Heart Rate Variability Accuracy Report of SDK 5.4

Executive Summary

Goal

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

Results

The HRV (meanRRi) measured by Binah's SDK was found to be **highly accurate and within the accuracy target (AE≤25 ms in >96%)** 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 II 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 HRV measured by Binah's SDK was found to be **robust, highly accurate and within the accuracy target (AE≤25 ms in >96%)** of the measurements for both Android and iOS operating system.

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).[1] HRV is generated by heart-brain interactions and autonomic nervous system processes. HRV helps the body adapt to environmental and psychological challenges. It reflects regulation of autonomic balance, blood pressure, blood vessel diameter, gas exchange, gut, and heart.[2] A healthy heart is not a metronome, and heartbeats do not occur at constant intervals, but rather with a small variance between them.[3] This variability in heartbeats provides the flexibility to rapidly cope with an uncertain and changing environment. [4]

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 to develop 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]

Binah.ai's HRV algorithm uses the photoplethysmography (PPG) signal recorded from facial skin tissue (remote PPG - rPPG). The algorithm identifies the heartbeat peaks, which represent the contraction of heart ventricles (R peaks of the QRS complex of the ECG wave).

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.

The variability of RRi is known as the Heart Rate Variability (HRV).
Binah.ai's HRV measurements are based on various parameters calculated from RRi values, for example, SDNN (msec) which represents the standard deviation of RRi. The accuracy is set according to the meanRRi

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

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 Israel, India, South Africa, and Japan that compares Binah.ai's vital signs measurements with the measurements of approved reference devices.

Methods

Binah.ai's HRV measurements were validated in comparison to the Polar H10 Heart Rate SensorTM and/ or Polar Verity Senes measurements. The experiments were conducted in Israel, India, South Africa, and Japan 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 Polar H10 Heart Rate SensorTM and/ or Polar Verity Sense which were placed on each participant's finger to measure HRV.

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, and Japan 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:

HRV: AE ≤ 25 ms in 90% of measurements.

Results – MeanRRi

Measurement disposition

Number of Measurements: 1076

Percentage of reported measurements (after signal quality check - confidence score medium and high): 96.7%

Number of subjects/measurements with reported HRV: 491/1041

Number of Unique Subjects and Measurements by Country and meanRRi distribution

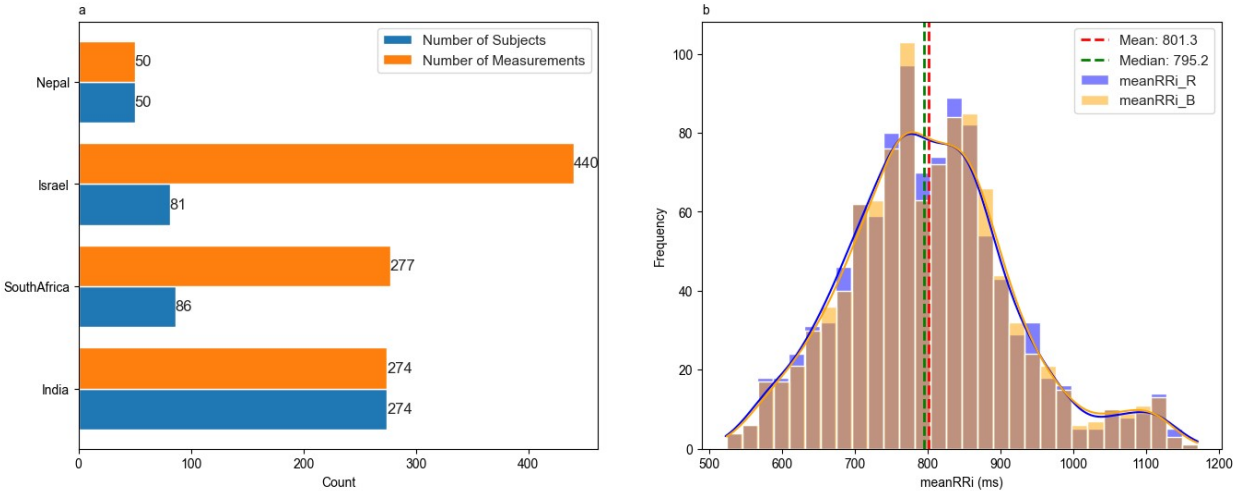

Figure 1:

