ClearRead CT™
BY RIVERAIN TECHNOLOGIES

Coronary Artery Calcification User Manual

Versions 1.2.2

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IMPORTANT

READ THIS MANUAL BEFORE USING THE SYSTEM

For continued safe use of this equipment, read, understand, and carefully follow the instructions contained in this manual before using the product, and refer to it as necessary.

The user of this product is solely responsible for any malfunction that results from improper use, unauthorized alteration or faulty service by any party not authorized by Riverain Technologies™ Inc. ("Riverain").

KEEP YOUR DOCUMENTATION CURRENT

Retain this manual for future reference.

Riverain Technologies reserves the right to periodically change or enhance its products and related documentation. If you update your product, make sure to update your documentation accordingly.

OBTAIN AUTHORIZATION PRIOR TO SHARING ANY CONTENT OF THIS MANUAL

Riverain's ClearRead products are licensed technology. The content of this manual is the property of Riverain and may not be reproduced, shared, or used without prior written permission from Riverain.

Note: Federal law restricts this device to sale by or on the order of a physician.

CONTENT

[1] About This Manual

[1.1] Audience and Scope

Congratulations on becoming a ClearRead™ user!

Coronary artery disease is the most common type of heart disease in the United States, with 382,820 reported deaths in 2020[1]. Coronary artery disease is caused by the buildup of plaque in the walls of the coronary arteries that supply blood to the heart.

Traditionally, ECG-gated non-contrast CT (NCCT) has been used to assess coronary arterial calcification (CAC) as it is a strong predictor of future cardiac events[2]. However, coronary artery calcium (CAC) can also be detected and quantified using non-gated CT scans. In 2006, there were 10.6 million non-gated chest CT scans performed, compared with 0.8 million CT scans for CAC scoring (gated and cardiac CT scans[3,4]). Reliable CAC screening on asymptomatic patients with non-gated CT scans could, therefore, lead to earlier detection of disease and thus reduce the incidences of adverse cardiovascular events.

The objective of ClearRead CT CAC is to aid physicians in assessing Coronary Artery Calcification while reviewing non-contrast, standard, or low-dose axial chest CT series.

This manual contains the information necessary for the safe and effective use and operation of ClearRead CT CAC. It provides physicians with indications for when and how to use the system, specifications of the expected system input, and descriptions of system output.

[1.2] Contact Information

For any questions, clarifications or concerns not addressed in this manual, or to seek a replacement copy of this manual visit www.riveraintech.com or contact us directly at:

Riverain Technologies
3130 S. Tech Blvd
Miamisburg, Ohio 45342

+1-937-425-6811 or info@riveraintech.com

Technical Support – Riverain Technologies Customer Success

- Email: support@riveraintech.com
- Phone Number: +1.800.914.1446 or +1.937.425.6950
- Fax: +1.937.425.6493

[1] https://www.cdc.gov/heartdisease/facts.htm
[2] Greenland, P., et al. (2018). Coronary Calcium Score and Cardiovascular Risk. *Journal of the American College of Cardiology*, 72(4), 434–447. https://doi.org/10.1016/j.jacc.2018.05.027
[3] Mettler, F. A., Jr, et al. (2008). Medical radiation exposure in the U.S. in 2006: preliminary results. *Health physics*, 95(5), 502–507. https://doi.org/10.1097/01.HP.0000326333.42287.a2
[4] Brenner, D. J., & Hall, E. J. (2007). Computed tomography--an increasing source of radiation exposure. *The New England journal of medicine*, 357(22), 2277–2284. https://doi.org/10.1056/NEJMra072149

If this product was obtained via an OEM provider as part of another product (such as a PACS or an Artificial Intelligence (AI) platform), first contact the OEM provider's Customer Support.

[1.3] Typography

The following symbols and typeface styles are used throughout this manual:

WARNING: Indicates a precaution to avoid adverse effect, including damage to equipment, negative impact to quality of treatment, personal injury, or death.

NOTE: Indicates important information or special attention is required to avoid errors or mistakes.

Bold text – Used for titles and to highlight specific terms when used for the first time.

`Fixed Font` – Used for folder names, file names, code examples, or system commands.

□ Bulleted narrow text – Used for stepwise execution directions.

[1.4] Glossary

CAC	Coronary Artery Calcification
CT	Computed Tomography
NCCT	Non-Contrast Computed Tomography
DICOM	Digital Imaging and Communications in Medicine
OEM	Original Equipment Manufacturer
PACS	Picture Archiving and Communications System

[1.5] Additional Reading

Additional content is available outside the scope of this manual which may be of interest:

[R1] ClearRead CT CAC Administrator Manual, available from Riverain, contains the information necessary to configure, administer, and monitor ClearRead CT devices.

[R2] ClearRead CT CAC DICOM Conformance Statement, available from Riverain, contains details of the DICOM objects generated by ClearRead CT CAC.

[R3] Additional products and support information available at www.riveraintech.com.

