

USER MANUAL

MNPG429-00 Edition 31/01/2022

Magnetotherapy model

LaMagneto X

I.A.C.E.R. Srl

www.itechmedicaldivision.com

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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.

Manufacturer

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

Via Enzo Ferrari, 2 • 30037 Scorzè (VE)

Tel. 041.5401356 • Fax 041.5402684

IACER S.r.l. is an Italian manufacturer of medical devices (CE certificate No. ITH13442941 issued by the Notified Body No. 1936 TÜV Rheinland Italia srl).

Declaration of conformity

IACER S.r.l., with registered office in via Enzo Ferrari 2 30037 Scorzè (VE), declares that the LAMAGNETO X device complies with the general safety and performance requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

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

Certification path: Annex IX..

The LaMagneto X device is a class IIa equipment according to Annex VIII, paragraph 3, point 6.1 rule 9 of Regulation (EU) 2017/745 (and subsequent amendments).

Scorzè, 16/01/2023

The legal representative

Massimo Marcon

Classifications

In compliance with article 2, point 1, of REGULATION (EU) 2017/745, the LaMagneto X device is a medical device as it consists of a device intended by the manufacturer to be used on humans for the treatment or mitigation of illnesses.

In compliance with point 1.2 of Annex VIII of REGULATION (EU) 2017/745, the LaMagneto X device is a type of device designed for continuous use for less than 24 hours, whose duration of use is therefore "short term". According to point 2.4 of the same annex, the device is an active therapeutic device as it depends on a source of electrical energy (active medical device), and is intended for the treatment of various types of pathologies (therapeutic device). In accordance with point 6.1 rule 9, annex VIII of regulation (EU) 2017/745, all therapeutic active devices intended to supply or exchange energy are classified as class IIa unless their characteristics are such as to allow them to supply energy to the human body or exchanging energy with the human body in a potentially dangerous form, taking into account the nature, density and point where the energy is applied, in which case they are in class IIb. Considering the fact that pulsed magnetic fields do not fall into the category of either ionizing radiation or potentially dangerous radiation, it can be said that the energy exchanged by the device with the human body is absolutely not dangerous.

Therefore, the LaMagneto X device is a class IIa active medical device. With regard to point 3.5 of the aforementioned annex, which states "If different rules or, within the same rule, more sub-rules apply to the same device according to its intended use, the more stringent rule and sub-rules that involve the higher classification must be applied ", it is stated that there are no other stricter rules to apply to the LaMagneto X device.

Therefore, the classification is IIa.

Basic UDI-DI: 8019781PEMFLFDEVP2

UDI-DI: 08019781202031

The LaMagneto X 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 and accessories supplied do not contain or incorporate a medicine, including a derivative of human blood or plasma;*
- *Device and accessories supplied do not contain or incorporate tissues or cells of human origin, or their derivatives;*
- *Device and accessories supplied do not contain or incorporate tissues or cells of animal origin, or their derivatives;*
- *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

LaMagneto X is a magnetotherapy device designed and indicated for the rehabilitation and functional recovery treatments of pathologies affecting:

- *joints of the wrist, hand, shoulder, foot, ankle and knee*
- *the musculoskeletal system*
- *muscular atrophies and dystrophies*
- *bruises;*
- *sprains;*
- *benign lesions and pulled muscles*

and for the care treatments of:

- *osteoporosis;*
- *bone edema;*
- *osteonecrosis;*
- *ulcers;*
- *neuropathies;*
- *arthrosis;*

- *bursitis*
- *periarthritis;*
- *tendinitis and tendinosis*

LaMagneto X is also particularly suitable for the treatment of fractures and consolidation delays..

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

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

*LaMagneto X 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.***

The patient population intended for magnetotherapy treatment using the LaMagneto X device includes patients of both sexes, men and women, and adult (unless otherwise indicated by medical practitioners). For further details, please refer to the Contraindications and Side Effects section.

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

<i>Power supply</i>	<i>Pow. UES36LCP1-150200SPA, out 15VDC-2A</i>
<i>Max. current consumption</i>	<i>1 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 (length x width x height)(mm)</i>	<i>180x110x50</i>
<i>Intensity of the field</i>	<i>Adjustable with increasing scale up to 200 Gauss (per channel).</i>
<i>Frequency of the square wave</i>	<i>1-120 Hz</i>
<i>Therapy time</i>	<i>User-settable</i>

The maximum magnetic field intensity is 200 Gauss per channel with a professional applicator with a pair of solenoids.

