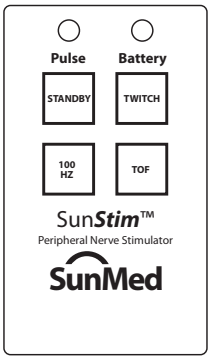
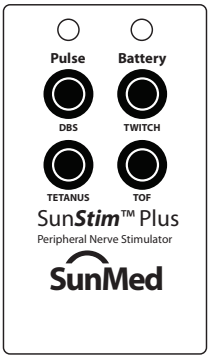
Sun*Stim*™ / Sun*Stim*™ Plus Peripheral Nerve Stimulator

SunMed



Sun*Stim*™
Peripheral Nerve Stimulator
8-1053-60



Sun*Stim*™ Plus
Peripheral Nerve Stimulator
8-1053-62

INSTRUCTIONS FOR USE

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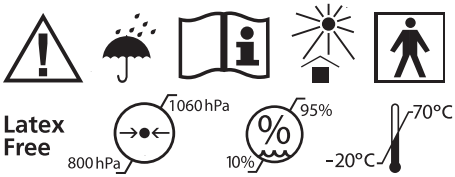


SunStim Instructions Rev. 1

1. INDICATIONS FOR USE

The Sun*Stim*™ and Sun*Stim*™ Plus Peripheral Nerve Stimulators are 9 Volt DC battery-powered, non-sterile devices, intended for monitoring the magnitude of neuromuscular block in general anesthesia, by delivering an electrical stimulus near a peripheral motor nerve and assessing the response of the muscle innervated by that nerve.

2. EQUIPMENT CLASSIFICATION

Per IEC 60601-1, Medical Device Equipment, General Requirements for Safety, SunStim™ or SunStim™ Plus Peripheral Nerve Stimulators are classified as follows:

Type BF Equipment

Type B of equipment provides a particular degree of protection against electrical shock, predominantly regarding allowable leakage current and reliability of the protective earth connection (grounding).

Type F part applies to extends from the patient into the equipment and is isolated from all other parts of the equipment.

Water Ingress Protection = IPX The Sun*Stim*™ or Sun*Stim*™ Plus Peripheral Nerve Stimulator do not have protection against ingress of water.

Continuous Operation The Sun*Stim*™ or Sun*Stim*™ Plus Peripheral Nerve Stimulator is designed for Continuous Operation.

Load Resistance = 510Ω

3. ACCESSORIES

The Sun*Stim*™ and Sun*Stim*™ Plus Peripheral Nerve Stimulators are provided with:

- Extension Leadwires
- Bipolar Probes

4. EQUIPMENT DISPOSAL

Dispose of Sun*Stim*™ or Sun*Stim*™ Plus Peripheral Nerve Stimulator should be done in accordance with local regulations.

5. WARNING / CAUTION STATEMENTS

CAUTION: Federal Law (USA) restricts this device to sale by or on order of a physician or appropriate licensed practitioner.

DO NOT: Use Sun*Stim*™ or Sun*Stim*™ Plus Peripheral Nerve Stimulator for nerve localization for anesthetic regional block.

DO NOT: Use Sun*Stim*™ or Sun*Stim*™ Plus Peripheral Nerve Stimulator on patients with neuromuscular or skin diseases.

DO NOT: Use Sun*Stim*™ or Sun*Stim*™ Plus Peripheral Nerve Stimulator in the proximity of equipment which produces electromagnetic fields, short or micro waves.

DO NOT: Use Sun*Stim*™ or Sun*Stim*™ Plus Peripheral Nerve Stimulator in the presence of a flammable anesthetic mixture with air or in the presence of a flammable anesthetic mixture with oxygen or nitrous oxide.

DO NOT: Modify any components of this equipment.

