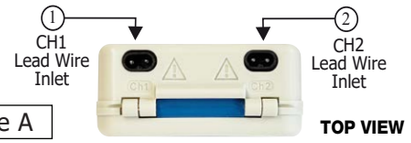
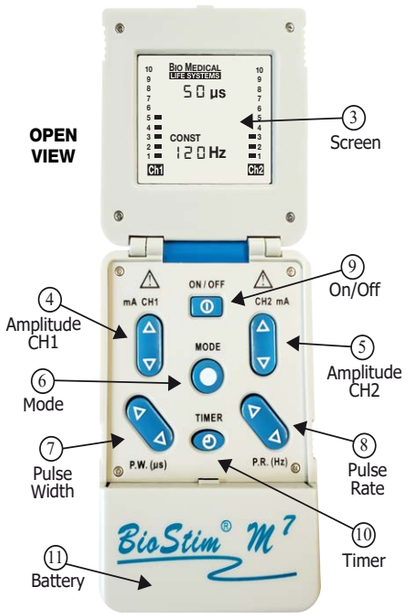


Figure A



Included Accessories

2 BMLS® touch proof lead wires
4 BioStim® electrodes
2 AA Batteries
1 Carrying pouch
1 Instruction maual

Optional Approved Accessories

- BMLS approved rechargable AA NiMH batteries
- BMLS approved battery charger for AA NiMH batteries
- Assorted Biostim® electrodes
- Bifurcated cable for adding additional electrodes

Specifications

Size	3.9" x 2.5" x 1.1"
Weight	3.25 oz.
Power Source	2 AA Batteries, Type LR6
Channels	Dual (2)
Waveform	Asymmetrical, biphasic square wave
Pulse Rate	1 - 200 Hz (Hertz or pps) adjustable

Pulse Width	10 - 250 microseconds (µs) adjustable
Modes	Continuous Pulse Rate Modulation Pulse Width Modulation Pulse Width & Rate Modulation Strength Duration 1 Strength Duration 2 Cycled Burst
Output	Constant current
Intensity	Continuously adjustable from 0- 98 mA zero to peak
Output Voltage	Continuously adjustable from 0-49 V zero to peak
Tolerances	+/- 10%

Output parameters are across a 500 ohm resistance

Graphic Symbol Definitions

Refer to operating instructions

Electronic waste should be disposed in the proper manner in accordance with local regulations.

Product Description

The BioStim® M7 is a portable dual channel transcutaneous electrical nerve stimulator (TENS). It utilizes small electrical currents affecting the nerves from sending pain signs to the brain so that pain is not perceived. It has been evaluated for pain relief effects of which has supportive evidence.

Patient Safety Information

Please read the following prescription information carefully before using the BioStim® M7. If you have any questions, consult with your clinician before proceeding.

Caution:
Federal law (USA) restricts the sale by, or on the order of, a physician licensed by the State.

Indications:
Only to be used under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions.

Applications:
Use for the relief from pain on targeted body parts.

Contraindications:
• Do not place electrodes and apply current to the carotid sinus (neck) regions.

• Do not use TENS on patients who have a demand-type cardiac pacemakers.

• Do not place electrodes in a manner that causes current to flow transcerebrally (through the head).

• Do not use TENS whenever pain syndromes are undiagnosed, until etiology is established.

Warnings:
• The safety of TENS during pregnancy, labor or delivery has not been established for either mother or fetus.

• TENS is not effective for pain of central origin. (This includes headaches)

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

• TENS devices have no curative value.

TENS is a symptomatic treatment and as such suppresses the sensation of pain which would otherwise serve as a protective mechanism.

• Kept out of reach of children.

• Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when TENS stimulation is in use.

Precautions:
• Isolated cases of skin irritation may occur at the site of electrode placement following long-term application.

• Effectiveness is highly dependent upon patient selection by a person qualified in the management of pain patients.

Adverse Reactions:
Improper use of stimulation or the use of non-approved BioMedical Life Systems (BMLS®) electrodes may result in skin irritation and/or burns.

