EME ITALY

MAGNETOMED 7200-8400

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

Italian manufacturer of physiotherapy equipment since 1983

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INFORMATION ON THE MANUAL

This manual is addressed to:

- user of the machine;

- owner;

- responsible;

-people in charge of moving;

- installers;

- users;

- people in charge of maintenance.

This document provides valuable information regarding the installation, set up and use of MAGNETOMED-series equipment.

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

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

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

The limits of this manual are:

- the user manual cannot replace proper experience;

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

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

This manual reflects the state of the art at the time of sale and cannot be considered inadequate because later updated based on new information. The manufacturer has the right to update products and manuals without necessarily updating preceding products or manuals unless these have implications for the safety of the device.

The company will not assume any responsibility for any major cases:

- improper use of the machine;

- use against to specific national regulations;

- incorrect installation;

- defects in power;

- serious shortcomings in maintenance;

- changes and unauthorized interventions;

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

- total or partial non-observance of the instructions;

- exceptional events.

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

WRITING CONVENTIONS

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

NOTE

These contain important information and useful tips for operating the equipment

CAUTIONS

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

! WARNING !

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

WARRANTY

EMEsrl guarantees the quality of its products for a period of 24 months from the date of purchase, when information contained in this manual regarding installation, use and maintenance is strictly adhered to and the warranty coupon is returned within 15 days of purchase.

The guarantee covers the replacement of faulty parts.

The warranty does not however, include the replacement of the equipment.

The warranty does not cover any malfunction or damage caused by:

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

EME srl registered offices provide the warranty.

Should you need to return the goods then please note the packing instructions as follows. Enclose a copy of the purchasing receipt.

You should insure the postal package.

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

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

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

1. unplug the machine and any connections, devices, applicators etc;
2. carefully clean and disinfect all parts of the machine and accessories which have been in contact with patients;

Any equipment which the technical department does not consider hygienic (Italian law T.U.S. 81/2008 on safety in the workplace) will not be accepted;

3. disassemble accessories and any mechanical supports;
4. use original box and packing materials;
5. enclose Service Request Form (available from the manufacturer) on which to write detailed informations regarding the nature of the problem in order to facilitate the technical department's intervention and save time on repair.

NOTES

PRELIMINARY NOTES

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

USE

- Each time you click the START button or the STOP button the machine will emit a long confirmation beep.
- Each time you select the SMART-CARD will take a few seconds to allow the machine to recognize and load the card: meanwhile it shows the message PLEASE WAIT.
- The selection of the SMART-CARD is possible only if previously inserted into the slot.
- To prevent erasure or formatting of SMART CARD, confirmation is required.
- To navigate the software it is necessary to use the encoder knob that can: rotate (both clockwise and anticlockwise) by moving the selection of an option, or confirm the selection by pressing the knob itself.
- The keys shown on the display are touch.
- The magnetotherapy treatment must not be performed keeping the couple applicators and the cylinders in contact with the skin, therefore it is advisable to carry out the treatment always interposing an ecological medical sheet between the patient and the portable cylinders / applicators.

MAINTENANCE

- For an optimal use of the device and to guarantee its maximum performance, it is recommended to perform maintenance at the correct time and suggested ways.

CAUTIONS

PRELIMINARY NOTES

- The custode is liable for all damage caused by inadeguated packaging of the material. Keep the original packaging of the unit: it will be needed if the unit is returned to the company
- Do not use the equipment in places where it might get wet.
- Before operating the machine carefully check the correctness of the connections according to the instructions.

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

USE

- On request we can provide the user manual in electronic form.
- Because of security reasons, the only specific software must be loaded into each machine. In case of exchange of software, the machine may immediately stop all its functions, requiring the intervention of EME srl technical assistance.
- The Smart Card has to be introduced keeping the golden chip facing up
- A new Smart-Card has to be initialized using FORMATTING before being used.
- If the card is introduced in wrong way or is not formatted or results not correct, a warning window will appear with the information about the error. Close the window clicking OK to continue.
- SMART-CARD option is visible (and therefore selectable) only if the smart-card is properly inserted in its slot. In case of lacked insertion of the Smart-card in its slot or Improper insertion, the option button SMART CARD is not visible, for which a possible selection does not involve any action.
- The selection of programs to be loaded takes place by default in the user memory, that in cases of non-presence of the Smart-card (due to its lack or to an improper insertion in its slot) is the only support of available memory to load customized programs.
- The appliance or the system must not be used near other equipment and, if it is necessary to use it near other equipment, the medical electrical equipment must be observed to check normal operation in the configuration in which it is used.
- If the electro-medical device, interacting with another device, causes or receives detectable interferences, the user is invited to limit the interference by adopting one or more of the following measures:
    - Reorient or reposition the receiving device;
    - Increase the distance between the devices;
    - Connect the equipment to a scale of a circuit different from or to devices that cause interference;
    - Contact the manufacturer or local technician for assistance.
- Portable and mobile radiocomunication devices can affect the operation of the device.
- transportable RF communication equipment (including peripherals such as antenna cables and external antennas) should be used at a distance not less than 30 cm (12 inches) from any part of the device, including the specified cables. Otherwise, the performance of this device may be degraded.

MAINTENANCE

- Use the probes/applicators with care: any misuse may affect their performance and features.
- Under no circumstances technicians not authorised by EME srl are allowed to open and/or disassemble the probe/applicator: such tampering, besides damaging its characteristics, immediately invalidate the right to warranty.
- The equipment should never be disassembled for cleaning or inspection purposes: the units does not have to be cleaned internally, and if for some reason the unit must be opened, it should only be done by specialized technicians authorized by EME srl.
- Do not use thinners, detergents, acid solutions, aggressive solutions or flammable liquids to clean the external parts of the unit and accessories. Using these substances, or misusing the accessories, will cause the immediate voiding of all warranty rights, as well as irreparably damaging the unit.
- For optimal use of the apparatus and to ensure its optimum performances it is recommended to perform properly within the time and in the manner recommended maintenance actions.
- For a correct replacement of the installed fuses, observe the following indications:
    1. disconnect the power supply and open the fuse box using a screwdriver, makingsure you insert the screwdriver in the slot on the fuse box and levering up outwards;
    2. insert a screwdriver into the two side holes for fuse expulsion
    3. remove the old fuses
    4. insert a new fuse at a time by using a slight pressure to the left, with a finger
    5. push the box back to fit into the slot.
- It is recommended to perform periodic maintenance every two years, in order to check:
    - the intensity of any leakage currents;
    - the continuity and thus the integrity, of the ground conductor;
    - the correctness of the value of insulation resistance;

  in order to ensure the electrical safety of the device, ensure that it is operating in a safe guaranteed. For this kind of intervention you should contact a qualified service technician or alternatively EME srl or one of its authorized service centers.

WORKING PROBLEMS

- Only technicians authorized by the manufacturer may access the interior of the unit.

- You should contact EME srl or its authorized service centres for any repair work or further information.

! WARNINGS !

