ASCVD Risk Accuracy Report of SDK 5.11

Executive Summary

Goal

This document evaluates the accuracy of ASCVD Risk in SDK 5.11 [iOS and Android] rPPG with reference devices, using data collected in Italy and India.

Results

The ASCVD Risk measured by Binah's SDK was found to be within the accuracy target (AE≤8%) in 85.3% 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 19 to 80
- Similar performance on both operating systems
- Similar performance in several countries with different ethnicities

Conclusions

The ASCVD Risk calculated by Binah's SDK was found to be highly correlated with ASCVD risk values (r=0.925) within the accuracy target (AE ≤ 8%) in 85.3% of the measurements in both operating systems.

Introduction

CVD (Cardio-Vascular Disease) is defined as a group of heart and blood vessel disorders[1,2]. Predicting CVD risk is an important aspect of current therapy for preventing CVD[3,4].

The Framingham Heart Study is a landmark research project aimed at identifying cardiovascular risk factors. It involved tracking the occurrence of new CVD cases over an extended period in a large cohort of Framingham, MA residents, who had not yet shown overt symptoms of the disease [5,6]. The Framingham Risk Score incorporates easily measurable clinical parameters to estimate an individual's 10-year risk of developing CVD[7-10]. It is calculated by an algorithm that uses a regression model to incorporate sex, age, BMI, systolic blood pressure, smoking, and diabetes status[11].

PPG (photoplethysmography) is a non-invasive, simple and low-cost tool that can reflect blood flow in blood vessels and blood volume changes. The PPG waveform comprises a pulsatile ('AC') physiological waveform attributed to blood volume changes with each heartbeat and is superimposed on a slowly varying ('DC') baseline with various lower frequency components attributed to respiration, sympathetic nervous system activity, and thermoregulation. The PPG technology has been used in a wide range of commercially available medical devices for measuring blood pressure, oxygen saturation, cardiac output, and for assessing autonomic function. [6] Camera-based approaches make it possible to derive remote PPG (rPPG) signals.

Binah.ai’s health algorithms use photoplethysmography (PPG) signals recorded from facial skin tissue (rPPG) to extract key physiological parameters. The system analyzes facial video images to generate an rPPG signal, which is processed using AI to provide real-time estimations of Blood Pressure (BP), HbA1c (as a diabetes indicator), enabling ASCVD risk calculations to the end user.

This report summarizes the results of a validation experiment evaluating the agreement between Binah.ai’s ASCVD Risk calculations, which utilize Binah-derived systolic blood pressure and HbA1c measurements, and calculations based on reference-grade measurement devices.

Methods

Binah’s ASCVD Risk estimations were compared with systolic blood pressure measured with Withings or Omron blood pressure cuffs in healthy individuals and patients with Hypertension and Diabetes.

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 BP reference devices included Withings and Omron blood pressure cuffs. The BP cuff was placed around each participant’s arm, at heart level, and BP was measured before and after the recording sessions. Two consecutive BP measurements were taken before and after Binah’s app recordings. If the difference between the two measurements exceeded 10 mmHg for systolic or 5 mmHg for diastolic BP, a third measurement was taken.
Blood tests were conducted as close as possible to the rPPG measurement to minimize timing discrepancies.

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.

ASCVD Risk is calculated by an algorithm that uses a regression model that incorporates sex, age, BMI, systolic blood pressure, smoking, and diabetes status.

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’s application.
Ref is the measurement of the reference device.
i is the index number of measurements.
For this report, Binah.ai’s SDK 5.11 was compared to a reference device.

The measurements were recorded by the mobile device models listed below.

- iOS: iPhone 11 Pro, iPhone 13 Pro, iPhone 13 Pro Max, iPhone 14, iPhone 14 Plus, iPhone 14 Pro, iPhone 14 Pro Max, iPhone 15 Pro
- Android: Xiaomi 14 CIVI, Samsung A56, Samsung S21 Ultra, Samsung S23 Ultra, Pixel 6 Pro, Google Pixel 8a.

