

# **Non-Invasive Methodology for Detection of Vital Signs by PPG Signals Collected from the Finger via Smartphone Camera for Individuals Aged 18 to 70: Randomized Controlled Trial**

Subhabrata Paul, Bibhas Banik, Bijan Basak, Insha Moin

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# Non-Invasive Methodology for Detection of Vital Signs by PPG Signals Collected from the Finger via Smartphone Camera for Individuals Aged 18 to 70: Randomized Controlled Trial

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## Abstract

**Background:** Monitoring vital signs is an essential part of evaluating health, and smartphones with built-in photoplethysmography (PPG) sensors are becoming viable alternatives to conventional, gold-standard medical equipment in vitals monitoring. It is critical, however, to compare newer technologies with more conventional medical tools. The focus of this research is to compare vital signs recorded using the smartphone app CarePlix Vitals to those collected from traditional, gold-standard medical equipment. Healthcare provider CareNow Pvt Ltd. funded this research.

**Objective:** This research aims to evaluate the accuracy of vital signs obtained by the smartphone app CarePlix Vitals in comparison to known methods.

**Methods:** The CarePlix Vitals app utilized PPG signals obtained from partially automated finger scanning on various smartphone models to measure the following vital signs readings: pulse, respiration rate, oxygen saturation, heart rate variability, and blood pressure. We compared these readings to those of the following traditional medical devices: the Polar H9, the Polar H10, the Omron HEM 7120 BP monitor, the Masimo MightySat Rx, and the Omron HEM 7120 BP monitor. We performed statistical analyses to validate the accuracy of CarePlix Vitals vital signs readings in comparison those made by traditional medical devices. The Confidence Interval for hypothesis testing was set at 95%. Participants were recruited offline from SSKM Hospital and participated in an unblinded, face-to-face, open trial. Ethical approval was obtained from all participants, and data quality control measures were implemented to ensure data accuracy.

**Results:** The following percentages were obtained by CarePlix Vitals in terms of accuracy: 98.56% for heart rate (HR), 98.18% for respiratory rate (RR), 98.14% for oxygen saturation (SpO2), 91.20% for systolic blood pressure (BP), and 89.89% for diastolic BP. There was an accuracy of 97.85% (AE≤12 msec) for RMSSD values of HRV, and a precision of 92.62% (AE≤25 msec) for SDNN measurements.

Our findings suggest that the CarePlix Vitals app could be used as an alternative for traditional methods such as a pulse oximeter, digital blood pressure, or polar belt in an adult population.

**Conclusions:** Results demonstrate that the vitals readings by the CarePlix Vitals app are substantially equivalent to those of predicate devices. As smartphone-based technologies continue to advance, this study contributes valuable insights to the field of vital signs monitoring.

Despite the promising results, we acknowledge certain limitations of this method, including PPG signal corruption due to movement artifacts. Addressing these limitations in future iterations will further enhance the practicality and precision of CarePlix Vitals. Further studies with larger and more varied populations will be crucial toward corroborating the efficacy and generalizability of the CarePlix Vitals app. Clinical Trial: CTRI/2023/07/055351

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## Original Manuscript

## Original Paper

Data Coordinator: Subhabrata Paul, Head of Research & Development and CIO, CarePlix-CareNow Healthcare Pvt Ltd

Research Coordinators: Insha Moin, Clinical and Compliance Associate – Research & Development, CarePlix-CareNow Healthcare Pvt Ltd and Bibhas Banik, Senior Manager, CarePlix-CareNow Healthcare Pvt Ltd

Principal Investigator: Dr. Bijan Basak, Professor, IPGMER and SSKM Hospital, Department of Otorhinolaryngology and Head of Neck Surgery (ENT)

# Non-Invasive Methodology for Detection of Vital Signs by PPG Signals Collected from the Finger via Smartphone Camera for Individuals Aged 18 to 70: Randomized Controlled Trial

## Abstract

### Background

Monitoring vital signs is an essential part of evaluating health, and smartphones with built-in photoplethysmography (PPG) sensors are becoming viable alternatives to conventional, gold-standard medical equipment in vitals monitoring. It is critical, however, to compare newer technologies with more conventional medical tools. The focus of this research is to compare vital signs recorded using the smartphone app CarePlix Vitals to those collected from traditional, gold-standard medical equipment. Healthcare provider CareNow Pvt Ltd. funded this research.

### Objective

This research aims to evaluate the accuracy of vital signs obtained by the smartphone app CarePlix Vitals in comparison to known methods.

### Methods

The CarePlix Vitals app utilized PPG signals obtained from partially automated finger scanning on various smartphone models to measure the following vital signs readings: pulse, respiration rate, oxygen saturation, heart rate variability, and blood pressure. We compared these readings to those of the following traditional medical devices: the Polar H9, the Polar H10, the Omron HEM 7120 BP monitor, the Masimo MightySat Rx, and the Omron HEM 7120 BP monitor. We performed statistical analyses to validate the accuracy of CarePlix Vitals vital signs readings in comparison those made by traditional medical devices. The Confidence Interval for hypothesis testing was set at 95%. Participants were recruited offline from SSKM Hospital and participated in an unblinded, face-to-face, open trial. Ethical approval was obtained from all participants, and data quality control measures were implemented to ensure data accuracy.

### Results

The following percentages were obtained by CarePlix Vitals in terms of accuracy: 98.56% for heart rate (HR), 98.18% for respiratory rate (RR), 98.14% for oxygen saturation (SpO<sub>2</sub>), 91.20% for systolic blood pressure (BP), and 89.89% for diastolic BP. There was an accuracy of 97.85%

( $AE \leq 12$  msec) for RMSSD values of HRV, and a precision of 92.62% ( $AE \leq 25$  msec) for SDNN measurements.

Our findings suggest that the CarePlix Vitals app could be used as an alternative for traditional methods such as a pulse oximeter, digital blood pressure, or polar belt in an adult population.

## Conclusion

Results demonstrate that the vitals readings by the CarePlix Vitals app are substantially equivalent to those of predicate devices. As smartphone-based technologies continue to advance, this study contributes valuable insights to the field of vital signs monitoring.

Despite the promising results, we acknowledge certain limitations of this method, including PPG signal corruption due to movement artifacts. Addressing these limitations in future iterations will further enhance the practicality and precision of CarePlix Vitals. Further studies with larger and more varied populations will be crucial toward corroborating the efficacy and generalizability of the CarePlix Vitals app.

## Trial Recordkeeping

The trial is recorded under the Clinical Trials Registry - India. Registration no. CTRI/2023/07/055351

## Keywords

Artificial intelligence (AI); photoplethysmography (PPG); pulse; oxygen saturation; respiration rate; HRV; blood pressure; remote sensing; signal processing

## Introduction

Vital signs, such as pulse rate, blood pressure, respiration rate, oxygen saturation, and heart rate variability serve as fundamental indicators of an individual's physiological status and overall health. These parameters play a pivotal role in clinical assessments, aiding in the diagnosis and management of various medical conditions. Traditionally, healthcare professionals rely on gold-standard medical devices, such as pulse oximeters, blood pressure cuffs, and electrocardiograms, for accurate and precise measurements of vital signs in clinical settings. However, the stationary nature of these devices limits their continuous monitoring capabilities and accessibility in remote healthcare scenarios.

