Prospective Adopters Packet

CCi-MOBILE Research Platform

Developed by the University of Texas at Dallas, Cochlear Implant Processing Laboratory – A part of the Center for Robust Speech Systems

September 2021

What is the CCi-MOBILE Research Platform?

A cochlear implant and hearing-aid research platform developed by the University of Texas at Dallas from a joint collaboration between UT-Dallas, University of Wisconsin-Madison, and New York University.

- Research interface for cochlear implants* and hearing-aids configured for in-laboratory, in-booth, and in-field testing
  - Sound coding strategies, speech enhancement, acoustic-to-RF stimulation control, real-time algorithmic development, bimodal and bilateral processing, etc.
  - Overview/Promotional Video
- Plug-and-play system that supports time synchronized acoustic and/or electric stimulation
  - CCi-MOBILE is a wearable device that allows investigators to test signal processing strategies programmed in Android smartphone, bypassing clinical speech processors*
  - In-Field Subject Testing Demonstrational Video
- Emulates commercial clinical processors with provided MAP configurations and MATLAB-based sound processing routines

*For implants manufactured by Cochlear Corp. At this time, only CI24 Cochlear Corp. implants are supported for direct connect RF stimulation

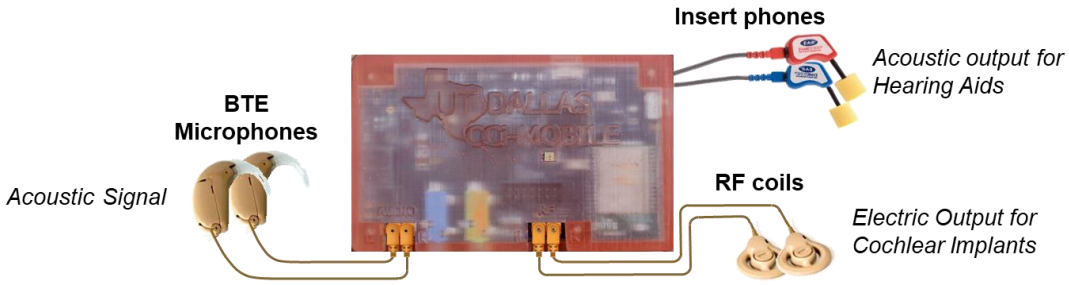


Figure 1. CCi-MOBILE Research Platform setup with behind-the-ear (BTE) microphones, insert phones for hearing-aid output (acoustic) and radio frequency (RF) coils for cochlear implant output (electric).

How is CCi-MOBILE currently supported or funded?

CCi-MOBILE is currently funded by a joint project between Dr. John Hansen (UT-Dallas), Dr. Ruth Litovsky (UW-Madison), and Dr. Mario Svirsky (NYU) under National Institutes of Health (NIH) Center for Deafness and Communication Disorders (NIDCD) DC010494-01A.

- Dr. Mario Svirsky – Laboratory for Translational Audio Research (NYU) – Profile
- Dr. Ruth Litovsky – Binaural Hearing and Speech Lab (UW-Madison) – Profile
- Dr. John Hansen – Cochlear Implant Processing Laboratory (UT-Dallas) – Profile

Dr. Ruth Litovsky (UW-Madison)

Dr. Mario Svirsky (NYU)

Dr. John Hansen (UT-Dallas)

What are the research capabilities with the CCi-MOBILE Research Platform?

You can explore and test custom signal processing solutions, psychoacoustic experiments, and other types of research in speech and hearing science. The platform is configured to perform a wide range of experiments such as:

- **Signal processing solutions,** i.e., compression, noise-suppression, speech enhancement, speech modification, pre-processing strategies, multi-microphone processing, binaural strategies, unilateral and bilateral strategies, etc.
- **Custom experimental designs** with human subjects, i.e., intelligibility in naturalistic environments, localization, modulation detection, etc.
- **Explore fitting parameters**, i.e., attack/release times, MCL/THR, frequency allocations, etc.
- **Specific control of stimulation,** i.e., by-pass clinical processor, directly connected to implant

