Exhibit of the research project, necessity of the wireless communication, and inadequateness of existing communication facility

Table of Contents

1. Exhibit of the research project

The authorization is to be used for providing wireless communication for an advanced wireless neurosensing device that will be used for epilepsy monitoring in a clinical setting and also in the home environment for research participants engaged in research sessions to investigating the BrainGate2 Neural Interface System (NIS). The wireless neurosensing device is dedicated for recording neural signals from the patients' cortical areas to facilitate epilepsy monitoring and diagnosis and also investigate feasibility of the NIS. The device is a head-mounted device that incorporates 96 channel ultralow noise ultralow power neural amplifiers, two successive approximate analog to digital converters, a custom controller ASIC, a low power On-Off keying custom wireless transmitter ASIC, and low dropout linear regulator (LDO). The wireless device will be used in conjunction with a pedestal connected to a microelectrode array (MEA) device that is 510K approved device for clinical use. The MEA device has 96 silicon electrodes and is pre-implanted into the targeted brain area of a patient, which can sense extracellular biological neural activities through its electrodes and pass the signals to the percutaneous pedestal connector. External to the patient, the wireless neurosensing device will interface with the pedestal connector, record the neural signals, and wirelessly transmit it to a receiver unit for further signal processing, display, and storage. The experiments will be carried out in a controlled and secured environment with an area of less than 10m diameter. This also indicates the wireless neurosensing device will be used for indoor short distance (a few meters) application. A detailed description of the wireless device is shown in Figure 1.

