Technical Report
TR-1268

Test Report: Oximeter Headband Initial Characterization Test on Form, Fit, and Function

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14 October 2021

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LEXINGTON, MASSACHUSETTS

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Massachusetts Institute of Technology
Lincoln Laboratory

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ABSTRACT

The oximeter headband is a new physiological status monitoring system developed by Massachusetts Institute of Technology Lincoln Laboratory (MIT LL), Lexington, Massachusetts and the Institute for Advanced Functional Fabrics of America (AFFOA), Cambridge, Massachusetts. It was tested for form, fit, and function during an internal test held at MIT LL. The oximeter headband system consists of a custom-made, textile-based headband. It is a noninvasive, non-subcutaneous, and non-radiation harming device that only maintains surface contact with the skin. It has been specifically designed to meet the needs of the military. The test described in this report assesses the first field-portable prototype of the oximeter headband device. Data was collected from eight test participants in two test scenarios, a functional evaluation, and a form and fit assessment. Results from the functional evaluation show that the oximeter headband device is capable of providing valid SpO2 estimates at varying activity levels (sit, walk, and run) with a residual sum of squares (RSS) as low as 27, however there is inconsistency in validity across the entire data set. In some instances, RSS was as high as 3.1E4. Further characterization is necessary to better understand the source of variation. In regards to form and fit, the oximeter headband was acceptable to wear as currently constructed. However, tightness of fit was the main concern with regard to comfort and user acceptability. Form was rated as a 4.9 for comfort on a seven-point discomfort/comfort scale, with the a 5 indicating 'slightly comfortable.' Fit was scored a 4.3 with a score of 4 equal to 'moderately good' and a score of 5 equal to 'extremely good.' The results of this initial evaluation provide a starting point for more extensive evaluation of form, fit, and function.

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ACKNOLWEDGEMENTS

We would like to thank our collaborators at the Advanced Functional Fabrics of America (AFFOA) for their vital role in the development of the oximeter headband system: Charlotte Fairless, Bruce Thompson, and Tong Heng. We would like to thank our colleagues at MIT Lincoln Laboratory whose previous work was incorporated into the software of the Oximeter Headband system: Brian Telfer and James Williamson. Lastly, we would like to thank USARIEM, specifically Reed Hoyt and Scott Montain for their support and management of the Oximeter Headband program, and the vision of this system in meeting the needs of tomorrow's warfighters.

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TABLE OF CONTENTS

TABLE OF CONTENTS
(Continued)

Page

LIST OF ILLUSTRATIONS

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LIST OF TABLES

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1. INTRODUCTION

Blood oxygenation (SpO2) is an important metric for monitoring altitude acclimation (Dunnwalk, et al. 2021), monitoring shock in the event of trauma or hemorrhage, as well as early detection of viremia (Rahman, et al. 2021). An individual's SpO2 can drop acutely in response to these environmental changes, often without warning. In these scenarios, continuous, real-time monitoring of blood oxygenation provides the ability for early warning and enables corrective action to take place prior to more adverse outcomes. This type of real-time SpO2 monitoring is particularly beneficial in use cases where a single end user is monitoring many individuals, such as a squad medic monitoring their entire team. However, commercial pulse oximeters currently available are either tethered to benchtop electronics, limited in their wear location, or only allow for a single patient or individual to be monitored by a single device.

Employing finger pulse oximeters or standard adhesive-type patches are not practical for many field applications because they interfere with the activities the user must accomplish, or are impractical for other varying reasons (Mendelson et al., 2013). Specifically, the finger-worn SpO2 monitor requires the user to position the sensor on the finger and remain relatively stationary for the assessment to take place. Conversely, there are monitoring systems primarily for use in the fitness arena that could be acceptable to wear, can be used in harsh environments, and do not interfere with job performance. These devices do not provide the accurate and precise physiological data needed to make mission or safety decisions, however. For example, the SpO2 monitor on the commercially available Apple Watch 6 (Apple Inc., Cupertino, CA) requires the user to remain motionless with their arm in a horizontal position for ten seconds. This is unacceptable for real-time monitoring of Warfighters while undergoing training or actual missions.

A suitable system must produce valid data, work reliably in the specific environment for which it is intended, be comfortable and easy to use, and not inhibit motion or job performance (Paradiso, et al., 2005). Furthermore, sensors must be of minimal weight and size, consume little power, and have negligible impact on the body (Patel et al., 2012). They must also provide accurate data that can be analyzed to provide actionable decision-making. To function in real time, the wearable SpO2 sensor must have reliable wireless body area network connections (Milenković et al., 2006). Without connectivity, PSM use reverts to physiological data collection and storage for post hoc analysis.

Recently, a prototype oximeter headband system was developed to provide real time SpO2 monitoring for a team of individuals. The purpose of this present test was to assess the form, fit, and function of the oximeter headband prototype system. In addition to the functionality of the developed SpO2 sensor system, the human factors aspects of the system were also evaluated. This test is the first assessment of the first set of field portable prototypes.

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2. METHODS

2.1 TEST PARTICIPANTS

Eight MIT LL employees served as test participants and wore the oximeter headband system. Inclusion criteria comprised of (1) participant consent and (2) participants to be greater than 18 years of age. Exclusion critera was defined as vulnerable populations, including children and populations vulnerable to COVID-19. Participants had an average head circumference of 56.8 +/- 0.5 cm (minimum: 54.0 cm, maximum: 58.0 cm). Seven individuals participated in Scenario 1, the treadmill test, and seven individuals participated in Scenario 2, the form and fit assessment (although they were not the same seven individuals in both scenarios). In Scenario 1, test participants only interacted with the oximeter headband device. In Scenario 2, test participants interacted with the oximeter headband device as well as the iPhone end user device (EUD).

2.2 TEST ARTICLES

The oximeter headband, a textile-based physiological status monitoring system, was developed and manufactured by MITLL and AFFOA for USARIEM with the operational military community as the ultimate customer. The oximeter headband system consists of a custom-made, textile-based headband integrated with a commercial off-the-shelf (COTS) SpO2 sensor device (Maxim Integrated; San Jose, CA) and COTS flex cables (Molex; Lisle, IL). The oximeter headband is a noninvasive, non-subcutaneous, and non-radiation harming device that only maintains surface contact with the skin. The oximeter headband was designed as a textile-based device for improved form (comfort), fit, and function. It has been specifically designed to meet the needs of the military. The oximeter headband pairs with an Apple iPhone (Apple, Inc.; Cupertino, CA) EUD via Bluetooth Low Energy (BLE) for data collection and display. The EUD has the ability to connect with multiple oximeter headband units such that a single end user can monitor the SpO2 of up to eight individuals at once. In the first generation (Gen 1) prototype devices tested, raw photoplethysmography (PPG) and accelerometer signals are sent from the oximeter headband to the EUD.

2.2.1 Oximeter Headband

The oximeter headband was designed to function on the head alone or under any head equipment, such as the standard-issued U.S. Army infantry helmet, head net, and/or other personal protective equipment (PPE). The PPG sensor module is located at the front of the headband and should reside at the forehead. The PPG sensor module consists of a red LED (660 nm), IR LED (940 nm), photodiode, and co-located accelerometer. The backend electronics puck should sit at the back of the head. The backend electronics puck consists of a LiPo battery, processor and BLE communication electronics. The sensor module is to be worn against the skin. However, the band itself and the puck that is located at the backend of the device can accommodate being worn over hair. The oximeter headband prototype is shown in Figure 1. The oximeter headband device has a maximum expected battery life of eight hours. A green LED located on the backend electronics puck will indicate if the

headband device is on. Red/yellow LED will alternately flash if the oximeter headband is plugged in and charging. The light will change to green when the headband oximeter is fully charged.

When the oximeter headband device is 'on' and the 'Fabric Sense' application (Fabric Sense is the name of the application on the EUD for this SpO2 headband system) on the EUD is open, the headband oximeter will automatically attempt to pair with the EUD. Once paired, the PPG sensor module will continuously acquire raw PPG signals, as well as the three-axis accelerometer data from the co-located accelerometer. Raw data is continually sent to the EUD for computation of SpO2 and heart rate. See Appendix A for additional details on oximeter headband operation.

Figure 1. Textile integrated oximeter headband sensing device (top). Internal electronics (bottom).

2.2.2 End User Device (EUD) Display

The EUD display resides on an Apple iPhone. 'Fabric Sense' is the custom iPhone application that connects to the oximeter headband and displays data from the oximeter headband. The 'Fabric Sense' application display has three screen views: home screen, grid view, and detail view. The home screen displays the name of each connected oximeter headband device, SpO2 value, and percent confidence value. Green indicates a SpO2 above 98%, yellow indicates SpO2 between 95-98% and red indicates a SpO2 values below 95%. The color coded SpO2 thresholds may be adjusted by the user.

Gray indicates that an oximeter headband device is not connected. The grid view is an alternative way to see the status of all connected oximeter headband devices at once. The detail view provides the raw PPG signal, trending SpO2 and trending heart rate values for a selected oximeter headband device. One can switch between the different views by swiping left and right. Examples of the display are shown below.

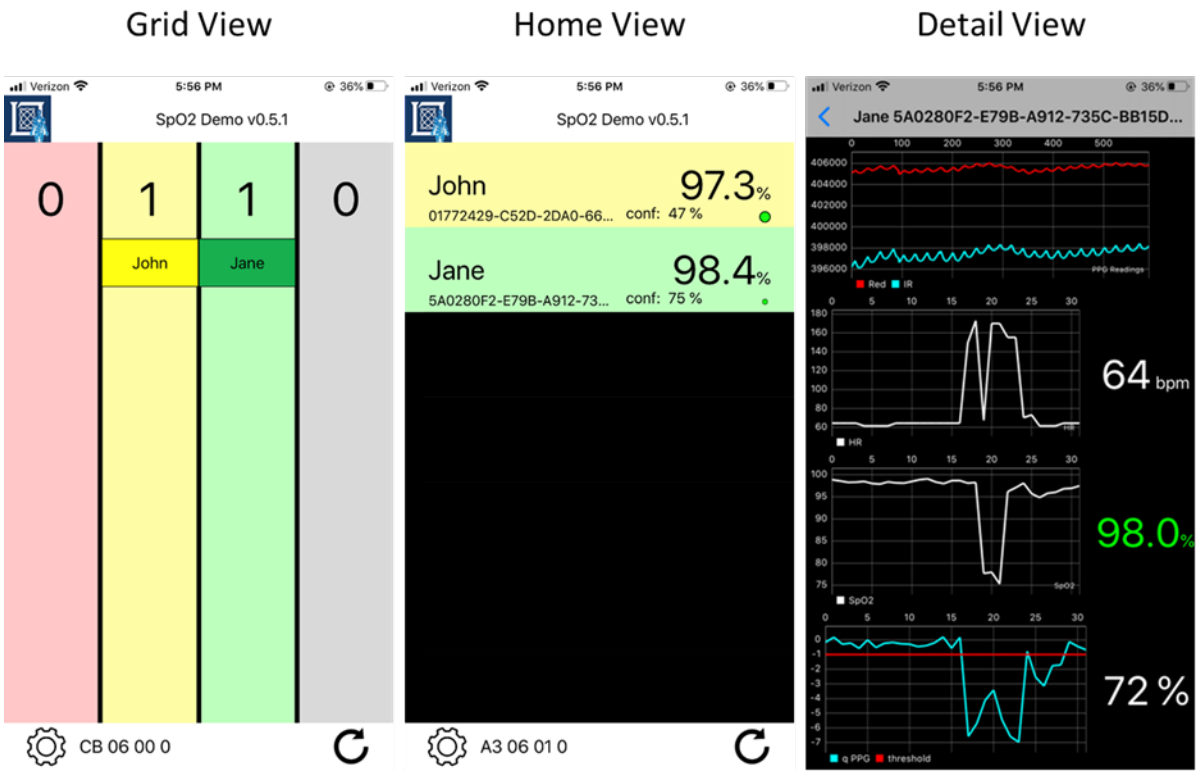

Figure 2. EUD display. Grid view (left), home screen (center), detail view (right).

