USER MANUAL

Magnetotherapy model

MAG2000

I.A.C.E.R. Srl
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R.E.A.: VE N. 120250 - M. VE001767 - Codice SDI/SDI Code: SUBM70N - Cap. Soc.: € 1.000.000,00 i.v.

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Manufacturer

I.A.C.E.R. S.r.l.

Via Enzo Ferrari 2 • 30037 Scorzè (VE)

Tel. 041.5401356 • Fax 041.5402684

IACER Srl is an Italian medical devices manufacturer (CE certificate n°0068/QCO-DM/230-2020 issued by MTIC InterCert S.r.l. notified body n°0068).

Declaration of conformity

I.A.C.E.R. S.r.l

Via Enzo Ferrari 2 – 30037 Scorzè (Ve), Italia

herewith declares under its own responsibility, that the family product

MAG2000

which includes the following models

MAG700, MAG2000, MAG2000 Premium e MAG2000 PLUS

UMDNS Code**: 12415**

has been designed and manufactured according to the European Medical Device Directive 93/4/EEC (transposed in Italy by the D.Lgs. 46/97), as modified by the Directive 2007/47/EC (D.Lgs.37/2010) and further modifications/integrations.

The products have been assigned to class IIa, according to Annex IX, rule 9 of the Directive 93/42/EEC (and further modifications/integrations) and bear the mark

CE 0068

Compliance of the concerned products with the Directive 93/42/EEC has been assessed and certified by the notified body:

0068 – MTIC InterCert S.r.l.

Via G. Leopardi 14, Milano (MI) 20123

Certified number: 0068/QCO-DM/230-2020

following the certification procedure according to Annex II (excluding point 4) of the Directive 93/42/EEC.

Scorzè, 31/01/2022 — MASSIMO MARCON

Place, date — *Legal Representative*

Classifications

MAG2000 has the following specifications:

- class IIa equipment (Directive 93/42/CEE, Annexed IX, rule 9 and following modifications).
- Class II applied part type BF (classif. EN 60601-1).
- IP21 protection equipment against solids, dust and liquids penetration.
- Equipment and accessories not subjected to sterilization.
- Use of the equipment is prohibited close to flammable substances when mixed with air, with nitrous oxide or when mixed with any flammable agents and in environments with high concentrations of oxygen.
- Continuous operating mode equipment.
- Equipment not suited to be used in external.

Purpose and scope

Clinical Purpose:	Therapeutic
Scope of Use:	Ambulatory/Hospital and domestic

MAG2000 is indicated for the treatment, rehabilitation and functional recovery of the following pathologies:

- wrist, hand, shoulder, foot, ankle and knee articulation
- skeletal motor apparatus
- arthrosis
- atrophies and muscular dystrophy
- bursitis
- bruises
- degeneration of locomotor apparatus
- sprains
- periarthritis
- benign lesions and muscular tears
- tendinitis

MAG2000 is particularly recommended for the treatment and care of osteoporosis and all pathologies borne by bone tissues. Thanks to the high intensity of the magnetic field that can generate, MAG2000 is particularly indicated in the treatment of bone fractures even in the presence of rigid bandages or plaster.

MAG2000 is a device intended for both the professional user (physician, therapist, etc.) and the patient at home. **In case of home therapy, the use of the device is recommended only on indication of the physician/therapist.**

The patient population intended for magnetotherapy treatment using the MAG2000 device includes patients of both sexes, men and women, of age (unless otherwise indicated by medical doctors). For further details, please refer to the *Contraindications* section.

Technical features

Characteristics	Specification	
Power supply	GJ24WA-1500120V,15V DC, 1.2A	
Max. absorbed current	0,8A	
Insolation class (EN 60601-1)	II	
Applied part (EN 60601-1)	BF	
Dimensions (length x width x height)	179x107x50 mm	
Field intensity	Adjustable on increasing level up to 100 Gauss (per channel) in P1-P20 programs. Adjustable on increasing level up to 150 Gauss (per channel) in P21-P35 programs.	
Squared wave frequency	Adjustable 1-100Hz	
Therapy time	Adjustable (**max 12 consecutive hours**)	
Environmental conditions of operation	Temperature	From +5 to + 28 °C
	Relative humidity	From 15 to 93%
	Pressure	From 700 to 1060hPa

ATTENTION! The device delivers current above 10mA.

In frequency programs (from 21 to 35) maximum magnetic field intensity is 150 Gauss for each channel with solenoids couple applicator. Intensity, frequency and time values are given with ±20% of accuracy.

Expected life of the device and its accessories: 2 years.

