Auditory Testing Group 1

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BME 460L: Devices for People with Disabilities

Abstract
For patients who experience loss of consciousness, it is important for hospitals to test when patients begin to regain consciousness. Our client was specifically interested in the auditory component of their test for regaining consciousness. In this test, one clinician would clap their hands next to the patient and the other clinician would check for a response. Their current system takes two clinicians and clapping noise levels would vary based on the clinician. Thus, our client was looking for a solution that would be more efficient and objective. We created an application, acquired a split speaker that could play sound from either the left or right side, and developed a carabiner attaching mechanism to fasten the device to the hospital bed rails. The application can play one sound at a time, multiple sounds in a routine, and record a custom sound. Feedback was positive for the device, and future iterations will enhance the custom sound functionality.

Introduction
The goal of our design was to develop an auditory testing system for patients in a minimally conscious state (MCS). Individuals who experience a stroke or a severe traumatic brain injury (TBI) can experience loss of consciousness for more than 24 hours [1]. Therefore, clinicians need to regularly test the consciousness of these patients in order to determine the progress of their recovery and adjust treatment. Two clinicians from the Duke Hospital approached us with a project on this topic given the challenges they were having with the current process of testing consciousness.

The most common protocol for testing consciousness is the Coma Recovery Scale (CRS), in which two clinicians work together in a patient's room to identify if a patient has the ability to localize sound [2]. Specifically, one clinician makes a loud noise on both sides of the patient while the other clinician watches the patient for head or eye movement, which would indicate successful localization. In an article by Seel et al., the authors compare various assessment scales for disorders of consciousness and state that the CRS has "excellent" content validity. The authors also express that it is the only scale that addresses all of the criteria created by the Aspen Workgroup, an authority in the MCS space [3]. Given this, they conclude that the CRS is the optimal test, which is why our clients have adopted it.

However, there are several problems with this test, as expressed to us by our client. First, two clinicians are needed to conduct the test, when in reality, there could be a solution that requires only one clinician to be in the room. Additionally, the test is subjective in nature, since neither the loud noise made by one clinician nor the tracking of head/eye movement by the other clinician are standardized. Further, the absence of an objective measure could result in a misdiagnosis of a patient's recovery stage. Thus, a new device that solved these problems could appeal greatly to both our client and the greater US hospital market.

Project Goals
Our goal was to design a device that would only require one clinician to perform the test in a more objective manner, thereby using fewer clinicians and producing more accurate results. Our device would need to create sounds similar to the sounds used in the test. This includes sounds like clapping and a bell ringing, but also could include custom sounds like the patient's name. While there are several constraints such as the inability to use phones, a limited number of iPads available in the hospital, and concerns with protected health information (PHI), we looked to develop a solution that would work within these constraints and achieve our goal. Apart from reducing the number of clinicians involved and making the

test more objective, several other criteria for success included the speed, customizability, and ease of use of the device. Hence, our device will aim to implement features that address these criteria as well.

Ideation Process

To develop ideas for our device, our group started by brainstorming 52 different ideas (please refer to Appendix F). These 52 ideas were then narrowed to a list of 25 based on client feedback, instructor feedback, and common sense. Specifically, through discussion, we realized that an iPad would be more versatile in controlling sounds than a Raspberry Pi. In addition, our client informed us that headphones could be a hazard to the patient, as they could lead to skull fractures or lacerations. Finally, we learned that the iPad speaker itself would neither be loud enough nor produce directional sound when held several feet in front of the patient.

The 25 most promising ideas were then generalized into 5 main ideas and put through Pugh scoring matrix, where ideas were evaluated on a 5-point scale (please refer to Appendix F). In this matrix, the idea of an iPad app that controls two mounted Bluetooth speakers performed the best. This was also our hypothesis before quantitatively evaluating the ideas, given that it would be easy to use and the clinicians were excited about the idea.

Moving forward with this idea, several prototypes of the iPad app and speaker enclosure were developed. Our first prototype had a UI (shown in Figure 1) that featured a timeline where users could drag and drop sounds and adjust the length of the pauses between each sound. It had 4 sound options to choose from and also had the ability to record a custom sound. For the speaker itself, we used two standard Bluetooth speakers that attached to each bed rail via a velcro strap.

