# On a mission to enhance the diagnosis of 100 million hearts

## Redeye Artificial Intelligence Seminar 2022


Helen Ljungdahl Round CEO
Samuel Schmidt R&D


*March 16, 2022*

# We all deserve to know immediately if our chest pain is related to heart disease or not


acarix

**Potential impact:**

- Patients
- Doctors
- Health Care Systems


# Acarix Leading the Paradigm Shift

## *AI-powered assessment of Coronary Artery Disease (CAD)*

**Only 1 out of 10**
with stable chest pain have CAD

**Rule-out of CAD in 10 min with > 96% confidence**
The CADScor® System enables non-invasive rule-out of patients

**More than 8,000 patients in clinical trials**
With unique CE-approved and FDA De Novo cleared AI technology

- >15 years of research and development
- 45 patents

**Razor / Razor Blade business model**
Attractive business model with installed CADScor®System and innovative single-use patches for each patient assessment


# Demonstrating Clinical Value in Less than 10 Minutes with CAD Rule-out

**Patient with stable chest pain and suspected CAD**

**CADScor® Rule-out**

## Intended use (FDA) [1]

The intended use of CADScor® System is to record heart sounds, i.e., murmurs and vibration for calculation of a patient specific score, the CAD-score, indicating the risk of coronary stenosis, as an aid in cardiac analysis and diagnosis.

