I-TECH
MEDICAL DIVISION

# USER MANUAL

**Magnetotherapy model**

# MAG1000


I.A.C.E.R. Srl
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## Manufacturer

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

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

Tel. 041.5401356 • Fax 041.5402684

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

## Declaration of conformity

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

Via S.Pertini 24/A – 30030 Martellago (Ve), Italy

herewith declares under its own responsibility, that the product

**MAG1000**

UMDNS Code**: 12415**

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

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

CE 0068

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

**0068 – MTIC InterCert S.r.l.**

**Via G. Leopardi 14, Milano (MI) 20123**

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

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

Martellago, 19/06/2020

*Place, date*

MASSIMO MARCON

*Legal Representative*

## Classifications

MAG1000 has the following specifications:

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

## Purpose and scope

Clinical Purpose: Therapeutic
Scope of Use: Ambulatory and domestic

MAG1000 is projected and indicated for healing, rehabilitation and functional recovery treatments for pathologies of:

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

MAG1000 is particularly suitable for the treatment and the care of the osteoporosis and all the pathologies on bony tissue.

MAG1000 is a device intended for both the professional user (physician, therapist, etc.) and the patient at home. **In case of home therapy, the use of the device is recommended only on indication of the physician/therapist.**

The patient population intended for magnetotherapy treatment using the MAG1000 device includes patients of both sexes, men and women, of age (unless otherwise indicated by medical doctors). For further details, please refer to the *Contraindications* section.

## Techinical features

| Characteristics | Specification | |
|---|---|---|
| Power supply | Rechargeable batteries, Ni-MH AA2300mAh 4,8V | |
| Battery charger | Input AC 110-240V, 50/60Hz, 200mA; Output DC 6.8V, 300mA | |
| Max current absorbed | ≤150mA (therapy mode) | |
| Isolation class (EN 60601-1) | II | |
| Applied part (EN 60601-1) | BF | |
| Field intensity | 40mW for channel<br>Adjustable on 3 levels:<br>low, medium, high | |
| Carrier frequency | 27MHz | |
| Squared wave frequency | From 8 to 640Hz | |
| Number of programmes | 20 | |
| Dimensions (length x width x height)) | 153x91x38mm | |
| Environmental conditions of operation | Temperature | From +5° to +40°C |
| | Relative humidity | From 30% to 80% |
| | Pressure | From 500 to 1060hPa |
| Transport and storage conditions | Temperature | From -10° to +55°C |
| | Relative humidity | From 10% to 90% |
| | Pressure | From 500 to 1060hPa |

Expected lifetime: 3 years.

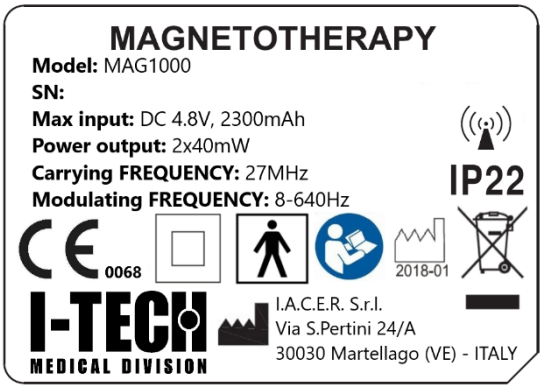
## Device and commands description


**Label (retro)**

| | |
|---|---|
| ⏻/■ | ON/OFF Key |
| ▶/❙ | Start/pause key |
| **TM.** | Time set key |
| **PR.** | Programs selection key |
| **IN.** | Field intensity key |

| | |
|---|---|
|  | Battery status indication |
| **PROGRAM P-01** | Selected program for therapy |
| **PULSE RATE 8Hz** | Selected pulse rate |
| **INTENSITY** | Magnetic field intensity level selected:<br>**1** - low, **2** - medium, **3** - high |
| **TIMER 45'00''** | Therapy time (minutes and seconds) |
| **A/B** | Working channel: **A** - channel1, **B**- channel2 |

