



**TASK ORDER NUMBER:** W81XWH-19-9-0001

**MTEC RESEARCH PROJECT NUMBER:** MTEC-17-08-Multi-Topic-0104

**EGS NUMBER:** MT190002

**TITLE:** Validation of Wearable Sleep and Fitness Monitor with SleepTank Model

**PRINCIPAL INVESTIGATOR:** Steven Hursh, PhD

**PERFORMING ORGANIZATION:** Institutes for Behavior Resources, Inc.

**CONTRACTING ORGANIZATION:** Medical Technology Enterprise Consortium (MTEC)

**REPORT DATE:** March 1, 2023

**TYPE OF REPORT:** Final Report

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

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**Final Technical Status Report for**  
**Validation of Wearable Sleep and Fitness Monitor with SleepTank Model**

**MTEC-17-08-Multi-Topic-0104**

**MT190002**

**Reporting Period: Effective Date – Effective Date- 26 February ‘19 – 28 February ‘23**

**MTEC Research Project Awardee**

Research Project Lead: Steven Hursh, PhD

Other Research Project Team Member: Jaime K. Devine, PhD

Research Project Technical POC: Steven Hursh, PhD

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Submitted: March 1, 2023

## 2. Project Status

### a. Accomplishments

- Year 1 (2019):
  - IBR identified two viable wearables for the SleepTank app—the Zulu watch and the Fitbit Versa series
  - IBR procured Zulu watches and completed the validation of the Zulu sleep algorithm against polysomnography (PSG)
  - IBR completed the development of the SleepTank Watch App for the Fitbit watch and began progress on the mobile app for SleepTank
  - IBR started research projects on the usability and efficacy of the Zulu watch with SleepTank
- Year 2 (2020):
  - IBR continued development of the SleepTank watch app and mobile app as well as a web version of SleepTank
  - IBR received IRB/HRPO exemption for two research studies to test SleepTank for usability and/or efficacy in operational environments; one to assess usability of SleepTank in Norwegian air ambulance pilots and the other to test efficacy in nurses in the USA
- Year 3 (2021):
  - A stable and publicly available version of the SleepTank mobile app was made available on the Apple App Store
  - Data collection began and was completed for two operational trials of SleepTank in nurses and air ambulance pilots
  - The SleepTank clockface was developed to provide a watch face-based version of SleepTank that doesn't require the user to navigate to a separate app
  - CSV- data download website underwent improvements to its stability and reliability. Users can download sleep data, SleepTank data, and app-usage data
  - IBR received approval for a third operational study in USAF servicemembers
  - IBR hired a new contractor to support the SleepTank applications
- Year 4 (2022/23):
  - IBR received approval to include data in the final report from two operational studies that used SleepTank but did not use MTEC fundings. One study tests the usability of the SleepTank mobile app and clockface in cargo pilots and one tests the efficacy of SleepTank in improving sleep hygiene in shift-working Royal Australian Navy (RAN) service members
  - IBR created a software requirement specifications (SRS) document to guide future improvements to the SleepTank applications
  - Data collection and analysis from air ambulance pilots, cargo pilots, first wave nurse and first wave RAN shift-workers was completed
  - Plans for second wave data collection for nurses and RAN shift-workers
  - Upgrades and stabilization of the mobile app is ongoing
  - IBR is pursuing a subcontractor to make next generation improvements to the SleepTank applications
  - SleepTank® was approved as a registered trademark

