Sys*Stim® 240 *for*

OrthodontiCell

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 Biphasic and TENS-Symmetrical Biphasic waveforms.

New touch-sensitive technology has been used to make starting a treatment easy. The high-resolution 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 electrical stimulation 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

⚠WARNING

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

⚠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 µC 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. One patient safety switch, (ME 2403)
3. Detachable U.L. listed, hospital–grade line cord (ME 7293)
4. Instruction Manual

1.7 Limited Warranty

The Sys∗Stim 240 neuromuscular electrical stimulation is warranted against defects in materials and workmanship for a period of two years 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.

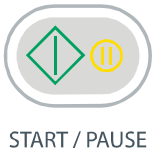
Any legal action brought by the buyer relating to this warranty must be commenced within one year from the date any claim arises and must be brought only in the state or federal courts located in Orange County, California.

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

Information selector

Biphasic

TENS-Symmetrical Biphasic

Amplitude Modulation (Vector, Surge and Reciprocation)

Pulse width and frequency


Time


Output intensity


Begin or forward (not selected)


Begin or forward (selected)


Back (not selected)


Back (selected)


Time in status bar


Output in status bar


Battery status


Device plugged in and running on mains power supply.


Info options


System check being conducted


AC power

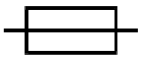

Attention, consult instruction manual.


Warning symbol indicates that the device emits laser energy and that proper precautions listed in this manual need to be taken.

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, dispose of separately from other trash.

