USER MANUAL

MNPG273-00 Edition 03/01/2020

Magnetotherapy model

MAG3000

I.A.C.E.R. Srl

www.itechmedicaldivision.com

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I-TECH
MEDICAL DIVISION

Summary

Introduction

Magnetotherapy

The treatment of certain conditions through low frequency and high intensity pulsed magnetic fields has garnered great consensus amongst international scientific circles for many years, especially as regards chronic and degenerative diseases.

Magnetotherapy uses low frequency and high intensity pulsed magnetic fields induced by the electric current that runs through a coil; due to its characteristics it is now universally recognised as the most suitable technique for the treatment of bone conditions and in particular for osteoporosis.

The biological modifications induced by the magnetic fields on the cell membranes guarantee a biostimulation able to restore the correct functionality of the cell itself.

According to the experiences of several authors, in cases of osteoporosis, already starting from the sixth treatment session there is a remarkable regression of pain symptoms and even more striking is that a significant increase in BMD (Bone Mass Density) is noted. The high magnetic field flux value (Gauss) generated by the device allows the treatment of the patient even in the presence of braces or plaster casts.

Technical specification

Manufacturer

I.A.C.E.R. S.r.l.
Via S. Pertini, 24/a • 30030 Martellago (VE)
Tel. 041.5401356 • Fax 041.5402684

IACER S.r.l. is an Italian manufacturer of medical devices (CE certificate No. issued by the Notified Body No. 1936 TÜV Rheinland Italia srl).

Declaration of conformity

IACER S.r.l., with registered office in via S. Pertini 24/A 30030 Martellago (VE), declares that the MAG3000 device complies with the essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (Leg. Decree46/97 of 24 February 1997 "Implementation of Directive 93/42/EEC concerning medical devices"), Annex II as amended by Directive 2007/47/EC of 5 September 2007 (Leg. Decree37/2010 of 25 January 2010).

Notified body:TÜV Rheinland Italia srl, Via Mattei 3 - 20010 Pogliano Milanese (MI) Italy.

Certification path:Annex II, excluding item 4.

The MAG3000 device is a class IIa equipment according to Annex IX, rule 9 of Directive 93/42/EEC (and subsequent amendments).

Martellago, 12/06/19

The legal representative

Massimo Marcon

Classifications

In accordance with point 1.1 of Annex IX of DIRECTIVE 93/42/EEC (and subsequent amendments), the MAG3000 is a type of device designed for continuous use for less than 24 hours. According to point 1.4 of the same annex, the device relies on an electrical energy source, therefore it is considered as an active medical device. With reference to point 1.5 of the mentioned annex, the MAG3000 is an active therapeutic device, as it is intended for the treatment of various types of conditions. In accordance with Rule 9, paragraph 3 of Annex IX of Directive 93/42/EEC, all active therapeutic devices intended for the administration or exchange of energy are in Class IIa unless their characteristics are such as to enable them to release energy to the human body or exchange energy with the human body in a potentially dangerous form, taking into account the nature, density and part where the energy is applied, in which case they fall into class IIb. Considering the fact that pulsed magnetic fields do not fall into the category of ionizing radiation, and that do not involve direct application of electric current on the patient, it can be said that the energy exchanged by the device with the human body is not at all dangerous.

Therefore, the devices of the LaMagneto line are active medical devices belonging to class IIa. With regard to the second sentence of Annex IX, "If several rules apply to the same device, based on the performance specified for the device by the manufacturer, the strictest rules resulting in the higher classification shall apply to the device of the LaMagneto line. Therefore the classification is IIa.

The MAG3000 device assumes the following classifications:

- *Class II with type BF applied part (Classif. IEC EN 60601-1);*
- *Device with IP21 degree of protection against the penetration of solid objects, powders and liquids.*
- *Device and accessories supplied non-sterile and not subject to sterilisation;*
- *Device not suitable for use in the presence of a flammable anaesthetic mixture with air, with nitrous oxide, with any flammable agent of any kind and in environments with a high concentration of oxygen;*
- *Device intended for continuous operation;*
- *Device not suitable for external use.*

Intended purpose and scope of use

Clinical purpose:	*Therapeutic*
Scope of use:	*Outpatient Clinic/Hospital and home*

MAG3000 is designed and indicated for the treatment, rehabilitation and functional recovery of conditions concerning:

- *joints of the wrist, hand, shoulder, foot, ankle and knee*
- *the musculoskeletal system*
- *arthrosis*
- *muscular atrophies and dystrophies*
- *bursitis*
- *bruises*
- *degenerative disease of the locomotor system*
- *sprains*
- *periarthritis*
- *benign lesions and pulled muscles*
- *tendinitis and tendinosis*

MAG3000 is particularly indicated for the treatment of delayed union, osteoporosis, bone oedema, osteonecrosis, as well as ulcers and neuropathies.

Thanks to the high intensity of the magnetic field it is able to generate, MAG3000 is particularly indicated in the treatment of bone fractures even in the presence of rigid bandages or plaster casts.

The distinctive feature of the MAG3000 device is the possibility of managing two treatments at the same time, by setting different times and programs.

