Development of a Hearing Loss Screener and Personal Sound Amplification Device

by

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Development of a Hearing Loss Screener and Personal Sound Amplification Device

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This thesis describes the development of a functional prototype of a device that can both screen for disabling hearing loss and provide personal sound amplification. Disabling hearing loss has been linked to low quality of life and increased medical expenses. Although an estimated 38 million people in the United States live with unreported hearing loss, the practical standard of care does not include hearing screening. A low-cost, easy-to-use device is needed for clinical use that can 1) accurately screen for hearing loss in a noisy background, and, if needed, 2) provide personal amplification for the duration of the healthcare visit.

Clinician needs and feedback regarding ergonomic and human interface design were translated into mechanical and electrical functional requirements for hearing screening, background noise level checking, and amplification. The background noise level check assesses whether the room is too noisy to screen hearing, and in a sufficiently quiet room, a hearing screening is conducted to assess disabling hearing loss within 30 seconds. Real-world background noise data were recorded to inform development of the noise level assessment algorithm.

Prototype design comprised two major technical aims: a.) assessment of monitoring microphone placement; and b.) development of the control box, which conducts the background level check and screening operations. Custom printed circuit boards (PCBs) that included microelectromechanical (MEMS) microphones were designed, fabricated, and embedded into supra-aural headsets. After calibration of the headset speakers with a coupler system, performance

of the microphones and headsets were characterized in an anechoic chamber. Development of the control box prototype involved combining an evaluation-style audio digital signal processing system, a microcontroller, and power electronics.

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1.0 Introduction

Many elderly patients in the healthcare system have undiagnosed or unrecognized hearing loss, which can impede communication with their healthcare professionals. Yet, the practical standard of care for elderly patients in a typical medical visit does not currently include a hearing screening. One in eight people in the United States have disabling hearing loss, and 50% of the population older than 75 suffer from disabling hearing loss [1]. Less than one in three of patients with disabling hearing loss have been diagnosed and thus able to notify their physician of their condition [2]. Conversations at a medical visit typically contain important questions regarding the patient's health and symptoms. For example, medications may be prescribed, including instructions regarding dosage and use provided by a physician. For a patient with hearing loss, these questions and directives can go unheard or misinterpreted. Patient readmissions stemming from hearing loss-related complications cost the U.S. healthcare industry an estimated $133 billion per year [3].

Performing formal hearing testing for patients during patient visits is not practical for routine healthcare. Testing would typically require a visit with an audiology specialist, requiring training that the average nurse or physician will not have. Audiology equipment is expensive and approximately 30 minutes are needed to conduct a proper hearing test. This time commitment is not suitable for a routine healthcare setting, where a typical patient spends less than 17 minutes with the physician [5]. A typical hearing evaluation will test different aspects of the patient's hearing profile (air conduction). A standard test is conducted in a sound-isolated booth using an audiometer, which plays single-frequency tones (pure tones) at various intensity levels to

determine the quietest sound a patient can recognize. The test results are collected in an audiogram, which can be used to prescribe hearing aids individualized to the patient's hearing loss [11]. An alternative to formal testing is a hearing screening.

Referral to audiology specialists typically follows a hearing screening, conducted with a purpose-built hearing screener which are faster and more portable than an audiometer. These screeners identify hearing loss on a pass-fail basis through the use of a calibrated headset and a test to ensure environmental sound levels will not invalidate test results. Although portable, and simpler than formal audiometric testing, hearing screening is still quite rare in a healthcare setting and are still often expensive. If a patient is screened and found to have hearing loss, short-term treatment devices exist, such as over-the-counter personal sound amplification devices (PSAD). However, use of PSADs is equally rare to hearing screening, even for patients who are found to fail a hearing screening.

There are currently no devices available to healthcare professionals that simultaneously provide a simple-to-use method of hearing screening with a personal sound amplification in order to address patient communication difficulties in healthcare. A device to identify the correct population that may have disabling hearing loss can 1) replace expensive screening machines inaccessible in a standard doctor's visit and 2) serve as a personal amplifier for the duration of the visit if the patient is suffering from hearing loss.

There is a strong need for a low-cost, low-profile, simple solution that any healthcare professional can use to perform a hearing screening within 90 seconds and provide subsequent, short-term amplification (if needed). The focus of this thesis is to develop and test such a device.

1.1 Thesis Contributions

This thesis presents the design of a novel, low-cost, portable device intended for clinical use that combines hearing screening and personal amplification. The major contributions to its design reported in this thesis include:

- Developing and refining the device requirements (e.g., overall form factor, electrical requirements, and software requirements) based on bench testing and stakeholder feedback from pre-alpha prototypes.
- Designing and building a high-fidelity prototype with full functionality. This embodiment comprises the user interface, background noise testing, amplification system and power electronics.
- Developing and executing a protocol for design verification via bench testing against a reference measurement microphone.
- Analyzing environmental noise in representative areas where the target population receives healthcare (e.g., hospital rooms, assisted living facilities, cafeterias) for future use in developing advanced hearing assessment tools.
- Developing an instruction set to assist in evaluation of prototypes by clinicians in health care settings.

2.0 Background

2.1 Impact of Disabling Hearing Impairment

Undiagnosed, disabling hearing loss in the United States is a growing health risk and impacts millions of Americans. The World Health Organization (WHO) has established a chart for Grades of Hearing Impairment, and defines disabling hearing loss as having more than 40 dB_{HL} or 35 dB_{HL} in the better ear of adults or children, respectively [6]. A modified classification, published on the Bulletin of the WHO, of disabling hearing impairment has been proposed by the Global Burden of Disease Hearing Loss Expert Group as 35 dB_{HL}, which encompasses all age groups, which will be used for the duration of the text [7]. The WHO further estimates that the number of people with disabling hearing loss has increased from 42 million in 1985 to 360 million in 2011, including a population of 7.5 million people who do not have aided hearing or even know they are living with hearing loss [16]. Over 38 million people living the US alone have unreported hearing loss, those who have hearing loss but do not seek treatment, including two-thirds of patients older than 70. Yet, less than 20% of these patients have hearing aids [8]. While one in eight people over the age of 12 in the United States are estimated to suffer from bilateral (both ears) hearing loss, over one in five people have at least unilateral (one ear) hearing loss [9]. In the past 15 years the number of Americans with hearing loss has doubled and is expected to continue to grow worldwide [10].

To test the impact of untreated hearing loss on the healthcare economy, patient outcomes, and their families, Johns Hopkins University conducted a study in 2017 to determine whether

untreated hearing loss was associated with increased health care cost, as defined by metrics such as medical costs, inpatient hospitalizations, and 30-day readmissions. Untreated hearing loss was associated with over $20,000 per patient in increased health care costs over a 10-year period. Further, patients with untreated hearing loss experienced more inpatients stays and were at greater risk for 30-day hospital readmission [12]. In the U.S., untreated hearing loss taxes the healthcare industry with readmission, additional procedures, etc., costing approximately $133 billion dollars per year [3]. Similar trends have been reported in European countries, and it is estimated to cost the global healthcare industry nearly $750 billion USD per year [13].

Untreated hearing loss impacts quality of life. *The Hearing Review* conducted a survey to validate smaller studies' reports on whether the value of hearing instruments can positively impact quality of life. Among other impacts, hearing instrument usage positively related to improved interpersonal relations, reduction in discrimination, reduction in the incidence of depression, increased emotional stability, reduction in anxiety and social phobias, and improved cognitive activity [14]. Without aided hearing, hearing impairment can affect compensation and employment rate [15]. It is clear that untreated hearing loss has a significant impact on healthcare for patients and healthcare providers. However, treating hearing loss normally requires that patients first be diagnosed through hearing testing, and then fitted with an appropriate hearing aid solution.

2.2 Hearing Loss Diagnosis and Treatment

There are multiple steps for diagnosing and treating hearing loss. Typical identification and treatment of hearing loss starts with healthcare professionals such as nurses and primary care

physicians who suspect hearing loss in their patient and then provide a referral to an audiologist. The audiologist will perform a formal evaluation, diagnosis, and provide treatment as appropriate. Treatment could be one of the many types of hearing aids available or perhaps suggest over the counter (OTC), personal sound amplifying devices, or PSADs. The rest of this chapter will review current methods for hearing loss diagnosis, hearing enhancement devices, and current limitations in practice of the healthcare system in diagnosing and treating hearing loss.

2.2.1 Hearing Loss Diagnosis

There are multiple aspects to conducting a hearing exam. When referred by a primary care physician (PCP) or another healthcare professional, the audiologist or health care professional will first evaluate the ear canal and the ear drum for physical issues (e.g., ear wax blockages, otitis, etc.) by otoscopy (an otoscope is the familiar device with a magnifying glass, light, and small cone that doctors use to check a patients nostrils or ear canals). Next, middle ear function and response is checked by the audiologist using tympanometry, an examination to test middle-ear function by measuring the mobility of the ear drum. Finally, either formal audiometry or a hearing screening is performed. Audiometry can precisely measure hearing acuity in both ears and detect abnormal variations in detecting sound level for various pitches. An audiogram is produced, which can be used to prescribe custom hearing aids for the patient. Hearing screening is a binary check for normal versus abnormal hearing with no details of the nature or severity of the hearing loss.

Audiometric testing requires specialized facilities, equipment, and training that are not typical in routine healthcare. The most accurate hearing tests are conducted in an audiometric sound booth, a sound proof room, or possibly a quiet space having little to no background noise.

Sound booths are bulky, cost tens of thousands of dollars, and require a trained audiologist to conduct the hearing tests. A patient will usually need to go to a facility that has been specifically outfitted for audiometry [18]. Bone conduction tests are often included with the audiometric testing, whereby a bone conduction speaker (vibration) is mounted to the mastoid of the skull and used to create perceived sound. This evaluates the hearing status of the inner ear, bypassing the outer and middle ear.

Figure 1. Audiometer in use to test patient's hearing in sound booth (Left), Example audiometer by Welch Allyn with noise isolating headset (Right) [19, 20]

In addition to a quiet space to conduct the audiometric tests, an audiometer and headphones are required to produce the tones at various levels (Figure 1). This device works by playing tones at different frequencies and levels into each ear of the patient, who is instructed to indicate when they perceive a sound. This allows the threshold of hearing to be determined for each frequency played. Typical tone frequencies include 500, 1000, 2000, 4000, and 8000 Hz. The difference between these tones is an octave, but sometimes an additional low-frequency octave is added at 250 Hz and intermediate tones may be added at 1500, 3000, and 6000 Hz for additional resolution.

This information is then recorded as an audiogram, which is a graph showing the threshold of hearing at each frequency for both ears [17]. If for example, someone has 40 dB of hearing loss at 2,000 Hz, a tone has to be 40 dB louder than the normal hearing threshold for the patient to barely perceive the tone in that ear. Since the values represent the amount of hearing loss, the levels are expressed in terms of dB_{HL} (Hearing Level (dB)). The various levels of hearing loss (representing different levels of impairment) along with an example audiogram for someone with moderate hearing loss are presented in Figure 2. The audiogram of Figure 2 has the vertical axis (Hearing Level (dB)) and is the same as dB_{HL}, as described above. This information is used to identify what type of hearing amplification to use.

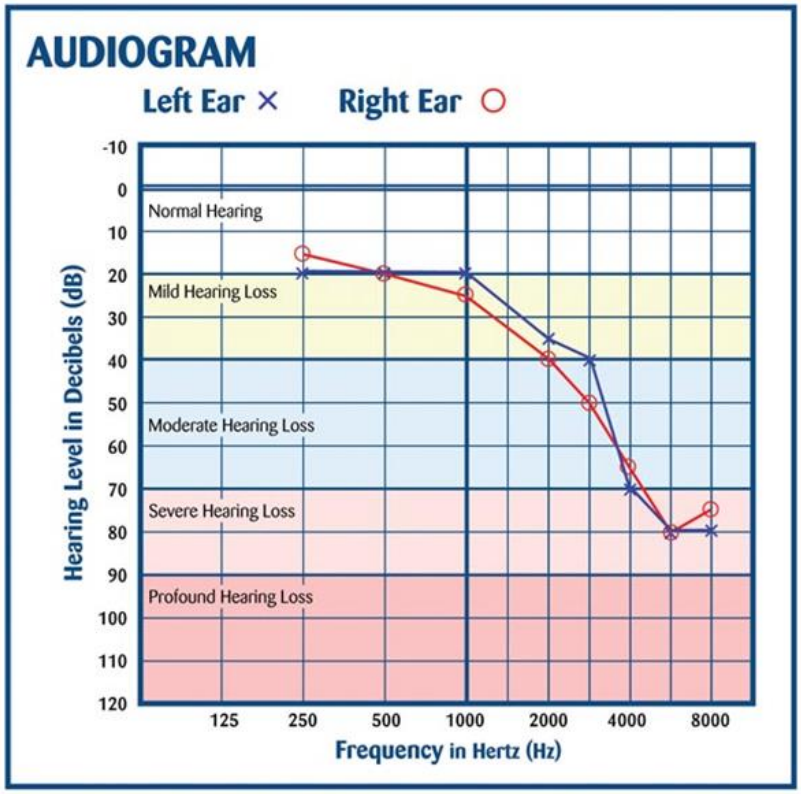


Figure 2. Example audiogram with labels of levels of hearing loss [21]

Given the precision of audiometers, they need to be (acoustically) calibrated frequently in order to ensure that the audiograms produced are accurate and reflective of the patients' actual hearing condition. This aspect is so important that the Occupational Safety and Health Administration (OSHA) mandates that audiometers used to check hearing loss in workers be calibrated at least annually following the 1910.95 Appendix E guide for Acoustic Calibration of Audiometers [22]. The usage of audiometers in a full hearing health screening is costly to the patient and not feasible for every patient who walks through the doors. Instead, doctor's offices can use hearing screeners (discussed below) to identify the presence of hearing loss, and then refer the patient to an audiologist. However, even these devices are rarely used for adults, including aging populations with a higher prevalence of hearing loss.

Portable hearing screeners (see Figure 3) or audiometers are a more convenient and simpler alternative to booth testing. They are quite compact, but can still be expensive, have specially designed headphones, and require some specialized training to conduct a hearing test. Their prices range from a little over $100 to several hundred dollars - even for devices that test only one ear at a time. High quality hearing screeners can still cost several thousand dollars. The cost of a screener is related to the capabilities of the device, such as the ability to upload screening data, background noise testing, hearing screening modes (number of frequencies). Some screeners will first evaluate the background noise levels to verify that a sound threshold has not been exceeded and hearing screening can accurately proceed. The primary difference between a hearing screener and an audiometer is that a hearing screener simply serves as a pass-fail device to indicate some form of hearing loss. Since no formal audiogram that details the nature of the hearing loss is produced, the physician is left quantitatively unsure of the severity of this hearing loss. Although faster and easier than conducting booth testing, screeners are not always intuitive to use and still require

several minutes to conduct a test. As a result, these are also not common equipment for practicing routine healthcare, with the exception of testing hearing in infants and children, which are much less prone to significant hearing loss than the elderly population.

Figure 3. Inexpensive hearing screener testing 4 tones (Left), Expensive hearing screener with additional features (Right) [23, 24]

2.2.2 Treatment of Hearing Loss

Once hearing loss has been identified, the audiologist will recommend a suitable solution for their patients. There are multiple kinds of amplification products available depending on hearing loss severity, including various types of hearing aids, PSADs, and cochlear implants. The latter option is typically only appropriate for patients with severe to profound hearing loss. Hearing aids are customized by equalizing the various frequency bands based on the patient's audiogram. Further, different equalization and gain are used for soft, moderate, and loud environments. Some

hearing aids include behind-the-ear (BTE) styles that are visible, in-the-ear styles (ITE) which sit in the ear and are more concealed, and in-the-canal (ITC, CIC, IIC) style which are inserted intra-aurally (Figure 4). Some hearing aids have additional features in addition to the amplification, such as feedback suppression, the ability to communicate with personal electronics, or directional microphones [26]. Cost for hearing aids vary greatly but the average cost is $3000.

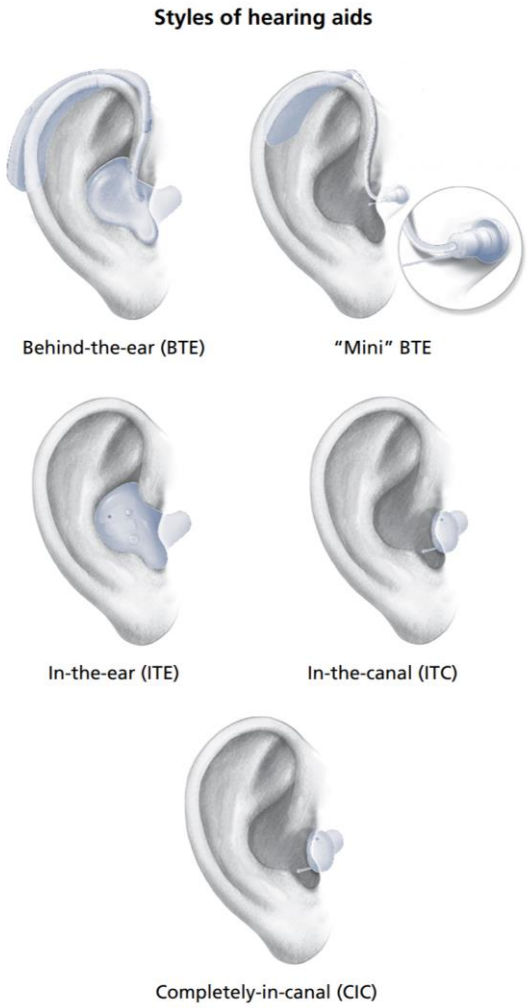


Figure 4. Various hearing aid styles available [25]

For immediate amplification needs, personal sound amplification devices (PSADs) can be used with prices ranging from $25 to over $100 for low-end and between $250 to $350 for higher quality devices. PSADs usually have a body containing an internal amplifier, a microphone, and a battery source that is either replaceable or rechargeable. They are bulky for everyday use and are not tailored to each individual (amplify all frequencies the same amount for any level of sound), but they are still quite useful for enhancing communication in a health care environment or in the home. Though PSADs are commercially available, they are not customized to a patient's hearing loss nor fitted, and are not meant to replace a trip to the audiologist. These devices have not been approved as medical devices by the FDA and are simply meant to serve as a short-term hearing boost for those with mild hearing loss or until a hearing examination can be conducted [27].

2.3 Clinical Problem

With so many patients having undiagnosed hearing loss, the health care industry is subject to billions of dollars in loss each year and the quality of life for millions of people each year is compromised. Though low-cost hearing screeners exist, their ability to quantify the level of hearing loss is questionable due to their lack of environmental sound level detection. In addition, even if a patient is screened and deemed to have hearing loss, many doctor's offices do not have PSADs available so that users can hear clearly during their doctors' visit or hospital stay.

The goal of this project is to develop a low-cost device that can both quickly and accurately screen for hearing loss in a real-world, noisy environment, and convert into a PSAD for the patient, upon failing a hearing screening. By creating an affordable and quick hearing screening method,

the hope is that use of the device would become part of routine health screenings performed by health aids (the aid would record the patients' pulse, temperature, blood pressure, and hearing status). The benefits of such a device are manifold:

1) Reduce burden on the healthcare system: The report by Johns Hopkins attributed hospital readmissions and associated costs to poor communication as a result of the patient having significant hearing loss [12]. Possible outcomes include:
    - Reduced hospitalizations and readmissions
    - Decrease in healthcare related costs for hospitals on patients' readmissions and increased hospital visits correlated to undiagnosed hearing loss
2) Correctly identify patients with disabling hearing loss, by accurately recommending more patients with undiagnosed hearing loss to the audiologist.

3.0 Design Requirements Overview

There are many aspects to consider when developing a device that can screen hearing and provide personal amplification. A low-cost or disposable device for the health care system would be desirable, such that the patient simply keeps the device and can take it home when they are done with care. It should be compact and easily attachable to the patient. Feedback from clinicians and patients revealed that a successful product needs to have an intuitive interface that is easy to understand and use with limited training. Yet it must be able to conduct accurate hearing screenings in a normal clinical setting with background noise by first performing a "Go/No Go" check of the background noise levels to ensure that they are within acceptable limits for screening. In the event that hearing loss is detected, the device should be easily convertible to provide personal amplification, which the patient can control the volume with a potentiometer. Some additional requirements include user access to common, replaceable batteries, and a safe operating voltage. Using replaceable batteries can help to contain system costs. The hearing amplifier (linear audio circuit) and the screener electronics (low-cost digital signal processor) should operate independently in order to save power. An inexpensive yet comfortable headset is needed. Market analysis revealed that low-cost personal amplifiers use over-the-ear (supra-aural) headsets, and old headsets from previously used PSADs can be used. These over-ear headphones have soft, foam ear pads and an adjustable headband. A $5 cost for these headphones in small quantities is reasonable for a prototype and a production assembly considering the bulk cost which would be vastly decreased, even disposable.

Design requirements were then subdivided into three main categories: form factor requirements (mechanical design requirements), electrical requirements, and usability/human factors requirements (tactile functions and interface).

A pre-alpha, low fidelity prototype (Figure 5) named LiDIA (Listening, Identification, and Instant Amplification) was made of foam board and had user controls and working LEDs to simulate device operation by Dr. Catherine Palmer and her team. These were used to conduct informal user feedback studies and demonstrate proof of concept. User validation of the structure and layout of these prototypes guided the mechanical and usability aspects of the design.

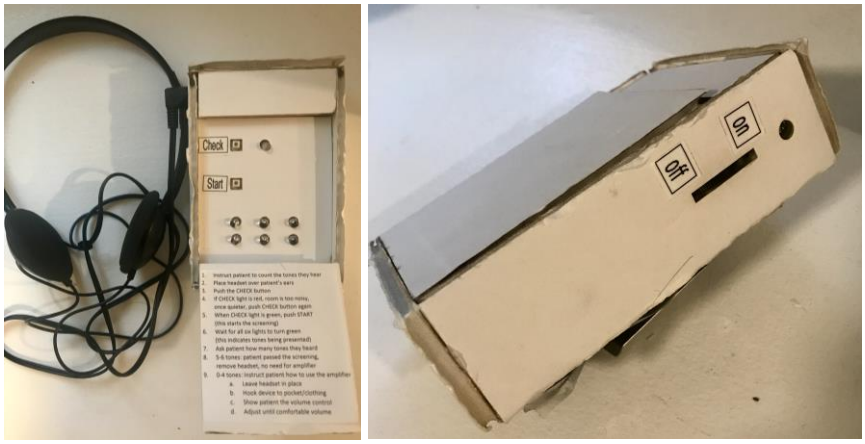


Figure 5. Pre-alpha mechanical prototype

3.1 Test Procedure

Device control can be divided into the two modes of operation, namely Hearing Screening Mode (broken into two sub-modes of Hearing Screening and Background Noise Test) and Amplification Mode. A process flow chart given in Figure 6 graphically depicts the device

operation, where the two main modes of operation are indicated in the dashed boxes. The diagram includes a mixture of human and computer control. The Hearing Screening Mode is performed by a digital signal processor (DSP), requiring that software be developed for those operations. Additional programming is required for timing processes, receiving inputs from momentary switches, and operating the LEDs that indicate device status. The green blocks within the diagram correspond to status indicators enabling the test administrator to easily use the device (through indicator lights and buttons). The blue diamonds indicate decisions that are determined by the operator's response to the question.

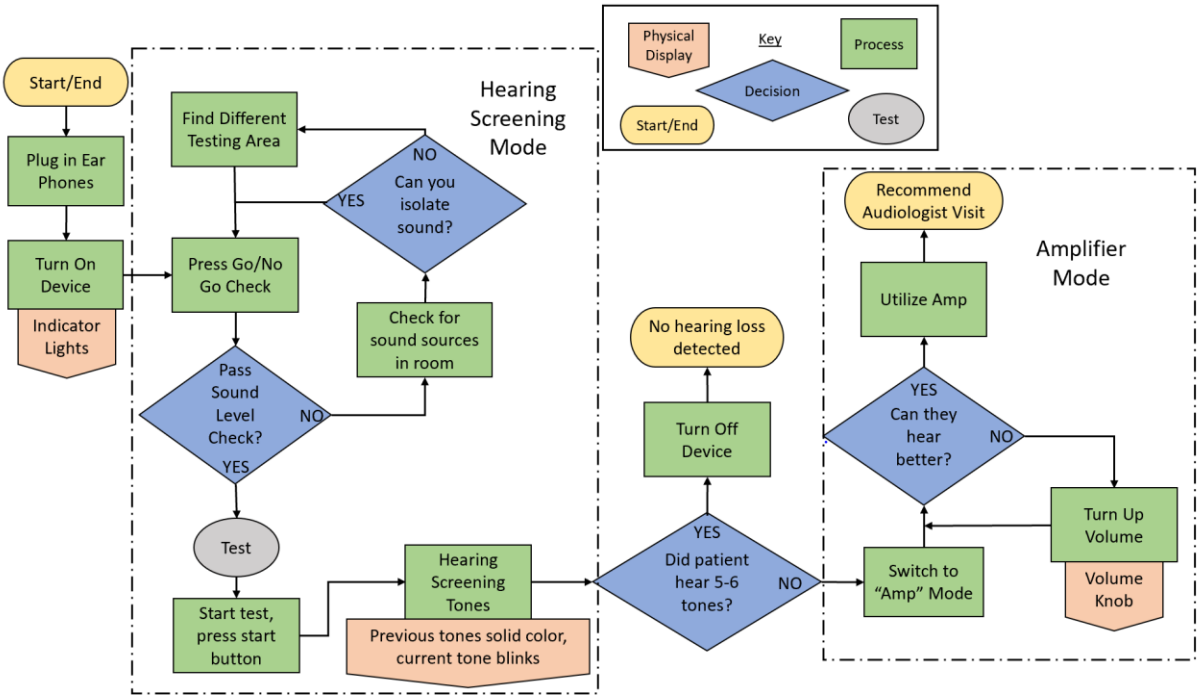


Figure 6. Block Diagram of System Flow Chart

3.1.1 Background Noise Test (Go/No Go Check)

Upon initial use and power-up, the device will enter a waiting mode, until the user presses the button to initiate the Background Noise Test. Indicator lights will inform the user of the system power status and readiness to conduct the background noise check. Signals recorded by an onboard microphone allow the system to compare the measured noise levels within the room to a predefined maximum permissible sound pressure level. If this threshold is exceeded, the device will indicate that the test failed by lighting a red LED (stop) and will prevent the hearing screening from being performed. The ambient noise levels must be low enough to permit a 35 dB_{HL} hearing loss to be detected in the patient at each of the desired frequencies. If the Background Noise Test fails, it may be possible to reduce excessive background noise by eliminating noise sources near the patient or by moving the test to a quieter location. However, if the background noise level is within acceptable limits, the software indicates this result by lighting an LED to inform the user that the hearing screening may proceed.

