Minima	Maxma			
PATHOLOGY 22	Post-surgical pain 2	Modulated Phradic	30	300 $\mu$ s	1	0			100	Variable positioning of the electrodes cannot be defined a priori.	
PATHOLOGY 23	Postoperative pain (lower abdomen)	Modulated Phradic	30	200 $\mu$ s	1	0			80	Variable positioning of the electrodes cannot be defined a priori.	20
PATHOLOGY 24	Post-surgical pain (inguinal hernia)	Biphasic S/A	30	100 $\mu$ s		0	100	100		Variable positioning of the electrodes cannot be defined a priori.	5
PATHOLOGY 25	Post-traumatic pain in the legs	Tens Random	30	50 $\mu$ s	1	0			10	Variable positioning of the electrodes cannot be defined a priori.	3
PATHOLOGY 26	Shoulder pain	Triangular	15	700 $\mu$ s		0	150	150			3
PATHOLOGY 27	Hemiplegic shoulder pain	Tens S/A/R	60	100 $\mu$ s		0	100	100			20
PATHOLOGY 28	Stabilized hip fracture (post surgery pain)	Tens S/A/R	30	200 $\mu$ s		0	100	100		Variable positioning of the electrodes cannot be defined a priori..	5
PATHOLOGY 29	Epicondylitis	Interphrenial	20			0			8000		6
PATHOLOGY 30	Epicondylitis (naproxen)	Interrupt Galvanic									1
PATHOLOGY 31	Fracture secondary to osteoporosis	Tens Random	30	50 $\mu$ s	1	0			10	Variable positioning of the electrodes cannot be defined a priori.	3
PATHOLOGY 32	Peripheral nerve entrapment	Tens Random	30	50 $\mu$ s	1	0			10	Variable positioning of the electrodes cannot be defined a priori.	3

Reference SW	Electrotherapy treatment	Waveform associated	Time length (min)	Pulse length	Action time (sec)	Pause time (sec)	Modulation (Hz)		Frequency (Hz)	Electrodes positioning	N°of sessions
							Minima	Maxma			
PATHOLOGY 33	Palm-plantar hyperhidrosis	Galvanic	20							Variable positioning of the electrodes cannot be defined a priori.	12
PATHOLOGY 34	Hypotrophy of the vastus medialis	Biphasic S/A	20	300 µs		3	40	40		Variable positioning of the electrodes cannot be defined a priori.	6
PATHOLOGY 35	Lower limb muscle ischemia from PAD (Muscle tone)	Neodynamic	60			0	1	250		Variable positioning of the electrodes cannot be defined a priori.	6
PATHOLOGY 36	Lower limb muscle ischemia from PAD (Muscle perfusion)	TENS S	45	200 µs		0	10	10		Variable positioning of the electrodes cannot be defined a priori.	15
PATHOLOGY 37	Peripheral nerve injury (pain)	Modulated Pharadic	20	200 µs	1	0			100	Variable positioning of the electrodes cannot be defined a priori..	10
PATHOLOGY 38	Acute low back pain	Interpherenial	30			0	140	140	4000		12
PATHOLOGY 39	Low back pain	Tens Random	30	50 µs	1	0			10		15
PATHOLOGY 40	Post-surgical neuralgia	Tens Random	30	50 µs	1	0			10	Variable positioning of the electrodes cannot be defined a priori.	3
PATHOLOGY 41	Post-herpetic neuralgia	Tens Random	30	50 µs	1	0			10	Variable positioning of the electrodes cannot be defined a priori.	3
PATHOLOGY 42	Knee osteoarthritis 1-2	Interpherenial	15			0	100	100	4000		10
PATHOLOGY 43	Knee osteoarthritis 2-2	Interpherenial	5			0	80	80	4000		10

