

## Medical Policy



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### **Title: Automated Point-of-Care Devices for Nerve Conduction Testing**

*See also: EMG, NCS, and Other Electrodiagnostic (EDX) Related Services policy*

#### **Professional**

Original Effective Date: October 13, 2008

Revision Date(s): April 21, 2009;

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#### **Institutional**

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#### **DESCRIPTION**

Nerve conduction studies (NCS) and needle electromyography (EMG), when properly performed by a trained practitioner, are considered the gold standard of electrodiagnostic testing. However, the need for specialized equipment and personnel may limit the availability of electrodiagnostic testing for some patients. Portable devices have been developed to provide nerve conduction evaluation at the point-of-care (in the provider's office) versus the standard laboratory study. These portable devices have computational algorithms that are able to drive stimulus delivery, measure and analyze the response, and provide a detailed report of study results. Automated nerve conduction could be used in various settings, including primary care, without the need for specialized training or equipment.

One proposed use of automated nerve conduction devices is to assist in the diagnosis of carpal tunnel syndrome (CTS). CTS is a pressure-induced entrapment neuropathy of the median nerve as it passes through the carpal tunnel, resulting in sensorimotor disturbances. This syndrome is defined by its characteristic clinical symptoms, which may include pain, subjective feelings of swelling, and nocturnal paresthesia. A variety of simple diagnostic tools are available, and a positive response to conservative management (steroid injection, splints, and modification of activity) can confirm the clinical diagnosis. (1) Electrodiagnostic studies may also be used to confirm the presence or absence of a median neuropathy at the wrist, assess the severity of the neuropathy, and assess alternate associated diagnoses. Nerve conduction is typically assessed prior to surgical release of the carpal tunnel, but the use of electromyography in the diagnosis of CTS is controversial.

Point-of-care nerve conduction testing has also been proposed for the diagnosis of peripheral neuropathy and, in particular, for detecting neuropathy in patients with

diabetes. Peripheral neuropathy is relatively common in patients with diabetes mellitus, and the diagnosis is often made clinically through the physical examination. Diabetic peripheral neuropathy can lead to important morbidity including pain, foot deformity, and foot ulceration. Clinical practice guidelines recommend using simple sensory tools such as the 10-g Semmes-Weinstein monofilament or the 128-Hz vibration tuning fork for diagnosis (2). These simple tests predict the presence of neuropathy defined by electrophysiological criteria with a high level of accuracy. Electrophysiological testing may be used in research studies and may be required in cases with an atypical presentation.

NC-stat® by NeuroMetrix is a portable nerve conduction test device designed to be used at the point-of-care. The system comprises a biosensor array, an electronic monitor, and a remote report generation system. The biosensor is a single use, pre configured array consisting of a stimulation anode and cathode, skin surface digital thermometer, and response sensor. Biosensor arrays are available for assessment of sensory and motor nerves of the wrist (median and ulnar), and for the foot (peroneal, posterior tibial, and sural). A chip embedded in the biosensor panel measures skin surface temperature, the analysis algorithm adjusts for differences in temperature from 30° C, or if skin surface temperature is less than 23° C the monitor will indicate that limb warming is necessary. Data are sent to a remote computer via a modem in the docking station, and the remote computer generates a report based on the average of 6 responses that is sent back by fax or e-mail. In addition to the automated stimulus delivery and reporting, NC-stat analysis adjusts the calculation for body temperature, height, and weight, and uses the average of 6 responses. Sensitivity of the device for sensory nerve amplitude potentials is 2.1 µV, values lower than this are analyzed as zero, and responses with artifact are automatically eliminated from the analysis.

