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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

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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, which has largely been accomplished. We first developed an analytical model to predict the pressure at the ear drum given velocity/pressure measurements and the system geometry. We then designed a new probe enclosure with a narrower tip based on the analytical model and analysis of data from the previous probe design. This was needed as the size of the tip in the previous prototype led to challenges in creating a leak-free acoustic fit necessary for accurate measurements. We designed and ordered miniaturized circuit boards, and developed a new system design to increase patient comfort, and assembled a next-generation alpha prototype for testing and verification of our new design and approach. We validated our calibration and analytical modeling approach by comparing the predicted pressure amplitude to the measured pressure amplitude at the ear drum using a reference, calibrated ear simulator (Bruel & Kjaer Type 4157, IEC 60318-4 coupler). Overall, the results of this test demonstrate the validity of our approach, and shows that reducing our probe's stem diameter can still give excellent results.					
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1. INTRODUCTION:

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. 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 1 (months 1-12) of a 3 year award. Actual completion dates are noted for tasks that had targeted completion dates in Year 1.

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	75% completion at month 11
Major Task 4: Evaluate probe performance	6-10	10
Major Task 5: Dissemination of results	10-14	In Progress
SPECIFIC AIM 2: Laboratory validation of intensimetric probe system		
Major Task 1: Prepare for recruitment and testing	6-15	75% completion at month 11
Major Task 2: Recruitment and data collection	16-31	
Major Task 3: Data analysis	20-32	
Major Task 4: Dissemination of results	20-36	
SPECIFIC AIM 3: Clinical validation of intensimetric probe system		
Major Task 1: Recruitment and data collection	16-31	
Major Task 2: Data analysis	20-33	
Major Task 3: Dissemination of results	21-36	

What was accomplished under these goals?

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

Task 1. Develop Hardware and Software

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

During the reporting period we:

- Developed an analytical model to predict the pressure at the ear drum given velocity/pressure measurements and the system geometry.
- Designed a new probe enclosure with a narrower tip based on the analytical model and analysis of data from the previous probe design.
- Assembled a next-generation alpha prototype for testing and verification of our new design and approach.
- Designed and ordered miniaturized circuit boards.
- Developed a new system design to increase patient comfort.

These items are detailed in the following sections.

1.1 Analytical Model Development and Validation

We developed an analytical model to predict the pressure at the ear drum given velocity/pressure measurements and the system geometry (Figure 1). This model also predicts the pressure emitted by the ear drum in response to a DPOAE exam based on velocity and pressure measurements at the probe. We developed this analytical model to generate a design that provides a better seal between the probe and the patient's ear canal. Our previous probe diameter was similar to a typical ear canal (approximately 7–10 mm), whereas our new generation probe has a smaller diameter (4 mm) so that it can be inserted further into the ear canal and create a better seal. The following provides an overview of the model and describes initial test results using the next-generation Alpha prototype.

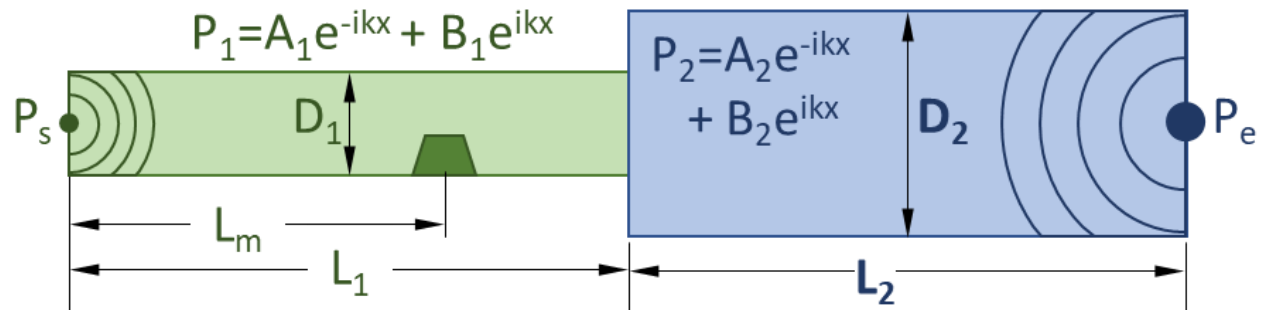


Figure 1. Schematic for Analytical Model. The green section (Left) represents probe “stem,” while the Right represents the ear canal. See text in Section 1.1.1 for an explanation of symbols.

1.1.1 Analytical Model Description

The important model parameters are shown in Figure 1, where:

- P_s is the pressure emitted by the probe speakers.
- P_e is the pressure reflected by the ear drum.
- P_1 is the pressure wave that exists in the probe.
- P_2 is the pressure wave that exists in the ear canal.
- L_m is the distance from the speaker outlet to the Microflow sensor.
- L_1 and D_1 are the known length and diameter of the prototype probe cavity.
- L_2 and D_2 are the estimated length and diameter of the ear canal.

The model is a 1-D, plane-wave solution to the linear acoustic wave equation. We are interested in frequencies ranging from 100 Hz to 10 kHz, which means the minimum wavelength of interest ranges from 3,400 mm to 34 mm, about 3–860 times the size of the probe or ear canal diameter (4/10 mm), so the plane wave assumption is reasonable.

To develop the model, we solve for the coefficients A_1 , B_1 , A_2 , and B_2 . This fully describes the solution of velocity and pressure in frequency space for all locations in the system. We solve for A_1 and B_1 by equating $U_1(x=L_m, k)=U_m(k)$ and $P_1(x=L_m, k)=P_m(k)$, where U_m and P_m are the velocity and pressure measured by the Microflow sensors

and k is the wave number. This gives the following solution for the pressure and velocity P_1, U_1 :

$$P_1(k, x) = \frac{1}{2} (P_m e^{iL_m k} + U_m Z_0 e^{iL_m k}) e^{-ikx} + \frac{1}{2} (P_m e^{-iL_m k} - U_m Z_0 e^{-iL_m k}) e^{ikx}$$

$$U_1(k, x) = \frac{1}{2Z_0} (P_m e^{iL_m k} + U_m Z_0 e^{iL_m k}) e^{-ikx} - \frac{1}{2Z_0} (P_m e^{-iL_m k} - U_m Z_0 e^{-iL_m k}) e^{ikx}$$

where Z_0 is the characteristic impedance in air.

