

Pulsed ElectroMagnetic Field Therapy



800-HDE
User Manual

WHAT'S INCLUDED

- 800-HDE PEMF generator Control unit
- Medical grade MAINS power cord
- User Manual
- Warranty Registration Card
- Selected Treatment Coils

CONTROL UNIT SPECIFICATIONS

- Voltage input: 110 VAC or 230VAC
- Current input: 0.5 Amp maximum
- Dimensions: 12 x 34 x 6.5 cm
- Assembly weight: 3.6 kg
- Shipping weight: 5.5 kg

INDICATIONS FOR USE

The 800-HDE is to be used as an adjunct therapy for the:

- Relaxation of muscle spasms
- Prevention or retardation of disuse muscle atrophy
- Increasing local blood circulation
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Muscle re-education, and
- Maintaining or increasing range of motion.

DESCRIPTION

The 800-HDE is a non-contact, non-invasive, pulsed electro-magnetic field (“PEMF”) generator comprised of a control unit and a treatment coil(s) used to provide a pulsed magnetic stimulation of nerves and muscles. 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 30 or 60 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).

Your shipment comes with the PEMF generator you ordered, the 800-HDE, and the treatment coils you selected.

FREQUENCY OF USE

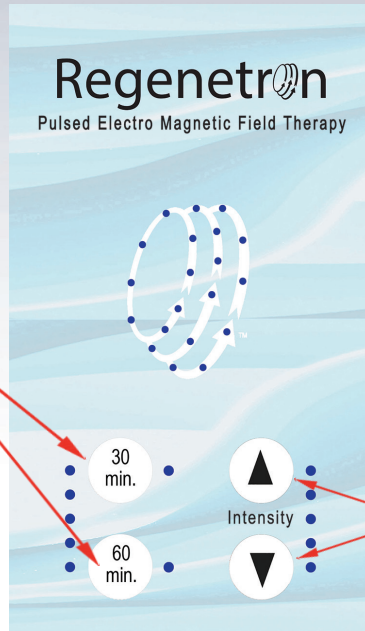
There are two different treatment duration: 30 min. or 60 minutes.

On the first use, the recommended treatment is one 30 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.

USER CONTROLS AND SYMBOLS

Press the 30 or 60 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 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".

After selecting a 30 or 60 minutes treatment, increase the intensity using the pushbuttons with up and down arrows; press ▲ to increase or ▼ to decrease the intensity to one of the five preset intensity levels. One to five blue lights will illuminate.

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



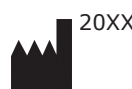
MAINS Power OFF



Catalogue or Reference Number



Serial Number



Manufacturer's Identification
with Date of Manufacture

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.

PRECAUTIONS

- Safety of PEMF generators for use 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.
- 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.
- The 1200 series control units should be used only with the treatment coils recommended for use by the manufacturer.
- Users taking pain, anxiety, depression, or any other medication should be carefully monitored when using the PEMF generator as medication effectiveness may be intensified.
- Detoxication may occur, drink plenty of water after pulsed magnetic stimulation.
- Overuse may cause muscle soreness.
- In the event of any adverse effects, stop using the PEMF generator and consult a physician.

DIRECTIONS FOR USE

Pulsed Magnetic Stimulation Cycle

A pulsed magnetic stimulation cycle lasts 30 min. or 60 min. Press the desired pushbutton to begin the pulsed magnetic stimulation. Each treatment cycle may be set at one of five intensity levels by pressing the up and down arrows.

Getting Started

Plug the enclosed power cord into the MAINS socket on the back of the PEMF generator control unit and into the MAINS on the other end.

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

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 30 min. or 60 min. pushbutton to begin the desired pulsed magnetic stimulation. Set the desired intensity level from one to five using the up and down arrows. 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 up or down arrow to select the desired intensity. One to nine blue lights will illuminate accordingly.

Press a 5 min. or 10 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 light flashes 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.

WARNINGS

- Pulsed magnetic stimulation should not be applied 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 neck or 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 the enclosed surge protector that has an output light indicator with the PEMF generator. The output light indicator must be on to safely use the PEMF generator. If the output light indicator is out, replace the surge protector with another that also has an output light indicator and low clamping voltage, 1000+ Joules rating and a 15 Amp breaker.
- Dangerous voltage is present inside the PEMF generator, DO NOT tamper with the PEMF generator or try to open the control unit.
- 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 pigtailed 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 one 5-minute treatment cycle followed by a five-minute pause within 25cm of any implanted metal objects before treating again.

TROUBLESHOOTING

If the PEMF generator fails to function after following the instructions detailed in the “Directions for Use” on page 6, 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 9 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 PEMF generator control unit and a MAINS outlet.
- Make sure the MAINS outlet is functional. Try plugging another electrical appliance into the outlet to determine if it works. If the outlet works, test the PEMF generator with another MAINS power cord.

If the PEMF generator still fails to start or function properly, contact the manufacturer, listed on page 16 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.

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 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 ^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

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° 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 PEMF generator securely before transporting.

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.



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