Pulse Rate Accuracy Report of SDK 5.9.1

Executive Summary

Goal

This document evaluates the accuracy of Pulse Rate in SDK 5.9 [iOS and Android] rPPG with reference devices, using data collected in Israel, India, Italy, South Africa, and Japan.

Results

- The Pulse rate measured by Binah's SDK was found to be highly accurate and within the accuracy target (AE<3 bpm) in 99.8% 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)
 - o Ages 18 to 77
 - BMI from light to morbid obesity
 - Distances close and far from the face
 - Luminance from dark to brighter surroundings
 - Various face angles, from wide to narrow
 - o Similar performance on all devices used for recordings
 - o Similar performance in several countries with different ethnicities

Conclusions

The pulse rate measured by Binah's SDK was found to be robust and highly accurate, meeting the accuracy target (AE \leq 3 bpm) in **99.8%** of measurements across both iOS and Android operating systems.

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Introduction

The human heart consists of four chambers: the left atrium, left ventricle, right atrium, and right ventricle. Each of the upper chambers (atria) functions as a receiving chamber, contracting to push blood into the lower chambers (ventricles). The ventricles serve as pumps, transporting oxygenated blood to the body's tissues and returning deoxygenated blood and carbon dioxide to the heart. Heartbeats are composed of alternating phases of heart muscle contraction and relaxation.¹

Pulse Rate (PR) refers to the number of times the heart beats per minute (the frequency of the cardiac cycle) as measured by palpation or photoplethysmography (e.g., finger or wrist). **Heart Rate (HR)** is defined as the average number of heartbeats per minute [bpm] measured directly from the heart, such as in an electrocardiogram (ECG). HR is also an important indicator of autonomic nervous system activity and metabolic rate.

Several factors can affect HR, including physical fitness, psychological status, diet, medication, and the interaction between genetics and the environment.² The normal resting HR for healthy adults typically ranges from **60 to 100 bpm**. **Tachycardia** refers to a resting HR above 100 bpm, while **bradycardia** refers to a resting HR below 60 bpm.³

The relationship between elevated resting HR and cardiovascular risk has been demonstrated in several large-scale epidemiological studies. These studies provide strong evidence that increased HR is an independent risk factor for all-cause and cardiovascular mortality.⁴–⁷ This highlights the importance of a simple, accessible method for measuring and monitoring HR.

Binah.ai's algorithm leverages **photoplethysmography (PPG)** technology recorded from facial skin tissue using a remote PPG (rPPG) method. The algorithm extracts face video images, generates an rPPG signal, analyzes the data, and provides the end user with real-time vital sign measurements.

This report presents the results of accuracy studies conducted in Israel, India, South Africa, Japan, and Italy, comparing Binah.ai's vital sign measurements (HR and BP) with those obtained from approved reference devices.

<u>Methods</u>

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

Measurement set-up:

At all sites, participants were instructed to sit as still as possible. Recordings were conducted in a controlled testing room with fixed artificial ambient lighting.

The pulse rate reference devices used included the Covidien Nellcor[™] finger pulse oximeter and the Masimo finger pulse oximeter, which were placed on each participant's finger to measure HR.

Pulse Rate Accuracy Report of SDK 5.9.1 Version 2.0

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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 forehead level and positioned perpendicular to the face. Participants were instructed to look at the screen throughout the recording.

Participants were also instructed to remove their glasses, remain still, and avoid movement, including talking. They were required to sit 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.

For this report, Binah.ai's **SDK 5.9** was compared to a reference device.

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

- iOS: iPhone 11 Pro, iPhone 13, iPhone 13 Pro, iPhone 13 Pro Max, iPhone 14 and iPhone 14 Pro
- Android: Samsung S21 ultra, Samsung S23 Ultra and Pixel 6 Pro

Accuracy criteria:

PR: MAE \leq 3 bpm in 85% of measurements.

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<u>Results</u>

Measurement disposition

Number of subjects/measurements with reported pulse rate: 1336/5819

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 reference device and Binah.ai's application, both measurements present overlapped normal distribution.

Demographics Data:

Subjects/Measurements	Age	BMI	Sex	
	(mean ± std)	(mean ± std)	(F/M)	
1336/ 5819	42.0 ± 16.4	25.6 ± 5.3	667 / 669	
Fitzpatrick Skin Tone	Beard	Glasses	Face cream	
(/ / / \/\/\/\)	(No/Yes)	(No/Yes)	(No/Yes)	
10 / 551 / 361 / 293 / 78 /	581 / 284	586 / 162	668 / 197	
43				
Distance	Luminance	Angle yaw	Angle roll	Angle pitch
(mean ± std)	(mean ± std)	(mean ± std)	(mean ± std)	(mean ± std)
0.28 ± 0.05	93.3 ± 71.0	5.2 ± 4.0	2.1 ± 1.7	10.9 ± 7.5

 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	1229	2859	0.7 ± 0.5	50.0 - 115.0
Android	1252	2960	0.7 ± 0.5	50.0 - 117.0

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 (99.8% 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 an accuracy analysis in which the pulse rate measured by Binah.ai's SDK was found to be robust and highly accurate, meeting the accuracy target (AE ≤ 3 bpm) in 99.8% of measurements across both iOS and Android operating systems.

References

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MED-000026

<u>Appendix</u>



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 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 \leq 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 \leq 3 bpm represents the value of the accuracy criterion.

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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 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.

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Pulse Rate Error by Face Angles



Figure 6:

a. **Bland-Altman plot by pitch angle (deg)** - demonstrated PR 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 PR 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 PR measurements obtained by Binah.ai 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 Accuracy Report of SDK 5.9.1 Version 2.0

MED-000026

Pulse Rate error by Devices



Figure 7:

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.

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Pulse rate error by Country



Figure 8:

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

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