

# MICRO-Z MINI™ Operations Manual

Please read all instructions  
carefully before use

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

Manufactured for:



**PRIZM MEDICAL INC.**

P. O. Box 40  
Oakwood, GA 30566 USA  
Tel: (770) 622-0933



Rev. 8/2007 – P/N 0-61-MZMMAN-0-1

# TABLE OF CONTENTS

## Section

### 1.0 MICRO-Z MINI™ SYSTEM DESCRIPTION

### 2.0 PATIENT INFORMATION

- 2.1 Indication for Use
- 2.2 Contraindications
- 3.3 Warnings
- 3.4 Precautions
- 3.5 Adverse Effects

### 3.0 System Components, Device Components and Markings

### 4.0 INSTRUCTIONS FOR USE

- 4.1 Unpacking the Device
- 4.2 Electrode Placement
- 4.3 Powering the Device
- 4.4 Connecting the Lead Wires
- 4.5 Turning the Device On
- 4.6 Protocol Selection
- 4.7 Treatment Intensity
- 4.8 Powering the Device Off

### 5.0 SETTING CLINICIAN VALUES

- 5.1 Protocols
- 5.2 Clinician Value Details
- 5.3 Rate

### 6.0 BATTERY CARE-LOW BATTERY

- 6.1 Battery Care
- 6.2 Low Battery

### 7.0 CARE AND CLEANING

### 8.0 TROUBLE SHOOTING

- 8.1 Device Will Not Turn On
- 8.2 No Stimulation
- 8.3 Program Failure

### 9.0 HELPFUL HINTS

### 10.0 LIMITED WARRANTY

## 1.0 MICRO-Z MINI™ SYSTEM DESCRIPTION

The Micro-Z Mini™ is:

- ***A one channel transcutaneous electrical nerve stimulator and electrical neuromuscular stimulator*** that delivers a pulsed DC current with a monophasic waveform to the surface area of our garment electrodes to provide electrical stimulation where there is an indication for use.
- ***Microprocessor controlled***, allowing easy alteration of the treatment parameters and precise control of each setting.
- ***Designed for ease of patient use*** with clearly marked patient intensity buttons.
- ***Designed for stand-alone use or, when used with an external programmer, as a programmable device*** for a full variety of frequencies, time settings, and delivery schedules.
- ***Designed for use with our patented garment electrodes***; wearable electrodes that cover a large surface area providing total stimulation to the treatment area.

## 2.0 PATIENT INFORMATION

### 2.1 INDICATIONS FOR USE

#### 2.1.1 TENS

- Symptomatic relief and management of chronic intractable pain
- Adjunctive treatment for post-surgical and post-trauma acute pain

#### 2.1.2 NMES

- Relaxation of muscle spasm
- Prevention or retardation of disuse atrophy
- Increasing of local blood circulation
- Muscle reeducation
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Maintaining or increasing range of motion

***Electrical stimulation devices should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.***

## **2.2 CONTRAINDICATIONS**

### **2.2.1 TENS**

- Do not stimulate over the carotid sinus nerves, laryngeal or pharyngeal muscles (anterior throat area); severe spasm may occur causing contractions that may be strong enough to close the airway or cause difficulty in breathing.
- Do not use TENS device on undiagnosed pain symptoms until the etiology has been established.
- Do not place electrical current transcerebrally (through the head).
- Do not use TENS on patients wearing a demand type cardiac pacemaker.

### **2.2.2 NMES**

- Electrical stimulation devices are contraindicated for patients with cardiac demand pacemakers.
- Electric stimulation devices should not be used on cancer patients.

## **2.3 WARNINGS**

### **2.3.1 TENS**

- Safety has not been established for the use of electrical stimulation devices during pregnancy.

- TENS is not effective for pain of the central origin. (This includes headache.)
- TENS devices should be used only under the continued supervision of a physician or qualified professional.
- 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.
- Keep electrical stimulators out of the reach of children.
- Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when TENS stimulation is in use.