**ECG Stress Test via treadmill[2]**

**CCTA -Stress Echo MPI Nuclear Imaging**

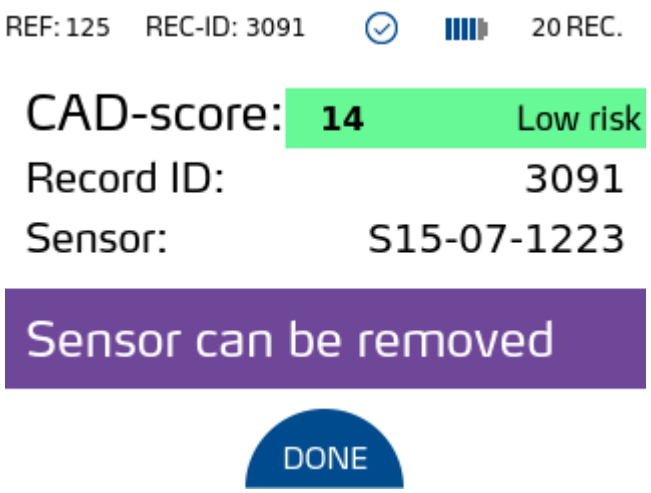
**Invasive Coronary Angiography**

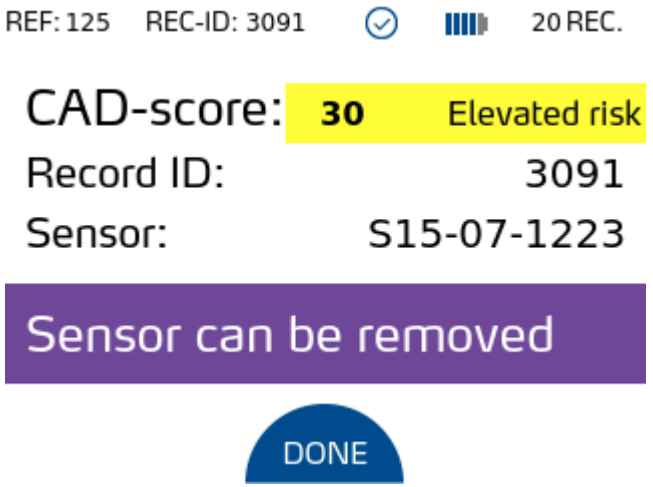
**Invasive Treatment (PCI etc)**

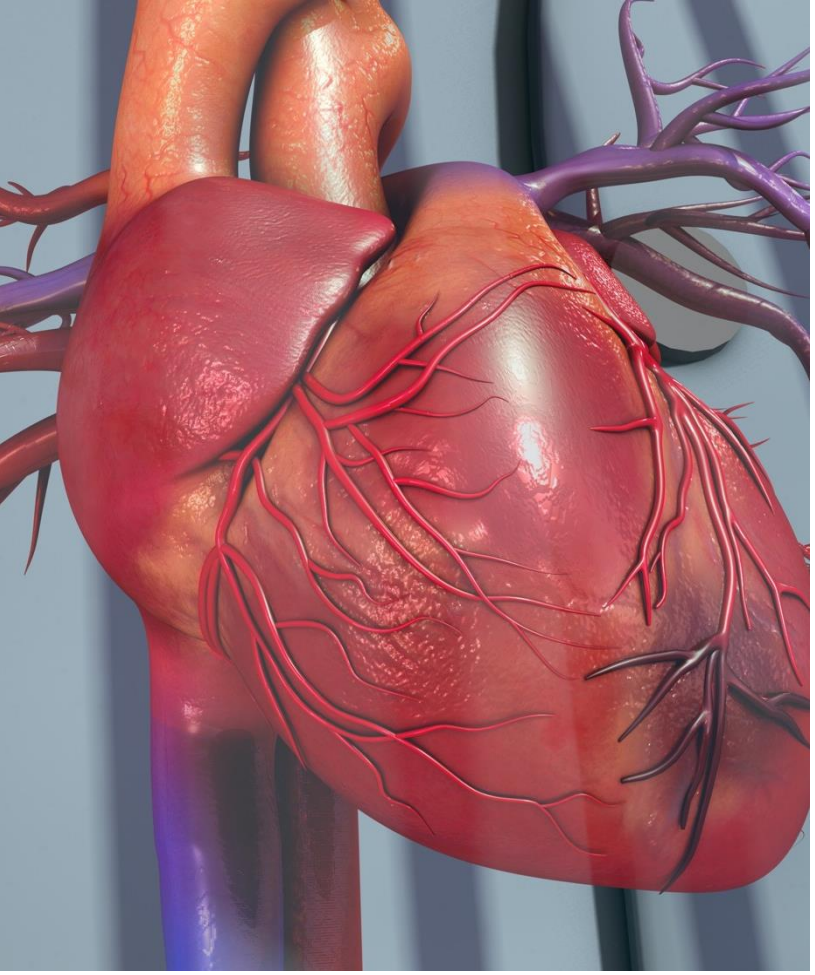
Radiation equivalent of 500-1,000x ordinary x-ray[14].

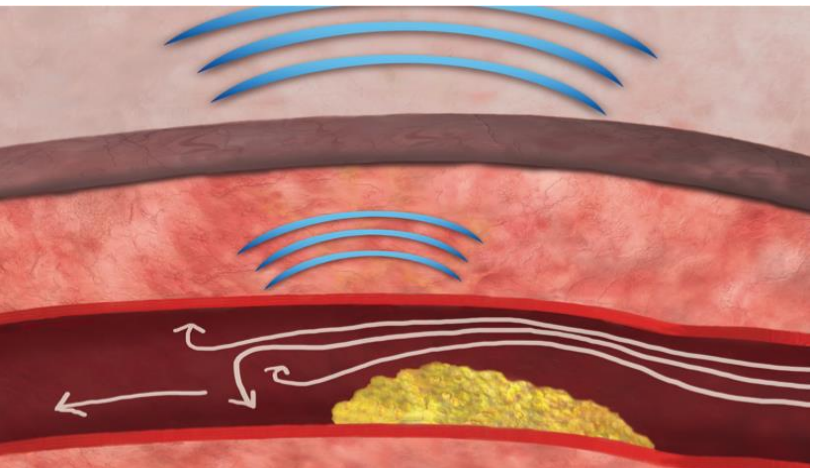
1. US user manual v.12.5, prevalence 10,7%, algorithm version US3.2
2. ESC 2019 guideline does not recommend if other diagnostic tools are available