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

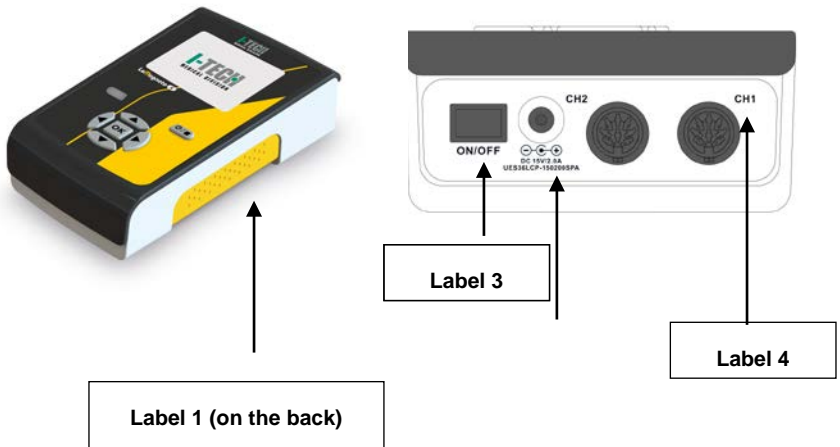
Environment operating conditions:

temperature from +5 to + 40°C

relative humidity from 15 to 93%










pressure from 700 to 1060 hPa

Labelling



Device labels in detail

Label 1

#	LaMagneto X	UDI	
SN	XXXXXX	LOT	AAAAMM
 UES36LCP1-150200SPA INPUT: 100-240~50/60Hz 1.0A OUTPUT: 15.0 V $\overline{\text{---}}$ 2.0A, 30.0W		(01)08019781202031 (10)AAAAMM (21)XXXXXX	
		 1936	 I-TECH MEDICAL DIVISION
		IP21 	I.A.C.E.R. Srl Via Enzo Ferrari 2 30037 Scorzè (VE)-ITALY

Label 2



DC 15V/2.0A

UES36LCP1-150200SPA




Label 3









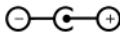




ON/OFF

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 Regulation (EU) 2017/745 and subsequent amendments
	Medical device
	Serial number
	Temperatures permitted
	Relative humidity
	Manufacturer's data
IP21	Degree of protection against the entry of solids, powders and liquids
	UDI vector for device traceability
	Center positive symbol
	Unique device identifier. Affixed near UDI vector
	Model
	Batch number
	Power supply (model and specifications)

Contents of the pack

The LaMagneto X pack contains:

- N°1 LaMagneto X 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 professional applicator with a pair of solenoids;
- N°1 device carry bag;

- Magnet for verifying therapy operation
- Non-woven fabric strip 15x150 cm (see page 15 for further details)

OSTEOMAT and TAP2000 solenoid mattresses are available as accessories. Visit the website www.itechmedicaldivision.com/en 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/en and refer to the section dedicated to magnetotherapy. In that section, within the LaMagneto X product page, a copy of the most updated revision of this user manual can be consulted under the heading "User Manual".

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";*
- *Use the device only with the supplied power supply model.*

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 authorised directly by the manufacturer.*
- *the electrical system of the environment in which LaMagneto X 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.

Radiation emitted for therapeutic purposes

The radiation emitted by the LaMagneto X device is the one produced by a pulsed electromagnetic field (CEMP). The magnetic field is induced by the passage of electric current through coils, made up of windings of copper cable. This magnetic field is pulsed as the generating electric current is not continuous (stationary) but pulsed (square wave electric pulse) with specific frequencies (fixed, if the programs with preset parameters are used, free if the Free Memory programs are used.).

The maximum intensity of the magnetic field generated by the LaMagneto X device is 200 Gauss per channel with the use of the professional applicator with a pair of two solenoids.

The frequency range of the square wave generating the CEMP is 1-120 Hz.

The intensity and frequency values are given with $\pm 20\%$ accuracy.

The therapeutic electromagnetic radiations generated during the operation of the device are located near the surface of the applicators in contact with the skin (green side). Outside the aforementioned distribution area, the intensity of the radiation is such that it does not entail any clinical benefit or decisive interaction with the tissues to be treated.

The radiation emitted by the device is not ionizing.

Fortuitous radiation

Given the nature and distribution of electromagnetic radiation emitted, no means of protection from accidental radiation is necessary either for patients, users or people close to them.