3.1.2 Hearing Screening

If the system passes the Background Noise Test, the healthcare provider will press a button to commence the Hearing Screening. Otherwise the software will start the hearing screening after a brief wait period, to avoid noise level changes in the room from interfering with the test results. Three sequential tones will be played in each ear of the patient (6 total tones). The tones span across three octaves and are within the primary hearing range (1 kHz, 2 kHz, 4 kHz) where hearing loss is typically prevalent and which are responsible for communication difficulties. Tone

amplitudes are set to correspond to the threshold of disabling hearing loss threshold (previously defined as 35 dB_{HL}). Clinicians will see six indicator LEDs light up in sequence, corresponding to the playback of the six tones. After playback completion, the patient will be instructed to report how many tones were heard during the test. If the user hears fewer than 5 tones, the patient is considered to have a high probability of disabling hearing loss. In this case, the device can be switched to amplifier mode and the patient can be referred to an audiologist for more rigorous hearing testing. If the patient indicates the perception of 5 or 6 tones, the clinician may turn off and remove the device and proceed with the healthcare visit since there is no indication of disabling hearing loss.

3.1.3 Amplification Mode

If the patient reports hearing less than 5 tones, disabling hearing loss will be assumed and the patient will be provided with short-term personal amplification. To do this, the clinician will switch the device to Amplification Mode without removing it from the patient. The device will have a conventional knob (potentiometer) to allow patients to adjust volume to comfort as well as a body clip to allow the patient to use the device hand-free.

3.2 Functional Requirements

The developed device concept is shown in Figure 7. Some of the key features depicted are a volume switch clearly visible to the user, a sliding cover to hide the environmental and screening

mode controls, a power switch to change the device between Hearing Screening Mode and Amplification Mode, a pushbutton for the hearing test initialization, and indicator light displays which indicate the status of device power, the background noise check, and hearing screening tone playback.

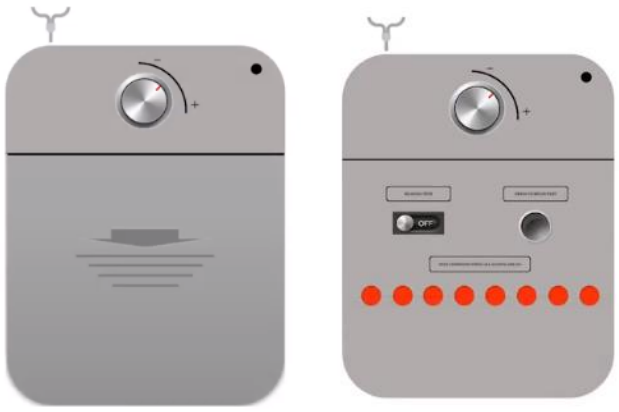


Figure 7. Concept drawing of user interface

Some additional functional elements were incorporated into the final design requirements, including:

- Form Factor
    - Hand held and small enough to be clipped on belt or gown
    - A cover over the test display
    - Working instructions for a clinician to follow during test procedure
    - Easy access to batteries for quick change (battery slot)
- Electrical Requirements
    - Indicator light for Go/No-Go Test and Testing Mode (Minimum of 2 colors)

    - Indicator lights for each frequency played during the hearing screening (Minimum quantity of 6)
    - External on/off light for power
    - Standard battery usage (AA, AAA, etc.)
    - 5V system, cordless
- Tactile Functions
    - Push button or switch utilized for environmental screening test
    - Push button to initialize the hearing screening
    - A rotating knob, that clearly switches the amplification mode on/off and provides volume control, with an audible click or spring function so that user can feel when the modes change

4.0 Detailed Device Design

This section details the evolution of the device design and important fabrication steps. Details of the electrical design and software flow are presented as they pertain to the overall system design. Testing procedures and methods used to verify subsystem functionality are discussed.

4.1 Characterization of Background Noise in Care Facilities

An evaluation was necessary of patients' ability to correctly identify tones with no hearing loss with and without a prescribed level of background noise (average of 35 dB_{HL} as stated in previous sections) in order to correctly determine the tone levels necessary for the hearing screening. Sound recordings were collected in every day geriatric environments to obtain data for typical background noise experienced. A free-field, Larson Davis System 824 Sound Level Meter (SLM) was used to record environmental noise levels, and a secondary microphone was connected to the NI-9234 Data Acquisition (DAQ) unit to collect backup sound data. Seven different environments, such as nursing home cafeterias and ER waiting rooms were evaluated. Each collected data sample was then cut into useable clips with low variability (where sound level is fairly steady, i.e., without doors slamming, human speech, etc.), scaled to be amplified, and looped to form WAV files for playback during screening. Spectrograms were then produced to present the spectral content of each clip before it was looping. The results are unweighted to the perception of human hearing and present low frequencies that are not typically audible however are in the

spectral content, found in Chapter 5. This information will set the stage for future evaluation of the impact of background noise on quality of audiometric prediction.

Microphones used do not have a weighting applied, with a flat response in the frequency bandwidth of interest, all equally weighted. This is unlike the human ear, which has dynamics in the frequency bandwidth of hearing (20Hz-20kHz), described by A-weight filtering, shown by Equation (4-1).

$$H_A(s) = \frac{k_A s^4}{(s+129.4)^2(s+676.7)^2(s+4636)(s+76655)^2} \tag{4-1}$$

Where $k_A = 7.39705 \times 10^9$ is a constant that normalizes the gain to unity at the frequency 1 kHz.

The A-weighted dB scale (dBA) is based on the Fletcher-Munson equal loudness curves for the human ear [33]. An equal-loudness contour is a measure of sound pressure in dB_{SPL} for which a human perceives constant loudness in the frequency spectrum of human hearing range.

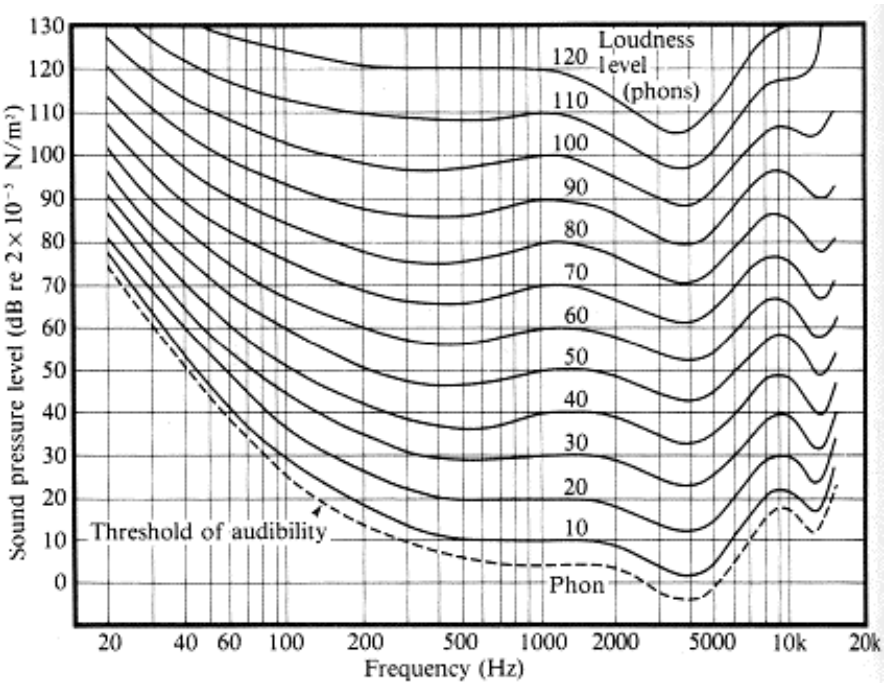


Figure 8. ISO 266 Standard Chart of Fletcher Munson Equal Loudness Curves [25, 31]

If a perfect microphone (flat frequency response) were exposed to broadband white noise, the autospectral density function (ASD, covered later) would theoretically be a flat line across all frequencies. By A-weighting the response, low and high frequencies are attenuated to mirror human perception. At 1kHz, there is absolutely no difference between the microphone and the A-weighted levels, shown circled in Figure 9. At 100 Hz, there is roughly 18 dB of attenuation, circled in Figure 9. Between 3 kHz to 6 kHz, the human ear slightly amplifies the incoming sound, as reflected in the gain above 0 dBA showing in the frequency response. These trends are noted in Figure 9, where the Z-weighting in orange indicates equal power across all frequencies and the A-weighting line in blue, which reflects human hearing.

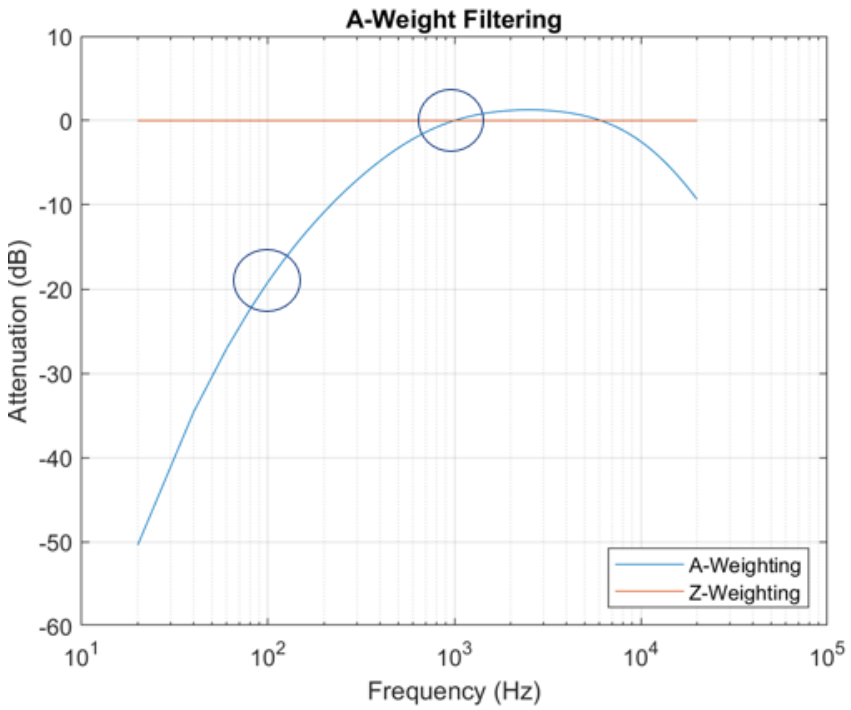


Figure 9. A-weighting and Z-weighting

A discrete version of the A-weighting filter was created using the AudioToolbox™ in MATLAB, specifically using the weightFilter() command. The toolbox uses a bilinear (or "Tustin") transform to discretize filters. Since many DSPs implement filters as biquad sections, the toolbox returned three digital biquad filters that can be placed in series to represent a discrete version of the seventh-order Laplace domain filter given in Equation (4-1). The getFilter() command was used to extract the filter coefficients, which are represented in Equations (4-2)-(4-4) below.

$$\frac{1 + 2z^{-1} + z^{-2}}{1 - 0.288z^{-1} + 0.0207z^{-2}} \tag{4-2}$$

$$\frac{1 + 2z^{-1} + z^{-2}}{1 - 1.9002z^{-1} + 0.9014z^{-2}} \tag{4-3}$$

$$\frac{1 + 2z^{-1} + z^{-2}}{1 - 1.995z^{-1} + 0.995z^{-2}} \tag{4-4}$$

In addition, a single gain of $k = 0.2186$ must be applied to the beginning of the filter chain, with a gain of $k = 1$ in between the other filters. These filters were used to A-weight the Background Noise Test [28].

4.2 Custom Headset Design

Several considerations were made concerning the headset design, including:

1) Experimentally determining whether the low-cost supra-aural headphones provide any insertion loss, which would be advantageous for conducting hearing screenings in a real-world environment
2) Investigation of the feasibility for the MEMS microphones to be integrated into the headset and used for the background noise check, as well as the amplifier mode
3) Performing any required mechanical redesign of the headset in order to integrate a MEMS microphone into the back of the headset cups, while providing isolation from the headset speaker
4) Experimental characterization of the frequency response for the unmodified (stock) headphones and those that have been outfitted with microphones

5) Evaluation of feedback potential by playing white noise into the modified headset speakers and measuring with the added microphones.

Integration of the microphones into the back of the headset would provide some advantages. For example, there would be less concern of the patient occluding the microphones with clothing (such as a sweater). Background noise measurements would be made in the vicinity of the patient's ear(s), giving a true reading of the impact of the background noise. There is a strong potential drawback of placing microphones on the back of the speaker cup: positive feedback could be introduced between the microphone and the earphone in Amplification Mode, as a result of the acoustic delay. If the patient turns the volume above a certain level, coupling between the headphone speaker and microphone could result in an undesirable squeal. If this is found to be a potential issue, the microphone will be placed in a more conventional location on the control box, as is common practice with current PSADs. Aside from the details of the physical integration, characterization is required to assess these issues, including:

1) Actual measurement of insertion loss for the modified headset
2) Measurement of the frequency response functions (FRFs) between the headphone speaker and the adjacent headphone microphone in order to determine stability margins for feedback when using the device in amplifier mode
3) Measurement of FRFs between the speakers and adjacent MEMS microphones for the modified headsets.

4.2.1 Microphone Board and Manufacturing

The microphone utilized for this system was a Knowles SPW2430HR5H-B Top-port SiSonic™, surface-mount, analog, omni-directional MEMS microphone, which measures 3.1×2.5×1 mm (see Figures 10 and 11). The microphone must be surface-mounted to a PCB, which supply power, ideally containing a small power conditioning capacitor and a direct current (DC) blocking capacitor to pass the alternating current (AC) microphone signal between the microphone output and external gain, which would otherwise be biased by the DC supply voltage, V_{DD}. Figure 12 shows a picture and schematic of the microphone and conditioning circuit. During testing, the inputs were AC-coupled to the NI- 9234 Data Acquisition (DAQ) system so that an onboard capacitor was unneeded.

A digital microphone (Knowles SPK0415HM4H-B) was evaluated, since it had the potential to reduce the noise of the system and provide for easier control of the microphone using our built-in software functions. Using the methods described in 4.1.1, a microphone board was constructed and bench-tested using an oscilloscope and a function generator as a clock input. Next, the digital MEMS microphone was connected to digital communication lines of the Audio digital signal processor (DSP) (further described in section 4.3), only to discover that differences in communication precluded using this microphone with the selected DSP. As a result, the design reverted to using the analog microphone, however a digital MEMS microphone could be considered for the commercial design.

The PCB was designed using the KiCad Electronics Design Automation (EDA) Suite, a PCB routing software. The pad dimensions in the schematic (reproduced in Figure 11) were drawn on the PCB, as well as holes around the perimeter where the GROUND, V_{DD} , and the OUTPUT

could be connected. Design files were next exported from KiCad in a standard format (GERBER) and uploaded to an online software to generate G-Code through the online Carbide 3D software, Carbide Copper, used by the Nomad 883 Pro, a table top CNC mill. The circuit board was then cut by importing the Nomad 883 Pro. A functional surface mount technology (SMT) assembly process was developed to mount the microphones to the cut boards by using the solder reflow profiles found within the datasheet as guidance.

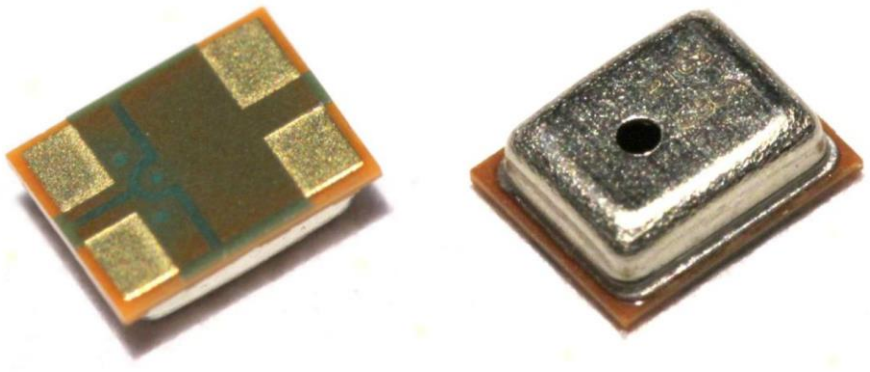


Figure 10. Knowles SPW2430HR5H-B MEMS Microphone [28]

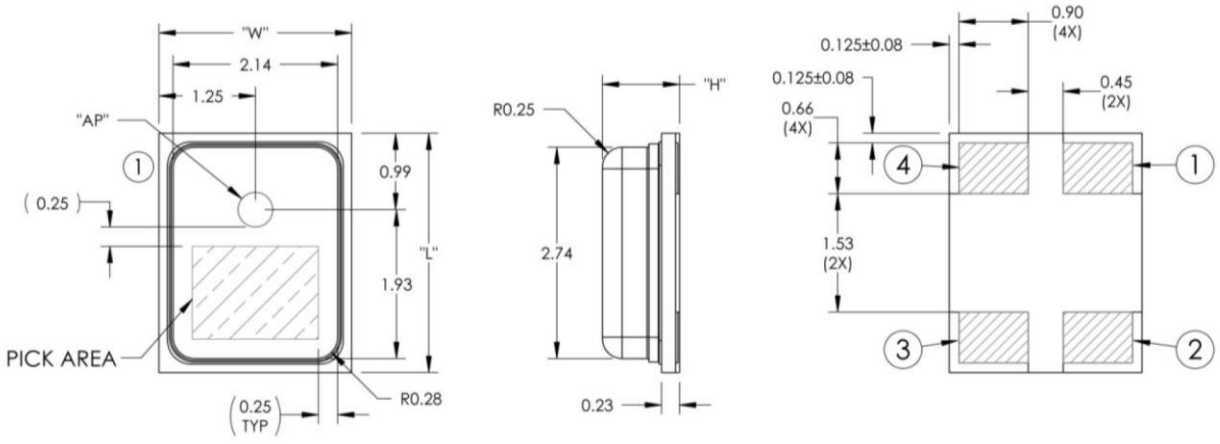


Figure 11. Knowles SPW2430HR5H-B foot print and overall package design [28]

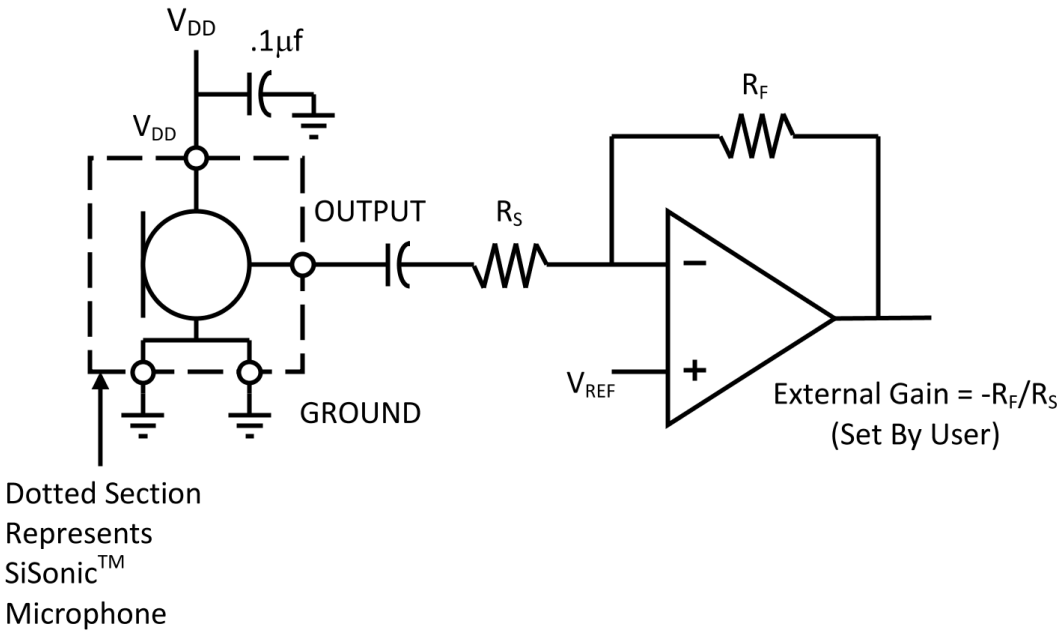


Figure 12. Example microphone wiring diagram [28]

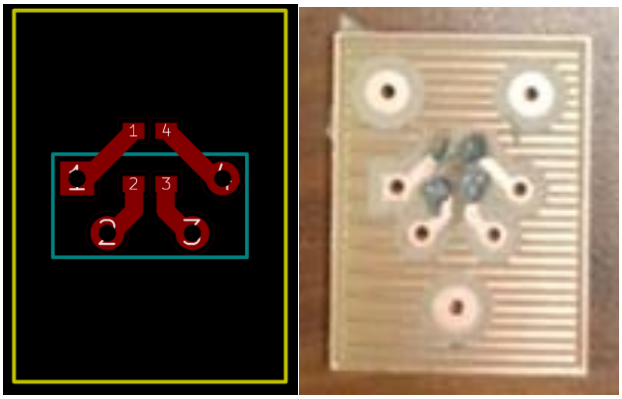


Figure 13. Microphone board in Kicad (Left), Revision 2 board is cut and has solder paste on the board

Once the board was milled, solder paste was added to the microphone installation pads (Figure 13). Next, the microphone was placed on the board and then heated to the appropriate temperatures given the reflow profile found in the Knowles SPW2430HR5H-B documentation. Wires were soldered to the connection points, and the completed board was tested. Connections for power (V_{DD}=3.3V), power GROUND, signal GROUNDs, and signal output were made to their respective instruments. A current-limited, external DC power source was used to supply the 3.3V and power GROUND. The output and signal GROUND pins were connected to an oscilloscope using a BNC connector to compare a single tone signal which was played into the microphone using a full range loudspeaker. The signals played were single-tone sine waves of 1 kHz, 2 kHz, and 4 kHz which are the desired tones used for the actual hearing screening.

The final prototype utilized a ready-made product that is mentioned in Chapter 4.3. In future production, a custom microphone board will be manufactured incorporating circuitry found in Figure 13.

4.2.2 Microphone Housing

Low cost headphones were selected from PSADs that are distributed by the UPMC Audiology Department (SuperEar SE-HP by SonicTechnologies). The outer speaker caps of the headset were deemed to be the most suitable location for integrated microphone placement. It was found that the small, snap-fit, injected molded piece was used to enclose a small chamber placed behind the speaker. Keeping this chamber intact was imperative for proper speaker operation (e.g. for baffling the source), however, there was not enough room to fit the microphone PCB. This part was then reverse-engineered, modified to provide a flat outer surface where the mic will be

installed, plus enough room to integrate the PCB, and then additively manufactured. This process is depicted in Figure 14, showing the original, deconstructed speaker, the 3D CAD depiction of the design, and the unmodified cap compared to the new assembly.

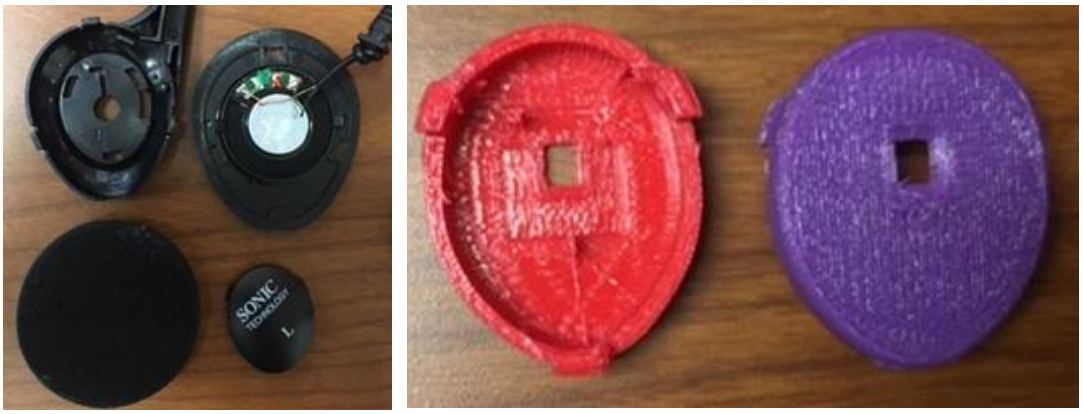


Figure 14. Design of New Caps for SE-HP Head Set

4.2.3 Assembly

The project used a total of three (3) headsets, that come with the common SonicTechnology SuperEar® PSADs. Four (4) headsets were provided for use and calibrated by Dr. Catherine Palmer using a flat, custom coupler and the averages are given in Table 1 and Table 2 for each of the key frequencies that are representative of the population in the left and right speakers. Remarkably, despite the low cost, the headphone speakers (left and right) were found to agree within 0.7 dB, as shown in Table 3. Two (2) of the headsets were modified, with the third being left as a control. Using the processes described in section 4.1.1, 6 microphone board assemblies were manufactured and tested for signal output to ensure that there was no defect in the circuitry, there was no interference from the microphone housing, and connection was maintained through

the manufacturing process and assembly. The microphone board was then connected respectively to 4-conductor, 28AWG braided cabling so that the signal output could be routed to where the speaker input cable was connected. The microphone circuit board was then fastened and secured to the modified caps using RTV, a black, synthetic rubber compound that acts as both an adhesive and damping material (see Figure 15). This layer served as an acoustic and vibration isolator between the speaker housing and the microphone to help reduce coupling between them.

