Masimo W1™

Hospital-Grade Continuous Monitoring of SpO_2 and Other Parameters in a Consumer Watch

WHITEPAPER

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I. INTRODUCTION

Continuous pulse oximetry has been widely used and recognized for over four decades as an essential clinical monitoring tool for detecting physiological changes in the cardio-pulmonary system. For years, positive outcome studies did not exist; however, no anesthesiologist would take their patient to the operating room without one. Masimo SET® has also been shown to help clinicians reduce severe retinopathy of prematurity in neonates,[1] improve CCHD screening in newborns,[2] and, when used for continuous monitoring with Masimo Patient SafetyNet™ in post-surgical wards, reduce rapid response team activations, ICU transfers, and costs.[3-6]

Masimo SET® is now widely recognized as the industry leader in pulse oximetry. Masimo SET® is used to monitor more than 200 million patients annually; and, is the primary pulse oximetry technology used at nine of the top 10 hospitals as ranked in 2022-23 *U.S. News & World Report* Best Hospitals Honor Roll. Masimo SET® has been shown in over 100 peer-reviewed studies to outperform other pulse oximeter technologies in hospital use. Masimo SET® technology, has primarily been utilized in hospitalized patients and other clinical settings (e.g., emergency medical services, etc.). However, some patients previously only cared for in the hospital are increasingly managed at home. Patient populations that can logically benefit from continuous pulse oximetry outside of the hospital include: 1) the chronically ill, such as those suffering from congestive heart failure (CHF), 2) patients recovering from surgery at home, 3) patients with COPD, 4) those with acute medical illness (e.g., Covid-19, pneumonia) at home, 5) all individuals taking opioids, by prescription or non-prescription use for acute post-surgical care, and for acute or chronic pain, 6) those with obstructive sleep apnea (OSA), and 7) post ICU care at home, amongst others. Continuous pulse oximetry monitoring can help improve patient safety and clinical outcomes, reduce hospital length of stay and emergency department (ED) visits, and decrease associated health care costs.[7,8] Furthermore, even healthy individuals interested in optimizing their cardiovascular fitness can utilize continuous oxygen saturation (SpO_2) tracking during training.

As the world leader in hospital-grade pulse oximetry technology, Masimo has developed the first consumer health watch, Masimo W1™, to offer the accuracy and reliability of advanced hospital-grade continuous pulse oximetry in a convenient, wrist-worn wearable device. For Masimo W1, we adapted monitoring technology based on Masimo SET® pulse oximetry to optimize the capture of health data on the wrist.

This white paper reviews basic features of the Masimo W1 watch, emphasizing the tangible benefits of hospital-grade technology and the importance of continuous accurate real-time health data. Next, several common and important confounders of SpO_2 measurement are reviewed (e.g., motion, low perfusion, and skin pigmentation), along with the solutions already addressed by Masimo Signal Extraction Technology® (SET®) that are incorporated into the Masimo W1 watch. The next section surveys the head-to-head comparison of the Masimo W1 watch versus the Apple Watch in terms of accuracy, as well as ability to detect falling SpO_2 values during sleep and during spot check with wrist and watch held in the sideways position. The penultimate section introduces a brand new parameter Hydration Index (Hi), which is of importance for both ill patients and healthy athletes. Finally, the "Eye to the Future" section provides a glimpse of upcoming features that will be available in yet to be released Masimo wrist-wearable products. Masimo W1 holds CE mark approval for use in medical applications, but FDA 510(k) clearance is currently pending at the time of this publication (Dec. 13, 2022).

II. THE MASIMO W1 HEALTH WATCH SOLUTION

Masimo has used its innovation and expertise in signal processing, photonics, bio-sensor design, to integrate its advanced continuous pulse oximetry technology into the Masimo W1 health watch (**Figure 1**).

FRONT BACK

Figure 1. Masimo W1 Advanced Health Tracking Watch

The Masimo W1 watch offers continuous health parameter data, including hospital-grade blood oxygen saturation (SpO_2), pulse rate, pulse rate variability, heart rate, respiratory rate, perfusion index (Pi), pleth variability index (PVi), calorie count, and a noninvasive continuous measurement of hydration, hydration index (Hi) **(Figure 2)**. As part of a future update, Masimo W1 will also measure temperature and VO_2Max and provide continuous health data tracking and oversight. The Masimo W1 can be used for a wide variety of applications in diverse settings, including remote patient monitoring in the hospital or home-care environment, and can help healthy individuals better understand and track their overall health, fitness, and daily activities. The Masimo W1 watch is currently limited to health and wellness applications in the U.S., as 510(k) medical device clearance is pending.

Oxygen level (SpO_2)*
A continuous measurement of functional oxygen saturation of arterial hemoglobin. Essentially, the blood oxygen levels, which can change with heart and lung function, activity, and altitude.

Pulse rate (PR)
A continuous measurement of the heart rate (beats per minute) derived from the pleth waveform. PR changes with illness, activity, and stress.

Pulse Rate Variability (PRV)
A continuous measurement of the variation in time between each pulse. The PRV changes with exercise and stress, including illness.

Pleth Variability Index (PVi®)
A dynamic index between 0-100 based on changes in perfusion index. PVi is affected by fluid volume changes occurring during the respiration cycle and typically increases with lower intravascular fluid levels. This increase in PVi with hypovolemia is termed preload dependence and occurs in fluid responders.

Perfusion Index (Pi)
A continuous calculation of the relative strength of the pulse, which changes based on circulation.

Hydration Index (Hi)™**
A dynamic index between -5 to +5 which measures the relative intra-cellular fluid (water) loss and gain based on changes in tissue water content. Hydration optimization can improve physical exercise endurance, sleep quality, cognition, mood, and more.

Heart rate (HR)
The number of times the heart beats in a minute, based on electrical signals from the ECG waveform.

Respiration Rate (RRp®‡)
A continuous measurement of respiration rate (breaths per minute) derived from changes in the pleth waveform. Advanced signal processing is used to calculate RRp, which can change with illness, physical activity, or mental or emotional states.

Activity (Steps)
The level of physical activity captured due to motion, represented in steps count.

Calories (kcal)
A calculated value of burned calories (level of energy consumption) based on the basal metabolic rate and physical exertion, represented as kcal. The calculated value also incorporates patient profile data (e.g., biological sex, age, weight and height).

Continuous On-demand

* Arterial oxygen saturation. ** Available with the Consumer Health version of Masimo W1. ‡ RRp stands for respiratory rate from the pleth.