NeuroMetrix received specific clearance to market NC-stat® via the U.S. Food and Drug Administration's (FDA) 510(k) process in 1998, listing as predicate devices the TECA model-10 electromyograph and the Neurometer by Neurotron, which measures vibration threshold. The FDA-listed intended use was "to measure neuromuscular signals that are useful in diagnosing and evaluating systemic and entrapment neuropathies." In addition, the approved application stated that "The NC-stat is intended to be used as an adjunct to and not a replacement for conventional electrodiagnostic measurements." NeuroMetrix subsequently received FDA clearance to market newer models with biosensors and engineering changes that enable the NC-stat to be used for motor and sensory nerves of the wrist (median and ulnar) and foot (peroneal, tibial, and sural). The intended use as listed on the 510(k) approval from 2006 (#K060584) is "to stimulate and measure neuromuscular signals that are useful in diagnosing and evaluating systemic and entrapment neuropathies."

Examples of Automated Point-of-Care devices not eligible for coverage as discussed in this policy:

- NC-stat System (NeuroMetrix)
- Neural-Scan (Nervepathology)
- Neural Scan Axon II
- Brevio (NeuMed)
- Neurometer (Neurotron)

Automated Point-of-Care devices not listed, but equivalent to the devices listed are also not eligible for coverage as discussed in this policy.

### **POLICY**

Automated nerve conduction tests are considered **experimental / investigational**.

### **RATIONALE**

Assessment of a diagnostic technology typically focuses on 3 parameters: 1) its technical performance; 2) diagnostic performance (sensitivity, specificity, and positive and negative predictive value) in appropriate populations of patients; and 3) demonstration that the diagnostic information can be used to improve patient outcomes.

This evaluation will assess the technical performance of NC-stat, the only automated nerve conduction test device that is currently marketed, and its reported performance in diagnosing patients (validity) with suspected deficits of neuronal transmission (e.g., diabetic neuropathy and carpal tunnel syndrome). Also, available evidence related to improvement of clinical outcomes with use of point-of-care automated nerve testing will be reviewed.

### **Technical Performance**

Technical performance of a device is typically assessed with 2 types of studies, those that compare test measurements with a gold standard and those that compare results taken with the same device on different occasions (test-retest). As discussed in the Background section, the gold standard for nerve conduction tests is the electrophysiologic nerve conduction study (NCS) combined with needle electromyography (EMG). Several studies have assessed the reliability and validity of NC-stat when used by personnel trained in electrophysiology. These studies, the majority of which are company sponsored, are described here.

### ***Comparison with the gold standard***

One recent study compared results for sensory nerve testing from NC-stat and the reference standard in median and ulnar nerves in 60 patients referred to an EMG laboratory for neck and shoulder pain who volunteered also to undergo testing with NC-stat. (3) The reported correlations (Pearson correlation) between the NC-stat and the reference standard were high (0.91 for median nerve distal sensory latency (DSL), 0.70

for ulnar DSL, and 0.88 for the median ulnar difference of the distal sensory latency). However, this final correlation was calculated only with the responses obtained for 81 of 120 possible nerve pairs. The authors of this study report systematic differences between the two techniques and indicate that use of the NC-stat would require applicable reference ranges.

A study of motor nerve function compared NC-stat with standard nerve conduction tests of the wrist in a small study of 17 subjects with diabetes mellitus who had clinical evidence of peripheral neuropathy in either the upper or lower extremity. (4) Again, Pearson correlation coefficients were relatively high and ranged from 0.70 for ulnar distal motor latency (DML) to 0.96 for median nerve DML.

Another NeuroMetrix-sponsored trial compared NC-stat and standard EMG results for peroneal and posterior tibial nerve conduction in 60 patients referred to an EMG laboratory. (5) The report indicates that all patients referred to the laboratory were offered the opportunity to participate, but does not provide the total number of referrals. F-wave latency (FLAT) was found to have the highest correlation (0.91, 0.90 Spearman correlation coefficient for peroneal and posterior tibial nerves, respectively), with moderate correlations for amplitude (0.86, 0.73) and distal motor latency (0.70, 0.45). The authors concluded that there was excellent criterion validity for the peroneal and posterior tibial FLAT and the peroneal amplitude; acceptable criterion validity for the peroneal DML and posterior tibial amplitude; but the validity of the posterior tibial DML could not be demonstrated. Although NC-stat results were significantly correlated with standard EMG tests in the study population as a whole, in a subgroup analysis of the most abnormal half of responses, the correlation coefficient for amplitude of the peroneal response was 0.62, and the correlation coefficient for distal motor latency was reduced to 0.32 for the posterior tibial nerve and 0.10 for the peroneal nerve. Thus, in this pathological subgroup analysis, criterion validity was lost for the peroneal distal motor latency and decreased from "excellent" to "acceptable" for the other parameters. The authors note that "this study did not address interpretations performed by physicians using NC-stat data, nor the validity of the reference ranges used or the way these were collected."

