

Superior Systems for Every Need™

**The Silverstein™ Facial Nerve
Monitor/Stimulator,
Model S8**

**Operator's Manual,
Version 2.3**

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1 WARNINGS AND CAUTIONS

MEMORIZE THESE WARNINGS BEFORE USING THIS INSTRUMENT IN THE O.R.

ELECTROCAUTERY WARNINGS

1. To avoid patient burns and damage to the unit, observe these electrocautery precautions:
 - a. Keep the return (“ground”) electrode pads of the electrocautery unit and stimulator unit separated by at least 18 inches, and keep the area between them free of electroconductive cream.
 - b. Do not allow the cables of the electrocautery unit to be routed near the stimulator/monitor cables or Cheek Muscle Sensor. Keep both sets of cables at least six inches apart.
 - c. Never allow the electrocautery probes, stimulator probes, or monitor Cheek Muscle Sensor to contact each other or simultaneously touch tissues or fluids in the surgical field. Electrocautery voltages can damage the stimulator and monitor circuits, and cause a burn at the location of the surface electrode pad if the stimulator probes are allowed to touch the patient’s tissues or fluids while electrocautery is energized.
 - d. Alarm artifacts can also occur when electrocautery units are energized. Interference from electrosurgery is common with many monitoring instruments. The high energy of electrocautery units simply cannot be kept out of sensitive monitoring circuitry. The monitor has been deliberately designed to be quite sensitive in order to respond to very small muscle response. This sensitivity can cause artifacts that are not a result of nerve stimulation. Patient movement and accidental contact with cables can also cause a monitor response. Operation of electrosurgery or electrocautery equipment may also cause a false response, depending on the equipment, cable, and electrode arrangement, and other unknown factors.

OTHER WARNINGS AND CAUTIONS

1. **SENSOR INSTALLATION:** Read and understand the section in this manual that describes proper insertion of the Cheek Muscle Sensor (see page 5.1, Insertion of the Cheek Muscle Movement Sensor).
2. **ALARM ARTIFACTS:** Read and understand the section in this manual that covers alarm artifacts and their causes and meaning. Monitor alarm may sound while output is being adjusted (see page 3.5, Monitor Sensitivity).
3. **SENSOR CARE AND STERILIZATION:** Read and understand the section in this manual that covers care of the Cheek Muscle Sensor and sterilization guidelines. Do not steam sterilize the Muscle Sensor or the Remote Probe. Do not immerse in fluids (see page 2.4, Sterilization Guidelines and page 3.2, Cheek Muscle Movement Sensor).

4. **PARALYZING DRUGS:** A fairly high concentration of Xylocaine injected in close proximity to the facial nerve can reduce the nerve's responsiveness to the stimulating current and/or paralyze the nerve so that the muscle does not respond to electrical stimulation. However, it has been found that 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. Succinylcholine can also cause muscle paralysis and prevent the facial muscles from contracting during stimulation.
5. **EXPLOSIVE GASES:** This unit is not explosion proof. Do not use this instrument in the presence of explosive gases.
6. **BATTERY INDICATOR AND RECHARGING:** Check battery condition prior to and during use. The monitor and stimulator circuits each have their own independent battery supply. The monitor battery should be fully charged before use. For full battery capacity, charge for 36 hours before use, or leave plugged in when not in use. Yellow warning light illuminates when approximately 30 to 120 minutes of battery power remains (depending on current-adjustment activity). Do not use instrument if FAIL light is illuminated. The stimulator battery will last approximately 300 hours, and must be replaced if the green light is out. Do not use the instrument without two positive green indications. Do not attempt to recharge the monitor battery while stimulating because the stimulus output display and output control circuit will be disabled (pulses will be delivered at the setting frozen on the display).
7. **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.
8. **SERVICE AND REPAIR:** Because of the specialized circuitry of this instrument, the need for special test instruments, and our familiarity and experience with this instrument, we recommend that the instrument be returned to the factory for any necessary checking or servicing except routine battery replacement. See the "Warranty, Service, and Rental Program" section of this manual for return instructions (page 6.1). This unit should be repaired only by qualified electronic technicians.
9. **GROUND ELECTRODE PLACEMENT:** Do not place any stimulator ground electrodes on the chest or in close proximity to a pacemaker. Interference with the pacemaker could occur. If there is any uncertainty as to stimulator-pacemaker interference, do not use the stimulator on pacemaker patients.

