USER MANUAL

MNPG396-00 Edition 22/11/21

I.A.C.E.R. Srl

www.koratherapy.com

Summary

Magnetotherapy

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

Magnetotherapy uses low frequency and high intensity pulsed magnetic fields induced by the electric current that runs through a coil; due to its characteristics it is now universally recognised as the most suitable technique for the treatment of bone conditions and in particular for osteoporosis.

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

According to the experiences of several authors, in cases of osteoporosis, already starting from the sixth treatment session there is a remarkable regression of pain symptoms and even more striking is that a significant increase in BMD (Bone Mass Density) is noted. The high magnetic field flux value (Gauss) generated by the device allows the treatment of the patient even in the presence of braces or plaster casts.

KORA

Technical specification

Manufacturer

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

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

Declaration of conformity

Kora device assumes the following classifications:

- *Device with IP21 degree of protection against the penetration of solid objects, powders and liquids.*
- *Device and accessories supplied non-sterile and not subject to sterilisation;*
- *Device not suitable for use in the presence of a flammable anaesthetic mixture with air, with nitrous oxide, with any flammable agent of any kind and in environments with a high concentration of oxygen;*
- *Device intended for continuous operation;*
- *Device not suitable for external use.*

Intended purpose and scope of use

Clinical purpose: *Therapeutic*

Scope of use: *Outpatient Clinic/Hospital and home*

Kora is designed and indicated for the treatment, rehabilitation and functional recovery of conditions concerning:

- *Tendons*
- *Cartilage*

- *Ligaments*

Kora is particularly indicated for the treatment of delayed union, osteoporosis, bone oedema, osteonecrosis, as well as ulcers and neuropathies.

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

In accordance with guidelines for medical devices, the manufacturer suggests a check of the efficiency and safety of the device every 24 months. Useful life of the device and its accessories (period after which it is suggested to send the device to the manufacturer):3 years

Technical characteristics

Power supply	*Pow. UES36LCP1-150200SPA, out 15VDC-2A*
Max. current consumption	*1 A*
Insulation class (CEI EN 60601-1)	*II*
Applied part (CEI EN 60601-1)	*BF*
Dimensions (length x width x height)(mm)	*180x110x50*
Intensity of the field	*Adjustable with increasing scale up to 150 Gauss (per channel).*
Frequency of the square wave	*1-75 Hz*
Therapy time	*User-settable*

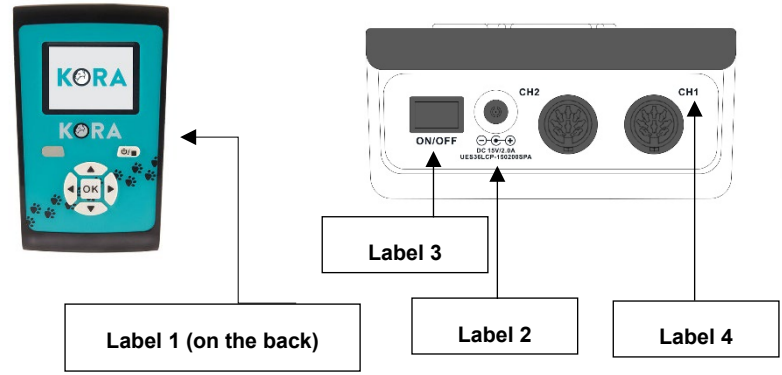
The maximum magnetic field intensity is 100 Gauss per channel.

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

Ambient operating conditions:

temperature	*from +5 to + 30°C*
relative humidity	*from 15 to 93%*
pressure	*from 700 to 1060 hPa*

Labelling



Device labels in detail

Label 1

Label 2

DC 15V/2.0A

Label 3

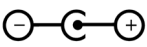
ON/OFF

Label 4

CH1 CH2

UES36LCP1-150200SPA

Description of the symbols (device and packaging)

	Follow the "instructions for use"
	Waste disposal (WEEE Directive)
	Class II device
	Applied part type BF
	CE conformity
	Date of manufacture (month/year)
	Serial number
	Temperatures permitted
	Relative humidity
	Manufacturer's data
IP21	Degree of protection against the entry of solids, powders and liquids
	Center positive symbol

Contents of the pack

Kora pack contains:

- *N°1 Kora device;*

- *N°1 medical power supply (approx 1.5mt cable);*
- *N°1 Use and maintenance manual;*
- *N°1 Kora-Mat (pillow applicator);*
- *Magnet for verifying therapy operation*

