USER MANUAL

Magnetotherapy model

ORTHOMAG

I.A.C.E.R. Srl
Via Enzo Ferrari 2 - 30037 Scorzè (VE) – Italia/Italy - Tel.: (+39) 041/5401356 - Email: iacer@iacer.it
PEC: iacer@pec.it - Web: www.itechmedicaldivision.com - Cod. Fisc./P.IVA/VAT N.: IT00185480274
R.E.A.: VE N. 120250 - M. VE001767 - Codice SDI/SDI Code: SUBM70N - Cap. Soc.: € 1.000.000,00 i.v.

Summary

Manufacturer

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

Via Enzo Ferrari, 2 • 30037 Scorzè (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 Enzo Ferrari, 2 – 30037 Scorzè (Ve), Italia

herewith declares under its own responsibility, that the product

ORTHOMAG

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.

Scorzè, 15/03/2022 — *Place, date*

MASSIMO MARCON — *Legal Representative*

Classifications

ORTHOMAG has the following specifications:

- Class IIa equipment (Directive 93/42/CEE, Annexed IX, rule 9 and following modifications).
- Class II applied part type BF (Classif. CEI EN 60601-1).
- IP22 protection equipment against solids, dust and liquids penetration.
- Equipment and accessories not subjected to sterilization.
- Use of the equipment is prohibited close to flammable substances when mixed with air, with nitrous oxide or when mixed with any flammable agents and in environments with high concentrations of oxygen.
- Continuous operating mode equipment.
- Equipment not suited to be used in external.

Purpose and scope

Clinical purpose: Therapeutic
Use: Clinic/Hospital and domestic use

ORTHOMAG is indicated for the treatment, rehabilitation and functional recovery of the following pathologies:

- wrist, hand, shoulder, foot, ankle and knee articulation
- skeletal motor apparatus
- arthrosis
- degeneration of locomotor apparatus
- sprains
- periarthritis
- muscular tears
- tendinitis

ORTHOMAG is particularly suitable for the treatment and the care of the osteoporosis and all the pathologies on bony tissues.

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

According to medical devices directives, the fabricant suggests a device control to check its efficiency and safety every 2 years.

Technical specifications

Feature	Specification	
Power supply	Lithium polymer batteries, 3.7V 900mAh	
Battery charger	model AK18WG-1200100V input 100-240V, 50/60Hz, 0.5A; output 12V, 1A	
Max. current consumption	≤300mA (in therapy)	
Insulation (EN 60601-1)	II	
Applied parts (EN 60601-1)	BF	
Field strength	20 Gauss ± 30%	
Square wave frequency	50Hz (L program) 75Hz (H program)	
Pulse width	16ms (L program), 10.66ms (H program)	
Duty cycle	80%	
Therapy duration	Preset to 4 hours	
Dimensions (Length x Width x Height)	97.9x71.8x30mm	
Weight	88g	
Usage conditions	Ambient temperature	From +5° to +40°C
	Relative humidity	From 30% to 85%
	Atmospheric pressure	From 700 to 1060hPa
Transport and storage conditions	Ambient temperature	From -5° to +40°C
	Relative humidity	From 10% to 93%
	Atmospheric pressure	From 700 to 1060hPa

Useful life of the device: 3 years.

Device description and controls

Label (back)

	Power on/off key
L	L Program key (50Hz)
H	H Program key (75Hz)

Labelling

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

Symbol	Description
I-TECH MEDICAL DIVISION	Manufacturer's logo.
CE 0068	Product certification issued by notified body No. 0068.
	Manufacturer's Data.
	Date of manufacture (YYYY-MM).
	Follow the instructions for use.
	WEEE directive for the disposal of electronic and electrical waste.
	Type BF applied part
	Allowed temperatures (storage and use temperatures, on the packaging and on the device body).
	Relative humidity (relative humidity for storage and use, on the packaging and on the device body).
IP22	Protection rating against ingress of solids, dusts and liquids (device protected against solid foreign objects of diameter ≥ 12.5 mm and against vertical drops of water when the device is kept at 15° from normal operating

