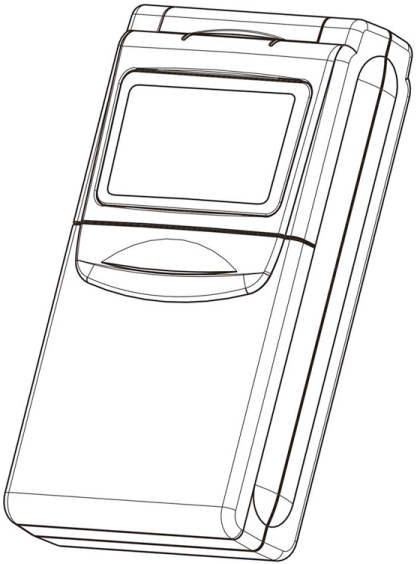
Reorder Number
ZZAIF400

BODYMED®

Interferential Current Stimulator

Instruction Manual



ENGLISH

READ THIS INSTRUCTION MANUAL CAREFULLY BEFORE USE

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General Description

Electrical myostimulation has proven to be highly valuable as a method of pain therapy. Interferential Stimulators help relieve some types of chronic and acute pain. The unit is a dual-channel electric stimulator for active treatment application, which is equipped with a Liquid Crystal Display indicating operation modes and output, as well as an 8-bit microcomputer for controlling the system. The unit creates electrical impulses. The intensity, duration, frequency per micro-second and modulation of these impulses can be adjusted through the device controls. The IF stimulator uses four (4) electrodes, which allows better focus and deeper tissue stimulation when compared to other types of electrical stimulation.

System Components

Your device may include the following components or accessories:

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

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

Limited Product Warranty

Your BodyMed® ZZAIF400 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® ZZAIF400 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.

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

Limited Product Warranty (continued)

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, 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 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 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

- Do not place electrodes in a way that applies current to the carotid sinus (neck) region
- Do not use unit if you have pain symptoms that are undiagnosed, until cause is determined.
- 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)

Warnings and Precautions

WARNINGS

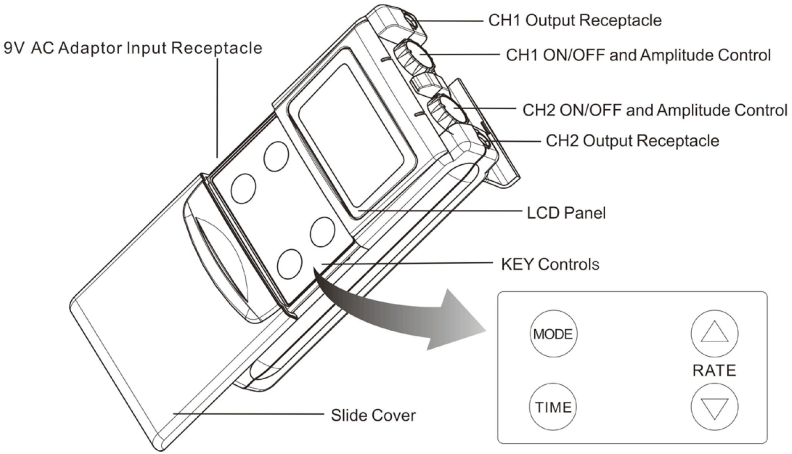
- The device must be kept out of reach of children.
- The safety of the device for use during pregnancy or delivery has not been established.
- Do not place electrodes on front of the throat. This may result in spasms of the laryngeal and pharyngeal muscles.
- Do not place the electrodes over the carotid 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.
- 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. The Interferential is a symptomatic treatment that suppresses the sensation of pain which would otherwise serve as a protective mechanism.
- Interferential 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.
- 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 ZZAIF400 unit until you have seen your physician or licensed practitioner.

About the Device

The device offers two controllable output channels. It creates electrical impulses whose amplitude, duration, and modulation can be altered with the device controls. The device controls are easy to use, and the Cap and Slide Cover prevents accidental changes in settings.



Device Controls

Slide Cover
A cover conceals the key controls for Mode, Time, Width and Rate. Press the front of the cover and pull down to open the cover.