Device and commands description

Label (retro)

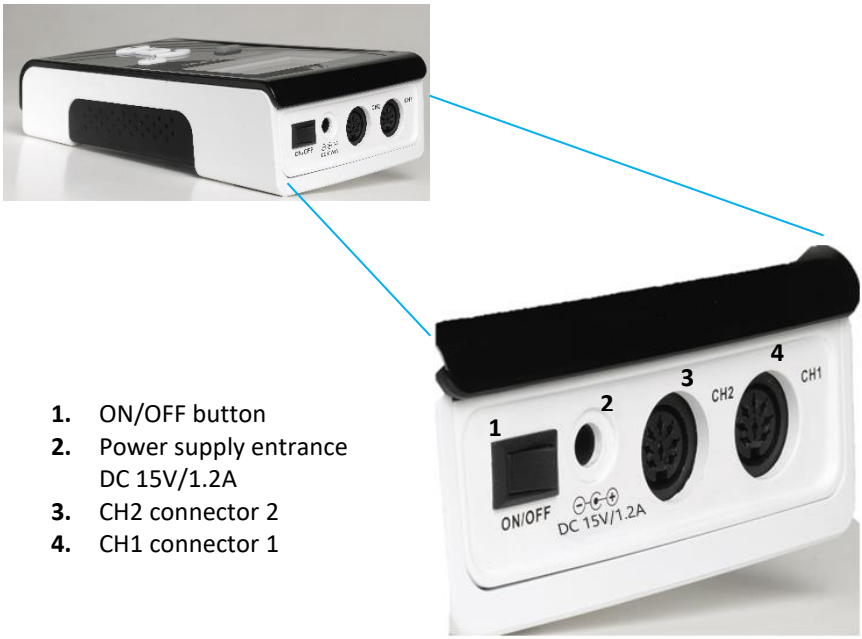
[⏻] Power button and return to the program choice menu.

OK OK key, confirmation button.

[▲] Selection/increment key.

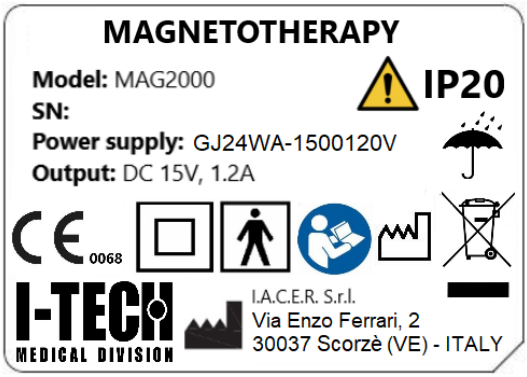
[▼] Selection/decrement key.

During the therapy a green light will turn on.



1. ON/OFF button
2. Power supply entrance DC 15V/1.2A
3. CH2 connector 2
4. CH1 connector 1

Labelling



The label above is placed on the back of the device.

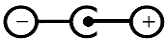
Code: 80001
Lot:

IP01

I.A.C.E.R. S.r.l
Via Enzo Ferrari, 2
30037 Scorzé (VE), Italia

The label is placed on the protective envelope.

Symbol	Description
	Manufacturer logo
CE 0068	Certification of the product issued by the notified body N° 0068.
	Manufacturer
	Manufacturing date (YYYY-MM)
	Attention, consult operating instructions.
	Product subject to WEEE regulations concerning separate waste collection of electronic equipment.
	Class II equipment.
	Applied part type BF.
	Admission temperature (storage, packaging).
	Relative humidity (storage, packaging).
IP20 **IP01**	Protection level against solids, dusts and liquids entrance (device protected against solid foreign

Symbol	Description
	objects ≥ 12,5 mm and greater and vertically falling water drops). The case of the device guarantees the IP20 level protection. The envelope guarantees the IP01 level protection. **The IP21 protection is guaranteed only when using the device inside the envelope.**
	Only domestic usage.
	Not protected against liquid entrance, keep dry.
	Power supply symbol.
	General warning sign: taking care regarding the hazard specified

Package content

The MAG2000 package contains:

- N°1 MAG2000 device;
- N°1 power supply (cable approx. 1.5m);
- N°1 operating and belt position manual;
- N°1 magnet tester;
- N°1 elastic therapeutic belt with 3 solenoids (cable 1.5m);
- N°1 carrying bag;
- N°1 protective envelope.

Solenoids couple, magnetotherapy carpet and OSTEOMAT mattress are available as accessories on demand. Visit website **www.itechmedicaldivision.com** to obtain more information.

Introduction to technology

It's a long time that low frequency and high intensity pulsed electromagnetic fields have met maximum scientific consent in chronic and degenerative diseases treatment.
Magnetotherapy uses low frequency and high intensity pulsed electromagnetic fields induced by electric current on a bobbin; due to its characteristics, the electro magnetotherapy is universally recognized as the most suitable technique for the treatment of the bony pathologies, in particular for the osteoporosis.
Pulsed electromagnetic fields induce biological modifications on biological membrane that assure a good biostimulation in order to re-establish correct cellular functions.
According to different authors experiences in osteoporosis a considerable disease regression is evident from the sixth treatment and moreover it's evident an important increase of BMD (Bone Mass Density). The magnetic field high value (gauss) generated by the device allows treatments in presence of braces or plaster bandage.

