**WNR Invention Disclosure Form**

|  |  |
| --- | --- |
| **1.** | **Title** |
|  | Wireless Neural Recorder |

**2. Description of the invention:**

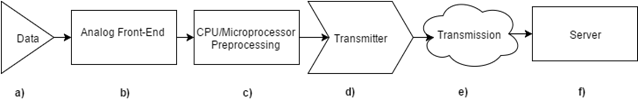
a) **General purpose**

We are applying IoT (internet of things) techniques to ECoG (electrocochleography) data collection by creating a new integrated device of unprecedentedly small form factor and long battery life that detects, processes and transmits brain signal wirelessly to a secure terminal.

b) **Technical description** *A detailed description that will be a primary source of information for the patent attorney as an application is being prepared.*

WNR is producing a new ECoG (a.k.a. Intracranial EEG) electrode that incorporates wireless connectivity via Bluetooth Low Energy between each individual intracranial electrode probe and a central recording terminal. Each electrode will be attached to a low-power analog to digital unit that will read and transmit neural data to a bluetooth microprocessor to transmit wirelessly in real-time to a receiver. An array of up to 16 wireless electrodes should be able to transmit simultaneously to a single recording receiver. From the receiver, medical professionals can access the data in real-time and analyze the captured data to best treat the patient.

The system is broken down as follow:



The brain signal that is fed into the system undergoes the following processes:

1. Amplified and converted to digital data by Analog-Front-End component
2. Compressed by nRF52 chip which integrates transmitter and microprocessor
3. Transmitted wirelessly by nRF52 over Bluetooth Low Energy protocol
4. Received by a central nRF52 which is connected to a terminal
5. Decompressed on the terminal

Detailed descriptions of the components are as follow:

1. Analog Front End

The analog signal generated by the brain and picked up by the electrodes go through the process of amplification and then Analog-to-Digital-Conversion (ADC). These two processes combined are termed the analog-front-end (AFE).

The amplification is important because brain signals have amplitudes on the of 100 uVpp (microvolt peak-to-peak) to 1 mVpp (millivolt peak-to-peak). To minimize the ADC error, the analog signal is first passed through a good amplifier which has a very low cut-off frequency (~0.01Hz) before being converted to a digital signal.

The amplification and ADC processes are integrated and implemented by the RHD2000 series of Intan TechnologiesTM. Our current choice of AFE chip is RHD2132, which offers 32 analog input channels. Because the current status quo of number of contacts points of a single ECoG electrode is ~16, 32 will give us sufficient margin for future improvement.

For development, Intan offers amplifier board which have RHD2132 chip soldered onto a custom PCB. This amplifier board, as mentioned, requires an additional LVDS component to communicate to. However, the LVDS converter will not be necessary in the final design as we will opt for a much less power-consuming standard CMOS signaling.

The RHD2132 communicates using standard Serial Peripheral Interface Bus (SPI) protocol. To program the chip, corresponding SPI pins on the RHD2132 chip are connected to the SPI pins on our microcontroller - nRF52. The RHD2132 chip is thus programmed through nRF52. Detail instructions of SPI commands built into RHD2132 can be found in its datasheet.

1. Compression
2. Bluetooth Low Energy(BLE) Wireless Transmission

nRF52 has a BLE component on-chip. Thus, creating wireless transmission functionalities entails programing nRF52.

For the purpose of this project, we need to establish a 1-to-many communication scheme with multiple peripheral chips (chips that collect brain signal) to a central chip (chip that interfaces with terminal where data from all peripheral chips can be accessed remotely).

1. Power Systems

The power system of the WNR system is pretty straight forward. The device is only powered via non-rechargeable batteries. The batteries selected must fit within the size requirements of 8mm diameter and ideally 4mm in height to allow for the rest of the system components to fit within the ideal desired 10mm height.

Currently, the WNR system is using off-the-shelf hearing aid device batteries. The medical grade batteries are utilizing zinc-air technology which allows for compact, lightweight power transmission to the rest of the WNR system. Our choice of Zinc Air P13 batteries are able to provide 310mAh at 1.45 V in just a 7.9mm diameter by 5.4mm height, weighing just 0.83g. However, the 1.45V is not enough voltage to power all the components in our system as our chips work at an ideal voltage of 3V. We will be using 2 Zinc Air P13 batteries in series to provide 2.9V at 310mAh, which will be sufficient enough to power our system for at least 24 hours. The batteries therefore will be stacked on top of each other and placed onto the negative battery pad and secured by the positive battery screw cap.