Figure 15. Caps assembled with Microphones isolated and intact

Table 1. Average SPL measurement during coupler plate testing of Right Speaker

Frequency (Hz)	Headset C (dBA)	Headset D (dBA)	Headset E (dBA)	Headset F (dBA)	Average (dBA)
500	90	89.7	90.1	89.6	89.9
1000	80.1	82	81.7	81.3	81.3
2000	79.8	79.8	79.5	79.8	79.7
3000	83.4	83.4	83	83.6	83.4
4000	77.7	77.5	77.4	78	77.7

Table 2. Average SPL measurement during coupler plate testing of Left Speaker

Frequency (Hz)	Headset C (dBA)	Headset D (dBA)	Headset E (dBA)	Headset F (dBA)	Average (dBA)
500	89.4	89.5	89.7	90.3	89.7
1000	80	81.5	80.8	81.8	81.0
2000	80.7	80.6	79.7	80.5	80.4
3000	83.9	84.2	82.2	84.4	83.7
4000	77.5	78.4	78.6	78.1	78.2

Table 3. Average difference between speakers on headset sample

Frequency (Hz)	Left (dBA)	Right (dBA)	Average (dBA)
500	89.7	89.9	0.2
1000	81.0	81.3	0.3
2000	80.4	79.7	0.7
3000	83.7	83.4	0.3
4000	78.2	77.7	0.5

The microphone assembly was then routed along with the speaker power cables by feeding the cable through a preexisting hole in the assembly to the speaker. A microphone board was installed to both sides of the headset so that directionality could be tested. The ends of the cables were connected to 2 BNC connectors (one for power (V_{DD}) and power GROUND, another for signal output and signal GROUND) so that the device could have a quick connect during test install.

As will be discussed in Section 4.2.6, the customized headsets with integrated MEMS microphones were found not to be suitable for this application.

4.2.4 KEMAR Testing

To characterize the insertion loss of the supra-aural headphones, a Knowles Electronic Manikin for Acoustic Research (KEMAR) was used (see Figure 16). The KEMAR is the industry standard method for approximating an average human's perception. The KEMAR uses anatomically correct average human torso (bust, skull, pinnae, and aural canals) for simulating the sound level at the ear drums by reproducing the refractive and resonant effects of the head and outer ear. B&K model 4166 Type 1 condenser microphones are embedded inside the skull of the manikin, with the microphone faces placed at the location where the tympanic membrane would be. The microphone signals were conditioned with B&K model 2807 preamplifier/power supply with no gain. The calibration factors were recorded so that the voltage signals could later be converted to sound pressure in Pascals.

Figure 16. KEMAR Set up in anechoic sound booth with speakers at locations about manikan

Experiments were conducted to address items 1, 4, and 5 listed at the beginning of Section 4.2. Namely, determining if the modified and unmodified headsets provide any insertion loss in the bands of interest, determining if the modified headset has a different frequency response between the headset output and the KEMAR Microphones (eardrums) as a result of the modifications, and determining the extent that feedback may be introduced by the headset mounted microphones. The KEMAR manikin was installed in the anechoic chamber in the Department of Communication Science & Disorders in the School of Rehabilitation Sciences. The chamber has an approximate volume of 1408 ft^3 (39.9 m^3) and a lower, anechoic cutoff frequency of about 220 Hz. Full-range loudspeakers mounted every 15º on a circular arc from −105 º to +105 º in azimuth, some of which can be seen in Figure 16. Pass-through cables enabled direct drive of each loudspeaker, as well as measurements from the KEMAR microphones and headset microphones from their respective signal conditioning. With a KEMAR located in the center of the speaker arc and facing 0º, all of the cables were connected to labeled pass-through jacks inside the chamber and then connected to a NI-9234 DAQ on the outside. The DAQ recorded these signals, as well as the input signal to the power amplifier, whether white noise or swept sine.

Each of the headsets were placed upon the head of the KEMAR and tested individually. A Larson Davis System 824 Sound Level Meter was placed near to the headset microphones. The custom developed control software for the anechoic chamber was used to record pre- and post-calibrations, by recording a swept sine input signal over the range of 20 Hz-20 kHz and with an amplitude of $0.1V_{pp}$. Once the pre-calibrations were completed, white noise was used for the performance tests, connected to a power amplifier and then to the desired loudspeaker inside the chamber. The loud speakers are connected through a pass-through panel with connectors corresponding to the speakers. Five azimuthal directions were tested: $\{-90°, -45°, 0°, 45°, 90°\}$,

which will be referred to as speaker numbers S1, S2, S3, S4 and S5, respectively, as shown in Figure 17. Sound levels were first measured inside the KEMAR at both ears and by a free-field microphone near the KEMAR head, which serves as a reference sound level at the KEMAR head. Next, the stock headphones were installed on the KEMAR and the process repeated. Finally, the modified headsets were installed on the KEMAR, except this time the measurements included the signals from the MEMS microphones. Two sets of each type of headset were tested to account for variability in the manufacturing process. One of these microphones was damaged during testing and given time constraints with the facility, it was not feasible to fix in the moment, so tests were recorded for three (3) of the headset microphones. BNC cables were fed through from the control room amplifier to a speaker panel associated with the 5 speakers used (S1 – S5) and the two headset speakers under test. BNC cables were connected to the DAQ and passed through the chamber wall and connected to the KEMAR (M1 and M2), SLM (M3), condenser (M4), and headset (M5 and M6) microphone signals M1-M6 (See Figure 17) were sent to the DAQ.

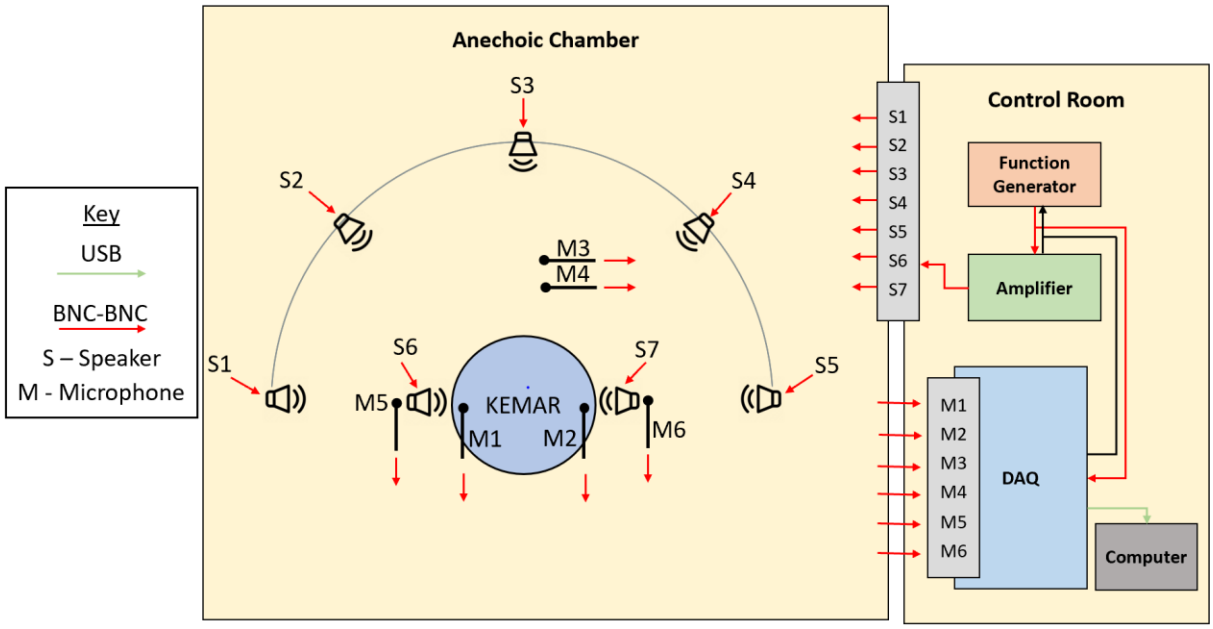


Figure 17. Anechoic chamber test connections for microphones

4.2.5 Signal processing

The recorded microphone voltage signals (up to five) were converted to acoustic pressures by accounting for the system gains and calibration constants. These in turn were used to compute the insertion loss and the FRFs between a number of signals. Insertion loss, IL, is defined as the difference in sound pressure levels between when a sound restricting object (e.g. barrier, muffler, enclosure, or headset in this case) is placed between and acoustic source and a receiver as:

$$IL = L_{p2} - L'_{p2} = 20\log_{10}\left(\frac{p_{rms,withheadset}}{p_{rms,noheadset}}\right) \tag{4-5}$$

For this example, $p_{rms,no\ headset}$ (with sound level L'_{p2}) and $p_{rms,with\ headset}$ (with sound level L_{p2}) are the root mean square (RMS) acoustic pressures that the KEMAR (subject) experiences at the ear, without and with, respectively, the headset placed over the patient's ears. Letting the autospectral density functions be defined by: $G_{xx} = E[(P(\omega)_{withheadset})^2]$ and $G_{yy} = E[(P(\omega)_{noheadset})^2]$, where E, is the expectation operator and $P(\omega)$ is the Fourier transform $p(t)$, representing raw pressure signals corresponding to the respective RMS pressures in Equation (5-1). $IL(\omega)$ can also be defined in the frequency domain (the insertion loss at each frequency bin) as:

$$IL_{xy}(\omega) = 10\log_{10}\left(\frac{G_{yy}(\omega)}{G_{xx}(\omega)}\right) \tag{4-6}$$

where G_{xx} the ASD with the headset and G_{yy} is the ASD of the pressure signal measured by the KEMAR without the headset.

ASD functions are notoriously noisy, even with lots of averages. As such, a method of computing IL was devised that uses the H_1 and H_2 FRF estimates. These were computed using ASDs and cross spectral density functions (CSDs) between channels that were computed using Welch's method (pwelch() in MATLAB for autocorrelation and cpsd() for input-output cross correlation), using 2^{14} overlapped samples, 2^{15} windows, 2^{15} number of discrete Fourier transform points:

$$\widehat{H}_1 = \frac{G_{xy}}{Gxx}, \tag{4-7}$$

$$\widehat{H}_2 = \frac{G_{yy}}{Gyx}, \tag{4-8}$$

Where G_{xy} is the cross-spectral density between the signal, x, and signal, y, and G_{xx} and G_{yy} are the ASDs for signals x and y, respectively. In this case, signal x can be one of the headset speakers or the SLM measurement. In addition, the ordinary coherence function was computed using:

$$\gamma_{xy}^2(\omega) = \frac{\left|G_{xy}\right|^2}{G_{xx}G_{yy}} = \frac{H_{1,xy}}{H_{2,xy}} \tag{4-9}$$

which can be thought of the frequency domain representation of the correlation coefficient between the two channels at each frequency, with $\gamma_{xy}^2(\omega) \in [0,1]$. When computing the IL from FRFs, an additional function Γ, is defined as:

$$\Gamma_{xy}(\omega) = |H_1 \cdot H_2| = \left|\frac{G_{xy}}{G_{xx}} \cdot \frac{G_{yy}}{G_{yx}}\right| = \frac{G_{yy}}{G_{xx}} \cdot \left|\frac{G_{xy}}{G_{yx}}\right| = \frac{G_{yy}}{G_{xx}} \tag{4-10}$$

since G_{xx} and G_{yy} are real-valued, and $\left|\frac{G_{xy}}{G_{yx}}\right| = 1$, since G_{xy} and G_{yx} are complex conjugates of one another. If signals x and y, were defined as in Equation (6-1), then the IL can be found from:

$$\Gamma_{xy}(\omega) = 10\log_{10}\left(\Gamma_{xy}(\omega)\right) \tag{4-11}$$

However, this would require simultaneous sampling of x and y, something this is not really compatible with the definition of IL. A common, reference signal z, can be introduced to

circumvent the issue. Defining three signals, $x, y,$ and z as: x is the in-ear pressure measured by the KEMAR microphone with a headphone installed, y is the in-ear pressure measured by the KEMAR with no headphones, and z is the pressure measured by a free field microphone outside and near to the headset, $IL_{xy}(\omega)$ can be computed using Equations (4-6), (4-10), and (4-11):

$$IL_{xy}(\omega) = 10\log_{10}\left(\frac{\Gamma_{zy}}{\Gamma_{zx}}\right) = 10\log_{10}\left(\frac{G_{yy}}{G_{zz}}\cdot\frac{G_{zz}}{G_{xx}}\right) = 10\log_{10}\left(\frac{G_{yy}}{G_{zz}}\right) \quad (4\text{-}12)$$

The signal y can be the KEMAR microphones (left or right) or the modified headset microphones (left or right). Three groups of FRFs that were computed and included in this thesis are listed in Table 4 below (Please refer to the schematic in Figure 17 above). G_{zx} and G_{zy} were used to compute IL given by Equation (4-12).

Table 4. Transfer function inputs and outputs for FRFs

Name $H_{1,2}$	Input	Output
H_{xz}	(*z*) White noise, As Measured by SLM (From Various Speaker Positions)	(*x*) KEMAR Microphone, No Headset (Left)
H_{yz}	(*z*) White noise, As Measured by SLM (From Various Speaker Positions)	(*y*) KEMAR Microphone, With Headset (Left)
H_{12}	(*1*) KEMAR Microphone (White Noise in Headset Speaker, Function Generator)	(*2*) MEMS Microphone (Headset, Left)

When examining the potential for feedback between the headset speaker and the microphone on the exterior of the headset, stability criteria must be analyzed. One way of determining stability is through the gain margin (GM) and phase margin (PM). The gain margin is defined as the difference in gain between unity (0 dB) and the FRF magnitude where the system FRF phase crosses -180 degrees, meaning that if the system gain is less than 0 dB at a phase of $-180°$, then the GM is positive (dB), and the system is stable. The phase margin is the difference between the phase of the system FRF and $-180°$ where the system FRF magnitude crosses 0 dB. If the phase at a magnitude of 0 dB is greater than $-180°$, then the PM is positive and the system is stable. If the gain is always below 0 dB, the phase margin is infinite and the system is unconditionally stable.

4.2.6 Evaluation of Suitability of Headset Mounted Microphones

During the manufacturing process, uniformity was difficult to achieve between modified headset assemblies. It was difficult to determine whether or not the microphone board was in contact with the cap or if it was vibrationally isolated from the speaker system. When the microphone's frequency response function between a headset speaker and adjacent MEMS microphone was plotted, the phase margin was deemed to be negative, indicating stability issues (feedback). These issues complicate collocating the microphones with the headset speakers.

In summary, based on the unfavorable results found in Section 5.1 from the development and characterization of headset-integrated microphones, the prototype will have a single analog MEMS microphone that is mounted to the front face of the base of the housing to reduce the risk of feedback from the headset speaker to the microphone. A single microphone (mono signal) is

adequate for speech communication and precludes having to clip the box to the patient in one particular orientation to provide proper stereo signals. Otherwise, incorrect spatial information could be received. Placing the microphone near the top of the box should provide good pickup of voice signals in the patients' surrounding, thus improving communication between the healthcare professional and patient.

4.3 Device Design

The following contributions were made to the functional prototype design:

1) Designed and built the electrical system and mechanical housing
2) Developed software algorithms using SigmaStudio® and the Arduino IDE to facilitate operational modes of: Background Noise Test/Hearing Screening and Amplification Mode, as well as for controlling light indicators that provide information to the user.
3) Devised a method to calibrate hearing screening tones in accordance with WHO and ISO (International Standards Organization) standards for hearing loss by applying appropriate output gains for each tone [24, 30].
4) Developed a test plan for both system validation and operating instructions.

4.3.1 Mechanical Design

The mechanical housing design was determined by the requirements in Chapter 2, but ultimately the final prototype envelope was limited by the space requirements of the electronics,

shown in Figure 18. After engaging in an iterative design process with clinicians, a box volume of $1.5 \times 5 \times 3$ inches was selected for its ability to fit the board stack into the device, while minimizing size to the extent possible. Although larger than the device size goals for a commercial product, the form will still fit into an adult hand comfortably, leaving the caregiver's other hand free to conduct the test. SolidWorks 2015 was used to design all of the mechanical parts, which were then 3D printed in polylactide (PLA) on a 5^{th}-generation MakerBot Replicator. The mechanical design includes two critical functional elements which will be described in further detail: the housing and the battery and housing covers.

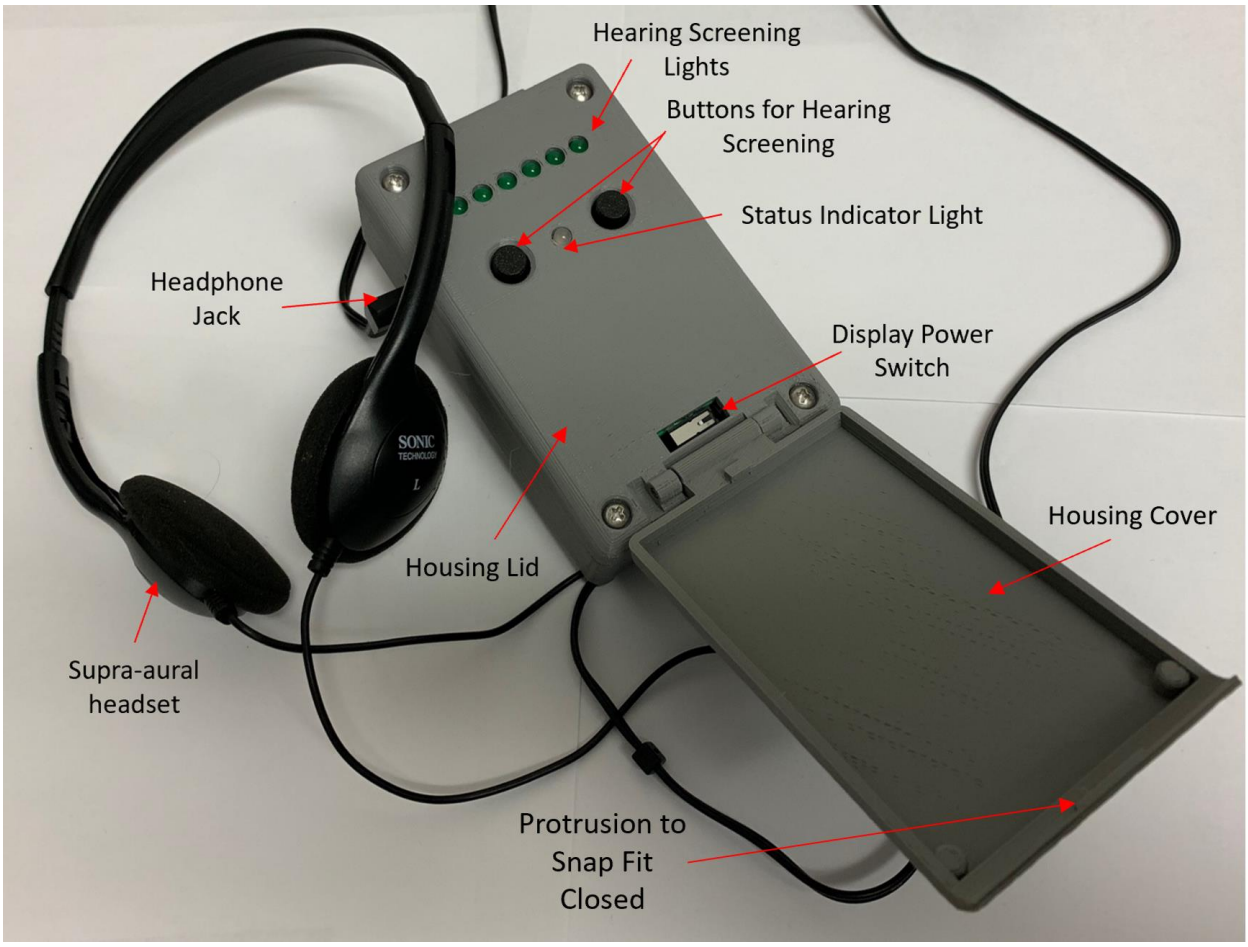


Figure 18. Fully assembled prototype.

4.3.1.1 Base and Lid of Housing

The design is compatible with large-scale injection molding fabrication techniques, incorporating draft angles, rounded edges and walls of proper thickness. The body consists of two parts: a lid and box, which can be modified independently (or together) to scale as the design changes. Mounting holes, cutouts, and standoffs for the various boards were included in the box design. The design was iterated to optimize the volume of the box to properly contain and secure the various boards in the design.

Panel holes are present on both sides of the box for the power switch, volume knob, indicator light, battery pack access, microphone, and the audio connector for speaker output (see Figures 18 and 19). These were added so that all of the electronics could be contained inside the box. On the lid, the hole pattern matches the layout of the LEDs and buttons on the User Interface Board. A large tolerance in the clearance fit for the holes was necessary so that the push buttons could freely move in their holes and the LEDs could slide through.

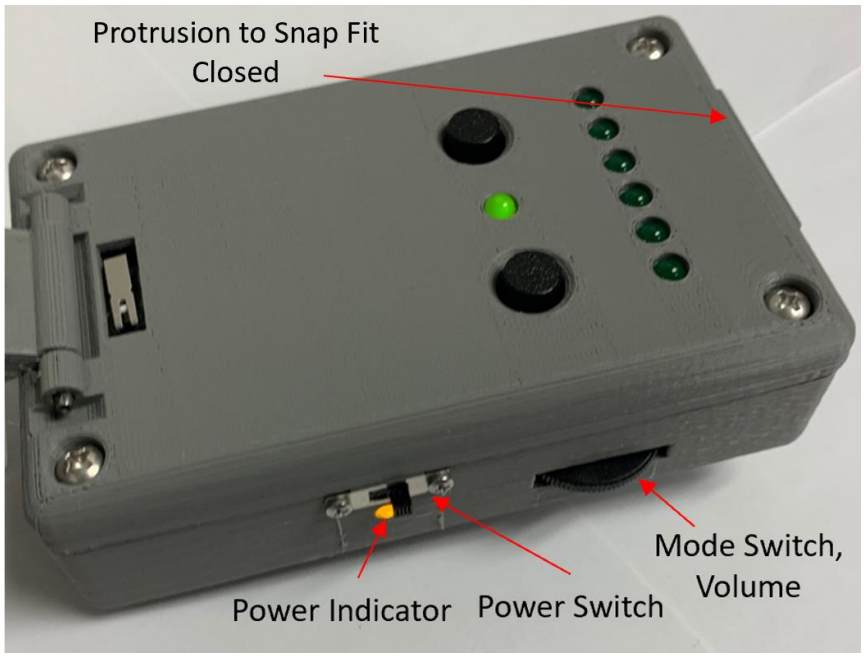


Figure 19. Device cutouts for indicator lights, switches, and fastening

4.3.1.2 Covers

Based on the design specifications, two different covers were designed for the box shown in Figures 18 and 20. The "Battery Cover" covers the battery compartment (for the replaceable battery power source – see Figure 20). The cover slides into place along a track that was designed into the housing until two teeth are adjacent to the inner face of the box and then is secured with two screws. The "Box Cover" sits on the top of the device to hide the interface from view when in Amplification Mode (bottom right of Figure 18, shown in the open position or hearing screening position). A hinge was designed into the bottom face of the cover using a spring pin with sufficient tolerance to permit the cover to swing freely. Towards the top of the box lid, there is a thin protrusion (see Figure 19) that serves as the latch between the free end of the box cover and box lid. When the user wishes to go from the hearing test to Amplification Mode or shut off the device, the user can simply swing the cover flush with the top of the lid and snap it closed. An additional

protrusion (see Figure 18) can be noted towards the top of the cover so that the user can easily unlatch the snap fit. The cover contains instructions on the inner face for conducting the Background Noise Test, Hearing Screening, and reset operations.

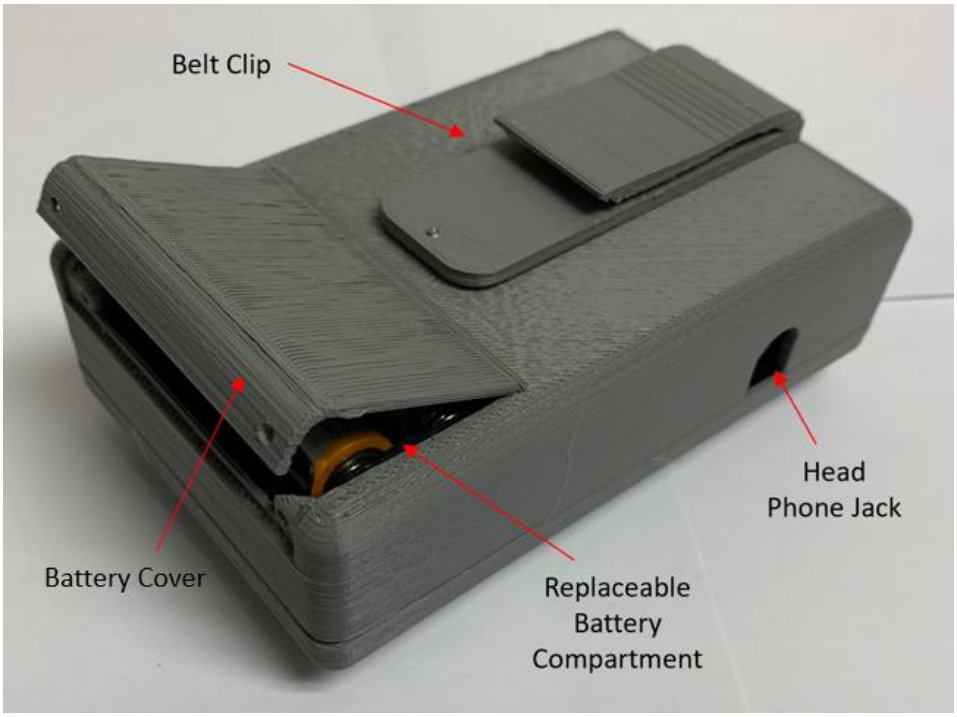


Figure 20. **Back face of device**

4.3.2 Electrical Design

The reader is referred back to Chapter 3.1 and Figure 6, which describe the operation of the device. There are two primary modes of operation, performing 3 tasks: Background Noise Test, Hearing Screening, and Amplification Mode. The electronics provide for process control, which includes a user interface (e.g. sending/receiving signals to/from lights, buttons, volume control, and switches). An important part of the user interface (UI) is mode switching and preventing accidental misuse, such that minimal training is required to use the device. Additional

considerations were required for meeting the unique power requirements for the different components and internal connectivity in order to use commercially available components for the prototype.

