UT Dallas – The Costakis Cochlear Implant Research Platform (CCi-MOBILE) for Basic Research

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1. Introduction: The CCi-MOBILE research platform is a sound processing device intended to perform basic research with cochlear implants manufactured by Cochlear Corporation. The research interface bypasses the clinical processor and acts as the sound processing unit to deliver electric signals directly to cochlear implant users. The platform consists of: 1) a computing device (e.g., a desktop/PC/laptop, smartphone/tablet) for sound processing computation, and 2) a custom-developed interface board to connect with commercial, FDA-approved RF transmitter coils. The processing pipeline is shown in Figure 1. The interface board was designed, engineered, and developed at UT-Dallas and is a successor to the PDA-based platform (FDA-IDE #G100069).

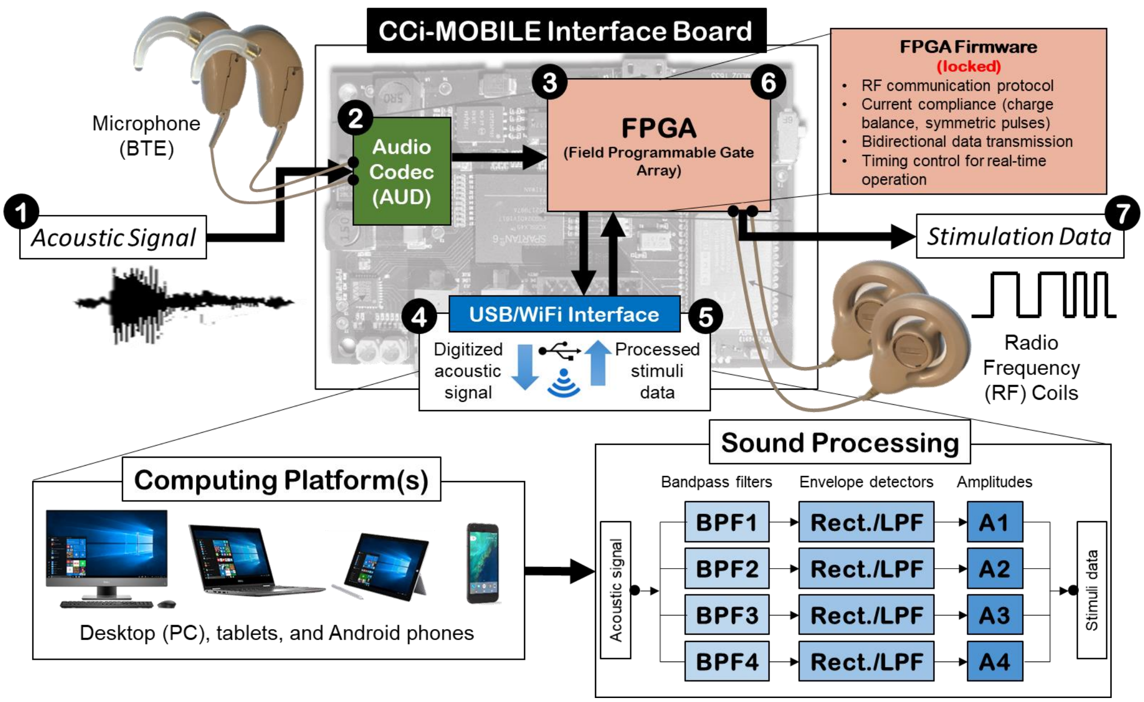


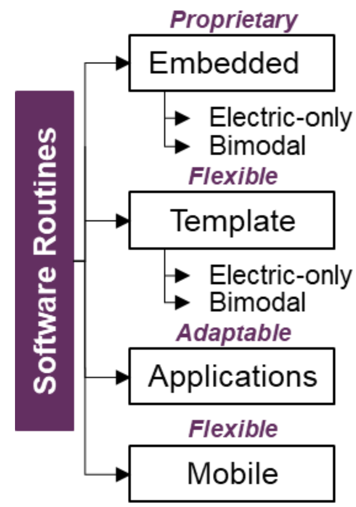
Figure 1. High-level overview of the CCi-MOBILE research platform. (1) Acoustic data is captured from the behind-the-ear (BTE) microphones; (2) the audio codec codifies the audio data on the interface board; (3) audio data is transmitted to the computing platform for sound processing via FGA processing; (4) audio data is passed through cochlear implant signal processing; (5) the processed stimulus data (electrode, mode, amplitudes) are transmitted back to the interface board; (6) the FPGA firmware (inaccessible to the user/researcher, i.e., locked) encodes the data uses RF communication protocols to stream the stimuli to the RF coils.