MAG3000 is a device intended for both professional users (doctor, therapist etc.) and for in-home therapy. ***With regard in-home therapy, it is recommended that the device only be used following advice from your doctor/therapist.***

In accordance with guidelines for medical devices, the manufacturer suggests a check of the efficiency and safety of the device every 24 months. Useful life of the device and its accessories (period after which it is suggested to send the device to the manufacturer):3 years

Technical characteristics

Power supply	*Pow. UES36LCP-150200SPA, out 15VDC-2A*
Max. current consumption	*1 A*
Insulation class (CEI EN 60601-1)	*II*
Applied part (CEI EN 60601-1)	*BF*
Dimensions (length x width x height)(mm)	*180x110x50*
Intensity of the field	*Adjustable with increasing scale up to 150 Gauss (per channel).*
Frequency of the square wave	*1-100 Hz*
Therapy time	*User-settable*

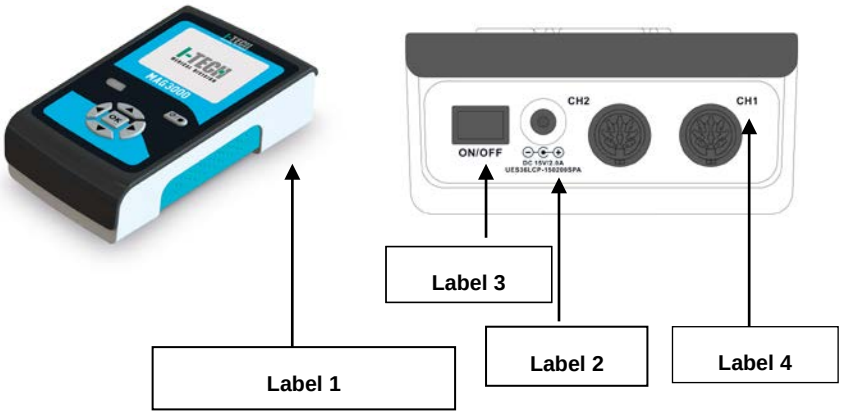
The maximum magnetic field intensity is 150 Gauss per channel with a professional applicator with a pair of solenoids (optional accessory).

The values of intensity, frequency and time are supplied with an accuracy of ± 20%.

Environment operating conditions:

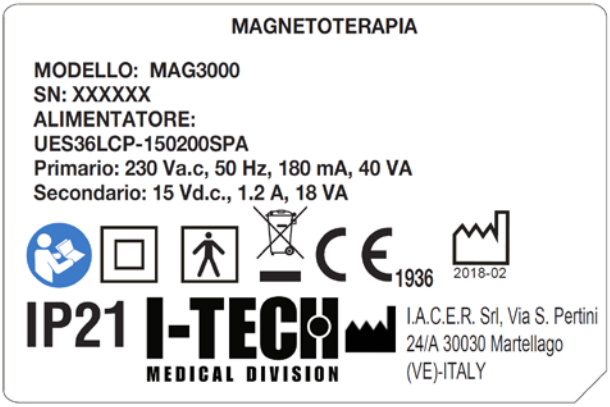
temperature	*from +5 to + 30°C*
relative humidity	*from 15 to 93%*
pressure	*from 700 to 1060 hPa*

Labelling

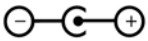


Device labels in detail

Label 1



Label 2



DC 15V/2.0A

UES36LCP-150200SPA

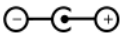
Label 3

ON/OFF

Label 4

CH1 CH2

Description of the symbols (device and packaging)

	Follow the "instructions for use"
	Waste disposal (WEEE Directive)
	Class II device
	Applied part type BF
	This product complies with European Community Directive 93/42/EEC and subsequent amendments
	Date of manufacture (month/year)
	Serial number
	Temperatures permitted
	Relative humidity
	Manufacturer's data
IP21	Degree of protection against the entry of solids, powders and liquids
	Center positive symbol

Contents of the pack

The MAG3000 pack contains:

- *N°1 MAG3000 device;*
- *N°1 medical power supply (approx 1.5mt cable);*
- *N°1 Use and maintenance manual;*
- *N°1 belt applicator with 3 solenoids (approximately 1.5mt cable);*

- *N°1 device carry bag;*
- *Magnet for verifying therapy operation*
- *Non-woven fabric strip 15x150 cm (see page 15 for further details)*

The professional applicator with a pair of solenoids is available as an optional accessory. Visit ***www.itechmedicaldivision.com/it*** *for more information.*

How to use the device

Warnings

It is recommended to read this manual carefully before using the device. For any further information and details we advise you to visit our website ***www.itechmedicaldivision.com/it*** *and refer to the section dedicated to magnetotherapy.*

Nevertheless, please follow the following instructions:

- *Check the location and meaning of all labels affixed to the device;*
- *Do not damage the applicator by acting on the connecting wire, also avoid winding the wire around the applicator or around the device;*
- *Check the integrity of the power supply each time it is used. Avoid use in the case of signs of damage to the casing or to the connecting wire;*
- *People who are not properly trained and who have not read this manual must not use the device;*
- *Avoid using the device while using ointments containing free ions of magnetisable metals;*
- *Avoid using the device in humid environments and/or in the presence of flammable agents;*
- *During therapy, the user and the patient are advised not to wear metal objects;*
- *Position the applicator in such a way that the green side is in contact with the patient's skin;*
- *Use only cables and applicators supplied by the Manufacturer. Inadequate cables and applicators could damage the device and/or cause harm to the patient;*