DO NOT: Use Sun*Stim*™ or Sun*Stim*™ Plus Peripheral Nerve Stimulator in case of battery leakage.

a) The Sun*Stim*™ or Sun*Stim*™ Plus Peripheral Nerve Stimulator may be hazardous to patients with implanted electrical, medical devices.

b) It is important to monitor the correlation of nerve reaction stimulation with the patient's clinical condition, as there may be a discrepancy between the degree of relaxation and of the monitored muscle at the site of surgery.

c) Tetanus nerve stimulation should be performed only after the anesthetic has been administered.

d) Stimulus current must be increased gradually, until supramaximal stimulus is achieved. Applying currents greater than necessary for supramaximal stimulation may increase the risk of skin burns.

e) Prior to Sun*Stim*™ or Sun*Stim*™ Plus Peripheral Nerve Stimulator usage, patient's skin should be cleaned and completely dried. This area should be free of excessive hair, scar tissue, or any other lesions.

f) This device should not fall into liquids. Liquids should not be spilled over or into the device.

g) The leadwire or bipolar probe electrodes would be attached to the instrument while the numbered control knob is in the OFF position.

h) Sun*Stim*™ or Sun*Stim*™ Plus Peripheral Nerve Stimulator must be used with 9V alkaline battery only.

i) The operator of this device cannot touch the actual battery and the patient simultaneously.

j) Battery should be removed if the Nerve Stimulator is not likely to be used for some time.

k) In case of battery leakage, the device should not be used.

l) Prior to each use, check the Sun*Stim*™ or Sun*Stim*™ Plus Peripheral Nerve Stimulator for proper condition and functioning.

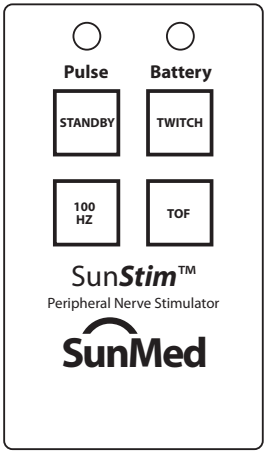
m) The Sun*Stim*™ or Sun*Stim*™ Plus Peripheral Nerve Stimulator should be stored/transport at the room ambient temperature, away from heat. No special ambient temperature range is specified for this device.

n) Caution should be used when switching between DBS (Double Burst) and Train-of-Four stimulation. Up to 92 seconds may be required before the responses are stabilized.

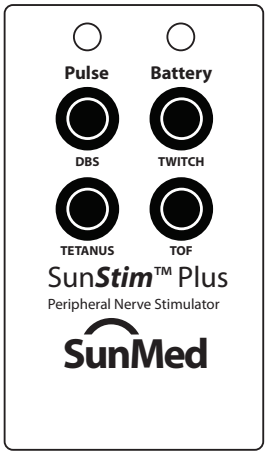
6. TECHNICAL DATA

Model	Sun*Stim*™	Sun*Stim*™ Plus
Type of Device	BF	BF
Membrane Touch Switch	StandBy Twitch 100 Hz Train-of-Four (TOF)	Double Burst Twitch Tetanus Train-of-Four (TOF)
Pulse Charateristics **Pulse Width:** **Pulse Type:**	 200 Microseconds Square Wave Monophasic	 200 Microseconds Square Wave Monophasic
Tetanus	100 Hz	50 Hz or 100 Hz
Double Burst Pulses (DOB)	N/A	Two (2) 60 ms bursts of 50 Hz separated by 0.75 seconds
Output Current	Adjustable 0-70mA	Adjustable 0-70mA
Display **Pulse LED:** **Battery LED:**	 Flash red when pulse is generated Steady green, when the unit is turned ON	 Flash red when pulse is generated Steady green, when the unit is turned ON
Battery Power	One 9V alkaline battery. Battery LED flashes when battery voltage is low	One 9V alkaline battery. Battery LED flashes when battery voltage is low
Power Supply	Internally powered ME equipment	Internally powered ME equipment
Power Consumption	Approximately 15.0 mA	Approximately 13.0 mA
Protection Grade	IPX0	IPX0
Operation Mode	Continuous Operation	Continuous Operation
Size	3.75"H x 2.25"W x 1"D	3.75"H x 2.25"W x 1"D
Weight (Including Battery)	0.25 lb	0.25 lb
Rheostat (control knob)	Controls the current	Controls the current

7. PANEL TOUCH SWITCHES



Sun*Stim*™
STANDBY: No stimulus pulses are generated.
TWITCH: Produce twitch stimulation, which is automatically repeated (one pulse per second), until the button is released. This button can be turned off, by pressing the STANDBY button.
100 Hz: Produce tetanic stimulation when pressed and held down. Tetanic stimulation consists of 100 Hz electrical stimuli.
Train-of-Four (TOF): Generate four (4) equal intensity single pulses in a period of two (2) seconds. This function can be repeated as often as needed.



