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Introduction

Traumatic brain injury (TBI) is a leading cause of morbidity and mortality in military populations, with elevated intracranial pressure (ICP) strongly associated with poor outcomes. Rapid, non-invasive ICP assessment remains an unmet need in battlefield and emergency care environments. The IHdetect device is being evaluated as a potential far forward solution in such environments.

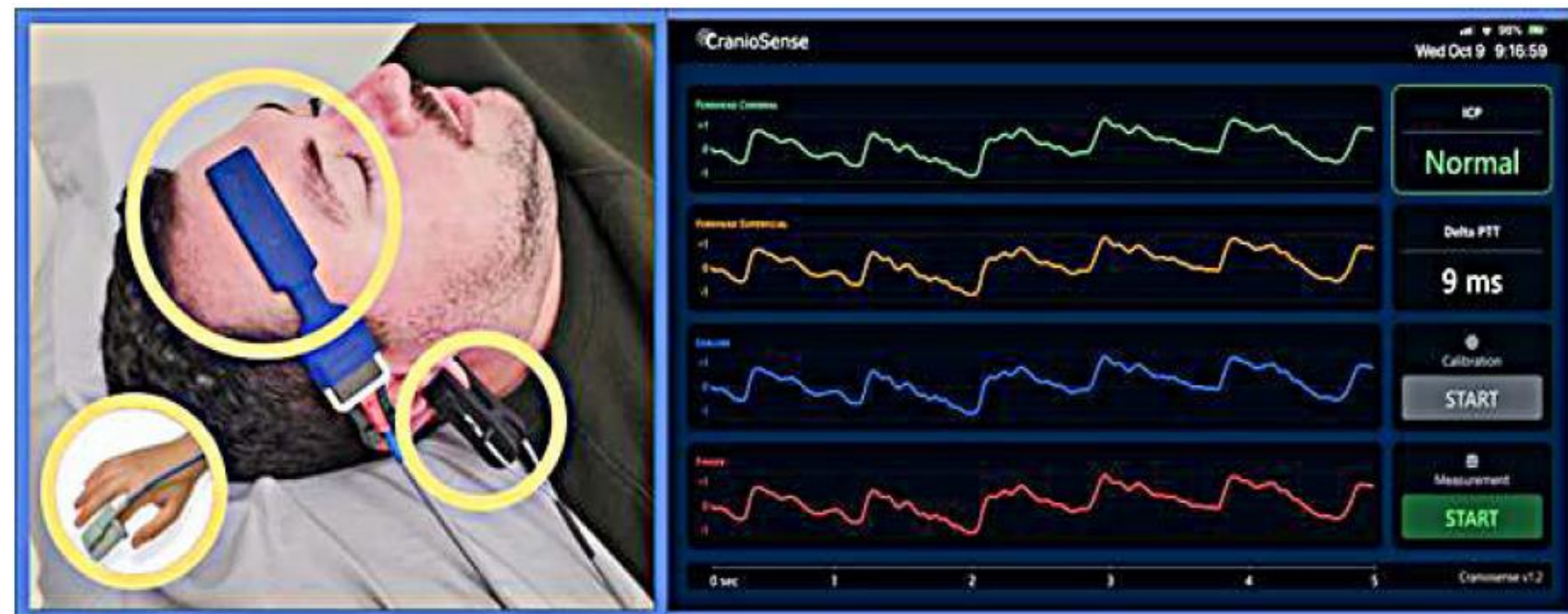


Figure 1: Clinical IHdetect system

Approach

- Prospective **lumbar puncture (LP)** pilot feasibility study conducted at Massachusetts General Hospital (**n = 46**)
- Patients evaluated across **three sequential cohorts** to support iterative improvements in system performance
- **Engineering updates** focused on signal acquisition, calibration efficiency, and hardware optimization
- **Formative Usability Study design** included nine (9) emergency department users, consisting of three nurses or ED technicians and six physicians or advanced practitioners, who completed simulated use activities, knowledge tasks, and interviews without prior training.

