EME ITALY

POLYTER EVO

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

Italian manufacturer of physiotherapy equipment since 1983

CE 0476

100% MADE IN ITALY
IT01

INDEX

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 POLYTER EVO, bringing together in a single container one or more modules of electrotherapy, ultrasound therapy, LLLT, high power laser therapy (HL), magnetotherapy and tecar-therapy.

It is a fundamental reference 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 guide cannot ever replace the adequate experience of the operator;

- the user guide, as far as complicated operations are concerned, can only represent 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

Underlining is used to highlight sections of the document.

NOTE

Notes highlight important information contained in the text.

CAUTION

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

! WARNING !

The ATTENTION message highlights 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.

During the warranty period the company can provide for the replacement or substitution 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;

- incorrect or improper user maintenance;

- non compliant use with the environmental specifications provided 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. disconnect power cables and all connectors to the handpieces, applicators, etc;

2. carefully clean and disinfect all parts of the machine and accessories which have been in contact with patients.

Due to sanitary reasons, in order to safeguard our technicians' health (Work Safety guideline, T.U.S. 81/2008), all equipment deemed unsanitary and therefore unsafe for the receiving personnel will not be inspected;

3. disassemble the accessories and any mechanical support;

4. use the original box and packing material for packaging;

5. Attach the Assistance Request Form to the delivery in which there will be the causes of the revision request, the type of failure: there are useful indications that will facilitate technical operations and will shorten the repairing time.

PRELIMINARY NOTES

PRELIMINARY NOTES

- Installing the device does not require particular attention and it is easy and straightforward.

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.
- The enable the supply activate the pedal. Once the pedal has been pressed, the machine will emit a short confirmation tone MAINTENANCE;
- In HL module, the pedal must be pressed and held during the whole treatment.
- In HL module, removing the foot from the pedal, the treatment will be suspended until the pedal will be pressed again.
- In HL module, when you remove the foot from the pedal, the machine will emit another short tone, indicating the interruption of the supply and the TIMER.
- 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 is advisable to switch periodically the polarity according to the way it is connected to the applicator plates: the switch allows increasing their duration.
- If the bipolar application probe (optional accessory for the tecar therapy module) is used, the resistive type must be selected as the electrode type.

CAUTIONS

PRELIMINARY NOTES

- The customer is liable for all damage caused by inadequate packaging of the material. Do not throw away the original package of the machine: it must be used in case of return 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 any accessory other than those provided to avoid damaging the device and therefore terminating the warranty benefits. 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.
- Periodically check the integrity of the electric power cable and the connection cable: they must not be damaged or worn out.
- 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 with LASER module both operator and patient must wear the PROTECTIVE GLASSES.**
- Before starting up the machine to perform treatment with LASER module (LL e HL), make sure it is inserted the key INTERLOCK that allows it to start.
- IN CASE OF TREATMENT WITH HIGH POWER LASER MODULE (HL), DURING THE TREATMENT IN CONTINUOUS MODE **IT IS FORBIDDEN TO KEEP THE HANDPIECE STEADY IN POINT IT IS ABSOLUTELY NECESSARY TO MOVE THE HANDPIECE SO AS TO CARRY OUT A SORT OF SCANNING ON THE TREATED AREA.**
- Once the laser module (HL) has been inserted into the slot, check that the EMERGENCY STOP button is not lowered. If the device has been switched on with the EMERGENCY STOP button lowered, it is necessary to follow the instructions provided in SETTINGS - NEW DISCOVERY SCHEDE or start the device again by checking that the button is raised.
- It is a class A device in terms of emission. The machine may be used in hospital and clinic premises, provided that the machine might disturb the action of electronic devices in its immediate vicinity.
- 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 handpieces of the same or different devices, because each handpiece emits at specific frequencies that are different from any other handpiece. These frequencies are previously set in the channel where the handpiece shall be used.
- The POLYTER EVO device in the module for ultrasound therapy automatically recognizes the handpiece plugged to the output connector. For the handpieces supplied with the device, this operation **is not executed** because the frequencies specific of the supplied handpiece 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 case of treatment with LASER HL module, to change the spot area in the handpiece, it is necessary to slide the spacer and then turn it slightly clockwise to lock it in the desired position.
- 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, which delivers adequate peak power without provoking overheating in the treated area.
- Tighten the nut of the HPLS laser handpiece otherwise the device will not detect the connection of the handpiece and it will not be possible to deliver the treatment;

- 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:
    - Reorient or reposition the receiving device;
    - Increase the distance between the devices;
    - Connect the equipment to a scale of a circuit different from or to devices that cause interference;
    - Contact the manufacturer or local technician for assistance.
- Portable and mobile radiocomunication devices can affect the operation of the device.
- 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.
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MAINTENANCE

- Handpieces-applicators must be handled with care: a rough handling can affect their performance and characteristics.
- It is forbidden to technical personnel not authorized by EME srl to open and/or disassemble the handpiece/applicator: such mishandling may not only damage the characteristics of the KIT POINT but shall also immediately nullify all warranty rights.
- The device should not be disassembled for cleaning or control purposes: there is no need to clean the device internally and in any event this operation may only be carried out by specialized technical personnel 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, makingsure you insert the screwdriver in the slot on the fuse box and levering up outwards;
    2. insert a screwdriver into the two side holes for fuse expulsion
    3. remove the old fuses
    4. insert a new fuse at a time by using a slight pressure to the left, with a finger
    5. push the box back to fit into the slot.
- It is recommended to perform **every two years** periodic maintenance in order to check:
    - the emission levels;
    - the intensity of any leakage currents;
    - 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, ensure that it is operating in a safe guaranteed. For this kind of operations, it is advisable to contact EME srl or one of its authorized centers.

TECHNICAL PROBLEMS

- 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.
- When electromagnetic disturbances such as electrostatic discharge (ESD) occur, the LED on the panel of the Tecar module may continue to flash despite the energy supply has been interrupted. In this case it is necessary to disconnect battery power supply of the device.

! ATTENTION !

PRELIMINARY NOTES

- Being a portable device equipped with wheels, the correct position of the machine is that the appliance POLYTER EVO is moved along the X-direction by taking on the telescopic handle or simply relieved through the use of side handle.
- 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.
- Contact authorized dealers EME srl for problems or difficult installation.
- Before connecting the cable to the mains plug, check that the equipment wasn't damaged during transport. Ensure that the power supply specifications on the mains socket correspond with the information on the label attached to the back of the unit.
- The electric current that powers the unit is VERY DANGEROUS. Before connecting or disconnecting the power cable from the connecter on the unit, make sure it is plugged out from the mains socket.
- The power cable has an earthed plug for safety reasons.
- Only use with a mains socket suitable for use with earthed systems.

- **The equipment should only be connected to electrical systems that fully comply with regulations**.
- When using an extension lead, make sure that it has been earthed
- Connect the equipment directly to the wall socket without using extensions. Failure to comply with the above instructions may lead to dangerous electrical discharge causing machine damage and harm to persons.
- Do not use the equipment with power if the apparent condition of the protective conductor of the power cord is considered questionable integrity. In this case, it is strongly advised to use the internal power source (if any) using the internal battery for operating the machine.
- If the internal battery, it is recommended that you do not hold the internal battery discharged for long periods of time: it could irreparably be damaged.
- 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.
- The 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 extern Interlock circuit, contact exclusively qualified technicians and supply them the scheme correspondent to the room used for the emission of the treatment. A bad installation of the device can to generate serious ocular lesions.
- The device of target pointing of the handpiece 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 (**at least every 2 years**) of the equipment. EME srl authorized personnel should carry out such operations.
- It absolutely forbidden the use of the device in the presence of a flammable anesthetic mixture and oxygen-rich environments. In the event of non-compliance to the designation given, EME srl shall not be responsible for any accidents.
- It is absolutely forbidden to cover the air slots: such an action may not allow the machine to work in safe conditions. In the event of non-compliance to the designation given, EME srl shall not be responsible for any accidents.
- It's important to pay the attention of the operator to the necessity to verify the correctness of the electric installation of device before activating the supply switch.
- It is advisable to suspend the therapeutic treatment if it were to appear some disturbances during its emission.
- It's strongly advised not to hold the device on in state of start without using the handpiece, 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 and tecar-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^2 (right value for efficacy. When using galvanic currents (Ionophoresis) do not exceeded for any electrode current density of 0,2mA/cm2.
- 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.
- It is strongly advisable to switch off the device when it is not needed, namely when the handpiece is not being used, because it could overheat excessively.
- In order for the ultrasound handpiece to be perfectly recognized by the device, make sure you connect/disconnect it while there is no treatment emission going on.
- Application of ultrasound therapy performed in the vicinity of a device for shortwave or microwave treatment can produce instability in the transmission of the ultrasound.
- 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 handpiece 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-handpieces for the emission of the laser-therapy treatments is invisible, the handpieces foresee on board the assemblage of two diodes led, of red color.

- The two pointer LED diodes, of red color, delimit the action area of the spot relative to the laser emission. Use the spots of the pointer-diodes as reference drive for the revealing of the position of the spot of the laser beam.
- The red led-diodes light on with the activation of the laser emission from the operator, and everyone of them they emits a pointer beam.
- The pointer-beams produce some red spot on the point of impact, and they delimit the region where the spot of the laser beam will be reverted, which 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 HANDPIECE 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 POLYTER EVO unit and/or persons involved in its use, do not apply to contact with patients laser handpieces that have not been thoroughly cleaned and disinfected at the end of the previous treatment.
- Before starting the tecar-therapy treatment, the operator must ensure that the patient has taken off all the metal objects worn, in order to avoid dangerous phenomena in combination with radio-frequency.
- While tecar-therapy is performing, the RF energy transmission (generated by the device) on the touch panel of the display can make the software use unreliable. To avoid this situation, we require the operator to:
    - once the therapy is started, avoid touching the resistive/capacitive electrode simultaneously with one hand, and the touch panel with the other hand to modify the parameters;
    - once the therapy is started, avoid touching the body of the patient undergoing treatment with one hand at the same time the touch panel with the other hand to modify the parameters.

- It is recommended never to dispense the following combinations simultaneously:
    - Iontophoresis treatments and ultrasound treatments
    - Currents with a non-zero average value (for example diadynamic) and ultrasound treatments

As they do not guarantee the maintenance of the patient's safety conditions during the delivery of the treatment to which the patient is subjected.

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.
- It is useful to recall the need for periodic maintenance of the handpieces/applicators. In particular, it is necessary to:
    - **every two years** submit to calibration/adjustment all the programmable accessories, such as handpieces/applicators, supplied with the device. For this kind of intervention please contact EME srl technical support service.
    - check **every week** the treatment head of the handpieces, in particular of the ultrasound-therapy handpieces and tecar-therapyin order to reveal eventual cracks which could lead to the entrance of conductor liquid;
    - check **before every treatment therapy** the integrity of the cable and connector of handpieces/applicators.
- Before every treatment, it is recommended to clean with caution all of the accessories and the parts of the equipment that have been to contact with the patient.
- 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.
- Check **before any treatment therapy** the integrity of the electric power cable and the applicators/accessories connection cables applied on the patient: they must not be damaged or worn out.
- 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.
- In case of replacement or insertion of the whole battery, do not open your POLYTER EVO but contact qualified and authorized personnel, who will carry out the usual maintenance tasks safely and avoid damage to the equipment; or please contact EME srl or its authorized service centers.
- Do not open the device; it houses high voltage electricity, which can be dangerous.
- Only personnel authorized by the manufacturer may access the internal components. For repairs and further information please contact EME srl or its authorized service centers.
- The electrode is considered a consumer good. It is necessary to replace electrodes periodically every 2-3 months in conditions of normal use: an electrode has 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 handpiece 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.

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 electric 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 electric point of view, human body works like an electrolyte solution: under the influence of the electric field, ions that are normally inside the organism 'migrate'.

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

These phenomena give rise to a series of effects that can be summarized 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-oedematigenous 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 fiber. The external surface of the membrane is positively charged with respect to the internal surface.

Contact with the negative pole leads to depolarization of the membrane, while the positive pole is hyperpolarized.

Even the conductibility 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 this category and the time the current takes to generate a complete sinusoid is called *period*. The space covered during the period is the *wavelength*.

The number of periods made by the current in one 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 the variable electrical currents described share certain features in terms of consequences of application: the most important biological effect is the excito-motor 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 summarized 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.

IONTOPHORESIS

Current thinking confirms that iontophoresis is an effective way of administering different substances when localized 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 neutralize 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 millimeters depth.

Excluding the cases where a localized 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 means.

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, it is important to highlight certain basic rules:

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 is prepared on the spot, the concentration of solution must be correctly chosen and measured (remember that it is unnecessary to use high concentrations: generally a weight of 1% is enough for the majority of the substances);

- if products contained in vials are used (for parenteral use) ensure that there are no products incompatible with the technique among the excipients. In case of a freeze-dried product, ensure that the solvent is not a physiological solution: in that case use distilled water if possible;

- avoid to associate different substance if you are not sure about their compatibility: 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.

Systemic allergic reaction are to be excluded.

ULTRASOUND-THERAPY

THE PHYSICS OF ULTRASOUNDS

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 alternate potential difference, with a frequency that can the crystal into resonance, is applied.

Ultrasonic vibrations propagate in different ways according to the means through which they travel and in relation to the ease and speed with which the means itself can be deformed.

This depends on a physical characteristic, which is also known as **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^2/sec.
Air	331	43
Carbon dioxide Hydrogen	260	51.5
Distilled water 19°	1260	11.5
Ice	1461	146,100
Iron	2100	190,000
Glass	5000	3,900,000
	5400	1,350,000

Table 1: 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 x V) and is specific to individual substances.

Ultrasound intensity is expressed in Watt/cm2, it refers to the average intensity of the field, and is got by measuring the total output of the treatment (Watts) from the handpiece and dividing by the radiating surface area of the applicator.

$$I = Wu / s$$

Where:

Wu = output in watts,
s= applicator surface.

The ultrasonic devices used in physical therapy are manufactured on the basis of the above outlined principles and are made of:

- 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 1cm2 and 10 cm2. The irradiation proprieties of each head depend on its diameter and the length of the wave, with the sound irradiation produced by the transducer penetrating the tissues with 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/cm2. A head with a radiating surface of 10 cm2 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 results into a high frequency cellular and intercellular massage action. The tissues irradiated with ultrasounds start vibrating as well, with a resulting waste 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 by penetrating into the tissues undergoes a progressive weakening in terms of intensity. In the crossing point 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 crossing point between the soft tissues and the bones, where the difference in resistance between the two means in contact causes particularly high reflection.

However, the bone tissue does not completely reflect the ultrasonic beam but rather absorbs a fraction of it, while a more significant fraction is absorbed by the periosteum which notably overheats with a consequent pain 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/cm2. 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 among the deep heating forms: in fact, it causes a relatively small increase of temperature in the tissue surfaces and has a greater probability of penetrating into the musculature and soft tissues compared to the diatermia 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 and tolerance levels without deleterious effects on other tissues.

Endotissular hyperthermia occurs 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, polymerization and macro-molecule destruction processes, etc.

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

The NEURAL effect is linked to the influence of ultrasounds on the neuro-vegetative system. Different tissues absorb the ultrasounds in a different way: the 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 pulsated mode.

The INDIRECT SUBAQUEOUS CONTACT treatment involves immerging 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 POLYTER EVO 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, malleolus, 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 localized 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 color defined by the active medium that produces it.

2) Coherence: it 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: it 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), an energy source, called pumping system,
3. an optical cavity, comprising two mirrors and the space in between them;
4. an output mechanism

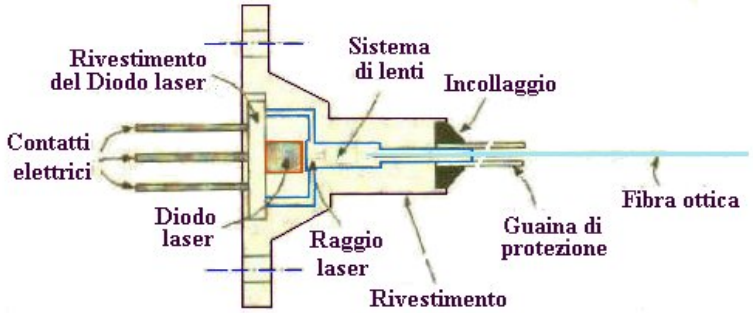
and obviously a mechanical support structure.

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

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:



outline structure of a laser diode.

Da A. Vasta: *i lasers terapeutici. Marrapese ed.. Roma 1998.*

A laser generator can be connected by a metallic layer to the external surface of a stack of layers. The side of the crystalline semiconductor is cut in such a way as to allow it to be used as an optical cavity mirror.

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

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

Special types of laser diodes have been developed to get high power laser diodes. These special diodes emit synchronized 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 bean

1. Frequency: this determines the average power of the laser and therefore the capacity of therapeutic lasers to penetrate tissue.

The higher the frequency, is obtained a greater penetration energy density. Clearly therefore, choosing low frequencies for analgesic purposes and high frequencies for anti-inflammatory purposes does not make scientific sense.

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

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

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

The evolution towards pulse lasers is very favorable from the therapeutic point of view and for the average power, since laser penetration into the body is improved.

4. Peak power: it 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 (thermal 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.

5. Irradiation dose (energy density): This is the most important parameter for the low level lasertherapy. It is even more important than the kind of laser used (visible or invisible, pulsed or continuous).
The irradiation dose represents the amount of energy that is transported into the tissue. It is very important to know whether this energy is conducted through a small point or through areas covering many square centimeters of tissue.

For an optimal therapeutic result, these concepts are fundamental:

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 doses in 1-7 days intervals produce effects as strong as the total dose irradiated in a single treatment.

EFFECTS OF DIODE LASER 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. Biostimulating and tissue regeneration effect

Recent studies have shown significant effects on the stimulation of the connective tissue and on the general mechanisms that regulate tissue regeneration. The main biological effect of lasers on the connective tissue is the quick proliferation of fibroblasts in cellular cultures.

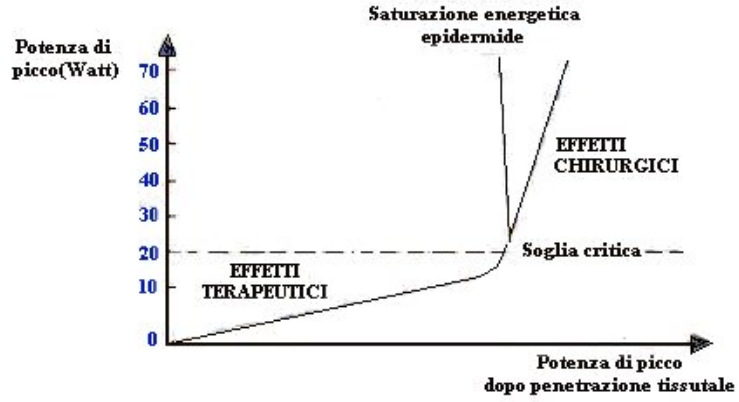


Image b: *peak power and critical threshold of the therapeutic effects of lasers.*
Da A. Vasta: *I lasers terapeutici. Marrapese ed.. . Roma,1998.*
Above the critical threshold, the skin becomes saturated of energy and it will be permeable only with a lower peak power. Above 20 Watt, photothermic effects might cause skin burn.

