NEUROPHYSIOLOGIC TESTING

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INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Medical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Medical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

COVERAGE RATIONALE

Electromyography (EMG)

Surface electromyography (SEMG) is unproven and not medically necessary.

There is limited and insufficient evidence to support the use of SEMG. Studies varied considerably in SEMG instrumentation, SEMG protocol, and diagnostic algorithm. Depending on the study’s SEMG approach, diagnostic performance ranged from poor to fair. Further research is needed to standardize SEMG approaches and diagnostic algorithms, increase diagnostic performance, and to assess the role of SEMG in clinical practice.
Macro electromyography (macro-EMG) testing is unproven and not medically necessary. There is limited and insufficient evidence to support the use of macro-EMG. Additional studies are needed to establish how this test improves diagnostic capabilities and physician decision-making.

**Nerve Conduction Studies**

**Nerve Conduction Studies Performed in Conjunction with Needle Electromyography**

Nerve conduction studies with or without late responses (e.g., F-wave and H-reflex tests) are proven and medically necessary when performed in conjunction with needle electromyography for any of the following known or suspected disorders:

- Peripheral nerve entrapment syndromes
- Generalized neuropathies
- Hereditary, metabolic, or degenerative polyneuropathy
- Plexopathy (acquired disorder in tissue along nerves that causes motor and sensory dysfunction)
- Neuromuscular junction disorders
- Myopathies
- Motor neuron disease
- Spine disorder with nerve root impingement symptoms
- Cervical, thoracic, and/or lumbosacral radiculopathy
- Guidance for botulinum toxin injection for spasmodic dysphonia or segmental dystonia when it is difficult to isolate affected muscles
- Traumatic nerve lesions

**Nerve Conduction Studies Performed without Needle Electromyography**

Nerve conduction studies with or without late responses (e.g., F-wave and H-reflex tests) are proven and medically necessary when performed without needle electromyography for patients who have any of the above known or suspected disorders with any of the following clinical indications:

- Patients treated with anticoagulants; or
- Patients with lymphedema; or
- Patients being evaluated for carpal tunnel syndrome

The American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) states that it is in the best interest of patients, in the majority of situations, for the needle EMG and the NCS examination to be conducted and interpreted on-site in real time. According to the AANEM, the use of the term “real time” with regard to nerve conduction studies indicates that information from the history and physical examinations are integrated, the specific and tailored electrodiagnostic (EDX) study is performed, and the analysis of the waveforms are all done at the same time and while the patient is present in the EDX laboratory (AANEM, Proper Performance and Interpretation of Electrodiagnostic Studies, 2014; AANEM, What does ‘On Site’ and ‘Real Time’ Mean?, 2014).

Nerve conduction studies are unproven and not medically necessary for all conditions other than those listed above as proven.

There is limited and insufficient evidence to conclude that nerve conduction studies are beneficial for health outcomes in patients with disorders other than those listed above as proven.

Non-invasive automatic, portable, or automated point of care nerve conduction monitoring systems (e.g., the NC-stat® System, the Brevio® NCS-Monitor, and the Advance™ System) that test only distal motor latencies and conduction velocities are unproven and not medically necessary for the purpose of electrodiagnostic testing.

Studies of these devices are primarily small case series comparing portable with conventional nerve conduction studies in the same patient. Studies that did use controls did not always report the patients' conditions. Large, robust randomized, controlled studies are needed to prove the safety and efficacy of this technology.

**Physiologic Recording of Tremor**

Physiologic recording of tremor using accelerometers is unproven and not medically necessary.

There is insufficient evidence and too few studies to conclude that these devices improve therapeutic responses for the purpose of decreasing tremor in patients with tremor. Well-designed controlled studies are needed to determine the usefulness of these devices.

**Quantitative Sensory Testing**

Quantitative sensory testing, including monofilament testing, pressure-specified sensory testing, computer assisted sensory examinations, and current perception threshold (CPT) testing is unproven and not medically necessary.
Definitive conclusions for current perception threshold (CPT) testing cannot be drawn due to evidence that is inconsistent. Furthermore, in the absence of other testing, CPT tests do not include sensory nerve conduction amplitudes or other critical data to reach conclusions on diagnoses. Further research is needed to validate the clinical utility of pressure-specified sensory testing.

**Visual Evoked Potentials for Glaucoma**

**Visual evoked potential testing is unproven and not medically necessary for diagnosing and evaluating glaucoma.**

Visual evoked potentials (VEPs) show some promise as a tool for diagnosing glaucoma, but definitive conclusions cannot be drawn due to evidence that is limited and inconsistent. Evidence regarding the use of VEP testing for monitoring progression in patients at risk for glaucoma is too limited to allow evaluation of sensitivity or positive predictive value. VEP has not been shown to be as good or better than standard visual testing in managing patients with glaucoma.

This policy does not address intraoperative neurophysiologic testing.

### APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0106T</td>
<td>Quantitative sensory testing (QST), testing and interpretation per extremity; using touch pressure stimuli to assess large diameter sensation</td>
</tr>
<tr>
<td>0107T</td>
<td>Quantitative sensory testing (QST), testing and interpretation per extremity; using vibration stimuli to assess large diameter fiber sensation</td>
</tr>
<tr>
<td>0108T</td>
<td>Quantitative sensory testing (QST), testing and interpretation per extremity; using cooling stimuli to assess small nerve fiber sensation and hyperalgesia</td>
</tr>
<tr>
<td>0109T</td>
<td>Quantitative sensory testing (QST), testing and interpretation per extremity; using heat-pain stimuli to assess small nerve fiber sensation and hyperalgesia</td>
</tr>
<tr>
<td>0110T</td>
<td>Quantitative sensory testing (QST), testing and interpretation per extremity; using other stimuli to assess sensation</td>
</tr>
<tr>
<td>0464T</td>
<td>Visual evoked potential, testing for glaucoma, with interpretation and report</td>
</tr>
<tr>
<td>95860</td>
<td>Needle electromyography; 1 extremity with or without related paraspinal areas</td>
</tr>
<tr>
<td>95861</td>
<td>Needle electromyography; 2 extremities with or without related paraspinal areas</td>
</tr>
<tr>
<td>95863</td>
<td>Needle electromyography; 3 extremities with or without related paraspinal areas</td>
</tr>
<tr>
<td>95864</td>
<td>Needle electromyography; 4 extremities with or without related paraspinal areas</td>
</tr>
<tr>
<td>95865</td>
<td>Needle electromyography; larynx</td>
</tr>
<tr>
<td>95866</td>
<td>Needle electromyography; hemidiaphragm</td>
</tr>
<tr>
<td>95867</td>
<td>Needle electromyography; cranial nerve supplied muscle(s), unilateral</td>
</tr>
<tr>
<td>95868</td>
<td>Needle electromyography; cranial nerve supplied muscles, bilateral</td>
</tr>
<tr>
<td>95869</td>
<td>Needle electromyography; thoracic paraspinal muscles (excluding T1 or T12)</td>
</tr>
<tr>
<td>95870</td>
<td>Needle electromyography; limited study of muscles in 1 extremity or non-limb (axial) muscles (unilateral or bilateral), other than thoracic paraspinal, cranial nerve supplied muscles, or sphincters</td>
</tr>
<tr>
<td>95872</td>
<td>Needle electromyography using single fiber electrode, with quantitative measurement of jitter, blocking and/or fiber density, any/all sites of each muscle studied</td>
</tr>
<tr>
<td>95873</td>
<td>Electrical stimulation for guidance in conjunction with chemodenervation (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>95874</td>
<td>Needle electromyography for guidance in conjunction with chemodenervation (List separately in addition to code for primary procedure)</td>
</tr>
</tbody>
</table>
### Neurophysiologic Testing

**CPT Code** | **Description**  
--- | ---  
95885 | Needle electromyography, each extremity, with related paraspinal areas, when performed, done with nerve conduction, amplitude and latency/velocity study; limited (List separately in addition to code for primary procedure)  
95886 | Needle electromyography, each extremity, with related paraspinal areas, when performed, done with nerve conduction, amplitude and latency/velocity study; complete, five or more muscles studied, innervated by three or more nerves or four or more spinal levels(List separately in addition to code for primary procedure)  
95887 | Needle electromyography, non-extremity (cranial nerve supplied or axial) muscle(s) done with nerve conduction, amplitude and latency/velocity study (List separately in addition to code for primary procedure)  
95905 | Motor and/or sensory nerve conduction, using preconfigured electrode array(s), amplitude and latency/velocity study, each limb, includes F-wave study when performed, with interpretation and report  
95907 | Nerve conduction studies; 1-2 studies  
95908 | Nerve conduction studies; 3-4 studies  
95909 | Nerve conduction studies; 5-6 studies  
95910 | Nerve conduction studies; 7-8 studies  
95911 | Nerve conduction studies; 9-10 studies  
95912 | Nerve conduction studies; 11-12 studies  
95913 | Nerve conduction studies; 13 or more studies  
95937 | Neuromuscular junction testing (repetitive stimulation, paired stimuli), each nerve, any 1 method  
95999 | Unlisted neurological or neuromuscular diagnostic procedure  
96002 | Dynamic surface electromyography, during walking or other functional activities, 1-12 muscles  
96003 | Dynamic fine wire electromyography, during walking or other functional activities, 1 muscle  
96004 | Review and interpretation by physician or other qualified health care professional of comprehensive computer-based motion analysis, dynamic planar pressure measurements, dynamic surface electromyography during walking or other functional activities, and dynamic fine wire electromyography, with written report

