



NAVAL MEDICAL RESEARCH UNIT DAYTON

***AN EVALUATION OF THE ELBIT CANARY AND  
DYNASENSE POCKETNIRS IN-FLIGHT  
PHYSIOLOGICAL MONITORING SYSTEMS***

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Although a wide array of sensors monitor the state of an aircraft, pilots are made to monitor themselves. Currently, pilots must recognize and respond to hypoxic events after physiological effects have already begun. Physiological sensors are required in order to alert pilots to possible hypoxia prior to impairment. This study evaluated two physiological sensor systems in order to determine their accuracy and sensitivity during exposure to acute hypoxic conditions: the Canary system (Elbit, Israel) and the PocketNIRS Duo (DynaSense, Japan). We found that the Canary system generally performed well. The Canary was faster to reach 90% blood oxygen saturation during hypoxic conditions compared to a traditional finger oximeter, but demonstrated more frequent heart rate signal loss vs. the finger oximeter. The PocketNIRS sensor appeared to collect data reliably and displayed the expected physiological changes during hypoxic exposures, but we noted considerable signal drift over time and the magnitude of physiological changes was less than observed using a separately validated NIRS system. Overall we feel that both the Canary and PocketNIRS systems show potential, but the Canary system is closer to maturity.

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## Evaluation of Elbit Canary and DynaSense PocketNIRS

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### **Abstract**

A complex network of sensors monitor vital systems aboard an aircraft, but the most important component (the pilot) is left to monitor themselves. Currently, pilots must recognize and respond to hypoxic events after physiological effects have already begun. Physiological sensors are required in order to alert pilots to possible hypoxia prior to impairment. This study evaluated two physiological sensor systems in order to determine their accuracy and sensitivity during exposure to acute hypoxic conditions: the Canary system (Elbit, Israel) and the PocketNIRS Duo (DynaSense, Japan). We found that the Canary system generally performed well. The Canary was faster to reach 90% blood oxygen saturation during hypoxic conditions compared to a traditional finger oximeter, but demonstrated more frequent heart rate signal loss vs. the finger oximeter. The PocketNIRS sensor appeared to collect data reliably and displayed the expected physiological changes during hypoxic exposures, but we noted considerable signal drift over time and the magnitude of physiological changes was less than observed using a separately validated NIRS system. Overall we feel that both the Canary and PocketNIRS systems show potential, but the Canary system is closer to maturity.

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## **Introduction**

Modern aircraft utilize many sensors and alarms to monitor the state of vast arrays of aircraft systems with the exception of the most vital system, the pilot. Pilots are expected to monitor themselves. The aviation community has long recognized hypoxia and other physiological threats as a danger, but pilots lack a reliable physiological sensor to alert them to the presence of possible hypoxic conditions. Just as sensors monitor an aircraft, physiological sensors would be ideal for monitoring the pilot in real-time and detecting potential hypoxia prior to severe impairment. The ideal sensor will accurately capture physiological data in the flight environment and respond to physiological changes quickly enough to facilitate pilot response before impairment, while avoiding false alarms. This study evaluated two such sensors: the DynaSense PocketNIRS Duo and the Elbit Canary.

Physiological threats such as hypoxia continue to jeopardize both aircrew and the operational readiness of aircraft. Although the 2011 grounding of the F-22 is the most obvious example of the negative effect that hypoxia-like incidences pose to operational readiness, the F-18 and recently the F-15 communities have experienced numerous incidents as well. Symptom onset can be gradual and insidious, causing impairment before the pilot realizes what has happened. An external warning system is necessary in order to detect physiological changes and alert the pilot to possible danger.

The lack of such a warning system means that current hypoxia training emphasizes the recognition of symptoms. Symptoms resulting from hypoxia include deficits in visual processing, attention, reaction time, and motor control (Artino, Folga, & Swan, 2006; Fowler, Banner, & Pogue, 1993; Fowler, Taylor, & Porlier, 1987; Fowler, White, Wright, & Ackles, 1982). Pilots under the current paradigm must notice their symptoms, recognize that they are

indicative of hypoxia, and initiate the appropriate emergency procedures. Pilots are therefore placed in a situation where they must react to an emergency in an already impaired state, rather than take action proactively to remove themselves and the aircraft from danger. Each of the previously mentioned impairments reduces the pilot's ability to safely execute emergency procedures. Sensors to monitor blood oxygen levels and heart rate would help detect the presence of hypoxic conditions and allow the pilot to take corrective action earlier, before more severe symptoms appear. Such sensors would also shift the diagnostic burden away from a pilot in the midst of a physiologic emergency. The remainder of the introduction describes the two types of sensors under consideration in this comparison, followed by a discussion of where best to place such sensors on the body and an overview of the two specific sensors evaluated here.

### *Types of sensors*

Two types of blood oxygen sensors appear well suited for this purpose: near-infrared spectroscopy (NIRS) sensors and reflectance oximeters. Each type of sensor relies on light to measure the properties of tissues.

### *Near-Infrared Spectroscopy (NIRS)*

NIRS is a non-invasive sensor that measures regional oxygen levels via light passed through the skull and underlying tissues. NIRS light frequencies are able to penetrate bone and can thus measure the perfusion of tissues such as the brain. The device emits light into the tissue, and the returned light is measured by two separate sensors at different distances from the light source. The depth of penetration by the light is a function of the distance between the source of the light and the sensor; NIRS can therefore measure cerebral oxygen saturation without interference from the skin, skull, or subcutaneous tissue (Casati, Spreafico, Putzu & Fanelli, 2006). Saturation is calculated based on the known light absorbing properties of oxygenated and

deoxygenated blood. NIRS systems can be excellent trend monitors to detect decreases from baseline.

### *Reflectance oximeters*

Reflectance oximeters shine red and infrared light through the skin and measure the amount of light that returns. While traditional pulse oximeters rely on light shined *through* tissue to a sensor on the other side, reflectance oximeters rely on reflected light returning to the source. Reflectance oximeters can therefore be placed nearly anywhere on the body, as opposed to traditional pulse oximeters that must be placed on a thin structure such as a finger or earlobe (Phillips, Warner, & Geyer, 2016).

Oxygenated and deoxygenated blood have different color properties, resulting in varying rates of light absorption (Phillips, Warner, & Geyer, 2016). Reflectance oximeters analyze the light reflected by the hemoglobin in the vessels as it interacts with the different wavelengths of light emitted from the sensor, using an algorithm to determine oxygen saturation (Rusch, Sankar, & Scharf, 1996; Wukitsch, Petterson, Tobler, & Polage, 1988). The signal from the reflected light is divided into two categories: a pulsatile flow signal (PFS) and a non-pulsatile flow signal (NPFS). The PFS and NPFS are calculated using differences in absorption across the wavelengths of light; the PFS is based on light absorbed in pulsating arterial blood while the NPFS is based on the light absorbed in venous blood, bone, and other tissue. The PFS is isolated from the NPFS and oxygen saturation is determined based on known reference values (Phillips, Warner, & Geyer, 2016). A more complete review can be found in Wagner & Ruskin (2007).

### *Sensor location*

In addition to the type of sensor, one must consider where the sensor should be placed. The temperature fluctuations, G forces, and manual requirements of flight can seriously impact the accuracy of physiological monitors placed on certain portions of the body. Anatomical considerations must also be taken into account. Candidate locations for physiological sensors have included the finger, arm, neck, temple, and ear canal (Phillips, Warner, & Geyer, 2016). Each of these locations can be problematic, however.

Pulse oximetry on the finger has been the standard in clinical settings for many years. However, pulse oximetry on the finger in an aviation environment leads to very poor data quality. Cool temperatures can cause vasoconstriction in the fingers, and manual tasks can restrict arterial blood. These issues make it difficult for the sensor to obtain a strong enough signal to accurately calculate blood oxygen concentrations (Phillips, Warner, & Geyer, 2016). Further, optimum quality of the pulse oximeter signal requires the hand to be at heart level, resting on a soft surface. These conditions do not exist in the flight environment and even something as simple as moving the arm while walking can lead to spurious desaturation readings (Phillips, Warner, & Geyer, 2016). The blood vessels of the finger and hand are also separate from those of the central nervous system, making it difficult to capture likely saturation in the brain. In addition, placing a pulse oximeter on the finger or other location on the hand may reduce manual dexterity and interfere with a pilot's ability to manipulate the flight controls.

These issues with placing a pulse oximeter on the finger caused researchers to explore other possible locations on the body, particularly on and around the head such as the ear, ear canal, temple, and forehead. In addition to avoiding some of the issues associated with sensors on the finger, centrally-located sensors (such as on the head) are also considered to be a more accurate indicator of brain oxygen concentrations and thus potentially a more accurate indicator

of cognitive function (Simmons, Chandler, & Horning, 2010). Sensors must be placed carefully, however, or accuracy problems will arise.

As with the finger or arm, the ear and ear canal are supplied by peripheral arteries rather than arteries shared by the central nervous system. The ear and ear canal experience vasoconstriction in the presence of cold temperatures or G stress just as the vessels in the finger, potentially causing spurious readings. Further, oximetry data measured at peripheral tissue beds, such as finger based oximetry, has been shown to respond to hypoxia more slowly than oximetry measured at more centralized tissue beds such as the forehead (Simmons, Chandler, & Horning, 2010).

Physiological sensors should be placed such that they can measure central blood vessels, but even here care must be taken. Large blood vessels such as those in the temple can redirect reflected light, altering the ratio of light absorbed and leading to inaccurate readings of blood oxygenation (Mannheimer, O'Neil, & Konecny, 2004). Testing conducted in our own laboratory at the Naval Medical Research Unit – Dayton (NAMRU-D) using a reflectance oximeter over the temporal artery indicated significant disparities between this sensor and a pulse oximeter at the finger (Phillips, Warner, & Geyer, 2016).

One alternative location that allows the sensor to read central blood vessels without interference is the forehead. The regions above the outer portion of the eyebrows contain fields of cutaneous tissue perfused by the supraorbital artery. This artery is supplied by the interior carotid, which also supplies parts of the brain. If placed low on the forehead and above the eye, the sensor can avoid the supraorbital artery, yet still measure oxygenation from this central blood vessel (Phillips, Warner, & Geyer, 2016). Oximeters placed on the forehead allow faster

response time to oxygen deprivation, while remaining as accurate as traditional pulse oximeters at the finger (Simmons et al., 2010).

Placing the sensors on the forehead can avoid many of the problems associated with other locations. In addition, placing the sensors on the head eliminates any interference with the pilot's manual dexterity and reduces the chance of excessive pressure on the sensors. In the case of NIRS systems, the oxygenation of parts of the brain can be assessed directly as well.

#### *The systems under evaluation*

Two head-mounted sensors in particular are under development and have been selected for evaluation in this study. The first is the PocketNIRS Duo manufactured by DynaSense (Japan). This system is a small NIRS sensor integrating Bluetooth technology for wireless data transfer. The second is the Canary system manufactured by Elbit (Israel). The Canary system integrates a reflectance oximeter and a NIRS sensor along with accelerometers into a single unit worn on the forehead. Each of these systems was tested under multiple acute hypoxic conditions to evaluate reliability, performance under hypoxic conditions, and correspondence with previously validated physiological measures. Both the PocketNIRS and Canary systems were tested as stand-alone systems, but they are ultimately intended to be mounted within a pilot's helmet to provide real-time monitoring capabilities.

### **Method**

#### *Participants*

A total of 21 active duty military personnel assigned to Wright-Patterson Air Force Base, OH completed this study. Participants included 20 males and 1 female ranging in age from 22 to 37. Participants were screened prior to participation to rule out any medical conditions or lifestyle issues that may have compromised safety or confounded the results (e.g., asthma,

anemia, sickle cell trait, history of fainting, tobacco use, excessive alcohol use, etc.; the full list of screening criteria is included in Appendix 1). None of the participants were licensed pilots, but some did report an interest in flying and prior experience using flight simulators. Fourteen participants reported prior experience with hypoxia.

### *Apparatus*

#### *Reduced Oxygen Breathing Device (ROBD-2)*

Participants were exposed to normobaric hypoxia via the Reduced Oxygen Breathing Device (ROBD-2; Environics). The ROBD-2 is a gas blending device that uses thermal mass flow controllers to deliver mixtures of compressed breathing air, nitrogen, and oxygen to simulate altitudes between ground level and 34,000 feet without altering the barometric pressure experienced by participants. Gas mixtures were delivered through a standard aviation mask attached to a flight helmet via bayonet clips.

#### *Physiological monitoring*

The first set of sensors was the DynaSense PocketNIRS Duo. The system consists of a reusable NIRS sensor applied to the forehead via adhesive strips (supplied by DynaSense), connected to a transmitter powered by standard AAA batteries. The transmitter was linked to a control computer via Bluetooth for data storage and system control. The system monitors percent change in oxygenated hemoglobin, deoxygenated hemoglobin, and total hemoglobin in three separate readings on a single display. Although the system can accommodate two sensors simultaneously (one on each side of the forehead), we only utilized one. The single PocketNIRS sensor was worn on the participant's left side of the forehead during testing in this study.

This sensor was used in conjunction with a previously validated NIRS sensor (INVOS Cerebral Oximeter, Somanetics) worn on the participant's right side of the forehead. This sensor

calculates regional oxygen saturation (rSO<sub>2</sub>) as a single output value. The Somanetics sensor is intended to be single-use; however, participants wore the same sensor for the duration of the study due to sensor cost and availability (sensors were not shared across participants). The Somanetics NIRS sensor was attached via the sensor's integrated adhesive for the participants' first visit, and via eyelash adhesive for participants' subsequent visits. The eyelash adhesive was supplemented with medical tape or Coban wrap when necessary. This procedure has been used successfully in previous studies at our lab.

The second sensor suite was the Elbit Canary system, consisting of a reflectance pulse oximeter and NIRS sensor integrated into a single headband. The headband also integrates accelerometers in order to evaluate G stress. The Canary system is able to monitor arterial blood oxygen concentration (SpO<sub>2</sub>), perfusion, acceleration along the X-Y-Z axes, and PFS quality. The headband is connected to a circuit box powered by connection to a USB power source or via an internal battery pack charged through the USB power supply. The circuit box was attached to a control computer via one USB cable for data collection and system control, and a separate cable for power/battery charging. The Canary sensor was placed in the center of the participants' forehead. For the purposes of testing, the Canary system was always run using USB power rather than the internal battery pack.

Participants wore only the PocketNIRS/INVOS combination or Canary on the forehead during each testing session (i.e., the two sensor packages were not evaluated simultaneously on a single individual). Although an effort was made to keep the forehead sensor worn by each participant consistent across testing sessions, many participants wore multiple sensors over the course of the study due to technical difficulties with the Canary system and/or requirements to ship the DynaSense system elsewhere for concurrent evaluations.

SpO<sub>2</sub> and heart rate were also monitored using a standard pulse oximeter (Model 3900P, Datex Ohmeda Corp.) placed on the index finger of the left hand. This sensor was worn by all participants for every visit regardless of which sensor was worn on the forehead. Finger oximeters such as this one are the current standard of care in most clinical settings and allowed us to compare sensor performance to a known device.

### *Performance tasks*

As part of a concurrent effort examining the cognitive effects of hypoxia, participants simultaneously performed two cognitive tasks during the exposure profile: a flight task and a time estimation task. These tasks are described here for completeness but will not be discussed further in this report. The primary flight task consisted of maintaining a straight and level course on a heading of 90° at an altitude of 12,000 feet and an airspeed of 150 knots. Participants were instructed that all three parameters would count equally toward their performance score. Participants used only the control stick and throttle to fly the aircraft – all other controls and cockpit switches were disabled. The aircraft was untrimmed and a steady quartering wind was blowing from 45° at five knots. Participants flew over a simulation of the terrain around Fallon Naval Air Station, Nevada, with clear weather.

Participants also performed a secondary task consisting of estimating 10 second intervals. While flying, participants received a prompt to “Begin counting 10 seconds now” displayed on the outside-the-cockpit viewing monitor as well as broadcast through speakers mounted to the simulator. Prompts were randomly timed to occur between 20 and 30 seconds apart. After each prompt, participants started the timer by pressing a button on the control stick. When the participant estimated that 10 seconds had elapsed, the participant pressed the same button again to stop the timer. Upon activation/deactivation of the timer, the perimeter of the outside the

window monitor flashed red to acknowledge the button press. Other than this indication that the timer had been successfully activated/deactivated, participants did not receive feedback regarding the time estimation task. Participants were not instructed to prioritize one task over the other.

### *Flight simulator*

Participants performed tasks in a fixed-based flight simulator operated via X-Plane software emulating a T-6 Texan. The flight instruments were displayed on a 26 inch diagonal ELO monitor, while the outside-the-cockpit view was displayed on a 60 inch diagonal Samsung LED High Definition TV, providing an 87° wide by 49° high field of view. A FitPC3Pro drove the outside the window scene graphics. Participants sat in an open cockpit on a SPARCO seat adjustable for height and seat back angle. Control inputs were made via a Thrustmaster Cougar joystick and Thrustmaster Warthog throttle.

### *Study design and procedure*

#### *Design*

Hypoxia exposures followed a 2x2 within subjects single blind design (Figure 1). Each exposure profile consisted of two altitudes. Altitude Equivalent 1 was either sea level<sup>1</sup> or 25,000 feet normobaric equivalent. Altitude Equivalent 2 was either sea level or 10,000 feet normobaric equivalent. For all flight profiles, participants breathed sea level air for five minutes (Segment 1; S1), followed by Altitude Equivalent 1 for five minutes (Segment 2; S2), another five minutes of sea level air (Segment 3; S3), Altitude Equivalent 2 for 30 minutes (Segment 4; S4), and a final five minutes of sea level air (Segment 5; S5). Participants were blinded regarding which flight profile was administered on any given visit. The order of the flight profiles was counterbalanced

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<sup>1</sup> “Sea level” in this paper refers to ground level. The altitude of Wright-Patterson AFB where testing occurred is approximately 823 feet above sea level.

across participants using a Latin Square design. See Figure 2 for a depiction of each flight profile.

|                       |     | Altitude Equivalent 2 |     |
|-----------------------|-----|-----------------------|-----|
|                       |     | 0                     | 10k |
| Altitude Equivalent 1 | 0   | A                     | B   |
|                       | 25k | C                     | D   |

*Figure 1: Experimental design*

S1 allowed the participant to acclimate to breathing through the ROBD-2 and wearing the equipment prior to hypoxic exposure. S3 allowed the participant to return to normal SpO<sub>2</sub> between simulated altitudes (thus separating the two exposures and reducing attrition due to low SpO<sub>2</sub> or participant withdrawal). S5 allowed the researchers to verify that the participant returned to normal saturation levels prior to the end of the flight profile. The exposure times for Altitudes 1 and 2 were within the limits listed in the Time of Useful Consciousness table (DeHart, 1985), and are reasonable estimates of how long exposure to each altitude may last in an aircraft as the pilot must first recognize hypoxia (Altitude Equivalent 1), descend, and then fly to an airfield to land after removing the flight mask (Altitude Equivalent 2).

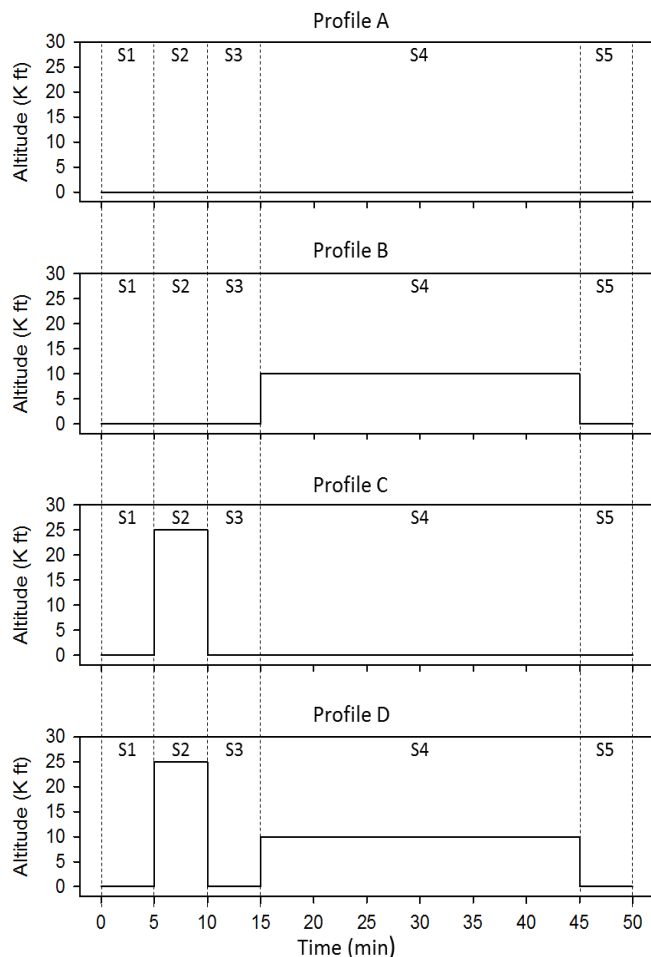


Figure 2: Exposure profiles for Conditions A, B, C, and D (see Figure 1 above), as well as the segments used for analysis.

### Arrival

Participants reported to the Naval Medical Research Unit – Dayton (NAMRU-D) on four separate occasions, experiencing a different exposure profile each visit. Visits were scheduled a minimum of 48 hours apart in order to ensure that the effects of hypoxia dissipated completely between visits. Upon arrival for their first visit to the laboratory, the participant was escorted to a wet lab where the study was explained and the participant had an opportunity to read the informed consent document and ask questions. After giving informed consent, participants

completed a brief questionnaire to confirm compliance with study requirements (Appendix 2), followed by a blood pressure check and a blood draw to ensure normal levels of hematocrit and hemoglobin (blood draw results remained valid for 72 hours; participants with prior medical clearance to become hypoxic due to routine hypobaric chamber or other exposures were exempted from the blood draws). Female participants were given a urine pregnancy test each visit to rule out pregnancy prior to any exposure. Following the informed consent, questionnaire, and physiological checks, participants were brought to the hypoxia lab to be fitted for a flight helmet and flight mask. After equipment fitting, participants were trained on the performance tasks and allowed to practice until they felt comfortable (approximately five minutes for most participants). Subsequent visits followed the same procedure except for the informed consent and equipment fitting.

#### *Hypoxia exposure*

Once participants indicated that they were comfortable with the flight task, the simulator was reset and the participant donned the helmet, flight mask, and physiological monitoring equipment. At this point the experimenters reminded the participant about the timing of the flight profile, gave the participant a five second countdown, and began the exposure. Participants performed both the flight task and the time estimation task for the entire duration of the exposure profile. In addition to the physiological sensors, participants were monitored via closed-circuit video as well as audio communication with the experimenters. Exposure to each altitude was terminated and the participant was advanced to the next sea level portion of the profile after the time limit was reached, if the participant's SpO<sub>2</sub> dropped to 55% at the finger or 60% at the forehead, if the participant became nonresponsive to verbal prompts, or if the participant requested to be brought back to sea level.

### *Recovery*

Upon completion of the flight profile, the experimenters disconnected the physiological monitoring equipment and escorted the participant to a break room where entertainment and snacks were provided. One hour and again two hours after the end of the exposure, the participant was reconnected to the monitoring equipment and completed a five minute flight while breathing sea level oxygen concentrations through the ROBD-2 (Recovery 1 and 2, respectively). Adhered sensors such as the NIRS systems remained in place on the forehead for the duration of the visit; other sensors were removed between follow up flights. The recovery flights were intended to monitor cognitive recovery from hypoxic exposures. We did not analyze the physiological readings as these were expected to return to baseline within minutes of return to sea level.

## **Results**

### *Analysis overview*

All data processing, including time line-up and calculation of physiological and outcome measure statistics, was performed in MATLAB (MathWorks, Inc.). Statistical tests were performed in SPSS (IBM). We applied a filter to the output for both sensors in order to reduce noise in the data and facilitate interpretation. This process is described in more detail below. We first describe the PocketNIRS results followed by the Canary results. Due to issues with the time stamps in the PocketNIRS data, we elected to use qualitative analyses based on representative case studies rather than quantitative comparisons in order to avoid interjecting subjective judgments into the analyses. Analyses of the Canary system followed a more traditional quantitative approach.

## *PocketNIRS*

### *Analysis description*

PocketNIRS data were collected using the PocketNIRS software provided with the device. A custom LabView program, housed on the same computer, was used to collect all other data streams relevant to this discussion (altitude, Somanetics NIRS, Ohmeda SpO<sub>2</sub>). These data will be referred to collectively below as LV data.

We also altered the Somanetics and Ohmeda data to make them compatible with the PocketNIRS data and facilitate analysis. Whereas the Somanetics system provides a single rSO<sub>2</sub> value as a data point, the PocketNIRS provides total hemoglobin, oxygenated hemoglobin, and deoxygenated hemoglobin as separate values. Further, rather than an absolute value, PocketNIRS outputs change from baseline. A representative from DynaSense informed us that PocketNIRS uses a modified Beer-Lambert Law to measure relative hemoglobin concentration changes, and that these values are difficult to use to estimate rSO<sub>2</sub> (L. Tripp, personal communication, September 8, 2016). Somanetics and Ohmeda signals were therefore converted from their raw values to percent change from baseline in order to facilitate comparisons with the PocketNIRS data.

