

Category

Best Startup

Product/Solution Name

Acorai

Date of Approval

N/A

Indications

NA

Therapeutic Categories

NA

Background information and need for solution/product

Heart failure costs the US economy \$100B annually, resulting in \$6B in preventable hospital losses. The market is represented by inadequate monitoring tools, which result in poor patient management. The initial diagnosis of patients are lengthy and costly, with 80% of patients diagnosed too late and the time to diagnosis often over 11 weeks. In acute (in-hospital) care, there are inexact and time-consuming products, resulting in 40% of patients still unstable at discharge, which leads to resource-intensive & loss-making admissions. The on-going treatment of heart failure is disjointed, often lacking sufficient tools to manage patients, as well as a general shortage in chronic disease centers for these types of patients.

Acorai is building a non-invasive heart failure monitoring platform with direct intracardiac pressure monitoring (ICPM) at its core. Heart failure monitoring today is either invasive or inaccurate and ineffective, resulting in high readmission rates, unnecessary complications and poor outcomes. Acorai offers accurate and cost-efficient heart failure care using patented technology that leverages a novel combination of sensor technologies and machine learning to enable non-invasive ICPM, the only proven way to improve outcomes in heart failure patients. The device has been clinically validated and will be entering the market in 2025.

History of the development of the solution/product

Acorai started in 2019 in Helsingborg, Sweden. The work with the Acorai Heart Monitor and the SAVE Sensor System started during that time, with focus on earlier research within the field. R&D has been done (and is still being done) on the product. A Pilot clinical study started in early 2022, at two of the leading hospitals in Sweden (Sahlgrenska University Hospital and Skane University Hospital). The Pilot study is now finalized with over 350 patients enrolled. Acorai's clinical study demonstrates equivalence to the gold standard in the field (right heart catheterization). Acorai has met clinical requirements and demonstrated its accuracy vs. right heart catheterization, including superiority to standard of care tools in identifying critically ill HF patients, similar performance to implantable devices in estimating pulmonary artery pressure and higher efficiency & measurement repeatability versus the standard of

care.

Acorai is planning a continuation of our clinical validation, including a machine learning generalization study to start during 2023 Q2 and a pivotal study to start in 2024 Q1. Both studies will cooperate with 10+ clinical sites in 5+ countries (including the US, UK, Sweden, Denmark and the country of Georgia). Acorai has an in-house clinical team and is working with clinical consultants and CRO's. The company also has a regulatory team, working towards product validation according to the FDA and CE-mark guidelines.

Why this solution/product is innovative, the broad implications for future research, and/or how it will improve the human condition

Acorai has developed the first handheld, non-invasive intracardiac pressure monitor to improve workflow efficiencies and patient outcomes. The unique and superior technology is built on the patented SAVE Sensor System, combining Seismocardiography(SCG), Acoustic (PCG), Visual (PPG), and Electrocardiography (ECG) sensors, as well as with one of the largest datasets of its kind. This creates accurate, absolute and actionable measurements within minutes, providing direct estimates of Right atrial pressure (RAP), pulmonary pressure (PAP), pulmonary capillary wedge pressure (PCWP), which are clinically preferred output for heart failure treatment. The solution improves time and cost efficiency, including removing delays in treatment and enable proactive care. Acorai allows healthcare professionals to diagnose, risk stratify, treat, and discharge plan with fewer resources, reducing readmissions and hospital costs resulting in average direct hospital care savings of \$1M p.a.

Acorai has a strong IP position, with 3 granted patent families, 4 patent families pending and large proprietary datasets for the machine learning and software architecture.

The implications for future research include the usefulness of non-invasive intracardiac pressure monitoring compared to the gold standard right heart catheterizations. This type of monitoring of heart failure patients will help decrease readmissions, lower costs of care, decrease resource requirements on the hospitals and improve the overall quality of life for heart failure patients.

Please provide appropriate references (ie Pubmed links)

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