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Toward Commercialization of a High-Efficiency AAC System with BCI Access for Individuals with Minimal Movement

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Introduction: Augmentative and alternative communication (AAC) systems are widely used for efficient communication, but require movement, preventing use by people with the most severe impairments. Wearable P300 brain-computer interfaces (BCIs) offer an alternative AAC access method.

Material, Methods and Results: AAC manufacturer and university research resources supported a mixed-methods approach for late-stage development to commercialize an AAC-BCI system (now at translational level T2). We have started a small clinical trial of in-home product use to optimize the design, evaluate training resources, plan future, larger clinical trials, and prioritize regulatory and reimbursement pathways.

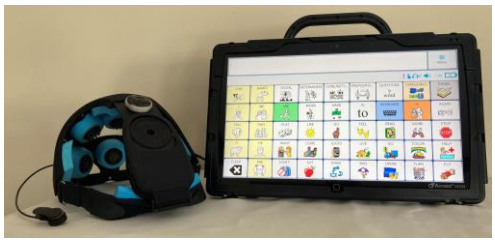

Figure 1: *The PRC AAC-BCI includes the Accent speech generating device and a VR300 dry electrode headset.*

The PRC BCI system (Fig. 1) is designed as an add-on access method for the PRC Accent speech generating device. The AAC-BCI consists of a Wearable Sensing VR300 dry electrode headset and the PRC BCI application program controlling all the BCI features and functionality. The BCI application is a stand-alone Windows program that has been granted permission to run in an overlay window on top of the Empower AAC program (design schematic in Fig. 2). The BCI app uses the Accent device's computational and display resources while Empower is waiting for the user to make a vocabulary selection. BCI prediction begins with the BCI app sending a Microsoft User Interface Automation (MUIA) command to Empower requesting a list of all the GUI elements on the AAC display. The BCI app creates a transparent layer of stimuli with the same size and location as the AAC display elements to produce the P300 evoked response from the user. The BCI application analyzes the resulting EEG, sends a MUIA command to activate the selected AAC key, and the Accent device produces the speech associated with that key.

Evaluation of dosage and delivery modality for AAC-BCI trainings and resources relied on published feedback results [1]. Competency-based assessment compared training types and lengths. A 3-day in-person, hands-on workshop resulted in PRC service delivery consultants achieving competence at the train-the-trainer level with a high degree of trainee satisfaction.

Conclusion: A small T2 clinical trial was initiated successfully to evaluate in-home use of a commercial AAC-BCI across the US. Paperwork is in development to ensure that the AAC-BCI qualifies for medical device reimbursement and other US and international regulations.

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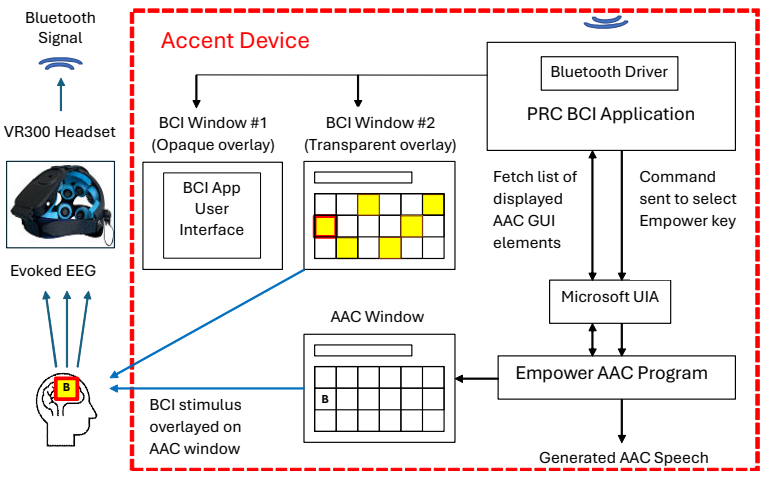

Figure 2: *Schematic of AAC-BCI system.*

References:

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