Performance of a wearable ring in a controlled hypoxia study: A prospective observational study

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Submitted to: JMIR Formative Research
on: November 14, 2023

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Abstract

Background: Over recent years, technological advances in wearables have allowed for continuous monitoring of vital signs and oxygen. These devices have primarily been used for sports and general wellness and may not be suitable for medical decision making, especially in saturations below 90% and in patients with dark skin tones. Wearable clinical grade saturation of peripheral oxygen (SpO2) monitoring can be of great value to patients with chronic diseases, enabling them and their clinicians to better manage their condition with reliable real time and trended data.

Objective: The objective of this study was to determine the SpO2 accuracy of the Movano Health wearable ring compared to arterial blood gas measurements in a hypoxia study based on the ISO 80601-2-61:2019 standard. Accuracy was evaluated over the range of 70-100% arterial oxygen saturation (SaO2) in volunteers with a broad range of skin tones (I to VI) using the Fitzpatrick scale during non-motion conditions. In parallel, accuracy was compared to a calibrated hospital-grade reference pulse oximeter (Masimo Radical-7).

Methods: We performed a single-center, blinded hypoxia study of the Movano Health ring in 12 healthy volunteers at the Hypoxia Research Laboratory, DepartmWe performed a single-center, blinded hypoxia study of the Movano Health ring in 12 healthy volunteers at the Hypoxia Research Laboratory, Department of Anesthesia and Perioperative Care, University of California, San Francisco under the direction of Philip Bickler, MD, PhD, and John Feiner, MD. Each volunteer was connected to a breathing apparatus for the administration of a hypoxic gas mixture. To facilitate frequent sampling, a radial arterial cannula was placed in either wrist of each subject. One test ring was placed on the index finger and another test ring was placed on the fingertip. Arterial blood gas (ABG) analysis to determine oxyhemoglobin saturation (SaO2) was performed using an ABL-90 multi-wavelength oximeter (Hemoximeter, Radiometer, Copenhagen, serial 1393- 090R0359N0002). Pulse rate accuracy of the ring was also compared to the Masimo Radical-7 pulse oximeter.

Results: A total of 258 SpO2 pairs were included in the analysis. The accuracy of the test ring in terms of root mean square error (RMSE) was 2.1% for both the fingertip placement and the finger placement compared to SaO2 while the Masimo Radical-7 had a RMSE of 2.8% compared to SaO2.

Conclusions: The Movano Health Ring meets an acceptable standard of accuracy for both SpO2 and pulse rate under non-motion conditions. Clinical Trial: Performance of the Movano Health Ring in a Controlled Hypoxia Study: Prospective Observational Study, NCT05920278, https://register.clinicaltrials.gov/prs/app/action/SelectProtocol?sid=S000D1OS&selectaction=Edit&uid=U0006N37&ts=2&cx=756sqx

(JMIR Preprints 14/11/2023:54256)
DOI: https://doi.org/10.2196/preprints.54256

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Performance of a wearable ring in a controlled hypoxia study: A prospective observational study

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Abstract

Background: Over recent years, technological advances in wearables have allowed for continuous home monitoring of heart rate and oxygen saturation. These devices have primarily been used for sports and general wellness and may not be suitable for medical decision making, especially in saturations below 90% and in patients with dark skin color. Wearable clinical grade saturation of peripheral oxygen (SpO_2) monitoring can be of great value to patients with chronic diseases, enabling them and their clinicians to better manage their condition with reliable real time and trended data.

Objective: The objective of this study was to determine the SpO_2 accuracy of a wearable ring pulse oximeter compared to arterial oxygen saturation (SaO_2) in a controlled hypoxia study based on the ISO 80601-2-61:2019 standard over the range of 70-100% SaO_2 in volunteers with a broad range of skin color (Fitzpatrick I to VI) during non-motion conditions. In parallel, accuracy was compared to a calibrated clinical grade reference pulse oximeter (Masimo Radical-7). Acceptable medical device accuracy was defined as maximum 4% root mean square error (RMSE) per the ISO 80601-2-61 standard and maximum 3.5% RMSE per the FDA guidance.

Methods: We performed a single-center, blinded hypoxia study of the test device in 11 healthy volunteers at the Hypoxia Research Laboratory, University of California at San Francisco (UCSF) under the direction of Philip Bickler, MD, PhD, and John Feiner, MD. Each volunteer was connected to a breathing apparatus for the administration of a hypoxic gas mixture. To facilitate frequent blood gas sampling, a radial arterial cannula was placed in either wrist of each subject. One test device was placed on the index finger and another test device was placed on the fingertip. SaO_2 analysis was performed using an ABL-90 multi-wavelength oximeter.

Results: For the 11 subjects included in the analysis for the test device placed on the finger, the test device placed on the fingertip, and the reference device, there were 236, 258, and 313 SaO_2-SpO_2 data pairs, respectively. The RMSE of the test device for all subjects was 2.1% for either finger or fingertip

placement, while the Masimo Radical-7 reference pulse oximeter RMSE was 2.8%, exceeding the standard (4% or less) and the FDA guidance (3.5% or less). Separately accuracy of SaO_2-SpO_2 paired data from the four subjects with dark skin in the study were analyzed for both test device placements and for the reference device. The test and reference devices exceeded the minimum accuracy requirements for a medical device with RMSE at 1.8% (finger) and 1.6% (fingertip) and for the reference device at2.9%.

Conclusions: The wearable ringmeets an acceptable standard of accuracy for clinical grade SpO_2 under non-motion conditions without regard to skin color.

Trial Registration: ClinicalTrials.gov NCT05920278

Keywords

Pulse oximetry, SpO2, pulse oximeter, hypoxia, hypoxemia, clinical trial, accuracy, digital health, wearable, smart ring, digital device, Evie, Movano Health, Movano, UCSF, ISO 80601-2-61, NCT05920278, racial bias, FDA, medical device

Introduction

The ability to seamlessly monitor health metrics at home with a wearable device which meets accuracy standards as provided by the Food and Drug Administration (FDA) [1] may have great value in the care of individuals living with chronic conditions, as well as in preventative care. Providing health monitoring at home has many possible benefits including the potential to reduce the costs of healthcare, provide care to people without access to clinical resources, identify potential health concerns early so care can be delivered in a timely fashion, and help individuals take more active control of their health, empowering them with a better understanding of how their lifestyle affects their health metrics.

Wearable devices to monitor health are available in several form factors including patches,

watches, rings, and more recently wearable biosensors including gloves and shirts. Wearables have the ability to offer clinical monitoring of metrics including peripheral blood oxygen saturation, glucose, and blood pressure. Wearables are available in consumer grade suitable for fitness use and also in clinical grade suitable for medical monitoring typically under the direction and care of a physician or other health care provider.

The test device aims to address health monitoring needs through the in a smart ring pulse oximeter which will monitor clinical grade SpO_2 and pulse rate at rest but also provides wellness metrics to provide a broad overview of health. The wellness metrics that the test ring provides include heart rate variability, average SpO_2, respiration rate, sleep duration and stages, and skin temperature during sleep, in addition to skin activity levels (steps), distance traveled, active minutes, and calories burned when awake, and also enables tracking of mood and menstrual cycle.

A pulse oximeter provides SpO_2, a noninvasive estimate of arterial blood oxygen saturation (SaO_2). Spot checks at home using pulse oximeters are important in detecting low oxygen levels that require medical intervention, and can play an important role in understanding health trends, especially when dealing with chronic conditions such as chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), asthma, bronchitis, anemia, cystic fibrosis, and sleep apnea. In addition, SpO_2 monitoring has been important in understanding the severity of acute respiratory illness including the coronavirus (COVID-19) [2] on the pulmonary system. Essentially, any condition affecting breathing or oxygen uptake would benefit from SpO_2 monitoring provided the data meets accuracy standards.

SpO_2 accuracy can be affected by sensor technology and placement, and by certain patient characteristics. For example, it has been known since 1990 [3] that skin color may affect measured SpO_2, with pulse oximeters typically overestimating SaO_2 in dark skin in the presence of occult hypoxemia. [4,5,6] Skin color is impacted not only by melanin pigment, but also by blood flow, skin thickness, and photoaging. [7] Other patient factors that can affect noninvasive pulse oximeter accuracy with optical sensors are anemia, skin temperature, tobacco use, and fingernail polish. [8] These known causes of SpO_2 overestimation inaccuracies for patients with dark skin color may result in significant underdiagnosis and

undertreatment, ultimately contributing to poor health outcomes and additional health disparities. [9] Accuracy and racial bias vary by device and manufacturer with clinical grade medical devices meeting FDA requirements for commercialization in the United States. [10,11]

In its guidance document, the FDA has recognized international standard ISO 80601-2-61:2019 [12] for the evaluation of safety and effectiveness of pulse oximeter devices, and the clinical study reported here employed a methodology consistent with the standard. Two important objectives of the defined clinical study requirements in the standard are: 1) to evaluate the sensors over a broad range of SpO_2 values (70-100%) when used per device instructions, and 2) to assure the device provides accurate data across the range of skin colors, including dark skin.

Figure *1* Image of the ring test device. The pulse oximeter sensors can be seen on the inner surface of the ring, which will fit against the palmar side of a finger.

Materials and Methods

The test device is a rechargeable, battery-operated ring design with working components including a printed circuit board assembly (PCBA), battery, and sensors placed between a metal outer shell and a plastic inner ring. See Figure 1. The test device uses reflectance photoplethysmography (R-PPG) technology of two optical sensors with two light emitting diodes (LED) or transmitters of multi-wavelengths (526 – 940 nanometors) and a photodiode receiver on the same side of a cutaneous vascular bed. [13] The reflected light absorption of oxygenated and deoxygenated blood is captured and the oxygen saturation ratio calculated to non-invasively monitor *in vivo* SpO_2. The ring collects, processes,

and stores data, and then sends data wirelessly to a compatible and connected smart phone where data are further processed, displayed, and stored using companion application software. For the study, test device data were continuously collected.

Study design

The study was an open enrollment, single-center, single blinded design using the investigational ring compared to arterial blood gas measurements (SaO_2) and to two commercially available hospital grade reference pulse oximeters (Massimo Radical-7 [14] and Nellcor N-595 [15]). The study was conducted at an independent lab (Hypoxia Research Laboratory, Department of Anesthesia and Perioperative Care, University of California San Francisco) under the direction of Phillip Bickler, MD, PhD and John Feiner, MD and sponsored by Movano Health (Pleasanton, California). The clinical study reported here employed a methodology for accuracy consistent with the FDA guidance document. [16]

Ethical Considerations

The test device, study, and study consent were reviewed and approved for use in a nonsignificant risk clinical trial by the University of California at San Francisco (UCSF) Committee on Human Research. Written informed consent was obtained from all subjects prior to testing. Subjects were paid $200 for their participation. All data used in the analysis were de-identified prior to analysis.

