CERTIFICATE

Reg. Numero / *Reg. Number*	MED 31009	Revisione / *Revision*	35
Primo rilascio / *First issue date*	2011-02-01	Valido da / *Valid from*	2020-07-20
Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-02-03

Certificato CE del Sistema di Garanzia della Qualità
EC Quality Assurance System Certificate

Si certifica che, sulla base dei risultati degli audit effettuati, il Sistema completo di garanzia di Qualità dell'Organizzazione/ *We certify that, on the basis of the audits carried out, the full Quality Assurance System of the Organization:*

EME S.r.l.

Sede Legale e Operativa / *Registered and Operational Headquarter:*
Via degli Abeti, 88/1
61122 Pesaro, PU - Italia

è conforme ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni, Allegato II escluso il pto 4, attuata in Italia con Dlgs. 46 del 1997/02/24 e successive modifiche ed integrazioni per le seguenti tipologie di Dispositivi Medici/ *Is in compliance with the applicable requirements of 93/42/EEC Directive as amended, Annex II without point 4, transposed in Italy by Dlgs. 46 of 1997/02/24 as amended for the following Medical Devices:*

Apparecchiature per ionoforesi ed elettrostimolazione / *Equipment for ionophoresis and electrostimulation*
Apparecchiature per magnetoterapia / *Equipment for magnetic therapy*
Apparecchiature per pressoterapia / *Equipment for pressure therapy*
Apparecchiature per radarterapia / *Equipment for microwaves therapy*
Apparecchiature per terapia a luce pulsata / *Equipment for pulsed light therapy*
Apparecchiature per terapia con onda d'urto / *Equipment for shock-wave therapy*
Apparecchiature per ultrasuonoterapia / *Equipment for ultrasounds therapy*
Dispositivi per terapia a radiofrequenza / *Medical devices for radiofrequency therapy*
Dispositivi per terapia combinata elettrostimolazione ed ultrasuoni / *Combined electro and ultrasound therapy devices*
Dispositivi per terapia combinata elettrostimolazione, ultrasuoni, magneto, laser e radiofrequenza / *Combined electro, ultrasound, magnetic, laser and radiofrequency therapy devices*
Dispositivi per vacuum terapia / *Vacuum therapy devices*
Laser terapeutici e manipoli / *Therapeutical lasers and probes*

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding S.r.l.
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www.kiwacermet.it

Rif. rapporto di audit/ *Ref. audit report:* del/dated 2020.10.26/ 2020.11.19-20/ 2020.11.24

Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da: BELCREDI GIAMPIERO
Data: 05/02/2021 10:56:01

CE

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 31009	Revisione / *Revision*	35
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Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Apparecchiature per magnetoterapia / *Equipment for magnetic therapy*

Modello / Model:

Modello / Model:

Marca / *Brandname:*

Modello / Model:

Marca / *Brandname:*

Modello / Model:

Modello / Model:

Marca / *Brandname:*

Modello / Model:

Marca / *Brandname:*
PHYSIOMED ELEKTROMEDIZIN AG

Modello / Model:
Mag Expert

Marca / *Brandname:*

Modello / Model:

NOTA: I CONTENUTI DI QUESTA PAGINA SONO STATI VOLUTAMENTE OSCURATI. SONO DISPONIBILI IN VERSIONE INTEGRALE SOLO SU RICHIESTA DI UN'AUTORITA' COMPETENTE.

NOTE: PARTS OF THIS PAGE HAVE BEEN INTENTIONALLY CONCEALED. THE COMPLETE VERSION IS AVAILABLE AT THE REQUEST TO A COMPETENT AUTHORITY.

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Technical sheet enclosed to the Certificate

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Tipologia / *Medical Devices:*
Apparecchiature per ultrasuonoterapia / *Equipment for ultrasounds therapy*

Marca / *Brandname:*

Modello / Model:

Marca / *Brandname:*

Modello / Model:

Marca / *Brandname:*
PHYSIOMED ELEKTROMEDIZIN AG

Modello / Model:
Physioson Basic

Marca / *Brandname:*

Modello / Model:

NOTA: I CONTENUTI DI QUESTA PAGINA SONO STATI VOLUTAMENTE OSCURATI. SONO DISPONIBILI IN VERSIONE INTEGRALE SOLO SU RICHIESTA DI UN'AUTORITA' COMPETENTE.

NOTE: PARTS OF THIS PAGE HAVE BEEN INTENTIONALLY CONCEALED. THE COMPLETE VERSION IS AVAILABLE AT THE REQUEST TO A COMPETENT AUTHORITY.

Tipologia / *Medical Devices:*
Dispositivi per terapia a radiofrequenza / *Medical devices for radiofrequency therapy*

Classe di rischio / *Risk class:*
II b

Codice NANDO / *NANDO codes:*
MD 1108, MDS 7010

Modello / Model:

Modello / Model:

Modello / Model:

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Chief Operating Officer
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Data: 05/02/2021 11:06:26

CE

Organismo Notificato n. 0476
Notified Body nr. 0476

SERTIFIKATAS

Reg. Nr.: MED 31009
Pirmo išleidimo data: 2011.02.01
Galiojimo data: 2024.05.26

Peržiūra: 35
Galioja nuo: 2020.07.20
Paskutinio pakeitimo data: 2021.02.03

EB kokybės užtikrinimo sistemos sertifikatas

Mes pažymime, kad atliktų auditų pagrindu pilna organizacijos kokybės užtikrinimo sistema

EME S.r.l.

Registruotas veikiantis biuras:
Via degli Abeti, 88/1
61122 Pesaro, PU – Italija

atitinka taikomus pataisytos Direktyvos 93/42/EEB su II priedu be 4 punkto, pritaikytos Italijai pagal pataisytą 1997.02.24 DLGS 46, reikalavimus šiems medicininiams produktams:

Jonoforezės ir elektrostimuliacijos įranga
Magnetinės terapijos įranga
Slėgio terapijos įranga
Mikrobangų terapijos įranga
Impulsinės šviesos terapijos įranga
Smūginių bangų terapijos įranga
Ultragarso terapijos įranga
Radijo dažnio terapijos medicininiai produktai
Kombinuoti elektros, ultragarso, magnetinės, lazerio ir radijo dažnio terapijos produktai
Vakuuminės terapijos produktai
Terapiniai lazeriai ir zondai

Audito ataskaitos Nr.: Data: 2020.10.26/2020.11.19-20/2020.11.24

Išversta teisingai pagal mano žinias ir įsitikinimus. Tekstas yra išverstas teisingai ir tiksliai bei be pakeitimų prasmėje.
Aš esu užtikrintas, kad lietuvių kalbos vertimas atitinka originalų dokumentą.