Amplitude Controls
The Amplitude Control Knobs are located on the top of the unit, under the cap. The Amplitude Control Knobs function as ON/OFF controls and adjust the intensity of the stimulation.

Mode
The Mode key is used to select/set the type of treatment utilized. There are nine modes: one Constant, three Auto Sweep, and five Frequency Shift. With each press of the key, you switch to the next mode. The selected mode will be shown on the LCD and will blink.

Device Controls (continued)

Rate
The Rate key regulates the number of pulses per second for both channels. This key selects the pulse frequency of the therapy current. By pressing the △, you can increase the frequency in 4 bps/step. By pressing the ▽, you can decrease the frequency in 4 bps/step.

Time
Treatment time can be set with Time key. There are two programs of fixed duration for 15 and 30 minutes. Press the Time key until the desired program is engaged. To reset timer, turn both channels off. When you are ready to begin another treatment cycle, turn the unit on as normal. The timer will be reset to its current setting.

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 ZZAIF400 EMS 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: 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 the lead wires to the electrodes before applying the electrodes to the skin.
3. 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. Locate the Amplitude Control Knob 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

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.

Adaptor and Battery Information

9-volt AC Adaptor
Because the current consumption is high for the IF unit, it is recommended to use the 9-volt AC adaptor. Place the AC plug into the AC jack of the unit, and plug the adaptor into a 110-volt wall outlet. Please be sure to use the correct polarity for the AC plug.

Battery
A 9-volt disposable battery is also provided with your unit. When the low-battery indicator appears, 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.

Note: Due to the high output of this device, the 9-volt battery will run out of power quickly. The 9-volt AC adaptor is the recommended power source.

Changing the Battery

When the low-battery indicator appears on the LCD panel, the battery should be replaced with a new 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.

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 low-battery indicator appears 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 5 seconds. Next, gradually turn the Amplitude Control Knobs clockwise until stimulation is felt. If device is still is not working, turn the unit off and contact BodyMed.

Troubleshooting

4. If the "hr" symbol is displayed when the unit is turned on, immediately turn the unit off. You may turn the unit back on once more and use normally if the "hr" symbol is not displayed. Do not hold down any keys when turning on the unit. Do not use the unit if the "hr" symbol is displayed. Contact your physician or licensed practitioner for more information.
5. If the "lock" symbol is displayed when the unit is turned on, this indicates that the unit has been locked by your physician or licensed practitioner. It can still be used, but treatment parameters cannot be changed. Please contact your physician or licensed practitioner to unlock the unit or change treatment parameters.

If any other problems occur, please consult or return the device to BodyMed. Do not 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
Carrier Frequency	4000 Hz fixed (CH1)
Modulating Frequency	4004-4160 Hz Adjustable (CH2)
IF Frequency Mode	Constant Mode: 4-160 bps, Adjustable Auto Sweep: 80 -145 bps, 4 - 45 bps, 4 - Set bps Frequency Shift: 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 returns to 30% below set
Output Configuration:	Quad polar (4 electrodes)
Wave Form:	Symmetrical balanced Sine wave
Interference Pulse Freq.:	4 - 160 bps, adjustable 4 bps/step
Pulse Duration:	125 µs maximum
Patient Compliance Meter:	Shows the treatment times in hours
Patient Lock System:	Prevents the user from changing any fixed parameters set by the physician or licensed practitioner
Timer:	15-, 30-minute
LCD:	Shows modes, bps rate, abrupt/ramp, timer and channels
Max. Charge per Pulse:	15 micro-coulombs maximum
Power Source:	9-volt AC adaptor, 500 mA or 9-volt battery (not recommended)
Dimension:	108 x 61.5 x 25 mm
Weight:	100 grams (without battery)
Tolerance:	+/-10%

Function Modes

Output Parameters: There are nine modes: five modes with Frequency Shift, three modes with Auto Sweep, and one mode that is fully adjustable.

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

Auto Sweep: Modulates 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 to 145 bps. The Sweep Time is 15 seconds and then repeats.

There are three modes of Auto Sweep:
1. 80 – 145 bps
2. 4 – 45 bps
3. 4 – SET bps

Frequency Shift: There are five modes:

1. 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).
2. 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).
3. 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).
4. 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).
5. 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).

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Made in Taiwan