I-TECH
MEDICAL DIVISION

USER MANUAL

MNPG207-00 Edition 09/11/2015

Model Magnetotherapy

ORTHOMAG®

I.A.C.E.R. Srl

www.itechmedicaldivision.com

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Summary

Introduction

Magnetotherapy (P.E.M.F)

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 osteoporosys a considerable disease regression is evident from the sixth treatment and moreover it's evident an important increase of BMD (Bone Mass Density). The magnetic field high value (Gauss) generated by the device allows treatments in presence of braces or plaster bandage.

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.

Technical Specifications

Manufacturer

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

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

Tel. 041.5401356 • Fax 041.5402684

IACER S.r.l. is an Italian medical devices manufacturer (CE medical certificate n° MED24021 issued by Cermet notified body n° 0476).

Declaration of conformity

IACER S.r.l., headquartered in Italy, via S. Pertini 24/A 30030 Martellago (VE), declares on its own responsibility that ORTHOMAG® is manufactured in conformity with Directive 93/42/EEC (MDD) dated 14 June 1993 (D. Lgs. 46/97 dated 24 February 1997 "Attuazione della Direttiva 93/42/CEE concernente i dispositivi medici), Annex II as modified by Directive 2007/47/CE dated 5 September 2007 (D. Lgs. 37/2010 dated 25 January 2010).

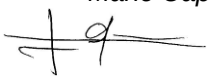
Notified body: Cermet, Via di Cadriano 23 – 40057 Cadriano di Granarolo (BO) Italy.

Certification Path: Annex II (excluded point 4).

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

Martellago Venice , 01/10/15

Legal Representative
Mario Caprara



Specifications

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 inflammable 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 outdoor;*

Purpose

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 manufacturer suggests a device control to check its efficiency and safety every 2 years. Expected lifetime of the device and its accessories: 5 years.

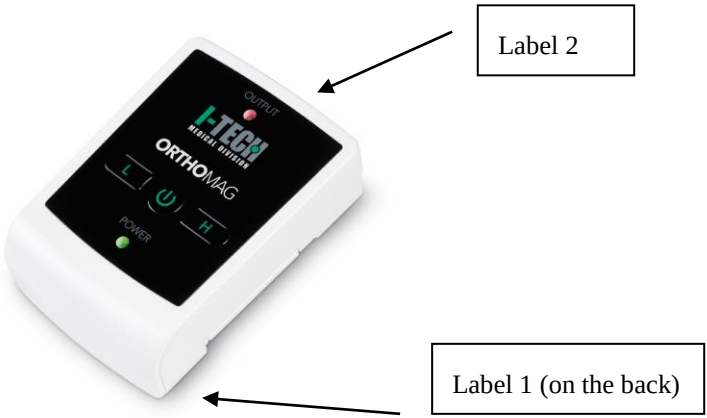
Technical features

Power supply	*DC 3.7V Lithium battery*
Battery charger	*12V/1A*
Max. absorbed current	*≤300 mA (therapy mode)*
Insulation class (CEI EN 60601-1)	*II*
Applied part (CEI EN 60601-1)	*BF*
Dimensions and Weight	*97,9x71,8x30mm, 88gr*
Peak of Intensity	*20 Gauss ±30%*
Frequency	*50 Hz (at "Low" mode), 75 Hz (at "High" mode)*
Pulse width	*16ms (at "Low" mode), 10,66ms (at "High" mode)*
Duty cycle	*80%*
Treatment time	*Presetted at 4 hours*

Environmental conditions of operation:

Temperature	*from +5 to + 40 °C*
Relative humidity	*from 30 to85%*
Pressure	*from 700 to1060 hPa*

Labelling



Label details

Label 1

Label 2

DC INPUT 12V 1A

Symbols description

	Attention, consult operating instructions
	Product subject to WEEE regulations concerning separate waste collection of electronic equipment
	Class II equipment

	Applied part type BF
	Compliance with Directive 93/42/EEC and following modifications
	Manufacturing date (month/year)
	Admission temperatures
	Relative humidity
	Manufacturer information
IP22	Protected from touch by fingers and objects greater than 12 millimetres. Protected from water spray less than 15 degrees from vertical.
	Indoor use only

Kit contents

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 band (S and L size);*
- *N°1 car charger (optional);*

*Visit website **www.orthomag.eu** for more information.*

Warnings

Please read carefully the user manual before using ORTHOMAG®

We recommend to visit magnetotherapy section on website www.itechmedicaldivision.com in order to obtain other information.

