

# Home-based Treatment for Overactive Bladder using a Physiologic Closed Loop Transcutaneous Tibial Nerve Neuromodulation System

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## Introduction

Tibial nerve stimulation has been demonstrated as an effective treatment for overactive bladder (OAB). Tibial neuromodulation can be applied via subcutaneous tibial implants, percutaneous needle electrodes, or transcutaneous skin surface electrodes. Transcutaneous systems are the least invasive and most patient-friendly option; however, they may be prone to variability in electrode placement, use environment, and patient behavior resulting in sub-optimal therapy delivery and effectiveness.

A physiologic closed-loop (PCL) system can compensate for these variabilities, providing an objective confirmation of target nerve activation and optimized therapeutic response. This study investigates the benefits of a wearable Tibial Neuromodulation (wTNM) system with physiologic closed-loop control for OAB treatment at home, requiring no clinician supervision during treatment sessions.

## Methods

To construct a closed-loop control system for wTNM, a mathematical transfer function is established between the tibial nerve stimulation and corresponding electromyogram (EMG) motor response as the feedback signal. This transfer function is computed for each patient through a calibration process, wherein the patient is subjected to a series of stimulation levels — with sensed EMG recorded at each step (Figure 1) — until the patient reaches a comfortable therapy limit. After a series of signal processing to minimize noise and stimulation artifacts, the EMG target is quantified using nerve activation threshold and patient comfort limit. It is then utilized as the target value for the control system, while stimulation pulsewidth of the biphasic waveform acts as the control variable.

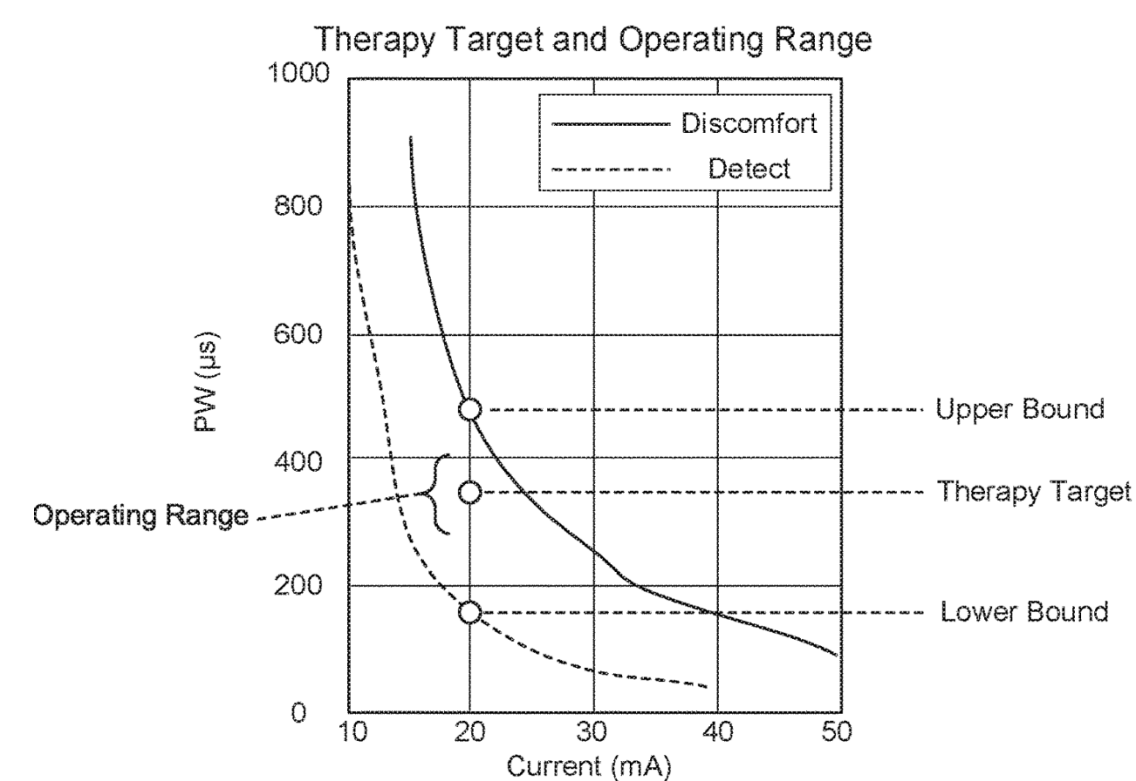


Figure 1: The therapy target is established during calibration.

