MFD-000021



# Respiratory Rate Accuracy Report of SDK 5.4

# **Executive Summary**

#### Goal

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

#### **Results**

The Respiratory rate measured by Binah's SDK was found to be **highly accurate and within the accuracy target (AE≤3 rpm in >93%)** 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 I to VI)
- Ages 19 to 77
- 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 Respiratory rate measured by Binah's SDK was found to be **robust**, **highly accurate and within the accuracy target (AE≤3 rpm in >93%)** of the measurements for both Android and iOS operating system.

# <u>Introduction</u>

The main function of the respiratory system is gas exchange. Oxygen is transferred from the environment into the bloodstream, while carbon dioxide is expelled. When inhaling, the air passes to the lungs. Gas exchange occurs when oxygen diffuses into the lung capillaries in exchange with carbon dioxide. Exhalation starts after the gas exchange, and the air containing carbon dioxide returns to the external ambient through the nose or mouth. In addition, the respiratory system has other secondary functions including filtering, warming, and humidifying the inhaled air. There is a close relationship between respiration and heart activity. Heart rate is regulated by respiration, increases during inhalation, and decreases during exhalation<sup>3</sup>.

Respiration Rate (RR), defined as the number of respirations per minute (rpm), is a clinical parameter that represents ventilation, i.e., the movement of air in and out of the lungs. The normal RR varies from person to person, but it generally lies between 12-20 respirations per minute at rest. RR is a valuable diagnostic and prognostic marker of health used in a range of clinical settings to identify abnormalities.

In hospital healthcare, it is a highly sensitive marker of acute deterioration.<sup>6</sup> For instance, elevated RR is a predictor of cardiac arrest<sup>7</sup> and in-hospital mortality<sup>8</sup>, and can indicate respiratory dysfunction<sup>9</sup>.

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RR is usually still measured by manually counting chest wall movements (outside of intensive care). This process is time consuming, inaccurate<sup>10,11</sup>, and poorly executed<sup>12,13</sup>. Therefore, there is a great need for a non-intrusive, automatic method of measuring RR.

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 RR - measurements were compared to the Vernier Go Direct® Respiration Belt and/or finger pulse oximeter measurements Masimo finger pulse oximeter 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 Respiration rate reference devices that were used included: the Vernier Go Direct® Respiration Belt and/or Masimo finger pulse oximeter which were placed on each participant's finger to measure RR.

For rPPG measurements, a mobile device was placed on a stand or held by the subject's hand, 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.

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### 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:

**RR:**  $AE \le 3$  rpm in 85% of measurements.

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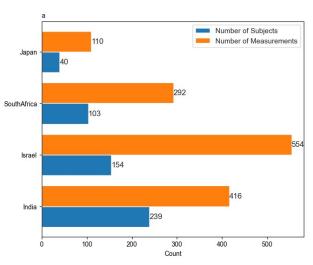
# Results

## Measurement disposition

Number of measurements: 1515

Percentage of reported measurements (after signal quality check where confidence score is high): 90.6% **Number of subjects/measurements with reported HRV**: 536/1372

#### Number of Unique Subjects and Measurements by Country and Respiration Rate distribution



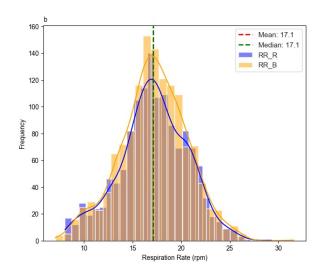


Figure 1:

- **a. Number of Unique Subjects and Measurements by Country** data presented includes all measurements with reference values.
- **b.** Distribution of Respiration rate 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)	
536 / 1372	37.5 ± 11.4	25.0 ± 5.2	272 / 264	
Fitzpatrick Skin Tone (I/II/III/IV/V/VI)	Beard (No/Yes)	Glasses (No/Yes)	Face cream (No/Yes)	
3 / 96 / 114 / 212 / 72 / 39	329 / 182	329 / 12	338 / 173	
Distance (mean ± std)	Luminance (mean ± std)	Angle yaw (mean ± std)	Angle roll (mean ± std)	Angle pitch (mean ± std)
0.23 ± 0.02	136.7 ± 134.4	5.0 ± 3.4	1.9 ± 1.5	10.9 ± 7.1

Table 1: Demographic data for experiments using phones with Android and iOS operating systems.

<sup>\*</sup> 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:**

Operation System	Measurements	MAE ± SD	Respiration Rate Range
Android	657	1.1 ± 1.0	8 - 29
iOS	715	1.0 ± 1.0	8 - 26

**Table 2:** Accuracy data for Android and iOS (MAE±SD) when compared to the reference device in the presented respiration rate range.

