Blood Pressure Accuracy Report of SDK 5.9.1

Executive Summary

Goal

This document evaluates the accuracy of Blood Pressure in SDK 5.9 [iOS and Android] rPPG with reference devices, using data collected in India and Italy.

Results

The Blood Pressure (BP) measured by Binah's SDK met the accuracy target in a high percentage of cases. Specifically, systolic BP measurements were within the accuracy target (AE ≤ 15 mmHg in the 100–160 mmHg range) in 87.9% of cases, and diastolic BP measurements were within the accuracy target (AE ≤ 10 mmHg in the 60–100 mmHg range) in 82.9% of cases. These results were consistent across iOS and Android devices and under the following conditions (see Appendix):

- Both female and male participants
- All skin tones (Fitzpatrick I to VI)
- Participants aged 18 to 81
- BMI ranging from underweight to morbid obesity
- Varying distances from the participant's face (close and far)
- Different lighting conditions, from dim to bright surroundings
- Various face angles, from wide to narrow
- Similar performance across all devices used for recordings
- Comparable results in multiple countries with participants of diverse ethnicities

Conclusions

The Blood pressure measured by Binah's SDK was found to be within the accuracy target (AE≤15 mmHg for systolic and AE≤10 mmHg) for systolic in **87.9%** of diastolic and **82.9%** of diastolic measurements across both operating systems.

Introduction

The heart pumps 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. BP is measured in millimeters of mercury (mmHg) and is represented by two values: 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 often impractical due to its inconvenient and cumbersome nature. [3–5]

Photoplethysmography (PPG) 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. Recent studies have proposed various machine learning methods to improve BP estimation using rPPG signals [for example: [3,7,8]].

To address the need for continuous, non-invasive BP monitoring, Binah.ai's BP algorithm leverages PPG technology recorded from facial skin tissue (rPPG). The algorithm extracts face video images, produces an rPPG signal, analyzes the data with AI, and provides the end user with BP measurements in real-time.

This report describes the results of a validation experiment that compares Binah.ai's BP measurements with the measurements of an accurate reference device.

Methods

Binah's systolic and diastolic BP estimations were compared to Withings BMP Connect / Schiller / Air BP / Omron BP cuff in healthy participants .

Measurement set-up:

At all sites, each participant was instructed to sit as still as possible. Recordings took place in a controlled testing room, with fixed artificial ambient light.
The BP reference devices used included Withings BMP Connect, Schiller, Air BP and Omron BP cuff. The BP cuff was positioned on the participant's arm at heart level. BP was measured twice before and after the Binah app recordings. If the two measurements before or after differed by more than 10 mmHg for systolic BP or 5 mmHg for diastolic BP, a third measurement was taken.

For rPPG measurements, a mobile device was placed on a stand in front of the participant. Participants were positioned so that their face filled most of the camera frame (approximately 20–40 cm distance) and centered within the frame. The camera was set at the forehead's level and perpendicular to the face. Participants were instructed to look at the screen throughout the recording.
Participants were asked to remove their glasses, remain still, and avoid movement, including talking, and to sit still with their feet flat on the floor. Each recording lasted 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 Binah.ai's application.
Ref is the measurement of the reference device.
i is the index number of measurements.

For this report, Binah.ai's SDK 5.9 was compared to a reference device.
The measurements were recorded by the mobile device models listed below.

- iOS: iPhone 13 Pro, iPhone 13 Pro Max, iPhone 14, iPhone 14 Plus, iPhone 14 Pro Max.
- Android Pixel 6 Pro, Samsung S21 Ultra, Samsung S22 Ultra, Samsung S23 Ultra, Google Pixel 8a, OnePlus, Xiaomi 14 CIVI.

Results – Systolic BP

Measurement disposition

Number of subjects/measurements with reported systolic blood pressure: 457/761

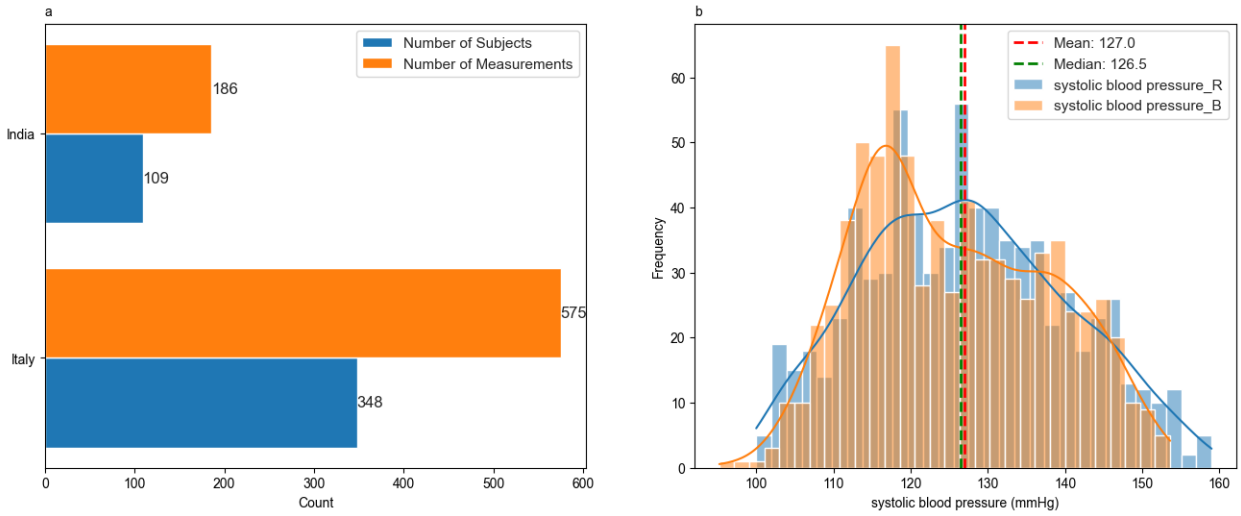

Figure 1:

a. **Number of Unique Subjects and Measurements (with reference values) for each country.**
b. **Distribution of systolic blood pressure measured by reference device and Binah.ai's application.** The mean and median lines are calculated for the reference values.

Demographics Data:

Subjects/Measurements	Age (mean ± std)	BMI (mean ± std)	Sex (F/M)	
457/ 761	54.5 ± 14.2	27.6 ± 5.4	234 / 223	
Fitzpatrick Skin Tone (I/II/III/IV/V/VI)	**Beard (No/Yes)**	**Glasses (No/Yes)**	**Face cream (No/Yes)**	
28 / 235 / 97 / 71 / 22 / 4	329 / 128	330 / 127	356 / 101	
Distance (mean ± std)	**Luminance (mean ± std)**	**Angle yaw (mean ± std)**	**Angle roll (mean ± std)**	**Angle pitch (mean ± std)**
0.27 ± 0.05	121.4 ± 85.6	4.9 ± 3.6	2.2 ± 1.7	7.3 ± 6.0

Table 1: Demographic data for experiments using the Binah.ai application

* Fitzpatrick skin tone classifications are I- Pale white, II- white, III- Darker white, IV- Light brown, V- Brown, VI- Dark brown or black.

