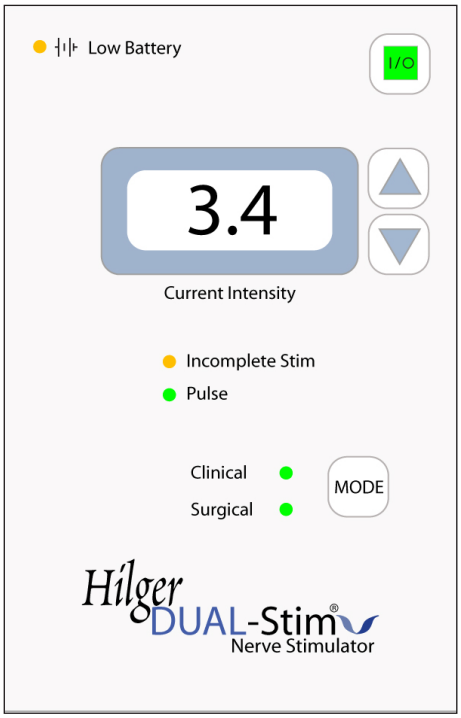
Hilger™ DUAL-Stim®

Nerve Stimulator



Instructions for Use,

Version 1.2

WR Medical Electronics Co.

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Hilger™ Dual-Stim Nerve Stimulator Instructions for Use, version 1.1, item number 3900, rev. 06/18.

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Comments or Questions?

We 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 the 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 electronics device, such as a cardiac pacemaker, should not be subject to stimulation unless specialist medical opinion has first been obtained.

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

WARNING: Avoid accidental contact between connected but unapplied 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 close in proximity.

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

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

WARNING: Operation in proximity of short wave or microwave therapy equipment may produce instability in the electrical stimulator output.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

CAUTION: This device is to be operated only by a physician or trained personnel under the direction of a physician.

CAUTION: The Hilger Dual-Stim Nerve Stimulator is not explosion-proof and should not be used in the presence of explosive gases.

DEVICE INFORMATION

Sterilization:

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

Batteries:

- Replace with four alkaline batteries, size C.
- Dispose of used batteries according to local regulations.

System Classification (IEC601-1 / EN 60601-1)

ENVIRONMENTAL RATINGS

After exposure to transport and storage extremes, allow the system to acclimate before operating. The system should not be subject to transport and storage extremes for an extended period of time.

Type of protection against electric shock	Type BF
Degree of protection against electric shock	Class II
Degree of protection against moisture ingress (IEC529)	Ordinary IPX1
Degree of protection in the presence of a flammable anesthetic mixture with air or with oxygen or with nitrous oxide	Not protected (unsuitable)
Mode of operation	Continuous

CLEANING

- Before cleaning always ensure that the unit is powered off. Never immerse the unit or any components. Do not apply cleaning solutions to the unit directly, instead apply to a cloth and then use it to clean the requisite components. To clean the main unit, bipolar clinical probe, and electrode pad cable;
    - Dust with a dry cloth
    - Use a damp cloth with water, enzymatic cleaner, 70% isopropyl alcohol, bleach wipes, or quarternary ammonium compound.
    - Do not autoclave, pressure sterilize, or gas sterilize
- Do not soak or immerse in any liquid
- Do not use petroleum based or acetone or other harsh solvents

RESPONSIBILITY OF THE SUPPLIER

- WR Medical Electronics Co. accepts responsibility for the affects of safety, reliability, and performance of the equipment, only if:
  - Assembly operation, extensions, readjustments, modifications, and re pairs are conducted by persons authorized by WR Medical Electronics Co.
  - The electrical installation of the room complies with local regulations.
  - The equipment is used in accordance with the Instructions for Use.

ELECTROMAGNETIC COMPATABILITY

- The system has been independently tested and found to comply with IEC60601-1-2
- Emissions are limited to CISPR 11 Class A Group 1 (industrial environment). Some care may be needed to minimize disturbance to sensitive receivers. Immunity from external disturbances is assured for operation in normal residential and clean industrial environments. If in doubt, consult WR Medical Electronics Co.

SAFETY AND INFORMATION SYMBOLS

Symbols that appear on the equipment have the following meaning:

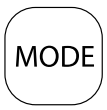
Attention, consult accompanying documents

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

Power on/off (|/0)

Increase current intensity

Decrease current intensity



Switch between surgical and clincal mode

Latex Statement

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

Environmental Protection and Disposal of Equipment

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

SYSTEM COMPONENTS

(Specific components may vary based on package purchased)

Part Number	Item description
3900	Hilger Dual Stim Main unit
3901	Bipolar Clinical Probe, Model DS
3905	Remote Surgical Probe, Model DS
3119	Electrode Cream
3903	Instructions For Use
3904	Adapter Model DS
3188	Monopolar Surgical Probe
3194	Electrode pad Cable
3214	Electrode Pads, pkg of 30

OPERATION OF THE HILGER DUAL-STIM NERVE STIMULATOR

Front Panel Description

I/O

On/Off Button

- The On/Off Button turns the instrument on and off. To operate, briefly press and hold the On/Off button. An audible, brief beep will occur on power on or power off.
- The instrument automatically powers off after 30 minutes with no user input activity.

