iSoothe™
WIRELESS RECHARGEABLE TENS

- Rechargeable Battery
- 20 Minute Treatment Timer
- 5 Preset Modes
- 15 Intensity Levels
- Auto Shut-Off

User Manual

INV-942R
This manual is applicable to the iSoothe Wireless Rechargeable TENS INV-942R.

This instruction manual is published by Innovo Groups. 

Innovo Groups reserves the right to update this manual at any time without prior notice. Amendments may however be published in new editions of this manual.

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Conformity to safety standards

Innovo Groups declares that the device complies with the following normative documents: ISO13485
CMDCAS, ISO9001 CERT, ISO13485 UKAS

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How does TENS work?
Scientific theory suggests that electrical stimulation therapy may work in several ways:

- The gentle electrical pulses block the "pain message" from the nerves from reaching the brain.
- The gentle electrical pulses induce an increase in the productions of endorphins, the body’s natural pain killer.

What conditions can TENS help relieve?
TENS provides pain relief for a number of different pain conditions associated with exercise, daily work and household activities. This product is designed for the temporary relief of muscle, joint and bone pain in the:

- Neck
- Waist
- Shoulder
- Upper Extremities (arms)
- Back
- Lower Extremities (leg)

The pain reliever should be applied to normal, healthy, clean and dry skin of adult patients.

What can I treat?
The TENS device can be used to manage many different types of pain. Please refer to the diagrams on page 21 for the ideal locations to place the gel pads for the treatment of the most common forms of pain. For other areas of pain, place the gel pads on either side of the pain area.

PLEASE NOTE: Never place the gel pads on the head, throat, face, heart, chest area, eyes, oral cavity, sexual organs or over the spine or bony areas.

How long can I use the Wireless TENS unit?
We recommend that you use the TENS unit for an average of 20 minutes a day for each area of treatment. For longer duration, please seek medical advice. If you exceed the recommended time, please check your skin where the gel pads have been placed to ensure that your skin does not become sore.

PLEASE NOTE: The gel pads are designed for temporary use. It should last for approximately 10 days when used for 20 minutes a day if stored & used as directed.

Package Contents:
- 1 x TENS Device
- 2 x Gel pads
- 1 x Wall Charger
- 1 x User manual
- 1 x Plastic Case
- 1 x USB Cable
- 1 x Carry Bag
**SAFETY SYMBOLS USED IN THIS MANUAL**

- Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
- Indicates a potentially hazardous situation which, if not avoided, could result in serious injury and equipment damage.
- Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user, or damage to the device or other property.

**IMPORTANT SAFETY PRECAUTIONS AND WARNINGS**

It is important that you read all the warnings and precautions included in this manual because they are intended to keep you safe, prevent injury and avoid a situation that could damage the device.

**DANGER**

This stimulator must not be used in combination with the following medical devices:

- Internally transplanted electronic medical devices, such as pacemakers.
- Electronic life-support equipment, such as respirators.
- Electronic medical devices attached to the body, such as electrocardiographs.

Using this stimulator with other electronic medical devices may cause erroneous operation of those devices.

**WARNING**

Consult with your physician before using this device. The device may cause lethal rhythm disturbances in certain susceptible individuals.

**DO NOT USE THIS DEVICE UNDER THESE CONDITIONS:**

- If you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.
- Together with a life-supporting medical electronic device such as an artificial heart, lung or respirator.
- In the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when the electrical stimulation device is in use.

**DO NOT USE ON THESE INDIVIDUALS:**

- Pregnant women, because the safety of electrical stimulation during pregnancy has not been established.
- Children or infants, because the device has not been evaluated for pediatric use.
- People incapable of expressing their thoughts or intentions.

- On open wounds or rashes, over swollen, red, infected, inflamed areas, or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins); or on top of, or in proximity to, cancerous lesions.
- Over areas of skin that lack normal sensation.
- On the opposite sides of your head since the effects of stimulation of the brain are unknown.
DO NOT USE THIS DEVICE DURING THESE ACTIVITIES:
- Bathing or showering;
- Sleeping;
- Driving, operating machinery or any activity in which electrical stimulation can put you at risk for injury.