Accuracy Data:

OS	Unique Subjects	Measurements	MAE±std	Measurements (%) of MAE ≤15	Ref Range
iOS	374	385	8.2 ± 5.2	86.5	100.0 - 160.0
Android	368	376	7.6 ± 5.2	89.1	100.0 - 160.0

Table 2: Accuracy data (MAE±STD) when Binah.ai's and the reference device's measurements are compared in the presented systolic blood pressure range (Ref range).
MAE - Mean Absolute Error, STD - Standard Deviation

Correlation and Bland-Altman plot by Operating System

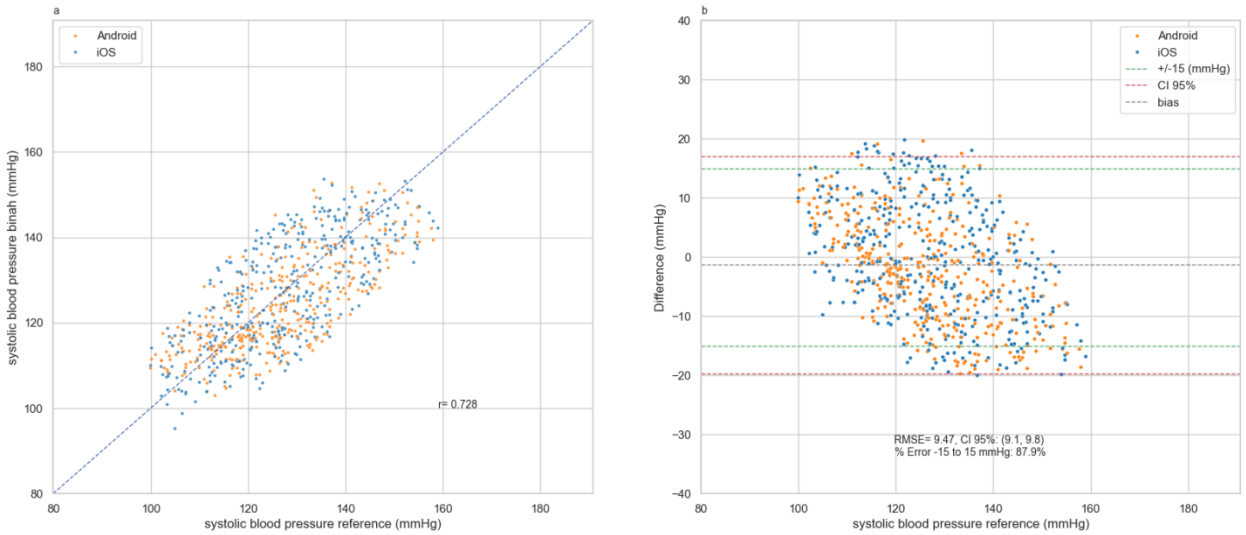

Figure 2:
a. Correlation plot by operating system - Binah.ai's systolic estimations versus reference device systolic measurements for both operating systems (Android and iOS). The correlation coefficient is R=0.728.
b. Bland-Altman plot by operating system - Bland-Altman plots for comparison between systolic measurements of the two methods (Binah's and the reference device) were within the target error in 87.9% of the measurements for both operating systems (Android and iOS) in the presented BP (systolic) range.

The "Bias" gray dashed line stands for the mean difference between measurements of Binah.ai and the reference device, the "Error" green dashed lines of ±3 bpm represent the value of the accuracy criterion, the "Limits of agreement" lines mark the limit of 95% of the samples.

Results - Diastolic BP

Measurement disposition

Number of subjects/measurements with reported diastolic blood pressure: 457/761

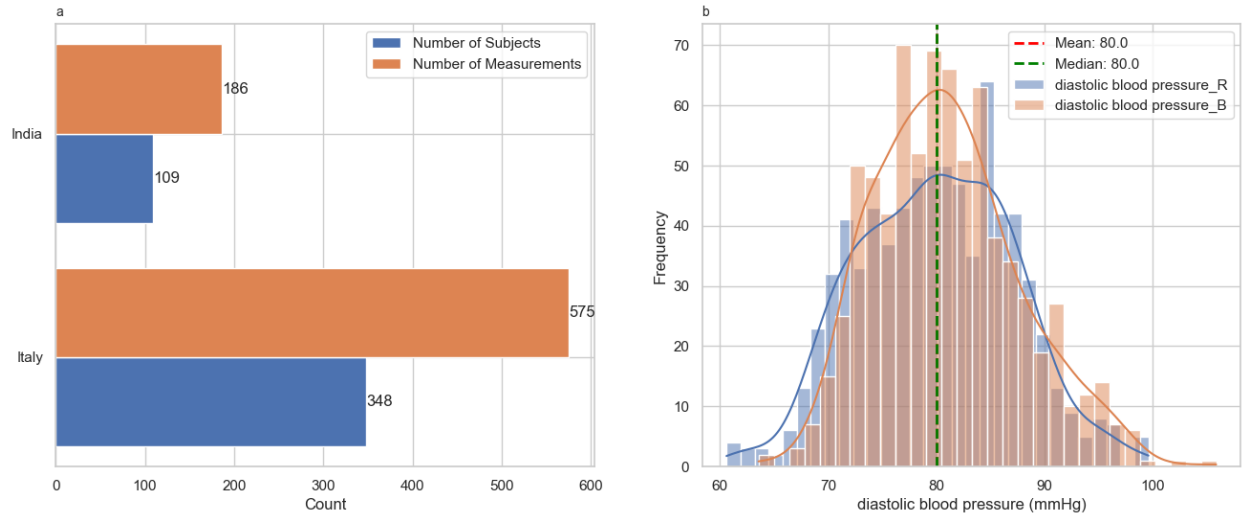

Figure 3:

a. Number of Unique Subjects and Measurements by Country data presented includes all measurements with reference values.

b. Distribution of diastolic BP measured by reference device and Binah.ai's application, both measurements present overlapped normal distribution.

Demographics Data:

Subjects/Measurements	Age (mean ± std)	BMI (mean ± std)	Sex (F/M)	
457/ 761	54.5 ± 14.2	27.6 ± 5.4	234 / 223	
Fitzpatrick Skin Tone (I/II/III/IV/V/VI)	**Beard (No/Yes)**	**Glasses (No/Yes)**	**Face cream (No/Yes)**	
28 / 235 / 97 / 71 / 22 / 4	329 / 128	330 / 127	356 / 101	
Distance (mean ± std)	**Luminance (mean ± std)**	**Angle yaw (mean ± std)**	**Angle roll (mean ± std)**	**Angle pitch (mean ± std)**
0.27 ± 0.05	121.4 ± 85.6	4.9 ± 3.6	2.2 ± 1.7	7.3 ± 6.0

Table 4: Demographic data for experiments using Binah.ai application.

* Fitzpatrick skin tone classifications are I- Pale white, II- white, III- Darker white, IV- Light brown, V- Brown, VI- Dark brown or black. ** Skin tone, beard, glasses, and face cream information does not exist for all subjects

Accuracy Data:

OS	Unique Subjects	Measurements	MAE±std	Measurements (%) of MAE ≤10	Ref Range
iOS	374	385	5.6 ± 3.6	84.4	60.0 - 100.0
Android	368	376	6.3 ± 3.9	81.4	60.0 - 100.0

Table 5: Accuracy data (MAE ± STD) when Binah.ai's and the reference device's measurements are compared in the presented diastolic blood pressure range (Ref range).