The advent of smartphones and their widespread integration into daily life has opened new avenues for innovative healthcare technologies. Smartphone-based solutions leveraging photoplethysmography (PPG) signals acquired through the smartphone's built-in camera have emerged as promising alternatives for vital signs monitoring. PPG technology captures variations in blood volume, enabling the measurement of key vital signs through the fingertip placed on the smartphone's camera. Photoplethysmography is simple to set up, accessible to use, and cost-effective. To detect the blood volume pulse, PPG uses a probe with a light source and a photodetector. The variation in blood volume correlates to the amount of backscattered light [1]. In 1938, Hertzman [2] was the first to discover a link between backscattered light intensity and blood volume. To detect PPG signals through the skin, traditional PPG systems often use a limited wavelength light source (i.e., light-emitting diodes with specified colors such as infrared, red, or green) and a specific photodetector. The smartphone camera, when used in conjunction with the LED illumination, can detect these minute differences in skin color induced by blood flow. Color discovery in the green, red and blue ranges is enabled by the camera's wide-bandwidth pixels (RGB-color). Peak-to-peak intervals (PPI) are generated from photoplethysmography, or PPG [3]. PPG is used to measure blood flow volume and can evaluate vital signs such as pulse rate [4, 5], Blood oxygen [6], blood pressure [7], and respiration rate [4, 8].

By allowing for the remote monitoring of patients' vital signs in real-time while offering individuals more control over their health, this accessible and non-invasive method has the potential to

revolutionize healthcare delivery.

CareNow Healthcare Pvt Ltd.'s CarePlix Vitals is a piece of wellness software that measures vital signs remotely utilizing PPG technology. The software takes advantage of the built-in camera possessed by smartphones to record the user's finger in real-time. It then runs a 60-second loop, during which it averages the colors in the user's finger. Vital signs readings are then derived by analyzing minor color changes.

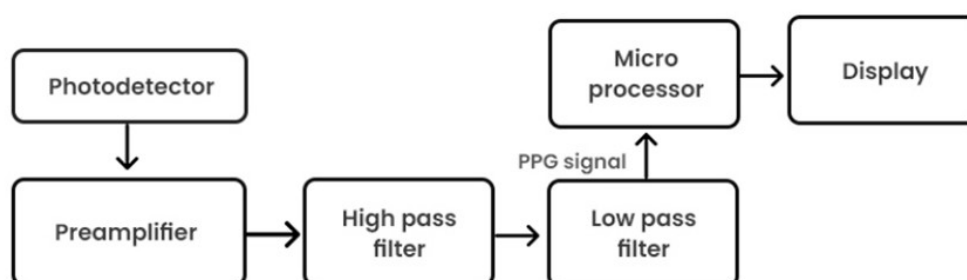
This study's primary objective is to validate and compare the vital signs measurements of CarePlix Vitals, a smartphone-based vital signs monitoring software, against those of established gold-standard medical devices. Through trials and comparative analyses, we aim to establish the reliability and effectiveness of the CarePlix Vitals app as a practical tool for vital signs measurement and remote health monitoring.

## Methods

### Careplex Vitals Working Principle

The following steps depict a high-level working flow of the estimation of vital signs using the Careplex Vitals app. The Careplex Vitals app is intended to be used for daily vital signs monitoring. To capture vitals from a smartphone, the first step is to start a finger scan which turns on the primary back camera and flashlight of the phone. The white light of the LED flash consists of red, green, and blue components, which are the method's primary elements for measuring body vitals. Once the flash is turned on, the primary camera and flash are covered with the fingertip such that the light reflects on the camera. The Careplex Vitals app then captures the video frames from the camera, and through digital image processing and several image processing algorithms, the video frame is converted into the desired format and then calculates the intensity components of the frames. Simultaneously, the quadrants of the frames are determined to calculate the best possible PPG signal in the frame, and algorithms detect the various intensities required to draw the ratio between them.

Careplex Vitals PPGs utilizes reflectance mode to enable sensor placement. However, echo mode PPG's accuracy is pretentious by movement pieces and pressure turbulences. Any bodily activity can introduce movement pieces that distort the Photoplethysmography signal and edge the precision of its measuring vitals. Additionally, pressure turbulences on the probe triggered by interaction force amid the Photoplethysmography sensor and measurement site can bend the Photoplethysmography signal's arterial geometry. As a result, PPG signals may be affected by pressure applied to the skin. With these factors under consideration, the Careplex Vitals app amplifies and filters raw PPG signals, and peaks are spotted in its Data Processing Model API. The PR is calculated from the intervals of the peaks. After finalizing the required intensity of the signals and ensuring the accuracy of the observations, the app runs its main algorithm.





**Figure 1.** Careplix Vitals data processing AI model**Figure 2.** Photoplethysmography (PPG) principle by smartphone**Figure 3.** Representative PPG was taken from Careplix Vitals scan

### Estimation of Heart Rate (HR)

CarePlix Vitals utilizes a change in light intensity due to changes in blood volume with every cardiac

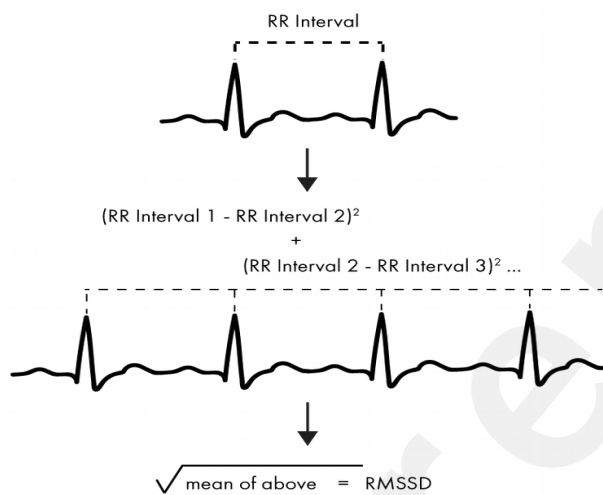
cycle. Each heartbeat corresponds to an increase in brightness after a period of reduced brightness. Each cardiac rotation appears as a peak, or R, as perceived in Figure 4. After measuring the numeral of peaks of the PPG signal within a specific sampling period, the heart rate is calculated using signal processing algorithms like Fast Fourier Transform (FFT).

**Figure 4.** Representative PPG taken from a CarePlix scan

### Estimation of Heart Rate Variability (HRV)

The PPG signal was analyzed using signal processing algorithms to extract the heart rate and then heart rate variability was calculated. In viewing several heartbeats next to each other, the milliseconds distance between each peak, or R, is defined as the RR interval.

Time domain analysis was completed by computing the arithmetical measures of mean, standard deviation, variance, and root mean square. These measures provide insights into the variability and regularity of the user's heart rate. HRV was calculated using SDNN and RMSSD. SDNN is the standard deviation of all of the RR intervals, the Root Mean Square of Successive Differences between each heartbeat is denoted as RMSSD.