Vaidas Vilmantas (MB „Beikeris“, įm .k. 304539005)

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all`attivita di direzione e coordinamento
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Vyresnysis vadovas:
Giampiero Belcredi

Skaitmeninis formatas:
BELCREDI GIAMPIERO
Data: 2021.02.05 10:56:01

CE
Registracijos įstaigos Nr.: 0476

Prie sertifikato pridedamas techninis lapas

Medicininių produktų identifikavimas:

Medicininiai produktai: magnetinės terapijos įranga

Modelis:

Modelis:

Prekės ženklas:

Modelis:

Modelis:

Prekės ženklas:

Modelis:

Prekės ženklas: PHYSIOMED ELEKTROMEDIZIN AG

Modelis: Mag Expert

Prekės ženklas:

Modelis:

PASTABA: ŠIO PUSLAPIO DALYS SPECIALIAI BUVO PASLĖPTOS, VISĄ VERSIJĄ GAUSITE, JEIGU KREIPSITĖS Į KOMPETENTINGĄ ĮSTAIGĄ.

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Vyresnysis vadovas:
Giampiero Belcredi

Skaitmeninis formatas:
BELCREDI GIAMPIERO
Data: 2021.02.05 10:57:52

CE
Registracijos įstaigos Nr.: 0476

Prie sertifikato pridedamas techninis lapas

Medicininių produktų identifikavimas:

Medicininiai produktai: ultragarso terapijos įranga

Prekės ženklas:

Modelis:

Prekės ženklas:

Modelis:

Prekės ženklas: PHYSIOMED ELEKTROMEDIZIN AG

Modelis: Physioson Basic

Prekės ženklas:

Modelis:

PASTABA: ŠIO PUSLAPIO DALYS SPECIALIAI BUVO PASLĖPTOS, VISĄ VERSIJĄ GAUSITE, JEIGU KREIPSITĖS Į KOMPETENTINGĄ ĮSTAIGĄ.

Medicininiai produktai: radijo dažnio medicininiai produktai

Rizikos klasė: IIb

NANDO kodai: MD 1108, MDS 7010

Modelis:

Modelis:

Modelis:

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Vyresnysis vadovas:
Giampiero Belcredi

Skaitmeninis formatas:
BELCREDI GIAMPIERO
Data: 2021.02.05 11:06:26

CE
Registracijos įstaigos Nr.: 0476

MAG-Expert®

Pulsating electromagnetic fields for the relief of osteoarthritis pain as well as sensory neurotoxicities

NEW - 3rd EDITION

MAG-Expert

Professional Magnetotherapy device for hospitals, rehab and physiotherapy centres

MAG-Expert is available in the following configurations:

NEW

With the brand new PHYSIOMED App treatment protocols can be created, archived and processed!

MAG-Expert with anthrazit Coil Ø60 cm integrated in a therapy couch for magnetic field therapy of the spine, pelvis and the whole body

Cylinder, Ø 30 cm for magnetic field therapy of the limbs and head

Magnetotherapy with set of applicators

Two-channel magnetotherapy

2.1.8. Magnetinės indukcijos reguliavimo ribos

MAG-Expert provides magnetic field treatment with a field-strength of 1–100 Gauss (adjustable in steps of one Gauss) and a frequency range from 1–100 Hz, with two completely independent channels and a treatment timer. Cylinders of different sizes as well as high performance applicators are a 2.1.7. Terapijos laikas 0 – 60 min. the efficiency of treatment.

MFC technology focuses the magnetic fields almost entirely on the inside of the cylinder. This avoids unnecessary exposure of the treatment team.

2.1.2. Fokusuoto magnetinio lauko technologija, sufokusuojanti magnetinį lauką cilindro viduje, kad būtų išvengta poveikio personalui

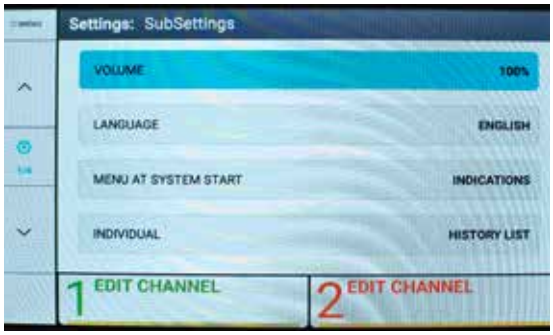
2.1.4. 7 colių spalvotas, lietimui jautrus ekranas

2.1.10. Tiesiogiai nustatant terapijos parametrus

2.1.10. Naudojantis užprogramuotomis gydymo indikacijomis

The detailed indication menu with practical filter functions

2.1.11.Galima filtruoti indikacijas pagal kūno vietą



2.1.13. Garsinis signalas pasibaigus terapijai

Two-channel magnetotherapy with visible parameters that can be changed at any time

SPECIAL FEATURES

Magnetotherapy

Magnetotherapy from 1–100 Gauss

Therapy frequency from 1–100 Hz 2.1.9. Dažnio reguliavimo ribos

Two independent channels 2.1.3. Du nepriklausomi kanalai

MFC technology for focussing magnetic fields

Synchronous mode emission Ch1 and Ch2 2.1.6. Sinchroninis režimas vienu metu naudojant du kanalus su aplikatoriais

Therapy time 0–60 Min

Automatic detection of connected accessories

Therapy couch

2.1.14.Automatinis prijungto priedo atpažinimas

Extremely stable treatm system for opening and easy installation of the coil

Precisely manufactered sliding for easy and comfortable positioning of the coil

GENERAL FEATURES

7" colour touchscreen monitor visualizing all main parameters of the active channels

12 Favorites menu with speed-dial memory for individual device functions

Comprehensive overview of the therapy parameters including all therapy timers

Fastest therapy start: directly, through channel selection, from program memory of indications index, individual or favourites menu 2.1.10. Naudojantis išsaugotomis individualiomis programomis