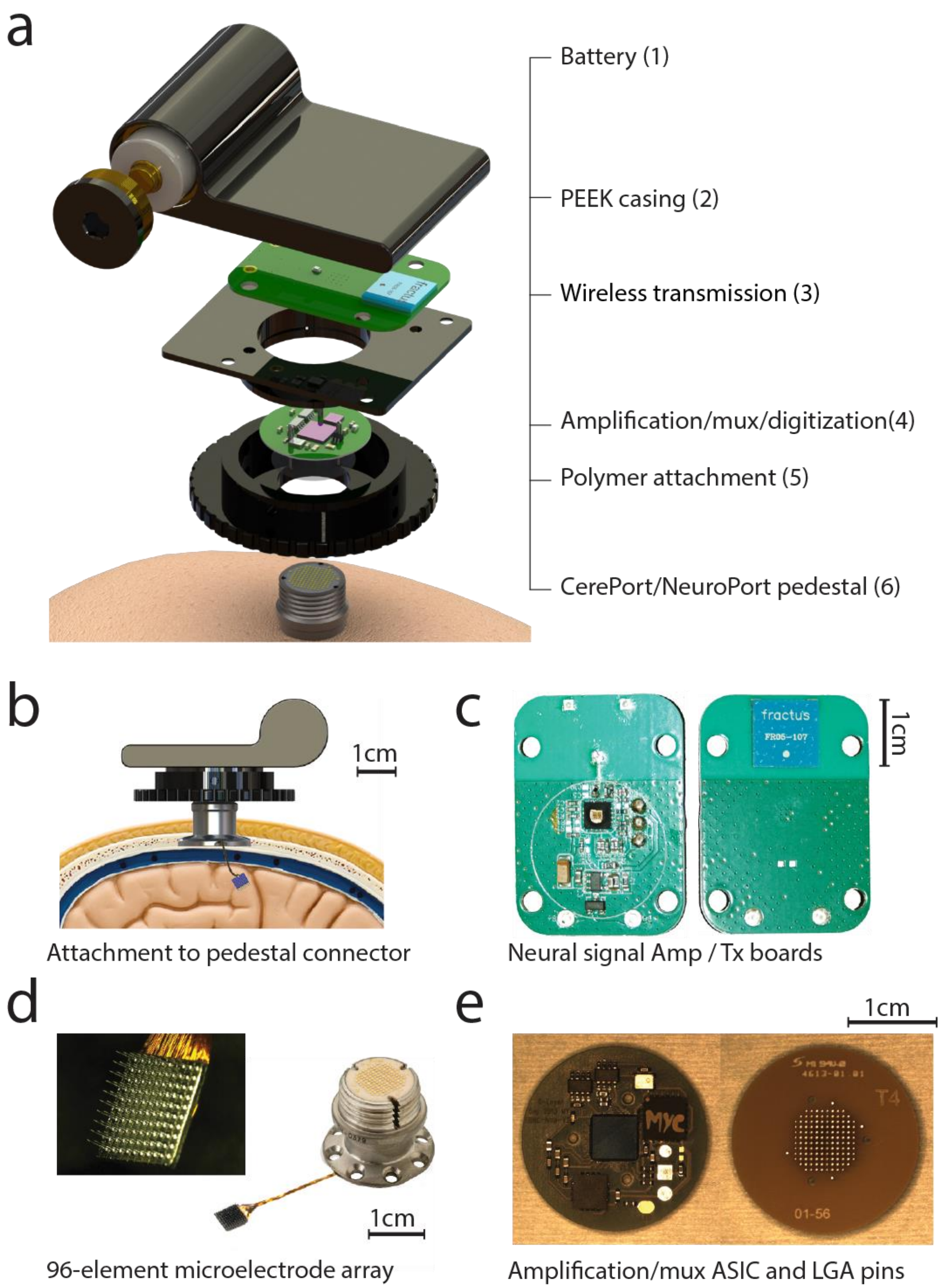

Figure 1. Architecture of the Wireless Transmitter Device:
(A) 3D computer-added design (CAD) model showing the complete assembly of the wireless device. (B) 3D CAD model showing the attachment of the wireless device to a head-mounted pedestal MEA device. (C) Photographs of the bottom and top views of the transmitter PCB. (D) Photograph of a commercial pedestal and microphotograph of the 96-electrode silicon-based MEA. (E) Photographs of the top and bottom views of the amplifier PCB.

The wireless communication for the device uses a simple On-Off Keying (OOK) modulation scheme at a nominal carrier center frequency of 3.5GHz. The signal that modulates the carrier is a single 48Mbps digital serial bit stream that is the Manchester encoded version of the digital neural data. In order to reduce the RF emission to the user (patient), the power of the wireless device (transmitter) is ultralow and is limited to be <1mW (0dBm) at the transmitter antenna input port, <0.5mW broadcasted by the antenna, and was measured to be -4.85dBm at the antenna input port, and –38.22dBm at 1m distance using an 10dBi directional planer antenna. The testing setups for the spectrum and power measurements are shown in Figures 2-4. The spectrums of the RF signal at the transmitter antenna input port and at the distance of 1m measured using a 10dBi receiving antenna and the Keysight N9020A MXA Signal Analyzer are shown in Figures 5-8 below. Considering possible minimum distance between the transmitter of the wireless device and the user under normal condition is >12mm, for Mobile and Portable Devices (KDB 447498), according to FCC 447498 D01 General RF Exposure Guidance v05r02 "Mobile and Portable Devices RF Exposure Procedures and Equipment Authorization Policies", "4.3. General SAR test reduction and exclusion guidance", the 1-g and 10-g SAR test exclusion thresholds for 100 MHz to 6 GHz at test separation distances ⩽ 50 mm are determined by: [(max. power of channel, including tune-up tolerance, mW)/(min. test separation distance, mm)] • [√ f(GHz)] ⩽ 3.0 for 1-g SAR and ⩽ 7.5 for 10-g extremity SAR. For the proposed wireless device, max. power of channel=0.33mW (-4.85dBm), min. test separation distance=12mm, f(GHz)= 3.5GHz. It will give us: 0.33/12* √ 3.5= 0.047, which is much less than both 3.0 for 1-g SAR and 7.5 for 10-g extremity SAR. In additional, according to "Mobile and Portable Devices RF Exposure Procedures and Equipment Authorization Policies", " Appendix A SAR Test Exclusion Thresholds for 100 MHz – 6 GHz and ⩽ 50 mm", for 3.6GHz at 10mm, the SAR Test Exclusion Threshold is 16mW, which is much larger than the proposed device, therefore the proposed device falls into "Standalone SAR test exclusion".

