Fifteenth Quarterly Progress Report

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Open Architecture Research Interface for Cochlear Implants

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1. Introduction

The main aim of this project is to develop a research interface platform which can be used by researchers interested in exploring new ideas to improve cochlear implant devices. This research platform includes a stimulator unit which can be used for electrical stimulation in animal studies, a recording unit for collecting evoked potentials from human subjects and a portable processor for implementing and evaluating novel speech processing algorithms after long-term use. The research platform chosen for this project is the personal digital assistant (PDA).

2. Summary of activities for the quarter

Work in this quarter focused on the implementation of the expanded protocol used in the Nucleus 22 (CI22) device. This was found necessary in order to make the developed PDA processor backwards compatible with the older generation Nucleus-22 device. The PDA processor is now compatible with all three generations of the Nucleus device (CI22, CI24 and CI24R(E)). As required for our IDE submission to FDA, we have sent the PDA processor for electromagnetic interference and environmental testing. The environmental testing, which evaluates the effects of environmental conditions such as temperature and humidity, has been completed. The PDA processor has been found to be compliant to IEC requirements in all environmental conditions.

3. Implementation of CI22 protocol

In order to make the developed PDA processor compatible with all three generations of the Nucleus cochlear implant (CI22, CI24 and CI24R(E)), we focused on implementing the protocol used in the CI22 implant. We found this necessary prior to our IDE submission to FDA to avoid submitting future supplemental applications requiring separate approval of the CI22 protocol implementation.

The Nucleus 22 (CI22) device uses a 2.5 MHz carrier signal, while the Nucleus 24 devices use a 5 MHz carrier. Hence, significant changes had to be made in the protocol implementation on the FPGA to accommodate the lower carrier frequency (2.5 MHz). Furthermore, the CI22 device uses a different protocol, known as the expanded protocol (Crosby *et al*., 1985). In the expanded protocol or SEMA (Sync, Electrode, Mode, Amplitude) protocol (Crosby *et al*., 1985), the transmission of data is done by a series of discrete data bursts which represent the Synchronization burst, chosen Electrode(s), the electrode Mode configuration, and Amplitude (stimulating current) determined by the duration of the amplitude burst. Figure 1 illustrates the power/data signal format from the FPGA based SDIO board stimulator. The data signal energy is also used to power the stimulator electronics.

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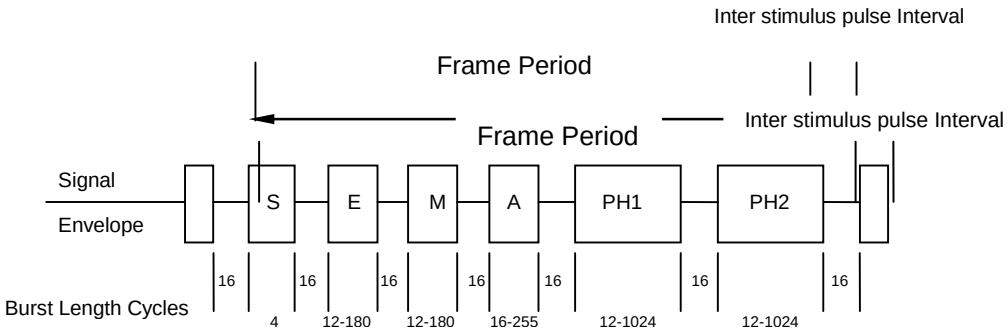

S - SYNC Burst
E - Active Electrode Burst
M - Mode Burst
A - Amplitude Burst
PH1 - Phase 1 Burst
PH2 - Phase 2 Burst

Figure 1. Power/Data Signal Format.

At the transmitter (FPGA), the number N which is to be transmitted, is encoded as the burst length 8N+4 RF cycles with frequency 2.5 MHz. Each time a stimulus is required, a data frame comprising six bursts of cycles is transmitted. The SYNC burst is sent at the start of the frame and comprises a burst of 4 cycles. The second burst encodes the Active electrode. The third (mode select) burst is used to encode the Reference electrode. This number is described as the stimulation mode.

The implementation supports both modes of the stimulus generation circuitry of the CI22 implant namely the multipolar or common ground (CG) mode and the bipolar (BP) mode. In the CG mode, one electrode is selected to be the active electrode or sink, and all other electrodes operate as a common current source. In phase 2, the connections are reversed so that the active electrode acts as the current source and the common electrodes act as a current sink. In the BP mode, stimulation is between two selected electrodes. In phase 1, current is sourced by the first electrode and sunk by the second electrode. In phase 2, current is sourced by the second electrode and sunk by the first electrode, and no other electrodes play any part in stimulation.

