EME® ITALY

SHOCK MED

Designed by ITALDESIGN

CE 1936

100% MADE IN ITALY IT01

INDICE

INFORMATION ON THE MANUAL

This manual is addressed to:

- user of the machine;

- owner;

- responsible;

- people in charge of moving;

- installers;

- users;

- people in charge of maintenance.

This document provides valuable information regarding the installation, set up and use of SHOCK MED equipment.

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

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

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

The limits of this manual are:

- the user manual cannot replace proper experience;

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

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

This manual reflects the state of the art at the time of sale and cannot be considered inadequate if later updated based on new information. The manufacturer has the right to update products and manuals without necessarily updating preceding products or manuals.

The company will not assume any responsibility for any of the following major cases:

- improper use of the machine;

- use against the specific national regulations;

- incorrect installation;

- defects in power;

- serious shortcomings in maintenance;

- changes and unauthorized interventions;

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

- total or partial non-observance of the instructions;

- exceptional events.

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

WRITING CONVENTIONS

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

NOTE

The notes contain important information and useful tips for operating the equipment.

CAUTIONS

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

! WARNING !

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

GARANZIA

EME srl guarantees the quality of its products, when used in accordance with the instructions provided in this manual, following these modalities:

- The device's warranty has duration for **24 months** from the date of purchase.

Wear parts, which are not covered by the 24 month-standard warranty of the device, are:

- APPLICATOR probe
- Transmitter/s
- INTERCHANGEABLE KIT

Note: as far as the INTERCHANGEABLE KIT is concerned, its warranty is valid **6 months** from the date of purchase, unless there are damages due to inappropriate use or improper maintenance.

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:

1) incorrect connection and installation;
2) incorrect use due to non-compliance with instructions contained in this manual;
3) use of the machine in environmental conditions which do not conform with those specified for the product;
4) improper or inadequate maintenance;
5) unauthorized opening of the outer casing;
6) tampering or unauthorized modifications;
7) use of non-original separable components.

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 back the machine for suspected malfunction, we recommend that first you carefully consult the sections regarding MAINTENANCE and TROUBLESHOOTING of the manual, as a large part of the problems and faults are usually due to inadequate maintenance or small technical problems which can often be easily solved by the user himself.

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

When re-packing the equipment for return to the manufacturer, proceed as follows:

1. unplug the machine and any connections, devices, applicators etc;
2. carefully clean and disinfect all parts of the machine and separable components which have been in contact with patients. Any equipment which the technical department does not consider hygienic (Italian law T.U.S. 81/2008 on safety in the workplace) will not be accepted;
3. disassemble separable components and any mechanical supports;
4. use original box and packing materials;
5. enclose detailed information regarding the nature of the problem in order to facilitate the technical department's intervention and save time on repair.

NOTES

PRELIMINARY NOTES

- The installation of the device does not require any special care, is therefore simple and immediate.

USE

- The keys shown on the display are touch in order to navigate the software.
- Shock Med devices recognize automatically the applicator plugged in to the output connector.
- When using the function MODIFY PATIENT FILE, click on ENTER to store new data, by doing so you shall cancel and overwrite any previous data. Old data shall then not be retrievable.
- Parameter values modified during the treatment cannot be stored directly in the patient file; therefore you shall have to create a personalised treatment, following the instructions given in USER PROGRAMS.
- When using the function CREATE FILE it is mandatory that you fill in the fields NAME or SURNAME and TREATMENT PROTOCOL of the disease. Failure enter does not allow saving the patient card.
- Every time you click on the button START o STOP the device shall emit a long beep sound as confirmation.
- After clicking on the button START, when setting off a treatment, the button shall then read STOP and vice versa.

- RESTORE FACTORY SETTINGS means deleting all tabs patients and custom protocols stored in the user; they will no longer be recoverable.
- The files and programs deleted with the function DELETE shall not be retrievable.
- After starting the function SCREEN CALIBRATION you shall have to complete it, there is no possibility to press the button ESC.

MAINTENANCE

- For an optimal use of the device and to guarantee its maximum performance, it is recommended to perform maintenance at the correct time and in the suggested ways.
- The maintenance of the applicator kit, through the use of the brush supplied with the equipment, allows to:
  - Clean the barrel from scroll residues of the bullet;
  - Lubricate the scroll barrel of the bullet to avoid frictions and air leaks

CAUTIONS

PRELIMINARY NOTES

- The customer is liable for all damage caused by inadequate packaging of the material. Keep the original packaging of the unit: it will be needed if the unit is returned to the company.
- Do not use the equipment in places where it might get wet.
- Before operating the machine carefully check the correctness of the connections according to the instructions.
- To avoid the risk of electric shock, this device must only be connected to power supply networks with protective earth.
- Do not use separable components other than the ones provided: they might damage the unit, causing the warranty to become void. In case you have any problems or difficulties with installation, contact EME srl technical support.
  If using the same extension for the unit and other units, make sure that the total current being absorbed by the connected units, does not exceed the max current allowed for that type of cable and that, however, it does not exceed 15 A.
- The therapeutic suggestions are stored in the permanent memory of the machine. These protocols can be edited but it is 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 suggested sessions to evaluate the effectiveness of the treatment, since they are related to the power delivered to the patient undergoing treatment. It is a task of the physician to decide the number of therapy sessions which subject the patient according to the specific requirements of the case, in order to ensure to the patient himself the execution of an effective treatment in time and place in conditions of absolute safety.
- Always control at times the integrity of the cable and of the applicator connector: they must not be damaged or worn.
- It is a class B device in terms of emissions. The machine can be used in a hospital or outpatient environment, as long as it is duly taken into account that the same machine could disturb electronic devices placed in the 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 separable components, 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, only the 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.
- Use a different name for each personalised program. You can avoid inserting the same name by checking in advance the list of the therapies stored.
- Before saving a personalised program check that you actually gave it a name, otherwise the program will not have a reference name.
- We advice the operator to familiarize with the typical marked noises, related to frequency and intensity of emitted pressure, that are connected to the emission of shockwaves.
- 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.

MAINTENANCE

- Use the applicator with care: any misuse may affect their performance and features.
- Under no circumstances technicians not authorized by EME srl are allowed to open and/or disassemble the applicator: such tampering, besides damaging its characteristics, immediately invalidates the right to warranty.
- The equipment should never be disassembled for cleaning or inspection purposes: the units does not have to be cleaned internally, and if for some reason the unit must be opened, it should only be done by specialized technicians authorized by EME srl.
- Do not use thinners, detergents, acid solutions, aggressive solutions or flammable liquids to clean the external parts of the unit and separable components. Using these substances, or misusing the separable components, will cause the immediate voiding of all warranty rights, as well as irreparably damaging the unit and the separable components.
- 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 in the 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 periodic maintenance every two years, in order to check:
  - 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 way. For this kind of intervention you should contact a qualified service technician or alternatively EME srl or one of its authorized service centers.
- For the correct maintenance of the applicator kit, perform **every two weeks** the procedure of cleaning through the supplied brush. Don't **completely** insert the brush into the barrel and never force the insertion

WORKING PROBLEM

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

! WARNING !

PRELIMINARY NOTES

- In order to avoid tipping over, the correct position of transport is such that the device SHOCK MED is moved only along the direction x (both sides), holding it with both hands on the curved profile of the device.
- The perfect functionality of the device is guaranteed in accordance with the rules of installation and of use included, only with original separable components and spare parts.
- If there are problems or installation difficulties, please contact the EME srl technical assistance department.
- Before connecting the cable to the mains plug, check that the equipment wasn't damaged during transport. Ensure that the power supply specifications on the mains socket correspond with the information on the label attached to the back of the unit.
- The electric current that powers the unit is VERY DANGEROUS. Before connecting or disconnecting the power cable from the connecter on the unit, make sure it is plugged out from the mains socket.
- The power cable has an earthed plug for safety reasons.
- Only use with a mains socket suitable for use with earthed systems
- **The equipment should only be connected to electrical systems that fully comply with**
- **regulations**.
- If using extension cords verify the presence and the integrity of the protective conductor to earth.
- Connect the equipment directly to the wall socket without using extensions. Failure to comply with these warnings may result in dangerous electrical discharges that could cause injury operators and compromise the functioning of the unit.
- The manufacturer is held responsible for the fundamental safety, reliability and performance of the device only if:
  - The electrical system of the premises complies with the appropriate regulations;
  - The device is used in accordance with the instructions for use.