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

b. Distribution of meanRRi 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)**	
491 / 1041	41.3 ± 11.6	25.6 ± 5.1	245 / 246	
Fitzpatrick Skin Tone (I/II/III/IV/V/VI)	**Beard (No/Yes)**	**Glasses (No/Yes)**	**Face cream (No/Yes)**	
0 / 44 / 78 / 266 / 69 / 34	270 / 194	359 / 19	337 / 127	
Distance (mean ± std)	**Luminance (mean ± std)**	**Angle yaw (mean ± std)**	**Angle roll (mean ± std)**	**Angle pitch (mean ± std)**
0.23 ± 0.02	141.1 ± 177.2	4.9 ± 3.7	2.1 ± 1.6	11.0 ± 6.5

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:

OS	Measurements	MAE ± SD	MeanRRi Range
Android	352	7.2 ± 10.0	550 - 1142
iOS	689	5.6 ± 8.2	522 - 1171

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

Correlation and Bland-Altman plot by operating system

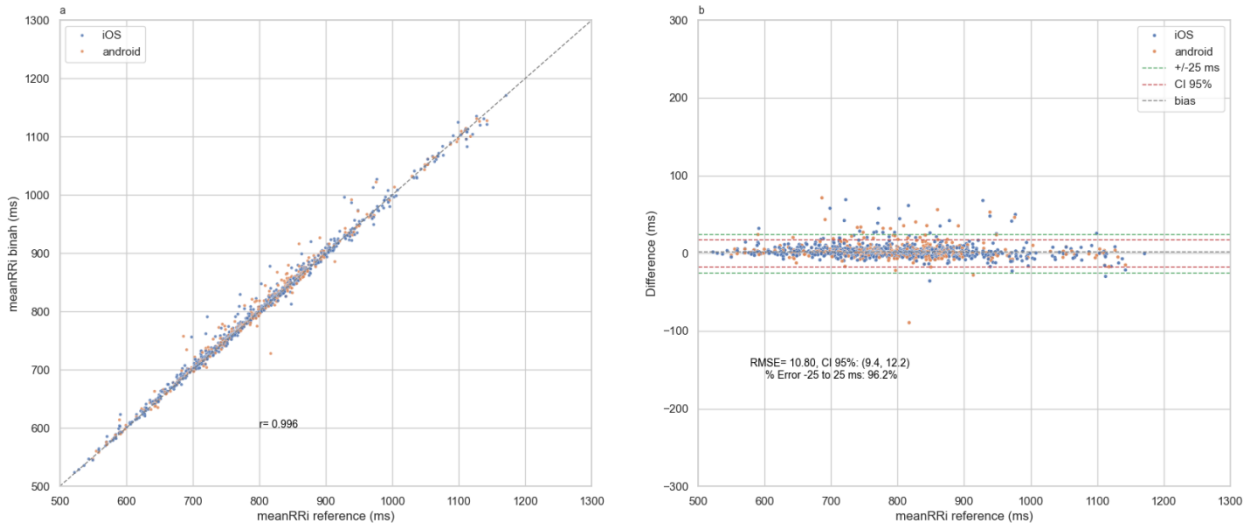

Figure 2:

a. Correlation plot by operating system - Binah.ai's meanRRi estimations versus reference device meanRRi measurements found to be very high (r=0.996) for both operating system (Android and iOS).

b. Bland-Altman plot by operating system - Bland-Altman plots for comparison between meanRRi measurements of the two methods (Binah's and the reference device) demonstrated high agreement between the two devices (96% 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 ± 25 ms 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 HRV measured by Binah.ai's SDK was found to be **robust, highly accurate and within the accuracy target** ($AE \leq 25$ ms in $>96\%$) of the measurements for both Android and iOS operating system.

