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

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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 monitoring and stimulation of cortical neural signals (for the use in a future visual prosthesis) in a clinical setting and also in the home environment for research participants engaged in research sessions to investigate the DARPA NESD BISC I neural interface. The wireless neurosensing device is dedicated for recording neural signals from the patients' cortical areas to facilitate recording and stimulation of neural signals for a visual prosthesis and to investigate the principle feasibility of the device. The device is a fully implantable device consisting of a 65,536-channel active CMOS flexible electrode array allowing simultaneous recording and stimulation from up to 1,024 channels simultaneously. The array of 65,536 channels for electrode inputs are connected to column and row selectors followed by filters to ultralow noise ultralow power neural amplifiers (LNA), successive approximate analog to digital converters for recording and a stimulator control circuit and a wireless data link embedded in one flexible CMOS platform.

The device will transmit and receive data over an RF link and receive power over an inductive link. The BISC I is intended to be implanted in a human patient for up to 4 months. An external, head mounted relay station will power the device, receive data and wirelessly relay it to a computer based base station for data acquisition and stimulation control.

External to the patient, the implantable wireless neurosensing device will interface with the implanted device via a near field link, record the neural signals, and wirelessly transmit those to a receiver unit for further signal processing, display, and storage. It will also receive wireless commands for stimulation. The experiments will be carried out in a controlled and secured environment with an area of less than 10 m diameter. The wireless neural interface device will be used for indoor short distance (a few meters) application. A detailed description of the wireless device is shown in Figure 1.

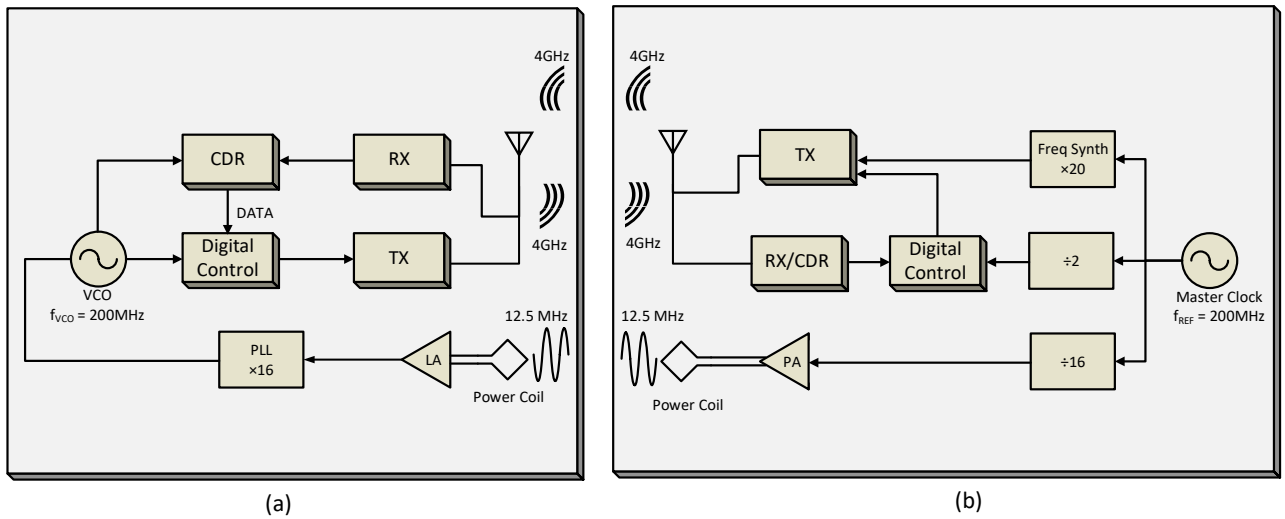


Figure 1. Architecture of implantable neural interface: (a); the Wireless Neural Interface: (b)

The BISC I device incorporates two sub-units, the implant unit and the Wireless Neural Interface (WNI) unit (external head mounted) as shown in Figure 1. The implant will be mounted between the dura and cortex, the WNI will be mounted on top of the skin. The BISC I device uses three additional customized wireless links for data and power transfer:

