NEUROTRON, INCORPORATED
INNOVATIVE MEDICAL TECHNOLOGY
USA
www.neurotron.com

January 25, 2010

Professional Feasibility Report: Neurometer® Electrodiagnostic Evaluation in Neurology

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Introduction

This document reviews the professional feasibility of the Neurometer® neuro-selective Current Perception Threshold (CPT®) electrodiagnostic sensory nerve evaluation in Neurology. Sensory nerves are very sensitive to diseases and conditions caused by both internal and external sources such as metabolic, hereditary or acquired diseases and trauma or toxic exposure. Evaluating sensory nerve function permits the early and accurate diagnosis of a wide range of diseases and injuries which the general population is at risk. The CPT evaluation is routinely utilized in Neurology for the diagnostic evaluation of sensory impairments located in the spinal cord (myelopathy), spinal nerve (radiculopathy), peripheral nerve (including polyneuropathy - axonal and demyelinating) as well as for focal/compressive lesions (e.g. carpal tunnel or trauma). The CPT measure is also used to monitor treatment efficacy, regeneration and recovery of function. The CPT evaluation is an automated standardized procedure that may be performed at any body site (e.g. cutaneous, mucosal).

CPT studies objectively detect and quantify sensory neuropathies from their earliest subclinical stages to most advanced anesthetic stages, by independently assessing conduction of all three major sub-populations of sensory nerve fibers. The sub-populations, illustrated in Figure 1 often have differential susceptibilities to various disease conditions.

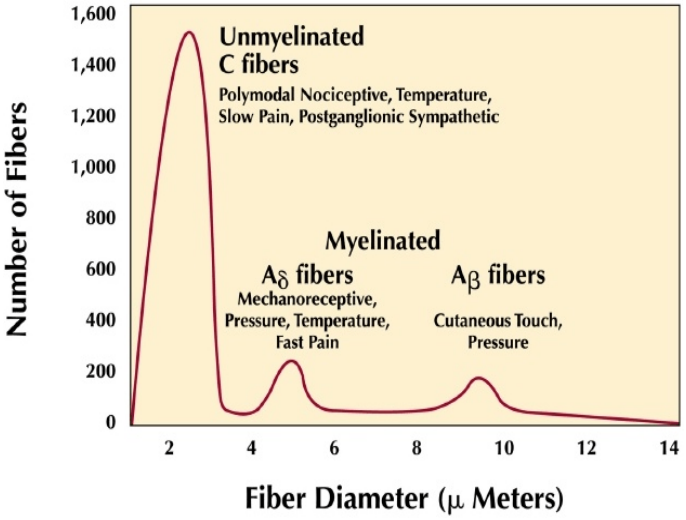

Fig. 1. Typical peripheral nerve fiber sub-population distribution. Note, only the smaller fibers are associated with both pain and non-pain sensory nerve conduction.

The unique ability of the CPT evaluation to neuroselectively evaluate sensory function in both clinical and sub-clinical conditions makes this study a more sensitive alternative to traditional electrodiagnostic and other types of sensory nerve studies for many conditions. CPT evaluations facilitate the early detection of neuropathological conditions before extensive damage has occurred which can result in a better prognosis and less expensive treatment.

Background

The CPT evaluation provides an objective measure of a stimulus detection threshold. CPT measures are obtained using a computerized automated double-blind procedure based on the standardized hearing test. The CPT test has been demonstrated to provide a reliable measure of sensory nerve functional integrity since initial studies were conducted in the 1980's at the Johns Hopkins Medical Institution, the University of Maryland and New York Medical College leading to the US FDA approval in 1986.[1] Subsequently, more than a million CPT diagnostic evaluations have been performed at more than 7000 research and medical institutions worldwide with more than 600 favorable peer reviewed scientific publications.

Purpose of the CPT Evaluation in Neurology

Neurologists obtain CPT studies to compliment their clinical evaluation and objectively document and localize the distribution of sensory dysfunction associated with conditions, such as symmetric or asymmetric inherited and acquired sensory neuropathies and assist in differentiating myelinopathies from axonopathies. CPT evaluations are used to evaluate both clinical and suspected sub-clinical sensory impairment, assess disease progression, regeneration and the efficacy of therapeutic intervention.

Role of the Neurometer® CPT Evaluation Among Sensory Diagnostic Tests

The traditional neurologic objective assessment of the sensory nervous system has relied on three types of studies: imaging such as MRI and skin punch biopsy, physiologic such as nerve conduction and evoked potential studies and functional such as quantitative vibratory and thermal test. The Neurometer CPT evaluation is both a physiologic and functional test. These other tests can involve referral to an outside specialist that can delay medical management and is time consuming for both the patient and the doctor. Most of these outside tests are unpleasant or expensive resulting in patient poor compliance for serial evaluations. Because the Neurometer CPT evaluation is painless and easily performed in a clinic by a technician and graded by computerized software it is convenient procedure for both the neurologists and their patients. Appendix A, Table 1 summarizes the utility of the CPT evaluation as compared to these other tests. The Neurometer® evaluation offers the following major advances over the older neurological electrodiagnostic tests:

1. No outside referral is necessary.
2. Neurometer CPT testing is painless so there is excellent patient compliance for follow-up evaluations.
3. The testing is standardized and automated. The evaluation is easily preformed by a technician. The reliability and reproducibility of CPT measures has been

1. Neurotron, Inc. 510Kk) application and clinical data. Re: K8536088 Neurometer, accepted June 12, 1986.

established.[2] Measures from one office, clinic or hospital may easily be compared with measures obtained from any other location.

4. Universally established normative values grade the patients measures, permitting evaluation of the severity of any detected abnormalities for the neurologist.

5. The ability to perform the CPT evaluation from practically any cutaneous test site permits objectively mapping the distribution of sensory impairments resulting from a variety of conditions.

6. The CPT test evaluates all the major subpopulations of nerve fibers. This provides the neurologist with key information related to autonomic, protective and tactile nerve function.

7. The CPT evaluation has the unique capability of measuring subclinical stages of metabolic neuropathy and obesity related neuropathy and other neurological impairments that are characterized as hyperesthetic. This permits earlier therapeutic intervention enhancing the patient's prognosis.

8. CPT measures are not effected by edema, skin temperature or impedance variations.

Neurometer CPT Testing Procedures

Neurometer® CPT studies are typically performed by applying a mild electrical stimulus through a pair of small disposable surface electrodes placed on the skin (Fig. 2 and 3). Three painless, neuro-selective electrical stimuli are applied to a peripheral nerve or dermatome innervation field in order to determine, confirm and record sensory detection threshold responses. Each stimulus evaluates the functioning of one of the three major subpopulations of sensory nerve fibers.

Fig.2 Neurometer® CPT electrodiagnostic device.


Fig. 3. CPT testing electrodes (gold). The cable electrode snap fasteners are red. A clear plastic spreader connects the electrodes.

2. Supporting publications cited in http://www.neurotron.com /documents/Neurometer_Overview_AppendixD.pdf and http://www.neurotron.com /documents/Neurometer_Overview_AppendixE.pdf .

Prescription Procedure The Neurometer® CPT evaluation is performed with a prescription by a physician. CPT studies follow a standardized, automated procedure to generate objective, sensitive and reliable measures of sensory nerve function. A detailed description is presented in Appendix B. Measures are obtained using microprocessor controlled constant alternating current (AC) sinusoid waveform stimuli presented at intensities ranging from 0.01 mAmperes to 9.99 mAmperes and at frequencies of 5 Hz, 250 Hz and 2000 Hz. The measures are in the form of Current Perception Threshold (CPT) values which represent the minimum intensity of a neuroselective, transcutaneous constant electrical current required to reproducibly evoke a sensation.

Patient Requirements: The patient must be capable of indicating when they detect the change of sensation evoked by the electrical stimulus at the site of simulation. There should be no open lesions at the skin or mucosa at the site being tested. Lesions prevent obtaining useful CPT measures. Although the test in not performed over open lesions and appropriate adjacent sites are tested instead.

Warnings/Precautions: The Neurometer CPT sensory neurodiagnostic evaluation has been safely performed in patient with implanted standard cardiac pacemakers. However, it should not be administered to patients with automatic defibrulating cardiac pacemakers or any other implanted medical device which monitors electrophysiological activity or may be effected by the Neurometer® electrical stimulus.

Performing the Neurometer CPT Evaluation

The Neurometer CPT evaluation is typically performed by a certified technician on the patient while they are seated in a quiet room. The CPT electrical stimulus is administered using a pair of 1 cm in diameter electrodes attached to a plastic spreader that keeps them separated by 1.7 cm (Fig. 3). A hypoalergenic chloride free electrolyte containing gel serves as a conducting medium between the electrode and the skin test site. The electrodes are held in place using non-conductive tape.

There are two modes for performing the CPT evaluation, the low resolution Ranged CPT (R-CPT, $p<0.05$) procedure (approximately 3 minutes per test site) and the and the high resolution Fully Automated CPT ($p<0.006$, resolution = +/- 20 µAmp.) procedure approximately 8 minutes per test site. Standard neurologic patient CPT evaluations utilize the Fully Automated CPT method. The R-CPT measure is only satisfactory for follow-up patient monitoring or screening studies. When the R-CPT measures are abnormal or fall near the border between normal and abnormal, the fully automated CPT evaluation should be performed. After the testing is completed at each test site, the data for all three stimulus frequencies tested is printed to provide a permanent record.

Indications & Clinical Applications of CPT Studies in Neurology Patient Management

CPT studies are performed to evaluate and document a variety of sensory neuropathological conditions that can result from metabolic impairments, compressive or traumatic lesions, toxic exposure, infectious/neoplastic diseases, immunological disorders, digestive impairments, hereditary impairments or environmental exposure. CPT findings assist in patient management in four primary areas:

1. Identifying abnormal sensory nerve function.
2. Localizing areas of abnormal function.
3. Quantifying the severity of an abnormality.
4. Monitoring the course of a progressive neuropathy, efficacy of a treatment or nerve regeneration.

CPT studies are indicated for patients with a suspected diagnosis of sensory nerve dysfunction in need of confirmation and evaluation.[3] The studies objectively quantify sensory function when the history (sensory symptoms) and physical examination (abnormalities detected with tuning fork, pinwheel, radiating pain reproduced with provocative orthopedic maneuvers etc.) merit further investigation. They are not indicated for routine use with every patient, however. For instance, gross, clearly delineated sensory impairments such as hemiplegia or paraplegia generally do not require electrodiagnostic evaluations.

Focal as well as diffuse sensory impairments, often require electrodiagnostic CPT evaluations to precisely localize the somatic distribution and determine the severity of the impairment. Incorporating clinical findings with the data provided by the CPT study can assist the neurologist in the diagnosis of conditions such as a spinal cord disorder, radiculopathy, polyneuropathy and compressive/focal neuropathy. CPT studies also assist in differentiating axonal from demyelinating and small fiber from large fiber neuropathies.[4]

CPT studies may be used to determine if a patient's symptoms are consistent with sensory neuropathy or with a non-neurological impairment. Non-neurological conditions, such as vascular insufficiency, soft tissue lesions, arthritis, ligament sprain or muscular strain can include symptoms of radiating pain that may mimic neuropathic conditions. Electrodiagnostic studies like the CPT are used to confirm or rule out sensory neuropathy, assist in reaching a diagnosis and help in prescribing appropriate treatment. Also, although sensory electrodiagnostic studies can not directly evaluate motor impairments, many insurance carriers support the use of sensory electrodiagnostic studies during the evaluation of ALS (motor neuron disease), myopathy (muscle disease) and neuromuscular junction disorders in order to objectively confirm the absence of sensory impairments.

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3. CPT study indications and utilization guidelines are presented in Appendices C and D.

4. http://www.neurotron.com/site/abstracts/index.php#17 provides a bibliography of selected publications for specific neuroselective pathological conditions.

Identifying Abnormal Nerve Function

Accurate identification of abnormal nerve functioning is *the* basic requirement for any neurodiagnostic procedure. Research using CPT measures to evaluate sensory nerve function have demonstrated that the sensitivity and specificity these studies range from being substantially equivalent to being markedly superior to traditional electrodiagnostic nerve tests like nerve conduction velocity studies. There are four features specific to CPT studies that make them highly sensitive and accurate neurodiagnostic tools.

Evaluate Hyperesthesia and Hypoesthesia: CPT studies detect and quantify sensory nerve impairments from the early hyperesthetic stage characterized by abnormally low sensory thresholds, through to the advanced or late stage neuropathies with hypoesthesia (elevated sensory thresholds) or anesthesia (complete loss of sensation). This unique ability of the CPT evaluation enables the early identification of many progressive neuropathies before the nerves have lost significant functioning. Traditional clinical and electrodiagnostic nerve tests are limited to identifying neuropathies only after they have progressed to the hypoesthetic stage and a significant loss of sensory function taken place. Conditions such as HIV infection, early diabetic neuropathy or radiculopathy and selective small fiber neuropathy can result in hyperesthetic abnormalities.[5]

Test Any Cutaneous Site: CPT studies may be conducted at practically any cutaneous or mucosal site, a feature which enhances the detection of both proximal and distal impairments and helps localize their distribution. Diseases effecting myelin function often initially impair nerve function proximally in the region of the dorsal root ganglia, while the most common metabolic diseases effecting nerve fiber function start at the tips of the longest nerve fibers. CPT studies may be conducted at both proximal and distal sites, e.g. the tips of the toes or proximally at a paraspinal site. Traditional electrodiagnostic studies, however, are generally limited to testing over major branches of peripheral nerves in the extremities, a location where neuropathies may not appear until many months or years after they first appear in the more distal sites.

