

Evaluation of SpO₂ and Pulse Rate Accuracy in Healthy Volunteers as Measured by the Corsano CardioWatch 287-2 System Under Controlled Hypoxia Conditions

Introduction

Abnormal readings of any of the five cardinal signs – respiratory rate, heart rate, blood pressure, temperature, and peripheral blood oxygen saturation (SpO₂) – may indicate clinical deterioration.¹ Clinical scoring systems, such as the National Early Warning Score (NEWS), use intermittent vital sign measurements to support early identification of clinical deterioration, with the aim of curbing preventable morbidity and mortality. However, intermittent monitoring has important limitations. In addition to being disruptive to patients, particularly overnight, intermittent vital sign monitoring may be inaccurate, incomplete, and miss changes in physiological parameters that occur between assessments.¹⁻³ Vital sign assessment also requires significant clinician time, and intermittent checks may be delayed or missed, notably during periods of understaffing, which has been associated with worse patient outcomes.⁴⁻⁷ Advances in biomedical engineering and data analytics have allowed for development of non-tethered, wearable patient monitoring technologies that can be worn by the patient across care settings and activities, including at home and during sleep.

Photoplethysmography (PPG) is a non-invasive method for monitoring certain blood-related measurements, such as SpO₂ and pulse rate (PR).⁸ PPG uses optical transmission measurements from two light-emitting diodes, one red (660 nm) and one infrared (940 nm), and a photo detector to evaluate light absorption to continuously monitor SpO₂ and PR. Relying on optical transmission, PPG measurements are impacted by light scattering, which occurs when light passes through different mediums. Though medical devices utilizing PPG are calibrated to account for scattering effect, scattering can contribute to attenuation of the PPG signal, leading to inaccurate readings.^{9,10} Melanin is known to have low absorption at infrared wavelengths and can contribute to scattering, with higher melanin levels demonstrating larger amounts of light scattering.¹¹ Previous work has suggested that SpO₂ can be overestimated in individuals with greater quantities of melanin, with the magnitude of this overestimation appearing to increase with decreasing SpO₂.¹² These errors have been shown to impact patient outcomes, with greater skin pigmentation associated with

missed (occult) hypoxemia,^{9,13,14} which may contribute to delayed care and poorer patient outcomes.^{15,16} As sick patients and urgent clinical decisions impacting medical interventions are made at lower SpO₂ ranges, inaccurate readings can have cascading effects on patients.

Evaluating performance of PPG-based medical devices across skin pigmentations is important to ensure accurate and equitable measurements.¹⁷ The purpose of this analysis was to evaluate the accuracy of SpO₂ and PR, across a range of skin pigmentations, as measured by the Corsano CardioWatch 287-2 system under controlled hypoxia conditions.

Methods

This non-randomized, prospective single-center study was performed in accordance with the Declaration of Helsinki under a protocol that was duly approved by the Salus Institutional Review Board (IORG #0005674). All participants provided written informed consent prior to study participation. This study was sponsored and completed by Medtronic, a distributor of the Corsano CardioWatch 287-2 system. To evaluate the accuracy of the Corsano CardioWatch 287-2 system, device measured SpO₂ and PR were compared to reference arterial blood oxygen saturation (SaO₂) and electrocardiogram (ECG) heart rate (HR), respectively, during a controlled hypoxia protocol. Study design was consistent with, but does not claim compliance to, regulatory expectations available at the time of protocol writing put forth by the Food and Drug Administration (FDA) and International Organization for Standardization (ISO) which apply to pulse oximeter equipment intended for use on patients in professional healthcare, home healthcare, and emergency medical service environments.

Corsano CardioWatch 287-2 system

The Corsano CardioWatch 287-2 system is a wrist worn, CE marked and FDA cleared multi-parameter monitor designed for continuous monitoring of PR, skin temperature, and SpO₂, and intermittent monitoring of respiratory rate (**Figure 1**).[†] The system may enable accessible at home monitoring with early identification

[†]The Corsano CardioWatch 287-2 should not be used as the sole basis for diagnosis or therapy and is intended only as an adjunct in patient assessment. It is not intended for use in high-acuity environments or on acutely ill cardiac patients with potential to develop life-threatening arrhythmias, or for SpO₂ monitoring in conditions of high motion or low perfusion.

of deviations in vital sign(s). The system may enable accessible at-home monitoring with early identification of deviations in vital sign(s). Studies have demonstrated the accuracy and reliability of the Corsano CardioWatch 287-2 system, with reported correlations between device measurements and invasive reference measurements.^{18,19} The Corsano CardioWatch 287-2 system should not be used as the sole basis for diagnosis or therapy and is intended only as an adjunct in patient assessment.