1. The data downlink from the implant to the WNI uses a simple On-Off Keying (OOK) modulation scheme at a nominal carrier center frequency of 4GHz for the transmission of data from the implant to the WNI. The signal that modulates the carrier is a single 100 Mbps digital serial bit stream that is the encoded version of the digital neural data. The data will be encoded in a 1ns pulse which has 1GHz bandwidth from the BISC chip to the wireless neural interface. And 2 ns pulse which 500MHz has bandwidth from the wireless neural interface to the BISC chip. In order to reduce the RF emission to the user (patient), the time-averaged power of the implantable wireless devices is ultralow and limited to be <0.35 mW or -4.5dBm. The simulation results are shown below (Figure 2-3), which clearly indicates the maximum average power it transmits is much less than the 1.0mW threshold per FCC 447498 D01 General RF Exposure Guidance v05r02 "Mobile and Portable Devices RF Exposure Procedures and Equipment Authorization Policies", "4.2.4 Transmitters implanted in the body of a user", "When the aggregate of the maximum power available at the antenna port and radiating structures of an implanted transmitter, under all operating circumstances, is ≤ 1.0 mW, SAR test exclusion may be applied." Therefore, the data downlink from the implant to the WNI falls into SAR test exclusion.

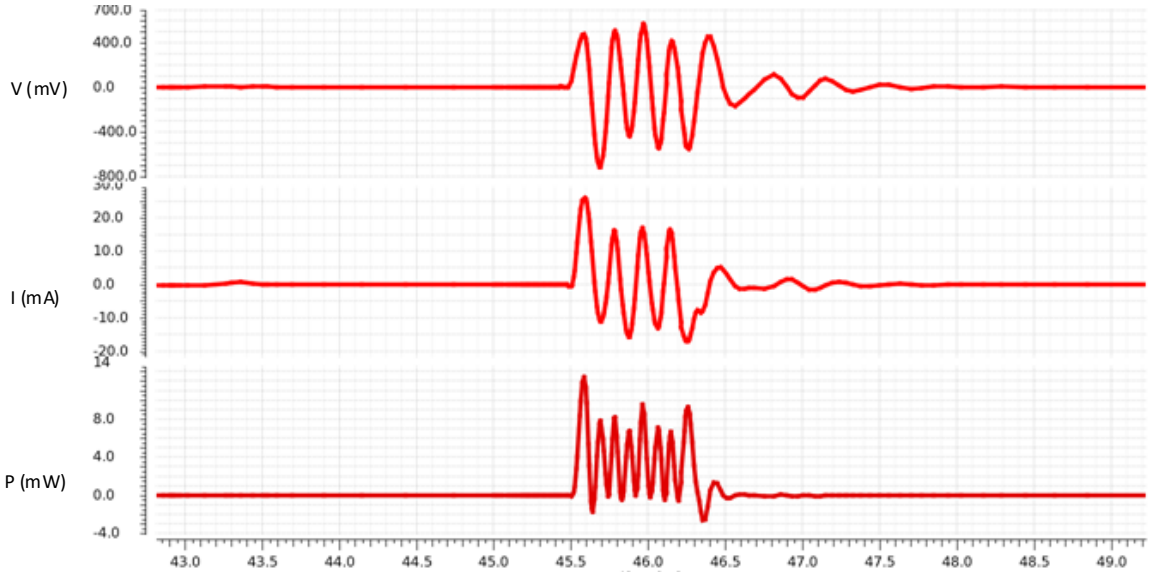


Figure 2. Simulated instantaneous voltage (V), current (I), and power (P) of a single pulse on implantable antenna input. P = V * I

