Icy Hot SmartRelief User's Manual

ICYHOT®

SMARTRELIEF™
TENS THERAPY

Relief for Muscle Aches and Pains, Arthritis, and Chronic Pain

Visit www.smartrelief.com for more information on SmartRelief and coupon offers.

0075688-02 **Patent Pending**

USER MANUAL

INTRODUCTION

What is TENS?

TENS stands for Transcutaneous Electrical Nerve Stimulation. TENS therapy uses mild electrical impulses applied to the skin for pain relief. The SmartRelief device is a battery-powered TENS device that transmits a mild electrical impulse, through conductive electrode pads applied on the skin, to underlying nerve fibers and muscles. TENS therapy is a safe and effective drug-free method of reducing pain that is used by physicians and pain clinics around the world.

INDICATIONS FOR USE

To be used for temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities.

To be used for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

CONTRAINDICATIONS

Do not use this device 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.

Usage

Refer to SmartRelief Quick Start Guide for setup and treatment instructions.

Distributed by Chattem, Inc.
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WARNINGS

- If you are in the care of a physician, consult your physician before using this device.
- If you have had medical treatment for your pain, consult with your physician before using this device.
- If your pain does not improve or becomes more than acute, stop using the device and consult with your physician.
- Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Doing so could cause electric shock, burns, electrical interference, or death.
- Do not place this device on your head.
- Do not place this device over your neck. Doing so could cause severe muscle spasms resulting in closure of your airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.
- Do not place this device across your chest. The introduction of an electrical current into the chest may cause rhythm disturbances to your heart, which could be lethal.
- Do not use this device in the presence of cardiac pacemakers or implants.
- Do not use this device during pregnancy.
- Do not place this device over the carotid sinus nerves, the front of the neck, or around the mouth.
- Do not place this device over open wounds, sores or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins).
- Do not use this device over, or in proximity to, cancerous lesions.
- Do not use this device when in the bath or shower.
- Do not use this device while sleeping.
- Do not use this device while driving, operating machinery, or during any activity in which electrical stimulation can put you at risk of injury.
- Do not use this device in the presence of electromagnetic fields.
- Do not use this device if case has been damaged.
- Do not use this device if you don't know the source of your pain.
- Do not use this device on children.

PRECAUTIONS

- The long-term effects of TENS therapy (cutaneous electrodes for electrical stimulation) are unknown.
- TENS is not a substitute for pain medications and other pain management therapies.
- Use caution if electrode pads are applied over areas of skin that lack normal sensation.
- Replace self-adhesive electrode pads if they no longer stick firmly to your skin.
- Reuse of the electrode pad by another user could cause the cross-infection of skin diseases.
- Clean and dry the area to which you will apply the electrode pad with water or alcohol prior to application.
- Use of accessories not approved by the manufacturer may cause harm or injury.
- Operation in close proximity to short wave or microwave therapy equipment may produce instability in the stimulator output.
- Keep the SmartRelief power unit clean by wiping with a damp cloth. Do not immerse.
- Do not disassemble the SmartRelief power unit.
- Electrode pads should only be applied to normal, intact, clean, healthy skin.
- The size, shape, and type of electrodes may affect the effectiveness of pain relief. Use only SmartRelief electrodes with your SmartRelief device and only use as directed.
- The adhesive characteristics of electrode pads may affect the safety and effectiveness of electrical stimulation. Clean and/or replace your electrode pads as directed.
- Using electrode pads that are too small or no longer adhere could result in discomfort, irritation, or minor skin burns.
- Choking hazard: Do not swallow battery.
- Keep this device out of reach of children.

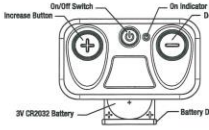
ADVERSE REACTIONS

- If you experience adverse reactions, stop using this device and consult with your physician.
- Users with sensitive skin may experience skin irritation in the area where the electrode pad is applied.
- You may experience headache and other painful sensations during or following the application of electrical stimulation near your eyes and to your head and face.

CARE AND STORAGE OF ELECTRODE PADS

- Clean the gel surface of the electrode pad by holding under dripping water and gently rubbing with your fingers for 5-10 seconds. Allow to air dry. This should only be done when the electrode pad has lost adhesion.
- Place electrode pad on the clear protective sheet and store the electrode pad in its re-sealable bag after each use. The life of the electrode pads varies depending on skin conditions, skin preparation, storage and climate.