Next, to solve for the pressure and velocity *in the ear canal*, we use continuity of pressure at the interface between 1–2, so $P_1(x=L_1, k) = P_2(x=L_1, k)$ and the volume flow rate (i.e., mass continuity), $S_1 U_1(x=L_1, k) = S_2 U_2(x=L_1, k)$, where the areas $S_1 = Z_0/Z_1$ and $S_2 = Z_0/Z_2$ are included in the impedance for each section. This gives the following solution for pressure and velocity P_2, U_2 :

$$P_2(x, k) = \frac{1}{4} \left(\left[P_m - U_m Z_0 + \frac{U_m Z_0 Z_2 - P_m Z_2}{Z_1} \right] e^{i2L_1 k} e^{-iL_m k} \right. \\ \left. + \left[P_m + U_m Z_0 + \frac{P_m Z_2 + U_m Z_0 Z_2}{Z_1} \right] e^{iL_m k} \right) e^{-ikx} \\ + \frac{1}{4} \left(\left[P_m + U_m Z_0 - \frac{U_m Z_0 Z_2 + P_m Z_2}{Z_1} \right] e^{-i2L_1 k} e^{iL_m k} \right. \\ \left. + \left[P_m - U_m Z_0 + \frac{P_m Z_2 - U_m Z_0 Z_2}{Z_1} \right] e^{-iL_m k} \right) e^{ikx}$$

$$U_2(x, k) = \frac{1}{4Z_0} \left(\left[P_m - U_m Z_0 + \frac{U_m Z_0 Z_2 - P_m Z_2}{Z_1} \right] e^{i2L_1 k} e^{-iL_m k} \right. \\ \left. + \left[P_m + U_m Z_0 + \frac{P_m Z_2 + U_m Z_0 Z_2}{Z_1} \right] e^{iL_m k} \right) e^{-ikx} \\ - \frac{1}{4Z_0} \left(\left[P_m + U_m Z_0 - \frac{U_m Z_0 Z_2 + P_m Z_2}{Z_1} \right] e^{-i2L_1 k} e^{iL_m k} \right. \\ \left. + \left[P_m - U_m Z_0 + \frac{P_m Z_2 - U_m Z_0 Z_2}{Z_1} \right] e^{-iL_m k} \right) e^{ikx}$$

We need one final equation for calibration. During calibration, we solve for $U_1(x=L_m)$ by setting the pressure in section 1 at L_m to the reference microphone pressure, $P_1(x=L_m) = P_{ref}$. Then we solve for U_1 given the known geometry and properties of the system. This gives:

$$U_1(x, k) = P_m \frac{R_2 [\{Z_1 - Z_2\} e^{ikL_1} + \{Z_1 + Z_2\} e^{2ikx}] + [-\{Z_1 + Z_2\} e^{2ikL_1} + \{Z_2 - Z_1\} e^{2ikx}] e^{2ikL_2}}{Z_0 (R_2 [\{Z_1 - Z_2\} e^{2ikL_1} - \{Z_1 + Z_2\} e^{2ikx}] + [-\{Z_1 + Z_2\} e^{2ikL_1} + \{Z_1 - Z_2\} e^{2ikx}] e^{2ikL_2})}$$

where R_2 is the reflection coefficient at the ear canal end.

These equations allow us to proceed with calibrating the Create probe.

1.1.2 Calibration

After discussion with engineers at Microflown, we determined that we needed a custom calibration for the sensor because of our enclosure. We calibrate the pressure measured by the Microflown sensor against a reference microphone, and we calibrate the velocity measured by the Microflown sensor using our analytical model and complete knowledge of a calibration chamber. There is a port in our probe at the same location as the Microflown microphone for inserting the reference pressure probe. The calibration chamber is a cylinder made of aluminum, and the calibration test for the Alpha prototype has the parameters as shown in Table 1.

Table 1. Parameters of the Microflown Calibration Geometry.	
Parameter	Value
P_s	A linear chirp from 100–10,000 Hz over 2 seconds
L_1	42.8 mm, which is the combined length of the probe (36.3 mm) + tip
L_2	21.2 mm, which is the length of the cylinder (27 mm) minus insertion depth
D_1	4.06 mm, the diameter of Creare's probe
D_2	10 mm, the diameter of the calibration chamber
R_1	0.9995 the reflection coefficient of the air/plastic probe interface (estimate)
R_2	0.9999 the reflection coefficient of the air/aluminum cylinder interface

The calibration procedure generates curves to convert the measured voltage to physical units and correct the measured phase to the reference microphone phase. We solve for the parameters of the Microflown calibration equations by minimizing the difference between the reference pressure measurement and our sensor. Figure 2 and Figure 3 show the resulting calibrations for pressure and velocity, respectively of our next generation alpha prototype.

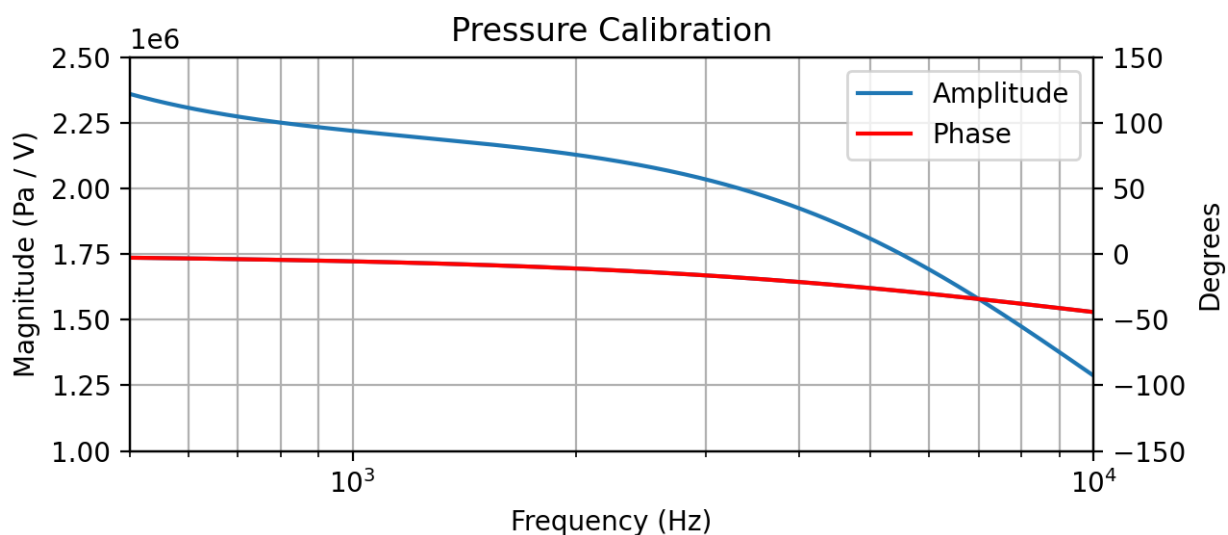


Figure 2. Creare Prototype Probe Pressure Calibration.