Figure 1. Corsano CardioWatch 287-2 System



Enrollment and Baseline Measures

Data was collected from healthy volunteers enrolled under a protocol with the primary aim of evaluating pulse oximetry systems under hypoxic conditions. Prior to testing, participants completed a health history assessment, modified Allen's test, and collection of baseline vital signs. In addition to being willing and able to provide written informed consent and complete study procedures, an individual was eligible for the study if they were 1) aged ≥ 18 to ≤ 50 years and 2) a non-smoker or had not smoked within 36 hours prior to data collection. Individuals were excluded from participation for any of the following reasons: 1) morbidly obese (BMI >39.5), 2) compromised circulation (i.e., Raynaud's Syndrome), injury, or physical malformation of fingers, toes, hands, ears or forehead/skull or other sensor sites which would limit the ability to test sites needed for the study 3) pregnant or trying to get pregnant (confirmed by positive urine pregnancy test), 4) self-reported respiratory, heart, cardiovascular, blood clotting, or any other self-reported health condition identified on the health assessment form, 5) severe allergy to standard adhesives, latex, silicone, ultrasound gel, iodine, or lidocaine, 6) failure of the Allen's test, and 7) tattoo, colored nail polish, non-clear artificial nails, or surgical hardware in the optical path of the device under test, which would limit the ability to test sites needed for the study.

Skin pigmentation was assessed using two measures: Monk Skin Tone Scale™* (MST) and Individual Typology Angle (ITA).²⁰ MST is a standardized skin pigmentation scale using visual assessment.²¹ Up to two blinded, independent observers assessed participant MST at the forehead. Skin pigmentation groups were categorized

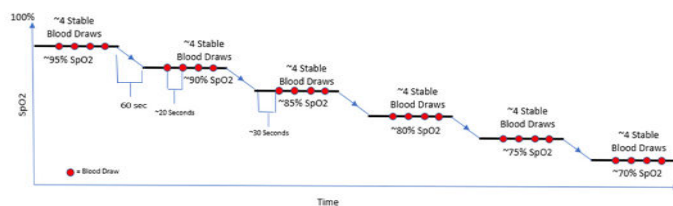
based on MST as follows: light = A - C, medium = D - G, dark = H - J. ITA was collected at the forehead and the dorsal distal interphalangeal (DIP) joint of the finger using a colorimeter.²² At each anatomical site, a single colorimetry measurement was obtained, and L^* , a^* , and b^* values were recorded. ITA was calculated from the corresponding L^* and b^* values; a^* was recorded but not used in the calculation.

Controlled Hypoxia Procedure

The Corsano CardioWatch 287-2 system was evaluated across the targeted SpO_2 range of 70-100% divided into six desaturation sequences, with the delivered gas mixture adjusted to decrease the displayed SpO_2 in approximately 5% steps (**Figure 2**). Each plateau lasted approximately five minutes, with four blood draws planned for each step. The Corsano CardioWatch 287-2 system was placed on the participant's left wrist and data was sent to a cloud-based platform via Bluetooth. HR reference data was collected via a 3-lead ECG. SaO_2 reference values were obtained from an arterial line and analyzed via CO-oximetry, with each blood sample assessed three times using three different CO-oximeters. CO-oximeter values were averaged to provide a single SaO_2 value for each blood draw.

Participants were connected to a breathing circuit via a mask. The gas mixture was delivered by a pre-set controller to induce hypoxia in a stair stepped manner to achieve the following target SpO_2 plateaus: 100%, 90 - 95%, 85 - 90%, 80 - 85%, 75 - 80%. At each plateau, once a stability period was achieved (defined as SpO_2 values changing not more than 3%; during 30 seconds prior to the first blood draw of each plateau and during 20 seconds prior to each subsequent blood draw of each plateau, and a SpO_2 change no more than 2% during the blood draw and 5 seconds after), a waste blood draw followed by an arterial blood sample was drawn, followed by a 15 - 30 second wait period and another waste draw and arterial blood sample draw (four arterial blood sample draws per plateau). The goal was to collect 24 paired observations ($SaO_2 - SpO_2$) per participant. Once the lowest level SpO_2 was achieved and data collection completed, the participant was given a gas mixture to aid in returning to baseline levels.

