Pulse Rate Accuracy Report of SDK 5.4

Executive Summary

Goal

This document evaluates the accuracy of Pulse Rate in SDK 5.4 (Android and iOS) rPPG with reference devices, using data collected in Israel, India, South Africa, Japan and USA.

Results

The Pulse rate measured by Binah's SDK was found to be **highly accurate and within the accuracy target (AE≤3 bpm in 95%)** of the measurements for Android and iOS. Similar results were found in the following confounding factors (see appendix):

- Both female and male
- All skin tones (Fitzpatrick I to VI)
- Ages 18 to 82
- BMI from light to morbid obesity
- Distances close and far from the face
- Luminance from dark to brighter surroundings
- Similar performance on all devices used for analysis
- Similar performance in several countries with different ethnicities

Conclusions

The Pulse rate measured by Binah's SDK was found to be **robust, highly accurate and within the accuracy target (AE≤3 bpm in 95%)** of the measurements for both Android and iOS operating system.

Introduction

The human heart consists of four chambers, the left atrium, the left ventricle, the right atrium, and the right ventricle. Each of the upper chambers (atriums) acts as a receiving chamber and contracts to push blood into the lower chambers (ventricles). The ventricles serve as a pump, transport oxygenated blood to the body's tissues and return deoxygenated blood and carbon dioxide to the heart. Heartbeats are composed of phases of heart muscle contraction and relaxation[1].

Pulse Rate (PR) is a term used to describe the number of times the heart beats per minute (the frequency of the cardiac cycle) as measured by palpation or photoplethysmography (e.g., finger, wrist). Heart Rate (HR) is defined as the average number of heartbeats per minute (bpm) as measured directly from the heart, like in an electrocardiogram (ECG), and can also be measured using the PPG Sensor which detects the Pulse Rate. PR also serves as an indicator of autonomic nervous system activity and metabolic rate.

Various factors can affect HR, including physical fitness, psychological status, diet, drugs, and the interaction of genetics and the environment[2] . The normal resting PR is 60 to 100 beats for healthy adults. Tachycardia, a high HR, is defined as above 100 bpm at rest. Bradycardia, a low HR, is defined as below 60 bpm at rest[3] . The relationship between elevated resting PR and cardiovascular risk has been demonstrated in several large-scale epidemiological studies. Those studies provide strong confirmation that increased PR is an independent risk factor for all-cause and cardiovascular mortalities[4–7]. Thus, the need for an easy-to-use and accessible method to measure and monitor PR is clear.

Therefore, the advantage of a non-intrusive, automatic, and accessible method for monitoring these vital signs is unquestionable.

Binah.ai's algorithm uses the photoplethysmography (PPG) signal recorded from facial skin tissue (using remote PPG - rPPG). The algorithm extracts face video images, produces an rPPG signal, analyzes the data, and provides the end user with vital signs measurements in real-time.

This report describes the results of accuracy studies conducted in Israel, India, South Africa, Japan and USA that compares Binah.ai's vital signs measurements (PR and BP) with the measurements of approved reference devices.

Methods

Binah.ai's PR measurements were compared to the Covidien NellcorTM finger pulse oximeter measurements or Schiller finger pulse oximeter measurements or Masimo finger pulse oximeter measurements. The experiments were conducted in Israel, India, South Africa, Japan and the USA with both healthy participants and participants with a medical background.

Measurement set-up:

In all sites, each participant was instructed to sit as stable as possible. Recordings were conducted in a testing room, with controlled and fixed artificial ambient light.
The Pulse rate reference devices that were used included: the Covidien NellcorTM finger pulse oximeter, Schiller finger pulse oximeter, or Masimo finger pulse oximeter which were placed on each participant's finger to measure HR.

For rPPG measurements, a mobile device was placed on a stand in front of the participant. The participant's face filled most of the frame's area (distance of about 20-40 cm) and was positioned in the center of the frame. The camera was set at the level of the forehead and positioned perpendicular to the face. Participants were instructed to look at the screen throughout recording.
Participants were instructed to take off their glasses and to avoid any movement, including talking, and were required 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 application.
Ref is the measurement of the reference device.
i is the index number of the measurements.
Participants with invalid reference device values and participants with very low signal quality were excluded from the analysis, as the confidence level low results are not reported by the SDK.