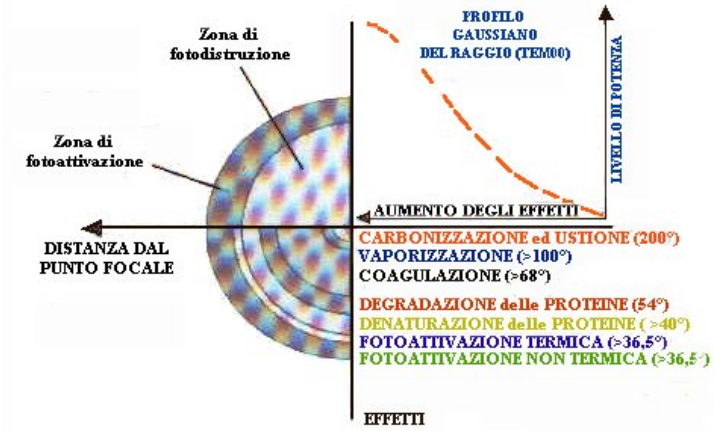


Image c*: representation of the typical Gaussian distribution of the power of the laser beam. The energy density is high at the center of the beam (surgical lasers) and it gradually decreases in the borders (therapeutic effects).*
Da: A.Vasta: *I lasers terapeutici. Marrapese editore. Roma,1998.*

4. Effect on microcirculation and blood vessels

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

5. Immuno-modulating effect

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

6. Enzymatic photo-activation effect

A photon can activate an enzymatic molecule that, in turn, can activate a biological process.

7. Placebo effect

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

MAGNETOTHERAPY

PHYSICS AND EFFECTS OF MAGNETIC FIELDS

The applied magnetic fields used in medicine are either low frequency or very low frequency fields (0-100 Hz) with variable intensities of between 5 and 100 gauss.

These are "*variable*" magnetic fields, that is to say, they are produced by inputting a variable current into the circuit (the solenoid), which can be modified to generate different types of waveforms and therefore create different types of magnetic fields.

The great number of studies carried out on the biological action of magnetic fields demonstrates that these can have a range of different effects on living matter, on one hand in relation to the characteristics of the field (orientation, intensity and frequency), and on the other in relation to the state of receptivity of each individual, that is to say, his/her dielectric properties.

The most important phenomenon evident in biological tissue exposed to a pulsated magnetic field is the contextual rise of induced micro-currents.

But how do these micro-currents interact with the body? Provide an example, let's start by stating that a great part of protein macro-molecules, called biopolymers, have piezoelectric properties and these behave as transducers, in the sense that every mechanical, thermal or electro-magnetic variation applied to them leads to a modification in their electric state. An injurious event, a trauma for example, determines a de-polarization of these protein structures with a reduction in the transmembraneous electric potential of the cell.

The micro-currents induced by magneto-therapy re-polarize the biopolymers and therefore re-establish the correct electric potential, accelerate ionic movements, reactivate enzymatic kinetics and, in short, reintegrating the tissue function.

A classification of the general biological effects of low frequency static and variable magnetic fields used in medicine is shown in the chart below.

PRIMARY	SECONDARY
1.Magneto-mechanical Cellular: – cellular membrane – orientation of the sub-cellular organelles and macromolecules (magnetosomes Fe3O4) – gradients of concentration, rotation, translation of the paramagnetic molecules (metalloprotein, cytochromes, molecular oxygen and free radicals) – orientation and electric dipoles and diamagnetic substances (retina rod cells, nucleic acids end enzymatic reactions) **2. Magneto-electrical:** – induction of currents in cellular membrane junction systems – induction of micro-currents(µA/ cm2) a) in conducting tissues b) in endovessel blood exposed to magnetic fields orthogonal to vessel – Gauss effect (modification of the electric resistance of electrical charges in movement)	**1. 1.Chemical** **2.Physical-chemical:** – modification of the diffusion coefficients in the cellular membrane – modification of the moving speed of the biological liquids in the vessels and intercellular spaces – modifying effect on osmotic pressure. **2. Physical:** on nucleic acids, water and acid mucopolysaccharidosis; electro-magnetic effects (Hall, Etinghausen and Nernst effect) **3.Thermic:** negligible for field intensities of less than 1000G and for frequencies of less than MHz. **4.Athermic effects:** resonance and coherence linked to the biological substrate receiving the incident impulses.
Biological effects on apparatuses and systems 1. Immune system 2. Bone tissue 3. Central Nervous System 4. Endocrine glands 5. Blood	

Charts I: Classification of the biological effects of the application of magnetic fields on cellular tissues (by F.Bistolfi:Magnetic fields in medicine, Ed.Minerva Medica-Turin. Modified).

Therefore, there is no doubt that the influence of low intensity and low frequency pulsated magnetic fields causes numerous bio-physical effects in the human body at different organizational levels of the living matter (cellular, tissular, organ-related and system-related), dependent on primary interactions of a magneto-mechanical and magneto-electrical nature. These fields act primarily:

- **on the plasmatic membrane**:
  - generating a modification of membrane *permeability* and therefore of the ionic balance on its two sides (improvement of ionic exchanges and an increase in the supply of oxygen and its utilization);

- influencing on the *flow of ions* (especially calcium) through the membrane itself in a specific manner for each frequency used (greater supply of oxygen, and therefore of energy, to the mechanisms that are at the basis of the ionic pumps);
- influencing many i*ntracellular enzymatic systems* and membrane systems;
- influencing the *relationships between antigens and anti-bodies*;
- influencing the *disposition and orientation of molecules* found at the sides of the membrane that posses their own magnetic momentum and that are involved in those biological processes that require precise steric orientation of the molecules (active transport, hormone-receptor complexes, receptor-transmitter enzymatic reactions, antigen-antibody reactions, etc.) in order to manifest themselves.

- **on the blood**: a positive effect on the calibre of the vessels and on the viscosity of the blood with improvements in local circulatory conditions and oxygen pressure (hypervascularization) which would also explain the acceleration of the healing processes of soft tissue and bone lesions, and trophic lesions of peripheral circulatory origin, as well as the beneficial effect on biological structures conditioned by the diffusion of oxygen such as, for example, cartilage;
- **on the immune system**: an increase of immunoglobulin-G and circulatingleukocytes reinforcing the immune system; in the regulation of the production of steroid substances and endogenous oppioides (and therefore modulating on the algic system);
- **on the endocrine system**: inhibition of some hormonal functions (parathyroid) and stimulation of others;
- **on the central and peripheral nervous system**: a reduction of the activity of the sympatic system (for hyper-polarization of the pre and post-synaptic membranes, or modulating the frequency of the stimuli in case of the vasodilatation); alterations of the activity of cerebral cells;
- **on the metabolism;**
- **on cellular reproduction**;
- **on tissue regeneration**: genesis of collagen on the part of fibroblasts and on angiopoiesis with vascular neo-formation (which would explain the favorable effects of magnetic fields on the healing processes of injuries, ulcers and torpid sores);
- **on bones**: the start of the osteogenesis is stimulated, where this does not happen naturally (pseudo-arthrosis, delayed consolidation), providing opportune signals of cell reactivation (mesenchimal of the periostosis, monocytes, fibroblasts, osteoblasts that act on the formation of the internal callus), improving the hematic supply, inhibiting the parathormone and therefore favouring the activity of the osteoblasts.

On the basis of these admissible effects the **biological action** of magnetic fields can be summarized principally in:

- **an anti-inflammatory and anti-edemigene action:** with a decrease in VES, an increase in gamma globulins and a decrease in alpha globulins as part of a generic anti-inflammatory action of the magnetic fields used;
- **anti-inflammatory effect:** able to alleviate pain in the treatment area
- **a tissue-repairing stimulating action.**

TECAR-THERAPY

The system of endothermic therapy is a therapeutic method that has been recently introduced in physical therapy. It allows It allows to stimulate from inside the biological structures and the natural anti-inflammatory and reparative processes by the application of energy, taking advantage of a form of interaction between the electromagnetic energy and the tissue that refers to the concept of the electric condenser.

The device consists of 2 facing elements (known as armors) and separated by an insulating material, connected to an electrical generator that creates a potential difference (d.d.p.) between the 2 plates. This causes the attraction and then the repulsion of the electric charges which then concentrate in the vicinity of the 2 elements. In this way, there will be an increase of positive charge density in one plate and an increase of the negative one in the other plate.

If we want to transfer this electric principle in the biological field we will have a handpiece or a mobile electrode used by the operator to treat the affected part by the disease, while the second armor is constituted by the biological tissue to be treated which behaves as a conductor of the second type.

The mobile electrode is connected to an electric generator (the machine body), which creates the d.d.p., to which is also connected the fixed return plate , which is placed in contact with the patient's skin more or less near the area to be treated to close the circuit.

The current generator works in the field of long-wave radiofrequencies ranging between 0.4 and 0.5 MHZ with a variable power up to a maximum of 200W.

In this way there is not external emission energy, but there is only a development of endogenous energy or at the level of internal biological tissues produced by the movement of ions and electrolytes, induced by the forces of attraction and repulsion that are generated between the plates 2 of the capacitor.

APPLICATIONS TECHNIQUES

The capacitive/resistive Tecartherapy (acronym of Transfer Electrical Capacitive And Resistive) is a therapy that stimulates the body's natural repair processes, shortening the motor recovery time.

Diatermia through the electromagnetic energy/tissue interaction produces a temperature increase that occurs within the tissues in a uniform and controlled way. Such electromagnetic interaction causes to the appearance of an ion flow with a micro-hyperemia which enhances the release of endogenous "substances" (mainly cortisone and endorphins) that serve to reduce the pain, edema and inflammation.

It is, therefore, stimulated the increase of blood flow in a direct way, thanks to the increase of temperature, and indirectly through the oxygen demand by the treated tissues; the blood increase allows the increase of the normal immune defenses and stimulates the regeneration of tissues.

The tecar-therapy works in two modes:

- if it works in capacitive mode there will be an increase of the charge density near the area below the mobile electrode and in particular at the level of the soft tissues like the muscle masses.

- if it works in resistive mode, the concentration of charges and therefore the biological effect occurs in the tissues with the highest resistance which are interposed between the mobile electrode and the return plate, namely bone, ligaments, etc.

HOW IT WORKS

In order to cause the phenomenon of the increase of the charge density it is necessary that the two armors of the capacitor are connected to an electric generator that has the task of supplying the armors with charges.

In this way, a real current is established, which in the accumulation phase goes from the generator to the capacitor. As the capacitor accumulates charges, the flow is reduced to zero when the capacitor is fully charged.

After this initial phase of the generator if the polarity is reversed, there will be a current in the opposite direction that the capacitor will charge with polarity opposite to the previous. If the generator reverses polarity cyclically there will be a two-way flow, that is, an alternating current.

The transfer by capacitive contact is made through a capacitive shield electrode covered with insulating ceramic material (of different sizes depending on the treated area) that mobilizes the ionic charges in the subcutaneous tissues.

The resistive one takes place by means of a non-isolated resistive electrode that mobilizes the charges by ensuring that they are concentrated in the areas of greater depth and resistivity (bone matrix and deep muscles).

The capacitive mode acts specifically on soft tissues (muscles, vascular and lymphatic circulatory system, adipose tissue), whereas the resistive mode acts on a the tissues with greater resistance (bone tissue, cartilage, tendons, serous bands).

A neutral plate (return pole) is placed in the vicinity of the treated structures to close the circuit and it is applied according to a geometric disposition that allows the position of the most resistive or capacitive point with respect to the therapeutic interest area (eg. In the treatment of a knee it should be placed at the popliteus level).

For a better transfer of energy to the tissues on the part to be treated it is used a coupling saline gel or in any case a transmissive gel that prevents the interposition of air between the electrode and the body surface allows the best "adherence" between the radiator and the epidermis.

LASER-THERAPY (HL)

The evolution of light

The new high power laser module has been made using optical fiber to transmit high laser powers (4 W) directly on the skin, without any dispersion.

In this way it is possible to apply real peak powers up to 4W max and let the laser performing its therapeutic action as an impressive regenerative stimulation in chronic pathologies, in the acceleration of the inflammation resolution and of the edema in acute pathologies, and in the rapid resolution of painful articular, muscular, neurogenal and soft tissues syndromes, both acute and chronic.

High power laser allows an immediate improvement in the symptoms of inflammatory and degenerative pathologies in the orthopedic, neurological, dermatological domain and a reduction of recovery times and presents itself as an indispensable therapy,

especially in Sports Medicine, since it allows rapid recovery for many sportsmen, for whom time is a determining factor in their career.

Lasertherapy benefits

Laser therapy is not based on heat development but on photochemical and photobiological effects in cells and tissues. It has been noted that if Laser light is distributed in moderation a stimulation of certain cellular functions is obtained, in particular in the case of cells with functional deficits. The biological action in the use of Laser in therapies produces a series of effects on cells through a "stimulating" action on the mitochondrial functions with a higher production of ATP.

High power laser applications produce in the treated tissues several effects:

1. increase of blood flow: vasodilatation of capillaries and arteries;
2. bio-stimulation: tissues regeneration, stimulation of protein synthesis, stimulation of the ATP production, stimulation for the fibroblasts mitosis, increase of collagen and elastin;
3. anti-inflammatory effect:
4. anti-edematous effect, with stimulation of the lymphatic system;
5. analgesic effect: increase of the threshold of perception of nerve endings.

Laser HL module is therefore a laser with the following characteristics:

- thanks to the high power supplied, it allows the stimulation of the deep layers of the tissue, thus facilitating a quick and widespread cellular regeneration.

With HL module it is possible to obtain a deep tissue stimulation and this makes possible to treat the most internal tissues and structures (such as the femoral joint) and chronic pathologies such as arthrosis;

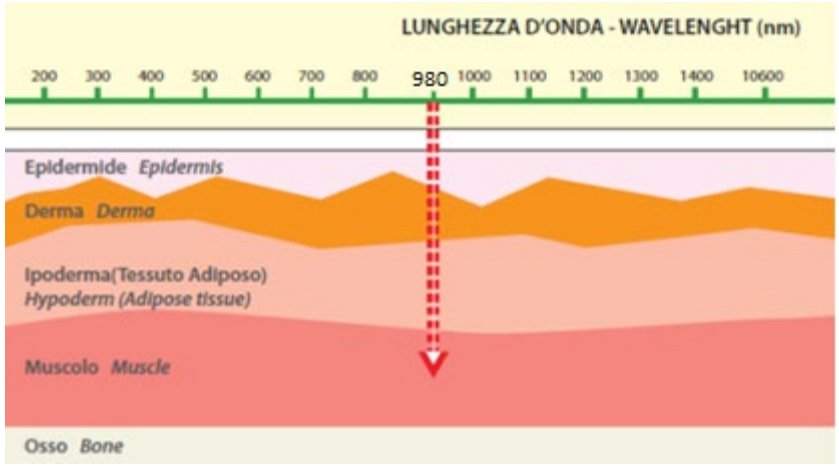
- may be used in many fields such as sports medicine, orthopedics, neurology, dermatology, rheumatology, odontology (conservative parodontology, medical treatment by implants, oral pathology, surgery, removal of tartar with pain) and acupuncture;

- crucial in acute, chronic and degenerative inflammations such as knee arthritis,

- automatically calculates the quantity of energy (fluence in joules) supplied in function of the different application modes, contact or through the 3 positions of the spacer included.

The HL module is a laser power, which works with a single wavelength: 980nm.

Using its peak power (4W) it is possible to supply up to 4W power and performing a therapeutic action as an impressive regenerative stimulation in chronic pathologies, in the acceleration of the inflammation resolution and of the edema in acute pathologies, and in the rapid resolution of painful articular, muscular, neurogenal and soft tissues syndromes.



The device has pre-loaded therapeutic suggestions with standard parameters derived from clinical studies. The effectiveness of the preset protocol is strongly conditioned by the type of patient treated. For this reason there is the possibility, for qualified personnel, to modify the parameters according to individual needs.

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 line, which offers an extremely logical operative sequence supported by a clearly legible monitor.

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

The new expandable modular design allows you to group in a single container one or more modules depending on the technology of interest.

A wide range of therapeutic applications, and guaranteed patient and therapist safety ensure that POLYTER EVO 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

POLYTER EVO is an electro-medical device for combined therapy capable of delivering therapeutic treatments, electrotherapy, ultrasound therapy, low and high level lasertherapy, magnetotherapy and tecar-therapy depending on the modules that make up the device.

In particular, the device may:

- provide electrotherapy treatments by applying conductive electrodes to the patient, regarding the electro-therapy module;
- deliver ultrasound energy through the use of probe/applicators with integrated contact sensors, regarding the ultrasound-therapy module;
- generate, using applicators, a low frequency (1-100Hz) and 1-100 Gauss power magnetic field, regarding the magnetotherapy module;
- supply Laser energy through mono-diodic and multi-diodic probes, as for the lasertherapy module;
- deliver therapeutic treatments with a power laser (4W), using a defocused laser probe, for the HL laser module.
- provide tecar-therapy treatments by using conductive electrodes mounted on handpieces/applicators, regarding the tecar-therapy module.
- deliver combined therapeutic treatments of electrotherapy and ultrasound-therapy, as for the electro-therapy and ultrasound-therapy modules.

The new concept of modularity, therefore expandable POLYTER EVO widely versatile equipment in which the operator can build the device according to their own needs.

The use of POLYTER EVO is reserved for operators such as physiatrists, physiotherapists 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.

It is a portable battery-operated device or via the mains.

POLYTER EVO can be used in a hospital environment or an 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.