Treatment index with intelligent filtering functions based on body region, sorted in alphabetical order

Extensive memory capacities, using the Individual, history and favourites menu

2.1.12. Galima išsaugoti dažnai naudojamas programas

LED for visual indicat

Audible signal for indication of end of treatment

PHYSIOMED App compatibilty

Report generation and error interpretation through QR-Code

TECHNICAL DATA

Protection class	1, Type BF
Power connection	230 V ±10 % or 115 V ±10 %
Mains frequency	50 – 60 Hz
Fuses	4 A (at 230 V) or 6.3 A (115 V)
Power consumption	410 VA
Therapy frequency	1-100 Hz
Power output	1-100 Gauss
Dimensions (W x H x D)	245 x 100 x 310 mm
Weight	6.8 kg
Therapy couch: Dimensions (W x H x D)	630 x 680 x 2020 mm
Weight	63 kg

STANDARD ACCESSORIES

[1] Connection cable

[1] Mains cable

[1] Operating instruction

[1] Test metal ring

ACCESSORIES DEPENDING ON THE CONFIGURATION

[1] Therapy couch with Coil Ø 60 cm, 230 V/115 V

[1] Coil Ø 30 cm, 230 V or 115 V

[1] Set of applicators 230 V / 115 V for local aplication

Magnetotherapy

2.1.1. Veikimas paremtas pulsuojančio elektromagnetinio lauko sukūrimo principu (angl. PEMF)

With therapeutic magnetic field devices, pulsating magnetic fields (PEMF) can be applied at various frequencies and intensities to produce good effects, specially to regenerate tissues and bones. Coils and applicators of different sizes can be used.
Magnetic field therapy can produce the following effects:

» Pain relief
» Suppression of inflammation
» Acceleration of healing processes
» Stimulation of blood circulation

MAIN INDICATIONS

» Recent fractures and consolidation delays
Magnetic fields accelerate the consolidation time in a very high number of cases by sti-mulating the osteogenic activity at the fracture rime level.
The recovery process of bone discontinuity takes place through the induction of the piezoelectric effect in the con-nective structures improving the local circulatory conditions.

» Pseudoarthrosis
Magnetic fields have been shown to be effective in treating pseudoarthrosis.

» Osteoporosis
Magnetic therapy was effective in 70 % of cases with osteoporosis.

» Inflammatory and degenerative arthropathy
Both inflammatory and degenerative arthropathies are treated by magnetic therapy. Positive results have been obtained for rheumatoid arthritis in hands and knees, spondylitis ankylopoetica, gonarthrosis and lumbar arthrosis

ADDRESS

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DEALER MARK / STAMP

TECHNOLOGY FOR THERAPY

PHYSIOMED®

Mag Expert

USER MANUAL

CE 0476

INDEX

INFORMATION ON THE MANUAL 1
WRITING CONVENTIONS 1
WARRANTY 2
NOTES 2
CAUTIONS 2
! WARNINGS ! 4
INTRODUCTION OF THE TECNOLOGY 5
IN GENERAL 6
INTENDED USE 7
INDICATIONS 7
CONTRA-INDICATIONS 7
PRELIMINARY NOTES 8
UNPACKING 8
SETTING UP 8
ACCESSORIES 8
USE OF ACCESSORIES 9
CONNECTIONS 9
DESCRIZIONE DELL'APPARECCHIO 10
HOW TO USE OF THE DEVICE 11
BEST USE 11
FREE PROCEDURE 12
MENU 13
PATHOLOGIES 13
INDIVIDUAL 13
FAVORITES 14
SETTINGS 14
PHYSIOMED ELEKTROMEDIZIN AG Smart Assistant 15
ELETTROMAGNETIC INTERFERENCES 17
TROUBLESHOOTING CHART 17
TECHNICAL FEATURES 18
APPENDICES 19
Appendix A - ENVIRONMENTAL CONSIDERATIONS 19
Appendice B – LABELS 19
Appendix C – LIST OF TERAPEUTIC SUGGESTION 20
Appendix D – ELECTRO-MAGNETIC COMPATIBILITY TABLES 21

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 Mag Expert 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 PHYSIOMED ELEKTROMEDIZIN AG, 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

PHYSIOMED ELEKTROMEDIZIN AG 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.

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.

PHYSIOMED ELEKTROMEDIZIN AG 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 PHYSIOMED ELEKTROMEDIZIN AG 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.
- To prevent erasure or formatting of SMART CARD, confirmation is required.
- 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 PHYSIOMED ELEKTROMEDIZIN AG 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 PHYSIOMED ELEKTROMEDIZIN AG, 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 PHYSIOMED ELEKTROMEDIZIN AG 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 PHYSIOMED ELEKTROMEDIZIN AG 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 PHYSIOMED ELEKTROMEDIZIN AG.
- 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 PHYSIOMED ELEKTROMEDIZIN AG 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 PHYSIOMED ELEKTROMEDIZIN AG or its authorized service centers for any repair work or further information.
- When an electromagnetic disturbance occurs, such as a burst, the device may react by making the message "device communication fault" appear, just press "confirm", stop the therapy, turn off the device, and once the disturbance has disappeared on the power supply, restart the device.

! 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 PHYSIOMED ELEKTROMEDIZIN AG 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 Mag Expert 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. PHYSIOMED ELEKTROMEDIZIN AG 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, PHYSIOMED ELEKTROMEDIZIN AG 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, PHYSIOMED ELEKTROMEDIZIN AG 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. PHYSIOMED ELEKTROMEDIZIN AG 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 PHYSIOMED ELEKTROMEDIZIN AG 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

PHYSIOMED ELEKTROMEDIZIN AG 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 Mag Expert 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 Mag Expert device is not intended for subjects in pediatric age (≤14 years).

