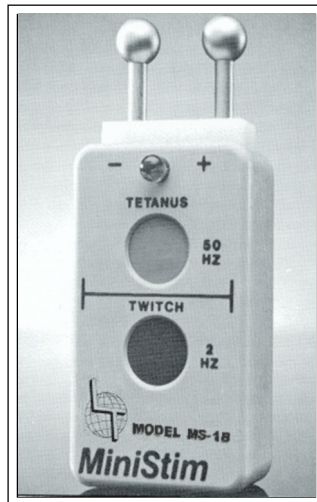


**NOTE: Warranty Information  
MUST Be Returned**



**MiniStim<sup>®</sup>**

**Peripheral Nerve Stimulator, Model MS-1B**

**INSTRUCTION MANUAL**



**Life-Tech<sup>®</sup>, Inc.**

4235 Greenbriar Dr. • Stafford, TX 77477-3995  
800-231-9841 • 281-491-6600 • Fax: 281-491-6646  
<http://www.life-tech.com>



# **OPERATING MANUAL**

## **MODEL MS-1B**

**MiniStim®**











**CAUTION:** FEDERAL (USA) LAW RESTRICTS  
THIS DEVICE TO SALE BY OR ON THE ORDER  
OF A PHYSICIAN.

M1042 Rev B

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## MEANING OF SYMBOLS

Your instrument may include symbols on the rear or front panel, the meaning for these symbols are listed below:

	Off
	On
	Danger, do not use in the presence of flammable anesthetics.
	Class II equipment
	Type B equipment
	Type BF equipment
	Dangerous voltage—refer servicing to qualified personnel.
	Attention—consult accompanying documents (Before connecting—read instructions).
	Protective Earth Ground
	Equipotentiality

## WARNING STATEMENTS

1. Caution Federal (USA) law restricts this device to sale by or on the order of a physician.
2. Never touch any exposed equipment metal surface and the patient at the same time.

## HOW TO STERILIZE REUSABLE PATIENT APPLIED PARTS

Never reuse or re-sterilize any patient applied part whose original package was labeled with **FOR ONE TIME USE, SINGLE USE, DISPOSE AFTER USE** or equivalent wording. When in doubt about whether a patient applied part can be re-sterilized, always consider it for one time use. The following sterilization procedure is intended for removable, reusable patient applied parts manufactured by Life-Tech (e.g., lead wires). For a product that is sold by Life-Tech but not manufactured by Life-Tech, refer to the sterilization procedures in that product's operating manual where appropriate.

**DO NOT STERILIZE THE INSTRUMENT.** To sterilize reusable patient applied parts manufactured by Life-Tech, follow these directions.

1. Place each part in a suitable vented sterilization pouch (e.g., with a Tyvak side or port). Include a sterility indicator designed for use with Ethylene Oxide and heat seal the package with a device specifically designed for this purpose.
2. Place the sealed packages in a sterilization chamber designed for 100% ethylene oxide gas. After loading the packages according to the sterilization chamber manufacturer's directions, close and secure the chamber door.

3. Evacuate the sterilization chamber to a pressure of 0.01 atmospheres (7.6 mm Hg.).
4. Fill the sterilization chamber with 100% ethylene oxide gas until the chamber pressure reaches 0.2 atmospheres (152 mm Hg).
5. Increase the sterilization chamber temperature to 48°C.
6. Maintain the sterilization chamber temperature at 48°C for 210 minutes (3.5 hours).
7. Reduce the sterilization chamber temperature to room temperature. Purge ethylene oxide from the sterilization chamber according to manufacturer's directions and local environmental regulations.
8. After sterilization, place the sealed packages in a quarantined, ventilated area away from human contact for at least two days to allow any residual ethylene oxide gas to disperse. Follow local environmental regulations in selecting the area and posting necessary cautionary statements.
9. Examine each sealed package's sterility indicator. Discard or re-sterilize any part if its sterility indicator is negative or the package is broken or opened. Store the sterilized packages in a cool, dry place.

Sterilization chamber conditions may be affected by age, lack of periodic re-calibration, metering errors or other problems. The effectiveness of the sterilization procedure with your specific equipment should be validated by an independent, accredited testing laboratory to certify sterility and package integrity after sterilization.

Check with a local accredited laboratory for further guidance. Never make the assumption that re-sterilized patient applied parts are sterile until sterility certification has been established. Life-Tech assumes no responsibility that this sterilization procedure for patient applied parts will be effective with your specific sterilization equipment.

Independent sterility certification by an accredited testing laboratory is the only validation method that can establish this level of confidence.

## PRECAUTIONS

Before using the instrument, please read these operating instructions carefully. Take special care to follow the warnings indicated on the instrument as well as safety suggestions below. Refer to this manual for additional information where appropriate.