Each connected oximeter headband device may be renamed in the 'Fabric Sense' application. The new name will continued to be tied to device, even after it is disconnected and reconnected to the EUD. See Appendix A for additional details on operation of 'Fabric Sense' application.

SpO2, heart rate, and motion mitigation algorithms employed on the EUD were previously developed by Williamson, et al. (2018). The SpO2 and heart rate values are calculated on the EUD from the red and IR PPG signals. Motion mitigation algorithm utilizes the accelerometer data to determine if a data frame is corrupted by motion artifacts. If a frame is deemed corrupt, it is not included in the multi-frame SpO2 estimate. Percent confidence metric uses the number of corrupt and uncorrupted

frames to provide an estimate for how confident one should be in the accuracy of the reported SpO2 value. The greater the number of motion corrupted frames, the lower the percent confidence value. The Gen 1 oximeter headband prototype user's guide may be found in Appendix A.

2.3 TEST PROCEDURE

2.3.1 Functional Evaluation

Participants were asked to concurrently wear the oximeter headband on the head and a benchmark commercial device (Masimo MightySat, Masimo Corporation; Irvine, CA) on the finger. Participants then carried out three pre-determined activities: sitting stationary, walking on treadmill, and running on treadmill. The participants' hand with the commercial finger clip device was held stationary and horizontal throughout each activity. Data was recorded for 3-5 minutes on both devices simultaneously, at each activity level. Observations of the participants' head movements and the time of movement events were recorded. Motion observation logs are shown in Appendix B.

Head circumference was measured in triplicate to the nearest 0.5 cm using a flexible tape measure around location of the head where the oximeter headband would reside.The head circumference measurement was carried out while the test participant was sitting stationary, prior to donning the oximeter headband device.

2.3.2 Form and Fit Assessment

Participants were asked to wear the oximeter headband and keep a log of the free-living activities they did while they were wearing the headband. Post-activity subjective feedback of the system was obtained via survey questionnaire.

Activities

Participants wore the oximeter headband for a mean time of 94.9 ± 47.7 minutes with a range of 25 to 160 minutes during free-living activities of their choosing. Most individuals wore the headband continuously but may have altered activities. A particular activity would be considered an activity session. Therefore, if a person was sitting, then rose and did a walking session and then sat again all continuously before taking the headband off, this was considered 3 activity sessions in the data described in Table 1 below.

TABLE 1

Activities Performed While Wearing the Oximeter Headband

Activity	Participants (Number)	Sessions Total (Number)	Mean ± S.D. Per Session (Minutes)	Minimum to Maximum Time Per Session (Minutes)
Sitting	7	12	31.9 ± 33.2	5.0 to 124.0
Standing	2	3	15.7 ± 11.2	6.0 to 28.0
Walking	6	7	16.7 ± 16.7	2.0 to 45.0
Walking Up/Down Stairs	1	1	8.0	
Sewing and Cutting	1	1	75.0	
Weaving	1	1	25.0	

Survey

Immediately upon completion of the free-living activity session, participants filled out a survey with Likert-type and open-ended response questions about the fit, comfort, impact of wearing the headband on the various activities, the impact of wearing the headband on the head, the durability of the system, functionality, and the overall acceptability of the headband. This survey may be found in Appendix C.

2.4 DATA ANALYSIS

For functional evaluation, individual time series data was plotted for SpO2 and heart rate by activity and participant, both for the oximeter headband and the benchmark commercial device (Masimo MightySat, Masimo Corporation; Irvine, CA). Physiological data obtained from the oximeter headband system was evaluated for (1) reasonableness (given the intensities of exercise the test participants engaged in) and (2) validity (comparison with the commercial benchmark device). Both the oximeter headband device and commercial benchmark device were evaluated for reasonableness. Given the nature of the test scenario, where there were no changes to oxygen supply, reasonable physiological data was defined as a stable SpO2 value between 94–100% and heart rate between 50–180 beats per minute (bpm). To evaluate validity, residual sum of squares (RSS) was calculated for each data set. Low RSS value indicates good agreement between the SpO2 estimate from the oximeter headband and the SpO2 estimate from the commercial benchmark device. A high RSS value indicates poor agreement between the SpO2 estimates of the two devices. Regression analysis was used to determine the effect of the participant, the individual headband, and the activity level (independent

variables) on the RSS between oximeter headband and commercial benchmark device (dependent variable). Dummy coding was used to identify categorical variables, with *sit*, *Participant 7*, and *Headband 6* used as reference levels.

For form and fit assessment, means and standard deviations (SD) were calculated from the subjective rating scales (Likert-type questions). Frequency of responses with proportion of various responses were tabulated for the survey data (open-ended questions).

3. RESULTS

3.1 FUNCTIONAL ASSESSMENT

3.1.1 SpO2

The SpO2 estimates and multi-frame SpO2 estimates from the oximeter headband and SpO2 estimates from commercial benchmark sensor are plotted for each test participant at each activity level, as shown in Figures 3–5. For stationary (sit) activity level, oximeter headband SpO2 estimates for 6 of 7 participants are reasonable with the multi-frame SpO2 estimate stable and above 95% (Participants 2–7). For the walk activity level, oximeter headband SpO2 estimates for 5 of 7 participants are reasonable with the multi-frame SpO2 estimates stable and above 94% (Participants 3-7). For the run activity level, oximeter headband SpO2 estimates for 4 of 7 participants are reasonable with multi-frame SpO2 estimates stable and above 94% (Participants 3–5 & 7). The commercial benchmark device provides reasonable SpO2 estimates in all cases aside from three instances where readings are unusually low (Participant 2 running, Participant 3 running, and Participant 5 running).

The RSS analysis shows there is a range of validity across the test participants and individual oximeter headband prototypes evaluated. In some cases, there is good agreement between the SpO2 and heart rate measurements from the oximeter headband and the commercial benchmark device (Participants 2, 3, 4, and 7 during sit activity and Participants 4 and 7 during walk and run activities). However, in other cases there is poor agreement, either due to an offset between oximeter headband and commercial device (Participant 5 and 6, sit) or unreasonable data (Participant 1, sit). Test participant 1 has unreasonably low SpO2 readings from the oximeter headband along with exceptionally high RSS values at all three activity levels (sitting, walking, and running). Overall, there is a lack of consistency across participants and/or individual oximeter headband prototypes. Further investigation is needed into the source of the variation. The fit of headband on each participant and assembly of individual oximeter headband prototype devices are both variables worth consideration.

Regression analysis indicates that variation in RSS across activity level is not statistically significant (95% confidence interval). The collected data set is insufficient to fully understand the effect of the participant versus the effect of the individual oximeter headband prototype and any interaction between.

3.1.2 Heart Rate

Heart rate estimates from the oximeter headband and commercial benchmark device are plotted for each test participant at each activity level in Figures 6–8. Heart rates obtained from the oximeter headband prototypes and the commercial benchmark device are reasonable across all three activity

levels, with no values below 50 bpm or above 180 bpm. As anticipated, heart rate increased with increased activity level (from sit to walk to run) for all seven participants.

Similar to SpO2 estimates, RSS analysis shows variation in validity across test participants and individual oximeter headband prototypes. In some cases, there is good agreement between the SpO2 and heart rate measurements from the oximeter headband and the commercial benchmark devices and in some cases poor agreement. Again, similar to SpO2 estimates, regression analysis indicates that variation in RSS across activity level is not statistically significant (95% confidence interval) while the collected data set is insufficient to fully understand the effect of the participant versus the effect of the individual oximeter headband prototype and any interaction between.

3.1.3 Communication

For test Scenario 1, functional evaluation, the EUD was always between 2 and 3 meters away from the oximeter headband. Once the EUD and headband were paired, there were no instances where BLE connection was lost during data collection. There were two instances of what appeared to be a loss in BLE connection, however this was revealed to be a bug in the EUD display code. The EUD display was designed to show the SpO2 estimate in gray when there is a loss of BLE connection, however the bug in EUD display code caused SpO2 estimate to also display gray when the magnitude of the acceleration exceeded a set threshold. The algorithm and embedded software were subsequently corrected.

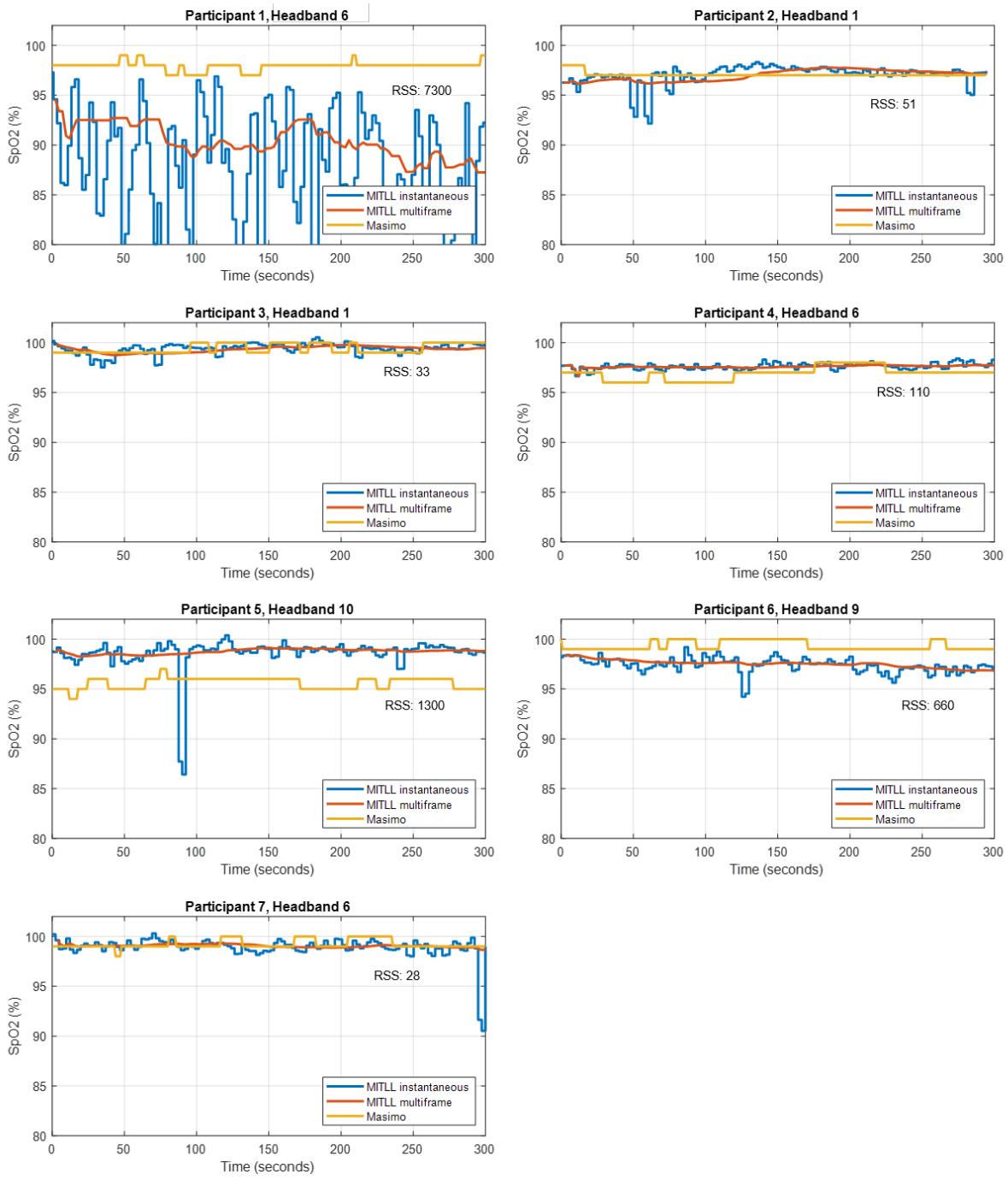

Figure 3. SpO2 measurements from oximeter headband (MITLL instantaneous, MITLL multi-frame) and truth device (Masimo). Activity level: stationary sitting.

