

### **USER MANUAL**

#### MNPG53-06 Edition 24/04/2014

Magnetotherapy model

# MAG2000 PLUS

I.A.C.E.R. SrI
www.iacer.it www.itechmedicaldivision.com



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# Summary

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#### Introduction

#### 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 bony pathologies, in particular for the osteoporosis.

Pulsed electromagnetic fields induces biological modifications on biological membrane assures a biostimulation in order to reestablish 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 PLUS is a high performances and easy to use device with also free memories (10 user programs in which you can adjust therapy time, magnetic field intensity and working frequency). MAG 2000 PLUS and its professional applicators allow treatment of big area with high magnetic field intensity.



# Technical specifications

#### Manufacturer

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

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IACER S.r.l. is an Italian medical devices manufacturer (CE medical certificate n°MED24021 issued by Cermet notified b ody 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 PLUS 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 dispositive 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, excluded point 4.

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

Martellago, 06/03/13

Legal Representative Mario Caprara

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#### **Specifications**

MAG 2000 PLUS 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);
- 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**

Clinic purpose: Therapeutic

Use: Clinic and domestic use

MAG2000 PLUS 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 PLUS is particularly suitable for the treatment and the care of the osteoporosis and all the pathologies on bony tissue.

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 PLUS is particularly suitable for the treatment of bone fractures also with rigid bandages or braces.

MAG2000 PLUS 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.

According to medical devices directives, the fabricant suggests a device control to check its efficiency and safety every 2 years. Expected lifetime of the device and its accessories (time after which we suggest sending the device to the manufacturer for safety checks): 2 years.

#### Technical features

Power Supply UE24WCP-150120SPA, out 15VDC-

1.2A

Max. absorbed current 0.6 A

Insulation class (CEI EN 60601-1)

Applied part (CEI EN 60601-1) BF

Dimensions (mm) 180x110x50

Field intensity Adjustable on increasing levels up to 100 Gauss

(each channel) in P1-P20 programs

Adjustable on increasing levels up to 150 Gauss

(each channel) in P21-P35 programs

Adjustable on increasing levels up to 200 Gauss

(each channel) in USER programs

Squared wave frequency Adjustable 1-120 Hz

Therapy time Adjustable by user

In free programs (User01-User10) maximum magnetic field intensity is 200 Gauss for each channel with professional solenoids couple.



Intensity, frequency and time values are given with  $\pm 20\%$  of accuracy.

The maximum therapy time recommended is 12 consecutive hours.

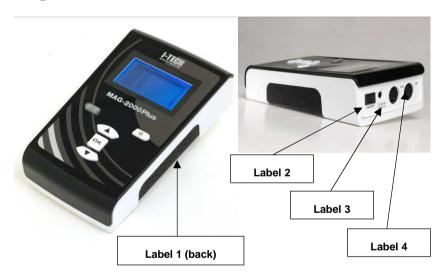
Environmental conditions of operation

temperature from +5 to + 28  $^{\circ}$ C

rel. humidity from 10 to 93%

pressure from 700 to 1060 hPa

#### Labeling





#### Label details

#### Label 1



Label 2 Label 3 Label 4
DC 15V/1A ON/OFF CH1 CH2

UE24WCP-150120SPA

#### Symbols description

	Attention, consult attached documentation
	Product subject to WEEE regulations concerning separate waste collection of electronic equipment
	Class II equipment
<b>*</b>	Applied part type BF
C E <sub>0476</sub>	Compliance with Directive 93/42/EEC and following modifications
س	Manufacturing date (month/year)



SN	Serial number
1	Admission temperatures
<b>%</b>	Relative humidity
	Fabricant information
IP20 IP01	Protection level against solids, dusts and liquids entrance (device protected against solid foreign objects of 12.5 mm and greater and vertically falling water drops). The case of the device guarantees the IP20 level protection. The PVC envelope guarantees the IP01 level protection. The IP21 protection is guaranteed only when using the device inside the PVC envelope.
Û	Only domestic use
<del>**</del>	Not protected against liquids entrance, keep dry.

