

NAVY SBIR TRANSITION PROGRAM

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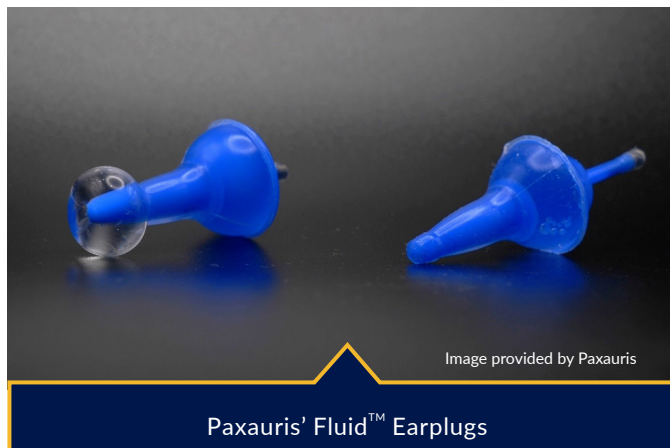
Innovative hearing protection: How Paxauris is changing the game with comfort, fit and performance

By Amie Alscheff

Noise-induced hearing damage, including hearing loss and tinnitus, is the most common form of disability affecting U.S. military veterans. As of 2020, more than 1.3 million veterans were receiving disability compensation for hearing loss, and more than 2.3 million were receiving compensation for tinnitus, according to the Veterans Benefits Administration. To address this issue, Phoenix-based small business Paxauris has leveraged SBIR funding from the Navy and the Defense Health Agency to develop two innovative hearing protection technologies aimed at preventing hearing loss.

The first, Paxauris' Fluid™ Earplugs, are a revolutionary design that, according to the company, "are almost impossible to insert incorrectly." The fluidic earplugs feature a soft silicone stem that easily slides into the ear. Once in place, the user presses an exterior bulb, inflating the stem to form a deep stable seal within the ear canal. Reversing the process is just as simple—the user pulls a tab connected to the bulb, which deflates the tip. "It's a different design of earplug which we've shown gives more consistent performance than standard foam earplugs," says Paxauris president Anthony Dietz. "It's also easier to use and more comfortable."

Comfort and ease of use are just as important



as performance when it comes to ensuring effective hearing protection, explains Navy audiologist Lieutenant Commander (LCDR) Kyle Shepard. "There's a lot of things we consider in the military and in general when it comes to hearing conservation. There's performance of the plug, fit of the plug and then comfort, and usually the fit and the comfort compete against one another. The tighter it fits, the less comfortable it is. The more comfortable it is, the less protection. With the fluidic technology Paxauris has developed, there's a really cool balance between the two. We're getting great subjective feedback about the ease of use and the comfort, which is huge because we rarely see one plug work so well across many ear canal sizes."

Shepard works within the Naval Air Warfare Center Aircraft Division Command (NAWCAD)

SPOTLIGHT

Innovative hearing protection: How Paxauris is changing the game with comfort, fit and performance....Continued

at Patuxent River where he manages research projects advancing hearing protection, including active noise reduction (ANR), 3D scanning and 3D printing to create custom earplugs, in-ear noise dosimetry, and human performance. As Paxauris' technical point of contact (TPOC) for a Navy SBIR Phase II award that concluded in the fall of 2024, he's worked closely with Dietz in developing Paxauris' second technology—the General Hearing and Occupational Safety Tracking (Ghost™) Hearable.

“Hearables” are smart in-ear devices that provide features such as audio amplification, communication or biometric tracking. Paxauris' Ghost™ Hearable provides transparent hearing protection with a hear-through capability

and includes an in-ear noise dosimeter that measures actual noise exposure inside the wearer's hearing protection. It consists of instrumented earpieces that sense binaural continuous and impulse noise exposure and can be configured to measure other biometrics such as head acceleration and body core temperature deep in the ear canal, where measurements are most accurate. The Ghost™

Hearable is designed to be worn with the Fluid™ Eartips but can be used with standard foam eartips as well.

Shepard is excited to use both products in his lab, starting with a human subject trial scheduled in 2025. The Ghost™ Hearable is expected to be a valuable tool for measuring the effectiveness of the advanced hearing protection technologies the Navy is introducing to protect workers in the most extreme noise

environments, such as aviation maintainers and flight deck crews.

“This in-ear noise dosimeter can help determine that the gear being worn is doing what it should and to help develop parameters to ensure people are not exceeding risk criteria for really high noise level jobs,” explains Shepard.



“Paxauris' fluidic eartips can attach to the dosimeter, and they've designed it so other types of eartips can attach to it as well, whether it's a custom tip, a foam tip or a fluted technology.”

