Study Title	Study to optimize and validate the treatment parameters for the Empower Neuromodulation System
Study & Revision Number	CRD-12-1154 Rev 1
Device	Empower Neuromodulation System
Objectives	1. Compare two active treatment electrode locations to evaluate the effect of electrode placement on the appearance of sensory nerve action potentials (SNAPs). The appearance of SNAPs indicates effective sensory nerve stimulation. 2. Evaluate the usability of each of the two active treatment electrode locations (via the System Usability Survey (SUS)). 3. For one sham treatment electrode location (i.e. Sham #1), evaluate subject blinding, i.e. does the subject believe it is the active or sham treatment. 4. Compare two sham treatment electrode locations to confirm that the sham locations do not induce SNAPs.
Indications for Use/Subject Population	After initial development, we will propose that the Empower Neuromodulation System is indicated for the treatment of alcohol use disorder (AUD). Per the inclusion criteria of this pilot study, enrollment in this study is not restricted to only subjects with AUD. The subject population is adult males or females age 21-75 years old.
Study Design	Pilot feasibility study to optimize and validate treatment parameters.
Number of Subjects	Up to 40
Number of Sites	One (1)
Study Procedures Outline	1. Screening and ICF 2. Breath alcohol test 3. Eligibility review 4. The subject will be administered a 5-minute treatment at a sham treatment location and then be asked if he/she believes it is the active treatment, sham treatment, or does not know. 5. *Sensory nerve action potential (SNAP) assessment*. A clinical-grade nerve conduction assessment system (UltraPro 1000, Natus, Inc.) will be used both to provide electrical stimulation at each of four locations (two potential active treatment sites and two potential sham treatment sites and to record SNAPs during stimulation. The appearance of SNAPs are an indication of sensory nerve stimulation. 6. The subject will self-administer a 10-minute treatment session at one active treatment site. After a 5-minute break, the subject will self-administer a 10-minute treatment session at the other active treatment site. After each

	treatment session, the subject will complete two usability surveys about the treatment. 7. Subject compensation
Inclusion Criteria	1. Is 21-75 years old 2. Can provide informed consent 3. Currently has a stable living situation 4. Had one heavy drinking week (>7 drinks/week for women; >14 drinks/week for men) over the past 6 months 5. Has a breath alcohol concentration of 0.00% at enrollment 6. Is willing to follow all study procedures
Exclusion Criteria	1. Has been diagnosed with schizophrenia, epilepsy, peripheral neuropathy, or nerve damage 2. Has implanted electrical and/or neurostimulator device (e.g. pacemaker, defibrillator, vagal neurostimulator, deep brain stimulator, spinal stimulator, sacral stimulator, bone growth stimulator, or cochlear implant) 3. Has a tattoo or conductive, ferromagnetic, or other magnetic-sensitive metals that cannot be removed from the skin at the electrode sites 4. Is currently pregnant or breastfeeding 5. Has a bleeding disorder, a history of deep vein thrombosis, or is on anticoagulation drugs 6. Has used an investigational drug/device therapy within the past 4 weeks 7. Is deemed unsuitable for enrollment in study by the PI
Safety	Adverse Events will be recorded and reported appropriately throughout the study.
Sample Size Calculations	For the two active treatment sites, the percent of subjects who experience effective stimulation of the nerve via SNAP assessment will be compared via a two-proportion z-test ($p \leq 0.05$ for statistical significance).