USE

- Shock wave therapy treatments must be provided, under the strict control of the operator, to "conscious" patients, able to interact with the operator in the face of the stresses transmitted by the machine.
- If the pain threshold of the patient does not allow the emission of the expected maximum energy density, it is advisable to use the maximum tolerated level. To achieve the maximum expected or tolerated energy in protocol you have to increase the energy density each 100 pulses.
- Before switching on the generator, adjust the nut on the correct value of the main voltage in use in the room where the treatment is carried out to avoid malfunction of the machine.
- DO NOT EVER START THE APPLICATOR BEFORE YOU HAVE CORRECTLY INSERTED THE SUPPLIED HEAD. DAMAGES OF THE SUPPLIED GUN IN THESE CONDITIONS ARE NOT COVERED BY WARRANTY.
- To get a perfect recognition of the applicator connected to the output channel, it is strongly recommended to connect / disconnect them when the emission of treatment is interrupted.
- Once you have started a program, the buttons on the toolbar are disabled; the only allowed operation is stopping the program by pressing the button STOP.
- In order to guarantee that the device works in safety conditions for the client, we advise that the device undergoes periodical check tests (at least every 2 years), as the device contains parts subject to electrical degradation and aging, such as the compressor.
- It is strictly forbidden to use the device in environments with high oxygen levels. If you fail to abide by this rule, EME srl shall not be deemed responsible for any accidents.
- It is absolutely forbidden to cover the ventilation slots: such an action may not allow the machine to work in safe conditions. In case of non-compliance with this indication, EME srl will not be responsible for any accidents.
- It is 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 there were to appear some disturbances during its emission.
- Before starting a treatment clean thoroughly and disinfect all the separable components and the parts of the device that got in contact with the patient, in particular the shockwave transmitters.

MAINTENANCE

- It is forbidden to remove the electrical/pneumatic connector of the applicator without first having downloaded the pneumatic circuit. So TURN OFF your device with the main switch and wait 10 seconds for pneumatic discharge. This procedure is introduced to safeguard the integrity of the O-Ring inserted into the connector.

- For safety reasons before carrying out any maintenance or cleaning of the unit, **YOU MUST** turn off the equipment with the power switch at the back and unplug the socket connected to the mains.
- Before every treatment, it is recommended to clean with caution all of the separable components and the parts of the equipment that have been in contact with the patient.
- The cleaning and disinfection must be done systematically before the therapeutic treatment conducted on the patient.
- We advise the operator to carry out periodical maintenance of probes/applicators, in particular:
  - Check the head of the applicator to make sure there are no cracks, wherefrom conductive liquid may penetrate;
  - Check the integrity of the cable and the connector of the probe/applicator.
- Do not spray or pour liquids on the external case of the device, air slots, the LCD touch-screen display or near it. In you fail to do so, inspect the device. EME srl will not be responsible for any damages on the device, if the abovementioned conditions will not be respected.
- Always control at times the integrity of the cable and of the applicator connector: they must not be damaged or worn.
- It is advised that personnel with technical preparation substitute the fuses, to perform the operation in safety conditions.
- Do not open the device: inside there are high voltages that may be hazardous.
- Only personnel authorized by the manufacturer may access the internal components. For repairs and further information please contact EME srl or its authorized service centers.

WORKING PROBLEM

- DO NOT OPEN the unit, as HIGH VOLTAGE ELECTRICITY is present and may prove VERY DANGEROUS.

INTRODUCTION OF THE TECNOLOGY

Shockwaves

From a physical point of view shockwaves are defined as high-energy acoustic waves. Specifically, they are pressure pulses generating direct mechanical force with the aim to convey energy to body tissues in order to stimulate healing processes.

Shockwave should not be confused with ultrasound wave that is normally used for diagnostic and therapeutic purposes. Unlike ultrasound, shockwave has a pulsed form and provide much higher pressure values, on average 1000 times higher.

The shockwaves used in therapy are specific acoustic waves with characteristics defined at the international level (D.I.G.E.S.T). In order to help the users make reliable assessments for the therapy and the research, the most representative parameters have been chosen and agreed upon by the International Society for Medical Shockwave Therapy (ISMST) and the producers of shockwave devices:

- the pressure (measured in MPa, 1MPa=10 bar that is about 10 atmospheres): SHOCK MED can generate up to 5bar of pressure and SHOCK MED SP up to 4 bar pressure;
- the energy flux density (measured in mJ/mm^2);
- the energy (measured in mJ);
- the dimensions of the focal volume, determined conventionally at 50% of the maximum pressure.

Propagation and diffusion speed of shockwaves

Shockwave propagation speed, as with each acoustic wave, is particularly related to the means that conveys it and to the intensity of the shockwave.

Biological structures like cell walls, whose thickness is comparable to few molecular layers, undergo very high pressure gradients when shockwaves pass.

The mechanical properties of the biological means that are hit by the shockwave, like elastic and compressible properties, influence the transmission of shockwave determining the propagation speed.

When shockwaves pass through a fluid, they generate various pressure differences that produce gas bubbles. The next shockwave hitting these bubble generate a strong implosion that will produce liquid spilling all over the tissue to be treated. As a consequence to these lesions some biological events occur, they differ according to the hit tissue.

In specific, in the bone tissue osteogenic and vascular reactions were observed, while in soft tissues there were anti-inflammatory, antalgic and vascular reactions.

The spreading of the acoustic wave in the tissues follows the laws of physics of acoustic wave that concern transmission, reflexion and absorption. These laws are linked to the characteristics of the means and are influenced inevitably by differing values of density and impedance of the skin, fat, muscles and bones.

Generation systems of shockwaves

There are different types of equipment for shockwave therapy that differ in the technology used to generate the waves. Generally speaking a shockwave generator is composed of:

- a device that creates the pressure shot;

- a water chamber for the concentration of the shockwave energy in the desired focal volume or a dome-shaped gum membrane to close the output gate of the shockwaves.

The membrane functions as a coupling means with the skin of the patient, or a ballistic system composed of a spring-geared metallic applicator (radial shockwaves).

In the medical field shockwave are created by a strong immediate increase of pressure inside the water chamber or the ballistic system.

In specific, in a ballistic or radial system the shockwave is generated in a gun-shaped applicator, where one end is closed by a metallic "lid" against which a steal gun is shot by means of compressed air at 4-5 bars. Following the collision the shockwave is generated and, through the metallic lid, it spreads radially in the skin and the first layer behind the skin.

The action mechanism

The action mechanism in the muscle-skeletal tissues is very complex and it is still subject to an in-depth research. The shockwaves act in different ways according to the different pathologic tissue they treat (bone, soft tissues, skin). Generally speaking, they stimulate the activation of natural biologic repair processes.

The action mechanism of the shockwaves seems to originate in two main effects:

1. direct physic-mechanical effects: the so-called "cavitation effect" and micro-streaming with consequent creation of new blood vessels that increases local afflux of blood and the production of new cells that speeds up the reparation of micro-lesions and improves tissue trophism;

2. indirect biological effects induce:

the reduction of the pain transmission stimulating nerve-ends and freeing substances that regulate its perception; vascularisation that produces bio-molecular modifications.

IN GENERAL

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

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

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

The equipment was planned and built in a manner that their use, if it happens at the conditions indicated, does not compromise the health and safety of the patients, of the users and of third, taking into consideration the benefit to the patient.

Such equipment is 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

SHOCK MED e SHOCK MED SP are an electro-medical device that provide therapeutic treatment that uses shock waves through the aid of a special applicator.

Shock waves are acoustic waves that carry high energy, transmitted through the surface of the skin and spread radially in the body, in the area of pain. The body responds with increased metabolic activity in the area of application, helping to decrease the inflammation caused by analgesic action induced by the local release of endorphins, stimulating and accelerating the healing process.

The use of this equipment SHOCK MED is reserved for operators such as physiatrists, physiotherapists and pain therapists that, by their training, provide assurance of proper use and safety for the patient.

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

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

SHOCK MED are radial shock waves, since the shock wave is generated by means of a special shaped handpiece gun, whose barrel is closed at the end by a metal cap against which a projectile of steel is launched by means of compressed air (5bar pressure).

This generates a shock wave which spreads radially expanding in the skin and underlying first layer of tissue, or in a focused way (depending on the transmitter used). The measure of the penetration depth varies from 4 to 7 cm.

INDICATIONS

The main applications are used in the following fields: Orthopedics, Rehabilitation and Sports Medicine.

The shock wave method is the preferred treatment for chronic insertional tendinopathy, characterized by poor vascularization osteotendinea junction, where the physiotherapy treatment (infiltration and laser therapy) has proven ineffective.

Here are the main diseases on which the shock waves are applied:

Elbow: epicondylitis and epitrocleitis

Epicondylitis and epitrocleitis are two inflammatory diseases due to a degeneration of the tendon insertion of the epicondylar muscles, that is the extensor muscles, and of the epitrochlear muscles, that is, the flexor muscles, of the elbow.

These pathologies arise as a consequence of tendon overload due to a continuous stress of the insertion of the aforementioned muscles.

Lateral epicondylitis, also known as "tennis elbow", is a syndrome that occurs in subjects who repeatedly perform pronation and supination movements of the forearm in a condition of complete elbow extension. It manifests itself as lateral pain in the elbow, during the extension of the wrist and high intensity pain during the movement performed to grasp objects.

Even in the case of epithrocleitis, or "golfer's elbow", tendon degeneration occurs due to incorrect use of the joint of its tendons.

The effectiveness of the shock wave treatment for the indicated pathologies seems to be due to the neovascularization of the tendon-bone junctions; in fact, by improving the flow of blood into the tissues, an increase in cell proliferation is achieved, which leads to the regeneration of tendon and bone tissues.

Shoulder: insertional tendinopathies, impingement

TENDONS are robust fibrous structures, with a pearly complexion, which unite muscles to bones. These important anatomical structures therefore function as real connections, capable of transforming the force generated by muscle contraction into movement.

Like all anatomical structures, tendons can also undergo degenerative phenomena with the passage of time. Furthermore, tendons have long healing times and a marked propensity to evolve into a state of chronic inflammation.

