The Silverstein™ Adapter for Continuous Stimulation (SACS™)

Operator's Manual,

Version 1.2

WR MEDICAL ELECTRONICS CO.

Copyright Information

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WARNINGS AND CAUTIONS

Do not steam sterilize any of the components. Gas sterilize only.

Do not use this device with electrically powered drills.

Do not use this device if paralyzing drugs have been used on the patient.

Do not allow any active electrocautery probes, stimulating tools, or probes to simultaneously touch each other, tissues, or fluids in the surgical field. Electrocautery units will cause patient burns and damage to the SACS™ cable and the stimulator.

Do not expect this device to take the place of thorough knowledge of anatomy and careful dissection techniques.

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.

WARNING FOR 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.

INTRODUCTION

DESCRIPTION OF THE DEVICE

The Silverstein Adapter for Continuous Stimulation™ (SACS™) allows a variety of microsurgical instruments and air drills to be adapted to carry stimulating current. This allows the surgeon to stimulate directly with these instruments instead of using a separate stimulating probe.

As shown in figure 1, a soft, coiled, flexible cable is used to transmit current from the stimulator, such as the Silverstein™ Facial Nerve Monitor/Stimulator, to the tool of choice. A “stackable banana”–type plug is attached to one end of the SACS™ cable. This plug fits directly into the control panel of the stimulator.

The opposite ends of the “Y” cable terminate in tip plugs, which in turn plug in to the modular clips (see figure 1). Clips of various sizes allow a wide variety of surgical tools to be adapted.

Each clip has a tip receptacle into which the ends of the SACS™ cable are inserted. The clips are then clipped directly onto the tool of choice. To change tools, the clips can be unclipped and moved to another tool, or the clips can be left fastened on the tools and the tip plugs can be removed from the ends of the clips.

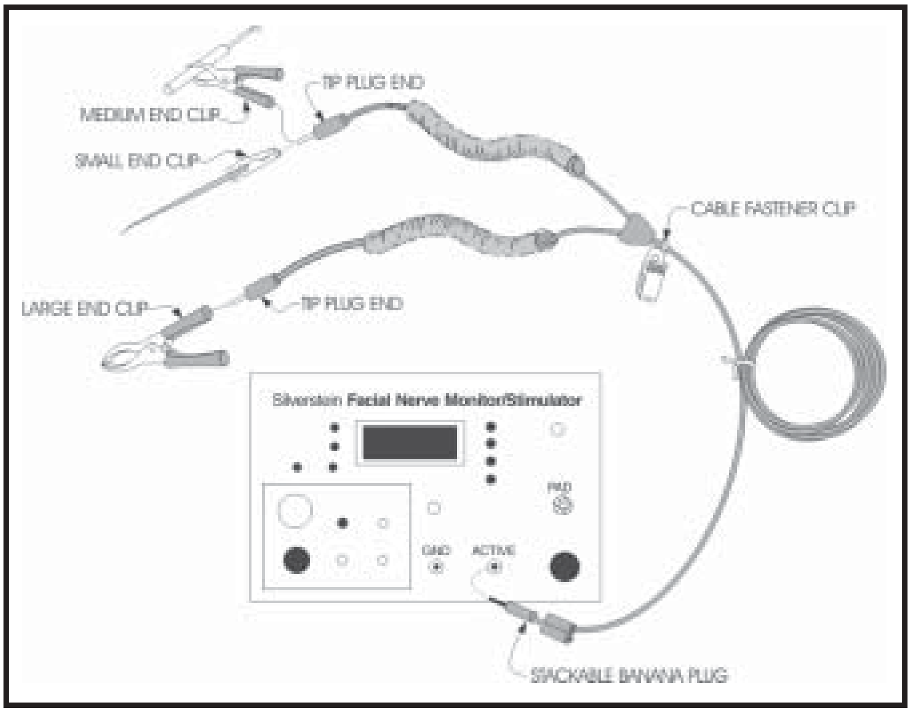


Figure 1.

The highly flexible coiled cable allows virtually unrestricted movement of surgical tools.

The Silverstein Adapter for Continuous Stimulation™ reduces surgical time and increases the surgeon’s awareness of the location and condition of the facial nerve, reducing iatrogenic injuries. By eliminating the time-consuming task of using a separate stimulating probe, the surgeon can move through the surgical procedure more efficiently.

The SACS™ cable may be used with the Silverstein™ Facial Nerve Monitor/Stimulator, or the Brackmann II™ EMG System (available from WR Medical Electronics Company).

