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Contactless measurement of heart rate, heart rate variability and breathing rate based on facial video analysis (remote photoplethysmography) - validation of the SHEN.AI Vitals software “(protocol number : MDF-01-008-01, version 01).”

CLINICAL VALIDATION REPORT

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INTRODUCTION

The Shen.AI Vitals technology developed by MX Labs is based on remote photoplethysmography (rPPG), which is a contactless optical technique of recording blood pulsations in the skin vasculature. The rPPG signals represent fluctuations in the intensity of light reflected from the skin, which are caused by changes in the amount of light absorbed by the blood in the superficial vessels as a result of their pulsation. These fluctuations are invisible to the naked eye but usually strong enough to be detected by a camera (e.g. in a smartphone, tablet, or laptop).

Shen.AI Vitals uses advanced face tracking and optical stabilization techniques to obtain rPPG signals from the facial skin during a 1-minute video recording and then employs various signal processing algorithms to analyze and combine information from those signals to estimate the heart rate (HR), heart rate variability (HRV), as well as breathing rate (BR). Additionally, every second during the measurement, Shen.AI calculates the instantaneous HR averaged over a shorter period of time (previous 10 s or 4 s).

The aim of this study was to assess the precision and accuracy of HR, HRV, and BR measurements performed using Shen.AI Vitals technology by comparison with reference measurements, i.e. electrocardiogram (ECG) for HR and HRV, and the electrical chest impedance recording of chest movements for BR.

METHODS

Subjects

The study was carried out at the University Clinical Research Support Center of Wroclaw Medical University (WMU) between April and July 2023. We studied 134 healthy, adult volunteers aged 19 to 80 years (mean 24 years), of whom 71 were females. Subjects were free from cardiovascular diseases and did not engage in any strenuous physical activity before participating in the study. Each participant was measured 8 times in various device configurations (smartphone/tablet/laptop) and lighting conditions (natural/artificial). That amounts to 1068 measurements before exclusions. Due to technical issues with ECG or impedance signals, we had to exclude data from four subjects, and hence the final analysis was based on data from 130 subjects (71 females). In 987 cases (92%), it was possible to conduct measurements on the tested product. In 15 cases, technical issues occurred during the transmission of measurement results from the mobile application to the server (only for the purpose of this analysis), and in 6 cases, there were problems with registering the reference ECG signal. Additionally, measurements conducted on participants with significant arrhythmia (numerous premature beats and atrial fibrillation) were excluded from the analysis. Ultimately, the analysis included 944 measurements from 130 subjects.

Table 1. Characteristics of study participants. Continuous variables presented as medians [interquartile range; full range]. Categorical variables presented as frequencies (percentages).

	Recruited (n = 134)	**Included in the analysis (n = 130)**
General characteristics		
Females, n (%)	72 (54%)	71 (55%)
Age, years	24 [22 – 30; 19 – 80]	24 [22 – 30; 19 – 80]
Body mass, kg	70 [61 – 82; 46 – 122]	70 [61 – 82; 46 – 122]
Body height, cm	175 [167 – 182; 150 – 197]	175 [167 – 181; 150 – 197]
Smokers, n (%)	23 (17%)	20 (15%)
Baseline physiological parameters		
Systolic blood pressure, mmHg	115 [109 – 126; 93 – 151]	115 [109 – 126; 93 – 151]
Diastolic blood pressure, mmHg	74 [69 – 81; 54 – 105]	75 [69 – 81; 54 – 105]
Heart rate, bpm	74 [68 – 82; 50 – 115]	75 [68 – 82; 52 – 115]
Hemoglobin, g/dL	14.8 [13.7 – 15.9; 11.1 – 17.4]	14.8 [13.7 – 16.0; 11.1 – 17.4]
Skin fototype (Fitzpatrick scale)		
I	5 (4%)	5 (4%)
II	42 (31%)	41 (32%)
III	44 (33%)	44 (34%)
IV	34 (25%)	34 (26%)
V	5 (4%)	4 (3%)
VI	4 (3%)	2 (2%)

Data collection

The video recordings of participant's faces were acquired using the front camera of a laptop, smartphone or tablet mounted on a tripod at a distance of about 50 cm from the face and equipped with a special research app developed by MX Labs. In parallel, a 5-lead ECG was recorded continuously using the Finapres Nova (Finapres Medical Systems B.V.) module, along with the measurements of impedance signal of chest movements for BR. A special audio signal was sent by the phone app to the Finapres Nova system at the beginning and end of each video recording to facilitate the synchronization of the reference signals. Signals from the Finapres Nova were exported to NovaScope (Finapres Medical Systems B.V.) and transformed into a .csv extension for further analysis.