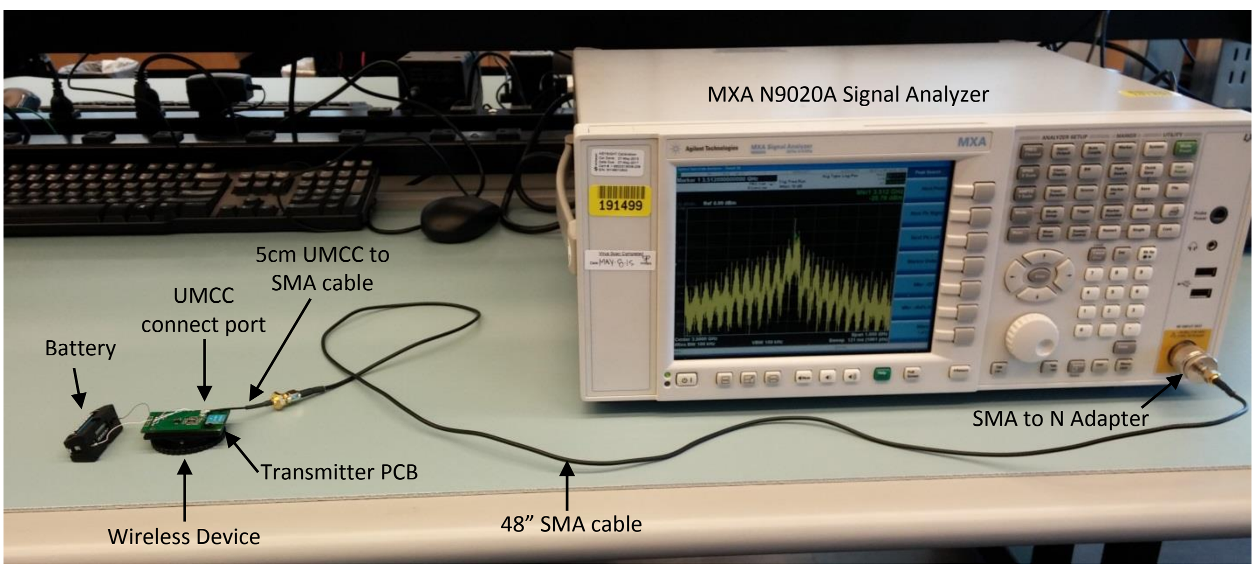

Figure 2. Testing setup for measuring the spectrum and power at the antenna input node of the wireless transmitter using the Keysight N9020A MXA Signal Analyzer. The estimated total insertion loss from the antenna input node to the MXA signal analyzer input includes the loss from: UMCC connector, 5cm UMCC to SMA cable, 48" SMA cable and the SMA to N adapter, and is about 3dB=(0.24+0.18+2.4+0.18).

