Sys*Stim® 240 Instruction Manual



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Section 1: Introduction

1.1 Introduction to the Sys*Stim 240

Thank you for purchasing the Sys*Stim 240 two-channel neuromuscular stimulator with optional light therapy capability. The technically advanced Sys*Stim 240 provides Interferential (4 pole), Premodulated (2 pole), Medium Frequency (Russian), Biphasic, High Volt Pulsed Galvanic, Microcurrent, TENS-Asymmetrical Biphasic, TENS-Symmetrical Biphasic and Galvanic (Continuous DC) waveforms.

New touch-sensitive technology has been used to make starting a treatment easy. The highresolution color display allows you to monitor all treatment parameters continuously. The patented M Wheel[™] provides easy navigation through all of the menus.



Figure 1.1— Sys*Stim 240

Treatment protocols complete with electrode placement guidance, allow you to quickly program treatment parameters for your patients. There is even space to save your own special treatment protocols for each waveform.

The Sys*Stim 240 has an optional battery pack so that you can take either electrical stimulation or light therapy to your patient. A carrying case is also available which holds the units and all the accessories necessary for therapy on the road.

The Sys*Stim 240 has been certified by Intertek Testing Services to meet the requirements for ETL Listing per the following standards:

- UL 60601-1 Standard for Safety Medical Electrical Equipment, Part 1: General Requirements for Safety.
- CSA C22.2.601.1 M90 Medical Electrical Equipment Part 1 General Requirements for Safety
- IEC / EN 60601-1 Standard for Safety Medical Electrical Equipment, Part 1: General Requirements for Safety
- IEC / EN 60601-2-10 Medical Electrical Equipment Part 2: Particular Requirements for the Safety of Nerve and Muscle Stimulators

- IEC / EN 60601-2-22 Medical Electrical Equipment Part 2-22: Particular Requirements for Safety and Essential Performance of Surgical, Cosmetic, Therapeutic and Diagnostic Laser Equipment
- IEC / EN 60825-1 Safety of Laser Products Part 1: Equipment Classification and Requirement
- IEC / EN 62471 Photobiological Safety of Lamps and Lamp Systems

In addition, the Sys*Stim 240 also meets the following standards for radio frequency emissions and immunity:

- IEC / EN 60601-1-2 Medical Electrical Equipment—Part 1-2: General Requirements for safety—Collateral Standard Electromagnetic Compatibility Requirements and Test
- FCC 47 CFR, FCC Sub Part 18 Industrial, Scientific and Medical (ISM) Equipment

Mettler Electronics Corp. has been certified by VTT Expert Services LTD to be compliant with EN ISO 13485:2003 and MDD 93/42/EEC Annex II requirements. In addition, Mettler is certified by DQS Medizinprodukte GMBH to be compliant with ISO 13485:2003 (CMDCAS) Canadian Medical Device requirements.

1.2 Introduction to This Manual

Read the contents of this manual before treating patients with the Sys*Stim 240.

This manual has been written to assist you with the safe operation of the Sys*Stim 240. It is intended for use by the owners and operators of the Sys*Stim 240. The goal of this manual is to direct the correct operation and maintenance of this unit.

The specifications and instructions presented in this manual are in effect at the time of its publication. These instructions may be updated at any time at the discretion of the manufacturer.

- The operating manual is required for safe use of the unit. If you lend or transfer the unit to another party such as a facility, be sure to provide this manual with the unit.
- Carefully read the Safety Precautions before operating the unit. Follow the precautions given.
- To prevent injury to the operator or patient or property damage, the manual uses the following terms and symbols to represent varying levels of danger. Make sure you understand what these symbols mean before reading the manual.



Improper handling may result in a high risk of death or serious injury.

Improper handling may result in a risk of death or serious injury.

Improper handling may result in injury or property damage.



Calls attention to Danger, Warning, or Caution items This particular symbol means "Electric Shock Hazard."

Indicates an action to be avoided.

This particular symbol means: "Do Not Disassemble."





Indicates a mandatory action.

This particular symbol means "Remove the plug from the power outlet."



1.3 Safety Precautions

(AWARNING)

The Sys*Stim 240 operates with high voltages. Qualified biomedical technicians with training in neuromuscular stimulator and light therapy service should perform servicing of the Sys*Stim 240 or it should be returned directly to the factory. To maximize safety during use, the unit should be plugged into a grounded wall outlet. General safety guidelines for medical electronic equipment should be followed.

Service may be obtained from the manufacturer by sending the Sys*Stim 240 in its original shipping container to Mettler Electronics Corp., 1333 South Claudina Street, Anaheim, CA 92805, ATTN: Service Department. (Telephone toll free: (800) 854–9305, *Alternate telephone number: 1* (714) 533–2221)

NOTE: All warranty repairs must be performed by Mettler Electronics Corp. or by a service facility authorized by Mettler Electronics to perform warranty repair work.

A service manual for the Sys*Stim 240 is available from Mettler Electronics Corp. for a nominal charge.

1.4 Caution



Rx only. Federal law restricts the sale of this device to, or on the order of a physician, dentist, veterinarian or any other practitioner licensed by law of the state in which he practices.

The electric energy delivered by this device may possibly be lethal. Treatment should be administered only under the direct supervision of a health care professional. The stimulus delivered by this device may be sufficient to cause electrocution. Electrical current above 25 μ C must not flow through the thorax because it may cause a cardiac arrhythmia.

If you choose to use either the optional cluster or laser applicator, use the protective glasses on both you and your patient to prevent eye exposure to infrared light.

1.5 Shipping Damage

Your new Sys*Stim 240 is shipped complete in one carton. Upon receipt, please inspect the carton and the unit for visible and hidden damage. If you discover any damage, hold all shipping materials, including the carton, and call the shipping agent who delivered the unit. **They are responsible for all damage in transit; therefore, all claims should be filed directly with them.** The factory will not be responsible for any damage in shipment, nor allow any adjustments unless proper formal claim has been filed by the receiver against the carrier.

The carton in which your new Sys*Stim 240 was received is specially designed to protect the unit during shipping. Please retain all shipping materials in the event that you will need to return your unit for servicing. NOTE: All warranty repairs are to be performed by Mettler Electronics Corp. or an authorized Mettler Electronics warranty repair center.

1.6 Package Contents

Your new Sys*Stim 240 comes complete with all the necessary components to perform neuromuscular electrical stimulation. Below is a list of items that are included in the shipping carton.

- 1. Sys*Stim 240
- 2. Two electrode cable sets, (ME 2260)
- 3. One package V Trodes, 2" diameter (ME 2702)
- 4. One package V Trodes, 2.75" diameter)ME2703)
- 5. Two pin to banana adapters, (ME 2027)
- 6. One patient safety switch, (ME 2403)
- 7. Detachable U.L. listed, hospital-grade line cord (ME 7293)
- 8. Instruction Manual on a CD ROM

1.7 Limited Warranty

The Sys*Stim 240 neuromuscular electrical stimulation with optional light therapy is warranted against defects in materials and workmanship for a period of two years from date of purchase. The Sys*Stim 240 cluster and laser applicators are warranted against defects in materials and workmanship for a period of one year from date of purchase. The battery is warranted against defects in materials and workmanship for a period of 90 days from date of purchase. During the applicable warranty period Mettler Electronics Corp. will, at its discretion, either repair or replace the Product without charge for these types of defects.

For service under this warranty, the Product must be returned by the buyer within the applicable warranty period to Mettler Electronics Corp. Shipping charges to Mettler Electronics Corp. under this warranty must be paid by the buyer. The buyer must also include a copy of the sales receipt or other proof of the date of purchase. If the Product is returned without proof of the date of purchase, it will be serviced as an out–of–warranty product at Mettler Electronics Corp.'s prevailing service rates.

Alteration, misuse, or neglect of the Product voids this warranty. Except as specifically set forth above, Mettler Electronics Corp. makes no warranties, express or implied, including without limitation any implied warranty of merchantability or fitness for a particular purpose, with respect to the Product. If any implied warranties apply as a matter of law, they are limited in duration to one year.

Mettler Electronics Corp. shall not be liable for any indirect, special, consequential or incidental damages resulting from any defect in or use of the Product.

Any legal action brought by the buyer relating to this warranty must be commenced within one year from the date any claim arises and must be brought only in the state or federal courts located in Orange County, California.

Some states do not allow limitations on how long an implied warranty lasts, or the exclusion or limitation of incidental or consequential damages, so the above limitations or exclusions may not apply to the buyer. This warranty gives the buyer specific legal rights, and the buyer may also have other rights which vary from state to state.

Section 2—Symbol Glossary, Control Descriptions and List of Abbreviations

2.1 Symbol Glossary



Stop all treatments selector

Start or pause a treatment



Enter control used to select an item.

Channel one selector

Channel two selector

Light (laser) therapy selector

Information selector

Interferential (4-pole) symbol

Select a preset protocol

Medium Frequency (Russian)

Biphasic



High Volt Pulsed Galvanic

Microcurrent

TENS-Symmetrical Biphasic

TENS-Asymmetrical Biphasic

Galvanic (Continuous DC)

Amplitude Modulation (Vector, Surge and Reciprocation)

Pulse width and frequency

Frequency Modulation

Polarity functions

Time

Output intensity

Laser applicator in use

Cluster applicator in use

No light therapy applicator installed

	5y3*5till 246 list detion Wandar (1601/25/1
	Enter passcode
\bigcirc	Begin or forward (not selected)
$\overline{\mathbf{e}}$	Begin or forward (selected)
G	Back (not selected)
C	Back (selected)
Θ	Time in status bar
\ominus	Output in status bar
\checkmark	Pencil electrode function active
	Battery status
Ð	Device plugged in and running on mains power supply.
	Info options
	System check being conducted
\sim	AC power
\triangle	Attention, consult instruction manual.
	Warning symbol indicates that the device emits laser energy and that proper precautions listed in this manual need to be taken.
$\mathbf{\dot{\star}}$	Type BF Equipment—Class I

 Mains On.

 Mains Off.

 Fuse rating symbol

 Patient safety switch symbol

 Recycle the rechargeable lithium ion battery.

 Rechargeable lithium ion battery.