POLYTER EVO 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

The ultrasounds are particularly indicated for the treatment of the following diseases (frequency of 1MHz)

1. Knee arthroses;
2. Vertebral column arthroses;
3. Small articulation arthroses (for example hands);
4. Bursites (sub-achromial, sub-deltoid and calcific) in chronic phase;
5. Periarticular calcifications;
6. Cervical brachialgias with treatment carried out on the cervical column and hyperesthesia zones;
7. Cheloid evolution scars (unit set at 3 MHz);
8. Muscle hematoma (fibrotic phase)
9. Entheropathies;
10. Epicondylites;
11. Dupuytren's disease: ultrasound is the main non-surgical treatment method for fibrous contracture of the palmar fascia. Notable recovery of extension movement is possible;
12. Hip periarthrites;
13. Shoulder periarthrites;
14. sciatic neuralgias and neurites: at reduced intensity close to the column and with stronger doses of irradiation along the cutaneous projection (Valleix's points) of the nervous trunk to be treated;
15. Carpal tunnel syndrome in initial phase;
16. ankylosing spondyloarthritis (Bechterew's disease): the earlier treatment is carried out the more evident the benefits. Ultrasound-therapy is one of the more popular treatment methods for this affection due to its anti-phlogistic, fibrolitic, decontracturing and stimulating action on metabolic and circulatory processes ;
17. Tendinitis (e.g., sovrapinus, biceps, goose foot, Achilles tendon);
18. Vertebral column hemilaminectomy post-surgery after-effects (very important in preventing post-operative adherences);Varicose ulcers:
19. (much quicker healing) with 3 MHz ultrasounds treating the edge of the ulcer with a commercially-available gel as a connective means (sonophoresis), also through subaqueous application;
20. Calcaneal spur syndrome;
21. Tendinosis;
22. Sinding – Larsen - Johanson disease;
23. Osgood-Schlatter disease;

With the ultrasound handpiece which acts at the frequency of 3MHz (or in addiction), it is possible to treat:

24. Fracture outcomes with consolidation delay: this type of treatment, which we are currently patenting, is carried out using our specifically designed unit. The special protocol required can be installed in the software on request. The treatment is carried out using low intensity ultrasounds and / or in conjunction with a direct current pulsated with a special maniple;
25. PEFS (cellulite): 3 MHz ultrasound treatment has proven to be particularly effective thanks to the following factors: the therapy acts exclusively on the zone in question and produces no collateral effects: in fact, the fragmentation and breaking down of the hardened connective tissue, with the resultant metabolic unblocking of subcutaneous fat, does not take place pharmacologically but rather thanks to the mechanical energic action and micro-massage concentrated in the initial 2.5 cm-deep area of localised cellulite (thanks to the special 3 MHz frequency).It is possible to treat all stages of cellulite. Ultrasound induce an increase in the permeability of the skin, facilitating the absorption of active substances; the disposing of the exceeding liquids in the system and the metabolic waste occurs through the natural reabsorption of the lymphatic system; the treatment is not invasive: it does not need any needle or infiltrations. The patient does not experience any discomfort. The treatment is extremely safe with no electric currents being applied to the patient.

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 fibromiopathies) 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: they 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: do not treat herpes lesions in the active phase, in order to avoid an increase in the rate of virus replication), carpal tunnel syndrome, headache, muscle tension headache , phantom limb or facial neuralgia and causalgia.
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.

MAGNETOTHERAPY

The magnetic therapy treatments are applied when there are the following pathologies:

1. acute arthropaties;
2. fracture outcomes (delays in consolidation and pseudo arthosis). A number of different factors may prolong, or even prevent, healing, for example:
   - severity of the trauma: fractures accompanied by crushing, loss of bone and cutaneous substance, as well as infections, present numerous problems in terms of treatment and healing;

- old age, the presence of metabolic illnesses (for example, diabetes) or the prescription of immunosuppressors that can have a negative influence on the healing process;
- insufficient activation of repairing processes, the cause of which is difficult to identify precisely. According to statistics, 5 to 10% of fractures involve delayed consolidation or non-consolidation, problems that in most cases can be effectively treated with electric and magnetic osteogenesis stimulation.

3. distorsion traumas;
4. contusions;
5. inflammatory and degenerative illnesses of bones and jints;
6. scapular-humeral periarthritis (also calcification);
7. osteoporosis.

The following table shows main therapeutic indications of low frequency pulsated magneto-therapy.

Traumatology	Pseudoarthrosis Fractures at risk of pseudo-arthrosis Delayed fracture consolidation Lesions of soft tissues (contusions, distorsions, metatarsalgy) Edemas Dislocations
Rheumathology	Degenerative rheumatisms Inflammatory rheumatisms Fibromyalgic rheumatisms
Neurology	Lumbago Sciatic neuralgia
Endocrinology	Senile and post-menopausal osteoporosis
Orthopedics	Knee arthrosis Vertebral arthrosis Bursitis Cervical brachialgia Strain backache Scapular-humeral periarthritis (also calcific)

TECAR-THERAPY

Tecar-therapy treatments are applied on the following pathologies:

- patellar chondropathy: treatment with resistive electrode placed laterally and medially to the patella, return plat at the level of the popliteus;
- coxarthrosis: treatment with the resistive electrode placed on the coxo-femoral articulation in paz. In the right or left lateral decubitus, the return plaque placed on the inner side of the thigh. Action on the cartilage;
- chronic lumbago: capacitive electrode to be slided along the para-vertebral muscle bundles with muscle relaxing action; then the treatment with resistive electrode placed on the lumbar and sacral spine follows. Return plate under the abdomen;
- shoulder periarthritis: resistive electrode at the level of the scapular-humeral articulation (action on the articular capsule and on the rotators cuff). Return plate at the scapular level. Subsequent treatment with capacitive electrode on the deltoid muscle, over-spinal, brachial biceps (improving trophism and muscle function)
- pubalgy: resistive electrode at the level of the right or left pubic symphysis and on the joint of the pubococcygeus muscles. Return plate at the gluteus level.
- heel spur syndrome: patient in supine mode, resistive electrode at the plantar level of the heel bone (action of spine remodeling). The treatemen with capacitive electrode on the plantar muscles (improvement of elasticity) follows;
- osteoarticular pathologies, such as outcomes of fractures, arthritic processes, arthritis, etc.
- musculoskeletal pathologies: eg muscle strains, elongations, contractures, muscle sprains, myositis, and in pathologies that affect the tendons, ligaments, joint capsules.

HIGH POWER LASER THERAPY (HL)

The fields of applications that can benefit from VIKARE lasertherapy are:

1. Sports traumatology

Strained or pulled muscle, articular distortions, epicondylitis, tendinitis and enthesitis, contusions, hematoma, bruises - bursitis.

2. Rheumatic disorders

Arthrosis, sciatica, scapulohumeral periarthritis, polyarthritis of hands or feet, epicondylitis, Initial stages of hip arthritis, knee arthritis with or without inflammation, myogenic stiff neck, back pain, myositis, etc.

3. Rehabilitation therapy

Articular motor rehabilitation after the removal of plaster casts or surgical orthopedic operations.

4. General medicine and dermatology

Pressure ulcers, keloids, torpid sores caused by the renowned bio-stimulating and anti-infective effects.

CONTRA-INDICATIONS

ELECTROTHERAPY

1. Application in the chest area on patients with: arrhythmia, congestive heart failure, recent myocardial heart attack 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. Tumors (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 alterations 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. However, it can be used on pregnant women on condition that there is no radiation over the abdomen.
3. Neoplasias: 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. Haemorrhagies: 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. Photosensitivity reactions: in certain patients who take known drugs these ones cause photosensitivity 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.

MAGNETOTHERAPY

The magnetic therapy treatments cannot be applied in case of:

1. patients with cardiac rhythm disorders: continuous magnetic fields used in RMN units have determined an increase in electro-cardiogram T wave width as well as a number of bradycardia-related phenomena and other arrhythmias. However, such reasonably rare effects can be reversed by decreasing the intensity of the field or suspending the treatment;
2. presence of metal prostheses (screws, cramps, pins) or clips (that are ferromagnetic);
3. patients with pacemaker (absolute contraindication): under no circumstances should such patients be exposed to more than 0.5 mT (0.5 millitesla = 5 gauss) (CERN studies 1995) as there is an elevated risk of applied static and pulsated magnetic fields causing pacemaker malfunctioning. In fact, alterations in the atrial system and the inhibition of the ventricular signal arouse. Such inhibition, when lasting more than a few seconds, can be clinically dangerous;
4. patients with active implantable devices;
5. slight rosacea,
6. epileptic patients even when undergoing pharmacological treatment;
7. neuro-vegetative system pathologies;
8. patients with general nervous disorders;
9. pregnancy (possible slowing and modifying of foetus growth, especially in the first two months of embryo life);
10. patients with particularly heavy menstrual cycles: the vasodilating effect of magneto-therapy may further increase an already heavy flow.
11. open hemorrhoids and vascular lesions in general: for the same reasons as the previous point;
12. patients with intrauterine devices (spiral).
13. patients with mycotic infections;
14. manifest hypersensitivity to electro-magnetic fields: this produces quite variable symptomatology which may consist of slight or marked asthenia, irritation, metal tastes and/or insomnia,
15. fever or thermoregulation disorders
16. cancer and tuberculosis;
17. Take particular care when treating patients taking Verapamil or other medicines that affect the calcium pump as such drugs are rendered less effective by pulsated magnetic fields;
18. in cases of arthrotomy postpone the use of magnetic fields for at least 15 days;
19. in cases of nerve root compression syndromes it is first necessary to remove the cause (for example, carpal tunnel syndrome);
20. in presence of cardiac valve prostheses.

TECAR-THERAPY

The tecar-therapy treatments cannot be applied in case of:

1. patients with active implantable devices;
2. pregnant women;
3. patients with venous insufficiency of the lower limbs;
4. bone neoplasms;
5. osteoporosis (at a medium and high capacitive and resistive transfer);
6. articular edema of any nature;
7. recent muscular hematoma (less than 15 days); it is useful in the resorption phase at medium capacitive level.
8. skin lesions (open wounds or recent burns)
9. thrombophlebitis
10. it is not contraindicated for prosthetic wearers

HIGH POWER LASER THERAPY (HL)

- Direct irradiation to the eyes: 4 class lasers are potentially harmful to the retina, although retina damage is extremely improbable. The special safety glasses (supplied) must always be worn by both the patient and the operator.
- Pregnancy: the laser should not be used over a pregnant woman's uterus. However, it can be used on pregnant women on condition that there is no radiation over the abdomen.
- Neoplasias: do not use the laser over primary or secondary wounds that have not been diagnosed. The laser treatment can be used to mitigate pain during the terminal stages of the disease; we recommend that it is performed with the full consent of the patient.
- Thyroid: laser must never be used over the thyroid.
- Hemorrhages: indirect laser vaso-dilatation may worsen the hemorrhaging.
- Immunosuppressive therapy: do not use laser therapy on patients undergoing this type of pharmacological treatment.
- Birthmark and suspect lesions: avoid laser irradiation on birthmarks, black spots, or suspect lesions on the skin.
- 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.

Other contra-indications:

- Atopic dermatitis and eczemas in acute phase
- Inflammations in the treated area
- Bruising
- Photoallergy
- Photodermatitis
- surgical operations or cryogenic therapy on the area of the skin to be treated.

Cautions

- Photosensitivity reactions: in certain patients who take known drugs these ones cause photosensitivity reactions. It is not fully understood how the combination of laser and medicine trigger these reactions. Patients who may be at risks for allergies, or who have a history of these reactions, should first be "tested" by applying treatment for a minimal time period.
- Means of fixation, metal and plastic plates DO NOT represent a counter-indication to the use of laser, which can safely be used on metal and plastic implants and sutures.

PRELIMINARY NOTES

UNPACKING

The equipment POLYTER EVO 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 device and accessories, located inside the battery compartment in the upper body, wrapped in a protective sheet of transparent polyethylene.

In the package are included:
- the User Manual;
- n.1 mains power supply cable;
- n.2 spare fuses (see technical specifications);
- n.1 key to close the trolley;

Moreover, according yo the modules present in the device:
- n.1 electrotherapy cable complete circular connector and pin (ET module);
- n.4 conductive rubber electrodes 6x8.5 cm (ET module);
- n.4 conductive rubber electrodes 5x5 cm (ET module);
- n.4 sponge for medium electrodes 6x8.5 cm (ET module);
- n.4 sponge for small electrodes 5x5 cm (ET module);
- n.2 elastic bands 1000x50mm (ET module);

- n.2 elastic bands 600x50mm (ET module);
- n.2 elastic bands 1000x50mm (MG module);
- n.1 multi-frequency handpiece 1/3MHz, 5cm2 (US module);
- n.1 magnetic ring to test the emission of magnetic field (MG module);
- n.1 pair of magnetic applicators (MG module);
- n.1 laser handpiece 25mW, 905nm (module LL);
- n.1 pair of safety goggles, OLV model (LL module);
- n.1 Interlock (module LL);
- n.1 handpiece holding capacitive electrodes (module TC);
- n.1 kit with three insertions for capacitive treatments: diameters 30, 50, 70 mm (module TC);
- n.1 handpiece holding resistive electrode (module TC);
- n.1 kit with three insertions for resistive treatments: diameters 30, 50, 70 mm (module TC);
- n.1 steel plate (module TC);
- n.1 bottle of conductive cream 1000 ml (module TC)
- n.1 laser probe defocused in optical fiber (Module HL);
- n.1 footswitch (HL);
- n.1 Safety glasses for operator, model YG3 (Module HL).
- n.1 Safety glasses for patient, model OLV (Module HL).

Always check the contents of the box. Should any of the components not be included, immediately contact the EME srl authorized dealer.

SETUP

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

The following environmental conditions are ideal when installing the equipment:

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

ACCESSORIES

The POLYTER EVO is equipped with power cable, and is compatible with the following accessory kit supplied in accordance with the form for your device.

POLYTER EVO description	Supplied	Optional
Power cable plug shuko	1	
Spare FUSES (see technical specifications)	1	
User Manual	1	
Key to close the trolley	1	
ELECTROTHERAPY MODULE 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
Handpiece 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 handpiece 1/3 MHz with a 5 cm2 emitting surface	1	
TV1 ultrasound handpiece 1/3 MHz with a 1 cm2 emitting surface		X
TV3 ultrasound handpiece 1/3 MHz with a 3 cm2 emitting surface		X
TV8 ultrasound handpiece 1/3 MHz with a 8 cm2 emitting surface		X
Ultrasound gel bottle 260ml		X

Ultrasound gel bottle 1000ml		X
Ultrasound gel soft pack 5000Ml		X
MAGNETOTHERAPY MODULE description	**Supplied**	**Optional**
Magnetic ring for testing the emission of magnetic field	**1**	
Pair of magnetic applicators	**1**	
Long elastic bands (100x5cm)	**1**	
Short elastic bands (60x5cm)	**1**	
Pair of magnetic applicators (16x10x3,5cm)		X
LASER MODULE description	**Supplied**	**Optional**
Laser handpiece 905nm with touch sensor. guide light +1 diode 25 mW	**1**	
Safety laser goggles, OLV model	**1**	
Interlock	**1**	
Laser handpiece 905nm with touch sensor. guide light +1 diode 25 mW		X
Laser handpiece 905nm with touch sensor. guide light +1 diode 100 mW		X
Laser handpiece 905nm with touch sensor. guide light+ 3 diode 25 mW (75mW total)		X
Laser handpiece 905nm with touch sensor. guide light+ 3 diode 100mW (300 mW total)		X
Laser handpiece 905nm with touch sensor. guide light+ +5 diode 25mW (125 mW total)		X
Laser handpiece 905nm with touch sensor. guide light+ +5 diode 100mW (500 mW total)		X
Safety laser goggles, OLV model		X
TECAR MODULE description	**Supplied**	**Optional**
Resistive massaging hand-probe	**1**	
Resistive electrode (diameteres 30,50,70 mm)	**3**	
Capacitive massaging hand-probe	**1**	
Capacitive electrode (diameteres 30,50,70 mm)	**3**	
Bottle conductive cream 1000 ml	**1**	
Steel plate	**1**	
Capacitive probe		x
Capacitive treatment insert diameter 30mm		x
Capacitive treatment insert diameter 50mm		x
Capacitive treatment insert diameter 70mm		x
Resistive probe		x
Resistive treatment insert diameter 30mm		x
Resistive treatment insert diameter 50mm		x
Resistive treatment insert diameter 70mm		x
Bipolar massaging hand-probe diameter 45 mm		x
Bipolar massaging hand-probe diameter 70 mm		x
Adhesive plates for moving applications		x
Return electrode in steel + cable		x
Kit for moving applications (cable + 10 adhesive plates)		x
LASER MODULE HL description	**Supplied**	**Optional**
Laser handpiece defocused in 4 spot optical fiber	**1**	
Footswitch	**1**	
Interlock		
Safety glasses for operator, model YG3	**1**	
Safety glasses for patient, model OLV	**1**	
Laser glasses YG3		X
Laser glasses OLV		X

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 connection of low power laser handpiece. The cable length must be less than 3m.

Fiber optic cable with two electric cables covered by a shielded steel sheath coated with a double layer of thermo-shrinking, for the connection of the high power laser handpiece. The length of the cables must be less than 3m.

Two-pole cable for connecting applicators and cylinders. The cable length must be less than 3m.

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

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

For patients or for module LL

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

HL MODULE operator glasses

- CE marking
- 840-950 DI LB5

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 conductive rubber electrode.

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

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

For mounting of electromagnets-applicators (MG module) you must connect the cable attached to each electromagnet-applicator-generator unit by inserting the plug jack into two connectors located on the front panel.

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

If one of the two LASER modules is present, the device is supplied with a security key (interlock) that consists of a special DIN pin to be inserted in the appropriate DIN socket on the frontal panel of LL module device and in the appropriate connector on the HL module.

The laser modules DOES NOT WORK WITHOUT THE INTERLOCK SAFETY KEY.

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

In order to connect the capacitive or resistive handpiece and the return plate (module TC) you must insert the connector in the corresponding sockets placed on the frontal panel of the TECAR module.

Contact authorized dealers EME srl for problems or difficult 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.

After the successful installation and assembly, actuate the power switch and press the power button on the front panel by checking the correct switching on the monitor.

In the presence of an internal battery charge, it is not necessary to operate the power switch but simply press the power button on the front panel to check the correct monitor lights up and the device itself.

It is a rechargeable battery with an autonomy of 3-4 hours of work.

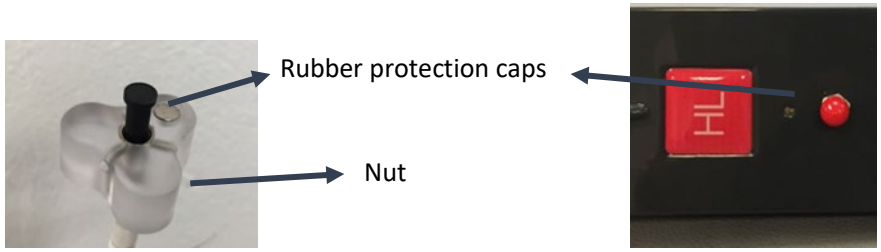
Using internal battery alone causes a gradual discharge, then the machine will switch off automatically.

To recharge the battery, simply keep POLYTER EVO constantly plugged into 220 Vac mains with the on/off switch on.

The maximum battery power is restored after a period of about 10 hours.

IMPORTANT: The MAGNETOTHERAPY module (MG module) and TECARTHERAPY module (TC module) are functioning ONLY with the device connected to the mains.

