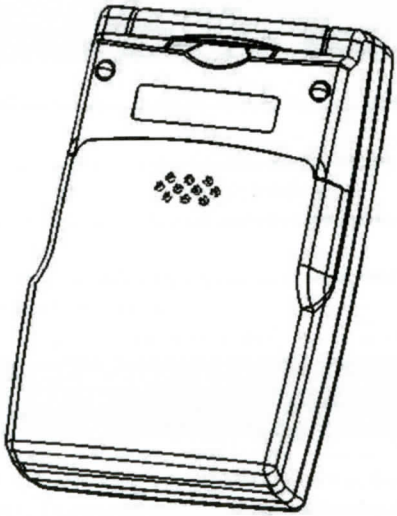
REORDER NO. ZZA250

BODYMED®

TRANSCUTANEOUS ELECTRICAL NERVE STIMULATOR

Operation Manual



ENGLISH • ESPAÑOL

READ THIS INSTRUCTION MANUAL CAREFULLY BEFORE USE

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GENERAL DESCRIPTION

Electrotherapy has proven to be highly valuable as a method of pain therapy. With some restrictions, physicians or licensed practitioners can prescribe the unit to patients for home use. The unit is a dual-channel electric stimulator for active treatment application, which is equipped with an 8-bit micro computer for controlling the system. The unit creates electrical impulses. The intensity, duration, frequency per second and modulation of these impulses can be adjusted through the device controls.

SYSTEM COMPONENTS

The following components or accessories should be included:

- Unit
- Carrying case
- 2 lead wires
- 4 Electrodes (1 pack)
- 9-Volt battery
- Operation manual

If you are missing any of these items, please contact BodyMed® at 1-866-528-2152 before using the unit.

LIMITED PRODUCT WARRANTY

Your BodyMed® ZZA250 Tens unit is warranted to be free from defects in materials and workmanship occurring within one year from date of purchase, when used in strict accordance with the instructions provided with the BodyMed® ZZA250 Tens unit. The sole remedy for a breach of this warranty is replacement of the defective materials or components. This warranty extends only to the original purchaser. The purchase receipt or other proof of date of original purchase is required before full replacement will be provided.

LIMITED PRODUCT WARRANTY

Please contact BodyMed® at 1-866-528-2152.

BODYMED® MAKES NO OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE ALL SUCH WARRANTIES BEING HEREBY EXPRESSLY EXCLUDED.

The warranty described above does not extend to the normal wear of the product and is void if the product housing has been removed or if the product fails to function properly as a result of an accident, misuse, abuse, neglect, mishandling, misapplication, defective batteries, faulty installation, set-up, adjustments, improper maintenance, alteration, maladjustment of controls, modification, power surges, commercial use of product, use of product which differs from the suggested use set forth in the product instructions, service by anyone other than an authorized service center of acts beyond the control of the manufacturer.

BODYMED® SHALL NOT BE LIABLE FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES WHETHER ARISING UNDER CONTRACT, TORT, STRICT LIABILITY, STATUTE OR OTHER FORM OF ACTION OR ANY DAMAGES IN EXCESS OF THE COST OF THE REPLACEMENT OF THE PRODUCT.

INDICATIONS AND CONTRAINDICATION

Read the operation manual before using the device. Federal Law restricts this device to sale by, or on the order of, a physician or licensed practitioner. Follow your physician's or licensed practitioner's precise instructions and let him/her show you where to apply the electrodes. For successful therapy, the correct application of the electrodes is an important factor. Carefully write down the settings your physician or licensed practitioner recommends.

INDICATIONS AND CONTRAINDICATIONS

INDICATIONS FOR USE

This is a prescription device, and should only be used for symptomatic relief of chronic intractable pain as prescribed by a physician or licensed practitioner.

CONTRAINDICATIONS

- Any electrode placement that applies current to the carotid sinus (neck) region.
- The use of TENS whenever pain syndromes are undiagnosed, until cause is determined.
- Patients with implanted electronic devices (for example, a pacemaker) or metallic implants should not use this device.
- Any electrode placement that causes current to flow through the head.

WARNINGS/PRECAUTIONS

WARNINGS

- The device must be kept out of reach of children.
- The safety of the device for use during pregnancy or delivery has not been established.
- Do not place electrodes on front of the throat. This may result in spasms of the laryngeal and pharyngeal muscles.
- Do not place the electrodes over the carotid nerve (the front and sides of the neck).
- The device is not effective for headaches.
- 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.

