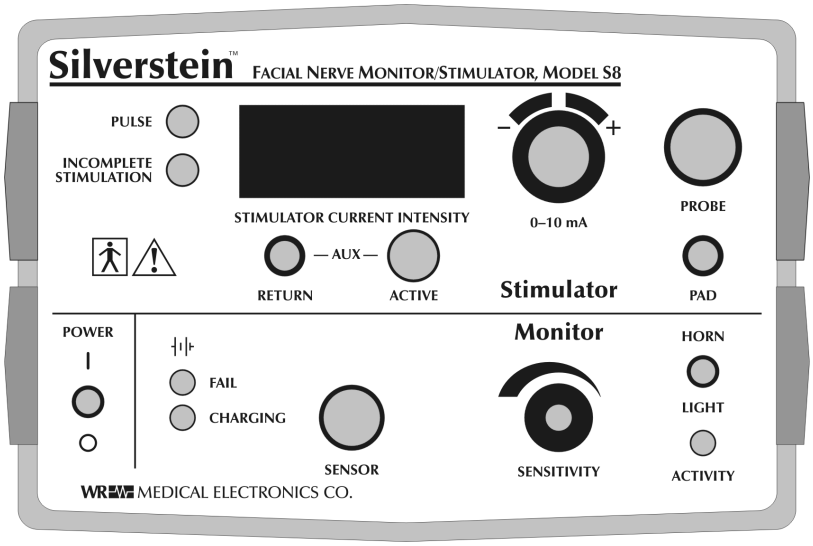
SILVERSTEIN™

FACIAL NERVE STIMULATOR/MONITOR
MODEL S8



Instructions for Use,
Version 3.1

WR Medical Electronics Co.

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Silverstein Facial Nerve Monitor/Stimulator, Model S8, **Instructions for Use,** version 3.0, item number 3035, revised 06/18.

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COMMENTS OR QUESTIONS?

We would appreciate receiving any suggestions, comments, or questions that would help us to improve this manual. Please forward comments to the address above.

WARNINGS & CAUTIONS

WARNING: Simultaneous contact of the stimulator probe and high frequency surgical equipment, such as an electrocautery device, to a patient may result in burns at the site of the stimulator electrodes and possible damage to the stimulator. Remove probe from operating site when using electrocautery or electrosurgery devices and keep electrode pad physically separated and electrically isolated from electrocautery or electrosurgery units.

WARNING: Simultaneous connection of a patient to a high frequency surgical equipment and to an electromyograph or evoked response equipment may result in burns at the site of the electrical stimulator or biopotential input part electrodes and possible damage to electrical stimulator or biological amplifiers.

WARNING: Operation in close proximity, to shortwave or microwave therapy equipment may produce instability in the electrical stimulator output.

WARNING: Portable and mobile RF communication devices may affect the Silverstein Facial Nerve Monitor/Stimulator. This device may also be interfered with by other equipment even if it complies with Cisper limits. In the event that any equipment is adversely affecting this device, remove the offending equipment from the area.

WARNING: Patients with an implanted electronic device, such as a cardiac pacemaker, should not be subjected to stimulation unless specialist medical opinion has first been obtained.

WARNING—PARALYZING DRUGS: Be aware of the effects of paralyzing drugs. When injected in close proximity to the nerve, the responsiveness of the nerve and muscle to stimulation may be affected.

WARNING: Battery charger must not be plugged into device when in use.

WARNING: Avoid accidental contact between connected but unapplied applied parts and other conductive parts including those connected to protective earth.

WARNING: Avoid trans-thoracic stimulation, for example maintenance of anode and cathode stimulating sites in close proximity.

CAUTION: Federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

CAUTION: The Silverstein Facial Nerve Monitor/Stimulator and SACS Cable are to be operated only by trained personnel under the direction of a physician.

CAUTION: The Silverstein Facial Nerve Monitor/Stimulator is not explosion-proof and should not be used in the presence of explosive gases.

CAUTION—INSTRUMENT PERFORMANCE: Caution must be exercised because there is no guarantee that the monitor system will always respond to a nerve stimulus. Current setting, distance from nerve, position and placement of Cheek Muscle Sensor, muscle response, and other factors will affect operation of the monitor. The monitor is designed to assist in locating nerves. No guarantee of performance is intended or implied.

CAUTION: Do not use the SACS™ cable with electrically powered drills. Do not allow any active ends of the cable or active tools/probes which are not in use to touch conductive materials such as the operating table, microscope, etc. The ends of the cable are "active" whenever the cable is connected to the stimulator.

ADVERTENCIAS Y PRECAUCIONES

ADVERTENCIA: el contacto simultáneo de la sonda del estimulador y el equipo quirúrgico de alta frecuencia, como un aparato de electrocauterio, con un paciente puede producir quemaduras en el lugar de los electrodos del estimulador y posibles daños a este. Extraiga la sonda del sitio de operación cuando utilice aparatos de electrocauterio o electrocirugía y mantenga la almohadilla del electrodo físicamente separada y eléctricamente aislada de las unidades de electrocauterio o electrocirugía.

ADVERTENCIA: la conexión simultánea de un paciente a un equipo quirúrgico de alta frecuencia y a un electromiógrafo o equipo de respuesta evocada puede producir quemaduras en el lugar del estimulador eléctrico o electrodos con piezas de entrada biopotenciales y posibles daños al estimulador eléctrico o a amplificadores biológicos.

