NC-stat® System, NeuroMetrix® Inc.
(Nerve Conduction Testing System)

Technology Assessment
Last revised: June 8, 2006

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INTRODUCTION

NC-stat by NeuroMetrix® is an automated nerve conduction testing system marketed as an alternative to conventional nerve conduction testing. It is a diagnostic and screening tool designed to perform nerve conduction studies (NCSs).

NCSs assess the integrity and may aid in diagnosing diseases of the peripheral nervous system by measuring the speed, size and shape of conduction through a nerve in response to a stimulus (AANEM). NCSs are commonly performed in to aid in diagnosis of many common conditions where nerves may be impinged, diseased or otherwise compromised. NCSs are commonly used to help confirm the presence of carpal tunnel syndrome (CTS).

The NC-stat system is marketed to "perform non-invasive nerve conduction testing" [http://www.NeuroMetrix®.com/products.htm, May 31, 2005] and consists of 4 components: 1) patented single use sensors, 2) a monitor that connects to the sensors and collects and stores information, 3) a docking station for the monitor and 4) the OnCall® information system to which test data are transmitted for analysis.

Manufacturer information explains that results can be analyzed and available within minutes and are transmitted to the physician's office via email, fax or an internet download [http://www.NeuroMetrix®.com/oncall.htm, May 31, 2005]. Personal health information is protected through use of a numeric coding of patient information. Interpretation of test data is performed by a computerized system available online "24/7". Marketing information also explains that as the system is hand-held and offers rapid turn-around of test results, it may be a useful addition for general practitioners at the "point-of-service". Benefits of this system may include ease of use and rapid results allowing for confirmation of diagnosis and subsequent treatment decisions.

The hand-held system was originally indicated to evaluate distal motor latency (DML) and F-wave latency in a primary care setting (FDA 510(k), K982359). The original version was designed to assess motor responses in the median and ulnar nerves. As of 2004 design revisions and FDA 510(k) notification allow the device to be marketed for use in assessing nerves of the upper and lower extremities including sensory responses in the median and ulnar nerves.

Food and Drug Administration Status of NC-stat (NeuroMetrix®)

The FDA determined the original NC-stat to be substantially equivalent to devices marketed prior to May 28, 1976. NeuroMetrix® was permitted to market the device as described in the 510(k) premarket notification provided by the company. Table 1 documents FDA 510(k) information available on NC-stat at the time of this report.

Table 1: FDA 510(k) information on NC-stat.

Date of 510(k) notification	Predicate Device	Biosensors for:	Intended Use from 510(k) Summary
October 1998 original	Neurotron Neurometer and TECA TD-10/TD-20 EMG	Median nerve DML and F-Wave	"intended to measure neuromuscular signals that are useful in diagnosing and evaluating systemic and entrapment neuropathies. The NC-stat is intended to be used as an adjunct to and not a replacement for conventional diagnostic measurements."
June 2000 modified	SE to NC-stat of prior approval	Addition of ulnar DML and F-Wave capability.	"intended to measure neuromuscular signals that are useful in diagnosing and evaluating systemic and entrapment neuropathies. The NC-stat is intended to be used as an adjunct to and not a replacement for conventional diagnostic measurements."
January 2001 modified	SE to original NC-stat and TECA TD-10/TD-20 EMG	Addition of median and ulnar evoked sensory nerve action potential providing DSL (distal sensory latency).	"intended to measure neuromuscular signals that are useful in diagnosing and evaluating systemic and entrapment neuropathies. The NC-stat is intended to be used as an adjunct to and not a replacement for conventional diagnostic measurements."
January 2002 modified	SE to original NC-stat and TECA TD-10/TD-20 EMG	Addition of tibial and peroneal biosensors for lower limb neuropathies.	"intended to measure neuromuscular signals that are useful in diagnosing and evaluating systemic and entrapment neuropathies."
August 2004 modified	SE to prior NC-stat devices and TECA TD-10/TD-20 EMG	Addition of sural nerve biosensor.	"intended to measure neuromuscular signals that are useful in diagnosing and evaluating systemic and entrapment neuropathies."

