

# *Pulsed ElectroMagnetic Field Therapy*



**800-HDE**  
**User Manual**

## **WHAT'S INCLUDED**

- 800-HDE PEMF generator Control unit
- Medical grade MAINS power cord
- Instructions For Use
- Warranty Registration Card
- Selected treatment coil(s).

Options are:

single and/ or double loop and/or  
paddle and/ or mat

## **CONTROL UNIT SPECIFICATIONS**

- Magnetic flux density: 15 Gauss to 900 Gauss
- Frequency range: 10 Hz, 7.83 Hz and gradually to .5 Hz
- Voltage input: 110 VAC or 240 VAC
- Current input: 1 Amp maximum
- Control unit dimensions: 4.75" x 27.9" x 2.75"  
12 x 20 x 7 cm
- Assembly weight: 0.8 kg/ 1.76 Lbs
- Shipping weight: 2.5 kg/ 5.5 Lbs including attachments

## **INDICATIONS FOR USE**

The 800-HDE delivers pulsed electro-magnetic field ("PEMF") therapy to the human body. The magnetic stimulation increases blood circulation and helps relax muscle spasms. Unless contraindicated on page 6 herein, typical treatment areas include large muscle groups (arm, thigh, buttocks, abdomen, back...) and bones and joints (elbow, ankle, shoulder, hip, knee...).

## **DESCRIPTION**

The 800-HDE is a non-contact, non-invasive, PEMF generator comprised of a control unit and a treatment coil(s) used to provide a pulsed magnetic stimulation of nerves, bones and muscles. The magnetic induction field is applied with a treatment coil outside clothing. There are no electrodes and no direct contact with the patient. The control unit is sealed (no user serviceable parts or user access) and stationary (it is not worn or carried). The PEMF generator uses standard household electrical current. There are three user-operated controls located on the control unit: a standard power rocker switch, a push button membrane switch with a choice of treatment duration (either 5 or 10 or 30 minutes) and an intensity selector to either increase the pulse intensity (signified by the up arrow) or decrease the pulse intensity (signified by the down arrow).

The treatment coil tubing, paddle and mat covers are manufactured from silicone and other materials that meet USP Class VI biocompatibility requirements, demonstrating acceptable biological safety. The material is suitable for patient skin contact.

## **FREQUENCY OF USE**

Recommended for adult use. There are three different treatment duration settings: 5 min. or 10 min. or 30 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.

## AVAILABLE TREATMENT COILS



### **SMALL MAT**

12" x 22" / 22cm x 56cm

**Pigtail length:**

- 6 ft./ 1m83



### **LARGE MAT**

18" x 23" / 46cm x 58cm

**Pigtail lengths:**

- 6 ft./ 1m83

- 12 ft./ 3m66 Equine



### **DOUBLE LOOP**

**Options:**

|                      |                |
|----------------------|----------------|
| Loop diameter        | Lead lengths:  |
| - 9" / 23cm standard | - 6 ft./ 1m83  |
| - 7" / 18cm custom   | - 12 ft./ 3m66 |
| - 24" / 61cm Equine  | Equine         |
| - 18" / 46cm custom  |                |



### **SINGLE LOOP**

**Options:**

|                 |                |
|-----------------|----------------|
| Loop diameter:  | Lead length:   |
| - 14" / 35.5cm- | - 6 ft./ 1m83  |
| - 24" / 61cm    | - 12 ft./ 3m66 |
|                 | Equine         |



### **PADDLE**

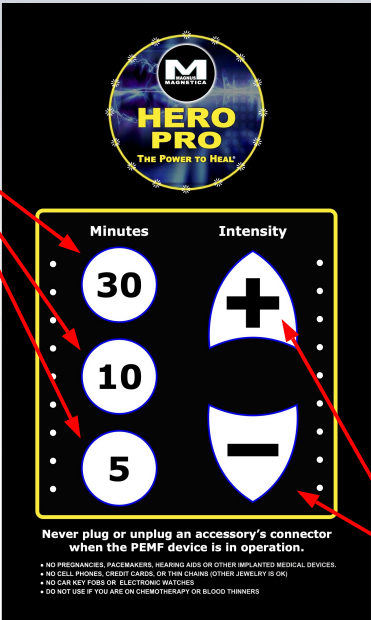
6.5" / 16.5cm diameter

**Lead lengths:**

- 6 ft./ 1m83  
- 12 ft./ 3m66 Equine

# USER CONTROLS AND SYMBOLS

Press the 5 or 10 or 30 minutes pushbuttons to begin a treatment. The left blue lights will turn on with a blue light nearest to the selected treatment time. The left blue lights will turn off incrementally as time elapses. All lights turn off & the control unit beeps 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".