**HCPCS Code** | **Description**  
--- | ---  
G0255 | Current perception threshold/sensory nerve conduction threshold test (sNCT), per limb, any nerve (Not covered by Medicare)  
S3900 | Surface electromyography (EMG)

### DESCRIPTION OF SERVICES

Neurophysiologic studies are used to evaluate patients with suspected or known central and peripheral nervous system disorders. This policy includes information on the following tests:

**Electromyography (EMG)**

EMG measures muscle response to electrical or nerve stimulation. The test is used to evaluate the function of individual nerves and muscles and has various applications in sports, ergonomics, rehabilitation, orthopedics, psychology, and neurology. Two main types of EMG exist: needle EMG (NEMG) and surface EMG (SEM). Surface electromyography (EMG) is a diagnostic technique in which electrodes are placed on the skin and used to measure the electrical activity of the underlying muscle in response to electrical or nerve stimulation. The surface electromyography (SEM) recordings, also referred to as the electromyogram, differ among patients and healthy persons and can potentially be used to detect impairments in nerve and/or muscle function. Paraspinal EMG is a type of surface EMG that is used to evaluate back pain. Needle electromyography requires insertion of needles through the patient’s skin and is helpful in determining whether muscle weakness results from an injury or a disorder in the nerves that control the muscles, the neuromuscular junction or the muscle itself.
Macrolelectromyography (macro-EMG) is an electrodiagnostic technique that is used to assess the size of the entire motor unit. It is performed by inserting a special type of needle into the muscle being studied.

**Nerve Conduction Studies (NCS)**

Nerve conduction studies are performed to assess the integrity and diagnose diseases of the peripheral nervous system. Specifically, they assess the speed (conduction velocity, and/or latency), size (amplitude), and shape of the response. In most circumstances, a properly performed electrodiagnostic (EDX) evaluation involves using both NCS and needle EMG. (AANEM, Proper Performance and Interpretation of Electrodiagnostic Studies, 2014)

Another type of NCS is late response testing (F wave and H-reflex testing). Late response studies are complementary to NCV and are performed during the same patient evaluation. In some cases, the late response may be the only abnormality (AANEM Recommended policy for electrodiagnostic medicine, 2014). The F-wave is a late response evoked by maximal stimulation during a motor nerve conduction study. The H-reflex is the electrophysiological component of the ankle reflex. The H-reflex is obtained from the calf muscle after stimulation of the posterior tibial nerve. In S-1 radiculopathy, the H-reflex is often absent or prolonged in latency. The H-reflex may also be recorded from other sites such as the quadriceps in the leg following femoral nerve stimulation and the flexor carpi radialis in the arm with median nerve stimulation.

The NC-stat is a non-invasive, automatic, portable nerve conduction monitoring system used for electrodiagnostic testing at the point of care setting. Other devices used for non-invasive nerve conduction measurement include the Brevio NCS-Monitor and the Advance System. A distinguishing feature of these devices is that they test distal motor latencies response amplitudes and conduction velocities but do not produce real time wave forms.

**Physiologic Recording of Tremor**

Physiologic recording of tremors using accelerometers and gyroscopes includes the use of devices such as Kinesia™ or Tremorometer™. Kinesia integrates accelerometers and gyroscopes in a compact patient-worn unit to capture kinematic movement disorder features. The Tremorometer is a physiologic recording system using accelerometers that generates precision tremor frequency and amplitude information. TremReport™ is a utility for generating comprehensive reports from tremor records and written interpretations. The current standard in evaluating Parkinson’s disease (PD) tremor is the Unified Parkinson's Disease Rating Scale (UPDRS), a qualitative ranking system typically completed during an office visit.

**Quantitative Sensory Testing (QST)**

QST is a testing method for objective assessments of peripheral sensory functions. QST usually evaluates the response to one particular stimulus, such as vibration, touch-pressure, heat or cold, and these tests are used to provide information about the function of specific types of nerve fibers. This type of testing includes monofilament stimuli like the Weinstein-Semmes filaments and computer assisted sensory examinations like the CASE IV, the Medoc systems, and the Vibratron or Biothesiometer. These tests have been used to detect and quantitate sensory deficits in diabetic ulcers and diabetic neuropathy in population bases studies and in drug treatment trials.

Two types of QST which use electrical current for stimulation of sensory axons are available. One is the current perception threshold (CPT) instrument (also called sensory nerve conduction threshold [sNCT] testing) and the other is the voltage actuated sensory nerve conduction threshold (V-sNCT) tests.

The pressure-specified sensory testing is another type of QST instrument and is used to assess nerve function by quantifying the sensory thresholds of skin by using with light quantifiable static, or moving cutaneous pressure stimuli. The NK Pressure-Specified Sensory Device is a pressure-specified sensory testing device that measures sensation using two rounded prongs that are pressed against the skin. The pressure of the stimuli is measured along with the patient’s response to the stimulus. The term sensory nerve conduction threshold (sNCT) tests should not be confused with the term motor and sensory nerve conduction studies (NCS), the latter type of tests include measurement of conduction velocity, onset latency and amplitude.

**Visual Evoked Potentials (VEPs) for Glaucoma**

VEPs measure the brain’s electrical response to a visual stimulus and can be used for neurological assessment of the visual system. Measurement of VEPs has been investigated as a method of diagnosing and monitoring glaucoma. Variations in VEP testing include multifocal VEP (mfVEP) testing, which allows assessment of many visual field locations independently and concurrently and produces a topographical representation of defects.

**Performance and Supervision of Testing**

The American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) recommends that needle EMG examination must be performed by a physician specially trained in electrodiagnostic (EDX) medicine, as these tests

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are simultaneously performed and interpreted. (AANEM Recommended policy for electrodiagnostic medicine, 2014; AANEM, Who is Qualified to Practice Electrodiagnostic Medicine? 1999. Updated and re-approved May 2012).

It is the AANEM’s position that EDX evaluations should be performed by a physician (a neurologist or physiatrist) who has special training in the diagnosis and treatment of neuromuscular diseases and in the application of neuropsychiologic techniques (AANEM, Who is Qualified to Practice Electrodiagnostic Medicine? 1999. Updated and re-approved May 2012). According to the AANEM, nerve conduction studies should be performed by a trained physician or a trained individual under direct supervision of a physician. Direct supervision indicates that the physician is in close physical proximity to the electrodiagnostic laboratory while testing is being done and is immediately available to provide assistance and direction (AANEM Recommended policy for electrodiagnostic medicine 2014).

Collection of the clinical and electrophysiologic data should be entirely under the supervision of the electrodiagnostic (EDX) physician. The physician may collect all of the data directly from the patient or may delegate collection of some data to a specifically trained technologist. Data collection may also be delegated to a physician in a residency training program related to neurology or physical medicine and rehabilitation or fellowship related to electrodiagnostic and/or neuromuscular medicine. In the case of NCSs and somatosensory evoked potential (SEP) testing, the EDX physician may be absent from the room when the procedure is performed but should be immediately available. Once the physician has determined the preliminary differential diagnosis on the basis of the patient’s history and examination, a technologist may perform the NCS and/or SEP tests selected by the physician. The physician should be alerted immediately during the testing if any results appear to be unusual or unexpected, so that there is opportunity to reassess the differential diagnosis and develop alternative testing strategies. The patient should remain in the room until the supervising EDX physician has reviewed NCS and diagnostic SEP results. SEPs are also frequently performed for preoperative baselines or prognosis after nerve trauma; those results can be reviewed by the physician at a later time (AANEM, Technologists Conducting Nerve Conduction Studies and Somatosensory Evoked Potential Studies Independently to be Reviewed by a Physician at a Later Time, 2009, modified November 2014).

### CLINICAL EVIDENCE

#### Surface Electromyography (SEMG)

**SEMG Used for Chronic Back Pain**

In a meta-analysis, Geisser et al. (2005) evaluated diagnostic performance of SEMG for low back pain among 44 studies that were published during the years 1988 to 2002. The mean sensitivity and specificity was 39.6% and 90.8% for static SEMG, 88.8% and 81.3% for dynamic SEMG, and 84.4% and 89.8% for static SEMG during isometric exertion, respectively. While SEMG could differentiate between patients with low back pain and healthy persons, effect sizes were small to moderate and sensitivity and specificity were poor to fair for all types of SEMG and varied considerably among studies.