2 INTRODUCTION

DESCRIPTION OF THE DEVICE

The Silverstein Nerve Stimulator/Monitor, Model S8, is a greatly enhanced version of the Jako Facial Nerve Monitor, which was developed in 1974. The methods of stimulation and monitoring have remained relatively unchanged from the Jako, and the intended use remains the same, but the Model S8 is much more sensitive and has additional controls to make operation of the instrument easier.

The Silverstein Facial Nerve Monitor/Stimulator, Model S8, uses adjustable, precisely controlled, low-energy pulses to stimulate the facial nerve. A highly sensitive Cheek Muscle Sensor detects the resulting muscle movement in the cheek and generates an audible or visual signal. The Muscle Sensor is a clothespin-shaped device, which slides easily onto the patient's cheek.

This allows detection of super-fine cheek contractions (finer than can be felt with the nurse's hand) and allows drapes over the face to remain undisturbed.

Pulses (current measured in amperes) are delivered to the tissues using a pencil-shaped probe. The current intensity can be accurately adjusted by the surgeon using push-buttons on the probe. At very low settings, the nerve will respond only when direct contact with the nerve is made.

By probing the surgical site, and finding the lowest current which will elicit the least contraction, the surgeon can locate the facial nerve.

The Model S8 utilizes two separate circuits, one for monitoring and one for stimulating. These circuits may be used concurrently or separately.

The unit may be used as a stimulator only for plastic and reconstructive surgery, orthopedic surgery, or other procedures where visual or EMG confirmation of stimulus exists, or with the monitor for procedures involving the facial nerve.



Figure 1.
*Silverstein Nerve
Stimulator/Monitor,
Model S8*

FEATURES OF THE MODEL S8

ULTRA-SENSITIVE, NON-INVASIVE CHEEK MUSCLE MOVEMENT SENSOR

Solid state circuit detects contractions finer than can be felt with the hand. The easy to use sensor slides onto the patient's cheek.

REMOTE CONTROL STIMULATOR PROBE

Convenient probe-mounted output control allows the surgeon to quickly adjust current as surgery proceeds, eliminating the need for additional personnel.

SAFE, LOW ENERGY, AND PRECISE CURRENT CONTROL

Constant current, pulsed stimulation eliminates the hazards of non-pulsed or constant voltage stimulation methods.

MULTIPLE ALARM SIGNALS

For noisy operating rooms, a high output audible alarm is provided, along with an alternate light signal. A remote light is available for placement in the surgeon's field of view. A foot switch that disables the alarm is also provided.

SPECIAL TISSUE RESISTANCE COMPENSATING CIRCUITRY

Automatically adjusts for varying tissue resistance to provide accurate stimulation levels. Monitors the integrity of all cable connections and verifies that proper current is being delivered.

SENSITIVITY ADJUSTMENT DIAL ON FRONT PANEL

Allows for varying degrees of sensitivity depending on requirements of the surgical procedure.

EASY-TO-READ LIGHTED DIGITAL CURRENT DISPLAY

Easily read from a distance in a darkened operating room.

INCOMPLETE STIMULATION LIGHT

The stimulus verification indicator monitors the integrity of all cable connections and verifies that proper current is being delivered.

SHATTERPROOF CASE

High impact ABS withstands accidental abuse.

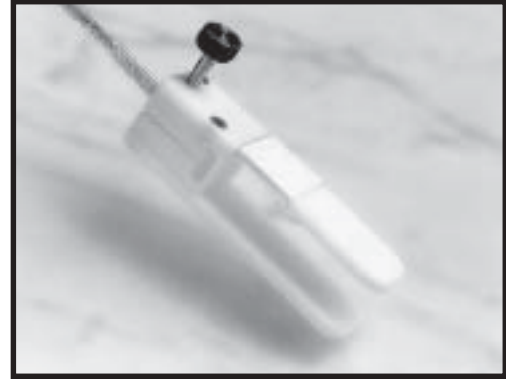


Figure 2. Cheek Muscle Movement Sensor

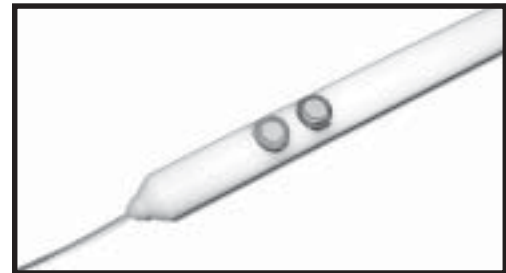


Figure 3. Remote Control Stimulator Probe

AUXILIARY PANEL JACKS

For additional probes or electrified instruments (see SACS, below).

BATTERY POWERED, LIGHTWEIGHT, AND PORTABLE

Easily transported between operating rooms. Battery power eliminates shock hazard.