The only processing performed on the PocketNIRS signals was smoothing, shifting (in time), and stretching (in time). Smoothing was performed in order to make plots more legible. PocketNIRS total hemoglobin (TotHB), oxyhemoglobin (OxyHB), and deoxyhemoglobin (DeoxyHB) signals were low-pass filtered using a 4<sup>th</sup> order, centered Butterworth filter with a frequency cutoff of 0.1 Hz.; the frequency cutoff was chosen to approximate the level of smoothing present in Somanetics NIRS and Ohmeda SpO<sub>2</sub> signals. Shifting and stretching were

performed in attempting to line up PocketNIRS and LV data. Further details are provided immediately below.

We noted marked inaccuracies in the elapsed time recorded by the PocketNIRS system, necessitating shifting and stretching of the data. Stretching of PocketNIRS signals occurred due to re-definition of elapsed time via first and last timestamps in PocketNIRS files. Time shifting was performed to line up PocketNIRS and LV data desaturation trends. Due to these issues in timekeeping, along with pronounced signal drift in the sensor, we were unable to perform quantitative comparisons between the PocketNIRS and the Somanetics systems. We therefore performed a qualitative evaluation. These issues and the results of the comparison are illustrated below in the form of two representative case studies. Below we also present vertically shifted segments of PocketNIRS OxyHB signals to remove the effect of device drift and in order to show the correspondence (or lack thereof) between the OxyHB and Somanetics NIRS signals. The complete set of plots is available in Appendix 3.

### *PocketNIRS results*

#### Case Study1: Subject 16, Profile D

*Time Line-up: Approach 1* - The PocketNIRS software enables users to mark events during an experiment. We used these event markers to indicate the start and end of LV data collection; only the first event marker was used for time line-up across the PocketNIRS and LV data. The first event marker was found in the PocketNIRS output file and the elapsed time at that point was used to zero out PocketNIRS elapsed time. Figure 3 shows that the first event marker lines up with LV data collection start, but that PocketNIRS elapsed time is inaccurate. PocketNIRS elapsed time ends about 12.5 min short of the full experiment run, and the PocketNIRS desaturation trends do not line up with LV altitude and desaturation trends.

Also of note in the PocketNIRS data is the upward drift of TotHB and OxyHB signals across the first several minutes. Upward drift in the Somanetics sensor signal during the first several minutes of operation has been noted in this and other experiments in our lab as well, but not to the degree seen in the PocketNIRS signals. OxyHB drifts at least 28% and TotHB at least 21% in this case. We will say more about this below.

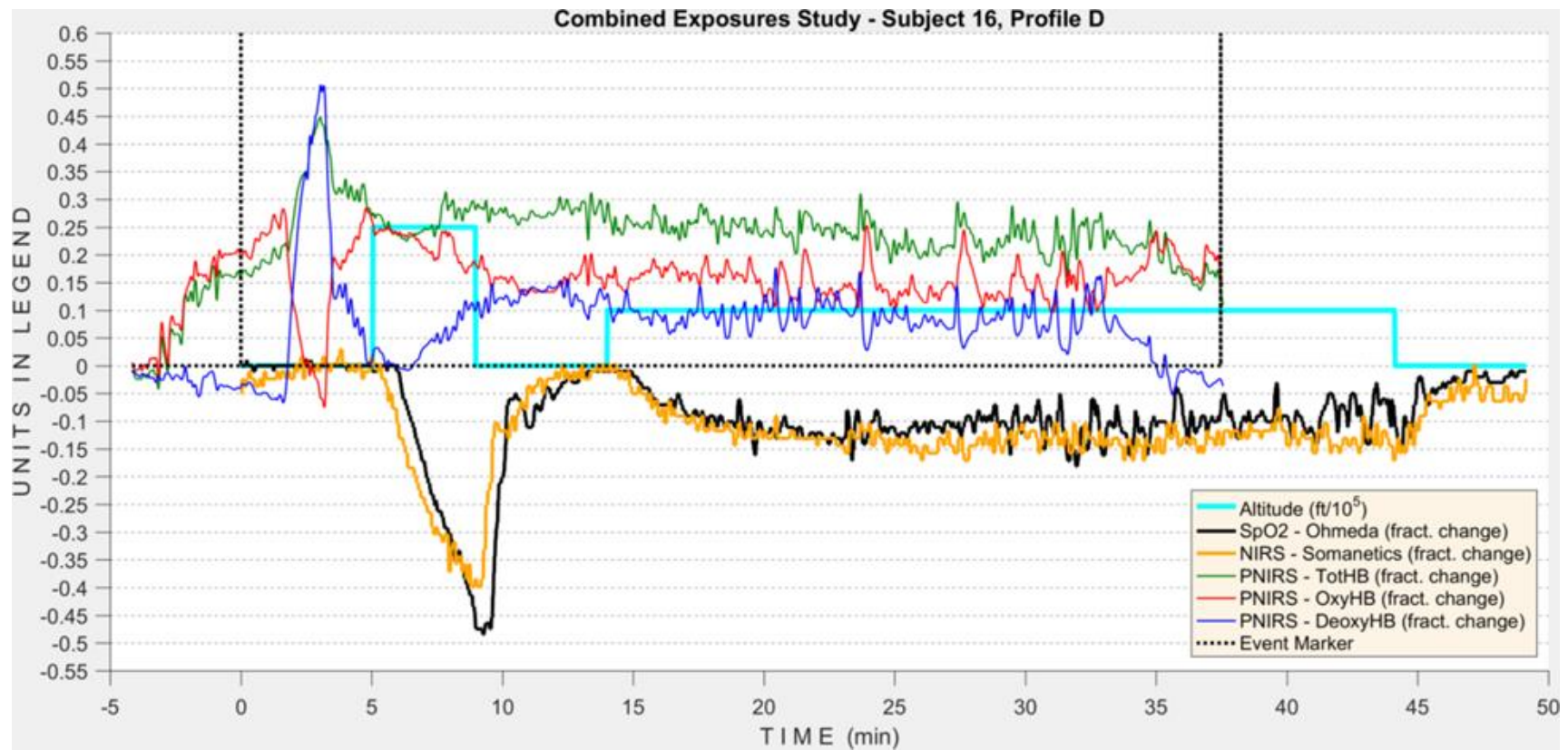


Figure 3. Plot of the PocketNIRS data vs. the Somanetics and Ohmeda data. Note the discrepancy between the endpoints of the data streams from the various sensors.

*Time Line-up: Approach 2* - Our second approach entailed calculating total elapsed time based on the first and last timestamps in the PocketNIRS file. We then created an equally incremented, artificial time vector. The MATLAB function 'etime' was used to calculate total elapsed time from the timestamps. The artificial time vector was zeroed out using the same method as previously described. Inspection of Figure 4 reveals that this method resulted in stretching of the PocketNIRS signals so that total elapsed time better matches LV data. However, the desaturation trends still do not line up.

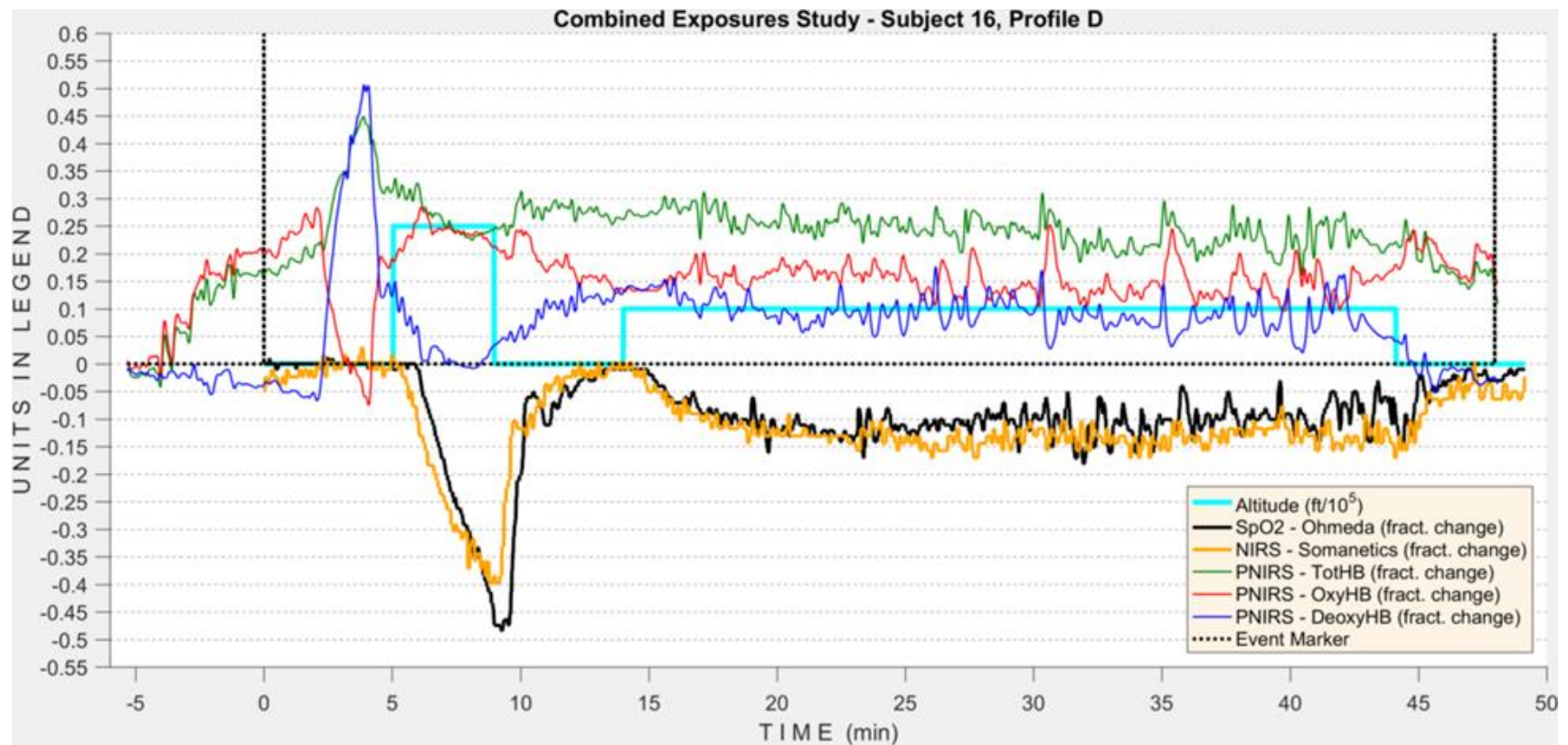


Figure 4. Plot of the PocketNIRS data vs. the Somanetics and Ohmeda data. Note that while the endpoints of the data streams are better aligned, the PocketNIRS desaturation events remain misaligned with the Somanetics and Ohmeda signals.

*Time Line-up: Approach 3* - In our third approach, we used the same artificial time vector, but ignored the event markers and lined up data according to the onset of desaturation trends during the 25,000 foot simulated normobaric exposure. Figure 5 shows the result. While the start of the desaturation trends now match up fairly well, the PocketNIRS desaturation event appears to be compressed in time. This is especially confusing considering that stretching the PocketNIRS signals in this manner causes the signals to be too long overall, overshooting the end of the experiment run by about 2 min. Furthermore, it is clear that attempting to apply a uniform “stretch factor” to the PocketNIRS data will not work, since this would result in even greater inaccuracy in the PocketNIRS end time and greater mismatch in the return to baseline trends (starting at approximately the 45 min mark in Figure 5).

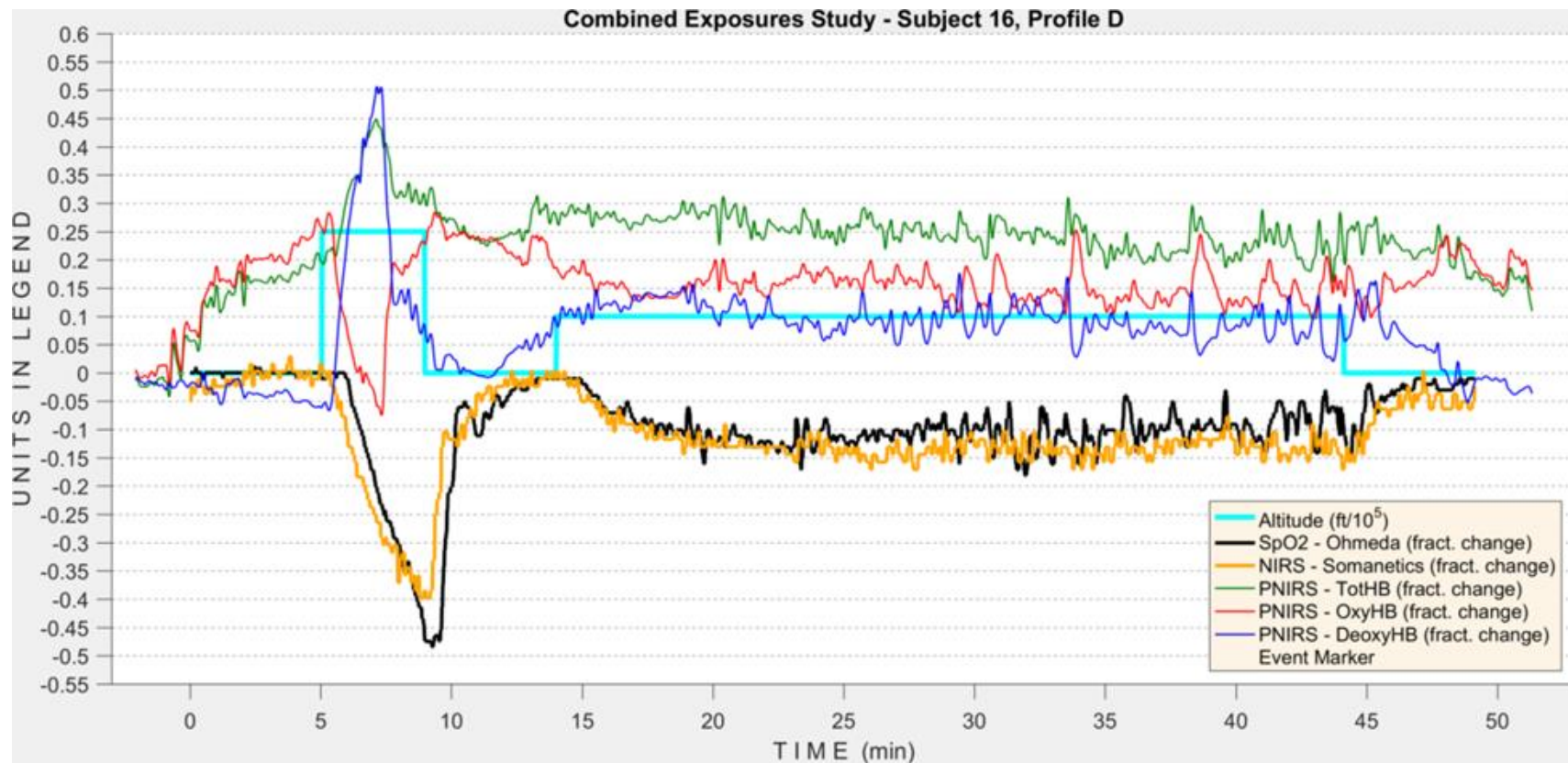


Figure 5. Plot of the PocketNIRS data vs. the Somanetics and Ohmeda data. Note that while the beginning of the desaturation event is better aligned across sensors, the PocketNIRS desaturation event is shorter than the Somanetics and Ohmeda events, despite a longer time period for the data file overall.

*Time Line-up: Segment Interpolation Method* - Because stretching the entire PocketNIRS signal uniformly was not a viable option, we used interpolation to stretch a segment of PocketNIRS data – specifically, the 25,000 foot simulated altitude desaturation event as registered by the PocketNIRS OxyHB signal. We also corrected for the apparent OxyHB signal drift by subtracting the peak value at the start of the desaturation from the entire interpolated segment. Interpolation was performed using the MATLAB ‘interp1’ function with the ‘pchip’ method. The end time for interpolation was based on a combination of signal features and trial and error.

Figure 6 shows the result. We have omitted superfluous signals for ease of viewing. Due to the subjective nature of this process, we decline to present any quantitative results regarding study-wide agreement between the PocketNIRS and Somanetics NIRS signals. In this case we can see that there is good agreement between the Somanetics NIRS and PocketNIRS signals after removal of PocketNIRS bias/time compression. This level of agreement, however, was rather exceptional relative to other comparisons in the data set.

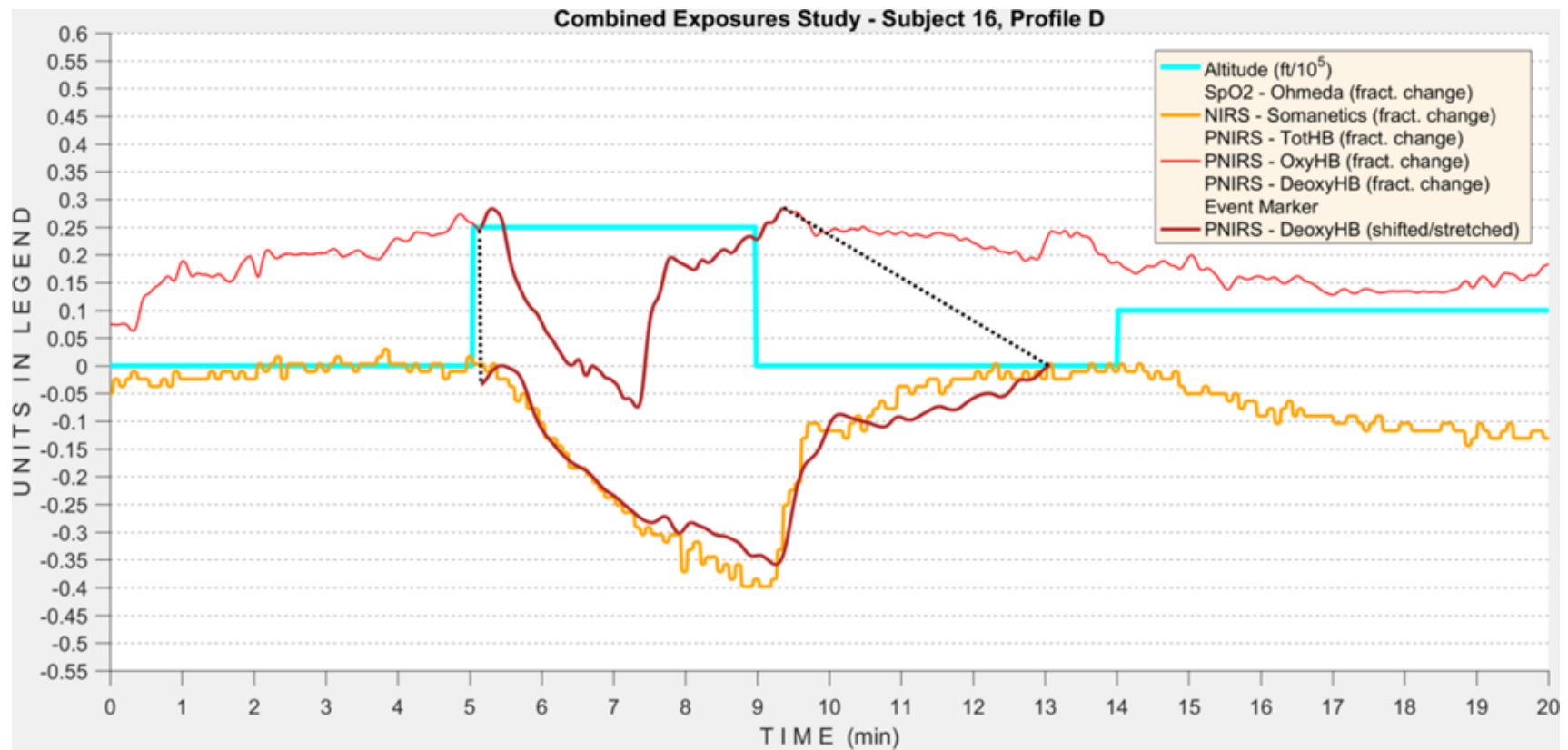


Figure 6. Plot of the stretched PocketNIRS data vs. the Somanetics data. After correcting for time and signal drift, this plot indicates good agreement between the two sensors. This level of agreement was not consistent across all data files, however.

Case Study 2: Subject 15, Profile C

Figure 7 displays the raw signals for this case. Elapsed time was calculated using first and last timestamps and then zeroed out to line up PocketNIRS/LV desat trends, as described above in Approach 3. Figure 8 displays a zoomed in view from 0 to 15 min, with all PocketNIRS signals zeroed out at the start of the 25,000 foot simulated exposure. In this case, the OxyHB signal drift appears to persist from approximately the beginning of the file up to approximately 13 min. This trend is nearly perfectly linear. The observed drift appears to contribute to a large amount of inaccuracy in the PocketNIRS signals, judging by the extent of the mismatch between OxyHB and Somanetics NIRS. (Note the good agreement between Somanetics NIRS and Ohmeda SpO2 signals. This was typical across subjects and bolsters our confidence in the accuracy of the Somanetics NIRS signal.)

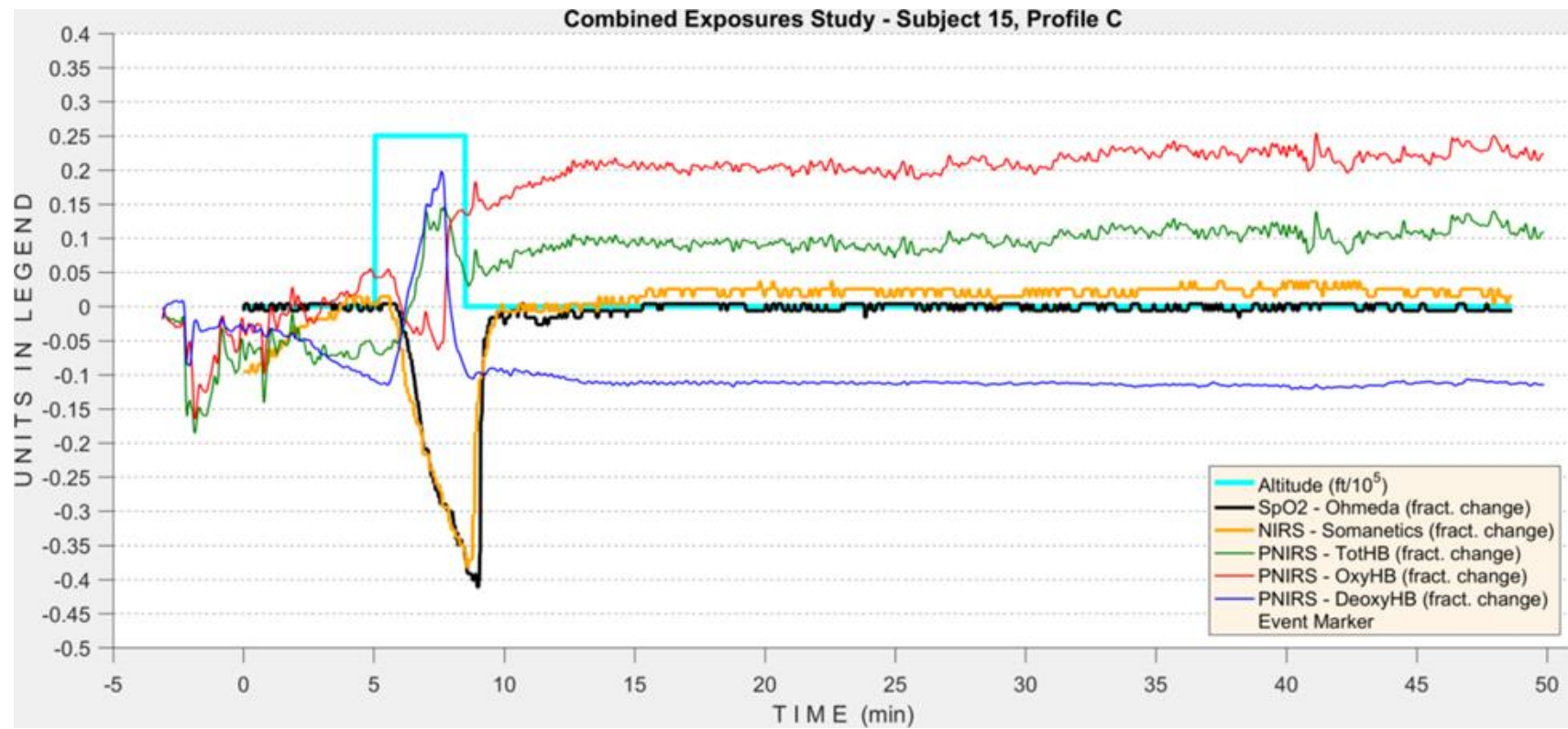


Figure 7. Raw PocketNIRS, Somanetics, and Ohmeda data for subject 15, profile C

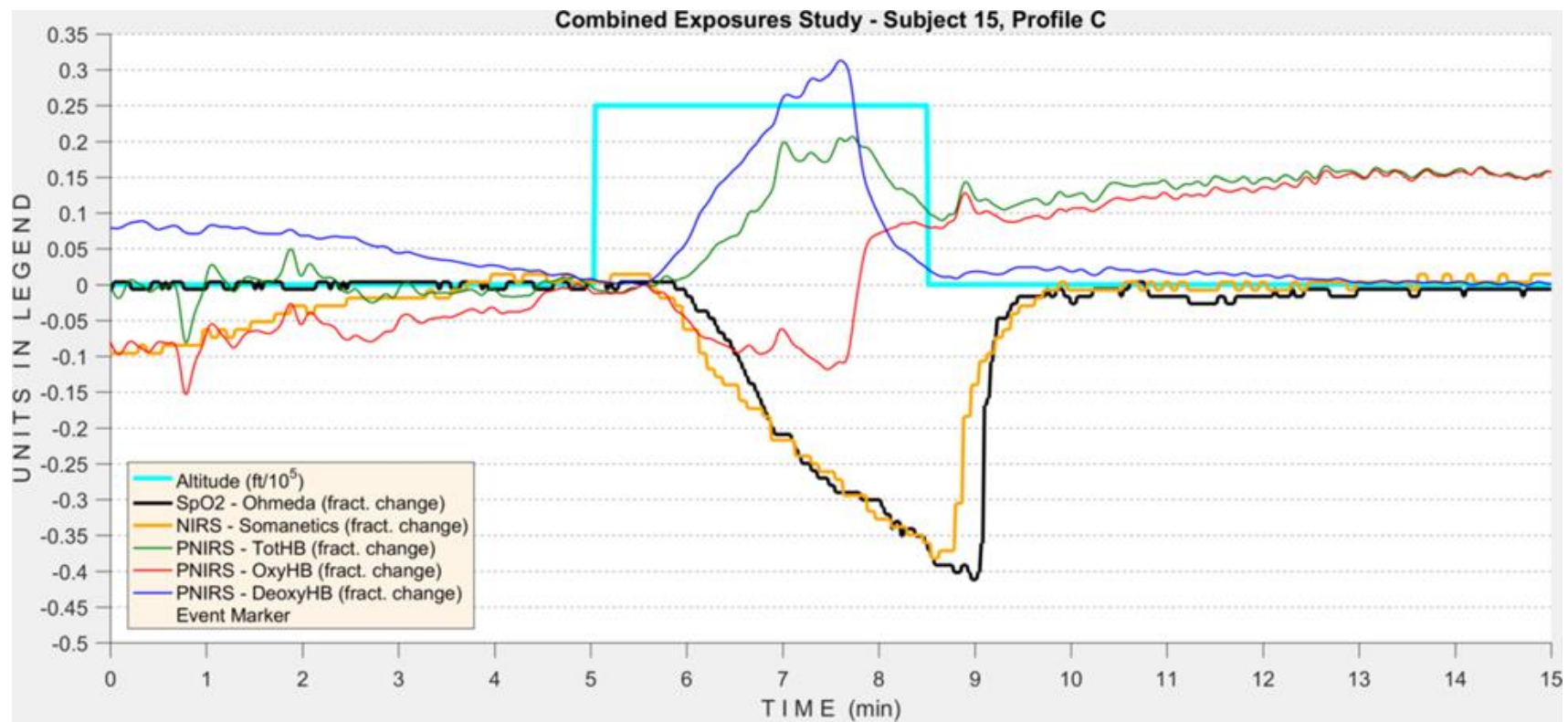


Figure 8. Zoomed in look at subject 15, profile C. PocketNIRS data has been zeroed at the beginning of the trial. Prolonged signal drift contributed to a mismatch between PocketNIRS and Somanetics signals.

