BODYMED®

TENS/EMS/IF COMBO UNIT

Instruction Manual

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ENGLISH

READ THIS INSTRUCTION MANUAL CAREFULLY BEFORE USE

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General Description

Electrotherapy has proven valuable as a means of helping experienced clinicians relieve pain in their patients. When indicated, a doctor may prescribe the at-home use of an electrotherapy unit, such as the one you have purchased, for patient pain relief. This dual-channel device you have purchased provides several functions. It features a Liquid Crystal Display indicating the operation modes and output, and is controlled by an 8-bit micro-computer. Its internal electronics create electric impulses. The intensity, duration, frequency and modulation of these impulses can be adjusted via the unit's controls.

Type Designation

BodyMed® TENS/EMS/IF Combo Device/Model ZZA900 with combination of T/E/IF, where "T" means TENS function, "E" means EMS function and "IF" means IF TENS.

System Components

Your device may include the following components or accessories:

- Unit
- Carrying case
- 2 Lead wires/4 Electrodes (1 pack)
- 9V battery
- Adaptor
- Operation manual

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

Limited Product Warranty

Your BodyMed® TENS/EMS/IF Combo Device is warranted to be free from defects in materials and workmanship occurring within one (1) year from date of purchase, when used in strict accordance with the instructions provided with the device. The sole remedy for a breach of this warranty is replacement of defective materials or components. This warranty extends only to the original purchase. The purchase receipt or other proof of date of original purchase is required before full replacement will be provided.

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.

Limited Product Warranty (continued)

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 the product which differs from the suggested use set forth in the product instructions, service by anyone other than an authorized service center or 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 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/her 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.

THE FOLLOWING STATEMENTS ARE FOR TENS OPERATION FUNCTION

INDICATIONS FOR USE (FOR "T")

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

CONTRAINDICATIONS

Do not place electrodes in a way that applies current to the carotid sinus (neck) region.

Do not use unit if you have any implanted electronic devices (for example, a pacemaker) or metallic implants.

Do not place electrodes in a way that causes current to flow trans-cerebrally (through the head).

Do not use unit if you have pain symptoms that are undiagnosed, until etiology is established.

THE FOLLOWING STATEMENTS ARE FOR EMS OPERATION FUNCTION

INDICATIONS FOR USE (FOR "E")

Relaxation of muscle spasms.
Prevention or retardation of disuse atrophy.
Increasing local blood circulation.
Maintaining or increasing range of motion.
Muscle re-education.
Immediate post-surgical stimulation of calf muscle to prevent venous thrombosis.

CONTRAINDICATIONS

Powered muscle stimulators should not be used on patients with cardiac demand pacemakers.
Do not place electrodes in a way that applies current to the carotid sinus (neck) region.

THE FOLLOWING STATEMENTS ARE FOR IF OPERATION FUNCTION

INDICATIONS FOR USE (FOR IF):

This device may be used, with a physician's prescription, for the symptomatic relief and management of chronic (long-term) pain and for the treatment of post-operative or post-traumatic pain.

CONTRAINDICATIONS

Patients with implanted electronic devices (for example, a pacemaker) or metallic implants should not undertake IF and HV treatment without first consulting a physician.

Do not place electrodes in a way that applies current to the carotid sinus (neck) region.

Do not place electrodes in a way that causes current to flow trans-cerebrally (through the head).

Do not use unit if you have pain symptoms that are undiagnosed, until etiology is established.

Warnings and Precautions

THE FOLLOWING STATEMENTS ARE FOR TENS AND IF OPERATION FUNCTION

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.

These devices have 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.

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.

THE FOLLOWING STATEMENTS ARE FOR EMS OPERATION FUNCTION

WARNINGS

The long-term effects of continuous electrical stimulation are unknown.

Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.

Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.

Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.

Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g. phlebitis, thrombophlebitis, varicose veins, etc.

Stimulation should not be applied over, or in proximity to, cancerous lesions.

Stimulation should not be applied trans-cerebrally (across the head).

EMS devices should be used only under the continued supervision of a physician.

PRECAUTIONS/ADVERSE REACTIONS

Safety of powered muscle stimulators for use during pregnancy has not been established.

Caution should be used for patients with suspected or diagnosed heart problems.

Caution should be used for patients with suspected or diagnosed epilepsy.

Caution should be used in the presence of the following:

a. When there is a tendency to hemorrhage following acute trauma or fracture;

b. Following recent surgical procedures when muscle contraction may disrupt the healing process;

c. Over the menstruating or pregnant uterus; and

d. Over areas of the skin which lack normal sensation.

Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement.

Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.

Powered muscle stimulators should be kept out of the reach of children.