For this report, Binah.ai's **SDK 5.4** was compared to a reference device.
The measurements were recorded in several locations in Israel, India, South Africa, Japan and USA using the mobile device models listed below:

- iOS: iPhone XR, iPhone 11 Pro, iPhone 13, iPhone 13 Pro and iPhone 13 Pro Max
- Android: Samsung S10, Samsung S21 ultra, Pixel 6 Pro, Huawei P30 Lite, Xiaomi Mi Note 10

Accuracy criteria:

PR: AE ≤ 3 bpm in 85% of measurements.

Results

Measurement disposition

Number of measurements: 3075

Percentage of reported measurements (after signal quality check where confidence score is high): 92.5%

Number of subjects/measurements with reported PR: 624/2843

Number of Unique Subjects and Measurements by Country and Pulse rate distribution

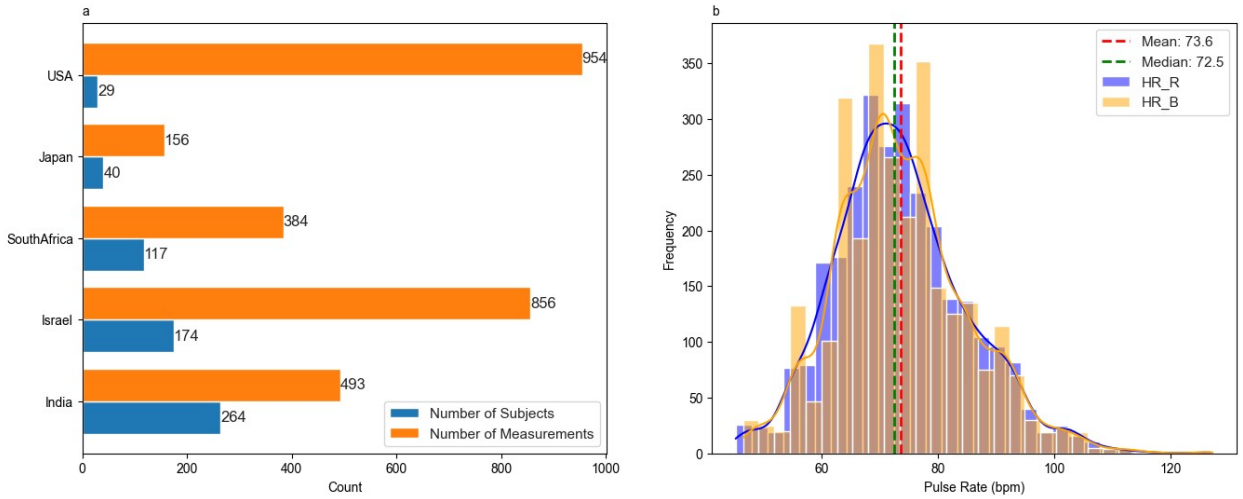

Figure 1:

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

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

Demographics Data:

Subject/Measurements	**Age (mean ± std)**	**BMI (mean ± std)**	**Sex (F/M)**	
624/ 2843	38.5 ± 12.0	25.3 ± 5.3	303 / 321	
Fitzpatrick Skin Tone (I/II/III/IV/V/VI)	**Beard (No/Yes)**	**Glasses (No/Yes)**	**Face cream (No/Yes)**	
4 / 116 / 136 / 237 / 80 / 51	354 / 211	355 / 15	378 / 187	
Distance (mean ± std)	**Luminance (mean ± std)**	**Angle yaw (mean ± std)**	**Angle roll (mean ± std)**	**Angle pitch (mean ± std)**
0.23 ± 0.02	140.5 ± 140.6	4.7 ± 3.3	2.0 ± 1.6	11.1 ± 7.0

Table 1: Demographic data for experiments using phones with Android and iOS operating systems.

* 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:

Operating System	Measurements	MAE ± SD	Pulse Rate Range
Android	1410	0.9 ± 0.8	45 - 127
iOS	1433	0.9 ± 0.88	45 - 125

Table 2: Accuracy data for iOS and Android (MAE±SD) when compared to the reference device in the presented pulse rate range.
MAE -Mean Absolute Error, SD - Standard Deviation

