Silverstein™ Adaptor for Continuous Stimulation (SACS™) Kit

Instructions for Use, Version 2.0

WR Medical Electronics Co.

Copyright Information

Silverstein Adaptor for Continuous Stimulation, Instructions for Use, version 2.0, item number 3033, revised 05/12, manual pages component number 920-W0-23033.

For more information, contact:

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- **E-mail:** info@wrmed.com (or) neuro@wrmed.com
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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.

CONTENTS

WARNINGS AND 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: 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: 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.

WARNING: Simultaneous connection of a patient to a h.f. 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: 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 SACS™ cable is to be operated only by trained personnel under the direction of a physician.

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.

MARKS OF COMPLIANCE

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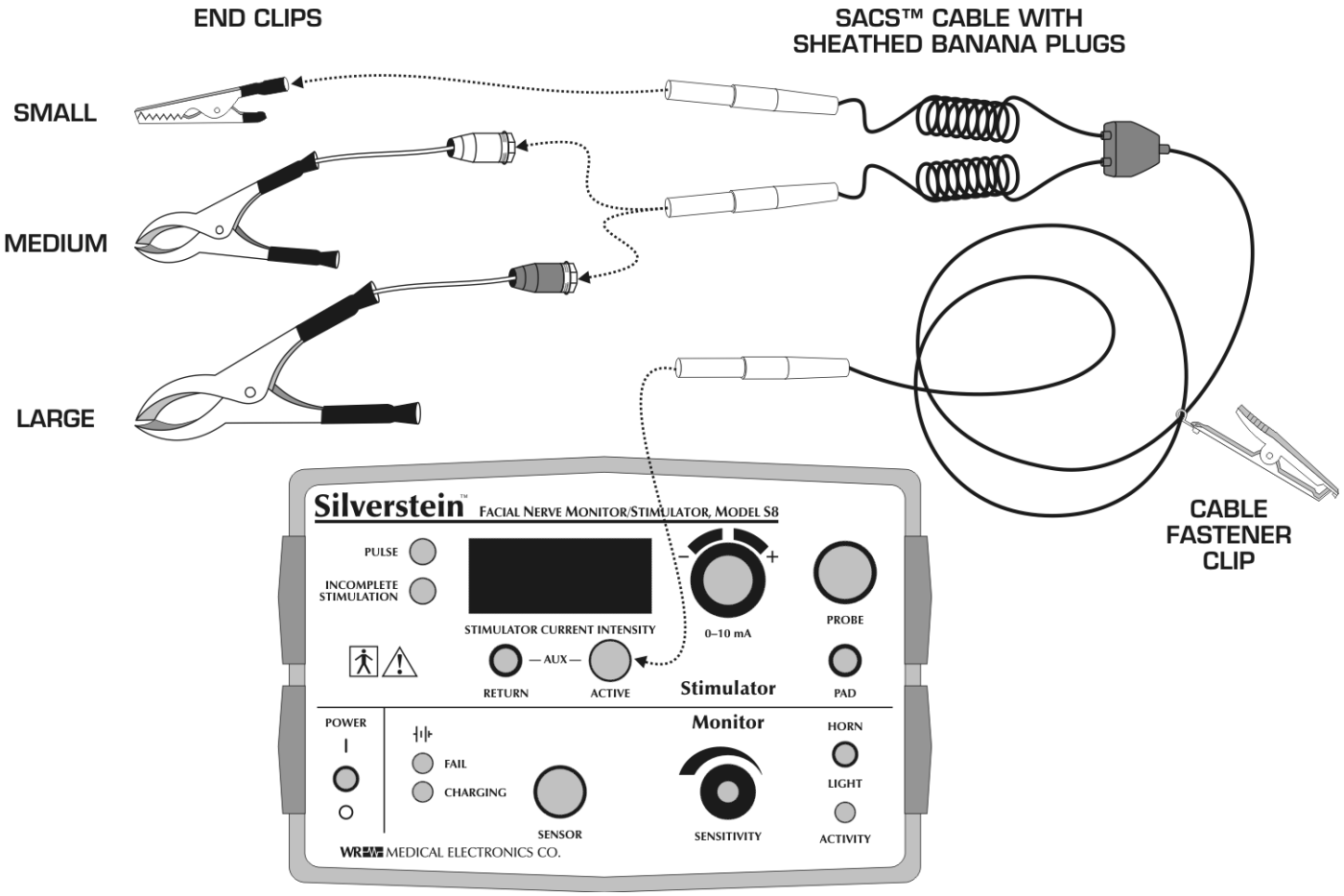
SYSTEM COMPONENTS

The SACS™ kit contains the following components:
SACS™ cable ..... #3197
End-clip (large) ..... #3152
End-clip (medium) ..... #3151
End-clip (small)..... #3150

Figure 1
SACS™ components

OPERATION



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 1001 or higher), insert the SACS™ cable's sheathed banana plug directly into the AUX:ACTIVE receptacle on the front panel. Keeping the banana plug ends of the cable clear of any conductive materials (such as a metal table top), turn the stimulator on. Touch both banana plug ends through something conductive (such as a paper clip or wire) to the AUX: RETURN receptacle 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 Instructions for Use for complete instructions.)

    b. If you do not have a Silverstein,™ the biomed department will need a volt-ohm-amp (VOM) meter to check the continuity of the cable. With the VOM meter set to ohms, connect one lead of the VOM to the banana plug end of the SACS™ cable. Touch the other VOM lead to each banana plug end of the SACS™ cable. The resistance reading on the meter should be zero.

