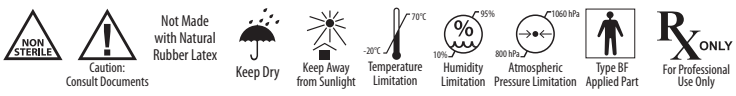
Instructions for Use:
SunStim™, SunStim™ Plus, and SunStim™ Pro Peripheral Nerve Stimulator



Indications for Use: SunStim™, SunStim™ Plus and SunStim™ Pro Peripheral Nerve Stimulators are each a battery-powered device intended for monitoring the magnitude of neuromuscular block in general anesthesia by delivering an electrical stimulus near a peripheral motor nerve.

This document is applicable to the following SunStim Peripheral Nerve Stimulators:

8-1053-60	SunStim Peripheral Nerve Stimulator
8-1053-62	SunStim Plus Peripheral Nerve Stimulator
8-1053-63	SunStim Pro Peripheral Nerve Stimulator

The following instructions will describe all three models collectively as *Nerve Stimulator* unless noted.

WARNINGS and CAUTIONS

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

⚠ DO NOT: Use Nerve Stimulator for nerve localization for anesthetic regional block.

⚠ DO NOT: Use Nerve Stimulator on patients with neuromuscular or skin diseases.

⚠ DO NOT: Use Nerve Stimulator in the proximity of equipment which produces electromagnetic fields, short or micro waves.

⚠ DO NOT: Use 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 Nerve Stimulator in case of battery leakage.

⚠ The Nerve Stimulator may be hazardous to patients with implanted electrical medical devices.

⚠ 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.

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

⚠ 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.

⚠ Prior to 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.

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

⚠ DO NOT: Attach lead wire or bipolar probe electrodes to the device until power is completely OFF.

⚠ The Nerve Stimulator must be used with 9V alkaline battery only.

⚠ The operator of this device must not touch the actual battery and the patient simultaneously.

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

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

⚠ Prior to each use, check the Nerve Stimulator for proper condition and functioning.

⚠ 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.

EQUIPMENT CLASSIFICATION

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

Type BF Equipment

Type B part 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 a part which is electrically isolated from ground and other parts of the medical equipment (i.e. floating).

Water Ingress Protection = IPX The Nerve Stimulator does not have protection against ingress of water.

Continuous Operation The Nerve Stimulator is designed for continuous operation.

Load Resistance = 510Ω

ACCESSORIES

The Nerve Stimulators are provided with:

- Extension Lead Wires
- Bipolar Probes

OPERATION INSTRUCTIONS

Switching the unit on and off; adjusting stimulation amplitude

1. The SunStim and SunStim Plus Peripheral Nerve Stimulator can easily be switched on and off by rotating the rheostat (control knob) clockwise; it is located on the left-hand side of the device. Once ON, the device will be in the Standby mode, and no pulses will be produced.
2. The SunStim Pro Peripheral Nerve Stimulator is turned on and off by pressing the ⏻ button for three seconds. The ⏻ button is located in the middle of the device faceplate. Once ON, the device will be in Standby mode, and no pulses will be produced.
3. On the SunStim and SunStim Plus Peripheral Nerve Stimulator, the numbered rheostat (control knob numbered from 1-10) is used 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 1, stimulation amplitude will not be delivered.
4. On the SunStim Pro Peripheral Nerve Stimulator, the +/- button is used to adjust the stimulation amplitude of the output current, which may range from 0 to 70 mA. The +/- button is located on the right-hand side of the device. If the output current level setting is zero, stimulation amplitude will not be delivered. The setting level and current output are displayed on the LCD screen.

Four Panel Touch Switches

1. Stimulation frequency patterns may be activated by pressing one of four panel touch switches (SunStim – STANDBY, TWITCH, 100 Hz, TOF; SunStim Plus – DBS, TWITCH, TETANUS, TOF; SunStim Pro – DBS, TWITCH, TETANUS, TOF).
2. Pulse LED will flash each time a pulse is generated.

Output Connectors

1. Transcutaneous stimulation can be carried out by using surface electrodes.
2. The Nerve Stimulator is supplied with metal ball electrodes and lead wires.
3. Two (2) connectors, RED (positive) and BLACK (negative), are located on the top of the Nerve Stimulator device.
4. The output current may reach up to 70 mA, measured with a 2K Ohm load, using a new 9V DC battery.
5. Provided lead wires with BLACK plug, should be connected to the black output connector. This connection will create the negative output.
6. Provided lead wires with RED plug, should be connected to the red output connector. This connection will create the positive output.
7. Bipolar probe electrodes can be connected to output connectors, by plugging them directly into the RED (positive) and BLACK (negative) connectors, located on the top of the Nerve Stimulator device.
8. 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 electrode displacement.
9. The Nerve Stimulator should be connected to electrodes that are positioned over the selected nerve, prior to anesthesia induction.