Coil Connector socket. Plug in the desired coil before turning the control unit on.

After selecting a 5 or 10 or 30 minutes treatment, increase the intensity using the pushbuttons with up and down arrows; press + (plus) to increase or - (minus) to decrease the intensity to one of the five preset intensity levels. One to nine blue lights will illuminate.

## DEFINITION OF SYMBOLS, LABELS AND MARKINGS



Read the entire User Manual BEFORE using the device



Medical Device



Type BF Applied Parts



Type II Equipment



Non-ionizing Radiation

IP21 IP rating



Dangerous Voltage



MAINS Power ON



MAINS Power OFF



Catalogue or Reference Number



Serial Number



20XX-XX

Date of Manufacture

## **DIRECTIONS FOR USE**

### **Pulsed Magnetic Stimulation Cycle**

A pulsed magnetic stimulation treatment cycle lasts 5 min. or 10 min. or 30 min. Press the desired pushbutton to begin the pulsed magnetic stimulation. Each treatment cycle may be set at one of nine intensity levels by pressing the plus or minus buttons.

### **Getting Started**

Plug the supplied power cord into the MAINS socket of the PEMF generator and into a UL Listed surge protector with an output light indicator, a low clamping voltage, a 1000+ Joules rating and a 15 Am breaker. Plug the surge protector into a MAINS outlet and turn on. The output light indicator must be on to safely use the PEMF generator.

Always lock a treatment coil connector into the connector socket on the front of the control unit before turning the MAINS power switch on the control unit on "I". The PEMF generator will not start if the treatment coil is not properly connected.

### **Selection of Treatment Frequency**

The lowest setting offers 10 Hz or pulses per second.

The next setting matches the Earth frequency of 7.83 Hz, also referred to as the Schumann frequency.

The highest setting is .5 Hz.

The settings in between offer intermediate frequencies in increments from 7.83 Hz to .5 Hz.

### **Inserting/Changing a Treatment Coil**

To connect a treatment coil, align the arrow on the coil connector with the arrow of the connector socket on the control unit. Push the connector into the socket until you hear a "click". The treatment coil is now locked into place.

To remove the treatment coil, turn the end of the coil connector to the left (counterclockwise) to disengage and pull it out.

DO NOT plug or unplug the treatment coil during an active treatment cycle.

### **Beginning Pulsed Magnetic Stimulation**

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

Press the 5 min. or 10 min. or 30 min. pushbutton to begin the desired pulsed magnetic stimulation. Set the desired intensity level from one to five using the plus and minus buttons. A corresponding number of blue lights will illuminate. The blue lights will turn off and the PEMF generator will emit a single long beep when the cycle ends.

Push the plus or minus button to select the desired intensity. One to nine blue lights will illuminate accordingly. Press a 5 min. or 10 min. or 30 min. pushbutton again to begin another treatment cycle.

### **Pausing/Resetting/Ending the Treatment Cycle**

During the treatment cycle, briefly press the active pushbutton to pause the pulsed magnetic stimulation. The corresponding blue lights flash continuously while in “pause mode”. To resume the cycle, briefly press the same pushbutton again.

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

## **CONTRAINDICATIONS**

DO NOT USE pulsed magnetic stimulation:

- If you are or may be pregnant,
- If you are receiving chemotherapy.
- If you have cancer, cancerous lesions, 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...),
- With cardiac demand 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 PEMF generator if you think you are at risk for any of these contraindications.

## **WARNINGS**

- Pulsed magnetic stimulation should not be applied directly over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
- Strong pulsed magnetic stimulation should not be applied over the heart as it may cause cardiac arrhythmias.
- Strong pulsed magnetic stimulation should not be applied over the mouth. Severe spasms of the laryngeal and pharyngeal muscles may occur, and the contractions may be strong enough to close the airway or cause difficulty in breathing.
- Strong pulsed magnetic stimulation should not be applied trans cerebrally.
- Strong pulsed magnetic stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g.: phlebitis, thrombophlebitis, varicose veins, etc.