### *Canary*

A low pass Butterworth filter with a cutoff frequency of 0.08 Hz was applied to the raw HR data to reduce variance attributable to the 3s averaging mode of the oximeter, thus stabilizing HR extremes. HR measures were calculated from filtered HR. Outliers were identified according to the Tukey hinges method. Mean replacement and/or subject exclusion are noted below, identified in the format participant(profile) (i.e., 1(A) means participant 1, profile A).

In order to be useful as an in-cockpit sensor, the Canary system must demonstrate reliable performance (i.e., minimal PFS dropout), good overall agreement with validated measures of SpO<sub>2</sub>, and minimal lag between the onset of hypoxic conditions and registering a change in physiology. We used several measures to examine the performance of the Canary system (Table 1). We looked for differences in these outcome measures between the Elbit Canary oximeter system and the Daytex Ohmeda using a series of paired t-tests.

As it was not feasible to place both the Canary system and the INVOS NIRS system on the participants' forehead simultaneously, we were unable to evaluate the performance of the NIRS component of the Canary system during this evaluation. However, we note that the Canary is unlikely to be able to measure cerebral saturation. The light sensors in the NIRS component of the Canary are very close to the light source - because the depth of NIRS penetration is a function of this distance, the Canary must measure saturation/perfusion in shallow tissue rather than brain tissue.

| Measure    | Description                                                                                 |
|------------|---------------------------------------------------------------------------------------------|
| T94_25K    | Time from the start of the 25,000 foot simulated altitude to reach 94% SpO2                 |
| T90_25K    | Time from the start of the 25,000 foot simulated altitude to reach 90% SpO2                 |
| T80_25K    | Time from the start of the 25,000 foot simulated altitude to reach 80% SpO2                 |
| SatMin_25K | Minimum SpO2 reached across the entire 25,000 foot simulated exposure and recovery          |
| SatAvg_25K | Average SpO2 in the 30s timespan preceding return to baseline                               |
| HRmax_25K  | Maximum heart rate across the entire 25,000 foot simulated exposure and recovery            |
| HRavg_25K  | Average heart rate across the SatAvg_25K timespan                                           |
| T94_10K    | Time from the start of the 10,000 foot simulated altitude to reach 94% SpO2                 |
| SatMin_10K | Minimum SpO2 reached across the entire 10,000 foot simulated exposure                       |
| SatAvg_10K | Average SpO2 across the last 15 minutes of exposure to 10,000 feet simulated altitude       |
| HRmax_10K  | Maximum heart rate across the entire 10,000 foot simulated exposure                         |
| HRavg_10K  | Average heart rate across the last 15 minutes of exposure to 10,000 feet simulated altitude |

*Table 1. Outcome measures used to evaluate the Elbit Canary system.*

Table 2 lists the means and standard deviations of outcome measures for both the Canary and Ohmeda oximeters, along with t statistics for each outcome measure. Overall the Canary performed comparably to the Ohmeda system, with the exception of a few outcome measures. We believe the majority of these differences are explained by factors other than the performance of the Canary system, and will address these explanations in the discussion section below.

| Measure               | Unit of measure | Ohmeda       | Canary        | Difference (Ohmeda - Canary) | <i>t</i> (df) | <i>p</i>      |
|-----------------------|-----------------|--------------|---------------|------------------------------|---------------|---------------|
| T94_25K               | Seconds         | 45.3 (7.9)   | 52.2 (12.2)   | -6.95                        | -1.73 (16)    | 0.10          |
| T90_25K               | Seconds         | 51.8 (9.2)   | 63.1 (12.1)   | -11.31                       | -2.80 (16)    | <b>0.01</b>   |
| T80_25K               | Seconds         | 98.6 (48.1)  | 94.0 (19.2)   | 4.57                         | 0.45 (16)     | 0.66          |
| SatMin_25K            | Percent         | 73.1 (6.8)   | 58.8 (7.0)    | 14.34                        | 7.26 (17)     | < <b>0.01</b> |
| SatAvg_25K            | Percent         | 74.3 (4.1)   | 62.9 (7.5)    | 11.41                        | 7.50 (16)     | < <b>0.01</b> |
| HRmax_25K             | BPM             | 116.9 (17.4) | 118.0 (16.5)  | -1.15                        | -0.91 (17)    | 0.38          |
| HRavg_25K             | BPM             | 109.2 (16.5) | 111.9 (16.6)  | -2.69                        | -2.68 (16)    | <b>0.02</b>   |
| T94_10K               | Seconds         | 116.6 (58.4) | 189.3 (121.7) | -72.71                       | -2.65 (14)    | <b>0.02</b>   |
| T94_10K (no outliers) | Seconds         | 107.6 (52.1) | 136.2 (53.5)  | -28.54                       | -1.65 (11)    | 0.13          |
| SatMin_10K            | Percent         | 87.3 (5.1)   | 88.2 (3.8)    | -0.87                        | -1.10 (17)    | 0.29          |
| SatAvg_10K            | Percent         | 92.1 (4.8)   | 92.2 (3.5)    | -0.17                        | -0.21 (17)    | 0.84          |
| HRmax_10K             | BPM             | 94.7 (11.3)  | 94.0 (12.4)   | 0.68                         | 0.47 (17)     | 0.64          |
| HRavg_10K             | BPM             | 80.7 (13.1)  | 81.7 (13.3)   | -1.05                        | -3.40 (17)    | < <b>0.01</b> |

Table 2. *t*-test results comparing the Canary to the Ohmeda pulse oximeter.

We next examined the reliability of the Canary system by examining signal dropout during the exposures. The Canary system demonstrated significantly more dropout in the heart rate signal than the Ohmeda ( $t(31) = 2.04$ ,  $p = 0.02$ ; 13D and 32A excluded as outliers). Neither the Canary nor the Ohmeda demonstrated sufficient dropout in the SpO<sub>2</sub> readings to warrant a *t*-test. Signal dropouts for each exposure can be seen in the graphs in Appendix 4.

In addition to total dropout, the Canary system occasionally exhibited long stretches of data with sporadic heart rate signal dropout accompanied by high variance in SpO<sub>2</sub> values. For example, in Figure 9 we can see that normalized SpO<sub>2</sub> (orange line) dips from expected (at sea level) normalized values of 100% to values as low as 86%. This occurs over a timespan with sporadic heart rate signal dropout and greater mismatch between Canary and Ohmeda HR readings than observed earlier in the profile.

Bad data such as in Figure 9 would cause false alarms during flight, indicating a possible lack of specificity in the Canary sensor. This depends on the Canary's artifact rejection capability. However, as will be explained below, we cannot quantify specificity (or sensitivity) of the sensor at this time because it is unclear what variable (if any) in the data files captures reliability information.

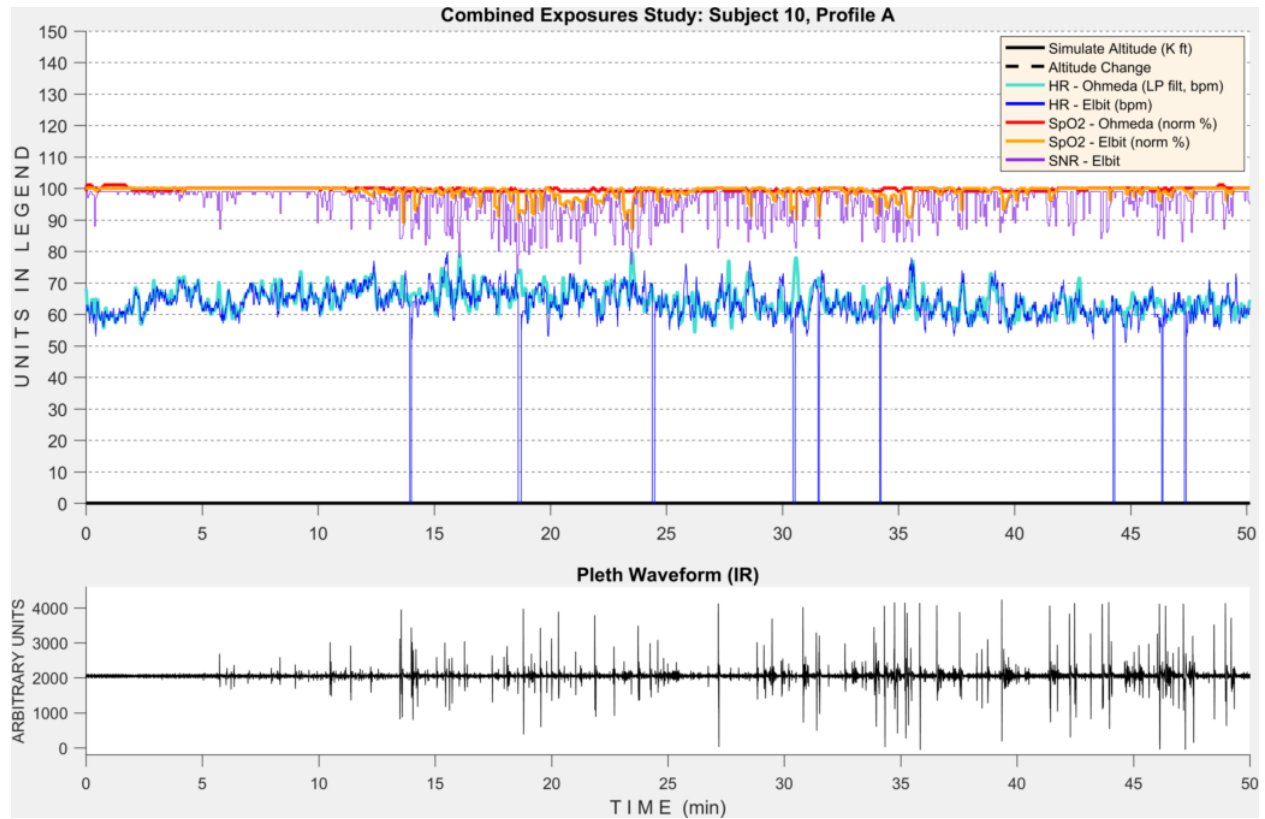


Figure 9. Illustration of heart rate dropout potentially causing spuriously low readings in the Canary  $\text{SpO}_2$  data.

Looking at Figure 9 again, it can be seen that Canary  $\text{SpO}_2$  dips coincide with obvious noise in the plethysmograph (pleth) waveform. Initially we thought that the SNR (purple line) signal in the Canary data files may provide a straightforward indication of the signal-to-noise ratio in the pleth waveform, presuming that low SNR values indicated low signal reliability. In

this particular case, that interpretation seems to hold. However, further inquiry cast doubt on this interpretation.

Figure 10 shows another file, Subject 06 – Profile D, with a pleth signal that is virtually noise-free. Note that the SNR signal is nearly perfectly correlated with the SpO<sub>2</sub> signal. We would instead expect SNR to hover around 100, presuming that SNR values were normalized to indicate percent reliability of the HR/SpO<sub>2</sub> signals. Clearly, this is not the case. It could be that SNR is expressed in terms of relative signal strength (this would be plausible, since the pleth signal is attenuated during the exposures), but this would be a strange way to express signal to noise ratio. Representatives from Elbit declined to share details of the SNR algorithm with the research team, so we are presently unsure of the meaning of this signal.

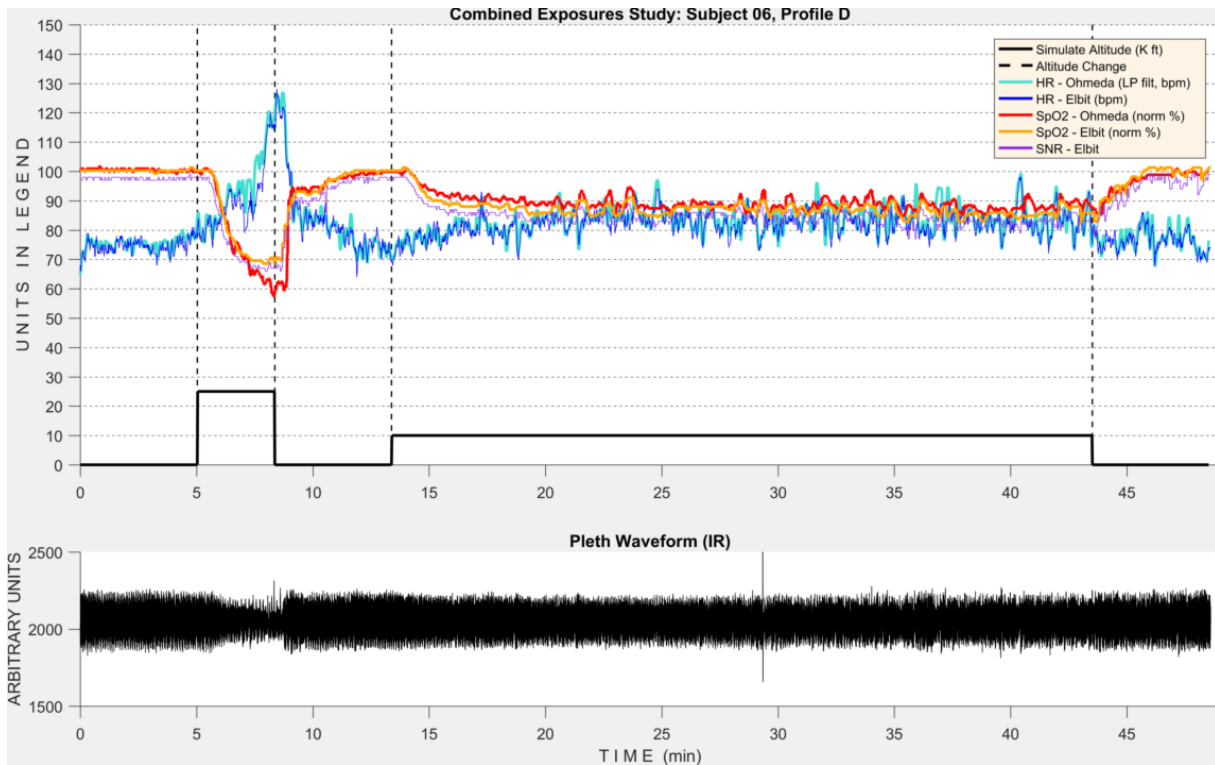
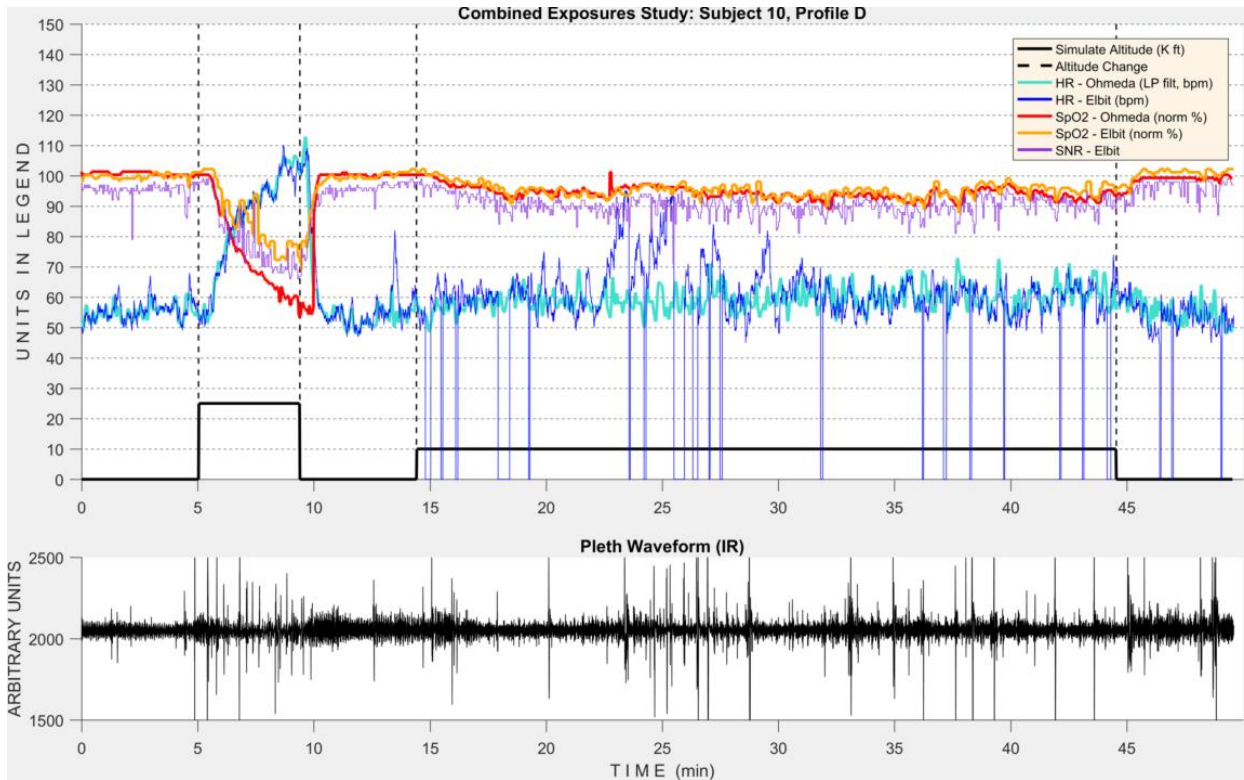


Figure 10. Example of SNR tracking with SpO<sub>2</sub>, which would not be expected if the value represented signal-to-noise.

As a last example, Figure 11 shows data from Subject 10 – Profile D. Given the level of noise in the pleth waveform (note the contrast with the pleth waveform in Fig. 10), this case indicates that the Canary system must have some manner of artifact rejection capability - the Canary HR signal is extremely unreliable across the 10,000 foot simulated exposure, but Canary SpO<sub>2</sub> tracks well with Ohmeda SpO<sub>2</sub> during this profile segment despite the poor data quality.



*Figure 11. Example with noisy pleth waveform, illustrating apparent artifact rejection capability during the 10K exposure, but a possible lack of sensitivity during the 25K exposure, due to inaccurately high Canary SpO<sub>2</sub> readings.*

Notably, however, the Canary sometimes demonstrated a lack of sensitivity. Figure 11 reveals large discrepancies between Canary and Ohmeda SpO<sub>2</sub> readings during the 25,000 foot simulated exposure. The biggest difference occurs at about 7.4 min, at which point the Ohmeda SpO<sub>2</sub> reading was 68.60% while the Canary reading was 94.96%. Figure 12 shows a similar instance. While we see little to no heart rate signal dropout, there is a notable lack of agreement

between the Canary and the Ohmeda heart rate signal in this case. Unless reliability can be improved, these data indicate a lack of sensitivity of the Canary system regardless of any artifact rejection algorithms in the Canary system.

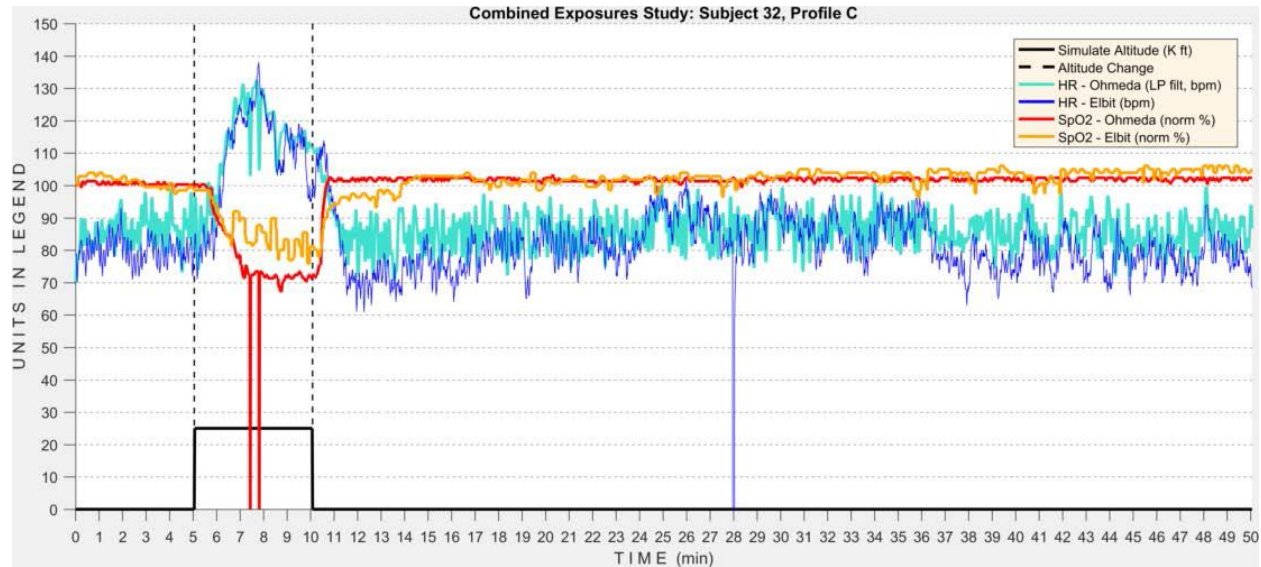


Figure 12. Illustration of Canary signal fluctuation during hypoxic conditions.

## Discussion

### Summary

We examined two separate sensor packages to determine how well they performed during exposure to acute hypoxia. We evaluated the DynaSense PocketNIRS and the Elbit Canary for their comparability to previously validated sensors in terms of speed of response to hypoxia as well as signal reliability.

The PocketNIRS hardware proved to be structurally sound and maintained functionality throughout the study without a need for maintenance. However, several major issues were encountered with PocketNIRS data files. Generally, these issues can be categorized as follows: (1) inaccurate elapsed time, (2) signal drift, and (3) shallow oxy-hemoglobin desaturation trends

(relative to Somanetics NIRS trends). While many data files exhibited good agreement between the PocketNIRS and Somanetics systems (after accounting for the aforementioned timing and drift issues), at least half of the data files showed poor agreement between the two sensors.

The Elbit Canary performed well overall during the evaluation. The data indicate that the Canary and the Ohmeda showed good agreement on most physiological measures compared in this study. The Canary was faster to reach the threshold value of 90% during the 25,000 foot simulated exposure, but demonstrated significantly greater heart rate signal dropout than the Ohmeda. This dropout and accompanying SpO<sub>2</sub> variability may lead to false alarms if not monitored and compensated for. However, it does appear that the Canary has some means of artifact rejection to account for this. We now conclude this report with a discussion of the strengths and weaknesses of NIRS sensors and reflectance oximeters generally, as well as our thoughts on the two specific devices under evaluation in this report. Finally, we describe future issues regarding the implementation of in-flight physiological monitors.

#### *General discussion about each type of sensor*

##### *NIRS*

NIRS systems mounted on the forehead such as those evaluated here offer some noteworthy advantages over other physiological monitoring systems. NIRS is capable of measuring cerebral oxygenation, which is very sensitive to changes in environmental oxygen concentration (Berkenbosch & Tobias, 2006). The central placement of the NIRS sensor also affords greater pilot mobility, allowing the system to be used in a cockpit more easily (Phillips, Warner, & Geyer, 2016). Finally, NIRS does not require a PFS, meaning that it is relatively resistant to the effects of the flight environment such as vibration, G-forces, or temperature

variation compared to reflectance or pulse oximetry (Kobayashi, 2000; Schramm, Bartunek, & Gilly, 1997).