 UL Recognized Component Mark

 FEC

 Tested to comply with FCC standards

 CE mark on battery

 ETL and C-ETL Listed

2.2 Control Descriptions

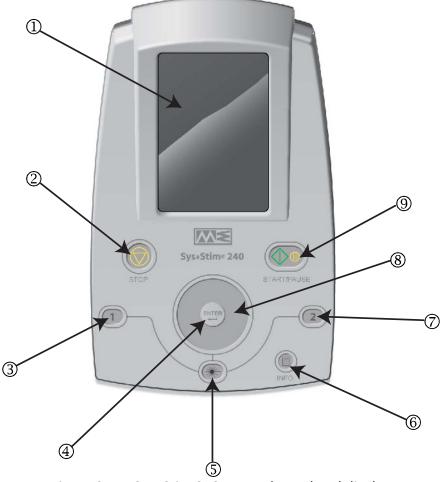


Figure 2.1— Sys*Stim 240, control panel and display

- 1. Back-lit LCD display
- 2. Stop all treatments button
- 3. Channel 1 selector button
- 4. Enter button
- 5. Light (Laser) selector button
- 6. Information selector button
- 7. Channel 2 selector button
- 8. M Wheel[™] rotary control dial
- 9. Start / Pause treatment button

2.3 Laser and Cluster Applicators – Controls, Output aperture and Indicators



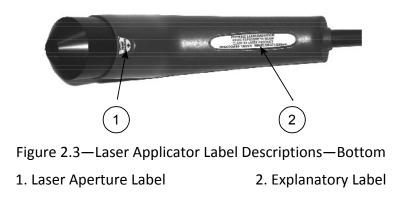
Figure 2.2— Laser Applicator Label Descriptions—Top

- 1. Laser Output Aperture
- 2. Aperture Warning Label
- 3. Laser On Indicator
- 4. "Laser Activate" Capacitance Switch
- 5. Increase Output Energy (repeat dosage)
- 6. Decrease Output Energy

Laser Warning Labels

The laser applicator has four warning labels; two of these labels are visible on figure 2.2. These two labels are the international Laser Hazard symbol which is located on the "Laser Activate" capacitance switch pad, and the other is the yellow Laser Aperture label which has an arrow pointing to the laser aperture at the front of the laser applicator.

The two other labels are shown in figure 2.3 below.



Laser On Indicator

The green Laser On indicator illuminates when the laser is lasing. When the laser beam is turned off after the treatment time has elapsed, the Laser On indicator will turn off.

Note: When the Sys*Stim 240 turned on, the Green Indicator will flash momentarily and you will hear a brief beep, this is normal and is provided as a start-up lamp test.

Please Note: When there is a problem with the laser applicator, the Laser On indicator will glow an amber color. The blue LEDs will not be illuminated, but it is possible that the laser diode will be active and therefore eye protection is still warranted. If the amber indicator light comes on and stays on when the capacitive switch is activated, return the laser applicator for service.

Laser Activate Capacitance Switch

The "Laser Activate" capacitance switch is located on the handle section of the laser applicator membrane. The capacitance switch works by measuring the practitioner's body capacitance across a sensing 'Pad'. The 'Pad' is a rectangular shaped area and has the words "Laser Activate" on it. By placing a finger or thumb over the 'Pad', the capacitance is increased and the switch is activated. The advantage is that it requires no force to actuate, and therefore reduces the strain a practitioner may experience holding down a mechanical switch for possibly long periods of time.

Increase/Decrease Output Energy Keys

The two membrane keys on the handle section of the applicator are used to increase or decrease the dosage energy. During the laser treatment, these keys are locked out so that the dosage cannot be accidentally increased.

2.4 L1	st of At	obreviations
AM	_	Amplitude Modulation (intensity is changed over time)
CC	—	Constant Current
CV	_	Constant Voltage
FM	—	Frequency Modulation (frequency is changed over time)
Hz	—	Hertz (pulses per second)
J	_	Joules
J/cm²	_	Joules per square centimeter
LCD	_	Liquid crystal display
μΑ	_	Microampere (1 x 10 ⁻⁶ ampere)
mA	_	Milliampere (1 x 10 ⁻³ ampere)
μs	_	Microsecond (1 x 10 ⁻⁶ second)
ms	_	Millisecond (1 x 10^{-3} second)
mm:ss	_	Minutes and seconds in timer
bps	_	Bursts per second
pps	_	Pulses per second
S	_	Seconds
Ser. No.	_	Serial Number
V	_	Volts
AC	_	Alternating Current

2.4 List of Abbreviations

Section 3—Installation

3.1 Installation Instructions

- 1. When installing the unit, pay attention to the following:
 - Install the unit beyond the reach of possible water splashes.
 - Install the unit where it will not be adversely affected by atmospheric pressure, temperature, humidity, sunlight, dust, ventilation, salt air, sulfur, or other such harmful substances.
 - Protect the unit against instability, vibration, or impact (including during transportation).
 - Do not leave the unit in locations with combustible airborne materials such as combustible anesthetic gases mixed with oxygen, nitrogen suboxide and air, or combustible disinfecting agents or cleaning agents mixed with air.
 - Do not install the unit where chemical products are stored or where gases may be emitted.
- 2. The Sys*Stim 240 may be susceptible to interference originating from shortwave diathermy units operating in close proximity to it. Avoid operating the Sys*Stim 240 adjacent to and simultaneously with operating shortwave devices.
- 3. If you have chosen the optional battery pack, install the battery as seen in Figures 3.1 and 3.2.
- 4. To install the optional battery first remove the power cord. Then, remove the screws located on the back panel of the Sys*Stim 240 on either side of the specification label using a Phillips screw driver, Figure 3.1.
- 5. Place the battery into the compartment as shown in Figure 3.2. Turn the unit upside down while installing the battery.
- 6. Close the battery compartment lid and reattach it by tightening the Phillips head screws.
- 7. Connect the line cord to the back of the Sys*Stim 240. (See Figure 3.3)
- Plug the line cord into a grounded wall outlet that is rated at 100-240 VAC 50/60 Hz. Your
 mains power supply must match the voltage requirements listed on the serial number label of
 your device. Do not connect the Sys*Stim 240 to a power supply rated differently than that
 described above.
- 9. The line cord comes equipped with a standard 3–prong plug. This plug provides grounding for the Sys*Stim 240. Do not defeat its purpose by using 3–to–2 prong adapters or any other means of attaching to a wall outlet.
- 10. If the optional battery is installed, it will begin charging as soon as the line cord is plugged into the wall and the Sys*Stim 240 is turned on using the switch on the back of the unit. The charging status will be displayed on the display. Full charging takes up to four hours. The unit may be used while it is charging.
- 11. Plug the electrode cables (ME 2260) into the electrode cable connections as seen in Figure 3.4.
- 12. If you have chosen to purchase either the optional laser or cluster kit, then install the applicator holders in Figure 3.5 on the side of the unit using the Phillips head screws included with the holders. Plug in the applicator into the front of the device as seen in Figure 3.6 and insert into the holder on the side of the unit. When using either the cluster or the laser

applicator, you must wear the protective glasses and instruct your patient to wear the glasses during treatment to prevent exposing the eyes to infrared energy.

- 13. Finally, plug the patient safety cable into the back of the unit as shown in Figure 3.3.
- 14. Once you have verified proper functioning of your Sys*Stim 240, using the instructions in Section 4, please go online to <u>www.mettlerelectronics.com</u> to register your product.
- 15. The optional battery pack may only be used in the Sys*Stim 240 or Sonicator 740. Do not attempt to use other batteries than Mettler part number ME7401. The batter is a lithium ion battery. Additional precautions for handling the optional battery include:
 - Do not store the Sys*Stim 240 for long periods with the battery installed.
 - Keep the Sys*Stim 240 plugged into the mains to assure full battery charge when needed.
 - Do not ship the Sys*Stim 240 with the battery installed.
 - Avoid shorting the battery
 - Do not immerse in water.
 - Do not disassemble or deform the battery
 - Do not expose the battery to fire.
 - Do not dispose of the battery in fire.
 - Avoid excessive physical shock or vibration.
 - Keep out of the reach of children.
 - Never use a battery that appears to have suffered abuse.
 - Lithium ion batteries are recyclable.
 - Regulations for disposal vary for different countries. Dispose of in accordance with local regulations.
 - Batteries are shipped with between 30% and 50% rated capacity and this provides a minimum of 90 days shelf life when stored at 25°C. If the temperature exceeds 25°C over this time then the shelf life will be reduced and provisions should be made to recharge the battery periodically.
 - In order to prevent parasitic drain on the battery, the electronics will go into a shutdown mode at 2.4±0.08V/parallel-cell-group. If this should happen, the battery pack will require an initial low charge to activate the electronics prior to the implementation of the normal charge. Any SMBus version 1.0, or higher, compatible charger is capable of providing this initial pre-charge.



Figure 3.1— Sys*Stim 240, Bottom View Showing battery door



Figure 3.2— Sys*Stim 240, Bottom View— Installing the battery



Figure 3.3— Sys*Stim 240, Back View Showing the On/Off Switch and Power Cord and Patient Safety Cable Connections



Figure 3.4— Sys*Stim 240, Side View Showing the Electrode Cable Connection



Figure 3.5— Sys*Stim 240, Side View Showing the Installation of the Applicator Holder



Figure 3.6— Sys*Stim 240, Front View Showing the Laser or Cluster Cable Connector

3.2 A Brief Operational Overview of the Sys*Stim 240

The Sys*Stim 240 has touch sensitive controls that include the patented M Wheel which is used to scroll through menu selections and increase or decrease treatment time, stimulation intensity or laser dosage. Below are listed some of the other features of the product.



- 1. Each menu item is color coded so that the clinician can determine the status of a particular menu item. A white background denotes an item that can be selected. A yellow background shows where the curser is. A dark blue background indicates that you have selected the item and now you can change its value. If a menu item is grayed out, it cannot be selected or edited.
- 2. Press either the Channel 1 or Channel 2 key to go to the Electrical Stimulation screen.
- 3. Press the Laser key to go to the Light Therapy screen.
- 4. Press the Info key to go to the Information menu.
- 5. Use the M Wheel to move through menu options or increase/decrease parameter values. Sliding your finger clockwise will move the cursor down or increase parameter values. Sliding you finger counterclockwise will move the cursor up or decrease parameter values.
- 6. Press the enter key to select a menu item.



STOP

- 7. Press the start/pause button to begin a treatment or the pause it in order to make changes to the electrode setup on your patient. You can also start a treatment by simply increasing the stimulation intensity.
- 8. Pressing the stop button will immediately stop all treatments that are running.

3.3 Optional Settings

The optional settings include language for all menus and setting the volume for the audio prompts made by the Sys*Stim 240.



- 1. Press the info key to enter into the information menu.
- 2. Use the M Wheel to scroll down to the Volume option and press enter.
- 3. Use the M Wheel to select the volume that you want and press enter. The sound you hear will increase or decrease as you look at the bar increasing or decreasing.
- 4. Press enter when the Back button is lit up to return to the information menu.
- 5. Use the M Wheel to scroll down to the Select Language option and press enter.



- 6. Use the M Wheel to scroll down to the Language you want for all of the menus and screens and press enter.
- 7. The new language will be set and you will return to the Information Menu.

3.4 EMC Guidance

<u>CAUTION</u>: Medical Electrical Equipment needs special precautions regarding Electromagnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the following tables.

Portable and mobile Radio Frequency (RF) communications equipment can affect Medical Electrical Equipment.

