CCi-MOBILE:
A Cochlear Implant and Hearing-Aid Research Platform

Developed by: University of Texas, Center for Robust Speech Systems (CRSS)
Cochlear Implant Processing (CILab) Laboratory

Joint Collaboration between UT-Dallas (Dr. John H.L. Hansen), New York University (Dr. Mario Svirsky), and University of Wisconsin-Madison (Dr. Ruth Litovsky)

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https://crss.utdallas.edu/CILab/

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Joint Collaborators

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

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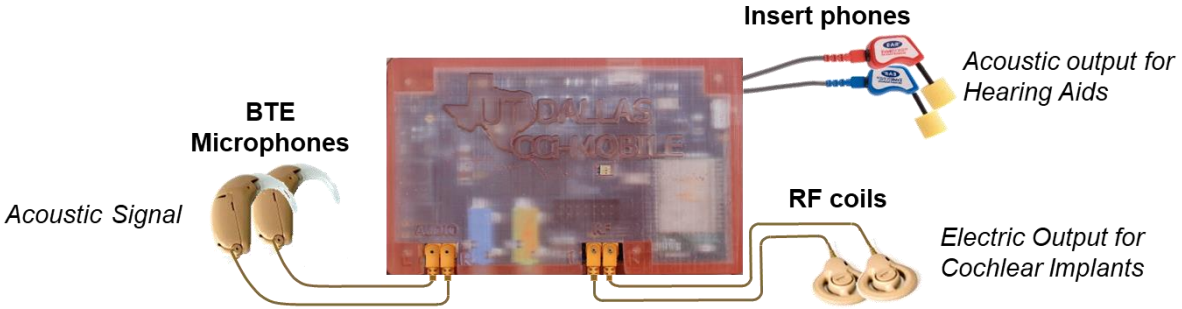
CCi-MOBILE

CCi-MOBILE Research Platform

- 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 (portable, wearable) supports time synchronized acoustic and/or electric stimulation
  - 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.

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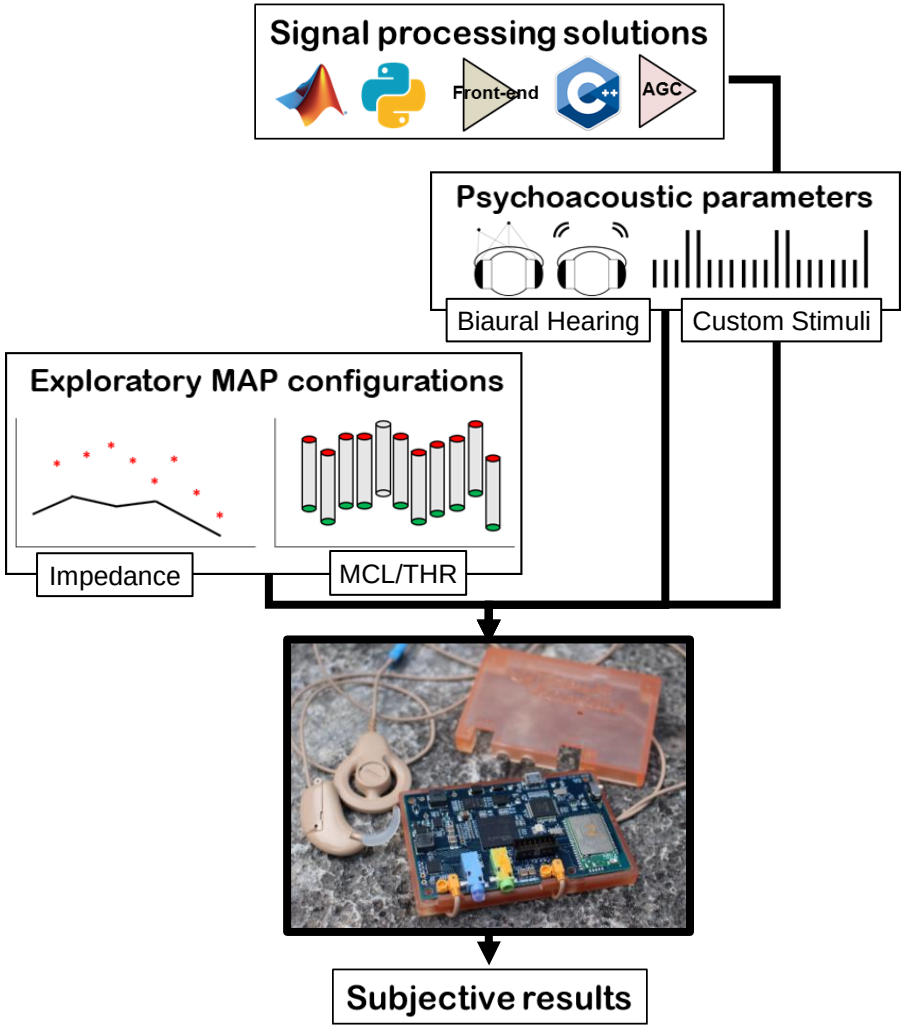
Research Capabilities

