CASE

Computer Aided Sensory Evaluator

Rev. 5/1/24
Instructions for Use

P/N 5027

For more information, contact:

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EC REP

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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.

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Product Description

The Case IV system is a computer assisted diagnostic device for detecting and characterizing sensory thresholds that have been altered by disease of sensory receptors, nerve fibers, central nervous system tracks, and cerebral association areas. The system also detects improvement in sensory perception that results from medical treatment. This device is unique in that it provides highly sensitive, quantified, and reproducible test results.

The CASE IV utilizes two carefully calibrated stimulators, Thermal and Vibration, to determine sensory threshold. WR Testworks software provides a simple means of recording and analyzing the patient's response. Patient responses to safe, effective stimuli are used to generate a sensory threshold level which is then compared to optional reference data available with the WR Testworks software.

Intended Use

The CASE IV System may be used on patients with neurological diseases, especially peripheral neuropathy. The system is designed to measure and log patient responses to a series of thermal or vibratory stimuli. The test results should be used with the results of other medically accepted tests to assist the physician in making a diagnosis. The CASE IV does not make a diagnosis or indicate by itself that any disease state exists.

Indications for Use

The CASE IV Quantitative Sensory Testing System provides tests that are non-invasive, standardized, quantitative, and easy to perform. It is intended to record and indicate the following modalities during sensory testing:

- Cooling and Warming threshold detection
  - 4-2-1 Stepping or Forced Choice algorithm
  - 25 stimulus levels
- Vibration threshold detection
  - 4-2-1 Stepping or Forced Choice algorithm
  - 25 stimulus levels
- Heat -as-pain threshold detection
  - Mid-level of pain, and pain tolerance
  - Non-repeating ascending Algorithm
  - 25 stimulus levels
- Smart Somatotopic sensation testing
  - Heat-as-pain
  - New test sites with site guidance
  - 25 stimulus levels

Intended Users

- Trained medical technicians
- Nurses
- Physicians

Intended Patient Population

- Age: Adolescent and adult
- Health: Suspected of, or having, autonomic disorders.
- Patient State: Not relevant

Usage Environment

The equipment is intended for use in an indoors clinic, hospital, or professional healthcare facility. Refer to the Instruction for Use for the Operating Environment temperature and humidity conditions

Contraindications

- Test only patients that are rested, attentive, and cooperative.
- Children under the age of eight are not sufficiently attentive for the duration of the tests to obtain reliable results.
- Patients with mental deficiencies or dementia cannot reliably be tested.
- Patients receiving sedatives, tranquilizers, mood- or mind-altering drugs, opiates, and analgesics should not be tested unless adequately withdrawn for a sufficient time as under a physician's care.
- Do not test on patients with exfoliated skin conditions, dermatitis, bruises, weeping skin, skin lesions, infected skin, or necrotic skin.
- Patients should be pretested for gross insensitivity or hyper-sensitivity to thermal and vibration stimuli, using medically accepted methods of testing.

Warnings and Cautions

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: This device is to be serviced only by trained biomedical technicians. Contact the factory for repair advice before attempting to repair.

CAUTION: Subjects to be tested must be examined by a physician before testing.

CAUTION: Do not allow the CASE IV Thermal Stimulator, Thermal Reservoir, Thermal Pump, or Water Hoses to freeze. These items must be drained if freezing conditions are expected. Failure to drain these items could result in damage to these items from freezing. Contact WR Medical Electronics Co. for instructions on how to drain the system.

WARNING: For maximum electrical safety, all mains-powered items should be powered by a medical grade isolation transformer. The use of a medical grade plug strip, which itself is plugged into the medical grade isolation transformer, is recommended.

WARNING: Do not use the device on any person when any covers of any equipment have been removed.

Advertencias y precauciones

PRECAUCIONE: Este aparato está restringido a la venta de médicos o por orden de estos.

PRECAUCIONE: Este aparato solo debe operarse por personal formado bajo la dirección de un médico.

PRECAUCIONE: Este aparato solo debe repararse por técnicos biomédicos formados. Contacte con la fábrica para buscar consejos de reparación antes de intentar repararlo.