Results

Measurement Disposition

Number of subjects/measurements with reported ASCVD Risk: 1109/1631

Number of Unique Subjects and Measurements by country and ASCVD Risk distribution

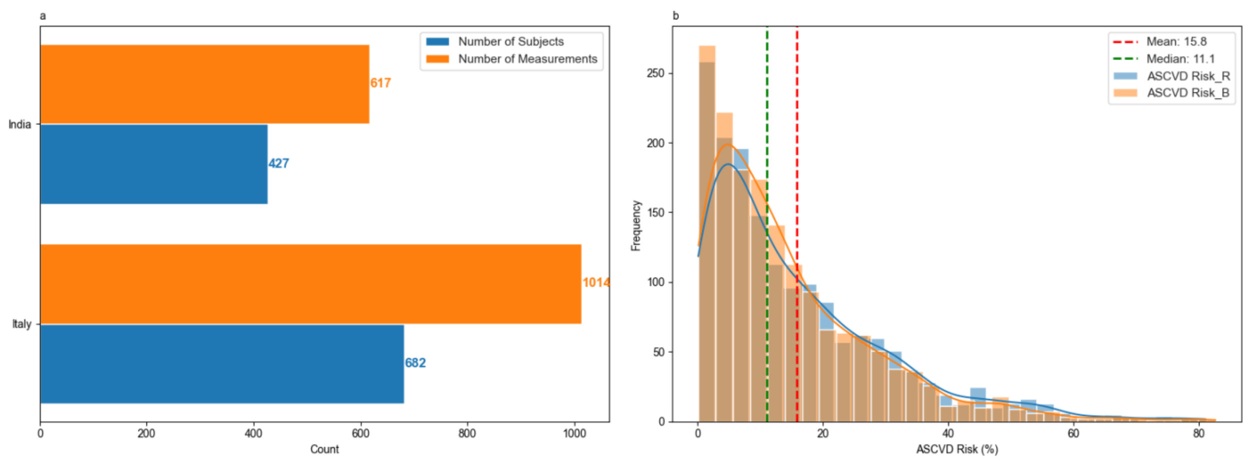

Figure 1:

a. **Number of Unique Subjects and calculations (with reference values) for each country.**
b. **Distribution of ASCVD Risk calculated by the references and by Binah.ai's application.** The mean and median lines are calculated for the reference values.

Demographics Data:

Subjects/Measurements	Age (mean ± std)	BMI (mean ± std)	Sex (F/M)
1109/ 1631	53.3 ± 13.6	27.3 ± 5.2	571 / 538
Fitzpatrick Skin Tone (I/II/III/IV/V/VI)	Beard (No/Yes)	Glasses (No/Yes)	Face cream (No/Yes)
28 / 430 / 265 / 277 / 100 / 6	780 / 326	777 / 329	843 / 263
Angle yaw (mean ± std)	Angle roll (mean ± std)	Angle pitch (mean ± std)	
5.6 ± 4.5	2.6 ± 2.1	9.9 ± 7.1	

Table 1: Demographic data for experiments using the Binah.ai application

* 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	Unique Subjects	Measurements	MAE ± STD	Within Range [%]	Ref Range
iOS	842	882	3.8 ± 4.3	85.4	0.0 - 81.0
Android	723	749	3.6 ± 4.3	85.3	0.0 - 78.0

Table 2: Accuracy data (MAE ± STD) when Binah.ai's and the reference device's measurements are compared in the presented ASCVD Risk range (Ref range).
MAE - Mean Absolute Error, STD - Standard Deviation