ADVERTENCIA: la operación cerca de equipos de terapia de microondas u onda corta puede producir inestabilidad en la salida del estimulador eléctrico.

ADVERTENCIA: los aparatos de comunicación por RF móviles y portátiles pueden afectar al estimulador/monitor del nervio facial Silverstein. Este aparato también puede recibir interferencias de otros equipos aunque cumpla los límites de Cisper. En caso de que algún equipo afecte adversamente a este aparato, retire el equipo de la zona.

ADVERTENCIA: los pacientes con un aparato electrónico implantado, como un marcapasos, no deben someterse a estimulación a menos que se obtenga primero la valoración médica de un especialista.

ADVERTENCIA DE FÁRMACOS PARALIZANTES: conozca los efectos de los fármacos paralizantes. Cuando se inyectan cerca del nervio, la respuesta de este y del músculo a la estimulación puede verse afectada.

ADVERTENCIA: el cargador de la batería no debe estar enchufado en el aparato durante su uso.

ADVERTENCIA: evite el contacto accidental entre piezas conectadas pero sin aplicar y otras piezas conductoras, incluidas las conectadas a la tierra de protección.

ADVERTENCIA: evite la estimulación transtorácica, por ejemplo el mantenimiento de los sitios de estimulación del ánodo y del cátodo en proximidad.

PRECAUCIÓN: la ley federal sólo permiten vender o hacer un pedido de este dispositivo a un médico (o a un profesional con la licencia pertinente).

PRECAUCIÓN: solo el personal formado bajo la dirección de un médico debe operar el estimulador/monitor del nervio facial Silverstein y el cable SACS.

PRECAUCIÓN: el estimulador/monitor del nervio facial Silverstein no es a prueba de explosión y no debe utilizarse en presencia de gases explosivos.

PRECAUCIÓN—RENDIMIENTO DEL INSTRUMENTO: tenga cuidado porque no hay garantía de que el sistema del monitor responda siempre a un estímulo del nervio. La configuración actual, la distancia del nervio, la posición y colocación del sensor del músculo de la mejilla, la respuesta del músculo y otros factores afectarán al funcionamiento del monitor. El monitor está diseñado para ayudar a localizar los nervios. No se pretende ni se implica ninguna garantía del rendimiento.

PRECAUCIÓN: no utilice el cable SACS™ con taladros eléctricos. No permita que los extremos activos del cable o las herramientas o sondas activas que no se estén utilizando toquen materiales conductores como la mesa quirúrgica, el microscopio, etc. Los extremos del cable están "activos" siempre que este se encuentre conectado con el estimulador.

AVERTISSEMENTS ET MISES EN GARDE

AVERTISSEMENT : L'application simultanée sur un patient de la sonde stimulatrice et d'un matériel chirurgical à haute fréquence, comme un électrocautère, peut provoquer des brûlures sur le site des électrodes stimulatrices et éventuellement endommager le stimulateur. Retirer la sonde du site opératoire lors de l'utilisation de dispositifs d'électrocautérisation ou d'électrochirurgie, et maintenir la plaque d'électrode physiquement séparée et électriquement isolée des appareils d'électrocautérisation ou d'électrochirurgie.

AVERTISSEMENT : la connexion simultanée d'un patient à un matériel chirurgical à haute fréquence et à un électromyographe ou à un équipement de réponse évoqué peut entraîner des brûlures sur le site du stimulateur électrique ou des électrodes côté entrée du biopotentiel, et des dommages éventuels au stimulateur électrique et aux amplificateurs biologiques.

AVERTISSEMENT : une utilisation à étroite proximité de matériel de thérapie à ondes courtes ou à micro-ondes peut entraîner une instabilité au niveau de la sortie du stimulateur.

AVERTISSEMENT : des appareils de communication RF portables et mobiles peuvent affecter le moniteur/stimulateur du nerf facial Silverstein. Ce dispositif peut également subir des interférences de la part d'autres équipements, même s'il satisfait aux seuils CISPR. Au cas où un matériel quelconque aurait un effet négatif sur ce dispositif, retirer ce matériel perturbateur de la zone de travail.

AVERTISSEMENT : les patients équipés d'un appareil électronique implanté, tel qu'un stimulateur cardiaque, ne doivent pas être soumis à une stimulation sans qu'un avis favorable d'un spécialiste ait été préalablement obtenu.

AVERTISSEMENT—MÉDICAMENTS PARALYSANTS : penser aux effets des médicaments paralysants. Lorsqu'ils sont injectés au voisinage immédiat du nerf, la réponse du nerf et du muscle à la stimulation peut en être affectée.

AVERTISSEMENT : le chargeur de batterie ne doit pas être branché dans l'appareil quand celui-ci est en cours d'utilisation.

AVERTISSEMENT : Éviter tout contact accidentel entre des parties connectées mais non appliquées et d'autres parties conductrices, y compris celles qui sont reliées à la terre de protection.

AVERTISSEMENT : Éviter la stimulation transthoracique, par exemple le placement à étroite proximité de sites d'anode et de cathode.

ATTENTION : la loi fédérale américaine limite la vente de ce dispositif aux médecins (ou aux praticiens détenteurs de la license appropriée).

ATTENTION : le moniteur/stimulateur de nerf facial Silverstein et le câble SACS ne doivent être utilisés que par du personnel formé, sous la direction d'un médecin.

