Performance evaluation of automatic symptom-ruled, real-world arrhythmic recordings

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Background:
Detection of treatment-demanding paroxysmal arrhythmias (AF) can be difficult. Patient engaged, symptom-ruled, real-world recordings can therefore be of significant clinical value.

Methods:
The Coala® Heart Monitor (Coala) system was evaluated by manual interpretation of 1,000 consecutive anonymous printouts of chest- and thumb-ECG waveforms, without any exclusion. The anonymized printouts contained three 10 s. strips of ECG at 25 mm/s, including mean heart rate, RR median and any user-provided annotation but with personal identification and algorithm analysis results removed (blinded), apart from gender and age within a 10-year span.

The recordings were derived from actual Coala users in Sweden with no training, control or influence, under a defined time period. The prevalence of cardiac conditions in the user population was unknown.

The blinded recordings were manually interpreted by a trained cardiologist. The interpretation was compared with the automatic analysis performed by the algorithm in the Coala Cloud to evaluate ECG signal performance and calculate performance metrics vs. manual interpretation.
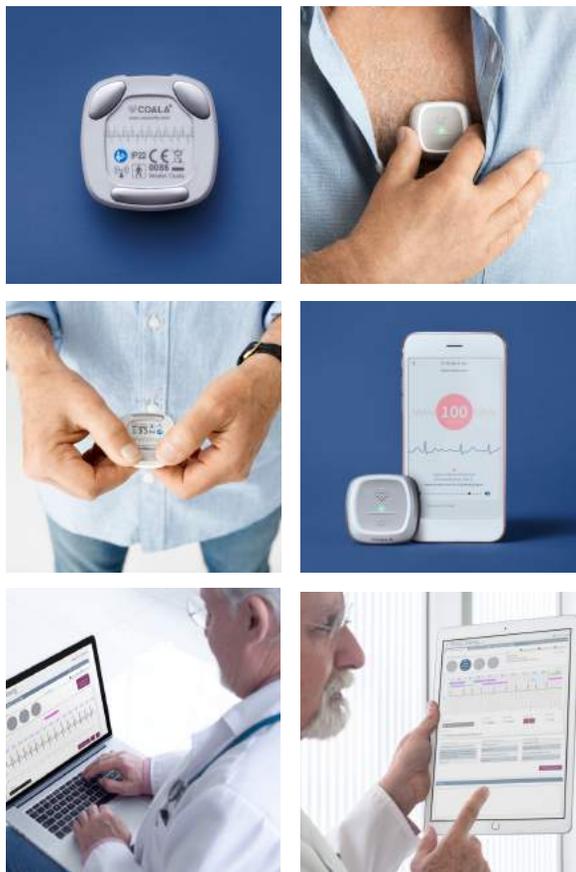
The Coala Heart Monitor is a CE-approved Class IIa medical device solution approved for home and professional use. It's a wireless and cloud-based service developed and produced in Sweden by Coala Life AB. The 2-lead, 1-channel ECG and synchronous heart sound recording system analyzes for 10 different arrhythmias, and to help detect murmurs. For more info, see www.coalalife.com.

Results:

Metrics	Results	Comments
Prevalence of AF in the recordings	14.4 %	(143 of 990 recordings)
Sensitivity for detecting AF	0.972	(95% CI = 0.930 – 0.992)
Specificity for detecting AF	0.946	(95% CI = 0.928 – 0.960)
Negative predictive value (NPV) for detecting AF	0.995	(95% CI = 0.987 – 0.999)
Positive predictive value (PPV) for detecting AF	0.751	(95% CI = 0.683 – 0.812)
Kappa coefficient	0.818	(95% CI = 0.769 – 0.866)

Conclusion:
Based on 1,000 real-world recordings the overall ECG signal quality and accuracy for detecting atrial fibrillation (AF) for the Coala was been found to be high (sensitivity of 0.97, specificity of 0.95) and supportive of the intended use of the device. The combination of chest- and thumb-ECG yields 99.2% of recordings that can be used for manual interpretation and was found to be superior to either thumb- or chest-ECG only.