PRECAUCIONE: Las personas que se sometan a la prueba deben pasar el examen de un médico previamente.

PRECAUCIONE: No permita que se congelen el estimulador térmico CASE IV, el depósito térmico, la bomba térmica ni los tubos de agua. Estos elementos deben vaciarse si se esperan condiciones de congelación. Si no vacía estos elementos podría dañarlos al congelarse. Contacte con WR Medical Electronics Co. para ver instrucciones acerca de cómo vaciar el sistema.

ADVERTENCIA: Para una máxima seguridad eléctrica, todos los elementos enchufados a la corriente deben disponer de un transformador de aislamiento de grado médico. Se recomienda utilizar un enchufe en línea de grado médico, que a su vez se enchufa al transformador de aislamiento de grado médico.

ADVERTENCIA: No utilice el aparato en ninguna persona cuando se hayan extraído las cubiertas de cualquier equipo.

Avertissements et précautions

PRECAUTION: Ce dispositif ne peut être vendu que par un médecin ou sur prescription médicale.

PRECAUTION: Ce dispositif ne peut être utilisé que par du personnel formé et sous la direction d'un médecin.

PRECAUTION: Ce dispositif ne peut être réparé que par des techniciens biomédicaux spécialement formés. Avant de tenter toute réparation, veuillez contacter le fabricant pour demander conseil.

PRECAUTION: Les patients à tester doivent d'abord être examinés par un médecin.

PRECAUTION: Ne pas laisser geler le stimulateur thermique CASE IV, le réservoir thermique, la pompe thermique ou les tuyaux d'eau. Si ces éléments risquent de geler, il faut impérativement les vidanger. Si ces éléments ne sont pas vidangés, le gel risquerait de les détériorer. Pour obtenir des instructions concernant la vidange du système, veuillez vous adresser à WR Medical Electronics Co.

AVERTISSEMENT: Pour une sécurité électrique maximale, tous les éléments alimentés par secteur doivent être alimentés par un transformateur de séparation de qualité médicale. L'utilisation d'une multiprise de qualité médicale, elle-même branchée sur le transformateur de séparation de qualité médicale, est recommandée.

AVERTISSEMENT: Ne jamais utiliser ce dispositif sur un patient quand l'un des capots de l'appareil a été retiré.

Warn- Und Sicherheitshinweise

SICHERHEITSHINWEISE: Dieses Gerät darf nur an einen Arzt oder auf Anordnung eines Arztes verkauft werden.

SICHERHEITSHINWEISE: Dieses Gerät darf nur von geschultem Personal unter Anleitung eines Arztes betrieben werden.

SICHERHEITSHINWEISE: Dieses Gerät darf nur von geschulten Technikern für biomedizinische Geräte gewartet werden. Wenden Sie sich an den Hersteller, um Hinweise für die Reparatur zu erhalten, bevor Sie versuchen, es selbst zu reparieren.

SICHERHEITSHINWEISE: Die zu testenden Personen müssen vor dem Test von einem Arzt untersucht werden.

SICHERHEITSHINWEISE: Der CASE IV Thermostimulator, der Wärmespeicher, die Wärmepumpe oder die Wasserschläuche dürfen nicht einfrieren. Diese Teile müssen entleert werden, falls Temperaturen unter dem Gefrierpunkt zu erwarten sind. Falls diese Teile einfrieren, ohne dass sie entleert wurden, können sie beschädigt werden. Wenden Sie sich an WR Medical Electronics Co., um zu erfahren, wie das System zu entleeren ist.

WARN : Um ein Höchstmaß an elektrischer Sicherheit zu gewährleisten, müssen alle an das Stromnetz angeschlossenen Teile durch einen für medizinische Geräte zugelassenen Trenntransformator versorgt werden. Es wird empfohlen, eine für medizinische Geräte zugelassene Steckerleiste zu verwenden, die an den für medizinische Geräte zugelassenen Trenntransformator angeschlossen wird.

WARN : Benutzen Sie das Gerät nicht an einer Person, wenn irgendeine Abdeckung eines Ausrüstungsteils entfernt wurde.

Sterilization

Not required.

