Blood Pressure Validation

Introduction

The heart pumps the blood through the blood vessels to all parts of the body. **Blood Pressure (BP)** is generated by the force of blood pushing against the walls of the arteries. It is measured in millimeters of mercury (mmHg) and is recorded as two numbers: systolic BP, the highest pressure (normal range 90-130 mmHg) in blood vessels (when the heart contracts), and diastolic BP, the lowest pressure (normal range 60-90 mmHg) in blood vessels (when the heart muscle relaxes). [1,2]

Hypertension, also known as high or raised BP, is a condition in which the blood vessels have persistently raised pressure. Elevated BP is the most important risk factor for death and disability worldwide, affecting more than one billion individuals and causing an estimated 9.4 million deaths every year. [1,2]

As the importance of ambulatory BP has been stressed in many recent studies, it can be deduced that while continuous monitoring is required in daily life for accurate diagnosis of BP and cardiovascular health, the conventional cuff-based method is not practical due to its inconvenient and cumbersome nature. [3–5]

PPG (photoplethysmography) is a non-invasive, simple and low-cost tool that can reflect blood flow in blood vessels and blood volume changes. The PPG waveform comprises a pulsatile ('AC') physiological waveform attributed to blood volume changes with each heartbeat and is superimposed on a slowly varying ('DC') baseline with various lower frequency components attributed to respiration, sympathetic nervous system activity, and thermoregulation. The PPG technology has been used in a wide range of commercially available medical devices for measuring blood pressure, oxygen saturation, cardiac output, and for assessing autonomic function. [6] Camera-based approaches make it possible to derive remote PPG (rPPG) signals, and therefore enable a non-invasive measurement of BP. Various methods relying on machine learning techniques have recently been published [for example: [3,7,8]].

QuickVitals BP algorithm uses the photoplethysmography (PPG) signal recorded from facial skin tissue (rPPG). The algorithm extracts face video images, produces a rPPG signal, analyzes the data using AI, and provides the end user with BP measurements in real time.

This report describes the results of a validation experiment, that compares QuickVitals BP measurements with the measurements of an accurate reference device.

Methods

QuickVitals systolic and diastolic BP estimations were compared to the BP monitor, Withings BMP Connect, in healthy participants.

Measurement set-up:
Participants were instructed to sit as stably as possible in front of a mobile device camera. A Withings BMP Connect monitor was used as a reference. The BMP Connect cuff was placed around each participant's arm, at heart level, and BP was measured before and after the recording sessions. Two consecutive BP measurements were taken before and after QuickVitals app recordings. If the difference between the two measurements exceeded 10 mmHg for systolic or 5 mmHg for diastolic BP, a third measurement was taken. Recordings were conducted in a testing room located inside QuickVitals office, with controlled and fixed artificial ambient light.

A mobile device was placed on a stand in front of each participant. The participant's face filled over 20% of the frame's area (distance of 30-40 cm) and positioned in the center of frame. The camera was set at the level of forehead and positioned perpendicular to the face. Participants were instructed to look at the screen throughout the entire recording. Each recording lasted approximately 60 seconds.

Statistical analysis:
Accuracy was calculated using the following parameters:

$$AE\ (Absolute\ Error) = App_i - Ref_i$$

$$RMSE = \sqrt{\frac{\sum_{i=1}^{N}(App_i - Ref_i)^2}{N}}$$

$$MAE = \frac{1}{N}\sum_{i=1}^{N}|App_i - Ref_i|$$

When,
N is the number of data points.
App is the measurement of the QuickVitals application.
Ref is the measurement of the reference device.
i is the index number of the measurements.

Confidence intervals (CI) were calculated using the bootstrap method and indicate where the estimator (i.e., AE < 10mmHg) would fall, with 95% confidence, for future samples.

Participants with outlier AE (defined as 3 standard deviations or more above the mean) and participants with invalid reference device values were excluded from analysis.

For this report, the QuickVitals SDK 4.10.1 version was used.
The measurements were recorded by the mobile device models listed below.
iOS: iPhone 13 Pro.
Android: Pixel 6 Pro, Samsung S21 Ultra.

Results

Demographic Data:

Table 1 includes participants' demographic data for each operating system (iOS and Android).

