# Neurophysiologic Testing and Monitoring (for Louisiana Only)

**Policy Number:** CS082LA.P~~O~~
**Effective Date:** ~~June 1, 2023~~**TBD**

➲ Instructions for Use

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## Application

This Medical Policy only applies to the state of Louisiana.

## Coverage Rationale

### Nerve Conduction Studies

**The following are proven and medically necessary:**

- Nerve conduction studies with or without **standard** late responses (e.g., F-wave and H-reflex tests) and **for** neuromuscular junction testing when performed in conjunction with needle electromyography for any of the following known or suspected disorders:
  - Peripheral neuropathy/polyneuropathy (e.g., inherited, metabolic, traumatic, entrapment syndromes)
  - Plexopathy
  - Neuromuscular junction disorders (e.g., myasthenia gravis)
  - Myopathy
  - Motor neuron disease
  - Radiculopathy (cervical, thoracic or lumbosacral)
  - Treatment guidance (e.g., muscle localization for botulinum toxin injections, when required to identify affected muscles warranting injection)
- Nerve conduction studies with or without **standard** late responses (e.g., F-wave and H-reflex tests) when performed without needle electromyography for individuals who have any of the above known or suspected disorders with any of the following clinical indications:

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

**The following are unproven and not medically necessary due to insufficient evidence of efficacy:**

- Nerve conduction studies for all **other** conditions ~~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 for the purpose of electrodiagnostic testing

### Other Neurophysiological Testing

**The following are unproven and not medically necessary due to insufficient evidence of efficacy:**

- Macroelectromyography (macro-EMG) testing
- Physiologic monitoring of seizure and/or movement disorder symptoms using wearable devices with accelerometers, electrodermal sensors or gyroscopes (e.g., wrist-devices, smartwatches)
- SEMG based seizure monitoring systems
- Surface electromyography (SEMG)
- Surface mechanomyography (sMMG)
- Quantitative sensory testing, including monofilament testing, pressure-specified sensory testing, computer assisted sensory examinations, and current perception threshold (CPT) testing
- Visual evoked potential testing for diagnosing and evaluating 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 federal, state, or contractual requirements 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 Guidelines may apply.

| CPT Code | Description |
|---|---|
| *0106T | Quantitative sensory testing (QST), testing and interpretation per extremity; using touch pressure stimuli to assess large diameter sensation |
| *0107T | Quantitative sensory testing (QST), testing and interpretation per extremity; using vibration stimuli to assess large diameter fiber sensation |
| *0108T | Quantitative sensory testing (QST), testing and interpretation per extremity; using cooling stimuli to assess small nerve fiber sensation and hyperalgesia |

| CPT Code | Description |
|---|---|
| *0109T | Quantitative sensory testing (QST), testing and interpretation per extremity; using heat-pain stimuli to assess small nerve fiber sensation and hyperalgesia |
| *0110T | Quantitative sensory testing (QST), testing and interpretation per extremity; using other stimuli to assess sensation |
| *0464T | Visual evoked potential, testing for glaucoma, with interpretation and report |
| *0533T | Continuous recording of movement disorder symptoms, including bradykinesia, dyskinesia, and tremor for 6 days up to 10 days; includes set-up, patient training, configuration of monitor, data upload, analysis and initial report configuration, download review, interpretation and report |
| *0534T | Continuous recording of movement disorder symptoms, including bradykinesia, dyskinesia, and tremor for 6 days up to 10 days; set-up, patient training, configuration of monitor |
| *0535T | Continuous recording of movement disorder symptoms, including bradykinesia, dyskinesia, and tremor for 6 days up to 10 days; data upload, analysis and initial report configuration |
| *0536T | Continuous recording of movement disorder symptoms, including bradykinesia, dyskinesia, and tremor for 6 days up to 10 days; download review, interpretation and report |
| *0778T | Surface mechanomyography (sMMG) with concurrent application of inertial measurement unit (IMU) sensors for measurement of multi-joint range of motion, posture, gait, and muscle function |
| 95860 | Needle electromyography; 1 extremity with or without related paraspinal areas |
| 95861 | Needle electromyography; 2 extremities with or without related paraspinal areas |
| 95863 | Needle electromyography; 3 extremities with or without related paraspinal areas |
| 95864 | Needle electromyography; 4 extremities with or without related paraspinal areas |
| 95865 | Needle electromyography; larynx |
| 95866 | Needle electromyography; hemidiaphragm |
| 95867 | Needle electromyography; cranial nerve supplied muscle(s), unilateral |
| 95868 | Needle electromyography; cranial nerve supplied muscles, bilateral |
| 95869 | Needle electromyography; thoracic paraspinal muscles (excluding T1 or T12) |
| 95870 | 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 |
| 95872 | Needle electromyography using single fiber electrode, with quantitative measurement of jitter, blocking and/or fiber density, any/all sites of each muscle studied |
| 95873 | Electrical stimulation for guidance in conjunction with chemodenervation (List separately in addition to code for primary procedure) |

| CPT Code | Description |
|---|---|
| 95874 | Needle electromyography for guidance in conjunction with chemodenervation (List separately in addition to code for primary procedure) |
| 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 plantar pressure measurements, dynamic surface electromyography during walking or other functional activities, and dynamic fine wire electromyography, with written report |



| HCPCS Code | Description |
|---|---|
| *A9279 | Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified |
| *A9280 | Alert or alarm device, not otherwise classified |
| G0255 | Current perception threshold/sensory nerve conduction test, (SNCT) per limb, any nerve |
| *S3900 | Surface electromyography (EMG) |

Codes labeled with an asterisk (*) are not on the State of Louisiana Medicaid Fee Schedule and therefore may not be covered by the State of Louisiana Medicaid Program.

## Description of Services

**Neurophysiologic or electrodiagnostic testing evaluates the conduction of electrical impulses along peripheral nerves. These tests are complementary to a thorough history and physical examination when there are subtle motor or sensory deficits requiring further workup for a definitive diagnosis.** ~~Neurophysiologic studies are used to evaluate and monitor individuals 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 (SEMG).

SEMG 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 SEMG recordings, also referred to as the electromyogram 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.

SEMG based seizure monitoring systems such as the SPEAC® System (Brain Sentinel® Seizure Monitoring and Alerting System) is a non-invasive monitor that is placed on the biceps muscles to analyze surface electromyography (SEMG) signals that may be associated with generalized tonic clonic (GTC) seizures. The system provides an alarm to alert caregivers of a possible GTC seizure.

Needle electromyography requires insertion of needles through the 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.

Macroelectromyography (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.