- *The user must periodically check the insulation (integrity) of the applicators and their cables and check that they are not damaged (contacting the manufacturer if needed);*
- *The user must pay attention when using the connecting cables of the belt and the power supply: strangulation risk.*
- *The materials used for producing the device exceed the required standards regarding material toxicity. In case of allergic reactions, discontinue therapy and consult a doctor.*
- *Do not connect the device and its accessories to other devices not indicated in this manual.*
- *Keep out of the reach of children and animals.*
- *Avoid exposing the device and its accessories to excessive direct light and dust. Refer to the indications in the paragraph "How to look after the device";*

CAUTION. Disconnect the power supply from the wall socket at the end of the therapy session.

The manufacturer is to be considered responsible for the safety, reliability and performance of the device provided that:

- *any additions, modifications and/or repairs are carried out by personnel authorized directly by the manufacturer.*
- *the electrical system of the environment in which MAG3000 is inserted complies with national laws.*
- *the devices are used in strict compliance with the instructions reported in this manual.*

Electromagnetic interference

It is advisable to use the device at a distance of at least 3 meters from televisions, monitors, mobile phones, WI-FI routers or any other electronic equipment as these devices could affect the operation of the device.

The device must be installed and operated in accordance with the electromagnetic compatibility information contained in this manual. See also the paragraph EMC tables.

The use of accessories, transducers and cables other than those specified, with the exception of those sold by the manufacturer as replacement parts for internal components, may result in increased emissions and decreased immunity.

The device should not be used near or placed on top of other equipment and, if it is necessary to use it near or placed on top of other equipment, it

should be observed to check normal operation in the configuration in which it is used.

Contraindications and side effects

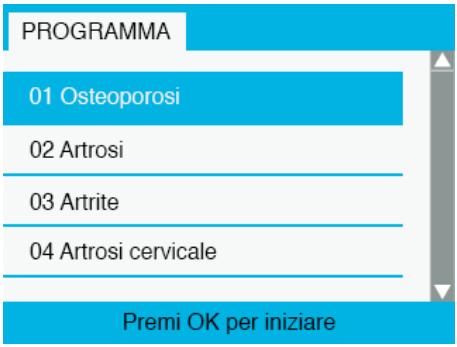
Pregnant women, patients with tuberculosis, juvenile diabetes, viral diseases (in the acute phase), mycosis, subjects with heart disease, those suffering from tumors, severe arrhythmias or pacemaker wearers, children, those with magnetisable prostheses, acute infections, epileptics (unless otherwise prescribed by doctors).

There are no known significant side effects related to therapy, nor have there been any problems reported related to excessive exposure to the electromagnetic field generated by the device.

Quick use of the device with preset parameters

To start using *MAG3000* quickly and easily, we recommend that you follow the steps below:

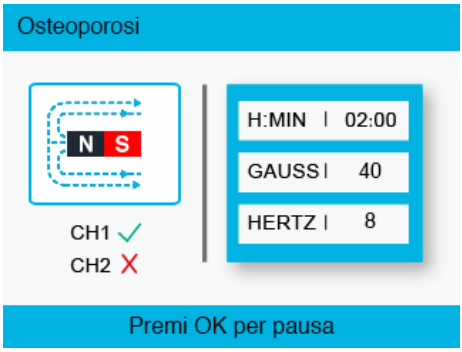
1. Connect the applicator (or applicators) to the device by connecting the plug of the applicator cable to one of the two ports (CH1-CH2) on the panel at the top of the appliance;
2. Connect the mains cable to the power supply and then connect the power supply outlet to the circular connector on the panel at the top of the appliance, near the ON/OFF switch:
3. Connect the plug of the mains cable to the mains socket (110-230VAC, 50-60 Hz);
4. Press the ON/OFF switch on the small panel on the upper part so it is in the ON position: the display will show the I-TECH MEDICAL DIVISION logo and then the main menu screen; for quick standard use, now select the first item "Single patient" by pressing the "OK" button.
5. Scroll through the program using the buttons ▲ and ▼ and select the desired program;



6. Press OK. The display will show **the basic setting time of the therapy (2 hours) and magnetic field intensity. These are the average values suggested by IACER to immediately start the treatment effectively.**

Label 1

7. Press the OK button. The device will start the treatment, displaying the magnet icon with the magnetic field flux. The green light below the display notifies the therapy is underway.



8. At the end of the therapy, the device will automatically return to the program menu screen.

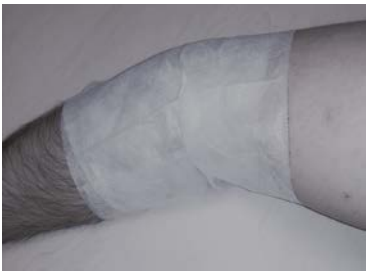
Note: it is possible to temporarily suspend therapy at any time by pressing the OK button. To resume therapy, press the OK button again. During the pause phase the green LED goes off, and then comes back on when the therapy is restarted.