### b. Reportable Outcomes

- Year 1 (2019):
  - Completed Fitbit watch app



- Year 2 (2020):
  - Publication of the Zulu watch laboratory validation study: Devine JK, Chinoy ED, Markwald RR, Schwartz LP, Hursh SR. "Validation of Zulu Watch against Polysomnography and Actigraphy for On-Wrist Sleep-Wake Determination and Sleep-Depth Estimation". *Sensors (Basel)*. 2020 Dec 25;21(1):76. doi: 10.3390/s21010076. PMID: 33375557; PMCID: PMC7796293
  - SleepTank iOS mobile app was made publicly available on the Apple App Store
  - SleepTank Fitbit watch app was made available to participating users via a download link
  - CSV download website was completed
- Year 3 (2021):
  - Publication of the Zulu watch field validation study: Devine, JK, Choynowski j, Garcia CR, Simoes AS, Guelere MR, de Godoy B, Silva DS, Pacheco P, and Hursh SR. "Pilot Sleep Behavior across Time during Ultra-Long-Range Flights." *Clocks & Sleep* 3, no. 4 (2021): 515-527. doi: 10.3390/clockssleep3040036. PMID: 34698137 PMCID: PMV8544349
  - Presentation of the SleepTank air ambulance trial data: Devine JK, Schwartz LP, Choynowski J, Hursh SR. "Efficacy of Real-Time Feedback from a Commercial Wearable Device on Sleep Behavior in Norwegian Helicopter Emergency Medical Service (HEMS) crew members" Military Health Systems Research Society annual meeting. August 2021 (virtual). Abstract ID: MHSRS-21-02641.
  - SleepTank clockface app was made publicly available on Fitbit clock gallery
- Year 4 (2022/23):
  - Version 1 of a software requirement specifications (SRS) document for SleepTank product applications
  - Data from the nurse and cargo pilot studies have been submitted for presentation at the Sleep Research Society's SLEEP conference in 2023
  - Data from the RAN SleepTank trial has been submitted for presentation at MHSRS 2023 and plans are in place to present the data at the Pacific and Australasian CRM Developers' and Facilitators' Forum (PACDEFF) conference in 2023

### c. Progress Detail

The first goal of this project was to develop the SleepTank algorithm into a multi-device application that can help users track their sleep debt and improve their sleep hygiene. IBR developed a commercial actigraph, the Zulu Watch, with an embedded SleepTank function. Sleep/wake determination in the Zulu watch has been validated against actigraphy and PSG in the laboratory and has been validated against self-report of sleep in the operational environment (humanitarian long-range flights). As of February 2023, IBR also has working versions of mobile, watch-based, clockface, and web versions of SleepTank for Fitbit and iOS devices. Our mobile version is available in the Apple App Store. Our watch-based app and clockface are fully functional and available through the Fitbit App Store. A web-based CSV-download function is also available for study administrators to download an anonymized CSV with their participants' sleep and SleepTank data. IBR is planning to further develop the SleepTank app for Android platforms and to develop a device-agnostic version of the app to be used with consumer sleep trackers other than Fitbit.

The second goal was to test the usability and efficacy of SleepTank in operational environments. As of February 2023, four studies have been completed that test usability and efficacy in operational populations. One study was with nurses and focused on the usability of the app. We received mixed feedback from them; primarily that they would forget to navigate to and use the mobile app. Recruitment for a second cohort began in February 2023 and aims to incorporate the clockface app to make SleepTank information more

available to nurse participants. The sleep data from the first cohort of nurses was analyzed and submitted for presentation at the SLEEP 2023 conference. The next study was with Norwegian air ambulance pilots. Access to the SleepTank app was related to increased sleep efficiency, faster reaction times, and fewer lapses on the PVT compared to access to the Fitbit app alone. These data were analyzed and presented at the Military Health System Research Symposium (MHSRS) in 2021. The third study focused on app usability in a cohort of cargo pilots through FedEx's Air Line Pilots Association. 100% of the pilots in this cohort found the app to be accurate at determining fatigue and most of them found the app was useful. Pilots expressed a desire to have the app work with devices other than Fitbit. Data from this study have been submitted for presentation at the SLEEP 2023 conference. The fourth study examined efficacy of the app to improve sleep in RAN shift workers. The first round of data collection for this study is complete; another round of data collection will begin in March 2023. Preliminary analysis indicates that access to the SleepTank app is associated with greater sleep efficiency during overnight shifts compared to access to the Fitbit app alone. Data from this study has been submitted for presentation at the MHSRS 2023 conference. Plans are in place to submit this data for presentation at the PACDEFF conference in September 2023.