Operating System	Number of Participants	Age Range (average)	Sex	Fitzpatrick Skin Tone *
iOS	60	21-77 (32)	F (53%), M (47%)	2 (41%), 3 (54%), 4 (6%)
Android	59	21-77 (32)	F (54%), M (46%)	2 (42%), 3 (53%), 4 (5%)

Table 1: Demographic data for experiments using phones with an iOS and Android operating systems.
* Fitzpatrick skin tone classifications are: 1- Pale white, 2- white, 3- Darker white, 4- Light brown, 5- Brown, 6- Dark brown or black.

Accuracy data:

Table 2 includes accuracy data for iOS and Android (RMSE, MAE±SD) for systolic and diastolic BP. The AE < 5, 10, 15 mmHg columns present the number (and percentage) of measurements with an absolute error, which is smaller than 5, 10, 15 mmHg respectively.

Operating System	Vital Signs	Number of measurements	RMSE	MAE±SD	AE < 5mmHg	AE < 10mmHg	AE < 15mmHg	AE < 10mmHg 95% CI
iOS	**SYS BP (mmHg)**	209	8	6.4±4.8	99 (47%)	166 (79%)	195 (93%)	[0.8, 0.9]
	DIA BP (mmHg)	205	5.1	4.3±2.9	138 (67%)	195 (95%)	204 (100%)	[0.9, 1.0]
Android	**SYS BP (mmHg)**	196	8.2	6.4±5.2	94 (48%)	155 (79%)	180 (92%)	[0.7, 0.9]
	DIA BP (mmHg)	194	5.4	4.3±3.1	124 (64%)	181 (93%)	194 (100%)	[0.9, 1.0]

Table 2: RMSE, MAE±SD, number of participants (and percentage) with AE < 5, 10, 15 mmHg, and AE < 10mmHg 95% CI for measurements using phones with an iOS and Android operating systems, when compared to the reference device. AE < 10mmHg 95% CI was calculated using the bootstrap method and is the range of % participants with an AE < 10mmHg in a confidence level of 95%. Abbreviations: RMSE - Root Mean Square Error, MAE -Mean Absolute Error, SD - Standard Deviation, AE – Absolute Error, CI - Confidence Intervals.

Pearson correlations between QuickVitals BP estimations versus Withings BMP Connect measurements were calculated and presented in **Figure 1**. Pearson correlation coefficients (R values) were high for both operating system (Android and iOS).
The Bland-Altman plots for comparison between measurements of the two methods (QuickVitals and the reference device) are presented in **Figure 2**.

