OBJECTIVE: As a means to monitor factors contributing to warfighter readiness, develop wireless sensors that can be integrated into commercial off-the-shelf (COTS) earplugs to enable continuous in-ear monitoring of warfighter noise exposure and physiological status.

DESCRIPTION: Hearing protection devices are mandatory for warfighters operating in noisy environments to reduce their exposure to potentially damaging noise levels. These hearing protection configurations often involve the use of earplugs. Earplugs used by warfighters range from COTS, disposable, universal-fit foam earplugs to reusable, custom-molded earplugs fit to the individual. Communications and Active Noise Reduction (ANR) technologies incorporated into in-ear hearing protection are working, but the earplug could serve as a platform to collect a large amount of valuable data from the warfighter via the ear. Data to collect includes: noise dosimetry, head vibration/bone conduction effects, ear canal pressure, head acceleration, and physiological data such as heart rate, body temperature, and pulse oximetry.

The Navy seeks a cost-effective system to collect warfighter data from the ear using wireless sensor capabilities. The initial focus of this SBIR effort should be binaural in-ear noise dosimetry, with the capability for the system to integrate additional sensors to capture supplementary types of data mentioned above. The sensors should be miniaturized to easily fit deep (beyond the second bend) inside most ear canals and capable to be used with a variety of earplugs (e.g., COTS foam/flange, custom fit). The proposer should conduct analysis to ensure it is safe for human in-ear use with potential risks and mitigations identified. Methodologies used to ensure safe-for-human use should be presented. A description of insertion and removal processes should be provided. The miniature wireless sensors should be durable enough for repeated use, but cost-effective so that they may be replaced if damaged or lost. The system should be acoustically transparent so as not to alter the noise attenuation of the earplug, thus allowing for accurate analysis of the earplug performance.

The rate of data collection for the system should allow for continuous monitoring of the warfighter, with the data transmitted wirelessly to a recording device to capture exposure vs. time for subsequent analysis, with the preferred ability to conduct live monitoring of data when desired. All components of the system worn on the head must fit under helmets (HGU-68/P, HGU-84/P, and HGU 56/P) and earmuffs (Aegisound DC2, Aegisound Argonaut, David Clark maintainer headsets, David Clark aviation headsets) without interfering with the attenuation properties of these devices. The proposer should clearly identify and discuss any expected calibration process of the entire system, including sensors. For noise dosimetry applications, the dynamic range of the system must comply with, but not be limited by, ANSI S1.25. Consideration should be made on collecting both in-ear and external continuous noise levels [70 – 140 dB], as well as capabilities to collect noise doses in impulse noise environments [140-170 dB peak sound pressure level (SPL) ambient noise]. The device must be suitable for aviation and shipboard environments. Initial focus should be on compatibility with universal and custom fit earplugs (ex. Sound Guard, EAR Classic, Elvex Quattro, Westone solid custom molded, and Westone CEP tips). Consideration would be given to a multi-sensor suite built into an earplug for use with the system as a long-term solution.

It is preferred that reusable components of the system not exceed $1,000 per unit and any small in-ear components or disposable units should not exceed $150. It is understood that prototypes and low quantity production of the system may be higher than these limits. The projected cost of the production units will be given careful consideration. The proposer should provide a cost-benefit analysis for anything exceeding these values.

Note: If required, NAVAIR will provide Phase I performers with the appropriate guidance for human research protocols so that they have the information to use while preparing their Phase II Initial Proposal. Institutional Review Board (IRB) determination as well as processing, submission, and review of all paperwork required for human subject use can be a lengthy process. As such, no human research will be allowed until Phase II and work will not be authorized until approval has been obtained, typically as an option to be exercised during Phase II.
PHASE I: Design wireless in-ear noise dosimeters for use with readily available COTS earplugs. Demonstrate proof of concept of critical features of the design through computational modeling or experimental testing. Outline concept for additional monitoring capabilities. Develop integration and calibration methods, and cost estimates. The Phase I effort will include prototype plans to be developed under Phase II. Note: Please refer to the statement included in the Description above regarding human research protocol for Phase II, should it be required.

PHASE II: Develop and produce ten functional prototype wireless in-ear noise dosimeters and demonstrate/validate their performance with several types of COTS earplugs (foam, flange, custom-molded). Expand upon and investigate the concept of miniaturized wireless sensors beyond noise dose monitoring to cover other forms of personnel monitoring that could be done via the ear. Develop lifecycle cost and supportability estimates of such sensors. Note: Please refer to the statement included in the Description above regarding human research protocol for Phase II, should it be required.

PHASE III DUAL-USE APPLICATIONS: Transition technology into production via sales to the Department of Defense and through commercial sales.

Wireless earplug sensors and the data obtained from them would be invaluable to both military and civilian communities that seek methods to monitor personnel in the field and evaluate real-world performance and safety of COTS earplugs. Further development in miniaturized wireless dosimeters and other sensors (sensors for blood pressure, temperature, heart rate, blood oxygenation, stress, etc.) would have many applications in numerous industries in the civilian sector.

REFERENCES:

KEYWORDS: Dosimetry; Monitoring; Hearing Protection; Sensor; Wireless; Earplug