- Accessories: Hospital Medical grade power cord of a maximum length of 120 inches or 3 meters
- WARNING: The use of accessories, other than those specified, except those supplied or sold by Mettler Electronics Corp., Incorporated as replacement parts for internal or external components, may result in increased EMISSIONS or decreased IMMUNITY of the Sys*Stim 240.

Guidance and manufacturer's declaration – electromagnetic emissions				
•	The Sys*Stim 240 is intended for use in the electromagnetic environment specified below. The customer or the user of the Sys*Stim 240 should assure it is used in such an environment.			
Emissions Test	Compliance	Electromagnetic environment-guidance		
RF emissions CISPR 11	Group 1	The Sys*Stim 240 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be effected.		
RF emissions CISPR 11	Class A	The Sys*Stim 240 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies		
Harmonic emissions IEC 61000-3-2	Applicable	buildings used for domestic purposes.		
Voltage fluctuations/flicker emissions	Applicable			
IEC 61000-3-3				

Guidance and manufacturer's declaration – electromagnetic immunity

The Sys*Stim 240 is intended for use in the electromagnetic environment specified below. The customer or the user of the Sys*Stim 240 should assure that it is used in such an environment.

discharge (ESD) IEC 61000-4-2 ± 8 kV air ± 8 kV airor ceran covered relative least 30Electrical fast transient/burst ± 2 kV for power supply lines ± 2 kV for power supply linesMains p that of a hospital modeSurge IEC 61000-4-4 ± 1 kV for input/output lines ± 1 kV for input/output linesMains p that of a hospital modeSurge IEC 61000-4-5 ± 1 kV differential mode ± 1 kV differential mode ± 1 kV differential modeMains p that of a hospital modeVoltage dips, short interruptions and voltage variations on power supply input lines $<5\% U_T$ (595% dip in U_T) for 5 cycles $<5\% U_T$ (60% dip in U_T) for 5 cyclesMains p that of a hospital iof that the for 0.5 cycleIEC 61000-4-11 $70\% U_T$ (30% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 5 cyclesMains p that of a hospital interruptions and voltage $40\% U_T$ (50% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 5 seconds $70\% U_T$ (50% dip in U_T) for 5 secondsPower frequency ($50/60$ Hz) magnetic field 3 A/m 3 A/mPower f should to of a type relation or the should to of a type	Electromagnetic environment – guidance
transient/burstsupply linessupply linesthat of a hospitalIEC 61000-4-4±1 kV for input/output lines±1 kV for input/output lineshospitalSurge±1 kV differential±1 kV differentialMains pIEC 61000-4-5±1 kV common mode±2 kV common mode±2 kV common modehospitalVoltage dips, short<5% UT	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%.
IEC 61000-4-5modemodemodethat of a hospital $\pm 2 \text{ kV common}$ mode $\pm 2 \text{ kV common}$ mode $\pm 2 \text{ kV common}$ modethat of a hospitalVoltage dips, short interruptions and voltage variations on power supply input lines $<5\% U_T$ for 5 cycles $<5\% U_T$ for 5 cyclesMains p that of a hospital of the St continue for 5 cyclesIEC 61000-4-11 $(>95\% \text{ dip in } U_T)$ 	Mains power quality should be that of a typical commercial or hospital environment.
short(>95% dip in U_T)(>95% dip in U_T)that of a for 0.5 cycleinterruptionsfor 0.5 cyclefor 0.5 cyclehospitaland voltage $40\% U_T$ $40\% U_T$ $40\% U_T$ of the Secontinuevariations on(60% dip in U_T)for 5 cyclesof the Secontinuepower supplyfor 5 cyclesfor 5 cyclescontinueinput lines $70\% U_T$ $70\% U_T$ for a supply.IEC 61000-4-11 $70\% U_T$ (30% dip in U_T)for a supply.for 25 cyclesfor 25 cyclesfor 25 cycles $<5\% U_T$ $(>95\% dip in U_T)$ for 5 secondssupply.for 5 secondsfor 5 seconds $3 A/m$ Power f should to of a typiPower frequency $3 A/m$ $3 A/m$ Power f should to of a typi	Mains power quality should be that of a typical commercial or hospital environment.
(50/60 Hz) should be of a type common	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Sys*Stim 240 requires continued operation during power mains interruptions, it is needed that the Sys*Stim 240 be powered from an uninterruptible power supply.
	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity

The Sys*Stim 240 is intended for use in the electromagnetic environment specified below. The customer or the user of the Sys*Stim 240 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Complianc e level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Sys*Stim 240, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 GHz	3 V	<i>d</i> = 1.2 <i>VP</i>
Radiated RF	3 V/m	3 V/m	<i>d</i> = 1.2√ <i>P</i> 80MHz to 800 MHz
IEC 61000-4-3	80 MHz to 2.5 GHz		<i>d</i> = 2.3√ <i>P</i> 800MHz to 2.5 GHz
			where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in meters (m).
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b
			Interference may occur in the vicinity of equipment marked with the following symbol:
			(((•)))

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Sys*Stim 240 is used exceeds the applicable RF compliance level above, the Sys*Stim 240 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Sys*Stim 240.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Sys*Stim 240

The Sys*Stim 240 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Sys*Stim 240 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Sys*Stim 240 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter m			
W	150 kHz to 80 MHz <i>d</i> = 1.2√ <i>P</i>	80 MHz to 800 MHz d = 1.2√P	800 MHz to 2.5 GHz <i>d</i> = 2.3√ <i>P</i>	
0.01	0.12	0.12	0.23	
0.1	0.38	0.38	0.73	
1	1.2	1.2	2.3	
10	3.8	3.8	7.3	
100	12	12	23	

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer's declaration			
No.	Mode Of Operation	Essential Performance Degradation Allowed	
1	Unit tested to 230 VAC for CE	Unit designed to be failure safe in abnormal condition	
	Unit tested to 120 VAC for US/Canada		
2	Unit has two stimulation channels with optional Light therapy	Reset allowed as long as failure safe	

Section 4—Operating Instructions



Figure 4.1—Touch controls and Display

4.1 A Note about Electrodes

To ensure safe operation of the Sys*Stim 240, follow the recommendations listed below:

- 1. We strongly encourage careful maintenance of the electrode system. This includes the lead wires as well as the pads themselves. Worn cables and/or poor pads (or the wrong sized pads) can have a significant impact upon treatment results.
- 2. We recommend the use of Mettler electrodes with this product.
- 3. Do not exceed the number of recommended uses listed on the instructions for V Trodes, EZ Trodes or other reusable self–adhesive electrodes.
- 4. Make sure that the entire surface of the electrode is contacting the patient.
- 5. Do not use moist hot packs to secure electrodes.
- 6. To avoid skin irritation due to high current density, do not use electrodes smaller in surface area than the 2" in diameter V Trode or EZ Trode self-adhesive electrode (ME 2702).
- 7. Thoroughly moisten the sponge in sponge electrodes prior to using with tap water. The sponge should be moist. Squeeze out excess water from the sponge to prevent water from pooling around or between the electrodes. Secure sponge electrodes to the patient's skin with electrode straps.
- 8. Do not use conductive carbon electrodes with this product.

- 9. Do not use self-adhesive electrodes with the Direct Current mode. They will be rendered inoperable due to the ion flow of the direct current. Use sponge type electrodes with plain tap water moistening the sponges.
- 10. Whenever clinically possible, utilize the largest possible electrode to reduce local increases in current density. In situations where small pads are required, use the lowest stimulation intensity necessary to achieve the desired clinical results.

The table below illustrates the relationship between electrode diameter and current density. As you can see, the current density increases rapidly when diameter decreases.

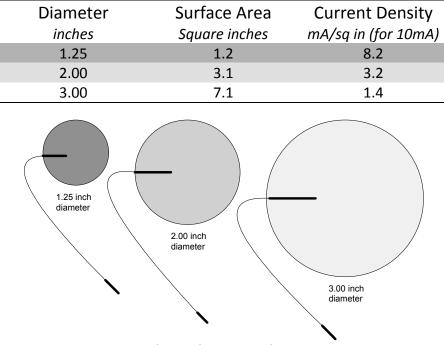


Figure 4.2—Electrode Sizes and Current Density

4.2 General Operating Instructions:

Before you start:

- a) Review precautions, contraindications and side effects/adverse reactions listed in Section 5.
- b) Use Mettler Electronics electrodes to ensure safe and effective operation.
- c) Verify connection of the line cord to a grounded wall receptacle and the Sys*Stim 240.
- d) For electrical stimulation, connect electrode cables (ME 2260) into the electrode connections for the channels that are going to be used.
- e) For waveforms that have polarity such as DC, microcurrent and high voltage, the redtipped electrode cable is the selected polarity. The black-tipped electrode cable is the opposite polarity.
- f) When the output current remains below the setting for a certain period of time, the setting may be automatically lowered. Check whether the electrodes are properly attached before using the Sys*Stim 240.
- g) Confirm that the attached electrodes are not touching before starting a treatment. If you attempt to turn up the output when electrodes are too close or touching an error message will appear, prompting you to adjust the electrodes.
- h) Note: Descriptions of the symbols used on controls are in Section 2.

4.3 Quick Set-up for Electrical Stimulation



- 1. Turn on the mains power switch located on the back of the unit by pressing dot on the switch to the "On" position. *Image shows switch in "Off" position.*
- 2. Press either "1" or "2" to select channel one or two. Please note that Interferential mode requires both channels.
- 3. Insert the electrode cable into the channel connector for the channel that you will be using.
- 4. Place the electrodes on the patient.
- 5. Insert the patient safety cable into the jack located on the back of the unit and hand the end with the button to the patient letting him/her know that they can push this button at any time during the treatment to stop it.
- 6. If all of the parameters are set correctly (*The default treatment mode is Interferential.*) press enter and then use the M Wheel by dragging your finger in a clockwise direction to adjust the intensity up. You will notice that if two channels are being used, they will go up simultaneously. The intensity in the digital display will go up and the green bar will get larger as the intensity increases. Moving your finger around the M Wheel in a counterclockwise direction will decrease the intensity. The time will begin to count down until the treatment is complete. A buzzer will sound and the end-of-treatment message will appear.

If you want to adjust just one channel in a 2-channel operation, drag your finger clockwise on the M Wheel and channel 1 will be highlighted and then channel 2. To select one to adjust, press enter and then adjust the intensity. If you press enter again, you can go to the other channel to adjust it independently.

7. These instructions are an overview of how to start a treatment quickly. For more details about each waveform, go to its specific instructions.

4.4 Set-up for Optional Light Therapy



- 1. Turn on the mains power switch located on the back of the unit by pressing dot on the switch to the "On" position. *Image shows switch in "Off" position.*
- 2. Please note: in order to perform light therapy you must purchase one of the following kits:

• 2405 Laser (785 nm, 80 mW) applicator kit: includes applicator holders (left and right), mounting hardware, and two pairs of protective glasses.