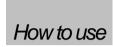
#### Kit contents

#### MAG2000 PLUS contains:

- Nº MAG2000 PLUS device:
- NY power supply (cable around 1.5 m);
- NY user and maintenance manual;
- N°1 elastic therapeutic belt with 3 solenoids (cabl e around 1.5 m);
- N°1 professional solenoids couple (cable around 1.5 m);
- Nº carriage bag
- Nº PVC envelope

Magnetotherapy carpet and OSTEOMAT mattress are available as accessory on demand. Visit website <a href="www.itechmedicaldivision.com">www.itechmedicaldivision.com</a> to obtain more information.





#### **Warnings**

Please read carefully the user manual before using MAG2000 PLUS. We recommend to visit magnetotherapy section on website <a href="https://www.itechmedicaldivision.com">www.itechmedicaldivision.com</a> in order to obtain other information.

#### Take care of what follows:

- Take care of position and meaning of the labels on MAG2000 PLUS;
- 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 PLUS to people not educated through the reading of the manual;
- Avoid the use of MAG2000 PLUS contemporary with ointments containing free ions of magnetic metals;
- Do not use the device in damp environments and/or 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).
- Pay attention to use belt connection cables and power supply: strangulation danger. Pay attention when the cables are next to the patient neck and head: in this case it is recommended to keep a safe position and to avoid sudden movements that could twist the cables.
- The materials used for the device production had passed the toxicity regulations. In case of allergic reactions please suspend the treatment and consult a doctor.
- Do not use on irritated skin or on open wound.



- Do not connect the device and its accessories to other devices not mentioned in the present user manual.
- Keep it out of children and animal's reach.
- Avoid the device and accessories exposition to excessive direct sunlight and dust. Make reference to "Maintenance paragraph".
- In case of prolonged treatments (even up to 8 hours) we suggest to use intensity lower than 50 for all programs. 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. We recommend to keep the device in a safe position in order to disconnect easily the cables. Place the device on a firm shelf (table, nightable) away from other devices that could make interferences or stop a safe use of the device and its connected accessories.

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

- Possible additions, changes and/or reparations are carried out from authorized personnel. It is forbidden any change, adding and/or reparation carried out from not authorized personnel because it could invalidate the safety of the device or its working.
- The electric plant of the environment in which MAG2000 PLUS is inserted it is conforming to the national laws.
- The instrument is employed in conformity to the instructions contained in this manual.

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.

#### Electromagnetic interference

Use the MAG 2000 PLUS device at least 3 metres away from televisions, monitors, mobile phones, WIFI routers or any other electronic device as they may affect its functioning.



In particular portable communication equipments as WIFI 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 "R.f. immunity aspects", column 800MHz-2,5GHz, paragraph EMC tables. Example: for a mobile phone with 2W maximum output power the separation distance d is 3,3 m 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 see the EMC Charts 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.

#### 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.

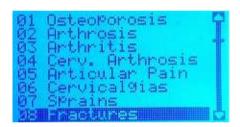
#### Quick use of the device with presetted parameters

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

 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;



- 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 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 recommended by IACER in order to start immediately the treatment.



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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 by 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 **U** key again 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  $\sqrt{}$  near to the channel number (1 or 2) is an indicator of correct connection and applicator recognition. The symbol  $\mathbf{X}$  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 warm 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:

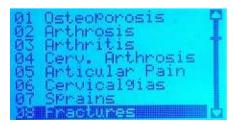
Applicator choice depends on operator discretion (solenoids couple or solenoids belt).

We recommend to use professional solenoids couple if you need an higher field intensity or in case of tissue treatment in depth or still in presence of rigid bandages or braces.

