



PROPRIETARY DOCUMENT

Development Of A Novel Wireless In-Ear Noise Exposure Monitor For The Prevention Of Occupational Hearing Loss

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1 LIST OF TERMS AND ABBREVIATIONS

ANSI American National Standards Institute
ASIC Application specific integrated chip
HPD hearing protection device
IEEE Institute of Electrical and Electronics Engineers
iPND in-ear personal noise dosimeter
LED light-emitting diode
NIHL noise induced hearing loss
NRR noise reduction rating
PND personal noise dosimeter
RFID radio frequency identification
RTH Red Tail Hawk
SPL sound pressure level
wiPND wireless in-ear personal noise dosimeter

2 ABSTRACT

According to the CDC, four million workers go to work each day in damaging noise, while ten million in the U.S. suffer from noise-related hearing loss. Hearing loss accounted for at least 14% of occupational illness in 2007, and approximately \$242M is spent annually on worker's compensation for hearing loss disability. To address this problem, employers are required by law to implement hearing conservation programs for employees at risk. Potential risk is determined by measuring cumulative noise exposure using personal noise dosimeters (PNDs). These instruments are typically worn *on-the-shoulder* as a surrogate position for *center-of-head* measurements.

The in-ear PND (iPNDTM) is a relatively new dosimeter that has significant advantages over traditional systems because iPNDsTM measure noise in the ear canal using a microphone located interior to any hearing protection. Traditionally, the protected exposure level is estimated by subtracting the noise reduction rating (NRR) of the hearing protection device (HPD) from the on-the-shoulder exposure level which can be an inaccurate estimate. This problem is well documented and contributes to noise induced hearing loss (NIHL) because the employee may be subjected to higher exposure levels than estimated. The iPNDTM avoids this shortcoming by directly measuring protected exposure when the user is wearing an HPD. Although these dosimeters provide superior performance and function, only two, are commercially available today. Their lack of popularity is primarily due to wires that connect the earplugs to a dosimetry processor, creating a nuisance and potential snag hazard.

A wireless iPNDTM (wiPNDTM) that would solve the aforementioned problems is being investigated. A relatively new wireless technology, radio frequency identification (RFID) can be used to transmit noise level data from a wiPNDTM earplug to a remote processor. Novel new features are provided with our wiPND system that will help prevent NIHL and improve acceptance of PNDs. The aim of the RTH wiPND system is the prevention of occupational noise induced hearing loss through noise dose monitoring using novel designs, inventions and concepts.

3 SIGNIFICANT OR KEY FINDINGS

The key findings can be found in Section 6.4. In summary, the feasibility of a wiPND system using RFID technology has been proved during the Phase I effort. The wiPND earplug is small enough to be comfortable in the ear, efficient enough to have sufficient battery duration and accurate enough to meet ANSI S1.25 noise dosimeter specifications.¹ This means that the wiPND earplug will be accepted by employees who work in loud noise environments, and this will prevent NIHL.

4 TRANSLATION OF FINDINGS

The RTH wiPND earplug not only provides hearing protection for the user but monitors noise dosage. In this way, the user is assured that he/she is not being exposed to damaging acoustic noise doses, much like the way a radiation badge works. The result of this SBIR research, at the conclusion of a Phase II effort, will be a noise dosimeter system, including the wiPND earplug, product. RTH plans to commercialize the system through its spin-off company, Nittany Acoustics.

5 RESEARCH OUTCOME/IMPACT

Occupational safety and health is significantly improved with the wiPND system by preventing NIHL. The wiPND system is a monitor that determines actual noise exposure rather than estimated exposure.