MAY BE USED WITH THE SILVERSTEIN ADAPTOR FOR CONTINUOUS STIMULATION (SACS)TM

The SACS kit consists of a special coiled cable and modular clips that allow any microsurgical tool or air drill to be electrified with stimulating current and be used as a stimulating probe. This allows the surgical procedure to progress more quickly and provides the surgeon with a greater margin of safety.

TECHNICAL SPECIFICATIONS

CURRENT CHARACTERISTICS

The Model S8 is safer than most constant-voltage or non-pulsed-DC stimulators because it delivers pulsed, constant-current stimulation. To illustrate, the amount of energy transmitted to the patient is proportional to the amplitude of current (in milliamperes, or mA) and the duration of the pulse. Constant-voltage units can deliver excessive current, because these units automatically deliver an unlimited amount of current (subject to circuitry limitations) to meet the voltage chosen by the operator. In some cases this can damage nerve tissue.

Likewise, non-pulsed-DC-stimulation may damage nerve tissue because they allow non-pulsed current to be transmitted through the nerve as long as the probe tip touches the nerve. The Model S8 allows stimulation to be applied directly on nerve tissue without risk of overstimulation. See figure 4.

OUTPUT PARAMETERS

The Model S8 provides a square-wave pulse, which is adjustable from 0.05 milliamperes (mA), residual current, to 10.0 mA, maximum current, by means of the buttons on the Remote Probe or the UP/DOWN switch on the front panel. Current intensity refers to the amplitude of the individual pulses, not to the average level of current. Between pulses there is no current.

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 CURRENT INTENSITY display.

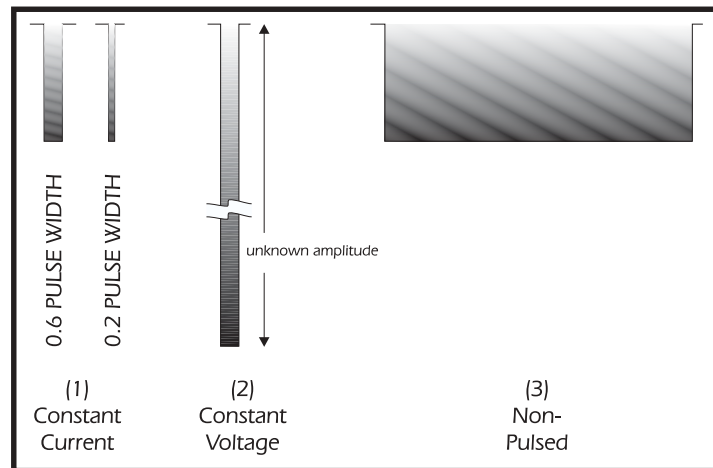


Figure 4.

1) Constant current, pulsed: 0.6 mA is used primarily in clinical settings, and 0.2 mA in surgical settings. The Silverstein Model S8 uses constant current, with a pulse width of 0.2 ms.
2) Constant voltage: amplitude is unknown.
3) Non-pulsed: current transmitted as long as the probe touches the tissues.

The pulse width is 0.0002 seconds, with an off-time of 0.1998 seconds, for a total period of 0.200 seconds. (The corresponding frequency is five pulses per second. There is a residual current of 0.05 mA when the display is at 0.0.)

The pulse width of 0.0002 seconds has been found to be optimal for subcutaneous (intraoperative) stimulation. For transcutaneous stimulation, a pulse width of 0.0006 seconds is required, due to the skin barrier. Stimulators with a 0.0006-second pulse width are available from WR Medical Electronics Co. Stimulators with a 0.0006-second pulse width may be used subcutaneously without ill effect, but a 0.0002-second wave will not be effective transcutaneously. See also figure 4.

SYSTEM COMPONENTS

When you unpack the Silverstein Facial Nerve Stimulator/Monitor, Model S8, make sure that the package is undamaged from shipping and that the items on your packing list are included. If you have questions about what you have been shipped, contact WR Medical Electronics Co.

A complete shipment might contain the items listed below. Your shipment may vary, depending on what was ordered. Again, compare the shipment with your packing list to identify what you received. Retain the packing list to place reorders.

