EME® ITALY

SHOCK MED

Designed by

ITALDESIGN

CE 1936

100% MADE IN ITALY IT01

INDEX

USER MANUAL INFORMATION

This user manual is addressed to:

- user of the machine;

- owner;

- responsible;

- travel agents;

- installers;

- users;

- those in charge of maintenance.

This document provides information for the installation and correct use of SHOCK MED shock wave therapy devices.

It is an indispensable reference guide for the user: before installing and using the machines it is essential to carefully read the contents of the manual and always keep it at hand for quick consultation.

Failure to comply, even partially, with the recommendations contained therein may give rise, in addition to malfunctions, to damage to the equipment, with invalidation of the warranty.

On the other hand, only by scrupulously following the prescriptions and recommendations provided by the manufacturer can you have the absolute certainty of obtaining maximum results and benefiting, if necessary, from a fast and efficient technical assistance service.

The limits of this user manual are:

- the user manual can never replace adequate user experience;

- the instruction manual, for particularly demanding operations, can only constitute a reminder of the main operations.

The user manual is to be considered part of the equipment and must be retained for future reference until the final dismantling of the equipment. The instruction manual must be available for consultation near the machine and stored correctly.

This user manual reflects the state of the art at the time of marketing and cannot be considered inadequate just because it was subsequently updated based on new experiences. The builder has the right to update production and manuals without the obligation to update previous production and manuals unless these have implications for the safety of the device.

The company considers itself relieved of any possible responsibility in the main cases:

- improper use of the machine;

- use contrary to specific national regulations;

- incorrect installation;

- power supply defects;

- serious shortcomings in the planned maintenance;

- unauthorized modifications and interventions;

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

- total or partial failure to comply with the instructions provided;

- exceptional events.

If you require any further information, consult the EME srl company directly; it is always updated on the best ways to use these machines and the optimal method to provide the necessary assistance.

WRITING CONVENTIONS

Underlining is used to highlight certain sections of the document.

NOTE

The notes highlight some important information contained in the text.

WARNING

Warning messages appear before operations which, if not observed, may cause damage to the machine and/or its separable components.

! ATTENTION !

ATTENTION messages indicate operations or situations which, if not known or not performed correctly, could cause problems for the user.

WARRANTY

EME srl guarantees the quality of its devices,when used in accordance with the instructions provided in this manual , in the following ways:

- The warranty period of the camera body lasts for**24 months** from the date of purchase.

The components subject to wear, on which the standard 24-month camera body warranty does not apply, are:

- APPLICATOR handpiece
- Transmitter(s).
- INTERCHANGEABLE KIT

Special note for the INTERCHANGEABLE KIT, whose warranty period lasts for**6 months** from the date of purchase, unless there is damage related to inappropriate use or improper maintenance.

During the warranty period, at the company's discretion, defective products will be repaired or replaced.

Under no circumstances will the appliance be replaced.

The warranty is not covered for malfunctions or damage resulting from :

- inadequate location, installation and implementation;

- incorrect use or use that does not comply with the provisions of this manual;

- improper or inadequate maintenance by the user;

- operation not compliant with the environmental specifications indicated for the product;

- unauthorized opening of the external packaging;

- tampering and/or unauthorized modifications;

- use of non-original separable components. The

guarantee is provided ex EME srl registered office.

If a return shipment is necessary, follow the packaging instructions below and attach a copy of the purchase receipt.

It is advisable to insure the shipment.

Before sending the machine due to a suspected malfunction, it is recommended to carefully consult the MAINTENANCE and TROUBLESHOOTING chapters.

OPERATION: the possible inconveniences are mostly attributable to poor maintenance or small technical problems which the user can effectively intervene on.

A simple phone call to the EME srl Technical Service can be of great help in solving a problem.

Instructions for packing and returning the appliance:

1. disconnect the power and connection cables with handpieces, applicator devices, etc.;

2. carefully clean and disinfect all separable components and parts of the machine that have been in contact with the patient. For obvious hygienic reasons, in order to guarantee adequate protection of the health of technical staff (workplace safety directive, TUS 81/2008), equipment deemed hygienically unsafe by the reception staff will not be checked;

3. dismantle the separable components and any mechanical supports;

4. reuse the box and original packaging materials;

5. attach to the shipment the Assistance Request Form on which to note the reasons for the revision request, the type of fault or malfunction: very useful information that will facilitate the work of the technicians by significantly shortening the repair times.

NOTE

PRELIMINARY NOTES

- Installing the device does not require particular attention and is therefore simple and immediate.

USE

- The keys shown on the display are touch and thanks to these it is possible to navigate the software.
- SHOCK MED devices are equipped with the automatic recognition function of the handpiece connected to the output connectors.
- When MODIFYING THE PATIENT CARD, by clicking the ENTER button, the new data will be saved on the selected card, deleting and overwriting the old ones which will no longer be recoverable.
- The data modified during the treatment cannot be saved directly in the patient file, it will be necessary to create a personalized treatment, as indicated in USER PROGRAMS in order to create a personalized program.
- When CREATING THE CARD it is mandatory to insert the NAME field or the SURNAME field and the treatment PROTOCOL of the pathology. Failure to enter does not allow the patient card to be saved.

- Every time the START button or the STOP button is selected the machine will emit a long confirmation beep.
- When starting the treatment, after selection the START button is replaced by the STOP button and vice versa.
- RESTORING THE FACTORY SETTINGS means deleting all patient records and personalized protocols saved in the user memory; they will no longer be recoverable.
- Cards and programs deleted using the DELETE procedure will no longer be recoverable.
- Once the SCREEN CALIBRATION has started it must necessarily be carried out, there is no possibility of pressing ESC as otherwise indicated in the on-screen instructions.

MAINTENANCE

- For optimal use of the device and to guarantee its maximum performance, it is recommended to correctly carry out maintenance within the recommended times and methods.
- Maintenance of the applicator kit, using the supplied brush, allows you to:

  or Clean the barrel from bullet debris;
  or Lubricate the bullet slide barrel to avoid friction and air leaks

WARNINGS

PRELIMINARY NOTES

- The responsibility for damage resulting from inadequate packaging lies with the customer.Keep the original packaging of the machine: it must be reused if returned to the company .
- Do not use the appliance in places where it could get wet.
- Carefully check the correctness of the connections according to the instructions provided before operating the machine
- To avoid the risk of electric shock, this device must only be connected to power networks with protective earth.
- Do not use separable components other than the original ones supplied: these could damage the machine and void the warranty. If problems or installation difficulties should occur, contact the EME srl technical assistance service.
- If you use an extension cord shared between the machine and other appliances, check that the total current absorption of the connected appliances does not exceed the maximum current allowed for that type of cable and that it does not exceed 15 A.
- Therapeutic suggestions are saved in the machine's fixed memory. These protocols can be modified if necessary but it is not possible to save any changes made.
- The therapeutic suggestion protocols preloaded into the machine cannot be deleted.
- It is not possible to define a suggested number of sessions to evaluate the effectiveness of the treatment, since they are linked to the power delivered to the patient undergoing treatment. It is the doctor's task to decide the number of therapeutic sessions to which the patient is subjected based on the specific needs of the case, in order to be able to guarantee the patient the execution of an effective treatment over time and carried out in conditions of absolute safety.
- Often check the integrity of the electrical power cable and the connection cable to the handpiece/applicator: these must not be damaged or worn.
- It is a class B car in terms of emissions. The machine can be used in hospital or outpatient settings, provided that due consideration is given to the fact that the machine machine could cause disturbance to electronic devices located in the immediate vicinity.
- Do not use the machine near HF SURGERY EQUIPMENT and rooms with RF shielding of an EM SYSTEM for magnetic resonance, where the intensity of EM DISTURBANCE is high.
- No modification of this appliance is permitted.
- The use of separable components, transducers and cables, other than those specified or supplied by EME srl, could lead to greater electromagnetic emissions or a decrease in the level of electromagnetic immunity of the device, with consequent incorrect functioning.