While NIRS systems offer potential advantages over reflectance or pulse oximetry methods, several disadvantages must be considered. While the fact that NIRS does not rely on a PFS to obtain a reading makes the system more robust against some of the perturbations associated with the flight environment, this feature can also make NIRS slightly less practical for operational use. Because NIRS does not separate signals into PFS and NPFS, the reading represents only an average saturation level of all tissues beneath the sensor (Phillips, Warner, & Geyer, 2016). A reading from a NIRS system does not readily translate into a comparable value for an oximetry system (e.g., an  $rSO_2$  reading of 80 does not indicate a blood oxygen saturation level of 80%; likewise, a percent change is only relative to the established baseline). NIRS is thus poorly suited for at-a-glance assessment of an operator's current physiological state. Instead, NIRS systems must be used as trend monitors to detect deviations from baseline (Phillips, Warner, & Geyer, 2016). Establishing such a baseline is not as straightforward as it may seem at first glance.

Good baseline values for  $rSO_2$  are typically around 85%, but can be as low as 65% based on sensor placement (Phillips, Warner, & Geyer, 2016). Baselines can also vary greatly between individuals due to differences in skull shape and the underlying tissues (Yoshtani et al., 2007). Some individuals may have baseline NIRS readings as low as 40%. In cases of extremely low baselines NIRS may not be able to adequately track tissue oxygenation trends (Phillips, Warner, & Geyer, 2016). The procedure to establish threshold values may take up to 10 minutes before each flight (Phillips, Warner, & Geyer, 2016). Once this baseline is established, it is very important not to move the sensor. Integrating a NIRS sensor into the helmet would help maintain

more consistent placement, but also limits the possible locations of the sensor. If the helmet does not cover a portion of the forehead that provides for a good baseline reading for a pilot, the utility of the system for that individual will be compromised.

Because of the sensitivity of NIRS systems to placement and individual variation in skull anatomy, a new baseline would have to be established for each pilot every time the pilot donned the sensor and any alarm would then have to be scaled to that baseline. Unlike a pulse oximeter (where an SpO<sub>2</sub> threshold value is easily set and roughly equivalent across individuals), the exact threshold of percent change from baseline that should trigger an alarm without a high rate of false positives has not been determined, and may vary across individuals.

NIRS is also very susceptible to G stress (Tripp et al., 2009). The rate of desaturation and heart rate data can be used to help differentiate between hypoxia due to oxygen loss and hypoxia due to G stress, but NIRS does not monitor heart rate. Preferably, any NIRS system should be coupled with an accelerometer in order to distinguish between hypoxic episodes induced by G stress vs. life support system failure (Phillips, Warner, & Geyer, 2016).

#### *Reflectance oximeters*

As with NIRS systems, reflectance oximeters offer noteworthy advantages over other systems, such as the ability to monitor central blood vessels and afford greater pilot mobility. An additional benefit of oximeters over NIRS systems is that they facilitate at-a-glance monitoring of a pilot's physiological state. However, reflectance oximeters also have some disadvantages.

Because reflectance oximeters rely on a PFS to generate reliable data, the sensors require some sort of monitoring system to ensure that the PFS is sufficient to support inferences about the state of the pilot. Otherwise, a high rate of false alarms is likely to result. Further, the sensor must be placed in a spot that avoids major blood vessels as pulse oximetry is designed to

function over a capillary bed. This is important because the presence of larger vessels has been shown to significantly compromise pulse oximetry accuracy (Mannheimer, O'Neil, & Konecny, 2004). Again, placing such a sensor in the helmet limits the flexibility to adjust sensor location to ensure that the sensor is not positioned above any major blood vessels.

#### *Discussion about the specific sensors*

##### *PocketNIRS*

Overall we found the hardware to be well-made and reliable, but we noted significant flaws in the data files. Because the separate data streams were recorded on the same computer, the timing issues described above cannot be attributed to clock synchronization errors. We also noted considerable signal drift over time that will have to be accounted for during any in-cockpit use. This drift could lead to inaccurate alarm thresholds if the signal is not allowed to stabilize prior to collecting baseline data. Allowing for signal stabilization is likely to add considerable time to any baseline procedure involving the PocketNIRS system.

As previously mentioned, we decline at this point to quantify the agreement between PocketNIRS and Somanetics NIRS because comparisons would necessarily entail subjective manipulation of the PocketNIRS signals (in terms of setting end points for OxyHB segment interpolation). By our qualitative estimation, even after accounting for PocketNIRS signal drift and timekeeping issues, over half of the files exhibited large discrepancies between OxyHB and Somanetics NIRS such as those seen in Subject 15, Profile C. On the other hand, files like Subject 16, Profile D indicate some promise in the PocketNIRS system. The sensor generally captured the expected trends during simulated hypoxic exposures, even if the signal did not align with the other sensors. We believe that the observed issues are fixable and that the system may

have potential, but significant improvements are needed before being declared ready for widespread use.

### *Canary*

We noted several differences between the Canary and the Ohmeda system during the analyses. However, we feel that several of these differences can be explained and do not necessarily represent issues with the quality of the Canary system. First, we noted significant differences between the Canary and the Ohmeda for both HRavg\_25K and HRavg\_10K. These differences are due to high correlations between the two sensors. The oximeter measures were correlated at  $r = 0.97$  and  $0.995$  for these measures, respectively, leading to a finding of a significant difference despite nearly identical means. The small discrepancy in values is most likely due to differences in averaging modes between the devices rather than a true bias in one or the other device. Visual inspection of the plots (Appendix 4) further supports that the heart rate data generally agreed across the two sensors.

We also noted significant differences between the Canary and the Ohmeda in the SatMin\_25K and SatAvg\_25K values. We believe this is due to the settings of the Canary rather than a flaw in operation. The Canary system does not read values below 70% SpO<sub>2</sub>. Most pulse oximeters (the Ohmeda included) do not guarantee accuracy below a certain threshold. While the Ohmeda continues reading below this threshold, the Canary appears to simply stop around 70% SpO<sub>2</sub>. During the 25,000 foot simulated altitude, SpO<sub>2</sub> routinely dropped below 70%. In this scenario the Canary would read 70% while the Ohmeda continued decreasing. This difference in settings caused the discrepancies between the SatMin and SatAvg values during the 25,000 foot simulated exposure.

While the Canary system ultimately provided reliable data, we did experience several hardware issues that give us pause. Wires in the sensor headband became loose or disconnected on multiple occasions and the circuit box had to be sent back to Israel for repair or replacement numerous times. Even the final iteration of the circuit box was not fully polished, as the power switch was not secured properly and would recede into the box after several uses. This required us to disassemble the box, reset the switch, and then reassemble the box every few testing sessions. To be fair, the versions we had were one-off prototypes made by hand and we expect that these issues would be overcome should the Canary enter full scale manufacture. However, the hardware issues were persistent throughout the evaluation even after multiple attempts to correct them. We feel that we would be remiss not to mention them here.

We also noted that the Canary system was very sensitive to the placement of the sensor. Depending on where the sensor was located on the forehead, baseline oxygenation values could be as low as 90%. This required careful adjustment prior to data collection for each participant – a process that would likely have to be repeated for pilots prior to takeoff. As noted before, a system integrated into the helmet will restrict the ability to adjust sensor placement as required for different individuals.

Finally, we were unable to evaluate the Canary system's NIRS component due to space restrictions on the forehead. The Somanetics NIRS system did not fit on the forehead in conjunction with the Canary system without interfering with the Canary system's performance. Placing the Somanetics sensor on the forehead would have forced the Canary system too far over on the forehead and having the additional sensor under the headband may have allowed too much light to enter the receiver, causing interference and poor data quality. In any case, we believe it would not have been an apples-to-apples comparison as it is unlikely the Canary is

capable of measuring cerebral oxygenation using NIRS due to the lack of distance between the light emitter and sensors. The NIRS component of the sensor will be limited to measuring oxygenation at shallower tissue depths, in contrast to the Somanetics.

### *Limitations*

Both NIRS and reflectance oximeters share certain limitations. First, desaturation trends can be slow to develop and any physiological sensor will require that the operator experience a physiologic change to trigger an alarm (Phillips, Horning, & Dory, 2012). Although a physiological sensor certainly represents an improvement over requiring a hypoxic pilot to serve as their own monitor, such sensors are not an entirely proactive solution.

Second, neither NIRS sensors nor reflectance oximeters are able to distinguish among different types of hypoxia such as histotoxic or contaminant-induced hypoxia (Phillips, Warner, & Geyer, 2016). This will make determining the cause of any in-flight physiological incident difficult. Further, the sensors must be integrated with accelerometers in order to eliminate false positives due to stagnant hypoxia during G stress (the Canary system has already integrated such accelerometers).

### *Future issues to overcome/integrate with the flight environment*

While controlled evaluations such as these are a critical step towards sensor implementation, more work remains to be done. The tactical flight environment is vastly different than the clinical environment in which many physiological sensors were developed and the laboratory environment in which they were tested. Fluctuations in G forces, vibration, and barometric pressure are all potential factors in the flight environment that may reduce the signal quality of a physiological sensor (Phillips, Warner, & Geyer, 2016).

Parameters measured by available physiological sensors rely on the isolation of a particular signal to provide accurate data. For instance, reflectance oximetry relies on the isolation of the PFS. Vibration, G-forces, and sensor movement in the flight environment may disrupt this signal and lead to low quality data and false alarms (Phillips, Warner, & Geyer, 2016). Vibration generates micro movements and induces light scatter and interference. G forces may force the helmet down on the head and disrupt sensor location, as well as reduce blood flow to the head (Phillips, Warner, & Geyer, 2016). As mentioned before, sensors should be coupled with accelerometers (already done in the Canary) in order to develop algorithms to distinguish between desaturations induced by G forces vs. life support system failure (Phillips, Warner, & Geyer, 2016).

For best results, physiological sensors on the forehead must be placed near, but not on top of, the supraorbital artery. The best location for sensor placement will vary across individuals due to individual differences in skull/tissue morphology (Phillips, Warner, & Geyer, 2016). Correct sensor placement is crucial for reliable and accurate signals, but integrating the physiological sensors into the flight helmet reduces the ability to adjust sensor location to accommodate individual variations in skull/tissue morphology. Procedures will likely have to be developed to ensure proper sensor location and signal quality prior to every flight (Phillips, Warner, & Geyer, 2016). Automated systems to adjust the pressure between the sensor and the skin may also be necessary to ensure stable sensor placement and maximum signal strength during pilot motion and flight maneuvers. Signal quality will also have to be monitored continuously in order to minimize false positives (Phillips, Warner, & Geyer, 2016).

In addition, none of the physiological sensors have been evaluated for accuracy in low pressure environments. No specific hypothesis suggests that low barometric pressure should

impact sensor accuracy. However, this possibility has not been tested and should be ruled out prior to full scale adoption of any sensor (Phillips, Warner, & Geyer, 2016).

### *Conclusions*

We evaluated two separate systems for their suitability as in-flight physiological monitors. Although hurdles remain before either (or any other) system can be fielded across the tactical aviation fleet, the Canary appears closer to maturity at this time. The Canary system performed well overall, but demonstrated problems with sporadic heart rate dropout and lack of sensitivity during some exposures. Although the system appears to have fairly robust artifact rejection capabilities to cope with signal dropout, the lack of sensitivity is troubling. In-flight hypoxic events are relatively rare – any sensor selected for use must be nearly 100% reliable to capture these events when they occur. We were unable to evaluate the NIRS aspect of the Canary at this time. The PocketNIRS demonstrated potential for future use, but significant issues with timekeeping and signal drift must be overcome prior to adoption.

Finally, it is our belief that even with additional development any physiological monitoring system should be utilized as only one component in a broader system of sensors and countermeasures to help reduce the rate of hypoxia-like events. Physiological sensors should be utilized in conjunction with other life support monitoring systems as well as operator training to provide multiple layers of defense against the threat of hypoxia (Phillips, Warner, & Geyer, 2016).

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*Appendix 1. Screening questionnaire for the study*

**THE EFFECTS OF SUBSEQUENT EXPOSURES TO MILD AND MODERATE HYPOXIA**

**INITIAL SCREENING QUESTIONNAIRE**

Participant #: \_\_\_\_\_ Date: \_\_\_\_\_  
 Gender: Male / Female Age: \_\_\_\_\_  
 Hand Dominance: Right / Left

**Medical/Background screening**

*To the participant:* Before we can schedule you for participation we need to ask a few questions about your background and medical history so that we can make sure that it's safe for you to be hypoxic. All information collected will be kept confidential.

1. Are you comfortable with a blood draw? YES NO
2. Do you have a recent history of living at altitude? (> 5000ft) YES NO  
 If YES, how recently and for how long? \_\_\_\_\_
3. Have you ever been exposed to a hypoxic environment for research or in-flight? YES NO  
 If YES, please explain (how long ago and why):  
 \_\_\_\_\_
4. Are you in your usual state of fitness? YES NO  
 If NO, please indicate the reason: \_\_\_\_\_
5. Do you currently have or have you ever been diagnosed with asthma? YES NO  
 If YES, do you have normal pulmonary function? YES NO
6. Have you ever been diagnosed with heart/circulatory disease? YES NO
7. Do you currently have or have you ever been diagnosed with high blood pressure? YES NO
8. Have you ever been diagnosed with emphysema? YES NO
9. Have you ever been diagnosed with anemia? YES NO
10. Have you been diagnosed with epilepsy? YES NO
11. Have you ever tested positive for the sickle cell trait? YES NO
12. Have you had pneumonia within the last year? YES NO
13. Have you used tobacco products habitually within the last 6 months (more than 2 cigarettes per day)? YES NO  
 If YES, please state frequency: \_\_\_\_\_

14. Do you have a history of fainting? YES NO
15. Have you donated blood or plasma in the past 30 days? YES NO
16. Are you taking any prescribed medication on a regular basis,  
or a temporarily prescribed medication, within the past 7 days? YES NO
- If YES, please list: \_\_\_\_\_
17. Do you take any over-the-counter medications (e.g., antacids,  
Benadryl, Tylenol,) on a regular basis (2 or more times a month)? YES NO
- If YES, please list: \_\_\_\_\_
18. Do you take an herbal, protein, or power enhancing supplement  
on a regular basis? YES NO
- If YES, please list: \_\_\_\_\_
19. How many alcoholic beverages do you consume per day on average? \_\_\_\_\_
20. Are you claustrophobic? YES NO
21. Can you think of anything else regarding your history or present physical state which might  
affect your performance?

*Appendix 2. Compliance questionnaire for each study visit*

**THE EFFECTS OF SUBSEQUENT EXPOSURES TO MILD AND MODERATE HYPOXIA**

**COMPLIANCE QUESTIONNAIRE**

Participant #: \_\_\_\_\_

Date: \_\_\_\_\_

1. Have you donated blood or plasma since screening (or your most recent visit)? YES NO

2. Have you used tobacco products since screening (or your most recent visit)? YES NO

3. Have you been ill in the past week? YES NO

If YES, please indicate:

1. The nature of the illness (flu, cold, etc.): \_\_\_\_\_

2. Severity of the illness: Very 1 2 3 4 5 6 7 8 9 Very  
Mild Severe

3. Length of illness: \_\_\_\_\_Hours \_\_\_\_\_Days

4. Major symptoms: \_\_\_\_\_

5. Are you fully recovered? YES NO

4. Have you consumed any caffeine within the past 48 hours? YES NO

a. If yes, how much? \_\_\_\_\_

b. Is this your normal amount? \_\_\_\_\_

5. Have you consumed any alcohol within the past 48 hours? YES NO

a. If yes, how many drinks? \_\_\_\_\_

6. Have you been above 5,000 feet since screening (or your most recent visit)? YES NO

7. Have you taken any supplements in the last 48 hours? YES NO

a. If yes, please list \_\_\_\_\_

8. Have you taken any over-the-counter medications in the last 48 hours? YES NO

a. If yes, please list \_\_\_\_\_

9. Have you taken any prescription medication in the last 48 hours? YES NO

a. If yes, please list \_\_\_\_\_

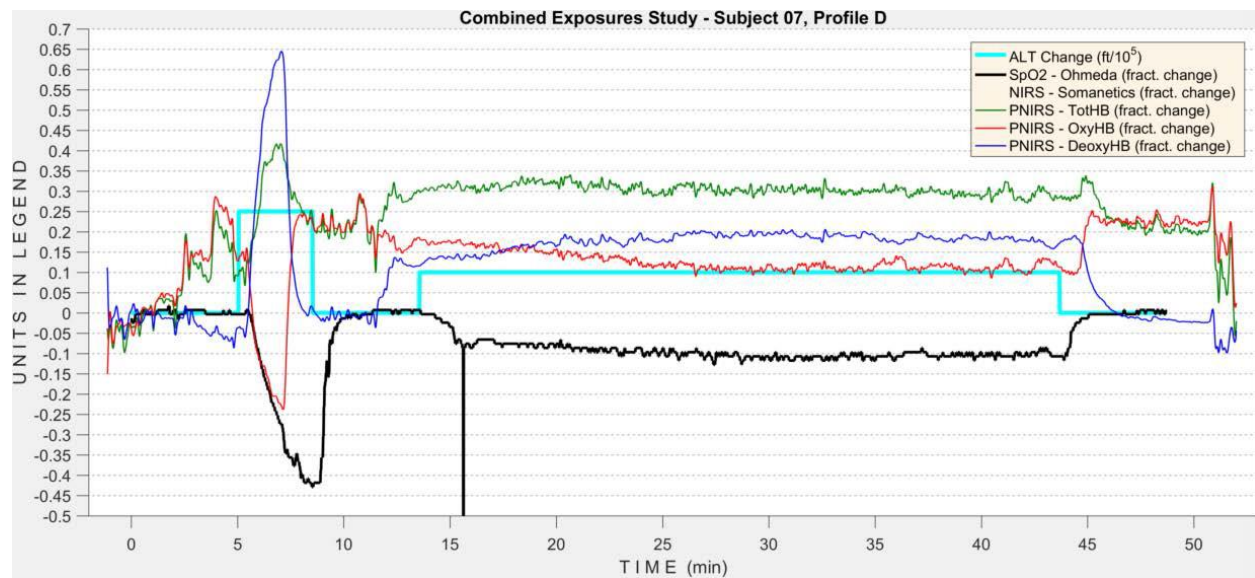
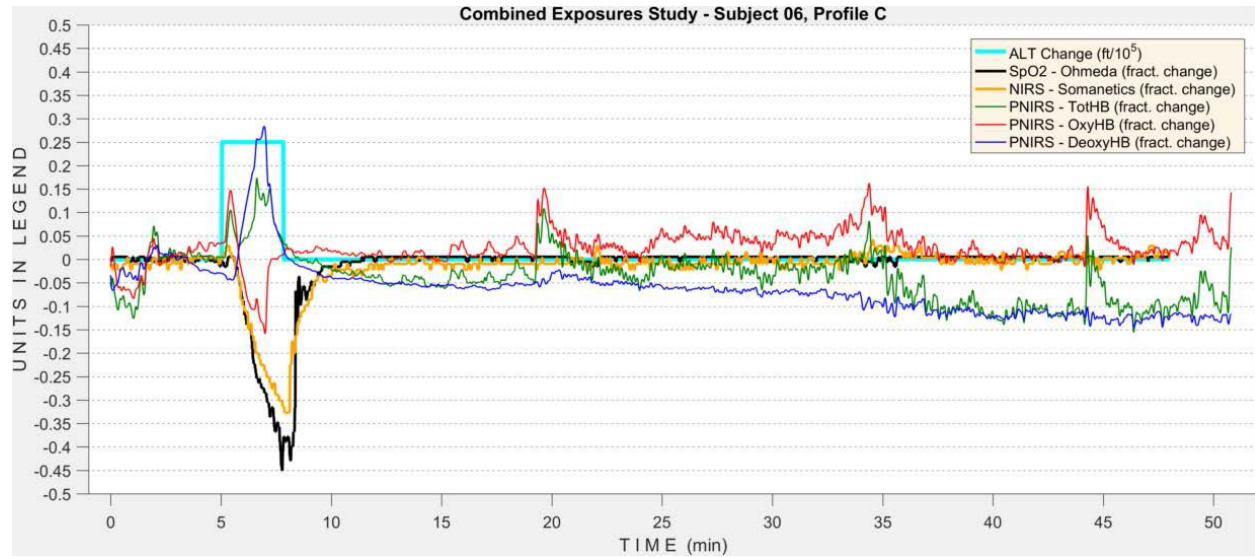
10. How many hours of sleep did you get last night?

\_\_\_\_\_Hours

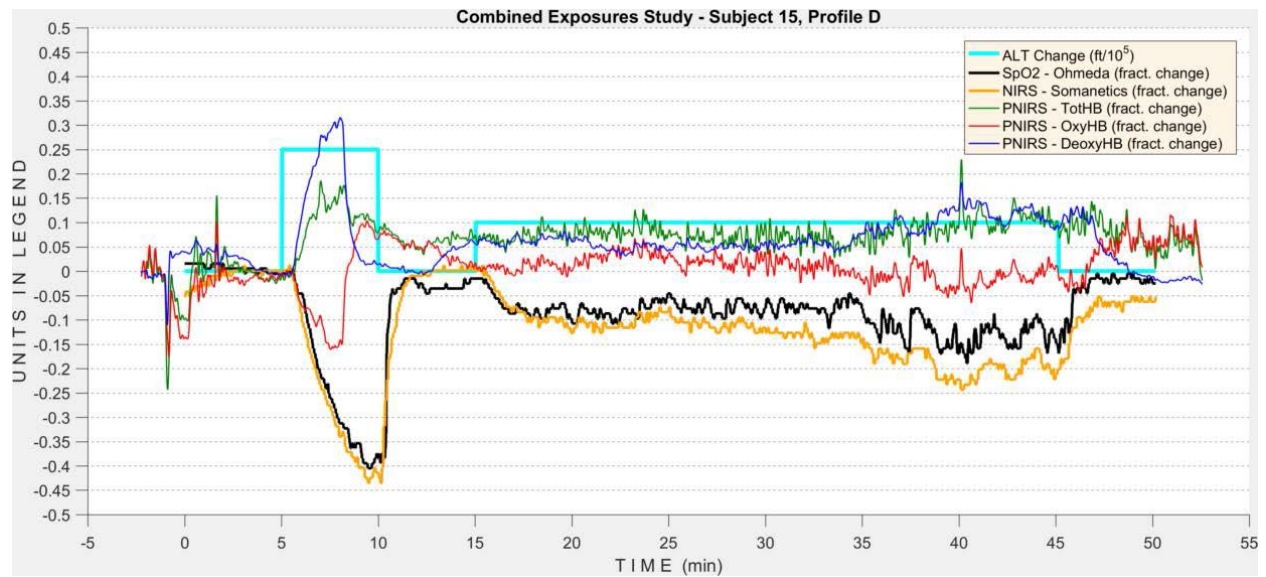
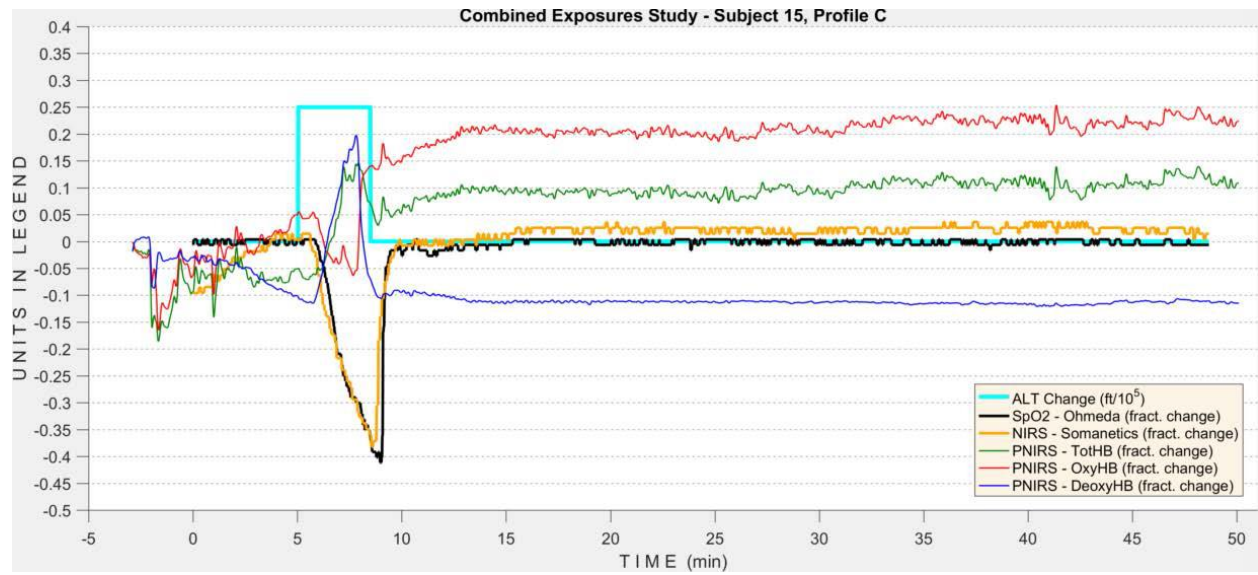
a. Was this amount sufficient? YES NO