- Silverstein Facial Nerve Stimulator/Monitor, Model S8 (main unit)
- Cheek Muscle Movement Sensor
- Remote Control Probe
- Monopolar Surgical Stimulating Probe, Disposable
- Surface Electrode Pad (Ground) Cable
- SACS Kit (Silverstein Adapter for Continuous Stimulation)
- Theratrode Disposable Electrode Pads (Pkg. of 30)
- Remote Indicator Light (optional)
- Wall-mount Battery Charger
- Carrying Case
- Foot Switch
- Operator's Manual, Service Manual, Reference Material, and Video Tape*
- Electrocautery Warning

STERILIZATION GUIDELINES

Gas sterilize only: Cheek Muscle Sensor, Remote Indicator Light, Remote Probe

Gas or low-pressure steam: Surface Electrode Pad Cable

Note: The Cheek Muscle Sensor, probes, and cables should not be immersed in liquids, but may be wiped with cleansing agents. The cables should be carefully coiled to prevent tangling and chinking.

3 OPERATION OF THE SILVERSTEIN MODEL S8

ON/OFF SWITCH

Located in the upper right corner, this switch turns the main unit on and off.

FRONT PANEL DESCRIPTION: MONITOR

The front panel on the Model S8 is divided into two portions: the monitor and the stimulator. Figure 2 illustrates the controls and lights on the front panel of the Silverstein Model S8. The controls for the monitor portion of the Silverstein are located in the lower left-hand corner.

SENSITIVITY DIAL

When the monitor's SENSITIVITY dial is in position 1, the monitor is most sensitive. To desensitize, turn the knob to numbers 2, 3, or 4. The sensitivity levels of each SENSITIVITY dial position can be checked and modified as outlined in the *Service Manual*. Settings should be set according to the latest standards issued by WR Medical Electronics Co.

ALARM LIGHT

The red ALARM light illuminates to signal the surgeon that the Cheek Sensor circuit was activated (when LIGHT is selected on the toggle switch, see below).

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 patient alarms have 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 sound attenuator on the face of the horn, which is located on the rear panel.

REMOTE LIGHT (OPTIONAL)

With the HORN/LIGHT switch in the LIGHT position, the REMOTE LIGHT indicator (if plugged in) will activate at the same time as the red panel ALARM light. The REMOTE LIGHT indicator may be placed in a position convenient to the surgeon's or other staff's field of vision. This is useful when the monitor, which is placed outside the surgical field, cannot be readily viewed.

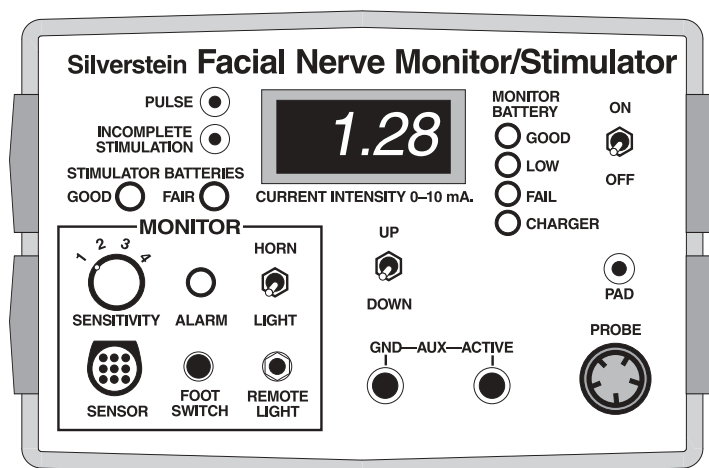


Figure 5

FOOT SWITCH

The foot switch may be used to disable the monitor during electrocautery. Heat from the cautery equipment can cause a spontaneous nerve impulse, which might result in a muscle contraction. Simply plug it into the FOOT SWITCH jack on the front panel and depress the foot pedal when muting is desired.

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 ALARM indicator light may give false indication due to pickup of stray electrical noise or signals. (See the Operational Notes, page 3.5, for further discussion.)

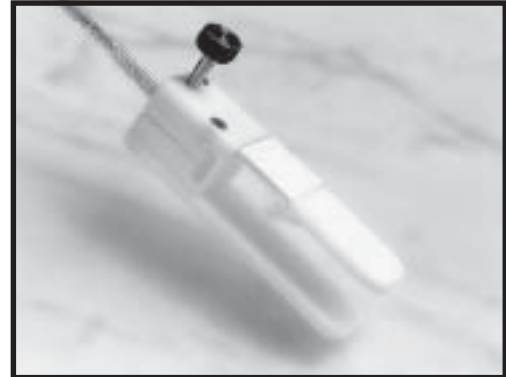


Figure 6. Cheek Muscle Movement Sensor

Care of the Sensor

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. The Sensor does not need to be sterilized because the patient's mouth is not a sterile field. The Sensor may be cleaned by wiping with cold cleaning or sterilizing solutions and may be gas autoclaved. It must not be immersed in cleaning solutions and must not be steam autoclaved because such procedures will draw moisture into the Sensor and the cable, causing corrosion and malfunctioning of the instrument.

