AWARD NUMBER: FMBB100158581

TITLE: Real-Time Telemetry Health and Safety Monitoring System Design and Implementation in a High Risk Training Environment

PRINCIPAL INVESTIGATOR: Dr. Regina Shia

CONTRACTING ORGANIZATIONS: Human Systems Integration; Vital Technologies, LLC; Torrey Pines Logic; and Guardian Premier Solutions, LLC

REPORT DATE: Dec 2019

TYPE OF REPORT: FINAL

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE *(DD-MM-YYYY)*	**2. REPORT TYPE**	**3. DATES COVERED** *(From - To)*
Dec 2019	Final	09/30/2015 - 09/30/2019

4. TITLE AND SUBTITLE

Real-Time Telemetry Health and Safety Monitoring System Design and Implementation in a High Risk Training Environment

5a. CONTRACT NUMBER

5b. GRANT NUMBER FMBB100158581

5c. PROGRAM ELEMENT NUMBER

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

6. AUTHOR(S)

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8. PERFORMING ORGANIZATION REPORT NUMBER

N/A

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

Air Force Materiel Command
Air Force Research Laboratory
711 Human Performance Wing
Airman Systems Directorate
Wright-Patterson Air Force Base, OH 45433

10. SPONSOR/MONITOR'S ACRONYM(S)

711 HPW/RHXB

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

AFRL-RH-WP-TR-2019-XXXX

12. DISTRIBUTION / AVAILABILITY STATEMENT

DISTRIBUTION STATEMENT A. Approved for public release; distribution is unlimited

13. SUPPLEMENTARY NOTES

This research was supported in part by an appointment to the Research Participation Program for the Air Force Research Laboratory, 711th Human Performance Wing, Airman Systems Directorate, Airman Bioengineering Division, Cognitive Enhancement and Bioengineering Branch administered by the Oak Ridge Institute for Science and Education through an Inter-agency agreement between the U.S. Department of Energy USAFRL.

14. ABSTRACT

Shallow water black-outs (SWBs) occur in all areas of the Department of Defense during training programs throughout the pipeline as well as in operations. Victims of SWBs usually lose consciousness within 15 feet of the surface, where expanding, oxygen-hungry lungs of breath-hold divers literally suck oxygen from their blood. SWBs are particularly frequent in environments that induce overexertion or self-induced breath holds. Hyperventilating adds very little oxygen to an individual's reserve, forcing carbon dioxide out of the lungs. Carbon dioxide is the trigger to the brain to breathe. Aquatic skills and water confidence training is a combat proven process and is an inter-service performance standard. This training however, is accompanied by certain levels of inherent and historical training risk. Trainee hypoxic episodes and shallow water blackouts are a common byproduct and are an assumed known constant during aquatic confidence training. The purpose of this effort is to develop and validate a heart rate and SpO2 sensor for real-time monitoring during water confidence training. Success in this program will reduce the probability of trainee fatalities.

15. SUBJECT TERMS

Special Operations Training, Water Confidence, Stress Exposure Training, Shallow Water Blackouts, SpO2, Heart Rate, Biometric Sensors

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			Dr. Regina Shia
Unclassified	Unclassified	Unclassified			**19b. TELEPHONE NUMBER** *(include area code)* 937-255-9717

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1. **INTRODUCTION:** *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

The proposed effort aims to provide special operations personnel and support staff with emerging technology that provides real-time vital sign monitoring in both land and aquatic environments. This technology is to be utilized during elevated risk training applications and as well as real world operational readiness training. The purpose of the effort is to advance the current health and safety monitoring process for heat stress reduction and apply this process to the aquatic component of training for the reduction of shallow water blackouts. The aquatic skills and water confidence training that these future Special Operations members participate in is a combat proven process and is an inter-service Special Operations Command (SOCOM) performance standards requirement. This training however, is accompanied by certain levels of inherent and historical training risk. Trainee hypoxic episodes and shallow water blackouts are a common byproduct and are an assumed known constant during aquatic confidence training. The purpose of this effort is to incorporate personalized, real-time monitoring technology into the training pipeline and in operational use.