## Methods (Continued)

During treatment, the wTNM system stimulates the tibial nerve through transcutaneous electrodes embedded in the wearable garment, which contains integrated sensors to measure surface EMG response at the foot. A controller with an analog convertor and microprocessor quantify the EMG signal and compute the required stimulation output using system transfer function, with the goal of maintaining the pre-defined target EMG value. A fixed-step increment is applied to the control variable to ensure a stable response, while the control system stays fully deterministic. If the EMG signal is noisy, such as caused by large body movements, the system transitions to open-loop control to continue therapy and reverts back to closed-loop control when the noise subsides.



Figure 2: The wTNM system with PCL stimulation and integrated garment with built-in electrodes shown on a patient's foot.

The wTNM system with physiologic closed-loop control (Figure 2) was employed in a multicenter clinical trial enrolling 96 subjects with OAB symptoms [Data on File. Avation Medical]. The mean age of participants was 60.8 years with 88.5% of population being female. The inclusion criteria required  $\geq 10$  average daily voids measured through a 3-day bladder diary, while additional OAB symptoms were also tracked for efficacy computations. Patients conducted 30-minute therapy sessions 1 to 3 times per week with symptom outcomes measured at baseline and after 12 weeks. All sessions were conducted at home by patients with help of a mobile app, while the system continuously self-adjusted through closed-loop control. Parameters monitored in the cloud included stimulation output, EMG signal, and therapy compliance, in addition to patient-reported OAB symptoms.

## Results

After 12 weeks of treatment using wTNM with PCL, responder rates (defined as proportion of subjects who exceeded a predefined symptom improvement) were significant at 61.8% for urge incontinence and 55.4% for urgency, and the combined responder rate for the three symptoms (incontinence, urgency, and voids) was 70.2% (Figure 3). The fluctuations in stimulation output were a clear indication of the varying electrical needs of each patient, the high variability in OAB symptoms, and the importance of leveraging closed-loop control for optimal therapeutic performance.