Surface mechanomyography (sMMG) uses wearable sensor devices that can be applied across a muscle group to provide a measurement of physical muscle output during a contraction. sMMG is thought to be the mechanical counterpart of sEMG which measure the electrical activity. Recent technologies include Surface sMMG with concurrent application of inertial measurement unit (IMU) sensors for measurement of multi-joint range of motion, posture, gait, and muscle function. One novel sMMG technology, Figure8 is intended to allow the clinician to pinpoint the source of injury and quantify the progression of musculoskeletal health recovery after injury.

### Nerve Conduction Studies (NCS)

NCS is 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, 2020).

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 evaluation. In some cases, the late response may be the only abnormality (AANEM Recommended policy for electrodiagnostic medicine, 2014. Updated November 2019). 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.

Non-invasive automatic, portable, or automated point of care nerve conduction monitoring systems include the NC-stat® System, 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.

## Neuromuscular Junction Testing

Neuromuscular junction testing also known as repetitive nerve stimulation is a type of electrodiagnostic test that is used to diagnose myasthenia gravis, Lambert-Eaton myasthenic syndrome, and other neuromuscular junction disorders. The test consists of recording muscle responses to a series of nerve stimuli and may be used in association with nerve conduction studies of the same nerves. At least one motor and one sensory nerve conduction study should be performed in a clinically involved limb, preferably in the distribution of a nerve studied with repetitive stimulation or single fiber electromyography (SFEMG). At least one distal and one proximal muscle should be studied by a needle EMG examination to exclude a neuropathy or myopathy that can be associated with abnormal repetitive stimulation studies or SFEMG (AANEM Recommended policy for electrodiagnostic medicine, 2014. Updated November 2019).

## Physiologic Recording of Movement and/or Seizure Disorder Symptoms

Physiologic recording of movement disorder symptoms using accelerometers and gyroscopes includes the use of devices such as Kinesia™, the Personal KinetiGraph™ or PKG™ system, or Tremorometer™. Kinesia integrates accelerometers and gyroscopes in a compact wearable unit to capture kinematic movement disorder features. The PKG system consists of a wrist-worn movement recording device that is worn by the individual for 6 to 10 days for the purpose of providing continuous, objective, ambulatory assessment of the treatable and disabling symptoms of Parkinson's disease including tremor, bradykinesia and dyskinesia. The Tremorometer is a physiologic recording system using accelerometers that generates precision tremor frequency and amplitude information. These devices are intended to improve management for individuals with movement disorders such as Parkinson's disease. 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.

Physiological signal-based seizure monitoring involves wearing a device that utilizes an electrodermal sensor to acquire electrodermal activity, and an accelerometer sensor to acquire movement data. to aid in seizure detection. One device is the Embrace which is a wearable biosensor device that is worn on the wrist, and senses Electrodermal Activity (EDA) and motion data to detect patterns that may be associated with generalized tonic

clonic seizures in patients with epilepsy or at risk of having epilepsy. When a seizure event is detected, Embrace sends a command to a paired wireless device that is programmed to initiate an alert to a designated caregiver. The System records and stores data from Accelerometers, EDA, and Temperature for subsequent review by a trained healthcare professional.

## 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 individual'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 includes 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. (AANEM Recommended Policy for Electrodiagnostic Medicine, 2014. Updated November 2019: AANEM, Who is Qualified to Practice Electrodiagnostic Medicine? 1999. Updated and re-approved November 2017).

In a position statement for Electrodiagnostic Services: Pay for Quality, the AANEM recommends that providers have demonstrable training and experience in electrodiagnostic (EDX) testing. According to AANEM, this can be demonstrated by appropriate training in a neurology or physical medicine and rehabilitation (PMR) residency/fellowship program and certification by a nationally recognized organization. The American Board of Electrodiagnostic Medicine (ABEM) is a certifying organization specifically for

physicians interested in EDX medicine. The AANEM also has developed an Electrodiagnostic Laboratory Accreditation Program to identify and acknowledge EDX laboratories for achieving and maintaining the highest level of quality, integrity, and safety. Accreditation of an EDX laboratory is a voluntary, peer review process that assesses the expertise of the staff, evaluates the policies and procedures utilized, and ensures the safety of the laboratory and equipment to improve accuracy and reliability of the EDX testing and the care being provided (AANEM Position Statement, Electrodiagnostic Services: Pay for Quality).

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 neurophysiologic techniques (AANEM, Who is Qualified to Practice Electrodiagnostic Medicine? 1999. Updated and re-approved November 2017). 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. Updated November 2017).

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 individual 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 individual'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 individual 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

## Macroelectromyography (Macro-EMG) Testing

Overall, there is weak evidence in the peer-reviewed literature regarding the efficacy of Macroelectromyography (Macro-EMG) Testing. Further studies are needed with robust evidence demonstrating consistent patient-relevant outcomes with the use of Macroelectromyography (Macro-EMG) Testing.

A small number of studies have evaluated the use of macro-EMG. 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)

Nerve conduction studies with or without late responses can be effective for diagnosing and evaluating the following conditions: peripheral nerve entrapment (Osiak et al, 2021, Shubert et al., 2019; Kasius et al., 2019; Pimentel et al., 2018; Galamb et al., 2015); generalized neuropathies (Kelmenson et al., 2019; Holiner et al., 2013); polyneuropathies (Karlsson et al., 2017; Koo et al., 2016; de Souza et al., 2015); neuromuscular junction disorders (Meriggioli and Sanders, 2005); myopathies including polymyositis, dermatomyositis, and congenital myopathies (Wang et al., 2010); motor neuron disease (Reniers et al., 2017); spine disorders and radiculopathy (Pawar et al., 2013); and guidance for botulinum toxin injection for spasmodic dysphonia or segmental dystonia, when it is difficult to isolate affected muscles (Albanese et al., 2011, reaffirmed 2016).

### *Point of Care Nerve Conduction Tests*

Overall, there is weak evidence in the peer-reviewed literature regarding the efficacy of Point of Care Nerve Conduction Tests. Further studies are needed with robust evidence demonstrating consistent patient-relevant outcomes with the use of 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 (Kamiya et a., 2020; Shibata et al., 2019; Kural et al., 2019; Vogt, et al., 2017; Chatzikosma et al., 2016; Dale et al., 2015).

Sharma et al. (2015) evaluated a point-of-care nerve conduction device (POCD; NC-stat®|DPNCheck™) for the assessment of diabetes polyneuropathy (DPN) and compared it with the LDIFLARE technique-which uses a laser-Doppler-imager for early detection of small fib**er**~~re~~ 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.

## *Clinical Practice Guidelines*

### 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. Updated November 2019)

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 are 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; Updated May 2017).

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)

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. Updated November 2019).

The AANEM states that it is in the best interest of individuals, 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 individual 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).