The term tendinopathy generically refers to a painful condition that develops in or around the tendon when subjected to overuse. When this involves the shoulder, we speak of "insertional tendinopathy of the rotator cuff", that is, inflammation of the tendons of some of the muscles responsible for shoulder movement, such as the supraspinatus, infraspinatus and teres minor.

The most common tendinopathies are those affecting the supraspinatus and infraspinatus, less common are those involving the subscapularis.

Impingement syndrome is a disease that can lead to the gradual degeneration of the supraspinatus muscle tendon. In impingement syndrome, during the lifting movement of the arm and in the phase of returning to the initial position, a compression of the tendon of the supraspinatus muscle occurs, which generates pain. The narrowing of the subacromial space due to anatomical causes or biomechanical alterations of the shoulder (e.g. imbalance between the rotator cuff muscles, misuse of the shoulder, chronic tension, repeated microtraumatism, etc.).

Impingement syndrome can lead to gradual degeneration of the tendons and, over time, even rupture.

Knee: patellar or goose leg tendinopathies

The patellar tendon connects the lower part of the patella with the upper part of the tibia and its function is to transmit the contraction of the quadriceps muscle to the tibia to extend the leg.

Patellar tendinopathy is a knee disorder that affects the part of the tendon below the patella. In most cases, the resulting pain is caused by chronic and continuous stress on the patellar tendon leading to small lesions, which can degenerate over time.

Patellar tendinopathy is a very frequent pathology and the subjects most at risk are those who practice sports in which the ischio-perineo-tibial muscles are subjected to continuous stress.

Pube: tendinopatie degli adduttori (pubalgie)

The adductor muscles are large muscles that allow a limb to be brought closer to the median axis of the body.

Adductor tendinopathy, also known as "hip adductor syndrome" or simply "groin", particularly affects the insertion of the adductor longus pubis and the pectineus

muscle. It can be caused by repeated microtrauma or following an episode of muscle distraction that has not been properly treated.

Adductor insertional tendinopathy is typical in people who play sports that require a high frequency of explosive actions and is generally caused by an imprudent or incomplete preparation of the athlete.

In initial cases, the pain appears upon awakening and at the beginning of sporting activity and then disappears once the athlete has warmed up. In the most severe forms, the pain does not subside as a result of muscle heating but tends to worsen to the point of compromising the continuation of activity.

Ankle: Achilles tendinopathies, ~~calcaneal apophysites~~.

The Achilles tendon is the largest tendon in the human body, capable of withstanding a load capacity of up to about 12.5 times the body weight and which connects the calf muscles to the heel.

Achilles tendinopathy involves inflammation of the Achilles tendon and is generally caused by an injury that occurred during running or sports.

~~An apophysitis is an inflammatory pathological state of an apophysis, that is, a bony prominence. Calcaneal apophysitis, or Sever's disease, is an inflammation of the apophysis of the calcaneus, where the Achilles tendon is inserted. It mostly appears following a sudden increase in workloads in children between the ages of 9 and 15. The cause for this pathology seems to be the tension exerted by the Achilles tendon on the calcaneal tuberosity which, not yet fully ossified during adolescence, is pulled away from the calcification core, inflaming the growth plate. A contributing factor may be the repeated stress caused by the impact of the heel on the ground during running and jumping.~~

CONTRA-INDICATIONS

Absolutes

- Pregnancy
- Coagulation disorders
- Presence of neoplasms of growth of nuclei in the field of applications
- Demyelinating polyneuropathy
- Infectious tenosynovitis
- The proximity of the lung parenchyma to the scope of application
- Acute infection of soft tissue/bone
- Epiphysiolysis in the focal point
- Patients with active implantable devices
- Brain, spinal cord, large nerves in the focal point (neurocranium, spinal column, ribs)
- Severe osteoporosis. It should be noted that in case of severe osteoporosis, i.e. when the T-score is greater than 3, of tendon injury, or of necrosis advanced bone, it is not possible to perform a therapy with shock waves.
- Metal implants
- Use of vaso-constrictors medicines
- Age below 18

Relatives

- Tear of the rotator cuff
- Tendinopathies associated with severe glenohumeral arthritis secondary to instability or capsular ligament
- Primary pernicious diseases
- Epiphysiolysis in the focal point
- Diseases of blood coagulation and use of anti-coagulants
- Lung tissue in the focal point

Collateral effects:

- Hematomas and/or petechiae particularly with high-energy pulses (>0,60mJ/mmq) ;
- Edema
- Exacerbation of symptoms over the next 2-3 days which either disappear by themselves or with cryotherapy and analgesic.

PRELIMINARY NOTES

UNPACKING

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

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

The unit and separable components are wrapped in transparent sheets of polyethylene protection and contain the following:

- n. 1 User Manual;
- n. 1 mains power supply cable;
- n. 2 spare fuses (see technical specifications);
- n.1 SWT Shock-Med applicator probe;
- n.2 interchangeable KIT for the applicator(one inside the gun);
- n.1 multi-focused transmitter 9 mm;
- n.1 focused transmitter 15 mm;
- n.1 multi-focused transmitter 15 mm;
- n.1 lubricate brush;
- n.1 conductive gel pack 1000 ml;
- n.1 key tube removing actuator
- n.1 key blade removing actuator
- n.1 ring nut fixing knob

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

SETTING UP

Installation of the shockwave therapy equipment is fast and simple.

After placing the device, block the wheels with brakes in order to avoid undesired movements.

The following environmental conditions are ideal when installing the equipment:

- room temperature: from +10° to +35°C;
- humidity level: from 10% to 80% without condensation;
- avoid direct exposure to sunlight, chemical products and vibrations;
- avoid using RF wireless communication devices in proximity (<0.30m).

SEPARABLE COMPONENTS

The devices can be used with the following separable components:

Description	Supplied	Optional
Power cable supply	**1**	
Spare FUSES (see technical specifications)	**1**	
Lubricate brush	**1**	
User manual	**1**	
SWT applicator	**1**	
Bottle of gel 1000 ml	**1**	
Focused transimitter 15 mm	**1**	
Multi-focused transimitter 9 mm	**1**	
Multi-focused transimitter 15 mm	**1**	
Interchangeable KIT for the applicator	**2** (one inside the gun)	
Key tube removing actuator	**1**	
Key blade removing actuator	**1**	
ring nut fixing knob	**1**	
Suitcase for applicator + shaped foam	**1**	
Applicator complete of transmitter 15 mm		X
Focused transimitter 15 mm		X
Multi-focused transimitter 9 mm		X
Multi-focused transimitter 15 mm		X
Multi-focused transimitter 35 mm		X
Wrench for 35mm focused transmitter		X
Interchangeable KIT for the applicator		X

Description	Supplied	Optional
American power cable supply		X
English power cable supply		X

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

Pneumatic-electric hybrid cable: 1 pneumatic tube and 3 electric cables. The cable length must be less than 3m.

The connection of the shockwave applicator is simple: we need to plug its connector into the socket on the back of the machine.

Contact authorized dealers EME srl for problems or difficulty of installation.

We recommend using the Gel marketed by Fiab, model G009, or an equivalent gel.

CONNECTIONS

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

The power entry module can be found on the back of the unit and consists of a three-pole socket for the cable set, an extractible fuse box with two fuses (see technical specifications) and the main switch.

Plug the three-pin plug of the power supply cable into the integrated board and ensure that it is correctly plugged into the connector.

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

DESCRIPTION OF THE EQUIPMENT

FRONT PANEL

Connection connector for the APPLICATOR handpiece

REAR PANEL

General ON / OFF switch

Fuses box

Tripolar jack for power cable supply

Cart power cord socket (not in use)

USB connector, cart data connection (not in use)

Connector for connecting the USB key

Footswitch connector (not in use)

SEPARABLE COMPONENTS

Lubricate Brush

APPLICATOR

Transmitter

Metal ring for the tightening

TUBE HANDLE including actuator

Actuator of shockwave

Actuator removal key

Knob key for transmitters

TRANSMITTER

Multi-focused transmitter, 15 mm

Focused transmitter, 15 mm

Multifocused transmitter, 9 mm

UTILIZZO DELLA MACCHINA

This chapter will provide important information on the correct use of the SHOCK MED shock wave therapy device.

All the control functions and the entire functional structure of the machine are managed and coordinated by a microcontroller: in addition to the task of making the application programs already stored available, it allows an optimal and safe use of the device in a personalized way.

The dialogue interface with the user is carried out by a large graphic backlit liquid crystal display (LCD) TOUCH SCREEN: all the operating messages of interest to the operator are displayed on it, as well as the functional status of the machine during normal operation. therapeutic activity, any error messages.

The following paragraphs illustrate the operations that must be carried out by the operator to make the most of the potential and technical peculiarities of the SHOCK MED device.

The different options are covered, from the selection of a pre-stored program for setting up a specific therapy, to the determination of the correct working parameters for a "customized" application.

The shock wave acoustic radiation delivered by SHOCK MED has a health purpose, so it cannot be minimized.

Therefore, no means of protection are required in this sense for the patient, who receives treatment for health purposes, nor for the operator, who is in no way affected by the acoustic radiation emitted by the applicator handpiece.

FUNCTIONING

The devices for shockwave therapy SHOCK MED have a control console optimized depending on the specific field of use and type of operation for which they are intended.