Objective of this Review

To evaluate the available peer-reviewed literature on the NC-stat nerve conduction testing system following inquires from community physicians and staff within the Department of Labor and Industries. The objective of this review is to assess the evidence of the diagnostic accuracy of the device for the intended use.

Search Strategy

Using the terms "NC-stat", "NCStat", "NeuroMetrix® ", PubMed was searched for English language, human studies. The NeuroMetrix® website was used as a source of information and to identify appropriate research articles. The search resulted in six peer-reviewed articles for this assessment in May 2005. This search was updated in March 2006 and 2 additional publications were found (Elkowitz and Kong).

Literature Review

Leffler et al., 2000. In this study two groups of 75 patients referred to a hospital electromyography lab for upper extremity or neck symptoms were studied with NC-stat administered by a technician and by conventional neurodiagnostic evaluation supervised and interpreted by neurologists. The objectives were to 1) compare results of NC-stat (DML and F-Wave of **median nerve** measures by a technologist) with conventional neurodiagnostic studies in symptomatic patients referred to an electromyography lab in a general hospital, 2) determine the value of clinical parameters and nerve conduction time provided by NC-stat in diagnosing median neuropathy at the wrist, and 3) evaluate patient acceptance of the NC-stat .

Subjects were enrolled consecutively from the standpoint of the technician. The initial group went through the study to include NC-stat testing by a technologist followed by clinical and conventional electrodiagnostics performed by a neurologist. The technician was blinded to NC-stat output when performing the studies. The neurologist was blinded to the NC-stat results when performing the clinical exam and electrodiagnostics. Conventional electrodiagnostics included needle electromyography if indicated. All subjects were studied with NC-stat for median neuropathy. Each NC-stat test reported median distal motor latency (DML) and median F-wave latency.

Following the initial study group modifications were made to processing algorithms in the NC-stat device and a validation group (n=75) was then consecutively enrolled and studied in the same manner as the initial group. Additionally, 95 asymptomatic subjects without diabetes or history of CTS, age 18-75, were tested to determine appropriate physiologic corrections with the final NC-stat device. Subjects in the initial and validation groups completed questionnaires on demographic and medical risk factors and a hand symptom diagram. Each patient received a formal neurodiagnostic evaluation including Phalen's and Tinel's tests.

Analysis included Pearson correlation of NC-stat measures with conventional NCS results as well as the percent of subjects NC-stat was capable of assessing compared to conventional means. Multivariate modeling was performed to evaluate the utility of supplementing clinical information with NC-stat measures.

Inclusion and exclusion criteria of 2 study groups:

Inclusion	Exclusion
• Age 18 to 75 • Symptoms for at least 1 month prior to examination and on most days in week prior	• Median nerve injection in previous 30 days

Results:

- Of 150 symptomatic subjects studied the neurologist diagnosed 69 (46%) with isolated MNW, 56 (37%) with normal median nerve function and 25 (17%) either coexisting ulnar neuropathy, cervical radiculopathy, polyneuropathy or contralateral median neuropathy.
- NC-stat detected DML in 97% of hands in the validation group and 92% in the initial group. Correlation between NC-stat with the conventional DML was 0.94 ($P<0.001$) in the validation group and 0.90 ($p<0.001$) in the initial group.
- NC-stat detected F-wave latency in 65% of subjects detected by conventional means in the initial group; 92% in the validation group, with correlations to conventional F-wave measures of 0.84 (retrospective analysis) and 0.86 respectively ($P<0.001$ in each).
- The neurologist diagnosed 117 (47%) of 248 symptomatic hands with MNW. At 90% specificity, the NC-stat had a sensitivity rate of 86% for MNW among those diagnosed with MNW by the neurologist.

- All 150 patients reported that they would be willing to undergo NC-stat again.

Conclusions:

The authors concluded that MNW diagnosis is significantly improved with an Automated Electrophysiologic Neurodiagnostic Device (AEND).

Rotman et al., 2004. NC-stat was used to identify predictors and outcome of recovery in subjects with carpal tunnel syndrome (CTS) treated by endoscopic carpal tunnel release surgery.

