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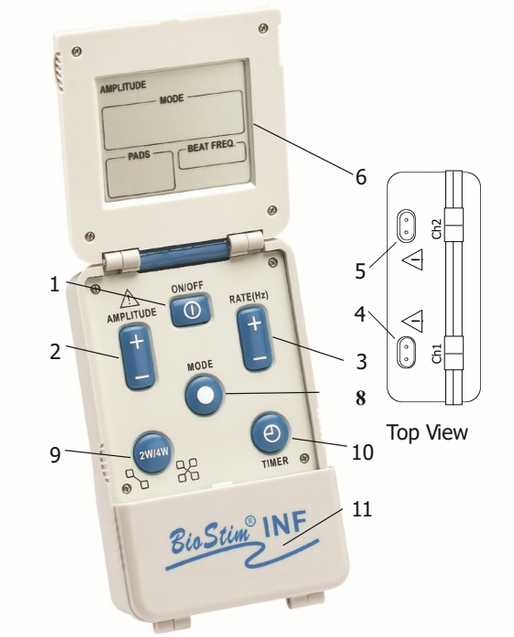

ACCESSORIES:

1. Electrodes
2. One set of lead wires
3. Four AA batteries or optional BioStim® wall adaptor.
4. One set of instruction

Only use accessories, electrodes, leadwires and batteries approved by BioMedical Life Systems, Inc.

SPECIFICATIONS:

Size	3.25" x 2.25" x 1 5/8" (82 mm x 70 mm x 45cm)
Weight	8 oz (226 grams)
Power Source	4 AA (L00083) batteries or optional BioStim® Wall Adaptor
Channels	Dual
Waveform	Premodulated Sine Wave
Carrier Frequency	4000 Hz, fixed
Interference Frequency	4001-4150 Hz, adjustable
Difference Frequency	1-150 beats per second, adjustable
Bipolar Stimulation	Channel 1
Pulse Width	125 microseconds for each phase

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Preset Sweeps	Continuous, 1-10 Hz over 6 seconds and 80-150 Hz over 8 seconds and 1-150 Hz over 10 seconds.
Output Voltage	0-33 Volts peak to peak
Output Current	0-66 milliamps peak to peak
Max. Charge per cycle	12.5 microcoulombs
Low Battery Indicators	Indicates when batteries are low
Electrodes / Lead Wires	2 Pair
Tolerances	+/- 1 %

(Data recorded across a 500 OHM load resistance)

Graphic Symbol Definitions

Refer to operating instructions

An IEC 601-1 safety standard instructions (type BF)

CE 0086

We herewith declare that the above-mentioned product meets the provisions of the Medical Device Directive.

Guidance and Manufacturer's declaration-electromagnetic emissions

This device is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.

Emissions Test	**Compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR11	Group 1	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.
RF Emission CISPR 11	Class B	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 for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/		
Flicker emissions IEC 61000-3-3	Complies	

This device was not tested for IMMUNITY to ELECTROMAGNETIC DISTURBANCES.

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Patients Safety Information

Caution:

Federal law (USA) restricts the sale by, or on the order of, a physician so licensed by the State. Keep out of reach of children.

Adverse Reactions:

Improper use of stimulation may result in skin irritation and burns beneath the electrodes.

Indications:

Interferential Stimulation is used for symptomatic relief and management of chronic pain and/or as an adjunctive treatment in the management of postsurgical and post-traumatic pain.

Contraindications:

Interferential Stimulation devices can affect the operation of demand-type cardiac pacemakers. Interferential Stimulation is not recommended for patients with known heart disease without a physician's evaluation of risk. Do not stimulate over eyes carotid sinus nerves. Do not apply Interferential Stimulation for 1. undiagnosed pain syndromes until etiology is established, 2. electrode placement that causes current to flow transcerebrally (through the head)

Warnings:

This device should be used only under the continued supervision of a physician. Interferential Stimulation is ineffective for pain of central origin (i.e. appendicitis, hepatitis). Interferential Stimulation is of no curative value; it is a symptomatic treatment which suppresses pain sensation which would otherwise serve as a protective mechanism on the outcome of clinical process. Safety of Interferential Stimulation devices for use during pregnancy or delivery has not been established. For external use only. Electronic equipment such as EKG monitors and EKG alarms may not operate properly when Interferential Stimulation is in use. The user must keep the device out of the reach of children.

Precautions:

Skin irritation may occur under electrodes in isolated cases following long-term application. Consult physician if skin irritation develops. The effectiveness of Interferential Stimulation directly depends upon patient selection. Do not immerse in water or other liquids.

EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE.

During use the surface of the BioStim® INF may get warm. This is normal, due to the high level of therapeutic power being produced. This unit fully complies with the requirement that under normal use the temperature never exceed that allowed by law.

