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TITLE: Field-Deployable Intensimetric Probe System for Early Diagnosis and Monitoring of Noised-Induced Hearing Loss and Traumatic Middle Ear Injury

PRINCIPAL INVESTIGATOR: Gabrielle R. Merchant, AuD, PhD

CONTRACTING ORGANIZATION: Father Flanagan's Boys' Home DBA Boys Town National Research Hospital (BTNRH), Omaha, NE

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14. ABSTRACT The goal of this project is to develop field-deployable technology for the early diagnosis and monitoring of NIHL and traumatic middle-ear injury in Service Members and Veterans, enabling both the more accurate evaluation and the application of preventative therapies and treatments for hearing injuries. Our main objective is to develop and validate a highly innovative intensimetric probe system that has a microphone for sensing acoustic pressure, and a velocimeter for sensing acoustic velocity, allowing for the direct measurement of acoustic impedance, without the need for Thévenin calibration. This will allow for the reliable assessment of middle and inner-ear auditory function ear function without the need for complex daily Thévenin calibration in a package that is suitable for field use. The first aim of the project is to refine an intensimetric probe system for the detection of hearing injury. We have accomplished this goal. During the reporting period, we assembled, calibrated, debugged, and tested one Beta prototype probe, developed a calibration procedure for the Microflown velocity sensor, updated the firmware to improve noise rejection for distortion product otoacoustic emissions (DPOAEs), and developed a MATLAB user interface for the probe. The second and third aims are laboratory and clinical validation of the intensimetric probe system, and we are making strong progress towards accomplishing those aims. During the reporting period, we prepared the documentation and software necessary for recruitment and testing, completed troubleshooting of the prototype probe in human subjects, began recruitment and data collection, and completed preliminary analyses of pilot data collection. To date, we have collected data on 49 participants (including 10 pilot participants). Preliminary analyses demonstrate that the Creare intensimetric probe is both accurate and reliable as compared to a commercial probe system (the Interacoustics Titan). Further, the Creare intensimetric probe may demonstrate increased reliability, at least for impedance-based measurements like wideband reflectance and absorbance, which is likely a result of directly measuring both pressure and velocity as opposed to solving for velocity through use of a Thevenin calibration.					
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1. INTRODUCTION:

The goal of this project is to develop field-deployable technology for the early diagnosis and monitoring of noise-induced hearing loss (NIHL) and traumatic middle-ear injury in Service Members and Veterans, enabling both more accurate evaluation and the application of preventative therapies and treatments for hearing injuries. Our main objective is to develop and validate a highly innovative intensimetric probe system. We previously built a mobile intensimetric probe system prototype that has a microphone for sensing acoustic pressure, and a velocimeter for sensing acoustic velocity, allowing for the *direct* measurement of acoustic impedance, without the need for Thévenin calibration. This work will further develop and refine the prototype for reliable assessment of middle and inner-ear auditory function without the need for complex daily Thévenin calibration in a package that is suitable for field use. This will be accomplished through the completion of three specific aims: 1) Refine an intensimetric probe system for the detection of hearing injury; 2) Laboratory validation of intensimetric probe system; and 3) Clinical validation of intensimetric probe system.

2. KEYWORDS:

Noise-induced hearing loss, Middle ear injury, Otoacoustic emissions, Ear canal reflectance.

3. ACCOMPLISHMENTS:

What were the major goals of the project?

We are completing Year 2 (months 13-24) of a 3-year award. Actual completion dates are noted for tasks that had targeted completion dates in Years 1 and 2.

Specific Aim/Task	Target Completion Date (Months)	Actual Completion Date (Months)
SPECIFIC AIM 1: Refine an intensimetric probe system for the detection of hearing injury.		
Major Task 1: Miniaturize electronics and develop compact packaging	1-6	9
Major Task 2: Develop firmware	1-6	9
Major Task 3: Develop software	6-14	17

Major Task 4: Evaluate probe performance	6-10	8-20
Major Task 5: Dissemination of results	10-14	Abstract for ARO in Prep
SPECIFIC AIM 2: Laboratory validation of intensimetric probe system.		
Major Task 1: Prepare for recruitment and testing	6-15	15
Major Task 2: Recruitment and data collection	16-31	Ongoing
Major Task 3: Data analysis	20-32	Ongoing
Major Task 4: Dissemination of results	20-36	Abstract of pilot data in prep for ARO or AAS meeting
SPECIFIC AIM 3: Clinical validation of intensimetric probe system.		
Major Task 1: Recruitment and data collection	16-31	Ongoing
Major Task 2: Data analysis	20-33	Ongoing
Major Task 3: Dissemination of results	21-36	Abstract of pilot data in prep for ARO or AAS meeting

What was accomplished under these goals?

SPECIFIC AIM 1: Refine an intensimetric probe system for detection of hearing injury.

The goal of this aim is to develop a next-generation probe and evaluate its performance in the laboratory.

During the reporting period we:

- Assembled, calibrated, debugged, and tested one Beta prototype probe.
- Developed a calibration procedure for the Microflow velocity sensor.
- Updated the firmware to improve noise rejection for DPOAEs.
- Developed a MATLAB user interface for using our probe.
- Evaluated the performance of our probe compared to a Titan probe.

These items are detailed in the following sections.

1.1. Task 1: Develop Hardware (Miniaturize electronics and develop compact packaging).

1.1.1. Hardware Assembly.

As shown in **Figure 1**, Creare assembled and delivered a probe. We modified a commercial headset and 3-D printed custom enclosures for both the probe head and ear cup. The probe head (bottom of figure), contains the Microflowm velocimeter and pressure sensor, two speakers, a signal conditioning board, and analog-to-digital conversion boards. This probe head is supported by a flexible green wire (which allows for a flexibility to achieve the best probe fit), and it is connected to the ear cup (top of figure) via a cable enclosed in an orange sleeve. This wire is additionally supported by a bracket to strain-relieve the cable (not shown in figure). The ear cup contains the battery and remaining electronics.



Figure 1. Assembled Creare Probe.

1.1.2. Probe Calibration.

The most challenging portion of the calibration procedure is to correctly calibrate the amplitude and phase of the Microflowm velocimeter sensor because there is no other device that can provide a reference measurement. As such, we created custom Aluminum

calibration cavities that match the outer-diameter of a plastic insert and have an internal edge that steps down to the interior-diameter of our probe (see **Figure 2** and **Figure 3**). The sections that match the interior-diameter have lengths of 12, 14.5, 17.5, and 20mm. We seal the plastic insert against the probe stem and cavern using putty. Then, we calibrate the microphone using a reference microphone. Then, knowing the internal geometry of our probe and the caverns, we can analytically compute the impedance of the system at any point as follows:

$$Z = \frac{P}{U} = \frac{Z_0 [R \exp(2ikx) + \exp(2ikL)] \exp(ik(L_p - L_u))}{R \exp(2ikL_u) - \exp(2ikL)} + 2i\pi f L_{ev}$$

Where:

- P is the pressure
- U is the velocity
- Z is the analytical impedance
- Z_0 is the characteristic impedance
- R is the reflectance at the ends of the tube
- k is the wave number
- L is the total length of the system (probe length + cavern length)
- L_p is the location of the microphone
- L_u is the location of the velocity sensor
- f is the frequency
- L_{ev} is the evanescent wavelength

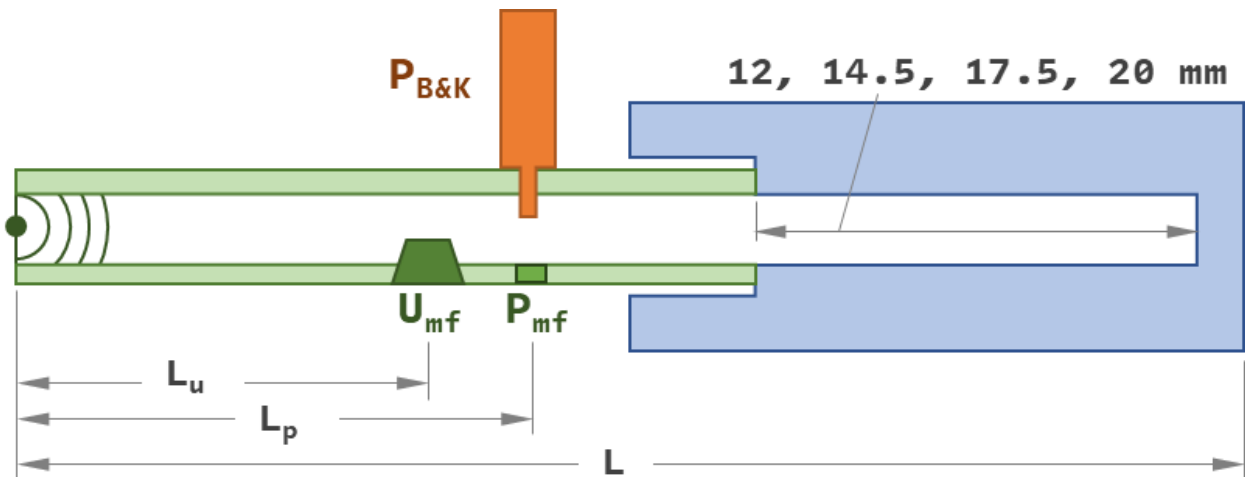


Figure 2. Calibration Procedure. We calibrate our probe (green, left) using cavities (blue, right) of various lengths. In the first step, we calibrate the pressure sensor against a B&K probe microphone (orange). In the second step we seal the pressure calibration port (remove orange component) and we calibrate the Microflown velocimeter using the analytical expression for the impedance of the system and the known (calibrated) pressure from the previous step.



Figure 3. Aluminum Cavities used for Probe Calibration.

With the pressure already calibrated, and the impedance analytically computed, we can compute what the velocity should be ($U=P/Z$) and use the value to calibrate our velocity sensor. Once we have a calibrated probe, we can compute the forward pressure level (FPL) as follows:

$$FPL = |P_2(L_m, k) + Z_0 U_2(L_m, k)|$$

Where:

- $U_2(x, k) = \frac{1}{4Z_0} \left(\left[P_m - U_m Z_0 + \frac{U_m Z_0 Z_2 - P_m Z_2}{Z_1} \right] e^{i2L_1 k} e^{-iL_m k} + \left[P_m + U_m Z_0 + \frac{P_m Z_2 + U_m Z_0 Z_2}{Z_1} \right] e^{iL_m k} \right) e^{-ikx} - \frac{1}{4Z_0} \left(\left[P_m + U_m Z_0 - \frac{U_m Z_0 Z_2 + P_m Z_2}{Z_1} \right] e^{-i2L_1 k} e^{iL_m k} + \left[P_m - U_m Z_0 + \frac{P_m Z_2 - U_m Z_0 Z_2}{Z_1} \right] e^{-iL_m k} \right) e^{ikx}$
- $P_2(x, k) = \frac{1}{4} \left(\left[P_m - U_m Z_0 + \frac{U_m Z_0 Z_2 - P_m Z_2}{Z_1} \right] e^{i2L_1 k} e^{-iL_m k} + \left[P_m + U_m Z_0 + \frac{P_m Z_2 + U_m Z_0 Z_2}{Z_1} \right] e^{iL_m k} \right) e^{-ikx} + \frac{1}{4} \left(\left[P_m + U_m Z_0 - \frac{U_m Z_0 Z_2 + P_m Z_2}{Z_1} \right] e^{-i2L_1 k} e^{iL_m k} + \left[P_m - U_m Z_0 + \frac{P_m Z_2 - U_m Z_0 Z_2}{Z_1} \right] e^{-iL_m k} \right) e^{ikx}$
- $L_m = 0.5(L_u + L_p)$
- U_m is the calibrated velocity measured by the Microflow sensor
- P_m is the calibrated pressure measured by the Microflow sensor
- $Z_1 = \frac{Z_0}{A_1}$
- $Z_2 = \frac{Z_0}{A_2}$
- A_1 and A_2 are the cross-sectional areas of the probe and ear, respectively, where we use a diameter of 7.5 mm for A_2

We use this FPL to compute the level correction needed to produce consistent amplitudes for stimuli during the DPOAE exam. We also use U_2 and P_2 to compute the impedance, reflectance, and absorbance, since we found that this most closely matches the Thévenin-based Titan probe results.

The full probe calibration procedure is described in detail in the following sections.

Speaker Calibration. To calibrate the speakers, we insert the probe into a Type 4157 Bruel & Kjaer (B&K) ear simulator. We then use Creare's automatic calibration procedure to produce 45 dB pure tones as measured by the ear simulator microphone. **Figure 4** shows the verification plot during calibration for a 10kHz tone, while **Figure 5** shows the resulting calibration.

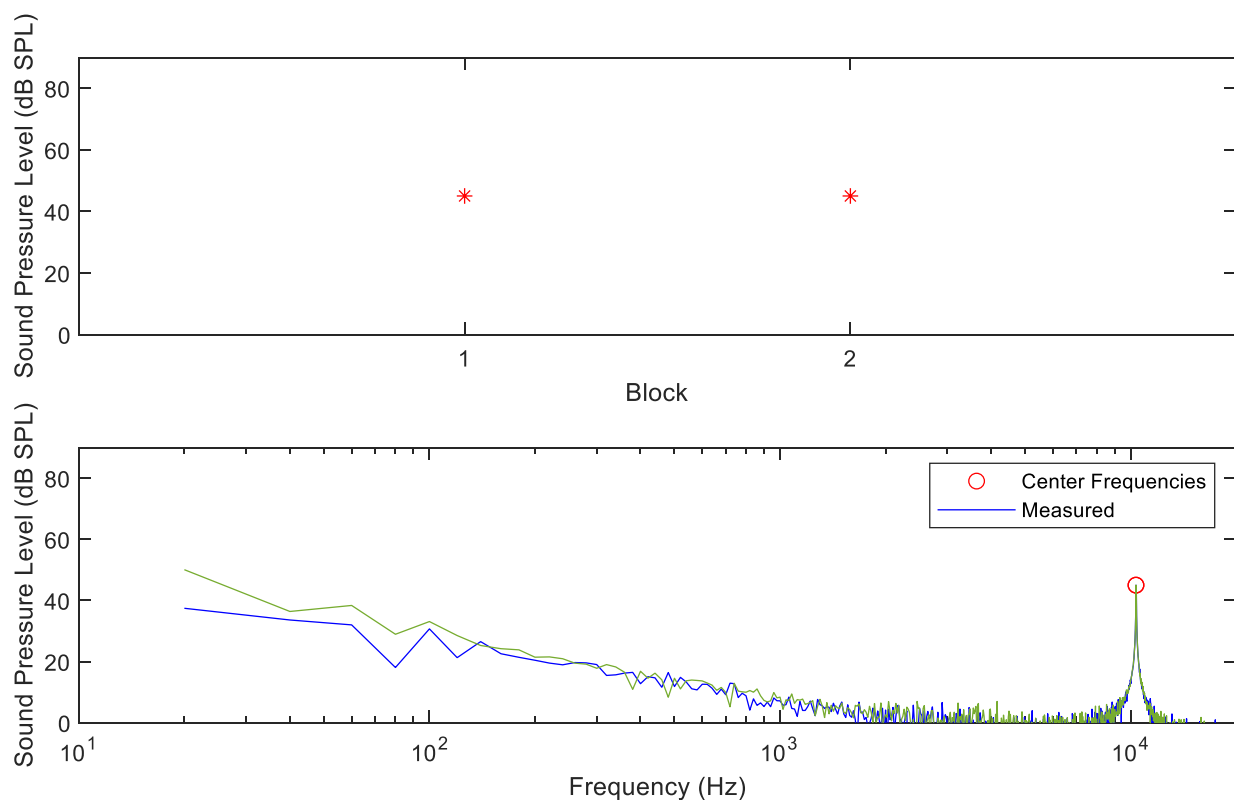


Figure 4. Speaker Calibration. The top plot shows the measured sound amplitude for two measurement blocks. The bottom shows the sound pressure level measured by the ear simulator for two different blocks (blue and green) for 10kHz frequency.

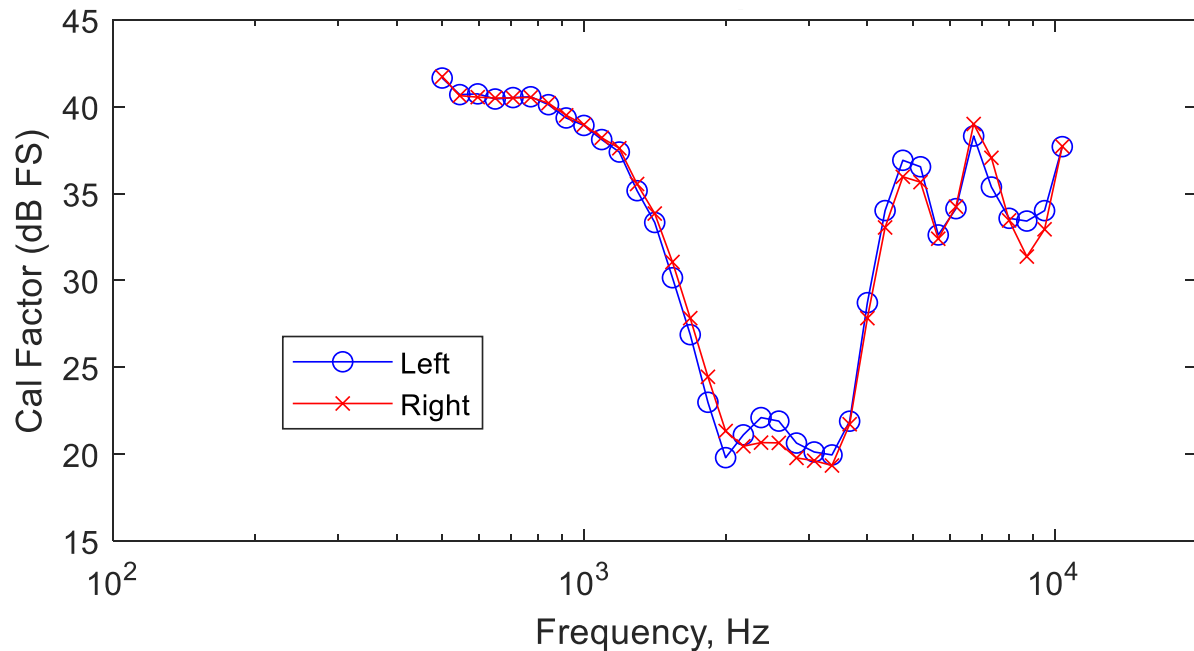


Figure 5. Creare Probe Speaker Calibration Curves. The left and right speakers match well.

Microphone Calibration. To calibrate the Microflown microphone, we insert a B&K probe microphone into a calibration port right above our microphone (see **Figure 6**). Then we insert the Creare probe into one of the calibration cavities and use our data collection routines to play a linear chirp at 75 dB SPL, recording simultaneously from both microphones. We repeat this procedure for all four calibration cavities.

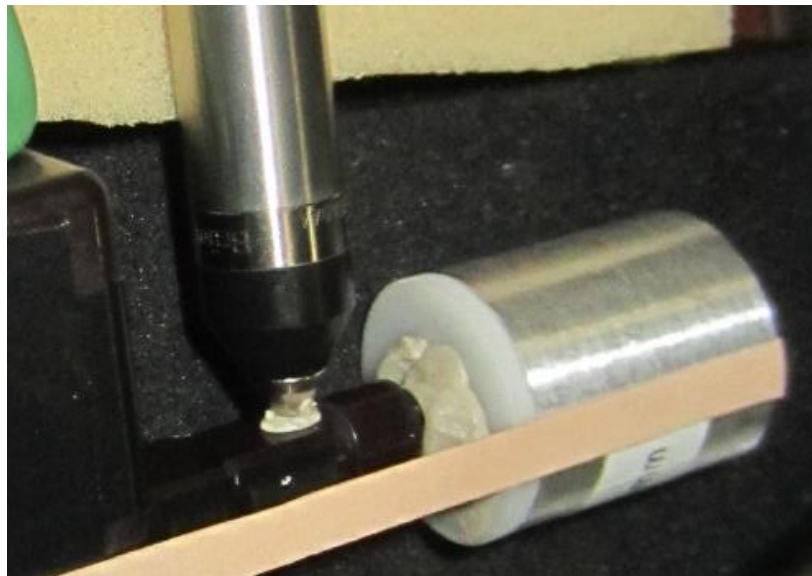


Figure 6. Pressure Calibration. We use a reference probe microphone to calibration the Microflown microphone.

We only solve for the amplitude calibration (setting the phase correction to zero), and we fit an 11th order polynomial through the required scaling factor needed to convert raw counts to Pa. After this step, we have a pressure amplitude calibration curve, and the results compared to the B&K reference microphone are shown in **Figure 7**.