Contraindications and side effects

Patient in pregnancy, tuberculosis, juvenile diabetes, viral (in acute phase) illnesses, mycosis, cardiopathic subjects, tumours, serious arrhythmias or pacemaker carriers, children, metallic prosthesis carriers, acute infections, epileptics (**different medical prescriptions excepted**).

No significant side effects are known of, nor are reported contraindications for excessive time length using the device.

Warnings

It is recommended that you read this manual carefully before using the device. For any further information and in-depth we suggest you visiting our website **www.itechmedicaldivision.com** in the section dedicated to magnetotherapy.
It is recommended to:

- Check the position and the meaning of all the labels on the equipment;

- Do not damage the applicator by acting on the connecting wire, and do not wrap the wire around the applicator or the appliance;
- Avoid the use of the system to persons not adequately educated by reading the manual. Keep out of the reach of children, animals and pests;
- During therapy it is advisable to the patient and user not to wear metallic objects;
- Check the integrity of the power supply before each use. Avoid use in case of signs of damage to the casing or to the connecting wire;
- ONLY use cables and applicators supplied by the manufacturer. Inadequate cables and applicators may damage the appliance and/or damage the patient;
- Do not hold the device in hand while using it. It Is recommended to place it on a table or similar support: position the device in such a way that this operation is always easy and can be safely executed. Place the device on a stable shelf (table, nightstand), away from other devices that may interfere or prevent safe use of the device and related accessories.

Is prohibited:

- The use of the device by persons incapable of understanding and wanting, suffering from sensitiveness to sensitivity, temporarily incapacitated if not assisted by qualified personnel;
- The use of the device near inflammable substances, gases, explosives, in environments with high concentrations of oxygen, in the presence of aerosols or in very humid environments (do not use in the bathroom or during the shower/bath);
- The use of the appliance in the presence of signs of deterioration and/or damage to the same or to the accessories (electrodes, chargers, etc.) and/or cables; contact the dealer or the manufacturer in accordance with the *Assistance* section. Check the integrity before each use;
- The use of the appliance contemporary to liniments containing free ions of magnetic metals;
- Use of the device on open wounds and/or irritated skin;
- To connect the device and its accessories to other devices not listed in this manual.

Warning:

- Position the applicator in such a way that the green side is in contact with the patient;
- The user must periodically check the insulation (integrity) of the applicators and their cables and check that they are not damaged (if necessary, contacting the manufacturer);
- The use of the connection cables of the belt and the feeder: danger of strangulation. Be extremely careful if it is necessary to pass the cables near the neck and the patient's head: In this case it is necessary to maintain a safe position and to avoid abrupt movements that can cause the cables to twist.
- To avoid exposing the device and its accessories to excessive direct light and dust. See the paragraph *Care of the device*.

The manufacturer shall be deemed to be responsible for the performance, reliability and safety of the appliance only if:

- any additions, modifications and/or repairs are carried out by authorized personnel directly by the manufacturer. Any modification, addition and/or repair performed by unauthorized personnel may result in the loss of safety of the device or its malfunction;
- the electrical system of the environment in which MAG2000 is inserted complies with national laws;
- the appliance is used in strict accordance with the operating instructions contained in this manual.

Should any foreign materials penetrate the device contact the retailer or manufacturer immediately. If dropped down, check that the housing is not cracked or damaged in any way; if so, contact the retailer or manufacturer.
Should you notice any changes in the device's performance during treatment, interrupt the treatment immediately and consult the retailer or manufacturer.

ATTENTION! Disconnect the power supply from the main socket at the end of each therapy session.

The materials used to produce the device have exceeded the prescribed standards for the toxicity of the materials themselves. In case of allergic reactions, discontinue therapy and consult a physician.