K. Martini, M., C. Blüthgen, M., M. Eberhard, M., A.L.N. Schönenberger, M., I. De Martini, M., F.A. Huber, M., . . . T. Frauenfelder, M. (2020). Impact of Vessel Suppressed-CT on Diagnostic Accuracy in Detection of Pulmonary Metastasis and Reading Time. *Academic Radiology*. doi:https://doi.org/10.1016/j.acra.2020.01.014

Lo, S. B., Freedman, M. T., Gillis, L. B., White, C. S., & Mun, S. K. (2018). Computer-Aided Detection of Lung Nodules on CT With a Computerized Pulmonary Vessel Suppressed Function. *American Journal of Roentgenology, 210*, 480–488. doi:10.2214/AJR.17.18718

Milanese, G., Eberhard, M., Martini, K., De Martini, I., & Frauenfelder, T. (2018, February 15). Vessel suppressed chest Computed Tomography for semi-automated volumetric measurements of solid pulmonary nodules. *European Journal of Radiology, 101*, 97–102. doi:https://doi.org/10.1016/j.ejrad.2018.02.020

Singh, R., & et al. (2018). Effect of Artificial Intelligence Based Vessel Suppression and Automatic Detection of Part Solid and Ground-Glass Nodules on Low-Dose Chest CT. Chicago, USA: RSNA. Retrieved from http://archive.rsna.org/2018/18014631.html

[2] SAFE USE

For continued safe use of this device, read, understand, and carefully follow the instructions contained in this manual before using the product, and refer to it as necessary.

In particular, heed the following:

WARNING: Only the original chest CT series is to be used for diagnostic interpretation by physicians. The device output is designed only as an aid to the interpretation process.

WARNING: Degraded image quality of input series from factors such as patient motion and/or manmade devices (e.g., pacemaker) in the field of view during the image acquisition, may lead to reconstruction artifacts and diminish the effectiveness of the device.

WARNING: Incorrect DICOM headers or other factors can cause the device to reject an input CT series, in which case no result will be returned. Do not delay your reading of the primary series in order to view the device results.

WARNING: Ensure all inputs meet device specifications. Invalid input may lead to no output being generated or to degraded device performance.

WARNING: Users should never be dissuaded from working up their own assessment, even if inconsistent with the device output. The device may under- or over-estimate the amount of coronary calcification.

WARNING: Measurement accuracy should be assessed carefully for Agatston scores greater than 500. More significant amounts of CAC may be associated with additional difficulties hindering accurate score measurement.

WARNING: Users should review the output segmentations for quality to assess the expected accuracy of the associated measurement outputs.

NOTE: Use of the device on any image projection other than the axial CT chest views is not supported.

Note: The user and/or patient should report any serious incident related to the use of this device to the manufacturer as well as the competent authority where the incident occurred.

NOTE: A standard CT series is expected to contain both lungs. Series not containing both lungs might fail to be processed.

NOTE: Input CT series is expected to contain an untruncated view of the heart chamber and major vessels in the mediastinum, or it might fail to process.

Administrators of ClearRead CT CAC should also heed the following (refer to the *ClearRead CT CAC Administrator Manual* [R1]):

WARNING: ClearRead CT CAC is a medical device. It should be used only as described in the accompanying manuals. Other activities, such as web browsing, email, or installation of third-party software without specific authorization from Riverain Technologies, are prohibited. Software authorized by Riverain Technologies should be scanned with anti-virus software before use.

WARNING: On servers provided by Riverain, the device should be installed, serviced, and configured only by trained personnel.

WARNING: Do not make changes to the system or to the system configuration, other than as explicitly described in the ClearRead CT CAC Administrator Manual, as this may lead to unpredictable system behavior.

WARNING: It is unlawful to use this software other than for its indicated use, or without a legitimate license.

WARNING: Use caution when creating patch rules. Incorrect use may create nonconforming DICOM messages.

[3] SYSTEM OVERVIEW

[3.1] System Description

ClearRead CT CAC is a computer aided quantification system intended to aid in the assessment of coronary artery calcification.

The system receives chest Computed Tomography (CT) studies as input, in DICOM® format, and generates output in DICOM (or other) format.

[3.2] Indication for use

ClearRead CT CAC is image processing software designed to aid physicians in assessing coronary artery calcification on non-gated, non-contrast, standard, or low-dose chest CT scans of adult patients 30 years of age or older.

The primary output of ClearRead CT CAC is the Agatston score. ClearRead CT CAC locates calcified coronary lesions and assigns them to one of several coronary arteries: the right coronary artery (RCA), the left main artery (LM), the left anterior descending artery (LAD), and the left circumflex artery (LCX). The software calculates the Agatston score as the sum for each artery while also providing the total across all coronary arteries. The total Agatston score is calibrated to 3.0mm slice thickness and is used to derive a CAC category and the arterial age. The provided segmentations are for illustrative purposes only and are not intended for diagnostic use. ClearRead CT CAC provides adjunctive information and is not intended to be used without clinical expert review.

[3.3] Contraindications

Not applicable.

[3.4] Adverse Effects

There are no known direct risks to the health or safety of the patient from the physical use of the ClearRead CT CAC system. This is a post-processing application and does not require added radiation dose to the patient.

Possible indirect risks are:

- A physician may be dissuaded from working up clinically significant CAC if the device under-estimates its presence, thus missing a possible CAC.
- A physician may be misled into working up clinically insignificant CAC that would not otherwise have been acted upon.