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

Degree of protection against moisture ingress (IEC529)	IPX0 - Ordinary
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

Safety and Information Symbols

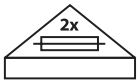
Attention, consult accompanying documents

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

Alternating Current

Power On

Power OFF



Replace fuse links as marked

Follow Instructions for Use

Approval marks. ETL listed for North America & CE with notified body number (Intertek SEMKO AB) for Europe.

Electromagnetic Compatibility

The system has been independently tested and found to comply with EN 60601-1-2:1993.

CAUTION: MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANING DOCUMENTS.

CAUTION: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the HRV, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

No.	Test/Standard	Port (enclosure, AC, DC, I/O)	Emissions Class and Group / Immunity Test Level
1	§36.201 CISPR 11:1997, Radiated and Conducted Emissions	Enclosure	Class A
	§36.202 Immunity test results:		
2	IEC 801-2 Electrostatic Discharge Immunity	Enclosure	±2kV, ±3kV, ±6kV contact, ±2kV, ±4kV, ±6kV, ±8kV air, ±8kV indirect via HCP and VCP
3	IEC 801-3 Radiated RF Immunity	Enclosure	3V/m, 26-1000MHz, 80% 1kHz AM
4	IEC 801-4 Burst Immunity	AC	±1kV, 5/50 Tr/Th µS, 5kHz to AC/DC power lines. ±0.5kV, 5/50 Tr/Th µS, 5kHz to interconnecting cables.
5	IEC 801-5 Surge Immunity	AC	±1kV, 1,2/50 Tr/Th µS to AC ports differential mode. ±2kV, 1,2/50 Tr/Th µS to AC ports common mode.

Parts of the device

The Case IV and its supporting parts are regarded as Class I.

Part Number	Description	Intended Use
5004B	Vibration Stimulator. Cable length 4.9 meters.	Provides a vibration stimulation to the patient.
5006	Thermal Stimulator. Cable length 4 meters.	Provides a warming or cooling stimulation to the patient.
5040C	Patient Cue. Cable length 2.4 meters.	Prompts the patient when to provide a response.
5041B	Patient Response. Cable length 1.5 meters.	Signals the software to record the patient's response.

5019	Liquid Crystal Paper	Used to check for correct heating of the Thermal stimulator.
5005	Headphones. Cable length 3 meters.	Masks outside noise during Vibration stimulation.
5050	Water Reservoir Cable length 1.2 meters.	Keeps the Thermal stimulator at a steady internal temperature.
5552	USB cable. Cable length 1.8 meters.	Data connection, Case IV to computer.
5027	Instructions for Use	Safety and Operating instructions.
0309	Power cord. Cable length 2.4 meters.	IEC320 Hospital grade.
5491	Set of three Straps	Used with the Thermal Stimulator.
5484	Medical Grade Putty	Used with the Vibration Stimulator.
5483	Test Platform	Used with the Vibration Stimulator.
P/N: 5448 (120V) or P/N: 0327 (240V)	Power Conditioner	Low-Impedance Isolation Transformer, 120V or 240V.

Description of the CASE IV System Hardware

Overview

The CASE IV System is made up of a personal computer, also called the Host Computer (with video screen and keyboard), which is used to enter biographical data and for display of operator instructions, menus, operating conditions, or problems; a Printer (for printout of test results); and a Main Unit or Microprocessor Control Unit (containing power supplies and electronic circuits). In addition, most CASE IV Systems have a Vibration Stimulator; a Thermal Stimulator; a Circulating Pump and Thermal Reservoir; a Patient Cueing Device, and a Patient Response Device. Customized systems may or may not have all of these components.