#### Adjustable programs instructions

With MAG2000 PLUS 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;
- 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 running through programs menu using **A** and buttons and put yourself on desired program;





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



- d) Press and keys 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 step 6 screen by 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 **t** key, screen will display the base setting (step 6). By

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

Attention: MAG2000 PLUS 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).

#### MAG2000 PLUS free memories use

MAG2000 PLUS has the possibility to store 10 free memories (from USER 01 to USER 10) choosing therapy parameters as treatment time, field intensity and working frequency.

In free memories only the professional solenoids couple must be used thanks to its rechargeable high intensity.



- 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. Running through programs menu using **A** and **V** 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 keys 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 keys to adjust the desired therapy minutes (from 0 to 59) and confirm by pressing OK key. Screen will highlight treatment intensity;



d) Press and keys to adjust the treatment intensity (from 0 to 200) and confirm by pressing OK key;



7. Press and keys to adjust the working frequency (from 0 to 120) and confirm by pressing OK key. Display will show 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 screen will display automatically the menu program.

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

Attention: MAG2000 PLUS recognizes applicators correct connection. During the treatment screen displays connection state under the magnet icon. The presence of symbol  $\sqrt{}$  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			Reco	ommended valu	ues
N°	Pathology	Hz	Time hours	Treatment cycles	Treatment interval
1.	Osteoporosis	50	2 - 6	30	24 hours
2.	Arthrosis	15	2 - 6	20	24 hours
3.	Arthritis	30	2 - 6	20	24 hours
4.	Cervical arthrosis	5	2 - 6	15	24 hours
5.	Articular pain	25	2 - 6	15	24 hours
6.	Cervicalgias	10	2 - 6	15	24 hours
7.	Sprains	50	2 - 6	15	24 hours
8.	Fractures	50	2 - 6	30	24 hours
9.	Epicondylitis	45	2 - 6	20	24 hours
10.	Epitrocleitis	40	2 - 6	20	24 hours
11.	Intercostal contusions	15	2 - 6	20	24 hours
12.	Lumbalgy	60	2 - 6	15	24 hours
13.	Lumbar pain	60	2 - 6	15	24 hours
14.	Shoulder arthrosis	30	2 - 6	15	24 hours
15.	Knee arthrosis	45	2 - 6	20	24 hours
16.	Periarthritis	50	2 - 6	20	24 hours
17.	Coxartrosis	50	2 - 6	20	24 hours
18.	Muscular atrophy	35	2 - 6	20	24 hours
19.	Muscular contracture	20	2 - 6	15	24 hours
20.	Osteonecrosis	50	2 - 6	20	24 hours
21.	Treat. 1 Hz	1	free	free	24 hours



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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

MAG2000 PLUS has also the possibility to store 10 user memories (USER01-USER10) choosing the work frequency, therapy time and field intensity.

\* 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 PLUS** 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 PLUS 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;
- 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%).

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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 to clean it carefully 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).

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

However we recommend to put away MAG2000 PLUS and its accessories in their own bag after every treatment. The admitted environmental conditions are indicated in the following chapter.

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

#### Storage precautions

MAG 2000 PLUS is protected till following environmental conditions:

Outside of the packaging

Rel. humidity

Temperature from +5 to + 40 ℃

from 10 to 93%

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Pressure from 700 to 1060 hPa

Inside of the packaging

Temperature from −5 to +40 °C

Rel. humidity from 10 to 93%

Pressure from 700 to 1060 hPa

#### 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 PLUS, 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 PLUS 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 manufacturer at the following address:

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Via S. Pertini, 24/a • 30030 Martellago (VE) - ITALY Tel. +39 0415401356 • Fax +39 0415402684

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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.I.

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www.itechmedicaldivision.com • iacer@iacer.it

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 manufacturer at following address:

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

Via S. Pertini, 24/a • 30030 Martellago (VE) - ITALY Tel.+39 0415401356 • Fax +39 0415402684

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

#### **EMC Tables**

Electromagnetic emission				
Emission test Compliance Electromagnetic environment –				
		guidance		
RF emissions Cispr 11	Group 1	MAG 2000 PLUS uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment		
RF emissions Cispr 11	Class B	MAG 2000 PLUS 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.		