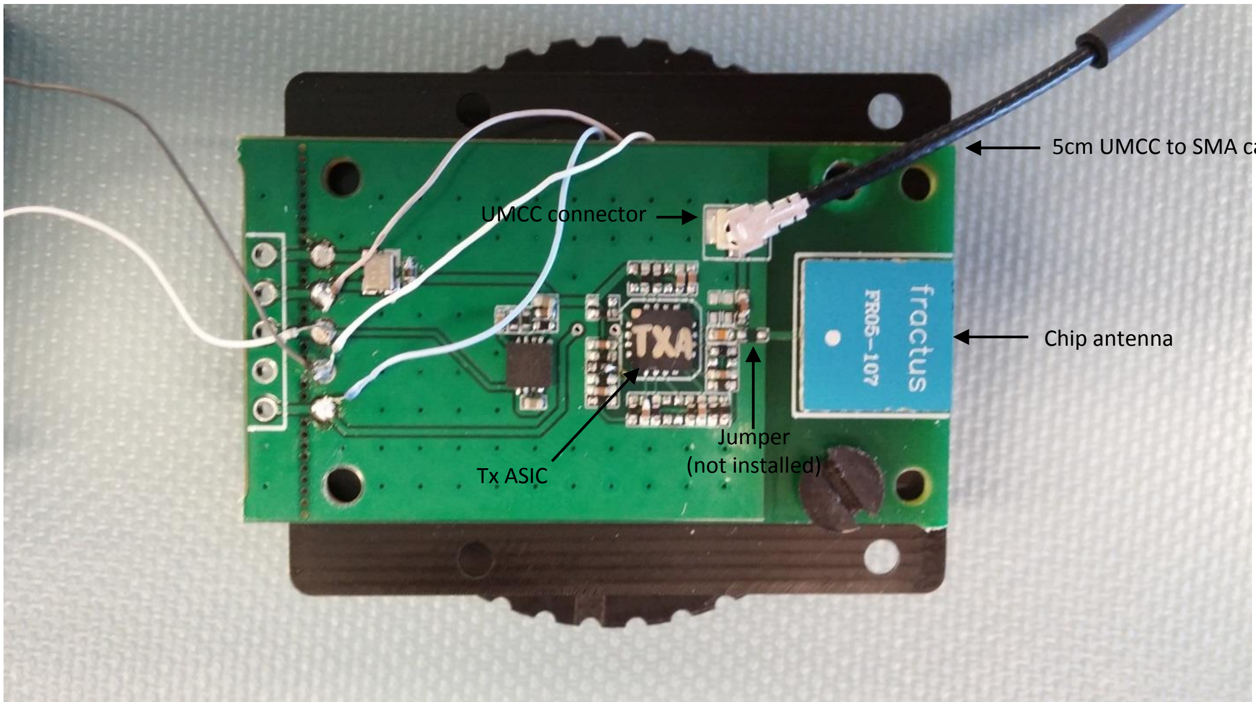

Figure 3. Detailed view of a testing transmitter PCB with additional antenna input UMCC port. The only difference between the testing transmitter PCB and the actual transmitter PCB on the real device is the testing PCB has an additional UMCC connector at the antenna input node for output power measurement.

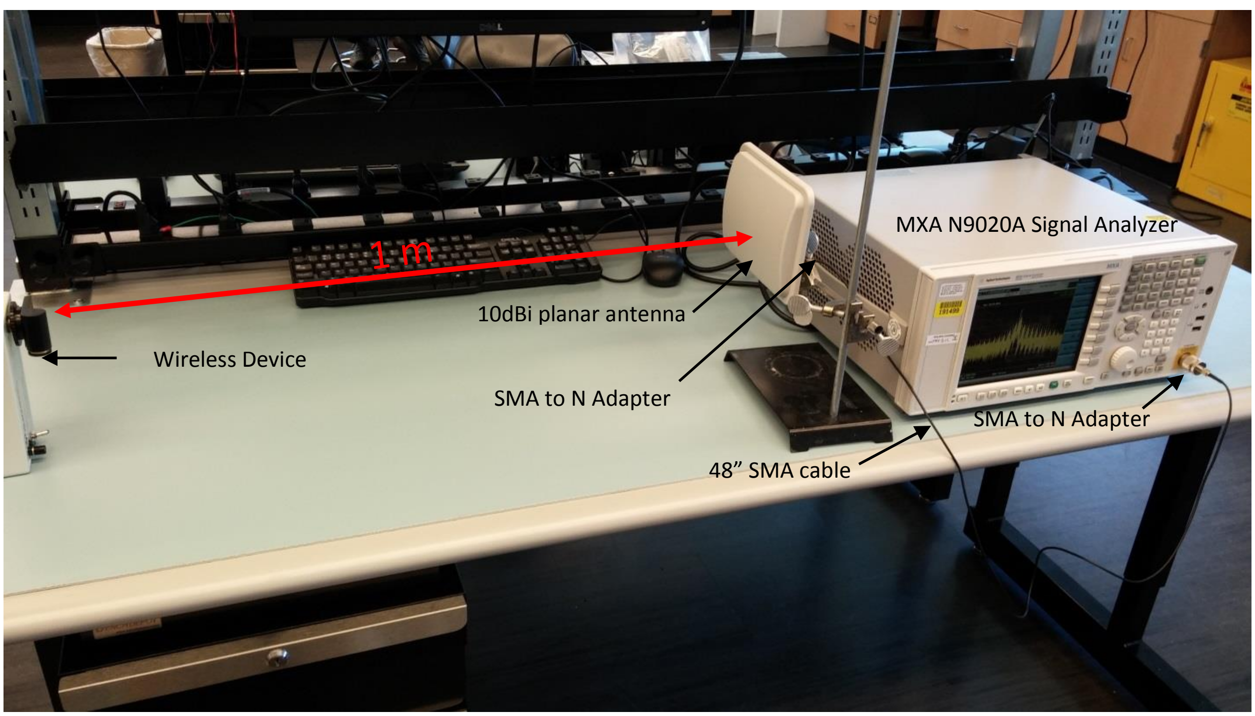

Figure 4. Testing setup for measuring the spectrum and power at 1 meter distance from the wireless transmitter using the Keysight N9020A MXA Signal Analyzer. The estimated total insertion loss from the receiving antenna to the MXA signal analyzer input includes the loss from: SMA to N adapter, 48" SMA cable and the SMA to N adapter, and is about 2.76dB=(0.18+2.4+0.18).

