Sys*Stim® 208A

Instruction Manual

METTLER ELECTRONICS®

Table of Contents

List of Figures

Section 1: Introduction

1.1 Introduction to the Sys*Stim 208A

Thank you for purchasing the Sys*Stim 208A two-channel Low Volt neuromuscular stimulator. The microprocessor controlled Sys*Stim 208A produces low volt current through two channels. The unit produces an asymmetrical electrically balanced waveform. There are four modes of operation: Pulse—1 to 80 Hz, Tetanize—80 Hz, Surge—80 Hz, On/Off times variable and Recip—80 Hz, output alternates between the two channels.

The Surge mode produces an On/Off time from 0.5 to 3.75 seconds. The Recip mode produces On/Off times in alternate channels from 0.5 to 3.75 seconds. Both modes are used to contract and relax muscles.

The Sys*Stim 208A is portable and beautifully designed. Up and down buttons control the timer while easy-to-use knobs allow you to select treatment parameters and adjust intensity.

An accessory for the Sys*Stim 208A is the Patient Safety Switch, which is connected to the jack located on back of the unit and handed to the patient during treatment so that they can stop treatment if it becomes uncomfortable.

Figure 1.1— Sys*Stim 208A

1.2 Introduction to This Manual

Read the contents of this manual before treating patients with the Sys*Stim 208A.

This manual has been written to assist you with the safe operation of the Sys*Stim 208A. It is intended for use by the owners and operators of the Sys*Stim 208A. 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.

1.3 Safety Precautions

The Sys*Stim 208A operates with high voltages. Only qualified biomedical technicians with training in neuromuscular stimulator service should perform servicing of the Sys*Stim 208A 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.

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 208A is available from Mettler Electronics Corp. for a nominal charge.

1.4 Caution

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.

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous exposure to electrical energy. 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.

1.5 Shipping Damage

Your new Sys*Stim 208A 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 208A 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.

1.6 Package Contents

Your new Sys*Stim 208A 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 208A
2. Two electrode cable sets, (ME 2260)
3. Two gray pin to banana adapters, (ME 2027)
4. One package V Trodes, 2" diameter (ME 2702)
5. One patient safety switch, (ME 2031)
6. Detachable U.L. listed, hospital–grade line cord, (ME 7293)
7. Instruction Manual

1.7 Limited Warranty

The Sys*Stim 208A neuromuscular electrical stimulator is warranted against defects in materials and workmanship for a period of two years 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.

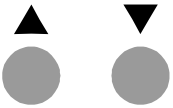
Any legal action brought by the buyer relating to this warranty must be commenced within one year from the date any claim arises and must be brought only in the state or federal courts located in Orange County, California.

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—Control Descriptions and List of Abbreviations

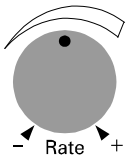
2.1 Control Descriptions

Time display shows time remaining in treatment in whole minutes. When the unit is first turned on the time display will show 15 minutes. You can set any time from 1-60 minutes.

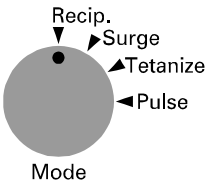


The timer controls allow you to adjust treatment time up or down.

The Reset indicator light turns off when the intensity controls are fully rotated to the “Off” position.

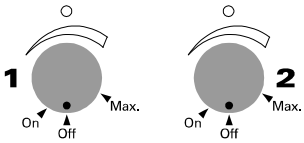


The Rate control knob adjusts Pulse frequency, Surge On/Off times and Recip. CH1/CH2 times.



The Mode control knob allows you to select the treatment mode.

Electrode cables are plugged into the electrode jacks, one for each channel.



The Intensity Controls allow you to adjust treatment intensity. The indicator lights will illuminate when stimulation output is active.

O

Mains Off.

I

Mains On.

Type BF Equipment—Class I

Attention, consult instruction manual.