Figure 2. Physiological Parameters Measured Continuously (Red) and On-demand (Blue) by Masimo W1

III. IMPORTANCE OF HOSPITAL-GRADE TECHNOLOGY

Utilization of Masimo W1 as a medical device pulse oximetry monitoring solution in the home offers numerous benefits to patients and health care providers. Doctors can prescribe remote pulse oximetry monitoring with the knowledge that the results will be accurate and more safely guide diagnosis and treatment recommendations than would occur with less accurate devices that can often be purchased over the counter or online without any assurance of accuracy. By using medical-grade technology in the home, doctors, patients, and their families can also all have greater peace of mind that they are receiving real-time, accurate and reliable physiological data to identify deterioration and help avoid preventable exacerbation of disease. The expectation is that more timely and accurate measurements of remotely monitored patients can lead clinicians to make earlier and more correct decisions that will improve patient health quicker, and hence reduce ED visits, hospital readmission rates, and decrease health care costs, while improving overall clinical outcomes. These benefits can be realized in healthy people as well (see Case Report below). It should be noted that Masimo W1 is not as reliable as Masimo RD SET® adhesive sensors, such as Radius PPG and RD-Neo. If a need for more reliable measurements arise, please use Radius PPG or the RD SET® sensors.

Case Report: Benefit of Masimo W1 Home Monitoring for Postoperative Opioid Use in a Healthy Patient

The case involved an otherwise healthy 21-year-old female who was prescribed and administered a commonly utilized combination opioid analgesic (Hydrocodone 5 mg / Acetaminophen 325 mg) immediately following surgical extraction of her wisdom teeth. At her father's insistence, she wore the Masimo W1 health watch for continuous pulse oximetry monitoring. Approximately one hour following administration of the opioid analgesic, her SpO2 began dropping and fell to nearly 70% **(Figure 3)**.

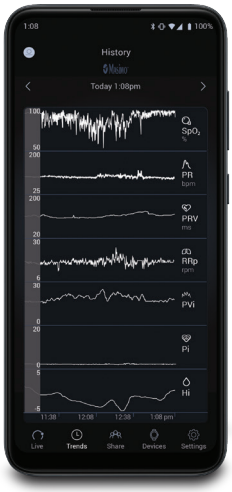


Figure 3. Masimo W1 Health Watch Continuous Data for a 21 Female Patient Taking Post-op Opioids. The data shown on this figure was downloaded as a screen shot from the smartphone used by the patient's father to monitor her. It shows the SpO2 decreased almost into the 70% range between 11:00 PM and midnight in association with the opioid use described in text.

SpO2 = oxygen saturation, PR = pulse rate, PRV = pulse rate variability, RRP = respiratory rate derived from the pulse oximeter pleth waveform, PVi = pleth variability index (measure of intravascular volume status), Pi = perfusion index (indicating the adequacy of perfusion to the measured digit).

The desaturation event depicted above **(Figure 3)** was remotely monitored and observed by her parents, who came to her room to assess her well-being (and woke her up, and aroused her), and together they agreed to minimize subsequent opioid doses, and utilize other means to assist pain control. In this case, there were no ill consequences. However, if this patient was taking a higher dose of opioids, had other comorbidities, or was not monitored, additional doses could have led to lower saturations and more severe respiratory depression, which might have become life threatening. Continuous monitoring can alert the users and their loved ones when a change in respiratory status might indicate the need for medical intervention, including a call to emergency medical services or a visit to the ED.

IV. VALUE OF CONTINUOUS MONITORING

Pulse oximetry is essential for monitoring individuals who may experience oxygen desaturation events, such as those with cardiovascular conditions, acute or chronic respiratory diseases, sleep-disordered breathing such as OSA, and those taking opioids (as shown in above Case Report), as well as those on other sedative medications. Significant or prolonged periods of blood oxygen desaturation can lead to tissue and organ hypoxia. Serious oxygen desaturation events can occur very quickly (e.g., in a couple of minutes) and can be prolonged; if they go undetected, they can lead to irreversible brain damage, or even death. Continuous monitoring enables timely detection of desaturation events that would otherwise be missed by intermittent spot checks. Thus, continuous SpO2 monitoring is critical for assessing the need for supplemental oxygen, or other interventions, and essential to the provision of enhanced patient safety.

A. In the Hospital

Numerous studies have demonstrated the benefits of continuous pulse oximetry monitoring in hospitalized patients beyond the intensive care unit, particularly in medical and surgical units where analgesic use is prevalent.[6,9-10] A systematic review and meta-analysis of 12 clinical studies comprising 841,424 patients revealed that the incidence of opioid-induced respiratory depression (OIRD) in postsurgical patients ranges from 0.04-0.5% when defined by naloxone administration, to 23-41% when defined by hypoxemia or bradypnea.[9] In addition, an investigation on the incidence, severity and duration of micro events (abnormal vital signs) in postoperative abdominal surgery patients demonstrated that micro events are common and frequently missed using an Early Warning Score (EWS) based on intermittent vital sign checks.[10] Indeed, continuous monitoring detected a SpO2 < 92% lasting > 60 minutes in 58% of patients vs 16% by EWS ($p < 0.0001$), a SpO2 < 85% lasting >10 minutes in 52% of patients vs 4% by EWS ($p < 0.0001$), tachycardia in 60% of patients vs 6% by EWS ($p < 0.0001$), bradycardia in 20% of patients vs 0% by EWS ($p = 0.0009$), tachypnea in 74% of patients vs 8% by EWS ($p < 0.0001$), and bradypnea in 64% of patients vs 2% by EWS ($p < 0.0001$).[10]

Most recently, a 10-year study out of Dartmouth Hitchcock Medical Center demonstrated the beneficial impact of continuous Masimo SET pulse oximetry monitoring in 126,697 hospitalized patients receiving sedative or opioid medications over that time

span. Indeed, the continuously monitored patients had a significantly reduced death rate compared to those without continuous monitoring (0.0009% vs. 0.02%, p = 0,03).[6]

Another recent study in post-op bariatric surgery patients showed that continuous SpO_2 monitoring resulted in lower odds of cardio-respiratory complications (odds ratio [OR]: 0.41, 95% confidence interval [CI]: 0.32-0.53, p < 0.001) and lower odds of prolonged hospital length of stay > 2 days (OR: 0.37, 95% CI: 0.28-0.49, p < 0.001) compared to the control group receiving intermittent "spot check" vital sign measurements, as presented in **Table 1**.[11]

Table 1. Outcomes of Continuous vs. Standard Monitoring Groups in postsurgical Bariatric Patients

	Continuous Monitoring (*n=752*) n (%)	Standard Monitoring (*n=698*) n (%)	*p*-value
Unplanned postoperative PAP treatment (%)	10 (1.3)	15 (2.1)	0.319
Unplanned ICU admission (%)	0 (0.0)	3 (0.4)	0.111
Prolonged hospital stay >2 days (%)	90 (12.0)	186 (26.6)	<0.001
Respiratory complication (%)	37 (4.9)	40 (5.7)	0.568
Composite cardiorespiratory events (%)	112 (14.9)	208 (29.8)	<0.001

Adapted from Tian et al., 2022, *J Clin Anesth*[11]

