

Clinical Evaluation Report

Evaluating the Interpretability of the Cardiac Zone Application Using an AI Algorithm in Conjunction with the Movesense Device

Date: 20 September 2024

Executive Summary

Cardiac Zone Platform Features

Cardiac Zone is a comprehensive platform connecting doctors and patients, offering the following key features:

1. Comprehensive Rhythm Monitoring: Facilitates cardiac health monitoring anytime, anywhere, with a user-friendly sensor.
2. Real-Time ECG Acquisition: Allows users and doctors to access live ECG signals.
3. AI-Powered Analysis: Employs advanced AI algorithms for real-time ECG analysis, assisting in identifying arrhythmias and cardiac anomalies.
4. Cloud-Based History Storage: Enables ongoing diagnostics by securely storing cardiac histories in the cloud.

Movesense Device Overview

The Movesense® Device, developed by Movesense Ltd. (Tammiston kauppatie 7A, 01510 Vantaa, Finland), is a reliable cardiac monitoring tool that integrates advanced AI algorithms. It is equipped with a lightweight, reusable, and water-resistant sensor worn on the upper chest, positioned at the 4th to 5th intercostal space along the mid-clavicular line. This device transmits real-time ECG recordings via Bluetooth Low Energy (BLE) to a Microsoft Azure-based secure cloud storage, accessible through a smartphone app (compatible with Android and iOS) and a web portal for both patients and healthcare professionals.

Background

Cardiac arrhythmias, particularly atrial fibrillation (AF), are often asymptomatic yet can lead to serious complications like embolic strokes. AF increases stroke risk fivefold, contributing to 20-30% of all strokes, and is the most common cardiac rhythm disorder and a significant mortality predictor. While the 12-lead ECG is the gold standard for diagnosing rhythm disorders, it provides only a brief snapshot of heart activity. Ambulatory ECG monitoring in outpatient settings, especially 24-hour monitoring, may not capture symptomatic episodes, despite evidence showing subclinical arrhythmias significantly impact health outcomes.

Purpose of the Report

This report aims to:

1. Evaluate the interpretability of ECG signals for rhythm analysis and their quality.
2. Assess ECG signal interpretability in repolarization analysis, including the quality of the

isoelectric line, P waves, R waves, and RR intervals, and evaluate clinician acceptability.

3. Evaluate ease of use for patients.

4. Assess the device's utility in diagnosing rhythm disorders.

App Overview

Functionality Description

The Cardiac Zone application, available in for both iOS and Android, has been utilized by many physicians-volunteers across diverse patient profiles. The app offers instant rhythm monitoring and immediate review, supporting monitoring durations from 1 hour up to 25 days- extendable.

Target Audience

Primary users of the Cardiac Zone app include:

- Healthcare Professionals: Physicians and cardiologists who want their patients to require real-time or prolonged rhythm monitoring.
- Patients: Individuals needing continuous cardiac monitoring for health management.
- General Public: Individuals interested in personal cardiac monitoring.

Specific Medical/Cardiac Rhythms Identified

The app is designed to assist in diagnosing various rhythm-related medical conditions, including:

- Normal sinus rhythm
- Sinus arrhythmia
- Supraventricular ectopics
- Ventricular ectopics
- Brady-Tachy syndrome
- Sinus tachycardia
- Sinus bradycardia
- Total number of supraventricular beats
- Total number of ventricular beats

Extensive rhythm monitoring has been shown to improve patient outcomes by aiding pronged rhythm availabilities.

Medical Hardware Overview

Description

The Movesense hardware includes an adjustable elastic belt with integrated skin sensors. A small sensor attached to the belt transmits signals to the application via Bluetooth, providing a comfortable and user-friendly experience.

Typical Use in Medical Settings

The device is suitable for multiple monitoring applications, including:

- Holter Monitoring: 24-48 hours of continuous ECG monitoring.
- Extended Ambulatory Monitoring: Monitoring over 1 to 3 weeks for detailed analysis.

- Telemetry: Real-time monitoring of patients' cardiac rhythms.
- General Public Use: Personal monitoring for palpitations and other cardiac concerns.

Certifications and Regulations

The Movesense hardware complies with relevant medical certifications, including CE approval, ensuring safety and efficacy in medical settings.

Current Use Cases

The Cardiac Zone app is actively used by physician (voluntary/research basis), with over 1,000 hours of rhythm monitoring performed to date. The device has identified multiple rhythm-related issues and provided critical diagnostic recommendations for physicians and cardiologists.