PRELIMINARY NOTES

- The correct position while moving the machine without trolley: the apparatus has to be moved exclusively by gripping it with both hands on the curved profiles of the lid.
- The correct movement of the trolley machine states that the device should be moved only by pushing it with both hands, pressing on the curved profiles of the cover.
- The perfect functionality of the device is guaranteed in accordance with the rules of installation and of use included, only with original accessories and spare parts.
- In the indicated temperature range, during normal use, in the case of continued use (up to 20 min) the cylinders and the applicator couple can reach temperatures of 46 °, 54 °, 62 ° without endangering the patient's health.
- If there are problems or installation difficulties, please contact the EME srl technical assistance department.
- Before connecting the cable to the mains plug, check that the equipment wasn't damaged during transport. Ensure that the power supply specifications on the mains socket correspond with the information on the label attached to the back of the unit.
- The electric current that powers the unit is VERY DANGEROUS. Before connecting or disconnecting the power cable from the connecter on the unit, make sure it is plugged out from the mains socket.
- The power cable has an earthed plug for safety reasons.
- Only use with a mains socket suitable for use with earthed systems.
- **The equipment should only be connected to electrical systems that fully comply with regulations**.
- If plug extensions are used, please verify the presence and integrity of the protective conductor to earth.
- Connect the equipment directly to the wall socket without using extensions. Failure to comply with these warnings may result in dangerous electrical discharges that could cause injury operators and compromise the functioning of the unit.
- The manufacturer is held responsible for the fundamental safety, reliability and performance of the device only if:
    - The electrical system of the premises complies with the appropriate regulations;
    - The device is used in accordance with the instructions for use.
- The use of MAGNETOMED device is not intended for subjects in pediatric age (≤14 years).

USE

- In order to ensure the functioning of the machine in conditions of absolute safety for the patient, the operator must pay attention to the necessity of a periodic maintenance (every 2 years) of the equipment. EME srl authorized personnel should carry out such operations.
- It absolutely forbidden the use of the device in the presence of a flammable anesthetic mixture and oxygen-rich environments. In case of non-compliance with this indication, EME srl will not be responsible for any accidents.
- It is absolutely forbidden to cover the ventilation slots: such an action may not allow the machine to work in safe conditions. In case of non-compliance with this indication, EME srl will not be responsible for any accidents.
- It's important to pay the attention of the operator to the necessity to verify the correctness of the electric installation of device before activating the supply switch.
- It is advisable to suspend the therapeutic treatment if it were to appear some disturbances during its emission.
- It's strongly advised not to hold the device on in state of start without using the probe, it could overheat.
- If the button OK is pressed to confirm the software updating before having onnected the USB-port to the source containing the software updating, the device goes out from the main program and enters in the updating routine waiting for the USB connection. A screen indicates the missed connection. If the support to connect to carry out the updating is not available, it is necessary to switch off the device and turn it on again through the general switch to restart the device with the available software.

MAINTENANCE

- For safety reasons before carrying out any maintenance or cleaning the unit, **YOU MUST** turn off the equipment with the power switch at the back and unplug the socket connected to the mains.
- Before every treatment, it is recommended to clean with caution all of the accessories and the parts of the equipment that have been to contact with the patient.
- The operator must pay attention to the necessity of a periodic maintenance (every 2 years) of the probes/applicators. EME srl authorized personnel should carry out such operations.
- The cleaning and disinfection must be done systematically before the therapeutic treatment which subject the patient.
- Do not use thinners, detergents, acid solutions, harsh solutions or flammable liquids to clean the outside of the unit and its accessories. The use of these substances, with the improper use of accessories, irreparably damages the equipment and the warranty will lapse.
- Always control sometimes the integrity of the cable and of the probe/applicator connector: they must not be damaged or worn.
- It is advised that personnel with technical preparation substitute the fuses, to perform the operation in safety conditions.
- Do not open the device: inside there are high voltages that may be hazardous.
- Only personnel authorized by the manufacturer may access the internal components. For repairs and further information please contact EME srl or its authorized service centers.

WORKING PROBLEMS

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

INTRODUCTION OF THE TECNOLOGY

PHYSICS AND EFFECTS OF MAGNETIC FIELDS

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

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

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

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

But how do these micro-currents interact with the body?

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

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

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

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

PRIMARY	SECONDARY
1.Magneto-mechanical **Cellular:** – cellular membrane	**1.Chemical** **2.Physical-chemical:** – modification of the diffusion coefficients in the cellular membrane
– orientation of the sub-cellular organelles and macromolecules (magnetosomes Fe_3O_4) – gradients of concentration, rotation, translation of the paramagnetic molecules (metalloprotein, cytochromes, molecular oxygen and free radicals) – orientation and electric dipoles and diamagnetic substances (retina rod cells, nucleic acids end enzymatic reactions) **2.Magneto-electric:** – induction of currents in cellular membrane junction systems – induction of micro-currents(μA/ cm^2) a) in conducting tissues b) in endovessel blood exposed to magnetic fields orthogonal to vessel – Gauss effect (modification of the electric resistance of electrical charges in movement)	– modification of the moving speed of the biological liquids in the vessels and intercellular spaces – modifying effect on osmotic pressure. **2.Physical:** on nucleic acids, water, mucopolysaccharidosis acids, electro-magnetic effects (Hall, Etinghausen and Nernst effect) **3.Thermic:** negligible for field intensities of less than 1000G and for frequencies of less than MHz. **4.Athermic effects:** resonance and coherence linked to the biological substrate receiving the incident impulses.
Biological effects on apparatuses and systems 1. Immune system 2. Bone tissue 3. Central Nervous System 4. Endocrine glands 5. Blood	

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

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

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

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

- **on the blood**: a positive effect on the *calibre of the vessels and on the viscosity* of the blood with improvements in local circulatory conditions and oxygen pressure (hypervascularization) which would also explain the acceleration of the healing processes of soft tissue and bone lesions, and trophic lesions of peripheral circulatory origin, as well as the beneficial effect on biological structures conditioned by the diffusion of oxygen such as, for example, cartilage;
- **on the immune system**: an increase of immunoglobulin-G and circulating

  leukocytes reinforcing the immune system; in the regulation of the production of steroid substances and endogenous oppioides (and therefore modulating on the algic system);
- **on the endocrine system**: inhibition of some hormonal functions (parathyroid) and stimulation of others;
- **on the central and peripheral nervous system**: a reduction of the activity of the sympatic system (for hyper-polarization of the pre and post-synaptic membranes, or modulating the frequency of the stimuli in case of the vasodilatation); alterations of the activity of cerebral cells;
- **on the metabolism;**
- **on cellular reproduction**;
- **on tissue regeneration**: genesis of collagen on the part of fibroblasts and on angiopoiesis with vascular neo-formation (which would explain the favourable effects of magnetic fields on the healing processes of injuries, ulcers and torpid sores);
- **on bone tissue**: the start of the osteogenesis is stimulated, where this does not happen naturally (pseudo-arthrosis, delayed consolidation), providing opportune signals of cell reactivation (mesenchimal of the periostosis, monocytes, fibroblasts, osteoblasts that act on the formation of the internal callus), improving the hematic supply, inhibiting the parathormone and therefore favouring the activity of the osteoblasts.

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

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

IN GENERAL

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

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

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

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

Such equipment are not bound to diagnosis, prevention, monitoring, compensation of injury or handicap, substitution or modification of the anatomy, control of the conception, support/vital support of functions but allow to treat special pathologies and to reduce the illness.

A special intervention is not required in the event of failure of the medical device, but just a normal maintenance/repair.

INTENDED USE

The MAGNETOMED-series equipment is a medical device, that emits magneto-therapy treatments with the auxilium of specific applicators, that allow the treatment emission generating a magnetic field adjustable in intensity and frequency ,producing an induction in the surrounding space.

The solenoid has the exclusive patent MFC, which drastically reduces the magnetic induction produced outside the solenoid and concentrates the force lines inside it, thus acting only on the patient and not on the operator.