B. From Hospital to Home

Continuous pulse oximetry has enabled clinicians to remotely monitor patients with acute and chronic illness while at home. Studies have shown that home pulse oximetry monitoring can help reduce the duration of home oxygen therapy in premature infants discharged from the NICU with bronchopulmonary dysplasia,[12] and can significantly reduce hospital re-admission (0.23 vs 0.68/patient; p = 0.002) and ED visits (0.36 vs 0.91/patient; p = 0.006) in adult patients with COPD.[13] In a study of 1,280 discharged patients at high risk of hospital readmission, remote patient monitoring with pulse oximetry reduced the risk of readmission or death within 30 days by 5.5% (95% CI, – 10.4 to – 0.6%; p =.03) and decreased ED visits within 30 days by 5.6% (95% CI, – 9.4 to – 1.8%; p =.005), as shown in **Table 2**.[14]

Table 2. Primary and Secondary Outcomes of Patients at High Risk of Hospital Readmission

Outcomes	Control Group		RPM Group		Difference
	% (n/N)	95% CI	% (n/N)	95% CI	% (95% CI)
Primary Outcome					
30-d death or hospital readmission	23.7 (137/578)	20.4 to 27.3	18.2 (87/477)	15.0 to 22.0	-5.5 (-10.4 to -0.6)
Components of Primary Outcome					
30-d death	1.9 (11/574)	1.1 to 3.4	1.7 (8/463)	0.9 to 3.4	-0.2 (-1.8 to 1.4)
30-d hospital readmission	22.5 (129/574)	19.3 to 26.1	17.0 (81/476)	13.9 to 20.7	-5.5 (-10.3 to -0.7)
Secondary Outcome					
30-d ED visit	14.2 (81/570)	11.6 to 17.3	8.6 (40/464)	6.4 to 11.5	-5.6 (-9.4 to -1.8)

Adapted from Dawson et al., 2021, *J Gen Intern Med*.[14] n = number of patients with the outcome; N = number of patients with available data; RPM = remote patient monitoring.

Recently, remote patient monitoring has been used to manage patients with COVID-19. In a pool of 9,378 adults diagnosed with COVID-19, 5,364 patients (57.2%) activated remote monitoring with a Masimo SET® pulse oximeter device, which resulted in a lower odds of hospitalization (OR: 0.68; 95% CI, 0.54-0.86; P = .001), a longer mean (standard deviation [SD]) time between test and hospitalization (6.67 [3.21] days vs 5.24 [3.03] days), a shorter length of stay (4.44 [4.43] days vs 7.14 [8.63] days), and less intensive care use (15 patients [0.3%] vs 44 patients [1.1%]), as presented in **Table 3**.[15]

Table 3. Clinical & Utilization Outcomes In COVID-19 Patients by Remote Monitoring Activation Status

	Patients, No. (%)		*P* value
Outcomes	**Activated (n=5364)**	**Not Activated (n=4014)**	
Hospitalized	128 (2.4)	158 (3.9)	<.001
Length of stay, mean (SD), d	4.44 (4.43)	7.14 (8.63)	.001
Time from symptoms to hospitalization, mean (SD), d	9.84 (3.69)	8.47 (4.21)	.004
Time from positive test to hospitalization, mean (SD), d	6.67 (3.21)	5.24 (3.03)	<.001
Intensive care utilization	15 (0.3)	44 (1.1)	.001
30-d Mortality	4 (0.1)	24 (0.6)	.001
90-d Mortality	10 (0.2)	26 (0.6)	.001

Adapted from Crotty et al., 2022, *JAMA Netw Open*.[15]

Cost savings have also been modeled to accrue with continuous pulse oximetry monitoring. In the hospital, continuous monitoring with pulse oximetry and capnography in high-risk patients on the general care floor was projected to reduce hospital costs by $535,531 annually and cumulative patient length of stay (LOS) by 103 days.[16] In the home-care environment, at-home pulse oximetry monitoring of moderate-to-severe COVID-19 patients was associated with cost savings of $11,472 per patient.[8] In addition, the COVID-19 patients with at-home monitoring experienced 87% fewer hospitalizations and 77% fewer deaths.[8]

C. In the Home

Pulse oximetry monitoring at home can also be useful in screening for suspected obstructive sleep apnea (OSA). Because there is night-to-night variability in oxygen desaturation events in subjects with OSA, some individuals with relevant OSA can have a missed diagnosis using only a single-night polysomnography test.[17] As shown in **Table 4**, the sensitivity of pulse oximetry monitoring to diagnose moderate OSA increased from 71.4% on the first night to 88.1% on the second night, and reached 100% between nights 10 to 13.[17]

Table 4. Accuracy Analyses of 1 to 13 Nights Using the Mean ODI3% to Define Moderate OSA

Nights	No. of Patients	Sensitivity		Specificity		Negative Predictive Value	
		Estimate (%)	95% CI (%)	Estimate (%)	95% CI (%)	Estimate (%)	95% CI (%)
1	108	71.43	55.42-84.28	89.39	79.36-95.63	83.10	72.37-90.95
1-2	106	88.10	74.37-96.02	85.94	74.98-93.36	91.67	8.61-97.24
1-3	103	85.37	70.83-94.43	90.32	80.12-96.37	90.20	80.12-96.37
1-4	103	87.80	73.80-95.92	91.94	82.17-97.33	91.94	82.17-97.33
1-5	101	82.93	67.94-92.85	95.00	86.08-98.96	89.06	78.75-95.49
1-6	99	87.50	73.20-95.81	94.92	85.85-98.94	91.80	81.90-97.28
1-7	95	86.84	71.91-95.59	96.49	87.89-99.57	91.67	81.61-97.24
1-8	93	94.44	81.34-99.32	96.49	87.89-99.57	96.49	87.89-99.57
1-9	86	90.91	75.67-98.08	96.23	87.02-99.54	94.44	84.61-98.84
1-10	85	100.00	89.42-100.00	96.15	86.79-99.53	100.00	92.89-100.00
1-11	81	93.75	79.19-99.23	97.96	89.15-99.95	96.00	86.29-99.51
1-12	73	96.55	82.24-99.91	97.73	87.98-99.9	97.73	87.98-99.94
1.13	62	100.00	85.75-100.00	100.00	90.75-100.00	100.00	90.75-100.00

Adapted from Roeder et al., 2021, *Chest*.[17]

ODI3% = Oxygen Desaturation Index 3%, the average number of 3% desaturation episodes per hour of recording. Sensitivity, specificity, and negative predictive value with two-sided 95% CI of mean nights ODI3% with reference test mean of ODI3% night 1 to ODI3% night maximum to diagnose moderate OSA (ODI3%, ≥ 15/h). Each individual was included into the analysis only up to the night before the last measured night (which was used for the reference test).

