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The Portable Helicopter Oxygen Delivery System in the Altitude Chamber: A Comparison Between Peripheral and Regional Blood Oxygen Saturation

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14. ABSTRACT
The Portable Helicopter Oxygen Delivery System (PHODS) provides supplemental oxygen (O2) up to altitudes of 18,000 feet (ft) above mean sea level (MSL). Previous PHODS testing at the U.S. Army Aeromedical Research Laboratory (USAARL) used conventional pulse oximetry to monitor peripheral blood O2 saturation (SpO2). The present PHODS test incorporates measures of regional cerebral blood O2 saturation (rSO2). Testing was conducted at pressure altitudes of 14,000 and 17,800 ft above MSL as well as at ground level. Army aircrew volunteers (N = 22) assessed PHODS' functionality and effectiveness during three tasks, 10 minutes (min) of the Psychomotor Vigilance Test, 5 min of text reading, and 2 min of self-paced squats. rSO2 and SpO2 were collected continuously throughout testing. Results indicate that the PHODS maintained SpO2 but not rSO2 throughout all testing. The operational significance of this finding is yet to be determined.

15. SUBJECT TERMS
PHODS, oxygen, altitude, rSO2, sPO2

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Summary

Introduction: The Portable Helicopter Oxygen Delivery System (PHODS) provides supplemental oxygen (O_2) to Army personnel in unpressurized aircraft up to altitudes of 18,000 feet (ft) above mean sea level (MSL). The PHODS attaches to the user's survival vest and helmet to deliver a predetermined bolus of nearly 95% O_2 via a flexible nasal cannula or face mask. Previous PHODS testing at the U.S. Army Aeromedical Research Laboratory (USAARL) used conventional pulse oximetry to monitor peripheral blood O_2 saturation (SpO_2). The present PHODS test incorporates measures of regional cerebral blood O_2 saturation (rSO_2).

Methods: The United States Army School of Aviation Medicine (USASAM) altitude chamber enabled the PHODS evaluation at pressure altitudes (PA) of 14,000 and 17,800 ft above MSL as well as at ground level, which is about 325 ft above MSL. At each altitude, twenty-two Army aircrew volunteered to assess PHODS' performance as prescribed in the PHODS user manual during 10 minutes (min) of the Psychomotor Vigilance Test (PVT), 5 min of text reading (TR) to challenge the PHODS's nasal cannula, and 2 min of self-paced squats as a standardized physical workload (WL) challenge. A commercial, off the shelf, near infrared transcranial spectroscopic (NIRS) device monitored rSO_2 in parallel with a standard commercial, off the shelf pulse oximeter measuring SpO_2.

Results: The analysis calculated the slope of the rSO_2 and SpO_2 over the duration of each task at each altitude. Thus, the figures of merit were rSO_2 and SpO_2 slopes over 10 min of PVT, 5 min of TR, and 2 min of WL at each altitude. Two-factor repeated analyses of variance compared slopes. The rSO_2 slope was significantly affected by task ($F(2, 160) = 193.66$, $p < 0.01$) and by the interaction of task by altitude ($F(4, 160) = 2.25$, $p < 0.04$). Specifically, rSO_2 slope was essentially flat over the PVT and TR for the three altitudes; but the WL slope was affected by altitude ($F(2, 40) = 4.28$, $p \leq 0.02$) such that the greater the altitude, the steeper the slope. Notably, SpO_2 slope was flat over all tasks.

Discussion: While the PHODS maintained rSO_2 over the duration of the PVT and TR for the 14,000 and at 17,800 ft PA, it progressively decreased during WL whereas SpO_2 was unaffected. This is a statistical finding; its operational importance remains to be determined, but clearly, the PHODS maintained SpO_2 but not rSO_2.

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The large number of authors attests to the profoundly collaborative nature of this research and each author made essential contributions to this study. Nonetheless, any shortcomings and errors in this report are Dr. Temme's responsibility. This research has been extensively aided by many conversations and consultations with Mr. James M. Cox, COL Mark Adams, and COL Ian Curry. The authors gratefully acknowledge the help and guidance of Ms. Jill Emerson and Ms. Stephanie Moon of the USAARL's Regulatory Compliance Office.

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Introduction

Hypoxia remains one of the most important hazards for aviation, particularly for aircrew in non-pressurized aircraft at altitude (Gradwell, 2006). According to Army Regulation 95-1, aircrew are to use supplemental oxygen for flights longer than 1 hour above 10,000 feet (ft) pressure altitude (PA), or flights longer than 30 minutes (min) above 12,000 ft PA (Army, 2018). For flights of any duration above 14,000 ft PA, aircrew and passengers are required to use supplemental oxygen (Army, 2018). Currently, Army Helicopter Pilots use supplemental oxygen provided by the commercially available (Capewell Aerial Systems, LLC) Portable Helicopter Oxygen Delivery System (PHODS). The PHODS, a flight certified, man-mounted system that attaches to the user's survival vest and helmet, delivers a predetermined bolus of about 95% oxygen via a flexible nasal cannula or facemask (Figure 1). Altitude determines the duration of the oxygen bolus; the higher the altitude, the longer the bolus (Aqua Lung, 2009, 2011) to a maximum of 500 msec (millisecond).

Figure 1. The PHODS mounted on a manikin illustrating its placement when in use.

Previous tests and evaluations (T&E) at the United States Army Aeromedical Research Laboratory (USAARL) used conventional finger pulse oximetry to measure PHODS performance under different physical workload (WL) demands in an altitude chamber. Pulse oximetry provides simultaneous measures of pulse rate and the percent oxygen saturation of peripheral blood hemoglobin (SpO_2) (Curry & Roller, 2007; Roller & Curry, 2008). The main conclusions of these studies were that the PHODS provides optimal oxygenation at rest and adequate oxygenation during exercise (Curry & Roller, 2007; Roller & Curry, 2008).

Subsequently, the effects of exercise at high altitude and the increased ventilatory drive during hypoxia have come into question. With increased rate/depth of breathing, or hyperventilation, the lungs can decrease the partial pressure of arterial carbon dioxide (P_aCO_2). This is important since P_aCO_2 impacts cerebral blood flow. Specifically, a drop in P_aCO_2 reportedly constricts the cerebral vasculature, thereby reducing cerebral blood flow; and conversely, increased P_aCO_2 can dilate cerebral vasculature, thereby increasing cerebral blood flow (Fan & Kayser, 2013; Ainslie & Ogoh, 2010). Because of the effects of P_aCO_2 on cerebral blood flow, hypocapnia resulting from hyperventilation may reduce cerebral blood flow, and consequently, oxygen delivery. Additionally, increased physical demand on non-Pilot aircrew, similar to mild or moderate exercise at high altitude, can result in a faster onset of hypoxia in these individuals due to increased workload and oxygen demand (Smith, 2007). Pulse oximetry provides a measure of peripheral arterial blood oxygen saturation; however, factors such as reduced peripheral perfusion, ambient light, motion artifact, and relative amounts of oxygenated to deoxygenated hemoglobin in a tissue bed can affect pulse oximeter readings (Hess & Branson, 1995; Trivendi, Ghouri, Shah, Lai, & Barker, 1997). Consequently, pulse oximetry may not necessarily be a good predictor of cerebral blood oxygen saturation.

These uncertainties generated the need to test and evaluate PHODS in the face of physical WL, particularly the ability of PHODS to maintain cerebral regional blood oxygen (rSO_2), as a figure of merit. Consequently, the USAARL Warfighter Performance Group (WPG) approached the Airworthiness Certification and Evaluation (ACE) team to assist in a T&E of the PHODS in an altitude environment. The present report documents the T&E methods, procedures, results, and conclusions concerning PHODS effectiveness in maintaining peripheral as well as cerebral blood oxygen saturation. The T&E implemented the ACE-2018-005, Revision 1 (Eshelman, 2018), test plan approved May 14, 2019 (USAARL Number 2018-031).