## **GENERAL SAFETY**

- ALWAYS use a UL Listed surge protector with the PEMF generator. The surge protector must have an output light indicator, a low clamping voltage, a 1000+ Joules rating and a 15 Amp breaker. The output light indicator must be on to safely use the PEMF generator.
- Dangerous voltage is present inside the PEMF generator, DO NOT try to open the control unit or tamper with or make any modification to the PEMF generator.
- DO NOT position the PEMF generator where it would be difficult to access the ON/OFF switch.
- DO NOT USE the PEMF generator near credit cards, security access cards, car keys, hearing aids, watches, cell phones, iPods, laptops, remote controls, or any other electronic media. The pulsed electro magnetic 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 PEMF generator. Keep away from sources of heat and moisture.
- PEMF generators, cables and packing materials should be kept out of the reach of children. Children may be at risk of strangulation with the power cord and the treatment coil pigtails or risk of asphyxiation with the packing materials.
- Metal objects, jewelry and metal chains will heat with prolonged exposure to pulsed electromagnetic fields. Use the PEMF generator for 5 minutes followed by a five-minute pause within 25 cm of any implanted metal objects before treating again.

## **PRECAUTIONS**

- The 800-HDE series control units can only be used with the treatment coils made by the manufacturer for this model. Select a single coil, a double coil, a paddle and/or a mat.
- Safety for use of these PEMF generators during pregnancy has not been established.
- Caution should be used for patients with suspected or diagnosed heart problems.
- Caution should be used for patients with suspected or diagnosed epilepsy.
- Caution should be used in the presence of the following:
  - When there is a tendency to hemorrhage following acute trauma or fracture,
  - Following recent surgical procedures as muscle contraction may disrupt the healing process,
  - Over the menstruating or pregnant uterus, and
  - Over areas of the skin which lack normal sensation.
- Do not place the treatment coil over a suture line within 3 days after surgery.
- Caution when applying the coil attachment as it may reach up to 44°C during treatment.
- Treatment coil placement and pulsed magnetic stimulation settings should be based on the guidance of the prescribing practitioner.
- Users with low blood pressure may feel temporarily dizzy when first standing up after pulsed magnetic stimulation.
- Users taking pain, anxiety, depression, or any other medication should be carefully monitored when using the PEMF generator as medication impact may be intensified.
- Drink plenty of water after pulsed magnetic stimulation as detoxication may occur,
- Avoid using on areas that have no skin sensitivity. Overuse may cause muscle soreness.
- In the event of any adverse effects, stop using the PEMF generator and consult a physician.

## **COIL POSITIONS**

The following coil positions are indicatives. Different types of coil attachments are available and many more positions can be explored according to individual needs when following the Instructions for Use.

Output intensity may need to be adjusted to a comfortable level for each area treated.

For best results, it is recommended to move the attachment to a different position or angle every five minutes.

**CHEST & NECK**



**NECK**



**ABDOMEN**



**KNEE**



**ANKLE**



**ELBOW**



**SHOULDER**



**ARM**



**UPPER BACK**



**MID BACK**



**LOWER BACK**



**HIP**



# ELECTROMAGNETIC IMMUNITY EMI

| Immunity Test                                                                                          | IEC 60601 Test Level                                                                                                                                                                              | Compliance Level                                                                                                                                                                                  | Electromagnetic Environment - Guidance                                                                                                                                                                                                                                                  |
|--------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Electrostatic discharge (ESD)<br>IEC 61000-4-2                                                         | ±6 kV contact<br>±8 kV air                                                                                                                                                                        | ±6 kV contact<br>±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<br>IEC 61000-4-4                                                       | ±2kV for power supply lines<br>±1 kV for input/output lines                                                                                                                                       | ±2kV for power supply lines<br>N/A - No Input/Output lines                                                                                                                                        | Mains power quality should be that of a typical commercial or hospital environment.                                                                                                                                                                                                     |
| Surge<br>IEC 61000-4-5                                                                                 | ±1 kV differential mode<br>±2 kV common mode                                                                                                                                                      | ±1 kV differential mode<br>±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<br>IEC 61000-4-11 | <5% $U_T$<br>(>95% dip in $U_T$ ) for 0.5 cycle<br>40% $U_T$<br>(60% dip in $U_T$ ) for 5 cycles<br>70% $U_T$<br>(30% dip in $U_T$ ) for 25 cycles<br><5% $U_T$<br>(>95% dip in $U_T$ ) for 5 sec | <5% $U_T$<br>(>95% dip in $U_T$ ) for 0.5 cycle<br>40% $U_T$<br>(60% dip in $U_T$ ) for 5 cycles<br>70% $U_T$<br>(30% dip in $U_T$ ) for 25 cycles<br><5% $U_T$<br>(>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<br>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.                                                                                                                                                                                                                                                                                                       |
|                               |                             |                  | <b>Recommended separation distance:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Conducted RF<br>IEC 61000-4-6 | 3 Vrms<br>150 kHz to 80 MHz | 3 Vrms           | $d = \frac{[3.5]}{V_i} \sqrt{P}$                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Radiated RF<br>IEC 61000-4-3  | 3 V/m<br>80 MHz to 2.5 GHz  | 3 V/m            | $d = \frac{[3.5]}{E_i} \sqrt{P}$ 80 MHz to 800 MHz<br><br>$d = \frac{[7]}{E_i} \sqrt{P}$ 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>a</sup> , should be less than the compliance level in each frequency range <sup>b</sup> . Interference may occur in the vicinity of equipment marked with the following symbol:<br> |