Reference SW	Electrotherapy treatment	Waveform associated	Time length (min)	Pulse length	Action time (sec)	Pause time (sec)	Modulation (Hz)		Frequency (Hz)	Electrodes positioning	N°of sessions
							Minima	Maxma			
PATHOLOGY 44	Knee osteoarthritis 3	Modulated Phradic	15	300 $\mu$ s	10	50			70		20
PATHOLOGY 45	Quadriceps strength recovery after ACL reconstruction (Anterior Cruciate Ligament)	Modulated Phradic	20	300 $\mu$ s	6	10			30	Variable positioning of the electrodes cannot be defined a priori.	10
PATHOLOGY 46	Sciatalgia 1	Tens Random	30	0.1 s	1	0			4		9
PATHOLOGY 47	Sciatalgia 2	Tens S/A/R	20	250 $\mu$ s		0	4	4			3
PATHOLOGY 48	Shoulder impingement syndrome 1	Interpherenial	19			0	50	120	2500		12
PATHOLOGY 49	Shoulder impingement syndrome 2	Tens S/A/R	20	100 $\mu$ s		0	100	100			12
PATHOLOGY 50	Painful myofascial syndrome [1]	Tens Random	30	50 $\mu$ s	1	0			10	Variable positioning of the electrodes cannot be defined a priori.	3
PATHOLOGY 51	Painful myofascial syndrome [2]	Interrupt Galvanic	20		6	3			8000	Variable positioning of the electrodes cannot be defined a priori.	9
PATHOLOGY 52	Patello-femoral pain syndrome	Biphasic S/A	30	500 $\mu$ s		0	50	50		Variable positioning of the electrodes cannot be defined a priori.	12
PATHOLOGY 53	Ankylosing spondylitis	Tens S/A/R	20	50 $\mu$ s		0	50	50		Variable positioning of the electrodes cannot be defined a priori.	15
PATHOLOGY 54	Perial stretch of the supraspinatus tendon	TENS S/A/R Random	20	150 $\mu$ s	1	0			100	Variable positioning of the electrodes cannot be defined a priori.	20
PATHOLOGY 55	Tendinopathy of the supraspinatus	Tens S/A/R	20	150 $\mu$ s	1	0			100		20

Reference SW	Electrotherapy treatment	Waveform associated	Time length (min)	Pulse length	Action time (sec)	Pause time (sec)	Modulation (Hz)		Frequency (Hz)	Electrodes positioning	N° of sessions
							Minima	Maxma			
PATHOLOGY 56	Insertional Tendonitis (Acetic Acid) Achilles	Galvanic	20							Variable positioning of the electrodes cannot be defined a priori.	1
PATHOLOGY 57	Painful tic	Tens S/A/R	30	50 µs	1	0			10	Variable positioning of the electrodes cannot be defined a priori.	3
PATHOLOGY 58	Ulcers (non-diabetic)	Biphasic S/A	30	250 µs		0	40	40		Variable positioning of the electrodes cannot be defined a priori.	20
PATHOLOGY 59	Vitiligo	Galvanic	10							Variable positioning of the electrodes cannot be defined a priori.	10 o più
TREATMENT 60	Passive warming * muscle	Kotz	12		1	0	100	100	2500	Variable positioning of the electrodes cannot be defined a priori.	12-15
TREATMENT 61	Passive toning * muscle	Kotz	20		1	0	50	50	2500	Variable positioning of the electrodes cannot be defined a priori.	15
TREATMENT 62	Muscle anti-fatigue treatment [1] *	Kotz	15		10	50	50	50	2500	Variable positioning of the electrodes cannot be defined a priori.	3-12
TREATMENT 63	Muscle anti-fatigue treatment [2]*	Monophase	15						50	Variable positioning of the electrodes cannot be defined a priori.	12

**\*treatment not covered by medical CE**

**Note:** The number of sessions depends on the pathology to be treated and by the patient subjected to special treatment, so the number of sessions required is defined by the medician based on patient's clinical condition and characteristics of the device with which the treatment is emitted.

