

USER MANUAL

MNPG52-02 Edition 10/05/2011

Magnetotherapy model

MAG2000

I.A.C.E.R. Srl

www.iacer.it www.itechmedicaldivision.com

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Magnetotherapy

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 electromagnetotherapy is universally recognized as the most suitable technique for the treatment of the bony pathologies, in particular for the osteoporosys.

Pulsed electromagnetic fields induce biological modifications on biological membrane, cells and blood vessels with different therapeutic effects: antiflogistic, antiedemigen and tissue repair. In general magnetotherapy assures a good biostimulation in order to re-establish correct cellular functions.

According to different authors experiences in osteoporosys 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.

MAG 2000 is a device able to satisfy home user needs thanks to its high magnetic intensity and its use facility.

Manufacturer

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

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IACER S.r.l. is an Italian medical devices manufacturer (CE medical certificate n°MED24021 issued by Cermet notified body n°0476).

Declaration of conformity

IACER S.r.l., headquartered in Italy, via S. Pertini 24/A 30030 Martellago (VE), declares on its own responsibility that MAG2000 is manufactured in conformity with Directive 93/42/EEC (MDD) dated 14 June 1993 (D. Lgs. 46/97 dated 24 February 1997 “Attuazione della Direttiva 93/42/CEE concernente i dispositivi medici), Annex II as modified by Directive 2007/47/CE dated 5 September 2007 (D. Lgs. 37/2010 dated 25 January 2010).

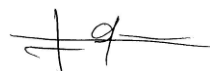
Notified body: Cermet, Via di Cadriano 23 – 40057 Cadriano di Granarolo (BO) Italy.

Certification Path: Annex II.

MAG2000 is a Class IIa equipment, with reference to Directive 93/42/EEC (MDD), annex IX rule 9 (and following modifications).

Martellago, 03/06/10

*Legal Representative
Mario Caprara*



Specifications

MAG 2000 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. CEI EN 60601-1);*
- *Equipment not protected against liquid penetration;*
- *Equipment and accessories not subjected to sterilization;*
- *Use of the equipment is prohibited close to flammable substances or in environments with high concentrations of oxygen;*
- *Continuous operating mode equipment;*
- *Equipment not suited to be used in external.*

Purpose

Clinical purpose: *Therapeutic*

Use: *Clinic/Hospital and domestic use*

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*

- *neuralgias*
- *periarthritis*
- *benign lesions and muscular tears*
- *tendinitis*

MAG2000 is particularly suitable for the treatment and the care of the osteoporosis and all the pathologies on bony tissue, for dermatologic applications (varicose ulcers, phlebitis ulcers, arteropatic ulcers, acne, burn sore, not healed wounds, cellulite, skin illnesses: in these cases we recommend a low treatment intensity, lower than 40). Moreover the device is indicated for tissue reconstruction.

Cellulite treatment is not inserted in the CE0476 marking of the device device. Cellulite treatment can be used only for beauty purposes.

Thanks to its high magnetic field intensity MAG2000 is particularly suitable for the treatment of bone fractures also with rigid bandages or braces.

MAG2000 device is indicated both for professional (physiotherapists, medics etc.) and for domestic user. **In case of home therapy we recommend using the device exclusively on medical/therapist suggestion.**

Expected lifetime: 5 years

Technical features

<i>Power supply</i>	<i>Power Supply MM1510 Series, 15VDC 1A</i>
<i>Max. absorbed current</i>	<i>0,5 A</i>
<i>Insulation class (CEI EN 60601-1)</i>	<i>II</i>
<i>Applied part (CEI EN 60601-1)</i>	<i>BF</i>
<i>Dimensions (mm)</i>	<i>180x110x50</i>
<i>Field intensity</i>	<i>Adjustable on increasing level up to 100 Gauss (each channel) in P1-P20 programs. Adjustable on increasing level up to 150 Gauss (each channel) in P21-P35 programs.</i>
<i>Squared wave frequency</i>	<i>1-100 Hz</i>
<i>Therapy time</i>	<i>Adjustable by user</i>

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 $\pm 20\%$ of accuracy.