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

How to use the device

Warnings

*It is recommended to read this manual carefully before using the device. For any further information and details we advise you to visit our website **www.koratherapy.com** .*
Nevertheless, please follow the following instructions:

- *Check the location and meaning of all labels affixed to the device;*
- *Do not damage the applicator by acting on the connecting wire, also avoid winding the wire around the applicator or around the device;*
- *Check the integrity of the power supply each time it is used. Avoid use in the case of signs of damage to the casing or to the connecting wire;*
- *People who are not properly trained and who have not read this manual must not use the device;*

- *Avoid using the device while using ointments containing free ions of magnetisable metals;*
- *Avoid using the device in humid environments and/or in the presence of flammable agents;*
- *During therapy, the user and the patient are advised not to wear metal objects;*
- *Position Kora-Mat pillow in such a way that the logo is in contact with the patient.*
- *Use only cables and applicators supplied by the Manufacturer. Inadequate cables and applicators could damage the device and/or cause harm to the patient;*
- *The user must periodically check the insulation (integrity) of the applicators and their cables and check that they are not damaged (contacting the manufacturer if needed);*
- *The user must pay attention when using the connecting cables of the belt and the power supply: strangulation risk.*
- *The materials used for producing the device exceed the required standards regarding material toxicity. In case of allergic reactions, discontinue therapy and consult a doctor.*
- *Do not connect the device and its accessories to other devices not indicated in this manual.*
- *Keep out of the reach of children.*
- *Avoid exposing the device and its accessories to excessive direct light and dust. Refer to the indications in the paragraph "How to look after the device";*
- *Do not damage the device and its applicators.*

CAUTION. Disconnect the power supply from the wall socket at the end of the therapy session.

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

- *any additions, modifications and/or repairs are carried out by personnel authorised directly by the manufacturer.*
- *the electrical system of the environment in which Kora is inserted complies with national laws.*
- *the devices are used in strict compliance with the instructions reported in this manual.*

Electromagnetic interference

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

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

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

The device should not be used near or placed on top of other equipment and, if it is necessary to use it near or placed on top of other equipment, it should be observed to check normal operation in the configuration in which it is used.

Contraindications and side effects

Pregnant patients, viral diseases (in the acute phase), 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 veterinarians).

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

Quick use of the device with preset parameters

To start using *Kora* quickly and easily, we recommend that you follow the steps below:

1. Connect the applicator (or applicators) to the device by connecting the plug of the applicator cable to one of the two ports (CH1-CH2) on the panel at the top of the appliance;
2. Connect the mains cable to the power supply and then connect the power supply outlet to the circular connector on the panel at the top of the appliance, near the ON/OFF switch:
3. Connect the plug of the mains cable to the mains socket (100-240VAC, 50-60 Hz);
4. Press the ON/OFF switch on the small panel on the upper part so it is in the ON position: the display will show the KORA logo and then the main menu screen; for quick standard use, now select the first item "Single patient" by pressing the "OK" button.
5. Scroll through the program using the buttons ▲ and ▼ select the desired program.
6. Press OK. The display will show **the basic setting time of the therapy (2 hours) and magnetic field intensity. These are the average values suggested by IACER to immediately start the treatment effectively.**

7. Press the OK button. The device will start the treatment, displaying the magnet icon with the magnetic field flux. The green light below the display notifies the therapy is underway.
8. At the end of the therapy, the device will automatically return to the program menu screen.

Note: it is possible to temporarily suspend therapy at any time by pressing the OK button. To resume therapy, press the OK button again. During the pause phase the green LED goes off, and then comes back on when the therapy is restarted.

Note: it is possible to exit the treatment at any time by pressing the ⏻ / ■ button once: the device will go back to the screen of the selected programme (point 6). By pressing the ⏻ / ■ button again the device will go back to the initial screen of the program menu (point 5).

Note: the device recognises if the applicators are connected correctly. During the therapy phase, the connection status is displayed below the magnet icon. The presence of the symbol ✓ next to the channel number (1 or 2) confirms the applicator is connected correctly and recognised.The **X** symbol next to the channel number (1 or 2) tells you that the applicator is not connected correctly, missing or not working correctly (see paragraph "Checking device operation").