## **WARNINGS Continued**

### **2.3.2 NMES**

- Safety has not been established for the use of electrical stimulation devices during pregnancy.
- Long-term effects of chronic electrical stimulation are unknown.
- Precautions should be taken in the case of persons with suspected or diagnosed epilepsy.
- Precautions should be taken in the case of persons with suspected heart problems.
- Due to possible arrhythmia, do not place an

electrical stimulator across a patient's heart or transthoracically.

- Do not stimulate over the carotid sinus nerves; especially for patients with known sensitivity to the carotid sinus reflex.
- Severe spasm of the laryngeal or pharyngeal muscles may occur when electrodes are placed over the neck or mouth area. Contractions may be strong enough to close the airway or cause difficulty in breathing.
- Do not apply electrical stimulation transcranially.
- Do not use electrical stimulation over swollen, infected or inflamed areas, or skin eruptions such as phlebitis, thrombophlebitis, or varicose veins.
- Keep electrical stimulators out of the reach of children.

## **2.4 PRECAUTIONS**

### **2.4.1 TENS**

- 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.

## **PRECAUTIONS Continued**

### **2.4.2 NMES**

1. Precautions should be taken in the presence of:  
A tendency to hemorrhage following acute trauma or fracture
  - Recent surgical procedures when muscle contraction may disrupt the healing process.
  - A menstruating uterus.
  - Sensory nerve damage (loss of normal skin sensation).
2. Some patients experience skin irritation or hypersensitivity due to the conductive medium or electrical stimulation. This condition can usually be reduced by alternative electrode placement or use of additional or a different conductive medium.
3. Electrode placement and stimulation settings should be based on the guidance of the prescribing physician.
4. Powered muscle stimulators should be used only with the lead wires and electrodes recommended for use by the manufacturer.

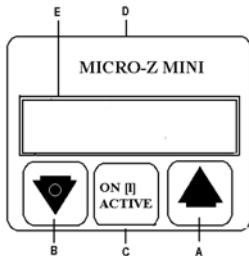
### **2.5 ADVERSE EFFECTS**

Skin irritation and burns beneath the electrodes have been reported from use of electrical stimulators.

### 3.0 SYSTEM COMPONENTS

#### DEVICE COMPONENTS AND MARKINGS

1. Micro-Z Mini™ Device
  2. Two (2) lead wires
    - One (1) red
    - One (1) black
  3. One (1) AAA Battery
  4. Velcro Arm / Leg Strap
  5. Conduct Mist™ or TheraCream™
- A. Intensity Control Increase  
B. Intensity Control Decrease  
C. On/Active Switch  
D. Micro-Z Mini™  
E. LCD Display



5



## **4.0 INSTRUCTIONS FOR USE**

### **4.1 Unpacking the Device**

Remove the Micro-Z Mini™ System Components from the packaging. Verify that all components listed in Section 3.0, System Components, are present. The garment electrodes and Conduct Mist™ spray may be packaged separately.

### **4.2 Electrode Placement** **WARNING!**

- Do not place an electrical stimulator across a patient's heart or transthoracically.
- Do not stimulate over the carotid sinus nerves.
- Severe spasm of the laryngeal or pharyngeal muscles may occur when electrodes are placed over the neck or mouth area. Contractions may be strong enough to close the airway or cause difficulty in breathing.
- Do not apply electrical stimulation transcranially.
- Do not use electrical stimulation over swollen, infected or inflamed areas, or skin eruptions such as phlebitis, thrombophlebitis, or varicose veins. Place electrodes according to prescribed treatment with the above cautions in mind. Follow all instructions for the electrode use.

### **4.3 Powering the Device**

The Micro-Z Mini™ is powered by one (1) AAA battery. Remove the battery compartment cover from the back of the device. Install the battery according to the illustration inside the battery compartment making certain the positive terminal of the battery aligns with the '+'. Replace the battery compartment cover.