Sterilization Guidelines

The SACS™ cable and clips can be sterilized, however steam should not be used. Always check functionality prior to use.

How to Connect the Tools

For most cases, use as many clips as you have tools to avoid removing and inserting the tip plugs during the procedure.

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

Regardless of the combination of clips and tools, ensure that the clip is securely attached to the tool and that the chosen clip-tool combination maintains the mechanical and electrical connection.

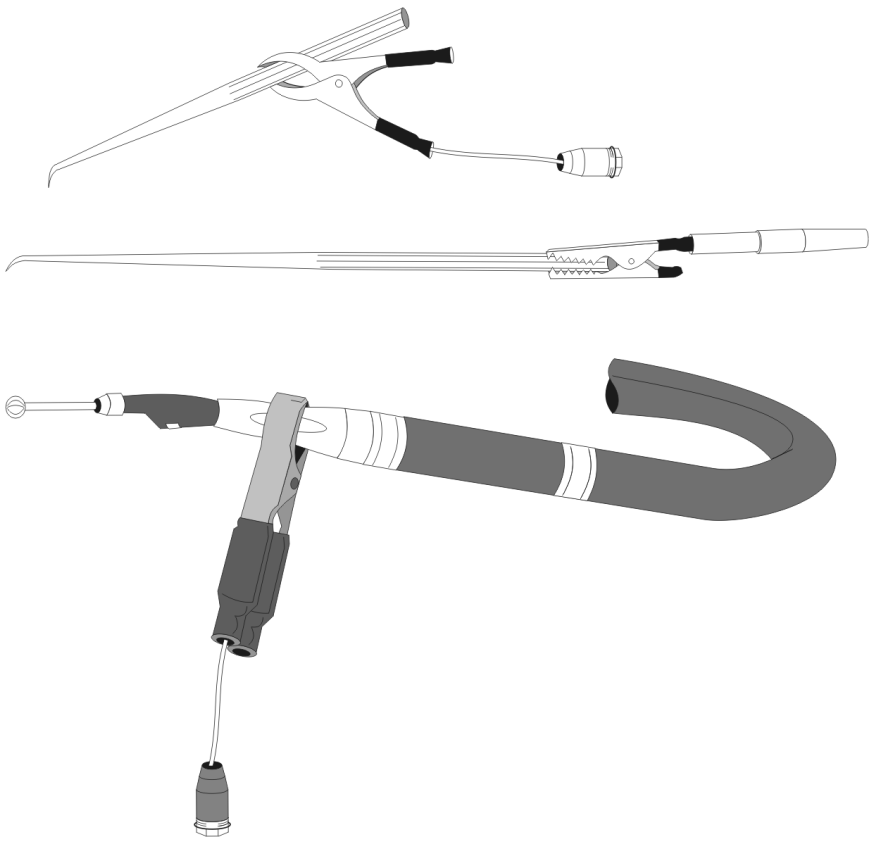


Figure 2

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 noninsulated 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 that 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™ to confirm conductivity.

Always know where the two banana 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 dial on the front panel of the device. Read and understand the usage instructions for 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 Instructions for Use for information on artifacts and sensor placement.

If you are using the SACS™ with a Silverstein™ Facial Nerve Monitor/Stimulator, you may use the Remote Probe as either a stimulating probe, or a nonstimulating probe to control current output to the SACS cable. 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 Silverstein™ Model S8's INCOMPLETE STIMULATION light, on the left of the STIMULATOR CURRENT INTENSITY display, verifies that stimulating pulses are being correctly administered to the patient. The INCOMPLETE STIMULATION light illuminates when the full amount of the specified current (as shown on the display) is **not** being administered to the patient. In other words, if the STIMULATOR CURRENT INTENSITY display reads 0.60, and the INCOMPLETE STIMULATION light is **off,** then 0.60 milliamps of current **are** being delivered.

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.

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 RETURN 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.

SERVICE INSTRUCTIONS

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 unit has been steam sterilized or 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. Ship the unit 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
1700 Gervais Avenue
Maplewood, MN 55109 USA

Repair Department:
Phone 651-604-8400
Toll-Free Phone 800-635-1312 (US and Canada only)
FAX 651-604-8499

Customer Service:
Phone 651-604-8400
Toll-Free Phone 800-635-1312 (US and Canada only)
FAX 651-604-8499
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.