

Design Specification

Following is the design specification before the development. There is a possibility of design specification change during the development, and both parties will ensure best acceptable change to ensure the project success.

Following is the summary of the Trial Device functional specification. Detail information is referred in document: DMF 4.0_Design Specification_Trial Device

Functional Specification

a. Sensing / Input

Function: To provide a high-fidelity, multi-channel interface to the Implantable Trial Lead for the continuous acquisition of low-amplitude sacral afferent nerve signals and real-time monitoring of lead-tissue impedance [FR-01, SIR-02, SIR-03, RR-04].

Specification:

- **Input Channels [SPEC_Input_01]:** 4 differential bipolar sensing channels.
- **Input Impedance [SPEC_Input_02]:** $\geq 1\text{ M}\Omega$, differential, at 10 Hz.
- **Signal Amplitude Range [SPEC_Input_03]:** The analog front-end shall process input signals from $\pm 5\text{ }\mu\text{V}$ to $\pm 250\text{ }\mu\text{V}$ without saturation.
- **Input-Referred Noise [SPEC_Input_04]:** $\leq 2\text{ }\mu\text{V}_{\text{rms}}$ over the 10 Hz – 1000 Hz operational bandwidth.
- **Common Mode Rejection Ratio (CMRR) [SPEC_Input_05]:** $\geq 60\text{ dB}$ at 50/60 Hz to filter environmental EMI.
- **Signal Bandwidth [SPEC_Input_06]:** 1 Hz to 3000 Hz (-3 dB).
- **Impedance Measurement [SPEC_Input_07]:**
 - **Range [SPEC_Input_07a]:** 200 Ω to 1.5 k Ω
 - **Impedance Accuracy [SPEC_Input_07b]:** $\pm 10\%$ or $\pm 50\text{ }\Omega$.

b. Signal Processing (Analog Front End)

Function: To amplify, filter, and digitize the raw nerve signals with sufficient resolution and speed to support the real-time closed-loop algorithm [FR-02, PR-04, MPR-03].

Specification:

- **Amplifier Gain [SPEC_AFE_01]:** Two stage amplifier: 20x (first stage), 200x (second stage)
- **ADC Resolution [SPEC_AFE_02]:** 16-bit.
- **Sampling Rate [SPEC_AFE_03]:** Selectable 2 kSPS or 10 kSPS per channel for high-resolution biomarker capture.
- **Bandpass Filtering [SPEC_AFE_04]:** Hardware-based 10 Hz – 5,000 Hz bandpass filter ($\geq 40\text{ dB}$ rejection).
- **Signal-to-Noise Ratio (SNR) [SPEC_AFE_05]:** Validated in-line calibration to ensure SNR $> 3:1$ for $\pm 5\text{ }\mu\text{V}$ signals [MPR-03].

c. Processing & Control (MCU / Controller)

Function: To execute the closed-loop algorithm, manage all therapy logging, enforce safety protocols, and control all system peripherals. The MCU is the central controller for the device [FR-02, FR-06, FR-07, RR-03].

Specification:

- **Processor Core [SPEC_MCU_01]:** ARM Cortex-M4 (with FPU) or equivalent.
- **Clock Speed [SPEC_MCU_02]:** ≥ 24 MHz.
- **Algorithm Latency [SPEC_MCU_03]:** Trigger detection to stimulation command delivery ≤ 500 ms [PR-01].
- **Data Security [SPEC_MCU_04]:** Onboard hardware AES-256 encryption engine for all logged data.
- **Safety & Timing [SPEC_MCU_05]:**
 - **Hardware Watchdog Timer [SPEC_MCU_05a]:** Independent hardware watchdog timer with a non-maskable timeout period of ≤ 500 ms that forces stimulation shutdown [SR-02].
 - **Real-Time Clock (RTC) [SPEC_MCU_05b]:** Onboard RTC with battery backup for accurate timestamping of all logged events.
- **Memory [SPEC_MCU_06]:**
 - **RAM [SPEC_MCU_06a]:** ≥ 256 KB.
 - **Non-Volatile Flash Memory [SPEC_MCU_06b]:** 32 GB to store firmware and a minimum of 14 days of continuous therapy data logs [FR-05]. The memory system must ensure data preservation on sudden power loss [DR-03].

d. Actuation / Output

Function: To generate safe, precise, and therapeutically effective electrical stimulation pulses as commanded by the MCU, and to provide clear visual status indicators to the user [FR-03, FR-08, FR-11, UIR-02].