In a retrospective study of consecutive patients, Hu et al. (2014) evaluated the prognostic value of quantitative surface electromyography (SEMG) for identifying patients with chronic low back pain (LBP) who may have a better response toward a rehabilitation program. The study included thirty-eight patients with chronic nonspecific LBP and 43 healthy subjects. Patients who suffered from chronic nonspecific LBP without the history of back surgery and any medical conditions causing acute exacerbation of LBP during the clinical test were enlisted to perform the clinical test during the 12-week physiotherapy (PT) treatment. Low back pain patients were classified into two groups: "responding" and "non-responding" based on the clinical assessment. The responding group referred to the LBP patients who began to recover after the PT treatment, whereas the non-responding group referred to some LBP patients who did not recover or got worse after the treatment. According to the authors, the discrepancies in quantitative dynamic sEMG topography of LBP group from normal group were able to identify those LBP subjects who would respond to a conservative rehabilitation program focused on functional restoration of lumbar muscle. The limitations of this study include non-randomization and small sample size.

Ritvanen et al. (2007) compared the dynamic surface electromyographic (SEMG) activities of back muscles and pain before and after traditional bone setting and physical therapy in 61 patients. The study failed to show a significant association between experienced low back pain and SEMG parameters.

**SEMG Used for Other Conditions**

Wang et al. (2016) performed a systematic review and meta-analysis of the published literature on the effect of surface electromyography (SEMG) as a measure of trunk muscle activity in patients with spinal cord injury (SCI). Eleven case-control, cohort, and cross-sectional studies were included in the review. Trunk muscle activities for the sitting condition were greater in patients with SCI than normal subjects. SEMG activity of trunk muscles for the sitting condition and posterior transfer was greater in patients with high level (HL)-SCI compared to those with low level (LL)-SCI. In addition, across studies, the level of trunk muscle activity for various difficulty settings was different for a given SCI group. According to the authors, this systematic review evaluated the value of trunk muscles for patients with SCI. There is no evidence from this study that this information will affect patient management.
Berni et al. (2015) evaluated the accuracy of surface electromyography (sEMG) activity in the diagnosis of temporomandibular disorder (TMD). One hundred twenty-three volunteers were evaluated using the Research Diagnostic Criteria for Temporomandibular Disorders and placed into two groups: women with myogenous TMD (n=80) and women without TMD (n=43). The volunteers were then submitted to sEMG evaluation of the anterior temporalis, masseter and suprahyoid muscles at rest and during maximum voluntary teeth clenching (MVC) on parafilm. The accuracy, sensitivity and specificity of the muscle activity were analyzed. Differences between groups were found in all muscles analyzed at rest as well as in the masseter and suprahyoid muscles during MVC on parafilm. Moderate accuracy of the root mean square (RMS) sEMG was found in all muscles regarding the diagnosis of TMD at rest and in the suprahyoid muscles during MVC on parafilm. Sensitivity ranged from 71.3% to 80% and specificity from 60.5% to 76.6%. In contrast, RMS sEMG did not exhibit acceptable degrees of accuracy in the other masticatory muscles during MVC on parafilm. According to the authors, sEMG activity of the masticatory muscles at rest and the suprahyoid muscles during MVC on parafilm demonstrated a moderate degree of accuracy for the diagnosis of myogenous TMD and should be used as a complementary tool in the diagnosis of this disorder as well as during the treatment follow up. The authors also indicated that the diagnosis by RMS sEMG is limited, as the specificity and sensitivity ranged from 60% to 80%, an ideal diagnostic test should have accuracy ranging from 0.9 to 1.0 as well as specificity and sensitivity close to 100%.

Archer et al. (2013) evaluated if measurement of SEMG activity during swallowing would distinguish between preserved and disordered swallow function in Duchenne muscular dystrophy (DMD). This comparative study investigated the peak, duration, and relative timing of muscle activity during swallowing. The study included three groups of participants: nine DMD patients with dysphagia, six DMD patients with preserved swallow function, and 12 healthy controls. Dysphagic DMD participants produced significantly higher normalized peak amplitude measurements than the healthy control group for masseter (61.77 vs. 5.07) and orbicularis oris muscles (71.87 vs. 26.22). Intra-subject variability for masseter peak amplitude was significantly greater for dysphagic DMD participants than the other groups. Different characteristic SEMG waveforms were observed for the three groups. According to the authors, SEMG provides useful physiological information for the evaluation of swallowing in DMD patients, justifying further study. Further research is needed to determine the clinical relevance of these findings.

Manfredini et al. (2011) assessed the diagnostic accuracy of commercially available surface electromyography (sEMG) and kinesiography (KG) devices for myofascial pain of jaw muscles. Thirty-six consecutive patients with diagnostic criteria for temporomandibular disorders (TMD) axis I diagnosis of myofascial pain and an age- and sex-matched group of 36 TMD-free asymptomatic subjects underwent sEMG and KG assessments. Receiver operating characteristics curve analysis showed that for most outcomes, sEMG and KG measures did not reach acceptable levels of sensitivity and specificity, with a 30-68-9% percentage of false-positive results. According to the authors, clinicians should not use sEMG and KG devices as diagnostic tools for individual patients who might have myofascial pain in the jaw muscles. Whether intended as a stand-alone measurement or as an adjunct to making clinical decisions, such instruments do not meet the standard of reliability and validity required for such usage.

**Professional Societies**

**American Academy of Neurology (AAN)**

The AAN considers the use of SEMG as unacceptable for the diagnosis of neuromuscular disease and low back pain. However, SEMG is an acceptable modality for kinesiologic analysis of movement disorders; for differentiating types of tremors, myoclonus, and dystonia; for evaluating gait and posture disturbances; and for evaluating psychophysical measures of reaction and movement time (based on Class III data - evidence provided by expert opinion, nonrandomized historical controls, or observation(s) from case series) (Pullman et al., 2000).

**American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM)**

According to an AANEM practice topic titled, Use of Surface Electromyography in the Diagnosis and Study of Neuromuscular Disorders, the data are insufficient to determine the clinical utility of surface electromyography (sEMG) for distinguishing between neuropathic and myopathic conditions or for detecting the more specific neuromuscular conditions of post-poliomyelitis syndrome, pathologic fasciculations, acquired demyelinating peripheral neuropathy, amyotrophic lateral sclerosis, myotonic dystrophy, and hypokalemic periodic paralysis (level U - data inadequate or conflicting). The AANEM states that on the basis of two class III studies, sEMG may be useful to detect the presence of neuromuscular disease (level C - possibly effective, ineffective, or harmful for the given condition in the specified population. Level C rating requires at least one class II study or two consistent class III studies) (Meekins, 2008).

**Macrolelectromyography (Macro-EMG) Testing**

A small number of studies have evaluated the use of macro-EMG. Lange et al. (1989) used quantitative motor unit potential analysis, single-fiber electromyography, and macrolelectromyography (macro-EMG) to determine if these techniques could identify weakening muscles. They classified 18 previously affected muscles according to strength from 12 patients who had had poliomyelitis 18 to 50 years earlier and concluded that low-amplitude macro-EMG signals may be useful in the identification of muscles weakened by postpolio muscular atrophy.
Sartucci et al. (2011) assessed changes in Motor Units (MU) and extent of MU loss using macro-electromyography (macro-EMG) and Motor Unit Number Estimation (MUNE) in 61 Amyotrophic Lateral Sclerosis (ALS) patients. Macro-EMG increased and fiber density decreased after 8 months of tracking the disease course. The authors concluded that combined use of macro-EMG and MUNE techniques in ALS patients allows the tracking of changes in muscle MU features and number in face of progressive anterior horn cells death over time during disease’s evolution. However, it is not clear how this information will affect patient management.

**Nerve Conduction Studies (NCS)**

The use of nerve conduction studies including F-wave and H-reflex tests for the diagnosis of early stage polyneuropathies and proximal nerve lesions is confirmed in several reviews and studies (Galamb et al., 2015; MacCabee et al., 2011; Trujillo-Hernandez et al., 2005; Bal et al., 2006).

Nerve conduction studies are indicated for the following conditions: peripheral nerve entrapment (Omejec, 2014; Park, 2014; Calfee, 2012; Kwon, 2008); generalized neuropathies (Holiner, 2013; Derr, 2009, Dyck, 2010, De Sousa, 2009); polyneuropathies (de Souza, 2015; Torvin Moller, 2009); plexopathy (Mulins, 2007); neuromuscular junction disorders (Meriggioi, 2005); myopathies including polymyositis, dermatomyositis, and congenital myopathies (Wang, 2010); motor neuron disease (Hammad, 2007); spine disorders and radiculopathy (Pawar, 2013; Alrawi, 2007; Haig, 2006); and guidance for botulinum toxin injection for spasmodic dysphonia or segmental dystonia, when it is difficult to isolate affected muscles (Molloy, 2002).