UL Recognized Component Mark

Tested to comply with FCC standards

CE mark on battery

ETL and C–ETL Listed

2.2 Control Descriptions

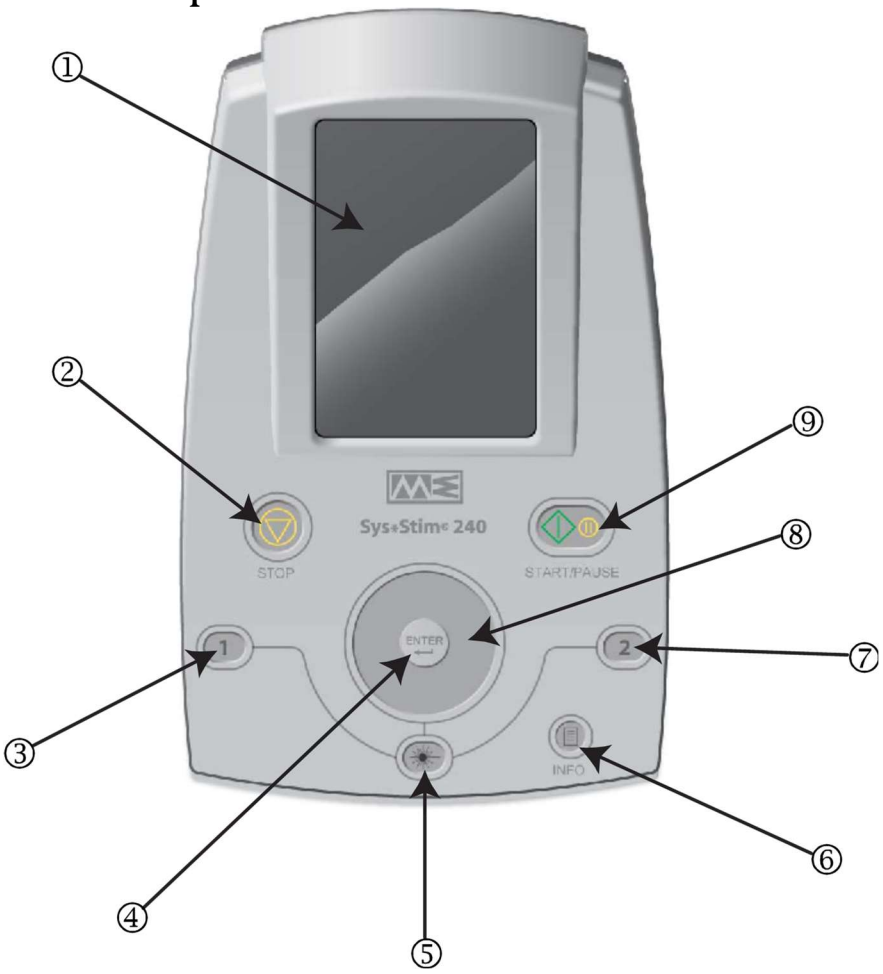


Figure 2.1— Sys∗Stim 240, control panel and display

1. Back-lit LCD display
2. Stop all treatments button
3. Channel 1 selector button
4. Enter button
5. Information selector button
6. M Wheel™ rotary control dial
7. Start / Pause treatment button

2.4 List of Abbreviations

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)
LCD	—	Liquid crystal display
μA	—	Microampere (1×10^{-6} ampere)
mA	—	Milliampere (1×10^{-3} ampere)
μs	—	Microsecond (1×10^{-6} second)
ms	—	Millisecond (1×10^{-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

Section 3—Installation

3.1 Installation Instructions

⚠CAUTION

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)
8. 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 mouthpiec electrode cables (Supplied by OrthodontiCell, Inc.) into the electrode cable connections as seen in Figure 3.4.
12. Finally, plug the patient safety cable into the back of the unit as shown in Figure 3.3.
13. Once you have verified proper functioning of your Sys∗Stim 240, using the instructions in Section 4, please go online to www.mettlerelectronics.com to register your product.
14. 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 battery 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

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.

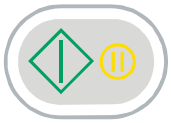
1. Each menu item is color coded so that the clinician can determine the status of a particular menu item. A white background denotes an item that can be selected. A yellow background shows where the curser is. A dark blue background indicates that you have selected the item and now you can change its 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 Info key to go to the Information menu.

4. 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.

5. Press the enter key to select a menu item.



START / PAUSE

6. 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.

STOP

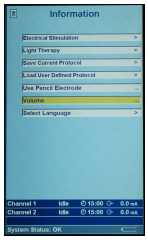
7. Pressing the stop button will immediately stop all treatments that are running.

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.

INFO

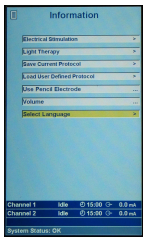
1. Press the info key to enter into the information menu.



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

CAUTION: 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 buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Applicable	

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**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 seconds	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 seconds	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 (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the A.C. mains voltage prior to application of the test level.			

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	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 GHz	3 V	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 $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80MHz to 800 MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d 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 W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
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 tested to 120 VAC for US/Canada	Unit designed to be failure safe in abnormal condition
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 the Mouthpiece

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 mouthpiece. Worn cables and/or tears or splits in the mouthpiece can have a significant impact upon treatment results.

4.2 General Operating Instructions:

Before you start:

a) Review precautions, contraindications and side effects/adverse reactions listed in Section 5.

b) Verify connection of the line cord to a grounded wall receptacle and the Sys∗Stim 240.

c) For electrical stimulation, connect the mouthpiece electrode cables (OrthodontiCell, Inc.) into the electrode connections for the channel that is going to be used.

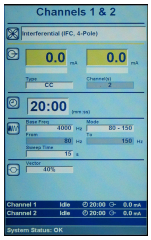
d) When the output current remains below the setting for a certain period of time, the setting may be automatically lowered. Check whether the electrodes are properly attached before using the Sys∗Stim 240.

e) 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.Do we need to alter this message?

f) Note: Descriptions of the symbols used on controls are in Section 2.

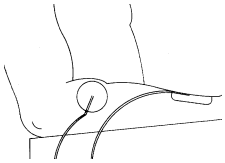
4.3 Quick Set-up for Electrical Stimulation

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 “1” to select channel one.

3. Insert the mouthpiece electrode cable into the channel connector.



4. Place the mouthpiece electrode in the patient’s mouth.

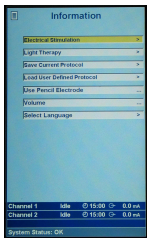
5. Insert the patient safety cable into the jack located on the back of the unit and hand the end with the button to the patient letting him/her know that they can push this button at any time during the treatment to stop it.

