Testing the Accuracy of ECG Captured by Cronovo through Comparison of ECG Recording to a Standard 12-Lead ECG Recording Device

Data Analysis

a) R-wave Comparison: The mean and standard deviation of R-wave amplitudes for the two devices were calculated and evaluated for significant difference using a paired t-test and a pairwise linear correlation analysis.

b) Validation of Cronovo ECG Signal Quality: Lead I ECG of each participant from Cronovo Smart watch and Philips Pagewriter Trim III was also saved for offline analysis. Philips ECG were first resampled from 500 Hz to match the sampling rate of Cronovo at 512 Hz, then two ECGs were preprocessed to remove noises or artifacts which contaminated the ECG raw signal, such as powerline interference, EMG noise, and baseline wander, using Cronovo's custom algorithms. After the preprocessing, the ECG data were converted to voltage range. The correlation coefficient, power spectral density, and the magnitude squared spectral coherence were calculated.

The Results

Of the 60 subjects, two cardiovascular doctors found that the morphology of QRS complex, P wave, and T wave to be the same between two device ECG recordings, though Cronovo ECG had more baseline noise than Philips ECG as illustrated in the example shown in Figure 1. They thought that Cronovo ECG was accurate for ECG assessment and ECG arrhythmias could be accurately diagnosed by Cronovo Lead I ECG tracings.

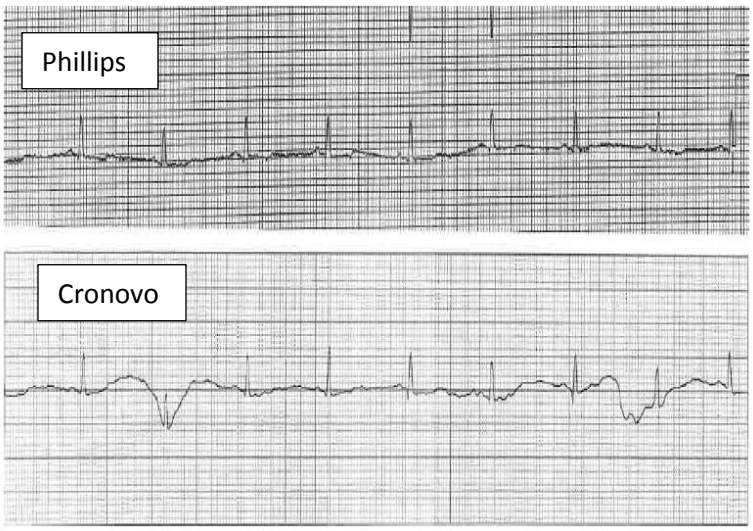


Fig. 1. Effect of baseline noise on Cronovo ECG

A variety of ECG arrhythmias were found among 60 subjects, as listed in Table 1. Of these, 27/60 (45%) subjects were detected having abnormal ECG, and 5/60 (8%) subjects were detected more than one ECG arrhythmia.

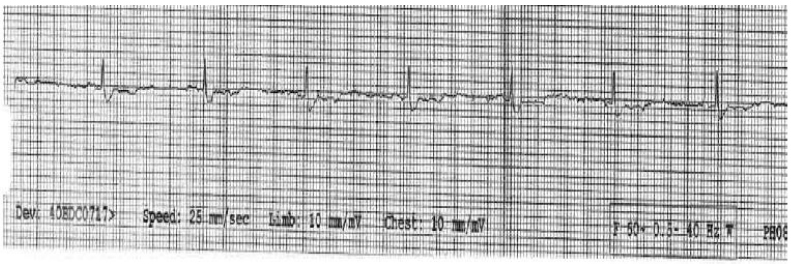
Detected Abnormal ECG	Number of Subjects
atrial fibrillation	2
RBBB	9
LBBB	1
LVH	1
PVC	1
sinus bradycardia	9
sinus tachycardia	1
myocardial ischemia	1
T wave inversion	3

Table 1. Detected arrhythmia

Clinical Cases

Several exemplary clinical cases demonstrated that Lead I Cronovo ECG enable to detect significant ECG abnormalities. The first case was sinus bradycardia with right bundle branch block (RBBB), manifesting slow heart rate = 49, broad QRS complex > 120ms, and wide, slurred S wave, shown in Figure 2. The second case was atrial fibrillation associated with a premature ventricular contraction (PVC), characterized by varied heart rate and one premature ventricular beat, shown in figure 3. And figure 4 shows a case of sinus tachycardia, with heart rate > 110.