A commercial design would of course have an application specific PCB (or chip) that performs all of these functions. However, the prototype development was greatly accelerated by using evaluation kits with the required specific functions that are commercially available. The functionality is the same, however more room is required to house the different boards in the box. In total, the overall system included 6 boards:

1. ADAU1701 Evaluation Board (audio digital signal processor (DSP))
2. Custom User Interface (UI) Board
3. Microphone and Circuitry Board
4. Microphone Pre-Amplifier Board
5. Pro Trinket Arduino-based microcontroller, and a
6. Voltage Boost Converter Board.

These six boards, and how they interrelate, can be seen in the overall electronic system schematic of Figure 21. The rest of Section 4.3.2 describes the major functions and high level electronic design.

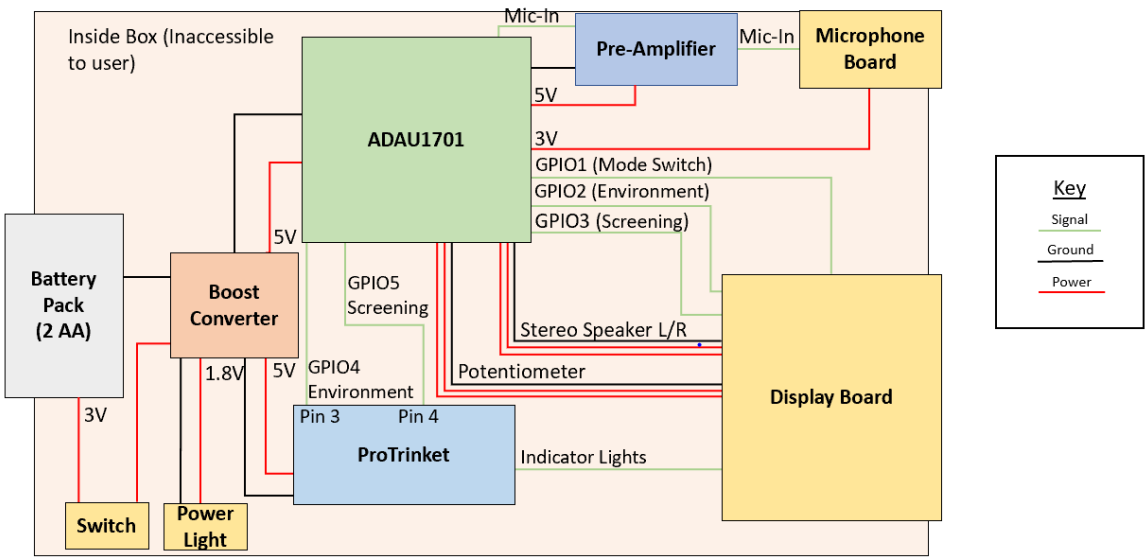


Figure 21. Overall System Diagram

4.3.2.1 Power Distribution

Three (3) different voltages were needed to power the various electronics: 1.8 volts (V) for the indicator lights, 3.3V for the microphone board, and 5V for the ADAU1701, Pro Trinket, and the pre-amplifier. In order to balance size and power, the device is powered using two AA batteries in series, resulting in an available voltage of 3V. A boost converter was required to increase the voltage from 3V to 5V. Voltage was lowered for the LEDs by using a resistor in series. Since these are low-power devices, the power loss is relatively insignificant. The Adafruit PowerBoost 500 Basic was selected for its small size and supporting documentation. A switch was placed in between the 3V battery pack and the boost converter, as shown in Figure 22, to prevent the boost converter from being in continuous operation (when the device is not being used) and draining the battery. The 3V power was then routed from the switch to the boost converter and grounded. From the boost converter, a line was connected from the 5V output to both the audio DSP evaluation

board and the microcontroller. The DSP and microcontroller supplied by two separate power pins. The indicator light for the power switch was connected in parallel with a preexisting, onboard, power indicator LED on the boost converter board in order to obtain a 1.8V signal for the device power light.

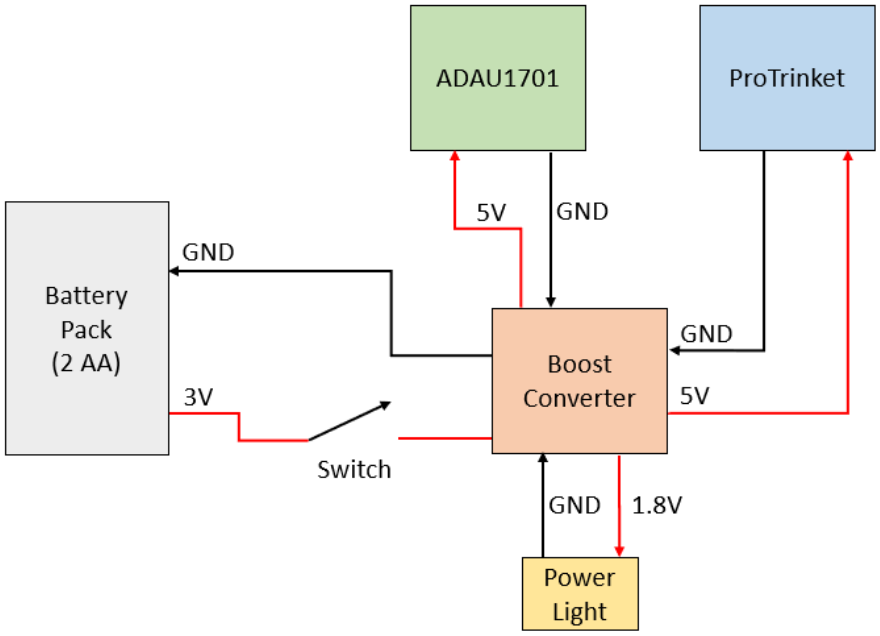


Figure 22. Power System Schematic

The integration of six boards and three operating modes required considerable attention to the power supply design to ensure that the appropriate parts are powered (or unpowered) for any given mode of operation. Another concern was preventing the amplifier mode from being enabled at high volume levels. To protect the user from this happening, an integrated power switch/volume knob was used to switch on the amplifier mode.

The desired power sequence for the prototype was intended to be:

- The volume potentiometer on the box or volume serve as the power on switch. This switch has tactile feedback with an obvious on and off position.
- When the cover is swung open, it would disable Amplification Mode and enter Hearing Screening Mode. The power to the DSP and microcontroller be turned on.

While it was possible to switch modes using the cover switch, it was not possible to switch on power to the UI Board. This limitation can be addressed for the commercial design. In the end, the power sequence for the prototype was adapted to the following:

- Turn on the device using the sliding switch on the side. A light would indicate to the user that the power is on.
- Power will now be going to the audio DSP only. If the user wishes, to switch to Amplification Mode, they can turn the volume knob/switch.
- If the user opens the cover, the cover switch will turn on the light display and initiate ready mode in the software. However, if the user tries to press the buttons, they will not be able to run the test if still in Amplification Mode.
- Once the user turns Amplification Mode off, the middle indicator light will flash red to indicate a mode change.
- When the device is ready for testing the middle indicator light will turn solid green (go) and the user can now run the Hearing Screening Mode.

4.3.2.2 Microcontroller and Audio DSP

The Analog Device's ADAU1701 (audio DSP) was selected for its affordability and size. To aid development, an ADAU1701 Evaluation Board was purchased. Initially, the Evaluation

Board was going to be used to carry out the Background Noise Test, Hearing Screening, and display lights to the user. When examining the user documentation provided for the ADAU1701 Evaluation Board, it became apparent that no break out pins existed to connect to the general-purpose input and output (GPIO) buses of the ADAU1701. However, access was gained to five GPIO busses: two (2) of these GPIO buses are connected to indicator lights on the board the DSP. To utilize the signals sent to these lights, leads were attached to the current limiting resistor right before the LEDs to access the digital signal pins from the ADAU1701, which could in turn be utilized to initialize the modes of operation. The DSP board contained three (3) pushbuttons that are attached to GPIO pins. These were removed and connected to the switches on the UI Board discussed in Section 4.3.2.3. The analog audio inputs shown to the left in Figure 23 were connected to the microphone preamplifier described in Section 4.3.2.4. The analog audio outputs shown to the right in Figure 23 were connected to the audio jack on the UI Board.

In order to drive the eight (8) LEDs on the UI Board, the ADAU1701 was digitally interfaced with the Adafruit® Pro Trinket (a 16MHz, 5V microcontroller), which is shown in Figure 24. The Pro Trinket was chosen for its compact size, simplicity, and ample GPIO pins (enough to drive all of the LEDs and communicate with the ADAU1701). Since there are eight (8) LEDs for the developed device, eight (8) of the GPIO pins on the Pro Trinket were connected to the LEDs on the UI Board using a breakout cable. The two leads that were connected to the indicator lights onboard the DSP (GPIO3 and GPIO4) were connected to the microcontroller (pins 3 and 4) used as flag pins, shown in Figure 21. The DSP polls the status of the GPIO pins associated with the push buttons to indicate what mode the system should be in and then relays this status to the microcontroller so that they can perform associated light displays. Pins 12 and 13 of the

microcontroller (Figure 24) were used to control the middle status indicator bipolar LED of the UI Board Pins 5-11 were utilized for the remaining indicator lights.

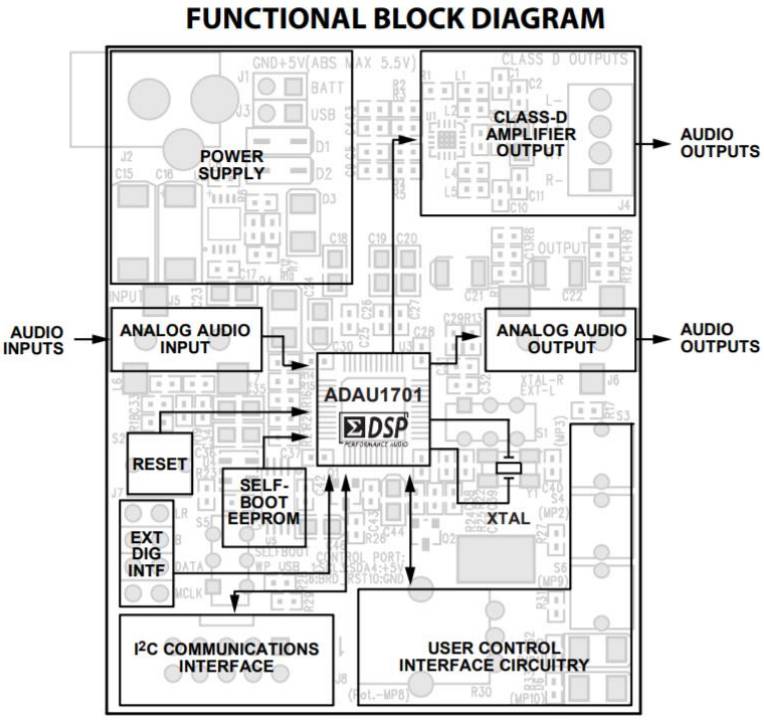


Figure 23. Audio DSP, ADAU1701 Evaluation Board, user interface including user controllable circuitry [34]

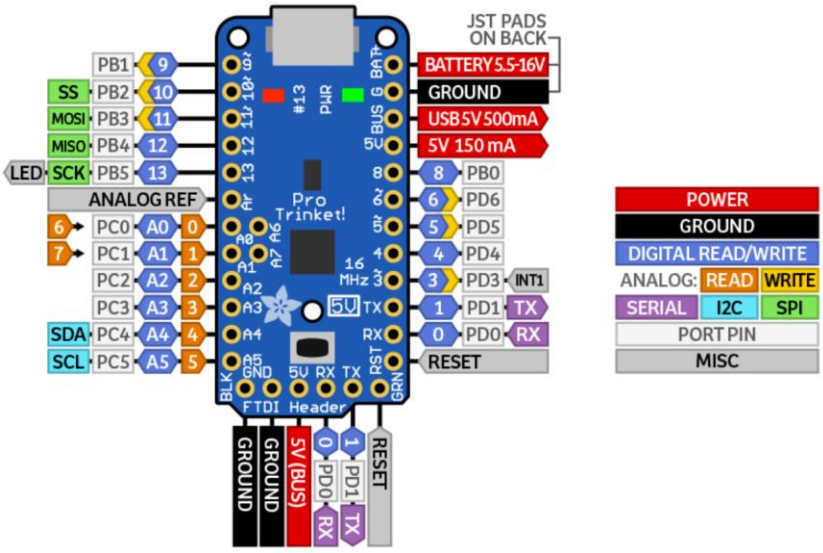


Figure 24. Pro Trinket microcontroller used for controlling light display with respective outputs [35]

After removing the three (3) user input buttons from the DSP, a breakout cable was attached to the vias, electrical through holes that are plated for internal connections between layers that were opened from removing the input buttons. This cable is then connected to the UI Board where the Amplification Mode, Background Noise Test, and Hearing Screening buttons are located.

A volume input (potentiometer) is found on the ADAU1701 DSP Evaluation Board, however the potentiometer was too large to fit within the envelope of the system. Board level modifications were again necessary to incorporate the rotary potentiometer for the volume knob. A breakout cable was soldered onto the clipped leads and the other ends were appropriately attached to the variable resistor on the UI Board. A passthrough cable was placed in between speaker jack on the DSP Evaluation Board and the speaker jack that is on the UI Board.

4.3.2.3 User Interface (UI) Board

In order to realize the desired user interface, a custom 2-layer PCB was designed and fabricated. This board contained the status LEDs, two momentary switches, the headphone jack, and the volume control knob/switch. To create the board, similar steps were used as mentioned in section 4.2.1 for the routing and CNC fabrication of the board. During the PCB design in KiCad, the geometry of the component placement was carefully chosen to match the layout of the mechanical assembly (the holes and slots in the enclosure). Various hole sizes were required for different components and the layer feature within KiCad was used to draw a two-layer board. The final circuit layout can be seen in Figure 23, which was realized using G-Code produced by the online Carbide 3D ® software. The G-Code was manually modified to add the provision of tooling changes for various hole sizes.

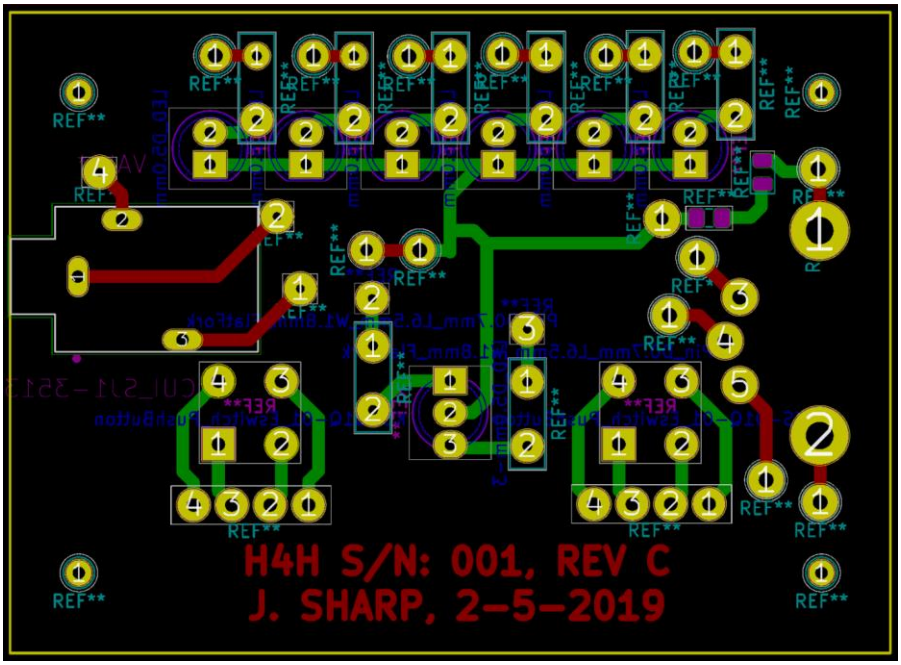


Figure 25. Wiring Schematic of UI Board (Red is Front Side and Green is Back Side)

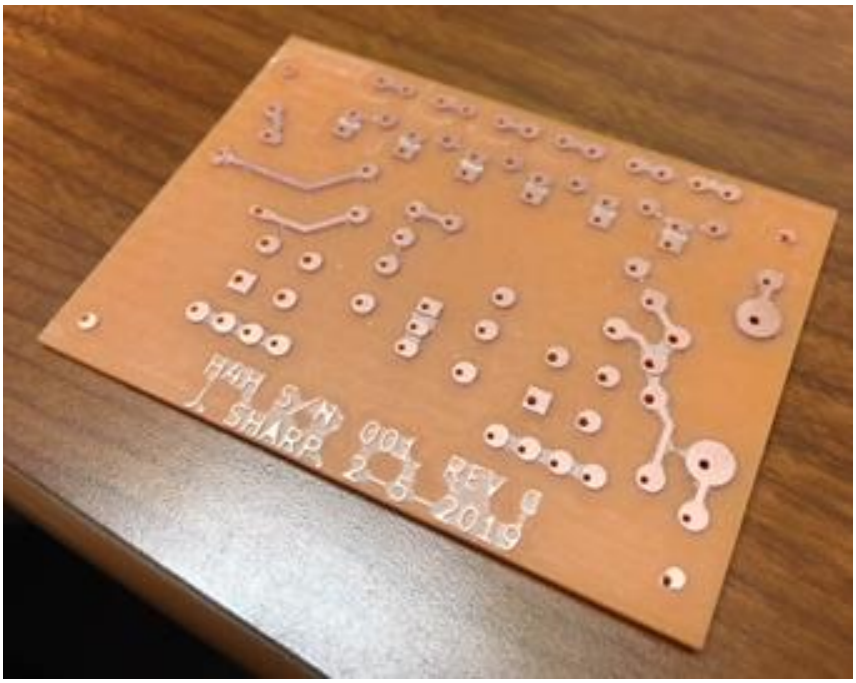


Figure 26. Front Side of Unpopulated Circuit Board

The raw circuit board was milled, rubbed out on both sides to remove excess copper, drilled for through holes, and then cut to size. The front side of the cut circuit board is shown in Figure 26. The board was populated with 6 green LEDs, and one bipolar LED (red/green). The 6 green LEDs blink in sequence to indicate the status of the hearing screening, as described in Section 3.1.2. The bipolar LED will blink at different rates and with each of the respective colors based on the stage of the Background Noise Test, Hearing Screening, and ready state, as described in Section 3.1. Each input required a resistor of value 2 kOhm to limit current to the LED. All of the LEDs were tied to a common ground line. Figure 25 shows the populated circuit board.

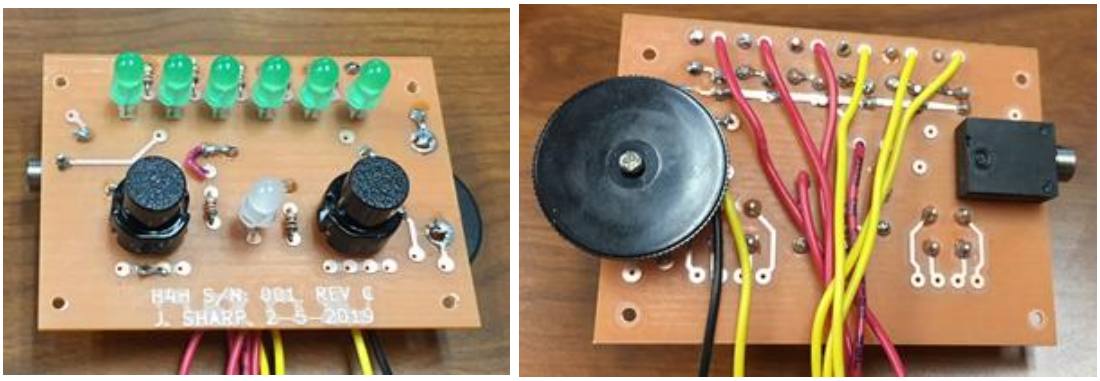


Figure 27. Populated Custom UI Board and Interface; Front (Left), Back (Right)

This UI Board contains the user inputs. A volume knob (far left side of right-hand picture in Figure 25 that doubles as both a variable resistor and on/off switch) was incorporated to switch from Amplification Mode to Hearing Screening Mode as well as serve as a volume adjuster for the amplifier. Two push buttons (black round devices in Figure 25 (left)) were added to initialize the “ Background Noise Test” and then the hearing screening. Lastly, an audio jack (far right of Figure 25) was added to the board so that users could plug in a new set of head phones if used for more than one patient. The audio jack was a standard, 1/8”, 3-pin terminal for stereo outputs seen

on a typical headset. Each grouping of components had its own interconnect to the DSP or microcontroller.

4.3.2.4 Microphone and Pre-Amplifier

The ADAU1701 evaluation board has two (2) analog-to-digital converters (ADCs). The evaluation board has four (4) digital to analog converters (DACs), two (2) that are connected directly to a stereo output jack and two (2) of which are outputs from on-board Class D stereo amplifiers. When using the Class D amplifiers, outputs were deemed to have too much electrical noise for this application, even after trying various approaches of filtering and noise gating. Even when switched to Background Noise Test mode, the device would still emit electrical noise to the headset. Therefore, the other set of DACs were used in conjunction with an alternate amplification.

The ADAU1701 evaluation board is equipped with audio input jacks that connect to the ADCs. These were tested with the custom fabricated microphone board (Section 4.2.1), which was found to have insufficient voltage output (and thus headphone volume), requiring a pre-amplifier. Rather than redesign the board to include a preamp and additional decoupling circuitry, it was decided to use commercially available devices in the interest of time. However, the custom microphone PCB could still be incorporated into a production design, if desired. The Adafruit Silicon MEMS Microphone Breakout SPW2430 Board was selected for the final prototype (see Figure 28) which utilizes the same microphone as the custom microphone board in Section 4.2. The SparkFun BOB-09816 LMV358 adjustable preamplifier board has sufficient gain and a 5V supply voltage that can be sourced off of the ADAU1701 (see Figure 29).

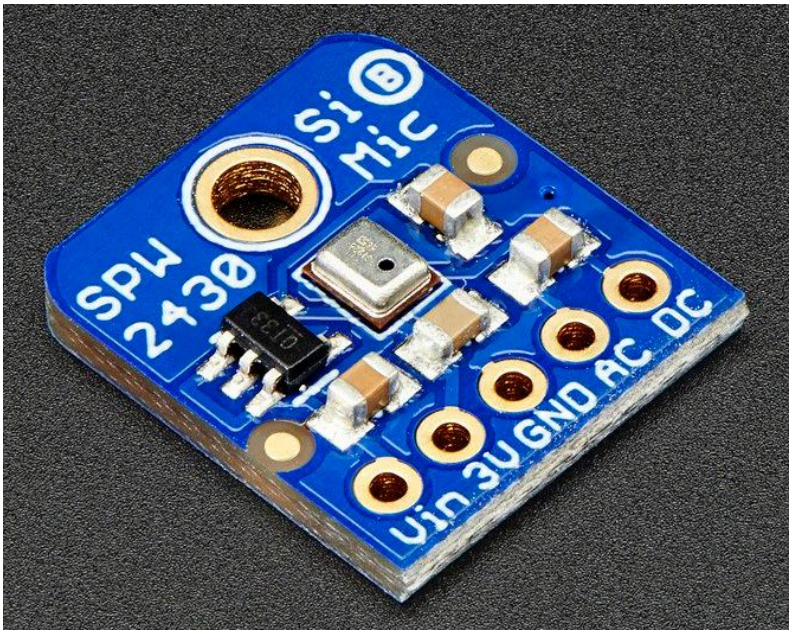


Figure 28. Adafruit MEMS Microphone Breakout Board for the Knowles SPW2430 [36]

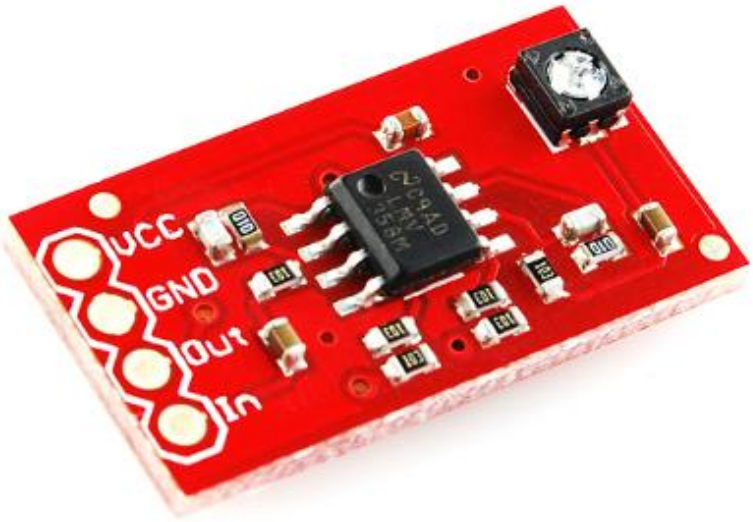


Figure 29. SparkFun's Op Amp Breakout board for the LMV358 Op Amp [37]

4.3.3 Software Architecture

Software was developed for both the audio DSP and the microcontroller to run the background noise checks to evaluate the incoming sound levels and to conduct the hearing screening. The DSP software is downloaded to the on-board electronics erasable programmable read-only memory (EEPROM) chip and executed using the integrated bootloader. This section describes the basic architecture of both the graphical algorithm that was developed for the audio DSP, as well as the Arduino sketch that was uploaded to the microcontroller. In addition, the rationale behind each step of the process will be described to justify decision making in the software trees.