## Labelling




The label on the side is placed on the back of the device

| Symbol | Description |
|---|---|
|  | Manufacturer logo |
|  | Certification of the product issued by the notified body N° 0068. |
|  | Manufacturer |
|  | Manufacturing date (YYYY-MM) |
|  | Attention, consult operating instructions. |

| Symbol | Description |
|---|---|
|  | Product subject to WEEE regulations concerning separate waste collection of electronic equipment. |
|  | Class II equipment. |
|  | Applied part type BF. |
|  | Permitted storage temperatures (on the box) |
|  | Relative humidity of storage (on the box) |
| **IP22** | Medical device protected against the penetration of solids (with a diameter d≥12,5mm) and against the vertical drops when the device is kept at 15° from its normal functioning position. |
|  | Power supply (DC 6.8V / 0.3A). |
| **A**<br>**B** | A / B (CH1 / CH2) channel 1/2. |
|  | Non ionizing |

## Package content

The Mag1000 package contains:

- n°1 MAG1000 device;
- n°1 elastic therapeutic belt;
- n°1 battery pack (inside the device);
- n°1 battery charger;
- n°1 user manual;
- n°1 carrying bag.

## Introduction to technology

Electromagnetotherapy distinguishes itself from the "traditional" magnetotherapy since it uses high frequency electromagnets instead of permanent magnets: particularly, we refer to electromagnetotherapy when using devices emitting high frequency and low intensity pulsed electromagnetic fields (PEMF, carrying frequency from 20 to 30 MHz, with frequencies up to 5.000 Hz).

The MAG1000 has been designed to exploit these fields, in fact it generates an electric signal with a carrier frequency of 27mhz, which is modulated with specific frequencies and therefore is able to soothe the anatomical site affected by pain. For this purpose, electromagnetic fields are generated by a radiant circuit (antennas) contained inside a special ergonomic container and therefore exploited mainly in the treatments for pain, that is to restore the biomagnetic cell field that with the disease had weakened. In fact, PEMFs are able to return to the altered biological system the ability to react with more energy against the damaging process, giving back to the cells the optimal energy lost.

The use of high frequency and to low intensity PEMFs, allows to get ample therapeutic results without collateral effects. This also allows the use in acute pathological trials. The electromagnetotherapy is particularly suitable for the care of the soft tissues pathologies, with extraordinary results in the regeneration of the tissues themselves.

Due to its characteristics, the electromagnetotherapy is universally recognized as the most suitable technique for the treatment of the bony pathologies, in particular for the osteoporosis.

There are lots of effects that can be brought back to electromagnetotherapy: the piezoelectric effect, the effect of orientation of the collagen, the stimulation of the calcic deposition (*Barker - Lunt 1983, Bassett – Pawluk – Pilla 1974, Bassett - Valdes – Hernandez 1982*).

Since the present day, all the equipments of electromagnetotherapy were built particularly to satisfy or the medical sector (with high prices) or the economic demands of patients, but with products of low quality.

MAG1000 is born really to reconcile the demand to have an equivalent device, for performances and effectiveness, to those devoted to medical sector, also maintaining a simplicity of use and an extremely favorable price.

## Controindications

Patient in pregnancy, tuberculosis, juvenile diabetes, viral (in acute phase) illnesses, mycosis, cardiopathic subjects, serious arrhythmias or pacemaker carriers, children, metallic prosthesis carriers, acute infections, epileptics (**different medical prescriptions excepted**).
The functioning of some electric implantable devices, such as pacemakers, could be compromised during a treatment with a short-wave therapy device. Consult a physician before starting the treatment.

### Side effects

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

## Warnings

It is recommended to:

- check the position and the meaning of all the labels on the equipment;
- do not damage the applicator by acting on the connecting wire, and do not wrap the wire around the applicator or the appliance;
- check the integrity of the power supply before each use. Avoid use in case of signs of damage to the casing or to the connecting wire;
- avoid the use of the system to persons not adequately educated by reading the manual;
- ONLY use cables and applicators supplied by the manufacturer. Inadequate cables and applicators may damage the appliance and/or damage the patient;
- during therapy it is advisable to the patient and user not to wear metallic objects.