### Safety

1. **Not Recommended** for use while operating Electro-surgical equipment.
2. **Danger:** Risk of explosion if used in the presence of flammable anesthetics.

### Environment

1. **Liquid and Moisture:** Do not situate unit where water can fall into the instrument.
2. **Heat:** The unit should be situated away from heat sources such as radiators and the like. It also should not be placed in temperatures less than 0°C (32°F) or greater than 45°C (113°F).

### Placement

1. **Foreign Material:** Care should be taken so that objects do not fall onto and liquids are not spilled into the instrument. Do not subject this instrument to excessive smoke, dust, mechanical vibration, or shock.

2. **Magnetism:** The instrument should be situated away from equipment or devices that generate strong magnetism.
3. **Stacking:** Do not place any heavy objects on top of the instrument.

### **Service**

1. **Damaging Requiring Service:** The unit should be serviced by qualified service personal when:
  - a. Objects have fallen onto or liquid has been spilled into the instrument; or
  - b. the instrument has been exposed to rain or moisture; or
  - c. the instrument does not appear to operate normally or exhibits a marked change in performance; or
  - d. the unit has been dropped, or the enclosure damaged.
2. **Servicing:** The user should not attempt to service the unit beyond that described in the Operating Manual unless directed by Life-Tech Service Personnel. All other servicing should be referred to qualified service personnel.

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# **SECTION 1**

## **GENERAL DESCRIPTION AND SPECIFICATIONS**

### **1.1 Introduction**

The MiniStim is a battery powered Peripheral Nerve Stimulator for monitoring the effects of skeletal muscle relaxants on the neuromuscular function.

MiniStim is a constant-voltage stimulator producing 0.20 millisecond square wave pulses with a maximum no-load output of 300 volts. The fixed stimulus voltage is adequate to ensure supramaximal subcutaneous stimulation of peripheral nerves in all but the most obese patients. Pulse delivery is indicated by flashing of the green LED.

Two push-button controls set the stimulus pulse rate at either 2 pulses per second (for Twitch or Train-of-Four), or 50 pulses per second for eliciting Tetanus.

## 1.2 Specifications

**Size (WXDXH):** 1.5" x 0.9" x 2.6" (3.8cm x 2.3cm x 6.6cm)

**Weight:** 3 oz (85gm) including battery

**Output Voltage:** 300V  $\pm$  30V (open circuit)

**Output Current:** 30 mA (2K ohms or less resistive load)

**Pulse Width:** 200 microseconds

**Pulse Risetime:** Less than 6 microseconds open circuit

**Twitch Pulse Frequency:** Two pulses per second

**Tetanus Pulse Frequency:** 50Hz

**Train-of-Four:** Hold Twitch down for four pulses

**Battery:** One 7.5 volt alkaline battery

## SECTION 2

### PANEL MARKINGS AND CONTROLS

The Ministim controls are illustrated in figure 2.1.

1. BATTERY ACCESS PLUG: Provides access to battery.
2. TWITCH/TRAIN-OF-FOUR PUSHBUTTON: Press and hold for Twitch or Train-of-Four stimulation. When using for Train-of-Four, release after fourth pulse.
3. TETANUS PUSHBUTTON: Press and hold for tetanus stimulation.
4. OUTPUT STIMULUS PULSE INDICATOR: Flashes green each time a stimulus pulse is delivered. This LED also serves as a low battery indicator. If the battery is low, you will see the LED - yellow in tetanus - green then red in twitch.
5. OUTPUT JACKS: Two output connectors on top of Ministim accept DP-MTP bipolar probe or EL-2MTP extension leads with alligator clips.

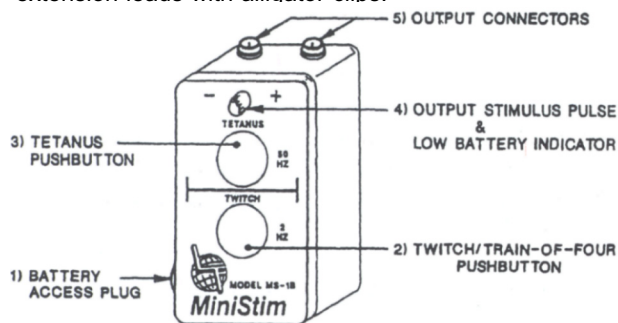


Figure 2.1: MS-1B Front Panel Controls

## SECTION 3

### OPERATING PROCEDURES

#### 3.1 General Precautions and Contraindications

**Explosive Atmospheres.** MiniStim is not intended for use in explosive atmospheres.

**Microshock Hazard.** In patients with pacemakers or cardiac abnormalities, the physician in charge of the patient must approve the use of the MiniStim.