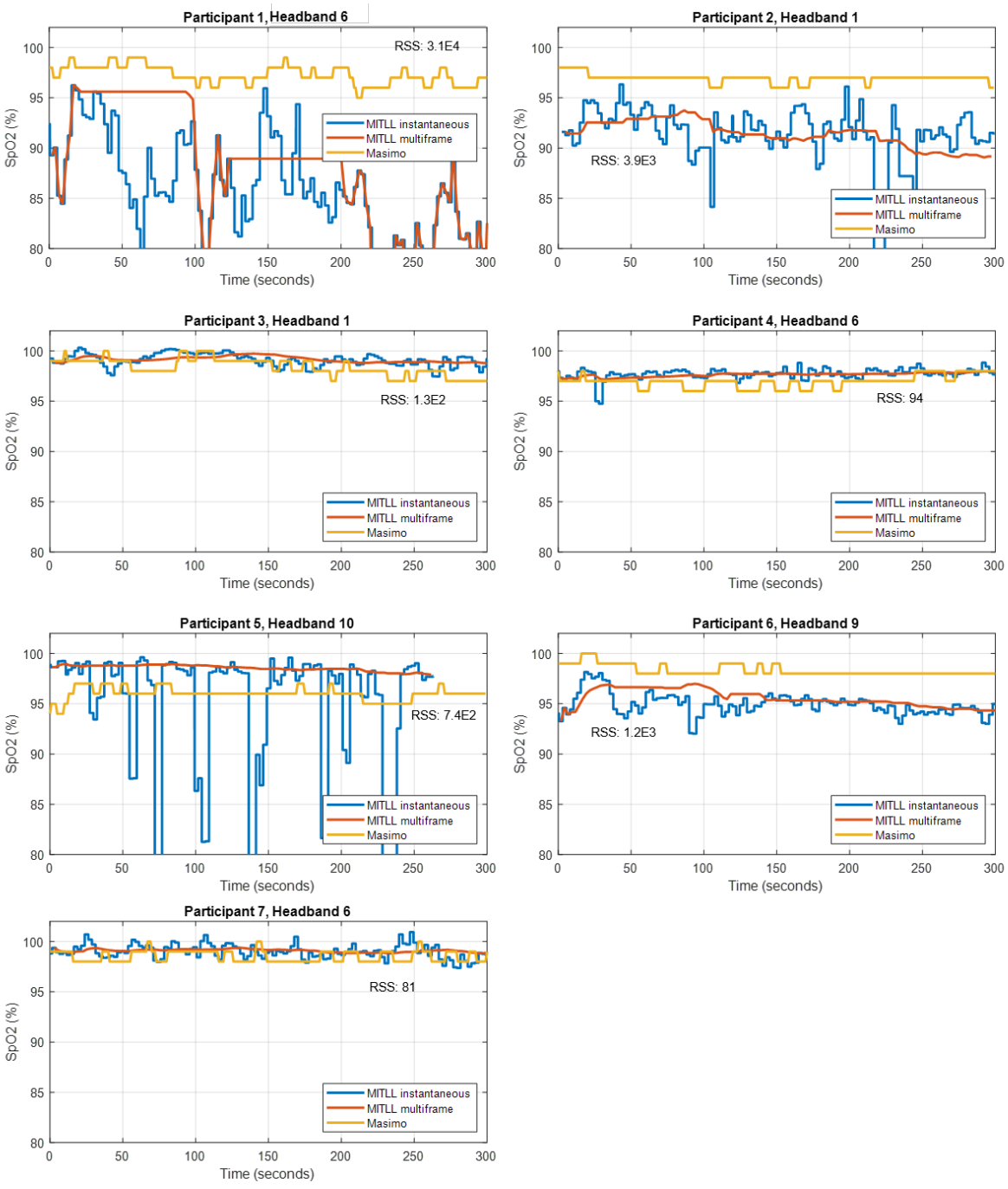

Figure 4. SpO2 measurements from oximeter headband (MITLL instantaneous, MITLL multi-frame) and truth device (Masimo). Activity level: walking.

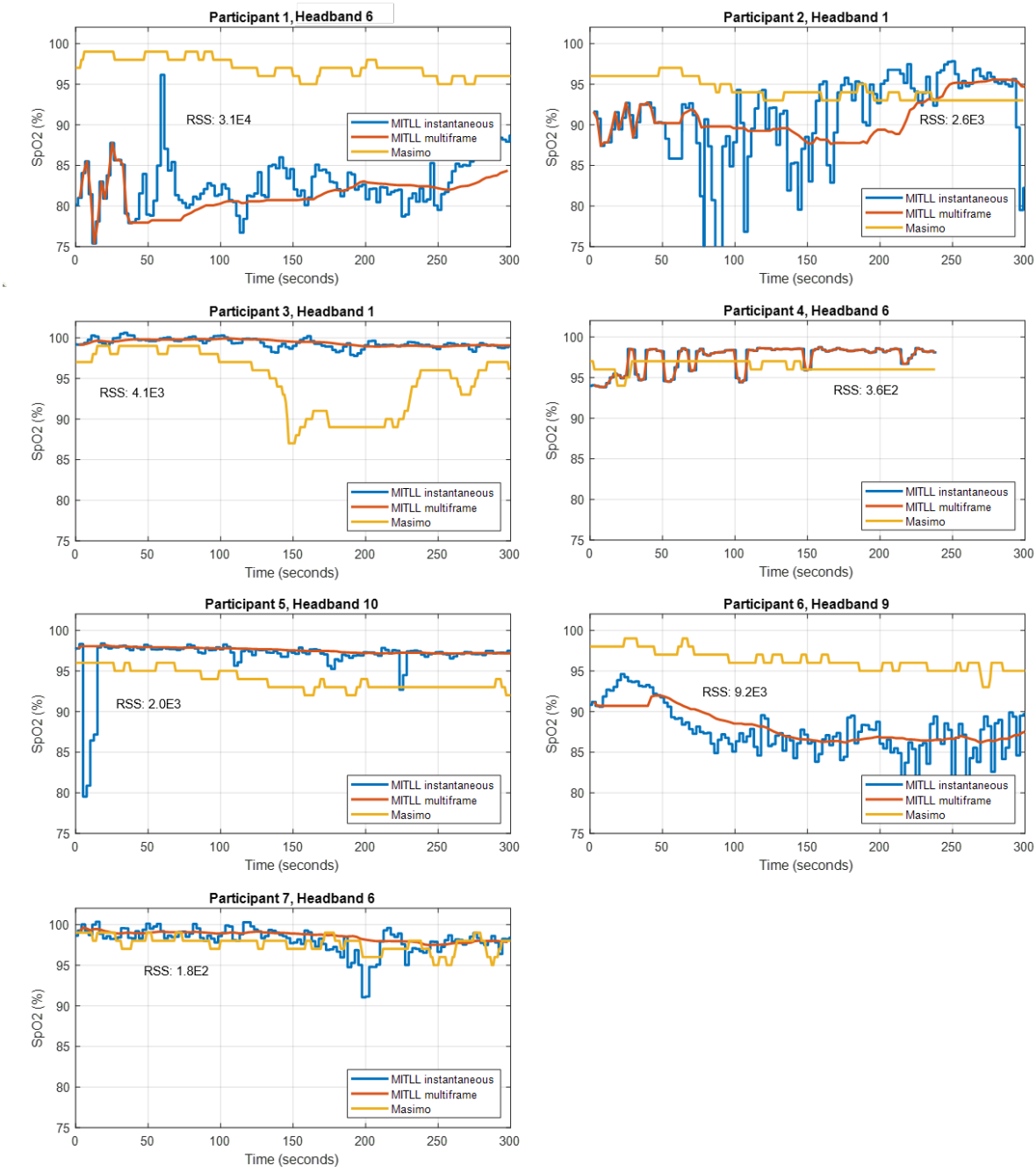

Figure 5. SpO2 measurements from oximeter headband (MITLL instantaneous, MITLL multi-frame) and truth device (Masimo). Activity level: running.

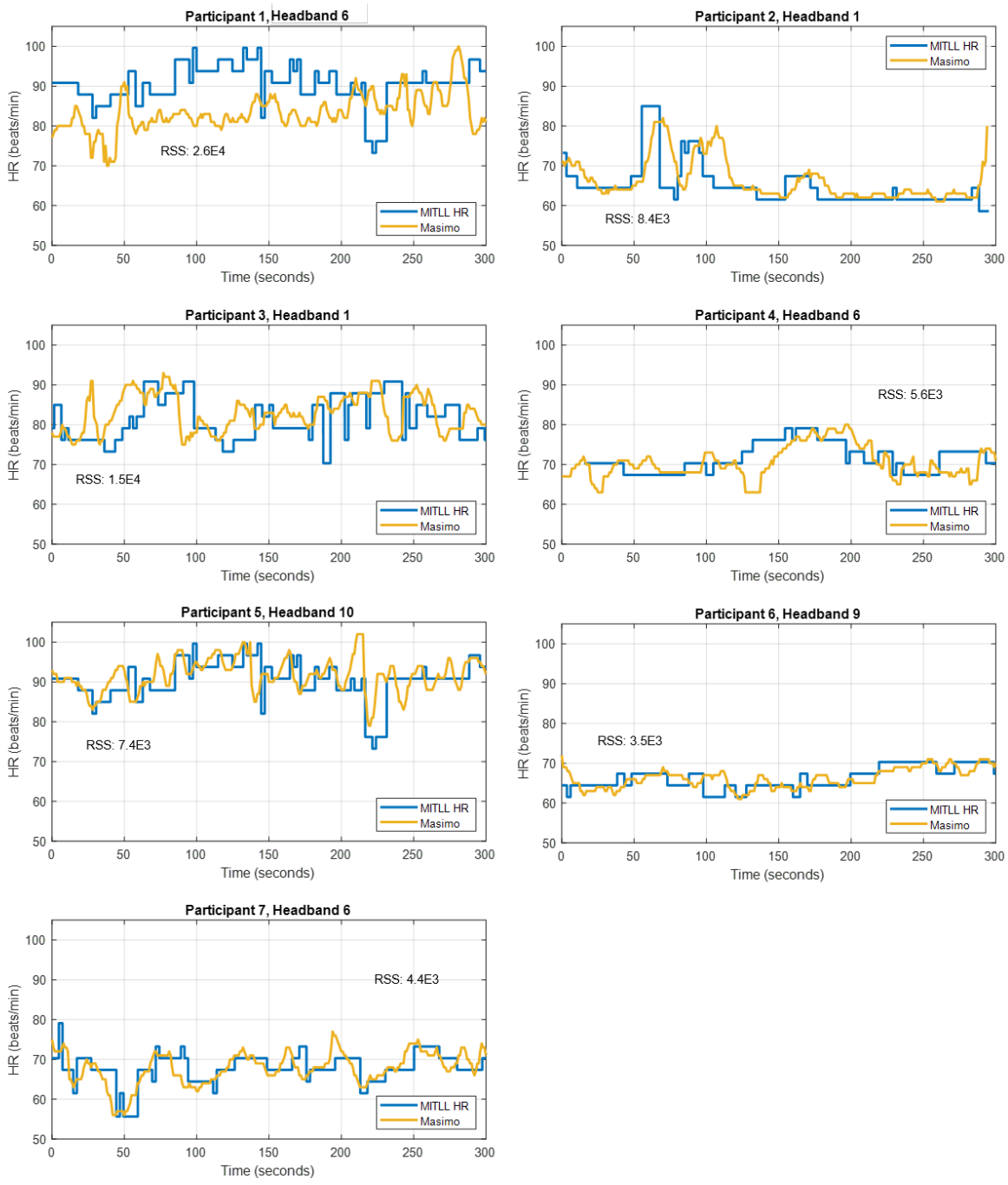

Figure 6. Heart rate measurements from oximeter headband (MITLL) and truth device (Masimo). Activity level: stationary, sitting.