Neuroselective Measures: CPT studies evaluate all three major sub-populations of sensory nerve fibers innervating the site of stimulation. A typical sensory nerve is comprised of large myelinated, small myelinated and unmyelinated fibers, however most progressive neuropathies don't effect all the subpopulations of sensory nerve fibers equally or at the same time. CPT studies evaluate all three major sub-populations of sensory nerve fibers, enabling them to detect a wider range of neuropathies than traditional electrodiagnostic studies that typically evaluate only the large myelinated fibers representing less than 10% of

5. This publication and others related to the ability of the CPT measures to evaluate the hyperesthetic condition are cited at http://www.neurotron.com/site/abstracts/index.php#hy.

the nerve (Fig. 1).[6]

Functional Physiological Evaluation: CPT studies evaluate the full length of sensory nerve conduction, from the site of stimulation to the brain where the signals from the nerve are translated into sensations such as heat, cold, touch and vibration.[7] Conditions exist in which a peripheral nerve function remains intact and functioning even though it is no longer conducting sensory information to the brain (e.g.., lower extremity innervation in paraplegia). Consequently, electrodiagnostic procedures that evaluate only a short segment of a nerve can fail to report any abnormality even when the nerve is no longer conducting sensory information to the brain. CPT electrodiagnostic studies, in contrast, are functional physiological evaluations that can detect an abnormality located anywhere along the length of the nerve transmission to the brain.

Localizing Areas of Abnormal Nerve Function

Areas of abnormal sensory nerve function or conduction can be localized by performing CPT studies at multiple cutaneous or mucosal sites. Localizing these impairments is often an essential element for an accurate diagnosis.[8] Multiple studies can also monitor the progress of a disease or the efficacy of a therapy or procedure.

The CPT evaluation of specific pathological conditions reveals the following distributions of sensory impairment:

Spinal Sensory Impairment: Presents with a segmental distribution of impairment. For example, the CPT evaluation of syringomyelia reveals a preferential loss of small fiber function isolated to a segmental distribution involving several adjacent dermatomes.[9]

Radiculopathy: Presents as a sensory impairment confined to a dermatome distribution.[10] For example, a herniated intervertebral disc impinging on a spinal nerve results in CPT abnormalities confined to a dermatome distribution.[11]

Focal Peripheral Sensory Impairment: Presents with a loss of sensory nerve

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6. Supporting publications cited in http://www.neurotron.com/site/abstracts/index.php and http://www.neurotron.com/documents/Neurotron_Update_20080501.pdf.

7. Brain mapping fMRI and related neurology publications are cited at: http://www.neurotron.com/site/abstracts/index.php#13gen.

8. Adams, R.D., Asbury A.K. Diseases of the Peripheral Nervous System. Harrison's Principals of Internal Medicine, 10th Edition, New York, McGraw-Hill Book Co., Chapter 368, pp. 2156-2169, 1983.

9. Cui, L., Zhu, P., Fu, H., Starr, A. Current Perception Threshold (CPT) in Syringomyelia. Journal of Chinese Neurology, Vol. 36(6):447-44, 2003.

10. Dermatomal distribution is based on the following:1) Keegan, JJ, Garrett, FD The segmental distribution of the cutaneous nerves in the limbs of man. Anat. Rec. 1948;102:409-437; 2)Kegan, JJ Neurosurgical interpretation of dermatome hypalgesia with herniation of the lumbar intervertebral disc. J. of Bone and Joint Surgery, 1944;26:238-248.; 3) Last, R.J. Innervation of the limbs. J. of Bone and Joint Surgery 1949;31(B)452-464.; 4) Cocchiarella, L., Andersson, G.B. Guides to the evaluation of Permanent Impairment, 5th Ed., page 377 and 381, American Medical Association Press, Chicago, IL USA, 2001.

11. Supporting bibliography at: http://www.neurotron.com/site/abstracts/index.php#21rad.

function distal to the site of the lesion. These impairments include vasculitis related mono-neuropathies which can effect sensory function at any cutaneous site, as well as compressive neuropathies such as Carpal Tunnel Syndrome (CTS).[12]

Polyneuropathy - Distal: Distal axonal neuropathy, the most common type of metabolic/toxic peripheral neuropathy, presents first at the tip of the great toe. CPT studies are capable of testing at that site, a feature which allows evaluation of this type of polyneuropathy months or years earlier than other electrodiagnostic studies.[13]

Diffuse Polyneuropathy: Diffuse polyneuropathy generally presents with sensory impairments involving both a proximal and a distal distribution, for example involving toes and legs, fingers and arms and effecting multiple nerves and dermatomes. Inflammatory polyneuropathies are primarily confined to impairments of myelinated fiber function and often result in diffuse polyneuropathies (e.g.. Chronic Inflammatory Demyelinating Polyneuropathy, Guillian-Barré Syndrome).[14]

Nerve Regeneration: CPT studies document a recovery of sensory function in the innervation field of a regenerating nerve. The CPT evaluation is unique among electrodiagnostic tests in its ability to neuroselectively quantify regeneration to provide critical information to the physician or surgeon.[15]

Quantifying the Severity of Sensory Impairment

Quantifying the relative severity of a sensory impairment is a key component in evaluating a disease or condition for selecting the most appropriate intervention. Unlike other electrodiagnostic tests that only report findings as being "normal" or "abnormal",[16] CPT reports grade the severity of the abnormality ranging from hyperesthesia through hypoesthesia (Appendix C). Examples of the clinical application of CPT diagnostic information would include in assisting to determine whether or not to recommend an increase in the duration of hemodialysis therapy for a patient with an equivocal presentation of mild to moderate uremic neuropathy. It may also be used to determine if a low back or neck injury with radiating pain includes spinal nerve impairment, or the advisability of a surgical referral for the treatment of Carpal Tunnel Syndrome versus more conservative treatment. Post intervention, CPT studies help

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12. Supporting bibliography at: http://www.neurotron.com/site/abstracts/index.php#22.

13. Supporting bibliography at: http://www.neurotron.com/site/abstracts/index.php#08

14. Berger JS, Brannagan TH, Latov N: Neuropathy with anti-myelin-associated glycoprotein antibodies: Quantitative sensory testing and response to intravenous immunoglobulin. Muscle & Nerve. Volume 20:1056-1057, 1997. Menkes, D.L., Swenson, M.L., Sander, H.W. Current Perception Threshold: An Adjunctive Test for Detection of Acquired Demyelinating Polyneuropathies. Electromyography and Clinical Neurophysiology, Vol. 40; Part 4:195-204, 2000.

15. Supporting bibliography at: http://www.neurotron.com/site/abstracts/index.php#20reg.

16. Dyck, P.J. et al. Use of percentiles and normal deviates to express nerve conduction and other test abnormalities. Muscle & Nerve, Volume 24:307-310, 2001.

determine if a surgical repair of a nerve injury is healing appropriately. A delay of return of sensation can indicate a neuroma formation which, if untreated, could impair or block recovery.

Neurodiagnostic Guidelines and Criteria for Performing CPT Evaluations

The neurologic community agrees that when characterizing any systemic impairment of peripheral sensory nerves (polyneuropathy) the condition is first classified by its distribution (distal vs diffuse). This classification requires accurate and reliable determinations of sensory nerve function from various body sites. The neuropathy is then noted for the type of nerve fiber involved (small fiber vs large diameter fiber) and then taking this information combined with other clinical and diagnostic findings the neuropathy is generally attributed to a specific disease condition such as diabetic, kidney, liver or HIV disease. Up-to-date bibliographies are available of Neurometer® CPT® publications on metabolic and toxic polyneuropathies.[17]

Appendix D. Provides the patient selection criteria for the CPT evaluation of specific neuropathological conditions including: Radiating Back/Neck Pain, Sensory Polyneuropathy, Nerve Compression Syndromes, Plexopathy, Intervention of Nerve Recovery and Direct Sensory Nerve Trauma

CPT evaluation procedure body test site selection flow chart guidelines for the differential diagnosis of radiating pain in the upper extremity, lower extremity, carpal tunnel syndrome, and polyneuropathy are presented on the in Appendix E. Depending upon the neurologist's diagnosis the patient may referred to the appropriate specialist (eg., orthopedic, vascular, rehabilitation, endocrine, pain, etc.). Examples of typical standardized test sites include:

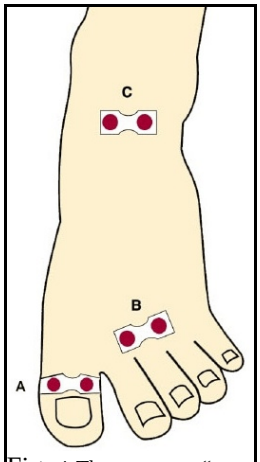

Fig. 4 The great toe "wrap around" site A is the most sensitive for distal polyneuropathy.

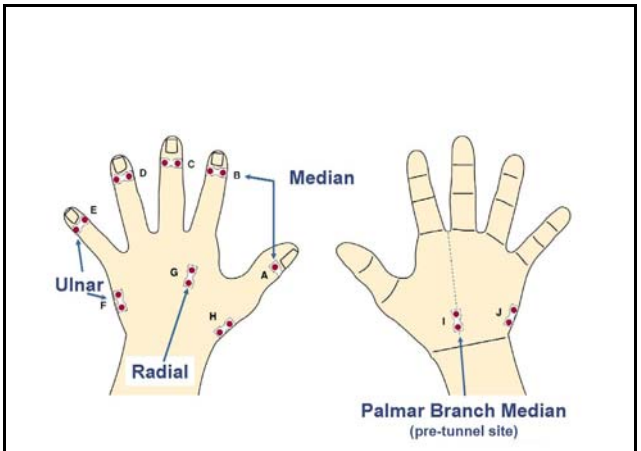

Fig. 5 Standardized hand test sites. For dermatomal testing: C6-thumb(A), C7-middle(C) and C8-little finger(E).

17. Supporting bibliography at: http://www.neurotron.com/site/abstracts/index.php#08 and http://www.neurotron.com/site/abstracts/index.php#23.

Other Neuropathological Conditions to Consider with the CPT Evaluation

Focal Compressive Neuropathies in Patients with Metabolic Disorders: Patients with diabetic/metabolic polyneuropathy are at increased risk for developing focal compressive neuropathies such as carpal and tarsal tunnel syndrome as well as radiculopathy. These focal neuropathies may cause pain that could mimic the pain associated with subtypes of diabetic /metabolic polyneuropathy. The pain from the these focal nerve lesions will primarily involve a selected nerve or dermatome and the loss of sensory nerve function they cause will not effect the CPT measures for diabetic/metabolic neuropathy at the toe, ankle and ring finger test sites due to over-lapping nerves and dermatomes at these sites. For example the diabetic patient may develop low back pain that appears to be a radiculopathy when in fact it is simply a sprain/strain type condition. The medical management is different between these two conditions.

Fig. 6 Patient self-administering Neurometer CPT evaluation .

Frequency of Routine CPT Evaluations and Number of Body Sites Tested

Follow-up evaluations are generally only required when: 1) there is a clinical question as to whether the patients sensory pathology is deteriorating or 2) there is a clinical question as to whether the patients sensory impairment is responding to therapeutic intervention. CPT studies may be prescribed for neuroselective assessment and monitoring of CNS sensory function following CNS vascular events and other types of CNS pathology (e.g. multiple sclerosis or spinal cord pathology that effects cutaneous or mucosal sensory function). The CPT evaluation is usually prescribed at an effected site(s) and a matched control site(s). The evaluation is not repeated unless there is a clinical suspicion of a deterioration of the patient's sensory condition requiring an objective quantitative neuroselective evaluation. CPT studies may also be used to confirm or evaluate a suspected radiculopathy or focal nerve lesion, such as a carpal tunnel syndrome and assist in determining the most appropriate therapeutic intervention. Normal CPT evaluation results indicate that no further studies are necessary unless a change in the clinical condition suggesting sensory dysfunction warrants an evaluation.

Statistical Evaluation of CPT Evaluation Data

Normative values have been established for the CPT measures obtained from the various body test sites mentioned in this report. Software is available for the clinical evaluation of Neurometer CPT measures. Measures are graded based on their number

of standard deviations the extend beyond range. Every measure is taken to ensure maximum specificity in order to avoid false positive findings. A detailed explanation of the statistical evaluation of the CPT measures is provided in Appendix C.

Neuroselective Evaluation of Pain

The Neurometer® device stimulus may be administered at intensities above the painless sensory threshold to measure the automated Pain Tolerance Threshold (PTT). This PTT measures have utility in pain medicine in assessing pathological conditions such as allodynia where patients perceive pain in response to a normally painless stimulus. Normative PTT values have been established for finger and toe test sites. The PTT measure also have utility in assessing analgesic interventions.[18]

Reimbursement for the Neurometer CPT Evaluation: Charge Code

Insurance companies reimburse for the CPT evaluation including both technical and professional components. This fee is often the same as that provided for the sensory nerve conduction velocity evaluation per nerve and approximately ten times less than the fee for a skin punch biopsy. The average reimbursement varies according to geographic location. Typically the reimbursement for a single nerve test can range from $35 to $85 and usually two to six nerves are tested during a standard evaluation.

