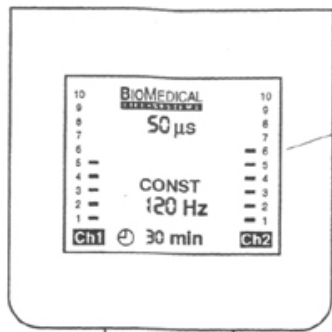


1

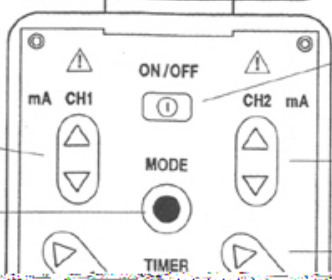
Figure A



3

4

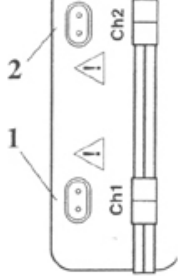
6



Top View

5

8



2

Strength  
Duration 1

Increase of set pulse width 40%, decrease of set pulse rate 45% and decrease of set amplitude 10% over a 3 second period. Values return to original settings over the next 3 second period. A full cycle is 6 seconds (See Figure F)

Strength  
Duration 2

Increase of set pulse width 60%, decrease of set pulse rate 90% and decrease of set amplitude 13% over 6 second period. Values return to original settings over the next 6 seconds. A full cycle is 12 seconds (See Figure F)

Cycled Burst

2.5 seconds on, 2.5 seconds off. Adjustable pulse rate from 1- 200Hz. Adjustable pulse width from 10-250 μs (see Figure G)

Electronic equipment such as ECG monitors and ECG alarms may not operate properly when TENS is in use. Using this device in proximity to any object that produces an electromagnetic current such as a microwave oven or cellular telephone could affect the performance of the device. The user must keep the device out of the reach of children. TENS is for external use only.

**Use of electrodes and accessories**

Electrodes used with the device should be no smaller than 3/4" in diameter. Please note that the smaller the size of the electrode used, the greater the intensity of stimulation at the electrode site which increases the likelihood of skin irritation at the site. Only BioMedical Life Systems authorized electrodes and accessories are to be used with this device. If you have any questions, please contact either your dealer/distributor or BioMedical Life Systems directly.

**Precautions**

Avoid adjusting controls while operating machinery or vehicles. Turn the stimulator off before applying or removing electrodes. Isolated cases of skin irritation may occur at the site of electrode placement following long-term application. Use only for the specific pain problem as prescribed by the physician, or outside the USA, by a qualified pain management specialist. Effectiveness is dependent upon patient selection by a qualified pain specialist.

**Adverse Reactions**

Possible allergic reaction to tape or gel. Possible skin irritation or electrode burn.

**Operating Instructions**

**General Description**

This device is a Transcutaneous Electrical Nerve Stimulator. One pair of electrodes can be connected to each output channel using the leadwires supplied. Stimulation pulses are transferred from the device through the leadwires to the electrodes. The intensity, duration, and number of pulses per second can be adjusted.

**Instructions for use**

- Attach leadwires to Channel 1 (CH1) and, if instructed by clinician, to Channel 2 (CH2). (1 and 2)
- Attach electrodes to leadwires following instructions on electrode packaging.
- Place electrodes on body as directed by clinician.
- Turn on device (9).
- Readout similar to (3) will appear on Display Screen.

**Programming a Stimulation Pattern**

• Select the desired stimulation pattern by pushing the Mode Button (6) until the desired stimulation pattern is displayed on the Screen (3). The patterns will appear in the following sequence:

- |               |   |                                       |
|---------------|---|---------------------------------------|
| CONST         | = | Constant                              |
| MODUL PW      | = | Pulse Width Modulation                |
| MODUL PR      | = | Pulse Rate Modulation                 |
| MODUL PW & PR | = | Pulse Width and Pulse Rate Modulation |
| SD 1          | = | Strength Duration 1                   |
| SD 2          | = | Strength Duration 2                   |
| BURST         | = | Cycled Burst                          |

Select the desired pre-programmed stimulation pattern by pushing the Mode Button (6) until the desired pattern is displayed on the screen (3).

