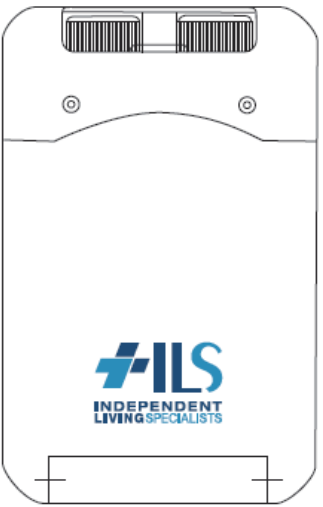
Transcutaneous Electrical Nerve Stimulation Device

REF WL-2103C/S12063



Operation Manual
Read Before Using

CE
1639

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INTRODUCTION TO TENS

What is Pain?

Pain is the body's warning system. Pain is important because it signals an unusual condition in the body and alerts us before additional damage or injury can occur. However, long-lasting, persistent pain, often called chronic pain, once diagnosed serves no apparent purpose. TENS is developed to help relieve some types of chronic and acute pain.

How does TENS work?

TENS is a method of treating pain that is non-invasive and non-narcotic.
The TENS device sends comfortable pulses through the skin that stimulate the nerve (or nerves) in the treatment area. In many cases this stimulation will greatly reduce or eliminate the pain sensation you feel by masking the original pain message sent to the brain.

It is also believed that TENS stimulation helps release endorphins into the blood stream thereby further reducing pain.

TENS devices are clinically proven useful in pain management for many patients. By reading this manual and carefully follow the treatment instructions given to you by your physician/clinician, you will attain the maximum benefit from your TENS device.

INDICATIONS AND CONTRAINDICATIONS

Read the operation manual before using TENS

INDICATIONS

Transcutaneous Electrical Nerve Stimulation (TENS) may be used, with a physician's prescription, for the symptomatic relief and management of chronic (long term) pain.

CONTRAINDICATIONS

- Patients with implanted electronic devices(for example, a pacemaker) or metallic implants should not undertake TENS treatment without first consulting a physician.
- Any electrode placement that applies current to the carotid sinus (neck) region.
- Any electrode placement that causes current to flow trans cerebrally (through the head).
- The use of TENS whenever pain symptoms are undiagnosed, until etiology is determined.

WARNINGS AND PRECAUTION

WARNINGS

- TENS devices must be kept out of reach of children.
- The safety of TENS devices for use during pregnancy or delivery has not been established.
- TENS is not effective for pain of central origin (headaches).
- If TENS treatment becomes ineffective or unpleasant, stimulation should be discontinue until reevaluated by a physician.
- Avoid adjusting controls while operating machinery or vehicles.
- Always turn the TENS device OFF before applying or removing electrodes.
- TENS may interfere with electronic monitoring equipment (ECG monitors/ alarms).
- Electrodes should not be placed over the eyes, in the mouth, or internally.
- TENS devices have no curative value.
- TENS is a symptomatic treatment and as such suppresses the sensation if pain which would otherwise serve as a protective mechanism.
- The patient is an intended operator.
- No servicing or maintenance while the equipment is in use.