The dosimeter will help determine which type of earplug is most appropriate for an end user, says Shepard. “I'm guessing it's going to be a

fluid earplug that's needed in environments where we're trying to get as much hearing protection as possible. In other environments too much protection could compromise situational awareness or the communications coming through certain gear. That balance is never ending, based on the performance of the hearing protector, the fit and the comfort. The technologies Paxauris is developing through their SBIRs are going to help us try to address that dilemma that we've had throughout hearing conservation history."

One of the first technologies Shepard plans to test with the Fluid™ Hearable in next year's human subject trial is the HGU-99 Hearing Protection Helmet, the Navy's newest helmet for flight deck crews. The Hearing Protection Helmet, developed by Creare, provides three layers of passive hearing protection while also incorporating electronic "hear-through" technology that recreates the ambient soundscape at a safe level. This allows crew members to protect their hearing without compromising situational awareness. "It is being transitioned now for users in really extreme environments—so loud that we need more than two layers of hearing protection, which is why the helmet was created. This in-ear noise dosimeter that can measure noise beyond hearing protection is going to be an excellent way to validate technologies like a triple hearing protection helmet," he says.

Interestingly, before founding Paxauris in 2016, Dietz was an engineer at Creare, where he initiated and led the development of innovative products including the Hearing Protection Helmet. With Paxauris, his mission from the start was to create a better earplug. "We're

very focused on hearing protection. Our company's goal is to eliminate noise-induced hearing loss. We're solely focused on these two products, although we're looking at a very broad market for them."

In terms of marketing to the military, hearing protection products face challenges because there is no program office or program of record devoted to them. Paxauris' SBIR Phase II for the in-ear dosimeter was sponsored by NAVAIR's Aircrew Systems Program Office (PMA-202). PMA-202 has been very supportive, says Dietz, but earplugs are so ubiquitous that they are not tied to a specific aircraft platform for purchasing purposes. Further, they are such a low-cost item that purchasing is typically done at the unit or ship level, or even left up to the individual user, rather than through large bulk orders. Without a program of record, Paxauris plans to initially sell to the Navy for research and development and hearing conservation studies, like those being carried out by Shepard's lab. Eventually, the plan is to make their earplug and in-ear dosimeter available to command-level purchasers through the General Services Administration (GSA). "Our challenge in bridging the gap to commercial transition," says Dietz, "is how to get sufficient funding to scale and then how to get the word out to the various groups that this new technology is available to protect their crews."

Outside the military, Paxauris is marketing the Fluid™ Earplug and the Ghost™ Hearable to anyone exposed to noise through workplace or recreational activities, including industrial workers, first responders, musicians, hunters and firearms enthusiasts. The earplugs can also be used for quieter travel, better sleep, and to

SPOTLIGHT

Innovative hearing protection: How Paxauris is changing the game with comfort, fit and performance....Continued

protect ears from water during swimming.

With small batches of the earplugs already manufactured, Paxauris is using them to conduct pilot studies not just with the Navy but also with local industrial sites in the Phoenix area.

“We’re actively looking for pilot study opportunities,” says Dietz. “Right now, we’re talking with the Phoenix police force to get a study going for their next Academy class during firing range training. It’s a great opportunity to educate recruits right at the beginning of their careers on the importance of hearing protection, so that they get their annual hearing tests and know how to select and properly use the correct earplug. We’re also talking to the Phoenix police about using it for their Academy shooting instructors. They move in and out of noise a lot during training. They’re very interested in the dosimeter because they don’t know how well protected they are right now.” The intermittent exposure to noise on the firing range is something Paxauris’ earplugs are uniquely designed to address. When deflated, they allow users to hear communications—such as instructions or feedback—without needing to remove the plugs from their ears. Pressing the bulb reinflates the plug giving instant full protection. It is essentially an on/off button for hearing protection.

The Fluid™ Earplug has completed the regulatory testing required by the Environmental Protection Agency (EPA) for sale in the United States, with a noise reduction rating (NRR) of 24 decibels. Paxauris is also testing against the latest American National Standard Institute (ANSI) standard, which the

military uses to rate hearing protection devices, as well as testing to meet standards required for sale in other countries. The Ghost™ Hearable is starting its own testing processes now and should be market-ready in about a year, according to Dietz.

Unlike many SBIR-funded technologies, Paxauris’ products are something the general public can purchase. “We’ve started accepting pre-orders for the earplugs on our website,” says Dietz. “We’re looking to scale production once we have finished our next round of customer feedback and the design changes to address that.” Through venture capital investment and automating parts of the manufacturing process, Dietz aims to bring the retail cost down to \$35 for a pair of Fluid™ Earplugs. Each pair will be reusable for three months with constant daily use, or up to a year with occasional use.

Paxauris means “peaceful ear” in Latin, and the company name reflects its goal of ending noise-induced hearing loss. As one of the company’s marketing statements puts it, “What we sell is quiet, whenever, wherever you want.” Further details and ordering information can be found on the Paxauris website at www.paxauris.com.