PAIN MANAGEMENT WARNINGS
- If you have prior medical or physical treatment for your pain, consult with your physician before using this device.
- If your pain does not improve, becomes seriously chronic or severe, or continues for more than five days, stop using the device and consult with your physician.
- Pain is an indicator that you might be ill. Therefore, if you are suffering from any serious illness, consult your physician to confirm that you can use the TENS unit.

WARNINGS AND PRECAUTIONS REGARDING THE GEL PADS
- Apply pads only to normal, healthy, clean and dry skin (of adult patients) because it may otherwise disrupt the healing process.
- If you experience any skin irritation or redness after a session, discontinue use immediately.

NEVER APPLY THE PADS TO:
- The head or any area of the face.
- The neck or any area of the throat because this can cause severe muscle spasms resulting in the closure of airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.
- Both sides of the thorax simultaneously (lateral or front and back), or across your chest because the introduction of electrical current may cause rhythm disturbances, which could be lethal.
- The spine or backbone.
- Any metal object, such as a belt buckle, necklace or other jewelry made from metal.

CAUTION WARNINGS AND CAUTIONS REGARDING THE GEL PAD
- Do not bend or fold because it may prevent the pad from functioning properly. Place the pad onto the plastic film and store in the plastic case when not in use.
- Do not apply ointment or any solvent to the pads or your skin because it will prevent the pad from functioning properly.
- The pad is already pre-gelled and will adhere to your skin.
- To avoid damage to the adhesive surface of the pad, put the pad only on clean and dry skin or on the plastic film provided.
- Always place clean pad in accordance with the illustrations provided (Refer to page 21 for electrode placement).
Do not share pad with another person. This may cause skin irritation or infection. Pad is intended for use by one person only.

Do not place or relocate the pad while the device is on.

Always turn the power off before removing or changing the pad location.

Do not leave pad attached to the skin after treatment.

CAUTION WHILE USING THE TENS UNIT

If the TENS unit is not functioning properly or you feel discomfort, stop using the device immediately.

GENERAL PRECAUTIONS

The long-term effects of electrical stimulation are unknown.

Apply stimulation to only normal, intact, clean, dry, and healthy skin.

TENS is not effective in treating the original source or cause of the pain, including headache.

TENS is not a substitute for pain medications and other pain management therapies.

TENS devices do not cure diseases or injuries.

TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a warning mechanism.

Effectiveness is highly individual dependent.

You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel) on the electrodes.

If you are at risk or diagnosed with a heart disease, you should follow precautions recommended by your physician.

If you are at risk or diagnosed with epilepsy, you should follow precautions recommended by your physician.

Use caution if you have a tendency to bleed internally, such as following an injury or fracture.

Consult with your physician prior to using the device after a recent surgical procedure, because stimulation may disrupt the healing process.

This stimulation should not be applied on menstruating or pregnant uterus.

This stimulation should not be applied to areas of skin that lack normal sensation.
Keep unit away from young children. The unit contains small pieces that may be swallowed and may cause choking. Contact your physician immediately if ingested.

Use this device only with iSoothe™ electrodes.

POSSIBLE ADVERSE REACTIONS

- Do not use the device to treat one region for an extended periods of time (more than 20 minutes a session, up to 2 times/day). This may cause exhaustion and soreness to the muscles in the treated region.
- You may experience skin irritation and burns beneath the stimulation electrodes.
- You should stop using the device and consult with your physician if you experience adverse reactions from using the device.

PACKAGE CONTENTS

- Protective Case
- Draw String Carrying Bag
- Instruction manual
- User Manual
- Clinically Proven
- Wireless Rechargeable TENS INV-942R
  - Rechargeable Battery
  - 20 Minute Treatment Timer
  - 5 Preset Modes
  - 15 Intensity Levels
  - Auto Shut-Off
- Power Adapter & USB Cable
- Two (2) Electrode Pads E-946R
  - iSoothe™ Wireless Rechargeable TENS
Know Your Device

Instructions For Use.
1. Battery comes precharged and is ready for use.
2. Battery should be charged by either connecting to a computer via USB or wall charger provided. A red light on the charger means that the device requires charging. Green light means the device is fully charged. When red and green light appears simultaneously, this means that the device is not connected to the charger. If you are charging the device via USB only, please let the device charge for at least 2 hours (as there is no indicator light on the device to show a complete charge). Once fully charged, the battery should last for at least 8 hours (depending on intensity level used).

