Quarterly Progress Report

Technical and Financial

Hypoxia, Monitoring, and Mitigation System

Contract Number: N00014-14-C-0276

Prepared for

Office of Naval Research (ONR) Code 342

For the Period

January 1, 2015 to March 31, 2015

Submitted By

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REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

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1. REPORT DATE *(DD-MM-YYYY)*
04/10/2015

2. REPORT TYPE
Quarterly Progress Report

3. DATES COVERED *(From - To)*
1 Jan 2015 to 31 Mar 2015

4. TITLE AND SUBTITLE
Quarterly Progress Report
Technical and Financial

Hypoxia, Monitoring, and Mitigation System

5a. CONTRACT NUMBER
N00014-14-C-0276

5b. GRANT NUMBER
NA

5c. PROGRAM ELEMENT NUMBER
NA

6. AUTHOR(S)
Mahoney, Sean, J

5d. PROJECT NUMBER
NA

5e. TASK NUMBER
NA

5f. WORK UNIT NUMBER
NA

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
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8. PERFORMING ORGANIZATION REPORT NUMBER
CDRL A001-2

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)
Steele, Christopher
Office of Naval Research (ONR) Code 342

10. SPONSOR/MONITOR'S ACRONYM(S)
ONR

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

12. DISTRIBUTION/AVAILABILITY STATEMENT
Approved for public release, distribution unlimited

13. SUPPLEMENTARY NOTES
None

14. ABSTRACT
The Hypoxia Monitoring, Alert and Mitigation System (HAMS) program is progressing as expected. The program consists of two baseline tasks and three optional task. Work has been started on Task 1. Task 2 will begin in May. Optional Tasks 3, 4 and 5 have not been exercised. Although performance of the initial arm mounted prototype was below expectations on initial testing, a mitigation strategy has been initiated that includes a multi-site approach. This approach has the potential to add redundancy to the sensor network that will further enhance the system. We recommend that the program continue as scheduled assuming the remaining funding is obligated to the contract.

15. SUBJECT TERMS
Hypoxia, Cognitive State, Oxygen Saturation, Altitude, Software Algorithms, Models

16. SECURITY CLASSIFICATION OF: a. REPORT	b. ABSTRACT	c. THIS PAGE	17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON / 19b. TELEPHONE NUMBER *(Include area code)*
U	U	U	UU		Mahoney, Sean, J / 515-288-3360 x103

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1.0 Summary

This quarterly progress report discusses the technical and financial program status for the period of September 2014 through December 2014. This is the first quarterly report on the program.

The Hypoxia Monitoring, Alert and Mitigation System (HAMS) program is progressing as expected with no technical issues to report.

The program consists of two baseline tasks and three optional task:

1. Initial Prototypes
2. Design and Development Evolution
3. *Production Ready HW/SW (Option)*
4. *Preliminary Human Testing of SpO2 Sensor and Electronics (Option)*
5. *Final Human Testing of SpO2 Sensor and Electronics (Option)*

Work has been started on Task 1. Task 2 will begin in May. Optional Tasks 3, 4 and 5 have not been exercised.

The first initial arm mounted prototypes were fabricated as well as the first reflectance sensor prototype specifically targeted for use on the arm. The initial prototypes were produced earlier than planned by modifying some existing circuit boards from another project. This will facilitate the iterative development process and feedback from evaluators. Perfomance of the prototype was below expectations on initial testing. To mitigate this design challenge, an additional multi-site approach was initiated.

System definition has started utilizing the TWR-K21D50M tower system for rapid development of component interactions. Arm mounted enclosure concepts have been generated for initial evaluation and sizing of electronics.

Sample data from USARIEM was provided and evaluated for future use. It also provided information for developing the CRADA needed between Athena and USARIEM for testing to be completed later in the program. A continuation of analysis of the USN data was accomplished this period with the SYNWIN task battery 20 second average composite scores from the hypoxia exposures to 18,000 and 25,000 feet. These results were compared to the neurological status model results for consistency.

A review of the US Army Altitude Acclimatization and Illness Management TB MED 505 document was done with an eye towards inclusion of acute altitude sickness monitoring and acclimatization tracking.

We recommend that the program continue as scheduled assuming the remaining funding is obligated to the contract.

2.0 Introduction

Special Notice 14-SN-0002 outlined a research thrust entitled "Hypoxia Monitoring, Alert and Mitigation System" (HAMS) that was launched under the ONR BAA 14-001 Long Range Broad Agency Announcement (BAA) for Navy and Marine Corps Science and Technology. The primary technology areas of interest for full system development over the lifetime of the program are 1) detection/prediction algorithm, 2) sensing suite, 3) warning modalities, and 4) modes of mitigation. This Special Notice is a follow on to Special Notice 13-SN-0003, published in November 2012. Overall, HAMS must be compatible with multiple operational environments. The intent is to develop a modular prototype, with capabilities for 1) ground troops at altitude and 2) CASEVAC. The team of Athena GTX (Athena) and Criterion Analysis Incorporated (CAI) collaborated, proposed and won an award under this effort.

This quarterly progress report discusses the technical and financial program status for the period of January 2015 through March 2015. It is intended to inform the Program Officer and Administrative Contracting Officer of the technical and financial progress of the HAMS program. This is the first quarterly report on the program.

The program initially launched via Special notice 13-SN-0003 concentrated only on algorithm development. Now this follow-on effort will develop the hardware necessary to implement HAMS. In addition, more data to refine the algorithms and data analysis approaches will be gathered. Sensors which detect SpO2, pulse/pulse rate, ECG, and skin temperature will be researched and evaluated for integration feasibility with a tactile vibrator for alerting the user to the suspicion of growing hypoxia. Novel and non-traditional sensor locations and technologies will be investigated as they impact data and algorithm design issues, and advanced signal processing techniques applied, and compared in this program for extensive technology leveraging.

The goal is to provide optimal protection of military personnel and equipment via intelligent monitoring and adaptive modeling that accounts for individual differences in physiologic tolerance and provides a timely notification/warning such that personnel can take corrective action before missions are compromised or injuries are aggravated. HAMS will address cognitive and physiological workload at altitude and the dynamic impact of sustained high altitude operations. The effort under this program allows for iterative prototype development and testing to occur leading to an option for development of systems that are FDA cleared and ready for full field use.

3.0 Technical Progress

3.1 Task 1 – Initial Prototypes

3.1.1 Sensor(s) Definition

The K70 tower system from Freescale was used to develop preliminary software structure for each of the modules. This tower was leveraged from previous R&D programs. Processor options are still to be determined based on the number of SPI ports, memory and processing capability needed.

The pulse ox development board from TI continued to be tested for data structure and circuit board leveraging for the custom design. Software testing has been the main focus on the developemnt board along with the custom algorithm development to convert the raw data receieved from the module.

A prototype leveraged from Minimedic was modified to setup and test preliminary sesnors and software functions. A device viewing and saving platform was devloped for the data to be transmitted in real time and analyzed at a later time. The device viewer software displays and stores device number, pulse ox, pulse rate derived from ECG and temperature. The temperature circuit is a custom design that allows the use of standard COTS thermistors.

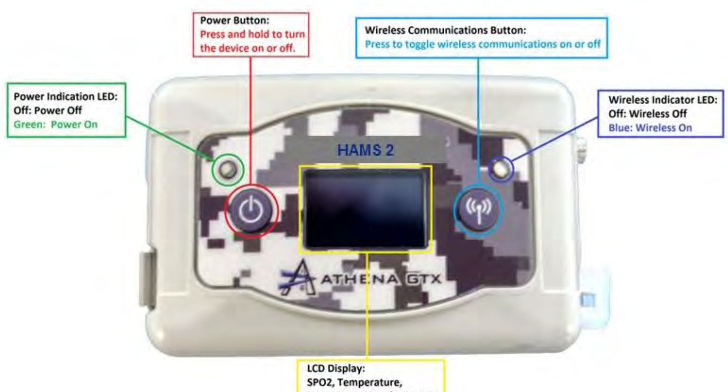
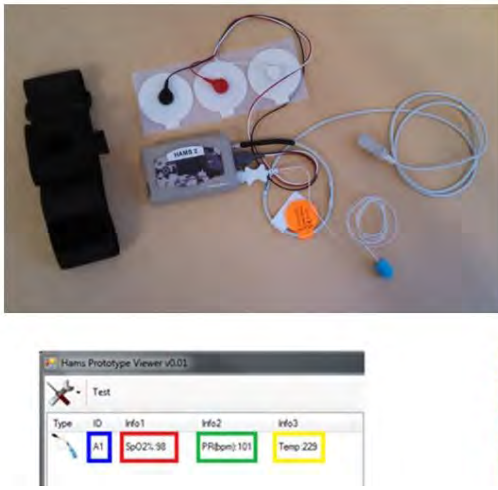


Figure 1: HAMS II: prototype variant



- Arm Strap
- OLED to verify sensor placement and validity
- Standard Ear or rectal probe interface
- Software Viewer Platform

Device Identification number
PulseOx output
Pulse Rate derived from ECG
Temperature in Celsius

Figure 2: Prototype & Software viewer

Figure 3: Pulse OX custom module

The first initial prototype arm sensor perfomance was below expectations on initial testing. To mitigate this design challenge, an additional multi-site approach was initiated. Three locations are under consideration: Arm, Ear and Wrist. The following design drivers were investigated.

Transmitter selection was determined in this reporting period. This determines size, data rates, and data syncing. Once the module was selected a pairing system was developed to syncronize the data packets and align the data at the receiver. Currently the system will be designed as a single system package but will need to be tested with multi devices for interference checks and timing issues. The crystal and clock accuracy ic chip will have to have limited drift capabilities.

Our choices of low power radios at this time are:

- Xbee Zigbee
  - 27.61mm x 24.38mm – but components can be placed underneath
  - Instant on/off – means we can be off when not sending
  - 50 mA when receiving or transmitting
  - Deterministic – very easy to sync
  - 100 bytes at a time max so several sends needed
  - Easiest to code for
- CC430
  - 14mm x 14mm - the CC430 is also a microcontroller so we can subtract about 7x7
  - Instant on/off - means we can be off when not sending
  - 38 mA max
  - need to test for sync
  - 64 bytes at a time max so even more sends needed
  - Medium coding difficulty
- Bluetooth
  - 17mm x 10mm
  - Not instant on/off – need to connect and stay connected (on)
  - 65 mA max, 30 mA typical
  - Not deterministic – very hard to sync
  - Large max payload – only 1 send needed
  - Most difficult coding

Figure 4: Wireless communication: Transmitter: options

The transmitter selected was Zigbee. This module has been used in previous programs and provides the multiple devices capability, accuracy, low battery power and ease of use. Bluetooth is low power but has limitations with pairing and number of devices that can be used simultaneuosly. The data transfer rate is is approximetly 32bytes per second depending on the crystal and internal processor clock. Figure 5 shows the overall system ear, arm, and wrist receiver unit. Each device will use a low power K21 processor from Freescale. Figure 6 describes the sync and timing breakout of the overall system. In order to improve battery efficiency the transmitter is placed in sleep mode once the data packets are sent, data is acquired, sent and idle.

