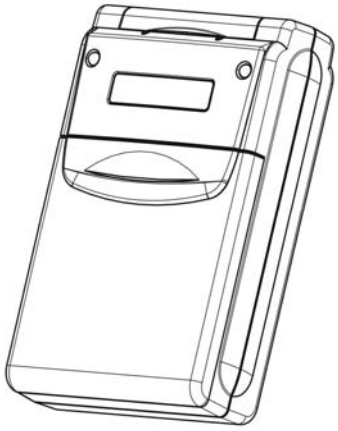
BioTENS2



FDA 510k

CE
0434

Transcutaneous Electrical Nerve Stimulator
Operation Manual

TABLE CONTENTS

GENERAL DESCRIPTION

Electrotherapy has been proven an effective modality for pain control.
The BioTENS 2 is a dual-Channel TENS (Transcutaneous Electrical Nerve Stimulator) device indicated for chronic and acute pain applications. It has an advanced 8-bit micro processor, controlling output and function, delivering an accurate and effective set of treatment parameters to include intensity, duration, frequency, rate, mode, and length of treatment, with a turn of a knob or the change of a switch.

SYSTEM COMPONENTS

Your device may include the following components or accessories:

- Unit
- Carrying case
- Lead wires / Electrodes
- 9-volt battery
- Operation Manual

WARRANTY

This device carries a one-year conditional warranty from the date of purchase. The warranty applies only to the device and covers necessary parts and labor. The distributor reserves the right to replace or repair the unit at their discretion.
The warranty does not apply to electrode, battery, lead wires, carrying case, damage resulting from failure to follow the operating instructions, accidents, abuse, alterations or disassembly by unauthorized individuals.

INDICATIONS AND CONTRAINDICATIONS

Read the operation manual before using the device.
Federal law (USA) restricts this device to sale by or on the order of a physician. Observe your physician's precise instructions and let him show you where to apply the electrodes. For a successful therapy, the correct application of the electrodes is an important factor.
Carefully write down the settings your physician recommended.

Indications for use
This device is a prescription device and only for symptomatic relief of chronic intractable pain.

Contraindications
- Any electrode placement that applies current to the carotid sinus (neck) region.
- Patients with implanted electronic devices (for example, a pacemaker) or metallic implants
- Any electrode placement that causes current to flow transcerebrally (through the head). The use of unit whenever pain symptoms are undiagnosed, unit etiology is determined.
- The use of TENS whenever pain syndromes are undiagnosed, until etiology is established.

WARNINGS AND PRECAUTIONS

Warnings
- The device must be kept out of reach of children.
- The safety of device for use during pregnancy or delivery has not been established.
- Do not place electrodes on front of the throat. This may result is spasms of the laryngeal and pharyngeal muscles.
- Do not place the electrodes over the carotid nerve.
- The device is not effective for pain of central origin (headaches).
- The device may interfere with electronic monitoring equipment (such as ECG monitors and ECG alarms).
- Electrodes should not be placed over the eyes, in the mouth, or internally.
- TENS has no curative value.
- TENS devices should be used only under the continued supervision of a physician.
- TENS is a symptomatic treatment and as such suppresses the sensation of pain which would otherwise serve as a protective mechanism.
- Do not recharge alkaline batteries.

Precautions/adverse Reactions

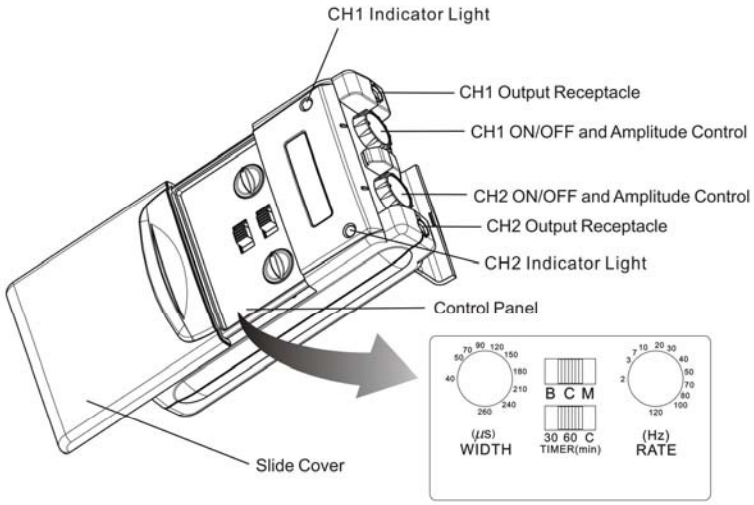
- Isolated cases of skin irritation may occur at the site of electrode placement following long-term application.
- Stimulation should be stopped and electrodes removed until the cause of the irritation can be determined.
- Effectiveness is highly dependent upon patient selection by a person qualified in the management of pain patients.
- If the device treatment becomes ineffective or unpleasant, stimulation should be discontinued until reevaluation by a physician/clinician.
- Always turn the device off before applying or removing electrodes.
- Skin irritation and electrode burns are potential adverse reactions.