b. Is this your normal amount? YES NO

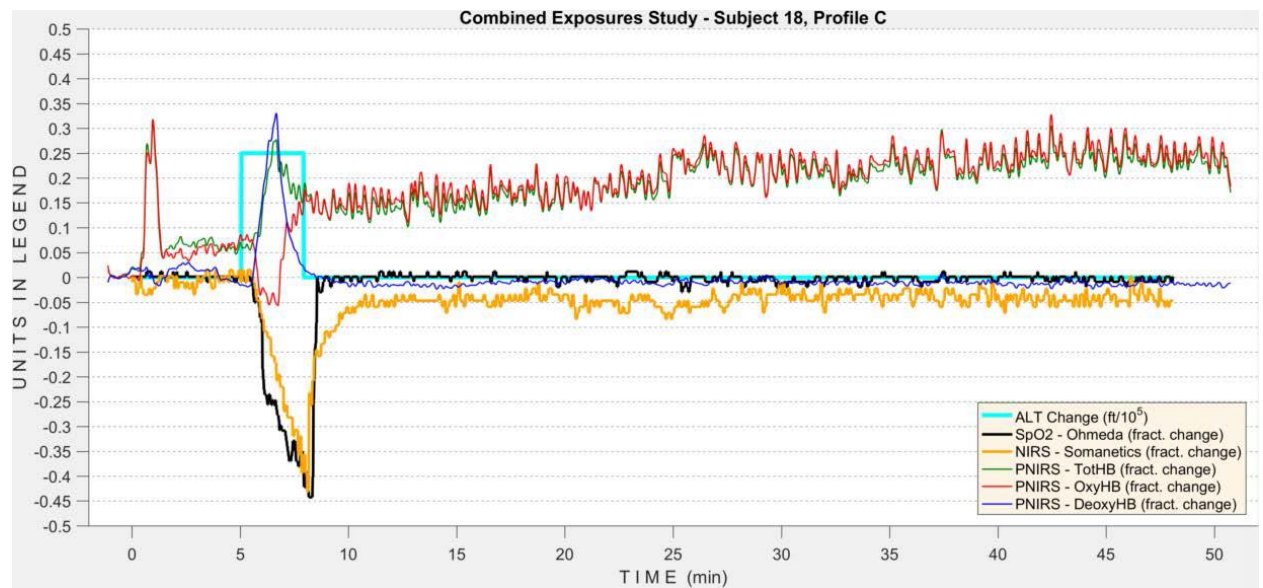
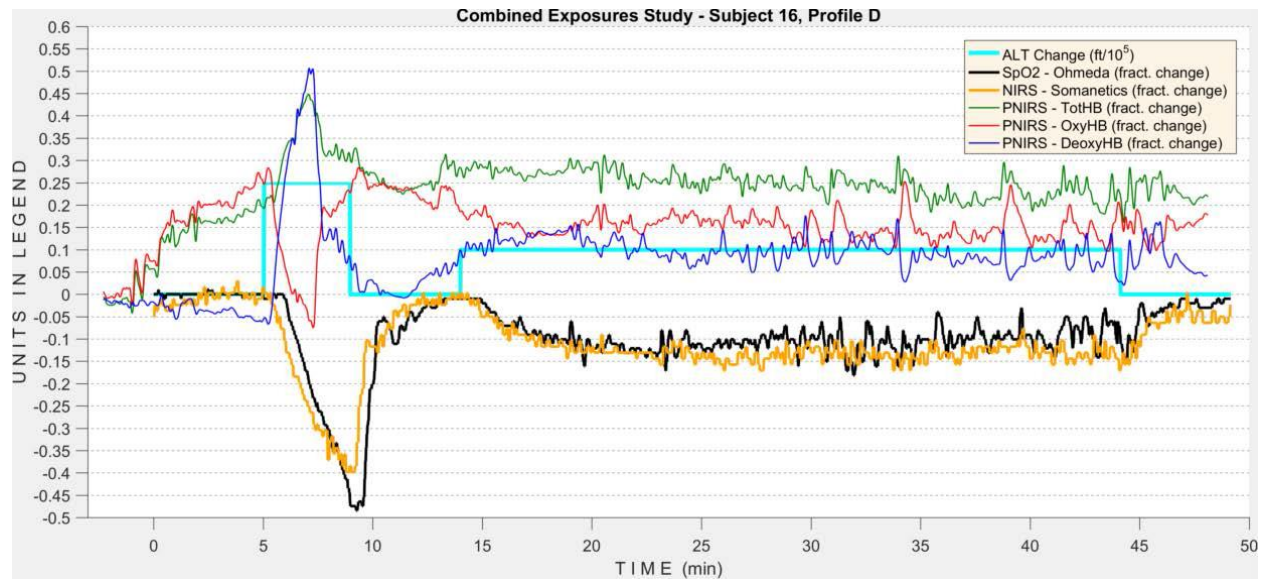
*Appendix 3. Plots for the PocketNIRS system vs. the Somanetics and Ohmeda systems (all converted to percent change)*



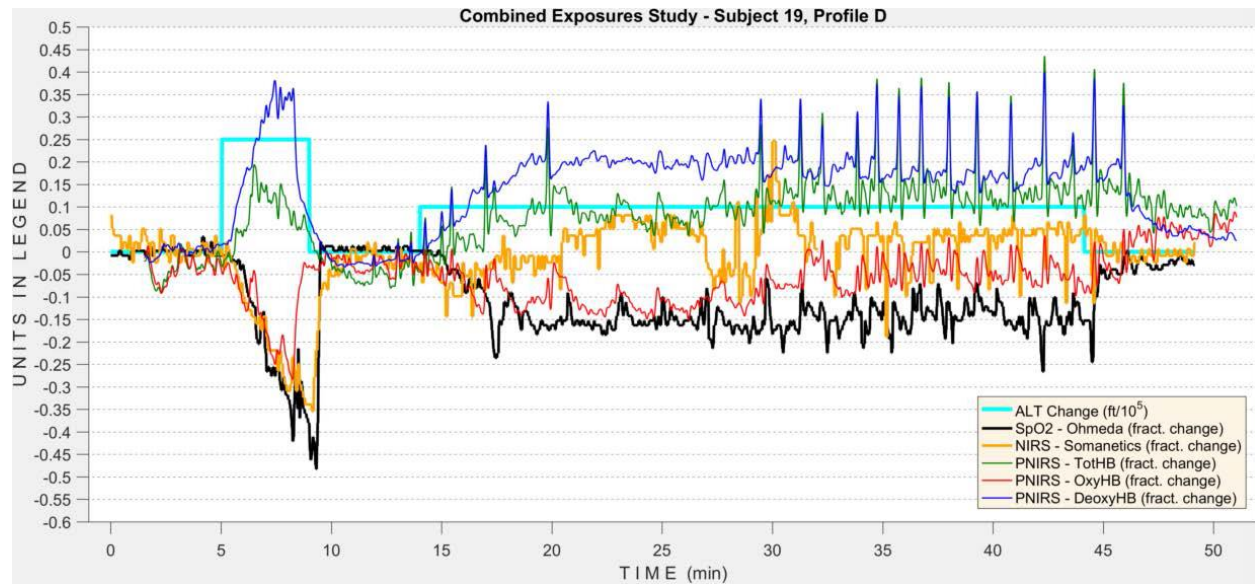
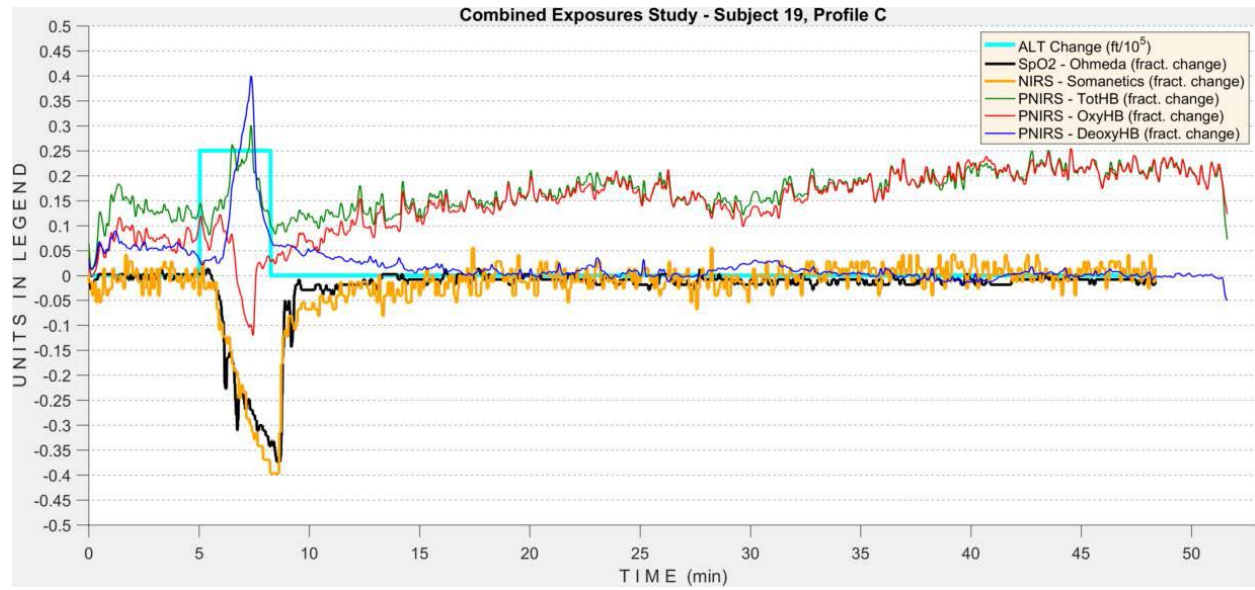
## Evaluation of Elbit Canary and DynaSense PocketNIRS



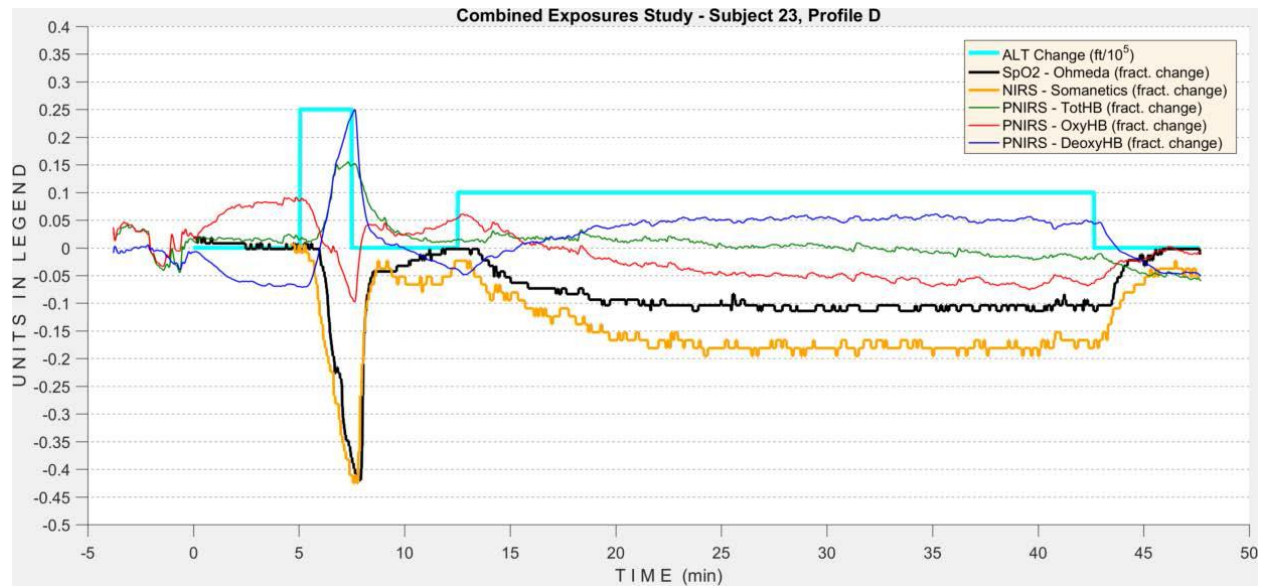
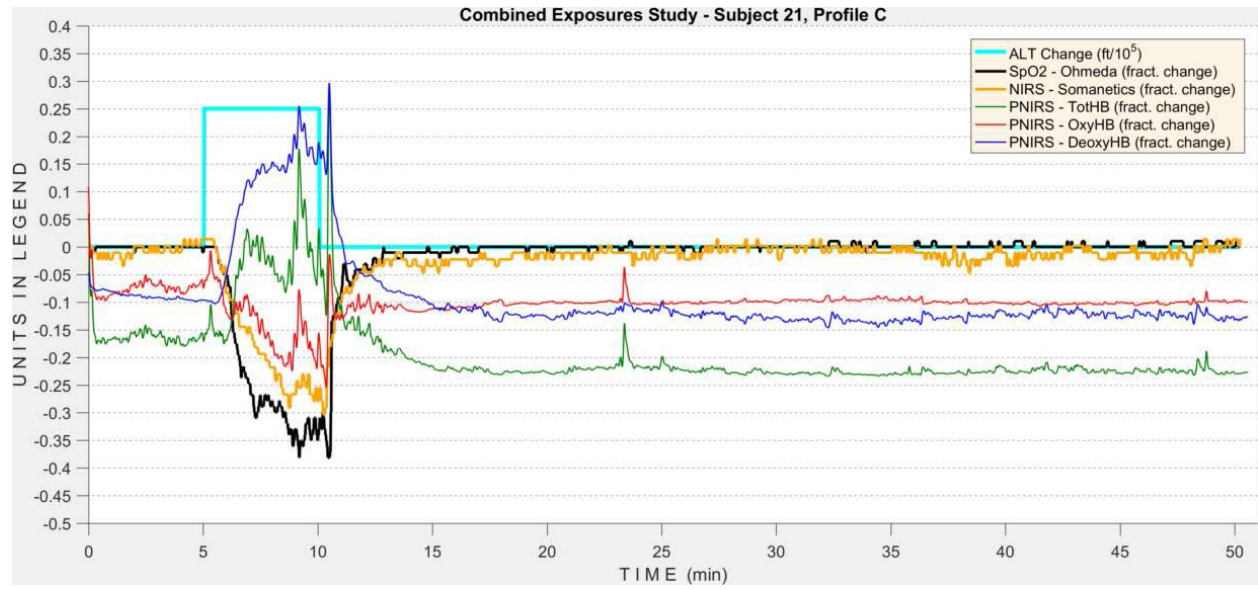
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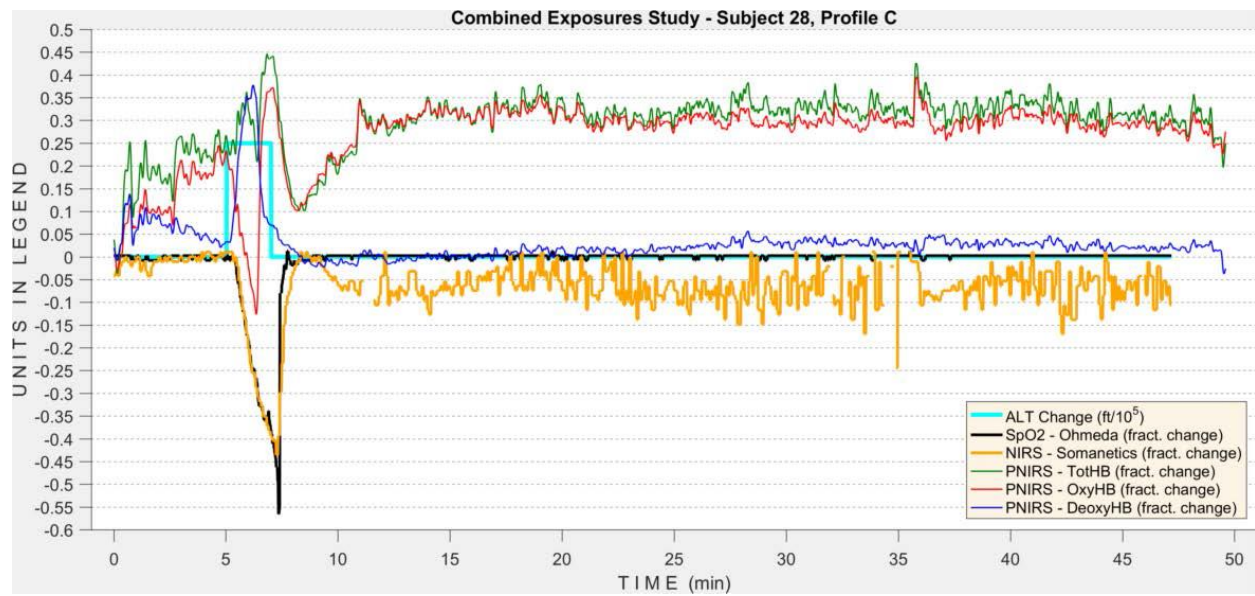
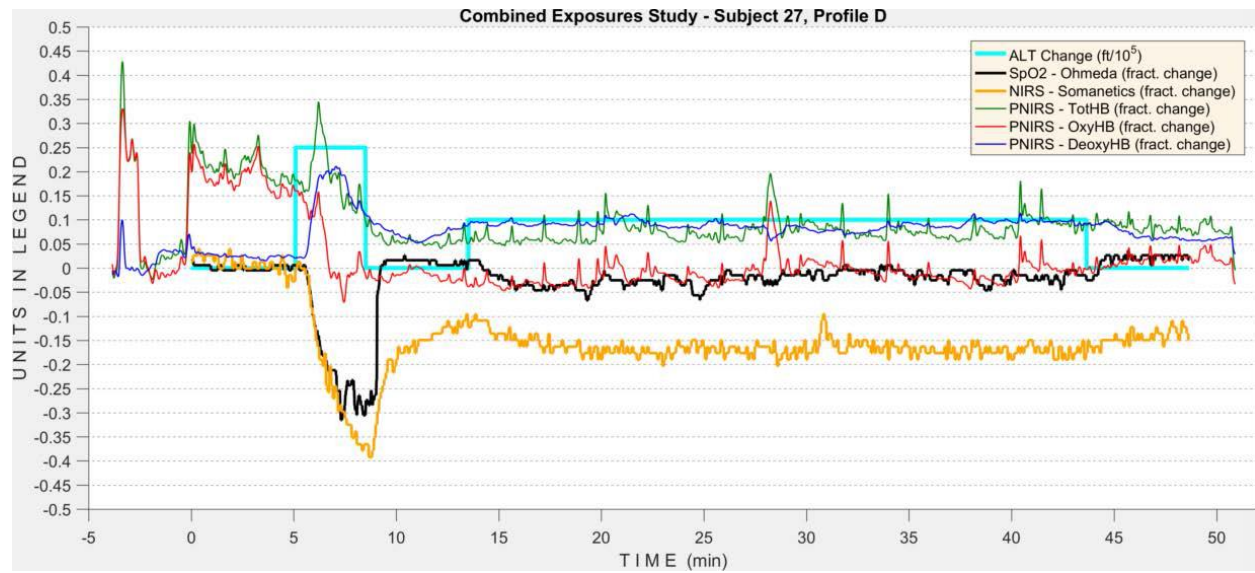
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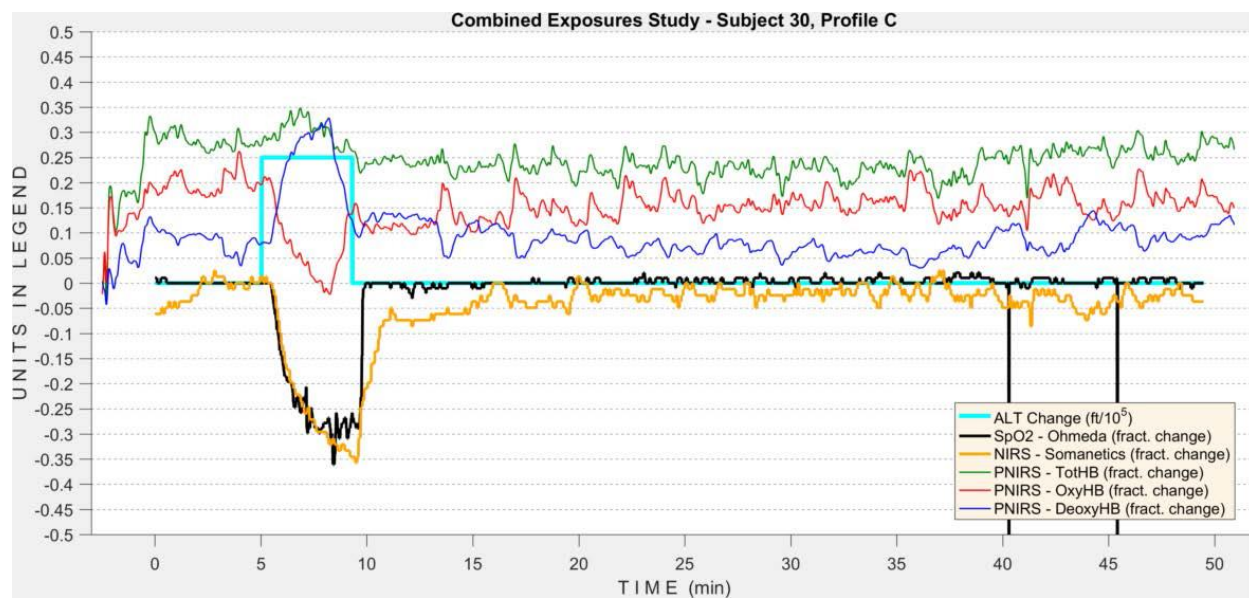
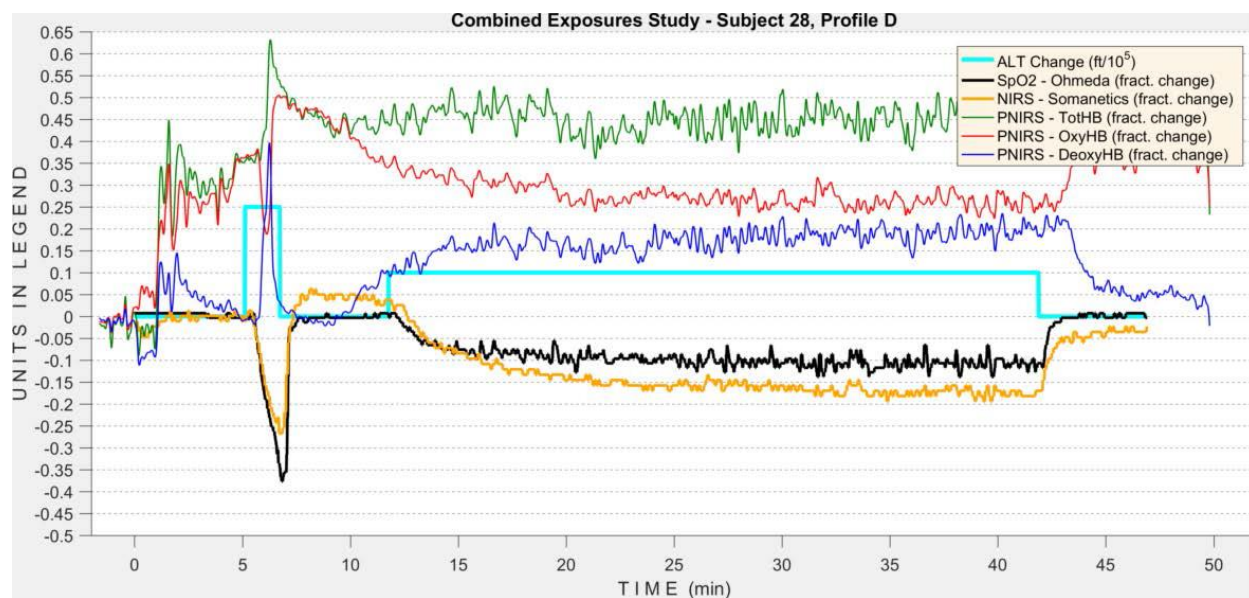
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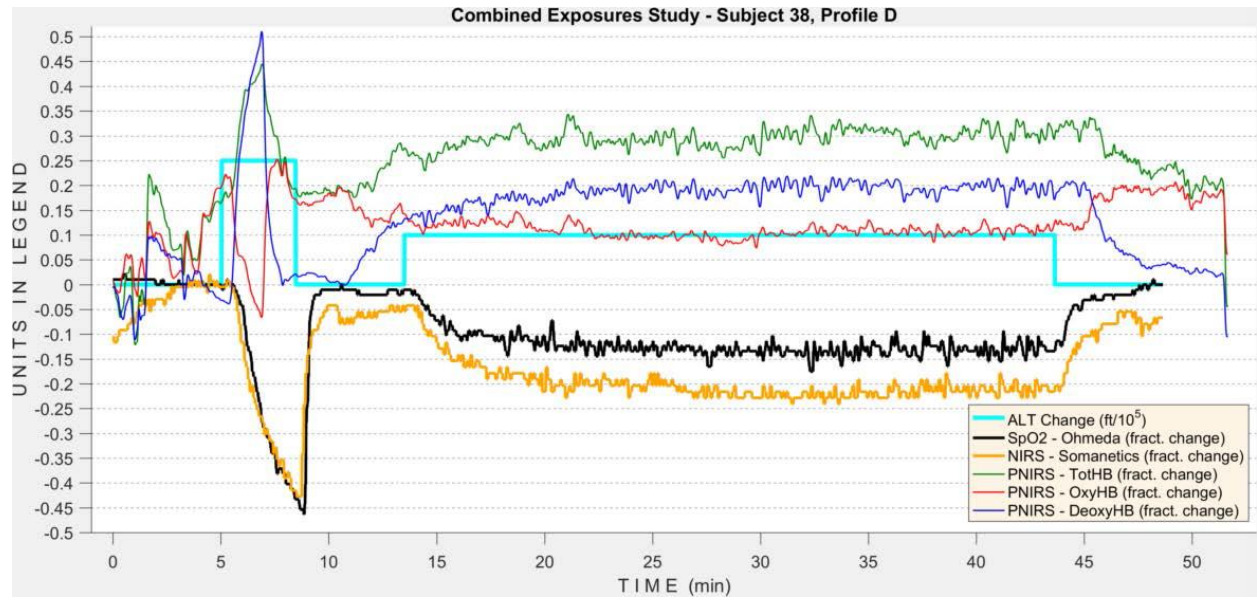