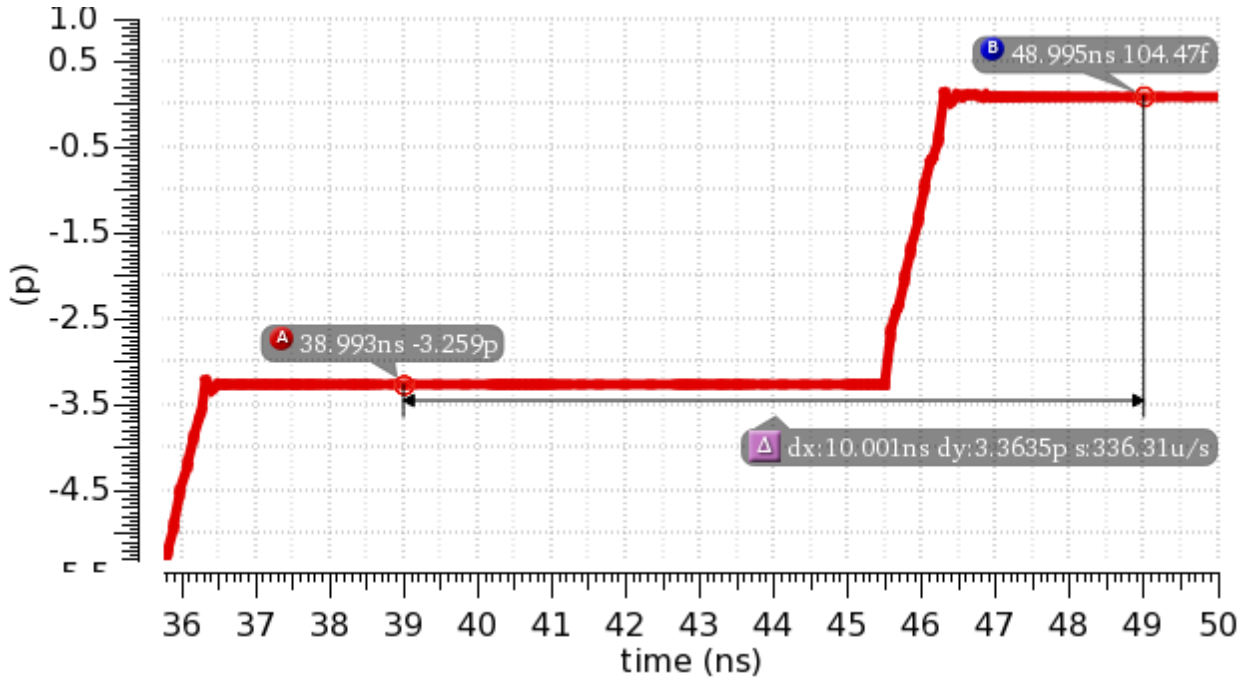


Figure 3. Simulated integrated instantaneous power ∫Pdt in pico-Joule. The pulse has 10% duty factor. Assuming maximum pulse repetition rate 100MHz, time-averaged power of a pulse in one period T=10ns is ∫Pdt /T = 0.336mW.

2. The data uplink from the WNI to the implant also uses a 4GHz OOK modulation ultralow power transmitter and is limited to be 0.135 mW or -8.3 dBm at the antenna input port. The simulation results (Figure 4) below show the schematic of the WNI module, which includes both the data uplink and the wireless power transfer module (which will

be address later in #3). For the uplink from WNI to the implant, as shown in Figure 4., the output of ADF4351BCPZ is set to +5dBm. Using the circuit configuration in "Linear Technology AN-98-8 'Nanosecond Pulse Width Generator'", 2ns pulse width 18dBm pulses can be generated from the pulse generator with maximum pulse repetition rate of 50 MHz. The pulses then attenuated 10 dB by Mini-Circuits LAT-10+. The conversion loss of the mixer is 6dB, and insertion loss the ADI HMC1118 switch is 0.7dB. The peak power at antenna port 18 – 10 – 6 – 0.7 = 1.3 dBm or 1.35mW. The time-averaged power at antenna will be 1.35mW * 2ns/20ns = 0.135mW or -8.7 dBm. Considering possible minimum distance between the external transmitter of the wireless device and the user under normal condition is > 10mm, , 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=1mW, min. test separation distance=10mm, f(GHz)= 4.0GHz. It will give us: 1/10*√4= 0.1, 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 5.2GHz at 10mm, the SAR Test Exclusion Threshold is 13 mW, which is much larger than the proposed device, therefore the proposed device data uplink falls into "Standalone SAR test exclusion".