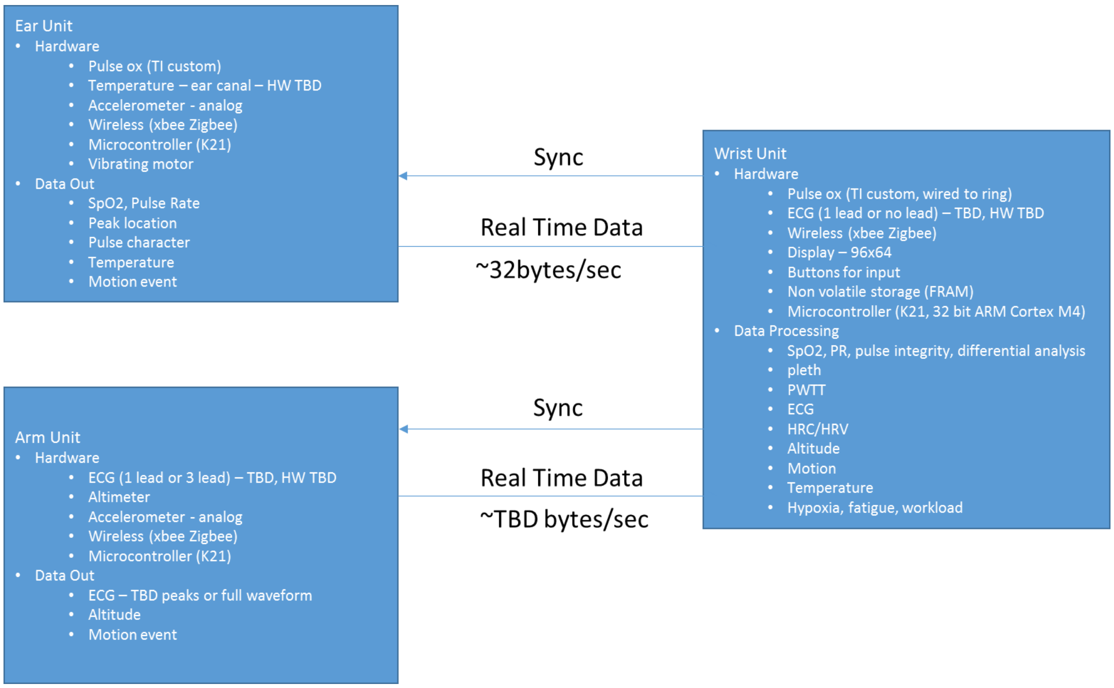


Figure 5: HAMS II System Block diagram

Wrist	Xbee On Processor idle	Send Sync Xbee sleep	Processor Idle	Begin data acquisition	Finish acquiring 5 Seconds of data Process the data Xbee on	Idle	Receive & Process Data	Idle	Receive & Process Data	Data processing Data display Data save Data send Xbee Sleep	
Ear	Xbee On Processor idle	Idle	Receive & Process Sync Xbee sleep	Begin data acquisition	Finish acquiring 5 Seconds of data Process the data Xbee on	Send data Xbee sleep	Idle	Idle	Idle	Idle	
Arm	Xbee On Processor idle	Idle	Receive & Process Sync Xbee sleep	Begin data acquisition	Finish acquiring 5 Seconds of data Process the data Xbee on	Idle	Idle	Send data Xbee sleep	Idle	Idle	
	Initial Condition	0	4	10	5010	6000	6004	6100	6104	6105-10,000	Initial Condition

Time (mSec)

Figure 6: Sync and timing Process

Three TWR-K21D50M tower systems were purchased (See Figure 7). These were configured to simulate the overall system setup and sensor interfaces. This also allowed us to quickly setup and reconfigure each section of the system without the need to remanufacture pcb circuit boards. Preliminary testing was completed using the K21 processor low power high processing module, interfacing the pulse ox custom module, Zigbee transmitter for communication and pressure sensor testing. Further testing will be completed next reporting period.

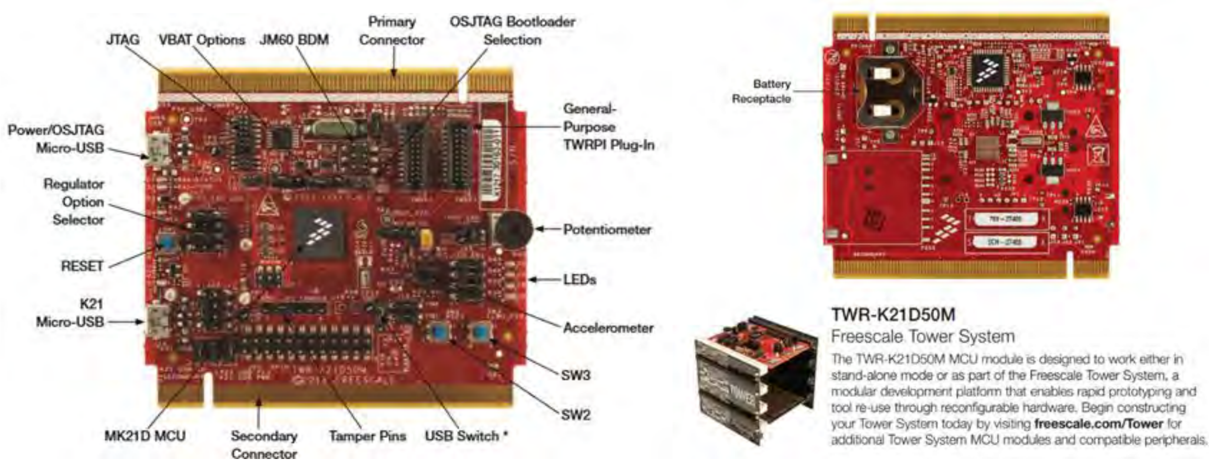


Figure 7: Freescale K21 tower system

3.1.2 Enclosure Concept Definition

Initial enclosure concepts were designed and 3D printed to facilitate size and layout of the electronic components. Refinement and adjustment will be made based on initial concepts and in house testing.

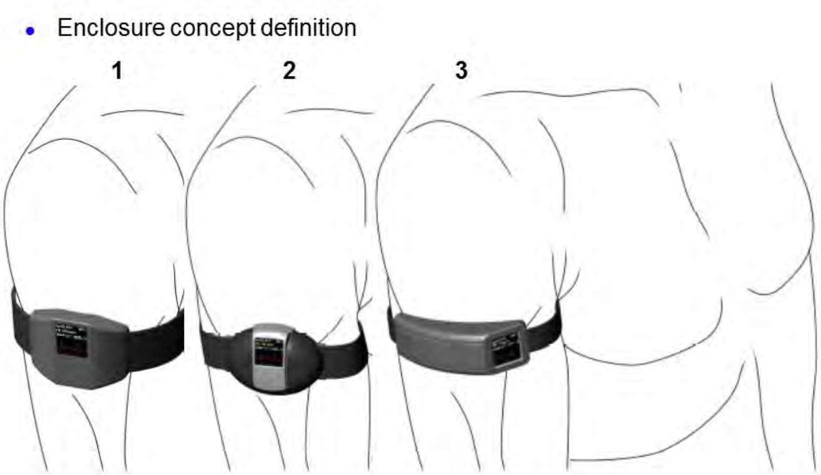


Figure 8: Enclosure concepts

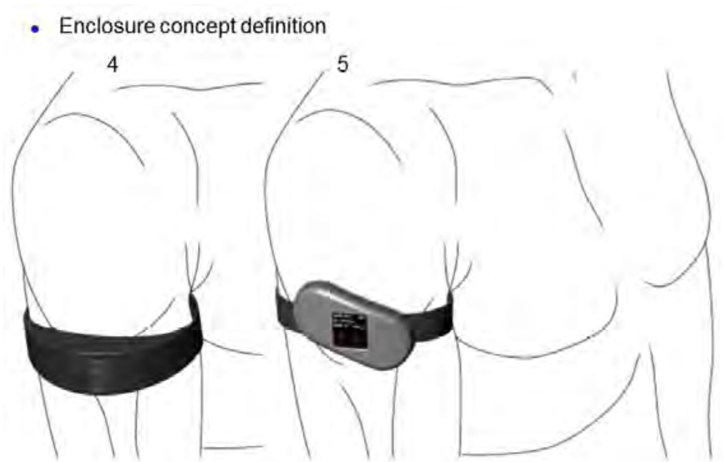


Figure 9: Enclosure concepts

3.1.3 Electronics Board Schematic and Layout

A custom pcb will be designed in the next reporting period to allow intial testing to be completed without additional components from the TI development board. This will also allow for more flexible control of the Pulse Ox chip module and lower power consumption to leverage into the design.

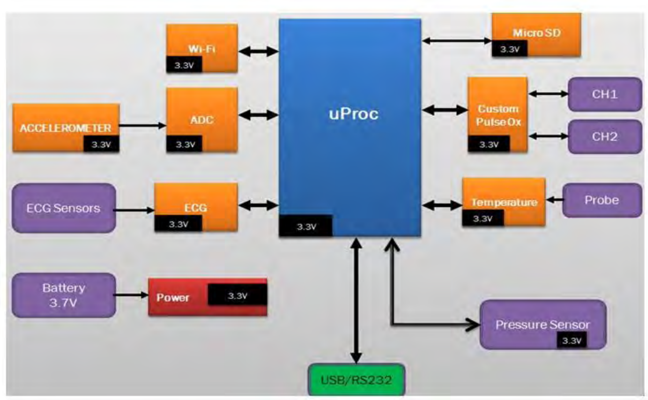


Figure 10: HAMS II Block Diagram: System w/ peripherals

Existing boards were modified for the initial prototype deliverable.

3.1.4 Software Functions and Design

No update on progress for this Subtask.

3.1.5 Algorithm(s) Incorporation

USARIEM Sample Data

Sample data from USARIEM was provided and evaluated for future use. It also provided information for developing the CRADA needed between Athena and USARIEM for testing to be completed later in the program. The data will likely be most useful in the following capacity:

- Steady state verification/validation of models
- Variability during steady-state
- Response to exercise/activity during steady state

Sample plots of the data are included below.

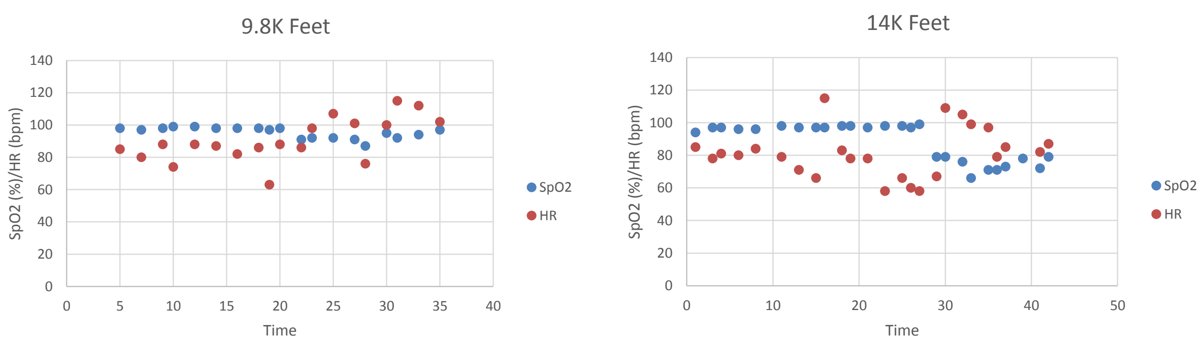


Figure 11. Sample Plots from USARIEM Data

SYNWIN Task Battery Analysis

A continuation of analysis of the USN data was accomplished this period with the SYNWIN task battery 20 second average composite scores from the hypoxia exposures to 18,000 and 25,000 feet. These results were compared to the neurological status model results for consistency.

Based on these limited numbers of subjects, the SYNWIN composite score would not seem suited for the mild hypoxia case, as in the mountain operations scenario. The severe hypoxia case resulted in more demonstrative results considering the composite score. For the mountain operations data gathering experiments we need to consider more operationally relevant data that can be suggested by operational personnel. The neurological model at this point predicts impairment once SaO_2 has crossed 80% which may be true in a standard sense but not specifically. This may mean personalization based on some basic physiological tests. LOC is uncommon at these altitude levels especially since no one in testing is allowed to have an LOC. So it is difficult to calibrate or validate that aspect. The requirement that the SaO_2 falls below 60% may be problematic since data at that level are not considered reliable. However this aspect can also be tuned using the software settings for cluster mass value to trigger an LOC indication. This adjustment may also need personalization to provide a robust prediction of the rare LOC at the operational ground unit altitudes.

Brief Description of Altitude Chamber Study – A more comprehensive description of the US Navy study can be found in the protocol (NAWCAD.2013.0008-CR01) uploaded to the project site. Subjects were exposed to altitudes of 18,000 and 25,000 feet for two separate exposures giving at most four data sets for analysis. Table 1 is reproduced from the protocol to give the procedure and process which the data response reflect where MH is moderate hypoxia and SH is severe hypoxia.

Table 1 Altitude Chamber Study Timeline.

