AI-Rad Companion (Cardiovascular)

Instructions for Use
VA23

siemens-healthineers.com

SIEMENS Healthineers

Legend

	Indicates a hint Is used to provide information on how to avoid operating errors or information emphasizing important details
	Indicates the solution of a problem Is used to provide troubleshooting information or answers to frequently asked questions
●	Indicates a list item
✓	Indicates a prerequisite Is used for a condition that has to be fulfilled before starting a particular operation
◆	Indicates a one-step operation
1 2 3	Indicates steps within operating sequences
Italic	Is used for references and for table or figure titles
➔	Is used to identify a link to related information as well as previous or next steps
Bold	Is used to identify window titles, menu items, function names, buttons, and keys, for example, the Save button Is used for on-screen output of the system including code-related elements or commands
Orange	Is used to emphasize particularly important sections of the text
`Courier`	Is used to identify inputs you need to provide
Menu > Menu Item	Is used for the navigation to a certain submenu entry
<variable>	Is used to identify variables or parameters, for example, within a string

⚠ CAUTION	CAUTION Used with the safety alert symbol, indicates a hazardous situation which, if not avoided, could result in minor or moderate injury or material damage. CAUTION consists of the following elements: • Information about the nature of a hazardous situation • Consequences of not avoiding a hazardous situation • Methods of avoiding a hazardous situation
⚠ WARNING	WARNING Indicates a hazardous situation which, if not avoided, could result in death or serious injury. WARNING consists of the following elements: • Information about the nature of a hazardous situation • Consequences of not avoiding a hazardous situation • Methods of avoiding a hazardous situation

1 AI-Rad Companion (Cardiovascular)

AI-Rad Companion (Cardiovascular) provides segmentation and measurements of the heart and the aorta to identify and analyze cardiovascular diseases, such as coronary plaque and aortic malformations.

This version of AI-Rad Companion (Cardiovascular) runs on AI-Rad Companion Engine, version VA32A and later. If you are using AI-Rad Companion (Cardiovascular) for the first time, please go through the information given in the AI-Rad Companion Engine Instructions for Use.

This version of AI-Rad Companion (Cardiovascular) is compatible with *syngo*.via, version VB60S_HF02 and later.

1.1 Intended Use

AI-Rad Companion (Cardiovascular) is intended to assist the physician in evaluating the heart and the aorta in non-cardiac chest CT.

1.2 Indications for use

AI-Rad Companion (Cardiovascular) is image processing software that provides quantitative and qualitative analysis from previously acquired Computed Tomography DICOM images to support radiologists and physicians from specialty care and general practice in the evaluation and assessment of cardiovascular diseases.

It provides the following functionality:

- Segmentation and volume measurement of the heart
- Quantification of the total calcium volume in the coronary arteries
- Segmentation of the aorta

- Measurement of maximum diameters of the aorta at typical landmarks
- Threshold-based highlighting of enlarged diameters.

The software has been validated for non-cardiac chest CT data with filtered backprojection reconstruction from Siemens Healthineers, GE Healthcare, Philips, and Toshiba/Canon. Additionally, the calcium detection feature has been validated on non-cardiac chest CT data with iterative reconstruction from Siemens Healthineers.

Only DICOM images of adult patients are considered to be valid input.

1.3 Contraindications

The device can be used for any non-cardiac chest CT data set. In principal, there are no limitations. In case of incomplete coverage of the heart or the aorta, one of the algorithms may fail and therefore yield no output. Thus, the radiologist must follow the workflow without the device.

Detection of coronary calcium: The device was not validated for patients with metal implants in the chest. In particular it is not intended for patients with previous cardiac implanted devices such as cardiac pacemaker, coronary stents, implantable defibrillator, or artificial valves.

1.4 Patient target group

AI-Rad Companion (Cardiovascular) requires images of patients of 22 years and older.

1.5 User profiles

AI-Rad Companion (Cardiovascular) is intended for the following user groups.

- Clinical User
- Clinical IT administrator

Clinical User

Licensed physician responsible for the interpretation of radiological exams, documentation, archiving and signing of the radiological report.