[3.5] Limitations

Valid Input	ClearRead CT CAC has been designed to accept non-contrast, standard, or low-dose axial chest CT scans as input, in DICOM format, that meet certain specifications (see [4.1] Input Data Requirements). Invalid input may lead to no output generated by ClearRead CT CAC or degraded device performance.
Quality Input	ClearRead CT CAC has been optimized to process scans configured to assist the assessment of coronary artery disease (see [4.2] Input Data Considerations). Results may not be optimal for scans that do not meet these considerations.
Over-Estimation and Under-Estimation	ClearRead CT CAC is designed for optimal measurement accuracy of coronary artery calcification. The following are the predominant sources of over- or under-estimation of CAC: • Imaging artifacts from motion or beam-hardening due to stents, surgical clips, or other man-made objects. • Image noise due to low-dose acquisition and partial volume errors. • Cardiac valves and aortic calcifications. • Enhancing kernels may result in over-estimation of CAC.
Patient Age	ClearRead CT CAC has been validated for adult patients and should only be used on patients 30 years old or older.

[4] SYSTEM INPUT

[4.1] Input Data Requirements

ClearRead CT CAC has been designed to process non-contrast, standard, or low-dose axial CT series, in DICOM format. Each series in an input study is considered **valid input** if it meets the following specifications:

- Axial orientation with no more than +/- 1 degree of rotation.
- Maximum slice thickness of 3mm with jitter of no more than 0.1mm.
- Maximum slice spacing of 3mm with jitter of no more than 0.1mm.
- Consistent table height and patient position throughout the series.
- Full heart in Field-of-view.

NOTE: ClearRead CT CAC relies on Patient Position and Patient Orientation information from the DICOM header. If the header is incorrect, the system might fail to process the series.

ClearRead CT CAC uses a rules engine to filter input based on DICOM header fields. Refer to the *ClearRead CT CAC Administrator Manual* [R1] for details on how to configure input filters.

Series that do not meet input constraints are marked as errors and are not processed.

WARNING: Invalid input or other factors can cause the device to reject an input CT series for processing, in which case no result will be returned. Do not delay your reading of the primary series in order to view the ClearRead CT results.

[4.2] Input Data Considerations

ClearRead CT CAC operates over a wide range of CT chest scans. Like a radiologist, ClearRead CT CAC prefers scans configured to aid quantification of CAC, such as the following:

- Non-enhancing kernels over enhancing ones.
- Thin-slice over thick-slice.
- Minimum image artifacts.
- No field-of-view clipping of the major cardiovascular structures.

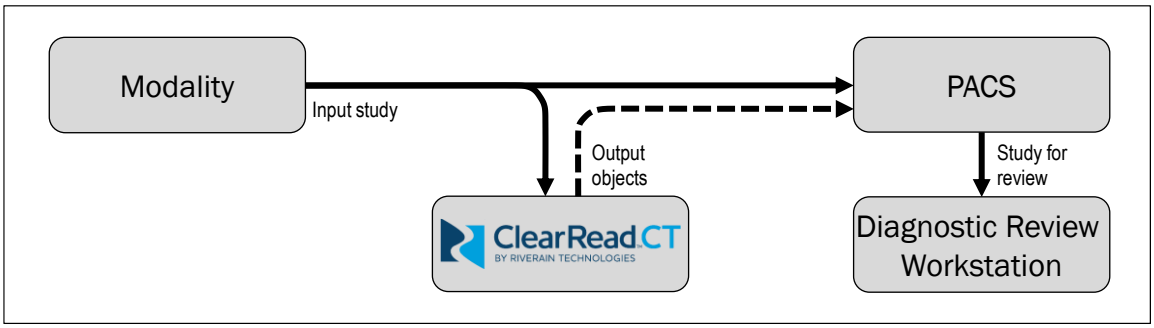
Scans that do not follow these recommendations are still processed, however, the results may not be as optimal as for scans that do.

[5] SYSTEM OUTPUT

[5.1] Connectivity

ClearRead CT CAC is designed to integrate with your native reading environment. In a typical deployment ClearRead CT CAC output objects are sent to the PACS (see Figure 1).

Figure 1: Typical viewing workflow with ClearRead CT CAC



The output results are sent for physicians to consume on one or more devices that conform to the ClearRead CT CAC DICOM Conformance Statement ([R2]).

The following sections describe each output object in detail.

[5.2] Output Objects

[5.2.1] Overview

ClearRead CT CAC generates **Output Objects** (also known as **Derived Objects**). Output objects generated do not alter any DICOM input (primary). These output objects are made available to clinicians to be used per device indications.

Available output objects are listed in Table 1. The actual output objects generated are configured per device, per local preferences, and available software license. Other configurations allow filtering invalid input, selecting presentation preferences, and more. See *ClearRead CT CAC Administrator Manual* [R1] for details on how to configure output objects.

NOTE: If ClearRead CT CAC is unable to process a scan, you will see the text "Image processing unsuccessful" displayed on a blank image.