**Battery Leakage.** If the unit is going to be stored for a prolonged period of time, we recommend that you remove the battery to protect the unit from damage caused by battery chemical leakage.

**Neuromuscular Disease.** Patients with symptoms of myasthenia gravis, Bell's palsy, muscle weakness, or paralysis may not respond normally to nerve stimulation.

**Skin Disease.** The electrodes should not be applied to an area of the skin where injury, inflammation or other pathology is present or suspected.

**Tetanic Stimulation.** The Twitch and Train-of-Four stimulus is usually well tolerated in awake patients; however, tetanic stimulation can be uncomfortable or fully conscious patients. It is recommended that tetanus stimulation be performed only after anesthesia.

**Needle Electrodes.** The Ministim is intended only for surface stimulation. DO NOT USE needle electrodes with Ministim or needle burns may occur.

**Nerve Location.** MiniStim is not intended for nerve location for regional block. The Tracer, EasyStim, and MaxiStim are specifically designed for this purpose.

### **3.2 Use of Surface Electrodes for Transcutaneous Stimulation**

1. *Cleaning the Skin.* Clean the skin with alcohol or skin cleaner, then wipe the skin dry.
2. *Location of the Electrodes.* The stimulating electrodes are usually placed on a motor point of the median or ulnar nerve at the wrist or on a motor point of the facial nerve. The negative electrode should be placed on the motor point, with the positive electrode nearby.

As shown in Figure 3.1, the median nerve motor point is located 10-20 mm proximal to the distal palmar crease between the tendons of the palmaris longus and the flexor carpi radialis; the ulnar nerve motorpoint is located 15-25 mm proximal to the pisiform bone on the thumb-side of the flexor carpi ulnaris tendon.

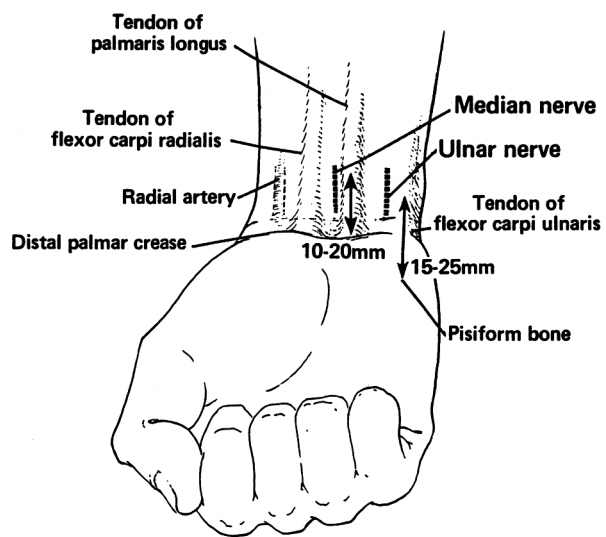
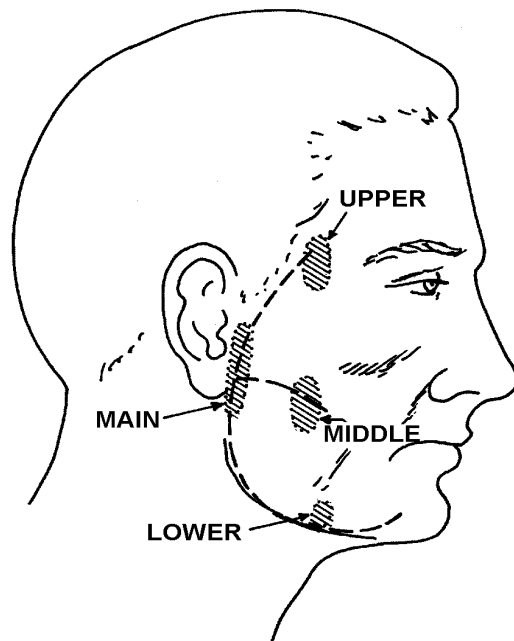


Figure 3.1: Wrist Motor Points



**Figure 3.2: Facial Motor Points**

As shown in Figure 3.2, the motor point for the upper branch of the facial nerve is located in the area behind the eyebrow; the motor point for the middle branch is located just below and behind the cheek bone, and the motor point for the lower branch (not generally used in muscle relaxant drug monitoring) is located on the ridge of the lower jaw at the submental

notch. The main submental motor point is located just anterior to the lower half of the pinna.