Sun*Stim*™ Plus
DBS (Double Burst Pulses): This stimulation produces two short sequences of 50 Hz tetanic stimuli separated by 750 msec. This stimulation should not be repeated at intervals of less than twelve (12) seconds.
TWITCH: Produce twitch stimulation, which is automatically repeated (one pulse per second), until the button is released. This button can be turned off by pressing the DBS or TOF button.
TETANUS: Produce rapidly repeated stimulation when pressed and held down. Provided electrical stimuli is set for 100Hz. This default can be changed to 50 Hz, by opening the battery cover and removing the battery. 50 Hz/ 100 Hz slide switch is located within the battery compartment. You may move the slide to the desired frequency (50 Hz or 100 Hz). Once this step is completed, reconnect the battery and close the battery cover, prior to start using the Sun*Stim*™ Plus unit again. The tetanus stimulation should not be repeated more often than every two (2) minutes, as its affect may fade.
Train-of-Four (TOF): Generate four (4) equal intensity single pulses in a period of two (2) seconds. This function can be repeated as often as needed.

8. OPERATION INSTRUCTIONS

8.1 Switching the unit on and off

A. The Sun*Stim*™ or Sun*Stim*™ Plus Peripheral Nerve Stimulator can easily be switched on and off by rotating the rheostat (control knob) clockwise. The rheostat (control knob) is located on the left hand side of the Nerve Stimualtor. Once ON, the device will be in the Stand-By mode, and no pulses will be produced.

B. The numbered rheostat (control knob) (numbered from 0-10) intended use it to adjust the stimulation amplitude of the output current, which may range from 0 to 70 mA. If the rheostat (control knob) is set to zero, stimulation amplitude will not be delivered.

8.2 Four Panel Touch Switches

A. Stimulation frequency patterns may be activated by pressing one of four panel touch switches (Sun*Stim*™ – STANDBY, TWITCH, 100 Hz, TOF; Sun*Stim*™ Plus – DBS, TWITCH, TETANUS, or TOF).

B. Pulse LED will flesh each time a pulse is generated.

8.3 Output Connectors

A. Transcutaneosly stimulation can be carried out by using surface electrodes.

B. Sun*Stim*™ or Sun*Stim*™ Plus Peripheral Nerve Stimulator is supplied with metal ball electrodes and lead wires.

C. Two (2) connectors, RED (positive) and BLACK (negative), are located on the top of the Sun*Stim*™ or Sun*Stim*™ Plus Peripheral Nerve Stimulator case.

D. The output current may reach up to 70 mA, measured with load of 2KOhm load, using a new 9V DC battery.

E. Provided lead wires with BLACK plug should be connected to the black output connector. This connection will create the negative output.

F. Provided lead wires with RED plug, should be connected to the red output connector. This connection will create the positive output.

G. Bipolar Probe Electrodes can be connected to output connectors, by plugging them directly into the two, RED (positive) and BLACK (negative), located on the top of the Sun*Stim*™ or Sun*Stim*™ Plus Peripheral Nerve Stimulator case, output connectors.

H. It is recommended to create a lead wires loop after they have been attached to electrodes, and a piece of tape placed over them in order to prevent possible electrodes displacement.

I. Nerve Stimulator should be connected to electrodes that are positioned over the selected nerve, prior to anesthesia induction.

9. PERIPHERAL NERVE MONITORING SITES

9.1 The site of stimulations should be away from the surgical field and its location accessible to the anesthesia provider.

9.2 Location of the instrument should approximately five (5) feet above the floor to provide easy viewing of the touch switches and indicators.

9.3 If visual or tactile nerve monitoring is to be used, the site location must be accessible to the anesthesia provider.