Is prohibited:

- the use of the device by persons incapable of understanding and wanting, suffering from sensitiveness to sensitivity, temporarily incapacitated if not assisted by qualified personnel;
- the use of the device near inflammable substances, gases, explosives, in environments with high concentrations of oxygen, in the presence of aerosols or in very humid environments (do not use in the bathroom or during the shower/bath);
- the use of the appliance in the presence of signs of deterioration and/or damage to the same or to the accessories (electrodes,

chargers, etc.) and/or cables; contact the dealer or the manufacturer in accordance with the *Assistance* section. Check the integrity before each use;

- the use of the appliance contemporary to liniments containing free ions of magnetic metals;
- to connect the device and its accessories to other devices not listed in this manual.

Warning:

- to connect the device and its accessories to other devices not listed in this manual;
- to connect the device and its accessories to other devices not listed in this manual;
- the use of the connection cables of the belt and the feeder: danger of strangulation. Be extremely careful if it is necessary to pass the cables near the neck and the patient's head: In this case it is necessary to maintain a safe position and to avoid abrupt movements that can cause the cables to twist;
- to avoid exposing the device and its accessories to excessive direct light and dust. See the paragraph *Care of the device*.

**WARNING!** Connect the battery charger plug to 230V main only when connected to MAG1000 device for batteries recharging. Disconnect the battery charger from main after each use.

**WARNING!** During therapy it is possible to hear a light hiss coming from MAG1000: such operation is normal and must not arouse worry.

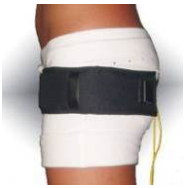
The manufacturer shall be deemed to be responsible for the performance, reliability, and safety of the appliance only if:

- any additions, modifications and/or repairs are carried out by authorized personnel directly by the manufacturer. Any modification, addition and/or repair performed by unauthorized personnel may result in the loss of safety of the device or its malfunction;
- the electrical system of the environment in which MAG1000 is inserted complies with national laws;
- the appliance is used in strict accordance with the operating instructions contained in this manual.

## Patient preparation: positioning of the therapeutic belt

Here below a list of main positions for the therapeutic belt. Wrap the belt around the area to be treated (or position the belt on the area, for example in vertebral column treatment). During this phase **take care to place the green side of the therapeutic belt on the skin**.


Ankle


Hip


Back (lumbar)


Knee


Shoulder


Wrist


Elbow


Cervical

## Instructions for use

Follow the instructions for the correct operation of the MAG1000:

1) Switch on MAG1000 pressing ON/OFF key ⏻/■.
2) Check battery status: if the icon ▬, on the upper side of the display is flashing, proceed to recharge the unit following the instructions (see chapter *Battery charging*.
3) Connect the therapeutic belt (or belts) to the plug A (CH1) / B (CH2) on device upper side.
4) Chose therapy program running through programs menu, using **PR.** Key
5) Set therapy time using **TM.** key: each program has its own set therapy time, which can be modified pressing **TM.** with 5 minutes steps. Therapy time can be increased up to 23 hours and 55 minutes. It's possible to quickly scroll time list pressing **TM.** key

6) MAG1000 is now ready for use: the display shows information about the program in use, the working frequency (not adjustable), the adjusted therapy time and field intensity (adjustable during the treatment).

7) Press ▶/❙ key: the display will show the remaining therapy time, while it will be possible to modify field intensity during the whole treatment, pressing more times **IN.** key. The relative icon is positioned on the lower right side of the display, with the indication of the three intensities (**1** - low intensity,**2** - medium intensity-two bars and **3** - high intensity).

8) The therapy can be suspended pressing the key ▶/❙: in basso a destra sul display verrà visualizzato l'indicatore lampeggiante ☐☐. Per riprendere la terapia premere nuovamente ▶/❙.

9) To end the therapy, press key ⏻/■ : MAG1000 will show again the selected program and adjusted therapy time. To switch off MAG1000, press again key ⏻/■.

