

PATIENT

ID:
Age: 34
Sex: Male

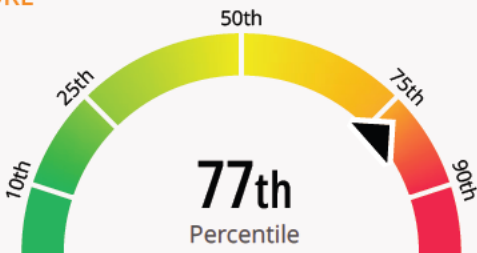
CLINICAL RISK FACTORS

Smoker: No
Hypercholesterolaemia: Yes
Diabetes: No
Hypertension: No

STUDY

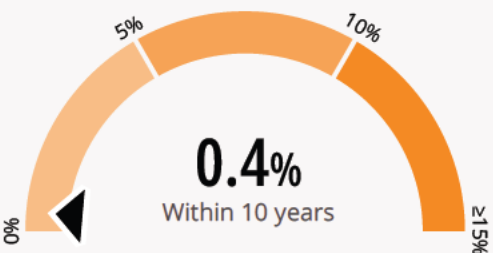
Report Date:
Referring Center:
CT Study Date:
Caristo Reference:
Study Description:

FAI-SCORE



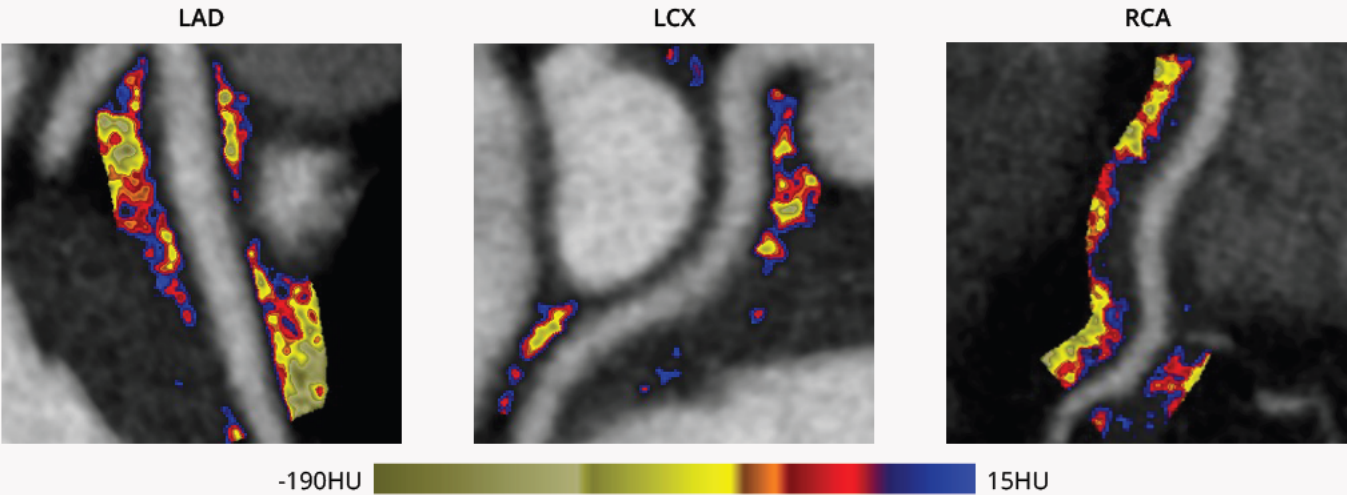
This is the FAI-Score percentile of the coronary artery with the highest inflammation.