Cost Savings and Diagnostic Advantages of CPT Studies

Early intervention in a disease often results in a better prognosis and less expensive treatment, which is how the use of CPT studies results in greater cost effectiveness for the general population and better clinical outcomes for patients. Patients additionally benefit from the painless non-invasive objective CPT evaluation of their sensory nerve function by not having to endure an unpleasant electrodiagnostic experience or the risks and scarring from a skin punch biopsy. The ability of CPT studies to accurately evaluate a wide range of neurological problems often before extensive damage occurs, permits earlier therapeutic intervention. Limitations of other sensory neurodiagnostic procedures can result in significant and costly delays in developing a timely diagnosis.

Each CPT study independently measures the functioning of all three major types of sensory nerve fibers in the same evaluation. Since diseases can effect some types of fibers while sparing the others, a broad spectrum assessment is critical for an early and accurate diagnosis. Other electrodiagnostic procedures evaluate less than 10% of the fiber types of a typical sensory nerve and their use, therefore, requires that other

18. Supporting bibliography at: http://www.neurotron.com/site/abstracts/index.php#03

additional types procedures such as a skin punch biopsy be performed in order to evaluate the same range of fibers examined in each CPT study.

CPT studies may be performed at the most distal sites on the body where many neuropathies initially appear. Other objective quantitative diagnostic studies are not able to test at these distal sites, and require waiting for a disease or condition to advance in severity until the nerve dies back to a more proximal point before the lesion can be detected by these other tests. This dying back process can take months or years to occur and can significantly delay effective treatment.

CPT studies can detect and quantify hyperesthesia the earliest stage of many neuropathies, including sub-clinical conditions that can occur before significant and irreversible damage takes place. Other electrodiagnostic studies are limited to evaluating only the more advanced hypoesthetic conditions, that may not occur until months or years later and for which treatment may be much more expensive.

CPT studies are immediately sensitive to impairments in spinal cord and spinal sensory nerve conduction that are generally not detectable by the NCV and other peripheral sensory nerve tests. The needle EMG is only sensitive to the related motor components of such impairments weeks or months after they have occurred. The early detection afforded by CPT studies can reduce expenses associated the optimal medical management of spinal cord disorders and radiculopathy by enabling earlier and more accurate treatment of the condition. As the test incorporates communication between the technician and the patient this enhanced communication has been found to provide beneficial information to nursing and physician staff in patient's overall clinical assessment.

High patient compliance with the painless and convenient CPT procedure combined with its high sensitivity, enhance it's use for the serial monitoring of diseases and therapies. A NIH Consensus Development Conference titled "Morbidity and Mortality of Dialysis" report along with a follow-up report 4 years later, demonstrated that the CPT studies provided measures that were "highly predictive" of mortality in non-diabetic hemodialysis patients. The NIH report indicated that the CPT measures were a more sensitive marker of mortality than a number routine blood chemistry measures. The study concluded that CPT studies for the evaluation of dialysis patients could assist in optimizing therapy which, "would reduce morbidity, mortality, and the cost of the ESRD in the United States."[19]

Finally, unlike other electrodiagnostic procedures, automated CPT studies do not require extensive training to perform and the measures are not distorted by inter-operator variability so they can easily be performed in the physician's office immediately after a suspected neuropathy is discovered and the data is easily shared between neurologists. This permits greater convenience for both the neurologists and their patients and lowered overall health care management costs.

19. Related publications are references at: http://www.neurotron.com/site/abstracts/index.php#13.

Together, these many different aspects and features of CPT studies combine to create an extremely efficient and sensitive diagnostic tool that enables the early and accurate and diagnosis of a wide range of neuropathological conditions. Alternative electrodiagnostic studies, limited by their narrow focus on a single small subpopulation of nerve fibers, their insensitivity to early neuropathies and inability to test at the most distal sites, can significantly delay intervention, adversely effecting the prognosis and significantly increasing the costs of treatment for many conditions.

Conclusion

An early and accurate diagnosis is the cornerstone of effective treatment, patient welfare and cost control. Without adequate diagnostic information, treatment is delayed until symptoms become more severe, the prognosis worsens and costs rise. The CPT is a neurodiagnostic tool that objectively evaluates a wider range of sensory nerve impairments from an earlier stage than other types of neurodiagnostic studies. The CPT evaluation fills an important gap in neurodiagnostic services by permitting the objective assessment of protective and other sensations, studies from any cutaneous site. Additionally the painless, automated and 'use anywhere' features of this diagnostic study contribute to its clinical utility. The clinician benefits primarily through the enhanced, safer and more convenient diagnostic evaluation of their patient's clinical condition. Health care insurance coverage for CPT studies benefits the management and care of neurology patients.

Appendix A. Comparison of CPT Evaluation With Other Sensory Neurodiagnostic Tests

The CPT evaluation is a painless noninvasive measure that neuroselectively evaluates the functional integrity of all the major subpopulations of sensory nerve fibers from any cutaneous site. The CPT quantifies both hyperesthesia and hypoesthesia with measures unaffected by skin thickness, edema, temperature or impedance variations. Normative CPT values have been established and an automated double blinded testing methodology is used to obtain measures.

Historically the standard neurological evaluation has included sensory testing with pin prick, light touch, vibration and temperature. These tests lack standardization and depend on the subject's recognition of a stimulus characteristic. Tactile sensitivity became quantified using the monofilament. Vibratory and thermal studies are now quantitative, referred to as Quantitative Sensory Tests (QSTs). QSTs have limitations based on the effects of skin thickness and bone conduction limiting the establishment of normative values. Physiologically, QSTs evaluate end-organ function in contrast with electrodiagnostic tests which directly excite the nerve fiber and bypass the end-organs. QST measures are unable to measure the hyperesthetic condition and are only sensitive to hypoesthesia.

The sensory nerve conduction velocity (sNCV) is the most widely utilized to electrodiagnostic sensory test and neurology today. In contrast with CPT evaluation it may not be conducted over any cutaneous site and is typically conducted only over an 8 to 20 cm segment of larger afferents located in the distal extremities. There are several limitations of the sNCV in contrast with the CPT.

1. There is poor patient compliance with the sNCV due to the discomfort associated with this test.

2. The distal sNCV is typically performed on the sural nerve on the back of the leg. Metabolic polyneuropathies start at the tips of the toes and take years to advance to impair nerve function on the back of the leg.

3. The sNCV only measures the function of the large myelinated nerve fibers which comprise less than 10% of the typical peripheral nerve. Diabetic neuropathy is not selective for these fibers. Small unmyelinated sensory fibers comprise over 90% of the peripheral nerve fibers. These small diameter fibers not evaluated by the nerve conduction velocity test are extremely susceptible to metabolic polyneuropathy and their integrity provides and index of critical autonomic and protective sensory function.

4. The sNCV test is only sensitive to the advanced stages of neuropathy that result in a loss of sensory function.

5. The nerve conduction velocity test measures are unobtainable from patients with edema, effected by skin temperature and relatively insensitive to diabetic neuropathy.

6. There is no standardization for performing or the interpretation of sNCV

findings. This limits a patient's sNCV measures from one hospital from being directly compared to those measures from another hospital.

The skin punch biopsy is a recognized tool primarily applied for the evaluation of small fiber neuropathy.[20] They are generally performed by neurologists after a normal sNCV (large diameter fiber test) finding is obtained is a patient suspected of having a neuropathy. This procedure is typically performed on the posterior leg.

The sweat test (quantitative sudomotor axonal reflex test) is a noninvasive test of peripheral sweat gland small unmyelinated autonomic nerve fiber innervation.

Both the EMG and the motor nerve conduction velocity (mNCV) are test of motor nerve function.

The following table provides a comparison between the diagnostic features of the various neurodiagnostic procedures.

20. Lauria, G., Devigili, G. Skin Biopsy as a Diagnostic Tool in Peripheral Neuropathy. Nature Clinical Practice Neurology, Vol 3(10):546-557, 2007.

Feature \ Procedure	Neuro meter® CPT	Neuro-Diagnostic Procedure					
		sNCV	mNCV	Biopsy	EMG	Mono-filament	Sweat Test
a) Selectively evaluate non-pain transmitting nerve fibers (10% of total fibers)	✓	✓	✓		n/a		
b) Selectively evaluate pain transmitting nerve fibers (90% of total fibers)	✓			✓	n/a		
c) Painless, does not cause patient discomfort	✓					✓	✓
d) Evaluate any body skin site for mapping/monitoring the extent and severity of the neuropathy	✓			✓	requires muscle tissue	✓	
e) Standardized method	✓						
f) Evaluate sub-clinical and clinical neuropathic hyperesthesia	✓						
g) Evaluate diabetic nerve function degeneration	✓				✓	✓	✓
h) Evaluate nerve regeneration	✓			✓		✓	
i) Unaffected by skin thickness variations/edema	✓			✓			
j) Automated Procedure	✓	✓	✓				✓
k) Invasive Procedure				✓	✓		
l) Risk of infection				✓	✓		

sNCV = sensory Nerve Conduction Velocity; mNCV= motor Nerve Conduction Velocity; EMG = needle electyomyography

Appendix B. Neurometer® Device and Detailed Summary of Services

Neurometer® Device

The electrical stimulus produced by the Neurometer® device is self-calibrating and able to maintain a constant current output regardless of normal variations in skin thickness and impedance. The system monitors the impedance at the skin electrode interface and instantly warns operators when conditions cause excessive impedance that could distort the accuracy of the measures. The system also monitors the consistency of a patient's responses to guard against false readings due to improper procedures or patient non-compliance. CPT studies follow a double blind, forced choice testing paradigm to determine Current Perception Threshold (CPT) measures (1 CPT = 0.01 mAmp.) with a resolution of +/- 20 μAmperes to a $p<0.006$.[21]

The equipment used for CPT studies is battery powered and portable and doesn't require any special electrical shielding for safe and reliable operation. Patients can be evaluated almost anywhere they can be made comfortable and in an environment free from interruptions. Studies have demonstrated the reliability of CPT evaluations conducted under a wide range of conditions, both in and out of clinical settings.

Summary of Services

Pre-Service Work: The examiner determines which nerves are to be studied based upon the physician's prescription and the available clinical information.

Intra-service Work: The physician supervises and/or performs patient preparation including electrode placement, explains the procedure and begins the automated threshold determination study. Each nerve test site is evaluated with the three CPT neuroselective electrical stimuli to assess both large and small fiber functioning. Additional testing may be prescribed during the course of the study in response to the information obtained.

Post-service Work: Examination data are entered into software that evaluates and grades the CPT measures based upon a comparison with standardized, clinically established normative values. These data are subjected to range analyses, intra-site and inter-site comparisons. The physician integrates the graded CPT findings with clinical and other laboratory findings into a report and defines or generates the diagnosis. On occasion, suggestions for additional work-up will be included.

Conducting a CPT Study

The patient is placed in a comfortable position - typically sitting - and in a location with minimal interruptions. The examiner connects the electrode cable to the CPT device, attaches a new set of 1 cm. diameter, disposable gold plated electrodes to the cable, and then powers up the equipment. The examiner then performs a Pre-Exam Cable Test by following the directions displayed on the device's LCD screen. Successful completion of this test confirms the proper functioning of the equipment, electrodes and cables prior to each examination.

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21. Katims, J.J. Electrodiagnostic Functional Sensory Evaluation of the Patient with Pain: A Review of the Neuroselective Current Perception Threshold (CPT) and Pain Tolerance Threshold (PTT). Pain Digest Volume 8(5), 219-230, 1998.

The examiner explains the general nature of the test to the patient, tells them what they can expect and answers any questions they may have. The examiner then examines the prescribed skin test sites to confirm that they are free of any signs of recent trauma which could effect the CPT measures. Finally, the examiner prepares each test site using a mildly abrasive skin prep paste that cleanses and hydrates the skin and facilitates the testing.

The electrodes are coated with a thin layer of electro-conductive gel and then taped to the test site on the patient. Next, the patient is presented with an automated or manual Intensity Alignment procedure that quickly narrows down the threshold level to a range of +/- 50 μAmperes out of a total range of 0 to 9.99 mAmperes. The Auto Test Mode then begins, which is a fully automatic, double-blind, forced choice procedure that determines the actual CPT measures. Patient are presented with randomly generated sets of a real and a placebo stimulus and must indicate which of the two - if either - felt stronger. Responses can be made verbally, by pushing a button or any other means through which the patient's intent can be communicated.

Depending upon the patient's response, the Neurometer® device automatically re-adjusts the output intensity of the stimulus and randomly generates a new testing order for the next pair of tests in the series. Because the CPT testing methodology is completely automated, neither the subject nor the operator can influence the testing sequence. The Auto Test Mode follows a testing paradigm similar to that used in standard objective auditory tests and determines the patient's CPT measures with a resolution of +/- 20 μAmperes to a $p<0.006$. When a sufficient number of correct consecutive responses have been obtained, the CPT device calculates and displays the CPT value for the test series and optionally prints out the results. The device also monitors patient responses for consistency and accuracy, and in the event that there are inconsistent responses, the operator is alerted so that the test may be repeated or discontinued. This testing sequence is repeated for each of the three stimulus frequencies at each site being studied.

The average time required to complete a three-frequency single site electrodiagnostic CPT evaluation is approximately 8 minutes. A typical evaluation could involve testing 2, 4 or 6 sites (bilateral evaluation of 1 to 3 peripheral nerves or dermatomes) and take approximately 20-60 minutes to complete including the initial equipment set-up and patient orientation. Electrodiagnostic testing is considered dynamic in that one test may indicate that an additional test or tests are indicated or not necessary.