Study protocol

The subjects remained seated throughout the study. The video recordings were started at least 3 min after connecting all devices and initiating the reference measurements in order to ensure that measurements were taken under rest conditions. Measuring session included 8 recordings in various setups:

1. Measurement performed by another person (previous study participant or study staff) using rear camera of the smartphone held in hand/hands,
2. Self-measurement performed at the participant discretion way
3. Self-measurement performed using a smartphone camera placed on a stand on a table,
4. Self measurement performed using a smartphone camera held in hand/hands
5. Self measurement performed using a tablet camera held in hand/hands,505
6. Self measurement performed using a laptop camera placed on a table,
7. Self measurement performed using a smartphone camera placed on a stand on a table with natural light (as opposed to artificial light in other measurements),
8. Self measurement performed using a smartphone camera held in hand/hands in a lying position (as opposed to a sitting position in other measurements).

The video recordings lasted 1 min and took place in parallel with the continuous reference measurements. The subjects were asked to remain steady during the video recording, to refrain from speaking, and to breathe normally.

Data analysis

The video recordings were analyzed by Shen.AI algorithms running on the end device (smartphones, laptops, tablets), providing the estimated values of HR (average and instantaneous values), HRV indices, and BR (breathing rate) for each recording. The analyzed HRV indices included SDNN (standard deviation of normal heartbeat intervals) and log-transformed RMSSD (root mean square of successive differences between the heartbeat intervals). The NovaScope software was used to detect QRS complexes in the ECG signals and to calculate the reference heartbeat intervals. The intervals from the studied 1 min period were then used to calculate the reference values of HR (average and instantaneous 4s and 10s), SDNN, and lnRMSSD. The reference BR values were obtained by impedance signal or manual (visual) counting of the breathing cycles visible in the signal. The results provided by the Shen.AI Vitals technology were then compared with the reference results.

RESULTS

HR

Heart rate measurement of the examined product proved to be highly accurate, both in terms of the average heart rate value over the entire measurement period and the quasi-instantaneous values (determined over 10- or 4-second intervals). In all cases, the median of absolute errors was 0 bpm (beats per minute), while the square root of the mean square error was 0.3, 0.4, and 0.8 bpm, respectively, for HR 1 min, 10 s and 4 s (Table 2.)

HRV

SDNN

Since short-term heart rate variability indicators (especially 1-minute variability such as SDNN) are not currently used in clinical practice, there are no established norms or guidelines regarding an acceptable measurement error limit for such indicators. In this analysis, an arbitrary measurement error limit for SDNN was set at ± 15 ms, which was determined as 10% of the expected measurement range of SDNN in the examined product, i.e., 150 ms. For this indicator an average error of 1.9ms and a root mean square error of 6.3ms were achieved.

In the range of 30 - 90 ms, where the most common values of SDNN are typically measured, 95% of measurements are observed to be within ± 15 ms. Beyond this range, 90.3 % of measurements have absolute error below 10ms.

lnRMSSD

In the case of the lnRMSSD indicator, slightly better measurement error levels were observed compared to the measurements of the SDNN indicator. The median of absolute errors was 0.2 (compared to 3.0 for SDNN), and the root mean square error was 0.38 (compared to 6.3 for SDNN). Approximately 69% of measurements showed an error of less than 10% (compared to 56% for SDNN). Within the arbitrary error range of ± 0.6 (i.e., 10% of the lnRMSSD measurement range), 90.5% of the results are included.

BR

In the design of this study, an arbitrary acceptable measurement error for breathing rate (BR) was set at ±4 bpm (breaths per minute) relative to reference measurements. The mean error was 0.0, and the root mean square error was 2.3 bpm. Among all the analyzed measurement results, an error of less than 4 bpm was found in 95.5% cases.

Altogether, results for heart rate, HRV and BR measurements are presented in the table below.

Table 2. Accuracy and precision of heart rate, heart rate variability, and breathing rate measurements performed with Shen.AI Vitals technology as compared with reference measurements. ME - mean error, SD - standard deviation of errors, MAE - mean absolute error, MedAE - median absolute error, RMSE - root-mean-square error, n – total number of data points. The data refer to all measurements included in the analysis.

	n	ME	SD	MAE	MdAE	RMSE	
Main parameters							
Heart rate (1 min)	936	0.2	0.3	0.1	0.0	0.3	bpm
Heart rate (10 s)	44447	0.0	0.4	0.2	0.0	0.4	bpm
Heart rate variability (SDNN)	936	1.9	6.0	4.4	3.0	6.3	ms
Breathing rate	598	0.0	2.3	1.3	1.0	2.3	bpm
Modified parameters							
Breathing rate ≥ 10 bpm	584	0.2	1.9	1.2	1.0	1.9	bpm
Additionally tested parameters							
Heart rate (4 s)	48887	0.0	0.8	0.5	0.0	0.8	bpm
Heart rate variability (lnRMSSD)	936	-0.01	0.38	0.29	0.20	0.38	-

