INSTRUCTION MANUAL

Multi-Mode
STIMULATOR

SPECIFICATIONS	
Therapy Output Channels:	2 Therapy Channels
Therapy Output Modes:	True interferential and conventional muscle stimulation
Waveform:	Symmetrical biphasic square wave with zero net DC component
Carrier Frequency:	4000 Hz
Interference Frequency (IF):	4001 Hz to 4150 Hz
Net Interferential Frequency:	1 to 150 Hz verifiable
Output Voltage:	22.5 volts peak / 0 - 45 volts peak-to-peak, adjustable in 1/10 volt increments
Output Current:	0 - 45 milliamps, adjustable
Pulse Width:	125 micro seconds
Power System:	2 AA batteries OR optional AC adapter
Dimensions:	3.2” W x 4.8” L x 1.1” Thick (81mm W x 122mm L x 27mm Thick)
Weight:	6.0 oz. (167 grams) including batteries
Preset Therapy Protocols:	14 (10 Interferential Stimulation, 4 Muscle Stimulation)

PRECAUTIONARY NOTICES

This device is **ONLY** to be used by and for the benefit of the person to whom it was prescribed. Use by any other person is prohibited and could result in injury.

CAUTION: Federal Law (USA) restricts this device to sale by, or on the order of, a practitioner licensed by the state in which he or she practices to use or order the use of the device.

PLEASE READ THIS MANUAL BEFORE USE
Prior to use, please read and understand the contraindications, warnings, precautions and adverse effects relating to this device.

KEEP THIS DEVICE OUT OF THE REACH OF CHILDREN

Follow your physician's or therapist's instructions as to which therapy presets to use, electrode placement and suggested amplitude levels.

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PACKAGE CONTENTS

Qty. (1) Multi-Mode Stimulator
Qty. (1) Patient Lead Wire Assembly
Qty. (1) Patient Instruction Manual
Qty. (1) Electrodes
Qty. (4) AA Alkaline Batteries
Qty. (1) Carrying and Storage Case

Optional Accessory
Qty. (1) AC Wall Adapter

⚠ **WARNING** - Only use the supplied UL approved AC wall adapter. Use of any other type or brand of wall adapter may cause damage to the device.

⚠	**Please read this manual carefully to become familiar with the features, benefits, and operation of the Multi-Mode Stimulator before using it.**

INTRODUCTION TO ELECTROTHERAPY

True interferential stimulation produces a different stimulation frequency through each of two channels—a “carrier” frequency that is fixed or doesn’t change and an “interference” frequency that does change depending on the therapy protocol. When these two stimulation frequencies cross and “interfere” with each other within the body, the two frequencies subtract resulting in a third frequency, which is the therapeutic frequency “seen” by the targeted injury site. This phenomenon of subtracting two frequencies to create a third frequency is called “beating”.

The Multi-Mode Stimulator uses a carrier frequency of 4000Hz (hertz or cycles per second). At this frequency the skin impedance or resistance to the stimulation is at a minimum so that the stimulation is allowed to penetrate deeply without significant discomfort for the patient. Interferential stimulation is used to treat chronic and traumatic pain.

Depending on the pre-set therapy protocol selected, the interference frequency utilized by the Multi-Mode Stimulator may vary between 4001 to 4150Hz. The

sophisticated, advanced electronic engineering utilized in the construction of the Multi-Mode Stimulator produces a very precise and repeatable interference frequency. This results in accurate therapeutic frequencies at the targeted injury site.

Neuromuscular stimulation uses low frequencies to stimulate the contraction of muscles. This low frequency electrical current is similar to the electrical impulses produced by the brain to perform a contraction of muscles. Neuromuscular stimulation uses an electrical pulse generator (Multi-Mode Stimulator), lead wires and electrodes to bring the electrical current to an individual muscle or muscle group. A contraction and relaxation rhythm is created in the muscle which helps to relieve muscle spasms, re-educates muscles, advances range of motion and resumption of motor control, helps prevent or retard muscle atrophy from disuse and increase local blood circulation. The treatment is safe and after the initial newness of the tingling sensation from the electrical current, can even become relaxing for the patient. The length of contraction and relaxation periods is a matter for discussion with your physician or therapist. The amplitude or intensity of the treatment is patient controllable.

INTRODUCTION TO THE MULTI-MODE STIMULATOR

The Multi-Mode Stimulator is a high-quality, advanced technology medical device designed to be used as a combination interferential and muscle stimulator. The Multi-Mode Stimulator is battery powered or power can be supplied with an AC wall adapter. Current is generated and controlled by the Multi-Mode Stimulator circuitry using Texas Instruments® microprocessor chips. These chips provide the Multi-Mode Stimulator with the greatest degree of control and intelligence on the market today. The Multi-Mode Stimulator was designed for the homecare market and many of the Multi-Mode Stimulator features are the result of countless discussions with patients, physicians and therapists as to what they want and need in a clinic and home use electrotherapy device.