### **4.4 Connecting the Lead wires**

The lead wires determine the polarity of the current and are coded accordingly; black is negative and red is positive. Connect the lead wire snaps to the Micro-z Mini™ by inserting the snap stud end into the inside position of the slot and sliding toward the outside position to lock in place. The red lead wire is placed on the right hand side and black on the left. Connect the garment electrodes to the lead wires by inserting the pin ends into the garment electrode.

### **Garment Electrode**

Please read the product insert accompanying the garment electrode. Connect the Silver-Thera™ or Electro-Mesh™ garment electrode to the lead wires using the female snaps.

## 4.5 Turning the Device On

The Micro-Z Mini™ is powered on by pressing and releasing the On [ ] / Active button for about 2 seconds until the display lights up with P1. Only the “P” will be flashing. The Unit should be connected to the garment electrodes and the garment should be worn at this point.

## 4.6 Protocol Selection

When the unit is powered on, select desired protocol P1 or P2 based on your clinician’s instructions (refer to Step 5 for more details). Protocol selection is made by repeatedly pressing the On [ ] / Active button until the desired Protocol is shown on the far left of the display, only the “P” will be flashing.

## 4.7 Treatment Intensity

Two buttons on the device control intensity **Increase** (▲) and **Decrease** (▼)

The intensity is always at five when the device is powered on or when the batteries have been removed and replaced.

Press the **Increase** button to set the protocol and intensity level. The “P” will stop flashing and as you continue to press the button, the intensity will increase and the LCD will display the numeric value. The intensity will

increase in increments of 5, up to the maximum intensity of 100. To decrease the intensity, press the **Decrease** (▼) button.

**Note:** The **Increase** and **Decrease** buttons lock out after 20 seconds of nonuse so that stimulation cannot be inadvertently changed during treatment.

To reactivate the intensity controls, press and release the **On** [ ] / **Active** button. Intensity controls will remain active for 20 seconds after the last button was pressed.

## 4.8 Powering the Device Off

The Micro-Z Mini™ will automatically power off when treatment is completed.

The Micro-Z Mini™ can be powered off manually at any time. To manually power off, press the On Active button for about 4 seconds and the device will turn off. Or you may press and hold the decrease button until the device reads 0, release it and press it again and the device will turn off.



## 5.0 SETTING CLINICIAN VALUES

### 5.1 Protocols

The Micro-Z Mini™ is factory programmed for two treatment protocols.

#### ***P1: Protocol One, 30 Minute Treatment,***

is a two-segment 30-minute treatment: Segment One runs 100 pps (Hz) for 15 minutes, Segment 2 runs 10 pps (Hz) for 15 minutes.

#### ***P2: Protocol Two, 8-Hour Treatment,***

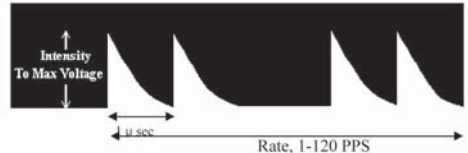
is an 8-hour routine that consists of 20 minutes of therapy followed by 40 minutes of rest every hour for 8 hours. The 20-minute treatment consists of 10 minutes at 80 pps (Hz) and 10 minutes at 8 pps (Hz).

After treatment P1 or P2 is complete, the Micro Z Mini™ will automatically turn itself off. Every 10 seconds during the protocol run the display will show time remaining in hours and minutes or minutes and seconds. During the Dwell time of protocol 2 (P2) the intensity setting will flash.

### 5.2 Clinician Value Details

The Micro-Z Mini™ can be programmed for

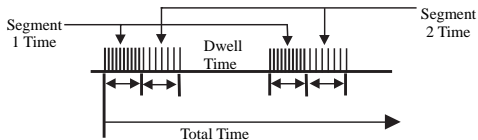
many different treatment protocols with the Prizm Medical Micro-Z Mini™ docking station to a PC. Check with your clinician or dealer for these options.