Interpreting the Clinical Significance of CPT Findings

CPT measures are evaluated by comparing them to healthy measures that have been established for dozens of different test sites. Both the CPT values and their ratios are considered when determining the degree of sensory nerve impairment and both contribute to the overall neurological diagnosis. The data analysis may include a determination of hyperesthetic and/or hypoesthetic conditions. Appendix C reviews CPT data evaluation.

A neurologist with appropriate training interprets the results of a CPT study by using the graded data analysis in conjunction with other laboratory data and clinical impressions of the patient. The location, distribution, neurospecificity and severity of the CPT abnormalities (if present) help the neurologist develop and confirm a diagnosis.

Appendix C. Evaluation of CPT Measures

CPT measures are compared to standardized, clinically established ranges of healthy measures in order to detect neuropathies and quantify their severity.[22] CPT measures falling either above or below the established range of healthy normative measures are graded to indicate the severity of the abnormality detected.

Normative CPT Values

The automated standardization of the CPT evaluation removes tester and testing method factors from effecting CPT measures obtained from different populations at different locations and time periods. In contrast, these factors present a confounding variable for sensory nerve conduction velocity studies.[23] Numerous studies from the past 23 years have evaluated CPT measures from healthy individuals from various populations and the following table summarizes findings from a representative example of these studies. The most commonly tested sites are the fingers and the toes. Standardized ranges of healthy CPT measures have been established for dozens of body sites through clinical studies conducted at several major institutions.

Healthy Mean CPT Values (SD) , 1 CPT = 10 microAmperes							
	Face (Trigeminal Nerve)		**Finger** (Median Nerve)			**Toe** (Peroneal Nerve)	
CPT Frequency	USA[24] (n=338)	Korea[25] (n=400)	USA (n=334)	Japan[26] (n=1632)	Taiwan[27] (n=50)	USA (n=310)	Taiwan[15] (n=50)
5 Hz	10 (10)	11 (8)	46 (27)	61 (30)	50 (25)	73 (34)	74 (30)
250 Hz	19 (14)	21 (12)	81 (42)	93 (44)	78 (30)	125 (52)	126 (50)
2000 Hz	118 (52)	99 (28)	226 (80)	236 (62)	230 (70)	322 (110)	325 (106)

22. Katims, J.J., Rouvelas, P., Sadler, B.T., Weseley, S.A. Current Perception Threshold: Reproducibility and Comparison with Nerve Conduction in Evaluation of Carpal Tunnel Syndrome. Transactions of the American Society of Artificial Internal Organs, Volume 35(3):280-284, 1989.

23. Chaudry, V. et al. inter- and Intraexaminer reliability of nerve conduction measurements in patients with diabetic neuropathy. Neurology. Volume 44;1459-1462, 1994. and Chaudry, V. et al. inter- and Intraexaminer reliability of nerve conduction measurements in normal subjects. Annals of Neurology, Volume 30(6):841-831, 1991.
Antoon A. Ven, Johan G. Van Hees, Karel H. Stappaerts Effect of size and pressure of surface recording electrodes on amplitude of sensory nerve action potentials. Muscle & Nerve, Volume 30(2):234-238, 2004.

24. Neuval® Database II - Normative Data, Neurotron, Inc. Baltimore, MD, USA, 2001. References available upon request.

25. Kim, H., Kho, H., Kim, Y., Lee, with., Chung, with. Reliability and Characteristics of Current Perception Thresholds. Journal of Orofacial Pain Volume 14(4): 286-292, 2000.

26. Takekuma, K., Ando, F., Niino, N., Shimokata, H. Age and gender differences in skin sensory threshold assessed by current perception in community-dwelling Japanese, Journal of Epidemiology, Volume10(1):S33-S38, 2000.

27. Ro, L.S., Chen, S.T., Tang, L.M., Hsu, W.C., Chang, H.S., Huang, C.C. Current Perception Threshold Testing in Fabry's Disease. Muscle & Nerve, Volume 22: 1531-1537, 1999.

Grading CPT Measures

CPT values and their ratios are both considered when determining the degree of sensory nerve impairment. The analysis can include determinations of hyper-esthetic, hypoesthetic and anesthetic neuropathological conditions. The grading system used to characterize CPT measures is presented in the table below. It allows a linear characterization of a sensory dysfunction from the earliest stage all the way through to the anesthetic stage(total loss of sensory function)

CPT Grading Parameters Table

Grade Range	Clinical Characterization	Statistical Parameters
10.00 - 12.00	Anesthetic at one or more frequencies	No response to maximum stimulus
9.00 - 9.90	Severely hypoesthetic at one or more frequencies	Above healthy range & More than 4 S.D. above mean
8.00 - 8.82	Moderately hypoesthetic at one or more frequencies	Above healthy range & 3+ to 4 S.D. above mean
7.00 - 7.74	Mildly hypoesthetic at one or more frequencies	Above healthy range & 2+ to 3 S.D. above mean
6.00 - 6.62	Moderately hyperesthetic at one or more frequencies	Below healthy range & More than 2.5 S.D. below mean
5.00 - 5.52	Mildly hypoesthetic at one or more frequencies	Below healthy range & 1 to 2.5 S.D. below mean
4.00 - 4.82	Mild sensory dysfunction	Within-site ratio beyond healthy range by more than 30%
3.00 - 3.70	Very Mild sensory dysfunction	Within-site ratio beyond healthy range up to 30%
2.00 - 2.78	Extremely Mild sensory dysfunction	Between-sites ratio beyond healthy range by more than 30%
1.00 - 1.66	Slight sensory dysfunction	Between-sites ratio beyond healthy range up to 30%
0	No Abnormalities Detected	All measures within healthy parameters

Sample Clinical Reports

The software that evaluates the CPT measures can also produce a two-part Clinical Report documenting the evaluation. The first part is a clinical summary and narrative page which summarizes the findings from test sites in a tabular form and creates a narrative detailing the findings. The second part is a raw intermediate calculations sheet that details the intermediate statistical calculations upon which the clinical summary is based. This part of the report is generated for documentation purposes only and does not necessarily represent a final determination of the condition of the nerve(s) being studied. It does, however, provide a level of detail that may be useful in assisting the health care provider in reaching certain diagnoses. As with any

neurodiagnostic test, a clinician's interpretation including a clinical correlation is essential and necessary for diagnostic purposes. Three sample reports follow:

Report #1: Lumbar (L5) Radiculopathy.

The patient in this report had CPT studies conducted at 3 sites bilaterally for the evaluation of lumbar/sacral radiculopathy:

#1 Dorsal medial big toe, superficial peroneal nerve, Lumbar 4 dermatome.
#2 Dorsal distal third toe, superficial peroneal nerve, Lumbar 5 dermatome.
#3 Dorsal lateral little toe, sural nerve, Sacral 1 dermatome.

The finding of an isolated sensory impairment of the sensory function at site #2 on the right side is consistent with an L5 radiculopathy. A lesion of the fifth lumbar nerve root (L5 radiculopathy) would show an impairment confined to the Lumbar 5 dermatome. This isolated abnormality finding helps rule out the possibility that the patients sensory impairment is the result of a lesion of the superficial peroneal nerve or from a polyneuropathy.

Report #2: Diabetic Distal Axonal Polyneuropathy, with loss of protective function at the big toe test site.

The patient in this report had CPT studies conducted at the big toe wrap around site bilaterally. Polyneuropathy is evaluated at this location because it includes both the deep and superficial peroneal nerves and the Lumbar 4^{th} and 5^{th} dermatomes. A loss of sensory function is only detected at this site if multiple nerve/dermatomes are impaired. Distal axonal polyneuropathy a predominant type of diabetic polyneuropathy begins first at the tips of the longest nerve fibers located in the big toe. The CPT findings from this study are consistent with a loss of protective sensation transmitted by the smaller diameter nerve fibers. This loss of small fiber function patient would also place this patient at increased risk of autonomic dysfunction. This neuropathy would not be detectable by NCV and ER electrodiagnostic tests because they do not evaluate smaller diameter nerve fiber function.

Report #3: Carpal Tunnel Syndrome (CTS).

The patient in this report had CPT studies conducted at 3 sites bilaterally for the evaluation of CTS:

#1 Tip of index finger (digital branch of the median nerve)
#2 Tip of little finger (digital branch of the ulnar nerve)
#3 Mid proximal palm (palmar branch of the median nerve)

The finding of an isolated sensory impairment of the median nerve function at the left index finger test site is consistent with the diagnosis of CTS. The finding of normal sensory function of the palmar branch of the left median nerve helps rule out the possibility that the patients median nerve sensory impairment in the hand is the result of a lesion proximal to the carpal tunnel. The finding of normal sensory function of the ulnar nerve at the little finger tests sites and at the right index finger test site helps to rule out the possibility that the patient's sensory impairment in the left index finger was consistent with a polyneuropathy.

Clinical Summary Report #1
Lumbar (L5) Radiculopathy

SENSORY NERVE CONDUCTION THRESHOLD (CPT) TEST: DATA ANALYSIS SUMMARY SHEET

PATIENT NAME: Public, John, Q
ID: 111 111 111 DOB: 01-01-1929 SEX: M
NOTE: radiating pain and numbness L5 dermatome R
DATE: 01-04-2001 TYPE: SIDE: B VER: nvdb 2.41 (Y2K)

CPT Measures and Analysis Summary

		2K Hz	250 Hz	5 Hz	GRADE
S.PERONEAL-toe1	:L	499	161	068	0.00
	:R	398	108	077	0.00
S.PERONEAL-toe3	:L	408	142	092	0.00
	:R	666	229	044	8.37
SURAL-toe5	:L	469	150	084	0.00
	:R	411	099	123	0.00

CPT Summary Report Observations

CPT Measures were taken from 6 sites. Bilateral measurements were obtained from the superficial peroneal n. on toe 1 (dorsal medial aspect); L4. The grade of the left side measures was 0.00 which indicates no abnormal measures. The grade on the right side was 0.00 indicating no abnormal measures.

Bilateral measurements were obtained from the superficial peroneal n. on toe 3 (dorsal distal aspect); L5. The grade of the left side measures was 0.00 which indicates no abnormal measures. The grade on the right side was 8.37 indicating a moderate hypoesthetic condition.

Bilateral measurements were obtained from the sural n. on toe 5 (dorsal lateral aspect); S1. The grade of the left side measures was 0.00 which indicates no abnormal measures. The grade on the right side was 0.00 indicating no abnormal measures.

Intermediate Calculations Report #1
Lumbar (L5) Radiculopathy

SENSORY NERVE CONDUCTION THRESHOLD (CPT) TEST: INTERMEDIATE CALCULATIONS

PATIENT NAME: Public, John, Q
ID: 111 111 111 DOB: 01-01-1929 SEX: M
NOTE: radiating pain and numbness L5 dermatome R
DATE: 01-04-2001 TYPE: SIDE: B VER: nvdb 2.41 (Y2K)

Current Perception Threshold (CPT) Measures & Range Analysis

	2K Hz	scr	250 Hz	scr	5 Hz	scr	GRADE
L-S.PERONEAL-toe1	499	(0)	161	(0)	068	(0)	0.00
L-S.PERONEAL-toe3	408	(0)	142	(0)	092	(0)	0.00
L-SURAL-toe5	469	(0)	150	(0)	084	(0)	0.00

Within Site CPT Ratios & Analysis

	2K:5	scr	2K:250	scr	250:5	scr	GRADE
L-S.PERONEAL-toe1	7.34	(0)	3.10	(0)	2.37	(0)	0.00
L-S.PERONEAL-toe3	4.43	(0)	2.87	(0)	1.54	(0)	0.00
L-SURAL-toe5	5.58	(0)	3.13	(0)	1.79	(0)	0.00

Between Sites CPT Ratios & Analysis

	2K:2K	scr	250:250	scr	5:5	scr	GRADE
L-S.PER-t3:L-S.PER-t1	0.82	(0)	0.88	(0)	1.35	(0)	0.00
L-SUR-t5:L-S.PER-t1	0.94	(0)	0.93	(0)	1.24	(0)	0.00
L-SUR-t5:L-S.PER-t3	1.15	(0)	1.06	(0)	0.91	(0)	0.00

Current Perception Threshold (CPT) Measures & Range Analysis

	2K Hz	scr	250 Hz	scr	5 Hz	scr	GRADE
R-S.PERONEAL-toe1	398	(0)	108	(0)	077	(0)	0.00
R-S.PERONEAL-toe3	666	(+2)	229	(+1)	044	(0)	8.37
R-SURAL-toe5	411	(0)	099	(0)	123	(0)	0.00

Within Site CPT Ratios & Analysis

	2K:5	scr	2K:250	scr	250:5	scr	GRADE
R-S.PERONEAL-toe1	5.17	(0)	3.69	(0)	1.40	(0)	0.00
R-S.PERONEAL-toe3	15.14	(0)	2.91	(0)	5.20	(0)	0.00
R-SURAL-toe5	3.34	(0)	4.15	(0)	0.80	(0)	0.00

Between Sites CPT Ratios & Analysis

	2K:2K	scr	250:250	scr	5:5	scr	GRADE
R-S.PER-t3:R-S.PER-t1	1.67	(0)	2.12	(0)	0.57	(0)	0.00
R-SUR-t5:R-S.PER-t1	1.03	(0)	0.92	(0)	1.60	(0)	0.00
R-SUR-t5:R-S.PER-t3	0.62	(0)	0.43	(0)	2.80	(2)	2.00

Bilateral/Between Sites CPT Ratios & Analysis

	2K Hz	scr	250 Hz	scr	5 Hz	scr	GRADE
S.PERONEAL-toe1 - L:R	1.25	(0)	1.49	(0)	0.88	(0)	0.00
S.PERONEAL-toe3 - L:R	0.61	(0)	0.62	(0)	2.09	(1)	1.00
SURAL-toe5 - L:R	1.14	(0)	1.52	(0)	0.68	(0)	0.00

Clinical Summary Report #2
Diabetic Distal Axonal Polyneuropathy

SENSORY NERVE CONDUCTION THRESHOLD (CPT) TEST: DATA ANALYSIS SUMMARY SHEET

PATIENT NAME: Smith, Joe, R
ID: 000-00-0000 DOB: 02-19-58 SEX: M
NOTE: R/O neuropathy
DATE: 01-10-98 TYPE: SIDE: B VER: nvdb 2.30

CPT Measures and Analysis Summary

		2K Hz	250 Hz	5 Hz	GRADE
S.PERONEAL-toe1	:L	318	650	999	10.45
	:R	298	705	999	10.45

CPT Summary Report Observations

CPT Measures were taken from 2 sites. Bilateral measurements were obtained from the superficial peroneal n. on toe 1 (dorsal medial aspect); L4. The grade of the left side measures was 10.45 which indicates a profound sensory loss anesthetic at one frequency. The grade on the right side was 10.45 indicating a profound sensory loss anesthetic at one frequency.