INDICATIONS FOR USE

Interferential Current Mode:

Symptomatic relief and management of chronic pain and/or as an adjunctive treatment for the management of post-surgical and post-traumatic pain.

Neuromuscular Stimulator Mode:

Relaxation of muscle spasm, increasing local blood circulation, maintaining and increasing range of motion, preventing or retarding disuse atrophy, muscle re-education, and immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.

CONTRAINDICATIONS

Cancer patients and anyone with a demand type cardiac pacemaker should not use the Multi-Mode Stimulator.

⚠ WARNINGS

1. The long-term effects of chronic electrical stimulation are unknown.
2. Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
3. Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur, and the contractions may be strong enough to close the airway or cause difficulty in breathing.
4. Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
5. Stimulation should not be applied transcerebrally.
6. Stimulation should not be applied over swollen, infected, or inflamed areas of skin eruptions, e.g. phlebitis, thrombophlebitis, varicose veins, etc.
7. Stimulation should not be applied over, or in proximity to cancerous lesions.
8. Stimulation should not be used whenever pain syndromes are undiagnosed until etiology is established.

PRECAUTIONS

1. The safety of electrical stimulation during pregnancy or delivery has not been established.
2. Caution should be used for patients with suspected or diagnosed heart problems or epilepsy.
3. **KEEP THIS DEVICE OUT OF THE REACH OF CHILDREN.**
4. Electrode placement and stimulation settings should be based on the guidance of a prescribing practitioner.
5. Precautions should be observed in the presence of the following:
   a. When there is a tendency to hemorrhage following acute trauma or fracture,
   b. Following surgical procedures when muscle contraction may disrupt the healing process,
   c. Over the menstruating or pregnant uterus,
   d. Where sensory nerve damage is present by a loss of normal skin sensation.

6. Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrically conductive medium. This irritation can usually be reduced by use of an alternate conductive gel.
7. Interferential stimulation is not effective on pain of central origin. This includes headache.
8. Interferential stimulation devices should only be used under the continued supervision of a physician.
9. Interferential stimulation devices have no curative value.
10. Interferential current therapy is a symptomatic treatment and as such suppresses the sensation of pain, which would otherwise serve as a protective mechanism.
11. Electronic monitoring equipment (such as ECG monitors and alarms) may not operate properly when interferential stimulation is in use.
12. Stimulus delivered by this device may be sufficient to cause electrocution. Electrical current of this magnitude must not flow through the thorax.
13. Effectiveness is highly dependent upon patient selection by a person qualified in the management of pain patients.
14. The Multi-Mode Stimulator should only be used with the patient lead wires provided with the device or original manufacturer replacement patient lead wires.
15. The Multi-Mode Stimulator should not be used while driving, operating machinery or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.

ADVERSE EFFECTS

1. Skin irritation and burns beneath the electrodes have been reported with the use of electrical stimulators.
2. Unusually high sensitivity to electrical stimulation may result in skin irritation and burns beneath the electrodes. If this occurs, discontinue use until the source has been determined and corrected.

ADDITIONAL FEATURES

Auto Shut-Off - To control the maximum treatment duration received by a patient, an automatic shut-off feature is incorporated into the Multi-Mode Stimulator. There are 20 and 30 minute time limits (depending on the selected preset) for each particular therapy duration. After the session timer reaches zero, the output amplitude of both channels is reduced to zero and the device remains in an idle state. After five minutes in an idle state, the device automatically shuts off to conserve battery power and prevent inadvertent operation.

Pause/Resume - The Multi-Mode Stimulator includes a pause and resume feature that allows the user to suspend or "pause" treatment to allow for the readjustment of electrodes or any external interruption such as a phone call. If the user wishes to pause treatment, simply press the PAUSE/OFF button once. The screen will display "PAUSED". When the user is ready to resume therapy, press the ENTER/ON button once and the previous therapy will resume where it left off with the exception that the amplitude (intensity) setting has been reset to zero for safety reasons. Increase the amplitude to the desired amplitude setting.