Contraindications and side effects

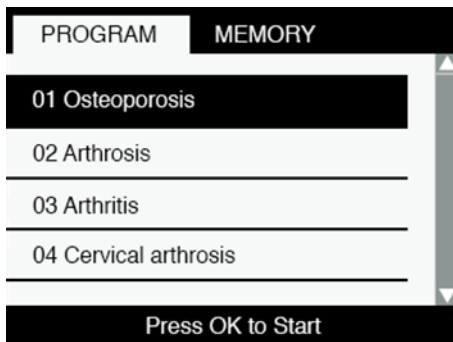
Pregnant women, patients with tuberculosis, juvenile diabetes, viral diseases (in the acute phase), mycosis, subjects with heart disease, those suffering from tumours, severe arrhythmias or pacemaker wearers, children, those with magnetisable prostheses, acute infections, epileptics (unless otherwise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

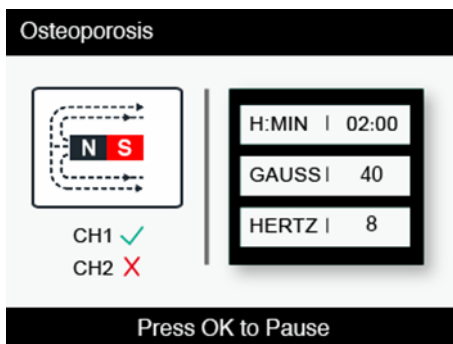
Quick use of the device with preset parameters

To start using *LaMagneto X* 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 (100-240VAC, 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.**
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 recognised. 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. This recommendation is also to be applied if the TAP2000 or OSTEOMAT applicators are used.*

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 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.





Vertebral column

Lumbar

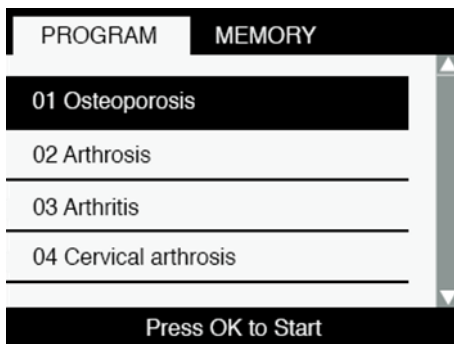
Suggestions for correct use:

- *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-P63 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.*

Instructions for using the preset programs

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

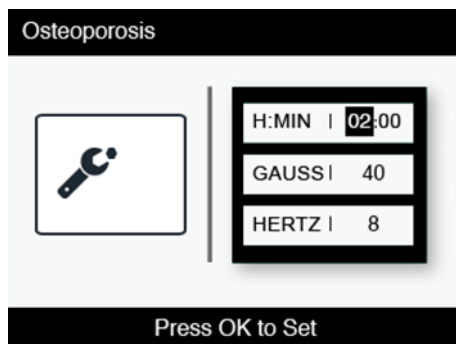
1. Connect the applicator (or applicators) to the device by connecting the plug of the applicator cable to one of the two ports (CH1-CH2) on the panel at the top of the appliance;
2. Connect the mains cable to the power supply and then connect the power supply outlet to the circular connector on the 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



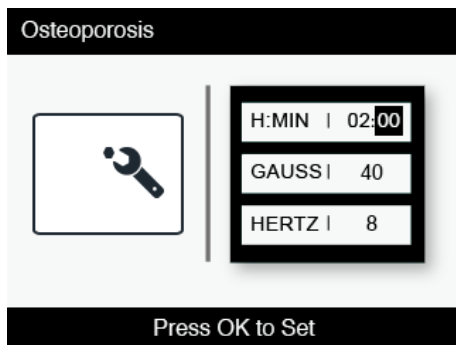
6. Press OK. The display will show the basic setting of therapy time (2 hours) and intensity of magnetic field that we will modify;



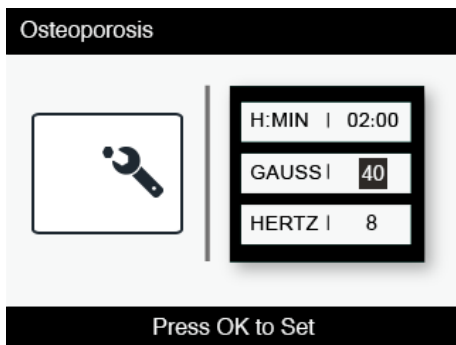
- a) Press the button ▼ so that the spanner is highlighted. At this point press OK: the display shows a moving spanner icon on the left-hand side;



- 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;

