Masimo W1™

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

WHITEPAPER

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I. INTRODUCTION

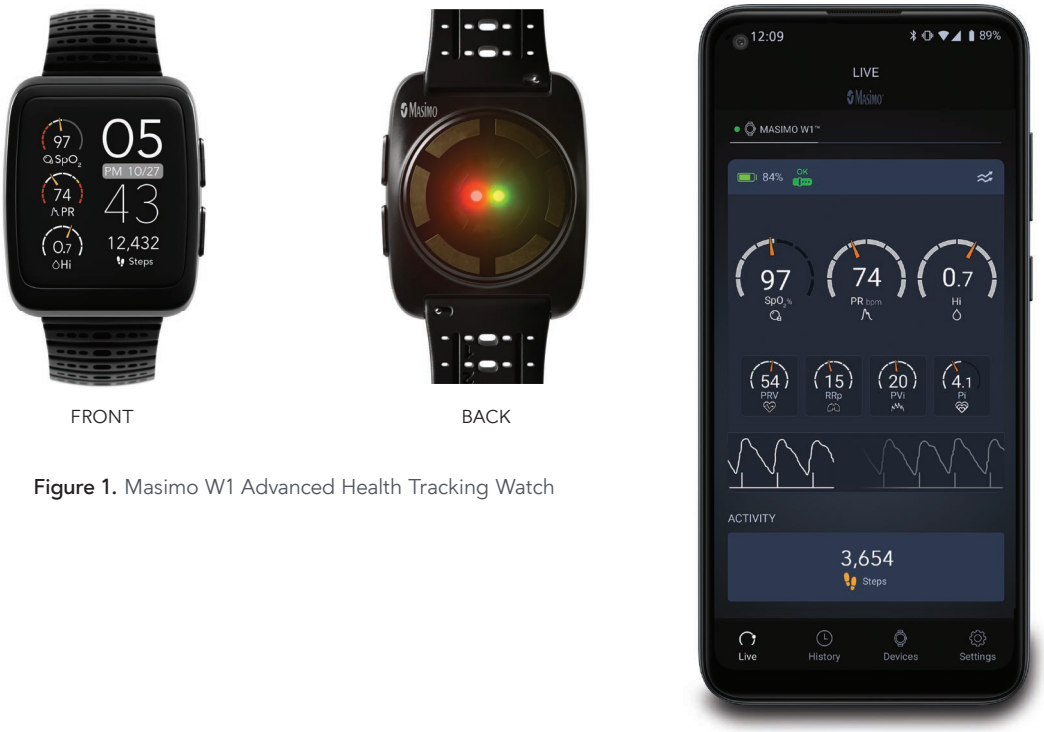
Continuous pulse oximetry has been widely used and recognized for over four decades as an essential clinical monitoring tool for detecting physiological changes in the cardio-pulmonary system. For years, positive outcome studies did not exist; however, no anesthesiologist would take their patient to 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 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. 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 whitepaper 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), a feature only available by Masimo, and is of importance for 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. This white paper anticipates the potential clinical benefits of the Masimo W1 after its FDA 510(k) clearance, which 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 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, 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 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.

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.

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 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 user 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. 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 1** reviews the problems and Masimo solutions.

Table 1. 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 Masimo 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 1** (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.

IV. 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.

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 3** below.

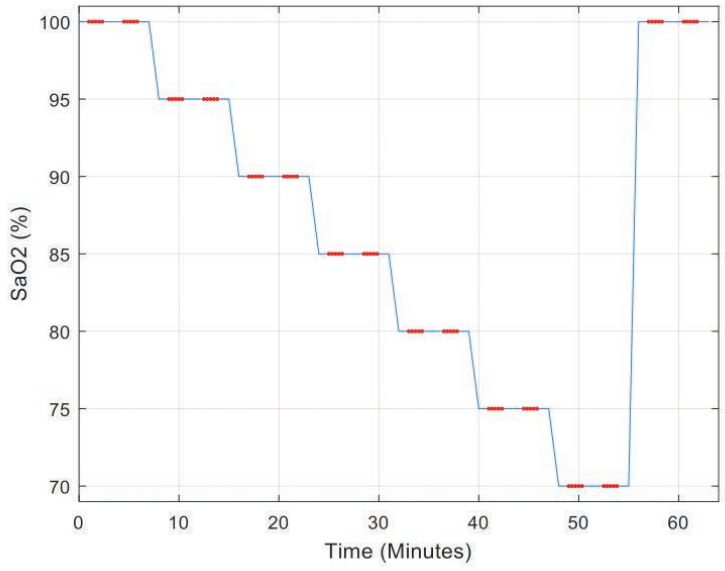


Figure 3.