10) A sound signal informs of the end of the program, and the display will show the flashing icons 0'00''; to start again a new therapy, press key ▶/❙ and then follow again the indications from step 4).

**WARNING:** In case no operation is performed for more than 2 minutes, MAG1000 automatically shuts down in order to preserve the battery.

## LIST OF STORED PROGRAMS

| Pr. | Carrier frequency (MHz) | Squared wave frequency (Hz) | Time (h/min) | Name | Area |
|---|---|---|---|---|---|
| P-01 | 27 | 8 | 45min | Arthritis-Arthrosis | Body, arms, legs |
| P-02 | 27 | 8 | 2h | Rheumatisms | Body, arms, legs |
| P-03 | 27 | 8 | 4h | Pain-Articular prosthesis | Body, arms, legs |

| Pr. | Carrier frequency (MHz) | Squared wave frequency (Hz) | Time (h/min) | Name | Area |
|---|---|---|---|---|---|
| P-04 | 27 | 16 | 45min | Herniated disc | Body |
| P-05 | 27 | 16 | 2h | Muscular pain | Body, legs |
| P-06 | 27 | 16 | 4h | Osteoporosis | Legs |
| P-07 | 27 | 32 | 2h | Fractures | Body, arms, legs |
| P-08 | 27 | 32 | 4h | Sprains | Arms, legs |
| P-09 | 27 | 48 | 2h | Dislocations | Arms, legs |
| P-10 | 27 | 48 | 4h | Traumas | Arms, legs |
| P-11 | 27 | 64 | 2h | Bruises | Arms, legs |
| P-12 | 27 | 64 | 4h | Myalgia | Arms, legs |
| P-13 | 27 | 80 | 2h | Tendonitis | Body, arms, legs |
| P-14 | 27 | 80 | 4h | Hematoma | Body, arms, legs |
| P-15 | 27 | 160 | 2h | Epicondylitis | Arms, legs |
| P-16 | 27 | 160 | 4h | Epytrocleitis | Arms, legs |
| P-17 | 27 | 320 | 2h | Lumbago | Body, arms, legs |
| P-18 | 27 | 320 | 4h | Muscular contractures | Body, arms, legs |
| P-19 | 27 | 640 | 2h | 2h Medium application | Body, arms, legs |
| P-20 | 27 | 640 | 4h | 4h Long application | Body, arms, legs |

IACER S.r.l. suggest the therapy time as shown on the table and pre-setted on MAG1000. However, the user can adjust the time as he prefers. MAG1000 uses therapy time values, working frequency values and field intensity values coming from scientific and medical literature, as result of well-known sperimentations and clinical evaluations (Barker - Lunt 1983, Bassett – Pawluk – Pilla 1974, Bassett - Valdes – Hernandez 1982).

## Maintenance

If used following the instructions given in this user guide, the equipment does not require any particular kind of maintenance.
It is recommended that the manufacturer carries out a functional test every 24 months. The manufacturer does not consider the MAG1000 device repairable by any personnel outside the company. Each operation of the kind perpetuated by personnel not authorized by the manufacturer will be considered as tampering the device, freeing the manufacturer from granting warranty and from any danger that the user or the operator may be exposed to.

**WARNING:** after a long period of inactivity, it may happen that the instrument does not turn on due to battery discharge, not due to actual malfunction; it is appropriate to charge the battery as indicated in the appropriate paragraph before assuming non-existent malfunctions.

**CLEANLINESS**

To clean the equipment from the dust, use a soft dry cloth. More resistant stains can be removed using a sponge soaked in water and alcohol solution (20% solution). In case of non-prolonged use, clean the device and its accessories as indicated above and store them in the transport bag and store them in the packaging box.
Device not subject to sterilisation.

**TRANSPORTATION AND STORAGE**

Precaution for the transportation

There is no particular precaution to be taken during transportation of the device, since MAG1000 is a portable device. In any case it is recommended to store MAG1000 and its accessories in the supplied carrying bag after each treatment.