Table 1: Available CAC output object

Code	Output Series Name	Format	# Of Slices	Prior Required	License Required
C3476	CR CT CAC Summary Report	DICOM secondary capture	Summary page	No	CAC

Code	Output Series Name	Format	# Of Slices	Prior Required	License Required
C2058	CR CT CAC Index	DICOM series with overlay	First, last, CAC contour slices	No	CAC
C2059	CR CT CAC Structured Report	DICOM Structured Report	N/A	No	CAC

Output objects may contain the following measurement information:

Agatston score[5]
The total Agatston score and per-artery Agatston score, calibrated to 3mm slice thickness. Artery is one of: left main coronary artery (LM), left circumflex artery (LCx), left anterior descending artery (LAD), or right coronary artery (RCA).

CAC Category
A CAC category based on the (total) Agatston score, one of:

CAC Category	CAC Category Label	Agatston Score
0	None	0
1	Mild	>0 and ≤99
2	Moderate	>99 and ≤399
3	Severe	>399

Arterial age
As defined in the MESA[6] study, calculated from the Agatston score:

*Arterial Age = 39.1 + 7.25 * log (Agatston Score + 1)*

Note that the Arterial Age saturates to *39 years* when the Agatston Score is 0.

Each output object generated does not alter the native DICOM input. The following sections describe each output object in detail.

[5.2.2] CAC Summary Report

The **ClearRead CT CAC Summary Report** (C3476) displays a summary of calcification findings such as the Agatston score for each artery while also providing the total across all coronary arteries. An illustrative, non-diagnostic image may be included that demonstrates the calcification.

[5] Agatston, A. S., et al.Janowitz, W. R., Hildner, F. J., Zusmer, N. R., Viamonte, M., Jr, & Detrano, R. (1990). Quantification of coronary artery calcium using ultrafast computed tomography. *Journal of the American College of Cardiology*, 15(4), 827–832. https://doi.org/10.1016/0735-1097(90)90282-t

[6] McClelland, R. L., Jorgensen, N. W., Budoff, M., Blaha, M. J., Post, W. S., Kronmal, R. A., Bild, D. E., Shea, S., Liu, K., Watson, K. E., Folsom, A. R., Khera, A., Ayers, C., Mahabadi, A. A., Lehmann, N., Jöckel, K. H., Moebus, S., Carr, J. J., Erbel, R., & Burke, G. L. (2015). 10-Year Coronary Heart Disease Risk Prediction Using Coronary Artery Calcium and Traditional Risk Factors: Derivation in the MESA (Multi-Ethnic Study of Atherosclerosis) With Validation in the HNR (Heinz Nixdorf Recall) Study and the DHS (Dallas Heart Study). *Journal of the American College of Cardiology*, 66(15), 1643–1653. https://doi.org/10.1016/j.jacc.2015.08.035

The following figure shows a typical output, with RCA, LAD, LCX, and LM calcification (Figure 2), with no measurable calcification (Figure 3), with optional CAC overlay (Figure 4), and with an error (Figure 5).