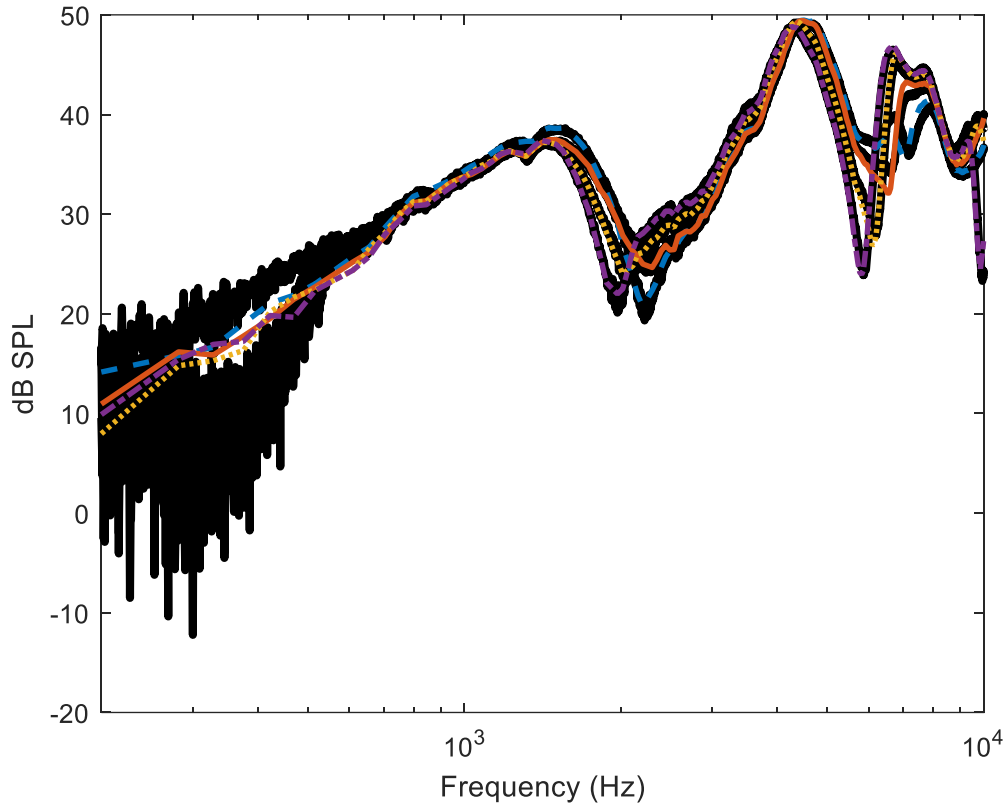


Figure 7. Comparison of Reference (Black) and Calibrated (Colored) Microphone for Different Caverns.

Velocimeter Calibration. To calibrate the Microflown velocimeter, we seal the microphone calibration port, and repeat the same procedure to collect the data.

Our calibration routines solve for the actual system length and evanescent wavelengths by ensuring the locations of the first two maximums and minimums in the measured impedance match the theoretical ones. With these lengths, we then compute the corrections in amplitude and phase needed (see **Figure 8**) for the velocity measurement so that the measured and theoretical impedance match. We fit a 9th order polynomial to the amplitude calibration, and a 4th order polynomial to the phase calibration. Note, the velocimeter's phase correction also includes the phase errors in the pressure sensor, which is not an issue for this application. To verify the data is consistent, we plot the measured and theoretical impedance after calibration for this data in **Figure 9**, as well as the reflectance in **Figure 10**. Above 0.5-1kHz, the calibrated and theoretical values match well. The final pressure and velocity calibration curves are shown in **Figure 11**.

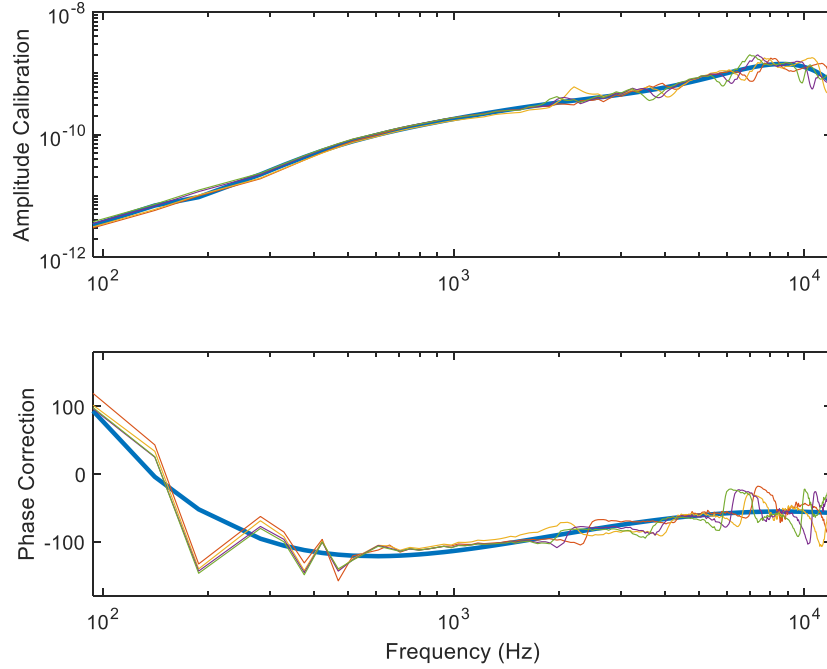


Figure 8. Velocimeter Calibration. We fit polynomials (thick blue lines) to the corrections (thin colored lines) needed to calibrate the velocimeter amplitude (top) and phase (bottom).

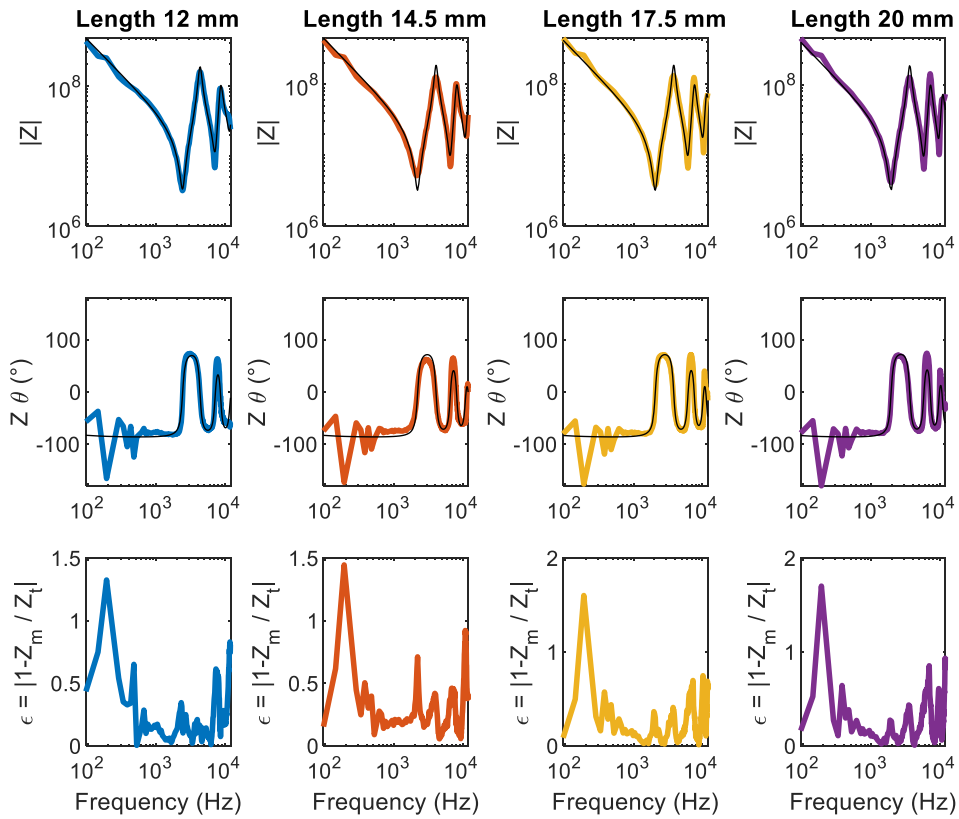


Figure 9. Calibrated (Thick Colored) Versus Theoretical (Thin Black) Impedance after Velocimeter Calibration.

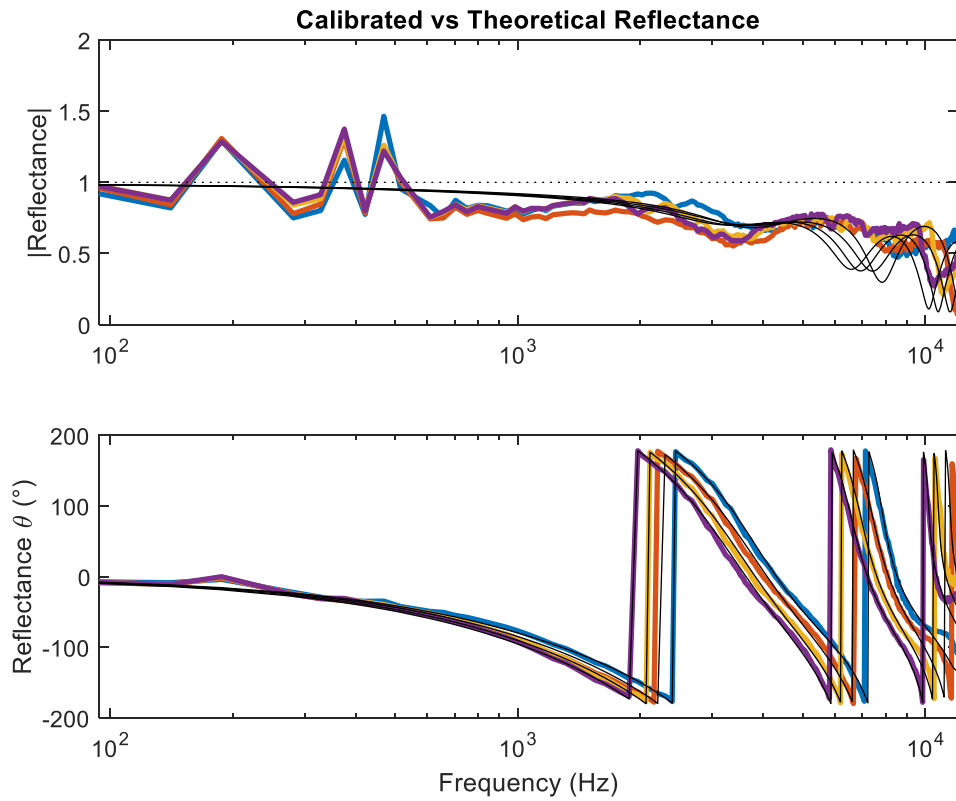


Figure 10. As in Figure 9, but for Reflectance.

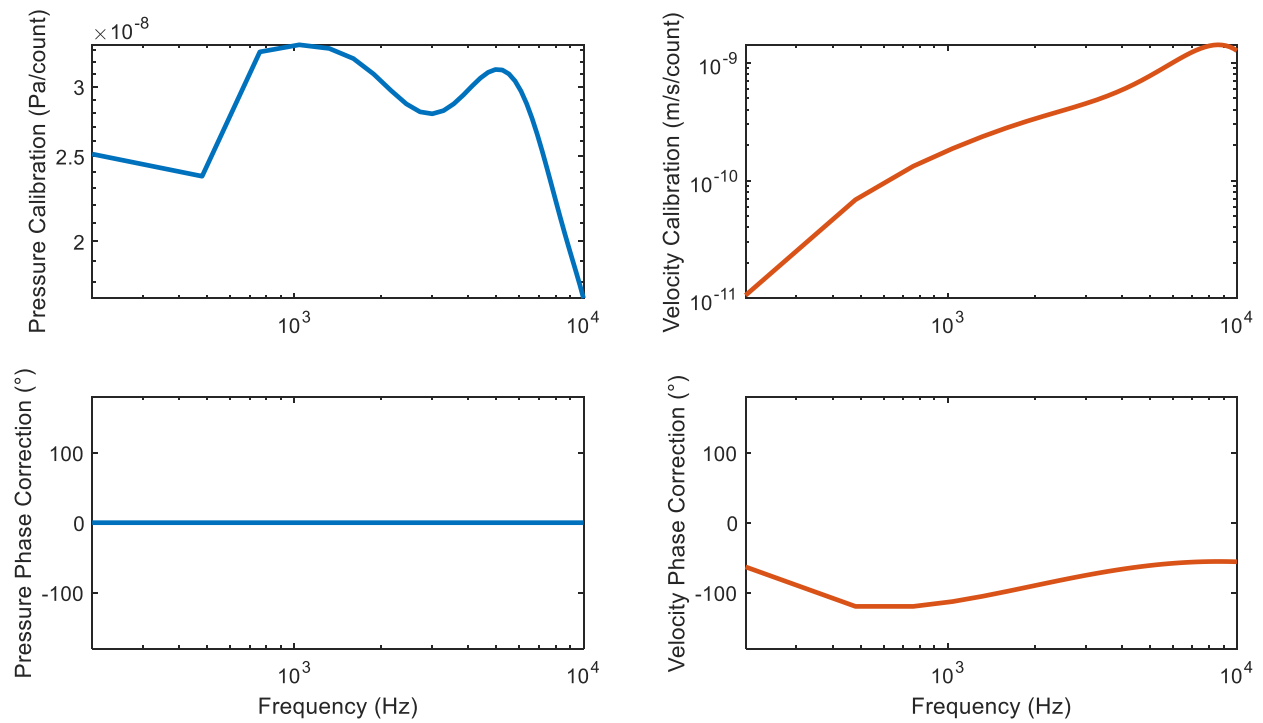


Figure 11. Final Pressure (left) and Velocity (right) Calibration Curves.

1.2. Task 2. Develop Firmware.

1.2.1. Firmware Updates.

During the reporting period, we updated the firmware to improve noise rejection for DPOAEs. The previous version of the noise rejection algorithm had been observed to report unrealistically low noise floors which were significantly lower than the DPOAE levels, even when there was no DPOAE present, such as in an artificial ear. The key differences from the previous algorithm are as follows:

Calculation of Noise Floor from a Single Block of Data. The previous algorithm calculated the noise floor as the average amplitudes of the “noise floor bins” (i.e., the frequencies near the DP frequency). The new algorithm calculates it as the root mean square of the amplitudes of those bins—properly recognizing that the squared amplitudes should follow a chi-squared distribution. Additionally, since the FFTs are calculated using fixed-point arithmetic, the new algorithm assumes that the minimum noise level is one least-significant bit.

Calculation of Noise Floor Uncertainty. The previous algorithm calculated the noise floor uncertainty as the standard deviation of the amplitudes of the “noise floor bins.” This necessarily underestimates the uncertainty caused by the mixed phases of noise. The new algorithm calculates it as equal to the noise floor—a property of the chi-squared distribution.

Calculation of Noise Floor from Multiple Blocks of Data. The previous algorithm calculated the noise floor from multiple blocks of data by averaging the FFTs and then computing the noise floor from the averaged FFT. This can be problematic when using the averaged noise floor level as a criterion for inclusion of that block because it leads the algorithm to selectively include blocks such that the complex values of the noise floor bins sum to zero. The new algorithm calculates the noise floor from each block individually and then explicitly calculates the noise floor of the average by assuming the phases of the noise in the two blocks are uncorrelated. This more accurately reflects that (1) the single-block noise floor is an estimate of the noise level at the DP frequency, and (2) the phase of the noise at the DP frequency is unknown.

1.3. Task 3. Develop Software.

1.3.1. User Interface Development.

During the reporting period, we developed a MATLAB user interface (UI) for data collection with our probe (**Figure 12**). The user interface has buttons to administer a reflectance/impedance test (left) and a DPOAE test (right). The DPOAE test runs twice, first in SPL without a forward pressure level (FPL) correction, and after with one. The bottom-right-hand plot displays the level correction needed for the first DPOAE (blue) and level-corrected DPOAE (red).

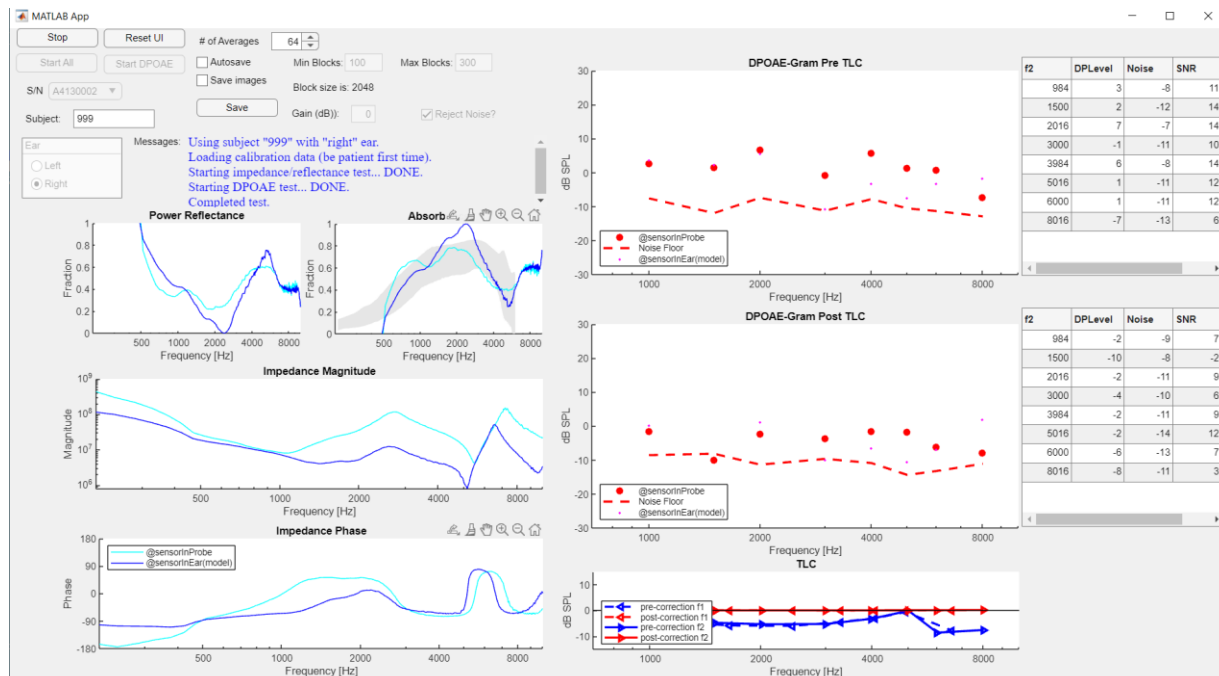


Figure 12. MATLAB UI. The left side displays the results of a reflectance/impedance test, while the right side focuses on DPOAE without (top) and with (bottom) FPL correction.

1.4. Task 4. Evaluate Probe Performance.

1.4.1. Performance Evaluation.

To evaluate and verify the probe performance, we test the calibrated probe using the B&K ear simulator. First, we determine the noise characteristics of the sensors by recording data while the probe is inserted in the ear simulator, but the speakers are not making a sound. The recorded data is averaged using the DPOAE averaging algorithm for 200 blocks, where each block is 2048 samples. From testing, we hit the noise floor at about 100 blocks. As shown in **Figure 13**, the pressure sensor noise is below -5 dB SPL above about 1kHz, while the velocimeter multiplied by the characteristic impedance is around 28 dB. Because the velocity noise floor is so high, we cannot accurately estimate the sound emitted by the ear drum using this approach, but we can still correct the FPL since the speaker tones are at a high enough level.