MAE - Mean Absolute Error, std - Standard Deviation

Correlation and Bland-Altman plot by Operating System

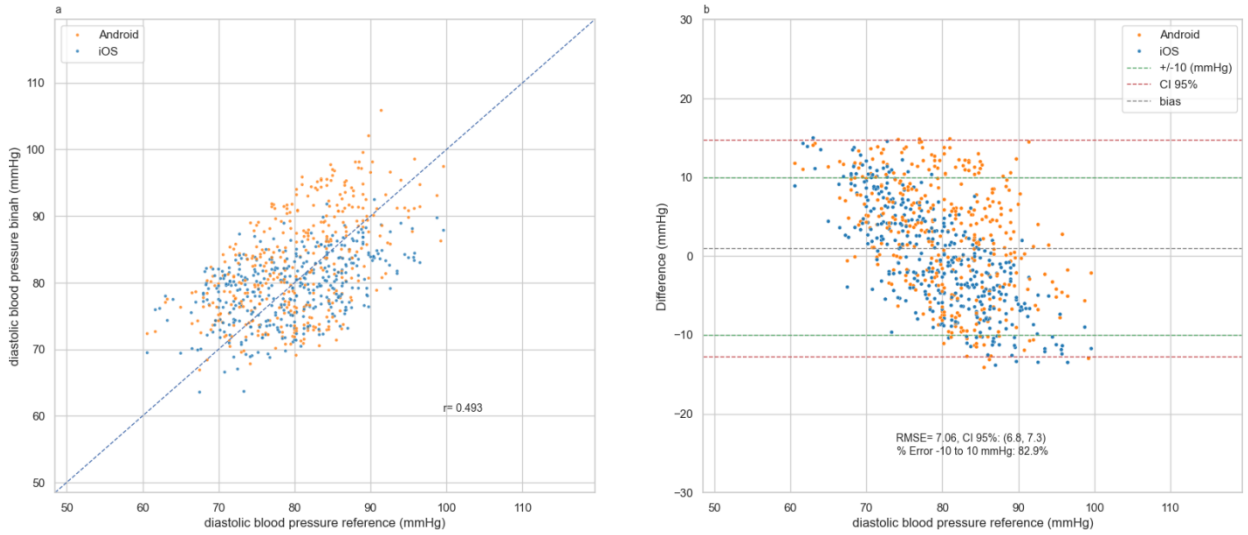

Figure 4:

a. Correlation plot by operating system - Binah.ai's diastolic estimations versus reference device systolic measurements for both operating systems (Android and iOS). The correlation coefficient is R=0.493.

b. Bland-Altman plot by operating system - Bland-Altman plots for comparison between diastolic measurements of the two methods (Binah's and the reference device) were within the target error in 82.9% of the measurements for both operating systems (Android and iOS) in the presented BP (diastolic) range.

The "Bias" gray dashed line stands for the mean difference between measurements of Binah.ai and the reference device, the "Error" green dashed lines of ±3 bpm 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 an accuracy analysis in which Binah.ai's BP measurements were found to correlate with measurements obtained from blood pressure cuffs. The Blood pressure measured by Binah's SDK was found to be within the accuracy target (AE≤15 mmHg for systolic and AE≤10 mmHg) for systolic in **87.9%** of diastolic and **82.9%** of diastolic measurements across both operating systems.

References

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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

Appendix

Systolic blood pressure error by Age and BMI

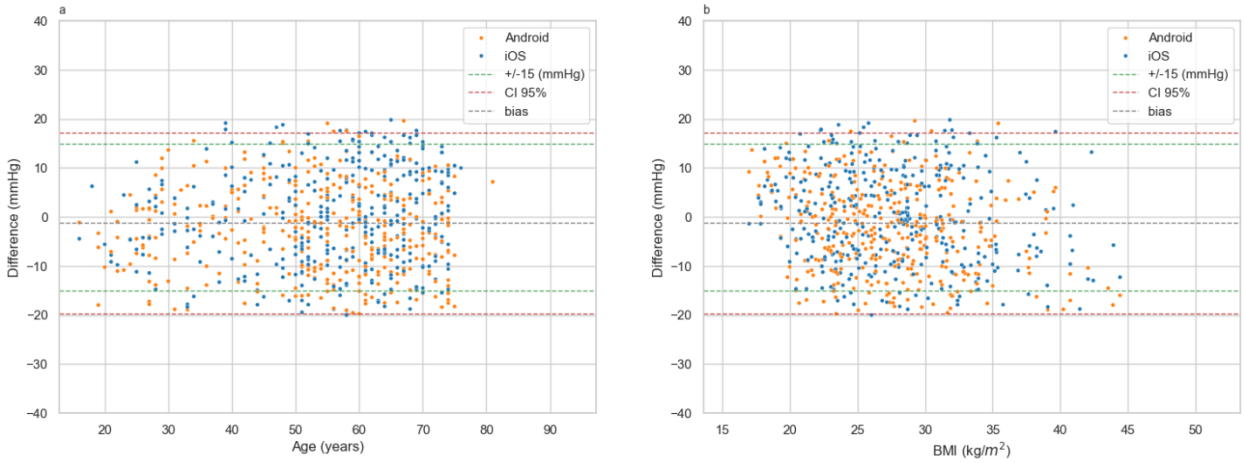

Figure 5:

a. Bland-Altman plot by age - demonstrated systolic measurements obtained by Binah.ai and the reference device for both operating systems (Android and iOS) within the presented AGE range from 18 to 81 years.

b. Bland-Altman plot by BMI - demonstrated systolic measurements obtained by Binah.ai and the reference device for both operating systems (Android and iOS) within the presented BMI range from low to very high.

The "Bias" gray dashed line stands for the mean difference between measurements of Binah.ai and the reference device, the "Error" green dashed lines of ±10 mmHg represent the value of the accuracy criterion, the "Limits of agreement" lines mark the limit of 95% of the samples.