Precaution for the storage

Store the device in a cool, well-ventilated place. Do not store heavy objects on the device.
It is recommended to switch off MAG1000 at the end of each treatment and to remove the cables from the connectors. MAG1000 should be kept in the supplied carrying bag, together with the rest of the equipment supplied and

carefully stored on a secure surface. The performances of the equipment are granted if it is stored according to the following conditions:

**Outside the carrying bag:**

| | |
|---|---|
| temperature | from +5 to + 40 °C |
| relative humidity | from 30 to 80% |
| atmospheric pressure | from 500 to 1060 hPa |

**Inside the supplied carrying bag:**

| | |
|---|---|
| temperature: | from -10°C to +55°C |
| maximum relative humidity: | from 10% to 90% |
| atmospheric pressure: | from 500 to 1060hPa |

## Troubleshooting

Any type of work on MAG1000 must be carried out exclusively by the manufacturer or by an authorized dealer. In any event, any presumed malfunction of MAG1000 must be verified before sending the device to the manufacturer.

Here below are some typical situations:

- check battery status;
- check the correct connection between MAG1000 and the therapeutic belt;
- check all the operations have been done properly.

If the problem persists contact the manufacturer.

### Battery charging

If the battery status is insufficient to complete the working program, the display will show the icon  on the upper right side, near wording PROGRAM.

To proceed with the charging, switch off MAG1000 pressing  and connect the battery charger to the plug on the upper side of MAG1000 MAG 1000 is equipped with a software protection that switch off the equipment when the battery charger is connected. Carry out two 5-hour charging cycles (maximum time set for charging) to obtain a full charge of the batteries, as it takes at least 8/10 hours. When the batteries are fully charged, the display displays the full battery charge icon.

**WARNING:** at the end of the charge wait at least 30 minutes before switching on the device; in order to allow the cooling of the battery

pack, overheated during charging and the closure of the integrated safety system that prevents the device from turning on.

### Replacing the battery

If, after normal recharging, the battery cannot sustain a full treatment session, recharge again, as it is probably approaching the end of its useful life. If even after a second recharge the battery still cannot complete a treatment session, follow the steps here below:

- Contact the manufacture or authorized dealer for original spare part;
- Open the battery compartment on the back side of MAG1000, disconnect the red/black wire from connector and remove the exhausted battery;
- Insert new battery and connect the red/black wire to the plug;
- Close battery compartment.

**WARNING:** for disposal exhausted battery follow the instructions on chapter *Disposal*.

Do not open or burn battery. Do not short circuit poles. Keep battery away from sparks or naked flames. In the event of internal electrolyte coming into contact with skin or garments, wash immediately with water. In the event of electrolyte coming into contact with eyes, rinse thoroughly and seek medical attention.

**WARNING:** It is suggested to recharge the device once a month in case of prolonged inactivity. This is for a correct battery maintenance.

## Disposal

The MAG1000 magnetotherapy apparatus, compatibly with the operating and safety requirements, has been designed and built to have a minimum negative impact on the environment, following the provisions of the European Directive 2012/19/EU on the disposal of waste electrical and electronic equipment.
The criteria followed are those of minimizing the amount of waste, toxic materials, noise, unwanted radiation and energy consumption.

Careful research on optimizing the efficiency of the machines guarantees a significant reduction in consumption, in harmony with the concepts of energy saving.

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

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

## Warranty

IACER Srl guarantees a warranty period from the purchasing date for MAG1000 device, unless information contained in this manual regarding installation, use and maintenance is strictly adhered. The wearing parts (batteries) are not included in the warranty, unless of visible manufacturing defects. The warranty is void in case of tampering of the device and in case of intervention on the same by personnel not authorized by the manufacturer or by the authorized dealer.
*As established by the Medical Device Directive 93/42/EEC, the manufacturer is obliged to trace at any time the equipment supplied to intervene promptly, if necessary, as a result of manufacturing defects.*
*The warranty conditions are those described in the following paragraph* Warranty conditions*. The warranty is provided by IACER.*
**WARNING!** In the event of non-shipment, the manufacturer declines all responsibility, if corrective action on the equipment is necessary.
Should you need to return the goods then please pack the device and all the accessories so that it won't be damaged during transportation. In order to be entitled to the warranty assistance, the purchaser must enclose to the device a copy of the purchasing receipt, proving origin and purchasing date. For more information on the warranty please contact the distributor or vendor, in order to check the norm and standard in force in your Country, or ultimately the manufacturer IACER Srl.