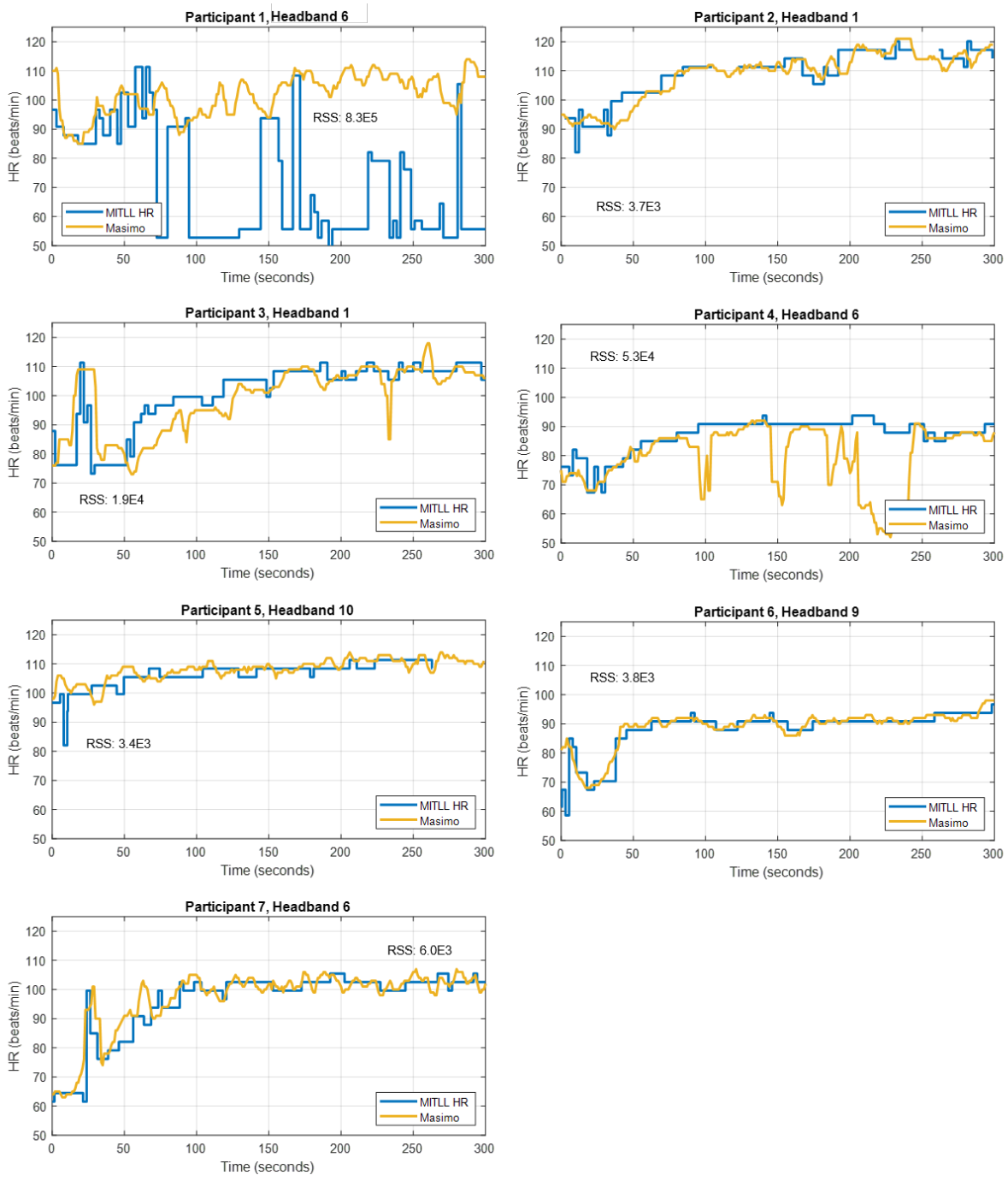

Figure 7. Heart rate measurements from oximeter headband (MITLL) and truth device (Masimo). Activity level: walking.

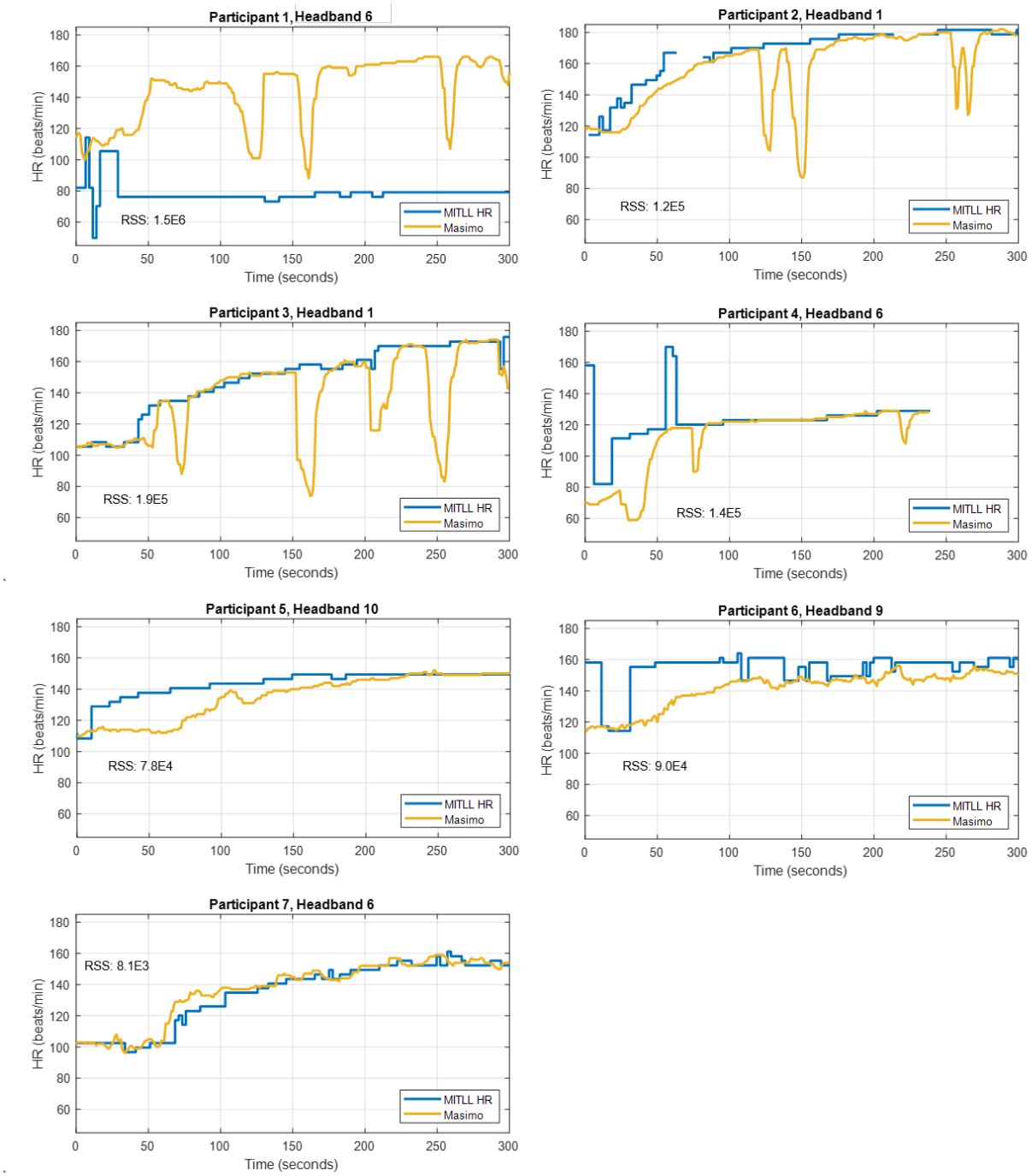

Figure 8. Heart rate measurements from oximeter headband (MITLL) and truth device (Masimo). Activity level: running.

3.2 FORM AND FIT ASSESSMENT

3.2.1 Fit

Test participants generally reported that the oximeter headband fit them well. From Table 2 it may be observed that mean ratings for fit were moderately good or better. Table 3 illustrates the ratings of tightness/looseness of fit of the oximeter headband. As the ratings indicate, the overall tightness/looseness of fit was just under slightly tight. A rating of as close to "4" of neither tight nor loose is what is strived for assuming data integrity and comfort are present. When participants were asked if they were able to put the headband on properly without the help of the research staff, six of seven participants indicated they were able to do so. The one individual who was unable was unsure where the SpO2 sensor was supposed to be located, and had to be directed to ensure it was positioned in the middle of forehead.

TABLE 2

Fit Ratings of the Oximeter Headband on Various Parts of the Head

Body Area of Fit	Mean ± S.D.
Overall	4.3 ± 0.5
Forehead	4.3 ± 0.8
Back of the Head	4.0 ± 0.8

1 = Extremely Poor, 2 = Quite Poor, 3 = Neither Good nor Poor, 4 = Moderately Good 5 = Extremely Good

TABLE 3

Tightness-looseness Ratings of the Oximeter Headband

Area of Fit	Mean ± S.D.
Overall Head	2.9 ± 1.0
Forehead	3.0 ± 1.0
Back of the Head	3.2 ± 1.0

1 = Very Tight, 2 = Moderately Tight, 3 = Slightly Tight, 4 = Neither Tight nor Loose, 5 = Slightly Loose, 6 = Moderately Loose, 7 = Very Loose

3.2.2 Comfort

Table 4 shows the overall oximeter headband system and each of the components and the impact of these parts of the system on the comfort of wearing the system on the participants' head. All ratings

were in the slightly comfortable range (i.e., a score of approximately 5.0). The strap material was rated the lowest with a score of 4.9 and may have accounted for the overall system to also be rated with a score of 4.9. All other components of the system elicited scores greater than 5.0.

TABLE 4

Comfort Ratings of the Oximeter Headband System Components

Comfort of System Component	Mean ± S.D.
Overall System	4.9 ± 1.3
Forehead Sensor	5.1 ± 1.2
Strap Material	4.9 ± 1.5
Electronics Puck	5.6 ± 1.0
Electronics in Strap	5.1 ± 1.3

1 = Very Uncomfortable, 2 = Moderately Uncomfortable, 3 = Slightly Uncomfortable, 4 = Neither Comfortable nor Uncomfortable, 5 = Slightly Comfortable, 6 = Moderately Comfortable, 7 = Very Comfortable

Five of the seven participants mentioned the nature of the discomfort they felt. Three of the participants mentioned issues with the headband feeling too tight or causing tingling feelings. One person felt that the headband was too tight initially, but after about 30 minutes they got used to wearing it. Another participant said that when they first put the headband on it felt tight, however they got used to wearing it. If they then had to wear it for an extended period of time, they said it would be uncomfortable. The two other individuals stated that the headband made their head hot or caused them to sweat in the head region. None of the participants reported a particular activity that caused them discomfort except for one participant, who said that when outside (presumably in warm and sunny weather) it caused a sweaty feeling to develop about the headband.

3.2.3 Impact on Daily Everyday Performance Tasks

Evaluation of the system on everyday tasks showed that there was a slight to moderate impact of wearing the system when wearing eyeglasses, as the mean score of 3.6 indicates. There was also a minor perceived effect when the individual was bending over. However, for overall performance of everyday tasks and ease of motion, the oximeter headband had no negative impact.