Name of user group	Qualified Medical Professionals (Clinical User – Radiologists, Physicians, Clinicians)
Demographic and physical specialties	Proficient in one of the supported GUI languages of AI-Rad Companion. No other demographic and physical requirements
Required qualification	Doctor of Medicine or equivalent professional degree. Users are credentialed by their medical institutions to read and report on Chest CTs.
Required professional experience	Basic knowledge of IT and working knowledge of PACS and/or RIS is required
Typical work environment	Healthcare environment at a radiological workplace (typically PACS) or on a workstation used for reporting or interpretation of Chest CTs images with a reading monitor. The work environment is typically a quiet room with ambient lighting and no disturbance.
Core Activities	Interprets, documents, archives, and signs off on reports involving Chest CTs. Configures application settings.
Typical equipment used to execute activities	Radiological workplace (typically PACS). A typical radiology workplace used for reading Chest CTs includes a multiple diagnostic grade monitor set up with use of keyboard, mouse, and dictation devices. Reading monitors could be configured in either portrait or landscape modes. Reading monitors display can be either colour or grayscale.
Expected training to use software	No training required (beside knowledge of Instructions for Use).

Clinical IT administrator

Licensed technologist responsible for patient handling, organization of the environment, performing the scans over to distribution of the right images and ensuring a clean environment. Technicians will configure, adjust, post-process, filter, modify and rank results provided by AI-Rad Companion (Cardiovascular), typical prior to the radiological interpretation, to support radiologist in their jobs to be done.

Name of user group	Clinical IT Administrator (incl. Technologists)
Demographic and physical specialties	Proficient in one of the supported GUI languages of AI-Rad Companion. No other demographic and physical requirements
Required qualification	Professional education in IT and/or medical IT-network responsible assigned by the healthcare organization.
Required professional experience	Experience installing and configuring DICOM nodes, DICOM routing rules and/or comparable medical devices.
Typical work environment	Normal office workplace
Core Activities	Configuration of input and output target nodes Support the clinical user with configuring and routing rules Management of institution roles and user privileges
Typical equipment used to execute activities	Notebook and Workstation
Expected training to use software	No training required

1.6 Clinical benefit

AI-Rad Companion (Cardiovascular) is an image processing software that provides quantitative and qualitative analysis from previously acquired Computed Tomography DICOM images to support qualified clinicians in the evaluation and assessment of Cardiovascular disease.

1.7 Limitations of Use

- AI-Rad Companion (Cardiovascular) is an adjunct tool and does not replace the role of a qualified medical professional. Qualified medical professionals reviewing chest radiographs must not use the AI-Rad Companion (Cardiovascular) generated output as the primary interpretation.
- AI-Rad Companion (Cardiovascular) is not designed to detect presence of radiographic findings other than the prespecified list. Qualified medical professionals should review original images for all suspected pathologies by following standard clinical procedures.

1.8 Side-effects

There are no known side-effects caused by using this device.

1.9 Storage and handling conditions

There are no known specific storage and handling conditions for this medical device.

1.10 User training

- This section provides information on how to access the training material and user documentation from the Patient List and Siemens Healthineers Document Library. This is applicable only for cloud-based and AI-Rad Companion edge deployment.
- For on-premise deployment, user documentation is provided as a PDF within the application. For information on how to access the training materials, refer to *syngo*.via Quick Startup Guide.

Siemens Healthineers offers training materials to enable you to operate AI-Rad Companion (Cardiovascular). Different kinds of trainings are available.

- Integrated **AI-Rad Companion (Cardiovascular) Help**

  You can access the **AI-Rad Companion (Cardiovascular) Help** by clicking the **Help** icon on the Access bar.

  For more information, see (➔ Page 41 *Accessing the Instructions for Use and the About tab cards*).

- Additional training material

  Training materials are available in the PEPconnect portal that can be accessed from the application. Click the **Training Material** icon on the Access bar and you are directed to the PEPconnect portal.

For more information on user training, contact your Siemens Healthineers sales representative or visit the Siemens Healthineers web page. Choose your country and then select the category Education & Training.