ATTENTION : le moniteur/stimulateur de nerf facial Silverstein n'est pas antidéflagrant et ne doit pas être utilisé en présence de gaz explosifs.

ATTENTION—PERFORMANCES DE L'INSTRUMENT : il convient de faire preuve de prudence, car il n'est pas garanti que le système de surveillance réponde toujours à une stimulation du nerf. Le paramétrage en cours, la distance par rapport au nerf, la position et le placement du détecteur du muscle de la joue, la réponse du muscle, et d'autres facteurs peuvent affecter le fonctionnement du moniteur. Ce moniteur est conçu pour aider à localiser les nerfs. Il n'offre aucune garantie de performance prévue ou implicite.

ATTENTION : ne pas utiliser le câble SACS™ avec des perceuses électriques. Ne laisser aucune extrémité active du câble, ni aucune sonde ni aucun outil actifs non utilisés, toucher des matériaux conducteurs, comme la table d'opération, un microscope, etc. Les extrémités du câble sont «actives», c'est-à-dire sous tension, chaque fois que le câble est connecté au stimulateur.

WARN- UND SICHERHEITSHINWEISE

WARNHINWEIS: Der gleichzeitige Kontakt eines Patienten mit der Stimulatorsonde und hochfrequenten chirurgischen Geräten, wie etwa Elektrokauter, kann zu Verbrennungen an der Stelle führen, wo die Stimulatorelektrode anliegt und mögliche Schäden am Stimulator verursachen. Entfernen Sie die Sonde aus dem Operationsfeld, wenn Sie Elektrokauter oder elektrische Operationsgeräte benutzen und sorgen Sie für die physische Trennung und elektrische Isolierung der Elektrodenunterlage von Elektrokauterisations- oder Elektrochirurgiegeräten.

WARNHINWEIS: Der gleichzeitige Anschluss eines Patienten an ein hochfrequentes chirurgischen Gerät und einen Elektromyographen oder ein Gerät zur evozierten Reaktion kann zu Verbrennungen an der Stelle führen, wo die Stimulatorelektrode oder die Elektroden zur Erfassung des Biopotenzials anliegen, und mögliche Schäden am elektrischen Stimulator oder an biologischen Verstärkern verursachen.

WARNHINWEIS: Der Betrieb in unmittelbarer Nähe eines Geräts zur Kurzwellen- oder Mikrowellentherapie kann zur Instabilität der Ausgangsleistung des Elektrostimulators führen.

WARNHINWEIS: Tragbare und mobile Funk-Kommunikationsgeräte können den Silverstein Facial Nerve Monitor/Stimulator (Gesichtsnerven-Monitor/Stimulator) beeinflussen. Das Gerät kann ebenfalls durch andere Geräte gestört werden, selbst wenn diese die CISPR-Grenzwerte einhalten. Sollte das Gerät durch ein anderes gestört werden, entfernen Sie das störende Gerät aus dem Arbeitsbereich.

WARNHINWEIS: Bei Patienten mit implantierten elektronischen Geräten wie Herzschrittmachern sollte eine Stimulation erst durchgeführt werden, nachdem die Meinung eines Spezialisten eingeholt wurde.

WARNHINWEIS – MEDIKAMENTE MIT PARALYSIERENDER WIRKUNG: Beachten Sie die Wirkungen von paralysierenden Medikamenten. Wenn diese in der Nähe des Nerven injiziert werden, kann die Reaktionsfähigkeit des Nerven und des Muskels auf die Stimulation beeinträchtigt werden.

WARNHINWEIS: Das Batterieladegerät darf während der Benutzung des Geräts nicht angeschlossen sein.

WARNHINWEIS: Vermeiden Sie versehentlichen Kontakt zwischen angeschlossenen, aber nicht verwendeten Teilen und anderen elektrisch leitenden Teilen, einschließlich solcher mit Erdung.

WARNHINWEIS: Vermeiden Sie eine transthorakale Stimulation, zum Beispiel indem Sie bei der Stimulation Anode und Kathode nah beieinander platzieren.

SICHERHEITSHINWEIS: Gemäß dem Bundesgesetz darf dieses Gerät nur an einen Arzt (oder einen zugelassenen Angehörigen der Heilberufe) oder auf Anordnung desselben verkauft werden.

SICHERHEITSHINWEIS: Der Silverstein Facial Nerve Monitor/Stimulator (Gesichtsnerven-Monitor/Stimulator) und das SACS-Kabel dürfen nur durch geschultes Personal unter Anleitung eines Arztes betrieben werden.

SICHERHEITSHINWEIS: Der Silverstein Facial Nerve Monitor/Stimulator (Gesichtsnerven-Monitor/Stimulator) ist nicht explosionsgeschützt und darf nicht in Gegenwart explosiver Gase angewendet werden.

SICHERHEITSHINWEIS – GERÄTELEISTUNG: Es ist besondere Vorsicht geboten, da keine Garantie dafür besteht, dass das Überwachungssystem immer auf einen Nervenreiz reagiert. Die aktuelle Einstellung, der Abstand zum Nerv, die Stelle und Positionierung des Wangenmuskelsensors, die Muskelreaktion und andere Faktoren beeinflussen den Betrieb des Überwachungsgeräts. Das Gerät ist zur Lokalisierung von Nerven gedacht. Es besteht keine beabsichtigte oder implizierte Garantie für die Leistung.