PHODS Description

Crewmembers onboard U.S. Army rotary-wing aircraft may use the PHODS up to altitudes of 18,000 ft. The PHODS attaches to a crewmember's survival vest and helmet to support flight missions in accordance with Army Regulation 95-1 (Army, 2018). The PHODS consists of an oxygen cylinder with regulator, an automatic oxygen pulse controller (OPC-M1) with inlet and outlet hoses, and a flexible nasal cannula with a quick disconnect coiled hose assembly (Figure 2). A PHODS mask may replace the nasal cannula when operational conditions and individual physiology dictate. The OPC-M1 contains an internal barometer that detects changes in altitude. When the PHODS OPC-M1 senses a pressure difference between its internal barometer and the nasal cannula due to the user's inspiration, the OPC-M1 automatically provides a pulse of oxygen for a predetermined duration. In its "on" state, the PHODS activates at 8000 ± 500 ft PA, delivering measured quantities of oxygen until the PA drops below 8000 ± 500 ft. According to the PHODS User Manual, the PHODS has been tested and approved for use on U.S. Army Chinook (CH-47), Blackhawk (H-60s), and Apache (AH-64) (pending approval) aircraft. The OPC-M1 unit has four user-controlled operational settings (Table 1).

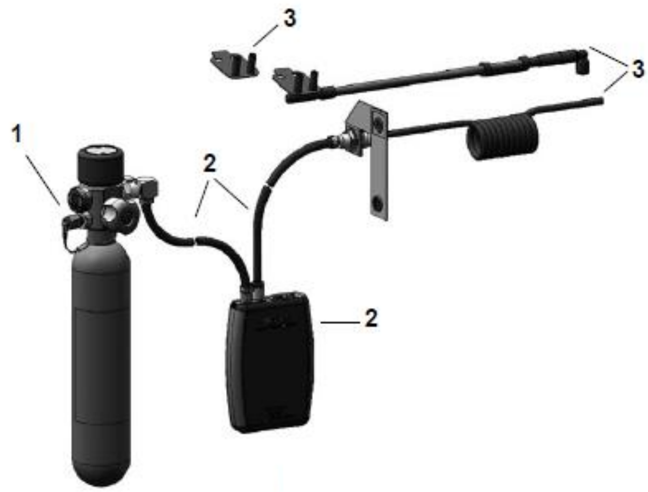

Figure 2. An exploded view of the PHODS that illustrates individual components. The numbered components are: 1. The oxygen cylinder and regulator; 2. The OPC-M1 with input and output hoses; 3. Flexible helmet mounted boom with the nasal cannula and soft rubber cannula insert that can be trimmed to fit individual nasal passages.

Table 1. PHODS Modes of Operation

Mode	Description
Off	PHODS is off; OPC-M1 is not-operational and powered down
On	Fully automatic pre-set O_2 delivery beginning between 8000 ± 500 ft PA to 10,000 ft PA; nasal cannula only
R/M	Reserve Manual Mode; maximum flow pulse upon inhalation at any altitude; setting not to be used above 16,000 ft
F20	Face Mask Mode; automatic at all altitudes; may be used with a face mask or nasal cannula; suggested mode for high workload environment; see Figure 7 for more specifics.

Methods

Test Instrumentation

Preparatory work ensured the devices supporting the present PHODS T&E were mutually compatible and were safe for use in an altitude chamber. This preparatory work developed and refined the test procedures as well as data synchronization, transfer, management, archiving, and quality control.

NONIN Life Sense Model LS1-9R.

The NONIN Life Sense Model LS1-9R (Figure 3) is a commercial, off the shelf (COTS), pulse oximeter integrated with a capnographer. Pulse oximetry is a non-invasive method to assess peripheral blood oxygen saturation by passing long (i.e., red) wavelength and infrared (IR) light through perfused tissue while detecting the changes in spectral transmittance caused by arterial pulses. Well-oxygenated blood is bright red, while poorly oxygenated blood is dark red. The pulse oximeter determines functional oxygen saturation of arterial hemoglobin (SpO_2) from these color differences by measuring the ratio of absorbed red and IR light as the volume fluctuates with each pulse. The NONIN Life Sense Model LS1-9R measures and records SpO_2 simultaneously with pulse rate.

Figure 3. The NONIN Life Sense Model LS1-9R pulse oximeter monitor.

NONIN Equanox Model 7600 regional oximeter System.

Nonin's non-invasive Equanox Model 7600 4-Channel Regional Oximeter system (Figure 4) is a clinical COTS device that uses near IR transcranial spectroscopy (NIRS) to monitor, in essentially real time, hemoglobin O_2 saturation of blood in the tissue illuminated by an IR light source. This NIRS system uses self-adhesive patches containing a matrix of IR light sources and sensors in a known configuration placed on the surface of the skin, in this case, the forehead. The characteristics of the reflected IR light recorded from the IR source/sensor matrix provide a measure of the oxygen saturation of the hemoglobin in the region of tissue beneath the source/sensor matrix adhesive patch. In the present configuration, the Nonin Equanox sampled regional cerebral blood oxygen saturation (rSO_2) every 4 seconds to assess the ability of the PHODS to maintain the blood oxygen saturation of the brain.

Figure 4. The NONIN Equanox Model 7600 regional oximeter system consisting of: 1. adhesive patches containing the IR source and sensor matrix; 2. signal processing unit; 3. display monitor containing the data acquisition system.

PVT-192 monitor (Psychomotor Vigilance Test).

The Psychomotor Vigilance Test (PVT) (Figure 5) is a COTS device that assesses simple reaction time to a visual cue presented at pseudo-random intervals ranging between 2 to 10 seconds. The visual stimulus appears as the red string of numbers in the window centered in the upper part of the PVT-192, identified by the arrow in Figure 5. As soon as the number appears in the window, it increments in milliseconds until the response button is pressed; in response to the button press, the number immediately stops incrementing and displays the reaction time in milliseconds. In this way, the PVT-192 provides immediate feedback, which can help maintain the performance of an intentionally boring vigilance task. The PVT provides an estimate of the ability of the PHODS to preserve reaction time and vigilance over the 10 min of continuous PVT testing.

Figure 5. The handheld PVT-192 device. The blue downward pointing arrow at the top of the device indicates the window in which the red stimulus numbers appear.

Testing Personnel

Twenty-two U.S. Army aircrew volunteered to evaluate the PHODS. Each of the PHODS evaluators was medically cleared for exposure to altitude in the chamber. A U.S. Army School of Aviation Medicine (USASAM) Flight Surgeon determined exposure limitations for the hypobaric environment used in testing. All evaluators complied with instructions set forth by the USASAM on each day of testing. Up to four evaluators assessed the PHODS inside the altitude chamber at one time. The test procedures specified that if an evaluator's SpO_2 fell below 70% for over 1 min or if an evaluator showed signs of hypoxia, the test was suspended and the evaluator immediately switched to chamber oxygen. Notably, this situation did not occur at any time during these tests.

In addition to the evaluators, two medically cleared, trained, and experienced USAARL staff members served as test managers (TM), coordinating all activities inside the chamber. Thus, up to six people were inside the altitude chamber in addition to a USASAM observer. On the day of testing, the USASAM cleared all testing personnel for altitude exposure.

Altitude Chamber

The PHODS T&E used the USASAM man-rated hypobaric chamber (Figure 6). The USASAM had oversight of all altitude chamber activities, and all procedures were in accordance with the USASAM standard operating procedures for hypobaric chamber operations.

Figure 6. Inside view of the USASAM altitude chamber. Various test devices such as the Nonin Life Sense are visible on the floor of the left side of the chamber near the seats. With four evaluators, two USAARL TMs, and the USASAM observer, space was limited. The chamber operator and other research staff and observers were positioned on the outside of the windows visible at the far end of the chamber.

Preparatory PHODS Training and Orientation

Before a chamber flight, the TMs ensured that all PHODS were operational at ground level (GL), per the manufacturer's recommendation, by setting the OPC-M1 to "Reserve Manual" (R/M) (see Table 1 and Figure 1) and ensuring PHODS oxygen delivery. The TMs then demonstrated the PHODS and its use to the evaluators. These demonstrations included the use of the nasal cannula as well as a properly sized and fitted PHODS mask. During this time, the evaluators signed an informed consent document, familiarized themselves with the PHODS, and practiced using it. When directed by the USASAM chamber operator, the two USAARL TMs breathed the chamber's supplemental oxygen using an Aviator's mask at their designated console station.