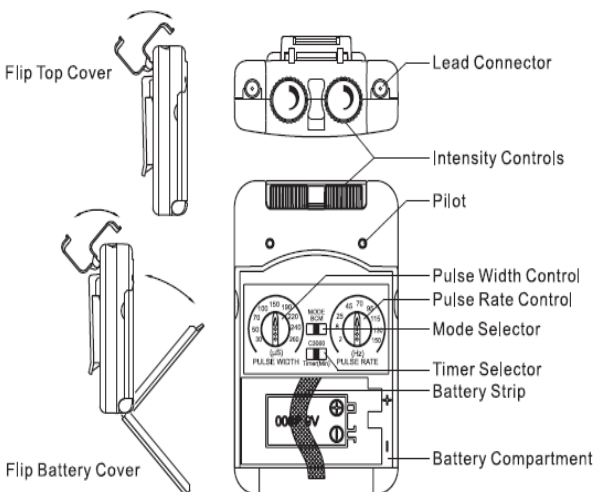
PRECAUTIONS/ADVERSE REACTIONS

- Isolated cases of skin irritations may occur at the site of electrode placement during long term application.
- Effectiveness is highly dependent upon patient selection by a person qualified in the management of pain patients.
- Skin irritation and electrode burns are potential adverse reactions.
- The applied part is electrode pad.
- Please dispose it according to the local rule of the disposition of electronic device/accessory.
- No modification of this equipment is allowed.
- Stimulation connection a PATIENT to a high frequency surgical ME EQUIPMENT may result in burs at the site o the STIMULATOR electrodes and possible damage to the STIMULATOR.
- Operation in close proximity (e.g. 1m) to a shortwave or microwave therapy ME EQUIPMENT may produce instability in the STIMULATOR output.
- Do not apply stimulation across the chest because the introduction of electrical into the chest may cause rhythm disturbances to the heart.

ABOUT THIS DEVICE

Your TENS device is a battery operated device that includes two controllable output channels. This TENS device creates electrical impulses whose amplitude, duration, and modulation can be altered with the controls or switches. The TENS dial controls are very easy to use and the slide cover prevents accidental changes in settings.

We recommend that you consult a physician/clinician before using TENS device.



UNIT CONTROLS

Panel Cover
A cover conceals the controls for Pulse Width, Pulse Rate, Mode Selector and Modulation Selector. The TENS dial controls are very easy to use and the slide cover protects accidental changes in settings.

Intensity
The intensity knobs located on the top of the unit affect the strength of the stimulation and also function as ON/OFF controls.

Mode
The Mode switch is used to select the type of treatment utilized. The three modes are Burst (B), Continuous (C), and Modulation (M).

Pulse Width
The Pulse Width knob regulates the pulse width for both channels.

Pulse Rate
The Pulse Rate knob regulates the number of pulses per second for both channels.

Time Control
Treatment Time of TENS can be preset with timer control. This switch has 3 positions: 30, 60 minutes and C (continuous). Push the mode selector until engaged in position desired.

Resetting the Timer
To resume operation or to reset the timer, simply turn the intensity control OFF and then ON again.

Mode Functions

Burst (B) releases individual bursts twice per second, pulse width is adjustable and the pulse rate is set at 100Hz per second.

Continuous (C) stimulation is delivered continuously at the settings determined by intensity, rate, and width knobs.

Modulation (M) pulse width decrease from its setting by 60% and maintain the decreased width for 2 seconds before returning to the original width setting, which is maintained for 3.5 seconds. The cycle is then repeated. The intensity and pulse rate are adjustable.

NOTE: Use care when you plug and unplug the wires. Pulling on the lead wire instead of its insulated connector may cause wire breakage.

CAUTION: Never insert the plug of the lead wire into an AC power supply socket.

ELECTRODE SELECTION AND CARE

Your physician/clinician should decide which type of electrode is best for your condition.
Follow application procedures outlined in electrode packaging will provide instructions for care, maintenance and proper storage of your electrodes.

TIPS FOR SKIN CARE

Good skin care is important for comfortable use of your TENS device.

- Always clean the electrode site with mild soap and water solution, rinse well and blot dry thoroughly prior to any electrode application.
- Any excess hair should be clipped, not shaved, to ensure good electrode contact with the skin.
- You may choose to use a skin treatment or preparation that is recommended by your physician/clinician. Apply, let dry, and apply electrodes as directed. This will both reduce the chance of skin irritation and extend the life of your electrodes.
- Avoid excessive stretching of the skin when applying electrodes. This is best accomplished by applying the electrode and smoothly pressing it in place from the center outward.
- When removing electrodes, always remove by pulling in the direction of hair growth.
- It may be helpful to rub skin lotion on electrode placement area when not wearing electrodes.

CONNECTING THE TENS DEVICE

1. Prepare the skin as previously discussed and according to instructions provided with your electrodes. Before attaching the electrodes, identify the area which your clinician has recommended for electrode placement.

2. Connect the lead wires to the electrodes before applying the electrodes to the skin.

NOTE: Be sure both intensity controls for Channel 1 and 2 are turned to the "OFF" position.