The following pre-programmed and programmable stimulation patterns are available:

**Constant:** 120 Hz and 50 ms. (See Figure B)

**Pulse Width Modulation :** 120 Hz and 50µs. 50% decrease over 3 seconds of the Pulse Width (µs) value, then back to its original value over 3 seconds. (See Figure C)

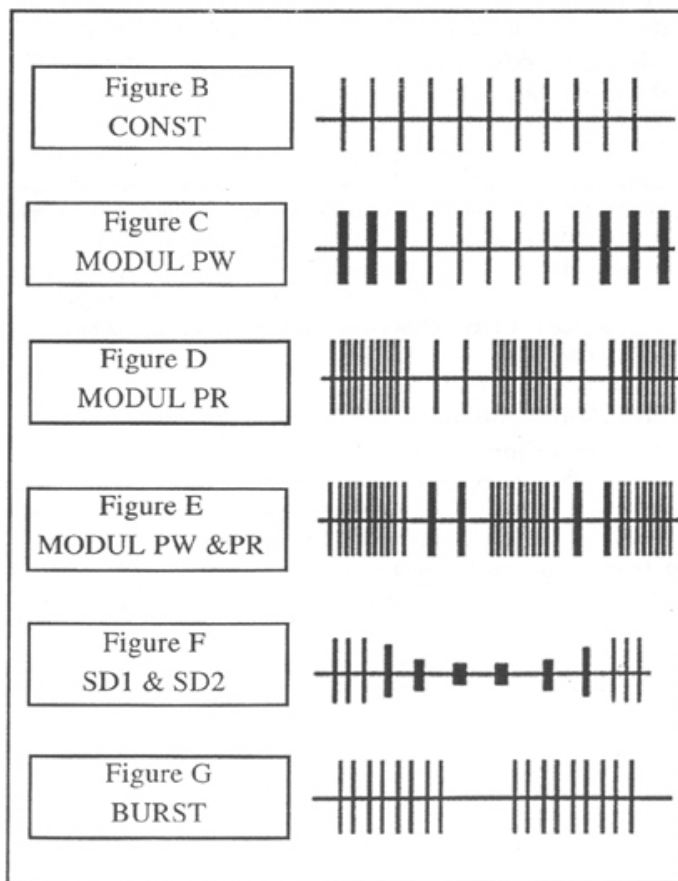
**Pulse Rate Modulation:** 120 Hz and 50µs. 50% decrease over 3 seconds of the Pulse Rate (Hz) value, then back to its original value over 3 seconds.(See Figure D)

**Pulse Width Modulation & Pulse Rate Modulation:** 120 Hz and 50 µs. Pulse Width (µs) and Pulse Rate (Hz) alternately decrease and increase 45% of their set values over 6 seconds.(See Figure E)

**Strength Duration 1:** 120 Hz and 50 µs. As Pulse Width (µs) increases 40%, Pulse Rate(Hz) decreases 45%, and Amplitude (mA) decreases 10% over a 3 second period. Values return to original settings over the next 3 second period. (See Figure F)

**Strength Duration 2:** 120 Hz and 50 µs. As Pulse Width (µs) increases 60%, Pulse Rate (Hz) decreases 90%, and Amplitude (mA) decreases 13% over a 6 second period. Values return to original settings over the next 6 second period. (See Figure F)

**Cycled Burst:** 120 Hz and 50 µs. 2.5 Seconds on/2.5 seconds off. (See Figure G)



## Programming

All pre-programmed stimulation patterns can be programmed for individual needs:

Increase or decrease the P.R. value by increasing the (+) or decreasing the (-) button (8). The P.R. is adjustable from 1-200 Hz in 5 Hz increments. Increase or decrease the P.W. value by increasing the (+) or decreasing (-) button (7). The P.W. is adjustable from 10-250 $\mu$ s in 10  $\mu$ s increments. Select the desired treatment time by pressing the Timer Button (10) until the desired treatment time is displayed; Continuous, 15, 30 and 60 minutes. When a treatment time (15, 30 or 60 minutes) has been selected, the device will count down the elapsed time and automatically turn off.

