

Pulsed ElectroMagnetic Field Therapy



9K-N915
User Manual

WHAT'S INCLUDED IN THE BOX

Control unit
Medical grade MAINS power cord
20cm diameter double loop treatment coil
30cm diameter single loop treatment coil
User Manual
Warranty Registration Card

DEVICE SPECIFICATIONS

Voltage input: 120 VAC, 60Hz
Current input: per device
Dimensions: per device
Weight: per device
Shipping weight: per device

INDICATIONS FOR USE

Temporarily reduces pain and inflammation, and temporarily improves range of motion of the area treated.

DESCRIPTION

This device has a treatment coil connected to a control unit which generates pulsed electromagnetic fields (PEMF). The treatment coil transfers the therapeutic PEMF to the body in five different intensity levels. Clinical research has demonstrated that this device is safe for use to treat inflamed and painful areas of the body when used according to the "Directions for Use" in this manual.

FREQUENCY OF USE

There are 4 different treatment cycles: 5 min., 10 min., 15 min. and 20 minutes.

On the first use, the recommended treatment is one 5 min. cycle per area treated. Thereafter, the treatment duration can be increased and different areas can be treated during a treatment cycle.

Additional treatments of the same area on the same day are not hazardous but do not offer additional therapeutic benefits.

CONTRAINDICATIONS

DO NOT USE:

- If you are, or may be pregnant,
- If you are receiving chemotherapy,
- If you have cancer or malignant tumors,
- If you have had surgery in the past 24 hours,
- If you have hemorrhagic tendencies, Purpura or Hemophilia,
- If you have major metabolic diseases uncontrolled by medication (HIV, ulcers, seizures...),
- Within 25cm of pacemakers, defibrillators or any other implanted electronic devices,
- Within 25cm of metallic implants (stents, pins, rods, or screws),
- Soon after taking any medication as their effects may be intensified.

Consult your health care provider to discuss using the device if you think you are at risk for any of these contraindications.

PRECAUTIONS

Dangerous Voltage inside, DO NOT tamper with or open the control unit.

DO NOT USE the device near credit cards, security access cards, car keys, hearing aids, watches, cell phones, IPODS, laptops, remote controls, or any other electronic media. The electromagnetic fields may disrupt their functioning and/or demagnetize them.

DO NOT USE while operating any machinery or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.

DO NOT USE in wet environments. Do not immerse any part of or pour any liquids on the device.

Keep away from sources of heat and moisture.

Keep the device out of the reach of children! Children may be at risk of strangulation with the power cord and/or treatment coil pigtails and risk asphyxiation with the packing materials.

Users with heart conditions should consult their physician before using the device.

Users with suspected or diagnosed epilepsy should consult their physician before using the device.

Do not place the treatment coil over a suture line within 3 days after surgery.

Users taking pain, anxiety, depression or any other medication should be carefully monitored when using the device as medication effectiveness may be intensified.

Applying directly over the menstruating uterus may cause increased bleeding.

Do not apply at high intensity over areas of the skin or body that lack normal sensation.

Users with low blood pressure may feel temporarily dizzy when first standing up after treatment.

Metal objects, jewelry and metal chains will heat with prolonged exposure to pulsed electromagnetic fields. Use the device for one 5-minute treatment cycle followed by a five minute pause within 25cm of any implanted metal objects before treating again.

ADVERSE REACTIONS

There are no known negative side effects, or reported adverse or allergic reactions with the use of this device.

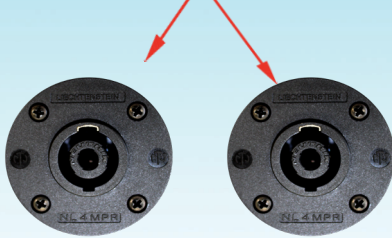
Detoxification may occur, drink plenty of water after treatment.

Overuse may cause muscle soreness.

In case of any adverse reaction, stop using the device and consult a physician.

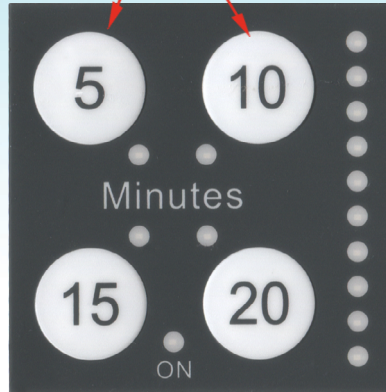
USER CONTROLS AND SYMBOLS

Pair of coil connector sockets allow one treatment coil to be safely and securely locked into place.



Intensity Dial: always set at lowest setting before beginning treatment. Increase to a comfortable level after treatment begins.