Battery Information

Instructions For Use.
1. Battery comes precharged and is ready for use.
2. Battery should be charged by either connecting to a computer via USB or wall charger provided. A red light on the charger means that the device requires charging. Green light means the device is fully charged. When red and green light appears simultaneously, this means that the device is not connected to the charger. If you are charging the device via USB only, please let the device charge for at least 2 hours (as there is no indicator light on the device to show a complete charge). Once fully charged, the battery should last for at least 8 hours (depending on intensity level used).

Treatment Information

Instructions For Use
Before use, it is recommended to charge the iSoothe™ device with the enclosed USB Cable/wall charger provided.

Step 1
Cleaning of skin
Clip excess hair from the treatment area. Wash area with soap and water, and dry completely.

Step 2
Standard For Battery Recharge
1. If you feel the stimulation is weak, the LED is dim or the device cannot power on, the battery may need to be recharged.
STEP 3
Preparation of the TENS unit

- Tear open the sealed electrode pad package.
- Peel off the blue plastic film, starting from one side of the enclosed gel electrode pad.

Note: Keep the protective transparent film. You will need to put it on the pad when the pad is not in use.

STEP 4
Placing the TENS unit

- Place the pad on the treatment area (see page 21 for placement suggestions). Press down firmly to ensure full contact with skin.

NOTE: GEL PADS ARE REPLACEABLE.

- iSoothe™ Pain Relief Pad Supply Kit Item #E-946R

STEP 5
Power On

- Press the "O" button to turn the indicator on. The LED will light up and you will hear a beep for one (1) second.

- When turned on, the device will work at Pulse Mode 1 by default.
STEP 6
Changing Modes
- Mode 1 is the default setting when you turn on the device.
- To change the mode, press the “+” button for 3 seconds to select the desired pulse mode (Mode 1 – 5). See chart to the right.
- By pressing the “-” button for 3 seconds you can also select the desired pulse mode in the opposite order.
- When the mode changes, the indicator light will flash twice and the sound will beep twice. See Step 7 for changing the intensity levels.

STEP 7
Changing Intensity Levels
- After mode selection, press the “+” or “-” button to increase or decrease the pulse intensity as desired.

<table>
<thead>
<tr>
<th>MODE</th>
<th>TYPE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Scraping</td>
</tr>
<tr>
<td>2</td>
<td>Massage</td>
</tr>
<tr>
<td>3</td>
<td>Tapping</td>
</tr>
<tr>
<td>4</td>
<td>Acupuncture</td>
</tr>
<tr>
<td>5</td>
<td>Combo</td>
</tr>
</tbody>
</table>

NOTE:
See page 24 for mode details.

STEP 8
Timer
- Once you have found the desired intensity/Mode, the timer will begin.
- The timer counts down from 20 minutes.
- When the timer is up the unit will turn off automatically. The unit can also be turned off by pressing . The light and sound will blink and beep 3 times to indicate that the device is powering down.

NOTE:
To conserve battery and prevent unexpected shock, the device will automatically power off when it is not in use on any treatment area. This is indicated by a single 5 seconds beep with light, followed by 5 beeps & flashes.
TREATMENT INFORMATION (cont.)

PLEASE NOTE:
- Do not move the gel pad to another part of your body without turning off the power.
- Keep the gel pads clean and do not expose to heat or direct sunlight.
- If the gel pads do not adhere to your body or are dirty, replace with a new replacement gel pad (item # E-946R).
- Do not clean the pad or adhesive gels with any chemical.
- Place the gel pads on clean skin only. Do not place on cuts or damaged skin.
- The iSoothe™ is for single person use.
- Place the blue plastic film on the gel pad when not in use.

GEL PAD POSITIONING

NOTE: The illustrations below show 2 suggested treatment sites per body part. However, only one device should be used at a time.
MAINTENANCE AND CAUTIONS

- Do not immerse the iSoothe™ INV-942R in water or any liquid. Do not drop the device or throw it from a height.
- After use, remove the gel pads from the skin and place on the protective transparent film.
- Always use the protective film when the gel pads are not in use.
- Do not use any chemical to clean the device or the gel pads. If you need to clean the unit, please wipe with a damp, lint-free cloth.
- Do not let the gel pads dry out or expose them to direct sunlight.
- Keep the gel pads clean.