Figure 2. Controlled Hypoxia Protocol. Red circles represent paired arterial blood draws at each plateau.



Statistical Analysis and Methods

Descriptive statistics were used to summarize demographics including mean, standard deviation,

*The Monk Skin Tone Scale™ is available under the Creative Commons Attribution 4.0 International license at <https://skintone.google/get-started>

median, minimum, and maximum for continuous variables, and counts and percentages for categorical variables. Analyses were conducted using paired SaO₂-SpO₂ data from participants with available measurements.

SpO₂ and PR accuracy were stated in terms of root-mean-square (RMS) difference between Corsano CardioWatch 287-2 system measured values (SpO₂ and PR) and reference measured values (SaO₂ and HR), according to the equation below. SpO₂ and PR accuracy were assessed across the 70-100% oxygen saturation range for overall sample, pigmentation subgroups, and by SpO₂ decade.

$$A_{RMS} = \sqrt{\frac{\sum_{i=1}^n (DUT_i - Ref_i)^2}{n}}$$

DUT = Device Under Test; Ref = reference value; n = number of data points

SpO₂ mean bias and standard deviation of the SpO₂ bias values were calculated for the specified SpO₂ range, pigmentation subgroups, and SpO₂ plateaus according to the equation below. PR mean bias and standard deviation were calculated for all available data.

$$Bias = \frac{\sum_{i=1}^n (DUT_i - Ref_i)}{n}$$

DUT = Device Under Test; Ref = reference value; n = number of data points

Additionally, upper 95% confidence limits for SpO₂ A_{RMS} were estimated using participant-level cluster bootstrapping.

Bland-Altman plots with 95% limits of agreement were generated for all collected data pairs within the 70 - 100% SaO₂ range. Repeated measurements were accounted for using subject-level clustering, treating all observations from each participant as a single unit to preserve within-subject correlation.

Results

Participant Characteristics

A total of 27 healthy adult participants were included in the analysis. Participant characteristics are provided in **Table 1**.

Table 1. Participant Characteristics	
Variable	Value
Number of Participants (count)	27
Sex (count, %)	
Female	14 (51.9%)
Male	13 (48.1%)
Skin Pigmentation Group (count, %)	
Light	11 (40.7%)
Medium	10 (37.0%)
Dark	6 (22.2%)

Overall Accuracy

SpO₂ and PR accuracy, linear regression, and Bland-Altman results are provided in **Table 2**. Across all participants and desaturation plateaus tested, the mean bias was 0.12% for SpO₂ and -0.31 bpm for PR, indicating close agreement with reference values. Bias is defined as the difference between blood reference measured SaO₂ and PPG measured SpO₂, where a lower number indicates greater alignment between the two measures. This agreement is visualized in the linear regression and Bland-Altman plots for SpO₂ (**Figure 3** and **Figure 5**, respectively) and PR (**Figure 4** and **Figure 6**, respectively). A small number of outlier points were observed during the rapid increase in oxygen saturation at the end of the desaturation sequence. Based on the pattern, these appear to reflect a transient algorithm response lag during abrupt recovery rather than a broader performance trend. These points were retained in the dataset and were not excluded from the analysis, as overall accuracy conclusions were unchanged.

Accuracy by Monk Skin Tone

To evaluate performance across skin pigmentation groups, accuracy results for SpO₂ and PR were also evaluated (**Table 3**). For all groups, ARMS was <3% for SpO₂ and <3bpm for PR. This tight agreement to reference measurements is depicted in the Bland-Altman plots in **Figure 7** for SpO₂ and **Figure 8** for PR. Table 4 presents the results for SpO₂ accuracy by SaO₂ decade for all participants and by skin pigmentation group.