TABLE 5

Impact of the Oximeter Headband System on Daily Everyday Performance Tasks

Impact on Every Day Daily Performance	*n* People Rating	Mean ± S.D.
Overall Performance	6	5.0
Ease of Motion	5	5.0
Ease of Movement	5	5.0
Impact on Bending	7	4.3 ± 1.9
Impact of Wearing Glasses	7	3.6 ± 2.4

1 = Extreme Negative Impact, 2 = Very Negative Impact, 3 = Moderate Negative Impact, 4 = Slight Negative Impact, 5 = No Negative Impact

3.2.4 Impact on the Head/Body

An examination of the overall system on the head revealed that the system had little to no impact on the head or the body (Table 6). All participants responding reported that the electronics in the strap had no impact at all on their head or body. Two of seven individuals indicated that the oximeter headband caused some skin irritation or discomfort. One person said that the system was too tight on their head and caused their skin to itch, whereas the other individual expressed the sensation of their skin tingling for approximately the first 30 minutes of wearing the system.

TABLE 6

Impact on the Head: Ratings of the Oximeter Headband System Components

Impact on the Head	*n* of Participants Responding	Mean ± S.D.
Overall System	7	4.7 ± 0.5
Forehead Sensor	6	4.7 ± 0.5
Strap Material	6	4.7 ± 0.5
Electronics Puck	6	4.8 ± 0.4
Electronics in Strap	6	5.0

1 = Extreme Negative Impact, 2 = Very Negative Impact, 3 = Moderate Negative Impact, 4 = Slight Negative Impact, 5 = No Negative Impact

3.2.5 Durability

No system broke during this evaluation.

3.2.6 Functionality

Most participants did not report on functionality issues of the system because they knew that was being examined separately by the research in a systematic way. However, three individuals over three sessions reported that it worked with no negative issues. Two individuals over two sessions reported that it worked intermittently, another individual during one session reported that they had to turn the system on and off to get it to work, while another individual had to refresh the system more than once during two sessions for it to work. Two individuals over three sessions reported that the system indicated low confidence in their data, even though they were just walking. Of note, one of the individuals who walked up and down stairs believed that the activity of stair ascending and descending was related to the SpO2 values and the associated low confidence scores in those values. Another participant reported that they believed that eyebrow or forehead movement (e.g., frowning) caused fluctuations in the data. Finally, an individual reported that the BLE connection was dropped during one of their sessions.

3.2.7 Acceptability

All test participants indicated that the SPO_2 headband system was acceptable to wear for at least two hours.

4. DISCUSSION

4.1 FUNCTIONAL ASSESSMENT

The results of the functional assessment show that the SpO2 data and heart rate data obtained from the oximeter headband device may be valid in certain instances, however there is inconsistency in validity across the entire data set. In some instances, the SpO2 estimates from the oximeter headband and the commercial benchmark device are in tight agreement, however in other instances there is an offset between the two measurements. In other instances, either the oximeter headband, the commercial benchmark device, or both devices provide unreasonable data based on the environmental conditions. Further characterization is necessary to better understand the source of the variation. This includes more rigorous investigation into the fit of the device on each participating individual, variation in assembly of each oximeter headband prototype, as well as how the algorithm processes the raw data.

It should be noted that the commercial benchmark device was not designed to be used under elevated activity levels. As part of the test protocol, we ensured that the hand using the commercial benchmark device was held horizontal and remained as still as possible throughout the three activity levels. That said, it is likely that motion artifacts may have also impacted the commercial benchmark device, as such reasonableness of the data was considered in addition to validity.

It should also be noted that the theoretical R-curve was used to provide SpO2 estimates from the oximeter headband device, thus the device is considered to be uncalibrated. To calibrate a new SpO2 sensing device, an invasive, co-oximeter blood test consisting of 200+ data points ranging from 70–100% SpO2 is necessary to provide a calibrated R-curve specific to the device hardware (ISO 80601-2-61:2017). This type of co-oximeter blood test was not within the scope of the initial characterization test. This lack of calibration may have contributed to poor agreement between the SpO2 estimates from the oximeter headband and the commercial benchmark device. Both calibration of the oximeter headband device and evaluation of the device at SpO2 values below 95% will be necessary in order to prove the system's validity and reliability. Nevertheless, the results of this initial evaluation provide a starting point for more extensive evaluation of validity and reliability.

The BLE communication was sufficient for a test scenario, where EUD and oximeter headband devices were maintained at 2–3m separation. At this distance, there was never a loss of BLE connection. Communication range necessary for intended use case will need to be understood and BLE will need to be evaluated specifically for this use case.

4.2 FORM AND FIT ASSESSMENT

The oximeter headband was acceptable to wear as currently constructed. As noted previously, SpO2 assessment at the forehead site requires proper sensor placement and enough tightness of the headband to hold the sensor in place (Schallom et al., 2007). However, the tightness of the band should be just taught enough to accurately obtain measurements. The width of the material, how tight the headband is, and type of material used to construct the headband are all considerations that need

to be taken into account. The current oximeter headband system should explore ways to use materials that may pose less of a thermal burden (i.e., making the person hot or sweaty) and be loose enough to still obtain accurate measurements. At this point, obtaining accurate measurements is the priority. Given that all individuals believed the system would be acceptable as is, searching for improvements for fit and comfort should only take place after a valid and reliable system has been developed. Nevertheless, the results of this evaluation do provide a starting point for some of the human factors considerations that could be addressed in the future.

5. CONCLUSIONS & RECOMMENDATIONS

- Calibration of oximeter headband devices is a necessary next step for device development.
- A more extensive reliability and validity study should be done, evaluating a range of SpO2 values, from 80%–100%. This should also be done with test participants who have a range of heart rates, movements, and skin pigmentation. The study should also examine test-retest reliability.
- Testing in a chamber where oxygen concentration of the ambient air can be changed will be necessary to assess the utility of the system in actual situations where SpO2 values are expected to change.
- Tightness of fit was the main concern with regard to comfort and user acceptability. Further investigation into how tightness of fit affects measurement accuracy and validity is recommended. Based on results from the investigation, changes to device architecture may be acceptable to address tightness of fit concerns.
- Further improvements to the system to address the specific needs of the intended use case is recommended. Changes to device communication, battery life, algorithm sensitivity, materials, etc. are likely needed for oximeter headband device to be ideally suited for target use case and end users.

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APPENDIX A
OXIMETER HEADBAND USER MANUAL

Document Description: Oximeter Headband			
Version	Date	Change	Author
0	10/01/2020	New Document	L. Cantley
1	01/06/2021	Added troubleshoot for low battery, procedure for exporting data files, and description of updated UI (UI v2)	L. Cantley
2	01/12/2021	New description for updated UI (UI v3)	L. Cantley
3	01/12/2021	Language updated in steps 4, 5, 6.	L. Cantley
4	06/01/2021	Updated images and text for v.0.5.1, procedure for naming devices in UI, multiple devices paired to single EUD, grid view	L. Cantley
5	06/03/2021	Added instructions for exporting log files using Google Drive and connecting to Wi-Fi. Corrected typos.	L. Ibanescu
6	6/15/2021	Update images and text to match software v.0.6.2	L. Cantley

Contact information:

Vendor Contact N/A

MITLL contacts:

Owner: Lauren Cantley

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1. PURPOSE

1. This document describes the procedure for operating the oximeter headband prototype device and the corresponding iPhone End User Device.

2. RESPONSIBILITY

3. It is the responsibility of all who utilize this equipment to follow this procedure.
4. It is the responsibility of the Equipment Owner(s) to maintain this document.

5. SAFETY

1. Only use prototype device as intended, described herein.
2. Do not wear, carry or use prototype device in the rain or fully submerge into water.

6. EQUIPMENT/MATERIALS

1. Oximeter headband prototype device
2. iPhone EUD with ‘Fabric Sense’ Application
3. iPhone charger
4. USB-C cable (for oximeter headband charging)

7. RELATED DOCUMENTS

1. MAX86161 datasheet
2. Other documents

8. DEFINITIONS

1. EUD: End User Device
2. UI: User Interface

PROCEDURE

1. **Operating Singe Headband Device Paired to Single EUD**
2. **Operating Multiple Headband Devices Paired to Single EUD**
3. **Exporting Data Logs**
4. **Algorithm Notes**

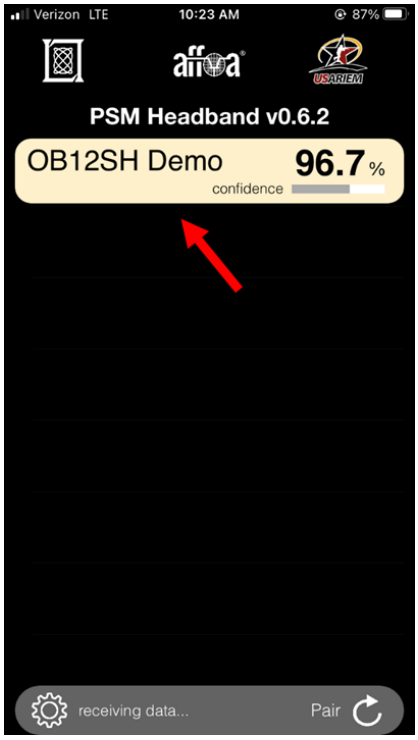
Operating Single Headband Device Paired to Single EUD

1.1 Press and hold power button on the back of oximeter headband to turn on the device. Green LED light will blink when device is on and functioning properly. Green light will continue to blink as long as the device is on.

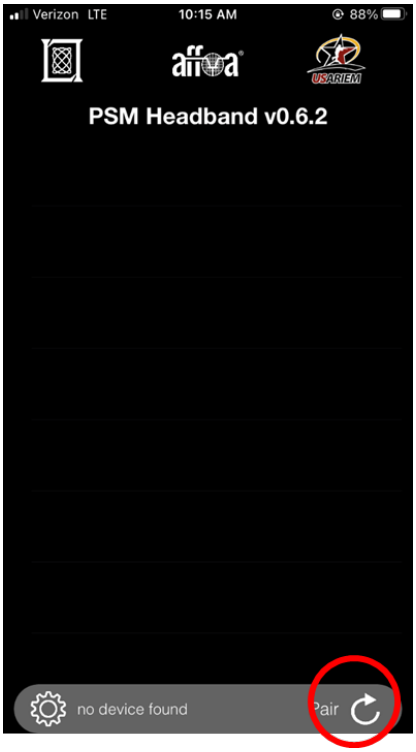
Troubleshoot: If the green light turns on once but does not continue to blink, this is a sign of low battery. Plug the USB cable into the device and charge the battery. A red and yellow light will blink alternately while the battery is charging. Green light will display when the battery is fully charged.

1.2 Unlock EUD. Passcode: 781981

1.3 Open 'Fabric Sense' Application. If Oximeter headband is 'On' and near EUD, oximeter headband will automatically pair with EUD application and device will display on home screen 'List View.'



1.4 If the ‘Device is not found,’ refresh search for device by pressing the circular arrow button in the lower right corner of the screen.