Intermediate Calculations Report #2

Current Perception Threshold (CPT) Measures & Range Analysis

	2K Hz	scr	250 Hz	scr	5 Hz	scr	GRADE
L-S.PERONEAL-toe1	318	(0)	650	(+3)	999	(+4)	10.45
R-S.PERONEAL-toe1	298	(0)	705	(+3)	999	(+4)	10.45

Within Site CPT Ratios & Analysis

	2K:5	scr	2K:250	scr	250:5	scr	GRADE
L-S.PERONEAL-toe1	0.32	(2)	0.49	(2)	0.65	(0)	4.41
R-S.PERONEAL-toe1	0.30	(2)	0.42	(2)	0.71	(0)	4.41

Between Sites CPT Ratios & Analysis

	2K:2K	scr	250:250	scr	5:5	scr	GRADE
L-S.PER-t1:R-S.PER-t1	1.07	(0)	0.92	(0)	1.00	(0)	0.00

Clinical Summary Report #3
Carpal Tunnel Syndrome (CTS)

SENSORY NERVE CONDUCTION THRESHOLD (CPT) TEST: DATA ANALYSIS SUMMARY SHEET

PATIENT NAME: Sample, Patient, E
ID: 500-10-1000 DOB: 10-06-58 SEX: F
NOTE: Lft wrist pain numbness, tingling in fingers
DATE: 08-18-98

CPT Measures and Analysis Summary

		2K Hz	250 Hz	5 Hz	GRADE
MEDIAN-index	:L	585	325	038	9.45
	:R	265	078	061	0.00
ULNAR-little	:L	238	088	042	0.00
	:R	243	088	035	0.00
MEDIAN-plmr/thnr	:L	225	076	037	0.00
	:R	302	081	063	0.00

CPT Summary Report Observations

CPT Measures were taken from 6 sites. Bilateral measurements were obtained from the median n. on the index finger; C7. The grade of the left side measures was 9.45 which indicates a very severe hypoesthetic condition. The grade on the right side was 0.00 indicating no abnormal measures.

Bilateral measurements were obtained from the ulnar n. on the little finger; C8. The grade of the left side measures was 0.00 which indicates no abnormal measures. The grade on the right side was 0.00 indicating no abnormal measures.

Bilateral measurements were obtained from the median nerve - palmar branch (thenar); C6, C7. The grade of the left side measures was 0.00 which indicates no abnormal measures. The grade on the right side was 0.00 indicating no abnormal measures.

Intermediate Calculations Report #3

SENSORY NERVE CONDUCTION THRESHOLD (CPT) TEST: DATA ANALYSIS SUMMARY SHEET

PATIENT NAME: Sample, Patient, E
ID: 500-10-1000 DOB: 10-06-58 SEX: F
NOTE: Lft wrist pain numbness, tingling in fingers
DATE: 08-18-98

Current Perception Threshold (CPT) Measures & Range Analysis

	2K Hz	scr	250 Hz	scr	5 Hz	scr	GRADE
L-MEDIAN-index	585	(+3)	325	(+3)	038	(0)	9.45
L-ULNAR-little	238	(0)	088	(0)	042	(0)	0.00
L-MEDIAN-plmr/thnr	225	(0)	076	(0)	037	(0)	0.00

Within Site CPT Ratios & Analysis

	2K:5	scr	2K:250	scr	250:5	scr	GRADE
L-MEDIAN-index	15.39	(1)	1.80	(0)	8.55	(2)	4.35
L-ULNAR-little	5.67	(0)	2.70	(0)	2.10	(0)	0.00
L-MEDIAN-plmr/thnr	6.08	(0)	2.96	(0)	2.05	(0)	0.00

Between Sites CPT Ratios & Analysis

	2K:2K	scr	250:250	scr	5:5	scr	GRADE
L-ULN-lttl:L-MED-indx	0.41	(2)	0.27	(2)	1.11	(0)	2.39
L-MED-plm/thn:L-MED-indx	0.38	(2)	0.23	(2)	0.97	(0)	2.39
L-MED-plm/thn:L-ULN-lttl	0.95	(0)	0.86	(0)	0.88	(0)	0.00

Current Perception Threshold (CPT) Measures & Range Analysis

	2K Hz	scr	250 Hz	scr	5 Hz	scr	GRADE
R-MEDIAN-index	265	(0)	078	(0)	061	(0)	0.00
R-ULNAR-little	243	(0)	088	(0)	035	(0)	0.00
R-MEDIAN-plmr/thnr	302	(0)	081	(0)	063	(0)	0.00

Within Site CPT Ratios & Analysis

	2K:5	scr	2K:250	scr	250:5	scr	GRADE
R-MEDIAN-index	4.34	(0)	3.40	(0)	1.28	(0)	0.00
R-ULNAR-little	6.94	(0)	2.76	(0)	2.51	(0)	0.00
R-MEDIAN-plmr/thnr	4.79	(0)	3.73	(0)	1.29	(0)	0.00

Between Sites CPT Ratios & Analysis

	2K:2K	scr	250:250	scr	5:5	scr	GRADE
R-ULN-lttl:R-MED-indx	0.92	(0)	1.13	(0)	0.57	(0)	0.00
R-MED-plm/thn:R-MED-indx	1.14	(0)	1.04	(0)	1.03	(0)	0.00
R-MED-plm/thn:R-ULN-lttl	1.24	(0)	0.92	(0)	1.80	(0)	0.00

Bilateral/Between Sites CPT Ratios & Analysis

	2K Hz	scr	250 Hz	scr	5 Hz	scr	GRADE
MEDIAN-index - L:R	2.21	(2)	4.17	(2)	0.62	(0)	2.39
ULNAR-little - L:R	0.98	(0)	1.00	(0)	1.20	(0)	0.00
MEDIAN-plmr/thnr - L:R	0.75	(0)	0.94	(0)	0.59	(0)	0.00

Appendix D. Criteria for the CPT Evaluation of Specific Neuropathological Conditions

1. Criteria for CPT Evaluation of Radiating Back/Neck Pain

Progressive Radiculopathy - radiating back/neck pain .Typically radiculopathy or spine sprain/strain injuries once clinically diagnosed are treated conservatively for 2-4 weeks and electrodiagnostic testing is not required. There are always exceptions and the neurologist's impression is key for management decisions. More severe presentations are treated more aggressively.

Symptoms of a radiculopathy where the CPT evaluation may be indicated when the clinical sensory evaluation findings are equivocal include the following:

1. The pain radiates in a dermatome(s) distribution.
2. Pain is reproducible using provocative orthopedic maneuvers.
3. Cervical: pain limiting use of upper extremity.
4. Low back: pain limiting weight bearing.
5. Symptoms same or worse after 2-4 weeks of conservative therapy.

The CPT electrodiagnostic evaluation may be indicated for a radiculopathic injury if:

1. The severity of a sensory nerve injury, if present, requires objective evaluation because the clinical neurological findings although present are equivocal as to the severity of the nerve dysfunction in the three individual sub-populations nerve fibers being evaluated. This information is needed for the appropriate intervention to be selected.
2. The distribution of a sensory nerve impairment, if present, requires objective evaluation because clinical neurological findings although present are equivocal as to actual distribution of dysfunction. This information is needed for the appropriate intervention to be selected.
3. The information is necessary to determine if and where an imaging study or motor electrodiagnostic study may be required.
4. Surgical intervention is being considered and objective evaluation of sensory function is required because clinical findings are not diagnostic, e.g. Radiculopathy vs Plexopathy vs Sprain/Strain.
5. The sensory nerve root ablation procedure is indicated and the neurosurgeon requests a CPT evaluation to localize the segmental level of sensory impairment.[28]
6. Imaging studies (eg. MRI) are not diagnostic of the sensory impairment, e.g., multiple disc herniations are visualized, The CPT evaluation is indicated to determine the functional significance of the observed herniations.

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28. Falci, S.P., Best, L.G, Bayles, R., Cown, C. Dorsal Root Entry Zone (DREZ) microcoagulation for central pain of spinal cord injury: operative intramedullary electrophysiological guidance and clinical outcome. Journal of Neurosurgery (Spine 2), vol 97:193-200, 2002.

Notes:

1. Pain associated with radiculopathy can interfere with accurate strength assessments distorting clinical measures of motor nerve function.

2. A radiculopathy may be motor, sensory or mixed. Most often sensory dysfunction precedes motor dysfunction. Motor dysfunction may be assessed by needle EMG evaluation but only approximately 5 weeks after the radiculopathic injury occurs. The delay for the needle EMG diagnostic test is necessary to allow for the paraspinal muscles to become denervated. The sensory CPT evaluation is immediately sensitive to radiculopathy and no waiting period is required after a radiculopathic injury to conduct a CPT evaluation. In contrast, the sensory nerve conduction velocity evaluation is insensitive to radiculopathy.

3. Occasionally a myelopathy may be detected during the course of a CPT evaluation of a suspected radiculopathy.

2. Criteria for the CPT Evaluation of Sensory Polyneuropathy

Sensory polyneuropathy may be the presenting symptom of a variety of metabolic, toxic, neoplastic, infectious, digestive and connective tissue disorders. The symptomatology may present with a wide range of symptoms as exemplified by the following three conditions:

1. Asymptomatic, yet polyneuropathy findings upon clinical evaluation.
2. Symptomatic consistent with clinical evaluation findings of polyneuropathy.
3. Symptoms of pain or numbness, but no findings on clinical evaluation.

The distribution of sensory impairments associated with such pathology is generally either diffuse or distal. The clinical evaluation of sensory polyneuropathy may sometimes yield equivocal results. The primary differential diagnosis of sensory polyneuropathy is axonal versus demyelinating. The objective assessment of the severity of such conditions may also be critical for determining appropriate patient management. The automated double blinded CPT evaluation is indicated for the differential diagnosis of these two types of polyneuropathy or for the evaluation of their severity. There are always exceptions (eg., polyneuropathy combined with an ischemic mono-neuropathy) and the Neurologist's impression is key for management decisions.

Progressive Polyneuropathy is often characterized by diffuse sensory abnormalities including pain and numbness. Typically a distal axonopathy appears at the tips of the toes first. When distal axonal polyneuropathy is overt, it is often clearly delineated and its etiology is often associated with a known metabolic or toxic condition (e.g. alcoholism, diabetes, chemotherapy), HIV infection or paraneoplastic syndrome. The electrodiagnostic CPT evaluation of such neuropathies when clearly discernable is not indicated.

Subclinical polyneuropathies are often characterized by hyperesthetic CPTs. This would include conditions such as metabolic syndrome, pre-diabetes and obesity. The CPT evaluation is utilized in evaluating for these polyneuropathies as well as for sensory impairments associated with early end-stage renal disease (ESRD).

The CPT electrodiagnostic evaluation may be indicated for sensory polyneuropathy if:

1. The severity of a sensory neuropathy, if present, requires objective evaluation because neurological findings although present are equivocal as to the actual severity

of the pathology in all 3 individual subpopulations of sensory nerve fibers being evaluated. This information is needed ascertain the etiology of the symptoms and to select the appropriate intervention.

2. The distribution of a sensory neuropathy, if present, requires objective evaluation because even with neurological findings their actual distribution is equivocal for permitting the differential diagnosis between axonal versus demyelinating polyneuropathy. This information is needed ascertain the etiology of the symptoms and to select the appropriate intervention (e.g.., Intra-venous immunoglobulin therapy for diffuse demyelinating polyneuropathy).

3. The information is necessary to determine if and where an imaging or motor electrodiagnostic study may be required.

4. Despite significant sensory complaints consistent with polyneuropathy, the clinical findings are normal.

Notes:

1. Pain associated with polyneuropathy can interfere with accurate strength assessments distorting clinical measures of motor nerve function.