General Information

BioMedical Life Systems, Inc.'s Model BioStim® INF offers the latest advances in Interferential Stimulation Treatment. Interferential Stimulation is different to that stimulation received from using TENS or NMS. In TENS and NMS stimulation, low frequencies or pulses per second are used over a wide area to achieve pain relief. Most stimulation is directly under the electrodes and radiates out. In

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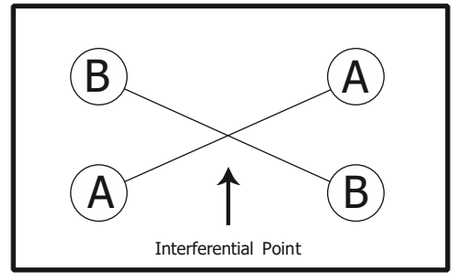
Interferential therapy, two medium frequencies of different cycles are used in such a way that they crisscross, delivering a low frequency at a specific point.



The Controls

The Model BioStim® INF has two types of frequency. One that is fixed at 4000 cycles per second and the other which is adjustable within the range 4001 to 4150 cycles per second. This in combination allows one to stimulate from 1 to 150 pulses per second, at a specific point.The BioStim® INF has two channels, can be used with two or four electrodes, and has four different stimulation patterns. At low levels of stimulation the BioStim® INF stimulates the sensory nerve cells that are used for pain relief.Be sure to follow the instructions of your health professional. If you do have questions or problems make sure you contact them for assistance. The (2) amplitude, (3) pulse rate, pulse width and the (8) mode selector operate independently of each other, but interact to give pain control which is unique to Interferential Stimulation. As individual pain syndromes differ, the controls are adjusted to a setting which gives optimal comfort and pain relief. There is no benefit to painful stimulation.

(2) The Amplitude: The amplitude controls the intensity and the depth of the pulse. The higher the amplitude, the higher the pulse peak and the stronger the pulse. If the electrodes are placed over scar or over adipose tissue, care should be taken that the amplitude is set at a level that is both effective for the patient's treatment and does not cause the patient any discomfort.

Pulse Width: The pulse width governs the width of the pulse. A comfortable sensation covering the injured area is the main purpose of the pulse width. The pulse width has been fixed (preset) in the BioStim®INF.

(3) Pulse Rate: The pulse rate controls the number of pulses emitted through the electrode to the skin.

The pulse rate is also referred to as:

1. Frequency
2. Cycles per second (c.p.s.)
3. Pulses per second (p.p.s.) A Hertz (Hz) is a unit of frequency equal to one pulse per second, e.g. 50 Hertz = 50 p.p.s.

Mode sectors

The (8) mode selector is used to alter the sequence of stimulation from a regular, conventional or continuous waveform, to an irregular one. The reasons for changing the waveform are to prevent accommodation to the stimulus and to provide alternative modes for the most effective patient treatment and comfort.

Mode 1 (C)

Continuous: No Change in Pulse Rate

Mode 2 (1/10)

Pulse Rate will modulate between 1 - 10 Hertz over a 6-second period. Used for edema and inflammation reduction.

Mode 3 (80/150)

Pulse Rate will modulate between 80 -150 Hertz over an 8-second period. Used for pain relief.

Mode 4 (1/150)

Pulse rate will modulate between 1-150 Hertz over a 10-second period.

Electrode Button

The (9) Electrode button determines the method in which the carrier and Interferential frequencies are mixed: externally (using 4 electrodes) or internally (using 2 electrodes [Channel 1 only]). Set the Electrode button in accordance to how many electrodes are being used.

Battery Cover

A hinged panel (11) covers the batteries to remove the cover, simply pull the cover slightly toward you. The (10) Timer button allows for a treatment period recommended by the health professional. When the button is pressed to a specific number, the BioStim® INF will operate for that period of time, shutting off automatically after the specified period of time. "0" on the button allows for continuous stimulation. The (6) Low Battery Indicator will flash battery symbols when battery power is low. To completely shut off the device, press down on the power button until the screen goes blank. To place batteries in the (11) battery compartment, slide panel down to expose compartment. Insert 4 AA batteries as indicated on the diagram inside the battery compartment. Be sure to observe the polarity directions imprinted in the battery compartment.

*Although it is not recommended, if you choose to use rechargeable Ni-Cad batteries, insert all AA Ni-Cads into an AA charger unit. Plug charger into standard 110 volt electrical outlet. Full charging will take 14 -16 hours.

Never attempt to recharge an alkaline or standard battery.

To maximize the peak efficiency of the Ni-Cad batteries, allow them to run all the way down before recharging. Never mix alkaline and Ni-Cad batteries.The (6) Low Battery Indicator will not illuminate during stimulation if batteries are fully charged. When the batteries need to be recharged (Ni-Cads) or replaced (alkaline), the battery indicator will show low battery power.