PERIPHERAL NERVE MONITORING SITES

1. The site of stimulations should be away from the surgical field and its location accessible to the anesthesia provider.
2. If visual or tactile nerve monitoring is to be used, the site location must be accessible to the anesthesia provider.
3. Electrical stimulus can be performed at the:

Ulnar Nerve - Leads/bipolar probes may be placed:
- Along the medial aspect of the distal forearm (wrist);
- Over the sulcus of the medial epicondyle of the humerus (elbow);
- 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.

Median Nerve - Leads/bipolar probes may be placed:
- Medial to the wrist;
- At the elbow adjacent to the brachial artery.

Tibial Nerve - Leads/bipolar probes may be placed:
- Along the lateral side of the popliteal fossa (behind knee).

Posterior Tibial Nerve - Leads/bipolar probes are placed:
- At the medial maleolus and anterior to the Achilles tendon at the ankle.

Peroneal Nerve - Leads/bipolar probes are placed:
- On the lateral aspect of the knee.

Facial Nerve - Leads/bipolar probes are placed:
- Negative electrode is placed anterior to the inferior

Continued on other side.

TECHNICAL DATA

Model	SunStim™ | 8-1053-60	SunStim™ Plus | 8-1053-62	SunStim™ Pro | 8-1053-63
Type of Device	BF	BF	BF
Membrane Touch Switches	StandBy Twitch 100 Hz Train-of-Four (TOF)	Double Burst (DBS) Twitch Tetanus Train-of-Four (TOF)	Double Burst (DBS) Twitch Tetanus Train-of-Four (TOF)
Pulse Characteristics **Pulse Width:** **Pulse Type:**	200 Microseconds Square Wave Monophasic	200 Microseconds Square Wave Monophasic	200 Microseconds Square Wave Monophasic
Tetanus	100 Hz	50 Hz or 100 Hz	50 Hz or 100 Hz
Double Burst Pulses (DBS)	N/A	Two (2) 60 ms bursts of 50 Hz separated by 0.75 secs (750 milliseconds)	Two (2) 60 ms bursts of 50 Hz separated by 0.75 secs (750 milliseconds)
Output Current	Adjustable 0-70 mA	Adjustable 0-70 mA	10 settings ranging from 10-70 mA
Display **Pulse LED:** **Battery LED:**	Flash *yellow* when pulse is generated Steady *green*, when the unit is turned ON	Flash *yellow* when pulse is generated Steady *green*, when the unit is turned ON	Flash *yellow* 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	One 9V alkaline battery Battery symbol on LCD screen and green battery light will flash simultaneously when battery voltage is low
Power Supply	Internally powered ME equipment	Internally powered ME equipment	Internally powered ME equipment
Power Consumption	Approximately 15.0 mA	Approximately 13.0 mA	Approximately 13.0 mA
Protection Grade	IP20	IP20	IP20
Operation Mode	Continuous Operation	Continuous Operation	Continuous Operation
Size	3.75" x 2.25" x 1" (95.25 mm x 57.15 mm x 25.4 mm)	3.75" x 2.25" x 1" (95.25 mm x 57.15 mm x 25.4 mm)	4.53" x 2.46" x 1.02" (115 mm x 62.5 mm x 26 mm)
Weight (With Battery)	0.25 lb	0.25 lb	0.25 lb
Rheostat (Control Knob)	Controls the current	Controls the current	NA
+ / – (Switch)	NA	NA	Controls the current

Continued from front.

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

Spinal Accessory Nerve - Leads/bipolar probes are placed:
- Over the depression between the ramus.

MAINTENANCE

1. Prior to use, make sure to read and understand provided Instructions for Use. Check condition of the Nerve Stimulator and provided connectors for proper functioning, prior to each use.
2. The Nerve Stimulator and all accessories must be visually inspected at regular intervals for any material degradation or battery leakage.
3. This device does not require user maintenance/service, except for periodic battery replacement.