2.2 List of Abbreviations

Hz	—	Hertz (pulses per second)
LED	—	Light Emitting Diode
µC	—	microcoulombs
µs	—	Microsecond (1 x 10^{-6} second)
mA	—	Milliampere (1 x 10^{-3} ampere)
min	—	Minutes
s	—	Seconds
S/N	—	Serial Number
V	—	Volts

Section 3—Installation

3.1 Installation Instructions

1. Connect the line cord to the back of the Sys∗Stim 208A. (See Figure 3.1)
2. Plug the line cord (ME 7293) into a grounded wall outlet that is rated at 100 to 240 Volt AC 50/60 Hz. Your power supply must match the voltage requirements listed on the serial number label of your device. **Do not connect the Sys∗Stim 208A to a power supply rated differently than that described above.**
3. The line cord comes equipped with a standard 3–prong plug. This plug provides grounding for the Sys∗Stim 208A. Do not defeat its purpose by using 3–to–2 prong adapters or any other means of attaching to a wall outlet.
4. Plug the electrode cables (ME 2260) into the electrode cable jacks as seen in Figure 3.2.
5. Plug the patient safety switch (ME2031) into the back of the unit as seen in Figure 3.1.
6. The Sys∗Stim 208A may be susceptible to interference originating from shortwave diathermy units operating in close proximity to it. Avoid operating the Sys∗Stim 208A adjacent to and simultaneously with operating shortwave devices.

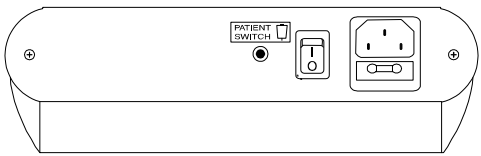


Figure 3.1— Sys∗Stim 208A, Back View—Mains Power Switch, Line Cord Connection and Patient Safety Switch Connection

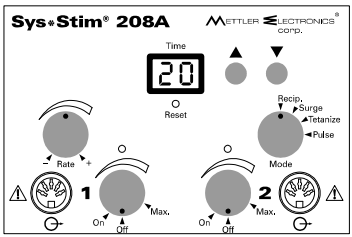


Figure 3.2— Sys∗Stim 208A, Front View—Electrode Cable Connections

Section 4—Operating Instructions

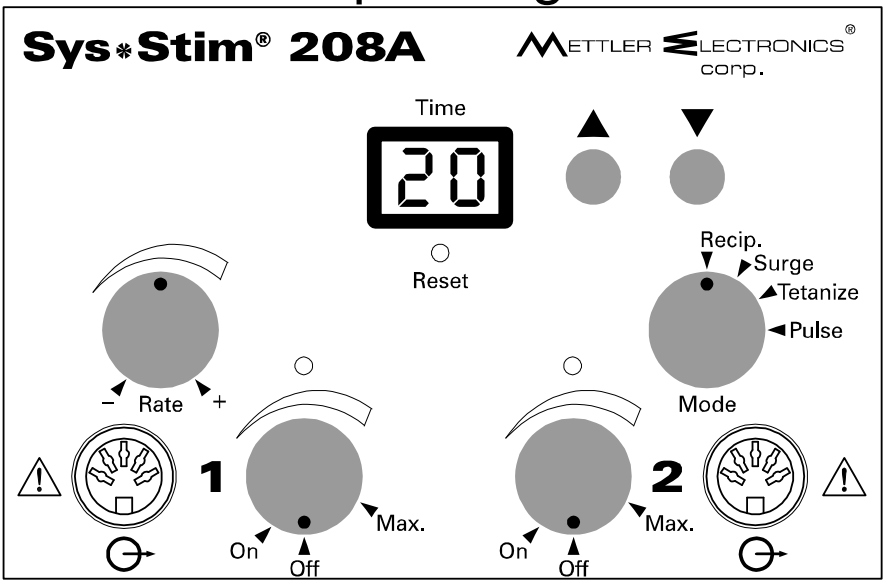


Figure 4.1—Front membrane panel and LED indicators

4.1 A Note about Electrodes

To ensure safe operation of the Sys*Stim 208A, 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. Do not exceed the number of recommended uses listed on the instructions for V Trodes or other reusable self–adhesive electrodes.
3. Make sure that the entire surface of the electrode is contacting the patient.
4. Do not use moist hot packs to secure electrodes.
5. To avoid skin irritation due to high current density, do not use electrodes smaller in surface area than the 2" diameter V Trode™ self-adhesive electrode (ME 2702).
6. Do not use conductive carbon electrodes with this product.
7. Whenever clinically possible, utilize the largest possible pads 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.