## Appendix D – LIST OF ULTRASOUNDS THERAPEUTIC SUGGESTIONS

Reference SW	List of therapeutic treatments	Time	Effective Int.	Pulsed	Frequency
		(min)	(W/cm <sup>2</sup> )	(%)	(MHz)
PATHOLOGY 01	Algia articolaz. temporo-mandibular	8	1.5	80	1
PATHOLOGY 02	Periarticular calcifications (shoulder)	15	2.0	20	1
PATHOLOGY 03	Shoulder adhesive capsulitis	5	1.5	100	1
PATHOLOGY 04	Keloid-evolving scars	3	2.0	80	3
PATHOLOGY 05	Myofascial pain	6	1.5	100	1
PATHOLOGY 06	Epicondylitis 1	5	1.5	100	1
PATHOLOGY 07	Epicondylitis 2	10	1.0	80	1
PATHOLOGY 08	Phonophoresis	10	1.0	100	1
PATHOLOGY 09	Low back pain	6	1.0	100	1
PATHOLOGY 10	Knee osteoarthritis 1	7	2.0	100	1
PATHOLOGY 11	Knee osteoarthritis 2	5	2.5	25	1
PATHOLOGY 12	Shoulder periarthritis	7	1.5	100	1
PATHOLOGY 13	Carpal tunnel syndrome	5	1.5	100	1
PATHOLOGY 14	Varicose ulcers	2	0.3	20	3
TREATMENT 15	Localized adiposity *	10	1.0	80	3
TREATMENT 16	Orange peel skin *	10	1.0	80	3
TREATMENT 17	Facial wrinkles *	10	1.0	80	3
TREATMENT 18	Toning lower limbs (thigh)*	10	2.5	80	1
TREATMENT 19	Toning lower limbs (leg)*	10	2.0	80	1
TREATMENT 20	Toning upper limbs (forearm)*	10	1.5	80	1
TREATMENT 21	Toning muscular upper limbs *	10	2.0	80	1
TREATMENT 22	Skin tissue toning *	12	1.0	80	3

\*treatment not covered by medical CE

## Appendix E – LIST OF COMBINED THERAPY ET+US THERAPEUTIC SUGGESTIONS

Reference SW	Combined treatment US + ET	Treatment time (min)	Frequency HANDPIECE/PROBE (MHz)	POWER (W/cm <sup>2</sup> )	DUTY-CYCLE (%)	WAVE SHAPE ET
PATHOLOGY 01	Algia temporo-mandibular joint	8	1	1.5	80	Tens S ( 0,5 msec , 50 Hz )
PATHOLOGY 02	Myofascial pain	6	1	1.5	100	Tens Random S (50 μs, 10 Hz )
PATHOLOGY 03	Myofascial neck pain	10	1	1.2	50	TENS BURST S (200 μs, 100 Hz)
PATHOLOGY 04	Neck pain (from herniated disc)	5	1	1.5	50	TENS BURST S (180 s, 80 Hz)
PATHOLOGY 05	Shoulder myofascial pain	6	1	0.5	100	TENS S (50 μs, 50 Hz)
PATHOLOGY 06	Epicondylitis *	5	1	1.5	100	Interferenziale (4000 Hz)
PATHOLOGY 07	Low back pain	6	1	1.0	100	Tens Random S (50 μs, 10 Hz)
PATHOLOGY 08	Knee osteoarthritis *	7	1	2.0	100	Faradica modulata (300 μs, 70 Hz)

\*All electrophoresis treatments with iontophoresis or non-zero mean value currents cannot be delivered simultaneously with the ultrasound therapy treatment but one must be delivered successively to the other.