	Altitude (ft)	Ambient O_2 partial pressure (mmHg)	Alveolar O_2 partial pressure (mmHg)	Description	%O2 in breathing air supply
MH	0	159.2	103.0	15 min at Ground Level (GL)	21%
				120s ascent to 10,000 ft at 5,000 fpm	21%
	10,000	109.5	61.2	10 min at 10,000 ft	21%
				Pre-breathe 100% O_2 for 30 minutes, switch to air (21% O_2) followed by 96s ascent to 18,000 at 5,000 fpm	100% / 21%
	18,000	79.6	37.8	Up to 20 min at 18,000 ft	21%
				216s descent* to GL at 5,000 fpm	21%
	0	159.2	103.0	15 min at GL	21%
SH	0	159.2	103.0	15 min at Ground Level (GL)	21%
				120s ascent to 10,000 ft at 5,000 fpm	21%
	10,000	109.5	61.2	10 min at 10,000 ft	21%
				Pre-breathe 100% O_2 for 30 minutes, switch to air (21% O_2) followed by 180s ascent to 25,000 at 5,000 fpm	100% / 21%
	25,000	59.2	30.4	Up to 20 min at 25,000 ft	21%
				300s descent* to GL at 5,000 fpm	21%
	0	159.2	103.0	15 min at GL	21%

The exposure was terminated if the SpO2 at finger fell below 60% for more than 10 seconds, the subject stopped responding to the multitask for more than 10 seconds, the exhaled end tidal oxygen pressure as measured by a Gas Chromatograph Mass Spectrometer fell below 30 mmHg. If the termination threshold was exceeded, 100% oxygen was provided and the chamber brought back down to ground level. The referenced multitask used was the SYNWIN task battery which data was collected except during the pre-breathe and descent periods. At present the results for four subjects was placed on the project site.

SYNWIN 20 second Composite Scores Analysis

The data for the 20 second average composite score was analyzed for average and standard deviation using Excel across the time history segments as indicated in Table 2.

Table 2 Time History Segments

Time History Coding Segments	Analyzed
SL 5 min	SL
10K	10K
begin 100% O2 prebreathe	
~ 5min 10K @ 100%O2	
Pre-breathe - no cognitive data collected	
~ 5min 10K @ 100%O2	
18 or 25K plateau	18K or 25K
descent - no cognitive data	
Recovery 5min	R5
Recovery 10min	R10
Recovery 15min	R15

The average composite scores during the 18,000 feet exposures are shown in Table 3. Little decrement in segment average composite score was seen at 10,000 feet with the highest reduction being 19%. While none of the subjects experienced loss of consciousness (LOC), segment average composite scores were reduced by 56%, 39% and 29% for S2, S3 and S4, respectively. This response was not repeatable however since the first runs for S2 and S3 showed mild reduction.

Table 3 Average Composite Score during the 18,000 feet Exposures

		S1	S1	S2	S2	S3	S3	S4
SL	**Mean**	43.79	46.79	55.50	64.19	55.88	57.38	53.94
	SD	9.42	14.21	19.93	16.17	12.15	7.80	16.99
10K	**Mean**	45.17	46.25	54.74	60.63	52.03	46.59	49.55
	SD	13.84	10.24	23.37	15.82	13.35	26.63	14.46
	Reduction (%)	-3%	1%	1%	6%	7%	19%	8%
18K	**Mean**	42.14	41.41	**24.33**	51.97	46.03	**34.97**	**38.20**
	SD	15.88	12.83	22.29	20.36	18.00	15.20	19.03
	Reduction (%)	4%	11%	**56%**	19%	18%	**39%**	**29%**
	Prediction	I	I/LOC	**I/LOC**	I	I	**I**	**I**
	Cluster ~ Zero	No	Yes	**Yes**	Yes	No	**No**	**No**
R5	**Mean**	47.00	48.14	**28.20**	61.33	52.33	41.00	43.13
	SD	12.70	17.05	17.49	16.85	13.79	13.91	13.41
R10	**Mean**	39.07	44.93	**37.00**	52.13	56.86	37.13	48.53
	SD	12.44	13.84	17.05	18.98	13.99	14.69	22.22
R15	**Mean**	47.73	45.80	**29.20**	56.44	52.33	35.00	29.79
	SD	15.47	23.84	14.52	19.09	17.49	14.54	15.85

While all subjects recovered to near control average composite scores, S2 during its second exposure demonstrated a persistent reduction though the recovery period.

The screenshots from the neurological state model are contained in Section 9.2. Examining these results indicate that all subjects were predicted to be impaired, due to the threshold setting of SaO_2 at 80%, but two subjects were predicted to have LOC, which did not occur. One of those subjects, S1, showed only 11% reduction in average composite score compared to sea level control. A cluster mass near zero, indicating a loss of grid connectivity, was examined. For those subjects with a high composite score reduction, in red, a cluster mass value near zero was not unambiguously indicative of the level of reduction. In this exposure case where the hypoxia was considered mild, the cognitive task composite score may represent the random population response and is perhaps not sensitive enough for mild hypoxia. The neurological model set up is sensitive to SaO_2, cluster mass size, and duration. S1 and S2 exposures resulted in momentary LOC indications which may have to be examined further for duration to be a true-positive indication. S2 also had a cluster mass near zero but not equal to zero in the second run which would have indicated a LOC if that cluster mass value had reached zero at any time.

The average segment composite scores during the 25,000 feet exposures are shown in Table 4. The average segment composite score for the 10,000 feet altitude were similar to that for the 18,000 feet exposure with small reduction values. Subjects 2, 3 and 4 had large composite score reductions during the 25,000 feet exposure that ranged from 96% up to 117%. The composite scores during the exposure segment was marked by negative values for the 20 second composite score.

Table 4 Average Composite Score during the 25,000 feet Exposures

		S1	S1	S2	S2	S3	S3	S4
SL	**Mean**	44.4	50.7	51.5	59.6	57.8	54.1	54.1
	SD	12.5	14.9	24.6	20.0	13.1	10.9	15.3
10K	**Mean**	46.3	45.8	35.4	50.5	52.6	48.2	51.4
	SD	12.7	13.5	26.5	23.0	14.3	12.6	14.0
	Reduction (%)	-4%	10%	31%	15%	9%	11%	5%
25K	**Mean**	**28.6**	**33.4**	**1.9**	**-10.2**	**23.4**	**-0.8**	**-7.0**
	SD	17.3	12.4	19.2	32.3	27.5	50.1	34.6
	Duration (s)	200.0	140.0	140.0	480.0	160.0	260.0	60.0
	Reduction (%)	**36%**	**34%**	**96%**	**117%**	**60%**	**102%**	**113%**
	Time to 0/- (s)	140.0	N/A	80.0	60.0	100.0	140.0	20.0
	Prediction	I/LOC	I	I	I/LOC	I	I	OK
	Cluster ~ Zero	Yes	Yes	Yes	Yes	No	Yes	No
R5	**Mean**	45.2	50.5	45.5	48.8	48.5	55.7	37.6
	SD	10.4	14.2	19.5	20.7	8.9	16.2	21.7
R10	**Mean**	46.3	46.5	55.8	58.1	57.1	59.6	35.9
	SD	16.4	15.0	17.0	19.7	11.0	10.2	23.1
R15	**Mean**	47.3	46.9	41.7	52.6	51.9	58.6	32.9
	SD	15.0	17.0	28.0	21.3	13.0	16.1	19.4

The neurological model runs for the 25,000 feet exposures are also in Section 9.2. While no one experienced LOC, runs were evidently cut short due to protocol criteria. Impairment was predicted in every case except S4 where the run lasted only 60 seconds but the composite scores were negative in the first 20 seconds. Evidently the run was terminated early in the exposure. The model predicted LOC in two cases, one where the percentage reduction was only 36% and another where the percentage reduction was 96%. The cluster mass was near zero in both cases. In the subjects where LOC was predicted the SaO_2 value had also dropped below 60%. Checking the 18,000 feet data there was also a spike below 60% SaO_2 to give the momentary LOC prediction. While the cluster mass may hover near zero, it must reach zero to give an LOC prediction which takes place in conditions where the SaO_2 drops below 60%. The reliability of SaO_2 data at 60% may be questionable depending upon device electronics, sensor location and stress conditions. As in the mild hypoxia condition, noise contributed to the transient LOC prediction.

Conclusions: Based on these limited numbers of subjects, the SYNWIN composite score would not seem suited for the mild hypoxia case, as in the Mountain Operations scenario. The severe hypoxia case resulted in more demonstrative results considering the composite score. For the mountain operations data gathering experiments we need to consider more operationally relevant data that can be suggested by operational personnel. The neurological model at this point predicts impairment once SaO_2 has crossed 80% which may be true in a standard sense but not specifically. This may mean personalization based on some basic physiological tests. LOC is uncommon at these altitude levels especially since no one in testing is allowed to have an LOC. So it is difficult to calibrate or validate that aspect. The requirement that the SaO_2 falls below 60% may be problematic since data at that level are not considered reliable. However this aspect can also be tuned using the software settings for cluster mass value to trigger an LOC indication. This adjustment may also need personalization to provide a robust prediction of the rare LOC at the operational ground unit altitudes.

TB MED 505 detailed review

A review of the US Army Altitude Acclimatization and Illness Management TB MED 505 document was done with an eye towards inclusion of acute altitude sickness monitoring and acclimatization tracking.

A demonstration of a performance training device was witnessed at Wright-Patterson AFB which may be useful in the mountain operations scenario. The device was the FITLIGHT Trainer. This may be a good addition to standard testing that incorporates the physical activity as the added stressor to cognitive and psychomotor performance.

To keep low level development underway for the neurological state model, the C code has been complied and loaded onto a TMS470M development board. The issues at present are mostly figuring out how to access the MCU and board functions to give indication of the software function at normal gravity and dummy SaO2 data in an array. This work is at a low level of effort to continue progress of the neurological state prediction model should it become useful on the designed unit.

See Section 9.3 for the TB MED 505 detailed review

3.1.6 Initial User's Manual

A quick start guide was created for the initial prototype deliverables.

3.1.7 Fabricate Prototypes

Initial prototypes were fabricated. First reflectance sensor prototype was fabricated.

3.1.8 Test Prototypes for Delivery

First initial prototypes were tested.

3.1.9 Deliver Initial Prototypes

First initial prototypes were delivered.

3.1.10 Test & Evaluation Support

This task has not been started.

3.2 Task 2 – Design and Development Evolution

This task has not been started.

3.2.1 Design Definition

This task has not been started.

3.2.2 Preliminary Design 1

This task has not been started.

3.2.3 Preliminary Design 2

This task has not been started.

3.2.4 Fabricate Prototypes

This task has not been started.

3.2.5 Test Prototypes for Delivery

This task has not been started.

3.2.6 Deliver Preliminary Prototypes

This task has not been started.

3.2.7 Test & Evaluation Support

This task has not been started.

3.3 Task 3 (Option) – Production Ready HW/SW

This task has not been exercised.

3.4 Task 4 (Option) – Preliminary Human Testing of SpO2 Sensor and Electronics

This task has not been exercised. This task will be performed in conjunction with Task 2 development. It is included as an option because it requires human testing.

3.5 Task 5 (Option) – Final Human Testing of SpO2 Sensor and Electronics

This task has not been exercised. This task will be performed in conjunction with Task 3 development. It is included as an option because it requires human testing.

4.0 Financial Progress

The total base budget for the HAMS program is $1,985K plus an Option 1 of $905K, Option 2 of $49K and Option 3 of $47K. The contractually obligated amount in FY2014 towards the total budget is $298K. The contractually obligated amount in FY2015 towards the total budget is $1,252K. Costs incurred to date through this performance period are $298K or 100% of the FY14 obligated funding and $140 or approximately 11% of the FY15 obligated funding.

The tables below summarize the costs incurred to date against the FY 2014 and FY 2015 obligated funding to date ($298K and $1,252K, respectively). A more detailed spread sheet has been included in the Appendix, Section 9.1.