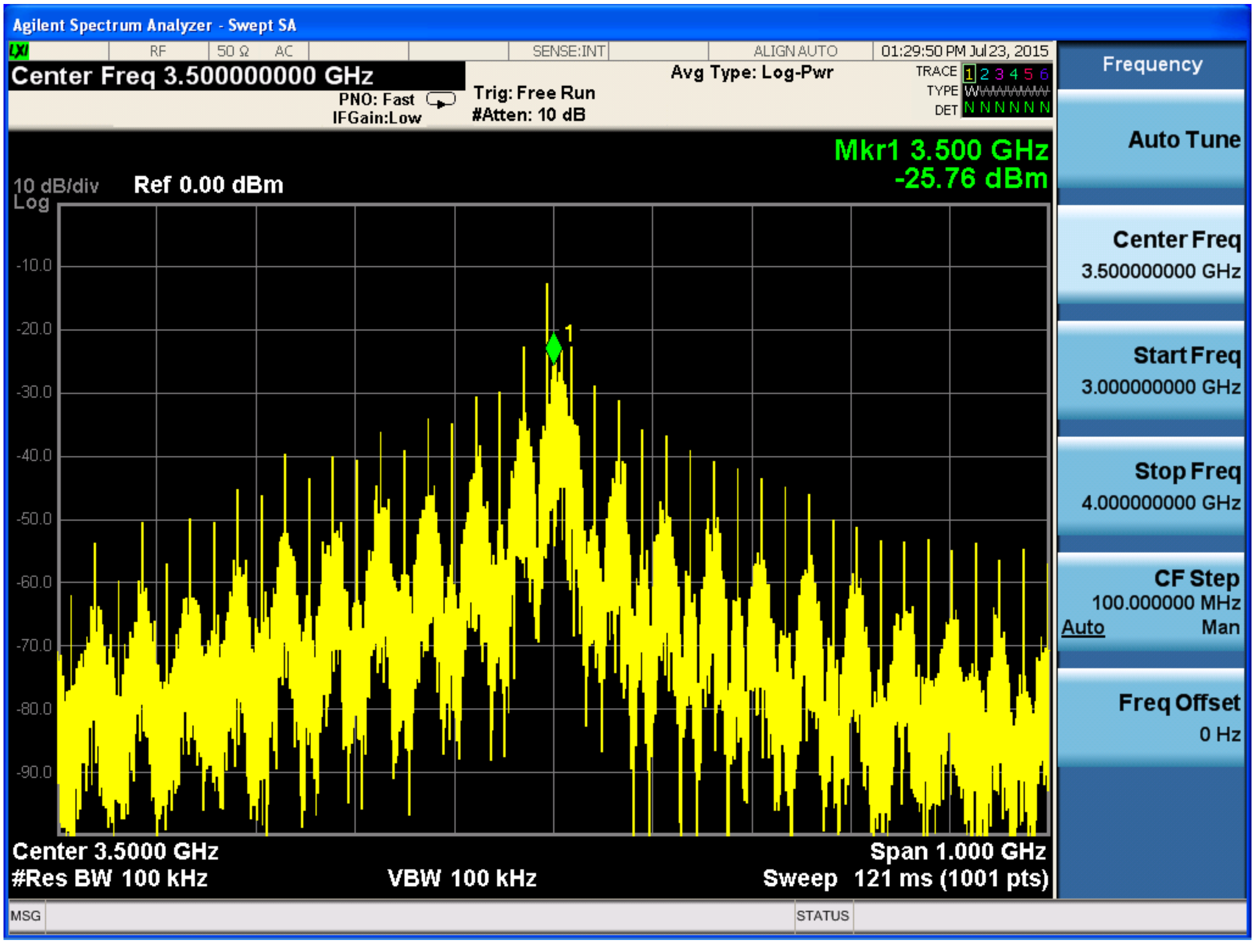

Figure 5. Spectrum of the wireless device measured at the output of the transmitter antenna input node (antenna is NOT loaded during this measurement) using the KeySight (Agilent) N9020A signal analyzer.