3. Place the electrodes on the skin as recommended by your physician/ clinician.

4. Insert Lead Wire Connector to TENS device Plug end of lead wire into the channel output receptacle to be used, pushing plug in as far as it will go.

5. Select Treatment Settings Check and be sure your unit is still set to the proper settings recommended by your physician/clinician.

6. Adjusting Channel Intensity Control

Locate the intensity control knob at the top of the unit. Turn channel 1 or 2 clockwise. The indicator light will light up as long as the unit is in operation. Slowly turn the channel control in a clockwise direction until you reach the intensity recommended by your medical professional. Repeat for the other channel if both channels are to be used.

Changing the Battery

When the yellow indicator light located on the front of the unit does not remain lit once the unit is turned on, the battery should be replaced with a new battery.

When the yellow indicator light on the front of the unit does not remain lit once the unit is turned ON, the battery should be replaced with a newly charged battery.

1. Remove the panel cover by pressing the top and sliding down until it is completely removed from the unit this will reveal the battery compartment.

2. Remove the discharged battery from the device.

3. Place new battery in compartment. Note the proper polarity alignment indicated on the battery and the compartment.

4. Remove the battery if not to be used for some time.

SYSTEM COMPONENTS

Your TENS device may include the following components or accessories:

TENS unit
Carrying case
Lead wires
Electrodes
Battery (Type 9F22)
Operation Manual

TECHNICAL SPECIFICATIONS

Channel:	Dual, isolated between channels
Modes of Operations:	Burst, Continuous, Modulation
Pulse Intensity:	Adjustable 0-80mA peak into 500 ohm load each channel, constant current
Pulse Rate:	2Hz-150Hz (adjustable)
Pulse Width:	30uS-260uS (adjustable)
Timer:	Continuous, 30 min., 60 min.
Burst Mode:	Burst consists 2 burst per sec at 100 Hz
Wave Form:	Asymmetrical Bi-Phasic square pulse
Voltage:	0-100 Volt (open current)
Power Source:	9 volt battery (Type 6F22)
Dimensions:	95(H) x 60(W) x 23 (T) mm
Weight:	115 grams (battery included)

Output Parameters

Mode	**Intensity (mA)**	**Width (uSec)**	**Pulse Rate Freq(Hz)**	**Cycle Time (Sec)**
Continuous	Adj. 0-80	Adj. 30-260	Adj. 2-150 Hz	N/A
Burst	Adj. 0-80	Adj.30-260	100Hz fixed 2 burst per sec.	N/A
Modulation	Adj.0-80	Modulates down from preset width setting by 60% then back to original setting	Adj.2-150Hz	5.5 sec total time

Description of Symbols :

(i) There are a number of technical symbols on your unit explained as follows:

SN	This symbols means “ Serial number “
	This symbols means “ Attention, consult the accompanying documents”
	This symbols means “ Manufacturer “
	This symbol means type BF equipment; this device offers protection against electrical shock by standard compliance to leakage currents of electrode pad.
	This device shall be disposed in accordance with national laws after their useful lives

(ii) there is a label on the package of electrode explained as follows :

	This symbol means “used before”, represent as “YYYY-MM” (for year and month).

Electromagnetic Compatibility

- The device complies with current specifications with regard to electromagnetic compatibility and is suitable for use in all premises, including those designated for private residential purposes. The radio frequency emissions of the device are extremely low and in all probability do not cause any interference with other devices in the proximity.
- It is recommended that you do not place the device on top of or close to other electronic devices. Should you notice any interference with other electrical devices, move the device or connect it to a different socket.
- Radio equipment may affect the operation of this device.

Electromagnetic Compatibility Information

Declaration – electromagnetic emissions		
The EMS Electrical Stimulator is intended for use in the electromagnetic environment specified below. The customer or the user of the EMS Electrical Stimulator should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
CE emissions CISPR11	Group 1	The Wireless Electrical Stimulator 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.
RE emissions CISPR11	Class B	The Wireless Electrical Stimulator 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	Class A	
Voltage fluctuations/	Complies	