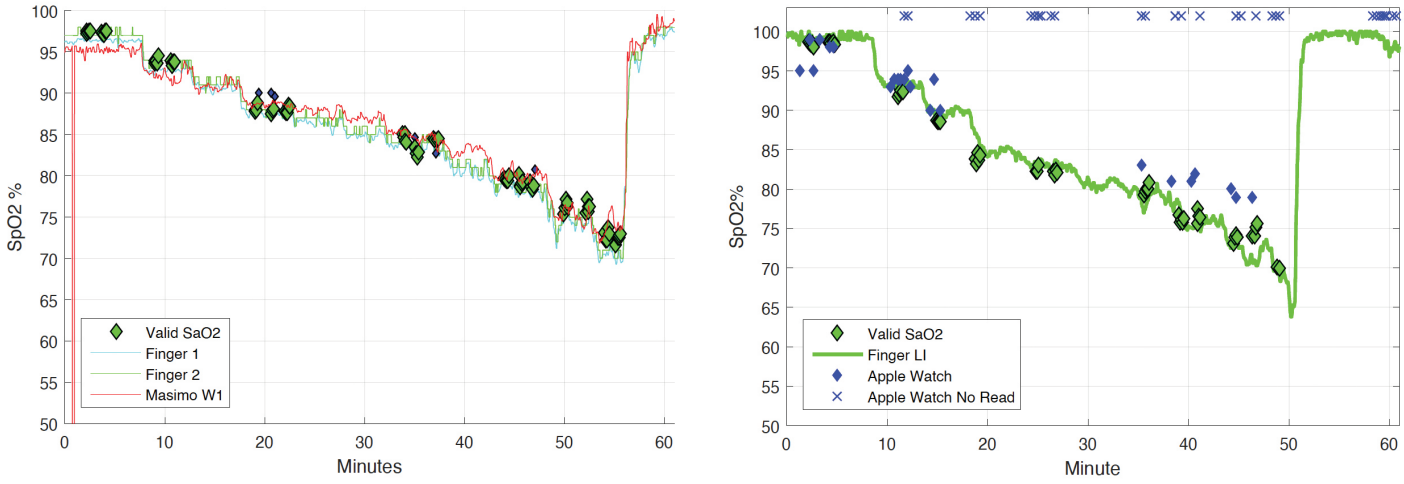
Target Blood Desaturation Profile

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 4** 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.

