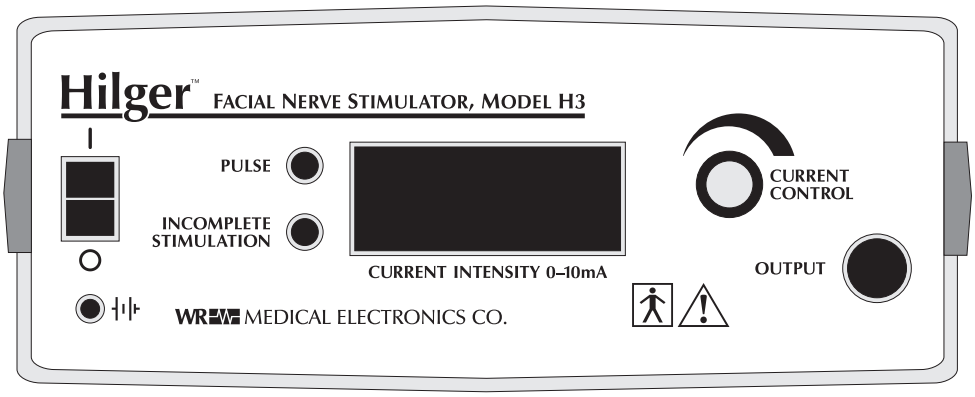
HILGER™

FACIAL NERVE STIMULATOR

MODEL H3



Instructions for Use, Version 4.0

WR Medical Electronics Co.

Copyright Information

Hilger Facial Nerve Stimulator, Model H3, **Instructions for Use,** version 4.0, item number 3034, revised 9/27/11.

For more information, contact:

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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 subject to stimulation unless specialist medical opinion has first been obtained.

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: This device is restricted to sale by or on the order of a physician.

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

CAUTION: The Hilger Facial 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 used only for clinical testing and should not require sterilizing. However, if desired, it may be gas sterilized. It must not be steam autoclaved.

Batteries

Replace with four alkaline batteries, size C, Mallory MN 1400 or equivalent. Refer to page 10 in this manual for the battery replacement procedure.

Service

Circuit diagrams, component parts lists, descriptions, and calibration instructions are available from WR Medical Electronics Co. Refer to the Service Information section, page 16, for additional service information.

System Classification (IEC601-1/ EN60601-1)

Type of protection against electric shock:	Type BF
Degree of protection against electric shock:	Class II
Degree of protection against moisture ingress (IEC529)	Ordinary IPXO
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

Environmental Ratings

After exposure to transport and storage extremes, allow the system to acclimatize before operating. The system should not be subject to transport and storage extremes for longer than 15 weeks.

	Operating	Transport and Storage
Temperature:	+10°C to +35°C	-10°C to +50°C
Relative Humidity:	30% to 75%	10% to 95% (non-condensing)
Atmospheric Pressure:	700hPa to 1060hPa	500hPa to 1060hPa

Preventive Maintenance and Cleaning

- Clean the equipment after each use and before storing. Surfaces should be cleaned using a dry cloth. For stubborn stains, a lightly dampened cloth and a mild detergent may be used.
- After each use, the Bipolar Clinical Probe should be wiped dry. The probe may be wiped with alcohol but must not be immersed in liquids, as this would damage the switch and may corrode the cables and connections.
- Never immerse any surface or component in water, and always ensure surfaces are dry before coupling to patient or storing.

Responsibility of the Supplier

WR Medical Electronics Co. accepts responsibility for the effects of safety, reliability and performance of the equipment only if:

- Assembly operations, extensions, readjustments, modifications, or repairs 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 Compatibility

The system has been independently tested and found to comply with IEC601-1-2/ EN60601-1-2.

- 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.

