USER MANUAL

KORA OXER

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KORA OXER

Summary

Manufacturer

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IACER S.r.l. is an Italian manufacturer of medical devices and veterinary medical devices.

Classifications

The KORA OXER device takes on the following classifications:

- Class II with applied part type BF (Classif. CEI EN 60601-1).
- Device with IP22 degree of protection against the penetration of solid objects, powders and liquids.
- Device and accessories supplied non-sterile and not subject to sterilisation;
- Device not suitable for use in the presence of a flammable anaesthetic mixture with air, with nitrous oxide, with any flammable agent of any kind and in environments with a high concentration of oxygen;
- Device for continuous operation;
- Device not suitable for external use.

Intended purpose and scope of use

Clinical purpose:	Therapeutic for veterinary use
Scope of use:	Outpatient and home care

KORA OXER is designed and indicated for treating horses. In particular, it is recommended for the treatment, rehabilitation and functional recovery of pathologies affecting:

- Superficial flexor tendon;
- Deep flexor tendon;
- Suspensory and collateral ligament;
- Coronary band;
- Foot;

- Carpus;
- Extensor branches and extensor carpi radialis;
- Fetlock.

KORA OXER is particularly indicated for the treatment of inflammation (including that of the nuchal ligament), for stimulating trigger points and for recovery from temporomandibular joint atrophy.

Technical features

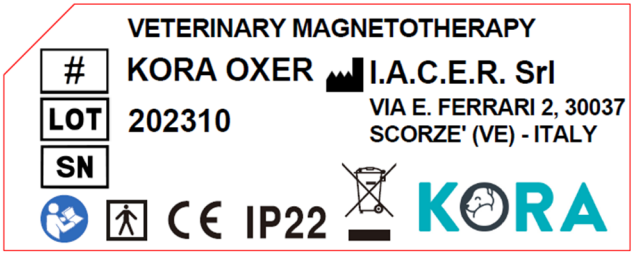
Feature	Specification	
Power supply	Lithium polymer batteries, 3.7V 900mAh	
Battery charger	model AK18WG-1200100V input 100-240V, 50/60Hz, 0.5A; output 12V, 1A	
Max. current consumption	≤300mA (in therapy)	
Insulation (EN 60601-1)	The	
Applied parts (EN 60601-1)	BF	
Field strength	20 gauss ± 30%	
Square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

Device description and controls

Label (back)

	Power on/off button
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
KORA	Manufacturer's logo
CE	CE conformity:
	Manufacturer data
#	Serial Number
LOT	Batch number
SN	Serial Number
	Follow the instructions for use
	WEEE directive for the disposal of electronic waste.
	Type BF applied part
	Permissible temperatures (storage and use temperatures, on packaging and device body)
	Relative humidity (relative humidity of storage and use, on packaging and 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 position).
	Power supply (DC12V/1A)

KORA OXER

Packaging contents

The KORA OXER package contains:

- No. 1 KORA OXER device;
- No. 1 battery charger (cable approx. 1.5 m);
- No. 1 user manual;
- No. 1 universal flexible applicator (cable approx. 1.5 m);
- No. 1 magnet tester;
- No. 2 elastic retaining bands (sizes S and L);

Visit **www.koratherapy.com** for more information.

Instructions for use

Introduction to technology

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

Magnetotherapy uses low-frequency, high-intensity pulsed magnetic fields induced by an electric current running through a coil; due to its characteristics, it is now universally recognised as the most suitable technique for the treatment of bone and joint pathologies.

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

According to the experiences of several authors, magnetotherapy in veterinary medicine is able to bring clear beneficial effects in chronic cases even after three weeks of therapy.

Thanks to its innovative, lightweight and flexible universal applicator and the portability ensured by its rechargeable lithium battery, the KORA OXER is an extremely effective, versatile and convenient device to use in all situations where practicality is required.

Contraindications

- Pregnant patients, viral diseases (in an acute phase), subjects with heart disease, tumours, severe arrhythmias or pace-maker wearers, foals, wearers of magnetisable prostheses, acute infections, epileptics (unless otherwise prescribed by a veterinary doctor).
- 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.
- 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.

WARNING: connect the battery charger to the mains only when connected to the device.