**Appendix F – LIST OF THERAPEUTIC SUGGESTIONS**

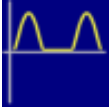
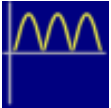
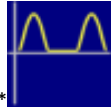
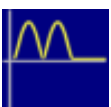
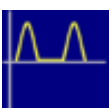
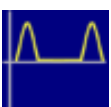
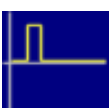
	Laser Therapy Treatments	Time (min.)	Frequency (Hz)	Energy density (J/cm <sup>2</sup> )
01	Acne	2	5000	2
02	Temporo-mandibular joint pain	3	5000	2
03	Phantom limb or causalgia	3	5000	2
04	Arthritis of the small joints	2	5000	2
05	Arthritis	2	10000	3
06	Arthritis hands	3	5000	2
07	Pre-patellar bursitis	5	5000	4
08	Patellar chondropathy	3	10000	5
09	Muscle-tension headache	3	10000	5
10	Neck pain (acute)	2	1000	1
11	Cervical pain	1	500	1
12	Cervicoarthrosis 1	1	500	1
13	Hypertrophic scars	2	10000	3
14	Contractures	2	5000	2
15	Myofascial pain	5	5000	4
16	Back pain	2	10000	3
17	Recent edema	2	10000	3
18	Epicondylitis or Tennis Elbow	2	1000	1
19	Plantar fasciitis	8	10000	12
20	Gonarthrosis 2	3	10000	5
21	Herpes Simplex, on the pustules without touching	1	500	1
22	Laser-acupuncture	2	1000	1
23	Injury to the flexor tendons (hand)	2	1000	6
24	Low back pain	3	10000	5
25	Lumbosciatalgia	2	10000	3
26	Carpal tunnel syndrome	2	5000	2
27	Painful shoulder	2	10000	3
28	Collateral ligament stretch 1	2	5000	2
29	Supraspinal tendinopathy	2	2000	1

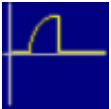

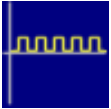



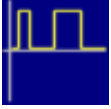

	Laser Therapy Treatments	Time (min.)	Frequency (Hz)	Energy density (J/cm <sup>2</sup> )
30	Achilles tendonitis	3	5000	3
31	De quervain tenosynovitis	5	5000	4
32	Trigger points	2	5000	2
33	Leg ulcer	2	1000	1
34	Diabetic ulcers	1	500	1


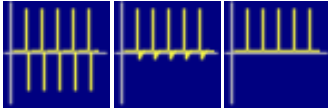
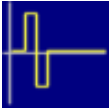

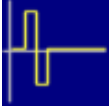
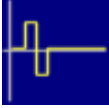
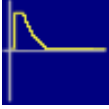
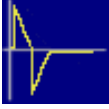
**The values of energy density given in the table were obtained by considering a MLA1 probe with diode 25mW and area of treatment equal to 1cm<sup>2</sup>. The device software automatically updates the parameters based on the selected handpiece while keeping the energy density constant.**


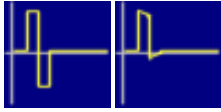

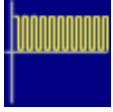

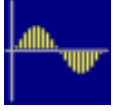


**NOTE:** is not possible to define a number of sessions, depending on the therapeutic suggestion used , as the duration of a session is not uniquely defined but depends on the pathology to be treated, by the patient subjected to special treatment and by the amount of power emitted by the device and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