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

Battery

Variability

Power off

Power on

Environmental Protection and Disposal of Equipment

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

TECHNICAL SPECIFICATIONS

- **Current output:** 0.0 to 10.0 milliamperes (mA) measured across a 1K ±1% resistive load. Tolerance at 0.0 indicated, with a residual current of 0.05 mA, is ±0.005 mA. Tolerance at 10.0 mA is ±0.4 mA.
- **Pulse width:** 0.0006 seconds ± 20 microseconds.
- **Pulse off time:** 0.1660 seconds.[1]
- **Pulse frequency:** 0.1666 seconds ± 5 milliseconds.
- **Dial accuracy:** Linear down to 0.15 mA, residual current of 0.05 mA at 0.0 indicated.
- **Batteries:** Four 1.5-volt alkaline C cells.
- **Battery life:** 200 hours continuous use between replacement.
- **Size:** 8.5 x 9 x 3 inches (21.6 x 22.8 x 7.6 cm).
- **Weight:** 4 pounds (1.82 kg).

[1] Defined as pulse frequency setting in seconds minus pulse width setting in seconds

SYSTEM COMPONENTS

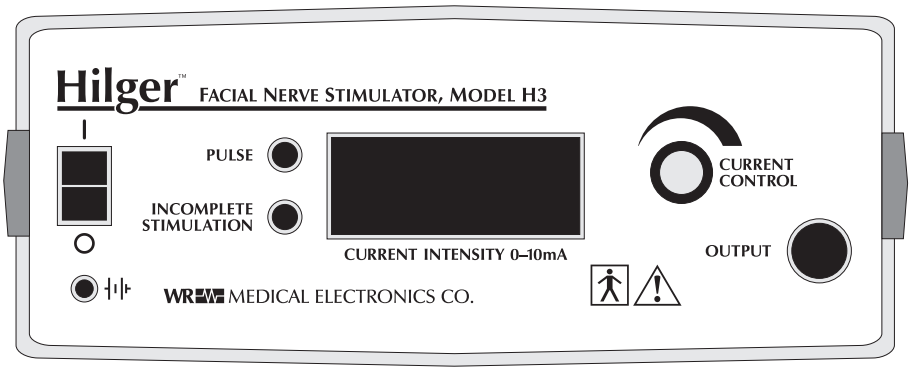
Specific component lists may vary, depending on what was ordered. Retain the packing list to place reorders. If you have questions, contact WR Medical Electronics Co.

Part Number	Item	Single Use or Reuse	Sterile	Repairable[1]
3912	Hilger Facial Nerve Stimulator, Model H3	Reuse	None[2]	Yes
3302	Hilger Bipolar Clinical Probe	Reuse	None[2]	No
3119	Electrode Cream, 5 oz.	Single	N/A	No
3034	Instructions for Use	N/A	N/A	No
3149	Carrying Case	Reuse	N/A	No

[1] See page 16 for replacement or servicing information
[2] See preventive maintenance and cleaning on page 6
[3] May be gas (ETO) sterilized

OPERATION OF THE HILGER FACIAL NERVE STIMULATOR

Front Panel Description



ON/OFF SWITCH

The ON/OFF switch turns the instrument on and off.

PULSE LIGHT

The PULSE light, to the right of the ON/OFF switch, flashes whenever the instrument is turned on.

INCOMPLETE STIMULATION LIGHT

The Hilger Facial Nerve Stimulator automatically compensates for changes or variations in tissue or contact resistance in order to maintain the current at a constant level. However, if the resistance is greater than that which the instrument can accommodate, or if there is a faulty connection or a break in the cable, the current reading as shown on the dial will not be valid, and the INCOMPLETE STIMULATION lamp will remain on. When the light goes off, the current as set on the dial is passing through the tissues. If the INCOMPLETE STIMULATION light stays on, try the following:

1) Check the REPLACE BATTERIES light. If the light is on, the batteries may need to be replaced.
2) Check the cables and connections by shorting the arms of the Bipolar Clinical Probe with a metallic object. If the INCOMPLETE STIMULATION light then goes off, it indicates there is no fault in the probe or cables.
3) Repeat the skin preparation more carefully to lower the resistance. If the lamp stays off at low current settings but comes on as the current is turned up, the instrument was able to accommodate the resistance at the lower current setting but not at the higher settings.