MAG EXPERT-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 arthropaties;
- fracture outcomes (delays in consolidation and pseudo arthosis). A number of different factors may prolong, or even prevent, healing, for example:
  - the seriousness of the trauma itself: fractures accompanied by crushing, loss of bone and cutaneous substance, as well as infections, present numerous problems in terms of treatment and healing;
  - old age, the presence of metabolic illnesses (for example, diabetes) or the prescription of immunosuppressors that can have a negative influence on the healing process;
  - insufficient activation of repairing processes, the cause of which is difficult to identify precisely. According to statistics, 5 to 10% of fractures involve delayed consolidation or non-consolidation, problems that in most cases can be effectively treated with electric and magnetic osteogenesis stimulation.
- distorsion traumas;
- contusions;
- inflammatory and degenerative illnesses of bones and jints;
- scapular-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;
- 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 [illegible]
2.1.15. CP30 portatyvus solenoidas (su kojelėmis), diametras 30cm
- n.1 mains power supply cable;
- n.2 spare fuses (see technical specifications);
- n.1 magnetic ring(to test the device)
- n.1 smart-card

Check the contents of the package and should any of the items be missing then contact your local authorized PHYSIOMED ELEKTROMEDIZIN AG 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**	
CP30 portable cylinder (with feet), diameter 30cm		x
CP60 portable cylinder (with feet), diameter 60cm		x
CP - Pair of magnetic applicators		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 PHYSIOMED ELEKTROMEDIZIN AG 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.

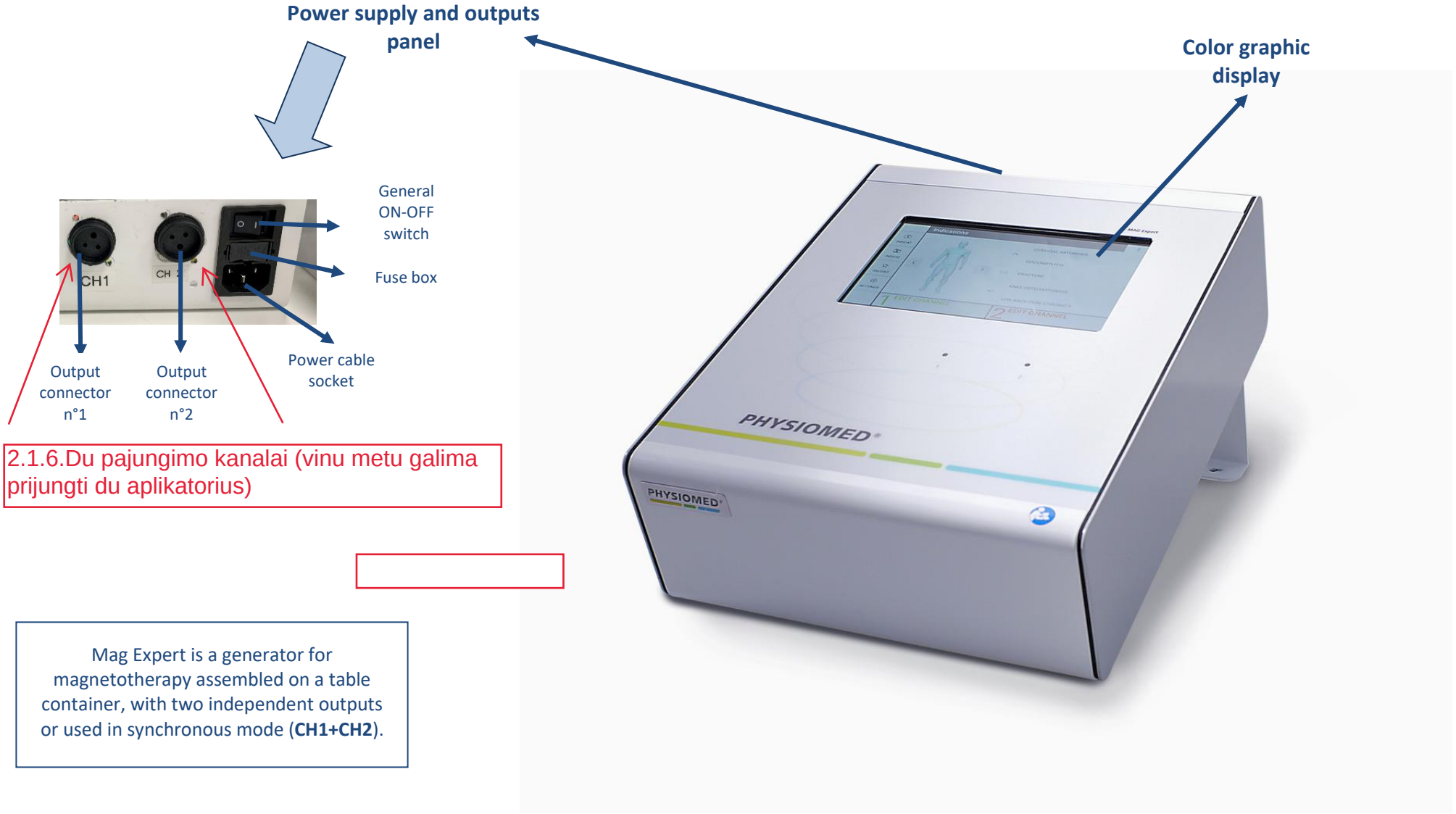
When using an extension lead, make sure that it has been earthed.

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.

DESCRIZIONE DELL'APPARECCHIO



2.1.6.Du pajungimo kanalai (vinu metu galima prijungti du aplikatorius)

Mag Expert is a generator for magnetotherapy assembled on a table container, with two independent outputs or used in synchronous mode (**CH1+CH2**).

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 Mag Expert.

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: 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.

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 Mag Expert 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.

After a few moments to load the settings, the LCD display will light up showing the logo, and the initial FREE PROCEDURE screen will appear (fig.1)