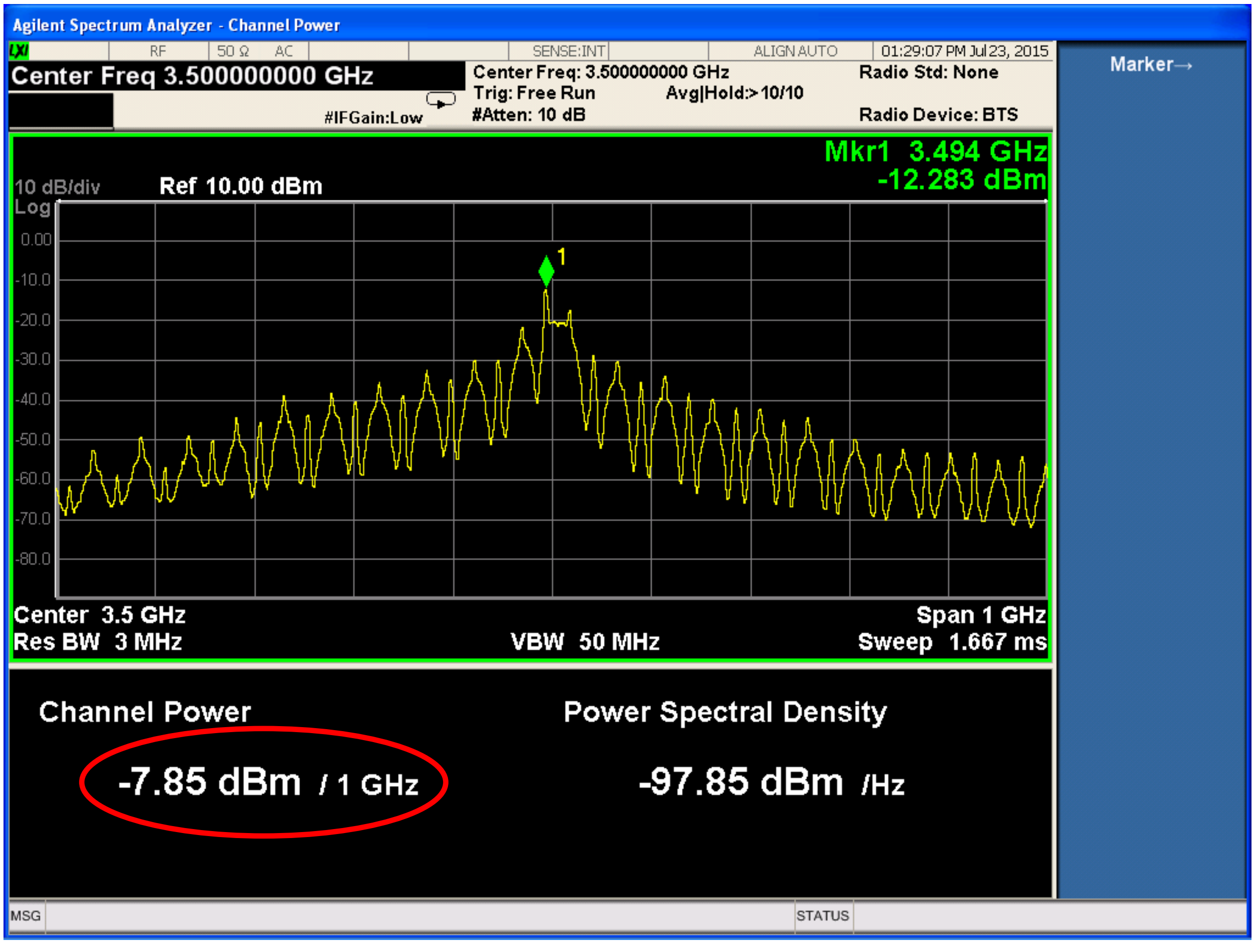

Figure 6. Total channel power of the wireless device measured at the output of the transmitter antenna input node (antenna is NOT loaded during this measurement) using the KeySight (Agilent) N9020A signal analyzer. Considering the insertion loss of the cabling for the measurement setup, this indicates a total transmitter power of -7.85+3=-4.85dBm at the antenna input node.