4.1 *FY2014 Funding ($298K)*

Month	HAMS Projected (%)	ONR Benchmarks FY14 Funding (%)	HAMS Actual (%)	Benchmark Delta (%)	Comments
SEP-OCT	25	58	34	-24	
NOV	50	63	54	-9	
DEC	75	68	72	+4	Additional funding received on DEC 12, 2015.
JAN	100	73	100	+27	

4.2 *Benchmarks for FY2015 Funding ($1,252K)*

Month	HAMS Projected (%)	ONR Benchmarks FY15 Funding (%)	HAMS Actual (%)	Benchmark Delta (%)	Comments
JAN	1	6	1	-5	Additional funding received on JAN 15, 2015
FEB	5	12	5	-7	
MAR	15	20	11	-9	Additional funding received on MAR 5, 2015.
APR		23			
MAY		29			
JUN		35			
JUL		42			

5.0 Schedule and Deliverables

5.1 Schedule

Tasks / Milestones	FY 2015											
	CY 2014			CY 2015								
	O	N	D	J	F	M	A	M	J	J	A	S
1. Initial Prototypes												
2. Design and Development Evolution												
3. (Option) Production Ready HW/SW												
4. Human Testing SpO2 sensor (Option)												
5. Human Testing SpO2 sensor (Option)												
Milestones / Deliverables												
Monthly Updates												
Quarterly Reports												
Initial Prototypes												
Preliminary FDA Compliance Review												

Progress/Completed
Planned

Tasks / Milestones	FY 2016											
	CY 2015			CY 2016								
	O	N	D	J	F	M	A	M	J	J	A	S
2. Design and Development Evolution												
4. Human Testing SpO2 sensor (Option)												
Milestones / Deliverables												
Monthly Updates												
Quarterly Reports												
IDR												
PDR												
PCDR												
Final Report												
Preliminary Prototypes												

Tasks / Milestones	FY 2017											
	CY 2016			CY 2017								
	O	N	D	J	F	M	A	M	J	J	A	S
2. Design and Development Evolution	■											
3. (Option) Production Ready HW/SW		■	■	■	■	■	■	■	■	■	■	■
5. Human Testing SpO2 sensor (Option)							■	■				
Milestones / Deliverables												
Monthly Updates	■	■	■	■	■	■	■	■	■	■	■	■
Quarterly Reports	■			■			■			■		
Final CDR		■										
Formal Test Devices (5) Complete						■						
Verification Design Review												■

Tasks / Milestones	FY 2018											
	CY 2017			CY 2018								
	O	N	D	J	F	M	A	M	J	J	A	S
3. (Option) Production Ready HW/SW	■	■	■	■	■	■	■	■	■			
Milestones / Deliverables												
Monthly Updates	■	■	■	■	■	■	■	■	■			
Quarterly Reports	■			■			■					
FDA 510(k) Submission			■									
Validation Design Transfer Review					■							
FDA Clearance Determination						■						
Final Design Review									■			
Deliver Final Test Units									■			

Progress/Completed
Planned

5.2 Deliverables

5.2.1 Monthly Updates

The following monthly reports have been submitted to ONR for this reporting period:

- A003-04 HAMS II Monthly Update – JAN 2015
- A003-05 HAMS II Monthly Update – FEB 2015
- A003-06 HAMS II Monthly Update – MAR 2015

5.2.2 Quarterly Reports

The following quarterly reports have been submitted to ONR for this reporting period:

- A001-2, Report for the period January 1, 2015 to March 31, 2015

5.2.3 Final Report

- A002 Not due until August 2016.

5.2.4 Initial Prototypes

- First initial prototype delivered to Dr. Shender.
- A004 Not due until July 2015.

5.2.5 Preliminary Prototypes

- A005 Not due until August 2016.

6.0 Conclusion

The Hypoxia Monitoring, Alert and Mitigation System (HAMS) program is progressing as expected. Although performance of the initial arm mounted prototype was below expectations on initial testing, a mitigation strategy has been initiated that includes a multi-site approach. This approach has the potential to add redundancy to the sensor network that will further enhance the system. Work has been started on Task 1. Task 2 will begin in May. Optional Tasks 3, 4 and 5 have not been exercised.

The first initial arm mounted prototypes were fabricated as well as the first reflectance sensor prototype specifically targeted for use on the arm. The initial prototypes were produced earlier than planned by modifying some existing circuit boards from another project. This will facilitate the iterative development process and feedback from evaluators.

System definition has started utilizing the TWR-K21D50M tower system for rapid development of component interactions. Arm mounted enclosure concepts have been generated for initial evaluation and sizing of electronics.

Sample data from USARIEM was provided and evaluated for future use. It also provided information for developing the CRADA needed between Athena and USARIEM for testing to be completed later in the program. A continuation of analysis of the USN data was accomplished this period with the SYNWIN task battery 20 second average composite scores from the hypoxia exposures to 18,000 and 25,000 feet. These results were compared to the neurological status model results for consistency.

A review of the US Army Altitude Acclimatization and Illness Management TB MED 505 document was done with an eye towards inclusion of acute altitude sickness monitoring and acclimatization tracking.

We recommend that the program continue as scheduled assuming the remaining funding is obligated to the contract.

7.0 Recommendations

We recommend that the program continue as scheduled assuming the remaining funding is obligated to the contract. We are encouraged that the ONR continues to pursue the remaining funding in a timely manner to keep the team together.

8.0 References

[1] Karinen, H. M., Uusitalo, A., Vähä-Ypyä, H., Kähönen, M., Peltonen, J. E., Stein, P. K., … Tikkanen, H. O. (2012). Heart rate variability changes at 2400 m altitude predicts acute mountain sickness on further ascent at 3000-4300 m altitudes. Frontiers in Physiology, 3 AUG(August), 1–7. doi:10.3389/fphys.2012.00336.

9.0 Appendix

9.1 Detailed Financial Spreadsheets (PDF)

N00014-14-C-0276 OVERALL SPENDING

		OCT 2014 MO-1	NOV 2014 MO-2	DEC 2014 MO-3	JAN 2015 MO-4	FEB 2015 MO-5	MAR 2015 MO-6
Base Contract Amount	**1,985,403**	100,199.76	61,234.13	53,650.29	94,811.41	53,810.48	74,705.55
	Expended % by Month	5.0%	8.1%	10.8%	15.6%	18.3%	24.6%
	Cumulative Spending	100,199.76	161,433.89	215,084.19	309,895.60	363,706.08	438,411.62

FUNDING 2014	**298,679**	100,200.00	61,234.00	53,650.00	83,594.00		
	2014 Benchmark	57.87%	63.12%	67.67%	73.02%		
	2014 FY Expend Rate	33.55%	54.05%	72.01%	100.00%		
	Invoice #	*1165, 1168, 1170*	*1176, 1178*	*1181, 1185*	*1189, 1190, 1197*		

FUNDING 2015	**1,251,787**				11,217.00	53,811.00	74,706.00
	2015 Benchmark	0.32%	1.34%	3.51%	6.25%	12.53%	20.00%
	2015 FY Expend Rate				0.90%	5.19%	11.16%
	Invoice #				*1198*	*1195, 1200, 1206*	*1209, 1215, 1216*

HAMS 2 FY 2014 - ACRN 000101-AA/000102-AB									
CONTRACT# N00014-14-C-0276									
Begins Sept 25, 2014 - Jan 31, 2015	4+ months		ACTUAL EXPENDITURE% BY MONTH based on 298K	33.55%	54.05%	72.01%	100.00%	100.00%	100.00%
HAMS 2 FY 2014	CUMULATIVE SPENT FY14 FUNDS - BUDGET 1	REMAINING BUDGET	% of Total FUNDS Expended	MO 1 - SEP-OCT 2014	MO 2 - NOV 2014	MO 3 - DEC 2014	MO 4 - JAN 2015	MO 5 FEB	MO 6 - MAR
COST INCURRED	$ 298,679	$ (0)	100%	$ 100,199.76	$ 61,234.13	$ 53,650.29	$ 83,594.80	$ -	$ -

HAMS 2 FY 20	BUDGET 1	MO 1 - SEP-OCT	MO 2 - NOV	MO 3 - DEC	MO 4 - JAN	MO 5 - FEB	MO 6 - MAR
BUDGET ACR	$ 298,679	$ 73,633.85	$ 75,254.92	$ 73,771.70	$ 76,018.10	$ -	$ -
	Projected expenditure %	24.65%	49.85%	74.55%	100.00%	100.00%	100.00%
	Benchmark FY14	57.87%	63%	67.67%	73.02%	76.04%	81.40%

HAMS 2 FY 2015 - ACRN 000103-AC									
CONTRACT# N00014-14-C-0276									
Begins JAN 2015 - JUN 2015	4+ months		ACTUAL EXPENDITURE% BY MONTH based on 118K	9.50%	55.08%	100.00%	100.00%	100.00%	100.00%
HAMS 2 FY 2014	CUMULATIVE SPENT FY15 FUNDS - BUDGET 2	REMAINING BUDGET	% of Total FUNDS Expended	MO 4 - JAN 2015	MO 5 - FEB 2015	MO 6 - MAR 2015	MO 7 - APR	MO 8 - MAY	MO 9 - JUN
COST INCURRED	$ 118,066.98	$ 0	100%	$ 11,216.61	$ 53,810.48	$ 53,039.90	$ -	$ -	$ -

HAMS 2 FY 20	BUDGET 2	MO 4 - JAN	MO 5 - FEB	MO 6 - MAR	MO 7 - APR	MO 8 - MAY	MO 9 - JUN
BUDGET ACR	$ 118,067	$ 14,192.55	$ 54,881.41	$ 48,993.07	$ -	$ -	$ -
	Projected expenditure %	12.02%	58.50%	100.00%	100.00%	100.00%	100.00%
	Benchmark FY15	6.25%	13%	20.00%	23.03%	29.22%	35.15%

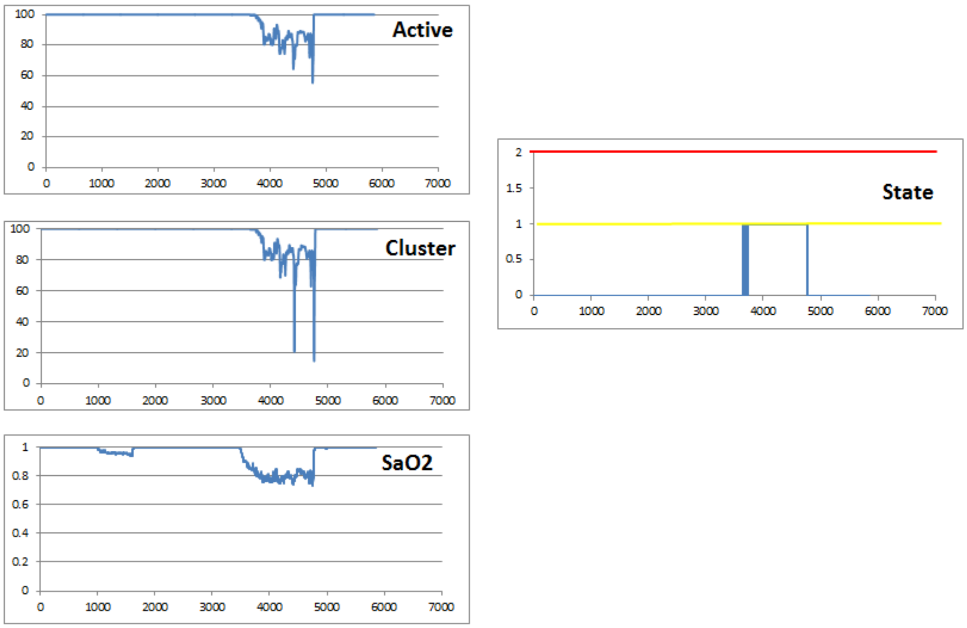
HAMS 2 FY 2015 - ACRN 000104/105-AD									
CONTRACT# N00014-14-C-0276									
Begins APR 2015 - AUG 2015	4+ months		ACTUAL EXPENDITURE% BY MONTH based on 328K	6.61%	6.61%	6.61%	6.61%	6.61%	6.61%
HAMS 2 FY 2014	CUMULATIVE SPENT FY15 FUNDS BUDGET 3	REMAINING BUDGET	% of Total FUNDS Expended	MO 6 -MAR 2015	MO 7 - APR 2015	MO 8 - MAY 2015	MO 9 - JUN 2015	MO 10 - JUL 2015	MO 11 - AUG 2015
COST INCURRED	$ 21,665.64	$ 306,147	7%	$ 21,665.64	$ -	$ -	$ -	$ -	$ -

HAMS 2 FY 20	BUDGET 3	MO 6-MAR	MO 7 - APR	MO 8 - MAY	MO 9 - JUN	MO 10 - JUL	MO 11 - AUG
BUDGET ACR	$ 327,813	$ 71,536.97	$ 17,094.67	$ 79,738.56	$ 77,684.88	$ 81,757.53	$ -
	Projected expenditure %	21.82%		51.36%	75.06%	100.00%	100.00%
	Benchmark FY15	20.00%	23.03%	29%	35.15%	42.12%	49.07%