Declaration – electromagnetic immunity			
The EMS Electrical Stimulator system is intended for use in the electromagnetic environment specified below. The customer or the user of the EMS Electrical Stimulator system should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV , ±4 kV , ±8 kV , ±15 kV air	±8 kV contact ±2 kV , ±4 kV , ±8 kV , ±15 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	±2 kV for power supply lines ±1 kV for input/output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV ±1 kV differential mode ±2 kV common mode	N/A	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	0 % U_T ; 0 , 5 cycle At 0° , 45° , 90° , 135° , 180° , 225° , 270° and 315° 0 % U_T ; 1 cycle and 70 % U_T ; 25/30 cycle Single phase: at 0°	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EQUIPMENT or SYSTEM requires continued operation during power mains interruptions, it is recommended that the EQUIPMENT or SYSTEM be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Declaration – electromagnetic emissions and immunity –
for EQUIPMENT and SYSTEMS that are use in the professional healthcare facility environment or in the home healthcare environment

<table>
<tr><th colspan="6">The EMS Electrical Stimulator declaration – electromagnetic immunity</th></tr>
<tr><td colspan="6">The EMS Electrical Stimulator system is intended for use in the electromagnetic environment specified below. The customer or the user of the EMS Electrical Stimulator system should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th colspan="2">IEC 60601 test level</th><th colspan="2">Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td colspan="2">3 Vrms ; 6 Vrms
150 kHz to 80 MHz</td><td colspan="2">N/A</td><td rowspan="14">Portable and mobile RF communications equipment should be used no closer to any part of the EQUIPMENT or SYSTEM including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Interference may occur in the vicinity of equipment marked with the following symbol.
  </td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td colspan="2">3 V/m ; 10V/m
80 MHz – 2.7 GHz
80%</td><td colspan="2">3 V/m ; 10V/m
80 MHz – 2.7 GHz
80%</td></tr>
<tr><td rowspan="13">Proximity fields from RF wireless Communications equipment
IEC 61000-4-3</td><td>27 V/m</td><td>385 MHz</td><td>27 V/m</td><td>385 MHz</td></tr>
<tr><td>28 V/m</td><td>450 MHz</td><td>28 V/m</td><td>450 MHz</td></tr>
<tr><td rowspan="3">9 V/m</td><td>710 MHz</td><td rowspan="3">9 V/m</td><td>710 MHz</td></tr>
<tr><td>745 MHz</td><td>745 MHz</td></tr>
<tr><td>780 MHz</td><td>780 MHz</td></tr>
<tr><td rowspan="3">28 V/m</td><td>810 MHz</td><td rowspan="3">28 V/m</td><td>810 MHz</td></tr>
<tr><td>870 MHz</td><td>870 MHz</td></tr>
<tr><td>930 MHz</td><td>930 MHz</td></tr>
<tr><td rowspan="3">28 V/m</td><td>1720 MHz</td><td rowspan="3">28 V/m</td><td>1720 MHz</td></tr>
<tr><td>1845 MHz</td><td>1845 MHz</td></tr>
<tr><td>1970 MHz</td><td>1970 MHz</td></tr>
<tr><td>28 V/m</td><td>2450 MHz</td><td>28 V/m</td><td>2450 MHz</td></tr>
<tr><td rowspan="3">9 V/m</td><td>5240 MHz</td><td rowspan="3">9 V/m</td><td>5240 MHz</td></tr>
<tr><td>5500 MHz</td><td>5500 MHz</td></tr>
<tr><td>5785 MHz</td><td>5785 MHz</td></tr>
</table>

Recommended separation distances between portable and mobile RF communications equipment and the ME equipment			
The EMS Electrical Stimulator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the EMS Electrical Stimulator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the EMS Electrical Stimulator 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 $d=\left[\frac{3,5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d=\left[\frac{3,5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d=\left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.1	0.1	0.2
0.1	0.4	0.4	0.7
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	11.7	11.7	23.3

Warranty

This Tens device carries a one-year warranty from the date of purchase.

The warranty does not apply to damage resulting from failure to follow the operating instructions, accidents, abuse, alterations or disassembly by unauthorized individuals.

The warranty applies to the main device and necessary parts and labor relating thereto. Battery, electrodes, and other accessories are warranted to be free from defects in workmanship and materials at the time of delivery.

The distributors reserve the right to replace or repair the unit at their discretion.

Manufactured for:

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