Diameter *inches*	**Surface Area** *Square inches*	**Current Density** *mA/sq in (for 10mA)*
1.25	1.2	8.2
2.00	3.1	3.2
3.00	7.1	1.4

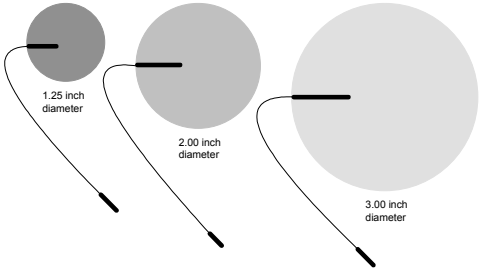


Figure 4.2—Electrode Sizes and Current Density

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.

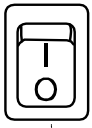
c) Verify connection of the line cord to a grounded wall receptacle and the Sys∗Stim 208A.

d) For electrical stimulation connect electrode cables (ME 2260) into the electrode connections for the channels that are going to be used.

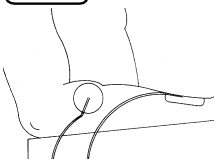
e) Connect the patient safety switch (ME2031) into the back of the unit and hand it to the patient.

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

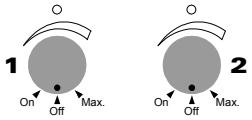
4.3 Operating Instructions



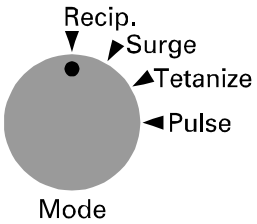
1. Turn on the mains power switch by pressing up on the On/Off switch located on the back of the unit.



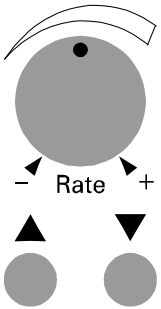
2. Apply the electrodes to the patient. Attach the electrode cables to the electrodes and to the Sys*Stim 208A.



3. Reset the intensity controls for both channels by rotating them fully counterclockwise to the "Off" position. The Reset LED indicator should turn off.

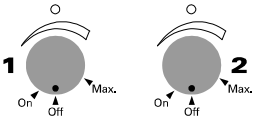


4. Select Treatment Mode:
   - Pulse, 1-80 Hz
   - Tetanize, 80 Hz
   - Surge, 80 Hz, 0.5 s to 3.75 s On/Off
   - Recip, 80 Hz, 0.5 s to 3.75 s C1/C2



5. Set the Rate by turning the control knob clockwise to increase and counterclockwise to decrease:
   - Pulse, 1-80 Hz
   - Surge, 0.5 s to 3.75 s On/Off
   - Recip., 0.5 s to 3.75 s CH1/CH2

6. Set the Timer by holding down the up arrow to increase the time and the down arrow to decrease the time. The default time is 15 minutes.



7. Adjust the stimulation intensity to patient tolerance by turning the intensity control knob for channel 1 or channel 2 clockwise to increase intensity or counterclockwise to decrease intensity.

8. At the end of the treatment the timer returns to zero and the unit will beep.

Section 5—Indications, Contraindications, Precautions and Adverse Reactions

5.1 Indications

The application of pulsating electric currents to the body via electrodes elicits responses from nerves, which conduct pain sensation and muscle contraction information. Stimulation of sensory fibers will help block pain while the stimulation of motor fibers will generate pulsatile contractions of the muscle groups innervated by the nerves being stimulated.

