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**CONFIDENCE**  
**EXPERIENCE**

# CASE IV™ SYSTEM

COMPUTER AIDED SENSORY EVALUATOR, VERSION FOUR, TYPE II

## For Quantitative Sensory Testing Measurement of Peripheral Sensory Thresholds: Vibration and Thermal (Cooling, Heat-Pain) *Sensitive, Specific, Reproducible, and Time-Efficient*

The CASE IV™ System is an automated device for characterizing peripheral sensory thresholds that have been altered by disease of sensory receptors, nerve fibers, central nervous system tracts, or cerebral association areas. Using a fully automated routine, the system administers noninvasive, precise, repeatable stimuli. It then records the patient's responses and quantifies the patient's sensory threshold using predetermined algorithms. The system is highly accurate, finely calibrated, and constructed so that test results generated by one system are comparable to all other units (all other testing factors being equal).

A physician need not be present during the testing process, as long as a competent technician is present to prepare and instruct the patient and then monitor the course of the test. The system allows a patient to be tested over a period of time, following the course of sensory abnormality or improvement.

Ultimately, inferences can be made about the course of a disease process or any effects of controlled clinical trials. Once a set of data has been collected, a database of normative values can be constructed, or the data can be compared with normative data already available, taking modality, site, age, and other variables into account. When patients are properly instructed and prepared for testing, the results of the sensory tests are highly sensitive, specific, repeatable, time-efficient, and quantified.



### IDEAL FOR:

- Controlled clinical trials
- Pharmaceutical research
- Clinical neurology
- Diabetes care
- Epidemiological studies
- Evaluation of therapeutic regimens
- Toxicology
- Occupational medicine
- Cancer and AIDS research

### TWO MODES OF TESTING:

The CASE IV™ System can determine three types of sensory thresholds using two modes, vibration and thermal:

- Vibratory Detection Threshold
- Cooling Detection Threshold
- Heat-Pain Detection Threshold

### FEATURES:

- Designed to rigorous scientific standards
- Precise hardware verifiable by physical standards and calibrations traceable to the National Institute of Standards and Technology (NIST)
- Automatic comparison to Rochester, MN, statistically validated normative data
- Only three minutes per test. A typical patient can be processed in less than 30 minutes
- Proven, validated algorithms
- Automated data collection
- Upgraded, Windows®-based software with "wizards" that guide users through testing and analysis

PHOTOS: *Thermal Stimulator (top), Vibration Stimulator (middle), Patient Cue and Response Devices (bottom)*



#### EDUCATIONAL RESOURCES:

- **Five-Volume Video Set:** Covers setup, calibration verification, patient preparation, administration of the tests, and scientific overview
- **Extensive Instructions for Use**
- **On-Site Training:** Our experienced staff can show any technician how to use the system in under three hours
- **Help Desk:** Telephone support available during normal business hours (M-F, 8:00AM-4:30PM Central Time); e-mail: [caseivhelp@wrmed.com](mailto:caseivhelp@wrmed.com)

#### CONTACT:

WR Medical Electronics Co.  
123 North Second Street  
Stillwater, MN 55082 USA

#### HARDWARE:

The CASE IV™ System is made up of carefully calibrated, high-quality components that enable precise stimuli to be administered, and that provide a simple means of recording and analyzing the patient's responses. A typical package includes:

- **Host Computer:** includes monitor, keyboard, and printer (laptop or desktop)
- **Main Unit:** Contains all of the circuitry for generation of stimuli, patient cueing, and patient response recording
- **Vibration Stimulator:**
  - ✓ 25 discrete levels of stimulation
  - ✓ Stimuli range from 0 to 576 micrometers of displacement at 125 cycles per second
  - ✓ 30-gram preloading weight at the location of the vibrating stylus
  - ✓ Stylus size approx. 1 cm.
- **Thermal Stimulator:**
  - ✓ Solid state thermoelectric units
  - ✓ 25 discrete levels of thermal stimulus intensity
  - ✓ 8 to 50 degrees C., with accuracy of  $\pm 0.25$  degrees C.
  - ✓ Surface area: 9 square cm.
- **Patient Cue Device**
- **Patient Response Device**
- **Calibration Verification Devices**
- **Patient Testing Supplies**
- **Equipment Cart**

#### POWER REQUIREMENTS:

- 100-240-volt, approx. 2 amps.

#### QUALITY AND SAFETY MARKS:

- ISO 9001:2000, ISO 13485:1996, and MDD compliant
- CE and CETL listed
- Contact WR for latest regulatory certifications

#### SOFTWARE:

The CASE IV™ System uses Windows-based software, WR TestWorks™ Neurological Testing Management Software. With WR TestWorks,™ you are able to record, display, save, and analyze patient test data and print reports in an HTML format.

The software can be tailored to support the specific needs of clinical trials (such as to enforce certain protocol procedures or to do certain post-test quality checks on the data prior to submission to the data collection organization). Please contact WR for information and price quotations on customized CASE IV™ software.

#### INDICATIONS AND CONTRAINDICATIONS:

##### INDICATIONS:

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, but does not make a diagnosis. The test results should be used with the results of other medically accepted tests in order to assist the physician in making a diagnosis.

##### CONTRAINDICATIONS:

Computer aided sensory evaluation is a psychophysical test requiring that the patient be rested, attentive, and cooperative. Do not test the patient if he/she does not meet these requirements.

Children under the age of eight years are not sufficiently attentive for the duration of the tests to obtain reliable results.

Patients with mental retardation or dementia cannot reliably be tested. Patients receiving sedatives or tranquilizers should be withdrawn from their medications for a sufficiently long time so that the test can be done.

This test cannot be given when the patient is inattentive, uncooperative, demented, sedated, or too ill to cooperate.

Drugs not to be used on the patient: mood- or mind-altering drugs of any kind, including opiates, tranquilizers, and analgesics.

This test cannot be given to patients with exfoliating skin conditions, dermatitis, bruises, weeping skin, skin lesions, infected skin, or necrotic skin.

Patients should be pretested for gross insensitivity or supersensitivity to thermal and vibration stimuli using medically accepted methods of testing.

If you have any questions about the testing techniques and procedures that are required for using this device, please contact the sponsor of your study.

**WR MEDICAL ELECTRONICS CO.**