6 SCIENTIFIC REPORT

6.1 Background

Figure 1 shows a typical personal noise dosimeter (PND) worn on the shoulder of an employee using earplugs to protect against NIHL. The PND measures the accumulated noise dose of the employee to document his daily exposure. However, the microphone of the PND is located on the employee's shoulder, and there may be a difference between the sound pressure level (SPL) there compared to the locations of his ears (or "center-head" position). This can be caused by standing acoustic waves, acoustical focusing and the head-shadow effect.² To correct for the sound attenuation of the earplug, the laboratory-derived attenuation of the earplug must be used to determine exposure. However, the estimates of HPD performance can be grossly inaccurate due to the user's desire to use the HPD properly and consistency of use. Moreover, if the user removes the earplug, the PND does not account for the increased noise exposure in the dose calculation. Lastly, the noise dose calculation assumes that the earplug in each ear is providing the same level of noise attenuation, which can be incorrect due to left/right canal geometry differences and variation in insertion depth. Using this system, there is no way to determine if the hearing protection is being worn properly or how much noise dose the employee has actually received. Once it is recognized that the real-world efficacy of HPD can never be estimated or predicted for individuals, the solution is obvious: the noise level in the protected ear canal must be measured.

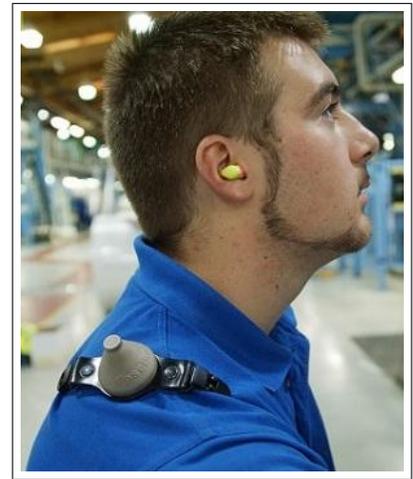


Figure 1: Worker with shoulder-worn PND and earplug.

In-ear dosimetry, measuring the actual protected noise level in a user's ear canal, provides an innovative solution to the aforementioned problems. The published NRR of the HPD involved then becomes irrelevant. In-ear dosimetry takes into account all the factors contributing to ambiguity in exposure that otherwise limit and ultimately control the effectiveness of a typical, traditional hearing protector. These include HPD fit and wearing time. When the dosimeter is deployed as an integral part of a continuous monitoring program to determine the actual noise dose of workers every day, it can become a powerful administrative tool to ensure that noise-exposed workers are protected to a safe noise exposure and to document their long-term noise exposures.

Michael & Associates and Dr. J. Alton Burks developed the QuietDose in-ear personal noise dosimeter (iPND) system, shown in Fig. 2 to address the problems of traditional noise dosimetry. The QuietDose system comprises a processing unit attached to the user's clothing and earplugs that incorporate microphones coupled to the ear canals through tubes in hollow-core eartips. Flexible cables connect the earplugs to the processing unit. This dosimeter determines the noise dose based on the SPL in the

ear canal; therefore, it is an accurate measurement of protected exposure. (This assumes flanking noise through the skull is minimal, which is typical for most industrial environments.) If the employee removes an earplug to talk to a co-worker, higher SPLs are measured by the earplug microphone, which estimates the noise level in the unprotected ear. There are a few issues regarding in-ear versus shoulder located PND microphones related to the change in acoustic response when the earplug is removed. Resonances associated with blocked versus open ear canals, due to the eartip, were not taken into account with the QuietDose system. NIOSH conducted an independent laboratory investigation of the validity of the iPND noise monitoring and methodology in 2004 and concluded that the in-ear exposure monitoring is valid and does not underestimate a workers noise dose, whether determined in the protected or unprotected (earplugs removed) condition.² However, the in-ear monitoring may overestimate a worker's noise dose due to the changes in acoustic response of the blocked versus open ear canal.