Table 2. Accuracy results for peripheral blood oxygen saturation (SpO₂) and pulse rate (PR) as measured by the Corsano CardioWatch 287-2 system for all participants

Accuracy	Number of Participants	Number of Data Points	Mean Bias (% or bpm)	Standard Deviation of Errors (% or bpm)	A _{RMS} (% or bpm)	A _{RMS} 95% Upper Confidence Limit (% or bpm)
SpO ₂ (70 - 100%)	27	651	0.12	2.16	2.16	[1.83, 2.53]
Pulse Rate (bpm)	27	651	-0.31	2.61	2.63	[2.28, 2.98]
Linear Regression	Intercept	Slope	Mean Bias (% or bpm)	Standard Error of Slope	A _{RMS} (% or bpm)	R ²
SpO ₂ (70 - 100%)	8.06	0.91	0.12	0.01	2.16	0.92
Pulse Rate (bpm)	2.88	0.96	-0.31	0.01	2.63	0.97
Bland-Altman	Number of Participants	Number of Data Points	Mean Bias (% or bpm)	Between-Subject Variance	Within-Subject Variance	95% Limit of Agreement (% or bpm)
SpO ₂ (70 - 100%)	27	651	0.12	1.53	3.13	[-4.11, 4.34]
Pulse Rate (bpm)	27	651	-0.31	0.00	6.81	[-5.43, 4.80]

Figure 3. Linear regression plots of blood oxygen saturation for all participants by A) unique study identifier (CAS_ID) and B) skin pigmentation group. Reference arterial blood oxygen saturation (SaO_2) measurements are provided on the x-axis and Corsano CardioWatch 287-2 system peripheral blood oxygen saturation (SpO_2) measurements are provided on the y-axis. The dotted red line represents the line of identity. Participant data are depicted as individual dots.

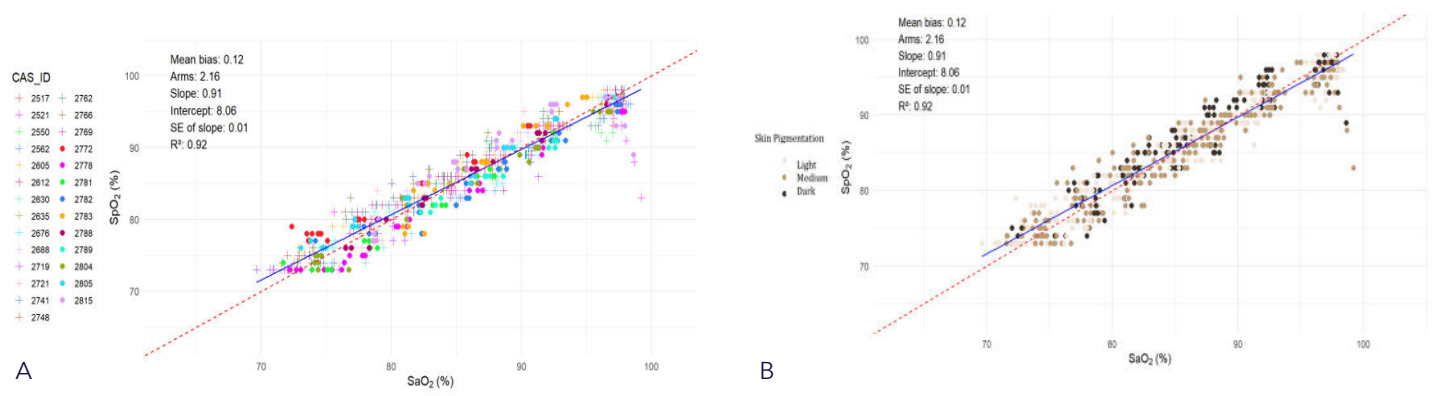


Figure 4. Linear regression plots of pulse rate (PR) for all participants by A) unique study identifier (CAS_ID) and B) skin pigmentation group. Reference electrocardiogram (ECG) heart rate measurements are provided on the x-axis and Corsano CardioWatch 287-2 system PR measurements are provided on the y-axis. The dotted red line represents the line of identity. Participant data are depicted as individual dots.