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).

In a policy statement on Electrodiagnosis for Distal Symmetric Polyneuropathy (AANEM, 2017), the AANEM recommends that electrodiagnostic (EDX) testing comprised of nerve conduction studies and needle electromyography should seriously be considered when any of the following criteria are met:

- The history, physical and standard neuropathy blood tests (diabetes, vitamin B12 deficiency and monoclonal gammopathy testing) do not indicate a likely etiology
- Symptoms and/or physical findings are moderate to severe
- An atypical presentation, such as predominantly motor symptoms or findings, proximal deficits, or asymmetry
- Rapid progression of signs or symptoms
- Presence of symptoms or signs indicating another disorder, such as lumbar radiculopathy
- Unknown duration or severity of the underlying cause
- Family history suggesting hereditary neuropathy
- Exposure to substances or medications known to cause neuropathy
- Discrepancy between signs and symptoms

The AANEM states that EDX testing is likely to be of low yield when:

- Symptoms and physical findings are mild;
- Findings are symmetric, distal, predominantly sensory;
- There is a known cause (e.g., diabetes mellitus); and
- There is little suspicion of a coexisting nerve disorder.

## 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 Movement and/or Seizure Disorder Symptoms

Overall, there is weak evidence in the peer-reviewed literature regarding the efficacy of Physiologic Recording of Movement and/or Seizure Disorder Symptoms. Further studies are needed with robust evidence demonstrating consistent patient-relevant outcomes with the use of Physiologic Recording of Movement and/or Seizure Disorder Symptoms.

Casanovas Ortega et al. (2022) conducted a systematic review and meta-analysis. Wearable devices for continuous seizure monitoring have drawn increased attention in the field of epilepsy research. These devices use electrodermal activity (EDA). The aim of this study was to systematically review the literature to estimate the incidence of electrodermal response during seizures. Authors searched all articles recording concurrent EDA and EEG activity during the pre-ictal, ictal, and postictal periods in children and adults with epilepsy. Studies reporting the total number of seizures and number of seizures with an EDA response were included for a random-effects meta-analysis. Nineteen studies, including 550 participants and 1,115 seizures were reviewed. All studies demonstrated an EDA increase during the ictal and postictal periods, while only three reported pre-ictal EDA responses. The meta-analysis showed a pooled EDA response incidence of 82/100 seizures (95% CI 70-91). Tonic-clonic seizures (both generalized tonic-clonic seizures [(GTCS])) and focal to bilateral tonic-clonic seizures [(FBTCS])) elicited a more pronounced (higher and longer-lasting) EDA response when compared with focal seizures (excluding FBTCS). Study limitations included the following: a small number of papers included, which prevented the assessment of factors influencing the EDA responses; understanding the different factors which can alter EDA response could possibly allow the development of modified thresholds for individual patients; the definition of EDA response was varied across the different studies and did not define EDA response threshold. A consistent definition of EDA response, including both amplitude and duration criteria, is needed to increase the validity of study results; a substantial proportion of studies included in this systematic review were from the same research group, which could mean certain measurements were repeated; some participants also had more than one seizure which was not accounted for and could have affected results; studies included in this review were carried out in controlled conditions and on hospitalized patients, making it difficult to evaluate the applicability of these findings in the ambulatory settings and on subjects performing daily activities. In conclusion, the authors note that epileptic seizures produce an electrodermal response detectable by wearable devices during the pre-ictal, ictal, and postictal periods. Further robust studies are needed to better recognize EDA changes and to analyze factors which may influence the EDA response.

Naganur et al. (2022) conducted a systematic review and meta-analysis investigating the performance of noninvasive wearable devices in detecting epileptic seizures and psychogenic nonepileptic seizures (PNES). They included studies that used video-electroencephalographic (EEG) monitoring as the gold standard to determine the sensitivity and false alarm rate (FAR) of noninvasive wearables for automated seizure detection. Twenty-eight studies met the criteria for the systematic review, of which 23 were eligible for meta-analysis. These studies (1269 patients in total, median recording time = 52.9 h per patient) investigated devices for tonic-clonic seizures using wrist-worn and/or ankle-worn devices to measure three-dimensional accelerometry (15 studies), and/or wearable surface devices to measure electromyography (eight studies). The mean sensitivity for detecting tonic-clonic seizures (TCS) was .91 (95% confidence interval [CI] = .85-.96, I2 = 83.8%); sensitivity was similar between the wrist-worn (.93) and surface devices (.90). The overall FAR was 2.1/24 h (95% CI = 1.7-2.6, I2 = 99.7%); FAR was higher in wrist-worn (2.5/24 h) than in wearable surface devices (.96/24 h). Three of the 23 studies also detected PNES; the mean sensitivity and FAR from these studies were

62.9% and .79/24 h, respectively. Four studies detected both focal and tonic-clonic seizures, and one study detected focal seizures only; the sensitivities ranged from 31.1% to 93.1% in these studies. This review had a number of limitations including: inability to analyze the parameters or the algorithms to detect specific motor seizure types; high level of heterogeneity in sensitivity and far in detecting TCS; and variability in the algorithms used to analyze the data collected by the devices. Authors note that reported noninvasive wearable devices have a high sensitivity but relatively high FARs in detecting tonic-clonic seizures during limited recording time in a video-EEG setting. Future more robust studies should focus on reducing FAR, detection of other seizure types and PNES, and longer recording in the community.

