FINETECH MEDICAL LIMITED

Clinician Manual and Instructions For Use

SURGICAL NERVE STIMULATION SYSTEM

CE 2797

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1. SYSTEM COMPONENTS

The *Surgical Nerve Stimulation System* is intended to be used in the operating theatre to facilitate the identification of nerves by electrical stimulation. The *Surgical Nerve Stimulation System* consists of the Surgical Stimulator, the Intrathecal Surgical Probe, and the Extradural Surgical Probe. The Intrathecal Surgical Probe is intended to be used to identify nerves that do not have a thick, protective lining (for example the spinal root nerves inside the dural lining). The Extradural Surgical Probe is intended to be used to identify nerves outside the dural lining or peripherally.

2. SURGICAL STIMULATOR

The Surgical Stimulator, shown in Figure 1 (front panel view) and Figure 2 (rear panel view) below, is provided non-sterile and is intended for use outside the sterile field. The battery operated Surgical Stimulator is intended to be used to generate stimulating currents that will be delivered to the nerve tissue through the Surgical Probes.

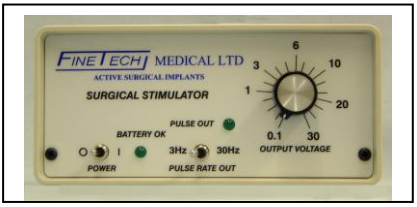


Figure 1

Figure 2

2.1 Stimulus Output & Connector

The Surgical Stimulator is a single channel, voltage output stimulator which delivers biphasic pulses of a fixed 350 μsec pulse duration. The frequency is switch selectable as 3 Hz or 30 Hz, and the amplitude is continuously adjustable (calibrated front panel knob) from 0.1v to 30v. The output of the Surgical Stimulator ensures that there is no DC current flow (i.e., zero net charge transfer).

Each Surgical Probe has a plug with a "D-shaped" cross section. This plug is aligned with the flat side UP before pushing the plug into the ELECTRODES receptacle on the rear panel of the Stimulator. When fully mated, the plug will lock

into place with a quiet "snap" sound. The plug can then be removed only by depressing (squeezing down on) the serrated locking tab on the top of the plug and then pulling it out of the receptacle.

2.2 Controls

The front panel of the stimulator contains two switches and a knob, which are used to adjust the output of the device. The POWER switch (on the left) is the ON/OFF switch with the O position being off, and | position being on. The PULSE RATE OUT switch (on the right) enables the user to select a stimulus frequency of 3 Hz or 30 Hz. When used in combination with each of the Surgical Probes, this feature enables the surgeon to identify specific muscle responses to either low or high frequency stimulation.

The OUTPUT VOLTAGE adjustment knob is labeled at output voltages of 0.1, 1, 3, 6, 10, 20, and 30 Volts. These settings correspond to the peak cathodic phase voltage under no load conditions.

2.3 Indicators

The green BATTERY OK indicator light serves two purposes. This indicator is illuminated when the device is turned on and the battery voltage is adequate to operate the device. When the BATTERY OK indicator is not illuminated there are no stimulus pulses generated by the system.

The green PULSE OUT indicator flashes with each stimulus pulse generated. Discrete flashes are clearly visible at the 3Hz stimulus frequency. At 30Hz stimulus frequency, the indicator appears to be constantly illuminated but upon further inspection, a faint flickering is visible

2.4 Battery

The 9-volt battery should be replaced if the green light does not illuminate when the On/Off switch is in the "ON" position. The battery should be removed immediately following each surgery

and a new battery inserted just prior to the next surgery. This assures that a fresh battery is available for each use; and it also ensures that no battery remains inside the Surgical Stimulator for an extended period of time.

To remove the battery, push in and lift up on the battery drawer as indicated on the battery drawer. The spring loaded drawer can then be removed from the Stimulator and the old battery removed. Proper environmental disposal techniques should be employed when discarding the used 9V battery. The battery should be discarded according to the instructions on the battery itself.

The new 9-volt alkaline battery (IEC-6LR61, ANSI 1604, or equivalent) is placed in the battery drawer in the polarity indicated. The battery drawer is then pushed back into the stimulator. Note that a reversed battery polarity will not operate the device; but neither will it damage the stimulator.

2.5 Cleaning and Maintenance

The Surgical Stimulator should be cleaned, if necessary, immediately after use. The Surgical Stimulator may be cleaned with a water dampened cloth over the exterior surfaces. Do not immerse the Surgical Stimulator for cleaning. For heavier dirt, a mild detergent such as dishwashing soap may be used for cleaning, followed by a cloth drying.
No other periodic maintenance or calibration activities (other than battery replacement) are required. Should repairs to the Surgical Stimulator be necessary, contact the manufacturer.