In January 2023, IBR completed a software requirement specifications (SRS) document to guide future app development and is currently looking for a development team that can guide future development of the app as a research tool as well as a business-to-business commercial product to facilitate fatigue risk management in safety-sensitive industries.

### 3. Future Plans

Plans for app development under the MTEC grant will be completed as of March 2023. IBR has met the goals of the initial MTEC grant. Our future plans are to partner with an app development team in order to address limitations to the first version of the SleepTank applications. Namely, future iterations of the app will be device-agnostic, i.e., the mobile app can be used in combination with consumer wearables other than Fitbit to collect sleep data. IBR also has plans to improve the web interface for study administrators and improve usability of the app as a research data collection tool.

### 4. Problems / Issues

#### a. Current Problems / Issues

A previously-planned data collection with USAF could not be achieved. IBR pivoted to data collection with cargo pilots and the Royal Australian Navy in place of the USAF study.

#### b. Anticipated Problems / Issues

None at this time.

### 5. Financial Health

IBR requires no additional funds to complete this project. The project is in good financial health.

### 6. Personnel Effort

Personnel	Role	Percent Effort
Steven Hursh, PhD	Research Project Lead	100%
Jaime K. Devine, PhD	Research Project Team Member 1	100%
Lindsay P. Schwartz, PhD	Research Project Team Member 2	100%

## 7. Protocol and Activity Status

### a. Human Use Regulatory Protocols

HRPO has determined three protocols funded by MTEC to be exempt. Salus IRB has determined two protocols funded internally by IBR to be exempt.

### b. Use of Human Cadavers for RDT&E, Education or Training

None

### c. Animal Use Regulatory Protocols

None

**Annual Business Status Report for**  
Validation of Wearable Sleep and Fitness Monitor with SleepTank Model

MTEC-17-08-Multi-Topic-0104

MT190002

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Submitted: March 1, 2023



## 1. CURRENT STAFF

<i>Personnel</i>	<i>% of Effort on project</i>
Research Project Lead	100%
Research Project Team Member 1	100%
Research Project Team Member 2	100%

## 2. CURRENT EXPENDITURES

DIRECTIONS: FILL OUT TABLE A OR B DEPENDING ON CONTRACT TYPE. TABLE A IS FOR COST REIMBURSBLE CONTRACTS AND TABLE B IS FOR FIX PRICED CONTRACTS.

### A. Cost Reimbursable Contracts: Complete only if your contract is Cost Reimbursable or Cost Plus Fixed Fee.

Expenditures should be reflective of cost incurred to date, not exceeding awarded project ceiling. Expenditures should coincide with the latest invoice for the reporting period. For cost reimbursable contracts please use the table below.

<b>Contract Expenditures</b>	<b>Current QTR Expenditures</b>	<b><i>Cumulative To Date Expenditures</i></b>
Labor (Personnel and Fringe)	\$	\$
Supplies/Materials	\$	\$
Travel	\$	\$
Equipment	\$	\$
Subcontractors and Consultants	\$	\$
Other Direct Costs	\$	\$
Indirect Costs	\$	\$
<b>Total</b>	\$	\$

## B. Fixed Priced Contracts: Complete only if your contract is Fixed Priced.

Expenditures should be reflective of milestones that are **100% complete** and **invoiced** for. Milestones reported below should correspond to the Milestone Payment Schedule in the Project Award. **Milestones can only be invoiced for if they are 100% Complete.** Expenditures should coincide with the latest invoice for the reporting period. For fixed priced contracts please use the table below.