Inclusion/Exclusion Criteria

To be included in the study, subjects had to meet all the inclusion criteria and not meet any of the exclusion criteria. For inclusion, subjects had to be in general good health, between 18 and 50 years old, fluent in written and spoken English, willing to provide consent and comply with study procedures, and willing to have their skin color assessed with a commercial instrument designed for that purpose. Subjects were excluded from participation if they did not meet the inclusion criteria or if they: were obese (defined as a body mass index (BMI) of 30 or greater), a current smoker, diabetic, pregnant, lactating, or trying to get pregnant; had a known diagnosis of Raynaud’s disease, asthma, sleep apnea (or were currently were using a continuous positive airway pressure (CPAP) device), clotting disorder, hemoglobinopathy/history of anemia,

or liver, heart, lung, kidney disease or any other serious systemic disease; had a history of fainting or vasovagal response or sensitivity to anesthesia; or if, in the opinion of the investigator, they were unsuitable for participation for any reason or based on the first blood draw, the subject had an unacceptable Allen's test [17], the subject had any systemic serious illness, the subject had any injury, deformity, or abnormality at the sensor sites that would interfere with the sensors working properly, or any other condition that would make them an unsuitable participant.

Procedure for Desaturation

Demographic data were recorded immediately following written consent, including self-reported ethnicity. In addition, trained clinical research staff evaluated skin color for each subject using the Fitzpatrick scale, the Monk scale, and a spectrometer for evaluation and potential future use. [18] Subject skin pigmentation was assessed at five different skin locations of each subject including the dorsal surface of the finger between the nail bed and the distal interphalangeal joint, the palmar surface of the distal phalanx, the inner upper arm, the front and back of the earlobe, and the external nare. Skin color of the dorsal distal index finger using the Fitzpatrick scale was used for skin color determination. Independently, subjects were asked to self-identify ethnicity and facial skin tone on the forehead was measured using a spectrometer to assure the optical monitoring approach is accurate across different ethnicities and skin color. Subjects in this study had various levels of skin color, ranging from very fair to dark or I to VI using the Monk scale and the Fitzpatrick scale, respectively [19,20,21].

Each subject had two testdevices placed: one at the base of the finger and one at the distal tip, similar to most commercially available pulse oximeters. In addition, calibrated, hospital-grade co-oximeters (Massimo Radical-7 and Nellcor N-595) were placed on the distal tips of fingers and used as reference devices. A radial arterial cannula was placed in either the left or right wrist of each subject for arterial blood sampling and blood pressure monitoring. Blood gas analysis, the gold standard to determine oxyhemoglobin saturation (SaO_2), was performed using an ABL-90 multi-wavelength oximeter [22] (Hemoximeter, Radiometer, Copenhagen, serial 1393-090R0359N0002). This instrument is factory

calibrated and contains quality control algorithms.

Each subject had two control blood samples taken at the beginning of each experiment, while breathing room air. Hands with test devices and reference pulse oximeters were maintained motionless on arm boards throughout the test. Hypoxemia was then induced to different and stable levels of oxyhemoglobin saturation (between 70-100%) by having subjects breathe mixtures of nitrogen, air, and carbon dioxide. The mixture of gases was controlled by the study physician by adjusting gas flows according to breath-by-breath estimates of oxygen saturation calculated from end-tidal partial pressure of oxygen (PO_2) and partial pressure of carbon dioxide (PCO_2) displayed on a screen using LabVIEW Software 2015. [23,24] Each plateau level of oxyhemoglobin saturation was maintained for at least 30 seconds or until readings of the reference pulse oximeters were stable. Two arterial blood samples were then obtained, approximately 30 seconds apart. Each stable plateau was maintained for at least 60 seconds with SpO_2 fluctuating by less than 2-3%. Target plateaus and arterial blood gas sampling points are shown in Figure 2.

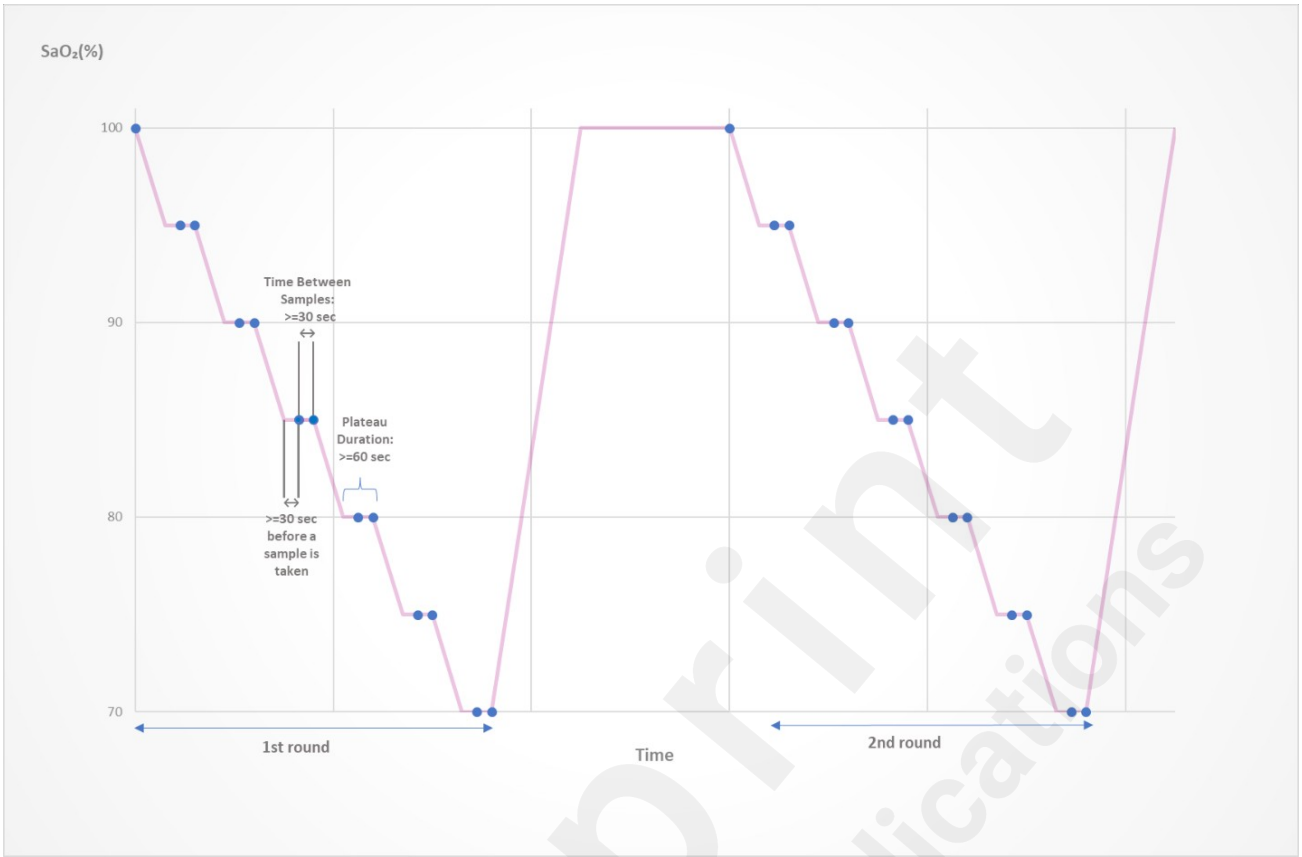

Figure 2 Target plateaus of oxygen saturation and sampling points. The blue dots represent the SaO_2 value at each sampling point. According to the SaO_2 stability standard of the pulse oximeter probe placement site, the first sample at each plateau was acquired 30 seconds after reaching a target plateau, and the successive sample was acquired at least 30 seconds after the first sample.

Overall, at least 230 arterial blood gas measurements were obtained and at least 200 paired data points collected for each investigational device placement and reference device combination studied. After the study, data from the test devices during arterial blood sampling times were provided to the clinical site for independent analysis.

Data Analysis

Test device data was taken at five second averages corresponding to the time when arterial blood samples were obtained. Individual data points were missed or excluded for dropped signals or failure of the oximeter signal to achieve an appropriate plateau. Subject 2 was used to calibrate the test data and

was not included in the analysis.

Data was plotted as hemoximeter data (SaO_2) compared to each test device and Masimo Radical-7 reference pulse oximeter (SpO_2) data with bias calculated as $SpO_2 - SaO_2$. Linear regression was plotted for all eleven (11) subjects' studies combined, and the equation R^2 was calculated. Mean bias and the upper and lower limits of agreement (mean bias ± 1.96•SD) were calculated and tabulated. Limits of agreement were adjusted when there were multiple readings per subject and multiple subjects according to the modified Bland and Altman methodology. [25] For the pooled plots, different markers were used for each subject.

Tables of count, missing data, mean, standard deviation, standard error, minimum, maximum, 95% confidence interval, and accuracy root mean square error (A_{RMS} or RMSE) were provided for each oximeter's bias, and all oximeters combined in the following ranges of SaO_2 (hemoximeter) deciles: 60 – 70%, 70 – 80%, 80 – 90%, and 90 – 100%, and over the test range 70 – 100%. A table of mean bias and RMSE was provided for each oximeter. A table of variances within and between study subjects was provided for each oximeter.

Accuracy root mean square error (A_{RMS} or RMSE) was calculated as follows:

$$\sqrt{\frac{\sum (SpO_2 - \Sigma \alpha O_2)^2}{n}}$$

Results

This study was performed October 26 and 27, 2022, and included 11 subjects consisting of five women and six men in the accuracy analysis. All the subjects enrolled in the study met the inclusion and exclusion criteria, had hemoglobin levels ≥ 10 gm•dl^{-1}, and all were healthy non-smoking individuals aged 22-34. A distribution of ethnicities and skin color based on the Monk scale [26] and the Fitzpatrick scale were studied, with four subjects having dark skin color both using a modified Monk scale (light,

medium, and dark) and the Fitzpatrick scale type V or VI, with three of the four self-reported as African American. The demographic data of the participants are provided in Table 1.

Table 1: Demographic Data

Subject	Gender	Age	BMI	Ethnicity	Monk Scale	Fitzpatrick Scale
Subject #1	Male	26	19	African American	9/10 (Dark)	Type V
Subject #3	Female	26	22	Caucasian	5/6 (Medium)	Type III
Subject #4	Male	34	21	Caucasian	1/2 (Light)	Type I
Subject #5	Female	25	29	Caucasian	1/2 (Light)	Type II
Subject #6	Female	22	22	Multiethnic	5/6 (Medium)	Type IV
Subject #7	Male	28	20	Asian	9/10 (Dark)	Type V
Subject #8	Male	25	24	Asian	5/6 (Medium)	Type IV
Subject #9	Female	24	21	Asian	5/6 (Medium)	Type III
Subject #10	Male	33	24	African American	9/10 (Dark)	Type VI
Subject #11	Female	22	18	Multiethnic	5/6 (Medium)	Type IV
Subject #12	Male	31	24	African American	9/10 (Dark)	Type VI

The baseline and desaturation plateaus were nominally at room air, and at 100%, 93%, 90%, 87%, 85%, 82%, 80%, 77%, 75% and 70% saturation. No adverse events occurred during the study. A total of 258 samples were obtained for the test device on the fingertip and 236 samples were obtained for the test device on the finger over the saturation plateaus. Tables present the statistical results for both the finger placement (Table 2) and the fingertip placement (Table 3) of the test device. The Masimo [27] Radical-7 [28] was selected as a reference pulse oximeter for comparison and device statistical results (Table 4) were included. The overall RMSE for the test device was about 2.1% for both the finger placement (2.07%) and the fingertip placement (2.11%) compared to SaO_2 while the overall RMSE for the Masimo Radical-7 reference device was 2.8% compared to SaO_2.