USE

- Upon request it is possible to provide the machine's user manual on computer support.
- For safety reasons it must be loaded into the machine**only and only**the software of the relevant machine. In the event of software exchanges, the machine could immediately block all its functions, requiring the intervention of the EME srl technical assistance centre.
- Use different names for each custom protocol. To avoid entering the same name for two different therapies, check the list of therapies before creating a new personalized one.
- Before saving the customized protocol, check that the associated name has been entered to avoid saving a therapy without a reference name.
- The operator is advised to familiarize himself with the typical rhythmic noises, linked to the frequency and intensity of pressure delivered, which accompany the emission of shock waves.
- The equipment or system must not be used in proximity to 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 electromedical device, by interacting with another device, causes or receives detectable interference, the user is invited to limit the interference by adopting one or more of the following measures:
  or Reorient or relocate the receiving device;
  or Increase the distance separating the appliances;
  or Connect the equipment into an outlet on a circuit different from the device(s) causing the interference;
  or Contact the manufacturer or local technician for assistance.
- Portable and mobile radio communications equipment can affect the operation of the device.
- Transportable RF communications equipment (including peripherals such as antenna cables and external antennas) should be operated no closer than 30 cm (12 inches) to any part of the device, including cables

specified. Failure to do so may result in degradation of the performance of this equipment.

MAINTENANCE

- Handle the applicator handpiece with care: rough handling can negatively influence its performance and characteristics.
- Unauthorized technical personnel are not allowed to open and/or disassemble the handpiece/applicator for any reason: this tampering, in addition to damaging the characteristics of the handpiece, immediately voids the right to the warranty.
- For no reason must the appliance be dismantled for cleaning or inspection purposes: there is no need to clean the inside of the machine, and in any case this operation must be carried out exclusively by specialized technical personnel authorized by EME srl.

- Do not use thinners, detergents, acidic solutions, aggressive solutions or flammable liquids to clean the exterior of the machine and separable components. The use of these substances, together with improper use of the separable components, in addition to irreparably damaging the device and the electrodes, invalidates the warranty right.
- For optimal use of the device and to guarantee its maximum performance, it is recommended that maintenance actions be carried out correctly within the recommended times and methods.
- To correctly replace the fuses on the machine, follow the instructions below:

  or unplug the plug and use a screwdriver to open the fuse holder, taking care to insert the screwdriver into the cutout made in the fuse holder and levering it outwards
  or insert a screwdriver into the two side holes of the tray for releasing the fuses
  or remove the old fuses
  or insert a new fuse at a time by applying light pressure, to the left, with a finger
  or push the tray back to fit it back into the slot.
- It is advisable to carry out periodic maintenance every two years, checking:
  or the intensity of any leakage currents;
  or the continuity, and therefore the integrity, of the earth
  or conductor; the correctness of the insulation resistance value

  in order to guarantee the electrical safety of the device, make sure that it operates in the guaranteed safety conditions. For this type of interest we recommend contacting a qualified technical service or alternatively EME srl or one of its authorized centres.
- For correct maintenance of the applicator kit, carry out **every two weeks** the cleaning procedure with a brush. Do not enter **completely** the brush inside the barrel and do not force its insertion

OPERATIONAL PROBLEMS

- Only technical personnel authorized by the manufacturing company can access the internal parts of the appliance.
- For repairs and further information it is necessary to contact EME srl or its authorized service centers.
- When the BURST disturbance occurs, the device goes into protection, interrupting the therapy and displaying the communication error on the screen. Once the disturbance is over, the device returns to working properly.
- When the SURGE disturbance arrives at ± 2 kV, the display loses functionality, causing the communication error message to appear on the screen, however the device continues to function, whether it is in the standby condition or in therapy delivery. At this point you only have the possibility to interrupt the therapy, only with the handpiece button. Once the key therapy has been interrupted and the disturbance is over, it is necessary to turn the device off and on again to be able to return to normal.
- When an electromagnetic compatibility disorder occurs, the device may react by interrupting the delivery of the therapy, the display working correctly (also displaying the communication error message) and giving the opportunity to pause and restart the therapy. If this were to happen, it is necessary to pause or stop the delivery of the therapy and then turn the device off and on again.

- When an electromagnetic compatibility disorder occurs, the device's display could react by freezing, making it mandatory to turn the device off and on again. If this should happen, you must turn the device off and on again.

PRELIMINARY NOTES

- The correct transport position of the machine requires that the appliance is moved exclusively by gripping the curved profiles of the cover with both hands.

- The perfect functionality of the appliance is guaranteed in compliance with the installation and use regulations indicated, only with separable components and original spare parts.
- If problems or installation difficulties should occur, contact the EME srl technical assistance service.
- Before connecting the cable to the mains plug, check that the appliance has not suffered damage during transport and make sure that the characteristics of the electricity supply on the available socket satisfy the data on the plate on the back of the machine.
- The electrical current supplied to the machine is VERY DANGEROUS. Before connecting or disconnecting the power cable from the connector on the machine, make sure you have previously disconnected it from the socket.
- For safety reasons, the power cable is supplied with a plug with a protective earth connection.
- Only use a suitable grounded power socket.
- **The connection of the appliance must only be done on compliant systems.**
- If extension cords are used, check the presence and integrity of the protective earth conductor.
- Connect the device directly to the wall socket, possibly without using extension cords. Failure to comply with this warning could cause dangerous electric shocks to people and alter the operation of the machine.
- The manufacturer is responsible for the fundamental safety, reliability and performance of the device only if:
  or The electrical system of the premises complies with the appropriate regulations;

or The device is used in accordance with the instructions for use.

USE

- Shock wave therapy treatments must be delivered, under the strict control of the operator, to "conscious" patients, capable of interacting with the operator in the face of the stresses transmitted by the machine.
- If the patient's pain threshold does not allow the delivery of the maximum energy density expected, use the maximum tolerated level. Achieve the maximum energy expected, or tolerated, in the protocol by increasing the energy density every 100 pulses.
- Before turning on the generator, adjust the ring nut to the correct value of the mains voltage in use in the room where the treatment will be provided so as not to cause malfunctions of the machine.
- NEVER OPERATE THE HANDPIECE BEFORE HAVING CORRECTLY INSERTED THE DISPENSING HEAD. DAMAGES SUFFERED BY THE DISPENSING GUN UNDER THESE CONDITIONS ARE NOT COVERED BY THE WARRANTY.
- To obtain perfect recognition of the handpiece connected to the output channel, it is strongly recommended to connect/disconnect them when the delivery of treatments is interrupted.

- Once delivery of a program begins, the toolbar buttons are disabled; the only operation allowed is stopping dispensing by pressing the STOP button.

- In order to guarantee the operation of the machine in conditions of absolute safety for the patient, it is recommended to subject the machine to a cycle of periodic checks (at least every 2 years) to be carried out by an authorized EME technician.
- The use of the device in the presence of flammable anesthetic mixtures and oxygen-rich environments is absolutely prohibited. In case of failure to comply with the instructions provided, EME srl will not be held responsible for any accidents.
- It is absolutely forbidden to cover the compressor's ventilation slots: such an action may not allow the machine to work in safe conditions. In case of failure to comply with the instructions provided, EME srl will not be held responsible for any accidents.
- It is important to draw the operator's attention to the need to verify the correctness of the electrical installation of the appliance before operating the mains switch.
- It is advisable to suspend the therapeutic treatment if any disturbances appear during its provision.
- Before each treatment, carefully clean and disinfect all separable components and parts of the machine that have been in contact with the patient, in particular the shock wave transmitters.

MAINTENANCE

- It is absolutely forbidden to remove the electrical/pneumatic connector of the applicator without first having discharged the pneumatic circuit. Then TURN OFF the device with the main switch and wait 10 seconds for the 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 and cleaning operations on the appliance, it is NECESSARY to turn off the appliance using the rear main switch and disconnect the power cable from the socket.
- It is recommended to carefully clean the machine and the separable components supplied before using it in contact with the patient.
- Cleaning and related disinfection must be carried out systematically before carrying out the therapeutic treatment to which the patient is subjected.
- It is useful to draw the operator's attention to the need for periodic maintenance of the handpieces/applicators, in particular:
  - ➢ checking the treatment head to detect any cracks that could allow the entry of conductive liquid;
  - ➢ check the integrity of the cable and the handpiece/applicator connector.
- Do not spray or pour liquids on the external container of the appliance, on the ventilation slots, in correspondence with the LCD TOUCH SCREEN display or on the fan grate. Otherwise, overhaul the machine, EME srl will not be held responsible for any damage caused following use of the machine in non-compliance with the conditions listed above.
- Often check the integrity of the electrical power cable and the connection cables of the applicators applied to the patient: these must not be damaged or worn.
- It is advisable to have the replacement of fuses carried out by personnel with adequate technical training, in order to carry out the operation in safe conditions.
- Do not open the device: there arehigh electrical voltages which can be dangerous.

- Only technical personnel authorized by the manufacturing company can access the internal parts of the appliance. For repairs and further information it is necessary to contact EME srl or its authorized service centers.**OPERATIONAL PROBLEMS.**

– DO NOT OPEN the unit, there are HIGH ELECTRICAL VOLTAGES inside which can be DANGEROUS .