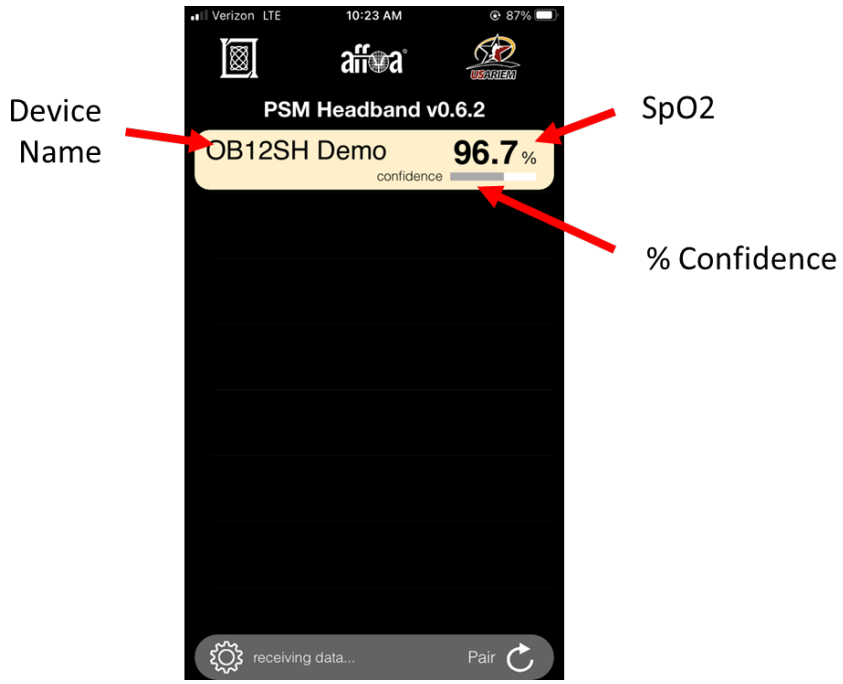


1.5 Once device is paired, red LED on the oximeter headband will blink and data will begin streaming to EUD from the oximeter headband.

1.6 Don oximeter headband, with red LED facing in towards forehead and module with green LED at the back of the head. Hold still for ~20 seconds to reduce motion artifacts and allow algorithm to collect enough data to calculate SpO2.

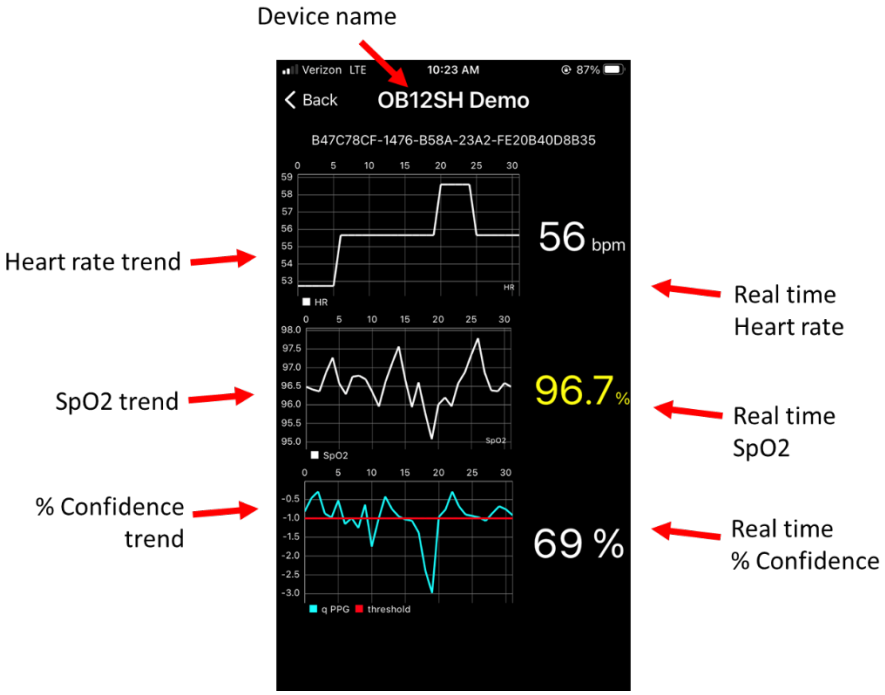
1.7 The EUD home screen displays ‘List View.’ The device name, SpO2 value and % confidence are displayed. The box surrounding device will display green for a SpO2 value of 98% or above, yellow for a

SpO2 value between 95–98%, and red for a SpO2 value below 95%. Box surrounding device will display gray and text will remain black if the device is unable to calculate reasonable SpO2 estimate. (See Algorithm Notes below for more information.) Box surrounding device will display gray and text will be gray if there is no BLE connection to the device.



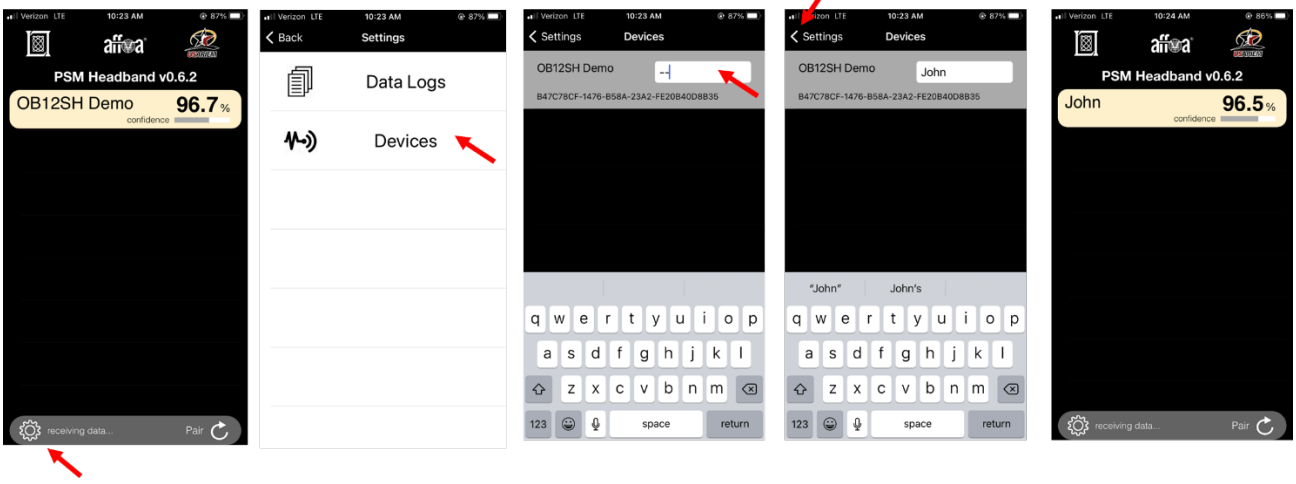
Troubleshoot: If box surrounding device is gray, however SPO2 estimate is still updating in real time, this is an indication that the BLE connection is sustained, however the algorithm is unable to calculate a reasonable SpO2 estimate, likely due to motion artifacts or poor positioning of the device on the users forehead. In this scenario, it is recommended that the user donning the headband oximeter remains still for 30–60 seconds to allow for the device to collect a sufficient amount of valid frames. (See Algorithm Notes below for more information).

1.8 Select the device to enter 'Detail View.'
1.9 In 'Detail View,' heart rate, SpO2, and percent confidence (an indicator of the confidence in the heart rate and SpO2 measurement) are displayed below. The real time value is shown on the right and a plot of trend on the left, with time (in seconds) along the x axis. SpO2 value of 98% or above displays in green, SpO2 value between 95–98% displays in yellow, and SpO2 value below 95% is shown in red.



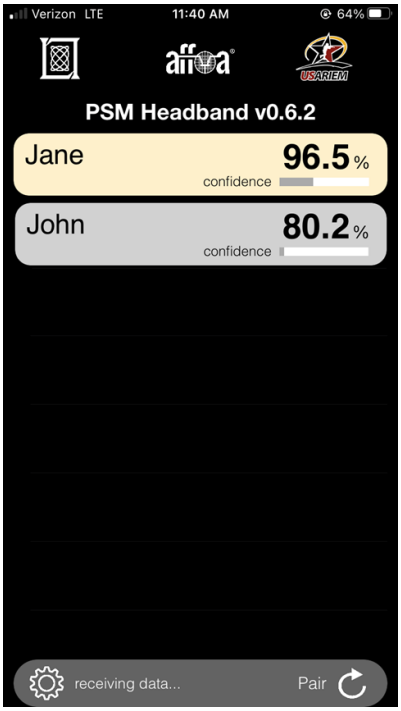
1.10 Data is continuously recorded while 'FabricSense' Application is open. Files are saved to the 'Data Logs' folder within the 'Fabric Sense' application as well as to the 'Files' Application on EUD.

1.11 Oximeter Headband will display default name when first paired to the EUD. To rename the device, enter the 'Settings' screen and select 'Devices.' Select the text entry box for the device you wish to rename and a keyboard will appear. Enter new device name and press 'return.' Navigate back to the home screen using the back button. The new device name should now appear in 'List View.'

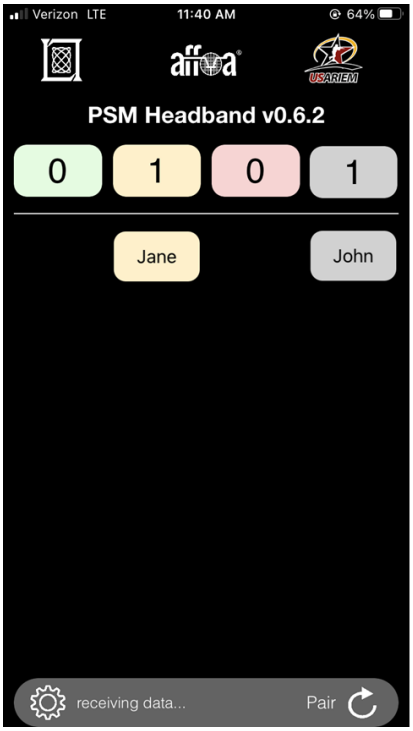


Operating multiple headband devices paired to single EUD

2.1 Similar to operating a single headband device, turn on each oximeter headband and open ‘Fabric Sense’ application on the EUD. If multiple headband devices are ‘On’ and within range of the EUD, they will automatically pair with the EUD. If a device is not found, press the refresh button to search and reconnect to all devices within range.



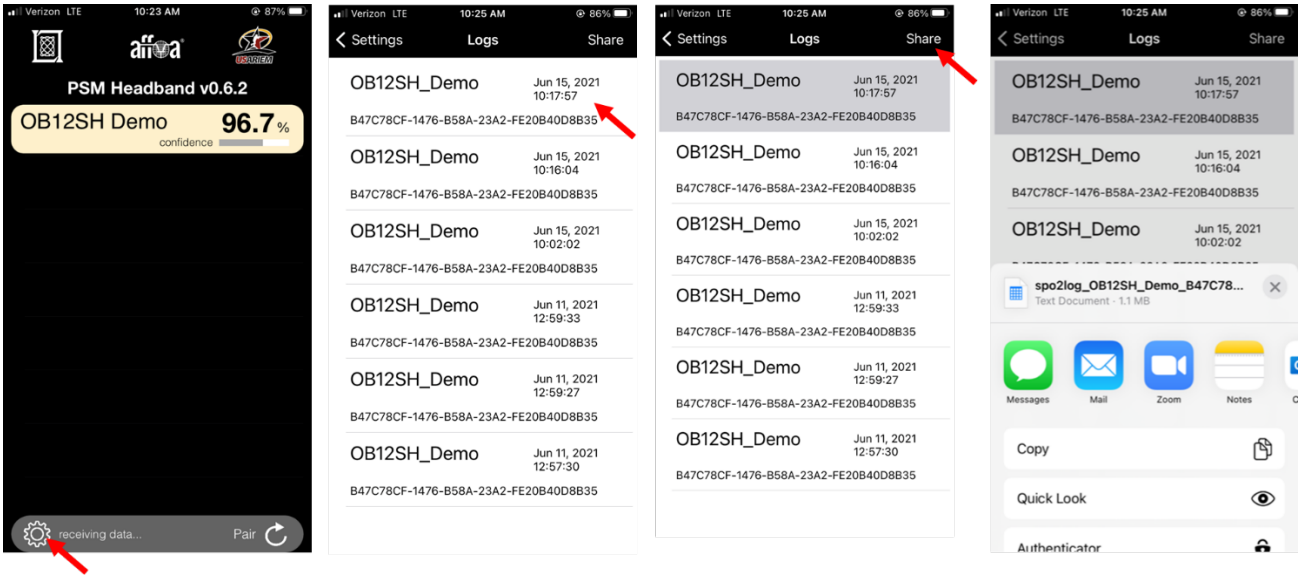
2.2 Each device can be renamed following the instructions outlined for a single oximeter headband device.
2.3 Select device of interest to enter ‘Detail View.’ Use back button to return to home screen “List View.’
2.4 Swipe right to show the ‘Grid View.’ Devices will be sorted into columns based on their SpO2 values. Total number of devices within a column will display at the top of column. Swipe left to return to ‘List View.’