Honeywell is currently manufacturing the QuietDose system; however, the problems associated with wires connecting the earpieces to the dosimeter are severe enough to prevent the adoption of iPNDs in industry. Wires create a safety hazard because they can get caught in machinery and pull the employee into a dangerous situation. Manufacturers take this issue extremely seriously. Wires are a nuisance because they are constantly tugging on earplugs as the user moves about and can pull out the earplug due to snagging. If the employee wears hazardous materials headgear or a respirator, wires can compromise the gas-tight seal. They also cause great discomfort and compromised noise attenuation when worn under earmuffs. Wires and connectors also reduce reliability due to breakage. Eliminating the wires of an iPND would significantly impact millions of workers exposed to damaging noise because wireless iPNDs would be used in the workplace in large numbers, and the important benefits of iPNDs would then be realized. Ultimately, creating an iPND system that would be acceptable to users would reduce or eliminate NIHL in the workplace.



Figure 2: QuietDose iPND.

Eliminating the wires is not a trivial issue. The noise measured is in the audio spectrum, so over 40,000 samples per second would need to be transmitted, wirelessly, at sufficient resolution to calculate an accurate noise exposure. Blue-tooth systems are relatively expensive, large, require high power and employ compression techniques that compromise the data accuracy. Batteries used in the earplugs would be large, and a separate relatively expensive receiver would be needed to calculate the noise dose. However, RTH has determined a way to create an inexpensive, small/comfortable, effective wireless iPND system with much greater functionality compared to existing systems.

6.2 Specific Aims

The specific aims from the Phase I proposal are reproduced here:

1. *Aim:* Design and prototype battery-free and rechargeable wiPND earplug power systems;
Milestone: Wireless power and rechargeable battery generate sufficient current to operate earplug;
2. *Aim:* Design and prototype ultra-low power earplug signal processing electronics;
Milestone: Signal processing meets ANSI S1.25 noise dosimeter specifications;¹
3. *Aim:* Design and prototype wireless data transmitter and earplug logging system;
Milestone: Dosimeter signal receiver is able to read earplug transmitted data and data logging is successful;
4. *Aim:* Determine magnetic field levels required by power/data transmission;
Milestone: Magnetic fields meet IEEE safe exposure recommendations;^{3,4}

5. *Aim:* Confirm feasibility of in-ear RFID wireless personal noise dosimeter concept;
Milestone: At least one of the three wiPND earplug versions functions properly.

6.3 Methodology

The purpose of the Phase I research was to demonstrate the feasibility of a wiPND system using RFID technology by researching three potential systems. In one version, a battery-free earplug was powered via a magnetic field generated by a loop transmitter worn around the neck, and the system had additional features of over-exposure alert and HPD fit-check. Another version used a rechargeable battery in the earplug and also incorporated the neckloop. The third version stored data in the earplug, using data logging, and transferred the data to a reader. The earplug electronic design would be essentially the same for all three versions, because they all used an RFID link for power and communications. The difference being that the battery-operated versions used the link for recharging, instead of as the primary power source, and the neckloop-free version used a coil in an RFID reader station instead of the neckloop as a transceiver for transmitting data. The project was to be considered successful if we could show feasibility of at least one of these systems. Ultimately, the two versions employing a neckloop were not considered viable because of the energy required from the neckloop resulted in unsafe electric field levels. However, the third version was very successful and proof of concept was clearly demonstrated. Moreover, we determined that we could incorporate the neckloop dose alert feature into an earplug dock clipped to a user's shirt.

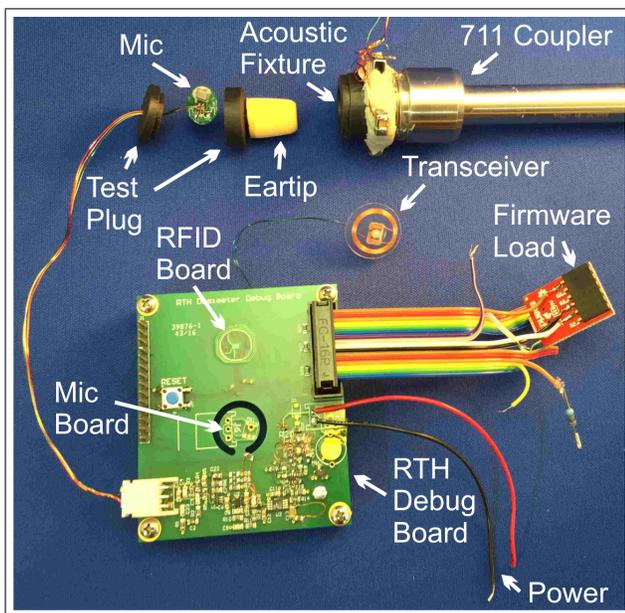


Figure 3: Bench setup for testing wiPND earplug acoustics and electronics using the RTH dosimeter debug board.