Host Computer, Main Unit, and Printer

The Host Computer runs the system software, which controls the user interface (what you see on the screen), evaluation algorithms, data logging, statistical analysis, and printing. At the end of each test, patient data and results are printed, and then they are stored on the hard disk of the computer. The Main Unit is separate from the Host Computer. The Main Unit contains the control computer, additional circulating pump, and interlock circuitry. The following list describes most CASE IV Systems (customized systems may differ slightly):

- The Host Computer may be any notebook, laptop, or desktop computer capable of operating Windows 10 and the system's controlling software. Please refer to the software user guide for full system specifications.
- The printer may be any type of printer that is fully supported by the Windows operating system installed on the computer.
- The CASE IV Main Unit contains all of the circuitry for generation of stimuli, patient cueing, and patient response recording. The Host Computer communicates with the Main Unit via USB connection with USB-A on the host and USB-B on the main unit. An independent thermal interlock system, located in the Main Unit, is used to prevent excessive thermal stimulation from occurring.

Main Unit Front Panel

- **Enable Thermal Stimulator:** This button is pressed to enable the Thermal Interlock System, allowing thermal stimulation. The CASE IV software will prompt the operator when to press this button. "Thermal Interlock" is an independent safety system that prevents harmful thermal stimuli—stimuli that is too hot or too cold—from being administered. The interlock system is manually engaged when the operator presses the Enable Thermal Stimulator button.
- **Power:** This green light indicates the Main Unit has power and is turned on.

Vibration Stimulator

The Vibration Stimulator provides the vibrating stimulus to the subject. The Vibration Stimulator uses a very precise electronic actuator known as a galvanometer. Vibration is at 125 cycles per second that is variable between 0 and 350 micrometers. The cantilevered design provides a 30-gram preloading force.

The area to be tested is placed under the stimulating stylus and the height of the stimulator is adjustable to compensate for different finger dimensions. Then, the Vibration Stimulator body is leveled by turning the

height adjustment knob. The finger or toe being tested should rest on a lump of a puttylike substance (such as artist's putty) to ensure that the finger (or toe) does not twist or rotate.

Thermal Stimulator, Circulating Pump and Thermal Reservoir

The Thermal Stimulator consists of a series of solid-state thermoelectric units that are used to draw heat away from the surface of the skin or to administer heat to the surface of the skin.

Three systems ensure that the Thermal Stimulator operates accurately and safely: Control circuitry utilizes a feedback network and constantly monitors the temperature of the surface of the Thermal Stimulator, the Circulating Pump and Thermal Reservoir (not shown) continuously pumps a cooling medium (distilled water or nontoxic antifreeze) through the Thermal Stimulator, and the hardware Thermal Interlock System monitors the Thermal Stimulator's surface temperature, shutting it off if temperatures exceed specified values.

The ceramic plate of the Thermal Stimulator is held in place on the hand, foot, or other anatomical part being tested by a Velcro strap, which wraps around the patient's hand (or foot). Then, during operation, the Thermal Stimulator produces a specified temperature on a 9.0-square-centimeter stimulating surface. The stimulating surface temperature typically can be varied from 8.0 to 50.0 degrees C. with accuracy of 1.25 to 0.25 degrees C., depending on temperature (traceable to National Institute of Standards and Technology, NIST, standards)

Place the water reservoir on a low, flat secure surface. Do not place over any other electrical equipment.

Patient Cue and Response Devices

Using the numbers "1" and "2" or red and green lights, the Patient Cue Device displays the time period in which a stimulus is given. Then, via the Patient Response Device, patients respond by indicating the period in which the stimulus was detected (or whether the stimulus was detected).

The Patient Response Device has two momentary contact buttons, typically labeled "l" and "2" or "Yes" and "No." The patient indicates his or her responses, and the operator depresses then releases the appropriate button. For example, if the patient detects a stimulus in period 1, he or she would say "', and the operator would depress and release the "1" button.

General Preparation of the Patient and Testing Environment

Note About Clinical Trials

Patient preparation for a specific clinical trial may differ from these instructions slightly. Consult your study's sponsor for more information.

Testing Environment

1. Ideally, the test should be performed in an isolated room from which distracting sounds and interruptions can be excluded. It should have enough light and air circulation, be at a comfortable

temperature, and should be free from drafts. It is extremely important that the patient stays focused on the test.
2. Headphones, which are provided with the CASE IV System, are worn by the patient during vibration testing. The headphones provide white noise to mask any distracting external noises.
3. A standard chair, without wheels, is best for testing.
4. For both the thermal and vibration tests, make sure the surface upon which the patient will be resting his or her limb is at a comfortable temperature.

