Pulse Rate Accuracy Report of SDK 5.11

Executive Summary

Goal

This document evaluates the accuracy of Pulse Rate in SDK 5.11 [iOS and Android] rPPG with reference devices, using data collected in Belgium, Ghana, Bangladesh, Israel, India, Italy, and South Africa.

Results

The Pulse rate measured by Binah's SDK was found to be **highly accurate and within the accuracy target (AE≤3 bpm) in 99.5%** of the measurements for iOS and Android and the following confounding factors (see appendix):

- Both female and male
- All skin tones (Fitzpatrick I to VI)
- Ages 18 to 100
- Similar performance on all devices used for recordings
- 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 99.5% of the measurements for both iOS and Android 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 heart beats per minute [bpm] as measured directly from the heart, like in an electrocardiogram (ECG). HR 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 HR 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 HR and cardiovascular risk has been demonstrated in several large-scale epidemiological studies. Those studies provide strong confirmation that increased HR 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 HR 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 (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 Belgium, Ghana, Bangladesh, Israel, India, Italy, and South Africa that compare Binah.ai's vital signs measurements (HR and BP) with the measurements of approved reference devices.

Methods

Binah.ai's HR measurements were compared to a 3-lead ECG, Covidien NellcorTM finger pulse oximeter measurements / Masimo / finger pulse oximeter measurements. The experiments were conducted in Belgium, Ghana, Bangladesh, Israel, India, Italy, and South Africa 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 used included a 3-lead ECG, Covidien NellcorTM 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 forehead's level and perpendicular to the face.
Participants were instructed to look at the screen throughout the 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 measurements.
Participants with invalid reference device values and participants with very low signal quality were excluded from the analysis.

For this report, Binah.ai's SDK 5.11 was compared to a reference device.

The measurements were recorded in several locations Belgium, Ghana, Bangladesh, Israel, India, Italy, and South Africa using the mobile device models listed below:

- iOS: iPhone 15 Pro, iPhone 14 Pro, iPhone 14 ProMax, iPhone 13 Pro, iPhone 13 Pro Max, iPhone 13
- Android: Samsung S21 ultra, Samsung S23 Ultra, Pixel 6 Pro and Basler aca 1440-220

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

Results

Measurement disposition

Number of subjects/measurements with reported pulse rate: 4246/9642

Number of Unique Subjects and Measurements by Country and Pulse Rate Distribution