MONITOR BATTERY

These indicator lights are located to the right of the current intensity display. The yellow warning light will illuminate when approximately 30 to 120 minutes of battery power remain (depending on current-adjustment activity). Do not use instrument if FAIL light is illuminated.

Charging the Monitor Batteries

To charge the monitor batteries, plug the wall mount charger into a 115-volt wall receptacle, and plug the small round connector into the back of the unit. (See figure 7.) The CHARGER light should illuminate and will become dim as battery reaches fully charged level. The monitor and stimulator will be disabled when the charger is plugged in. The stimulator will still deliver pulses but the current level will be frozen at whatever reading is displayed on the LCD readout at the time the connector was plugged in. You will not be able to adjust the stimulus output level while recharging.

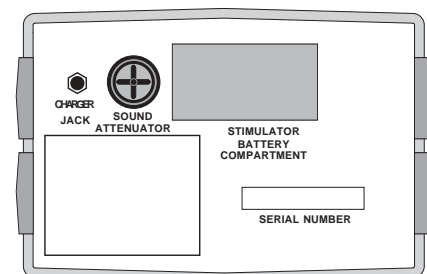


Figure 7. Rear Panel

FRONT PANEL DESCRIPTION: STIMULATOR

The controls, jacks, and indicators for the stimulator portion of the Silverstein are located in the lower right hand corner of the front panel as well as the upper left hand corner.

PULSE LIGHT

When the instrument is on, the clear PULSE light (to the right 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 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 INCOMPLETE STIMULATION indicator would be illuminated). See the “Incomplete Stimulation and Resistance” section for further discussion.

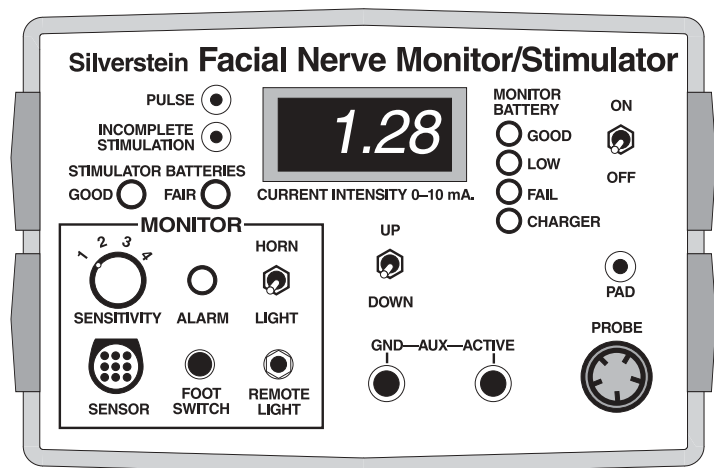


Figure 8

STIMULATOR BATTERIES

The stimulator battery will last approximately 300 hours, and must be replaced if the green light is out. Do not use instrument without positive green indications.

Replacing the Stimulator Batteries

To replace the stimulator batteries, simply open the small door on the rear panel. (See figure 9.) Use size AA batteries.

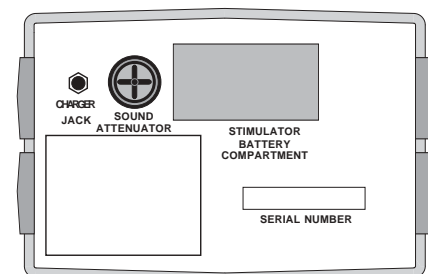


Figure 9. Rear Panel

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 UP/DOWN switch on the front panel. At a reading of 0.0 there is a residual current of about 0.05 mA.

UP/DOWN TOGGLE SWITCH

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 above the connector for the probe.

PROBE JACK

Plug the Remote Probe into this jack. Connect the Remote Probe to the front panel at the connector labeled PROBE in the lower right corner of the front panel; first align connectors, insert plug, and rotate locking collar on plug.

AUXILIARY JACKS — GROUND AND ACTIVE

In early 1996, WR Medical Electronics Co. introduced a series of lightweight, flexible-shaft probes, both monopolar and bipolar. These probes may be used with the Silverstein, and are plugged into the AUX jacks. In addition, any standard bipolar forceps-type probe can be used. Current to these probes can be controlled using either the Remote Probe, or the UP/DOWN switch 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 (GND 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.

REMOTE PROBE

The Remote Probe has a .55mm flexitip that is fixed in place. This is flush-tipped, insulated to the end, and can be bent to any angle. This probe is reusable and can be sterilized by methods listed in “Sterilization Guidelines,” page 2.4.