2. **KEYWORDS:** *Provide a brief list of keywords (limit to 20 words).*

Special Operations Training, Water Confidence, Stress Exposure Training, Shallow Water Blackouts, Peripheral Capillary Oxygen Saturation (SPO2), Heart Rate, Biometric Sensors

3. **ACCOMPLISHMENTS:** *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

What were the major goals of the project?

List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

Specific Aim 1: Product Development YEAR 1	**Timeline**	**Complete**
Major Task 1: Approvals and Planning	Months	
Subtask 1: IRB, ORP, and HRPO Approval	1-6	Non-Human Use
Subtask 2: System Evaluation/Equipment Testing	1-3	
Subtask 3: Interface Design/Data Analytics	1-6	
Major Task 2: Software Design		
Subtask 1: Material Engineering	12-30	Gen II Complete
Subtask 2: Software Programming	12-30	Gen II Complete
Subtask 3: DBIT Certification	1-12	No longer needed

	Year 2		
Target Enrollment (per quarter)	**Q1**	**Q2**	**Q3/Q4**
350th BA TS (now SWTS)	0	60	57

Site 2 USAF Combat Dive School			~12
Site 3 Combat Rescue Officer Phase II Assessment and Selection			~5
Completed Validations		**60**	**74**

Year 3 and 4 Follow-on (FY 18-19)

Activities	18Q1	18Q2	18Q3	18Q4	19Q1	19Q2	19Q3	19Q4
Propose FSO 2 year follow-on								
AETC Technology Transfer Agreement (TTA)								
Identify FSO organization								
Get FSO org on contract								
Begin AMFS ATT Sensogram and FSO organization communication (establish NDAs)								
Location specific measurement								
Internal Software Development								
Design Integration								
Form factor establishment								
Dashboard design								
Deliverables (brass board prototype) and Tranision Plan								
Final Report								

General Description of Goals:

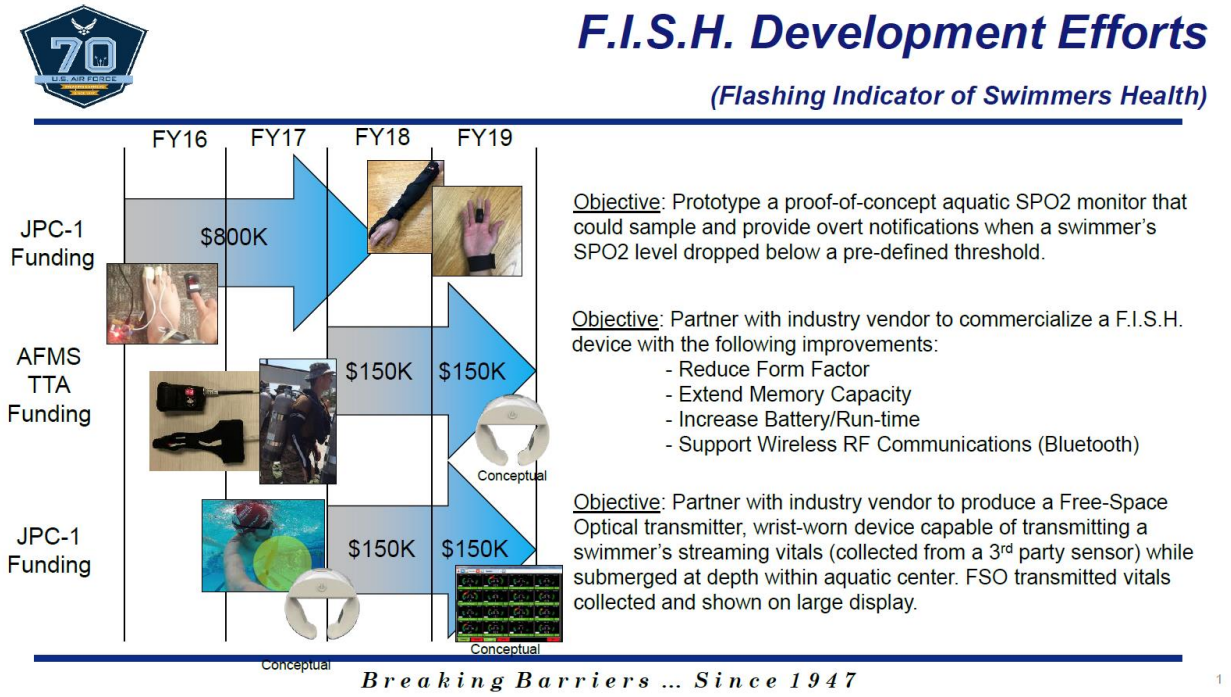
The Battlefield Air Targeting Man-Aided kNowledge Group of the Battlefield Acoustics Branch and the Applied Neuroscience Branch of the Airmen Systems Directorate of the Air Force Research Laboratory have been funded to design and validate a performance and safety on-body heart rate and SpO2 monitor for transition into an aquatic environment. The F.I.S.H. (Flashing Indicator of Swimmer Health), is an original system with a framework built with the proven Nonin 8000 Series sensor. This system was designed with input from several Battlefield Airmen subject matter experts, cadre, and leadership. Required trainee peripheral dexterity, aquatic environmental depth, length of training exercises, and cadre visibility were also considered during system design. The current system senses SpO2 and heart rate and transmits data to a device, which stores the recorded data. This device also includes flashing indicators to denote alarm and warning vital thresholds as well as sensor discovery status. This presentation will discuss the team's initial stages of validation testing and will discuss the impact of performance and safety monitoring during water confidence training, including the potential to reduce deaths due to SWBs.