Preset 5, 10, 15 or 20 minutes pushbuttons; press one to begin a treatment. Blue lights illuminate when a cycle begins and turn off incrementally during treatment. All blue lights turn off with a beep at the end of the treatment.



MAINS socket to plug in the medical grade power cord.



The MAINS power rocker switch turns the device on "I" and off "O".

DEFINITION OF SYMBOLS, LABELS AND MARKINGS



Read the entire User Manual BEFORE using the device



Medical Device



Type B Applied Parts



Type II Equipment



Non-ionizing Radiation



MAINS Power ON



MAINS Power OFF



Catalogue or Reference Number



Serial Number



Manufacturer's Identification
with Date of Manufacture

DIRECTIONS FOR USE

Treatment Cycle

A treatment cycle lasts 5, 10, 15 or 20 minutes. Press the desired pushbutton to begin a treatment. The treatment intensity may be set to a comfortable level for each area treated using the intensity dial. Set the intensity at its lowest level before beginning any treatment and increase the intensity until the desired level is reached after treatment begins.

Getting Started

Connect the power cord into the MAINS socket on the front of the device.

Always lock a treatment coil connector into the two connector sockets on the front of the device before turning the MAINS power switch on "I". The device will not start if the treatment coil is not properly connected.

Inserting/Changing a Treatment Coil

To connect a treatment coil, push one of its connectors with the silver tab up into one of the coil connector sockets on the front of the device and rotate it clockwise until it clicks. Repeat with the other connector into the other socket. The treatment coil is then locked into place. To remove the treatment coil, slide the silver tab of each connector back and turn the connector counter-clockwise, then pull it out.

Do not plug or unplug the treatment coil during an active treatment cycle.

Beginning Treatment

Press the MAINS power rocker switch to "I" to turn the device on.

Place a treatment coil on or around the desired treatment area. The closer the coil is to the treatment area, the more effective the treatment will be. Users can remain fully clothed and no direct contact between the coil and the skin is necessary for the treatment to be effective.

Before starting any treatment on any area, set the intensity level to the lowest level. Press the 5, 10, 15 or 20 min. pushbutton to begin a treatment. Increase the intensity to a comfortable level after treatment begins. Blue lights will turn on then off incrementally. All lights turn off with a long beep at the end of the treatment.

Press a 5, 10, 15 or 20 min. pushbutton again to begin another treatment cycle.

Pausing/Resetting/Ending the Treatment

During the treatment cycle, briefly press the active treatment pushbutton to pause the treatment. The corresponding pushbutton blue light flashes continuously while in "pause mode". To resume the treatment cycle, briefly press the same pushbutton again.

To end the treatment cycle prior to completion, press and hold the active treatment pushbutton until you hear a single long beep and all the blue lights turn off.

FOOT



ANKLE



ANKLE



KNEE



KNEE



KNEE



KNEE



ELBOW



ELBOW



HAND & WRIST



NECK



NECK



SHOULDER



SHOULDER



CHEST & SHOULDER



ABDOMEN



CHEST



UPPER BACK



MID BACK



MID TO LOW BACK



MID TO LOW BACK



LOW BACK



HIPS



HIPS



TROUBLESHOOTING

If the device fails to function after following the instructions detailed in the “Directions for Use” on page 4, use the following troubleshooting steps:

If there are beeping sounds:

Proceed to identify the beep sequence the device emits:

- ***Single two second beep*** = End of session

Solution: Press a start pushbutton to begin a new treatment.

- ***Three short beeps & one long beep*** = The coil is not connected properly or was disconnected while the device was in use

Solution: Connect the coil properly following the instructions on page 4 and press a start pushbutton to begin a treatment.

- ***Two short beeps three times followed by one long beep*** = Device overheating

Solution: Allow the device to cool down for 10 minutes by leaving the power on while no treatment is activated. The cooling fan will cool the device. Press a start pushbutton to begin a treatment after the 10 minutes have elapsed.

If the lights do not illuminate and there are no beeping sounds:

- Make sure the MAINS power cord is properly connected at the control unit and a MAINS outlet.
- Make sure the MAINS outlet is functional. Try plugging another electrical appliance into the MAINS outlet to determine if it works. If the outlet works, test the device with another MAINS power cord.

If the device still fails to start or function properly, contact the manufacturer, listed on page 12 to get a Return Merchandise Authorization (RMA) number. Disconnect the coil and the power cord. Package the device securely and return it to the manufacturer for servicing with the RMA number and your contact information.

MAINTENANCE

Service

The device has no user serviceable parts and must be returned to the manufacturer for servicing.