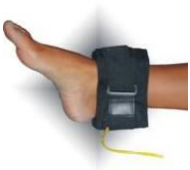
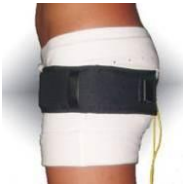
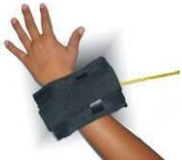
In case you need to use the extended treatment device (even up to 8 hours) it is advisable to use an intensity not exceeding 50G for all programs. In this case the efficacy of the treatment is given by the

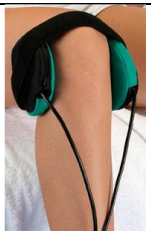
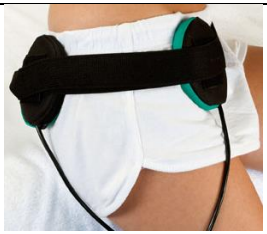
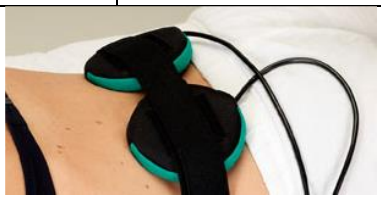
prolonged time of therapy rather than the maximum field intensity settable. High field intensities (above 80/100G) are indicated for short treatments (up to 2 hours) or in the presence of rigid bandages/braces.

Applied parts. It's necessary to consider as applied parts not only all accessories (belt with 2/3 solenoids, professional solenoids couple, etc.) but also the device and the power supply that can get in contact with the user during the treatment.

Patient preparation: positioning of the therapeutic belt and solenoids, main applications and suggestions

Here below a list of main positions for the therapeutic belt and for the solenoids couple.
Wrap the belt around the area to be treated (or position the belt on the area, for example in vertebral column treatment). During this phase **take care to place the green side of the therapeutic belt on the skin**.
The professional solenoids couple must be placed on the area to be treated (in opposite position or position on the area, for example in vertebral column treatment). Also, in this case take care **to place the green side of the therapeutic belt on the skin.**

 Ankle	 Hip	 Back (lumbar)	 Knee
 Shoulder	 Wrist	 Elbow	 Cervical

 Knee	 Tibia/fibula	 Ankle
 Shoulder	 Femoral head	 Femur
 Vertebral column	 Lumbar	

Suggestions for proper use:

- In P1-P20 programs a longed treatment with an intensity higher than 60 can heat the 3 solenoids belt and this aspect makes therapy less comfortable: we recommend spacing out treatments and to not go over 2 consecutive hours of therapy;
- In P21-P35 programs we recommend using the professional solenoids couple (available as optional accessories) if you want to adjust an intensity higher than 100G and a treatment time longer than 2 hours;
- Do not adjust intensity higher than 50G if you use magnetotherapy carpet (optional accessory) for prolonged treatments.

We recommend to use professional solenoids couple, available as optional accessories, (which guarantee high performance and greater field strength

and tissue penetration.) if you need an higher field intensity or in case of tissue treatment in depth or still in presence of rigid bandages or braces.

Setup and programs instructions

Connections and power on

For proper installation of the device, we recommend to carefully read and follow the below steps:

1. connect the applicator (or the applicators) to the device by connecting applicator cable to one of the two plugs (CH1-CH2) placed on the device upper side;
2. connect the power supply cable to the main, then connect the power supply plug to the circular connector placed on the device upper side, near to the ON/OFF switch;
3. connect the power supply plug to the main socket (110-230VAC, 50-60 Hz);
4. Move the ON/OFF switch, placed on device upper side, to the ON position: I-TECH logo and programs menu will be displayed on screen.

ATTENTION! To keep the device protected from penetration of solid objects, powders and liquids, it is recommended to use it ALWAYS INSERTED inside the envelope of protection!

Main menu

The MAG2000 device is equipped with 35 programs with preset and user-modifiable values according to your needs. The first 20 programs are associated with the treatment of specific pathologies with preset parameters recommended by IACER, while the following 15 have only the preset working frequency, leaving the user the freedom to choose the duration and the cycles of sessions.

LIST OF PROGRAMS

Pre-adjusted values		Recommended values		
N°	Pathology	Hz	Time (hours)	Treatment cycles
1	Osteoporosis	50	2 - 6	30
2	Arthrosis	15	2 - 6	20
3	Arthritis	30	2 - 6	20
4	Cerv. Arthrosis	5	2 - 6	15
5	Articular Pain	25	2 - 6	15
6	Cervicalgias	10	2 - 6	15
7	Sprains	50	2 - 6	15
8	Fractures	50	2 - 6	30
9	Epicondylitis	45	2 - 6	20
10	Epitrocleitis	40	2 - 6	20
11	Intercost. Con.	15	2 - 6	20
12	Lumbalgy	60	2 - 6	15
13	Lumbar Pain	60	2 - 6	15
14	Shoulder Art.	30	2 - 6	15
15	Knee Arthrosis	45	2 - 6	20
16	Periarthritis	50	2 - 6	20
17	Coxarthrosis	50	2 - 6	20
18	Musc. Atrophy	35	2 - 6	20
19	Musc. Contract.	20	2 - 6	15
20	Osteonecrosis	50	2 - 6	20
21	1Hz	1	free	free
22	3Hz	3	free	free
23	5Hz	5	free	free
24	10Hz	10	free	free
25	15Hz	15	free	free
26	20Hz	20	free	free
27	30Hz	30	free	free
28	40Hz	40	free	free
29	50Hz	50	free	free
30	60Hz	60	free	free
31	70Hz	70	free	free