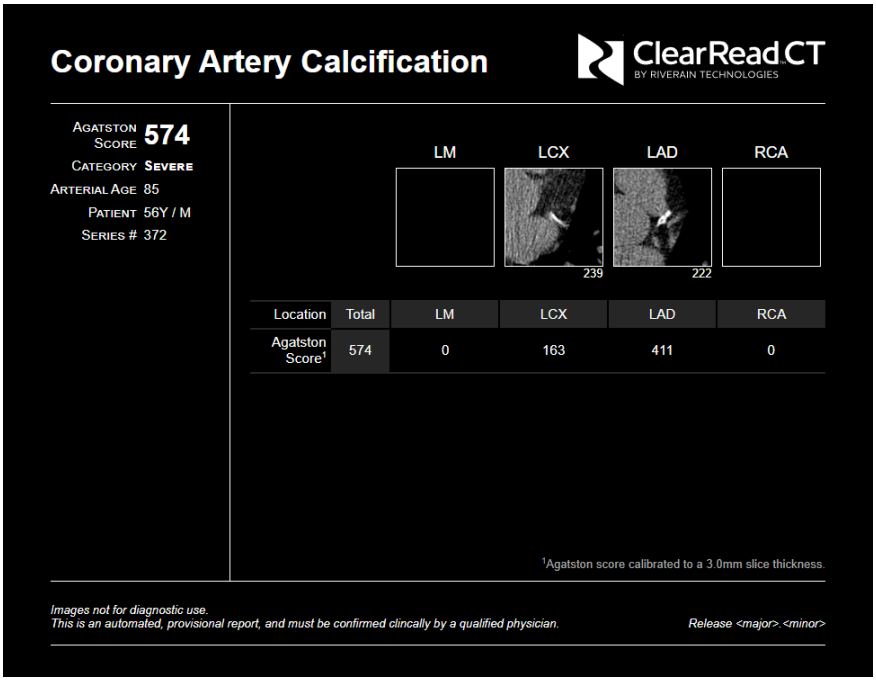


Figure 2 - Calcification

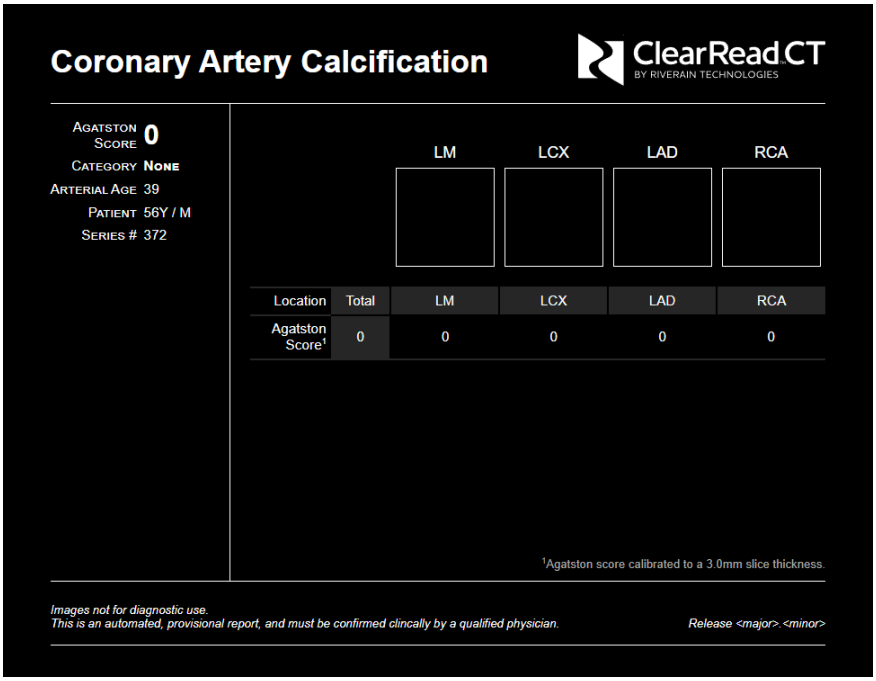


Figure 3 - No Measurable Calcification

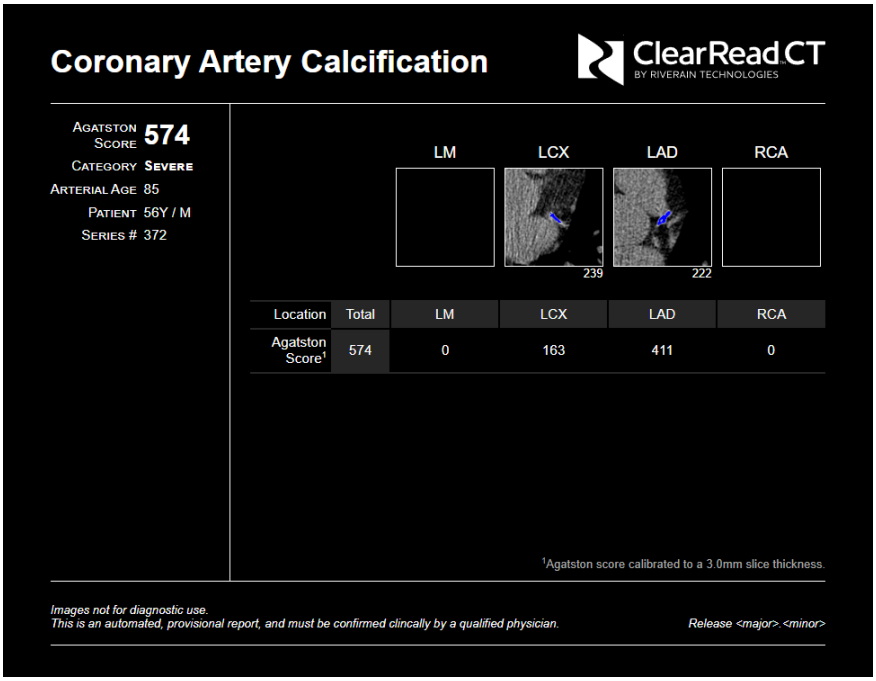


Figure 4 - Optional CAC Overlay

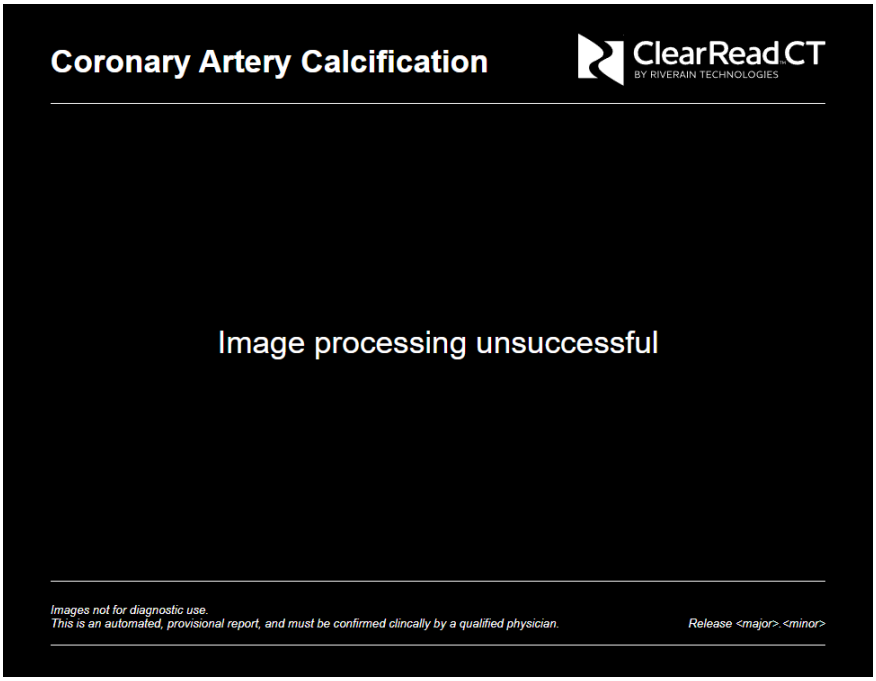


Figure 5 - Error Example

[5.2.3] Indexed Primary Volume with CAC Mask Overlay

The **Indexed Primary Volume with CAC Mask Overlay** (C2058) output object contains copies of the input (primary) images where suspected CAC was detected. The **Index** object series

only contains the first image, the last image, and any images where CAC was detected. Synchronizing the ***Index*** with the native input series makes it easy to navigate frames of the primary volume where CAC was detected.

The following figure shows the native series on the left and the CAC Mask Index series on the right (Figure 6). Scrolling frames in the CAC Mask Index series rapidly navigates the native series to images detected with CAC.

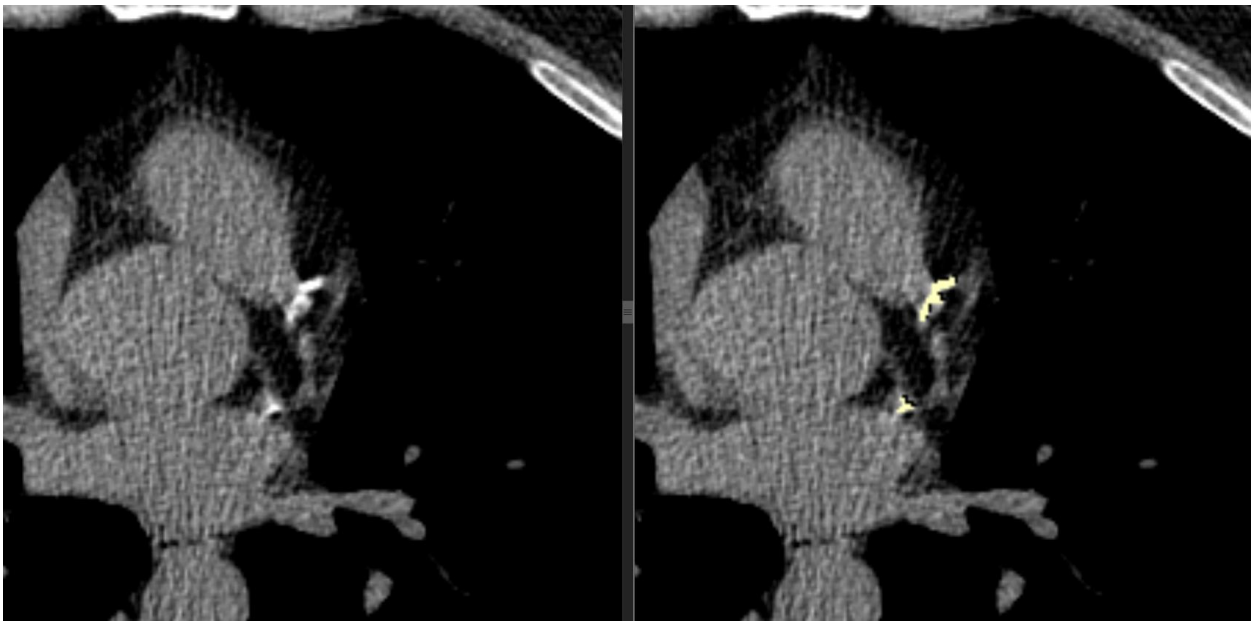


Figure 6 - Native (left) / Native + CAC Mask (right)

[5.2.4] CAC Structured Report

The **CAC DICOM Structured Report** (C2059) summarizes calcification findings such as the total Agatston Score, CAC Category and Arterial Age in DICOM SR format. This is intended for integration with other medical devices and is not intended for use by physicians.

[5.3] How to Use System Output

[5.3.1] Interpreting A Case

Upon seeing a calcification measurement, the physician assesses whether they are consistent with coronary calcification visible in the source study and determines how to include the measurements in their report.

Rules may be created by qualified physicians that take the automated measurement of CAC into account when prioritizing a patient worklist for reading.

NOTE: The provided segmentations are for illustrative purposes only and are not intended for diagnostic use. They should be reviewed as a confirmatory step prior to acceptance of machine scores.

In any case, the criteria for any further evaluation should be the same, whether the physician measured CAC with or without the aid of ClearRead CT CAC.