# The SCIENCE behind CADScor®System and the CAD-score







# The Idea Behind the CAD-Score

Coronary artery disease (CAD) causes week alterations in the heart sounds

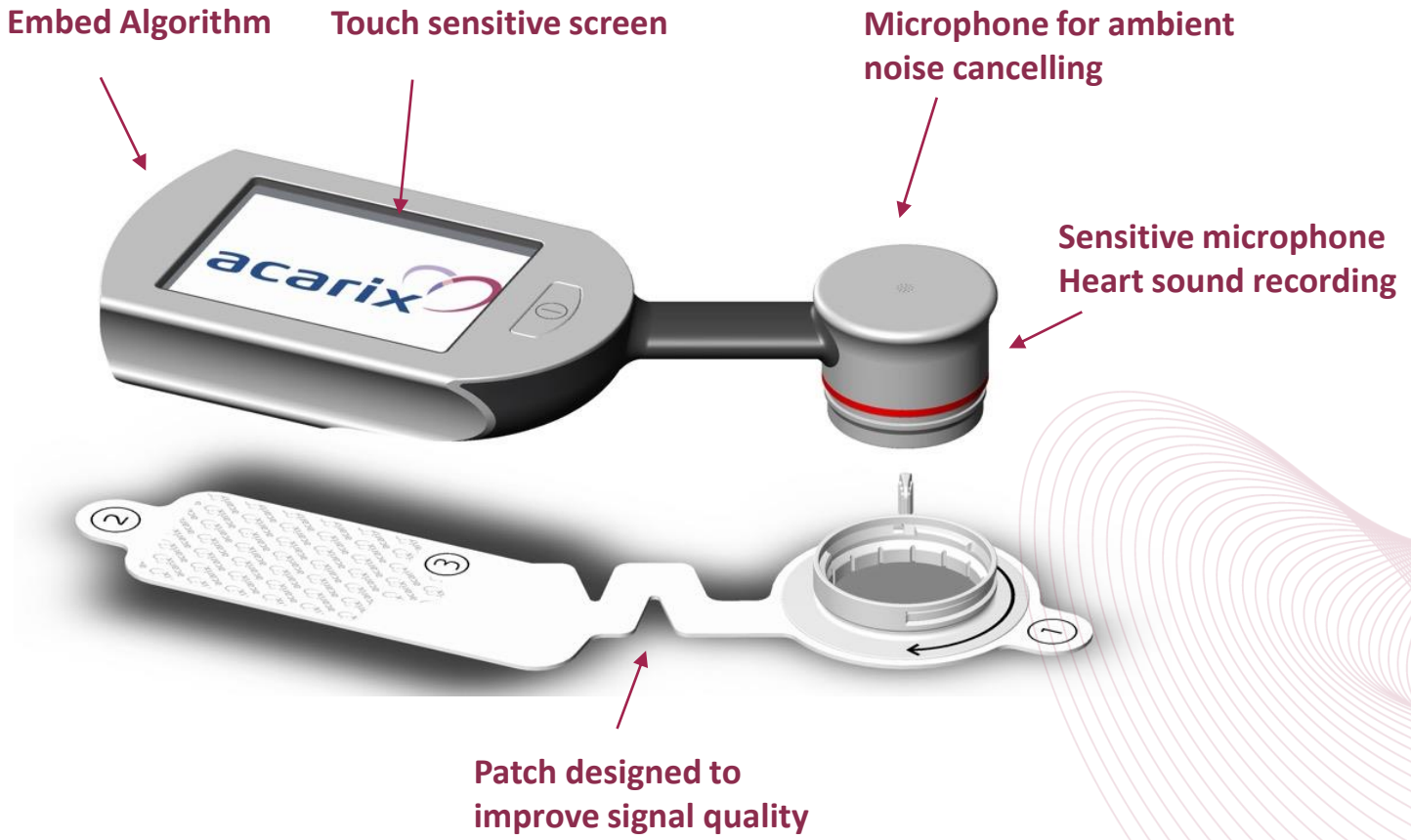
- Narrowing's caused by plaque build up will produce turbulent blood flow, which makes a weak noise
- The relaxation of the heart is altered by CAD, which changes the heart sounds