*Stimulation of the:*

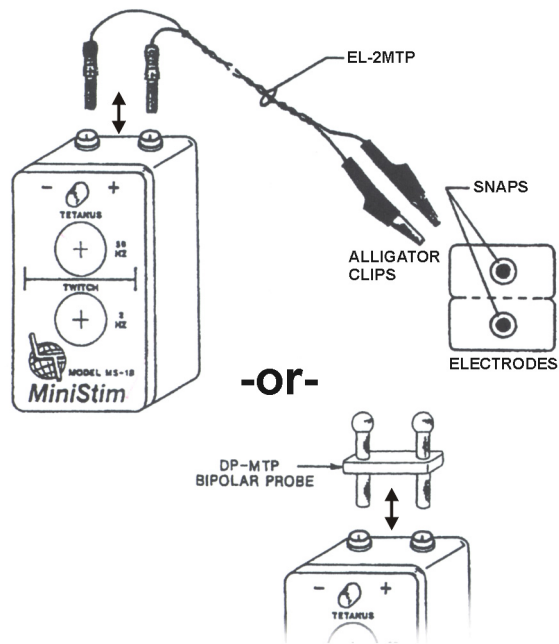
- *Upper branch* causes twitching of the eyebrow and eyelid.
- *Middle branch* causes twitching of the muscles lateral to and above the mouth.
- *Lower branch* causes twitching of the chin.
- *Main motor point* causes twitching of the facial muscles supplied by all branches of the facial nerve, but usually preferentially elicits twitching in the vicinity of the eyebrow.

If one of the branch motor points is used, care should be taken that the muscle twitch which is monitored is located some distance away from the stimulating (negative) electrode, to avoid the possibility of direct muscle stimulation.

3. *Attachment of Extension Leads and surface electrodes.* To use the MiniStim with the EL-2MTP extension lead and surface electrodes (Figure 3.3):
  - a. Remove the DP-MTP Bipolar Probe and insert the color coded connectors of the EL-2MTP into the connector jacks on the top panel of the MiniStim.
  - b. Then, open the alligator clip and place it around the snap on the electrode. Be sure to align the alligator clips so they do not touch each other, thereby shorting the output of the Stimulator.

### 3.3 Use of the DP-MTP Bipolar Probe

Remove the EL-2MTP leads (if attached) and insert the posts of the DP-MTP Bipolar Probe into the MiniStim output connectors. The Bipolar Probe can be used to perform transcutaneous stimulation without attachment of surface electrodes.



**Figure 3.3: Attachment of EL-2MTP Extension Leads or DP-MTP Bipolar Probe**

## SECTION 4 MAINTENANCE

### 4.1 General

Other than replacing the battery periodically and keeping the unit free of debris and contaminants, the Ministim requires no user maintenance, and is not user serviceable.

### 4.2 Battery Replacement

1. Using a coin or screwdriver, unscrew the Battery Access Plug (Figure 2.1).
2. Tap the unit gently against your palm to dislodge the battery into your hand.
3. Replace with a fresh battery taking care to match polarity signs located on the back of the Ministim.
4. Screw the Battery Access Plug back into the Ministim.

**NOTE: Please note that the battery supplied with this unit is an alkaline battery, therefore battery life will be approximately 1/3 of mercury batteries that were previously provided (discontinued due to environmental regulations) or an average of 8 months with normal use. We suggest spare batteries be available for each unit.**

### 4.3 Cleaning & Disinfection

#### To clean the Ministim:

1. Mix approximately a 1% solution of mild detergent (e.g., Ivory liquid) and water (10cc of detergent mixed with 1 liter of water).
2. Turn the unit off.

3. Dampen a clean, soft cloth with the fresh detergent solution and wipe to remove visible contaminants from the outside of the unit. **NEVER** pour or spray cleaning solution directly onto the unit, or submerge it in a solution.
4. Dampen another clean, soft cloth with sterile or distilled water and wipe to remove all residual detergent solution.
5. Dry thoroughly with another clean, dry cloth.

**To disinfect the Ministim:**

1. Leave the unit off.
2. Dampen a clean soft cloth with either 90% isopropyl alcohol, or any commercially available solution intended for surface disinfection of medical electrical equipment, and wipe the exterior surface thoroughly. If solution is in spray form, spray it onto the cloth. **NEVER** pour or spray disinfecting solution directly onto the unit, or submerge the unit in the solution.
3. Allow the solution to air dry for at least one minute, then dry thoroughly with another clean, dry cloth.

**SECTION 5**  
**ACCESSORIES AND**  
**SPARE PARTS**

<b>Extension Leads</b> Two-foot long paired leads with touch proof connectors at one end and alligator clips at the other	<b>EL-2MTP</b>
<b>Bipolar Probes</b> Paired ball probes	<b>DP-MTP</b>
<b>Carrying Case</b> Ministim vinyl case	<b>CC-M</b>
<b>Battery</b> Alkaline Battery	<b>H1000</b>

**SECTION 6**

**LIMITED WARRANTY**

**Refer to LIMITED WARRANTY card  
for complete information.**