Correlation and Bland-Altman plot by Operating System

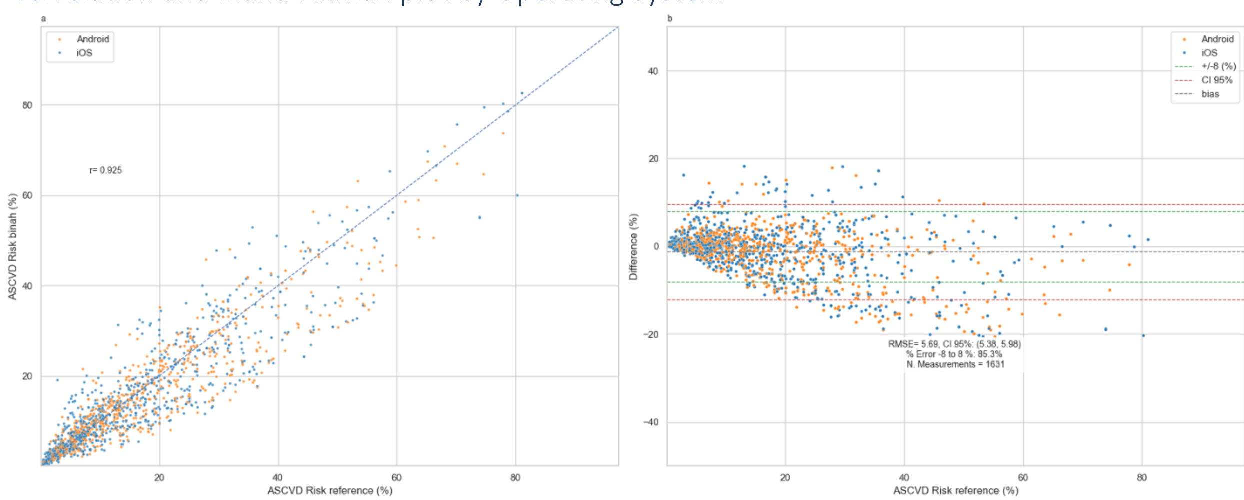

Figure 2:
a. Correlation plot by operating system - Binah.ai's ASCVD Risk estimations versus reference device ASCVD Risk calculations for both operating systems (Android and iOS). The correlation coefficient is R = 0.925.
b. Bland-Altman plot by operating system - Bland-Altman plots for comparison between ASCVD Risk calculations of the two methods (Binah's and the reference device) were within the target error in 85.3% of the calculations for both operating systems (Android and iOS) in the presented ASCVD Risk 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 ± 8 % 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 Binah.ai's ASCVD Risk calculations were found to be correlated with ASCVD Risk calculations from references. ASCVD Risk had an absolute error ≤ 8% in 85.3% of the measurements both iOS and Android operating systems.