## ELECTROMAGNETIC EMISSIONS EMC

| Emission Tests                                             | Compliance | Electromagnetic Environment - Guidance                                                                                                                                                                                |
|------------------------------------------------------------|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| RF emissions<br>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<br>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<br>IEC 61000-3-2                        | Class A    |                                                                                                                                                                                                                       |
| Voltage fluctuations/Flicker<br>Emissions<br>IEC 61000-3-3 | Complies   |                                                                                                                                                                                                                       |

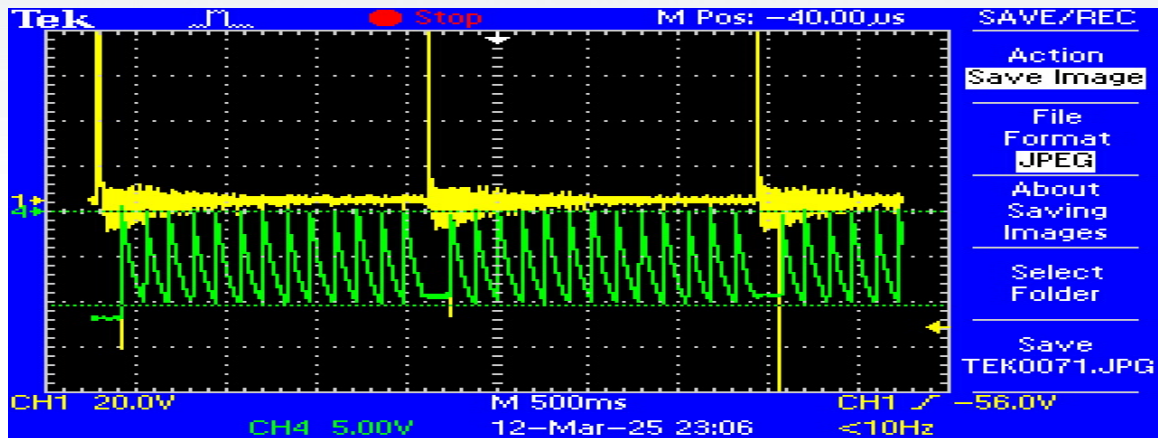
## SEPARATION DISTANCES FROM PORTABLE AND MOBILE RF EQUIPMENT

| Rated Maximum Output Power of<br>Transmitter<br><br><b>W</b> | Separation Distance According to Frequency of Transmitter<br>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                            |