## Appendix H – WAVEFORMS

N°	Name of the current waveform		Rise time [sec]	Decay time [sec]	Action time [sec]	Pause time [sec]	Pulse duration	Frequency [Hz]
			Default (Range)	Default (Range)	Default (Range)	Default (Range)	Default (Range)	Default (Range)
			Min time [sec]	Max time [sec]	Monophase duration [sec]	Diphase duration [sec]	Frequency A [Hz]	Frequency B [Hz]
			Default (Range)	Default (Range)	Default (Range)	Default (Range)	Default (Range)	Default (Range)
1	MONOPHASE*		/	/	/	/	20ms	50
			/	/	/	/	/	/
2	DIPHASE*		/	/	/	/	10ms	100
			/	/	/	/	/	/
3	SYNCHOPED MONOPHASE*		1 (0 ÷ 30)	1 (0 ÷ 30)	6 (1 ÷ 120)	5 (0 ÷ 120)	20ms	50
			/	/	/	/	/	/
4	SYNCHOPED DIPHASE*		1 (0 ÷ 30)	1 (0 ÷ 30)	6 (1 ÷ 120)	5 (0 ÷ 120)	10ms	100
			/	/	/	/	/	/
5	SHORT PERIOD*		/	/	/	2 (0 ÷ 120)	20ms MONOPHASE 10ms DIPHASE	50 MONOPHASE 100 DIPHASE
			/	/	1 (1 ÷ 60)	1 (1 ÷ 60)	/	/
6	LONG PERIOD*		/	/	/	6 (0 ÷ 30)	20ms MONOPHASE 10ms DIPHASE	50 MONOPHASE 100 DIPHASE
			/	/	6 (1 ÷ 60)	6 (1 ÷ 60)	/	/
7	RECTANGULAR*		1 (0 ÷ 30)	1 (0 ÷ 30)	/	5 (0 ÷ 120)	500 us (100us ÷ 9.0ms)	/
			1 (0 ÷ 120)	3 (1 ÷ 120)	/	/	50 (1 ÷ freq.B) *2	100 (freq.A ÷ 250) *2

N°	Name of the current waveform		Rise time [sec]	Decay time [sec]	Action time [sec]	Pause time [sec]	Pulse duration	Frequency [Hz]
			Default (Range)	Default (Range)	Default (Range)	Default (Range)	Default (Range)	Default (Range)
			Min time [sec]	Max time [sec]	Monophase duration [sec]	Diphase duration [sec]	Frequency A [Hz]	Frequency B [Hz]
			Default (Range)	Default (Range)	Default (Range)	Default (Range)	Default (Range)	Default (Range)
8	ESPONENTIAL*		1 (0 ÷ 30)	1 (0 ÷ 30)	/	5 (0 ÷ 120)	500 us (100us ÷ 9.0ms)	/
			1 (0 ÷ 120)	3 (1 ÷ 120)	/	/	50 (1 ÷ freq.B) *2	100 (freq.A ÷ 250) *2
9	TRIANGULAR*		1 (0 ÷ 30)	1 (0 ÷ 30)	/	5 (0 ÷ 120)	500 us (100us ÷ 9.0ms)	/
			1 (0 ÷ 120)	3 (1 ÷ 120)	/	/	50 (1 ÷ freq.B) *2	100 (freq.A ÷ 250) *2
10	TRAEBERT*		/	/	/	Pausa impulso:5.0 ms (100 us - 2 s)	2.0ms (100us ÷ 2s)	140
			/	/	/	/	/	/
11	RECTANGULAR PHARADIC*		1 (0 ÷ 30)	1 (0 ÷ 30)	/	5 (0 ÷ 120)	500 us (100us ÷ 9.0ms)	/
			1 (0 ÷ 120)	3 (1 ÷ 120)	/	/	50 (1 ÷ freq.B) *2	100 (freq.A ÷ 250) *2
12	MODULATED PHARADIC*		1 (0 ÷ 30)	1 (0 ÷ 30)	6 (1 ÷ 120)	5 (0 ÷ 120)	1.0ms (100us ÷ 9.0ms)	100 (1 ÷ 250)
			/	/	/	/	/	/
13	TRIANGULAR NEODYNAMIC*		1 (0 ÷ 30)	1 (0 ÷ 30)	/	0 (0 ÷ 120)	/	/
			0 (0 ÷ 120)	1 (1 ÷ 120)	/	/	200 (1 ÷ freq.B) *2	200 (freq.A ÷ 250) *2
14	NEODYNAMIC*		1 (0 ÷ 30)	1 (0 ÷ 30)	/	0 (0 ÷ 120)	/	/
			3 (0 ÷ 120)	3 (1 ÷ 120)	/	/	200 (1 ÷ freq.B) *2	200 (freq.A ÷ 250) *2
15	TENS S/A/R*		1 (1 ÷ 30)	1 (1 ÷ 30)	/	3 (0 ÷ 120)	100us (50us ÷ 1ms)	/
			0 (0 ÷ 120)	1 (1 ÷ 120)	/	/	100 (1 ÷ freq.B) *2	100 (freq.A ÷ 250) *2