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

In fact, the operator must be appropriately qualified and he carefully studied the contents of the user manual in order to use the device; or, it must operate under the supervision of a health professional adequately qualified to use the machine, able to understand the benefits and the limits of therapy and to work in conditions of safety for the person undergoing treatment.

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

The use of MAGNETOMED device is not intended for subjects in pediatric age (≤14 years).

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

INDICATIONS

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

- acute arthropathies;
- outcomes of fractures (delays in consolidation and pseudarthrosis). Several causes that can prolong or even prevent healing for example:
  - the severity of the trauma: fractures accompanied by crushing, loss of bone and skin substance and infection present many problems both in treatment and in healing;
  - advanced age, the presence of metabolic diseases (for example diabetes) or treatment with immune-suppressing drugs adversely affects the healing process;
  - insufficient activation of reparative processes, the cause of which cannot be identified with certainty. 5-10% of fractures, depending on the statistics, can result in delayed or non-union, which can be effectively treated in most cases by electrical and magnetic stimulation of osteogenesis;
- distortion trauma;
- bruises;
- inflammatory and degenerative diseases of the bones and joints;
- scapulo-humeral periarthritis (also calcification);
- osteoporosis.

CONTRA-INDICATIONS

The magnetic therapy treatments cannot be applied in case of:

- patients with cardiac rhythm disorders: continuous magnetic fields used in RMN units have determined an increase in electro-cardiogram T wave width as well as a number of bradycardia-related phenomena and other arrhythmias. However, such reasonably rare effects can be reversed by decreasing the intensity of the field or suspending the treatment;
- presence of metal prostheses (screws, cramps, pins) or clips (that are ferromagnetic);
- patients fitted with pacemakers (absolute contraindication): under no circumstances should such patients be exposed to more than 0.5 mT (0.5 millitesla = 5 gauss) (CERN studies 1995) as there is an elevated risk of applied static and pulsated magnetic fields causing pacemaker malfunctioning. In fact alterations of the atrial system and subsequently inhibition of the ventricular signal have been observed and such inhibition, if protracted for more than a few seconds, can have significant clinical consequences;
- Patients with active implantable devices
- slight rosacea,
- epileptic patients even when undergoing pharmacological treatment;
- neuro-vegetative system pathologies;
- patients with general nervous disorders;
- pregnancy (possible slowing and modifying of foetus growth, especially in the first two months of embryo life);
- patients with particularly heavy menstrual cycles: the vasodilating effect of magneto-therapy may further increase an already heavy flow.

- open hemorrhoids and vascular lesions in general: for the same reasons as mentioned in the preceding point.
- patients fitted with intrauterine devices (spiral).
- patients with mycotic infections;
- manifest hypersensitivity to electro-magnetic fields: this produces quite variable symptomatology which may consist of slight or marked asthenia, irritation, metal tastes and/or insomnia,
- fever or thermoregulation disorders
- cancro e tubercolosi;

Take particular care:

- when treating patients taking Verapamil or other medicines that affect the calcium pump as such drugs are rendered less effective by pulsated magnetic fields;
- in cases of arthrotomy postpone the use of magnetic fields for at least 15 days;
- in cases of nerve root compression syndromes it is first necessary to remove the cause (for example, carpal tunnel syndrome);
- in presence of cardiac valve prostheses.

PRELIMINARY NOTES

UNPACKING

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

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

The unit and accessories are wrapped in transparent sheets of polyethylene protection and contains the following:

- the User Manual;

- n.1 mains power supply cable;

- n.2 spare fuses (see technical specifications);

- n.1 magnetic ring(to test the device)

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

SETTING UP

Installation of the magneto-therapy equipment is fast and simple.

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

The following environmental conditions are ideal when installing the equipment:

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

If the device is used at an ambient temperature above 35 °, it is not possible to use the device by setting the maximum power value since the cylinders and the applicator pair can reach temperatures of 54 °, 46 ° and 62 ° respectively. In this case, set a power value equal to 50% of the maximum allowed value.

ACCESSORIES

The devices can be used with the following accessories:

Descriptions	Supplied	Optional
Power cable supply	**1**	
Spare FUSES (see technical specifications)	**1**	
User manual	**1**	
Magnetic ring for testing the device	**1**	
LC60 Couch with manual sliding. Couch in light-weight aluminium alloy with 1 sliding track, 1 solenoid diam., 60cm and 30cm large (manual sliding)		x
LC60/2 Couch in light-weight .aluminium alloy with 2 sliding track, 2 solenoids, diam. 60 cm, largeness 30, for total body treatment.		x
CP30 portable cylinder (with feet), diameter 30cm		x
CP60 portable cylinder (with feet), diameter 60cm		x
American power cable supply		x
English power cable supply		x
3 shelf trolley (60x37x86cm)		x
Smart-card		x
Kit software update		x
CP - Pair of magnetic applicators (16x10x3,5 cm)		x
Cable for the cylinder		x

Descriptions	Supplied	Optional
LC60 Couch with ELECTRIC sliding. Couch in light-weight aluminium alloy with 1 sliding tracks, 1 solenoids diam. 60cm and 30cm large and 1 telecontrol (electric sliding)		x
Solenoid 60x30 cm for magnet bed with sliding bed		x
Carrying case in TNT		x
Therapy manual		x
User manual paper		x
Poster Magnetomed		x

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

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

It is easy to assemble the cylinders/applicators that generate the magnetic field: once you have securely positioned the cylinder on the bed or on the support, you must connect the power cable of the cylinder/applicator to the unit/generator by inserting it into one of the connectors (the number of channels that can be used depends on the model) on the back panel.

Contact authorised dealears EME srl for problems or difficulty installation.

USE OF ACCESSORIES

Portable cylinder: on the solenoid there is an arrow indicating the north. This arrow must point proximally.
Cylinder on the bed: on the solenoid there is an arrow that must face the patient's head.
Pair of applicators: the blue side represents the south pole while the gray side the north.
The pair of applicators can be used in the following ways:

- or interposing the part to be treated to the couple of applicators: in this case it is necessary to put the opposite poles in contact with the skin;
- or by placing the applicators pair alongside the area to be treated: in this case the two applicators must have the same polarity (same color).

CONNECTIONS

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

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

When using an extension lead, make sure that it has been earthed.

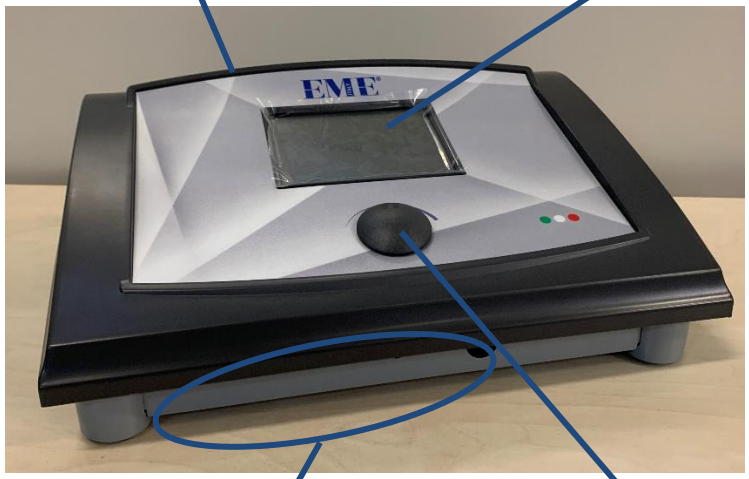
Failure to comply with the above instructions may lead to dangerous electrical discharge causing machine damage and harm to persons.