Dashed lines on a charts indicate the accepted error limits for individual parameters, specifically:

- For HR: ±5 bpm (in accordance with norm ANSI/AAMI/IEC 60601-2-27:2011 [R2016])
- For BR: ±5 bpm (typical error range between observers in the case of the classical method for measuring breathing rate in clinical practice, i.e., chest movement counting)
- For HRV indicators: ±10% of the measurement range (i.e., ±15 ms for SDNN, ±0.6 for lnRMSSD)

Heart rate (1 min)

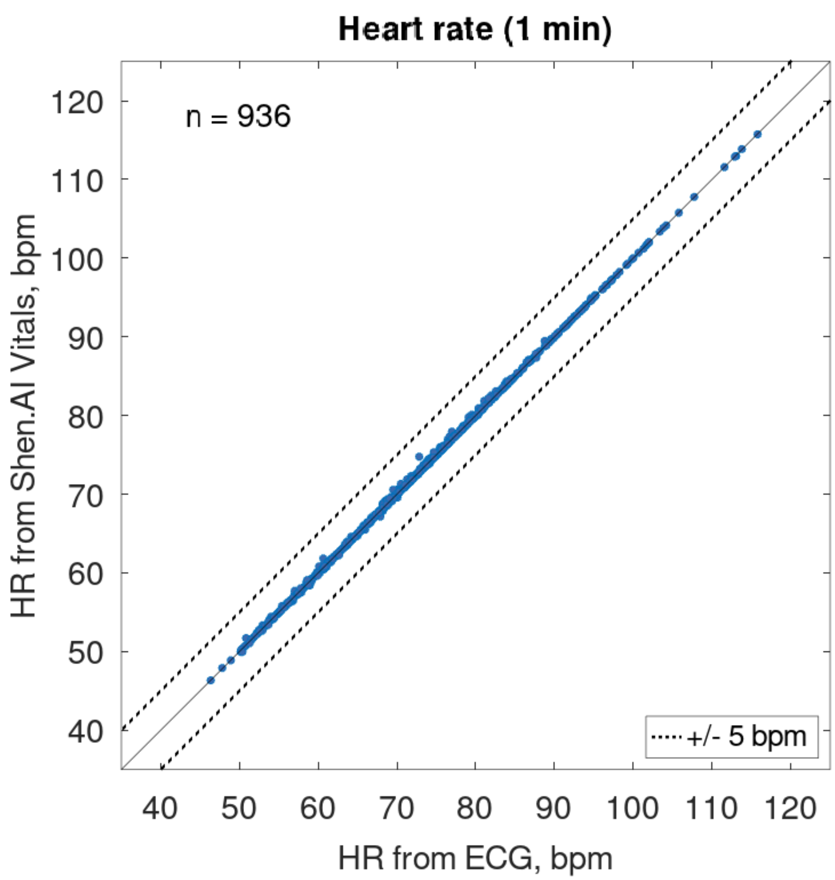

Figure 1. Average (1-minute) heart rate estimated using the Shen.AI Vitals technology plotted against the reference values obtained simultaneously with the ECG.

Heart rate (10 s)