SICHERHEITSHINWEIS: Verwenden Sie das SACS™-Kabel nicht mit elektrisch betriebenen Bohrern. Stromführende Enden oder stromführende Werkzeuge, die nicht benutzt werden, dürfen keine leitenden Teile, wie Operationstisch, Mikroskop usw. berühren. Die Kabelenden sind „stromführend", solange das Kabel am Stimulator angeschlossen ist.

Sterilization

- The Remote Surgical Probe and the Monopolar Surgical Probe are provided sterile and are SINGLE-USE devices. They are not intended to be reprocessed (cleaned, disinfected/sterilized). Single-use devices do not undergo extensive testing validation and testing for reuse. Reprocessing may alter device characteristics and performance may be compromised as a result.
- The Surface Electrode Pad Cable is a non-critical reusable device.

Batteries

This unit uses two 8.4V, 2500mA or 2600mA Nickel-Cadmium (Ni-Cad) battery packs. Each pack contains seven 1.2V 2500mA or 2600mA cells. Replacement batteries and instructions are available from WR Medical Electronics Co. Dispose of used batteries according to local regulations.

System Classification (IEC601-1/ EN60601-1)

ENVIRONMENTAL RATINGS

After exposure to transport and storage extremes, allow the system to acclimatize before operating. The system should not be subject to transport and storage extremes for

Type of protection against electric shock:	Type BF
Degree of protection against electric shock:	Class II
Degree of protection against moisture ingress (IEC529), S8 Main Unit (p/n 3910):	Ordinary IPXO
Degree of protection against moisture ingress (IEC529), Footswitch (p/n 3130):	IPX8
Degree of protection in the presence of a flammable anesthetic mixture with air or with oxygen or with nitrous oxide:	Not protected (unsuitable)
Mode of operation:	Continuous
Desktop Medical Switching Battery Charger (p/n 3442):	EN60601-1, IEC 601-1

CLEANING

Before cleaning always ensure that the unit is powered off. Never immerse the unit or any components. Do not apply cleaning solutions to the unit directly, instead apply to a cloth and then use it to clean the requisite components. To clean the main unit, cheek muscle movement sensor, and electrode pad cable;

- Dust with a dry cloth
- Use a damp cloth with water, enzymatic cleaner, 70% isopropyl alcohol, bleach wipes, or quarternary ammonium compound.
- Do not autoclave, pressure sterilize, or gas sterilize
- Do not soak or immerse in any liquid
- Do not use petroleum based or acetone or other harsh solvents.

RESPONSIBILITY OF THE SUPPLIER

WR Medical Electronics Co. accepts responsibility for the affects of safety, reliability and performance of the equipment only if:

- Assembly operations, extensions, readjustments, modifications, or repairs are conducted by persons authorized by WR Medical Electronics Co.
- The electrical installation of the room complies with local regulations.
- The equipment is used in accordance with the Instructions for Use.

ELECTROMAGNETIC COMPATIBILITY

The system has been independently tested and found to comply with IEC601-1-2/EN60601-1-2.

Emissions are limited to CISPR 11 Class A Group 1 (industrial environment). Some care may be needed to minimize disturbance to sensitive receivers. Immunity from external disturbances is assured for operation in normal residential and clean industrial environments. If in doubt, consult WR Medical Electronics.

SAFETY AND INFORMATION SYMBOLS

Symbols that appear on the equipment have the following meaning:

Attention, consult accompanying documents

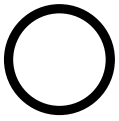
Type BF Applied Part — F Type patient contact part isolated from other parts of the equipment such that patient leakage currents cannot exceed allowed limits in NORMAL and SINGLE FAULT CONDITION

Footswitch

Battery

Variability

Variability with a preset starting point



Power off

Power on

Latex Statement

No natural rubber latex is used in the manufacturing of this equipment or accessories.

Environmental Protection and Disposal of Equipment

At the end of service, consult local regulations for disposal of batteries and other system parts.

OUTPUT PARAMETERS

The Silverstein Model S8 provides a square-wave pulse, which is adjustable from 0.05 milliamperes (mA), residual current, to 10.0 mA, maximum current, by using the buttons on the Remote Probe or the dial on the front panel. Current intensity refers to the amplitude of the individual pulses, not to the average level of current. There is no current between pulses.

Nerve response to electrical stimulation is a function of current intensity through the nerve rather than of applied voltage. Consequently, precise control of current intensity is essential for quantitative evaluation of nerve response. In the Model S8, the voltage is automatically adjusted (utilizing a constant current output) to compensate for any changes in the patient-stimulator circuit resistance so that the current is constant at any given setting of the STIMULATOR CURRENT INTENSITY display.

SYSTEM COMPONENTS

(Specific component lists may vary based on package purchased)

Part Number	Item description
3910	Silverstein Model S8 Main Unit
3129	Cheek-Muscle Movement Sensor
3217	Remote Surgical Probe (single-use)
3188	Monopolar Surgical Probe (single-use)
3194	Electrode pad Cable with Protected Plug
3214	Electrode Pads, pkg of 30
3442	Universal Charger
0309	Hospital Grade Power Cord
3130	Foot Switch
3035	Instructions For Use, Silverstein, Model S8
3197	SACS Cable with Protected Plug
3150	Small End Clip for SACS Cable
3152	Large End Clip for SACS Cable
3033	Instructions For Use, SACS Kit

Power Switch

Located in the lower left corner, this switch turns the main unit on and off.

