The Portable Neuromodulation Stimulator (PoNS™)
FACT SHEET

What is the PoNS?
The Portable Neuromodulation Stimulator (PoNS) device is an investigational medical device being studied for the treatment of neurological symptoms caused by disease or trauma. The PoNS is currently being studied in the United States for the treatment of balance disorder related to mild to moderate Traumatic Brain Injury (mTBI), and in Canada for the treatment of gait and balance disorder for patients with Multiple Sclerosis (MS). It represents the first in a series of non-invasive devices -- based on the patented PoNS platform -- designed to amplify the brain’s powerful ability to heal itself. This is part of a new approach being studied for “symptom treatment” for the rising number of patients who have experienced loss of function as a result of neurological disease or trauma.

What is the potential impact of the PoNS?
As a result of their disease or injury, many patients are left with disrupted neural networks in the brain that are unable to carry neural impulses completely or efficiently. Neural impulses are the signals responsible for directing the functions of the body, such as movement control or sensory perception. Researchers believe that significantly increasing the activation of these neurons through electrical stimulation, combined with targeted functional therapy, may help reorganize and reactivate the networks responsible for those functions.

While physicians and patients turn to available options to manage a host of neurological symptoms today, for millions living with these chronic disorders, there exists limited treatment options that actually help patients rehabilitate lost functions. The PoNS device is being studied as new potential option for the treatment of these chronic neurological symptoms of disease or trauma.

What is the growing science behind the PoNS?
The PoNS device is based on almost 40 years of research in the field of neuromodulation – the use of external stimulation to intentionally change and regulate the electrochemical environment of the brain. Other contemporary forms of neurostimulation aimed at inducing neuromodulation are costly and invasive, with the potential for adverse effects. For example, deep brain stimulation, which uses implanted pacemaker-like electrical devices to decrease tremors in Parkinson’s, carries surgical risks.¹

Neuromodulation enhances neuroplasticity, the brain’s ability to restructure or relearn in response to new experiences, sensory input and functional demands.² The process of neuroplasticity underlies all cerebral learning, training, and rehabilitation.
How Does the PoNS work?
In the research setting, the PoNS device is placed on the tongue while specially patterned electrical impulses are generated by the device. For 20-30 minutes the electrical stimulation is coupled with targeted functional therapy, called Cranial Nerve Non-Invasive Neuromodulation (CN-NINM). Therapy consists of targeted physical, occupational, and cognitive exercises, based on the patient's deficits. Clinical research shows that electrical stimulation of the tongue stimulates two major cranial nerves -- the trigeminal (the nerve responsible for sensations in the face, biting and chewing) and the facial (the nerve responsible for motor control of most of the muscles of facial expression). The electrical stimulation of the cranial nerves creates a flow of neural impulses that are then delivered directly into the brain stem – the main control center for many life functions including sensory perception and movement. From the brain stem, these impulses travel throughout the brain and activate or reanimate neurons and structures involved in human function – the cortex, spinal cord and potentially the entire central nervous system. How does this happen? Researchers believe that sustained stimulation initiates a sequential cascade of changes in the actual interconnected nuclei, or the neuronal network, that is at the core of major anatomical components of the brain.³

What is unique about the PoNS™?
The PoNS device is believed to be the first non-invasive means for delivering neurostimulation through the tongue. Researchers believe that use of the tongue as a gateway to the brain may be one of the most natural, non-invasive and direct ways to stimulate the brain. The tongue is anatomically unique, with high nerve sensitivity, thousands of nerve fibers and is tied to the brainstem with two major cranial nerves. Researchers point to the intensity of the signal the brain receives, after a person accidently bites down on his/her tongue, as a good example of the power of the tongue to send intense messages directly to the brain.⁴

PoNS Device Clinical Study
Data from multiple pilot studies with IRB oversight and several case studies conducted since 2007, with more than 200 subjects using the PoNS device in conjunction with physical or cognitive therapy, have shown anecdotal positive results in rehabilitating a range of symptoms caused by neurological disorders or injury. The PoNS device has shown to improve and sustain functional rehabilitation to address brain dysfunction from traumatic, degenerative, developmental, chemical, or unknown origins.

Clinical trials are now underway and others are planned to study the safety and effectiveness of the PoNS device including:

- A pilot study of chronic balance deficit due to mild-to-moderate traumatic brain injury (TBI) being conducted at the Tactile Communication and Neurorehabilitation Laboratory (TCNL) at the University of Wisconsin-Madison. Launched recently, the study is expected to yield interim results in the first quarter of 2015. For more information about the trial please contact TCNL at jruhland@wisc.edu, or see http://go.wisc.edu/i24mx8. This clinicaltrials.gov identifier is NCT02158494.

- A second pilot study trial is underway at the Montreal Neurological Institute designed to study the effect of the PoNS device on balance in patients with MS. Pilot studies here will continue through Q1, 2015.
Pivotal Phase 3 trials in MS is scheduled to start in the first half of 2015 at Montreal Neurological Institute and Hospital.

Pivotal Phase 3 trials in TBI are scheduled to start in the first half of 2015 at Oregon Health Sciences University, Orlando Regional Medical Center, Montreal Neuro-feedback Institute.

Results of these PoNS device trials are expected to be submitted to Health Canada and the US Food & Drug Administration (FDA) for review in the second half of 2016.

**Limited Treatments for Neurologic Symptoms**

The relief of neurological symptoms as a result of disease or trauma represents a high unmet need in society today including:

**Traumatic Brain Injury (TBI) -- a serious public health problem in the United States.**

No pharmacologic or biologic treatment for improving outcomes of traumatic brain injury have been approved. Current approaches include rehabilitation to teach patients how to cope with their specific injury-related symptoms. There are approximately 5.3 million Americans living with a TBI-related disability and the consequences that can affect all aspects of an individual’s life. Since 2000, more than 287,000 U.S. service members have sustained a TBI.

**Multiple Sclerosis (MS) -- an estimated 2.3 million people are affected by MS worldwide.** Experts believe currently 250,000 to 350,000 people in the United States are diagnosed with MS. Medications help reduce inflammation in the Central Nervous System (CNS), reduce the frequency and severity of MS attacks and the numbers of lesions in the CNS, and may slow the progression of disability. However, medication does not address the rehabilitation of loss of function.

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5. The Centers for Disease Control.
8. The Defense and Veterans Brain Injury Center.
9. National Multiple Sclerosis Society
10. National Institute of Neurological Disorders and Stroke
11. National Multiple Sclerosis Society