**These sound are not audible by the human ear**

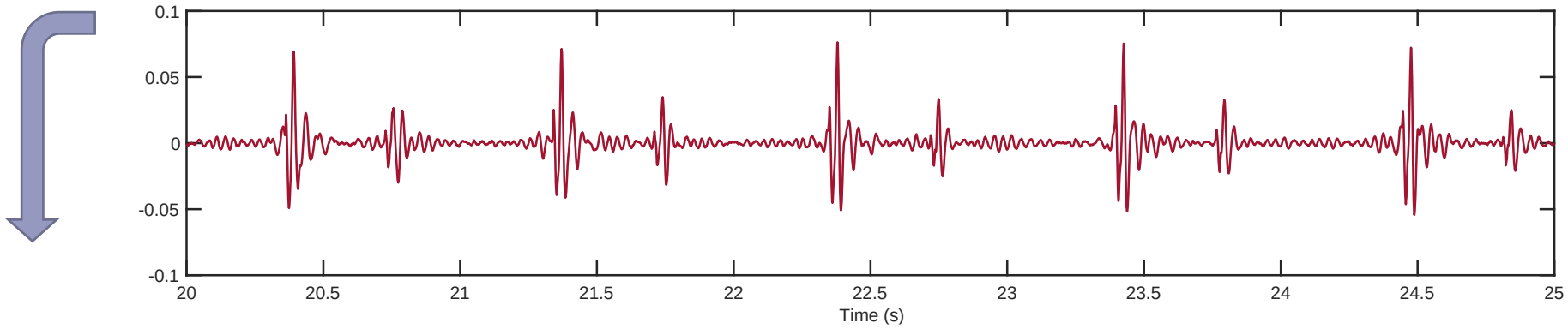
**But AI can learn to detect these**


# The NOVEL CADScor®System

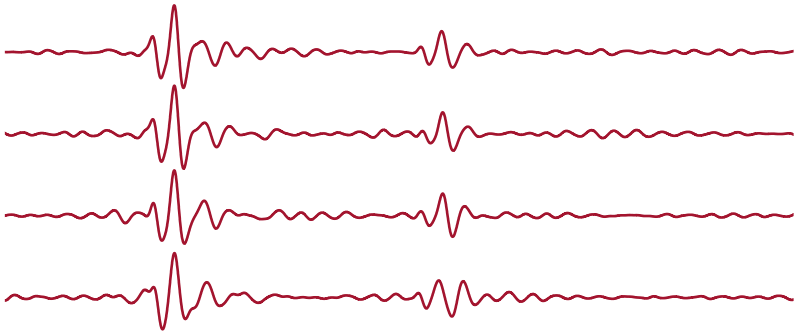
Ultra sensitive and intelligent AI-powered diagnostic aid, rooted in strong Danish audio industry and academia



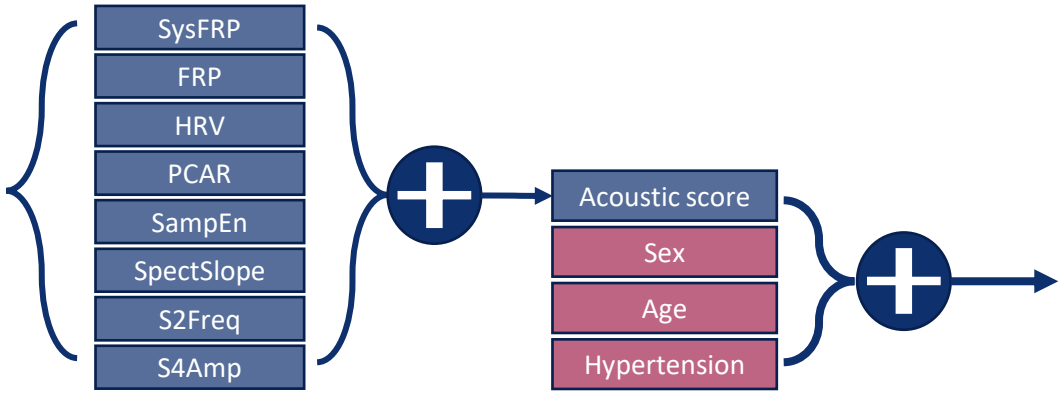
# AI Algorithm for Acoustic Detection of CAD