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 in the lower right corner of the front panel.

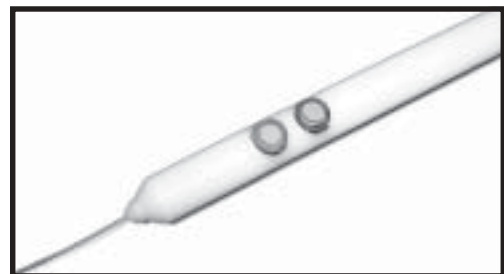


Figure 10. Remote Probe

TILT STAND

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 ALARM 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 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 to the next level (to desensitize, turn the knob clockwise to larger numbers). Generally you will want to use the instrument on the most sensitive setting possible.

Alarm artifacts sometimes signify a problem and sometimes 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 alarm 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 NiCad battery pack (due to current draw by the motorpot);
- Energizing of electrocautery. Artifact sometimes occurs when cautery is energized. Use the foot switch provided with the instrument to disable the alarm. 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.

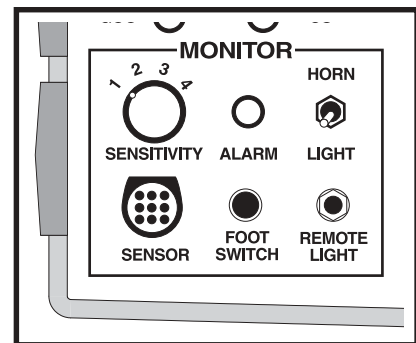


Figure 11

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 “1,” 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 1.2, “Paralyzing Drugs” section, 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 verifies that stimulating pulses are being correctly administered to the patient. The INCOMPLETE STIMULATION 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, or attempting to stimulate through an area that does not conduct well, such as dry bone. Another obvious, but often overlooked, cause of high circuit resistance is 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 INCOMPLETE STIMULATION indicator would be illuminated). This is due to the fact that 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 (using the UP/DOWN switch, which is below the CURRENT INTENSITY display, or the controls on the Remote Probe) 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 CURRENT INTENSITY display will be administered. The INCOMPLETE STIMULATION light going out will also show correct probe contact with patient tissue.

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 GROUND and ACTIVE connectors (use the jack labeled AUX). 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.

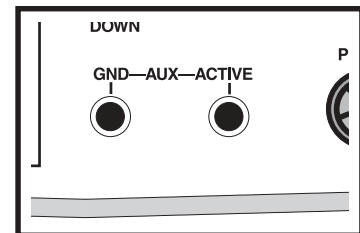


Figure 12

4 GENERAL THEORY OF NERVE STIMULATION

Electrical stimulation of a nerve or nerve branch evokes contractions of associated muscles, affording a visual confirmation of the response to the stimulation. A certain minimum level of current intensity through the nerve tissue is required to reach the stimulation threshold and produce minimal muscle contractions. As the current is increased above this level, the contractions become progressively stronger until the point at which the entire muscle is responding fully.

When a stimulating current is applied directly to an exposed nerve (see figure 13) virtually the entire current flows

through the nerve tissue. Consequently, the muscle response occurs at a relatively low current setting. When the current is applied at a point remote from the nerve, the current flow is diffused through the tissues, and only a portion of the applied current actually reaches the nerve. Inasmuch as the muscle response is a function of current intensity through the nerve, a higher level of current is required to evoke a given muscle response than when the current is applied directly to the exposed nerve. The current level required for a given response is generally proportional to the square of the distance between the nerve and the point at which the current is applied.

It is not possible to set forth a definite numerical relationship between current setting and distance in millimeters from the nerve. Rather, the current settings must be considered as indicating relative distances as you work progressively closer to the nerve during a given procedure. When the signal sounds at a relatively low current setting, it indicates that the surgical instrument is correspondingly close to the nerve. With experience, the user will be able to relate current settings to approximate distances from the nerve. Silverstein has found that one millimeter of bone needs approximately one milliamp of current to stimulate the facial nerve. (See suggested readings.) Stimulation through soft tissue will evoke a response at lower settings.

The relationship between current intensity and distance is nonlinear, as shown graphically in figure 14, and a given increment of current intensity does not correspond to a fixed increment of distance. In close proximity to the nerve, a given increment of distance (Δd) corresponds to a smaller increment of current intensity (ΔI_1) than at greater distances from the nerve (ΔI_2).