2. A polyneuropathy may be motor, sensory or mixed. Most often sensory dysfunction precedes motor dysfunction.

3. Criteria for Evaluation of Nerve Compression Syndromes

Typically, the clinical evaluation of a focal compressive neuropathy is straightforward, i.e. there is normal nerve function proximal and abnormal nerve function distal to the lesion. Conditions such as sprains, strains, Carpal Tunnel Syndrome (CTS), Guyon's Canal Syndrome, Vibration Neuropathy, Pronator Syndrome, Cubital Tunnel Syndrome and Tarsal Tunnel Syndrome can often be clinically diagnosed and respond effectively to conservative management (NSAID therapy, splinting, physical therapy for two to three weeks). Patients may present with a poor association between symptoms and physical findings and an objective electrodiagnostic evaluation is required. Compression syndromes, when obvious, do not require electrodiagnostic CPT evaluations. There are always exceptions and the neurologist's impression is key for management decisions. More severe presentations are treated more aggressively.

Occasionally, confounding variables such as arthralgias, vascular insufficiency, radiculopathy, plexopathy and referred pain can result in misleading or questionable clinical findings with respect to the actual sensory impairment. Under such circumstances, an electrodiagnostic evaluation may assist in selecting the most appropriate patient management. The CPT electrodiagnostic evaluation may be indicated for the evaluation of sensory nerve compression syndromes if:

1. The severity of a sensory impairment, if present, requires objective evaluation because the neurological findings, although present, are equivocal as to actual severity of the pathology in all 3 individual subpopulations of sensory nerve fibers being evaluated. This information is needed ascertain the etiology of the symptoms and to select the appropriate intervention.

2. The distribution of a sensory neuropathy, if present, requires objective evaluation because even with neurological findings their actual distribution is equivocal for permitting the differential diagnosis between a distal focal compressive neuropathy versus a more proximal focal compressive neuropathy or an axonal versus demyelinating polyneuropathy. Occasionally a compressive neuropathy such as Carpal Tunnel Syndrome (CTS) may be superimposed upon a systemic poly-neuropathy.[29] This information is needed ascertain the etiology of the symptoms and to select the appropriate intervention.

3. The information is necessary to determine if and where an imaging or motor electrodiagnostic study may be required.

4. Despite significant sensory complaints consistent with a focal compressive , the clinical findings are normal.

Notes:

1. Pain associated with focal compressive neuropathy can interfere with accurate strength assessments distorting clinical measures of motor nerve function.

2. A focal compressive neuropathy may be motor, sensory or mixed. Most often sensory dysfunction precedes motor dysfunction (which appears in the more advanced stages).

4. Criteria for the CPT Evaluation of Plexopathy

Plexopathies are primarily traumatic, e.g. brachial plexopathy caused by a direct blow to the shoulder in a motor vehicle accident. Most plexopathies may be diagnosed by clinical evaluation findings (e.g. Fig. 7). Typically plexopathy injuries are treated conservatively for 2-4 weeks and no electrodiagnostic testing is required. There are always exceptions and the neurologist's impression is key for management decisions, more severe presentations are treated more aggressively:

Symptoms of a plexopathy where the CPT evaluation may be indicated when the clinical sensory evaluation findings are equivocal include the following:

1. The pain not consistent with a peripheral nerve or dermatomal distribution.
2. Pain is reproducible using provocative orthopedic maneuvers.
3. Cervical: pain limiting use of upper extremity.
4. Low back: pain limiting weight bearing.
5. Symptoms same or worse after 2-4 weeks of conservative therapy.

29. Katims, J.J., Rouvelas, P., Sadler, B.T., Weseley, S.A. Current Perception Threshold: Reproducibility and Comparison with Nerve Conduction in Evaluation of Carpal Tunnel Syndrome. Transactions of the American Society of Artificial Internal Organs, Vol. 35(3):280-284, 1989.

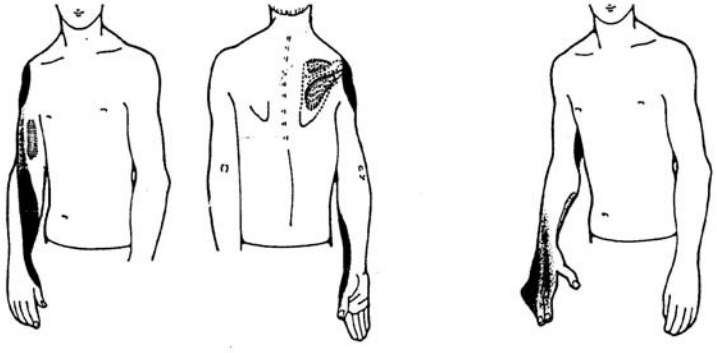

Fig. 7. Brachial plexopathy symptoms, shaded areas indicate maximum symptomatology. Two left figures represent upper brachial plexopathy and the right figure represents lower brachial plexopathy.

The CPT evaluation may be indicated for a plexopathy injury if:

1. The severity of a sensory nerve injury, if present, requires objective evaluation because the clinical neurological findings although present are equivocal as to the severity of the nerve dysfunction in the three individual sub-populations nerve fibers being evaluated. This information is needed ascertain the etiology of the symptoms and to select the appropriate intervention.
2. The distribution of a sensory nerve impairment, if present, requires objective evaluation because even with neurological findings their actual distribution of dysfunction is equivocal. This information is needed ascertain the etiology of the symptoms and to select the appropriate intervention.
3. The information is necessary to determine if and where an imaging study or motor electrodiagnostic study may be required.
4. Surgical intervention is being considered and objective evaluation of sensory function is required because clinical findings are not diagnostic, e.g. Radiculopathy vs Plexopathy.
5. Imaging studies are not diagnostic of the sensory impairment, e.g., multiple disc herniations are visualized, CPT is indicated to determine functional significance of each.

Note:

1. Pain associated with plexopathy can interfere with accurate strength assessments distorting clinical measures of motor nerve function.
2. A plexopathy may be motor, sensory or mixed. Most often sensory dysfunction precedes motor dysfunction (which appears in the more advanced stages). Motor dysfunction may be assessed by needle EMG evaluation which requires approximately 5 weeks after the plexopathy injury occurs. This delay is necessary to permit the effected muscles to become denervated. The sensory CPT evaluation is immediately sensitive to plexopathy and no waiting period is required after a plexopathy injury to conduct a CPT evaluation of sensory nerve function.

5. Criteria for Evaluation of Therapeutic Intervention of Nerve Recovery
(e.g. toxin recovery, nerve regeneration, medication)

Occasionally a therapeutic intervention of a sensory neuropathological condition will yield equivocal clinical findings of the response to the intervention. Rather than continue with potentially ineffective, toxic and expensive intervention it is more efficient to conduct an objective electrodiagnostic CPT evaluation to gage the patients sensory nervous function in response to the therapy. A few examples follow:

1. Evaluate the efficacy of steroid or IVIg therapy of a demyelinating polyneuropathy.
2. Evaluate possible recovery of nerve function following nerve repair to rule out the need for follow-up surgery to remove a possible neuroma formation interfering with nerve regeneration.[30]
3. To evaluate the efficacy of therapeutic intervention of diabetic neuropathy[31].
4. To monitor for the toxicity of cancer chemotherapy[32].
5. To evaluate the efficacy of therapeutic intervention of pain. This may include using the PTT Pain Tolerance Threshold (PTT) measure[33].

6. Criteria for Evaluation of Direct Sensory Nerve Trauma

Sensory nerve trauma is often the result an acute event, most frequently caused by laceration, contusion or a vascular accident. It is a situation that occurs if there is a laceration of a nerve with associated sensory symptomatology, and there is uncertainty as to whether the condition represents a neuropraxia, axonotmesis or neurotmesis. The prognosis for neuropraxia and axonotmesis is favorable, however when there is neurotmesis if possible, a surgical repair is indicated. If a nerve is obviously completely transected then a sensory electrodiagnostic evaluation would not be indicated. It is only when the extent of the nerve damage is not clear and the clinical evaluation yields equivocal findings that the CPT evaluation may be considered.

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30. Inada, Y., Morimoto, S., Takakura, Y., Nakamura, T. Regeneration of Peripheral Nerve Gaps with a Polyglycolic Acid-Collagen Tube. Neurosurgery Vol. 55(03):640-648, 2004.

31. Winkler, G., Pal, B., Nagybeganyi, E., Ory, I., Porochnavec, M., Kempler, P. Effectiveness of different benfotiamine dosage regimens in the treatment of painful diabetic neuropathy. Arzneim.-Forsch./Drug Reseach, Volume 49:220-224, 1999.

32. New, P. Neuro-selective Current Perception Threshold (CPT) quantitative sensory test: A re-evaluation, Neurology, Volume 49(5):1482, 1997.)

33. Angst, M.S., Drover, D.R., Lötsch, J., Ramaswamy, B., Naidu, S., Wada, D.R., Stanski, D.R. The pharmacodynamics of orally administered sustained release hydromorphone in humans. Anesthesiology, Volume 94:63-73, 2001.

Appendix E. Differential Diagnosis Guideline Flow Charts for the CPT© Evaluation

Introduction

The following pages contain flow charts designed to provide the clinician with suggested guidelines for prescribing the Current Perception Threshold (CPT) evaluation. The suggestions should be modified based upon clinical impression. The most frequently prescribed testing sites are illustrated and described on the "Testing Sites Figures" page. The "CPT Evaluation Prescription Form" lists and illustrates the test sites available in the CPT evaluation software.

Categories of Sensory Nerve Impairment

The differential diagnosis of a peripheral sensory nerve impairment includes four basic categories:

Polyneuropathy

Polyneuropathy involves multiple nerves usually presenting with a characteristic "stocking glove dying back" distribution of sensory abnormalities. The sensory abnormalities usually occur earliest in the longest sensory nerves (toes and/or fingers) and progress proximally. CPTs are usually abnormal distally and normal proximally in the same nerves. Polyneuropathy is often associated with metabolic or toxic conditions such as diabetes or alcoholism.

Compressive Neuropathy

Compressive neuropathy results from entrapment of a nerve in a closed space. CPTs are normal proximal to and abnormal distal to the site of entrapment. Carpal tunnel syndrome is a common example of this type of neuropathy.

Radiculopathy

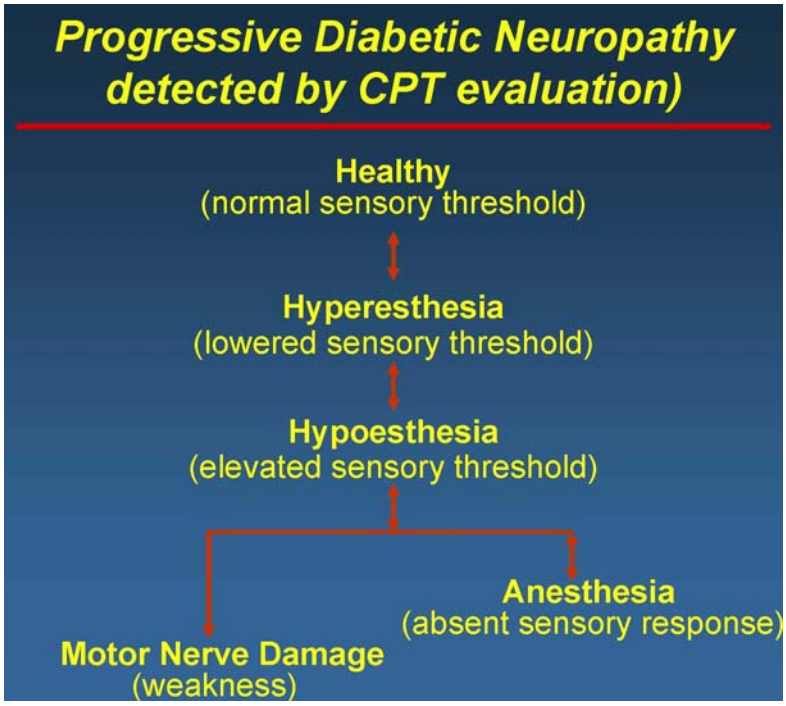
Radiculopathy refers to any diseased condition of a spinal nerve root resulting in a neurological impairment confined to a dermatomal distribution. CPT abnormalities associated with radiculopathies are confined to the effected dermatomes.

Focal Nerve Lesions

Focal nerve lesions are primarily the result of traumatic injury. Depending on the degree of trauma, they may present with a mixed sensory/motor deficit of variable severity. CPTs are normal proximal to and abnormal distal to the site of injury.

Stages of Nerve Impairment

Sensory neuropathies usually present with the following sequence of development: **hyperesthesia** (inflamed or irritated nerves - neuritis); followed by **hypoesthesia** (loss of function - neuropathy); and with advanced stages **anesthesia** (no response to test stimulus). Motor nerve impairment also occurs in advanced stages. *Sensory* impairments are frequently reversible. Complete return of function with *motor* neuropathy is rare. Refer to the following chart.



Bilateral Test Sites

Bilateral testing is recommended to enhance the sensitivity of this diagnostic procedure. Specific combinations of additional test sites are also suggested to assist in the differential diagnosis of a patient's condition if necessary.

Standard and Non-Standard Test Sites

There are standardized sites for which normative CPT values are available and they should be employed whenever possible. The CPT evaluation, however, may be performed at any cutaneous site. When a patient has a condition where the area of maximal symptomatology does not correspond to a peripheral nerve site or dermatome with normative values, then that site is evaluated by comparison with contralateral or adjacent sites. This is referred to as matched sites comparison.

Flow Chart Test Site Summary

The CPT evaluation flow chart guidelines for the differential diagnosis of radiating pain in the upper extremity, lower extremity, carpal tunnel syndrome, and polyneuropathy are presented on the following pages. All charts represent procedural suggestions only and should be modified based on clinical impression.