Only qualified users shall operate this device. For further details, see (➔ Page 8 *User profiles*).

1.11 Supported user interface languages

AI-Rad Companion (Cardiovascular) supports different user interface languages for example, English, German, French, Spanish, Japanese, Korean, Russian, and Simplified Chinese.

Other languages may be included in future releases, always refer the provided release information.

If you select the language that is not supported by AI-Rad Companion (Cardiovascular), then the user interface is displayed in English.

Users must be proficient in any of the supported languages of the user interface.

1.12 Measurement accuracy

The measurement tools provided by AI-Rad Companion (Cardiovascular) are developed using established mathematical and scientific methods. However, the accuracy of a measurement is primarily determined by the image data to which the measurement tools are applied.

The following factors influence measurement accuracy:

- Accuracy and calibration of the CT scanner used to acquire the images
- Image reconstruction settings, such as reconstruction kernel, slice thickness, spacing, resolution, and Field of View (FoV)
- If applicable, quantity of contrast media and injection protocol used
- Scan protocol used
- Patient compliance during image acquisition, for example, breathhold and motion
- Patient anatomy
- Patient orientation and position during image acquisition
- Zoom factor and image orientation when the measurements are performed
- Placement of the end points of the measurement; placement is more accurate when the image is zoomed in

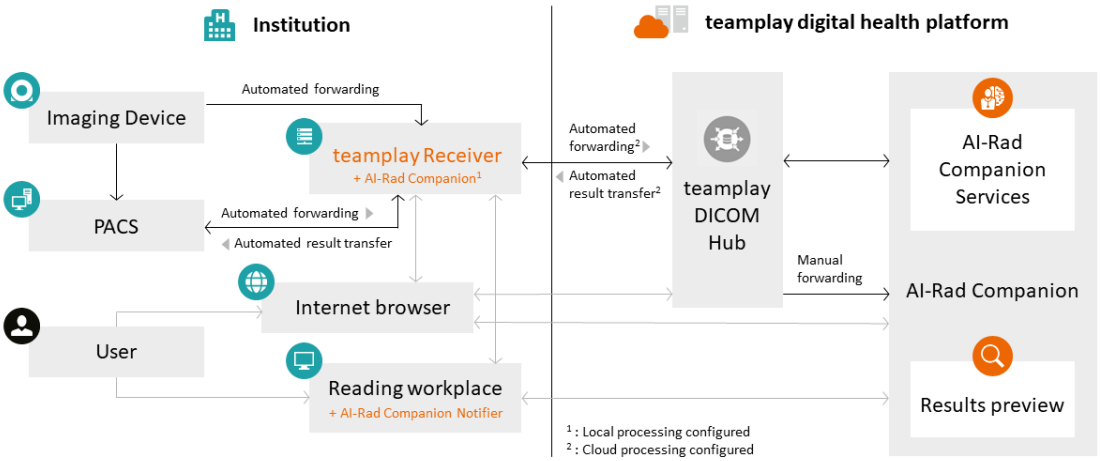
1.12.1 Display accuracy in AI-Rad Companion (Cardiovascular)

The following table shows the unit and the accuracy of the specific measurement tools in AI-Rad Companion (Cardiovascular):

Tool	Property	Unit	Display accuracy
Heart	Heart volume	ml	0.1 ml
	Coronary Calcium	mm^3	0.1 mm^3
Aorta	American Heart Association (AHA) Max. 2D ∅	mm	1 mm

1.13 Data flow of AI-Rad Companion

Cloud-based and AI-Rad Companion edge deployment



The above workflow diagram illustrates the use of hybrid computing in AI-Rad Companion product family. The AI-Rad Companion product family includes the software operating platform AI-Rad Companion Engine and at least one AI-Rad Companion extension. The AI-Rad Companion Engine provides the communication means for independent clinical extensions. Hybrid computing enables data storage and processing in the cloud or within the institution depending on your use cases and preferences. Thus, the institutions can select the preferred option that suits their requirements.

AI-Rad Companion supports cloud-based and on-edge services. In AI-Rad Companion on-edge deployment, patient data processing and storage is handled within the institution whereas logging, auditing, institution management, and key vault is handled in the cloud.