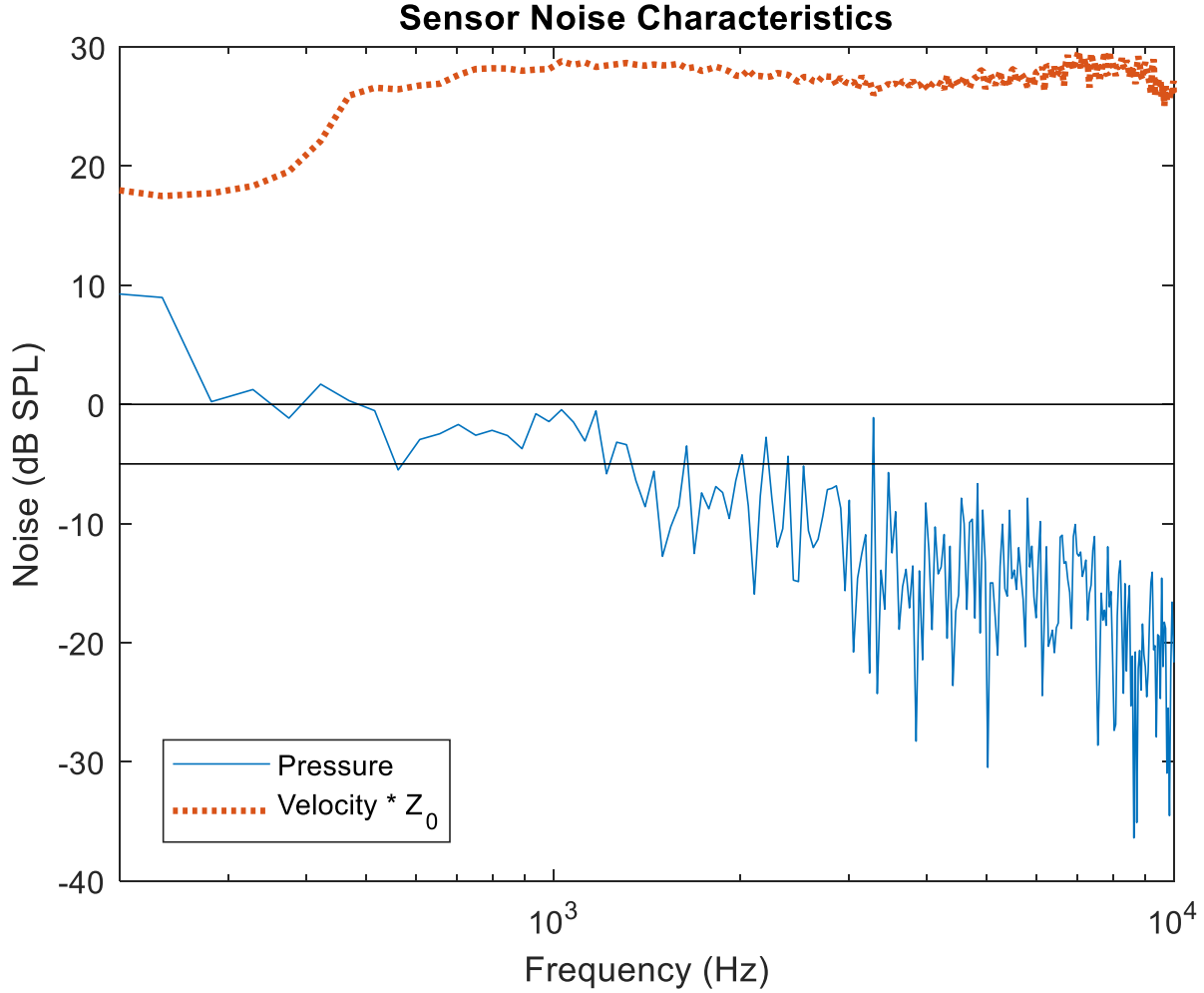


Figure 13. Probe Noise Characteristics using DPOAE Averaging 200 Blocks.

To validate our approach for the FPL computation, we play a chirp using one of the speakers while the probe is inserted in the ear simulator, and we record the sound with both the probe and the reference microphone. Then, we use the FPL to predict the pressure amplitude measured by the ear simulator. **Figure 14** shows the result, where the top plots give the difference between measurements and the ear simulator results while the bottom plots give the absolute measured amplitudes over the different frequencies. This plot shows that our FPL estimates of the pressure amplitude at the simulated ear are better than the amplitude measured by the pressure sensor alone. As a further verification, we also plot the reflectance for the same test in **Figure 15**. In this plot, we also used our analytical model to predict the reflectance at the ear (red line), using the ear simulator geometry, and evaluating U_2/P_2 at $x=L$, instead of $x=L_m$ (yellow line). Since the model predicts a reflectance greater than one when evaluated at the ear canal entrance, we prefer the reflectance computed at the sensor, which also happens to more closely match the Thévenin-based Titan probe results.

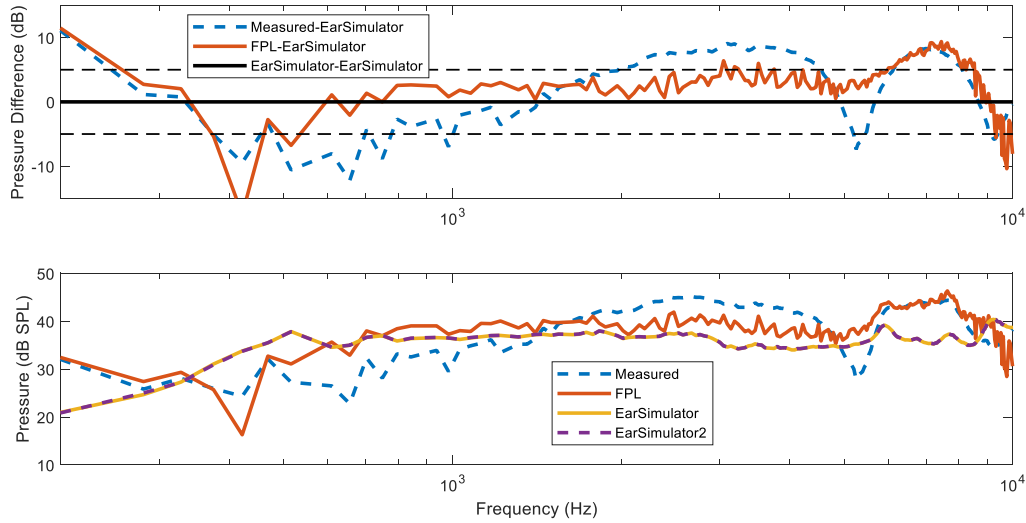


Figure 14. Sensor Validation in Ear Simulator (Pressure). The top plot shows the difference between the pressure measured by our probe and the ear simulator (blue, dashed), as well as the FPL computed by combining the velocimeter and pressure measurements (Red). The bottom plot shows the same without taking the difference. This plot also shows two chirps measured by the ear simulator during the same test. The FPL prediction is within 5 dB of the ear simulator pressure in the range of 1-6kHz, and it is closer to the correct pressure amplitude compared to the pressure measurement alone.

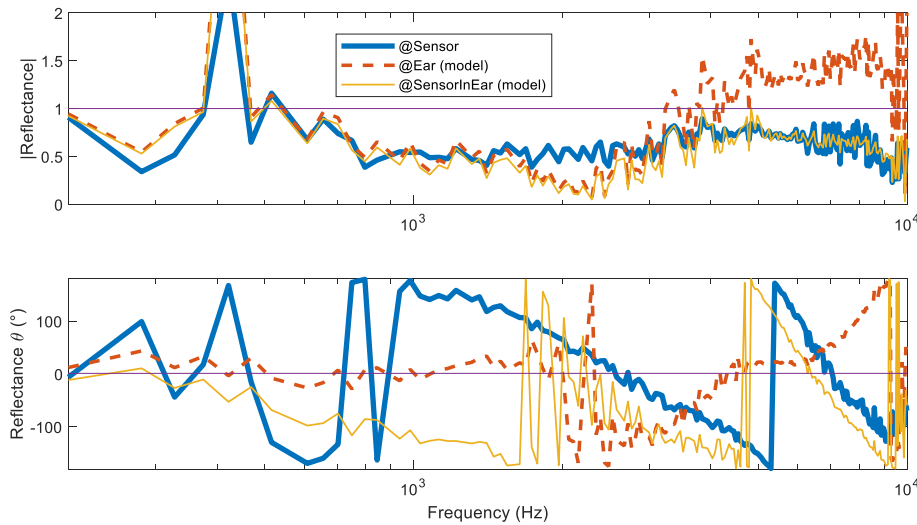


Figure 15. Sensor Validation in Ear Simulator (Reflectance). The top plot shows reflectance magnitude, and bottom gives the phase. The thick blue line displays the reflectance as measured at the sensor location (no modeling). The red dashed line models the reflectance expected at the ear simulator microphone. The thin yellow line models the reflectance at the sensor location as though the diameter of the probe matched the ear simulator diameter. Since reflectance is expected to be less than one, we do not trust the model-predicted pressure at the ear and prefer to use the FPL calculation at the sensor location (thin yellow line) instead. Additionally, we found the FPL calculation to most closely follow the Thévenin-based Titan probe measurement.

1.5. Task 5: Dissemination of Results.

1.5.1. Presentation.

An abstract of the above results is in preparation for presentation at the 2024 Midwinter Meeting of the Association for Research in Otolaryngology.

1.5.2. Lessons Learned.

In this section we record lessons learned and various issues encountered while testing the Creare probe.

- Microflown developed a custom sensor and electronics package for this project. We found that the connector between the Microflown sensor and signal conditioning board was unreliable. It caused intermittent issues, ranging from increased noise to complete failure of one of the two sensors. After careful inspection, we found debris (suspected to be residual flux) inside the connector and found improved performance after cleaning this debris.
- We had intermittent noise issues where the speakers would suddenly play high amplitude noise during tests. This only started happening after extended periods of testing. We traced the issue to the cable connecting the two halves of the device. After replacing the cable, and adding more strain relief to those wires, this issue was resolved.
- We initially used the B&K type 4157 ear simulator to calibrate the Microflown sensor, but we found that matching the pressure phase between two different data acquisition systems had too much uncertainty. We also found our original assumption that neglected the pressure phase information was not valid, since the physical location of the probe microphone and ear simulator microphone were different.
- The microphone on the Microflown sensor has slightly higher noise characteristics (~5 dB higher) than other pressure sensors used in OAE measurement applications. This has reduced the sensitivity of our DPOAE measurements at lower emission levels.

SPECIFIC AIM 2: Laboratory validation of intensimetric probe system.

Tasks completed during the reporting period under Specific Aim 2 include:

Finalize preparation for recruitment and testing.

- Troubleshooting of probe issues
- Beginning recruitment and data collection
- Preliminary analyses of pilot data collection
- Preliminary dissemination

2.1. Task 1: Prepare for Recruitment and Testing.

2.1.1. Develop Software for Data Collection with the Interacoustics Titan.

During the reporting period, we developed and customized three software interfaces using MATLAB for the Interacoustics Titan device. The Interacoustics Titan device can be run through a clinical software platform, the Titan Suite. However, there is also an option to drive the device through a research platform, but this requires the user to develop software to do so. The advantage of running the device through the research platform is that you have maximum control over how the device is running and how data are collected and processed. The clinical software suite includes proprietary signal processing algorithms that could affect comparisons to the Creare intensimetric probe system, so utilizing a custom data software platform for data acquisition allows us to make the most direct comparisons possible (Eberhard et al., 2022).

Three software graphical user interfaces (GUIs) were developed and/or customized, one to collect wideband acoustic immittance data (absorbance, impedance magnitude, and impedance phase), one to collect DPOAE data in dB sound pressure level (SPL), and one to collect DPOAE data with a forward pressure level (FPL) calibration included using the Thévenin calibration. All three software applications were thoroughly troubleshooted and debugged prior to data collection in participants. Example are shown in **Figure 16** and **Figure 17**.

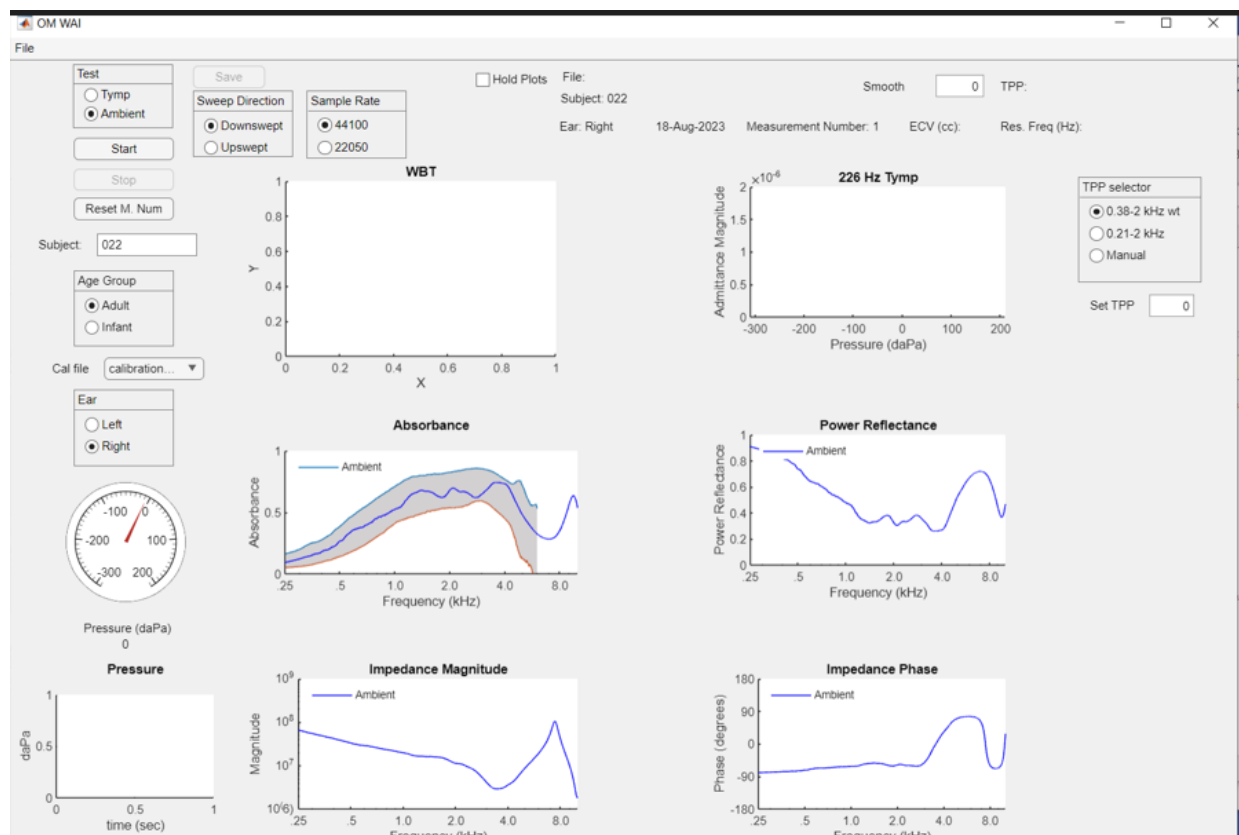


Figure 16. Screenshot of GUI developed to collect wideband acoustic immittance data.

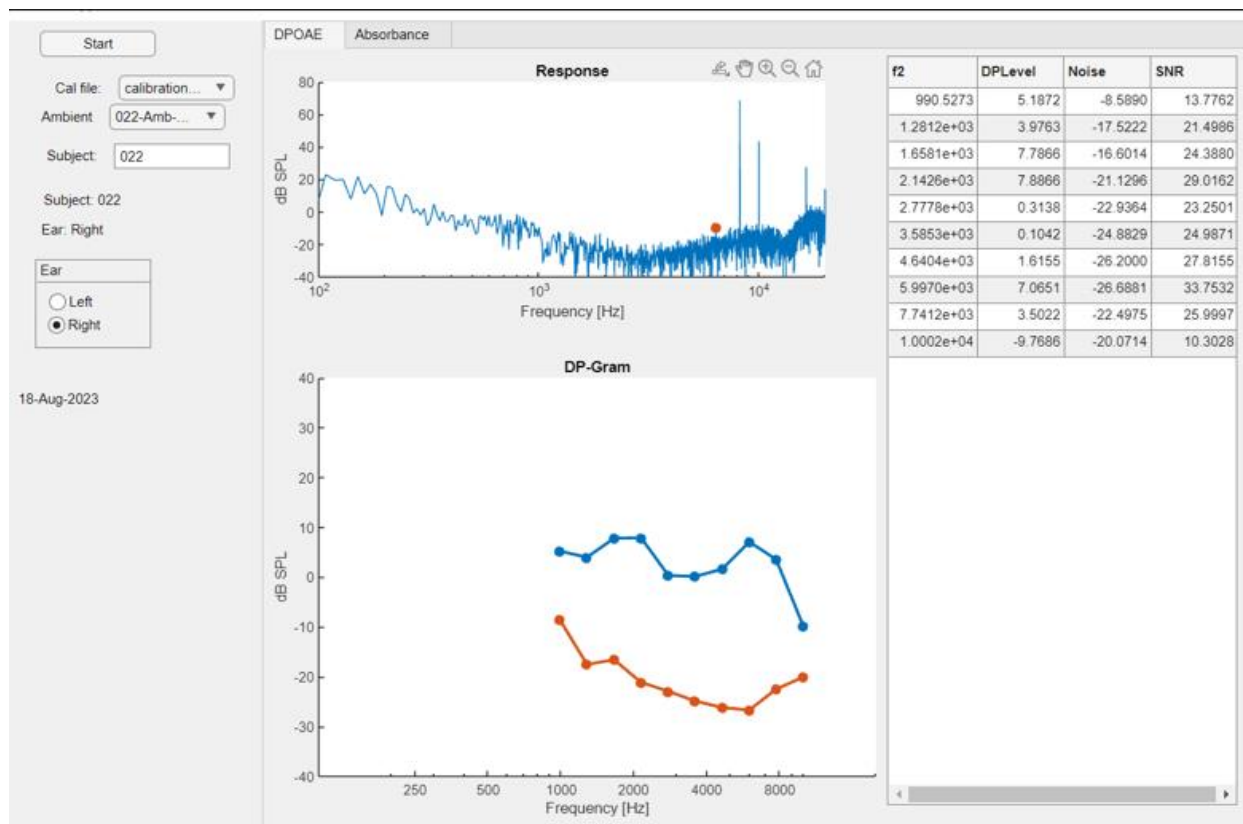


Figure 17. Screenshot of GUI developed to collect DPOAE data with FPL. The DPOAE GUI that collects data in SPL looks nearly identical.

2.1.2. Create Recruitment and Data Collection, Tools, Procedures, and Protocols.

Several tools were created to facilitate both recruitment and data collection during the last reporting period. This includes several forms for informed consent, demographic surveys, and payment, all of which were developed in REDCap. TimeTap was used to set up a way to track participant appointments, including a self-scheduler, which we find increases participation. We also created an initial contact list from the Boys Town National Research Hospital (BTNRH) research subject database based on inclusion criteria for the study and added information about the study to relevant BTNRH websites for recruitment. We also developed a number of marketing materials to facilitate participant recruitment.

Study protocols were developed based on the procedures described in the research strategy and a study binder for tracking was created.

2.2. Task 2: Recruitment and Data Collection.

2.2.1. Troubleshoot Probe.

The first step in recruitment and data collection for laboratory validation involved initial testing of the Create intensimetric probe at BTNRH. Create engineers Drs. Odile Clavier and Matt Ueckermann flew to Omaha in early February 2023 with the probe prototype to

meet in person with the BTNRH team (Drs. Merchant, Harris, and McCreery) and for initial laboratory testing and validation. This meeting allowed for direct comparisons of the prototype probe with the Titan device and for productive in-person troubleshooting. While several issues were discovered that required modifications to the probe, significant progress was made, and potential solutions identified. The teams worked together in the coming months to ensure all issues were addressed before the final prototype was delivered back to BTNRH.

2.2.2. Initial Recruitment and Data Collection.

The probe was returned to BTNRH in June 2023 and pilot testing began immediately. As of the time of this report, data has been collected on 49 participants (including 10 pilot participants). 24 of these participants have completed both study visits (with visit 2 scheduled for the remaining 15). Data was collected on both ears of 44 participants, as the second ear in the remaining 5 participants did not meet the inclusion criteria. Thus, we have collected data so far on 94 ears.

2.3. Task 3: Data Analysis.

2.3.1 Preliminary analysis of pilot data collection.

Preliminary comparisons of pilot data focused on assessing the accuracy and reliability of the intensimetric probe. To assess accuracy, comparisons were made between the intensimetric probe with the Titan device. To assess reliability, comparisons were made across multiple measurements from each probe both within a single visit (with separate probe insertions) and between visits across multiple days.

2.3.1.1. Wideband Acoustic Immittance Absorbance Data.

Figure 18 displays a representative example of wideband absorbance data collected with the intensimetric probe (left) and the Titan probe (right) from a single ear of a single participant. 3 measurements are shown: two taken on the same day with different probe insertions, and a third taken during visit 2 on a different day.

Comparing measurements between the two figures, the intensimetric probe produces absorbance tracings that are reasonably similar as compared to the Titan probe, demonstrating reasonable accuracy of the probe for these measurements. Note that data was not plotted below 500 Hz due to the noise floor of the Microflown velocity sensor.

Comparing the three measurements on each panel, the intensimetric probe appears to demonstrate substantially *less* variability than the Titan probe, suggesting the intensimetric probe may be more reliable.