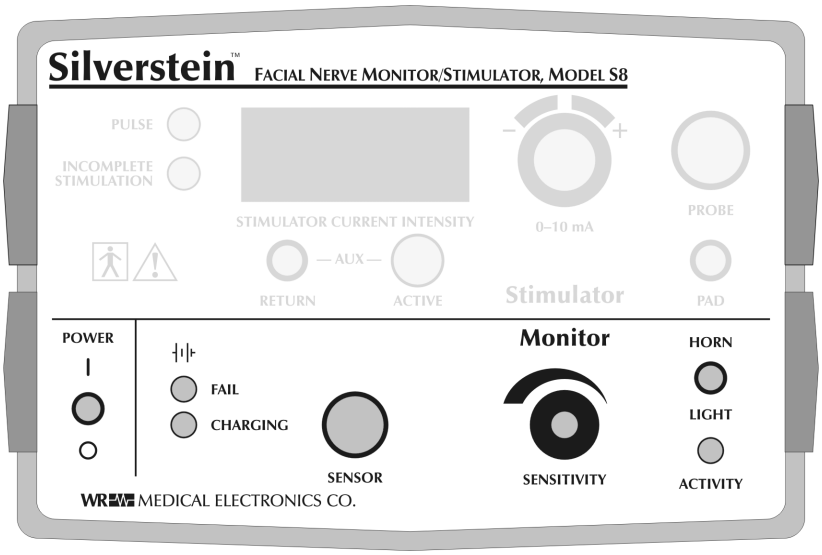


Figure 2

Front Panel: Monitor

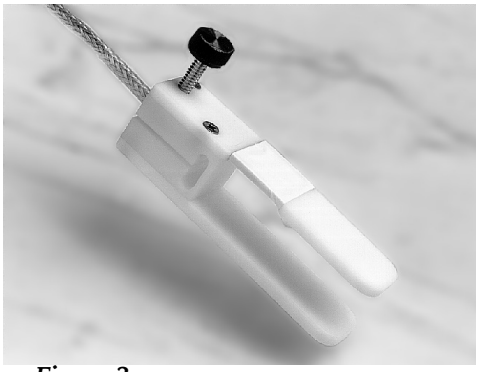


Figure 3

Cheek Sensor

MONITOR CONTROLS

Sensitivity Dial

When the monitor's SENSITIVITY dial is fully counter-clockwise, the monitor is most sensitive. To desensitize, turn the knob clockwise.

Activity Light

The yellow ACTIVITY light illuminates to signal the surgeon that the Cheek Sensor circuit was activated (when LIGHT is selected on the HORN/LIGHT switch).

Horn/Light Switch

The HORN/LIGHT toggle switch is used to select an aural or visual signal, at the option of the surgeon. In cases where other equipment in the room has a similar aural signal, or where the operating environment may be too noisy to hear the audible tone, the visual signal may be selected. The sound level may be adjusted by turning the dial on the rear panel (see figure 4).

Cheek Muscle Movement Sensor

The Cheek Muscle Movement Sensor is inserted into the mouth and is attached to the cheek of the intubated patient on the same side as the intended surgical procedure. The plug on the end of the Cheek Muscle Sensor cable is plugged into the SENSOR jack on the instrument panel. A sensor should be connected to the SENSOR jack at all times that the monitor is in use. If a sensor is not connected, the audible tone or activity indicator light may give false indication due to pickup of stray electrical noise or signals. The Cheek Muscle Sensor is quite delicate and should be treated with care. Pulling on wires, repeated bending, especially sharp bends, can cause broken wires or intermittent false signals.

Battery Fail Light

The FAIL light indicates that the battery level is too low for operation of the device. Do not use instrument if FAIL light is illuminated.

Charging the Batteries

When the unit is on and the battery FAIL light is illuminated, the Ni-Cad batteries will require charging. To charge, turn the unit off, plug the battery charger into a 100-240VAC receptacle and plug the small round connector into the back of the unit. The batteries will charge only when the unit is off. The green CHARGING light on the front panel should illuminate. The unit will be fully charged in 30-36 hours. **Do not charge longer than 36 hours.** The charging circuit is disabled if the battery charger is plugged into the connector and the unit is on.

- **NOTE: The output voltage of the charger must be +24VDC center positive. The output current of the charger must not be less than 0.4A and must not be greater than 2A. Plug is Switchcraft 760 or equivalent.**

Foot Switch

The Foot Switch may be used to disable the ACTIVITY light or the horn. Heat from the cautery equipment can cause a spontaneous nerve impulse, which might result in a muscle contraction. Simply plug the pedal into the FOOT SWITCH jack on the rear panel and depress the foot pedal when muting is desired.

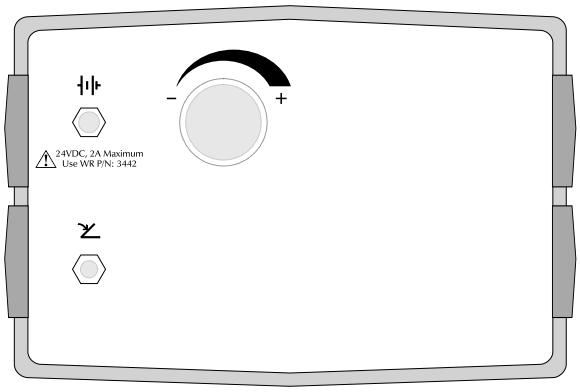


Figure 4

Rear Panel

STIMULATOR CONTROLS

Pulse Light

When the instrument is on, the clear PULSE light (to the left of the CURRENT INTENSITY display) flashes with each pulse of the stimulating current, indicating that the instrument is on and that the stimulator section is functioning. Between stimulating or monitoring activity, turn the instrument off to conserve battery power.