All operating parameters are managed and controlled in real time by a sophisticated electronic circuit with microcontroller, with clear representation and signaling of the various functions by means of a backlit LCD touch-screen display (located on the machine) and appropriate acoustic signals.

SHOCK MED gives the possibility to save personalized programs and patient cards in the memory support called USER MEMORY in which both personalized protocols and patient files can be stored.

The standard therapeutic suggestion protocols are saved in an additional fixed internal memory of the machine. This memory is not manageable by the user: the data can neither be deleted nor formatted. To make any changes made available, they must be stored on one of the alternative media, creating a customized protocol.

BEST USE

After installing and positioning the machine according to the instructions provided in the previous chapters, and having applied the cable for connecting the handpiece to the appropriate connector, insert the power plug into the wall socket (230Vac) and activate the device setting the main ON / OFF switch on the rear panel to the “ON” position.

This operation prepares SHOCK MED for operation, causing the lighting of the backlit LCD display which signals the condition of the device ready to operate.

fig. 1

The LCD display will light up highlighting a presentation screen (fig. 1) and then a PASSWORD ENTERING screen:

1. type the access PASSWORD
    - in the event of an incorrect password, an information appears that warns the user to type the password again
2. once the correct password has been entered, the main screen will be accessed where it will be possible to select the desired operating mode from the 4 available.

The password has been set by default to 12345: to enter it, simply press the 5 numeric buttons in sequence and then the OK button. Entering the code prepares SHOCK MED for operation.

This code can be modified by the user (see SETTINGS - DEVICE MAINTENANCE - GENERAL section).

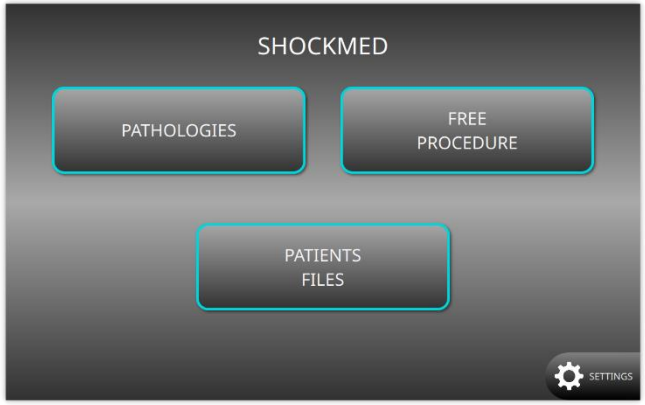


fig. 2

In the initial screen it is possible (Fig. 2):

- access the FREE PROCEDURE section
- access the PATHOLOGIES section
- access the PATIENT CARDS section
- access the SETTINGS section by clicking on the button at the bottom right.

The operation of each key will be described below.

Before starting any treatment it is very important to connect the handpiece to the appropriate connector on the front panel of the machine.

FREE PROCEDURE

By pressing the FREE PROCEDURES button a screen appears (fig. 3) in which you can:

- modify the processing data, proceeding as indicated in MODIFY;
- save any modified parameters proceeding as indicated in SAVE;
- upload a personalized treatment as indicated in LOAD;
- start the treatment, following the START procedure.

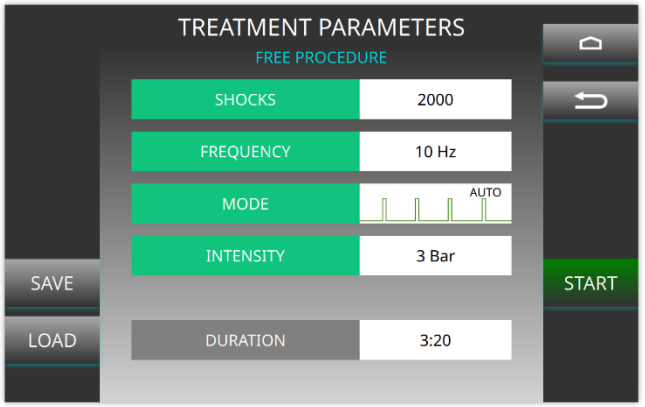


fig3

MODIFY

In this section it is possible to modify the treatment parameter values set by default in the machine in order to create customized programs.

1. Click on the parameter to be modified, the modification screen appears showing the name of the parameter to be modified and it is possible to increase or decrease the value using the + or - buttons or by scrolling the cursor to the right or left until to reach the desired value;

fig 4

2. For the SHOCKS parameter (number), increase or decrease the value using the + or - buttons or by scrolling the cursor to the right or left until the desired value is reached (figure 4). It is possible to vary the URTI parameter between 10 and 10000.
    - Click on **CONFIRM** (green tick) to save the parameter set value and return to the main screen;
    - Click **BACK** (grey x) to cancel the parameter modification operation, you return to the main screen without having made any changes.

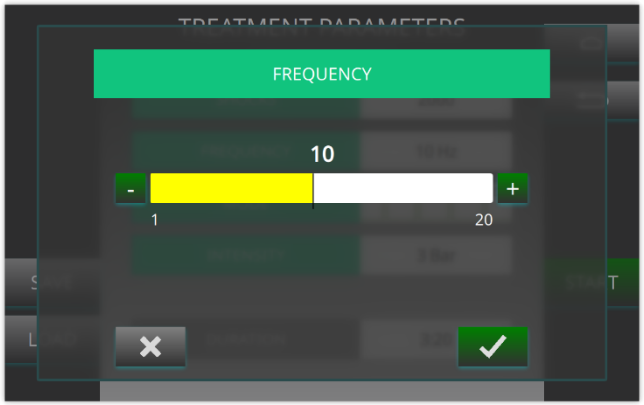


fig.5

3. For the FREQUENCY (Hz) parameter, increase or decrease the value using the + or - buttons or by scrolling the cursor to the right or left until the desired value is reached (figure 5). It is possible to vary the FREQUENCY parameter between 1 and 20 Hz.
    - Click on **CONFIRM** (green check) to save the parameter set value and return to the main screen;
    - Click **BACK** (grey x) to cancel the parameter modification operation, you return to the main screen without having made any changes.
4. For the **MODE** parameter, change the mode using the + or - buttons until you reach the desired one. This parameter represents the delivery mode of the strokes emitted by the applicator handpiece during treatment, the choice is between 5 emission modes: SINGLE, CONTINUE, BURST, CONTINUE AUTO, BURST AUTO.

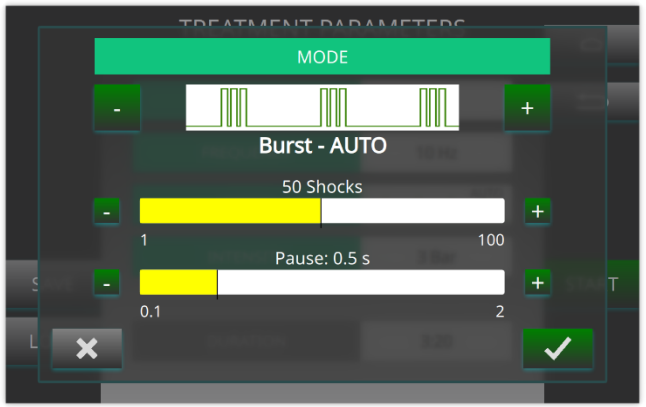


fig 6

- By selecting the BURST AUTO and BURST delivery modes, other modifiable parameters appear on the screen (figure 6): SHOCKS or the number of pulses that make up the burst (or pulse train) and PAUSE (ms) (only in BURST AUTO mode) or the pause between consecutive bursts.
- By selecting the SINGLE delivery mode, the FREQUENCY parameter cannot be changed.
    - Click on **CONFIRM** (green check) to save the parameter set value and return to the main screen;
    - Click **BACK** (grey x) to cancel the parameter modification operation, you return to the main screen without having made any changes.

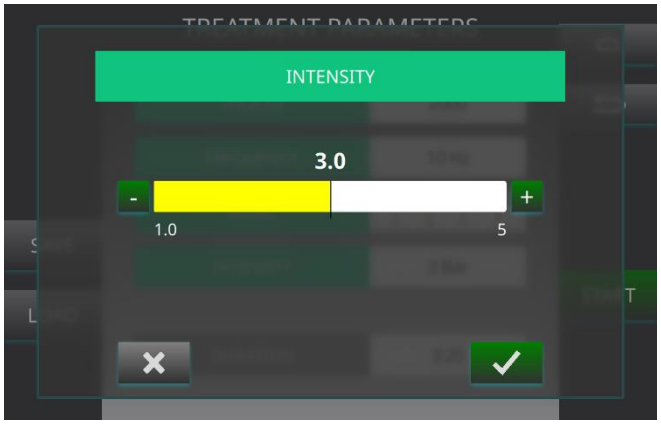


fig 7

5. For the **INTENSITY** (Bar) parameter, increase or decrease the value using the + or - buttons or by scrolling the cursor to the right or left until the desired value is reached (figure 7). It is possible to vary the INTENSITY parameter between 1.0 and 5.0.
    - Click on **CONFIRM** (green check) to save the parameter set value and return to the main screen;
    - Click **BACK** (grey x) to cancel the parameter modification operation, you return to the main screen without having made any changes.
6. For the **DURATION** (minutes) parameter it is a parameter that cannot be changed directly but varies automatically as the number of SHOCKs, the frequency and the MODE set vary.