3. INTRATHECAL SURGICAL PROBE

The Intrathecal Surgical Probe is intended to be used with the Surgical Stimulator to stimulate and identify nerve roots Intrathecally. The level of stimulation is adjusted while monitoring the patient's physiological responses. The electrode end of the probe, shown in Figure 3, has three blunted hooks, which the surgeon uses to gently lift the nerve to be stimulated away from surrounding nerves. The back of the hooks are insulated so that the stimulus will flow only to the nerves acquired in the hooks.

Care should be taken to lift the nerves away from surrounding fluids and nerve tissue to minimize spillover stimulation (unintentional stimulation of nearby electrically excitable tissue). Similarly, care should be exercised to prevent excessive stretching or physical trauma to the nerve through its manipulation. The Intrathecal Surgical Probe is provided sterile (by Steam) in a double peel pouch.

The Surgical Probe is intended for a single use only.

Figure 3
Intrathecal Surgical Probe

4. EXTRADURAL SURGICAL PROBE

The Extradural Surgical Probe is intended to be used with the Surgical Stimulator to stimulate and identify nerves extradurally or peripherally. The level of stimulation is adjusted while monitoring the patient's physiological response. The electrode end of the probe, shown in Figure 4 below, has two blunted hooks. The probe hooks are placed around the nerve to be stimulated by the surgeon. The back of these hooks are uninsulated so that the nerve may be stimulated by holding the back of the hooks against the nerve or by lifting the nerve in the hooks.

Care should be taken to lift the nerves away from surrounding fluids and nerve tissue to minimize spillover stimulation (unintentional stimulation of nearby electrically excitable tissue). Similarly, care should be exercised to prevent excessive stretching or physical trauma to the nerve through its manipulation. The Extradural Surgical Probe is provided sterile (by Steam) in a double peel pouch.

The Surgical Probe is intended for a single use only.

Figure 4
Extradural Surgical Probe

5. CAUTIONS & WARNINGS

All the components of the *Surgical Nerve Stimulation System* should be examined for signs of damage prior to their use. Sterile peel pouches should be free of tears, punctures, or stains suggesting exposure to water or spilled fluids. The Surgical Probes should only be used if they are in their original, factory sealed double peel pouches. Damaged or suspicious sterile packages should be returned to the manufacturer.

- The *Surgical Nerve Stimulation System* delivers electrical currents intended to stimulate nerve and muscle tissue. This device should be operated only by personnel trained in the safe use of electrical stimulation. This equipment should not be used within an opened thoracic cavity or around other equipment with a direct electrical connection to the heart.

- The operation of the *Surgical Nerve Stimulation System* may interfere with the operation of ECG, EMG, EEG, or other patient monitoring equipment measuring physiologically generated electrical potentials. This potential disruption exists only while stimulus current is being delivered to the patient. Similarly, the *Surgical Nerve Stimulation System* should not be used with patients with implanted cardiac pacemakers.

- The Surgical Stimulator may be damaged and patient burns may result if the Surgical Probe is in contact with patient tissue during electrosurgical (HF Surgical Equipment) or cardiac defibrillation procedures.

6. EXAMPLE USE OF THE INTRATHECAL SURGICAL PROBE

In general, the Intrathecal Surgical Probe is intended to be used to stimulate and identify nerves within the dura of the spine. The specific example of using the Intrathecal Surgical Probe and Surgical Stimulator for Sacral Posterior Root Rhizotomy procedure to eliminate bladder spasticity is described below:

The Surgical Stimulator and Intrathecal Surgical Probe are used to identify the afferent (posterior) sacral nerves leading from the bladder. While knowledge of the spinal anatomy guides a surgeon to identify the posterior roots, the *Surgical Nerve Stimulation System* can be used as a means of confirming a lack of motor or bladder response in a particular sacral nerve root. In patients with higher spinal lesions (above T6), there may also be a rise in blood pressure during stimulation of a posterior root.

The goal of a rhizotomy is to surgically divide all posterior roots from S2- S5 which **do not** produce bladder contraction when stimulated at 30 Hz. Testing during a rhizotomy is accomplished in the following manner:

- The bladder contains fluid and the bladder fluid pressure is monitored.
- The Intrathecal Surgical Probe and the Surgical Stimulator are used to stimulate the nerve believed to be correct.
- After the probe is in good contact with the nerve and is not contacting other structures, stimulation is applied.
- The Surgical Stimulator is turned on at the minimum OUTPUT VOLTAGE setting and a PULSE RATE OUT of 3Hz.
- Increase the voltage ***slowly*** looking for:
    - a possible rise in blood pressure (for lesions above T6)
    - a lack of motor response (*e.g.* absence of plantar flexion twitch at lower voltages). *Note that higher voltages may produce reflex contraction of lower limb muscles.*

If no motor response is observed,

- the OUTPUT VOLTAGE is turned back to minimum, and the PULSE RATE OUT is set to 30Hz.
- Increase the voltage slowing looking for:

    - a lack of ***bladder*** response
    - a lack of motor response (absence of tetanic plantar flexion) at lower voltages
    - an increase in blood pressure

This testing is typically performed on each of the posterior sacral nerves (S2- S5) on both the left and right sides. If possible, avoid handling anterior roots. After testing is completed, allow the bladder to drain.