SYSTEM COMPONENTS

The Silverstein Adapter for Continuous Stimulation™ kit consists of the following components:

SACS™ Cable
End-clip (large)
End-clip (medium)
End-clip (small)

These components may be purchased separately to fulfill the needs of your particular operating room.

PREPARATION FOR USE

PRETESTING AND INSPECTION

1. Examine the cable for cuts in the insulation, and examine the cable-ends to make sure the connectors are securely attached.

2. Examine the clips to make sure they have proper spring action and that the insulation is not cracked or missing.

3. The continuity of the cable can be checked by one of the following tests (choose the one which fits your situation):

a. *If you have a Silverstein™ Facial Nerve Monitor/Stimulator, Model S8 (serial number 450 or higher)*, insert the SACS™ cable's stackable banana plug directly into the ACTIVE receptacle on the stimulator's front panel. Keeping the tip plug ends of the cable clear of any conductive materials (such as a metal table top), turn the stimulator on. Touch both tip plug ends, one at a time, to the GROUND jack of the stimulator. When contact is made, the INCOMPLETE STIMULATION light should cease to illuminate. This indicates that the cables have no breaks and that they are working properly. (Please refer to the Silverstein™ Facial Nerve Monitor/Stimulator's *Operator's Manual* for complete instructions on use of the Silverstein.™)

b. *If you have a Brackmann II™ EMG System*, insert the SACS™ cable's stackable banana plug directly into the ACTIVE receptacle on the Stimulator Pod. Keeping the tip plug ends of the SACS™ cable clear of any conductive materials (such as a metal table top), turn the stimulator on. Touch both tip plug ends, one at a time, to the RETURN receptacle of the Stimulator Pod. When contact is made, the COMPLETE CIRCUIT light on the front panel of the Brackmann II™ Main Unit should illuminate. This indicates that the cables have no breaks and that they are working properly. (Please refer to the Brackmann II™ EMG System's *Operator's Manual* for complete instructions on use of the Brackmann II.™)

c. *If you do not have a Silverstein™ or Brackmann II*,™ you will need a volt-ohm-amp (VOM) meter to check the continuity of the cable. Your biomed department can help you perform this test. With the VOM meter set to ohms, connect one lead of the VOM to the stackable banana plug end of the SACS™ cable. Touch the other VOM lead to each tip plug end of the SACS™ cable. The resistance reading on the meter should be zero.

STERILIZATION GUIDELINES

The SACS™ cable and clips should be gas sterilized. The use of steam may cause corrosion and discoloration of the components and failure of the insulation.

OPERATING INSTRUCTIONS

HOW TO CONNECT THE TOOLS

For most cases, you may wish to use as many clips as you have tools. This will allow the clips to remain attached to each tool throughout the procedure, with the changing of tools being accomplished by removing and inserting the tip plugs. Alternatively, you may utilize a minimum number of clips during the procedure by clipping and unclipping whatever tools are in use.

As shown in figure 2, clips of various sizes are used to adapt the desired tools. Large clips should be used to adapt air-powered drills. Medium and small clips should be used to adapt smaller hand tools.

Some tools may have a small hole drilled in the end to directly accept the tip plug end of the SACS™ cable. This eliminates the need for a small clip to connect to the tool.

Regardless of what combination of clips and tools are used, you must ensure that the clip is securely attached to the tool in use. Make sure that the chosen clip-tool combination is secure enough to maintain the mechanical and electrical connection.

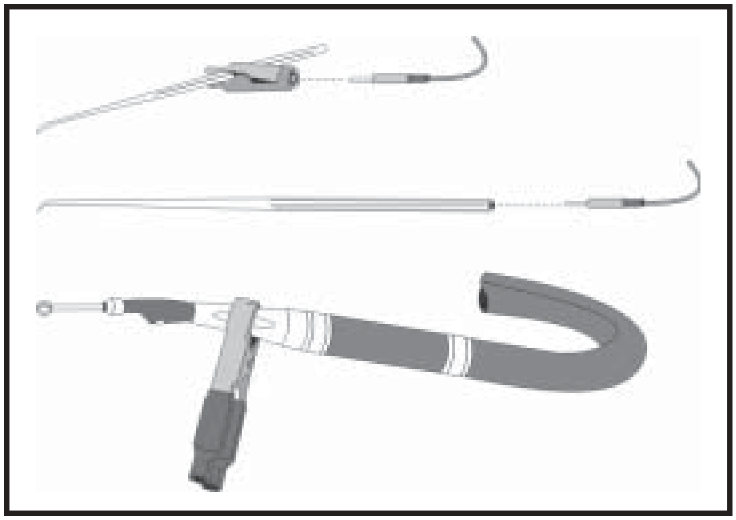


Figure 2:
Various Combinations of Tools and Clips.