Correlation and Bland-Altman plot by operating system

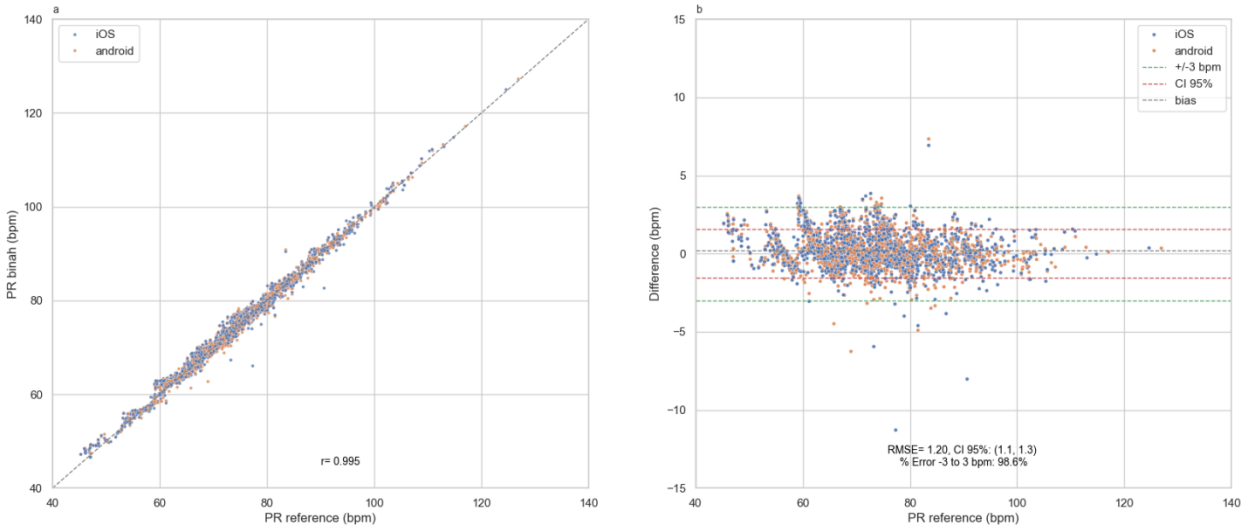

Figure 2:
a. Correlation plot by operating system - Binah.ai's PR estimations versus reference device PR measurements found to be very high (r=0.995) for both operating system (Android and iOS).
b. Bland-Altman plot by operating system - Bland-Altman plots for comparison between PR measurements of the two methods (Binah's and the reference device) demonstrated high agreement between the two devices (99% of the measurements are within target error) for both operating systems (Android and iOS) in the presented pulse rate 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 accuracy analysis in which the Pulse rate measured by Binah.ai's SDK was found to be **robust, highly accurate and within the accuracy target (AE≤3 bpm in 95%)** of the measurements for both Android and iOS operating system.

References

1. Betts, J. G. Heart Anatomy. in Anatomy & physiology 787–846 (2013).

2. Zhang, G. Q. & Zhang, W. Heart rate, lifespan, and mortality risk. Ageing Res. Rev. **8**, 52–60 (2009).

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5. Kannel, W. B., Kannel, C., Paffenbarger, R. S. & Cupples, L. A. Heart rate and cardiovascular mortality: The Framingham study. Am. Heart J. **113**, 1489–1494 (1987).

6. Gillum, R. F., Makuc, D. M. & Feldman, J. J. Pulse rate, coronary heart disease, and death: The NHANES I Epidemiologic Follow-up Study. Am. Heart J. **121**, 172–177 (1991).