Standard Reading



Cronovo

Fig. 2. ECG of sinus bradycardia with right bundle branch block (RBBB).

Standard

Cronovo

Fig. 3. ECG of atrial fibrillation associated with premature ventricular contraction (PVC).

Standard

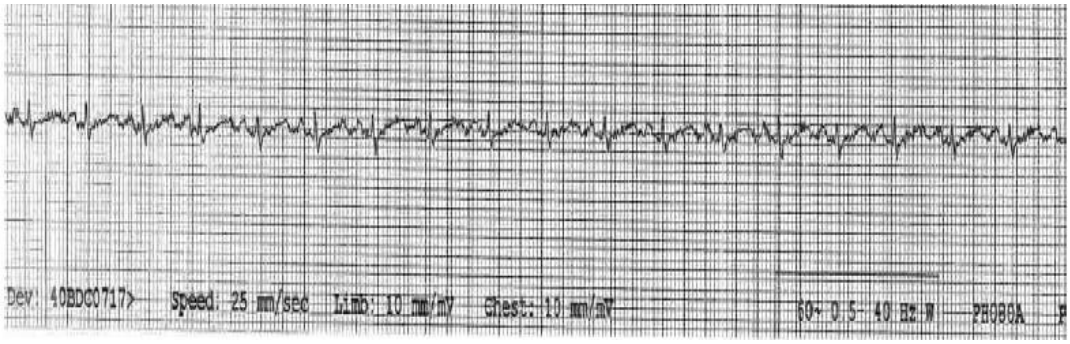


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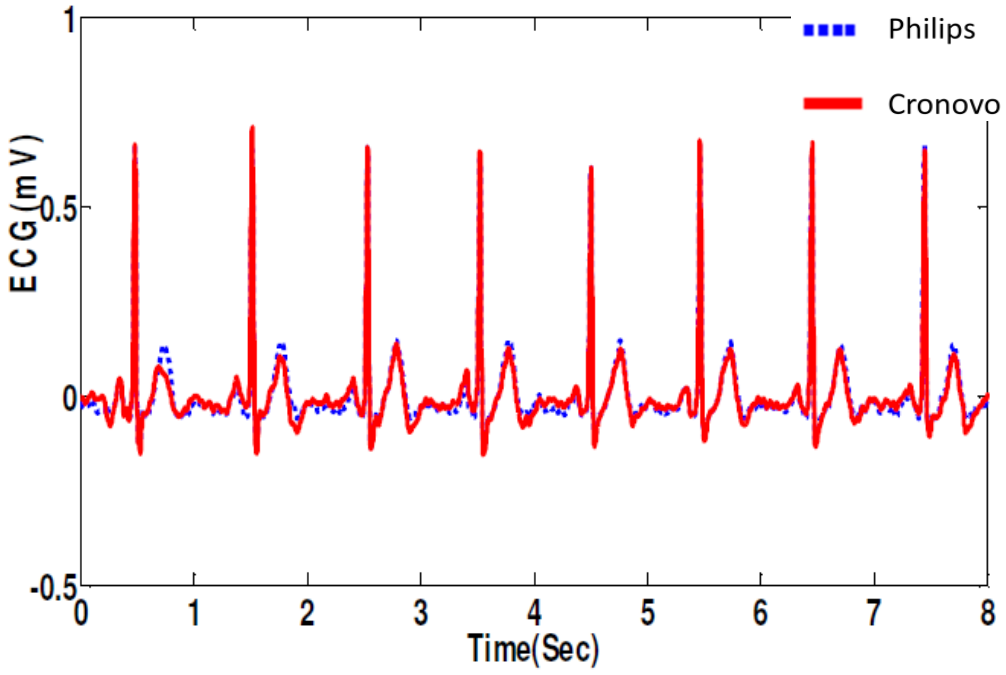
Fig. 4. ECG of sinus tachycardia.