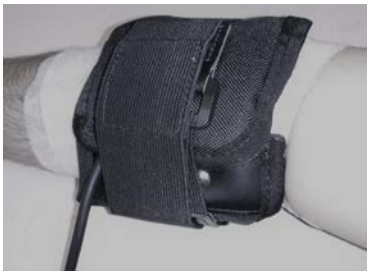
Note: it is possible to exit the treatment at any time by pressing the ⏻/■ button once: the device will go back to the screen of the selected program (point 6). By pressing the ⏻/■ button again the device will go back to the initial screen of the program menu (point 5).

Note: the device recognises if the applicators are connected correctly. During the therapy phase, the connection status is displayed below the magnet icon. The presence of the symbol √ next to the channel number (1 or 2) confirms the applicator is connected correctly and recognized. The **X** symbol next to the channel number (1 or 2) tells you that the applicator is not connected correctly, missing or not working correctly (see paragraph "Checking device operation").

Use of the therapeutic belts and solenoids, main applications and suggestions

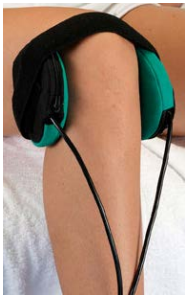
Some of the main positions for applying the therapeutic belt and the solenoids are given below.
***N.B:** it is recommended to interpose the non-woven fabric strip between the skin and the applicator.*
Wrap the 3-solenoid belt (applicator) around the area to be treated (or place it over the area, such as in the treatment of the vertebral column) taking care that the green side of the belt is placed in contact with the skin. Two photos are given below by way of example.

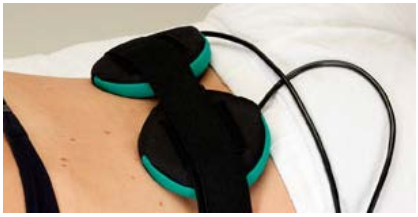




The professional solenoids (accessory to be purchased separately) must be placed on the area to be treated, opposite each other, taking care that the green side is placed on the same side of the skin.

The photos below are for illustration purposes only concerning applicator placement. Remember that between the applicator and the skin it is necessary to interpose the non-woven fabric strip contained in the pack.

 Ankle	 Hip	 Back (lumbar)	 Knee
 Shoulder	 Wrist	 Elbow	 Cervical vertebrae
 Knee	 Tibia / fibula	 Ankle	
 Shoulder	 Femoral head	 Femur	

	
Vertebral column	Lumbar

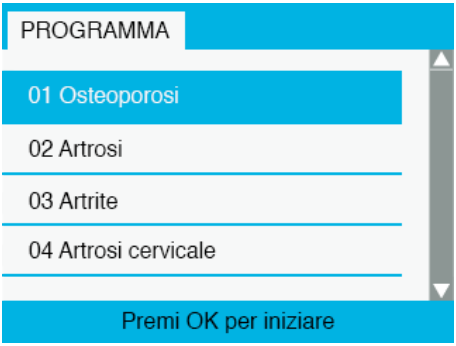
Suggestions for correct use:

- *The device and the applicators are designed to operate in the temperature ranges indicated with treatments of up to 12 consecutive hours;*
- *In the P1-P41 programs, if you set an intensity higher than 100, with extended therapy times, the 3-solenoid belt could heat up thereby making the therapy uncomfortable: it is advisable to split up the treatment sessions and do not exceed 2/3 consecutive hours of therapy;*
- *In P42-P45 programs, if you want to set an intensity higher than 100 with treatments over 2 hours, we recommend using the professional applicator with a pair of solenoids available as an optional accessory for MAG3000.*

Instructions for using the preset programs

To use *MAG3000* by freely setting the parameters regarding therapy time and magnetic field intensity, follow these simple steps:

1. Connect the applicator (or applicators) to the device by connecting the plug of the applicator cable to one of the two ports (CH1-CH2) on the panel at the top of the appliance;
2. Connect the mains cable to the power supply and then connect the power supply outlet to the circular connector on the panel at the top of the device, near the ON/OFF switch;
3. Connect the plug of the mains cable to the mains socket (110-230VAC, 50-60 Hz);
4. Press the ON/OFF switch on the small panel in the upper part so it is in the ON position: the display will show the I-TECH MEDICAL DIVISION logo and then the main menu screen;
5. Select "Single Patient" and scroll through the programs using the ▲ and ▼ buttons and select the desired program



6. Press OK. The display will show the basic setting of therapy time (2 hours) and intensity of magnetic field that we will modify;

a) Press the button ▼ so that the spanner is highlighted. At this point press OK: the display shows a moving spanner icon on the left-hand side;

b) Use the ▼ and ▲ buttons to set the desired therapy hours (from 0 to 24) and confirm by pressing the OK button. The display will highlight the minutes of therapy;

c) Use the ▲ and ▼ buttons to set the desired therapy minutes (from 0 to 59) and confirm by pressing the OK button. The display will highlight the intensity of the treatment;

d) Use the ▲ and ▼ buttons to set the treatment intensity and confirm by pressing the OK buttons.