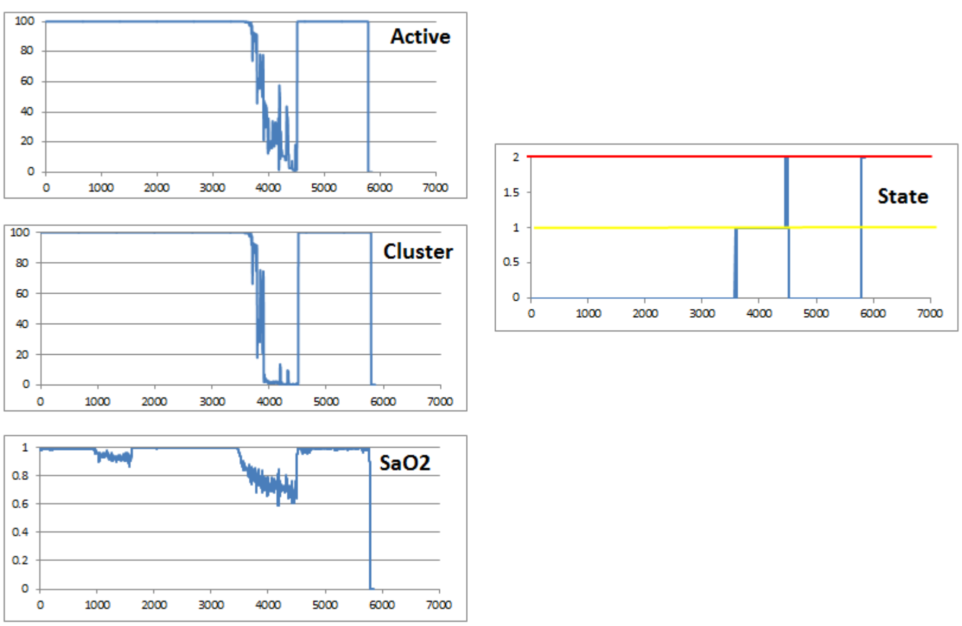
9.2 Neurological State Predictions

18,000 feet

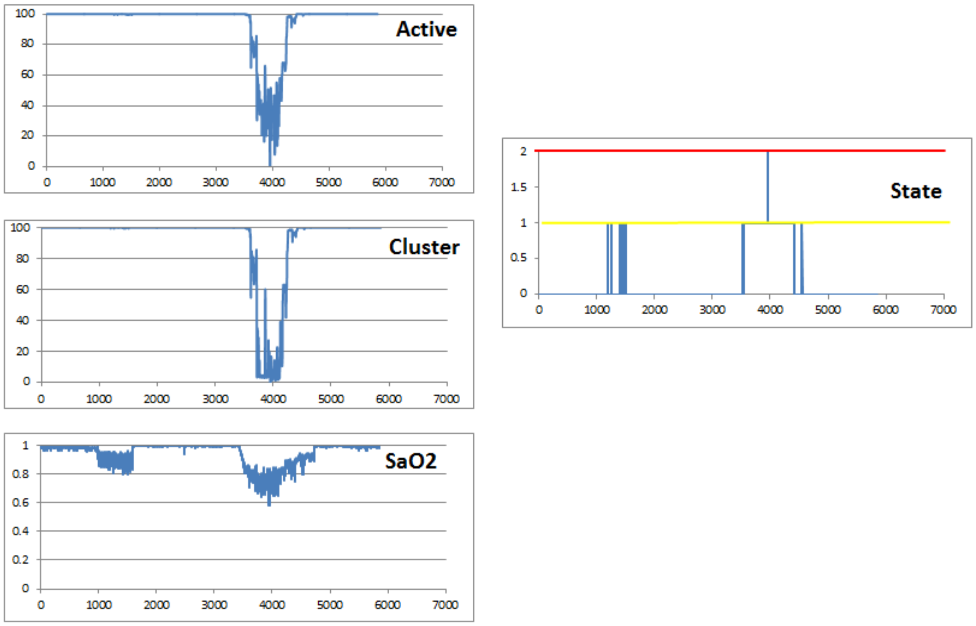
S1 – 1



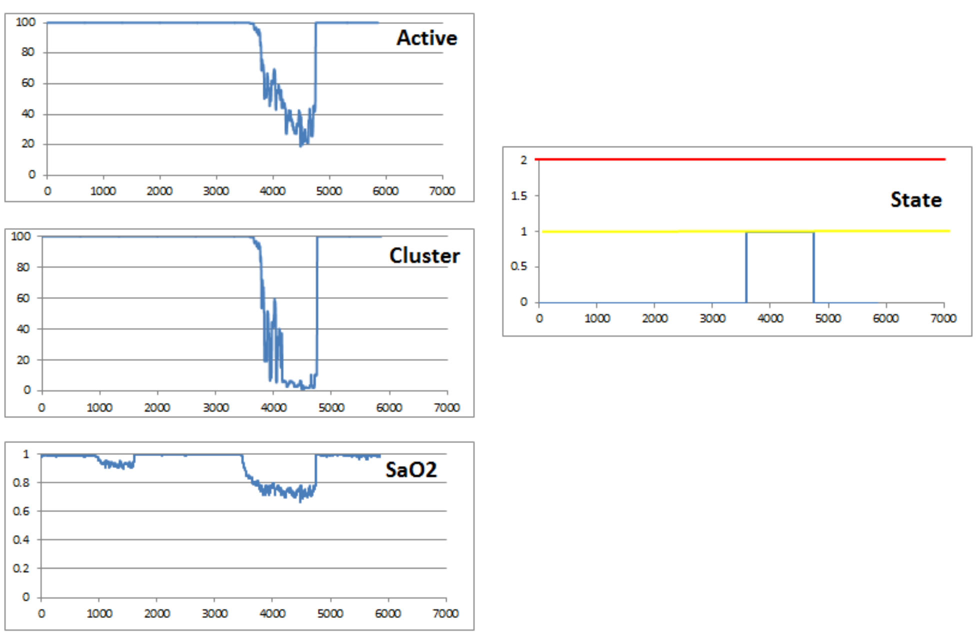
S1 - 2



S2 -1


Active
Cluster
SaO2
State
0
1000
2000
3000
4000
5000
6000
7000

S2 - 2


Active
Cluster
SaO2
State
0
1000
2000
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4000
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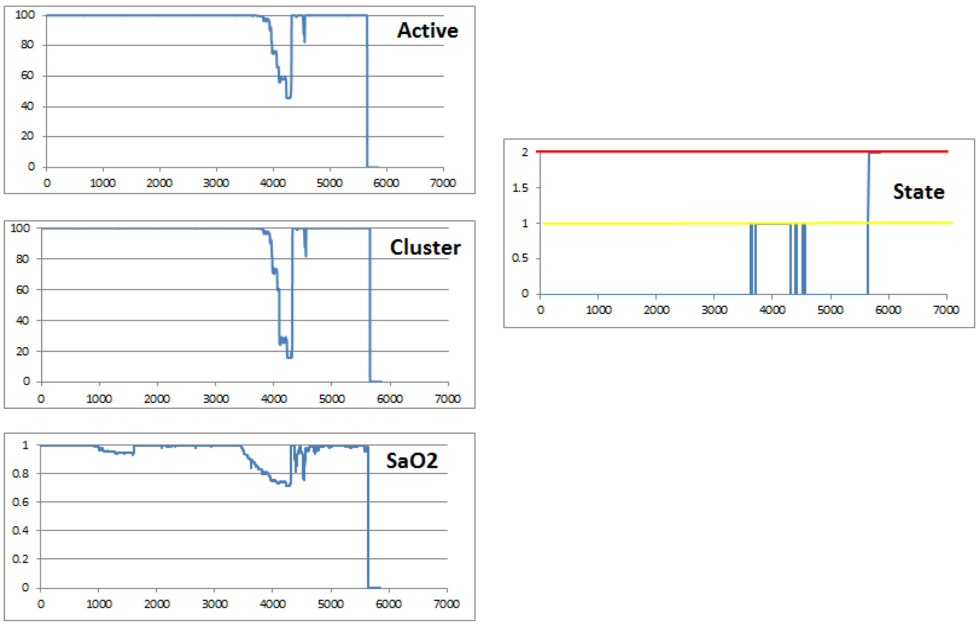
6000
7000

S3 - 1


Active
0
20
40
60
80
100
0 1000 2000 3000 4000 5000 6000 7000
Cluster
0
20
40
60
80
100
0 1000 2000 3000 4000 5000 6000 7000
SaO2
0
0.2
0.4
0.6
0.8
1
0 1000 2000 3000 4000 5000 6000 7000
State
0
0.5
1
1.5
2
0 1000 2000 3000 4000 5000 6000 7000

S3 - 2


Active
0
20
40
60
80
100
0 1000 2000 3000 4000 5000 6000 7000
Cluster
0
20
40
60
80
100
0 1000 2000 3000 4000 5000 6000 7000
SaO2
0
0.2
0.4
0.6
0.8
1
0 1000 2000 3000 4000 5000 6000 7000
State
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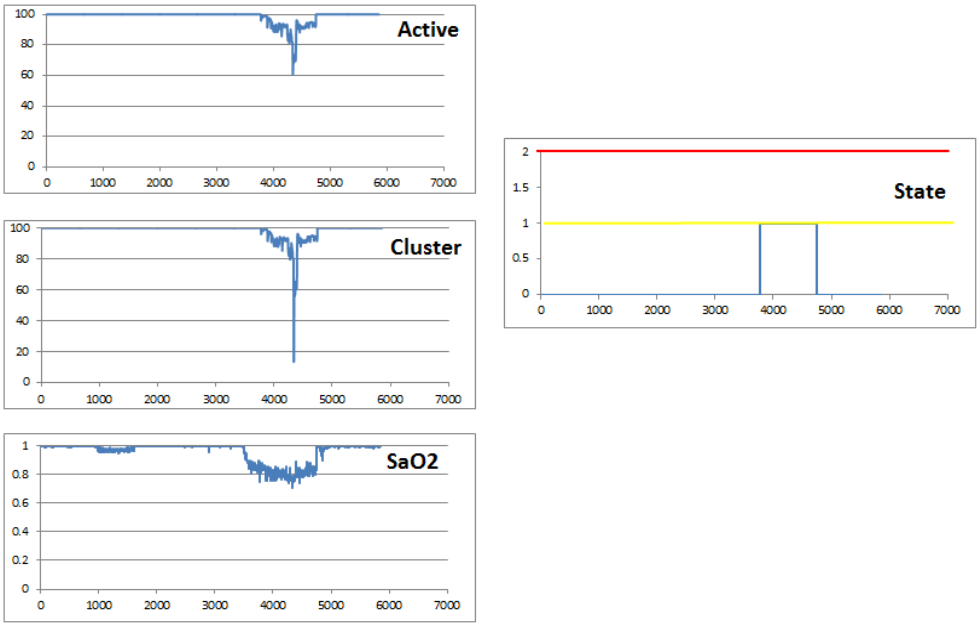
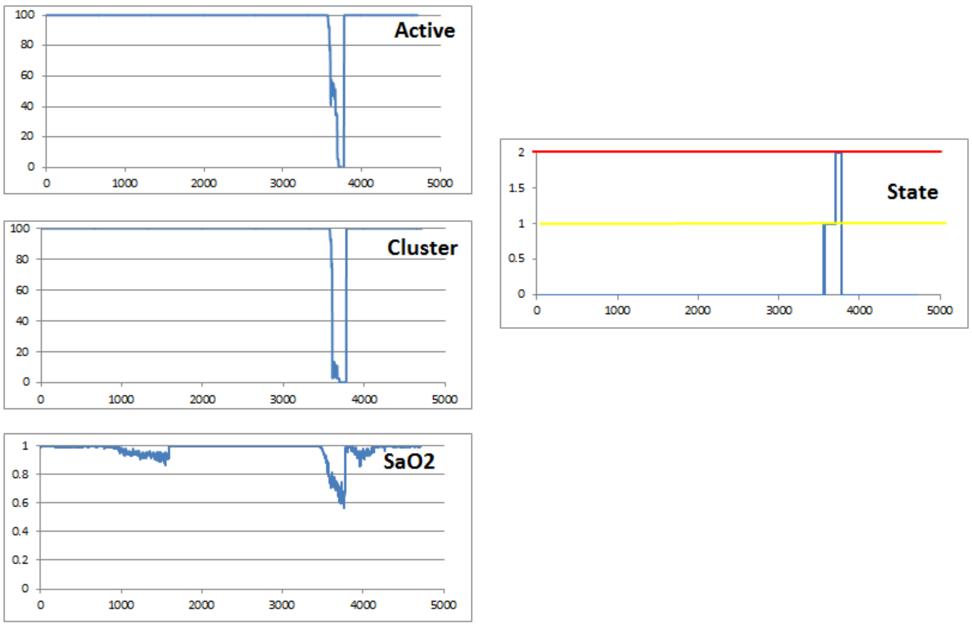
0.5
1
1.5
2
0 1000 2000 3000 4000 5000 6000 7000