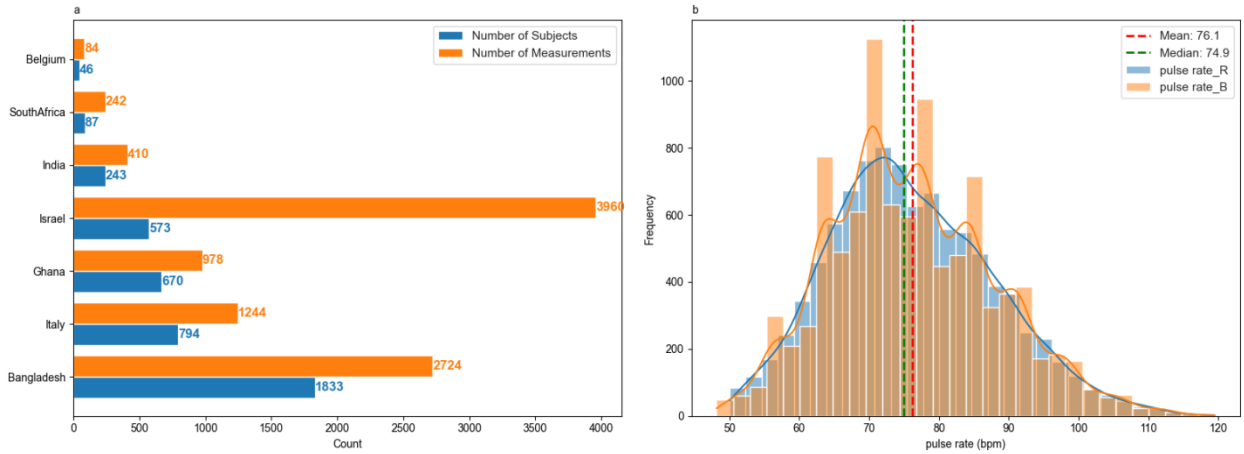

Figure 1.
a. Number of Unique Subjects and Measurements by Country data presented includes all measurements with reference values.
b. Pulse rate distribution measured by the reference device and Binah.ai's application, both measurements present an overlapped normal distribution.

Demographics Data:

Subjects/Measurements	Age (mean ± std)	BMI (mean ± std)	Sex (F/M)
4246/ 9642	46.7 ± 15.6	26.6 ± 5.6	2578 / 1668
Fitzpatrick Skin Tone (I/II/III/IV/V/VI)	**Beard (No/Yes)**	**Glasses (No/Yes)**	**Face cream (No/Yes)**
44 / 787 / 1287 / 1286 / 660 / 182	899 / 338	798 / 340	1012 / 225
Angle yaw (mean ± std)	**Angle roll (mean ± std)**	**Angle pitch (mean ± std)**	
6.2 ± 5.4	2.9 ± 2.4	9.0 ± 6.7	

Table 1. Demographic data for experiments using phones with iOS and Android 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	Unique Subjects	Measurements	MAE ± STD	Ref Range
iOS	3802	5283	0.7 ± 0.6	50.0 - 119.0
Android	2732	4359	0.7 ± 0.6	50.0 - 119.0

Table 2. Accuracy data for iOS and Android (MAE ± STD) 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

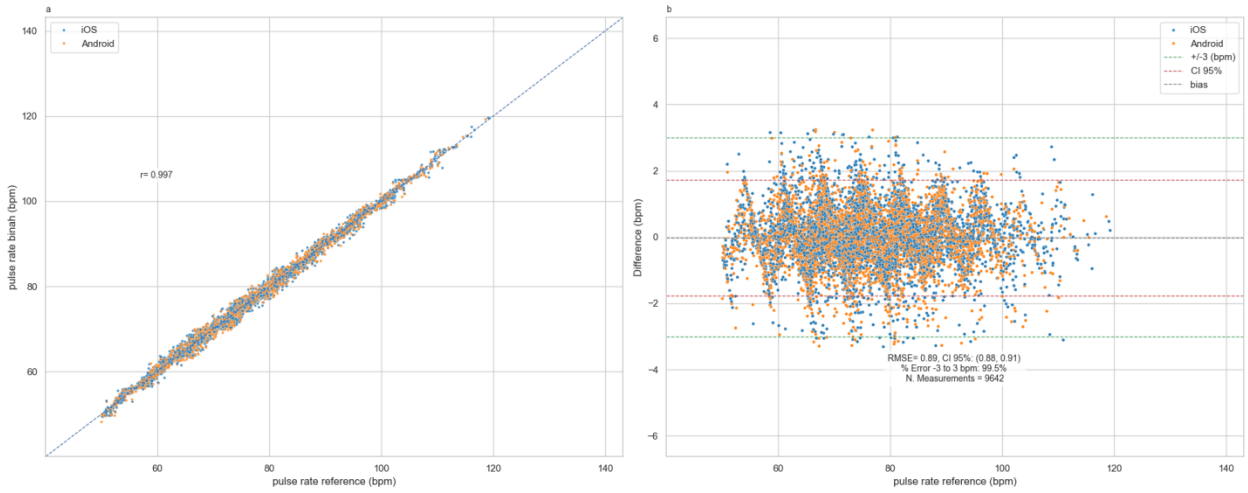

Figure 2.
a. Correlation plot by operating system - Binah.ai's PR estimations versus reference device PR measurements found to be very high (r=0.997) for both operating system (Android and iOS).
b. Bland-Altman plot by operating system - Bland-Altman plots for comparison between PR measurements of the two methods (Binah's and the reference device) demonstrated high agreement between the two devices (99.5% 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 99.5%)** of the measurements for both iOS and Android operating systems.