Results

LP Feasibility Study

- Clinical setting: Expanded to awake and alert patients
- Calibration: Reduced from ~25 mins to <0.5 mins
- Signal performance: Improved gain control, resolution, SNR, and waveform feature extraction (Figure 2)
- Motion: Reduced motion artifact in awake population
- **Outcome**: Stable, repeatable signals and finalized system architecture
- **Outcome**: Pivotal study design review complete

Formative Usability Study

- Users generally found IHdetect intuitive and straightforward. Findings informed improvements to sensor guidance, result visibility, signal quality support, and disposal instructions

IHdetect Hardware Development

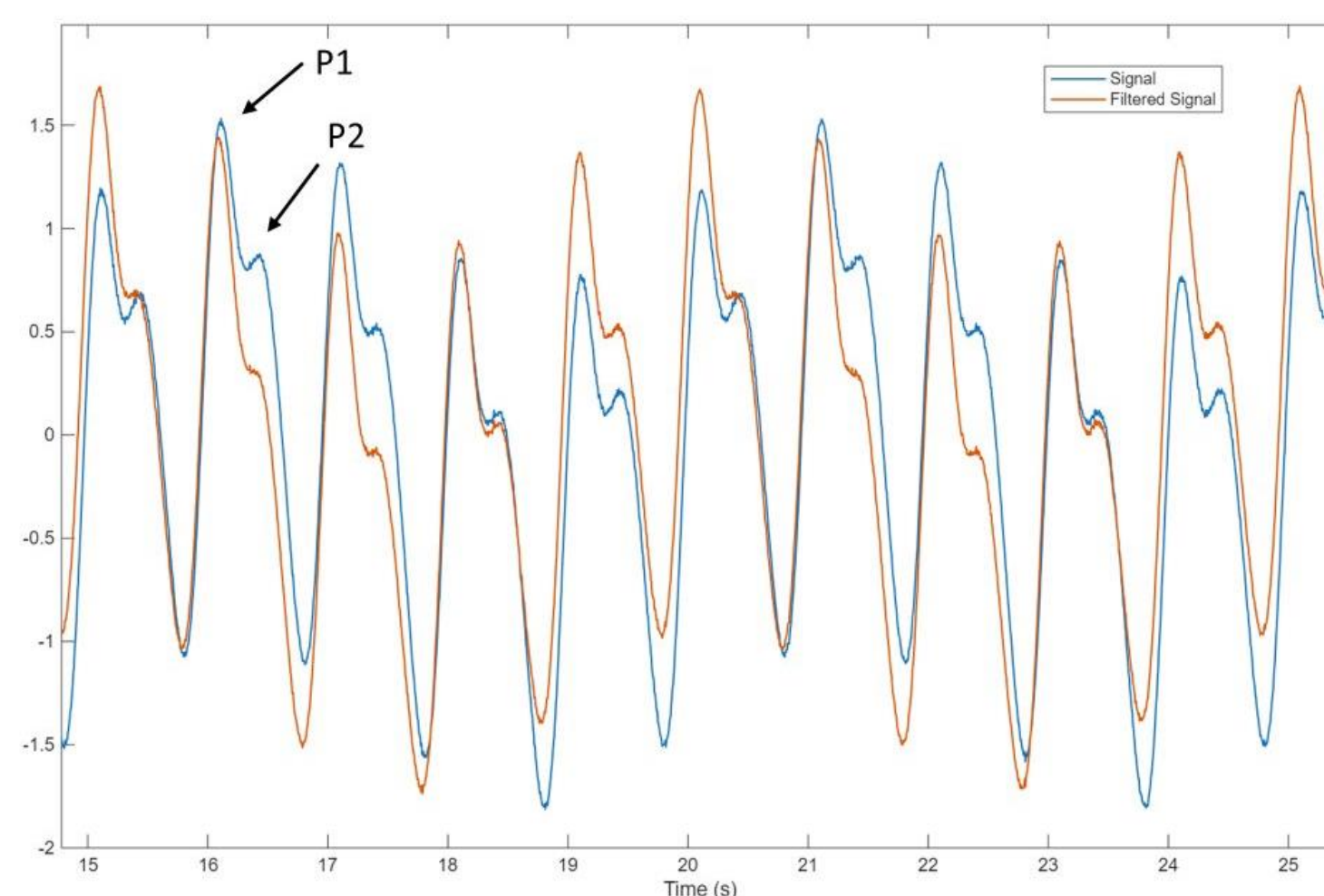


Figure 2: Filtering optimization preserved waveform fidelity and reduced signal distortion

Conclusions and future directions

The **LP feasibility** study demonstrated reliable signal acquisition and guided improvements in calibration, hardware, and signal processing

Formative usability testing confirmed IHdetect could be successfully operated with minimal training

These results **support progression** to a final clinical feasibility study, followed by a multicenter pivotal study to validate diagnostic performance and support regulatory clearance

Acknowledgements

This material is based upon work supported by the U.S. Army under Co IHdetect incorporates technology licensed from Vivonics, Inc. Development was supported by private funding and by U.S. Government awards W81XWH-17-C-0006, W81XWH-15-9-0001/W81XWH21900006, HT942525CE007, and NIH/NIBIB Grant U54EB033664 through The Johns Hopkins University



MHSRS-26-5914