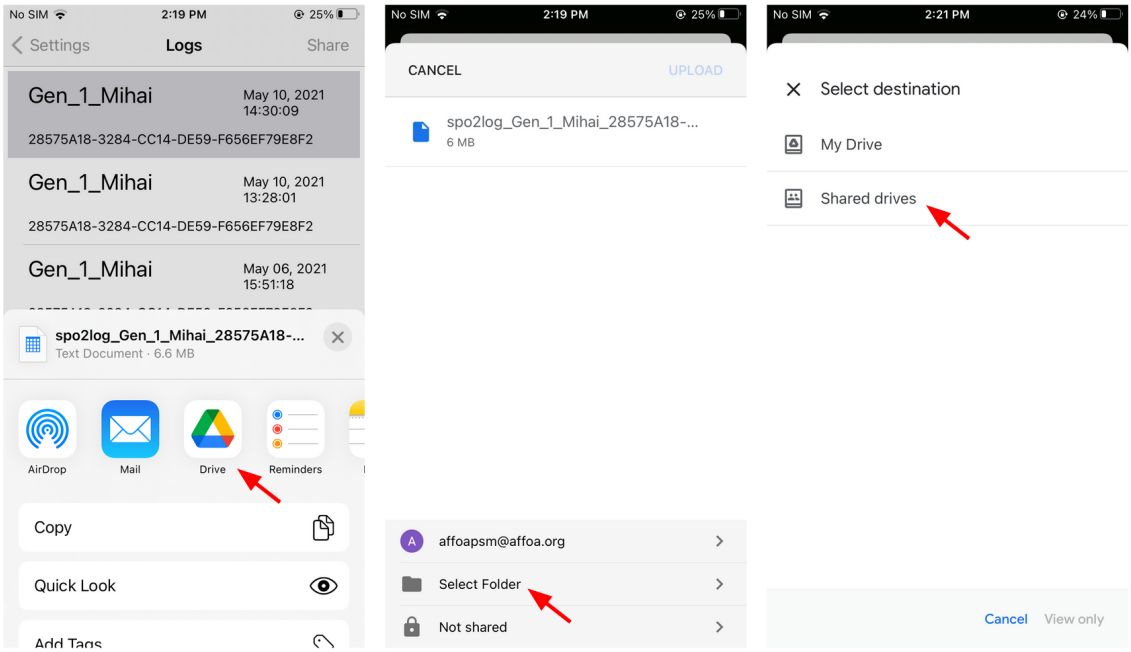
Exporting Data Logs

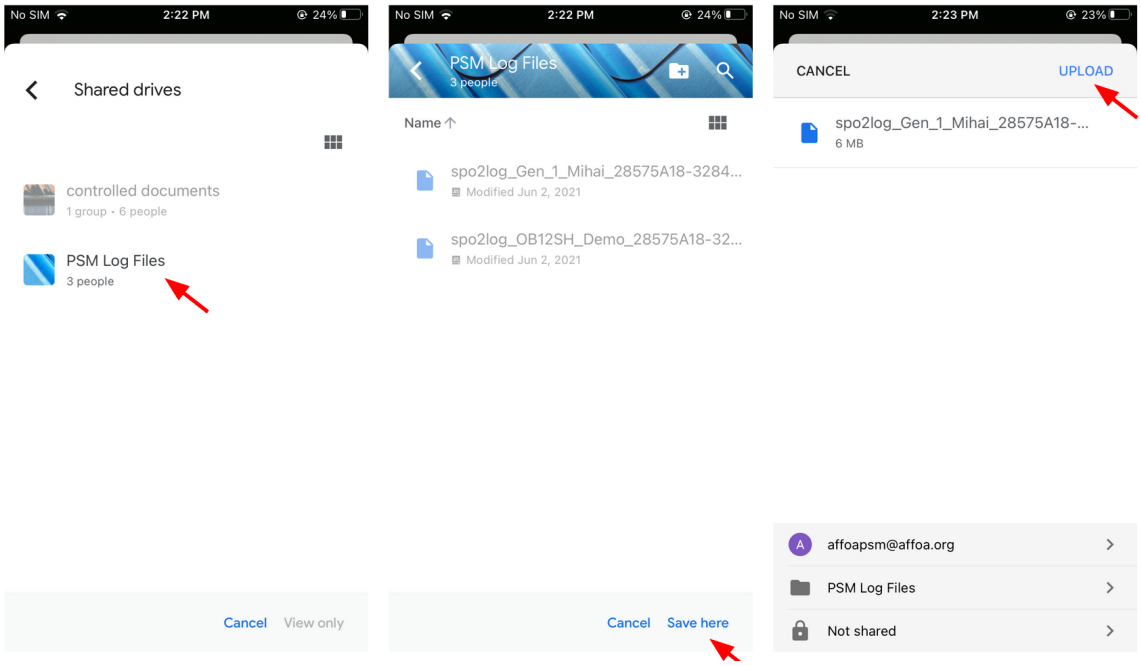
3.1 Before exporting log files off of the EUD device, connect it to a Wi-Fi network: from the iPhone home screen tap ‘Settings’ then ‘Wi-Fi.’ Select a network from the list and enter the password.

3.2 To export files off of EUD device, select ‘Settings’ button in the lower left hand corner of the home screen ‘List View.’ Within the ‘Settings’ screen, select ‘Data Logs.’ Within the ‘Data Logs’ screen, select the file you wish to export. The file name will then be highlighted in gray. Press the ‘Share’ button in the upper right-hand corner, and choose the method with which you would like to export the file (for example, email).



3.3 To export log files using the Google Drive method, select 'Drive,' then tap 'Select Folder' at the bottom of the screen. Select 'Shared drives' and then select 'PSM Log Files.' Tap 'Save here' at the bottom of the screen and then tap 'UPLOAD' at the top of the screen.





Algorithm Notes

- SpO2 algorithm developed by MITLL G24 is utilized for calculating heart rate and SpO2. Further details of algorithm outlined in publication: https://ieeexplore.ieee.org/document/8329662
- Above algorithm has been adapted for real time SpO2 estimate.

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APPENDIX B
MOTION OBSERVATION LOGS

Motion Observation Log for Participant 1, Functional Assessment

Time* (s)	Activity	Motion Event
50	Sit	Head look up & left 'slight'
73	Sit	Head look up & left 'slight'
84	Sit	Head shake (left & right)
280	Sit	Head look down
309	Sit	Head look down
14	Walk	Head look down 'slight'
27	Walk	Head look down 'slight'
41	Walk	Head tilt to the right 'slight'
205	Walk	Head look down 'moderate'
285	Walk	Fast movement with head to sigh
11	Run	Head movement to the left 'slight'
57	Run	Head nod (up & down) 'slight'
69	Run	Head look to left 'moderate'
108	Run	Fast head up & left
150	Run	Head look up 'slight'
220	Run	Head look down & left 'slight'
294	Run	Head look down 'slight'

*time from start of each activity. Head straight forward unless otherwise noted.

Motion Observation Log for Participant 3, Functional Assessment

Time* (s)	Activity	Motion Event
20	Sit	Head shake (back & forth)
70	Sit	Head nod (up & down)
120	Sit	Head nod (up & down)
120	Sit	Head look left ‘slight’
120	Sit	Head look down
120	Sit	Head look up
180	Sit	Head shake (left & right)
240	Sit	Head nod (up & down)
240	Sit	Head tilt left
300	Sit	Head nod (up & down)
120	Walk	Head look right ‘slight’
120	Walk	Head shake (left & right)
120	Walk	Head nod (up& down)
180	Walk	Head shake (left & right)
240	Walk	Head look left ‘slight’
240	Walk	Head look down
240	Walk	Head look right ‘slight’
60	Run	Head look left ‘slight’
60	Run	Head look up
120	Run	Head look down & left
240	Run	Head look down & left

*time from start of each activity. Head straight forward unless otherwise noted.

Motion Observation Log for Participant 4, Functional Assessment

Time* (s)	Activity	Motion Event
60	Sit	Head Look down ‘slight’
30	Walk	Head shake (left & right)
91	Walk	Head nod
140	Walk	Head look right & down
187	Walk	Head shake (left & right) ‘slight’
300	Walk	Head look right ‘slight’
33	Run	Head look up
201	Run	Speaking

*time from start of each activity. Head straight forward unless otherwise noted.

Motion Observation Log for Participant 5, Functional Assessment

Time* (s)	Activity	Motion Event
60	Sit	Head shake (back & forth)
60	Sit	Head look down ‘slight’
180	Sit	Head look down ‘slight’
	Walk	Unable to observe head movement.
	Run	Unable to observe head movement.

*time from start of each activity. Head straight forward unless otherwise noted.

Motion Observation Log for Participant 6, Functional Assessment

Time* (s)	Activity	Motion Event
60	Sit	Head look up & left
120	Sit	Head shake (left & right) ‘ slight’
180	Sit	Head look up & left
240	Sit	Head nod (up & down) ‘slight’
240	Sit	Head shake (left & right)
300	Sit	Head shake (left & right) ‘ slight’
180	Walk	Head look down & right

*time from start of each activity. Head straight forward unless otherwise noted.

Motion Observation Log for Participant 7, Functional Assessment

Time* (s)	Activity	Motion Event
60	Sit	Head look up
120	Sit	Head nod (up & down) ‘slight’
240	Sit	Head nod (up & down) ‘slight’
60	Walk	Head look down
60	Walk	Head nod (up & down)
120	Walk	Head look down
120	Walk	Head look right
120	Walk	Head nod (up & down)
180	Walk	Head look right
180	Walk	Head look down
240	Walk	Head look right

300	Walk	Head look right
60	Run	Head look down
120	Run	Head look down
180	Run	Head look down
180	Run	Head look right
180	Run	Head look right
240	Run	Laugh
240	Run	Head look right
240	Run	Head look down

*time from start of each activity. Head straight forward unless otherwise noted.

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APPENDIX C
OXIMETER HEADBAND
INITIAL CHARACTERIZATION
TEST

Test Participant Number: _____

Head circumference: measurement 1: _____
measurement 2: _____
measurement 3: _____

Test Scenario 2 - Activity Log:
Date:_____

Start time	Activity	Duration	Oximeter functionality	Notes

Comfort, Fit, and Usability Assessment:

1. The fit of the system on my body was:

	Extremely Poor	Quite Poor	Neither Good nor Poor	Moderately Good	Extremely Good
	1	2	3	4	5
Overall Fit	O	O	O	O	O

2. Using the following scale please rate how acceptable the fit of the monitoring system for the following areas:

	Extremely Poor	Quite Poor	Neither Good nor Poor	Moderately Good	Extremely Good
	1	2	3	4	5
a. overall	O	O	O	O	O
b. forehead					
c. back of head	O	O	O	O	O

3. Using the following scale please rate, how tight or loose, the fit of the monitoring system was for the following areas:

	Very Tight	Moderately Tight	Slightly Tight	Neither Tight nor Loose	Slightly Loose	Moderately Loose	Very Loose
	1	2	3	4	5	6	7
a. overall	O	O	O	O	O	O	O
b. forehead							
c. back of head	O	O	O	O	O	O	O

4. Were you able to put the system on without any help from the research staff?

O Yes

O No If No: 4a. How did they help you?