References

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12. Sztajzel, J. Heart rate variability: a noninvasive electrocardiographic method to measure the autonomic nervous system. Swiss Med. Wkly. 134, 514–522 (2004).

Appendix

meanRRi error by Age and BMI

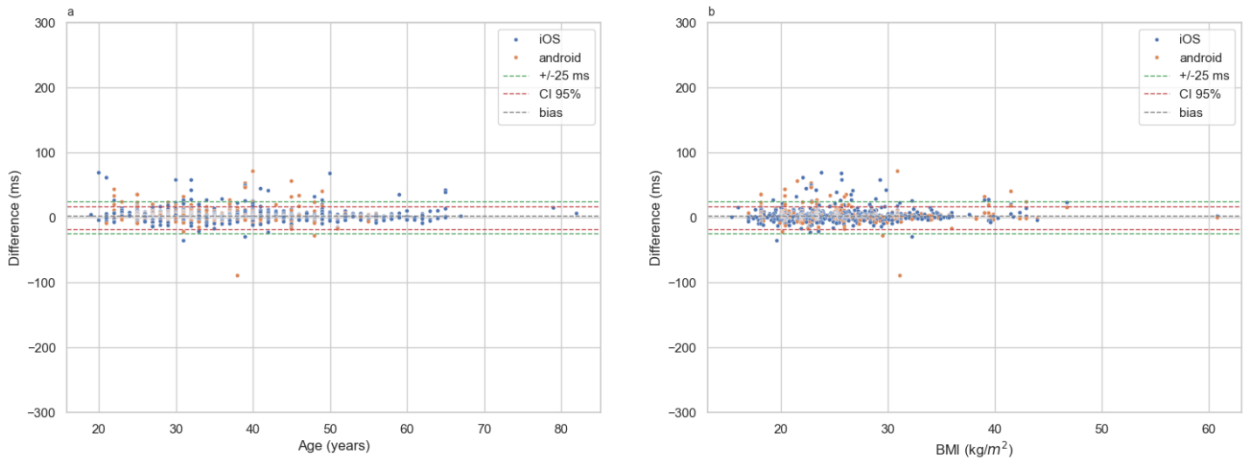

Figure 3:
a. Bland-Altman plot by age - demonstrated high agreement between meanRRi measurements obtained by Binah.ai and the reference device for both operating systems (Android and iOS) within the presented age range.

b. Bland-Altman plot by BMI - demonstrated high agreement between meanRRi 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.