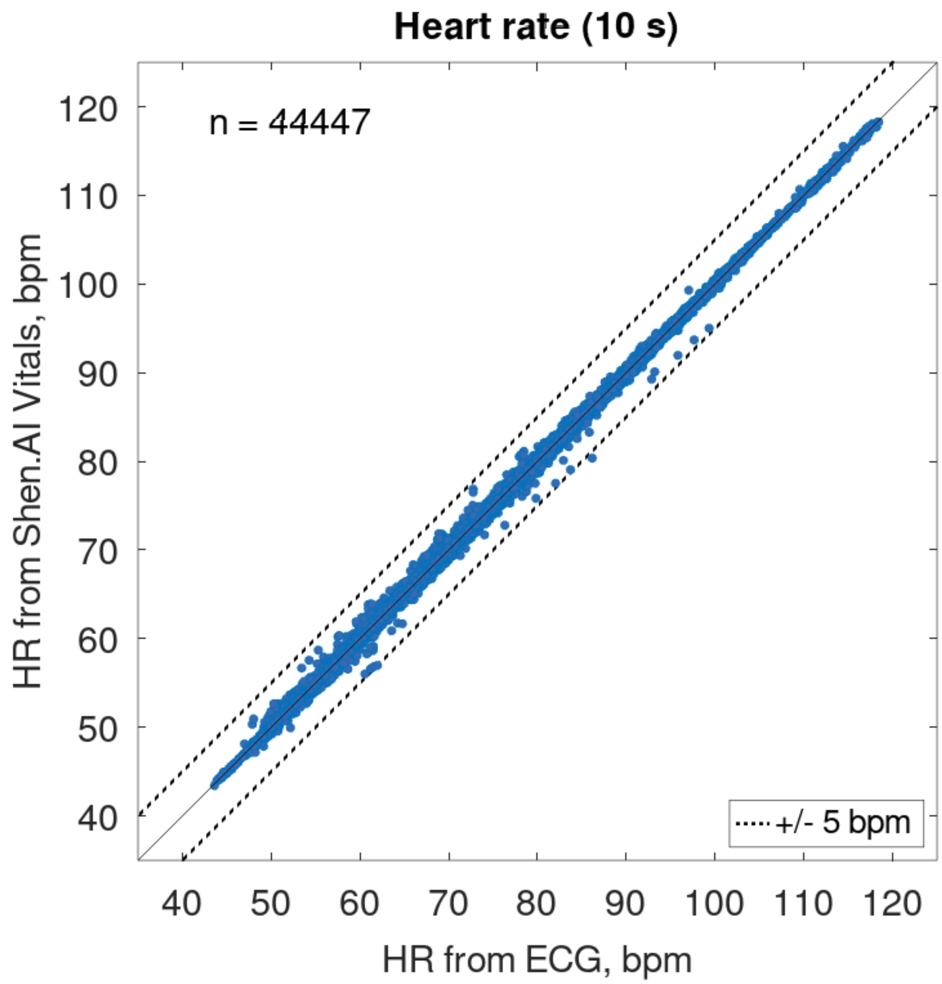

Figure 2. Quasi-instantaneous heart rate values estimated using the Shen.AI Vitals technology (average values from 10 s; up to 49 values per 1-minute measurement) plotted against the reference values obtained simultaneously with the ECG.

Heart rate (4 s)