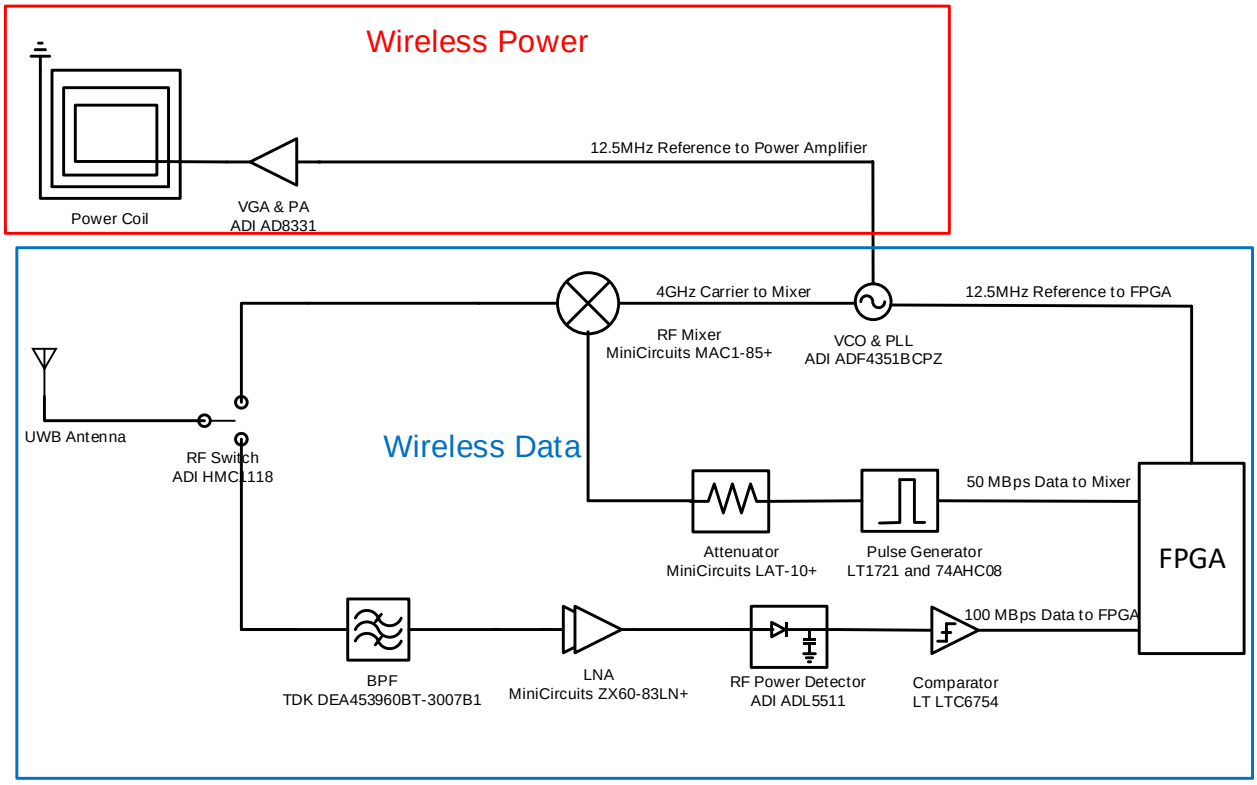
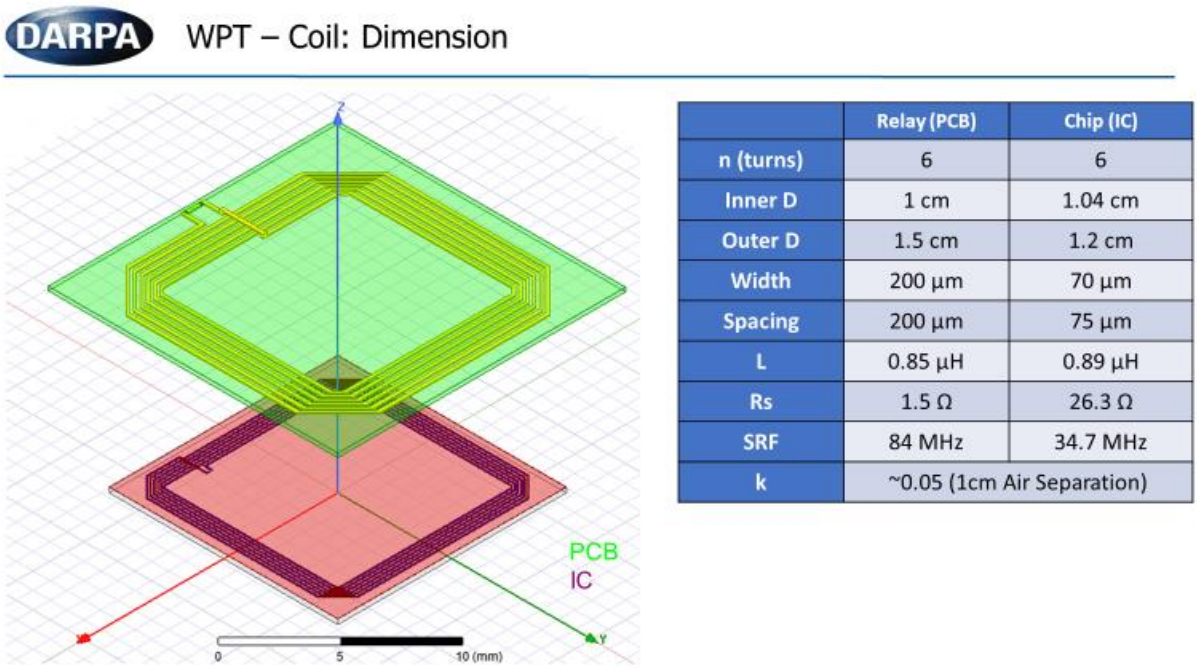