Systolic Blood Pressure Error by Skin Tone with Gender and Operating System

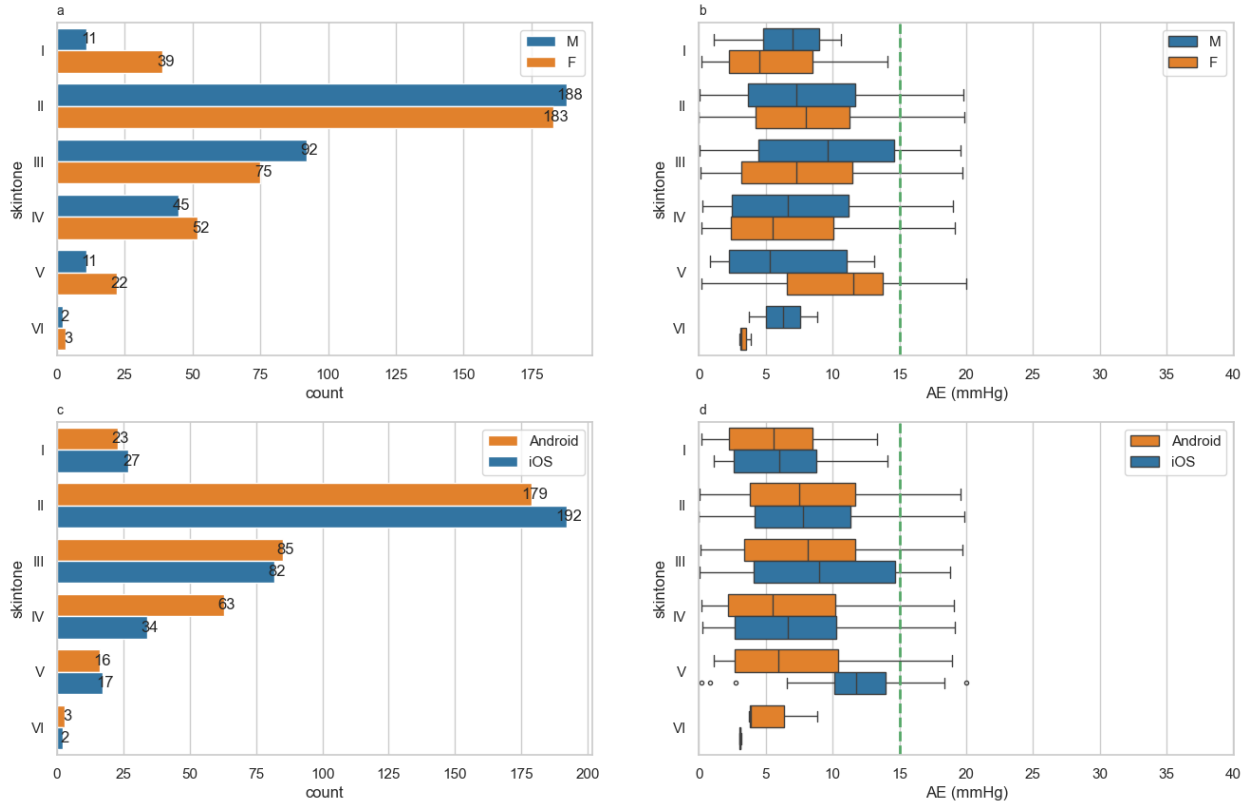

Figure 6:

a. Number of measurements by Fitzpatrick skin tone and sex (female and male).

b. Box plot by Fitzpatrick skin tone and Sex – Systolic blood pressure measurements obtained by Binah.ai in comparison to the reference device for both sexes (female and male) across all presented skin tones.

The green dashed "Error" lines set at ≤10 mmHg represent the value of the accuracy criterion.

c. Number of measurements by Fitzpatrick skin tone and operating system (Android and iOS).

d. Box plot by Fitzpatrick skin tone and operating system- Systolic blood pressure measurements obtained by Binah.ai versus the reference device for both operating systems (Android and iOS) across all presented skin tones.

The green dashed "Error" lines set at ≤10 mmHg represent the value of the accuracy criterion.

Systolic Blood Pressure Error by Distance and Luminance

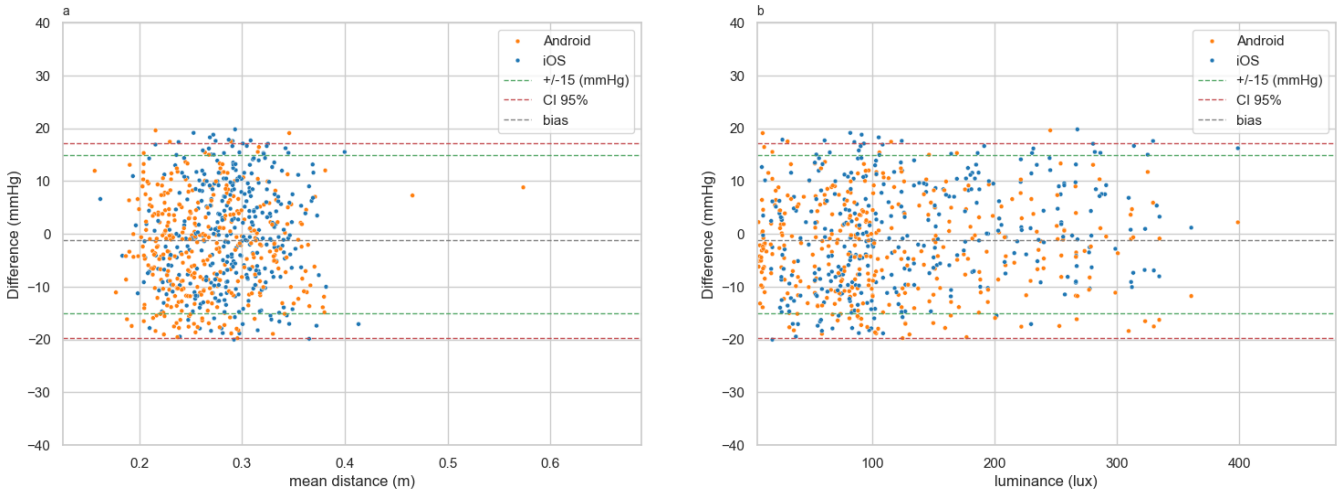

Figure 7:

a. Bland-Altman plot by Distance (m) - demonstrated systolic BP measurements obtained by Binah.ai and the reference device for both operating systems (Android and iOS) within the presented distance range between the camera and the subject's face.

b. Bland-Altman plot by Luminance (lux) - demonstrated systolic BP measurements obtained by Binah.ai and the reference device for both operating systems (Android and iOS) within the presented luminance range from dark surroundings (<150 lux) to brighter ones.

The "Bias" gray dashed line stands for the mean difference between measurements of Binah.ai and the reference device, the "Error" green dashed lines of ±10 mmHg represent the value of the accuracy criterion, the "Limits of agreement" lines mark the limit of 95% of the samples.

Systolic Blood Pressure Error by Face Angles

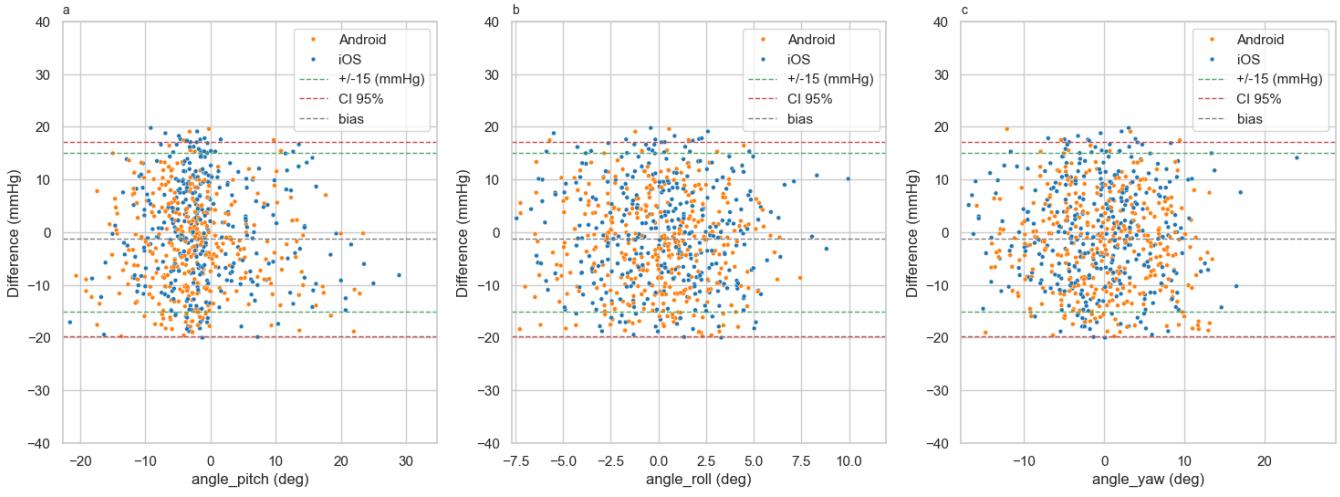

Figure 8:

a. **Bland-Altman plot by pitch angle (deg)** - demonstrated systolic BP measurements obtained by Binah.ai and the

reference device for both operating systems (Android and iOS) within the presented pitch angle range.
b. **Bland-Altman plot by roll angle (deg)** - demonstrated systolic BP measurements obtained by Binah.ai and the reference device for both operating systems (Android and iOS) within the presented roll angle range.
c. **Bland-Altman plot by yaw angle (deg)** - demonstrated systolic BP measurements obtained by Binah.ai and the reference device for both operating systems (Android and iOS) within the presented yaw angle range.

The "Bias" gray dashed line stands for the mean difference between measurements of Binah.ai and the reference device, the "Error" green dashed lines of ±10 mmHg represent the value of the accuracy criterion, the "Limits of agreement" lines mark the limit of 95% of the samples.

Systolic Blood Pressure Error by Devices

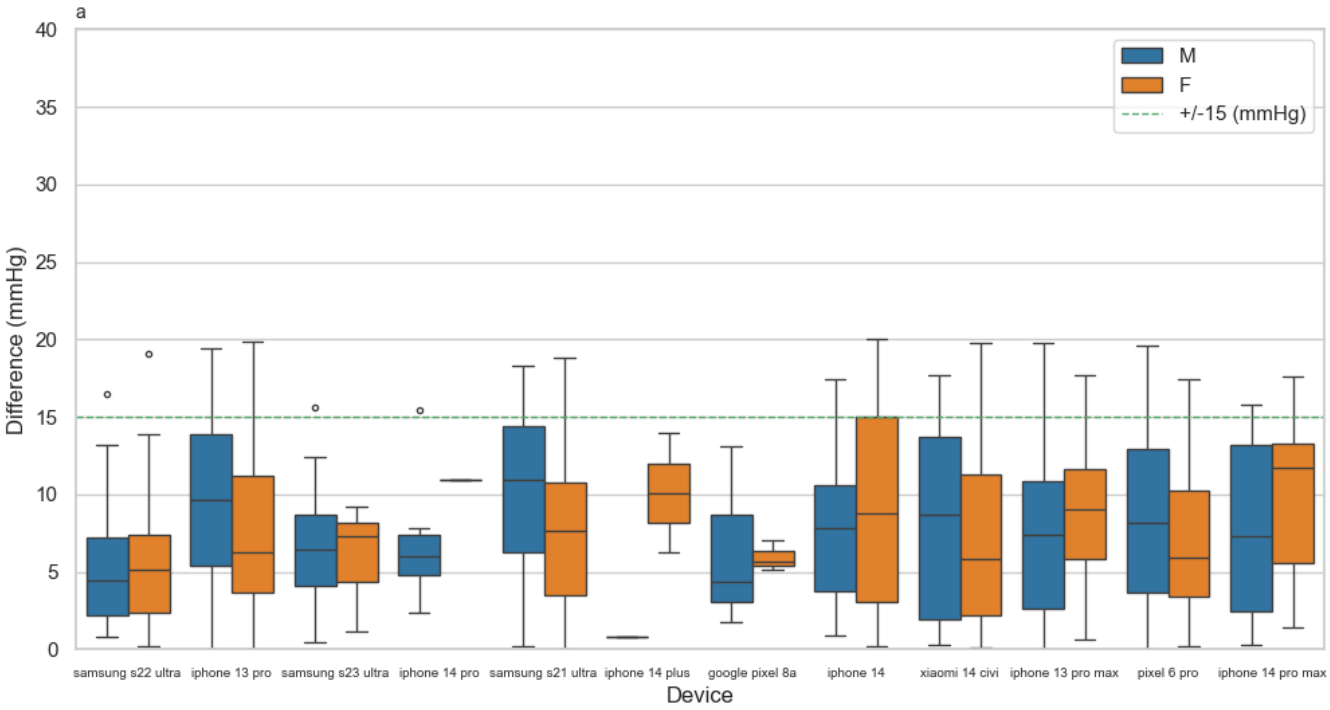

Figure 9:
a. Box plot by device – Systolic BP measurements obtained by Binah.ai versus the reference device for both sexes (female and male) on all devices.

The green dashed "Error" lines set at ≤10 mmHg represents the value of the accuracy criterion.