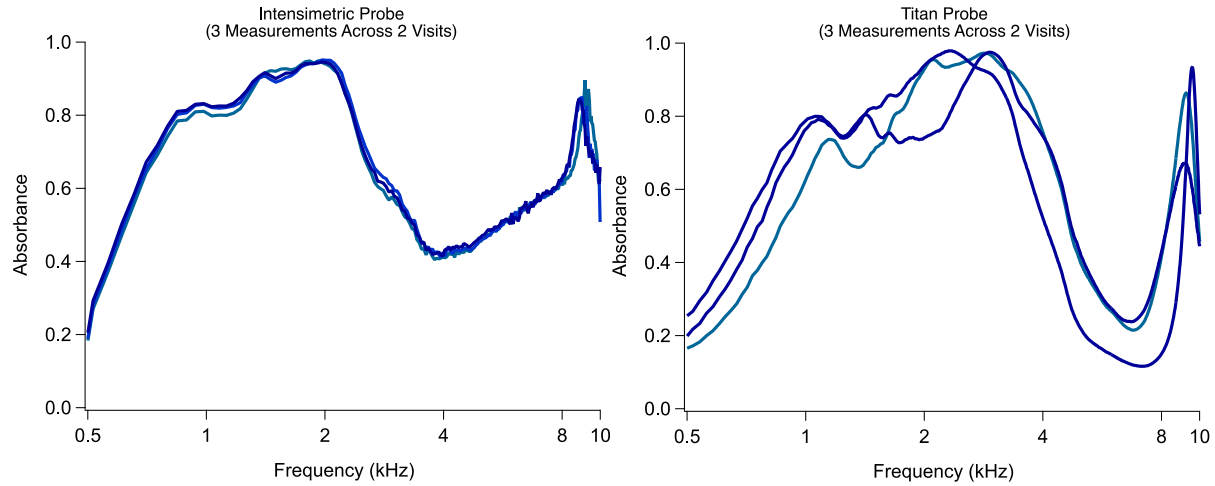


Figure 18. A representative example of wideband acoustic immittance absorbance data collected with the intensimetric probe (left) and the Titan probe (right) from a single ear of a single participant. 3 measurements are shown collected across 2 visits on two different days.

If the intensimetric probe is more reliable, this would be a significant advancement in this measurement technique, as reduced within-subject variability would significantly increase diagnostic precision. To further explore this increased reliability, individual differences between 1) measurement 1 and measurement 2 during visit 1 (i.e., two measurements on the same day) and 2) measurement 1 from visit 1 and visit 2 (i.e., two measurements from different days) were calculated for each ear of the first 10 participants. The results are shown in **Figure 19**. Both individual differences and the means and standard deviations of the individual differences are smaller and demonstrate increased reliability for measurements taken with the intensimetric probe. We hypothesize this is because the intensimetric probe is directly measuring impedance through measurement of pressure and velocity, and not solving for it through a combination of a pressure measurement and the Thévenin calibration.

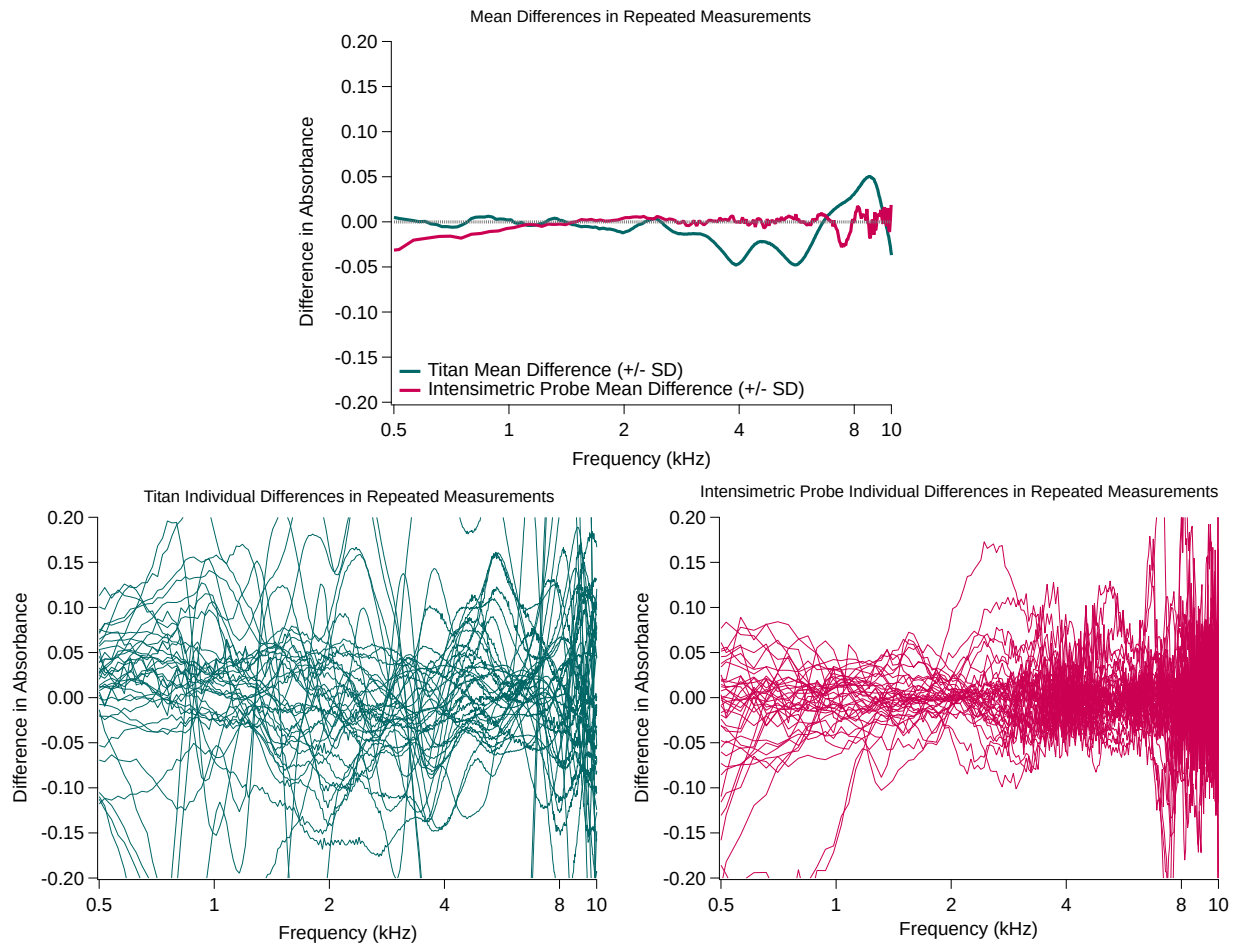


Figure 19. Average (top) and individual (bottom) differences in repeated measures between measurement 1 and measurement 2 from visit 1 (same day) and measurement 1 from visit 1 and visit 2 (different days) of each probe. Titan measurements are shown in teal and the intersimetric probe differences are shown in pink.

Statistical analyses comparing the Titan and the intersimetric probe are ongoing.

2.3.1.2. DPOAE Data.

Figure 20 displays DPOAE data from the same representative example in **Figure 18** for the intersimetric probe (top) and the Titan (bottom) in both SPL (left) and FPL (right). The higher noise floor for the intersimetric probe is apparent when comparing the top row and the bottom row. However, looking at DPOAE level across the two devices demonstrates a similar magnitude and shape of the DPOAEs across frequency, and good reliability within and across test sessions.

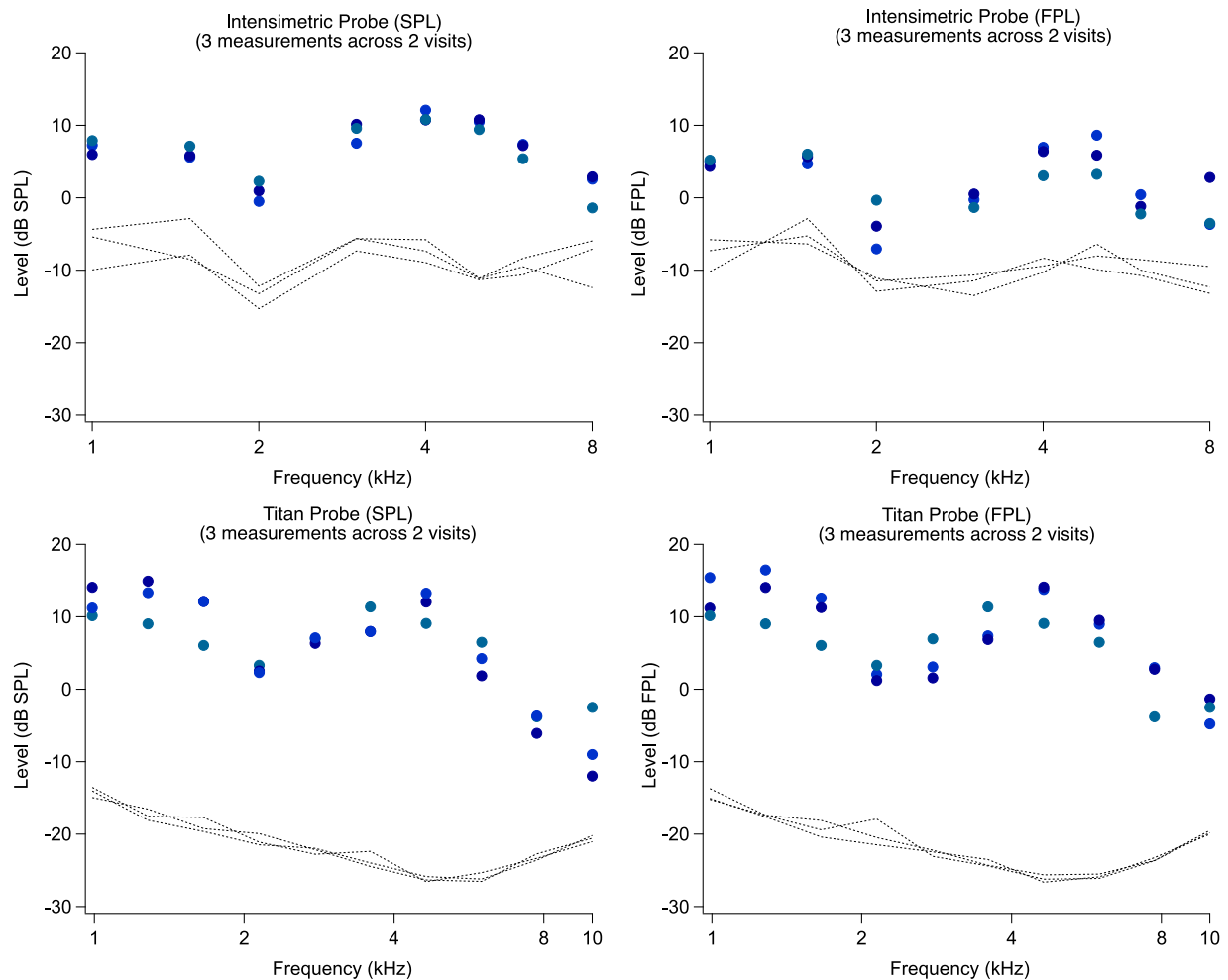


Figure 20. A representative example of DPOAE data for the intensimetric probe (top) and the Titan (bottom) in both SPL (left) and FPL (right).

Preliminary statistical analyses were completed on an initial dataset that included 10 pilot participants and 18 participants, for 28 participants total.

Bland-Altman analyses were conducted for each frequency and visit combination. Since the goal is to determine the repeatability of the probes to obtain the same reading when used repeatedly, data pairing by ear within subject and subject within visit was maintained. Measurements taken on the same subject, but different ears, were treated as an independent test of the probe.

To compare visit 1 to visit 2 within probe, the two measures at each visit were averaged, and these averages were compared via Bland-Altman Analysis. Analyses were conducted and presented by frequency, resulting in over 40 Bland-Altman plots being generated. The summaries presented here are for the average agreement and the associated confidence interval. The limits of agreement and their associated confidence intervals are not presented to provide clarity.

INTENSIMETRIC PROBE DPOAE DATA

Measurement 1 vs. Measurement 2 dB SPL

Figure 21 and **Table 1** display the Bland Altman results for the intensimetric probe in dB SPL between measurement 1 and 2 for both visits. These data suggest good agreement between repeated DPOAEs measurements taken on the same day with the intensimetric probe, with an average agreement of within 1.5 dB at all frequencies.

Figure 21. Intensimetric Probe dB SPL Comparisons: Measurement 1 vs. Measurement 2 with different probe insertions for each visit (visit 1 in black visit 2 in red). Agreement is in units of dB SPL.

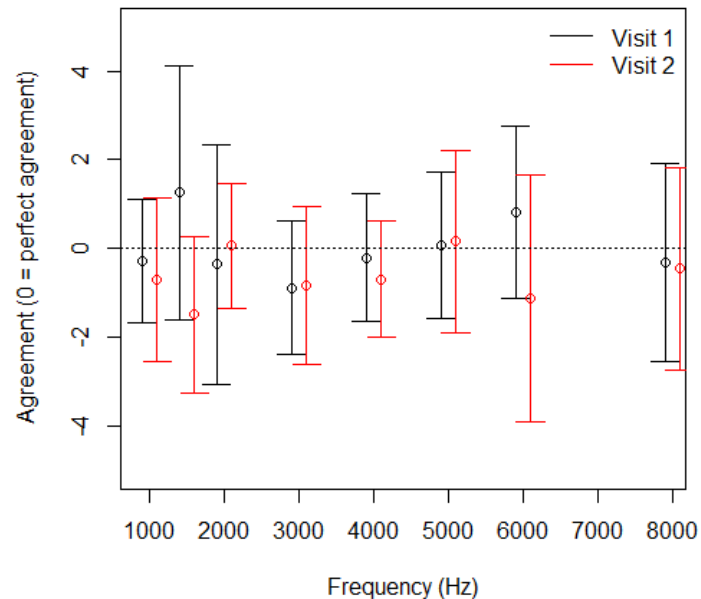


Table 1. Intensimetric probe agreement for DPOAE level (dB SPL) between measurements 1 and 2. Agreement and confidence intervals are in units of dB SPL.

Frequency	Visit	Observed	95% Confidence Interval	
		Agreement	Lower Bound	Upper Bound
1000Hz	1	-0.28	-1.67	1.11
1500Hz	1	1.26	-1.59	4.11
2000Hz	1	-0.35	-3.05	2.34
3000Hz	1	-0.88	-2.39	0.63
4000Hz	1	-0.20	-1.63	1.23
5000Hz	1	0.06	-1.58	1.71
6000Hz	1	0.82	-1.13	2.77
8000Hz	1	-0.32	-2.55	1.92
1000Hz	2	-0.70	-2.53	1.14
1500Hz	2	-1.48	-3.25	0.29
2000Hz	2	0.06	-1.35	1.48
3000Hz	2	-0.84	-2.62	0.94
4000Hz	2	-0.68	-1.98	0.61
5000Hz	2	0.16	-1.89	2.22
6000Hz	2	-1.12	-3.91	1.67
8000Hz	2	-0.45	-2.72	1.81

Measurement 1 vs. Measurement 2 dB FPL

Figure 22 and **Table 2** display the Bland Altman results for the intensimetric probe in dB FPL between measurement 1 and 2 for both visits. These data also suggest good agreement between repeated DPOAEs measurements taken on the same day with the intensimetric probe, with an average agreement of within 1.5 dB at all frequencies. Agreement averages and confidence intervals are similar between dB SPL and dB FPL.

Figure 22. Intensimetric Probe dB FPL Comparisons: Measurement 1 vs. Measurement 2 (same day) with different probe insertions for each visit (visit 1 in black, visit 2 in red). Agreement is in units of dB FPL.

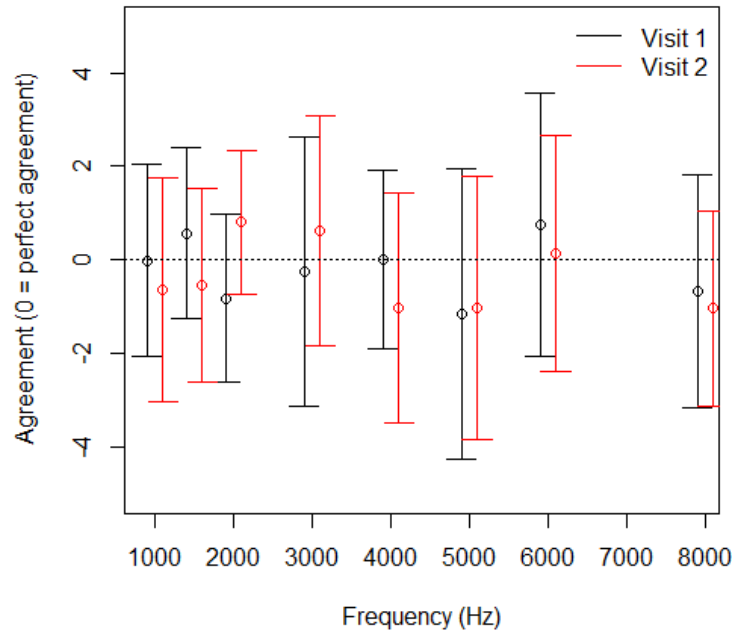


Table 2. Intensimetric probe agreement for DPOAE level (dB FPL) between measurements 1 and 2. Agreement and confidence intervals are in units of dB FPL.

Frequency	Visit 1			Visit 2		
	Average Agreement Bias	Confidence Interval		Average Agreement Bias	Confidence Interval	
		Lower Bound	Upper Bound		Lower Bound	Upper Bound
1000Hz	-0.02	-2.07	2.03	-0.62	-3.02	1.77
1500Hz	0.57	-1.26	2.40	-0.53	-2.59	1.53
2000Hz	-0.82	-2.62	0.98	0.81	-0.72	2.33
3000Hz	-0.26	-3.14	2.62	0.62	-1.84	3.07
4000Hz	0.02	-1.89	1.93	-1.02	-3.48	1.45
5000Hz	-1.14	-4.25	1.96	-1.03	-3.84	1.78
6000Hz	0.76	-2.06	3.57	0.14	-2.38	2.67
8000Hz	-0.68	-3.16	1.81	-1.03	-3.11	1.04

Visit 1 vs. Visit 2 dB SPL

Figure 23 and **Table 3** display the Bland Altman results for the intensimetric probe in dB SPL between measurement 1 from visit 1 and 2. These data suggest good agreement between repeated DPOAEs measurements taken on different days in the same ear with the intensimetric probe, with an average agreement of within 1 dB at all frequencies.

Figure 23. Intensimetric Probe dB SPL comparisons across the 2 visits (different days). Agreement is in units of dB SPL.

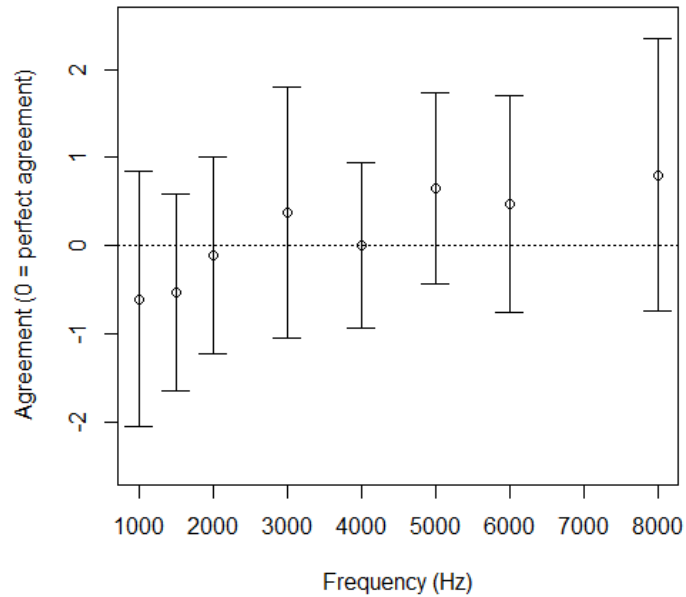


Table 3. Intensimetric probe agreement for DPOAE level (dB SPL) between visits 1 and 2. Agreement and confidence intervals are in units of dB SPL.

Frequency	Observed	95% Confidence Interval	
	Agreement	Lower Bound	Upper Bound
1000 Hz	-0.61	-2.05	0.84
1500 Hz	-0.53	-1.65	0.59
2000 Hz	-0.10	-1.22	1.01
3000 Hz	0.38	-1.04	1.80
4000 Hz	0.01	-0.93	0.94
5000 Hz	0.65	-0.44	1.74
6000 Hz	0.48	-0.75	1.71
8000 Hz	0.81	-0.73	2.35

Visit 1 vs. Visit 2 dB FPL

Figure 24 and **Table 4** display the Bland Altman results for the intensimetric probe in dB FPL between measurement 1 from visit 1 and 2. These data also suggest good agreement between repeated DPOAEs measurements taken on different days in the same ear with the intensimetric probe, with an average agreement of within 1.5 dB at all

frequencies. Agreement averages and confidence intervals are similar between dB SPL and dB FPL.