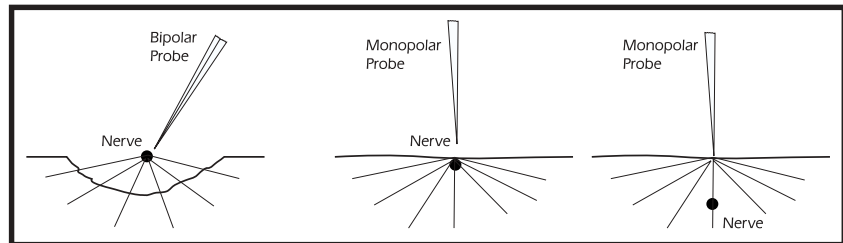


Figure 13

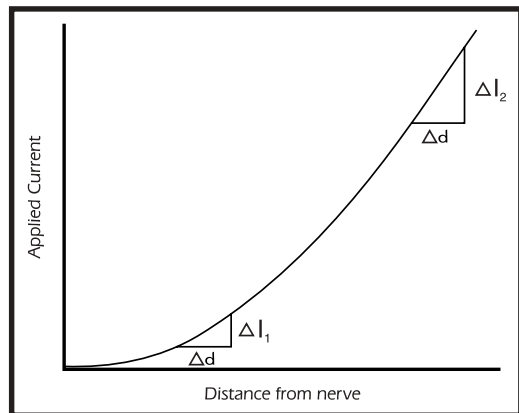


Figure 14

5 GENERAL PROCEDURE FOR USING THE SILVERSTEIN™ MODEL S8

WARNING: Check battery condition prior to and during use. The monitor and stimulator circuits each have their own independent battery supply. The monitor battery should be fully charged before use. For full battery capacity, charge for 36 hours before use, or leave plugged in when not in use. The yellow warning light will illuminate when approximately 30 minutes to 120 minutes of battery power remain (depending on current-adjustment activity). Do not use instrument if FAIL light is illuminated. The stimulator battery will last approximately 300 hours, and must be replaced if the green light is out. Do not use instrument unless the green light is illuminated.

PATIENT PREPARATION

SKIN PREPARATION FOR SURFACE ELECTRODE PAD

A surface electrode pad, also called a ground pad, is applied to the skin outside the sterile field. This completes the stimulator circuit through the patient. Use WR Medical self-adhesive Theratrod III Pads for best results.

Prep the skin with an alcohol wipe, and snap the cable onto the pad prior to applying the pad to the patient. Typical placement of the surface electrode pad is on the shoulder opposite the surgical site. Keep surface electrode pad at least 18 inches from other ground pads.

INSERTION OF THE 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 side with the adjusting screw goes on the outside against the cheek. The blade inside the mouth should angle upward toward the eye between the gum and the oral mucosa on the inside of the cheek. Bunch the cheek up in between the blades while pushing the Cheek Muscle Sensor in tightly. The thumbscrew should be adjusted so the blades grasp the patient's cheek securely, with a light pressure. Excessive pressure may impair the response. The Sensor may be secured to the cheek with strips of adhesive tape.

After installing the Sensor (but before draping the face), cover the eyes with eye protectors, and then cover the Sensor with a hard surgical mask to prevent the

drapes from impeding muscle movement and to prevent the drapes from brushing up against the Sensor (which would cause alarm artifacts). **See figure 15. The Cheek Muscle Sensor cable should also be taped to the head.**

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 ALARM indicator light may give false indication due to pickup of stray electrical noise or signals.

Each contraction of the cheek muscles causes a slight displacement of the white plastic blade on both sides of the cheek. The strain gauge on the blades transmits an electrical signal, which actuates the audible or visual alarm on the instrument.



Figure 15: Photograph showing hard surgical mask covering Cheek Muscle Sensor to prevent drapes from impeding muscle movement.

STIMULATION AND MONITORING OF THE NERVE

During surgery, the lowest possible current should be used, especially in a wet field close to the nerve. With a bipolar probe on a nerve, a fraction of a milliamp should be sufficient. With a monopolar probe, high current settings will cause nerve and muscle response at a greater distance from the nerves.

FINDING A NERVE UNDERLYING OTHER TISSUE

The selected probe is applied to the tissue bed overlying the nerve, and the current intensity is turned up until muscle contractions are observed. The probe is then applied at intervals along a line at right angles to the general course of the nerve. At each point, the current intensity is readjusted to the minimum level that will produce muscle contractions, and the current reading is noted. The successive current readings will vary depending upon the square of the distance between the probe tip and the nerve. The nerve underlies the point at which muscle contractions occur with the lowest current setting.