R-wave comparison

For each subject's printed copies of both Cronovo Lead I and Philips Pagewriter Trim III Lead I ECG, R-peak amplitude was measured to the nearest tenth of a millimeter on the corresponding pairs of QRS complexes. The mean and standard deviation of R-peak amplitudes for Cronovo and Philips ECG recordings were 0.72/0.24 mV and 0.71/0.24 mV, respectively. Of the 60 subjects, eight subjects' R-peak amplitude of Cronovo were different to that of Philips, six subjects 0.1 mV Cronovo higher than Philips, one subject 0.2 mV Cronovo higher than Philips, and one subject 0.1 mV Cronovo lower than Philips. Paired t test (MatLab R2013b Statistics Toolbox) resulted in $p<0.05$, indicating statistically non-significant amplitude difference. Pairwise linear correlation coefficient further suggested the similarity in R-peak amplitudes from two devices, $r=0.9855$, $p<0.0001$.

Validation of Cronovo ECG Signal Quality

Offline analysis was applied to validate the similarity of ECGs from both devices, in both time domain and frequency domain. The middle 8-second data in the 10-second recording were used to calculate correlation coefficient, power spectral, and coherence. Coherence was calculated the mean value between 5 Hz and 25 Hz which contains the major frequency components of ECG signal. Figures 5 – 8 take one subject's plots of ECG waveforms, power spectral, and coherence as an example.