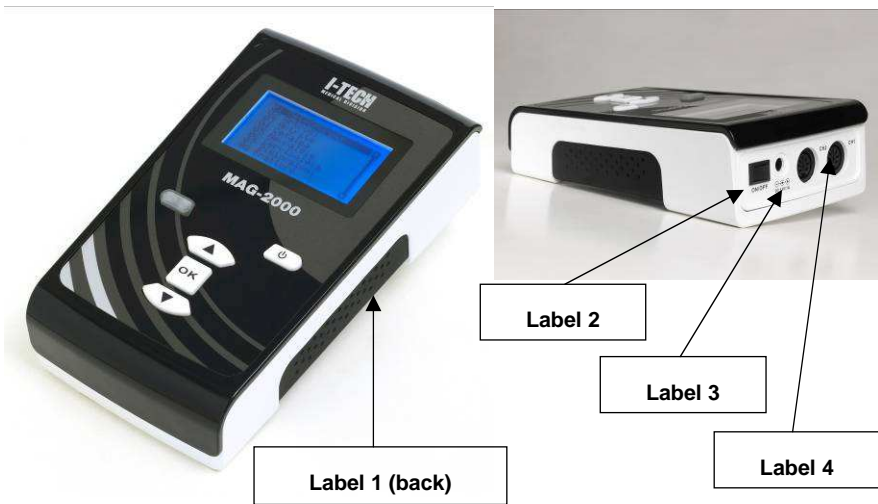
Environmental conditions of operation

Temperature from +5 to + 40 °C

Relative humidity from 30 to 80%

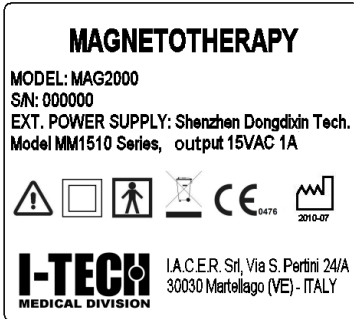
Pressure from 500 to 1060 hPa

Labelling



Label details

Label 1



Label 2

DC 15V/1A






Label 3

ON/OFF

Label 4

CH1 CH2

Symbols description

	Attention, consult operating instructions
	Product subject to WEEE regulations concerning separate waste collection of electronic equipment
	Class II equipment
	Applied part type BF
CE 0476	Compliance with Directive 93/42/EEC and following modifications
	Manufacturing date (month/year)

Kit contents

MAG2000 contains:

- *N°1 MAG2000 device;*
- *N°1 power supply;*
- *N°1 user and maintenance manual;*
- *N°1 elastic therapeutic belt with 3 solenoids;*
- *N°1 carriage bag*

Moreover solenoids couple and magnetotherapy carpet are available as accessories.

Visit website www.iacer.it to obtain more information.

How to use

Warnings

Please read carefully the user manual before using MAG2000.

We recommend to visit magnetotherapy section on website www.iacer.it in order to obtain other information.

Take care of what follows:

- *Take care of position and meaning of the labels on MAG2000;*
- *Do not damage the therapeutic belt acting on connection cable and avoid to roll up the cable around the belt or the device;*
- *Check the integrity of the power supply before use. Avoid the use in case of damage to the case or to the wire;*
- *Avoid the use of MAG2000 to people not educated through the reading of the manual;*
- *Avoid the use of MAG2000 contemporary with ointments containing free ions of magnetic metals;*
- *Do not use the device in damp environments;*
- *Do not use in presence of inflammable agents;*
- *Do not wear metallic objects during therapy;*
- *Take care to place the green side of the therapeutic belt on the skin;*
- *Use only cables and applicators supplied by the Manufacturer. Inadequate cables and applicators could damage the device and/or could be hazardous for the patient;*
- *The user must periodically verify cables and applicators insulation and control their integrity (eventually by contacting the manufacturer).*

- *In case of prolonged treatments (even up to 8 hours) we suggest to use intensity lower than 50. In this case the efficacy is given by the prolonged treatment time rather than maximum adjustable intensity;*
- *High magnetic field intensity (higher than 80/100 Gauss) are recommended for short treatments (up to 2 hours) or in presence of rigid bandages/braces.*

WARNING. Disconnect the power supply from the main after each treatment.