Amplitude Lockout - To prevent an accidental increase or decrease of the treatment amplitude (intensity), the Multi-Mode Stimulator has an intra-therapy amplitude lock feature. Sixty seconds after the last increase or decrease of the amplitude, the device will go into amplitude lock mode. If the device is in Amplitude Lockout mode and the user accidentally pushes the "+" or "-" buttons (increase or decrease amplitude) the LCD screen will display a message indicating the amplitude is locked. If the device is in Amplitude Lockout mode and the user wishes to increase or decrease the amplitude, they can press the ENTER/ON button to remove the amplitude lock and then increase or decrease the amplitude as desired.

Quick Start - If the Multi-Mode Stimulator is placed into Therapy Protocol Lockout mode the Quick Start feature will be activated. The Quick Start feature is the fastest and easiest way to start a therapy. Ask your healthcare professional to place the device into Therapy Protocol Lockout mode.

Multilingual - The Multi-Mode Stimulator's user interface (the information shown on the display) is available in three common languages: English, Spanish and French. To change the language (with the device on) hold down the ENTER/ON button and at the same time press the "+" button. Scroll through the languages and press the ENTER/ON button when the desired language is flashing.

PRE-SET THERAPY PROTOCOLS

Pre-set therapy protocols do not have variable adjustment parameters other than treatment amplitude (intensity). All functions are subject to treatment time.

Dual Therapy - Output base frequency for set dwell time, then abrupt jump to high frequency for set dwell time, then repeat. After treatment time reaches ½ total treatment time, smooth ramp from 80 or 100Hz to 150Hz over set sweep time, then back.

Ramp - Smooth ramp from base frequency to high frequency over set sweep time, then back.

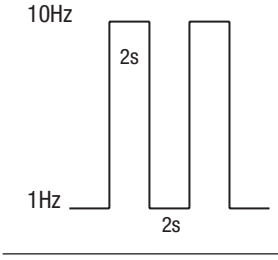
Abrupt - Output base frequency for set dwell time, then abrupt jump to high frequency for set dwell time, then abrupt drop to base frequency, repeat.

Relax and Contract Stimulation (muscle stimulation) - Relax = On for set dwell time at pre-set base frequency and zero amplitude (intensity), then Contract = fast amplitude ramp to amplitude (intensity) setting and maintain contraction for set dwell time at preset base frequency of 50Hz. Contraction indicated by asterisk on screen. The amplitude cannot be increased during the contract state.

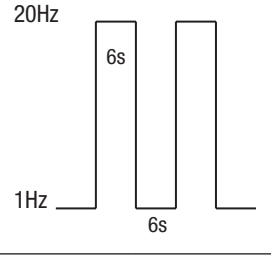
PRE-SET THERAPY PROTOCOLS

Protocol #	Function	Treatment Timer	Base Freq.	High Freq.	Dwell Time
Protocol 1	Abrupt 2/2	30 minutes	1 Hz	10 Hz	2 seconds
Protocol 2	Abrupt 6/6	30 minutes	1 Hz	20 Hz	6 seconds
Protocol 3	Abrupt 9/9	30 minutes	1 Hz	30 Hz	9 seconds

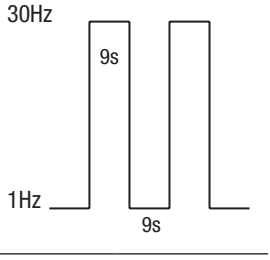
Protocol 1



Protocol 2



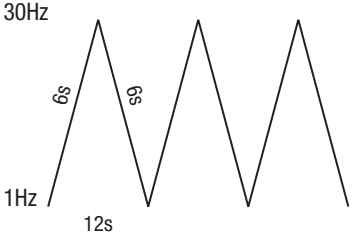
Protocol 3



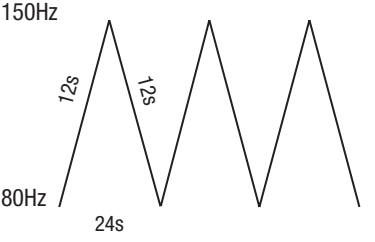
PRE-SET THERAPY PROTOCOLS *(Continued)*

Protocol #	Function	Treatment Timer	Base Freq.	High Freq.	Sweep Time
Protocol 4	Ramp 6 sec. “low”	30 minutes	1 Hz	30 Hz	6 seconds
Protocol 5	Ramp 12 sec. “high”	30 minutes	80 Hz	150 Hz	12 seconds