A Pearson correlation coefficient of 0.944 was reported for DML for 46 patients with CTS who had a nerve conduction study at a different time (average of 28 days difference). (6) Another study compared results from NC-stat and standard nerve conduction studies in a previously diagnosed patient population. (7) This study compared distal motor latency of the median nerve in 72 patients (of 400 treated) with established CTS before and after surgical intervention, finding a correlation coefficient of 0.88 for the median nerve DML. However, a scatter plot indicates a poor correlation for longer latencies.

### ***Test-retest***

NeuroMetrix reported intra-operator reliability in 15 healthy subjects who underwent measurements 7 days apart. (8) The report states that "each upper and lower extremity

nerve was tested twice by the same technician,” and that 9 subjects participated in both upper and lower extremity studies. It is not clear from the report whether the upper and lower extremities were designed as separate studies, or if 12 of 42 (29%) measurements did not provide usable data. Of the data reported, the coefficient of variation ranged from 0.013 for F-wave latency to 0.298 for the compound muscle action potential amplitude of the peroneal nerve.

### **Diagnostic Performance**

Diagnostic performance is evaluated by the ability of a test to accurately diagnose a clinical condition in comparison with a gold standard. The sensitivity of a test is the ability to detect a disease when the condition is present (true positive), while specificity indicates the ability to detect patients who are suspected of disease but who do not have the condition (true negative).

Evaluation of diagnostic performance, therefore, requires independent assessment by the 2 methods in a population of patients who are suspected of disease but who do not all have the disease. An additional issue with NC-stat is that this device is designed to be used by minimally trained personnel (about 1 day for device specific training), while the comparison standard is performed by specialists with extensive training in EMG and electrophysiology. Studies that do not meet these criteria (broad patient population and comparison of point-of-care use with the standard laboratory EMG) may be considered relevant to the technical performance of the device, but are inadequate for evaluation of its diagnostic performance.

In an early report of the NC-stat technology using DML to diagnose CTS, Leffler and colleagues reported that in 248 symptomatic hands (apparently a combination of an initial and validation group), compared with conventional diagnosis, testing using this device had a sensitivity of 86% and specificity of 90%. (9) In the report by Rotman (6), the NC-stat DML was shown to have a sensitivity of 89% “at the predetermined specificity of 95%” for the diagnosis of CTS for “70 hands” that met the standardized CTS case definition.

However, in a point-of-care study evaluating industrial workers for possible CTS using distal motor latency, many individuals who were identified with prolonged DML by NC-stat fell within the normal range (using 95% cutoff point) as defined by this study population. (10) This study also comments on the importance of sensory nerve findings in the diagnosis of CTS, suggesting a need to better define “normal” values.

Another study assessed the validity of NC-stat to diagnose diabetic peripheral neuropathy through sural nerve testing in patients from diabetes and diabetic neuropathy outpatient practices. (11) Seventy-two consecutive patients (64 with type 2 diabetes) who completed a clinical evaluation, a conventional nerve conduction study, and a point-of-care NC-stat assessment were enrolled. The point-of-care assessment was independently conducted by non-technologist research staff following a single 1-hour lesson in the NC-

stat protocol. The amplitude potential of the sural nerve was tested as an early indicator of diabetic neuropathy. Using a threshold of 6  $\mu\text{V}$ , the authors report that the sensitivity and specificity of NC-stat for diagnosis of diabetic sensorimotor polyneuropathy, as defined by clinical and conventional electrophysiological evaluation, was 92% and 82%, respectively. The Spearman correlation coefficient (compared with the reference standard) was 0.95. As noted by the authors, further study is needed in a broad spectrum of patients, including those who present with atypical neuropathy in a clinical setting. The authors also note that further investigation is needed into specific approaches that include the point-of-care nerve conduction study as a component of the clinical care of those with polyneuropathy.