[5.3.2] Over-Estimation and Under-Estimation

ClearRead CT CAC automatically measures coronary artery calcification, however, the physician makes the final clinical determination. Specifically:

- When the physician agrees with the measurement, patient workflow should be the same as if the physician measured the calcification without the use of ClearRead CT.
- When the physician does not agree or does not understand a measurement by ClearRead CT CAC they should follow standard of care for assessing CAC. This may occur when the device determines calcification in an area where there is none (over-estimation), or when the device fails to identify calcified areas (under-estimation).
- If device output is not available a physician may still read the case and assess it following standard of care. Similarly, clinical action should match the physician's diagnosis and never be reversed based on the device output measurements.

[6] INTEGRATIONS

[6.1] General

ClearRead CT CAC offers a powerful set of configurations for input selection and output delivery. These are designed to allow users the flexibility to integrate ClearRead CT CAC into their workflow in the most effective and seamless way possible.

Most configurations can be set up at device installation. See *ClearRead CT CAC Administrator Manual* [R1] for details on available settings.

[6.2] Nuance PowerScribe Integration

To facilitate review workflow, ClearRead CT CAC can integrate with the Nuance PowerScribe reporting software.

In a typical configuration, ClearRead CT CAC automatically updates the order associated with the Accession Number of the processed series and populates an Auto-Text field (e.g., CRCT_CAC) with CAC findings information. The Auto-Text field can be added to a report template or added manually to a specific report.

NOTE: PowerScribe integration is typically configured as part of the device installation, where many aspects of the report generation can be controlled. See *ClearRead CT CAC Administrator Manual [R1]* for details.

Figure 7 and Figure 8 show an example of the ClearRead CT CAC findings populated into a PowerScribe template. The report summarizes the total Agatston Score, CAC Category and Arterial Age.

Figure 7: PowerScribe showing ClearRead CT CAC output.

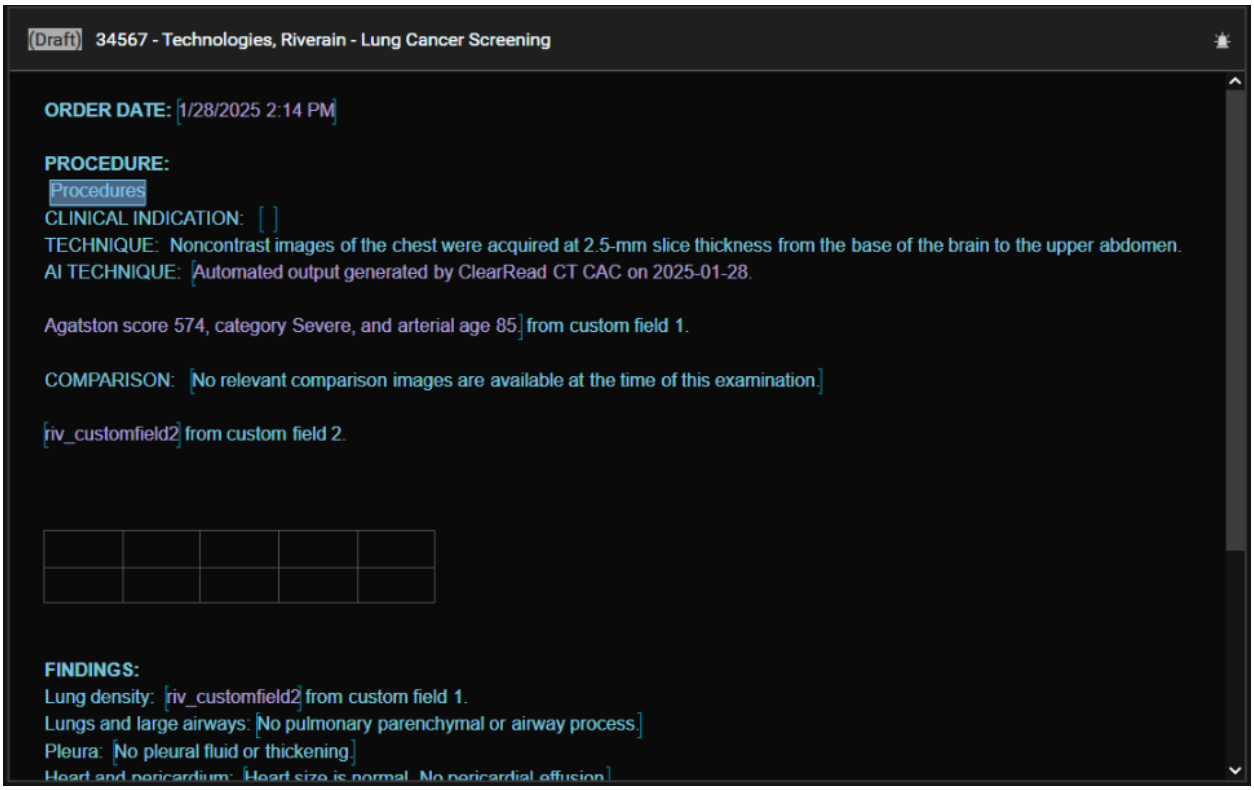
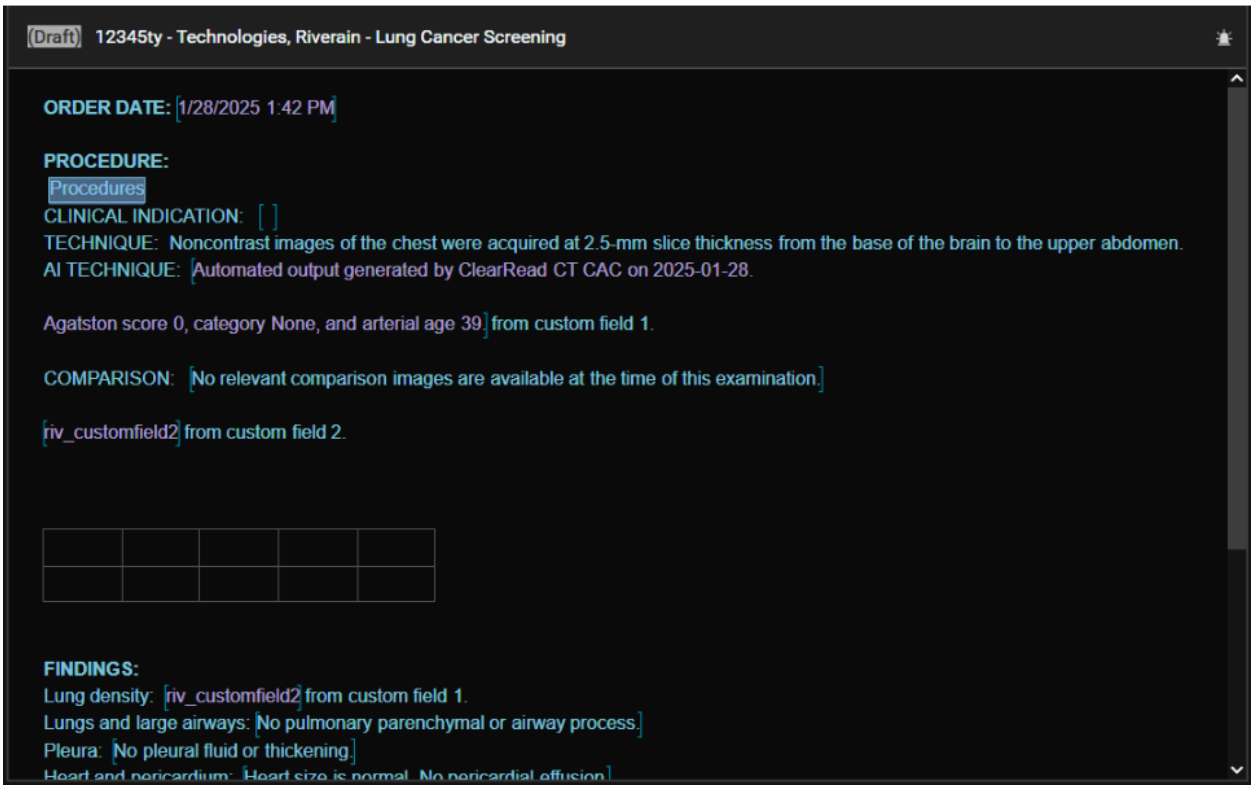