The manufacturer is considered responsible of the performances, reliability and safety of the instrument only if:

- *Possible additions, changes and/or reparations are effected from authorized personnel.*
- *The electric plant of the environment in which MAG2000 is inserted it is conforming to the national laws.*
- *The instrument is employed in conformity to the instructions contained in this manual.*

Electromagnetic interference

The device doesn't produce and doesn't receive interferences from other equipments. However it's opportune to use the instrument keeping it at least at 3 meters from televisions, monitors, cellular telephones or any other electronic equipment.

Contraindications and side effects

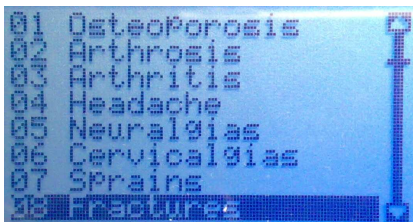
Patient in pregnancy, tuberculosis, juvenile diabetes, viral (in acute phase) illnesses, mycosis, cardiopathic subjects, tumours, serious arrhythmias or pacemaker carriers, children, metallic prosthesis carriers, acute infections, epileptics (different medical prescriptions excepted).

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

Quick use of the device with presetted parameters

We recommend to read the following instructions for an easy and quick use of MAG2000:

1. Connect the applicator (or the applicators) to the device, by connecting the applicator cable to one of two plugs (CH1-CH2) placed on device upper side;
2. Connect the power supply cable to the main, then connect the power supply plug to the circular connector placed on device upper side, near to ON/OFF switch.
3. Connect the power supply plug to the main (110-230 VAC, 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;
5. Select the therapy program running through programs menu, using ▲ and ▼ buttons and put yourself on desired program;



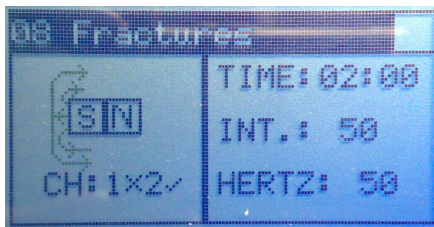
6. Press OK. Screen will display **base setting with therapy time (2 hours) and magnetic field intensity (50 int.). These mean values are recommend by IACER in order to start immediately the treatment.**



7. Press ▼ button highlighting magnet icon on left down position;





8. Press OK key. The device will start the treatment and on screen will be displayed the magnet icon with magnetic field flux. Display green light indicates that therapy is running.




9. At the end of therapy the screen will display automatically the menu programs.

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

Attention: it's possible to get out from the treatment at any time pressing once  key: screen will display the base setting (step 6). By pressing again  key screen will display the programs menu (step 5).

Attention: MAG2000 recognizes applicators correct connection. During the treatment screen displays connection state under the magnet icon.

The presence of symbol  near to the channel number (1 or 2) is an indicator of correct connection and applicator recognition. The symbol **X** near to the channel number (1 or 2) indicates a not correct connection of applicator, or its absence or even its incorrect functioning (see "Functioning control" paragraph).

Therapeutic belt and solenoids couple positioning

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 have to be placed in opposite positions on the area to be treated. Also in this case take care to place the green side of the therapeutic belt on the skin.





Suggestions for a correct use:

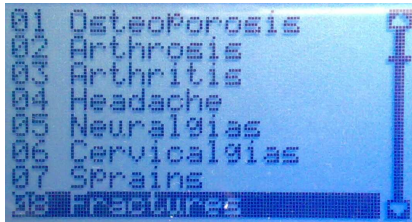
- *In P1-P20 programs a longed treatment with an intensity higher than 60 can heat the 3 solenoids belt and this aspect makes therapy less comfortable: we recommend to space out treatments and to not go over 2 consecutive hours of therapy;*
- *In P21-P35 programs we recommend to use the professional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

Adjustable programs instructions

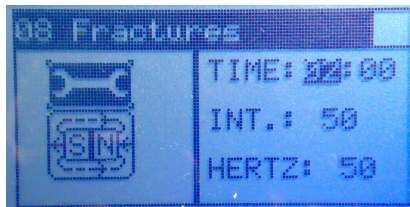
With MAG2000 you can adjust time therapy and magnetic field intensity parameters as indicated in the following steps:

1. Connect the applicator (or the applicators) to the device by connecting applicator cable to one of two plugs (CH1-CH2) placed on device upper side;
2. Connect the power supply cable to the main, then connect the power supply plug to the circular connector placed on device upper side, near to ON/OFF switch;
3. Connect the power supply plug to the main (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;

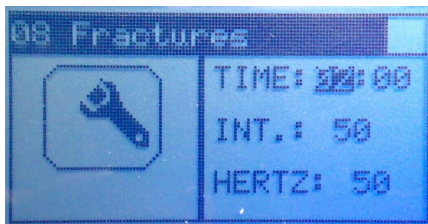
5. Select therapy program running through programs menu using ▲ and ▼ buttons and put yourself on desired program;



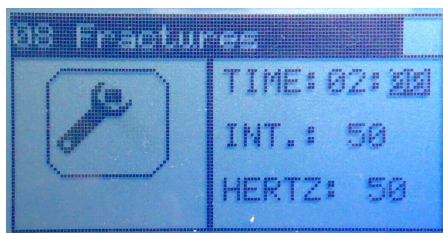
6. Press OK. Screen will display base setting with therapy time (2 hours) and magnetic field intensity (50 int.). These parameters can be modified as follows:



- a) Press OK button: screen displays a moving key icon on the left side;



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



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

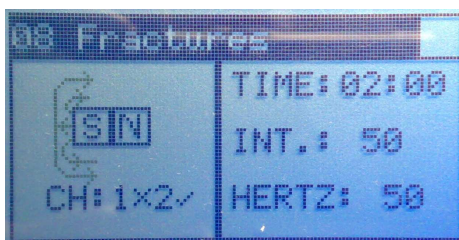


- d) Press ▲ and ▼ key to adjust the treatment intensity (from 5 to 100 Gauss on P1-P20 programs, from 5 to 150 Gauss on P21-P35 programs) and confirm by pressing OK key;

7. Display will show the step 6 screen highlighting the key icon on the left side: press ▼ key to highlight the magnet icon;



8. Press OK: the device will start the treatment displaying on screen the magnet icon with magnetic field flux. Green light indicates that therapy is running.





9. At the end of therapy the screen will display automatically the menu programs.

Attention: it's possible to stop temporary the therapy at any time pressing OK key at least for 2 seconds. Press again OK key to continue


the treatment. During pause time green led turns off till the treatment restarts.

Attention: it's possible to get out from the treatment at any time by

pressing once  key, screen will display the base setting (step 6). By

pressing again  key screen will display programs menu (step 5).

Attention: MAG2000 recognizes applicators correct connection. During the treatment screen displays connection state under the magnet icon.

The presence of symbol  near to the channel number (1 or 2) indicates correct connection and applicator recognition. The symbol **X** near to the channel number (1 or 2) indicates a not correct connection of applicator, or its absence or even its incorrect functioning (see "Functioning control" paragraph).

Stored programs list




Pre-adjusted values			Recommended values		
N°	Pathology	Hz	Time hours	Treatment cycles	Treatment interval
1.	Osteoporosis	50	2 - 6	30	24 hours
2.	Arthrosis	12	2 - 6	20	24 hours
3.	Arthritis	25	2 - 6	20	24 hours
4.	Headache	3	2 - 6	15	24 hours
5.	Neuralgias	25	2 - 6	15	24 hours
6.	Cervicalgias	12	2 - 6	15	24 hours
7.	Sprains	50	2 - 6	15	24 hours
8.	Fractures	50	2 - 6	30	24 hours
9.	Cicatrizations	50	2 - 6	20	24 hours
10.	Ulcers	50	2 - 6	20	24 hours
11.	Intercostal Neuralgia	12	2 - 6	20	24 hours
12.	Lumbalgy	25	2 - 6	15	24 hours
13.	Sciatalgy	25	2 - 6	15	24 hours
14.	Trigeminal Neuralgias	12	2 - 6	15	24 hours