The two USAARL TMs ensured that the evaluators had the PHODS OPC-M1 set to "ON" and that the nasal cannula fit properly. As mentioned above and as illustrated in Figure 7, when the OPC-M1 reaches a pressure altitude of between 8000 ± 500 ft to 10,000 ft with the "ON" setting, the PHODS begins delivering standard pulses of oxygen appropriate for an individual breathing via the cannula. On ascent, the evaluators using the PHODS and nasal cannula verbally confirmed the delivery of oxygen.

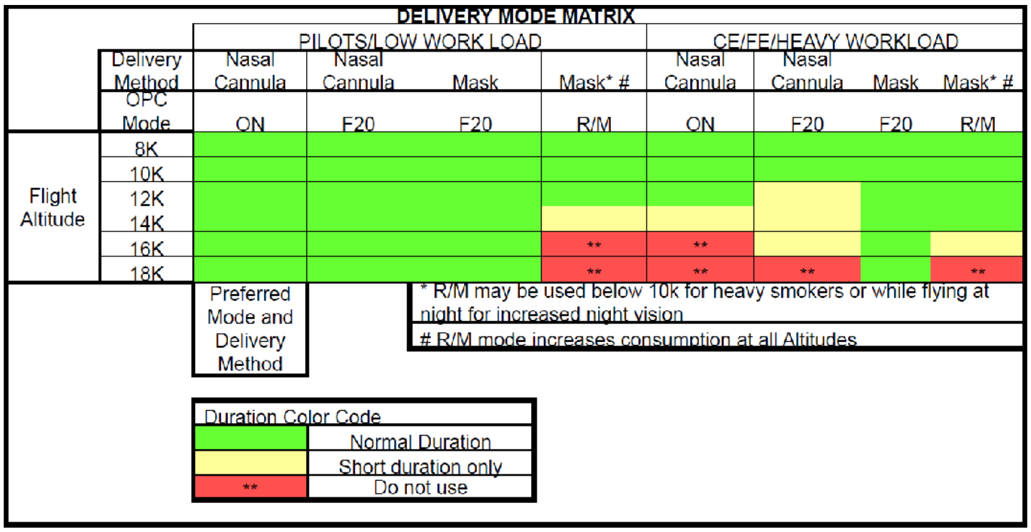

Figure 7. The PHODS manufacturer's recommended delivery mode matrix and use (Aqua Lung 2009, 2011). For pilots and others engaged in low physical workload demands at PA between 8000 ft to 18,000 ft, the recommended OPC-M1 setting is "ON," to be used with the nasal cannula. Furthermore, the figure indicates that the "F20" mode may be used with either the nasal cannula or the PHODS mask. However, the "R/M" setting on the OPC-M1 is not recommend for use with the mask above 14,000 ft PA, and for only short durations between 12,000 and 14,000 ft PA. The right side of the figure addresses heavy workload, and indicates that the "F20" setting may be used with the nasal cannula up to 10,000 ft PA; but, from 10,000 ft to 16,000 ft PA, the nasal cannula may be used with the "F20" setting for short durations only. For longer durations and for altitudes up to 18,000 ft PA, the mask is to be used with the "F20" setting.

As shown in left side of the Delivery Mode Matrix in Figure 7, the manufacturer describes 'ON' with nasal cannula as the preferred mode of the PHODS operation and oxygen delivery at altitudes up to 18,000 ft for those engaged in low physical workload. For heavy workload, however, the right side of Figure 7 applies, showing that the manufacturer recommends the OPC-M1 setting of "F20" be used with the mask at all altitudes. The footnote to the matrix in Figure 7 points out that the PHODS in the "R/M" mode may benefit heavy smokers as well as improve vision at night. The "R/M" mode is specified in these conditions presumably since the “R/M” mode enables the PHODS’ oxygen delivery at altitudes from 8000 ft PA down to GL.

Chamber Altitude Profile

Figure 8 displays the chamber PA profile as a function of time in min. The numbers and arrows indicate scheduled events as described below. The horizontal lines indicate three regions of constant altitude; GL, 14,000 ft PA, and 17,800 ft PA. The slopes indicate changes in PA. All times are approximate. The numbers and arrows in Figure 8 indicate the occurrence of the scheduled events listed in Table 2.

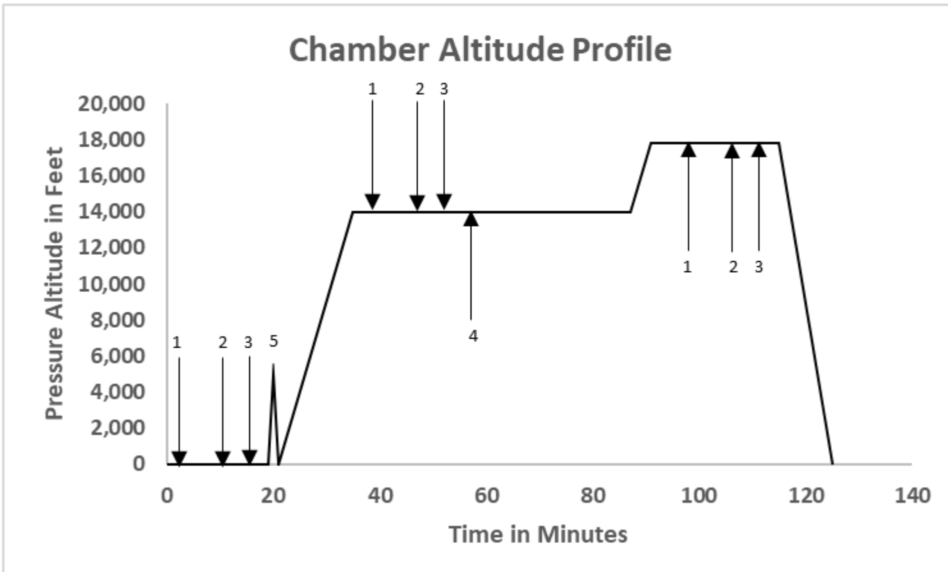

Figure 8. Chamber altitude test profile as a function of time in min. Arrows indicate approximate times of specific scheduled events. The horizontals of the profile indicate periods of constant PA, of which there are three, GL, 14,000 ft PA and 17,800 ft PA. The slopes suggest rates of climb and descent. All times are approximate. The spike at 20 min identified as “5” in the figure is the sinus check, which consisted of a brief ascent to 5000 ft PA to verify that chamber occupants can clear their sinuses as per the chamber standard operating procedures followed by a return to GL.

Table 2. Events Scheduled During the Chamber Run

Event	Scheduled Events
1	Psychomotor Vigilance Test (PVT) performed continuously for 10 minutes
2	Vocalized text reading (TR) for 5 minutes
3	Workload (WL) knee bend squats in place for 2 minutes
4	30 minute pre-breathing of 100% O_2
5	Brief ear and sinus check per USASAM SOP

Scheduled Chamber Events

Scheduled Event 1 is the 10 min of PVT, described above. Scheduled Event 2 is 5 min of vocalized text reading (TR) intended to challenge the PHODS’ performance by disrupting nasal breathing without rigorously enforced mouth breathing. The text selected for the TR task addressed topics irrelevant to Army aviation or the PHODS. The texts were read aloud with no requirement of comprehension; the only purpose of the reading was to disrupt nasal breathing by requiring vocalizations. Scheduled Event 3 is 2 min of WL in the form of self-paced squats. Squats were chosen as the WL task due to the limited space of the altitude chamber. Note that the three scheduled events 1, 2, and 3 occurred in the same sequential order for each altitude, GL, 14,000 ft PA, and 17,800 ft PA.

Scheduled Event 4 marks the start of 30 min of O_2 pre-breathing of the altitude chamber O_2 as required by Army Regulation 95-1 Flight Regulations Chapter 8 Section II 8-6 Oxygen system (Manned) (2)(b). “For flights above 18,000 feet pressure altitude, oxygen pre-breathing will be accomplished by aircrew members. Pre-breathing may utilize either 100 percent gaseous aviator’s oxygen from a high-pressure source or an onboard oxygen generating system that supplies at least 90 percent oxygen. Pre-breathing will be for not less than 30 min at GL and will continue while en-route to altitude” (U.S. Army, 2018).