Based on this information, some of the indications for use are as follow:

1. Symptomatic relief of chronic intractable pain, acute post traumatic pain or acute post surgical pain.
2. Temporary relaxation of muscle spasm.
3. Prevention of post–surgical phlebo–thrombosis through immediate stimulation of calf muscles.
4. Increasing local blood circulation.
5. Prevention or retardation of disuse atrophy.
6. Muscle re–education.
7. Maintaining or increasing range of motion.

5.2 Contraindications

1. Electrical neuromuscular stimulation should not be administered to individuals who are or may be pregnant.
2. Do not stimulate a patient who has a cardiac demand pacemaker.
3. Patients with implanted electronic devices should not be subjected to stimulation.
4. Placement of electrodes across the chest laterally or anterior/posterior creates a possible hazard with cardiac patients and is therefore not recommended. Do not use transthoracically in any mode. Great care should be exercised in applying the electrical stimulus current to any region of the thorax because the stimulus current may produce cardiac arrhythmia. In patients with known heart disease, electrical stimulation should be used only after careful physician evaluation and patient instruction.
5. Place electrodes in such a way to avoid stimulation of the carotid sinus (neck) region.

6. Patients with arterial or venous thrombosis, or thrombophlebitis are at risk of developing embolisms when electrical stimulation is applied over or adjacent to the vessels containing the thrombus. If a patient has a history of deep vein thrombosis, even many years past, the affected area should not be stimulated.
7. Do not use over swollen, infected, or inflamed areas. Do not place electrodes over skin eruptions.
8. Fresh fractures should not be stimulated in order to avoid unwanted motion.
9. Do not apply stimulation transcerebrally (through the head).
10. Do not use on cancer patients.
11. Stimulation should not be applied immediately following trauma or to tissues susceptible to hemorrhage.
12. Positioning electrodes over the neck or mouth may cause severe spasm of the laryngeal or pharyngeal muscles. These contractions may be strong enough to close the airway or cause difficulty in breathing.
13. Do not apply stimulation for undiagnosed pain syndromes, until etiology is established.
14. Do not apply electrodes directly over the eyes or inside body cavities.
15. Do not use electrical stimulation in conjunction with high frequency surgical equipment or microwave therapy systems.

5.3 Warnings

1. Electrical stimulation is ineffective for pain of central origin, this includes headache.
2. Electrical stimulation must be applied by a physician or other qualified practitioner and should be used for only the prescribed purposes.
3. Electrical stimulation is of no curative value.
4. Electrical stimulation is a symptomatic treatment and as such suppresses the sensation of pain, which could serve as a protective mechanism.
5. The safety of electrical stimulators for use on children has not been determined. Keep out of reach of children.
6. The long–term effects of chronic electrical stimulation are unknown.
7. Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when electrical stimulation is in use.

5.4 Precautions

1. Care should be taken in the treatment of patients receiving another type of electrotherapeutic treatment (such as conventional TENS) or having indwelling electrodes, lead wires, or transmitters (for electrophrenic pacing or cerebellar or urinary bladder stimulation). Stimulation currents should not cross the lead wires or electrodes.
2. 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.
3. To prevent burns, avoid current densities exceeding 2 mA/cm² when using this device.
4. Isolated cases of skin irritation may occur at the site of electrode placement following long–term application.
5. Avoid placing electrodes directly over open wounds since current density tends to concentrate in these areas.
6. Use extreme caution when treating desensitized areas or on patients who may not be able to report discomfort or pain.
7. Use caution in applying electrical stimulation over areas where there is a loss of normal skin sensation.
8. Adequate precautions should be taken in the case of persons with suspected or diagnosed epilepsy.
9. Never leave the patient unattended during treatment without placing the patient treatment safety switch within the patient's reach and instructing the patient how to use it.
10. Care should be taken following recent surgical procedures when muscle contraction may disrupt the healing process.
11. Do not apply electrical stimulation over the menstruating uterus.
12. Effectiveness for pain management is highly dependent upon patient selection by a person qualified in the management of pain patients.
13. Electrode placement and stimulation settings should only be based on the guidance of the prescribing practitioner.
14. Electrical stimulators should be used only with the leads and electrodes recommended for use by the manufacturer.
15. Turn on the Sys*Stim 208A before applying electrodes to the patient.