Santiago et al. (2019) evaluated the impact of using continuous objective measurement using the Personal KinetiGraph (PKG) Movement Recording System in the routine clinical care of patients with Parkinson's disease (PD). Physicians used the PKG in patients for whom they were seeking objective measurement. Patients wore a PKG data logger for ≥ 6 days during routine daily living activities. During the survey period of December 2015 through July 2016, physician surveys were completed by four Movement Disorder Specialists for whom measurements from the PKG were available during a subsequent routine clinic visit. Of 112 completed physician surveys, 46 (41%) indicated the PKG provided relevant additional information sufficient to consider adjusting their therapeutic management plan; 66 (59%) indicated the PKG provided no further information to support a therapeutic decision differing from that made during a routine clinical evaluation. Upon further review of these 46 surveys, 36 surveys (78%) revealed the information provided by the PKG ultimately resulted in adjusting the patient's medical management. The authors concluded that the PKG provided novel additional information beyond that captured during a routine clinic visit sufficient to change the medical management of patients with PD. According to the authors, the use of the PKG may provide for better informed therapeutic decisions, improving the quality of life for patients with PD. The authors indicated that physician assessment of clinical value derived from continuous objective measurement use may have been limited by the extent of physician familiarity and knowledge of product use and interpretation, variation in duration between the clinic visit and survey completion, and logistical complexity of adding new technology into existing clinical practice flow. Khodakarami et al. (2019) used data from the KinetiGraph device to aid the non-specialist in making timely referrals for device-assisted therapy (DAT) for people with Parkinson's disease. Subjects were randomly assigned to either a construction set (n = 112, to train, develop, cross validate, and then evaluate the classifier's performance) or to a test set (n = 60 to test the fully specified classifier), resulting in a sensitivity and specificity of 89% and 86.6%, respectively. The classifier's performance was then assessed in people with Parkinson's disease who underwent deep brain stimulation (n = 31), were managed in a non-specialist clinic (n = 81) or in people with Parkinson's disease in the first five years from diagnosis (n = 22). The classifier identified 87%, 92%, and 100% of the candidates referred for DAT in each of the above clinical settings, respectively. Furthermore, the classifier score changed appropriately when therapeutic intervention resolved troublesome fluctuations or dyskinesia that would otherwise have required DAT. According to the authors, this study suggests that information from objective measurement could improve timely referral for DAT. Well designed, controlled studies with larger patient populations are needed to evaluate clinical outcomes in people with Parkinson's disease who use KinetiGraph. This study was funded by an unspecified Grant-in-Aid from Global Kinetics Corporation (GKC), the manufacturer and distributor of KinetiGraph.

Boroojerdi et al. (2019) conducted a two-part pilot study to evaluate the accuracy of the NIMBLE wearable biosensor patch (containing an accelerometer and electromyography sensor)

to record body movements in clinic and home environments versus clinical measurement of motor symptoms in patients with Parkinson's disease (PD). Patients had motor symptom fluctuations and were on a stable levodopa dose. Part 1 investigated different sensor body locations (six patients). In Part 2, 21 patients wore four sensors (chest, and most affected side of shin, forearm and back-of-hand) during a 2-day clinic- and 1-day home-based evaluation. Patients underwent Unified Parkinson's Disease Rating Scale assessments on days 1-2 and performed pre-defined motor activities at home on day 3. An algorithm estimated motor-symptom severity (predicted scores) using patch data (in-clinic); this was compared with in-clinic motor symptom assessments (observed scores). The overall correlation coefficient between in-clinic observed and sensor algorithm-predicted scores was 0.471. Predicted and observed scores were identical 45% of the time, with a predicted score within a ±1 range 91% of the time. Exact accuracy for each activity varied, ranging from 32% (pronation/supination) to 67% (rest-tremor-amplitude). Patients rated the patch easy-to-use and as providing valuable data for managing PD symptoms. Overall patch-adhesion success was 97.2%. The patch was safe and generally well tolerated. The authors concluded that this study showed a correlation between sensor algorithm-predicted and clinician-observed motor-symptom scores. The findings of this study need to be validated by well-designed controlled studies with larger sample sizes.

Lipsmeier et al. (2018) assessed the feasibility, reliability, and validity of smartphone-based digital biomarkers of Parkinson's disease (PD) in a clinical trial setting. During a 6-month, phase 1b clinical trial with 44 Parkinson participants, and an independent, 45-day study in 35 age-matched healthy controls, participants completed six daily motor active tests (sustained phonation, rest tremor, postural tremor, finger-tapping, balance, and gait), then carried the smartphone during the day (passive monitoring), enabling assessment of, for example, time spent walking and sit-to-stand transitions by gyroscopic and accelerometer data. Adherence was acceptable: Patients completed active testing on average 3.5 of 7 times/week. Sensor-based features showed moderate-to-excellent test-retest reliability. All active and passive features significantly differentiated PD from controls. All active test features except sustained phonation were significantly related to corresponding International Parkinson and Movement Disorder Society-Sponsored UPRDS clinical severity ratings. On passive monitoring, time spent walking had a significant relationship with average postural instability and gait disturbance scores. Of note, for all smartphone active and passive features except postural tremor, the monitoring procedure detected abnormalities even in those Parkinson participants scored as having no signs in the corresponding International Parkinson and Movement Disorder Society-Sponsored UPRDS items at the site visit. The authors concluded that these findings demonstrate the feasibility of smartphone-based digital biomarkers and indicate that smartphone-sensor technologies provide reliable, valid, clinically meaningful, and highly sensitive phenotypic data in Parkinson's disease. The study did not confirm the utility of such findings in improving care and outcome of patients.

Silva de Lima et al. (2017) conducted a systematic review of the use of wearable systems to assess freezing of gait (FOG) and falls in Parkinson's disease (PD). In total, 27 articles were selected for review. Of those, 23 related to FOG and 4 to falls. FOG studies were performed in either laboratory or home settings, with sample sizes ranging from 1 PD patient up to 48 PD patients presenting Hoehn and Yahr stage from 2 to 4. The shin was the most common sensor location and accelerometer was the most frequently used sensor type. Validity measures ranged from 73-100% for sensitivity and 67-100% for specificity. Falls and fall risk studies were all home-based, including samples sizes of 1 PD patient up to 107 PD patients, mostly using one sensor containing accelerometers, worn at various body locations. Despite the promising validation initiatives reported in

these studies, they were all performed with relatively small sample sizes, and there was a significant variability in outcomes measured and results reported. The authors concluded that because of these limitations, the validation of sensor-derived assessments of PD features would benefit from more focused research efforts, increased collaboration among researchers, aligning data collection protocols, and sharing data sets.

Godinho et al. (2016) performed a systematic review in order to list, compare and classify technological-based devices used to measure motor function in individuals with Parkinson's disease into three groups, namely wearable, non-wearable and hybrid devices. A systematic literature search of the PubMed database resulted in the inclusion of 168 studies. These studies were grouped based on the type of device used. For each device the authors reviewed availability, use, reliability, validity, and sensitivity to change. The devices were then classified as recommended, suggested or listed based on the following criteria: (1) used in the assessment of Parkinson's disease (yes/no), (2) used in published studies by people other than the developers (yes/no), and (3) successful clinimetric testing (yes/no). The authors reviewed the Kinesia system which they classified as recommended. The authors based the clinimetric properties on one study (Giuffrida et al., 2009) which evaluated individuals with PD who performed the tremor subset of the UPDRS III while wearing Kinesia. Quantitative kinematic features were processed and highly correlated to clinician scores for rest tremor ($r^{(2)}$ = 0.89), postural tremor ($r^{(2)}$ = 0.90), and kinetic tremor ($r^{(2)}$ = 0.69). According to the authors, the Kinesia device has been shown to be able to successfully ascertain tremor. However, it suffered from poor subject acceptability. The authors indicated that a limitation of the review was grouping all types of validity into a single yes/no binary answer since this may not accurately reflect the maturity/validity of a certain system given the different types of validity and many degrees of validity that exist.