The functionality of some implantable electrical devices, such as pacemakers, may be impaired during treatment with shortwave devices.

Side effects

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

Warnings

Please read this manual carefully before using the device. For any further information, please visit the magnetotherapy section on our website *www.koratherapy.com*.
It is recommended to:

- 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;
- 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;
- only use cables and applicators supplied by the manufacturer.

It is forbidden:

- to use the device near flammable agents, gases, explosives, in environments with high oxygen concentrations, in the presence of aerosols or in very humid environments;
- to 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;
- connect the device and its accessories to other devices not indicated in this manual.

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 device is used in strict compliance with the instructions given in this manual.

Parts applied. 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.

Instructions for use

Battery insertion

- remove the belt clip by sliding it downwards;
- Open the battery compartment by acting on the sealing hook;
- insert the battery;

- close the battery compartment;
- reinsert the belt clip.

How to use the device with the power supply adapter

- Connect the applicator to KORA OXER.
- Place the applicator on the part of the body to be treated and secure it with the elastic band supplied.
- Connect the power supply to KORA OXER (the POWER LED starts flashing green).
- Switch on the KORA OXER by pressing the central 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 KORA OXER without having first inserted the battery, the device will beep and the chosen programme 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 KORA OXER.
- Place the applicator on the part of the body to be treated and secure it with the elastic band supplied.
- Switch on the KORA OXER by pressing the central 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 TREATMENTS - THERAPEUTIC INDICATIONS

Pathologies of the carpus

Programme H, at least 30 minutes per session.

Pathologies of the superficial and deep flexor tendon

Programme L, at least 30 minutes per session.

Pathologies of the suspensory and collateral ligament, extensor branches and extensor carpi radialis

Programme L, at least 30 minutes per session.

Treatment examples for the anterior and posterior suspensory ligament

NB: Should the elastic band slip down the horse's leg, you can use a shin pad (first picture) or use the longer elastic band, placing it above the knee and securing it there.

Pathologies of the fetlock

Programme L, at least 30 minutes per session.

Pathologies of the coronary band and foot

Programme H, at least 30 minutes per session.

TMJ atrophy

Programme L, at least 30 minutes per session.

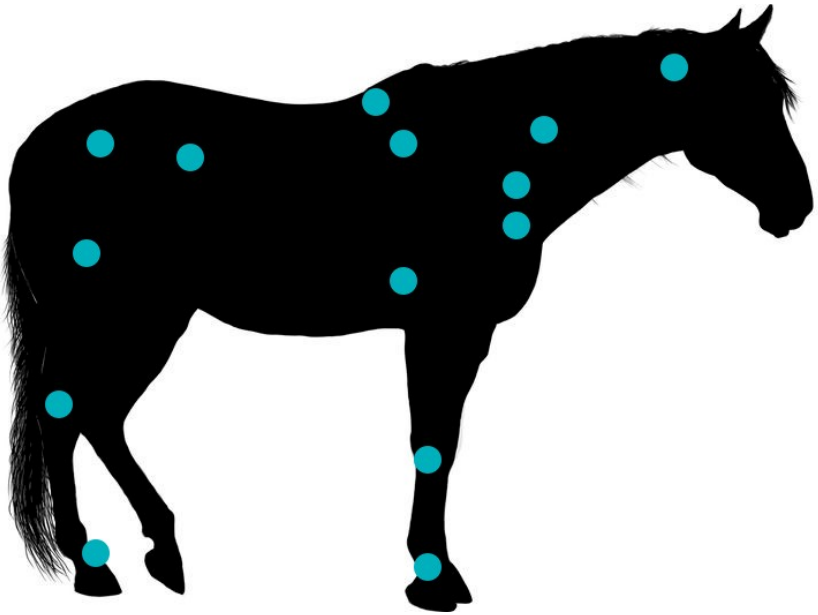
Inflammation of the nuchal ligament - cervicalgia

Programme H, at least 30 minutes per session.

Trigger points

Programme H, at least 30 minutes per session.

The trigger points that can be treated with the device are shown below.



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

ATTENTION: if the applicator is disconnected, the output LED flashes and the device emits 3 consecutive beeps. Check if the applicator and the cable are intact and if the device is connected correctly.