N°	Name of the current waveform		Rise time [sec]	Decay time [sec]	Action time [sec]	Pause time [sec]	Pulse duration	Frequency [Hz]		
			Default (Range)	Default (Range)	Default (Range)	Default (Range)	Default (Range)	Default (Range)		
			Min time [sec]	Max time [sec]	Monophase duration [sec]	Diphase duration [sec]	Frequency A [Hz]	Frequency B [Hz]		
			Default (Range)	Default (Range)	Default (Range)	Default (Range)	Default (Range)	Default (Range)		
16	TENS RANDOM S/A/R*				/	/	1 (1 ÷ 120)	1 (0 ÷ 120)	50us (50us ÷ 1s)	100 (1 ÷ 200)
			/	/	/	/	/	/		
17	TENS BURST S/A/R*				/	/	1 (1 ÷ 120)	1 (0 ÷ 120)	50us (50us ÷ 1s)	/
			/	/	/	/	100 (1 ÷ 200) *3	2 (1 ÷ 10) *3		
18	MODULATED TENS				1 (1 ÷ 30)	1 (1 ÷ 30)	/	3 (0 ÷ 120)	120us (50us ÷ 1s)	/
			0 (0 ÷ 120)	10 (1 ÷ 120)	/	/	30 (1 ÷ 100) *6	200 (100 ÷ 250) *6		
19	SHORT-INTENSE TENS				1 (1 ÷ 30)	1 (1 ÷ 30)	/	3 (0 ÷ 120)	300us (50us ÷ 1s)	/
			0 (0 ÷ 120)	1 (1 ÷ 120)	/	/	100 (1 ÷ 100) *6	150 (100 ÷ 250) *6		
20	AL-TENS				1 (1 ÷ 30)	1 (1 ÷ 30)	/	3 (0 ÷ 120)	200us (50us ÷ 1s)	/
			0 (0 ÷ 120)	1 (1 ÷ 120)	/	/	4 (1 ÷ 100) *6	10 (1 ÷ 250) *6		
21	MICRO- CURRENTS				1 (1 ÷ 30)	1 (1 ÷ 30)	/	1 (0 ÷ 120)	300us (50us ÷ 1s)	/
			0 (0 ÷ 120)	2 (1 ÷ 120)	/	/	75 (1 ÷ 100) *6	100 (100 ÷ 250) *6		
22	APS				1 (1 ÷ 30)	1 (1 ÷ 30)	/	5 (0 ÷ 120)	500us (50us ÷ 1s)	/
			1 (0 ÷ 120)	3 (1 ÷ 120)	/	/	50 (1 ÷ 100) *6	100 (100 ÷ 250) *6		
23	H-WAVE				1 (1 ÷ 30)	1 (1 ÷ 30)	/	5 (0 ÷ 120)	500us (50us ÷ 1s)	/
			1 (0 ÷ 120)	3 (1 ÷ 120)	/	/	50 (1 ÷ 100) *6	100 (100 ÷ 250) *6		