SAVE

To save any changes made to the parameters and store a personalized therapy program:

1. Click the **SAVE** button;

   NB: It is possible to save the protocols only in the INTERNAL MEMORY of the machine. It is not possible to store personalized treatments on the USB.

2. Type on the virtual keyboard the name to be assigned to the created therapy program;
3. Click on CONFIRM (green tick) to continue with the program saving operation;
    - Otherwise, click on BACK (grey x) to cancel saving the therapy program, the screen with the modified treatment;
4. To start the saved customized program proceed as described in the START section.

When saving a new customized program, the software checks the programs already present in the database.

If the therapeutic program has an existing identification name, the inability to save data with that specific name will be reported unless you choose to overwrite the therapy:

- Click **YES** to proceed with overwriting the therapy;
- Click **NO** to cancel therapy overwriting and enter a new name to be assigned to the created therapy program.

START

By clicking START it will be possible to start the treatment according to the selected delivery mode.

Connect the applicator handpiece in the appropriate connector on the front panel of the machine.

- If you start the treatment without connecting the handpiece, an error message "HANDPIECE ERROR" appears on the screen which prevents the start of treatment.

BURST AUTO delivery METHOD

To start the provision of a treatment:

1. Place the applicator handpiece on the part to be treated;
2. proceed with the emission by initially pressing the trigger on the handpiece (or the footswitch): in this way the emission is enabled autonomously;
3. At the end of the burst, the next train of pulses is automatically emitted after a pause time set directly by the operator;
4. select STOP to end the treatment early,
5. or wait for the timer to reset which indicates that the treatment has been completed and then select the OK button.

CONTINUOUS AUTO delivery METHOD

To start the treatment:

1. place the handpiece on the part to be treated
2. touch the START button
3. proceed with the emission by initially pressing the trigger on the handpiece (or the footswitch): this enables the autonomous emission of a succession of impulses set for the delivery of the treatment.
4. to suspend dispensing, press the applicator trigger (or the footswitch
5. to resume the treatment, press the applicator trigger again (or the footswitch);
6. select STOP to prematurely end the treatment,
7. or wait for the timer to reset which indicates that the treatment has been completed and then select the OK button.

BURST delivery method

To start the treatment:

1. place the handpiece on the part to be treated;
2. touch the START button;
3. proceed with the emission by pressing while continuously pressing the trigger (or the footswitch) on the handpiece: this enables the emission of the first pulse train (burst);
4. At the end of the burst, the next pulse train is automatically emitted after a pause time set directly by the operator;
5. To suspend the delivery between one burst and another, remove the pressure on the applicator trigger (or on the footswitch);
6. to resume the treatment, keep the trigger pressed continuously, as previously seen;
7. select STOP to prematurely end the treatment,
8. or wait for the timer to reset which indicates that the treatment has been completed and then select the OK button.

CONTINUOUS delivery METHOD

To start the treatment:

1. place the handpiece on the part to be treated;
2. touch the START button;
3. proceed with the emission by continuously pressing the trigger on the handpiece (or the footswitch): this enables the rapid succession of the impulses set for the delivery of the treatment;
4. to suspend dispensing, remove pressure on the applicator trigger (or on the footswitch);
5. to resume the treatment, keep the trigger pressed continuously, as previously seen;
6. select STOP to prematurely end the treatment,
7. or wait for the timer to reset which indicates that the treatment has been completed and then select the OK button.

SINGLE delivery method

To start the treatment:

1. place the handpiece on the part to be treated;
2. touch the START button;
3. to proceed with the emission, press the trigger on the handpiece (or the footswitch);: this enables the emission of a single shot;
4. to deliver new shots, repeatedly press the trigger (or the footswitch);
5. select STOP to terminate the treatment early,
6. or wait for the timer to reset which indicates that the treatment has been completed and then select the OK button.

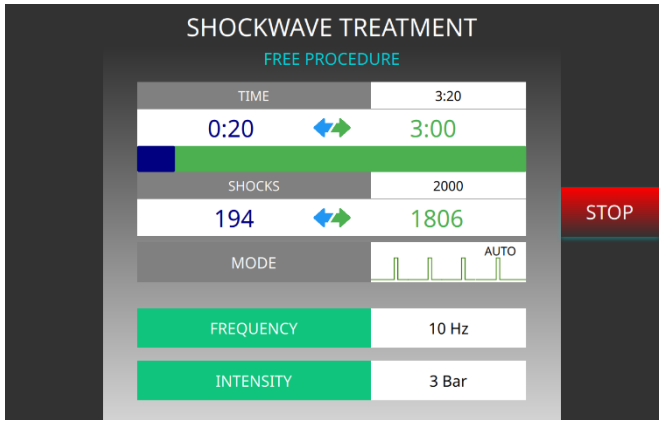


fig.8

In each delivery mode, during the treatment, shocks performed during the delivery of the therapy and the time remaining at the end of the therapy are displayed (Fig. 8). It is calculated on the basis of:

- the number of pulses remaining
- at the pulse frequency
- the way of working.

During the delivery of treatments, it is possible to change the FREQUENCY parameter except in the SINGLE delivery mode and the INTENSITY parameter.

LOAD

In this section it is possible to load a PROGRAM choosing from the customized ones, following the instructions below:

1. Select LOAD from the FREE PROCEDURES screen in figure 3;
2. If necessary, scroll the list of therapies up or down using the appropriate side scroll bar;
3. Select the desired customized program in the list of therapies, the button will appear  (figure 9). Press the key to open the treatment;
    - Otherwise, press the BACK button to return to the main screen.

At this point it is possible:

- modify the processing data, proceeding as indicated in **MODIFY**;
- save any modified parameters proceeding as indicated in **SAVE**;
- start the treatment, following the **START** procedure;
- press the BACK button to go back to the main screen;

If you want to delete a custom treatment:

7. press for a few seconds on the name of the selected treatment, a yellow button will appear with a trash can symbol;
8. Pressing the button depicting the bin leads to the appearance of two other symbols: a prohibition and an X (figure 9).
9. Press the X to cancel or press the prohibition to proceed with the elimination.

- Press the BACK button to go back to the main screen.

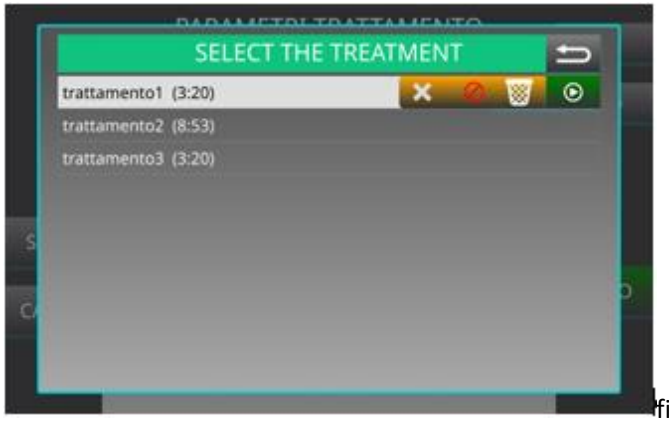


fig9

PATHOLOGIES

Pressing the **PATHOLOGIES** button on the main screen (Figure 2) allows you to access the selection screen of the anatomical treatment area (Figure 10).

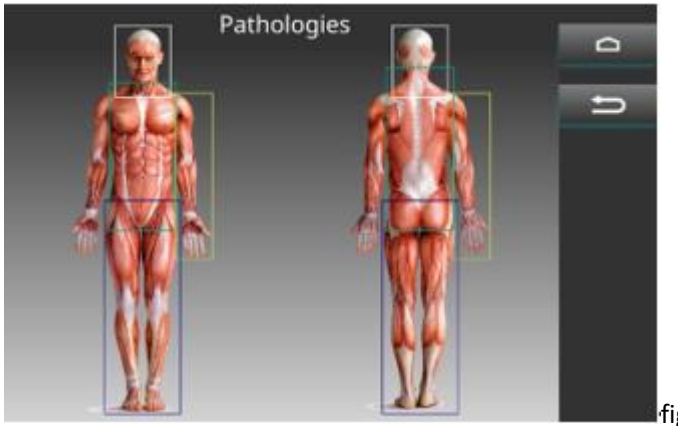


fig 10

It will be sufficient to select one of the eight anatomical areas (delimited by colored boxes) in the human body shown in the display to then proceed with the selection of the anatomical area of interest.

The anatomical areas that can be selected are the following:

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

By selecting an anatomical area, the list of possible pathologies for the selected area is available and the associated therapeutic suggestion protocol can be loaded.

This is a list of pathologies containing the programs preloaded in the machine's internal memory.