Treatment coils, mats and MAINS power cords are available from the manufacturer.

The device is a sealed unit and lint, dust, light, including sunlight, etc. have no effects on it.

Dangerous Voltage inside; DO NOT remove the cover or tamper with the device.

REMOVING THE COVER OR TAMPERING WITH THE DEVICE VOIDS THE WARRANTY.

Contact the distributor for assistance in setting up, using or maintaining the device.

Disposal

This device is an electronic device. Electronics should never be disposed of with regular trash. Take non-working electronics to an electronics recycling center.

Cleaning

There is no mandatory or scheduled cleaning, maintenance or sterilizing necessary.

If you choose to clean the device:

- Disconnect the device from the MAINS before cleaning,
- DO NOT immerse any part or pour any liquids on the device.

STORAGE & TRANSPORTATION


Keep the device dry and store in a dry place. Storage in a damp place may cause corrosion.

Store and transport at temperatures between 5° to 50°C at a relative humidity of up to 93% non-condensing.

Remove the MAINS power cord and the detachable treatment coils from the control unit and pack all parts of the device securely before transporting.

ELECTROMAGNETIC IMMUNITY EMI

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment - Guidance |
|--|---|---|---|
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±6 kV contact ±8 kV air | ±6 kV contact ±8 kV 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 IEC 61000-4-4 | ±2kV for power supply lines ±1 kV for input/output lines | ±2kV for power supply lines N/A - No Input/Output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ±1 kV differential mode ±2 kV common mode | ±1 kV differential mode ±2 kV common mode | Mains power 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% dip in U _T) for 0.5 cycle 40% U _T (60% dip in U _T) for 5 cycles 70% U _T (30% dip in U _T) for 25 cycles <5% U _T (>95% dip in U _T) for 5 sec | <5% U _T (>95% dip in U _T) for 0.5 cycle 40% U _T (60% dip in U _T) for 5 cycles 70% U _T (30% dip in U _T) for 25 cycles <5% U _T (>95% dip in U _T) for 5 sec | Mains power quality should be that of a typical commercial or hospital environment. If the user of the PEMF Family Group requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment - Guidance |
|-------------------------------|-----------------------------|------------------|--|
| | | | Portable and mobile RF communications equipment should be used no closer to any part of the PEMF Family Group, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. |
| | | | Recommended separation distance: |
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz | 3 Vrms | $d = \frac{[3.5]\sqrt{P}}{V_i}$ |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | 3 V/m | $d = \frac{[3.5]\sqrt{P}}{E_i}$ 80 MHz to 800 MHz $d = \frac{[7]\sqrt{P}}{E_i}$ 800 MHz to 2.5 GHz |
| | | | where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> 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:  |

ELECTROMAGNETIC EMISSIONS EMC

| Emission Tests | Compliance | Electromagnetic Environment - Guidance |
|--|------------|---|
| RF emissions CISPR 11 | Group 1 | The PEMF Family Group 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 A | The PEMF Family Group is suitable for use in all establishments, other than domestic, 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 | Complies | |

SEPARATION DISTANCES FROM PORTABLE AND MOBILE RF EQUIPMENT

| Rated Maximum Output Power of Transmitter W | Separation Distance According to Frequency of Transmitter m | | |
|--|--|---------------------------------|-------------------------------|
| | 150 kHz to 80 MHz | 80 MHz to 800 MHz | 800 MHz to 2.5 GHz |
| | $d = \frac{[3.5]\sqrt{P}}{V_i}$ | $d = \frac{[3.5]\sqrt{P}}{E_i}$ | $d = \frac{[7]\sqrt{P}}{E_i}$ |
| 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 |

WARRANTY

The Warranty Registration Card must be filled out and returned to the manufacturer within 30 days of the date of purchase to activate the warranty.

The manufacturer warrants this device to operate properly for a period of three years from the date of the original purchase invoice. In the event of a malfunction during the warranty period, the manufacturer will, at its discretion, replace or repair the device to its original operating condition. Freight and insurance to and from the manufacturer's repair facility are not included. Freight and Insurance are the responsibility of the registered owner.

A Return Material Authorization (RMA) number must be obtained from the manufacturer prior to returning any device or accessory for service. The device must be delivered with prepaid freight, the RMA provided, the registered owner's name and address, and a brief description of the difficulties encountered. The device is to be shipped to the address designated by the manufacturer.

Such service, repair or adjustment of the device is guaranteed to the original purchaser provided the device has not been tampered with, does not have any physically broken parts and the control unit was not opened, altered or damaged as a result of misuse, accident, water, grit, impact, or lack of proper care.



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