1. Introduction

The objective of this project is to develop a electrical stimulation system. The device will incorporate stimulation control based on predefined parameters.

The electronic designer will be responsible for developing the circuit design, PCB layout, and firmware integration, ensuring the device meets performance, safety, and regulatory requirements. Technical and scientific input will be provided by the project owner to align with the overall project goals and ensure efficient project delivery.

The device operates by generating electrical impulses using a Howland current source. These impulses are non-invasively transmitted to the to body via clip-type electrodes. The electrodes are connected to the stimulator via an audio jack. The stimulation parameters, including intensity, frequency, and waveform, are configured wirelessly through a Bluetooth-enabled microcontroller, which communicates with a PC-based application.

The stimulation parameters will be adjusted in real-time on the PC and sent to the stimulator via Bluetooth. Additionally, the stimulator continuously transmits real-time data, including output voltage, load voltage, and battery status, back to the PC for monitoring and analysis.

User interaction is facilitated via a simple user interface consisting of a start/stop key and a three-color LED indicator and optional session info display. The entire system is powered by an internal rechargeable battery, designed to last approximately one week under typical usage conditions.

Block	Description	
Power	Ensures stable power delivery to all components. The system is powered	
Management	by an internal rechargeable battery, initially charged via a standard USB	
	plug, with plans for inductive charging in future iterations.	
Microcontroller	Manages signal processing, stimulation parameter control, and	
Unit (MCU)	communication interfaces. Suggested BLE-enabled microcontrollers	
	ESP32 series.	
Stimulation	Generates a current stimulation waveform for safe and effective nerve	
Circuit	activation. The stimulator is based on arbitrary waveform current	
	stimulation, using a Howland current source (open for change if better	
	alternatives are provided). The device includes <u>two</u> independent	
	stimulators, allowing simultaneous operation with different stimulation	
	parameters.	
User Interface	Provides user control through a power button, session adjustment	
(UI)	buttons ("+" and "-"), and an "Enter" button for confirmation. The LED	
	display shows session time, stimulation intensity, and battery level. A	
	blue LED indicates active stimulation, and the rightmost LED flashes	
	when the session is paused. A battery indicator alerts the user when	

2. System Overview and Architecture

	charging is needed. The UI supports mid-session intensity adjustments using a double-press of the Enter button. Additionally, a dedicated LED will indicate Bluetooth connection status, showing advertising, connected, or disconnected states. (see reference device for details)	
Safety and	Basic overcurrent/voltage protection (e.g. using current limiting CRD	
Compliance	diode, TVS, varistors etc) is included in the design. Compliance with EMC, isolation, and other regulatory standards is not within the scope of this phase.	
Bluetooth Control	Stimulation parameters are configured via Bluetooth from a PC, enabling remote control and adjustments.	
Status Reporting	The system reports real-time stimulation status, including load voltage, and battery state, back to the PC via Bluetooth.	
Electrode	Electrodes are connected to the stimulator via a 3.5mm audio jack, with a	
Connection	clip-type electrode interface at the user end. (Nurosym, see section 7)	
PCB Size	The PCB dimensions will be aligned with the mechanical enclosure. (Nurosym, see section 7).	
Battery Life and Portability	The device is designed for a battery life of approximately one week under typical usage. It will be lightweight and compact to ensure portability.	
Cost	The design prioritizes cost-effectiveness without compromising	
Considerations	functionality.	
Open	All design files, including schematics and firmware, will be shared for	
Development	transparency and further development.	

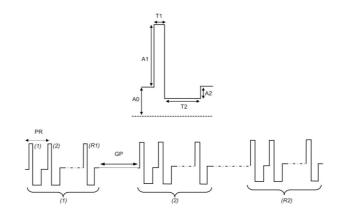
3. Components & Considerations

Block	Components & Considerations		
Power Management	Uses a rechargeable Li-Ion/Li-Po battery, voltage regulation, and		
	USB-C charging (future inductive charging planned). Suggested		
	components: TI BQ series battery management ICs		
	(BQ24080DRCR), MAX17048, LT1615ES5, XL6009.		
Microcontroller Unit	Low-power MCU, featuring integrated BLE and ADC for		
(MCU)	stimulation control. Suggested components, ESP32-WROOM.		
Stimulation Circuit	current source with safety circuitry. Supports sinusoidal,		
	biphasic, and monophasic waveforms (see section 4 for more		
	details on stimulation parameters). Voltage compliance: ~40V,		
	max stimulation current: 5mA (step resolution: best case 10µA,		
	worst case $100\mu A$). see also sample design for reference.		
	Suggested components: LM358, MCP4822, current source		
	topology Howland current source.		
User Interface (UI)	On/off key for stimulation control, three-color LED indicator.		
	Suggested components: HSMF-C113 (open to alternative).		
	Preferred: same as the reference design (Nurosym, see section 7)		
Bluetooth Control	BLE 5.0 for secure communication and status reporting.		
	Suggested components: see MCU section.		
Electrode Connection	Uses a standard 3.5mm TRS audio jack.		

4. Stimulation Parameters

Example biphasic current stimulation. Maximum stimulation duration should not exceed 60 min (resolution 10 second). In the image below a gap between T1 and T2 should be

considered i.e. T3 with amplitude same as A0. Monophasic pulse is similar to biphasic except omission of A2/T2 or A1/T1. Sinusoidal current features includes frequency, peak to pick amplitudes, baseline current, number of burst.



Symbol	Description	Range
Ao	Baseline current (µA)	
Aı	Amplitude of the 1st phase (μA)	
A ₂	Amplitude of the 2nd phase (μA)	
CH	Stimulation channel	1-2
T ₁	Pulse width of the 1st phase (μS)	$1 \leq T_1 \leq 100000$
T ₂	Pulse width of the 2nd phase (μS)	$1 \leq T_1 \leq 100000$
PR	Period of stimulus (µS)	
R1	Number of stimuli in each burst	
GP	Gap time between bursts (mS)	
R ₂	Number of bursts	

5. Validation and Verification The validation and verification process will ensure the system meets performance and safety requirements. The following key validation methods will be used:

Validation Method	Description	
Output Evaluation	The stimulator's output will be measured and evaluated using a	
	resistor to verify waveform accuracy and consistency.	
Functional Testing	Each block of the system, including power management,	
	stimulation circuit, and communication modules, will undergo	
	functional verification.	
User Interface Testing	g The start/stop control and LED indicators will be tested to	
	confirm expected behavior. Preferred: same as the reference	
	design (Nurosym, see section 7)	
Wireless	Bluetooth transmission reliability will be evaluated to ensure	
Communication	stable remote control and data reporting.	
Testing		

6. Next Steps

- 1. Define exact component specifications and shortlist potential ICs.
- 2. Develop schematics and PCB layout.
- 3. Prototype and evaluate the electronic design.
- 4. Iterate based on feedback to refine performance.

7. References & Reference Designs

- Howland Current Source Design: Sample device:

• NuroSym <u>https://nurosym.com/en-de</u>

Sample design in Proteus (attached)