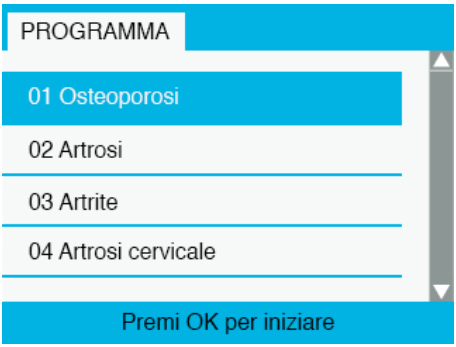
7. The device will return to the screen in point 6.Press OK: the device will start the treatment, displaying the magnet icon with the magnetic field flux. The green light tells you the therapy is underway.

8. At the end of the therapy, the device will automatically return to the program menu screen.

Instructions for using programs in Double Patient mode

To use the "Double Patient" mode of the *MAG3000* device, follow these simple steps:

1. Connect the applicator (or applicators) to the device by connecting the plug of the applicator cable to one of the two ports (CH1-CH2) on the panel at the top of the appliance;
2. Connect the mains cable to the power supply and then connect the power supply outlet to the circular connector on the panel at the top of the device, near the ON/OFF switch;
3. Connect the plug of the mains cable to the mains socket (110-230VAC, 50-60 Hz);
4. Press the ON/OFF switch on the small panel in the upper part so it is in the ON position: the display will show the I-TECH MEDICAL DIVISION logo and then the main menu screen;
5. Select "Double Patient" by pressing the button ▶ and press OK;
6. Scroll through the programs using the buttons ▲ and ▼ and select the desired program;



Choose the desired settings:

a) Use the ▲ and ▼ buttons to set the desired therapy hours (from 0 to 24) and confirm by pressing the OK button. The display will highlight the minutes of therapy;

b) Use the buttons ▲ and ▼ to set the desired therapy minutes (from 0 to 59) and confirm by pressing the OK button. The display will highlight the intensity of the treatment;

c) Use the ▲ and ▼ buttons to set the treatment intensity and confirm by pressing the OK button;

7. The device will now let you select the second program to be carried out. Follow the procedure described in point 6.
8. At the end of the therapy, the device will automatically return to the program menu screen.

Note: it is possible to temporarily suspend therapy at any time by pressing the OK button. To resume therapy, press the OK button again. During the pause phase the green LED goes off, and then comes back on when the therapy is restarted.

Note: it is possible to exit the treatment at any time by pressing the ⏻/■ button once: the device will go back to the screen of the selected programme (point 6). By pressing the ⏻/■ button again the device will go back to the initial screen of the programme menu (point 5).

Note: the device recognises if the applicators are connected correctly. During the therapy phase, the connection status is displayed below the magnet icon. The presence of the symbol ✓ next to the channel number (1 or 2) confirms the applicator is connected correctly and recognized. The **X** symbol next to the channel number (1 or 2) tells you that the applicator is not connected correctly, missing or not working correctly (see paragraph "Checking device operation").

List of stored programs

Preset values			Recommended values		
No.	**Condition**	**Hz**	**Duration hours**	**Session cycles**	**Interval between sessions**
1.	**Osteoporosis**	**8**	**2 – 6**	**30 – 60**	**24 hours**
2.	**Arthrosis**	**30**	**2 – 6**	**30 – 60**	**24 hours**
3.	**Arthritis**	**30**	**2 – 6**	**30 – 60**	**24 hours**
4.	**Cervical arthrosis**	**10**	**2 – 6**	**30 – 60**	**24 hours**
5.	**Articular pain**	**30**	**2 – 6**	**30 – 60**	**24 hours**
6.	**Cervicalgias**	**20**	**2 – 6**	**30 – 60**	**24 hours**
7.	**Chronic pain**	**10**	**2 – 6**	**30 – 60**	**24 hours**
8.	**Fractures**	**25**	**2 – 6**	**30 – 60**	**24 hours**
9.	**Epicondylitis**	**25**	**2 – 6**	**30 – 60**	**24 hours**
10.	**Epitrocleitis**	**25**	**2 – 6**	**30 – 60**	**24 hours**
11.	**Pseudoarthrosis**	**75**	**2 – 6**	**30 – 60**	**24 hours**
12.	**Lumbalgy**	**50**	**2 – 6**	**30 – 60**	**24 hours**
13.	**Lumbar pain**	**50**	**2 – 6**	**30 – 60**	**24 hours**
14.	**Shoulder Arthrosis**	**30**	**2 – 6**	**30 – 60**	**24 hours**
15.	**Knee arthrosis**	**30**	**2 – 6**	**30 – 60**	**24 hours**
16.	**Scapulohumeral periarthritis**	**4**	**2 – 6**	**30 – 60**	**24 hours**
17.	**Coxarthrosis**	**30**	**2 – 6**	**30 – 60**	**24 hours**
18.	**Muscular atrophy**	**30**	**2 – 6**	**30 – 60**	**24 hours**
19.	**Muscular treatment**	**30**	**2 – 6**	**30 – 60**	**24 hours**
20.	**Osteonecrosis**	**75**	**2 – 6**	**30 – 60**	**24 hours**
21.	**Algodystrophy**	**30**	**2 – 6**	**30 – 60**	**24 hours**
22.	**Cartilage lesion**	**75**	**2 – 6**	**30 – 60**	**24 hours**

