BETTER. SMARTER. **Soterix** medical

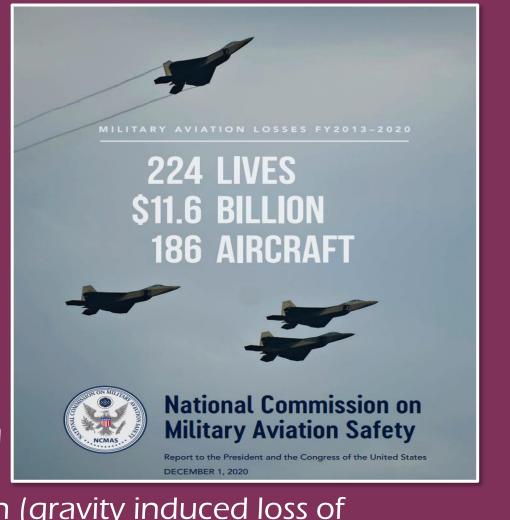
Abstract

To address the Air Force's needs to monitor the vitals and cognitive states of military craft and plane operators, QUASAR is developing an ecG eOg Electric Stimulator (GO E-Stim), a closed-loop fatigue detection and mitigation solution that could reduce the rate of mishaps and improve operational efficiency. QUASAR will embed its high-fidelity and artifact resistant electrooculography (EOG) sensors, along with temperature sensors and optical pulse oximetry (SpO2) sensors into a headband that can be worn with an avionics helmet. In addition, Soterix Medical Inc (SMI) will provide transdermal vagus nerve stimulator (tVNS) to interface into this headband. An EOG-based fatigue detection algorithm will be implemented to trigger the stimulation in a closed loop fashion. The system will be tested in flight simulations and on a plane.

Military Health Significance

The National Commission on Military Aviation Safety identified that the military's sustained high tempo is causing fatigue-related aviation accidents in all military branches, and that between 2013 and 2020, 224 lives, and 186 aircraft were lost due to military aviation mishaps amounting to losses of \$11.6 billion. *

It is well documented that there is a negative impact on mission performance and an increased risk of accidents associated with sleep deprivation, extended time on intense attention demanding tasks, physical exertion, acute or chronic stress, strong and extended acceleration (gravity induced loss of consciousness (G-LOC)), as well as hypoxia, etc.



* National Commission on Military Aviation Safety, Military Aviation Losses 2013-2020. (2020)

Accessed online 6/12/2022 https://s3.documentcloud.org/documents/20419375/ncmas_final_report.pdf

Background

The Air Force has identified electro-oculogram (EOG), thermal imaging, and heart rate variability (HRV) as promising approaches for cognitive workload monitoring and fatigue detection and neuromodulation as a promising approach for fatigue mitigation in aerospace environments.

Existing technologies often suffer from poor signal quality, reliability issues in high-motion environments, and challenges in integrating with aerospace equipment. QUASAR, a leader in physiological monitoring technologies, has experience integrating high-fidelity sensors into military-grade helmets for realtime operator state monitoring (OSM). QUASAR's patented hybrid capacitive and resistive dry electrode technology has been developed under DoD funding to address this usability challenge by enabling gel-free high-fidelity EXG recordings that are resistant to motion and electrical artifacts. This technology has been validated in various military relevant environments, including dismounted warfighters, and simulations such as UAV control and stationary flight simulators.

In this project, QUASAR will integrate dry electrode EOG and temperature sensors and commercial SpO2 sensors into a headband compatible with avionics helmets. OUASAR will incorporate a transcutaneous vagus nerve stimulation (tVNS) system from SMI to provide closed-loop fatigue mitigation.

Company Overview

Ouantum Applied Science and Research (OUASAR) has developed revolutionary noninvasive electrophysiological sensors with machine learning algorithms for cognitive & physiological monitoring in military, medical, & consumer applications. QUASAR's Dry Sensor Interface (DSI) EEG technology is being commercialized by Wearable Sensing for novel applications in the fields of Brain-Computer Interface (BCI), Cognitive Monitoring, Augmented Cognition, Biomarkers, Neurofeedback, Neurorehabilitation, Neuroergonomics, Neuroeducation, etc.