N°	Name of the current waveform		Rise time [sec]	Decay time [sec]	Action time [sec]	Pause time [sec]	Pulse duration	Frequency [Hz]
			Default (Range)	Default (Range)	Default (Range)	Default (Range)	Default (Range)	Default (Range)
			Min time [sec]	Max time [sec]	Monophase duration [sec]	Diphase duration [sec]	Frequency A [Hz]	Frequency B [Hz]
			Default (Range)	Default (Range)	Default (Range)	Default (Range)	Default (Range)	Default (Range)
24	HVPC		/	/	4 (0 ÷ 120)	1 (0 ÷ 120)	90us (0us ÷ 120us)	100 (0 ÷ 120)
			/	/	/	/	/	/
25	BIPHASIC S/A*		1 (1 ÷ 30)	1 (1 ÷ 30)	/	3 (0 ÷ 120)	250us (50us ÷ 2ms)	/
			0 (0 ÷ 120)	1 (1 ÷ 120)	/	/	100 (1 ÷ freq.B) *2	100 (freq.A ÷ 250) *2
26	GALVANIC (IONOPHORESIS)*		/	/	1 (1 ÷ 120)	0 (0 ÷ 120)	/	/
			/	/	/	/	/	/
27	INTERRUPTED GALVANIC (IONTOPHORESIS)*		/	/	1 (1 ÷ 120)	0 (0 ÷ 120)	/	8000 (2000 ÷ 8000)
			/	/	/	/	/	/
28	KOTZ		/	/	1 (1 ÷ 120)	0 (0 ÷ 120)	/	/
			/	/	/	/	2500 (1000 ÷ 5000) *4	50 (1 ÷ 250) *4
29	INTERPHERENTIAL		1 (0 ÷ 30)	1 (0 ÷ 30)	/	2 (0 ÷ 30)	/	2500 (2500 o 4000) *5
			0 (0 ÷ 120)	1 (1 ÷ 120)	/	/	1 (0 ÷ freq.B) *2	2 (freq.A ÷ 250) *2
30	INTERPHERENTIAL CLASSIC		1 (0 ÷ 30)	1 (0 ÷ 30)	/	2 (0 ÷ 120)	/	2500 (2500 o 4000) *5
			0 (0 ÷ 120)	1 (1 ÷ 120)	/	/	50 (0 ÷ freq.B) *2	120 (freq.A ÷ 250) *2
31	INTERPHERENTIAL ISOPLANAR*		1 (0 ÷ 30)	1 (0 ÷ 30)	/	2 (0 ÷ 120)	/	2500 (2500 o 4000) *5
			0 (0 ÷ 120)	1 (1 ÷ 120)	/	/	50 (0 ÷ freq.B) *2	120 (freq.A ÷ 250) *2

N°	Name of the current waveform		Rise time [sec]	Decay time [sec]	Action time [sec]	Pause time [sec]	Pulse duration	Frequency [Hz]
			Default (Range)	Default (Range)	Default (Range)	Default (Range)	Default (Range)	Default (Range)
			Min time [sec]	Max time [sec]	Monophase duration [sec]	Diphase duration [sec]	Frequency A [Hz]	Frequency B [Hz]
			Default (Range)	Default (Range)	Default (Range)	Default (Range)	Default (Range)	Default (Range)
32	INTERPHERENTIAL VECTORIAL*		1 (0 ÷ 30)	1 (0 ÷ 30)	/	2 (0 ÷ 120)	/	2500 (2500 o 4000) *5
			0 (0 ÷ 120)	1 (1 ÷ 120)	/	/	50 (0 ÷ freq.B) *2	120 (freq.A ÷ 250) *2

Note: S -> simmetric, A -> asimmetric, R -> rectangular.

\*Non-zero average value currents;

\*2 the general range of variation of frequency is (0 Hz ÷ 250 Hz).

\*3 in the waveform TENS BURST S/A/R the Frequency A and the Frequency B represent, respectively, the frequency TENS and the frequency BURST with their range of variation.

\*4 in the waveform KOTZ the Frequency A and the Frequency B represent, respectively, the CARRIER frequency and the MODULATION frequency with their range of variation.