AI-Rad Companion is accessible from the teamplay digital health platform. Data transfer is handled by the teamplay DICOM Hub infrastructure and uses the DICOM standard. The AI results are sent back to a configurable target node via the teamplay digital health platform infrastructure, in accordance to the DICOM standards. For detailed information about teamplay digital health platform, see *teamplay digital health platform Datasheet*.

The typical data flow of AI-Rad Companion can be described as follows:

- After DICOM studies are transferred to the teamplay Receiver from modalities, the images are sent to AI-Rad Companion for post-processing according to configured auto-routing rules.
- The dedicated AI-Rad Companion extensions process the images and generate AI results.
- If provided by AI-Rad Companion (Cardiovascular), the clinical user can preview the generated results in the Results Preview. The clinical user can decide either to confirm or decline the results.
- Accepted results are sent back to the teamplay Receiver that passes this back to the configured DICOM node, for example, PACS. Declined results are deleted.

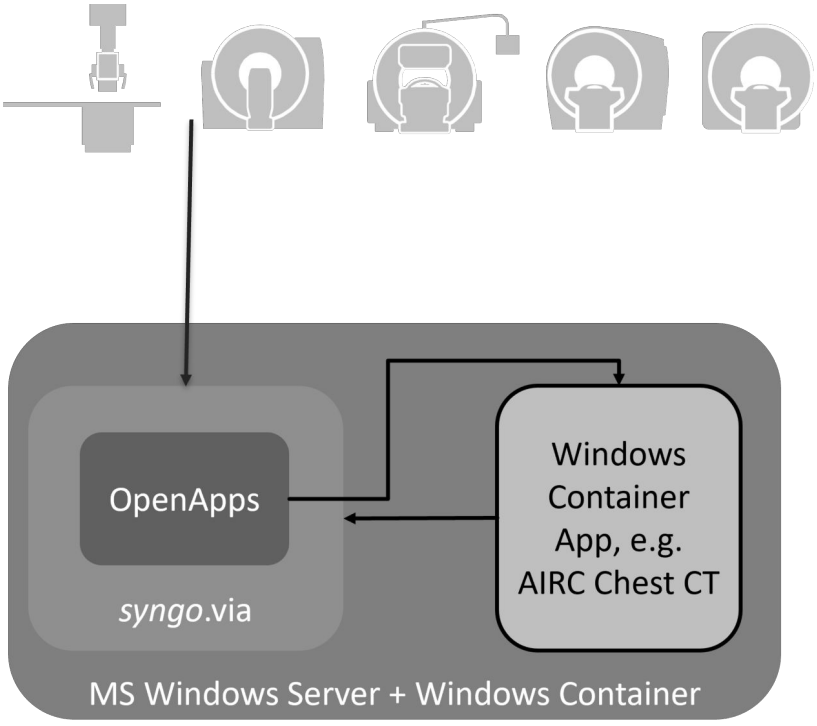
In case of an institution downtime or loss of web connection, this can lead to temporary unavailability of AI-Rad Companion services.

When using AI-Rad Companion in time-critical use scenarios, the customer is solely responsible for thoroughly evaluating and testing the workflow in the intended environment. AI-Rad Companion product does not represent, warrant, or guarantee any availability or specific turn-around times based on an emergency usage profile and does not assume any responsibility in this respect.

For more information on the overall security characteristics of the system, see *AI-Rad Companion Security Whitepaper and MDS2*.

For more information on data privacy aspects, see *AI-Rad Companion Data Privacy and Security Whitepaper*.

On-premise deployment



syngo.via OpenApps is a software framework which provides access to the central SHS Digital Marketplace which offers additional applications in an online store, the "SHS Digital Marketplace" . Applications can be provided by SHS or 3rd party vendors.

syngo.via serves as the integration and hosting platform for the applications that are downloaded from the SHS Digital Marketplace. AI-Rad Companion (Cardiovascular) is integrated and hosted on *syngo*.via OpenApps.