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

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

DESCRIPTION OF THE EQUIPMENT

MAGNETOMED 7200



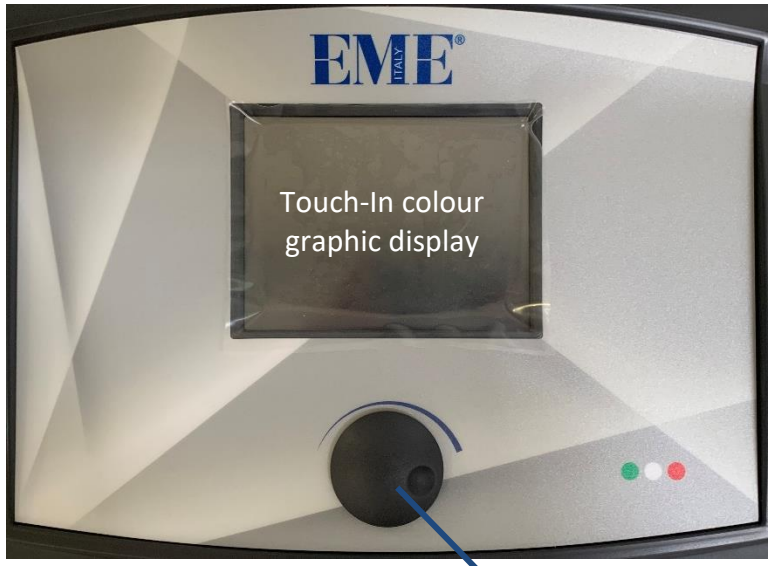
MAGNETOMED 7200 is a generator for ass

embled magneto-therapy on table case, with two independent outputs or used in synchronous mode (**CH1+CH2**).

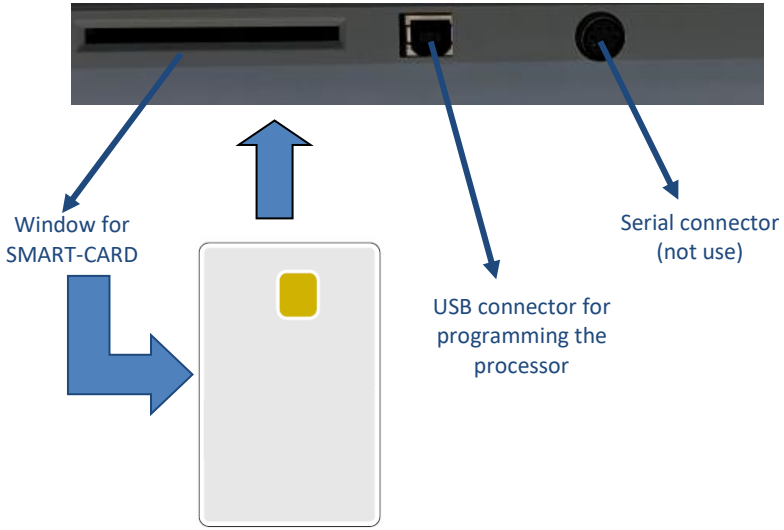
MAGNETOMED 8400

MAGNETOMED 8400 are generators for magnetic therapy, mounted on trolley, with four independent outputs. It allow the following combinations in synchronous mode : (**CH1+CH2),(CH3+CH4), (CH1+CH2+CH3+CH4)**.

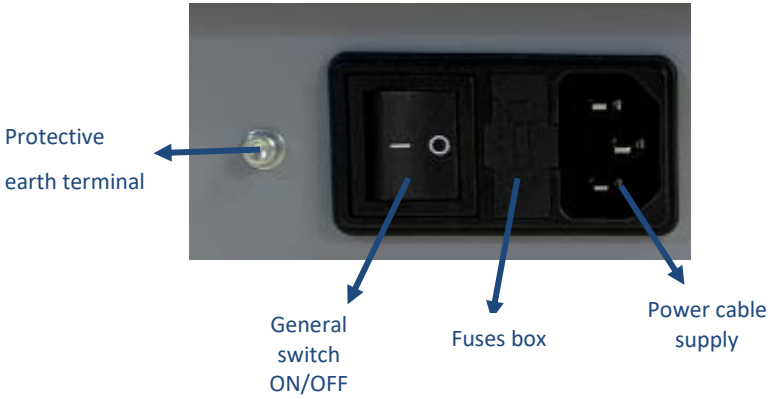
FRONTAL PANEL



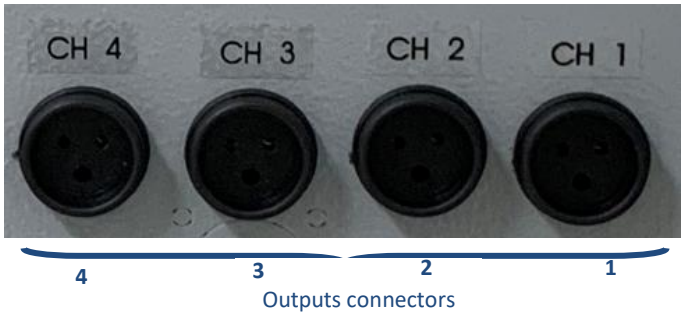
PROGRAMMING PANEL



POWER SUPPLY BOARD



OUTPUTS PANEL



Note:

1) output connector n°1
2) output connector n°2
3) output connector n°3 (only for MAGNETOMED 8400)
4) output connector n°4 (only for MAGNETOMED 8400)

HOW TO USE OF THE DEVICE

This section provides important information and instructions on how to make the best use of the equipment for magneto-therapy MAGNETOMED-series.

All the control functions and the machine itself are handled and co-ordinated by a microprocessor: apart from making pre-memorised programmes available for application, the microprocessor ensures that the machine can be personalised and operated in a highly safe and efficient manner.

Interfacing allows for the operator to communicate with the unit by means of a large, clear graphic backlit liquid crystal display screen (LCD) through which all operational messages required by the operator, work status during operation, and errors are visualised.

The following paragraphs illustrate the procedures to be carried out and the technical specifications of the MAGNETOMED-series unit. They also deal with the different options available, from the selection of a pre-memorised programme for use in specific treatments as well as how to determine the correct working parameters for “personalised” applications.

BEST USE

After having installed and correctly positioned the machine as per the instructions described in the previous sections and connecting the applicator correctly, plug the machine into a 230Vac wall socket and switch on using the ON/OFF main switch on the back panel of the unit.

Once turned on, the LCD display lights up and unit is ready for use.

With the first turn on of the device, you can set the language from the six available. Turn the encoder to select the desired language and press it to confirm the selection. Then press the SAVE button to save the changes. A confirmation message will inform you of any modification.

After a few moments to load the settings, the LCD display will light up showing the logo (see Fig.1), and appears a screen that allows you to select between four operating modes (Fig.2) by tapping the corresponding button on the screen.

If you want to use the Smart-Card to create new customised programmes or to run those already stored, insert it as shown in the Fig.3, with the chip facing upward.