What was accomplished under these goals?

Following Year 2 Gen II prototype demonstration, AMFS funding was awarded in order for Human Systems Integration (HSI) to design a manufacturable Gen II F.I.S.H. to be delivered to AETC. During this time, the JPC-1 staff awarded an additional $300k for the development of a Free Space Optical solution (via Torrey Pines Logic) for the F.I.S.H. $150 of FY18 funds were received. The additional $150 for FY19 was not received.

1. *Environmental analysis of swimming area at the 350th BA TS Year 3 Q4 – This has been changed due to a rebuild of the aquatic training area at the 350th. The FSO version of the F.I.S.H will be flexible and able to function in most environments.*
2. *Form factor development Year 4 Q4- underway*
3. *In-house software development Year 4 Q3*
4. *Interface development – Need funding*
5. *Deliverable/Final Report Y4 Q4 (Delayed)*
6. *See below for overall plan from FY16-FY19. This plan is delayed due to the final AFMS manufactured solution of Gen II being delayed. FSO solution must integrate with this final deliverable*

Final report due Dec-19



What opportunities for training and professional development has the project provided?

Multiple engineers, as a part of the Battlefield Air Targeting Man-Aided kNowledge Group of the Sensory Systems Branch contributed to the F.I.S.H. project. During this time, multiple presentations and demonstrations took place.
Regular briefs to the Commander of the 350Th TRS;
• June 27th, 2016, San Antonio, TX
• August 3rd, 2016, Dayton, OH
• May 1, 2017, Denver CO
Capt Trent Joy, Detachment Commander for Combat Control School
LT General Roberson AETC/SG, Dayton, OH
Capt. Ryan Hatfield; Det 1 350 TS Dive School – F.I.S.H demonstration Sept 18 2017
Military Health System Research Symposium 2019

How were the results disseminated to communities of interest?

This project has been communicated to a wide range of audiences. Most recently, a Gen II demonstration occurred at Wright State University. During this demonstration, several images were captured by the 711th Human Performance Wing Program Office, and Public Affairs conducted an interview with Lt. David Sardo.

General Goldfein received a demonstration of the F.I.S.H. from Patrick Wilson – Retired Chief of Security Forces and GPS full-time employee supporting the JPC-1 effort (CSAF and CMSAF Visit to Lackland AFB, July 2017). Also in 2017, the Guardian Angel Senior Leader Working Group was briefed.

The F.I.S.H. was briefed and demonstrated to Gen. Cooley – AFRL Commander in 2017

The F.I.S.H. prototypes were also tested and demonstrated in multiple environments: 350th TS, Combat Rescue Officer Phase II, USAF Combat Dive School, and the Naval Special Warfare Center

4. IMPACT:

One major impact is a better understanding of how shallow water blackouts may occur, specifically in this population of interest. Prior over-exertion upon entering the pool reduces the amount of carbon dioxide levels available when submerged. As oxygen is depleted in water, carbon dioxide increases to trigger the brain to breath. If this increase is slow due to a prior lack of carbon dioxide, this trigger does not occur.