23.	**Ligament lesion**	**75**	**2 – 6**	**30 – 60**	**24 hours**
24.	**Bone oedema**	**75**	**2 – 6**	**30 – 60**	**24 hours**
25.	**Tendinitis**	**73**	**2 – 6**	**30 – 60**	**24 hours**
26.	**Chondropathy**	**30**	**2 – 6**	**30 – 60**	**24 hours**
27.	**Anti-inflammatory**	**75**	**2 – 6**	**30 – 60**	**24 hours**
28.	**Whiplash syndrome**	**20**	**2 – 6**	**30 – 60**	**24 hours**
29.	**Healing**	**12**	**2 – 6**	**30 – 60**	**24 hours**
30.	**Cutaneous ulcers**	**12**	**2 – 6**	**30 – 60**	**24 hours**
31.	**Discopathy**	**25**	**2 – 6**	**30 – 60**	**24 hours**
32.	**Myalgia**	**1**	**2 – 6**	**30 – 60**	**24 hours**
33.	**Neuropathy**	**10**	**2 – 6**	**30 – 60**	**24 hours**
34.	**Muscle strain**	**1**	**2 – 6**	**30 – 60**	**24 hours**
35.	**Muscular cramp**	**1**	**2 – 6**	**30 – 60**	**24 hours**
36.	**Rhizarthrosis**	**25**	**2 – 6**	**30 – 60**	**24 hours**
37.	**Impingement syndrome**	**50**	**2 – 6**	**30 – 60**	**24 hours**
38.	**Carpal tunnel**	**50**	**2 – 6**	**30 – 60**	**24 hours**
39.	**Titanium prosthesis**	**75**	**2 – 6**	**30 – 60**	**24 hours**
40.	**Rotator cuff**	**73**	**2 – 6**	**30 – 60**	**24 hours**
41.	**Tarsal tunnel**	**30**	**2 – 6**	**30 – 60**	**24 hours**

Osteoporosis: specific program for stimulating bone regeneration.

Arthrosis: program designed to reduce pain and slow down the degenerative process.

Arthritis: program designed to reduce pain and slow down the degenerative process.

Cervical arthrosis: program designed to reduce pain and slow down the degenerative process in the cervical area.

Articular pain: analgesic program designed for the joints.

Cervicalgias: specific program for the reduction of cervical pain.

Chronic pain: program designed to reduce pain and inflammatory processes. It is recommended to use the applicators on the area where the pain is felt.

Fractures: specific program for the stimulation of bone regeneration in a post-traumatic condition.

Epicondylitis: specific program for this condition, aimed at promoting the recovery of the joint in an inflammatory condition of the tendons.

Epitrocleitis: specific program for this condition, aimed at promoting the recovery of the joint in an inflammatory condition of the tendons.

Pseudoarthrosis: specific program for the stimulation of bone regeneration in the tibia in situations where there is no union.

Lumbalgy: program designed for the treatment of lower back pain with a view to reducing pain.

Lumbar pain: program designed for the treatment of lumbar-sacral pain with a view to reducing pain.

Shoulder arthrosis: program designed to reduce pain and slow down the degenerative process in the shoulder area.

Knee arthrosis: program designed to reduce pain and slow down the degenerative process in the knee area.

Scapulohumeral periarthritis: program designed to reduce pain and slow down the degenerative process of the scapulohumeral structure.

Coxarthrosis: program designed to reduce pain and slow down the degenerative process in the hip area.

Muscle Atrophy: program designed to stimulate muscle tissues.

Muscular treatment: program designed to stimulate muscle tissues and reduce pain.

Osteonecrosis: specific program for the stimulation of bone tissue in cases of osteonecrosis, in order to counter the progress of the disease and alleviate pain.

Algodystrophy: analgesic program designed for pain relief in forms of algodystrophy.

Cartilage lesion: program designed for the regeneration of cartilaginous tissues.

Ligament lesion: program designed for post-surgery recovery.

Bone oedema: specific program for the stimulation of bone tissues in cases of bone oedema.

Tendinitis: program designed for the treatment of inflammation of tendon tissues.

Chondropathy: specific program for osteoarthritis (a particular type of chondropathy), designed for the reduction of inflammation of cartilaginous tissues.

Anti-inflammatory: program to mitigate inflammatory and painful conditions. Useful also in cases of post-surgery recovery.

Whiplash syndrome: program designed for post-traumatic recovery, with a view to reducing pain.

Healing: specific program for increasing circulation and reducing the damaged area.

Cutaneous ulcers: specific program to increase circulation and decrease the damaged area, even in cases of diabetic foot.

Discopathy: specific program for the treatment of diseases affecting vertebral discs, relative to bone and cartilage tissues, also useful in post-surgery.

Myalgia: program designed to stimulate muscle tissues and increase oxygenation.

Neuropathy: specific program to obtain an analgesic and anti-inflammatory effect on the peripheral nerves.

Muscle strain: program designed to stimulate muscle tissues and increase oxygenation.

Muscular cramp: program designed to stimulate muscle tissues and increase oxygenation.

Rhizarthrosis: program designed to reduce pain and slow down the degenerative process in the hand area.