MTEC Milestone Number	Milestone Description	Due Date	Government Funds
1.	Procure wearable devices: First lot of 150 devices, with shipping	3/1/19	\$15,364
2.	Procure wearable devices: Second lot of 150 devices, with shipping	4/1/19	\$15,364
3.	Quarterly Report 1 (January – March, Technical and Business Reports)	4/25/19	\$ 0
4.	Purchase test off-the-shelf wearables devices	5/1/19	\$ 5,000
5.	SleepTank application design and specification for off-the-shelf wearables	7/1/19	\$ 29,518
6.	Quarterly Report 2 (April – June, Technical and Business Reports)	7/25/19	\$ 0
7.	Algorithm Validation Studies Complete	8/1/19	\$ 15,000
8.	Complete Development of SleepTank App	8/1/19	\$ 42,978
9.	Algorithm Validation Studies Data Analysis & Report	10/1/19	\$ 20,009
10.	Quarterly Report 3 (July – September, Technical and Business Reports)	10/25/19	\$ 0
11.	Annual Report 1	01/25/20	\$ 0
12.	Quarterly Report 4 (January-March, Technical and Business Reports)	4/25/2020	\$ 0
13.	Distribute and Support SleepTank™ application	6/1/2020	\$20,000
14.	Quarterly Report 5 (April-June, Technical and Business Reports)	7/25/2020	\$ 0
15.	Procure off-the-shelf wearable devices, with shipping	08/01/2020	\$18,251
16.	Quarterly Report 6 (July-September, Technical and Business Reports)	10/23/2020	\$ 0
17.	Validate usability/applicability of wrist-worn devices in the operational environment	12/01/2020	\$ 14,970
18.	Annual Report 2	01/25/2021	\$ 0
19.	Quarterly Report 7 (January-March, Technical and Business Reports)	04/25/2021	\$ 0
20.	Quarterly Report 8 (April-June, Technical and Business Reports)	07/25/2021	\$ 0

21.	Quarterly Report 9 (Jul – September, Technical and Business Reports)	10/25/2021	\$ 0
22.	Annual Report 2	01/25/2022	\$ 0
23.	Quarterly Report 10 (January – March, Technical and Business Reports)	04/25/2022	\$ 0
24.	Quarterly Report 11 (April – June, Technical and Business Reports)	07/25/2022	\$ 0
25.	Quarterly Report 12 (July – September, Technical and Business	10/25/2022	\$ 0
26.	Demonstrate SleepTank™ leads to improved mission performance through increased sleep health awareness	12/01/2022	\$19,925
27.	Validate off-the-shelf device with built-in SleepTank™ improves sleep hygiene along with off-the-shelf wearable (Fitbit) usability	12/01/2022	\$14,970
28.	SleepTank Validation Studies Data Analysis & Report	02/15/2023	\$13,600
29.	Final Report	03/01/2023	\$ 0
	<b>Total Expenditures</b>		\$244,949

### C. Cost Share Contributions: Complete only if you're reporting Cost Share:

Cost sharing includes any costs a reasonable person would incur to carry out (necessary to) proposed projects' statements of work not directly paid for by the Government. There are two types of cost sharing: **(1) Cash:** Outlays of funds to perform the proposed project. Cash includes labor, materials, new equipment, and relevant subcontractor efforts. Sources include new IR&D funds, profit or fee from another contract, overhead or capital equipment expense pool. **(2) In-Kind:** Reasonable value of in-place equipment, materials or other property used in performance of the proposed project. All cash or in-kind cost sharing availability must be clearly and convincingly demonstrated by the Offeror. The Offeror will be required to provide financial reporting with appropriate visibility into expenditures of Government funds vs. private funds.