An even bigger impact is knowing that technology can provide an alert for low SPO2 levels and that the potential to reduce deaths due to shallow water blackouts is possible.

What was the impact on other disciplines?

Assuming that validity and feasibility testing results in a transitional product, the need for aquatic SPO2 monitoring devices spans all of DoD as well as several Olympic training facilities, childcare facilities offering swimming lessons, and public/private schooling entities where swimming teams spend hours in the water.

What was the impact on technology transfer?

Gen II F.I.S.H. will transition to AETC in 2020

What was the impact on society beyond science and technology?

Nothing to Report

5. CHANGES/PROBLEMS:

Nothing to Report. The status of this project is that a Free Space Optical solution is designed and ready for integration with the final Gen II form factor still being manufactured by Human Systems Integration.

Actual or anticipated problems or delays and actions or plans to resolve them

The status of this project is that a Free Space Optical solution is designed and ready for integration with the final Gen II form factor still being manufactured by Human Systems Integration. The team will deliver a ¼ pool solution for Free Pace Optical – awaiting the final form factor from HSI (Gen II).

Changes that had a significant impact on expenditures

Expenditures (For TPL) are delayed until Gen II is complete.

Significant changes in use or care of human subjects

NA

Significant changes in use or care of vertebrate animals

NA

Significant changes in use of biohazards and/or select agents

NA

6. PRODUCTS: *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."*

- **Publications, conference papers, and presentations**
  Report only the major publication(s) resulting from the work under this award.

  Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

NA

  Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

NA

Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

Sardo, D., & Burnett, D. (2017). Performance and Safety for Optimized Water Confidence Training. The 88th Annual Aerospace Medical Association Conference. Denver, CO. Shia, R. M., Miller, D., Mack, C., Sardo, D., Feibus, D., Burnett, G., & Romigh, G. (2019). Enhancing human performance & survivability in extreme environments: Performance and safety in aquatic environments. Military Health Systems Research Symposium, Orlando, FL.

- **Website(s) or other Internet site(s)**
  List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