DANGER

The device does not have AP/APG protection. Explosion hazard is possible if used in the presence of explosives, flammable materials or flammable anesthetics. Caution should be used when applying the device to patients suspected of having heart disease. Further clinical data is needed to show if there are adverse side effects on those with heart disease.

ABOUT THE DEVICE

Your device offers two controllable output channels. This device creates electrical impulses whose Amplitude, Width, Rate and Modulation can be altered with the switches or knobs. The device controls are very easy to use and the slide cover protects accidental changes in settings.



THE DEVICE CONTROLS

Panel cover
A cover conceals the controls for Mode, Time, Width and Rate. Press the topside of the cover and pull down in order to open the cover.

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

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

Time
Treatment Time of device can be pre-select / set with Time switch. There are two programs fixed duration of 30 and 60 minutes and one program of continuous output. Set the switch to the position desired.

WIDTH
The pulse Width controller regulates the pulse width for both channels.

RATE
The pulse Rate controller regulates the number of pulse per second for both channels.

ATTACHING THE LEAD WIRES

The lead wires provided with the device insert into the jack sockets located on top of the unit. Hold the insulated portion of the connector, and push the plug end of the wire into one of the jacks. After connecting the wires to the stimulator, attach each wire to an electrode.

Lead wires provided with the device are FDA compliant.

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/practitioner 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 instruction for care, maintenance and proper storage of your electrodes.

TIPS FOR SKIN CARE

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

- Always clean the skin at 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. Apply, let dry, and apply electrode 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 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 in which your physician/practitioner 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 Skin
Place the electrodes on the skin as recommended by your clinician.

4. Insert Lead Wire Connector to 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 set to the proper settings as recommended by your physician/practitioner.

6. Adjusting Channel Intensity Control
Locate the intensity control knobs at the top of the unit. Slowly turn the intensity control knob for Channel 1 clockwise until you reach the intensity recommended by your medical professional. Always start with the lowest step and increase slowly. Repeat the same process for Channel 2, if appropriate.

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

BATTERY INFORMATION

A 9-volt disposable battery is provided with your unit. Dimming of the indicator light signifies that the battery should be replaced with a new one as soon as possible. However, the stimulator will continue to operate for several more hours.

CHANGING THE BATTERY

To replace the battery:
1. Remove the slide 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 both the battery and the compartment.

CLEANING FOR YOUR DEVICE

Your 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 device for an extended periods 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 device does not function properly:

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

2. If the intensity has been adjusted and there is 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 occurs, 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) for about 7 sec.** Then gradually turn the intensity Control Knob clockwise until stimulation is felt. If device still is not working, turn the unit off and contact your distributor.

If any other problems occur, please consult or return the device to your distributor. Don't try to repair a defective device.

TECHNICAL SPECIFICATIONS

Channel:	Dual, isolated between channels
Pulse intensity:	Adjustable 0-80mA peak into 500 Ω load each channel, constant current
Pulse Rate:	2Hz-120Hz (adjustable).
Pulse Width:	40μs - 260μs (adjustable).
Timer :	30, 60 minute and continuous mode selectable

Function Modes:

B: Cycle Bursts, 2 Bursts/sec, 9 pulses/Burst, 100Hz, width is adjustable.
C: Continuous Mode. Pulse Rate, Pulse Width and Intensity are adjustable.
M: Modulated Width. Pulse Width is automatically varied in an interval of 6 seconds. The modulation range of pulse width is from setting value to 35% less than the control setting value, then returns to the setting value. Rate, Width and Intensity are fully adjustable.
Wave form: Asymmetrical Bi-phasic square pulse.
Voltage: 0-110 Volt (Open Circuit).
Max charge per pulse: 21 micro-coulombs
Power Source: 9-Volt Battery.
Dimensions: 95 mm(H) ×61.5mm(W) ×26m(T).
Weight: Approx. 120grams (battery included).

All electrical specifications are ±10% except the amplitude is +/- 20% (500Ω load).

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