Warranty Information MUST Be Returned

MiniStim®
Peripheral Nerve Stimulator
OPERATOR'S MANUAL

Life-Tech®, Inc.
MEANING OF SYMBOLS

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

- **O** Off
- **I** On
- **Danger, do not use in the presence of flammable anesthetics.**

- **Type BF equipment**
- **Dangerous voltage - refer servicing to qualified personnel.**
- **Attention, consult accompanying documents (before connecting, read instructions).**
WARNING STATEMENTS

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
Declaration of Conformity

Standards to which conformity is declared: ISO 13485
EN80601-1, EN80601-1-2
Annex II
Classification: Class IIa

Manufacturer: Life-Tech, Inc.
Manufacturer's Address: 4235 Greenbrier Drive
                      Stafford, TX USA
                      77477-3995

Type of Equipment: Nerve Stimulator/Redirector Instrumentation & Accessories

Model Number(s): Trace III, EZselect, Minitim

Part Number(s): NL-3, E5400, MS-1B, MS-SVA, FC-1.5, NL-2-FC, TPTA-245, RDW-5, RBW-5L, RDW-SLBB,
                NS-9, FS-1, EL-6TP, EL-2MTF, SL-405, SL-605, BAS1, BA02, MD-4, MB-5, DP-MTP,
                                H1723, H1300, GS-M, SP9

I, the undersigned, hereby declare that the instrument specified above conforms to the Council Directive(s) specified above.

Stafford, Texas, USA

(Place)

31 July 2006

(Date)

Jeff Kasoff, RAC

(Signature)

(Full Name)

Director, Regulatory Affairs

(Title)

Under the supervision of:
SGS United Kingdom Ltd SSC
Weston Super Mare, UK
Nominated Body #6120
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>GENERAL DESCRIPTION AND SPECIFICATIONS</td>
<td>1</td>
</tr>
<tr>
<td>1.1 Introduction</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>1.2 Specifications</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>1.3 Sterilization of reusable Patient Applied Parts</td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>1.4 Precautions</td>
<td></td>
<td>6</td>
</tr>
<tr>
<td>1.5 Placement</td>
<td></td>
<td>7</td>
</tr>
<tr>
<td>1.6 Service</td>
<td></td>
<td>8</td>
</tr>
<tr>
<td>2.</td>
<td>PANEL MARKINGS AND CONTROLS</td>
<td>9</td>
</tr>
<tr>
<td>3.</td>
<td>OPERATING PROCEDURES</td>
<td>12</td>
</tr>
<tr>
<td>3.1 General Precautions and Contraindications</td>
<td></td>
<td>12</td>
</tr>
<tr>
<td>Figure</td>
<td>Description</td>
<td>Page</td>
</tr>
<tr>
<td>----------</td>
<td>--------------------------------------------------</td>
<td>------</td>
</tr>
<tr>
<td>Figure 2.1</td>
<td>MiniStim Front Panel Controls</td>
<td>9</td>
</tr>
<tr>
<td>Figure 3.1</td>
<td>Wrist Motor Points</td>
<td>15</td>
</tr>
<tr>
<td>Figure 3.2</td>
<td>Motor Points of the Facial Nerve</td>
<td>16</td>
</tr>
<tr>
<td>Figure 3.3</td>
<td>Output Connections to MiniStim</td>
<td>20</td>
</tr>
<tr>
<td>Figure 4.1</td>
<td>Battery Replacement</td>
<td>22</td>
</tr>
</tbody>
</table>
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. The Stimulus Amplitude Control dial provides variable current control (0 to 50 mA into a 2K ohm load). The maximum output is more than adequate to ensure supramaximal subcutaneous stimulation of peripheral nerves in all patients and supramaximal transcutaneous stimulation of peripheral nerves in all but the most obese patients.

The Output Stimulus Pulse Indicator flashes each time current passes through the patient. Conditions such as an open lead or electrode will prevent indicator from flashing to alert the operator. Five stimulus patterns can be generated: Train-of-Four, Double Burst, Twitch, and 50 Hz and 100 Hz Tetanus. Double Burst (3/3 pattern) and Train-of-Four stimuli groups are generated upon demand. The twitch is repeated automatically every second.
Pressing either the 50 Hz or 100 Hz keys overrides all other stimulus pattern with tetanic stimulus rates of either 50 or 100 pulses per second so long as the key is depressed.

The Power indicator lights while the unit is ON and flashes when the battery needs replacement.

The stimulator is certified to function properly in the presence of electrosurgery equipment and with electrosurgical procedures, providing that the electrosurgery site is at least 1 foot (30cm) from the stimulator patient lead connection point.