AI-Rad Companion (Cardiovascular) are scanned for potential security vulnerabilities prior to its availability in market place. The applications are running on the *syngo*.via server. User interfaces get streamed and integrated inside the *syngo*.via client through remote desktop techniques.

Most of the applications do not need permissions to communicate over the network and have only limited permissions on the *syngo*.via server machine. User Interface allows to grant network access by administrator if required. Updates of the applications are provided through the Digital Marketplace, which require an outbound internet connection for the time of download.

Patient data from the imaging device can be configured to be automatically forwarded to *syngo*.via server. With the required routing configuration on *syngo*.via server, patient data gets routed and processed by AI-Rad Companion (Cardiovascular) deployed and available on *syngo*.via OpenApps.

Results generated by AI-Rad Companion (Cardiovascular) are pushed back automatically and made available for review on the *syngo*.via Reading workstation.

1.14 Multi-vendor support

AI-Rad Companion (Cardiovascular) has been validated for non-cardiac chest CT data with filtered backprojection reconstruction from Siemens Healthineers, GE Healthcare, Philips, and Toshiba/Canon. Additionally, the calcium detection feature has been validated on non-cardiac chest CT data with iterative reconstruction from Siemens Healthineers.

1.15 Image requirements for data loading

AI-Rad Companion (Cardiovascular) analyzes and processes DICOM images provided by your computed tomography system.

For scan, reconstruction, and image format, the following criteria must be fulfilled.

- Scan
  - Only data from computed tomography systems is accepted.
  - The patient is at least 22 years old.
  - Gantry tilt is not allowed.

DICOM Tag	Value
Modality (0008, 0060)	CT
PatientAge (0010, 1010)	>= 022Y
GantryDetectorTilt (0018, 1120)	0

- Reconstruction
  - Modality: CT
  - Bits allocated: 16
  - Images must be reconstructed in axial orientation.
  - Maximum slice thickness is 3 mm.
  - A series must contain at least 3 images, gaps are not allowed.
  - Series Description does not contain Patient Protocol.
  - Image size must be 512x512 pixels.
  - FOV of chest- Pixel spacing >0.52 OR Body part examined does not contain 'Brain', 'Head', 'Skull'. However, Body part examined is given preference over FoV. If Body part examined rule fails, FoV will be checked. If Body part examined rule passes, FoV will not be checked and the case will be routed.

DICOM Tag	Value
ImageType (0008, 0008)	ORIGINAL\PRIMARY\AXIAL
SliceThickness (0018, 0050)	<= 3
InstanceNumber (0020, 0013)	Continuous without gaps
Rows (0028, 0010), Columns (0028, 0011)	512 x 512

- Image format
  - Image orientation of the patient must be 1\0\0\0\1\0.
  - Image type must be ORIGINAL, PRIMARY, AXIAL.
  - Image type does not contain PROT and LOCALIZER.
  - SOP Class UID ≠ 1.2.840.10008.5.1.4.1.1.88.67 (Dose SR)
  - SOP Instance UID Not Empty
  - Photometric interpretation must be MONOCHROME2.
  - Each voxel of the images must be stored in 16 bit (1 sample per pixel).
  - Maximum Rescale slope is 5.
  - kVp must be greater than or equal to 100

DICOM Tag	Value
ImageOrientationPatient (0020, 0037)	1\0\0\0\1\0
ImageType (0008, 0008)	ORIGINAL
PhotometricInterpretation (0028, 0004)	MONOCHROME2
BitsAllocated (0028, 0100)	16
RescaleSlope (0028, 1053)	5

If any of the criteria is not fulfilled by the imported data set, the images will not be processed and an error message is displayed.

1.16 Operating environment of AI-Rad Companion (Cardiovascular)

AI-Rad Companion (Cardiovascular) is expected to be operated in a healthcare environment (for example, hospital and radiology center). AI-Rad Companion (Cardiovascular) is exclusively designed as a part of the Siemens Healthineers digital environment with restricted access to authorized personnel only.

AI-Rad Companion (Cardiovascular) supports cloud-based, on-edge, and on-premise deployment services. For cloud and on-edge deployment, the user interface can only be accessed with a web browser and optionally, from the AI-Rad Companion Notifier component.