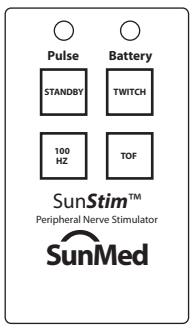
Battery Maintenance/Replacement

1. This device shall be used with 9V alkaline battery only.
2. Battery replacement is needed when the Battery LED flashes during use.
3. Prior to battery replacement, make sure that the device is turned OFF.
4. Slide off the battery compartment cover.
5. Remove the old battery, and install the new battery.
6. Correct polarity is needed for proper battery function.
7. Place the battery cover back into the original position.

The Nerve Stimulator should not be used in case of battery leakage, as the acid may impair internal circuits.

TOUCH PANEL BUTTONS + SWITCHES

SunStim™ | 8-1053-60



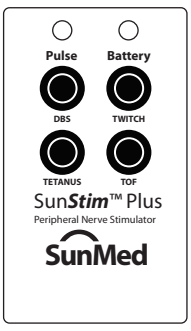
STANDBY: No stimulus pulses are generated.

TWITCH: Produce twitch stimulation, which is automatically repeated (one pulse per second), once the button is pushed. 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.

SunStim™ Plus | 8-1053-62



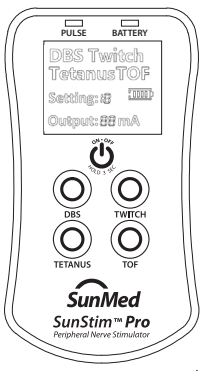
DBS (Double Burst Pulses): This stimulation produces two short sequences of 50 Hz tetanic stimuli separated by 0.75 sec. (750 millisecond). This stimulation should not be repeated at intervals of less than twelve (12) seconds.

TWITCH: Produce twitch stimulation, when pressed and held down, 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 using the SunStim™ Plus unit again. The tetanus stimulation should not be repeated more often than every two (2) minutes, as its effect 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.

SunStim™ Pro | 8-1053-63



ON/OFF: When device is off, it can be turned ON by pressing and holding power button for three (3) seconds. When device is on, it can be turned OFF by pressing and holding power button for three (3) seconds.

DBS (Double Burst Pulses): This stimulation produces two (2) short sequences of 50 Hz tetanic stimuli separated by 0.75 sec. (750 millisecond). This stimulation should not be repeated at intervals of less than twelve (12) seconds.

TWITCH: Produce twitch stimulation, when pressed and held down, 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 using the SunStim™ Pro unit again. The tetanus stimulation should not be repeated more often than every two (2) minutes, as its effect may fade.

Train-of-Four (TOF): Generate four (4) equal intensity single pulses in a period of 2.0 seconds. This function can be repeated as often as needed.

Current Switch: Increase current intensity by one step by pressing and releasing "+" switch. Pressing and holding "+" will continuously increase current by one step every 0.25 second. Decrease current intensity by one step by pressing and releasing "–" switch. Pressing and holding "–" will continuously decrease current by one step every 0.25 second.

DBS	Indicates device is working in DBS mode.
Twitch	Indicates device is working in TWITCH mode.
Tetanus	Indicates device is working in TETANUS mode.
TOF	Indicates device is working in TOF mode.
	Indicates remaining capacity of battery; each bar represents 25% of battery capacity. Flashing symbol indicates battery is low.
1 - 10	Setting: 1-10
10 - 70 mA	Output: indicates current output (10-70 mA).

CLEANING

⚠ Use a clean cloth with 70% isopropanol to wipe down entire nerve stimulator for at least 15 seconds. Do no submerge device in liquid, as liquids or humidity can damage this device. Let the device dry at least 5 minutes before using on a patient.

SERVICE

⚠ The 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.

EQUIPMENT DISPOSAL

⚠ Disposal of Nerve Stimulator should be done in accordance with local regulations.

STORAGE AND TRANSPORT

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

Operating Temperature	$^{+}$10°C to $^{+}$40°C ($^{+}$50°F to $^{+}$104°F)
Operating Humidity	30% RH to 85% RH
Storage/Transport Temperature Range	$^{-}$20°C to $^{+}$70°C ($^{-}$4°F to $^{+}$158°F)
Storage/Transport Humidity	20% RH to 95% RH
Operating & Storage/Transport Atmospheric Pressure	800hPa to 1,060hPa

WARRANTY

The Nerve Stimulator is 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 Nerve Stimulator has not be abused, and/or subjected to unauthorized repair.

SunMed

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SunStim.INIFU Rev.6