15.	Varicose Ulcers	50	2 - 6	20	24 hours
16.	Periarthritis	50	2 - 6	20	24 hours
17.	Coxartrosis	50	2 - 6	20	24 hours
18.	Muscular atrophy	25	2 - 6	20	24 hours
19.	Muscular contracture	12	2 - 6	15	24 hours
20.	Osteonecrosis	50	2 - 6	20	24 hours
21.	Treat. 1 Hz	1	free	free	24 hours
22.	Treat. 3 Hz	3	free	free	24 hours
23.	Treat. 5 Hz	5	free	free	24 hours
24.	Treat. 10 Hz	10	free	free	24 hours
25.	Treat. 15 Hz	15	free	free	24 hours
26.	Treat. 20 Hz	20	free	free	24 hours
27.	Treat. 30 Hz	30	free	free	24 hours
28.	Treat. 40 Hz	40	free	free	24 hours
29.	Treat. 50 Hz	50	free	free	24 hours
30.	Treat. 60 Hz	60	free	free	24 hours
31.	Treat. 70 Hz	70	free	free	24 hours
32.	Treat. 80 Hz	80	free	free	24 hours
33.	Treat. 90 Hz	90	free	free	24 hours
34.	Treat. 100 Hz	100	free	free	24 hours
35.	Autoscan*	*	2 - 6	20	24 hours

***Autoscan program allows to adjust the desired therapy time then it will start automatically a frequency cycle from 10 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 I.A.C.E.R. S.r.l. however the user can adjust the time as he prefers. **MAG2000** uses therapy time values, working frequency values and field intensity values coming from scientific and medical literature, as result of well known sperimentations and clinical evaluations (Barker - Lunt 1983, Bassett – Pawluk – Pilla 1974, Bassett - Valdes – Hernandez 1982).

Set up (language selection)

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

Maintenance

Functioning control

Mag2000 equipment offers a magnet in order to control the device functioning.

Control procedure:

- 1. switch on the device in according to user manual safety prescriptions;*
- 2. start a treatment in according to user manual instructions;*
- 3. get the magnet and put it near to applicator;*
- 4. check magnet vibration (it will be proportional to selected treatment frequency).*

Please contact the manufacturer in case of magnet vibration absence.

Cleaning

Clean the equipment from the dust using a dry soft cloth.

Resistant stains can be removed using a sponge soaked in solution of water and alcohol (20%).

We recommend to disconnect 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 using water and mild soap and wait for the complete drying before reconnecting the applicators.*

ATTENTION: always respect the applicators polarity paying attention to insert the bobbins with the side indicated by + symbol turned to the green side of elastic belt (therapeutic side)

Carriage and storage

Carriage precautions

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

However we recommend to put away MAG2000 and its accessories in their own bag after every treatment.

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

Storage precautions

MAG 2000 is protected till following environmental conditions:

Outside of the packaging

<i>Temperature</i>	<i>from +5 to + 40 °C</i>
<i>Rel. humidity</i>	<i>from 30 to 80%</i>
<i>Pressure</i>	<i>from 500 to 1060 hPa</i>

Inside of the packaging

<i>Temperature</i>	<i>from –10 to +55 °C</i>
<i>Rel. humidity</i>	<i>from 10 to 90%</i>
<i>Pressure</i>	<i>from 500 to 1060 hPa</i>

Disposal

The equipment is subjected to WEEE regulations (see the symbol



on the label) concerning separate waste collection: when disposing this product, please use the designed areas for disposing electronic waste or contact the manufacturer.

Troubleshooting

If it is used in accordance with the instructions of the user manual, MAG2000 does not need a particular regular maintenance.

If you find any malfunctioning using MAG2000, please follow these instructions:

- *check the main integrity by connecting a running device to the same main;*
- *check the connection with power supply and connection cables integrity;*
- *check the correct connection between MAG2000 and the applicator (or the applicators);*

- *check all the operations have been done properly;*
- *every two years we suggest a complete check of device (contact the manufacturer or locator dealer).*

If you find any problems contact immediately the National Distributor or the manufacturer at the following address:

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Assistance

Every intervention on device must be performed by manufacturer. For any assistance intervention contact the National Distributor or the manufacturer at the following address:

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

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You can get any technical documentation on spare parts but only prior business authorization.

Spare parts

For original spare parts contact the National Distributor or the manufacturer at following address:

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

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To preserve product warranty, functionality and product safety we recommend to use only original spare parts.

Warranty

Make reference to the national laws for any warranty conditions by contacting the national distributor (or directly the manufacturer IACER).

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

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