meanRRi error by skin tone with Gender and Operating system

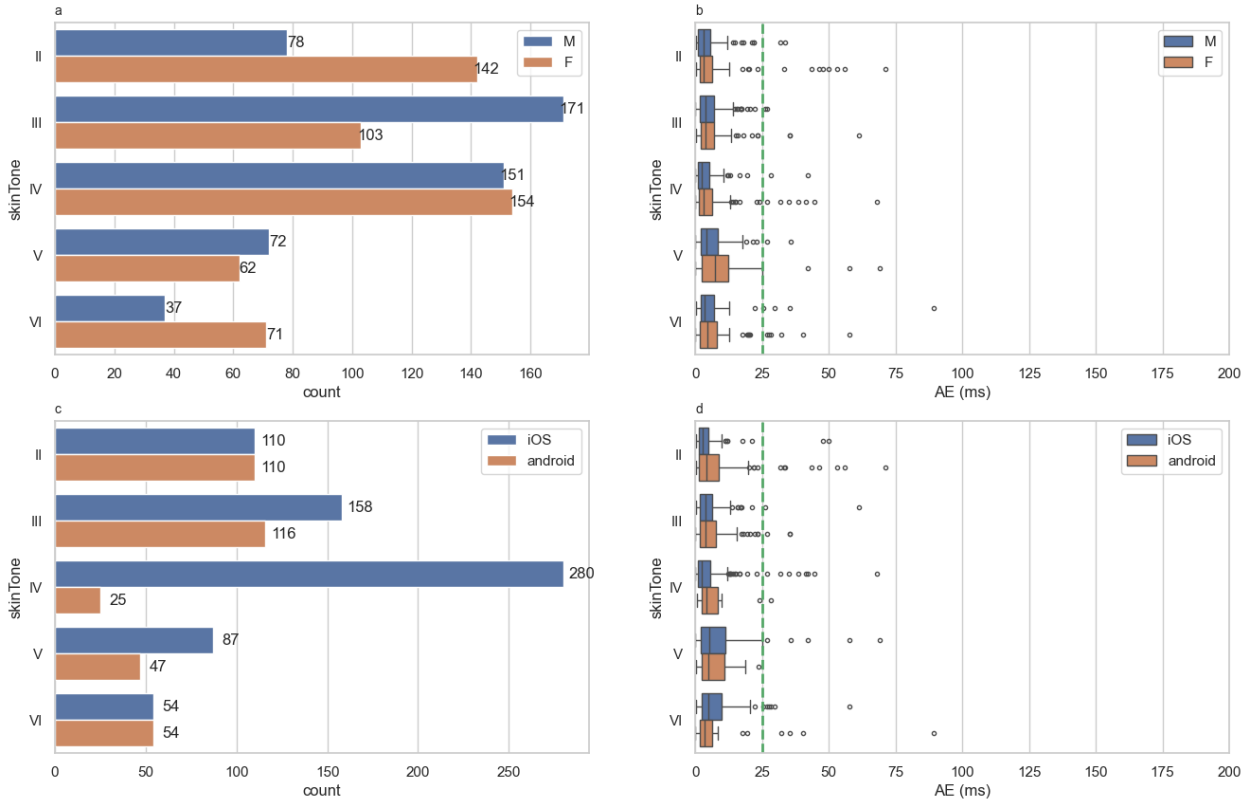

Figure 4:

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

b. **Box plot by Fitzpatrick skin tone and Sex** – meanRRi 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**- meanRRi 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.

meanRRi error by distance and luminance

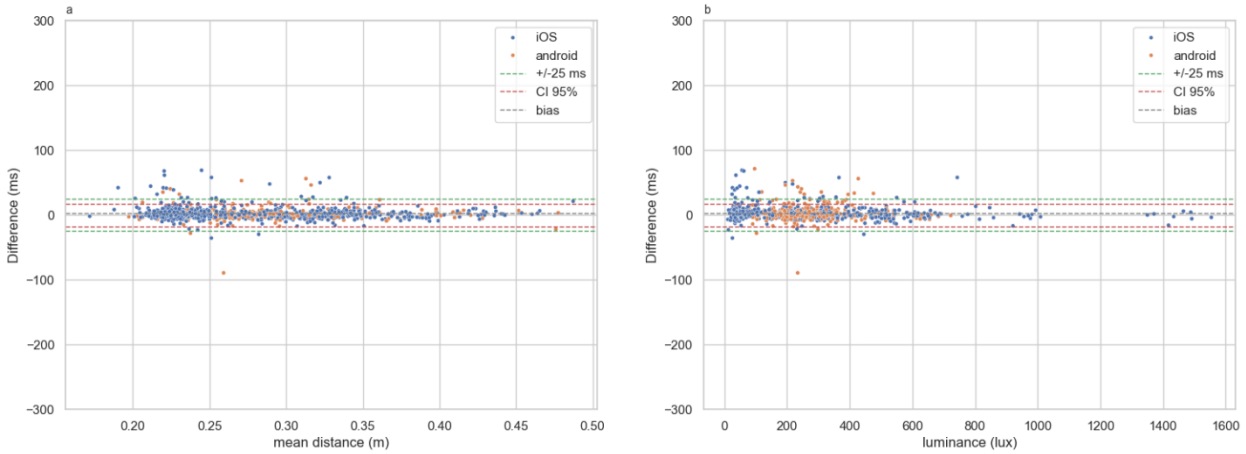

Figure 5:
a. **Bland-Altman plot by Distance (m)** - demonstrated high agreement between meanRRi measurements obtained by Binah.ai's and the reference device for both operating systems (Android and iOS) within the presented distance range between the camera and the subject's face.

