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Peer-Reviewed Study Confirms CADScor System Can Diagnose Heart Failure With Far Fewer False Positives Than Standard Blood Test

Aalborg University-led research, published in PLOS Digital Health, found the CADScor System's acoustic sensing platform identified heart failure with diagnostic accuracy comparable to a leading blood test, and with significantly fewer false positives

Acarix AB (publ) today announced the publication of a peer-reviewed study in PLOS Digital Health showing that the seismocardiography (SCG) technology at the heart of its CE-marked, FDA-cleared CADScor®System can also detect heart failure (HF), a condition distinct from the coronary artery disease (CAD) the device is currently indicated for.

Heart failure affects millions of people worldwide and is a leading cause of hospitalisation, yet it can be difficult to diagnose quickly. Tools recommended by European Society of Cardiology (ESC) guidelines, such as echocardiography and NT-proBNP blood testing, are effective but come with real-world limitations, including long imaging wait times, operator-dependent results, and blood biomarkers that can be elevated for reasons unrelated to the heart. The study explored whether SCG, which uses a small accelerometer to capture the chest's vibrations from each heartbeat, could help close that gap.

“Heart failure and coronary artery disease are the two biggest reasons patients end up in front of a cardiologist, and this new research opens up a whole new frontier for our CADScor System,” said Aamir Mahmood, Chief Executive Officer of Acarix. “We built CADScor to give clinicians a fast, accurate, first-line tool for cardiac triage, and these results show we can bring that same value to heart failure, one of the most common and costly diagnoses in cardiology. That is a significant expansion of what CADScor can do for patients and for our business.”

Researchers enrolled 218 patients: 198 referred by their general practitioners for suspected heart failure, plus an additional 20 patients with previously confirmed HFrEF enrolled separately to strengthen testing of the algorithm. Using machine learning, the team developed two SCG-based algorithms: an "AnyHF-score" to flag heart failure of any type, and an "HFrEF-score" to specifically identify heart failure with reduced ejection fraction (HFrEF), the most severe form of the condition.

The study found that:

- The AnyHF-score detected heart failure of any type with 90.9% sensitivity and an 87.5% negative predictive value, correctly flagging the large majority of patients who did have the condition.

- The HFrEF-score performed comparably to NT-proBNP, the current standard blood test, in identifying reduced heart function, with similar diagnostic accuracy (92.9% vs. 94.7% AUC) and sensitivity, but with significantly higher specificity (92% vs. 68.8%, p<0.001) and a more than doubled positive predictive value (57.7% vs. 27.1%, p=0.007), meaning far fewer false alarms.
- The SCG-based scores identified 71 of 139 patients (51%) referred for suspected heart failure but ultimately found not to have the condition as "minimal risk," pointing to a potential role for SCG in helping clinicians reduce unnecessary echocardiogram referrals.

The authors describe the results as exploratory, noting that the study was conducted in a relatively small population at two centres and that the algorithms will require external validation in larger, independent cohorts before broader clinical use. The HF algorithm is investigational and has been built into the mechanics of Acarix's Gen 2 device, but it is not yet included in the CADScor System's CE mark or FDA clearance, both of which currently cover rule-out of coronary artery disease. Acarix will need to submit the HF algorithm for regulatory approval, a process that will likely require a larger validation trial than the current feasibility study.

The study, “A feasibility study evaluating seismocardiography for the detection of heart failure,” was authored by researchers at Aalborg University Hospital, Aarhus University Hospital and Odense University Hospital in Denmark, and funded by Acarix. It is available at: **journals.plos.org/digitalhealth**.

About the CADScor®System

The CADScor System is a point-of-care diagnostic aid that uses highly sensitive acoustics and advanced computational analysis and AI to assess a patient's coronary blood flow. It calculates a patient-specific CAD-score and combines it with clinical risk factors to rapidly indicate the risk of significant coronary stenosis, prior to potential secondary evaluation. The system produces a result in under 10 minutes and is designed to rule out significant CAD with at least 96% negative predictive value at point of care. The CADScor System has been used in over 60,000 patient assessments, is built on 15+ years of R&D covered by 45 patents, is CE-marked in accordance with EU MDR 2017/745, and has received FDA De Novo clearance as a diagnostic aid for symptomatic patients with suspected CAD.

About Acarix

Acarix is a Swedish medical device company that develops solutions for rapid, AI-based rule-out of coronary artery disease at the point of care. The CE-marked and FDA De Novo-cleared CADScor System is intended for patients experiencing chest pain with suspected CAD and is designed to support clinical decisions by helping reduce unnecessary, invasive, and costly diagnostic procedures. Acarix is listed on the Nasdaq First North Premier Growth Market in Stockholm (ticker: ACARIX) and cross-traded on the OTCQB market in the US (ticker: ACIXF). The Company’s Certified Adviser is Tapper Partners AB. For more information, please visit **www.acarix.com**

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Attachments
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