**Warranty conditions**

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

## Assistance

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

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

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

### Spare parts

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

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

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

## Interference and elctromagnetic compatibility tables

The MAG100 equipment has been designed and manufactured according to the TECHNICAL STANDARD on ELECTROMAGNETIC COMPATIBILITY legislation EN 60601-1-2:2015 with the aim of providing adequate protection from harmful interference when installed in homes and health establishments.

The apparatus does not generate or receive interference from other equipment. The device should be installed and put into service in accordance with the information contained in the accompanying documents.

Wireless communication devices such as home wireless devices (modem/router), mobile phones, cordless phones and their charging bases, walkie-talkies can interfere with the device and should be kept at least at a distance d from the device. The distance d is calculated by the manufacturer in the column 800mhz to 2.5ghz of the ELECTROMAGNETIC IMMUNITY TO RF table in the following paragraph.

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

## ELECTROMAGNETIC COMPATIBILITY TABLES

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – ELECTROMAGNETIC EMISSIONS – FOR ALL DEVICES AND SYSTEMS</th></tr>
<tr><td colspan="3">The MAG1000 device is expected to operate in the electromagnetic environment below specified. The customer or user of the MAG1000 device must ensure that it is used in such environment.</td></tr>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions<br><br>CISPR 11</td><td>Group 1</td><td>MAG1000 device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are unlikely to cause any interference in nearby electronic equipment</td></tr>
<tr><td>RF emissions<br><br>CISPR 11</td><td>Class B</td><td>MAG1000 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions<br><br>IEC 61000-3-2</td><td>Class A</td><td rowspan="2">It is possible to use the apparatus in all buildings, including domestic buildings, and those directly connected to the low-voltage public power supply that supplies buildings for domestic use.</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions<br><br>IEC 61000-3-3</td><td>Compliant</td></tr>
</table>

| Guidance and manufacturer's declaration – ELECTROMAGNETIC IMMUNITY – FOR ALL DEVICES AND SYSTEMS | | | |
|---|---|---|---|
| MAG1000 is intended for use in the electromagnetic environment specified below. The user or operator of MAG1000 should assure that is used in such environment. | | | |
| **Immunity test** | **Test level IEC 60601** | **Compliance level** | **Electromagnetic environment – guidance** |
| Electrostatic discharge (ESD)<br><br>IEC 61000-4-2 | ±6kV at contact<br>±8kV in air | ±6kV at contact<br>±8kV in air | Floors should be wood, concrete or ceramic tile. If floor is covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient/burst<br><br>IEC 61000-4-4 | ±2kV<br>for power supply lines | ±2kV<br>for power supply lines | Mains power quality should be at least that one of a typical commercial or hospital environment. |
| Impulses<br><br>IEC 61000-4-5 | ±1kV<br>differential mode | ±1kV<br>differential mode | Mains power quality should be at least that one of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br><br>IEC 61000-4-11 | <5% $U_T$<br>(>95% dips of $U_T$)<br>for 0,5 cycle<br><br>40% $U_T$<br>(60% dips of $U_T$)<br>for 5 cycle<br><br>70% $U_T$<br>(30% dips of $U_T$)<br>for 25 cycle<br><br><5% $U_T$<br>(>95% dips of $U_T$)<br>for 5s | <5% $U_T$<br>(>95% dips of $U_T$)<br>for 0,5 cycle<br><br>40% $U_T$<br>(60% dips of $U_T$)<br>for 5 cycle<br><br>70% $U_T$<br>(30% dips of $U_T$)<br>for 25 cycle<br><br><5% $U_T$<br>(>95% dips of $U_T$)<br>for 5s | Mains power quality should be at least that one of a typical commercial or hospital environment.<br>If the user of the MAG1000 requires continued operating during power mains interruptions, it is recommended that MAG1000 be powered from an uninterruptible power supply (UPS) or a battery |