Pulse Indicator

- The Pulse indicator will flash each time the current pulse is successfully delivered. It will also flash during power up. The pulse indicator will not flash if the Incomplete Stimulation indicator is on.

Incomplete Stimulation Indicator

- The Hilger Dual-Stim automatically compensates for changes or variations in tissue or contact resistance in order to maintain the current constant level. However, if the resistance is greater than that which the instrument can accommodate, or if there is a faulty connection or break in the cable, the current reading as shown on the display will not be valid, and the Incomplete Stimulation indicator will flash. When the light goes off, the current as set on the display is passing through the tissues, and the Pulse indicator will be flashing. If the Incomplete Stimulation indicator stays on, try the following:
- Check the Low Battery indicator. If the light is on, the batteries may need to be replaced.
- Repeat the skin preparation more carefully to lower the resistance. If the indicator light is not illuminated at low current settings, but comes on as the current is increased, the instrument is not able to accommodate the resistance at the higher settings.
- In some cases, the indicator may intermittently flash when the display is set at 0.1mA.

Low Battery indicator

- This instrument is powered by four alkaline batteries, size “C”, which have a useful life of approximately 100 hours. If the Low Battery indicator is illuminated, the battery voltage is too low for the stimulator to work correctly and the batteries should be replaced immediately. When the Low battery indicator first illuminates, there is less than one hour of battery life remaining. We recommend using industrial grade Alkaline C Cell batteries for replacement.

Current Intensity Display

- The backlit digital display indicates current intensity and displays the current reading in milliamperes (mA). The current intensity can be adjusted from 0.0 to 10.0 mA using the Current Control buttons located to the right of the digital display, or by using the buttons on the remote probe (in a surgical setting).

Current Intensity Increase/Decrease Buttons

- To increase or decrease current intensity, press the designated arrow to the right of the display. Press and release the desired button to change the intensity setting by 0.1 mA. Press and hold the desired button to rapidly change current intensity.

Mode Indicator

The Hilger Dual-Stim has two modes of operation.

- Press the MODE button to toggle between these modes. The active mode will be indicated by the designated LED light.

Clinical Mode	**Surgical Mode**
Pulse width (on time) 0.006 seconds	Pulse width (on time) 0.002 seconds
Pulse off time 0.166 seconds	Pulse off time 0.1998 seconds
Frequency 6 Hz	Frequency 5 Hz

Bipolar Clinical Probe

- The smaller stainless steel ball on the Bipolar Clinical Probe is the active electrode, and is applied to the area of the nerve trunk or branches to deliver the stimulating current. The larger ball is the return, or “indifferent” electrode, which must also be in contact with the skin to complete the current path through the tissues. Be aware that placing the large ball directly over one of the nerve branches may cause secondary stimulation of one of the other branches.
- The small button at the center of the probe body is used activate the current. Current will be applied while the button is depressed. When placing the probe on the skin or removing it from the skin, the current switch must be off (not depressed). Making or breaking contact with the skin while the current is on can cause patient discomfort.
- The arms of the probe can be adjusted to a distance of about 3 inches for testing.
- To ensure good skin conductivity, remove cosmetics and skin creams from the areas where the electrodes will be applied. Massage electrode cream into the skin, and allow it to penetrate for a few minutes. Apply a small amount of electrode cream to the ball tips of the electrode. If an excessive amount of electrode cream is on the skin, some current may travel through the cream instead of passing through the tissues.

Remote Surgical Probe

- The Remote Surgical Probe has a 0.55mm flexible tip which is flush-tipped, insulated, and can be bent to any angle. This probe is single-use and should not be reprocessed.
- The Remote Surgical Probe has two buttons on the hand piece for controlling current output.
- The front button increases current output, and the back button decreases current output. Do not simultaneously press both buttons.
- Connect the Remote Surgical Probe at the connector labeled Probe on the bottom of the unit.
- An Electrode Pad Cable and electrode must always be used when using the Remote

Surgical Probe. Affix the electrode pad to the patients shoulder opposite to the site of surgery.
- Excessive current of repeated stimulation applied to a nerve can cause nerve fatigue

Monopolar Surgical Probe

- The Monopolar Surgical Probe has a 0.55mm flexible tip which is flush-tipped, insulated, and can be bent to any angle. This probe is single-use and should not be reprocessed.
- Connect the Monopolar Surgical Probe into the Adaptor Cable, and connect the adaptor Cable into the connector jack labeled Probe on the bottom of the unit. An Electrode Pad Cable and electrode must always be used when using the Monopolar Surgical Probe. Affix the electrode pad to the patients shoulder opposite to the site of surgery.
- Excessive current of repeated stimulation applied to a nerve can cause nerve fatigue.