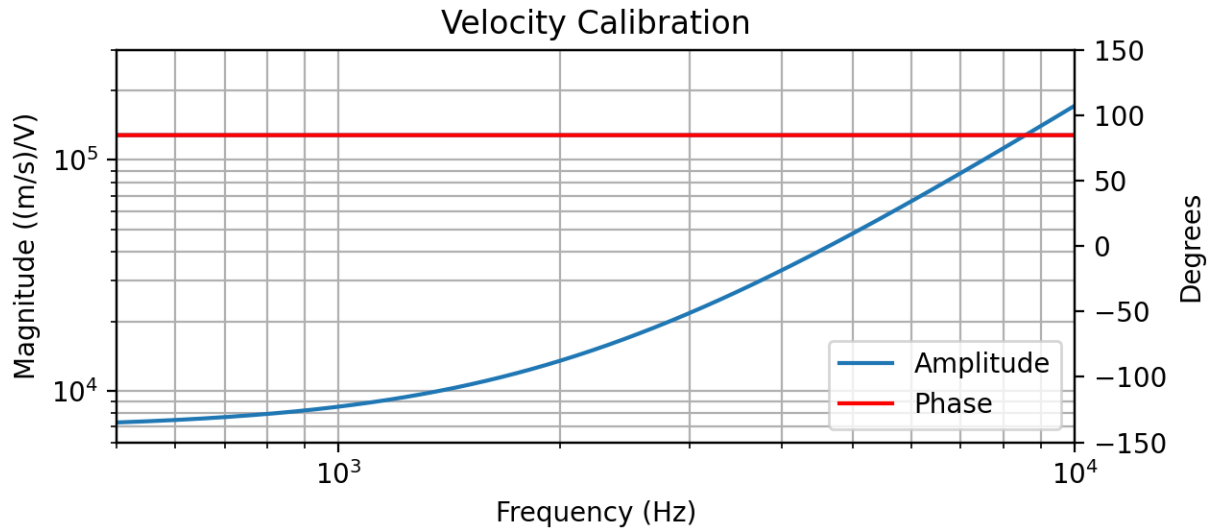


Figure 3. Create Prototype Probe Velocity Calibration.

1.1.3 Validation

We validate our calibration and analytical modeling approach by comparing the predicted pressure amplitude to the measured pressure amplitude at the ear drum using a reference, calibrated ear simulator (Briel & Kjaer Type 4157, IEC 60318-4 coupler). For this validation test, we use the known diameter of the ear simulator ($D_2=10$ mm) and estimate the distance from the probe exit to the ear simulator pressure sensor ($L_2=4.9$ mm) based on our estimated insertion depth. Figure 4 shows the results of this validation test. We also plot $P_{\text{sum}}=0.5|P_1 + Z_0U_1| + 0.5|P_1 - Z_0U_1|$, which works well when there is no change in area between the probe and the ear canal. The figure shows that our approach correctly predicts the pressure at the ear drum to within 2.5 dB up to about 8 kHz, with a 5 dB spike around 9 kHz. The figure also shows that our method is not too sensitive to the insertion depth, where we also plotted the predicted pressure when the estimate is off by a factor of two (thin green line). In this case, only frequencies beyond 4 kHz are affected, and the error increases in some places, while it actually decreases at 9 kHz. Overall, this test demonstrates the validity of our approach, and shows that reducing our probe's stem diameter can still give excellent results.

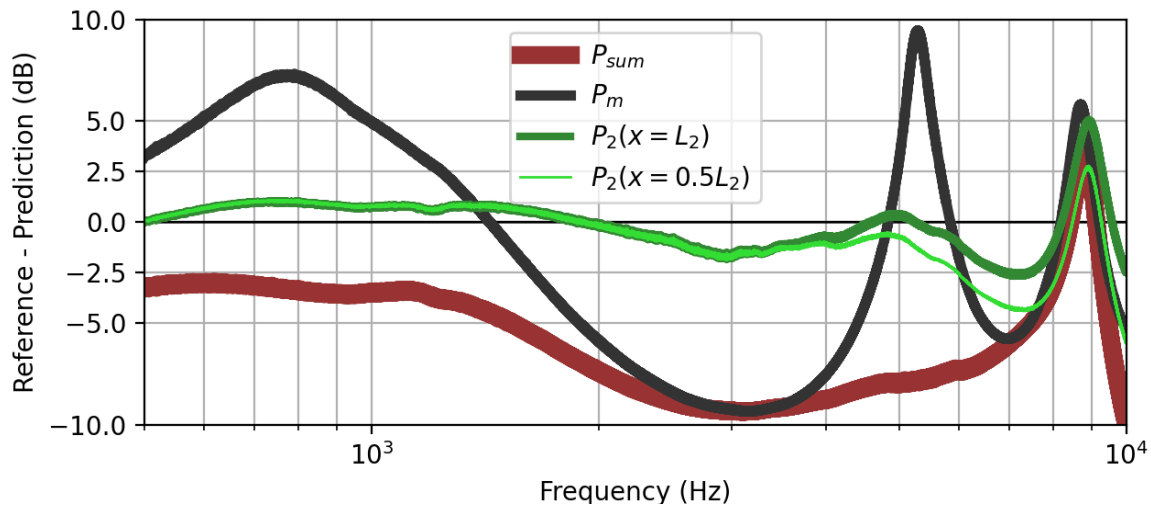


Figure 4. Validation of Analytical Pressure Estimation Approach. Estimating the pressure ($P_2(x=L_2)$) gives a lower error compared to using the pressure as measured (P_m), or using the summed pressure (P_{sum}). Since the insertion depth (L_2) is not necessarily known, we also show that our prediction changes most at higher frequencies when the insertion depth is changed.

1.2 Next Generation Probe Design

Using an analytical model similar to the one described in Section 1.1 (except with an additional area change), we analyzed data from Phase II of this project. Based on that analysis, we designed the next generation probe shown in

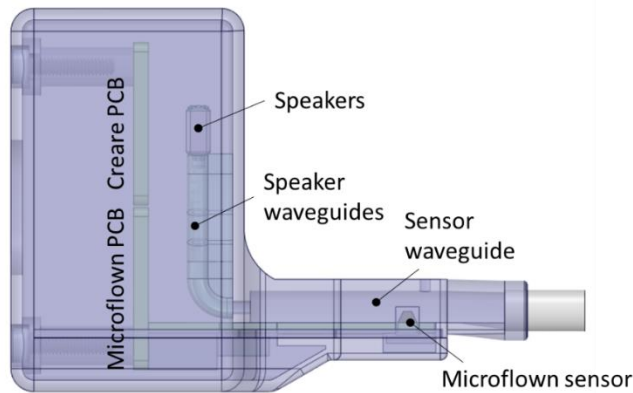


Figure 5. Next Generation Alpha Prototype Design.

. This probe features smaller speakers that can fit inside the probe head, as well as a new Create PCB for digitizing audio. By digitizing audio close to the signal, we reduce electromagnetic noise compared to the previous model. The sensor waveguide is also simplified to give a constant cross-sectional area up to the point where the sound enters the ear canal. As discussed in Section 1.1, this smaller diameter (4 mm compared to 10 mm) stem was designed to enable better insertion of the probe into the ear canal, which should create a better seal for improved test data. As discussed in the next section, we manufactured and assembled a prototype version of this design for testing the

acoustic properties of this sensor. Our next step is to design a Beta version of this prototype based on testing and the finalized sizes of our new electronics.