QUASAR is experienced in integrating multimodal wearable physiological sensors into military helmets and armor for operator state monitoring. Workload Engagement Fatigue

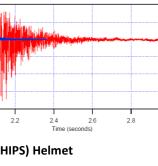
AMRAA SBIR Phase I/II contract: W81XWH-06-C-0045 POP: 2005 - 2009. PM: Steve Van Albert (WRAIR) ECG + Ballistic Impact Detection Sensors (BIDS) integrated into body armor



Closed-Loop Feedback Control for Transcranial Direct Current Stimulatio USAF/AFMC Phase I/II SBIR: FA8650-18-P-6920 / FA8650-19-C-6041 PoP· 2017 –2022 PM· Richard "Andy" McKinle

Closed-loop Improved Cognition (CLIC) headset





PoP: 2024 – 2024 PM: Kevin Baugher Cognitive Health, Impact, and Physiological Sensor (CHIPS) Helmet with BIDS

DHA Phase I SBIR: HT942524P0027

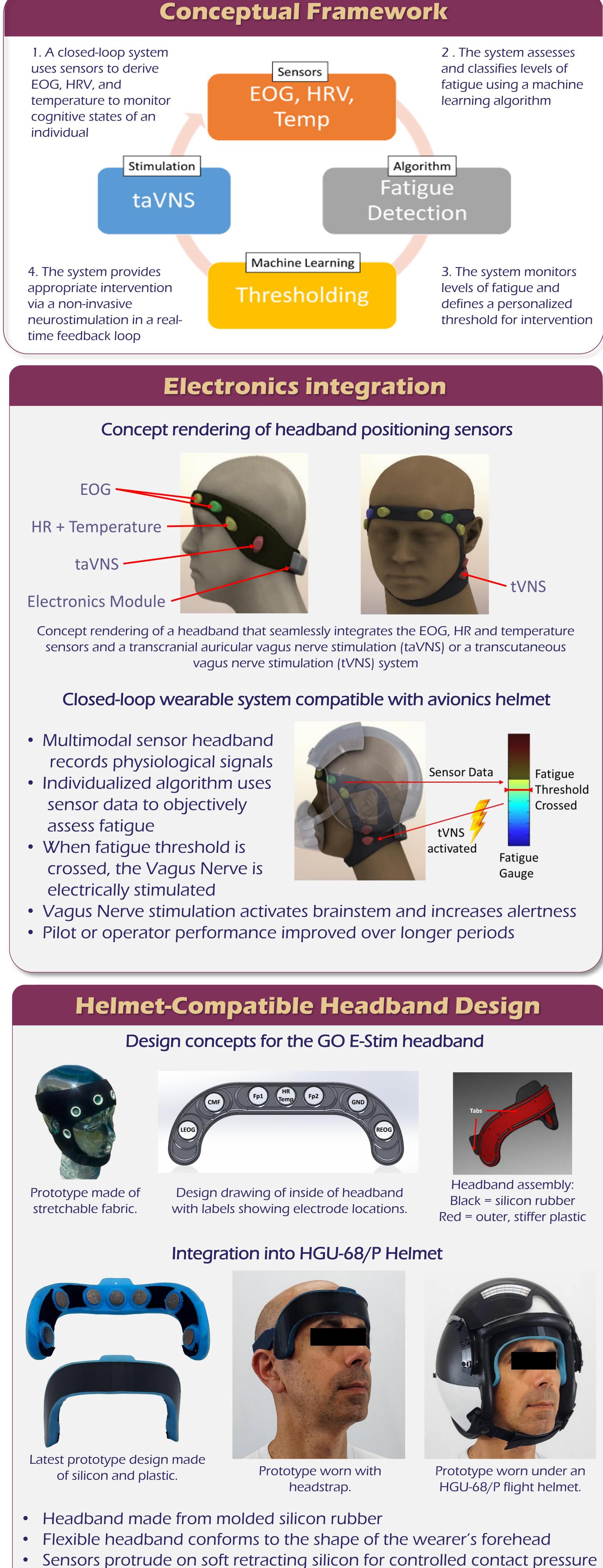
Research Sponsorship & Disclosures

This material is based upon work supported by the US Air Force under Contract No. FA8650-22-C-5030. Any opinions, findings and conclusions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of the US Air Force. N. McDonald, K. Ermolaev, T. McManus, M. Steindorf, M Poquette, & W. Soussou are employees of OUASAR Inc. Y. Valter, G. Turnquist, K. Nazim, & A. Datta are employed by Soterix Medical, Inc., which manufactures and sells components of the developed device. Abhishek Datta holds equity in Soterix Medical.