Scheduled Event 5, marking an ascent from GL to 5000 ft and a return to GL, is the USASAM standard operating procedure to ensure that all chamber occupants can clear their sinuses and have no sinus blockages using the Valsalva maneuver.

Procedures

Table 3 provides the approximate scheduled times of events, procedures, and tasks, as well as PHODS configurations. Before the evaluators entered the altitude chamber, USASAM personnel provided a review of altitude physiology. A detailed description and demonstration of the PHODS followed, with a discussion of the background, goals, and purposes of the T&E, including detailed descriptions of all activities, tasks, and risks. All the measurements were described, along with the equipment, procedures, and methods used to record the physiological measurements. The USASAM and USAARL personnel asked whether the evaluators had any additional questions or wanted further clarifications, and these were addressed as requested. Following this discussion, each individual evaluator documented his/her willingness to participate in the T&E. The evaluators were then fitted with the safety harness containing the PHODS. Due to space limitations in the chamber, some sensors were applied to the evaluators prior to entering the chamber. Once appropriately seated in the chamber, the rest of the instrumentation was applied to the evaluators. The functionality of all instrumentation, including the PHODS, was again ensured by TMs as indicated in Table 3. Note that the PHODS ground check was with the nasal cannula and the OPC-M1 in the “R/M” mode.

Table 3. Detailed T&E Event Schedule, Approximate Times, PHODS Configuration, and Oxygen Delivery Method, Nasal Cannula or Mask.

Min (Clock)	Altitude	Event	Nasal Cannula	Aviator Mask	OFF	R/M	ON	F20 (PHODS Mask)
-45	GL	Verbal briefs (USAARL/USASAM)			X			
-35	GL	Participant signatures			X			
-30	GL	Equipment Preparation (helmet modifications, instrument participants, etc.)			X			
1	GL	PHODS ground check	X			X		
2	GL	PVT (10 min)	X					
12	GL	TR (5 min)	X					
17	GL	WL (2 min)	X					
19	GL, 5000 ft, GL	Ear and sinus check (Valsalva)	X				X	
21	14,000 ft	Ascent to 14,000 ft (~1000 ft/min)	X				X	
35	14,000 ft	5 min acclimation	X				X	
40	14,000 ft	PVT (10 min)	X				X	
50	14,000 ft	TR (5 min)	X				X	
55	14,000 ft	WL (2 min)						X
57	14,000 ft	Participants switch to Chamber O_2 for 30 min; Hypoxia symptoms questionnaire		X				
87	14,000 ft	Ascent to 17,800 ft (~1000 ft/min)		X				
91	17,800 ft	5 min acclimation	No supplemental oxygen					
96	17,800 ft	1 min acclimation to nasal cannula	X				X	
97	17,800 ft	PVT (10 min)	X				X	
107	17,800 ft	TR (5 min)	X				X	
112	17,800 ft	WL (2 min)						X
114	17,800 ft	Hypoxia symptoms questionnaire						X

The ascent from GL to 5000 ft PA and return to GL from min 19 to 21, Event 5 in Table 2, is the USASAM standard operating procedure to ensure that all chamber occupants can clear their sinuses using the Valsalva method. During this sinus check, the OPC-M1 was in the "ON" mode and the nasal cannula was in place. This configuration was maintained through to min 50.

Following the sinus check ending at min 21, the chamber ascended to 14,000 ft PA at a rate of 1000 ft/min. Upon arriving at 14,000 ft at min 35, evaluators acclimated to chamber altitude for 5 min while breathing the PHODS supplemental O_2 with the nasal cannula. After the 5 min of acclimation, evaluators performed the PVT for 10 min, from min 40 through min 50. This was followed by 5 min of TR, the interval from min 50 to min 55. After TR, the TMs replaced the PHODS nasal cannula with the mask for each evaluator and changed the OPC-M1 mode from "ON" to "F20" before the evaluators began the 2 min of WL, at min 55 through 57. At min 57, the evaluators switched from breathing the PHODS supplemental O_2 to breathing chamber O_2 via the aviator's mask, marking the beginning a 30 min period of O_2 pre-breathing spanning the interval from min 57 to 87. The ascent at 1000 ft/min to 17,800 ft PA followed the period of pre-breathing.

Upon arriving at 17,800 ft PA, at approximately min 91, the evaluators acclimated to the ambient chamber air with no supplemental oxygen of any sort for 5 minutes. At min 96, evaluators switched the OPC-M1 to the "ON" setting and donned the PHODS nasal cannula to acclimate for 1 min. At min 97, at 17,800 ft PA, with the OPC-M1 in the "ON" mode and with the nasal cannula, evaluators began 10 min of PVT testing. After the 10 min of PVT testing, at min 107, evaluators began 5 min TR. At min 112, the evaluators switched from the nasal cannula to the PHODS mask and switched the OPC-M1 from "ON" to "F20" for 2 min WL. The chamber then descended to GL.

Physiological Measures

During the chamber altitude exposures, the NONIN Life Sense monitor provided a synchronized, time stamped recording of SpO_2, pulse rate, and end tidal carbon dioxide ($EtCO_2$) sampled via a second nasal cannula. Similarly, the NONIN Equanox model 7600 regional oximeter provided a synchronized, time stamped recording of rSO_2. Reported here are the SpO_2 and rSO_2 data since they are the most immediately informative. Subsequent reports address such other measures as $EtCO_2$, respiration and pulse rates.

Results

Oxygen Saturation of Peripheral Blood (SpO_2)

The SpO_2 measurements were recorded every second continuously for the duration of the PVT, TR, and WL tasks at GL, 14,000 ft PA and 17,800 ft PA. Thus, the SpO_2 data record spanned an interval of 10 min for the PVT, an interval of 5 min for the TR, and an interval of 2 min for the WL tasks. Consequently, 1020 data points were recorded from each of the 22 evaluators over the three tasks at each altitude to produce 3060 data points for each evaluator. With 22 evaluators, the SpO_2 database comprised 67,320 data points. These SpO_2 values, averaged over the 22 evaluators at each second, for the three tasks at each of the three altitudes are displayed in Figure 9.