REPLACE BATTERIES LIGHT

This instrument is powered by four manganese-alkaline batteries, size "C," which have a useful life of about 200 hours. If the REPLACE BATTERIES light (located below the ON/OFF switch) is illuminated, the battery voltage is too low for the stimulator to work correctly and the batteries should be replaced immediately. When the REPLACE BATTERIES indicator is on, the instrument may still produce a stimulating current, but the intensity and other parameters are liable to be incorrect, and the current reading would not be valid.

CURRENT INTENSITY DISPLAY

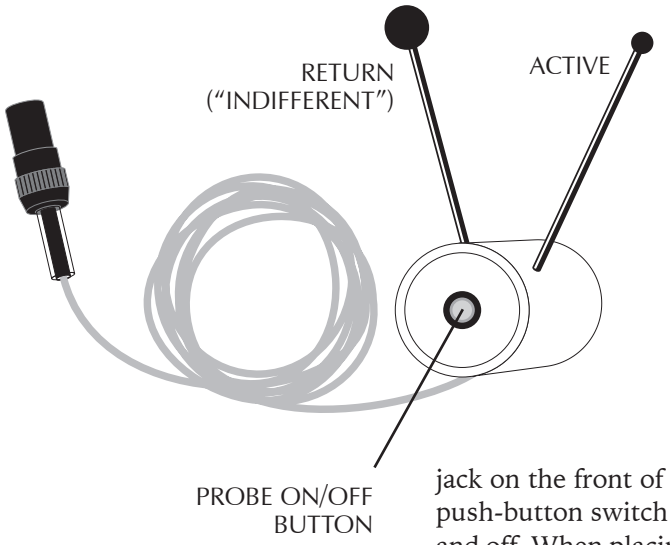
This backlit digital display indicates current intensity and gives the current reading in milliamperes (mA). The current intensity can be adjusted from 0.0 to 10.0 mA using the CURRENT CONTROL knob to the right of the digital display.

The current is linear with respect to the dial readings, down to a setting of 0.15 mA, which is considerably below the settings normally used, especially in clinical testing. At settings below 0.15 mA, the actual current is higher than shown on the display, and at a setting of 0.0 there is a residual current of about 0.05 mA (used to determine excess resistance). Below a setting of 0.15 mA, the display readings must be considered as relative rather than absolute measures of current intensity.

CURRENT CONTROL KNOB
This knob is used to set the output, as shown on the CURRENT INTENSITY display. Turning the knob clockwise increases the output.

OUTPUT JACK
The Bipolar Clinical Probe is plugged into this jack.

Bipolar Clinical Probe



The small 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. (See page 13, "Evaluating Facial Nerve Excitability," for specific placement instructions.)

The arms of the probe may be closed for storage, but should be fully opened to a distance of about three inches when the probe is used. The large ball (or return electrode) should preferably be applied where it is not directly over one of the nerve branches to avoid any possibility of secondary stimulation of one of the other branches.

The plug on the end of the probe cable goes into the output jack on the front of the instrument and must be pushed all the way in. The small push-button switch at the center of the probe body is used to turn the current on and off. When placing the probe on the skin or removing it from the skin, the current switch must be off. Making or breaking the contact with the skin while the switch is on can cause patient discomfort.

After each use, the Bipolar Clinical Probe should be wiped dry. The probe may be wiped with cleaning solutions but must not be immersed in liquids, as this would damage the switch and corrode the cables and connections. The Bipolar Clinical Probe is used only for clinical testing and should not require sterilizing. However, if desired, it may be gas sterilized. It must not be steam autoclaved.