Taking care of the device

Maintenance

If used in accordance with the information reported herein, this device requires no particular routine maintenance operations.
In the event of malfunction, first follow these simple steps:

- make sure that the power outlet to which the device is connected is working properly by connecting another working device;
- check the connection 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.

OPERATION CONTROL

A magnet (white plastic box) is supplied with the device for an indicative function check.

Testing procedure:

1. switch on the device following all the safety instructions provided in this manual;
2. start any therapy, following the instructions for use of this manual;

3. Hold the supplied magnet and bring it close to the applicator;
4. check the vibration of the magnet.

Contact the manufacturer if the magnet does not vibrate.

CLEANING

WARNING: before proceeding with any cleaning work on the device, applicator and other parts, it is recommended to disconnect the device from the mains and remove the battery from the battery compartment (see section 'Charging and replacing the battery').

We recommend removing any traces of dust after each use of the device and its accessories using a soft dry cloth.

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

In the event of prolonged non-use, remove the battery (as indicated in the section on "replacing the battery") and clean the device and its accessories as indicated above, place them in the transport bag and store them in the packaging box.

For cleaning the applicator, it is recommended to disconnect the applicator from the device before performing any operation.

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

TRANSPORT AND STORAGE

Transport precautions

There is no special care to be taken during transport as KORA OXER is a portable device.

The permissible environmental conditions are as follows.

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

Storage and transport precautions

The storage location should have the following characteristics:

Without the packaging provided

room temperature	from +5 to +40 °C
relative humidity	from 30 to 85%
pressure	from 700 to 1060 hPa

With the package provided

room temperature	From -5 to 40 °C
relative humidity	from 10 to 93%
pressure	from 700 to 1060 hPa

Troubleshooting

Battery charging

To recharge the device, proceed as follows:

- connect the battery charger to the mains;
- Connect the battery charger plug to the device.

The POWER LED will flash green until it switches off (charging completed). During charging, it is still possible to use the device for therapy, in which case the POWER LED will be steady green.

Replacing the battery

To replace the battery, proceed as follows:

- Disconnect the device from the charger;
- remove the belt clip by sliding it downwards;
- Open the battery compartment by acting on the sealing hook;
- remove the battery;
- insert the new battery (use only original spare parts supplied by the manufacturer);
- close the battery compartment;
- reinsert the belt clip.

Proceed with a full charge of the device as indicated above.

Information for disposal

The KORA OXER magnetotherapy device has been designed and manufactured to have a minimal negative impact on the environment, in accordance with European Directive 2012/19/EU on the disposal of waste electrical and electronic equipment.

This symbol indicates that this product should not be disposed with other household waste.

The user must dispose of the equipment to be scrapped by taking it to the collection centre indicated for the subsequent recycling of electrical and electronic equipment.
For more detailed information on the disposal of obsolete equipment, contact your local council, waste disposal service or shop where you purchased the product.

Warranty

KORA OXER is covered by a 2-year warranty from the date of purchase on electrical and electronic parts. The warranty does not cover parts subject to normal wear and tear (e.g. piston rings) and all parts that are defective due to negligence or carelessness in use, incorrect maintenance or in the event of tampering with the appliance and intervention on it by personnel not authorised by the manufacturer or authorised dealer.
The warranty terms and conditions are those described under “Warranty terms and conditions”.
The warranty is provided ex IACER S.r.l. registered office.
In the event of a service work covered by warranty, the equipment must be packaged so as to avoid damage during transport and sent to the manufacturer together with all accessories. In order to be entitled to make a warranty claim, the purchaser must send the product together with the receipt or invoice proving the origin of the product and the date of purchase.

Guarantee

1. Any warranty claim must be accompanied by the receipt or invoice, that will be sent together with the goods to the manufacturer.
2. The warranty period is 2 years (two) and covers the electronic parts of the device. The warranty claim can be addressed to the dealer from which you have purchased the device or directly to the manufacturer.
3. The warranty covers exclusively product damage causing a malfunction.
4. The term “warranty” means exclusively the repair or replacement of components or parts of the equipment that show manufacturing or material defects, including the labour.