Systolic Blood Pressure Error by Country by OS

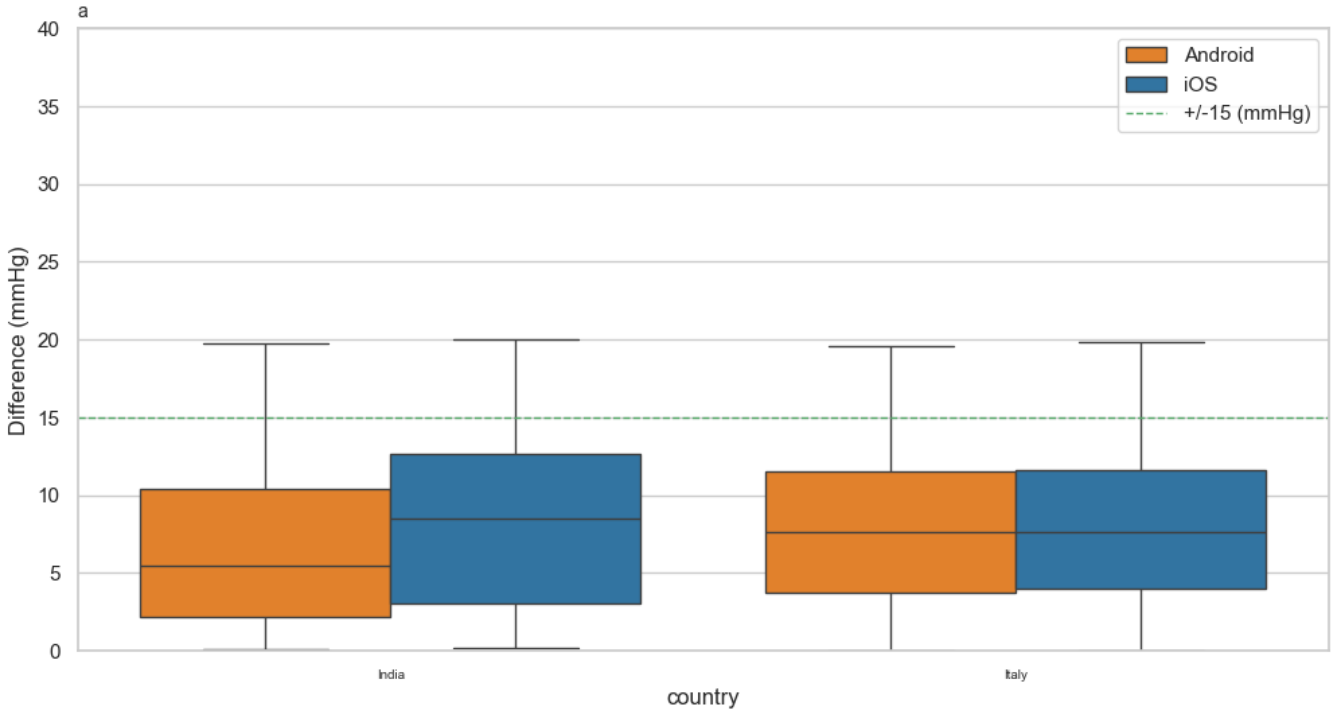

Figure 10:

a. Box plot by country - Systolic BP measurements obtained by Binah.ai's versus the reference device for both operation systems (Android and iOS) presented by countries.

The green dashed "Error" lines set at ≤10 mmHg represents the value of the accuracy criterion.

Diastolic Blood Pressure Error by Age and BMI

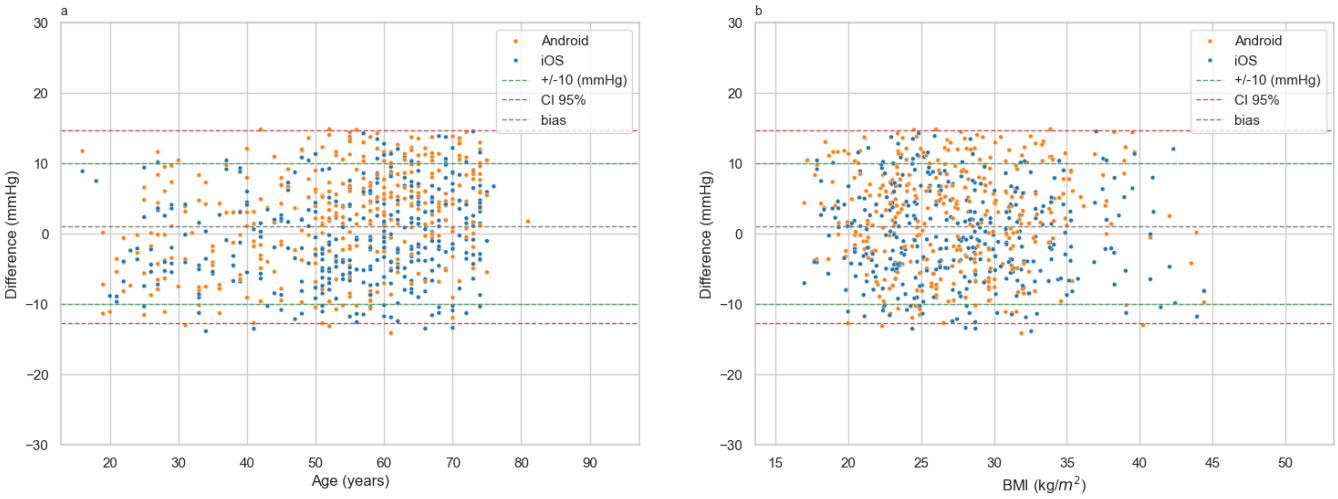

Figure 11:

a. Bland-Altman plot by age - demonstrated diastolic measurements obtained by Binah.ai and the reference device for both operating systems (Android and iOS) within the presented Age range.

b. Bland-Altman plot by BMI - demonstrated diastolic measurements obtained by Binah.ai and the reference device for both operating systems (Android and iOS) within the presented BMI range from low to very high.

The "Bias" gray dashed line stands for the mean difference between measurements of Binah.ai and the reference device, the "Error" green dashed lines of ±10 mmHg represent the value of the accuracy criterion, the "Limits of agreement" lines mark the limit of 95% of the samples.

Diastolic Blood Pressure Error by Skin Tone with Gender and Operating System

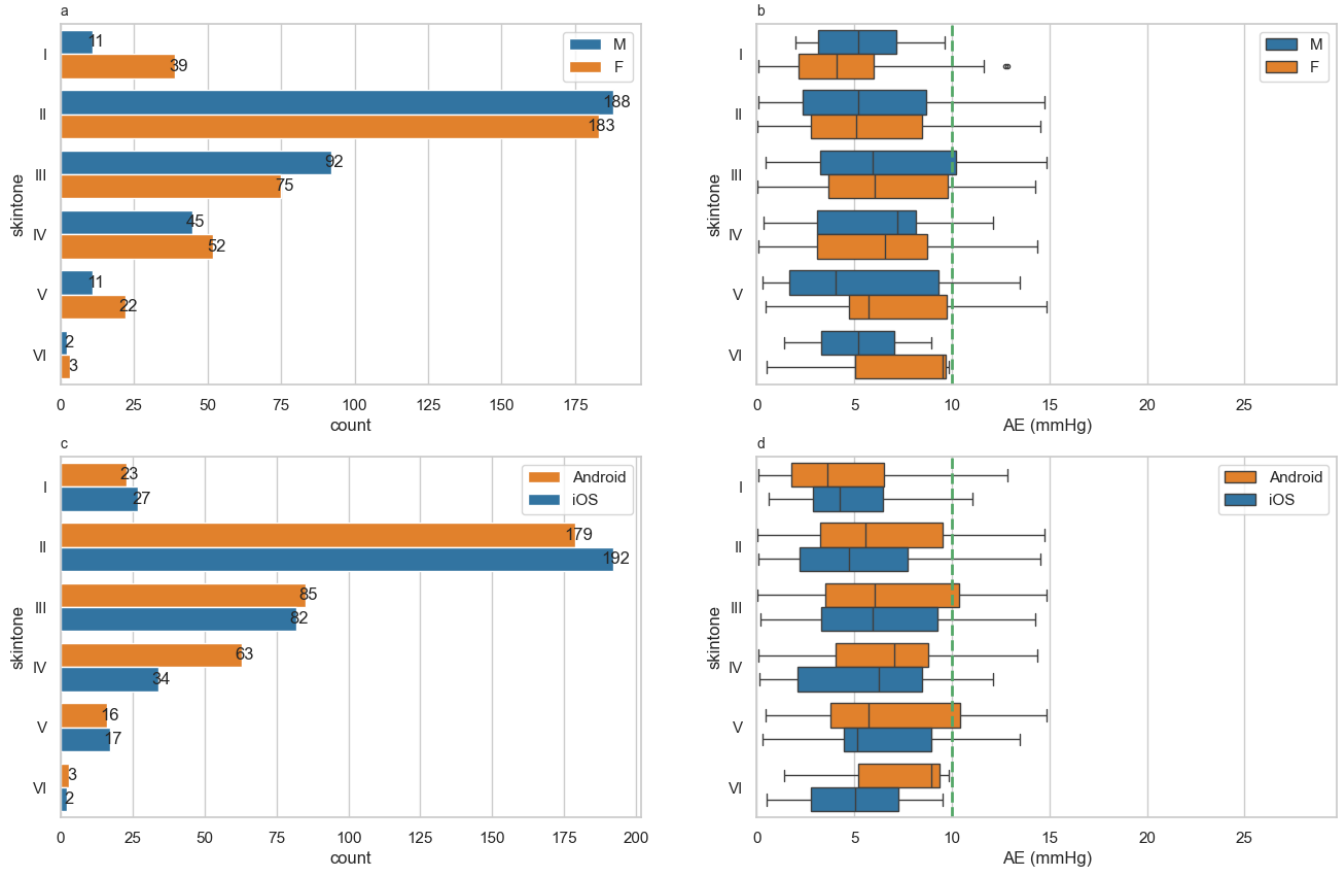

Figure 12:

a. Number of measurements by Fitzpatrick skin tone and sex (female and male).

b. Box plot by Fitzpatrick skin tone and Sex – Diastolic blood pressure measurements obtained by Binah.ai in comparison to the reference device for both sexes (female and male) across all presented skin tones.

The green dashed "Error" lines set at ≤10 mmHg represent the value of the accuracy criterion.

c. Number of measurements by Fitzpatrick skin tone and operating system (Android and iOS).

d. Box plot by Fitzpatrick skin tone and operating system - Diastolic blood pressure measurements obtained by Binah.ai versus the reference device for both operating systems (Android and iOS) across all presented skin tones.

The green dashed "Error" lines set at ≤10 mmHg represent the value of the accuracy criterion.

Diastolic Blood Pressure Error by Distance and Luminance

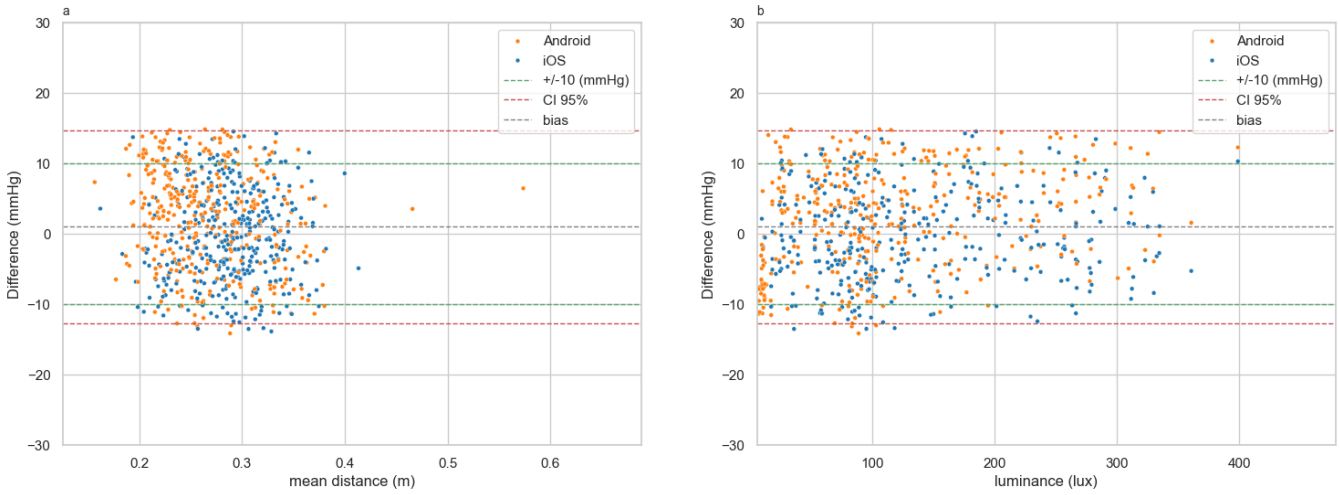

Figure 13:

a. Bland-Altman plot by Distance (m) - demonstrated diastolic BP measurements obtained by Binah.ai and the reference device for both operating systems (Android and iOS) within the presented distance range between the camera and the subject's face.

b. Bland-Altman plot by Luminance (lux) - demonstrated diastolic BP measurements obtained by Binah.ai and the reference device for both operating systems (Android and iOS) within the presented luminance range from dark surroundings (<150 lux) to brighter ones.

The "Bias" gray dashed line stands for the mean difference between measurements of Binah.ai and the reference device, the "Error" green dashed lines of ±10 mmHg represent the value of the accuracy criterion, the "Limits of agreement" lines mark the limit of 95% of the samples.

Diastolic Blood Pressure Error by Face Angles

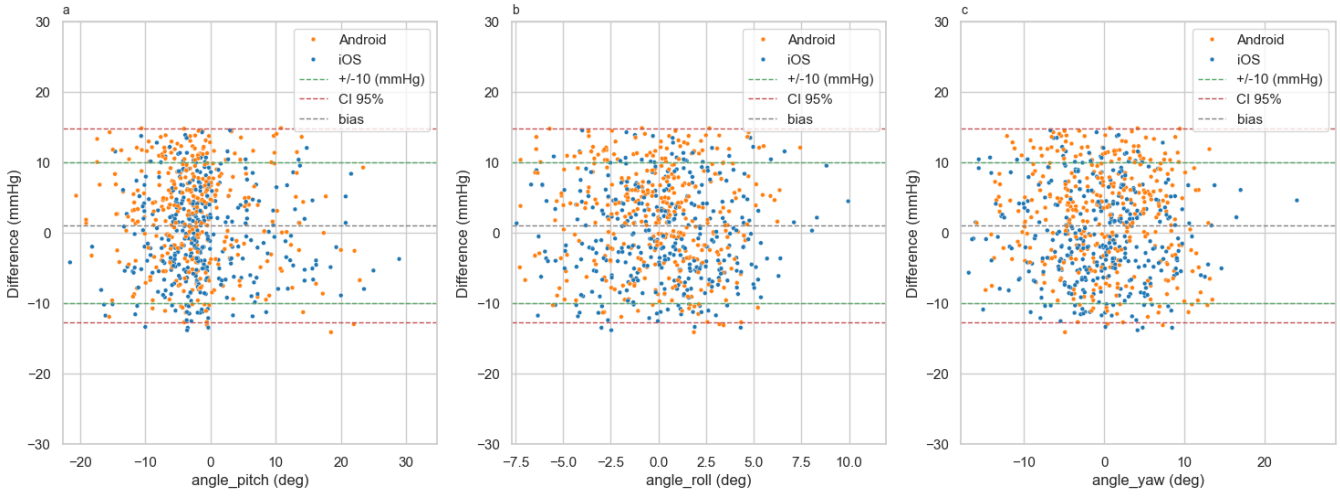

Figure 14:

a. **Bland-Altman plot by pitch angle (deg)** - demonstrated diastolic BP measurements obtained by Binah.ai and the

reference device for both operating systems (Android and iOS) within the presented pitch angle range.

b. **Bland-Altman plot by roll angle (deg)** - demonstrated diastolic BP measurements obtained by Binah.ai and the reference device for both operating systems (Android and iOS) within the presented roll angle range.

c. **Bland-Altman plot by yaw angle (deg)** - demonstrated diastolic BP measurements obtained by Binah.ai and the reference device for both operating systems (Android and iOS) within the presented yaw angle range.