Take care of what follows:

- *Read carefully the user manual and follow the instructions given.*
- *This device can be used for a domestic personal use.*
- *The device has to be used in an environment with a temperature range from 5 to 40°C.*
- *Do not expose to temperatures above 55 ° C or below -10 ° C.*
- *Do not use the device in an environment with humidity higher than 90%.*
- *Storage the device in a clean and dry environment.*
- *Avoid the device and accessories exposition to excessive direct sunlight, dust and water.*
- *Avoid electrical shock to the device.*
- *Avoid accidental fall of the device.*
- *Do not open the device, in case of problems , contact the manufacturer.*
- *ORTHOMAG® is a medical device. Keep it out of children and animal's reach.*
- *Do not use the device in case of anomalies or malfunctions.*
- *Medical electronic require special precautions with regard to electromagnetic compatibility.*
- *The device must be operated in accordance with the requirements of the EMC tables.*
- *The device should not be used in environments where there is a presence of strong electromagnetic interference : close to televisions, microwave ovens or mobile phones etc.*
- *Use of the device is not intended for people (including children) with physical, sensor and motor deficit, or uneducated to use the device without the supervision of skilled / educated person. These people could not use the device properly in accordance with the user manual.*
- *Do not modify the device or the accessories without the authorization. of the manufacturer. It can cause malfunctions.*
- *This device is designed to treat one person only.*
- *Check the integrity of the wall mount charger before use. Avoid the use in case of damage to the case or to the wire.*

- *Do not use the device in damp environments and/or in presence of inflammable agents.*
- *Do not wear metallic objects during therapy.*
- *Use only cables and applicators supplied by the Manufacturer. Inadequate cables and applicators could damage the device and/or could be hazardous for the patient.*
- *The user must periodically verify cables and applicators insulation and control their integrity (eventually by contacting the manufacturer).*
- *Take care to place the "+" side of the applicator on the skin.*

WARNIG. Disconnect the wall mount charger from the mains after each treatment. We recommend to keep the device in a safe position in order to disconnect the cables easily. Place the device on a firm shelf (table, nigh table) away from other devices that could make interferences or stop a safe use of the device and its connected accessories.

The manufacturer is considered responsible for the performance , reliability and safety of the equipment only if :

- *Possible additions, changes and/or reparations are effected from authorized personnel.*
- *The electric plant of the environment in which ORTHOMAG® is inserted it is conforming to the national laws.*
- *The instrument is employed in conformity to the instructions contained in this manual.*

Applied parts. It's necessary to consider as applied parts the device and the power supply that can get in contact with the user during the treatment.

Electromagnetic interference

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.

Contraindications and side effects

- *Patient in pregnancy, tuberculosis, juvenile diabetes, viral (in acute phase) illnesses, mycosis, cardiopathic subjects, tumours, serious arrhythmias or pacemaker carriers, children, metallic prosthesis carriers, acute infections, epileptics (different medical prescriptions excepted). Consult doctor/therapist for any doubt.*
- *Do not use on irritated skin or on open wound.*
- *Do not place the applicator near cancerous lesions as it may have a negative effect on disease.*
- *Do not place the applicator in the cavity , such as the mouth. The device is intended only for external use.*
- *Avoid quick movements / sudden that might cause malfunction.*
- *Do not place the applicator on the chest, could increase the risk of cardiac fibrillation.*
- *Do not use the device when connected to other medical devices , particularly surgical devices at high frequency. Risk of burns in the treatment area and damage to the device.*
- *Do not use if you are under medical supervision and did not consult the same doctor about treatment with the device .*
- *If you spill interiors following trauma or injury, do not use the device.*
- *Do not use the device in the presence of water or other liquids (in the bathroom , in the shower , in the pool , etc.) as this may increase the risk of electric shock.*

WARNING: connect the charger to the mains only when the charger is connected to the device. Do not leave the charger connected to the mains 230V, disconnect it after each use.
WARNING: during therapy, you may hear a slight hum coming from the device: it is a normal noise and should not cause concern.

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

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

Use of the device

Connect the applicator to the plug on the top of the device and press the power button (place the applicator following the information given in the next chapter, or following the suggestion given from your doctor). You will hear a sound and the POWER led (green one) and the OUTPUT led (red or green) will light on.

Press the L button (LOW frequency program, 50 Hz) or H button (HIGH, frequency program 75 Hz) to select the program. The OUTPUT led will light on in green light (L program) or in red light (H program).

Press again the L button, to start the LOW frequency program, or H button, to start the HIGH frequency program. The OUTPUT led will flash in green light (LOW frequency program) or in red light (HIGH frequency program). If the device is connected to the charger the POWER led will light with a green light, if the device is in battery mode the POWER led will flash.

In general , treatment L (50 Hz) is used in the problems such as fractures, osteoporosis, arthrosis, while the program H (75 Hz) is indicated for typical problems of the inflammatory state (arthritis , joint pain, etc). It is advisable to always refer to the suggestion of your physician.