Battery Replacement

The batteries are good until the REPLACE BATTERIES light is illuminated. If the light is on, replace the batteries immediately. The batteries have a shelf life of about two years, irrespective of the amount of use. To extend the battery life, be sure the instrument is turned off when not in use.

The instrument uses four manganese-alkaline, size "C" batteries. Be sure to use manganese-alkaline rather than zinc-carbon batteries.

To replace the batteries, remove the screws from the bottom of the instrument, separate the case, and remove the old batteries from the holder. Insert the new batteries, being sure that the contacts (plus and minus terminals) of each battery are against the contacts of the holder.

Turn the instrument on to check that the REPLACE BATTERIES light is off, and that the PULSE indicator and INCOMPLETE STIMULATION lights come on.

CLINICAL TESTING PROCEDURES

Skin Preparation for Good Conductivity

The Hilger Facial Nerve Stimulator compensates for variations in the resistance of the current path through the skin and tissues in order to maintain a constant current intensity as set on the display. However, it is essential that the contact resistance between the electrode and the skin be kept as low as possible to ensure that the resistance does not exceed the compliance limits of the instrument, especially at higher current settings.

To ensure good skin conductivity, any cosmetics or skin creams must be removed from the areas where the electrodes are to be applied. This can be accomplished by washing with warm water and soap and rinsing thoroughly to remove all of the soap before drying.

Massage electrode cream into the skin, working it in thoroughly to break down the natural oils of the skin, which increase its electrical resistance. The cream should be allowed to penetrate for a few minutes, and a second light application should be made, leaving the skin just slightly moist. Note: If an excessive amount of the electrode cream is allowed to remain on the skin, a portion of the current may travel through the cream instead of passing through the tissues, invalidating the current readings. Also, apply a small amount of the electrode cream to each of the electrode balls.

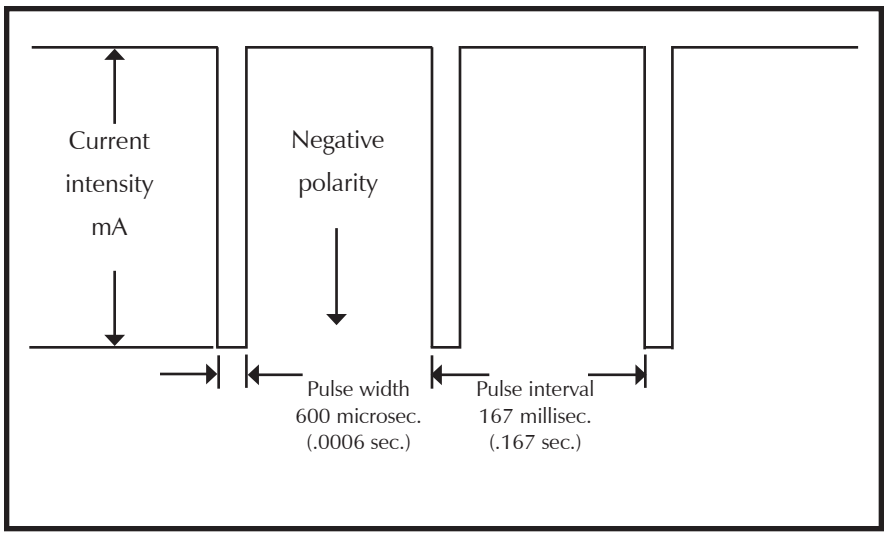
If, after applying the Bipolar Clinical Probe to the skin, the INCOMPLETE STIMULATION light does not go out, resistance is too high or there may be a break in the cables. If the cables appear to be in order, repeat the skin preparation more carefully.

Application of the Bipolar Clinical Probe

As mentioned in the previous chapter, open the arms of the Bipolar Clinical Probe to a distance of about three inches. The large ball (or return electrode) should preferably be applied where it is not directly over one of the nerve branches to avoid any possibility of secondary stimulation of one of the other branches.