SPECIAL CAUTIONS FOR THE CABLE AND TOOLS

The use of insulated surgical tools will help prevent shorting of current during stimulation.

When using non-insulated tools, care must be taken not to allow the tool handle to touch skin, bone, or soft tissue at the same time the facial nerve is being stimulated.

Note: Some materials, such as anodized aluminum, will not conduct very well. Some air drills have poor conductivity on their housing, or through their ball bearings. In some situations, the only way to confirm conductivity is to try using the item. WR's stimulators have circuitry which will adjust the stimulation voltage to ensure constant current (based on the resistance of the item you are attaching a clip to). However, in some situations the resistance may be too high for the simulators to compensate for. Watch the INCOMPLETE STIMULATION light (on the Silverstein™ S8) or the COMPLETE CIRCUIT light (on the Brackmann II) to confirm conductivity.

Always know where the two tip-plug ends of the cable are so that they do not short against the patient, the operating table, or any other conductive material. When not *using an end, keep it clear of conductive materials so that full stimulation can be delivered through the tool or probe in use.*

If you are using the SACS™ with a Silverstein™ Facial Nerve Monitor/Stimulator, be aware that the sensitivity of the monitor may be adjusted with a switch on the front panel of the device. Also be sure that you read and understand the instructions on how to install the cheek-muscle-movement-sensor. False artifacts can occur with frequency unless the sensor is installed properly and protected from the drapes with a surgical mask. *Read the Model S8 Operator's Manual for information on artifacts and sensor placement.*

If you are using the SACS™ with a Silverstein™ Facial Nerve Monitor/Stimulator Model S8, you may use the Remote Probe as either a stimulating probe, or a nonstimulating remote control. If used as a nonstimulating remote control, take care to protect the tip from any conductive materials. The tip is "active" whenever connected to the front panel.

CIRCUIT RESISTANCE AND THE SILVERSTEIN MODEL S8

The purpose of the Silverstein™ Model S8's INCOMPLETE STIMULATION light, which is found to the left of the lighted CURRENT INTENSITY display, is to provide a way to verify that stimulating pulses are being correctly administered to the patient. How this works is really pretty simple. 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 by the stimulator portion of the Silverstein™ Model S8. In other words, 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 using the SACS with a Brackmann II,™ please read about circuit resistance in the Brackmann II™ Operator's Manual.

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.

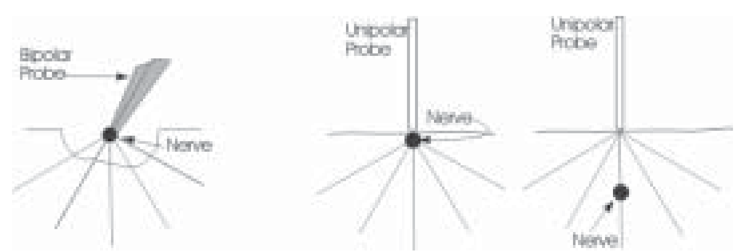
But note: If the INCOMPLETE STIMULATION light *is* on, the stimulator may still be delivering current, and may still be capable of stimulating a nerve. A fractional amount of the stimulating current being delivered to the patient *may* be sufficient to evoke a nerve response (and because it would be 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 current control, or UP/DOWN switch, which is below the CURRENT INTENSITY display) 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. 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.

A 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 stimulator GROUND and ACTIVE connectors (use the jacks labeled AUX). The INCOMPLETE STIMULATION indicator should go out when the conductive object is in place, and should light when it is removed. If you feel the INCOMPLETE STIMULATION indicator is functioning incorrectly, please contact the factory.

GENERAL THEORY OF NERVE STIMULATION

Electrical stimulation of a nerve or nerve branch evokes contractions of associated muscles, affording an electrical or mechanical 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.



(a) Nerve Exposed

(b) Overlying Tissue

Figure 3: *Probe Applied to Nerve*

When a stimulating current is applied directly to an exposed nerve, as in figure 3, 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.