Warning: in case that the applicator is not connect correctly to the device the OUTPUT led will flash and you will hear three sounds. In this case please verify cables and applicators insulation and check their integrity (eventually by contacting the manufacturer).

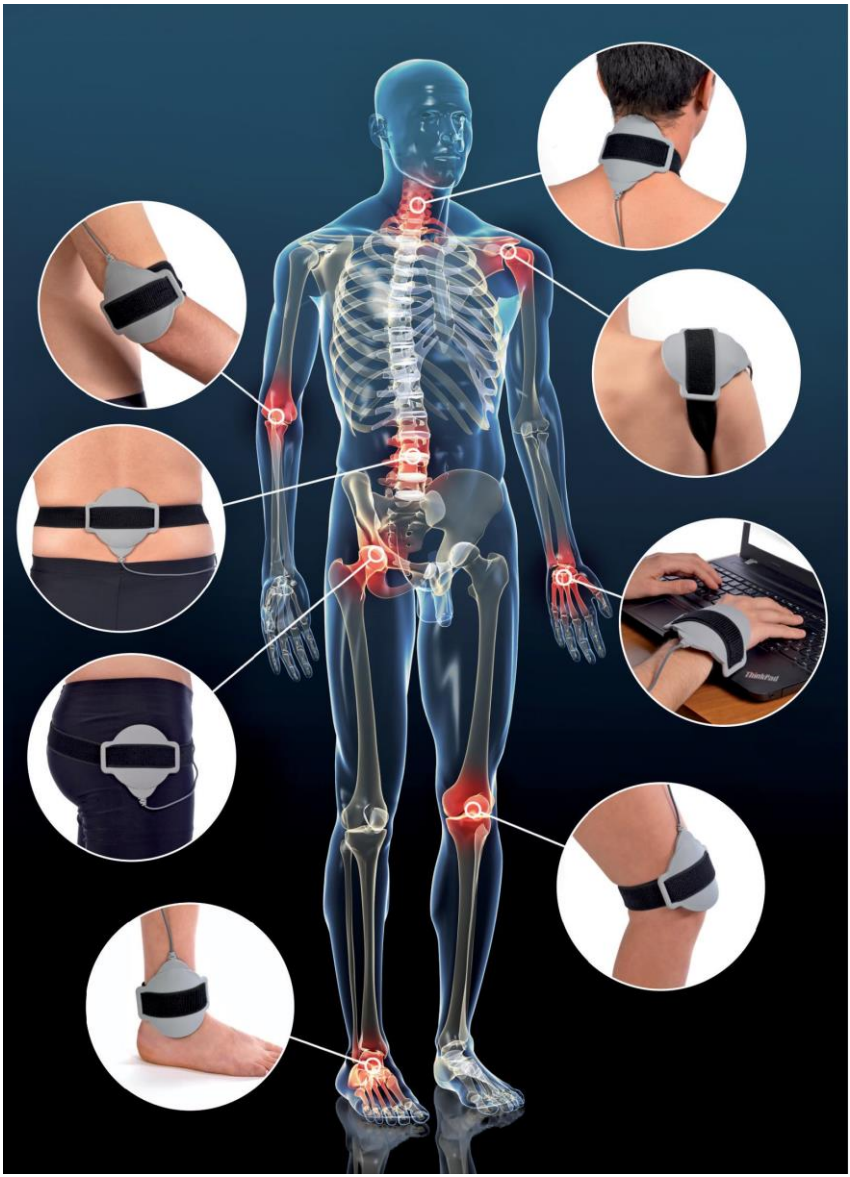
Placement of the applicator

Thanks to its light and flexible structure, ORTHOMAG® universal applicator allows a perfect contact with the body.

The image below gives some of the possible applications for the most common diseases treated with P.E.M.F. such as cervical osteoarthritis and / or joints of the elbow / knee arthritis bachelor / joint, back pain , fractures , sprains .

Find the most comfortable way to place the applicator on the treatment area , securing it in place through the use of elastic bands provided.

It is recommended to start treatment with P.E.M.F devices under the supervision of your physician and / or therapist .



Maintenance

Battery recharge and replacement

Recharge the device following the instructions:

- *Plug the charger to the mains*
- *Connect the charger's plug to the device*

The POWER led will flash in green light till the end of the recharge cycle, than the light will switch off.

During the recharge cycle you can use the device.

Replace the battery following the instructions:

- *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 clip.*

Before use the device complete a charge cycle.

Functioning control

ORTHOMAG® is provided with a magnet in order to control the device functioning.

Control procedure:

1. *Switch on the device in according to user manual safety prescriptions.*
2. *Start a treatment in according to user manual instructions.*
3. *Take the magnet in your hand and pass it near to applicator.*
4. *Check magnet vibration (it will be proportional to selected treatment frequency).*

Please contact the manufacturer in case of magnet vibration absence.

