

Technical Specifications & Recommendations for a Portable TMS Device

Background: The L-neuro+ is a portable medical device designed to treat major depressive disorders using transcranial magnetic stimulation (TMS); a noninvasive brain stimulation technology used for therapy in a wide range of neurological and psychiatric disorders. TMS has shown [high clinical outcome](#) in treating patients with major depressive disorder who have failed to receive satisfactory improvement prior to antidepressant medication in the current episode. Given the high cost and lack of accessibility of the healthcare facility-bound TMS treatment, a novel approach to delivering treatment in a cost effective, accessible way would be necessary to enable access to all unserved patients who need it desperately.

The L-neuro+ device principle of operation is based on the discharge of a high voltage capacitor through a stimulation coil; the pulsed magnetic field generated by the discharge current penetrates through neuromuscular tissues nearby to induce electrical currents in cortical neurons. The recommended standard treatment is in accordance with the newly FDA cleared Intermittent Theta-burst (iTBS) [protocol](#). Performed at 80% motor threshold. The train(s) consist of 30 pulses: 10 bursts (3 pulses/burst) delivered at 5.0 bursts per second for a total of 2 seconds followed by a break of 8 seconds and then repeated 20 times. Inside each burst are 3 pulses delivered at 50 times per second or one pulse every 0.02 seconds.

The following is a high-level technical and user requirements to design a portable TMS for use at the home of a patient to treat their depressive disorder safely, and effectively:

Hardware Design:

L-neuro+ is designed to be portable, for use at home that fits within a standard suitcase.

Major components of the device

- Stimulus generator
- Wearable headset
- Battery
- Connectivity

1. **Stimulus generator:** a portable, compact, lightweight stimulus generator that contains a miniature coil capable of generating a high intensity electromagnetic field required for effective treatment. The coils must be miniature, and compact in configuration that allows for cooling to sustain an entire treatment duration without heating.

2. **Wearable headset with embedded electrodes:** designed to be worn comfortably with electrodes around the headset allowing for regular daily activities during treatment without interference. The headset is lockable and becomes immobile once placed on the head, and the electrodes can be moved and adjusted given the target brain region for the specific patient.

5. **Battery Operated:** Equipped with a rechargeable battery capable of generating a high EM field, and its life covers the entirety of a treatment episode.

5. **Wireless Connectivity:** ability to connect the hardware device wirelessly (e.g. secure bluetooth) with an app in order to activate it, plan a treatment, operate it, and import and send treatment data. This is critical in order to create a closed-loop biofeedback and personalized treatment for patients.

Software Design:

1. **AI-Powered monitoring capability:** Integration of AI software to existing wearable devices to deeply understand the patient's condition and outcome of the treatment, which enables the AI system to personalize and iterate on the optimal treatment protocol for them. Biosignals like ECG, blood oxygen level, temperature, blood pressure, etc. are insights into the status of the depressive symptoms that the patient is experiencing. The analysis of this data is presented in real-time to the patient (through a user-friendly mobile app) to indicate how they may be reacting to the treatment, as well as suggestions for adjustments of treatment protocol that will be shared with their care provider for approval. The integration of the L-neuro+ with wearable device enables the closed-loop biofeedback intended to personalize the treatment protocol for the patient.