APPENDIX A PRODUCT SPECIFICATIONS

SURGICAL STIMULATOR (MODEL BSD 260)

Output:

- 1 channel, biphasic, capacitively coupled waveform; (see diagram below)
  - 2.3μF effective output capacitor & 110Ω output resistance
  - current limited at less than 110mA
  - max. 10μA DC leakage current
- User adjustable stimulus amplitude from 0.1 to 30 Volts (peak voltage, cathodic phase, unloaded, ± 5%)

Pulse Duration: 350 μS ± 20 μS

Pulse Frequency: 3 Hz ±0.5 Hz **OR** 30 Hz ± 2HZ (user selectable)

Power Supply: User replaceable 9V alkaline battery

Indicators: Green Battery OK Indicator, Green Pulse Indicator

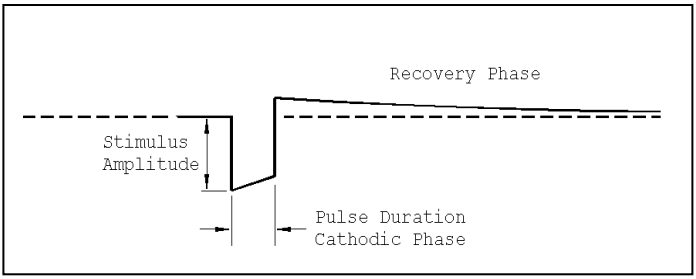
Equipment Classification (IEC-601):

- Internally Powered
- Type BF Applied Part
- Ordinary Equipment (no protection against ingress of water)
- Not Sterile
- Not Suitable for Use in Presence of Flammable Anesthetic Mixtures
- Intended for Continuous Operation

Physical Dimensions: 15cm X 7cm X 16cm (wide X high X deep);

Mass: 570 grams (without 9V battery)

Stimulus Waveform:



EXTRADURAL PROBE (MODEL BSD 259)

Design:

- Bipolar hook electrode, approximately 6.5mm between contacts (center to center)
  - inside and outside of hooks are active (conductive)
  - offset handle to allow good visualization of hooks along length of probe
- materials in direct tissue contact:
  - 304 stainless steel (electrical conductor)
  - medical grade polyolefin tubing
  - medical grade UV cure adhesive

Cable: coaxial cable (approximately 3m length) with silicone rubber sheath

Plug: 3-Contact, polarized locking plug with plastic shell

Packaging: Double Peel Pouch (bag inside a bag) Product is supplied sterile; sterilized by Steam

INTRATHECAL PROBE (MODEL BSD 264)

Design:

- Tripolar hook electrode (anode-cathode-anode), approximately 3mm between contacts (center to center) of outside hooks
  - inside of hooks are active (conductive)
  - outside of hooks are insulated
  - offset handle to allow good visualization of hooks along length of probe

- materials in direct tissue contact:
- 304 stainless steel (electrical conductor)
  - medical grade polyolefin tubing
  - medical grade UV cure adhesive
  - medical grade polyfluorocarbon

Cable Description: Approximately 3m with 3-Contact locking plug plastic shelled

Packaging: Double Peel Pouch (bag inside a bag) Product is supplied sterile; sterilized by Steam

ENVIRONMENTAL CHARACTERISTICS (ALL COMPONENTS)

Transport and Storage: Temperature -40°C to +70°C
Relative Humidity: 10 to 90%
Pressure: 500 to 1060 hPa
Operating Temperature: 10°C to 40°C

APPENDIX B GLOSSARY OF INTERNATIONAL SYMBOLS

The following symbols are used on the panels and / or labeling of the components of the *Surgical Nerve Stimulation System*.

	Attention, Consult Documentation
	Reference (model) Number
	Serial Number
	Off
	On
	Do Not Reuse
	Use By Indicated Date
	Date Of Manufacture
	Name and Address of Manufacturer
	Keep Dry
	Temperature Range
	Keep Out Of Direct Sunlight
	Sterilised By Steam
	Do Not Use If Packaging Damaged
	Type BF Equipment