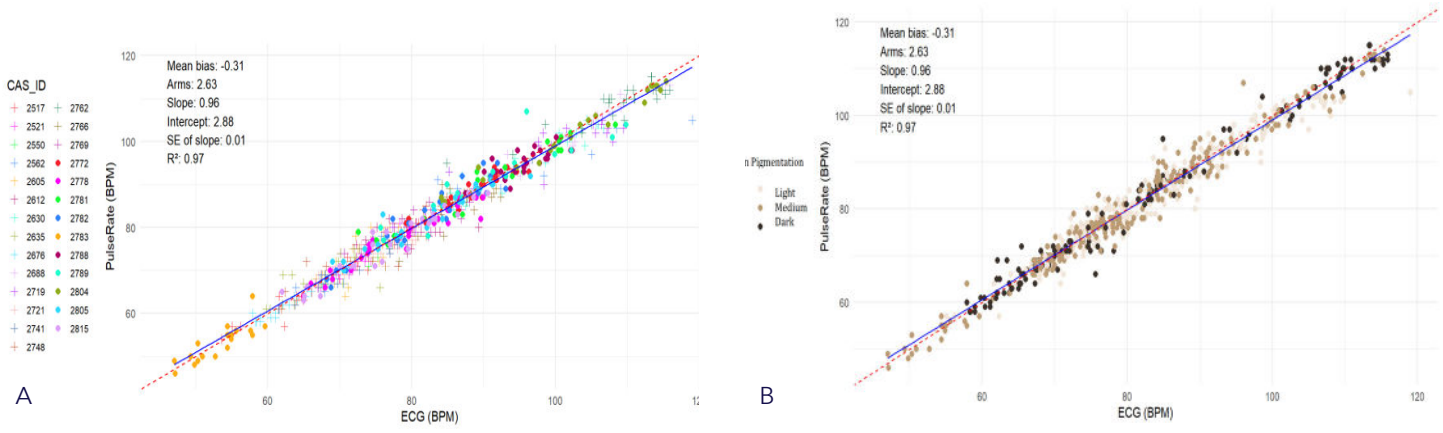


Figure 5. Modified Bland Altman plots of blood oxygen saturation for all participants by A) unique study identifier (CAS_ID) and B) skin pigmentation group. Reference arterial blood oxygen saturation (SaO_2) measurements are provided on the x-axis and the y-axis presents the difference between peripheral blood oxygen saturation (SpO_2), as measured by the Corsano CardioWatch 287-2 system, and reference SaO_2 . The dashed blue line represents mean bias and dashed red lines represent 95% limits of agreement. Participant data are depicted as individual dots.

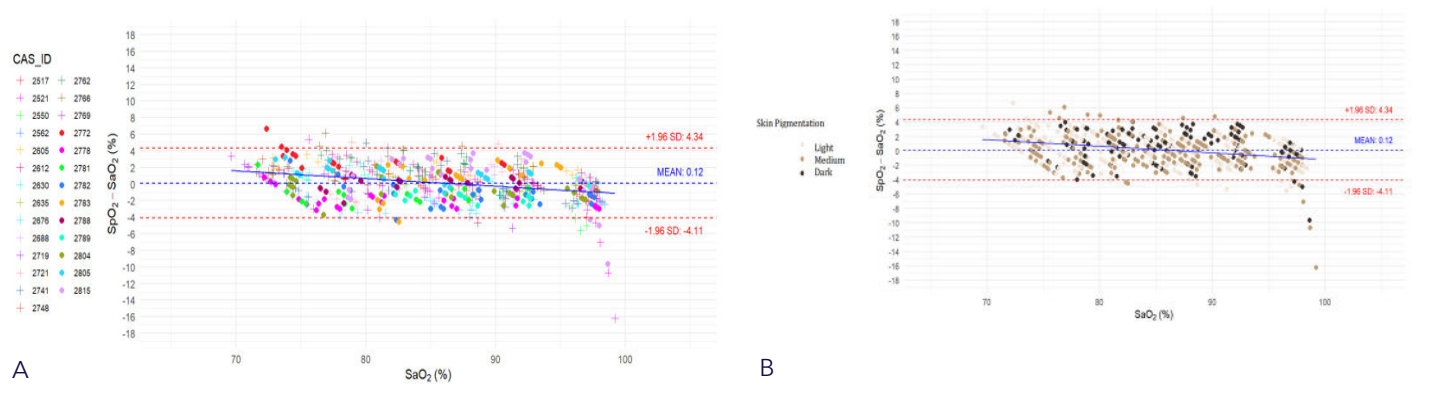


Figure 6. Modified Bland Altman plots of pulse rate for all participants by A) unique study identifier (CAS_ID) and B) skin pigmentation group. Reference electrocardiogram (ECG) measurements are provided on the x-axis and the y-axis presents the difference between pulse rate, as measured by the Corsano CardioWatch 287-2 system, and reference ECG. The dashed blue line represents mean bias and dashed red lines represent 95% limits of agreement. Participant data are depicted as individual dots.