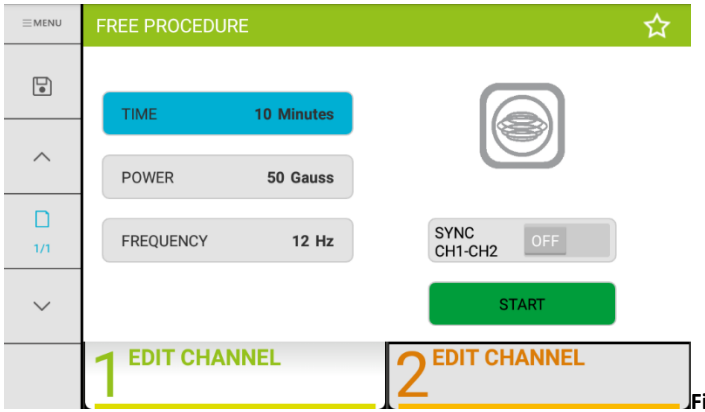


Fig.1

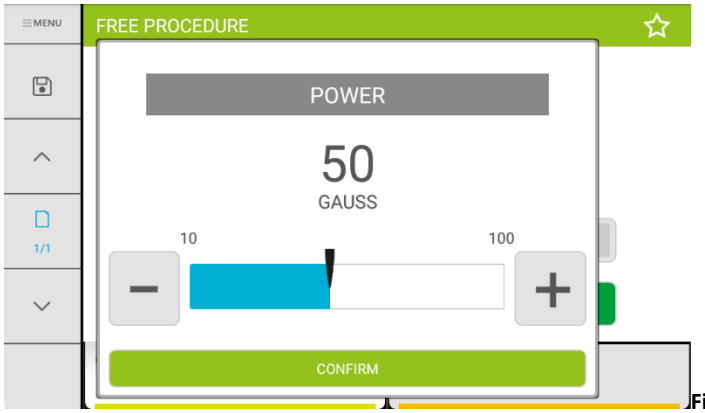


Fig.2

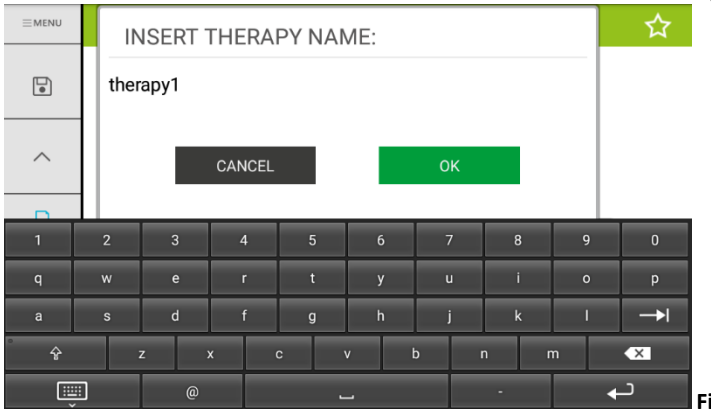


Fig.3

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.

Before starting treatment, you can change the parameters of treatment such as duration, power and frequency pressing the relative buttons, will appear the screen shows in figure 2.

Use the + and – buttons to set the desired value and press CONFIRM to save the changes

By pushing the button EDIT CHANNEL 1 or 2 it is possible to choose the treatment channel: therefore channel 1 will alternate with channel 2 and channel 1 + 2.

For the synchronous mode CH1-CH2 it is necessary to set the SYNC button to ON; to deactivate it, move to OFF.

If you want to save the treatment with the parameters just set, press the button with the save symbol on the side MENU, the screen in figure 3 appears allowing you to enter the name you want to assign to the therapy; press OK to save or otherwise press CANCEL.

Press the START key to move on to the execution of the treatment: appears the screen shown in figure 4, in the buttons below, the delivery channel used appears ad ACTIVE, in which the duration parameter marks the remaining treatment time that can be viewed via the backwards count of the minutes.

Pressing the STOP button the emission is suspended; pressing again the button START the emissions resumed from the point where it was interrupted and continues until the set time runs out, in this case the system signals to the operator by means of a video message that the treatment has ended and you return to the screen as in figure 1. While pressing the STOP button the emission finally ends and you return to the screen of the figure 1.