Pre-adjusted values		Recommended values		
N°	Pathology	Hz	Time (hours)	Treatment cycles
32	80Hz	80	free	free
33	90Hz	90	free	free
34	100Hz	100	free	free
35	Autoscan*	*	2 - 6	20

***Autoscan program allows to adjust the desired therapy time then it will start automatically a frequency cycle from 5 Hz to 100 Hz with a time therapy of 5 minutes for each frequency. It's an ideal program for the regeneration of both hard tissues (bones) and soft tissues (tendons, ligaments) in the same treatment.**

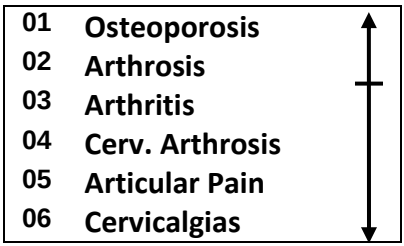
Therapy duration values are recommended by IACER however the user can adjust the time as he prefers. Also, for each seating cycle (column *Treatment cycles* of the table *List of programs* above) the manufacturer IACER recommends **at least one treatment/session per day of the ongoing seating cycle.**

MAG2000 uses therapy time values, working frequency values and field intensity values coming from scientific and medical literature, as result of well-known experimentations and clinical evaluations (Barker - Lunt 1983, Bassett – Pawluk – Pilla 1974, Bassett - Valdes – Hernandez 1982).

Program selection

Here are the instructions to follow for choosing the appropriate program according to the pathology:

1. Within the menu, scroll through the list of programs by using the keys ▲ and ▼, then select the desired program and press OK.

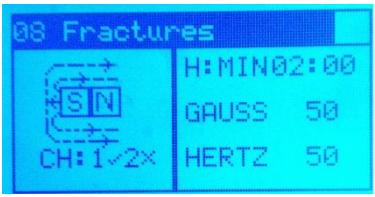


07	Sprains
08	Fractures

2. The display will show the basic therapy time setting (from the figure, 2 hours) and the magnetic field intensity (50G) of the selected program. These are average values suggested by IACER to start the treatment immediately and effectively.

3. Press the button ▼ by highlighting the magnet icon in the lower left then press OK.

4. The device will begin the treatment, displaying the magnet icon with the magnetic field flow on the display. The green light below the display alerts you to the current therapy.



5. At the end of the therapy the device will automatically return to the Program menu screen.

ATTENTION: The device recognizes the correct connection of the applicators. During the treatment, below the magnet icon, the connection status is displayed. The presence of the symbol ✓ next to the channel number (Ch1 or Ch2) confirms the correct connection and recognition of the applicator. The symbol **X** next to

the number of the channel (Ch1 or Ch2) warns of the incorrect connection of the applicator, its absence or its incorrect functioning (see *Functioning control* paragraph).

ATTENTION: it's possible to temporary stop the therapy at any time by pressing OK key at least for 2 seconds. Press again OK key to continue the treatment. During the pause time, the green led turns off until the treatment restarts.

ATTENTION: it's possible to get out from the treatment at any time by pressing once ⏻ key, the screen will display the basic settings (step 2). By pressing again ⏻ key the screen will display programs menu (step 1).

SETTABLE PROGRAMS INSTRUCTIONS

MAG2000 allows the user to modify the preset parameters in the programs associated with the pathologies. After choosing the desired program, follow these steps to change the parameters related to the therapy time and the intensity of the magnetic field:

1. In the program detail press OK button to select the moving wrench icon on the left side.

2. Press ▲ and ▼ buttons to adjust the desired therapy hours (from 0 to 24) and confirm by pressing OK. Screen will highlight the therapy minutes.

3. Press ▲ and ▼ key to adjust the desired therapy minutes (from 0 to 59) and confirm by pressing OK key. Screen will highlight treatment intensity;

4. Press ▲ and ▼ key to adjust the treatment intensity (from 5 to 100G on P1-P20 programs, from 5 to 150G on P21-P35 programs) and confirm by pressing OK key.

5. To start the therapy and continue as in the previous paragraph from step 2, press the button ▼ and then OK to select the magnet icon and confirm the start of the treatment. Green light indicates that therapy is running. At the end of therapy, the screen will display automatically the menu programs.

Language selection

Move the ON/OFF switch, placed on device upper side, to the ON position. Immediately after keep pressed the ⏻ button until the language list appears on the display. Release the button: select the chosen language by using the ▲ and ▼ buttons. Press OK key to confirm your selections.