INDICATING PROXIMITY OF A NERVE

At the beginning of the surgical procedure, while the exposed tissues are still a good distance from the nerve, turn the current up high enough to cause a muscle contraction and sound the signal. This will verify that the instrument is functioning properly and will establish as a reference the current intensity corresponding to the initial distance from the nerve. Then turn the current down until the signal stops sounding. As you dissect the overlying tissues and get closer to the nerve, you will provide sufficient intensity through the nerve to evoke contractions and sound the signal.

As you continue the dissection, turn the current to successively lower levels to

sound the signal at correspondingly shorter distances from the nerve. Experience with the instrument enables the surgeon to relate the current settings required to evoke contractions to the corresponding distances from the nerve.

It must be borne in mind that as you approach a nerve, a given change in current setting corresponds to progressively smaller increments of distance. When a current setting of about 0.2 milliamperes actuates the signal, it indicates that the nerve is quite close.

If the signal does not sound after further dissection of the tissue has brought you significantly closer to the nerve, turn the current setting back up enough to actuate the signal. This assures that the system is functioning and provides a new reference point with respect to current setting.

CAUTION: Sounding of the signal indicates that the nerve is within the relative distance corresponding to the current setting. However, absence of the audible signal should not be construed as assurance that the nerve is beyond the distance corresponding to the current setting. The usual caution must be used in approaching the nerve, even though the current setting may indicate that it is still a safe distance away. Normal precautions must be taken to see that the lead wires do not become disconnected from the instruments or from the output receptacles. If a particular lead wire should be disconnected, the signal would not sound regardless of the proximity of that instrument to the nerve.

NERVE IDENTIFICATION

In differentiating a nerve from fibrous tissue, the current intensity should be set at the minimum level that will evoke muscle contractions with the probe applied directly to the nerve. When the probe is applied to other tissues at this same setting, there should be no response. If the current is set too high, the nerve may be stimulated when the probe is applied to other tissues and the test will not differentiate the nerve.

In differentiating two nerves or nerve branches in close proximity, the stimulating current is applied to each in turn, and the differential muscle response is observed. It is essential that the current intensity be set low enough to stimulate only the nerve to which the probe is applied. Too high a current could stimulate both nerves simultaneously.

NERVE EVALUATION

When greater-than-threshold electrical stimulation is applied to an exposed nerve, the presence or absence of muscle contractions indicates the viability of the nerve.

Stimulation of the exposed facial nerve with currents of 0.05 to 0.2 milliamperes will indicate normal facial function postoperatively.

OPERATION CHECKLIST

PRIOR TO USE

- Check the monitor battery condition. If battery is low, recharge it before use.
- Sterilize the Cheek Muscle Movement Sensor, remote probe, and surface electrode pad cable. Cables, muscle sensor, and remote probe must be gas sterilized. Tips can be steamed.
- Check the stimulator battery condition. Replace the AA batteries if necessary.
- 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 *Operator's Manual* 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 monitor battery status again.
- Adjust the monitor sensitivity. Begin with setting 1 (most sensitive) and adjust the knob during the case to a lower sensitivity setting (toward 4).
- 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 *Operator's Manual* 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 electro-surgical 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 to the main unit.
- Turn the power switch to "on." Check the stimulator battery condition.
- Adjust the current intensity prior to surgery. Begin at or around 2.5 when stimulating through bone.

6 WARRANTY, SERVICE, AND RENTAL PROGRAM

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 factory.

SERVICE

Service and technical questions are welcome. Because of the specialized circuitry of this instrument, the need for special test instruments, and our familiarity and experience with this instrument, we recommend that the instrument be returned to the factory for any necessary checking or servicing except routine battery replacement. To return a unit, ship the unit with its Remote Probe and Cheek Sensor via insured parcel post or insured UPS. Be sure to pack with plenty of padding to prevent damage during shipping. If shipping from overseas, please specify that the goods are USA-made, and are being returned for repair.

Ship to:

WR Medical Electronics Co.
Technical Service Department
123 North Second Street
Stillwater, MN 55082 USA

Repair Department:

Phone 651-430-1200
Toll-Free Phone 800-635-1312
FAX 651-430-8449

Customer Service:

Phone 651-430-1200
Toll-Free Phone 800-635-1312
FAX 651-439-9733
Toll-free FAX 800-990-9733

RENTAL PROGRAM

Rental units are available at a minimal charge. Hospitals are required to issue a purchase order for rental and associated charges. The unit must be returned within 30 days.

7 SUGGESTED READINGS

The following references will provide excellent reading. Pay particular attention to the articles written by Herbert Silverstein, MD, and view the video provided with the instrument.

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