Ideally, the battery technology will be updated before going into mass production with a custom higher density lithium ion battery providing more than 500mAh at 3V.

1. WNR System Housing

The final design of the alpha version of WNR system will be enclosed in an 3D printed enclosure cap measuring 8.5mm in diameter by 12mm in height. Inside the cap will be the PCB containing all of the WNR system’s necessary components such as electrode inputs, A2D chip, Bluetooth Low Energy chip, and battery. The components will each exist on its own layer of PCB and manually connected via jumpers to each other layer. The electrode inputs will exist on the bottom layer of the PCB along with the A2D chip. The next layer will be the bluetooth chip layer. Finally the last layer will be the negative battery interface pad. These 3 PCB layers are to be printed and milled by a PCB machine and cut into a 8mm diameter circle. The 3 layers will be connected by jumpers and inserted into the 3D printer enclosure cap and topped off with positive battery connector screw cap. The bottom of the cap allows for the electrode needle probe pins to connect to the first layer of PCB with the electrode input holes.

For the mass production of the WNR system, the WNR system will be enclosed in an IP68 medical grade aluminum cap containing the PCBs with A2D and Bluetooth Low Energy chips. This will ensure the device is dust and waterproof for submersion in water past 1m. The PCBs will also be professionally printed on a multilayer PCB without the need for jumper connectors and will allow for a lower total stacked height. The layered PCB will be inserted into the milled aluminum cap and topped off with an aluminum battery connector screw cap.

c) **Utility**

The primary purpose of the invention is to enable wireless connection between ECoG electrodes and data loggers. This will serve to untether epilepsy patients who currently have to be physically connected to cumbersome data logging machines during diagnosis procedures that could last days. The invention will drastically improve the well-beings of these patients during ECoG procedures. It will also reduce cost of ECoG procedures as the invention costs significantly less currently available ECoG machines.

However, the device we create can be used for any general IoT applications that require ruthless form factor and battery life requirements. It allows a simple interface of transmitting analog data to a secure terminals wirelessly and there is no limit to the type of data being recorded and transmitted.

d) **Novelty**

Traditional approaches to ECoG procedures require physical wires which significantly limit mobility of the patients.

Other more modern approaches to tetherless ECoG procedures record data onto a memory card. This design is awkward in that the memory card need to be removed from the device and replaced with empty memory card every few hours. This approach also does not allow real-time analysis of the data which means that, because the recorded data is only accessed after the memory card is removed from the device, practitioners are not able to see the brain data “live”.

Our invention will solve the tether problem by creating a wireless solution which also allows real-time data analysis. Because the data is sent wirelessly to the practitioners as soon as it is generated by the brain, there is essentially no delay in observing brain signals. Moreover, our design can run for days on end because instead of replacing memory card regularly, our device can run until the battery runs out of power. With our extremely low-power design, a normal coin cell battery can power the device on the order of days.

e) **Steps involved**

The device is a system on board. It is made by:

1. fabricating custom PCB
2. solder chips purchased from supplier companies onto these PCBs
3. Assemble PCBs into a custom container which resembles a miniature cylinder.

f) **Limitations**

The current limitation is the aggregate throughput of Bluetooth Low Energy protocol. This limitation can be overcomed with imminent advent of Wi-fi HaLow technology which will provide much more data-rate with comparable power consumption.

g) **Variations**

The device currently operates with Bluetooth Low Energy(BLE) at its communication protocol. A possible variation would to use other wireless communications like Wifi Halow which should have better speed than Bluetooth while requiring comparable power as BLE.

h) **Status**

Prototype

i) **Additional Work Planned**

Final prototype - May 2016

Animal Testing - June 2016

FDA approval application - Jan 2016

Production - After FDA approval

j) **References (relevant literature/patents)**

[1] "Method of the Month: EEG." *Brain In A Vat*. 4 Sept. 2007. Web. 25 Sept. 2015.

[2] 한양대학교 Jang’s Lab." *한양대학교 Jang’s Lab*. Web. 25 Sept. 2015.