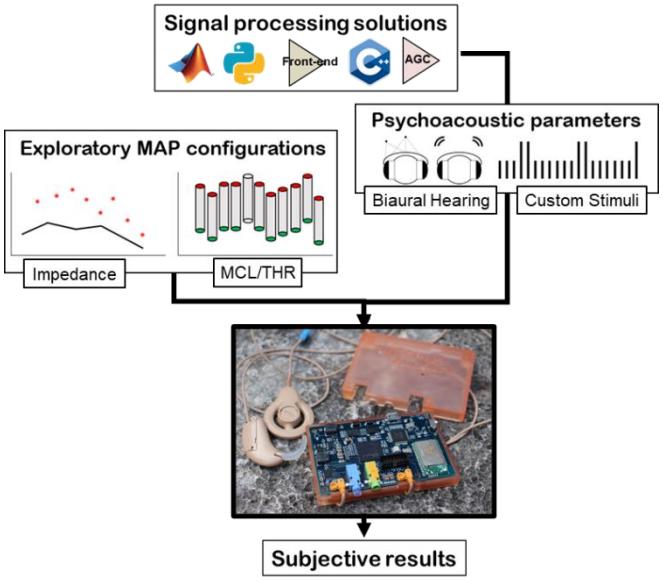


Figure 2 (right). CCi-MOBILE Research Platform setup with behind-the-ear (BTE) microphones, insert phones for hearing-aid output (acoustic) and radio frequency (RF) coils for cochlear implant output (electric).

What are the hardware specifications of the CCi-MOBILE Research Platform?

The computing engine behind CCi-MOBILE is a custom-built FPGA (using Xilinx ISE) with processing and communication routines written in Verilog. These routines are used to communicate to the RF coils and/or acoustic output as well as the computing platform. As a user, you are able to control the signal processing, i.e., the process of developing electrode/clinical level pairs associated with the incoming live audio or offline audio. From the computing platform, the communication routines on the hardware develop the RF stimuli and biphasic pulse generation according to charge and phase parameters. It should be noted that the Verilog scripts are proprietary and are inaccessible to the user, i.e., users are unable to bypass the RF generation routines. If bypassed, the platform will deliver null stimulation and notify the user that the stimulation is outside compliance and processing specifications.

- Real-time performance (10.4ms average delay) using incoming/outgoing data on a frame-by-frame basis
- Data synchronization managed using handshake design techniques
- Implant-specific stimuli generation (for CI24 implants) – Cochlear Ltd. Only
    - Sends individual stimuli data

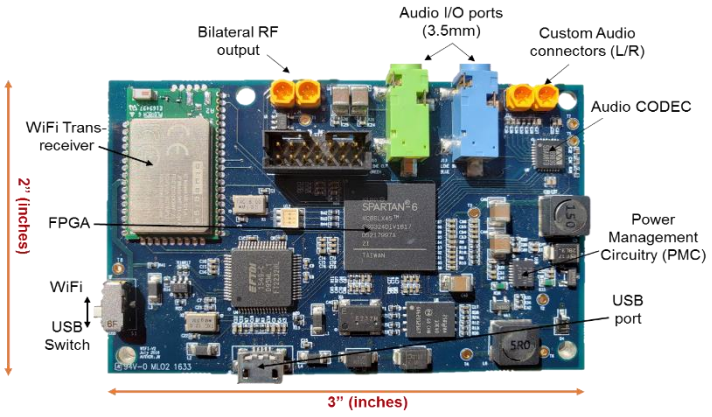
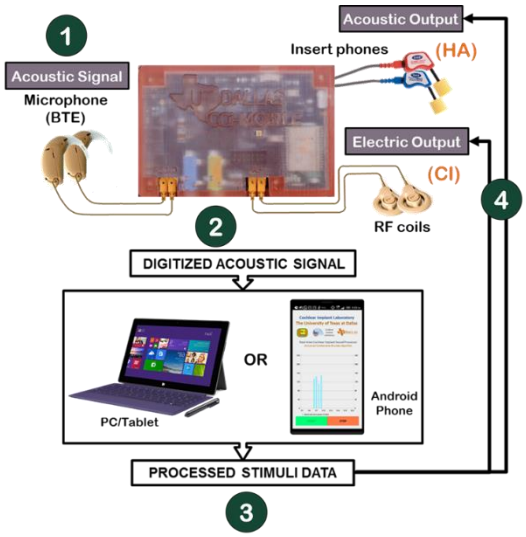


Figure 3 (right). CCi-MOBILE Research Platform hardware overview and individually labeled components.

What is the working sequence of CCi-MOBILE?

The figure below indicates the data processing flow from the original signal generation to the output electric/acoustic stimulation. Inputs to the system can be sampled in real-time from the acoustic audio input or the BTE microphones. For offline processing, audio can be processed from storage on the Android or computer/tablet.

