Respiration Rate Validation Report Version 1.0

MED-000005

Respiration Rate Validation

Introduction

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 exhalation³.

Respiration Rate (RR), or the number of respirations per minute, is a clinical parameter that represents ventilation, i.e., the movement of air in and out of the lungs.¹ The normal RR varies from person to person, but it generally lies between 12-20 respirations per minute at rest.⁴ RR is a valuable diagnostic and prognostic marker of health used in a range of clinical settings to identify abnormalities.⁵ In hospital healthcare, it is a highly sensitive marker of acute deterioration.⁶ For instance, elevated RR is a predictor of cardiac arrest⁷ and in-hospital mortality⁸, and can indicate respiratory dysfunction⁹.

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

Binah.ai's RR algorithm uses the photoplethysmography (PPG) signal recorded from facial skin tissue (remote PPG - rPPG). The rPPG signal comprises a pulsatile component (AC) provided by the cardiac variations in blood volume that arise from heartbeats, and a DC component, affected by various factors, including respiration¹⁴.

Definitions:

Respiration Rate is defined as the average number of respirations per minute [rpm].

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

Methods

Binah.ai's RR measurements were compared to the Vernier Go Direct® Respiration Belt in healthy participants.

Measurement set-up:

Each participant was instructed to sit as stably as possible. A Go Direct® Respiration Belt by Vernier was placed around the participant's chest. Recordings were conducted in a testing room located in Binah.ai's offices, with controlled and fixed artificial ambient light.

A mobile device was placed on a stand in front of the participant. The participant's face filled over 20% of the frame's area (distance of 30-40 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 during the whole recording and to avoid any movement (including talking). Each recording lasted approximately 60 seconds.

Statistical analysis:

Accuracy was calculated using the following parameters:

$$AE (Absolute Error) = App_i - Ref_i$$

$$\mathit{RMSE} = \sqrt{\frac{\sum_{i=1}^{N} (App_i - Ref_i)^2}{N}}$$

$$MAE = \frac{1}{N} \sum_{i=1}^{N} |App_i - Ref_i|$$

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 the measurements.

Confidence intervals (CI) were calculated using the bootstrap method and indicate where the estimator (i.e., RMSE) would fall, with 95% confidence, for future samples.

Participants with outlier AE (defined as 3 standard deviations or more above the mean) and participants with invalid reference device values were excluded from analysis.

For this report, the Binah.ai's SDK 4.10.1 version was used.

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

iOS: iPhone 11Pro, iPhone 13 Pro.

Android: Samsung S10, Samsung S21 Ultra, Pixel 6 Pro.

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Results

Demographic Data:

Table 1 includes participants' demographic data for each operating system (iOS and Android).

Operating	Number of	Age Range			
System	Participants	(average)	Sex	Fitzpatrick Skin Tone *	
iOS	132	18-78 (35)	F (42%), M (58%)	2 (36%), 3 (60%), 4 (4%)	
Android	128	18-78 (36)	F (42%), M (58%)	2 (35%), 3 (60%), 4 (4%)	

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

Accuracy Data:

Table 2 includes accuracy data for iOS and Android (RMSE, RMSE CI 95%, MAE±SD). The AE < 1, 2, 3 rpm columns present the number (and percentage) of measurements with an absolute error, which is smaller than 1, 2, 3 rpm respectively. RR range used for analysis was 8-30 rpm.

Operating		Number of		RMSE				
System	Vital Sign	measurements	RMSE	CI 95%	MAE±SD	AE < 1rpm	AE < 2rpm	AE < 3rpm
iOS	RR (rpm)	425	1.3	[1.1, 1.5]	0.8±1.1	318 (75%)	387 (91%)	403 (95%)
Android	RR (rpm)	316	1.6	[1.4, 1.9]	1.1±1.3	206 (65%)	264 (84%)	293 (93%)

Table 2: RMSE, RMSE CI 95%, MAE±SD, and number of participants (and percentage) with AE < 1, 2, 3 rpm, for measurements using phones with an iOS and Android operating systems, when compared to the reference device. CI were calculated using the bootstrap method. Abbreviations: RMSE - Root Mean Square Error, CI - Confidence Intervals, MAE -Mean Absolute Error, SD - Standard Deviation, AE – Absolute Error.

Pearson correlations between Binah.ai's RR estimations versus Vernier Go Direct® measurements were calculated and presented in **Figure 1.** Pearson correlation coefficients (R values) were high for both operating systems (Android and iOS).

The Bland-Altman plots for comparison between measurements of the two methods (Binah.ai's and the reference device) are presented in **Figures 2**.

^{*} Fitzpatrick skin tone classifications are: 1- Pale white, 2- white, 3- Darker white, 4- Light brown, 5- Brown, 6- Dark brown or black.



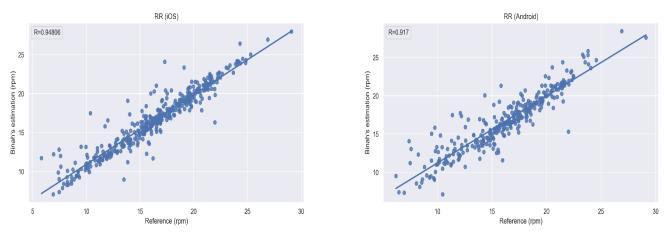


Figure 1: Binah.ai's RR estimations vs. reference device measurements. Pearson correlations were calculated, and correlation coefficients are presented on each plot (R). Plots describe measurements conducted with both operating systems (iOS and Android).

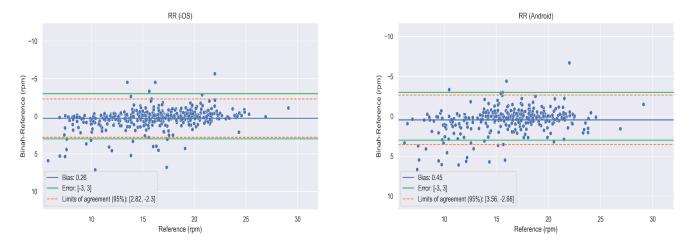


Figure 2: Bland-Altman plots for comparison between the two methods used to measure RR (Binah.ai's and the reference device). Plots describe measurements conducted using both operating systems (iOS and Android). The "Bias" line stands for the mean difference between measurements of Binah.ai and the reference device, the "Error" lines 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 validation experiments in which Binah.ai's RR measurements were found to be highly correlated with the reference device.

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