S4 - 1

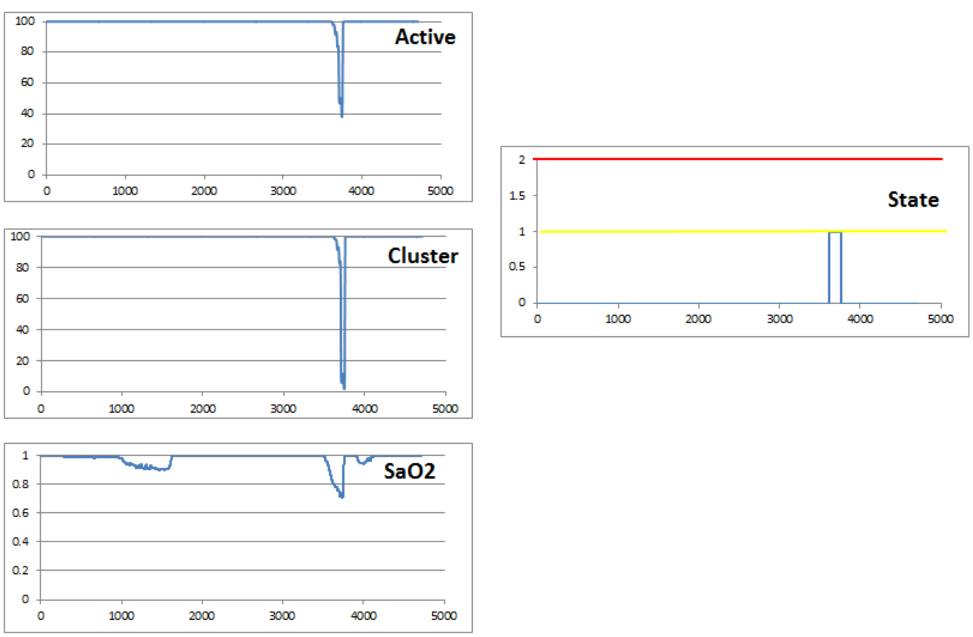

Active
Cluster
SaO2
State
0
1000
2000
3000
4000
5000
6000
7000

25,000 feet

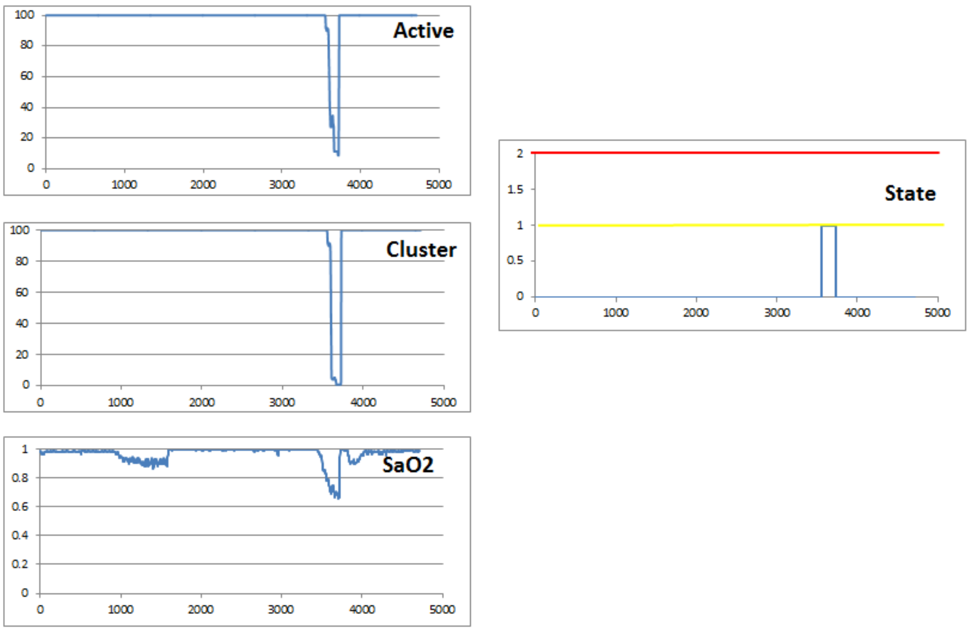
S1 -1



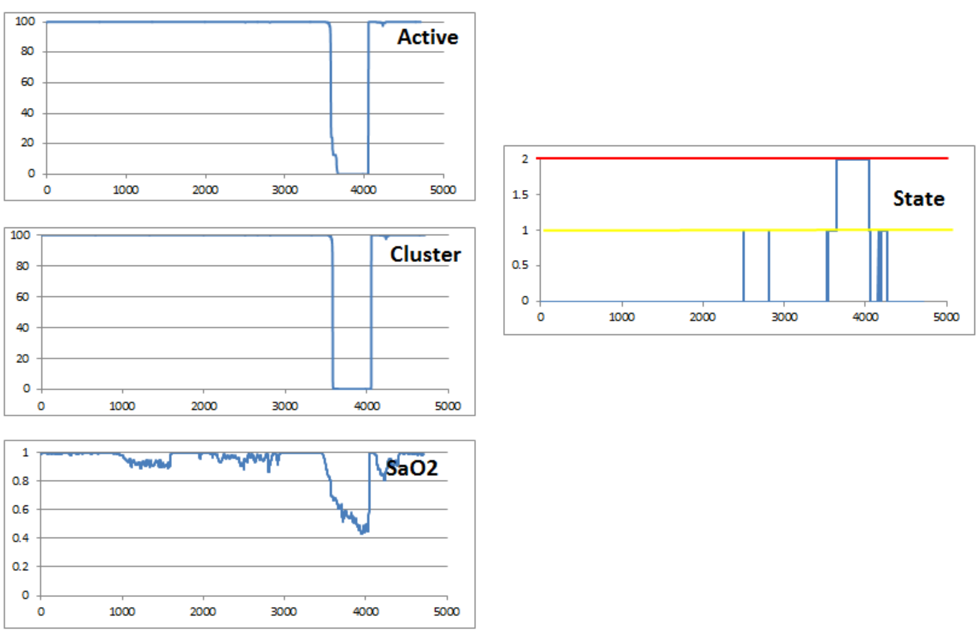
S1 - 2



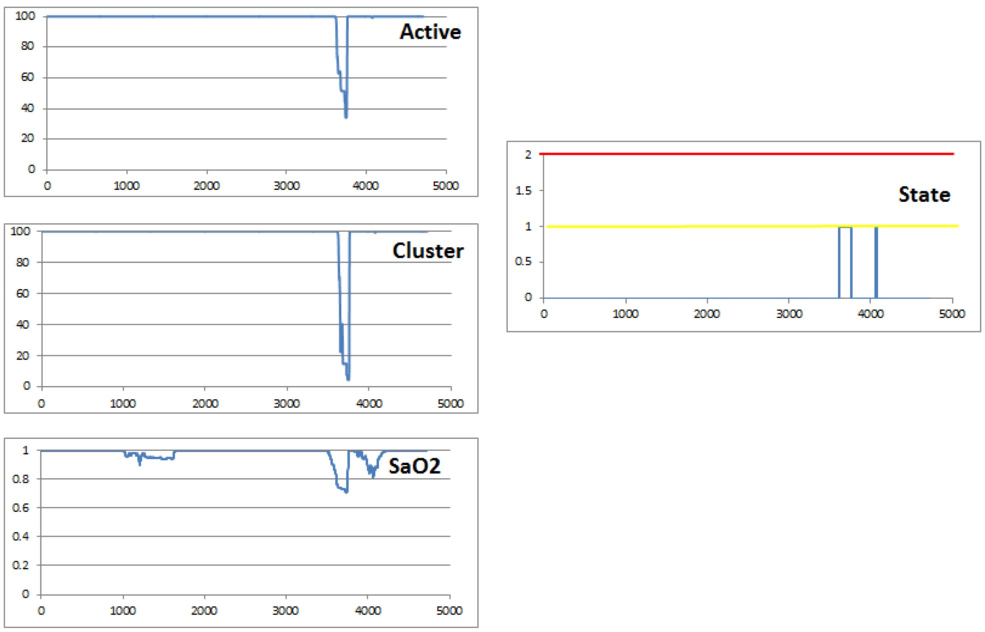
S2 - 1



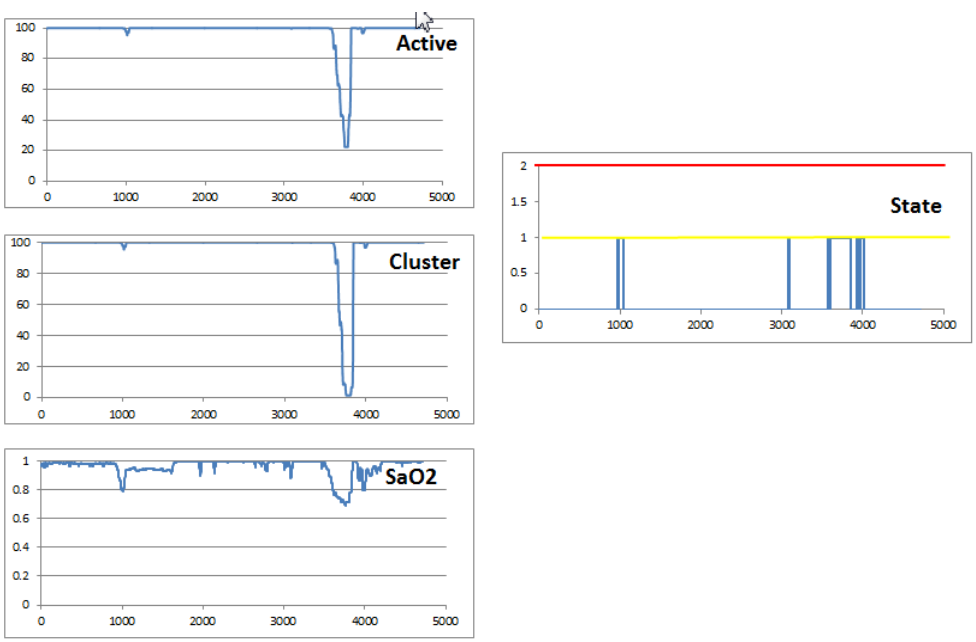
S2 - 2



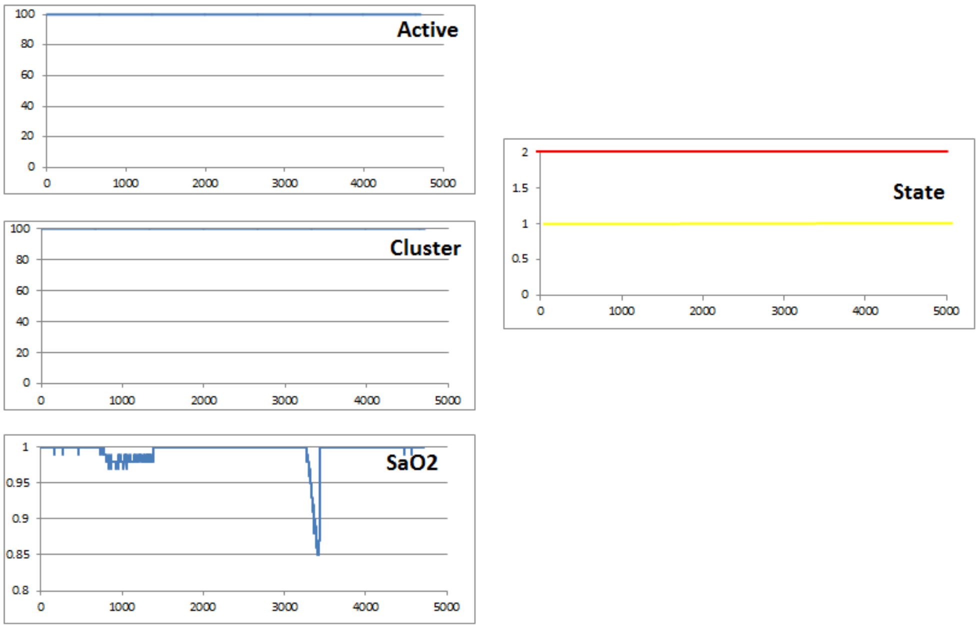
S3 - 1



S3 - 2



S4 - 1


Active
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SaO2
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1.5
2
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2000
3000
4000
5000

9.3 TB MED 505 Detailed Review

HAMS II Functional Implications from Altitude Acclimatization and Illness Management TB MED 505

Since Acute Mountain Sickness seems to be a major contributor to loss of mission effectiveness, the TB MED 505 on altitude acclimatization and illness management was reviewed from the perspective of potential additional functions and features that an operational HAMS II device might possess.

