

Press release

Malmö, May 29, 2017

Acarix CADScor®System – an advanced, easy to use, frontline test to rule out Coronary Artery Disease with high accuracy. On display at British Cardiovascular Society Meeting in Manchester, June 5-7.

In preparation for launch, Swedish/Danish Acarix AB's (publ) ("Acarix") CADScor®System will be on display at the British Cardiovascular Society Annual Meeting in Manchester, June 5-7. Delegates will have the opportunity to review first results from a study that was presented at the American College of Cardiology Annual Scientific Meeting held in Washington, March 17-19, 2017 showing that CADScor®System non-invasively rules out Coronary Artery Disease (CAD) with 97% negative predictive value. According to figures from the British Heart Foundation, cardiovascular disease accounts for around 26% of all deaths in the UK, some 116,000 per year with earlier diagnosis being a clear priority for the NHS.

About the study

The research was led by Principal Investigator Morten Böttcher, MD PhD FESC and by Simon Winther, MD PhD, Department of Cardiology, Aarhus University Hospital, Denmark: *"Despite the availability of improved risk stratification algorithms, the incidence of normal investigations such as nuclear or CT imaging remains high. We therefore tested the diagnostic accuracy of the CADScor®System for ruling out CAD to see if it could be used to reduce demand for more advanced diagnostic modalities. We have concluded that, with its ability to rule out CAD with a 97% negative predictive value, this advanced, easy to use, stethoscope like device could indeed be deployed as a frontline test."*

Acarix CEO Søren Rysholt Christiansen commented:

"We are very pleased with the results of the trial and are now preparing for launching the device. As well as being a major problem in the UK, CAD affects more than 120 million people worldwide but the current diagnostic pathway, which can rapidly escalate to imaging and coronary angiography can be significantly improved. If adopted, the CADScor®System can provide rapid frontline assessment which could translate into an improved triage thus securing that patients in need of further diagnostic tests get them and that patients with symptoms unrelated to CAD do not."

About the CADScor®System

The CADScor®System uses ultra-sensitive phonocardiography combined with advanced electronics and algorithms to rule out CAD with 97% negative predictive value. CADScor®System is fast, radiation-free, non-invasive and can be performed in every standard point-of-care environment in less than 10 minutes.

In patients with suspected CAD, the current practice includes one or several examinations, i.e. stress tests, nuclear imaging and invasive coronary angiography. In many cases, these patients are either healthy or end up not needing any treatment. The new CADScor®System is designed to provide a first rapid and non-invasive, investigative step and by ruling out CAD earlier, the diagnostic pathway improves.

CADScor®System will be on display at the British Cardiovascular Society Annual Meeting in Manchester, booth number 17.

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Notes to editors:

Acarix , CADScor®System and cardiac sound measurement

Acarix A/S was established in 2009, and since 2010 investors SEED Capital (DK) and Sunstone Life Science Ventures (DK) have supported it towards market introduction. Acarix has attracted a highly-experienced management team who have held senior positions in international medical device companies - CEO Søren Rysholt Christiansen with ELOS Medtech, GN ReSound and Cook Medical.

Acarix's CADScor®System is based on engineering excellence in sound recording and signal processing. It has long been known that both cardiac contraction movement and turbulent flow can generate sound. Contraction related sounds are in lower frequency, whereas turbulent sounds in the streaming blood caused by partial obstruction (stenosis) in the coronary arteries are of higher frequencies. The detection of these murmurs is delicate, since the energy of the murmurs is very weak. Detecting and recording the coronary murmurs requires not only an advanced sensor but also means for proper attachment to the skin above the heart to optimize the recorded signal and to avoid external noise.

The Acarix CADScor®System has been designed to be an all-in-one system in the sense that the heart signal will be recorded, processed and displayed as a patient specific score, the CAD-score, on the device screen. The CADScor®System contains the necessary electronics to instruct professionals during use and to guide through the recording periods. The system also contains a docking station for daily qualification of the sensor. Further the system integrates with an adhesive patch for locking the CADScor® sensor to a fixed position above the heart during the recording.

The software embedded in The Acarix CADScor®System ensures that adequate recording conditions are controlled at every examination.

The CADScor®System is CE Marked (by TÜV in 2015) and planned for commercial launch in Q2 2017. See more at www.acarix.com. Press kit: <http://www.acarix.com/about-us/press-downloads/>.