INTRODUCTION TO TECHNOLOGY

The shock waves

From a physical point of view, shock waves are defined as high-energy acoustic waves. In particular,they are pressure pulses that generate a direct mechanical force, with the main objective of transferring energy to the body tissues for stimulate its reparative processes.

The shock wave should not be confused with the ultrasound wave which is frequently used for both diagnostic and therapeutic purposes. Unlike the ultrasonic wave, the shock wave has an impulse pattern and generates much higher pressure values, on average 1000 times higher.

The shock waves used in therapy are particular acoustic waves with characteristics specified at an international level (DIGEST). To allow users to make reliable and useful measurements for therapy and research, the most representative parameters of the acoustic field were chosen, in agreement with the International Society for Medical Shockwave Therapy (ISMST) and the manufacturers of shock wave equipment:

- therepressure (measured in MPa, 1MPa=10 bar i.e. approximately 10 atmospheres): SHOCK MED is able to generate up to 5 bar of pressure and SHOCK MED SP up to 4 bar of pressure;
- thereenergy flux density (measured in mJ/mm2);
- L'power (measured in mJ);
- thedimensions of the focal volume, defined by convention at 50% of the maximum pressure.

Propagation speed and diffusion of shock waves

The speed of propagation of a shock wave, as for any acoustic wave, depends above all on the medium in which it is transmitted and on the intensity of the shock wave itself.

Biological structures such as cell walls, whose thickness is comparable to a few molecular layers, are therefore subjected to very high pressure gradients when shock waves transit.

The mechanical properties of biological media subjected to shock waves, such as elasticity and compressibility, influence the transmission of acoustic waves, determining their propagation speed.

When shock waves pass through a fluid they generate multiple pressure differences which give rise to the formation of gas bubbles. A subsequent shock wave that hits the bubbles thus formed gives rise to a violent implosion which forms a jet of liquid which will hit the tissue to be treated. In the face of such lesions, a series of desired biological events are generated which trigger different types of responses depending on the tissue affected.

In particular, an osteogenic and a vascular type reaction were observed in the bone tissue, while in the soft tissues an anti-inflammatory and analgesic effect occurred, as well as a vascular response.

The diffusion of the acoustic wave in the tissues follows the physical laws of the acoustic waves of transmission, reflection and absorption, which are linked to the characteristics of the medium and are inevitably affected by the differences in density and impedance of the skin, fat, muscles and bone.

Shock wave generation systems

There are different types of shock wave therapy equipment which are distinguished by the technological methods with which these waves are generated. In general a shock wave generator is made up of:

- adevice to cause pressure stroke;
- onewater chamber to concentrate the shock wave energy into the focal volume desired or aDomed rubber membrane to close the shock wave output window.

This membrane acts as a means of coupling with the skin of the patient to be treated or as a ballistic system consisting of a spring-loaded metal applicator (radial shock waves).

In the medical field, shock waves are therefore produced through a strong and immediate increase in pressure inside a water chamber or a ballistic system obtained.

Specifically, in a ballistic or radial system the shock wave is generated in a pistol-shaped handpiece in which the end is closed by a metal "cap" against which it is launched, using compressed air at 5 bar pressure a steel bullet. The collision generates a shock wave which spreads through the metal cap, expanding radially onto the skin and into the first underlying layer of tissue.

The Mechanism of Action

The mechanism of action in musculoskeletal tissues is very complex and still under in-depth study. Shock waves act differently depending on the pathological tissue they treat (bones, soft tissues, skin). In general they stimulate the activation of natural biological repair processes.

However, the mechanism of action of shock waves seems to be attributable to two main effects:

1. direct physical-mechanical effects:

the so-called "cavitation effect" and micro-streaming resulting in the formation of new blood vessels to increase the local blood flow and the production of new cells to speed up the repair of micro-lesions and improve tissue trophism;

2.indirect biological effects induce:

the reduction of pain transmission by stimulating nerve endings and releasing substances that modulate its perception; the vascularization that produces biomolecular modifications.

IN GENERAL

EME srl has recently developed a complete series of devices, accessories and equipment, designed and built according to the highest quality standards, adopting cutting-edge technologies in full compliance with current directives and standards.

Particular attention was paid to design, ease of operation, functionality and safety. The result is a compact unit, equipped with a modern design, capable of proposing an extremely logical operating sequence, supported by a clearly legible display.

The multiple possibilities of therapeutic applications, together with the guarantee of safety for the patient and the therapist himself (the unit complies with international regulations), make the machine a high quality piece of equipment.

These machines have been designed and manufactured so that their use, if it occurs under the conditions and for the intended uses, does not compromise the health and safety of patients, users and third parties, taking into account the benefit brought to the patient.

These machines are not reserved for diagnosis, prevention, monitoring, compensation of injury or handicap, replacement or modification of the anatomy, control of conception, support/support of vital functions but they allow the treatment of particular pathologies and the reduction of the disease.

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

INTENDED USE

SHOCK MED and SHOCK MED SP is an electro-medical device that provides therapeutic treatments in which the shock wave is used with the aid of a special handpiece/applicator.

Shock waves are acoustic waves that transfer high energy, transmitted through the surface of the skin and spread radially throughout the body, in the area of pain. The body responds with an increase in metabolic activity in the area of application, favoring the reduction of inflammation caused by a pain-relieving action induced by the local release of endorphins, thus stimulating and accelerating the healing process.

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

The operator, in fact, must be appropriately qualified and have carefully studied the contents of the user manual in order to use the device; or, it must operate under the supervision of a healthcare professional adequately qualified to use the machine, able to understand the advantages and limitations of the therapy and to work in safe conditions for the person undergoing treatment.

This machine can be used in a hospital or outpatient setting, provided it is used by qualified personnel in this regard and in accordance with what is stated in the user manual.

SHOCK MED are radial shock waves, as the shock wave is generated using a special pistol-shaped handpiece, the barrel of which is closed at the end by a metal element against which a steel bullet is launched by compressed air (up to 5bar pressure).

A shock wave is thus generated which spreads, expanding radially in the skin and in the first underlying layer of tissue, or in a focused manner (depending on the transmitter used). The measurement of the penetration depth varies from 4 to 7 cm.

INDICATIONS

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

The shock wave method is the treatment of choice in chronic insertional tendinopathies, characterized by poor vascularization of the osteotendinous junction, where physiotherapeutic treatment (infiltration and laser therapy) has proven ineffective.

The list of the main treatable pathologies includes: **Elbow:**

epicondylitis and epitrochleitis

Epicondylitis and epitrochleitis are two inflammatory pathologies due to a degeneration of the tendon insertion of the epicondylar muscles, i.e. the extensor muscles, and the epitrochlear muscles, i.e. the flexor muscles, of the elbow.

These pathologies arise as a consequence of tendon overload due to continuous stress on 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 extension of the elbow. It manifests itself as lateral elbow pain during wrist extension and high intensity pain during movements performed to grasp objects.

Even in the case of epitrocleitis, or "golfer's elbow", there is tendon degeneration due to incorrect use of the articulation of its tendons.

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

Shoulder: insertional tendinopathies, impingement

TENDONS are robust fibrous structures, with a mother-of-pearl color, that connect 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 over time. Furthermore, tendons have long healing times and a marked propensity to evolve into a state of chronic inflammation.

The term tendinopathy refers generically 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", i.e. an 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, while those involving the subscapularis are less common.

Impingement syndrome is a pathology 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, there is a compression of the supraspinatus muscle tendon, which generates pain. 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 microtraumas, etc.).

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

Knee: tendinopathies of the patellar or quill

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 underneath the kneecap. In the majority of cases, the resulting pain is caused by chronic and continuous stress on the patellar tendon which leads 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 activities in which the ischio-perineotibial muscles are subjected to continuous stress.

Pubis: adductor tendinopathies (pubalgia)

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 "pubalgia", particularly affects the pubic insertion of the adductor longus and the pectineus muscle. It can be caused by microtraumas

repeated or following an episode of muscular distraction not correctly treated.

Insertional adductor tendinopathy is typical in subjects who practice sports that require a high frequency of explosive actions and is generally caused by careless 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 ease following muscle warming but tends to worsen to the point of compromising the continuation of the activity.

Ankle: Achilles tendinopathies, calcaneal apophysitis.

The Achilles tendon is the largest tendon in the human body, capable of withstanding a load capacity of up to approximately 12.5 times 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 occurs during running or playing sports.