Maintance

If used as prescribed on this manual, the equipment does not require a specific routine maintenance.
In case of malfunctioning problems, please follow these simple instructions:

1. check that the power outlet to which the appliance is connected works regularly by connecting another working device;
2. check the connection with the power supply and the integrity of all the connection cables;
3. check the connection with the applicator (or the applicators);
4. make sure that all the operations have been properly done;
5. verify every two years the device and its full functionality (by contacting the manufacturer).

If you are experiencing any problems or if you need any further information, please contact the manufacturer immediately.

FUNCTIONING CONTROL

MAG2000 is equipped with a magnet (small ring or metal or metal/plastic disc) in order to control the device functioning.
Control procedures:

1. switch on the appliance according to all the safety requirements defined in this manual;
2. activate any therapy in accordance to user manual instructions;
3. get the supplied magnet and place it close to the applicator;
4. check the vibration of the magnet (it will be proportional to the frequency of the selected therapy).

Please contact the manufacturer in case of magnet vibration absence.

CLEANLINESS

It is suggested to remove any trace of dust after each use of the device (and its accessories) by using a soft dry cloth.
We recommend disconnecting the applicator from the device before cleaning the elastic therapeutic belt with 3 solenoids or the circular cases of professional solenoids couple.
Extract the cable with 3 solenoids by removing the 2 silver studs through a screwdriver or open the circular cases through lateral zip.

Clean the tissue by using water and mild soap and wait for the complete drying before reconnecting the applicators.

ATTENTION! Always respect the polarity of the applicators paying attention to insert the bobbins with the side indicated by the **+** symbol turned to the green part of the elastic belt (therapeutic side).

When not using the device for a long time, clean the device and its accessories as mentioned before. Place the device and the accessories in the carriage bag and store them in their box.

When using the same applicator (belt with 3 solenoids or professional solenoids couple) in different patients, we recommend cleaning it carefully as mentioned before.

Pay attention to respect the temperature, humidity and pressure limits mentioned in this manual also during the cleaning of the device and its accessories.

CARRIAGE AND STORAGE

Carriage precautions

MAG2000 is a portable device, so it does not need any carriage precautions.

However, we recommend putting away MAG2000 and its accessories in their own bag after every treatment, and store everything inside the packaging box.

The environmental conditions allowed are the same as per following.

We recommend not to roll up the power supply and the applicators cables.

Storage precautions

The equipment is protected upon the following environmental conditions:

Outside the carrying bag:

temperature	from +5 to + 40 °C
relative humidity	from 10 to 93%
atmospheric pressure	from 700 to 1060hPa

Inside the supplied carrying bag (even for transport):

temperature	from –5 to +40 °C
relative humidity	from 10 to 93%
atmospheric pressure	from 700 to 1060hPa

Disposal

The MAG2000 magnetotherapy apparatus, compatibly with the operating and safety requirements, has been designed and built to have a minimum negative impact on the environment, following the provisions of the European Directive 2012/19/EU on the disposal of waste electrical and electronic equipment.
The criteria followed are those of minimizing the amount of waste, toxic materials, noise, unwanted radiation and energy consumption.
Careful research on optimizing the efficiency of the machines guarantees a significant reduction in consumption, in harmony with the concepts of energy saving.

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

The correct disposal of obsolete equipment, accessories and especially batteries, helps to prevent possible negative consequences on human health and the environment.
The user must dispose of the equipment to be scrapped by taking them to the collection center indicated for the subsequent recycling of electrical and electronic equipment.
For more detailed information on disposing of obsolete equipment, please contact the City Council, the waste disposal service or the shop where you purchased the product.

Warranty

IACER Srl guarantees a warranty period from the purchasing date for MAG2000 device, unless information contained in this manual regarding installation, use and maintenance is strictly adhered. The wearing parts (batteries) are not included in the warranty, unless of visible manufacturing defects. The warranty is void in case of tampering of the device and in case of intervention on the same by personnel not authorized by the manufacturer or by the authorized dealer.
As established by the Medical Device Directive 93/42/EEC, the manufacturer is obliged to trace at any time the equipment supplied to intervene promptly, if necessary, as a result of manufacturing defects.
The warranty conditions are those described in the following paragraph Warranty conditions*. The warranty is provided by IACER.*

Should you need to return the goods then please pack the device and all the accessories so that it won't be damaged during transportation. In order to be entitled to the warranty assistance, the purchaser must enclose to the device a copy of the purchasing receipt, proving origin and purchasing date. For more information on the warranty please contact the distributor or vendor, in order to check the norm and standard in force in your Country, or ultimately the manufacturer IACER Srl.

