

## CADScor® System Clinical Report

Patient Name:		Date:
DOB:	Gender:	Time Exam:
Patient ID #:	Insurance Company:	Policy #:

**CPT Code:**

**0716T** - Cardiac acoustic waveform recording with automated analysis and generation of coronary artery disease risk score.

**ICD-Diagnosis codes:**

**Primary symptoms:**

- I20.89 Other forms of angina pectoris
- M79.601 Pain in right arm
- M79.602 Pain in left arm
- R06.00 Dyspnea, unspecified
- R06.02 Shortness of breath
- R06.89 Other abnormalities of breathing
- R07.2 Precordial pain

- R07.82 Intercostal pain
- R07.89 Other chest pain
- R07.9 Chest pain, unspecified
- R55 Syncope and collapse

**Primary Risk Factors:**

- E10. \_\_\_\_\_ Type 1 Diabetes
- E11. \_\_\_\_\_ Type 2 Diabetes
- E78.0 Pure Hypercholesterolemia, unspecified
- E78.2 Mixed Hyperlipidemia

- I10 Essential Hypertension

**Secondary Factors:**

(Must have primary symptom selected.)

- E66.3 Overweight
- E66.8 Other obesity
- E83.52 Hypercalcemia
- Z72.0 Tobacco Use
- Z82.40 Family history of ischemic heart disease
- Other: \_\_\_\_\_

**CAD-score Exam Result:** \_\_\_\_\_

The CAD-score is indicating risk of having significant coronary artery disease (CAD), defined as having  $\geq 50\%$  luminal diameter reduction.<sup>1</sup>

Two risk categories are defined using the CADScor System:

<b>CAD-score:</b>	<b><math>\leq 20</math></b>	<b><math>&gt; 20</math></b>
<b>Risk Group:</b>	<b>Low Risk</b>	<b>Elevated Risk</b>

**About CAD-score risk group:**

The CAD-score is a patient specific heart murmur score indicative of Coronary Artery Disease (CAD)/Chronic Coronary Syndrome (CCS) for immediate risk stratification, prior to potential secondary evaluation.<sup>1</sup>

A CAD-score at or below 20 indicates that your risk of significant CAD is low.

If your CAD-score is in the elevated risk group, you may be reevaluated at a later time or be referred onto secondary evaluation.

**Physician Clinical Assessment:**

**Physician Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**SUMMARY**

1. **FDA Clearance:** CADScor System is an FDA De Novo cleared class II device (DEN190047).
2. **Intended Use:** The intended use of CADScor System is to record heart sounds, murmurs and vibration, for calculation of a patient specific score, indicating the risk of coronary stenosis, as an aid in cardiac analysis and diagnosis.<sup>1</sup>
3. **Indications for Use:** The CADScor System is indicated for use as a diagnostic aid in symptomatic patients with suspected stable Coronary Artery Disease/Chronic Coronary Syndrome.<sup>1</sup>
4. **Clinical Data:** More than 6,000 patients studied in the CADScor System clinical program. Several clinical studies have been published demonstrating the efficiency of the CADScor System including two peer-reviewed published studies with independent patient populations (n=3,977) demonstrate that a CAD-score of 20 or less indicates no significant CAD, with a negative predictive value (NPV) reported between 95.4-97.2%.<sup>2,3</sup> The FDA labeling for the CADScor System is a NPV of 96.2%.<sup>1</sup>
5. **Acarix collaborated with the American College of Cardiology (ACC) Innovation Program** ([www.acc.org/about-acc/innovation](http://www.acc.org/about-acc/innovation)) to develop a clinical workflow for the proposed use of the CADScor System as a first line diagnostic aid in patients with stable chest pain ([www.acarix.com/resources/downloads/us](http://www.acarix.com/resources/downloads/us)).
6. **National Institute for Health and Care Excellence (NICE):** NICE MIB defines the CADScor System as a stable coronary artery disease rule-out method after first clinical evaluation (clinical history, physical examination, 12-lead ECG) and before CT coronary angiography (CTCA) ([www.nice.org.uk/advice/mib174/chapter/summary](http://www.nice.org.uk/advice/mib174/chapter/summary)).

1. User manual US-FDA v.12.Y  
 2. Schmidt SE, Winther S, Larsen BS, et al. Coronary artery disease risk reclassification by a new acoustic-based score. *Int J Cardiovasc Imaging*. 2019;35(11):2019-2028. doi:10.1007/s10554019-01662-1 <https://pubmed.ncbi.nlm.nih.gov/31273633/>  
 3. Rasmussen LD, Winther S, Karim SR, et al. Likelihood reclassification by an acoustic-based score in suspected coronary artery disease [published online ahead of print, 2023 Mar 16]. *Heart*. 2023;heartjnl-2023-322357. doi:10.1136/heartjnl-2023-322357 <https://pubmed.ncbi.nlm.nih.gov/36878672/>