The Micro-Z Mini™ delivers a high voltage twin peak monophasic wave form. The maximum voltage as indicated on the packaging would coincide with the numeric intensity value on the LCD display  
Contact Prizm Medical, Inc.  
for additional information including ranges, accuracy and precision of the displayed intensity readings.

### 5.3 Rate

Rate selects the number of times the waveform repeats every second. Note that P1 is programmed at 100 pps for 15 minutes and



10 pps for 15 minutes for a total treatment of 30 minutes. P2 is programmed at 80 pps for 10 minutes and 8 pps for ten minutes totaling 20 minutes of treatment for each hour of the 8-hour routine.

## 6.0 Battery Care – Low Battery

### 1.1 Battery Care

The Micro-Z Mini™ uses one AAA battery. To replace the battery, open the battery compartment at the back of the device and insert a new battery. Be sure the '+' symbol on the battery lines up with the '+' symbol in the compartment.

### 6.2 Low Battery

When the battery is low, a battery symbol will flash on the far right of the display. Replace the battery at the first indication of low battery life. The device will turn off automatically if there is not enough voltage to sustain therapy.

## 7.0 CARE AND CLEANING

- Do not store the Micro-Z Mini™ with the battery installed. Battery acid causes irreparable damage, which is not covered by the warranty.
- When not in use, make certain the device is turned off.
- Turn the power off when cleaning the device. Do not immerse the device in liquid. Avoid spilling liquids on the Micro-Z Mini™.
- The surface of the Micro-Z Mini™ may be wiped with a soft cloth or sponge dampened with a mild soap solution. Avoid caustic cleansers.

## 8.0 TROUBLE-SHOOTING

### 8.1 Device will not turn on

- Check for proper battery installation
- Replace battery.

### 8.2 No Stimulation:

- Check lead wires for proper connection onto the device.
- Check for proper patient electrode application
- Apply conductive spray or cream to the area to be stimulated
- Check treatment time for expiration.

### **8.3 PROGRAM FAIL**

- Call your Micro-Z Mini™ dealer.

### **9.0 HELPFUL HINTS**

- Electrotherapy, like medications, should be dosed correctly. Too much stimulation does not equal better or more rapid results. Stimulate based on clinical goals.
- Patients with loss of sensory perception or insensate skin should not over-stimulate. Consult your physician, therapist, nurse or trainer, etc.
- Always prepare the skin correctly by washing it and removing all dirt, oils, and dead skin before applying electrodes.
- If the stimulation becomes uncomfortable, causing a stinging sensation, when using the Silver-Thera™ or Electro-Mesh™ garments during treatment, re-apply Conduct-Mist™ conductive spray or TheraCream™ over the treatment area.

### **10.0 LIMITED WARRANTY**

The Micro-Z Mini™ is warranted against defects in material and workmanship for one (1) year from the date of purchase. The manufacturer, at its sole discretion, will repair or replace at no charge, defective parts provided the device has been properly packaged and returned postage prepaid to the manufacturer. This warranty is rendered void if damage to the device results from mishandling, misuse, abuse, or if the device is disassembled. Furthermore, no warranty will apply to damage resulting from the customer's use of parts, fittings, or accessories not specified by the manufacturer, or from service or modifications performed by unauthorized personnel.

This warranty shall not apply to lead wires, electrodes, or batteries.

The manufacturer shall not be liable for incidental or consequential damages including loss of use, property damage, or to the extent allowed by law, personal injury that results from breach of warranty. This warranty is in lieu of all other warranties, expressed or implied, including warranties of merchantability and fitness for a particular purpose.

### **CAUTION**

Federal law restricts the device for sale by, or on the order of anyone other than a licensed physician or any other practitioner licensed by the law of the state in which he or she practices, to use or order the use of this device.

**CE**  
**0088**