For the connection of the defocused laser probe it is necessary to remove the rubber protection caps present on the connectors of the module (red) and of the probe (black). Once the protections have been removed, the nut on the laser probe connector must be fully tightened. If this is not screwed correctly, the laser probe is not recognized by the device and it will not be possible to proceed with the delivery of the treatment.



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:

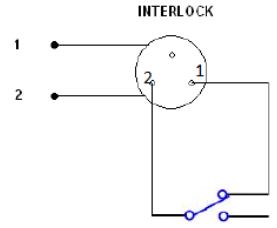


Figure d

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

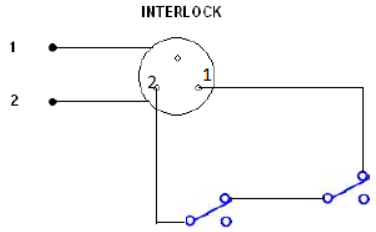
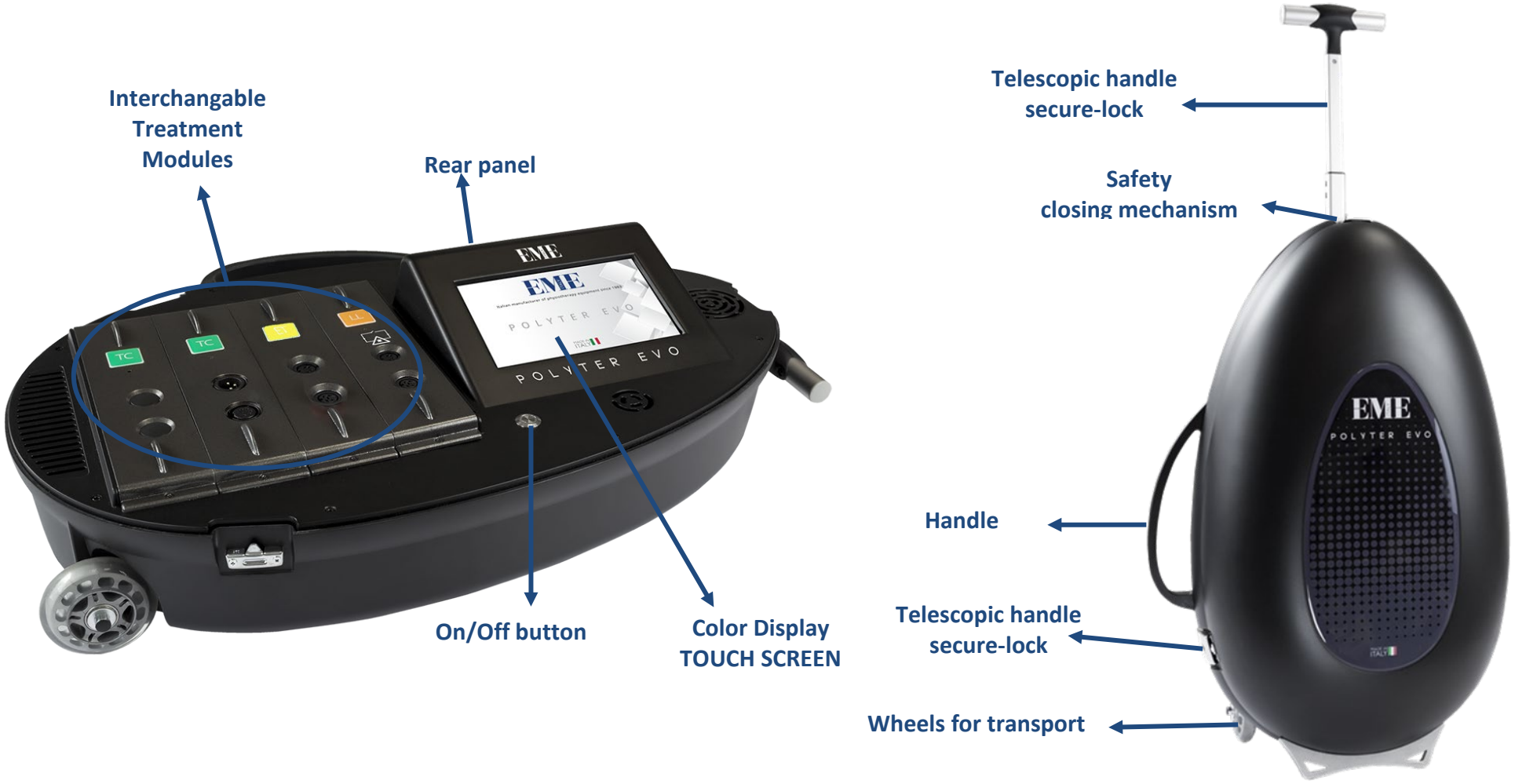
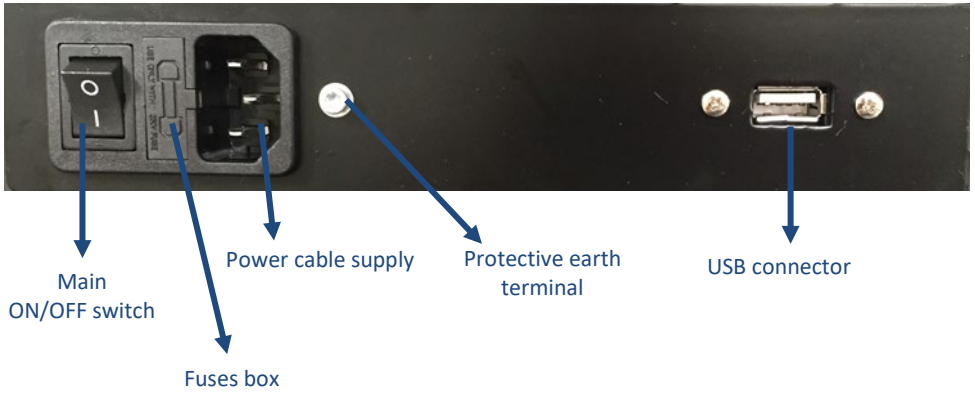


Figure e

DEVICE DESCRIPTION

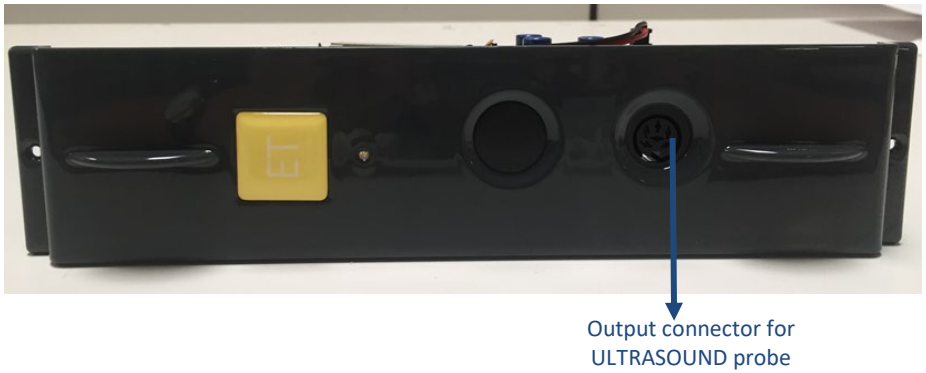


REAR PANEL

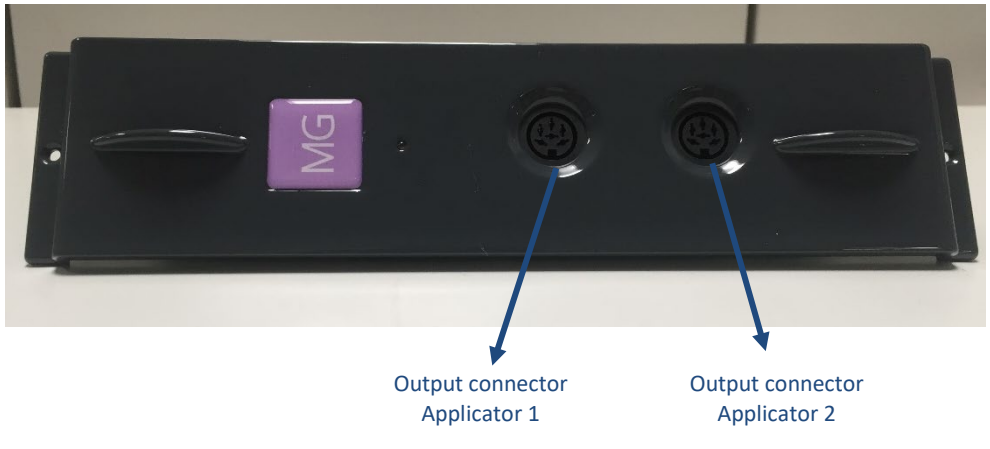


ELECTROTHERAPY MODULE

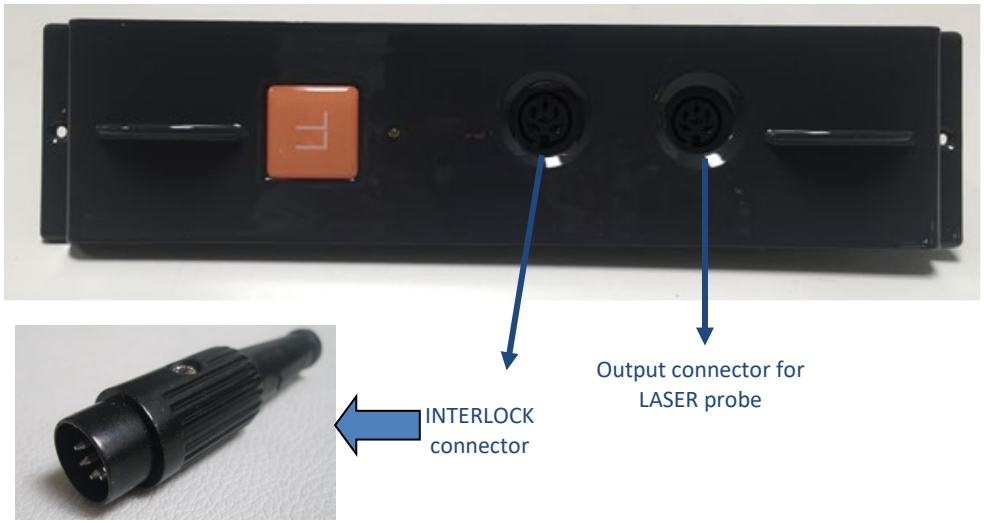
ULTRASOUND MODULE



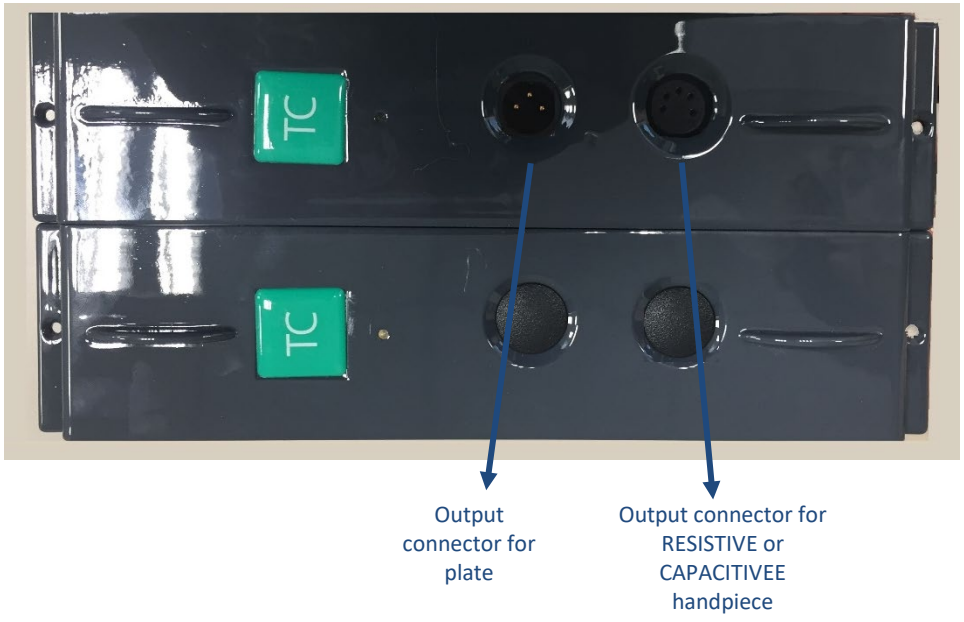
MAGNETOTHERAPY MODULE



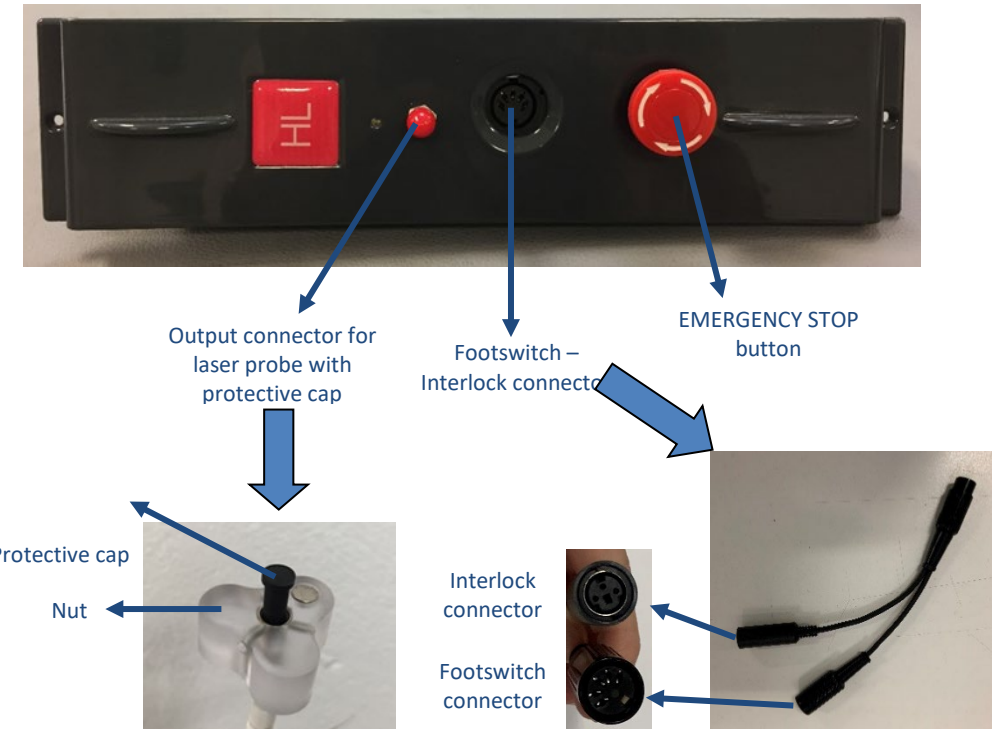
LASER MODULE



TECAR MODULE



HP LASER MODULE



<u>To remove a module</u> from the container, unscrew the screws, hold with both hands on the handles provided for each module and pull up.

On the other hand to insert a module you must place it in the guide, force with both hands on the handles provided for each module and make sure that the module is firmly connected to the MAIN BOARD. Finally, screw on the module with the screws.

POLYTER EVO has 4 slots, where it is possible to place the therapy modules, such as electro-therapy, ultrasound-therapy, laser-therapy LLLT, magneto-therapy and tecar-therapy. Each therapy module requires the use of one slot, with the exception of the TECAR module.

In fact, the tecar-therapy treatment requires the use of two slots of the device, by making possible the use of other two therapy modules. In this case the technologies present in the machine can be maximum 3 and not 4.

ACCESSORIES

ULTRASOUNDS HANDPIECE

LASER HANDPIECE

APPLICATOR FOR MAGNETOTHERAPY

ACCESORIES FOR TECAR-THERAPY

RESISTIVE HANDPIECE

CAPACITIVE HANDPIECE

CAPACITIVE ELECTRODES ..... **RESISTIVE ELECTRODES**

STEEL PLATE

BIPOLAR HANDPIECEwith integrated 70 mm electrode

BIPOLAR HANDPIECE integrated 45 mm electrode

HIGH POWER THERAPY LASER ACCESSORIES

QUADRIFOCAL DEFOCAL LASER PROBE IN FIBER OPTIC (4 positions)

FOOTSWITCH

HOW TO USE THE DEVICE

This chapter provides important information about the right uses of the device for combined therapy POLYTER EVO, that groups in a single container one or more modules between electro-therapy, ultrasound-therapy, laser-therapy LLLT, magneto-therapy and tecar-therapy, high power laser therapy.

All control functions and the entire functional structure of the machine are managed and coordinated by a micro-processor (or MAIN BOARD): in addition to the task of making available application programs already stored, it allows an optimal, safe and personalized use of the device.

The user dialogue interface is conducted by a large and clear graphic LCD display where there are displayed all operational messages interesting to the Operator, the functional state of the machine during the normal therapeutic activity and any error message.

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 POLYTER EVO.

Both the selection of a pre-stored program to apply specific treatments and the evaluation of the correct work parameters needed for a 'customized' application are treated.

OPTIMAL USE

After installing and positioning the device according to the instructions provided in the previous chapters, and having applied the cable(s) to connect the handpieces / applicators into the connector, insert the plug into the wall outlet (230 Vac) and power the device switching "ON" with the power switch on the rear panel.

The button on the front panel starts flashing: it means that the device is powered and the battery (if provided) is charging.

The next press of the button on the front panel causes the power of the device. The steady red light on the button indicates that the device is turned ON.

PLEASE NOTE: if the battery is loaded, turn the device on by pressing button in front panel without connecting the net switch. The device can work 3-4 hours with the rechargeable battery.

With the first start up of the device it is possible to set and choose the language of the six 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 a REMINDER is displayed 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.eme-srl.com/premium-service.

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

1. Enter the PASSWORD
   - 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 has been set by default and is **12345**: to insert it is necessary to press the 5 numeric buttons and then OK. By entering the correct code prepares POLYTER EVO for the operation.

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

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.

POLYTER EVO 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.

Standard protocols are stored in another internal memory of the machine. This memory cannot be handled by the operator: the data cannot be deleted nor formatted. To turn the device off press the button on front panel.

To turn it again it is necessary to wait approx. 10 seconds.

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 edited in the display FREE PROCEDURE correspond to the therapy modules present in the device:

- ✓ ELECTROTHERAPY
- ✓ ULTRASOUNDS
- ✓ COMBINED
- ✓ MAGNETOTHERAPY
- ✓ LASER
- ✓ TECAR
- ✓ HIGH POWER LASER THERAPY

If one or more modules are not installed on device, the buttons of these therapies will not be editable.

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

Modify the data of treatment, by acting as described in section MODIFY;

- 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**;
- Load a program by choosing one of the customized ones, created by the operator, as described in **LOAD**;
- Open the screen to select the module by pressing the button **BACK**;
- Go back to the main menu by pressing **HOME**.