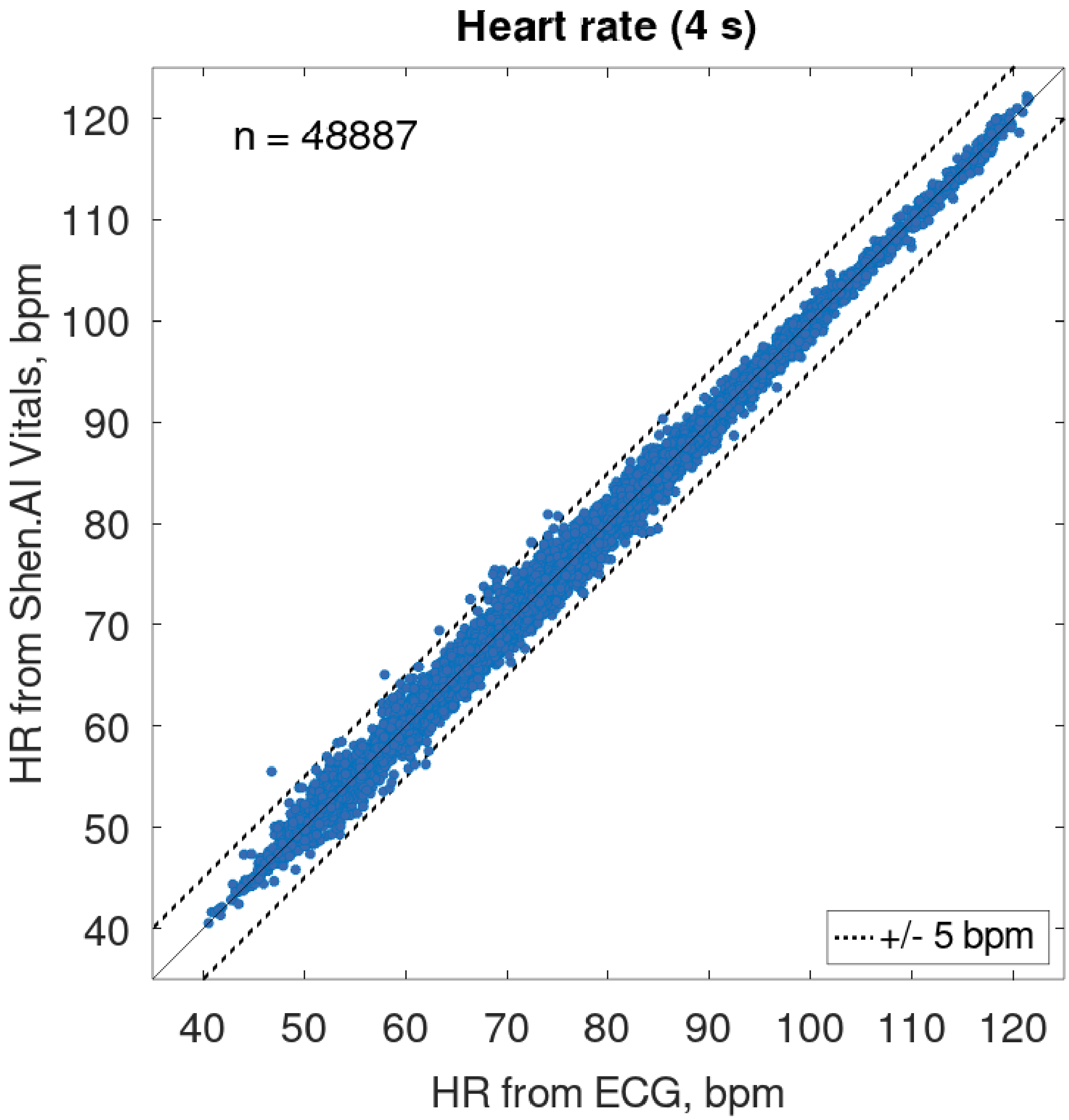

Figure 3. Quasi-instantaneous heart rate values estimated using the Shen.AI Vitals technology (average values from 4 s; up to 54 values per 1-minute measurement) plotted against the reference values obtained simultaneously with the ECG.

Heart rate variability (SDNN)

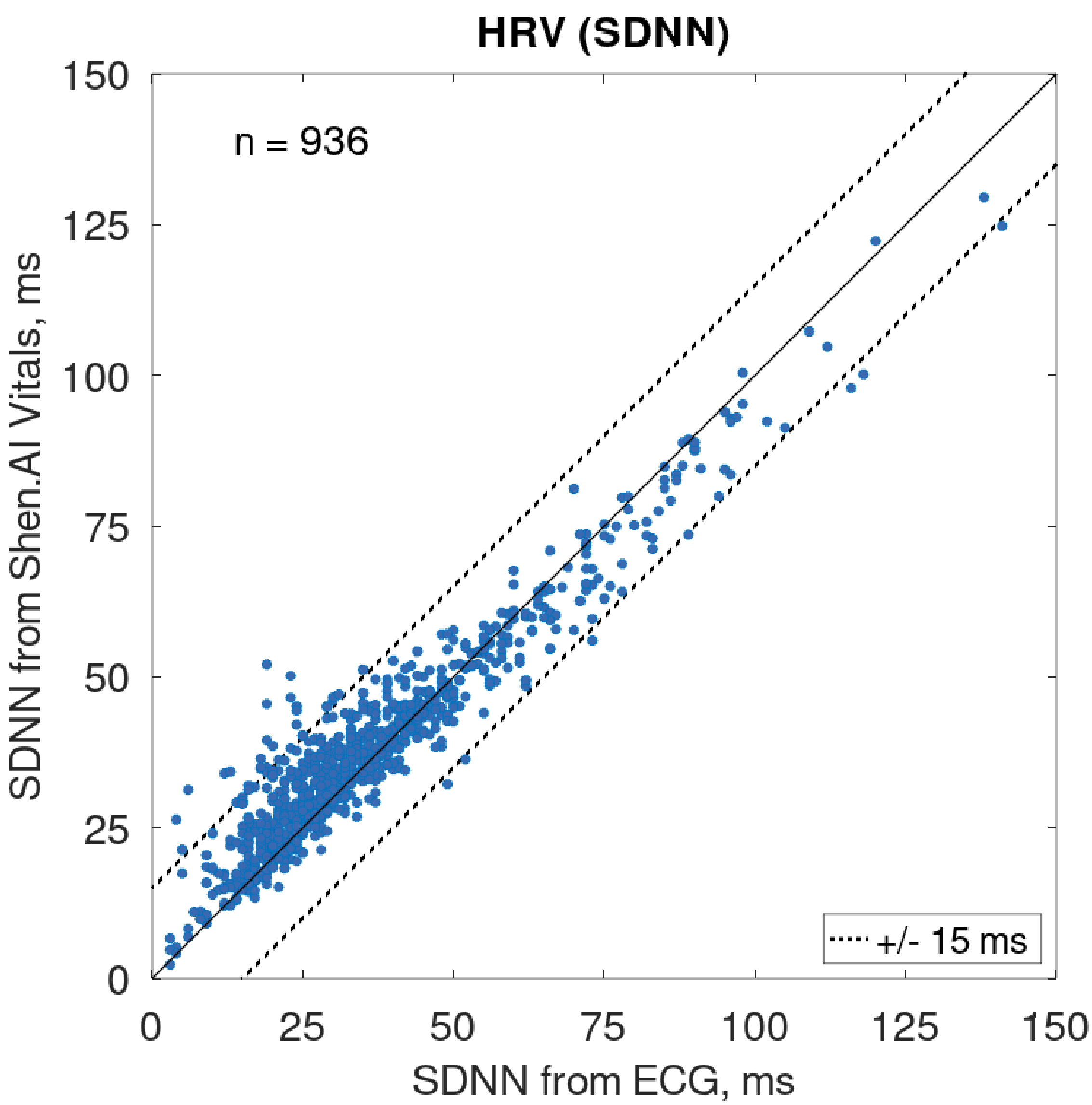

Figure 4. Ultra short-term (1 min) heart rate variability index (SDNN – standard deviation of normal heartbeat intervals) estimated using the Shen.AI Vitals technology plotted against the reference values obtained simultaneously with the ECG.