CARI-HEART® RISK

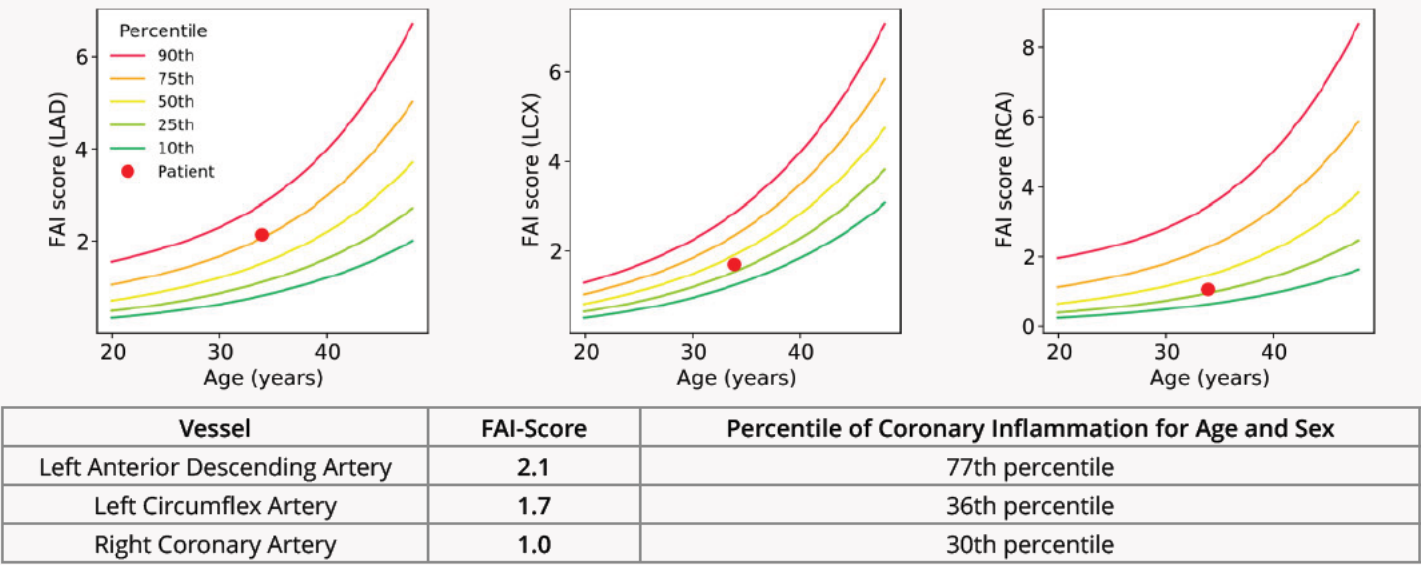


Risk of a fatal cardiovascular event if existing treatment is unchanged, based on the FAI-Score values, the coronary atherosclerotic plaque burden and the clinical risk factors.

FAT ATTENUATION INDEX (FAI)



FAI-SCORE: A STANDARDISED MEASURE OF CORONARY INFLAMMATION FOR AGE AND SEX



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 vascular inflammation from coronary computed tomography angiography (CCTA) images and measure risk of cardiovascular mortality due to coronary inflammation and other clinical risk factors. Operators can also quantify plaque and stenosis from CCTA images.

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.

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.

DEVICE INFORMATION



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Produced using CaRi-Heart® v2.10.1
UDI-DI: 5060737370017
UDI-PI: PMDUKCHRT2D10D1



Instructions for use are supplied electronically (Electronic Instructions For Use) and are available at: www.caristo.com. A paper copy may be requested from the manufacturer at no additional cost and will be provided within 7 days.