Symbol	Description
	position).
	Power supply (DC12V/1A)

Package content

ORTHOMAG kit:

- N°1 ORTHOMAG device;
- N°1 wall mount charger (cable 1.5 m);
- N°1 user and maintenance manual;
- N°1 universal flexible applicator (cable 1.5 m);
- N°1 carriage bag;
- N°1 test emissions magnet;
- N°2 elastic bands (S and L size);
- N°1 car charger (optional).

Visit website **www.orthomag.eu** to obtain more information.

Introduction to technology

It's a long time that low frequency and high intensity pulsed electromagnetic fields have met maximum scientific consent in chronic and degenerative diseases treatment.
Magnetotherapy uses low frequency and high intensity pulsed electromagnetic fields induced by electric current on a bobbin; due to its characteristics, the electromagnetotherapy is universally recognized as the most suitable technique for the treatment of the bony pathologies, in particular for the osteoporosis.
Pulsed electromagnetic fields induce biological modifications on biological membrane in order to re-establish correct cellular functions.
According to different authors experiences in osteoporosis a considerable disease regression is evident from the sixth treatment and moreover it's evident an important increase of BMD (Bone Mass Density). The magnetic field high value (Gauss) generated by the device allows treatments in presence of braces or plaster bandage.
Thanks to its innovative universal applicator, light and flexible, and to the portability guarantee by a lithium rechargeable battery, ORTHOMAG represents an extremely powerful, easy-to-use device to be used everywhere.

Contraindications

- 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).Check with your doctor/therapist if you have any doubts/questions.
- Do not place the applicator on damaged, dirty or wounded skin. Irritated skin, lesions or ulcers can cause infection in the applicator placement area.
- Do not place the applicator near cancerous lesions as it may worsen the disease.
- Do not place the applicator in cavities, such as the oral cavity. The device is indicated for external use only.

- Avoid rapid/sudden movements that could cause the device to malfunction.
- Do not place the applicator on the chest, it could increase the risk of cardiac fibrillation.
- Do not use the device when connected to other medical devices, especially high frequency surgical devices. Danger of burns in the treatment area and damage to the device.
- Do not use if you are under medical supervision and have not consulted your doctor about treatment with the device.
- In case of internal effusions as a result of trauma or accident, do not use the device.
- Do not use the device in the presence of water or other liquids (in the bathroom, while showering, in the swimming pool, etc.) as this can increase the risk of electric shock.

WARNING: connect the battery charger to the mains only when connected to the device. Do not leave the battery charger connected to the 230V mains, make sure you disconnect it after each use.

WARNING: a slight hum from the device may be heard during therapy - this is normal and nothing to worry about.

The functionality of some implantable electrical devices, such as pacemakers, may be impaired during treatment with shortwave devices. Consult your doctor before using the device.

Side effects

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

Warnings

Please read this manual carefully before using the device. For any further information and details we advise you to visit our website *www.itechmedicaldivision.com* and refer to the section on magnetotherapy.
You should:

- read the user manual carefully and follow the instructions;
- check the location and meaning of all labels affixed to the device;
- only use the device in accordance with the instructions for use contained in this manual;

- use and store the device in a clean and dry place;
- not expose the device to dust, dirt, direct sunlight and water;
- avoid electric shocks to the device;
- not drop or allow the device to fall;
- not open the device, in case of problems contact the manufacturer;
- not use the device in case of faults or malfunctions;
- not modify the device or the applicator without the manufacturer's authorisation as malfunctions may occur;
- check the condition of the battery charger before use: do not use if the plastic casing or cable are damaged or have deteriorated;
- not wear metal objects during therapy;
- only use cables and applicators supplied by the manufacturer.