Apophysitis is a pathological inflammatory state of an apophysis, i.e. a bony prominence. Calcaneal apophysitis, or Sever's disease, is an inflammation of the calcaneal apophysis, where the Achilles tendon inserts. It mostly appears following a sudden increase in workloads in children aged between 9 and 15. The cause for this pathology appears to be the tension exerted by the Achilles tendon on the calcaneal tuberosity which, not yet being completely ossified during adolescence, is pulled away from the calcification nucleus, inflaming the growth cartilage. A contributing factor may be the repetitive stress caused by the impact of the heel on the ground during running and jumping.

COUNTER-INDICATIONS

Absolute

- Pregnancy
- Coagulation disorders
- Presence of neoplasms or growth nuclei in the application field
- Demyelinating polyneuropathies
- Infectious tenosynovitis
- The proximity of the lung parenchyma to the scope
- Acute soft tissue/bone infection
- Epiphysiolysis at the focal point
- Patients with active implantable devices
- Brain, spinal cord, large nerves at the focal point (neurocranium, spine, ribs)
- Severe osteoporosis. It should be noted that in cases of severe osteoporosis or advanced bone necrosis, shock wave therapy cannot be performed.
- Surrounding metal prostheses
- Use of vasoconstrictor drugs

Relative

- Rotator cuff tear
- Tendinopathies associated with severe glenohumeral arthritis or secondary to capsular-ligament instability.
- Pernicious primary diseases
- Epiphysiolysis at the focal point
- Blood clotting diseases and use of anti-coagulants
- Lung tissue at the focal point

Side effects

- Hematomas and/or petechiae particularly with high energy pulses (>0.60mj/mm2);
- Edemi
- Flare-up of symptoms in the following 2-3 days which disappear on their own or with cryotherapy and painkillers.

PRELIMINARY NOTES

UNPACKING

SHOCK MED shock wave therapy devices are packaged and prepared for shipping with their box, complete with filling, designed for safe storage and transport.

To unpack the machine, place the box on a flat, solid surface and remove the top polystyrene part. Remove the appliance carefully.

The machine and the separable components are wrapped in a protective transparent polyethylene sheet and the package always contains:

- n.1 user manual;
- n.1 mains power cable;
- n.2 reserve fuses (see technical characteristics);
- n.1 SWT Shock-Med applicator handpiece;
- n.1 9 mm multi-focused transmitter;
- n.1 15 mm focused transmitter;
- n.1 15 mm multi-focused transmitter;
- n.1 lubricated brush;
- n.1 gel 1000 ml;
- n.2 interchangeable applicator kits (one is the one inserted in the gun);
- n.1 actuator removal wrench tube
- n.1 actuator removal wrench handle
- 1 knob wrench for fixing the ring nut.

Check the contents of the package. If any element is missing, immediately contact the authorized EME srl dealer.

INSTALLATION

The installation of shock wave therapy devices does not require particular attention and is therefore simple and immediate.

Once the device has been positioned, block the wheels with the appropriate brake to prevent involuntary movements.

The environmental characteristics recommended for the installation of SHOCK MED are the following:

- ambient temperature: from +10° to +35°C;
- relative humidity: 10% to 80% non-condensing;
- avoid direct exposure to sunlight, chemical products, high intensity magnetic fields and vibrations;
- avoid using in close proximity (<0.30m) to wireless RF communication devices

SEPARABLE COMPONENTS

The appliance is supplied with a mains power cable and is compatible with the following kit of separable components:

Description	Supplied	Optional
Shuko plug power cable	**1**	
Pair of FUSES (see table)	**1**	
Lubricated brush	**1**	
User manual	**1**	
Shockwave gun	**1**	
1000 ml gel bottle	**1**	
15mm focused transmitter	**1**	
9 mm multi-focused transmitter	**1**	
15 mm multi-focused transmitter	**1**	
Interchangeable KIT for applicator	**2**one is that inserted into the pistol	
Actuator removal wrench tube	**1**	
Actuator removal key handle	**1**	
Ring fixing knob wrench	**1**	
Handpiece case + shaped polystyrene	**1**	
Applicator including 15 mm transmitter		X

Description	Supplied	Optional
15mm focused transmitter		X
9 mm multi-focused transmitter		X
15 mm multi-focused transmitter		X
35mm focused transmitter		X
35mm focused transmitter wrench		X
Interchangeable applicator kit		X

The separable components that can be replaced by the RESPONSIBLE ORGANIZATION and which can affect 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 assembly of the separable components is simple and intuitive: should problems or installation difficulties arise, contact the EME srl technical assistance service.

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

CONNECTIONS

Connecting the shock wave handpiece/applicator is simple: you need to plug its connector into the appropriate socket on the front panel of the machine.

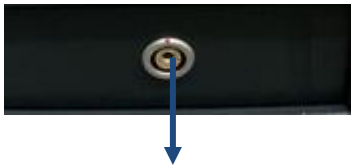
In the rear part of the machine there is the integrated mains power module, which includes the three-pole connector for the power cable, the removable fuse holder with two fuses (see technical characteristics) and the two-pole main switch.

Insert the three-pole female plug of the power cable into the integrated module, checking that it is perfectly inserted inside the connector.

After having checked the correct installation and assembly, turn on the main power switch and check that the display turns on correctly.

DESCRIPTION OF THE APPLIANCE

FRONT PANEL



Connector
link for the
APPLICATOR handpiece

BACK PANEL

Switch
ON/OFF
general

Tray
fuse holder

Three-pole socket
for cable
diet

Socket for trolley
power cable (not
in use)

USB connector,
cart data connection
(not in use)

Connector for
connection of
USB pendrive

Pedal connector
(not in use)

SEPARABLE COMPONENTS

Lubricated brush

APPLICATOR

Transmitter

Tightening ring nut

TUBE WITH HANDLE
including the actuator

Wave actuator
shock

Removal key
actuator

Knob wrench
for transmitters

TRANSMITTERS

Transmitter
multi focused
15 mm

Transmitter
focused 15 mm

Transmitter
multi focused
9mm

USE OF THE MACHINE

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 for optimal and safe use of the device in a personalized way.

The dialogue interface with the user is carried out by a large backlit graphic liquid crystal display (LCD) TOUCH SCREEN: all the operational messages of interest to the operator are displayed on it, as well as the functional status of the machine during normal 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 a specific therapy, up to the determination of the correct working parameters for a "personalized" application.

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

There is therefore no need for protection means in this sense for the patient, who receives treatment for healthcare purposes, nor for the operator, who is not in any way affected by the acoustic radiation emitted by the applicator handpiece.

OPERATION

The SHOCK MED shock wave therapy devices have a control console optimized according to the specific sector of use and the type of operation for which they are intended.

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

SHOCK MED gives the possibility of saving personalized programs and patient cards in the memory medium calledUSER MEMORY in which both personalized protocols and patient records can be stored.

The standard therapeutic suggestion protocols are saved in an additional fixed internal memory of the machine. This memory is not user-manageable: data cannot be deleted or formatted. To make any changes made available, you need to store them on one of the alternative media by creating a customized protocol.

OPTIMAL USE

After having installed and positioned 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 bringing the main ON/OFF switch on the rear panel to the “ON” position.

This operation prepares SHOCK MED for operation, causing the backlit LCD display to turn on, signaling that the device is ready to operate.

fig. 1

The LCD display will light up, highlighting a presentation screen (fig.1). followed by a PASSWORD ENTRY screen:

1. type the login PASSWORD

   orin the event of an incorrect password, a warning information appears the user to retype the password

2. once you have entered the correct password you will access the main screen where you can select the desired operating mode from the 4 available.

The password has been set by default to**1 2 3 4 5**: to type 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).