STORAGE

- After use, disconnect the gel pads. Store safely and out of the reach of children.
- Store the iSoothe™ INV-942R in a cool, dry place, -14°F – 131°F; 10% – 95% relative humidity.
- Do not expose the gel pads to direct sunlight and protect them against dirt and moisture.
- If the gel pads no longer adhere to your skin or the gel pads are broken, you should replace with new pads.
- The iSoothe™ INV-942R is intended for single patient use. Do not share with others.

TECHNICAL SPECIFICATIONS

<table>
<thead>
<tr>
<th>Type</th>
<th>iSoothe™ Wireless Rechargeable TENS (INV-942R) DC 3.7V Rechargeable Battery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power supply</td>
<td>DC 3.7V Rechargeable Battery</td>
</tr>
<tr>
<td>Wave form</td>
<td>Bi-phase square pulse wave</td>
</tr>
<tr>
<td>Frequency</td>
<td>0 ~ 200Hz</td>
</tr>
<tr>
<td>Pulse width</td>
<td>100 μS</td>
</tr>
<tr>
<td>Intensity</td>
<td>15 Levels</td>
</tr>
<tr>
<td>Mode</td>
<td>5 Modes</td>
</tr>
<tr>
<td>Output voltage</td>
<td>20mA</td>
</tr>
<tr>
<td>Output intensity level</td>
<td>0 ~ 15 levels</td>
</tr>
<tr>
<td>Treatment time</td>
<td>20 minutes</td>
</tr>
<tr>
<td>Operating conditions</td>
<td>14°F–104°F (-10°C ~ 40°C); 30%RH+85%RH</td>
</tr>
<tr>
<td>Storage conditions</td>
<td>14°F–131°F (-10°C ~ 55°C); 10%RH–95%RH</td>
</tr>
<tr>
<td>Size</td>
<td>11.7 (L) x 7.1 (W) x 1.1 (H) cm</td>
</tr>
<tr>
<td>Device Weight</td>
<td>0.04 oz.</td>
</tr>
</tbody>
</table>

NOTE: Design and specifications are subject to change without notice.
**PROGRAM**

The iSoothe™ INV-942R unit is preset with a combination program that delivers three phases of alternating therapy. They are specified as follows:

<table>
<thead>
<tr>
<th>Mode</th>
<th>Frequency</th>
<th>Pulse width</th>
<th>Cycle Time</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>35.7Hz</td>
<td>50 – 100 μS</td>
<td>5 sec. ON 1 sec. OFF</td>
<td>The pulse width changes in a cycle, ranging from 50 – 100 μS at a frequency of 35.7Hz. The cycle time is 6 seconds.</td>
</tr>
<tr>
<td>2</td>
<td>60Hz</td>
<td>50 – 100 μS</td>
<td>2.5 sec. ON 1 sec OFF</td>
<td>The pulse width changes in a cycle, ranging from 50 – 100 μS at a frequency of 60Hz. The cycle time is 3.5 seconds.</td>
</tr>
<tr>
<td>3</td>
<td>6.6Hz</td>
<td>50 – 100 μS</td>
<td>150 mS</td>
<td>The pulse width changes in a cycle, ranging from 50 – 100 μS at a frequency of 6.6Hz. The cycle time is 150 milliseconds.</td>
</tr>
<tr>
<td>4</td>
<td>80Hz</td>
<td>50 – 100 μS</td>
<td>7.5 sec. ON 1 sec. OFF</td>
<td>The pulse width changes in a cycle, ranging from 50 – 100 μS at a frequency of 80Hz. The cycle time is 8.5 seconds.</td>
</tr>
<tr>
<td>5</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Cycles through modes 1 – 4 at 30 second intervals.</td>
</tr>
</tbody>
</table>

**DISPOSAL**

When the battery is dead and will not hold a charge anymore, the unit must be disposed of in a specially-labeled collection container, at toxic waste collection points or through an electrical retailer. You are under legal obligation to dispose of batteries correctly.

Please dispose of the device in accordance with appropriate laws.
# TROUBLESHOOTING

If the unit does not operate after taking these measures, contact your nearest dealer.