Explore & Test

- **Signal processing solutions,** i.e., compression, noise-suppression, speech enhancement, unilateral/bilateral strategies, biaural experiments/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 implants



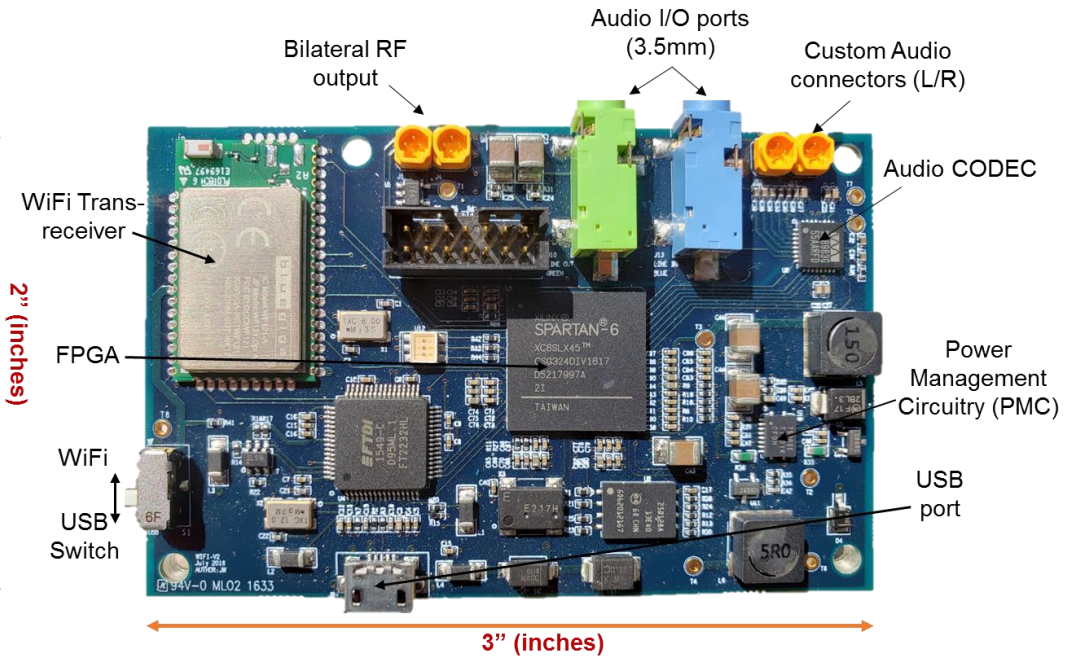
Platform Specifications

Hardware

- FPGA-based design, programmed in Verilog using Xilinx ISE software
- 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)
  - Sends individual pulse characteristics