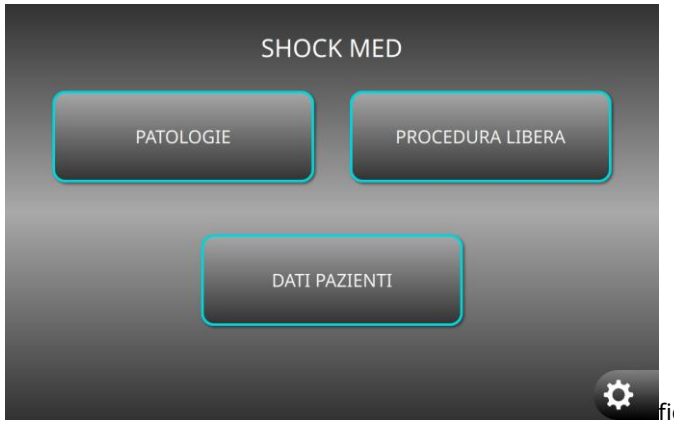


fig. 2

On the home screen you can (Fig.2):

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

The operation of each button 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 PROCEDURE button a screen appears (fig.3) where you can:

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

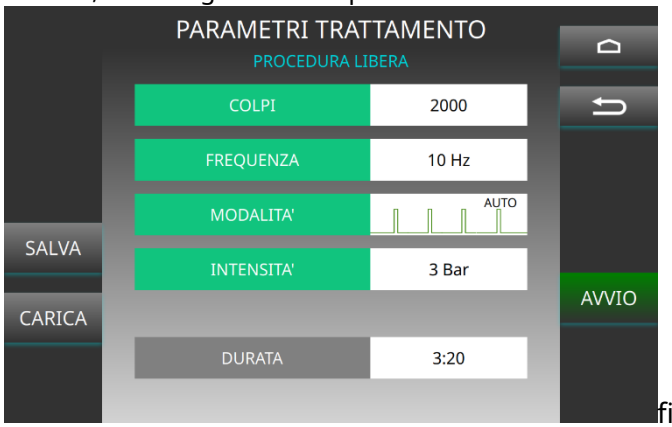


fig3

EDIT

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

1. Click on the parameter to be modified, the modification screen appears where the name of the parameter to be modified is shown 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 reaching the value desired;

fig 4

2. For the parameter**HITS**(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.

   or Click on**HE CONFIRMS**(green tick) to save the set value of the parameter and return to the main screen;

   or Click on**BACKWARDS**(x gray) to cancel the parameter modification operation, you return to the main screen without having made any changes.

fig 5

3. For the parameter**FREQUENCY**(Hz) 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.

   or Click on**HE CONFIRMS**(green tick) to save the set value of the parameter and return to the main screen;

   or Click on**BACKWARDS**(x gray) to cancel the parameter modification operation, you return to the main screen without having made any changes.

4. For the parameter**MODE**change the mode using the + or – buttons until you reach the desired one. This parameter represents the delivery mode of the shots emitted by the applicator handpiece during the

treatment, the choice is between 5 emission modes: SINGLE, CONTINUOUS, BURST, CONTINUOUS AUTO, BURST AUTO.

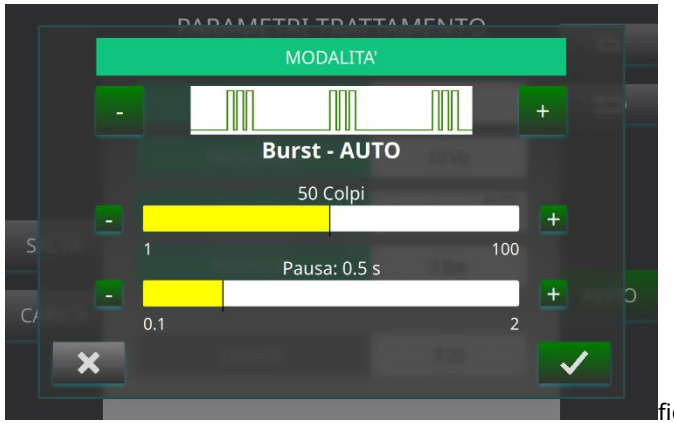


fig 6

- By selecting the AUTO BURST and BURST delivery modes, other editable parameters appear on the screen (figure 6): SHOTS, i.e. the number of pulses that make up the burst (or train of pulses) and PAUSE (ms) (only in the AUTO BURST mode), i.e. the pause between consecutive bursts.
- By selecting the SINGLE delivery mode, the FREQUENCY parameter cannot be modified.

   or Click on**HE CONFIRMS**(green tick) to save the set value of the parameter and return to the main screen;

   or Click on**BACKWARDS**(x gray) to cancel the parameter modification operation, you return to the main screen without having made any changes.

fig 7

5. For the parameter**INTENSITY'**(Bar) 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.

   or Click on**HE CONFIRMS**(green tick) to save the set value of the parameter and return to the main screen;

   or Click on**BACKWARDS**(x gray) to cancel the parameter modification operation, you return to the main screen without having made any changes.

6. For the parameter**DURATION**(minutes) is a parameter that cannot be modified directly but varies automatically as the number of IMPACTS, the frequency and the set MODE vary.

SAVE

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

1. Click the button**SAVE**;

   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 the name to assign to the created therapeutic program on the virtual keyboard;

3. Click on**HE CONFIRMS**(green tick) to continue with the program saving operation;

   or Otherwise, click on**BACKWARDS**(x gray) to cancel saving the therapeutic program, the screen with the modified treatment parameters will reappear;

4. To start the saved customized program, proceed as described in the START section.

When saving a new customized program, the software performs a check on the programs already present in the database.

If the therapeutic program has an already existing identifying name, the impossibility of saving the data with that specific name will be indicated unless you choose to overwrite the therapy:

   or Click**YES**to proceed with overwriting the therapy;

   or Click**NO**to cancel overwriting the therapy and enter a new name to assign to the created therapy program.

START

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

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

- If you start the treatment without having connected the handpiece, an error message “HANDPIECE ERROR” appears on the screen which prevents the start of the treatment.

AUTO BURST delivery MODE To start

delivering 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 pedal): this enables the emission autonomously;
3. At the end of the burst, the next pulse train is emitted automatically 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 MODE To

start 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 pedal): this enables the autonomous emission of a succession of pulses set for the delivery of the treatment.
4. to suspend delivery, press the applicator trigger (or the pedal);
5. to resume treatment, press the applicator trigger (or the pedal) again;
6. select STOP to end the treatment early,
7. or wait for the timer to reset which indicates that the treatment has been completed and then select the OK button.

BURST delivery MODE To

start treatment:

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

CONTINUOUS delivery MODE To

start treatment:

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

SINGLE delivery MODE To start

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 pedal): this enables the emission of a single shot (or the pedal);
4. to fire new shots, press the trigger repeatedly;
5. select STOP to end 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.

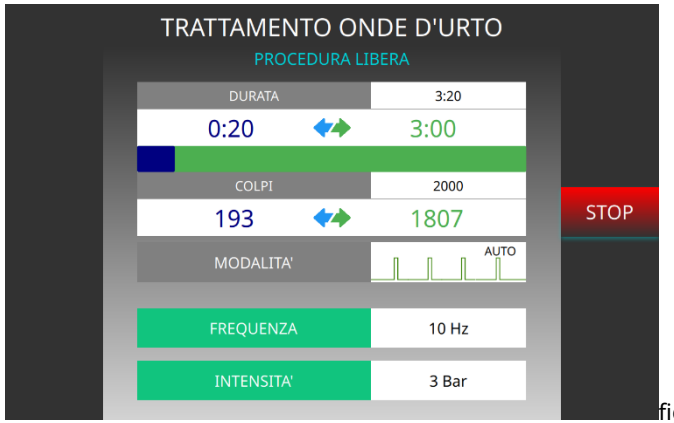


fig.8

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

- to the number of remaining pulses
- to the pulse frequency
- to the working method.

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

LOAD

In this section it is possible to load a PROGRAM by 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 personalized program in the therapy list, the button will appear (figure 9). Press the button to open the treatment;

   or Otherwise press the button**BACKWARDS**to return to the main screen.

At this point it is possible:

or modify the processing data, proceeding as indicated in**EDIT**;

or save any modified parameters by proceeding as indicated in **SAVE**;

or start treatment, following the procedure**START**;

or press the button**BACKWARDS**to go back to the main screen;

If you want to delete a personalized treatment:

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

orPress the BACK button to return to the main screen.

fig 9

PATHOLOGIES

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

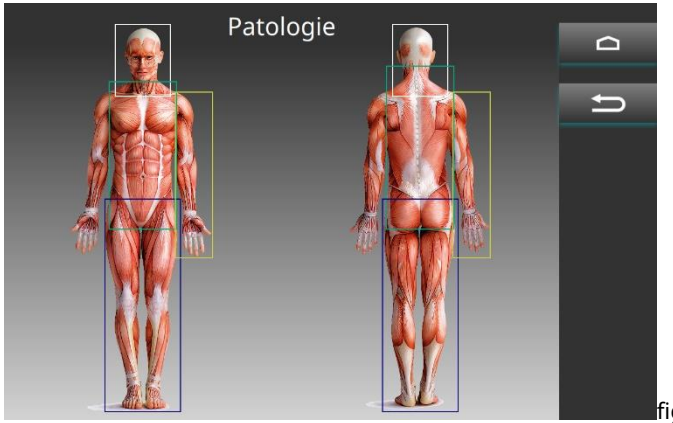


fig 10

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

The anatomical zones 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 i**preloaded programs**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 key**PATHOLOGIES**;
2. In the image of the body shown on the display, select the anatomical treatment area among those delimited by rectangles;

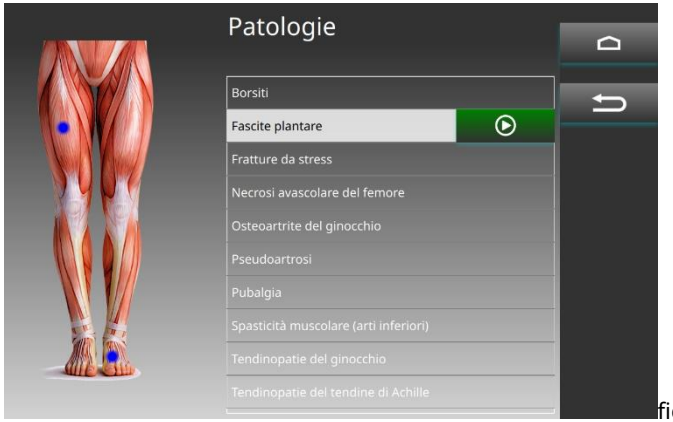


fig.11

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

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

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

PATIENT DATA

Pressing the button**PATIENT DATA**on the main screen (figure 2) allows access to a screen containing a possible list of patient records.