In addition, in-hospital polysomnography tests can affect the person's normal sleep, and pulse oximetry monitoring at home could offer a more consistent and accessible screening tool for OSA.[18] In both inpatient and outpatient settings, the combination of nocturnal pulse oximetry monitoring with the standard STOP-BANG questionnaire has demonstrated greater accuracy as a screening tool for OSA than using STOP-BANG ($p < 0.05$) alone.[19]

V. COMMON PULSE OXIMETRY CONFOUNDERS AND MASIMO SOLUTIONS

Masimo has been a global leader in medical-grade pulse oximetry for over 30 years. Its Signal Extraction Technology® (SET®) was designed address the common confounders of conventional pulse oximetry such as motion, low perfusion, and skin pigment. **Table 5** reviews the problems and Masimo solutions.

Table 5. Pulse Oximetry Confounders and Masimo Solutions

Conventional Pulse Oximetry Confounder	Impact on SpO_2 Measurement	Addressed by Masimo SET Pulse Oximeters and CO-Oximeters	Addressed by W1 Health Watch
Motion	Non-arterial and venous noise reduce accuracy	Yes	Yes
Low Perfusion	Impaired blood flow can generate signal artifacts and decrease accuracy	Yes	Yes
Skin Pigment	Static absorbers (i.e., skin pigment, tissue thickness) affect the light absorbance signal and reduce accuracy	Yes	Yes

Masimo addressed the confounders listed in Table 5 (above) using advanced signal processing techniques, including parallel engines and adaptive filters, to separate the arterial signal from sources of noise (including the venous signal) and significantly reduce the impact of static absorbers such as skin pigment and tissue thickness (e.g., finger, toe, or earlobe). In addition, Masimo continues to iterate regarding enhancements to sensor design. This cutting-edge SET® technology has enabled Masimo pulse oximeter devices to measure SpO_2 accurately and minimize common confounders of conventional pulse oximetry, including motion, low perfusion, and varying skin pigmentation. These advancements served as the foundation for the hospital grade SpO_2 monitoring technology now available in the Masimo W1 Watch.

VI. CLINICAL PERFORMANCE OF MASIMO W1 VERSUS APPLE WATCH SERIES 7

Recent studies were conducted in the Masimo laboratory to compare the performance of the Masimo W1 health watch with the Apple Watch Series 7 in healthy adult volunteers. This investigation included an analysis of SpO_2 accuracy based on arterial blood desaturation studies, using a CO-oximeter for reference arterial blood oxygen saturation (SaO_2) measurements. In addition, studies assessing the ability to detect SpO_2 during rapid desaturation events using the Apple watch "sleep mode" with the watch in a normal upright position, and during spot check measurements with the wrist rotated externally 90 degrees (thumb facing up), were conducted as detailed below. In all cases, the Masimo W1 resulted in far superior measurement efficacy, and remains as the only commercially available wearable device capable of accurate and continuous SpO_2 measurements under common clinical conditions.

A. Accuracy (Based on desaturation studies compared to arterial blood samples)

Healthy adult subjects were exposed to a desaturation protocol that sequentially decreased the SpO_2 in a stepwise fashion, achieving stable plateau values between 100 and 70%, while recording simultaneous SaO_2 readings. The target desaturation profile is shown in **Figure 4** below.

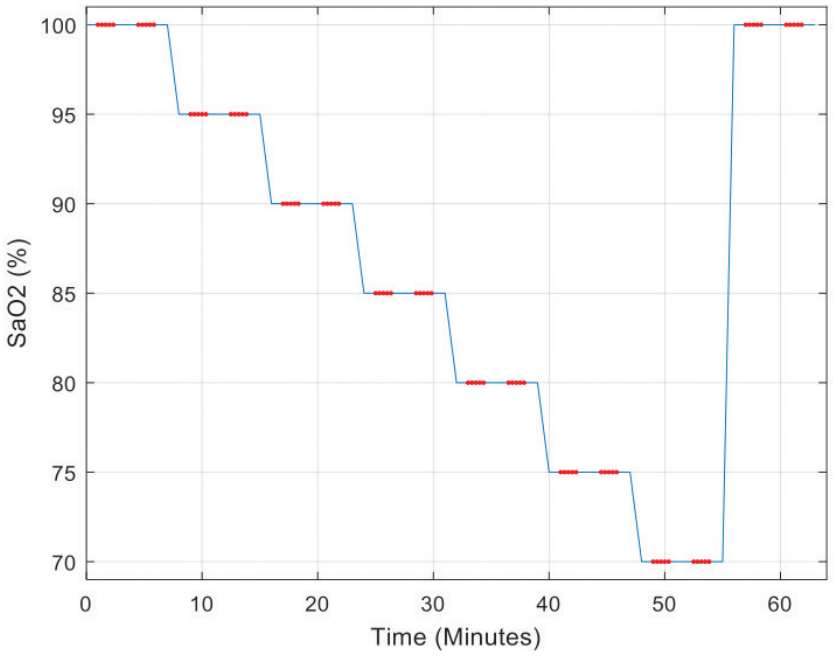


Figure 4.

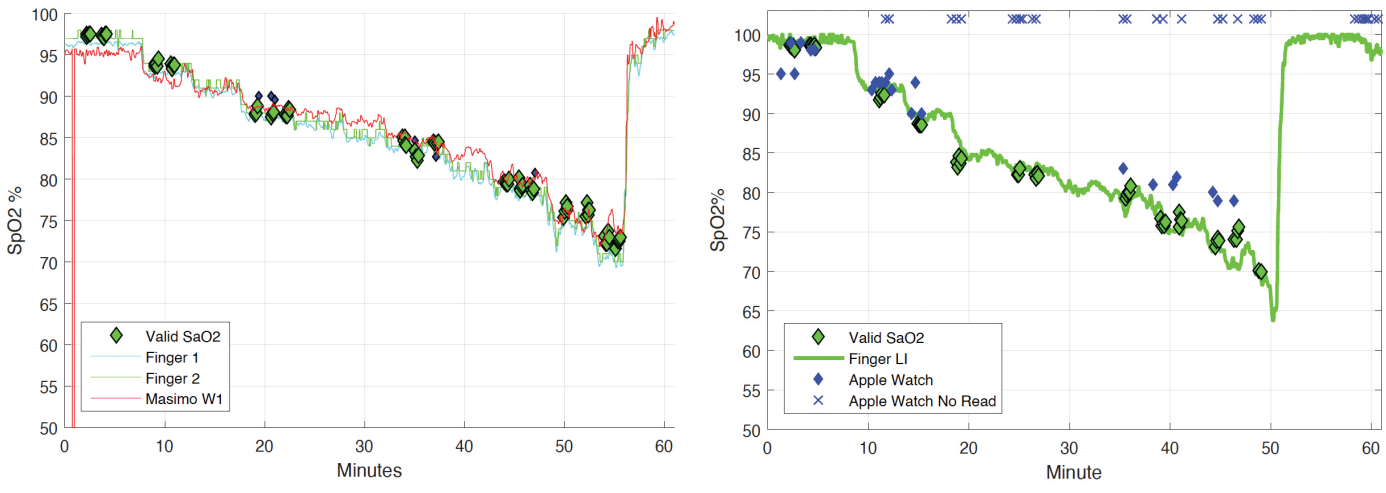
Target Blood Desaturation Profile

This figure shows the optimal oxygen saturation target levels for a desaturation study ranging from 100% sat to 70% sat. At each plateau (between red dashes), arterial blood samples are taken to match with the stable saturation value. SaO_2 = arterial blood saturation.