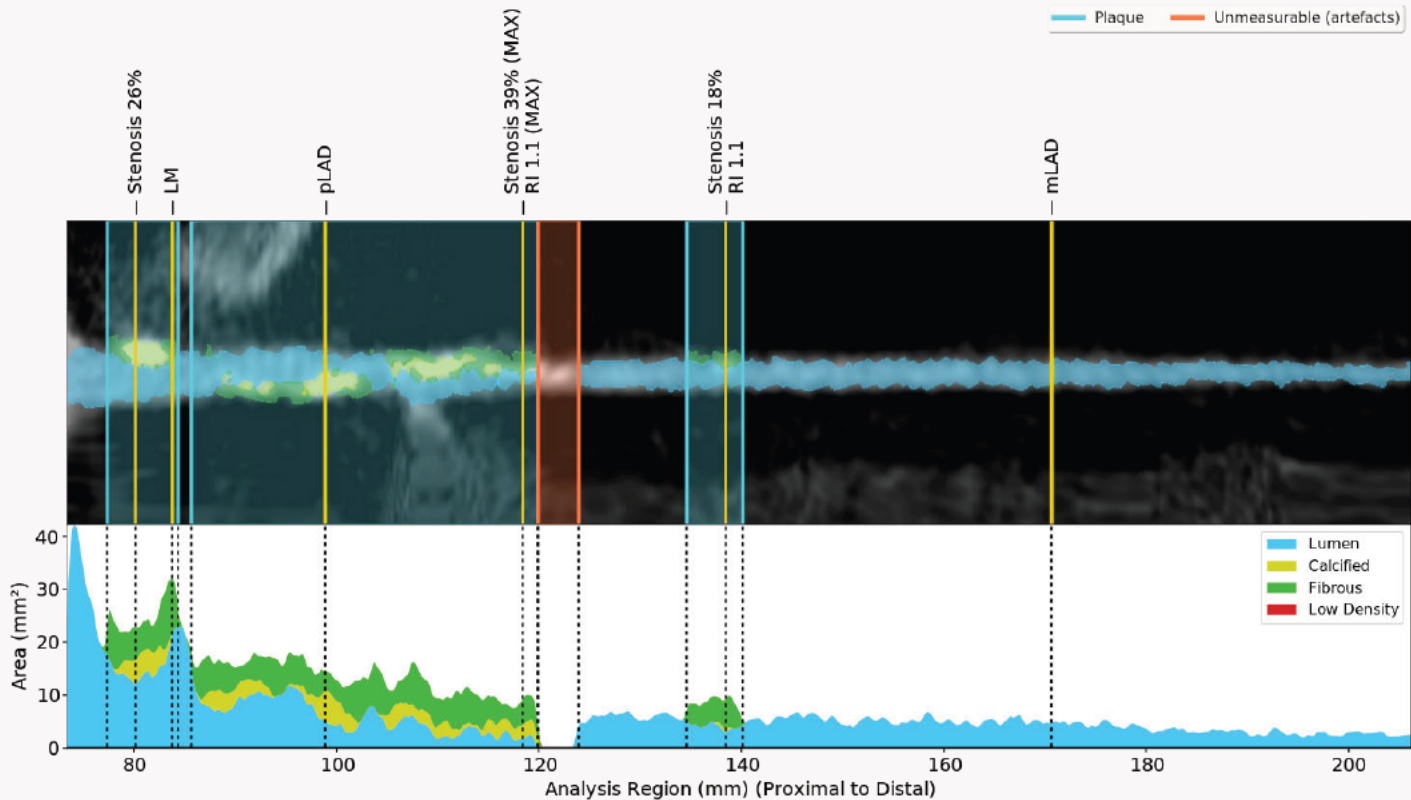
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Hypertension: Yes

STUDY

Report Date:
Referring Center:
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Caristo Reference:
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PLAQUE ANALYSIS: LM AND LAD