The device/app has been used by various patients and the experiences are as follows;

https://cardiac-zone.com/real_story_details.php?id=16

Case 1:

Title: Palpitations with Lightheadedness/Dizziness

My mother is 82 years old. She has been getting intermittent palpitations (Heart racing) feelings. We admitted to emergency department multiple times. Each time during the admission, the heart monitor in the hospital showed extra-beats. The doctors started her on medications to reduce extra beats and discharged home. After starting medications, she had lightheaded and dizziness. We spoke to the doctor of this device and the doctor kindly attached it to my mother.

During the first few days of monitoring the device found significant lower heart rate due to start of betablocker medications and underlying slow-heart rhythm.

The doctor informed me immediately and the betablockers were stopped. We continued to further monitor my mother for few more days and she remained stable.

Physician Review / Comments:

This patient was given betablockers based on the extra-beats they found initially. Although beta-blockers is the treatment for such conditions in majority of patients, but in this case she is 82 years old and the medications made her clinical status worse. The patient was diagnosed with Sick Sinus Disease and may require pacemaker in future.

We successfully diagnosed the patients and now she will be monitored with the help of our devices for the need of pacemaker.

Patient/Relative Comments:

The doctors team has successfully diagnosed my mother with the help of cardiac zoned. Extremely Friendly to use with instant results. Interestingly the diagnosis and treatment were adjusted very easily. No-wires attached to the patient and she was very comfortable to use. Thanks, team.

ECG Pictures:



Case 2;

Title: Dizziness with Very Slow Heart Beats (Heart Block)

A 76-year-old diabetic and hypertensive patient with a history of end-stage renal failure requiring long-term hemodialysis is experiencing recurrent episodes of palpitations. Recently diagnosed with a minor stroke, she was prescribed beta-blockers to reduce and suppress extra beats found on cardiac monitor in hospital. Although prolonged Holter monitoring was challenging to arrange in the hospital, Cardiac-Zone was consulted, and a device was affixed for extended monitoring.

The device remained attached for 5 days, during which extensive heart rhythm analysis was conducted. The monitoring revealed intermittent short pauses, occasional extra beats, ventricular couplets/triplets, and episodes of heart block. No atrial fibrillation was detected during this period.

Physician Review / Comments:

This patient was found to have a range of different heart rhythm abnormalities during monitoring. Fortunately, there were no signs of irregular heartbeats such as atrial fibrillation, which, if untreated, can lead to stroke.

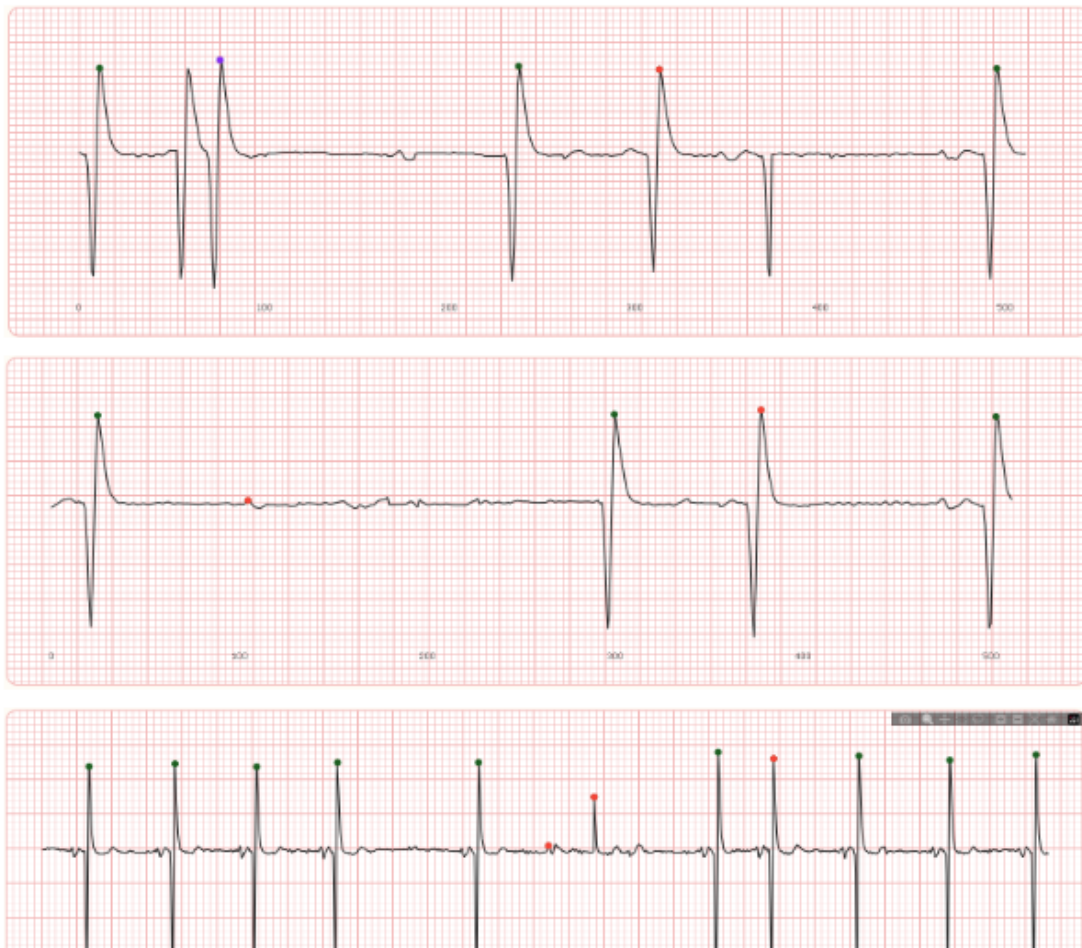
Furthermore, based on the findings from the Holter monitor, we adjusted the beta-blocker dosage downwards.