For the Masimo W1, which measures SpO_2 continuously, the SpO_2 measurements can be observed to synchronize with the reference SaO_2 measurements. The Apple Watch measures SpO_2 as a spot check reading, and spot check measurements were recorded simultaneously with the blood draw. **Figure 5** demonstrates a representative example of the data acquired by the Masimo W1 and Apple Watch during the blood desaturation protocol. The side-by-side plots derived from the Apple Watch and Masimo W1 illustrate the differences between the Masimo W1 (red line), which synchronizes with the SaO_2 measurements, and the Apple Watch (blue diamond), which has spot check measurements initiated by a laboratory investigator. The failed spot check measurements with the Apple Watch (no readings) are shown with the blue X's along the top of the plots, which occurred at both high and low oxygen saturations.

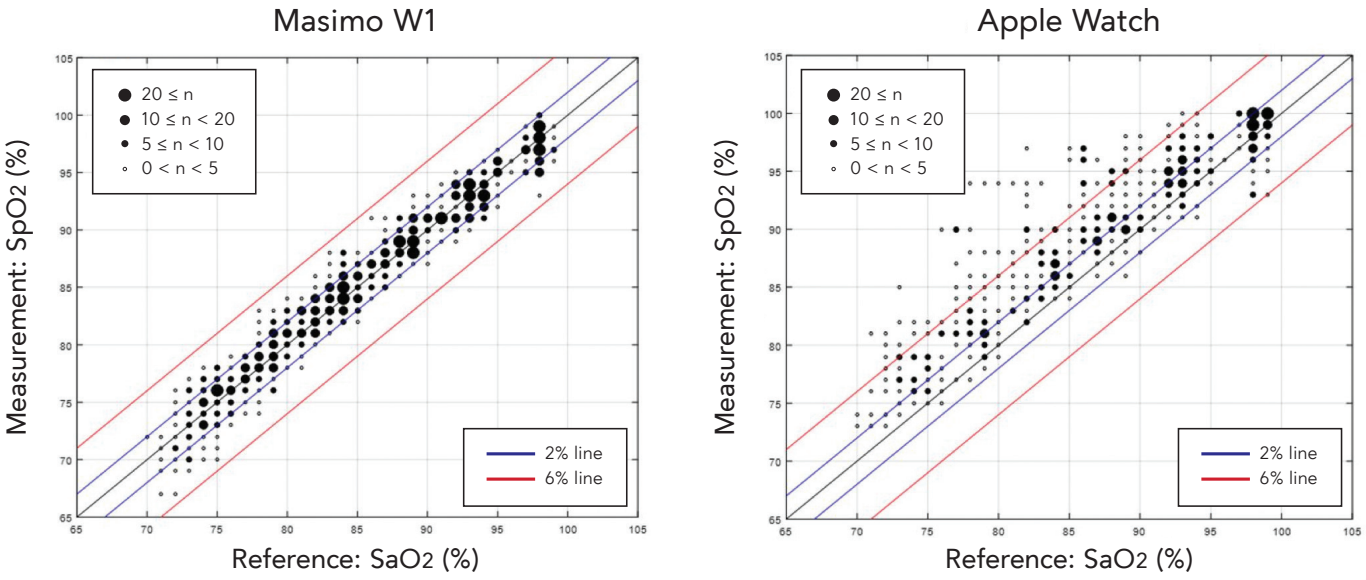
Figure 5.

Representative saturation vs time plots from subjects monitored with Masimo W1 (left panel) and Apple Watch (right panel) during blood desaturation studies. Masimo W1 SpO_2 values are recorded as red line. The Apple Watch SpO_2 values are shown as blue diamonds when values could be obtained. When no value could register, an "X" is shown at the top. The valid reference arterial blood saturation (SaO_2) value is shown in green diamonds for each device. There are two additional SpO_2 references (from Masimo RD SET® Sensors) shown for the Masimo W1 study (Fingers 1 and 2) and one additional SpO_2 reference for the Apple Watch (Finger L1). The Masimo W1 tracked with the reference pulse oximeters and SaO_2 values quite well. However, there are numerous examples of "failure to read" (X) for the Apple Watch.



Summary data scatterplots of the SpO2 versus SaO2 values for the Masimo W1 (N=27) and Apple Watch (N=20) are shown in **Figure 6** below.

Figure 6. Scatterplots (SpO2 vs. SaO2) of Masimo W1 and Apple Watch



Statistical calculations for the data shown in **Figure 6** (above) included values of bias (mean SpO2-SaO2 difference), precision (standard deviation of the difference), and accuracy (root-mean-square error [ARMS]). Since the blood sampling procedure uses paired replicates nested within each subject, additional sources of variation occur that require "adjustments" of the calculated precision. Therefore, the Adjusted Precision and Adjusted ARMS were calculated to account for repeated measures within subjects and within the paired replicates. The Adjusted ARMS was then calculated as shown below.

$$AdjustedPrecision = \sqrt{BetweenSubjectVariance + WithinSubjectVariance}$$

$$AdjustedARMS = \sqrt{Bias^2 + AdjustedPrecision^2}$$

A summary of the performance statistics is shown in **Table 6**. Bias and adjusted precision are 0.2% ± 1.6% for the Masimo W1 and 3.1% ± 3.4% for the Apple Watch. Adjusted ARMS is 1.6% for the Masimo W1 and 4.6% for the Apple Watch. Note for all values in **Table 6**, lower numbers are better, and a typical pulse oximeter in a hospital must have and ARMS <3% for FDA clearance, and <2% to be considered a satisfactory device.