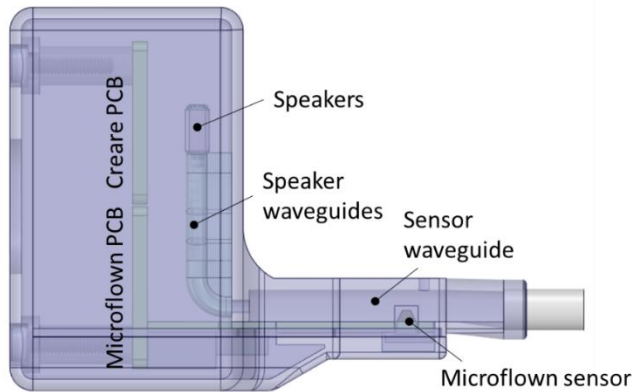


Figure 5. Next Generation Alpha Prototype Design.

1.3 Alpha Prototype Assembly

We ordered a 3-D printed enclosure and assembled a new alpha prototype using our existing electronics as shown in Figure 6. The purpose of this prototype is to verify the acoustic properties of the new design to ensure our approach for reducing the tip diameter is valid. Since our redesigned electronics are not yet ready, we reused the electronics from our previous effort but with the new enclosure and new miniaturized speakers. Results from this prototype are described in Section 1.1.



Figure 6. Assembled Alpha Prototype.

1.4 Miniaturized Electronics

We designed a new set of miniaturized electronics. For this iteration, we split the functionality across two PCBs (Figure 7). The first board contains the audio codec and

is housed inside the probe head to enable analog to digital conversion of the signal close to the measurement source. This reduces noise due to electromagnetic interference. The second PCB contains the remaining components, including the processor and Bluetooth wireless communications chip.

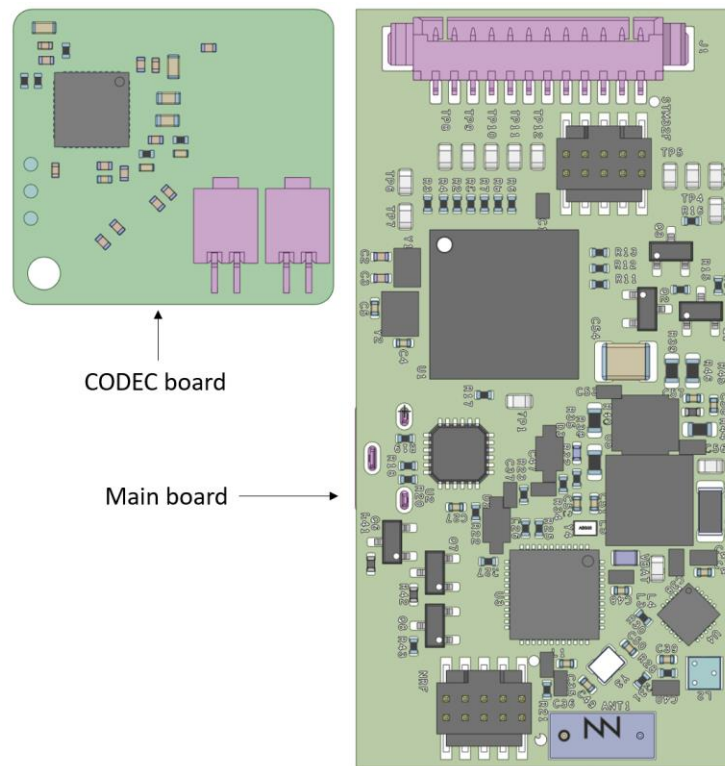


Figure 7. Our Redesigned PCBs. These PCBs have a much smaller footprint while separating the boards reduces EMI noise.

We reduced the size of main PCB significantly compared to the previous design shown in Figure 6. The new board can nearly fit inside the probe head, and measures approximately 50 mm x 25 mm. We have ordered four assemblies of both boards, and these are currently being tested with our new firmware.

1.5 Probe System Design

We developed a new system prototype design based on feedback received from the previous phase of this project. The new design uses a commercial off the shelf (COTS) headset (Figure 8, Left) and an adjustable wire, coiled in a spiral shape (Figure 8, Right). The spiral shape gives the user significant flexibility in placing the probe, offering the ability to rotate and translate in any direction about its mount *and* retaining the position once set. We disassemble the COTS headset, completely removing one of the cups. We then interface our probe with the removed cup through a wire, which supports the probe head and enables large adjustments to the probe position. This design gives free access to the listener's ear, without bulky supports in the way. We also

disassemble the remaining ear cup, removing the existing COTS components and replacing them with our main PCB and batteries, which completes the overall system.



Figure 8. Our Next Generation Design Concept. This combines a COTS headband and adjustable wire to provide comfort to the patient and flexible placement to the audiologist.

SPECIFIC AIM 2: Laboratory validation of intensimetric probe system.

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

1. Completing and submitting our IRB for approval
2. Obtaining IRB approved
3. Submitting IRB and human subjects' documentation to HRPO for approval
4. Obtaining HRPO approval
5. Purchasing the Titan Probe System and Computer
6. And to begin to prepare the data collection protocol

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: test our new PCBs; assemble, calibrate, and test three Beta prototype probes; update the system firmware and companion MATLAB software to support the human study design; evaluate the new probe performance; and disseminate results. We plan to submit an abstract in September to the Association of Research in Otolaryngology Midwinter Meeting to be held in the winter.

SPECIFIC AIM 2: Laboratory validation of intensimetric probe system.

During the next reporting period, we plan to: finish preparing for recruitment and testing by hiring a graduate research assistant and finalizing data collection protocols, begin recruitment and data collection, begin preliminary data analyses, and begin preparing a manuscript to disseminate findings from this Aim.

SPECIFIC AIM 3: Clinical validation of intensimetric probe system.

During the next reporting period, we plan to: begin recruitment and data collection, begin preliminary data analyses, and begin preparing a manuscript 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 sound proof booths and specialized equipment, opening up more access to hearing healthcare.

5. CHANGES/PROBLEMS:

In month 3 of the project, Creare Project Engineer, Dr. Amelia Servi took a new

position outside of the company and was no longer able to serve as Project Engineer. Dr. Servi's position was replaced by Creare Engineer Dr. Mattheus Ueckermann, Ph.D. Dr. Ueckermann had the needed expertise and experience to develop and support the new prototype intensimetric probe as Project Engineer, and has been an excellent addition to the project. This did result in a small delay due to the time it took to onboard Dr. Ueckermann, but we should be able to make up for those delays and they should not impact overall project completion deadlines.

Changes in approach and reasons for change

Nothing to report.

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

There have been some small delays in the probe development (Specific Aim 1) due to the change in Creare project engineer (see above), supply chain delays for parts, and the need for a custom calibration for the velocimeter from Microflown. All of these issues and delays have been resolved and while some tasks were or will be completed slightly later than our target date, we do not anticipate this to impact our overall timeline.

Changes that had a significant impact on expenditures

Year 1 expenditures were less than anticipated due to two favorable developments:

1) not having to purchase new Microphone velocimeter sensors at this time (though we have not fully ruled out this need prior to the end of the project) and 2) not hitting as many hurdles as anticipated in probe development. Expenditures were also reduced due to minor timeline delays, as described above. Some of these expenditures thus will carry over into Year 1, 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: *ort.*

- **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 (No Change)**
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 preparation for data collection.*

Funding Support:

Name: **Ryan McCreery, PhD (No Change)**
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:

Name: **Odile Clavier, PhD (No Change)**
Project Role: Consortium Lead Investigator
Researcher Identifier (e.g. ORCID ID): 0000-0003-4439-4120
Nearest person month worked: 1
Contribution to Project: Leverages her prior experience in hearing and mobile health applications to guide the design and testing of the prototype. She will also ensure that the transition from development to human testing goes smoothly.