Ghassemi et al. (2016) attempted to differentiate patients with essential tremor (ET) from tremor dominant Parkinson disease (PD). Accelerometer and electromyographic signals of hand movement from standardized upper extremity movement tests (resting, holding, carrying weight) were extracted from 13 PD and 11 ET patients. The signals were filtered to remove noise and non-tremor high frequency components. A set of statistical features was then extracted from the discrete wavelet transformation of the signals. Principal component analysis was utilized to reduce dimensionality of the feature space. Classification was performed using support vector machines. The proposed method was evaluated by using leave one out cross validation and the overall accuracy of the classification was reported. With this method, it was possible to discriminate 12/13 PD patients from 8/11 patients with ET with an overall accuracy of 83%. In order to individualize this finding for clinical application the authors generated a posterior probability for the test result of each patient and compared the misclassified patients, or low probability scores to available clinical follow up information for individual cases. This non-standardized post hoc analysis revealed that not only the technical accuracy but also the clinical accuracy limited the overall classification rate. The authors indicated that in addition to the successful isolation of diagnostic features, longitudinal and larger sized validation is needed in order to prove clinical applicability.

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.

### *Clinical Practice Guidelines*

#### International League Against Epilepsy (ILAE) and the International Federation of Clinical Neurophysiology (IFCN) (Beniczky, 2021)

- The ILAE-IFCN Working Group recommends using clinically validated wearable devices for automated detection of **generalized tonic clonic seizure (**GTCS**)** and **focal bilateral tonic clonic seizures (**FBTCS**)** when significant safety concerns exist, especially in unsupervised patients who do not share a bedroom but where alarms can result in rapid intervention, within 5 minutes (weak/conditional recommendation).
- The ILAE-IFCN Working Group, at present, does not recommend clinical use of the currently available wearable devices for seizure types other than GTCS and FBTCS, as more research and development are needed for this application (weak/conditional recommendation).

## Surface Electromyography (SEMG) and SEMG Based Seizure Monitoring Systems

Overall, there is weak evidence in the peer-reviewed literature regarding the efficacy of Surface Electromyography (SEMG) and SEMG Based Seizure Monitoring Systems. Further studies are needed with robust evidence demonstrating consistent patient-relevant outcomes with the use of Surface Electromyography (SEMG) and SEMG Based Seizure Monitoring Systems.

AbuNurah et al. (2020) performed a systematic review on the quality of literature available on using extra-diaphragmatic sEMG as an assessment technique of respiratory responses during mechanical ventilation (MV). The current evidence supporting the utilization of surface EMG (sEMG) of extra-diaphragmatic muscles for monitoring of ventilation (MV) assistance is unclear. Studies using sEMG of extra-diaphragmatic respiratory muscles during MV were carefully chosen by two independent researchers after carrying out a database search of PubMed, CINAHL, GOOGLE SCHOLAR. Exclusion criteria were studies of patients with neuromuscular disorders, receiving neuromuscular blocking agents, receiving non-invasive MV, using needle EMG, and studies in languages other than English. Quality of identified studies was assessed with the Quality Assessment of Diagnostic Accuracy Studies (QUADAS-2). This study is registered with PROSPERO, number (CRD42018081341). 596 references were identified and 7 studies were included in the review. Findings demonstrate that sEMG of extra-diaphragmatic muscle activity is a valid and applicable tool to evaluate mechanical loading/unloading of respiratory muscles and respiratory drive or sensation. But the quality of literature supporting sEMG as monitoring tool of respiratory responses were categorized by a high unclear risk of bias. While it appears to be an effective test, there is a lack of literature that directly

demonstrates the diagnostic accuracy of sEMG of extra-diaphragmatic muscles in monitoring respiratory mechanics and respiratory drive or sensation during MV assistance across wide populations and conditions. Study limitations included small sample sizes and the evidence of value of this tool across a more broad population of patients on MV is limited. Also, there is a lack of a systematic and well-designed method for evaluating sEMG diagnostic performance, which includes: random sampling of patients, blinding to index test and reference standards, and the use of gold standard reference tests for assessing MV outcomes (i.e., rapid shallow breathing index [~~(~~RSBI]~~)~~ and MIP). Larger well-designed studies are needed to test the accuracy of sEMG as a clinical diagnostic method, which might benefit in the decision making of MV liberation. Additional studies should address the diagnostic accuracy of MV monitoring. Future research should also look at the comparison with other standard methods of MV monitoring used in the critical care settings. Dos Reis et al. (2019) identified the most common procedures used to record sEMG of inspiratory muscles in adults through a systematic review and evaluated the quality of the report presented by the studies. The electronic search retrieved a total of 6697 titles and 92 of them were included. A great variability on the methods applied to both recording and processing/analyzing data was found. Therefore, the synthesis of practical/clinical evidence to support immediate recommendations was impaired. In general, the descriptions presented by the studies are poor. According to the authors, methodological studies with objective comparisons are needed for improving standardization, given the impossibility of making recommendations from this review.

Bashford et al. (2020) in a systematic review explored the evidence of surface electromyography (sEMG) in amyotrophic lateral sclerosis (ALS) patients. 41 studies were identified focusing on surface EMG and its associated analytical methods in the diagnosis, prognosis and monitoring of ALS patients. A wide variety of analytical techniques were identified, involving motor unit decomposition from high-density grids, motor unit number estimation and measurements of neuronal hyperexcitability or neuromuscular architecture. Some studies have planned specific diagnostic and prognostic criteria however clinical calibration in large ALS cohorts is at this time lacking. The most validated method to monitor disease is the motor unit number index (MUNIX), which has been implemented as an outcome measure in two ALS clinical trials. Surface EMG offers important practical and analytical flexibility compared to invasive techniques. To benefit from this technology, the focus should be placed upon the multi-disciplinary collaboration of clinicians, bioengineers, mathematicians and biostatisticians. Future studies should focus on the multi-disciplinary development of electronic hardware and automated analytical tools that are able to identify the advantages of surface EMG.