Compliance

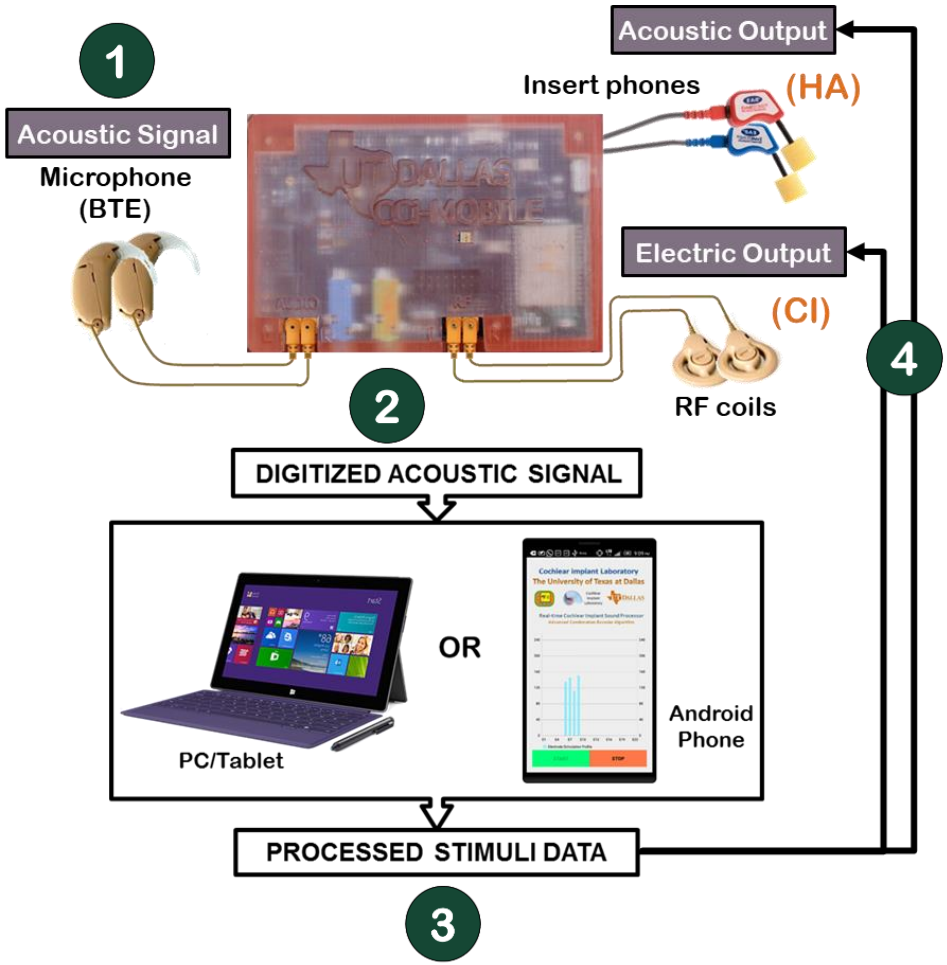
- RF stimuli generation Verilog routines are inaccessible to the user to ensure safe and reliable stimulation delivery



Data Processing

Working Sequence

1. **Input** – Audio is sampled at 16 kHz via stereo codec at 5Mbps
   - Input audio can be acquired in real-time audio or offline/offloaded audio from Android/computer/tablet
2. **Data Transmission** – Parallel computation at 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 "locked"* firmware to produce biphasic pulses
4. **RF Communication** – FPGA sends time synchronous data to CI/HA transducers

