

New published study validating diagnostic accuracy of Coala Heart Monitor

Non-invasive Coala Heart Monitor has been validated for diagnostic accuracy, compared to reference standard 12-lead-electrocardiogram, to help detect atrial tachyarrhythmia and atrial fibrillation.

Coala Life, an innovative Swedish medical device company offering remote patient monitoring solutions, today announce the results of yet another study validating the use of Coala Heart Monitor. In this validation study, Coala Heart Monitor was compared to standard clinical 12-lead-ECGs. Measurements were collected from 189 patients with a history of atrial arrhythmia. The aim of the study was to evaluate the diagnostic accuracy of the Coala device for the detection of atrial tachyarrhythmia (ATA) and atrial fibrillation (AF).

All participants performed a 10-second 12-lead-ECG, immediately followed by a 30-second chest recording and a 30-second thumb recording with the Coala Heart Monitor. Two electrophysiologists independently performed manual analysis (in line with current European guidelines for screening) of all 12-lead-ECGs and Coala recordings in random order.

Supports previous findings

Previous validation studies with Coala Heart Monitor have supported high accuracy for detecting AF in remote patient use. But this is the first study directly comparing ECG results against gold standard 12-lead-ECG evaluation. The results show that Coala Heart Monitor has a very high accuracy for manual interpretation of atrial tachyarrhythmia and atrial fibrillation in a group with high prevalence of atrial arrhythmias. In addition, the study showed that the automatic interpretation algorithm of the Coala system also has a high sensitivity and accuracy. The authors conclude that these results make the Coala device suitable for screening.

“We are very glad to see these excellent results for Coala Heart Monitor compared to 12-lead reference and the author's conclusion that our device is well suited for screening. It really shows that the quality of our device is to a level of those used in a clinical setting and can be a reliable and important tool to support and reduce the burden on healthcare providers.

The Coala Heart Monitor uses a unique combination of chest- and thumb lead ECG which gives the best conditions for accurate diagnosing of AF as compared to one-lead only devices where P-waves can be difficult to detect”, says Dan Pitulia, CEO, Coala Life AB.

The study is accessible with free access through Expert Review of Medical Devices: *Astrid Paul Nordin, Carina Carnlöf, per Insulander, Amina Mohammad Ali, Mats Jensen-Urstad, Ott Saluveer & Nikola Drca (2023) Validation of diagnostic accuracy of a handheld, smartphone-based rhythm recording device*, Expert Review of Medical Devices, 20:1, 55-61, DOI [10.1080/17434440.2023.2171290](https://doi.org/10.1080/17434440.2023.2171290).

About us

Coala-Life Group AB ("Coala Life" or the "Company") founded in 2015, is a Cloud Based Software as a Service provider, and medical device developer and reseller, listed on Nasdaq First North Growth Market. The Company focuses on B2B solutions for managed Remote Patient Monitoring ("RPM"), offering medical care providers, primarily in the US, with a highly scalable, cost-efficient platform to remotely and virtually manage large volumes of patients suffering from chronic diseases. The company offers care providers a comprehensive solution and lifts the administrative work from the care providers regarding, amongst other things, follow-up, 24/7 monitoring, as well as the reimbursement process from state and private health insurance companies. Patients are monitored long-term in everyday life and typically have diabetes, obesity, and /or cardiovascular disease.

For more information see www.coalalife.com

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Attachments

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