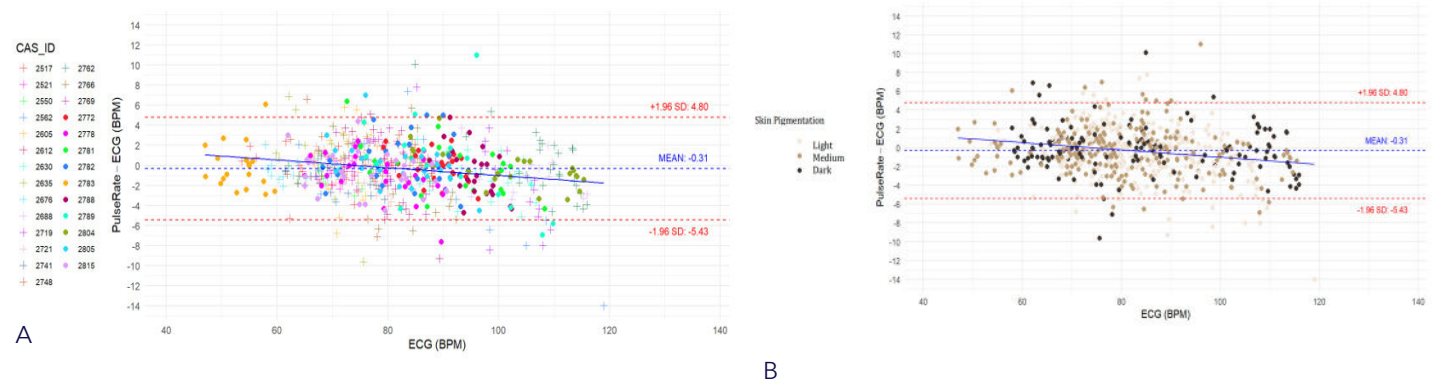
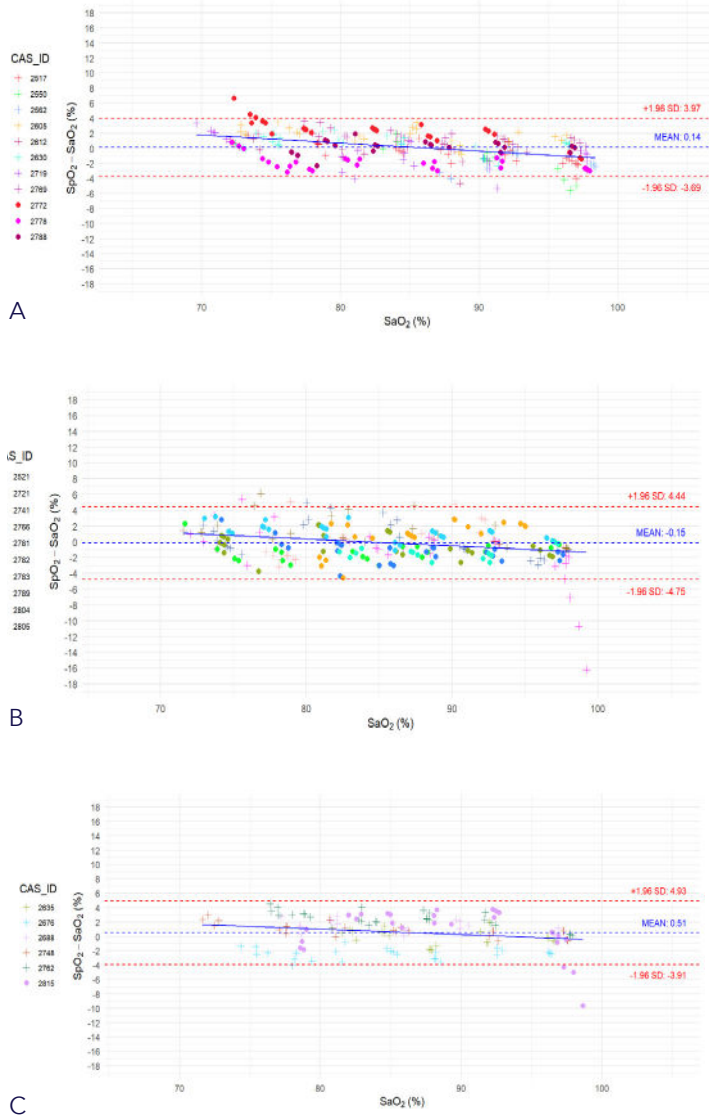


