Department of the Navy SBIR/STTR Transition Program

DISTRIBUTION STATEMENT A. Approved for public release. Distribution is unlimited. ONR Approval #0543-1237-23 Topic # N21A-T013 Real-time Monitoring for Decompression Sickness Clearsens Inc.

WHO

SYSCOM: ONR

Sponsoring Program: Office of Naval Research (ONR) Code 34

Transition Target: U.S. Navy's Naval Sea Systems Command Supervisor of Salvage and Diving (NAVSEA SUPSALV), Naval Special Warfare (NSW), and/or Naval Air Systems Command (NAVAIR) Aircrew Systems Program Office (PMA-202)



Clearsens Inc. 2023

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Other Transition Opportunities: Healthcare Industry: Improved ultrasound medical devices Wearable Ultrasound for Imaging/Stimulation Long-term ultrasound monitoring Marine Mammal Research

Notes:

WHEN Contract Number: N68335-23-C-0037			Ending on: Jan 15, 2025	
Milestone	Risk Level	Measure of Success	Ending TRL	Date
Fabrication of ultrasonic sensors	N/A	Complete fabrication and acoustic characterization	3	1st QTR FY24
Inital Prototype	Low	Design complete backed by laboratory experiments	4	3rd QTR FY24
Wearable Prototype	Low	Verified functionality in a hyperbaric chamber	5	2nd QTR FY25
Demonstrate Operation (per Phase II Option)	Medium	Field Tests	6	2nd QTR FY27

WHAT

Operational Need and Improvement: Decompression Sickness (DCS) is a leading risk to divers and timelimiting factor for diving operations. Currently, there is no technology to tailor decompression schedules to the physiological state of individual divers. ClearSens provides unique ultrasonic sensors with simplified manufacturing process that enables highly efficient, small form factor arrays suitable for a wearable imaging and sensing system. With the licensed technology, Clearsens is developing a wearable device that can assess the level of decompression bubbles in real-time during dive. Accordingly, it provides information that can be used toward a personalized decompression schedule.

Specifications Required: Device should target bubbles in micron scales as is possible with capacitive micromachined ultrasound transducer (CMUT) technology, and capable of capturing bubble formation and presence in both blood and tissue.

Technology Developed: Clearsens packaged the sensing unit and finished the initial tests in a hyperbaric chamber. The sensing unit is functional up to 10 ATA. Micobubble detection was demonstrated using a tissue mimicking phantom. we demonstrated the feasibility of a CMUT approach to real-time wearable decompression bubble imaging with experimental tests and simulations, including underwater operation (pressure testing and sensitivity compensation), bubble detection (flowing and stationary). Now our goal is to build a wearable prototype and we plan to prove our solution via physical tests in our academic partner's (Duke University Hyperbaric Medicine Clinic) hyperbaric chambers and verification tests over human subjects.

Warfighter Value: The wearable device has the potential to improve safety for military divers and at the same time expand operational capabilities. The system will provide a personalized decompression schedule and reduce the time underwater for time sensitive operations.

HOW

Projected Business Model: Clearsens provides novel ultrasonic sensors (CMUTs) with simplified manufacturing process that enables highly efficient, small form factor ultrasound arrays. The licensed technology enables wearable ultrasound imaging and sensing systems.

Company Objectives: Clearsens aims to build a wearable system and commercialize a product for the scuba-diver domain. The company identified foundry partners for manufacturing, distribution partners, analytics partners that help us further optimize our algorithms to increase the accuracy of detection and, now seeking for investment partners that can provide capital to go for large scale production.

Potential Commercial Applications: The wearable device can be adapted for potential ultrasound applications in the medical field. It can be used for ultrasound related health monitoring or long-term continuous monitoring of internal organs (ex. obstetrics, urology, and prenatal care).