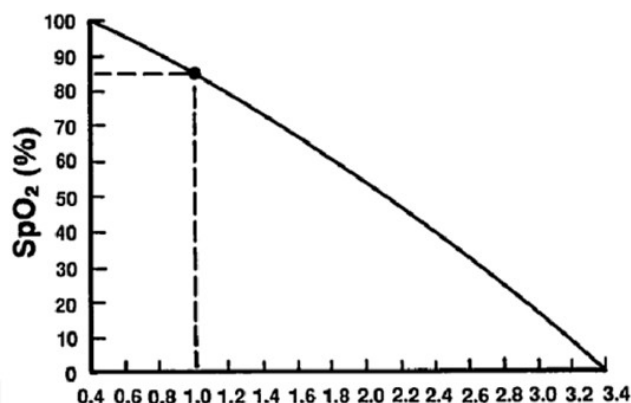


**Figure 5.** RMSSD formula

### Estimation of Oxygen Saturation (SpO<sub>2</sub>)

The CarePlix Vitals app utilizes blue and red channels to construct PPG signals. The amount of absorbed light fluctuates according to the pulsations of blood within the finger. The changing Photoplethysmography signal is revealing the changes in the blood's volume and oxygen saturation. Blue light is absorbed more effectively by oxygenated hemoglobin, while red light is absorbed more properly by deoxygenated blood. The proportion of the detected intensities gives the oxygen in the blood to compute the ratio of red to blue light, the amplitude of absorbed light is mined from the raw photoplethysmography signal. The signal's AC component is connected to the pulsatile blood, while the DC component is related to non-pulsatile tissue like skin and bone. The ratios utilized for estimating SpO<sub>2</sub> are shown in Equation 1, where the variables for red and blue lights are, respectively, r and b.

The equation is as follows:  $R = (ACr / DCr) \times (DCb / ACb)$



$$R = \frac{AC_{660}/DC_{660}}{AC_{940}/DC_{940}}$$

**Figure 6.** SpO<sub>2</sub> formula

### Estimation of Blood Pressure (BP): Systolic and Diastolic

The Careplix Vitals app uses a calibration dataset to map the features extracted from the pre-processed PPG signal to actual blood pressure values. A machine learning algorithm is trained on a large dataset of around 5 million PPG signals containing 7 seconds of continuous PPG and their discrete Blood pressure values and blood pressure measurements to establish a mapping function. The Careplix Vitals app applies ResNet with skip connections to predict blood pressure using photoplethysmography (PPG) data obtained from the finger. By adapting the input layer and using a regression layer, the Careplix Vitals app analyzes the PPG time series and estimates systolic and diastolic blood pressure.

### Ethics Consent

Ethical consent for CarePlix Vitals was approved by the IPGME & R Research Oversight Committee (IPGME&R/IEC/2022/306). All members provided written well-versed consent.

### Eligibility Standards

The study comprised 2,785 outpatients of SSKM Hospital in Kolkata. Participants were recruited offline and participated in an unblinded, face-to-face, open trial. The Careplix Vitals app was free of cost to the participants. Participation was voluntary, and participants were not compensated for their period. The finger scan process was explained to all participants and each participant was provided with a written informed consent form. Data was composed and managed namelessly, and in accordance with regulations on ethics, data guard, and written informed consent. Reasons for data exclusion were an age of less than 18 years, incorrect or incomplete data entry, and scans with low signal quality (because of excessive movement of the finger).

Healthy outpatients of the ENT (Otorhinolaryngology) Department were included. Inclusion criteria consisted of (1) individuals aged 18-70 years, (2) subjects willing to participate and can provide written informed consent, and (3) individuals possessed basic smartphone literacy. Exclusion criteria were (1) subjects who are incapable to follow basic directives due to dementia, altered mental status, delirium, or other conditions; (2) subjects who had coffee/tea in the past hour; (3) subjects who have shaky hands due to nervous disorder, tremors, Parkinson's disease or other incapacities resulting in the inability to remain still; and (4) subjects with poor finger perfusion, such as exhaustive callus formation or perniosis.

### Data Collection and Statistical Analysis

Careplix Vitals was measured against the following predicate devices. These predicate devices are considered as Gold Standard for measuring the said vital parameters.

- Heart rate: Omron HEM 7120 BP monitor
- SpO<sub>2</sub>: Masimo MightySat Rx
- Respiration rate: Masimo MightySat Rx
- Blood pressure: Omron HEM 7120 BP monitor
- Heart rate variability: Polar H9, Polar H10

A trained clinical trial representative attached the Polar H9 and Polar H10 to each participant's chest. The Omron HEM 7120 BP monitor was attached to each participant's left arm, and Masimo MightySat Rx was placed to each participant's left finger.

For the finger scan, the subject placed their right index finger on the rear primary camera of a smartphone. Vitals measurement began, while the trained clinical trial representative used the predicate devices to take and record the participant's actual readings alongside the participant's Careplix Vitals readings.

The meta-analysis was divided based on each vital parameter and primary outcomes were assessed by calculating RMSE, SD, MAE, and CI.

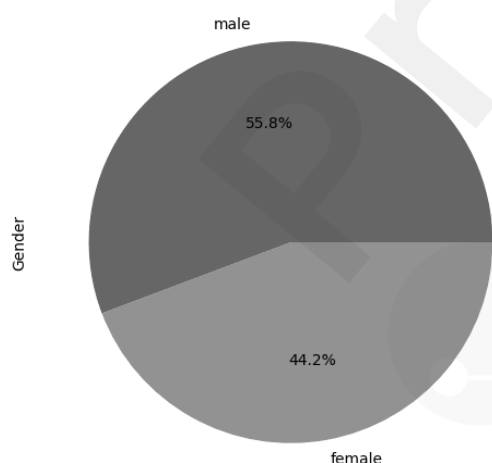
## Results

The trial was completed on August 24th, 2023.

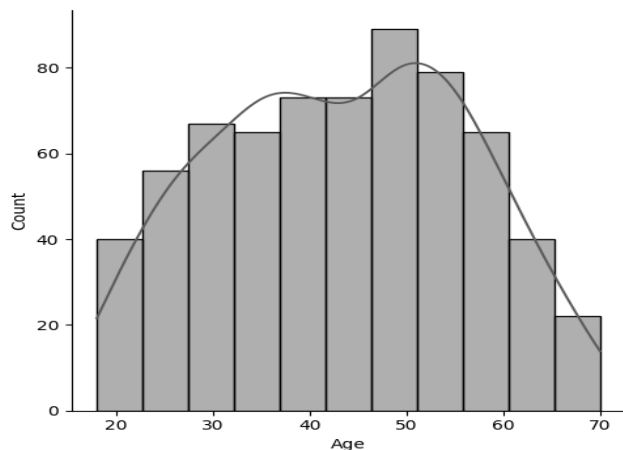
### Heart Rate (HR) Analysis

#### Participant Distribution

The HR trial encompassed both Android and iOS devices, with a total of 669 participants.