Radiating Pain Upper Extremity

Thumb (C6)
Index Finger or Middle (C7)
Little Finger (C8)

Carpal Tunnel Syndrome

Index Finger (median nerve)
Little Finger (ulnar nerve)
Median Nerve Palmar Branch (median nerve)

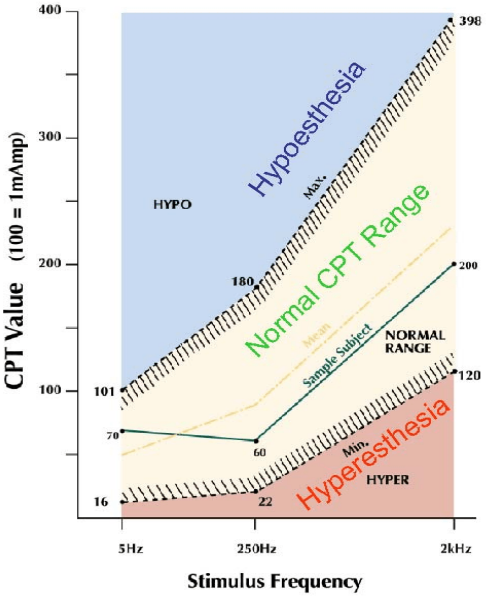
Radiating Pain Lower Extremity

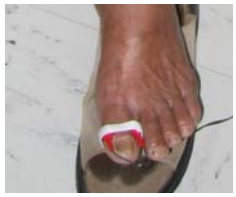
Toe 1 (L4)
Toe 3 (L5)
Toe 5 (S1)

Polyneuropathy

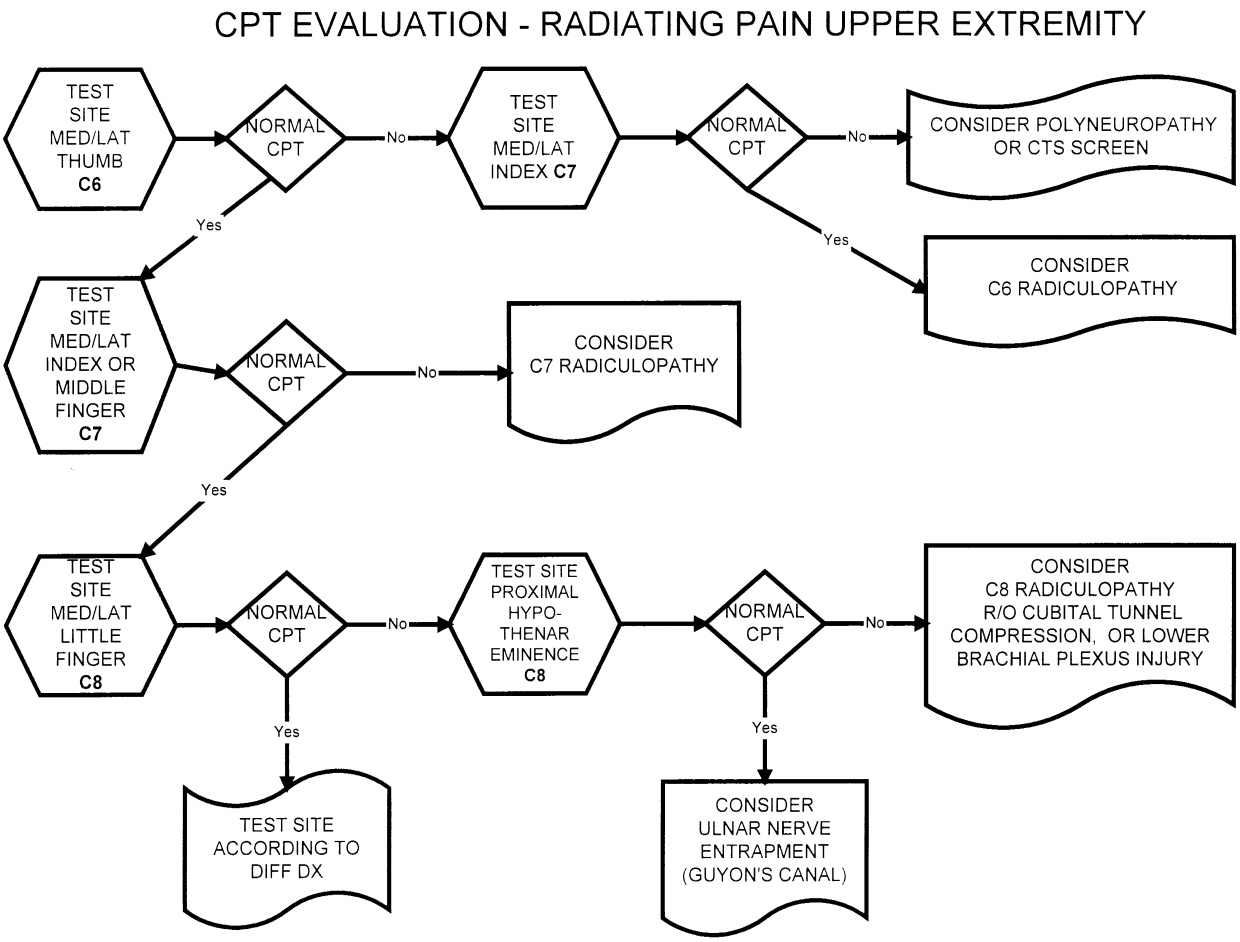
Toe 1 (med/lat) - L4/L5 superficial and deep peroneal nerve
Ring Finger - C7/C8 median and ulnar nerve

CPT Finger

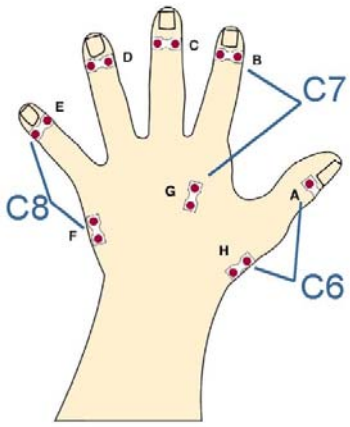




CPT Evaluation of Radiating Pain Into the Upper Extremity



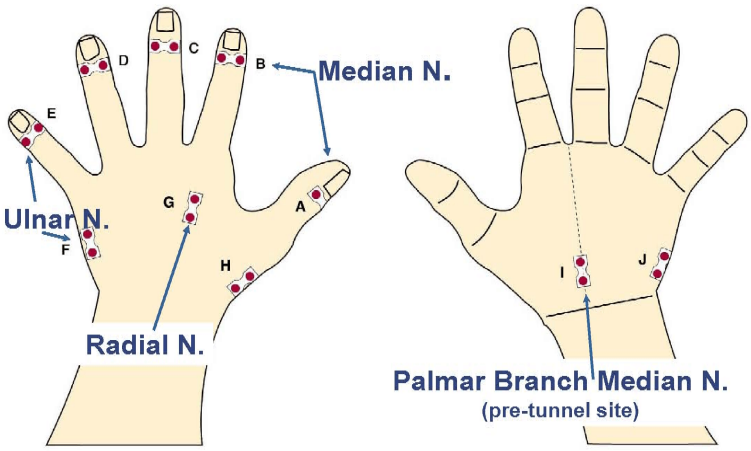
This flow chart serves as a guide for using the CPT procedure to perform differential diagnosis in order to evaluate pain in the upper extremity. Bilateral testing enhances sensitivity. This chart represents procedural suggestions only and should be modified based on clinical impression.



CPT Evaluation of Carpal Tunnel Syndrome

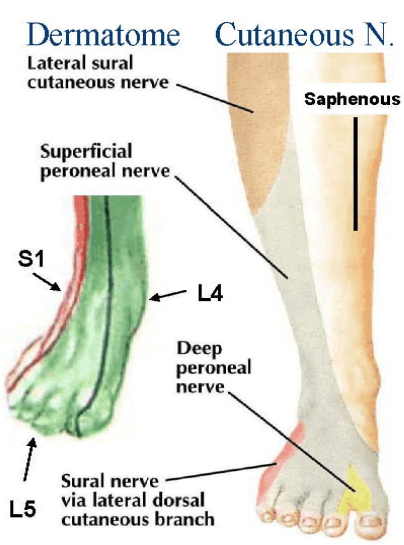
This flow chart serves as a guide for using the CPT procedure to perform a differential diagnosis on a patient suspected of having carpal tunnel syndrome. Bilateral testing enhances sensitivity. This chart represents procedural suggestions only and should be modified based on clinical impression.

** If the abnormal median nerve CPT grade is greater than 8 above the ulnar nerve grade, CTS superimposed on polyneuropathy needs to be ruled out (Appendix C). A lower extremity polyneuropathy evaluation is suggested.

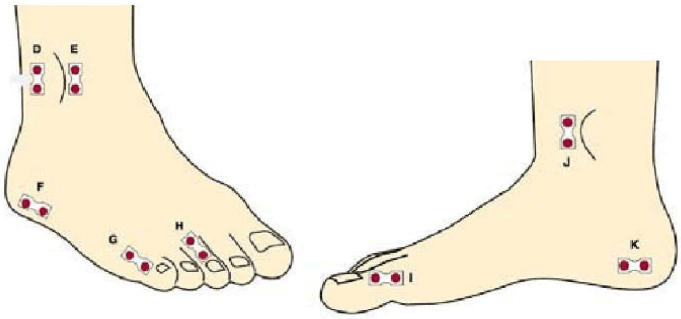


CPT Evaluation of Radiating Pain Lower Extremity

This flow chart serves as a guide for using the CPT procedure to perform differential diagnosis in order to evaluate pain in the lower extremity. Bilateral testing enhances sensitivity. This chart represents procedural suggestions only and should be modified based on clinical impression.



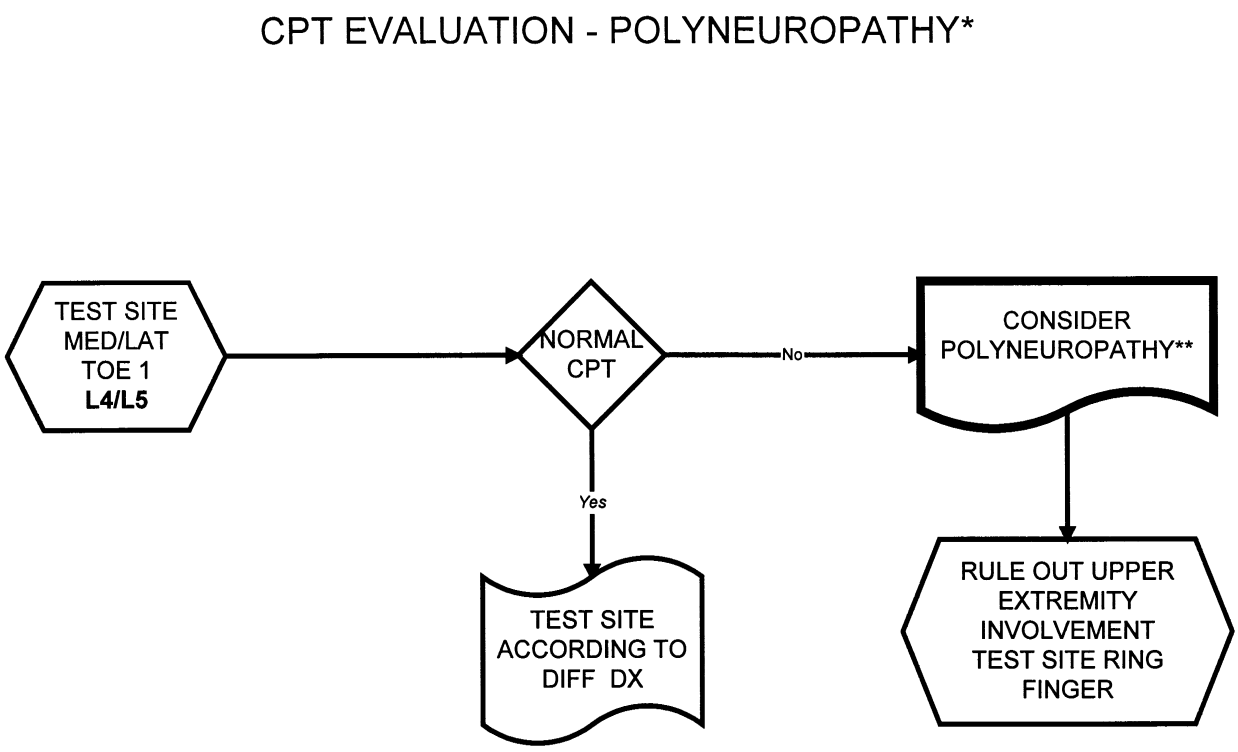
Standardized CPT Test Sites (Norms Established)



D - (S1) Sural N.
F - (S1) Sural N.
H - (L5) Sup. Peroneal N.
J - (L4) Saphenous N.

E - (L5) Sup. Peroneal N.
G - (S1) Sural N.
I - (L4) Sup. Peroneal N.
K - (L4/S2) Tibial N.

CPT Evaluation of Polyneuropathy



This flow chart serves as a guide for using the CPT procedure to perform a differential diagnosis on a patient suspected of having a polyneuropathy. Bilateral testing enhances sensitivity. All 3 CPT frequencies should be tested regardless of anesthetic values at one frequency. A non-anesthetic proximal test site must be established. *This chart represents procedural suggestions only and should be modified based on clinical impression.

