CaRi-Heart® Coronary Inflammation and Risk Report Instructions for Use

31 January 2025

Intended Audience

This document is for use by healthcare professionals who will receive a CaRi-Heart Coronary Inflammation, Plaque, and Risk Report from Caristo Diagnostics.

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.

CaRi-Heart is to be used by trained operators. CaRi-Heart analysis results are to be used by Healthcare Professionals.

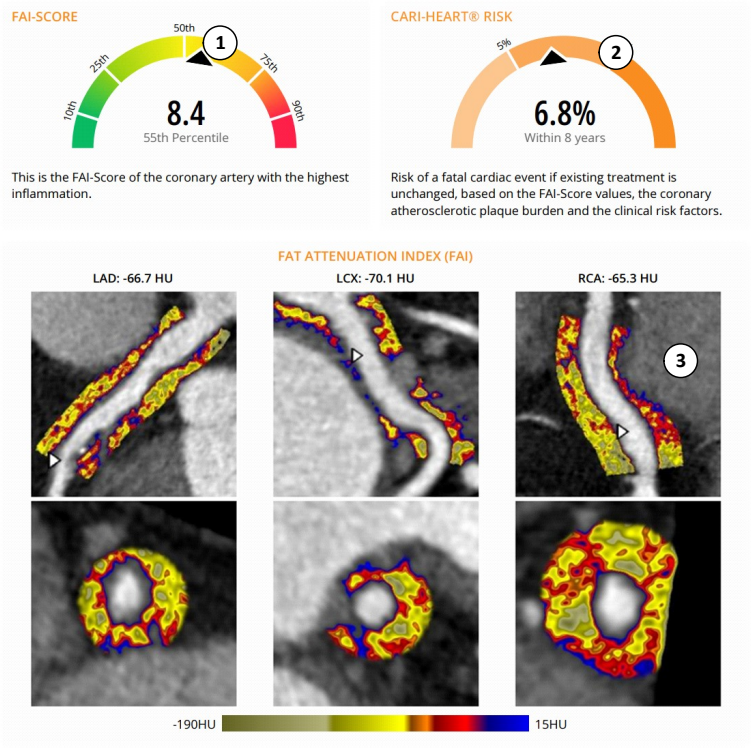
CaRi-Heart analysis results should be reviewed with other clinical information which may include, but is not limited to: the patient's original CT images, clinical history, symptoms, clinical risk factors, results of other diagnostic tests, and the clinical judgement of appropriately qualified Healthcare Professionals.

Imaging pre-requisites

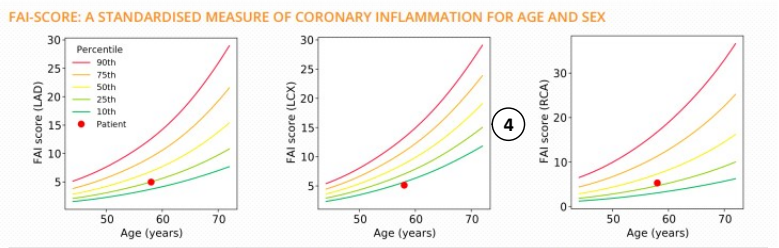
- Patient should be between 30 - 80 years old.
- Images should be acquired using a CCTA protocol on a 64-slice scanner or above.
- Images should have a slice thickness of less than 1mm.
- Matrix size of 512x512
- 12-16bit pixel data
- Non Deep-learning reconstruction or filtering for inflammation evaluations.
- Images should be acquired at peak energies of 70, 80, 90, 100, 110, 120, 140 kVp or on a photon counting scanner using a 140kVP tube voltage and a 67 or 100 keV virtual monoenergetic image with a QR44 Filter for reconstruction.
- Images should include the pulmonary artery bifurcation cranially and fully include the apex of the heart caudally. 10cm to 50cm field of view extents.