**Figure 7.** HR participant distribution by gender



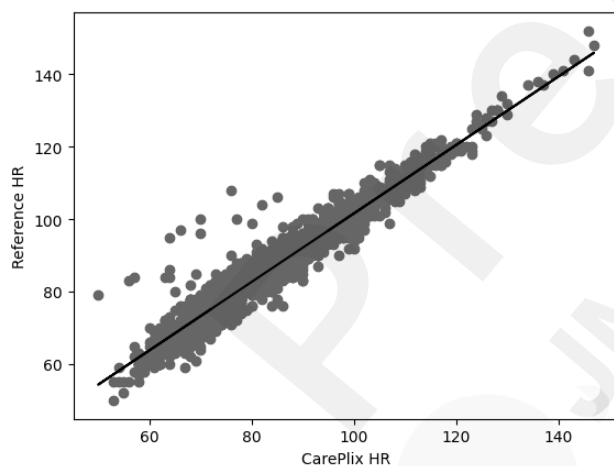
**Figure 8.** HR participant distribution by age

### Accuracy Analysis

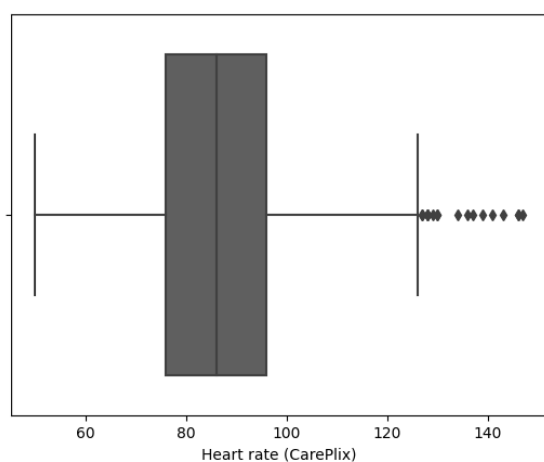
To calculate the accuracy, we found the following values:

RMSE	SD	MAE	Confidence ( $\alpha = 0.05$ )	CI 95%	MAE $\pm$ SD
4.59	3.327	3.16	0.1598	[ 3.0002, 3.3198 ]	3.16 $\pm$ 3.327

**Table 1.** HR RMSE, SD, MAE Confidence & Confidence Interval with a significance level of 0.05

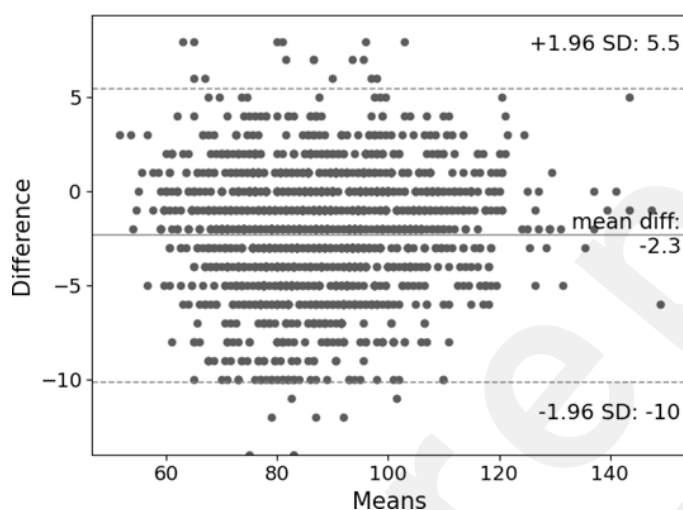


**Figure 9.** Scattered plot of HR readings of the CarePlix app vs. Reference HR



**Figure 10.** Box plot of CarePlix HR readings

## Bland-Altman Plot and Analysis



**Figure 11.** Bland-Altman plot for HR

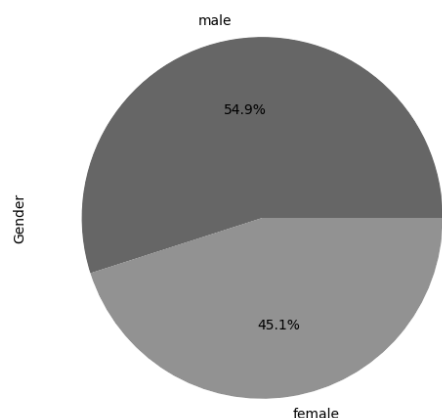
The Bland-Altman plot's x-axis shows the CarePlix Vitals app's and reference instrument's average measurements. The y-axis shows the variance amid the measurements of the CarePlix Vitals app and the reference instrument. The black solid line shows the average difference between the measurements of the CarePlix Vitals app and the reference instrument. The two dashed lines show the average difference's 95% confidence interval limits.

The average difference is -2.3 and the average difference's 95% confidence interval is [-10, 5.5].

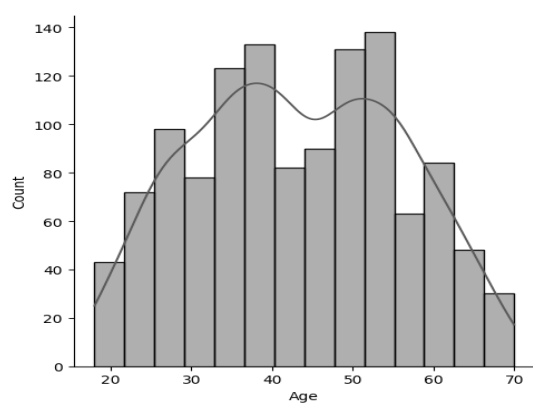
## Respiration Rate (RR) Analysis

### Participant Distribution

The RR trial encompassed both Android and iOS devices, with a total of 597 participants.



**Figure 12.** RR participant distribution by gender



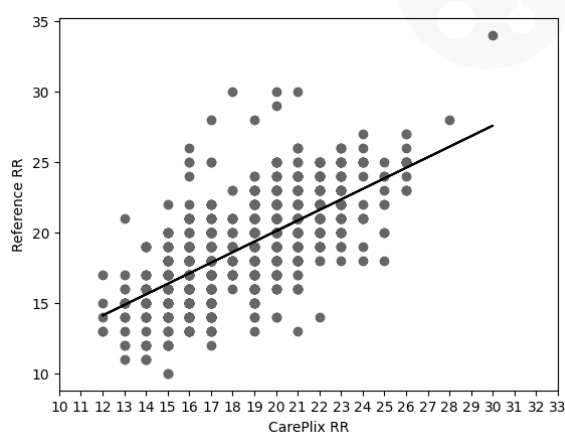
**Figure 13.** RR participant distribution by age

### Accuracy Analysis

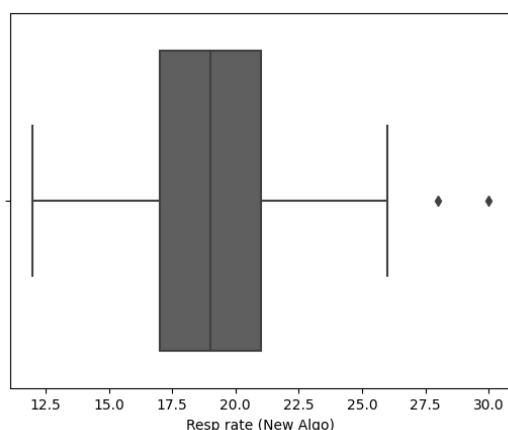
To calculate the accuracy, we found the following values:

RMSE	SD	MAE	Confidence ( $\alpha = 0.05$ )	CI 95%	MAE $\pm$ SD
2.45	1.54	1.90	0.087	[ 1.813, 1.987 ]	1.90 $\pm$ 1.54