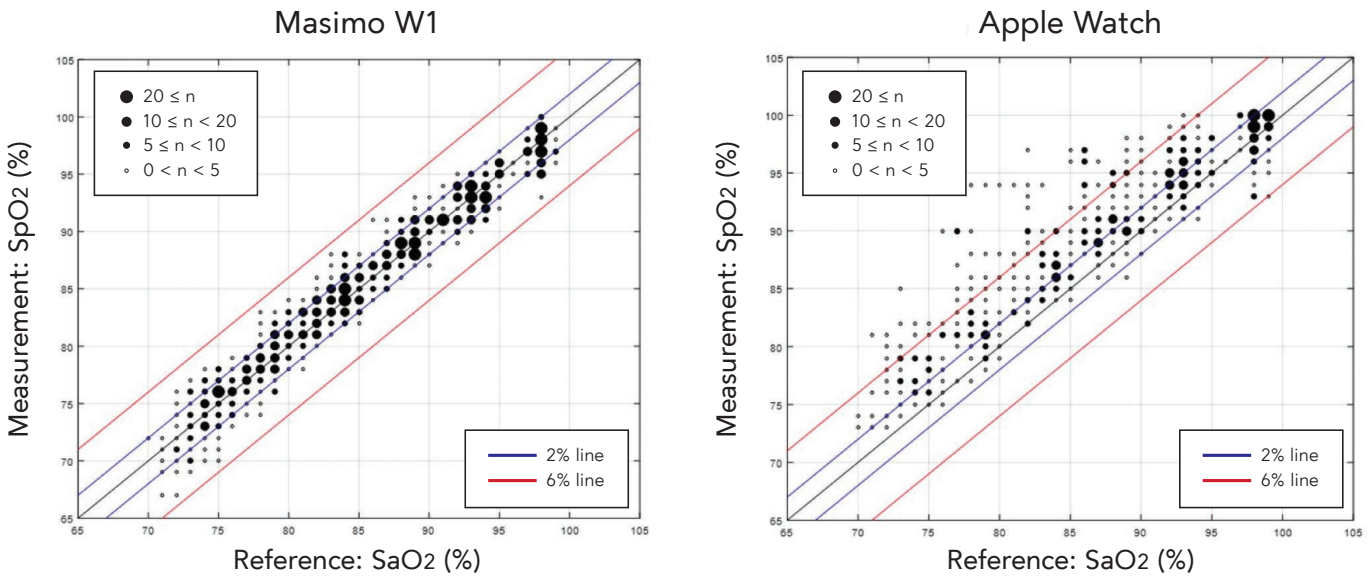
Figure 4.

Representative saturation vs time plots from subjects monitored with Masimo W1 (left panel) and Apple Watch (right panel) during blood desaturation studies. Masimo W1 SpO2 values are recorded as red line. The Apple Watch SpO2 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 (SaO2) value is shown in green diamonds for each device. There are two additional SpO2 references (from Masimo RD SET® Sensors) shown for the Masimo W1 study (Fingers 1 and 2) and one additional SpO2 reference for the Apple Watch (Finger L1). The Masimo W1 tracked with the reference pulse oximeters and SaO2 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 5** below.

Figure 5. Scatterplots (SpO2 vs. SaO2) of Masimo W1 and Apple Watch



Statistical calculations for the data shown in **Figure 5** (above) included values of bias (mean SpO_2-SaO_2 difference), precision (standard deviation of the difference), and accuracy (root-mean-square error [A_{RMS}]). 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 A_{RMS} were calculated to account for repeated measures within subjects and within the paired replicates. The Adjusted A_{RMS} 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 2**. Bias and adjusted precision are 0.2% ± 1.6% for the Masimo W1 and 3.1% ± 3.4% for the Apple Watch. Adjusted A_{RMS} is 1.6% for the Masimo W1 and 4.6% for the Apple Watch. Note for all values in **Table 2**, lower numbers are better, and a typical pulse oximeter in a hospital must have and A_{RMS} <3% for FDA clearance, and <2% to be considered a satisfactory device.