Table 2: Test Devices Bias, Finger Placement

Hemoximeter Range	60-70	70-80	80-90	90-100	70-100
Count of Data	9	59	90	87	236
Count of Missing Data	0	23	28	27	78
Mean (%)	2.48	1.42	0.66	0.78	0.89
Standard Deviation (%)	2.04	1.64	1.58	2.22	1.88
Standard Error (%)	0.68	0.21	0.17	0.24	0.12
95% Confidence Limit (%)	1.56	0.43	0.33	0.47	0.24
Limits of Agreement (%)	N/A	-1.90, 4.75	-2.55, 3.86	-3.70, 5.25	-2.86, 4.65
Maximum (%)	5.30	6.30	5.20	6.10	6.30
Minimum (%)	-0.40	-1.60	-2.10	-5.60	-5.60
Root Mean Square Error (%)	3.13	2.16	1.71	2.34	2.07

Table 3: Test Devices Bias, Fingertip Placement

Hemoximeter Range	60-70	70-80	80-90	90-100	70-100
Count of Data	9	66	104	88	258
Count of Missing Data	0	16	14	26	56
Mean (%)	3.31	1.62	0.89	0.98	1.11
Standard Deviation (%)	1.45	2.15	1.60	1.66	1.80
Standard Error (%)	0.48	0.27	0.16	0.18	0.11
95% Confidence Limit (%)	1.11	0.53	0.31	0.35	0.22
Limits of Agreement (%)	N/A	-2.76, 6.01	-2.31, 4.09	-2.37, 4.34	-2.49, 4.71
Maximum (%)	5.20	7.70	5.80	3.80	7.70
Minimum (%)	0.96	-1.90	-1.90	-4.60	-4.60
Root Mean Square Error (%)	3.58	2.68	1.82	1.92	2.11

Table 4: Masimo Radical-7 Device Bias

Hemoximeter Range	60-70	70-80	80-90	90-100	70-100
Count of Data	9	82	117	114	313
Count of Missing Data	0	0	1	0	1
Mean (%)	3.90	2.09	2.41	1.21	1.89
Standard Deviation (%)	1.57	2.06	2.12	1.85	2.07
Standard Error (%)	0.52	0.23	0.20	0.17	0.12
95% Confidence Limit (%)	1.21	0.45	0.39	0.34	0.23
Limits of Agreement (%)	0.84, 6.96	-2.07, 6.26	-1.89, 6.70	-2.51, 4.93	-2.27, 6.05
Maximum (%)	6.60	7.60	9.90	6.50	9.90
Minimum (%)	2.10	-1.10	-1.00	-2.30	-2.30
Root Mean Square Error (%)	4.17	2.93	3.20	2.20	2.80

Modified Bland-Altman plots of the test devices by placement (finger and fingertip) and of the Masimo co-oximeter reference device are shown in Figures 3-5. Correlation plots with linear regression lines of best fit for all subjects for the three devices are presented in Figures 6-8.

We performed a secondary analysis to explore whether the devices accurately measured SpO_2 in dark skin due to concerns that have been raised with traditional pulse oximeters before and throughout the course of COVID-19 [29] where it was shown the oximeters may over-read the actual oxygen concentration in dark skin. [30] In this secondary analysis, we included the Masimo Radical-7 reference device. Figures 9-11 show the results solely from subjects with dark skin using the Fitzpatrick scale V and VI subjects. As is shown, the test device maintains strong accuracy over the range 70-100% with root mean square error of 1.8% for the traditional ring or finger placement, and 1.6% for fingertip placement, whereas the Masimo Radical-7 reference oximeter RMSE was 2.9% with a bias of 2.2% over the same range. Accuracy degrades for the Masimo Radical-7 device at lower SaO_2 measurements with a bias to over-read SpO_2 compared to SaO_2 in dark skin .

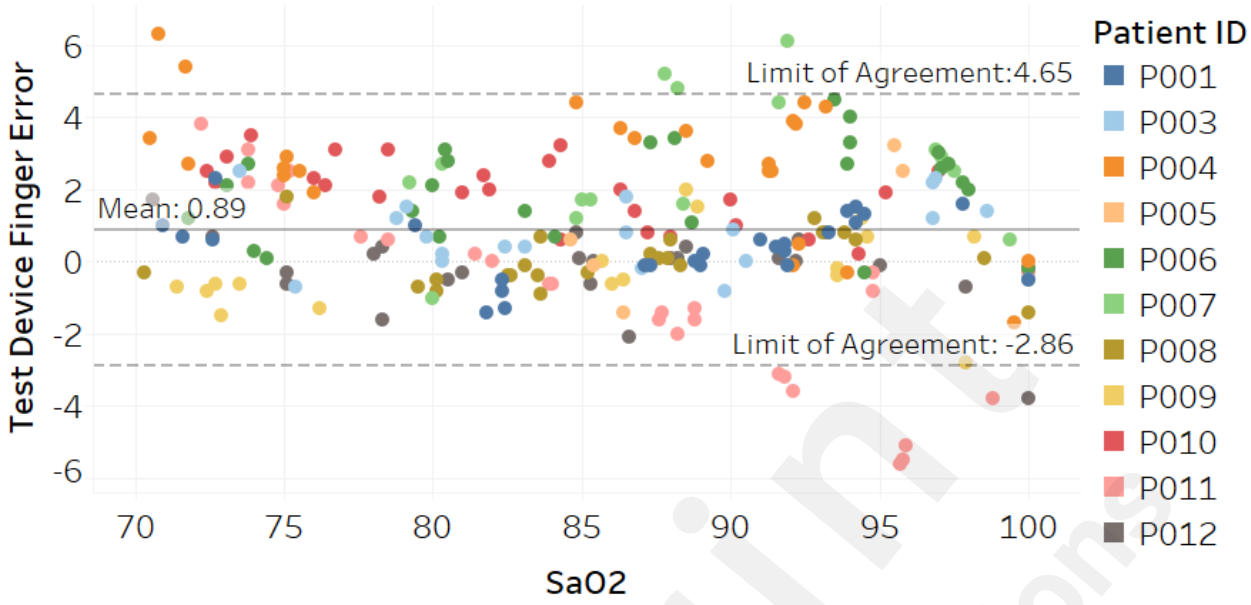

Figure 3: Modified Bland-Altman plot for test device finger placement.

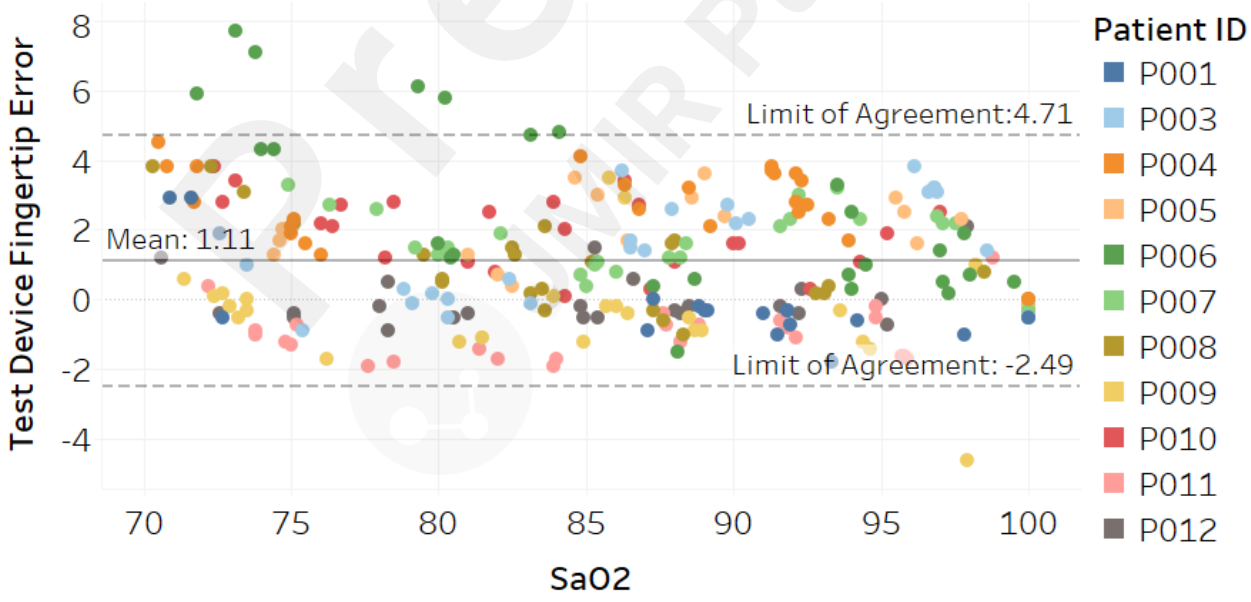

Figure 4: Modified Bland-Altman plot for test device fingertip placement.

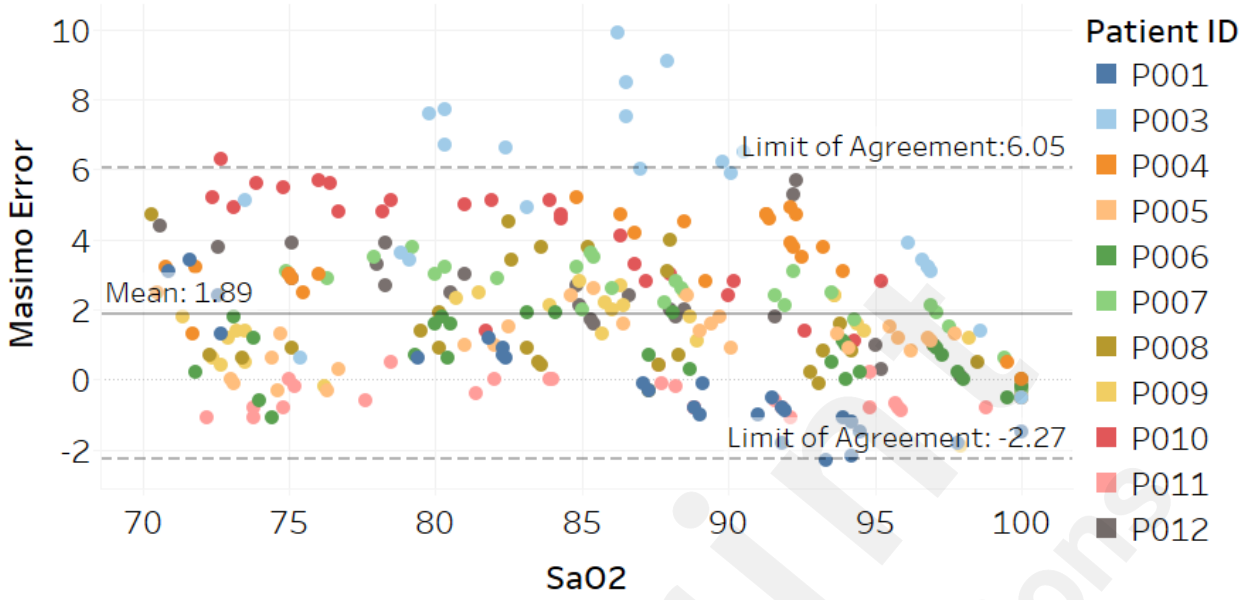

Figure 5: Modified Bland-Altman plot for Masimo Radical-7 reference device.