Preparation

1. The subject or patient should agree to being tested. He/she should have had a good night's sleep before the test. Sedatives, tranquilizers, opiates, or stimulants should not have been taken in the preceding 12 hours. If the subject has come in from the cold, the temperature of the site to be tested should not be less than 30 degrees C. The patient should not have consumed excessive amounts of hot drinks or soups just before or during tests to avoid excessive sweating.

2. The patient should not be able to see the operator's computer screen. Before each test, the operator should read a predetermined instructional script (developed by the testing site or study sponsor) to the patient and the operator should verify that the patient understands how to respond to test stimuli.

3. The site to be tested should be at, or greater than, 30 degrees C. but not higher than 35 degrees C. If it is lower than 30 degrees C., the part should be warmed by a water bath or by surrounding it with a thermal electric blanket. If the site to be tested (hand, foot, or other part) has an excessive amount of hair, the hair may have to be removed to avoid interfering with the application of stimuli or injury to the skin.

4. For vibratory testing of the foot:
    - The toe being tested should rest on a lump of putty (such as medical putty or modeling clay) to ensure that it does not twist or rotate.
    - Place the Vibration Stimulator on the midline of the great toe between the base of the nail and the first knuckle. The stylus must make full contact with the skin.
    - The stimulator should be positioned so that the body of the stimulator is horizontal. Level the stimulator from front to back by adjusting the knob. Check the level bubble on the stimulator. Leveling from side to side is not possible.
    - During the test, the toe must remain motionless. It is very important that the toe does not move at all.
5. For vibratory testing of the hand:
    - The finger being tested should rest on a lump of putty (such as medical putty or modeling clay) to ensure that it does not twist or rotate.
    - Place the stimulator on the base of the nail of the index finger. The stylus must make full contact with the skin.
    - The stimulator should be positioned so that the body of the stimulator is horizontal. Level the stimulator from front to back by adjusting the knob. Check the level bubble on the stimulator. Leveling from side to side is not possible.
    - During the test, the finger must remain motionless. It is very important that the finger not move at all.

6. For thermal testing of the foot:

- Remove excess moisture by dabbing the skin with a dry towel.
- Do not use any kind of lotions or creams.
- Cover the foot with a sock into which a hole has been cut.
- Cover the rest of the patient's body, except for neck, face, and hands, so that cool or warm drafts will not be interpreted spuriously as thermal stimuli. Also cover the foot not being tested with a sock.
- Place the Thermal Stimulator on the dorsal surface of the foot. The surface must be flat against the skin. Pull the Velcro strap snug.
- View the stimulator from both sides to make sure it is contacting the skin at all four corners.
- Make sure the stimulator isn't loose, and that it is comfortable for the patient. Use a rolled towel or small bag of sand under the cord to help support the stimulator.

7. For thermal testing of the hand:
    - As with the foot, remove excess moisture by dabbing the skin with a dry towel.
    - Do not use any kind of lotions or creams.
    - Place the stimulator on the dorsal surface of the hand. The surface must be flat against the skin. The thumb goes on the inside of the strap. Pull the Velcro strap snug.
    - View the stimulator from both sides to make sure it is contacting the skin at all four corners.
    - Make sure the stimulator isn't loose, and that it is comfortable for the patient. Use a rolled towel or small bag of sand under the cord to help support the stimulator.

Sample Sequence of Patient Instruction

Each CASE IV System site, or each clinical trial, is responsible for developing its own set of patient instructions. The following are examples and guidelines only and are not to be considered standard patient instructions for each testing situation. Patient instruction cards are available from WR Medical Electronics Co., but again, each study is responsible for writing its own protocol.