Protocol 4

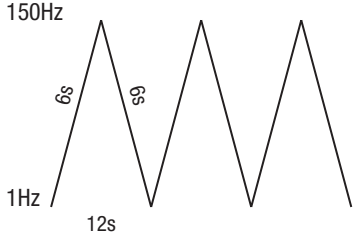


Protocol 5

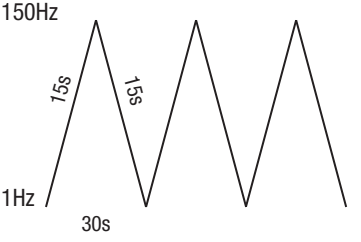


Protocol #	Function	Treatment Timer	Base Freq.	High Freq.	Sweep Time
Protocol 6	Full Sweep 6 seconds	30 minutes	1 Hz	150 Hz	6 seconds
Protocol 7	Full Sweep 15 seconds	30 minutes	1 Hz	150 Hz	15 seconds

Protocol 6



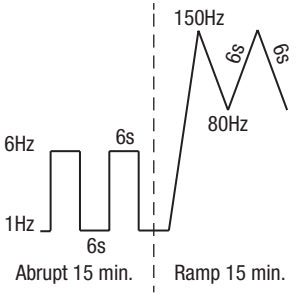
Protocol 7



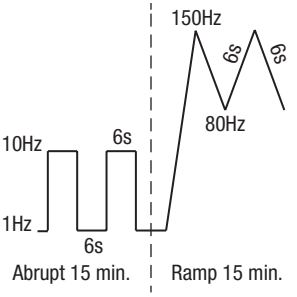
PRE-SET THERAPY PROTOCOLS *(Continued)*

Protocol #	Function	Treatment Timer	Base Freq.	High Freq.	Sweep or Dwell Time
Protocol 8 Dual LOW	Abrupt shift Ramped shift	15 minutes 15 minutes	1 Hz 80 Hz	6 Hz 150 Hz	6 seconds 6 seconds
Protocol 9 Dual MED	Abrupt shift Ramped shift	15 minutes 15 minutes	1 Hz 80 Hz	10 Hz 150 Hz	6 seconds 6 seconds
Protocol 10 Dual HIGH	Abrupt shift Ramped shift	15 minutes 15 minutes	10 Hz 100 Hz	20 Hz 150 Hz	6 seconds 6 seconds

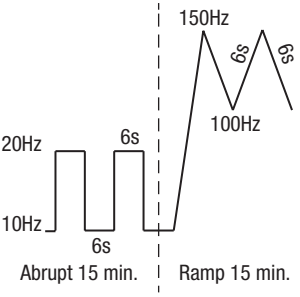
Protocol 8



Protocol 9



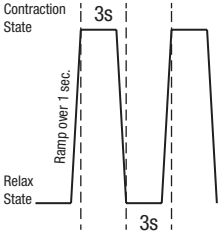
Protocol 10



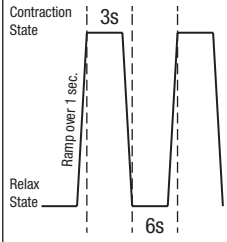
PRE-SET THERAPY PROTOCOLS *(Continued)*

Protocol #	Function	Treatment Timer	Base Freq.	High Freq.	Sweep or Dwell Time
Protocol 11	Muscle Simulation	20 minutes	50 Hz	50 Hz	3 sec. ON / 3 sec. OFF
Protocol 12	Muscle Simulation	20 minutes	50 Hz	50 Hz	3 sec. ON / 6 sec. OFF
Protocol 13	Muscle Simulation	20 minutes	50 Hz	50 Hz	6 sec. ON / 6 sec. OFF
Protocol 14	Muscle Simulation	20 minutes	50 Hz	50 Hz	5 sec. ON / 10 sec. OFF

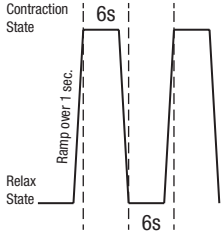
Protocol 11



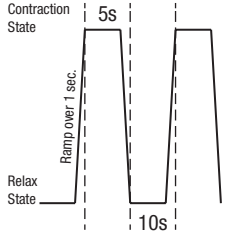
Protocol 12



Protocol 13



Protocol 14



All protocol illustrations are for reference and not to scale.

DEVICE CONTROLS

STOP	**STOP!** Do not use the Multi-Mode Stimulator until you have read the entire instruction manual, especially the warnings and precautions on *pages 5-6*.

STANDARD OPERATION INSTRUCTIONS

1. Begin by placing the electrodes on your skin at the treatment location. Follow your healthcare professional's instructions as to the correct placement of the electrodes. A successful and beneficial therapy session is highly dependent on the proper placement and attachment of the electrodes. Use care at this important step.
2. Make sure the stimulator is turned OFF. Connect the lead wires to the electrodes and connect the opposite end to the therapy cable connector on the top of the stimulator.
3. Turn the stimulator ON. In a few moments, you will see a screen asking you to make a therapy selection. Using the "+" and "-" buttons scroll through the protocols until you locate the desired therapy protocol.
4. Press ENTER to select the therapy protocol. The therapy has begun but the amplitude is set at zero. Increase the amplitude to the level recommended by your healthcare professional. Use the "+" or "-" buttons to adjust the amplitude to your desired level.