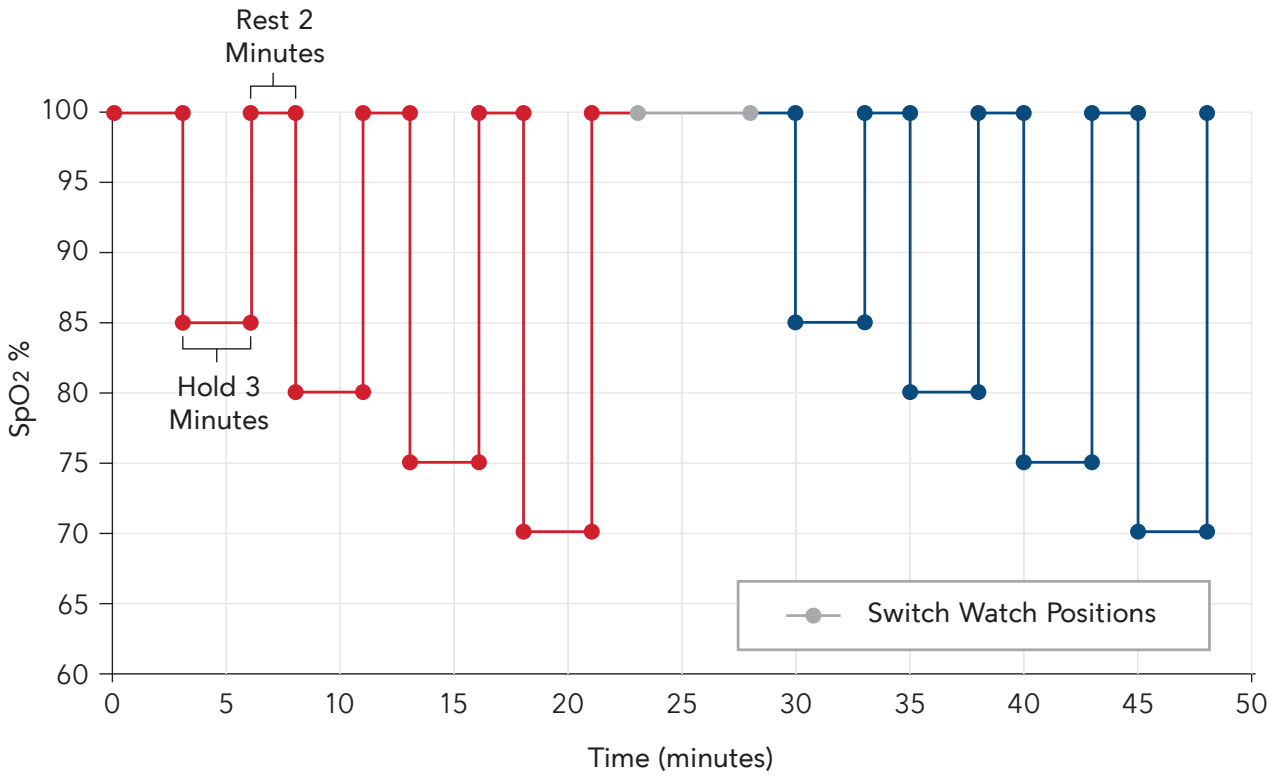
Table 2. Tabulated Summary of Performance Statistics for Masimo W1 and Apple Watch

	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 6** illustrates the fast desaturation profile.

Figure 6. Fast Desaturation Profile (used for "Sleep Mode" and Spot Check)



The subjects were exposed to a fast desaturation protocol (**Figure 6** 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.

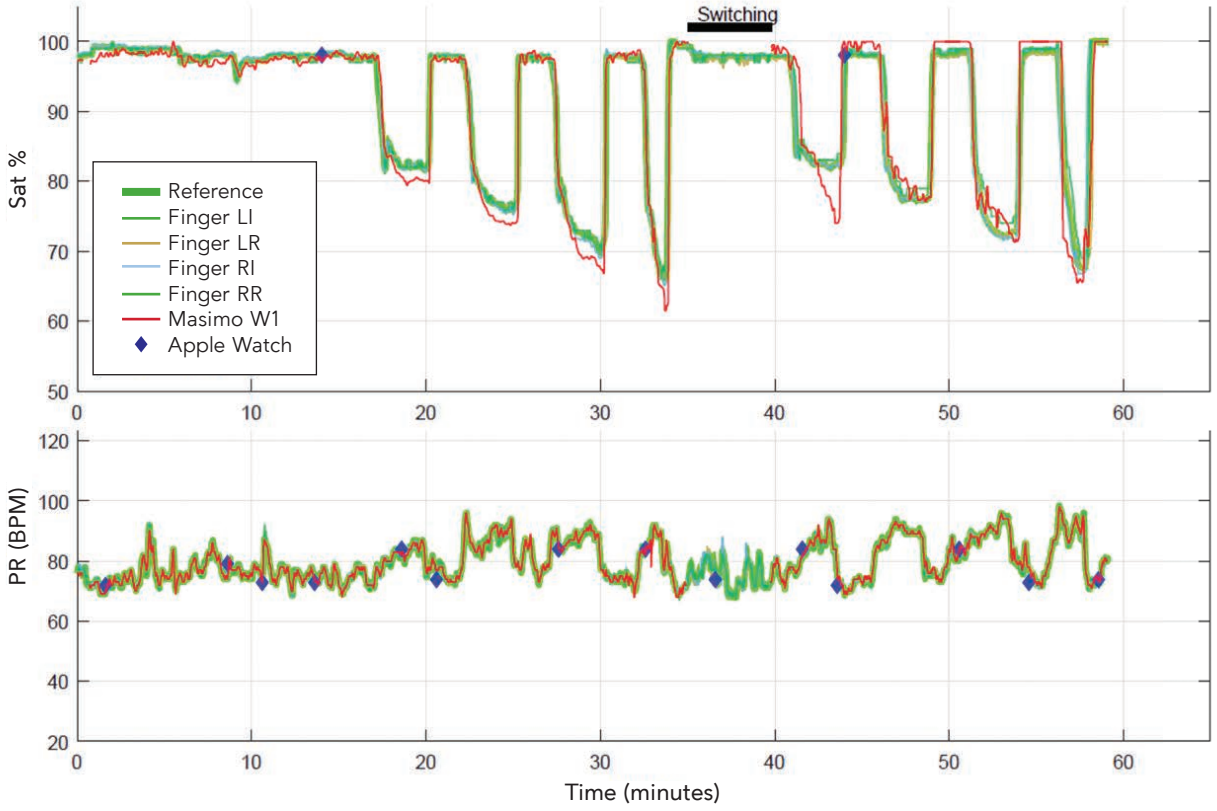
For each desaturation event, if the minimum reference SpO2 value during the event was ≤ 92%, it was then compared with the SpO2 readings from both watches. If the Masimo W1 also displayed a SpO2 reading ≤ 92%, it was recorded as a successful detection. Similarly, if the Apple Watch also displayed a SpO2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