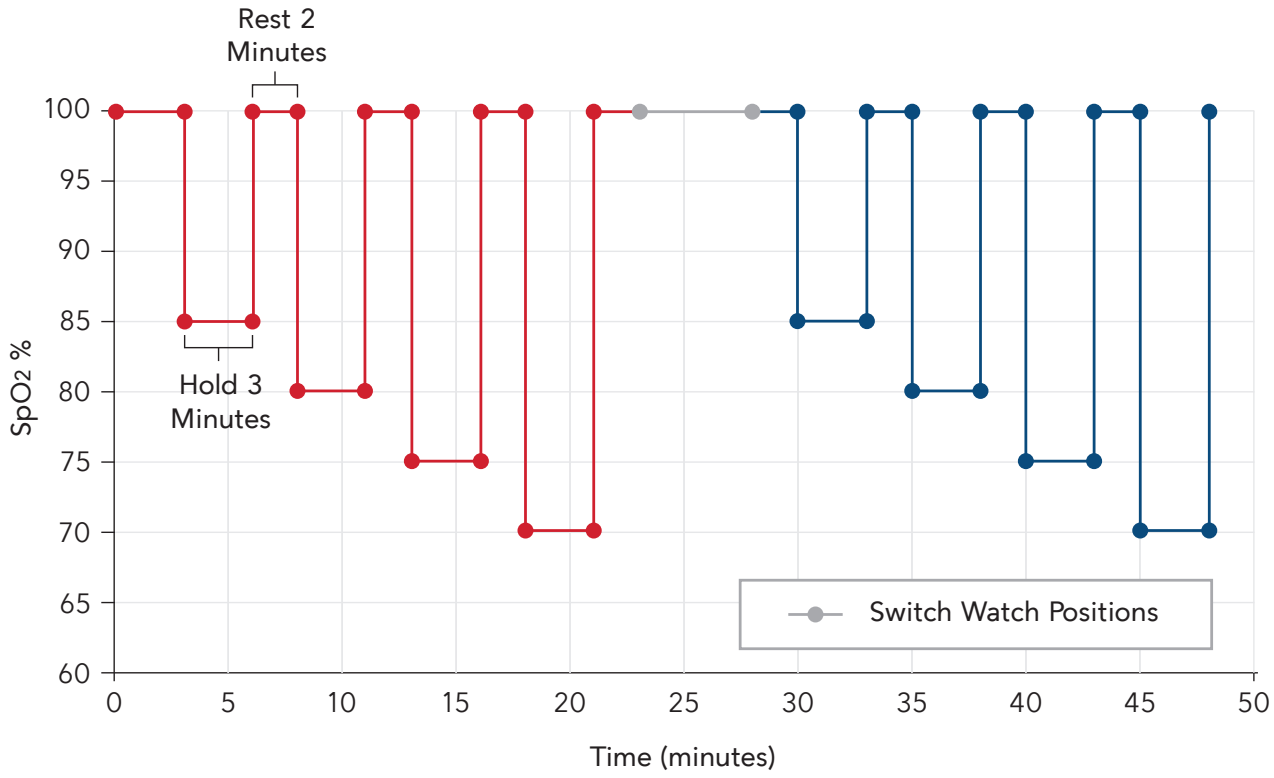
Table 6. Tabulated Summary of Performance Statistics for Masimo W1 and Apple Watch

	Bias (%)	Precision (%)	A_{RMS} (%)	Adjusted Precision (%)	Adjusted A_{RMS} (%)
Masimo W1	0.2	1.5	1.5	1.6	1.6
Apple Watch	3.1	3.2	4.4	3.4	4.6

B. Detection of SpO2 During Rapid Desaturations Using "Sleep Mode" and Spot Check

The fast desaturation protocol included four fast desaturation events at SpO2 plateau values between 100 and 70%. Each fast desaturation event was a three-minute long plateau (hold) followed by two minutes of resting period. **Figure 7** illustrates the fast desaturation profile.

Figure 7. Fast Desaturation Profile (used for "Sleep Mode" and Spot Check)



The subjects were exposed to a fast desaturation protocol (**Figure 7** above) using two test configurations with both the Masimo W1 and Apple Watch. In both configurations, the watches were applied to the back (dorsal) side of the wrist per manufacture instructions. In Configuration 1 (used for the "sleep mode" test), both watches faced up (palm facing down). In Configuration 2 (used for the spot check testing), both watches were placed per manufacture recommendations, but the forearm was externally rotated 90 degrees from Configuration 1, so the thumb (in Configuration 2) was facing up and watch facing same direction as back (dorsum) of hand.

The Masimo Radical-7® was used to collect reference SpO2 values using disposable RD SET® sensors applied to four fingers (left Index, left ring, right index and right ring fingers) of each subject. The median SpO2 values from the four finger sensors were computed as the reference SpO2 values.

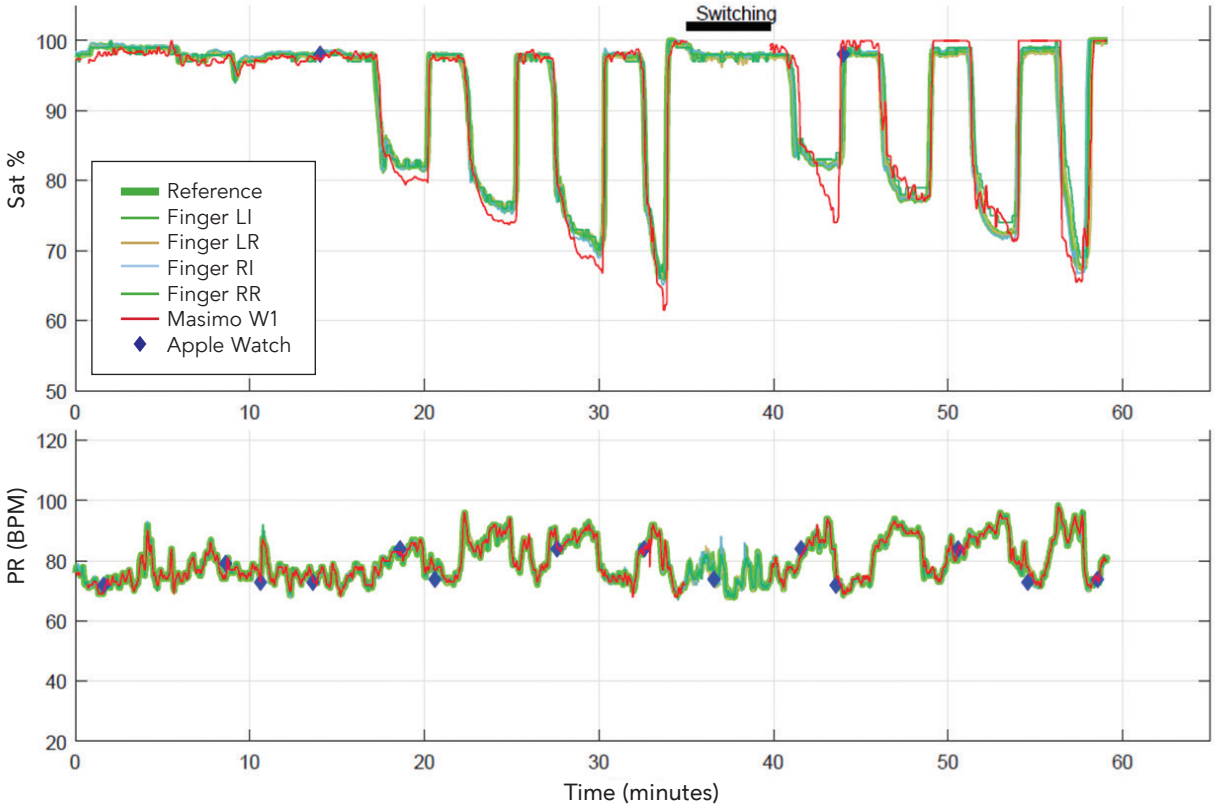
For each desaturation event, if the minimum reference SpO2 value during the event was ≤ 92%, it was then compared with the SpO2 readings from both watches. If the Masimo W1 also displayed a SpO2 reading ≤ 92%, it was recorded as a successful detection. Similarly, if the Apple Watch also displayed a SpO2 reading ≤ 92%, it was recorded as a successful detection.