The figure below shows the time course of events during acclimatization for low altitude residents. Ascent and over the first 3-4 days are the most critical for expressing physiological and cognitive symptoms and developing acute mountain sickness.

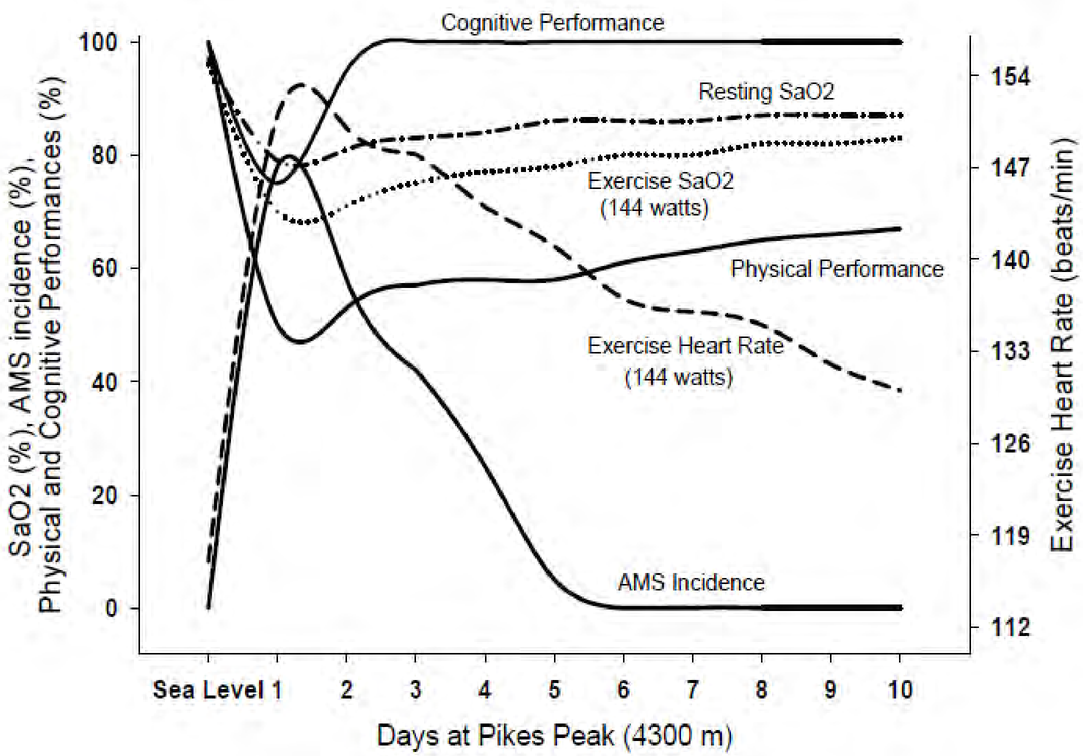

Figure 2–4. Representative time course for altitude acclimatization of low altitude residents directly ascending to 4,300 meters

Heart rate and SaO_2 show the effects of acute hypoxia but also the progression toward acclimatization. An additional use for the HAMS II device could be as an acclimatization monitor to determine if the process is progressing in the right direction. Since the changes occur over days, there may be no need for constant monitoring and data acquisition could occur in bursts at long time intervals of as a suggestion 4 or 6 hours. Activity is also a key component where effects are greater with increased work rate. Measuring the work rate of locomotion could be done through accelerometer but the work rate of a manual manipulation task could be more difficult and require the user enter an activity which would have a pre-entered work rate associated with it. The altitude exposure for the above curve is relevant at 14,000 feet and some cognitive decline is indicated. Cognitive assessment during military operations is difficult. The risk factors during altitude operations are in the copied table in Exhibit 1 – Risk Factors.

The following sections in boxes were taken directly from the TB MED 505 as having direct influence on and suggestion of device features or function.

> **2–4. Individual factors modifying physiological responses to high altitude**
> *a.* Currently, no tests can predict individual susceptibility to altitude sickness or the adaptability to altitude of a healthy man or woman residing at low altitudes. Prior histories of altitude sickness or maladaptations to altitude are the best predictors of likely individual responses to future altitude exposures

This text suggests that a useful feature for the device would be personalization where past history of mountain sickness or other altitude related events would be known and taken into account.

<u>Key Mission Factors</u>

Key mission factors appear to be the ascent rate, duration and work rate with rations playing a role as well. The activity of the individual soldier or group could be monitored for the rate of ascent using the barometric pressure reading which can be following in time that is maintained on the device. The work rate may be more difficult to determine without using a metric used to judge stress but accelerometry may be useful in marching or climbing activities. However this would not be useful in manual manipulation activities. In this case perhaps a manual input of activity and duration would suffice such as placing sandbags for an hour.

> The risk of an unacclimatized Soldier developing altitude illness following rapid ascent to high altitude varies as a function of altitude exposure duration; that is, the risk is low during the first 6 to 12 hrs, increases between 12 to 48 hrs, and usually decreases to near 0 after 3 to 5 days of exposure. However, continued ascent to increasingly higher altitudes significantly increases the risk of developing altitude illness. Conversely, Soldiers well acclimatized to 2,000 m or higher will be at relatively low risk for developing altitude illness following rapid ascent to altitudes 1,000 to 2,000 m above their acclimatization altitude.

This text points to the short period of time that monitoring would be critical and that taking readings would not have to be constant but could be at intervals especially if monitoring acclimatization progress. An essential part of monitoring for AMS is incorporating in an automated basis the Lake Louise AMS Scoring System as shown in the Exhibit 2 – AMS Scoring System.

Acclimatization Procedures

The text boxes that follow outline three acclimatization procedures which could be part of the software function of a HAMS II device or base-station. Through procedure selection the software would guide the user through the stages and perform the monitoring of progress and potential for AMS development.

ALTITUDE ACCLIMATIZATION PROCEDURES

Key Points

- Ascend high enough to induce adaptions, but not so high as to develop altitude illness.
- Unacclimatized Soldiers should *not* ascend above 2,400 m.
- Stage 4–6 days between 2,000–2,400 m.
- Stage 7–14 days between 1,400–2,000 m.
- Staging reduces AMS incidence for altitudes 1,000 to 2,000 m above the staging altitude.
- Graded ascents above 2400 m should not exceed 300 m/day.
- Graded ascents greater than 300 m/day should include a rest day at each higher altitude.

This test indicates potential user interface aspects in terms of key information to enter into the device and what method of acclimatization is being used. In the following text segments different acclimatization procedures are recounted and the specific protocols could be part of the assessment algorithm for hypoxia and acclimatization.

To maximize improvement of physical performance capabilities at altitude, at least 1 hr of moderate-intensity activity (~60 percent maximum heart rate) should be conducted each staging day to promote improved physical performance at that altitude. The greatest physical performance improvements will be attained if the 1-hr aerobic exercise training can be conducted at altitudes at or above 2,000 m.

The above text would indicate that a programmed function to initiate physical activity which is followed by activity and heart rate monitoring could be part of an acclimatization regimen.

Graded Assent Profile

(1) Recommended graded ascent profiles limit the ascent rate to 150–600 m per day and may include a non-ascent day at various intervals. Above 4,000 m, graded ascent profiles should not exceed 300 m over 2 days and should include a non-ascent day every second or third day.

(2) Generally, the slower the ascent above 2,400 m, the lower the risk of developing altitude illness and the better the sustainment of physical and cognitive work performances.

(3) Graded ascent profiles can be used with staging ascent profiles to effectively acclimatize. For example, after using a staged ascent profile from figure 3–1, the acclimatized unit can rapidly ascend to 3,500 m with minimal risk of developing AMS. To ascend above 3,500 m, the unit can use one of the slow ascent profiles in figure 3–2. Personnel rapidly ascending from below 1,200 m should not ascend above 2,400 m for the first night at altitude. Thereafter, one of the three graded ascent profiles should be followed. At altitudes above 4,000 m, daily ascent should not exceed 150 m per day or 300 m every 2 days and should include a non-ascent day every 1 to 2 days.

Intermittent Altitude Exposure

At a minimum, IHE protocols should use altitudes >2,000 m, exposure durations from 3 hrs to as long as possible, and daily exposures, if possible, repeated for a period of at least 1 week or more. Several IHE protocols are presented in table 3–3. Generally, longer daily exposures to altitudes >2,500 m for more than 1 week are more likely to induce functionally useful altitude acclimatization.

Monitoring and Assessment of Acclimatization

A useful and practical measure of ventilatory acclimatization is resting SaO2 by pulse oximetry.
Soldiers with resting SaO2 at or below the median value are at greater risk of developing altitude illness than individuals with resting SaO2 higher than the median SaO2 for that altitude.
At altitudes >3,000 m, resting heart rate is usually elevated during acute exposure and returns to sea-level values with acclimatization. The increase in resting heart rate is proportional to the altitude and ranges from 10 to 30 percent over the Soldier's low-altitude resting heart rate.

The above text box reinforces the measurement modalities for heart rate and SaO_2. Additionally time history interpretation would be a key to following acclimatization progress. Not in this US Army document, but an additional role for heart rate is the determination of heart rate variability (HRV). Karinen et al (2012) showed in 36 healthy climbers that the changes in supine HRV at 2400m were related to AMS at 3000-4300m. (Karinen et al., 2012) The root mean square successive differences and high frequency power of HRV at 2400m were 17-51% lower in climbers that experienced AMS at 300-4300m. Thus an indicator of potential AMS may be found in the heart rate data.

Physical Performance

Two mile run time to estimate VO2max

A Soldier with a high VO2max generally can perform a given task that requires a fixed amount of O2 for a longer period of time than a Soldier with a lower VO2max (that is, the former compared to the latter will be working at a lower percent VO2max and heart rate).

VO2max represents the functional limit of their respiratory and circulatory systems to deliver O2 to active muscles and the ability of their active muscles to utilize the O2 delivered. With increasing elevation, there is a progressive reduction in PB, with resultant declines in inspired, alveolar, and arterial PO2. As a consequence, V˙ O2max declines for all individuals from sea level at a rate proportional to the increase in altitude. The decline in VO2max at altitude has a direct influence on nearly all tasks performed at altitude.