\*5 in the waveforms INTERPHERENTIAL, INTERPHERENTIAL CLASSIC, INTERPHERENTIAL ISOPLANAR, INTERPHERENTIAL VECTORIAL the Frequency represents the CARRIER Frequency.

IMPORTANT: the following waveforms INTERPHERENTIAL CLASSIC, INTERPHERENTIAL ISOPLANAR and INTERPHERENTIAL VECTORIAL can only be used on channels CH1+CH2.

\*6 in the waveforms MODULATED TENS, TENS SHORT INTENSE, AL-TENS, MICRO-CURRENT, APS, WAVE H the Frequency A and the B represent, respectively, the minimum and maximum modulation frequency.

## Appendix I – ELECTRO-MAGNETIC COMPATIBILITY TABLES

Guidance and manufacturer's declaration – electromagnetic emissions FOR ALL EM EQUIPMENT		
The EM EQUIPMENT is intended for use in the electromagnetic environment specified below. The customer or the user of the EM 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 is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes .
RF Emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

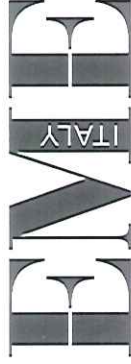
Guidance and manufacturer's declaration – electromagnetic immunity FOR ALL EM EQUIPMENT			
The ME EQUIPMENT is intended for use in the electromagnetic environment specified below. The customer or the user of the ME EQUIPMENT should assure that it is used in such an environment..			
Immunity test	IEC 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 <sub>T</sub> for 0,5 cycles	0% U <sub>T</sub> 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 <sub>T</sub> for 1 cycles	0% U <sub>T</sub> for 1 cycles	
	70% U <sub>T</sub> for 25 cycles	70% U <sub>T</sub> for 25 cycles	
	0% U <sub>T</sub> for 250 cycles	0% U <sub>T</sub> 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 : UT is the a.c. mains voltage prior to application of the test level			

**Guide and declaration of the manufacturer - electromagnetic immunity**

The ME EQUIPMENT is designed to work in the electromagnetic environment specified below. The client or user of the ME EQUIPMENT should ensure that it is used in this environment  
 Portable and mobile RF communications equipment should not be used closer to any part of, including cables, than the recommended separation distance calculated with the equation applicable to the transmitter frequency.

Immunity test	Trial level of the IEC 60601	Level of compliance	Recommended separation distance d:
Conducted RF IEC 61000-4-6	3 Veff from 150kHz to 80 MHz	3 Veff	d= 30 cm
Radiated RF IEC 61000-4-3	3 V/m from 80 MHz to 2,7 GHz	3 V/m	d= 30 cm
Immunity to proximity fields from wireless RF communication devices IEC 61000-4-3	TETRA 400 380 – 390 MHz	27 V/m	d= 30 cm
	GMRS 460 FRS 460 430 – 170 MHz	28 V/m	
	LTE Band 13, 17 704 – 787 MHz	9 V/m	
	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 800 960 MHz	28 V/m	
	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 5 1700 – 1990 MHz	28 V/m	
	Bluetooth, WLAN, 802.11 b/g/n, RIFD 2450, LTE Band 70 2400 – 2570 MHz	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



Aesthetic & Medical Technologies

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

**Il Fabbricante / The manufacturer**

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

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

Apparecchiature per terapia combinata elettrostimolazione ultrasuoni laser /  
*Equipment for combined electro ultrasound laser therapy :*

**COMBIMED 4000**

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

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

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

La macchina è marcata / The equipment is marked :

**CE 0476**

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

Pesaro, 13/10/2015

EME srl

L' Amministratore unico / Administrator

# EME

ITALY



Italian manufacturer of physiotherapy equipment since 1983

**EME Srl**

Via degli Abeti 88/1, Pesaro (PU) 61122 ITALY

T +39 0721400791 - F +39 072126385 - [info@eme-srl.com](mailto:info@eme-srl.com) - [www.eme-srl.com](http://www.eme-srl.com)