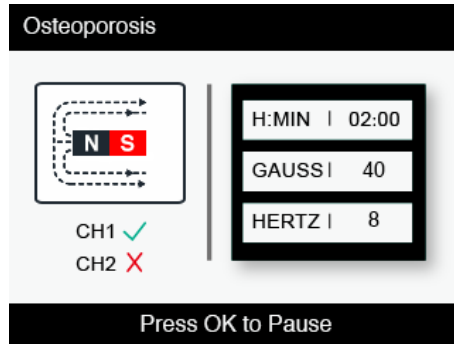


- c) Use the ▲ and ▼ buttons to set the desired therapy minutes (from 0 to 59) and confirm by pressing the OK button. The display will highlight the intensity of the treatment;



- 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.

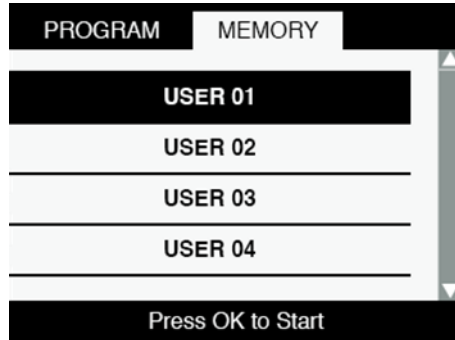


8. At the end of the therapy, the device will automatically return to the program menu screen.

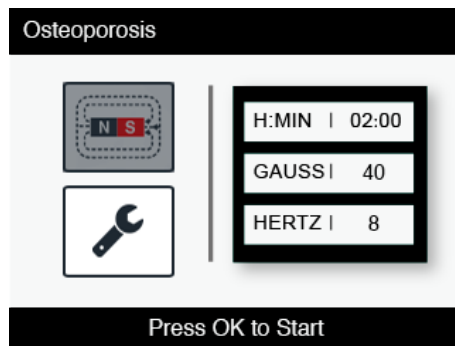
Instructions for using the Free memory slots

To use *LaMagneto X* 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 (100-240VAC, 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 press the arrow  to select "Memory slots". Choose the desired memory slot.



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






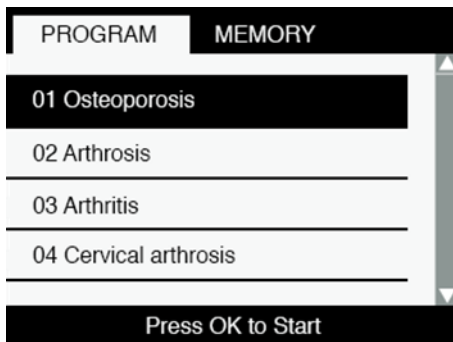
- a) Press the button ▼ so that the spanner is highlighted. At this point press OK: the display shows a moving spanner icon on the left-hand side;
- b) Use the ▼ and ▲ buttons to set the desired therapy hours (from 0 to 24) and confirm by pressing the OK button. The display will highlight the minutes 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 button (up to 200 Gauss);

- e) Use the ▲ and ▼ buttons to set the hertz (frequency) of the treatment and confirm by pressing the OK button (up to 120 Hz, from 1 to 20Hz with a step of 1Hz, from 25 to 120Hz with a step of 5Hz).
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. Only for USER 07-10 programs it's possible to modify the duty cycle (up to 50%).
9. At the end of the therapy, the device will automatically return to the program menu screen.

Instructions for using programs in Double Patient mode

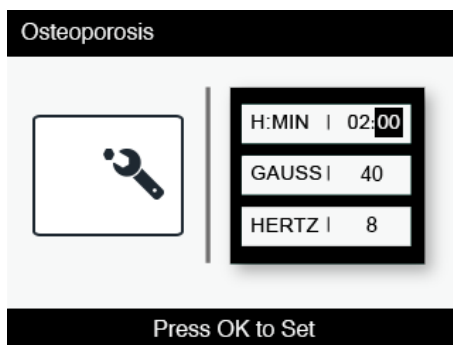
To use the "Double Patient" mode of the *LaMagneto X* device, follow these simple steps:

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 (100-240VAC, 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;

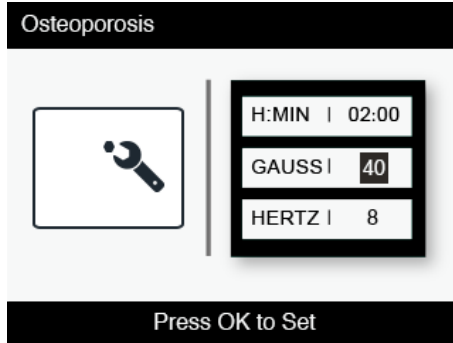


Choose the desired settings:

- 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 recognised. 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

ATTENTION: programs from 42 to 63 are programs to be used exclusively following specific medical advice.