Increase or decrease the intensity of the device by pressing down the +/- for CH1 (4) or CH2 (5). There are 20 levels of intensity available.

If a new mode selection (6) is made during treatment, the intensity of the device automatically drops to Level 0.

To immediately turn off the device at any time press the On/Off (9) button.

After the treatment period, disconnect leadwires from device (1 & 2). Store electrodes as per instructions on electrode package. If the device is not going to be used for long periods of time the batteries should be removed (11).

### ■ Batteries

In order to maintain the functional operation of the BioStim<sup>®</sup> M<sup>7</sup> the batteries will have to be changed periodically. The device is supplied with 2 AA Alkaline batteries.

**Warning:** We do not recommend the use of rechargeable batteries, as they may weaken the performance and/or read-out of the device.

#### To change batteries:

- Before opening the battery compartment, check to make sure that the device is switched off (9).
- Slide the battery compartment cover (11) down.
- Remove the batteries (11) from the compartment. Gently insert the new batteries by matching the +/- end of each battery with the +/- symbol found inside the battery compartment.
- Replace the battery compartment cover and slide up to close.
- Remove the batteries if you do not plan to use the device for long periods of time. Otherwise leakage and damage to the device can occur.
- Dispose of batteries in a proper manner.

### ■ Recommendations for the Therapist

#### Tips for Skin Care

Skin should be cleaned prior to placement of the electrodes. If the electrodes do not contain gel, then gel should be applied directly to the skin prior to placement of the electrodes.

#### Electrode Placement Alternatives

- Place directly over the area from which the pain is emanating.
- Encircle the area of pain.
- Place proximally above the main nerve stem of the peripheral nerve responsible for the pain area.
- On specific points such as trigger points or acupuncture points.
- Place in the area of the pain site.

The treatment, when applied independently or in conjunction with medicinal therapy, should first be attempted with Low Frequency TENS treatment control settings.

A consistent application of approximately 2 Hz has been shown to produce effective stimulation.

The Amplitude and Width settings should be set as high as possible without causing discomfort. The treatment period should be at least 20 - 30 minutes as the pain-inhibiting effect only commences after approximately 15 - 20 minutes. In the most favorable case, treatment lasting thirty minutes could contribute to a reduction in the need for analgesics. This will, however, be dependent upon the seriousness of the patient's condition.

Should Low Frequency TENS treatment not yield the desired result, High Frequency TENS treatment should be applied as follows:

(High Frequency TENS Treatment) Frequencies are found in the range of 100 - 150 Hz. The pulse width settings are generally set between 10 - 100  $\mu$ s. However, the wide range of settings on this device allows the treatment to be customized to achieve optimal results for the patient.

The pain-inhibiting effect should commence within a few minutes. The treatment period should be between 20 - 30 minutes. In some cases, desensitizing must be carried out for several applications.

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

**Warning:** Only electrodes and leadwires authorized by the device manufacturer should be used.

## Safety and Technical Checks

Once a year, a maintenance check should be performed on the device as follows:

- Visually check the exterior case of the device for damage.
  - Visually check the input and output sockets for damage.
  - Visually check the device for clarity of reading instructions and indicator decals.
  - Visually check that the illumination of the LCD is operating correctly.
- Visually check the leadwires and electrodes for wear.

## Malfunctions

Should any malfunctions occur while using this device, check:

- whether the leadwires and electrodes are correctly connected to the device. The leadwires should be inserted firmly into the device sockets.
- whether the screen (LCD) is illuminated. If not, insert new batteries.
- for possible damage to the leadwires. Change the leadwires if any damage is detected.