Subjects without prior hand surgery referred to one hand surgeon were recruited. There were 2 overlapping study groups; one consisted of subjects with pre-surgery NC-stat and conventional NCS studies available to establish diagnostic validity by assessing **median nerve DML** for comparison to traditional EMG tests. NC-stat validity was shown by comparing distal motor latencies (DMLs) obtained prior to surgery with reference DMLs obtained by referral to an electromyography lab (conventional NCS). The second group included subjects with NC-stat DML values available prior to surgery and from at least one test post surgery.

Results

- Forty-eight subjects were enrolled and 46 subjects (88 hands) had referral lab NCS results by conventional electromyography. Median number of days between referral lab results and NC-stat studies was 28.3 and 98% (45/46) subjects had conventional (referral lab) testing before NC-stat studies.
- Pearson correlation coefficient between the two DML measures was 0.94 ($P<0.0001$).
- NC-stat sensitivity was 89% (62 hands of 70 meeting standardized CTS definition) at predetermined specificity of 0.95.

Conclusions

Authors conclude that the diagnostic validity of NC-stat median nerve DML is verified by the high correlation between automatic and traditional results. The sensitivity and specificity of the nerve conduction monitoring system in detecting and aiding in the diagnosis of CTS is useful in the management of patients with CTS.

Wells et al., 2002. Case-control study in which NC-stat was used to assess DML and F-wave latencies in **tibial and peroneal nerves** bilaterally in subjects with MRI confirmed L5-S1 nerve root compression (n=35) and a control group (n=35) of asymptomatic individuals with no history of radiculopathy. The objective was to evaluate the diagnostic efficacy of a composite nerve conduction measurement for detection of lumbosacral nerve root compression.

Posterior tibial and deep peroneal nerves were studied bilaterally in all subjects using NC-stat device, consisting of DMLs and F-wave latencies that assess nerve root pathophysiology.

A statistical model was used to define a composite nerve conduction measurement from NC-stat acquired F-wave and DMLs using status in control or compression group (confirmed by MRI) and clinical factors, as the dependent variable.

Results

- NC-stat results were acquired in 100% of control limbs (35 subjects) and 76% of compression group limbs (25 subjects of 33 tested, 2 apparent dropouts). Reasons for incomplete results in compression group included unrecordable responses (4), technical difficulties (2), inability to tolerate stimuli (2). Dropouts not explained.
- Five F-wave latency parameters were predictive of nerve root compression.

- The composite constructed of the 5 predictive parameters yielded a receiver operating characteristic curve of 0.91.
- In retrospective analysis of subjects the composite of parameters assessed with NC-stat resulted in a diagnostic specificity and sensitivity of 84% and 83% respectively.

Conclusions

The authors concluded that a novel composite measurement based on F-wave latency parameters may be effective at detecting lumbosacral nerve root compression confirmed by MRI. These measurements may be of diagnostic value to clinicians as they are non-invasive and provide objective evidence of nerve root compromise. These measures may be valuable in evaluating patients with low back and leg pain.

Vinik et al., 2004. Case-series, seventeen diabetic subjects studied with NC-stat and conventional NCS performed by a neurologist to evaluate the robustness and diagnostic validity of NC-stat for upper extremity nerve abnormalities in subjects with diabetes. **Median and ulnar DML and F-waves** obtained by both methods. Acquisition of NC-stat and conventional NCS measurements was alternated sequentially.

Data were analyzed per hand. Validity of NC-stat was assessed by 1) Pearson correlation between DML as measured by NC-stat and reference method and 2)NC-stat results were compared to a historical control population and defined as having diabetic peripheral neuropathy (DPN) if at least 2 NCS parameters were equal to or greater than the 99th percentile in the control population.

Results

Table 1:DML and F-wave results acquired in study subjects. NC-stat did not return ulnar nerve DML and F-waves results in one subject, and ulnar F-wave in a second subject.