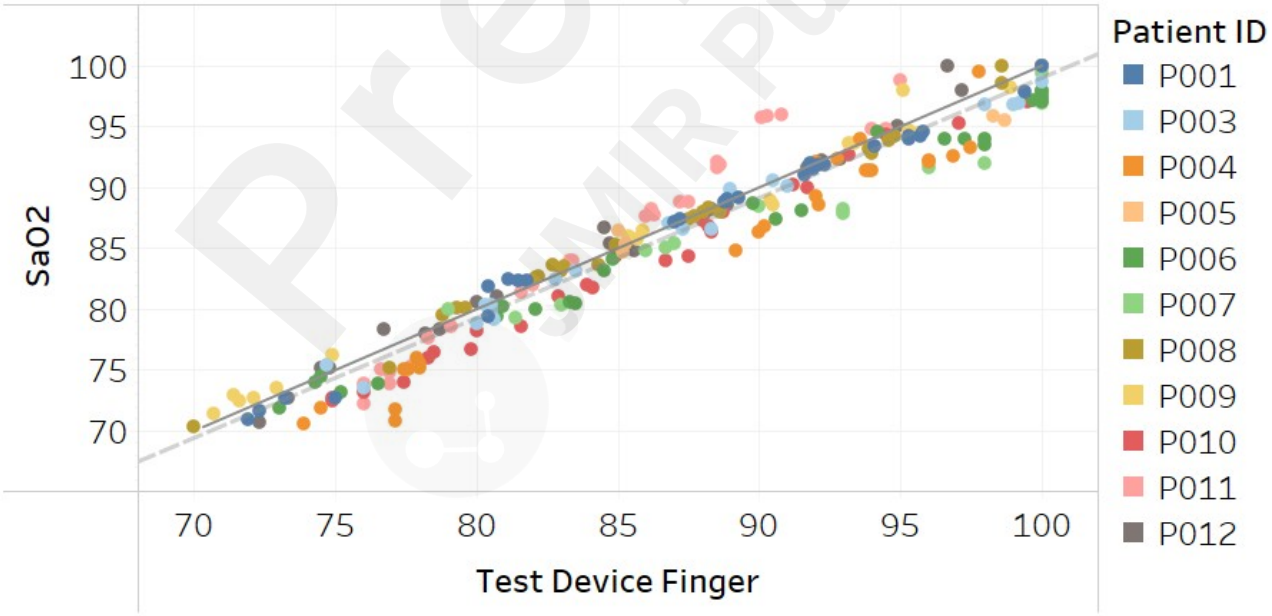

Figure 6: Correlation plot of SaO_2 vs test device finger placement SpO_2 for all subjects. Solid line is a diagonal reference line. Solid line is a diagonal reference line. Dotted line is the linear regression line of fit with formula $SaO_2 = 0.988 * \text{Test Device Finger} + 0.188$, $R^2 = 0.95$.

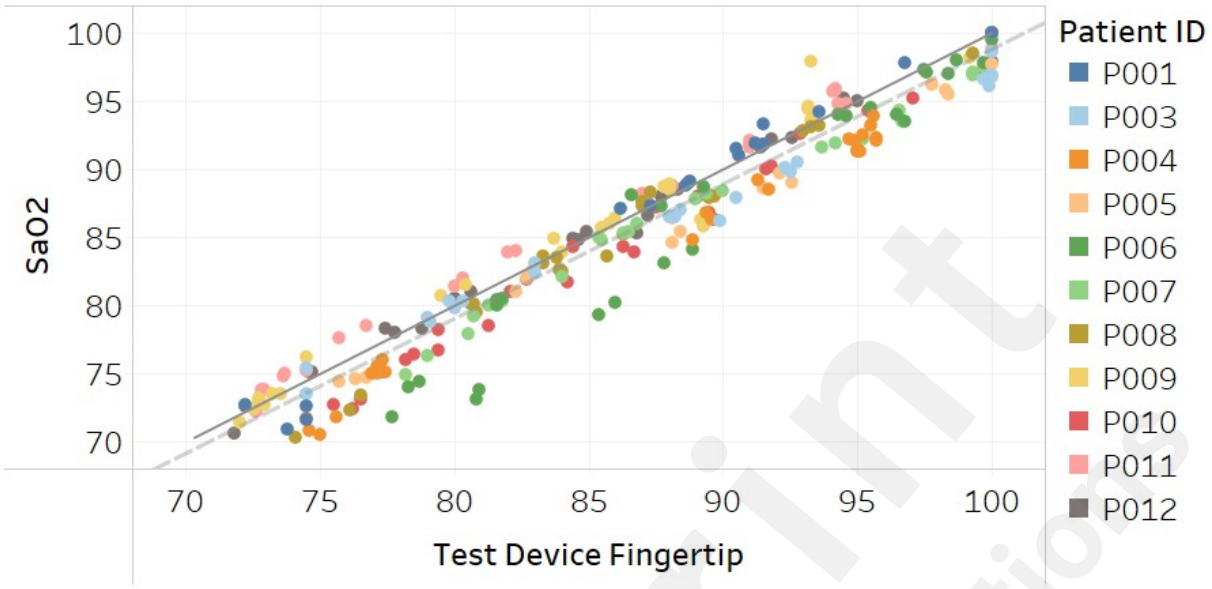

Figure 7: Correlation plot of SaO_2 vs test device fingertip placement SpO_2 for all subjects. Solid line is a diagonal reference line. Dotted line is the linear regression line of fit with formula SaO_2 = 0.990 * Test Device Fingertip – 0.199, R^2 = 0.95.

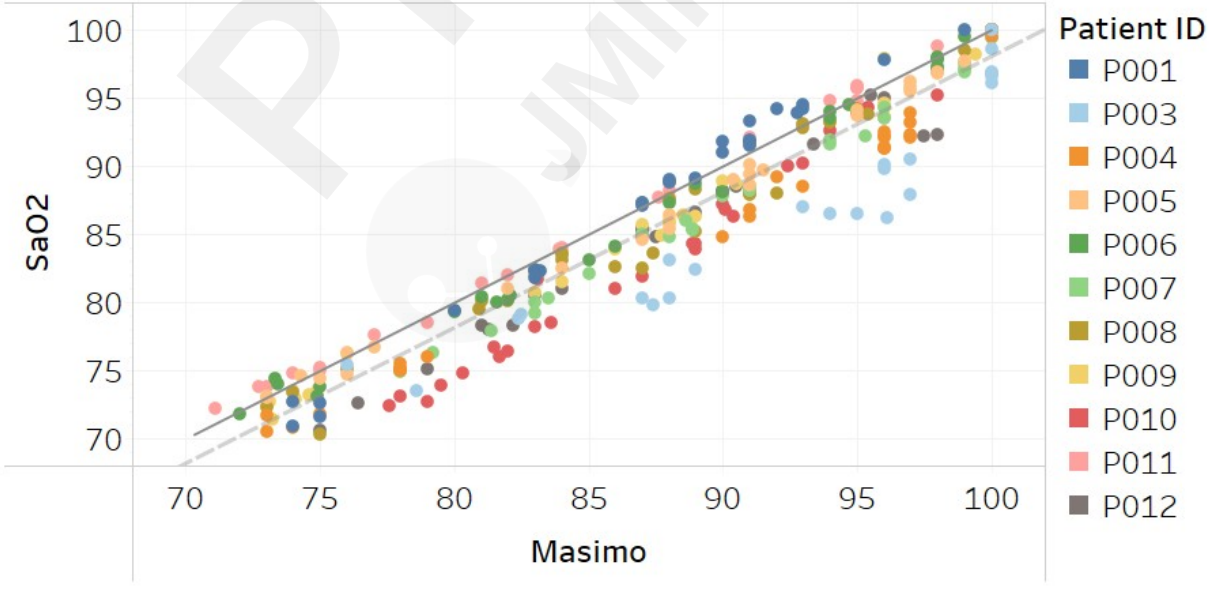

Figure 8: Correlation plot of SaO_2 vs Masimo Radical-7 reference device SpO_2 for all subjects. Solid line is a

diagonal reference line. Dotted line is the linear regression line of fit with formula SaO_2 = 0.997 * Masimo – 1.682, R^2 = 0.94.

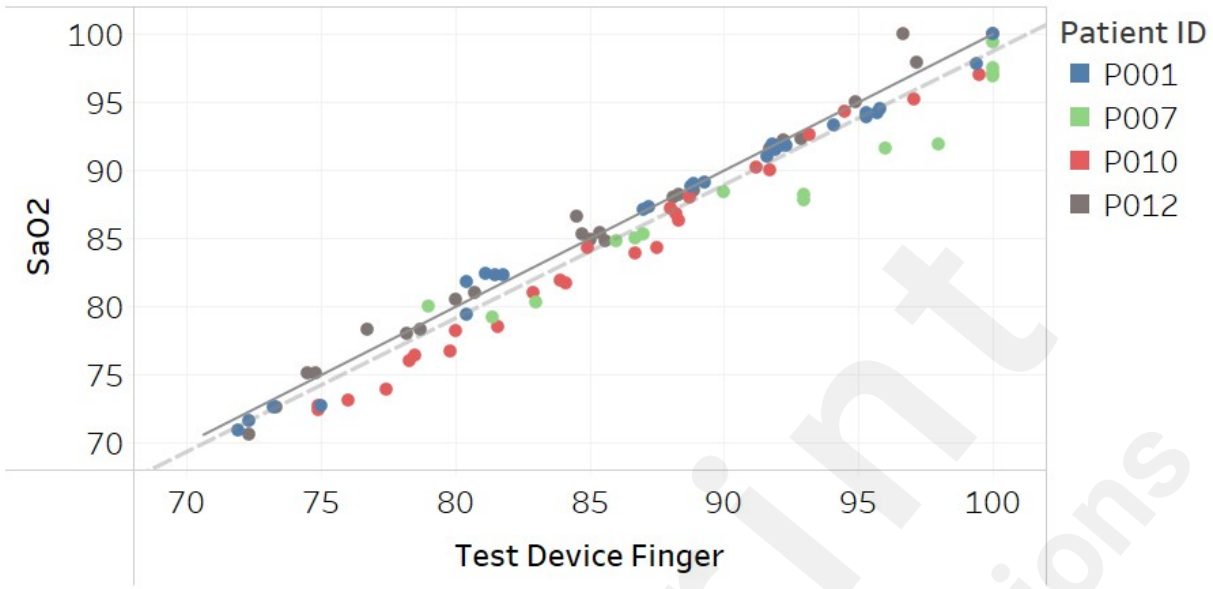

Figure 9: Correlation plot of SaO_2 vs test device finger placement SpO_2 for subjects determined to be V-VI or dark skinned using the Fitzpatrick scale. Solid line is a diagonal reference line. Dotted line is the linear regression line of fit with formula $SaO_2 = 0.981 * \text{Test Device Finger} + 0.577$, $R^2 = 0.96$.