Figure 8 - PowerScribe showing ClearRead CT CAC output with Agatston score of 0.



[6.3] Health Level Seven (HL7) Integration

To facilitate exchanging study-level and CAC-level information with compatible devices, ClearRead CT CAC can send HL7 messages when processing completes.

HL7 messages are typically configured as part of the device installation. They require integration with the destination device, see *ClearRead CT CAC Administrator Manual [R1]* for details on HL7 integration.

```
MSH|^~\&|ClearReadCT|Riverain|||20250128121706||ORM^O01|2025012812170|P|2.3.1||||||
PID|||Calcification-01||||
PV1||
OBR||||examcode^examdescription|||||||F|||||||||||||A
OBX|1|TX|UDI|1|M722C25030CA241430||||||A|||||||
OBX|2|TX|ERROR||0||||||A|||||||
OBX|3|TX|STATUS||Processing successful||||||A|||||||
OBX|4|TX|AGATSTONSCORE||574||||||A|||||||
OBX|5|TX|CACCATEGORY||Severe||||||A|||||||
OBX|6|TX|ARTERIALAGE||85||||||A|||||||
```

[7] REGULATORY

[7.1] Device Manufacturer and Specifications Designer

Riverain Technologies, Inc.
3130 South Tech Blvd.
Miamisburg, OH 45342 U.S.A.
Phone: +1.937.425.6811
www.riveraintech.com

Technical Service
Office: +1-937-425-6811
Email: support@riveraintech.com

EC REP
EMERGO EUROPE
Westervoortsedijk 60
6827 AT, Arnhem
The Netherlands

CE
2862
Intertek Medical
Notified Body AB

Importers into specific regions:

MedEnvoy Global B.V.
Prinses Margrietplantsoen 33 – Suite 123
2595 AM The Hague
The Netherlands

MedEnvoy UK Limited
85, Great Portland Street, First Floor
London, W1W 7LT
United Kingdom

MedEnvoy Switzerland
Gotthardstrasse 28
6302 Zug
Switzerland

Australian Sponsor

Emergo Australia

Level 20 Tower II Darling Park
201 Sussex Street
Sydney, NSW2000 Australia

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