Table 3. SpO ₂ and PR accuracy by Skin Pigmentation Group						
Skin Pigmentation Group	Number of Participants	Number of Data Points	Mean Bias (% or bpm)	Standard Deviation of Errors (% or bpm)	A _{RMS} (% or bpm)	Arms (% or bpm) 95% Upper Confidence Limit
SpO ₂ (70 - 100%)						
Light	11	262	0.14	1.92	1.92	2.20
Medium	10	241	-0.15	2.33	2.33	2.96
Dark	6	148	0.51	2.21	2.26	2.67
Pulse Rate (bpm)						
Light	11	261	-0.45	2.84	2.87	3.41
Medium	10	242	-0.23	2.43	2.43	2.88
Dark	6	148	-0.21	2.47	2.47	2.94
Bland-Altman	Number of Participants	Number of Data Points	Population Mean Bias (% or bpm)	Between-Subject Variance	Within-Subject Variance	95% Limits of Agreement (% or bpm)
SpO ₂ (70 - 100%)						
Light	11	262	0.14	1.69	2.13	[-3.69, 3.97]
Medium	10	241	-0.15	1.01	4.50	[-4.75, 4.44]
Dark	6	148	0.51	2.41	2.67	[-3.91, 4.93]
Pulse Rate (bpm)						
Light	11	261	-0.45	0.07	8.02	[-6.02, 5.13]
Medium	10	242	-0.23	0.00	5.88	[-4.99, 4.52]
Dark	6	148	-0.21	0.01	6.08	[-5.04, 4.63]

Table 4. Accuracy by SaO ₂ decade and Skin Pigmentation Group						
Skin Pigmentation Group	SaO ₂ Range	Number of Participants	Number of Data Points	Mean Bias (%)	Precision (%)	A _{RMS} (%)
Light	[70%, 80%)	9	79	1.15	1.84	2.16
Light	[80%, 90%)	11	87	0.23	1.73	1.73
Light	[90%, 100%]	11	95	-0.82	1.67	1.85
Medium	[70%, 80%)	8	62	0.42	2.21	2.23
Medium	[80%, 90%)	10	96	0.03	1.88	1.87
Medium	[90%, 100%]	10	83	-0.80	2.73	2.82
Dark	[70%, 80%)	5	32	0.71	2.42	2.48
Dark	[80%, 90%)	6	67	0.89	1.96	2.15
Dark	[90%, 100%]	6	49	-0.13	2.29	2.27