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.	Epitrocleititis	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 periarthrititis	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
42.	Night 1 Hz	1	Free	Free	24 hours
43.	Night 15 Hz	15	Free	Free	24 hours
44.	Night 50 Hz	50	Free	Free	24 hours
45.	Night 75 Hz	75	Free	Free	24 hours
46.	Auto Scan *	*	2 - 6	30 – 60	24 hours

47.	Treat. 1 Hz	1	Free	Free	24 hours
48.	Treat. 4 Hz	4	Free	Free	24 hours
49.	Treat. 5 Hz	5	Free	Free	24 hours
50.	Treat. 8 Hz	8	Free	Free	24 hours
51.	Treat. 10 Hz	10	Free	Free	24 hours
52.	Treat. 15 Hz	15	Free	Free	24 hours
53.	Treat. 16 Hz	16	Free	Free	24 hours
54.	Treat. 20 Hz	20	Free	Free	24 hours
55.	Treat. 30 Hz	30	Free	Free	24 hours
56.	Treat. 40 Hz	40	Free	Free	24 hours
57.	Treat. 50 Hz	50	Free	Free	24 hours
58.	Treat. 60 Hz	60	Free	Free	24 hours
59.	Treat. 70 Hz	70	Free	Free	24 hours
60.	Treat. 75 Hz	75	Free	Free	24 hours
61.	Treat. 80 Hz	80	Free	Free	24 hours
62.	Treat. 90 Hz	90	Free	Free	24 hours
63.	Treat. 100 Hz	100	Free	Free	24 hours

***The Automatic Scan program allows you to set the desired therapy time, by automatically managing the frequency cycle from 5 Hz to 100 Hz with 5 minutes of therapy for each frequency.**

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.

Programs from 47 to 63 vary in frequency but are the same in terms of waveform. In particular, programs from 42 to 45 (night) are indicated for a therapy time ranging from 6 to 10 hours, during sleep.

After long and exhaustive bibliographic research, the correspondence between the possible treatments and specific frequencies have been outlined, in line with the clinical studies taken as reference. A table follows that lists such associations.

We remind you once again that these programs are for professional use only, therefore we do not recommend home treatment without detailed medical advice.




42	Delayed onset muscle soreness
43	Delayed union
44	Impingement syndrome, carpal tunnel
45	Osteonecrosis, recovery after arthroscopy: knee cartilage, LCA
47	Delayed onset muscle soreness
48	Scapulohumeral periarthrititis
49	Cervical arthrosis
50	Osteoporosis
51	Chronic pain
52	Delayed union
53	Intercostal bruising
54	Cervical pain
55	Osteoarthritis, muscle strengthening
56	Golfer's elbow
57	Impingement syndrome, carpal tunnel
58	Lumbar-sacral pain, lumbago
59	Rotator cuff tendinitis
60	Osteonecrosis, recovery after arthroscopy: knee cartilage, LCA

61	Bone fractures
62	Patellar chondropathy, muscle pain
63	Chondrites, rheumatic diseases



The therapy duration values are those recommended by IACER S.r.l. and can be altered by the user. The **LaMagneto X** 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).

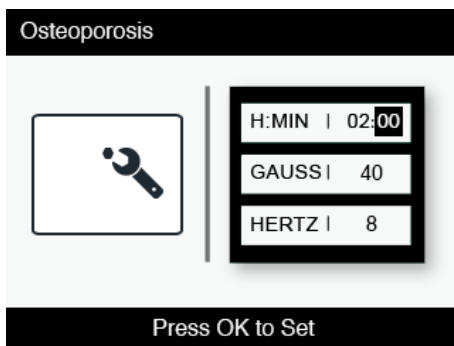
Last 10



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

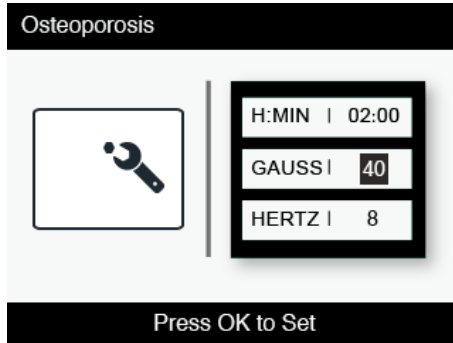
From the main menu, press  until "Last 10" is selected, then press OK. Choose the therapy from those listed by pressing the  and  buttons followed by OK.