For the CG stimulation, Mode = 1 and the Active electrode is the same as the Reference electrode. For BP stimulation (BP+x, x=1 to 20) the Mode field selects the offset of the Reference electrode from the Active electrode. Mode is equal to the Reference electrode number - Active electrode number + 1. If the selected Reference electrode number decoded in the stimulator exceeds 22 then the actual Reference electrode will be that selected minus 22.

The amplitude of the output current I_0 is transmitted by the duration of the amplitude burst and is expressed by the approximate relationship:

$$I_0 = I_{\max} \times e^{-k \cdot t} \text{ mA}$$

where I_{max}= 2.0 mA, k = 0.1 and t = amp burst length (in µS).

This burst has a minimum length of 16 cycles, which produces the maximum stimulus current of about 1.055 mA, and the amplitude is reduced in steps of about 3% for every 400 nS (1 RF cycle) increase in burst duration. The stimulus amplitude is coded as 255-CL where CL is the clinical level unit and can range from 0 to 239.

The durations of the two phases of the biphasic stimulation pulse are transmitted as the fifth and sixth bursts respectively. The pulse duration is adjusted in steps of 400 nS. The maximum length of a stimulation burst is 1024 cycles or 409.6 µS. The duration of the two phases of the biphasic pulse are set to be equal so that the stimulus is charge balanced. The interburst interval and the inter stimulus pulse interval were set to 16 RF cycles or 6.4 µS.

The expanded protocol, by specification, is a variable rate protocol since the electrode, mode and amplitude depend on the coded burst durations. To maintain a specific pulse rate for a given electrode, the PDA computes a number of null frame pulses which need to be inserted after each group of N_{maxima} pulses (for the SPEAK strategy) signaled to the Freedom Coil. A null frame has a duration of T_{NF} = 68.8 µS and consists of a sync burst = 4 cycles (1.6 µS), phase duration = 16 cycles (6.4 µS), amplitude = 0 = 16 cycles (6.4 µS), mode = 1 = 12 cycles (4.8 µS), electrode = 1 = 12 cycles (4.8 µS), interburst interval = 16 cycles (6.4 µS), # interburst intervals = 6. The PDA computes the number of groups of N_{maxima} pulses, *NG* to fill the basic 11.6 ms stimulation frame of the PDA required for achieving the desired stimulation rate, *R*. For each group a number of null frames is computed to be inserted to compensate for the rate variation due to the SEMA parameters. This computation is done for each of the *NG* groups every 11.6 ms, by first summing the burst durations of the SEMA parameters including inter burst and inter stimulus pulse intervals and subtracting from 1/*R*, and then dividing the result by $T_{NF.}$ For the bilateral stimulation implementation, a burst duration total is obtained for each of the Left and Right ear stimulations and the larger burst duration total is chosen to compute the number of null frames required to achieve the selected per electrode pulse rate. On the FPGA side, the Left and Right ear stimulation is synchronized by having the side which completes the transfer (transmission to the Freedom Coil) first wait for the completion of the transfer from the contralateral side during the transmission of the electrode and amplitude bursts. The mode and phase duration are common for both the Left and Right ear stimulation and their transfers are thus automatically synchronized.

The protocol was tested by transmitting a known pulse sequence to a CI22 Freedom Coil attached to a Cochlear Corporation Processor Controller Interface (PCI). The PCI was connected to an IF5 card in a 16-bit ISA slot in a Windows 98 PC. The RF Statistics software was used to capture and decode the RF and verify the protocol implementation.

4.0 Electromagnetic interference and environmental testing of PDA processor

In preparation for our IDE submission to FDA, we have sent the PDA processor for electromagnetic interference and environmental testing. Current FCC and FDA regulations require that class B computing devices and medical devices meet specified maximum levels for both radiated and conducted electromagnetic interference (EMI).

Radiated EMI covers the frequency range from 30 MHz to 1.0 GHz. EMI arises due to the transfer of energy from one source conducting RF currents to other radiating or conducting elements such as cables or power cords. The PDA processor has been sent to Southwest Research Institute, San Antonio, TX for EMI testing, and specifically for compliance to the applicable emission and immunity requirements of IEC 60601-1-2.

The PDA processor has also been sent to OMEDtech, Edmond, OK for environmental testing to assess the effects of environmental conditions such as temperature and humidity. All testing was done according to the following standards: IEC 60068-2-1, IEC 60068-2-2, IEC 60068-2-20 and IEC 60068-2-61. The testing has been completed and the PDA processor has been found to be compliant to all requirements specified in the above IEC standards in all environmental conditions.

REFERENCES

Crosby, P., Daly, C., Money, D., Patrick, J., Seligman, M. and Kuzma, J. (1985). "Cochlear implant system for an auditory prosthesis," US Patent 4,532,930