5. The warranty does not apply to damages caused by negligence or use that does not comply with the instructions provided, damages caused by unauthorised interventions, accidental damage or damages due to buyer's negligence, with particular reference to the external parts.
6. The warranty also does not apply to damage caused to the device by unsuitable power supply units.
7. The parts subject to wear are not covered by warranty.
8. The warranty does not cover transport costs, that shall be borne by the buyer, depending on the means and time of transport.
9. After two years, the warranty expires. In this case, the service will be performed by charging the replaced parts, labour and transport expenses according to the fees in force.
10. Any disputes that may arise shall be settled exclusively before the court of Venice.

Support

The manufacturer is the only point of contact for technical support regarding the device. Should you need technical support, please contact:

I.A.C.E.R. S.r.l.
Via Enzo Ferrari, 2 • 30037 Scorzè (VE)
Ph. 041.5401356 • Fax 041.5402684

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

Spare parts

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

I.A.C.E.R. S.r.l.
Via Enzo Ferrari, 2 • 30037 Scorzè (VE)
Ph. 041.5401356 • Fax 041.5402684

In order to preserve the warranty, guarantee operation and safety of the product, it is recommended to only use original spare parts supplied by the manufacturer (also see the *Warnings* paragraph).

Electromagnetic interference and EMC tables

The KORA OXER magnetotherapy device is designed and manufactured in accordance with the current ELECTROMAGNETIC COMPATIBILITY TECHNICAL STANDARD EN 60601-1-2:2015, with the aim of providing reasonable protection from harmful interference in residential civil and healthcare installations.

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

In particular, wireless communication devices such as wireless network devices, mobile telephones, cordless telephones and their respective base stations, walkie-talkies, can affect the medical device and must be kept at least at a distance "d" calculated by the manufacturer in the 800MHz-2.5GHz column of the table "ELECTROMAGNETIC IMMUNITY - FOR EQUIPMENT AND SYSTEMS NOT SUPPORTING VITAL FUNCTIONS" under EMC Tables. For example, for a mobile phone with a maximum output power of 2W, a distance d=3.3m must be observed for an immunity level of 3V/m or a distance d=0.5m for an immunity level of 20V/m.

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

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

The device should not be used near or superimposed on other equipment and, if it must be used near or superimposed on other equipment, it should be observed to check normal operation in the configuration in which it is used

ELECTROMAGNETIC COMPATIBILITY TABLES

Guidance and manufacturer's declaration - ELECTROMAGNETIC EMISSIONS - FOR ALL EQUIPMENT AND SYSTEMS
KORA OXER is intended to operate in the electromagnetic environment specified below. The customer or user of KORA OXER must ensure that it is used in such an environment.

Emission test	Conformity	Electromagnetic environment - Guide
RF Emissions CISPR 11	Group 1	KORA OXER uses RF energy only for its internal operation. Therefore, its RF emissions are very low and are unlikely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	KORA OXER is suitable for use in all premises including domestic premises and those directly connected to a low-voltage public mains supply that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Emissions of voltage fluctuations/flickers IEC 61000-3-3	Conform	

Guidance and manufacturer's declaration - ELECTROMAGNETIC IMMUNITY - FOR ALL EQUIPMENT AND SYSTEMS			
KORA OXER is intended to operate in the electromagnetic environment specified below. The customer or user of KORA OXER must ensure that it is used in such an environment.			
Immunity test	**Test level IEC 60601**	**Compliance level**	**Electromagnetic environment - Guide**
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV; +8kV contact ±8kV; +15kV in air	±6kV; ±8kV; contact ±8kV; +15kV in air	Floors should be made of wood, concrete or ceramic. If the floors are covered with synthetic materials, 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	The mains voltage quality should be that of a typical commercial or hospital environment.
Overvoltages IEC 61000-4-5	±1kV line to line	±1kV line to line	The mains voltage quality should be 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% hole in U_T) for 0.5 cycles <5% U_T (>95% hole in U_T) for 1 cycle 70% U_T (30% hole in U_T) for 25 cycles	<5% U_T (>95% hole in U_T) for 0.5 cycles <5% U_T (>95% hole in U_T) for 1 cycle 70% U_T (30% hole in U_T) for 25 cycles	The mains voltage quality should be that of a typical commercial or hospital environment. If the KORA OXER user requires continuous operation even during mains power failure, it is recommended to power the KORA OXER with an uninterruptible power supply (UPS) or batteries.