[3] Bharucha, Eric, Hassan Sepehrian, and Benoit Gosselin. "A Survey of Neural Front End Amplifiers and Their Requirements toward Practical Neural Interfaces." *Journal of Low Power Electronics and Applications JLPEA* (2014): 268-91. Print.

[4] Harrison, R.r., and C. Charles. "A Low-power Low-noise Cmos for Amplifier Neural Recording Applications." *IEEE J. Solid-State Circuits IEEE Journal of Solid-State Circuits*: 958-65. Print.

[5] Harrison, Reid R. "Wireless Neural Recording With Single Low-Power Integrated Circuit." *IEEE TRANSACTIONS ON NEURAL SYSTEMS AND REHABILITATION ENGINEERING* 17.4 (2009): 322-29. Print.

[6] Harrison, R.r. "The Design of Integrated Circuits to Observe Brain Activity." *Proceedings of the IEEE Proc. IEEE*: 1203-216. Print.

[7] "Bluetooth 4.2 Core Specifications Finalized." *RSS*. Web. 25 Sept. 2015.

[8] Smith, P. (2011, August 8). Comparing Low-Power Wireless Technologies. Retrieved September 25, 2015.

[9] Guidance Documents (Medical Devices and Radiation-Emitting Products). (n.d.). Retrieved September 25, 2015.

[10] Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff. (n.d.). Retrieved September 25, 2015.

[11] HHS.gov. (n.d.). Retrieved September 25, 2015.

[12] Alpert, Alec. "Understanding How Hospitals Buy Medical Technology." 2009. Web. 25 Sept. 2015.

[13] "Fast Facts on US Hospitals." *Fast Facts on US Hospitals*. Web. 25 Sept. 2015.

[14] "Number of Medicare Certified Rural Health Clinics." *Number of Medicare Certified Rural Health Clinics*. Web. 25 Sept. 2015.

[15] Fallon, L. Fleming. "[Electroencephalography.](http://www.encyclopedia.com/doc/1G2-3406200141.html)" Gale Encyclopedia of Surgery: A Guide for Patients and Caregivers. 2004. *Encyclopedia.com.* 25 Sep. 2015

[16] "MouseLog-16 - Neural Recorder for Small Animals - Deuteron Technologies Ltd." *Deuteron Technologies Ltd*. 10 Oct. 2014. Web. 25 Sept. 2015.

[17] "NeuroPace | Product | Overview." *NeuroPace | Product | Overview*. Web. 25 Sept. 2015.

[18] "64 Channel Wireless Neural Recording System." *Triangle BioSystems*. Triangle BioSystems International. Web. 25 Sept. 2015.

[19] "RNS System Patient Manual." NeuroPace. Web. 25 Sept. 2015.

[20] Decuir, Joe. "Bluetooth 4.0: Low Energy." Web. 25 Sept. 2015.

[21] Giuliano Antoniol and Paolo Tonella, “EEG Data Compression Techniques”, *IEEE TRANSACTIONS ON BIOMEDICAL ENGINEERING*, VOL.44, NO.2, Feb 1997.

[22] "Medical Devices." *U.S. Food and Drug Administration*. U.S. Food and Drug Administration. Web. 23 Oct. 2015.

[23] "Intan Technologies, LLC: Low-noise Amplifier Microchips for Electrophysiology, EKG, EMG, EEG, ECoG, and Neural Recording Headstages and Bio Instrumentation." *Pricing*. Web. 22 Oct. 2015.

[24] "Digital Electrophysiology Interface Chips." INTAN TECHNOLOGIES, LLC, 11 Dec. 2012. Web. 22 Oct. 2015.

[25] "Low-Noise, 8-Channel, 24-Bit Analog Front-End for Biopotential Measurements." Texas Instruments, 1 July 2012. Web. 22 Oct. 2015.

[26] Tseng, R., B. Von Novak, S. Shevde, and K. A. Grajski. "Introduction to the Alliance for Wireless Power (A4WP) Loosely- Coupled WPT Specification 1.0." Introduction to the Alliance for Wireless Power (A4WP) Loosely- Coupled WPT Specification 1.0 (2013): n. pag. IEEE, 15 May 2013. Web. 21 Oct. 2015.

[27] "What's the Best Battery?" Advantages and Limitations of the Different Types of Batteries. Battery University, 01 Nov. 2010. Web. 21 Oct. 2015.