- Enter the patient's data into the computer before explaining the test or setting up.
- If you are testing a foot, warm the foot to 30 degrees C., and cover the foot with a sock.
- If vibration sensory thresholds are being tested on the foot, a piece of modeling clay placed under the toe will help to stabilize the toe.
- Explain the equipment to the patient such as the headphones, Patient Response keys, Patient Cues (lights), Thermal Stimulator, and Vibration Stimulator.
- Read instructions aloud (developed by the testing site or study sponsor) to the patient slowly and clearly using eye contact, placing the visual cards close enough for patient to read along with you.
- To reinforce to the patient how the CASE IV System works, demonstrate the system before starting the test. Do not give samples of the Heat-Pain test.
- Before starting the actual test, ask the patient if he or she has questions. Also ask, "Are you comfortable doing the test?"
- Before starting the vibration test and after the patient has been instructed (and the technician is ready to start), hand the patient the headphones to cover his or her ears. This blocks out any sound that the stimulator could make when buzzing at high magnitudes against the skin. The patient should feel the stimulus, not hear the stimulus.

Possible Patient Problems

- The patient may be elderly, tired, hard of hearing, blind, or apprehensive of the test. Observation and some conversation with patient will help define problems.
- The patient must be alert and able to comprehend directions.
- The person administering the Heat-Pain Non-Repeating Algorithm with Null Stimuli (HP-NRA-NS) test should remind the patient to watch screen for the number "1" light so they know when a stimulus is given. Otherwise, the patient tends to look at the visual scale card and won't know when the stimulus is on. The patient should wait until light is out before giving an answer.
- The person administering the test needs to monitor the patient closely during the test. Other noise or distraction while they are testing could disturb the patient's concentration and alter test results. Close observation will alert you to problems the patients may be having and help you decide if the patients are understanding the test and doing it right.
- Always check the Thermal Stimulator's ceramic place from each side (of hand or foot) to see that it is making a good contact with skin.

Sites to be Tested on the Patient

For evaluation of neuropathy and central nervous system tracts, favorable sites are the following. A variety of other sites may be chosen, depending on the purpose of the study.

Vibration Testing:

1. **Foot:** midline of the great toe between the base of the nail and the first knuckle;
2. **Hand:** base of the nail of the index finger.

Thermal Testing:

3. **Foot:** dorsal surface;
4. **Hand:** dorsal surface;
5. **Lateral shoulder:** apex of the deltoid muscle, lateral aspect of the shoulder;
6. **Volar forearm:** midpoint of the distance between the medial epicondyle to the end of the radius;
7. **Anterior thigh:** midpoint of a line from the inguinal crease to the midpoint of the patella;
8. **Lateral leg:** midpoint of a line from the tip of the head of the fibula to the tip of the lateral malleolus.

Inspection Instructions

Full Visual Inspection (conduct weekly)

1. Visually inspect Main Unit:
    - Verify that no physical damage exists.
    - Verify that the cables and power cords are correctly installed and secured.

2. Visually inspect Host Computer:

- Verify that no physical damage exists.
- Verify that the cables and power cords are correctly installed and secured.

3. Visually inspect Circulating Pump and Thermal Reservoir:
    - Verify that no physical damage exists.
    - Verify that no leaks exist.
    - Verify that the hoses and power cords are correctly installed and secured.
    - Verify that the liquid level in the Thermal Reservoir is within normal range (liquid level should be between level marks). Add distilled water and bactericide if required.
    - Verify the proper flow of water by lifting the end of the water return hose (located inside tank) above water line and observing water flow.

4. Visually inspect Thermal Stimulator:
    - Verify that no physical damage exists.
    - Inspect the cable and hose assembly. Check for loose wires, frayed ends, etc.
    - Inspect the Thermal Stimulator's surface (ceramic plate). Check for cracks, chips, or any other surface irregularities. A Hot Spot Test should be performed before every test. (P.15)

5. Visually inspect Vibration Stimulator:
    - Verify that no physical damage exists.
    - Inspect the cable assembly. Check for loose wires, frayed ends, etc.
    - Verify that the Vibration Stimulator body rotates freely at pivot point.
    - Verify that the stimulation arm is securely fastened to the output shaft.
    - Inspect the vibration stimulation surface. Check for security and any surface irregularities.

6. Visually inspect Patient Response Device:
    - Verify that no physical damage exists.
    - Inspect the cable assembly. Check for loose wires, frayed ends, etc.
    - Verify that the patient response buttons are smoothly operating.

