Version 2.0

MFD-000052

Heart Rate Variability Data Accuracy Report of SDK 5.11

Executive Summary

Goal

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

Results

The HRV (Mean RRi) measured by Binah's SDK demonstrated high accuracy, consistently meeting the accuracy target (AE \leq 25 ms) in 99.1% of measurements across both iOS and Android platforms, regardless of the following confounding factors (see appendix):

- o Both female and male
- o All skin tones (Fitzpatrick I to VI)
- o Ages 18 to 100
- 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 HRV (Mean RRi) measured by Binah's SDK was **found to be robust and highly accurate, consistently meeting the accuracy target (AE ≤ 25 ms) in 99.1%** of the measurements across both iOS and Android operating systems.

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Introduction

Heart rate (HR) is the number of heart beats per minute. **Heart Rate Variability (HRV)** is the fluctuation in the time intervals between adjacent heartbeats (RR intervals – RRi). In other words, the variability of RRi is known as the Heart Rate Variability (HRV). HRV is generated by heart-brain interactions and autonomic nervous system processes. HRV helps the body adapt to environmental and psychological challenges. It reflects the regulation of autonomic balance, blood pressure, blood vessel diameter, gas exchange, gut, and heart. A healthy heart is not a metronome, and heartbeats do not occur at constant intervals, but rather with a small variance between them. This variability in heartbeats provides the flexibility to rapidly cope with an uncertain and changing environment.

Physical or emotional stress results in faster, monotonic heartbeats, causing HRV to decrease. Relaxation results in slower, less regular heartbeats, and higher HRV.⁵ Normal HRV is associated with a lower risk of developing depression and post-traumatic stress disorder.^{6,7} Moreover, decreased HRV has been identified as an independent predictor of cardiovascular and overall mortality.^{8–10} Thus, HRV is a noninvasive method that can be used to evaluate autonomic nervous system activity and physical and emotional status in a variety of clinical situations. ^{11,12}.Therefore, the advantage of a non-intrusive, automatic, and accessible method for monitoring this vital sign is unquestionable.

Binah.ai's algorithm utilizes the photoplethysmography (PPG) signal recorded from facial skin tissue (remote PPG - rPPG) to extract and analyze vital signs in real-time. It processes face video images to generate an rPPG signal, identifies heartbeat peaks corresponding to the contraction of heart ventricles (R peaks of the QRS complex in the ECG wave), and delivers accurate physiological measurements to the end user.

Binah.ai's HRV measurements are based on various parameters calculated from RRi values, such as, SDNN [in msec] which represents the standard deviation of RRi.

This report describes the results of accuracy studies conducted in Belgium, Israel, South Africa, India, Ghana and Bangladesh that compare Binah.ai's HRV measurements with the measurements of approved reference devices.

Methods

Binah.ai's HRV measurements were validated in comparison to the Polar H10 or 3-lead ECG measurements. The experiments were conducted in Belgium, Israel, South Africa, India, Ghana and Bangladesh with both healthy participants and participants with a medical background.

HRV Extraction

To evaluate the performance of Binah.ai's algorithm, its output was compared with results obtained from Kubios HRV, a widely recognized software for heart rate variability (HRV) analysis. Kubios processes ECG, PPG, and RR interval data and is extensively utilized in research to assess autonomic nervous system function, stress levels, and cardiovascular health.

For this comparison, the same RPPG signal was used as input for both Binah.ai's algorithm and Kubios HRV, ensuring a direct evaluation of the computed metrics. In Kubios, time-domain HRV analysis derives parameters from the beat-to-beat RR interval series, denoted as RR = (RR1, RR2, ..., RRN). Among these metrics, SDNN (the standard deviation of normal-to-normal RR intervals) represents overall heart rate variability by capturing both short-term and long-term fluctuations. Meanwhile, RMSSD (the root mean square of successive RR interval differences) quantifies short-term HRV, primarily influenced by parasympathetic activity.

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.

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 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,

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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.

Definitions:

- RR intervals (RRi) are defined as the difference between successive R peaks.
- RR intervals are calculated as: RR(n) = R(n)-R(n-1), where n is the beat index number.

For this report, Binah.ai's **SDK 5.11** was compared to reference devices. The measurements were recorded in several locations in Belgium, Israel, South Africa, India, Ghana and Bangladesh using the mobile device models listed below:

- iOS: iPhone 11, iPhone 13, iPhone 13 Pro, iPhone 13 Pro Max, iPhone 15 Pro.
- Android: Samsung S21 Ultra, Pixel 6 Pro, Basler aca1440-220.