Funding Support:

Name: **M.P. Ueckermann**
Project Role: Consortium Project Engineer
Researcher Identifier (e.g. ORCID ID): 0000-0003-3615-4610
Nearest person month worked: 2
Contribution to Project: 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:

Name: **B.M. Poland**
Project Role: Consortium Electronics Engineering Technician
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 1
Contribution to Project: Mr. Poland is responsible for miniaturizing the probe electronics.

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

Support_Merchant -and-
Support_McCreery

CURRENT/PREVIOUS SUPPORT

(Other Support Changes from Previous Submission Marked with Border in Right Margin.)

MERCHANT, G.

CURRENT / PREVIOUS - Nothing to Report.

MCCREERY, R.W.

CURRENT

W81XWH-21-1-0658 Merchant (PI) 08/15/21-08/14/24 0.96 CY months
Department of Defense

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

Agency Contact: Congressionally Directed Medical Research Program Office
(usarmy.detrick.medcom-cdmrp.mbx.cdmrp-award@mail.mil)

5 R01 DC013591-09 McCreery (PI) 08/01/19-07/31/24 2.76 CY months
NIH-NIDCD

Complex Listening Skills in School-age Hard of Hearing Children

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

Agency Contact: Eric Nunn (eric.nunn@nih.gov)

5 R01 DC015056-05 Leibold & Buss (MPI) 08/10/16-07/31/23 (no-cost ext.) 1.80 CY months
NIH-NIDCD

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

The goal of this project is to develop, refine and evaluate a pediatric speech perception test for use with English-speaking, Spanish-speaking, and bilingual children.

Role: Co-Investigator

Agency Contact: Christopher Myers (cm143g@nih.gov)

5 P20 GM109023-09 Leibold (PD) 04/01/19-03/31/24 1.20 CY months
NIH-NIGMS (Phase II)

Center for Perception and Communication in Children (CPCC) - 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.

Role: Co-Director

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

Role: Internal Mentor, Project 11

Agency Contact: Courtney Tardd-Wright (tarddwrightc@mail.nih.gov)

Support_McCreery

CURRENT/PREVIOUS SUPPORT

(Other Support Changes from Previous Submission Marked with Border in Right Margin.)

5 R01 DC018330-03 McCreery (PI) 07/20/20-06/30/25 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

Agency Contact: Eric Nunn (eric.nunn@nih.gov)

5 R01 DC019081-02 Walker (PI) 07/01/21-06/30/26 0.96 CY months
NIH-NIDCD (subaward w/Univ. of Iowa)

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

Agency Contact: Kelly Anne King (kingke@nidcd.nih.gov)

Change: New funded grant, starting 07/01/21

1 P20 GM144641-01 Wilson (PD) 03/01/22-01/31/27 0.48 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.

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

Agency Contact: Yang Zhou (yang.zhou@nih.gov)

Change: New funded grant, starting 03/01/22

IN-KIND

1 R21 DC020544-01 Lalonde (PI) 06/03/22-05/31/25 0.00 CY months
NIH-NIDCD

Factors Influencing Audiovisual Speech Benefit in Children with Hearing Loss

Visual speech is helpful in real-world environments when access to acoustic speech is reduced by hearing loss. This project examines how hearing loss, and particularly frequency-specific audibility, influences benefit from visual speech among school-age children. Results will inform data-driven clinical recommendations regarding the best type of spoken language intervention for children with hearing loss.

Dr. McCreery will lend his expertise in assessing hearing, speech perception, and outcomes in children with hearing loss to advise the PI regarding experimental design, data analysis, and data

Support_McCreery

CURRENT/PREVIOUS SUPPORT

(Other Support Changes from Previous Submission Marked with Border in Right Margin.)

interpretation. Dr. McCreery has mentorship effort on a COBRE grant (P20 GM109023) that is specifically dedicated to providing support for early-career scientists at BTNRH, which will cover his support of the project.

Role: Other Significant Contributor/Consultant

Agency Contact: Kelly Anne King (kingke@nidcd.nih.gov)

Change: New funded grant, starting 06/03/22

OVERLAP: None to report.

PREVIOUS

5 P20 GM109023-08 Leibold (PD) 04/01/20-03/31/22 (*no-cost ext.*) 1.20 CY months *IK*
NIH-NIGMS (Phase II) (*IK=In-kind, no salary support*)

Center for Perception and Communication in Children (CPCC) - 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.

Pilot Project: Predictors of Sequential Learning and Language in Children with Hearing Loss

- The proposed research is relevant to public health because it will show us how language development in children who are deaf or hard of hearing is the result of interactions among auditory experience, language exposure, and fundamental learning and processing mechanisms. This work therefore can be used to help predict which children will experience the greatest delays in outcomes as well as inform intervention by considering the role played by environmental experiences and sequential learning abilities.

Role: Project Lead, Pilot Project

Agency Contact: Courtney Tardd-Wright (tarddwrightc@mail.nih.gov)

Change: Grant ended on 03/31/2022

5 R01 DC011038-11 Leibold (PI) 07/01/16-06/30/22 (*no-cost ext.*) 0.36 CY months
NIH-NIDCD

Susceptibility to and Release from Masking in Infancy and Childhood

The long-term aim of this project is to identify and explain the factors responsible for the development of hearing in complex acoustic environments that contain multiple sources of sound.

Role: Co-Investigator

Agency Contact: Maria Garcia (mg421s@nih.gov)

Change: Grant ended on 06/30/22

5 T35 DC008757-15 Janky (PD) 04/04/17-03/31/22 0.00 CY months
NIH-NIDCD

Short-Term Research Training for AuD Students

The goals of the Short-Term Training Program for AuD students at BTNRH is to give 5 AuD students per year the opportunity to pursue a full-time hands-on clinical or translational research experience in the hearing sciences over a 3-month period.

Role: Co-Director

Agency Contact: Christopher Myers (cm143g@nih.gov)

Change: Grant ended on 03/31/22

CURRENT/PREVIOUS SUPPORT

(Other Support Changes from Previous Submission Marked with Border in Right Margin.)

5 R44 DC015445-05 Clavier (PI) 07/01/16-08/31/22 (*no-cost ext.*) 0.00 CY months
NIH-NIDCD

(SBIR Phase I & II Subaward w/CreareLLC)

Open Design Tools for Speech Signal Processing

The open source library will allow researchers to evaluate novel signal-processing algorithms. The wearable device will allow for evaluations outside the laboratory setting in real-world environments and under conditions that closely mimic use of real hearing aids.