• 2406 Cluster (600/950 nm, 500 mW) applicator kit: includes applicator holders (left and right), mounting hardware, and two pairs of protective glasses.

• 2407 Applicator kit: includes the cluster (600/950 nm, 500 mW) and laser (785 nm, 80 mW) applicators along with applicator holders (left and right), mounting hardware, and two pairs of protective glasses.

- 3. To reduce the potential hazard associated with using the laser, two sets of protective glasses have been supplied in the kit with the applicator(s). It is strongly recommended that both the practitioner and the patient wear a set of these glasses during treatment when laser energy is being administered to prevent inadvertent exposure to laser light energy.
- 4. The laser energy emitted by this device is relatively low power but because it is in the low red/infrared region of the visible spectrum there is a potential hazard when using this device. Although the laser beam is divergent and not finely focused it is possible the laser energy can be a risk to the naked eye. The laser applicator should never be directed at the eyes of the patient or the practitioner, particularly during treatment.
- 5. Insert the cable from the cluster or the laser applicator into the connector located at the front of the Sys*Stim 240. You must plug in the applicator of your choice to proceed to the next step.
- 6. Press the button labeled with the symbol for light therapy. Use the M Wheel to increase the number to "01" and then press "Enter". Entering this code is a safety feature that prevents unauthorized use of the laser part of the Sys*Stim 240. If you have both applicators, you may switch them at any time. The Sys*Stim 240 will automatically recognize the type of applicator plugged in and will make the necessary adjustments.







Light Therapy

- Press enter to select "Dose". Adjust the time or dose using the M Wheel. Press the enter key to accept the dose value before proceeding to the next step.
- 8. Once the desired parameters have been set, the laser output can be initiated by placing a finger or thumb over the top of the "Laser Activate" pad on the laser treatment applicator. This pad is a capacitance switch which relies on the capacitance of the human body to sense when the practitioner wishes to operate the laser. Each time suitable contact is made over the pad a beep will sound. The glass surface of the applicator should touch the skin during treatment.
- 9. Some treatments require the same dosage of laser energy to be applied at several different points of the patient's body. Once the first treatment has been performed (treatment time counted down to zero, i.e.: Timer is 00:00) the same dosage can be achieved by pressing the Output "Up" button once on the Laser applicator (ensure your thumb is off the "Laser Activate" capacitance pad), the display will show the previous dosage energy and time. Once the laser applicator has been moved to the application point, the laser can be activated to deliver this dosage.
- 10. When treatment is complete, leave the message stating "Treatment Complete. Press Enter to Continue." Press "enter" only if you wish to do another light therapy treatment. You can also unplug the cluster or laser applicator at this time.

4.5 Using Preset Programs











- 1. Press the "Info" button.
- 2. You will get the screen to the right. Use the M Wheel to scroll to either "Electrical Stimulation", "Light Therapy" or "User Defined Protocol". Press "Enter" when you get to the one that you would like to use.
- 3. You may choose between anatomical or general protocols for electrical stimulation or light therapy. For electrical stimulation you may also choose a protocol by waveform type.
- 4. Each protocol will have a treatment diagram, some notes and the treatment parameters on one screen. If this is the one you want, you will press the "Enter" key to go to the treatment screen.
- 5. Once you get to the treatment screen, you can change any of the parameters shown. You would set up the patient for the protocol that you are using. For electrical stimulation follow the instructions in section 4.3. For light therapy follow the instructions in section 4.4.

4.6 Saving a Treatment Protocol

- 1. Either select stimulation or light therapy.
- 2. Setup the protocol that you would like to save into memory.
- 3. Press the "Info" button.
- 4. Scroll down to "Save Current Protocol" and press "Enter".
- 5. Scroll down to the channel that you have your protocol setup on or to "Light Therapy" and press "Enter".
- 6. A message box will indicate that "Save Current Protocol" Succeeded along with a number indicating the slot it was saved into. Press "Enter" to continue. There are ten slots for each waveform as well as one each for the cluster or laser applicator. The numbers are assigned in sequence.



4.7 Interferential (IFC, 4-Pole) Procedure















- 1. Turn on the mains power switch located on the back of the unit by pressing dot on the switch to the "On" position. *Image shows switch in "Off" position.*
- 2. Press either "1" or "2" to select channel one or two. Please note that Interferential mode requires both channels.
- 3. Insert the electrode cable into the channel connector for the channel that you will be using.
- 4. Place the electrodes on the patient.
- 5. Insert the patient safety cable into the jack located on the back of the unit and hand the end with the button to the patient letting him/her know that they can push this button at any time during the treatment to stop it.
- 6. Use the M Wheel to scroll to any of the parameters that you would like to change. The parameters and their ranges are listed here for your reference:

1	
Carrier frequency:	2500, 4000 or 5000 Hz
Interference frequency	0-250 Hz
Frequency Modulation:	Low set: 0-250 Hz
	High set: 0-250 Hz
Preset Frequency Sweeps	s: 1-15 Hz, 80-150 Hz, 1-150 Hz
Vector:	10%, 40% and 100%
Туре:	CC or CV

- 7. If all of the parameters are set correctly press "Enter" and then use the M Wheel by dragging your finger in a clockwise direction to adjust the intensity up. If two channels are being used, they will go up simultaneously. The intensity in the display will go up and the green bar will get larger as the intensity increases. Moving your finger around the M Wheel in a counterclockwise direction will decrease the intensity. The time will begin to count down until the treatment is complete. A buzzer will sound and the end-oftreatment message will appear. *Please note:* If you change time during a treatment, press "Enter" once the time is entered to restart the timer at the new time. The time will then count down from the newly entered time. Failure to do this will cause the treatment to go on indefinitely.
- 8. Notes: Once you finish turning up the intensity, "Restarting" will appear to indicate that the vector program is starting.

4.8 Premodulated (IFC, 2-Pole) Procedure



ENTER



- 1. Turn on the mains power switch located on the back of the unit by pressing dot on the switch to the "On" position. Image shows switch in "Off" position.
- 2. Press either "1" or "2" to select channel one or two. Please note that Reciprocation requires 2 channels.
- 3. Insert the electrode cable into the channel connector for the channel that you will be using.
- 4. Place the electrodes on the patient.
- 5. Insert the patient safety cable into the jack located on the back of the unit and hand the end with the button to the patient letting him/her know that they can push this button at any time during the treatment to stop it.
- 6. Use the M Wheel to scroll to any of the parameters that you would like to change. The parameters and their ranges are listed here for your reference:

Carrier frequency:		2500, 4000 or 5000 Hz
Interfere	nce frequency:	1-250 Hz
Frequenc	y Modulation:	Low set: 1-250 Hz
		High set: 1-250 Hz
Preset Fre	equency Sweeps	s: 1-15 Hz, 80-150 Hz, 1-150 Hz
Amplitud	e Modulation:	
Surge:	On (s)/Off (s)	5/5, 4/12, 10/10, 10/20, 10/30,
		10/50, Manual: 1-240/1-240
Recip: Ch1 (s)/Ch2 (s)		5/5, 4/12, 10/10, 10/20, 10/30,
		10/50, Manual: 1-240/1-240
Ramp:		0.5, 1, 2 or 5 seconds
Type:		CC or CV
Options:		Channel(s) 1 or 2

7. If all of the parameters are set correctly, position the cursor over the output window and press "Enter". Then use the M Wheel by dragging your finger in a clockwise direction to adjust the intensity up. You will notice that if two channels are being used, they will go up simultaneously. The intensity in the digital display will go up and the green bar will get larger as the intensity increases. Moving your finger around the M Wheel in a counterclockwise direction will decrease the intensity. The time will begin to count down until the treatment is complete. A buzzer will sound and the end-oftreatment message will appear. *Please note:* If you change time during a treatment, press "Enter" once the time is entered to restart the timer at the new time. The time will then count down from the newly entered time. Failure to do this will cause the treatment to go on indefinitely.

8. Notes:

You will adjust each channel separately for the "Reciprocation" mode since both channels cannot be "On" at the same time.
When using the "Surge" or "Reciprocation" modes, once you turn up the intensity to the desired level, "Restarting" will appear in a window indicating that the surge or recip program is starting.

4.9 Medium Frequency (Russian) Procedure



- 1. Turn on the mains power switch located on the back of the unit by pressing dot on the switch to the "On" position. Image shows switch in "Off" position.
- 2. Press either "1" or "2" to select channel one or two. Please note that Reciprocation requires 2 channels.
- 3. Insert the electrode cable into the channel connector for the channel that you will be using.
- 4. Place the electrodes on the patient.
- 5. Insert the patient safety cable into the jack located on the back of the unit and hand the end with the button to the patient letting him/her know that they can push this button at any time during the treatment to stop it.
- 6. Use the M Wheel to scroll to any of the parameters that you would like to change. The parameters and their ranges are listed here for your reference:

Duty Cycle (%):		10, 20, 30, 40 and 50
Burst Frequency:		20-100 bps
Amplitude Modulation:		
Surge:	On (s)/Off (s)	5/5, 4/12, 10/10, 10/20, 10/30,
		10/50, Manual: 1-240/1-240
Recip: Ch1 (s)/Ch2 (s)		5/5, 4/12, 10/10, 10/20, 10/30,
		10/50, Manual: 1-240/1-240
Ramp:		0.5, 1, 2 or 5 seconds
Туре:		CC or CV
Options:		Channel(s) 1 or 2

- 7. If all of the parameters are set correctly, position the cursor over the output window and press "Enter". Then use the M Wheel by dragging your finger in a clockwise direction to adjust the intensity up. You will notice that if two channels are being used, they will go up simultaneously. The intensity in the digital display will go up and the green bar will get larger as the intensity increases. Moving your finger around the M Wheel in a counterclockwise direction will decrease the intensity. The time will begin to count down until the treatment is complete. A buzzer will sound and the end-oftreatment message will appear. *Please note:* If you change time during a treatment, press "Enter" once the time is entered to restart the timer at the new time. The time will then count down from the newly entered time. Failure to do this will cause the treatment to go on indefinitely.
- 8. Notes:

You will adjust each channel separately for the "Reciprocation" mode since both channels cannot be "On" at the same time.
When using the "Surge" or "Reciprocation" modes, once you turn up the intensity to the desired level, "Restarting" will appear in a window indicating that the surge or recip program is starting.

4.10 Biphasic Procedure

ENTER

- 1. Turn on the mains power switch located on the back of the unit by pressing dot on the switch to the "On" position. Image shows switch in "Off" position.
- 2. Press either "1" or "2" to select channel one or two. Please note that Reciprocation requires 2 channels.
- 3. Insert the electrode cable into the channel connector for the channel that you will be using.
- 4. Place the electrodes on the patient.
- 5. Insert the patient safety cable into the jack located on the back of the unit and hand the end with the button to the patient letting him/her know that they can push this button at any time during the treatment to stop it.