Impingement syndrome: specific program for the reduction of inflammation in the shoulder tissues for this type of condition, also known as the subacromial impingement syndrome.

Carpal Tunnel: specific program to relieve painful symptoms.

Titanium prosthesis: specific program to promote osseointegration with the implanted hip prosthesis.

Rotator cuff: program designed for functional recovery and pain reduction for this type of condition.

Tarsal tunnel syndrome: program designed to reduce the pain of this condition and other polyneuropathies.

The therapy duration values are those recommended by IACER S.r.l. and can be altered by the user. The ***MAG3000*** magnetotherapy device incorporates the indications regarding magnetic field, frequency of therapy and power delivered that are found in scientific and medical literature, the result of experiments and clinical evaluations carried out (Barker - Lunt 1983, Bassett - Pawluk - Pilla 1974, Bassett - Valdes - Hernandez 1982).

Last 10

This mode allows direct access to the last 10 therapies used by the user.

From the main menu, press ▶ until "Last 10" is selected, then press OK. Choose the therapy from those listed by pressing the ▲ and ▼ buttons followed by OK.
Choose the desired settings:

a) Use the ▼ and ▲ buttons to set the desired therapy hours (from 0 to 24) and confirm by pressing the OK button. The display will highlight the minutes of therapy;

b) Use the ▲ and ▼ buttons to set the desired therapy minutes (from 0 to 59) and confirm by pressing the OK button. The display will highlight the intensity of the treatment;

c) Use the ▲ and ▼ buttons to set the treatment intensity and confirm by pressing the OK button.

Settings (language selection)

Press the ON/OFF switch located on the small panel in the upper part so it is in the ON position. After the I-TECH MEDICAL DIVISION logo appears, press ▶ and select the "Settings" menu. At this point select "Language" and use the ◀ and ▶ buttons to select the desired language.

N.B.: to turn off the device, press the ON/OFF switch on the back or press the ⏻/■ button until the screen turns off.

How to look after the device

Checking device operation

A magnet (small ring or disc in metal or metal/plastic) is supplied with the appliance to check device operation.

Procedure for checking:

1. *switch on the device following all the safety instructions provided in this manual;*
2. *start any therapy, following the instructions for use of this manual;*
3. *hold the supplied magnet and bring it closer to the applicator;*
4. *check that the magnet vibrates (proportional to the frequency of the selected therapy).*

Contact the manufacturer if the magnet fails to vibrate.

Cleaning the device

Use a soft dry cloth to remove any dust from the device.

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

To clean the 3-solenoid belt or the circular cases of the professional applicator with a pair of solenoids, it is recommended to disconnect the applicator from the device before carrying out any operation.

- *Remove the 3-solenoid cable by removing the 2 silver studs with a screwdriver or open the circular cases using the side zip.*
- *Clean the fabric with water and neutral soap and wait for it to dry completely before replacing the applicators. The fabric used is designed to withstand 10 cleaning cycles while still maintaining its original characteristics.*

*CAUTION: always respect the polarity of the applicators taking care to insert the coils with the side indicated by the **+** sign towards the green part of the belt (therapeutic side).*

Respect the temperature, humidity and pressure limits indicated in this manual even when cleaning the device and its accessories.

Transport and storage

Transport precautions

There is no particular care to be taken during transport as MAG3000 is a portable device.

It is recommended to store MAG3000 and its accessories in the bag supplied after each use and store everything inside the original box.

It is recommended not to twist the power supply and applicator cables.

Storage precautions

The storage location should have the following characteristics:

ambient temperature	*from +5° to +40°C.*
relative humidity	*from 15 to 93%*
pressure	*from 700 to 1060 hPa*

Disposal

The product is subject to the WEEE regulation (the symbol is present  *on the label*  *) concerning separate collection: to dispose of the product, make use of special areas equipped to collect electronic material by contacting the competent authorities in your country or the manufacturer directly.*

Maintenance

If used in accordance with the information reported herein, this device requires no particular routine maintenance operations.

In the event of malfunction, first follow these simple steps:

- *make sure that the power outlet to which the device is connected is working properly by connecting another working device;*
- *check the connection to the power supply and the integrity of all connection cables;*
- *check the connection with the applicator (or applicators);*

- *verify that all operations have been performed correctly;*
- *every two years check that all functions of the device work correctly (contact the manufacturer).*

If you discover a problem or you require further information, please contact the manufacturer immediately at:

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

Via S. Pertini, 24/a • 30030 Martellago (VE)

Tel. +39 0415401356 • Fax +39 0415402684

Support

The manufacturer is the only point of contact for technical support regarding the device. For all technical support matters, please contact:

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

Via S. Pertini, 24/a • 30030 Martellago (VE)

Tel. +39 0415401356 • Fax +39 0415402684

Technical documentation concerning repairable parts may be provided, but only with prior company authorization and only after giving proper training to the maintenance personnel.

Spare parts

Original spare parts for this device can be ordered at any time from the manufacturer. To order them contact:

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

Via S. Pertini, 24/a • 30030 Martellago (VE)

Tel. +39 0415401356 • Fax +39 0415402684

Use only original spare parts supplied by the manufacturer; if non-original spare parts are used, the operation and safety of the product might be affected and the warranty will be null and void.