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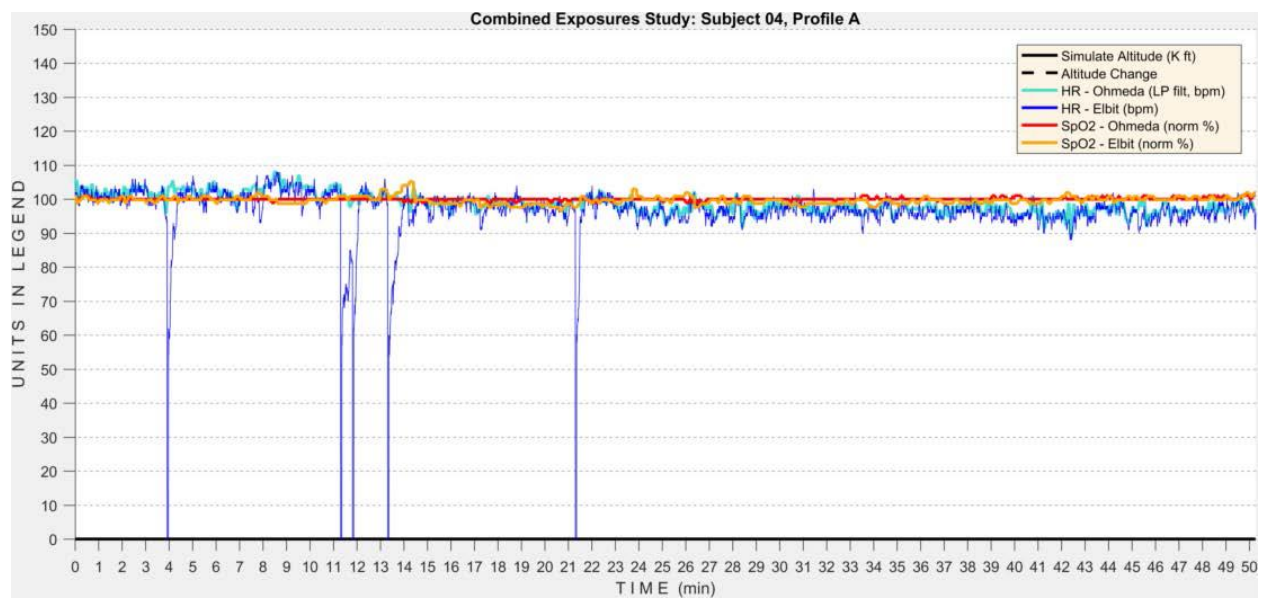
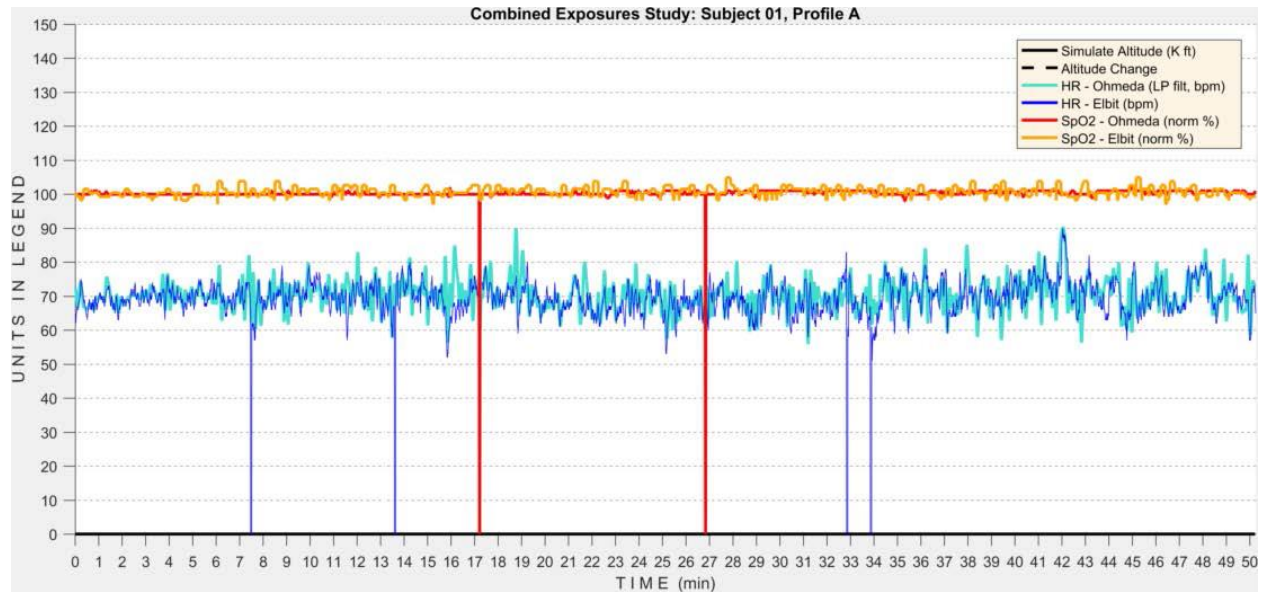


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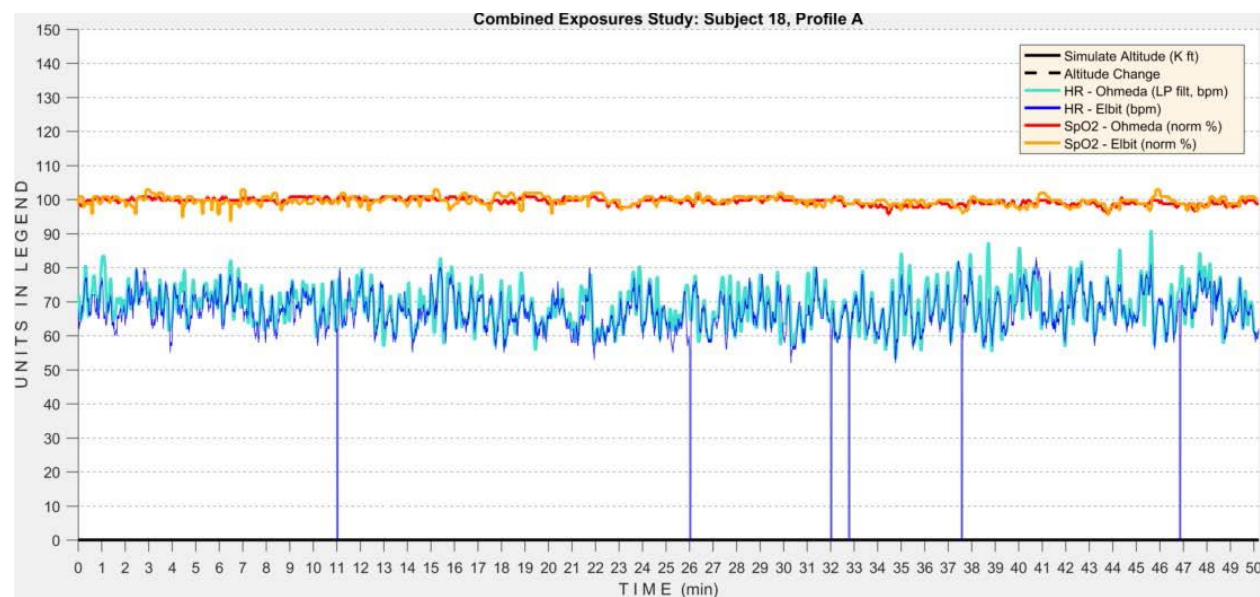
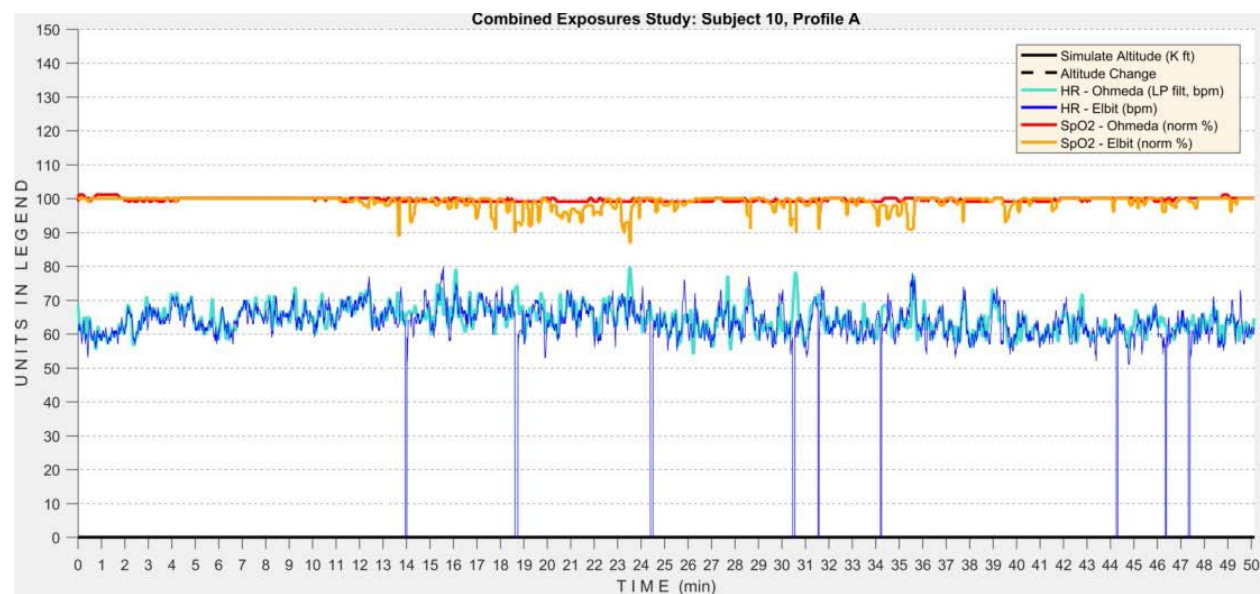




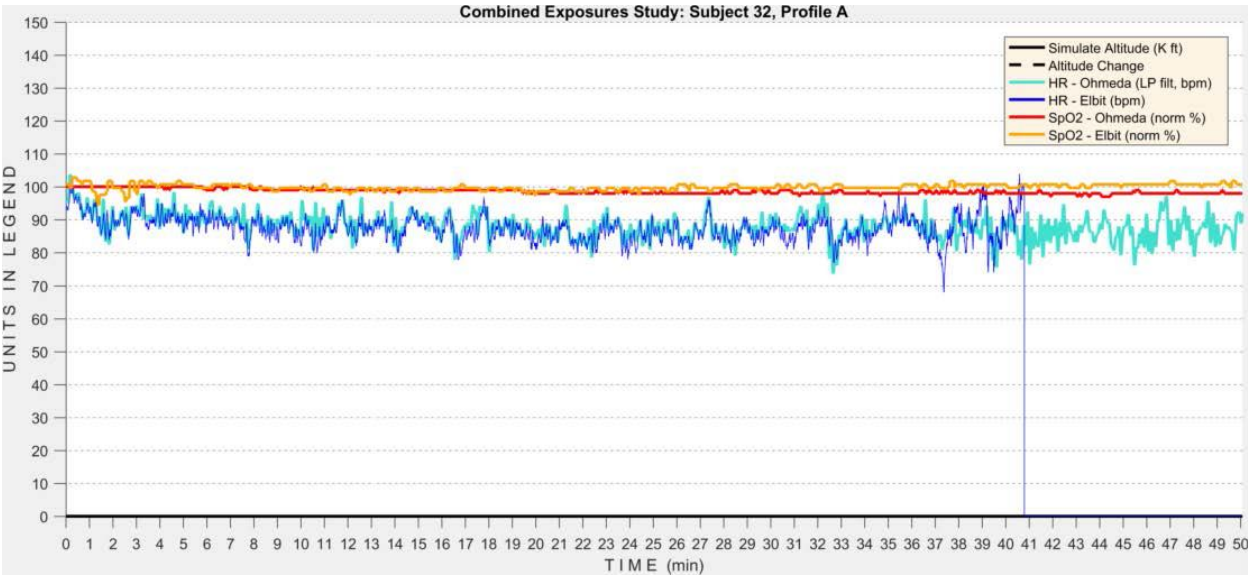
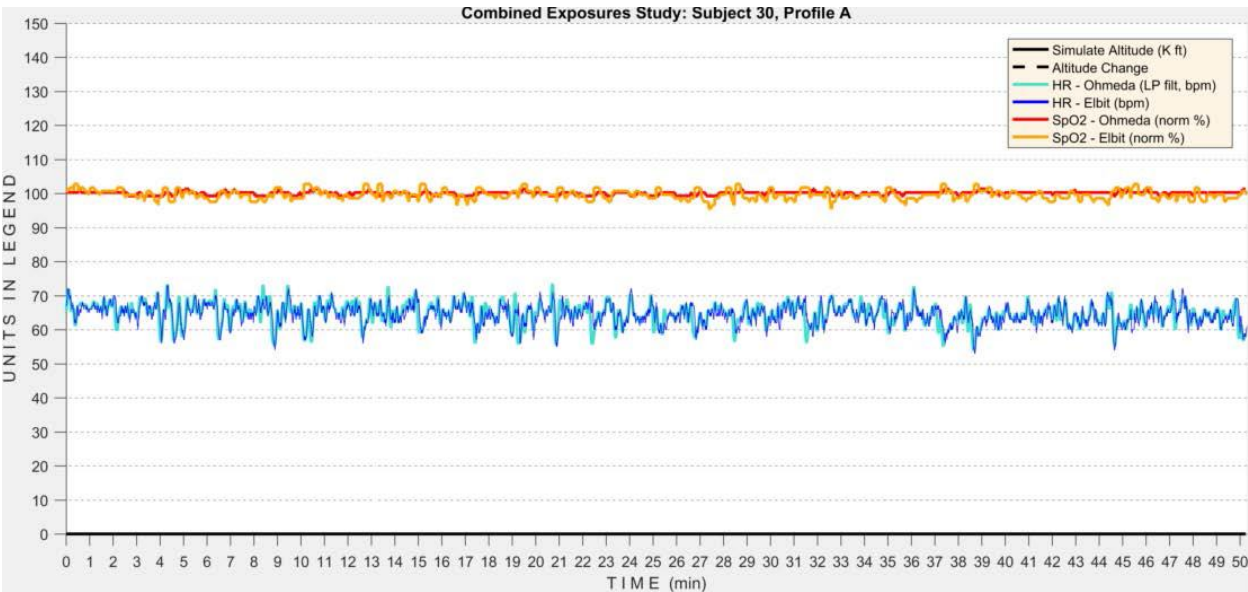
Appendix 4. Plots for the Elbit Canary system vs the Ohmeda pulse oximeter.