Accuracy criteria:

HRV: AE \leq 25 ms in 90% of measurements.

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Results

Mean RRi

Measurement disposition

Number of subjects/measurements with reported HRV: 2893/5286

Number of Unique Subjects and Measurements by Site and Mean RRi distribution

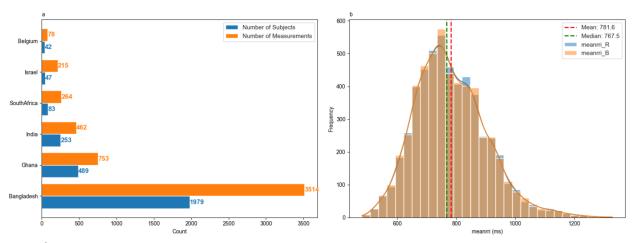


Figure 1:

- **a. Number of Unique Subjects and Measurements by Site** data presented includes all measurements with reference values.
- **b.** Distribution of mean RRi 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)
2893/ 5286	46.0 ± 14.1	25.6 ± 4.9	1757 / 1136
Fitzpatrick Skin Tone	Beard	Glasses	Face cream
(/ / / V/V/V)	(No/Yes)	(No/Yes)	(No/Yes)
8 / 74 / 763 / 1318 / 555 / 175	212 / 171	282 / 18	272 / 111
Angle yaw	Angle roll	Angle pitch	
(mean ± std)	(mean ± std)	(mean ± std)	
7.1 ± 6.5	2.8 ± 2.3	9.1 ± 6.9	

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. ** Skin tone, beard, glasses, and face cream information do not exist for all subjects.

Accuracy Data:

Operation System	Unique Subjects	Measurements	MAE ± STD	Ref Range
iOS	2738	3045	2.2 ± 2.9	483.0 - 1329.0
Android	2039	2241	3.7 ± 5.6	479.0 - 1329.0

Table 2: Accuracy data for iOS and Android (MAE±STD) when compared to the reference device in the presented Mean RRi range.

MAE -Mean Absolute Error, STD - Standard Deviation

Correlation and Bland-Altman plot by Operating System

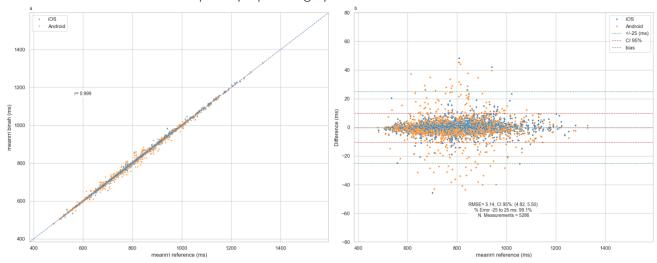


Figure 2:

- a. Correlation plot by operating system Binah.ai's Mean RRi estimations versus reference device Mean RRi measurements were found to be very high (r=0.999) for both operating systems (Android and iOS).
- b. Bland-Altman plot by operating system Bland-Altman plots for comparison between Mean RRi measurements of the two methods (Binah's and the reference device) demonstrated high agreement between the two devices (99.1% of the measurements are within target error) for both operating systems (Android and iOS) in the presented Mean RRi 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 \pm 25 ms represent the value of the accuracy criterion, the "Limits of agreement" lines mark the limit of 95% of the samples.

SDNN

Accuracy Data:

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Operation System	Unique Subjects	Measurements	MAE ± STD	Ref Range
iOS	2719	3029	4.7 ± 4.8	7.0 - 119.0
Android	2037	2243	5.4 ± 5.3	7.0 - 112.0

Table 3: Accuracy data for iOS and Android (MAE±STD) when compared to the reference device in the presented SDNN range.

RMSSD

Accuracy Data:

Operation System	Unique Subjects	Measurements	MAE ± STD	Ref Range
iOS	2729	3040	9.5 ± 8.7	7.0 - 133.0
Android	2032	2239	9.9 ± 9.2	7.0 - 132.0

Table 4: Accuracy data for iOS and Android (MAE±STD) when compared to the reference device in the presented SDNN range.

Conclusions

This report summarizes the results of an accuracy analysis, using the data collected in different geo locations, by different organization data, demonstrating that the HRV measured by Binah.ai's SDK was robust, highly accurate, and consistently met the Mean RRi accuracy target (AE \leq 25 ms) in 99.1% of the measurements across both iOS and Android operating systems.