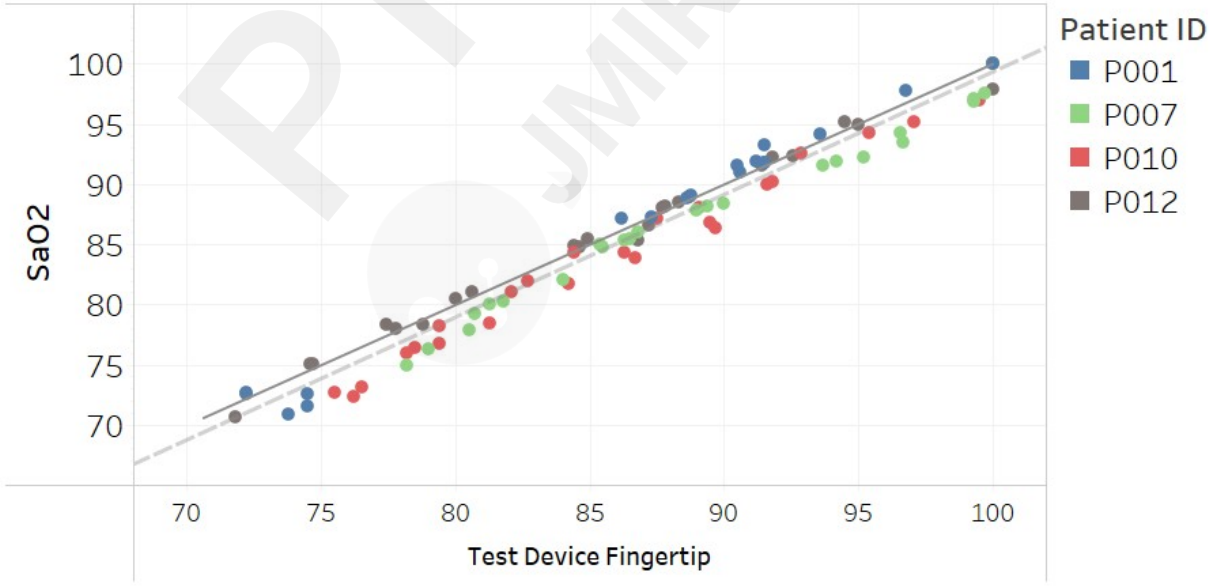

Figure 10: Correlation plot of SaO_2 vs test device fingertip placement SpO_2 for subjects determined to be

V-VI or dark skinned using the Fitzpatrick scale. Solid line is a diagonal reference line. Dotted line is the linear regression line of fit with formula SaO_2 = 1.022 * Test Device Fingertip – 2.849, R^2 = 0.95.

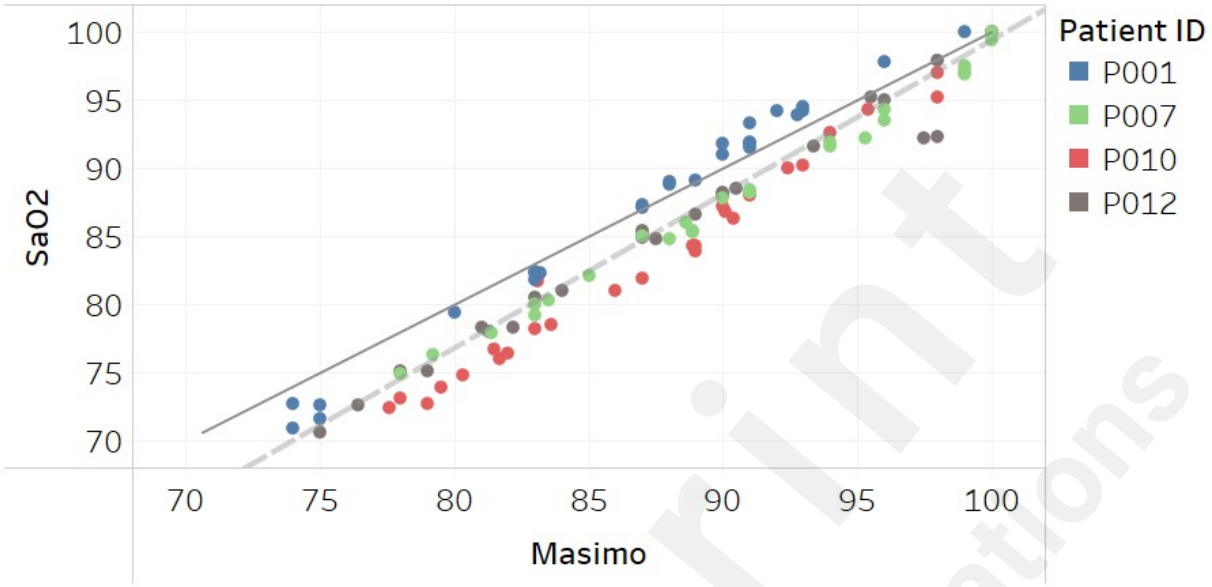

Figure 11: Correlation plot of SaO_2 vs Masimo Radical-7 reference device SpO_2 for subjects determined to be V-VI or dark skinned using the Fitzpartick scale. Solid line is a diagonal reference line. Dotted line is the linear regression line of fit with formula SaO_2 = 1.133 * Masimo – 13.878, R^2 = 0.95.

Results and Discussion

Over the past several years as people have become more aware and attuned to their health, especially through the course of the COVID-19 pandemic, wearable products have expanded in popularity and matured to provide additional features including the monitoring of pulse and blood oxygen saturation. Although most wearables are wellness devices, there is a need for clinical grade wearables which may have utility in both the clinical management of chronic conditions as well as prevention.

The test device is designed to serve this purpose and has demonstrated clinical grade accuracy in the monitoring of peripheral oxygenation saturation or SpO_2. SpO_2 and pulse are essential elements of the product solution, although monitoring of activity, sleep, skin surface temperature, and other metrics help to provide a more comprehensive picture of health.

This study tested the investigational ring as a clinical grade pulse oximeter both when worn at the base of a finger and also when held at the fingertip. Collected noninvasive investigational SpO_2 data were

then compared to invasive SaO_2 arterial blood gas measurements and to other commercially available, hospital grade devices, according to an internationally accepted standard for demonstrating accuracy.

Acceptable RMSE accuracy for medical devices per the international standard is 4% and per FDA is 3.5%. Over the SpO_2 range, the test device RMSE was 2.1% when worn on the finger at the base and also when held between the thumb and fingertip. While this compared favorably to RMSE of 2.8% for the Masimo Radical-7 reference device in the study, all devices tested met the minimum accuracy requirements. The correlation plots and associated linear regression formulas show a strong relationship between estimates and actual SaO_2 values, evidenced by slope terms being near 1 and intercept values being close to 0. The one departure from this trend is Figure 11 for the Masimo device in dark skin, where the regression line is not parallel to the diagonal reference line, indicating differing levels of accuracy between low and high values of SaO_2. The intercept term of -13.9 is also an indication of lack of fit.

Limitations

There are several limitations of this study. First, in accordance with the standard and FDA guidance, the study is based on a small sample of healthy, young adult volunteers and may not apply to younger, older, more diverse, or ill patients. Due to the nature of the study, the standard requires a total of ten subjects, with at least 20% of the samples from subjects with dark skin. Accuracy in this study was determined using 11 subjects, with 36% from subjects with dark skin.

Another limitation is the use of the Fitzpatrick and Monk scales to determine skin color. These tools are flawed as they are subjective and not developed for this purpose. Better tools are being tested, including spectrometers. [31] Once validated and readily available, spectrometers designed to measure skin color should help remove subjectivity and ensure consistency across studies and in clinical practice.

Conclusion

The results of this study demonstrated the ability of the test device to accurately monitor SpO_2 as a ring and a fingertip medical device, meeting the FDA and ISO standard accuracy requirements of

RMSE less than 3.5% and 4%, respectively. Furthermore, the test devices met a RMSE less than 3% for all subjects for both the finger and fingertip placements of the test device (RMSE 2.1%) as proposed by Okunlola (2022) [32] and for the subset of subjects with dark skin color (4/11) in the study (RMSE 1.8% finger and 1.6%). By any of these standards, the test data supports accuracy for a clinical grade pulse oximeter medical device over the full tested range of 70 to 100% SaO_2 when worn on a finger or held between the fingertip and thumb for all subjects and for subjects with dark skin. This bodes well for the future of FDA-cleared home wearables with optimized reflective optical technology providing accurate data for the user and their clinician alike.

Acknowledgments

JM and KT are primary and secondary authors, ML and JS performed the data analysis. All authors reviewed and approved the manuscript. This research project was funded by Movano Health. The Hypoxia Lab, University of California San Francisco, under the direction of Philip Bickler, MD, PhD, conducted the trial and developed the protocol, obtained consent, submitted to [redacted] and obtained approval, recruited subjects, study conduct, and reported results.

Conflicts of Interest

All authors are employees and stockholders or stock option holders of the company (NYSE: MOVE), the sponsor of the study and manufacturer of the devices tested in this manuscript.