- Use the M Wheel to scroll to any of the parameters that you would 6. like to change. The parameters and their ranges are listed here for your reference: 1-200 pps Frequency: Phase Duration 20-400 µs Amplitude Modulation: On (s)/Off (s) 5/5, 4/12, 10/10, 10/20, 10/30, Surge: 10/50, Manual: 1-240/1-240 Recip: Ch1(s)/Ch2(s)5/5, 4/12, 10/10, 10/20, 10/30, 10/50, Manual: 1-240/1-240 Ramp: 0.5, 1, 2 or 5 seconds Type: CC or CV Options: Channel(s) 1 or 2
- 7. If all of the parameters are set correctly, position the cursor over the output window and press "Enter". Then use the M Wheel by dragging your finger in a clockwise direction to adjust the intensity up. You will notice that if two channels are being used, they will go up simultaneously. The intensity in the digital display will go up and the green bar will get larger as the intensity increases. Moving your finger around the M Wheel in a counterclockwise direction will decrease the intensity. The time will begin to count down until the treatment is complete. A buzzer will sound and the end-oftreatment message will appear. *Please note:* If you change time during a treatment, press "Enter" once the time is entered to restart the timer at the new time. The time will then count down from the newly entered time. Failure to do this will cause the treatment to go on indefinitely.
- 8. Notes:

You will adjust each channel separately for the "Reciprocation" mode since both channels cannot be "On" at the same time.
When using the "Surge" or "Reciprocation" modes, once you turn up the intensity to the desired level, "Restarting" will appear in a window indicating that the surge or recip program is starting.

4.11 High Volt Procedure

1. Turn on the mains power switch located on the back of the unit by pressing dot on the switch to the "On" position. Image shows switch in "Off" position.



- 2. Press either "1" or "2" to select channel one or two. Please note that Reciprocation requires 2 channels.
- 3. Insert the electrode cable into the channel connector for the channel that you will be using.



- 4. Place the electrodes on the patient.
- 5. Insert the patient safety cable into the jack located on the back of the unit and hand the end with the button to the patient letting him/her know that they can push this button at any time during the treatment to stop it.
- 6. Use the M Wheel to scroll to any of the parameters that you would like to change. The parameters and their ranges are listed here for your reference:

1	
Polarity:	Positive or Negative
Frequency:	10-120 pps
Frequency Modulation:	1-10, 80-120, 1-120 pps
Amplitude Modulation:	
Surge: On (s)/Off (s)	5/5, 4/12, 10/10, 10/20, 10/30,
	10/50, Manual: 1-240/1-240
Recip: Ch1 (s)/Ch2 (s)	5/5, 4/12, 10/10, 10/20, 10/30,
	10/50, Manual: 1-240/1-240
Ramp:	0.5, 1, 2 or 5 seconds
Display:	Voltage or Current
Options:	Channel(s) 1 or 2
Please note: Frequency N	Iodulation is not available in 2 channel

mode in the interest of patient comfort.

- 7. If all of the parameters are set correctly, position the cursor over the output window and press "Enter". Then use the M Wheel by dragging your finger in a clockwise direction to adjust the intensity up. You will notice that if two channels are being used, they will go up simultaneously. The intensity in the digital display will go up and the green bar will get larger as the intensity increases. Moving your finger around the M Wheel in a counterclockwise direction will decrease the intensity. The time will begin to count down until the treatment is complete. A buzzer will sound and the end-oftreatment message will appear. *Please note:* If you change time during a treatment, press "Enter" once the time is entered to restart the timer at the new time. The time will then count down from the newly entered time. Failure to do this will cause the treatment to go on indefinitely.
- 8. Notes:

You will adjust each channel separately for the "Reciprocation" mode since both channels cannot be "On" at the same time.
When using the "Surge" or "Reciprocation" modes, once you turn up the intensity to the desired level, "Restarting" will appear in a window indicating that the surge or recip program is starting.
Stated polarity is for the red lead wire.





4.12 Microcurrent Procedure















- Turn on the mains power switch located on the back of the unit by pressing dot on the switch to the "On" position. Image shows switch in "Off" position.
- 2. Press either "1" or "2" to select channel one or two.
- 3. Insert the electrode cable into the channel connector for the channel that you will be using.
- 4. Place the electrodes on the patient.
- 5. Insert the patient safety cable into the jack located on the back of the unit and hand the end with the button to the patient letting him/her know that they can push this button at any time during the treatment to stop it.
- 6. Use the M Wheel to scroll to any of the parameters that you would like to change. The parameters and their ranges are listed here for your reference:

1	
Polarity:	Positive, Negative or Both
Phase Duration:	1-1,000 ms
Frequency:	0.5-500 pps
Options:	Channel(s) 1 or 2

- 7. If all of the parameters are set correctly, position the cursor over the output window and press "Enter". Then use the M Wheel by dragging your finger in a clockwise direction to adjust the intensity up. You will notice that if two channels are being used, they will go up simultaneously. The intensity in the digital display will go up and the green bar will get larger as the intensity increases. Moving your finger around the M Wheel in a counterclockwise direction will decrease the intensity. The time will begin to count down until the treatment is complete. A buzzer will sound and the end-oftreatment message will appear. *Please note:* If you change time during a treatment, press "Enter" once the time is entered to restart the timer at the new time. The time will then count down from the newly entered time. Failure to do this will cause the treatment to go on indefinitely.
- 8. Notes:
 - Stated polarity is for the red lead wire.

4.13 TENS, Symmetrical Biphasic Procedure

- 1. Turn on the mains power switch located on the back of the unit by pressing dot on the switch to the "On" position. Image shows switch in "Off" position.
- 2. Press either "1" or "2" to select channel one or two.
- 3. Insert the electrode cable into the channel connector for the channel that you will be using.
- 4. Place the electrodes on the patient.
- 5. Insert the patient safety cable into the jack located on the back of the unit and hand the end with the button to the patient letting him/her know that they can push this button at any time during the treatment to stop it.
- 6. Use the M Wheel to scroll to any of the parameters that you would like to change. The parameters and their ranges are listed here for your reference:

,	
Phase Duration:	20-1,000 μs
Frequency:	1-250 pps
Frequency Modulation:	0-250 pps
Amplitude Modulation:	40, 60, 80, and 100%
Burst frequency:	0-30 bps
Туре:	CC or CV
Options:	Channel(s) 1 or 2
Please note: Frequency N	Aodulation is not available i

Please note: Frequency Modulation is not available in 2 channel mode in the interest of patient comfort.

7. If all of the parameters are set correctly, position the cursor over the output window and press "Enter". Then use the M Wheel by dragging your finger in a clockwise direction to adjust the intensity up. You will notice that if two channels are being used, they will go up simultaneously. The intensity in the digital display will go up and the green bar will get larger as the intensity increases. Moving your finger around the M Wheel in a counterclockwise direction will decrease the intensity. The time will begin to count down until the treatment is complete. A buzzer will sound and the end-oftreatment message will appear. *Please note:* If you change time during a treatment, press "Enter" once the time is entered to restart the timer at the new time. The time will then count down













from the newly entered time. Failure to do this will cause the treatment to go on indefinitely.

- 8. Notes:
 - FM and Burst may not be used simultaneously.
 - FM may not be used if two channels are selected.

- When using the "AM" mode, once you turn up the intensity to the desired level, "Restarting" will appear in a window indicating that AM is starting.

4.14 TENS, Asymmetrical Biphasic Procedure

- 1. Turn on the mains power switch located on the back of the unit by pressing dot on the switch to the "On" position. Image shows switch in "Off" position.
- 2. Press either "1" or "2" to select channel one or two.
- 3. Insert the electrode cable into the channel connector for the channel that you will be using.
- 4. Place the electrodes on the patient.
- 5. Insert the patient safety cable into the jack located on the back of the unit and hand the end with the button to the patient letting him/her know that they can push this button at any time during the treatment to stop it.
- 6. Use the M Wheel to scroll to any of the parameters that you would like to change. The parameters and their ranges are listed here for your reference:

1	
Phase Duration:	20-1,000 μs
Frequency:	1-250 pps
Frequency Modulation:	0-250 pps
Amplitude Modulation:	40, 60, 80, and 100%
Burst frequency:	0-30 bps
Туре:	CC or CV
Options:	Channel(s) 1 or 2
Please note: Frequency N mode in the interest of p	<i>Nodulation is not available in 2 channel atient comfort.</i>









- 7. If all of the parameters are set correctly, position the cursor over the output window and press "Enter". Then use the M Wheel by dragging your finger in a clockwise direction to adjust the intensity up. You will notice that if two channels are being used, they will go up simultaneously. The intensity in the digital display will go up and the green bar will get larger as the intensity increases. Moving your finger around the M Wheel in a counterclockwise direction will decrease the intensity. The time will begin to count down until the treatment is complete. A buzzer will sound and the end-oftreatment message will appear. *Please note:* If you change time during a treatment, press "Enter" once the time is entered to restart the timer at the new time. The time will then count down from the newly entered time. Failure to do this will cause the treatment to go on indefinitely.
- 8. Notes:
 - FM and Burst may not be used simultaneously.
 - FM may not be used if two channels are selected.

- When using the "AM" mode, once you turn up the intensity to the desired level, "Restarting" will appear in a window indicating that AM is starting.

4.15 DC Low Amplitude Procedure

- 1. Turn on the mains power switch located on the back of the unit by pressing dot on the switch to the "On" position. Image shows switch in "Off" position.
- 2. Press either "1" or "2" to select channel one or two.
- 3. Insert the electrode cable into the channel connector for the channel that you will be using.
- 4. Place the electrodes on the patient. For this waveform use sponge electrodes only. Do not use V Trodes.
- 5. Insert the patient safety cable into the jack located on the back of the unit and hand the end with the button to the patient letting him/her know that they can push this button at any time during the treatment to stop it.



ENTER











6.	5. Use the M Wheel to scroll to any of the parameters that you wo like to change. The parameters and their ranges are listed here f your reference:			
	Polarity:		Positive or Negative	
	Amplitude	Modulation:		
	Surge:	On (s)/Off (s)	5/5, 4/12, 10/10, 10/20, 10/30,	
			10/50, Manual: 1-240/1-240	
	Recip: Ch	1 (s)/Ch2 (s)	5/5, 4/12, 10/10, 10/20, 10/30,	
			10/50, Manual: 1-240/1-240	
	Polarity Re	eversal:	If "On" then at 50% of the treatment	
			time the polarity will reverse.	
	Options:		Channel(s) 1 or 2	

- 7. If all of the parameters are set correctly, position the cursor over the output window and press "Enter". Then use the M Wheel by dragging your finger in a clockwise direction to adjust the intensity up. You will notice that if two channels are being used, they will go up simultaneously. The intensity in the digital display will go up and the green bar will get larger as the intensity increases. Moving your finger around the M Wheel in a counterclockwise direction will decrease the intensity. The time will begin to count down until the treatment is complete. A buzzer will sound and the end-oftreatment message will appear. *Please note:* If you change time during a treatment, press "Enter" once the time is entered to restart the timer at the new time. The time will then count down from the newly entered time. Failure to do this will cause the treatment to go on indefinitely.
- 8. Notes:
 - Stated polarity is for the red lead wire.