References

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Appendix

ASCVD Risk Error by Skin Tone with Gender and Operating System

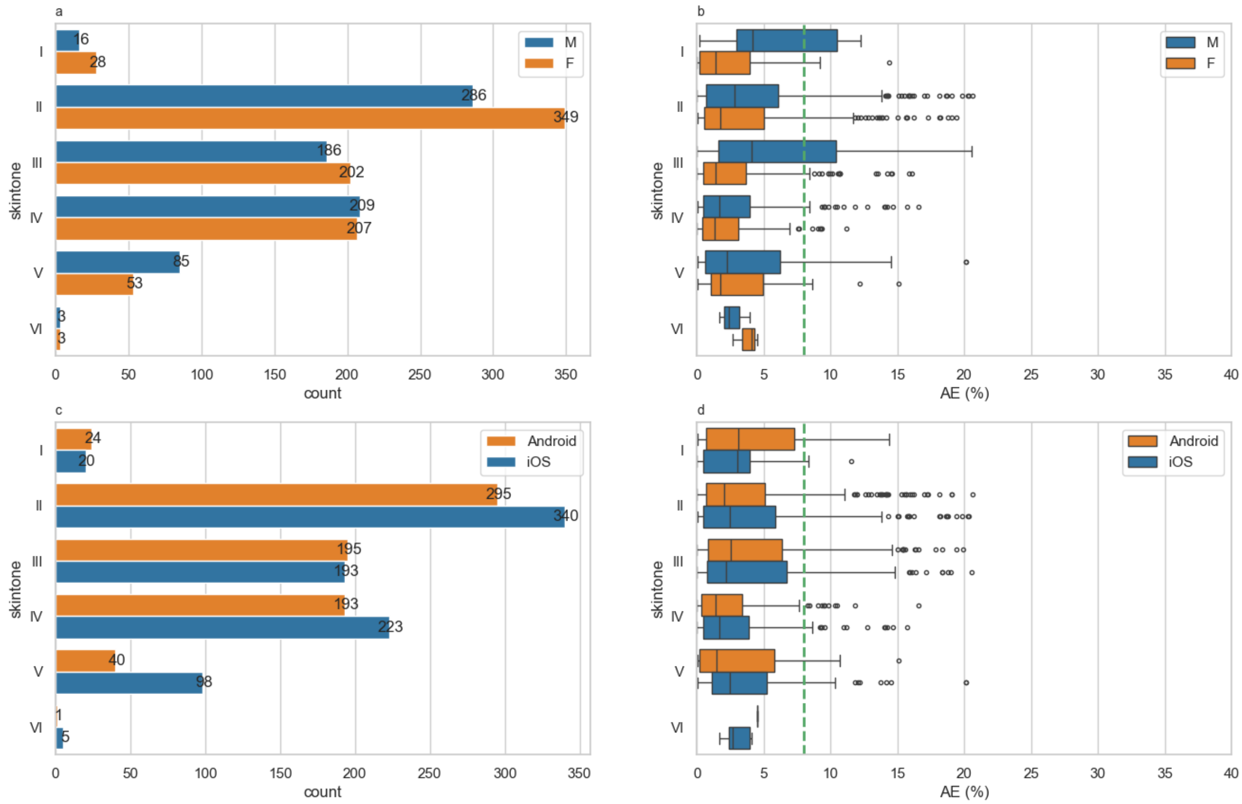

Figure 3:

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

b. Box plot by Fitzpatrick skin tone and Sex – ASCVD Risk calculations obtained by Binah.ai in comparison to the reference device for both sexes (female and male) across all presented skin tones.

The green dashed “Error” lines set at ≤ 8 % 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 - ASCVD Risk calculations obtained by Binah.ai versus the reference for both operating systems (Android and iOS) across all presented skin tones.

The green dashed “Error” lines set at ≤ 8 % represent the value of the accuracy criterion.

ASCVD Risk Error by Face Angles

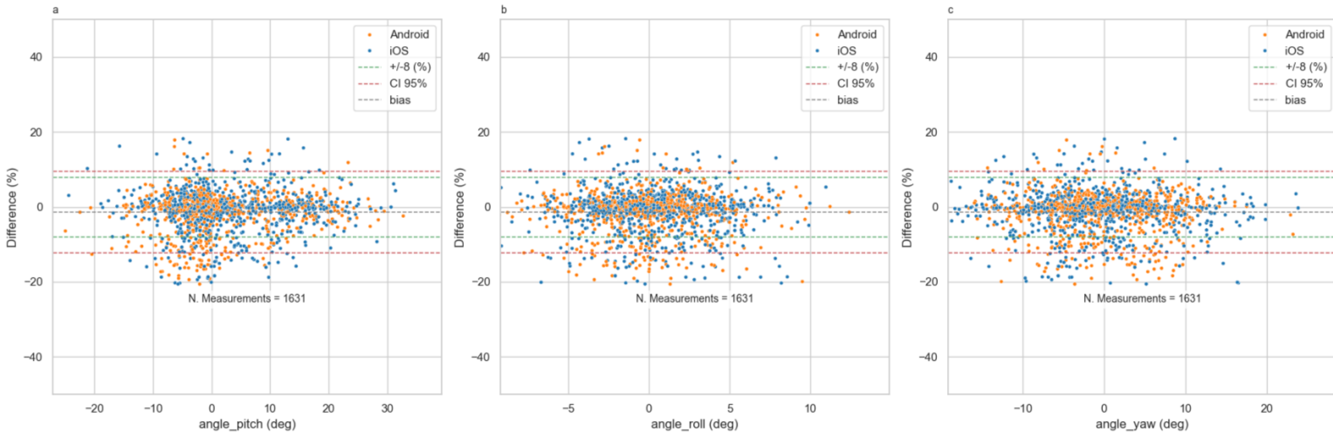

Figure 4:

a. **Bland-Altman plot by pitch angle (deg)** - demonstrated ASCVD Risk calculations 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 ASCVD Risk calculations 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 ASCVD Risk calculations obtained by Binah.ai and the reference device for both operating systems (Android and iOS) within the presented yaw angle 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 ± 8 % represent the value of the accuracy criterion, the "Limits of agreement" lines mark the limit of 95% of the samples.

