

# CaRi-Heart® Coronary Inflammation and Risk Report

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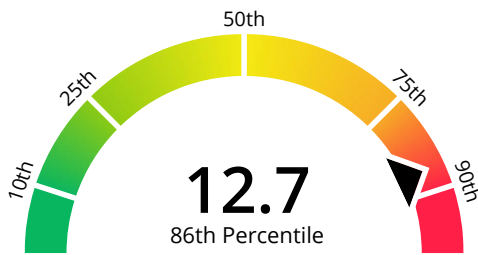
## PATIENT

Patient ID: Sample 3  
Age: 59  
Sex: Male  
Smoker: No  
Hypercholesterolaemia: No  
Diabetes: No  
Hypertension: No

## STUDY

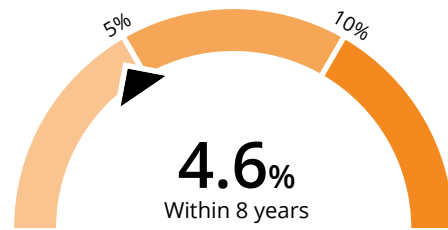
Report Date: 25 May 2022  
Referring Center: CM1  
CT Study Date: 04 May 2022 11:49:37  
Caristo Reference: VNV / 3ky2e-n5v80-9s1 / v4ncu-kdmkk-s8w  
Study Description: CT Cardiac Lungs

## FAI-SCORE



This represents the weighted Fat Attenuation Index (FAI) of the coronary artery with the highest degree of inflammation.

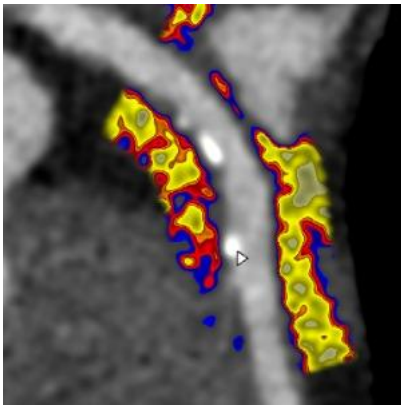
## CARI-HEART® RISK



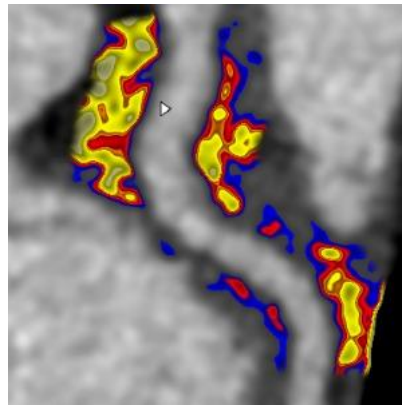
Risk of a fatal cardiac event if left untreated, based on the FAI-Score values, the coronary atherosclerotic plaque burden and the clinical risk factors.

## FAT ATTENUATION INDEX (FAI)

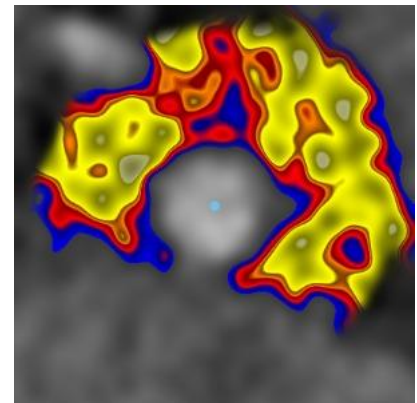
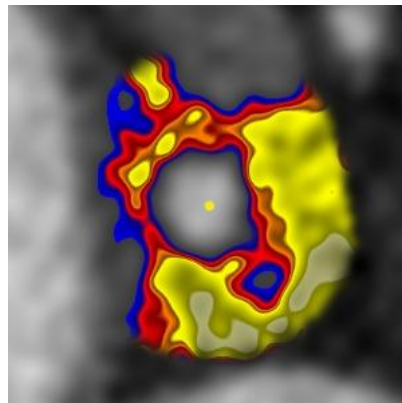
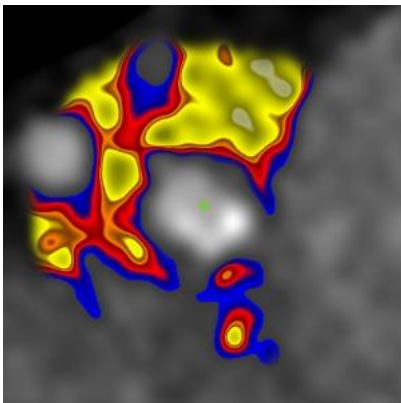
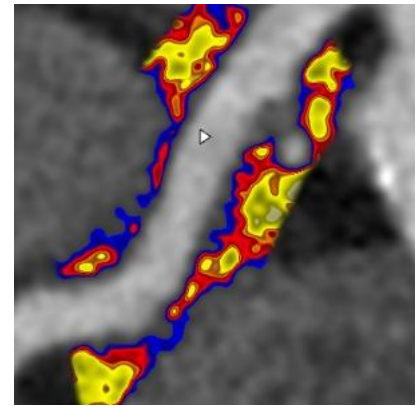
LAD: -78.6 HU