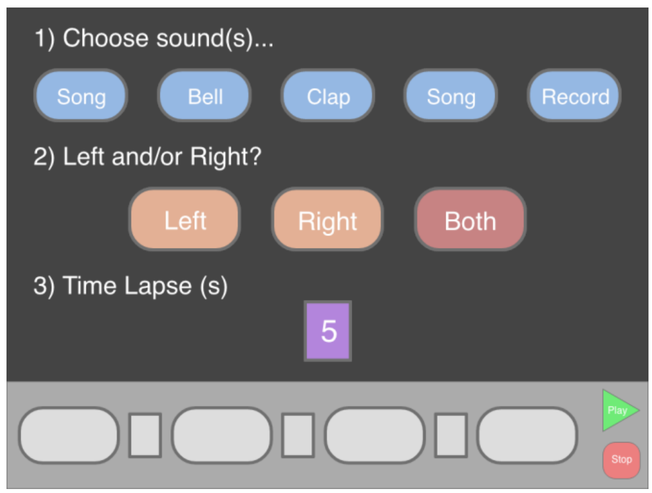

Figure 1: UI in the First Prototype

After the first prototype evaluation and discussions with our client, we realized that the UI would better address the client's needs if it had two separate sections: a Therapy screen and an Assessment screen. The Therapy screen would play one sound at a time while the Assessment screen would have the aforementioned timeline setup. Additionally, our clients wanted more standard sounds to choose from, as well as the ability to create and rename custom routines. Finally, our client wanted us to explore alternatives to the speaker velcro strap that would take less time to connect to the bed rail. Our learnings from our first prototype, as well as our other prototypes, were subsequently implemented in our final device design.

Design & Development

Our final device design involves an iPad app and a dual-channel waterproof Bluetooth speaker made by Kove (Kove Commuter 2 179-S) connected to bed rails via a carabiner. The clinician will first attach the speaker to each bed rail through unlocking and locking the carabiner. Then, the clinician will open up the iPad app, which will connect to the speaker via Bluetooth. Within this app, the clinician can trigger the speaker to play various sounds in a sequence to replicate the standard CRS test. After the sounds are played, the clinician can record on paper which sounds elicited a patient response, close the app, and detach the speaker from the bed rails. The entire device was designed with our design specifications in mind (refer to Appendix C).

The iPad app was built with the intention of making it very clear and easy for the user to play sounds. The Home screen (as shown in Figure 2a) links to three other screens: Therapy, Assessment, and My Sounds. The Therapy screen (Figure 2b) allows for clinicians to try out different sounds on either the left or right speaker to measure the patient's auditory responsiveness. This is primarily intended for patients who have recovered from a minimally conscious state (MCS). On the Therapy screen, one can select a sound, pick the side on which they want the sound to play, and adjust the volume via the built-in iPad volume controls.

Next, the Assessment screen (Figure 2c) is intended for clinicians who are performing the CRS test for patients still in an MCS. On this screen, users can choose from playing pre-created routines or creating a custom routine. These routines are based off of the aforementioned timeline setup where various sounds and time delays can be put in an order and played back. The pre-created routines typically have 4 of the same sound, each of which plays for 5 seconds, with 10 second pauses in between. The custom routines allow for the user to edit the actual sounds, time delays, and whether the sound is played on the left or right speaker. Since the client mentioned that the time delay would remain the same throughout a given routine, changing one time delay to another value automatically changes the other time delays to that same value. Additionally, the page has a stop button to allow for the routine to be stopped at any point.

Finally, within the My Sounds screen (Figure 2d), the user has the ability to record and play back a custom sound (in accordance with the storage of PHI). This serves as an alternative to the Therapy page, since it allows for recorded sounds rather than stock sounds to be played whenever the "Play" button is toggled. Typically, these custom sounds are either the patient's name or a popular song. The user is able to name this custom sound and to abide by PHI rules, the user is instructed in the user manual to only type the initials of the patient as the sound's name. The UI for this screen, along with the other screens, was translated into actual code through using the Dart programming language, which made it easy to simultaneously create iOS and Android versions of the app. The app has been uploaded to TestFlight for beta testing with ourselves, classmates, and the clients.