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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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 Skin Tone with Gender and Operating System

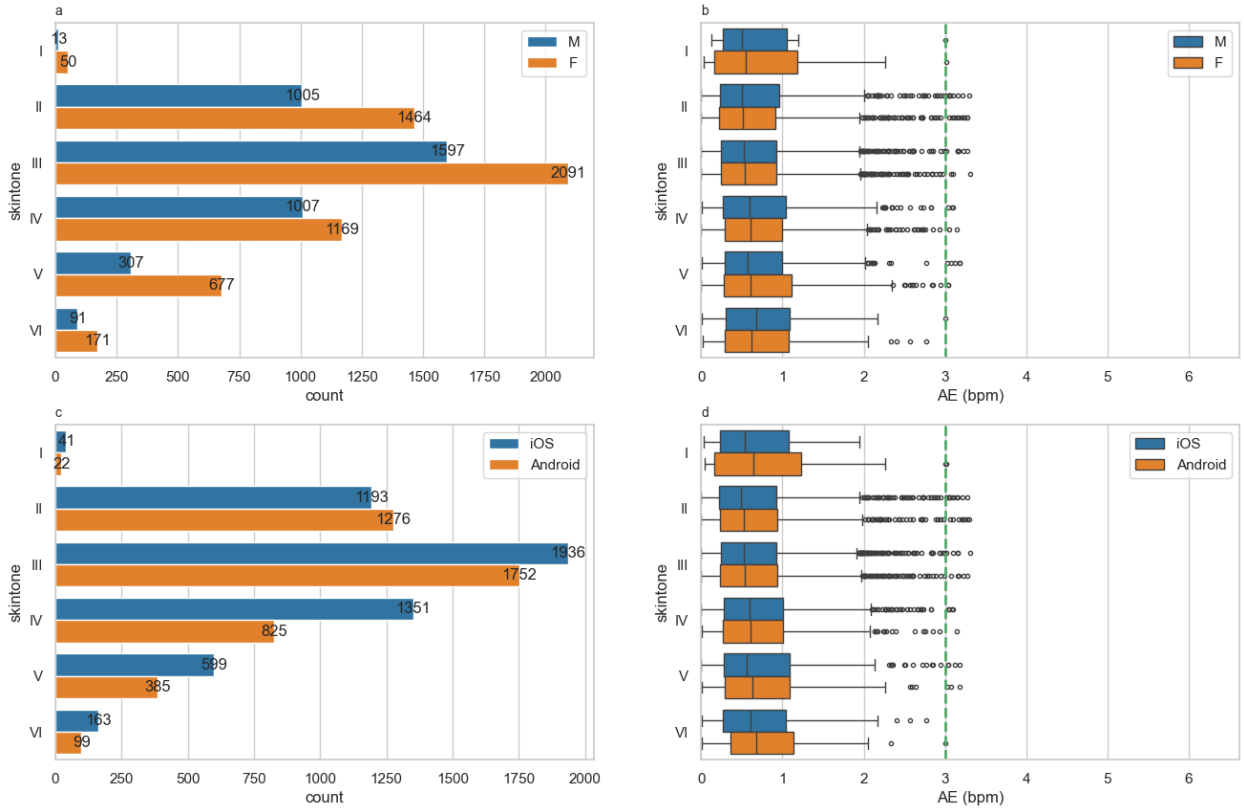

Figure 3.

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 compared 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 represents 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 represents the value of the accuracy criterion.