4.3.3.1 Microcontroller Code

Code was developed for the using the Arduino Integrated Development Environment (IDE), after installing the Adafruit library and drivers for the Pro Trinket microcontroller. The connections to the microcontroller included eight GPIO output pins for display signals (to LEDs), two GPIO input pins to trigger the individual testing sub-modes, and a main power and ground line to the switch on the lid.

Functions were written to perform different light displays that indicate the outcome of the environmental sound level test and operation of the hearing screening tones. Table 5 provides a summary of the functions that were written for the microcontroller and the resulting actions that will be exhibited by the display lights.

Table 5. Microcontroller Functions and their durations

Function Name	Light Display Description	Blink Rate
BlinkGo	• Bipolar LED, Flashes Green	2 Hz
BlinkNo	• Bipolar LED, Flashes Red	2 Hz
HearingTest	• Bipolar LED, Solid Green • Test Lights, Flash Green in Sequence While Testing a Tone Then Turn Solid Green Once Finished	2 Hz

The flow of the microcontroller sketch is found in Figure 30. Using timers, loops were delayed in the timing between the Arduino and the DSP within 1 second. Intentional delays were incorporated using the functions from Table 5 to allow enough reset time for the DSP, and to ensure the systems reset completely before re-allowing a loop.

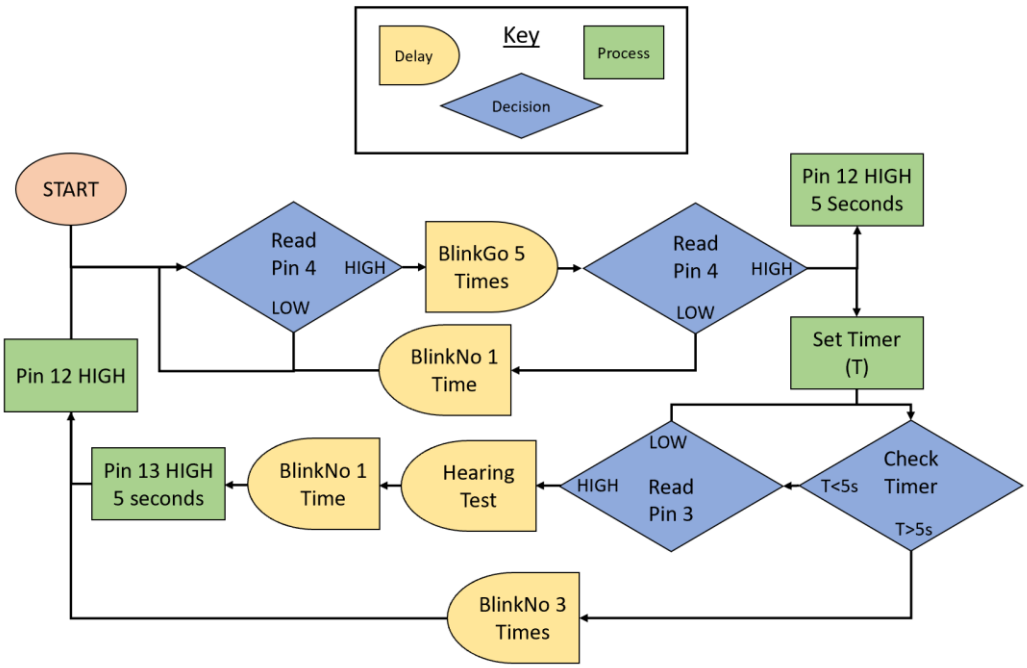


Figure 30. Microcontroller operation flow diagram for the Hearing Screening Mode (Figure 6, Sect. 3.1)

When the microcontroller boots up, the system will flash the middle indicator light rapidly until it is ready to enter testing mode. The middle indicator light will become solid green when the test is ready to proceed. To ensure the DSP is in testing mode, the clinician will need to ensure that Amplification Mode (GPIO1) is turned off, which can be confirmed by rotating the roller counterclockwise until an audible click is heard. If the buttons are pressed while still in Amplification Mode, the indicator light will remain green and no actions will occur by the DSP or the microcontroller.

When the middle indicator light is solid green, indicating ready status, the overall loop will begin for the Arduino sketch. Two of the microcontroller pins were assigned digital input status, waiting for flags that are passed through the DSP. These flags indicate respective button presses on the UI Board. The connections between the custom UI Board, the DSP, and the controller are

shown in Figure 31. Referring back to Figure 21 for a graphical depiction of the pins GPIO1-GPIO5, when the Environment Test button (GPIO2) is pressed, a flag (GPIO4) will be set HIGH the DSP for the microcontroller. As this is happening, the microcontroller is continuously polling the status of its pins. When the flag is set to HIGH, Pin 3 on the microcontroller will become HIGH. The system will go into a 5 second timer loop while the DSP records the environmental noise, where the BlinkGo function will be called 5 times. If the system fails the sound level test, the DSP will reset and the indicator light will call the BlinkNo function and return to its original ready state. If the peak sound level did not exceed its threshold, the flag (GPIO4) will remain HIGH to the microcontroller and it will set the indicator light will return to a solid green. The system will enter a while loop for 5 seconds. If the Hearing Screening button (GPIO2) is not pressed, the while loop will run out and the system will play BlinkNo for 3 seconds. If the hearing screening button is pressed, the second flag (GPIO5) will be set to HIGH, and the microcontroller Pin 4 will be set to HIGH, initializing the HearingTest function. The display output will be as follows: As the first tone is played into the left year, the first green light will flash, when the second tone is played, the first will go solid green while the second light flashes, and so on until both ears at 3 different tones are played back to the patient. Upon completion of the test, the BlinkNo once and then remain on solid red for 5 seconds until the DSP and the microcontroller return to their initial state.

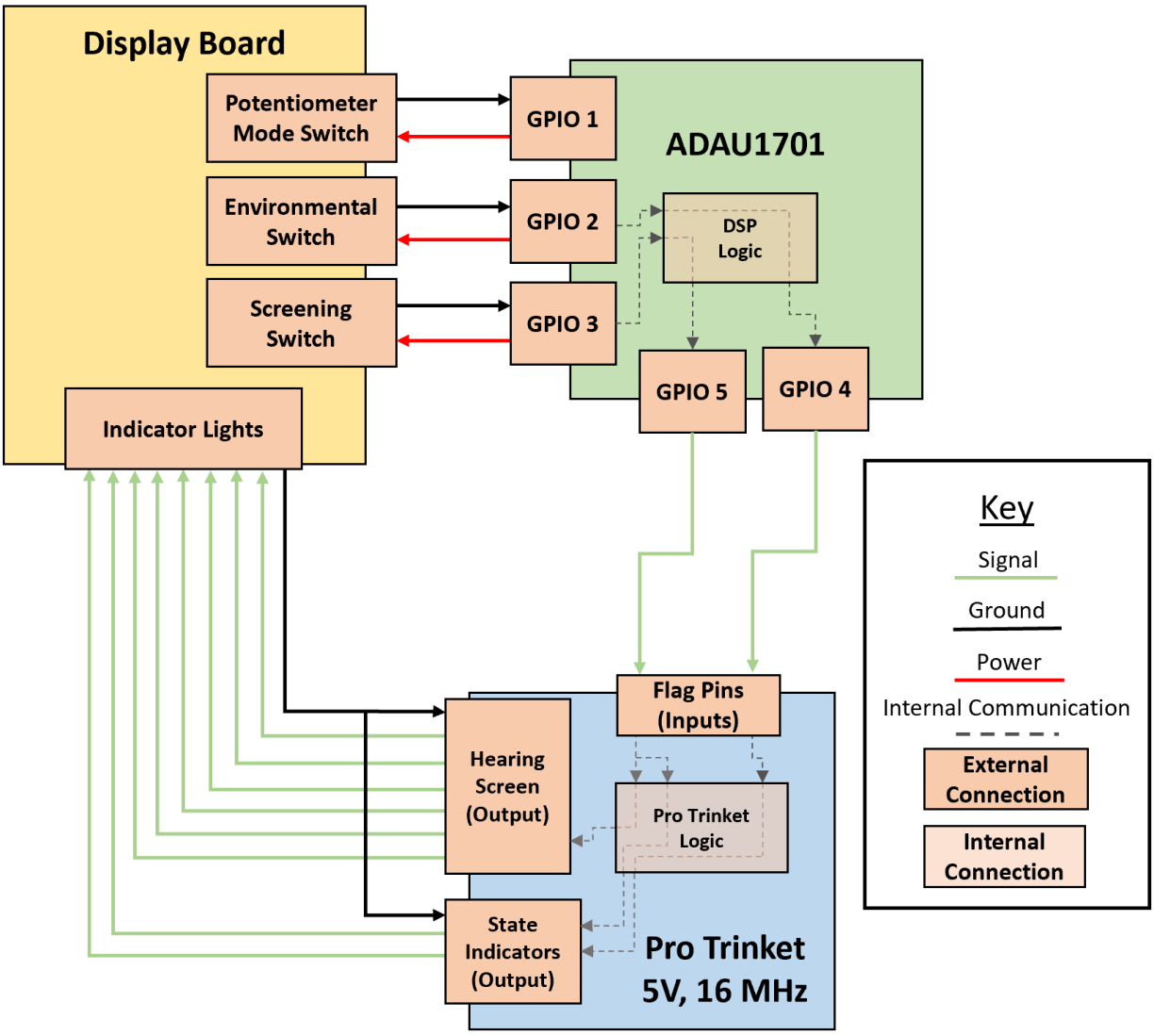


Figure 31. Microcontroller operation flow diagram

4.3.3.2 ADAU1701 Code

Most of the Analog Devices™ ADI DSP audio processors are programmed with the SigmaStudio® graphical development tool. Using building blocks for a variety of signal processing algorithms, the user can easily select commands from the programming library into a schematic where a system flow diagram can be drawn between the ADCs and DACs. In this section, descriptions of each of the main steps in the algorithm will be described.

The code relies on input from clinician using the UI Board. By scrolling the potentiometer on the side of the box (GPIO 1 – Figure 21) until it is in the on position, enables the Amplification Mode. When the potentiometer is in the off position but the main power switch remains on, the audio DSP will automatically assume that the board is in Hearing Screening Mode and will wait for the Background Noise Test button to be pressed (GPIO 2). Once this button is pressed, it will trigger a timer and will wait for the Background Noise Test to perform the noise level check. If the test passes, then a second timer will start, waiting for the screening button to be pressed. A similar timer is used for the Hearing Screening button (GPIO 3), however in order to initialize the Hearing Screening, the Background Noise Test must be complete and pass. If this is true and the Hearing Screening button is pressed, a HIGH signal is set in the board initializing timers that will be shown below in Figure 34. When the button for each respective loop is triggered, the input is sent into a logic block and then passed through if the logic is true. Each logic sequence is held on for a given period of time and then disabled by a trigger. Total run time will be a maximum of 20 seconds. A flow diagram of this logic train is displayed in Figure 32.

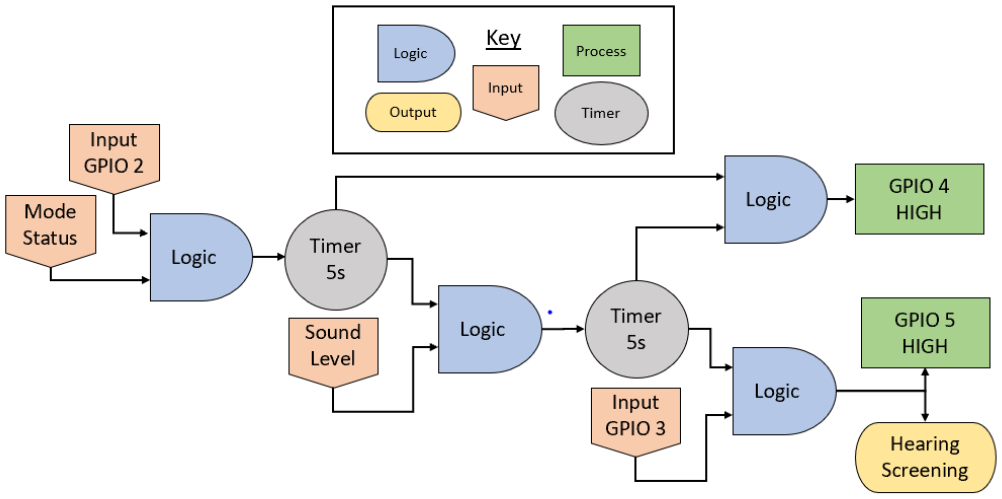


Figure 32. Flow diagram of initialization of Background Noise Test and Hearing Screening

The audio-line in is split into two paths, Amplification Mode and Hearing Screening Mode (see Figure 33). When in the Hearing Screening Mode the audio-in signal is used for the Background Noise Test, and the audio in is A-weighted. The background noise is then sampled for 5 seconds and the maximum value is used as an input. This input is then fed into a look-up table that has predetermined voltage levels that are associated with the background noise limits. The input signal from the microphone is sent through an A-weighting filter using the transfer function blocks in SigmaStudio® with coefficients adjusted to match the transfer function given in Chapter 4.1. A-weighting is required for the background sound level detection process, since it mirrors human perception of sound (see Section 4.1). Once the device has entered the Hearing Screening sub-mode the system will initialize a series of timers (see Figure 34). These timers will produce a HIGH signal that is fed to an adder block that will indicate to the multiplexer (mux) what signal should be passed through. The 1 kHz, and 2 kHz, 4 kHz signals are connected to the

mux will be passed through to a designated output when the value of the adder changes to an associated value.

When in Amplification Mode the signal is sent through a low pass filter and then scaled using the volume roller (potentiometer) on the UI Board. Connecting the microphone input and potentiometer together, the output is fed through to the output algorithm that will be connected to the headset audio jack on the UI Board.

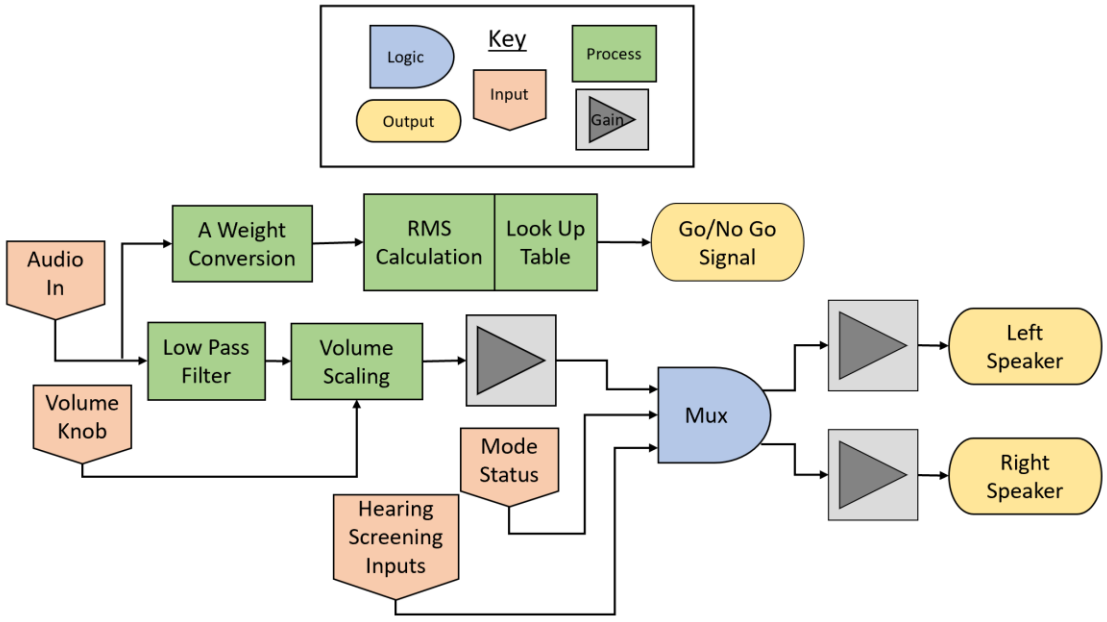


Figure 33. Flow diagram of microphone line in to the speaker output and " Background Noise Test" validation

When designing the Amplification Mode, the output level out of the DACs to the headset was lower than expected even when the volume knob was turned to its highest setting. A set value gain was added directly before the DAC output blocks in the software. When designing the Hearing Screening, the default output from the ADC when playing the given screening tones (1 kHz, 2

kHz, 4 kHz) were far higher than the desired tone levels necessary to achieve the sound pressure levels described in Section 4.3.4. Gain blocks (a set value) is added between the two multiplexers and additional gain blocks were added between each frequency tone block and the mux (see Figure 34). The test conducted for determining these gains will be discussed in Section 4.3.4. The signals are then tied to a second mux, the one used to decide between Amplification Mode and Hearing Screening Mode. Upon completion of the test the timers will all be reset and the device will wait for further input from the clinician. The output tone will be passed first to one path associated with the left speaker and then a second path associated with the right speaker.

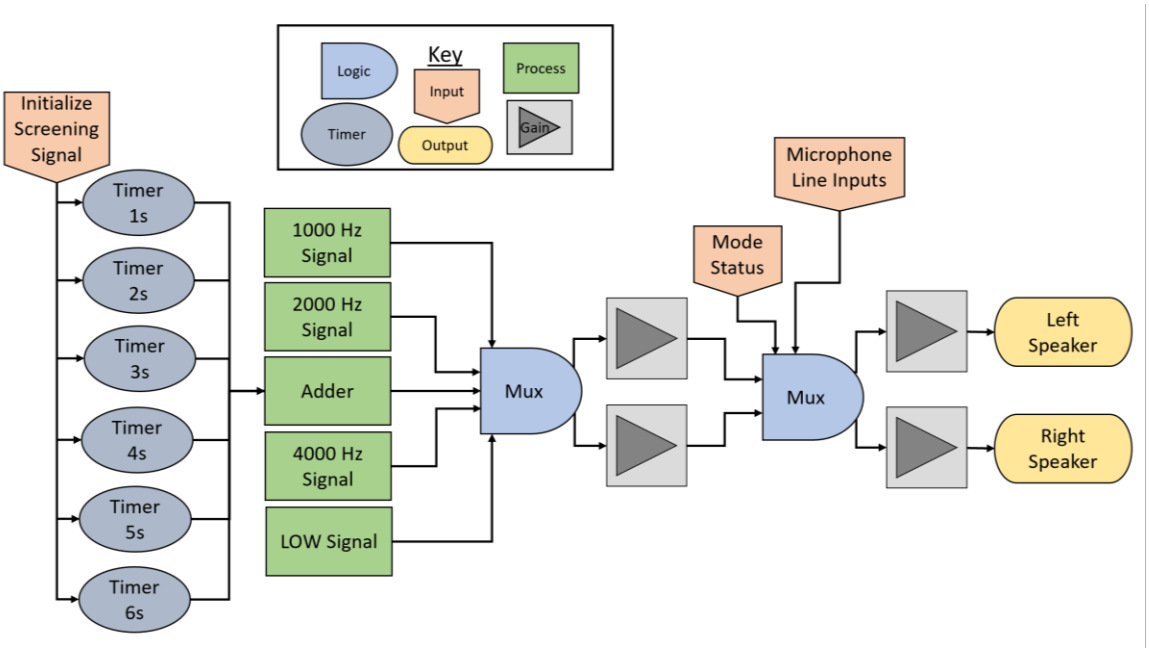


Figure 34. Flow diagram of hearing screening

4.3.4 Validation and Calibration

Two (2) test plans were created. One was used to calibrate the signal output frequencies used in the hearing screening, which if less than 4 of 6 are correctly identified indicates 35 dB_{HL}, as discussed in Section 3.1.2. The other was used to determine the calibration factor for the MEMS microphone that is used to measure the background noise level. For the first calibration, the ANSI S3.6-1996 standard was used to determine the audiometric zero (0 dB_{HL}), conversion between dB_{SPL} to dB_{HL} is shown in Tables 6 and 7 [32]:

Table 6. Standard Conversion to Audiometric Zero, dB_{HL} to dB_{SPL}

Frequency (Hz)	dB_{SPL}	dB_{HL}
500 Hz	13.5	0
1000 Hz	7.5	0
2000 Hz	9	0
4000 Hz	12	0

Table 7. Sound level in dB_{SPL} to indicate hearing loss at 35 dB

Frequency (Hz)	dB_{SPL}	dB_{HL}
500 Hz	48.5	35
1000 Hz	42.5	35
2000 Hz	44	35
4000 Hz	47	35

The ADAU1701 was programmed to produce the four (4) pure tone cases of 500 Hz, 1 kHz, 2 kHz, and 4 kHz (See Section 2.2.1). Though the device currently tests only three (3) frequencies (1 kHz, 2 kHz, 4 kHz), a fourth frequency of 4 kHz can be added in the future. The gain block directly following the signal block was added to adjust the gain to produce an output level that is consistent with the sound levels (dB_{SPL}) given in Table 6. The output leads connected to the DAC output (head phone jack) permitted one to easily connect a pair of supra-aural headphones to test the KEMAR as shown in Figure 35.

Calibration is conducted in an anechoic chamber, to remove effects from external noise sources. First, a portable audiometer (type to be determined) tested each pure tone case stated above on the KEMAR at disabling hearing loss as denoted in Table 7. The pressure level in dB_{SPL} was measured in real-time for each frequency. Once all levels are recorded, the audiometer was replaced with the programmed ADAU1701 that was preprogrammed to deliver each pure tone through a set of headphones that were used for the final deliverable. Each frequency was played continuously, while the gain is decreased or increased to the point where the KEMAR microphone output is equal to the sound pressure levels recorded from the audiometer. This test set up is shown in Figure 35.

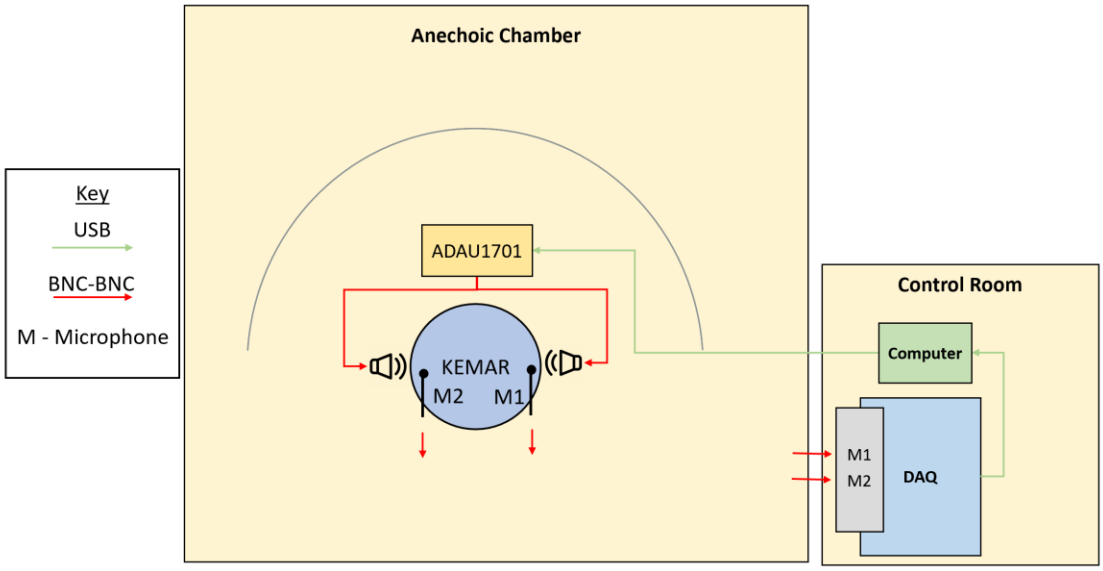


Figure 35. **Anechoic Chamber Set Up for Sine Tone Calibration**

The second calibration was with the fully functional prototype, but disassembled. The programming port will be used to supply power to the board and to read in real-time the V_{RMS} values directly from the ADAU1701 through the I2C programming cable. Data was captured at various sound levels by both the SLM (as mentioned in Section 4.1) and the MEMS microphone in the prototype, by playing a 1 kHz tone.