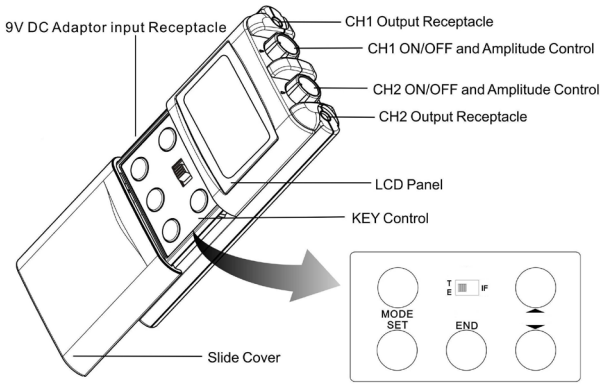
Powered muscle stimulators should be used only with the leads and electrodes recommended for use by the manufacturer.

[FOR PORTABLE DEVICES ONLY] Portable powered muscle stimulators should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.

Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle stimulators.

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.



Device Controls

PANEL COVER

A cover conceals the controls for MODE, SET, END, ▲▼ and T-E or IF slide switch. Press the top side of the cover and pull down in order to open the cover.

T-E/IF

The T-E/IF slide switch is located on the middle-top of key control area.

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.

SET

The SET button is used to set the Timer, Pulse Rate, Pulse Width, Cycle On time, On Ramp time and Cycle Off time. The selected parameter will flash during adjust. Use right ▲▼ to move through the options for each aspect of the treatment.

END
The END button is used to end the programming mode and enter the treatment mode.

MODE
The Mode key is used to select/set the type of treatment utilized. The available stimulation modes for each unit are as indicated in the following table:

Identification	Function	Available Mode
T	TENS	B (Burst), C (Normal), M (Modulation), H1 (MR-Modulation with Rate), H2 (MRW-Modulation with Rate/Width)
E	EMS	S (Synchronous), C (Constant), A (Alternating)
IF	Interferential TENS	C (Constant), A (Auto Sweep), S (Frequency Shift)

TIME (Set + right ▲▼)
Treatment Time of device can be pre-selected/set with Time key. There are four programs with fixed durations of 15, 30, 60 minutes and continue. Press the key until engaged in position desired.

WIDTH (Set + right ▲▼)
The pulse Width key regulates the pulse width for both channels.

RATE (Set + right ▲▼)
The pulse Rate key regulates the number of pulses per second for both channels.

OPERATION PROCEDURES:
1. After device is switched "ON", the operator may choose between the following main operation mode via select switch, the "T/E" and "IF".
2. The operator may press "MODE" button for changing operation mode or direct operation by using the last operation setting. (If no change, then to adjust the stimulation output intensity for each channel use "adjusting knob" directly.)
3. After that, the operator may choose to set and change operation parameters via using "SET" and "Right ▲▼" buttons, and confirm the final setting by using "END" button.
4. After the operation mode and parameters are determined, the operator may initiate and adjust the stimulation output intensity for each channel by using "adjusting knob".

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 the manufacturer and/or the similar FDA legally marketed electrode, in particular the same cross section area.

Tips for Skin Care

GOOD SKIN CARE IS IMPORTANT FOR COMFORTABLE USE OF YOUR 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. Apply, let dry, and then 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 wearing electrodes.

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.

Cleaning the 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 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.

Battery Information

The 9V battery is provided with your unit. When the low battery symbol appears on the LCD, the battery has become too weak to power the unit and it is time to change the battery. At this point, the unit will shut off until a fresh battery is inserted.

Changing the Battery

When the low battery symbol appears on the LCD panel, the battery should be replaced with the fresh battery.

Remove the battery Cover by pressing this cover and sliding down until it is completely removed from the unit. This will reveal the battery compartment.
Remove the discharged battery from the device.
Place new battery in compartment. Note the proper polarity alignment indicated on the battery and the compartment.

9-Volt DC Adaptor

Because the IF current consumption is large for the device, it is recommended to use the 9V DC adaptor. Plug the DC plug into the DC jack of the unit, and plug the adaptor into your 110V (or 220V) wall outlet. Please be sure you are using the correct polarity of DC plug. Due to the high output of IF TENS, the battery may run out of power very soon; therefore the 9-Volt DC adaptor is recommended.

Troubleshooting

If the device does not function properly:

Make sure the battery is properly installed or replace battery. Be sure to observe proper polarity markings when replacing the battery. If the low battery symbol appears on the LCD panel when the unit is turned on, replace the battery and check again.

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, but there is no stimulation, the lead wires or electrodes may need to be replaced.

If the battery appears to be charged, but the unit is not functioning, turn both intensity control knobs to the OFF position (counter-clockwise) for about 7 seconds. Then turn on the unit again. If the device is still not working, turn off your device and contact your distributor.

Note: If any other problems occur, please consult or return the device to your distributor. Do not try to repair a defective device.