Parameter Median nerve N=17	NeuroMax EMG Mean ms (SD)	NC-stat Mean ms (SD)	Paired t-test	Pearson Correlation
DML N=17	4.6 (1.12)	3.97 (0.76)	<0.001	0.96 (p<0.001)
F-wave N=17	31.1 (2.90)	31.0 (2.8)	NS	0.89 (p<0.001)
Ulnar nerve				
DML N=16	3.10 (0.35)	2.87 (0.38)	<0.05	0.70 (p<0.001)
F-wave N=15	31.1 (2.7)	31.0 (3.0)	NS	0.78 (p<0.001)

Table 2: Comparison of NC-stat results in subjects with diabetes compared to controls.

Parameter	Diabetes	Control		
Median nerve N=17	Mean ms (SD)	Mean ms (SD) abnormality threshold	Paired t-test	Abnormality rate
DML N=17	3.9 (0.76)	3.38 (0.34) 4.17	<0.05	17.7%
F-wave N=17	30.3 (2.8)	27.6 (1.7) 31.6	<0.005	23.5%
Ulnar nerve				
DML N=16	2.82 (0.36)	2.57 (0.24) 3.13	<0.05	25.0%
F-wave N=15	30.0 (3.2)	28.1 (1.7) 32.1	<0.05	26.7%

Reported abnormality rate using normative data by – median DML 17.7%, F-wave 23.5% - ulnar DML 25.0%, F-wave 26.7%. Twenty-five percent of subjects met the case definition for DPN; 50% for median neuropathy of the wrist, defined by median DML greater than 1ms compared to ulnar DML.

Conclusions

NC-stat results are similar to those obtained with traditional NCS. The widespread availability of the NC-stat system may provide a robust and objective method for identifying DPN and other neuropathies in patients with diabetes. Additional comparative studies in the lower extremities and for sensory nerve conduction measures may help clarify the utility of this device when used in managing diabetic patients.

Guyette et al. 2004. Fifty-two subjects with complete data from prospective database of 400 subjects between the ages of 20 and 90 who were scheduled for carpal tunnel release were studied. Exclusion criteria were previous CTS surgery, surgery not performed by a Curtis National Hand Center surgeon, current pregnancy or renal dialysis or history of acute peripheral neuropathy from lead exposure. Pre- and post-operative data were examined to identify pre-operative factors determining clinical, functional and symptomatic outcomes. Data were collected through clinical exams, patient questionnaires and electrophysiologic testing with NC-stat (DML and F-wave).

Data analysis included pre- and post-surgery comparison of the presence or absence or Tinel's or Phalen's signs were assessed, grip strength, DML and F-wave changes and symptom severity and functional scores. Also assessed were the time course of symptom severity and functional changes based on open or endoscopic surgery, age (below or above 60), symptom duration prior to surgery, Workers' Compensation status and symptom severity and functional status prior to surgery.

Results

NC-stat F-wave latency did not decrease significantly at 6 months, but did at 12 months. DML improved significantly at 6 months and did not change from 6 to 12 months.

Conclusions

Electrophysiologic studies had variable post-operative course. Recognition of differential electrophysiologic changes after surgery will aid in interpretation of postoperative studies.

Study limitations include sample size (13% of 400 subjects in database with complete data) and that subjects were studied at only one site and may not be representative of the population undergoing CTS surgery.

Fisher MA, 2004. Retrospective comparison of NC-stat acquired F-waves recorded from peroneal nerve to evaluate the accuracy and reliability of an automated analysis method. Eighty F-wave sets of data from 2 previously reported studies were used. Comparison of a neurologist's (study author) manual analysis of F-waves acquired by NC-stat were compared with an automatic, computerized analysis of the same data. Exclusion criteria were F-wave sets with obvious A-waves.

Results

Fifty-five subjects were included in analysis, 40 female. Mean age was 57 (25-80), 33% evaluated for sciatica, 25% for diabetic peripheral neuropathy, 24% for leg pain, 18% for a "variety of other reasons".

There was high correlation between the automatic analysis and the manual analysis (100% yield and correlation coefficient of 0.996 for median F-wave measures).