PLAQUE

Plaque Burden: 36%
CP Volume: 91.9 mm³
Total Plaque Volume: 346.2 mm³

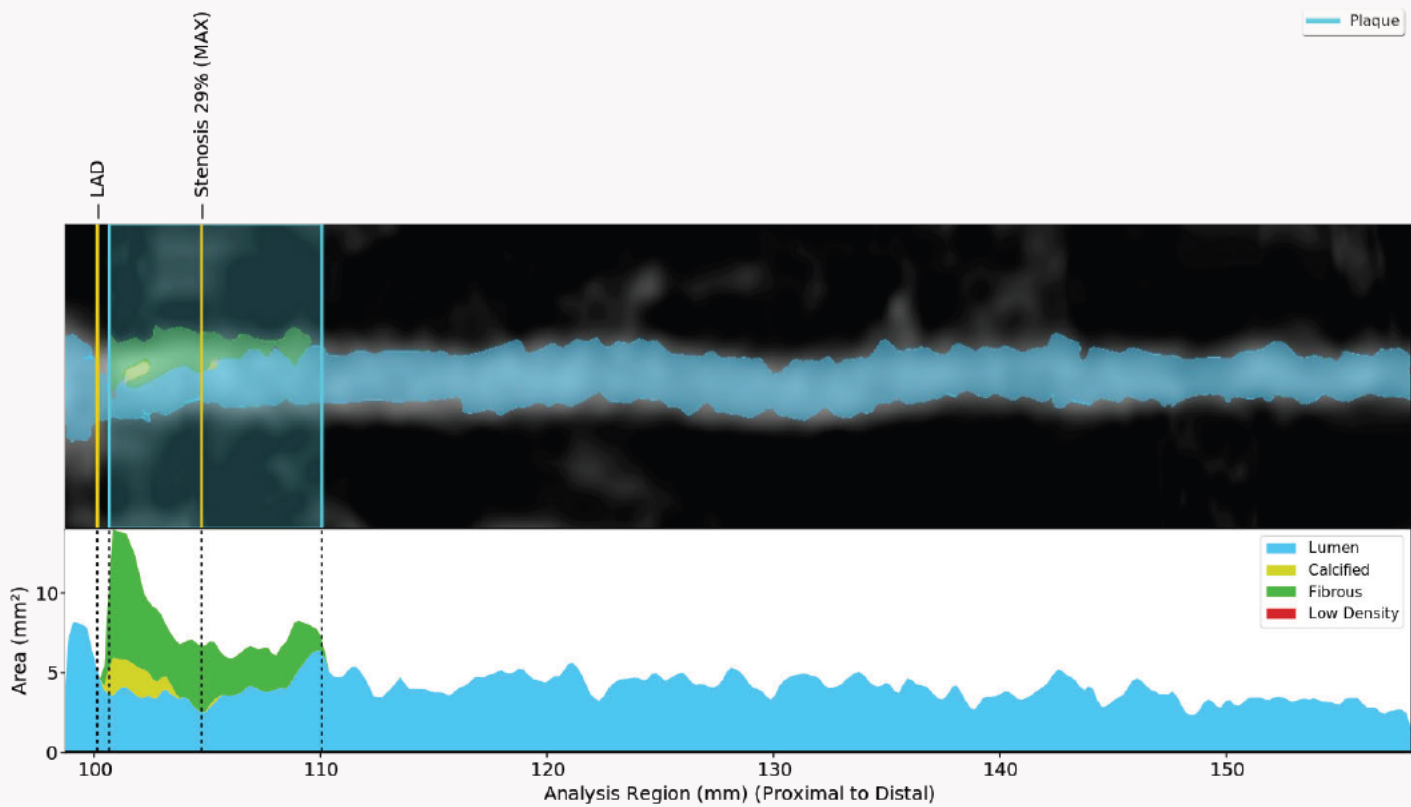
NCP Volume: 254.2 mm³
LD-NCP Volume: 0.0 mm³

STENOSIS

Remodelling Index: 1.1
Maximum Stenosis: 39%

Quantitative analysis could not be performed on the unmeasurable region(s).