The Cardiac-Zone device proved effective in monitoring this 76-year-old patient at home, eliminating the need for hospital visits.

Patient/Relative Comments:

See the above text/experience

ECG Pictures:



Case 3:

Title: Palpitations with Multiple Extra Heart Beats

I am PhD student and had been struggling with intermittent palpitations. I visited cardiologist few times that advised Holter monitoring. I was given a 24 hours-Holter machine from hospital. The hospital Holter had several ECG leads attached to my body, which were not pleasant at all.

I then decided to be volunteered to use the Cardiac-Zone app/device.

My heart was monitored for 48 hours and found to have multiple extra beats. I was able not only to see the extra beats (several thousands) myself on my mobile application but the research Cardiologist sitting several thousand miles away could see live my heart rhythm.

I was immediately contacted by cardiologist and started on Beta-blockers. He also requested other tests, such as echocardiography monitoring, which were luckily normal. I kept the device for 6 days without any discomfort. The device is much comfortable compared to a Holter machine given by a hospital and very easy to wear it on and off.

I would say this is the best ever artificial-intelligence device I have seen. The device helps to monitor my heart rhythm and alerts whenever I have discomfort so that I can adjust my activities to have a perfect routine life. Thanks a lot to the wonderful Cardiac Zone team.

Physician Review / Comments:

The story of this PhD scholar exemplifies a common occurrence of palpitations among young individuals. Through Cardiac-Zone monitoring, her heart was extensively observed, revealing an excess of extra beats. Our physician recommended further investigations, and she was treated with medications as advised. Following treatment, she experienced significant improvement and is now completely stable.

Patient/Relative Comments:

See the above the experience

Name: Aysen Degerli Ahishali, Tampere University, Finland

ECG Pictures:



Conclusion;

The Movesense device, integrated with Cardiac Zone's AI, offers a powerful, precise solution for monitoring palpitations and related heart conditions. With over 1,000 hours of effective use, it provides reliable, accurate data, supporting both patients and physicians in enhancing cardiac care and safety. Future updates will expand its capabilities, further advancing patient outcomes and insights into heart health. Together, Movesense and Cardiac Zone represent a transformative leap in accessible, effective cardiac monitoring.

References (Peer-reviewed)