Pulse Rate Error by Face Angles

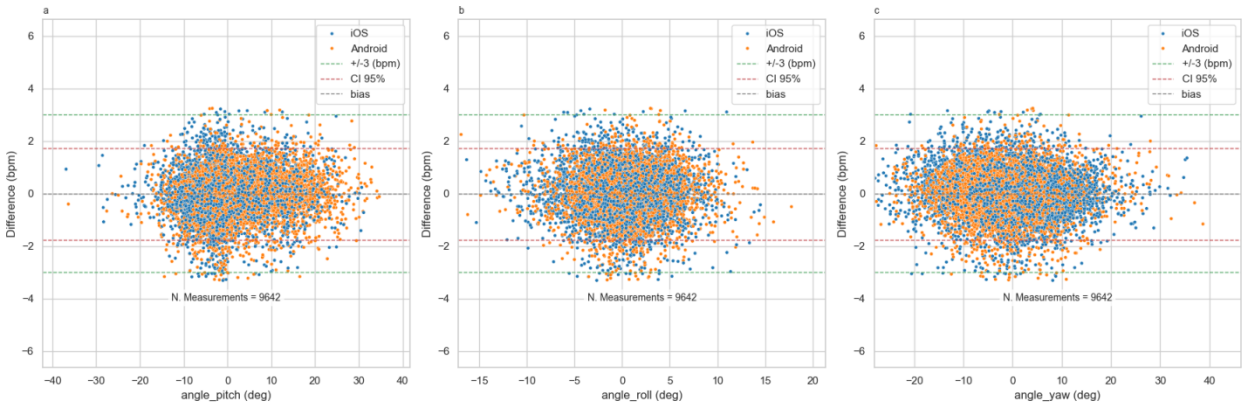

Figure 4.

a. **Bland-Altman plot by pitch angle (deg)** - 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 pitch angle range.

b. **Bland-Altman plot by roll angle (deg)**- 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 roll angle range.

c. **Bland-Altman plot by yaw angle (deg)**- 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 yaw angle range.

The gray dashed "Bias" line stands for the mean difference between measurements of Binah.ai and the reference device, 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