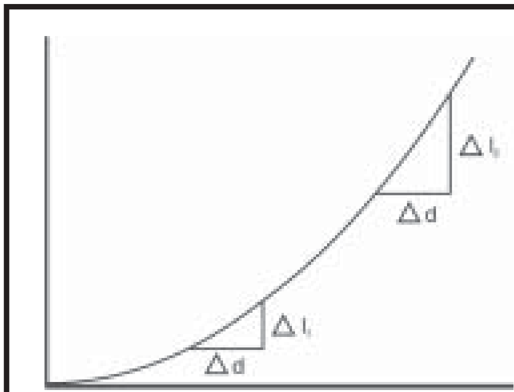


Figure 4: *General relationship between applied current and distance from nerve.*

It is not possible to set forth an exact 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. (Silverstein has found that 1 millimeter of bone needs approximately 1 milliamp of current to stimulate the facial nerve. See Suggested Reading.) 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.

It should be noted that the relationship between current intensity and distance is nonlinear, as shown graphically in figure 4, 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).

GENERAL PROCEDURE FOR USING THE SACS CABLE

The basic procedure for locating the facial nerve is to find the least current which will produce the least contraction or EMG response. Therefore, the lowest currents are always used during the locating phase of the procedure. Stimulation at very high current levels should be avoided because of the possibility of over stimulation, causing neuropraxia and postoperative facial weakness. Using too high a current can also result in spread of current from adjacent tissue to the facial nerve, giving a false impression as to the location of the facial nerve. This effect is not as pronounced when shorting to bone; however, it should always be avoided regardless of the surrounding anatomy. During surgery, the lowest possible current should be used, especially in a wet field close to nerves. With the bipolar probe on a nerve, a fraction of a milliampere should be sufficient. With the monopolar probe, high current settings will cause nerve and muscle response at a greater distance from the nerves.

WARNING: *Do not expect this device to take the place of thorough knowledge of anatomy or careful dissection techniques. The monitor is designed to assist in locating nerves. No guarantee of performance is intended or implied. Current setting, distance from nerve, position and placement of sensor, muscle response, and other physiological factors will affect operation of the monitor.*

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 verifiable muscle contractions. 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, just until the contractions are no longer verifiable. By doing this, as you dissect the overlying tissues and get closer to the nerve, you will provide sufficient intensity through the nerve to evoke contractions.

As you continue the dissection, turn the current to successively lower levels to sound the signal at correspondingly shorter distances from the nerve. Experience 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 milliamps (mA) evokes a verifiable contraction, it indicates that the nerve is quite close.

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

Finding a Nerve Underlying Other Tissues

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 which 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.

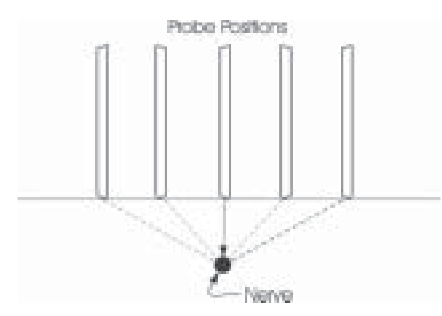


Figure 5: *Finding a Nerve Underlying Other Tissues*

Nerve Identification

In differentiating a nerve from fibrous tissue, the current intensity should be set at the minimum level which 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 mA will indicate normal facial function postoperatively.

CARE AND STORAGE

After each procedure and prior to re-use, inspect the components as outlined above. Do not immerse the components in fluids. Store the components at room temperature in an environment which is free from excessive moisture.

SERVICE AND WARRANTY

The Silverstein Adapter for Continuous Stimulation is warranted to be free of defects in material and workmanship for a period of one year from purchase. Warranty is void if the cable has been steam sterilized or has been damaged from electrocautery. Because of specialized repair techniques, we recommend you return it to us for any repairs. Loaner instruments are available at a minimal charge. Pack the cable carefully and ship via parcel post or UPS.

Ship to:
WR Medical Electronics Co.
321 South Main Street
Stillwater, MN 55082 USA

Repair Department:
Phone 651-430-1200
FAX 651-430-9930

Customer Service:
Phone 651-430-1200
FAX 651-439-9733

SUGGESTED READING

Silverstein, H.: “Adapter for Continuous Stimulation (SACS) with the WR-S8 Monitor/Stimulator.” Presented at the American Academy of Otolaryngology, September 25, 1989.

Silverstein, H.: “Microsurgical Instruments and Nerve Stimulator-Monitor for Retrolabyrinthine Vestibular Neurectomy.” *Otolaryngol Head Neck Surg*. 94(3): 409–411, 1986.

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