If your MiniStim fails to meet the following specifications, please contact Life-Tech or your local distributor for service. (EC Representative: FBI Fred Berninger Import)
1.2 Specifications

1.2.1 Size: 2.4"W x 4.2"L x 0.8" (6.1cm x 10.7cm x 2cm).

1.2.2 Weight: 5 oz (142 gm) including battery.

1.2.3 Maximum Output Voltage: 400V ± 10% (open circuit).

1.2.4 Output Current: Measured with load of 2K ohm (+/-10%):
   1) 0 to 50 mA @ 9.2 volts.
   2) 0 to 42 mA @ 7.5 volts (low battery alert threshold).

1.2.5 Pulse Width: 0.22 milliseconds.

1.2.6 Pulse Risetime: Less than 10 microseconds open circuit.

1.2.7 Twitch Pulse Frequency: One pulse per second; automatically repeated every second.

1.2.8 Train-of-Four Frequency: Two pulses per second for two seconds.
1.2.9 Double Burst Frequency: Each Double Burst stimulus consists of two groups of 3 pulses each. Within a group, the individual pulses are separated by 20 ms (50 Hz rate); the second group of three pulses follows the first after 750 ms.

1.2.10 Tetanus Pulse Frequency: Either 50 or 100 pulses per second.

1.2.11 Power On/Off: Press to turn unit On or Off. Indicator lights when unit is On and flashes when battery is ready to be replaced.

1.2.12 Battery: Standard nine volt alkaline battery provides adequate power for several months of operation. Replace when Power/Battery indicator flashes when On.
1.3 Sterilization of 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.

**DO NOT STERILIZE THE INSTRUMENT.**

Should sterilization of a reusable patient applied part be necessary then we recommend the use of a validated ethylene oxide process.
1.4 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. **Power Source:** Use only an Alkaline 9 volt battery.

2. **Danger:** Risk of explosion if used in the presence of flammable anesthetics.
1.5 Placement

1. **Electrosurgery**: Do not attach the stimulator patient leads within 1 foot (30cm) of an electrosurgical application point.

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

3. **Magnetism**: The instrument should be situated away from equipment or devices that generate strong electro-magnetic field.

4. **Stacking**: Do not place any heavy objects on top of the instrument.

5. **Heat**: The instrument 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).
1.6 Service

1. **Damage Requiring Service**: The instrument should be serviced by qualified service personal when:
   a. Objects have fallen or liquid has been spilled into the instrument.
   b. The instrument does not appear to operate normally or exhibits a marked change in performance.
   c. The instrument has been dropped, or the enclosure damaged.

2. **Servicing**: The user should not attempt to service the instrument beyond that described in the Operating Manual unless directed by Life-Tech Service Personnel. All other servicing should be referred to qualified service personnel.
SECTION 2 – PANEL MARKINGS AND CONTROLS

Figure 2.1 MiniStim Front Panel Controls
1. **Stimulus Amplitude Control Dial:** Rotate clockwise to increases stimulus current.

2. **Output Jacks:** Two Touchproof connectors for probes and leads. Red jack is (+) and black jack is (-).

3. **Output Stimulus Pulse/Open Lead Indicator:** Flashes with each delivered stimulus pulse (if current is being delivered). An open lead or electrode will prevent current from being delivered which will keep the indicator from flashing.

   **NOTE:**

   *If the Stimulus Amplitude Control Dial is set to 0, no stimulus current is delivered. Consequently the indicator will not flash.*

4. **Power/Battery Indicator:** Lights when unit is On, flashes when time to replace battery.

5. **On/Off key:** Press to turn unit On, press again to turn unit Off.
6. **50 HZ Key**: Press and hold for Tetanus at fifty pulses per second.
7. **100 HZ Key**: Press and hold for Tetanus at one hundred pulses per second.
8. **DBL BURST Key**: Press and release for double burst stimulation.
10. **Twitch Key**: Press and release for twitch stimulation. Unit automatically repeats twitch (one pulse per second) until turned Off or until either DBL BURST or TRAIN-OF-FOUR key is pressed.
11. **Battery Access Door (rear)**: Slide open to replace battery.
13. **Belt/Pocket Clip (rear)**: Use to attach instrument to clothing.
SECTION 3 – OPERATING PROCEDURES

3.1 General Precautions and Contraindications

3.1.1 **Explosive Atmospheres.** The Instrument is not intended for use in explosive atmospheres.