PRODUCT DIAGRAM



TROUBLESHOOTING GUIDE

Problem	Possible Cause	Corrective Action
No stimulation felt	• Dead battery • Wrong size battery • Battery installed incorrectly • Dirty or not sticky electrode • Damaged electrode	• Replace battery (3V CR2032) • Insert battery correctly (+ side up) • Clean skin and electrode per instructions • Replace electrode
Intermittent Stimulation	• Poor connection • Damaged electrode • Dirty or not sticky electrode	• Re-attach power unit to electrode • Replace electrode • Clean skin and electrode per instructions
Stimulation not powerful enough	• Low battery • Damaged electrode • Dirty or not sticky electrode	• Replace battery (not all 3V CR2032 batteries are of the same quality) • Replace electrode • Clean skin and electrode per instructions
Stimulation surges	• Poor connection • Dirty or not sticky electrode • Incorrect size battery	• Re-attach power unit to electrode • Clean skin and electrode per instructions • Replace electrode • Replace battery (3V CR2032)
Unwanted muscle twitches	• Intensity too high • Electrode placement	• Decrease intensity • Adjust electrode position
Stimulation ineffective against pain	• Electrode placement • Intensity too low • Skin not clean	• Adjust electrode position • Increase intensity • Clean skin and electrode per instructions
Stimulation feels weaker a few minutes after starting	• Normal operation – electrical output pattern is cyclic	• Increase intensity if desired
LED light not lit	• Dead battery	• Replace battery (3V CR2032)
LED light on but no output	• Low battery • Incorrect size battery • Dirty or not sticky electrode • Skin not clean	• Replace battery (not all batteries are of the same quality) • Replace with battery 3V CR2032 • Clean skin and electrode per instructions • Replace electrode

ELECTROMAGNETIC COMPATIBILITY (EMC)

1. Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.
2. Portable and mobile Radio Frequency (RF) communications equipment can affect Medical Electrical Equipment.
3. The use of accessories, transducers and cables other than those specified by the manufacturer may result in increased emissions or decreased immunity of the SmartRelief device.
4. The SmartRelief device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the SmartRelief device should be observed to verify normal operation in the configuration in which it will be used.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The SmartRelief device is intended for use in the electromagnetic environment specified below. The customer or the user of the SmartRelief device should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air
Electrical fast transient / burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input/ output lines	Not Applicable
Surge IEC 61000-4-5	+/- 1 kV line(s) to line(s) +/- 2 kV line(s) to earth	Not Applicable
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	<5% *Ur* (>95% dip in *Ur*) for 0,5 cycle 40% *Ur* (60% dip in *Ur*) for 5 cycles 70% *Ur* (30% dip in *Ur*) for 25 cycles <5% *Ur* (>95% dip in *Ur*) for 5 seconds	Not Applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A / m	3 A / m

NOTE *Ur* is the A.C. mains voltage prior to application of the test level.

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Electromagnetic Environment - Guidance
Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Mains power quality should be that of a typical commercial or hospital environment.
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Mains power quality should be that of a typical commercial or hospital environment. If the user of the SmartRelief device requires continued operation during power mains interruptions, it is recommended that the SmartRelief device be powered from an uninterruptible power supply or a battery.
Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The SmartRelief device is intended for use in the electromagnetic environment specified below. The customer or the user of the SmartRelief device should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80MHz	3 Vrms
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5GHz 10 V/m 26MHz to 1000MHz	3 V/m 10 V/m

NOTE 1 at 80MHz and 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.

a) 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 SmartRelief device is used exceeds the applicable RF compliance level above. The SmartRelief device should be observed to verify normal operation. If abnormal performance is observed additional measures may be necessary such as reorienting or relocating the SmartRelief device.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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Electromagnetic Environment - Guidance
Portable and mobile RF communications equipment should be used no closer to any part of the SmartRelief device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 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, (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:

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The SmartRelief device is intended for use in the electromagnetic environment specified below. The customer or the user of the SmartRelief device should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The SmartRelief 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 CISPR 11	Class B	The SmartRelief device is suitable for use in all establishments, including domestic establishments 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	

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.

Recommended separation distances between portable and mobile RF communication equipment and the SmartRelief device

The SmartRelief device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SmartRelief device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SmartRelief device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter w	Separation distance according to frequency of transmitter m 150 kHz to 80 MHz $d = 1.2\sqrt{P}$	 80 MHz to 800 MHz $d = 1.2\sqrt{P}$	 800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
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

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.

ENVIRONMENTAL AND TECHNICAL

Store between: -40 and 70 degrees C
10% - 90% Relative humidity
Atmospheric Pressure 50 – 106 kPa

Dimensions: 64x38x13mm
Weight: 20g
Power Supply: 3V CR2032 Battery
Channels: 1 channel output through female snaps
Output Current: 0-63mA peak into a 500-ohm load
Intensity Control: Adjustable in 63 steps
Timer: Device turns off after 30 minutes
Waveform: Asymmetrical Biphasic Pulse, 0 net DC Charge
For Use in Home, Office or Workplace
Operating Temperature: 10 -, 40 degrees C
Operating Humidity: 30% to 75%
Atmospheric Pressure 50 - 106 kPa