Harmonic emissions IEC 61000-3-2	Class A Complies	The MAG 2000 PLUS is suitable for use in all establishments, other than domestic establishments and those
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes

#### **Electromagnetic immunity**

MAG 2000 PLUS is intended for use in the electromagnetic environment specified below. The customer or the user of MAG 2000 PLUS should assure that is used in such environment.

Immunity test	Test level EN 60601-1-2	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) EN 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	Floors should be wood, concrete or ceramic tile. If floor are 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 per power supply lines	Mains power quality should be at that of a typical commercial or hospital environment.
Impulses EN 61000-4-5	±1kV differential mode	±1kV differential mode	Mains power quality should be at that 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 <sub>T</sub> (>95% dips of U <sub>T</sub> ) per 0,5 cycles  40% U <sub>T</sub> (60% dips of U <sub>T</sub> ) per 5 cycles  70% U <sub>T</sub> (30% dips of U <sub>T</sub> ) per 25 cycles  < 5% U <sub>T</sub> (>95% dips of U <sub>T</sub> ) per 5 seconds	< 5% U <sub>T</sub> (>95% dips of U <sub>T</sub> ) per 0,5 cycles  40% U <sub>T</sub> (60% dips of U <sub>T</sub> ) per 5 cycles  70% U <sub>T</sub> (30% dips of U <sub>T</sub> ) per 25 cycles  < 5% U <sub>T</sub> (>95% dips of U <sub>T</sub> ) per 5 seconds	Mains power quality should be at that of a typical commercial or hospital environment. If the user of the MAG2000 requires continued operation during power mains interruptions, it is recommended that MAG2000 be powered from an uninterruptible power supply or a battery.
Mains power electromagnetic field EN 61000-4-8	3 A/m	3 A/m	Mains power quality should be at that of a typical commercial or hospital environment.

	r.f. immunity				
MAG 2000 PLUS	is intended for use in	n the electromagnet	c environment specified below.		
The customer or	The customer or the user of MAG 2000 PLUS should assure that is used in such				
environment					
Immunity test	Immunity test				
60601-1-2 level environment – guidance					
Conducted RF	3 Veff from	3 Veff from	Portable and mobile RF		
EN 61000-4-6	150kHz to 80MHz	150kHz to 80MHz	Portable and mobile RF		



RF Radiata EN 61000-4-3	3 Veff from 80MHz to 2,5GHz	3 Veff from 80MHz to 2,5GHz	communications equipment should be used no closer to any part of MAG 2000 PLUS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance:
			d = 1,2 ·√P 150kHz to 80MHz
			d = 1,2 ·√P 80 MHz to 800 MHz
			d = 2,3 √P 800 MHz to 2,5 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, are determined by an electromagnetic site survey, should be less than the compliance level in each frequency rage.

Interference may occur in the vicinity of equipment marked with the following symbol:

## Recommended separation distances between portable and mobile communications equipment and the MAG 2000

MAG 2000 PLUS is intended for the use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of MAG 2000 PLUS can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and MAG 2000 PLUS as recommended below, according to the maximum output power of the communication equipment.

Rated maximum power of the	Separation distance according to the frequency of the transmitter (m)				
transmitter (W)	150kHz to 80MHz d = 1,2 $\cdot$ √P d = 1,2 $\cdot$ √P 80MHz to 800MHz d = 2GHz d = 2,3 $\cdot$ √P				
0,01	0,12	0,12	0,23		
0,1	0,38	0,38	0,73		
1	1,2	1,2	2,3		
10	3,8	3,8	7,3		
100	12	12	23		



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.

#### Warranty

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

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I.A.C.E.R. Srl 35 MNPG53-06

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