A Flight-helmet Compatible Closed-loop Electrooculography and Vagal Nerve Stimulation Device for Fatigue Mitigation in Pilots

Neil McDonald, PhD¹, Konstantine Ermolaev, PhD¹, Tobin McManus¹, Marty Steindorf¹, Melissa Poquette¹, Walid Soussou, PhD¹, Yishai Valter, MS², Gunnar Turnquist², Kamran Nazim, MS², Abhishek Datta, PhD²

1. Quantum Applied Science and Research (QUASAR), San Diego, California, USA, 2. Soterix Medical, New York, NY 10001 USA



[•] Plastic tabs allow for easy coupling with a helmet

Ramp and Flight Testing Measurements The GO E-Stim device did not interfere with the plane's electronic equipment during ramp testing Max Magnetometer Deviation Screen captures of the Global Positioning System (GPS) signal power received from each Maximal magnetometer deviations plotted for each detected satellite (one green bar per satellite) in various modes of operation of the GOexperimental condition E-Stim Device: A) OFF, B) ON, C) streaming via BT, D) stimulation activated. A flight was safely conducted with the GO-E-Stim actively acquiring and transmitting data, without any observed operational challenges Individual wearing GO E-Stim device Individual wearing GO E-Stim GPS signal checker detected over The internal system tester passed on device and flight communication 13 satellites with sufficient power all its parameters during flight with during flight GO E-Stim during flight with GO E-Stim headset on top of it The plane's engine does not generate artifacts in the GO E-Stim data during ramp testing - Baseline (no shielding) Baseline recordings with plane Baseline recordings with plane High frequency artifacts generated Bench-top tests indicate shielding of systems and engine OFF systems and engine ON by the pilot communicating to the headset and main electronics Fatigue control tower reduces EMI pickup. Threshold Results Crossed • High-frequency artifact appeared consistently whenever the • The GO E-Stim device did not interfere with the plane's pilot communicated with the tower control via the radio magnetometer, GPS or other electronic equipment. • OUASAR has identified the circuit node most responsible for • There were no observable artifacts in the GO E-Stim data pickup of EMI interference via shielding tests and has due to the engine starting up or the device wearers suggested several shielding configurations to reduce EMI touching the instruments and surfaces in the cockpit. pickup to be used in the next prototype design. **Feasibility Study: Fatigue Detection Protocol** Saccade Measurement Power Law Fit Simultaneously EOG and EEG data collection device Array of fixation points for VEOG measurements for spatial cueing paradigm Magnitude of saccade peak velocity as a function spatial cueing paradigm. of the magnitude of saccade amplitude (n=1). The during Fatigue protocol. used in preliminary tests. slope of a linear fit to log-transformed data can be interpreted as the exponent of the power law. Preliminary Results Saccade peak velocity-amplitude relationship Test data consistent with Di Stasi et al. (2013). HEOG saccade peak velocity and magnitude during office task shows a strong correlation with Self-Reported Sleepiness (KSS) KSS scores. Slope of power law fit during office EEG-based ML fatique classifier vs KSS • EEG-based fatigue detection shows a very strong activities vs. KSS score (n=1). HEOG is scores (n=1). EEG-based fatigue detection correlated with KSS score (p=0.015). correlation with KSS scores. is strongly correlated with KSS (p=0.004) Conclusions • OUASAR integrated physiological sensors into an under-helmet headband and interfaced it with a tVNS system. • The GO E-Stim electronics did not interfere with aircraft electronics during ramp testing and flight. • The only interference to GO E-Stim was from communications to radio tower, which was mitigated with new shielding. • OUASAR's EOG and fatigue detection models can accurately detect saccades and participant fatigue respectively. The GO E-Stim system is showing promise for use as a closed-loop fatigue mitigation solution for long flights.