A; Relevant literature on the app

- S. Kiranyaz, T. Ince, and M. Gabbouj, "Real-Time Patient-Specific ECG Classification by 1D Convolutional Neural Networks", *IEEE Trans. on Biomedical Engineering*, vol. 63, no. 3, pp. 664-675, Mar 2016.
- M. U. Zahid and S. Kiranyaz and T. Ince and O. C. Devecioglu and M. E. H. Chowdhury and A. Khandakar and A. Tahir and M. Gabbouj, "Robust R-Peak Detection in Low-Quality Holter ECGs using 1D Convolutional Neural Network", *IEEE Trans. on Biomedical Eng.*, vol. 69, pp. 119-128, June 2021.
- J. Malik, O. C. Devecioglu, S. Kiranyaz, T. Ince, M. Gabbouj, "Real-Time Patient-Specific ECG Classification by 1D Self-Operational Neural Networks," *IEEE Transactions on Biomedical Engineering Dec. 2021. DOI: 10.1109/TBME.2021.3135622*
- M. Gabbouj, S. Kiranyaz, J. Malik, M. U. Zahid, T. Ince, M. Chowdhury, A. Khandakar, and A. Tahir, "Robust Peak Detection for Holter ECGs by Self-Organized Operational Neural Networks", in *IEEE Trans. on Neural Networks and Learning Systems*, pp. 1-12, March 2022 .DOI: 10.1109/TNNLS.2022.3158867
- S. Kiranyaz, O. C. Devecioglu, T. Ince, J. Malik, M. Chowdhury, T. Hamid, R. Mazhar, A. Khandakar, A. Tahir, T. Rahman, and M. Gabbouj, "Blind ECG Restoration by Operational Cycle-GANs", *IEEE Trans. on Biomedical Eng.*, pp. 1-12, May 2022. doi: 10.1109/TBME.2022.3172125
- M. Uzair, S. Kiranyaz and M. Gabbouj, "Global ECG Classification by Self-Operational Neural Networks with Feature Injection", *IEEE Trans. on Biomedical Eng.*, pp. 1-12, July 2022. DOI: 10.1109/TBME.2022.3187874

A; Relevant literature on the Device (Movesense)

- Automatic Mobile Health Arrhythmia Monitoring for the Detection of Atrial Fibrillation: Prospective Feasibility, Accuracy, and User Experience Study, Onni E Santala, Jari Halonen, Susanna Martikainen, Helena Jäntti, Tuomas T Rissanen, Mika P Tarvainen, Tomi P Laitinen, Tiina M Laitinen, Eemu-Samuli Väliäho, Juha E K Hartikainen, Tero J Martikainen, Jukka A Lipponen, Link: <https://mhealth.jmir.org/2021/10/e29933>
- Effectiveness of the Chest Strap Electrocardiogram to Detect Atrial Fibrillation, Hartikainen S, Lipponen JA, Hiltunen P, Rissanen TT, Kolk I, Tarvainen MP, Martikainen TJ, Castren M, Väliäho ES, Jäntti H., Am J Cardiol. 2019 May 15;123(10):1, 643-1648. doi: 10.1016/j.amjcard.2019.02.028. Epub 2019 Feb 23, Link: <https://www.ncbi.nlm.nih.gov/pubmed/30878151>
- Commercially-available heart rate monitor repurposed into a 9-gram standalone device for automatic arrhythmia detection with snapshot electrocardiographic capability: a pilot validation, Chiara Martini, Bernardo Di Maria, Claudio Reverberi, Domenico Tuttolomondo, Nicola Gaibazzi, Link: <https://www.mdpi.com/2075-4418/12/3/712/htm>
- Estimation of Respiratory Frequency in Women and Men by Kubios HRV Software Using the Polar H10 or Movesense Medical ECG Sensor during an Exercise Ramp, Bruce Rogers, Marcelle Schaffarczyk, Thomas Gronwald, Link: <https://www.mdpi.com/1424-8220/22/19/7156/htm>
- The Movesense Medical Sensor Chest Belt Device as Single Channel ECG for RR Interval Detection and HRV Analysis during Resting State and Incremental Exercise: A Cross-Sectional Validation Study, Bruce Rogers, Marcelle Schaffarczyk, Martina Clauß, Laurent Mourot, Thomas Gronwald, Link: <https://www.mdpi.com/1424-8220/22/5/2032/htm>
- Comparison of Heart Rate Monitoring Accuracy between Chest Strap and Vest during Physical Training and Implications on Training Decisions, Jakub Parak, Mikko Salonen, Tero Myllymäki, Ilkka Korhonen, Link: <https://www.mdpi.com/1424-8220/21/24/8411/htm>
- Fractal Correlation Properties of Heart Rate Variability: A New Biomarker for Intensity Distribution in Endurance Exercise and Training Prescription?, Thomas Gronwald, Bruce Rogers and Olaf Hoos, Link: <https://www.frontiersin.org/articles/10.3389/fphys.2020.550572/full>

Dr Tahir Hamid

FRCP (London), MRCP (UK), CCT (Cardiology/GIM) FESC, FRCPC (Canada)

Alumni

1. University of Toronto, Canada (Toronto General Hospital, St Mikes Hospital)
2. Manchester University NHS Foundation Trust, United Kingdom
3. The Dudley Gorup NHS Foundation NHS Trust, (University of Birmingham-teaching hospital- United Kingdom