4.16 Using the pencil electrode

The pencil electrode is used for the stimulation of small muscles or painful areas. It is also useful to help identify the exact motor point of a muscle or muscle group. It is used by a therapist for short periods of time only. Due to its small surface area and large current density, the pencil point attachment should only be used briefly (a few seconds only) for treating high pain areas. The attachment that is the size of a quarter is suited for finding motor points and manual stimulation protocols.



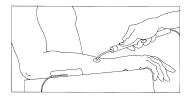
INFO

- Turn on the mains power switch located on the back of the unit by pressing dot on the switch to the "On" position. Image shows switch in "Off" position.
- 2. Press the "Info" button.









- 3. You will get the screen to the right. Use the M Wheel to scroll to either "Use Pencil Electrode". Press "Enter" when you get to it and then select which channel you would like to use for combination therapy. This will defeat the sensor that detects whether an electrode has become disconnected and you will be able to use the pencil electrode successfully. The symbol for pencil electrode will appear in that channel's status window.
- 4. Press either "1" or "2" to the channel that you just enabled the use of the pencil electrode.
- 5. Insert the electrode cable into the channel connector for the channel that you will be using. Attach the pencil electrode to the black electrode cable using a pin to banana adapter. Attach the red electrode cable to a dispersive pad. Apply dispersive electrode in such a manner to prevent transthoracic stimulation.
- 6. Pressing the switch located on the pencil electrode will allow treatment currents to be delivered to the patient. Four tips of different sizes are included with the pencil electrode. The figure on the left shows an application of the pencil electrode.
- 7. With the button depressed on the pencil electrode adjust the intensity of the simulation up to the desired level. Typically you will use only continuous modes when using the pencil electrode. Releasing the button will stop the stimulation.

4.17 Combination Therapy Setup Procedure

Application of simultaneous therapeutic ultrasound and electrical neuromuscular stimulation can be accomplished using the Sys*Stim 240 with any Sonicator[®] therapeutic ultrasound unit from Mettler Electronics Corp.



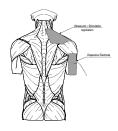
1. Turn on the mains power switch located on the back of the unit by pressing dot on the switch to the "On" position. Image shows switch in "Off" position.











- 2. Press the "Info" button.
- 3. You will get the screen to the right. Use the M Wheel to scroll to either "Use Pencil Electrode". Press "Enter" when you get to it and then select which channel you would like to use for combination therapy. This will defeat the sensor that detects whether an electrode has become disconnected and you will be able to do combination therapy successfully. The symbol for pencil electrode will appear in that channel's status window. ■
- 4. Press either "1" or "2" to the channel that you just enabled the use of the ultrasound applicator.
- 5. Insert the electrode cable into the channel connector for the channel that you will be using. Plug in the black end of the lead wire into the receptacle on the ultrasound indicated with the A mark. For most Sonicators this will require a pin to banana adapter. The red lead wire is connected to a dispersive electrode which is applied to the patient to complete the electrical circuit. When the electrical output is generated by the stimulator, it will be passed through the metal ring on the applicator head by means of this connection.
- 6. Please review all therapeutic ultrasound precautions and contraindications listed in the Sonicator instruction manual before proceeding with combination therapy.
- 7. The timer on the Sonicator will control the length of time ultrasound is delivered. Press "Start" on the Sonicator 740 and adjust the intensity the Sys*Stim 240 to begin treatment. The ultrasound intensity is adjusted on the ME 740. When the selected time has completed on the Sonicator 740, press "Stop" on the Sys*Stim 240 before removing the applicator from the patient. This will turn off the stimulation output to the applicator.

Section 5—Indications, Contraindications, Precautions and Adverse Reactions

- 5.1 Indications for Medium Frequency (Russian), Biphasic, High Volt Pulsed Current (HVPC), Interferential (4P) and Premodulated (2P) waveforms
 - Relaxation of muscle spasms
 - Prevention or retardation of disuse atrophy
 - Increase local blood circulation
 - Muscle re-education
 - Maintaining or increasing range of motion
 - Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- 5.2 Additional Indications for Microcurrent, Interferential (4P), Premodulated (2P), Biphasic and TENS waveforms
 - Symptomatic relief and management of chronic, intractable pain
 - Post-traumatic acute pain
 - Post-surgical acute pain

5.3 Indications for DC (Direct Current) Mode

• Relaxation of muscle spasm

5.4 The laser and cluster applicators of the Sys*Stim 240 emit infrared energy for:

- Temporary increase in local blood circulation
- Temporary relief of minor muscle and joint aches, pains and stiffness
- Relaxation of muscles
- Temporary relief of muscle spasms
- Temporary relief of minor pain and stiffness associated with arthritis

5.5 Contraindications for Neuromuscular Electrical Stimulation

- 1. Powered muscle stimulators should not be used on patients with cardiac demand pacemakers.
- 2. Do not use this device on patients who have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device, because this may cause electric shock, burns, electrical interference, or death.
- 3. Do not use this device on patients whose pain syndromes are undiagnosed.
- 4. Do not use electrical stimulation in conjunction with high frequency surgical equipment or microwave or shortwave therapy systems.

5.6 Contraindications for use of a Therapeutic Laser

- 1. Avoid direct irradiation of the eyes.
- 2. Do not use within 4 to 6 months after radiation therapy.
- 3. Do not use over hemorrhaging regions
- 4. Do not treat locally over the endocrine glands.
- 5. Do not treat ischemic tissues in individuals with vascular disease where the blood supply would be unable to follow the increase in metabolic demand and tissue necrosis might result.

5.7 Warnings for Neuromuscular Electrical Stimulation

- 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 or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
- 7. Stimulation should not be applied over, or in proximity to, cancerous lesions.
- 8. Consult with the patient's physician before using this device, because the device may cause lethal rhythm disturbances to the heart in susceptible individuals.
- 9. Apply stimulation only to normal, intact, clean, healthy skin.
- 10. Do not apply stimulation in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when the electrical stimulation device is in use.

5.8 Precautions for Neuromuscular Electrical Stimulation

- 1. Safety of powered muscle stimulators for use during pregnancy has not been established.
- 2. Caution should be used for patients with suspected or diagnosed heart problems.
- 3. Caution should be used for patients with suspected or diagnosed epilepsy.
- 4. Caution should be used in the presence of the following:
 - a. When there is a tendency to hemorrhage following acute trauma or fracture;

b. Following recent surgical procedures when muscle contraction may disrupt the healing process;

c. Over the menstruating or pregnant uterus; and

d. Over areas of the skin which lack normal sensation.

- 5. Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium or alternate electrode placement.
- 6. Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.

- 7. Powered muscle stimulators should be kept out of the reach of children.
- 8. Powered muscle stimulators should be used only with the leads and electrodes recommended for use by Mettler Electronics Corp.
- 9. TENS is not effective for pain of central origin, including headache.
- 10. TENS is not a substitute for pain medications and other pain management therapies.
- 11. TENS devices have no curative value.
- 12. TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism.
- 13. The long-term effects of electrical stimulation are unknown.
- 14. Since the effects of stimulation of the brain are unknown, stimulation should not be applied across the head, and electrodes should not be placed on opposite sides of the head.
- 15. It is advisable to insulate patients, preferably by use of a wooden treatment table or one that is completely padded by non-conductive material. Added safety is provided if the patient cannot touch any grounded metal parts.
- 16. Limit treatment intensity to 50 mA (50 V) or less, when using small electrodes (2" diameter), to reduce the chance of thermal burns due to high current density. Avoid current densities exceeding 2 mA/cm² when using this device.
- 17. Turn on the stimulator before applying electrodes to the patient.

5.9 Precautions for use of a Therapeutic Laser

- 1. Only authorized and trained practitioners are to apply the treatment.
- 2. Protective eyewear to be used always.
- 3. Ensure shiny patient jewelry is removed from treatment region.
- 4. Avoid treatment over shiny surfaces.
- 5. Switch Laser On before applicator is touching the skin, use blue target illumination to direct treatment to desired application area and then slowly move applicator toward skin surface for contact. The applicator should be touching the skin during treatment.
- 6. Use laser therapy only on or over the treatment region.
- 7. Never look into laser beam or laser aperture.
- 8. Laser therapy should not be applied in areas of reduced sensation or circulation. Patients having reduced sensation will not be able to notify the practitioner of discomfort if the intensities are too high.

5.10 Side Effects/Adverse Reactions for Neuromuscular Electrical Stimulation

- 1. Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle stimulators.
- 2. Patients may experience headache and other painful sensations during or following the application of electrical stimulation near the eyes and to the head and face.

Section 6—Maintenance and Troubleshooting

6.1 Cleaning the Sys*Stim 240

- 1. The Sys*Stim 240 can be wiped off with a damp cloth. The power cord should be disconnected from the unit before this is done. In the case of stubborn dirt a gentle household cleaner can be sprayed on the cloth and then wiped on the unit. If this method is used, remove any cleaner residue with a damp cloth. Do not spray cleaner into the vents of the unit.
- 2. Do not allow any liquids to penetrate the unit or its accessories while cleaning and disinfecting. Dry all sockets and connectors that have become wet before any further use!
- 3. Follow the V Trode package insert for the use and care of the electrodes supplied with the Sys*Stim 240.
- 4. For routine cleaning of the electrode cables use soap and water. Thoroughly dry after cleaning.
- 5. Even though the patient treatment applicators do not contact open wounds or broken skin it is still possible for them to carry infections by the mere fact that they contact bare skin. The applicators should be thoroughly cleaned after a treatment session with one patient is completed prior to a new session beginning with another patient. The treatment applicators are not suitable for autoclaving.
- 6. The treatment applicators should be kept free from any build up of material particularly on the glass cover protecting the laser diode in the tip of the applicator. Regular cleaning with a damp cloth soaked in a mixture of mild soap and water is recommended. Note: The Laser or Cluster Applicator must be disconnected from the front panel socket when cleaning. This is a precaution to ensure the laser applicator has no power and therefore cannot activate while looking at the cover glass.
- 7. If there are concerns about cross infection the applicator's surface which contacts the patient can be wiped with a surface disinfectant. Care should be taken not to contact the grey plastic parts of the treatment applicator with the disinfectant.
- 8. If sponge electrodes are used, clean them with soap and water and thoroughly rinse them to remove any soap residue.