B1. SpO2 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 7 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.

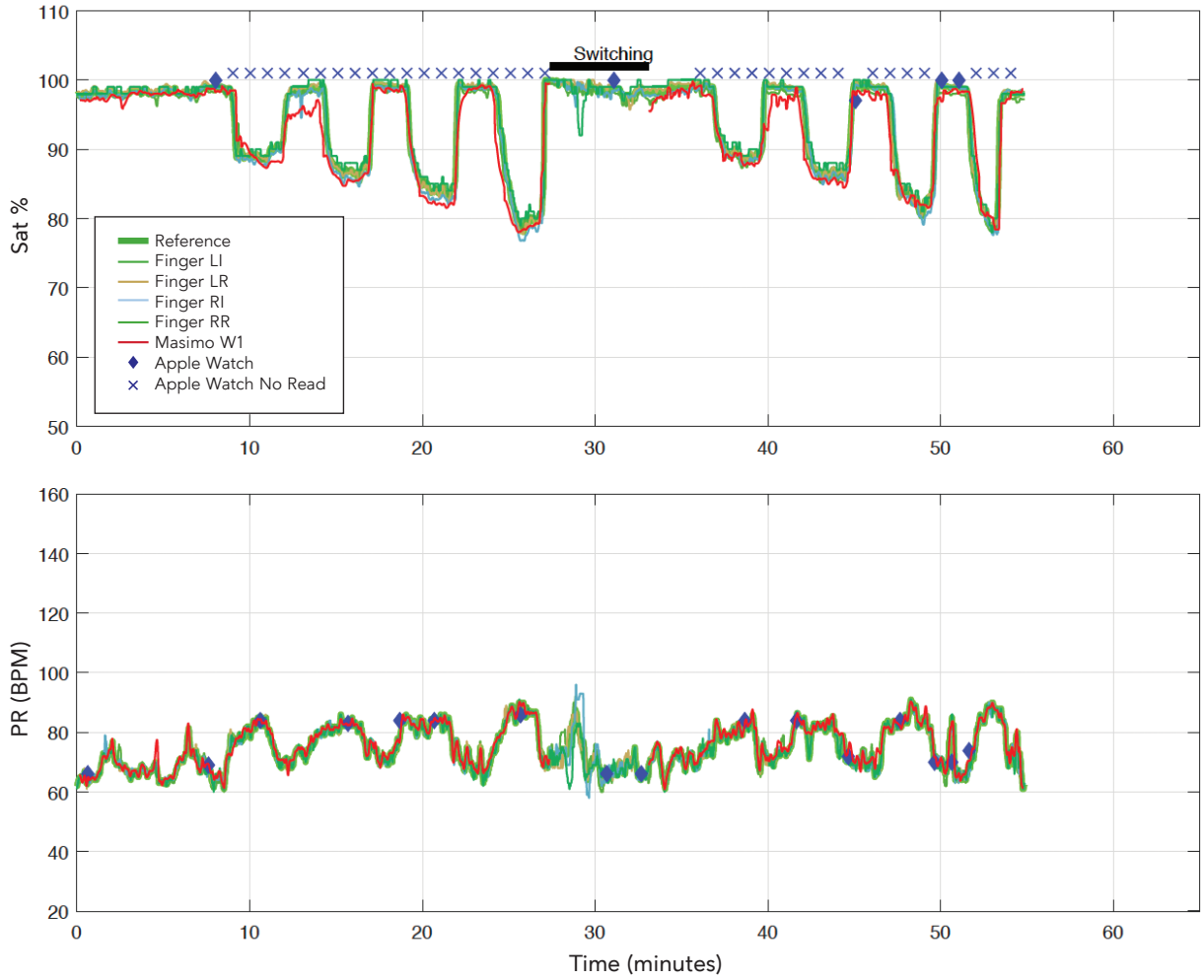
Figure 7. Representative sample from subjects monitored during rapid desaturation events with Masimo W1 (red line) vs Apple Watch in sleep mode (blue diamond) in top graph. Bottom graph depicts pulse rate tracking.