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Appendix



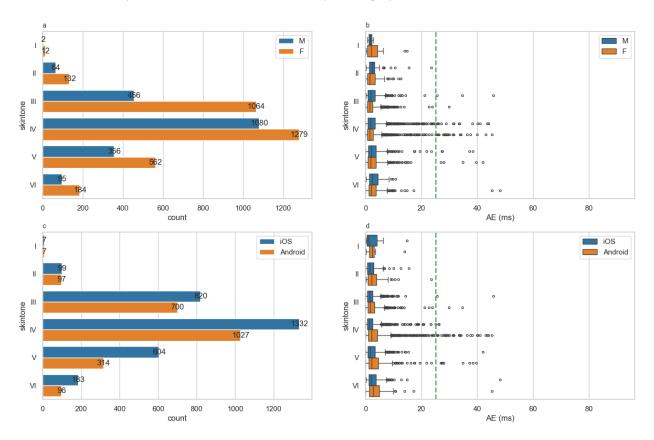


Figure 3:

- a. Number of measurements by Fitzpatrick skin tone and sex (female and male).
- b. Box plot by Fitzpatrick skin tone and Sex Mean RRi 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 ≤25 ms 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 Mean RRi 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 ≤25 ms represent the value of the accuracy criterion.

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Mean RRi Error by Face Angles

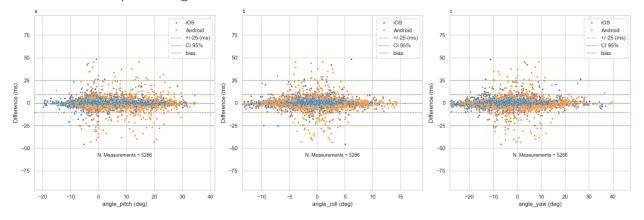
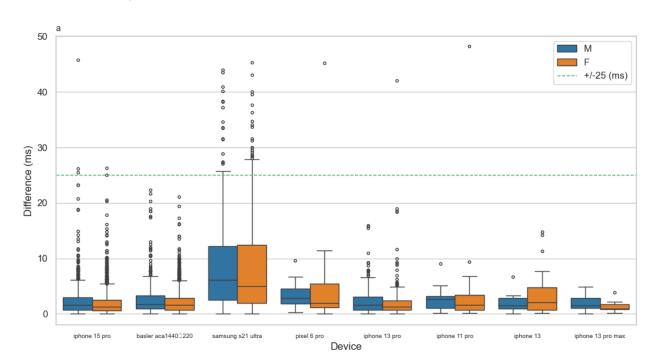


Figure 4:

- a. Bland-Altman plot by pitch angle Comparison between Mean rri measurements obtained by Binah.ai and the reference device for both operating systems (Android and iOS) within the presented pitch range.
- b. **Bland-Altman plot by roll angle** Comparison between Mean rri measurements obtained by Binah.ai and the reference device for both operating systems (Android and iOS) within the presented roll range.
- c. **Bland-Altman plot by yaw angle** Comparison between Mean rri measurements obtained by Binah.ai and the reference device for both operating systems (Android and iOS) within the presented yaw 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 ±25 ms represent the value of the accuracy criterion, the "Limits of agreement" lines mark the limit of 95% of the samples.

Mean RRi Error by Mobile Device Models



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Figure 5:

a. **Box plot by device** – Mean RRi 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 \leq 25 ms represent the value of the accuracy criterion

Mean RRi Error by Country

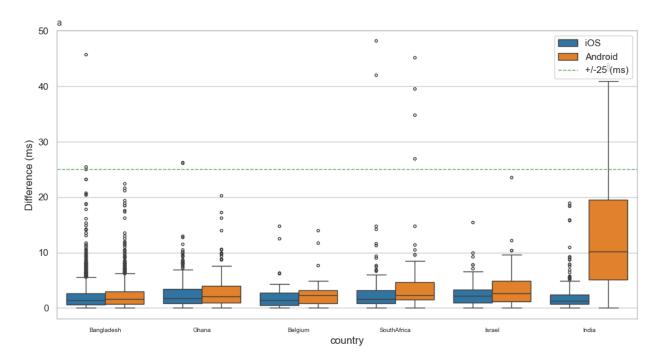


Figure 6:

a. **Box plot by country** – Mean RRi measurements obtained by Binah.ai's versus the reference device is highly accurate for both operating systems (iOS and Android) in all countries.

The green dashed "Error" lines set at \leq 25 ms represent the value of the accuracy criterion.