**Table 2.** RR RMSE, SD, MAE Confidence, and Confidence Interval with a significance level of 0.05

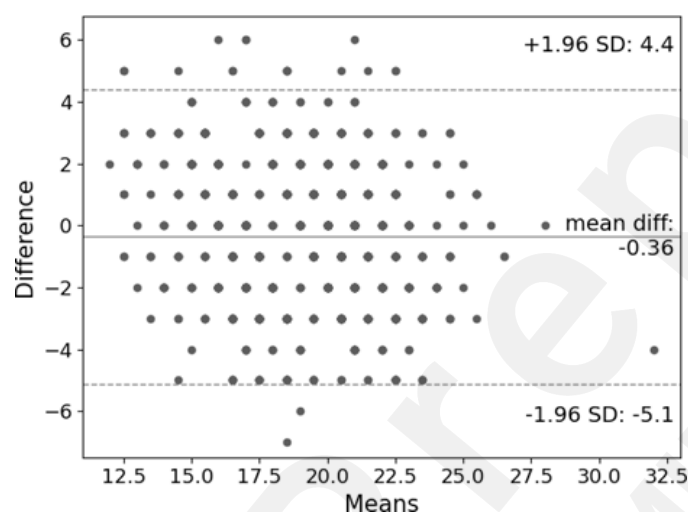


**Figure 14.** Scattered plot of Reference RR vs. RR readings of the CarePlix app



**Figure 15.** Box plot of CarePlix RR readings

## Bland-Altman Plot and Analysis



**Figure 16.** Bland-Altman plot for RR

The Bland-Altman plot's x-axis shows the CarePlix Vitals app's and reference instrument's average measurements. The y-axis shows the variance amid the measurements of the CarePlix Vitals app and the reference instrument. The black solid line shows the average difference between the measurements of the CarePlix Vitals app and the reference instrument. The two dashed lines show the average difference's 95% confidence interval limits.

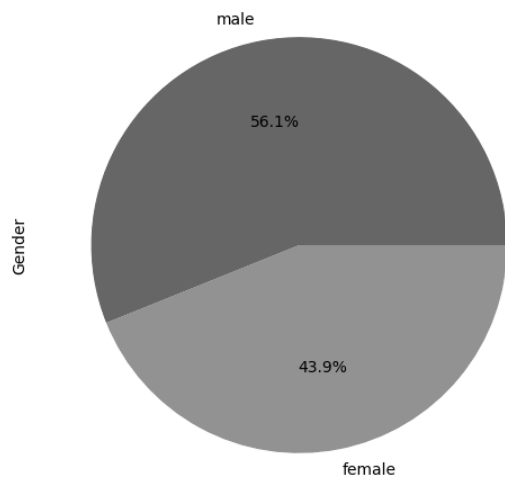
The average difference is -0.36 and the average difference's 95% confidence interval is [-5.1, 4.4].

## Heart Rate Variability (HRV) Analysis

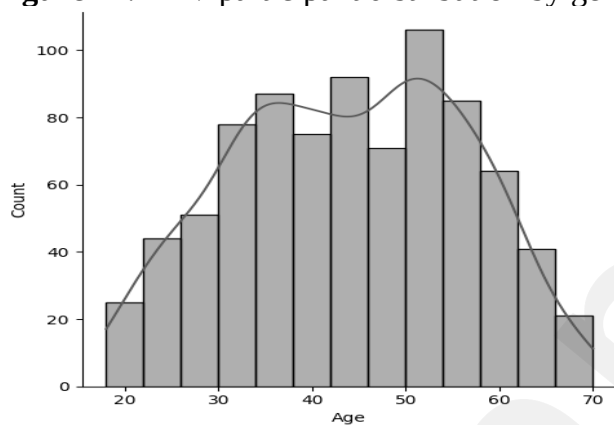
### Participant Distribution

The HRV trial encompassed both Android and iOS devices, with a total of 476 participants.





**Figure 17.** HRV participant distribution by gender



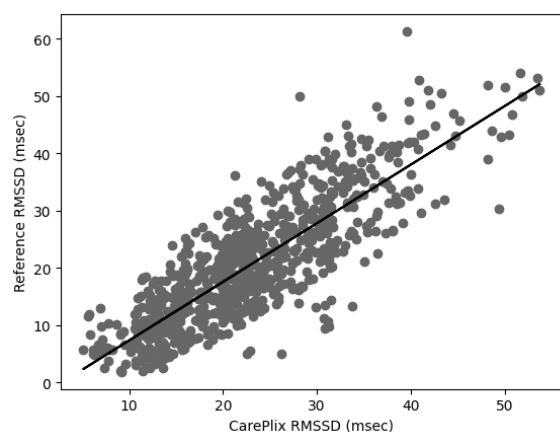
**Figure 18.** HRV participant distribution by age

### Accuracy Analysis: RMSSD

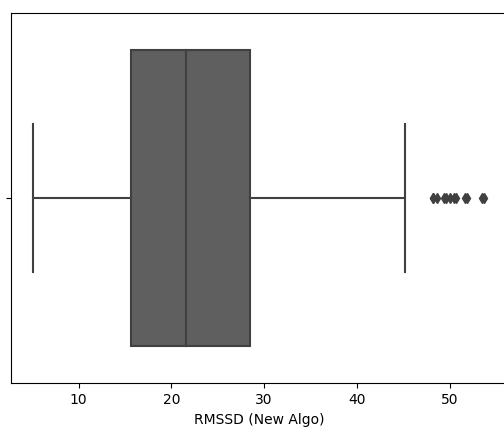
To calculate the accuracy, we found the following values:

RMSE	SD	MAE	Confidence ( $\alpha = 0.05$ )	CI 95%	MAE $\pm$ SD
6.41	3.78	5.17	0.256	[ 4.914, 5.426 ]	5.17 $\pm$ 3.78

**Table 3.** RMSSD RMSE, SD, MAE Confidence, and Confidence Interval with a significance level of 0.05

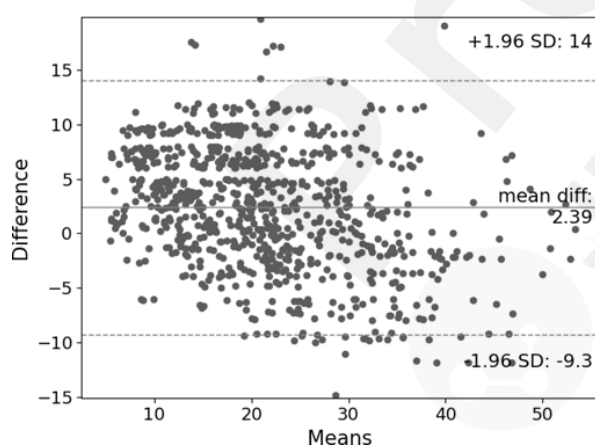


**Figure 19.** Scattered plot of Reference RMSSD vs. RMSSD readings of CarePlix app



**Figure 20.** Box plot of CarePlix RMSSD readings

## Bland-Altman Analysis and Plot: RMSSD



**Figure 21.** Bland-Altman plot for RMSSD

The Bland-Altman plot's x-axis shows the Careplix Vitals app's and reference instrument's average measurements. The y-axis shows the variance amid the measurements of the Careplix Vitals app and the reference instrument. The black solid line shows the average difference between the measurements of the Careplix Vitals app and the reference instrument. The two dashed lines show the average difference's 95% confidence interval limits.