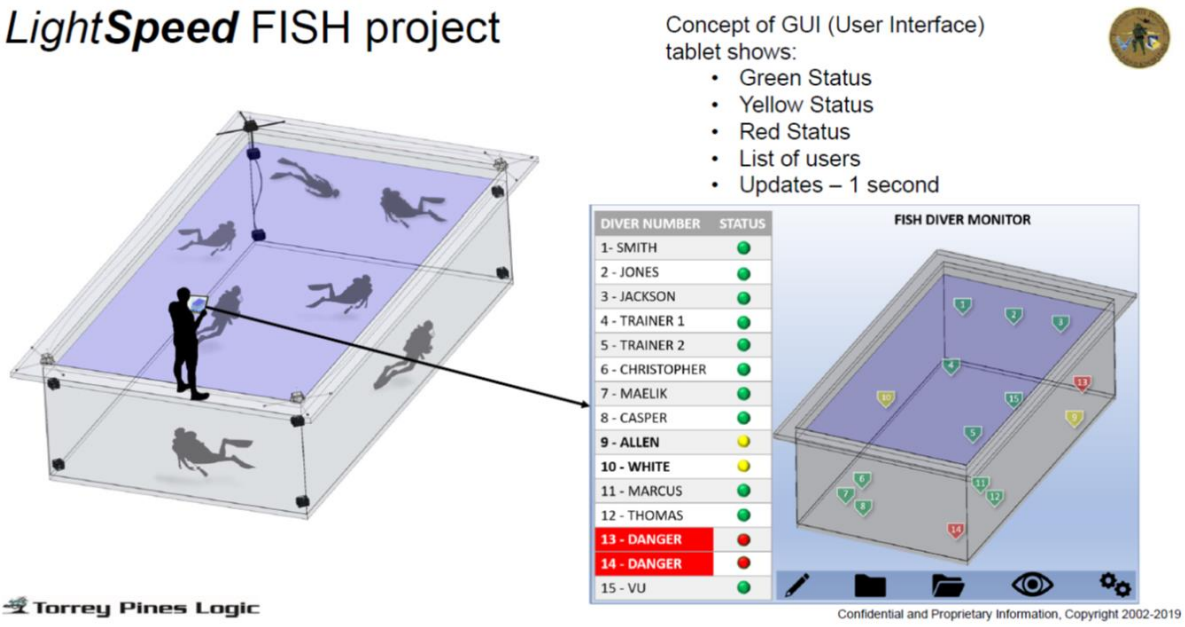
  NA

- **Technologies or techniques**
  Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

  Technologies include F.I.S.H. Generation 1; Generation II in a final stage of development to be delivered to AETC (funded through AFMS); and a Generation III Free Space Optical Design currently under development. This design is call *LightSpeed* and is shown below.

  The capabilities of F.I.S.H. Gen I included:
  - 15 foot depth (deeper depths currently untested)
  - 5 hour battery life when system is not flashing; 3 hour batter life when flashing at a constant rate
  - Second by second SPO2 and heart rate time stamped logged data while worn under water
  - Adjustable warning thresholds for individualized programming of trainee/operator sensor
  - Completely interoperable with various forms of footwear

  Generation II:
  - A two-digit viewing of SpO2 levels is now visible on the FISH.
  - Remote overt notification of HR and SpO2
  - 5-hour stand-by battery life; 3-hour operation
  - Waterproof up to 18 feet
  - LED alert thresholds
  - Sensor attachment at the base of the finger



Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

AETC Technology Transition Agreement
AFMSA/SG5 Acquisition Decision Memorandum (ADM)
United States Patent Application 20190239786

- **Other Products**

Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

- *data or databases;*
- *physical collections;*
- *audio or video products;*
- *software;*
- *models;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

NA

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name: Regina Shia
Project Role: Principle Investigator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 4
Contribution to Project: Dr. Shia has performed overall project oversite managing documentation and reporting, timeline and expenditure management, and customer awareness and communication. Dr. Shia maintains all approvals required during the effort. Dr. Shia has regular meetings with all parties of the team to ensure synchrony.
Funding Support: NA

Name: Joshua Hagen
Project Role: Co-Principle Investigator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 3 (from 2015-2016)
Contribution to Project: Dr. Hagen performed the initial assessment of current physiological monitoring systems that may be functional in aquatic environments. Dr. Hagen determined that an Under Armour (UA) prototype currently under development would serve as the ideal aquatic vital sign monitor to date. This technology would advance the current practice at the 350th allowing for monitoring during aquatic training, but would not be able to detect changes in SPO2. Dr. Hagen continues to provide updated information for the team and has been working to transition the UA technology for various special operations units – Date TBD
Funding Support: Under Armour is currently funded under an active BAA initiative monitored via the Airmen Systems Directorate

Name: Gregory Burnett
Project Role: Co-Principle Investigator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 4
Contribution to Project: Dr. Burnett is the Chief Engineer for the BATMAN team. Dr. Burnett has led the development and manufacturing of the current form factor for FISH Dr. Burnett is also involved in the presentation of system development and reporting. Dr. Burnett is also the author of the patent application.
Funding Support: NA

Name: David Sardo, Lt USAF
Project Role: FISH Engineer
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 5
Contribution to Project: Lt Sardo, under the direction of Dr. Burnett, has been the Lead Engineer for hardware and software development and testing. Lt Sardo is also instrumental in customer briefing and public presentation.
Funding Support: NA

Name: Pat Wilson
Project Role: Subject Matter Expert and Research Technician
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 6
Contribution to Project: Pat Wilson has performed and extensive search for current technology and methods for measuring SPO2 levels in order to identify options for design. Pat Wilson also communicates regularly with the Battlefield Airmen cadre to gage system design feedback and trainee uniform compatibility. He will

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to report

What other organizations were involved as partners?

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Ph: 978-501-7500

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: *For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to* ***https://ers.amedd.army.mil*** *for each unique award.*

QUAD CHARTS: *If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.*

9. APPENDICES: *Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.*