

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

December 13, 2021

Intended Audience

This document is for use by healthcare professionals who will receive a CaRi-Heart Coronary Inflammation 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 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.
- Image scan should include the pulmonary artery bifurcation cranially and fully include the apex of the heart caudally.

Description of CaRi-Heart Report Content

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

FAI	for each coronary vessel: a modifiable measure of coronary inflammation
FAI-Score	for each coronary vessel: a standardised modifiable measure of coronary inflammation
CaRi-Heart Risk	a measure of the 8-year risk of cardiac mortality, taking into account coronary inflammation, atherosclerotic plaque, patient demographics and clinical risk factors.

A paper copy of this eIFU may be requested from the manufacturer at no additional cost. A paper copy will be provided within 7 days of request.

Device: CaRI-Heart 2.4
Reference: 1494
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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:** CaRi-Heart reports are not intended to be used to guide revascularization strategy.
-  **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

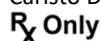
-  **NOTICE:** If a serious incident occurs in relation to the use of reports produced by the device, the competent authorities of the Member State and the Manufacturer shall be notified.

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

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