YOU MUST NOT :

- allow the device to be used by people (including children) with reduced physical, sensory and motor skills or by people not instructed to use it without the supervision of someone who has been trained how to use the device.Such people may not use the device correctly or in accordance with the information provided in this manual, and may be harmed as a result;
- use the device near flammable substances, gases, explosives, in environments with high oxygen concentrations, in the presence of aerosols or in very humid environments (do not use in the bathroom or while showering/bathing);
- use the device in the presence of signs of deterioration and/or damage to it or to the accessories (applicator, battery charger, etc.) and/or cables: contact the dealer or the manufacturer as indicated in the *Support* paragraph. Check the condition of the device before each use;
- use the device while using ointments containing free ions of magnetisable metals;
- use the device on open wounds and/or irritated skin;
- connect the device and its accessories to other devices not indicated in this manual.

Warning:

- The device can be used for personal home use;
- Medical device. Keep out of the reach of children in order to avoid inhalation or ingestion of small parts;

- Electronic medical devices require special precautions regarding electromagnetic compatibility;
- The device must be put into operation in accordance with the provisions of the EMC tables;
- The device should not be used in environments with strong electromagnetic interference: near televisions, microwave ovens or mobile phones, etc .;
- The device is suitable for use on a single person;
- Unsuitable cables and accessories could damage the device and could endanger the patient;
- The user must periodically check the condition and insulation of the cables and applicators;
- Position the applicator so that the side with the "+" symbol is in contact with the patient.

WARNING: If you are using the device connected to the mains, disconnect the battery charger from the mains socket at the end of the therapy session.It is recommended to position the device so that this operation is always easy and safe to perform. Place the device on a stable shelf/support (table, bedside table), away from other devices that may interfere or prevent safe use of the device and its connected accessories.

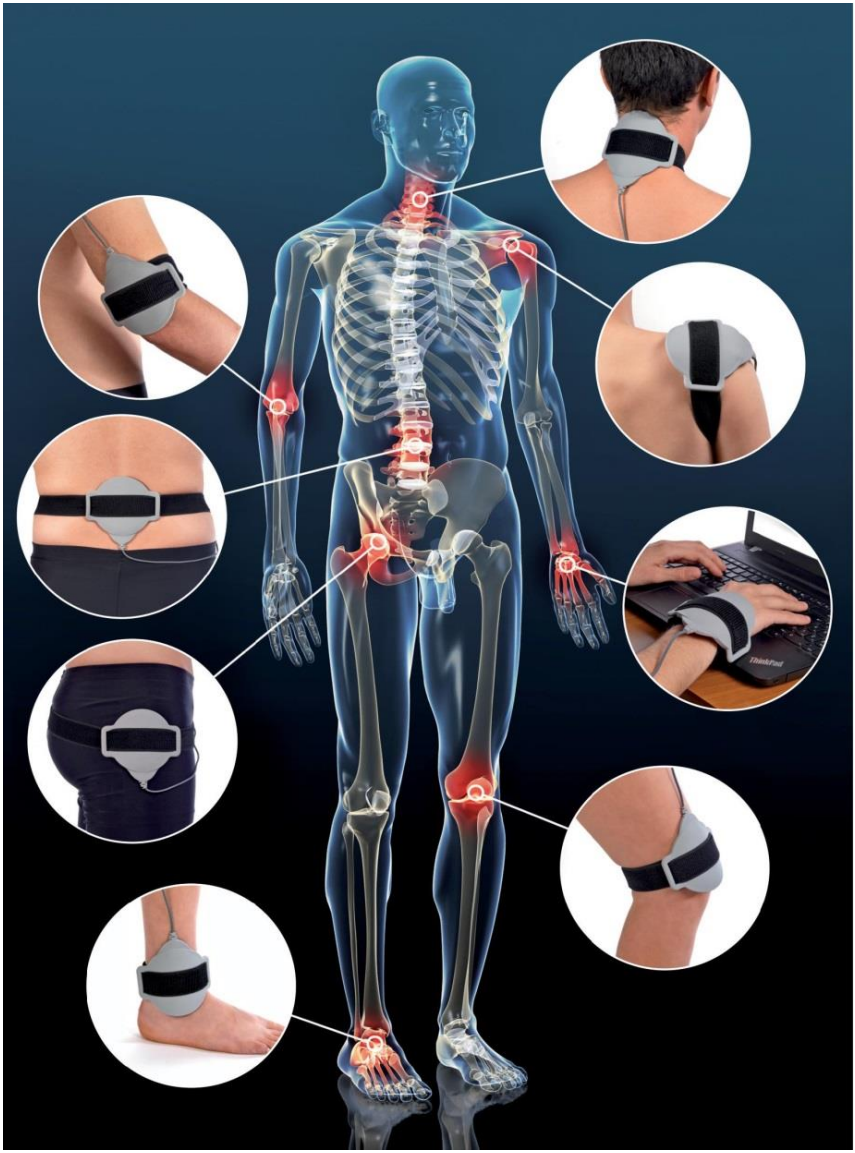
The manufacturer is to be considered responsible for the safety, reliability and performance of the device provided that:

- Any additions, modifications and/or repairs are carried out by personnel authorised directly by the manufacturer. Any modification, addition and/or repair carried out by unauthorised personnel is prohibited as it could result in the loss of safety of the device or its malfunction.
- The electrical system of the environment in which ORTHOMAG is inserted complies with national laws.
- The device is used in strict compliance with the instructions given in this manual.

Applied Parts In addition to the applicator, parts applied to the patient are also considered to be the device itself and the battery charger that may come into contact with the user during treatment.

Preparing the patient: main positions of the applicator

The flexible applicator guarantees a comfortable fit and wearability, adapting effectively to different parts of the body. It is also very light and compact.
The following image provides some of the possible applications for the most common conditions treatable with magnetotherapy such as cervical and/or elbow/knee joint arthritis, scapula/humeral arthritis, lumbar pain, fractures, sprains.
Position it in the most comfortable way on the area to be treated, fixing it in position using the elastic straps provided.
It is recommended that you undergo magnetotherapy treatment under the supervision of your doctor and/or therapist.



How to use the device

How to insert the battery

- remove the belt clip by sliding it downwards;
- open the battery compartment by acting on the retaining hook;
- insert the battery;
- close the battery compartment;
- reinsert the clip to attach it to the belt.

How to use the device with the power supply adapter

- Connect the applicator to the Orthomag.
- Place the applicator onto the part of the body to be treated (see picture at page 16) and fix it with the elastic strap supplied.
- Connect the power supply adapter to Orthomag (the POWER LED starts blinking green).
- Switch on the Orthomag by pressing the middle button.
- Choose the program L (50 Hz) or H (75 Hz) by pressing the L button or the H button, respectively.
- When the program L starts, the OUTPUT LED flashes green.
- When the program H starts, the OUTPUT LED flashes red.

⚠ WARNING: if you connect the power supply to Orthomag without having previously inserted the battery, the device will beep and the selected program will not start.

How to use the device with battery

- Before proceeding, ensure that the device was previously charged at full capacity (at least 4/5 hours).
- Connect the applicator to the Orthomag.
- Place the applicator onto the part of the body to be treated (see picture below) and fix it with the elastic strap supplied.
- Switch on the Orthomag by pressing the middle button.
- Choose the program L (50 Hz) or H (75 Hz) by pressing the L button or the H button, respectively.
- When the program L starts, the OUTPUT LED flashes green.
- When the program H starts, the OUTPUT LED flashes red.

POWER LED BEHAVIOUR IN BATTERY MODE

POWER LED green steadily lit: battery fully charged that allows you to complete the treatment.

POWER LED flashing alternating green/red: battery half charged (emission of magnetic field is guaranteed but not sufficient to start a complete new cycle of therapy).
POWER LED red steadily lit: battery is low. The magnetic field is still emitted until the device is switched off.