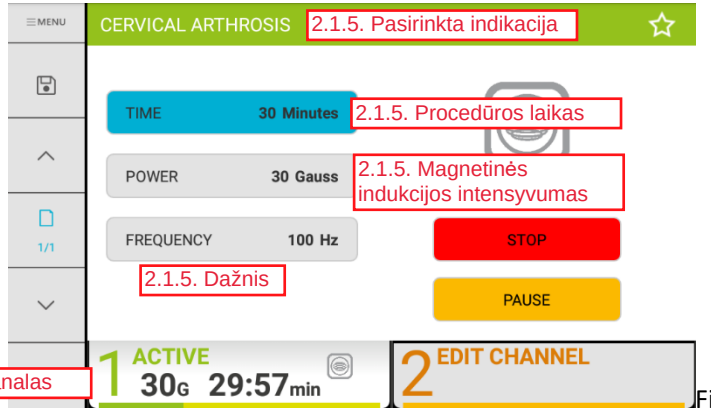


Fig. 4

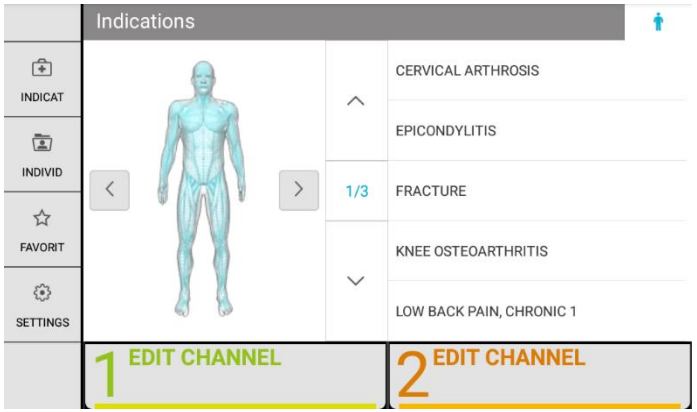


Fig. 5

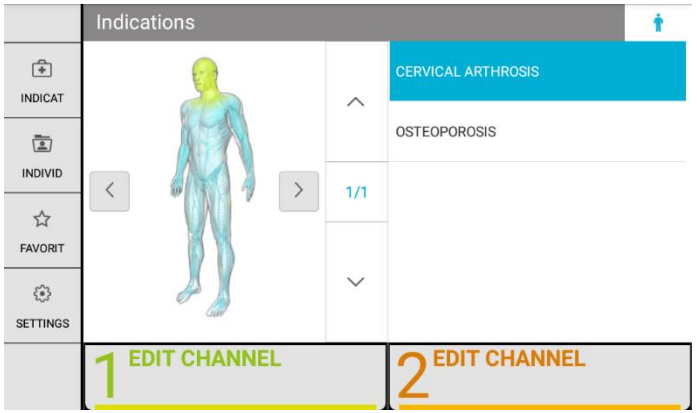


Fig. 6

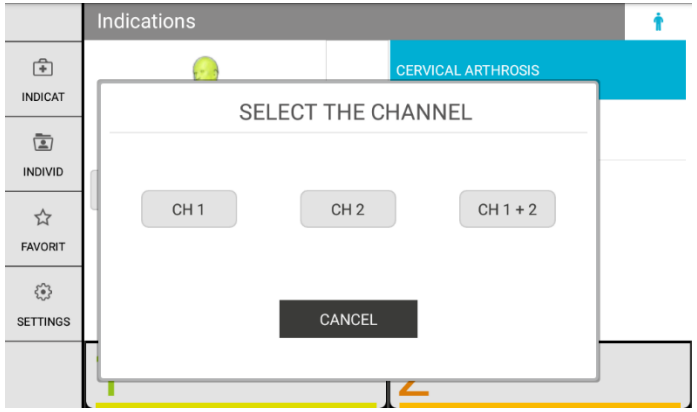


Fig. 7

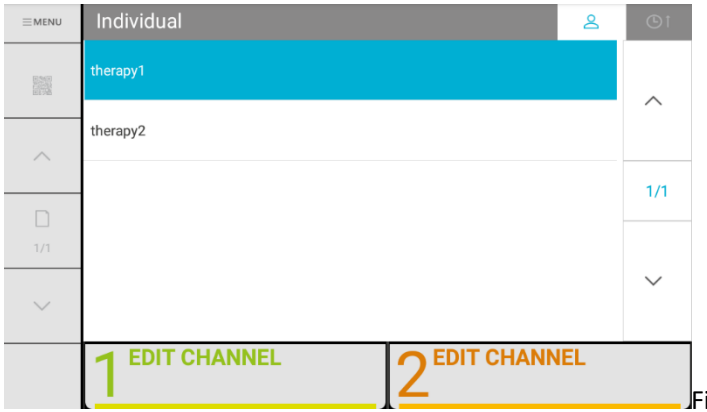


Fig. 8

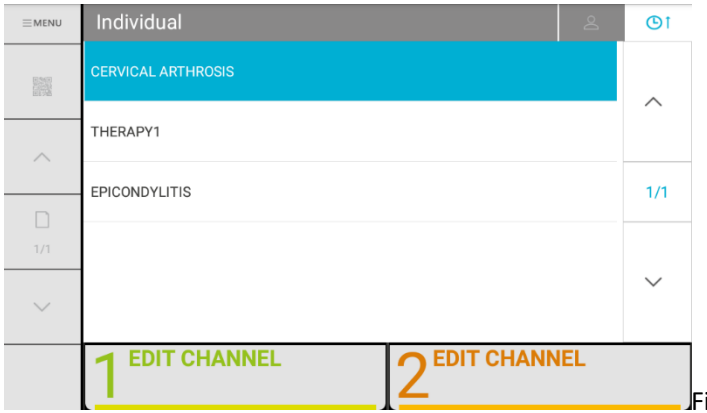


Fig. 9

MENU

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

By pressing the MENU button, a drop-down menu appears in the side bar from which you can access the different sections.

PATHOLOGIES

At the side menu, press the PATOLOG button to access the PATHOLOGIES section; then the screen shown in figure 5 appears.

Using the side arrows you can select the anatomical area of interest; depending on the selected area, the list of respective pathologies appears on the right (figure 6).

Use the up and down arrows to scroll through the list of pathologies.

By pressing on the pathology of interest, the screen in figure 7 appears, from which it is possible to select the treatment delivery channel among the three available (CH1), (CH2), (CH 1 +2); set the desired parameters as described in the FREE PROCEDURE section, and start the treatment using the START button.

The stored programs proposed are the result of operational experience gained over years of support to professionally expert users.

Appendix C contains the list of available protocols.

INDIVIDUAL

The individual specification is a section through which it is possible to access to previously saved treatments through the list of user programs of treatments performed, through the history list.

To access the list of saved therapies, press the INDIVID button from the side menu and select the user profile between the two buttons at the top right (figure 8).

If you want to access the history of the therapies performed, from the INDIVIDUAL page, press the button with the clock symbol at the top right (figure 9).