Balbierz et al. (1998) investigated whether needle evaluation added any important clinical information to normal nerve conduction studies in the evaluation of carpal tunnel syndromes in a retrospective review. The investigators determined whether needle examination was abnormal when nerve conduction studies were normal. In patients in whom only carpal tunnel syndrome was suspected, normal nerve conduction studies predicted that EMG would be normal 89.8% of the time. Testing based on a larger sample size might increase the predictive value. According to the investigators, there may be a subpopulation of patients referred for carpal tunnel syndrome who may be adequately evaluated by nerve conduction studies alone.

Wee (2002) evaluated if needle EMG examination of the thenar muscles could provide useful information in addition to the nerve conduction (NC) studies. Electrophysiologic procedures performed on 84 patients (103 hands) consistent with carpal tunnel syndrome (CTS) were reviewed. The median thenar motor NC data were matched with the needle EMG findings in the abductor pollicis brevis (APB) muscle. The severity of the needle EMG findings in the APB muscle correlated well with the severity of the motor NC data. As the thenar compound muscle action potential amplitude decreased and the degree of nerve conduction slowing and block across the wrist increased, there was a corresponding increase in the number of enlarged motor units and decrease in the recruitment pattern in the needle EMG findings. According to the investigators, needle EMG examination confined to the thenar muscles in CTS does not provide any further information when the NC data had already established this diagnosis, and it should not be performed routinely.

Shon et al. (2011) used a nationally representative sample of Medicare beneficiaries with diabetes who used electrodagnostic services (most commonly nerve conduction studies and EMG) to examine whether specialists and non-specialists were different in the rates of identifying common neuromuscular conditions. Specialists (neurologists and physiatrists) performed 62% of electrodagnostic consultations; non-specialist physicians and non-physicians performed 31% and 5%, respectively. After adjusting for age, race/ethnicity, diabetes severity, and comorbidities, specialists were 1.26-9 times more likely than non-physicians to diagnose polyneuropathy, lumbosacral radiculopathy, cervical radiculopathy, carpal tunnel syndrome, and ulnar neuropathy. Almost 80% of electrodagnostic studies performed by specialists included electromyography testing; fewer than 13% by non-specialists did. The authors concluded that inadequate use of electromyography and fewer specific diagnoses suggest that many non-specialists perform insufficiently comprehensive electrodagnostic studies.

**Point of Care Nerve Conduction Tests**

The results of preliminary studies for automatic or portable nerve conduction monitoring systems are promising; however the studies are primarily small case series comparing portable with conventional nerve conduction studies or clinical examination in the same patient (Chatzikosma et al., 2016; Dale et al., 2015; Fisher, 2008; Perkins, 2008; Armstrong, 2008).

Sharma et al. (2015) evaluated a point-of-care nerve conduction device (POCD; NC-stat® | DPNCheck™) for the assessment of diabetes polyneuropathy (DPN) and diabetes compared it with the LDIFLARE technique-which uses a laser-Doppler-imager for early detection of small fibre dysfunction. A total of 162 patients with diabetes (DM) and 80 healthy controls (HC) were recruited. Based on the 10-point Neuropathy Disability Score (NDS), (DPN) was categorized into none (<2), mild (3-5) moderate (6-7), and severe (8-10). The associations between POCD outcomes and the LDIFLARE within the NDS categories were evaluated using regression analysis. In HC and DM, SNCV measured with the POCD correlated significantly with the LDIFLARE technique; in addition, significance was found in
all categories of DPN. ROC curves within each category of DPN showed that the POCD was sensitive in the assessment of DPN. The authors concluded that the NC-stat®DPNCheck™ system appears to be an excellent adjunctive diagnostic tool for diagnosing DPN in the clinical setting. According to the authors, the NC-stat® may be limited because it is dependent on the presence of an accessible sural nerve which can be anatomically absent in up to 9% of healthy subjects. This study was limited because the sample size was too small to draw clear conclusions.

Bourke et al. (2011) investigated the use of a clinic-based, handheld, non-invasive electrophysiological device (NC-stat®) in 71 patients with suspected carpal tunnel syndrome. These patients were compared to a similar cohort of 71 age-matched patients in whom formal nerve conduction studies were performed at a local neurophysiology unit. Outcome measures were time from presentation to carpal tunnel decompression, the cost of each pathway and the practicalities of using the device in a busy hand unit. According to the authors, the NC-stat® proved to be a successful device when compared with referring patients out for more formal nerve conduction studies, shortening the time from presentation to surgery from 198 days to 102 days. These findings need confirmation in a larger study.

Katz (2006) conducted a study to establish a normal data set for median nerve studies in industrial workers using NC-stat technology. Sixteen hundred ninety-five persons applying for employment at a single heavy industry plant without symptoms of carpal tunnel syndrome (CTS) were studied. Based on the results of the study, the investigators concluded that NC-stat technology using distal motor latency (DML) appears to be no more sensitive or specific than a traditionally performed DML for the diagnosis of carpal tunnel syndrome (CTS). Until sensory studies using NC-stat technology are better defined, this technology cannot be recommended for screening or diagnosis of CTS in an industrial population.

Tan et al. (2012) assessed the clinical impact of replacing standard neurophysiologic testing with a hand-held device (Mediracer) for diagnosis of carpal tunnel syndrome (CTS). One hundred patients (200 hands) with suspected CTS were studied by blinded assessors [Hand-therapist (HT1) and Consultant Neurophysiologist] using the Mediracer, followed by standard neurophysiologic testing. To simulate testing by personnel without neurological training, Mediracer recordings were analyzed separately by an assessor who had not seen the patients (HT2). Correlation of the CTS grades was 0.94 for the results obtained by HT1, and 0.87 for HT2. The sensitivity and specificity of the Mediracer was 0.85 and 0.9, respectively, by HT1, and 0.84 and 0.89 for HT2. Nine patients had conditions other than CTS, and 35 patients were judged to require further investigation. The authors concluded that the Mediracer should only be used in patients with typical CTS symptoms and signs and no muscle wasting who have had careful neurological assessment. These findings need confirmation in a larger randomized controlled trial.

Schmidt et al. (2011) compared the specificity and sensitivity of a hand-held nerve conduction study (NCS) device for the detection of lumbosacral radiculopathy (LSR) with standard electrodiagnostic study (EDX). Fifty patients referred to a tertiary referral electromyography (EMG) laboratory for testing of predominantly unilateral leg symptoms (weakness, sensory complaints, and/or pain) were included in the investigation. Twenty-five normal "control" subjects were later recruited to calculate the specificity of the automated protocol. All patients underwent standard EDX and automated testing. Raw NCS data were comparable for both techniques; however, computer-generated interpretations delivered by the automated device showed high sensitivity with low specificity (i.e., many false positives) in both symptomatic patients and normal controls. The authors concluded that the automated device accurately recorded raw data, but the interpretations provided were overly sensitive and lacked the specificity necessary for a screening or diagnostic examination.

**Professional Societies**

**American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM)**

The AANEM recommends that a typical examination performed for nerve conduction studies (NCSs) include:
- Development of a differential diagnosis based upon appropriate history and physical examination,
- Nerve conduction studies of a number of nerves by recording and studying the electrical responses from peripheral nerves or the muscles they innervate,
- The completion of indicated needle EMG studies to evaluate the differential diagnosis and to complement the nerve conduction study.

The minimum standards for NCV testing are as follows:
- The testing is medically indicated.
- It is performed using equipment that provides assessment of all parameters of the recorded signals (equipment designed for screening purposes is not acceptable).
- The test is performed by a physician, or by a trained technician under the direct supervision of a physician.
- The EMG must be performed by a trained physician.
- One physician supervises and performs all components of the exam.

(AANEM recommended policy for electrodiagnostic medicine, 2014)
A task force of the AANEM (Charles Cho et al. 2010) evaluated the evidence and made recommendations regarding the use of electrodiagnostic (EDX) testing of patients with suspected lumbosacral radiculopathy. The task force concluded the following:

- In patients with suspected lumbosacral radiculopathy, the following EDX studies probably aid the clinical diagnosis:
  - Peripheral limb EMG (Class II evidence, Level B (probably effective) recommendation).
  - Paraspinal mapping (PM) with needle EMG in lumbar radiculopathy (Class II evidence, Level B recommendation).
  - H-reflex in S1 radiculopathy (Class II and III evidence, Level C (possibly effective) recommendation).
- Evidence suggests a low sensitivity of peroneal and posterior tibial F-waves (Class II and III evidence, Level C recommendation).
- There is inadequate evidence to reach a conclusion on the utility of the following EDX studies:
  - Dermatomal/segmental somatosensory evoked potentials (SEP) of the L5 or S1 dermatomes (Class III evidence, Level C recommendation).
  - Paraspinal mapping (PM) with needle EMG in sacral radiculopathy (one small Class II study, Level U (data inadequate or conflicting).
  - Motor evoked potential (MEP) with root stimulation in making an independent diagnosis of lumbosacral radiculopathy (Class III evidence, Level U).