1. **Input(s) –** Real-time audio is either sampled at 16 kHz or processed offline via the stereo codec located on the FPGA at 5Mbps
2. **Data Transmission –** Parallel data analysis and computation via 8ms data packets
    - Frame-by-frame processing to convert audio data to electrodes/clinical levels
3. **Data Processing –** FPGA (CCi-MOBILE) receives EAS stimulation, encodes acoustic/electric stimuli
    - Uses proprietary* firmware to produce biphasic pulses
4. **RF Communication –** FPGA sends time synchronous data to CI/HA transducers



* Verilog routines to develop biphasic pulses is "locked", which means is inaccessible to the user and unable to be modified, controlled externally, or removed from the platform.

Figure 4 (right). Processing sequence and work flow from the CCi-MOBILE Research Platform to the computing platform (tablet/Android) and transmission to acoustic (for HAs) and electric (for CIs) outputs.

How is the electric signal generated using CCi-MOBILE?

The signal processing routines on CCi-MOBILE were adapted from the Nucleus MATLAB Toolbox from Cochlear Corp. The entire software suite is located online and is freely available. For future adopters, see the Github to view the routines and determine if the language is high-level enough for you/your research team. Also freely available are documentation, video walk-through, and sample applications ideal for drag-and-drop experiments.

- Freely available online, easy-to-use, adaptable software based on user-feedback
    - CCi-MOBILE Software Suite
- Adapted routines from Nucleus MATLAB Toolbox (Cochlear Corp.)
    - **Default stimulation strategy:** Continuous Interleaved Sampling (CIS)
- In-line documentation, detailed headers, intuitive program structures, and video walk-throughs
    - How to Use CCi-MOBILE
    - Software Suite Overview

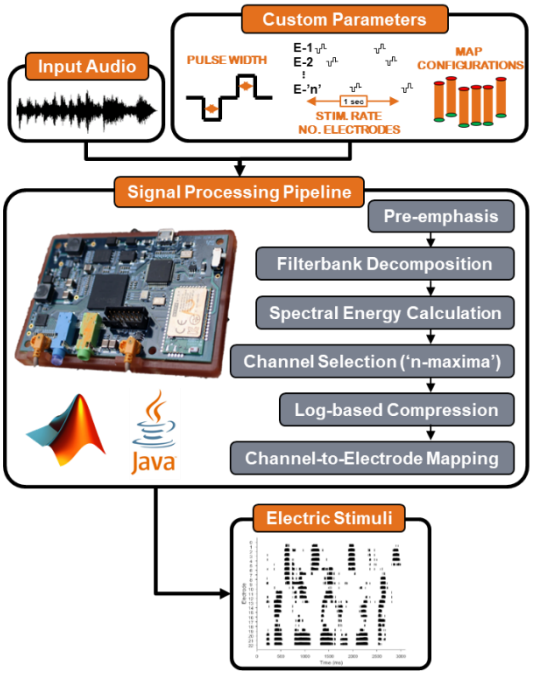


Figure 5 (right). Overview of the CCi-MOBILE electric routines for cochlear implant signal processing. Routines are mimicked in both MATLAB (tablet/computer) and in JAVA (Android).

Is there any clinical or regulatory guidance on CCi-MOBILE?

Presently, CCi-MOBILE does **NOT** fall under the scope of the Food and Drug Administration (FDA) Investigational Device Exemption (IDE) (21 CFR 812). However, your organization/institution **must have IRB approval** from your respective institution to conduct research with human subjects. Examples of IRB applications, consent forms, experimental protocol can be provided upon request. Please reach out to either Dr. Hansen or Dr. Saba to request these documents.

- CCi-MOBILE Research Platform is meant for non-clinical experimental investigations
- FDA submission (February 2017) for FDA-IDE status resulted in the following response:
  - "…we have determined that your study does not fall within the scope of the IDE regulation, and an IDE application is not required to be submitted to FDA for your proposed study."
- Individual control of stimuli (by the user) is regulated at the firmware-level **(inaccessible to the user)** and corresponds to verbose notification software to maintain charge limits and stimulation parameters (<14,400 total pulses/sec/channel)
  - All CCi-MOBILE units undergo thorough testing paradigm
  - Automatic adjustment of user-specified parameters within operating specifications
  - For stimulation or MAP configurations that are outside operating regions, NULL stimulation will be delivered, i.e., no stimulation will occur to prevent the CI listener from experiencing sounds outside of either operating specifications of the device or outside the user's clinical configuration (stimulation rate, pulse width, number of channels, and MCL/THR combinations used)

How can you obtain CCi-MOBILE for your Institution/Company?