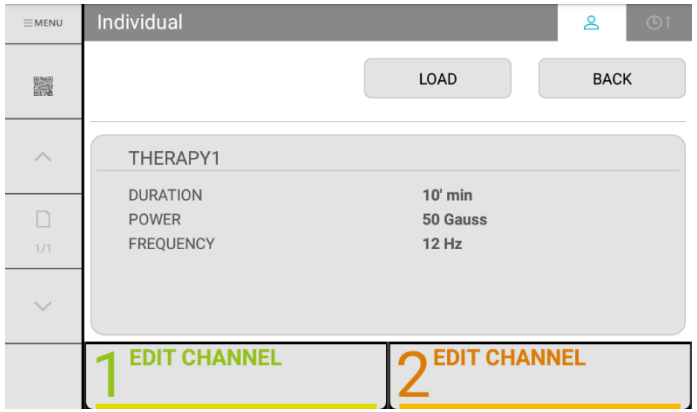


Fig. 10

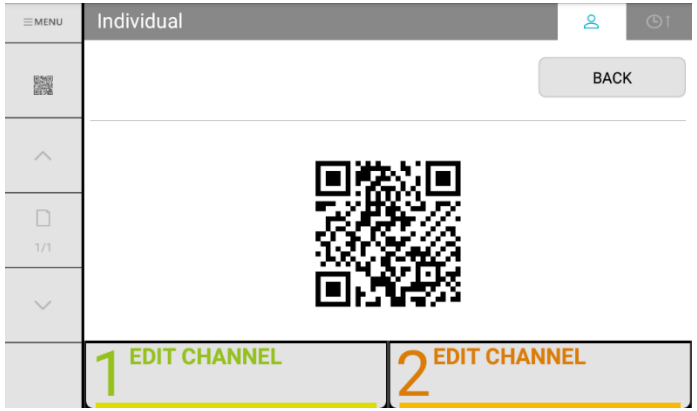


Fig. 11

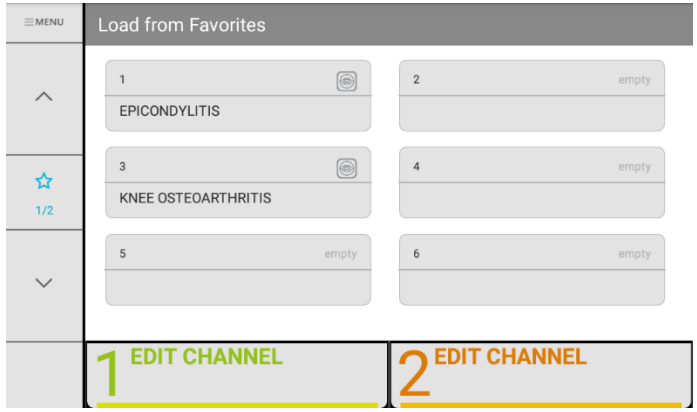


Fig.12

From both lists, using the touch-screen, it is possible to select and start a therapy in the list; the treatment summary parameters screen appears (fig. 10). Press LOAD to load and, after selecting the delivery channel, start the treatment, or BACK to return to the previous screen with the list of treatments.

It is possible to send the data saved in the two lists to the user, by pressing the QR Code button from the menu sidebar, the screen shown in figure 11 appears (see section PHYSIOMED ELEKTROMEDIZIN AG Smart Assistant).

FAVORITES

It is possible to save the treatments (see FREE PROCEDURE section) and access them from the main MENU using the FAVORITES button.

From the screen "LOAD FROM FAVORITES" 8figure 12) it is possible to load a previously saved treatment by pressing the corresponding button, set the desired parameters as described in the FREE PREOCEDURE section and press the START button to start the treatment.

SETTINGS

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

To access the setting, press the SET button from the side MENU, the screen shown in figure 13 will appear.

Using the side arrows, select the function you want to modify, then press the button to confirm the choice.

The first two pages (fig. 13) refer to the System settings, from where it is possible to modify the following specifications:

- VOLUME: by pressing this button and using the + or – side buttons, you can adjust the volume of the sounds emitted by the machine, until they are deactivated by setting the volume to OFF;
- DATE: by pressing this button the screen shown in figure 14 appears from where it is possible to enter the date using the keyboard. Press OK to confirm or CANCEL to cancel the changes.
- TIME FORMAT: by pressing this button and using the + or – side buttons, it is possible to set the time format from 12 or 24 hours.
- TIME: by pressing this button, a screen appears where you can enter the time via the keyboard. Press OK to confirm or CANCEL to cancel the changes.

From the menu settings, scrolling through the pages, you can select:

- LANGUAGE: by pressing this button and using the + or – side buttons, it is possible to choose the language in which all the messages and commands of the machine will be written, choosing between the two available (Italian and English)
- START-UP MENU: by pressing this button and using the + or – side buttons, you can choose the screen that appears after the machined is turned on by choosing from the available ones (INDIVIDUAL, FAVORITES, MAGNETOTHERAPY, PATHOLOGIES)
- INDIVIDUAL: by pressing this button and using the + or – side buttons, you can choose whether to save the HISTORY LIST or USER PROGRAM LIST (see INDIVIDUAL section).

Scrolling with the side arrows to the fourth page of the main MENU, the CONTACTS screen appears (fig. 15).

To access the DEVICE INFORMATION, it is necessary to scroll with the side arrows to the fifth page of the main MENU, a screen appears with the version of the software and firmware installed on the machine and the serial number.

If is necessary to perform a software update, press the UPDATE APPLICATION button, a WARNING screen appears, press YES to continue with the update or NO to cancel.

Scrolling with the side arrows to the fifth page of the main MENU, the screen in figure 17 appears, PHYSIOMED ELEKTROMEDIZIN AG Smart Assistant, with which the user can interact via the QR Code.

PHYSIOMED ELEKTROMEDIZIN AG Smart Assistant

Through the PHYSIOMED ELEKTROMEDIZIN AG application, downloadable from smartphone, the user can interface with the machine by using the QR Code (fig. 16), allowing him to receive the treatments performed, the parameters set and any error diagnostic messages.

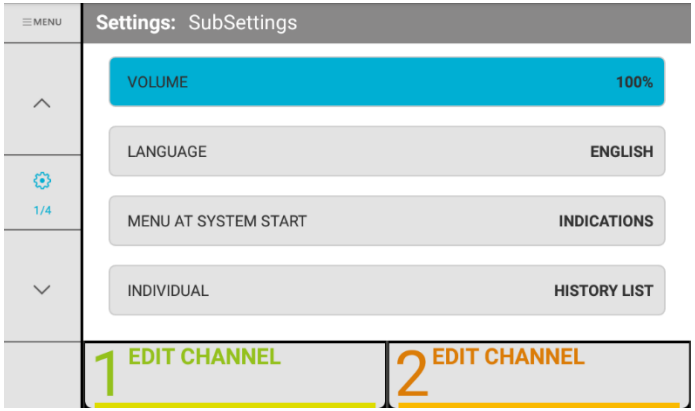


Fig. 13

Fig. 14

Fig. 15

Fig. 16

To send data relating to a specific treatment, from the INDIVIDUAL screen, select the treatment of interest and press the button with the QR Code symbol from the sidebar of the MENU, in this way the user will receive the parameters used on the smartphone.

In the event of an error message, the user can send the error diagnostics to the smartphone by pressing the SHOW QR CODE button, and then, after having scanned the QR Code, press CONFIRM.

MAINTENANCE

The Mag Expert 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 PHYSIOMED ELEKTROMEDIZIN AG 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 PHYSIOMED ELEKTROMEDIZIN AG authorised personnel should carry out such operations.

The expected work life of device is 10 years.

TECHNICAL PROBLEMS

The equipment for magneto-therapy Mag Expert 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 PHYSIOMED ELEKTROMEDIZIN AG 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.