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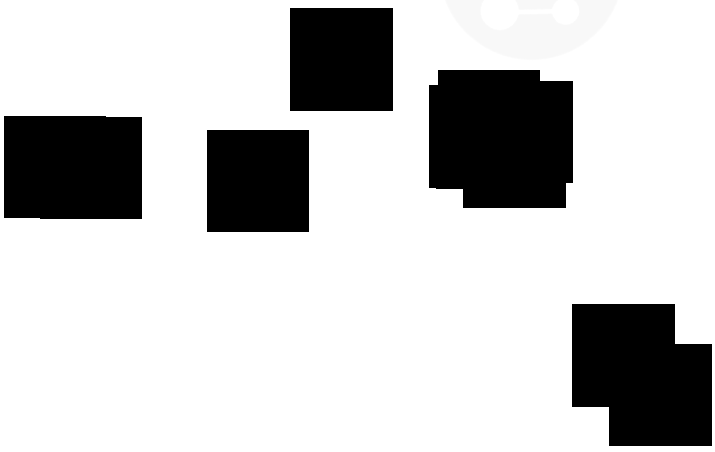
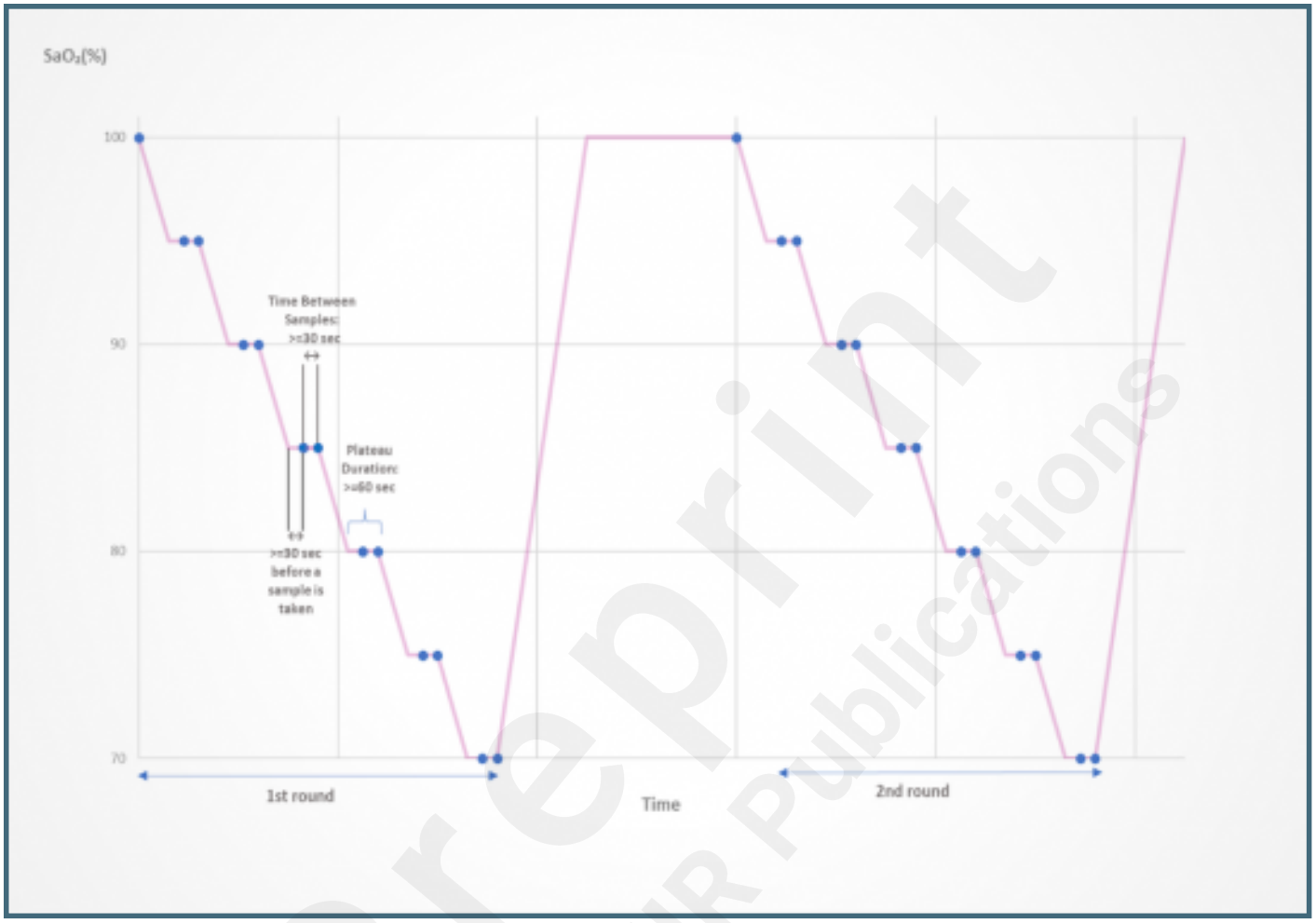


Supplementary Files

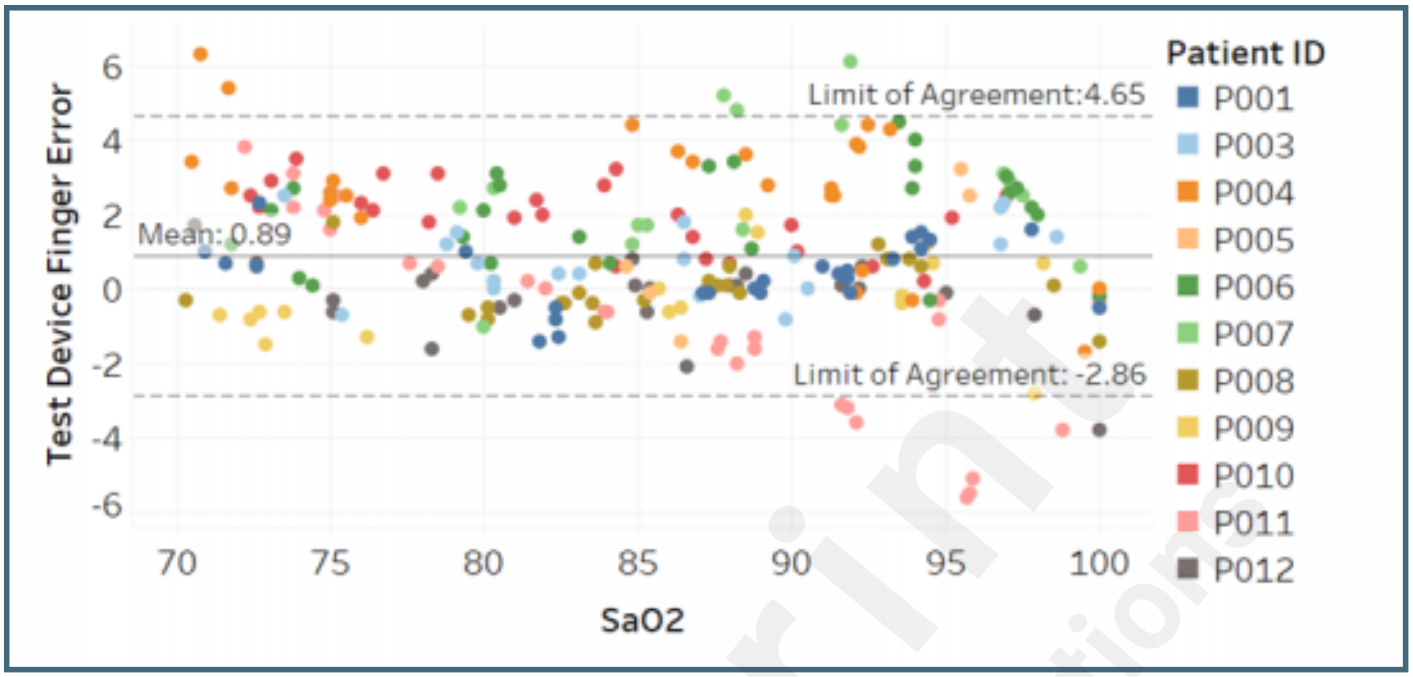
Figures

Image of the ring test device. The pulse oximeter sensors can be seen on the inner surface of the ring, which will fit against the palmar side of a finger.

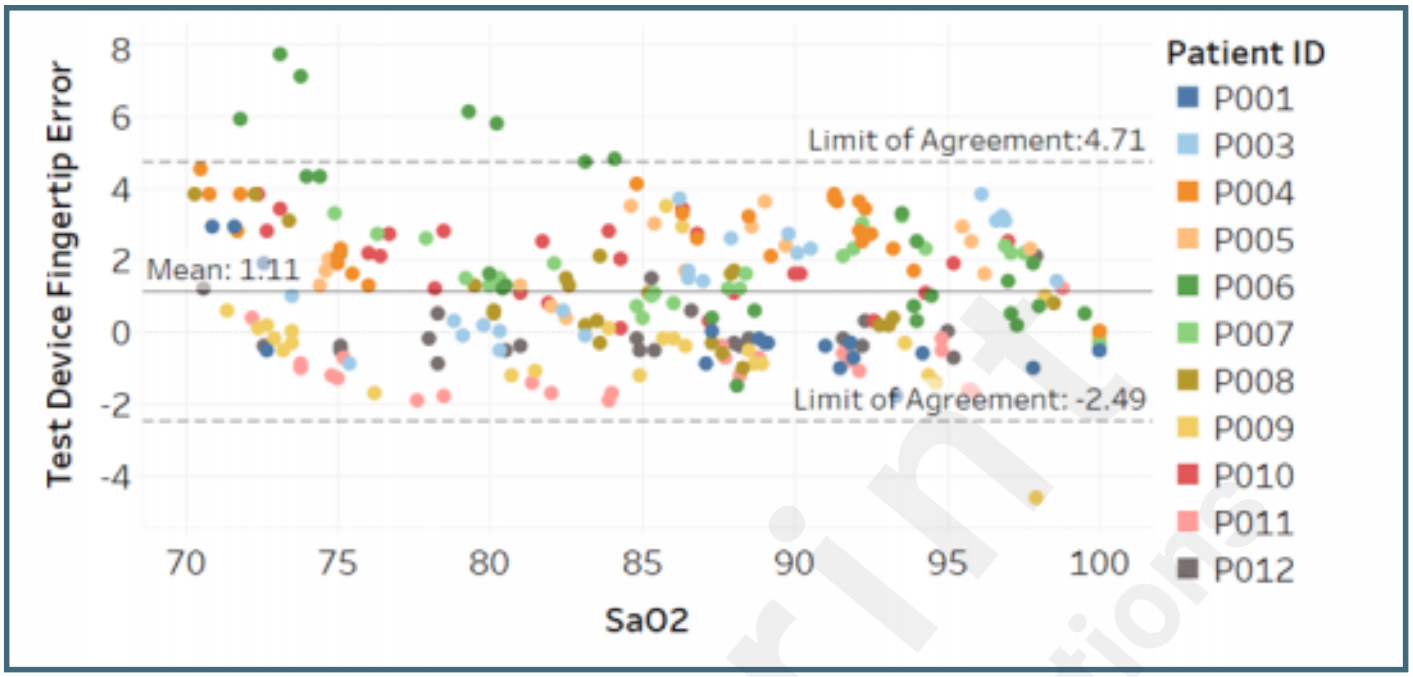
Target plateaus of oxygen saturation and sampling points. The blue dots represent the SaO2 value at each sampling point. According to the SaO2 stability standard of the pulse oximeter probe placement site, the first sample at each plateau was acquired 30 seconds after reaching a target plateau, and the successive sample was acquired at least 30 seconds after the first sample.