WARNINGS/PRECAUTIONS

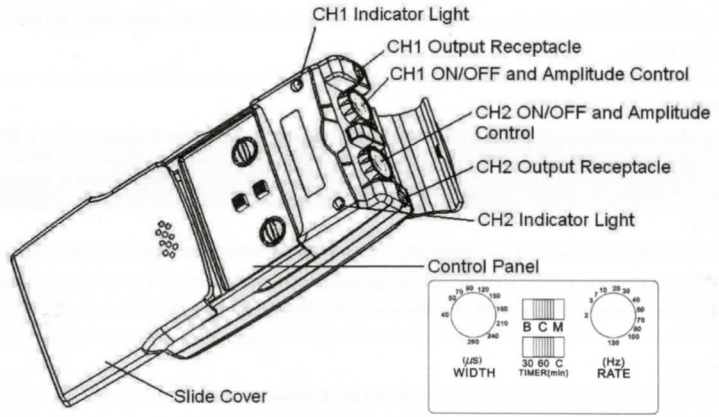
- The device may interfere with electronic monitoring equipment (such as ECG monitors and ECG alarms).
- Electrodes should not be placed over the eyes, in the mouth, or internally.
- These devices have no curative value. TENS is a symptomatic treatment that suppresses the sensation of pain which would otherwise serve as a protective mechanism.
- TENS devices should be used only under the continued supervision of a physician or licensed practitioner.
- Do not use on broken skin.
- Effectiveness is highly dependent upon patient selection by a person qualified in pain management using TENS.
- If the device treatment becomes ineffective or unpleasant, stimulation should be discontinued until re-evaluation by a physician or licensed practitioner.
- Always turn the device off before applying or removing electrodes.
- The device does not have AAP/APG protection. An explosion hazard is possible if used in the presence of explosives, flammable materials or flammable anesthetics.

Adverse Reactions

Skin irritation and electrode burns are potential adverse reactions. Stimulation should be stopped and electrodes removed until the cause of the irritation or burns can be determined. Isolated cases of skin irritation may occur at the site of electrode placement following long-term application. Always properly clean skin before use. If skin irritation occurs, discontinue use. Do not resume use of the ZZA250 Tens unit until you have seen your physician or licensed practitioner.

ABOUT THE DEVICE

The device offers two controllable output channels. This device creates electrical impulses whose amplitude, duration and modulation can be altered with the device controls. The device controls are easy to use, and the slide cover protects accidental changes in settings.



THE DEVICE CONTROLS

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

AMPLITUDE CONTROLS
The Amplitude Control knobs are located on the top of the unit. The Amplitude Control knobs function as ON/OFF controls and adjust the intensity of the stimulation.

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

TIME
Treatment time can be set with the Time switch. There are two programs of fixed duration for 30- and 60-minutes and one program of continuous output. Press the Time switch until the desired position is engaged.

WIDTH
The Width dial regulates the width of the pulse for both channels.

RATE
The Rate dial regulates the number of pulses per second for both channels.

ATTACHING THE LEAD WIRES

Insert the lead wires into the output receptacle located on top of the unit by holding the insulated portion of the connector, and pushing the plug end of the wire into one of the jacks. After connecting the wires to the unit, attach each wire to an electrode. Lead wires provided with the device are compliant with mandatory compliance standards as set forth by the FDA. **Note: Use caution when you plug and unplug the wires. Pulling on the lead wire instead of the 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 or licensed 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 packaging will provide instructions for care, maintenance and proper storage of the electrodes.

Be sure to use the electrodes provided by BodyMed® and/or similar FDA legally marketed electrodes that are the same size, or larger than, the electrodes that are provided with this ZZA250 Tens unit.

CONNECTING THE DEVICE

IMPORTANT: Be sure both Amplitude Control knobs for Channel 1 and 2 are turned to the OFF position before connecting the device.

1. Prepare the Skin. Always clean the electrode site with mild soap and water, rinse well and blot dry thoroughly. 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 or licensed practitioner. This will reduce the chance of skin irritation and extend the life of the electrodes.
2. Connect lead wires to the electrodes. Connect the lead wires to the electrodes before applying the electrodes to the skin.
3. Place electrodes on skin. Place the electrodes on the skin as recommended by your physician or licensed practitioner. 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.
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 that the unit is set to the proper settings as recommended by your physician or licensed practitioner.
6. Adjusting the Amplitude Control knobs. Locate the Amplitude Control knobs at the top of the unit. Slowly turn the Amplitude Control knob for Channel 1 clockwise until you reach the intensity recommended by your physician or licensed practitioner. Always start with the lowest intensity 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. If problems persist, stop treatment and contact your physician or licensed practitioner.

BATTERY INFORMATION

A 9-volt disposable battery is provided with the unit. When the indicator light is dimming, the battery has become too weak to power the unit and will need to be changed. At this point, the unit will shut off until a new battery is inserted.

CHANGING THE BATTERY

When the indicator light is dimming, the battery should be replaced with a fresh 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 old battery from the device.
3. Place a new battery in the compartment. Note the proper polarity alignment indicated on the battery and the compartment.
4. Make sure to safely dispose of the old battery.

CLEANING THE DEVICE

The 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 if they become soiled.

To properly store the device for an 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 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 recheck.
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 Amplitude Control knobs to the OFF position (counterclockwise) for about 7 seconds. Next, gradually turn the Amplitude Control K-knobs clock wise until stimulation is felt. If device is still not working, turn the unit off and contact BodyMed®.

If any other problems occur, please consult or return the device to BodyMed®. Do not repair a defective device.

TECHNICAL SPECIFICATIONS

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

TECHNICAL SPECIFICATIONS

Function Modes:

B: Cycle Bursts, 2 bursts/sec., 9 Pulses/burst, and 100 Hz, width is adjustable.

C: Continuous mode. Pulse rate, pulse width and intensity are adjustable.

M: Modulated Width. Pulse width is automatically varied in a six-second interval. 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), 61.5 mm(W), Q26 m(T).

Weight: Approx. 120 grams (battery included).

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