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 PHYSIOMED ELEKTROMEDIZIN AG assistance centre.
	No mains voltage.	
Front panel display doesn't come on.	Defective components in the electronic control board.	Contact the PHYSIOMED ELEKTROMEDIZIN AG assistance centre.
Some commands on the front control panel are not working properly.	Defective keys or buttons	Contact the PHYSIOMED ELEKTROMEDIZIN AG 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 PHYSIOMED ELEKTROMEDIZIN AG assistance centre..
The equipment works properly but there is a notable fall in treatment efficiency.	Cylinder/applicator connection not perfectly effective.	Contact the PHYSIOMED ELEKTROMEDIZIN AG 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%
	115 Vac 50-60 Hz ±10% *
Maximum Absorbed power	410VA
Double fuse protection (T)	4 A - T - 5 x 20 mm for 230Vac power supply 6.3 A – T - 5 x 20 mm for 115 Vac power supply
Backlit LCD display to view and check the operating parameters	graphic 320 x 240 pixel touch screen + encoder
Programmable treatment time	Up to 60 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	2 independent
Mag Expert series : trolley container in plate , external size (width x height x depth)	25 x H10 x 31 cm
Unit body weight	6,8 Kg

2.1.16.Maitinimo šaltinis 230V, 50-60 Hz

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

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

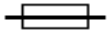
Rigorous standards were followed in order to minimise the amount of waste, use of toxic materials, noise, non-required radiation and energy consumption.

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

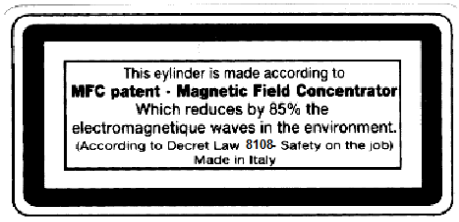
This symbol means that the product should not be disposed of as domestic waste.

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
	Input voltage to the device (mains)
	Fuses: 2xT6.3AL250V / 2xT4AL250V
	Input power of the device (absorbed power)

Simbol	Mean
	Input frequency of the device
	Device model
	Serial number
	Output characteristics of the device
	Output power supply
	Output frequency of the device
	Temperature limitation
	Limitation of atmospheric pressure
	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..
	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)
	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).

Appendix C – LIST OF TERAPEUTIC SUGGESTION

ELENCO TRATTAMENTI TERAPEUTICI	INTENSITA' (Gauss)	FREQUENZA (Hz)	DURATA (Min)
Knee osteoarthritis	50	100	30
Cervical arthrosis	1	15	30
Lumbo-sacral arthrosis	38	15	40
Osteoarthritis disk spine	60	50	20
Epicondylitis	60	25	30
Fractures	20	15	25
Shoulder rotator cuff tendonitis (painful phase)	25	70	60
Chronic low back pain 1	100	20	30
Chronic low back pain 2	20	50	29
Peripheral Neuropathy (Pain)	20	30	60
Osteoporosis	40	30	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 1	Equipment in which the radio-frequency energy in the frequency range 9KHz to 400 GHz in not intentionally generated and used or only used, in the form of electromagnetic radiation, inductive and/or capacitive couplig for the treatment of material or inspection.
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	

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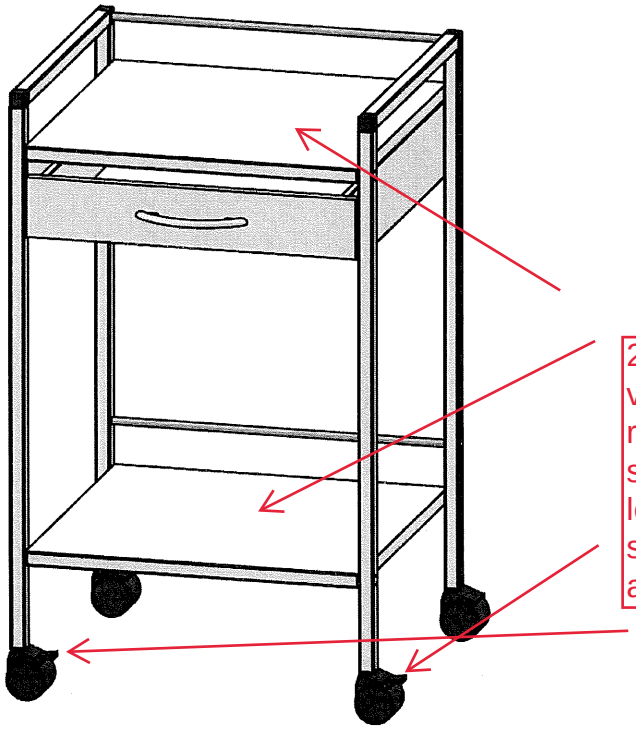
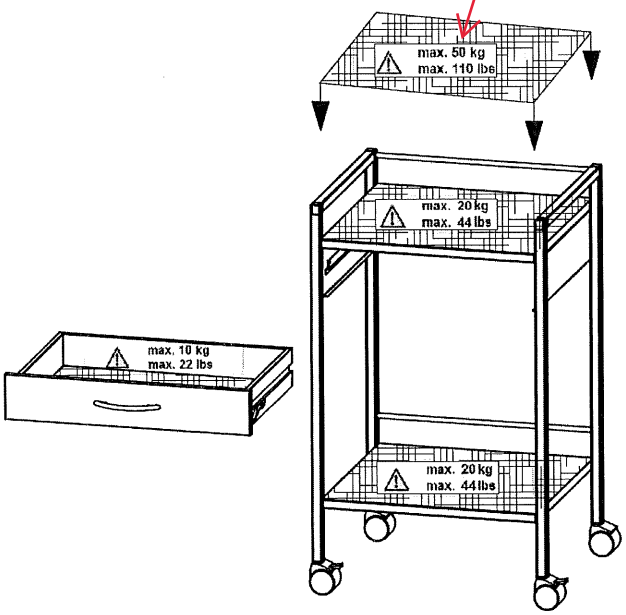
Gerätewagen *Universal*
Trolley *Universal*
Chariot *Universal*
Carro *Universal*

PHYSIOMED®

Montageanleitung / Assembly instructions / Instructions de montage / Instrucciones de montaje



2.1.15. Mobilus vežimėlis su ratukais, du iš jų su stabdžiais, 2 lentynėlės ir stalčius. Maksimali apkrova 50kg.



Alle Belastungsangaben sind Maximalwerte unter Berücksichtigung der Kippsicherheit gemäß EN 60601/1.

All load figures are maximum values taking into account stability as per EN 60601/1.

Les indices de charges sont des valeurs Maximales, compte tenu de la stabilité au renversement, conformément á EN 60601/1.

Todos los indices de carga son valores máximos en atención a la seguridad de inclinación según EN 60601/1.