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.

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 Using Preset Programs

1. Press the “Info” button.



2. You will get the screen to the right. Use the M Wheel to scroll to “User Defined Protocol”. Press “Enter”.

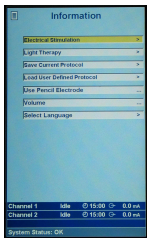
3. Electrical stimulation allows a protocol by waveform type.

4. 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.

4.5 Saving a Treatment Protocol

1. Select stimulation.
2. Setup the protocol that you would like to save into memory.

3. Press the “Info” button.



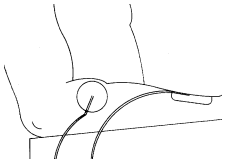
4. Scroll down to “Save Current Protocol” and press “Enter”.
5. Scroll down to the channel that you have your protocol setup on and press “Enter”.
6. A message box will indicate that “Save Current Protocol” Succeeded along with a number indicating the slot it was saved into. Press “Enter” to continue. There are ten slots for each waveform.

4.6 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 “1” to select channel one.

3. Insert the mouthpiece electrode cable into the channel connector for the channel that you will be using.



4. Place the mouthpiece electrode in the patient’s mouth.

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.

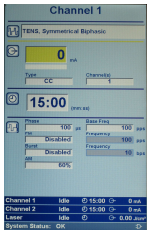
6. Use the M Wheel to scroll to any of the parameters that you would like to change. The parameters and their ranges are listed here for your reference:

Frequency:		1-200 pps
Phase Duration		20-400 µs
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
Type:		CC or CV
Options:		Channel 1

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-of-treatment 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.

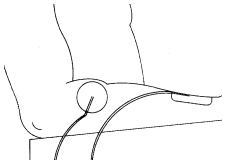
4.7 TENS, Symmetrical Biphasic Procedure

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 “1” to select channel one.

3. Insert the mouthpiece electrode cable into the channel connector for the channel that you will be using.



4. Place the mouthpiece electrode in the patient's mouthpiece.

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
Type:	CC or CV
Options:	Channel 1

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-of-treatment 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. - 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.

Section 5—Indications, Contraindications, Precautions and Adverse Reactions

5.1 Indications for Biphasic,

- Increase local blood circulation
- Improved cellular activity
-

5.2 Additional Indications for Biphasic and TENS waveforms

- Symptomatic relief and management of chronic, intractable pain
- Post-traumatic acute (orthodontic) pain
- Post-surgical acute Micro-osteo perforation) pain

5.3 Precautions for Biphasic and TENS waveforms

Powered muscle stimulators should be used only with the leads and electrodes recommended for use by Mettler Electronics Corp.

1. TENS is not effective for pain of central origin, including headache.
2. TENS is not a substitute for pain medications and other pain management therapies.
3. TENS devices have no curative value.
4. TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism.
5. The long-term effects of electrical stimulation are unknown.
6. 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.
7. 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.
8. 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.
9. Turn on the stimulator before applying electrodes to the patient.

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. For routine cleaning of the electrode cables use soap and water. Thoroughly dry after cleaning.

6.2 Routine Maintenance

1. 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
2. Inspect electrode cables and associated connectors for damage.
3. Never open the Sys∗Stim 240. Doing so may lead to malfunctions or accidents.
4. 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.
5. 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.
6. 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.**

6.3 Troubleshooting the Sys∗Stim 240

	Symptom	Action
1.	Nothing lights when main power switch is turned on.	Is line cord connected to outlet? Does the outlet have power? Unit may require servicing if none of the above resolves the problem.
2.	Self-Test Failed	Turn off the unit and then back on again. If the error persists the Sys∗Stim 240 requires servicing.
3.	Screen goes blank or comes up blank.	There has been an either a hardware or software 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.
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 mouthpiece electrode or cables. It will appear at 5 mA in continuous current or 50 volts in high volt. Check all cables and the mouthpiece 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 mouthpiece electrode cable connections to make sure that they are connected. Make sure the mouthpiece electrode is attached to the cables and to the patient. Try unplugging and replugging the mouthpiece electrode and or cable 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 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 mouthpiece electrode is removed from the mouth 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 mouthpiece electrode. 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. 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.
11. Error E90 - Impedance Too Low	Check the mouthpiece electrode. Reseat in the mouth 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.