Heart rate variability (lnRMSSD)

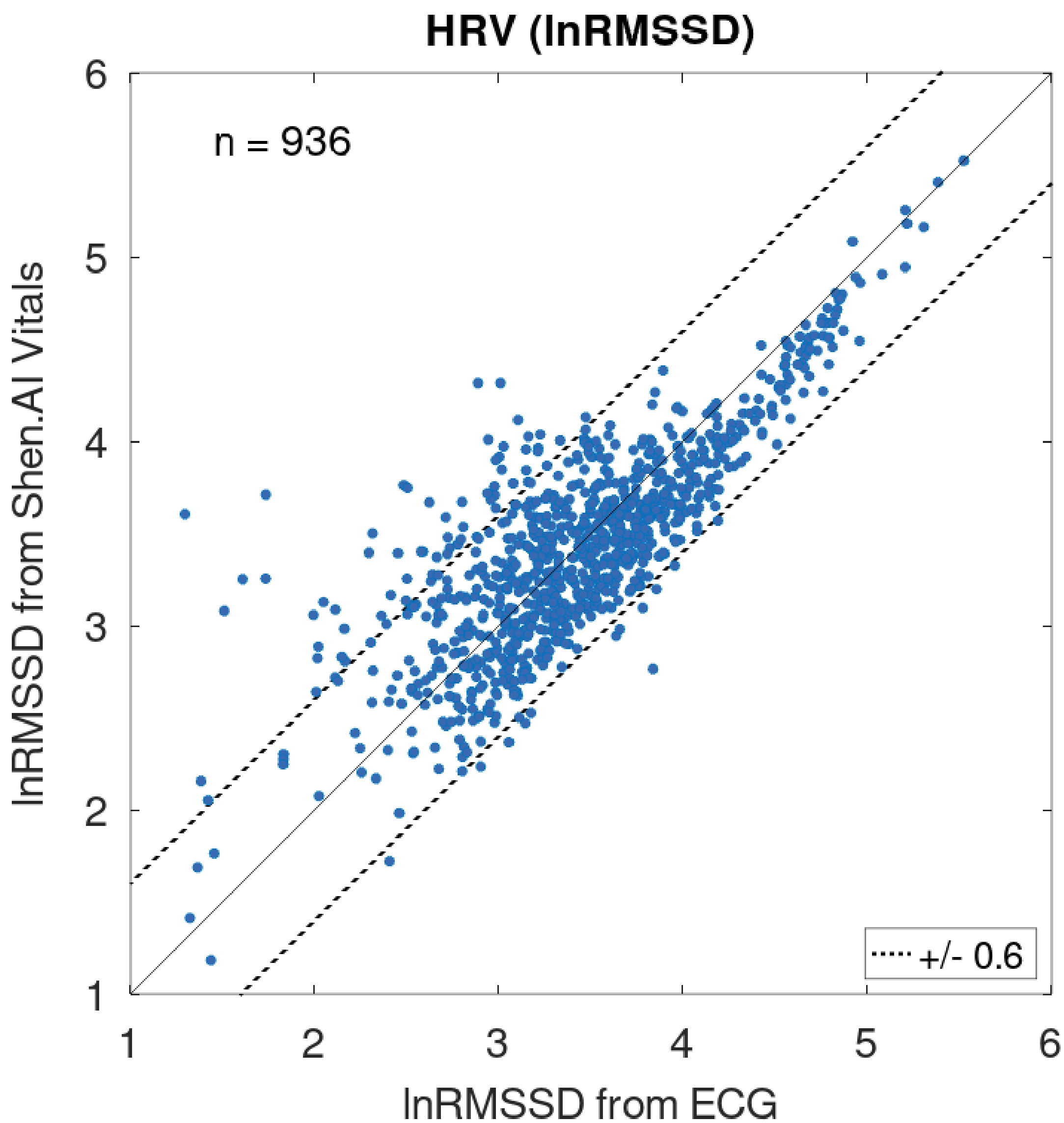

Figure 5. Ultra short-term (1 min) heart rate variability index (lnRMSSD – natural logarithm of the root mean square of successive differences in heartbeat intervals) estimated using the Shen.AI Vitals technology plotted against the reference values obtained simultaneously with the ECG.