The position statement of the AANEM regarding the performance and interpretation of electrodiagnostic studies states that the performance of or interpretation of NCS separately from the needle EMG component of the testing should clearly be the exception. The AANEM states that when NCSs are performed without needle EMG, the additional and complementary information provided by the needle EMG results (except in limited circumstances) is not available. Without the information provided by the needle EMG examination, valuable data that may be essential in establishing an accurate diagnosis is missing. For example, performing both studies together is critically important when evaluating patients with suspected radiculopathy, plexopathy, and motor nerve or motor neuron disease. According to the AANEM, NCS and EMG may be performed for carpal tunnel syndrome to ensure that an underlying medical condition is not missed (AANEM, Proper performance and interpretation of electrodiagnostic studies, 2014).

A 2002 practice parameter for electrodiagnostic studies in carpal tunnel syndrome developed by the AANEM, American Academy of Neurology, and the American Academy of Physical Medicine and Rehabilitation, lists NCS as a standard diagnostic test for carpal tunnel syndrome and NEMG as an optional test for diagnosing carpal tunnel syndrome (Jablecki et al., 2002).

A 2005 AANEM practice guideline for usefulness of electrodiagnostic techniques in the evaluation of suspected tarsal tunnel syndrome recommends NCS for confirming the presence of tarsal tunnel syndrome. The guideline states that the utility of needle EMG in the assessment of tarsal tunnel syndrome is unclear (Patel et al., 2005).

A 2005 AANEM practice parameter for utility of electrodiagnostic techniques in evaluating patients with suspected peroneal neuropathy states that NCSs are possibly useful to make or confirm the diagnosis of suspected peroneal neuropathy. The guideline indicates that the data are insufficient to determine the role of needle EMG in making the diagnosis of peroneal neuropathy (Marciniak et al., 2005).

A 1999 practice parameter for electrodiagnostic studies in ulnar neuropathy at the elbow by the AANEM, American Academy of Neurology, and American Academy of Physical Medicine and Rehabilitation, states that ulnar sensory and motor NCSs should be performed with surface stimulation and recordings for patients with suspected ulnar neuropathy at the elbow. The guideline also states that depending on the results of NCSs, needle EMG may be indicated (AANEM practice parameter for electrodiagnostic studies in ulnar neuropathy at the elbow: summary statement, 1999; Reaffirmed on October 18, 2003, July 28, 2006, and February 5, 2010).

In a policy for electrodiagnostic medicine, the AANEM recommends that a typical EMG examination includes all of the following: development of a differential diagnosis based upon appropriate history and physical examination, completion of indicated nerve conduction studies (recording and studying of electrical responses from peripheral nerves or muscles), and the completion of indicated needle EMG studies for selected muscles. The needle EMG studies are interpreted in real time as they are being performed. In addition, the AANEM recommends that one attending physician perform and supervise all components of the electrodiagnostic testing and that the testing occur on the same day. Reporting NCS and EMG results into separate reports is inappropriate and would be an exception to clinical practice (AANEM Recommended Policy for Electrodiagnostic Medicine, 2014).

Based on the literature, the AANEM's position is that there are no contraindications to EMG in patients with lymphedema. However, the AANEM believes that reasonable caution should be taken in performing needle examinations in lymphedematous regions to avoid complications. Clinical judgment should be used in deciding whether the risk of complication is greater than the value of the information to be obtained from the EMG (AANEM, Needle EMG in certain uncommon clinical contexts, 2005).
According to the AANEM, nerve conduction studies may be performed without needle electromyography in patients on anticoagulants, patients who have lymphedema, or patients who are being evaluated for carpal tunnel syndrome. (AANEM, Needle EMG in certain uncommon clinical contexts, 2005; Jablecki et al., 2002)

According to a literature review prepared for the AANEM, the Nervepace Digital Electroneurometer (NDE) is experimental and is not an effective substitute for standard electrodiagnostic studies in clinical evaluation of patients with suspected carpal tunnel syndrome (David, 2003).

According to a model policy for needle electromyography and nerve conduction studies developed by AANEM, electrodiagnostic testing is indicated for the following:
- Focal neuropathies, entrapment neuropathies, or compressive lesions/syndromes such as carpal tunnel syndrome, ulnar neuropathies, or root lesions, for localization
- Traumatic nerve lesions, for diagnosis and prognosis
- Generalized neuropathies, such as diabetic, uremic, metabolic, toxic, hereditary, or immune-mediated
- Neuromuscular junction disorders such as myasthenia gravis, myasthenic syndrome or botulism
- Symptom-based presentations such as "pain in limb," weakness, disturbance in skin sensation or "paraesthesia" when appropriate pre-test evaluations are inconclusive and the clinical assessment unequivocally supports the need for the study
- Radiculopathy-cervical, lumbosacral
- Plexopathy-idiopathic, trauma, inflammatory or infiltrative
- Myopathy-including polymyositis and dermatomyositis, myotonic disorders, and congenital myopathies
- Precise muscle location for injections such as botulinum toxin, phenol, etc.
(American Association of Neuromuscular and Electrodiagnostic Medicine Model Policy for Needle Electromyography and Nerve Conduction Studies Updated January 2016)

American Academy of Orthopaedic Surgeons (AAOS)
The AAOS Clinical Practice Guideline on the management of carpal tunnel syndrome states that limited evidence supports the use of a hand-held nerve conduction study (NCS) device for the diagnosis of carpal tunnel syndrome (AAOS 2016).

Physiologic Recording of Tremor
Heldman et al. (2014) evaluated the reliability and responsiveness of a portable kinematic system for quantifying Parkinson’s disease (PD) motor deficits as compared to clinical ratings. Eighteen PD patients with subthalamic nucleus deep-brain stimulation (DBS) performed three tasks for evaluating resting tremor, postural tremor, and finger-tapping speed, amplitude, and rhythm while wearing a wireless motion-sensor unit (Kinesia) on the more-affected index finger. These tasks were repeated three times with DBS turned off and at each of 10 different stimulation amplitudes chosen to yield small changes in treatment response. Each task performance was video-recorded for subsequent clinician rating in blinded, randomized order. Test-retest reliability was calculated as intraclass correlation (ICC) and sensitivity was calculated as minimal detectable change (MDC) for each DBS amplitude. ICCs for Kinesia were significantly higher than those for clinician ratings of finger-tapping speed, amplitude, and rhythm, but were not significantly different for evaluations of resting or postural tremor. Similarly, Kinesia scores yielded a lower MDC as compared with clinician scores across all finger-tapping sub-scores, but did not differ significantly for resting and postural tremor. The authors concluded that the Kinesia portable kinematic system can provide greater test-retest reliability and sensitivity to change than conventional clinical ratings for measuring bradykinesia, hypokinesia, and dysrhythmia in PD patients. The study did not confirm the utility of such findings in improving care and outcome of patients.

Scanlon et al. (2013) investigated the properties of oscillatory movement, at rest and in posture, in both the upper and lower limbs of Parkinson’s disease (PD) patients with clinically undetectable to modest rest/postural tremor and healthy controls. PD patients (N=16) and controls (N=8) were examined clinically by a movement disorders specialist and oscillatory movements in all four extremities by using a portable biaxial accelerometer. While tremor intensity and frequency did not differ between groups, the intraindividual variability of rest and postural tremor frequency in the dexterity-dominant lower limb was lower in people with PD than in healthy adults. Additionally, rest tremor frequency was discrepant between upper and lower limbs in PD. According to the authors, this introduces the possibility that minute variations in lower limb movements, which are imperceptible upon clinical exam, can be used to differentiate a diseased sample from a healthy one. More research is needed to evaluate the validity and clinical utility of tremor measurement.

Quantitative Sensory Testing
In a systematic review, Hirschfeld et al. (2014) summarized the findings with regard to the diagnostic accuracy of the Semmes-Weinstein monofilament and the Rydel-Seiffer tuning fork in detecting diabetic peripheral neuropathies (DPN) in children and adolescents compared with the gold standard nerve conduction studies. A total of 72 articles were
identified for review. Studies were included that: (1) assessed DPN with the gold standard nerve conduction studies; (2) used noninvasive screening for DPN (monofilament, tuning fork, or biothesiometer); and (3) were performed in the relevant population (children with diabetes). Five articles met these criteria. Study quality was assessed by using the revised Quality Assessment of Diagnostic Accuracy Studies criteria. Heterogeneous methods precluded a formal meta-analysis of effects. Diagnostic accuracies were heterogeneous for the different screening methods. Sensitivities ranged from 1% to 19% for the tuning fork (3 studies); from 61% to 80% for the biothesiometer (2 studies); and from 19% to 73% for the monofilament (2 studies). The authors concluded that data show extremely low diagnostic utility for standard screening methods (tuning fork and 10-g monofilament) but acceptable utilities for biothesiometry and finer (1 g) monofilaments. According to the authors, these noninvasive methods have low sensitivity and are therefore often not able to detect nerve complications.