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 8**, on the next page, 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 8. **Representative sample from subjects monitored during rapid desaturation events (SpO_2 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 SpO_2 (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 3** 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 3. 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 SpO_2

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 4** 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 4** below).

Table 4. 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 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 is shown in **Figure 9** (below).

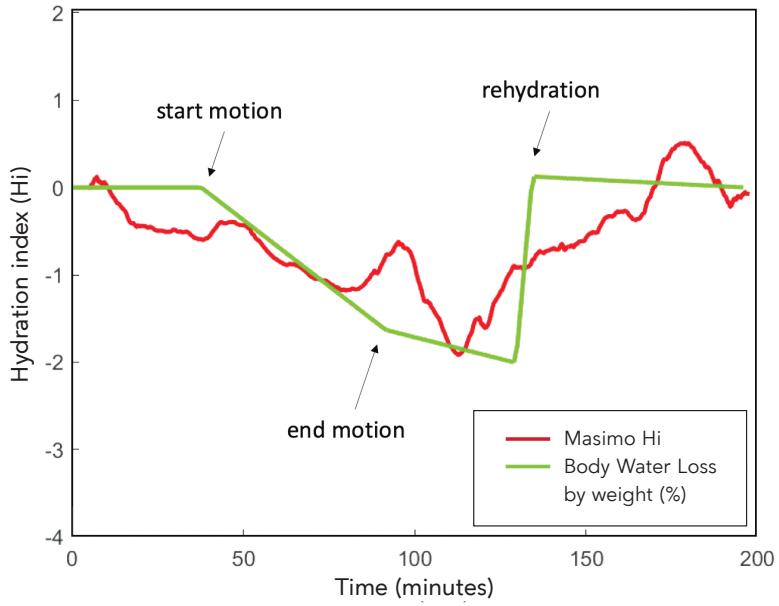


Figure 9.

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 is shown with the first two arrows, and rehydration (drinking water) is shown with third arrow going from left to right.

Hydration level has been one of the most sought out parameters by athletes, vocalists, and others seeking to optimize their performance. Whether you're an elite athlete 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

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. As a health and wellness device, the Masimo W1 health watch 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 in the home.

X. REFERENCES

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6969PLM-15384A-0323

For professional use. See instructions for use for full prescribing information including indications, contraindications, warnings and precautions. Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Masimo U.S.
Tel: 1 877 4 Masimo
info-america@masimo.com

Masimo International
Tel: +41 32 720 1111
info-international@masimo.com

MASIMO