Description of CaRi-Heart Report Content

CaRi-Heart® Coronary Inflammation and Risk Reports provide information about plaque, coronary-related inflammation and the inflammation-associated risk of cardiac mortality. The CaRi-Heart® Plaque, Coronary Inflammation and Risk Report provides the following measures:



1	**FAI-Score**	The highest percentile FAI-Score of vessels measured: a standardised modifiable measure of coronary inflammation reported per patient.
2	**CaRi-Heart Risk**	A modifiable measure of the 8-year risk of cardiac mortality, taking into account coronary inflammation, atherosclerotic plaque, patient demographics and clinical risk factors.
3	**FAI**	Reported per vessel: a modifiable measure of coronary inflammation (Fat Attenuation Index) Displayed with corresponding images.



Vessel	FAI-Score	Percentile of Coronary Inflammation for Age and Sex
Left Anterior Descending Artery	5.0	24th percentile
Left Circumflex Artery	5.1	6th percentile
Right Coronary Artery	5.3	31st percentile

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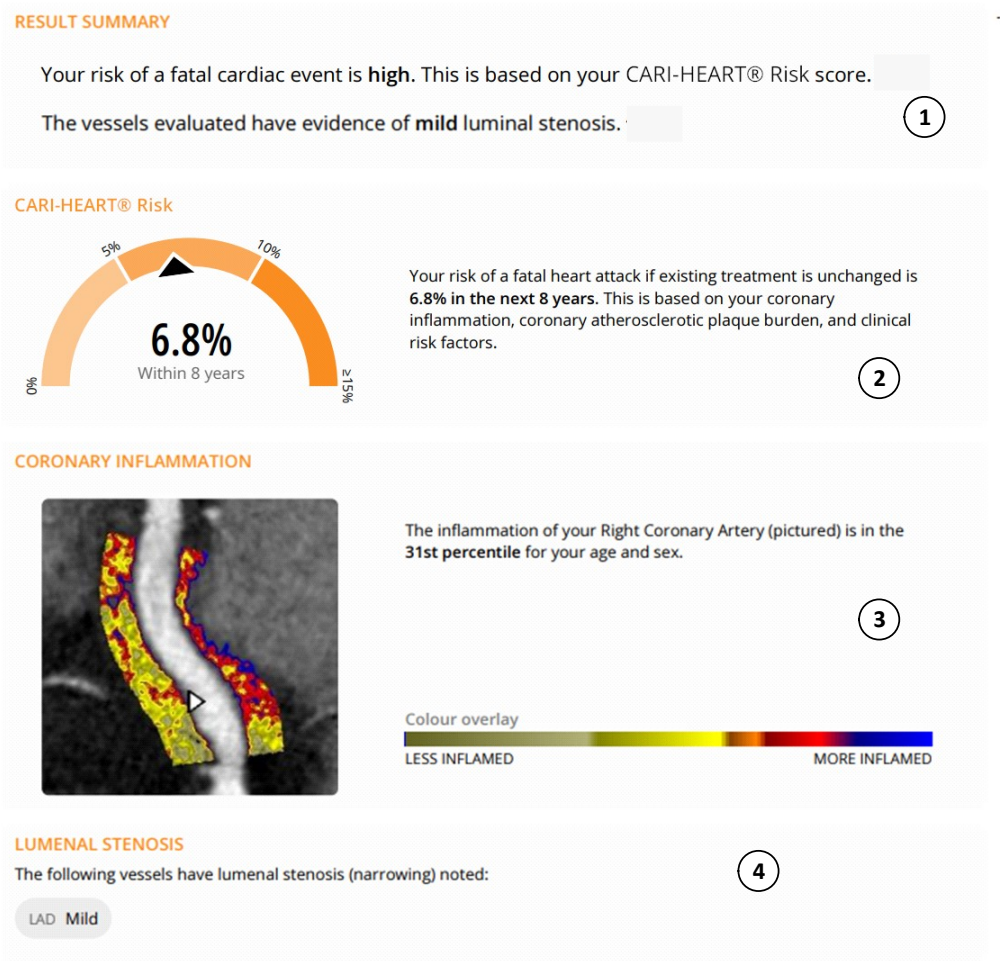
4	**FAI-Score charts**	Display the age and sex percentiles for the patient's cohort per-vessel. The point shown on each illustrates where the patient's FAI-Score sits within that cohort.
5	**FAI-Score and percentile**	The per-vessel FAI-Score and percentile value.