Warranty conditions

1) Should assistance be needed, enclose the purchasing receipt when sending the device to the manufacturer.
2) The warranty period is valid only on the electronic parts. The warranty will be granted by the shop or directly by the manufacturer.
3) The warranty covers only the product damages, which causes its malfunctioning.
4) Warranty means that only the manufacturing defect components or material are covered by reparation or free substitution, hand work included.
5) Warranty is not applied to damages caused by negligence or use not compliant to the given instructions, by intervention on the device from personnel not authorized, accidental causes or negligence form the purchaser.
6) Warranty is not applied in case of damages caused by unsuitable power supplies.
7) Warranty does not apply to wearing parts.
8) Warranty does not include transportation costs which have to be covered by the purchaser.
9) After the warranty period, the warranty is no more applicable. In this case all the assistance interventions will be performed by debiting the costs of the substitution of the parts, the hand work and the transportations costs.
10) The court of Venice has exclusive jurisdiction over any dispute.

Assistance

The manufacturer is the sole agent for technical assistance on the equipment. For any technical assistance, please contact:

I.A.C.E.R. S.r.l.

Via Enzo Ferrari 2 • 30037 Scorzè (VE)
Tel. 041.5401356 • Fax 041.5402684

Any technical documentation concerning repairable parts may be provided, but only after company authorization and only after having given adequate instruction to the intervention personnel.

Spare parts

The manufacturer shall make available the original spare parts for the equipment at any time. To request them:

I.A.C.E.R. S.r.l.
Via Enzo Ferrari 2 • 30037 Scorzè (VE)
Tel. 041.5401356 • Fax 041.5402684

For the purpose of maintaining the warranty, the functionality and safety of the product it is recommended to use only original spare parts supplied by the manufacturer (also consult the *Warnings* paragraph).

Interference and electromagnetic compatibility tables

The MAG2000 equipment has been designed and manufactured according to the TECHNICAL STANDARD on ELECTROMAGNETIC COMPATIBILITY legislation EN 60601-1-2:2015 with the aim of providing adequate protection from harmful interference when installed in homes and health establishments.
It Is advisable to use the device at a distance of at least 3 meters from televisions, monitors, mobile phones, WI-FI devices or any other electronic equipment as such equipment may affect the operation of the device.
In particular, portable communication equipment such as WI-FI devices, mobile phones, cordless phones and their base stations, walkie-talkie, can affect the medical device and it's recommended a separation distance d calculated from the fabricant in table *RF IMMUNITY ASPECTS*, column $800MHz - 2{,}5GHz$, paragraph EMC tables. Example: for a mobile phone with $2W$ maximum output power the separation distance $d = 3{,}3m$ in order to obtain an immunity level of $3V/m$ or a separation distance $d = 0{,}5m$ for an immunity level of $20V/m$.. The device must be installed and commissioned in compliance with the information on electromagnetic compatibility supplied in this manual. Also consult the *EMC Tables* paragraph.

Using accessories, transducers and cables other than those specified, except for those transducers and cables sold by the manufacturer as spare parts for internal components, may result in increased emissions or decreased immunity of the device.
The device should not be placed next to or on top of other devices. Should it prove necessary to place it next to or on top of other devices, supervision is essential at all times to control its normal functioning.
In particular, in order to prevent any interference problems, it is advisable to operate any therapy device sufficiently distant from critical equipment to monitor patient's vital functions and to use caution in therapeutic applications on patients carrying cardiac stimulators.

For more details consult the compatibility tables in Italian/English at the end of the manual.

ELECTROMAGNETIC COMPATIBILITY TABLES

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – ELECTROMAGNETIC EMISSIONS – FOR ALL DEVICES AND SYSTEMS</th></tr>
<tr><td colspan="3">MAG2000 family is expected to operate in the electromagnetic environment below specified. The customer or user of the MAG2000 family must ensure that it is used in such environment.</td></tr>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions

CISPR 11</td><td>Group 1</td><td>MAG2000 family uses RF energy only for its internal function. Therefore, its RF emissions are very low and are unlikely to cause any interference in nearby electronic equipment</td></tr>
<tr><td>RF emissions

CISPR 11</td><td>Class B</td><td rowspan="3">MAG2000 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions

IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions
IEC 61000-3-3</td><td>Compliant</td></tr>
</table>