Incomplete Stimulation Light

The INCOMPLETE STIMULATION light provides a way to verify that stimulating pulses are being correctly administered to the patient. The INCOMPLETE STIMULATION light illuminates when the full amount of the specified current (as displayed on the STIMULATOR CURRENT INTENSITY display) is **not** being administered to the patient. The light will go off when the full amount of the specified current **is** being administered to the patient. For example, if the current intensity display reads 0.60, and the INCOMPLETE STIMULATION light is off, then 0.60 milliamps of current are being delivered.

NOTE: If the INCOMPLETE STIMULATION light is on, the stimulator may still be delivering current, and may still be capable of stimulating a nerve. A fractional amount of the stimulating current being delivered to the patient may be sufficient to evoke a nerve response (and because it would be a percentage of what is indicated in the display, the indicator would be illuminated). See the Incomplete Stimulation and Resistance section, page 14, for further discussion.

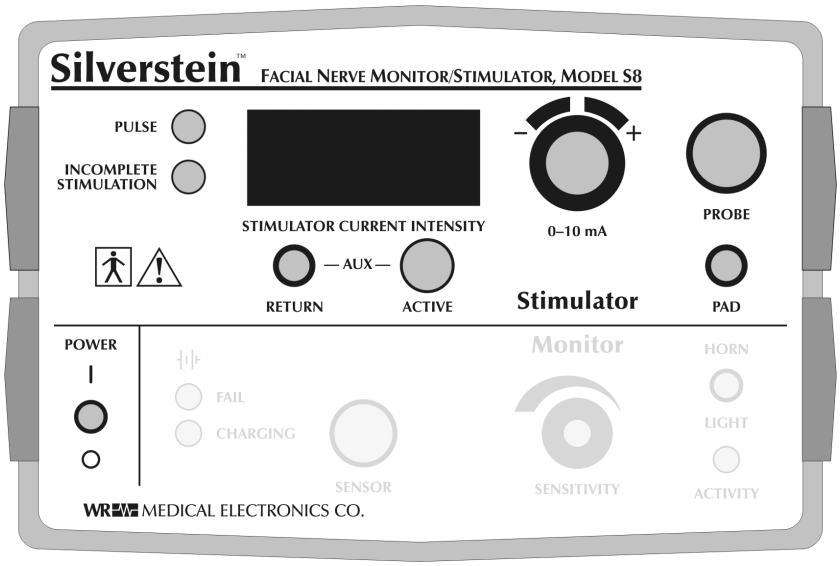


Figure 5

Front Panel: Stimulator

Stimulator Current Intensity Display

This backlit digital display indicates current intensity and gives the current reading in milliamperes (mA). The current intensity can be adjusted from 0.0 to 10.0 mA using the buttons on the Remote Probe or the dial on the front panel. At a reading of 0.0 there is a residual current of about 0.05 mA.

Current Intensity Dial

This is one of two ways to control the current as shown on the CURRENT INTENSITY display. See also the Remote Probe section, below.

Pad Jack

When a Monopolar Probe or the Remote Probe is used, a surface electrode ("ground") pad must be used to complete the electrical path through the patient. Plug the cable for the surface electrode pad into the jack labeled PAD directly below the connector for the probe.

Probe Jack

Connect the Remote Probe to the front panel at the connector labeled PROBE: First align connectors, insert plug, and rotate locking collar on plug.

Auxiliary Jacks — Return And Active

Monopolar and bipolar probes may be used with the Silverstein, and are plugged into the AUX jacks. Current to these probes can be controlled using either the Remote Probe, or the dial on the front panel. If the Remote Probe is used to control current, use caution as the tip is "active" whenever it is plugged in. The AUX binding posts accept banana plugs, spade lugs, alligator clips, or bare wire. Either plug can be connected to either AUX jack (RETURN or ACTIVE). Shorting the probe tips or AUX jacks together will not harm the instrument. No reference electrode (ground) pad is required when a bipolar stimulating probe is used. Surgical instruments having a black non-reflective coating are not suitable for applying the stimulating current because of the high electrical resistance of the coating.

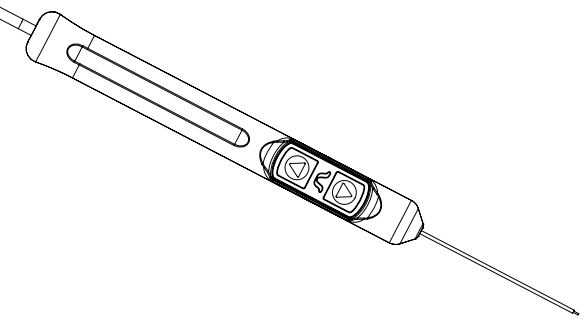


Figure 6
Remote Probe

REMOTE PROBE

The Remote Probe has a 0.55mm flexitip that is fixed in place. This is flush-tipped, insulated to the end, and can be bent to any angle. The remote probe is a single-use item and shouldn't be reprocessed.