Role: Co-Investigator

Agency Contact: Roger Miller (millerr@nidcd.nih.gov)

Change: Grant ended on 08/31/22

3 U2C AG057441-03S1 Gershon (PI) 11/15/20-04/30/21 0.60 CY months
NIH-NIA (subaward w/Northwestern U.)

ARMADA: Advancing Reliable Measurement in Alzheimer's Disease and Cognitive Aging

Aging-associated cognitive decline, whether mild or severe, can profoundly affect the independence, well-being, and quality of life of those aged 65 and older. Development of effective interventions and treatments for this requires standard, psychometrically sound, easy-to-use measures that are sensitive to early indicators of cognitive decline and also capture non-cognitive factors associated with or predictive of cognitive changes. "Advancing Reliable Measurement in Alzheimer's Disease and cognitive Aging" (ARMADA) proposes to meet this need by validating and expanding the NIH Toolbox for Assessment of Neurological and Behavioral Function® (NIHTB) for use in studies of cognitive aging beginning with normal cognition through progression into mild cognitive impairment and into early stages of Alzheimer's dementia.

Role: Co-Investigator

Agency Contact: Dallas Anderson (andersda@nia.nih.gov)

Change: Subaward ended on 04/30/21

*Name of Individual: Wichman, C.S.

CURRENT/PREVIOUS SUPPORT

(Other Support Changes from Previous Submission Marked with Border in Right Margin.)

CURRENT

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.

Specific Aims: Aim 1: Refine an intensimetric probe system for the detection of hearing injury. We will develop compact packaging of the device and software interface for ease of use in remote settings. Aim 2: Laboratory validation of intensimetric probe system. We will validate the accuracy and reliability of the intensimetric probe system on ear-canal acoustic measurements by comparing against a standard commercially available device. Aim 3: Clinical validation of intensimetric probe system. A clinical population will be used to determine if the device can help with diagnosis of middle-ear and inner-ear injuries.

Project Number: W81XWH2110658

Name of PD/PI: Merchant (Subaward Investigator: Wichman)

Source of Support: DoD/USAMRAA (Subaward with Father Flanagan's Boys' Home dba Boys Town National Research Hospital)

Project/Proposal Start and End Date: (MM/YYYY) (if available): 08/2021 – 08/2024

Contracting/Grants Officer: Fox, Jennifer L CIV USARMY USAMRAA (USA)

<jennifer.l.fox1.civ@mail.mil>

Total Award Amount (including Indirect Costs):

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

Year (YYYY)	Person Months (##.##)
1. 2021	0.25 calendar
2. 2022	0.6 calendar
3. 2023	0.6 calendar
4. 2024	0.35 calendar

Title: Scar Detection and Treatment with Droplet Activation

Major Goals: Developing myocardial scar can be quantified with delayed acoustic activation of intravenously administered perfluoropropane droplets. Furthermore, we project that ultimate scar zone size can be reduced by the local alterations in NO production following droplet activation and cavitation.

Specific Aims: AIM 1: Microvascular and Vascular Acoustic Activation Thresholds (Year 1). AIM 2: Effects of Infarct Zone Activation at Various Time Periods Post Ischemia/Reperfusion (Year 1-3). AIM 3: Characterization and Quantification of Infarct Size with Droplet Activation at Various Time Points Post Ischemia/Reperfusion In a Large Animal Model (Year 3-4). AIM 4: Bioeffects of Acoustic Activation within Scar at Various Time Points Post Infarction in an established pig model of ischemia-reperfusion. (Year 3-5).

Project Number: 5R01HL146489-02

Name of PD/PI: Porter, T.R.

Source of Support: NHLBI

Contracting/Grants Officer: Narasimhan Danthi ndanthi@mail.nih.gov

Project/Proposal Start and End Date: (MM/YYYY) (if available): 04/2020 – 03/2024

*Name of Individual: Wichman, C.S.

CURRENT/PREVIOUS SUPPORT

(Other Support Changes from Previous Submission Marked with Border in Right Margin.)

Total Award Amount (including Indirect Costs):

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

Year (YYYY)	Person Months (##.##)
1. 2020	0.9 calendar
2. 2021	1.2 calendar
3. 2022	1.2 calendar
4. 2023	1.2 calendar
5. 2024	0.3 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.

Specific Aims: Aim 1. Validate cadaveric limb flexion-induced deformations using bent-limb patient CTAs. Aim 2. Develop and manufacture optimized and generic stents for the FPA. Aim 3. Compare optimal, generic, and commercial stents in a preclinical swine model.

Project Number: 44-1014-1006-201

Name of PD/PI: Mactaggart J.N.

Source of Support: University of Nebraska Omaha (subcontract)

Contracting/Grants Officer: University of Nebraska-Omaha, Sponsored Programs and Research unosponpro@unomaha.edu

Project/Proposal Start and End Date: (MM/YYYY) (if available): 03/2020 – 02/2025

Total Award Amount (including Indirect Costs):

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

Year (YYYY)	Person Months (##.##)
1. 2020	0.68 calendar
2. 2021	0.81 calendar
3. 2022	0.81 calendar
4. 2023	0.81 calendar
5. 2024	0.81 calendar
6. 2025	0.13 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.

Name of PD/PI: Scarsi K.

Source of Support: Merck Sharp & Dohme Corp.

Contracting/Grants Officer:

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

Total Award Amount (including Indirect Costs):

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

*Name of Individual: Wichman, C.S.

CURRENT/PREVIOUS SUPPORT

(Other Support Changes from Previous Submission Marked with Border in Right Margin.)

Year (YYYY)	Person Months (##.##)
1. 2021	0.0 calendar
2. 2022	0.6 calendar
3. 2023	0.6 calendar

Title: Effects of aortic compliance and Winkessel 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.

Specific Aims: Specific Aims. In Aim 1 we will manufacture nanofibrillar elastomeric stent-grafts with tunable compliance. In Aim 2 we will quantify the effect of stent-graft compliance on Windkessel function in human and porcine aortas using an ex vivo flow model. Finally, in Aim 3 we will assess the in vivo effects of stent-graft compliance on hemodynamics and cardiac and aortic pathologies in a swine model.

Project Number: 44-1014-1004-201

Name of PD/PI: Mactaggart J.N.

Source of Support: University of Nebraska Omaha (subcontract)

Contracting/Grants Officer: University of Nebraska-Omaha, Sponsored Programs and Research unosponpro@unomaha.edu

Project/Proposal Start and End Date: (MM/YYYY) (if available): 09/2019 – 08/2024

Total Award Amount (including Indirect Costs):

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

Year (YYYY)	Person Months (##.##)
1. 2020	0.2 calendar
2. 2021	0.6 calendar
3. 2022	0.6 calendar
4. 2023	0.6 calendar
5. 2024	0.4 calendar

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.

Specific Aims: 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.

Project Number: 5U24MH100925-09

Name of PD/PI: Fox H.S.

Source of Support: NIMH

Contracting/Grants Officer: Collene Lawhorn collene.lawhorn@nih.gov

Project/Proposal Start and End Date: (MM/YYYY) (if available): 03/2018 – 02/2023

Total Award Amount (including Indirect Costs):

*Name of Individual: Wichman, C.S.

CURRENT/PREVIOUS SUPPORT

(Other Support Changes from Previous Submission Marked with Border in Right Margin.)