MAE -Mean Absolute Error, SD - Standard Deviation

#### Correlation and Bland-Altman plot by Operating System

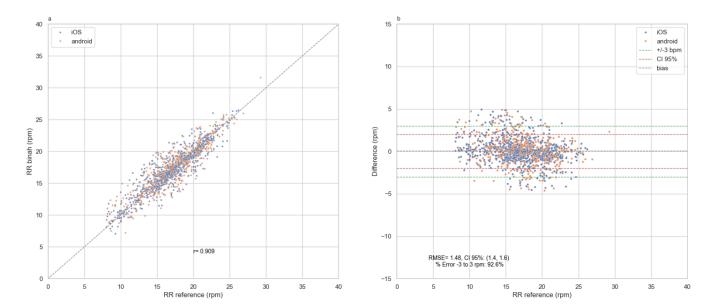


Figure 2:

- **a. Correlation plot by operating system** Binah.ai's RR estimations versus reference device RR measurements found to be with correlation of r= 0.909 for both operating system (Android and iOS).
- **b. Bland-Altman plot by operating system** Bland-Altman plots for comparison between RR measurements of the two methods (Binah's and the reference device) demonstrated agreement between the two devices (93% of the measurements are within target error) for both operating systems (Android and iOS) in the presented respiration 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 rpm 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 Respiratory rate measured by Binah.ai's SDK was found to be **robust**, **highly accurate and within the accuracy target (AE≤3 rpm in 93%)** of the measurements for both Android and iOS operating system.

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# References

- 1. Ali, M., Elsayed, A., Mendez, A., Savaria, Y. & Sawan, M. Contact and remote breathing rate monitoring techniques: A review. *IEEE Sens. J.* (2021).
- 2. Tu, J., Inthavong, K. & Ahmadi, G. *Computational fluid and particle dynamics in the human respiratory system*. (Springer Science & Business Media, 2012).
- 3. Pallas-Areny, R., Colominas-Balague, J. & Rosell, F. J. The effect of respiration-induced heart movements on the ECG. *IEEE Trans. Biomed. Eng.* **36**, 585–590 (1989).
- 4. Barrett, K. E., Barman, S. M. & Boitano, S. Ganong's review of medical physiology McGraw-Hill Education. (2019).
- 5. Charlton, P. H. *et al.* Breathing rate estimation from the electrocardiogram and photoplethysmogram: A review. *IEEE Rev. Biomed. Eng.* **11**, 2–20 (2017).
- 6. Cretikos, M. *et al.* The objective medical emergency team activation criteria: a case–control study. *Resuscitation* **73**, 62–72 (2007).
- 7. Schein, R. M. H., Hazday, N., Pena, M., Ruben, B. H. & Sprung, C. L. Clinical antecedents to inhospital cardiopulmonary arrest. *Chest* **98**, 1388–1392 (1990).
- 8. Duckitt, R. W. *et al.* Worthing physiological scoring system: derivation and validation of a physiological early-warning system for medical admissions. An observational, population-based single-centre study. *Br. J. Anaesth.* **98**, 769–774 (2007).
- 9. Gravelyn, T. R. & Weg, J. G. Respiratory rate as an indicator of acute respiratory dysfunction. *Jama* **244**, 1123–1125 (1980).
- 10. Philip, K. E. J. *et al.* The accuracy of respiratory rate assessment by doctors in a London teaching hospital: a cross-sectional study. *J. Clin. Monit. Comput.* **29**, 455–460 (2015).
- 11. Lovett, P. B., Buchwald, J. M., Stürmann, K. & Bijur, P. The vexatious vital: neither clinical measurements by nurses nor an electronic monitor provides accurate measurements of respiratory rate in triage. *Ann. Emerg. Med.* **45**, 68–76 (2005).
- 12. Pimentel, M. A. F., Charlton, P. H. & Clifton, D. A. Probabilistic estimation of respiratory rate from wearable sensors. in *Wearable electronics sensors* 241–262 (Springer, 2015).
- 13. Philip, K., Richardson, R. & Cohen, M. Staff perceptions of respiratory rate measurement in a general hospital. *Br. J. Nurs.* **22**, 570–574 (2013).

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# **Appendix**

## Respiration Rate error by Age and BMI

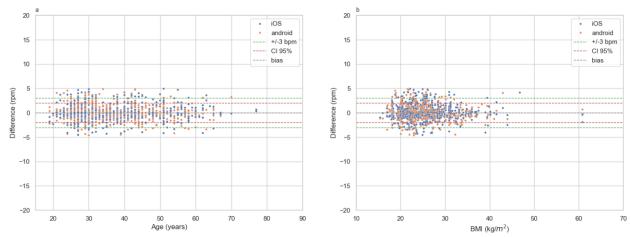


Figure 3:

a. Bland-Altman plot by age - demonstrated RR measurements obtained by Binah.ai and the reference device for both operating systems (Android and iOS) within the presented AGE range.