6.2 Routine Maintenance

- Standard medical electrical safety checks should be performed annually by qualified biomedical engineers or technicians trained to perform these procedures. If the light therapy option is installed, output must be verified on an annual basis. Please refer to the Maintenance Manual for the cluster and laser calibration procedures or return the product to Mettler for calibration.
- 2. Inspect electrode cables and associated connectors for damage.
- 3. Inspect the light therapy applicator cables and their connectors for damage.
- 4. The applicator is an integral part of delivering safe and effective laser and light therapy. Avoid rough handling of the laser and cluster applicators since they are relatively fragile and can be damaged if dropped or otherwise abused.
- 5. Never open the Sys*Stim 240. Doing so may lead to malfunctions or accidents.

- 6. Do not damage, break, modify, bend forcibly, tug on, twist, or bundle the electrode cord. If a heavy object is placed on the cord or it is pinched or modified, the cord may be damaged, resulting in fire, electric shock, or other accident.
- 7. In order to separate the two lead wires, do not pull on them. Use a sharp pair of scissors using the indentation down the middle of the lead wire as a guide.
- 8. When cleaning the unit, do not wipe using paint thinner, gasoline, kerosene, polishing powder, hot water, or chemicals to prevent discoloration of the main unit and applicators. Wipe with a cloth soaked in cold water or lukewarm water and then wrung out.
- **9.** If you plan to use a unit that has been left standing for some time, always check to ensure that the unit functions **normally and safely**.

Symptom Action Is line cord connected to outlet? 1. Nothing lights when main power switch is turned on. Does the outlet have power? Unit may require servicing if none of the above resolves the problem. Self-Test Failed Turn off the unit and then back on again. If the error 2. persists the Sys*Stim 240 requires servicing. There has been an either a hardware or software 3. Screen goes blank or comes up blank. error. All patient output has been terminated. Remove the electrode cables from the unit. Then turn the unit Off and turn it back ON and retry the treatment. If this does not correct the problem, the unit requires servicing. Report the error to service provider to assist with hardware troubleshooting. 4. Warning - Battery Power Low Plug into wall outlet with the power switch in the "On" position to charge the battery.

6.3 Troubleshooting the Sys*Stim 240

5.	Error E60 - Output Voltage Error	There is an output voltage error for electrical stimulation. This error happens only in constant voltage mode, when the output voltage exceeds the target voltage by 20%.
		Press "Enter" to return to the waveform screen. Press the "Start/Pause" key and to restart the treatment and return to the previously set intensity.
		Or press the "Stop" button to stop the treatment and return to the treatment screen. Pressing the "Start/Pause" key will restart the treatment at the beginning. You will need to press "Enter" to begin to increase the intensity and start the treatment.
		If the above does not correct the error. Remove the electrode cables from the unit. Then turn the unit Off and turn it back ON and retry the treatment. If this does not correct the problem, the unit requires servicing. Report the error to service provider to assist with hardware troubleshooting.
6.	Check Patient Contact	This message will appear in the status bar when intensity is being turned up when the current is not flowing properly due to electrodes or cables. It will appear at 5 mA in continuous current or 50 volts in high volt. Check all cables and electrodes for the channel that is affected. Then resume turning up the intensity.
7.	Error E65 – Voltage too low	Press "Enter" to return to the waveform screen. Check the electrodes. Check the electrode cable connections to make sure that they are connected. Make sure both electrodes are attached to the cables and to the patient. Try fresh electrodes and or cables to resolve this problem.
		Press the "Start/Pause" key and to restart the treatment and return to the previously set intensity.
		Or press the "Stop" button to stop the treatment and return to the treatment screen. Pressing the "Start/Pause" key will restart the treatment at the beginning. You will need to press "Enter" to begin to increase the intensity and start the treatment.
		If the above does not correct the error. Remove the electrode cables from the unit. Then turn the unit Off and turn it back ON and retry the treatment. If this does not correct the problem, the unit requires servicing. Report the error to service provider to assist with hardware troubleshooting.

8.	Error E70 - Impedance Too High	Appears when a current flow is interrupted during treatment. (e.g., an electrode is detached from the treatment area, electrode partially detached, electrodes worn out or electrode cable either not connected or damaged).
		Press "Enter" to return to the waveform screen. Check the electrodes. Check the electrode cable connections to make sure that they are connected. Make sure both electrodes are attached to the cables and to the patient. Try fresh electrodes and or cables to resolve this problem.
		Press the "Start/Pause" key and to restart the treatment and return to the previously set intensity.
		Or press the "Stop" button to stop the treatment and return to the treatment screen. Pressing the "Start/Pause" key will restart the treatment at the beginning. You will need to press "Enter" to begin to increase the intensity and start the treatment.
		If the above does not correct the error. Remove the electrode cables from the unit. Then turn the unit Off and turn it back ON and retry the treatment. If this does not correct the problem, the unit requires servicing. Report the error to service provider to assist with hardware troubleshooting.

		,
9.	Error E80 - Overcurrent Error	Appears when the current level spikes (e.g., the electrode is partly detached from the treatment area or moved out of position).
		Press "Enter" to return to the waveform screen. Check the electrodes. Check the electrode cable connections to make sure that they are connected. Make sure both electrodes are attached to the cables and to the patient. Try fresh electrodes and or cables to resolve this problem.
		Press the "Start/Pause" key and to restart the treatment and return to the previously set intensity.
		Or press the "Stop" button to stop the treatment and return to the treatment screen. Pressing the "Start/Pause" key will restart the treatment at the beginning. You will need to press "Enter" to begin to increase the intensity and start the treatment.
		If the above does not correct the error. Remove the electrode cables from the unit. Then turn the unit Off and turn it back ON and retry the treatment. If this does not correct the problem, the unit requires servicing. Report the error to service provider to assist with hardware troubleshooting.
10.	Error E85 – Current too low	Check the electrodes. Resume the treatment by doing the following:
		Press "Enter" to return to the waveform screen. Check the electrodes. Check the electrode cable connections to make sure that they are connected. Make sure both electrodes are attached to the cables and to the patient. Try fresh electrodes and or cables to resolve this problem.
		Press the "Start/Pause" key and to restart the treatment and return to the previously set intensity.
		Or press the "Stop" button to stop the treatment and return to the treatment screen. Pressing the "Start/Pause" key will restart the treatment at the beginning. You will need to press "Enter" to begin to increase the intensity and start the treatment.
		If the above does not correct the error. Remove the electrode cables from the unit. Then turn the unit Off and turn it back ON and retry the treatment. If this does not correct the problem, the unit requires servicing. Report the error to service provider to assist with hardware troubleshooting.

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11. Error E90 - Impedance Too Low	Check the electrodes. Move further apart, make sure the area between the electrodes is clean and dry and then resume treatment by doing the following:
	Press "Enter" to return to the waveform screen. Check the electrodes. Check the electrode cable connections to make sure that they are connected. Make sure both electrodes are attached to the cables and to the patient. Try fresh electrodes and or cables to resolve this problem.
	Press the "Start/Pause" key and to restart the treatment and return to the previously set intensity.
	Or press the "Stop" button to stop the treatment and return to the treatment screen. Pressing the "Start/Pause" key will restart the treatment at the beginning. You will need to press "Enter" to begin to increase the intensity and start the treatment.
	If the above does not correct the error. Remove the electrode cables from the unit. Then turn the unit Off and turn it back ON and retry the treatment. If this does not correct the problem, the unit requires servicing. Report the error to service provider to assist with hardware troubleshooting.
12. Error E100, E101, E102, E103, E104, E105, E106 – System errors	Remove electrode cables from the Sys*Stim 240. Turn power off and on again. Plug the cables back in, set up resume treatment. If the error repeats, the Sys*Stim 240 requires servicing. Report the error to service provider to assist with hardware troubleshooting.
13. Error E110, E111, E112, E113, E 120, E121, E122, E123 – System errors	Remove electrode cables from the Sys*Stim 240. Turn power off and on again. Plug the cables back in, set up resume treatment. If the error repeats, the Sys*Stim 240 requires servicing. Report the error to service provider to assist with hardware troubleshooting.
14. Error E200, E211, E212, E221, E222, E231, E232, W241, E242 – System errors	Remove electrode cables from the Sys*Stim 240. Turn power off and on again. Plug the cables back in, set up resume treatment. If the error repeats, the Sys*Stim 240 requires servicing. Report the error to service provider to assist with hardware troubleshooting.
15. Patient Safety Switch Pressed	Check patient status and resume treatment if everything checks out with the patient.
16. Stop Button Pressed	Press start to resume treatment. You will need to turn back up the intensity for the stimulation.

17. Unknown or No Applicator Plug in either a cluster or a laser applicator. If one is plugged in, inspect the cable and the connector to make sure they are not damaged. If you have a second applicator, plug it in and see if the error message is resolved. If neither applicator is recognized, Sys*Stim 240 requires servicing.

If problem is not addressed above, or if additional troubleshooting guidance is desired, call (800) 854-9305 or email our service department at <u>service@mettlerelectronics.com</u>. The distributor who sold the Sys*Stim 240 should be able to assist you with a loaner unit during warranty service.

Section 7—References

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References for Laser and Light Therapy:

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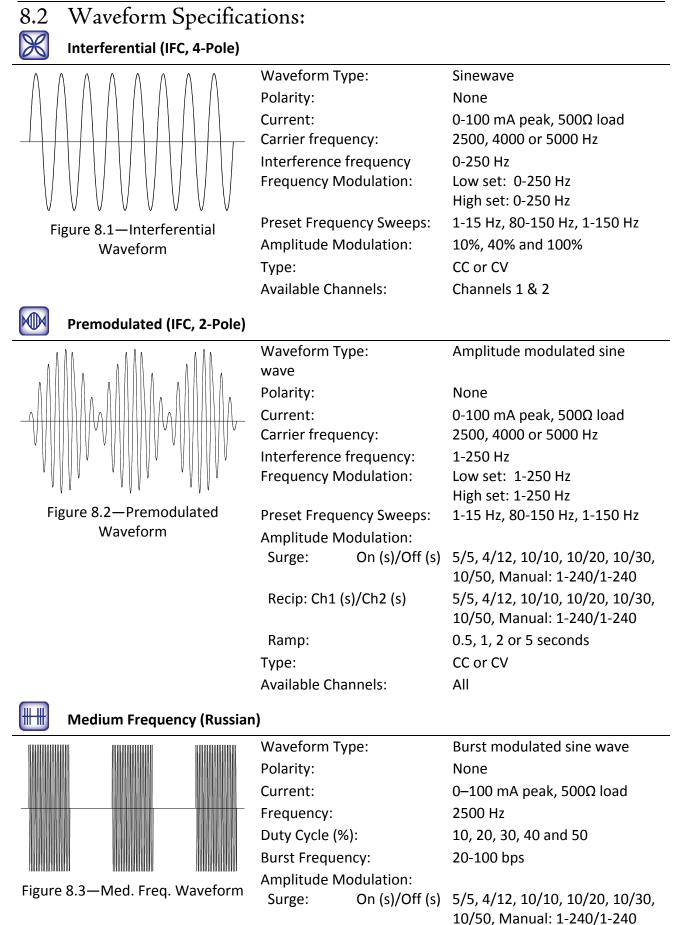
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- 10. Weisberg J: 26. Lasers from Physical Agents: A Comprehensive Text for Physical Therapists, Appleton & Lange, 1994.