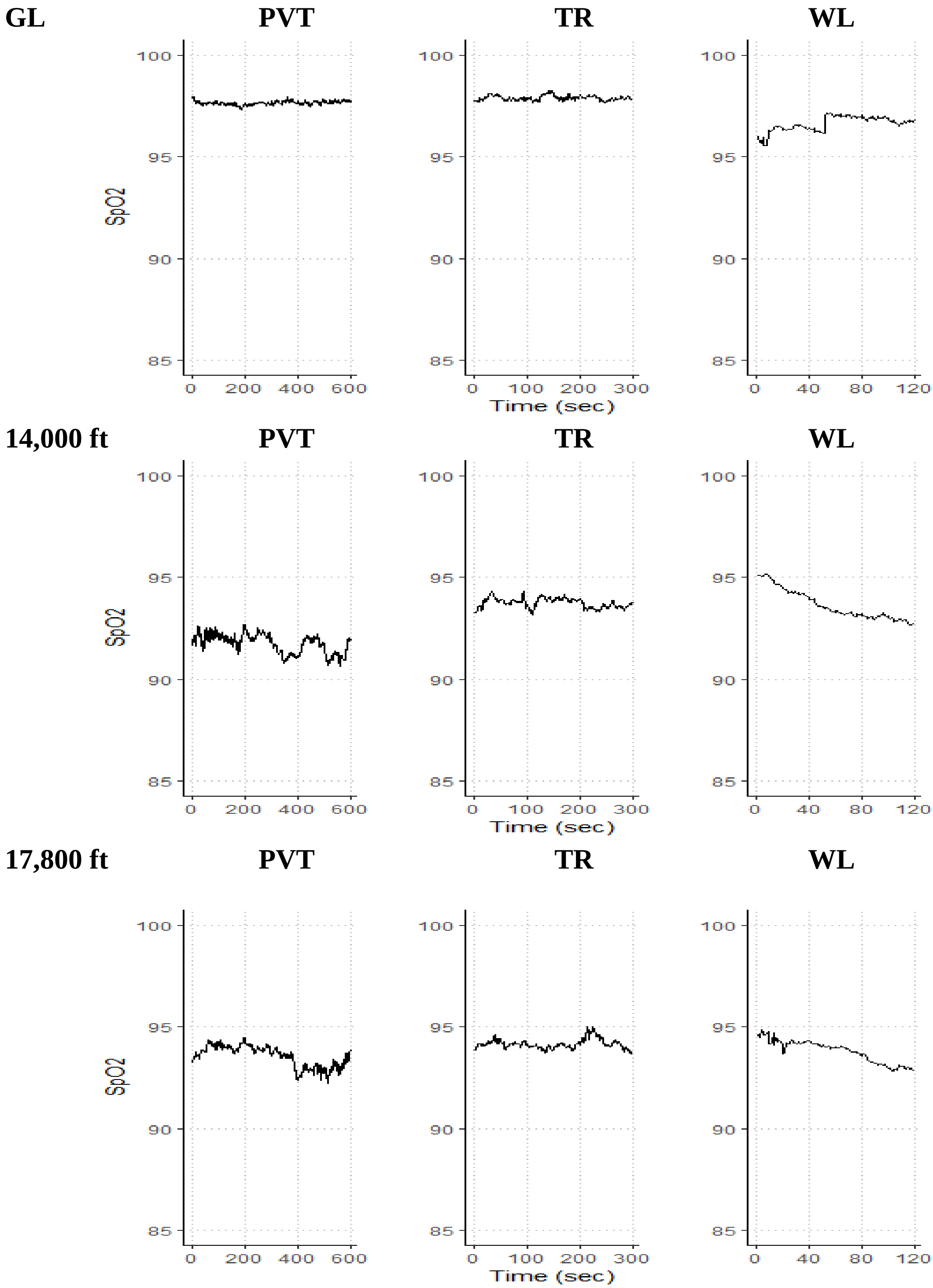

Figure 9. Mean SpO_2 as a function of time in seconds for the PVT (left panel), TR (center panel), and WL (right panel) at GL (top panel), 14,000 ft PA (middle panel), and 17,800 ft PA (bottom panel).

Table 4 provides means, standard deviations (SD) and standard errors of the mean (SEM) for the SpO_2 data presented in Figure 9. These summary statistics were calculated over the 10 min of PVT, the 5 min of TR, and the 2 min of WL for each evaluator, which were then averaged over the group of evaluators.

Table 4. Summary of SpO_2 During All Tasks Averaged Over All Evaluators

Altitude	Test	Mean	SEM	SD
GL	PVT	97.7	0.01	1.09
	TR	97.9	0.01	0.86
	WL	96.6	0.06	2.97
14,000 ft	PVT	91.6	0.05	5.64
	TR	93.8	0.04	3.03
	WL	93.8	0.07	3.39
17,800 ft	PVT	93.2	0.03	3.61
	TR	94.0	0.04	3.19
	WL	93.9	0.07	3.32

The summary statistics presented in Table 4 collapse SpO_2 over time, but the duration of the altitude exposure is central for the evaluation of PHODS performance. To assess the importance of duration, a least square regression was fit for each evaluators' SpO_2 for each task as a function of task duration producing the slope of SpO_2 as a function to time. Thus, for each of the three tasks at each of the three altitudes, a linear regression over time calculated SpO_2 slope for each evaluator; these slopes were averaged over the evaluators. These average slopes, shown in Table 5, are the rate of change of SpO_2 per min unit time.

Table 5. Slope of Averaged SpO_2 Change Calculated Over the Task Duration

Altitude	PVT	TR	WL
GL	0.01057	-0.00214	0.01761
14,000 ft	-0.12814	0.01393	-0.56938
17,800 ft	-0.10137	-0.10789	-0.24810

These slope data were evaluated statistically to determine whether they would support a parametric, two-factor repeated measures analysis of variance (ANOVA). These data did not meet the required assumptions nor was an appropriate data transformation identified. Consequently, a non-parametric Kruskal-Wallis test determined whether the slopes were significantly different among altitudes or tasks. The results of the Kruskal-Wallis test are presented in Table 6, which shows that neither altitude ($\chi^2 = 5.77$, $p > 0.05$) nor task ($\chi^2 = 3.42$, $p > 0.05$) significantly affected the slope of SpO_2 over time. Figure 10 graphically illustrates these results.

Table 6. Kruskal-Wallis Analysis of the Slopes of the Three Altitudes and the Three Tasks

Source	*df*	χ^2	*p-value*
Altitude	2	5.77	0.06
Task	2	3.42	0.18

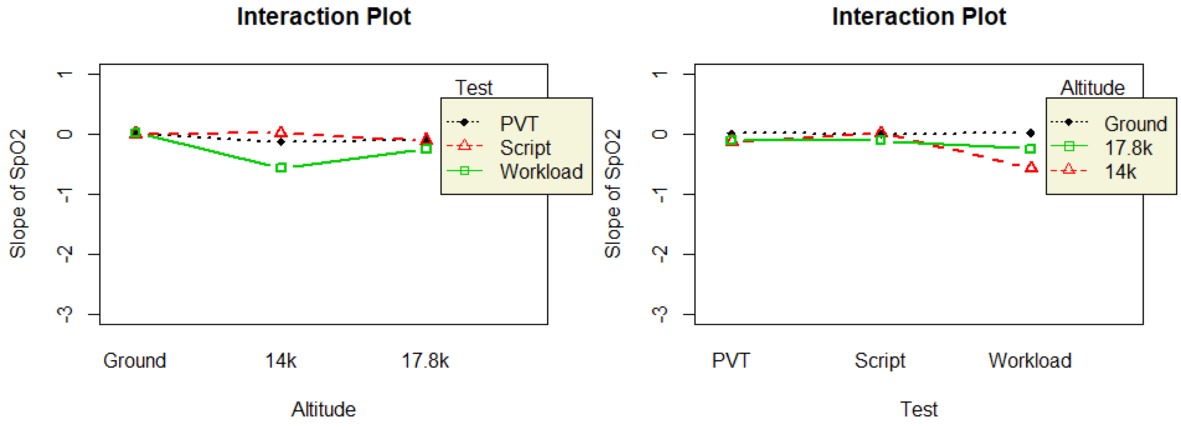

Figure 10. Interaction plots of the SpO_2 slope plotted from Table 5 with task as the parameter in the left graph and altitude as the parameter in the right graph.

The Kruskal-Wallis test calculated a nearly significant ($p > 0.06$) probability for altitude, suggesting that the slope of SpO_2 merited further evaluation. From Figure 10, it can be seen that the negative slope of SpO_2 during WL at 14,000 ft (-0.5694) is steeper than the slopes for GL (0.01761) and 17,800 ft (-0.2481); thus the greater steepness of the WL slope may be the reason that altitude slope approached significance. Thus, the hypothesis that SpO_2 slope during WL is different across the three altitudes was tested. Prior to the one factor ANOVA, the assumptions of normalcy and homogeneity of the database of SpO_2 slopes during WL over the three altitudes were evaluated and found to be satisfied. Thus, the data supported a one factor repeated measures ANOVA to evaluate whether there were differences in the SpO_2 slope during WL across the three altitudes. Table 7 summarizes the results of this analysis and shows that the slopes during WL at the three altitudes are not statistically different.

Table 7. Summary of Slope of SpO_2 Averaged Over All Evaluators for Duration of WL Task

Source	*df*	*Sum of Squares*	*Mean Squares*	*F-ratio*	*p-value*
Altitude	2	0.0132	0.01149	1.93	0.159
Error	38	0.2262	0.00595		

Regional Cerebral Oxygen (rSO_2) Saturation

The rSO_2 measurements were recorded every 4 seconds continuously for the duration of the PVT, TR, and WL tasks at GL, 14,000 ft PA and 17,800 ft PA. Thus, the rSO_2 data record spanned an interval of 10 min for the PVT, an interval of 5 min for the TR, and an interval of 2 min for the WL tasks. Consequently, 255 data points were recorded from each evaluator over the three tasks at each altitude producing 765 data points for each evaluator. Because of missing data, the number of complete evaluator datasets is 21; thus, the rSO_2 database comprised 16,065 data points. These rSO_2 values, averaged over the 21 evaluators in 4 second intervals, for the three tasks at each of the three altitudes, are displayed in Figure 11.

