PoNS®
Portable Neuromodulation Stimulator

PoNS Therapy Registry (PoNSREM)

Long-Term Health Economic and Clinical Outcomes in Neurological Disorders

Advancing Evidence for PoNS Therapy in Neurological Disorder Care

The PoNS Therapy Registry (PoNSREM) is designed to gather important health economic and clinical information to better understand the value of PoNS Therapy on long-term therapeutic outcomes for people with gait and/or balance deficit due to a neurological disorder.

Purpose of the Registry:

The registry is designed to:

- Establish a database of patients treated with PoNS
- Evaluate the long-term value of PoNS Therapy in real-world clinical settings.
- Collect health economic data related to patient outcomes and healthcare utilization.
- Assess changes in functional ability, safety outcomes, and overall medical status over time.
- Expand clinical knowledge to support physicians, rehabilitation teams, patients, and healthcare payers.

What Participation Involves

Participation in PoNSREM allows HCPs to enter patients to be treated or already treated with PoNS into the registry.

HCPs can access the registry through a URL link or by scanning the QR code (both below) that will allow them to get an individualized login account to access the registry in an electronic data capturing system (TrialKit). The HCPs can limit their PoNSREM participation by simply entering patients' information in the demographic section.

Why Your Participation Matters

PoNSREM is structured not only to track access to PoNS Therapy but, most importantly, to monitor key long-term therapeutic outcomes, including changes in cardiovascular condition, weight, functional ability, disease-associated injury risks such as falls, onset of new comorbidities, changes in existing medical conditions, need for new pharmacological or non-pharmacological therapies, changes in ongoing pharmacotherapy or other interventions, number of hospital stays or office visits, and reported side effects.

Your participation helps build real-world evidence that can:

- Improve understanding of PoNS Therapy outcomes.
- Support future clinical research.
- Inform healthcare providers and patients.
- Help demonstrate the value of PoNS Therapy to healthcare systems and payers.

Access PoNSREM in two ways:

Scan the QR code:

or use this link:
https://bit.ly/4ima3hG

Entering Patients into the registry:

Since the registry is structured to collect outcome measures (i.e. disability status, return to work, quality of life, fitness, impact on other medical conditions/clinical symptoms, and PoNS therapy outcomes), HCPs have the option to complete the outcome measure questionnaires.

If the HCP chooses to fill out the questionnaires (13 easy questions with a drop-down-answer structure, which won't take more than 5-10 min to complete) they will be required to complete:

1. **Baseline Questionnaire** (one time) when a patient is enrolled in the registry:
   - Collects information about patients' medical history and health status before beginning PoNS Therapy
2. **Follow-up Questionnaire(s)** anytime the patient completes a 12- or 14-week course of PoNS Therapy.
   - Captures information about patients' treatment experience, functional progress, and overall outcomes.
3. **Long-term Outcome Questionnaires** to be filled out at any follow up visit (at least 2) after patient completes a course of PoNS Therapy

By filling out the questionnaires, HCPs will have the opportunity to view/use the data from their patients comprehensively and, if interested, they can request access to relevant data across the broader database for research and publication purposes.

The HCP will scan the QR code to access the PoNSREM access form to be completed with their information.

Upon submission, a login link from **webmaster@clsds.com** will be sent to access the registry and enable the HCP to enter patient information and fill out the questionnaires. All questionnaires are available by clicking patients name/ID # and are completed through the TrialKit website.

Baseline and 12- or14-wk follow up questionnaires will automatically appear. Baseline questionnaire must be filled out before being able to access any follow-up questionnaire. Each questionnaire takes about 5-10 minutes. TrialKit will automatically email HCP when a questionnaire is due.

Patients must provide consent and electronically sign the consent form before participating, which needs to be uploaded to enroll the patient. Patients may withdraw from the registry at any time.

Access PoNSREM in two ways:

Scan the QR code:

or use this link:
https://bit.ly/4ima3hG

bioness®

Indication for Use: The PoNS device is indicated for use as a short term treatment of gait deficit due to mild to moderate symptoms from multiple sclerosis and is to be used as an adjunct to a supervised therapeutic exercise program for adults 22 years of age and over by prescription only. The PoNS device is indicated for use as a treatment of dynamic gait deficits due to chronic symptoms from stroke and is to be used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over by prescription only.

The PoNS device delivers electrical stimulation directly to the surface of the tongue. Precautions for use are similar to those for wearable electrical stimulation medical devices. Electrical stimulation should not be used: if there is an active or suspected malignant tumor, in areas of recent bleeding or open wounds, and in areas that lack normal sensation. The PoNS has not been tested on, and thus should not be used by individuals who are pregnant. Do not use the PoNS if you are sensitive to nickel, gold or copper.

Full prescribing information can be found in product labeling or at https://bionessmedical.com/pons/safety-information/.

PoNS, PoNS Therapy, Bioness and the Bioness Logo are registered trademarks of Bioness Medical, Inc. | BionessMedical.com | **Rx Only**

© 2026 Bioness Medical, Inc. MPR-005516A 08/26