7. Visually inspect Patient Cueing Device:
    - Verify that no physical damage exists.
    - Inspect the cable assembly. Check for loose wires, frayed ends, etc.

IMPORTANT: If any damage or errors are noted, record them and contact WR Medical Electronics Co.

CASE IV™ Thermal Stimulator Temperature Check

Introduction

- P/N 5019 is a liquid crystal paper used to check the surface of the CASE IV™ Thermal Stimulator for hot spots.
- A user performing Heat-as-Pain test should complete this inspection process prior to each test. Since TEU failures are not predictable by any party, the only way to be certain a hot spot does not exist is to check the TEU prior to each Heat-as-Pain test conducted.
- Testing patients for thermal thresholds can introduce some risk of burns if the testing is done at the higher temperature levels and if there is a malfunction of the ceramic stimulator surface, whether it is visible or invisible.
- While the number of reported burns is extremely low (considering the number of Heat-as-Pain tests conducted by CASE IV™ users and the actual number of burns reported), the possibility still exists of a user unknowingly affixing a damaged thermal stimulator to a patient where a hot spot is present. Such hot spots can produce a burn during the application of hot stimuli.
- It is impossible to predict with any certainty if, when, or how a given thermo-electric unit (TEU) will fail. The manner in which the stimulator is handled, and the frequency of its use may have an effect on the failure rate, but the actual relationship between these variables is not known. It is evident, however that the hot spot failures are relatively rare.
- This bulletin provides guidance for reducing the possibility of a burn.

To do so, follow this inspection process:

1. Securely place the thermal stimulator on a flat surface with the ceramic side up.
2. Place the liquid crystal sheet, shiny side up, on the thermal stimulator so that it is in complete contact with the ceramic surface.
3. Run a Hot Spot Test using TestWorks3 following the prompts.
4. Observe the liquid crystal sheet. A blue/green coloration should become consistent across the entire ceramic surface. Any inconsistency in color may indicate damage to the ceramic surface.
5. If a hot spot is evident, do not use the stimulator on the patient. Contact WR Medical Electronics Co. at 1-800-635-1312 for further guidance.

Responsibility of the Supplier

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

- Assembly operation, extensions, readjustments, modifications, and 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.

Cleaning Instructions

Before cleaning, ALWAYS ensure that the unit is powered off and that the power cord is disconnected. NEVER immerse the unit or any components. NEVER apply cleaning solutions or moisture the unit directly, instead apply to the cloth and use it to then clean the requisite components. ALWAYS ensure that the unit is clean and dried completely before reconnecting power and resuming testing.

Main Unit, Stimulators, Patient Cue and Patient Response

- May be cleaned with a dry, lint-free clean cloth.
- May be cleaned with a damp, lint-free cloth, enzymatic cleaner, quaternary ammonium compound, or bleach wipes.
- May be cleaned with Isopropyl alcohol (70%) as an alternative, but may over time strip ink from printed labels and printed materials on the surface of the unit

Maintenance

Calibration

WR Medical Electronics Co. recommends annual calibration of the main unit and stimulators. Calibration is performed at the manufacturer facility by authorized electronics technicians.

Thermal Stimulator

Store the thermal stimulator in the protective cover when not in use. If damage is suspected please contact WR Medical Electronics Co. for advice.

Vibration Stimulator

Store the vibration stimulator in its protected area on top of the Main Unit when not in use. If damage is suspected, contact WR Medical Electronics Co. for advice.

Water Reservoir

Maintain the water level at the optimal level, between the lines indicated on the side of the unit, at all times.

Service and Technical Support

Caution: The CASE IV Main Unit and peripheral items are to be serviced or modified only by WR Medical Electronics CO. If servicing is done by any party other than WR Medical Electronics CO., the product warranty and/or safety or quality certifications could become invalid. Contact WR Medical Electronics CO. for advice before returning for repair.

Please contact the Technical Support/Help Desk for a Return Authorization Number before initiating a return.

Technical Support/Help Desk
WR Medical Electronics Co., 1700 Gervais Avenue, Maplewood, MN 55109 USA
Phone: 651-604-8483 or toll-free: 800-635-1312)
Fax: 651-604-8499
E-mail: helpdesk@wrmed.com
Web: www.wrmed.com

Please have your serial number available.