List of stored programs

PROGRAMMES		
1. Analgesic	7. Healing	13. Osteonecrosis
2. Arthritis	8. Ligament lesion	14. Osteoporosis
3. Arthrosis	9. Tendon lesion	15. Treat. 1 Hz
4. Muscular atrophy	10. Sciatic nerve	16. Treat. 18 Hz
5. Discopathy	11. Neuropathy	17. Treat. 50 Hz
6. Fractures	12. Prostheses	18. Treat. 75 Hz

Analgesic: program to mitigate inflammatory and painful conditions. Also useful in cases of recovery after surgery.

Arthritis: program designed to reduce pain and slow down the degenerative process..

Arthrosis: program designed to reduce pain and slow down the degenerative process.

Muscular Atrophy: program designed to stimulate muscle tissues.

Discopathy: specific program for the treatment of diseases against the vertebral discs, with regard to bone and cartilage tissues, also useful in post-surgery.

Fractures: specific program for the stimulation of bone regeneration in a post-traumatic condition.

Healing: specific program for increasing circulation and reducing the damaged area.

Ligament lesion: program designed for post-surgery recovery.

Tendon lesion: program designed for post-surgery recovery

Sciatic nerve: specific program to obtain an antalgic effect in favor of the sciatic nerve.

Neuropathy: specific program to obtain an analgesic and anti-inflammatory effect on the peripheral nerves.

Prosthesis: specific program to promote osseointegration with the implanted prosthesis.

Osteonecrosis: specific program for the stimulation of bone tissue in cases of osteonecrosis, in order to counter the progress of the disease and alleviate pain.

Osteoporosis: specific program for stimulating bone regeneration.

The therapy duration values are those recommended by IACER S.r.l. and can be altered by the user. Kora magnetotherapy device incorporates the indications regarding magnetic field, frequency of therapy and power delivered that are found in scientific and medical literature.
It is suggested to leave the device on connected to the mattress for very long periods of time (even 10-12 hours) in case the animal often moves from the applicator. In this way, adequate effective treatment time can be guaranteed.

Last 10

This mode allows direct access to the last 10 therapies used by the user. From the main menu, press ▶ until "Last 10" is selected, then press OK. Choose the therapy from those listed by pressing the ▲ and ▼ buttons followed by OK.

Settings (language selection)

Press the ON/OFF switch located on the small panel in the upper part so it is in the ON position. After Kora logo appears, press ▶ and select the "Settings" menu. At this point select "Language" and use the ◀ and ▶ buttons to select the desired language.

N.B.: to turn off the device, press the ON/OFF switch on the back or press the ⏻/■ button until the screen turns off.

Settings (factory reset)

Press the ON/OFF switch located on the small panel in the upper part so it is in the ON position. After Kora logo appears, press ▶ and select the "Settings" menu. At this point select the factory reset option and insert the code “18273”. The values associated with the therapeutic protocols have been restored to their original condition.

How to look after the device

Checking device operation

A magnet (small ring or disc in metal or metal/plastic) is supplied with the appliance to check device operation.

Procedure for checking:

1. *switch on the device following all the safety instructions provided in this manual;*
2. *start any therapy, following the instructions for use of this manual;*
3. *hold the supplied magnet and bring it closer to the applicator;*
4. *check that the magnet vibrates (proportional to the frequency of the selected therapy).*

Contact the manufacturer if the magnet fails to vibrate.

Cleaning the device

Use a soft dry cloth to remove any dust from the device.

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

For cleaning the pillow case it is recommended to disconnect the applicator from the device before performing any operation. At this point, once the zip is opened, it is recommended to remove the internal mattress. Wash the pillowcase in the washing machine at a maximum of 40 C.

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

Transport and storage

Transport precautions

There is no particular care to be taken during transport as Kora is a portable device.

It is recommended to store Kora and Kora-Mat pillow in the original box after each use.