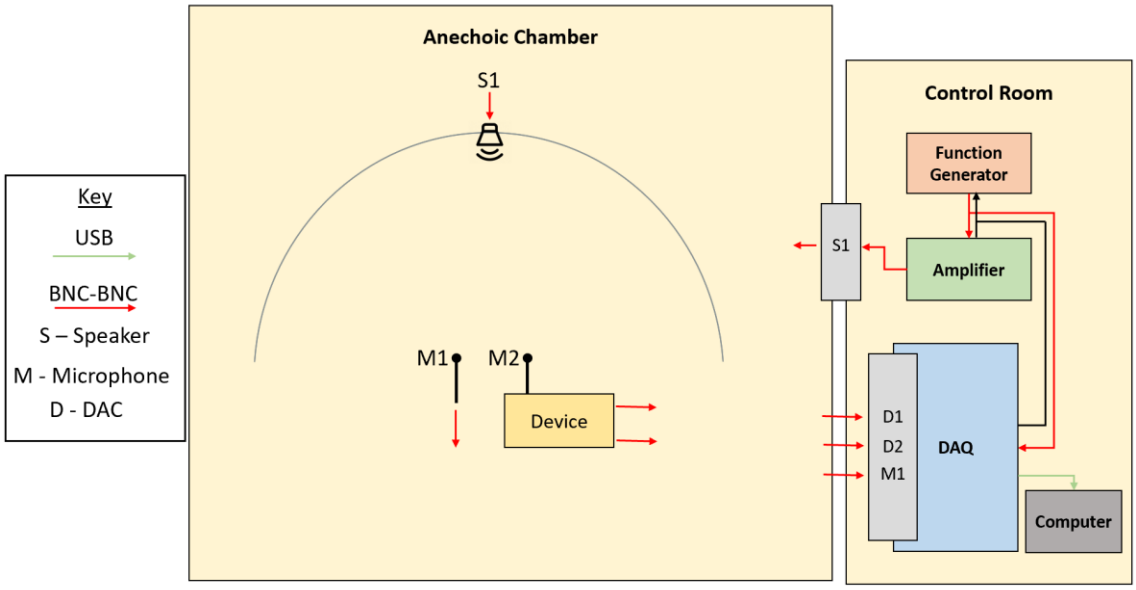


Figure 36. **Anechoic Chamber Set Up for MEMS Microphone Calibration**

5.0 Environmental Recordings, Headset Performance, and Prototype Calibration

5.1 Recording Results

Plots were generated to understand the spectral content of various environments where geriatric patients may be screened for hearing loss such as emergency rooms, inpatient care centers, and waiting rooms. First, standard spectrograms were created without A-weighting the spectra. Key frequencies can be noted in yellow (see Appendix A). These spectrograms were created from WAV audio files that were created when measuring raw acoustic signals from the various environments. The WAV files were trimmed into useable sections to remove noise uncharacteristic of the environment (slammed doors, loud conversation, etc.) and then looped. PSDs were generated from the full WAV file, while spectrograms were generated from the un-looped clip. Certain frequencies have a higher power density, represented by a lighter color, such as roughly 2.3 kHz, where a solid yellow band shown in Figure 37.

A-weighted PSDs were created by post-filtering to better represent the impact on human hearing (see Appendix B).

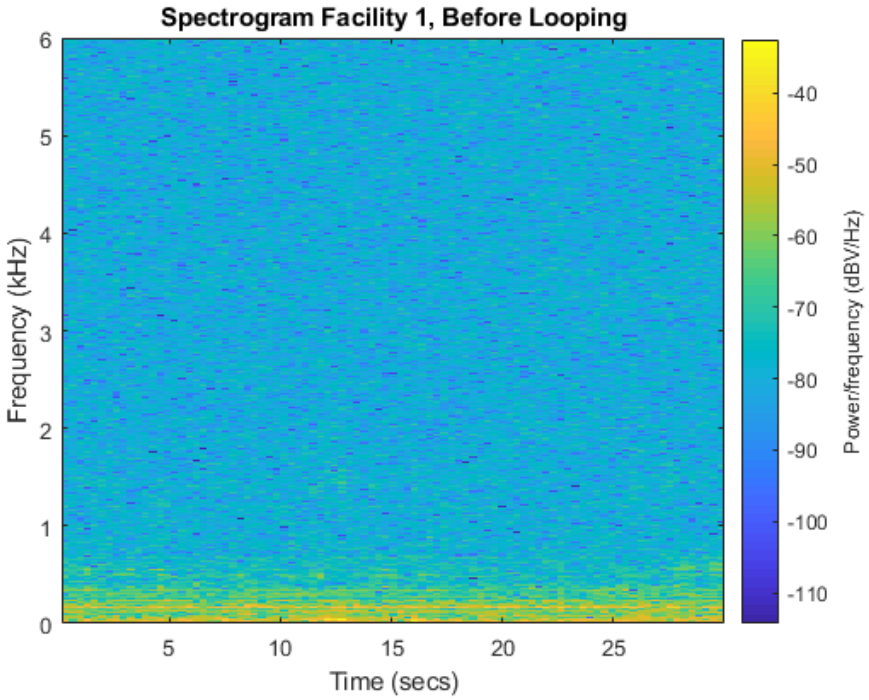


Figure 37. Spectrogram Assisted Care Facility 1

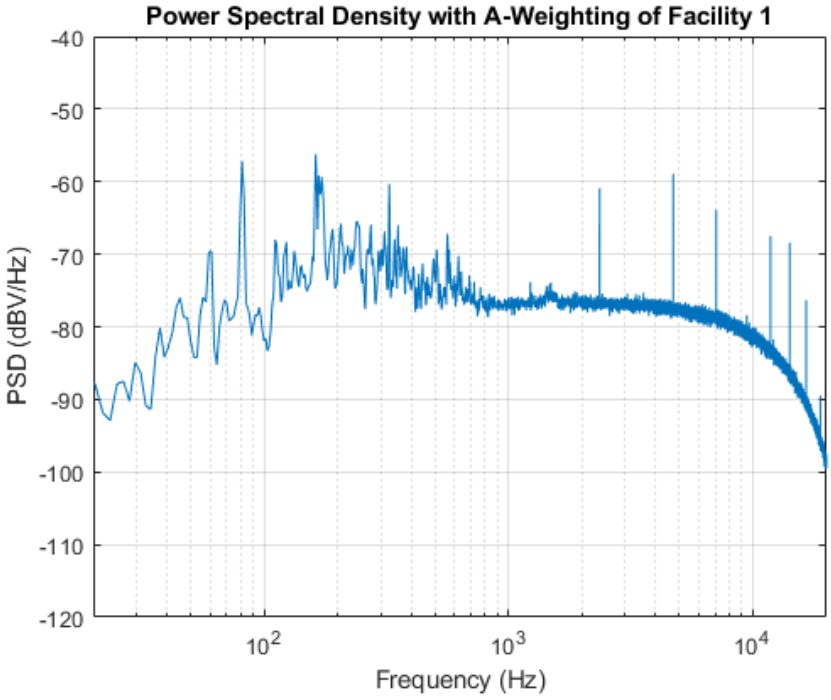


Figure 38. A-Weight Power Spectral Density Assisted Care Facility 1

5.2 Headset Testing Results

This section discusses the test results from the anechoic chamber testing of the headsets, starting with insertion loss measurements.

5.2.1 Insertion Loss Measurements

Insertion loss was calculated from data that was recorded using the measurement setup shown in Figure 17. Equation (5-1), was next used to compute $IL_{xy}(\omega)$. The result is given in Figure 37, where signal x is the left KEMAR microphone (with headset), y is the left KEMAR microphone (with no headset), and signal z is the white noise from speaker 5 (angle +90 degrees) measured by the free-field mic (see Table 4). The reader is reminded that positive IL indicates a reduction in sound level as a result of adding the headphone. It can be seen from the figure that IL hovers near zero from 20-1,000 Hz, with a modest increase to 5 dB around 2,000 Hz, shown in Figure 39. Then the IL becomes considerably negative (indicating amplification) from 4-9 kHz. A strong peak occurs at 10 kHz, followed by more amplification from 12-18 kHz.

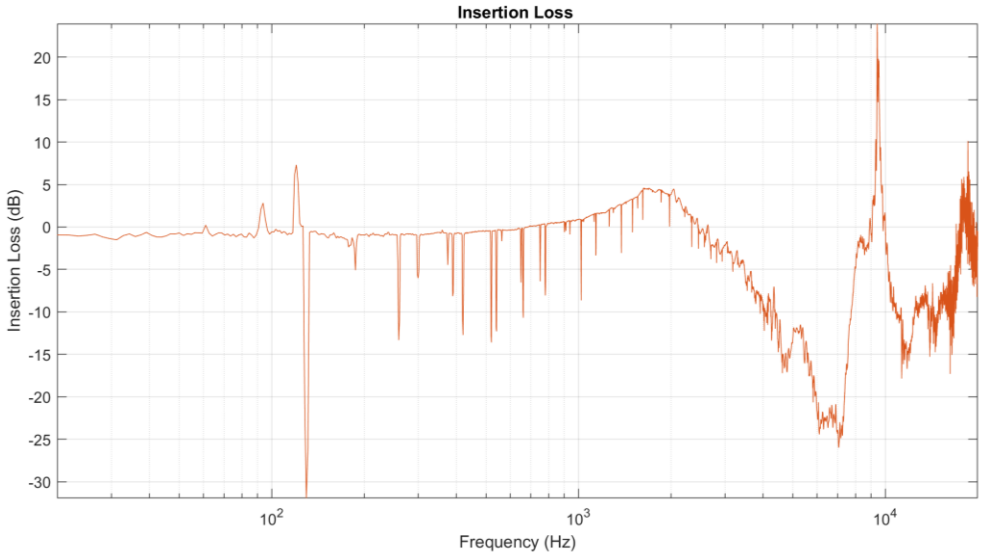


Figure 39. Insertion loss when modified headset is used

5.2.2 Diffraction Effects

A test was conducted where a sound was played from the left side (speaker 1) and the responses of both MEMS microphones (left and right) were recorded. Two FRFs are plotted below, 1) between the input white noise (playing from speaker 1) and the left MEMS headset microphone and 2) between the input white noise (playing from speaker 1) and the right MEMS headset is given in Figure 40. These responses are denoted by the legend.

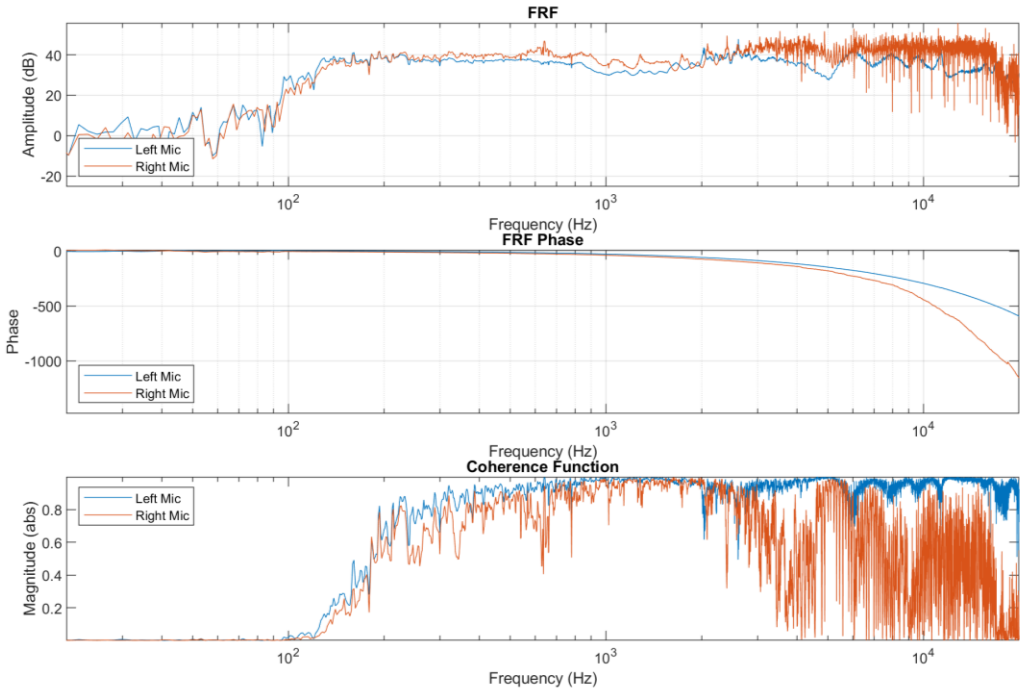


Figure 40. Loss between microphones with sound from speaker 1

At low frequencies (< 500 Hz) the response of both microphones indicates that there is little difference in performance, despite the signal coming from the left direction of the KEMAR head. However, below 150 Hz, the coherence is quote low, owing to the low-pass characteristic of speaker 1. From 500-2,000 Hz there is a modest difference noted between the two microphones. At frequencies above 2000 Hz, two observations can be made: The magnitude and phase differences between the two microphones become more pronounced, and the coherence of the right-side (the back-side from the speaker) microphone becomes relatively poor. Both of these effects can be attributed to the additional travel time (additional phase delay) and diffraction effects (different and noisy magnitude and poor coherence).

5.2.3 Gain and Phase Margins

Figure 41 presents the FRF between the headset speaker and the MEMS microphone (magnitude in the top plot, phase in the middle plot) and coherence in the bottom plot. Aside from the harmonic peaks from 60 Hz noise, the coherence between the adjacent speaker and microphone is essentially zero, except above 1,000 Hz, with the strongest coherence (γ_{xy}^2 >0.2) occurring between 2-5 kHz. It is expected that the low-frequency coherence is missing due to dipole radiation of the open-ear headset. Above 6 kHz, coherence is presumed to be somewhat lower due to absorption, which is stronger for higher frequency bands. Based on the coherence results, we are only concerned about feedback occurring above 1 kHz and aside from 2-5 kHz and 6 kHz, the FRF results are not very representative (noisy) due to especially low coherence. Looking at the magnitude and phase in the 2-5 kHz region, we see that the gain is about 20 dB (greater than 0 dB), while at the same time, the phase decreases by over 360 degrees. As described in Section 4.2.5, the phase and gain margins requirements are not met, indicating that the system can become unstable and acoustic feedback is very likely to occur at high volume levels. This is too risky for the patient use and therefore, the mic will be placed on the control box, as is common with existing personal amplification products on the market.

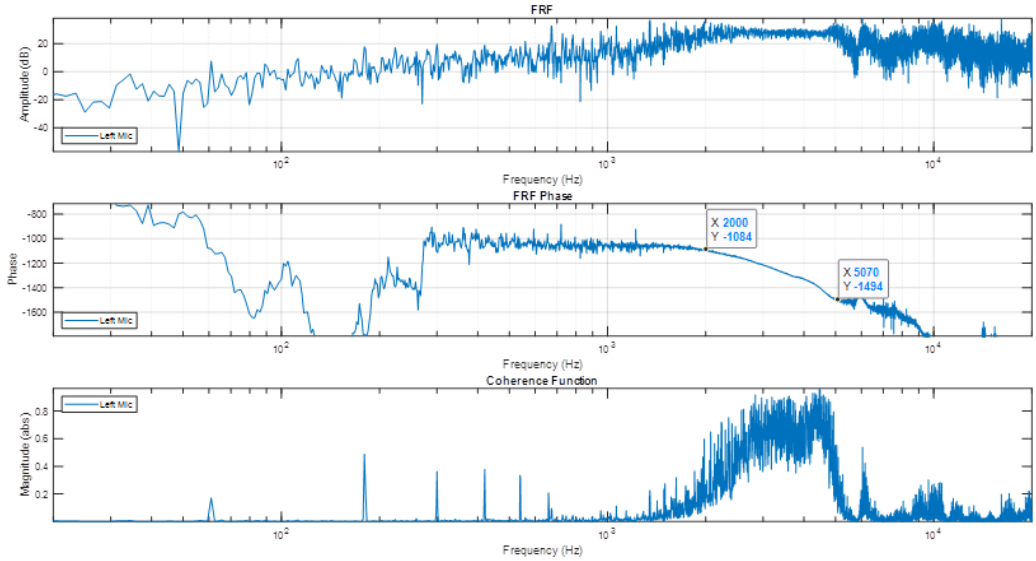


Figure 41. Frequency response function and coherence between an adjacent headset speaker and MEMS microphone.

5.3 Final Device Testing & Validation

5.3.1 Validation of Prototype & User Operation

During preliminary testing, it was found that the systems had mechanical robustness issues, was susceptible to EMI from the cable routing, and after many test cycles, connections between components became strained. To address issues of ruggedness, test instructions were created and is named Device Validation Check Sheet (sample images in Appendix C). In order to resolve the above issues:

- Power lines from the battery to the microcontroller, audio DSP, and pre-amplifier were twisted and taped off using copper tape to reduce EMI and electrical noise.

- Mechanical ruggedness was tested through various mechanical tests such as repetitive closing and opening of the cover, shaking the device profusely, and performing 6” drop tests.
- Cable reliability was tested by cycling through the Background Noise Test, Hearing Screening, and Amplification Mode five (5) times.

A master copy of the product instruction set was created for new clinicians to understand the functional prototype and how it operates, named Hearing Screening Instruction Set. The document describes the orientation of the device and what lights the user should see upon power up and the different test states. In addition, the document includes explicit instructions for how to turn on the device, check and choose Amplification Mode, run the Background Sound Test and conduct the Hearing Screening. Pictures documenting the test procedure are present to guide the user through the testing modes. There are current timing limitations discussed in Chapter 6, and these are accounted for in the instruction set to mitigate user error by adding explicit instructions for the user to wait a given number of seconds, wait for the board cycle to reset. This is found in Appendix D.

5.3.2 Calibration of Prototype

For the Hearing Screening calibration, the portable audiometer, was set to a level equivalent of 35 dB_{HL} for each of the Hearing Screening tones and played into the KEMAR. The left KEMAR microphone output voltage was recorded and converted to dB_{SPL}. The bare ADAU1701 evaluation board, mentioned in Section 4.3.4, was connected to a headset and placed on the KEMAR head. As each tone was played, the equivalent dB_{SPL} was calculated, and the step

was repeated changing the gain blocks described in Section 4.3.3.2 until the equivalent sound pressure level matched that of the audiometer. Gain block values are listed below:

Table 8. Gain Calibrations for Hearing Screening

Frequency (Hz)	Sound Level (dB_{SPL})	Gain
500	69.0	0.35
1000	78.2	0.8
2000	92.4	2.1
4000	82.3	0.9

The second calibration was used to collect the output voltage of the MEMS microphone to be used for the Background Noise Test threshold RMS values when programming the ADAU1701 evaluation board. Using a direct data collection, 1000 Hz was played for each of the pressures listed in Table 9 as measured by the SLM to measure the average voltage output of the microphone and pre-amplifier assembly.

Table 9. Microphone Output Voltage

Voltage Input to Speakers (V_{PP})	Measured Sound Level (dB_{SPL})	Voltage (V_{PP})
0.5	80.5	0.0246
0.35	77.5	0.0158
0.25	76.4	0.0123
0.125	67.6	0.00579
0.0.065	62.5	0.0031

6.0 Conclusion

6.1 Prototype Limitations

Current prototype limitations are primarily due to the internal circuitry of the system and board to board interactions. In the device's current prototype state, there are 3 separate boards that must communicate with each other, the microcontroller, the DSP, and the UI Board in order to execute the Background Noise Test and the Hearing Screening. On a high level, this has created strong possibility for failure especially during the assembly process, as wires can be crushed, not to mention there is potential solder fractures on the user interface board (indicator light and button traces). This initial prototype of the system utilizes an evaluation board ADAU1701, where the user cannot remove components that are not in use and have to use a predefined circuitry. Although the ADAU1701 chip has many general-purpose input/output pins (GPIO), most of these pins are not accessible on the audio DSP. This is due to routing adopted by the manufacturer. As a result, the process trigger pins had to be connected via fragile solder connections through modification of the Evaluation Board. This sort of connection is fine for bench testing, but for long term clinical testing, the risk for disconnect is too high. Strain-relief mechanisms were deployed; however, these have proven not to be uniform enough during the manufacturing process.

The current software algorithm limitations are due to the systems dependence on the timing between the DSP and the microcontroller. This can be fixed by implementing a handshaking method between board on future prototypes, discussed in Section 6.2. Due to these limitations, screening instructions were produced for the healthcare professional to conduct the Background

Noise Test as well as the Hearing Screening so that clinicians can correctly identify whether the device was operational and performing correctly.

6.2 Future Work

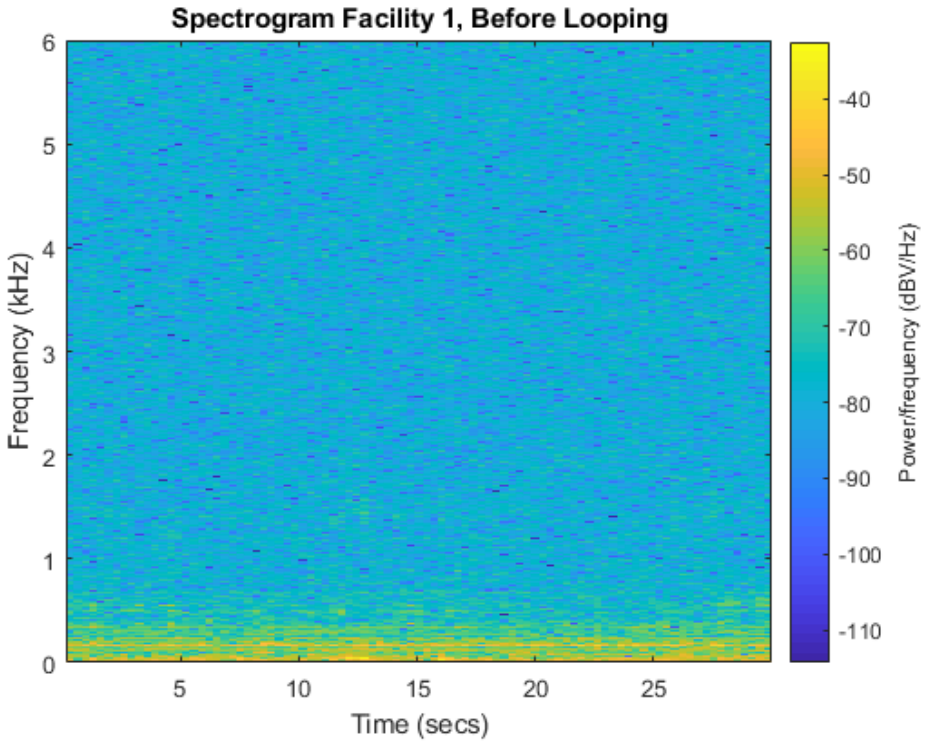
The work completed for the presentation of this thesis has produced a functional prototype with electrical limitations that dictate the software structure and mechanical form factor. Despite these limitations and its crude form factor, the prototype is fully functional and ready to be tested clinically. IRB-approved testing will identify the hearing characteristics of test subjects with no hearing loss in a sound booth using the device. The real-world noise recorded in patient rooms discussed in Section 4.1 will be played at a known sound level and used to test a subject's (who has no hearing loss) ability to identify sound tones (1000 Hz, 2000 Hz, and 4000 Hz) in each ear. Using this first-generation functional prototype as proof of concept, testing help shape the software algorithm. Future testing will be conducted in a clinical setting to patients with a known level of hearing loss to validate the previous sound booth testing.

The second-generation prototype will use custom circuitry for the DSP, power system, audio components processes, and UI on one board. The unnecessary components from the audio DSP evaluation board will be removed from the schematic and the microcontroller will no longer be necessary due to access to a larger number of GPIO pins on the DSP. A mux should be used to simplify the decision making of the current light display eliminating board timing as a failure point in testing during. More reliable buttons can be selected with a clear tactile feedback in addition to smaller display lights to decrease the board footprint and energy consumption. With a new

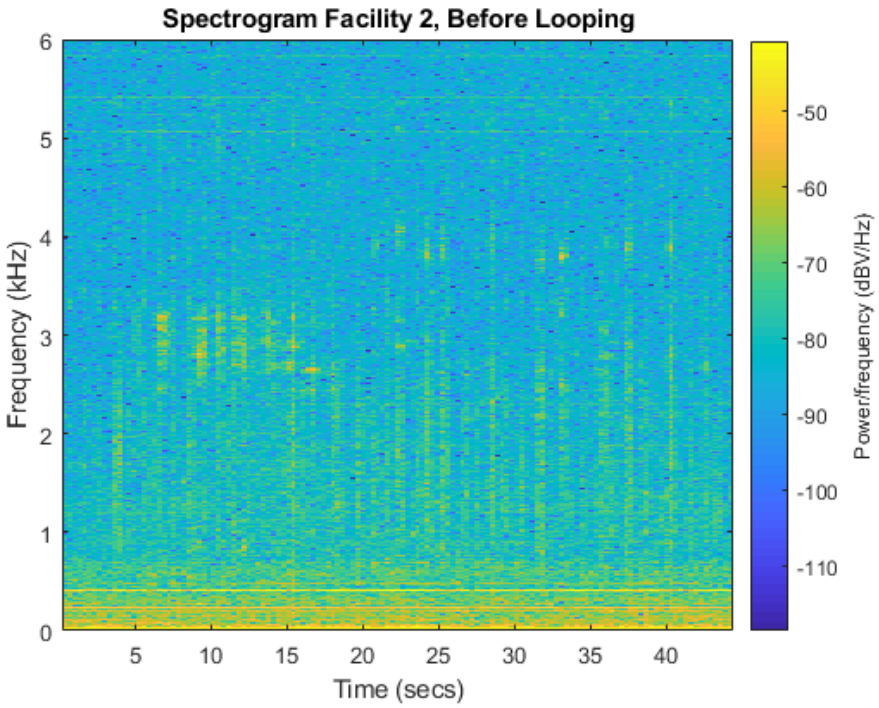
electrical scheme allowing for slimmer device design, a sleeker, more compact mechanical package will be produced in an injection molded process, while at the same time reducing costs.