b. **Bland-Altman plot by Luminance (lux)**- demonstrated high agreement between meanRRi 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 Th
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.

meanRRi error by Devices

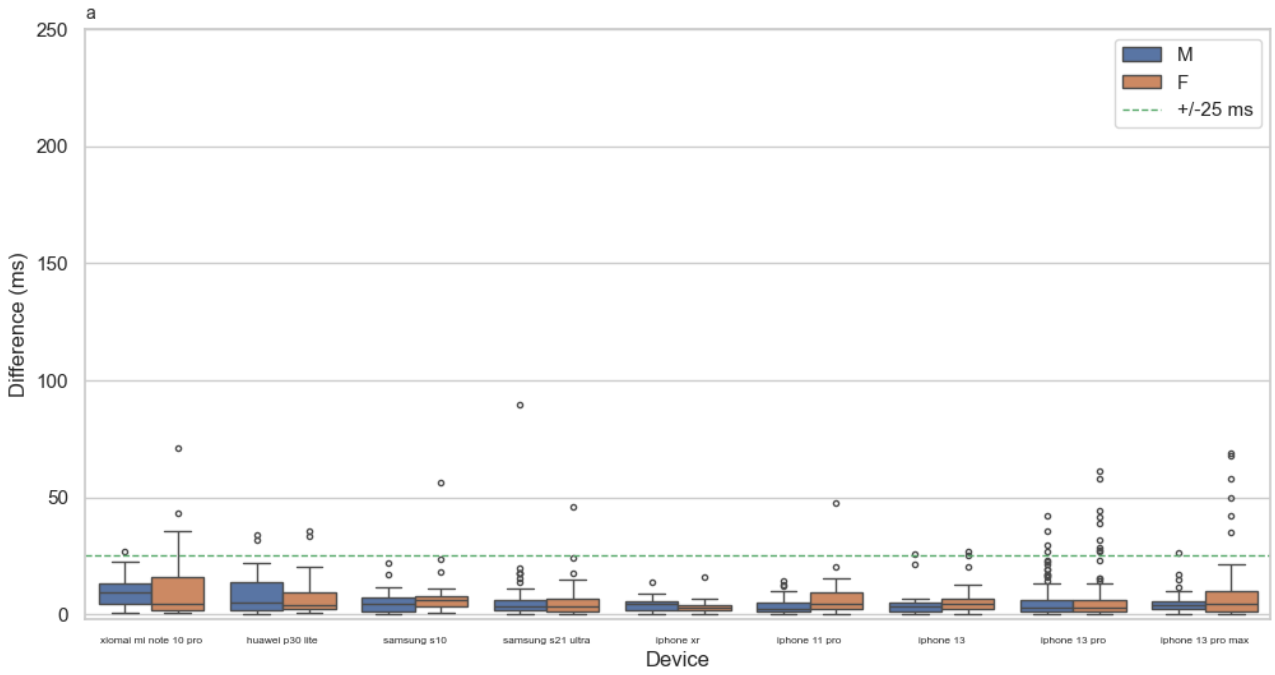

Figure 6:
a. **Box plot by device** - meanRRi measurements obtained by Binah.ai's versus the reference device are highly accurate for both sexes (female and male) on all devices.
The green dashed "Error" lines set at ≤ 25 ms represent the value of the accuracy criterion.