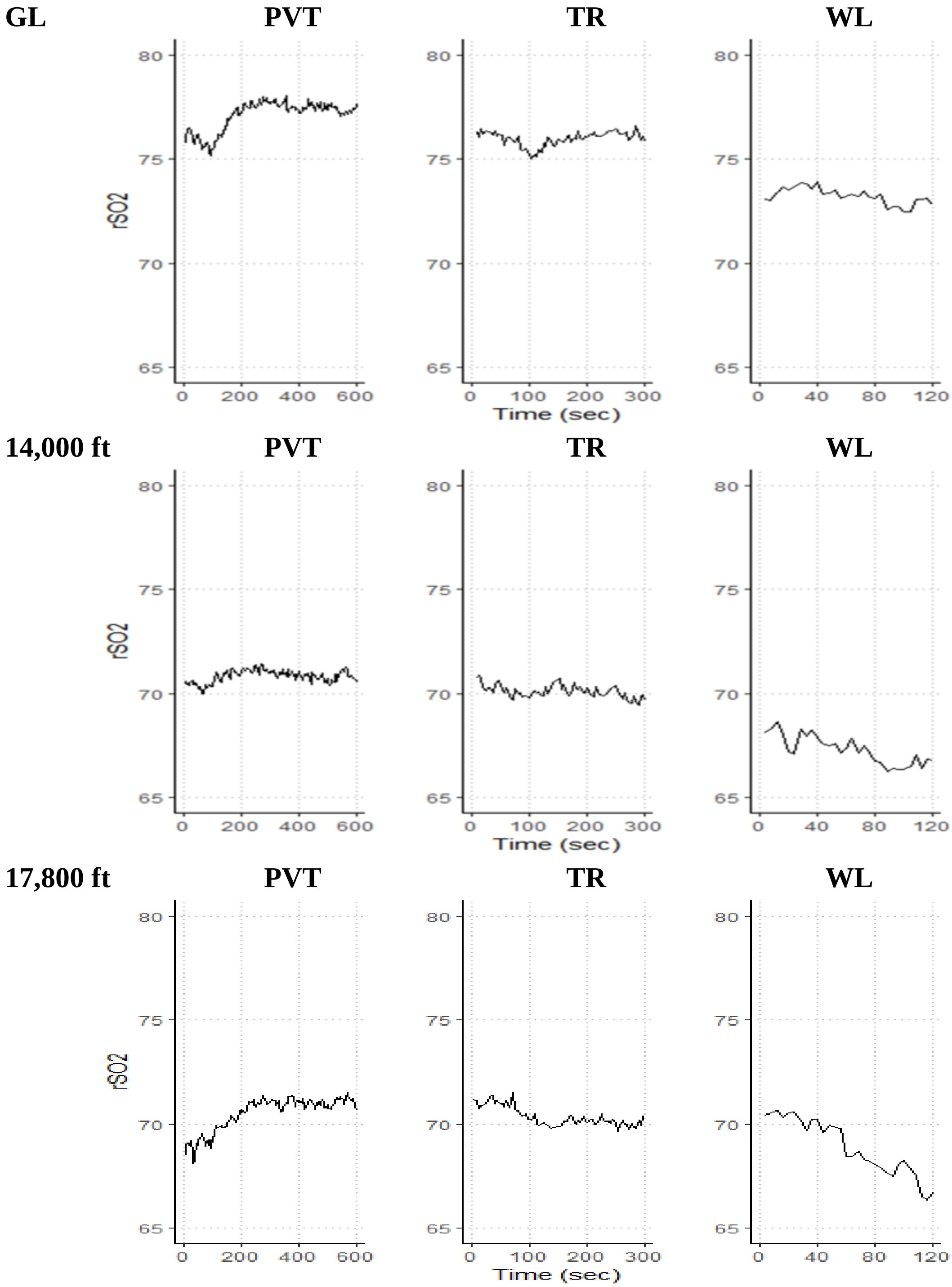

Figure 11. Mean rSO_2 as a function of time in seconds for the PVT (left panel), TR (center panel), and WL (right panel) at the GL (top panel), 14,000 ft PA (middle panel), and 17,800 ft PA (bottom panel).

Table 8 provides means, standard deviations (*SD*) and standard errors of the mean (*SEM*) for the rSO_2 data presented in Figure 11. These summary statistics were calculated over the 10 min of PVT, the 5 min of TR, and the 2 min of WL for each evaluator, which were then averaged over the group of evaluators.

Table 8. Summary of rSO_2 Averaged over All Evaluators for Each Test at Each Altitude

Altitude	**Test**	***Mean***	***SEM***	***SD***
GL	PVT	76.5	0.12	6.94
	TR	75.6	0.16	6.31
	WL	72.6	0.26	6.72
14,000 ft	PVT	70.4	0.10	5.48
	TR	69.8	0.15	5.88
	WL	67.1	0.28	7.04
17,800 ft	PVT	70.5	0.09	5.27
	TR	70.3	0.15	6.08
	WL	68.6	0.29	7.44

The summary statistics presented in Table 8 collapse rSO_2 over time, but the duration of the altitude exposure is crucial for the evaluation of PHODS performance. To assess the role of duration, a least square regression was fit for each evaluator's rSO_2 for each task as a function of task duration. This regression provided the slope of rSO_2 over the duration of the task. Thus, for each of the three tasks at each of the three altitudes, a linear regression over time calculated rSO_2 slope for each evaluator, which was then averaged for the group. These average slopes, shown in Table 9, are rate of change of rSO_2 per min unit time.

Table 9. Average Slope of rSO_2 Over Task Duration

Altitude	**PVT**	**TR**	**WL**
GL	0.04473	0.06977	-0.71755
14,000 ft	0.00862	-0.10685	-1.13480
17,800 ft	0.04566	-0.21352	-2.10030

The slopes in Table 9 were evaluated to determine whether they would support a parametric, two-factor repeated measures ANOVA. These data did not meet the required assumptions without a standard transformation. Since the transformed data did meet the assumptions of homogenaity and normalcy, a two factor repeated measures ANOVA tested the null hypothesis that rSO_2 slope is unaffected by either altitude and/or task. The ANOVA output summary table (Table 10) shows a significant effect of task ($F(2, 160) = 193.66$, $p < 0.01$) as well as a significant interaction between altitude and test ($F(4,160) = 2.52$, $p = 0.04$).

Table 10. Summary of rSO_2 Averaged over All Evaluators and Tasks

Source	***df***	***Sum of Squares***	***Mean Squares***	***F-ratio***	***p-value***
Altitude	2	3.5	1.74	1.94	0.15
Task	2	347.6	173.78	193.66	< 0.01
Altitude:Task	4	9.0	2.25	2.51	0.04
Error	160	143.6	0.90		

Interaction plots, as shown in the two panels of Figure 12, facilitated the interpretation of these statistical analyses. The left panel shows rSO_2 slope for each task with the altitude as the parameter while the right panel shows rSO_2 slope at each altitude with the task as the parameter. The graph in the left panel shows no evidence that rSO_2 slopes during the PVT and the TR tasks differ among the three altitudes whereas the rSO_2 slopes during the WL task are different among the three altitudes. This difference is shown clearly in the right panel. The rSO_2 slopes over time for PVT and TR approximate zero across the three altitudes whereas the rSO_2 slopes for WL become increasingly negative with increasing altitude.