Funding Source (Cash)	This Period	Cumulative to Date
Cash	\$0.00	\$0.00
Labor Dollars	\$0.00	\$0.00
Indirect Labor Rates (Overhead/Fringe Benefits)	\$0.00	\$0.00
Travel	\$0.00	\$0.00
General & Administrative Services	\$0.00	\$0.00
Equipment (New)	\$0.00	\$0.00
Material	\$0.00	\$0.00
Other Direct Costs	\$0.00	\$0.00
Other *	\$0.00	\$0.00
<b>Sub-Total</b>	\$0.00	\$0.00

Funding Source (In-Kind)	This Period	Cumulative to Date
Use of Existing Equipment (Estimated fair market value)	\$0.00	\$0.00
Use of Existing Software (Estimated fair market value)	\$0.00	\$0.00
Intellectual Property (Estimated fair market Value)	\$0.00	\$0.00
Space (Land or buildings)	\$0.00	\$0.00
<b>Sub-Total</b>	\$0.00	\$0.00
<b>Cost Share Total</b>	\$0.00	\$0.00

### 3. STATUS OF MILESTONES – FILL OUT FOR ALL CONTRACT TYPES (all project milestones are to be included)

All project milestones from the Milestone Payment Schedule, in the project award, should be accounted for below.

MTEC Milestone Number	Milestone Description	Due Date	% Completed this Reporting Period	Cumulative % Complete
1	Procure wearable devices: First lot of 150 devices, with shipping	03/01/2019	100%	
2	Procure wearable devices: Second lot of 150 devices, with shipping	04/01/2019	100%	
3	Quarterly Report 1 (January – March, Technical and Business Reports)	04/25/2019	100%	
4	Purchase test off-the-shelf wearables devices	05/01/2019	100%	
5	SleepTank application design and specification for off-the-shelf wearables	07/01/2019	100%	
6	Quarterly Report 2 (April – June, Technical and Business Reports)	07/25/2019	100%	
7	Algorithm Validation Studies Complete	08/01/2019	100%	
8	Complete Development of SleepTank App	08/01/2019	100%	
9	Algorithm Validation Studies Data Analysis & Report	10/01/2019	100%	
10	Quarterly Report 3 (July – September, Technical and Business Reports)	10/25/2019	100%	
11	Annual Report 1	01/25/2020	100%	
12	Quarterly Report 4 (January-March, Technical and Business Reports)	04/25/2020	100%	

13	Distribute and Support SleepTank™ application	06/01/2020	100%	
14	Quarterly Report 5 (April-June, Technical and Business Reports)	07/25/2020	100%	
15	Procure off-the-shelf wearable devices, with shipping	08/01/2020	100%	
16	Quarterly Report 6 (July-September, Technical and Business Reports)	10/23/2020	100%	
17	Validate usability/applicability of wrist-worn devices in the operational environment	12/01/2020	100%	
18	Annual Report 2	01/25/2021	100%	
19	Quarterly Report 7 (January-March, Technical and Business Reports)	04/25/2021	100%	
20	Quarterly Report 8 (April-June, Technical and Business Reports)	07/25/2021	100%	
21	Quarterly Report 9 (Jul – September, Technical and Business Reports)	10/25/2021	100%	
22	Annual Report 3	01/25/2022	100%	
23	Quarterly Report 10 (January – March, Technical and Business Reports)	04/25/2022	100%	
24	Quarterly Report 11 (April – June, Technical and Business Reports)	07/25/2022	100%	
25	Quarterly Report 12 (July – September, Technical and Business)	10/25/2022	100%	
26	Demonstrate SleepTank™ leads to improved mission performance through increased sleep health awareness	12/01/2022	100%	
27	Validate off-the-shelf device with built-in SleepTank™ improves sleep hygiene along with off-the-shelf wearable (Fitbit) usability	12/01/2022	100%	
28	SleepTank Validation Studies Data Analysis & Report	02/15/2023	100%	
29	Final Reports (technical and financial report)	03/01/2023	100%	

#### 4. DEVIATION FROM PROJECT PLAN

There are currently no major deviations from the project plan aside from delays due to app development. No additional funds are requested.

**Please name this annual report file as EGS#\_Annual Report\_Y# (For example MT160001.01\_Annual Report\_Y2)**

**Please submit as a PDF file.**

**Please make sure to fill in the page number on page 3 Table of Contents.**

**Don't forget to submit an updated Quad Chart as well. Please name the Quad chart file as EGS#\_Quad Chart\_Y#.**