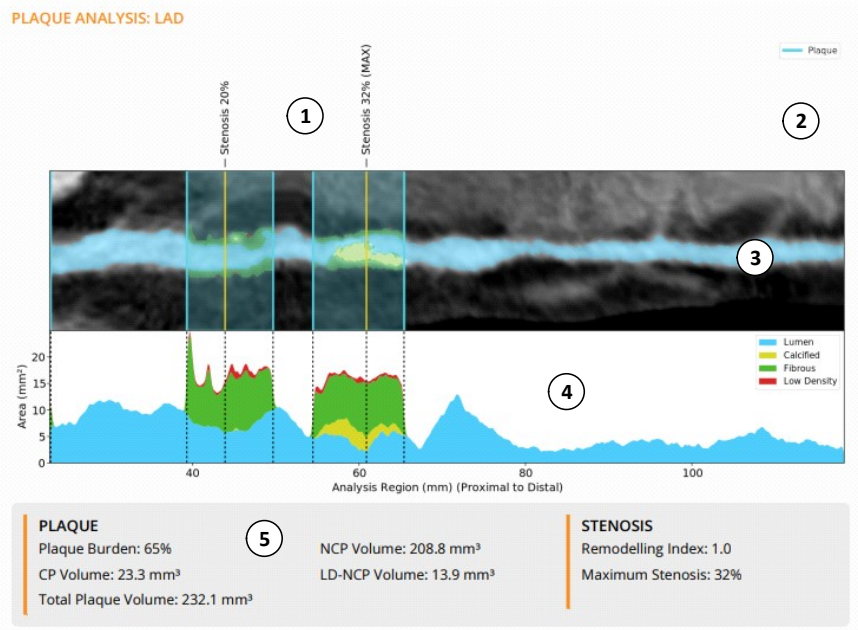
Description of CaRi-Heart additional Primary Care report

For distribution to primary care physicians a summary report with the following elements:



1	**Result summary**	A summary of the analysis with respect to current guidance for inflammation assessment.
2	**CaRi-Heart Risk**	A modifiable measure of the 8-year risk of cardiac mortality, taking into account coronary inflammation, atherosclerotic plaque, patient demographics and clinical risk factors.
3	**Coronary Inflammation**	The vessel with the highest FAI-Score percentile of the vessels measured: a standardised modifiable measure of coronary inflammation reported per patient:
4	**Luminal stenosis**	A summary of the severity of luminal stenosis for vessels where stenosis from plaque has been observed.

Description of CaRi-Heart additional quantitative plaque reporting



The following plaque and stenosis information are provided for each measured coronary artery:

1	**Stenosis and Remodelling index**	Available for each plaque measured on the vessel when stenosis is greater than zero or the remodelling index is greater than one.
2	**Overlay for each plaque region**	Plaque regions demarcated by vertical light blue transparent regions with vertical lines indicating the start and end of each region.
3	**Straightened CPR visualization**	Colour overlays are used to show the segmentations of different anatomical structures as shown in the key.
4	**Cross-sectional area chart**	Chart displaying the area of the lumen and plaque found along the vessel from proximal to distal coloured according to the key.
5	**Quantitative measures**	Calcified plaque (CP) volume, Low density non-calcified plaque (LDNCP) volume, Non-calcified plaque (NCP) volume (LDNCP + fibrous), Total Plaque volume (CP + NCP). Plaque Burden, Maximum Stenosis, and Remodelling index (described below)

Maximum Stenosis

A quantitative measure of the maximum narrowing of the lumen due to atherosclerosis. As calculated from the minimum luminal diameter (MLD) measured at the point of maximal stenosis to a luminal diameter at a healthy reference point.

$$Stenosis = \left(1 - \frac{MLD}{reference\ lumen\ diameter}\right) * 100$$

Remodelling index

A measure of change in the vessel diameter due to atherosclerosis within the vessel wall. It is calculated as the ratio of the outer elastic boundary at the point of maximal stenosis to the outer elastic boundary at a healthy reference point.

$$RI = \frac{vessel\ diameter\ at\ MLD}{reference\ vessel\ diameter}$$

CP Volume

The volume in mm3 of calcified plaque (CP) within sections of vessel containing plaque.