Appendix A Spectrograms

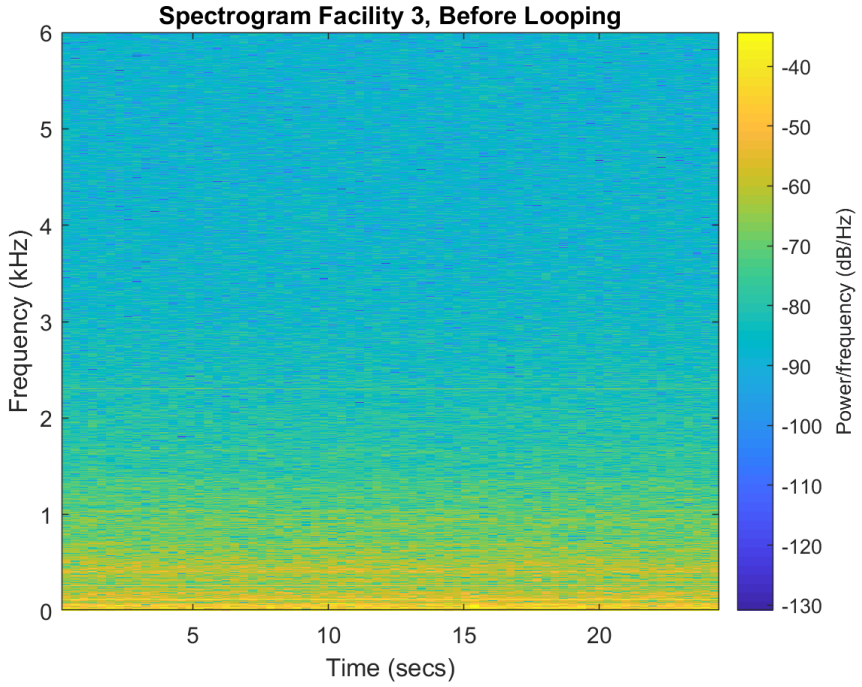
This appendix contains the spectrograms of various background noise samples from different geriatric healthcare environments. Each plot has been de-identified and given a facility number.



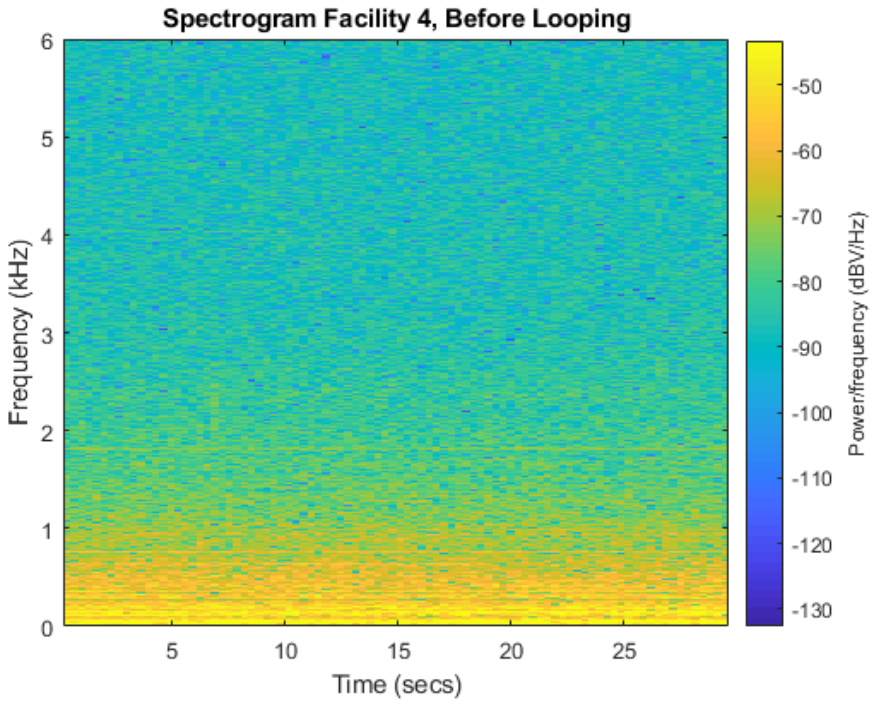
Appendix Figure 1 Spectrogram Assisted Care Facility 1



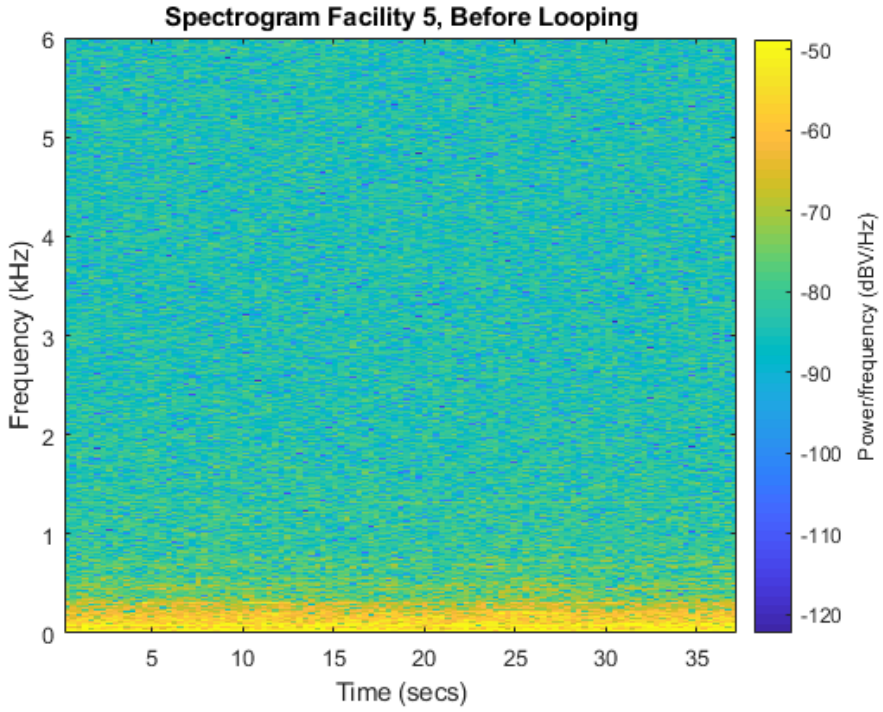
Appendix Figure 2 Spectrogram Assisted Care Facility 2



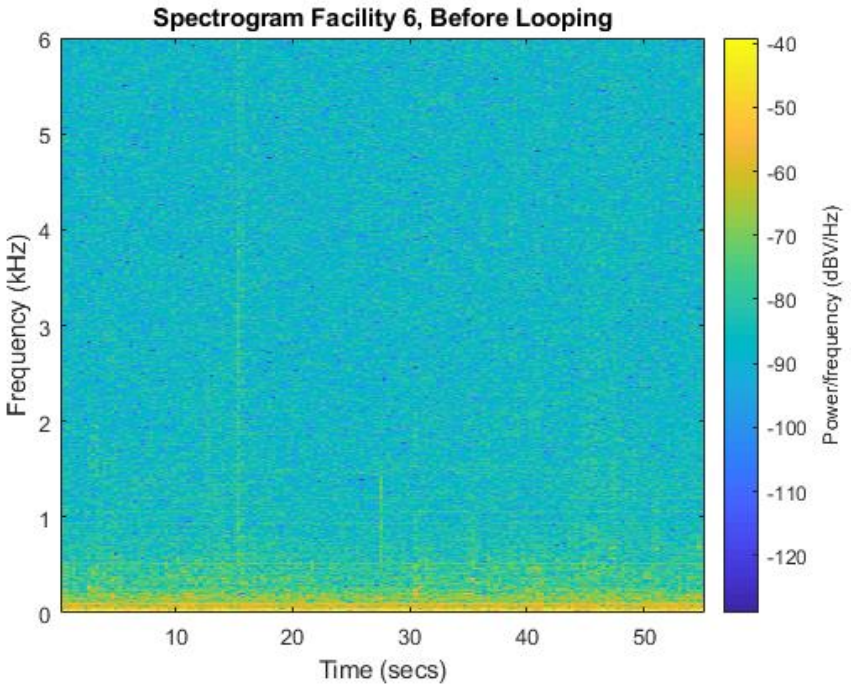
Appendix Figure 3 Spectrogram Dining – Assistive Living Facility 3



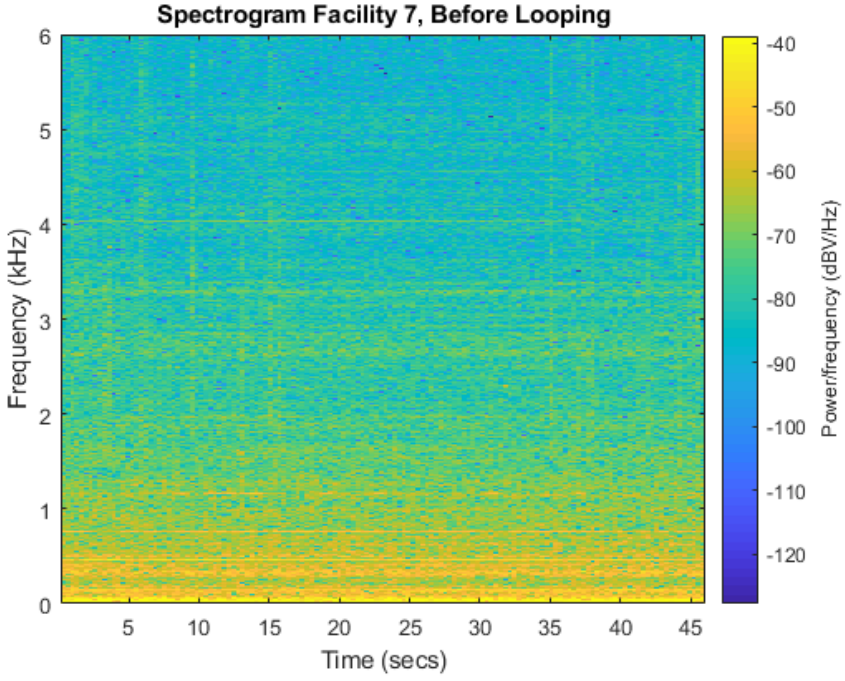
Appendix Figure 4 Spectrogram Dining – Assistive Living Facility 4



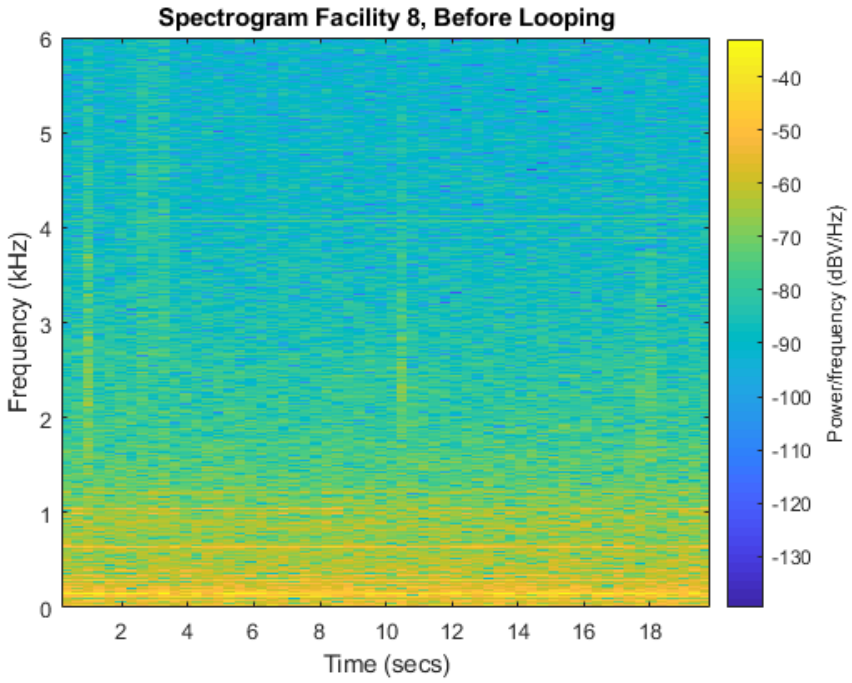
Appendix Figure 5 Spectrogram Assistive Care Facility 5



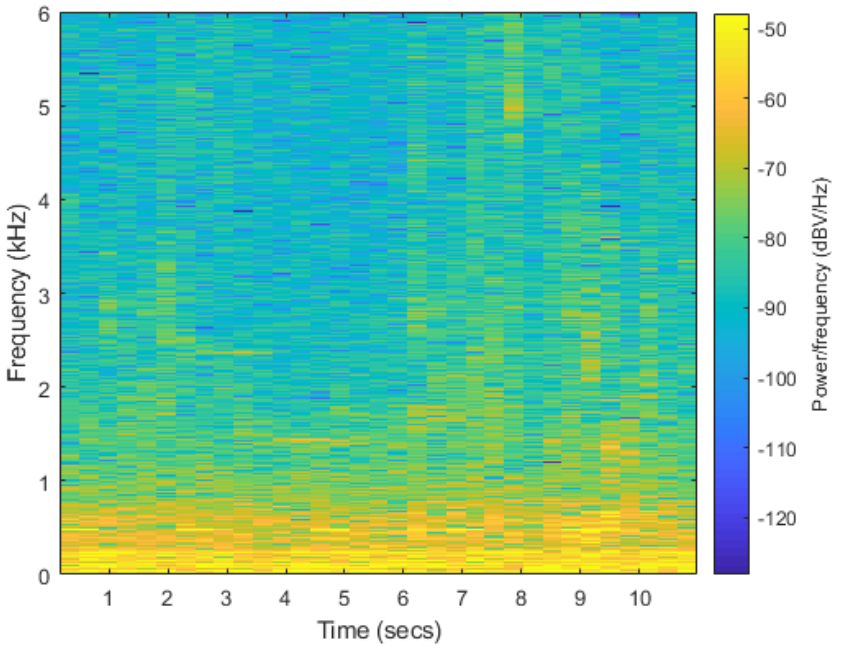
Appendix Figure 6 Spectrogram Assisted Care Facility 6



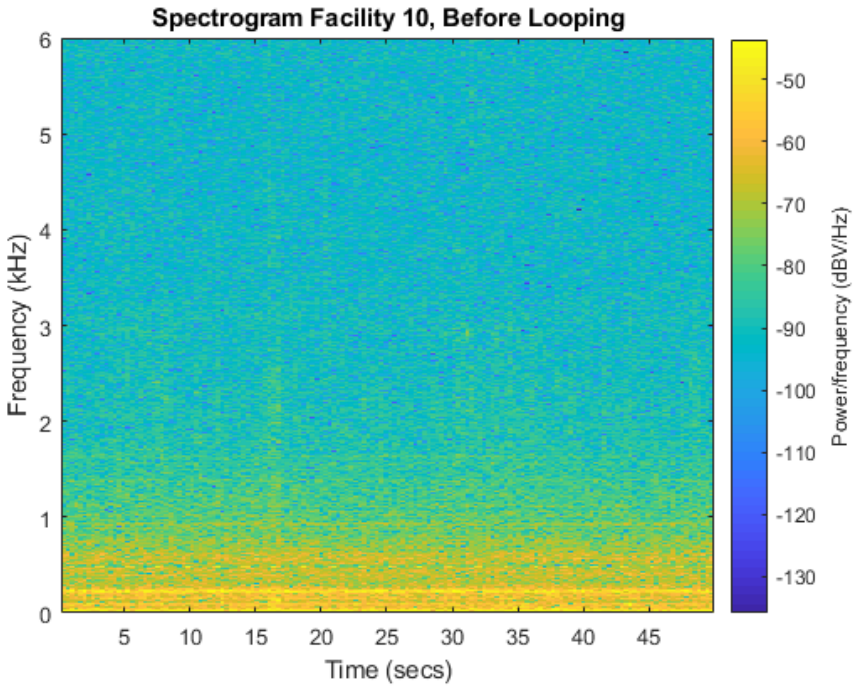
Appendix Figure 7 Spectrogram Assisted Care Facility 7



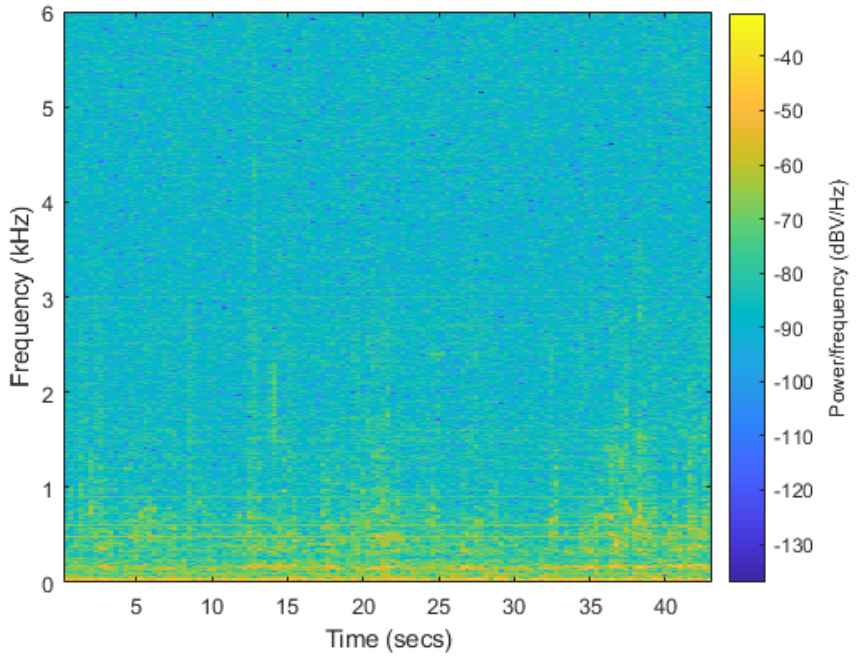
Appendix Figure 8 Spectrogram Assisted Care Facility 8



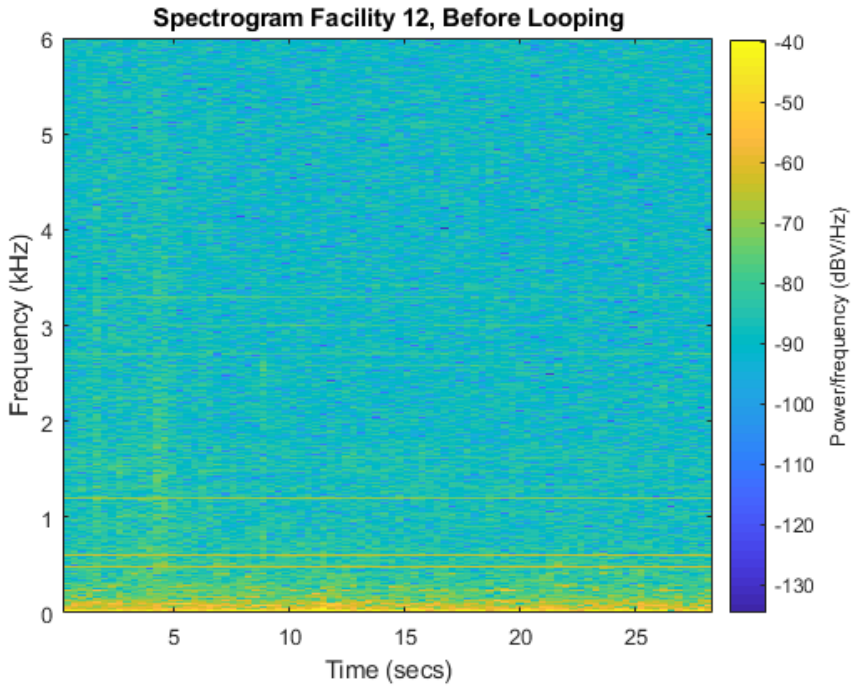
Appendix Figure 9 Spectrogram Hospital Facility 9



Appendix Figure 10 Spectrogram Hospital Facility 10



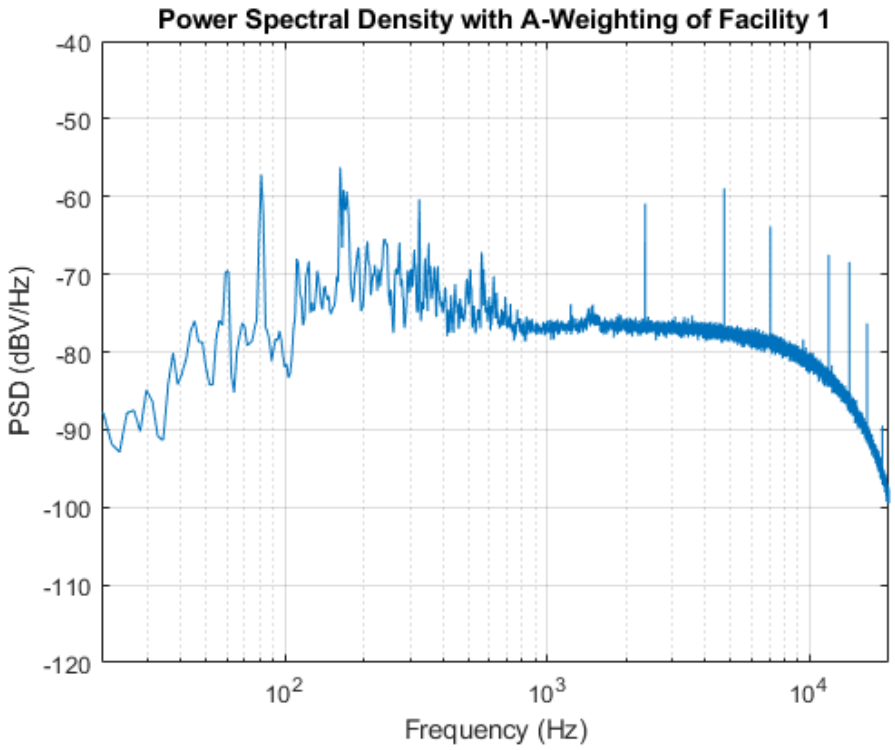
Appendix Figure 11 Spectrogram Hospital Facility 11



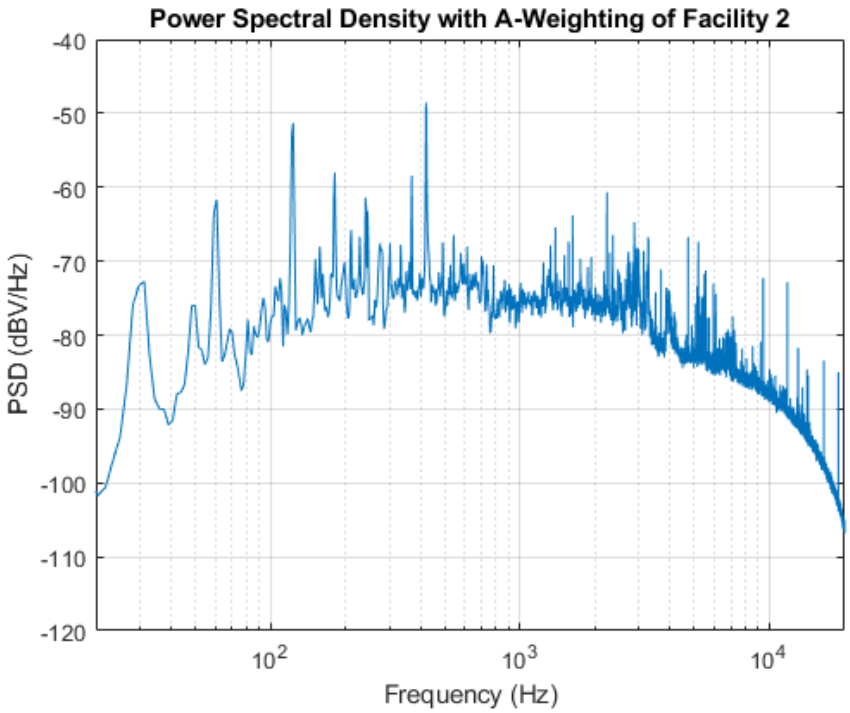
Appendix Figure 12 Spectrogram Hospital Facility 12

Appendix B A-Weighted Power Spectral Density Plots

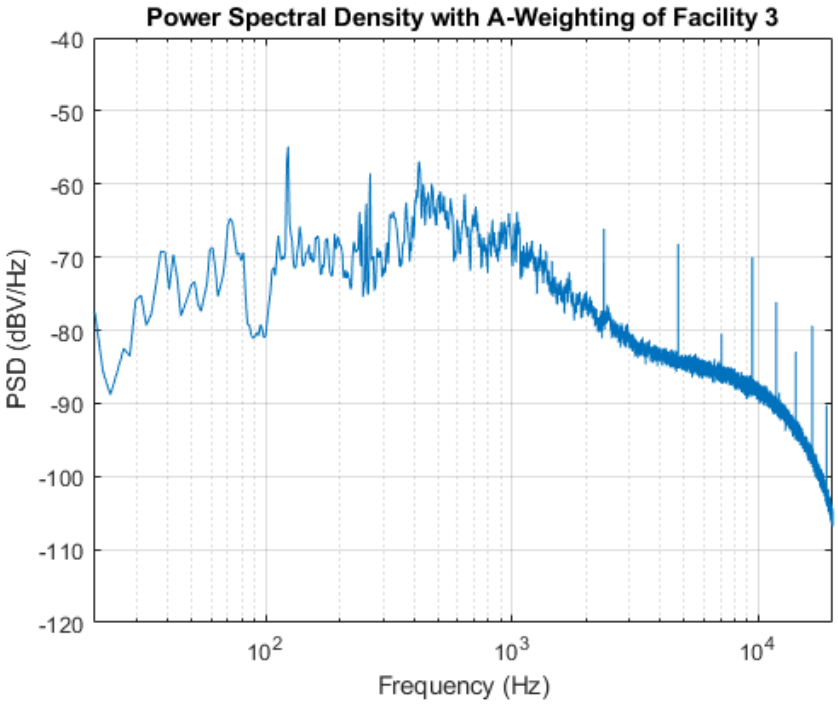
This appendix contains power spectral density plots from A-weighting the environmental noise samples that will be used in sound booth testing of the functional prototype. The facility numbers correspond to the facilities given in Appendix A.