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

3.1.3 **Neuromuscular Disease.** Patients with symptoms of myasthenia gravis, Bell’s palsy, muscle weakness, or paralysis may not respond normally to nerve stimulation. The responses may be difficult or impossible to interpret relative to the state of muscle relaxation due to muscle relaxant drugs.

3.1.4 **Skin Disease.** The electrodes should not be applied to an area of the skin where injury, inflammation or other pathology is present or suspected.
3.1.5 Tetanic Stimulation. Tetanic stimulation can be uncomfortable for fully conscious patients. It is recommended that tetanus stimulation be performed only after anesthesia.

3.1.6 Needle Insertion. Insertion of a needle electrode for subcutaneous stimulation should be performed after adequate sedation. Needle electrodes should be placed in close proximity but not directly into the nerve.

This instrument is not intended for nerve location for regional block. The EZStim® and Tracer® are specifically designed for this purpose.

3.1.7 Needle Burns. When a needle electrode is used for subcutaneous stimulation, the small exposed conductive area of the needle can produce tissue burns if excessive stimulating current is used. Start with the Stimulus Amplitude Control dial set to 0 and slowly increase current as required.
3.2 Use of Surface Electrodes for Transcutaneous Stimulation

3.2.1 *Skin Preparation.* Skin should be cleaned (degreased) and dried prior to electrode application.

3.2.2 *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. Figure 3.1 shows the motor point locations at the wrist and Figure 3.2 shows the motor points of the facial nerve.
Figure 3.1 Wrist Motor Points

As shown, 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 motor point is located 15-25 mm proximal to the pisiform bone on the thumb-side of the flexor carpi ulnaris tendon.
Figure 3.2 Motor Points of the Facial Nerve

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 cheekbone, 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.
3.2.3 Attachment of Lead Wires to Surface Electrodes. Surface electrodes have a male snap on the top. To attach the EL-2MTP leads to the electrodes, open the electrode clip and place around the male snap on each electrode. Align the electrode clips so they do not touch each other thereby shorting out the stimulus. When using the optional, SL-40S or SL-60S Snap-On Connector Extension leads (Figure 3.3), simply press the female snap on the lead wire onto the male snap on the surface electrode.

**NOTE:**
The negative electrode is the active (stimulating) electrode. Therefore, the most effective stimulation is obtained when the black (negative) output connector of MiniStim is attached to the electrode placed distally along the nerve - i.e. at the location closest to the muscle.
The touch proof connectors on either the Model EL-2MTP, SL-40S, or SL-60S are inserted into the output connectors (Figure 2.1) on the top of MS-IVA.

3.3 Use of the DP-MTP Bipolar Probe

The DP-MTP Bipolar Probe plugs directly into the MiniStim Output Connectors (Figure 2.1). The Bipolar Probe can be used to perform transcutaneous stimulation without surface electrodes.

3.4 Use of Needle Electrodes for Subcutaneous Stimulation

MiniStim can be used for subcutaneous stimulation when necessary (e.g. excessively obese patient). When such a situation arises, insulated needles with compatible touch proof connectors are recommended.
CAUTIONS

1. Needle electrodes should be inserted in close proximity to, but not directly into the nerve.
2. Stimulus current required for subcutaneous stimulation is lower than with transcutaneous stimulation. Always set the Stimulus Amplitude Control dial to 0 and increase the stimulus intensity slowly until satisfactory response to stimulation is obtained.
3. The small exposed surface area of needle electrodes may produce tissue burns if excessive stimulus current is used.
4. This instrument is not intended for nerve location for regional blockade. The EZStim® and Tracer® are specifically designed to locate nerves for regional blockade.
Figure 3.3 Output Connections to MiniStim
SECTION 4 – MAINTENANCE

4.1 General
Other than replacing the battery periodically, this instrument requires no user maintenance.

4.2 Battery Replacement
Replace the 9 volt alkaline battery when the Power/Battery indicator flashes during use.

To replace the battery follow these steps:
1. Slide off the battery access door (Figure 4.1).
2. Remove the old battery.
3. Remove the battery snaps.
4. Align the battery snaps with the new battery leads.
5. Replace the battery snaps on the new battery.
6. Replace the new battery.
7. Slide the battery access door back into place.

Figure 4.1 Battery Replacement
<table>
<thead>
<tr>
<th>DESCRIPTION</th>
<th>PART NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extension Leads</td>
<td>EL-2MTP</td>
</tr>
<tr>
<td>Bipolar Probe</td>
<td>DP-MTP</td>
</tr>
</tbody>
</table>
SECTION 6 – LIMITED WARRANTY

Refer to LIMITED WARRANTY card for complete information.
Date of Delivery: ____________________