This manual has been written as a guideline for the correct use of the Sys*Stim 240. Reading the above references will provide a more complete understanding of the correct use of neuromuscular stimulation and laser and light therapy.

Section 8—Specifications

8.1 General Specifications:

Input:	100-240VAC , 50/60 Hz
External Fuse:	1.0 A, 250 V, GDC/S506 5 X 20 mm, Time Delay 2 X T1.0, AL250V
ETL and C-ETL Listed:	Model ME 240 (9801427)
Classification:	Protective Class I Equipment and Internally Powered Equipment Type BF Equipment
	Enclosed equipment without protection against ingress of water.
	Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with nitrogen oxide.
Certification	The Sys*Stim 240 complies with the light-emitting and laser product performance standards set forth in the Code of Federal Regulations, Title 21 (Food and Drugs), Parts 1040.10 and 1040.11.
US Patent:	D593684
Weight:	4.5 pounds (5.5 pounds with battery)
Dimensions:	13" (L) x 8" (W) x 8" (H)
Temperature Operating: Nonoperating:	50°F to 104°F -40°F to 167°F
Humidity: Operating: Non-Operating:	30% to 75% Relative Humidity at 104°F Non-Operating, 5% to 95% Relative Humidity, non- condensing
Treatment Time:	1-60 minutes
Optional Battery:	Rechargeable Smart Lithium Ion Battery Pack rated at 10.8Vand 4.8Ah



	Sys*Stim 24	0 Instruction Manual — Rev.I_09/23/19
	Recip: Ch1 (s)/Ch2 (s)	5/5, 4/12, 10/10, 10/20, 10/30, 10/50, Manual: 1-240/1-240
	Ramp:	0.5, 1, 2 or 5 seconds
	Type:	CC or CV
	Available Channels:	All
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Biphasic		
	Waveform Type: wave	Amplitude modulated sine
	Polarity:	None
	Current:	0–100 mA peak, 500Ω load
	Frequency:	1-200 pps
	Phase Duration	20-400 μs
	Amplitude Modulation:	
Figure 8.4—Biphasic Waveform	Surge: On (s)/Off (s)	5/5, 4/12, 10/10, 10/20, 10/30, 10/50, Manual: 1-240/1-240
	Recip: Ch1 (s)/Ch2 (s)	5/5, 4/12, 10/10, 10/20, 10/30, 10/50, Manual: 1-240/1-240
	Ramp:	0.5, 1, 2 or 5 seconds
	Туре:	CC or CV
	Available Channels:	All
High Volt		
	Waveform Type:	Monophasic twin peak
	Polarity:	Positive, negative or both
	Voltage:	0 to 500 V peak, 500Ω load)
	Phase Duration:	~15 μs
	Frequency: 10-120) pps
Figure 8.5— High Volt Waveform	Frequency Modulation:	1-10, 80-120, 1-120 pps
	Amplitude Modulation:	
		5/5, 4/12, 10/10, 10/20, 10/30, , Manual: 1-240/1-240
	Recip: Ch1 (s)/Ch2 (s) 10/50	5/5, 4/12, 10/10, 10/20, 10/30, , Manual: 1-240/1-240
	Ramp:	0.5, 1, 2 or 5 seconds
	Type: CV	•••
	Available Channels: All	
Microcurrent		
	Waveform Type:	Monophasic or Biphasic square
	Polarity:	Positive, negative or both
-	Current:	0 –1,000 μA peak, 500Ω load
Figure 8.6—Microcurrent Waveform	Phase Duration:	1-1,000 ms

Frequency:	0.5-500 pps
Туре:	CC
Available Channels:	All



TENS, Symmetrical Biphasic

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Figure 8.7—TENS Sym. Waveform						

Waveform Type:	Biphasic square
Polarity:	None
Current:	0 –80 mA peak, 500Ω load
Phase Duration:	20-1,000 μs
Frequency:	1-250 pps
Frequency Modulation:	0-250 pps
Amplitude Modulation:	40, 60, 80, and 100%
Burst frequency:	0-30 bps
Туре:	CC or CV
Available Channels:	All



TENS, Asymmetrical Biphasic

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Figure 8.8—TENS Asym. Waveform

C					
	Waveform Type:		Asymmetrical biphasic		
	Polarity:		None		
	Current:		0 –110 mA peak, 500Ω load		
	Phase Duration:		20-1,000 μs		
	Frequency:	1-250	pps		
Frequency Modulation:			0-250 pps		
Amplitude Modulation:			40, 60, 80, and 100%		
	Burst frequency:		0-30 bps		
	Туре:	CC or (CV		
	Available Channels:	All			

DC Low Amplitude

Waveform Type:	Continuous DC
Polarity:	Positive or Negative
Current:	0-4 mA DC, 500Ω load
Amplitude Modulatio	on:
Surge: On (s)	/Off (s) 5/5, 4/12, 10/10, 10/20, 10/30,
	10/50, Manual: 1-240/1-240
Recip: Ch1 (s)/Ch2 (s) 5/5, 4/12, 10/10, 10/20, 10/30,
	10/50, Manual: 1-240/1-240
Polarity Reversal:	If "On" then at 50% of the
	treatment time the polarity will
	reverse.
Туре:	CC
Available Channels:	All

8.3 Optional Laser Performance:

Output power:	Dependent on Applicator (automatically sensed)
Laser diode applicator	80 mW at 785nm
Optional: cluster applicator	500 mW at 660/950nm
Delivered energy:	0.01 to 99.99 Joules
Operation modes:	Continuous and Pulsed
Pulse mode:	
Pulse width:	
Laser	100 μs nominal
Cluster	50% duty cycle
Pulse frequency:	
A)	Continuous
В)	10 Hz, 25 Hz, 50 Hz, 100 Hz, 250 Hz, 500 Hz, 1 kHz, 2.5 kHz, 5 kHz (Pulses per Second)
C)	Sweep from 10 to 5 kHz (inc continuous) in 10 seconds (1 second at each step)
Timer	0 to 99 minutes 59 seconds, 1 second increments (decrementing). Audible signal and output termination at time expiration

8.4 Optional Applicator Specifications:

Lasing device:	Sanyo Single AlGaAs Diode (Class 3B laser device)	
Wavelength:	785 nm ± 10 nm	
Power:	80 mW ± 10 mW	
Treatment area illumination:	Three Blue LED's (470 nm, visible through eyewear protection that attenuates Infrared/Near Infrared)	
Output activation:	Capacitance Switch on Laser Applicator handle	
NOHD	Nominal Ocular Hazard Distance is less than 35 cm.	
MPE (skin only)	~ 3.3 MPE, less than maximum allowable of 5 MPE	
Beam spot	Elliptical beam spot 2.8 mm x 1.1 mm (elliptical beam area of = 9.2 mm²) at the aperture.	
Divergence	Elliptical Beam divergence 18 degrees and 7 degrees	
Eye protection	Uvex glasses with a minimum of 80% attenuation in the wavelength range of 780 nm to 860 nm. The Uvex glasses supplied with the unit meet these requirements.	
Cluster Applicator		
SLD	Twelve 950 nm Super luminescent Diodes	

SLD	Twelve 950 nm Super luminescent Diodes
LED	Seven 660 nm Light Emitting Diodes

Total Power	500 mW ± 50 mW
Treatment area illumination	The 660 nm LED's are visible and illuminate treatment area
Output activation	Capacitance Switch on Cluster Applicator handle
Eye protection	Uvex glasses with a minimum of 80% attenuation in the
	wavelength range of 780 nm to 1200 nm. The Uvex glasses
	supplied with the unit meet these requirements.

Section 9—Accessories

9.1 Ordering Information:

Therapy products and accessories are available from Mettler Electronics authorized Distributors. For information regarding either Mettler products or a distributor near you, please call toll free, (800) 854–9305 or phone (714) 533–2221 in areas outside the continental United States. Ask for Customer Service. Mettler Electronics is open from 7 AM until 5 PM Pacific Time for your convenience. You can also reach our Customer Service Department via email at *mail@mettlerelectronics.com*.

Catalogue #	Item Description
2000	4 Sponge electrodes (2" x 2")
2001	24 Sponge inserts (2" x 2")
2002	4 Sponge electrodes (4" x 4")
2003	24 Sponge inserts (4" x 4")
2004	1 Sponge electrode (3.5" x 7")
2005	12 Sponge inserts (3.5" x 7")
2006	1 Sponge electrode (8" x 10")
2007	12 Sponge inserts (8" x 10")
2008	4 Electrode straps (24")
2009	4 Electrode straps (48")
2023	Pencil electrode set with push button stimulation control, (includes handle, 4 different sizes of stainless steel spot electrode tips, and carrying case)
2027	Pin to banana adapter set to be used with ME 2260 or 2201 electrode cables. Four each, gray.
2230	Bifurcation cable set, 2 cables, one red and one black, pin termination
2221	EZ Trode – 2" diameter round self–adhering, reusable electrodes with lead wires; case of ten packages (four electrodes/pkg.)
2222	EZ Trode – 2.75" diameter round self–adhering, reusable electrodes with lead wires; case of ten packages (four electrodes/pkg.)
2223	EZ Trode – 2" x 4" self–adhering, reusable electrodes with lead wires, case of 10 packages (2 electrodes/pkg.)
2224	EZ Trode – 2" square self–adhering, reusable electrodes with lead wires; case of ten packages (four electrodes/pkg.)
2260	Electrode cable
2403	Patient safety switch
2410	Applicator holder (left) with mounting hardware
2411	Applicator holder (right) with mounting hardware
2702	V Trode –2" diameter round electrodes with lead wires, case of ten packages (four electrodes/pkg.)
2703	V Trode –2.75" diameter round electrodes with lead wires, case of 10 packages

9.2 Sys*Stim 240 Accessories

	(four electrodes/pkg.)		
2704	V Trode –2" x 4" oval electrodes with lead wires, case of 10 packages (four electrodes/pkg.)		
2705	V Trode –2" square electrodes with lead wires, case of 10 packages (four electrodes/pkg.)		
5403	One pair of protective glasses		
7293	Detachable U.L. listed, hospital–grade line cord		
73	Three-shelf mobile cart for all Sys*Stim or Sonicator products. Holds unit on the top shelf with lower shelves for accessories.		
7401	Optional battery pack		
97	Sturdy stainless steel cabinet with a platform for Mettler electrotherapy products and three shelves with a plastic door with two locking wheels.		