Conclusions

The high yield rate and correlation to manual analysis by an experienced clinical neurologist indicates that a clinically useful automated method should be feasible.

Elkowitz et al. 2005. The objective of this study was to determine the utility of NC-stat as a diagnostic tool and to evaluate patient satisfaction with the test equipment. Seventy-two subjects with complete data from prospective database of 400 subjects at the Curtis Hand Institute were studied. Pre- and post-operative data (NCS from NC-stat and traditional testing) were collected and compared. Reference testing was only collected pre-operatively. A distal motor latency (DML) of 4.2 ms was considered abnormal. The methods of reference tests are not described. NC-stat data from 72 subjects prior to surgery and 54 subject post surgery at 6 month follow-up were available. DML from NC-stat is the mean of 8 readings.

Results

Pre-operative DML values from reference and NC-stat testing were 5.3 ms. (SD 1.8 ms). The correlation coefficient was 0.88 ($p<0.001$) for DML by reference and NC-stat.

Fifty-four subjects with post-surgery NC-stat tests at 6 months showed drop in DML from pre-surgery 5.3 ms to 4.4 ms ($p=0.002$).

Mean time to collect NC-stat data was 20 minutes compared to mean time of traditional testing of 2 weeks between time of ordering tests and patient return to discuss findings.

Patients reported NC-stat testing was more comfortable than traditional testing.

Conclusions

A limitation of this study is the lack of a control group without which the authors were not able to indicate sensitivity or specificity of NC-stat testing. More studies are needed to address these parameters.

This portable electrodiagnostic device provides a reliable, convenient, and relatively inexpensive way to obtain objective data that can be used in diagnosing, evaluating, and treating carpal tunnel syndrome.

Kong et al. 2006. The objective of this study is to evaluate the validity and reliability of NC-stat median and ulnar sensory nerve conduction studies. Consecutive patients between 18 and 75 years, referred to one EMG lab for evaluation of upper extremity or neck symptoms were eligible. Patients were not excluded based on diagnosis; there were no exclusion criteria noted. Patients had electrodiagnostic evaluation and those meeting inclusion criteria were offered the opportunity to be in the study. Those who consented were assigned a sequential serial number.

Reference Studies

All subjects received NCS from a neurologist of technologist under the direction of neurologist. Two neurologists performed tests, both board certified and neither with financial connections to the company.

NC-stat Studies

Median and ulnar nerve studies were performed on both hands by technicians. Technicians were trained according to manufacturer's instructions and were blinded to the reference study results.

Results

Nerve conduction studies were performed on 60 subjects and results are reported per limb. Mean age of subjects was 51.1 (SD 15.9), 50% female. Seventy-four percent of subjects had 'any hand symptoms', 12% diabetes mellitus.

Reference studies were obtained in 118 median and 114 ulnar nerves. NC-stat studies were obtained in 92% of median (108) and 90% (102) of ulnar nerves where reference values were obtained. Reasons for not acquiring results with NC-stat include: operator error (1 median, 1 ulnar) or inadequate motor response (9 median, 11 ulnar). Reference testing identified 8 median and 4 ulnar as absent sensory responses while NC-stat identified 6 and 3 respectively among these. NC-stat identified 2 median and 2 ulnar sensory nerves as absent where reference results were acquired.

For 22 out of 232 nerves tested NC-stat reported non-diagnostic studies. These specific nerve studies were counted as missing data in the analysis.

Table: Results comparing NC-stat studies with reference studies.

Parameter	NC-stat	Reference	t-test	Pearson	ICC	Bias	Precision
Median (n=108)							
DSL (n=98)	**3.85 (0.74)**	**3.28 (0.75)**	**<0.001**	**0.91**	**0.91**	**0.56**	**0.31**
SNAP	**30.1 (24.4)**	**32.8 (21.7)**	**0.019**	**0.88**			
Ulnar (n=102)							
DSL (n=96)	**3.09 (0.35)**	**2.78 (0.41)**	**<0.001**	**0.70**	**0.69**	**0.31**	**0.30**
SNAP	**30.5 (22.6)**	**25.1 (16.8)**	**<0.001**	**0.83**			
MUD (n=81)	**0.81 (0.56)**	**0.47 (0.63)**	**<0.001**	**0.88**	**0.87**		

Conclusions

The authors conclude that NC-stat median and ulnar validity and reliability are similar to traditional NCS. Use of NC-stat would require an applicable reference range as there are systematic differences between NC-stat and traditional test results.