Breathing rate

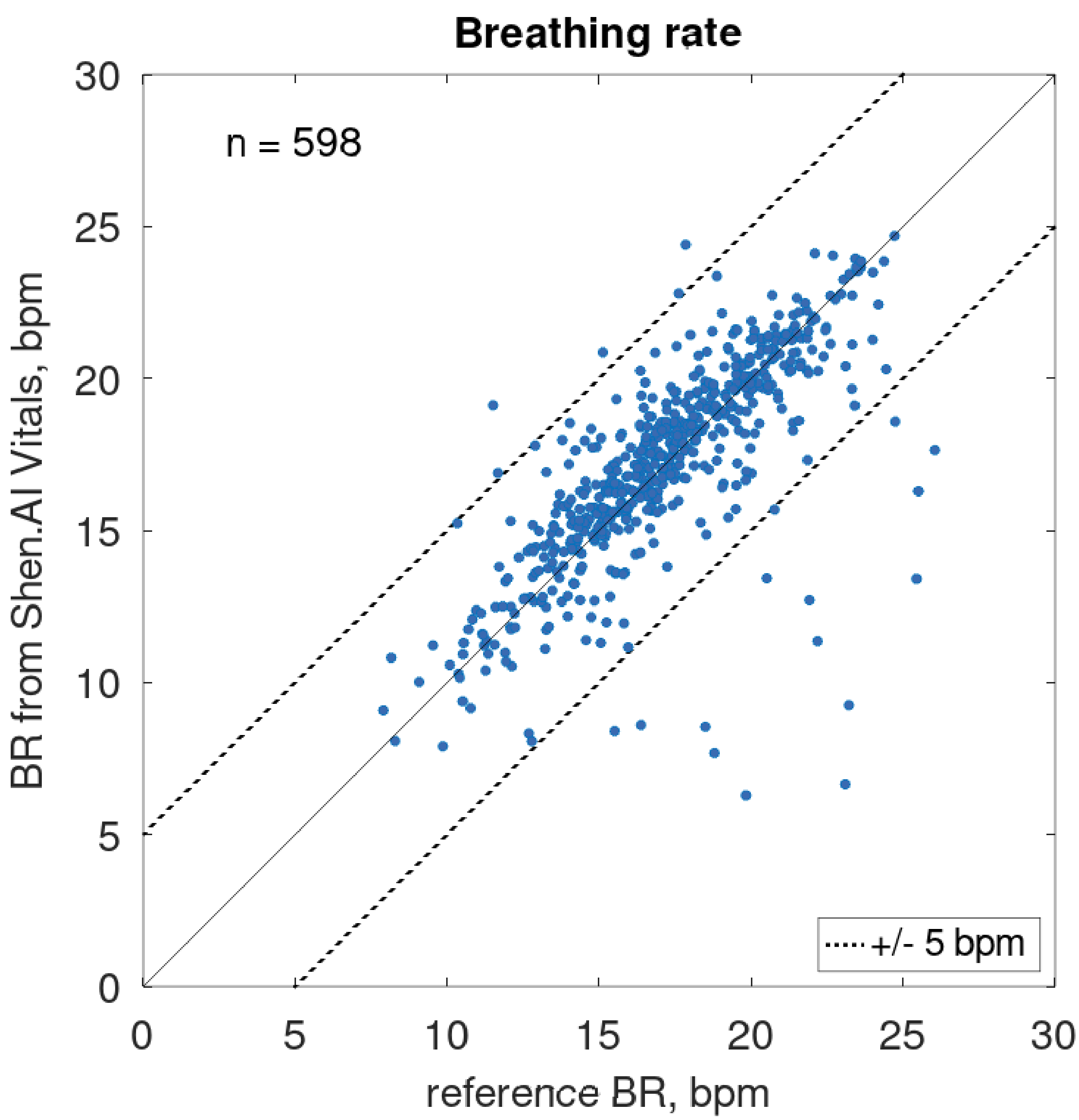

Figure 6. Breathing rate (1-min average) estimated using the Shen.AI Vitals technology plotted against the reference values obtained simultaneously with impedance pneumography (or in some cases judged visually from the video recording).