The Remote Probe has two buttons for controlling current output. The front button is up, the rear button is down. Never simultaneously press both up and down buttons.

Connect the Remote Probe at the connector labeled PROBE on the front panel.

TILT STAND (HANDLE)

The tilt stand can be rotated to raise the front panel of the instrument for better visualization by the surgeon. It can also be rotated to the rear of the instrument to allow placement on a stack of monitoring equipment. To rotate, simultaneously pull both stand-out hubs (on either side of the unit) and rotate the handle underneath the instrument.

OPERATIONAL NOTES

Monitor Sensitivity and Activity Artifacts

The Silverstein Model S8 is highly sensitive and has been designed to pick up the slightest vibrations and contractions of the cheek muscle. The sensitivity of the instrument is primarily determined by how the Cheek Muscle Sensor is installed and by physiological factors of the patient. It is impossible to quantify how small of a contraction could be detected, but the instrument has the capability (under certain conditions) to pick up the expansion of tissue due to blood flow. This has been demonstrated in the lab and has been reported by surgical personnel.

If you detect a blood pulse, turn the SENSITIVITY dial clockwise to desensitize the instrument. Generally, use the instrument on the most sensitive setting possible.

Activity artifacts sometimes signify a problem and other times can be ignored. It is imperative that their causes and meanings are understood. Artifacts may be caused by the following:

- Movement of the drapes, operating table, or tubes near the face or in the mouth.
- Adjustment of the stimulus output current. The horn will sound when the current is being adjusted on some or all sensitivity levels. This is a normal occurrence and does not indicate a fault with the unit. This occurs because the monitor is so sensitive it can detect the loss of electrons from the Ni-Cad battery pack (due to current draw by the motorpot).
- Energizing of electrocautery. Artifact sometimes occurs when cautery is energized.

Use the Foot Switch pedal provided with the instrument to disable the horn. The light position (on the HORN/LIGHT switch) may also be used. When locating nerves, be sure that interfering equipment is off. Since the cheek can contract only as a result of nerve impulses, and since Cheek Muscle Sensor picks up contractions only as a result of impulses (natural or artificial stimulation), most artifacts can be ignored—with this exception:

- In some cases the exposed nerve will spontaneously fire impulses when it is directly manipulated with a surgical instrument, bumped with a tool, or irrigated with cold fluids. If the spontaneous impulses are large enough, they will cause a contraction that will be detected by the Cheek Muscle Sensor.

Checking the Sensor Circuit

You may test the functioning of the monitoring circuit and audible signal by lightly touching the Cheek Muscle Sensor. When the SENSITIVITY dial is set to maximum, the sensor will be so sensitive that if you set it on a flat surface and blow on it, you will set it off. You should be able to touch the patient's cheek lightly and get a response.

- **Note: As stated on page 4, only solutions containing one percent or less of Xylocaine injected in normal quantity and not unduly close to the nerve do not appear to affect the function of the Model S8. Higher concentrations can reduce the nerve's responsiveness to the stimulating current.**

Incomplete Stimulation and Resistance

The INCOMPLETE STIMULATION light verifies whether stimulating pulses are being correctly administered to the patient. The light will go out when the full amount (as shown on the display) is administered.

The most common cause of the stimulator not delivering the full amount of specified current is high resistance being encountered somewhere between the stimulator output (or "active") and the stimulator return (or "ground"). High circuit resistance may be caused by a variety of factors, including marginal probe contact with patient tissue, poor contact between the stimulator return electrode ("ground pad") and patient skin, attempting to stimulate through an area that does not conduct well (such as dry bone), or the stimulating probe or stimulator return cable not being plugged in.

- **NOTE: If the INCOMPLETE STIMULATION light is on, the stimulator may still be delivering current, and may still be capable of stimulating a nerve. A fractional amount of the stimulating current being delivered to the patient may be sufficient to evoke a nerve response (and, because it would be a percentage of what is indicated in the display, the indicator would be illuminated). This is because the stimulation pulse intensity may be at its highest output voltage as a result of high circuit resistance, and the stimulator circuit is unable to deliver the specified amount of current. This mode of stimulating is not harmful to the patient in any way, but the surgeon will not be able to determine the exact amount of current being delivered to the patient.**

  If this should occur, the stimulator intensity should be turned down while the stimulator probe is in contact with the patient until the INCOMPLETE STIMULATION light turns off. At this point, the specified current level shown on the display will be administered. The INCOMPLETE STIMULATION light going out will also show correct probe contact with patient tissue.

  Many people falsely believe that they should increase the current intensity in order to get the INCOMPLETE STIMULATION indicator to turn off. Note that the lower the specified current, the greater the range of circuit resistance that can be accommodated by the stimulator circuit. This is due to the relationship of voltage, resistance, and current as defined by Ohms Law.

Testing for Stimulus Output

The unit may be tested for output by touching the probe to the metal snap on the surface electrode pad. If the amber INCOMPLETE STIMULATION light goes out, the instrument is working properly.

Another simple way of verifying that the incomplete stimulation indicator is working correctly is to place something conductive (such as a paper clip or wire) between the RETURN and ACTIVE connectors (use the AUX jacks). The INCOMPLETE STIMULATION indicator should go out when the conductive object is in place, and should light when it is removed.