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Appendix

Pulse rate error by Age and BMI

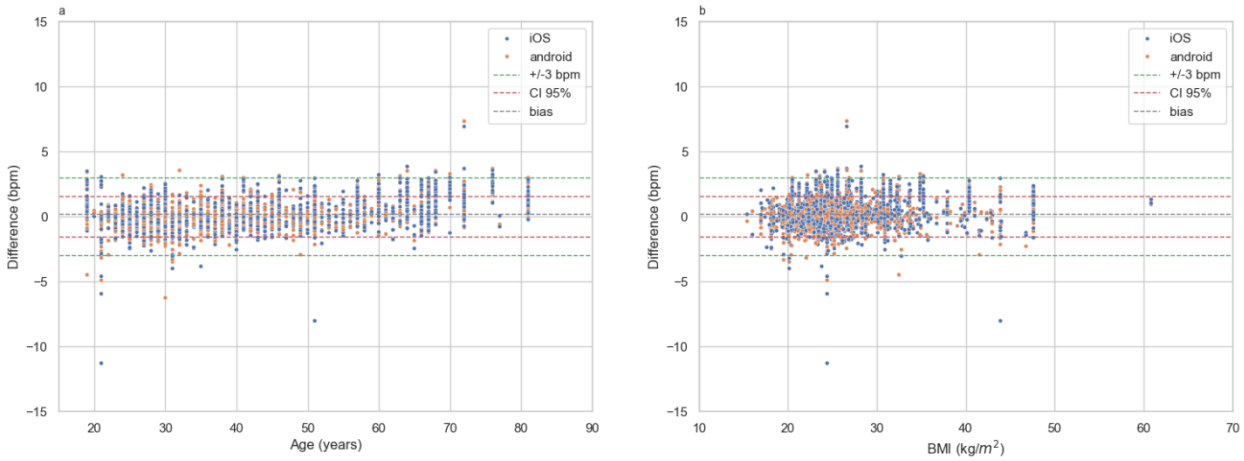

Figure 3:
a. Bland-Altman plot by age - demonstrated high agreement between PR measurements obtained by Binah.ai and the reference device for both operating systems (Android and iOS) within the presented age

b. Bland-Altman plot by BMI - demonstrated high agreement between PR 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 ±3 bpm represent the value of the accuracy criterion, the "Limits of agreement" lines mark the limit of 95% of the samples.

Pulse rate error by skin tone with Gender and Operating system

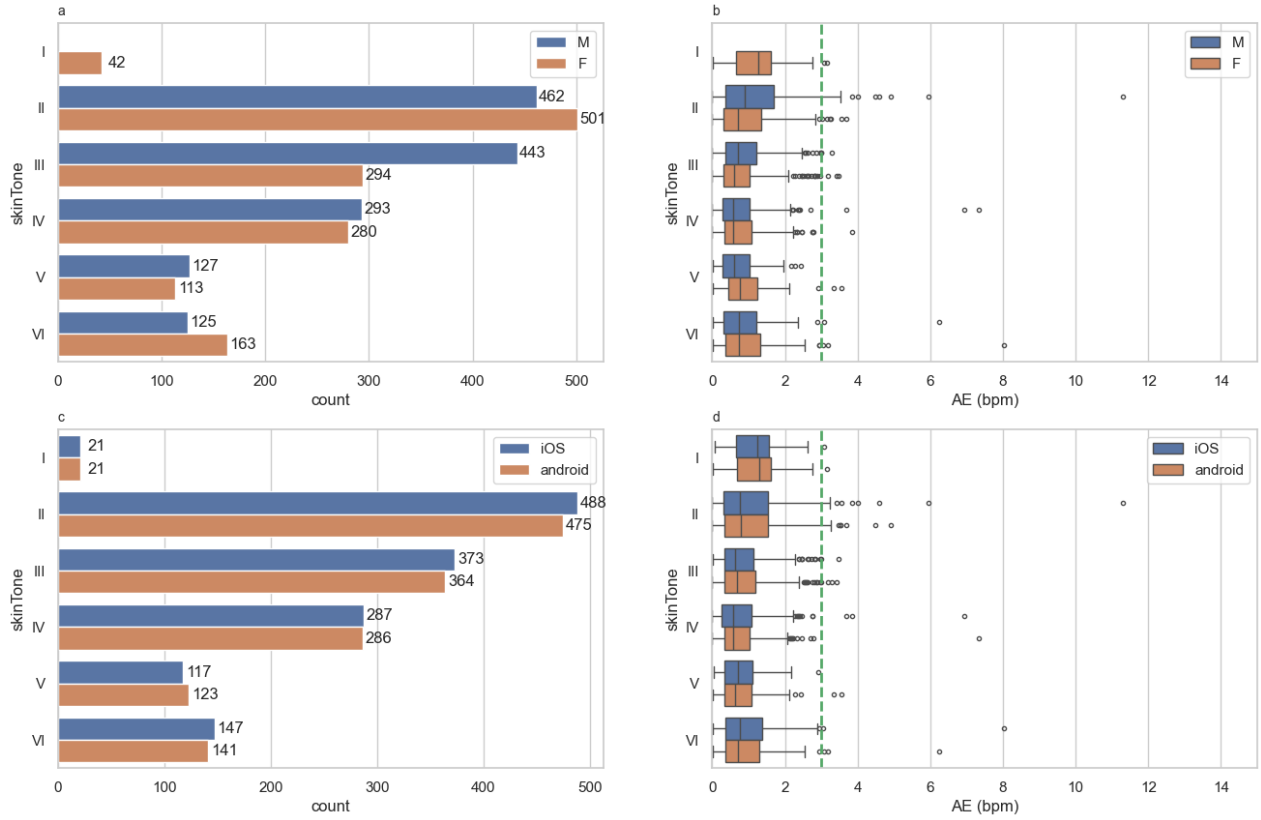

Figure 4:

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

b. **Box plot by Fitzpatrick skin tone and Sex** – PR measurements obtained by Binah.ai's in comparison to the reference device are highly accurate for both sexes (female and male) across all presented skin tones.
The green dashed "Error" lines set at ≤3 bpm 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**- PR measurements obtained by Binah.ai's versus the reference device are highly accurate for both operating systems (Android and iOS) across all presented skin tones.
The green dashed "Error" lines set at ≤3 bpm represent the value of the accuracy criterion.