When the device is turned on for the first time there is no list of patient cards, so move on to creating new patient cards by following the procedure described in "CREATE a CARD" (green "+" button).

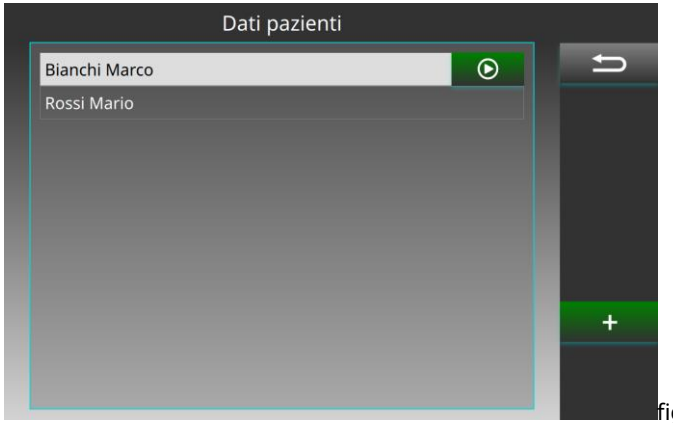


fig. 12

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

OR START the PATIENT CARD previously saved in memory by pressing the button;

OR MODIFY PATIENT DATA by pressing the MODIFY button ;

OR DELETE PATIENT DATA by pressing the DELETE button ;

OR Access the list of treatments performed for that patient .

CREATE a CARD

1. Select the button from the main menu (figure 3).**PATIENT DATA,** the screen in figure 11 appears;
2. Select the button**NEW SHEET**(green "+" button);
3. In the screen that appears, fill in the following fields: or

   SURNAME (mandatory insertion)

   or NAME (mandatory insertion) DATE

   or OF BIRTH

   or ADDRESS

   or TELEPHONE

   or E-MAIL

   or HISTORY

   or NOTE

4. Click on the item to insert;
5. Use the relevant commands to enter the data:

   orBy selecting the fields SURNAME, NAME, ADDRESS, TELEPHONE, , HISTORY, NOTES type on a virtual keyboard to enter the requested information;

6. Click on SAVE (green tick) to save the new patient card; or

   Otherwise click**CANCEL**(red x) to cancel saving the new patient card.

7. The screen will appear in which the patient card with his treatment data will be displayed;
8. Click**BACKWARDS**to go back to the screen containing the list of patient records created.

At this point it is possible:

or Modify the patient record and the corresponding data by continuing as described in the EDITING a RECORD section;

or Open a patient card by pressing the OPEN button;

orDelete the displayed patient card by selecting the button**DELETE**;

OPEN a CARD

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

At this point it is possible:

- Start a FREE PROCEDURE treatment;
- Start treatment for PATHOLOGIES;

When you perform a treatment for a patient, an icon remains visible at the bottom left indicating the name and surname of the patient for whom you are performing the treatment. Once a patient card has been opened, to close it you need to press and hold the icon at the bottom left for a few moments and click on the prohibition symbol that appears.

- Load the list of recently performed treatments and start the treatment;
- Delete the selected patient card by clicking the button**DELETE CARD**, a window will appear asking you to select:

or **Prohibition symbol**to confirm permanent deletion of the patient record

or **X**to cancel the deletion of the patient card.

MODIFY a CARD

1. Select the button from the main menu (figure 3).**PATIENT CARDS**, the screen in figure 12 appears;
2. Tap the patient card you want to open;
3. Select**YOU OPEN**to open the patient card;
4. Select**EDIT**

orchanges may be made to the following data:

- SURNAME
- FIRST NAME
- DATE OF BIRTH
- ADDRESS
- TELEPHONE
- E-MAIL
- HISTORY
- NOTE
-

5. Click on the item to modify;
6. Use the relevant 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 his treatment data.

SETTINGS

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

figure 13.

On the screen you can view the software and firmware version.

From this screen you can:

or Access the device SETTINGS Access the

or treatment HISTORY

orAccess the section dedicated to the MAINTENANCE of the device 

SETTINGS

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

By pressing the button**SETTINGS**  a screen appears where it is possible to select:

- **TONGUE**

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

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 HOUR**

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

1. Press the “+” or “-“ buttons to adjust 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 history section contains 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 machine settings by pressing on GENERAL or access information on SHOCK MED maintenance using the SHOCK MED MAINTENANCE button.

By pressing the GENERAL button you can:

- Enable or disable the password using the appropriate switch;
- Changing your login password:

To change the access code proceed as follows: 1.

Click on the button**CHANGE PASSWORD**;

2. Type 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, type it for the second time and click confirm (green tick).

Entering the new password will be confirmed on the screen with the message “PASSWORD CHANGED”.

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

Furthermore, every time you change the gun's Interchangeable Kit, you must proceed as described below:

1. Select the HANDPIECE MAINTENANCE button and enter: or
   ENTER KIT SERIAL NUMBER ENTER
   or 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 must be sprinkled with a rather generous layer of "GEL" contact substance (interface that favors the acoustic conduction of ultrasound energy).

The distribution of the radiant energy must take place by means of a massage, i.e. by moving the radiating head on the treated part, 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 its delivery.

The proposed memorized programs are the result of the operational experience gained over years of support from professionally expert users and will be useful as a guiding suggestion for starting the treatment. The possibility of modifying the parameters according to the operator's needs guarantees versatility of use that is essential in medical contexts.

IMPORTANT

- **NEVER OPERATE THE HANDPIECE BEFORE HAVING CORRECTLY INSERTED THE DISPENSING HEAD.**
- **IT IS STRICTLY FORBIDDEN TO REMOVE THE ELECTRICAL/PNEUMATIC CONNECTOR OF THE APPLICATOR WITHOUT FIRST DRAINING THE PNEUMATIC CIRCUIT. Then TURN OFF the device with the main switch and wait 10 seconds for the pneumatic discharge. This procedure is introduced to safeguard the integrity of the O-Ring inserted into the connector.**

DAMAGES SUFFERED BY THE MACHINE UNDER THESE CONDITIONS ARE NOT COVERED WITH WARRANTY.

MAINTENANCE

The SHOCK MED shock wave therapy machines do not require any particular maintenance operations, other than periodic maintenance and cleaning of the applicator kit and applicator handpieces, with the aim of ensuring the best operating conditions, to guarantee the effectiveness of the treatment and patient safety.

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

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 also 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.

Replacing the interchangeable kit is recommended starting from 900,000 shots, to avoid losing the effectiveness of the treatment. In fact, once the delivery of 900,000 shots has been reached, every time you turn it on, the message "please order a new kit" is displayed. .

Upon reaching 1,000,000 the message changes warning that the Kit needs to be replaced.

The handpieces/applicators, especially the treatment head, must be periodically cleaned withwater and denatured alcohol.

Carefully store the handpieces/applicators at the end of each treatment.

Maintenance of the applicator kit, using the supplied brush, allows you to:

- Clean the barrel from bullet debris;
- Lubricate the bullet slide barrel to avoid friction and air leaks.

The applicator kit must be maintained**every two weeks**, using the brush supplied with the device.

The brush must be inserted halfway up the barrel for a minimum of 4/5 times until it becomes easy to insert the brush inside the barrel. Then gradually increase the insertion depth of the brush until it reaches the bottom of the barrel, and repeat the operation a minimum of another 4/5 times.