Guidance and manufacturer's declaration - ELECTROMAGNETIC IMMUNITY - FOR ALL EQUIPMENT AND SYSTEMS			
KORA OXER is intended to operate in the electromagnetic environment specified below. The customer or user of KORA OXER must ensure that it is used in such an environment.			
Immunity test	**Test level IEC 60601**	**Compliance level**	**Electromagnetic environment - Guide**
	<5% U_T (>95% hole in U_T) per 5s	<5% U_T (>95% hole in U_T) per 5s	
Magnetic field at mains frequency (50/60 Hz) IEC 61000-4-8	30A/m	30A/m	Mains frequency magnetic fields should have levels characteristic of a typical location in a commercial or hospital environment.
Note: U_T is the AC mains voltage before application of the test level.			

Guidance and manufacturer's declaration - ELECTROMAGNETIC IMMUNITY - FOR EQUIPMENT AND SYSTEMS NOT SUPPORTING VITAL FUNCTIONS			
KORA OXER is intended to operate in the electromagnetic environment specified below. The customer or user of KORA OXER must guarantee that it is used in such an environment.			
Immunity test	**Test level IEC 60601**	**Compliance level**	**Electromagnetic environment - Guide**
Portable and mobile RF communication equipment should not be used near any part of the KORA OXER, including cables, except when the recommended separation distances, calculated from the equation applicable to the frequency of the transmitter, are met.			
			Recommended separation distance
Conducted RF IEC 61000-4-6	$3V_{eff}$ 150 kHz - 80 MHz $6V_{eff}$ from 150 kHz to 80 MHz for ISM band	$3V_{eff}$ ([V_1] V) $6V_{eff}$ ([V_1] V)	$d = \left[\frac{3,5}{V_1}\right]\sqrt{P} = d = \left[\frac{12}{V_1}\right]\sqrt{P}$ for ISM band
Radiated RF IEC 61000-4-3	10V/m from 80 MHz to 2.7 GHz	10V/m [E_1] V/m	$d = \left[\frac{12}{E_1}\right]\sqrt{P}$ from 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ from 800 MHz to 2.7 GHz
Radiated RF for radio communication devices IEC 61000-4-3	3 V/m from 80 MHz to 6 GHz	3V/m [E_1] V/m	$d = \left[\frac{6}{E_1}\right]\sqrt{P}$ from 80 MHz to 6 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 metres (m). The field strengths of fixed RF transmitters, as determined by an electromagnetic survey[a] of the site could be lower than the compliance level in each frequency range[b] Interference could occur in the vicinity of devices marked with the following symbol: 			
Note: (1) At 80 MHz and 800 MHz; the higher frequency range applies			

Guidance and manufacturer's declaration - ELECTROMAGNETIC IMMUNITY - FOR EQUIPMENT AND SYSTEMS NOT SUPPORTING VITAL FUNCTIONS	
(2)	These guidelines may not apply in all situations. Electromagnetic propagation is subject to absorption and reflection by structures, objects and people
a)	Field strengths from fixed transmitters, such as base stations for radio (mobile/cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. In order to assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the field strength measured in the place where KORA OXER is used exceeds the applicable compliance level above, the normal operation of KORA OXER should be observed. If abnormal performance is noticed, additional measures such as a different orientation or position of the KORA OXER may be necessary.
b)	The field strength in the frequency range from 150 kHz to 80 MHz should be less than [V_1] V/m.

Recommended separation distances between portable and mobile radiocommunication devices for the MAG2000 family that are not life-supporting

KORA OXER is designed to operate in an electromagnetic environment where radiated RF interference is under control. The customer or operator of KORA OXER can help prevent electromagnetic interference by ensuring a minimum distance between mobile and portable RF communication equipment (transmitters) and KORA OXER as recommended below, in relation to the maximum output power of the radio communication equipment.

Maximum specified output power of the transmitter (W)	**Separation distance at the transmitter frequency (m)**			
	$from\ 150kHz\ to\ 80\ MHz$	$from\ 150kHz\ to\ 800\ MHz$ (ISM band)	$from\ 80MHz\ to\ 800\ MHz$	$da\ 800MHz\ a\ 6\ GHz$ (to radio frequency wireless 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 p.m.	20	12.00 p.m.	23.00

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

Note

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