To select an anatomical area and load the corresponding list of therapies, follow the instructions below:

1. Select the **PATHOLOGIES** key;
2. In the body image shown on the display, select the anatomical treatment area from those delimited by rectangles;

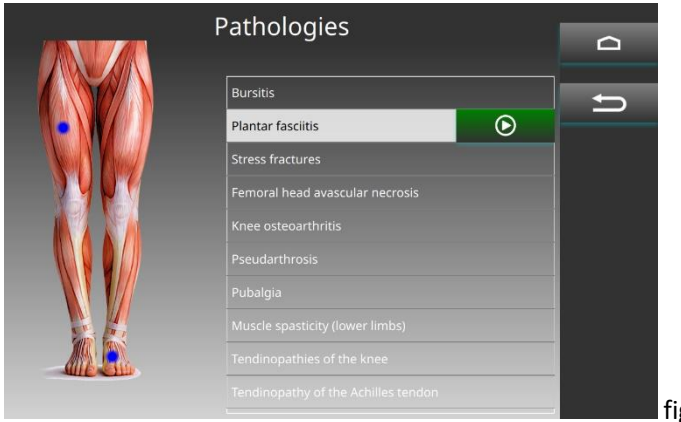


fig.11

3. A screen appears containing the zoom of the selected treatment area in which the possible anatomical areas and the list of treatments associated with that area are highlighted with blue dots (Figure 11);
4. Select the anatomical area by clicking directly on the blue dot;
5. A list of therapy protocols available for that specific area appears;
6. Select the desired treatment and to open it press the key  (figure 10).

<u>For any treatment it is possible:</u>

- START the treatment proceeding as indicated in the START section.

PATIENT FILES

Pressing the PATIENT FILES button in the main screen (Figure 2) allows you to access a screen containing a possible list of patient records.

When the device is first switched on, there is no patient card list, so go to the creation of new patient cards following the procedure described in “CREATING A CARD” (green “+” key).

fig. 12

Once the patient card of interest has been identified (figure 12), select it and then open it by pressing the OPEN key . At this point it is possible:

- START the patient card previously saved in the memory by pressing the key ;
- MODIFY patient data by pressing the EDIT KEY ;
- DELETE PATIENT DATA by pressing the DELETE key ;
- Access the list of treatments performed for that patient .

CREATE a CARD

1. Select the **PATIENT FILES** button from the main menu (figure 3), the screen in figure 12 appears;
2. Select the **NEW CARD** button (green "+" key);
3. In the screen that appears, fill in the following fields:
   - SURNAME (mandatory entry)
   - NAME (mandatory entry)
   - DATE OF BIRTH
   - ADDRESS
   - PHONE
   - E-MAIL
   - ANAMNESIS
   - NOTES
4. Click on the item to insert;
5. Use the relative commands to enter the data:
   - By selecting the SURNAME, NAME, ADDRESS, TELEPHONE,, ANAMNESI, NOTES fields, type on a virtual keyboard to enter the required information;
6. Click on SAVE (green tick) to save the new patient card;
   - Otherwise click **CANCEL** (red x) to cancel the saving of the new patient card.
7. The screen will appear in which the patient card with its treatment data will be displayed;
8. Click **BACK** to go back to the screen containing the list of patient files created.

At this point it is possible:

- Modify the patient card and the corresponding data by continuing as described in the MODIFYING a CARD section;
- Open a patient card by pressing the OPEN key;
- Delete the patient record displayed by selecting the **DELETE** button;

OPEN a CARD

1. Select the PATIENT FILES button from the main menu (figure 3), the screen in figure 12 appears;
2. Touch the patient card you want to open and the button to open the patient card will appear ;
3. Select **OPEN** to open the patient record:

At this point it is possible:

- Start a FREE PROCEDURE treatment;
- Start a PATHOLOGY treatment;

When performing a treatment for a patient, an icon is visible in the lower left corner indicating the name and surname of the patient for whom the treatment is being performed. Once a patient file has been opened, to close it it is necessary to hold down the icon at the bottom left for a few moments and click on the prohibition symbol that appears.

- Upload the list of recently performed treatments and start the treatment;
- Delete the selected patient card by clicking the **DELETE CARD** button, a window will appear where you will be asked to select:
  - **Prohibition symbol** to confirm the permanent deletion of the patient card;
  - **X** to cancel the deletion of the patient card.

MODIFY a CARD

1. Select the **PATIENT CARDS** button from the main menu (figure 3), the screen in figure 12 appears;
2. Touch the patient card you want to open;
3. Select **OPEN** to open the patient record;
4. Select **EDIT**
   - changes may be made to the following data:
     - SURNAME (mandatory entry)
     - NAME (mandatory entry)
     - DATE OF BIRTH
     - ADDRESS
     - PHONE
     - E-MAIL
     - ANAMNESIS
     - NOTES
5. Click on the item to be changed;
6. Use the relative commands to make the changes:
7. click **SAVE** (green tick) to save the modified data by overwriting the old ones;
8. After a few seconds, the modified patient card screen will appear with its treatment data.

SETTINGS

By pressing the SETTINGS key, the screen in figure 13 appears.

figura 13.

The screen shows the software and firmware version

From this screen you can:

- Access the device SETTINGS
- Access the HISTORY of treatments
- Access the section dedicated to the MAINTENANCE of the device

SETTINGS

Allows you to modify and save the general basic settings in the internal memory which will be automatically recalled each time the machine is turned on.

By pressing the **SETTINGS** button  , a screen appears in which you can select:

- **LANGUAGE**

  By pressing the LANGUAGE button you can select the language settings of the machine.

  To select the desired language:

  1. Click directly on the flag representing the language of interest and press CONFIRM;

  The selected language will be automatically enabled: all machine messages and commands will be displayed in the chosen language.

- **DATE / TIME**

  By selecting the DATE / TIME button you can adjust the date and time of the machine:

  1. Press the "+" or "-" buttons to set the day, month, year, hours and minutes. Then press SET DATE / TIME to confirm.

- **SOUND**

  By selecting the SOUND button you can change the volume of the machine sounds (screen touch sound, system sounds, treatment sounds).

HISTORICAL

The historical section shows a list of all the treatments carried out with the machine, identifying the date and time.

DEVICE MAINTENANCE

In this section it is possible to modify some settings of the machine by pressing on GENERAL or to access information on the maintenance of the SHOCK MED using the MAINTENANCE key SHOCK MED.

Pressing the GENERAL key is possible:

- Enable and disable the password using the appropriate switch;
- Change the access password:

  To change the access code proceed as follows:

  1. Click on the **CHANGE PASSWORD** button;
  2. Enter the current password using the numeric keypad on the screen and click confirm (green tick);
  3. Type the new access password and click confirm (green tick);
  4. To confirm the new password, enter it for the second time and click confirm (green tick).

The insertion of the new password will be confirmed on the screen with the message "PASSWORD CHANGED".

By pressing the SHOCK MED MAINTENANCE button it is possible to view the total shots delivered by the handpiece and the device.

In addition, each time the Interchangeable Gun Kit is changed, the following must be done:

1. Select the HANDPIECE MAINTENANCE key and enter:
   - ENTER THE KIT SERIAL NUMBER
   - ENTER THE MAINTENANCE KIT CODE

NB: Both information are supplied with the Interchangeable Kit and are specific to each Kit:

2. Press confirm (green tick) to proceed or cancel (orange button) to cancel.
3. After confirming the HANDPIECE COUNTER is automatically reset.

EXECUTION OF THE TREATMENT

The surface of the area to be treated should be sprinkled with a rather abundant layer of "GEL" contact substance (interface that favors the acoustic conduction of ultrasound energy).

The distribution of radiant energy must take place by means of a massage, that is by moving the radiating head on the treated area, in order to respect the principle of "equal distribution of the energy dose".

Loading a treatment is performed as described in the FREE PROCEDURE sections. When the window relating to the chosen work program appears on the display, press the START button to activate delivery.

The stored programs proposed are the result of the operational experience gained over years of support from professionally experienced users and will be useful as a

guiding suggestion for starting treatment. The ability to modify the parameters according to the operator's needs guarantees versatility of use which is essential in medical contexts.

IMPORTANT

- **NEVER PUT THE HANDPIECE INTO OPERATION BEFORE HAVING PROPERLY INSERTED THE DISPENSING HEAD.**
- **IT IS STRICTLY FORBIDDEN TO REMOVE THE ELECTRIC / PNEUMATIC CONNECTOR OF THE APPLICATOR WITHOUT FIRST DOWNLOADING THE PNEUMATIC CIRCUIT. Then TURN OFF the device with the main switch and wait 10 seconds for pneumatic unloading. This procedure is introduced to safeguard the integrity of the O-Ring inserted in the connector.**

DAMAGE TO THE MACHINE UNDER THESE CONDITIONS IS NOT COVERED BY THE WARRANTY.

MAINTENANCE

The SHOCK MED shock wave therapy machines do not require special maintenance operations, other than periodic maintenance and cleaning of the applicator kit and applicator handpieces, in order to ensure the best operating conditions, to guarantee the effectiveness of the treatment and patient safety.

No special intervention is required in case of failure of the medical device, but only a normal maintenance / repair intervention.

The external cleaning of the appliance must be done exclusively with a soft cloth moistened with hot water, or using non-flammable cleaning liquids.

It is possible to clean the front control panel in the same way.

Do not place objects that produce heat or contain water or other liquids on the machine.

Do not place the machine near machines that produce high intensity electric, magnetic or electro-magnetic fields.

The replacement of the interchangeable kit is recommended starting from 900,000 shots, in order not to incur a loss of treatment effectiveness. In fact, once the delivery of 900,000 shots has been reached, the message "please order a new kit" is displayed at each ignition.

Upon reaching 1,000,000, the message changes and warns that the Kit must be replaced.