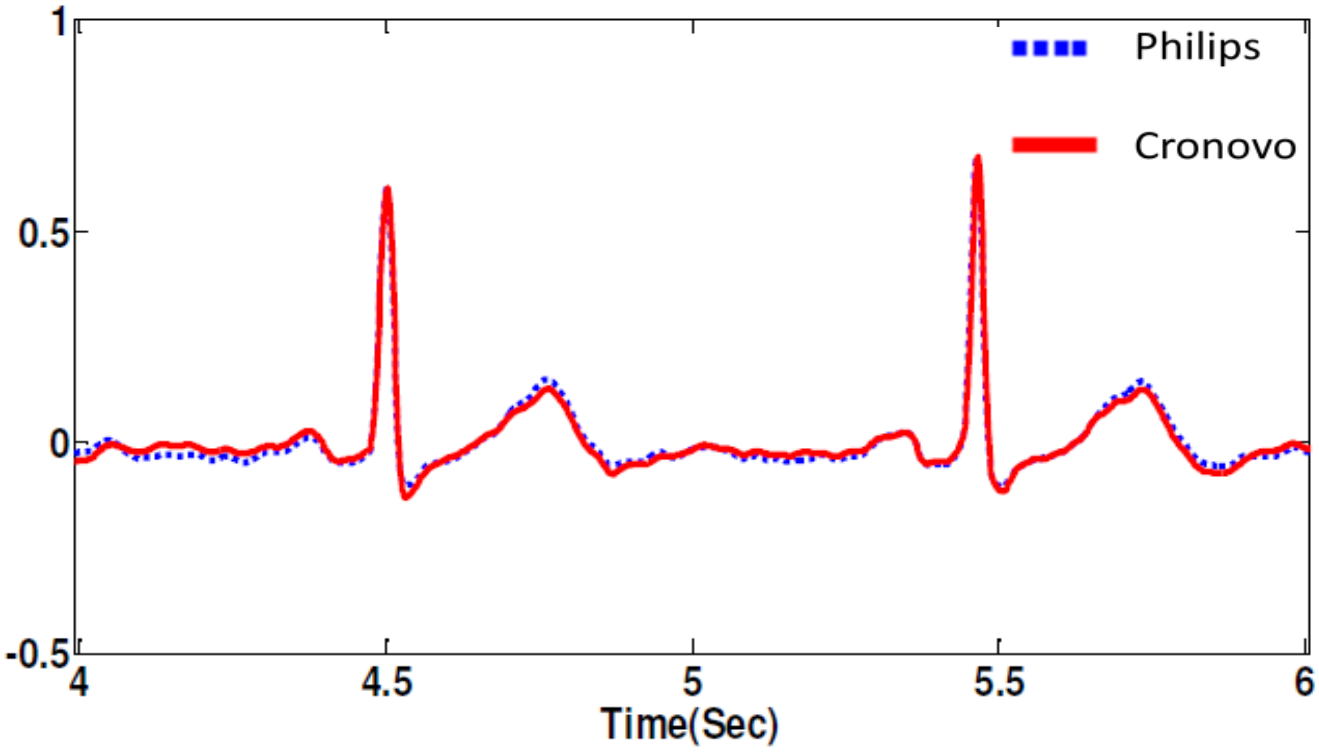


Fig. 6. Power spectral of Cronovo ECG (red, solid) and Philips ECG (blue, dashed)

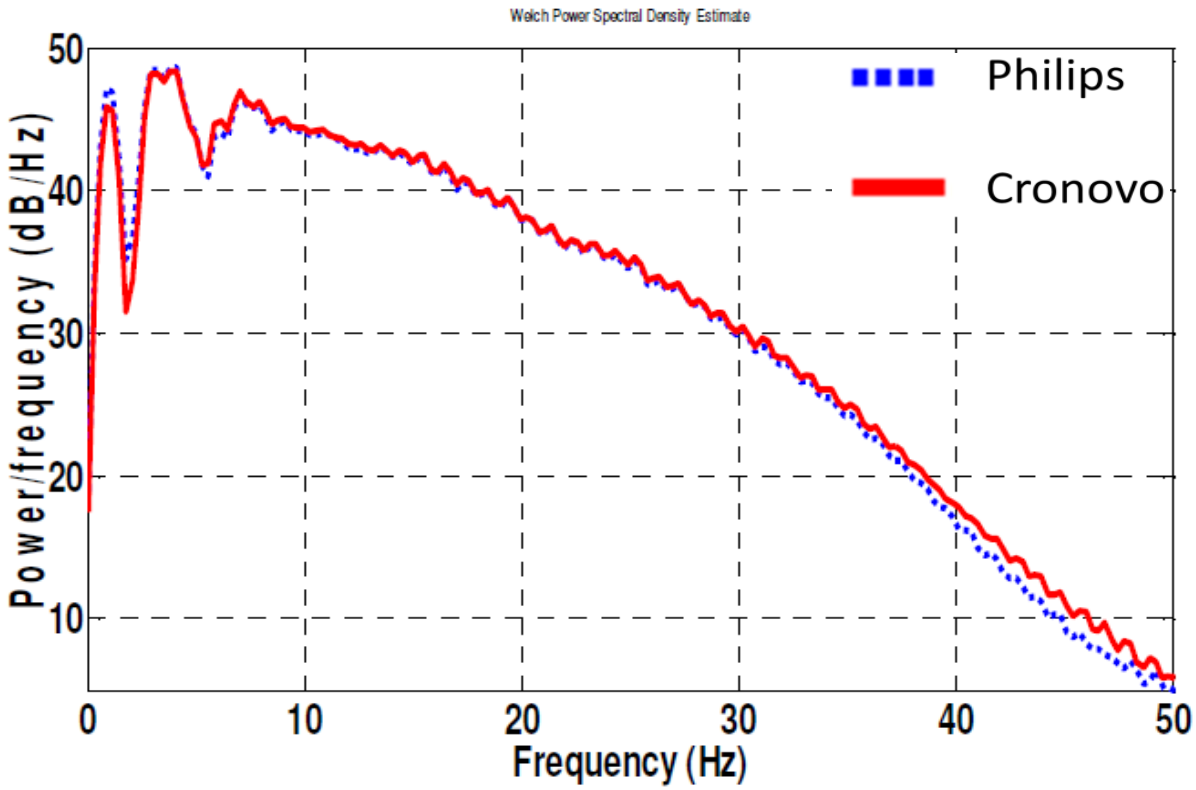


Fig. 5. Preprocessed Cronovo ECG (red, solid) and Philips ECG (blue, dashed), and zoomed view.