| Guidance and manufacturer's declaration – ELECTROMAGNETIC IMMUNITY – FOR ALL DEVICES AND SYSTEMS | | | |
|---|---|---|---|
| MAG1000 is intended for use in the electromagnetic environment specified below. The user or operator of MAG1000 should assure that is used in such environment. | | | |
| **Immunity test** | **Test level IEC 60601** | **Compliance level** | **Electromagnetic environment – guidance** |
| Mains power electromagnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | Mains power quality should be at least that one of a typical commercial or hospital environment. |
| Note: $U_T$ is the AC mains voltage before the application of the Test level. | | | |

| Guidance and manufacturer's declaration – ELECTROMAGNETIC IMMUNITY FOR DEVICES AND SYSTEMS THAT ARE NOT OF VIABLE FUNCTION | | | |
|---|---|---|---|
| The MAG1000 device is expected to operate in the electromagnetic environment below specified. The user or operator of the MAG1000 device must ensure that it is used in this environment. | | | |
| **Immunity test** | **Test level IEC 60601-1-2** | **Compliance level** | **Electromagnetic environment – guidance** |
| Portable and mobile RF communications equipment should not be used near any part of the MAG1000 device, including cables, except where recommended separation distances are observed, calculated from the equation applicable to frequency of the transmitter. | | | |
| | | | **Recommended separation distance** |
| Conducted RF<br>IEC 61000-4-6 | $3V_{eff}$ from 150kHz to 80MHz | $3V_{eff}$ from 150kHz to 80MHz | Recommended separation distance:<br>$d = 1,2 \cdot \sqrt{P}$ 150kHz to 80MHz |
| Irradiated RF<br>IEC 61000-4-3 | $3V_{eff}$ from 80MHz to 2,5GHz | $3V_{eff}$ from 80MHz to 2,5GHz | $d = 1,2 \cdot \sqrt{P}$ 80 MHz to 800 MHz<br>$d = 2,3 \cdot \sqrt{P}$ 800 MHz to 2,5 GHz |
| where (P) is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer and (d) is the recommended separation distance in meters (m).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b].<br>Interference may occur in the vicinity of equipment marked with the following symbol:  | | | |
| Note:<br>(1) At 80 MHz and 800 MHz the separation distance for the higher frequency range applies. | | | |

| Guidance and manufacturer's declaration – ELECTROMAGNETIC IMMUNITY FOR DEVICES AND SYSTEMS THAT ARE NOT OF VIABLE FUNCTION | |
|---|---|
| (2) | These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. |
| a) | Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the MAG1000 is used exceeds the applicable RF compliance level above, the MAG1000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MAG2000. |
| b) | Between the frequencies 150 kHz and 80 MHz, field strengths should be less than 3 V/m. |

| Recommended separation distances between portable and mobile RF communications equipment for MAG1000 that are not life-supporting | | | |
|---|---|---|---|
| MAG1000 is intended for the use in an electromagnetic environment in which radiated RF disturbances are controlled. The user or the operator of MAG1000 can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and MAG1000 as recommended below, according to the maximum output power of the communication equipment. | | | |
| **Rated maximum power of the transmitter (W)** | **Separation distance according to the frequency of transmitter (m)** | | |
| | from 150kHz to 80 MHz $d = 1,2\sqrt{P}$ | 80MHz to 800MHz $d = 1,2\sqrt{P}$ | 800MHz to 2,5GHz $d = 2,3\sqrt{P}$ |
| 0,01 | 0,12 | 0,12 | 0,23 |
| 0,1 | 0,38 | 0,38 | 0,73 |
| 1 | 1,2 | 1,2 | 2,3 |
| 10 | 3,8 | 3,8 | 7,3 |
| 100 | 12 | 12 | 23 |
| For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer. | | | |
| Nota<br>(1) At 80 MHz and 800 MHz the separation distance for the higher frequency range applies.<br>(2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |



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