The handpieces / applicators, in particular the treatment head, must be periodically cleaned with water and denatured alcohol.

Store the handpieces / applicators carefully at the end of each treatment.

The maintenance of the applicator kit, through the use of the supplied brush, allows you to:

- Clean the barrel from the sliding residues of the bullet;
- Lubricate the sliding barrel of the projectile to avoid friction and air leaks.

The maintenance of the applicator kit must be carried out every two weeks, using the brush supplied with the device.

It is foreseen the insertion of the brush up to the middle of the barrel for a minimum of 4/5 times until there is an ease of insertion of the brush inside it. Then gradually increase the depth of insertion of the brush until it reaches the bottom of the barrel, and repeat the operation for a minimum of 4/5 more times.

Contact the authorized EME srl centers for information on original separable components and spare parts.

Do not immerse the machine in water.

After any external cleaning of the box, dry all parts perfectly before putting the appliance back into operation.

For no reason should the appliance be disassembled for cleaning or checking purposes.

There is no need to clean the SHOCK MED machines internally, and in any case this operation must be done exclusively by specialized and authorized EME srl technical personnel.

The useful life of the device is 10 years.

To ensure the safety and correct operation of the equipment, the following maintenance program must be observed.

PART	OPERATION	FREQUENCY	RESPONSIBLE
Applicator kit	Procedure of cleaning and manintenance with brush	Every two weeks	User
Gun	Verification of the gun cable integrity	Every month or every time the gun is disconnected	User
Gun	Verification of the gun connector integrity	Every month or every time the gun is disconnected	User
Transmitters	O-ring check	Every time the transmitter is removed	User
Transmitters	O-ring removal	Every 2 years	User
Power cable and socket	Verification of the power cable and socket integrity	Every week or every time the device is switched on in case of displacement of the device	User
Device	Instrumental verification of the electrical safety	Every 2 years	Producer or Assistance Center
Interchangeable kit	Replacement of the interchangeable kit	Every 1,000,000 shots.	User

Cleaning modality

The device must be periodically cleaned. Unplug the power cable.

PART	OPERATION	FREQUENCY	RESPONSABLE
Case	Cleaning and hygienization	Every day	User
Gun	Cleaning and hygienization of the device and the emitting head	At the end of every treatment	User

WORKING PROBLEMS

The equipment for shockwave therapy SHOCK MED has been planned with technological solutions and high quality components, for a very efficient and reliable use.

If any problems should arise in the operation, please consult the following guidelines before you contact an authorized service centre.

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

- the power cable or rear power entry module are worn or damaged;
- liquid has spilt inside the equipment;
- the equipment has been exposed to rain.

ELECTRO-MAGNETIC INTERFERENCES

The shock wave therapy SHOCK MED equipment has been designed and built in compliance with current DIRECTIVES on ELECTROMAGNETIC COMPATIBILITY 2014/30/UE with the aim of providing reasonable protection from damaging interference in residential and health related installations.

The CE mark means that it complies with that directive.

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. Customers may view the EMC measurement reports, upon request at the company.

Due to its operating principle, the shock wave therapy SHOCK MED equipment generates an acceptable quantity of radiofrequency energy, and it has a sufficient immunity level to radiating electromagnetic fields: therefore they do not detrimentally interfere with radio-electric communications, electro-medical equipment for monitoring, diagnosis, therapy and surgery, office electronic devices such as computers, printers, photocopiers, fax machines, etc. or any electric or electronic equipment used in these environments, as long as said equipment complies with the ELECTROMAGNETIC COMPATIBILITY directive.

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

TROUBLESHOOTING CHART

PROBLEM	POSSIBLE CAUSE	SOLUTION
Front panel LCD display or indicators do not come on: the unit does not work.	Mains plug not plugged in properly.	Check that the mains socket is working.
	Mains cable not properly connected to the equipment.	Plug in properly and connect cable to the equipment.
	Mains cable worn or blocked.	Replace mains cable.
	Power switch off.	Switch on the mains switch.
	Fuse or fuses defective or blown.	Substitute the missing, defective or blown fuses.
	Electronic control circuit malfunction.	Contact a EME srl assistance centre.
	Defective components on the control board.	Contact a EME srl assistance centre.
Some controls of the front control panel do not work properly.	Damaged keys or buttons.	Contact a EME srl assistance centre.
	Damaged electronic control circuit.	
The device does not emit shockwaves.	Defective connections on the output circuit applied to the patient.	Carefully check the correctness and integrity of the output connections
	Applicator cable interrupted or wrongly connected.	Replace the defective applicator which presents clear wear signs on the emitting head and on the cable.
	Output cables damaged and/or with uncertain contact.	
	Fault on the electronic circuit of the current generator.	Contact a EME srl assistance centre.
The device works properly, but a fall in treatment effectiveness is observed	Connection of the output circuit of the applicator not perfectly efficient.	Carry out the maintenance operations provided. Install and place the device as suggested. Check the integrity of the cable and of the connector of the applicator.
	The actuator of the applicator damaged or worn.	Replace the actuator by following the appropriate procedure.
	Mechanical damages (following crashes or big shocks) occurring to the applicator, in particular to the dispensing head (or transmitter).	Check the perfect cohesiveness of the dispensing head (or transmitter) and the surface undergoing the treatment.
	Possible fault of the current generating circuit of the device.	Contact a EME srl assistance centre.

TECHNICAL FEATURES

Mains power supply of the device:		230 Vac, 50-60 Hz, ±10%
		115 Vac, 50-60 Hz*,±10%
Maximum mains power absorption of the device:		190 VA
Double protection fuse on the delayed type network (T):	**230 Vac**	2 A-T - 5 x 20 mm
	115 Vac	5 A-T - 5 x 20 mm
Backlit LCD display, to view and check the operating parameters		Touch screen a colori 10.1”
Shock emission modes		AUTO BURST
		AUTO CONTINUOUS
		BURST
		CONTINUOUS
		SINGLE
Burst emission typology		(1-100) burst pulses
		(10 – 2000) msec pause between pulses burst
Intensity of pressure that can be delivered	**SHOCK MED**	MAX 23 MPa
	SHOCK MED SP	MAX 19 MPa
Shock emission pressure	**SHOCK MED**	(1.0 - 5) bar, step of 0.1 bar
	SHOCK MED SP	(1.0 - 4) bar a step di 0.1 bar
Shock emission frequency	**SHOCK MED**	(1 – 20) Hz, step of 1 Hz
	SHOCK MED SP	(1 – 15) Hz a step di 1 Hz
Number of tested shocks		2.000.000
Classification according to the directive 93/42/CEE		II B
Insulation class / parts applied according to EN 60601-1		I / BF
Protection degree from liquids according to EN 60601-1		IPX0

Output channels		1
Storable protocols on the user memory:		200
Patient cards can be stored in the user memory		Depending on the number of characters used
External dimensions (width x depth x height.):		41x35x19 cm
Weight		10.1 Kg
Terms of use	Room temperature	(+10 : +35) °C
	Relative humidity	(10 : 80) % without condensation
Conditions of storage/transport	Room temperature	(-40 : +70) °C
	Relative humidity	(10 : 100) % without condensation
	Atmospheric pressure	(500 : 1060) hPa

* The nominal voltage at 115Vac does not cover European countries.

APPENDICES

Appendix A - ENVIRONMENTAL CONSIDERATIONS

SHOCK MED equipment for shock wave therapy has been designed and manufactured to have minimal negative environmental impact, in line with its operational and safety requirements.

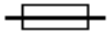
Rigorous standards were followed in order to minimise the amount of waste, use of toxic materials, noise, non-required radiation and energy consumption.

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

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

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

Appendice B – ETICHETTE

Symbol	Meaning
CE 1936	Product certification issued by the notified body N° 1936
	Applied part BF
	Manufacturer
	Date of manufacture
	Consult instructions for use
	Attention
	The product must be disposed of as “electronic waste”, not as “domestic waste”
V	Input voltage to the device (mains)
	Fuses: 2xT2AL250V/2xT5AL250V DIM:5x20mm
P	Input power of the device (absorbed power)
F	Input frequency of the device
REF	Commercial model of the machine

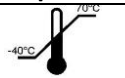
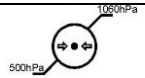
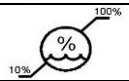
Symbol	Meaning
SN	Serial number
Pressione	Output pressure of the device
Frequenza	Output frequency of the device
	Temperature range
	Atmospheric pressure range
	Humidity range

Table 1

Label	Meaning
	Label showing devices sensitivity to electrostatic charges, placed near the USB connector used to program the equipment
FOOTSWITCH	“FOOTSWITCH” label, located on the rear panel of the machine near the footswitch connector.
	Label indicating the mandatory reading of instructions, located on the front panel of the device or near the output connectors

Table 2

Appendice C – LIST OF THERAPEUTIC SUGGESTIONS

N°	Shock wave therapy treatments	Pressure (bar)	Frequency (Hz)	Pulses (N°)	Transmitter
1	Bursitis	4	10	2000	15 mm
2	Epicondylitis and epitrocleitis	3	10	2000	9 mm
3	Plantar fasciitis	4	10	2000	15 mm
4	Stress fractures	3	15	4000	15 mm
5	Avascular necrosis of the femur	3	12	2000	15 mm
6	Pseudarthrosis	4	15	3000	15 mm multi focused
7	Pubalgia	3	15	1500	15 mm multi focused
8	Tendinitis and tendinopathies	3	10	2000	15 mm

Note: In veterinary treatments are provided as in the human context, the use is primarily targeted to diseases of the musculo-skeletal.