Additional Concerns:
• TENS is not recommended for patients with known heart disease or cancer.

• Adequate precautions should be taken for persons with suspected or diagnosed epilepsy.

• Do not place electrodes across laryngeal and pharyngeal muscles (throat). Stimulation may be strong enough to close off the airway or cause difficulty in breathing.

• Never operate potentially dangerous machinery such as power saws, automobiles, etc. during stimulation.

• Do not use on swollen, infected or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis or varicose veins.

• Some patients may experience skin irritation hypersensitivity due to electrical stimulation or the electrical conductive medium used. Should this occur, remove the electrodes, discontinue stimulation and consult your clinician to determine the cause of irritation.

• Turn the stimulator off before applying or removing electrodes.

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

General Operating Instructions

Leadwire (1, 2) and electrode connection
Connection of the electrodes is made using the leadwires with each connector firmly placed into the device sockets. Then attach electrodes to leadwires.

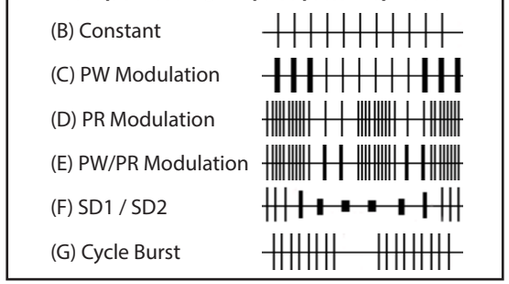
Power button (9) to turn on device
Similar Display Screen (3) will appear.

Pulse Rate P.R. button (8)
Set value by pressing (+) to increase or (-) to decrease as needed. Your selection will be displayed on the screen between 1 - 120Hz.

Pulse Width P.W. Dial (7)
Set value by pressing (+) to increase or (-) to decrease as needed. Selection will be displayed on the screen between 50-250µs. Higher P.W. will provide a more aggressive feel.

Mode button (6)
Select between 7 mode selections. All pre-programmed stimulation patterns can be adjusted for individual needs. Once a mode has been selected the mode will appear on the screen:

Unique BioStim® M7 pulse pattern by mode



- CONSTANT: (See Figure B)
- PULSE WIDTH MODULATION: 50% decrease over 6 seconds of the pulse width value, then back to its original value over 6 seconds. (See Figure C)
- PULSE RATE MODULATION: 50% decrease over 6 seconds of the pulse rate value, then back to its original value over 6 seconds.(See Figure D)
- PULSE WIDTH & RATE MODULATION: Pulse width and pulse rate alternately decrease and increase 45% of their set values over 6 seconds.(See Figure E)
- STRENGTH DURATION 1: As pulse width increases 40%, pulse rate decreases 45%, and amplitude decreases 10% over a 3 second period. Values return to original settings over the next 3 second period. (See Figure F)
- STRENGTH DURATION 2: As pulse width increases 60%, pulse rate decreases 90%, and amplitude decreases 13% over a 6 second period. Values return to original settings over the next 6 second period. (See Figure F)
- CYCLED BURST: 2.5 Seconds on/2.5 seconds off. (See Figure G)

Amplitude (4, 5)
Set the stimulation intensity by pressing the CH1 (4) and/or CH2 Intensity (5) buttons to increase (+) or decrease (-) to your own comfort level. Your selection will be displayed on either side of the screen. There are 20 levels of intensity available.

Timer (10)
Select the desired treatment time by pressing the timer button to continuous, 15, 30, or 60 minutes.

Battery (11)
In order to maintain the functional operation of the BioStim® M7 the batteries will have to be changed periodically. The device is supplied with 2 AA Alkaline batteries.

To change batteries:

- Before opening the battery compartment, check to make sure that the device is switched off (6).
- Open battery compartment (11).
- Gently insert batteries by matching the +/– end of each battery to the symbol found in the battery compartment.

Electrode Placement Guidelines

• Clean skin prior to placement of electrodes.

• Encircle the area of pain. The pads should never touch and should be at least, 2" apart.

• Do not to place directly over a joint such as the knee, elbow or ankle as movement can alter pad placement.