LD-NCP Volume	The volume in mm3 of low-density non calcified plaque (LD-NCP) within sections of vessel containing plaque.
NCP Volume	The volume in mm3 of non-calcified or fibrous plaque (NCP) within sections of vessel containing plaque.
Total Plaque Volume	The total amount of plaque found within the measured region of the vessel $$Total\ Plaque\ Volume = CP\ volume + NCP\ volume$$
Plaque Burden	The total plaque volume as a percentage of the aggregate volume of vessel segments containing plaque. $$Plaque\ Burden = \frac{Total\ Plaque\ Volume}{Aggregate\ volume\ of\ vessel\ segments\ conmtaining\ plaque} * 100$$

Warnings and Cautions

⚠ **CAUTION:** CaRi-Heart reports should not be used as a primary means of diagnosis.

⚠ **CAUTION:** CaRi-Heart reports are not a substitute for standard CCTA reports and do not contain incidental findings.

⚠ **CAUTION:** CaRi-Heart reports should be interpreted by a healthcare professional who retains the ultimate responsibility for making the pertinent diagnosis based on their standard practice.

⚠ **CAUTION:** Timeframes for analysis results provision are contractually defined and are subject to delay. CaRi-Heart reports should not be requested for patients with unstable coronary syndromes or in patients where urgent and timely workup and evaluation is critical.

Notices

❗ **NOTICE:** If a serious incident occurs in relation to the use of reports produced by the device, the competent authorities of the Member State and the Manufacturer shall be notified.

❗ **NOTICE:** CaRi-Heart 2.6 & 2.7 use an updated reference cohort for calculating FAI-Score percentiles, which may impact comparisons with previous versions of the device.

❗ **NOTICE:** CaRi-Heart uses tri-linear and tri-cubic interpolation in the display and rendering of evaluation and output images, this does not guarantee the absence of plaque which is at or below the resolution of the data provided as an input.

Performance Characteristics

Reports from CaRi-Heart are not intended to provide a diagnosis and are intended only to be used as an additional clinical data point as part of a wider diagnostic process. The software and/or its methodologies have been validated through a variety of studies which have been widely published. A short sampling of the published data is as follows:

1. Chan K, Wahome E, Tsiachristas A, Antonopoulos AS, Patel P, Lyasheva M, et al. Inflammatory risk and cardiovascular events in patients without obstructive coronary artery disease: the ORFAN multicentre, longitudinal cohort study. *www.thelancet.com*. *Lancet* 2024; https://doi.org/10.1016/S0140-6736(24)00596-8

2. Oikonomou EK, Antonopoulos AS, Schottlander D, et al. Standardized measurement of coronary inflammation using cardiovascular computed tomography: integration in clinical care as a prognostic medical device. *Cardiovasc Res* 2021; 117: 2677–90

3. Oikonomou EK, Marwan M, Desai MY, et al. Non-invasive detection of coronary inflammation using computed tomography and prediction of residual cardiovascular risk (the CRISP CT study): a post-hoc analysis of prospective outcome data. *Lancet* 2018;392(10151):929-939

4. Antoniades C, Shirodaria C. Detecting Coronary Inflammation With Perivascular Fat Attenuation Imaging: Making Sense From Perivascular Attenuation Maps. *JACC Cardiovasc Imaging* 2019;12(10):2011-2014

5. Antonopoulos AS, Sanna F, Sabharwal N, et al. Detecting human coronary inflammation by imaging perivascular fat. *Sci Transl Med* 2017;9(398).

Device Information

Device: CaRI-Heart 2.7
Reference: 2135
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