Appendice D – ELECTRO-MAGNETIC COMPATIBILITY TABLES

Guidance and manufacturer's declaration – electromagnetic emissions FOR ALL EM EQUIPMENT		
The EM EQUIPMENT is intended for use in the electromagnetic environment specified below. The customer or the user of the EM EQUIPMENT should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF Emissions CISPR 11	Group 1	Equipment in which radiofrequency energy in the 9 kHz to 400 GHz frequency range is NOT intentionally generated and used or used only, in the form of electromagnetic radiation, inductive and / or capacitive coupling, for material handling or inspection
RF Emissions CISPR 11	Class B	The EM device is suitable for use in all environments, including domestic ones and those connected directly to a low voltage public mains power supply that powers buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	Balanced three-phase equipment; household appliances, excluding equipment identified as class D; instruments, except portable instruments; dimmer for incandescent lamps; audio equipment
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

13.4.1 Guidance and manufacturer's declaration – electromagnetic immunity FOR ALL EM EQUIPMENT			
The EM EQUIPMENT is intended for use in the electromagnetic environment specified below. The customer or the user of the EM EQUIPMENT should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment –guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8kV contact	± 8kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
	± 2; 4; 8; 15 kV air	± 2; 4; 8; 15 kV air	
Electrical fast transient/burst IEC 61000-4-4	± 2kV per power supply lines	± 2kV per power supply lines	Mains power quality should be that of a typical commercial or hospital environment
	± 1kV for input / output lines	± 1kV for input / output lines	
Surge IEC 61000-4-5	± 1kV line(s) to line(s)	± 1kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment
	± 2kV line(s) to earth	± 2kV line(s) to earth	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T for 0,5 cycles	0% U_T for 0,5 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EM EQUIPMENT requires continued operation during power mains interruptions, it is recommended that the EM 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 have characteristic levels of a typical location in a typical commercial or hospital environment
NOTE : UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity				
The EM device is designed to work in the electromagnetic environment specified below. The customer or the user of the EM device should ensure that it is used in such an 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	Livello di prova della IEC 60601		Compliance level	**Recommended separation distance d:**
RF Conduct IEC 61000-4-6	3 Veff da 150kHz a 80 MHz		3 Veff	**d**= 30 cm
RF Radiate IEC 61000-4-3	3 V/m da 80 MHz a 2,7 GHz		3 V/m	**d**= 30 cm
Proximity field immunity 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	

Model SHOCK MED:
Version SW : 1.0.1
Version FW : 1.0

Model SHOCK MED SP:
Version SW : 1.0.1dep
Version FW : 1.0

SHOCK-WAVE ACTUATOR REPLACEMENNT PROCEDURE

Tools: 1 replacement kit, 1 knob key and 1 actuator removal key.

WARNING: It is necessary to turn off the machine with the general switch ON / OFF located on the rear side before proceeding with the replacement of the kit.

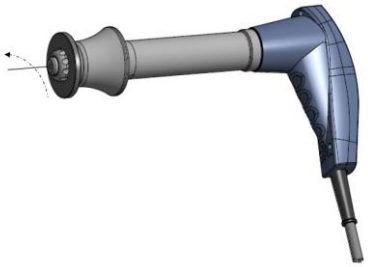
!ATTENTION!: EME SRL warranty does not cover any damage due to negligence in the replacement of the kit.

IMPORTANT: NEVER START UNTIL YOU HAVE PROPERLY INSERTED THE DISPENSING HEAD.

Replacement procedure

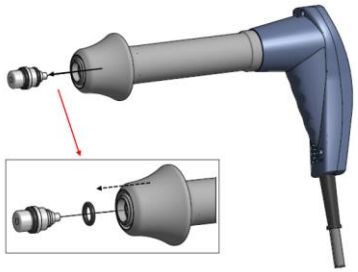
1. Insert the knob-key in the metal ring

2. Turn the key to loosen the tightening of the ring

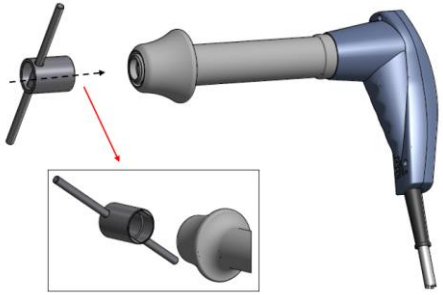


3. Remove the ring

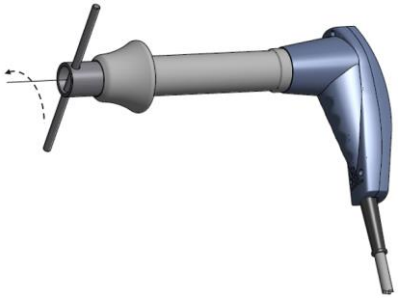
4. Pull out the dispenser head (even the O-ring in case that does not remain on the head)



5. Insert the removal key to unscrew the tube



6. Turn the key to unscrew the tube

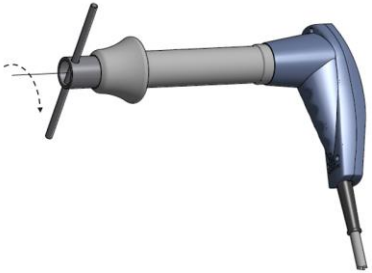


7. Remove the tube

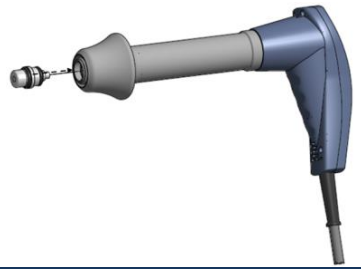
8. Pull out the shock-wave actuator

9. Replace the actuator following the direction shown in picture

10. Screw the tube in the applicator



11. Insert the dispensing head (including of O-ring seal)



12. Tighten the lock ring

13. The gun is again ready for the emission.

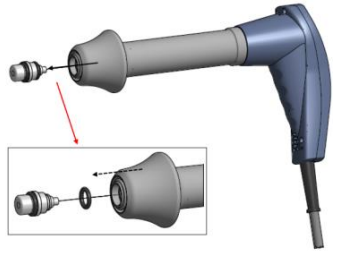
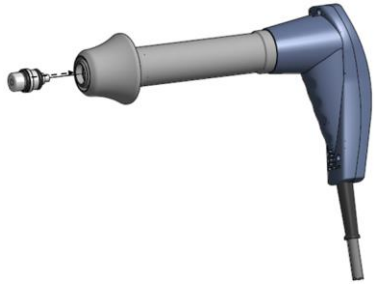
PROCEDURE OF TRANSMITTERS REPLACEMENT

Tools: 1 replacement kit, 1 knob key.

WARNING: Before proceeding with the replacement of the transmitter is necessary to turn off the machine with the main switch ON / OFF located on the back.

!ATTENTION!: EME SRL warranty does not cover any damage due to negligence in the replacement of the kit.

IMPORTANT: NEVER START UNTIL YOU HAVE PROPERLY INSERTED THE DISPENSING HEAD.

Procedure of replacement of physiotherapy transmitters	
1. Insert the knob-key in the metal ring 	2. Turn the key to loosen the tightening of the ring 
3. Remove the ring 	4. Pull out the dispenser head (even the O-ring in case that does not remain on the head) 
5. . Insert the dispensing head (including of O-ring seal) 	6. Tighten the lock ring 

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 ad onde d'urto /
Equipment for shock-wave therapy:

SHOCK MED

è conforme ai requisiti essenziali della direttiva comunitaria 93/42/CEE e successive integrazioni e modifiche (Allegato I), 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 I) , 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. HD 60139851 / *Certificate n. HD 60139851*

Allegato II escluso punto 4 / *Annex II except point 4*

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

CE 1936

Organismo Notificato / *Notified Body*
TÜV Rheinland Italia S.r.l.

Pesaro, 28/04/2020

EME srl
L'Amministratore unico / Administrator
Salvatore Vanella

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 ad onde d'urto /
Equipment for shock-wave therapy:

SHOCK MED SP

è conforme ai requisiti essenziali della direttiva comunitaria 93/42/CEE e successive integrazioni e modifiche (Allegato I), 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 I) , 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.*

Digitally signed by Armasu Sergiu
Date: 2025.12.21 18:54:56 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA BORGEAÀ

Certificato n. HD 60139851 / *Certificate n. HD 60139851*

Allegato II escluso punto 4 / *Annex II except point 4*

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

CE 1936

Organismo Notificato / *Notified Body*
TÜV Rheinland Italia S.r.l.

Pesaro, 28/04/2020

EME srl
L'Amministratore unico / Administrator
Salvatore Vanella

EME® ITALY

Italian manufacturer of physiotherapy equipment since 1983

EME Srl
Via degli Abeti, 88/1, Pesaro (PU) 61122 ITALY
T. +39 0721 400791 - F. +39 0721 26385
info@eme-srl.com
www.eme-srl.com

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