LCX: -78.6 HU

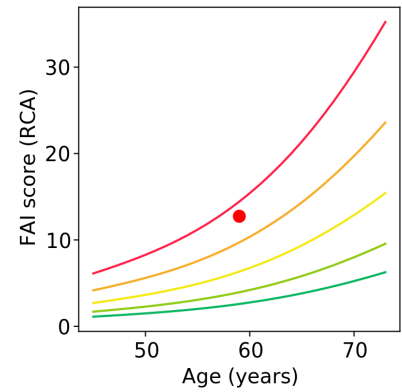
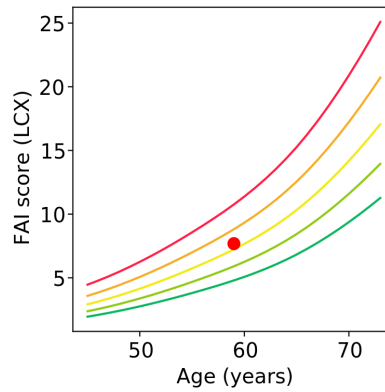
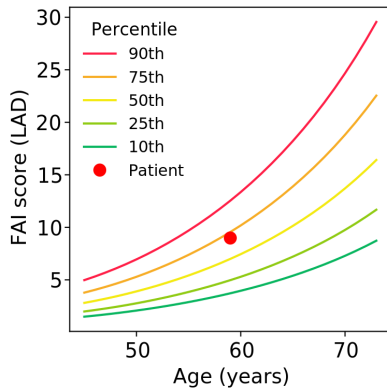


RCA: -74.0 HU



-190HU 15HU

## FAI-SCORE - RELATIVE RISK, ADJUSTED FOR AGE AND GENDER



Vessel	FAI-Score	Percentile of Coronary Inflammation for Age and Gender
Left Anterior Descending Artery	9.0	71st percentile
Left Circumflex Artery	7.7	57th percentile
Right Coronary Artery	12.7	86th percentile

## COMMENTS

None.

## CAUTIONS

- ⚠ This report should not be used as a primary means of diagnosis.
- ⚠ This report is not a substitute for a standard CCTA report and does not contain incidental findings.
- ⚠ This report should be interpreted by a healthcare professional who retains the ultimate responsibility for making the pertinent diagnosis based on their standard practice.
- ⚠ This report is not intended to be used to guide revascularization strategy.

## INDICATIONS FOR USE

- CaRi-Heart® is a software device used to produce analysis results to assist Healthcare Professionals in patient management. It helps operators assess information about vascular-related inflammation from computed tomography angiography images and calculates measures related to the risk of cardiac mortality due to coronary-related inflammation and other clinical risk factors.
- CaRi-Heart® and its analysis results are indicated for use for all adult patients referred for CCTA imaging.
- CaRi-Heart® is to be used by trained operators. CaRi-Heart® analysis results are to be used by Healthcare Professionals.
- CaRi-Heart® analysis results should be reviewed with other clinical information which may include, but is not limited to: the patient's original CT images, clinical history, symptoms, clinical risk factors, results of other diagnostic tests, and the clinical judgement of appropriately qualified Healthcare Professionals.

V: eu-west-2/nv/v2.4.1 R: 20a44434-cd62-4e93-b33e-d9bf08f89b02 U: f717f69a-05b1-46e0-b4dc-968856588a33

## DEVICE INFORMATION



**Legal Manufacturer**  
Caristo Diagnostics Ltd.  
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EC REP



2797

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Produced using CaRi-Heart® v2.4.1  
**UDI-DI:** 5060737370017  
**UDI-PI:** VNVCHEART2D4D1



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