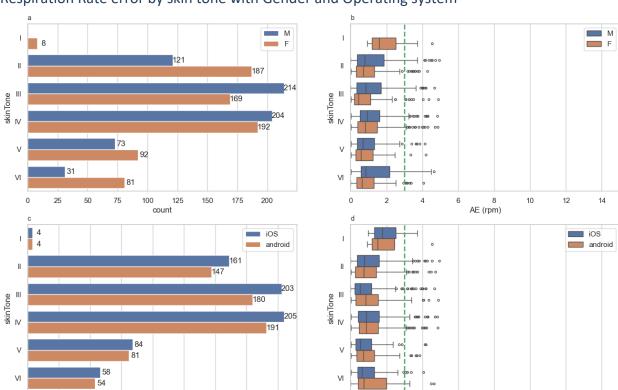
**b. Bland-Altman plot by BMI** - demonstrated RR measurements obtained by Binah.ai and the reference device for both operating systems (Android and iOS) within the presented BMI range from low to very high.

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 rpm represent the value of the accuracy criterion, the "Limits of agreement" lines mark the limit of 95% of the samples.

14

AE (rpm)





# Respiration Rate error by skin tone with Gender and Operating system

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Figure 4:

75

100

125

- a. Number of measurements by Fitzpatrick skin tone and sex (female and male).
- **b.** Box plot by Fitzpatrick Skin tone and Sex RR measurements obtained by Binah.ai's in comparison to the reference device are highly accurate for both sexes (female and male) across most of presented skin tones. The green dashed "Error" lines set at  $\leq 3$  rpm 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- RR 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 rpm represents the value of the accuracy criterion.

### Respiration Rate error by Distance and Luminance

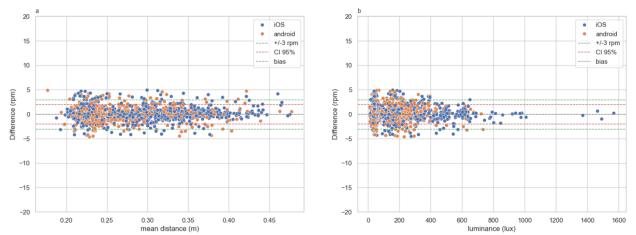


Figure 5:

- **a. Bland-Altman plot by Distance (m)** demonstrated agreement between RR measurements obtained by Binah.ai 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 agreement between RR 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 "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 rpm represent the value of the accuracy criterion, the "Limits of agreement" lines mark the limit of 95% of the samples.

### Respiration Rate Error by Devices

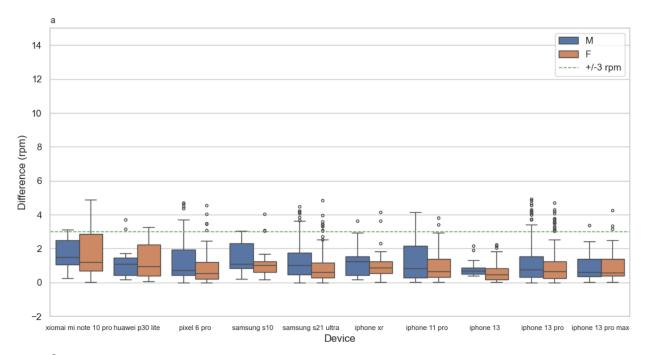


Figure 6:

**a. Box plot by device** - RR measurements obtained by Binah.ai versus the reference device for both sexes (female and male) on all devices.

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

## **Respiration Rate Error by Country**

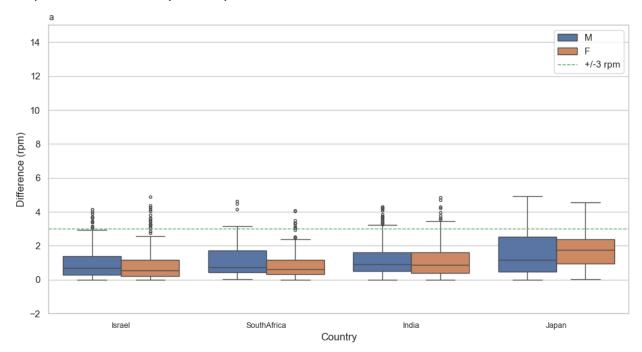


Figure 7:

a. Box plot by country - RR measurements obtained by Binah.ai versus the reference device for both sexes (female and male) in all countries.

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