Figure 24. Intensimetric Probe dB FPL comparisons across the 2 visits (different days). Agreement is in units of dB FPL.

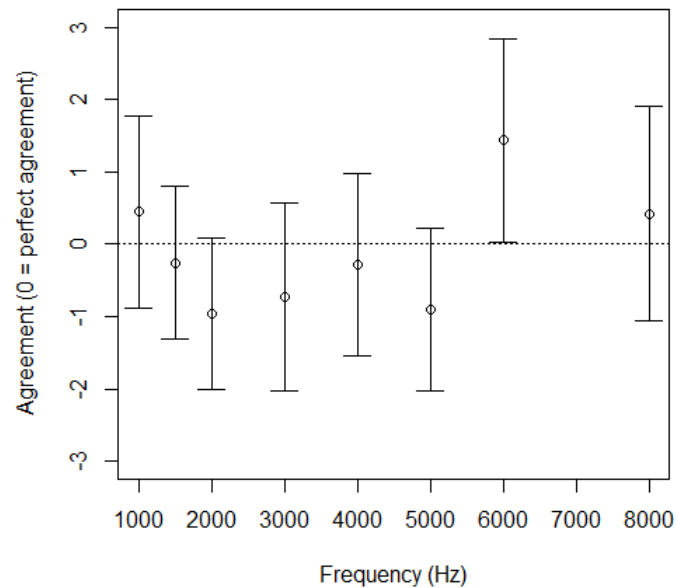


Table 4. Intensimetric probe agreement for DPOAE level (dB FPL) across visits 1 and 2. Agreement and confidence intervals are in units of dB FPL.

Frequency	Average Agreement Bias	Confidence Interval	
		Lower Bound	Upper Bound
1000 Hz	0.45	-0.89	1.78
1500 Hz	-0.26	-1.32	0.80
2000 Hz	-0.96	-2.00	0.09
3000 Hz	-0.73	-2.03	0.57
4000 Hz	-0.29	-1.55	0.97
5000 Hz	-0.91	-2.04	0.22
6000 Hz	1.44	0.03	2.84
8000 Hz	0.42	-1.06	1.91

TITAN PROBE DPOAE DATA

Measurement 1 vs. Measurement 2 dB SPL

The same analyses were completed for the Titan probe. **Figure 25** and **Table 5** display the Bland Altman results for the Titan probe in dB SPL between measurement 1 and 2 for both visits. These data suggest good agreement between repeated DPOAEs

measurements taken on the same day with the Titan probe, with an average agreement of within 1.6 dB at all frequencies.

Figure 25. Titan Probe dB SPL Comparisons: Measurement 1 vs. Measurement 2 with different probe insertions (visit 1 in black, visit 2 in red). Agreement is in units of dB SPL.

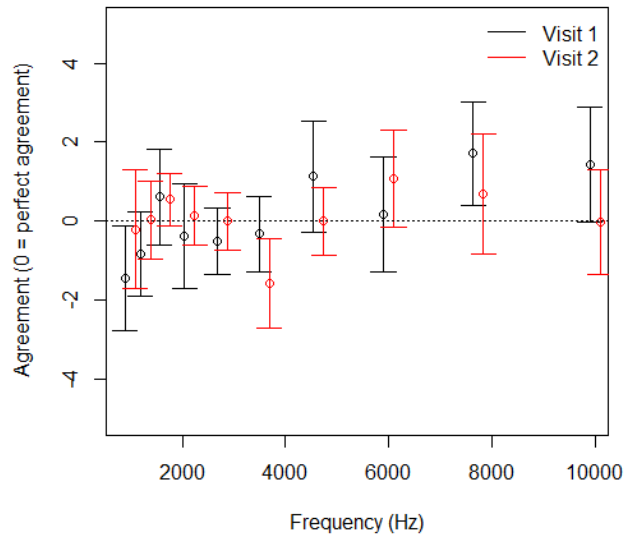


Table 5. Titan probe agreement for DPOAE level (dB SPL) between measurements 1 and 2. Agreement and confidence intervals are in units of dB SPL.

Frequency	Visit	Observed	95% Confidence Interval	
		Agreement	Lower Bound	Upper Bound
990.5273 Hz	1	-1.45	-2.77	-0.12
1281.2256 Hz	1	-0.83	-1.89	0.22
1658.0566 Hz	1	0.62	-0.59	1.83
2142.5537 Hz	1	-0.37	-1.69	0.96
2777.7832 Hz	1	-0.50	-1.34	0.34
3585.2783 Hz	1	-0.32	-1.26	0.63
4640.4053 Hz	1	1.14	-0.26	2.54
5996.9971 Hz	1	0.17	-1.29	1.64
7741.1865 Hz	1	1.72	0.42	3.01
10002.1729 Hz	1	1.43	-0.01	2.87
990.5273 Hz	2	-0.20	-1.70	1.29
1281.2256 Hz	2	0.03	-0.95	1.01
1658.0566 Hz	2	0.55	-0.12	1.22
2142.5537 Hz	2	0.14	-0.61	0.88
2777.7832 Hz	2	0.01	-0.71	0.73
3585.2783 Hz	2	-1.56	-2.69	-0.42
4640.4053 Hz	2	0.00	-0.87	0.87
5996.9971 Hz	2	1.07	-0.15	2.30
7741.1865 Hz	2	0.69	-0.82	2.20
10002.1729 Hz	2	-0.02	-1.35	1.30

Measurement 1 vs. Measurement 2 dB FPL

Figure 26 and **Table 6** display the Bland Altman results for the Titan probe in dB FPL between measurement 1 and 2 for both visits. These data also suggest good agreement between repeated DPOAEs measurements taken on the same day with the Titan probe, with an average agreement of within 1.5 dB at all frequencies. Note that one confidence interval for comparisons for Visit 2 at a single frequency (2142 Hz) did not include zero, suggesting slightly poorer repeatability at that frequency. Overall, however, agreement averages and confidence intervals are similar between dB SPL and dB FPL.

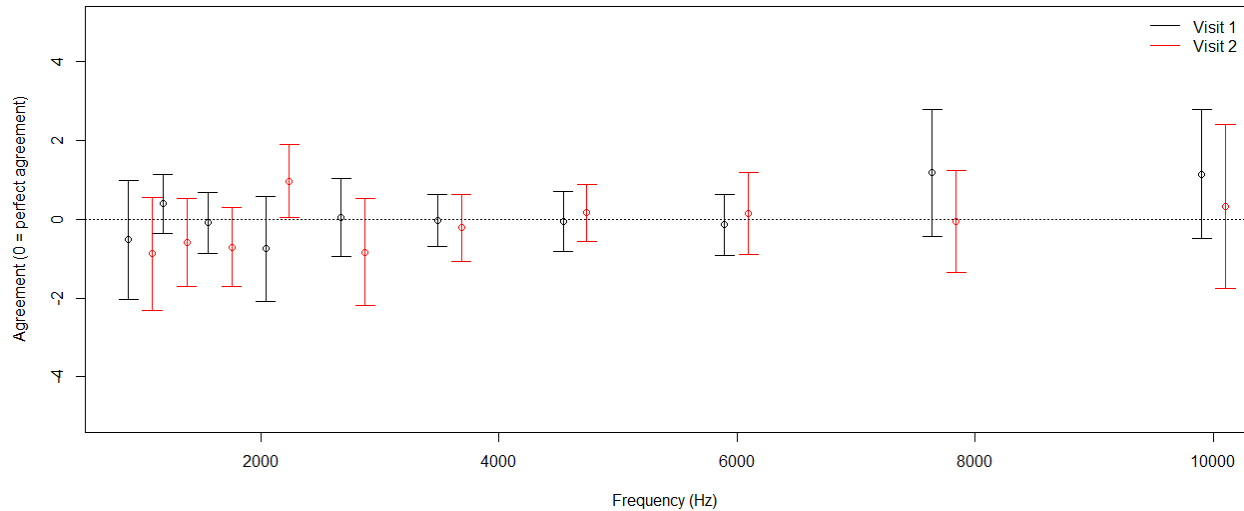


Figure 26. Titan Probe dB FPL Comparisons: Measurement 1 vs. Measurement 2 with different probe insertions (visit 1 in black, visit 2 in red). Agreement is in units of dB FPL.

Table 6. Titan probe agreement for DPOAE level (dB FPL) between measurements 1 and 2. Agreement and confidence intervals are in units of dB FPL.

Frequency	Visit 1			Visit 2		
	Average Agreement Bias	Confidence Interval		Average Agreement Bias	Confidence Interval	
		Lower Bound	Upper Bound		Lower Bound	Upper Bound
990.5273 Hz	-0.51	-2.02	0.99	-0.88	-2.31	0.55
1281.2256 Hz	0.40	-0.35	1.15	-0.58	-1.71	0.54
1658.0566 Hz	-0.09	-0.87	0.69	-0.70	-1.70	0.30
2142.5537 Hz	-0.75	-2.08	0.59	0.97	0.04	1.90
2777.7832 Hz	0.05	-0.94	1.05	-0.84	-2.20	0.52
3585.2783 Hz	-0.02	-0.68	0.64	-0.21	-1.06	0.63
4640.4053 Hz	-0.05	-0.81	0.72	0.17	-0.56	0.89
5996.9971 Hz	-0.14	-0.91	0.63	0.14	-0.90	1.18
7741.1865 Hz	1.19	-0.43	2.80	-0.05	-1.34	1.24
10002.1729 Hz	1.15	-0.50	2.79	0.33	-1.75	2.41

Visit 1 vs. Visit 2 dB SPL

Figure 27 and **Table 7** display the Bland Altman results for the intensimetric probe in dB SPL between measurement 1 from visit 1 and 2. These data suggest good agreement between repeated DPOAEs measurements taken on different days in the same ear with the intensimetric probe, with an average agreement of within 1.5 dB at all frequencies.

Figure 27. Titan Probe dB SPL comparisons across the 2 visits. Agreement is in units of dB SPL.

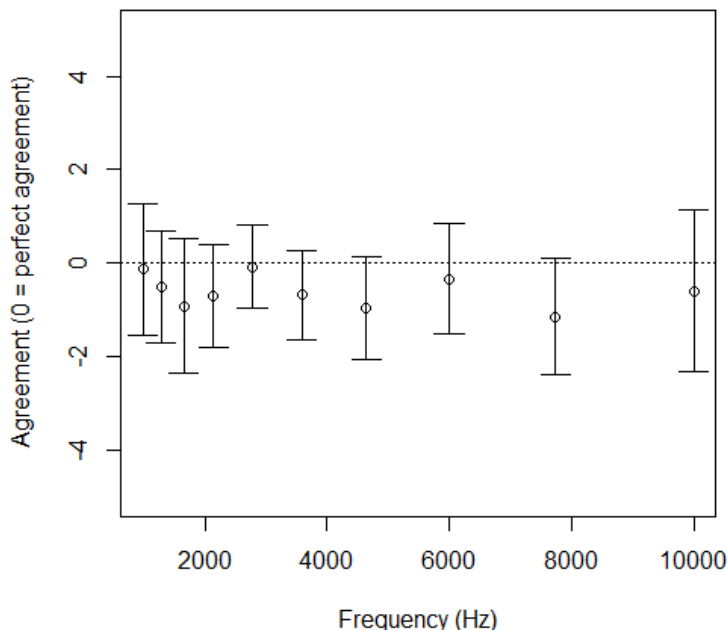


Table 7. Titan probe agreement for DPOAE level (dB SPL) between measurements 1 and 2. Agreement and confidence intervals are in units of dB SPL.

Frequency	Average Agreement	Confidence Interval	
		Lower Bound	Upper Bound
990.5273 Hz	-0.12	-1.52	1.28
1281.2256 Hz	-0.51	-1.70	0.69
1658.0566 Hz	-0.92	-2.35	0.52
2142.5537 Hz	-0.69	-1.79	0.41
2777.7832 Hz	-0.08	-0.97	0.80
3585.2783 Hz	-0.67	-1.63	0.28
4640.4053 Hz	-0.95	-2.04	0.14
5996.9971 Hz	-0.33	-1.52	0.87
7741.1865 Hz	-1.14	-2.38	0.09
10002.1729 Hz	-0.59	-2.31	1.14

Visit 1 vs. Visit 2 dB FPL

Figure 28 and **Table 8** display the Bland Altman results for the Titan probe in dB FPL between measurement 1 from visit 1 and 2. These data also suggest good agreement

between repeated DPOAEs measurements taken on different days in the same ear with the Titan probe, with an average agreement of within 2 dB at all frequencies. Agreement averages and confidence intervals are similar between dB SPL and dB FPL. Interestingly, as with comparisons in dB FPL between measurement 1 and measurement 2, note that one confidence interval at a single frequency (2142 Hz) did not include zero, suggesting slightly poorer repeatability at that frequency.

Figure 28. Titan Probe dB FPL comparisons across the 2 visits. Agreement is in units of dB FPL.

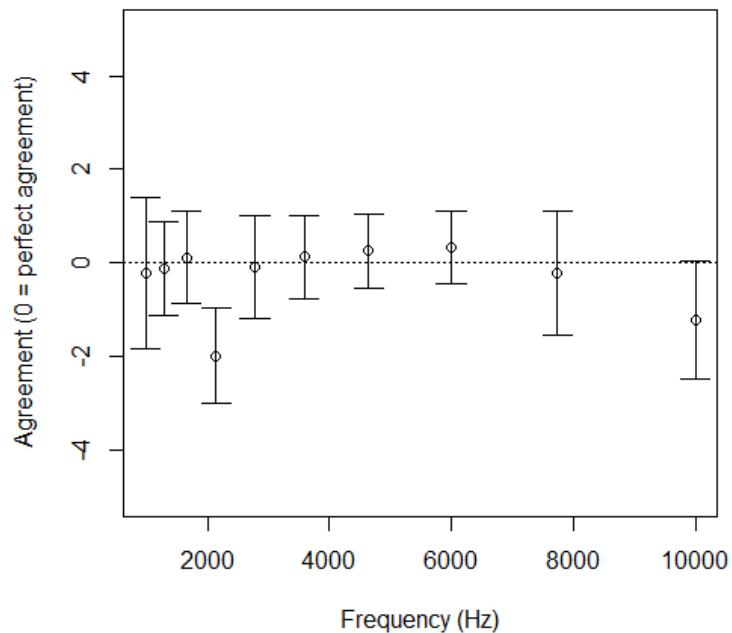


Table 8. Titan probe agreement for DPOAE level (dB FPL) between measurements 1 and 2. Agreement and confidence intervals are in units of dB FPL.

Frequency	Average Agreement Bias	Confidence Interval	
		Lower Bound	Upper Bound
990.5273 Hz	-0.21	-1.82	1.39
1281.2256 Hz	-0.12	-1.12	0.88
1658.0566 Hz	0.12	-0.86	1.10
2142.5537 Hz	-1.97	-3.00	-0.95
2777.7832 Hz	-0.08	-1.17	1.01
3585.2783 Hz	0.13	-0.76	1.02
4640.4053 Hz	0.26	-0.53	1.06
5996.9971 Hz	0.32	-0.45	1.10
7741.1865 Hz	-0.22	-1.55	1.10
10002.1729 Hz	-1.22	-2.48	0.05

Summary of DPOAE Preliminary Analyses of Reliability

Overall, these preliminary analyses suggest that both the intensimetric probe and Titan probe show good reliability for DPOAE measurements taken in the same ear on the same day with different probe insertions and on different days. Interestingly, though we hypothesized that data collection in dB FPL would increase reliability, we see similar reliability in this preliminary dataset for both dB SPL and dB FPL DPOAE data.

INTENSIMETRIC VS. TITAN PROBE DPOAE COMPARISON

To assess accuracy of the intensimetric probe, we compared DPOAE results collected with the intensimetric probe with the Titan probe.

One caveat to this comparison is that the two probes do not collect DPOAE data at identical frequencies due to different sampling rates. Thus, to compare the intensimetric probe and the Titan, the Titan DP Level was inferred using linear interpolation. For example, the inferred Titan 1000 Hz measure was calculated as follows:

$$(\text{Intensimetric Probe Freq} - \text{Most Adjacent Titan Freq below Intensimetric Probe Freq}) * (\text{Most Adjacent Titan DP Level above Intensimetric Probe Freq} - \text{Most Adjacent Titan DP Level below Intensimetric Probe Freq}) /$$

$$(\text{Most adjacent Titan Freq above Intensimetric Probe Freq} - \text{Most adjacent Titan Freq below Intensimetric Probe Freq}).$$

Results comparing measurement 1 from each visit were compared. Results were first compared in dB SPL and then in dB FPL.

Figure 29 and **Table 9** display the Bland Altman results for the in dB SPL between measurement 1 from visit 1 and 2 for the intensimetric probe versus the Titan. Average agreement between the two devices was within 4.5 dB across all frequencies. Several average agreement bias confidence intervals (3 for visit 1 comparisons, 5 for visit 2) did include 0.

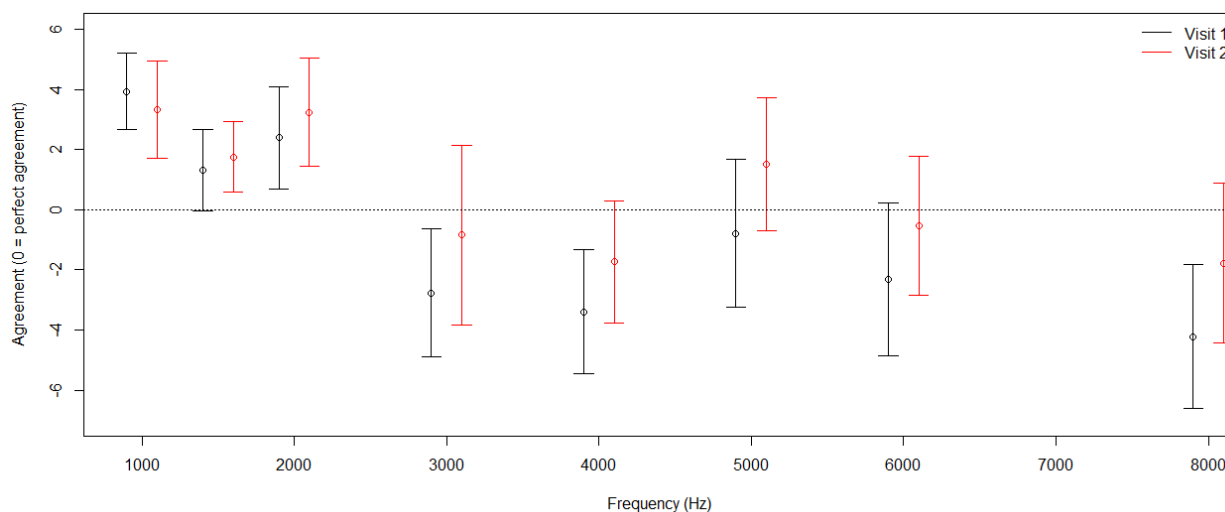


Figure 29. Intensimetric Probe vs. Titan Probe dB SPL comparisons across the 2 visits. Agreement is in units of dB SPL.

Table 9. Intensimetric Probe vs. Titan Probe dB SPL comparisons across the 2 visits. Agreement and confidence intervals are in units of dB SPL.

Frequency	Visit 1			Visit 2		
	Average Agreement Bias	Confidence Interval		Average Agreement Bias	Confidence Interval	
		Lower Bound	Upper Bound		Lower Bound	Upper Bound
1000 Hz	3.93	2.67	5.20	3.34	1.72	4.95
1500 Hz	1.30	-0.05	2.65	1.76	0.60	2.92
2000 Hz	2.39	0.69	4.09	3.24	1.43	5.05
3000 Hz	-2.77	-4.89	-0.65	-0.85	-3.84	2.14
4000 Hz	-3.39	-5.46	-1.33	-1.74	-3.76	0.28
5000 Hz	-0.79	-3.25	1.66	1.52	-0.70	3.73
6000 Hz	-2.32	-4.86	0.21	-0.53	-2.84	1.78
8000 Hz	-4.22	-6.62	-1.83	-1.78	-4.43	0.88

Figure 30 and **Table 10** display the Bland Altman results for the in dB FPL between measurement 1 from visit 1 and 2 for the intensimetric probe versus the Titan. Average agreement between the two devices was within 5.5 dB across all frequencies. 3 average agreement bias confidence intervals did include 0 for each visit.