Specification:

- **Output Channels [SPEC_Output_01]:** 4 independent stimulation channels.
- **Waveform Type [SPEC_Output_02]:** Charge-balanced, biphasic, constant current pulses.
- **Amplitude Range [SPEC_Output_03]:** 0.0 mA to 2.0 mA (Resolution: 0.1 mA) [FR-07].
- **Pulse Width [SPEC_Output_04]:** 50 μ s to 500 μ s (Resolution: 10 μ s).
- **Frequency Range [SPEC_Output_05]:** 1 Hz to 400 Hz (Resolution: 1Hz).
- **Hardware Current Limiter [SPEC_Output_06]:** Redundant hardware clamp at 3.0 mA (absolute max) [FR-07, PWR-02].
- **User-Facing LED [SPEC_Output_07]:** Multi-color LEDs (Green, Blue, Red)
 - **Therapy Mode [SPEC_Output_07a]:** Solid Green
 - **Device ON [SPEC_Output_07b]:** Solid Blue
 - **Fault Detection [SPEC_Output_07c]:** Flashing Red
- **Button [SPEC_Output_8]:** Mechanical button to restart therapy mode when pressing longer than 3 seconds.

e. Communication

Function: To provide a secure, authenticated, and encrypted communication link with the Clinician Programmer for data transfer and therapy programming [FR-05, SIR-01, CSR-03].

Specification:

- **Wired Interface [SPEC_Comm_01]:** USB Type-C for data transmission

f. Mechanical / Structural

Function: To provide a lightweight, discreet, durable, and biocompatible enclosure that protects the internal electronics and provides a secure connection to the lead cable [FR-15, PMR-04, ER-01, ER-03].

Specification:

- **Dimensions [SPEC_Mech_01]:** < 105 mm x 85 mm x 20 mm (± 5 mm) [PMR-04].
- **Weight [SPEC_Mech_02]:** ≤ 300 g (including battery).
- **Ingress Protection (IP) Rating [SPEC_Mech_03]:** IP24 minimum, protecting against dust ingress and splashing water from any direction [ER-01].
- **Durability [SPEC_Mech_04]:** Functional after 1.0-meter drop onto concrete [ER-03].
- **Materials [SPEC_Mech_05]:** ISO 10993 Biocompatible polycarbonate [FR-15, SRR-08].
- **Lead-to-Device Connector Integrity [SPEC_Mech_06]:** Keyed, locking lead connector rated for ≥ 20 cycles [SIR-02].
- **Operating Temp [SPEC_Mech_07]:** 5°C to 40°C [ER-02].
- **User Input Button [SPEC_Mech_8]:** A single, user-actuated physical button on the device enclosure, sealed to maintain the IP rating [SPEC_Mech_04], rated for a minimum of 1,000 actuation cycles for reliability, and ergonomically located to balance easy access with protection against accidental presses.

g. Power System

Function: To provide uninterrupted power for the 14-day trial with minimal user burden and failsafe shutdown logic [PWR-01, PWR-03, RR-02].

Specification:

- **Battery Type [SPEC_Power_01]:** Non-rechargeable Primary battery
- **Operating Life [SPEC_Power_02]:** Minimum 10 days continuous operation [PWR-01].
- **Power-on operation [SPEC_Power_03]:** When devices connected to Programmer through Type-C, the power can be used from Programmer instead of battery.
- **Safety Circuitry (BMS) [SPEC_Power_06]:** Hardware protection for over-charge, over-discharge, and thermal runaway [PWR-02].
- **Surface Temperature [SPEC_Power_07]:** < 41°C during charging and maximum stimulation delivery [SRR-11].