Halford et al. (2017) conducted a prospective multicenter phase III trial to evaluate the performance and tolerability in the epilepsy monitoring unit (EMU) of an investigational wearable surface electromyographic (sEMG) monitoring system for the detection of generalized tonic-clonic seizures (GTCSs). One hundred ninety-nine patients with a history of GTCSs who were admitted to the EMU in 11 level IV epilepsy centers for clinically indicated video-electroencephalographic monitoring also received sEMG monitoring with a wearable device that was worn on the arm over the biceps muscle. All recorded sEMG data were processed at a central site using a previously developed detection algorithm. Detected GTCSs were compared to events verified by a majority of three expert reviewers. For all subjects, the detection algorithm detected 35 of 46 (76%) of the GTCSs, with a positive predictive value (PPV) of 0.03 and a mean false alarm rate (FAR) of 2.52 per 24 hours. For data recorded while the device was placed over the midline of the biceps muscle, the system detected 29 of 29 GTCSs (100%), with a detection delay averaging 7.70 s, a PPV of 6.2%, and a mean FAR of 1.44 per 24 hours. Mild to moderate adverse events were reported in 28% of subjects and led to study withdrawal in

9% (17 of 199). These adverse events consisted mostly of skin irritation caused by the electrode patch that resolved without treatment. No serious adverse events were reported. The authors concluded that detection of GTCSs using a sEMG monitoring device on the biceps is feasible. According to the authors, improvements in the device are needed to decrease the number of false-positive detections.

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%.

## *Clinical Practice Guidelines*

### 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).

## Surface Mechanomyography (sMMG)

There are few published studies addressing the use of surface mechanomyography with concurrent application of inertial measurement unit (IMU) sensors for measurement of multi-joint range of motion, posture, gait, and muscle function. Therefore, it is not possible to conclude whether this surface mechanomyography musculoskeletal assessment system has a beneficial effect on health outcomes.

## Quantitative Sensory Testing (QST)

Overall, there is weak evidence in the peer-reviewed literature regarding the efficacy of Quantitative Sensory Testing (QST). Further studies are needed with robust evidence demonstrating consistent patient-relevant outcomes with the use of Quantitative Sensory Testing (QST).

Georgopoulos et al. (2019) systematically reviewed the evidence for ability of quantitative sensory testing (QST) to predict pain, disability and negative affect. Of the 37 eligible studies included in the review (n = 3860 participants), 32 were prospective cohort studies and 5 randomized controlled trials. Pain was an outcome in 30 studies, disability in 11 and negative affect in 3. Meta-analysis revealed that baseline QST predicted musculoskeletal pain and disability. Baseline modalities quantifying central mechanisms such as temporal summation (TS) and conditioned pain modulation (CPM) were associated with follow-up pain, whereas baseline mechanical threshold modalities were predictive of follow-up disability. According to the authors, QST indices of pain hypersensitivity might help develop targeted interventions aiming to improve outcomes across a range of musculoskeletal conditions. However, this needs to be validated in additional studies.

Assessment of pain processing by quantitative sensory testing (QST) prior to surgery has been proposed as a method to identify patients at risk for postoperative pain, although results have been conflicting. Sangesland et al. (2017) conducted a systematic review to evaluate whether assessment of experimental pain processing including measures of central pain mechanisms prior to surgery was associated with pain intensity after surgery. The authors performed systematic database searches for studies that assessed the association between QST and pain after surgery. Studies were included if (1) QST was performed prior to surgery, (2) pain was assessed after surgery, and (3) the association between QST and pain after surgery was investigated. Forty-four unique studies were identified, with 30 studies on 2738 subjects meeting inclusion criteria. Most studies showed moderate to high risk of bias. The majority of the preoperative QST variables showed no consistent association with pain intensity after surgery. Thermal heat pain above the pain threshold and temporal summation of pressure pain were the QST variables which showed the most consistent association with acute or chronic pain after surgery. The authors concluded that QST before surgery does not consistently predict pain after surgery. According to the authors, high quality studies investigating the presence of different QST variables in combination or along with other pain-related psychosocial factors are warranted to confirm the clinical relevance of QST prior to surgery.

A systematic review conducted by O'Leary et al. (2017) investigated whether nervous system sensitization in peripheral musculoskeletal (MSK) conditions predicts poorer clinical outcomes in response to a surgical or conservative intervention. Four electronic databases were searched to identify the relevant studies. Eligible studies had a

prospective design, with a follow-up assessing the outcome in terms of pain or disability. Studies that used baseline indices of nervous system sensitization were included, such as quantitative sensory testing (QST) or questionnaires that measured centrally mediated symptoms. Thirteen studies met the inclusion criteria, of which six were at a high risk of bias. The peripheral MSK conditions investigated were knee and hip osteoarthritis, shoulder pain, and elbow tendinopathy. QST parameters indicative of sensitization (lower electrical pain thresholds, cold hyperalgesia, enhanced temporal summation, lower punctate sharpness thresholds) were associated with negative outcome (more pain or disability) in 5 small exploratory studies. Larger studies that accounted for multiple confounders in design and analysis did not support a predictive relationship between QST parameters and outcome. Two studies used self-report measures to capture comorbid centrally mediated symptoms and found higher questionnaire scores were independently predictive of more persistent pain following a total joint arthroplasty. The authors concluded that this systematic review found insufficient evidence to support an independent predictive relationship between QST measures of nervous system sensitization and treatment outcome. Self-report measures demonstrated better predictive ability. According to the authors, further high-quality prognostic research is needed.

Wang et al. (2017) systematically evaluated the diagnostic accuracy of monofilament tests for detecting diabetic peripheral neuropathy. The authors searched EMBASE (OvidSP), MEDLINE (OvidSP), the Cochrane Library, and Web of Science to identify diagnostic accuracy trials of monofilament tests for detecting diabetic peripheral neuropathy. A total of 19 comparative trials met the inclusion criteria and were part of the qualitative synthesis. Eight trials using nerve conduction studies as the reference standard were selected for the meta-analysis. The pooled sensitivity and specificity of monofilament tests for detecting diabetic peripheral neuropathy were 0.53 and 0.88, respectively. The pooled positive likelihood ratio and negative likelihood ratio were 4.56 and 0.53, respectively. The authors concluded that the review indicated that monofilament tests had limited sensitivity for screening diabetic peripheral neuropathy. According to the authors, the clinical use of the monofilament test in the evaluation of diabetic peripheral neuropathy cannot be encouraged based on currently available evidence.

Marcuzzi et al. (2016) conducted a systematic review to summarize the emerging body of evidence investigating the prognostic value of QST measures in people with low back pain (LBP). An electronic search of six databases was conducted from inception to October 2015. Experts in the field were contacted to retrieve additional unpublished data. Studies were included if they were prospective longitudinal in design, assessed at least one QST measure in people with LBP, assessed LBP status at follow-up, and reported the association of QST data with LBP status at follow-up. Statistical pooling of results was not possible due to heterogeneity between studies. Of 6,408 references screened after duplicates removed, three studies were finally included. None of them reported a significant association between the QST measures assessed and the LBP outcome. Three areas at high risk of bias were identified which potentially compromise the validity of these results. The authors indicated that due to the paucity of available studies and the methodological shortcomings identified, it remains unknown whether QST measures are predictive of outcome in LBP.