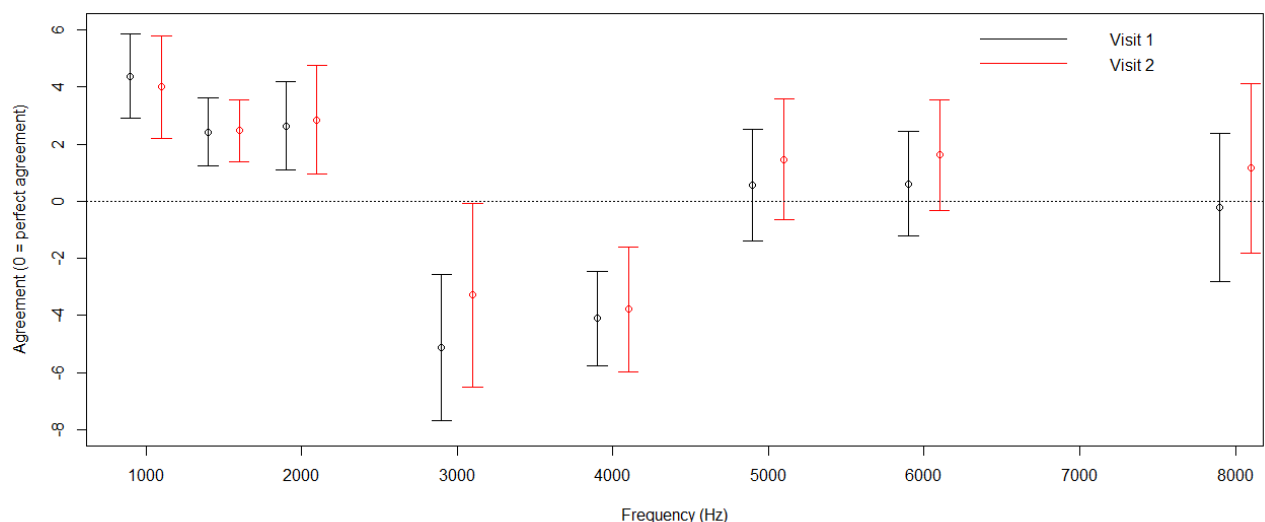


Figure 30. Intensimetric Probe vs. Titan Probe dB FPL comparisons across the 2 visits. Agreement is in units of dB FPL.

Table 10. Intensimetric Probe vs. Titan Probe dB FPL comparisons across the 2 visits. Agreement and confidence intervals in units of dB FPL.

Frequency	Visit 1			Visit 2		
	Average Agreement Bias	Confidence Interval		Average Agreement Bias	Confidence Interval	
		Lower Bound	Upper Bound		Lower Bound	Upper Bound
1000 Hz	4.38	2.89	5.86	4.00	2.20	5.80
1500 Hz	2.42	1.23	3.62	2.47	1.39	3.56
2000 Hz	2.64	1.10	4.17	2.84	0.95	4.74
3000 Hz	-5.13	-7.68	-2.58	-3.29	-6.51	-0.07
4000 Hz	-4.11	-5.77	-2.45	-3.79	-5.98	-1.59
5000 Hz	0.55	-1.40	2.51	1.45	-0.67	3.57
6000 Hz	0.61	-1.22	2.43	1.62	-0.32	3.56
8000 Hz	-0.22	-2.81	2.36	1.16	-1.80	4.12

Summary of DPOAE Preliminary Analyses of Accuracy

Agreement between devices was poorer than agreement within a device. However, the devices were still within 5.5 dB or less of each other, on average, and qualitative impressions suggest reasonable accuracy of the intensimetric probe. It is important to note that our preliminary analyses did not account for DPOAE responses that were in the noise floor of a given probe. Given the increased noise floor of the intensimetric probe, we suspect this may be leading to some of the decreased agreement. Our results could have also been influenced by our initial interpolation approach. We anticipate overcoming these limitations with more comprehensive analyses when the final dataset is collected.

2.3. Task 4: Dissemination of Results

An abstract describing probe development and our preliminary data analysis is in preparation to be submitted at the end of September for presentation at the 2024 Midwinter Meeting of the Association for Research in Otolaryngology. We are also considering presenting data from this project at the Annual meeting of the American Auditory Society in February 2024, and plan to also attend and present at the 2024 Military Health System Research Symposium.

SPECIFIC AIM 3: Clinical Validation of Intensimetric Probe System.

Major tasks for Aim 3 include:

- 1) Recruitment and data collection
- 2) Data analysis
- 3) Dissemination of results

Aim 3 overlaps significantly with recruitment and data collection in Aim 2. As such, the same results for the current reporting period apply here. The goal of Aim 3 is to recruit a diverse sample of participants with both normal hearing and varying degrees of hearing loss to assess the diagnostic specificity of the intensimetric probe using clinical decision

theory. We do not yet have a sufficiently diverse sample to complete that analysis, but our recruitment efforts are targeting participants with both normal hearing and varying degrees of hearing loss with an equal number of participants per decade of life (19-29, 30-49, 40-59, 50-59, 60-69).

What opportunities for training and professional development has the project provided?

Nothing to report.

How were the results disseminated to communities of interest?

An abstract to be submitted to the Association for Research in Otolaryngology Midwinter meeting is in preparation.

What do you plan to do during the next reporting period to accomplish the goals?

SPECIFIC AIM 1: Refine an intensimetric probe system for the detection of hearing injury. During the next reporting period, we plan to: provide support during laboratory and clinical validation and disseminate results.

SPECIFIC AIM 2: Laboratory validation of intensimetric probe system.

During the next reporting period, we plan to: complete recruitment and data collection, complete data analyses, and prepare manuscripts to disseminate findings from this Aim.

SPECIFIC AIM 3: Clinical validation of intensimetric probe system.

During the next reporting period, we plan to: complete recruitment and data collection, complete data analyses, and prepare manuscripts to disseminate findings from this Aim.

4. IMPACT:**What was the impact on the development of the principal discipline(s) of the project?**

Noise-induced hearing loss is a leading cause of medical referral for Service Members returning from deployments, while traumatic middle-ear injury occurs in a majority of Service Members with traumatic brain injury. The detection and triaging of inner and middle ear injuries for these Service Members currently relies on audiometry and basic tympanometry (226 Hz). Although several studies have demonstrated that forward pressure level calibration provides better reliability and diagnostic specificity of audiometry and otoacoustic emissions compared to currently adopted procedures, forward pressure level has not been adopted in the clinic. Similarly, wideband acoustic reflectance (and absorbance) has not been adopted for clinical use despite its demonstrated diagnostic power when compared to 226-Hz tympanometry. Thévenin calibration is one of the major barriers for the clinical acceptance of both procedures because it requires an amount of time that is not acceptable clinically, it is complicated, and has to be performed daily.

We are developing a portable intensimetric ear-canal probe system that does not require daily Thévenin calibration because of its ability to measure impedance directly. This system will enhance the reliability of clinical measures due to the ability to use forward pressure level calibration and will lead to significant advancement in the clinical diagnosis of hearing injury. The enhanced reliability will also lead to more accurate monitoring of noise-induced hearing loss and traumatic middle-ear injury in Service Members and Veterans, enabling both the evaluation and the application of preventative therapies and treatments for hearing injuries. The portability of the device will enable more frequent assessments and the option for remote testing. Our development of the probe, especially the proposed performance validation using waveguides with known models of impedance, may also advance our theoretical understanding of acoustic impedance and reflectance.

What was the impact on other disciplines?

While the focus of this work is on a field-deployable portable device, the ability to make these clinical measurements without Thévenin calibration will also reduce barriers to making these measurements more accessible in audiology clinics worldwide, broadly improving general audiological patient care.

What was the impact on technology transfer?

The goal of this project is to develop, evaluate and clinically validate a highly innovative intensimetric probe system that will provide a more reliable and efficient diagnosis of middle- and inner-ear injuries compared to existing systems. This technology, if successful, could be used to provide clinicians across both the Military and Civilian healthcare systems with a clinical and highly portable tool to assess hearing injury and formulate the best intervention. Successful commercialization of any research and development is dependent not only on commercial potential, but also on the ability of the development team to realize that potential by successfully delivering a product to market. Creare, our commercialization partner in this project, has a long track record of successfully commercializing varied technologies. Creare ownership recently established a sister company, Edare Incorporated, to focus on manufacturing and commercialization of small market technologies, newly budding technologies with developing markets, and technologies that require significant and continued technical interaction with the inventors. Our collaborator at Creare, Dr. Clavier, will bring her experience to support the transition of the Intensimetric Probe to Edare and to market.

What was the impact on society beyond science and technology?

The ability to assess outer, middle, and inner ear function with high precision in a portable device may allow for broader access to diagnostic audiology services worldwide, particularly in locations and settings that do not have comprehensive audiology centers with soundproof booths and specialized equipment, opening up more access to hearing healthcare.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

Nothing to report.

Actual or anticipated problems or delays and actions or plans to resolve them

Delays from the last reporting period due to the change in Creare project engineer, supply chain delays, and the need for a custom calibration for the Microflown velocimeter were further exacerbated by delays with probe development during the reporting period. Many of these delays, however, resulted in an advancement of our scientific and theoretical understanding of the intensimetric probe system. Still, this resulted in data collection beginning several months later than planned. However, due to the careful planning and preparation in anticipation of beginning data collection, we were able to begin data collection as soon as the probe was delivered and believe that these delays should not impact our ability to complete data collection and analysis during the grant period.

Changes that had a significant impact on expenditures

Year 2 expenditures were less than anticipated due to delays in beginning data collection and the carryover funds from Year 1. Some of these expenditures thus will carry over into Year 3, while some may result in meeting project objectives at less cost than anticipated.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Significant changes in use or care of human subjects

Nothing to report.

Significant changes in use or care of vertebrate animals

N/A

Significant changes in use of biohazards and/or select agents

N/A

6. PRODUCTS:

- **Publications, conference papers, and presentations**
Journal publications.

Nothing to report.

Books or other non-periodical, one-time publications.

Nothing to report.

Other publications, conference papers and presentations.

Nothing to report.

- **Website(s) or other Internet site(s)**

Nothing to report.

- **Technologies or techniques**

Nothing to report.

- **Inventions, patent applications, and/or licenses**

Nothing to report.

- **Other Products**

Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name: **Gabrielle Merchant, AuD, PhD**
Project Role: *Principal Investigator*
Researcher Identifier (e.g., ORCID ID): 0000-0001-7251-1879
Nearest person month worked: 5
Contribution to Project: Oversight of all aspects of the project, regular communication and input with Creare regarding probe prototype development, IRB and HRPO protocol applications and approval, and oversight and contributions to recruitment, data collection, and data analysis.

Funding Support:
Name: **Sara Harris, AuD**
Project Role: *Research Audiologist*
Researcher Identifier (e.g., ORCID ID):
Nearest person month worked: 6
Contribution to Project: Dr. Harris provides clinical expertise and input to probe development, helps prepare for data collection, and leads recruitment and data collection efforts.

Funding Support:

Name: **Ryan McCreery, PhD**
Project Role: *Co-Investigator*
Researcher Identifier (e.g., ORCID ID): 0000-0002-0733-7269
Nearest person month worked: 1
Contribution to Project: Contributed expertise in audiology, large-scale data analysis, as well as clinical interpretation of findings to various aspects of the project include probe and protocol development.

Funding Support:

<i>Name:</i>	Odile Clavier, PhD
<i>Project Role:</i>	Consortium Lead Investigator
<i>Researcher Identifier (e.g., ORCID ID):</i>	0000-0003-4439-4120
<i>Nearest person month worked:</i>	1
<i>Contribution to Project:</i>	Leverages her prior experience in hearing and mobile health applications to guide the design and testing of the prototype. She also ensured that the transition from development to human testing went smoothly.

Funding Support:

<i>Name:</i>	M.P. Ueckermann
<i>Project Role:</i>	Consortium Project Engineer
<i>Researcher Identifier (e.g., ORCID ID):</i>	0000-0003-3615-4610
<i>Nearest person month worked:</i>	2
<i>Contribution to Project:</i>	Dr. Ueckermann is responsible for the day-to-day management of the project at Creare and provides project engineering support critical to probe development.

Funding Support:

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

See attachment for Other Support.

What other organizations were involved as partners?

Creare LLC
16 Great Hollow Road, Hanover, New Hampshire 03755

- Collaboration

University of Nebraska Medical Center
987835 Nebraska Medical Center, Omaha, NE 68198-7835

- Collaboration

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

QUAD CHARTS:

See attachment.

9. APPENDICES:

Project Title: Field-Deployable Intensimetric Probe System for Early Diagnosis and Monitoring of Noised-Induced Hearing Loss and Traumatic Middle Ear Injury

Log Number: RH200006

Award Number: W81XWH-21-1-0658



PI: Gabrielle R. Merchant

Org: Boys Town National Research Hospital

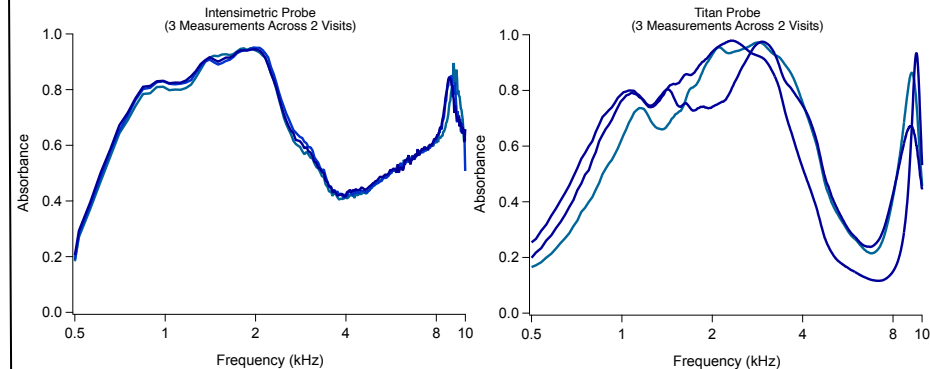
Award Amount: \$1,249,586.00

Study/Product Aim(s)

- Develop a hearing test device that can objectively assess the health status of the middle- and inner-ear.
- Utilize an innovative sensor to allow for improved accuracy and reliability of measurements without the need for a complex daily calibration.
- Design the device so it is portable and easy to use by non-experts so that it can be deployed in the field.

Approach

This work will further develop and refine a prototype for reliable assessment of middle- and inner-ear auditory function without the need for complex daily Thévenin calibration in a package that is suitable for field use. This will be accomplished through the completion of three specific aims: 1) Refine an intensimetric probe system for the detection of hearing injury; 2) Laboratory validation of intensimetric probe system; and 3) Clinical validation of intensimetric probe system.



Accomplishment: Absorbance collected with the intensimetric probe (left) resembles absorbance collected with the Interacoustics Titan (right), demonstrating accuracy, and shows better reliability between measurements within the same day and across different days.

Timeline and Cost

Activities	CY	21	22	23	24
Refine intensimetric probe					
Laboratory Validation: Accuracy					
Laboratory Validation: Reliability					
Clinical Validation					
Estimated Budget (\$K)		\$250	\$500	\$300	\$200

Goals/Milestones

CY22 Goal – Next generation intensimetric probe complete

- ☒ Analytical Model Development and Validation
- ☒ Custom Calibration
- ☒ Next Generation Probe Design
- ☒ Software Development
- ☒ Final Assembly and testing of Next Generation Probe

CY23 Goals – Begin Laboratory & Clinical Validation

- ☒ Obtain IRB and HRPO Approval
- ☒ Begin Human Studies (45/145 participants recruited & tested so far)

CY24 Goal – Complete Laboratory & Clinical Validation

- ☐ Complete Human Subjects Studies

Comments/Challenges/Issues/Concerns

- Some probe development delays led to delays in beginning Human Subjects data collection. However, careful planning allowed us to ramp data collection very quickly to help decrease impact of delays.

Budget Expenditure to Date

Projected Expenditure: \$942,434

Actual Expenditure: \$768,511

Updated: August 29, 2023

Support_Merchant

CURRENT/PREVIOUS SUPPORT

(Changes Marked with Border in Right Margin—previously pending grant is now active, and/or previously active grant has closed.)

MERCHANT, G.

CURRENT

W81XWH-21-1-0658 Merchant 08/15/2021-08/14/2024 5.04 CY months
(Dept. of Defense (DoD))

Field Deployable Intensimetric Probe System for Early Diagnosis and Monitoring of Noise-Induced Hearing Loss and Traumatic Middle-Ear Injury

The goal of this project is to develop field-deployable technology for the early diagnosis and monitoring of NIHL and traumatic middle-ear injury in Service Members and Veterans, enabling both the more accurate evaluation and the application of preventative therapies and treatments for hearing injuries.

Role: PI

TPOC: Sherry Apperson and Jennifer Fox

Overlap: None

1 R56 DC021320-01 Merchant 07/05/2023-06/30/2024 6.00 CY months
NIH-NIDCD

Hearing Loss, Prognosis, and Long-Term Impact of Otitis Media with Effusion in Children

Otitis media with effusion (OME) is a common childhood condition that can have serious negative immediate and long-term consequences. Many of these consequences are likely related to the resulting hearing loss that OME can cause but characterizing that hearing loss is limited by challenges associated with behavioral audiometric testing in young children. The goal of this work is to improve the diagnosis and understanding of OME and its associated hearing loss, including the development of an objective and non-invasive automated estimate of that hearing loss, as well as determine how variations in OME and its related hearing loss impact binaural processing.

Role: PI

TPOC: Bracie Watson

Overlap: None

PREVIOUS

5 P20 GM109023-10 Leibold 04/01/2019-07/04/2023 6.00 CY months
NIH-NIGMS

COBRE: Center for Perception and Communication in Children

The goal of the CPCC, a COBRE at the Boys Town National Research Hospital in Omaha, Nebraska, is to expand the range of the current research program by providing a unique environment for the development of junior faculty who have an interest in understanding the consequences of childhood hearing loss for speech and language perception and processing, and ultimately describing performance of children with hearing loss in the real world. ***COBRE Project 9: Differential Diagnosis of Otitis Media*** The long-term goal of this work is to understand how differences in Otitis Media affect long-term outcomes. The results of the proposed study will lead to more effective and evidence-based treatment protocols and reduce the likelihood of antibiotic prescription where it is not indicated.

Role: Project Lead

TPOC: Yang Zhou

Change: Ended 7/4/2023

Support_Merchant

3 R01 DC011038-10S1 Leibold

09/13/2019-06/30/2022 (NCE)

2.40 CY

months

NIH-NIDCD

Susceptibility to and Release from Masking in Infancy and Childhood

The proposed research is relevant to public health because it is focused on understanding how hearing develops in real-world environments for children with normal hearing and with hearing loss. The results of the proposed experiments will contribute to our basic understanding of the factors that limit how well infants, preschoolers and school-age children perceive speech in adverse listening conditions that contain multiple sources of competing sounds. In addition, this work is expected to generate practical intervention options that may improve speech perception in competing speech for children with hearing loss.

Susceptibility to and Release from Masking in Infancy and Childhood [INCLUDE Supplement]

This work is expected to generate practical intervention options that may improve communication outcomes for individuals with Down syndrome.

Role: Co-Investigator

TPOC: Kelly King

Change: Ended 6/30/2022

CURRENT/PREVIOUS SUPPORT

(Changes Marked with Border in Right Margin—previously pending grant is now active, and/or previously active grant has closed.)

CURRENT

5 P20 GM109023-10 Leibold 05/15/2014-03/31/2024 1.20 CY months
NIH-NIGMS

COBRE: Center for Perception and Communication in Children - The goal of the CPCC, a COBRE at the Boys Town National Research Hospital in Omaha, Nebraska, is to expand the range of the current research program by providing a unique environment for the development of junior faculty who have an interest in understanding the consequences of childhood hearing loss for speech and language perception and processing, and ultimately describing performance of children with hearing loss in the real world.

Core A - Administrative Core - The Administrative Core provides the oversight and infrastructure required to stimulate and support clinical-translational research focused on perception and communication in children.

Role: Co-Director/Internal Mentor

TPOC: Yang Zhou

Overlap: None

5 R01 DC013591-10 McCreery 12/01/2013-07/31/2024 2.76 CY months
NIH-NIDCD

Complex Listening Skills in School-age Hard of Hearing Children

The purpose of this research proposal is to investigate the underlying mechanisms that support speech recognition in noise for school-age children with hearing loss. The proposed research is relevant to public health because it will provide important insights into the impact of hearing loss on the ability to listen and learn in background noise. This project is highly related to the NIH's mission because the data will lead to improved and more individualized treatment options for individuals with mild to severe hearing loss and has the potential to improve how children who wear hearing aids function in every day listening environments.

The long-term goal of this research program is to optimize amplification and speech understanding in Children who are hard of hearing (CHH) by identifying the underlying processes that support listening in academic and social situations.

Role: PI

TPOC: Kelly King

Overlap: None

5 R01 DC018330-04 McCreery 07/20/2020-06/30/2025 2.76 CY months
NIH-NIDCD

Developing Evidence-Based Clinical Tools for Managing Mild Hearing Loss in Children

Children with mild bilateral hearing loss (MBHL) do not receive hearing aids as often as peers with greater degrees of hearing loss due to a lack of clinical tools to assess their listening needs. This research proposal would address this critical need by developing clinical novel clinical assessment and outcome measures for children with MBHL. The result will be improved communication, academic, and social outcomes for this underserved population.