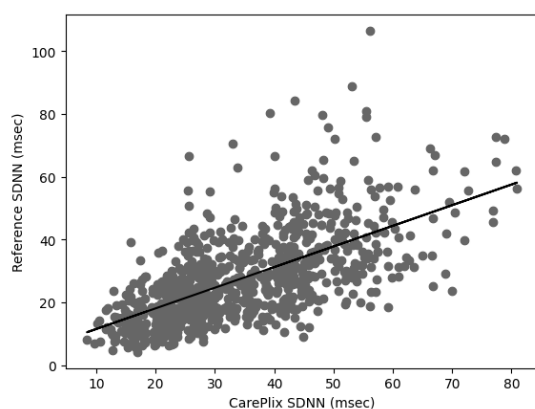
The average difference is 2.39 and the average difference's 95% confidence interval is [-9.3, 14].

## Accuracy Analysis: SDNN

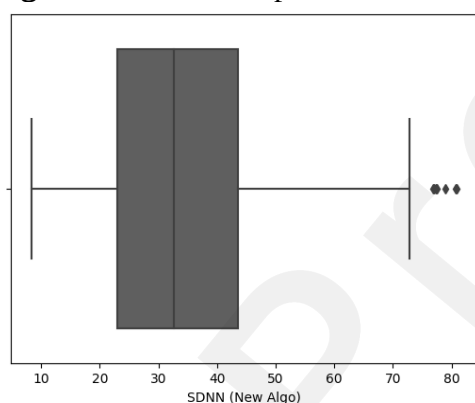
To calculate the accuracy, we found the following values:

RMSE	SD	MAE	Confidence ( $\alpha = 0.05$ )	CI 95%	MAE $\pm$ SD
13.74	8.47	10.82	0.573	[ 10.247, 11.393 ]	10.82 $\pm$ 8.47

**Table 4.** SDNN RMSE, SD, MAE Confidence & Confidence Interval with a significance level of 0.05

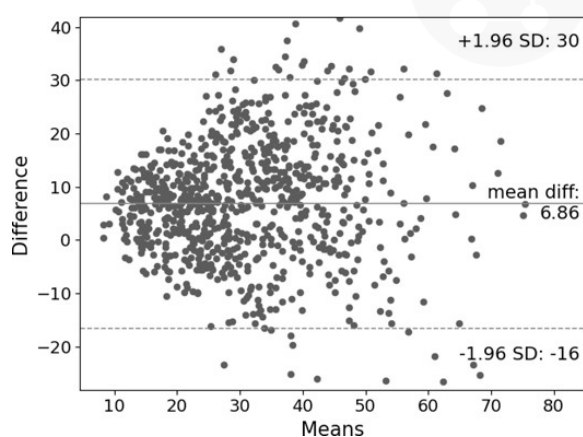


**Figure 22.** Scattered plot of Reference SDNN vs. SDNN readings of the CarePlix app



**Figure 23.** Box plot of CarePlix SDNN readings

## Bland-Altman Analysis and Plot: SDNN



**Figure 24.** Bland-Altman plot for SDNN

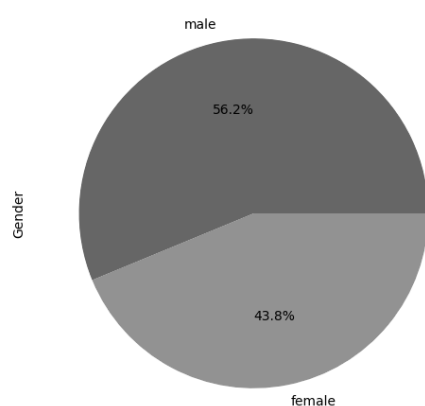
The Bland-Altman plot's x-axis shows the Careplix Vitals app's and reference instrument's average measurements. The y-axis shows the variance amid the measurements of the Careplix Vitals app and the reference instrument. The black solid line shows the average difference between the measurements of the Careplix Vitals app and the reference instrument. The two dashed lines show the average difference's 95% confidence interval limits.

The average difference is 6.86 and the average difference's 95% confidence interval is [-16, 30].

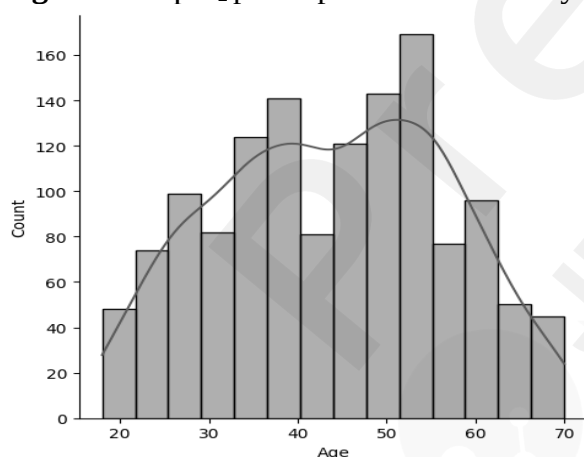
## Oxygen Saturation (SpO<sub>2</sub>) Analysis

### Participant Distribution

The SpO<sub>2</sub> trial encompassed both Android and iOS devices, with a total of 610 participants.



**Figure 25.** SpO<sub>2</sub> participant distribution by gender



**Figure 26.** SpO<sub>2</sub> participant distribution by gender

## Accuracy Analysis

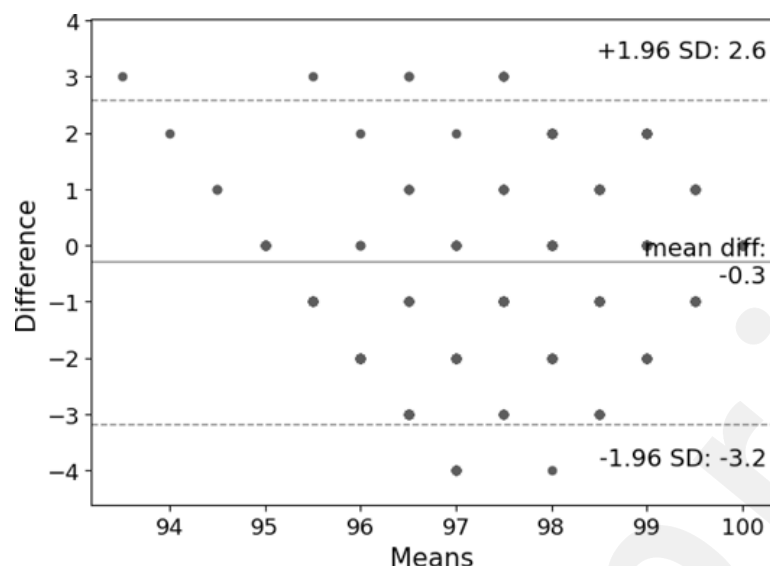
To calculate the accuracy, we found the following values:

RMSE	SD	MAE	Confidence ( $\alpha = 0.05$ )	CI 95%	MAE $\pm$ SD
------	----	-----	--------------------------------	--------	--------------

1.5	0.98	1.13	0.052	[ 1.078, 1.182 ]	1.13 ± 0.98
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**Table 5.** SpO<sub>2</sub> RMSE, SD, MAE Confidence & Confidence Interval with significance level of 0.05