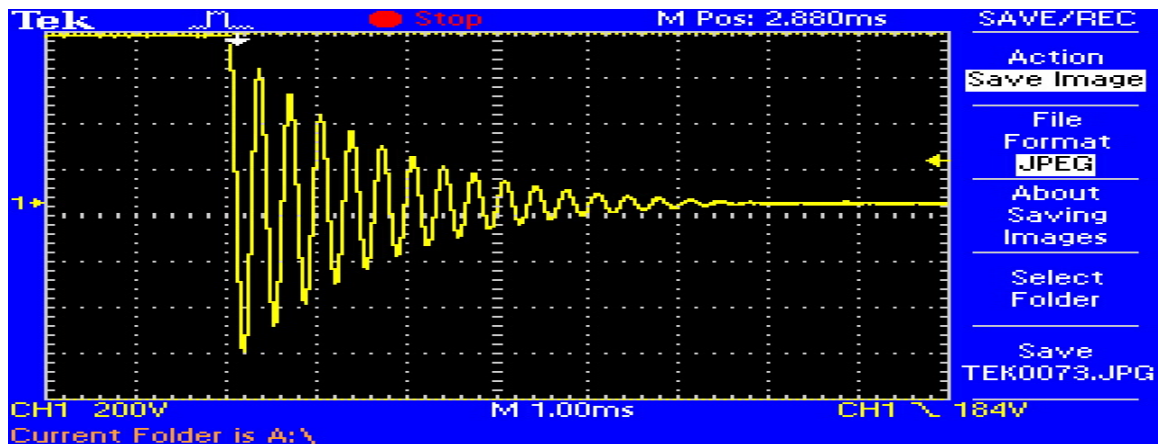
## TECHNICAL DATA

The 800-HDE is an Electro-Magnetic pulsed therapy device that has three timer settings for 5 and 10 and 30 minute sessions. Depending on what application the device is used for, a variety of output (patient) coils are available. Our technology runs two different devices simultaneously, a high power device with selectable treatment intensity and a low power device with the Earth frequency. The system has 9 preset intensity levels and a low power output that runs in the back- ground simultaneously with the higher power settings. This low power output pulses at a 7.83 Hz frequency, also known as the Schumann Resonance, which is a natural electromagnetic frequency of the Earth. Proponents suggest that the earth frequency can promote relaxation, improve sleep, and enhance overall well-being when used as therapy. As can be seen in Figure 1, both the higher power pulses in yellow running off the vertical scale and the lower power back-ground frequency of 7.83hz in green are simultaneous outputs generated by the 800-HDE.

Figure1



As can be seen on Figure 2, the higher power pulse decaying oscillation extends the treatment time per pulse



## **MAINTENANCE**

### **Service**

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

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

Dangerous Voltage inside; DO NOT tamper with the PEMF generator or remove the cover of the control unit.

REMOVING THE COVER OR TAMPERING WITH THE PEMF GENERATOR VOIDS THE WARRANTY.

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

### **Disposal**

This PEMF generator is an electronic device. Electronics should never be disposed of with regular trash.

Take non-working electronics to an electronics recycling center.

### **Cleaning**

The PEMF generator has a sealed control unit and lint, dust, dirt, etc. have no effects on it.

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

If you choose to clean the PEMF generator, control unit and/or treatment coils:

- Disconnect the control unit from the MAINS before cleaning,
- DO NOT immerse any part or pour any liquids on the PEMF generator,
- Use a damp cloth with a mild soap solution to clean the treatment coils.

## **STORAGE & TRANSPORTATION**

Keep the PEMF generator dry and store it in a dry place. Storage in a damp place may cause corrosion.

Store and transport at temperatures between 5°C to 40°C with atmospheric pressure of 70kPa to 106kPa and 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 PEMF generator securely before transporting.

## **TROUBLESHOOTING**

If the PEMF generator 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 PEMF generator emits:

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

Solution: Press a start pushbutton to begin a new pulsed magnetic stimulation cycle.

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

Solution: Connect the coil properly following the instructions on page 4 and press a start pushbutton to begin a pulsed magnetic stimulation cycle.

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

Solution: Allow the PEMF generator to cool down for 10 minutes by leaving the power on while no treatment is activated. The cooling fan will cool the PEMF generator. Press a start pushbutton to begin the pulsed magnetic stimulation 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 at the UL Listed surge protector.
- Make sure the surge protector is properly plugged into a MAINS outlet. Make sure the MAINS outlet is functional. Try plugging another electrical appliance into the outlet and the surge protector to determine if they work.
- If all the connections work, test the device with another MAINS power cord.

If the PEMF generator still fails to start or function properly, contact the manufacturer, listed on page 15 to get a Return Merchandise Authorization (RMA) number. Disconnect the coil and the power cord. Package the PEMF generator securely and return it to the manufacturer for servicing with the RMA number and your contact information.

## **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 PEMF generator 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 PEMF generator 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 PEMF generator or accessory for service. The PEMF generator 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 PEMF generator is to be shipped to the address designated by the manufacturer.

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

### **CONTACT INFORMATION:**

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