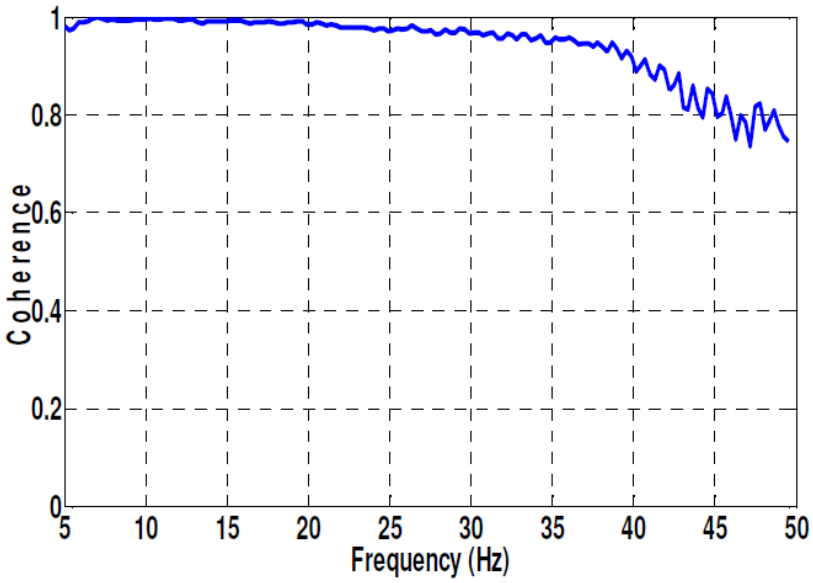


Fig. 7. Coherence function between Cronovo ECG and Philips ECG

The mean value of correlation coefficients for all subjects is 0.942, shown in Figure 8. Among total 60 Subjects, 52 subjects (87%) had correlation coefficient over 0.9, 5 subjects (8%) between 0.85 and 0.9, and 3 subjects (5%) less than 0.85 but greater than 0.8. Examining the ECG waveforms of those having low correlation coefficients found that baseline noise contaminating Cronovo ECG was a major reason. Presumably, dry electrodes of Cronovo are more sensitive to change of skin-electrode impedance than gel-based electrodes used by medical devices. The mean value of coherence for all 60 subjects was 0.945, 55 subjects (92%) above 0.9, 5 subjects (8%) below 0.9, as shown in Figure 9. Offline analysis indicated the high correlation between the two ECGs.

CONCLUSIONS

Philips Pagewriter Trim III has been FDA approved and widely used for years in medical care environments, as a valid ECG recording tool for cardiac conditions diagnosis. Comparing ECG recorded by this device and by the Cronovo's ECG produced no significant difference both clinically and statistically. The high similarity and correlation of the two recordings were further proofed by offline analysis. Therefore, Cronovo's ECG will accurately measure ECG and allow users to learn about and characterize their heart rate and rhythms. Widespread use of the technology could improve public awareness of heart health and identify unknown cardiac conditions at early stage.