### Bland-Altman Plot and Analysis



**Figure 27.** Bland-Altman plot for SpO<sub>2</sub>

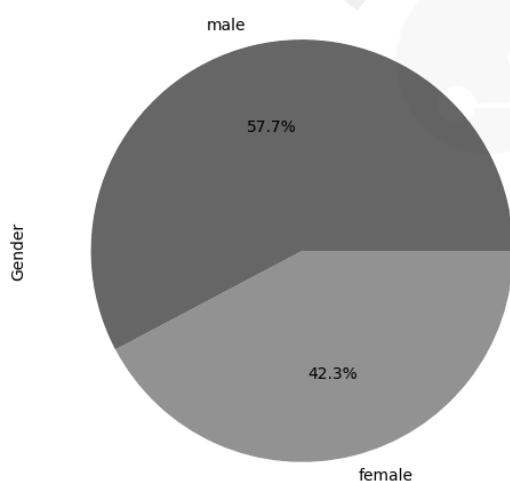
The Bland-Altman plot's x-axis shows the Careplix Vitals app's and reference instrument's average measurements. The y-axis shows the variance amid the measurements of the Careplix Vitals app and the reference instrument. The black solid line shows the average difference between the measurements of the Careplix Vitals app and the reference instrument. The two dashed lines show the average difference's 95% confidence interval limits.

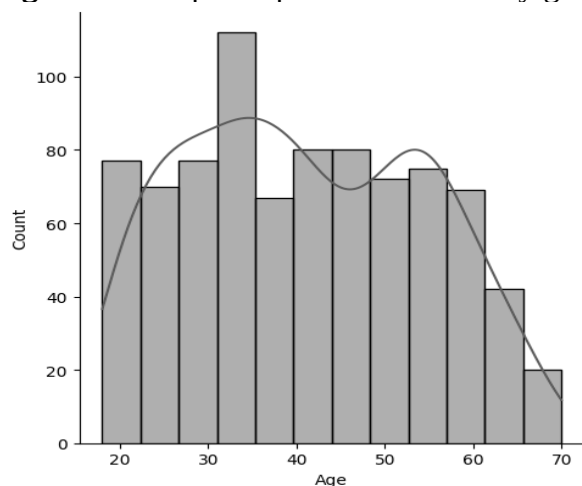
The average difference is -0.3 and the average difference's 95% confidence interval is [-3.2, 2.6].

### Blood Pressure (BP) Analysis

#### Participant Demographics

The BP trial encompassed both Android and iOS devices, with a total of 433 participants.

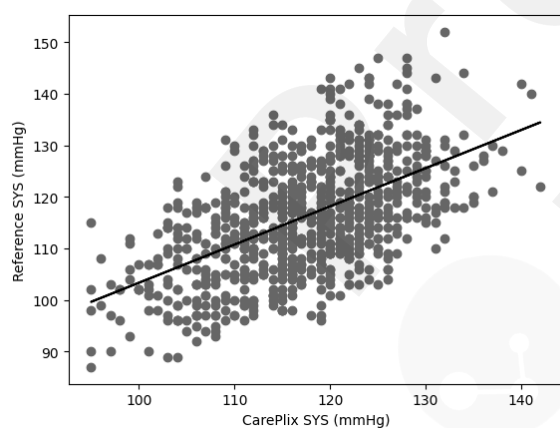


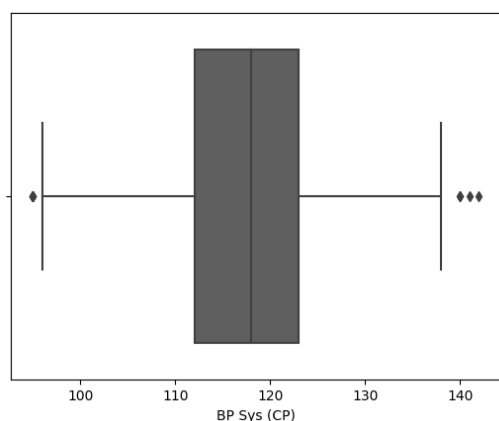
**Figure 28.** BP participant distribution by gender**Figure 29.** BP participant distribution by age

### Accuracy Analysis: Systolic Blood Pressure (SYS)

To calculate the accuracy, we found the following values:

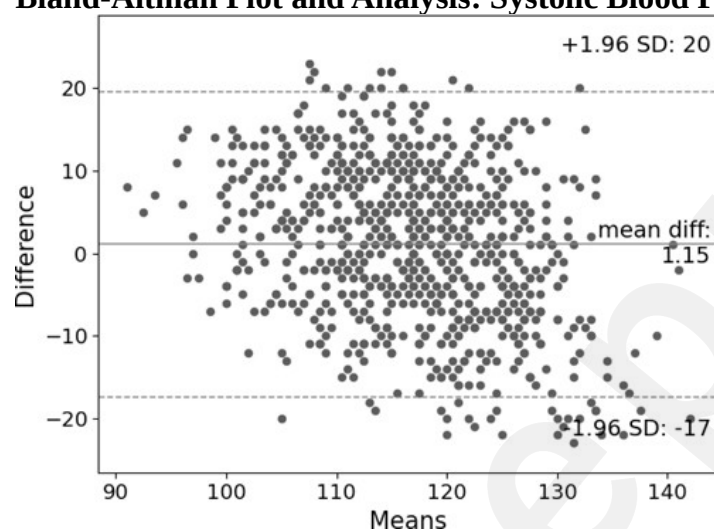
RMSE	SD	MAE	Confidence ( $\alpha = 0.05$ )	CI 95%	MAE $\pm$ SD
9.49	5.31	7.87	0.359	[7.511, 8.229]	7.87 $\pm$ 5.31

**Table 6.** SYS RMSE, SD, MAE Confidence & Confidence Interval with a significance level of 0.05**Figure 30.** Scattered plot of Reference SYS vs. SYS readings of the CarePlix app



**Figure 31.** Box plot of CarePlix SYS readings

### Bland-Altman Plot and Analysis: Systolic Blood Pressure (SYS)



**Figure 32.** Bland-Altman plot for SYS

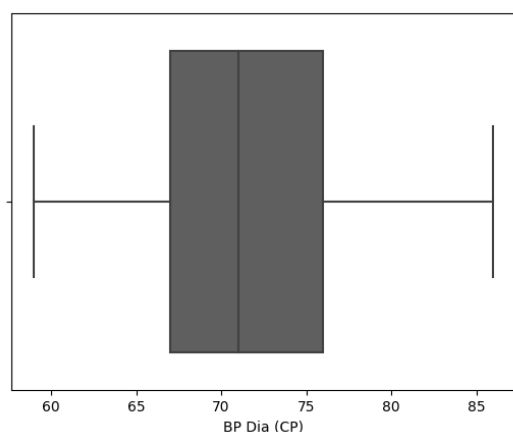
The Bland-Altman plot's x-axis shows the Careplix Vitals app's and reference instrument's average measurements. The y-axis shows the variance amid the measurements of the Careplix Vitals app and the reference instrument. The black solid line shows the average difference between the measurements of the Careplix Vitals app and the reference instrument. The two dashed lines show the average difference's 95% confidence interval limits.

The average difference is 1.15 and the average difference's 95% confidence interval is [-17, 20].