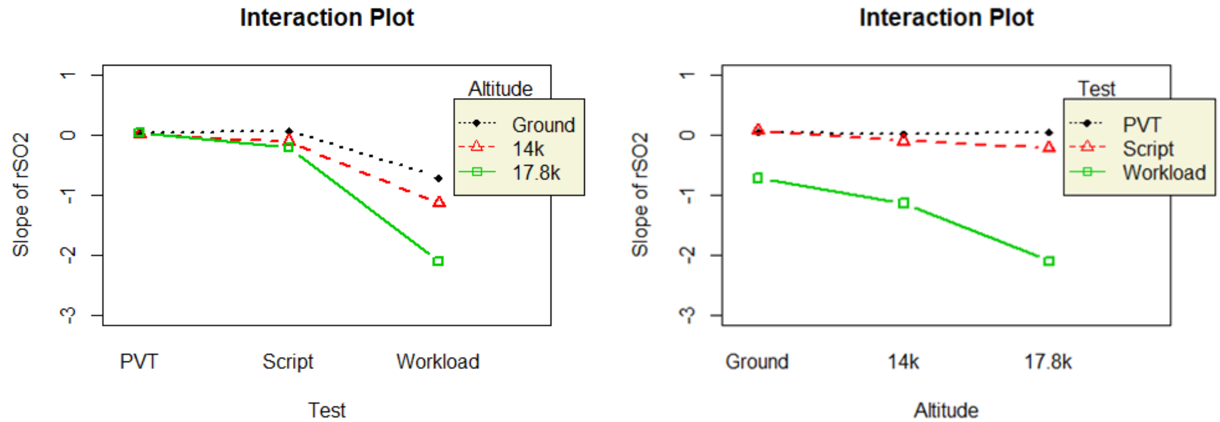

Figure 12. Interaction plots of the rSO_2 slope plotted from Table 9 with task as the parameter in the left graph and altitude as the parameter in the right graph.

As a follow-up, a one factor repeated measures ANOVA compared the differences in rSO_2 slope during WL task between altitudes. The results of the ANOVA are summarized in Table 11 confirming that the slopes of the rSO_2 are significantly affected by altitude during the WL task, ($F(2, 40) = 4.28$, $p = 0.02$).

Table 11. ANOVA Summary

Source	***df***	***Sum of Squares***	***Mean Squares***	***F-ratio***	***p-value***
Altitude	2	9.16	4.579	4.28	0.02
Error	40	42.76	1.069		

Post-hoc analysis of the WL data showed: (1) slopes at GL and 14,000 ft PA were not statistically different; (2) slope at 17,800 ft PA was significantly more negative than at GL although (3) slopes at 14,000 ft PA and 17,800 ft PA were not statistically different; furthermore, (4) slope at GL did not differ significantly from zero whereas (5) slopes at 14,000 ft PA and 17,800 ft PA did differ significantly from zero.

Discussion

The present T&E assessed the ability of the PHODS to maintain adequate blood oxygen saturation at PA of 14,000 ft and at 17,800 ft, both generated in an altitude chamber. In addition, data collected during the familiarization and rehearsal of the testing procedure at GL (327 ft) provide insights that aid the interpretation and evaluation of the altitude data even though the evaluators were still inexperienced with testing procedures.

At each altitude, three tasks challenged the PHODS' ability to provide and maintain adequate blood oxygen saturation. The first challenge was 10 min of the PVT that, while not imposing any physical exertion or movement, did impose the challenge of a tedious task while encouraging sedentary behavior. The second challenge was 5 min of vocalized TR. The TR challenged the PHODS performance by disrupting normal nasal breathing by imposing mouth breathing consequent to vocalized speech. Vocalization is an important potential challenge to the PHODS performance since the device typically delivers supplemental O_2 via a nasal cannula and thus depends upon nasal inhalation. The third challenge was 2 min of continuous, self-paced, in-place, knee bend squats as a surrogate physical WL demand that confronts non-Pilot aircrew.

The T&E data presented in Figures 9 and 11 show, respectively, SpO_2 and rSO_2 averaged over evaluators as a function of time in min for the 9 (3 altitudes by 3 tasks) test conditions. The SpO_2 and rSO_2 data were collected at the same time so they show, respectively, the simultaneous peripheral and cerebral blood oxygen saturations during identical stimulus conditions. The testing schedule and specifics of the stimulus conditions are listed in Table 3. The three upper coordinates in Figures 9 and 11 reflect blood oxygen measures made during the GL familiarization stage. The PHODS was set to the "OFF" position on the OPC-M1 during this familiarization stage, but the nasal cannula was in place in the nares. The top left hand coordinate set in Figures 9 and 11, plotting the 10 min of PVT data, were collected first. The upper center coordinates in the figures, plotting the 5 min of TR data, were recorded immediately following the PVT data. Lastly, the upper right coordinates in the figures plot the 2 min of WL data, which were recorded immediately following the TR data. Thus, these data were collected sequentially as were the data recorded at 14,000 ft PA and the data at 17,800 ft PA. The sequential nature of the data collection make it necessary to consider the influence of order effects while interpreting these data.

The GL data plotted in the upper three coordinates in Figure 9 have several notable characteristics. The slope of the SpO_2 is essentially flat over time for the PVT, TR, and WL. The statistical tests summarized in Table 6 along with the summary graphs of Figure 10 corroborate this impression. Furthermore, the mean SpO_2 values are within a normal expected range for GL although the values during WL are slightly less and more erratic than the values obtained during the PVT and TR tasks. These differences in SpO_2 between the WL data and the PVT and TR data may reflect the transitions of evaluators from the TR to the WL task. To perform the WL task, the evaluator cohort, usually four individuals, got to their feet in the confined chamber space, positioned themselves as guided by the pair of TMs while ensuring that the numerous cables and hoses attached to each evaluator remained free and intact. At GL, the transition from TR to WL was the most uncertain, precarious, and disruptive since this was the first time the evaluators performed the transition between tasks. The primary purposes of the GL conditions were to rehearse the transition at GL so they would be executed without incident during the altitude testing and to provide physiological baseline reference data. Thus, the most likely interpretation of the various features evident in the plot of the upper right in Figure 9 is that the features reflect variability and uncertainty in the data collection rather than a physiological characteristic.

The rSO_2 data plotted in Figure 11 support similar observations. Notably, the mean rSO_2 recorded during the PVT and TR are within one unit of each other and have a negligible slope.

While the mean rSO_2 during WL is less by about three units and has a steeper slope, the statistical tests summarized in Tables 10 and 11 support the conclusion that the slopes of the PVT, TR, and WL are not statistically different from each other nor from zero. The uncertainty introduced by the transition from TR to WL, due possibly to the inexperience of the evaluators mentioned in the previous paragraph, makes the drop in mean rSO_2 between TR and WL difficult to interpret. Regardless, the mean rSO_2 values recorded during the PVT and TR can be compared with the respective SpO_2 values recorded during the PVT and TR, showing that a mean rSO_2 of about 76 units is associated with an SpO_2 of about 97%.

Following the WL task at GL, the altitude chamber decompressed to 14,000 ft PA, at a rate of 1000 ft/min, imposing a period of inactivity of about 14 min followed by a 5 min acclimation period. The PHODS nasal cannula was in place during the GL data collection. At the beginning of ascent, the PHODS was set to “ON” on the OPC-M1 so that when PA reached 8000 ft $\pm$ 500 ft the PHODS began providing supplemental oxygen as determined by its controlling algorithm. During ascent, the evaluators remained seated and inactive so that nearly 15 min of inactivity lapsed between the completion of the WL data at GL and the beginning of the PVT data collected at 14,000 ft PA.

The middle three graphs plotted in Figures 9 and 11 show respectively the SpO_2 and rSO_2 recorded during the PVT performance at 14,000 ft PA. The SpO_2 slope over the PVT is essentially flat (-0.128) while the mean SpO_2 has dropped to about 91.6% from the GL value of 97.7%. Notably, Figure 11 shows that the rSO_2 collected during the PVT task are also essentially flat (0.009) while the mean value has dropped to about 70.4. Within a min of completing the collection of the PVT data, the TR data collection began. The TR slopes for the SpO_2 and rSO_2 during the TR are again essentially zero (0.014 and -0.107, respectively). The average rSO_2 recorded during the TR is about 69.8. These data clearly show that at 14,000 ft PA, the PHODS does not maintain either peripheral or regional cerebral blood oxygen levels equivalent to normal GL. The drop of about 6% in SpO_2 is associated with a drop of nearly six units in rSO_2.

At 14,000 ft PA, the average SpO_2 during the PVT was about 2% less than during the TR. This difference may be the consequence of 14 min of ascent and the 5 min of acclimation during which the evaluators remained physically inactive followed by another 10 min of inactivity during the PVT task. Shallow breathing consequent to the extended, physical inactivity may have contributed to the low SpO_2 relative to the values found during TR. For the transition from PVT to TR, the evaluators remained seated but repositioned themselves, and interacted with the two TMs, returning the PVT device to the TMs and taking the printed text sheet to read aloud. Thus, there was at least upper body moment that may have stimulated blood flow. Notably, this effect, if real, was limited to the SpO_2; rSO_2 was unchanged.