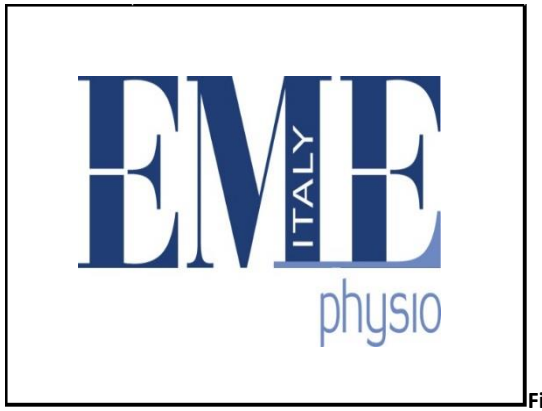


Fig.1

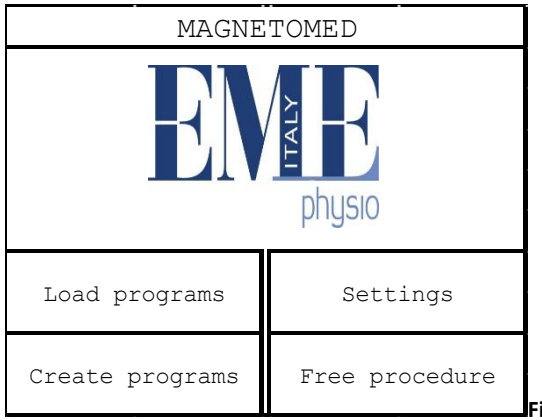


Fig.2

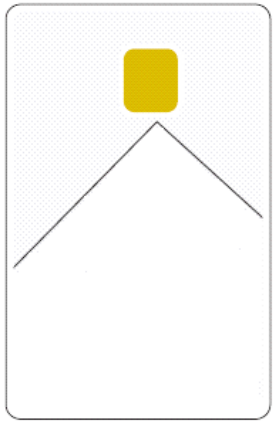


Fig.3 – SMART-CARD

SETTINGS

The basic settings can be modified and stored in the internal memory and will be called automatically when the unit is switched on.

Pressing the button for the function SETTTINGS appears the screen of the fig.4.

Turning the encoder (by the default this is located on the menu VARIOUS) you select the function that you want to change, then pressing this knob confirms the choice.

The screen displays also the version of the software installed on the equipment and contacts of the company.

Pressing the button EXIT, to return to the screen of the fig.2.

VARIOUS

In the screen of fig. 4, press the encoder knob to select VARIOUS section (which is selected by default); then appears the screen of fig.5.

You can perform the following operations:

- format the secondary supports of memory available such as smart-card and user's memory;
- customize or turn off the acoustic signal to suit operator preferences;
- enable or disable the functionality of synchronization of the output channels between the three available: (1+2), (3+4), (1+2+3+4), enabling the machine to provide the same therapeutic treatment on the output channels selected for synchronization.

For to format one of the secondary supports of memory available, first turn the encoder knob until to position the cursor on the menu of memory that you want to format, then push the encoder knob to confirm the choice.

If you select the FORMAT SMART-CARD function (which is selected by default), appears the screen where you are asked to confirm the operation in order to avoid accidental formatting (fig.6).

Pressing the EXIT button to cancel the format operation of the selected memory support and returns to the screen in fig.5. Pressing again the EXIT button to return to the screen in fig.2.

To confirm the format operation , press instead the function key for the button FORMAT.

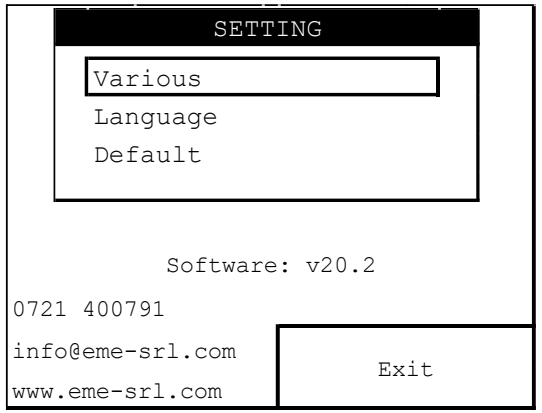


Fig.4

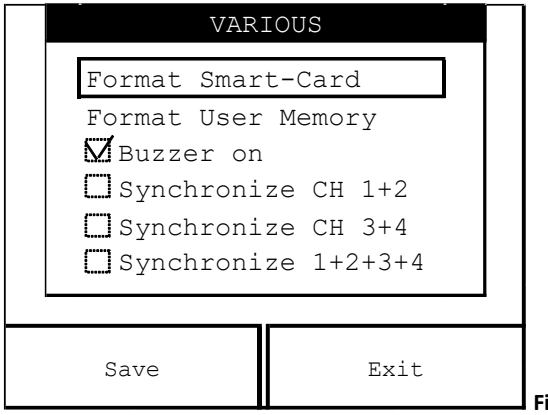


Fig.5

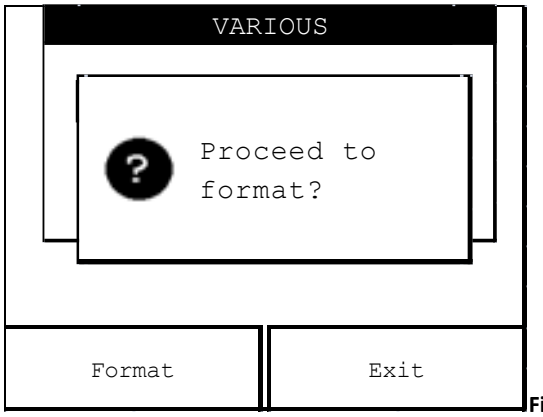


Fig.6

If the smart card is not properly inserted, a message will appear, in which the user is informed that the smart card is not inserted. The operation fails and returns to the screen in fig. 5.

Instead in the case of correct insertion of the smart card in its slot, press the FORMAT button, the machine displays a message that informs the user on the progress of the selected operation, and when finished you will see a screen that informs the user of the end of the requested operation (see Figure 7). After few seconds you return to the main screen of this section.

It is important to remember that the smart-card formatting is necessary when you insert a new card that has never been used, and you can use the FORMAT SMART-CARD to delete it completely , making it available, i.e. to use it in a different equipment.

The formatting of user memory is performed in the same way to that of smart card, selecting the menu USER MEMORY FORMAT in place of SMART CARD FORMAT menu.

Pressing the encoder knob on the BUZZER menu , it's possible to turn on or to turn off the acoustic signal. When there is a check the acoustic signal is on.

Pressing the SAVE button, stores the desired sound settings. Pressing the SAVE button, returns of the screen of the fig.4

LANGUAGE

To choose the language in which you wish to have all the commands and messages, rotate the encoder knob then press this knob at the LANGUAGE menu (see fig.4).

To select the desired language (italian, english, french, spanish, german and russian) rotate the encoder knob until to reach the correspondent language, then push this knob for to confirm the choice. Finally, press the button for the function SAVE for to train the device to work with the selected language. It returns to the screen in fig.4.

Otherwise pressing the EXIT button, you return to the screen of fig.4 without that is applied any modification.

To change the language back, you can repeat this procedure at any time.

DEFAULT

Allows to set the parameters of a standard therapy, most commonly used, that can be immediately used with the FREE PROCEDURE function.

On the screen of fig.4 turn and then press the encoder knob at the DEFAULT menu to enter in this section.