Contact EME srl authorized 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.

Under no circumstances should the appliance be dismantled for cleaning or inspection purposes.

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

The useful life of the device is 10 years.

To guarantee the safety and correct functioning of the equipment, the following maintenance program must be respected.

COMPONENT	KIND OF OPERATION	CADENCE	PERFORMER
Applicator kit	Procedure cleaning and maintenance using a brush	Every two weeks	User
Pistol	Verify of integrity cable of the gun	Every month or every disconnection of the pistol	User
Pistol	Verify of integrity of the connector from the pistol	Every month or every disconnection of the pistol	User
Transmitters	O-ring check	With every removal of the transmitter	User
Transmitters	O-ring removal	Every 2 years	User
Cable and socket diet	Verify of integrity of the cable and power socket	Everything is fineweek or Everything is fine mass in function of the device in case of movement of the device	User
Device	Verify instrumental of electrical safety	Every 2 years	Manufacturer or Center Assistance
Interchangeable kit	Replacement of the Interchangeable kit	Every 1,000,000 of hits.	User

Sanitization Method

The device must be sanitized periodically. Disconnect the power plug from the outlet.

COMPONENT	KIND OF OPERATION	CADENCE	PERFORMER
Container	Cleaning ed sanitation	Daily	User
Pistol	Cleaning ed sanitation of body and of dispensing head	At the end of each treatment	User

OPERATIONAL PROBLEMS

The SHOCK MED shock wave therapy machines have been designed and built adopting advanced technological solutions, quality components, for continuous use that is always efficient and reliable.

However, should any problems arise during operation, we recommend that you consult the following guide before contacting an authorized assistance centre.

When the conditions listed below occur, disconnect the appliance from the electrical system and contact the EME srl technical assistance service:

- the rear power cable or integrated module is worn or damaged;
- liquid has entered the appliance;
- the appliance has been exposed to rain.

ELECTROMAGNETIC INTERFERENCE

The SHOCK MED shock wave therapy devices have been designed and built in compliance with the current ELECTROMAGNETIC COMPATIBILITY DIRECTIVE 2014/30/EU, with the aim of providing reasonable protection from harmful interference in residential, civil and healthcare installations.

The CE marking covers conformity regarding this directive

All the necessary measurements and checks were carried out at the internal Test, Measurement and Inspection Laboratory (LPMC) of EME srl and at specialized external centres. Upon request, customers are given the opportunity to view the reports relating to EMC measurements within the company.

Based on their operating principle, these devices do not generate significant radio frequency energy and have an adequate level of immunity to radiating electromagnetic fields: in these conditions, harmful interference cannot occur with radioelectric communications, with the operation of electromedical equipment used for monitoring, diagnosis , therapy and surgery, the operation of electronic office devices such as computers, printers, photocopiers, faxes, etc. and to any electrical or electronic equipment used in such environments, provided that they comply with the ELECTROMAGNETIC COMPATIBILITY directive.

In any case, to prevent any interference problem, it is advisable to operate any therapy device sufficiently distant from critical equipment for monitoring patients' vital functions and to use caution in therapeutic applications on patients with cardiac pacemakers.

DIAGNOSTIC TECHNICAL DATA SHEET

PROBLEM	POSSIBLE CAUSE	SOLUTION
It doesn't turn on LCD display on panel front: the appliance does not works.	Mains plug not inserted correctly into the socket.	Check the operation of the power socket.
	Network cable incorrectly inserted into the connector of the appliance.	Insert the plug and cable correctly into the connector of the machine.
	Worn and broken network cable.	Replace the network cable.
	Switch off.	Turn on the mains switch.
	Fuse or fuses defective or interrupted.	Replace the missing fuse(s), defective or interrupted.
	Electronic circuit failure check.	Contact a centre EME srl assistance.
	Defective components on the board control electronics.	Contact a centre EME srl assistance.
Some commands of the panel front control do not work regularly.	Defective keys or buttons.	Contact a centre EME srl assistance.
	Faulty electronic control circuit.	
The appliance it does not activate in the provision of shock waves.	Faulty connections in the circuit output applied to the patient	Carefully verify the correctness and integrity of the output connections.
	Handpiece-applicator cable interrupted or incorrectly connected	Replace the defective applicator handpiece which shows obvious signs of wear in the dispensing head and on the cable.
	Output cables worn and/or from contact uncertain.	
	Fault in the electronic circuit of electricity generator.	Contact a center EME srl assistance.
The appliance works regularly, but you notice a notable decline of the effectiveness of treatment.	Not perfectly efficient connection of the output circuit of the handpiece-applicator.	Carry out the maintenance operations described. Install and position the appliance as described. Check the integrity of the cable and the handpiece connector-applicator.
	Applicator handpiece actuator	Replace the actuator following
	damaged or worn.	the appropriate procedure.
	Mechanical damage (following falls or to violent impacts) on the applicator handpiece, in particular on the head dispenser (or transmitter).	Check perfect adhesion of the dispensing head (or transmitter) on the surface interested in the treatment.
	Possible failure of the generator circuit current of the appliance.	Contact a center EME srl assistance.

TECHNICAL FEATURES

Mains power:		230 Vac, 50-60 Hz, ±10%
		115 Vac, 50-60 Hz*,±10%
Maximum power absorbed from the network:		190 VA
Double delay type protection fuse on the mains (T):	**230 Vac**	2 AT - 5 x 20 mm
	115 Vac	5 AT - 5 x 20 mm
Backlit LCD display, for viewing and controlling operating parameters		10.1" color touch screen
Type of shot emission		CAR BURST
		CONTINUE AUTO
		BURST
		CONTINUES
		SINGLE
Type of burst emission		(1-100) burst pulses
		(10 – 2000) msec pause between burst pulses
Intensity of pressure deliverable	**SHOCK MED**	MAX 23 MPa
	SHOCK MED SP	MAX 19 MPa
Pressure operation machine	Of from the **SHOCK MED**	(1.0 - 5) bar in steps of 0.1 bar
	SHOCK MED SP	(1.0 - 4) bar in steps of 0.1 bar
Emission frequency	**SHOCK MED**	(1 – 20) Hz in 1 Hz steps
	SHOCK MED SP	(1 – 15) Hz in 1 Hz steps
Number of shots that can be delivered per treatment		(0 - 10000)
Number of shots tested		2,000,000
Classification according to directive 93/42/EEC		II B
Insulation class / applied parts according to EN 60601-1 standard		I / BF

Degree of protection against the ingress of liquids according to the EN 60601-1 standard		IPX0
Output channels		1
Protocols that can be stored in user memory:		200
Patient cards can be stored in user memory		Depending on the number of characters used to compile the
External dimensions (W x D x H):		41x35x19 cm
Machine body weight		10.1kg
Terms of use	room temperature	(+10 : +35) °C
	relative humidity	(10 : 80) % non-condensing
Conditions of storage/transport	room temperature	(-40 : +70) °C
	relative humidity	(10 : 100) % non-condensing
	atmospheric pressure	(500 : 1060) hPa

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

APPENDICES

Appendix A - ENVIRONMENTAL PROTECTION

The SHOCK MED shock wave therapy devices, compatibly with operational and safety requirements, have been designed and built to have a minimal negative impact on the environment.

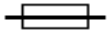
The criteria followed are those of minimizing the amount of waste, toxic materials, noise, unwanted radiation and energy consumption.

Careful research into optimizing machine performance guarantees a significant reduction in consumption, in harmony with energy saving concepts.

This symbol indicates that the product must not be disposed of with other household waste.

The user must dispose of the equipment to be scrapped by taking it to the designated collection center for the subsequent recycling of electrical and electronic equipment.

Appendix B – LABELS

Symbol	Meaning
CE 1936	Product certification issued by the notified body N° 1936
	Applied part BF
	Manufacturer
	Manufactured on
	Consult the user manual
	Attention, see the documents accompanying the product
	The product must be disposed of appropriately as "electronic waste", not together with other household waste
V	Mains powered
	Fuses: 2xT2AL250V/2xT5AL250V DIM:5x20mm
P	Power absorbed by the network
F	Emission frequency on the network

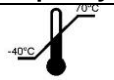
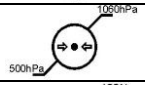
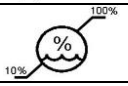
Symbol	Meaning
REF	Commercial model of the machine
SN	Badge number
Pressure	Device outlet pressure
Frequency	Output frequency
	Temperature limitation
	Limitation of atmospheric pressure
	Humidity limitation

Table 1

Label	Meaning
	Label indicating devices sensitive to electrostatic charges placed near the USB connector used for programming the machine.
FOOTSWITCH	"FOOTSWITCH" label, located on the rear panel of the machine near the pedal connector.
	Label indicating the mandatory reading of the instructions, located on the front panel of the device or near the output connectors

Table 2

Appendix C – LIST OF THERAPEUTIC SUGGESTIONS

No	Shockwave therapy treatments	Pressure (Cafe)	Frequency (Hz)	Pulses (No.)	Transmitter
1	Bunions	4	10	2000	15 mm
2	Epicondylitis and epitrochleitis	3	10	2000	9mm
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	15mm multi focused
7	Pubalgia	3	15	1500	15mm multi focused
8	Tendinitis and tendinopathies	3	10	2000	15 mm

Note: In the veterinary field, treatments are provided as in the human field; its use is mainly aimed at pathologies of the musculoskeletal system.