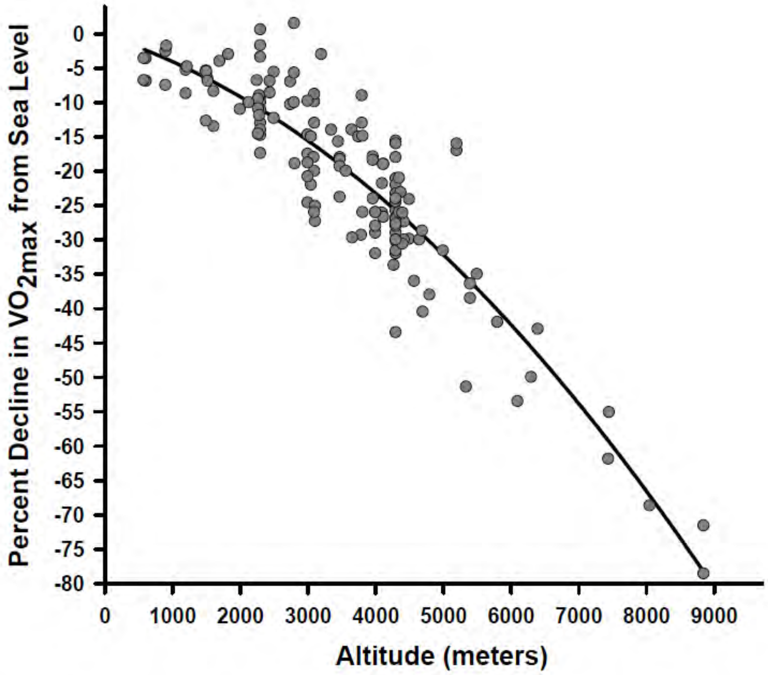

Figure 4–1. Relationship between increasing elevation and decline in maximal oxygen uptake

The above box and graph give good information if VO2max is needed for any calculations. By having the user enter their 2-mile run time a VO2max can be estimated and then graded based on altitude in terms of work capacity.

Neuropsychological and Cognitive Effects

Changes in neuropsychological function are most evident in unacclimatized Soldiers **during the first 24 hrs of their ascent above 3,000 m**. Also, there is a progression in the deleterious effects of hypoxia on the central nervous system. **The higher cortical centers are the most sensitive, followed by the cerebellum, medulla, and spinal cord.** **Higher-level brain functions involving cognition, decision-making, and reasoning are most sensitive to the effects of altitude and oxygen deprivation.**

Bold underline emphasis added

Sleep deprivation, poor sleep quality and quantity, and physical fatigue will contribute to the direct effects of hypoxia on neuropsychological function. Sleep quality and quantity are decreased at altitude due to increased awakenings resulting from central sleep apnea. Soldiers experiencing more frequent awakenings demonstrate greater impairments in cognition.

Altitudes above 3,000 m can produce substantial impairments in a number of cognitive and psychomotor performance measures. Cognitive performance is more affected at altitude than psychomotor performance, and complex tasks are usually affected before simple tasks. Successful execution of many military tasks is dependent upon the integration of multiple cognitive functions.

Cognitive and psychomotor performance changes do not follow the same time course at altitude as do symptoms of AMS. Within minutes of exposure to altitudes above 3,000 m, cognitive and psychomotor performances decrease, whereas development of AMS may not occur for 4 or more hrs. At altitudes below 5,000 m, cognitive performances improve and return toward baseline after 24 to 48 hrs. Cognitive performances improve less in individuals afflicted with AMS during this period. Soldiers afflicted with severe AMS will have greater impairment of cognitive performances than Soldiers with lesser symptoms. Upon return to low altitude, cognitive and psychomotor performances quickly return to normal. However, some cases of long-term to permanent cognitive impairments have been reported in climbers who ascended to extreme altitudes (>5,500 m).

Tasks requiring assimilation of novel information and/or requiring decisions and strategies (for example, friend-foe identification, targeting, tactical maneuvering, etc.) are more vulnerable to hypoxia than simple and more automated tasks (for example, weapon function check, donning mission-oriented protective posture gear, etc.). Performances involving visual processing of shapes, patterns, and contours are more affected at altitude than those involving numbers, words or characters. Vigilance is decreased and may be related to the fatigue or lethargy caused by hypoxia. Psychomotor tasks, such as choice reaction time, finger dexterity, and arm-hand coordination, are degraded above 3,000 m but to a lesser extent than cognitive performance tasks. There are no validated predictive models of cognitive and psychomotor performances as a function of altitude and exposure duration. Given the progressive severity of hypoxia with increasing altitude, adverse changes in cognitive and psychomotor performances are expected to be greater at progressively higher altitudes. Sleep deprivation and fragmented sleep caused by hypoxia may also contribute to reduced cognitive and psychomotor performances at high altitudes.

Cognitive performance impairments at altitude result from either decreased accuracy (that is, increased errors), slowing of performance (that is, decreased speed), or a combination of both. Most cognitive performance impairments at altitude result primarily from a slowing of performance rather than decreased accuracy. However, more errors are likely to occur at altitude when tasks are paced by external conditions. The goal of the task can also alter the tradeoff between accuracy and speed on task impairment at altitude. For example, during a marksmanship task with a goal of hitting as many targets as possible within a prescribed period, time taken to sight the target was reduced, and accuracy was less than sea-level performance.

The above boxes highlight the neuropsychological and cognitive effects and the time course of greatest concern upon ascent. The first 24 hours are the most critical above 3000m with the higher cortical centers being the most sensitive. Hence the first acclimatization point to 2400m. Poor sleep is a hallmark sign; an additional use of the HAMS II as a sleep monitor – actigraph via accelerometer motion detection is a potential additional use of a HAMS II unit for monitoring hypoxia effects. Cognitive assessment during the course of daily activities would appear difficult if one wished to avoid the interruption of duties. Interval cognitive assessment as part of a battery of tests where eye motion and blink can simultaneous be measured would serve as an adjunct to the real-time monitoring.

<u>Reference</u>

Karinen, H. M., Uusitalo, A., Vähä-Ypyä, H., Kähönen, M., Peltonen, J. E., Stein, P. K., … Tikkanen, H. O. (2012). Heart rate variability changes at 2400 m altitude predicts acute mountain sickness on further ascent at 3000-4300 m altitudes. *Frontiers in Physiology*, *3 AUG*(August), 1–7. doi:10.3389/fphys.2012.00336

Exhibit 1 - Risk Factors

Table 3–2
Selected risk factors with known impact on either physical or cognitive work performances at altitude and susceptibility to altitude illness

Risk Factor	Risk Impact		
	Physical Work Performance	**Cognitive Performance**	**Altitude Illness**
Environmental Factors			
Altitude:			
Moderate (1,200–2,400 m)	↓	↔	↓
High (2,400–4,000 m)	↓↓	↓	↓↓
Very High (4,000–5,500 m)	↓↓↓	↓↓↓	↓↓↓
Extreme (>5,500 m)	↓↓↓	↓↓↓	↓↓↓
Cold Temperatures	↔	↔	↓↓
Hot Temperatures	↓↓	↔	↓
Steep and Rugged Terrain	↓	↔	↔
Carbon Monoxide (heaters)	↓↓↓	↓↓↓	↓↓↓
Mission Factors			
Ascent Rate Above 2,400 m:			
>600 m/day	↓↓↓	↓↓↓	↓↓↓
300–600 m/day	↓↓	↔	↓↓
<300 m/day	↓	↑	↓
Duration Above 2,400 m:			
<12 hrs	↓	↓	↔, ↓
12–24 hrs	↓	↔	↓↓↓
1–2 days	↓	↔	↓↓
3–5 days	↓	↑	↓
>5 days	↑	↑	↑
Work Rate:			
Low–Moderate	↓	↔	↓
High–Intense	↓↓	↔	↓↓↓
Individual Factors			
Acclimatized >2,000 m	↑	↑	↑
High Physical Fitness	↑	↔	↔
Adequate Hydration	↑	↑	↑
Nutrition:			
Negative Energy Balance	↓	↓	↓
Increased Carbohydrates	↑	↔	↑, ↔
Preexisting Illness	↔, ↓	↔, ↓	↓
Sleep Deprivation	↓↓	↓↓	↔, ↓

Legend: ↑ = beneficial; ↔ = no risk; ↓ = slight risk; ↓↓ = moderate risk; ↓↓↓ = significant risk

Exhibit 2 - AMS Scoring System

APPENDIX F

THE LAKE LOUISE ACUTE MOUNTAIN SICKNESS SCORING SYSTEM

Name ______________________ Age ______ Sex ____________ Date ______________

Time ___ ___ ___ ___ ___

Altitude ___ ___ ___ ___ ___

Self-Reported Symptoms:

1. Headache:							
	No headache	0	___	___	___	___	___
	Mild headache	1	___	___	___	___	___
	Moderate headache	2	___	___	___	___	___
	Severe, incapacitating	3	___	___	___	___	___
2. Gastrointestinal:							
	No gastrointestinal symptoms	0	___	___	___	___	___
	Poor appetite or nausea	1	___	___	___	___	___
	Moderate nausea or vomiting	2	___	___	___	___	___
	Severe nausea and vomiting, incapacitating	3	___	___	___	___	___
3. Fatigue/weakness:							
	Not tired or weak	0	___	___	___	___	___
	Mild fatigue/weakness	1	___	___	___	___	___
	Moderate fatigue/weakness	2	___	___	___	___	___
	Severe fatigue/weakness, incapacitating	3	___	___	___	___	___
4. Dizzy/lightheaded:							
	Not dizzy	0	___	___	___	___	___
	Mild dizziness	1	___	___	___	___	___
	Moderate dizziness	2	___	___	___	___	___
	Severe, incapacitating	3	___	___	___	___	___
5. Difficulty sleeping:							
	Slept well as usual	0	___	___	___	___	___
	Did not sleep as well as usual	1	___	___	___	___	___
	Woke many times, poor night's sleep	2	___	___	___	___	___
	Could not sleep at all	3					
Self-Reported Symptom Score:			___	___	___	___	___
Clinical Assessment:							
6. Change in mental status:							
	No change	0	___	___	___	___	___
	Lethargy/lassitude	1	___	___	___	___	___
	Disoriented/confused	2	___	___	___	___	___
	Stupor/semiconsciousness	3	___	___	___	___	___
7. Ataxia (heel-to-toe walking):							
	No ataxia	0	___	___	___	___	___
	Maneuvers to maintain balance	1	___	___	___	___	___
	Steps off line	2	___	___	___	___	___
	Falls down	3	___	___	___	___	___
	Cannot stand	4	___	___	___	___	___
8. Peripheral edema:							
	No edema	0	___	___	___	___	___
	One location	1	___	___	___	___	___
	Two or more locations	2	___	___	___	___	___
Clinical Assessment Score:			___	___	___	___	___
Total Score (Add Self-Reported Symptom and Clinical Assessment Scores):			___	___	___	___	___

10.0 List of Symbols, Abbreviations and Acronyms

[O2]	Concentration of Oxygen
ADC	Analog to Digital Converter
AMS	Acute Mountain Sickness
ANS	Autonomic Nervous System
CASEVAC	Casualty Evacuation
CDR	Critical Design Review
CO	Cardiac Output
COTS	Commercial Off The Shelf
CRADA	Cooperative Research and Development Agreement
DAC	Digital to Analog Converter
DSP	Digital Signal Processing
ECG	Electrocardiogram
EVM	Evaluation Module
FDA	Food and Drug Administration
FRS	Functional Requirements Specification
ft	Feet
FTP	File Transfer Protocol
Gz	Gravitational Force from head to feet while standing upright
HAMS	Hypoxia Monitoring, Alert and Mitigation System
hrs	Hours
HRV	Heart Rate Variability
HW	Hardware
IDR	Initial Design Review
INA	Instrumentation Amplifier
JTAG	Joint Test Action Group
LED	Light Emitting Diode
LOC	Loss of Consciousness
m	Meters
MCU	Microcontroller
MDK	Medical Development Kit
NIRS	Near Infrared Spectroscopy

OLED	Organic Light Emitting Diode
ONR	Office of Naval Research
OPA	Operational Amplifier
PaCO2	Alveolar Pressure of Carbon Dioxide
PaO2	Alveolar Pressure of Oxygen
PDR	Preliminary Design Review
R&D	Research and Development
RER	Respiratory Exchange Ratio
ROBD	Reduced Oxygen Breathing Device
SaO2	Arterial Oxygen Saturation Measured via CO-Oximeter
SD	Secure Digital
SDD	Software Design Description
SL	Sea Level
SPI	Serial Peripheral Interface
SpO2	Arterial Oxygen Saturation Measured via Pulse-Oximeter
SRS	Software Requirements Specification
SV	Stroke Volume
SVR	Systemic Vascular Resistance
SW	Software
SYNWIN	Cognitive Assessment Software Tool
TI	Texas Instruments
TUC	Time of Useful Consciousness
uPROC	Micro-Processor
USARIEM	US Army Research Institute of Environmental Medicine
USB	Universal Serial Bus
USN	United States Navy
VO2	Oxygen Consumption
VO2max	Maximum Oxygen Consumption
WiFi	Wireless Communications
WVSM	Wireless Vital Signs Monitor

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