PLAQUE ANALYSIS: D1



PLAQUE

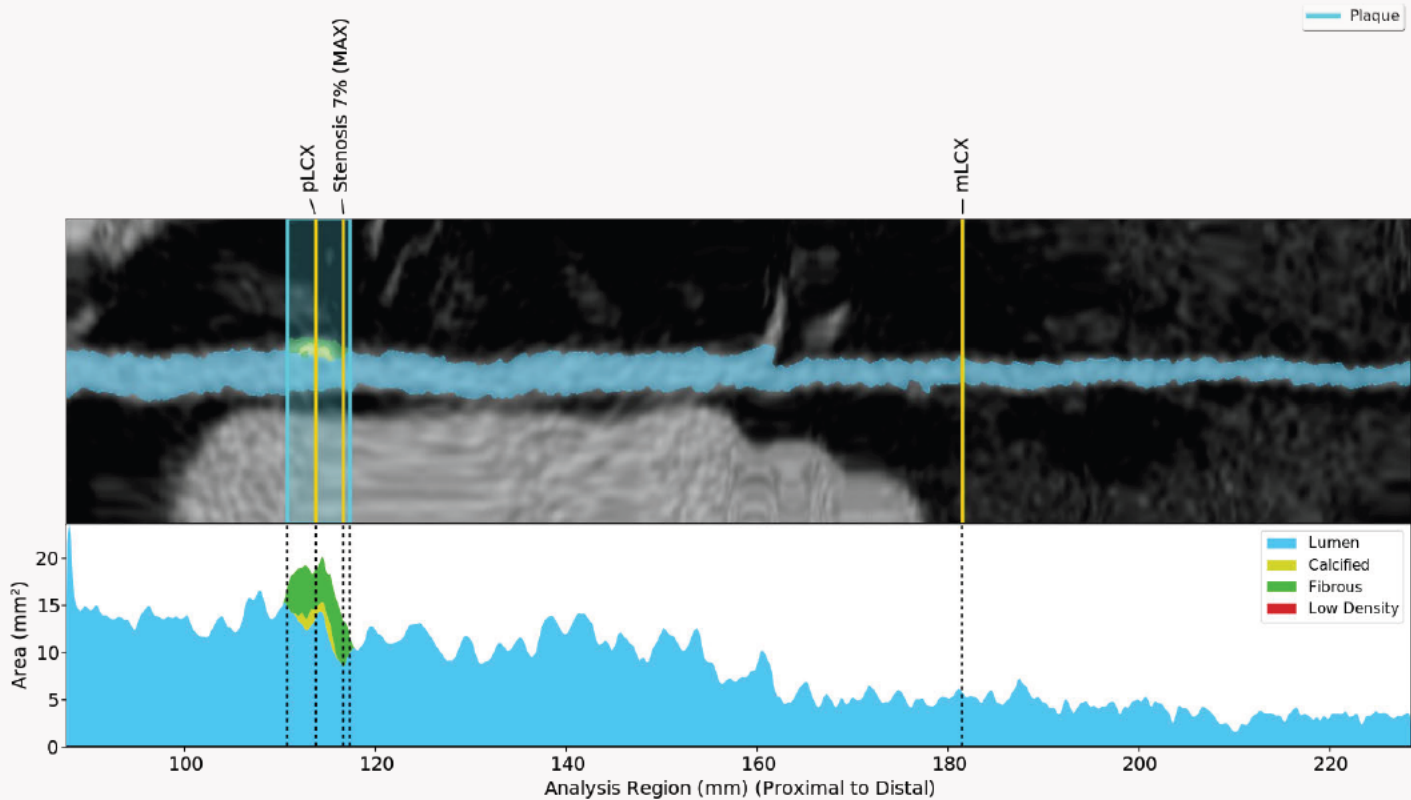
Plaque Burden: 33%
CP Volume: 4.8 mm³
Total Plaque Volume: 38.6 mm³

NCP Volume: 33.9 mm³
LD-NCP Volume: 0.0 mm³

STENOSIS

Remodelling Index: 1.0
Maximum Stenosis: 29%

PLAQUE ANALYSIS: LCX



PLAQUE

Plaque Burden: 24%
CP Volume: 5.5 mm³
Total Plaque Volume: 38.1 mm³

NCP Volume: 32.5 mm³
LD-NCP Volume: 0.0 mm³

STENOSIS

Remodelling Index: 1.0
Maximum Stenosis: 7%

COMMENTS

Aortic plaque noted in LM ostium but not included in the analysis due to plaque location.
Plaque noted in RCA but is not measurable due to reduced image quality.

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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, plaque and stenosis 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.

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DEVICE INFORMATION

		
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Produced using CaRi-Heart® v2.8.4
UDI-DI: 5060737370017
UDI-PI: PMDUKCHEART2D8D4



00862797