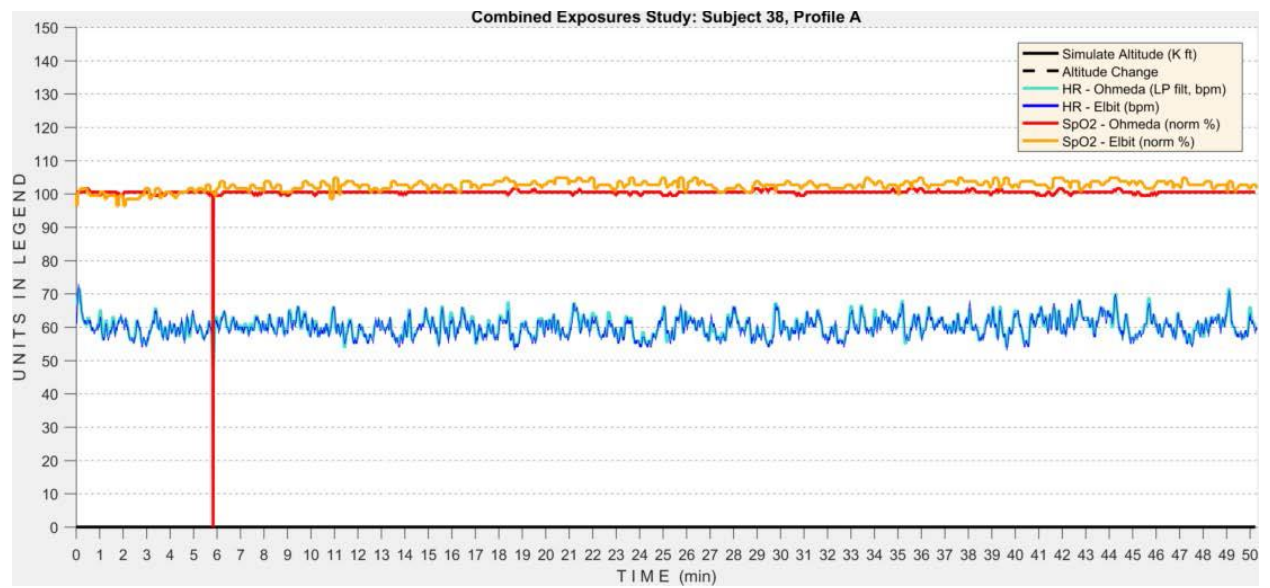
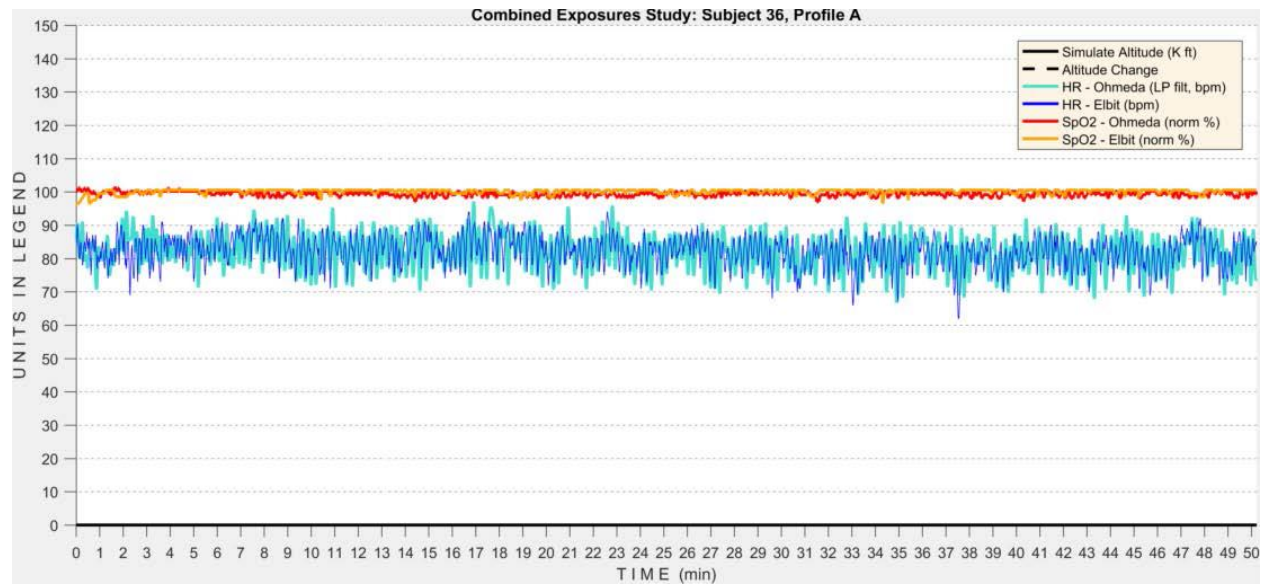
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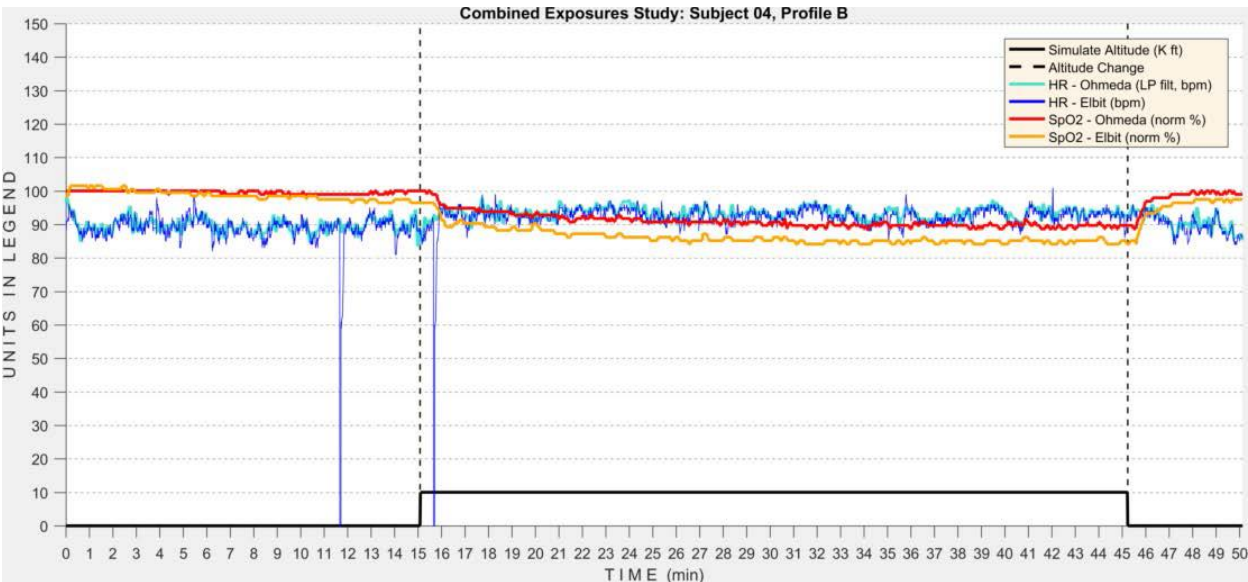
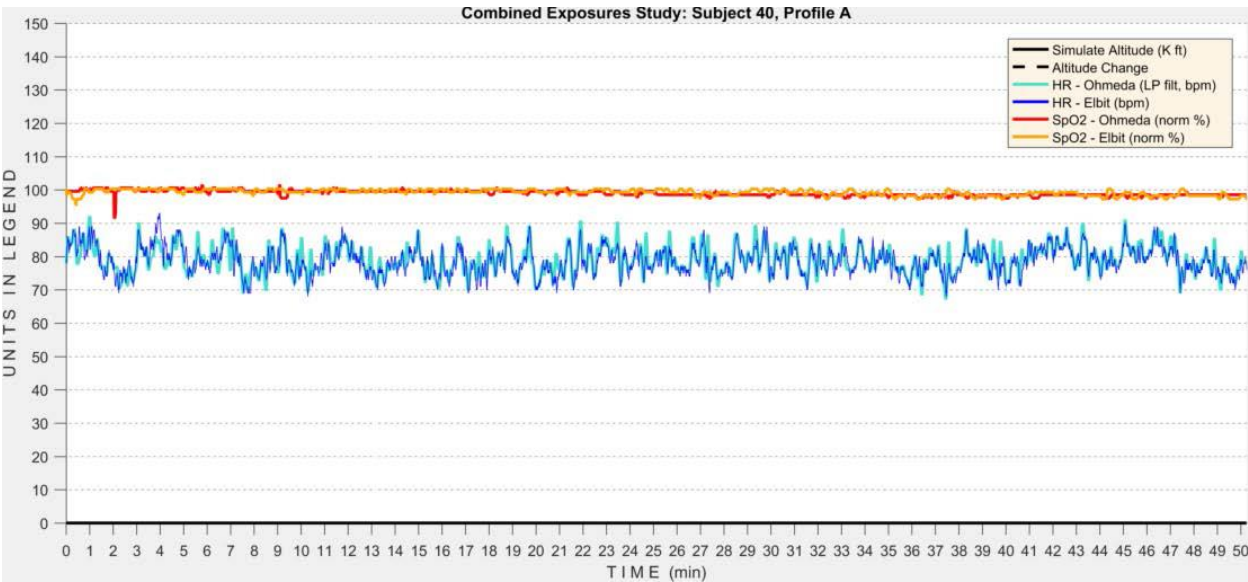
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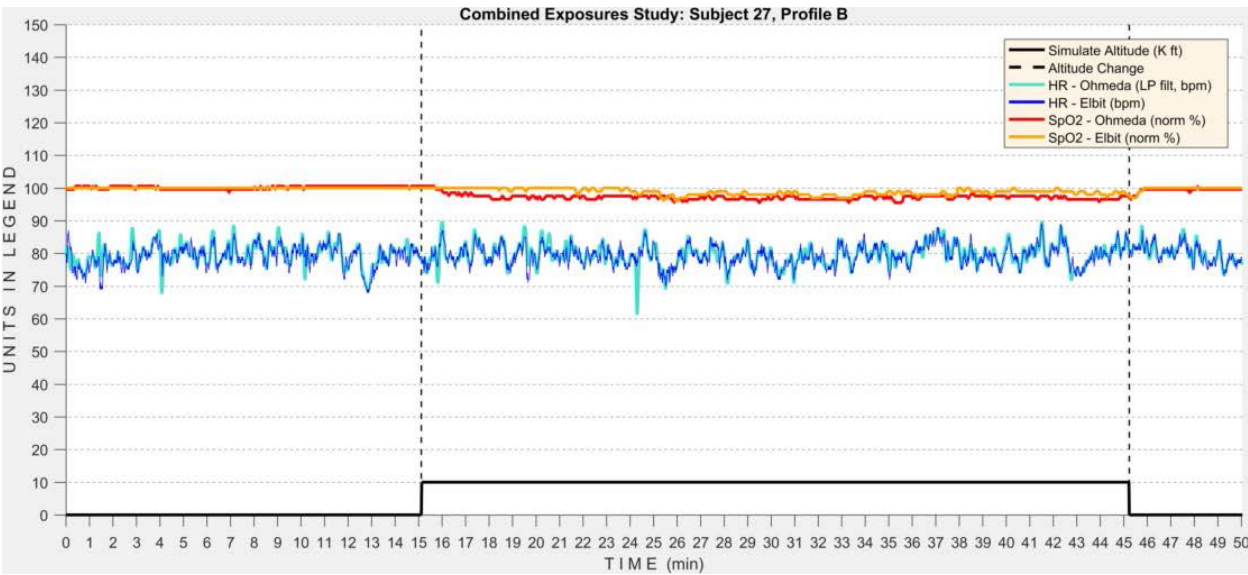
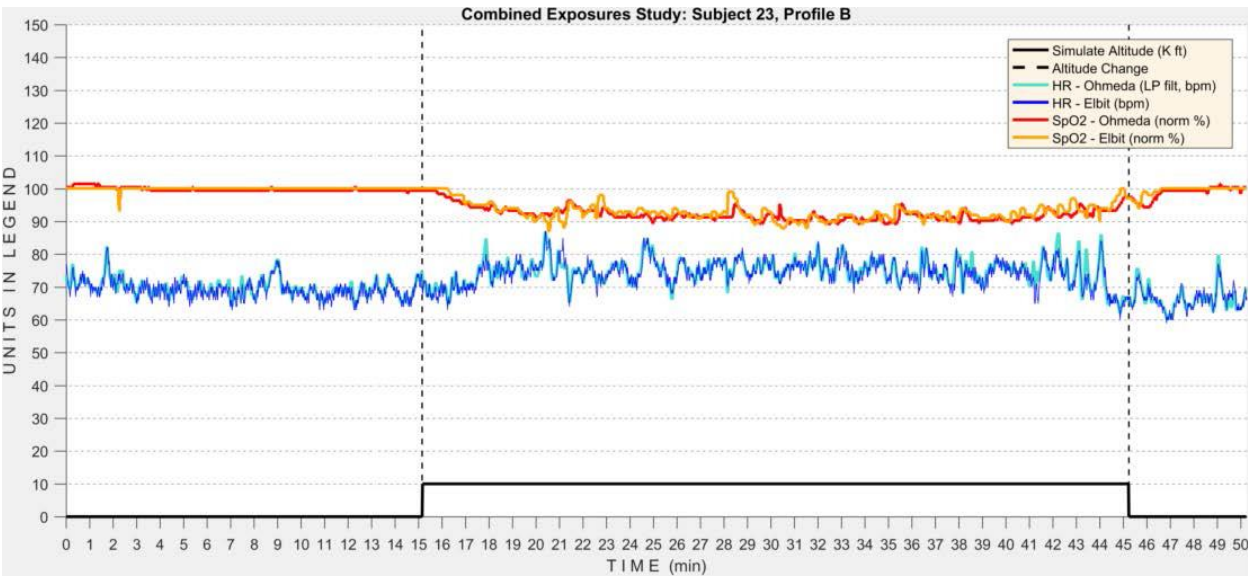
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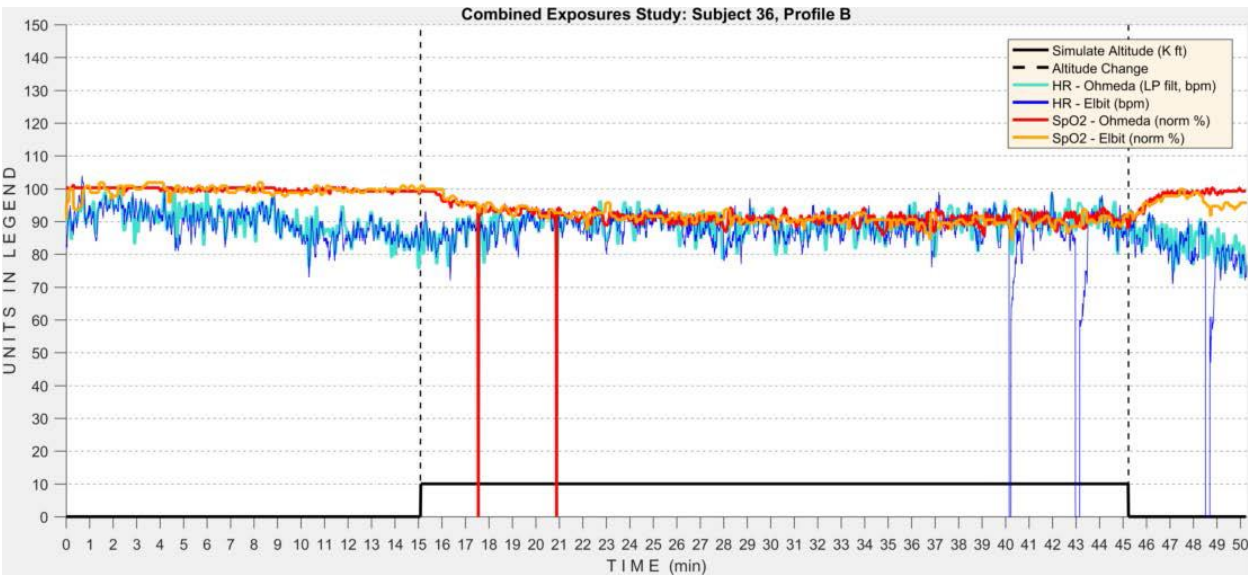
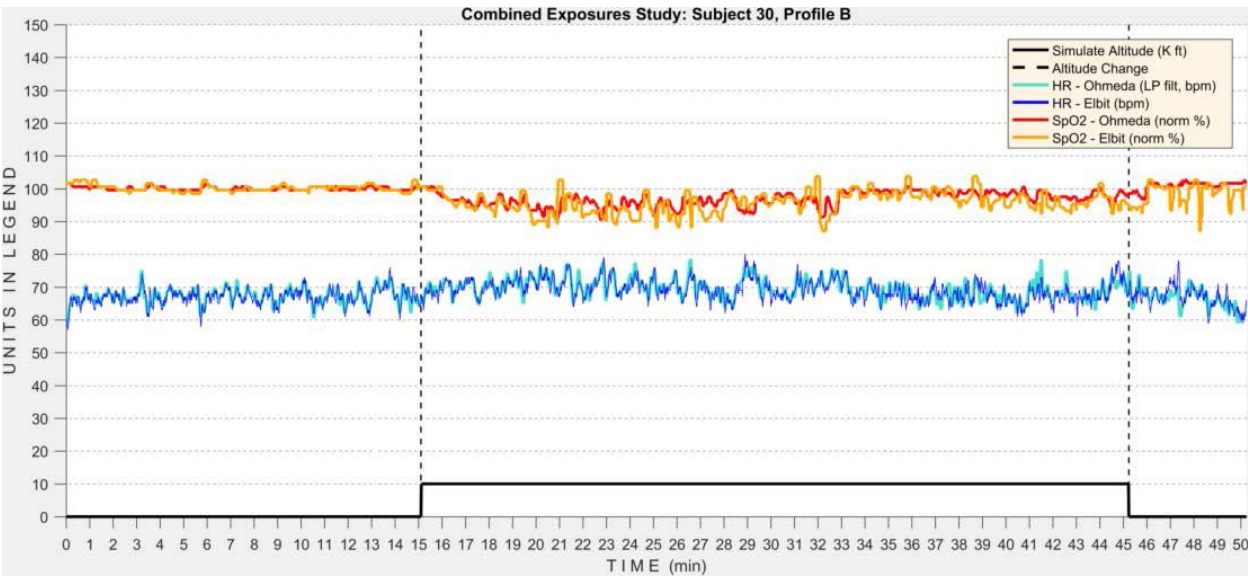
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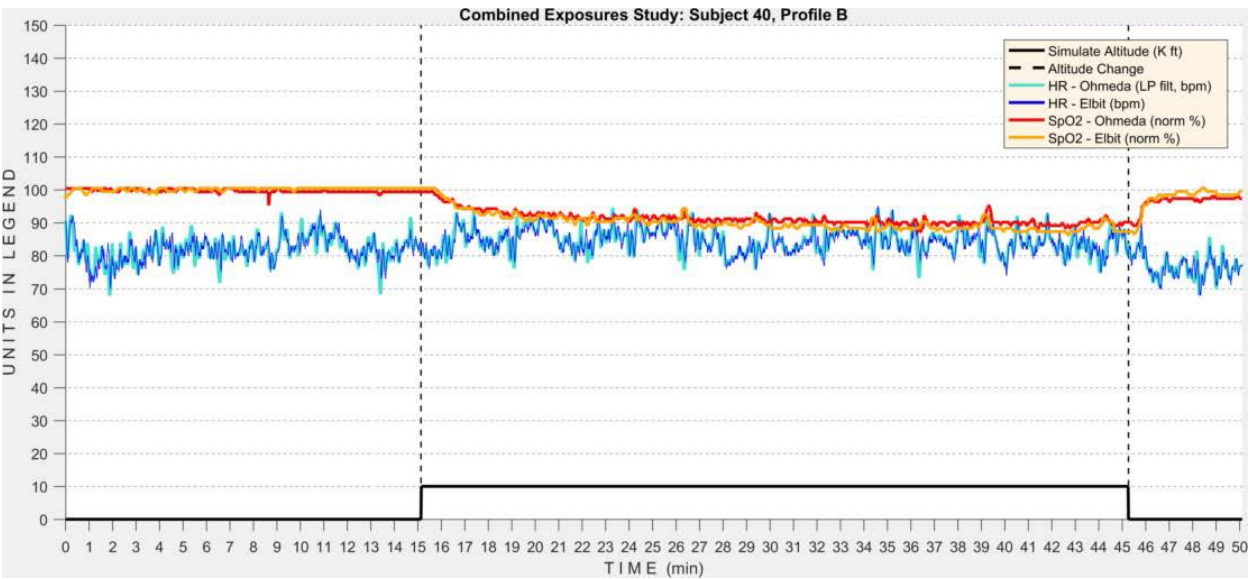
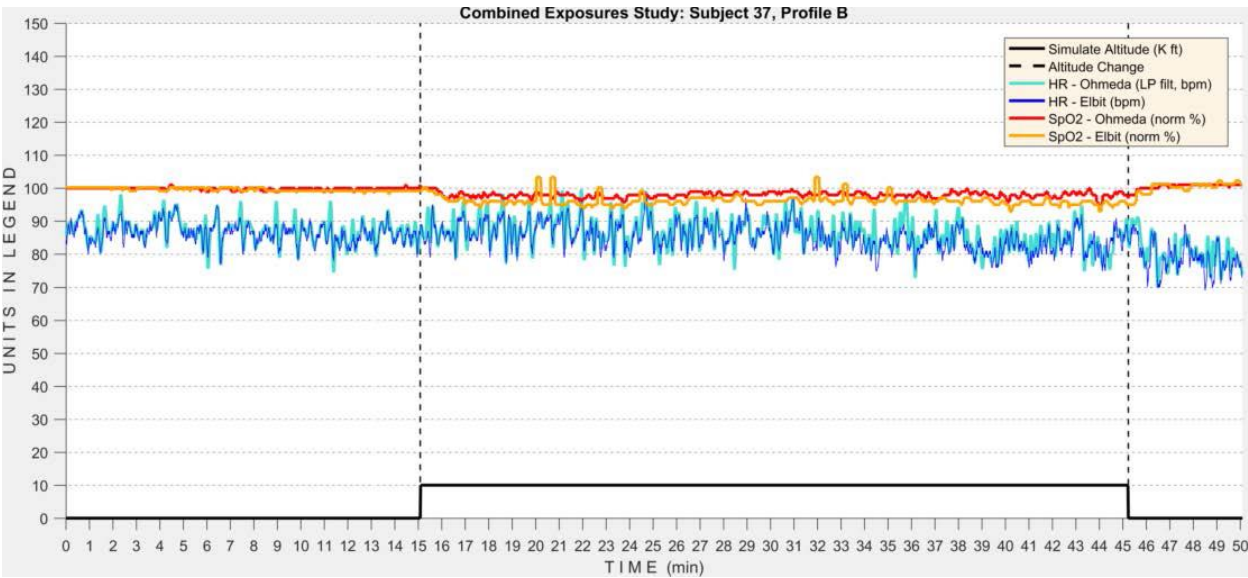
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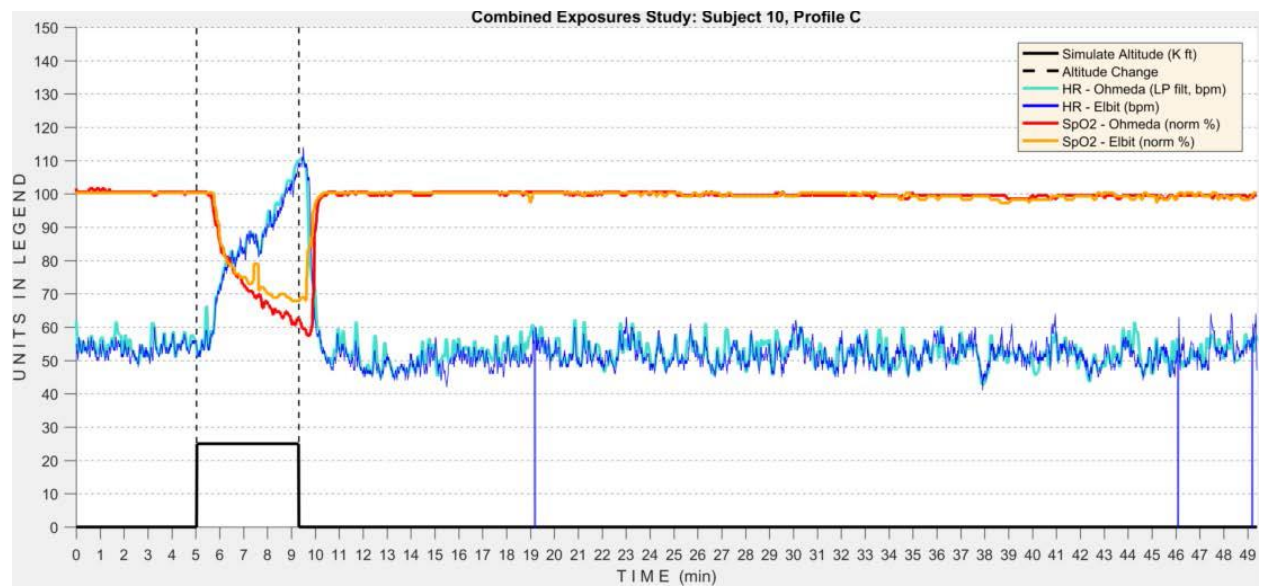
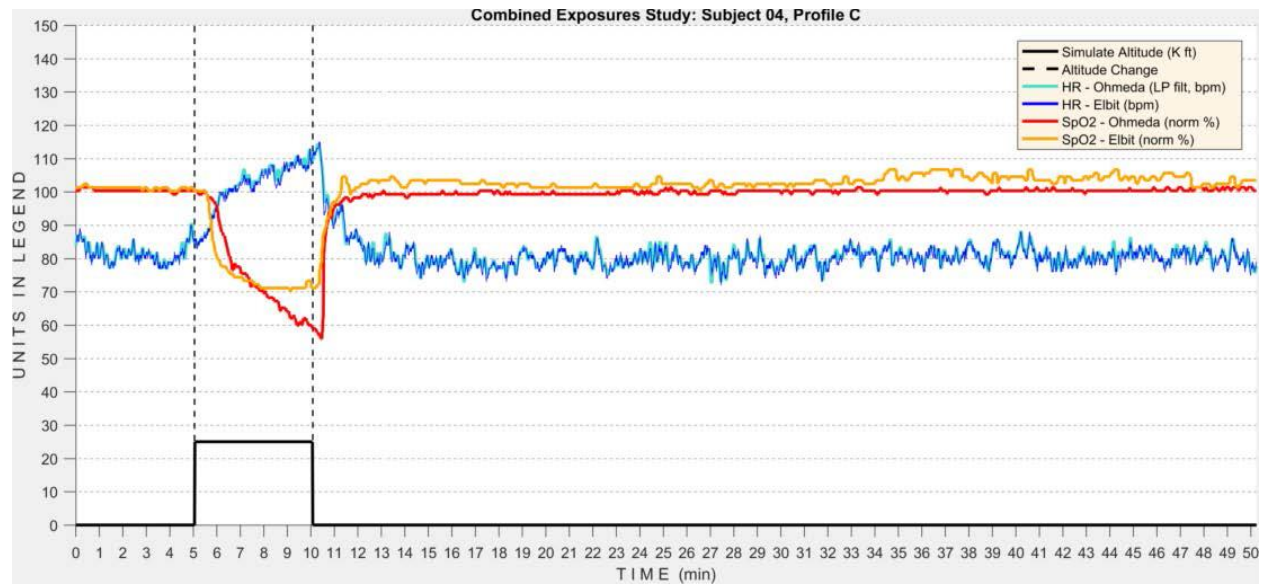
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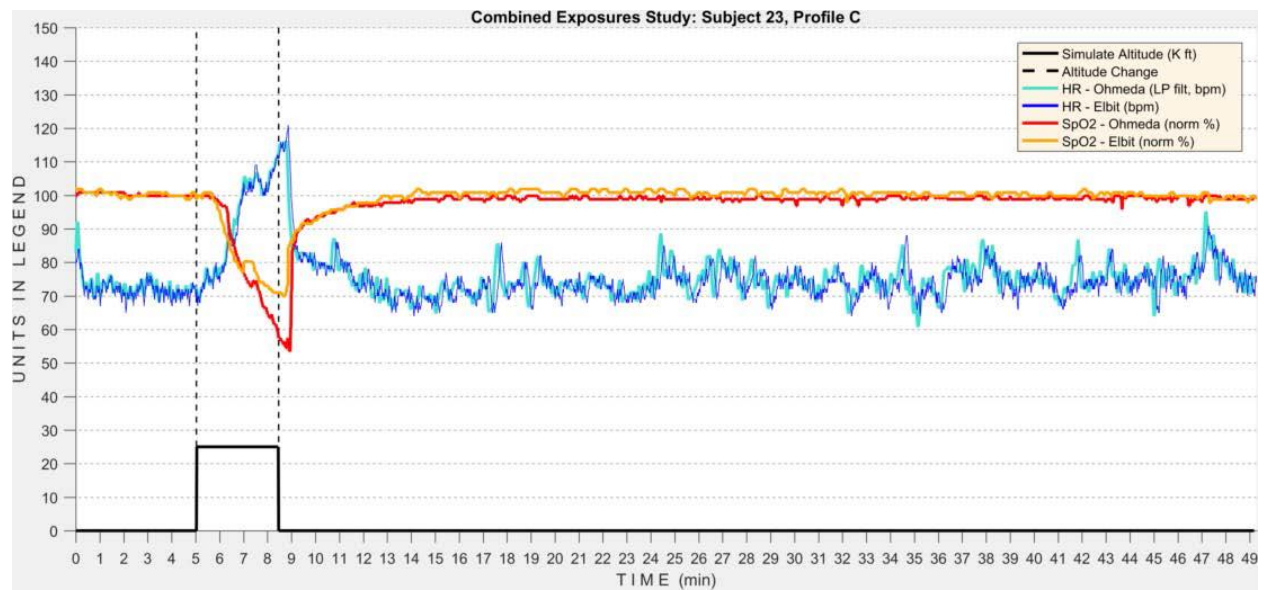
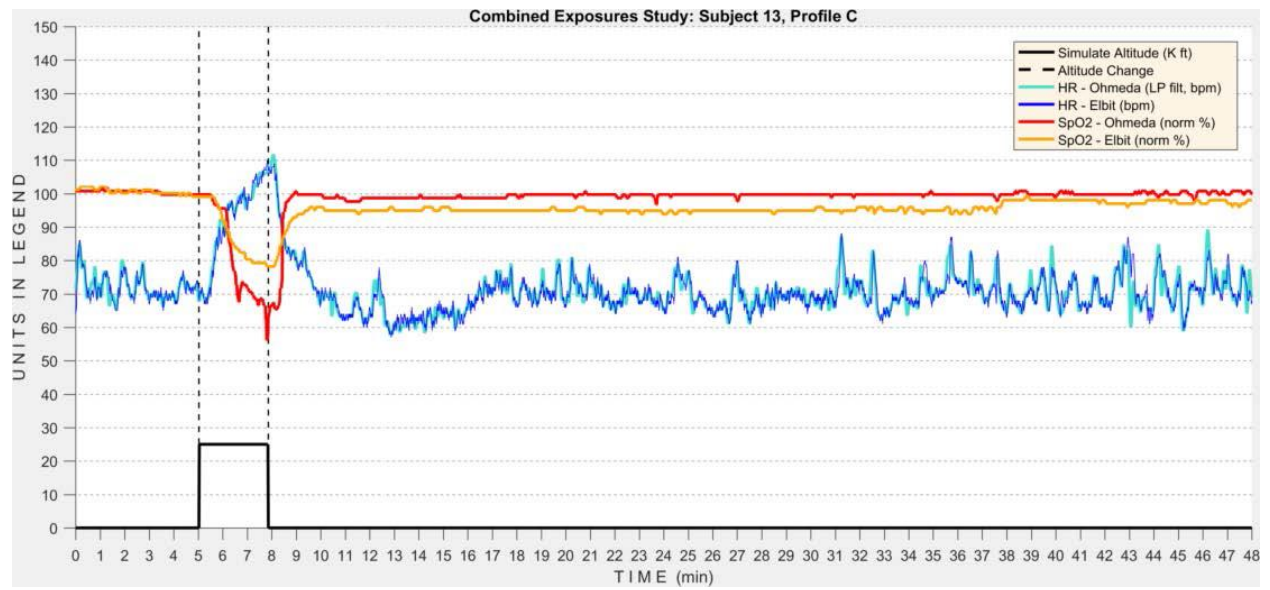
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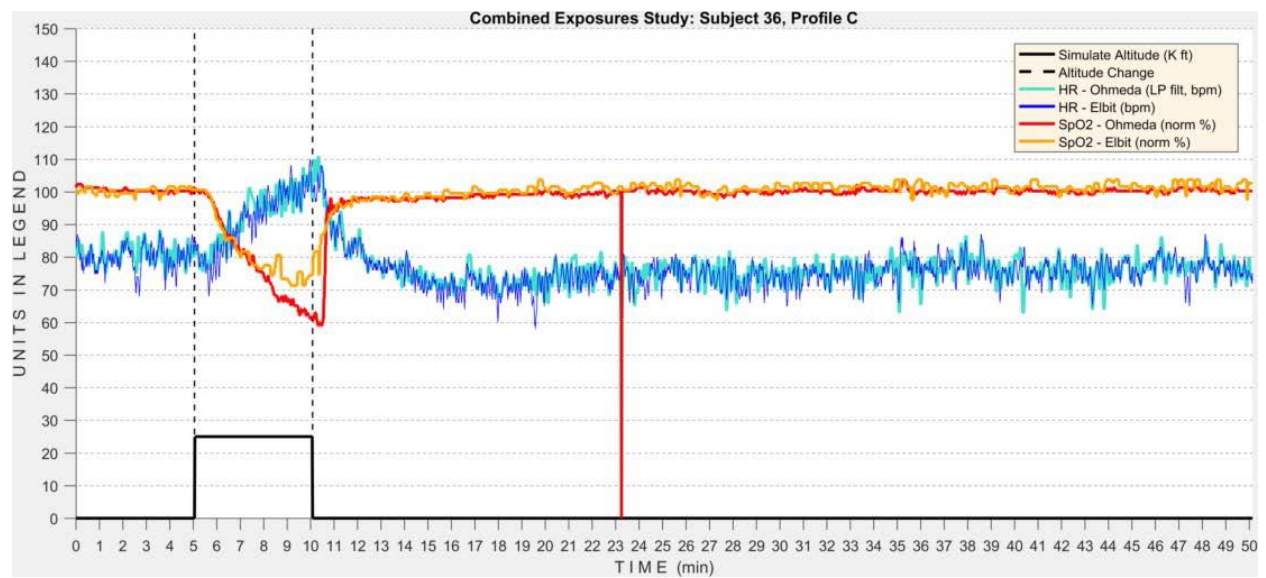