Role: PI

TPOC: Kelly King

Overlap: None

Support_McCreery

5 R01 DC019081-03 Walker 07/01/2021-06/30/2026 0.96 CY months
NIH-NIDCD

Factors Associated with Reading Comprehension in Adolescents Who Are Hard of Hearing

The proposed work will lead to a more nuanced understanding of the variation in reading development in CHH and the core skills that support reading comprehension over time. This outcome will allow interventions and academic instruction to be tailored to individual difference in learning, thus allocating resources more appropriately. This outcome is also consistent with recommendations for intensifying services for students who are not responding to intervention.

Role: Co-Investigator

TPOC: Kelly King

Overlap: None

W81XWH-21-1-0658 Merchant 08/15/2021-08/14/2024 0.96 CY months
Dept. of Defense (DoD)

Field Deployable Intensimetric Probe System for Early Diagnosis and Monitoring of Noise-Induced Hearing Loss and Traumatic Middle-Ear Injury

The goal of this project is to develop field-deployable technology for the early diagnosis and monitoring of NIHL and traumatic middle-ear injury in Service Members and Veterans, enabling both the more accurate evaluation and the application of preventative therapies and treatments for hearing injuries.

Role: Co-Investigator

TPOC: Sherry Apperson and Jennifer Fox

Overlap: None

5 P20 GM144641-02 Wilson 03/01/2022-01/31/2027 0.50 CY months
NIH-NIGMS

Center for Pediatric Brain Health

This application would initiate a Center of Biomedical Research Excellence (COBRE) at Boys Town National Research Hospital in Omaha, Nebraska, with a focus on pediatric neuroscience, developmental neuroimaging, and brain health. ***Center for Pediatric Brain Health:***

Administrative Core - The Administrative Core will manage and continuously evaluate the Center's major programs and provide oversight of the fiscal and scientific components of the Center

Role: Co-Mentor

TPOC: Wuhong Pei

Overlap: None

1 R21 DC020270-01A1 Heinrichs-Graham 04/01/2023-03/31/2026 0.36 CY months
NIH-NIDCD

Spatiotemporal Dynamics of Language Processing in School-Age Children with Mild-to-Severe Hearing Loss

It is well-established that children with mild-to-severe hearing loss are at risk for widespread language delays throughout development compared to children with normal hearing, and these deficits are exacerbated by poor hearing aid fit (e.g., aided audibility) and inconsistent hearing aid use. However, the impact of mild-to-severe hearing loss on the brain dynamics supporting these language processes remains unknown, and a comprehensive characterization of these neural patterns may help clarify the exact nature of language difficulties in these children. The proposed study will determine the impact of mild-to-severe hearing loss and the subsequent effects of hearing aid use and fit on multiple facets of language processing in children using a

Support_McCreery

cutting-edge multimodal imaging approach coupled with advanced behavioral and neuropsychological measures.

Role: Co-Investigator

TPOC: Kelly King

Overlap: None

3 R01 DC020229-02S1 Leibold

06/01/2022-05/31/2027

0.96 CY months

NIH-NIDCD

Speech Perception And Auditory Abilities In Infants, Children, And Adults With Down Syndrome

The results generated from this project are expected to provide new information about the factors that support communication outcomes for individuals with Down syndrome, and support the development of interventions to maximize listening, learning, and communication in noisy listening environments, such as classrooms.

[SUPPLEMENT]: There are over 200,000 individuals with Down syndrome in the United States, and most rely on hearing to communicate. The proposed research is relevant to public health because it is focused on understanding how speech perception and auditory skills mature for infants, children, and young adults with Down syndrome. The results generated from this project are expected to provide new information about the factors that support communication outcomes for individuals with Down syndrome, and support the development of interventions to maximize listening, learning, and communication in noisy listening environments, such as classrooms.

Role: Co-Investigator

TPOC: Kelly King

Overlap: None

PREVIOUS

5 R01 DC011038-10 Leibold

07/01/2016-06/30/2022 (*no-cost ext.*)

0.96 CY months

NIH-NIDCD

Susceptibility to and Release from Masking in Infancy and Childhood

The proposed research is relevant to public health because it is focused on understanding how hearing develops in real-world environments for children with normal hearing and with hearing loss. The results of the proposed experiments will contribute to our basic understanding of the factors that limit how well infants, preschoolers and school-age children perceive speech in adverse listening conditions that contain multiple sources of competing sounds. In addition, this work is expected to generate practical intervention options that may improve speech perception in competing speech for children with hearing loss.

Role: Co-Investigator

TPOC: Yang Zhou

Change: Ended 6/30/2022

5 R01 DC015056-05 Leibold

08/10/2016-07/31/2023 (*2nd no-cost ext.*)

1.80 CY months

NIH-NIDCD

A Test of Children's English/Spanish Speech Perception in Noise or Speech Maskers

Speech perception testing is a critically important tool for assessing children's auditory skills, determining candidacy for sensory devices and guiding language intervention. A large number of children in the US are raised in Spanish-speaking households (>15%), but speech perception testing is typically performed in English or omitted altogether, due to a lack of appropriate test

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materials and a shortage of Spanish-speaking audiologists. Moreover, speech perception testing is typically performed in quiet or in relatively steady state noise despite the prevalence of complex and time varying sounds in children's real-world listening environments. The proposed work will develop an easy-to-administer clinical test of speech perception, allowing audiologists (regardless of their language proficiency) to appropriately evaluate Spanish- and English-speaking children in both noise and two-talker backgrounds. The proposed work will develop an easy-to-administer clinical test of speech perception, allowing audiologists (regardless of their language proficiency) to appropriately evaluate Spanish- and English-speaking children in both noise and two-talker backgrounds.

Role: Co-Investigator

TPOC: Kelly King

Change: Ended 7/31/2023

Support_Clavier

CURRENT/PREVIOUS SUPPORT

(Changes Marked with Border in Right Margin—previously pending grant is now active, and/or previously active grant has closed.)

CLAVIER, O.H.

CURRENT

W81XWH-21-10658 Merchant (PI) 08/15/2021–08/14/2024 9%

(Subcontract to Father Flanagan's Boys' Home dba Boys Town National Research Hospital)

Field Deployable Intensimetric Probe System for Early Diagnosis and Monitoring of Noise-Induced Hearing Loss and Traumatic Middle-Ear Injury

Develop and validate a highly innovative intensimetric probe system that can provide a more reliable diagnosis of middle and inner ear dysfunctions compared to existing systems. Creare will provide the resources necessary to develop and support a new prototype intensimetric probe to allow BTNRH to conduct human studies investigating the usability, accuracy, and clinical performance of the device.

Role: Investigator TPOC: Sherry Apperson and Jennifer Fox

Overlap: None

W81XWH-22-C-0066 Clavier (PI) 07/01/2022–10/31/2024 10%

DoD/Other

Noise Dosimeter for Low-Level Blast and Impulsive Noise in Realistic Operational Settings

Develop a complex noise dosimeter that is specifically designed to record and compute the total noise exposure dose in the presence of mixed continuous, intermittent, and impulsive noises.

Role: PI TPOC: Jaclyn Schurman

Overlap: None

W81XWH-19-C-0076 Clavier (PI) 08/12/2019–10/25/2023 10%

DoD/Other

Multi-Function In-Ear Probe

Design, build, and test a system that will provide hearing protection during activities in noisy environments, record personal noise dose, and monitor hearing function over time.

Role: PI TPOC: Ben Sheffield

Overlap: None

Change: End date extended from 01/11/23 to 10/25/23

2R44DC01793002 Clavier (PI) 07/16/2021–05/31/2024 10%

DHHS

Diagnostic Hearing Test System for Telehealth in Underserved Communities

Develop a mobile, diagnostic hearing test system to reach rural and underserved communities and expand the reach of audiologists by supporting remote telehealth testing.

Role: PI TPOC: Roger Miller

Overlap: None

Change: End date extended from 05/31/23 to 05/31/24

1 R44 CE002936-01-00 Clavier (PI) 09/30/2018–09/29/2023 10%

NIH-ODCDC

OnTRACK: Mobile Application for Pediatric Post-TBI Patient Management

Develop a medical mobile application that will help children who sustain a concussion with symptom management during their recovery.

Role: PI TPOC: Dr. Marcienne Wright

Overlap: None

9 R44 GM130224-03 Clavier (PI) 09/20/2018–09/19/2023 6%

Support_Clavier

CURRENT/PREVIOUS SUPPORT

(Changes Marked with Border in Right Margin—previously pending grant is now active, and/or previously active grant has closed.)

NIH-NIGMS

STEM Interactive Digital Tool to Educate and Promote Hearing Health and Science for 4th to 7th Grade

Develop an engaging game that teaches fundamental STEM concepts and intuition to youth while changing knowledge, attitudes, and intended behavior toward hearing health and the prevention of noise-induced hearing loss.

Role: PI TPOC: Dr. Lawrence Beck

Overlap: None

W81K0422P0015

Clavier (PI)

09/26/2022–09/25/2023

5%

DoD/Other

Multi-Function In-Ear Probe Integration into the IPCAM and Noise Exposure Study Support

Creare will integrate the M-Plug into the Integrated Platform for Clinical Assessment and Monitoring (IPCAM) and to support human studies and public health projects that will use both the M-Plug and the IPCAM across the Department of Defense. The program will provide support for the execution of studies that evaluate the effects of chronic noise exposure on human listeners.

Role: PI TPOC: Ben Sheffield

Overlap: None

R1635

Buckey (PI)

07/01/2022–07/30/2027

2%

Subcontract to Dartmouth College

Engineering Support for Central Auditory Tests Used to Predict HIV Cognitive Outcomes

Provide engineering support to the ongoing longitudinal study Dartmouth is conducting in Tanzania to study the impact of HIV/AIDS and its treatment on hearing and cognitive health.

Role: Investigator TPOC:

Overlap: None

R1186

Buckey (PI)

08/16/2018–04/30/2024

2%

Subcontract to Dartmouth College

Engineering Support of Audiological Test Hardware

Creare is providing technology support in the form of innovative hardware (wireless, highly noise attenuating headset) and software to administer the various hearing tests to the children enrolled in this study.

Role: Investigator TPOC:

Overlap: None

PREVIOUS

1 R21 DC017603-01A1

Buckey (PI)

08/01/2019–07/31/2023

2%

Subcontract to Dartmouth Hitchcock Medical Center

Long-Term Effects of Zika Virus Infection on Sound Processing in the Brain

Support and maintain hardware and software for use in audiological field testing of individuals who have contracted the Zika Virus in Brazil.

Role: Co-I TPOC:

Overlap: None

Change: ended on 07/2023

Support_Clavier

CURRENT/PREVIOUS SUPPORT

(Changes Marked with Border in Right Margin—previously pending grant is now active, and/or previously active grant has closed.)

W81XWH-20-C-0004	Clavier (PI)	12/09/2019–04/08/2023	10%
U.S. Army Medical Research Acquisition Activity			
<i>Automated Vestibular Rehabilitation Management System</i>			
Design, implement, and test a system that allows audiologists to administer vestibular rehabilitation without the need for a specialized physical therapist present.			
Role: PI		TPOC: Michael Elliott	
Overlap: None			
Change: ended on 04/2023			
W81XWH-21-C-0082	Clavier (PI)	09/24/2021–09/23/2022	10%
U.S. Army Medical Research Acquisition Activity			
<i>Mobile Application for Aural Rehabilitation</i>			
Provide engineering support to the Hearing Center of Excellence and the Walter Reed National Military Medical Center in deploying new hearing health monitoring technology across the services and addressing emerging threats.			
Role: PI		TPOC: Ben Sheffield	
Overlap: None			
Change: ended on 09/2022			
9 R44 MH119027-02	Clavier (PI)	09/10/2018–12/31/2022	3%
NIH-NIMH			
<i>Adaptable Pediatric Neurocognitive Assessment</i>			
Develop an adaptable, tablet-based assessment battery, which includes both rating scale and neurocognitive measures, to greatly increase access to essential pediatric assessment in all settings, including lower and middle income countries and underserved communities in resource-rich countries.			
Role: PI		TPOC: Dr. Margaret Grabb	
Overlap: None			
Change: ended on 12/2022			
5 R44 DC015445-05	Clavier (PI)	08/07/2016–07/31/2023	3%
NIH-NIDCD			
<i>Open Source System for Audio Processing</i>			
Develop a user-friendly, portable, upgradable, and wearable “master hearing aid” (MHA) which will allow collaborative development and the open exchange of new processing algorithms within the broader hearing research community, including both academia and industry.			
Role: PI		TPOC: Dr. Roger Miller	
Overlap: None			
Change: ended on 07/31/2023			
GC10489-01	Saunders (PI)	09/01/2020–08/31/2023	2%
Subcontract to Dartmouth-Hitchcock			
<i>Engineering Support for Studies of Central Auditory Processing</i>			
Creare will support Dartmouth's study that aims to evaluate the impact of exposure to heavy metals on hearing health in mining communities in Nicaragua. In particular, Creare will implement new central auditory processing tests for the Wireless Automated Hearing Test System (WAHTS) and the TabSINT software.			
Role: Investigator		TPOC:	
Overlap: None			
Change: ended on 08/31/2023			

CURRENT/PREVIOUS SUPPORT

(Changes Marked with Border in Right Margin—previously pending grant is now active, and/or previously active grant has closed.)

Ueckermann, M.P.

CURRENT

W81XWH-21-10658 Merchant (PI) 08/15/2021–08/14/2024 14%

(Subcontract (96489-B) to Father Flanagan's Boys' Home dba Boys Town Nat'l Res. Hosp.)

Field Deployable Intensimetric Probe System for Early Diagnosis and Monitoring of Noise-Induced Hearing Loss and Traumatic Middle-Ear Injury

Develop, test, and deliver a next generation intensimetric probe system for early diagnosis and monitoring of noise induced hearing loss and traumatic middle-ear injury and support human study of approach.

Role: Project Engineer

TPOC: Sherry Apperson and Jennifer Fox

Overlap: None

FA875023C1012 Ueckermann (PI) 03/28/2023–12/28/2023 25%

DoD/Other

Generating 3D Models of Unknown Space Systems

Creare and the Florida Institute of Technology (FIT) are developing SAT3D. SAT3D generates high-resolution parametric models of space systems. It uses structure from motion (SfM) and machine learning (ML) models to generate 3-D point cloud data of space systems based on EO imagery. To train our ML models, we augment available real-world data with synthetic data generated by our multi-faceted simulation and lab-based approach.

Role: PI

TPOC: Peter Rocci

HDTRA123P0013 Bieszczad (PI) 05/22/2023–11/21/2023 30%

DoD/Other

3D Reconstruction, Visualization, and Modeling of Buildings from Multiple Image Sources

Creare's Topological Optimization Software (TOS) package will interface with existing FEA software, enforce the necessary subtractive manufacturing constraints, and output CAM ready CAD files for CNC machining.

Role: TE

TPOC: Chia-Wei Tsai

W912HZ23F0037 Bieszczad (PI) 12/16/2022–12/15/2023 5%

DoD/Other

GeoWATCH Enhancements and Technical Transition. Creare's GeoWATCH product produces high resolution downscaled soil moisture to support vehicle mobility applications. Enhance GeoWATCH and support technical transition of the capability to the DoD.

Role: TE

TPOC: John Eylander

PREVIOUS

N6833523C0666 Wilbur (PI) 08/01/2023–02/20/2023 10%

DoD/Other

Efficient Algorithms for Automated Battle Damage Assessment. Creare's Automated Underwater Explosion (UNDEX) Damage Assessment Tool (AUDAT), analyzes UNDEX waveforms to determine the number of UDNE events, and the bearing, range, depth, and estimated yield of each event.

Role: PE

TPOC: Christopher Sermarini

CURRENT/PREVIOUS SUPPORT

(Changes Marked with Border in Right Margin—previously pending grant is now active, and/or previously active grant has closed.)

N6833522C0281 Bieszczad (PI) 06/06/2022–12/06/2022 25%

Naval Air Warfare Center

Automated Assessment of Pier Damage from Multimodal 3-D Survey Data

Develop the Repier software to rapid and automatic assessment of pier damage based on point cloud data from in situ scans.

Role: TE

TPOC: Katelyn Rydberg

Overlap: None

W9132V19C0002 Bieszczad (PI) 09/10/2019–01/21/2023 25%

U.S. Army ERDC

Near-Real-Time Integration of Soil State Information

Develop the SoilMAP software framework to enable geospatial analysts to ingest, fuse, process, and visualize soil moisture, soil characteristics, and vehicle mobility in an integrated and timely manner.

Role: PE

TPOC: Delma Delbosque

Overlap: None

9 R44 GM130224-03 Clavier (PI) 09/20/2018–09/19/2022 6%

NIH-NIGMS

STEM Interactive Digital Tool to Educate and Promote Hearing Health and Science for 4th to 7th Grade

Develop an engaging game that teaches fundamental STEM concepts and intuition to youth while changing knowledge, attitudes, and intended behavior toward hearing health and the prevention of noise-induced hearing loss.

Role: PE

TPOC: Dr. Lawrence Beck

Overlap: None

N6833522C0212 Kattamis (PI) 03/23/2022–04/08/2023 10%

Naval Air Warfare Center, Aircraft Division

Software Optimized Subtractive Manufacturing

Creare's Topological Optimization Software (TOS) package will interface with existing FEA software, enforce the necessary subtractive manufacturing constraints, and output CAM ready CAD files for CNC machining.

Role: TE

TPOC: Joseph Johns

**For New and Renewal Applications - DO NOT SUBMIT UNLESS REQUESTED
PHS 398 OTHER SUPPORT**

Name of Individual: Wichman, Christopher S

Commons ID: Wichman.Christopher

Other Support - Project/Proposal

ACTIVE

Title: Effects of aortic compliance and Windkessel reduction on cardiac and aortic pathophysiology

Major Goals: We propose to test the hypothesis that preservation of aortic compliance with a new-generation compliant stent-graft results in normal hemodynamics and prevents cardiac and aortic pathologies

Status of Support: Active

Project Number: 44-1014-1004-201

Name of PI/PD: Mactaggart, Jason Neal

Source of Support: DHHS/NIH/NHLBI

Primary Place of Performance: University of Nebraska Medical Center

Project/Proposal Start and End Date: (MM/DD/YYYY) (if available): 09/01/2019 - 08/31/2024 Total

Award Amount (including Indirect Costs):

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
4. 2023	0.60 calendar
5. 2024	0.60 calendar

Title: Translating Efficacious Pediatric Weight Management Interventions into Rural & Micropolitan Communities

Major Goals: Our approach will use an implementation research explanatory process and outcome model to allow us to test hypotheses related to implementation and sustainability, engaging community/clinical partners in the implementation and sustainability process, and evaluate outcomes at both the individual and organizational level.

Status of Support: Active

Project Number:

Name of PI/PD: Hill

Source of Support: DHHS/CDC

Primary Place of Performance: University of Nebraska Medical Center

Project/Proposal Start and End Date: (MM/DD/YYYY) (if available): 04/01/2019 - 03/31/2024

Total Award Amount (including Indirect Costs):

Person Months (Calendar/Academic/Summer) per budget period. N/A

Title: NNTC Data Coordinating Center

Major Goals: The NNTC has served as a valuable resource to the NeuroAIDS research community since 1998. Its continuation is critical given the need for quality CNS tissues and related antemortem clinical data. For this grant I serve as the leader of the Steering Committee which determines direction and policy to serve investigators using these resources (a consortium of 4 brain banks) to examine emerging research topics in the NeuroAIDS field such as: a) eradication of HIV from persistent CNS reservoirs; b) pathogenic mechanisms of HIV-associated neurocognitive disorders (HAND) in setting of long term HAART; and c) HIV and aging. Furthermore we are responsible for all the data obtained clinically on the subjects and experimentally on the specimens, and are the interface between requesting scientists and the brain bank sites.

Status of Support: Active

Project Number: 5U24MH100925-10

Name of PI/PD: Fox, Howard S

Source of Support: DHHS/NIH/NIMH

Primary Place of Performance: University of Nebraska Medical Center

Project/Proposal Start and End Date: (MM/DD/YYYY) (if available): 03/01/2019 - 02/29/2024

Total Award Amount (including Indirect Costs):

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
4. 2023	1.20 calendar
5. 2024	1.20 calendar

Title: Cognitive Neuroscience of Development and Aging (CoNDA) Center

Major Goals: This project investigates if peripheral immunometabolism changes correlate with neuroimaging findings and can be used to evaluate Parkinson's Disease (PD) onset and progression.