Limitations noted by authors include that for 9.5% of nerves NC-stat reported 'non-diagnostic' nerve study due to data quality or other factors. The exclusion of these nerves may bias the results in favor of NC-stat by excluding lower quality data. This study does not directly measure the equivalence of NC-stat to reference lab diagnosis as this was not the objective of this study.

Richard Katz published an analysis of 1695 nerve conduction studies (NCS) performed on a series of job applicants to a single heavy industry plant in St. Louis, Missouri. NCS and assessment of clinical features of carpal tunnel syndrome (CTS) were performed on applicants in an attempt by the company to decrease worker's compensation costs.

The objectives of this study were to provide normal data for a large set of industrial workers and to determine if these data corresponded with reference range information provided on NeuroMetrix reports.

Methods
Job applicants with the necessary qualifications for employment with the company were screened for CTS. Clinical symptoms (hand numbness, tingling, pain, nocturnal waking) and NC-stat median motor latency tests were evaluated. NC-stat results were reported via NeuroMetrix OnCall system. All studies were performed between 2003 and 2005.

Results
The mean age of the 1695 workers was 31.5 years with standard deviation of 7.9 years. Height ranged from 5'1" to 6'6" and 43 applicants were female.

Table 1: Results for DML recorded among all applicants.

	DML Mean (SD) Range	**95% upper limit**	**97% upper limit**	**99% upper limit**
All N=1695	3.81 (0.57) 2.55-11.65	4.75	5.10	5.60
Male N=1652	3.81 (0.54) 2.55-7.35	4.75	5.10	5.57
Female N=43	3.74 (1.34) 2.70-11.65	4.55	4.66	8.73

F-waves were obtained in 94% of applicants tested.

NeuroMetrix reports of "borderline" DML results did not correspond with normal data obtained in this cohort for 221 (13%) workers with results between 3.6 and 4.3 ms. One hundred ninety five (11.5%) workers with values between 3.95 and 4.6 were identified as "prolonged" by the NeuroMetrix report though these results were below the 95% upper limit of this population. Of 172 applicants identified as "very prolonged" with DML between 4.05 and 11.65, 81 (4.8%) were under the 95% upper limit of this population.

Author's Conclusions
NC-stat evaluation using DML is an ineffective method of screening or diagnosing CTS in industrial workers.

The DML recorded by NC-stat in this group of workers results in normal values essentially identical to DML measured by traditional methods in industrial workers.

NeuroMetrix, using it's own normal data, significantly overdiagnoses CTS is an asymptomatic population of industrial workers.

Professional Associations

American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM): No formal policy or assessment of NC-stat. Excerpts from the AANEM Position Statement: Proper Performance and Interpretation of Electrodiagnostic Studies. Rochester, MN: AANEM 2006 include:

- "strongly recommends that electrodiagnostic procedures be performed by physicians with comprehensive knowledge of neurological and musculoskeletal disorders to assure accurate interpretation and diagnosis. Individuals without medical education in neuromuscular disorders and without special training in electrodiagnostic procedures typically are not qualified to interpret the waveforms generated by NCSs and needle EMGs or to correlate the findings with other clinical information to reach a diagnosis."
- NCSs should be performed in a setting where needle EMG testing is available if indicated by NCSs. "Needle EMG studies are a necessary part of the evaluation in the diagnosis of myopathy, radiculopthy, plexopathy, disorders of the peripheral motor nerves. When NCS is used on its own without integrating needle EMG findings or when an individual relies solely on a review of NCS data, the results can often be misleading, and important diagnoses may be missed. Patients may thus be subjected to incorrect, unnecessary, and potentially harmful treatment interventions."