B1. SpO_2 Detection During Apple "Sleep Mode" (During rapid desaturations, watch facing upward)

During the "sleep mode" testing for Apple Watch, Configuration 1 (described above) was used. The Apple Watch was set to "sleep mode" (default measurements are automatically taken approximately every 30 seconds), whereas the Masimo W1 was, by design, able to measure continuously.

Figure 8 shows a representative example of the data acquired by the Masimo W1 (red line) and the Apple Watch (blue diamond). Note that the Masimo W1 tracks with the reference device and captures every rapid desaturation event. Whereas the Apple Watch, which by default only measures approximately every 30 seconds, failed to detect any of the falling desaturation events in this subject. If the Apple watch was the only survey utilized for desaturation events, there would have been a complete failure to detect the events.

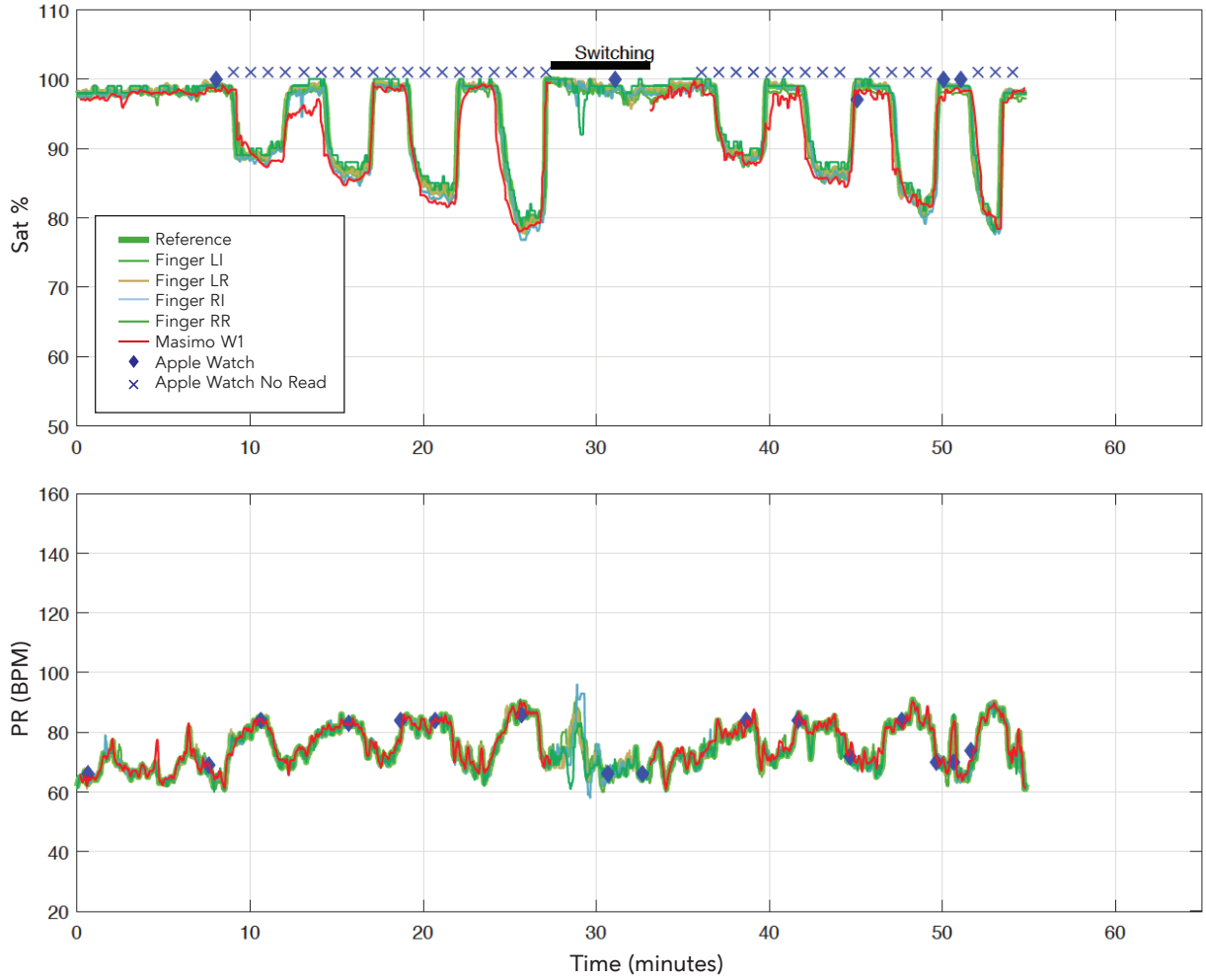
Figure 8. Representative sample from subjects monitored during rapid desaturation events with Masimo W1 (red line) vs Apple Watch in sleep mode (blue diamond) in top graph. Bottom graph depicts pulse rate tracking.



B2. Spot Check Detection (Read vs no-read of rapid desaturations, watch facing sideways)

The no read rate (failure rate) was determined for spot check measurements with the Apple Watch during the blood desaturation and fast desaturation studies discussed above. **Figure 9** shows a representative sample of the subject data acquired during fast desaturation with the Masimo W1 (red line), which measured continuously, and the Apple Watch (blue diamond) spot check measurements. Note that there were numerous episodes where the Apple Watch had no SpO2 reading (blue X), as shown in the top graph, but the pulse rate measurement occurred with fairly good fidelity (bottom graph) with both the Masimo W1 and the Apple Watch.

Figure 9. Representative sample from subjects monitored during rapid desaturation events (SpO2 top panel, and Pulse Rate [PR], bottom panel). Masimo W1 values are recorded using red line, Apple Watch spot check values are shown as blue diamonds. When the Apple Watch could not measure SpO2 (no reading) during spot check attempt a blue "X" was placed along top of the upper panel.



The total number of valid desaturation events and the detection rate for each device under two separate test configurations are summarized in **Table 7** below. The fast desaturation detection rate is 100.0% for the Masimo W1, but only 6.1% for the Apple Watch in Configuration 1 "sleep mode" (watch face up, palm down). Whereas, the fast desaturation detection rate was also 100.0% for the Masimo W1, but only 6.7% for the Apple Watch in Configuration 2 spot check (watch face sideways, thumb facing up).