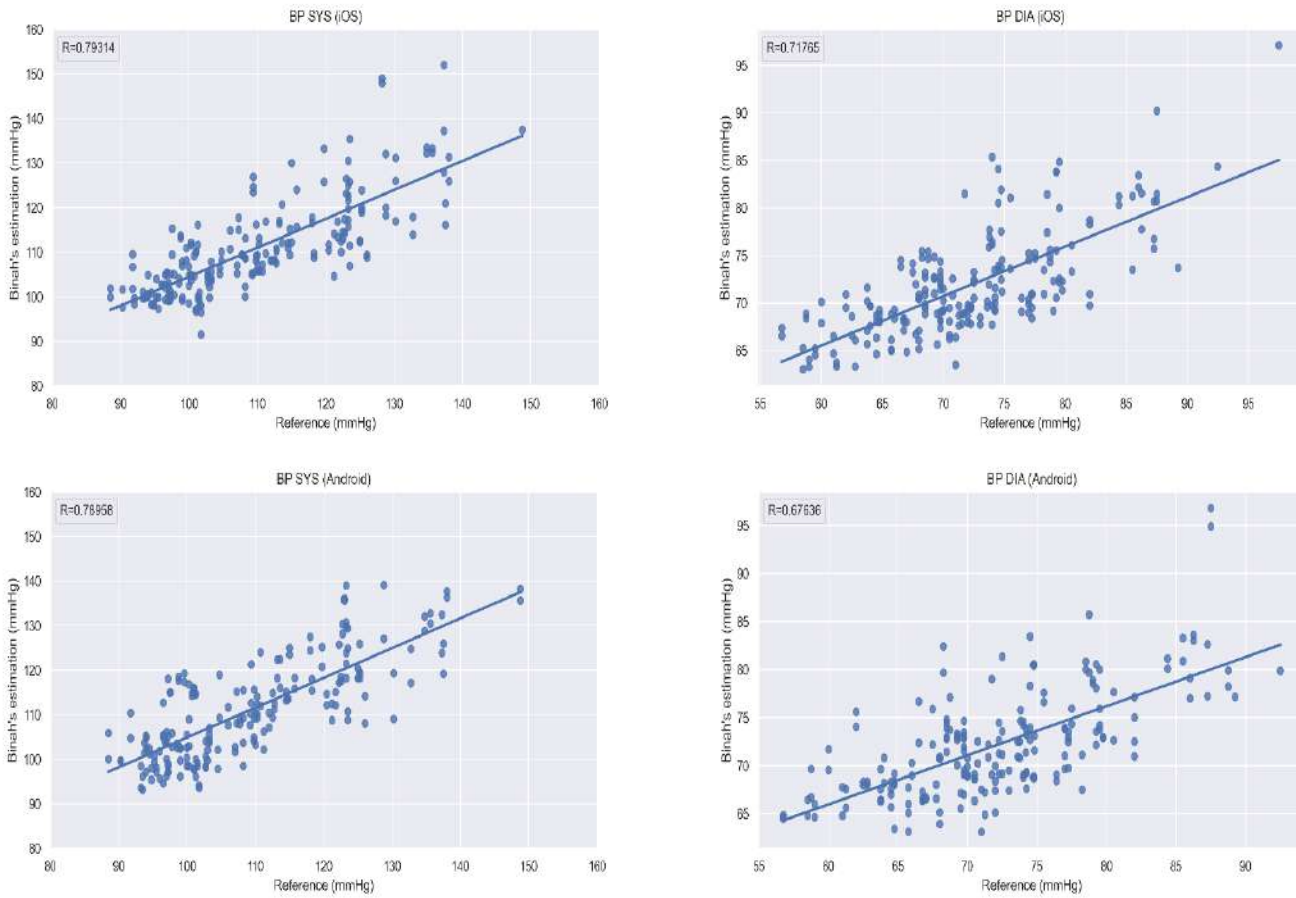

Figure 1: QuickVitals BP estimations for systolic (SYS) and diastolic (DIA) BP vs. reference device measurements. Pearson correlations were calculated and correlation coefficients are presented on each plot (R). Plots describe measurements conducted with both operating systems (iOS and Android).