[28] "Battery Chemistry Comparison Chart." Battery Chemistry Comparison Chart. ICCNexergy, n.d. Web. 21 Oct. 2015.

[29] "Weird and Wonderful Batteries." Weird and Wonderful Batteries. Battery University, 17 Aug. 2011. Web. 21 Oct. 2015.

[30] Dondelinger, Robert M. "Batteries: From Alkaline to Zinc-Air." (2004): n. pag. FDA, Mar. 2004. Web. 21 Oct. 2015.

[31] "Battery Cell Types." Most Common Primary Battery Sizes Available. Epec, n.d. Web. 21 Oct. 2015.

[32] "CC2650 SimpleLink™ Multistandard Wireless MCU." Texas Instruments, 1 Feb. 2015. Web. 22 Oct. 2015.

[33] "MSP432P401x Mixed-Signal Microcontrollers." Texas Instruments, 1 Mar. 2015. Web. 22 Oct. 2015.

[34] "CC110L Value Line Transceiver." 1 May 2011. Web. 22 Oct. 2015.

[35] "Huffman Codes." *American Mathematical Society*. Web. 22 Oct. 2015.

[36] "FCC." *FCC*. Web. 23 Oct. 2015.

[37] "Health Information Privacy." *HHS*. Web. 23 Oct. 2015.

[38] Rolston, John D., David Ouyang, Dario J. Englot, Doris D. Wang, and Edward F. Chang. "National Trends and Complication Rates for Invasive Extraoperative Electrocorticography in the USA." Journal of Clinical Neuroscience: 823-27.

[39] "Comparing Low-Power Wireless Technologies." *DigiKey Electronics*. DigiKey Electronics. Web. 23 Oct. 2015.

[40] "A Technology Comparison: Adopting Ultra-Wideband for Memsen’s File Sharing and Wireless Marketing Platform." Memsen Corporation. Web. 23 Oct. 2015.

[41] "A BLE Advertising Primer." *Argenox Technologies*. Web. 23 Oct. 2015.

[42] "UM10204: I2C-bus Specification and User Manual." NXP Semiconductors, 4 Apr. 2014. Web. 23 Oct. 2015.

[43] Cerf, V., and R. Kahn. "A Protocol for Packet Network Intercommunication." *IEEE Transactions on Communications IEEE Trans. Commun.*: 637-48. Print.

[44] Mcghee, Joseph. "RS 232 and EIA/TIA 232 Serial Interface." *Handbook of Measuring System Design* (2005). Print.

[45] "SPI Implementation in IQRF for (DC)TR-7xD Technical Guide." IQRF. Web.

[46] "Bluetooth Smart (Low Energy) Technology." *Bluetooth Development Portal*. Bluetooth. Web. 23 Oct. 2015.

[47] “Basic Rate/Enhanced Data Rate (BR/EDR).” *Bluetooth Technology Basics.* Bluetooth.

Web. 13 Dec. 2015.

[48] “NeuroPort System.” Blackrock Microsystems. Web. 10 Dec. 2015

[49] “Cervello Elite: Designing the Future.” Blackrock Neuromed. Web. 10 Dec. 2015

[50] "New Aluminum Air Battery Could Blow past Lithium-ion, Runs on Water." *ExtremeTech*.

ExtremeTech. Web. 14 Dec. 2015.

[51] "CC2640 BLE Throughput." *Texas Instruments Wiki*. Texas Instruments. Web. 14 Dec.2015.

[52] "CC256x Bluetooth and Dual-Mode Controller (Rev. D)." Texas Instruments, 1 July 2012.

Web. 13 Dec. 2015.

[53] "MSP430F543xA, MSP430F541xA Mixed-Signal Microcontrollers (Rev. E)." Texas

Instruments, 2010. Web. 13 Dec. 2015.

[54] Horspool, R.n., and W.j. Windels. "An LZ Approach to ECG Compression."*Proceedings of*

*IEEE Symposium on Computer-Based Medical Systems (CBMS)*. Print.

[55] Stian. "Current Measurement Guide: Measuring Current with PCA10040 V0.9.0." Tutorials.

Nordic, 27 Nov. 2015. Web. 24 Feb. 2016.

[56] Veilleux, Daniel. "Intro to ShockBurst/Enhanced ShockBurst." Blogs. Nordic, 7 Nov. 2015.