LIST OF PROGRAMS

Therapeutic indications (average time of therapy 2/4 hours per day)

Program L (50 Hz)	Program H (75 Hz)
Algodystrophy	Scar adherence
Gonarthrosis	Arthritis
Cartilage degeneration	Arthrosis
Fractures	Bursitis
Cartilage injuries	Brachialgy
Osteoarthrosis	Capsulitis
Osteonecrosis	Cervical pain
Osteoporosis	Whiplash
Delayed calcification	Chondropathy
Pseudo-arthrosis	Contusions
	Coxarthrosis
	Articular pain
	Rheumatic disorders
	Back pain
	Epicondylitis
	Epitrochleitis
	Discal Hernia
	Plantar fasciitis
	Lumbago
	Meniscopathy
	Metatarsal pain
	Periarthritis
	Pubalgy
	Rheumatisms
	Rhizarthrosis
	Sciatalgy
	Inflammatory diseases
	Muscle strains

To stop therapy and turn off the device, press and hold the on/off key for 3 seconds.

WARNING: if the applicator is disconnected, the output LED flashes and the device emits 3 consecutive beeps. Check the condition of the applicator, the cable and the correct connection to the device.

WARNING: in the case of equipment supplied for hire, ORTHOMAG can be locked in the L or H program in order not to allow the program to be changed by the end user (this is in order to strictly follow the instructions given by medical personnel).This function can only be enabled via software/PC by authorised personnel.

In this case, the device only allows switching on/off and starting therapy via the ON/OFF key. The OUTPUT LED indicates the active program (green LED = program L, red LED = program H).If you try to choose a different program, you will hear a beep (3 consecutive beeps).Therapy can be suspended (paused) by pressing the L or H key once (depending on the active therapy).Press the button again to restart the treatment.

Maintance

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 with the battery charger and the condition of all connection cables;
- check the connection with the applicator;
- recharge the battery until the charging LED goes off;
- verify that all operations have been performed correctly;
- every two years check that all the functions of the device work correctly (contact the manufacturer).

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

CHECKING DEVICE OPERATION

A magnet (small ring or disc in metal or metal/plastic) is supplied with the device to check its 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 magnet supplied and bring it close to the applicator;
4. check that the magnet vibrates (proportional to the frequency of the selected therapy).

Contact the manufacturer if the magnet does not vibrate.

CLEANLINESS

ATTENTION: before start any cleaning operations on device always disconnect the device from mains and extract the battery form battery compartment (see “Battery recharge and replacement” paragraph”).

Clean the equipment from the dust using a dry soft cloth.
Resistant strains can be removed using a sponge soaked in solution of water and alcohol (20%).

When not using the device for a long time, clean the device and its accessories as mentioned before. Place the device and the accessories in the carriage bag and store them in their box.
When using the same applicator on different patients, we recommend to clean it carefully using a sponge soaked in solution of water and alcohol (20%)
We recommend to disconnect the applicator from the device before cleaning the it.
Pay attention to respect the temperature, humidity and pressure limits mentioned in this manual also during the cleaning of the device and its accessories.

CARRIAGE AND STORAGE

Carriage precautions
ORTHOMAG is a portable device, so it does not need any particular carriage precautions.
However we recommend to put away ORTHOMAG and its accessories in their own bag after every treatment.
We recommend to not roll up wall mount charger and applicator cable.

Storage precautions

ORTHOMAG is protected till following environmental conditions:

Outside of the packaging	
Temperature	from +5 to + 40 °C
Rel. humidity	from 10 to 93%
Pressure	from 700 to 1060 hPa
Inside of the packaging	
Temperature	from –5 to +40 °C
Rel. humidity	from 10 to 93%
Pressure	from 700 to 1060 hPa

Troubleshooting

Battery recharge

For charge the device follow the instructions bellow:

- Plug the charger to the power socket
- Connect the charger's plug to the device

The POWER led will flash with a green light till the achievement of the complete charge of the battery, than the light will switch off (charge

complete, 4-6 hours). During the charge the devise can be used, in this case the POWER led will light with a green light.

