

# Coala Heart Monitor is recommended by the Swedish Medical Technology Product Council for clinical use

The Swedish Medical Technology Product Council (MTP) recommends the use of Coala Heart Monitor in all Swedish regional councils for assessment and diagnostics of patients with suspected atrial fibrillation. The recommendation is based on an overall assessment of clinical relevance, cost-effectiveness, and data security.

The MTP council determines which medical devices are to be included in national recommendations and how they should be introduced and used in Sweden's municipalities and regions. Since 2020, the council has investigated products for diagnosing atrial fibrillation through self-registration.

In February this year, the Swedish Dental and Pharmaceutical Benefits Agency's (TLV) health economic assessment of Coala Heart Monitor Pro for investigation and diagnosis of atrial fibrillation was published. The conclusion of the assessment is that Coala Heart Monitor Pro was cost-saving and generated greater benefit for the patient by detecting symptoms to a greater extent and thereby enabling treatment to reduce the incidence of stroke.

As basis for its combined assessment and recommendation, the MTP council has also obtained a legal review from Manolis Nymark Consulting AB regarding the protection of personal data in the product and its associated services.

Overall, the MTP council, with the support of Nymark's legality review, assesses that the Coala Heart Monitor meets the requirement for strong authentication in line with the National Board of Health and Welfare's regulations and general advice on a caregiver is responsible for the processing of personal data collected.

"It is obvious that our platform and our products are clinically relevant and cost-effective for healthcare, but also offer a high level of safety. We are pleased that the MTP council has stated that this is the case. With this recommendation, the foundation is in place enabling hundreds of thousands of Swedes with symptoms that can be suspected to be atrial fibrillation to be able to use the Coala Heart Monitor for diagnostics in everyday life", comments Dan Pitulia, CEO of Coala Life.

The MTP council has also outlined purchasing strategies and had a dialogue with several groups within the regions' knowledge management as well as experts appointed by these groups.

The MTP council legality testing has been done with a focus on the processing and protection of personal data in the product and related services with regard mainly to the Data Protection Ordinance (GDPR), the Act (2018: 218) with supplementary provisions to the EU Data Protection Ordinance (Data Protection Act), the Public Access and Secrecy Act (2009: 400), the Patient Data Act (2008: 355) and the National Board of Health and Welfare's supplementary regulations and general Council (HSLF-FS 2016: 40) on record keeping and processing of personal data in healthcare.

## About us

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Coala Life is a medical device company founded in Sweden focusing on cloud-based cardiac and pulmonary diagnostics. The company has developed and launched the Coala Heart Monitor - a multi-award winning, FDA-cleared and CE-approved product platform enabling long-term remote monitoring, analysis and algorithm-based diagnostics of heart and auscultation of lungs, remote in real-time. The Coala Heart Monitor is mainly marketed to healthcare providers as an Rx solution for use in patient's everyday life and home environment. The company's solutions are based on over 10 years of R&D, and are protected by more than 30 patents. The head office is based in Uppsala, Sweden and since 2019, the US office is based in Irvine, California. More than 10,000 patients have used, been diagnosed or are under long-term monitoring with the Coala Heart Monitor. In the Coala Care Portal, there are currently more than 1,700 doctors and nurses connected to more than 500 care providers. For more information see [www.coalalife.com](http://www.coalalife.com)

## For more information, contact:

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## Attachments

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