Technical Specifications

TECHNICAL SPECIFICATIONS FOR T/E (TENS/EMS)

Channel:	Dual, isolated between channels
Pulse Amplitude:	Adjustable 0-80mA peak into 500 Ω load each channel, constant current
Pulse Rate:	1Hz-160Hz (adjustable), 1Hz/step
Pulse Width:	a. 50-260μs adjustable for TENS, 10μs/step. b. 300μs fixed for EMS.
Software ramp up feature:	Pulse width ramp up when change mode
Patient Compliance counter:	Shows the treatment times. Account by hours.
Timer:	15, 30, 60 minute and continue selectable

Function Modes: TENS:

B:	Cycle Bursts, 2 bursts/sec, 9 pulses/burst, 100Hz, width is adjustable.
C:	Continuous mode. Pulse rate pulse width, and intensity are fully 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. And then returns to the setting value. Rate, width and intensity are fully adjustable.
H1 (MR):	Modulated Rate. Pulse rate is automatically varied in an interval of 6 seconds. The modulation range of pulse rate is from setting value to 35% less than the control setting value, then returns to the setting value.
H2 (MRW):	Modulated Rate/Width. Pulse rate and width are automatically varied in an interval of 6 seconds. The modulation range of pulse rate and width are from setting value to 35% less than the control setting, then returns to the setting value.

EMS:

S:	Synchronous.
C:	Constant.
A:	Alternating.
On Ramp:	Adjustable 1-8 seconds.
Cycle ON Time:	Adjustable 1-30 seconds.
Cycle OFF Time:	Adjustable 1-30 seconds.
Wave Form:	Asymmetrical Bi-Phasic square pulse.
Max charge per pulse:	21 micro-coulombs for TENS & 24 micro-coulombs for EMS
Voltage:	0-110 Volt (Open Circuit).
Power Source:	9-Volt battery or 9-Volt adaptor.
Dimension:	128mm(H) x 70mm(W) x 26mm(T).
Weight:	175 grams (battery included).

Except intensity with +/-20%, all electrical specifications are +/- 10% 500 Ω load.

TECHNICAL SPECIFICATIONS FOR IF

Channel:	Dual, isolated between channels
Pulse Intensity:	Adjustable 0-90mA peak into 500 Ω load each channel, constant current
Carrier Frequency:	4000Hz fixed (CH1)
Modulating Frequency:	4004-4160Hz Adjustable (CH2)
IF Frequency Mode:	Constant Mode (C): 4-160 bps, Adjustable
Auto Sweep (A):	80-145 bps, 4-45 bps, 4 Set bps
Frequency Shift (S):	1/1 abruptly shift, 6/6 abruptly shift, 6/6 ramped, 10/10 abruptly shift, 10/10 ramped
Sweep Time:	15 seconds
Frequency Shift Percent:	Frequency shifts from 30% below set frequency to 60% above and return to 30% below set.
Output Configuration:	Quanta polar (4 electrodes)
Wave Form:	Symmetrical balanced sine wave
Interference Pulse Freq:	4-160 bps, Adjustable 4 bps/step
Pulse Duration:	125μs maximum
Patient Compliance meter:	Shows the treatment times
Patient Lock:	Prevents the patient from changing any of the parameters set by the physician/practitioner.
Timer:	15, 30 minute selectable
LCD:	Shows modes, bps rate, abrupt/ramp, timer and channels
Max charge per Pulse:	22.5 Micro-coulombs Maximum
Power Source:	9-Volt battery or 9-Volt adaptor
Tolerance:	Except intensity with +/-20%, all electrical specifications are +/- 10% 500 Ω load.

****** bps: number of pulses per second**

Output Parameters

There are nine modes: five with frequency shift, three with auto sweep, and one fully adjustable.

Constant Mode (C)

Maintains set pulse frequency. (SET: bps can be adjusted.)

Auto Sweep (A)

It will modulate frequency between the range that is selected. For example, select 80-145 bps auto sweep model. The modulation range of pulse frequency is from 80 bps to 145 bps. The sweep-time is 15 seconds and repeat.

There are three modes of Auto Sweep:

80 – 145 bps
4 – 45 bps
4 – SET bps

Frequency Shift (S)

There are five modes of Frequency Shift

1/1 abruptly shift: The pulse frequency varies from –30% to +60% of the set pulse frequency. One second at the lower frequency, and one second at the higher frequency. The transition is abrupt (square wave function).

6/6 abruptly shift: The pulse frequency varies from –30% to +60% of the set pulse frequency. Six seconds at the lower frequency, and six seconds at the higher frequency. The transition is abrupt (square wave function).

6/6 ramped shift: The pulse frequency sweeps from –30% to +60% of the set pulse frequency. Six seconds from the lower frequency modulate to the high frequency, and six seconds from the higher frequency modulate to the lower frequency. The transition is ramping (triangular wave function).

10/10 abruptly shift: The pulse frequency varies from –30% to +60% of the set pulse frequency. Ten seconds at the lower frequency, and ten seconds at the higher frequency. The transition is abrupt (square wave function).

10/10 ramped shift: The pulse frequency sweeps from –30% to +60% of the pulse frequency. Ten seconds from the lower frequency modulate to the high frequency, and ten seconds from the higher frequency modulate to the lower frequency. The transition is ramping (triangular wave function).

TENS/EMS/IF COMBO UNIT

REORDER NO. ZZA900

Manufactured for BodyMed®
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Made in Taiwan