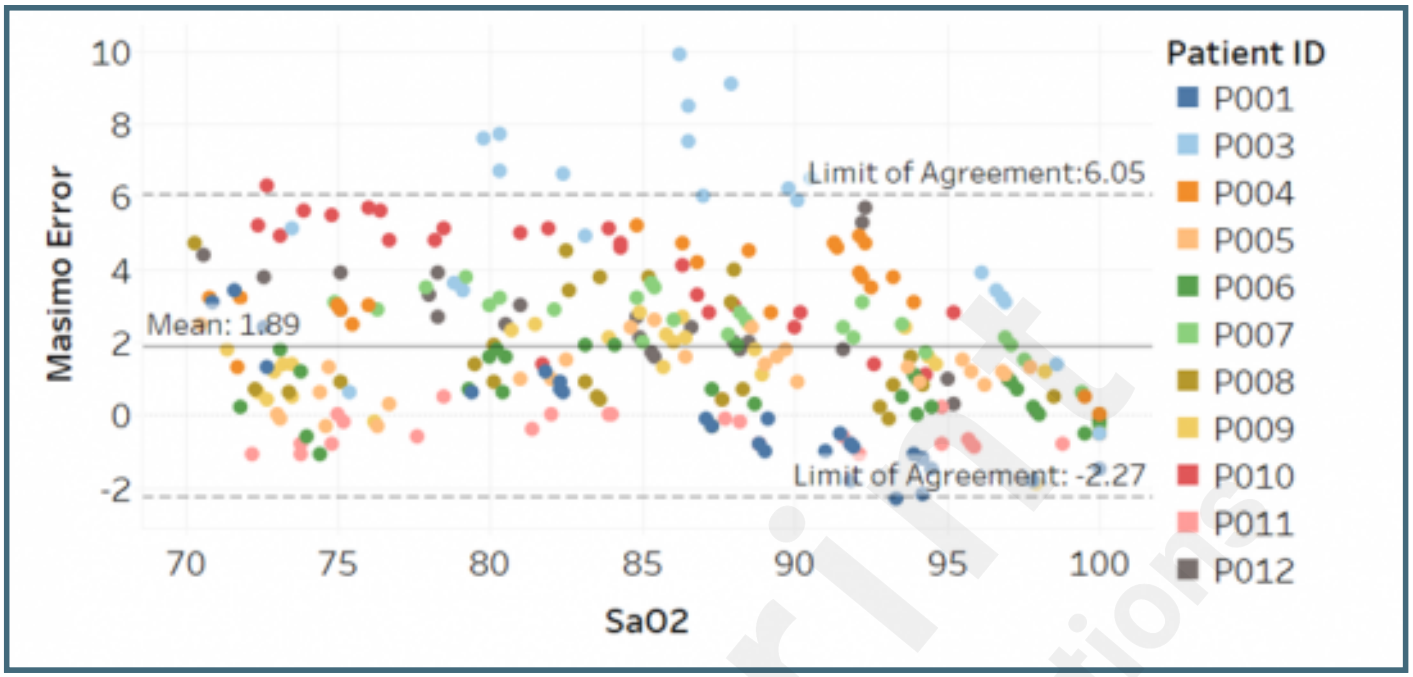
Modified Bland-Altman plot for test device finger placement.



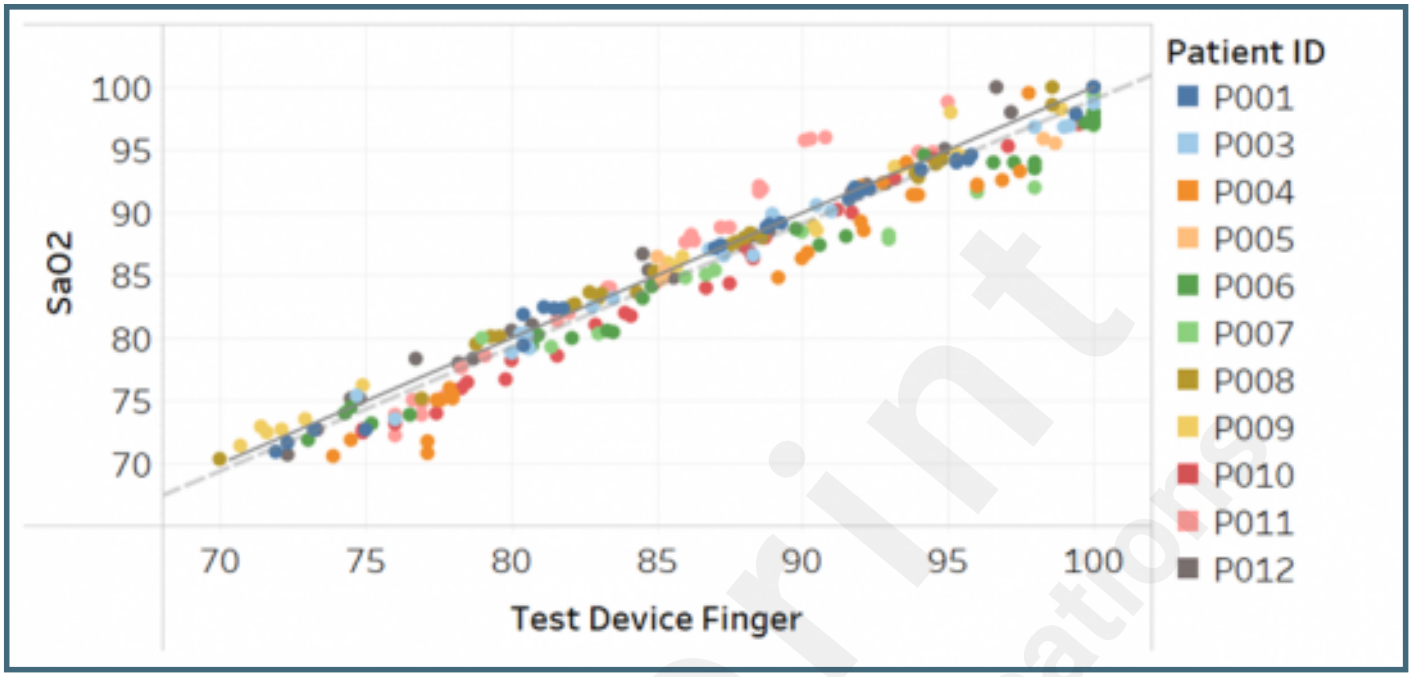
Modified Bland-Altman plot for test device fingertip placement.



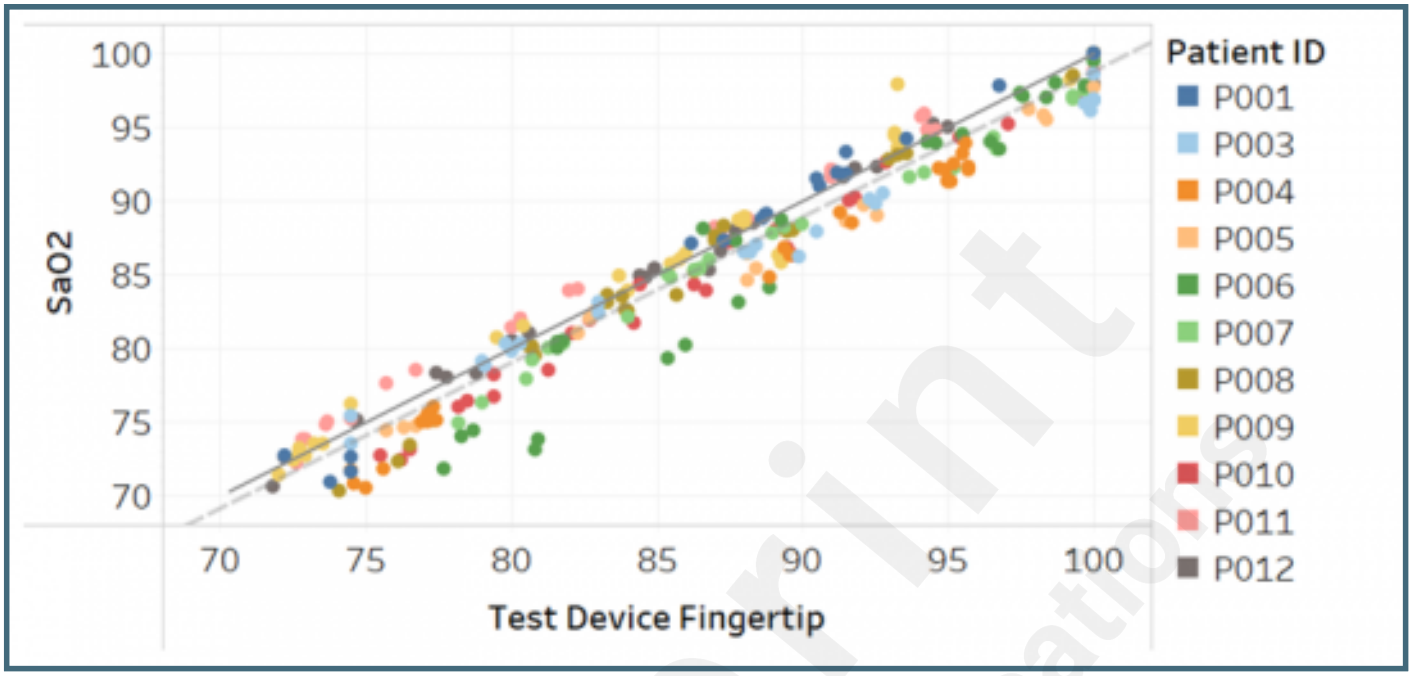
Modified Bland-Altman plot for Masimo Radical-7 reference device.



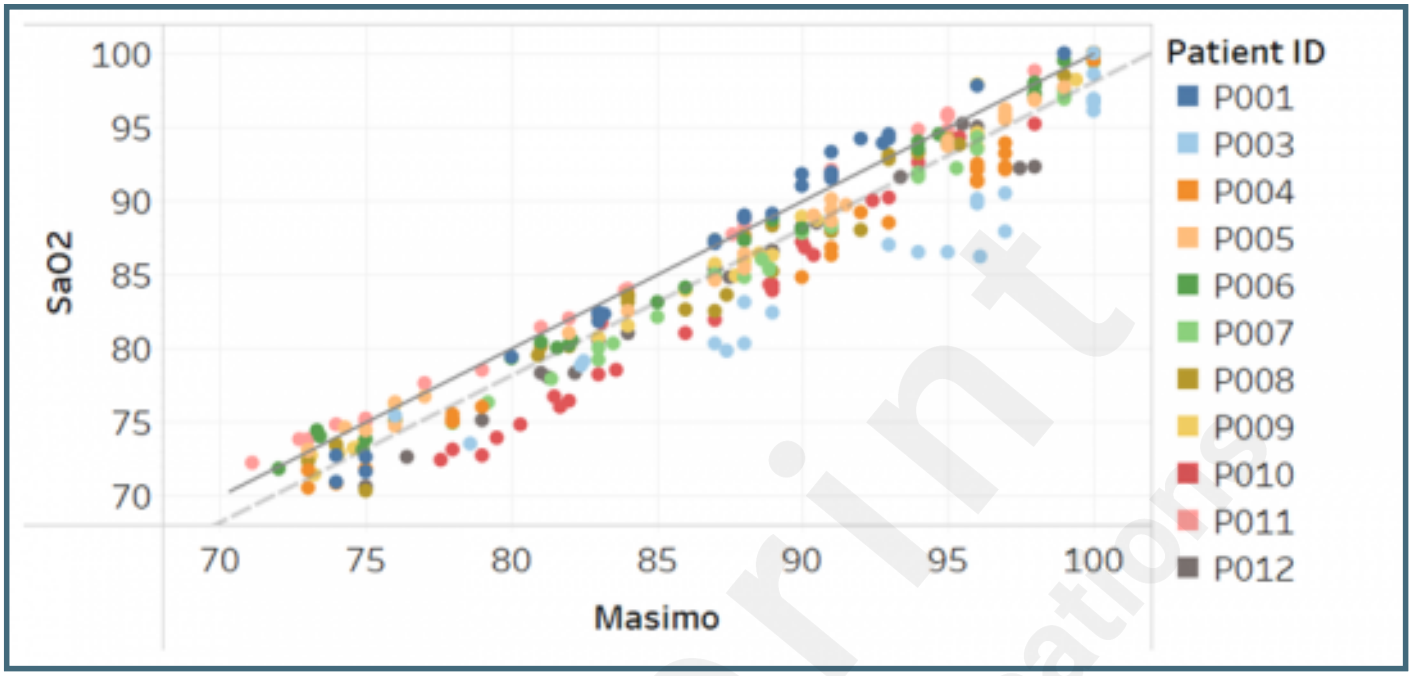
Correlation plot of SaO2 vs test device finger placement SpO2 for all subjects. Solid line is a diagonal reference line. Solid line is a diagonal reference line. Dotted line is the linear regression line of fit with formula SaO2 = 0.988 * Test Device Finger + 0.188, R2 = 0.95.