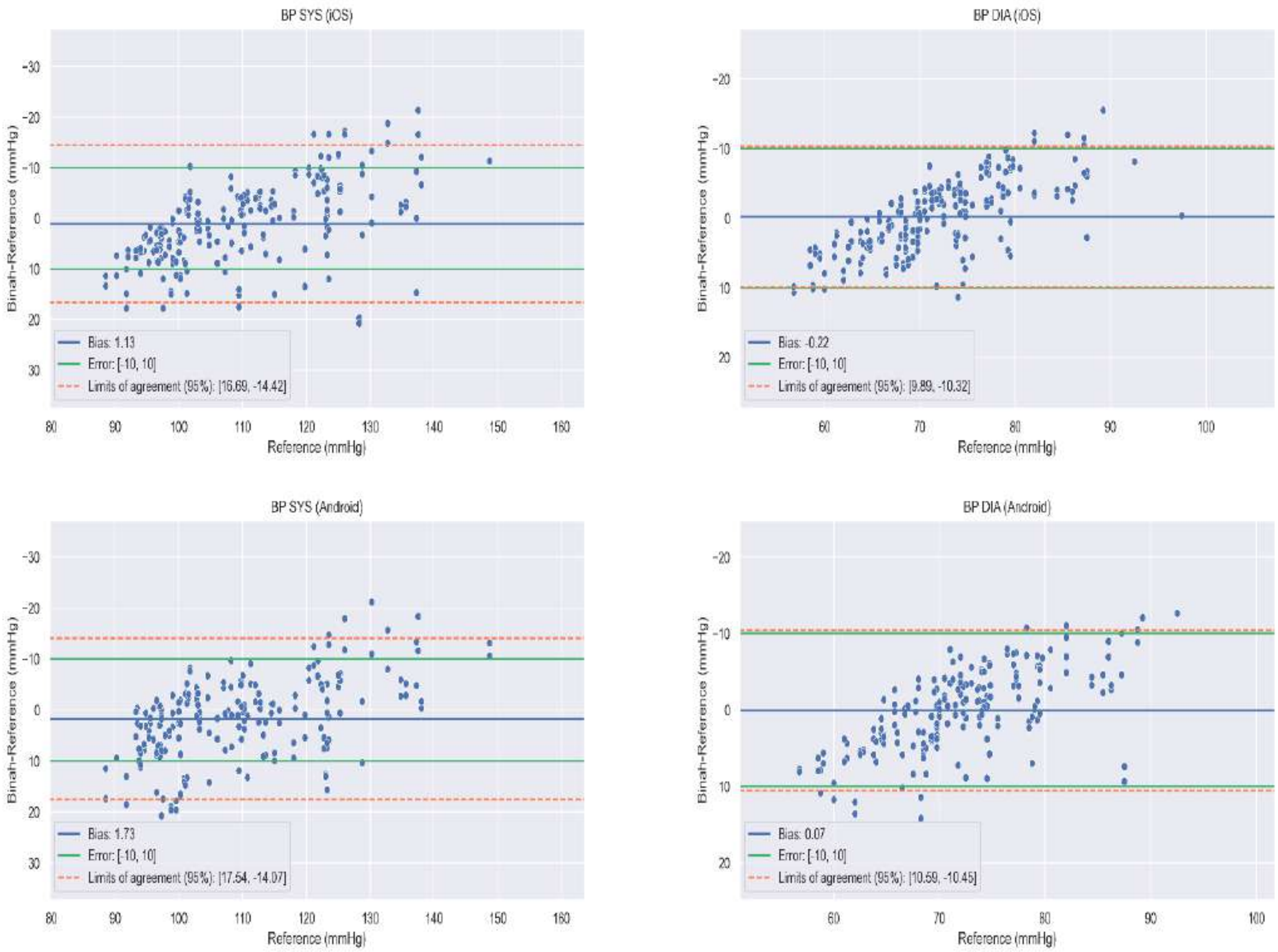

Figure 2: The Bland-Altman plots for systolic (SYS) and diastolic (DIA) BP measurements for comparison between measurements of the two methods (QuickVitals and the reference device). Plots describe measurements conducted with both operating systems (iOS and Android). The “Bias” line stands for the mean difference between measurements of QuickVitals and the reference device, the “Error” lines represent the value of the accuracy criterion, the “Limits of agreement” lines mark the limit of 95% of the samples.

Conclusions

This report summarizes the results of validation experiments in which QuickVitals BP measurements were found to be correlated with home blood pressure calf. BP measurements had an absolute error ≤10mmHg in 79% of systolic and 93-95% of diastolic values .

References

1. Ettehad D, Emdin CA, Kiran A, et al. Blood pressure lowering for prevention of cardiovascular disease and death: A systematic review and meta-analysis. Lancet. 2016;387(10022):957-967. doi:10.1016/S0140-6736(15)01225-8

2. Haldar RN. Global Brief on Hypertension: Silent Killer, Global Public Health Crisis. Indian J Phys Med Rehabil. 2013;24(1):2-2. doi:10.5005/ijopmr-24-1-2
3. Yang S, Sohn J, Lee S, Lee J, Kim HC. Estimation and Validation of Arterial Blood Pressure Using Photoplethysmogram Morphology Features in Conjunction with Pulse Arrival Time in Large Open Databases. IEEE J Biomed Heal Informatics. 2021;25(4):1018-1030. doi:10.1109/JBHI.2020.3009658
4. Pickering TG, Harshfield GA, Devereux RB, Laragh JH. What is the role of ambulatory blood pressure monitoring in the management of hypertensive patients? Hypertension. 1985;7(2):171-177. doi:10.1161/01.HYP.7.2.171
5. Verdecchia P, Porcellati C, Schillaci G, et al. Ambulatory blood pressure: An independent predictor of prognosis in essential hypertension. Hypertension. 1994;24(6):793-801. doi:10.1161/01.HYP.24.6.793
6. Allen J. Photoplethysmography and its application in clinical physiological measurement. Physiol Meas. 2007;28(3). doi:10.1088/0967-3334/28/3/R01
7. Schrumpf F, Frenzel P, Aust C, et al. Assessment of Non-Invasive Blood Pressure Prediction from PPG and rPPG Signals Using Deep Learning †. Published online 2021:19-25. doi:10.3390/s21186022
8. Sugita N, Yoshizawa M, Abe M, Tanaka A, Homma N, Yambe T. Contactless Technique for Measuring Blood-Pressure Variability from One Region in Video Plethysmography. J Med Biol Eng. 2019;39(1):76-85. doi:10.1007/s40846-018-0388-8
9. Quick Vitals is a exclusive licensed operator of Binah.ai