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 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), **ROTATION TIME** 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 P**OLARITY, 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**, **INTERVAL** 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. For the parameter ROTATION ANGLE (expressed in °) increase or decrease the rotation angle using the + or - buttons or by scrolling the cursor to the right or to the left until the desired value is assigned to the parameter in question;
9. Press on **CONFIRM** to confirm the modification of parameter; the main screen will appear;
    - 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.

A long press of the SAVE button allows you to quickly save the parameters set in free procedure as default parameters. Confirmation will be asked to proceed:

- Click YES to proceed with saving the default parameters;
- Click NO to cancel.

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. The led on electrotherapy module turns on to show that the treatment has been started;
5. 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.
6. 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 on, it will be necessary to set **INTENSITY 1** and **INTENSITY 2** parameters;
    - Other parameters that can be personalized during the treatment are in yellow color and on the right of the screen. To change them follow the instructions as per section MODIFY;
7. 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**.
8. The led on electrotherapy module turns off;
9. 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.
10. To start again emission of treatment press on button **START** and set the value of parameter **INTENSITY**;
    - 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 on, it will be necessary to set **INTENSITY 1** and **INTENSITY 2** parameters;
11. To stop definitively the emission of electrotherapy treatment press on button **STOP**;
12. The led on electrotherapy module turns off;
13. A window will appear, then select:
    - **YES** to stop the treatment
    - **NO** to continue the treatment.
14. To confirm the stop of treatment on selected channel press on **OK**.

The countdown and the emission go on until:

- The selected time ends: in this case, the device will emit a tone.
- The button STOP is not pressed and the end of therapy is confirmed: the device will emit a tone.

Now it is possible to:

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

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 go back to the main screen of ELECTROTHERAPY menu.

Now it is possible to:

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

ULTRASOUNDS

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 **TIME(min), POWER (W/cm2), 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 10%-60% the POWER can be modified from 0.1W/cm2 to 3W/cm2;
    - If the value of DUTY-CYCLE is between 0%-60% the POWER can be modified from 0.1W/cm2 to 2W/cm2;
3. As for parameter **FREQUENCY** (MHz) press on button 1MHz/3MHz in the middle of screen;
4. For the 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 handpiece, that has a contact sensor, detects that the area to be treated is near or in contact, through the gel, with the handpiece.
5. 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 **BACK** 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.

A long press of the SAVE button allows you to quickly save the parameters set in free procedure as default parameters. Confirmation will be asked to proceed:

- Click YES to proceed with saving the default parameters;
- Click NO to cancel.

START

To start the emission of a treatment for ultrasound therapy:

1. Connect the ultrasound handpiece to the connector on front panel of device;
2. Press on **START**, a beep confirms that the treatment has been started;
3. The led on ultrasound module turns on showing that the treatment is going on ;
4. If work mode is CONTINUOUS the us handpiece connected is working immediately, that means that emission starts immediately even if there is no contact with the skin; the led on handpiece turns on (red color);
    - Otherwise if work mode is AUTOMATIC the handpiece starts emission only when contact sensor is in contact with the area; in this moment the led on handpiece (red color) turns on.
5. A window appears that shows the ongoing treatment in which:
    - 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.
6. To stop temporarily the emission in continuous mode press on button **PAUSE** and the handpiece will be in pause;
    - Otherwise, in AUTOMATIC work mode, to stop temporarily the emission it is necessary to distance the handpiece from the treated area and it will be in CONTACT PAUSE.
7. The led on handpiece and on ultrasound module turns off;
8. The timer stops and a PAUSE screen appears;
9. To start the treatment again press on **START** button and follow instructions as from point 2;
10. To stop the emission of ultrasound treatment press on **STOP**;
11. The led on handpiece and on ultrasound module turns off;
12. A window will appear, then select:
    - **YES** to stop the treatment
    - **NO** to continue the treatment.
13. To confirm the end of therapy press on **OK**.

The countdown and the emission go on until:

- The selected time ends: in this case, the device will emit a tone.
- The button STOP is not pressed and the end of therapy is confirmed: the device will emit a tone.

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 ULTRASOUND menu.

Now it is possible to:

- 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 the button **BACK** to enter the main screen of ULTRASOUND module;
- press **HOME** to enter the main screen.

COMBINED

The COMBINED MODE ELECTROTHERAPY and ULTRASOUND allows the user to supply combined treatments of electrotherapy with constant voltage (CV) and ultrasound treatments in CONTINUOUS MODE, using the channel CH1 of the ELECTROTHERAPY module.

In order to perform a combined treatment, you need to apply only the positive electrode of the channel CH1 to the patient and the ultrasound handpiece, since it represents the negative electrode of the channel CH1.

This connection allows you to replace at the hardware level the negative electrode of the negative electrode of the electro-therapeutic channel 1 with the handpiece of the ultrasounds handpiece applicator.

In the main screen of the COMBINED mode, after selecting the ELECTROTHERAPY module and/or the ULTRASOUND module, it is possible to:

- modify the treatment data of the available modules, proceeding as described in the sections **ELECTROTHERAPY - MODIFY** and/or **ULTRASOUND - MODIFY;**
- start the combined treatment, following the procedure START as in **ELECTROTHERAPY - START** and/or **ULTRASOUND - START**;
- Open the screen to select the module by pressing the button **BACK**;
- Go back to the main menu by pressing **HOME**.

MAGNETOTHERAPY

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 **TIME** (s), **POWER** (W/cm2), **DUTY-CYCLE** (%) and **FREQUENCY** (Hz), increase or decrease their value using the keys + or -, or scrolling the cursor left or right to set the desired value;
3. Press on **CONFIRM** to confirm the modification of the parameter; in this way, the machine will go back to the main screen of MAGNETOTHERAPY module;
    - otherwise press on BACK to delete the modification of the parameter, in this case the main screen of MAGNETOTHERAPY 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.

A long press of the SAVE button allows you to quickly save the parameters set in free procedure as default parameters. Confirmation will be asked to proceed:

- Click YES to proceed with saving the default parameters;
- or Click NO to cancel.

START

In order to start a magnetotherapy treatment:

1. Plug in the handpieces in the correspondent connectors in the front panel of the device;
2. Press on **START** and the device will emit a start tone;
3. The led on the electrotherapy module will be turned on to indicate the emission of the treatment;
4. A window appears that shows the ongoing treatment in which:
   - The timer with time left to the end of treatment;
   - The applicator/applicators connected are OPERATIVE;
5. The user may vary the **POWER, FREQUENCY** and **DUTY-CYCLE** parameters 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.
6. To stop the emission of the treatment press on **PAUSE**;
7. The led of the magnetotherapy is switched off;
8. The timer stops and a PAUSE window appears:
   - handpieces are in PAUSE;
9. To resume the treatment from the the moment in which it has been interrupted, press **START**;
10. To stop definitively the magnetotherapy treatment, press **STOP**;
11. The led of the magnetotherapy is switched off;
12. A window will appear, then select:
    - **YES** to confirm the interruption of the magnetotherapy treatment
    - **NO** to continue the treatment.
13. To confirm the end of therapy press on **OK**.

The countdown and the emission go on until:

- The selected time ends: in this case, the device will emit a tone.
- The button STOP is not pressed and the end of therapy is confirmed: the device will emit a tone.

Now it is possible to:

- press the button **BACK** to enter the main screen of MAGNETOTHERAPY module;
- Press **HOME** to enter the main screen.

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 MAGNETOTHERAPY menu.

Now it is possible to:

- 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 the button **BACK** to enter the main screen of MAGNETOTHERAPY module;
- press **HOME** to enter the main screen.

LASER

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

After modifying/confirming the dimension of treated area (cm2), 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 (cm2), 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^2) 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/cm2) 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/cm2) 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 handpiece and started the program.
3. For the 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 handpiece, that has a contact sensor, detects that the area to be treated is near or in contact, through the gel, with the handpiece.
4. Press on **CONFIRM** to confirm that the parameter has to be modified; the main screen of LASER appears;
    - otherwise press on **BACK** 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.

A long press of the SAVE button allows you to quickly save the parameters set in free procedure as default parameters. Confirmation will be asked to proceed:

- Click YES to proceed with saving the default parameters;
- Click NO to cancel.

START

To start the treatment:

1. Connect the applicator/applicators in connectors on front panel of device;
2. Select the dimension o f the area to treat by using the parameter **TREATED AREA** (cm2) as described in FREE PROCEDURE– LASER - MODIFY;
3. Press on **START**, a beep confirms that the treatment has been started;
4. The led on laser module turns on to show that the treatment has been started;
5. If work mode is CONTINUOUS the us handpiece connected is working immediately, that means that emission starts immediately even if there is no contact with the skin; the led on handpiece turns on (red color);
    - Otherwise if work mode is AUTOMATIC the handpiece starts emission only when contact sensor is in contact with the area; in this moment the led on handpiece (red color) turns on.
6. A window appears that shows the ongoing treatment in which:
    - The timer with time left to the end of treatment;
    - The parameters **EMITTED ENERGY** (J) and **REMAINING ENERGY** (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.
7. 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.
8. To stop temporarily the emission in continuous mode press on button **PAUSE** and the handpiece will be in pause;
    - Otherwise, in AUTOMATIC work mode, to stop temporarily the emission it is necessary to distance the handpiece from the treated area and it will be in CONTACT PAUSE.
9. The led on module and on handpiece turn off;
10. The timer stops and a PAUSE window appears:
    - The counter of parameters EMITTED ENERGY and REMAINING ENERGY is stopped ;
11. To start the treatment again press on **START** button and follow instructions as from point 2;
12. To stop the emission of laser treatment press on **STOP**;
13. The led on module and on handpiece turn off;

14. A window will appear, then select:
    - **YES** to stop the treatment
    - **NO** to continue the treatment.
15. To confirm the end of therapy press on **OK**.

The countdown and the emission go on until:

- The selected time ends: in this case, the device will emit a tone.
- The button STOP is not pressed and the end of therapy is confirmed: the device will emit a tone.

Now it is possible to:

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

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 to:

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

TECAR

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. For the parameter **TIME** (min) increase or decrease the value by using buttons + or – or scrolling the cursor to the right or to the left until reaching the desired value. It is possible to vary the parameter TIME between 1 and 30 minutes.
    - Press **CONFIRM** to save the parameter set value and to go back to the main screen of the TECAR module;
    - Press **BACK** to delete the modification of the parameter, in this case you go back to the main screen of TECAR module without any modification.
3. For the parameter **WORK MODE** (CAPACITIVE or RESISTIVE) press on the button CAPACITIVE/RESISITVE in the middle of screen.
    - Press **CONFIRM** to save the set mode and to go back to the main screen of the TECAR module;
    - Press **BACK** to delete the modification of the parameter, in this case you go back to the main screen of TECAR module without any modification.
4. For the parameter **HEATING MODE** the 3 available modes appear on the screen: ATHERMY, HOMEOTHERMY, HYPERTHERMY.
    - Press on the heating mode that you want to set, then you go automatically to the main scree of the TECAR module with the new set mode.
    - Press on BACK to go back to the main screen of the TECAR module withou any modification of the parameter.
5. For the parameter **POWER** 3 available power levels appear on the screen: LOW, MEDIUM, HIGH. The POWER parameter allows setting the percentage of emitted power at the beginning of the treatment, in particular:
    - By choosing the LOW level the initial power percentage is 0%;

- By choosing the MEDIUM level the initial power percentage is 33 %;
- By choosing the HIGH level the initial power percentage is 66 %;

  - Press on the power level that you want to set, then you go automatically to the main scree of the TECAR module with the new set power.
  - Press on BACK to go back to the main screen of the TECAR module without any modification of the parameter.

6. For the parameter **ELECTRODES DIMENSION** 3 typologies of electrodes appear on the screen, which can be connected to the handpiece applicator and differentiate themselves for their diameter: 30 mm, 50 mm, 70 mm. The electrodes that are currently selected are green highlighted.

   - Press on the electrode type that you want to set, then you go automatically to the main scree of the TECAR module with the new set mode. The chosen electrodes are displayed in a little image in the left-upper part of the screen, together with the connected handpiece.
   - Press on BACK to go back to the main screen of the TECAR module without any modification of the parameter.

   The electrodes dimension does not affect the supply mode of the treatment; it is a simple suggestion for the operator.

7. For the parameter **WORK MODE** (AUTO, CONTINUOUS), press on the button AUTO/CONTINUOUS in the middle of screen.

   - If work mode is CONTINUOUS the handpiece connected is working immediately, that means that emission starts immediately even if there is no contact with the skin;
   - If work mode is AUTO the handpiece connected is working immediately, that means that emission starts immediately, only in the moment in which rhe contact sensor reveals a contact with the skin. When there is no contact with the skin anymore, the treatment stops.

     - Press CONFIRM to save the set mode and to go back to the main screen of the TECAR module;
     - Press BACK to delete the modification of the parameter, in this case you go back to the main screen of TECAR module without any modification.

SAVE

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

1. Press the button **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 **OK** to save the program;

   - Otherwise press on **CANCEL** to cancel the saving operation of the therapeutic 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 **YES** to overwrite the therapy;
- Press **NO** to cancel the procedure and insert a new name for the just created program.

A long press of the SAVE button allows you to quickly save the parameters set in free procedure as default parameters. Confirmation will be asked to proceed:

- Click YES to proceed with saving the default parameters;
- Click NO to cancel.

START

To start the emission of an TECAR-THERAPY treatment:

1. Connect the handpiece applicator in proper connector in front panel of the machine;
   - If a treatment starts without having connected the handpiece, an error message "HANDPIECE ERROR" appears on the screen, which does not allow the emission of the treatment.
2. Place the handpiece applicator on the body part to be treated;
3. Check the recognition of the handpiece connected to the device.
   - In the left part of the main screen of the TECAR module the status of the handpiece is displayed: CONNECTED or NOT CONNECTED. If the handpiece is correctly connected the type of connected handpiece (capacitive or resistive) is indicated). Otherwise, the status of not connected handpiece is indicated.
4. Set the parameter **MODE** (see the MODIFICATION section) according to the connected handpiece.
   - If the capacitive handpiece is connected, set the CAPACITIVE mode;
   - If the resistive handpiece is connected, set the RESISTIVE mode;
   - If you connect the BIPOLAR handpiece (optional accessory), set RESISTIVE mode. During treatments with BIPOLAR handpiece (unlike capacitive and resistive handpieces) it is not necessary to use the return plate.
   - If a treatment starts and you have selected in MODE a handpiece that is different from the one that is actually connected, an error message "HANDPIECE ERROR" appears on the screen, which does not allow the emission of the treatment.
5. Press on **START**, and a beep will confirm that the treatment has been started;
6. The led on TECAR module turns on showing that the treatment is going on ;
7. A window appears and it shows:
   - The timer with time left to the end of program.
   - An animation accompanies the supply of the therapy.
   - The FEEDBACK bar fills in proportional manner to the actual transfer of energy to the patient.
   - The value of the emitted power can be adjusted during the treatment.
     - Press on the parameter **POWER** to gradually increase and decrease the value using the + and - buttons. The starting value is the same one that is set in the general screen of the TECAR module (see section MODIFY - parameter POWER).
   - The heating mode idicated is the one set in the general screen of the TECAR module (see section MODIFY - parameter HEATING MODE).
8. To stop temporarily the emission of the treatment press on **PAUSE**;
   To stop temporarily the emission of the treatment in CONTINUOUS mode press on **PAUSE** and the handpiece connected will be IN PAUSE;
   - Otherwise, in AUTOMATIC work mode, to stop temporarily the emission it is necessary to distance the handpiece from the treated area and it will be in CONTACT PAUSE.
9. The led on TECAR module turns off;
10. The timer stops and an intermittent PAUSE window appears:
11. To resume the treatment from the the moment in which it has been interrupted, press **START**
12. To stop definitely the emission of tecar-therapy treatment press on **STOP**;
13. A window will appear, then select:
    - **YES** to confirm the stop of the tecar-therapy treatment in progress
    - **NO** to cancel the interruption of the treatment.

The countdown and the emission go on until:

- The selected time ends: in this case, the device will emit a tone.
- the button **STOP** is not pressed and the end of therapy is confirmed: the device will emit a beep.

At this point a message appears on the screen signaling the completing of the program.

By pressig OK you go back to the screen of the supply of the treatment.

- Press the button BACK to go back the main screen of TECAR module;
- Press **HOME** to enter the main screen.

!ATTENTION!: While tecar-therapy is performing, the RF energy transmission (generated by the device) on the touch panel of the display can make the software use unreliable. To avoid this situation, we require the operator to:

- once the therapy is started, avoid touching the resistive/capacitive electrode simultaneously with one hand, and the touch panel with the other hand to modify the parameters;
- once the therapy is started, avoid touching the body of the patient undergoing treatment with one hand at the same time the touch panel with the other hand to modify the parameters.

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 where you want 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;
9. Otherwise press on button **BACK** to go back to the main screen of the TECAR module.

Now it is possible to:

- Modify the data of treatment, as per instructions in **MODIFY**;
- save the parameters that have been modified as indicated in section **SAVE**;
- start the treatment, as per instructions in **START**;
- press the button **BACK** to go back the main screen of TECAR module;
- press on **HOME** to enter the main menu screen.

If any customized program has been previously saved, a signal message appears on the screen.

- Press the button BACK to go back the main screen of TECAR module;

LASER HL

When selecting the LASER HL module, the display / modification of the treatment area appears as the first screen.

Only after modifying or confirming the size of the TREATED AREA (cm^2), as described below in the MODIFICATION section, it is possible to proceed with the operations foreseen in the 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^2), TIME (s), POWER (W) and DUTY-CYCLE (%)** increase or decrease the value by using buttons + or – or scrolling the cursor until the required value;
   - When TIME, TREATED AREA, DUTY-CYCLE and POWER (modifiable parameters) are changed, the value of the **ENERGY TO BE EMITTED** (J) automatically vary;
   - When POWER (this parameter can be modified) is changed, the **FREQUENCY** (Hz) is automatically 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 handpiece and started the program.

3. Click on the image of the laser probe to select the spot area: POS1 - 0.78 cm^2, POS2 - 1.76 cm^2, POS3 - 3.14 cm^2, POS4 - 4.90 cm^2. Clicking on the desired

position automatically returns to the parameter setting screen and the abbreviation in the image indicates the position just selected.

- Check that the area of the set spot is the same as that set in the laser probe.

4. Press on **CONFIRM** to confirm that the parameter has to be modified; the main screen of LASER appears;
   - otherwise press on **BACK** 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.

A long press of the SAVE button allows you to quickly save the parameters set in free procedure as default parameters. Confirmation will be asked to proceed:

- Click YES to proceed with saving the default parameters;
- Click NO to cancel.