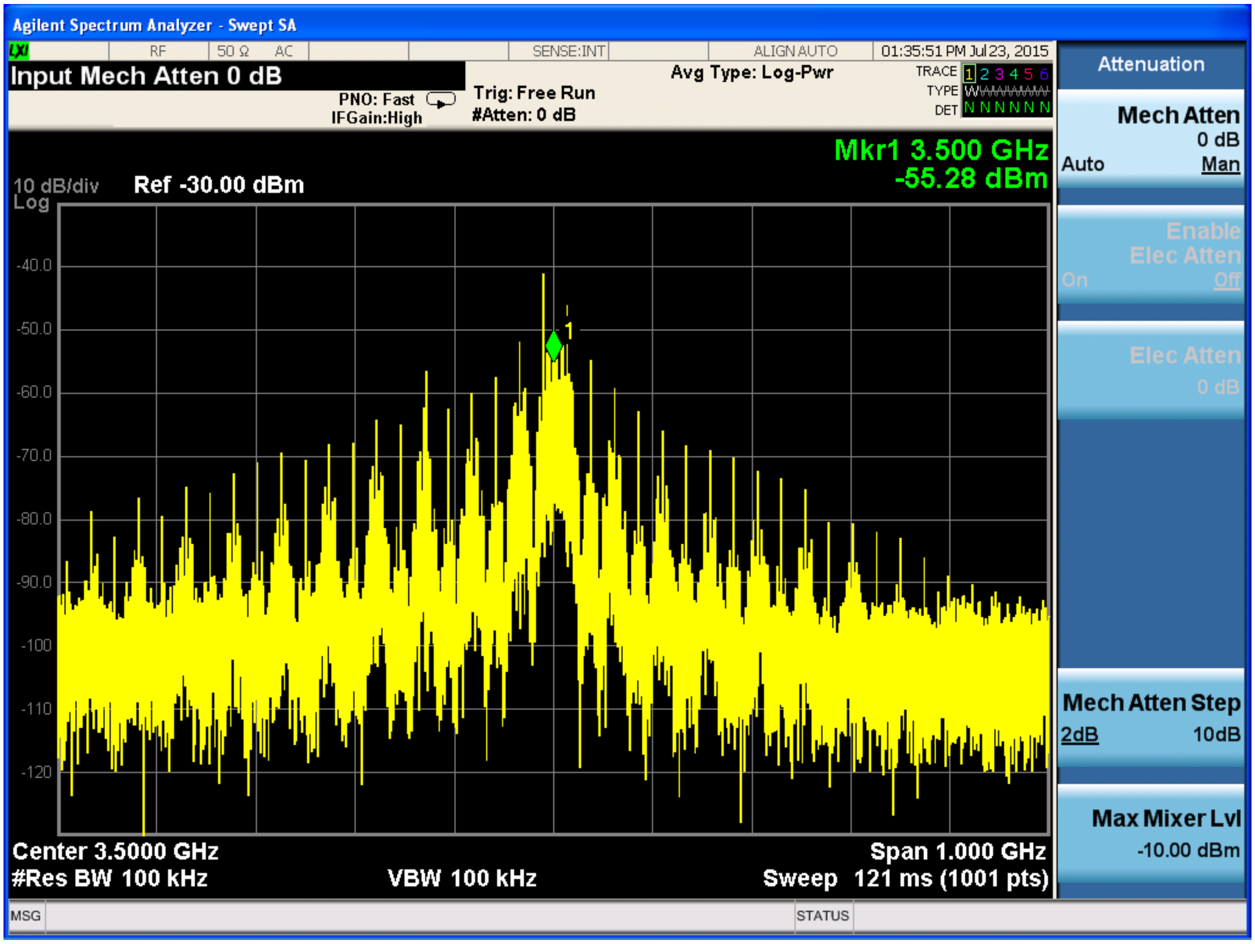

Figure 7. Spectrum of the wireless device measured at 1 meter distance with a 10dBi planar directional antenna (PA-333810-NF, FT-RF Antenna, Inc., Taiwan) using the KeySight (Agilent) N9020A signal analyzer.