Web. 24 Feb. 2016.

|  |  |
| --- | --- |
| **3.** | **Grant or Contract Number:** |
|  | **Sponsor(s):**  **Dr. Nitin Tandon** |

|  |  |
| --- | --- |
| **4.** | **Material Transfer or Software Agreement(s) Used:** |
|  | **NA** |

|  |  |  |
| --- | --- | --- |
| **5.** | **History of the Invention:** *Please record the history of the invention, giving attention to the legally important events of conception (5a), the first actual reduction to practice (5d), and the establishment of a publication bar (5e,f). In the United States a patent application must be filed no later than one year after the publica­tion describing the associated invention. In most other countries, filing must take place before the invention is known or available to others or published. Copies of signed and dated notebook pages validating the dates cited will be valuable attachments.* | |
|  | a) Date invention first conceived by inventor(s): | 9/18/2016 |
|  | b) Date first sketch of invention prepared: | 9/25/2016 |
|  | c) Date first written description prepared: | 9/25/2016 |
|  | d) Date of first successful demonstration, if any: | 2/25/2016 |
|  | e) Date of first external oral presentation or disclosure which describes the invention, if any. Attach copies of presentation materials if possible. | 11/12/2015 |
|  | f) Date of first publication containing description of invention, if any. Attach copies: | NA |
|  | g) If not previously disclosed orally or in writing, are their plans to do so? What are the dates of planned disclosures? | NA |

|  |  |
| --- | --- |
| **6.** | **Potential Licensees:**  NA |
|  |  |
|  |  |
| **7.** | **Technology Class:** *Check the appropriate box that indicates the primary and secondary (if applicable) technology class of this invention.*  □ Big Data  □ BioEngineering  □ Ecoli  □ Genetic Engineering  □ Metabolic Engineering  □ CleanTech  □ Energy  □ Devices  □ Diagnostics  □ Global Health  □ Imaging  □ Materials  □ Catalysts  □ Nanomaterials  □ Semiconductors  □ SiOx  □ Tissue Engineering  □ Networking Systems  □ Software  □ Therapeutics  □ Cancer |
|  |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **8.** | **Inventor Signature Page** | | | | | |
|  | **Full Name: Stephen Xia** | | | | **Citizenship: NA** | |
|  | **Percent contribution to invention** | | | | | **25 %** |
|  | **Inventive steps made by this inventor** Wireless communication | | | | | |
|  | As an inventor under [generic company’s] policy, I hereby agree to cooperate in the filing of patent applications and to make any assignments of ownership that may be required by [generic employer] | | | | | |
|  | **Inventor’s Signature** **NA** | | **Date Signed** **NA** | | | |
|  |  |  |  |  |  |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Inventor Signature Page** | | | | | |
| **Full Name: Tingkai Liu** | | | | **Citizenship: NA** | |
| **Percent contribution to invention** *The percentages should be agreed among the inventors prior to signing this document; in the absence of this information it will be assumed that each inventor made an equal contribution to the invention.* | | | | | **25 %** |
| **Inventive steps made by this inventor** Analog-Front-End  Compression | | | | | |
| As an inventor under [generic company’s] policy, I hereby agree to cooperate in the filing of patent applications and to make any assignments of ownership that may be required by [generic employer] | | | | | |
| **Inventor’s Signature** **NA** | | **Date Signed** **NA** | | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Inventor Signature Page** | | | | | |
| **Full Name: Yuan Gao** | | | | **Citizenship: NA** | |
| **Percent contribution to invention** | | | | | **25 %** |
| **Inventive steps made by this inventor** Compression | | | | | |
| As an inventor under [generic company’s] policy, I hereby agree to cooperate in the filing of patent applications and to make any assignments of ownership that may be required by [generic employer] | | | | | |
| **Inventor’s Signature** **NA** | | **Date Signed** **NA** | | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Inventor Signature Page** | | | | | |
| **Full Name: Xin Huang** | | | | **Citizenship: NA** | |
| **Percent contribution to invention** | | | | | **25 %** |
| **Inventive steps made by this inventor** Wireless communication | | | | | |
| As an inventor under [generic company’s] policy, I hereby agree to cooperate in the filing of patent applications and to make any assignments of ownership that may be required by [generic employer] | | | | | |
| **Inventor’s Signature** **NA** | | **Date Signed** **NA** | | | |