Katz et al. (2015) conducted a systematic review of clinical studies to evaluate the use of quantitative sensory testing methods to detect hyperalgesia in chronic pain patients on long-term opioids. Fourteen articles were included in the review; there was one randomized controlled trial, one prospective controlled study, three prospective uncontrolled studies, and nine cross-sectional observation studies. Hyperalgesia measurement paradigms used included cold pain, heat pain, pressure pain, electrical pain, ischemic pain, and injection pain. Although none of the stimuli were capable of detecting patients’ hyperalgesia, heat pain sensitivity showed some promising results. The authors concluded that none of the quantitative sensory testing methods reviewed met the criteria of a definitive standard for the measurement of hyperalgesia. According to the authors, additional studies that use improved study design should be conducted.

Hubscher et al. (2013) conducted a systematic review that examined the relationship between QST and self-reported pain and disability in patients with spinal pain. One hundred and forty-five effect sizes from 40 studies were included in the meta-analysis. The authors found low or no correlation between pain thresholds, as assessed by QST and self-reported pain intensity or disability. This finding suggests low accuracy of QST for diagnosing level of spinal pain and disability.

In a systematic review, Grosen et al. (2013) assessed the role of quantitative sensory testing (QST) in prediction of analgesic effects in healthy volunteers, surgical patients and patients with chronic pain. Fourteen studies (including 720 individuals) met the inclusion criteria. Significant correlations were observed between responses to analgesics and several QST parameters including (1) heat pain threshold in experimental human pain, (2) electrical and heat pain thresholds, pressure pain tolerance and suprathreshold heat pain in surgical patients, and (3) electrical and heat pain threshold and conditioned pain modulation in patients with chronic pain. According to the authors, although it is promising, the current evidence is not sufficiently robust to recommend the use of any specific QST parameter in predicting analgesic response.

Moloney et al. (2012) systematically searched the literature using key medical databases to assess the reliability of thermal QST. Of the 21 studies included in this review, 5 were considered to have high methodological quality. Narrative analysis revealed that estimates of reliability varied considerably, but overall, the reliability of cold and warm detection thresholds ranged from poor to excellent, while heat and cold pain thresholds ranged from fair to excellent. According to the authors, the methodological quality of research investigating the reliability of thermal QST warrants improvement, particularly in terms of appropriate blinding. The authors concluded that the results from this review showed considerable variability in the reliability of each thermal QST parameter.

Suokas et al. (2012) systematically reviewed the use of quantitative sensory testing (QST) in pain characterization in osteoarthritis (OA). Of 20 studies comparing people with OA and healthy controls, seven provided sufficient information for meta-analysis. Compared with controls, people with OA had lower pressure pain thresholds (PPTs) both at the affected joint and at remote sites. The authors concluded that QST of PPTs demonstrated good ability to differentiate between people with OA and healthy controls. The authors stated that more research is needed to determine the clinical utility of QST.

Dros et al. (2009) conducted a systematic review of studies in which the accuracy of monofilament testing was evaluated to detect peripheral neuropathy of any cause using nerve conduction as reference standard. Methodological quality was assessed using the Quality Assessment of Diagnostic Accuracy Studies (QUADAS) tool. The investigators identified 54 potentially eligible studies, of which 3 were finally selected for data synthesis. All studies were limited to patients with diabetes mellitus and showed limitations according to the QUADAS tool. Sensitivity ranged from 41% to 93% and specificity ranged from 68% to 100%. Because of the heterogenous nature of the studies, a meta-analysis could not be accomplished. According to the investigators, despite the frequent use of monofilament testing, little can be said about the test accuracy for detecting neuropathy in feet without visible ulcers. Optimal test application and defining a threshold should have priority in evaluating monofilament testing, as this test is advocated in many clinical guidelines. Accordingly, the investigators do not recommend the sole use of monofilament testing to diagnose peripheral neuropathy.
Cettomai et al. (2013) investigated the utility of screening tools administered by non-physician healthcare workers (HCW) and quantitative sensory testing (QST) administered by trained individuals for identification of moderate/severe neuropathy. The study included 240 HIV-infected outpatients using 2-stage cluster randomized sampling. HCWs administered several screening tools. Tools were validated against a clinical diagnosis of neuropathy. Sixty-five percent of the participants were taking antiretrovirals, and 18% had moderate/severe neuropathy. The screening tests were 76% sensitive in diagnosing moderate/severe neuropathy with negative predictive values of 84-92%. QST was less sensitive but more specific. The authors concluded that QST showed promise for research use.

Yildirim and Gunduz (2015) investigated the ability of Semmes-Weinstein Monofilament testing to detect carpal tunnel syndrome, as well as moderate-to-severe carpal tunnel syndrome using varying thresholds and methods. Clinical and electrophysiological data of 62 patients (124 hands) with a mean age of 49.09±10.5 years were evaluated in this study. The criteria of 2.83-conventional method yielded a sensitivity of 98% and a specificity of 17% in the diagnosis of carpal tunnel syndrome. The threshold value of 3.22 using a conventional method was found to detect moderate-to-severe carpal tunnel syndrome with high sensitivity (80%) and excellent specificity (93%). A statistically significant difference was observed in the mean strength values of the monofilaments in moderate-to-severe carpal tunnel syndrome hands and hands without carpal tunnel syndrome. The authors concluded that Semmes-Weinstein monofilament testing might be a valuable quantitative method for detecting moderate-to-severe carpal tunnel syndrome. According to the authors, future studies with a larger sample size, as well as further analyses of different threshold abnormalities of moderate-to-severe CTS hands, are needed.

Mythili et al. (2010) evaluated the discriminative power of the Diabetic Neuropathy Examination Score (DNE), 10-g Semmes-Weinstein Monofilament Examination (SWME) and Quantitative Sensory Testing by Vibration Perception Threshold (VPT) in the diagnosis of diabetic polyneuropathy and sought an optimal screening method in 100 consecutive patients with Type 2 diabetes. Sensitivity and specificity for the DNE, SWME and VPT were calculated, taking NCS as gold standard. Seventy one of 100 subjects had evidence of neuropathy confirmed by nerve conduction studies, while 29 did not have neuropathy. The DNE score gave a sensitivity of 83% and a specificity of 79%. The sensitivity of SWME was 98.5% and specificity was 55%. Vibration Perception Thresholds yielded a sensitivity of 86% and a specificity of 76%. The investigators concluded that a simple neurological examination score is as good as Vibration Perception threshold in evaluation of polyneuropathy in a diabetic clinic.

According to a National Institute for Health and Care Excellence (NICE) Guidance for VibraTip for testing vibration perception to detect diabetic peripheral neuropathy, the current evidence does not support the case for routine adoption of this device (NICE 2014, updated March 2015).

**Visual Evoked Potentials for Glaucoma**

In a prospective study, Fuest et al. (2015) compared changes in Blue-yellow short wavelength testing (BY-VEPs) and standard pattern visual evoked potentials (VEPs) in phakic and pseudophakic glaucoma patients and controls. The eyes of 57 healthy controls (18 pseudophakic and 39 phakic) and 67 glaucoma patients (29 pseudophakic and 38 phakic) were included in the study. Phakic eyes were arranged in three groups according to the Lens Opacities Classification System III. Transient on/off isoluminant blue-yellow 2° checks were used for BY-VEPs, transient large 1° (M1) and small 0.25° (M2) black-white checks for standard pattern reversal VEPs, according to the ISCEV standards. Latencies and amplitudes of M1 and M2 did not differ significantly between groups or lens status. ANOVA analysis revealed significantly longer BY-VEP latencies in glaucoma compared to controls, independently of the lens status. The amplitudes showed no such pattern. Mean defect (MD) was significantly negatively correlated to BY-VEP latency only in pseudophakic glaucoma patients. Different stages of cataract did not show a significant effect on the BY-VEP latencies. The authors concluded that glaucoma led to a significant increase of BY-VEP latencies, while standard pattern VEPs were not influenced. The correlation of MD and BY-VEP latency only in pseudophakic glaucoma patients indicates a substantial confounding effect of lens opacifications on the diagnostic value of BY-VEPs in glaucoma. There is no evidence from this study that this information will affect patient management.