Diastolic Blood Pressure Error by Devices

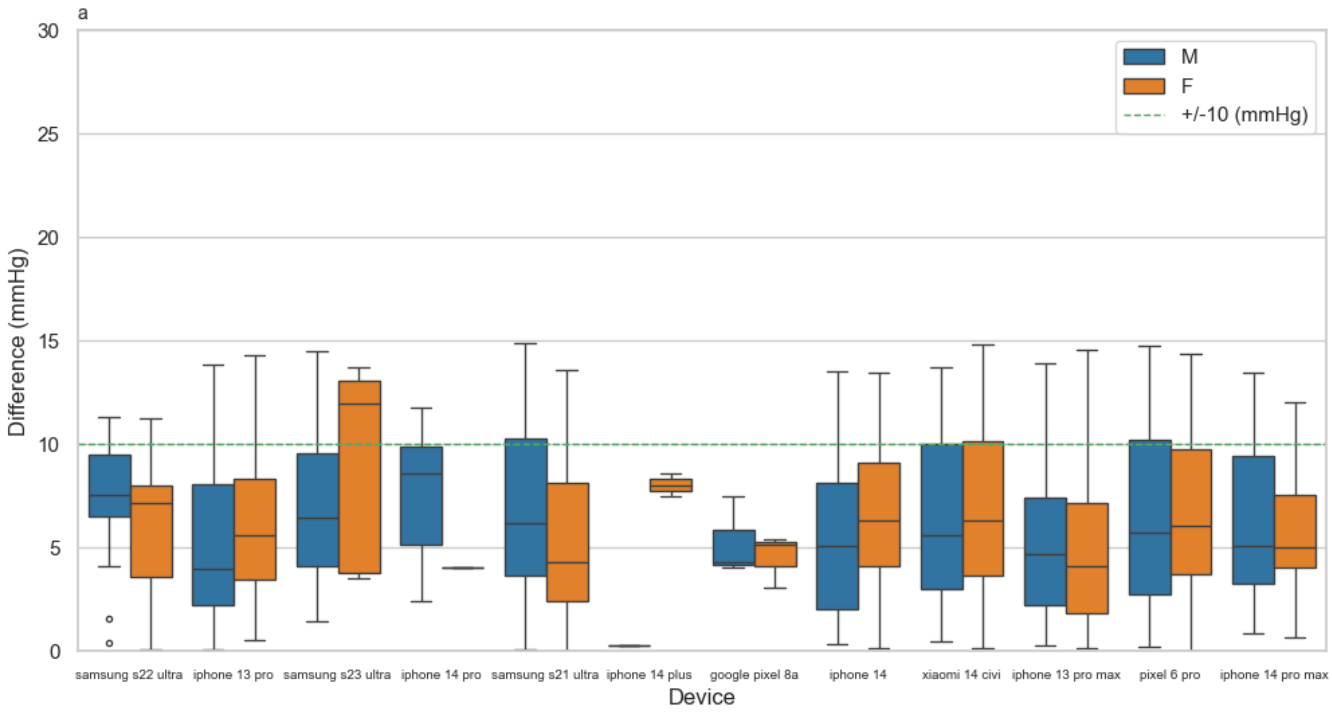

Figure 15:
a. Box plot by device – Diastolic BP measurements obtained by Binah.ai versus the reference device for both sexes (female and male) on all devices.

The green dashed "Error" lines set at ≤10 mmHg represents the value of the accuracy criterion.

Diastolic Blood Pressure Error by Country by OS

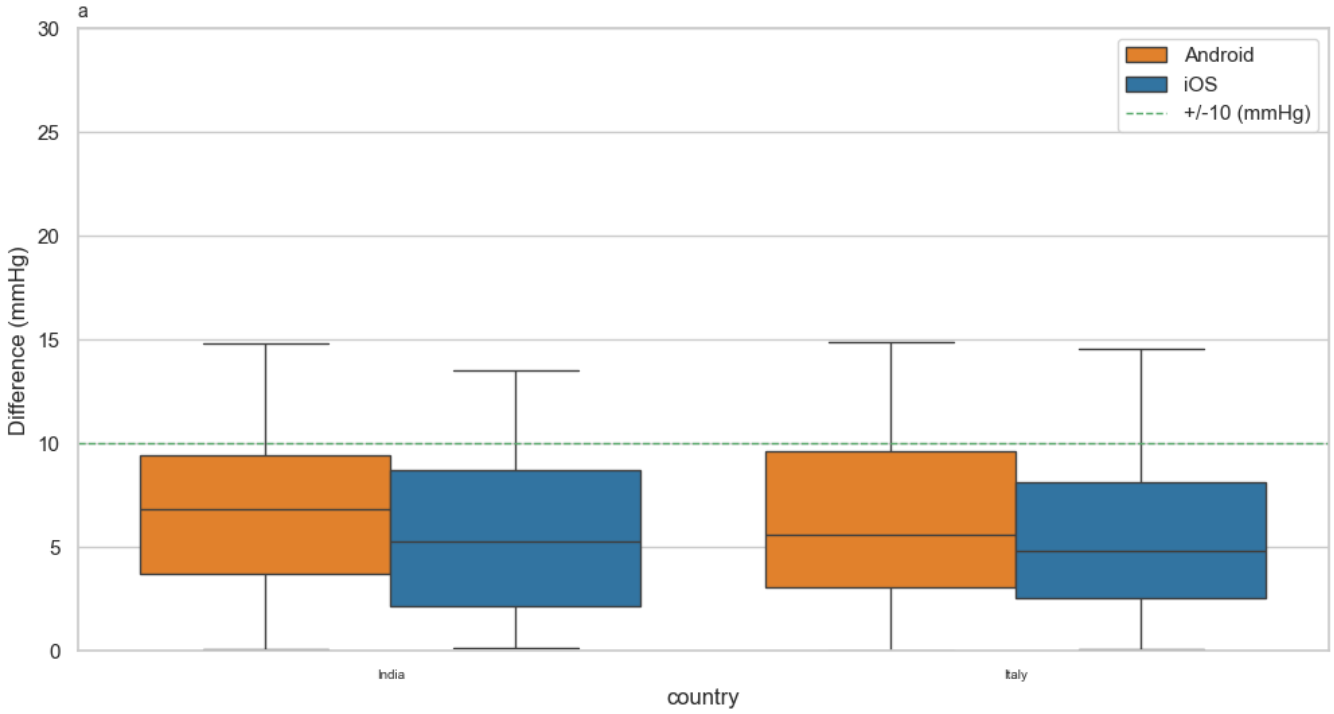

Figure 16:

a. Box plot by country - Diastolic BP measurements obtained by Binah.ai versus the reference device for both operating systems (Android and iOS) presented by countries.

The green dashed "Error" lines set at ≤10 mmHg represent the value of the accuracy criterion.