Battery replacement

For change battery please follow the instructions bellow:

- Disconnect the device from the charger.
- Remove the belt clip by pushing it down lightly
- Open the battery compartment
- Pull out the battery;
- Insert the new battery (please use only battery provided by the manufacturer);
- Close the battery compartment;
- Put back the belt.

Before use it please finish a charge clip.

Disposal

The ORTHOMAG 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 ORTHOMAG device, unless information contained in this manual regarding installation, use and maintenance is strictly adhered. The wearing parts (applicators' fabric as well as elastic velcro closure of the same) 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.*

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 Enzo Ferrari, 2 • 30037 Scorzè (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 Enzo Ferrari, 2 • 30037 Scorzè (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 electromagnetic compatibility tables

The ORTHOMAG 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.

Use the device at least 3 metres away from televisions, monitors, mobile phones, WIFI routers or any other electronic device as they may affect its functioning.
In particular portable communication equipment as WIFI devices, mobile phones, cordless phones and their base stations, walkie-talkie, can affect the medical device and it's recommended a separation distance "d" calculated from the fabricant in table "R.f. immunity aspects", column 800MHz-2,5GHz, paragraph EMC tables. Example: for a mobile phone with 2W maximum output power the separation distance d is 3,3 m in order to obtain an immunity level of 3V/m or a separation distance d=0,5m for an immunity level of 20V/m.
The device must be installed and commissioned in compliance with the information on electromagnetic compatibility supplied in this manual. Also see the EMC Charts paragraph.
Using accessories, transducers and cables other than those specified, except for those transducers and cables sold by the manufacturer as spare parts for internal components, may result in increased emissions or decreased immunity of the device.
The device should not be placed next to or on top of other devices. Should it prove necessary to place it next to or on top of other devices, supervision is essential at all times to control its normal functioning.

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

ELECTROMAGNETIC COMPATIBILITY TABLES

Guidance and manufacturer's declaration – ELECTROMAGNETIC EMISSIONS – FOR ALL DEVICES AND SYSTEMS		
MAG2000 family is expected to operate in the electromagnetic environment below specified. The customer or user of the MAG2000 family must ensure that it is used in such environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	MAG2000 family 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
RF emissions CISPR 11	Class B	MAG2000 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Compliant	

Guidance and manufacturer's declaration – ELECTROMAGNETIC IMMUNITY – FOR ALL DEVICES AND SYSTEMS			
MAG2000 is intended for use in the electromagnetic environment specified below. The user or operator of MAG2000 should assure that is used in such environment.			
Immunity test	**Test level IEC 60601**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV; +8kV at contact ±8kV; +15kV in air	±6kV; ±8kV at contact ±8kV; +15kV 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 IEC 61000-4-4	±2kV for power supply lines	±2kV for power supply lines	Mains power quality should be at least that one of a typical commercial or hospital environment.
Impulses	±1kV	±1kV	Mains power quality

Guidance and manufacturer's declaration – ELECTROMAGNETIC IMMUNITY – FOR ALL DEVICES AND SYSTEMS			
MAG2000 is intended for use in the electromagnetic environment specified below. The user or operator of MAG2000 should assure that is used in such environment.			
Immunity test	**Test level IEC 60601**	**Compliance level**	**Electromagnetic environment – guidance**
IEC 61000-4-5	line - line	line - line	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 IEC 61000-4-11	<5% U_T (>95% dips of U_T) for 0,5 cycle <5% U_T (>95% dips of U_T) for 1 cycle 70% U_T (30% dips of U_T) for 25 cycles <5% U_T (>95% dips of U_T) for 5s	<5% U_T (>95% dips of U_T) for 0,5 cycle <5% U_T (>95% dips of U_T) for 1 cycle 70% U_T (30% dips of U_T) for 25 cycles <5% U_T (>95% dips of U_T) for 5s	Mains power quality should be at least that one of a typical commercial or hospital environment. If the user of the MAG2000 requires continued operating during power mains interruptions, it is recommended that MAG2000 be powered from an uninterruptible power supply (UPS) or a battery
Mains power electromagnetic field (50/60Hz) IEC 61000-4-8	30A/m	30A/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 MAG2000 Family is expected to operate in the electromagnetic environment below specified. The user or operator of the MAG2000 family must ensure that it is used in this environment.			
Immunity test	**Test level IEC 60601**	**Compliance level**	**Electromagnetic environment – guidance**