ASCVD Risk Error by Country

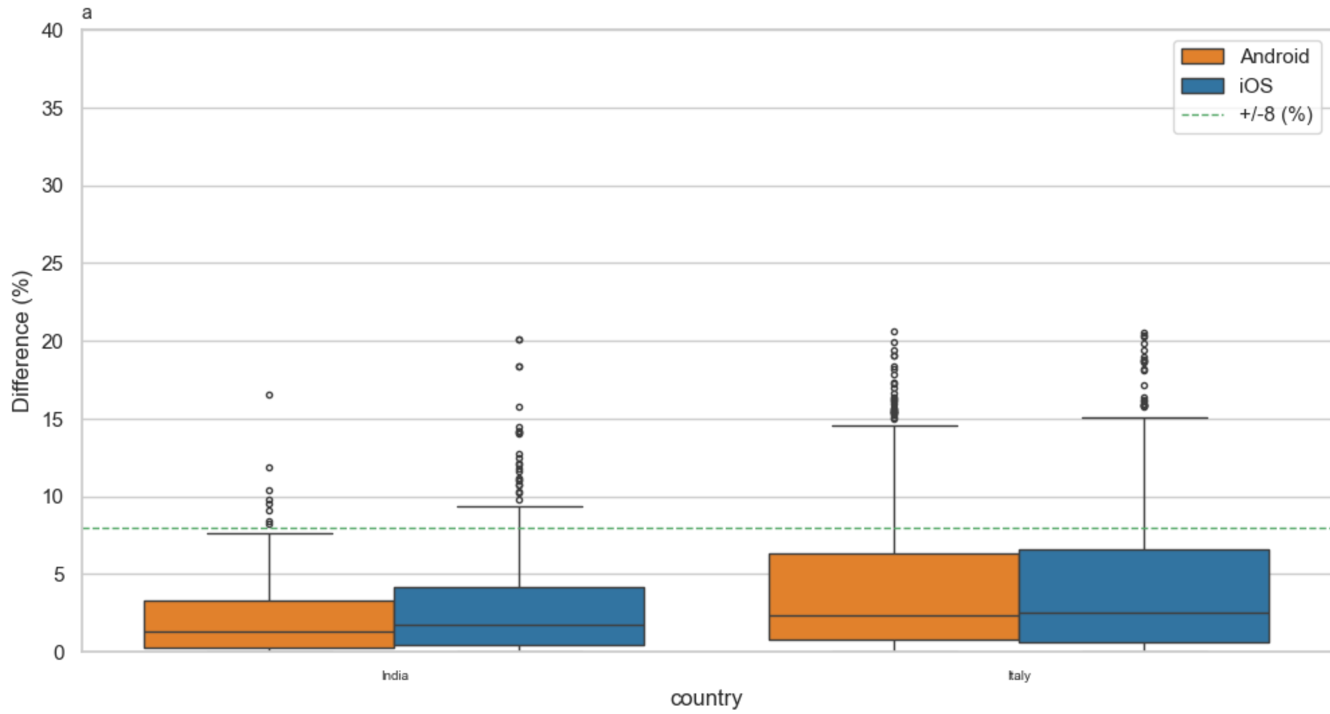

Figure 5:

a. Box plot by country - ASCVD Risk calculations obtained by Binah.ai's versus the reference for both operating systems (Android and iOS) in all countries.

The green dashed "Error" lines set at ≤ 8 % represents the value of the accuracy criterion.