Status of Support: Active

Project Number: 5P20GM130447-04

Name of PI/PD: Dunaevsky, Anna

Source of Support: DHHS/NIH/NIGMS

Primary Place of Performance: University of Nebraska Medical Center

Project/Proposal Start and End Date: (MM/DD/YYYY) (if available): 03/15/2020 - 01/31/2025

Total Award Amount (including Indirect Costs):

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
4. 2024	0.00 calendar
5. 2025	0.00 calendar

Title: Optimized Stents for the Femoropopliteal Artery

Major Goals: We would like to focus our renewal on translating the results obtained with human cadaver models to patients, and testing the hypothesis that a new optimized stent design capable of withstanding the severe mechanical environment of the flexing limbs would improve arterial healing.

Status of Support: Active

Project Number: 44-1014-1006-201

Name of PI/PD: Mactaggart, Jason Neal

Source of Support: DHHS/NIH/NHLBI

Primary Place of Performance: University of Nebraska Medical Center

Project/Proposal Start and End Date: (MM/DD/YYYY) (if available): 03/01/2020 - 02/28/2025

Total Award Amount (including Indirect Costs):

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
4. 2024	0.76 calendar
5. 2025	0.76 calendar

Title: Optimized Stents for the Femoropopliteal Artery

Major Goals: We would like to focus our renewal on translating the results obtained with human cadaver models to patients, and testing the hypothesis that a new optimized stent design capable of withstanding the severe mechanical environment of the flexing limbs would improve arterial healing.

Status of Support: Active

Project Number: 44-1014-1006-201

Name of PI/PD: MacTaggart

Source of Support: University of Nebraska-Omaha (subcontract of NIH/NHLBI)

Primary Place of Performance: University of Nebraska Medical Center

Project/Proposal Start and End Date: (MM/DD/YYYY) (if available): 03/01/2020 - 02/28/2025

Total Award Amount (including Indirect Costs):

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2023	0.81 calendar
2. 2024	0.81 calendar
3. 2025	0.81 calendar

Title: Great Plains IDeA-CTR - Cycle 2

Major Goals: Goal: to transform the culture at partner institutions to bolster CTR capabilities, translate laboratory research to measurable health outcomes, and bring community and clinician-generated ideas and experience back to the lab specific aims: 1. Maintain strong leadership and governance. The PI, core directors, and institutional leadership will have the authority and credibility to effectively manage personnel, facilities, budget, and resources, in line with institutional and NIH policies. 2. Enhance the operations and contributions of our effective SC and advisory committees. SC enhancements will further enable strategic and operational plans, improve access to Core facilities and services, and maximize GP IDeA-CTR impact across the network. We will maintain our effective IAC and EAC to advise on strategic plans and add an Academic Public-Private Board to advise on innovative methods to catalyze CTR and drive findings to the marketplace. 3. Advance overall plans for managing, coordinati

Status of Support: Active

Project Number: 5U54GM115458-07

Name of PI/PD: Rizzo, Matthew

Source of Support: DHHS/NIH/NIGMS

Primary Place of Performance: University of Nebraska Medical Center

Project/Proposal Start and End Date: (MM/DD/YYYY) (if available): 07/01/2021 - 06/30/2026

Total Award Amount (including Indirect Costs):

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
2. 2023	1.44 calendar
3. 2024	1.44 calendar
4. 2024	1.44 calendar
5. 2025	1.44 calendar
6. 2026	1.44 calendar

Title: Field Deployable Intensimetric Probe System for Early Diagnosis and Monitoring of Noised/Induced Hearing Loss and Traumatic Middle-Ear Injury

Major Goals: Our objectives are to develop and validate a highly innovative intensimetric probe system. Our central hypothesis is that the new field deployable device will provide a more reliable and efficient diagnosis of middle and inner ear injuries compared to existing systems because of its insensitivity to probe placement and standing waves in the ear canal.

Status of Support: Active

Project Number: 96489-A

Name of PI/PD: Wichman

Source of Support: Father Flanagan's Boys' Home (subcontract NIH/NHLBI)

Primary Place of Performance: University of Nebraska Medical Center
Project/Proposal Start and End Date: (MM/DD/YYYY) (if available): 08/15/2021 - 08/14/2024
Total Award Amount (including Indirect Costs):
Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2023	0.56 calendar
2. 2024	0.56 calendar

Title: The Nebraska Solution: Diabetes Care

Major Goals: To build community relationships across the diabetes care continuum thereby improving diabetes outcomes. To establish a common data system for continuity of care providers to track community diabetes health and to identify gaps that can be targeted to improve diabetes / pre-diabetes care and management.

Status of Support: Active

Project Number: 37-5450-6000-010

Name of PI/PD: Dzelatowski

Source of Support: Nebraska Diabetes Foundation / University of Nebraska Medical Center

Primary Place of Performance: University of Nebraska Medical Center Project

Project/Proposal Start and End Date: (MM/DD/YYYY) (if available): 08/01/2021 - 08/31/2024

Total Award Amount (including Indirect Costs):

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
2. 2023	2.40 calendar
3. 2024	2.40 calendar

Title: An intra- and inter-laboratory comparison of etonogestrel bioanalytical assays

Major Goals: To compare the accuracy and precision of etonogestrel bioanalytical assays in both plasma and serum from both prepared and human samples at five research laboratories.

Status of Support: Active

Project Number: 60723

Name of PI/PD: Scarsi, Kim K

Source of Support: Merck Sharp & Dohme Corp.

Primary Place of Performance: University of Nebraska Medical Center

Project/Proposal Start and End Date: (MM/DD/YYYY) (if available): 01/01/2021 - 12/31/2023

Total Award Amount (including Indirect Costs)

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
2. 2023	0.60 calendar

Title: Phase I/II Study to Test the Immunostimulatory Effects of Consolidative Hypofractionated Radiation Therapy (hfRT) for Boosting the Residual Primary Lung Cancer in Combination with Anti-PD-L1 Immunotherapy After Definitive Chemoradiation Therapy for Stage

Major Goals: This study is designed to determine if combining consolidative radiation therapy (RT) using a hypofractionated regimen (hfRT) of 10Gy x 2 fractions for boosting the residual primary lung cancer with adjuvant anti-PD-L1 therapy concurrently will provide better tumor control locoregionally and distantly than either modality alone. For safety reasons, consolidative hfRT will start from 6.5Gy x 2

fractions and dose escalate to 10Gy x 2 fractions in a 3+3 design. Consolidative hfRT will be delivered one to two months after finishing definitive chemoradiation therapy (dCRT) and concurrently with adjuvant anti-PD-L1 therapy using durvalumab in stage III non-small cell lung cancer (NSCLC).

Status of Support: Active

Project Number: MEDI4736

Name of PI/PD: Zhang, Chi

Source of Support: AstraZeneca Pharmaceuticals LP

Primary Place of Performance: University of Nebraska Medical Center

Project/Proposal Start and End Date: (MM/DD/YYYY) (if available): 04/27/2021 - 08/31/2024

Total Award Amount (including Indirect Costs):

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
2. 2023	0.12 calendar
3. 2024	0.12 calendar

Title: Implementing and Evaluating the Comprehensive Integration of Physical Activity into a Major Health System and Connecting Patients to Community-Based Physical Activity Programs

Major Goals: This proposal seeks to <i>directly</i> test, in a cluster randomized controlled trial, the effectiveness of an intervention to integrate physical activity (PA) assessment and brief counseling in clinical settings with referral to community-based resources, to increase and maintain health-enhancing PA levels, among inactive adults with one or more cardio-metabolic risk factors.

Status of Support: Active

Project Number: 23-5105 PO 200006

Name of PI/PD: Wichman, Christopher S

Source of Support: DHHS/NIH/NHLBI

Primary Place of Performance: University of Nebraska Medical Center

Project/Proposal Start and End Date: (MM/DD/YYYY) (if available): 09/23/2022 - 08/31/2023

Total Award Amount (including Indirect Costs):

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
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Title: PARITY: An integrated community care and strengths-based technology intervention to improve maternal wellness and reduce health disparities in Black women

Major Goals: The overall objective of this Certified Nurse Midwife-led proposal is to test the clinical, behavioral, and strength building effectiveness of the PARITY program and explore how it achieves its outcomes in pregnant Black women. We hypothesize that Black women enrolled in the PARITY program will experience reduced severe maternal morbidity, mortality, and cesarean birth and have improved wellness-related behavioral outcomes and empowered strengths compared to women in an information-only usual care control group. Aim 1: Determine the effects of the PARITY program on severe maternal morbidity (primary outcome), maternal mortality, and cesarean birth (secondary outcomes) in pregnant Black women. Aim 2: Determine the effects of the PARITY program on wellness-related behavioral outcomes including nutrition, physical activity, sleep, and healthcare adherence. Aim 3: Assess whether changes in maternal outcomes are mediated by changes in wellness-related behavioral outcomes (nutrition, physical activity, sleep, and healthcare adherence) and whether the effects of PARITY on wellness-related behavioral outcomes are mediated by changes in empowered strengths including self-efficacy, social support, motivation, resilience, problem-solving, and self-regulation. Aim 4: Identify barriers, facilitators, and perceived benefits of the PARITY intervention.

Status of Support: Active

Project Number: 1R56NR020707-02
 Name of PI/PD: Mollard, Elizabeth Kirstin
 Source of Support: DHHS/NIH/NINR
 Primary Place of Performance: University of Nebraska Medical Center
 Project/Proposal Start and End Date: (MM/DD/YYYY) (if available): 09/23/2022 - 07/31/2024
 Total Award Amount (including Indirect Costs):
 Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
2. 2024	0.12 calendar

Title: Aging trajectories and outcomes of older adults with acute myeloid leukemia
 Major Goals:
 Status of Support: Active
 Project Number: 1R01CA276928-01A1
 Name of PI/PD: Bhatt, Vijaya R
 Source of Support: DHHS/NIH/NCI
 Primary Place of Performance: University of Nebraska Medical Center
 Project/Proposal Start and End Date: (MM/DD/YYYY) (if available): 07/12/2023 - 06/30/2028
 Total Award Amount (including Indirect Costs):
 Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2024	0.60 calendar
2. 2025	0.60 calendar
3. 2026	0.60 calendar
4. 2027	0.60 calendar
5. 2028	0.60 calendar

Title: Behavioral Economic and Staffing Strategies To Increase Adoption of the ABCDEF Bundle in the ICU (BEST-ICU)
 Major Goals: Our project specifically focuses on building and evaluating BE theory-based interventions fostering ABCDEF bundle adoption in everyday ICU practice and improving the clinical outcomes of critically ill adults who require MV
 Status of Support: Active
 Project Number: 1UG3HL165740-01A1
 Name of PI/PD: Balas, Michele C
 Source of Support: DHHS/NIH/NHLBI
 Primary Place of Performance: University of Nebraska Medical Center
 Project/Proposal Start and End Date: (MM/DD/YYYY) (if available): 04/01/2023 - 03/31/2028
 Total Award Amount (including Indirect Costs):
 Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2024	0.30 calendar
2. 2025	0.30 calendar
3. 2026	0.30 calendar
4. 2027	0.30 calendar
5. 2028	0.30 calendar

Title: Community-Based Organizations and Development of Implementation Strategies for Brain Injury Screening Resulting from Intimate Partner Violence

Major Goals:

Status of Support: Active

Project Number: 1R01NS130574-01A1

Name of PI/PD: Rajaram, Shireen S

Source of Support: DHHS/NIH/NINDS

Primary Place of Performance: University of Nebraska Medical Center

Project/Proposal Start and End Date: (MM/DD/YYYY) (if available): 07/15/2023 - 05/31/2027

Total Award Amount (including Indirect Costs):

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2024	1.20 calendar
2. 2025	1.20 calendar
3. 2026	1.20 calendar
4. 2027	1.20 calendar

PENDING

Title: Engaging community to develop an Indigenous centered pregnancy care program

Major Goals: This study will utilize an Indigenous CBPR approach to implement a culturally congruent Indigenous prenatal care pilot program, to assess feasibility, acceptability, cultural congruence and associated changes in outcomes for Native American mothers.

Status of Support: Pending

Project Number: 1 R21 NR021064-01

Name of PI/PD: Maloney, Shannon I

Source of Support: DHHS/NIH/NINR

Primary Place of Performance: University of Nebraska Medical Center

Project/Proposal Start and End Date: (MM/DD/YYYY) (if available): 12/01/2023 - 06/30/2025

Total Award Amount (including Indirect Costs):

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2024	0.36 calendar
2. 2025	0.36 calendar

Title: Center for Cardiovascular Research in Biomechanics

Major Goals: The goal for this COBRE (P20) Phase I is to provide mentoring guidance to research trainees and help bridge it with clinical practice as well as promote the training and career development of the trainees by guiding them to develop innovative methods and technologies to strengthen translational research.

Status of Support: Pending

Project Number:

Name of PI/PD: Pipinos, Iraklis I

Source of Support: University of Nebraska - Omaha

Primary Place of Performance: University of Nebraska Medical Center

Project/Proposal Start and End Date: (MM/DD/YYYY) (if available): 12/01/2023 - 11/30/2028

Total Award Amount (including Indirect Costs):

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2024	0.60 calendar
2. 2025	0.60 calendar
3. 2026	0.60 calendar
4. 2027	0.60 calendar
5. 2028	0.60 calendar

Title: PARITY: An integrated community care & strengths-based technology intervention to improve maternal wellness & reduce health disparities in Black women

Major Goals:

Status of Support: Pending

Project Number: 1R01NR020707-01A1

Name of PI/PD: Mollard, Elizabeth Kirstin

Source of Support: DHHS/NIH/NINR

Primary Place of Performance: University of Nebraska Medical Center

Project/Proposal Start and End Date: (MM/DD/YYYY) (if available): 09/01/2023 - 08/31/2028 Total

Award Amount (including Indirect Costs):

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2024	0.60 calendar
2. 2025	0.60 calendar
3. 2026	0.60 calendar
4. 2027	0.60 calendar
5. 2028	0.60 calendar

Title: Motivational Enhancement and Device Support Interventions to Increase Continuous Positive Airway Pressure Therapy Adherence in Adults with Obstructive Sleep Apnea

Major Goals: Our long-term goal is to develop effective, patient-centered, and scalable interventions to increase CPAP adherence. The overall objective of the proposed project is to identify an optimal adaptive intervention to promote CPAP adherence and improve outcomes of persons newly diagnosed with OSA and increase understanding of potential mediators and moderators of treatment response.

Status of Support: Pending

Project Number:

Name of PI/PD: Miller

Source of Support: DHHS/NIH

Primary Place of Performance: University of Nebraska Medical Center

Project/Proposal Start and End Date: (MM/DD/YYYY) (if available): 09/01/2023 - 08/31/2028

Total Award Amount (including Indirect Costs):

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2024	0.60 calendar
2. 2025	0.60 calendar
3. 2026	0.60 calendar
4. 2027	0.60 calendar
5. 2028	0.60 calendar

Title: Facilitating Health System Implementation of Physical Activity Screening and Referral to Community-Based Programs: Exercise is Medicine Greenville

Major Goals:

Status of Support: Pending

Project Number:

Name of PI/PD: Wichman, Christopher S

Source of Support: DHHS/NIH

Primary Place of Performance: University of Nebraska Medical Center

Project/Proposal Start and End Date: (MM/DD/YYYY) (if available): 04/01/2024 - 03/31/2028

Total Award Amount (including Indirect Costs):

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2025	1.20 calendar
2. 2026	1.20 calendar
3. 2027	1.20 calendar
4. 2028	1.20 calendar

Title: Above Knee Artery Calcification as a Driver of Below Knee Ischemia and Neuropathy

Major Goals: remove not funded

Status of Support: Pending

Project Number:

Name of PI/PD: Mactaggart, Jason Neal

Source of Support: DHHS/NIH

Primary Place of Performance: University of Nebraska Medical Center

Project/Proposal Start and End Date: (MM/DD/YYYY) (if available): 04/01/2024 - 03/31/2029

Total Award Amount (including Indirect Costs):

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2025	0.60 calendar
2. 2026	0.60 calendar
3. 2027	0.60 calendar
4. 2028	0.60 calendar
5. 2029	0.60 calendar

Title: Community-Based Organizations and Development of Implementation Strategies for Brain Injury Screening Resulting from Intimate Partner Violence

Major Goals:

Status of Support: Pending

Project Number: 1R01NS136382-01

Name of PI/PD: Rajaram, Shireen S

Source of Support: DHHS/NIH/NINDS

Primary Place of Performance: University of Nebraska Medical Center

Project/Proposal Start and End Date: (MM/DD/YYYY) (if available): 04/01/2024 - 03/31/2028

Total Award Amount (including Indirect Costs):

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2025	1.20 calendar
2. 2026	1.20 calendar
3. 2027	1.20 calendar
4. 2028	1.20 calendar

Title: Linking Signs and Symptoms to Action in Socioeconomically Deprived Patients with Heart Failure
Major Goals: We propose a 2-month, 3-arm (LINKS2A, RNC, or Usual Care [UC]) repeated measure randomized controlled trial to test the effects of the interventions against UC on symptom reduction, health-related quality of life, healthcare utilization, and costs in socioeconomically deprived patients with HF.

Status of Support: Pending

Project Number: 1R01NR020351-01A1

Name of PI/PD: Schmaderer, Myra S

Source of Support: DHHS/NIH/NINR

Primary Place of Performance: University of Nebraska Medical Center

Project/Proposal Start and End Date: (MM/DD/YYYY) (if available): 04/01/2024 - 03/31/2029

Total Award Amount (including Indirect Costs):

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2025	0.60 calendar
2. 2026	0.60 calendar
3. 2027	0.60 calendar
4. 2028	0.60 calendar
5. 2029	0.60 calendar

Title: Sit Less, Exercise More: A Self-managed Behavioral Intervention to Improve Physical Function in Older Cancer Survivors

Major Goals: The objective of the proposed study is to examine the independent and combined effects of reducing daily sitting time and/or increasing regular MVPA on physical function and musculoskeletal health in older cancer survivors (aged 65+ years) who have completed primary cancer treatment.

Status of Support: Pending

Project Number: 1 R01 CA282164-01

Name of PI/PD: Dickinson, Kristin A

Source of Support: DHHS/NIH/NCI

Primary Place of Performance: University of Nebraska Medical Center

Project/Proposal Start and End Date: (MM/DD/YYYY) (if available): 02/01/2024 - 01/31/2029

Total Award Amount (including Indirect Costs):

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2025	0.60 calendar
2. 2026	0.60 calendar
3. 2027	0.60 calendar
4. 2028	0.60 calendar
5. 2029	0.60 calendar

Title: Promoting Cardiovascular Health in Hispanic/Latino Meatpacking Workers: A Community-Informed,

Multilevel Approach Using Fitness-Based Risk Screening and Management

Major Goals: Develop and conduct a multi-level (individual, interpersonal, and organizational) intervention targeting primary and secondary CV risk with HLA workers in meatpacking, an essential critical infrastructure industry.

Status of Support: Pending

Project Number: 1 R01 HL172967-01

Name of PI/PD: Rowland, Sheri Anne

Source of Support: DHHS/NIH/NHLBI

Primary Place of Performance: University of Nebraska Medical Center

Project/Proposal Start and End Date: (MM/DD/YYYY) (if available): 04/01/2024 - 03/31/2028

Total Award Amount (including Indirect Costs):

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2025	1.20 calendar
2. 2026	1.20 calendar
3. 2027	1.20 calendar
4. 2028	1.20 calendar

Title: Fostering local community-driven innovation systems for child population physical activity: A cluster randomized trial comparing feedback coordination design principles for equitable performance

Major Goals:

Status of Support: Pending

Project Number: 1 R01 MD019404-01

Name of PI/PD: Dzewaltowski, David A

Source of Support: DHHS/NIH/NIMHD

Primary Place of Performance: University of Nebraska Medical Center

Project/Proposal Start and End Date: (MM/DD/YYYY) (if available): 05/01/2024 - 04/30/2029

Total Award Amount (including Indirect Costs):

Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2025	0.60 calendar
2. 2026	0.60 calendar
3. 2027	0.60 calendar
4. 2028	0.60 calendar
5. 2029	0.60 calendar

In-KIND

None

Overlap

Overlap: Any pending awards received that would result in exceeding 100% FTE, will be transferred to another biostatistician within the department.

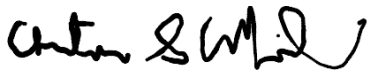
Signature

I, PD/PI or other senior/key personnel, certify that the statements herein are true, complete and accurate

to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

Signature: Wichman, Christopher S

Date: 09/01/2023

A handwritten signature in black ink, appearing to read "Chris S. Wichman". The signature is written in a cursive, flowing style with a large initial "C" and a stylized "S".

This electronic signature was captured in a UNMC system designed to meet NIH audit requirements.