The small push-button switch at the center of the probe body is used to turn the current on and off. When placing the probe on the skin or removing it from the skin, the current switch must be off. Making or breaking the contact with the skin while the switch is on can cause patient discomfort.

Square Wave Current and Nerve Response



Square wave pulsed current for nerve stimulation

The current provided by the Hilger Facial Nerve Stimulator for stimulation of the nerve consists of square wave pulses of negative polarity and 0.6 milliseconds (0.0006 sec.) duration, with a pulse frequency of 6.0 pulses per second.

These parameters were determined by testing a large number of subjects, and were selected to give the best response without undue discomfort.

The current intensity is adjustable from 0.05 to 10.0 milliamperes (mA) by means of the CURRENT CONTROL knob, and is displayed on a backlit digital display. Current intensity refers to the height of the individual pulses as represented in the adjacent figure, and not to the average level of current.

When the pulsed current is applied to a normal nerve and the current intensity through the nerve tissue is high enough to reach the stimulation threshold, contractions of the associated muscles is evoked. The muscles contract with each pulse of the current and relax between pulses, resulting in repetitive contractions at a rate of six per second.

When the current intensity is just at the stimulation threshold, minimal and localized contractions are produced. As the current is increased above this level, the contractions become progressively stronger and more extensive until the entire muscle is responding fully.

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 Hilger Facial Nerve Stimulator, the voltage is automatically adjusted to compensate for any differences in tissue or contact resistance so that the current is constant at any given setting of the CURRENT CONTROL knob. In addition, the INCOMPLETE STIMULATION light gives a visual signal if the resistance should exceed the compliance limits of the instrument.

Basis for Nerve Excitability Testing in Facial Palsy

Clinical findings indicate that nerve excitability measurements aid in the evaluation and prognosis of facial palsy (see references). Jerome A. Hilger, M.D., states:

> Comparison of the level of current required to produce twitching of the facial muscles on the affected side as compared to that required on the normal side was found to indicate the condition of the nerve. Equal response of the two sides at the same current intensity indicates that the block of the affected side is physiologic. Response of the affected nerve, but at higher current levels than on the normal side, indicates partial degeneration of the neuraxones. Lack of response on the affected side, even at high current intensities, indicates complete nerve degeneration.[1]

The work of Campbell and his associates demonstrated the value of the nerve excitability measurements in the evaluation and prognosis of facial palsy. They state:

> The distal portion of the nerve maintains its electrical excitability for 48 to 72 hours, after which the axis cylinders fragment with abolition of excitability and conduction. The motor end-plate however, retains its full excitability for a further 5 to 10 days, during which time the last fragments of axis cylinder in the motor end-plate disappear. The excitability of the end-plate then diminishes. Thus the characteristics of reaction of degeneration and the changes of denervation in the intensity-duration curve occur. In practice, therefore, if electrical stimulation is applied directly to recently denervated muscle it may respond with the characteristics of normal muscle for up to 10 days before showing the characteristics of denervated muscle. If, however, the motor-nerve trunk is stimulated, excitability and conduction will generally disappear three days after a denervating lesion has occurred. By this method, therefore, the state of the nerve may be determined earlier than by plotting of intensity duration curves derived from affected muscles.[2]

Evaluating Facial Nerve Excitability

In testing facial nerve excitability with the Hilger Facial Nerve Stimulator, the square wave stimulation current is applied first to the normal side and then to the paralyzed side to determine the current intensity in milliamperes (mA) required to produce muscle contractions of comparable strength on the two sides.

The motor-nerve trunk is stimulated by applying the active electrode to the skin overlying the stylomastoid foramen. The proper area is usually within one centimeter beneath the ear lobe and posterior to the ramus of the mandible. Starting with a current setting of about 1.5 mA, the region of the stylomastoid foramen is explored with the active electrode and the current is turned up slowly. Some sensation will usually be noted by the patient before detectable twitch of the muscles occurs.