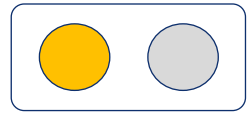

Segment the heart sound recording into heart beats → Noise reduction → Feature extraction → Classification



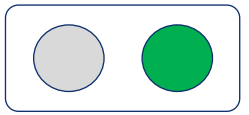
***+45 patens in 8 patent families + 2 pending***




CAD-score >20
Elevated risk of CAD



CAD-score ≤20
Low risk of CAD



# The need for Rapid Rule-out

Low diagnostic yield of current diagnostic methods

**Current noninvasive testing includes:**

- Cardiac CT
- Stress ECG
- SPECT

**Current noninvasive testing is**

- Costly
- Depends on specialized equipment located at hospitals

**90-94%**

**patients undergoing noninvasive testing do not suffer from CAD [1,2]**

1 Therming C et al (2018) Low diagnostic yield of non-invasive testing in patients with suspected coronary artery disease: results from a large unselected hospital-based sample. Eur Heart J - Qual Care Clin Outcomes 4:301–308
2 Winther, Simon, et al. "Diagnostic performance of an acoustic-based system for coronary artery disease risk stratification." Heart (2017): heartjnl-2017

# Rule-out Capacity of CADScor®System

The point-of-care CADScor®System can safely rule out more than one third of patients referred for non-invasive testing with at least 96% certainty


2/3

**Non-invasive testing**

1/3

**No further assessment for CAD**

Schmidt, S. E., et al. "Coronary artery disease risk reclassification by a new acoustic-based score." *The international journal of cardiovascular imaging* 35.11 (2019).

# A Clinical Powerhouse and Continued Clinical Development


acarix

**Patients included:**

- Reported studies: 2,790
- Ongoing studies: ~3,800

**Clinical trials used for development and validation of Algorithm**

| ADOPT CAD (2012-13) | BIO-CAC (2014-2015) | DAN-NICAD (2014-16) |
|---|---|---|
| N = 228<br>CAD Prevalence 28%*<br>Gold standard ICA confirmed CAD | N = 661<br>Technical Data Sub-study – DanRisk study<br>Gold standard ICA confirmed CAD | N = 1,675<br>CAD Prevalence 10.4%<br>Gold standard ICA confirmed CAD, including FFR |

**Clinical trials used for external validation**

| VALIDATE (2016-17) | DAN-NICAD II (2018-20) |
|---|---|
| N= 226<br>CAD Prevalence 39%<br>Gold standard ICA confirmed CAD | AKUSTIK (2019-20) |
| | FILTER-SCAD (2019-ongoing) |

New data is used for further algorithm development

Current CE-mark evidence  Pending Publication  Key Studies: Ongoing/Reporting Phase

# Why engage and invest in Acarix?

1. **Solid R&D and patented technology, published clinical data and regulatory approvals**
   Strong platform foundation with patented technology. Clinical data completed and published. Now ready to scale and drive impact for Acarix, health care providers and patients

2. **Strengthened EU position**
   Growing installed base and increased utilization of patches; ongoing work with G-BA and NICE

3. **US market opportunity**
   Timing is ideal: FDA De Novo, CPT Code and new Guidelines Significant unmet need with matching business model

4. **Strong experienced team to make it happen!**

# Thank you!