### **Clinical Outcomes**

The NeuroMetrix data registry was analyzed for all NC-stat studies performed over a period of 10 days that were coded for CTS and performed by a primary care provider. (12) The initial data set consisted of studies on 1,190 patients performed by 613 different physician practices; studies that met CTS testing guidelines (82% met strict guidelines and 93% met less restrictive guidelines) were further analyzed. Thus, in nearly 1 of 5 patients (18.4%), the studies did not meet strict CTS testing guidelines. From the limited set, 31% were identified as normal, 53% exhibited CTS, 5% demonstrated an ulnar neuropathy, and 11% showed a nonspecific neuropathy. No comparison was made with standard nerve conduction testing nor was an assessment made of the impact of this testing on relevant clinical outcomes.

Early identification of asymptomatic diabetic neuropathy could potentially be important to institute appropriate clinical management before the onset of ulcerations. (11) However, no studies were identified that assessed the influence of point-of-care nerve conduction tests on health outcomes in this population.

Practice Parameters (2002) from the American Association of Electrodiagnostic Medicine, American Academy of Neurology, and American Academy of Physical Medicine and Rehabilitation recommended measuring sensory and motor nerve function in patients with suspected CTS. (13) In 2006, the American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) issued a position statement that illustrates how standardized nerve conduction studies performed independent of needle EMG studies may miss data essential for an accurate diagnosis, and how nerve disorders are far more likely to be misdiagnosed or missed completely if a practitioner without the proper skill and training is interpreting the data, making a diagnosis, and establishing a treatment plan. (14) The organization states that, "the standard of care in clinical practice dictates that using a predetermined or standardized battery of NCSs for all patients is inappropriate," and concludes that, "It is the position of the AANEM that, except in unique situations, NCSs and needle EMG should be performed together in a study design determined by a trained neuromuscular physician."

## Summary

While studies have shown the correlation of portable automated nerve conduction test results with standard testing, the diagnostic performance and clinical utility (i.e., impact on outcomes) of point-of-care automated testing has not been determined. Thus, use of this device is considered investigational.

## 2008 Update

A search of the MEDLINE database was performed for the period of January 2007 through February 2008. One study used NC-Stat to assess the effect of a pharmaceutical agent on nerve conduction in patients with diabetic peripheral neuropathic pain. (15) No studies were identified that addressed the utility of automated nerve conduction tests in a clinical setting. Particularly needed are data on the sensitivity and specificity of automated nerve conduction tests performed at the point-of-care in comparison with the "gold standard" of laboratory EMG. Overall, evidence remains insufficient to evaluate the effect of point-of-care automated nerve conduction tests on health outcomes. Therefore, point-of-care automated nerve conduction tests are considered investigational.

## **CODING**

**The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.**

### CPT/HCPCS\*

S3905 Non-invasive electrodiagnostic testing with automated computerized hand-held device to stimulate and measure neuromuscular signals in diagnosing and evaluating systemic and entrapment neuropathies

\*CPT codes not appropriate for use for automated nerve conduction testing, but frequently used are 95900, 95903, and 95904.

## **REVISIONS**

10-13-2008	The Automated Point-of-Care Devices for Nerve Conduction Testing medical policy is a new free-standing policy developed from one indication discussed in the Electrodiagnostic (EDX) Medicine and Related Services medical policy – effective date December 1, 2006 (revised and retitled Electromyography, Nerve Conduction Studies and Other Electrodiagnostic Related Services – effective November 12, 2008).
04-21-2009	Listed examples of Automated Point-of-Care devices.
08-11-2009	In Description section: <ul style="list-style-type: none"> <li>• Removed ADVANCE NCS/EMG System (NeuroMetrix) as this device is not an automated point-of-care device.</li> </ul>

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