1. **Apply –** Applicants are required to disclose research interests, objectives of incorporating CCi-MOBILE to support hypotheses, and intended use; applications are reviewed by CCi-MOBILE Advisory Committee
   - Complete Online Application
2. **Choose Membership Plan** – All CCi-MOBILE units are funded through membership options (full ownership, annual/monthly leases)
   - Choose Your Membership Plan
   - Watch and learn from our Membership Overview Video
   - All funds are used to support units in the field (updates, repairs, etc.)
   - *For NIH Investigators* – Supplemental requests can be made to obtain CCi-MOBILE (contact Dr. Hansen for more information)
3. **MTA Processing –** Material transfer agreements (MTA) will be sent from the UT-Dallas Office of Research to your institutions/company's contracts office for signatures, export controls, shipping, etc.
4. **Receive IRB Approval** – Required at home-institution for use with human subjects

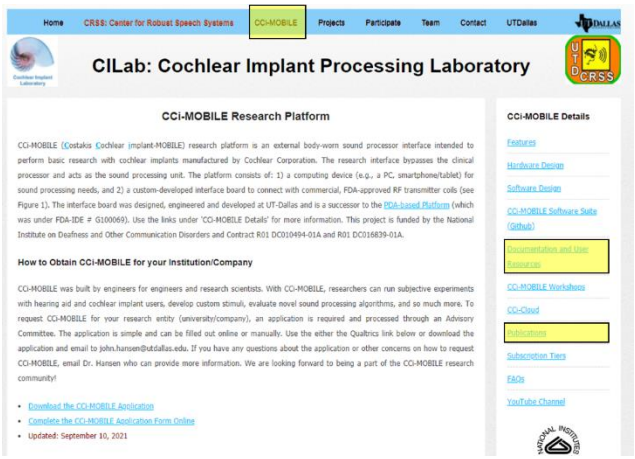
Where can you learn more about CCi-MOBILE?

The majority of the information on CCi-MOBILE can be found online, in publications, or by interacting with the folks in our lab or in our collaborating labs. Below are a set of quick links that may help guide you and your research institution in the right direction to see if CCi-MOBILE can benefit your research.

Helpful Links

- Application for CCi-MOBILE
- CCi-MOBILE Home Page
- Frequently Asked Questions
- Executive Summary of CCi-MOBILE
- UT-Dallas Manual for System Level Design
- UT-Dallas Manual for Software Routines
- Additional Documentation
- Membership Subscription Tiers
- Past CCi-MOBILE Workshops
- CCi-MOBILE Software Suite
- Video Demonstrations (YouTube)
- Publications Featuring CCi-MOBILE

Website Preview/CCi-MOBILE Tabs and Links:



Overview Publications on CCi-MOBILE

- Ghosh, R., Ali, H., and Hansen, J.H.L. (2021) "CCi-MOBILE: A Portable Real Time Speech Processing Platform for Cochlear Implant and Hearing Research" submitted to IEEE Transactions on Biomedical Engineering. Accepted: September 14, 2021.
  - **Pre-print available online**
- Hansen, J.H.L., Ali, H., Saba, J.N., R.C.M.C., Mamun, N., Ghosh, R., and Brueggeman, (2019) "CCi-MOBILE: Design and evaluation of a cochlear implant and hearing aid research platform for speech scientists and engineers," in IEEE EMBS International Conference on Biomedical and Health Informatics (BHI), Chicago, IL, pp. 1-4. doi: 10.1109/BHI.2019.8834652
- Ali, H., Lobo, A., Loizou, P.C. (2013) "Design and evaluation of a PDA-based research platform for cochlear implants", IEEE Transactions on Biomedical Engineering, 60(11): 3060–3073. doi: 10.1109/TBME.2013.2262712

Questions?

Feel free to reach out to our center director, Dr. John Hansen (UT-Dallas), or for minor questions to our lab manager, Dr. Juliana Saba (UT-Dallas). We also encourage you to engage with our collaborators Dr. Ruth Litovsky (UW-Madison) and Dr. Mario Svirsky (NYU) for additional questions.

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- Dr. Ruth Litovsky Phone: (608) 262-5045 Email: litovsky@waisman.wisc.edu
- Dr. Mario Svirsky Phone: (212) 263-7217 Email: Mario.Svirsky@nyumc.org
- (Lab Manager) Dr. Juliana N. Saba Email: Juliana.Saba@utdallas.edu