2. Operational Details/Signal Flow: The operational details of the platform are repeated on frame-by-frame basis to maintain real-time operation and are as follows:

- **Data Capture:** The acoustic signal is first acquired from either the clinical BTE microphones or the acoustic earphone input in real-time or acquired from offline processed audio on the computing platform (Android/computer/tablet) and is sampled digitally by an on-board audio codec; audio sampling rate is *fixed* at 16 kHz, which is similar to the commercial Nucleus Freedom processors (Cochlear Corp.).
- **Signal Transfer:** The sampled digital signal is transmitted to the computing platform using either a wired connection (USB) or a secured, dedicated wireless (Wi-Fi) connection.
- **Computing Infrastructure:** The computing platform, which could either be a PC or a portable mobile device, receives packets of stereo acoustic data and processes them through a sound coding strategy on a frame-by-frame basis – Continuous Interleaved Sampling (CIS) method is the default stimulation strategy. A set of stimulation sequences are generated which consists of electrode, mode, amplitude (EMA) of each biphasic pulse, along with the timing parameters (i.e., the “stimulation data”).
- **Stimulation Data Transfer to the RF Coil:** The stimulation data is transmitted back to the interface board where it is encoded using transmission protocols for the implant model inside the FPGA. Finally, this digital data is streamed to the implant via RF coil for stimulation.

NOTE: The firmware running on the FPGA is “locked”, i.e., not accessible to the user or researcher for external control, adjustments, or customization. This ensures safe and regulated stimuli delivery.

3. Software Architecture and Stimuli Verification: The software architecture of the platform is comprised of four types of software routines and are as follows:



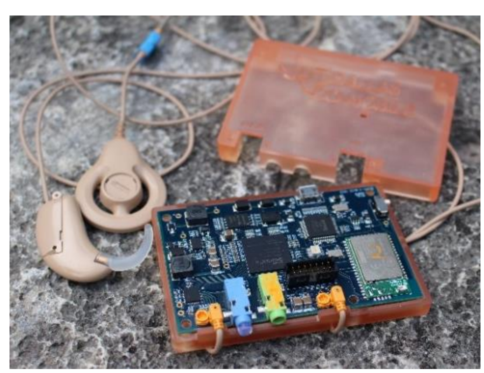
i. <u>Embedded Routines:</u> Proprietary routines (Verilog) installed onto the FPGA interface board – Inaccessible to the user/researcher
ii. <u>Template Routines:</u> Signal processing pipeline (MATLAB) to generate acoustic/electric stimuli – Enables users to embed custom algorithms and signal processing strategies
iii. <u>Software Applications:</u> Speech processing applications (MATLAB) to record speech, visualize waveforms, stream to CI users both in offline and real-time – Enables users to adapt the built-in applications to meet experimental needs
iv. <u>Mobile Routines:</u> Signal processing pipeline (JAVA) to generate acoustic/electric stimuli using an Android device as the processing unit – Enables users to embed experimental/proposed strategies for on-to-go testing in the field

Sound processing algorithms that run on the computing device and embedded firmware that runs on the FPGA and implements communication protocols needed for effective real-time communication with the implanted receiver/stimulator unit. The Continuous Interleaving Sampling (CIS) strategy is the default signal processing strategy. An implementation of an 'n'-of-'m' strategy, Advanced Combination Encoding (ACE) from Cochlear Corp., is the default and can be modified accordingly or other processing strategies can be imported directly into the MATLAB environment. The *firmware is locked* (inside the FPGA) and inaccessible to users for safe and reliable operation of the platform. The firmware hosts routines to ensure charge balance, pulse-width limits, and symmetric pulses. Sound processing routines are re-configurable within the processing specifications of the hardware and software constraints to ensure RF compliance. Pulse-width and total current limits are based on the implant/electrode mode as well as maximum current levels (MCL) provided by audiologists in the cochlear implant user's MAP. These processing specifications are set so that CI users are not overstimulated and the platform can only deliver charge-balanced, symmetric biphasic pulses. Furthermore, the platform can only drive active RF coils which accepts digital stimulus data only (RF modulation is carried out in the coils). The platform currently does NOT support delivery of asymmetric/tri-phasic pulses.

4. Features: Some key features of the platform are as follows:

- **Unilateral Electric Stimulation:** The platform can generate stimulation data for unilateral CI users
- **Bilateral Electric Stimulation:** The platform can deliver time-synchronized, bilateral stimulation data for bilateral CI users. Time-synchronized bilateral stimulation is used to describe pulses on both left and right implants arriving at the exact same time.
- **Electric and Acoustic Stimulation (EAS):** The platform can be configured to provide both electric and acoustic stimulation (EAS) concurrently.
- **Operational Modes:** The platform can be used in both real-time and offline (pre-processed) modalities. The real-time mode works similar to a clinical body-worn processor to conduct in-field or take-home experiments using the BTE microphones. The bench-top mode, on the other hand, can stream pre-processed stimuli (e.g., audio files) in a laboratory environment.
- **MATLAB-based Processing:** One of the unique and powerful capabilities of the platform is the ability to perform real-time processing and streaming using a MATLAB programming environment.

5. Summary: The CCi-MOBILE research platform enables evaluations and investigations of alternative speech processing strategies both inside and outside the traditional laboratory setting. The platform uses existing FDA-approved microphones and RF coils to communicate with the internal implanted receiver-stimulator. Such a setup allows investigators to implement/test custom sound processing strategies. Compliance implemented at several software layers ensures safe operation which is within the prescribed limits of the implant model. The platform is intended to be used strictly for non-commercial, non-clinical, and experimental use only, with the sole purpose to advance basic research in sound processing for cochlear implants.



For more information, visit the CCi-MOBILE website: https://crss.utdallas.edu/CILab/CCi-MOBILE.html