Appendix D – ELECTROMAGNETIC COMPATIBILITY TABLES

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

Guidance and manufacturer's declaration – electromagnetic immunity **FOR ALL EM EQUIPMENT**			
The EM device is designed to operate in the electromagnetic environment specified below. The customer or user of the EM equipment should ensure that it is used in such an environment.			
Immunity test	**Test level IEC 60601**	**Level of compliance**	**Electromagnetic environment – guide**
Download electrostatic (ESD) IEC 61000-4-2	± 8kV contact	± 8kV contact	Floors must be wood, concrete or ceramic tile. If the floors are covered with synthetic material, the relative humidity should be at least 30%
	±2; 4; 8; 15 kV in air	±2; 4; 8; 15 kV in air	
Transients/sequence of fast electrical pulses IEC 61000-4-4	± 2kV for power lines	± 2kV for power lines	The quality of the mains voltage should be that of a typical PC room
	±1kV for input/ output lines	± 1kV for lines input / exit	
Over-voltages IEC 61000-4-5	± 1kV between phases	± 1kV between phases	The quality of the mains voltage should be that of a typical PC room
	± 2kV between phase(s) and earth	± 2kV between phase(s) and earth	
Voltage dips, short interruptions and voltage variations on input lines of nutrition IEC 61000-4-11	0% U_T for 0.5 cycles	0% U_T for 0.5 cycles	The quality of the mains voltage should be that of a typical PC room. If the user of the EM device requires continued operation during mains voltage interruptions, it is recommended to power the EM device with an uninterruptible power supply.
	0% U_T for 1 cycle	0% U_T for 1 cycle	
	70% U_T for 25 cycles	70% U_T For 25 cycles	
	0% U_T for 250 cycles	0% U_T for 250 cycles	
Magnetic field at network frequency (50/60Hz) IEC 61000-4-8	30 A/m	Not applicable, the device does not contains components susceptible to magnetic fields.	Power frequency magnetic fields should have levels characteristic of a typical PC room
NOTE: U_T is the AC mains voltage before the test level is applied			

Guidance and manufacturer's declaration – electromagnetic immunity				
The EM device is designed to operate in the electromagnetic environment specified below. The customer or user of the EM equipment should ensure that it is used in such an environment. Portable and mobile RF communications equipment should be used no closer to any part, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.				
Proof of Immunity	Test level of IEC 60601		Level of conformity to	**Distance of separation recommended by:**
RF Conducted IEC 61000-4-6	3 Veff from 150kHz to 80 MHz		3 Veff	**d**= 30 cm
RF Radiated IEC 61000-4-3	3 V/m from 80 MHz to 2.7 GHz		3 V/m	**d**= 30 cm
Immunity to fields of proximity from devices communication Wireless RF 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	

SHOCK MED model:
SW version: 1.0.1
FW version: 1.0

SHOCK MED SP model:
SW version: 1.0.1dep
FW version: 1.0

SHOCK WAVE ACTUATOR REPLACEMENT PROCEDURE

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

WARNING: Before proceeding with the replacement of the kit it is necessary to turn off the machine with the main ON/OFF switch positioned at the rear. !

ATTENTION!: The EME warranty does not cover any damage due to negligence in replacing the kit.

IMPORTANT: NEVER OPERATE THE HANDPIECE BEFORE HAVING CORRECTLY INSERTED THE DISPENSING HEAD.

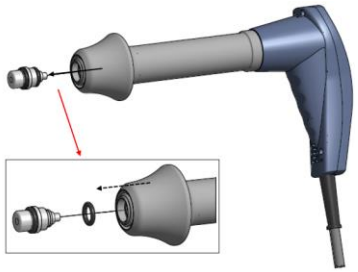
Replacement procedure

1. Insert the knob wrench onto the ring nut

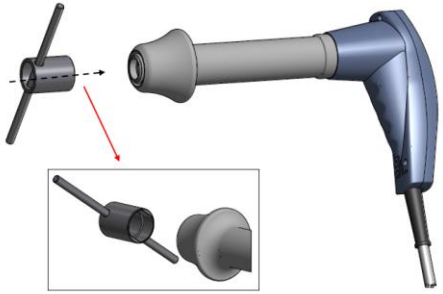
2. Rotate the wrench to loosen the tightening of the ring nut

3. Remove the ring

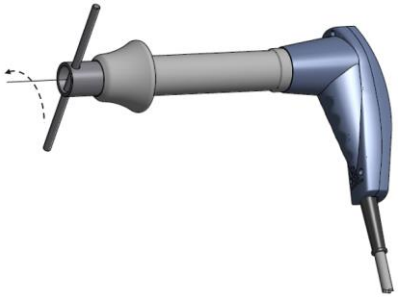
4. Extract the dispensing head (also the O-ring in case it does not remain on the head)



5. Insert the actuator removal wrench to unscrew the handle tube



6. Rotate the wrench to unscrew the handle tube

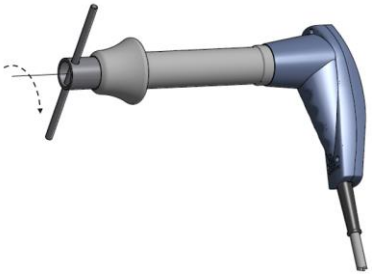


7. Remove the handle tube

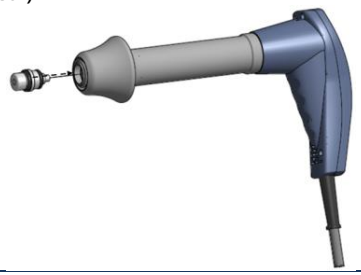
8. Pull out the shock wave actuator

9. Replace the actuator following the direction shown in the figure

10. Screw the handle tube back into the handpiece



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



12. Screw the tightening ring back on

13. The handpiece is ready for delivery again.

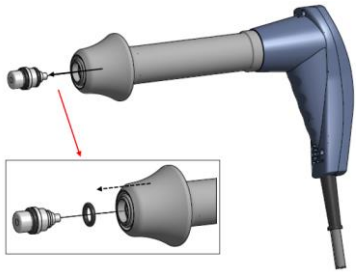
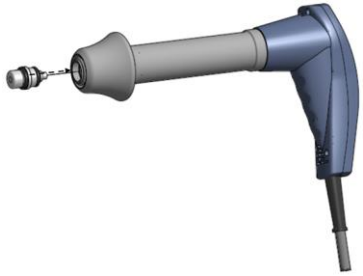
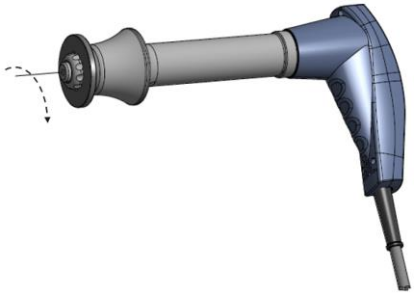
TRANSMITTER REPLACEMENT PROCEDURE

Tools: 1 Replacement Kit, 1 Knob Wrench.

WARNING: Before proceeding with the replacement of the transmitter it is necessary to turn off the machine with the main ON/OFF switch positioned at the rear. !

ATTENTION!: The EME warranty does not cover any damage due to negligence in replacing the transmitter.

IMPORTANT: NEVER OPERATE THE HANDPIECE BEFORE HAVING CORRECTLY INSERTED THE DISPENSING HEAD.

Physiotherapy transmitter replacement procedure	
1.Insert the knob wrench onto the ring nut 	2.Rotate the wrench to loosen the tightening of the ring nut 
3.Remove the ring 	4. Extract the dispensing head (also the O-ring in case it does not remain on the head) 
5.Insert the new dispensing head (including O-ring seal) 	6.Screw the tightening ring back on 

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

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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.

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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

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