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

Year (YYYY)	Person Months (##.##)
1. 2018	0.5 calendar
2. 2019	0.6 calendar
3. 2020	0.6 calendar
4. 2021	0.6 calendar
5. 2022	0.6 calendar
6. 2023	0.1 calendar

Title: Great Plains IDeA-CTR – Cycle 2

Major Goals: The aim of the RIISCC model is to reduce readmissions and emergency room visits in high-risk, high-utilization, and high severity diabetic patients; thus improving quality of care and reducing cost. This program will focus on Innovation Category Four- to improve the health of populations through better prevention efforts and will have a specific focus on underserved populations. The purpose is to develop and test a new care delivery and payment model utilizing telehealth strategies for targeted case management.

Specific Aims:

Project Number: 2U54GM115458-06

Name of PD/PI: Rizzo M.

Source of Support: NIGMS

Contracting/Grants Officer: Crina Frincu crina.frincu@nih.gov

Project/Proposal Start and End Date: (MM/YYYY) (if available): 09/2021 – 06/2026

Total Award Amount (including Indirect Costs):

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

Year (YYYY)	Person Months (##.##)
1. 2021	0.4 calendar
2. 2022	1.2 calendar
3. 2023	1.2 calendar
4. 2024	1.2 calendar
5. 2025	1.2 calendar
6. 2026	0.6 calendar

Title: IPA for Christopher Wichman

Major Goals: Concentrated animal feeding operations (CAFO) housing thousands of animals are increasingly used in the United States and global meat industry, and CAFO workers, including rural veterans, are at increased risk for lung diseases caused by inhaled CAFO dusts. The proposed studies will identify how the lung responds to and repairs damage caused by these dust exposures, including how the pro-repair molecule amphiregulin is regulated by cell signaling responses and influenced by dietary fatty acids (omega 3). These studies are relevant to rural veterans and the public health in that they will support our long-term goal of developing new treatment strategies to prevent or reduce lung disease in CAFO workers.

Specific Aims: Aim 1: Identify the function of AREG in mediating lung repair following organic dust exposures. Aim 2: Define the mechanisms regulating AREG activities in the lung following organic dust exposures. Aim 3: Identify how PUFA regulate AREG-mediated lung repair following organic dust exposures.

*Name of Individual: Wichman, C.S.

CURRENT/PREVIOUS SUPPORT

(Other Support Changes from Previous Submission Marked with Border in Right Margin.)

Project Number: Awd Ltr 120721

Name of PD/PI: Romberger D.

Source of Support: V.A. Medical Center - Omaha

Contracting/Grants Officer:

Project/Proposal Start and End Date: (MM/YYYY) (if available): 10/2021 – 09/2022

Total Award Amount (including Indirect Costs):

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

Year (YYYY)	Person Months (##.##)
1. 2021	0.09 calendar
2. 2022	0.27 calendar

Title: Diabetes, the Nebraska Solution

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.

Specific Aims:

Project Number: No project number

Name of PD/PI: Dzewaltowski D.

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

Contracting/Grants Officer:

Project/Proposal Start and End Date: (MM/YYYY) (if available): 12/2021 – 08/2024

Total Award Amount (including Indirect Costs):

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

Year (YYYY)	Person Months (##.##)
1. 2021	0.2 calendar
2. 2022	2.4 calendar
3. 2023	2.4 calendar
4. 2024	1.6 calendar

Change: New funded grant, starting 12/2021

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.

Specific Aims: Our first aim is to collaboratively refine and develop an intervention package for the TLD that includes all of the materials necessary for others to implement the intervention in new micropolitan and rural locations. Our second aim is to perform a rigorous, mixed-methods pilot implementation research study using an innovative community application process to identify 4 to 8 new communities to pilot test the utility of the packaged PWMI and training materials when coupled with a learning collaborative facilitation strategy and sustainability action planning process in supporting PWMI adoption, implementation,

*Name of Individual: Wichman, C.S.

CURRENT/PREVIOUS SUPPORT

(Other Support Changes from Previous Submission Marked with Border in Right Margin.)

and sustainability when compared to receiving access to the packaged program and training materials alone. Additional outcomes will include start-up and ongoing costs while tracking intervention reach, representativeness, and effectiveness in reducing and maintaining child weight status relative to a matched cohort. Our third aim is to use the pilot evaluation data and results of the sustainability action plan to refine program and training materials and develop a dissemination plan to move the program to other communities.

Project Number: 5U18DP006431

Name of PD/PI: Hill J.

Source of Support: DHHS/CDC

Contracting/Grants Officer: Marissa Sucosky Email: aq18@cdc.gov

Project/Proposal Start and End Date: (MM/YYYY) (if available): 04/2019 – 03/2024

Total Award Amount (including Indirect Costs):

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

Year (YYYY)	Person Months (##.##)
1. 2019	0.9 calendar
2. 2020	1.2 calendar
3. 2021	1.2 calendar
4. 2022	1.2 calendar
5. 2023	1.2 calendar
6. 2024	0.3 calendar

IN-KIND

Title: Osteoarthritis After ACL Injury: Establishing Cumulative Joint Loading as A Preventative Target

Major Goals: The purpose of this study is to identify markers that predict the earliest signs of poor joint outcomes after ACL injury.

Specific Aims: Aim 1, we will determine how physical activity levels and biomechanical function before and after ACL reconstruction relate to changes in T2 relaxation time at 6 months after ACL reconstruction. Cumulative joint loading (product of mean steps per day and knee flexion moment) will be tested against individual physical activity and biomechanical factors to determine the strongest joint loading determinant of T2 relaxation time. In Aim 2, we will identify levels of daily physical activity that predict poor post-operative knee function on the KOOS. This work will define movement biomarkers that predict early changes in cartilage microstructure (Aim 1) and post-operative knee joint function (Aim 2) after ACL injury. Successful completion of this study will result in identification of an initial target or range of healthy knee joint loading levels after ACL.

Project Number: 5R21AR075254-02

Name of PD/PI: Wellsandt E.

Source of Support: DHHS/NIH/NIAMS

Contracting/Grants Officer: Charles Washabaugh washabac@mail.nih.gov

Project/Proposal Start and End Date: (MM/YYYY) (if available): 02/2020 – 01/2023

Total Award Amount (including Indirect Costs):

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

*Name of Individual: Wichman, C.S.

CURRENT/PREVIOUS SUPPORT

(Other Support Changes from Previous Submission Marked with Border in Right Margin.)

Year (YYYY)	Person Months (##.##)
1. 2020	0.12 calendar
2. 2021	0.24calendar
3. 2022	0.0 calendar
4. 2023	0.0 calendar

PREVIOUS

Title: Understanding suprathreshold hearing deficits

Major Goals / Specific Aims: The goal will be achieved by pursuing three aims: Aim1: Develop a statistical model of HHL for individuals with normal hearing Aim 2: Develop a statistical model of HHL for individuals with clinical hearing loss caused by noise exposure and Aim 3: Validate a predictive model of HHL and demonstrate its relation to speech understanding in noise.