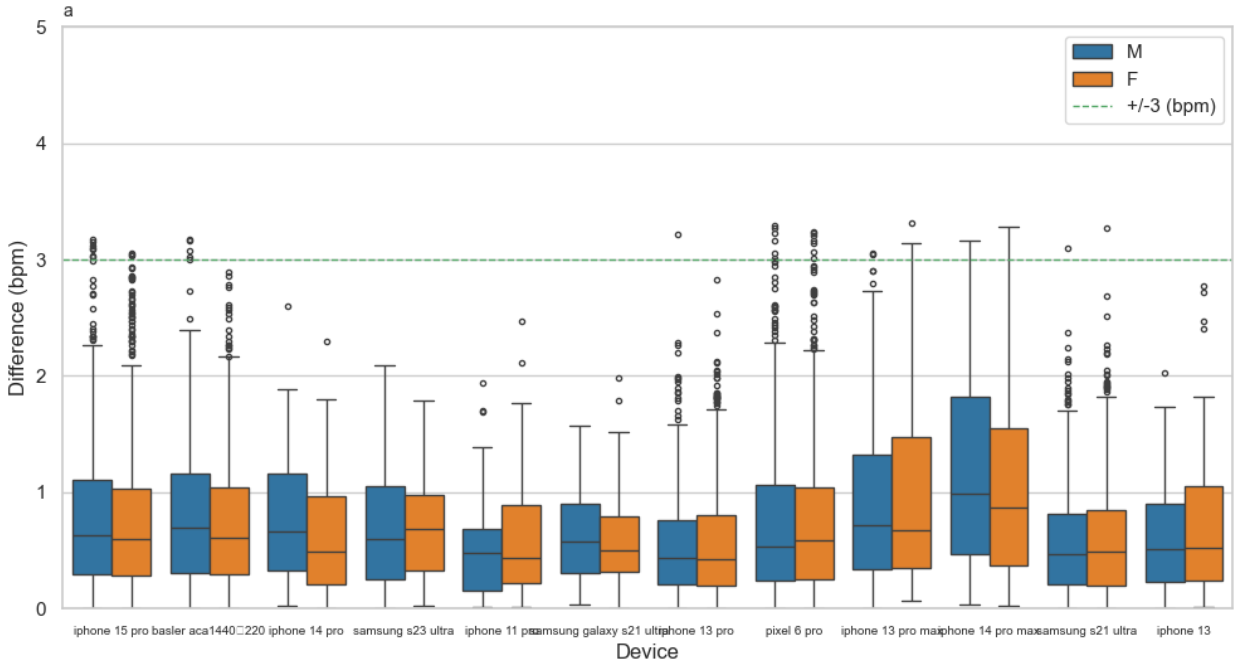

Figure 5:

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 represents the value of the accuracy criterion.

Pulse Rate Error by Country

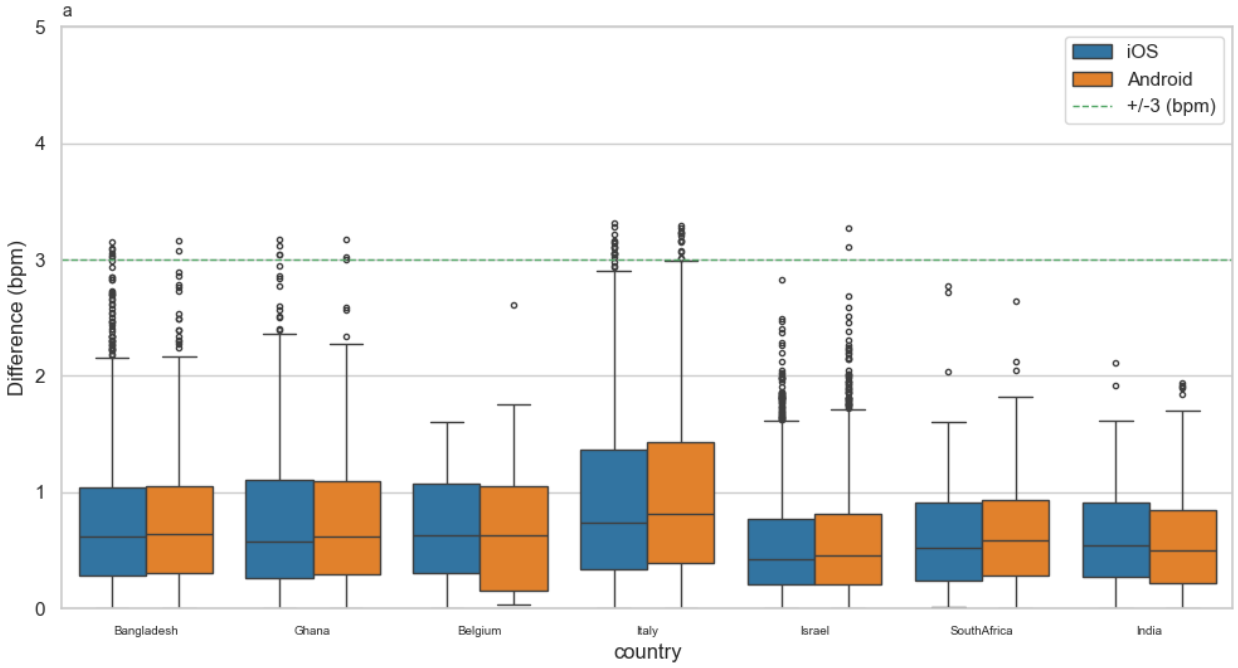

Figure 6:

a. **Box plot by country** - PR measurements obtained by Binah.ai's versus the reference device, are highly accurate for both operating systems (Android and iOS) in all countries.

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