After TR task data collection, the WL task challenged the PHODS. For these measurements, the TMs assisted the evaluators in substituting the PHODS mask for the nasal cannula and switching the PHODS to the “F20” operating mode on the OPC-M1, appropriate for mask use as specified in Table 3. Following these changes in configuration, the evaluators generated the SpO_2 and rSO_2 data plotted as the last set of coordinates in the middle row of Figures 9 and 11, respectively. Notably, SpO_2 and the rSO_2 data over time had a negative slope. However, the statistical tests summarized in Table 7 along with the summary graphs of Figure 10 show that the slope of the SpO_2, (-0.569), though negative, was not significantly statistically different from the slopes found during the PVT and TR tasks. Thus, it is hard to argue for a significant decrease in SpO_2 over the 2 min of WL. On the other hand, while the negative rSO_2 slope (-1.13) over the 2 min of the WL interval is not statistically different from the rSO_2 WL slope (-0.718) at GL, the slope is statistically steeper than zero and not statistically different from the slope measured during WL at 17,800 ft PA, (-2.100). We conclude that at 14,000 ft PA, while the PHODS maintained a constant SpO_2 during WL, cerebral oxygen levels fell, a clear indication that the SpO_2 need not reflect rSO_2. Furthermore, while the use of the PHODS mask during WL makes it difficult to compare SpO_2 or rSO_2 between the WL data and the PVT and TR data collected with the nasal cannula, it is noteworthy that the WL SpO_2 (93.8) is nearly identical to that measured during the PVT (91.5) and TR (93.8). On the other hand, the average rSO_2 during WL (67.1) is lower than that during the PVT (70.4) and TR (69.8). Thus, rSO_2 started out lower and continued to fall during the 2 min of WL.

At the completion of the WL testing, but before ascending to 17,800 ft PA, (Table 3) the evaluators switched from breathing PHODS supplemental oxygen to chamber oxygen for a 30 min pre-breathing period prior to ascent, in accordance with Army Regulation 95-1 to reduce the body's reservoir of nitrogen. This is a precaution against the possibility of developing altitude decompression sickness during exercise near 18,000 ft PA. Following the 30 min pre-breathing, the chamber decompressed to a PA of 17,800 ft at a rate of 1000 ft/min. Upon reaching 17,800 ft PA, the evaluators breathed chamber air without supplemental oxygen for 5 min to acclimate to the altitude and reduce the accumulated oxygen. This was followed by a 1 min period breathing PHODS supplemental oxygen using the nasal cannula. The PHODS testing then commenced with the PVT, TR, and WL tasks as before. The SpO_2 and rSO_2 recorded during these tasks are the lower trio of graphs in Figures 9 and 11 respectively.

The SpO_2 recorded during the PVT shows a slope of -0.101, which does not differ statistically from the slopes found at the 14,000 ft PA or GL, as can be seen in Figure 10 and Table 7. The rSO_2 slope during PVT shows a distinct linear increase over the first 250 seconds or so of the PVT. This increase in rSO_2 over time suggests the possibility that without supplemental oxygen during the 5 min of acclimation to 17,800 ft PA, regional cerebral oxygen decreased; and that the PHODS (with the nasal cannula) replenished the lost oxygen over the 1 min prior to PVT testing and the first four or so min of PVT testing. The slopes remain essentially constant during TR for both the SpO_2 and rSO_2 data. Following the TR tasks, the PHODS masks replaced the nasal cannula and the PHODS was switched to “F20” on the OPC-M1 as per the manufacture's recommendations in the user manual for situations involving WL. Both the SpO_2 and rSO_2 data recorded during WL with the PHODS in this configuration show a negative slope over time. Notably, the slope describing the drop in SpO_2 over time (-0.248) was not statistically different from the SpO_2 slopes for any of the testing conditions used. On the other hand, the slope describing the drop in rSO_2 over time during WL (-2.10), a factor of 10 steeper than the SpO_2 slope, was significantly greater than the slope found at GL, as summarized in Figure 12 and Table 11. This slope suggests a drop in rSO_2 of one unit per min.

The average SpO_2 values were essentially indistinguishable across the three test conditions at 14,000 ft PA and 17,800 ft PA. Thus, at altitude, the PHODS maintained the average SpO_2, albeit at a value of about 7 to 9% lower than normally seen at GL. These values were all above 90%, which is the conventional benchmark on the oxygen disassociation curve below which the drop in blood oxygen saturation becomes precipitous and thus can rapidly become dangerous. Using the metric of SpO_2, the PHODS in its appropriate, manufacturer recommended configurations, seems to maintain adequate oxygenation since the SpO_2 were all above the 90% threshold. Thus in the presence of the PHODS supplemental oxygen, a drop in SpO_2 from that at GL to that at either 14,000 ft PA or 17,800 ft PA was relatively constant at 7 to 9%. For the rSO_2, magnitude drop was associated with a drop of approximately six to seven rSO_2 units. During the PVT and TR tasks, the PHODS maintained the rSO_2 values relatively constant. However with the introduction of physical WL, the rSO_2 values dropped over time with a slope that was greater at the higher altitude. This finding suggests that the magnitude of the drop is a function of altitude. In Figure 11, the dropoff in rSO_2 with WL appears evident within 40 seconds. The systematic differences between SpO_2 and rSO_2 speak to the validity and accuracy of using finger pulse oximetry and its limitations under certain conditions and in certain environments. Further tests would be necessary to establish the time course and characterize the effect of WL, and the interdependencies of altitude, oxygen consumption, hyperventilation, and recovery.

Conclusions

1. When used in accordance with the manufacture's recommended configurations for PAs of 14,000 ft and 17,800 ft, the PHODS maintained SpO_2 at levels generally recognized as adequate, albeit at levels lower than expected at MSL.
2. Similarly, when used in accordance with the manufacture's recommended configurations for PAs of 14,000 ft and 17,800 ft, the PHODS maintained peripheral blood oxygen saturation when challenged by 2 min of physical WL as well as speech-imposed interruptions of nasal breathings.
3. The results obtained with regional cerebral blood oxygen are more complicated, reflecting a disassociation of SpO_2 from rSO_2; that is, SpO_2 does not predict rSO_2.
4. At 17,800 ft PA there is a suggestion that, under the conditions of the present experiment, regional cerebral blood oxygen may recover more slowly than peripheral blood oxygen saturation.
5. During 2 min of physical WL at 14,000 ft PA and 17,800 ft PA, there is evidence that the PHODS did not sustain the regional cerebral blood oxygen levels; rather, the regional cerebral blood oxygen fell over time.
6. The steepness of the fall in regional cerebral blood oxygen levels was less during workload at 14,000 ft PA than at 17,800 ft PA, suggesting that the rapidity of the drop-off is not a constant but rather is dependent on altitude.
7. The time course of the decrease in regional cerebral blood oxygen, its severity, and recovery are yet to be determined.

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Abbreviations

ACE	Airworthiness Certification and Evaluation
ANOVA	Analysis of Variance
COTS	Commercial of the Shelf
F20	Face Mask PHODS setting
ft	Feet
GL	Ground Level
IR	Infrared
msec	millisecond
MSL	Mean Sea Level
NIRS	Near IR Transcranial Spectroscopy
O_2	Oxygen
OPC-M1	PHODS automatic oxygen pulse controller
PA	Pressure Altitude
P_aCO_2	Partial pressure of arterial carbon dioxide
PHODS	Portable Helicopter Oxygen Delivery System
PVT	Psychomotor Vigilance Test
P_aCO_2	Partial pressure of arterial carbon dioxide
R/M	Reserve Manual Mode PHODS setting
rSO_2	regional cerebral blood oxygen saturation
SD	Standard Deviation
SEM	Standard Error of the Mean
SpO_2	peripheral blood oxygen saturation
T&E	Test and Evaluation
TM	test Managers
TR	Text Reading
USAARL	United States Army Aeromedical Research Laboratory
USASAM	United States Army School of Aviation Medicine
WL	Work Load
WPG	Warfighter Performance Group

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