meanRRi error by Country

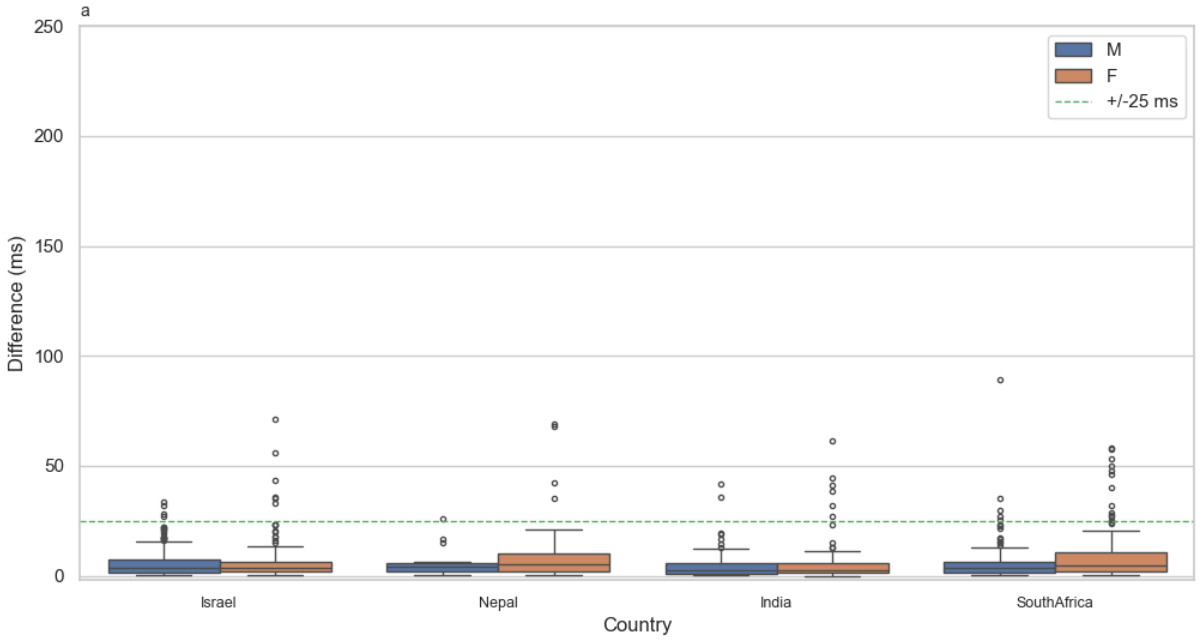

Figure 7:
a. **Box plot by country** - meanRRi measurements obtained by Binah.ai's versus the reference device is highly accurate for both sexes (female and male) on all countries.
The green dashed "Error" lines set at ≤ 25 ms represent the value of the accuracy criterion.

Additional HRV parameters accuracy values

Accuracy of SDNN:

Operating system	Measurements	MAE ± SD	SDNN Range
Android	344	6.1 ± 5.8	5.0 - 70.5
iOS	676	7.4 ± 6.6	2.9 - 85.3

Table 3: Accuracy data for Android and iOS (MAE±SD) when compared to the reference device in the presented SDNN range.
MAE -Mean Absolute Error, SD - Standard Deviation

Accuracy of RMSSD:

Operating system	Measurements	MAE ± SD	RMSSD Range
Android	348	9.2 ± 8.3	2.9 - 93.0
iOS	676	9.9 ± 8.8	2.3 - 128.7

Table 4: Accuracy data for Android and iOS (MAE±SD) when compared to the reference device in the presented RMSSD (Root Mean Square of Successive Differences between normal heartbeats) range.
MAE -Mean Absolute Error, SD - Standard Deviation

Accuracy of PNS Index:

Operating system	Measurements	MAE ± SD	PNS Index Range
Android	351	0.4 ± 0.3	-2.9 - 2.0
iOS	677	0.4 ± 0.3	-3.0 - 3.6

Table 5: Accuracy data for Android and iOS (MAE±SD) when compared to the reference device in the presented PNS (Parasympathetic nervous system) Index range.
MAE -Mean Absolute Error, SD - Standard Deviation

Accuracy of SNS Index:

Operating system	Measurements	MAE ± SD	SNS Index Range
Android	343	0.7 ± 0.6	-1.2 - 8.0
iOS	680	0.7 ± 0.6	-1.4 - 8.4

Table 6: Accuracy data for Android and iOS (MAE±SD) when compared to the reference device in the presented SNS (Sympathetic nervous system) Index range.
MAE -Mean Absolute Error, SD - Standard Deviation