Pulse rate error by distance and luminance

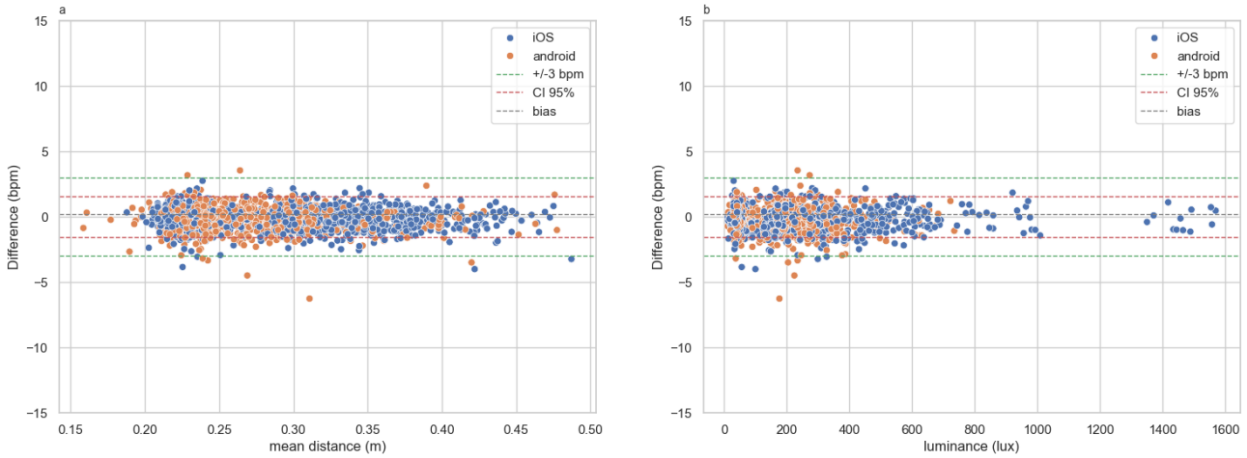

Figure 5:
a. **Bland-Altman plot by Distance (m)** - demonstrated high agreement between PR measurements obtained by Binah.ai's and the reference device for both operating systems (Android and iOS) within the presented distance range from 0.20 to 0.45 m between the camera and the subject's face.

b. **Bland-Altman plot by Luminance (lux)**- demonstrated high agreement between PR measurements obtained by Binah.ai's 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 gray dashed "Bias" line stands for the mean difference between measurements of Binah.ai and the reference device, the The green dashed "Error" lines set at ±3 bpm represent the value of the accuracy criterion, the "Limits of agreement" lines mark the limit of 95% of the samples.

