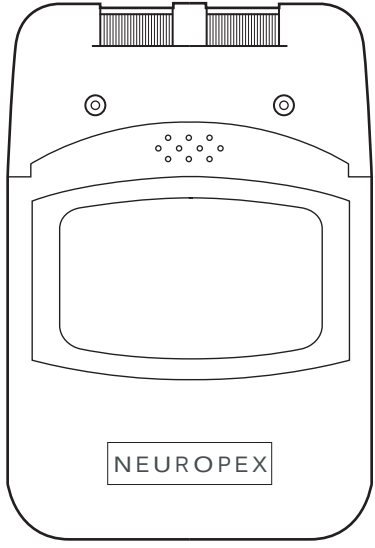
Transcutaneous Electrical Nerve Stimulation Device

REF ENT001 / WL-2103A



Operation Manual

Read Before Using Device

CE 0120

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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 impulses 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 to be useful in pain management for many patients. By reading this manual and carefully following the treatment instructions given to you by your 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) is intended for pain relief.

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 transcerebrally. (through the head).
- The use of TENS whenever pain symptoms are undiagnosed, until etiology is determined.

WARNINGS

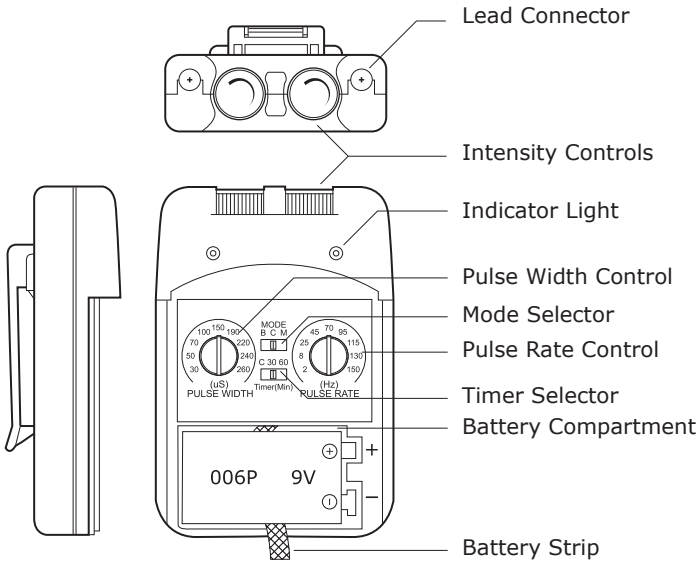
- TENS devices must be kept out of reach of children.
- The safety of TENS devices for use during pregnancy or delivery has not been established.
- TENS is not effective for pain of central origin (headaches).
- If TENS treatment becomes ineffective or unpleasant, stimulation should be discontinued until re-evaluation 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.

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.



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 protects accidental changes in settings.

UNIT CONTROLS

Panel Cover
A cover conceals the controls for Pulse Width, Pulse Rate, Mode Selector and Modulation Selector. Press the top side of the cover and pull down in order to open the cover.

Intensity
The intensity knobs located on the top of the unit affects the strength of the stimulation and also functions as the ON/OFF control.

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 minutes, 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 decreases from its setting by 60% and maintains 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.

ATTACHING THE LEAD WIRES

The lead wires provided with the TENS device insert into the jack sockets located on top of the unit. Holding the insulated portion of the connector, push the plug end of the wire into one of the jacks; one or two sets of the wires may be used. After connecting the wires to the stimulator, attach each wire to an electrode.

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 to maintain stimulation and prevent skin irritation. The 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
Prepare the skin as previously discussed and according to instructions provided with your electrodes. Before attaching the electrodes, identify the area which your physician/clinician has recommended for electrode placement.

2. Connect lead wires to the electrodes
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 electrodes on the skin
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 physician/clinician. Repeat for the other channel if both channels are to be used.

If the stimulation levels are uncomfortable or become uncomfortable, reduce the stimulation amplitude to a comfortable level or cease stimulation and contact your physician if problems persist.

BATTERY INFORMATION

If your TENS device is equipped with a rechargeable battery system, it will contain two rechargeable Ni-Cad batteries and a battery charger. This allows you to charge one battery while the other one is being used in your unit. To protect the life of your batteries, it is important to continue using a battery until the indicator light is no longer lit. Removing the battery and charging it after only a short usage can actually shorten the life of the Ni-Cad battery.

When the indicator light located on the front of the unit will no longer light, the battery has become too weak to power the unit and it is time to charge the battery. At this point the unit will shut off until a fresh battery is inserted.