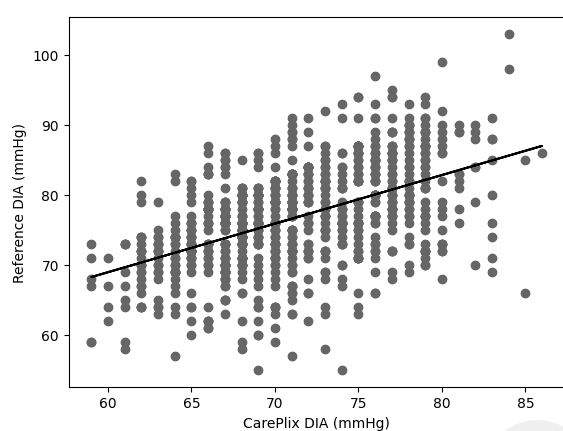
**Accuracy Analysis: Diastolic Blood Pressure (DIA)**

RMSE	SD	MAE	Confidence ( $\alpha = 0.05$ )	CI 95%	MAE $\pm$ SD
8.69	4.63	7.35	0.313	[7.037, 7.663]	7.35 $\pm$ 4.63

**Table 7.** DIA RMSE, SD, MAE Confidence & Confidence Interval with significance level of 0.05

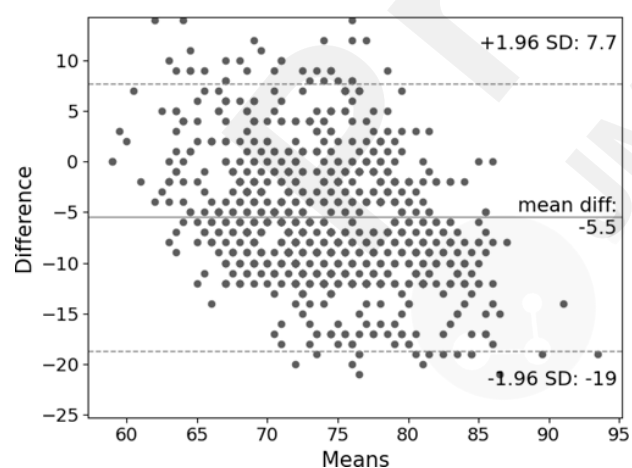


**Figure 33.** Scattered plot of Reference DIA vs. DIA readings of the CarePlix app



**Figure 34.** Box plot of CarePlix DIA readings

### Bland-Altman Analysis and Plot: Diastolic Blood Pressure (DIA)



**Figure 35.** Bland-Altman plot for DIA

The Bland-Altman plot's x-axis shows the CarePlix Vitals app's and reference instrument's average measurements. The y-axis shows the variance amid the measurements of the CarePlix Vitals app and the reference instrument. The black solid line shows the average difference between the measurements of the CarePlix Vitals app and the reference instrument. The two dashed lines show the average difference's 95% confidence interval limits.

The average difference is -5.5 and the average difference's 95% confidence interval is [-19, 7.7].



## Discussion:

### Results

In measuring vital signs, CarePlix Vitals has an accuracy level of 98.56% (AE≤10 bpm) for HR, 98.18% (AE≤5 breaths/min) for RR, 98.14% (AE≤3 %) for SpO<sub>2</sub>, 91.20% (AE≤15 mmHg) for systolic BP, 89.89% (AE≤12 mmHg) for diastolic BP, 97.85% (AE≤12 msec) for RMSSD and 92.62% (AE≤25 msec) for SDNN measurements. Our findings demonstrate promising results for smartphone PPG-based vital signs measurements in the adult population. These results propose that a CarePlix app originating vitals from a photoplethysmography signal could be used as a different for already authenticated methods such as a pulse oximeter, digital blood pressure, and polar belt in an adult people in latent sinus rhythm.

### Limitations

While this study contributes valuable insights into the accuracy and reliability of CarePlix Vitals for smartphone-based vital signs monitoring, several limitations warrant consideration. These limitations may influence the interpretation of the results and offer directions for future research and development.

The study was confined to specific smartphone models and camera specifications. Variability in hardware and features among different devices could impact the consistency and accuracy of measurements when applied to other smartphones. Factors such as fluctuating lighting conditions, involuntary participant movement, or unstable positioning of the fingertip on the camera might introduce noise into the photoplethysmography signals, potentially impacting measurement accuracy.

Skin type can introduce potential errors to the measurements of PPG devices. Melanin absorbs green light, which could lead to higher measurement errors in individuals with darker skin than in individuals with lighter skin [9]. While the Fitzpatrick Skin Type Scale is currently regarded as the benchmark standard [10], concerns exist regarding perceived racial biases, limited correlation with skin color, and significant distinctions in skin tone within individual groups. An approach that has emerged as a viable alternative is spectroradiometry, a methodology utilizing multiple factors to objectively classify skin tone [10]. Its incorporation into later studies may yield further validation of our findings. The precision of the CarePlix algorithms is anticipated to enhance as data collection continues.

### Implications

Within the Bland Altman plot, a strong agreement is seen between the actual and expected measurements. The narrow limits of agreement and minimal bias suggest that the CarePlix Vitals app's measurements are accurate when compared to those of gold-standard devices.

### Conclusion

The analysis states that the CarePlix Vitals readings against the reference readings are highly correlated and it rejects the null hypothesis.

This meta-analysis suggests that vital signs measurements by the CarePlix Vital app agree with measurements of validated, gold-standard devices in an adult population. This is provided that during measurement, the measuring point remains motionless, and the appropriate reading is maintained. In a routine application setting, users could administer the CarePlix Vitals app's finger scan individually and independently from clinical representatives.

The use of the Careplix Vitals app is currently not supported in a pediatric population. Future studies should be conducted with a larger and more diverse study population. It is further recommended that the Careplix Vitals app be tested in a wider range of clinical scenarios that include fluctuations in a normal heart rate and during arrhythmias.

## Acknowledgements

Lauren Flowers, BA provided writing and editing assistance to the study.

## Conflicts of Interest

Subhabrata Paul and Insha Moin serve as authors of this article. Insha Moin serves as a Clinical and Compliance Associate and has been involved in coordinating the clinical trials of the non-invasive methodology for detection of vital signs described herein. Subhabrata Paul is the Head of Research and Development, and the Chief Information Officer of CarePlix-CareNow Healthcare Pvt Ltd. As employees of CarePlix-CareNow Healthcare Pvt Ltd, they may have a vested interest in the success of the methodology. However, the authors declare that these potential conflicts of interest did not influence the design, conduct, analysis, or reporting of the research findings presented in this article. The data analysis and interpretation were conducted impartially, and the conclusions drawn are based solely on the results obtained from the clinical trials.

## Abbreviations

AC: alternating current

AE: absolute error

AI: artificial intelligence

BP: blood pressure

BPM: beats per minute

CI: confidence interval

DC: direct current

DIA: diastolic blood pressure

FFT: Fast Fourier Transform

HR: heart rate

HRV: heart rate variability

LED: light-emitting diode

MAE: mean absolute error

PPG: photoplethysmography

PPI: peak-to-peak intervals

RMSE: root mean square error

RMSSD: root mean square of successive differences

RR: respiration rate

SEM: standard error of the mean

SD: standard deviation

SDNN: standard deviation of NN intervals

SpO<sub>2</sub>: oxygen saturation

SYS: systolic

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