When one or more of the facial muscles can be seen to twitch, the area is explored further to find the optimum location that produces muscle contractions at the lowest current setting. This minimum current intensity is the measure of nerve excitability on the two sides.

A variation of this procedure is to start with a high current setting and turn the current down until contractions become minimal. Another approach is to base the comparative current readings on stronger and more complete rather than minimal muscle contractions. However, this involves a greater element of judgment in adjusting the current to produce contractions of the same intensity and extent on the two sides.

The various branches of the facial nerve, such as those controlling the forehead, eye, and mouth, may also be stimulated individually. Comparative current intensities required to evoke contractions of the corresponding muscles on the two sides of the face afford further insights into the condition of the nerve on the paralyzed side.

Serial testing is particularly important until it is established whether the paralysis resulted from a physiologic block or degeneration of the nerve. Nerve excitability should be tested daily if pain was a clinical feature of the onset, or every other day if pain was not a feature. This regime should be followed until either the response is lost entirely or decreasing difference in current intensity indicate definite continuing improvement. The nerve excitability test aids not only in diagnosis and prognosis, but also in monitoring nerve response during and following treatment.

Developmental testing of the stimulator on normal subjects showed a stimulation threshold of around 3.0 mA applied to the nerve trunk to be modal. Thresholds on both sides of the same normal subject were nearly identical, and retesting also

showed thresholds nearly identical with the original determinations. A difference of about 2.5 to 3.0 mA between the two sides in stimulating the nerve trunk is generally considered as indicating significant nerve degeneration. The facial nerve branches respond at lower current settings than the nerve trunk, and correspondingly small side-to-side differences are considered significant.

Maximal Stimulation Testing

The detailed testing procedure outline below is based on the concept of stimulating the nerve trunk, starting with a low current setting and turning the current up slowly until minimal contractions occur. However, this procedure can readily be adapted to other approaches.

1. Seat the patient comfortably in a position with good lighting so you can readily observe the muscle contractions.
2. Explain that the patient may experience a tingling sensation but that it is completely harmless.
3. Prepare the patient's skin on both sides of the face as explained in the preceding section.
4. Spread the arms of the Bipolar Clinical Probe fully and plug it into the output jack, making sure that the plug is all the way in.
5. Using the CURRENT CONTROL knob, set the current intensity to about 1.5 mA for the nerve trunk or 0.3 mA for the branches.
6. With the switch on the front panel, turn the instrument on, being sure that the PULSE light and the INCOMPLETE STIMULATION light are blinking.
7. Check to make sure that the REPLACE BATTERIES light is off. If the REPLACE BATTERIES light is off, there is sufficient voltage for the stimulator to function correctly.
8. With the switch on the Bipolar Clinical Probe off, apply the return electrode to an area away from the facial nerve trunk or its main branches and apply the active electrode to the skin overlying the nerve trunk or the particular branch you are testing. Then press the probe switch button to turn on the current.
9. Check that the INCOMPLETE STIMULATION light goes off and remains off, indicating that the current as set on the dial is actually passing through the tissues.
10. Explore the area of the nerve trunk or branch with the active electrode while turning the current up slowly until muscle contractions are observed. Then explore the area further to find the optimum location at which contractions occur with the lowest current setting.
11. Test the normal side first, then the paralyzed side.

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 H3 is warranted to be free of defects in material and workmanship for a period of two years from purchase (90 days for Bipolar Clinical Probe). Warranty is void if the unit has been damaged by electrocautery. All warranty service is to be provided at the WR Medical 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 Bipolar Clinical Probe via insured parcel post or insured UPS. Use adequate 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

Phone: 651-604-8400
Toll-free phone: 800-635-1312 (US and Canada only)
FAX: 651-604-8499
E-mail: ent@wrmed.com

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.