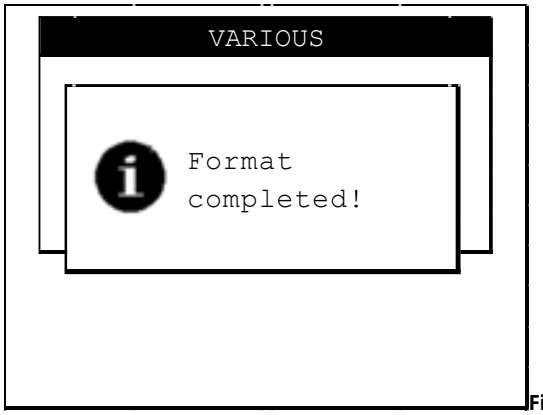


Fig.7

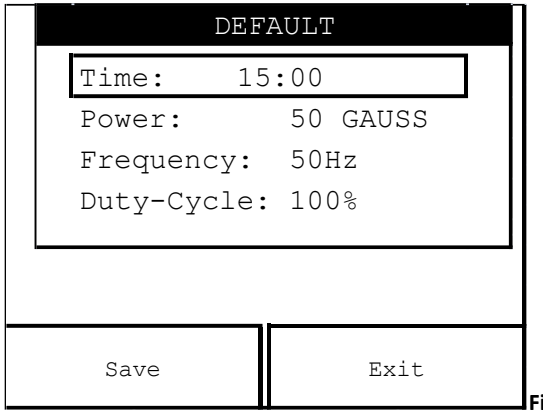


Fig.8

Appears the screen of fig.8 where it's possible to set the default program of the device intervening on duration, power, frequency and duty-cycle as parameters; selecting them by the rotation of the encoder knob and then pressing this knob to highlight the selected parameter.

Then turn again the knob (in clockwise way for increasing values, in counter-clockwise way for decreasing value) until to reach the desired value to assign at the selected parameters and push again the encoder knob to exit the modification procedure.

Pressing the button for the function SAVE, you return to the screen of the fig.4.

Otherwise pressing the EXIT button, you return to the screen of fig.4 without that is applied any modification.

FREE PROCEDURE

It Allows to use very quickly the therapic parametrs, saved by DEFAULT function and allows you to create customized programs that can be used immediately but not stored.

NOTE: Remember to perform magnetotherapy treatment avoiding direct contact between the patient's skin and the applicator pair or cylinders. It is advisable to deliver the treatment by always placing an ecological medical sheet between the patient and the portable cylinders / applicators.

Pressing the FREE PROCEDURE taste (fig.2), appears the screen of the fig.9.

Before starting treatment, you can change the parameters of treatment such as duration, power, frequency and duty-cycle, select them rotating the encoder knob and then pressing it on the selected parameter.

Then turn again the knob to modify the parameter value and push again the encoder knob to exit the modification procedure.

By pushing the button related to the function CHANNEL 1 you can choose the treatment channel: the channel 1 will be alternated by channel 2 and by channel 1+2 in the Magentomed 7200, instead for the Magnetomed 8400 in the independent mode the channel 1 will be alternated by the channel 2, by the channel 3 and by the channel 4. For the Magnetomed 8400 in the synchronize mode 1+2 the channel 1+2 will be alternated by the channel 3 and by the channel 4, instead in the synchronize mode 3+4, the channel 1 will be alternated by the channel 2 and by the channel 3+4.

Push the button START to run the selected treatment: a rotating hourglass shows that the device is emitting, the duration parameter shows the remaining treatment time with a countdown. The emitting channel currently used is shown with a small sign inside the frame of the button EXIT, in its upper side.

Pressing the STOP button the emission is suspended and appears the screen of the fig.10.

By pushing again the button START the emissions resumed from the point where it was interrupted and continues until the set time runs out. Then the system communicates to the operator with a message that the treatment is finished and the software loads back the screen as in fig. 9. While pressing the STOP button the emission finally ends and you return to the screen of the fig.9.

Pressing the button for the function EXIT you return to the screen of the fig.2.

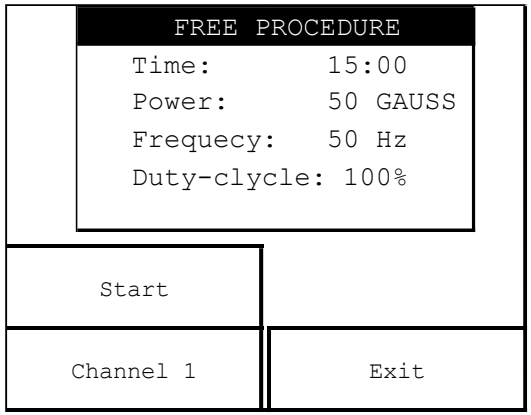


Fig.9

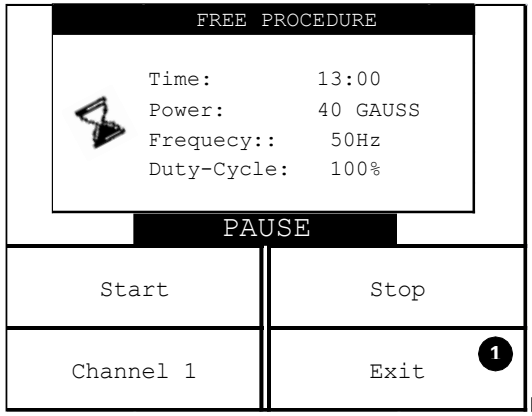


Fig.10

LOAD PROGRAMS

Pressing the LOAD PROGRAM button on the screen (see fig.2), appears the list of therapeutic protocols stored in the main memory (as shown by the frame around the STANDARD PROGRAMS button which is selected by default). These programs cannot be deleted but can be overwritten by changing the parameters of interest without saving.

Instead pressing the USER PROGRAMS button, appear on the screen the numbered sections (with default parameters) that will contain the programs created with the CREATE PROGRAMS function, and you can load programs stored in the user memory.

Finally pressing the SMART-CARD PROGRAMS taste, appear on the screen the numbered sections (with default parameters) that will contain the programs created with the CREATE PROGRAMS function, and you can load customized programs, stored in the smart-card.

NOTE: If you save a program on Smart-Card but the Smart-Card is not inserted, the operator is alerted by an alarm message to the not inclusion of the Smart Card into place and then the inability to be able to continue in the operation of storage programs.

The stored programmes reflect the fruit of many years experience supporting expert professional operators. Appendix **C** shows a list of the programmes available .

Pressing the EXIT button (whatever the memory selected) returns to the screen of the fig.2.

To start the desired treatment, turn the encoder knob to reach the desired protocol, then press it to confirm the selection.

Once the display shows the selected program screen, you can go directly to its execution by simply pressing the START button.

Before initiation of therapy, however, you can modify any parameter, as discussed in section FREE PROCEDURE, but the program can neither be stored nor renamed.

CREATE PROGRAMS

This function allows to create and to store "customized" therapeutic programs in the Smart-card or in the user memory, which are the only memory available to save the new programs.

Pressing the CREATE PROGRAMS taste on the screen (see fig.2) to create a program; appears the screen of the fig.11.

Pressing the encoder knob, you can start by default the creation of the program on the user memory (as shown by the frame around the USER PROGRAM button).

Instead, press the SMART-CARD PROGRAMS button to create a program on the smart-card.

NOTE: If you save a program on Smart-Card but the Smart-Card is not inserted, the operator is alerted by an alarm message (see dfig.12) to the not inclusion of the Smart Card into place and then the inability to be able to continue in the operation of storage programs.

Once you select the support of memory in which to save the program, press the encoder knob to confirm the selection. It appears the screen of the figure 13.

At this screen, to assign a name to the program press the encoder knob: appears a cursor under the first character (see Figure 14), indicating the possibility to switch between the characters that you want to change by turning the knob. Then press the encoder knob at the character to confirm your choice.

Now the selected character is surrounded by two sliders (fig. 15), which means that the character is changed. Rotating the encoder to choose a new character to enter and press the encoder knob to confirm the selection. This exits from the routine to change the selected character.

Repeat the procedure for all the characters that you want to change, then press the OK button to confirm the new name to be entered. You return to the screen of the fig.13, where, however, the program now has a new name.

Before making the save, you can change the parameters of treatment, as described above in the FREE PROCEDURE menu.