Your unit may also be powered by a 9 volt disposable alkaline battery. This type of battery cannot be recharged and should be discarded when the yellow light no longer lights.

Changing the Battery

When the 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.

Recharging Batteries

1. Take care to note the proper polarity of the battery. If positioned properly, it will not be necessary to force the battery.

Caution: The battery may overheat and rupture if it is inserted backwards.

2. Plug the charger and allow it to remain undisturbed for 8 to 10 hours. Remove battery upon completion.

3. Batteries should always be stored fully charged. After being stored for 60 days or more, the Ni-Cad batteries may lose some or most of their charge and should be charged prior to use.

CARING FOR YOUR TENS DEVICE

Your TENS device may be cleaned by wiping gently with a damp cloth moistened with mild soap and water. Never immerse the device in water or other liquids.

Wipe lead wires with a damp cloth as above if they become soiled.

To properly store the TENS device for extended period of time, remove the battery from the unit. Put the unit and accessories in the carrying case and store in a cool dry location.

TROUBLESHOOTING

If the TENS device does not function properly:

1. Make sure the battery is properly installed or replace battery. Be sure to observe proper polarity markings when replacing the battery. If the yellow light on the front of the unit does not stay lit when the unit is turned on, replace the battery and check again.

2. If the ON/OFF Indicator Light is flashing and you still feel no stimulation, check that the lead wires are properly connected and the electrodes are in place. If the unit appears to be functioning and no stimulation, the lead wires or electrodes may need to be replaced.

3. If the battery appears to be charged and the unit is not functioning, turn both Intensity Control Knobs to the OFF position(counter clockwise). Then gradually turn the Intensity Control Knob to the on position.

If there is any other problem, please consult or return the device to your distributor, Do not try to repair a defective device.

SYSTEM COMPONENTS

Your TENS device may include the following components or accessories:

- TENS unit
- Lead wires
- Electrodes
- Battery
- Carry case
- Operation Manual

TECHNICAL SPECIFICATIONS

Channel: Dual, isolated between channels
Modes of Operations: Continuous, Burst, 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: Cont., 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 (alkaline or nickel-cadium rechargeable)
Dimensions: 95(H) x 65(W) x 23.5 (T) mm
Weight: 115 grams (battery included)

OUTPUT SPECIFICATIONS

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

WARRANTY

This TENS device carries a two year warranty from the date of purchase. The warranty applies to the TENS device and necessary parts and labour relating thereto. The distributor reserves the right to replace or repair the unit at their discretion.

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

Batteries and electrodes are consumable products and as such are not included within the warranty.

DESCRIPTION OF SYMBOLS:

	Caution (Output)
	TYPE BF equipment
	Follow instructions for use
	Do not dispose in normal dustbin.

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Taiwan

EC REP Sanico Srl
via Turati, 7 - 20121 Milano

Well Life model # WL-2103A corresponds to Neuropex Model ENT001

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

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration
– electromagnetic emissions</th></tr>
<tr><td colspan="3">This device is intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions</th><th>Compliance</th><th>Electromagnetic environment guidance</th></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>This 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 CISPR 11</td><td>Class B</td><td rowspan="3">This 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.</td></tr>
<tr><td>Harmonic emissions IEC 61000-3-2</td><td>Not Applicable</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions IEC 61000-3-3</td><td>Not Applicable</td></tr>
</table>

Guidance and manufacturer's declaration – electromagnetic immunity			
This device is intended for use in the electromagnetic environment specified below. The customer or the user of this device 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	±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	±2 kV for power supply lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) and neutral	Not applicable	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% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of this device requires continued operation during power mains interruptions, it is recommended that this device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field	3 A/m	3 A/m	This device power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial of hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level			

Guidance and manufacturer's declaration – electromagnetic immunity			
This device is intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment guidance**
Conducted RF IEC 61000-4-6	3 Vms 150 kHz to 80 MHz	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of this 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 = $1{,}2\sqrt{P}$ 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 metres (m). 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: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
NOTE 1 At 80 MHz 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			

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 this device is used exceeds the applicable RF compliance level above, this device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this device.

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

Recommended separation distance between portable and mobile RF communications equipment and the device

This device is intended for use in an electromagnetic in which radiated RF disturbances are controlled. The customer or the user of this device help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this 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	N/A	0.12	0.23
0.1	N/A	0.38	0.73
1	N/A	1.2	2.3
10	N/A	3.8	7.3
100	N/A	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distanced 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

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