Patient and Clinician Guidelines

Step 1

Open the flip top (11) and insert batteries according to the battery diagram on the inside of the battery compartment and close the battery compartment.

- **A.** Flip open the main portion of the device to expose the screen and buttons.
- **B.** Press the on/off button to turn the device on.
- **C.** Set the (9) Electrode Button to the number of electrodes being used.
- **D.** Set the (8) Mode to the desired treatment. (If using Const. use the Rate Button to set desired beat frequency)
- **E.** The (10) Timer Button determines the length of your treatment. Move switch to the time your health professional prescribed.

Step 2

Attach lead wires to electrodes, and place electrodes firmly to your body as you were shown by the health professional.

WARNING: Lead Wires not for use with Apnea Monitors or Electrical Outlets.

Step 4

Insert input plug of lead wire into desired (4, 5) channel. When using two electrodes, (5) Channel 1 is used.

(In this mode, the Interferential Frequency is already pre-mixed inside the unit).

Step 5

If using Constant Stimulation, press the (3) rate button until the desired beat frequency is acheived. Keep the setting the same as your health professional has indicated.

Step 6

Once all desired settings are chosen, begin stimulation by pushing the (2) Amplitude button. You will see bars appear under the word "amplitude" on the top of the screen. You will start to feel the stimulation through the electrodes. Turn up to the desired strength that your health professional has indicated to you.

Step 7

The BioStim® INF is equipped with a belt clip that can be attached to a belt or waistband.

Step 8

At the end of the treatment:

- **A.** Turn off unit by pressing the on/off button.
- **B.** Unplug lead wires.
- **C.** Disconnect electrodes from lead wires.
- **D.** Store electrodes according to the directions on the electrode package.

Maintenance and Care

Alcohol is suitable for cleaning the device. NOTE: Do not smoke or work with open lights (for example, candles, etc.) when working with flammable liquids!

Stubborn stains and spots can be removed with a cleaning agent.

Do not submerge this device in any liquid or use excessive cleaning liquid when cleaning the surface area. If the device is not to be used for a long period of time, remove the battery from the battery compartment unless there is no risk of a SAFETY HAZARD arising (acid can leak from old and used batteries and damage the device). Batteries should be disposed of in the proper manner.

Warranty

LIMITED THREE-YEAR WARRANTY (U.S. Only)* BioMedical Life Systems, Inc. promises to the original consumer-purchaser to repair or, at the option of BioMedical Life Systems, Inc., to replace any neurostimulator which malfunctions or proves defective in materials or workmanship under normal use for a period of three years from the date of purchase. During the three years, BioMedical Life Systems, Inc. will provide all labor and parts necessary to correct such defects or malfunctions free of charge. It is the duty of the consumer-purchaser to deliver the unit to a service facility of the factory as described under service.

EXCLUSIONS

This warranty shall not apply to damage resulting from failure to follow the operating instructions in the user manual, accident, abuse, alteration, or disassembly by unauthorized personnel. This warranty does not extend to accessory items such as rechargeable batteries, electrodes, electrode leads, and conductive gel which are not an integral part of the stimulator. These items can be provided by your service representative, but costs for repair or replacement will be the responsibility of the consumer-purchaser. BioMedical Life Systems, Inc. shall not be liable for incidental or consequential damages resulting from the sale or use of the unit. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

WARNING

Only use accessories, electrodes, lead wires and batteries approved by BioMedical Life Systems, Inc.

NO OTHER WARRANTIES

This limited warranty is the only express warranty given by BioMedical Life Systems, Inc. Implied warranties, including, but not limited to, warranties of merchantability and fitness for a particular purpose are limited to the warranty period set forth above. Some states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you. This warranty gives you specific legal rights, and you may also have rights which vary from state to state. *For more detailed information on limited three-year warranty, please contact our Customer Service Department. Outside USA, please contact your distributor.

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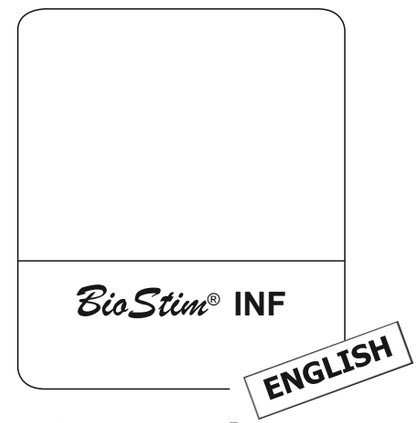
BIOMEDICAL LIFE • SYSTEMS

BioMedical Life Systems, Inc.

Interferential Device

BioStim® INF



Instructions

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