Other Insurers

Aetna's Clinical Policy Bulletin 0502, Nerve Conduction Velocity testing, describes non-coverage of F-wave measures for carpal tunnel syndrome as this is deemed not medically necessary for CTS diagnosis. Non-coverage of NCS performed using hand-held devices is included in this policy as these devices do not provide waveform analysis. No specific mention is made of NC-stat in Aetna's policy (Aetna 2005).

Cigna Healthcare Coverage Position 0117. Cigna covers nerve conduction velocity studies when performed with needle electromyogram studies to confirm diagnosis for: motor neuron disease, myopathies, radiculapothies, plexopathies, neuropathies, nerve compression syndromes, neuromuscular junction disorders, neurotrauma. Cigna does not cover nerve conduction studies not performed with needle electromyogram studies as it is considered unproven, experimental or investigational.

Oregon Workers' Compensation does cover NC-stat, separate from evaluation and management code. Oregon Workers' Comp., July 26, 2001, available at:
www.cbs.state.or.us/external/wcd/policy/issues/policyissues.html.

Health Plan of Nevada does not cover nerve conduction studies performed with, portable hand-held devices incapable of waveform analysis, studies for screening of polyneuropathy of diabetes or end-stage renal disease or nerve conduction studies for the sole purpose of monitoring disease intensity or treatment effectiveness for polyneuropathy of diabetes or end-stage renal disease. Health Plan of Nevada's policy also states "NCV studies should only be performed and interpreted by a neurologist and/or physiatrist". (Health Plan of Nevada/Sierra Health and Life Insurance Company, 10/20/2005).

Colorado Workers' Compensation Rule 17, Exihibit 2: Carpal Tunnel Syndrome (CTS) Medical Treatment Guidelines. Revised September 2005. The following excerpt from addresses the use of a portable, automated electrodiagnostice device not identified by name and no reference to described investigational study described:

> **"<u>Portable Automated Electrodiagnostic Device</u>:** Measures distal median nerve motor latency and F-wave latency at the wrist and has been tested in one research setting. It performed well in this setting following extensive calibration of the device. Motor nerve latency compared favorably with conventional electrodiagnostic testing, but F-wave latency added little to diagnostic accuracy. It remains an investigational instrument whose performance in a primary care setting is as yet not established, and is not recommended as a substitute for conventional electrodiagnostic testing in clinical decision-making. "

Billing Codes

Codes

The following codes may be applicable to testing performed with NC-stat

CPT® Codes*	Description		CPT Modifier	
		Global	-26	-TC
95900		$90.88	$32.38	$57.98
95903		$96.63	$46.48	$50.14
95904		$77.30	$26.64	$50.66

Fees effective 7/1/2005. Fee schedule is updated annually.

Summary

NC-stat is marketed and is in use in Washington state as an equivalent or alternative to traditional testing. We reviewed available peer-reviewed literature to determine if the diagnostic accuracy or performance of NC-stat is shown to be comparable to traditional tests. Potential advantages of increased access to NCS through automation may include earlier diagnosis and treatment and ease of access (less wait time for referrals, less travel etc.). Other benefits cited include the lower initial cost of the equipment (Elkowitz) though data appear to indicate automation does not reduce the amount paid for such testing, though it is reported to require less time and may require less expertise.

CONCLUSIONS

The evidence evaluating the use of NC-stat is most abundant for nerve testing that may be useful to diagnose or screen for conditions at the wrist (ie. Median and ulnar nerve studies). There is very little or no available evidence (high quality, peer-reviewed) supporting the use of NC-stat and specific biosensors for testing of nerves in the lower extremities.

At this time there is not adequate scientific evidence to conclude that NC-stat is equivalent to traditional nerve conduction study methods for use in evaluating the functioning of the median, ulnar, peroneal, sural or tibial nerves. The diagnostic accuracy of NC-stat is not yet demonstrated in the scientific literature to be equivalent to traditional or gold-standard testing methods. NC-stat is therefore considered experimental and investigational.

NC-stat is considered controversial as the performance of testing at the point-of-service may not be supported by recommendations of the American Association of Neuromuscular & Electrodiagnostic Medicine.

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