Table 7. Tabulated Summary of Fast Desaturation Events and Detection Rates for Masimo W1 vs Apple Watch

Test Configuration	Number of Subjects	Number of Valid Events	Detection Rate for Masimo W1	Detection Rate for Apple Watch
Configuration 1	7	49	49/49=100%	3/49=6.1%
Configuration 2	8	60	60/60=100%	4/60=6.7%

Detection Rate = (Nt / Ndesat) x 100 (%), Nt = Number of Detected Event by Test Device, Ndesat = Number of All Valid Fast Desaturation Events by Reference SpO2

The Apple Watch "no read" rate was 17.3% for SpO_2 spot checks during the blood desaturation study (Configuration 1 with watch facing up) and 90.4% in the fast desaturation study (Configuration 2 with watch facing sideways) see **Table 8** below. Whereas, the Masimo W1 "no read" rate was 0.0 % for both conditions; in other words, the Masimo W1 reads SpO_2 100% of the time (also shown in **Table 8** below).

Table 8. Tabulated Summary of Apple Watch Orientation and No Read Rate

	Watch Orientation	Apple Watch No Read Rate for Spot Check Readings*	Masimo W1 No Read Rate for Spot Check Readings*
Blood Desaturation Study	Faced Up	158/912 = 17.3%	0.0% (reads continuously)
Fast Desaturation Study	Faced Side	293/324 = 90.4%	0.0% (reads continuously)

*Note: Apple spot check readings require an individual to initiate. No Read Rate = (Nf / Nspotcheck) x 100 (%), Nf = Number of Spot Checks without Valid SpO_2 (Failed for SpO_2 Measurement), Nspotcheck = Number of All Spot Checks using Apple Watch

The results of the blood desaturation and fast desaturation studies demonstrate that continuous SpO_2 monitoring with the Masimo W1 is highly accurate with bias and adjusted precision of 0.2% +/- 1.6% and adjusted A_{RMS} of 1.6%. In addition, the Masimo W1 achieved a high detection rate of fast desaturation (100.0% with watch faced up and 100.0% with watch faced sideways). The blood desaturation and fast desaturation studies demonstrated that the Apple Watch has an excessive "no read" rate for SpO_2 spot check measurements (17.3% and 90.4%, respectively), a low detection rate of fast desaturation (6.1% with watch faced up and 6.7% with watch faced sideways), and the adjusted A_{RMS} of 4.6% achieved in the blood desaturation study does not meet FDA standards for clinical-grade SpO_2 measurement ($A_{RMS} \leq 3\%$).

VII. HYDRATION INDEX

On December 7, 2022, Masimo announced the full market release of Hydration Index (Hi™), a powerful new tool for the Masimo W1 watch. Lack of proper hydration affects many physiological parameters, as the body works to restore homeostasis. Masimo W1 leverages such measurements to establish the hydration baseline, alerting individuals when they may be under- or over-hydrated – both of which can affect a patient's recovery from disease or an athlete's performance capabilities. A representative example of the data plots obtained in our Masimo Laboratory of a subject undergoing a Hi trial during exercise on a treadmill and then re-hydrating by consuming water are shown in **Figure 10** (below).

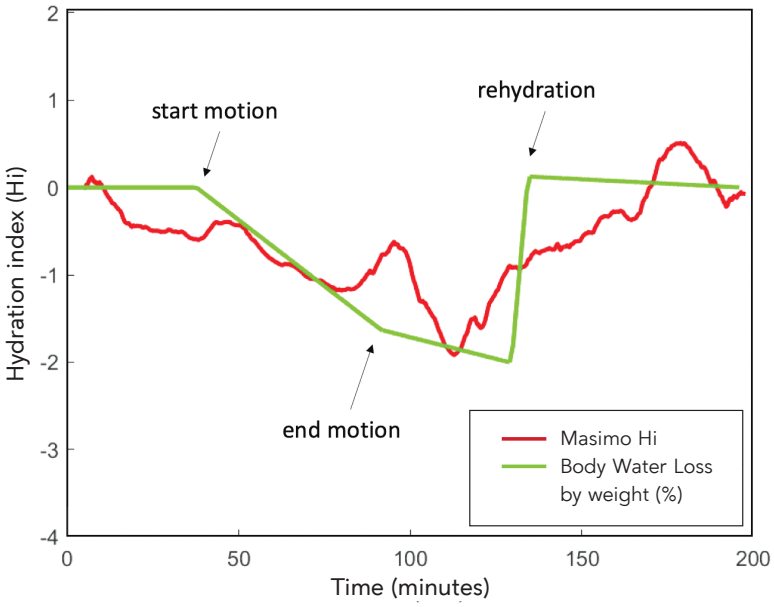


Figure 10.

Hydration Index Laboratory Study

Hydration index (Hi) on Y -axis, and weight loss (dehydration) due to exercise on treadmill, and weight gain (rehydration) also shown on Y-axis. Time is displayed in minutes on the X -axis. Start and end of treadmill exercise are shown with the first two arrows, and rehydration (drinking water) is shown with third arrow going from left to right.

The Hi is particularly important for athletes while training. Hi is also important in patients with acute critical illness and chronic disease conditions such as CHF. Whether you're an elite athlete, living with a chronic illness, or just keen to gain more insight into your body's physiological status, Masimo W1 with Hi is a game changer.

VIII. EYE TO THE FUTURE

Masimo is further expanding its advanced SET® pulse oximetry solution to the consumer market with the Masimo W1 health watch, providing the benefits of medical-grade continuous pulse oximetry in a convenient, wearable device. Masimo will continue to build on its portfolio of wearable solutions with the Masimo Freedom health watch, scheduled to launch in 2023. This consumer-friendly watch will include additional features to integrate personal smartphone applications alongside Masimo's advanced continuous pulse oximetry monitoring. Future technology updates to these wearable products include the measurement of temperature, and maximum oxygen consumption (VO_2Max) during exercise.

IX. SUMMARY

Continuous, medical-grade pulse oximetry is essential for monitoring patients in any environment, and facilitates the early and accurate detection of patient deterioration, helping to avoid preventable death or injury. Continuous medical-grade pulse oximetry is anticipated to improve clinical outcomes, as has been shown for hospitalized patients,[6] with evidence that it can reduce hospital length of stay, ED visits, and decrease health care costs.[8] The Masimo W1 health watch is the only wearable device that provides the leading medical-grade technology to consumers in a convenient, wrist-worn device. Equally valuable in the hospital or home, the Masimo W1, as a CE marked medical device, will reliably track the patient's physiologic parameter data and also relay this information remotely to clinical staff who can assist in monitoring and interpretation. The Masimo W1, as a health and wellness device, also enables individuals of all fitness levels, to track their overall condition, make healthier lifestyle choices, and achieve their conditioning goals. Masimo remains committed to pursuing advanced technology that can improve the quality of life for everyone by expanding access to accurate and reliable physiological data from the hospital to the home.

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