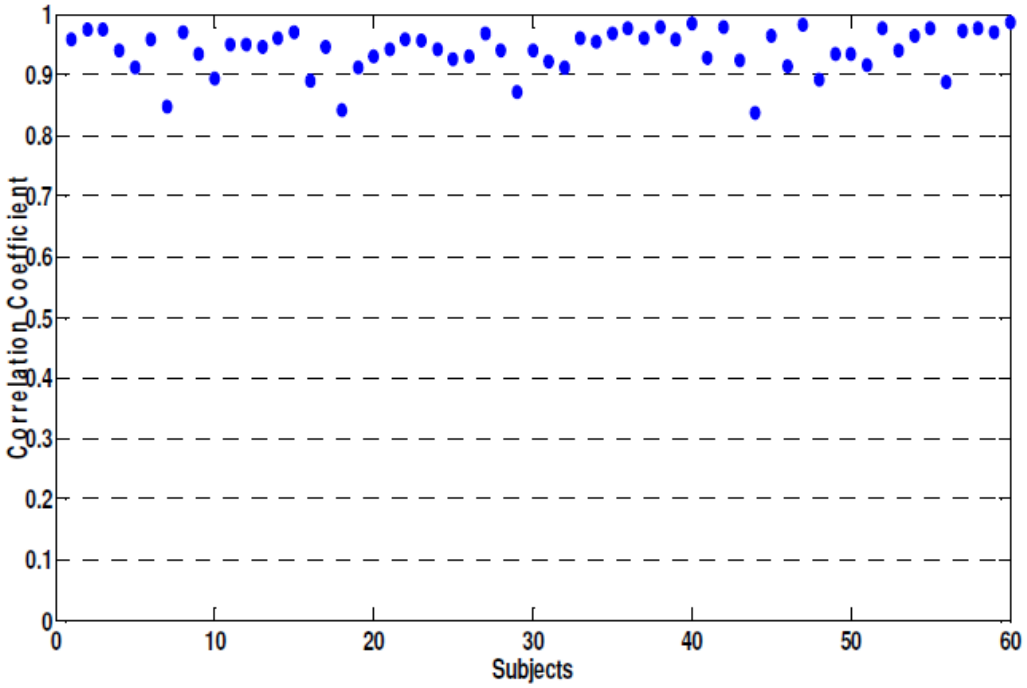


Fig. 8. Correlation coefficients of each subjects

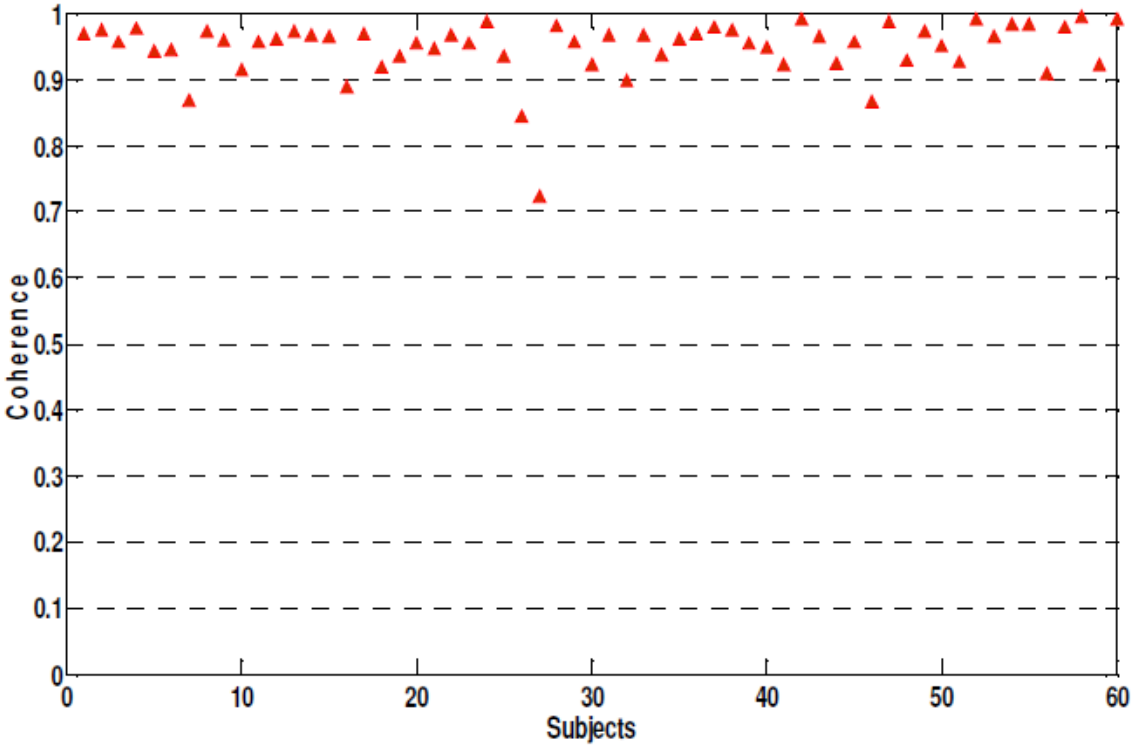


Fig.9. Coherence of each subject