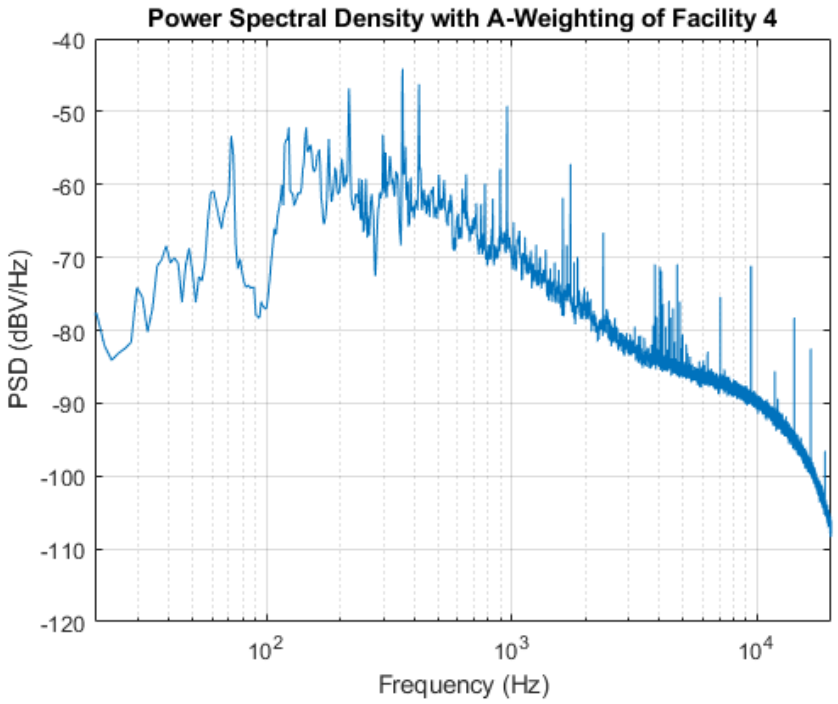
Appendix Figure 13 A-Weight Power Spectral Density Assisted Care Facility 1



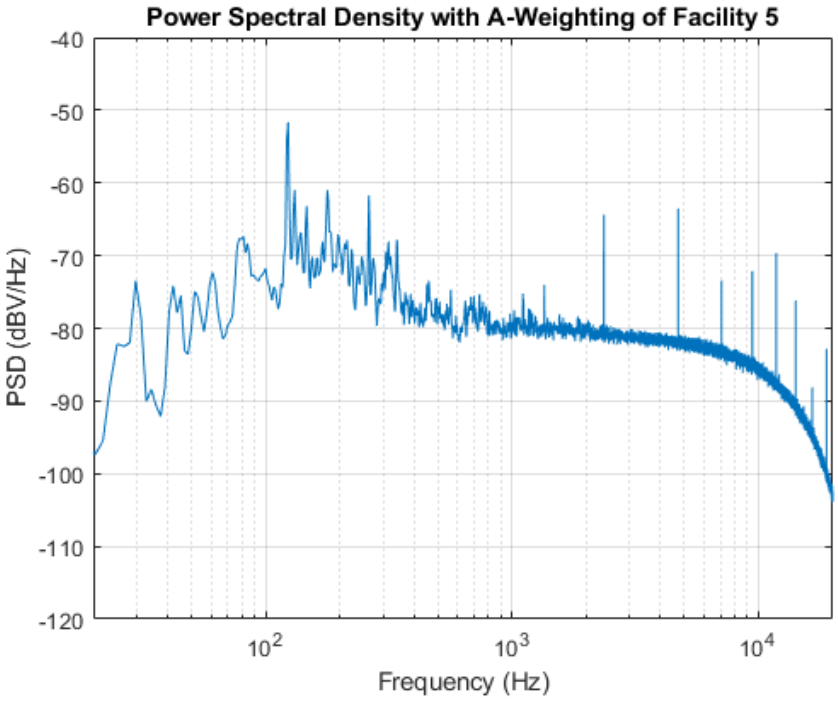
Appendix Figure 14 A-Weight Power Spectral Density Assisted Care Facility 2



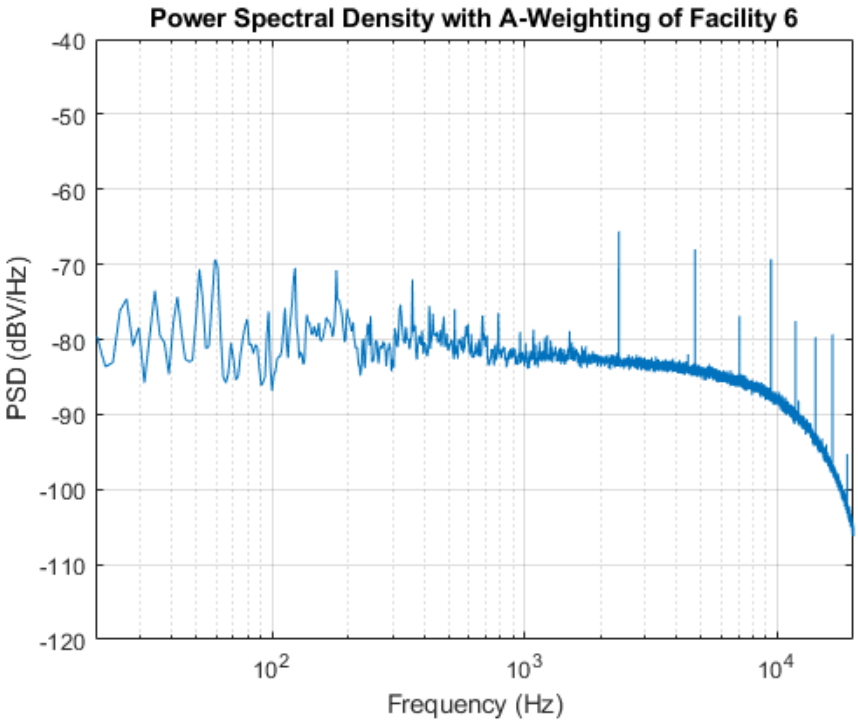
Appendix Figure 15 A-Weight Power Spectral Density Dining – Assistive Living Facility 3



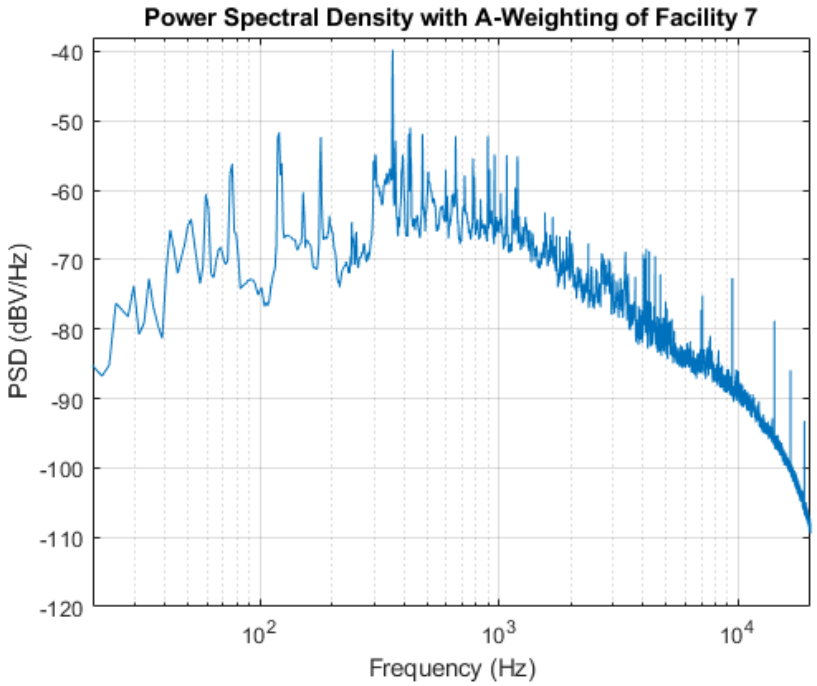
Appendix Figure 16 A-Weight Power Spectral Density Dining – Assistive Living Facility 4



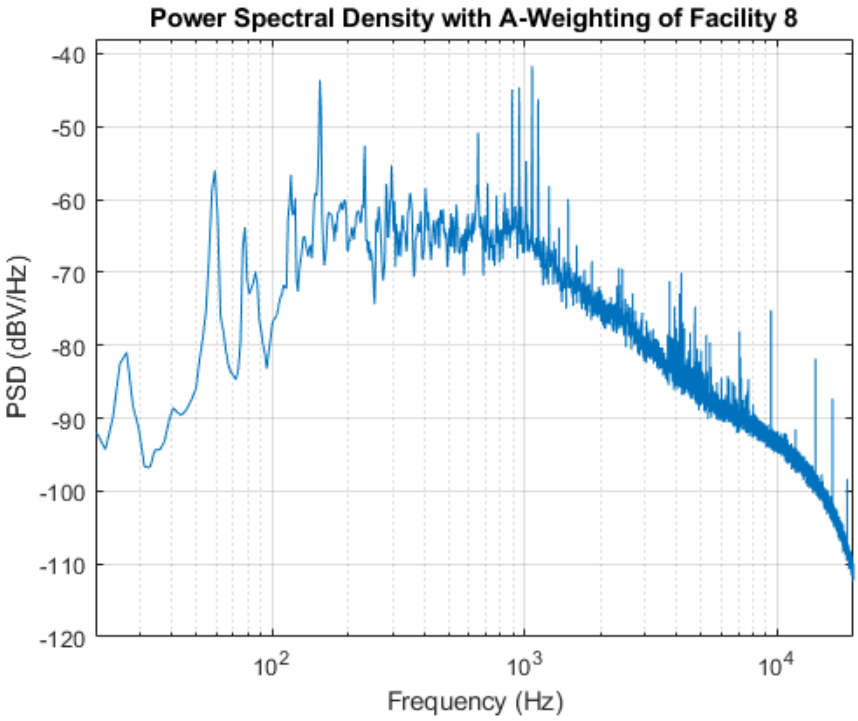
Appendix Figure 17 A-Weight Power Spectral Density Assistive Care Facility 5



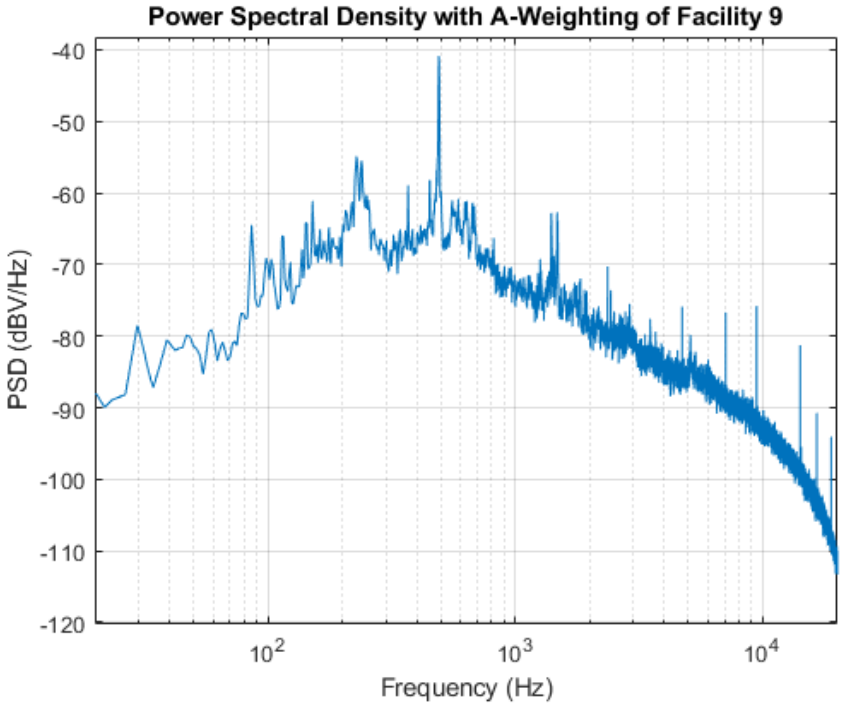
Appendix Figure 18 A-Weight Power Spectral Density Assisted Care Facility 6



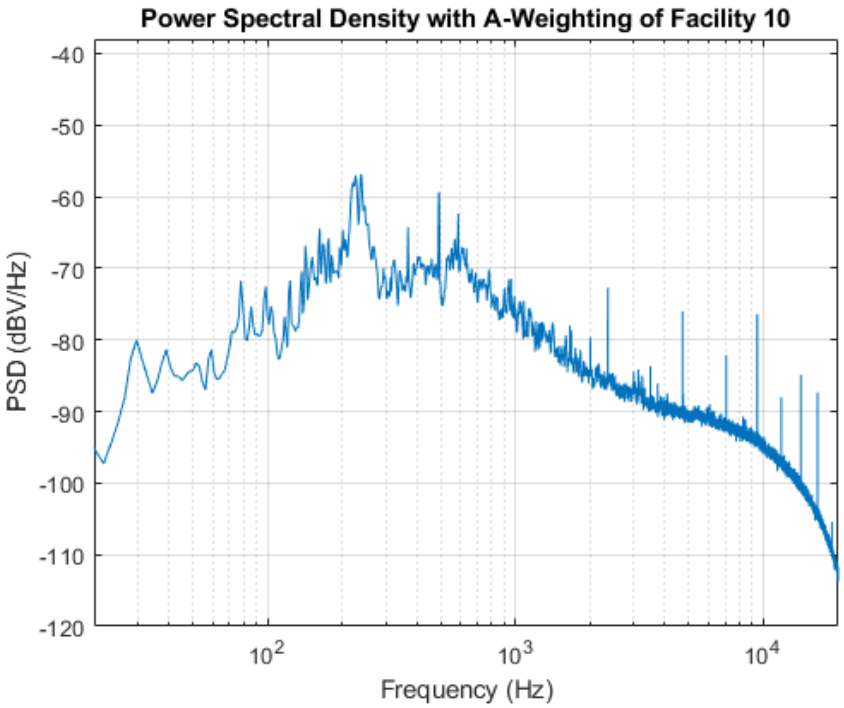
Appendix Figure 19 A-Weight Power Spectral Density Assisted Care Facility 7



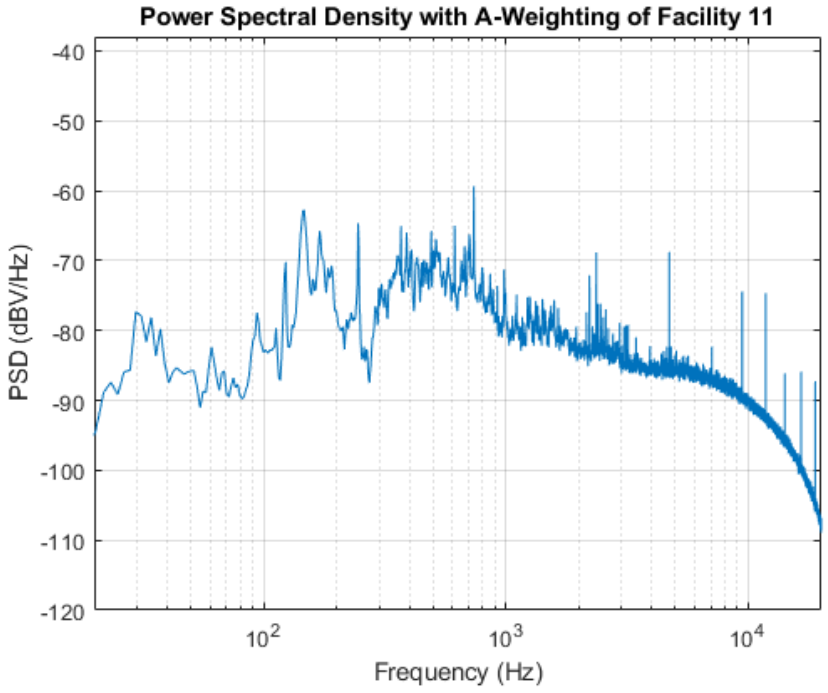
Appendix Figure 20 A-Weight Power Spectral Density Assisted Care Facility 8



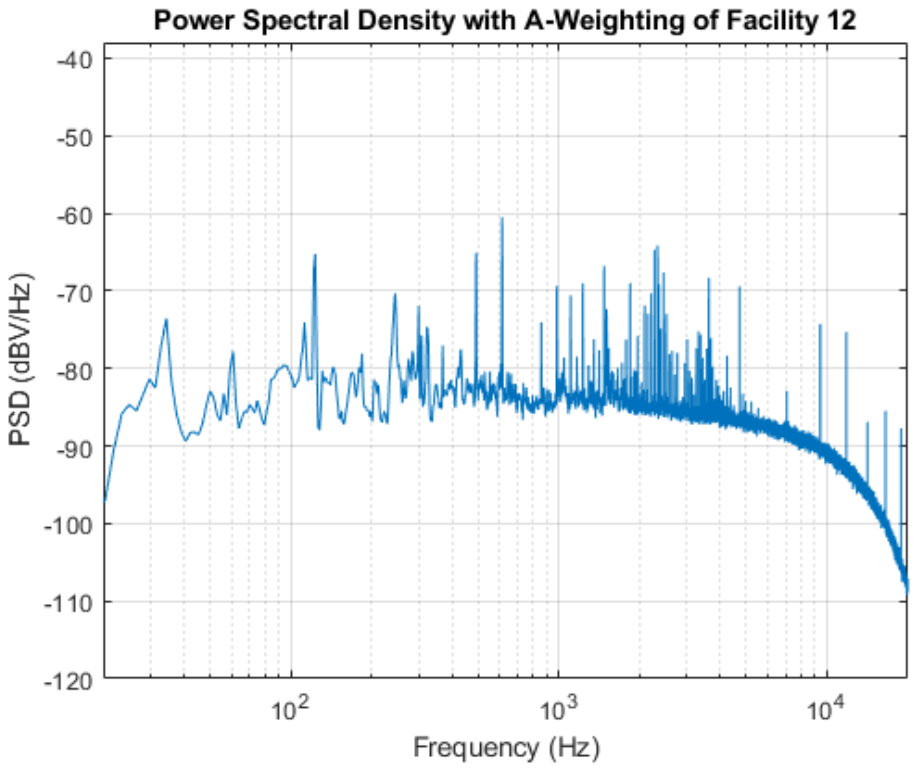
Appendix Figure 21 A-Weight Power Spectral Density Hospital Facility 9



Appendix Figure 22 A-Weight Power Spectral Density Hospital Facility 10



Appendix Figure 23 A-Weight Power Spectral Density Hospital Facility 11



Appendix Figure 24 A-Weight Power Spectral Density Spectrogram Hospital Facility 12

Appendix C Device Validation Check Sheet

This appendix contains sample pages from the device validation check sheet for user reference.

PITT | SWANSON ENGINEERING

HEARING FOR HEALTH

DEVICE VALIDATION CHECKSHEET

Prepared By: Jacalynn Sharp

Version: A

Date: 11/7/2019

Principal Investigator: Jeffrey Vipperman, PhD
Catherine Palmer, PhD

Version Number	Date	Author	Notes
A	11/7/2019	Jacalyn Sharp	Original Version

Appendix Figure 25 Title Page to Device Validation Check Sheet

PERFORMANCE CHECK LIST

Operation

- ☐ Slide on-off button forward.
  - Yellow indicator will become solid yellow if functional.
- ☐ Open up cover.
  - Middle indicator should blink for 3-4 seconds (red or green)
  - Indicator light will turn solid green when testing is ready.

Environmental Test & Order Verification

- ☐ Press Environmental Test Button
  - Indicator light should blink green for 5 seconds.
  - Indicator light will then go solid green for 5 seconds.
  - If no other button has been pushed, the middle indicator light will blink red for 3 seconds
  - Indicator light will resume to solid green, ready for testing again.
- ☐ Press Hearing Screening button
  - Indicator light should remain solid green.
  - Press environmental test button and allow program to run.
  - If pressing the environmental test button results in the above status lights, the system is clear.
  - If the hearing screening commences, this performance check has failed.

Hearing Screening

- ☐ Press Environmental Test Button
  - Indicator light should blink green for 5 seconds.
  - Indicator light will then go solid green, press the hearing screening button.
- ☐ Screening Lights
  - 1st light blinks for one second and then goes solid green
  - 2nd light blinks for one second and then goes solid green
  - 3rd light blinks for one second and then goes solid green
  - 4th light blinks for one second and then goes solid green
  - 5th light blinks for one second and then goes solid green
  - 6th light blinks for one second and then goes solid green
- ☐ Screening Tones
  - 1000 Hz in right ear (1st light blinks)
  - 2000 Hz in right ear (2nd light blinks)
  - 4000 Hz in right ear (3rd light blinks)
  - 1000 Hz in left ear (4th light blinks)
  - 2000 Hz in left ear (5th light blinks)

Appendix Figure 26 Page 1 to Device Validation Check Sheet

- 4000 Hz in left ear (6th light blinks)

☐ Reset Display

- Once tones have finished playing, indicator light will flash red for 1 second.
- Indicator light will become solid red for 5 seconds.
- Indicator light will flash red for 2 seconds.
- Indicator light returns to green, ready for next test.

Mode Switching

☐ Shut cover of device.

- Allow device to remain in testing mode by leaving the device on but not turning up the volume knob.
- If the hearing screening plays after 20 seconds of wait time, the device has failed inspection.

Amplification mode

☐ Amplification mode

- Turn knob on side of box. Audible click should be heard when changing mode.
- Sound should be heard out of right speaker.
- Sound should be heard out of left speaker.

☐ Loudness Check

- Scroll volume knob up to maximum, sound should grow as scrolling.

Other Functional Tests

☐ Temperature Regulation

- Allow device to remain on for 5 minutes.
- Check for extreme warm locations in box.
- If none are found, device passes.

☐ Durability

- Shake device vigorously for 30 seconds.
- Turn on device and ensure all tests are operational.

Check List Completed By (Initials, Print): _____

Appendix Figure 27 Page 2 to Device Validation Check Sheet

Appendix D Device Instruction Sheet

This appendix contains sample pages from the device instruction set for user reference including the title page and body pages.

HEARING FOR HEALTH

HEARING SCREENING INSTRUCTION SET

Prepared By: Jacalynn Sharp

Version: A

Date: 11/7/2019

Principal Investigator: Jeffrey Vipperman, PhD
Catherine Palmer, PhD

Version Number	Date	Author	Notes
A	11/7/2019	Jacalynn Sharp	Original Version

Appendix Figure 28 Title Page to Device Instruction Set

DEVICE ORIENTATION AND POWER UP

Orientation of the Device

1) The following image shows the orientation of the box so that it can be described in further instructions. The top orientation is the upward pointing arrow, bottom is the downward pointing arrow and right and left are given.

Figure 1: Orientation of box for instruction set

Power Up

1) To turn on the system, slide the power switch forward. It can be found on the ride side of the box.

2) Once the device is powered up, a yellow indicator light will turn on to notify the user that power is on.

Figure 2: Yellow Indicator light shows that power is running to system

Appendix Figure 29 Page 1 to Device Instruction Set

SCREENING

Enter Testing Mode

1) Roll volume knob downward until an audible click is heard or until the knob cannot be turned anymore. There should be no sound coming from the headset speakers.

2) Place the headset on the patient.

3) Open the cover to the device, allowing the cover to swing down.

4) The middle indicator light will blink rapidly for 3 seconds until the microcontroller boots up. Do not press any of the buttons.

5) Once the device is ready to test, the middle indicator light will become solid green.

Figure 3: Middle indicator light on front face will become solid green when ready to test

Environmental Test

1) To initialize the environmental test, firmly press down on the left button as shown in Figure 4. Remove finger and wait for environmental test to be conducted.

Figure 4: Environmental button being pressed

Appendix Figure 30 Page 2 to Device Instruction Set

2) The device will now test the sound level of the environment for 5 seconds, flashing the middle indicator light green as it tests.
    a. If the test fails, the indicator light will become red once the 5 seconds has lapsed.
    b. Find a new area to test in or try and isolate the noise source.

3) If the test passes, the indicator light will go solid green, and the hearing screening can begin.

*NOTE: DO NOT PUSH ANY OTHER BUTTONS WHILE THE ENVIRONMENT IS BEING TESTED.

Hearing Screening

1) To start the hearing screening, press firmly on the screening button on the right. This must be done within 5 seconds, or the environmental test must be conducted again. Remove finger and wait for hearing screening to be conducted.
    a. If the button is not pressed within the time allotted, the light will flash red for 3 seconds and then become solid green.
    b. Once the light is solid green, the environment can be tested again.

Figure 5: Hearing Screening button pressed

2) Once the hearing test has begun, the lights will flash for 1 second as their respective tone is being played:
    a. Light 1 – 1 kHz, Right Ear
    b. Light 2 – 2 kHz, Right Ear
    c. Light 3 – 4 kHz, Right Ear
    d. Light 4 – 1 kHz, Left Ear
    e. Light 5 – 2 kHz, Left Ear
    f. Light 6 – 4 kHz, Left Ear

3) Once the tone has been played, the light will go solid green throughout the duration of the hearing screening.

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Figure 6: Hearing Screening Lights as Test Proceeds

4) Once the test has completed, the boards will go through a reset cycle. The middle indicator light will first flash red for 1second, become solid red for 5 seconds, and then flash red for 1 more second.

Figure 7: Device in Reset Mode

5) The light will then become solid green when the system is ready to test again.

6) Close the cover ensuring that the snap fit has been locked in place. Closing the cover should turn off the light display.

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AMPLIFICATION MODE

1) In order to enter amplification mode, simply roll the knob on the right side of the box upward until an audible click is heard.

2) To increase volume simply roll the knob upward until the knob can no longer turn. This will set to maximum amplification.

*Note: Ensure that patient does not direct microphone within 8", towards speakers of headsets to remove chances of feedback noise.

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