START

To start the treatment:

1. Connect the laser probe and the footswitch in connectors on front panel of device;
   - Insert the laser probe in the appropriate connector after removing the protective caps (red the one in the module and black the one on the laser probe);
   - Screw the nut in the connector to fix the laser probe. If the connector is not completely tightened, the laser probe will not be recognized;
2. Position the laser probe on the part to be treated, keeping the spacer in contact with the skin;
3. Click the START button, a warning will appear to remind the operator to verify that the area of the spot set in the software corresponds to that chosen in the probe and to wear protective glasses. Press OK to proceed. In the screen that appears you can view:
   - the writing "PAUSED PEDAL" indicates that the program is waiting for the pedal to be pressed;
   - in the screen the POWER and DUTY CYCLE parameters can be modified during the treatment.

4. to proceed with the emission, operate the footswitch by applying pressure through the foot and move the applicator in such a way as to scan all the affected area:
    - the start of the dispensation is signaled by a beep and in the timer the countdown of the dispensing time starts;
    - The led on laser module turns on to show that the treatment has been started;
    - the rectangle on the right turns red indicating the emission status and the image of the laser probe shows the delivery of the laser beam;
    - with the start of the delivery the number of EMITTED ENERGY will be increased and the number of ENERGY LEFT will be decreased;
5. if the pressure on the footswitch is suspended, the treatment stops until the pedal is pressed again;
6. to put the device in PAUSE press the PAUSE button; if there is any pressure on the pedal, there is no emission;
7. To start the treatment again press on **START** button and follow instructions as from point 3;
8. To stop the emission of laser treatment press on **STOP**;
9. The end of the treatment is signaled by an acoustic warning and a video message. Press OK to continue and the HOME or BACK key will return to the main screen or modify the parameters as described in the MODIFY;

The countdown and the emission go on until:

- The selected time ends: in this case, the device will emit a tone;
- the footswitch is kept pressed;
- The button STOP is pressed and the end of therapy is confirmed.

If any critical problems arise during the treatment or there is a need to IMMEDIATELY STOP delivery for any reason, it is possible to use the EMERGENCY STOP BUTTON.

EMERGENCY STOP BUTTON allows instantaneous interruption of laser delivery.

LOAD

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

5. Select **LOAD**;
6. Press on **INTERNAL** or **USB** depending on the memory to load the customized program;
7. If necessary, scroll the list of therapies;
8. 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 to:

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

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 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. Press **THERAPIES** to visualize all suggested therapeutic protocols for each anatomical region, divided by therapy module (that is ET,US, MT, LASER, TECAR, LASER HL). The keys (ET, US, LL, MG, TC, HL) at the top left allow to filter the treatments by technology.
   - Otherwise, select **COMBINED THERAPIES** if you want to visualize the therapeutic suggestion protocols that can be performed with the combination of ELECTROTHERAPY and ULTRASOUND THERAPY modules.

     If in the device both modules are loaded, this button does not appear on the display. Therefore, it is not possible to perform combined treatments.
   - Otherwise, select MULTITHERAPIES if you want to visualize the therapeutic suggestion protocols linked to a particular body part, that can be performed using a sequence of different treatment modules (e.g. ET-US-LASER, ET-US-MT, ET-US-LASER-MT..)

     There are no multi-therapy protocols with the TECAR and LASER HL module.
3. Select the anatomical region to treat in picture of body shown on display;
4. On 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.
   - Otherwise, if the button **COMBINED THERAPIES** was selected, each therapeutic protocol of the list is associated to ELECTROTHERAPY and ULTRASOUND modules of treatment.
   - Otherwise, if the button MULTITHERAPIES has been previously selected, each therapeutic protocol in the list will be associated to all treatment modules to which it can be connected.
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 to:

- 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.

In case of **COMBINED THERAPIES** it is possible to:

- MODIFY the data of treatment, as described in section MODIFY of the ELECTROTHERAPY and ULTRASOUND modules;

- START the treatment depending on the sequence of therapy modules for the selected pathology;

In case of **MULTITHERAPIES** it is possible to:

- START the treatment using the sequence of modules dedicated to 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.

Start the treatment to as described in section START of each therapy module.

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

1. Press the **STOP** button on display of therapy module;
2. A window will appear, then select:
    - **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 is possible to:

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

PATIENT'S CARD

By pressing the button **PATIENT'S CARD** in the 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 "CREATE 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 PATIENT'S CARD that has been previously saved in the memory;
- MODIFY the PATIENT'S CARD;
- CANCEL the patient's card.

CREATE A CARD

1. Select the button **PATIENT'S CARD** on the main menu;
2. Press the buttons **INTERNAL** or **USB** to choose the memory in which the patient's card will be saved;
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'S ANAMNESIS
    - TREATMENT from list of pathologies
    - Date of BEGINNING OF THERAPY
    - N. SESSIONS IN TOTAL

- N. SESSIONS CARRIED OUT
- RESULTS

5. Press on the field to complete;
6. Operate the corresponding controls to introduce data:
   - Selecting the fields SURNAME, NAME, ADDRESS, PHONE, ANAMNESIS PATIENT, N. SESSIONS IN TOTAL, N. SESSIONS CARRIED OUT and RESULTS, type on the virtual keyboard to insert the requested information;
     - To hide / show the virtual keyboard, press on the keyboard symbol.
   - Selecting the fields DATE OF BIRTH and BEGINNING OF THERAPY, set the day, month and year operating on the corresponding selection arrows and confirm by pressing **SET**;
   - 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. A screen with the name of card and data of treatments will appear.
   - 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 i twill 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 to:

- 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 the main menu;
2. Press the buttons **INTERNAL** or **USB** to choose the memory to load the patient's card;
3. Depending on the selected memory, a screen will appear displaying the list of all cards stored in the memories;
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 to:

- Modify the parameters of the patient's card before starting the treatment proceeding as described in 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;
- Delete 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.

MODIFY a CARD

1. Select the button **PATIENT'S CARD** on the main menu;
2. Press the buttons **INTERNAL** or **USB** to choose the memory in which the patient's card will be saved;
3. Depending on the selected memory, a screen will appear displaying the list of all cards stored in the memories;
4. Select the card you want to open;
5. Select **OPEN** to open the patient's card;
6. Select **EDIT**
    - The following data can be modified:
        - SURNAME
        - NAME
        - ADDRESS
        - PHONE
        - 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:
    - When modifying the fields SURNAME, NAME, ADDRESS, PHONE, ANAMNESIS PATIENT, N. SESSIONS IN TOTAL, N. SESSIONS CARRIED OUT and RESULTS, type on the virtual keyboard to perform the modifications;
    - To modify the field DATE OF BIRTH and TREATMENT START, press the correspondent arrows to change day, month and year and press 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) :
10. After some seconds on screen will appear the patient's card with the name of card and the data of treatment.

Now it is possible to:

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

SETTINGS

By pressing **SETTINGS** in the main screen you can go to the information of each therapy module present in the device, by pressing the corresponding buttons:

- ELECTROTHERAPY
- ULTRASOUNDS
- MAGNETOTHERAPY
- LASER
- TECAR
- HIGH POWER LASER

and to the geenral settings by pressig the button:

- GENERAL SETTINGS

ELECTROTHERAPY SETTINGS

In this section it is possible to:

- 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 / disable the contact control functions of the electrodes:
  - **ELECTRODES CONTACT CONTROL** set on **ON**: in case of a lack of connection, an error message will be displayed on the screen;
  - **ELECTRODES CONTACT CONTROL** set on **OFF**: in case of a lack of connection, an error message will not be displayed on the screen;
- 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 displayed in the section FREE PROCEDURE of the ELECTROTHERAPY module.

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

1. Select the supply channel among **CH1, CH2, CH1+2**;
2. Depending on the selected channel, a screen will appear in which default data can be modified;
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 new default values
   - Otherwise press **CANCEL**, in this case the default program will not be modified.

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 **DEACTIVATED** button:

- The DEACTIVATED button will be replaced by **ACTIVATED** button;
- A window will appear, then 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;
   - A window will appear, then select:
     - **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**;
3. A window will appear, then select:
   - **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 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 ELECTROTHERAPY module in USB key:

1. Insert the USB key into the connector;
2. A window will appear, then 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 to:

- Press the button **BACK** to go to 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.

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 proceed with software update of the electrotherapy module
- **NO** to cancel the software updating procedure

5. Select the file to load;
6. A window will appear, then select:
   - **OK** to proceed with software update of the electrotherapy module
   - **CANCEL** to cancel the software updating procedure
7. Now follow the instructions on screen .

After some seconds POLYTER EVO 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 to:

- 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 default parameters that can be modified are:

TIME (min)

FREQUENCY (MHz)

POWER (W/cm2)

DUTY-CYCLE (%)

PULSED FREQUENCY (HZ)

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 – ULTRASOUND
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 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 ULTRASOUND 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, then 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;
- A window will appear, then select:
  - **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 ULTRASOUND module:

1. Select one or more records to delete: they will be highlighted in blue;
2. Press on **DELETE**;
3. A window will appear, then select:
   - **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, then 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 to:

- Press the button **BACK** to go to 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.

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 proceed with software update of the ultrasounds module
   - **NO** to cancel the software updating procedure
5. Select the file to load;
6. A window will appear, then select:
   - **OK** to proceed with software update of the ultrasounds module
   - **CANCEL** to cancel the software updating procedure
7. Now follow the instructions on screen .

After some seconds POLYTER EVO will have the updated software version for ULTRASOUNDS module.

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

MAGNETOTHERAPY SETTINGS

In this section it is possible to:

- Visualize, modify and save in internal memory the basic settings of MAGNETOTHERAPY 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 of section FREE PROCEDURE of MAGNETOTHERAPY module.

The default parameters that can be modified are:

TIME (min)

POWER (Gauss)

FREQUENCY (Hz)

DUTY-CYCLE (%)

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

TREATMENT CHRONOLOGY

To have the complete chronology of treatments carried out with the MAGNETOTHERAPY 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, then 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;
    - A window will appear, then select:
        - **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 MAGNETOTHERAPY module:

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

- **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 MAGNETOTHERAPY 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 MAGNETOTHERAPY module in USB key:

1. Insert the USB key into the connector;
2. A window will appear, then 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 to:

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

INFORMATION

To visualize the diagnostic information of the MAGNETOTHERAPY 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 MAGNETOTHERAPY module only with the necessary 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 proceed with software update of the magnetotherapy module
   - **NO** to cancel the software updating procedure
5. Select the file to load;
6. A window will appear, then select:
   - **OK** to proceed with software update of the magnetotherapy module
   - **CANCEL** to cancel the software updating procedure
7. Now follow the instructions on screen .

After some seconds POLYTER EVO will have the updated software version for MAGNETOTHERAPY module.

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

LASER SETTINGS

In this section it is possible to:

- 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 appears is the screen where is possible to visualize/modify the area of treatment :

1. Increase or decrease the value of the **TREATED AREA** (cm2) by using the buttons + or – or scrolling the cursor to right or left until reaching the desired value to attribute to the parameter in question;
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, then 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;
    - A window will appear, then select:
        - **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**;
3. A window will appear, then select:

- **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, then 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 to:

- Press the button **BACK** to go to 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.

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 proceed with software update of the laser module
   - **NO** to cancel the software updating procedure
5. Select the file to load;
6. A window will appear, then select:
   - **OK** to proceed with software update of the laser module
   - **CANCEL** to cancel the software updating procedure
7. Now follow the instructions on screen .

After some seconds POLYTER EVO will have the updated software version for LASER module.

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

TECAR-THERAPY SETTINGS

DEFAULT PROGRAM

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

The default parameters that can be modified are:

TIME (min)

(CAPACITIVE, RESISITVE) MODE

HEATING MODE (ATHERMY, HOMEOTHERMY, HYPERTHERMY)

POWER LEVEL (LOW, MEDIUM, HIGH)

ELECTRODES DIMENSIONS (30 mm, 50 mm, 70 mm)

WORK MODE (CONTINUOUS, AUTO)

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

1. select the parameter to be modified and proceed as described in FREE PROCEDURE – TECAR– section MODIFY
2. Press on **SAVE**;
3. In the appearing window select **OK** to save the new data set as new default values
    - Otherwise **CANCEL** to cancel the modifications of the default program.

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 – TECAR–section LOAD.

TREATMENT CHRONOLOGY

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

1. Select **TREATMENT CHRONOLOGY**;
2. Enable the chronology by pressing **DEACTIVATED**:
    - The DEACTIVATED button will be replaced by **the ACTIVATED button**;
    - A window will appear, then select:
        - **YES** to enable the treatment chronology
        - **NO** to disable the treatment chronology
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. To disable the treatments chronology press **ACTIVATED**:
    - The ACTIVATED button will be replaced by DEACTIVATED button;
    - The automatic saving will be deleted but the saved data won't be deleted;
    - A window will appear, then select:
        - **YES** to disable the chronology treatments
        - **NO** to not disable the chronology treatments

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

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

To delete the complete chronology of treatments carried out with the TECAR 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 TECAR module in USB key:

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

Now it is possible to:

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

INFORMATION

By pressing the button **INFORMATION**you can visualize the diagnostic information of the TECAR module about:

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

The authorized personnel can update the software of the TECAR module only using the available and 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 **SW UPDATE**;
4. A window will appear, then select:
    - **YES** to proceed with software update of the TECAR module
    - **NO** to cancel the software updating procedure
5. Select the file to load;
6. A window will appear, then select:
    - **OK** to proceed with software update of the HR TEK module
    - **CANCEL** to cancel the software updating procedure
7. Now follow the instructions on screen .

After some seconds POLYTER EVO will have the updated software version for TECAR module.

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

HIGH POWER LASER THERAPY SETTINGS

In this section it is possible to:

- Visualize, modify and save in internal memory the basic settings of LASER HL 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 HL module.

The first screen that appears is the screen where is possible to visualize/modify the area of treatment:

4. Increase or decrease the value of the **TREATED AREA** (cm^2) by using the buttons + or – or scrolling the cursor to right or left until reaching the desired value to attribute to the parameter in question;
5. Press on **CONFIRM** to confirm the modification of the parameter; the LASER HL default screen will appear;
    - otherwise, to cancel the modification of the parameter press on **BACK**; the LASER HL default screen will appear and the parameter will not be changed.
6. In LASER default screen it is possible to modify the other default parameters.

The default parameters that can be modified are:

TIME (min)

POTENZA (W)

DUTY-CYCLE (%)

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

7. Select the parameter to change and proceed as described in FREE PROCEDURE – LASER HL– section MODIFY

8. Press on **SAVE**;
9. 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 HL–section LOAD.

TREATMENT CHRONOLOGY

To have the complete chronology of treatments carried out with the LASER HL 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, then 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;
    - A window will appear, then select:
        - **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**;
3. A window will appear, then select:
    - **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, then 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 to:

- Press the button **BACK** to go to 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 laser module ;
- The HARDWARE version;
- The SOFTWARE version.

The authorized personnel can update the software of the LASER module only with the necessary 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 proceed with software update of the laser module
    - **NO** to cancel the software updating procedure
5. Select the file to load;
6. A window will appear, then select:
    - **OK** to proceed with software update of the laser module
    - **CANCEL** to cancel the software updating procedure
7. Now follow the instructions on screen.

After some seconds POLYTER EVO 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 possible to select:

- SOUND MANAGEMENT
- MEMORIES MANAGEMENT
- PASSWORD MANAGEMENT
- SYSTEM MANAGEMENT

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 to:

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

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 POLYTER EVO 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 POLYTER EVO 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 POLYTER EVO APPLICATION SETTING.

Now it is possible to:

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

RESET DEFAULT SETTINGS

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 button **SW UPDATE**;
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 POLYTER EVO 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 POLYTER EVO do not require any particular maintenance operations , but only a periodic maintenance and cleanliness of the handpieces, in order to ensure the better operating conditions, guarantee the effectiveness of the treatment and the safety of the patient.

It is recommended to perform **every two years** periodic maintenance in order to check:

- the emission levels;
- the intensity of any leakage currents;
- 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, ensure that it is operating in a safe guaranteed. For this kind of operations, it is advisable to contact EME srl or one of its authorized centers.

Furthermore, it is necessary to perform a period maintenance of the handpieces/applicators. In particular, it is necessary to:

- **every two years** submit to calibration/adjustment all the programmable accessories, such as handpieces/applicators, supplied with the device. For this kind of intervention please contact EME srl technical support service.
- check **every week** the treatment head of the handpieces, in particular of the ultrasound-therapy handpieces in order to reveal eventual cracks which could lead to the entrance of conductor liquid;
- check **before every treatment therapy** the integrity of the cable and connector of handpieces/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 handpieces, 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 handpieces / 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 handpieces.

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.

In case of replacement or insertion of the internal battery, do not open the device POLYTER EVO but contact authorized and specialized personnel, to perform the maintenance operations in safety and to avoid damages on device; or contact EME or its authorized service centre.

The life of the device is approximately 10 years.

TECHNICAL PROBLEMS

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

However, should you have any operational problems, we recommended that you consult the following manual before contacting any of our authorized service centers.

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 POLYTER EVO 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.

On the basis of their functioning principle, the POLYTER EVO devices generate an acceptable amount of radiofrequency energy and present an adequate level of immunity from irradiating electromagnetic fields. In these conditions damaging interference cannot occur to radioelectric communications, to the functioning of electro-medical devices used for monitoring, diagnosis, treatment and surgery, to the functioning of electronic office equipment such as computers, printers, photocopiers, faxes, etc. nor to any electrical or electronic device used in the same environment, provided that these meet the requirements of the directive on ELECTROMAGNETIC COMPATIBILITY.

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

FUNCTIONING WITH POWER CABLE		
PROBLEM	**POSSIBLE CAUSE**	**SOLUTION**
The LCD display on the front panel does not switch on: the device does not work.	Network socket incorrectly inserted into the power outlet.	Check that the socket is working correctly.
	Power cable incorrectly inserted into the connector of the unit.	Correctly insert the plug and the cable into the connector of the unit.
	Cable is worn or blocked.	Replace the power cable.
	The switch on the rear of the unit is turned off.	Turn on the switch.
	Start button not pressed.	Press start button.
	Fuses faulty or blocked.	Replace any missing, faulty or blocked fuses.
	Failure of the electronic control circuit.	Contact EME srl Service centre.
The monitor on front panel does not light up	Defective parts on electronic control board.	Contact EME srl Service centre.

INTERNAL BATTERY FUNCTIONING		
PROBLEM	**POSSIBLE CAUSE**	**SOLUTION**
The LCD display on the front panel does not switch on: the device does not work.	Low battery.	Recharge battery.
	Start button not pressed.	Press start button.
	Charging circuit not working.	Check **FUNCTIONING WITH MAIN CABLE.**
	Failure of the electronic control circuit.	Contact EME srl Service centre.
The monitor on front panel does not light up	Defective parts on electronic control board.	Contact EME srl Service centre.