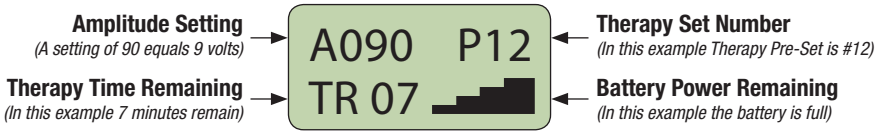
QUICK START INSTRUCTIONS

Note to user: your device must be placed in therapy lockout mode by your health-care professional before you can utilize the quick start feature.

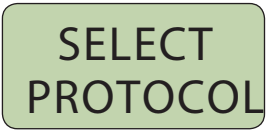
Begin by following steps 1 and 2 in the Standard Operation Instructions section. To use the device in Quick Start mode simply turn the device on by pressing the ENTER/ON button.

You will now see the therapy status screen displayed. Your therapy protocol has been pre-selected for you. Your therapy has begun. Use the "+" or "-" buttons to adjust the amplitude to the level recommended by your healthcare professional.

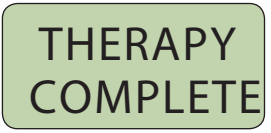
THERAPY STATUS SCREEN



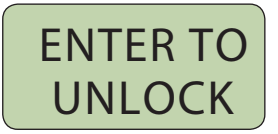
TYPICAL DISPLAY SCREENS



When this screen is displayed, scroll through the 14 preset therapy protocols and press the ENTER button to select.

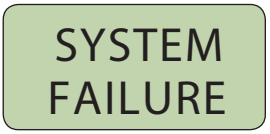


This screen will appear at the end of a therapy.



The two screens to the left will be displayed alternately when the amplitude is locked for safety reasons. Press ENTER to unlock the amplitude. When the amplitude is unlocked, it will be at the previous setting.

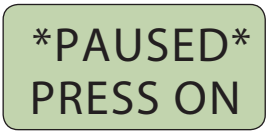
TYPICAL DISPLAY SCREENS *(Continued)*



This screen and the one below will both appear when the device operating system detects a fault.

Do not use the device if this screen appears.

This screen will appear when the batteries need to be replaced. Insert fresh batteries.



When the device is in the paused state, the two screens to the left will be displayed alternately. Press the ON button (ON/ENTER) to resume your therapy. When the therapy resumes the amplitude is set to zero for patient safety reasons.

TROUBLESHOOTING

PROBLEM	SOLUTION
Device Does Not Turn On	Remove old batteries and disconnect wall adapter. Wait 60 seconds to allow device electronics to power down. Install fresh batteries or re-connect wall adapter.
Device Turns On, but No Stimulation is Felt	***a.*** Check all therapy cable connections—both at the stimulator and electrodes. ***b.*** Remove and reattach electrodes. ***c.*** At a low amplitude wiggle the lead wires—if intermittent stimulation is felt the lead wires are defective. Please contact manufacturer for replacement lead wires.
Simulation Felt, but the Device is Off	Device is defective—DO NOT USE—please contact manufacturer for repair or replacement.

CARE AND MAINTENANCE

The Multi-Mode Stimulator is easy to maintain in top condition.
Follow the simple practices below:

- Clean the device by wiping gently with a damp cloth and mild soap
- Do not use any abrasive cleaners
- Do not immerse the device in water or other liquids
- Do not allow the device to be splashed with water or other liquids
- Do not drop the device or treat it roughly
- Store the device in the provided carrying case
- Remove the batteries from the device during storage

WARRANTY INFORMATION

Elite Medical Supply of NY warrants the Multi-Mode Stimulator against any defects in materials and workmanship for a period of one year from the date the device is entered into service but no longer than 15 months from the date of sale. Warranty does not cover accessories such as wall adapter or patient lead wires. Warranty does not cover batteries or electrodes as these are considered consumables.

CUSTOMER SERVICE

To obtain warranty service please call our customer service line at (866) 712-0881 and a customer service representative will assist you.

MANUFACTURER INFORMATION

Manufactured by Elite Medical Supply of NY, LLC
1900 Ridge Road
Suite #125
West Seneca, NY 14224
(866) 712-0881

For questions regarding proper use or to request more supplies, please contact Elite Medical Supply of NY at: (866) 712-0881

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