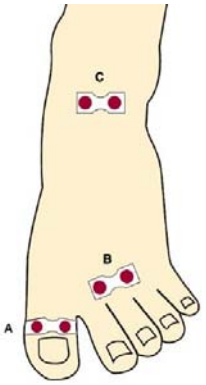
Note: Unobtainable CPT Measures: Unobtainable CPT measures indicate that the subject was insensitive to the maximum output intensity of the CPT measure (i.e. CPT = 999 or 9.99 mAmp.) with all free stimulation frequencies. Unobtainable CPTs reflects a profound severe loss of sensory function. When this finding is made at the great toe "wrap around" site L4/L5 dermatomes and Superficial/Deep Peroneal nerves , the electrodes should be evaluated to confirm that there was not excessive electrode gel or the gel did not smear between the electrodes possibly creating a short-circuit that would result in unobtainable CPTs. Patients with this severe neuropathy have a clinically apparent loss of sensory function and a higher prevalence of foot ulceration. Unobtainable CPT measures from a test site are not sufficient for neurological evaluation as it would be impossible to tell if the subjects neuropathy was advancing on follow-up evaluation. When CPT measures are unobtainable from this site, it is necessary to test the foot more proximally at the ankle level. Typically profound diabetic metabolic neuropathy does not advance beyond the level of the dorsum of the

foot so CPT measures are obtainable from this ankle test site which like the toe test site includes multiple nerves (Saphenous and Superficial Peroneal Nerves) and multiple dermatomes (L4, L5 and S1).

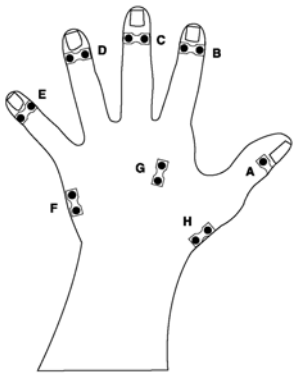
The Neurometer CPT device stimulus is an alternating current (AC) that passes back an forth between the electrodes. The stimulus is regulated to be of constant current intensity so it is not effected by skin thickness variations or the trophic skin changes that are common in diabetes. Wrapping these electrodes around the distal phalange of the great toe means that the stimulus is being applied to two different peripheral nerves (deep and superficial peroneal nerves) and two different dermatomes (Lumbar 4 and Lumbar 5). Consequently, CPT measures from this big toe wrap around test site is generally insensitive to mono-neuropathies and mono-radiculopathies but are sensitive to polyneuropathies that is the primary concern of the clinician treating a patient with diabetic/metabolic polyneuropathy.

To rule out sciatic nerve lesion, compare test sites anterior to the medial malleolus (L4, saphenous nerve, femoral branch) to anterior to the lateral malleolus (L5, sural nerve, sciatic branch).

- if both sites have normal measures, suspect polyneuropathy
- if both sites have abnormal measures, suspect severe dying back polyneuropathy.
- if only the lateral site results in an abnormal measure, suspect sciatic nerve lesion (e.g. pyriformis syndrome)
- the classic distal polyneuropathy associated with diabetic/metabolic disorders is expected to be more severe in the toe than the finger test site. If both of these test sites have similar degrees of sensory impairment in all nerve fiber sub-populations, then a concurrent demyelinating polyneuropathy should be suspected (e.g.. Myelin Anti-Globulin, HIV etc.). Proximal testing at the ankle will show a similar degree of myelinated fiber impairment with a demyelinating polyneuropathy. If less severe CPT abnormalities of the myelinated fibers are noted at the proximal ankle test site, then the neuropathy is consistent with a metabolic distal polyneuropathy and not a demyelinating condition. Patients detected with a demyelinating polyneuropathy should be monitored closely by the neurologist and treated accordingly (e.g.., IVIg therapy, plasmapheresis, etc.).



Testing Sites Figures - **Dermatomes and Nerves**

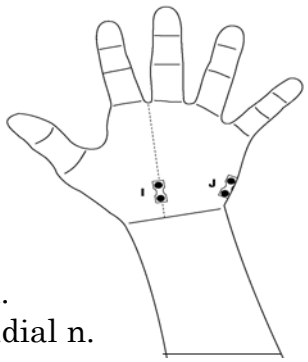


Dorsal Hand

Hand Testing Sites

Dorsal

A) Thumb, C6, median n.
B) Index finger, C7, median n.
C) Middle finger, C7, median n.
D) Ring finger, (C7,C8) median and ulnar n.
E) Little finger, C8, ulnar n.
F) Dorsum little finger metacarpal, C8, dorsal ulnar n.
G) Dorsum index finger metacarpal, C7, superficial radial n.
H) Dorsum thumb metacarpal, C6, superficial radial n.



Palmar Hand

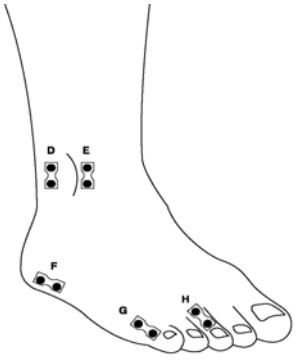
Palmar

I) Thenar, (C6,C7, C8), median n. palmar branch
J) Hypothenar, C8, ulnar n. palmar branch

Foot Testing Sites (Polyneuropathy Screen)

Dorsal

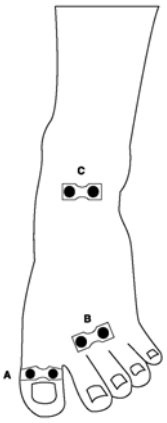
A) Toe 1 wrap around, L4/L5, superficial and deep peroneal n.
B) Dorsal Foot, superificial peroneal n.
C) Ankle-Anterior surface at midline



Lateral Foot

Lateral

D) Posterior lateral. malleolus, S1, sural n.
E) Anterior lateral. malleolus. L5, S. peroneal
F) Heel posterior lateral, S1, lateral sural n.
G) Lateral base fifth toe, S1, sural n.
H) Third toe dorsal distal, L5, S. peroneal n.



Dorsal Foot

Medial

I) First toe dorsal medial, L4, S. peroneal n.
J) Anterior medial malleolus, L4, saphenous n.
K) Heel posterior inferior medial, S2, med. calcaneal n.

CPT Evaluation Prescription Form

Patient: ..... Differential Dx: .....

Date: ..... Prescribed By: .....

Performed By: .....

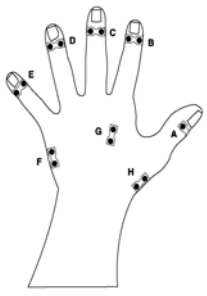
Upper Body Test Sites

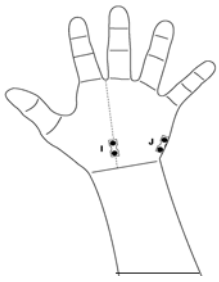
1. Trigeminal N.
   1) Trig. N. Trunk - Anterior to ear tragus **V**
   2) Trig. N. Mandibular div (jaw) **V3**
   3) Trig. N. Maxillary div. (cheek) **V2**
   4) Trig. N. Opthalmic div. (forehead) **V1**
2. Lessor Occipital N. - post. to ear - **C2**
3. Transverse Cervical N. - lateral neck - **C3**
4. Posterior Cervical N. - post. inferior neck- **C4**
5. Upper Lat. Brachial Cutan. N. - lat shoulder - **C5**
6. Lat. Antebrachial Cutan. N. - lat forearm - **C6**
7. Hand
   1) Median N. Palmar Br. - palm thenar - **C6/C7/C8 (Site I)**
   2) Median N. - thumb - **C6 (Site A)**
   3) Median N. - index finger - **C7 (Site B)**
   4) Median N. - middle finger - **C7 (SiteC)**
   5) Median/Ulnar Nerves. - ring finger - **C7/C8 (Site D)**
   6) Ulnar N. - little finger - **C8 (Site E)**
   7) Ulnar N. - Palmar Br. - palm hypothen. - **C8 (Site J)**

Combination Sites

Polyneuropathy Evaluations

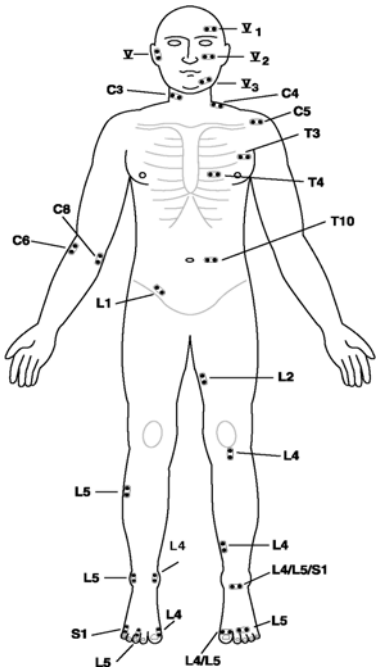
1. Trigeminal, Median (index), Superficial and Deep Peroneal (Toe 1, wrap around).
2. Lessor Occipital, Median and Ulnar (ring), Superficial and Deep Peroneal (Toe 1, wrap around). **L4/L5**
3. Median (index), Ulnar (little), Superficial and Deep Peroneal (Toe 1 wrap around).
4. **CTS:**
   Median (index), Ulnar (little), Median (palmar)
5. **Upper Extremity Radiculopathy**: Median (thumb) **C6**, Median (index) **C7**, Ulnar (little) **C8**
6. **Lower Extremity Radic**.: S. Peroneal (toe 1) **L4**, S. Peroneal (toe 3) **L5,** Sural (toe 5) **S1**

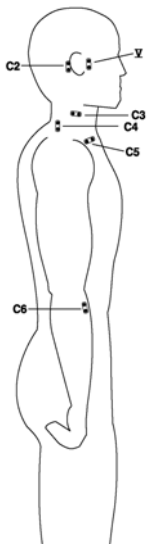




Lower Body Test Sites

1. Knee (midline infrapatellar)
2. Leg
   1) Sural Cutaneous N. - post. lat. leg- **S1**
   2) Lat. Sural Cut. N.- ant. lat. upper leg **- L5**
   3) Saphenous N. -inferior patella midline - **L4**
3. Ankle
   1) Ankle - ant. midline - **L4/L5**
   2) Saphenous N. Medial Crural Br. - anterior medial malleolus - **L4**
   3) Superficial Peroneal N. - anterior lateral malleolus - **L5**
   4) Sural N. - posterior to lateral malleolus - **S1**
4. Superficial Peroneal N. - foot dorsum - **L5**
5. Heel
   1) Tibial N. Medial Calcaneal Br. - posterior inferior medial aspect - **L4/L5**
   2) Sural N. - post. inferior lateral aspect **S1**
6. Toes
   1) Superficial and Deep Peroneal Nerves - toe 1 wrap around - **L4/L5**
   2) Sup. Peroneal N. - toe 1 dorsal medial - **L4**
   3) Deep Peroneal N. - first toe web space - **L5**
   4) Peroneal N. - toe 2 - dorsal distal - **L5**
   5) Sup. Peroneal N. - toe 3 - dorsal distal - **L5**
   6) Sup. Peroneal N. - toe 4 - dorsal distal - **L5**
   7) Sural N. - toe 5 - dorsal lateral - **S1**





Patient Guide to the Current Perception Threshold (CPT) Test

WHAT IS IT?

The CPT test is a diagnostic procedure used to measure the condition of your sensory nerves that is based on the hearing test. CPT stands for Current Perception Threshold. A CPT measure is the minimum amount of a current required cause a sensation. The CPT testing device uses an electrical stimulus to obtain CPT measurements. It is a painless test and does not involve needles. You will be given a very small electrical stimulus that will determine the lowest level of stimulus you can detect.

WHY TEST MY NERVES?

The condition of the human sensory nervous system provides a very sensitive window to distress occurring within the body. This makes the sensory nervous system an ideal place to assess a patient's health. The best way to determine the condition of your nerves is through the CPT test. This gives your doctor valuable information about the health of your nerves. Certain disease states and other conditions can impair and damage nerve function.

WHAT WILL THE DOCTOR DO WITH THE TEST RESULTS?

Upon completing the evaluation, the test results are analyzed. The results will assist your doctor in diagnosing your condition and determining the appropriate treatment.

IS THE CPT TEST PAINFUL OR DANGEROUS?

No, the CPT test is not painful, nor is it dangerous. As soon as you detect a sensation, the stimulus is stopped.

HOW IS THE TEST CONDUCTED?

The CPT test is performed by a technician under the prescription of a doctor. Typically, a pair of small electrodes are taped to your skin at different sites on your body. The device slowly increases the intensity of the stimulus until you report detecting a sensation at the electrode site. Your part in the test is to inform the technician whether or not you detect the stimulus or press a button to indicate detection of the stimulus. You will be given a series of tests in order to find the least amount of stimulus you can detect. Before beginning the CPT test, the technician will explain the procedure to you and can answer any questions you may have about the CPT test.

HOW LONG WILL THE TEST TAKE?

The usual time to complete a test is approximately 3-8 minutes per testing site. Depending upon the specific test selected.

WHAT CLOTHING SHOULD I WEAR?

You may be asked to wear clothing that can be easily removed depending on the sites being tested. You will want to determine if this is necessary before the test.

HOW OFTEN WILL THE CPT TEST BE PERFORMED?

Your doctor will determine how often the CPT test will be repeated. This will depend on your condition.