Press the button corresponding to the SAVE button to confirm saving the custom program with the new name on the storage support initially selected. The operator will be notified of the rescue, then the screen will appear in fig.16.

After a few moments it returns to the screen in fig.11. Press the EXIT button to return to the fig.2.

MAINTENANCE

The MAGNETOMED-series device for magnetotherapy do not require any particular maintenance operations , but only a periodic maintenance and cleanliness of the probes, in order to ensure the better operating conditions, guarantee the effectiveness of the treatment and the safety of the patient. A special intervention is not required in the event of failure of the medical device, but just a normal maintenance/repair .

When cleaning the outer part of the equipment, make sure to use a soft, clean cloth dampened with luke-warm water or very mild non inflammable detergents. The front panel can be cleaned in the same way .

The cylinders/applicators must be cleaned with water and denaturated alcohol only. All parts must be completely dry before re-using them.

Replace the cylinders/applicators with care at the end of each treatment session.

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

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

Do not immerse the unit in water.

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

The unit must under no circumstances be opened or dismantled in order to clean or check inner parts of equipment does not require cleaning of inner parts and in all cases, only specialised technicians or EME srl authorised personnel should carry out such operations.

The expected work life of device is 10 years.

TECHNICAL PROBLEMS

The equipment for magneto-therapy MAGNETOMED-series has been designed and manufactured using highly advanced technology and first class components for reliable and efficient performance.

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

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

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

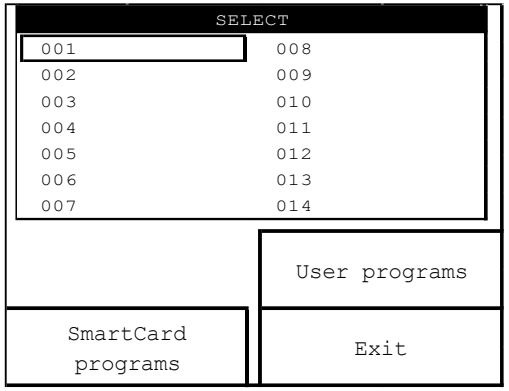


Fig.11

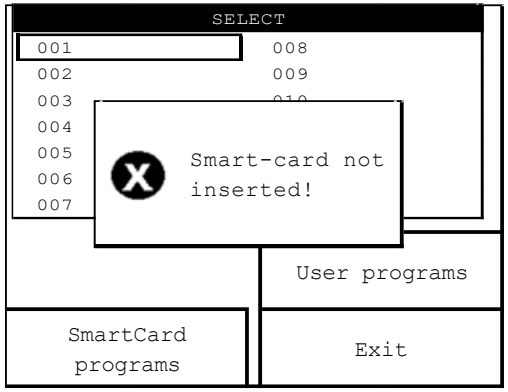


Fig.12

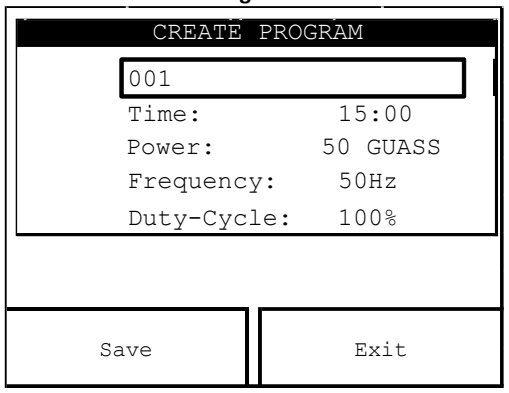


Fig.13

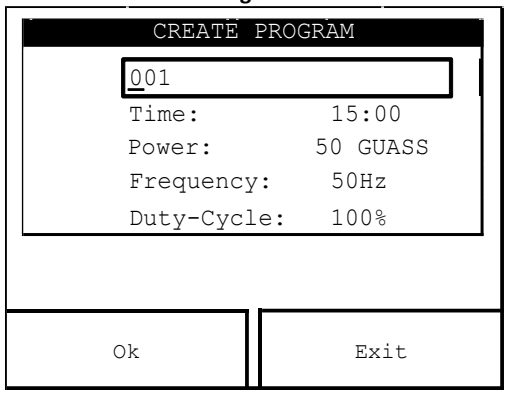


Fig.14

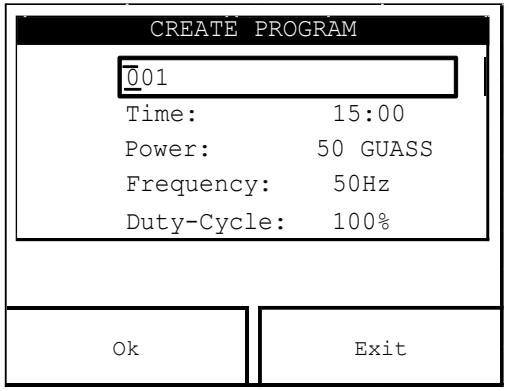


Fig.15

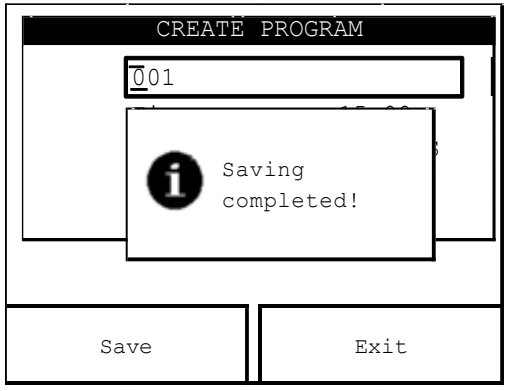


Fig.16

ELETTROMAGNETIC INTERFERENCES

The equipment for magneto-therapy has been designed and manufactured according to the ELECTROMAGNETIC COMPATIBILITY DIRECTIVE 2014/30/UE with the aim of providing adequate protection from harmful interference when installed in homes and health establishments.

All required measurements and tests have been carried out in EME's internal Testing,

Measurement and Inspection laboratory (LPMC), in addition to other external specialised institutes.

The customer, upon prior request, may view the reports relative to EMC measures within the company.

The equipment does not generate significant radio frequency energy and is adequately immune to radiated electromagnetic fields. Therefore it does not detrimentally interfere with radio-electric communications, electro-medical equipment for monitoring, diagnosis, therapy and surgery, office electronic devices such as computers, printers, photocopiers, fax machines, etc. or any electric or electronic equipment used in these environments, as long as said equipment complies with the ELECTROMAGNETIC COMPATIBILITY directive .

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

TROUBLESHOOTING CHART

PROBLEM	POSSIBLE CAUSE	SOLUTION
Front panel LCD display doesn't come on. The equipment doesn't work..	Mains plug not plugged in properly.	Check that the mains socket is working.
	Mains cable not properly connected to the back connector on the equipment	Plug in properly and connect cable to the back connector of the equipment
	Mains cable worn or blocked.	Replace the mains cable.
	Back switch off.	Switch on the mains switch.
	Fuse or fuses defective or blown	Substitute the missing, defective or blown fuses.
	Electronic control circuit malfunction.	Contact the EME srl assistance centre.
	No mains voltage.	
Front panel display doesn't come on.	Defective components in the electronic control board.	Contact the EME srl assistance centre.
Some commands on the front control panel are not working properly.	Defective keys or buttons	Contact the EME srl assistance centre.
	Electronic control system malfunction.	
The equipment turns on, but there is no magnetic field emission.	Faulty connections in the output circuit of the cylinders/applicators.	Check the correct application of the output and the condition of the connections.
	Cylinder/applicator cable blocked or badly connected.	Replace the faulty cylinder/applicator or those that show evident signs of wear and tear on the covering or on the cable.
	Output cable worn and/or faulty connections.	
	Current generator electronic circuit fault.	Contact the EME srl assistance centre..
The equipment works properly but there is a notable fall in treatment efficiency.	Cylinder/applicator connection not perfectly effective.	Contact the EME srl assistance centre.
	Cylinder/applicator damage (following a fall or violent impact), especially in the point of connection of the power cable.	
	Interruption of the internal conductors of the cylinder.	
	Electronic circuit current generator not properly calibrated or defective..	