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.

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.

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).

## *Clinical Practice Guidelines*

### American Academy of Neurology (AAN)

In a 2003 report (reaffirmed in January 2019), 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, January 2016, and~~ January 2019).

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 et al., 2009).

### American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) [formerly known as the 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).

## Visual Evoked Potentials for Glaucoma

Overall, there is weak evidence in the peer-reviewed literature regarding the efficacy of Visual Evoked Potentials for Glaucoma. Further studies are needed with robust evidence demonstrating consistent patient-relevant outcomes with the use of Visual Evoked Potentials for Glaucoma.

Wang et al. (2020) performed a cross-sectional study by using a new device to assess the isolated-check visual evoked potential (icVEP) for primary open angle glaucoma (POAG) patients with highly myopia and non-highly myopia and compared the diagnostic efficacy of the signal to noise (SNR) from icVEP with those of parameters assessed by optical coherence tomography (OCT) and Heidelberg retinal tomography (HRT). A total of 126 participants were recruited, including 31 highly myopic participants with POAG (HM-POAG), 36 non-highly myopic participants with POAG (NHM-POAG), 25 highly myopic participants without POAG (HM) and 34 controls without high myopia (Normal). All the participants underwent a comprehensive ophthalmic examination. The signal-to-noise ratio (SNR) was used to assess the icVEP. Both qualitative and quantitative diagnostic performances of OCT, HRT and the icVEP were analyzed and compared. Based on the measure of SNR ≤ 1, the diagnostic performance of the icVEP in highly myopic subjects was better than that in non-highly myopic subjects. In distinguishing the HM-POAG and HM groups, the AUC of the SNR was not different from those of the OCT and HRT parameters ($P$~~p~~ > 0.05) in either the qualitative or quantitative comparison. In the qualitative analysis, the icVEP showed good consistency with damage to the central 10° of the visual field (kappa = 0.695-0.747, $P$~~p~~ < 0.001). The icVEP has the potential to single out individuals with and without POAG, especially in patients with high myopia. Limitations included a small sample size and the fact it was a cross-sectional study. Also, the icVEP device has been intended to reduce interference but the signal may still be affected by noise. Larger studies are needed to confirm these potential findings.

In a cross-sectional study, Fan et al. (2018) evaluated whether an isolated-check visual evoked potential (icVEP) could be used to detect visual function abnormalities in early-stage open-angle glaucoma (OAG). The study included 37 OAG patients with early-stage visual field loss detected by the Humphrey Field Analyzer and 26 controls. Optical coherence tomography (OCT) was used to detect retinal nerve fiber layer (RNFL) defects. The icVEP preferentially evaluates the magnocellular-ON pathway. VEPs were recorded and signal-to-noise ratios (SNRs) were derived based on multivariate analysis. Eyes that yielded an SNR ≤ 1 were considered abnormal. Receiver operating characteristic (ROC) curve analysis was used to estimate the accuracy of group classification. Correlations between SNRs and related factors were analyzed. Based on an SNR criterion of 1, the icVEP had a sensitivity of 62.2% and a specificity of 92.3% for diagnosing early-stage OAG with 74.6% classification accuracy. The ROC curve analysis, however, suggested that an SNR criterion of 0.93 would produce the highest classification accuracy (77.3%). Both RNFL thinning in the temporal superior quadrant on OCT and number of abnormal test points in the central 11° visual field significantly correlated with the SNR. The authors concluded that icVEP detected visual function abnormalities in approximately 3/5 of eyes with early-stage OAG with greater than 90% specificity. This study is limited by a small study

population. The authors indicated that further multiple center studies with a larger sample are needed to confirm the accuracy of this diagnostic test.

In a cross-sectional study, Amarasekera et al. (2018) evaluated two office-based electrophysiological diagnostic tests, steady-state pattern electroretinogram and short-duration transient visual evoked potentials to discern between glaucomatous and healthy eyes. Forty-one patients with glaucoma and 41 healthy volunteers participated in the study. Steady-state pattern electroretinogram and short-duration transient visual evoked potential testing was conducted in glaucomatous and healthy eyes. Steady-state pattern electroretinogram parameters compared were MagnitudeD, MagnitudeD/Magnitude ratio, and the signal-to-noise ratio. Short-duration transient visual evoked potential parameters compared were amplitude and latency. MagnitudeD was significantly lower in glaucoma patients when using a low-contrast and high-contrast 64-bar-size steady-state pattern electroretinogram stimulus. Short-duration transient visual evoked potential amplitude and latency were not significantly different between the two groups.

Xu et al. (2017) conducted a study to determine the diagnostic accuracy, sensitivity and specificity of isolated-check visual evoked potentials (icVEP) in primary open-angle glaucoma (POAG). Ninety POAG patients and sixty-six healthy controls were recruited consecutively. All subjects underwent icVEP and visual field testing. Swept icVEP response functions were obtained by increasing contrast in six stimulus steps, recording the electroencephalogram synchronized to the stimulus display's frame rate and calculating the corresponding signal-to-noise ratio (SNR) of the response at the fundamental frequency to evaluate visual function. The results show that SNR is contrast dependent. It significantly rose as contrast increased. The areas under receiver-operating-characteristic curves (AUCs) indicating classification accuracy for all POAG cases in comparison with normal subjects were 0.790 (sensitivity 91.1%, specificity 69.7%) with the cutoff SNR of 0.85, and 0.706 (sensitivity 95.6%, specificity 51.5%) with the cutoff SNR of 1. The AUC of early glaucoma cases (EG) in comparison with normal subjects was 0.801 (sensitivity 93.3%, specificity 69.7%) with the cutoff SNR of 0.85, and 0.717 (sensitivity 97.8%, specificity 51.5%) with the cutoff SNR of 1. The authors concluded that icVEP has good diagnostic accuracy (high sensitivity and moderate specificity) in distinguishing early POAG patients from healthy subjects. According to the authors, icVEP might be a promising device to use in conjunction with complementary functional and structural measures for early POAG detection. The sample size in this study is too small to prove the usefulness of the icVEP test as a diagnostic tool.