EMC Tables

Emission aspects		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions Cispr 11	Group 1	The MAG3000 product uses RF energy only for its internal operation. Therefore, its RF emissions are very low and not likely to cause interference in nearby electronic equipment.
RF emissions Cispr 11	Class B	The MAG3000 is suitable for use in all buildings in addition to domestic ones and those directly connected to a low-voltage power supply network that supplies buildings for domestic use
Harmonic emissions IEC 61000-3-2	Class A Complies	
Voltage fluctuations and flicker IEC 61000-3-3	Complies	

Immunity aspects			
The MAG3000 is intended to work in the electromagnetic environment specified below. The customer or user should make sure that it 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	± 8kV contact ± 15kV air	± 8kV contact ± 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst EN 61000-4-4	±2kV power supply lines	±2kV power supply lines	Mains power quality should be that of a typical business or hospital environment.
Impulses EN 61000-4-5	±1kV differential mode	±1kV differential mode	Mains power quality should be that of a typical business or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	0% $_{UT}$ for 0.5 cycles, different angles 0% U_T for 1 cycle 70% U_T for 25/30 cycles 0% U_T for 5 seconds	0% U_T for 0.5 cycles, different angles 0% U_T for 1 cycle 70% $_{UT}$ for 25/30 cycles 0% U_T for 5 seconds	Mains power quality should be that of a typical business or hospital environment. If the user requires continuous operation even during the interruption of the mains voltage, it is recommended to power the device with an uninterruptible power supply (UPS) or with batteries.
Magnetic field at mains frequency EN 61000-4-8	30 A/m	30 A/m	The magnetic fields at mains frequency should be at levels typical of a business or hospital environment.

<table>
<tr><th colspan="4">RF immunity aspects</th></tr>
<tr><td colspan="4">The MAG3000 is intended to work in the electromagnetic environment specified below. The customer or user should make sure that it is used in such environment</td></tr>
<tr><th>Immunity test</th><th>Test level EN 60601-1-2</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Conduct RF EN 61000-4-6</td><td>3 Veff. 150kHz to 80MHz</td><td>3 Veff. 150kHz to 80MHz</td><td rowspan="2">Portable and mobile RF communications equipment should not be used near any part of the equipment, including cables, except when respecting the recommended separation distances calculated from the equation applicable to the transmitter frequency
Recommended separation distances
d = 1.2 ·√P 150kHz to 80MHz
d = 1.2 ·√P 80 MHz to 800 MHz
d = 2.3 ·√P 800 MHz to 2.7 GHz
where P is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters
(m).</td></tr>
<tr><td>Radiated RF EN 61000-4-3</td><td>10 V/m 80 MHz to 2.7 GHz</td><td>10 V/m 80 MHz to 2.7 GHz</td></tr>
<tr><td colspan="4">The field strength from fixed RF transmitters, as determined by an electromagnetic site survey, may be less than the compliance level in each frequency range.
Interference may occur in the vicinity of equipment marked with the following symbol:</td></tr>
</table>

Recommended separation distance between portable and mobile radio communication devices and the MAG3000 device			
The MAG3000 is intended to operate in an electromagnetic environment in which RF irradiated disturbances are controlled. The customer or the operator of the device can help prevent electromagnetic interference by ensuring a minimum distance between mobile and portable RF communications devices (transmitters) and the device, as recommended below, in relation to the maximum output power of the radio communication devices.			
Maximum rated output power of the transmitter (W)	**Separation distance to the frequency of the transmitter (m)**		
	150kHz to 80MHz d = 1.2 ·√P	**80MHz to 800MHz d = 1.2 ·√P**	**800MHz to 2.7GHz d = 2.3 ·√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 specified for a maximum output power not listed above, the recommended separation distance d in metres (m) can be calculated using the equation applicable to the frequency of the transmitter, where P is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer.

Note:
(1) At 80 MHz and 800 MHz the highest 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

MAG3000 is covered by a 2 year warranty starting from the date of purchase on the electrical and electronic parts. The parts subject to normal wear and tear are not covered by the warranty (fabric case of applicators as well as velcro elastic closure of the same) and all parts that may be defective due to negligence or neglect of use, incorrect maintenance or in case of tampering with the device and intervention on the same by personnel not authorized by the manufacturer or authorized dealer. The warranty conditions are those described in the following paragraph "Warranty conditions".
As established by the European Medical Devices Directive 93/42/EEC, the manufacturer must maintain the traceability of the equipment, in order to be able to intervene promptly in case needed as a consequence of manufacturing defects.

Please therefore: ***send the blue postcard and keep the green postcard.***

ATTENTION: If not sent, the manufacturer declines any responsibility should any corrective interventions on the device be needed.

In the event of subsequent warranty intervention, the equipment must be packaged so as to avoid damage during transport and sent to the manufacturer together with all accessories. To be eligible for warranty work, the purchase must send the appliance with the receipt or invoice proving the correct origin of the product and the date of purchase.

Warranty conditions

1. *Should assistance be needed, enclose the purchasing receipt when sending the device to the manufacturer.*
2. *The warranty period (2 years) 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 (2 years) 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.*

Unlock code:

18273

I-TECH
MEDICAL DIVISION

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