using a surface mount electronics rework station. Firmware was loaded using the ribbon cable and serial data interface. Test points were made available through a row of header pins on the left side. The debug board made it very efficient to experiment with various designs and test the performance of different sections of the system.

Figure 3 shows some of the apparatus used during the Phase I effort. RTH first designed a wiPND electronics circuit with full functionality and minimal components count. We gave the design to Critical Link, who laid out the components on 12 mm diameter double-sided and 13 mm single-sided boards using the smallest components commercially available. The 12 mm "mic board" contained a MEMS microphone and all analog electronics, while the 13 mm "RFID board" contained only the components associated with the RFID chip. The boards would be connected to each other using a flex strip, and folded to fit in the earplug. This exercise proved that all the required components could fit on miniature boards with a battery in the earplug shell shown in Fig. 5. Next, one relatively large "debug" board, seen in Fig. 3, was laid out by Critical Link with the RFID board unchanged, but with the mic board electronics spread out and using larger, easier-to-handle, components for debugging. RTH populated test boards using

Two transceiver coil designs, among many others, that were tested can be seen in Fig. 3. One of them is built into the RFID board section (the spiral traces can be seen in Fig. 3 and Fig. 4) and another was an external coil. These had to be tuned for proper 13.56 MHz RFID operation. We stuck with proper small sized components (such as 0201 sized chips) for the RFID board because we wanted to ensure that the circuit performance wasn't affected by long traces or larger components.

An additional, separate, microphone board was created in the center of the debug board with a breakaway tab so that it could be separated from the debug board to test MEMS microphones in acoustic fixtures, as seen in the upper region of Fig. 3. (This microphone board was removed from a different debug board than the one shown.) A test fixture plug was printed using our 3D printer. The test plug was inserted in an acoustic test fixture, designed and fabricated for this project, and the test fixture was attached to an IEC 711 occluded ear simulator with instrumentation microphone for in-ear measurements. The test fixture incorporates four high-output hearing aid speakers used to generate high sound pressure levels to test to the ANSI S1.25 standard with a cavity that matches the size of the eartip. Sound is channeled through the RTH acoustic fixture into the ear canal cavity of the 711 coupler to simulate noise in the ear canal.

Multiple electronic designs were considered. The debug board was used to test them by changing components and using jumpers to splice in additional components. Also, multiple acoustic designs and acoustic fixtures were 3D printed and tested in the course of the Phase I. For example, coupling the microphone through the eartip can be done a few different ways, each resulting in different acoustical responses. Various sized coupling tubing with dampers were first simulated using RTH custom acoustics software, then verified on the bench. Acoustical responses were measured in the ear canal fixture and in the free field to simulate in-ear and in-dock responses.

6.4 Results and Discussion

Progress towards Aim 1: Low Power

Innovative designs were used to create earplug circuits that only required 1.69 mW. We identified a rechargeable size 13 battery for our application, which is very small (8 mm diameter by 5.5 mm tall) and fits in the outer portion of the earplug seen in Fig. 5. We were also able to fit a battery recharger system into the earplug, so the battery does not need to be removed except after 500 charges, or approximately every 2 work years. Using this battery with the earplug circuits at normal operation yielded a 20 hour duration. Fully charging a discharged battery using the earplug charger took 8 hours, measured in the laboratory, which is not a problem because the user stores the earplugs in a reader station over night. Hence, we were able to create the sophisticated electronics design needed for the wiPND earplug to function properly while maintaining a small form factor earplug and long operating time.