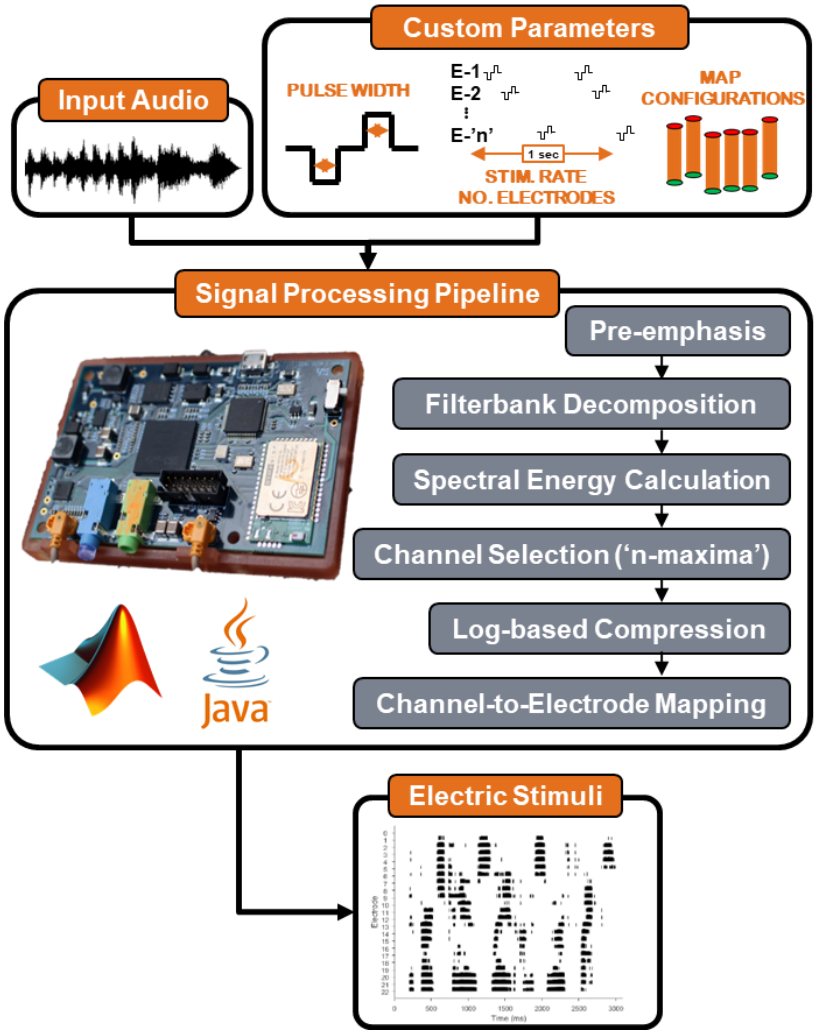


* Firmware to produce RF stimuli (within charge compliance) is inaccessible to the user, editing disabled, i.e., "locked"

CI Signal Processing

CCi-MOBILE Software Suite

- Freely available online, easy-to-use, mendable software based on user-feedback
  - CCi-MOBILE Software Suite
- Adapted routines from Nucleus MATLAB Toolbox (Cochlear Corp.)
  - Default stimulation strategy: Continuous Interleaved Sampling (CIS)
  - An implementation of Advanced Combination Encoding (ACE, Cochlear Ltd.) is provided
- In-line documentation, detailed headers, intuitive program structures, and video walk-throughs
  - How to Use CCi-MOBILE
  - Software Suite Overview



FDA Guidance

FDA Regulatory Status

- CCi-MOBILE does NOT fall under the scope of the Food and Drug Administration (FDA) Investigational Device Exemption (IDE) (21 CFR 812)
- Your organization/institution must have IRB approval from your respective institution to conduct research with human subjects
  - 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."

Charge Compliance

- 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

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Request CCi-MOBILE

How to Obtain CCi-MOBILE for your Institution/Company

1. **Apply** -- Applicants 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*
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

* Example supplement letter and IRB applications can be provided upon request

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Resources

Helpful Links

- Application for CCi-MOBILE
- CCi-MOBILE Home Page
- Frequently Asked Questions
- Additional Documentation
- Membership Subscription Tiers
- Past CCi-MOBILE Workshops
- CCi-MOBILE Software Suite
- Video Demonstrations (YouTube)
- Publications Featuring CCi-MOBILE

Questions?

John Hansen, Principal Investigator; CRSS-CILab Center Director at John.Hansen@utdallas.edu

Juliana N. Angell (Saba), Lab Manager at Juliana.Saba@utdallas.edu

CCi-MOBILE Publications

- Ghosh, R., et al., "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., et al., (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