<table>
<thead>
<tr>
<th>PROBLEM</th>
<th>POSSIBLE CAUSES</th>
<th>POSSIBLE SOLUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>The unit does not power on</td>
<td>The battery is exhausted</td>
<td>Recharge the battery.</td>
</tr>
<tr>
<td>Stimulation is weak or cannot feel any</td>
<td>Gel pads are dried out or dirty.</td>
<td>Replace with new gel pads.</td>
</tr>
<tr>
<td>Stimulation is uncomfortable</td>
<td>Gel pads cannot adhere to skin properly.</td>
<td>Clean treatment area of dirt and/or oily substances (lotion).</td>
</tr>
<tr>
<td></td>
<td>Battery has a low charge</td>
<td>Recharge the battery.</td>
</tr>
<tr>
<td>The skin becomes red and/or you feel a</td>
<td>Intensity is too high.</td>
<td>Decrease intensity.</td>
</tr>
<tr>
<td>stabbing pain</td>
<td>Device is not operated according to the</td>
<td>Please check the manual before use.</td>
</tr>
<tr>
<td></td>
<td>manual instructions</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Using the gel pad on the same site every</td>
<td>Re-position the gel pad.</td>
</tr>
<tr>
<td></td>
<td>time.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>The gel pad is not sticking onto the skin</td>
<td>Ensure that the gel pad is securely placed on treatment area.</td>
</tr>
<tr>
<td></td>
<td>properly.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>The gel pad is dirty.</td>
<td>Replace with new gel pad.</td>
</tr>
<tr>
<td></td>
<td>The surface of the gel pad is scratched.</td>
<td>Replace with new gel pad.</td>
</tr>
<tr>
<td></td>
<td>If problems persist.</td>
<td>Contact your physician.</td>
</tr>
</tbody>
</table>

---

**IMPORTANT INFORMATION REGARDING ELECTROMAGNETIC COMPATIBILITY (EMC)**

With the increased number of electronic devices such as computers and mobile (cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and create a potentially unsafe situation. Medical devices should also not interfere with other devices.

In order to regulate the requirements for EMC (Electromagnetic Compatibility) with the aim to prevent unsafe product situations, the IEC60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices.

Medical devices manufactured for Innovo Groups conform to this IEC60601-1-2:2007 standard for both immunity and emissions.

Nevertheless, special precautions need to be observed:

- The use of accessories other than those specified by Innovo Groups, may result in increased emission or decreased immunity of the device.
- Refer to the EMC table guidance regarding the EMC environment in which the device should be used.
Soothe™ electrical stimulators are intended for use in the electromagnetic environment specified below. The customer or the user of these electrical stimulators should assure that it is used in such environment.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

**Emissions test**  
Compliance  
Electromagnetic environment - guidance

- **RF emissions CISPR 11**  
  Group 1  
The device 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 CISPR11**  
  Class B  
The device 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**  
  Not applicable

- **Voltage fluctuations/ flicker emissions IEC 61000-3-3**  
  Not applicable

**TABLE 1:**

<table>
<thead>
<tr>
<th>Emission Test</th>
<th>Compliance</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>The device 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.</td>
</tr>
<tr>
<td>RF emissions CISPR11</td>
<td>Class B</td>
<td>The device 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.</td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations/ flicker emissions IEC 61000-3-3</td>
<td>Not applicable</td>
<td></td>
</tr>
</tbody>
</table>

**Guidance and Manufacturer's Declaration – Electromagnetic Immunity**

Soothe™ electrical stimulators are intended for use in the electromagnetic environment specified below. The customer or the user of these electrical stimulators should assure that it is used in such environment.

**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  
  Not applicable
  Not applicable
  Not applicable

- **Surge** 
  IEC 61000-4-5  
  Not applicable
  Not applicable
  Not applicable

- **Voltage dips, short interruptions and voltage variations on power supply input lines** 
  IEC 61000-4-11  
  Not applicable
  Not applicable
  Not applicable

- **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.

**TABLE 2:**

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>±6 kV contact</td>
<td>±8 kV air</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>Electrical fast transient/burst</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Surge</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Voltage dips, short interruptions</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Voltage variations on power supply input lines</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Power frequency (50/60Hz) magnetic field</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>
Soothe™ electrical stimulators are intended for use in the electromagnetic environment specified below. The customer or the user of these electrical stimulators should assure that it is used in such environment.