Progress towards Aim 2: Accurate Signal Processing

The wiPND earplug electronics incorporate a magnetic field sensor, an A-weighted filter with microphone amplifier, a true rms detector, electronic filters that are used when the earplug is in the ear versus in the

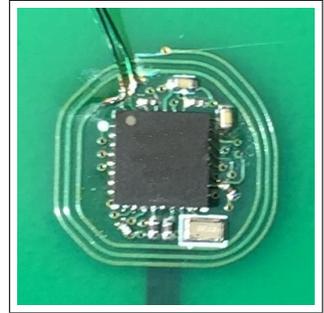


Figure 4: Bottom side of RTH RFID board. RFID chip measures 5 mm x 5 mm.

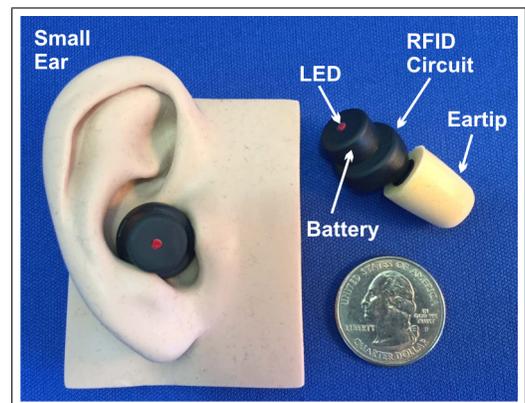


Figure 5: RTH wiPND earplug in, and next to, a KEMAR small ear and quarter.

dock, an RFID chip, a custom coil antenna, an LED, a voltage regulator and a microphone. All of this requires only 1.41 mA of current from a 1.2 Vdc battery due to innovative circuit design by RTH. The resulting electronics were tested to the ANSI S1.25¹ noise dosimeter specifications and meets them, such as: proper time constants (1 sec), linearity (within .25 dB), dynamic range (over 50 dB), and pulse range (over 52 dB), all measured in the RTH laboratory.

Although one can meet ANSI specifications by meeting the 1 sec impulse response requirement, the specification also specifies impulses down to 1 msec. The manufacture only needs to specify which impulses meets specification. However, we would like to meet ANSI specification down to 1 msec so that the device would be appropriate for use in short impulse noise environments. A 1 msec impulse response is very difficult to meet using off-the-shelf analog chips. In the second half of the Phase I project, we investigated many innovative circuits that might meet this specification. We were not able to meet the quicker impulse response specification with components that would fit in the small form factor and draw minimal power. However, based on our study, we found that we could incorporate circuits in an ASIC along with the RFID circuits that would meet the faster impulse response specification. Being on the ASIC, the new electronics wouldn't require additional space. We discussed an ASIC with our RFID chip supplier, and they are willing to provide the ASIC for a fee. We plan to pursue this during the Phase II effort.

Progress towards Aim 3: Functional Logging/Wireless

RTH worked with the RFID chip manufacturer to modify the chip firmware. Custom firmware was written and tested that logs temperature, squared pressure data and magnetic switch state, which indicates if the earplug is in the dock. The data are sampled every 1 sec and average levels are logged every 10 seconds. There is enough memory for 18 hours of data: over two working shifts. The firmware was successfully tested in the RTH laboratory. It was also determined that the chip could handle the noise exposure calculation. The RFID chip manufacturer and RTH also modified the RFID GUI interface software to facilitate debugging of the system.

A number of small earplug transceiver coil geometries were tested with battery charging (in the reader) and RFID data transfer. The coil needed to be small enough to fit within a reasonable earplug form factor. The coil operates at 13.56 MHz, so intercoil capacitance and interaction with earplug electronics was an issue. However, we created a design that fits in the earplug shown in Fig. 5, along with the circuit boards and battery, and it functions properly for communications and battery recharging. This was tested with the commercial reader shown in Fig. 6.