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

Section 7—References

References for Neuromuscular Electrical Stimulation:

1. Bélanger A: Therapeutic Electrophysical Agents: Evidence Behind Practice, Williams and Wilkins, A Walters Kluwer Business, 2010.
2. Cohn JC and Mullin C: Neuromuscular Applications for Electrical Stimulation, from Physical Agents for the Physical Therapist Assistant, FA Davis Company, 1996.
3. Gillespie CA: Foundations for Electrical Stimulation, from Physical Agents for the Physical Therapist Assistant, FA Davis Company, 1996.
4. Hooper PD: Physical Modalities-A Primer for Chiropractic, Williams & Wilkins, 1996
5. Kenna KM: Pain Management with Electrical Stimulation, from Physical Agents for the Physical Therapist Assistant, FA Davis Company, 1996.
6. Knight KL and Draper DO: Electrotherapy from Therapeutic Modalities: The Art and Science, Lippincott Williams & Wilkins, a Wolters Kluwer business, 2008.
7. Mehreteab TA, Weisberg J and Nelson A: Electrotherapy from Physical Agents: A Comprehensive Text for Physical Therapists, Appleton & Lange, 1994.
8. Mullin D and Gardner ER: Physiologic Basis of Electrical Stimulation, from Physical Agents for the Physical Therapist Assistant, FA Davis Company, 1996.
9. Prentice W: Therapeutic Modalities: For Sports Medicine and Athletic Training, Mc Graw Hill Companies, 2008.
10. Shapiro s: Electrical Currents from Rehabilitation: From Research to Practice, Elsevier, 2008.
11. Sparrow KJ: Electrotherapeutic Modalities: Electrotherapy and Iontophoresis, from Modalities for Therapeutic Intervention (Contemporary Perspectives in Rehabilitation), F.A. Davis Company, 2005.
12. Starkey C: Electrical Agents, from Therapeutic Modalities, FA Davis Company, 1999.
13. Stillwell GK: Electrotherapy from Krusen's Handbook of Physical Medicine and Rehabilitation, W.B. Saunders Company, 1982.

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

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:	50°F to 104°F
Nonoperating:	-40°F to 167°F
Humidity:	
Operating:	30% to 75% Relative Humidity at 104°F
Non-Operating:	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

8.2 Waveform Specifications:

Biphasic

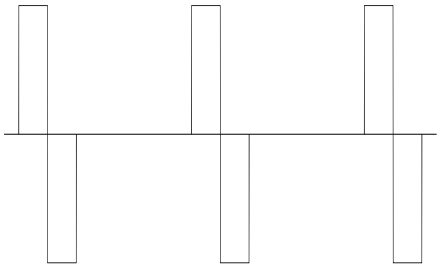


Figure 8.4—Biphasic Waveform

Waveform Type:		Amplitude modulated sine wave
Polarity:		None
Current:		0–100 mA peak, 500Ω load
Frequency:		1-200 pps
Phase Duration		20-400 µs
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
Type:		CC or CV
Available Channels:		All

TENS, Symmetrical Biphasic

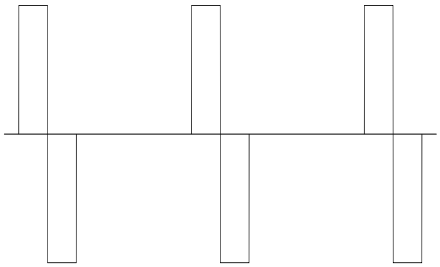


Figure 8.7—TENS Sym. Waveform

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
Type:	CC or CV
Available Channels:	All

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*.

9.2 Sys∗Stim 240 Accessories

Catalogue #	Item Description
2260	Electrode cable
2403	Patient safety switch
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