Mousa et al. (2014) evaluated the validity of multifocal visual evoked potential (mfVEP) and whether it could be used effectively for early detection of visual field defects in glaucoma. Three groups were tested; normal controls (38 eyes), glaucoma patients (36 eyes) and glaucoma suspect patients (38 eyes). All subjects had a two standard Humphrey field analyzer (HFA) test 24-2 and a single mfVEP test undertaken in one session. Analysis of the mfVEP results was done using a new analysis protocol: the hemifield sector analysis (HSA) protocol. Analysis of the HFA was done using the standard grading system. Analysis of mfVEP results showed that there was a statistically significant difference between the three groups in the mean signal to noise ratio. Sensitivity and specificity of the HSA protocol in detecting glaucoma was 97% and 86%, respectively, and for glaucoma suspect patients the values were 89% and 79%, respectively. According to the authors, the new HSA protocol used in the mfVEP testing can be applied to detect glaucomatous visual field defects in both glaucoma and glaucoma suspect patients. Using this protocol can provide information about focal visual field differences across the horizontal midline, which can be utilized to differentiate between glaucoma and normal subjects. The authors indicated that the sensitivity and specificity of the mfVEP test showed very promising results and correlated with other anatomical changes in glaucoma field loss. According to the

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authors, there are significant reasons which made the use of mfVEP as a primary tool for objective visual field testing limited. The test is lengthy, specifically in the two runs mode which is the one used for diagnosis and monitoring, and performing the test needs qualified and well-trained technical staff that can connect the electrodes accurately and monitor for any intra- test errors. Despite this, many patients prefer the mfVEP test over standard HFA testing protocols because it is less dependent on patients’ responses. However, for clinicians it cannot be performed on all glaucoma patients in daily practice because of its lengthy testing duration. The interpretation of mfVEP test results is another limiting factor, as it requires the clinician to possess a good knowledge of VEP testing and potential sources of testing error. All these factors have put the mfVEP test behind where it should be as a highly sensitive and repeatable objective perimetry testing tool.

Kanadani et al. (2014) evaluated the sensitivity and specificity of frequency-doubling perimetry (FDT) and multifocal visual evoked potential (mfVEP) tests in normal, suspect, and glaucomatous eyes and compare the monocular and interocular mfVEP. Ninety-five eyes from 95 individuals (23 controls, 33 glaucoma suspects, 39 glaucomatous) were enrolled. All participants underwent a full ophthalmic examination, followed by SAP, FDT, and mfVEP tests. The area under the curve for mean deviation and pattern standard deviation were 0.756 and 0.761, respectively, for FDT, 0.564 and 0.512 for signal and alpha for interocular mfVEP, and 0.568 and 0.538 for signal and alpha for monocular mfVEP. This difference between monocular and interocular mfVEP was not significant. The authors concluded that the FDT Matrix was superior to mfVEP in glaucoma detection. The difference between monocular and interocular mfVEP in the diagnosis of glaucoma was not significant. The authors could not confirm the efficacy of mfVEP in detecting early glaucomatous defects, and found no difference in area under curve (AUC) between the interocular and monocular mfVEP analysis.

Pillai et al. (2013) evaluated the ability of the short-duration transient visual evoked potential (SD-tVEP) to discriminate between healthy eyes and with early to advanced glaucomatous visual field loss. The study included 30 eyes of 30 healthy controls and 45 eyes of 35 glaucoma patients. Normal eyes had 20/30 or better visual acuity and normal 24-2 Swedish interactive thresholding algorithm (SITA) Standard visual fields. There were 15 eyes in each group. SD-tVEPs were recorded using the Diopsys NOVA-LX System. Each eye was stimulated with a low (Lc) and a high (Hc) Michelson contrast checkerboard pattern. Each test resulted in an Lc and an Hc SD-tVEP response. Each response was evaluated for overall waveform quality, P100 latency, and P100 amplitude referenced to the N75. The sensitivity, specificity, negative predictor value (NPV), and positive predictor value (PPV) were calculated. Lc latency showed the highest accuracy for discrimination using receiver operating characteristic curves for high and low contrast parameters. The analysis for all subjects resulted in a 91.1% sensitivity, 93.3% specificity, 95.3% PPV, and an 87.5% NPV. Evaluating the mean Lc latency of the mild, moderate, and severe glaucoma patients against controls showed discrimination consistent with the glaucoma severity. The authors concluded that short-duration transient VEP objectively identified decreased visual function and discriminated between healthy and glaucomatous eyes, and also showed good differentiation between healthy eyes and those with early visual field loss. According to the authors, further studies are warranted to determine if modifications to the present protocol could better isolate the M and P pathways VEP responses. This study is limited by a small study population.

De Moraes et al. (2012) tested a framework that describes how the multifocal visual-evoked potential (mfVEP) technique is used in a particular glaucoma practice. In this prospective, descriptive study, glaucoma suspects, ocular hypertensives and glaucoma patients were referred for mfVEP testing by a single glaucoma specialist over a 2-year period. All patients underwent standard automated perimetry (SAP) and mfVEP testing within 3 months. Two hundred and ten patients (420 eyes) were referred for mfVEP testing for the following reasons: (1) normal SAP tests suspected of early functional loss (ocular hypertensives, n = 43; and glaucoma suspects on the basis of suspicious optic disks, n = 52): (2) normal-tension glaucoma patients with suspected central SAP defects (n = 33); and (3) SAP abnormalities needing confirmation (n = 82). All the glaucoma suspects with normal SAP and mfVEP results remained untreated. Of those with abnormal mfVEP results, 68 % (15/22) were treated because the abnormal regions on the mfVEP were consistent with the abnormal regions seen during clinical examination of the optic disk. The mfVEP was abnormal in 86 % (69/80) of eyes with glaucomatous optic neuropathy and SAP damage, even though it did not result in an altered treatment regimen. In NTG patients, the mfVEP showed central defects in 44 % (12 of 27) of the eyes with apparently normal central fields and confirmed central scotomata in 92 % (36 of 39), leading to more rigorous surveillance of these patients. The authors concluded that in a clinical practice, the mfVEP was used when clinical examination and subjective visual fields provided insufficient or conflicting information and this information influenced clinical management. According to the authors, it was not their purpose to compare the diagnostic ability of the mfVEP to that of other technologies, nor can they rule out that the possibility that the diagnostic power of detecting glaucoma could be increased by replacing the mfVEP test with other diagnostic tests (e.g., SWAP) or even repeated conventional perimetry. Instead, the authors sought to describe how the mfVEP was used in a clinical practice, as despite extensive debate on the performance of each technique, little is known on how they are used in practice and how they influence clinical decisions. This study did not confirm the usefulness of multifocal visual-evoked potential (mfVEP) in improving care and outcome of patients.
Moschos et al. (2012) evaluated the anatomical and functional changes of optic nerve in eyes with primary open angle glaucoma (POAG) by the joint use of optical coherence tomography (OCT) and multifocal visual evoked potentials (mfVEP). Twenty-nine eyes with open angle glaucoma and visual field defects, as well as 20 eyes of 10 age-matched control normal subjects were tested. All participants underwent a complete ophthalmological examination. Moreover, Humphrey visual field test, OCT examination and recording of mfVEP were performed. Amplitude and implicit time of mfVEP, as well as RNFL thickness were measured. Differences in density components of mfVEP and in RNFL thickness among POAG eyes and control eyes were examined using Student’s t-test. In glaucomatous eyes the mean Retinal Response Density (RRD) was lower than normal in ring 1, 2 and 3 of mfVEP. Specifically the mean amplitude of mfVEP in POAG eyes was estimated at 34.2 ± 17.6 nV/deg2, 6.9 ± 4.8 nV/deg2 and 2.6 ± 1.6 nV/deg2 in rings 1, 2 and 3 respectively. In contrast the mean implicit time was similar to control eyes. In addition, the mean RNFL thickness in POAG eyes was estimated at 76.8 ± 26.6 μm in the superior area, 52.1 ± 16.3 μm in the temporal area, 75.9 ± 32.5 μm in the inferior area and 58.6 ± 19.4 μm in the nasal area. There was a statistically significant difference in RNFL thickness in all peripapillary areas between POAG eyes and controls, with superior and inferior area to present the highest decrease. The authors indicated that although Standard Automatic Perimetry is the gold standard to evaluate glaucomatous neuropathy, the joint use of mfVEP and OCT could be useful in better monitoring glaucoma progression. This study did not validate multifocal visual evoked potentials findings with improved treatment outcomes.

Professional Societies

American Academy of Neurology (AAN)

In a 2003 report (reaffirmed in July 2013), the AAN noted quantitative sensory testing (QST) is a potentially useful tool for measuring sensory impairment for clinical and research studies. However, QST results should not be used as a sole method for diagnosis of pathology. The authors identified no adequately powered class I studies demonstrating the effectiveness of QST in evaluating any particular disorder. Lesser quality studies indicated that QST may be useful in identifying small or large fiber sensory abnormalities in some clinical conditions. The AAN indicated QST poses technical challenges in the methodology of testing, reproducibility, and psychophysical factors which limit the objectivity of testing results. The recommendations for use of QST include:

- Based on Class II evidence, QST measuring vibration and thermal perception thresholds is probably an effective tool in the documentation of sensory abnormalities in patients with diabetic neuropathy (Level B recommendation).
- Based on several Class II studies, QST is probably useful in documenting changes in sensory thresholds in longitudinal evaluation of patients with diabetic neuropathy (Level B recommendation).
- Although there is data to suggest that QST abnormalities may be detectable in the absence of clinical evidence of neuropathy in diabetic patients, there is no credible prospective evidence that patients with these abnormalities will ultimately go on to develop clinical neuropathy. Thus, whether QST is useful in preclinical neuropathy detection is unproven (Level U recommendation - current knowledge is conflicting, unproven, or inadequate) (Shy et al., 2003; reaffirmed in July 2013).

