NeuStim™ Model NN-01

MODULAR TRANSMITTER INSTRUCTION MANUAL

1.0 INTRODUCTION

The purpose of this document is to provide integration instructions for integrating a module (i.e. modular transmitter) in a host product, i.e. the NeuStim™ Model NN-01.

2.0 INTEGRATION INSTRUCTIONS

2.1 General

Sections 2.2 through 2.12 describe the necessary items that are required in the integration instructions for the host product manufacturer (i.e. Neuvotion Inc.) to use when integrating a module in a host product.

Note: The modular transmitter is only approved for use by the grantee, i.e. Neuvotion Inc., in its own host product, and not intended for sale to third parties.

2.2 List of applicable FCC Rules

The following FCC rules are applicable to the modular transmitter:

47 CFR § 1.1310 Radiofrequency radiation exposure limits.

47 CFR § 2.1093 Radiofrequency radiation exposure evaluation: portable devices.

47 CFR § 15.247 Operation within the bands 902–928 MHz, 2400–2483.5 MHz, and 5725–5850 MHz.

2.3 Summary of Specific Operational Use Conditions

The Intended Use of the host product is to be used in an environmentally controlled indoor clinical environment, e.g. doctor's office, occupational/physical rehabilitation clinic – per the published environmental specifications in the NeuStim™ Model NN-01 User Manual.

Furthermore, the Intended Use of the host product is as a portable device (as defined in 47 CFR § 1.1307(b)(2)), for use within 20 centimeters of the body of the user.

2.4 Module Procedures

The host product is a regulated FDA Class II Medical Device with Special Controls Guidance; design, development, manufacturing, changes, and post-market surveillance are per Neuvotion Quality Management System iaw 21 CFR 820 Quality System Regulation (relevant highlights as follows:)

- All changes/change requests controlled via a change control process and change review board {21 CFR 820.30 Design Controls}. It is during this process that any change request that could potentially impact the integration of the module in the host product is evaluated.
- Detailed design and verification data maintained as part of the host product Design History File {21 CFR 820.30 Design Controls}. It is during this process that the integration of the module in the host product is analyzed and tested for compliance.
- Detailed manufacturing drawings are maintained as part of the host product Device Master Record {21 CFR 820.181 Device Master Record}. It is during this process that the integration of the module in the host product manufacturing drawings (e.g. manufacturing specifications, component specifications, assembly drawings, inspection criteria, etc.) are controlled and maintained.
- Detailed records of each host device are maintained as part of the host product Device History Record {21 CFR 820.184 Device History Record}. It is during this process that the integration of the module in the host product for a given serialized host product is documented and remains associated with the given serialized host product until host product retirement.
- The host product module software and firmware are validated and verified {21 CFR 820.30 Design Controls}. It is during this process that the integration of the module in the host product that the software and embedded firmware used to configure and operate the module is validated for compliance.
- The host product module Cybersecurity is validated including provisioning of WiFi {Federal Food, Drug, and Cosmetic Act (FD&C Act) section 524B, Ensuring Cybersecurity of Devices (section 3305)}. It is during this process that the integration of the module in the host product has considered and implemented controls to mitigate against cybersecurity incursions that could impact the module compliance.

- The host product manufacturing process and controls are validated, including the loading of the firmware into the host device {21 CFR 820.181 Device Master Record}. It is during this process that the integration of the module in the host product manufacturing processes are validated and controlled (assures that a manufacturing process does not impact the module compliance).

2.5 Trace Antenna Designs

The module integrated into the host product has a self-contained permanently attached trace antenna that is not subject to modification. The module has been FCC certified for use with the self-contained permanently attached trace antenna (FCC ID 2AC7Z-ESPWROOM32D).

2.6 RF Exposure Considerations

The intended use of the host product is for portable operations. The integrated module in the host product has been evaluated to 47 CFR § 2.1093 Radiofrequency radiation exposure evaluation: portable devices iaw 47 CFR § 1.1310 Radiofrequency radiation exposure limits.

The NeuStim™ Model NN-01 User Manual contains the following labeling:

"The NeuStim ™ Model NN-01 intended use is for within 20 centimeters of the body of the user. The NeuStim ™ Model NN-01 has been evaluated to applicable FCC regulations and requirements as of the date of this manual (refer to Section 10, Conformance to Regulations and Standards)"

Specific Absorption Rate testing iaw 47 CFR § 2.1093 Radiofrequency radiation exposure evaluation: portable devices. The test results are documented in test report number: SAR.20220801 Revision A; attached as an appendix.

2.7 Antenna

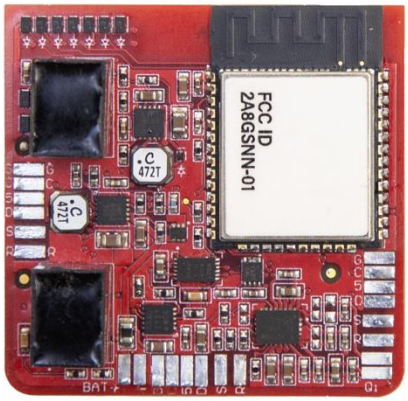
The module integrated into the host product has a self-contained permanently attached trace antenna that is not subject to modification. There are no provisions for an external antenna or a different internal antenna. The self-contained permanently attached trace antenna has a nominal matched impedance of 50 Ohms, and a gain of 3.7 dBi. The module location within

the host product is fixed, and controlled by manufacturing drawings regulated by 21 CFR 820.30 (h) Design Transfer, 21 CFR 820.30 (i) Design Changes, 21 CFR 820.30 (j) Design History File, and 21 CFR 820.181 Device Master Record.

2.8 Labeling and Compliance Information

Photograph of the exterior of the host product with required labeling:

Photograph of the internal host product with required labeling:



2.9 Information on Test Modes and Additional Testing Requirements

To engage RF Test Modes and perform RF testing, the Espressif RF Test Tool and Test Guide is to be used.

- The Espressif RF Test Tool and Test Guide may be downloaded from https://www.espressif.com/en/support/download/other-tools
    - *"Quickly get Espressif's RF performance test tool, test firmware, test guide and certification test guide for ESP32, ESP32-C3, ESP32-S2,ESP32-C6,ESP32-C2,ESP32-H2, and ESP8266 series of product."*
    - After unzipping, the file to run is the executable EspRFTestTool_vx.x_manual.exe where x.x is the current version number.
- Access the host product internal System-on-a-Chip serial port and connect to the PC that the above executable is located on. Information on accessing the serial port may be obtained from https://docs.espressif.com/projects/esp-idf/en/latest/esp32/get-started/establish-serial-connection.html

- No firmware, operational or test, is downloaded to the host product; just execute the above application from the PC
- Configure the desired RF test modes from the Espressif executable application, and execute

2.10 Additional testing, Part 15 Subpart B disclaimer

The host product also contains unintentional-radiator digital circuity, and as such will be complaint with 47 CFR 15 Subpart B with the module installed.

2.11 Note EMI Considerations

The host product with the integrated module has been demonstrated to be in compliance with IEC 60601-1-2 Ed. 4.1 en:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests; and IEC/TR 60601-4-02 Ed. 1.0 en:2016 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.

2.12 How to make Changes

Note: The modular transmitter is only approved for use by the grantee, i.e. Neuvotion Inc., in its own host product, and not intended for sale to third parties.