Progress towards Aim 4: Safe Field Exposure

We believed it would be possible to power and communicate with an RFID earplug using a neckloop transceiver, similar to those worn by users of hearing aids. But instead of using audio frequencies, the neckloop would generate RFID fields at 13.56 MHz to communicate with the RFID chip in the earplug. Kirschenbaum and Wool found that RFID tags could be read at a distance of 25 cm using a 40 cm diameter loop antenna, and they generated 180 Volts (143 V/m) into the loop antenna using only a 17 Vdc power source by creating a high-Q resonator circuit with a tuned capacitor.⁵

RTH constructed an 18 cm diameter neckloop, among other neckloop geometries, using a single loop of 20 AWG wire. A single loop was used to eliminate intercoil capacitance. The inductance of the coil, at 0.4 μ H, dominates the neckloop impedance at 13.56 MHz. With a 4 Vrms (7.14 V/m), signal input



Figure 6: *wiPND earplug in earplug dock next to a commercial RFID reader.*

to the loop, we were able to generate 3 Vdc at the RFID receiver output, which is needed to achieve communications. But at the center of the neckloop we were only able to generate 3 mVdc. The IEEE standard for safe continuous electromagnetic field exposure (Table 8) is 138.8 V/m, at this frequency.³ Hence, we could increase the input voltage by a factor of 19.4. However, this would only yield 58.2 mVdc, which is short of the 3 Vdc required. The ICNIRP standard indicates peak levels could be as high as approximately 3.6 kV/m (using Table 2), which would achieve 1.54 Vdc for the center location, but this is still short of 3 Vdc.⁶ Even if we improved the efficiency by a factor of 4, the voltage levels would be unwieldy.

Kirschenbaum and Wool were probably able to read at 25 cm because they used an RFID tag with transceiver coils that are credit-card sized, whereas our earplug transceiver coil has to be around 13 mm in diameter to fit in an earplug. Hence, our earplug antenna coil area is approximately 0.04 times that used by Kirschenbaum and Wool, and the spacing of our coils is much closer, due to size restrictions, which significantly increases the intercoil capacitance and degrades the quality factor. Using 143 V/m and compensating for the coil areas, we would have achieved 2 Vdc. Factoring in a much higher quality factor probably accounts for Kirschenbaum and Wool's success. However, we were able to use a commercial reader for the Phase I to communicate properly with the wiPND earplug version that didn't employ a neckloop. Therefore, we have shown that the system can function with a reader that meets FCC, IEEE and ICNIRP standards.

Progress towards Aim 5: Confirm Feasibility of wiPND Concept

We confirmed feasibility of the wiPND concept with the rechargeable neckloop-free version of the earplug. We were able to 1) collect noise level data in the ear canal with enough dynamic range and accuracy to calculate the noise dose; 2) collect temperature and dock status data; 3) wireless data transmission was achieved through a custom-made transceiver coil with RFID link; 4) a rechargeable battery would last 20 hours on a charge, and the battery was able to be recharged using a charger built into the earplug; 5) even with all the electronics required, the earplug was able to be made small enough to fit easily in an ear; 6) 18 hours of data were able to be recorded; and 7) the estimated selling price of the earplug, at \$ 75 is well within market tolerance. In the future, we plan to incorporate an ASIC into the wiPND design to reduce power, cost, size and improve performance.

6.5 Conclusions

The feasibility of a wiPND system using RFID technology has been proved as shown in the previous subsections. RTH will continue to develop the wiPND during a Phase II effort, if awarded, and will incorporate an ASIC in the new design.

7 PUBLICATIONS

On Apr. 26, 2017 RTH submitted a utility patent application (In-Ear Noise Dosimetry System 15,497,970). The utility application added additional features to an RTH noise dosimeter invention that was described in a cited provisional application within the utility application.

8 HUMAN SUBJECTS

No human subjects have been or will be used during the Phase I effort.

9 MATERIALS AVAILABLE FOR INVESTIGATORS

An RTH utility patent application, In-Ear Noise Dosimetry System 15,497,970, will be made public on Apr. 26, 2018, according to USPTO rules, and will then be available for investigators to read.

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