5.5 Side Effects/Adverse Reactions

1. Skin irritation and burns beneath the electrodes have been reported with the use of electrical muscle stimulators.
2. Possible allergic reactions to tape, gel or electrodes may occur.

Section 6—Maintenance and Troubleshooting

6.1 Cleaning the Sys*Stim 208A

1. The Sys*Stim 208A 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.
2. Follow the V Trode package insert for the use and care of the electrodes supplied with the Sys*Stim 208A.
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.
2. Inspect electrode cables and associated connectors for damage.

6.3 Changing Fuses

Follow the sequence below when changing fuses:

1. Unplug the power cord from the wall and the back of the unit.
2. Pull out fuse drawer. The Fuse Block is located at below the Mains Plug on the unit. Pull it out until it comes completely out of the unit.
3. Remove fuse located at the rear of the fuse block. Please note: The fuse in the hollow tube of the fuse block is a spare.
4. Replace with a fuse of the same type and value.
5. Place fuse block back into Power Inlet.

6.4 Troubleshooting the Sys*Stim 208A

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 a new fuse. See Section 6.3 for replacing the fuse.
2. There is no stimulation output.	Turn intensity controls to the “Off” position. The “Reset” indicator should go out. If there is still no output, check the lead wires and electrodes for damage. If none of these actions is successful, the unit may require servicing.

Section 7—Specifications

7.1 General Specifications:

Input:	100 to 240 Volt AC 50/60 Hz, 0.75 Amp (max)
External Fuse:	0.75 A, 250 V, Slow Blow
Weight:	1.5 pounds
Dimensions:	2.75 in (H) x 6.1 in (D) x 8 in (L)
Maximum Treatment Time:	60 minutes

7.2 Output Specifications:

Channels:	Two
Waveform:	Asymmetrical biphasic with zero net DC
Voltage:	110 V Peak into a 1k ohm load 28 V Peak into a 100 ohm load
Intensity:	56 µC Max per Pulse into a 100 ohm load
Phase Duration:	200µS @ 50% Max Amplitude
Frequency:	Pulse Mode: 1-80 Hz Tetanize Mode: 80 Hz Surge Mode: 80 Hz Recip. Mode 80 Hz
Surge Cycle:	0.5 to 3.75 seconds On/Off
Recip. Cycle:	0.5 to 3.75 seconds CH1/CH2

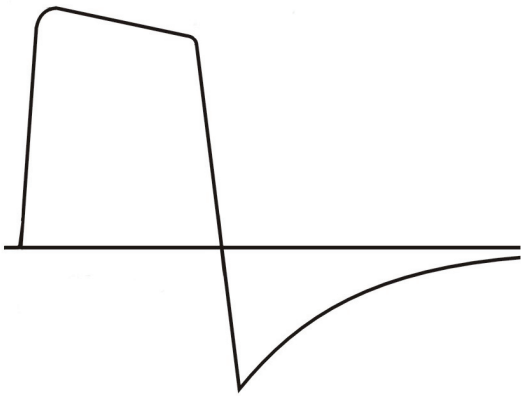


Figure 7.1—Waveform Illustration

Section 8—Accessories

8.2 Sys*Stim 208A Accessories

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")
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 plug set to be used with ME 2260 or 2261 electrode cables. Four each, gray.
2030	Bifurcated cord set, one red and one black, pin termination
2031	Patient safety switch
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 5" 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 for the Sys*Stim 208A with pins
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 (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.)
7293	Detachable U.L. listed, hospital–grade line cord

NOTES

NOTES