Chen and Zhao (2017b) compared the diagnostic performance of isolated-check visual evoked potential (icVEP) with that of retinal ganglion cell-inner plexiform layer (GCILP) analysis using optical coherence tomography (OCT). A total of 45 patients were enrolled: 25 patients with open-angle glaucoma and 20 healthy patients. All patients underwent a complete ophthalmological examination. The quantitative and qualitative comparisons between the diagnostic power of GCIPL analysis and that of icVEP were performed. The areas under the receiver operating characteristic curves (AUC) of GCIPL analysis and icVEP were compared using the Clarke-Pearson method. The sensitivity and specificity of the two techniques were analyzed and compared using the McNemar test. With the quantitative comparison, the AUC of icVEP (AUC = 0.892) was higher than that of GCIPL analysis (AUC = 0.814). However, there was no statistical significance between the AUCs of icVEP and GCIPL. With the qualitative comparison, the sensitivity of icVEP was 80%, and its specificity was 90%. The sensitivity of GCIPL analysis was 72%, and its specificity was 85%. There was no significant difference between the sensitivities or specificities of icVEP and GCIPL analysis. Moreover, 30 (66.67%) eyes had similar results between icVEP and GCIPL analysis, and 15 (33.33%) eyes had different results (7 eyes had

abnormal results with GCIPL analysis but normal results with icVEP, and 8 eyes had normal results with GCIPL analysis but abnormal results with icVEP). The authors concluded that the diagnostic power of icVEP was close to that of GCIPL analysis whether the comparison was based on the qualitative or quantitative data. According to the authors, this study was limited because the small sample size does not provide strong evidence for the results.

Chen and Zhao (2017a) compared the diagnostic performance of isolated-check visual evoked potential (icVEP) and standard automated perimetry (SAP), for evaluating the application values of icVEP in the detection of early glaucoma. In total, 144 subjects (288 eyes) were enrolled in this study. icVEP testing was performed with the Neucodia visual electrophysiological diagnostic system. A 15% positive-contrast (bright) condition pattern was used in this device to differentiate between glaucoma patients and healthy control subjects. SAP testing was performed with the Humphrey Field Analyzer II. The authors found there was no statistical significance between the sensitivity or specificity of SAP and icVEP, regardless of which diagnostic standard was used. The authors concluded that the diagnostic performance of icVEP is not better than that of SAP in the detection of early glaucoma.

## U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

### Electromyography (EMG)

EMG devices are approved by the FDA as Class II medical devices. Refer to the following website for more information (use product code IKN): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed **August 2, 2023** ~~September 12, 2022~~)

### *Surface Electromyography (SEMG) Based Seizure Monitoring Systems*

The FDA granted a de novo classification to market the SPEAC® System, the Brain Sentinel® Seizure Monitoring and Alerting System (Brain Sentinel, Inc.) on February 16, 2017. The SPEAC System is indicated for adjunctive seizure monitoring in adults at home or in healthcare facilities during periods of rest. The monitor analyzes surface electromyography (sEMG) signals that may be associated with generalized tonic-clonic seizures. It is worn over the bicep muscle belly of the upper arm. The SPEAC System records and stores sEMG data for subsequent review by a trained healthcare professional. Refer to the following website for more information: https://www.accessdata.fda.gov/cdrh_docs/pdf14/DEN140033.pdf. (Accessed **August 2, 2023)** ~~September 12, 2022)~~

### 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, GXB, LQW, and GWI. 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. Refer to the following website for more information (use product codes LLN, GXB, LQW, or

GWI): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed **August 2, 2023** ~~September 12, 2022~~)

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" (search GXB, GWI, LLN, or LQW in the product code field): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed **August 2, 2023** ~~September 12, 2022~~)

The Neurometer® **was** 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. Refer to the following website for more information: http://www.neurotron.com/downloads/Clinical_Overview/Appendix_J.pdf. (Accessed **August 2, 2023** ~~September 12, 2022~~)

### *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.

Point of care nerve conduction devices are classified under the product code JXE. Refer to the following website for more information: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed **August 2, 2023** ~~September 12, 2022~~)

### Physiologic Recording of Movement and/or Seizure Disorder Symptoms

The Personal Kinetigraph or PKG system (Global Kinetics Corporation) received FDA 510(k) clearance on August 22, 2014. The PKG is intended to quantify kinematics of movement disorder symptoms in conditions such as Parkinson's disease, including tremor, bradykinesia and dyskinesia. It includes a medication reminder, an event marker and is intended to monitor activity associated with movement during sleep. The device is indicated for use in individuals 46 to 83 years of age. Refer to the following websites for more information:

- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K140086
- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K161717

(Accessed **August 2, 2023** ~~September 12, 2022~~)

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. Refer to the following website for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf6/K063872.pdf. (Accessed **August 2, 2023** ~~September 12, 2022~~)

The Tremorometer (FlexAble Systems, Inc.) received 510(k) FDA clearance on July 25, 2001. The Tremorometer is indicated to measure and record tri-axial readings of a patient's tremor motions, to optionally combine the three-axis tremor information into a single measurement of total tremor movement by a proprietary algorithm that eliminates some of the rotational orientation and other artifacts, to display the information graphically, and to transfer the data to a personal computer (PC) for further analysis, display, printing or storage. Refer to the following website for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K010270. (Accessed **August 2, 2023** ~~September 12, 2022~~)

The Embrace (Empatica. Inc) received FDA approval in January 2018 to be used use as an adjunct to seizure monitoring of adults in home or healthcare facilities during periods of rest. The device is worn on the wrist, and senses Electrodermal Activity (EDA) and motion data to detect patterns that may be associated with generalized tonic clonic seizures in patients with epilepsy or at risk of having epilepsy. When a seizure event is detected, Embrace sends a command to a paired wireless device that is programmed to initiate an alert to a designated caregiver. The System records and stores data from Accelerometers, EDA, and Temperature for subsequent review by a trained healthcare professional. Refer to the following website for more information: https://www.accessdata.fda.gov/cdrh_docs/pdf17/K172935.pdf.

### 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). Refer to the following website for more information: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed **August 2, 2023** ~~September 12, 2022~~)

### Additional Products

#### *Quantitative Sensory Testing and Nerve Conduction Studies*

Testing devices include but are not limited to the following: Medi-Dx 7000TM Single-Electrode Sensory Nerve Conduction Threshold Device (NDA Inc, Laguna Beach, CA), Neurometer® CPT Electrodiagnostic Neurostimulator (Neurotron Inc, Baltimore, MD), NC-stat System (NeuroMetrix, Inc.), Brevio (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.); Neurometer® (Neurotron Inc.); Vibrameter™ (Somedic AB, Sweden); Thermal sensitivity tester (Sensortek, Inc., Clifton, NJ); Axon-II™ NCSs System™.

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## Policy History/Revision Information

| Date | Summary of Changes |
|---|---|
| **TBD** | **Coverage Rationale**<br>***Nerve Conduction Studies***<br>• **Updated list of proven and medically necessary indications; replaced references to "nerve conduction studies with or without late responses" with "nerve conduction studies with or without *standard* late responses"**<br>**Supporting Information**<br>• **Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information**<br>• **Archived previous policy version CS082LA.O** |

## Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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