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

Storage precautions

The storage location should have the following characteristics:

ambient temperature	*from +5° to +40°C.*
relative humidity	*from 15 to 93%*
pressure	*from 700 to 1060 hPa*

Disposal

The product is subject to the WEEE regulation (the symbol is present on the label  *) concerning separate collection: to dispose of the product, make use of special areas equipped to collect electronic material by*

EMC Tables

Emission aspects		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions Cispr 11	Group 1	Kora product uses RF energy only for its internal operation. Therefore, its RF emissions are very low and not likely to cause interference in nearby electronic equipment.
RF emissions Cispr 11	Class B	Kora is suitable for use in all buildings in addition to domestic ones and those directly connected to a low-voltage power supply network that supplies buildings for domestic use The device can be used in all buildings, including domestic buildings, and those directly connected to the public low-voltage power supply network that supplies buildings for domestic use.
Harmonic emissions IEC 61000-3-2	Class A Complies	The device can be used in all buildings, including domestic buildings, and those directly connected to the public low-voltage power supply network that supplies buildings for domestic use.
Voltage fluctuations and flicker IEC 61000-3-3	Complies	

Immunity aspects			
Kora is intended to work in the electromagnetic environment specified below.The customer or user should make sure that it is used in such environment			
Immunity test	**Test level EN 60601-1-2**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) EN 61000-4-2	± 8kV contact ± 15kV air	± 8kV contact ± 15kV air	Floors should be wood, concrete or ceramic tile.If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst EN 61000-4-4	±2kV power supply lines	±2kV power supply lines	Mains power quality should be that of a typical business or hospital environment.
Impulses EN 61000-4-5	±1kV differential mode	±1kV differential mode	Mains power quality should be that of a typical business or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	0% $_{UT}$ for 0.5 cycles, different angles 0% U_T for 1 cycle 70% U_T for 25/30 cycles 0% U_T for 5 seconds	0% U_T for 0.5 cycles, different angles 0% U_T for 1 cycle 70% $_{UT}$ for 25/30 cycles 0% U_T for 5 seconds	Mains power quality should be that of a typical business or hospital environment. If the user requires continuous operation even during the interruption of the mains voltage, it is recommended to power the device with an uninterruptible power supply (UPS) or with batteries.
Magnetic field at mains frequency EN 61000-4-8	30 A/m	30 A/m	The magnetic fields at mains frequency should be at levels typical of a business or hospital environment.

RF immunity aspects			
Kora is intended to work in the electromagnetic environment specified below. The customer or user should make sure that it is used in such environment			
Immunity test	**Test level EN 60601-1-2**	**Compliance level**	**Electromagnetic environment - guidance**
Immunity to conducted disturbances induced by radio-frequency fields EN 61000-4-6	3 Veff. 150kHz to 80MHz	3 Veff. 150kHz to 80MHz	Portable and mobile RF communications equipment should not be used near any part of the equipment, including cables, except when respecting the recommended separation distances calculated from the equation applicable to the transmitter frequency
Radiated RF EN 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	Recommended separation distances $d = 1.2 \cdot \sqrt{P}$ 150kHz to 80MHz $d = 0.35 \cdot \sqrt{P}$ 80 MHz to 800 MHz $d = 0.7 \cdot \sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
The field strength from fixed RF transmitters, as determined by an electromagnetic site survey, may be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 			

Recommended separation distance between portable and mobile radio communication devices and Kora device

Kora is intended to operate in an electromagnetic environment in which RF irradiated disturbances are controlled. The customer or the operator of the device can help prevent electromagnetic interference by ensuring a minimum distance between mobile and portable RF communications devices (transmitters) and the device, as recommended below, in relation to the maximum output power of the radio communication devices.

Maximum rated output power of the transmitter (W)	**Separation distance to the frequency of the transmitter (m)**		
	150kHz to 80MHz $d = 1.2 \cdot \sqrt{P}$	**80MHz to 800MHz** $d = 0.35 \cdot \sqrt{P}$	**800MHz to 2.7GHz** $d = 0.7 \cdot \sqrt{P}$
0.01	0.12	0,04	0,07
0.1	0.38	0,11	0,22
1	1.2	0,35	0,7
10	3.8	1,1	2,2
100	12	3,5	7,0

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

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

Warranty

Kora is covered by a 2 year warranty starting from the date of purchase on the electrical and electronic parts. The parts subject to normal wear and tear are not covered by the warranty (fabric case of applicators as well as velcro elastic closure of the same) and all parts that may be defective due to negligence or neglect of use, incorrect maintenance or in case of tampering with the device and intervention on the same by personnel not authorized by the manufacturer or authorized dealer. The warranty conditions are those described in the following paragraph "Warranty conditions".

In the event of subsequent warranty intervention, the equipment must be packaged so as to avoid damage during transport and sent to the manufacturer together with all accessories. To be eligible for warranty work, the purchase must send the appliance with the receipt or invoice proving the correct origin of the product and the date of purchase.

Warranty conditions

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