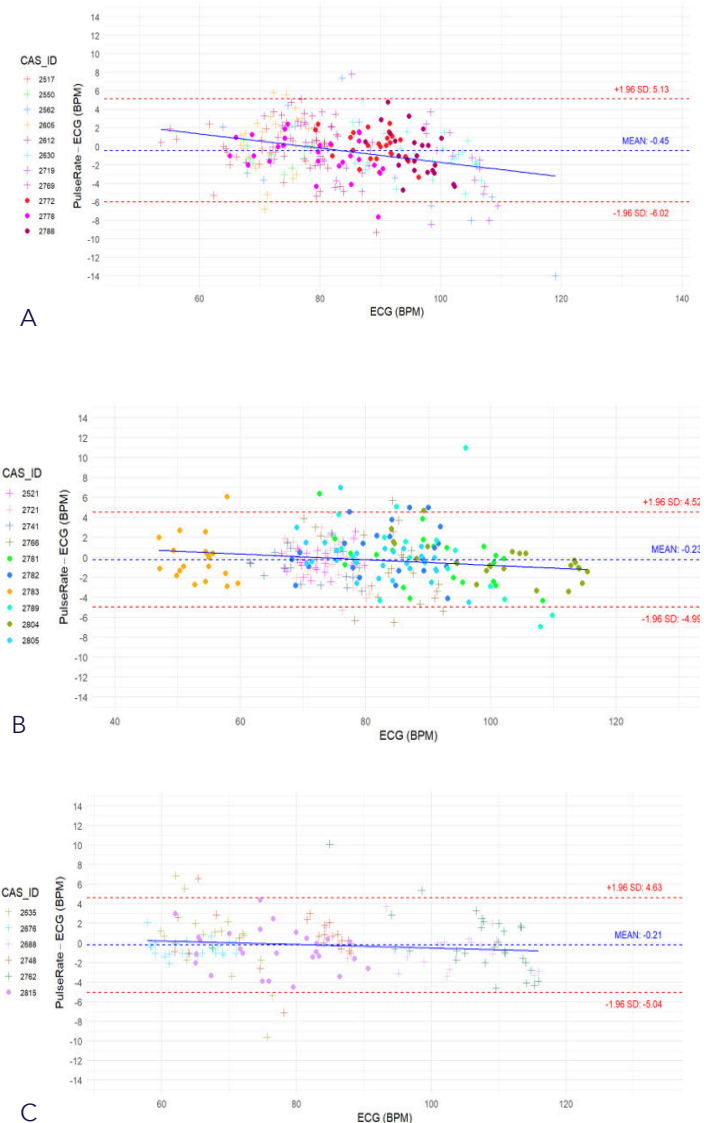
Figure 7. Modified Bland Altman plots of blood oxygen saturation by skin pigmentation group. A) light, B) medium, and C) dark. Reference arterial blood oxygen saturation (SaO_2) measurements are provided on the x-axis and the y-axis presents the difference between peripheral blood oxygen saturation (SpO_2), as measured by the Corsano CardioWatch 287-2 system, and reference SaO_2 . The dashed blue line represents mean bias and dashed red lines represent 95% limits of agreement. Participant data is depicted as colored dots, with each participant represented by a specific color.



Discussion

These results support the notion that the Corsano CardioWatch 287-2 system provides acceptable accuracy in measuring SpO_2 and PR in healthy adults across skin pigmentations and saturation levels, in line with previous studies.^{18,23,24} Overall, the mean bias for SpO_2 was 0.12%, with an ARMS of 2.16, indicating close agreement with reference SaO_2 measures. This finding is reflected in PR, which showed close agreement to reference ECG across all participants. The reported values from the current analysis are similar to those reported in a group of healthy volunteers completing a high-intensity cycling

Figure 8. Modified Bland Altman plots of pulse rate (PR) by skin pigmentation group. A) light, B) medium, and C) dark. Reference electrocardiogram (ECG) measurements are provided on the x-axis and the y-axis presents the difference between pulse rate, as measured by the Corsano CardioWatch 287-2 system, and reference ECG. The dashed blue line represents mean bias and dashed red lines represent 95% limits of agreement. Participant data is depicted as colored dots, with each participant represented by a specific color.



session, where the Corsano CardioWatch 287-2 system demonstrated an A_{RMS} of 1.28% and 2.51 bpm for SpO_2 and PR, respectively, with similar accuracy results across skin pigmentation.²³ Notably, data in the previously published study were collected under motion conditions, which is known to challenge accuracy in PPG-based devices.

Wearables provide an opportunity to monitor patients across care settings, including at home, providing an “extra set of eyes” without the need for tethered devices. Changes in vital signs often precedes decompensation

events, and continuous vital sign monitoring is recognized as an effective intervention in reducing severe adverse events through early recognition of deterioration.^{1,25,26} Indeed, one pilot study using the Corsano CardioWatch 287-2 system found strong alignment between NEWS2 risk scores calculated from wearable data and those based on intermittent vital signs.²⁷ Across different settings, wearables such as the Corsano CardioWatch 287-2 system can provide multiple parameter monitoring in a format that is easy to use for both patients and clinicians.^{26,27}

This analysis has several strengths, including using a controlled desaturation protocol that spanned an SpO₂ range of 70 – 100% to allow for evaluation of accuracy at values where critical medical decisions are made. Further, device measured values were compared to prospectively collected, paired gold-standard measurements of SaO₂ and ECG, for SpO₂ and PR, respectively. All testing was completed on healthy adults in a controlled laboratory setting, which may not accurately reflect complex and diverse patient physiology or care settings.

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