Correlation plot of SaO2 vs test device fingertip placement SpO2 for all subjects. Solid line is a diagonal reference line. Dotted line is the linear regression line of fit with formula SaO2 = 0.990 * Test Device Fingertip – 0.199, R2 = 0.95.



Correlation plot of SaO2 vs Masimo Radical-7 reference device SpO2 for all subjects. Solid line is a diagonal reference line. Dotted line is the linear regression line of fit with formula SaO2 = 0.997 * Masimo – 1.682, R2 = 0.94.



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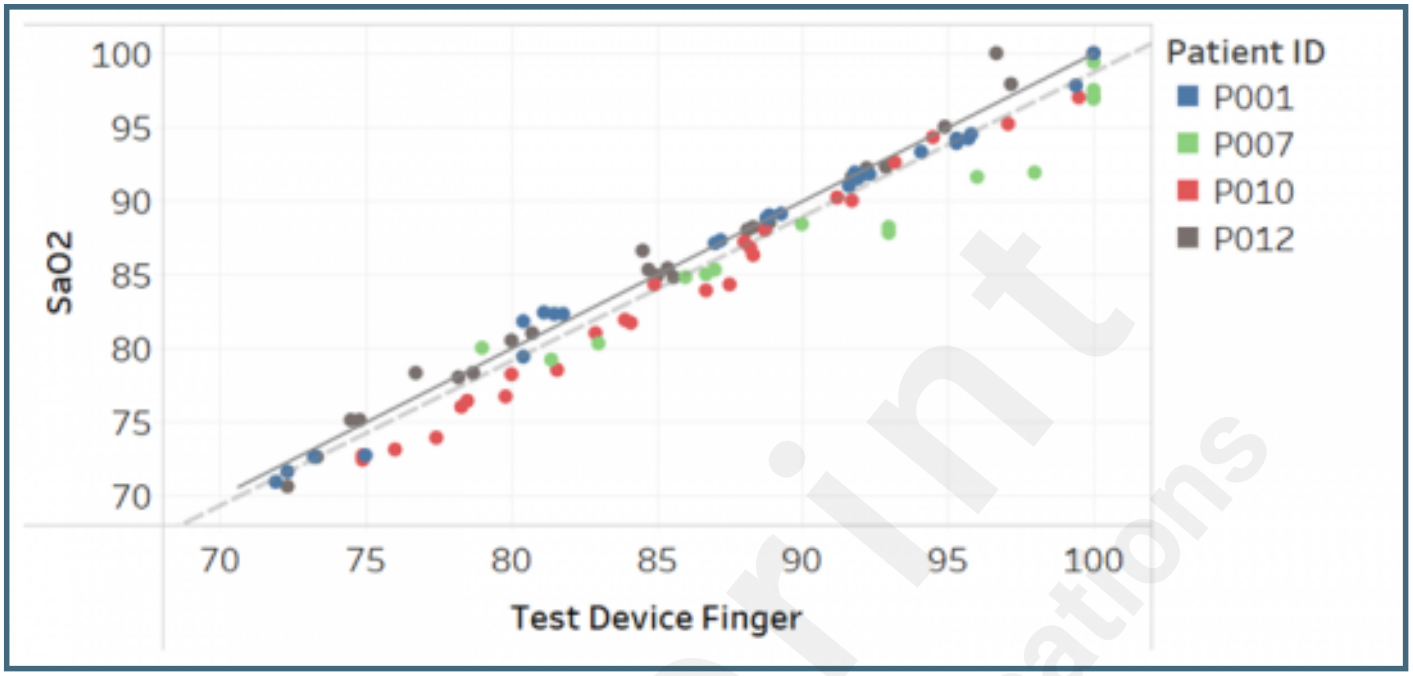

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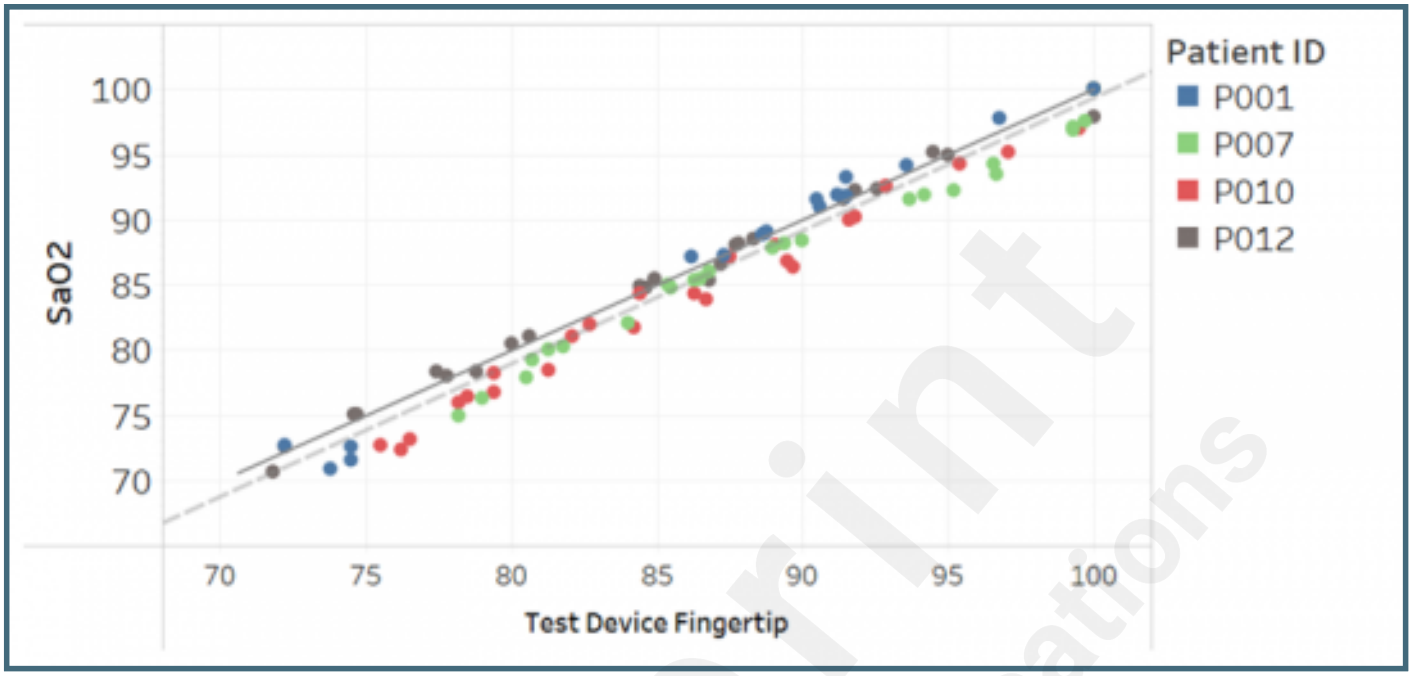

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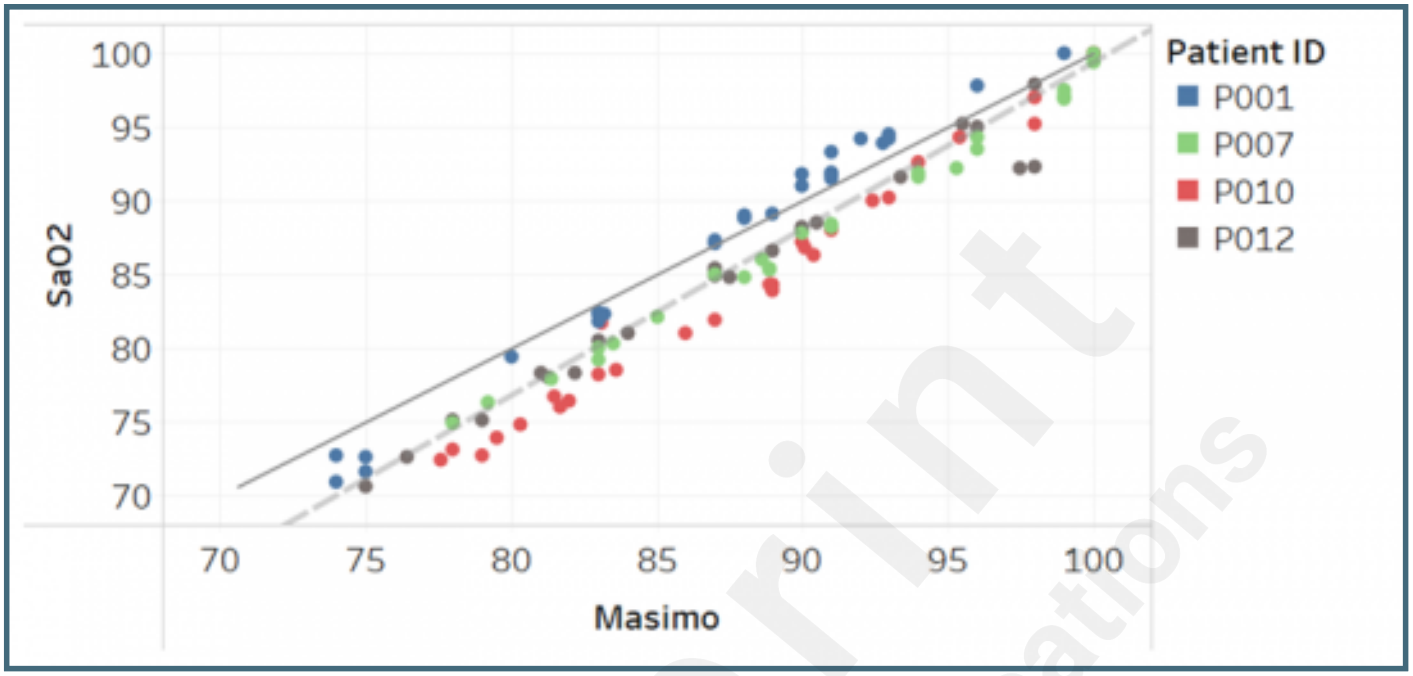

Multimedia Appendixes

Test data.
URL: http://asset.jmir.pub/assets/4734aba2c84b63dd663e97cefc8b0e3b.docx