The stimulus verification circuitry monitors the integrity of the patient/instrument circuit, including continuity of the probe and cable. When proper current is being delivered, the amber INCOMPLETE STIMULATION light will go out. It will flash at all other times—for example, when there are broken cables, disconnected cables, poor ground, poor probe contact, etc. (See also the above section, Incomplete Stimulation and Resistance.)

Verification of stimulation can also be obtained by touching the forearm or wrist area of a test subject, starting with a low current setting and increasing to a reasonable level (up to six or eight milliamps (mA) may be required due to the narrow pulse width of 0.0002 sec.). Use a non-sterile probe for this procedure so that sterile probes will be available for surgery.

The unit may also be tested on an oscilloscope using a 1K precision resistor across the output. The oscilloscope will then display the pulse amplitude directly in milliamperes (1 volt = 1 mA).

The active probe can be shorted to the surface electrode pad without damage to the circuitry.

Check the stimulator output with an oscilloscope monthly.

OPERATION CHECKLIST

Prior to Use

- Check the battery condition. If battery indicator is in fail mode, recharge it before use.
- Clean the Cheek Muscle Movement Sensor.
- Position the instrument in the operating room using the adjustable tilt handle.

Setup List for Monitor

(If using both the stimulator and monitor, follow steps in both lists.)

- Read all warnings and cautions before beginning. Read the Instructions for Use thoroughly. This list is only a summary.
- Position the main unit so that it is convenient for the person operating the device.
- Position the Cheek Muscle Movement Sensor on the operative side of the patient's cheek after patient has been anesthetized.
- Connect the sensor cable to the main unit.
- Turn the power switch to "on." Check the battery status again.
- Adjust the monitor sensitivity. Begin with the most sensitive position (fully counter-clockwise) and adjust the knob clockwise during the case to a lower sensitivity setting.
- Choose either HORN or LIGHT by moving the toggle switch.

Setup List for Stimulator

(If using both the stimulator and monitor, follow steps in both lists.)

- Read all warnings and cautions before beginning. Read Instructions for Use thoroughly. This list is only a summary.
- Position the main unit so that it is convenient for the person operating the device.
- If using a Monopolar Probe or the Remote Probe, snap a surface electrode cable to a surface electrode pad. Affix the surface electrode pad to the contralateral shoulder. Plug the surface electrode cable into the main unit.
- If desired, attach the optional Foot Switch (used to mute the horn when electrosurgical devices are used).

- Connect any optional equipment to the main unit (such as the Silverstein™ Adaptor for Continuous Stimulation, SACS, used to electrify surgical tools so they essentially become stimulator probes).
- Attach the sterile Remote Probe or Monopolar Probe to the main unit.
- Turn the power switch to "on." Check the battery status again.
- Adjust the current intensity prior to surgery. Begin at or around 2.5 mA when stimulating through bone.

SERVICE INFORMATION

Warranty

The Silverstein Model S8 is warranted to be free of defects in material and workmanship for a period of two years from purchase (90 days for batteries, probes, and cables). Warranty is void if the unit has been damaged by electrocautery. All warranty service is to be provided at the WR Medical factory.

Service

Service and technical questions are welcome. Due to the specialized circuitry of this instrument and the need for specialized test instruments, we recommend that it be returned to the manufacturer for necessary servicing.

Please contact us for an RMA and for return instructions.

Send to:

WR Medical Electronics Co.
Technical Service Department
1700 Gervais Avenue
Maplewood, MN 55109 USA

Phone:	651-604-8400
Helpdesk	651-604-8483
Fax:	651-604-8499
E-Mail:	helpdesk@wrmed.com

SALES SPECIFICATION SHEET - **Silverstein, Model S8**

WR Medical Electronics Co.
1700 Gervais Avenue
Maplewood, MN 55109
www.wrmed.com | 651-604-8400

PHYSICAL DIMENSIONS

Height:	5.5 in. (13.97 cm.)
Width:	10.25 in. (26.04 cm.)
Depth:	10 in. (25.4 cm.)
Weight:	6.1 lbs. (2.76 kg.)

POWER REQUIREMENTS

Power: Internal batteries are rechargable

WR Medical Part # : 3442 (charger)

RATED AC INPUT	RATED DC OUTPUT
100 - 240 VAC, 50/60 Hz	+24VDC - 500mA

ENVIRONMENT

	OPERATING	TRANSPORT AND STORAGE
Temperature:	20 - 25.6 degrees C	0 - 40 degrees C
Relative Humidity:	30 - 85% (non condensing)	0 - 80% (non condensing)
Atmospheric Pressure:	N/A	300 hPa – 1060 hPa

STIMULATOR SPECIFICATIONS

Pulse Width:	0.0002 seconds +20 microseconds
Pule Time Off:	0.1998 seconds
Pulse Frequency:	0.200 sec at ±5 milliseconds
Hertz:	5
Dial Accuracy:	Linear down to 0.15 mA, residual current of 0.05 mA at 0.0 indicated
Current Output:	0.0 to 10.0 milliamperes (mA) measured across a 1K ±1% resistive load.
	Tolerance at 0.0 indicated, with a residual current of 0.05 mA, is ±0.005 mA.
	Tolerance at 10.0 mA is ±0.4 mA.

REGULATORY

FDA MDL Number:	D009017
FDA Device Class:	II
Health Canada License Number :	36768