Electrode Pad Cable

- The Electrode Pad Cable plugs into the connector labeled Return Pad on the bottom of the unit. An electrode pad is attached to the snap end, and is placed on the patients shoulder opposite to the surgical site. An Electrode Pad Cable is not required when using the Bipolar Clinical Probe.

Electrodes

- Current densities for any electrode exceeding 2 mA r.m.s./cm^2 may require the special attention of the operator.
- WR Medical recommends the use of electrodes capable of allowing a maximum output value of 15 mA.

Battery Replacement

- If battery replacement is necessary, as indicated by the Low Battery indicator, replace the batteries immediately. This instrument uses four alkaline size “C” batteries. We recommend the use of industrial grade Alkaline C Cell batteries.

References and Suggested Readings

References

1. Hilger, Jerome A. "Facial Nerve Stimulator," trans., American Academy Opthalmology and Otolaryngology 64:74–76, Jan.–Feb., 1964.

2. Campbell, E.D.R.; Hickey, R.P.; Nixon, K.H.; and Richardson, A.T. "Value of Nerve Excitability Measurements in Prognosis of Facial Palsy," British Medical Journal 2:7–10, July 7, 1962.

Suggested Readings

Adour, Kedar K. "Global MST: Predicting Prognosis for Bell's Palsy and Ramsay Hunt Syndrome Patients." Report from instructional course given at the American Academy of Otolaryngology, Head and Neck Surgery, San Diego, CA, Sept., 1994.

Campbell, E.D.R. "A Simple Prognostic Test in Facial Palsy," Journal of Laryngology 77:462–66, June, 1963.

Gates, George A. "Nerve Excitability Testing: Technical Pitfalls and Threshold Norms Using Absolute Values." Laryngoscope 103:379–85, Apr., 1993.

Lewis, Brent I.; Adour, Kedar K.; Kahn, Jonathan M.; Lewis, Alison J. "Hilger Facial Nerve Stimulator: A 25-Year Update." Laryngoscope 101:71–74, Jan., 1991.

May, M. "Maximum Stimulation Test (MST)." In The Facial Nerve. Thieme Medical Publishers, New York: 1986.

Manos-Pujol, Manuel; Adour, Kedar K. "Who's Afraid of the Facial Nerve." Excerpted from Otology (Chapter 21), S.E. Lucente, ed. St. Louis: Mosby, 1995.

Ruboyianes, John M.; Adour, Kedar K.; Santos, David W.; Von Doersten, Peter G. "The Maximal Stimulation and Facial Nerve Conduction Latency Tests: Predicting the Outcome of Bell's Palsy." Laryngoscope 104:1–6, Jan., 1994.

Service Information

Warranty

The Hilger Dual-Stim Nerve Stimulator is warranted to be free of defects in material and workmanship for a period of two years from purchase date. Probes and cables are warranted for 90 days from purchase date. Warranty is void if the unit has been damaged by electrocautery. All warranty service must be performed at WR Medical Electronics Co.

Service

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

Please contact us for an RMA and for return instructions.

Send to:

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

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

SALES SPECIFICATION SHEET - **Hilger Dual-Stim®**

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PHYSICAL DIMENSIONS

Height:	8.5 in. (21.6 cm.)
Width:	9 in. (22.8 cm.)
Depth:	3 in. (7.6 cm.)
Weight:	3.6 lbs. (with pole clamp) (1.6 kg.)

POWER REQUIREMENTS

Power:	4 alkaline batteries, Size C

ENVIRONMENT

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

STIMULATOR SPECIFICATIONS

	CLINICAL MODE	SURGICAL MODE
Pulse Width:	0.0006 seconds +25 microseconds	0.0002 seconds +25 microseconds
Pule Time Off:	0.1666 seconds	0.1998 seconds
Pulse Frequency:	0.1666 sec +7 milliseconds	0.200 sec at +7 milliseconds
Hertz:	6	5

REGULATORY

FDA MDL Number:	D009007
FDA 510K:	K063560
FDA Device Class:	II
Health Canada License Number :	73478