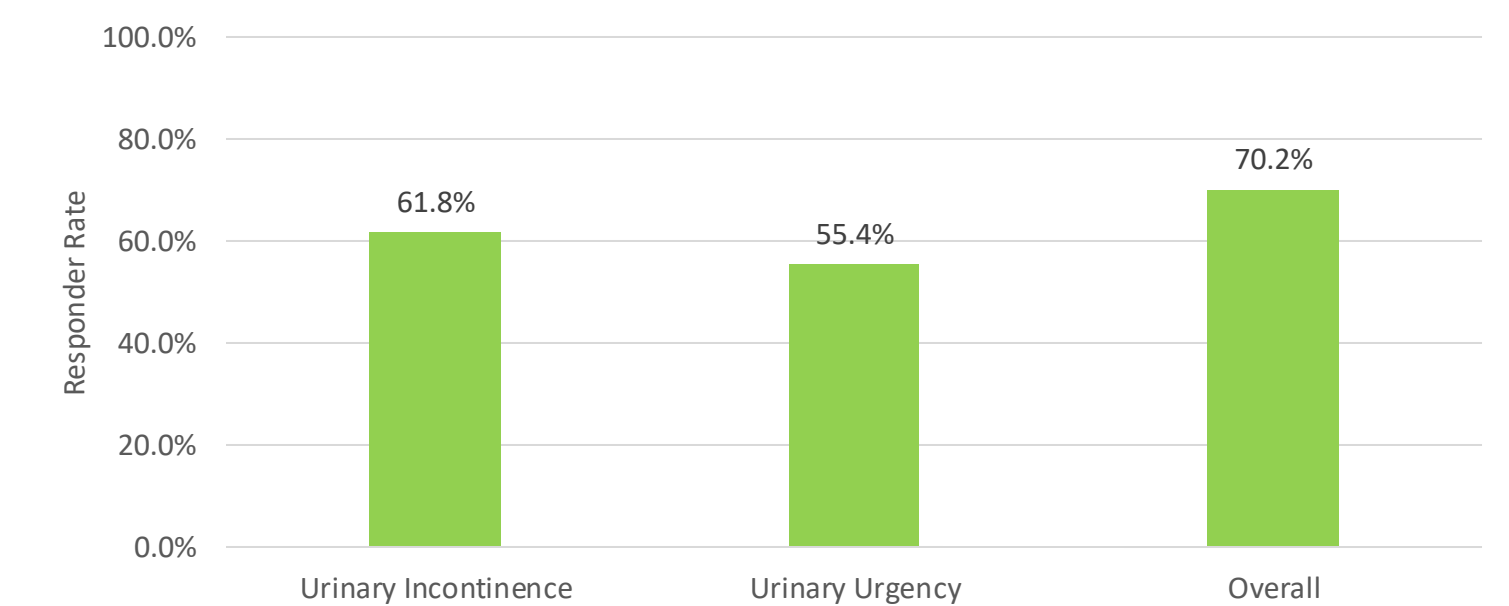


Figure 3. Responder rates for wTNM system with PCL therapy.

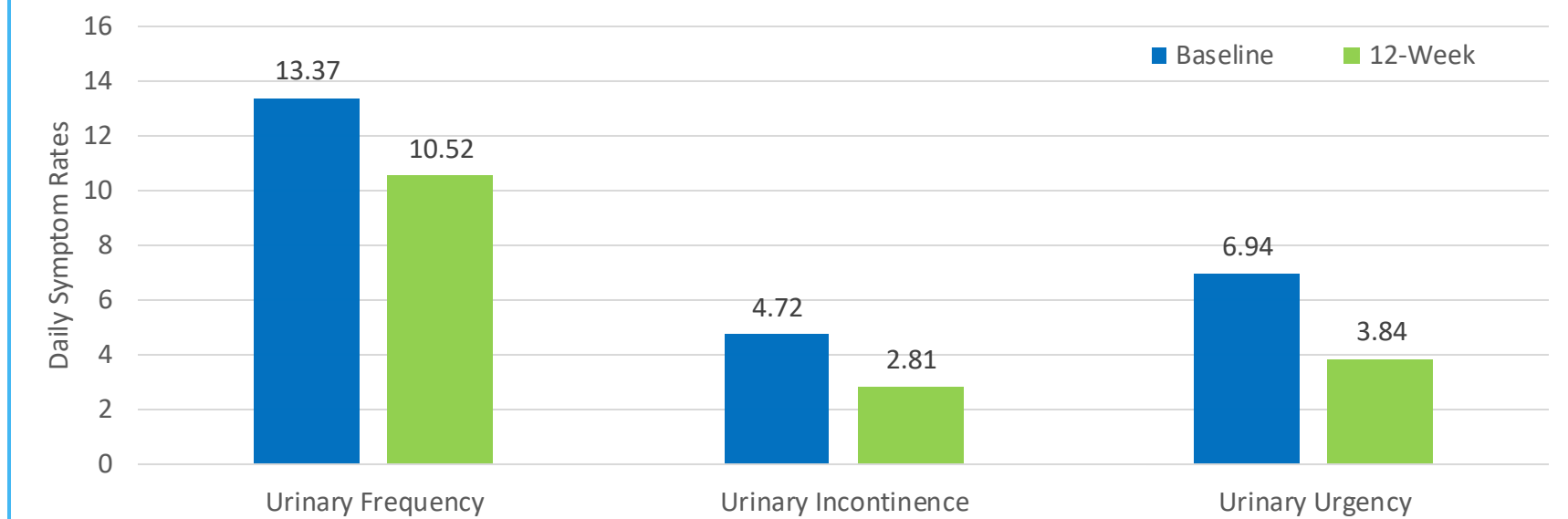


Figure 4. Symptom changes in response to wTNM with PCL therapy.

Figure 4 shows the symptom changes after 12 weeks (lower number implies improvement). There were no serious device-related adverse events, with high usability (98%), patient satisfaction (87%) and therapy compliance (88.5%), likely facilitated by the closed-loop control technology.

## Conclusion

A physiologic closed-loop controlled system allows for effective home-use wearable neuromodulation for OAB. The clinical evidence shows that wTNM, with physiologic closed-loop control, provides safe and optimal at-home therapy with high efficacy, user satisfaction, and therapy compliance.