### Electromagnetic Immunity

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>Not applicable</td>
<td>3 V/m</td>
<td>Portable and mobile RF</td>
</tr>
<tr>
<td>IEC 61000-4-6</td>
<td></td>
<td></td>
<td>Communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>3 V/m 80 MHz to 2.5 GHz</td>
<td></td>
<td>Recommended separation distance</td>
</tr>
<tr>
<td>IEC 61000-4-3</td>
<td></td>
<td></td>
<td>d = 1.2√P</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>d = 1.2√P 80 MHz to 800 MHz</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>d = 2.3√P 800 MHz to 2.5 GHz</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>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).</td>
</tr>
</tbody>
</table>

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

**NOTE 1** At 80 MHz ends 800 MHz, the higher frequency range applies.

**NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

*Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.*
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter (W)</th>
<th>Separation distance according to frequency of transmitter (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 kHz to 80 MHz</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.38</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

Table 4:

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

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Note: EMC tests conducted including attached electrode cord of 1.5 m length.
EXPLANATION OF SYMBOLS

- Applied part of type BF
- Disposal in accordance with Directive 2002/96 EC (WEEE)
- The name and the address of the manufacturer
- Refer to Instruction Manual.

WARRANTY

You will be required to register your product for warranty. Visit our website www.innovogroups.com for more information. You will have to enclose a copy of your receipt. The following warranty terms apply:

1. The warranty period for the device is one year from date of purchase. In case of a warranty claim, the date of purchase has to be proven by means of the sales receipt or invoice.
2. Repairs under warranty do not extend the warranty period either for the device or for the replacement parts.
3. The following is excluded under the warranty:
   - All damage due to improper treatment, e.g. non-observance of the user instruction.
   - All damage due to repairs or tampering by the customer or unauthorized third parties.
   - Damage during transport from the manufacturer to the consumer or during transport to the service center.
   - The battery and gel pads which are subject to normal wear and tear.
4. Liability for direct or indirect consequential losses caused by the unit is excluded even if the damage to the unit is accepted as a warranty claim.
LIMITED ONE YEAR WARRANTY

Limited Consumer Product Warranty (United States)

This Soothe™ Wireless Rechargeable TENS is warranted to the original consumer “the purchaser” to be free from defects in material and workmanship which are not commercially acceptable for the period of one year from the date of purchase. Warranty coverage terminates if you sell or otherwise transfer this product to another person. This warranty gives you specific legal rights and you may also have other rights, which vary by location.

INNOVO GROUPS MAKES NO EXPRESS WARRANTY OF ANY KIND REGARDING THIS PRODUCT OTHER THAN THOSE WARRANTIES SET FORTH HEREIN. ANY IMPLIED WARRANTY, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE TO THE EXTENT PERMITTED BY LAW, SHALL BE LIMITED IN DURATION TO A PERIOD OF 120 DAYS FROM THE DATE OF PURCHASE BY THE ORIGINAL PURCHASER.

In the event that this product is found by INNOVO GROUPS to not meet the above limited warranty, as purchaser’s sole and exclusive remedy, INNOVO GROUPS will repair or at the discretion of INNOVO GROUPS, replace this product without charge for such replacement parts or labor. The purchaser shall bear all expenses related to returning this product to INNOVO GROUPS.

This warranty does not apply to any part of the product that has been subject to misuse, abuse, or alteration. Improper or incorrectly performed maintenance or repair voids this warranty.

TO THE EXTENT PERMITTED BY LAW, INNOVO GROUPS SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES INCLUDING, BUT NOT LIMITED TO, REPLACEMENT COSTS RESULTING FROM THE BREACH OF ANY WRITTEN OR IMPLIED WARRANTY.

LIMITED ONE YEAR WARRANTY (CONT.)

If you wish to make a claim under this warranty, please contact cs@innovogroups.com or Tel: +1-858-888-9781.

You will need the following information when making your claim:

- The entire original Soothe™ product and packaging
- The original receipt showing date of purchase
- Detailed description of the problem

Soothe™ Model: ________________________________

Serial Number: ________________________________

Date of Purchase: ________________________________

Distributor: ________________________________