Project Number: 5R01DC016348-05

Name of PD/PI: Neely (Subaward Investigator: Wichman)

Source of Support: NIH/NIDCD (Subaward with Father Flanagan's Boys' Home dba Boys Town National Research Hospital)

Contracting/Grants Officer: Grants Specialist: GARCIA, MARIA (mg421s@nih.gov)

Project/Proposal Start and End Date: (MM/YYYY) (if available): 09/2021 – 08/2022

Total Award Amount (including Indirect Costs):

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

Year (YYYY)	Person Months (##.##)
2. 2022	0.43 calendar

Change: Subaward ended on 08/2022

OVERLAP - None

I, PD/PI or other senior/key personnel, certify that the statements herein are true, complete and accurate to the best of my knowledge, agree to update such disclosure at the request of the agency prior to the award of support and at any subsequent time the agency determines appropriate during the term of the award and accept the obligation to comply with Section 223(a) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

*Signature: _____



Date: 09/07/2022

CURRENT/PREVIOUS SUPPORT

(Other Support Changes from Previous Submission Marked with Border in Right Margin.)

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

Change: New funded grant, starting 07/2022

W81XWH-19-C-0076 Clavier (PI) 08/12/2019–01/11/2023 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

2R44DC01793002 Clavier (PI) 07/16/2021–05/31/2023 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

W81XWH-20-C-0004 Clavier (PI) 12/09/2019–04/08/2023 10%

U.S. Army Medical Research Acquisition Activity

Automated Vestibular Rehabilitation Management System

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

CURRENT/PREVIOUS SUPPORT**(Other Support Changes from Previous Submission Marked with Border in Right Margin.)**

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

W81XWH-21-C-0082 Clavier (PI) 09/24/2021–09/23/2022 10%
U.S. Army Medical Research Acquisition Activity

Mobile Application for Aural Rehabilitation

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

9 R44 GM130224-03 Clavier (PI) 09/20/2018–09/19/2023 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: PI TPOC: Dr. Lawrence Beck

Overlap: None

9 R44 MH119027-02 Clavier (PI) 09/10/2018–12/31/2022 3%
NIH-NIMH

Adaptable Pediatric Neurocognitive Assessment

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

5 R44 DC015445-05 Clavier (PI) 08/07/2016–07/31/2023 3%
NIH-NIDCD

Open Source System for Audio Processing

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

CURRENT/PREVIOUS SUPPORT**(Other Support Changes from Previous Submission Marked with Border in Right Margin.)**

GC10489-01	Saunders (PI)	09/01/2020–08/31/2023	2%
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Subcontract to Dartmouth-Hitchcock

Engineering Support for Studies of Central Auditory Processing

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

Overlap: None

Change: Funded grant not included on the 4/29/2021 Other Support list.

PREVIOUS

1 R44 OH011714-01	Clavier (PI)	09/01/2020–8/31/2022	10%
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DHHS/CDC

A Wireless Audiometric Headset that Integrates Hearing Testing, Education, and Personalized Hearing Protection Fitting

Creare is now developing a mobile low-cost fit testing device, with integrated audiometer, to help noise-exposed workers confirm they are adequately protected and lower their daily exposure. Such an approach has the potential for high impact at very low cost because it requires minimal effort on the part of the employers and workers to greatly improve the existing hearing conservation programs.

Role: PI

TPOC: Dr. Bridgette Garrett

Overlap: None

Change: ended on 08/2022

1 R21 DC017603-01A1	Buckey (PI)	08/01/2019–07/31/2022	2%
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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

Overlap: None

Change: ended on 07/2022

1 R01 HD095277-01	Buckey (PI)	08/16/2018–04/30/2022	3%
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Dartmouth Hitchcock Medical Center

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: Co-I

TPOC: Dr. Howard Hoffman

Overlap: None

Change: ended on 04/2022

CURRENT/PREVIOUS SUPPORT

(Other Support Changes from Previous Submission Marked with Border in Right Margin.)

Ueckermann, M.P. (Ueckermann replaced Amelia T. Servi)**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

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

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

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

N6833522C0212 Kattamis (PI) 03/23/2022–04/08/2023 25%

Naval Air Warfare Center, Aircraft Division

Software Optimized Subtractive Manufacturing

Create'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

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

QUAD CHARTS:

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

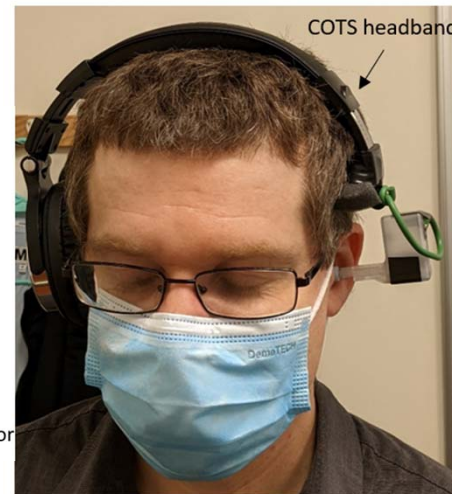
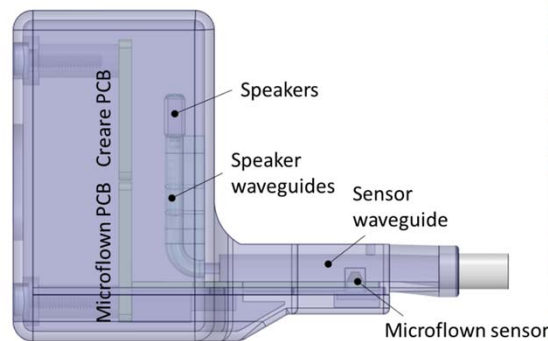
Award Amount: \$1,249,586.00

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 improve 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: Prototype of our next generation design concept. This combines a COTS headband and an adjustable wire to provide comfort to the patient and flexible placement to the technician. The reduced size of the probe allows for an improved acoustic seal.

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 – Laboratory Validation for Accuracy and Reliability

- ☒ Obtain IRB and HRPO Approval
- ☐ Human Subjects Studies

CY24 Goal – Clinical Validation

- ☐ Human Subjects Studies

Comments/Challenges/Issues/Concerns

- Under budget in Year 1 as we did not need to purchase new velocity sensors and did not hit some anticipated hurdles.

Budget Expenditure to Date

Projected Expenditure: \$641,600

Actual Expenditure: \$350,000

Updated: August 26, 2022

9. APPENDICES:

Human Subjects Education: CITI Program for Mattheus Ueckermann (Creare LL),
Completion Date (23-Mar-2022)



Completion Date 23-Mar-2022
Expiration Date 22-Mar-2025
Record ID 48099576

This is to certify that:

Mattheus Ueckermann

Has completed the following CITI Program course:

Not valid for renewal of certification
through CME.

Human Research
(Curriculum Group)
Biomedical Research Investigators
(Course Learner Group)
3 - Refresher Course
(Stage)

Under requirements set by:

Creare LLC

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w7e2fdf3e-e35c-4afb-a88b-77b0bc961fe1-48099576