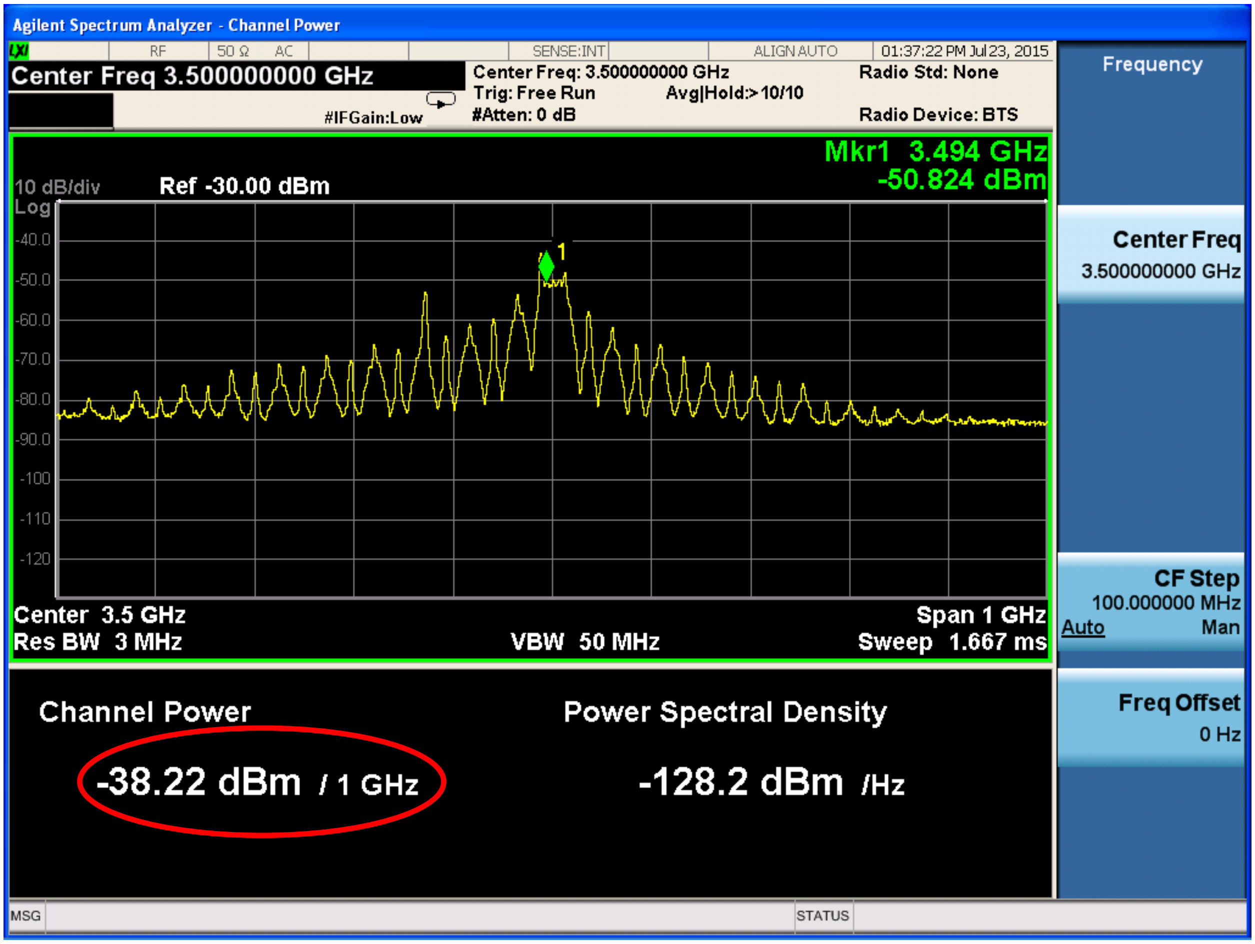

Figure 8. Channel power of the wireless device measured at 1 meter distance with a 10dBi planar directional antenna (PA-333810-NF, FT-RF Antenna, Inc., Taiwan) using the KeySight (Agilent) N9020A signal analyzer. This indicates a total channel power of -38.22dBm. Considering the insertion loss of the cabling for the measurement setup, this indicates a total transmitter power of -38.22+2.76=-35.46dBm at 1 meter distance with a 10dBi planar antenna.

2. Exhibit of the necessity of the wireless communication

The wireless communication proposed for this application is one of the key technical advances for this project. Without the wireless communication, a traditional wired neurosensing system has to be used requiring a tethered connection between the subject and the system, which not only greatly limits the patient mobility and patient care cost, but requires a percutaneous connector. In addition, the ultralow power feature provides minimum RF emission and low heat generation of the device. The 48Mbps data is produced by the 100-channel high resolution recording of the device and is a requirement of the research project. The use of OOK modulation scheme is an essential tradeoff between wireless transition power, device simplicity, wireless link fidelity, and patient safety. Due to its simplicity, OOK can reduce the electronics resources needed to be implemented on to the wireless device which will be attached to the subject’s head. This means, the size and power dissipation of the device will be greatly reduced from the wired device, hence the weight of the device will be greatly reduced as well.

3. Exhibit of the inadequateness of existing communication facility

Considering the high data rate and low power requirements of the device used in the research project, feasible commercial wireless communication electronics are inadequate at this point. For instance, to satisfy the 48Mbps data rate, 802.11 wireless LANs such as a, g, n, or ac, are needed. However, these commercial wireless communication options usually deliver very high power up to 1W (usually a few hundred mW) to the transmitting antenna. This is about 1000 times higher than the proposed wireless scheme. Such high RF output power could pose RF emission risks to the subject and often requires even higher power dissipation (a few watts) at the transmitter causing increased heat generation and larger form factor of the head-mounted wireless device.