• When the pain is in a small area (e.g. calf pain): Place pads in parallel on each side of the pain.

• When the pain overlaps a joint (e.g. elbow pain): Place each pad on the muscle or soft tissue just above and below the joint in a horizontal and parallel direction.

• When the pain is wide (e.g. between your shoulders below the neck): Place the pads to the left and right side of your spine in a vertical direction.

• Place electrodes firmly to your body as you were shown by your healthcare professional.

Warning: Only electrodes and lead wires authorized by the device manufacturer should be used.

Treatment Guidelines

Step 1

A. Insert battery and close battery cover (11).

B. Set mode (6) as recommended by your health professional.

C. Adjust settings (P.R.(8) & P.W.(7)) as recommended by your health professional.

NOTE: Should a low frequency P.R. (5-20 Hz) TENS treatment not yield the desired result a high frequency TENS treatment

should be applied in the range of 100-150 Hz. If no P.W. recommendations are given, a pulse width setting of 50-100 µs are generally used.

D. Set the timer switch (10) to the desired treatment time.

Step 2
Attach lead wires to electrodes, and place electrodes firmly to your body as you were shown by your health professional.

Step 3
Insert lead wires into device outlet (1,2).

Step 4
Slowly increase intensity by pressing the "UP arrow" sign or decrease by pressing "DOWN arrow" on CH1 (4) and/or CH2 (5) amplitude buttons. Increase amplitude as high as possible without causing discomfort.

NOTE: The correct level of stimulation should feel comfortable to the patient and should never be set at levels that cause discomfort.

Step 5 (End of treatment)
A. Turn off device.
B. Unplug lead wires.
C. Disconnect electrodes from lead wires.
D. Store electrodes according to the instructions on the electrode package.

Patient Compliance Meter

PATIENT LOCK
The BioStim® M7 has a patient lock feature. When "turned on", this feature only allows the patient to adjust the intensity controls and timer. No other parameters (mode, pulse rate, pulse width) can be changed by the patient.

TURN ON
After the desired time has been selected, press the timer button (10) and the mode button (6) simultaneously. Hold both buttons until you see the clock diagram flashes on screen. The patient lock feature is now activated.

TURN OFF
Press the timer button (10) and the Mode Button (6) simultaneously. Hold both buttons until the clock diagram stops flashing. The patient lock feature is now deactivated.

PATIENT COMPLIANCE COUNTER
When turning off the patient lock feature, the amount of time the patient has used the device is displayed in the number of hours the device has been used will be displayed. Once 99 hours has been reached, a bar will appear next to the "1" on the left amplitude display. Each bar indicates 100 hours of use. A maximum of 1099 hours will be displayed.

CLEAR STORED HOURS
To clear the amount of usage hours stored, press and hold the CH1 "DOWN arrow" and CH2 "DOWN arrow" simultaneously. Continue to hold until the patient compliance meter resets to display 0 hours of use.

Device Maintenance

• Isopropyl alcohol is suitable for cleaning this device.

• Do not smoke or work with open flames when working with flammable liquids!

• 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.

• Remove the batteries for long term storage.

• Damaged or leaking batteries should be disposed of in the proper manner in accordance with local regulations.

• Use only BioMedical Life Systems, Inc. approved accessories and electrodes. Non-approved accessories and electrodes may damage your device and affect your warranty.

Warranty

LIMITED TWO-YEAR WARRANTY
BioMedical Life Systems, Inc. promises to the original consumer-purchaser to repair or replace, at the option of BioMedical Life Systems, Inc., any neurostimulator which malfunctions or proves defective in materials or workmanship under normal use for a warranty period from the date of purchase. During the warranty period, 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 with a receipt of purchase. For further instructions, please call 800-726-8367.

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 and leads wires 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.

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BioMedical Life Systems®

Manufactured for and Distributed by:

BioMedical Life Systems, Inc.

Transcutaneous Electrical Nerve Stimulator

BioStim® M7

Instructions

BIOSTIM® M7 3/18/22 REV. L