Cleaning

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

Clean the equipment from the dust using a dry soft cloth.

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

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 store ORTHOMAG® and its accessories in their own bag after every treatment.

We recommend to not roll up wall mount charger and applicator cables.

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*

Disposal

The equipment is subjected to WEEE regulations (see the symbol on the label) concerning separate waste collection: when disposing this product, please use the designed areas for disposing electronic waste or contact the manufacturer.

Troubleshooting

If it is used in accordance with the instructions of the user manual, ORTHOMAG® does not need a particular regular maintenance.

If you find any malfunctioning using ORTHOMAG®, please follow these instructions:

- *Check the mains socket integrity by connecting a working device to the same socket.*
- *Check the connection with working wall mount charger and applicator.*
- *Check the correct connection between ORTHOMAG® and the applicator (or the applicators).*
- *Check the battery is fully charged (green led on the device must switch off during recharge).*
- *Check all the operations have been done properly.*
- *We suggest a complete check of device every 2 years (contact the manufacturer or locator dealer).*

If you find any problem contact immediately the National Distributor or the manufacturer at the following address:

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

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

Tel. 041.5401356 • Fax 041.5402684

Assistance

Every intervention on device must be performed by manufacturer. For any assistance intervention contact the National Distributor or the manufacturer at the following address:

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

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

Tel. 041.5401356 • Fax 041.5402684

You can get any technical documentation on spare parts

Spare parts

For original spare parts contact the National Distributor or the manufacturer at following address:

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

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

Tel. 041.5401356 • Fax 041.5402684

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

EMC tables

Electromagnetic emission		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions Cispr 11	Group 1	*ORTHOMAG*® uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions Cispr 11	Class B	*ORTHOMAG*® is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A Complies	*ORTHOMAG*® is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Electromagnetic immunity			
ORTHOMAG® is intended for use in the electromagnetic environment specified below. The customer or the user of *ORTHOMAG*® should assure that is used in such environment.			
Immunity test	**Test level EN 60601-1-2**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) EN 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines	± 2kV per power supply lines	Mains power quality should be at that of a typical commercial or hospital environment.

Impulses EN 61000-4-5	±1kV differential mode	±1kV differential mode	Mains power quality should be at that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (>95% dips of U_T) per 0,5 cycles 40% U_T (60% dips of U_T) per 5 cycles 70% U_T (30% dips of U_T) per 25 cycles < 5% U_T (>95% dips of U_T) per 5 seconds	< 5% U_T (>95% dips of U_T) per 0,5 cycles 40% U_T (60% dips of U_T) per 5 cycles 70% U_T (30% dips of U_T) per 25 cycles < 5% U_T (>95% dips of U_T) per 5 seconds	Mains power quality should be at that of a typical commercial or hospital environment. If the user of the *ORTHOMAG®* requires continued operation during power mains interruptions, it is recommended that *ORTHOMAG®* be powered from an uninterruptible power supply or a battery.
Mains power electromagnetic field EN 61000-4-8	3 A/m	3 A/m	Mains power quality should be at that of a typical commercial or hospital environment.

r.f. immunity			
ORTHOMAG® is intended for use in the electromagnetic environment specified below. The customer or the user of *ORTHOMAG®* should assure that is used in such environment			
Immunity test	**Test level EN 60601-1-2**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF EN 61000-4-6	3 Veff from 150kHz to 80MHz	3 Veff from 150kHz to 80MHz	**Portable and mobile RF communications equipment should be used no closer to any part of *ORTHOMAG®*, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.** **Recommended separation distance:** **d = 1,2 ·√P 150kHz to 80MHz** **d = 1,2 ·√P 80 MHz to 800 MHz** **d = 2,3 ·√P 800 MHz to 2,5 GHz** where (P) is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer and (d) is the recommended separation distance in meters (m).
RF Radiata EN 61000-4-3	3 Veff from 80MHz to 2,5GHz	3 Veff from 80MHz to 2,5GHz	
Field strangths from fixed RF transmitters, are determined by an electromagnetic site survey, should be less than the compliance level in each frequency rage. Interference may occur in the vicinity of equipment marked with the following symbol: 			

Recommended separation distances between portable and mobile communications equipment and the *ORTHOMAG®*

ORTHOMAG® is intended for the use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of *ORTHOMAG®* can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and *ORTHOMAG®* 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 the transmitter (m)**		
	150kHz to 80MHz d = 1,2 ·√P	**80MHz to 800MHz d = 1,2 ·√P**	**800MHz to 2GHz d = 2,3 ·√P**
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

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

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

Warranty

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

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