Guidance and manufacturer's declaration – ELECTROMAGNETIC IMMUNITY – FOR ALL DEVICES AND SYSTEMS			
MAG2000 is intended for use in the electromagnetic environment specified below. The user or operator of MAG2000 should assure that is used in such environment.			
Immunity test	**Test level IEC 60601**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV; +8kV at contact ±8kV; +15kV in air	±6kV; ±8kV at contact ±8kV; +15kV in air	Floors should be wood, concrete or ceramic tile. If floor is covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines	±2kV for power supply lines	Mains power quality should be at least that one of a typical commercial or hospital environment.
Impulses IEC 61000-4-5	±1kV line - line	±1kV line - line	Mains power quality should be at least that one of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dips of U_T) for 0,5 cycle <5% U_T (>95% dips of U_T) for 1 cycle 70% U_T (30% dips of U_T) for 25 cycles <5% U_T (>95% dips of U_T)	<5% U_T (>95% dips of U_T) for 0,5 cycle <5% U_T (>95% dips of U_T) for 1 cycle 70% U_T (30% dips of U_T) for 25 cycles <5% U_T (>95% dips of U_T)	Mains power quality should be at least that one of a typical commercial or hospital environment. If the user of the MAG2000 requires continued operating during power mains interruptions, it is recommended that MAG2000 be powered from an uninterruptible power supply (UPS) or a battery

Guidance and manufacturer's declaration – ELECTROMAGNETIC IMMUNITY – FOR ALL DEVICES AND SYSTEMS			
MAG2000 is intended for use in the electromagnetic environment specified below. The user or operator of MAG2000 should assure that is used in such environment.			
Immunity test	**Test level IEC 60601**	**Compliance level**	**Electromagnetic environment – guidance**
	for 5s	for 5s	
Mains power electromagnetic field (50/60Hz) IEC 61000-4-8	30A/m	30A/m	Mains power quality should be at least that one of a typical commercial or hospital environment.
Note: U_T is the AC mains voltage before the application of the Test level.			

Guidance and manufacturer's declaration – ELECTROMAGNETIC IMMUNITY FOR DEVICES AND SYSTEMS THAT ARE NOT OF VIABLE FUNCTION			
The MAG2000 Family is expected to operate in the electromagnetic environment below specified. The user or operator of the MAG2000 family must ensure that it is used in this environment.			
Immunity test	**Test level IEC 60601**	**Compliance level**	**Electromagnetic environment – guidance**
Portable and mobile RF communications equipment should not be used near any part of the MAG2000 family, including cables, except where recommended separation distances are observed, calculated from the equation applicable to frequency of the transmitter.			
			Recommended separation distance
Conducted RF IEC 61000-4-6	$3V_{eff}$ from 150 kHz to 80 MHz $6V_{eff}$ from 150 kHz to 80 MHz for ISM band	$3V_{eff}$ ([V_1] V) $6V_{eff}$ ([V_1] V)	$d = \left[\frac{3,5}{V_1}\right]\sqrt{P} = d = \left[\frac{12}{V_1}\right]\sqrt{P}$ for ISM band
Irradiated RF IEC 61000-4-3	10V/m from 80 MHz to 2,7 GHz	10V/m [E_1] V/m	$d = \left[\frac{12}{E_1}\right]\sqrt{P}$ from 80 MHz to 800 MHz

Guidance and manufacturer's declaration – ELECTROMAGNETIC IMMUNITY FOR DEVICES AND SYSTEMS THAT ARE NOT OF VIABLE FUNCTION			
			$d = \left[\frac{7}{E_1}\right]\sqrt{P}$ from 800 MHz to 2,7 GHz
Irradiated RF for radio communication devices IEC 61000-4-3	3 V/m from 80 MHz to 6 GHz	3V/m [E_1] V/m	$d = \left[\frac{6}{E_1}\right]\sqrt{P}$ from 80 MHz to 6 GHz
where (P) is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer and (d) is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 			
Note: (1) At 80 MHz and 800 MHz the separation distance for the higher frequency range applies. (2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the MAG2000 is used exceeds the applicable RF compliance level above, the MAG2000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MAG2000. b) Between the frequencies 150 kHz and 80 MHz, field strengths should be less than [V_1] V/m.			

Recommended separation distances between portable and mobile RF communications equipment for MAG2000 that are not life-supporting
MAG2000 is intended for the use in an electromagnetic environment in which radiated RF disturbances are controlled. The user or the operator of MAG2000 can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and MAG2000 as recommended below, according to the maximum output power of the communication equipment.

Recommended separation distances between portable and mobile RF communications equipment for MAG2000 that are not life-supporting				
Rated maximum power of the transmitter (W)	**Separation distance according to the frequency of transmitter (m)**			
	from 150kHz to 800 MHz	from 150kHz to 800 MHz (ISM band)	from 80MHz to 800 MHz	from 800MHz to 6 Hz (to RF wireless radio communication equipment)
0,01	0,12	0,2	0,12	0,23
0,1	0,38	0,63	0,38	0,73
0,2	–	–	–	–
1	1,20	2,0	1,20	2,30
1,8	–	–	–	–
2	–	–	–	–
10	3,80	6,3	3,80	7,30
100	12,00	20	12,00	23,00
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer.				
Note 1) At 80 MHz and 800 MHz the separation distance for the higher frequency range applies. 2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.				

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