Figure 4. Schematic of Wireless Interface Board.

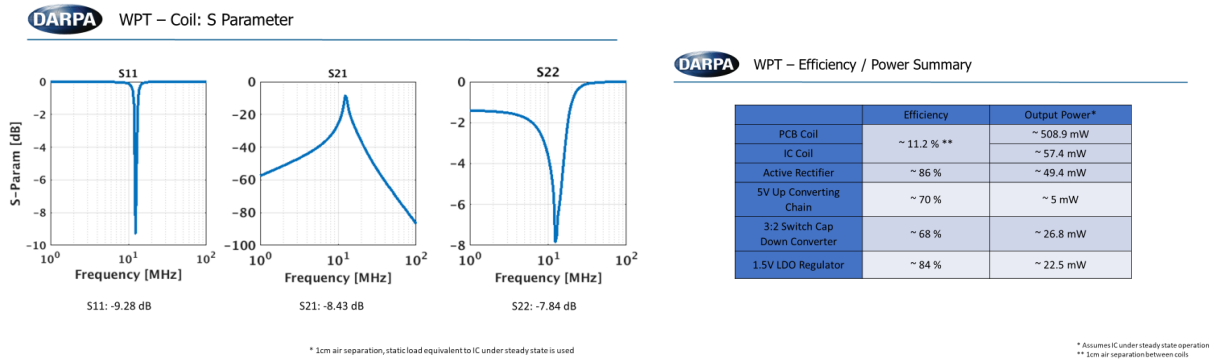
3. The power link from the WNI to the implant use a high efficiency inductive link running at 12 MHz. The schematic of the power transmitter is shown in Figure 4. The VCO maximum output power is 5dBm and the variable gain amplifier AD8331 is set to be no more than 22dB. Therefore, the maximum output power at the input of the WNI primary coil will be 5+22 = 27dBm or 508mW. Figure 5-6 shows the primary and secondary coils design and the simulated results of the power link indicating a maximum transmitting power of 508mW and an efficiency of 11.2%. 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", "4.3.1 c) 2)", the maximum allowed power is calculated as:
    a. 1-g: $3*50/\sqrt{0.0125}*[1+\log(100/12.5)]*1/2=1276$mW
    b. 10-g: $7.5*50/\sqrt{0.0125}*[1+\log(100/12.5)]*1/2=3192$mW

   Since the maximum power transmitted by the primary coil on the WNI will be only 508mW, it is much less than both the 1-g and 10-g threshold for SAR exclusion under the operating frequency and distance, then the power link of the BSIC device also falls in the SAR exclusion category.



	Relay (PCB)	Chip (IC)
n (turns)	6	6
Inner D	1 cm	1.04 cm
Outer D	1.5 cm	1.2 cm
Width	200 µm	70 µm
Spacing	200 µm	75 µm
L	0.85 µH	0.89 µH
Rs	1.5 Ω	26.3 Ω
SRF	84 MHz	34.7 MHz
k	~0.05 (1cm Air Separation)	

Figure 5. Configuration of the power coil



	Efficiency	Output Power*
PCB Coil	~ 11.2 % **	~ 508.9 mW
IC Coil		~ 57.4 mW
Active Rectifier	~ 86 %	~ 49.4 mW
5V Up Converting Chain	~ 70 %	~ 5 mW
3:2 Switch Cap Down Converter	~ 68 %	~ 26.8 mW
1.5V LDO Regulator	~ 84 %	~ 22.5 mW

Figure 6. Simulation results of the power coil. The total required power input to the primary side of the power coil on is 509 mW. Received power from the secondary coil on the implantable chip is 57.4 mW.

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 100 Mbps data is produced by the 65,535-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 (external wireless headstage and implantable device). 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 100 Mbps 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.