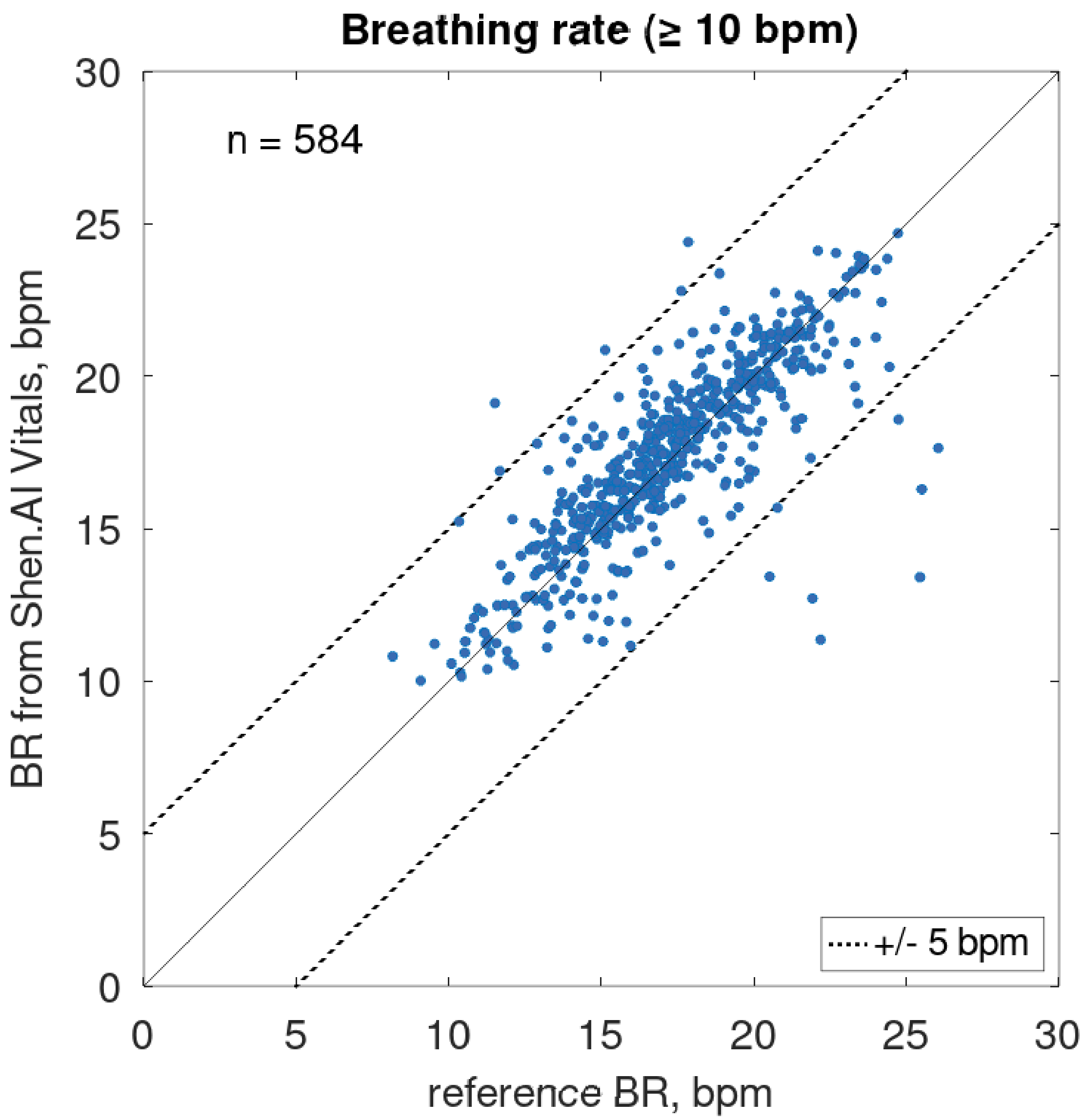

Figure 7. Breathing rate (1-min average) estimated using the Shen.AI Vitals technology (limited to values greater or equal to 10 bpm) plotted against the reference values obtained simultaneously with impedance pneumography (or in some cases judged visually from the video recording).

CONCLUSIONS

The examined product Shen.AI Vitals exhibits very high accuracy in HR measurement, meeting the requirements of the ANSI/AAMI/IEC 60601-2-27:2011 (R2016) standards for ECG devices. This accuracy is evident both in the case of average values over the entire measurement (99.9% of results with an error ≤ 1 bpm) and quasi-instantaneous values determined over 10-second intervals (99.6% of results with an error ≤ 1 bpm) or 4-second intervals (95.8% of results with an error ≤ 1 bpm, 99.97% of results with an error ≤ 5 bpm).

Among the analyzed HRV indicators, in SDNN the error (RMSE) was at the level of 6.3 ms. For 56% of the results it was below 10% of the measured value, with median of absolute errors of 3.0 ms which indicates satisfactory accuracy, although slightly less accurate than lnRMSSD. Median of absolute error for the lnRMSSD indicator demonstrates the highest measurement accuracy (69% of results with an error below 10%, and a median of absolute errors of 0.2).

The examined product generally exhibits good accuracy in measuring BR (over 97% of measurements with an error ≤ 5 bpm). However, there is tendency to underestimate the high BR values (even after the proposed introduction of reporting results as values not lower than 10 bpm).

Measurements using laptop cameras exhibit lower measurement accuracy for all analyzed physiological parameters, although this may only be of practical significance in the case of BR and HRV indicators. In the case of the SDNN indicator, lower measurement accuracy was also observed when using tablet cameras (compared to smartphone cameras).