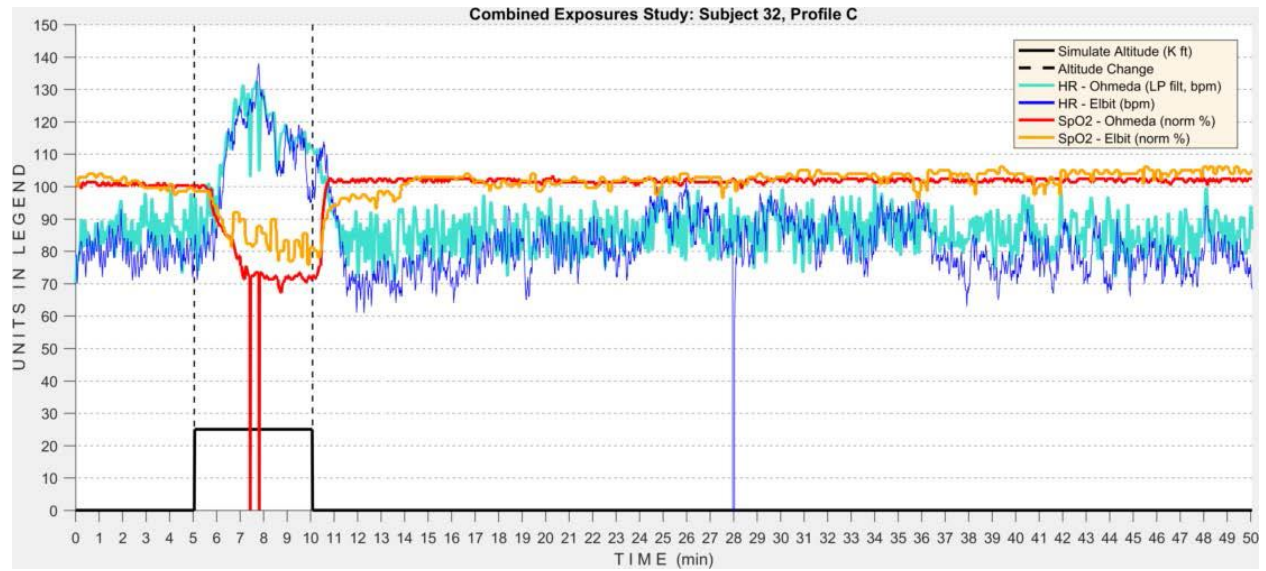
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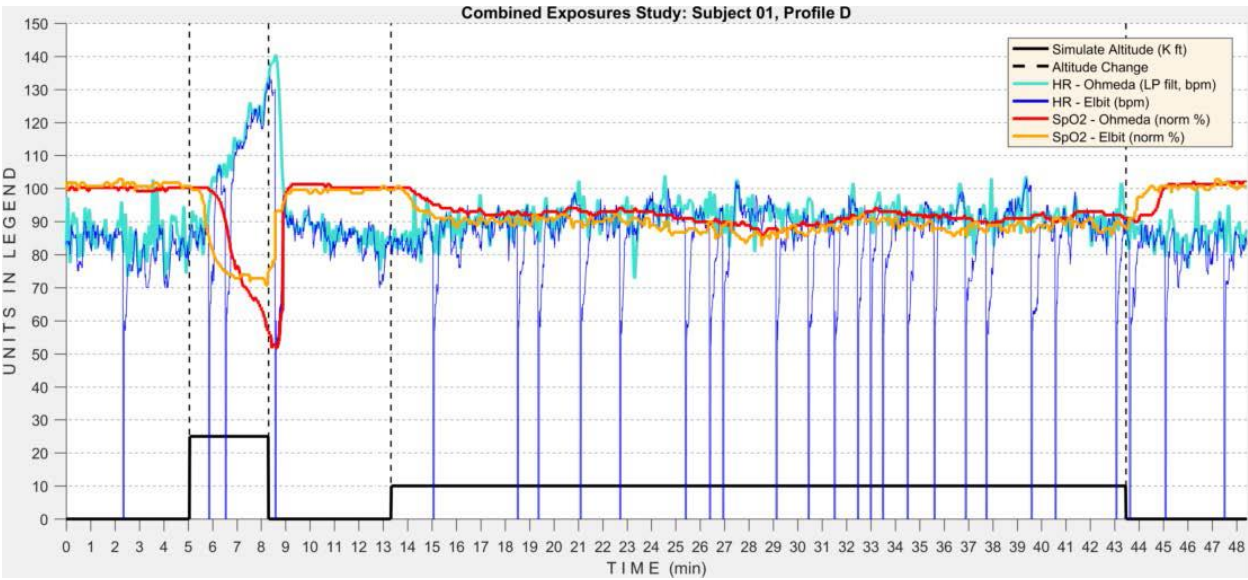
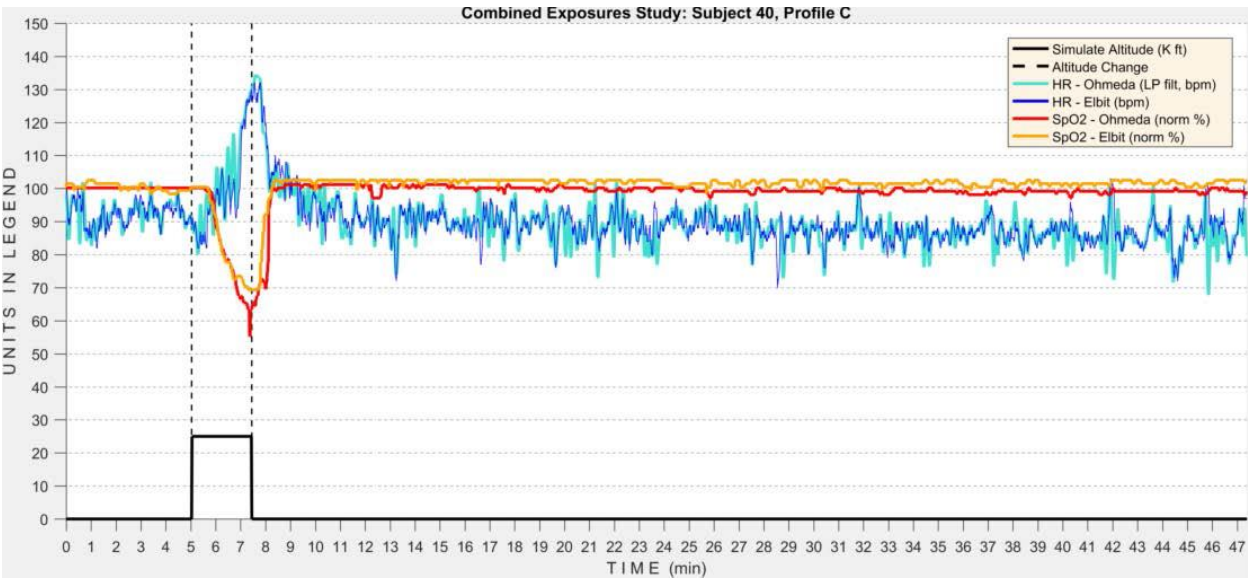
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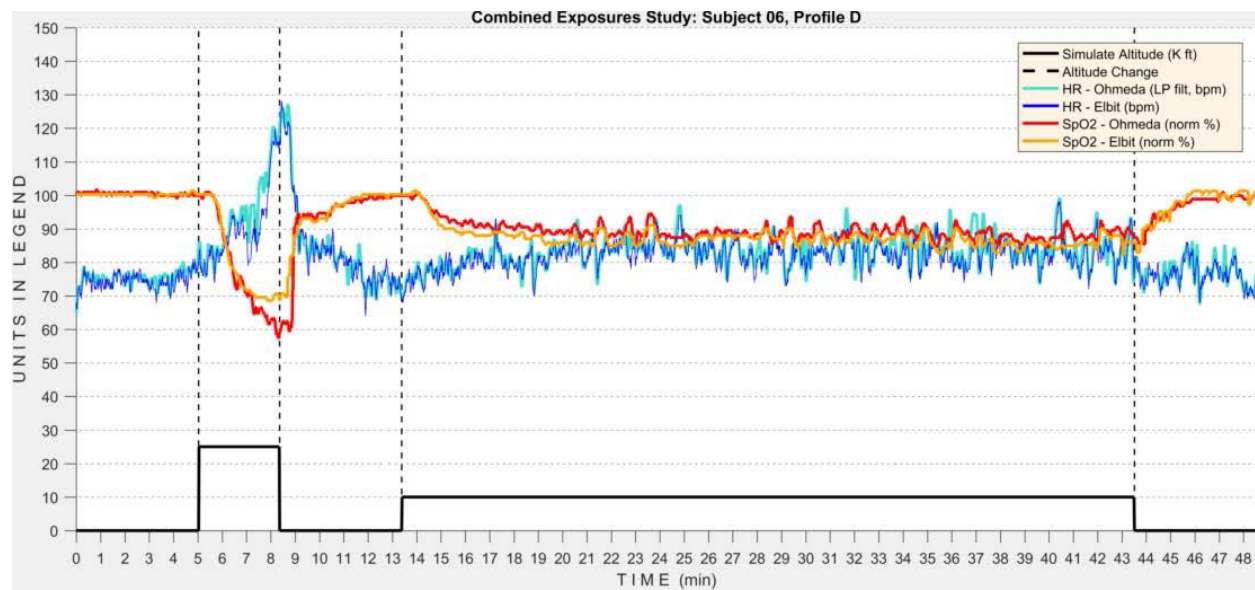
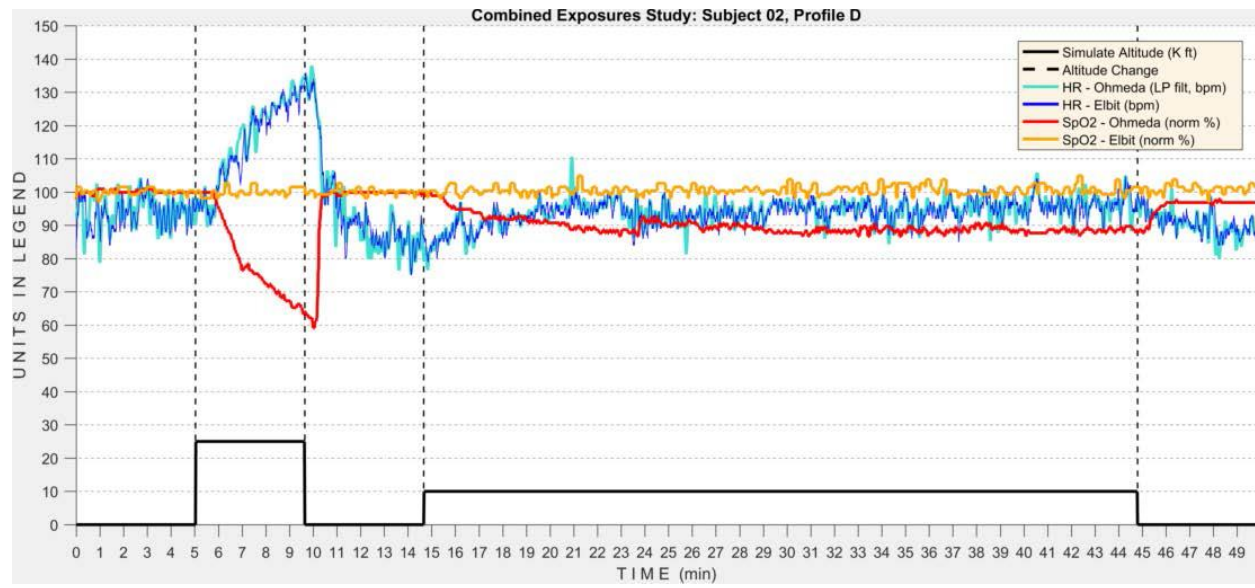
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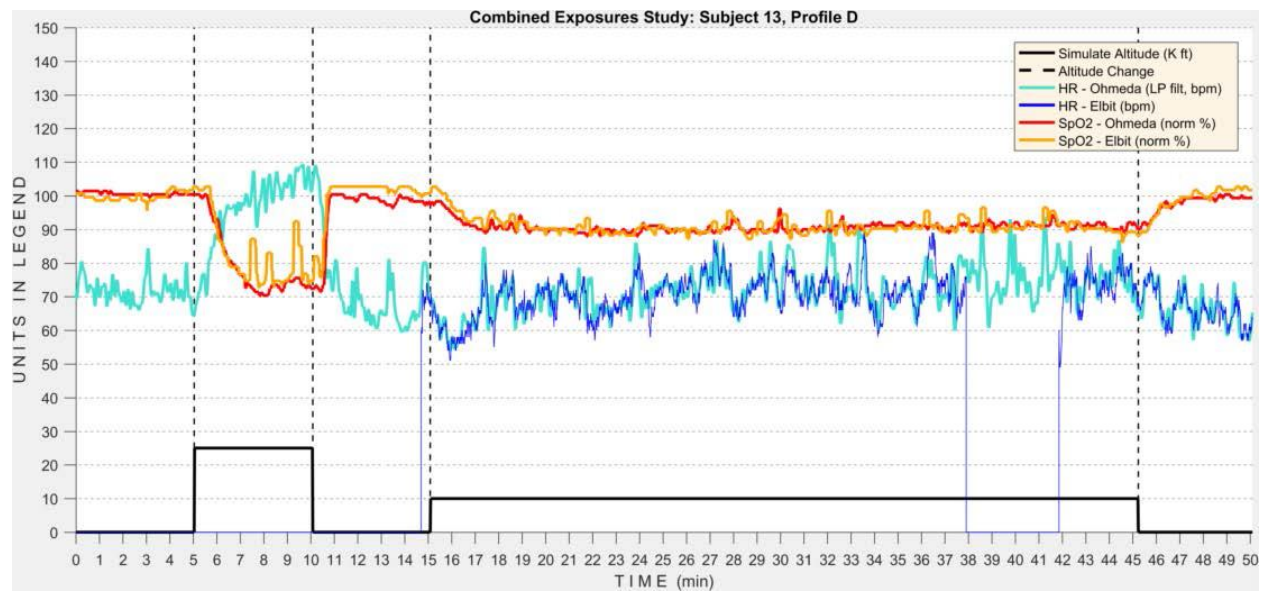
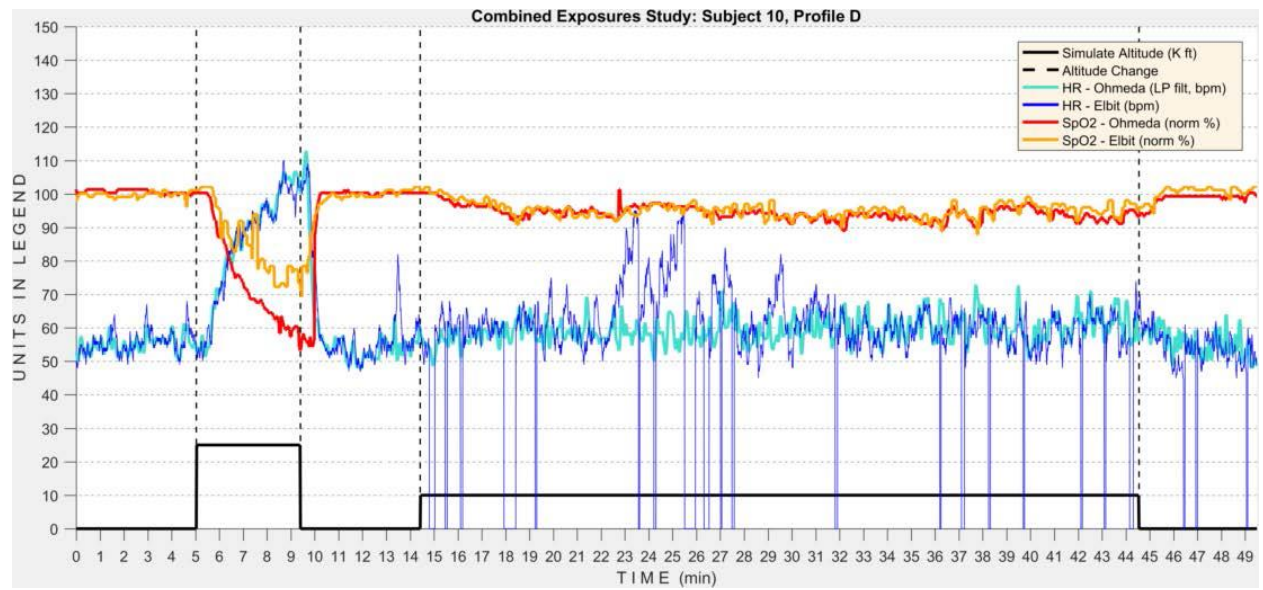
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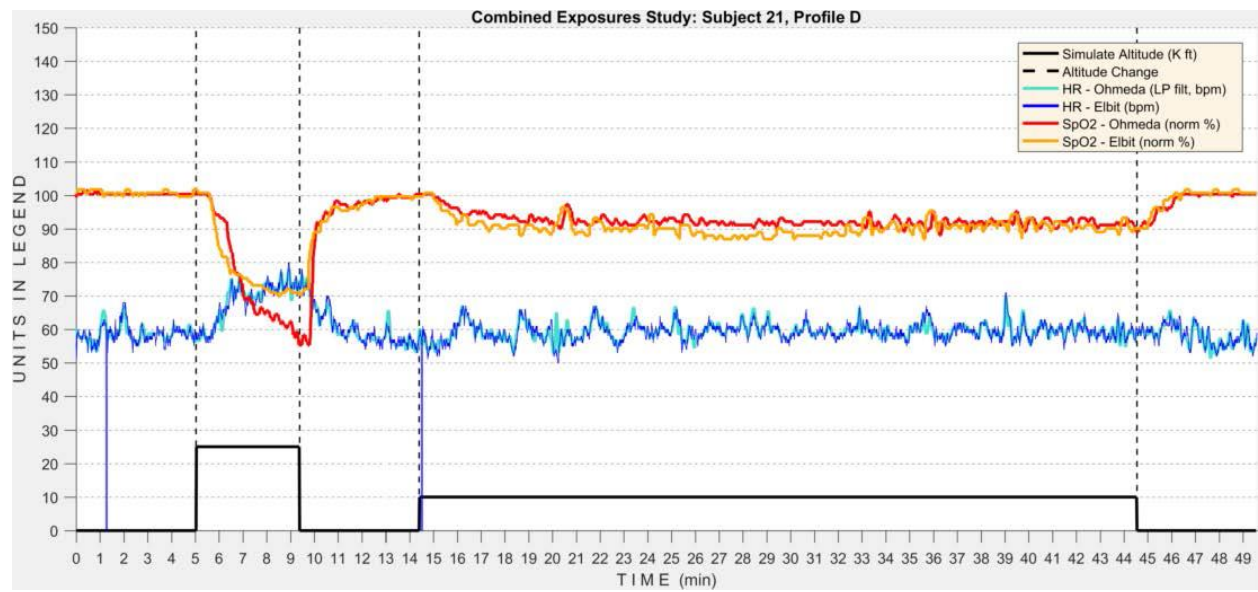
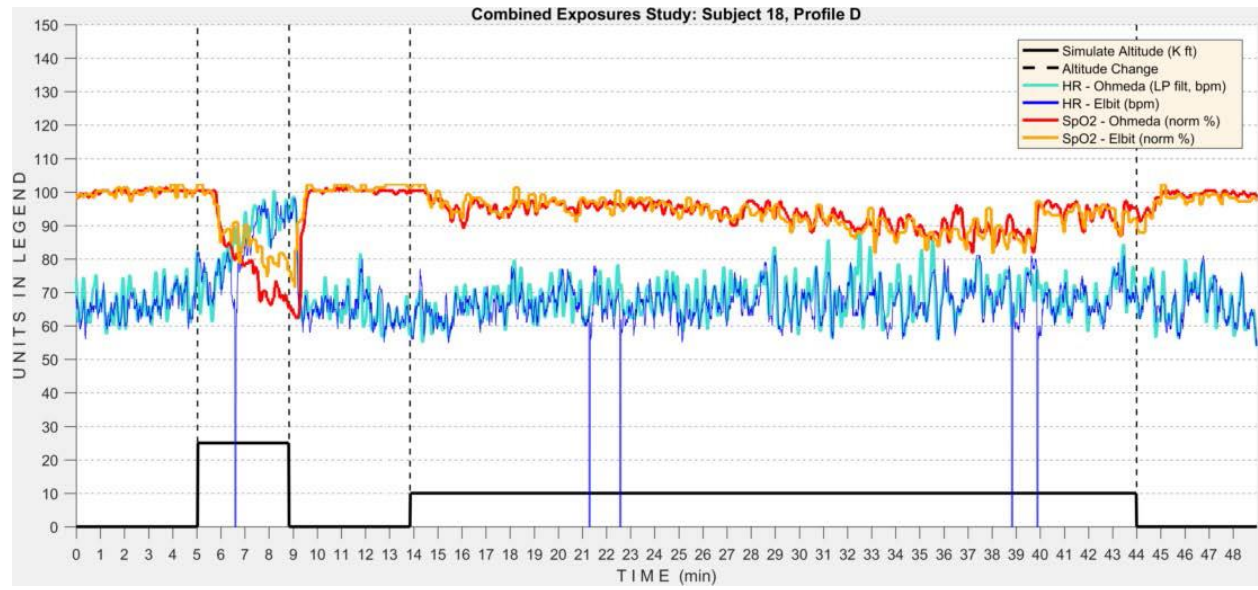
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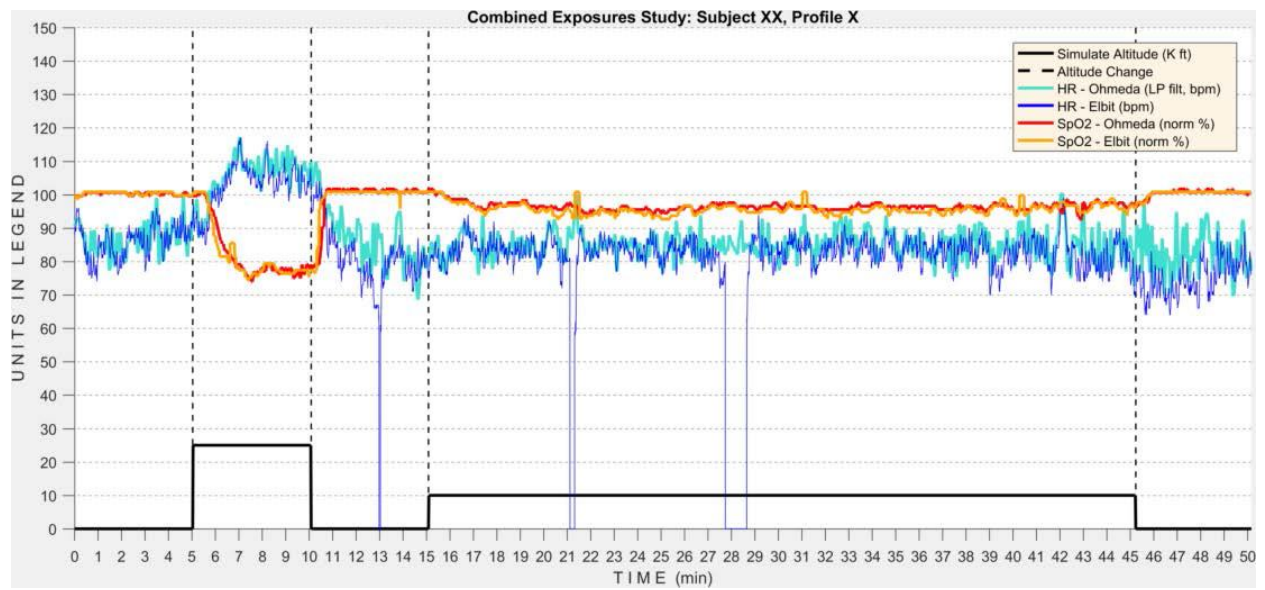
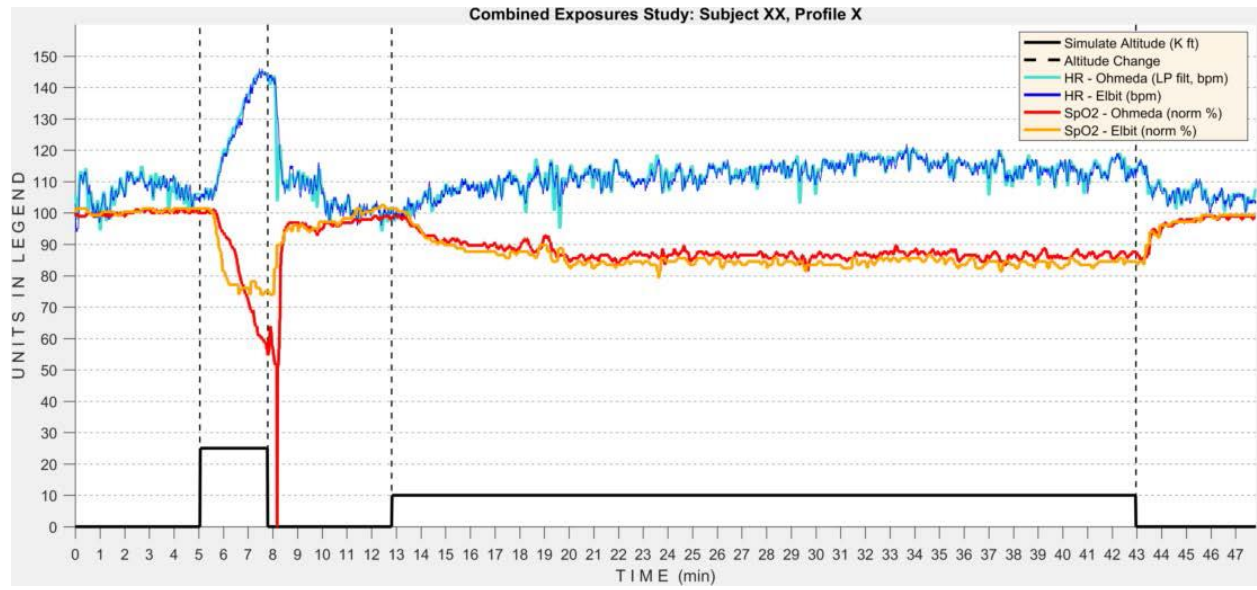
## Evaluation of Elbit Canary and DynaSense PocketNIRS



## Evaluation of Elbit Canary and DynaSense PocketNIRS



## Evaluation of Elbit Canary and DynaSense PocketNIRS



Evaluation of Elbit Canary and DynaSense PocketNIRS