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – ELECTROMAGNETIC IMMUNITY FOR DEVICES AND SYSTEMS THAT ARE NOT OF VIABLE FUNCTION</th></tr>
<tr><td colspan="4">Portable and mobile RF communications equipment should not be used near any part of the MAG2000 family, including cables, except where recommended separation distances are observed, calculated from the equation applicable to frequency of the transmitter.</td></tr>
<tr><td colspan="4">Recommended separation distance</td></tr>
<tr><td>Conducted RF

IEC 61000-4-6</td><td>3V_{eff}
from 150 kHz to 80 MHz

6V_{eff}
from 150 kHz to 80 MHz for ISM band</td><td>3V_{eff}
([V_1] V)

6V_{eff}
([V_1] V)</td><td>$d = \left[\frac{3,5}{V_1}\right]\sqrt{P} = d = \left[\frac{12}{V_1}\right]\sqrt{P}$
for ISM band</td></tr>
<tr><td>Irradiated RF

IEC 61000-4-3</td><td>10V/m
from 80 MHz to 2,7 GHz</td><td>10V/m
[E_1] V/m</td><td>$d = \left[\frac{12}{E_1}\right]\sqrt{P}$
from 80 MHz to 800 MHz
$d = \left[\frac{7}{E_1}\right]\sqrt{P}$
from 800 MHz to 2,7 GHz</td></tr>
<tr><td>Irradiated RF for radio communication devices

IEC 61000-4-3</td><td>3 V/m
from 80 MHz to 6 GHz</td><td>3V/m
[E_1] V/m</td><td>$d = \left[\frac{6}{E_1}\right]\sqrt{P}$
from 80 MHz to 6 GHz</td></tr>
<tr><td colspan="4">where (P) is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer and (d) is the recommended separation distance in meters (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b].
Interference may occur in the vicinity of equipment marked with the following symbol:  </td></tr>
<tr><td colspan="4">Note:
(1) At 80 MHz and 800 MHz the separation distance for the higher frequency range applies.
(2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">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 MAG2000 is used exceeds the applicable RF compliance level above, the MAG2000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may</td></tr>
</table>

Guidance and manufacturer's declaration – ELECTROMAGNETIC IMMUNITY FOR DEVICES AND SYSTEMS THAT ARE NOT OF VIABLE FUNCTION
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 [V_1] V/m.

Recommended separation distances between portable and mobile RF communications equipment for MAG2000 that are not life-supporting

MAG2000 is intended for the use in an electromagnetic environment in which radiated RF disturbances are controlled. The user or the operator of MAG2000 can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and MAG2000 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 800 MHz	from 150kHz to 800 MHz (ISM band)	from 80MHz to 800 MHz	from 800MHz to 6 Hz (to RF wireless radio communication equipment)
0,01	0,12	0,2	0,12	0,23
0,1	0,38	0,63	0,38	0,73
0,2	–	–	–	–
1	1,20	2,0	1,20	2,30
1,8	–	–	–	–
2	–	–	–	–
10	3,80	6,3	3,80	7,30
100	12,00	20	12,00	23,00

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer.

Note

1) At 80 MHz and 800 MHz the separation distance for the higher frequency range applies.
2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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