In a practice topic for the evaluation of distal symmetric polyneuropathy, Definition for Clinical Research, the American Academy of Neurology, American Association of Neuromuscular and Electrodiagnostic Medicine, and American Academy of Physical Medicine and Rehabilitation state that the sensitivities and specificities of quantitative sensory testing (QST) varied widely among studies. These psychophysical tests have greater inherent variability, making their results more difficult to standardize and reproduce. Reproducibility of QST varied from poor to excellent. The practice parameter indicated that there is too much inconsistency among the studies describing the accuracy of QST for its incorporation into the case definition (England, 2009).

American Association of Electrodiagnostic Medicine (AAEM)

In 2004, AAEM reviewed the technical aspects and reproducibility of different methods to determine threshold for light touch-pressure, vibration, thermal, and pain stimuli. Clinical uses and limitations of QST were also reviewed. The report found that the results of QST are highly dependent on methodology and the full cooperation of the subject. QST has been shown to be reasonably reproducible over a period of days or weeks in normal subjects. The use of QST in research and patient care should be limited to instruments and their corresponding methodologies that have been shown to be reproducible. Literature data do not allow conclusions regarding the relative merits of individual QST instruments (Chong and Cros, 2004). AAEM concluded the following:

- QST is a reliable psychophysical test of large- and small-fiber sensory modalities.
- QST tests the integrity of the entire sensory axis from receptors to brain. Abnormalities do not localize dysfunction to the central or peripheral nervous system, or any particular location along the peripheral nervous system.
- QST is highly dependent on the full cooperation of the patient and may be falsely abnormal if the patient is biased toward an abnormal result or is cognitively impaired. No algorithm can reliably distinguish between psychogenic and organic abnormality.
- QST has been shown to be reasonably reproducible over a period of days or weeks in normal subjects. Since longitudinal QST studies of patients in drug trials are usually done over a period of several months to a few years, reproducibility studies on the placebo-controlled group should be included.
- The reproducibility of thermal thresholds may not be as good as that of vibration threshold.
• For individual patients, more studies are needed to determine the maximum allowable difference between two QSTs that can be attributed to experimental error.
• Different commercially available QST instruments have different specifications (thermode size, stimulus characteristics), testing protocols, algorithms, and normal values. Only QST instruments and their corresponding methodologies that have been shown to be reproducible should be used for research and patient care.
• The results of QST can only be interpreted properly if machine calibration and testing protocol are strictly followed.
• The published evidence does not allow a conclusion to be made regarding whether any QST instrument is better than another.

According to a model policy for needle electromyography and nerve conduction studies developed by American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM), the current perception threshold/sensory nerve conduction threshold test (sNCT) is investigational (American Association of Neuromuscular and Electrodiagnostic Medicine Model Policy for Needle Electromyography and Nerve Conduction Studies Updated January 2016).

American College of Foot and Ankle Surgeons
In 2010, the American College of Foot and Ankle Surgeons revised a clinical practice guideline for the diagnosis and treatment of heel pain, which states that diagnostic studies [for heel pain] may include electromyography (EMG), nerve conduction velocity (NCV) test, magnetic resonance imaging (MRI), and the pressure-specified sensory device test (Thomas et al. 2010).

International Association for the Study of Pain
The International Association for the Study of Pain published guidelines for the assessment of patients with neuropathic pain. According to the guideline, clinical examination, including accurate sensory examination, is the basis of neuropathic pain diagnosis. For more accurate sensory profiling, quantitative sensory testing is recommended for selected cases in clinic, including the diagnosis of small fiber neuropathies and for research purposes. The associations states that QST can be used in clinic along with bedside testing, but it cannot allow for estimation of the level of the lesion within the neuraxis. The relevance of QST to predict therapeutic outcome has yet to be established in prospective studies (Haanpaa et al. 2011).

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Electromyography (EMG)
EMG devices are approved by the FDA as Class II medical devices. See the following website for more information (use product code IKN): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed October 5, 2016)

Quantitative Sensory Testing and Nerve Conduction Studies
Devices used for current perception threshold and sensory nerve conduction threshold testing are classified under product codes LLN and GWF. Note that there are numerous 510(k) marketing clearances for these codes and that not all of these clearances are for devices indicated for nerve threshold testing. Neurosensory testing systems such as the NK Pressure-Specified Sensory Device (PSSD) are regulated by the FDA as Class II devices. The PSSD was approved via the FDA 510(k) process (K934368) on August 11, 1994. See the following website for more information: (use product codes LLN or GWF) http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed October 5, 2016)

The FDA classifies instruments for quantitative sensory testing (QST) as Class II devices under the generic names “esthesiometer” (product code GXB), “2-point discriminator” (product code GWI), “vibration threshold measurement device” (product code LLN), or “temperature discrimination test” (product code LQW) (search GXB, GWI, LLN, or LQW in the Product Code field: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed October 5, 2016)

The Neurometer® approved for marketing in June 1986. A similar device, the Medi-Dx 7000TM Single-Electrode Sensory Nerve Conduction Threshold Device (NDA Inc, Laguna Beach, CA) received marketing approval from the FDA in December 1997. See the following website for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf/K964622.pdf. (Accessed October 5, 2016)

Automated Point of Care Nerve Conduction Tests
Several point of care nerve conduction devices have received FDA 510(k) clearance. These devices are regulated as Class II devices. Examples of FDA approved devices include, but are not limited to, the NC-stat® System, the Brevio® NCS-Monitor, and the Advance™ System.

**Accelerometers**

Kinesia (Cleveland Medical Devices Inc.) received FDA approval in April 2007 to be used for monitoring physical motion and muscle activity to quantify kinematics of movement disorder symptoms such as tremor and assess activity in any instance where quantifiable analysis of motion and muscle activity is desired. Kinesia, a quantitative motor assessment system, is a compact wireless system that uses accelerometers and gyroscopes to monitor three-dimensional motion. The device is worn on the wrist and finger of the patient and can be used to monitor upper extremity movement disorder symptoms and their fluctuations. See the following website for more information: [http://www.accessdata.fda.gov/cdrh_docs/pdf6/K063872.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf6/K063872.pdf) (Accessed October 5, 2016)

**Visual Evoked Potentials (VEPs) for Glaucoma**

Numerous evoked response photic stimulators have been approved by the FDA (Class II, product codes GWE and HLX). These devices may also have recording/measuring capabilities, or the visual signals produced by these devices may be recorded and measured by standard EEG recording devices (product code GWQ).

**Additional Products**

**Electromyography (EMG)**

A number of EMG devices are available that are too numerous to mention here. Surface EMG devices include but are not limited to the following: Spinoscope (Spinex Corp.)

**Quantitative Sensory Testing and Nerve Conduction Studies**

Testing devices include but are not limited to the following: Medi-Dx 7000™ Single-Electrode Sensory Nerve Conduction Threshold Device (NDA Inc, Laguna Beach, CA), Neumometer® CPT Electrodagnostic Neurostimulator (Neurotron Inc, Baltimore, MD), NC-stat System (NeuroMetrix, Inc.), Brevo (NeuMed,Inc.), NervePace (Neurotron, Inc.); Neural-Scan, formally known as Medi-Dx 7000® (Neuro-Diagnostic Associates); Nk Pressure-Specified Sensory Device (Nk Biotechnical Engineering); Vibration Perception Threshold (VPT) Meter® (Xilas Medical Inc.); Medi-Dx 7000 (Neuro-Diagnostic Assoc. (NDA) Inc.); CASE™ IV System: Computer Aided Sensory Evaluator (WR Medical Electronics Co.); Neumometer® (Neurotron Inc.); Vibrameter™ (Somedic AB, Sweden); Thermal sensitivity tester (Sensortek, Inc., Clifton, NJ); Axon-II™ NCSs System™.

**REFERENCES**


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<td>05/01/2017</td>
<td>- Reorganized and revised coverage rationale for nerve conduction studies; modified language to clarify nerve conduction studies with or without late responses (e.g., F-wave and H-reflex tests) are proven and medically necessary when: &lt;br&gt; - Performed in conjunction with needle electromyography for any of the listed known or suspected disorders &lt;br&gt; - Performed without needle electromyography for patients who have any of the listed known or suspected disorders with any of the following clinical conditions:  &lt;br&gt; - Diabetic neuropathy &lt;br&gt; - Amyotrophic lateral sclerosis &lt;br&gt; - Multiple sclerosis &lt;br&gt; - Parkinson’s disease &lt;br&gt; - Cerebral palsy &lt;br&gt; - Friedreich’s ataxia</td>
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