The Help Desk staff is available during normal business hours (8:00 am to 4:30 pm, Monday - Friday, Central Standard Time).

Warranty

WR Medical standard 1-year warranty from date of purchase for main device. Cords and Cables are 90-days. If additional warranty is needed, please contact the sales department for additional information.

Disposal

WEEE Directive 2012/19/EU - Do not dispose of WEEE products in general waste. At the end of life of the product, contact WR Medical Electronics Co.'s Customer Service for return instruction.

Disposal of devices or consumables must be done in accordance with local, state, and federal laws and regulations.

Suggested Readings

- Dyck, P. J. (2005). *Peripheral Neuropathy*. Elsevier Inc., Chapter 42.
- Dyck, Peter J., and P. Thomas K. "Chapter 42 - Quantitative Sensation Testing" Peripheral Neuropathy. 4th ed. Vol. 1. Philadelphia: Elsevier Saunders, 2005.
- Dyck, P. J., P. O'brien C., J. Kosanke L., D. Gillen A., and J. Karnes L. "A 4, 2, and 1 Stepping Algorithm for Quick and Accurate Estimation of Cutaneous Sensation Threshold." Neurology 43.8 (1993): 1508.
- Dyck, P. J., I. Zimmerman, D. Gillen A., D. Johnson, J. Karnes L., and P. O'brien C. "Cool, Warm, and Heat-pain Detection Thresholds: Testing Methods and Inferences about Anatomic Distribution of Receptors." Neurology 43.8 (1993).

- Dyck, Peter J., and P. Thomas K. "Chapter 42 - Quantitative Sensation Testing" Peripheral Neuropathy. 4th ed. Vol. 1. Philadelphia: Elsevier Saunders, 2005.
- Dyck, P. J., P. O'brien C., J. Kosanke L., D. Gillen A., and J. Karnes L. "A 4, 2, and 1 Stepping Algorithm for Quick and Accurate Estimation of Cutaneous Sensation Threshold." Neurology 43.8 (1993): 1508.

- Dyck, Peter J., Irvin Zimmerman R., David Johnson M., Delores Gillen, Jenny Hokanson L., Jeannine Karnes L., Gregory Gruener, and Peter O'brien C. "A Standard Test of Heat-pain Responses Using CASE IV." Journal of the Neurological Sciences 136.1-2 (1996): 54-63.

- Dyck, P. J., I. Zimmerman, D. Gillen A., D. Johnson, J. Karnes L., and P. O'brien C. "Cool, Warm, and Heat-pain Detection Thresholds: Testing Methods and Inferences about Anatomic Distribution of Receptors." Neurology 43.8 (1993).

Technical Specifications

SALES SPECIFICATION SHEET- **CASE®**

WR Medical Electronics Co.
1700 Gervais Avenue
Maplewood, MN 55109
www.wrmed.com | 651-604-8400

PHYSICAL DIMENSIONS	
Height:	10 in. (25.4 cm.)
Width:	11 in. (27.9 cm.)
Depth:	18 in. (45.7 cm.)
Weight:	27.0 lbs. (12.3 kg.)

POWER REQUIREMENTS	
Power:	100 - 240 VAC, 50/60 Hz
Max Power Draw:	250VA
Protection:	2 x F1.25A (5x20mm IEC127)

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	THERMAL STIMULATOR	VIBRATION STIMULATOR
Stimulation Levels:	25	25
Stimulation Range:	9° C - 49° C	0-350 micrometers of displacement (under load) at 125 Hz
Stimulaton Surface Area:	9 sq. cm.	N/A
Weight of Stylus:	N/A	30 grams preloaded

SOFTWARE REQUIREMENTS	
Application Software:	WR TestWorks®

REGULATORY	
FDA MDL Number:	D009010
FDA 510K:	K910624
FDA Device Class:	I
Health Canada License Number :	9616
Device Directive 93/42/EEC for Medical Devices	
Certificate No.:	41314493-02
EC Class:	I, Measuring

ETL CLASSIFIED
C ETL LISTED US
Intertek
CE 0413