9.4 Electrical stimulus can be performed at the:

9.4.1. Ulnar Nerve - Leads/bipolar probes may be placed:

9.4.1.1 Along the medial aspect of the distal forearm (wrist);

9.4.1.2 Over the sulcus of the medial epicondyle of the humerus (elbow);

9.4.1.3 On hand, by placing the negative electrode on the palm between the base of the thumb, and the second finger, and the positive electrode in the same position on the dorsal side of the hand.

9.4.2 Median Nerve - Leads/bipolar probes may be placed:

9.4.2.1 Medial to the wrist;

9.4.2.2 At the elbow adjacent to the brachial artery.

9.4.3 Tibial Nerve - Leads/bipolar probes may be placed:

9.4.3.1 Along the lateral side of the popliteal fossa.

9.4.4 Posterior Tibal Nerve - Leads/bipolar probes are placed:

9.4.4.1 At the medial maleolus and anterior to the Achilles tendon at the ankle.

9.4.5 Peroneal Nerve - Leads/bipolar probes are placed:

9.4.5.1 On the lateral aspect of the knee.

9.4.6 Facial Nerve - Leads/bipolar probes are placed:

9.4.6.1 Negative electrode is placed anterior to the inferior part of the ear lobe, and the positive electrode is placed posterior or inferior to the lobe.

9.4.7 Spinal Accessory nerve - Leads/bipolar probes are placed:

9.4.7.1 Over the depression between the ramus.

10. MAINTENANCE

10.1 Prior to use, make sure to read and understand provided Instructions for Use. Check condition of the Sun*Stim*™ or Sun*Stim*™ Plus Peripheral Nerve Stimulator and provided connectors for proper functioning, prior to each use.

10.2 The Sun*Stim*™ or Sun*Stim*™ Plus Peripheral Nerve Stimulator and all accessories must be visually inspected at regular intervals for any material degradation or battery leakage.

10.3 This device does not require user maintenance/service, except the periodic battery replacement.

10.3.1 Battery Maintenance/Replacement

a. This device may be used with Alkaline 9V battery only.

b. Battery replacement is needed when the Battery LED flashes during the use.

c. Prior to battery replacement, make sure that the device is turned OFF, by rotating the control knob to the "OFF" position.

d. Slide off the battery compartment cover.

e. Remove the old battery, and install the new battery.

f. Correct polarity is needed for battery proper functionality.

g. Place the battery cover back into the original position.

The Sun*Stim*™ or Sun*Stim*™ Plus Peripheral Nerve Stimulator should not be used in case of battery leakage, as the acid may impair internal circuits.

11. CLEANING

Only soft, damp, clean cloth is recommended for cleaning of Sun*Stim*™ or Sun*Stim*™ Plus Peripheral Nerve Stimulator. Liquids or humidity can damage this device, and their usage is strictly prohibited.

12. SERVICE

The Sun*Stim*™ or Sun*Stim*™ Plus Peripheral Nerve Stimulator should not be serviced by the end user (s). End user (s) may replace batteries only.

In a case of device damage or malfunction, do not attempt any repairs. In such case, contact SunMed Customer Service at 800.433.2797 immediately.

13. STORAGE AND TRANSPORT

The environmental conditions of use including conditions for transport and storage are as listed below:

Operating Temperature	+10°C to +40°C
Operating Humidity	30% RH to 85% RH
Storage/Transport Temperature Range	-20°C to +70°C
Storage/Transport Humidity	10% RH to 95% RH
Operating and Storage/ Transport Atmospheric Pressur	800hPa to 1,060hPa

14. WARRANTY

The Sun*Stim*™ or Sun*Stim*™ Plus Peripheral Nerve Stimulator are free from defects in workmanship and materials for one (1) year from purchase, when used for the intended purpose and cared for in accordance with recommended procedure.

No charge repairs will be made during the one year warranty period, only if the Sun*Stim*™ or Sun*Stim*™ Plus Peripheral Nerve Stimulators have not be abused, and/or subjected to unauthorized repair.

15. SYMBOL MEANINGS