Pulse rate error by Devices

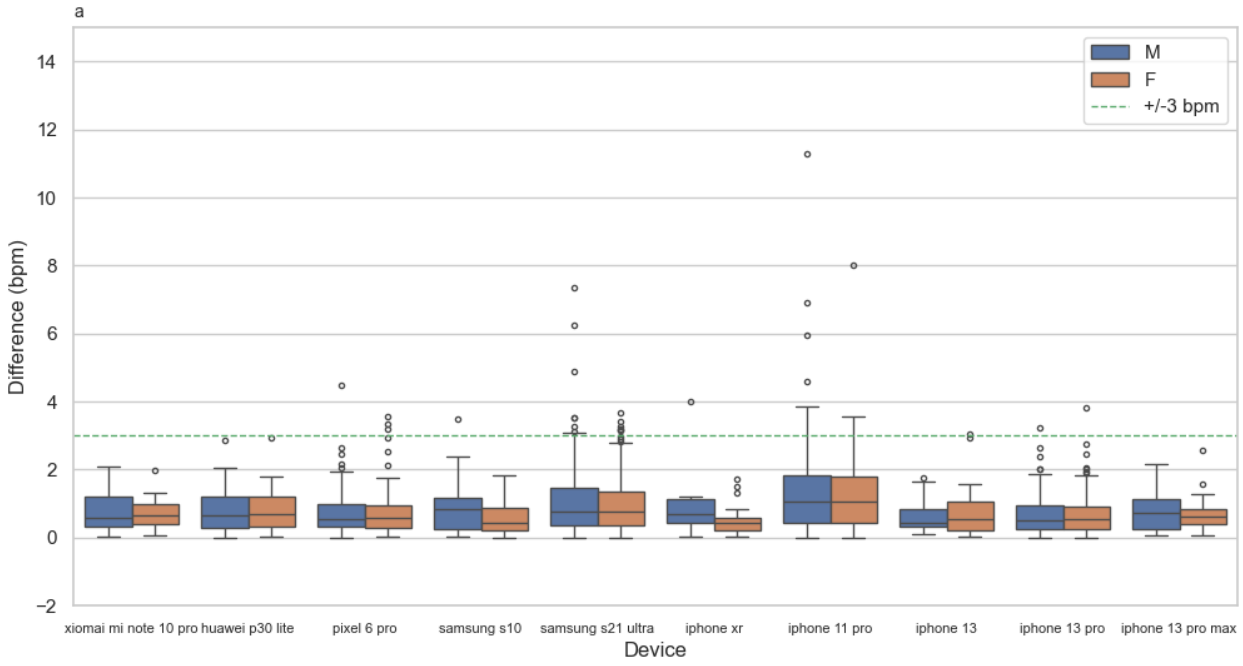

Figure 6:

a. **Box plot by device** - PR measurements obtained by Binah.ai's versus the reference device are highly accurate for both sexes (female and male) on all devices.

The green dashed "Error" lines set at ≤3 bpm represent the value of the accuracy criterion.

Pulse rate error by Country

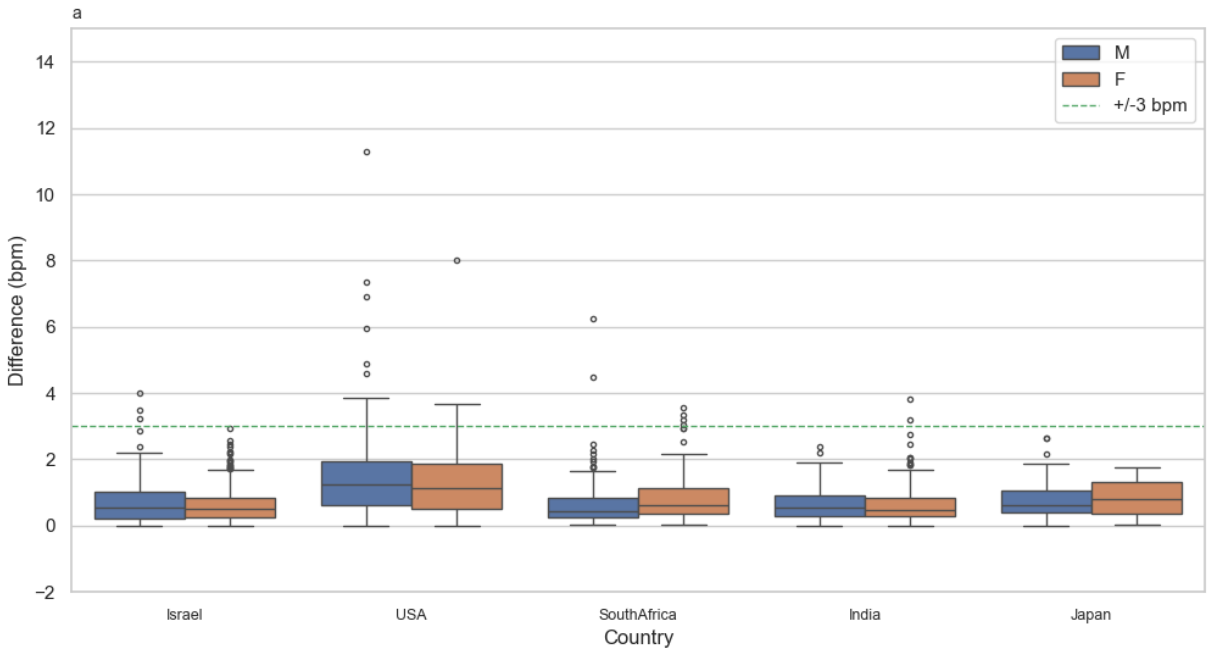

Figure 7:

a. **Box plot by country** - PR measurements obtained by Binah.ai's versus the reference device are highly accurate for both sexes (female and male) on all countries.

The green dashed "Error" lines set at ≤3 bpm represent the value of the accuracy criterion.