5. Please rate how comfortable or uncomfortable you found the system during your activity. Rate the system overall and for the individual parts of the headband listed for the question:

	Very Uncomfortable	Moderately Uncomfortable	Slightly Uncomfortable	Neither Uncomfortable or comfortable	Slightly Comfortable	Moderately Comfortable	Very Comfortable
	1	2	3	4	5	6	7
a. overall	O	O	O	O	O	O	O
b. forehead sensor	O	O	O	O	O	O	O
c. strap material	O	O	O	O	O	O	O
d. electronics puck	O	O	O	O	O	O	O
e. electronics in strap	O	O	O	O	O	O	O

If certain areas caused discomfort, please briefly describe why they were uncomfortable:

6. Was there a particular activity when you found the system to be more uncomfortable to wear?

O No

O Yes If Yes: 6a. What was the activity(s)?

7. Please rate whether the system had an impact on your overall performance and for the other activities listed:

1

	Not applicable	Extreme Negative Impact	Very Negative Impact	Moderate Negative Impact	Slight Negative Impact	No Negative Impact
		1	2	3	4	5
a. overall impact on performance	[redacted]	O	O	O	O	O
b. Ease of motion		O	O	O	O	O
c. Ease of movement		O	O	O	O	O
d. Jumping	O	O	O	O	O	O
e. Landing	O	O	O	O	O	O
f. Running	O	O	O	O	O	O
g. Bending	O	O	O	O	O	O
h. Lying on back	O	O	O	O	O	O
i. Lying on stomach	O	O	O	O	O	O
j. Lying on side	O	O	O	O	O	O
k. Wearing helmet	O	O	O	O	O	O
l. Wearing glasses	O	O	O	O	O	O

8. During your activity did the system cause any skin irritation, or other discomfort?

O No

O Yes If Yes: 8a. What was/were the problem/s? Describe the nature of the discomfort and exact location on the head (e.g. forehead, back of the head, side of the head near ears):

_____

_____

_____

_____

9. Please rate overall the impact of wearing the system on your head, i.e., any pains or discomfort felt.

Extreme Negative Impact	Very Negative Impact	Moderate Negative Impact	Slight Negative Impact	No Negative Impact
1	2	3	4	5
O	O	O	O	O

10. For each of the system components listed below, please rate if there was any negative impact on your head.

	Extreme Negative Impact	Very Negative Impact	Moderate Negative Impact	Slight Negative Impact	No Negative Impact
	1	2	3	4	5
a. overall	O	O	O	O	O
b. forehead sensor	O	O	O	O	O
c. strap material	O	O	O	O	O
d. electronics puck	O	O	O	O	O
e. electronics in strap	O	O	O	O	O

11. Did they system come apart or break?

O No

O Yes If Yes: 11a. Please explain how the system broke or came apart, and how you fixed the problem:

_____

_____

_____

_____

12. Is the system acceptable to wear for an extended period of two hours or more?

O Yes

O No If No: 12a. Please explain why the system is not.

_____

_____

_____

_____

13. Any other comments please feel free to write them below or on the back of this form.

_____

_____

_____

_____

_____

_____

_____

_____

APPENDIX D
REGRESSION ANALYSIS

SPO2

				ACTIVITY		PARTICIPANT						HEADBAND		
RSS - SpO2	activity	participan	headband	X1	X2	Y1	Y2	Y3	Y4	Y5	Y6	Z1	Z2	Z3
7.31E+03	sit	1	6	0	0	0	0	0	0	0	1	0	0	0
50.7464	sit	2	1	0	0	1	0	0	0	0	0	1	0	0
33.8922	sit	3	1	0	0	0	1	0	0	0	0	1	0	0
106.2651	sit	4	6	0	0	0	0	1	0	0	0	0	0	0
1.29E+03	sit	5	10	0	0	0	0	0	1	0	0	0	1	0
655.0965	sit	6	9	0	0	0	0	0	0	1	0	0	0	1
27.7675	sit	7	6	0	0	0	0	0	0	0	0	0	0	0
3.10E+04	walk	1	6	1	0	0	0	0	0	0	1	0	0	0
3.86E+03	walk	2	1	1	0	1	0	0	0	0	0	1	0	0
128.7052	walk	3	1	1	0	0	1	0	0	0	0	1	0	0
94.8002	walk	4	6	1	0	0	0	1	0	0	0	0	0	0
737.318	walk	5	10	1	0	0	0	0	1	0	0	0	1	0
1.20E+03	walk	6	9	1	0	0	0	0	0	1	0	0	0	1
80.5396	walk	7	6	1	0	0	0	0	0	0	0	0	0	0
3.08E+04	run	1	6	0	1	0	0	0	0	0	1	0	0	0
2.61E+03	run	2	1	0	1	1	0	0	0	0	0	1	0	0
4.09E+03	run	3	1	0	1	0	1	0	0	0	0	1	0	0
3.55E+02	run	4	6	0	1	0	0	1	0	0	0	0	0	0
2.03E+03	run	5	10	0	1	0	0	0	1	0	0	0	1	0
9.16E+03	run	6	9	0	1	0	0	0	0	1	0	0	0	1
181.8865	run	7	6	0	1	0	0	0	0	0	0	0	0	0

SUMMARY OUTPUT

Reference: Sit
Reference: Participant 7
Reference: Headband 6

Regression Statistics	
Multiple R	0.899210592
R Square	0.808579689
Adjusted R Sc	0.430966149
Standard Erro	5142.481105
Observations	21

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	11	1340483482	121862134.7	6.336159052	0.004938381
Residual	12	317341343	26445111.92		
Total	23	1657824825			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	-3114.154871	3366.544132	-0.925030164	0.373178638	-10449.22442	4220.914675	-10449.22442	4220.914675
X1	3953.813614	2748.771773	1.438392831	0.17588886	-2035.245592	9942.87282	-2035.245592	9942.87282
X2	5678.8446	2748.771773	2.065957114	0.061123644	-310.2146059	11667.90381	-310.2146059	11667.90381
Y1	0	0	65535	#NUM!	0	0	0	0
Y2	-754.583	4198.81824	-0.179713185	#NUM!	-9903.022051	8393.856051	-9903.022051	8393.856051
Y3	88.7217	4198.81824	0.02113016	0.983489113	-9059.717351	9237.160751	-9059.717351	9237.160751
Y4	1255.4748	4198.81824	0.299006703	0.770050008	-7892.964251	10403.91385	-7892.964251	10403.91385
Y5	3577.167633	4198.81824	0.851946293	0.410924242	-5571.271418	12725.60668	-5571.271418	12725.60668
Y6	22945.00213	4198.81824	5.464633338	0.000144225	13796.56308	32093.44118	13796.56308	32093.44118
Z1	2076.484267	4198.81824	0.494540165	0.629854301	-7071.954784	11224.92332	-7071.954784	11224.92332
Z2	0	0	65535	#NUM!	0	0	0	0
Z3	0	0	65535	#NUM!	0	0	0	0

HEART RATE

				ACTIVITY		PARTICIPANT						HEADBAND		
RSS - HR	activity	participant	headband	X1	X2	Y1	Y2	Y3	Y4	Y5	Y6	Z1	Z2	Z3
2.55E+04	sit	1	6	0	0	0	0	0	0	0	1	0	0	0
8436.2	sit	2	1	0	0	1	0	0	0	0	0	1	0	0
14833	sit	3	1	0	0	0	1	0	0	0	0	1	0	0
5603.3	sit	4	6	0	0	0	0	1	0	0	0	0	0	0
7.38E+03	sit	5	10	0	0	0	0	0	1	0	0	0	1	0
3488.5	sit	6	9	0	0	0	0	0	0	1	0	0	0	1
4416.8	sit	7	6	0	0	0	0	0	0	0	0	0	0	0
8.27E+05	walk	1	6	1	0	0	0	0	0	0	1	0	0	0
3.65E+03	walk	2	1	1	0	1	0	0	0	0	0	1	0	0
18539	walk	3	1	1	0	0	1	0	0	0	0	1	0	0
53402	walk	4	6	1	0	0	0	1	0	0	0	0	0	0
3441.3	walk	5	10	1	0	0	0	0	1	0	0	0	1	0
3.80E+03	walk	6	9	1	0	0	0	0	0	1	0	0	0	1
6022.1	walk	7	6	1	0	0	0	0	0	0	0	0	0	0
1.46E+06	run	1	6	0	1	0	0	0	0	0	1	0	0	0
1.16E+05	run	2	1	0	1	1	0	0	0	0	0	1	0	0
1.88E+05	run	3	1	0	1	0	1	0	0	0	0	1	0	0
1.37E+05	run	4	6	0	1	0	0	1	0	0	0	0	0	0
7.79E+04	run	5	10	0	1	0	0	0	1	0	0	0	1	0
9.03E+04	run	6	9	0	1	0	0	0	0	1	0	0	0	1
8083	run	7	6	0	1	0	0	0	0	0	0	0	0	0

SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.824016527
R Square	0.679003237
Adjusted R Square	0.215005395
Standard Error	255968.2143
Observations	21

Reference: Sit
Reference: Participant 7
Reference: Headband 6

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	11	1.66312E+12	1.51193E+11	3.172944318	0.046885006
Residual	12	7.86237E+11	65519726735		
Total	23	2.44936E+12			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	-129601.7905	167570.5311	-0.773416362	0.45424254	-494706.6135	235503.0325	-494706.6135	235503.0325
X1	120849.3429	136820.7657	0.883267553	0.394442819	-177257.4968	418956.1825	-177257.4968	418956.1825
X2	286477.9286	136820.7657	2.093819071	0.058179776	-11628.91108	584584.7682	-11628.91108	584584.7682
Y1	0	0	65535	#NUM!	0	0	0	0
Y2	30839.06667	208997.1718	0.14755734	#NUM!	-424526.6526	486204.786	-424526.6526	486204.786
Y3	59031.13333	208997.1718	0.282449436	0.782411556	-396334.586	514396.8526	-396334.586	514396.8526
Y4	23394.7	208997.1718	0.111937878	0.912723288	-431971.0193	478760.4193	-431971.0193	478760.4193
Y5	26341.16667	208997.1718	0.126035996	0.901790489	-429024.5526	481706.886	-429024.5526	481706.886
Y6	763896.3667	208997.1718	3.655055999	0.003295902	308530.6474	1219262.086	308530.6474	1219262.086
Z1	36674.3	208997.1718	0.175477494	0.863630666	-418691.4193	492040.0193	-418691.4193	492040.0193
Z2	0	0	65535	#NUM!	0	0	0	0
Z3	0	0	65535	#NUM!	0	0	0	0

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13. SUPPLEMENTARY NOTES

13. ABSTRACT

The oximeter headband is a new physiological status monitoring system developed by Massachusetts Institute of Technology Lincoln Laboratory (MIT LL), Lexington, Massachusetts and the Institute for Advanced Functional Fabrics of America (AFFOA), Cambridge, Massachusetts. It was tested for form, fit, and function during an internal test held at MIT LL. The oximeter headband system consists of a custom made, textile-based headband. It is a noninvasive, non-subcutaneous, and non-radiation harming device that only maintains surface contact with the skin. It has been specifically designed to meet the needs of the military. The test described in this report assesses the first field-portable prototype of the oximeter headband device. Data was collected from eight test participants in two test scenarios, a functional evaluation, and a form and fit assessment. Results from the functional evaluation show that the oximeter headband device is capable of providing valid SpO2 estimates at varying activity levels (sit, walk, and run) with a residual sum of squares (RSS) as low as 27, however there is inconsistency in validity across the entire data set. In some instances, RSS was as high as 3.1E4. Further characterization is necessary to better understand the source of variation. In regards to form and fit, the oximeter headband was acceptable to wear as currently constructed. However, tightness of fit was the main concern with regard to comfort and user acceptability. Form was rated as a 4.9 for comfort on a seven-point discomfort/comfort scale, with the a 5 indicating 'slightly comfortable.' Fit was scored a 4.3 with a score of 4 equal to 'moderately good' and a score of 5 equal to 'extremely good.' The results of this initial evaluation provide a starting point for more extensive evaluation of form, fit, and function.

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