POLYTER EVO		
PROBLEM	**POSSIBLE CAUSE**	**SOLUTION**
Some commands on the front control panel are not working properly.	Not aligned or not working touch screen.	Contact EME srl Service centre.
	Electronic control circuit does not work.	

ELECTROTHERAPY MODULE		
PROBLEM	**POSSIBLE CAUSE**	**SOLUTION**
The display indicates 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, bad connected or connected on wrong module.	
	Output cables worn and/or with problems in contact.	
	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 clear signs of wear.
	Electrodes in conductive rubber worn that need to be replaced.	Ensure that the electrodes properly adhere to the patient, replace defective and/or worn electrodes.
	Insufficient, faulty, and/or uncertain contact with the patientt.	Contact EME srl Service centre.
	Fault in the electric circuit of the current generator.	
The unit works properly but there is a notable fall in treatment efficiency.	The output circuit of the patient is not properly connected.	Carry out maintenance operations as described.
		Install and place the unit as described.
	Uncertain or defective electrodes in conductive rubber contacts (including the electrode-holder sponge pockets) with the surface to be treated.	Check the integrity of the cables, the connectors and the output circuit of electrodes.
		Check that the electrodes perfectly adhere to the treated area.
		Moisten the electrode-holder sponge pockets.
	Possible current generator circuit fault in the equipment.	Contact EME srl Service centre.

ULTRASOUND 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.
	Handpiece cable damaged or incorrectly inserted or connected to wrong module.	Replace any handpiece handpiece-applicator that shows evident signs of wear in the supply head or cable.
	Output cables worn and/or with problems in contact.	
	Fault in the electric circuit of the current generator.	Contact EME srl Service centre.
The unit works properly but there is a notable fall in treatment efficiency.	Handpiece handpiece-applicator output circuit not connected properly.	Carry out maintenance operations as described.
	Handpiece handpiece-applicator piezoelectric transducer damaged.	Check the condition of the cable and the handpiece handpiece/applicator connector.
	Mechanical damage (following a fall or violent impact) of the handpiece handpiece-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 handpiece following non authorized opening of the radiating head.	Use the acoustic conductor gel.
	Electronic circuit of the ultrasound generator not perfectly calibrated.	Contact EME srl Service centre.
	Possible current generator circuit fault in the equipment.	

MAGNETOTHERAPY MODULE		
PROBLEM	**POSSIBLE CAUSE**	**SOLUTION**
The equipment turns on, but there is no magnetic field emission.	Faulty connections in the output circuit of the cylinders/applicators	Check the correct application of the output and the condition of the connections.
	Connection cables damaged or incorrectly inserted or connected to wrong module.	Replace the faulty cylinder/applicator or those that show evident signs of wear and tear on the covering or on the cable.
	Output cables worn and/or with problems in contact.	
	Fault in the electric circuit of the current generator.	Contact EME srl Service centre.
The unit works properly but there is a notable fall in treatment efficiency.	Connection of applicators not perfectly efficient.	Contact EME srl Service centre.
	Applicators damaged (due to a fall or hit), especially in the connection point.	
	Interruption of the internal conductors of the cylinder.	
	Electronic circuit current generator not properly calibrated or defective.	

LASER MODULE		
PROBLEM	**POSSIBLE CAUSE**	**SOLUTION**
The unit lights up but does not emit energy	Parameters not set correctly	Make sure that operating parameters have been set correctly.
	Laser source does not function or has run out.	Check laser source emissionis operating.
	Faulty components on electronic control circuit	Contact EME srl Service centre.
	Faulty supply on laser circuit	
The unit works properly but there is a notable fall in treatment efficiency.	The front lens of handpiece is dirty.	Carefully clean the front lens of handpiece.
	Faulty or depleted laser source.	Contact 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.

TECAR 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.
	The cable of the handle-applicator has been cut off or connected improperly	Replace any handpiece handpiece-applicator that shows evident signs of wear in the supply head or cable.
	Output cables worn and/or with problems in contact.	
	Fault in the electric circuit of the current generator.	Contact EME srl Service centre.
The unit works properly but there is a notable fall in treatment efficiency.	Connection of the output circuit of the handle-applicator is not perfectly efficient.	Carry out maintenance operations as described. Install and place the unit as described. Check the condition of the cable and the handpiece handpiece/applicator connector.
	Mechanical damage (following a fall or violent impact) of the handpiece handpiece-applicator, especially on the radiating head.	Ensure that the radiating head adheres perfectly to the treatment surface.
	Electronic circuit of the ultrasound generator not perfectly calibrated.	Contact EME srl Service centre.
	Possible current generator circuit fault in the equipment.	
The touch control panel does not work properly.	Energy transmission on the touch panel	Make sure there is no RF energy transmission on the touch panel. See the Attention-Use section.

TECHNICAL FEATURES

POLYTER EVO			
Power	supply:	230 Vac, 50-60Hz, ±10%	115 Vac, 50-60Hz, ±10% *
	Internal battery	Nominal Voltage: 24V	Nominal Capacity: 4500mAh
Double protection fuse on power supply (T):		1,6 A-T	3,15 A-T
Max power absorption:		215 VA	
Display		Color TOUCH SCREEN, 7”	
Emission		N°01 technology / module at a time, except the combined mode ET+US	
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	
Trolley of polyurethane, external dimensions (width. x depth x height.):		61x37x23H cm	
Weight of the device body:		depending on the basis of included modules	
Use conditions	Room temperature	(+10 +40) °C	
	Relative humidity	(10 - 80) % without condensation	
Stocking/transport conditions	Room temperature	(-40 +70) °C	
	Relative humidity	(10 - 100) % without condensation	
	Atmospheric pressure	(500 - 1060) hPa	

*upon request

ELECTROTHERAPY MODULE		
Programmable treatment time		Up to 99 minutes
Emission frequency		25 kinds of wave Low and medium frequency currents
Functioning		Constant Voltage (CV) Constant Current (CC)
Peak current (Load resistance 1KOhm)	Impulsive currents	100 mA
	Diadynamic currents	70 mA
	Continuous currents	50 mA
Peak voltage (Load resistance 1KOhm)	Impulsive currents	100 V
	Diadynamic currents	70 V
	Continuous currents	50V
Output channels		2 independent
Stored protocols:		124
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:		---

ULTRASOUND MODULE		
Programmable treatment time		Up to 30 minutes
Emission		Continuous / Pulsed
Emission frequency		1 MHz and 3 MHz ± 15%
Adjustable Duty Cycle:		(10 ÷ 100) %
Adjustable Frequency Duty Cycle		(10 ÷ 100)Hz
Continuous peak power		2 W / cm^2 ± 20%
Pulsed peak power		3 W / cm^2 ± 20%
Output channels		1
ERA (Effective Radiating Area)	TV1	1.0 cm^2
	TV3	3.0 cm^2
	TV5	5.0 cm^2
	TV8	8.0 cm^2
BNR (Beam Non-Uniformity Ratio)	TV1	Max 5:1
	TV3	Max 5:1
	TV5	Max 5:1
	TV8	Max 5:1
Stored protocols:		69
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:		---

COMBINED MODE: ET - US	
Programmable treatment time	Up to 30 minutes
Electrotherapy Functioning	Constant Voltage (CV)
Work mode Ultrasound	Continuous
Current type	Low frequency
	Medium frequency
Emission frequency	See ELECTROTHERAPY and ULTRASOUND MODULES
Adjustable Duty Cycle:	See ULTRASOUND MODULE
Continuous peak power	See ULTRASOUND MODULE
Pulsed peak power	See ULTRASOUND MODULE
Output channels	1
Stored protocols:	17

MAGNETOTHERAPY MODULE	
Programmable treatment time	Up to 99 minutes
Adjustable Duty Cycle	(10 ÷ 100) %
Programmable treatment frequency	(0 - 200) Hz
Maximum induction	100 Gauss ± 20%
Output channels	1
Stored protocols	87
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	---

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
Laser classification according to EN 60825-1		3B
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: **depending on the handpiece** (See Accessories)		
Target pointing device characteristics	Target pointing device in conformity with the UNI EN 60601-2-22 standard	Light-drive
	Light-drive device	Led-diode
	Light-drive color	Red
	Light-drive representation on the impact point	Spot with red as colour
Typology for emission of the treatment		Automatic emission
		Continuous emission
Output channels		1
Stored protocols		87
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:		---

LASER PROBES SPECIFICATION	
MLA1 (25) – pulsed laser diode	
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^2
EMP (Maximum allowed exposure) pulse train	2,06 mJ/m^2
EMP (Maximum allowed exposure) average	2,57 mJ/m^2
DNRO (Nominal eye-hazard distance) direct light	116.3 mm
MLA1 (100) – pulsed laser diode	
Number of laser diodes	1
Wavelength	905nm
Divergence of the beam	192x436mrad
Duration of the impulse	100 ns
Programmable pulse frequency	100 – 10.000 Hz
Peak power	100W
EMP (Maximum allowed exposure) single pulse	5,14 mJ/m^2
EMP (Maximum allowed exposure) pulse train	2,06 mJ/m^2
EMP (Maximum allowed exposure) average	2,57 mJ/m^2
DNRO (Nominal eye-hazard distance) direct light	251 mm

MLA3 (75) – pulsed laser diode	
Number of laser diodes	3
Wavelength	905nm
Divergence of the beam	192x436mrad
Duration of the impulse	100ns
Programmable pulse frequency	100 – 10.000 Hz
Peak power	75 W
EMP (Maximum allowed exposure) single pulse	5,14 mJ/m^2
EMP (Maximum allowed exposure) pulse train	2,06 mJ/m^2
EMP (Maximum allowed exposure) average	2,57 mJ/m^2
DNRO (Nominal eye-hazard distance) direct light	116.3 mm
MLA3 (300) – pulsed laser diode	
Number of laser diodes	3
Wavelength	905nm
Divergence of the beam	192x436mrad
Duration of the impulse	100 ns
Programmable pulse frequency	100 – 10.000 Hz
Peak power	300 W
EMP (Maximum allowed exposure) single pulse	5,14 mJ/m^2
EMP (Maximum allowed exposure) pulse train	2,06 mJ/m^2
EMP (Maximum allowed exposure) average	2,57 mJ/m^2
DNRO (Nominal eye-hazard distance) direct light	251 mm

MLA5 (125) – pulsed laser diode	
Number of laser diodes	5
Wavelength	905nm
Divergence of the beam	192x436mrad
Duration of the impulse	100ns
Programmable pulse frequency	100 – 10.000 Hz
Peak power	125 W
EMP (Maximum allowed exposure) single pulse	5,14 mJ/m^2
EMP (Maximum allowed exposure) pulse train	2,06 mJ/m^2
EMP (Maximum allowed exposure) average	2,57 mJ/m^2
DNRO (Nominal eye-hazard distance) direct light	116.3 mm
MLA5 (500) – diodo laser pulsato	
Number of laser diodes	5
Wavelength	905nm
Divergence of the beam	192x436mrad
Duration of the impulse	100 ns
Programmable pulse frequency	100 – 10.000 Hz
Peak power	500 W
EMP (Maximum allowed exposure) single pulse	5,14 mJ/m^2
EMP (Maximum allowed exposure) pulse train	2,06 mJ/m^2
EMP (Maximum allowed exposure) average	2,57 mJ/m^2
DNRO (Nominal eye-hazard distance) direct light	251 mm

TECAR MODULE	
Programmable treatment time	1-30 minutes
Peak Power	200 Wpk max
Adjustable power	0 - 100%
Supplied handpieces	Handpieces holding-electrodes resistive electrodes
	Handpieces holding-electrodes capacitive electrodes
Output channels	1 single connector for resistive and capacitive handpiece
	1 connector for the return plate
Emission frequency of the handle	445 kHz
Type of used electrodes	Resistive, made of stainless steel
	Capacitive, made of stainless steel and covered with nylon
Diameter of the capacitive and resistive electrodes	Diameter 30 mm
	Diameter 50 mm
	Diameter 70 mm
Stored protocols	58
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:	---

HIGH POWER LASER MODULE		
Programmable treatment time		Fino a 99 minuti
Interlock socket / security key (normally closed contacts)		Presa DIN a 3 Contatti
Maximum power		4W ± 20%
Emission wavelength Laser Diode		980 nm
Laser classification		4
DNRO (m)		1.445 m
Divergence of the beam		443,3 mrad
MPE		36,3 W/m^2
Laser emission mode		PW e CW
Percentage of emitted power selectable		0% - 100%
Frequency of issue		100 Hz – 10000 Hz
Percentage of emitted power selectable		10% - 100%
Laser source type		Diode laser
		Source installed on the module
Laser probe pointing device		Contact treatment
Treatment implementation command		Via footswitch
Output channels		1
Minimum optical density (protection factors for goggles required for the minimum distance indicated)		2.3 (0.1 m of distance)
Configuration of the laser probe	Made of optical fiber	
	Defocused	
	Non-integral laser probe with module, SMA connector for laser probe connection	
Security checks	Current laser source feedback	
	Laser probe connection to module	
	Interlock presence	
Distance of the laser emission point from the skin	POSITION 1 (on contact)	6 mm

	POSITION 2	13 mm
	POSITION 3	21 mm
	POSITION 4	28 mm
Diametro dello spot incidente sulla pelle del paziente trattato	POSITION 1 (on contact)	10 mm
	POSITION 2	15 mm
	POSITION 3	20 mm
	POSITION 4	25 mm
Area of the incident spot on the treated patient's skin	POSITION 1 (on contact)	0.78 cm^2
	POSITION 2	1.76 cm^2
	POSITION 3	3.14 cm^2
	POSITION 4	4.90 cm^2
Protocols stored		32
Protocols that can be stored on the user memory		--
Protocols that can be stored on USB		--

APPENDICES

Annex A - ENVIRONMENTAL CONSIDERATIONS

The equipment for combined therapy POLYTER EVO, 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 minimize 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 optimize power consumption in keeping with energy saving principles.

This symbol means that the product should not be disposed of as domestic waste, because it may also contain an internal battery.

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

Annex B – LABELS

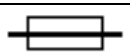
Table 1	
Symbol	**Meaning**
CE 0476	Product certification released from the Notified Body N° 0476
	Applied part BF
	Manufacturer
	Date of manufacture
	Consult instructions for use
	Attention, check the accompanying documents of the product
	The product must be dispose of as “electronic waste”, not as “domestic waste”, because it may also contain an internal battery.
	Input characteristics
	Network power supply
	Fuses: 2xT1.6AL250V / 2xT3.15AL250V
	Absorbed power
	Network emission frequency
REF	Device model
SN	Serial number
	Output characteristics

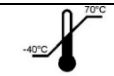
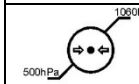
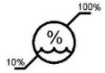
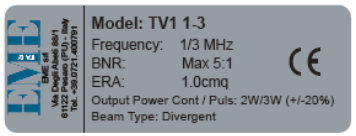
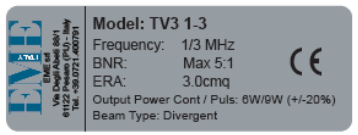
Table 1	
Symbol	**Meaning**
	Output voltage of the device
	Output current of the device
	Output frequency of the device
	Output power supply
	Duty-cycle step
	Temperature range
	Atmospheric pressure range
	Humidity range

Table 2	
Labels	**Meaning**
	Label showing devices sensitivity to electrostatic charges, placed near the USB connector used to program the equipment.

Table 3	
Labels for US module	**Meaning**
 	Labels on the handpiece of ultrasounds module, with properties.

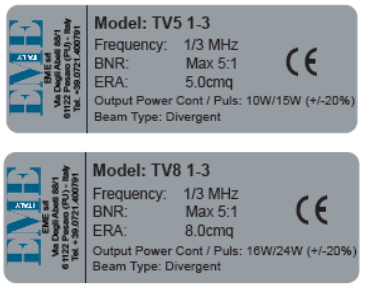
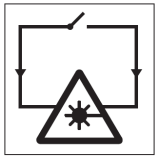
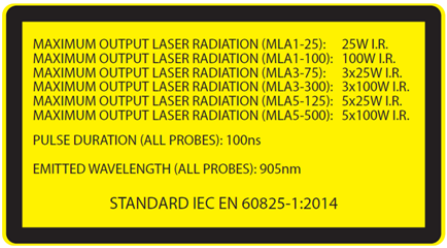
	

Table 4	
Labels for TC module	**Meaning**
	Label indicating the presence of output RadioFrequency singal, placed near the connector for tecar-therapy handpieces.

Table 5	
Labels for LASER LL module	**Meaning**
	“INTERLOCK” label , situated on the front panel of the device near the interlock connector.
	Label indicating "laser emission" placed near the connector of the laser probe.



Label on the rear panel of the display, showing the characteristics of the laser probe:

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

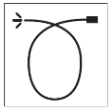
Label on the rear panel of the display, showing the characteristics of the laser probe:

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

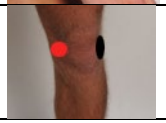
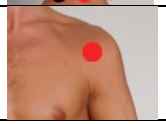
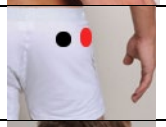
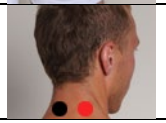
Label indicating "LASER OPENING", placed near the firing part of the laser probe.

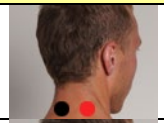
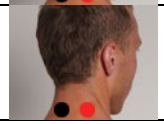
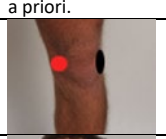
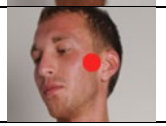
Label indicating mandatory reading of instructions, located on the front panel of the device or near the output connectors.

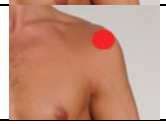
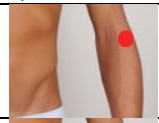
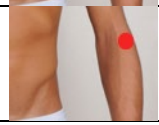
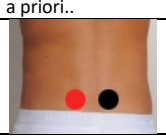
Table 6

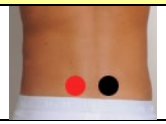
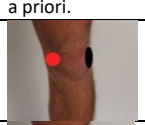
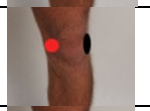
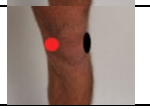
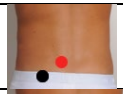
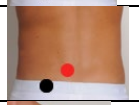
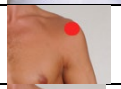
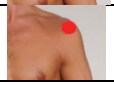
Labels for LASER LL module	Meaning
	"INTERLOCK" label , situated on the interlock connector.
	Label indicating "laser emission" placed near the connector of the laser probe.
	"Laser beam attention" label on the left side panel of the display **Texts on the label** / **Meaning** Warning / Warning Invisible laser radiation / Presence of invisible laser radiation Avoid unnecessary exposure / Avoid a direct exposure to laser beam Class 3B laser product / Class 4 laser product
	Label indicating "LASER OPENING", placed near the firing part of the laser probe.
	Label "Emergency STOP".
	FIBER OPTIC label.
	"FOOTSWITCH" label located on the front panel of the machine near the connector for the pedal.
	Label indicating mandatory reading of instructions, located on the front panel of the device or near the output connectors.