TECHNICAL FEATURES

Power supply		230 Vac 50-60 Hz ±10%
Maximum Absorbed power	**MAGNETOMED 8400**	900 VA
	MAGNETOMED 7200	450VA
Double fuse protection (T)	**MAGNETOMED 8400**	6.3 A - T - 5 x 20 mm for 230Vac supply
	MAGNETOMED 7200	3.15 A - T - 5 x 20 mm for 230Vac supply
Backlit LCD display to view and check the operating parameters		graphic 320 x 240 pixel touch screen + encoder
Programmable treatment time		Up to 99 minutes
Duty Cycle adjustable		(10÷100) %
Programmable treatment frequency		(1 - 100)Hz
Electrical insulation class / applied parts in compliance with the UNI EN 60601-1 standard		I/BF
Device class in compliance with the 93/42/CEE directive		II A
Degree of protection against the input of liquids according to the UNI EN 60601-1 standard		IPX0
Maximum induction		100 Gauss ± 20%
Output channels	**MAGNETOMED 8400**	4 independent
	MAGNETOMED 7200	2 independent
Stored protocols		81
Storable protocols in the smart-card		200
Storable protocols in the user memory		200
Magnetomed 8000 series : trolley container in plate , external size (width x height x depth)	**MAGNETOMED 8400**	39 x H89 x 30 cm
Magnetomed 7000 series : plastic desktop container , external size (width x height x depth)	**MAGNETOMED 7200**	39 x H14 x 30 cm
Unit body weight	**MAGNETOMED 8400**	23,5 Kg
	MAGNETOMED 7200	3,9 Kg
Conditions for use	Room temperature	(+10 ÷ +40) °C
	Relative humidity	(10 ÷ 80) % without condensation
Conditions for stocking / transport	Room temperature	(-40 ÷ +70) °C
	Relative humidity	(10 ÷ 100) % without condensation
	Atmospheric pressure	(500 ÷ 1060) hPa

APPENDICES

Appendix A - ENVIRONMENTAL CONSIDERATIONS

MAGNETOMED-series equipment for magneto therapy has been designed and manufactured to have minimal negative environmental impact, in line with its operational and safety requirements.

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

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

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

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

Appendice B – LABELS

Simbol	Mean
CE 0476	This product complies with regulations issued under the certification from a Notified Body
	Applied part BF
	Manufacturer
	Date of manufacture
	Consult instructions for use
	Attention
	The product must be dispose of as “electronic waste”, not as “domestic waste”
	input characteristics
V	Input voltage to the device (mains)
	Fuses: 2xT6.3AL250V o 2xT3.15AL250V
W	Input power of the device (absorbed power)
F	Input frequency of the device

Simbol	Mean
REF	Device model
SN	Serial number
	Output characteristics of the device
W	Output power supply
F	Output frequency of the device
70°C -40°C	Temperature limitation
1060hPa 500hPa	Limitation of atmospheric pressure
100% % 10%	Humidity limitation

Simbol	Mean
	Label indicating the mandatory reading of instructions, located on the front panel of the device
	Label showing devices sensitive to electrostatic charges, placed near the serial connection connector..
CH 1	Label located near the connector of the output channel 1. Similar labels are also present in the connectors of the output channel 2,3,4.
	Label located on the solenoids (the arrow indicates the direction of the Magnetic Field)
This cylinder is made according to **MFC patent - Magnetic Field Concentrator** Which reduces by 85% the electromagnetique waves in the environment. (According to Decret Law 8108- Safety on the job) Made in Italy	Label located on the solenoids: this cylinder is made according to **MFC patent – Magnetic Field Concentrator** which reduces by 85% the electromagnetic waves in the environment. (According to Decret Law 8108 – safety on the job).
	Label indicating prohibited push to be applied behind the trolley at the top center (present only in MAGNETOMED 8400 devices)

Appendix C – LIST OF THERAPEUTIC SUGGESTIONS

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

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

Appendix D – ELECTRO-MAGNETIC COMPATIBILITY TABLES

Guidance and manufacturer's declaration – electromagnetic emissions FOR ALL ME EQUIPMENT		
The ME EQUIPMENT is intended for use in the electromagnetic environment specified below. The customer or the user of the ME EQUIPMENT should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF Emissions CISPR 11	Group 2	The ME EQUIPMENT must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11	Class A	The ME EQUIPMENT is suitable for use in all establishments other than domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

13.4.1 Guidance and manufacturer's declaration – electromagnetic immunity FOR ALL ME EQUIPMENT			
The ME EQUIPMENT is intended for use in the electromagnetic environment specified below. The customer or the user of the ME EQUIPMENT should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment –guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8kV contact	± 8kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
	± 2; 4; 8; 15 kV air	± 2; 4; 8; 15 kV air	
Electrical fast transient/burst IEC 61000-4-4	± 2kV per power supply lines	± 2kV per power supply lines	Mains power quality should be that of a typical commercial or hospital environment
	± 1kV for input / output lines	± 1kV for input / output lines	
Surge IEC 61000-4-5	± 1kV line(s) to line(s)	± 1kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment
	± 2kV line(s) to earth	± 2kV line(s) to earth	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T for 0,5 cycles	0% U_T for 0,5 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ME EQUIPMENT requires continued operation during power mains interruptions, it is recommended that the ME EQUIPMENT be powered from an uninterruptible power supply or a battery.
	0% U_T for 1 cycles	0% U_T for 1 cycles	
	70% U_T for 25 cycles	70% U_T for 25 cycles	
	0% U_T for 250 cycles	0% U_T for 250 cycles	
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A / m	Not applicable, the device does not contain components susceptible to magnetic fields	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
NOTE : UT is the a.c. mains voltage prior to application of the test level			

Guide and declaration of the manufacturer - electromagnetic immunity				
The ME EQUIPMENT is designed to work in the electromagnetic environment specified below. The client or user of the ME EQUIPMENT should ensure that it is used in this environment Portable and mobile RF communications equipment should not be used closer to any part of, including cables, than the recommended separation distance calculated with the equation applicable to the transmitter frequency.				
Immunity test	Trial level of the IEC 60601		Level of compliance	**Recommended separation distance d:**
Conducted RF IEC 61000-4-6	3 Veff from 150kHz to 80 MHz		3 Veff	**d**= 30 cm
Radiated RF IEC 61000-4-3	3 V/m from 80 MHz to 2,7 GHz		3 V/m	**d**= 30 cm
Immunity to proximity fields from wireless RF communication devices IEC 61000-4-3	TETRA 400 380 – 390 MHz	27 V/m	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	

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 magneto terapia /
Equipment for magneto therapy :

MAGNETOMED 7200 - MAGNETOMED 7400 MAGNETOMED 8400

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

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

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

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

CE 0476

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

Pesaro, 14/04/2016

EME srl
L'Amministratore unico / Administrator

Italian manufacturer of physiotherapy equipment since 1983

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