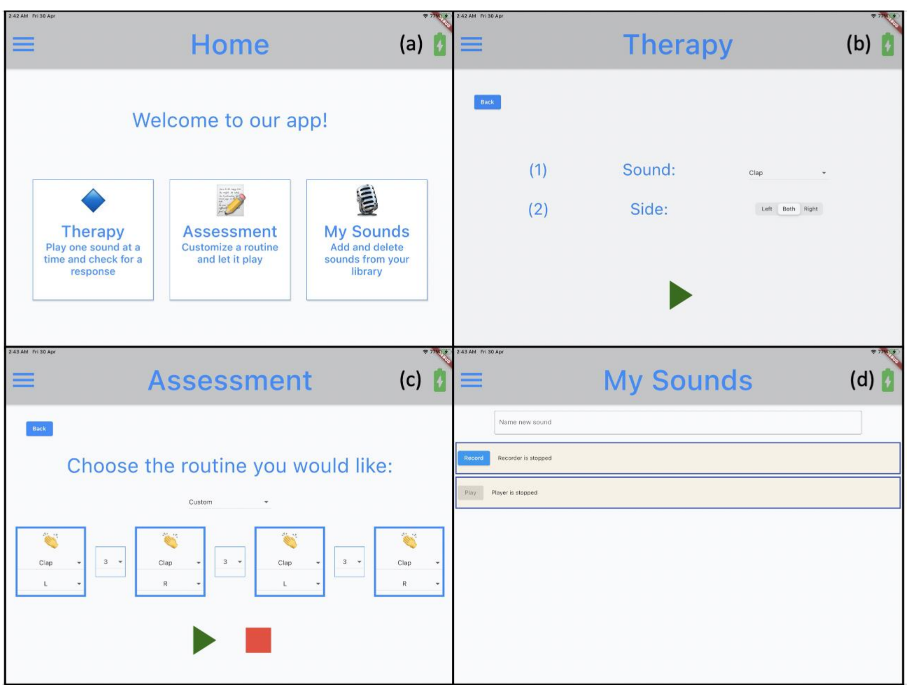

Figure 2: UI of app; (a) Home page, (b) Therapy, (c) Assessment, (d) My Sounds

The other component in our design was a Bluetooth speaker, along with the mechanism that would attach the speaker to the bed rail. We decided upon the Kove Commuter 2 primarily because the speaker could be split into two smaller speakers, where one speaker is the left channel and the other is the right channel.

Figure 3: Speaker + Carabiner Set-Up

This setup makes it easy to program sounds to be played on either side of the patient. Additionally, the speaker is IPX7 water resistant and thus can be disinfected without worry. Each speaker will be attached directly adjacent to the patient's head on the bed rail via a carabiner (as shown in Figure 3). The carabiner would be put through the loop on either side of the speaker and would allow for a secure connection to the bed rail with minimal hassle. We found the carabiner to be the most versatile option, since it could securely attach the speaker regardless of the angle of the bed rail. Overall, our client agreed that this design would be the easiest to use and would satisfy their expressed needs.

Design for All

When creating our device, we did our best to ensure that the device could be operated by and used on all people. While our design does not impact public health per se, thousands of individuals enter an MCS every day. Our solution can help clinicians ensure that these patients are on the right track to recovery, and in this way, our design can affect the health of many people. Public safety is addressed in ensuring that our device will not cause harm to the hospital bed or the hospital at large. Hazard analysis was also performed to ensure the device operators would not be harmed. While our initial customers are based in the US, the design can be used globally. We chose sounds that were not specific to American culture, and the iPad accessibility and language settings can be adjusted to meet other users' needs. Cultural factors surrounding the usage of technology and effectiveness of speaker-generated clapping may impact our device's adoption. Since the design is minimalistic and its components are durable, there are not too many byproducts from the device. In the rare case that an electronic component breaks, it would be important for the user to dispose of items at electronic waste collection sites. The most expensive component of the device is the iPad, but many hospitals throughout the world are moving to high-tech solutions within their hospitals. Thus, it is reasonable to expect our device to be financially accessible for many US hospitals and a growing number of global hospitals.

Evaluation

To evaluate our device, we engaged in self-testing, testing with classmates, testing with friends, and most importantly, testing with the clients. Overall, the device was first evaluated to see if it could play multiple sounds, be used by only 1 clinician, and play custom sounds. For these design specifications, we developed performance criteria, verification, and validation tests, most of which we were able to satisfy through our robust testing. Our clients were pleased with the app, stating that it "looks great!" and as currently formulated, the separate "Therapy and Assessment pages will be super helpful for measuring the patient's responsiveness." The full evidence of client testing (with quotes from the client) and all of the verification and validation tests (along with justifications for the performance criteria) are provided in Appendix C. As an example, one important test worth mentioning is the one for ensuring that the maximum volume of the speaker is no more than 75 dB, a limit recommended by the CDC. For this, we used an iPhone app that measured the dB of a sound when played, and for both the verification and validation plan tests, the volume never exceeded 75 dB. Our client was pleased with the results of this test, as this would help minimize the risk for patient hearing loss. Additionally, through further testing, we were able to ensure that our device does not cause harm to the user or patient and that it ensures the privacy of all parties' information.

Discussion/Conclusion
Overall, our device satisfies almost all of our design criteria, except for the ability to store custom sounds. Given the many attempts to try to get this functionality to work and input from the instructors and clients, we have decided to leave that functionality out of this version of the app. As a next step though, we will try to use a different package in order to get it to work. The rest of the results from testing, which include the confirmed ability to play multiple sounds in either a one-off or routine basis using only one clinician, show that our project goals and design criteria have mostly been met. Thus, our device indeed provides a simple and objective way to gauge consciousness for patients in an MCS.

References
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