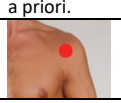
Appendix C – LIST OF ELECTROTHERAPY PROTOCOLS

Reference SW	Electrotherapy threatment	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 Pharadic	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 Random S/A/R	30	50 µs	1	0			10	Variable positioning of the electrodes cannot be defined a priori.	3
PATHOLOGY 06	Cervical arthritis	TENS Random S/A/R	30	50 µs	1	0			10		3
PATHOLOGY 07	Arthrosis of the acromioclavicular joint	TENS Random S/A/R	20	150 µs	1	0			100		12
PATHOLOGY 08	Muscle atrophy **(only on Paraplegics)**	Modulated Pharadic	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 Random S/A/R	30	200 µs	1	0			100		10
PATHOLOGY 11	Myofascial cervical pain 1	Bifasica asimmetrica	20	250 µs		0	100	100			20

Reference SW	Electrotherapy threatment	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 12	Myofascial cervical pain 2	Interpherential	20			0	100	100	4000		20
PATHOLOGY 13	Neck pain	Tens S/A/R	30	150 µs		0	80	80			15
PATHOLOGY 14	Chronic pain	Tens S/A/R	20	200 µs		0	2	2		Variable positioning of the electrodes cannot be defined a priori.	15
PATHOLOGY 15	Pain Phantom limb	Tens Random	30	50 µs	1	0			10	Variable positioning of the electrodes cannot be defined a priori.	3
PATHOLOGY 16	Causal Pain	Tens Random	30	50 µs	1	0			10	Variable positioning of the electrodes cannot be defined a priori.	3
PATHOLOGY 17	Atypical facial pain	Tens Random	30	50 µs					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 µs	1	0			10	Variable positioning of the electrodes cannot be defined a priori.	3
PATHOLOGY 22	Post-surgical pain 2	Modulated Pharadic	30	300 µs	1	0			100	Variable positioning of the electrodes cannot be defined a priori.	
PATHOLOGY 23	Postoperative pain (lower abdomen)	Modulated Pharadic	30	200 µs	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 µs		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 µs	1	0			10	Variable positioning of the electrodes cannot be defined a priori.	3

Reference SW	Electrotherapy threatment	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 26	Shoulder pain	Triangular	15	700 µs		0	150	150			3
PATHOLOGY 27	Hemiplegic shoulder pain	Tens S/A/R	60	100 µs		0	100	100			20
PATHOLOGY 28	Stabilized hip fracture (post surgery pain)	Tens S/A/R	30	200 µs		0	100	100		Variable positioning of the electrodes cannot be defined a priori..	5
PATHOLOGY 29	Epicondylitis	Interpherential	20			0			8000		6
PATHOLOGY 30	Epicondylitis (naproxen)	Interrupt Galvanic									1
PATHOLOGY 31	Fracture secondary to osteoporosis	Tens Random	30	50 µs	1	0			10	Variable positioning of the electrodes cannot be defined a priori.	3
PATHOLOGY 32	Peripheral nerve entrapment	Tens Random	30	50 µs	1	0			10	Variable positioning of the electrodes cannot be defined a priori.	3
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	Interpherential	30			0	140	140	4000		12

Reference SW	Electrotherapy threatment	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 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	Interpherential	15			0	100	100	4000		10
PATHOLOGY 43	Knee osteoarthritis 2-2	Interpherential	5			0	80	80	4000		10
PATHOLOGY 44	Knee osteoarthritis 3	Modulated Pharadic	15	300 µs	10	50			70		20
PATHOLOGY 45	Quadriceps strength recovery after ACL reconstruction (Anterior Cruciate Ligament)	Modulated Pharadic	20	300 µs	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 µs		0	4	4			3
PATHOLOGY 48	Shoulder impingement syndrome 1	Interpherential	19			0	50	120	2500		12
PATHOLOGY 49	Shoulder impingement syndrome 2	Tens S/A/R	20	100 µs		0	100	100			12
PATHOLOGY 50	Painful myofascial syndrome [1]	Tens Random	30	50 µs	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

Reference SW	Electrotherapy threatment	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 52	Patello-femoral pain syndrome	Biphasic S/A	30	500 µs		0	50	50		Variable positioning of the electrodes cannot be defined a priori.	12
PATHOLOGY 53	Ankylosing spondylitis	Tens S/A/R	20	50 µs		0	50	50		Variable positioning of the electrodes cannot be defined a priori.	15
PATHOLOGY 54	Perial stretch of the supraspinatus tendon	TENS Random S/A/R	20	150 µs	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 µs	1	0			100		20
PATHOLOGY 56	Insertional Achilles Tendonitis (Acetic Acid)	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 muscle warming *	Kotz	12		1	0	100	100	2500	Variable positioning of the electrodes cannot be defined a priori.	12-15
TREATMENT 61	Passive muscle toning *	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

***treatments 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 doctor based on patient's clinical condition and characteristics of the device with which the treatment is emitted.

Appendix D – LIST OF ULTRASOUNDS THERAPY PROTOCOLS

Reference SW	List of therapeutic treatments	Time (min)	Effective Int. (W/cm^2)	Pulsed (%)	Frequency (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 PROTOCOLS (ET+US)

Reference SW	Combined treatment US + ET	Treatment time (min)	Frequency HANDPIECE/PROBE (MHz)	POWER (W/cm^2)	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.

*Treatment not covered by medical CE

Appendix F – LIST OF MAGNETOTHERAPY PROTOCOLS

	LIST OF THERAPEUTIC TREATMENTS	INTENSITY(Gauss)	FREQUENZACY (Hz)	DURATION (Min)
01	Cervical osteoarthritis	10	15	30
02	Arthrosis lumbosacral	40	15	40
03	Spinal disc arthrosis	60	50	20
04	Epicondylitis	60	25	30
05	Fractures	20	15	25
06	Should.rotator cuff tendo.(PainfulPhase)	30	75	60
07	Chronic lumbago 1	100	25	30
08	Chronic lumbago 2	20	50	29
09	Osteoarthritis knee	50	100	30
10	Osteoporosis	40	25	60
11	Neuropathy, peripheral (painful)	20	25	60

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 doctor based on patient's clinical condition and characteristics of the device with which the treatment is emitted.

Appendix G – LIST OF LASERTHERAPY PROTOCOLS

	Laser Therapy Treatments	Time (min.)	Frequency (Hz)	Energy density (J/cmq)
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 candropathy	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
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

	Laser Therapy Treatments	Time (min.)	Frequency (Hz)	Energy density (J/cmq)
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^2. The device software automatically updates the parameters based on the selected handpiece while keeping the energy density constant.

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

Appendix I – LIST OF TECAR-THERAPY PROTOCOLS

	TREATMENTS	Capacitive or Resistive	Cap. Power	Res. Power	Cap. duration (min)	Res. duration (min)	Number of sessions
01	ARTHRITIS IN THE HAND	Resistive	/	67-100%	/	20	10
02	COXARTROSIS	Capacitive	0-33%	/	10	/	
03	MUSCULAR CONTUSION OF THE QUADICEPS	Resistive	/	34-66% (Set a maximum power value such that the patient does not feel a temperature increase in the underlying skin layer)	/	10	10
04		Capacitive	34-66% (Set a maximum power value such that the patient does not feel a temperature increase in the underlying skin layer)	/	20	/	
05	MUSCULAR CONTUSION OF THE SURAL TRICEPS	Resistive	/	34-66% (Set a maximum power value such that the patient does not feel a temperature increase in the underlying skin layer)	/	10	10
06		Capacitive	34-66% (Set a maximum power value such that the patient does not feel a temperature increase in the 07underlying skin layer)	/	20	/	
07	MUSCULAR CONTUSION OF THE SIDE BAND TENSOR	Resistive	/	34-66% (Set a maximum power value such that the patient does not feel a temperature increase in the underlying skin layer)	/	10	10
08		Capacitive	34-66% (Set a maximum power value such that the patient does not feel a temperature increase in the underlying skin layer)	/	20	/	
09	CERVICALGIE and CERVICOBRACHIALGIE	Capacitive	34-66%	/	6	/	8
10		Resistive	/	34-66%	/	6	8
11	MUSCULAR CONTRACTURES OF THE QUADRICEPS	Capacitive	4-100% according to patient feedback	/	5	/	
12		Resistive	/	4-100% according to patient feedback	/	10	
13	MUSCULAR CONTRACTURES OF THE POSTERIOR MUSCLES OF THE THIGH	Capacitive	4-100% according to patient feedback	/	5	/	
14		Resistive	/	4-100% according to patient feedback	/	10	
15	MUSCULAR CONTRACTURES OF THE LOWER PARASPINAL MUSCLE	Capacitive	4-100% according to patient feedback	/	5	/	
16		Resistive	/	4-100% according to patient feedback	/	10	

	TREATMENTS	Capacitive or Resistive	Cap. Power	Res. Power	Cap. duration (min)	Res. duration (min)	Number of sessions
17	LUMBAR DYSCOPATHY	Resistive	/	67-100%	/	20	10
18	MUSCLE COOLING DOWN *	Capacitive	0-33%	/	12	/	/
19	MUSCLE WARMING *	Capacitive	0-33%	/	15	/	/
20	PASSIVE MUSCLE TONING *	Capacitive	0-33%	/	12	/	/
21	EPICONDYLITIS	Resistive	/	34-66% (Set a maximum power value such that the patient does not feel a temperature increase in the underlying skin layer)	/	10	10
22		Capacitive	34-66% (Set a maximum power value such that the patient does not feel a temperature increase in the underlying skin layer)	/	20	/	
23	LUMBALGIA AND LUMBOSCIATALGIE	Capacitive	34-66%	/	9		15
24	DEFORMING CERVICAL SPONDYLOSIS	Resistive	/	67-100%	/	20	10
25	DEFORMING LUMBAR SPONDYLOSIS	Resistive	/	67-100%	/	20	10
26	CERVICAL DISTORTION	Resistive	/	67-100%	/	20	10
27	TWIN STRETCHING	Capacitive	34-66%	/	10	/	10
28		Resistive	/	34-66%	/	10	10
29	QUADICEPS STRETCH FEMORAL	Capacitivo	67-100%	/	15	/	10
30		Resistivo	/	34-66%	/	15	10
31	FEMORAL BICEPS STRETCH	Capacitivo	34-66%	/	15	/	10
32		Resistivo	/	34-66%	/	15	10
33	POST SURGICAL TREATMENT OF FEMUR FRACTURES 2nd DAY	Capacitivs	4-100% according to patient feedback	/	20	/	/
34	POST SURGICAL TREATMENT OF FEMUR FRACTURES 3rd DAY	Capacitivs	4-100% according to patient feedback	/	15	/	/
35		Resistive	/	4-100% according to patient feedback	/	5	/
36	POST SURGICAL TREATMENT OF FEMUR FRACTURES 4th - 5th DAY	Capacitivs	4-100% according to patient feedback	/	20	/	/
37		Resistive	/	4-100% according to patient feedback	/	10	/
38	POST SURGICAL TREATMENT OF FEMUR FRACTURES 2nd - 6th week	Capacitive	4-100% according to patient feedback	/	15	/	/
39		Resistive	/	4-100% according to patient feedback	/	15	/
40	POST SURGICAL TREATMENT OF FEMUR FRACTURES 7th - 12th week	Capacitive	4-100% according to patient feedback	/	5	/	/
41		Resistive	/	4-100% according to patient feedback	/	20	/

	TREATMENTS	Capacitive or Resistive	Cap. Power	Res. Power	Cap. duration (min)	Res. duration (min)	Number of sessions
42		Capacitive	4-100% according to patient feedback	/	5	/	/
43	TENDINITIS ACHILLA TENDON	Resistivo	/	34-66%	15	/	10
44	SHOULDER PERIARTHRITIS 1	Resistive	/	34-66%	/	15	10
45	SHOULDER PERIARTHRITIS 2	Capacitive	34-66%	/	10	/	10
46		Resistive	/	67-100%	/	10	
47	MASSAGE PREPARATION *	Capacitive	0-33%		15		
48	KINESITHERAPY PREPARATION *	Capacitive	0-33%		15		
49	KNEE OSTEOARTHRITIS	Capacitivo	0-33%	/	5	/	6
50		Resistive	/	34-66%	/	20	
51		Capacitivo	0-33%	/	5	/	

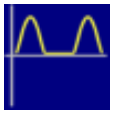
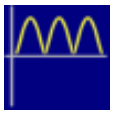
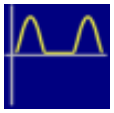
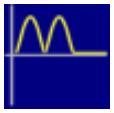
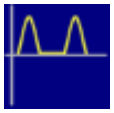
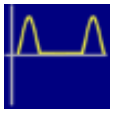
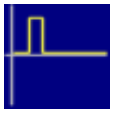
*Treatment not covered by medical CE

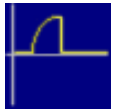
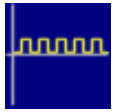
Appendix I – LIST OF HIGH POWER LASER-THERAPY PROTOCOLS

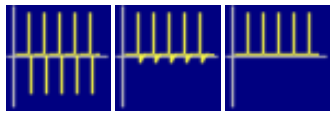
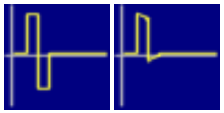
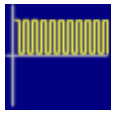
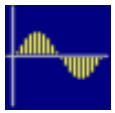
	Therapy name	Frequency (Hz)	Spot time (s)	Density	Spot Area (Position = 4)	Pulsed (%)
01	Middle joint arthritis	6000	5	5,00	4,90	100
02	Arthritis large joints 1	6000	5	5,00	4,90	100
03	Large joint arthritis 2	8500	4	6,00	4,90	100
04	Cervicalgia	5000	4	3,00	4,90	100
05	Hematomas (recent)	4000	6	4,00	4,90	100
06	Hematomas (outcomes)	6000	8	8,00	4,90	100
07	Epicondylitis	6500	7	7,00	4,90	100
08	Epitrocleitis	4500	4	3,00	4,90	100
09	Lumbar disc herniation	7000	3	3,00	4,90	100
10	Gonarthrosis	7500	7	8,00	4,90	100
11	Ankle injuries	6500	5	5,00	4,90	100
12	Low back pain	7500	1	1,00	4,90	100
13	Knee osteoarthritis	5000	4	3,00	4,90	100
14	Painful shoulder	6000	5	5,00	4,90	100
15	Frozen shoulder	6000	5	5,00	4,90	100
16	Heel spur	7000	5	6,00	4,90	100
17	Patellofemoral syndrome and patellar tendonitis	7500	7	8,00	4,90	100
18	Muscular stretch, acute phase	6500	2	2,00	4,90	100
19	Muscular stretch, sub acute phase	5500	2	1,50	4,90	100
20	Achilles tendonitis	6500	1	1,50	4,90	100
21	Small tendon tendinopathies	5500	2	1,50	4,90	100
22	Tendinopathies of the large tendons	5500	2	2,00	4,90	100
23	Rotator cuff tendinopathy	4500	2	1,50	4,90	100
24	Rotator cuff tendinopathy (trigger point)	5000	2	2,00	4,90	100
25	Trigger points	6000	4	4,00	4,90	100

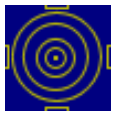
***It is not an adjustable parameter in the SW, it indicates the area considered for the definition of the treatment parameters.**

Appendix L – WAVEFORMS

N°	Name of the current waveform		Output 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		Output 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*		/	/	/	Pulse pause :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		Output 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	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
19	GALVANIC (IONOPHORESIS)*		/	/	1 (1 ÷ 120)	0 (0 ÷ 120)	/	/
			/	/	/	/	/	/
20	INTERRUPTED GALVANIC (IONTOPHORESIS)*		/	/	1 (1 ÷ 120)	0 (0 ÷ 120)	/	8000 (2000 ÷ 8000)
			/	/	/	/	/	/
21	KOTZ RUSSIAN CURRENT		/	/	1 (1 ÷ 120)	0 (0 ÷ 120)	/	/
			/	/	/	/	2500 (1000 ÷ 5000) *4	50 (1 ÷ 250) *4
22	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
23	CLASSIC INTERPHERENTIAL*		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		Output 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	ISOPLANAR INTERPHERENTIAL*		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
25	VECTORIAL INTERPHERENTIAL*		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 RUSSIAN CURRENT 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.

APPNEDIX M - ELECTROMAGNETIC COMPATIBILITY TABLES

Guidance and manufacturer's declaration – electromagnetic emissions		
The ME EQUIPMENT is intended for use in the electromagnetic environment specified below. The customer or the user of the 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 EM EQUIPMENT uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The ME EQUIPMENT is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and MANUFACTURER'S declaration – electromagnetic IMMUNITY			
The ME EQUIPMENT is intended for use in the electromagnetic environment specified below. The customer or the user of the ME EQUIPMENT should assure that it is used in such an environment.			
Immunity test	**Test level IEC 60601**	**Test 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 withsynthetic 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 powersupply lines	± 2kV per powersupply lines	Mains power quality should be that of a typical commercial or hospital environment.
	± 8kV for input / output lines	NOT APPLICABLE	
Surge IEC 61000-4-5	± 1kV line(s) to line(s)	± 1kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment.
	± 2kV line(s) to earth	± 2kV line(s) to earth	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T for 0,5 cycles	0% U_T for 0,5 cycles	The quality of the mains voltage must be that of a typical commercial or hospital premises. If the user of the ME EQUIPMENT requires continued operation during power mains interruptions, it is recommended that the ME EQUIPMENT be powered from an uninterruptible power supply or a battery.
	0% U_T for 1 cycles	0% U_T for 1 cycles	
	70% U_T for 25 cycles	70% U_T for 25 cycles	
	0% U_T for 250 cycles	0% U_T for 250 cycles	
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A / m	Not applicable, the device does not contain components susceptible to magnetic fields	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
NOTE: U_T is the AC mains voltage before the application of the test level			

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

*For these devices, Proximity Field Immunity tests from wireless RF communication devices are not applied.

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

EME ITALY
Aesthetic & Medical Technologies

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

Il Fabbricante / *The manufacturer*

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

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

Apparecchiature per terapia combinata elettrostimolazione ultrasuoni magneto, laser,diatermia /
Equipment for combined electro ultrasound magnetic, laser,diathermy therapy :

POLYTER EVO

è conforme ai requisiti essenziali 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 essential requirements of 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, 03/02/2020

EME srl
L'Amministratore unico / Administrator

Italian manufacturer of physiotherapy equipment since 1983

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