Choose the desired settings:

- 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;



- 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.

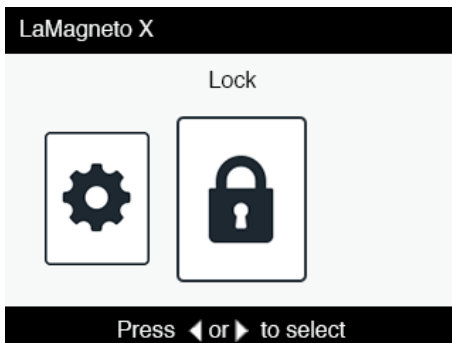
Settings (language selection)

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.

Lock

This mode allows you to set a personalized therapy as the only therapy that can be carried out. This option, once properly set up by a competent person, is useful to guarantee any end user obtains the specific use for their condition.

From the main menu press ► until "Lock" is selected, then press OK.



Choose the therapy from those listed by pressing the ▲ and ▼ buttons followed by OK.


Choose the desired settings:

- 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;
- 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;
- Use the ▲ and ▼ buttons to set the treatment intensity and confirm by pressing the OK button;
- Confirm the device lock by pressing the OK button.

At this point all the functions of the device are locked except for the "Single Patient" mode; selecting this mode starts the programme and the parameters chosen during the locking phase.

To unlock the device (from the main menu) press the button ▶ and press the OK button on the "Unlock" item.

Enter the digits of the unlocking key: use ◀ and ▶ to move between the digits and ▲ and ▼ to select the numerical value of the digit. After entering the key, press OK.

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 LaMagneto X is a portable device.

It is recommended to store LaMagneto X 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:

<i>ambient temperature</i>	<i>from +5° to +40°C.</i>
<i>relative humidity</i>	<i>from 15 to 93%</i>
<i>pressure</i>	<i>from 700 to 1060 hPa</i>

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 Enzo Ferrari, 2 • 30037 Scorzè (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 Enzo Ferrari, 2 • 30037 Scorzè (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 Enzo Ferrari, 2 • 30037 Scorzè (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 LaMagneto X 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 LaMagneto X 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 The device can be used in all buildings, including domestic buildings, and those directly connected to the public low-voltage power supply network that supplies buildings for domestic use.
Harmonic emissions IEC 61000-3-2	Class A Complies	The device can be used in all buildings, including domestic buildings, and those directly connected to the public low-voltage power supply network that supplies buildings for domestic use.
Voltage fluctuations and flicker IEC 61000-3-3	Complies	The device can be used in all buildings, including domestic buildings, and those directly connected to the public low-voltage power supply network that supplies buildings for domestic use.

Immunity aspects			
The LaMagneto X 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% U_T 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% U_T 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.

RF immunity aspects

The LaMagneto X 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
Immunity to conducted disturbances induced by radio-frequency fields EN 61000-4-6	3 Veff. 150kHz to 80MHz	3 Veff. 150kHz to 80MHz	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
Radiated RF EN 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	Recommended separation distances $d = 1.2 \cdot \sqrt{P}$ 150kHz to 80MHz $d = 0.35 \cdot \sqrt{P}$ 80 MHz to 800 MHz $d = 0.7 \cdot \sqrt{P}$ 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).

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:

Recommended separation distance between portable and mobile radio communication devices and the LaMagneto X device

The LaMagneto X 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 $d = 1.2 \cdot \sqrt{P}$	80MHz to 800MHz $d = 1.2 \cdot \sqrt{P}$	800MHz to 2.7GHz $d = 2.3 \cdot \sqrt{P}$
0.01	0.12	0,04	0,07
0.1	0.38	0,11	0,22
1	1.2	0,35	0,7
10	3.8	1,1	2,2
100	12	3,5	7,0

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.

Incident reporting

In compliance with the provisions of Regulation (EU) 2017/745, the manufacturer places the need to report any serious accident in relation to the device to the attention of the user.

The report must be addressed:

- *to the device manufacturer:*

I.A.C.E.R. Srl

Via Enzo Ferrari 2 – 30037

Scorzè (VE) ITALY

Tel. +39 041 5401356 – Fax +39 041 5402684

e-mail: iacer@iacer.it

Warranty

LaMagneto X 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”.

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 from 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.*

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Unlock code:

18273

I-TECH

MEDICAL DIVISION



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