Cloud-based deployment

For cloud-based deployment, the system hosting the teamplay Receiver requires access to the hospital intranet and with at least 100Mbit/s bandwidth to the Internet.

AI-Rad Companion edge deployment

For AI-Rad Companion on-edge deployment, the data processing is performed within the institution whereas login, institution management, logging, and auditing are performed in the cloud. It is the institution's responsibility to secure the physical access to the AI-Rad Companion on-edge deployment components.

This documentation provides a list of minimum of hardware requirements but it is the institution's responsibility to own the hardware. AI-Rad Companion (Cardiovascular) supports small-grade server configuration. The minimal server configuration must meet the small-grade server configuration for running AI-Rad Companion (Cardiovascular). For more information on minimum hardware requirements, see (➔ Page 39 *Minimum hardware requirements*).

AI-Rad Companion (Cardiovascular) can also be used on medium-grade and large-grade server configuration. For more information on hardware recommendations depending on the institution size and requirements, see *Hardware recommendations for AI-Rad Companion edge deployment* in the AI-Rad Companion Engine Instructions for Use.

- AI-Rad Companion (Cardiovascular) was tested on Microsoft Windows 10.
- AI-Rad Companion (Cardiovascular) is not validated on any other operating system, for example, macOS.
- AI-Rad Companion (Cardiovascular) is not validated for use with touch screen or mobile devices.

On-premise deployment

AI-Rad Companion (Cardiovascular) is available on OpenApps and can be hosted on your *syngo*.via system. For on-premise deployment, patient data processing, storage, logging, auditing, institution management and key vault remains in the institution premises.

AI-Rad Companion Notifier

AI-Rad Companion Notifier indicates whether AI-Rad Companion (Cardiovascular) has completed the processing, processing is in progress, or processing has failed. The following are the different types of result notifications that are visually supported with respective icons.

- Results available
- In progress
- Failure

AI-Rad Companion Notifier requires a 64-bit Windows Operating System (Windows 10 recommended). It is recommended to use Google Chrome as a preferred web browser for use with AI-Rad Companion (Cardiovascular).

For more information on result notifications, see (➔ Page 80 *Using the Results Notifications*).

AI-Rad Companion Notifier is available only for cloud-based and AI-Rad Companion edge deployment.

1.16.1 Supported Internet browsers

AI-Rad Companion (Cardiovascular) was tested with Google Chrome and Microsoft Edge. Although other browsers with Java Script enabled may be compatible, Siemens Healthineers strongly recommends using AI-Rad Companion with Google Chrome.

AI-Rad Companion (Cardiovascular) does not support Internet Explorer.

To ensure performance and security of AI-Rad Companion (Cardiovascular), regularly update your browser to the latest version.

1.17 Interfaces, options, and accessories

For the data to be processed by AI-Rad Companion (Cardiovascular), the input data must be sent to the correct DICOM node. Typically, AI-Rad Companion (Cardiovascular) receives the imaging data to be processed in different ways.

- Imaging modality
- Autorouting from the PACS system
- Autorouting from a DICOM gateway

Data transfer is handled by the teamplay Images infrastructure and uses the DICOM standard. The results are sent back to a configurable target node via the teamplay digital health platform infrastructure in accordance with the DICOM standards.

1.17.1 Interface requirements

For AI-Rad Companion (Cardiovascular), the same interface requirements apply as for the AI-Rad Companion Engine.

Please go through the information given in the section *Interface requirements* in the AI-Rad Companion Engine Instructions for Use. Additional details are available in the *teamplay digital health platform Installation and Startup - Configuration and Setup guide*.

For information on interface requirements for on-premise deployment, see the *syngo*.via Administrator Manual.

1.18 IT security

AI-Rad Companion supports Azure cloud, on-edge and other on-premise deployment options. The data centers hosting the data have strong physical security measures in place to shelter data from unauthorized access and from environmental threats. The institution is responsible for the physical protection of the devices used to access AI-Rad Companion.

For AI-Rad Companion on-edge deployment and other on-premise deployments, the hardware requirements specify to use a hardware lock or mechanism for the usage of locks. It is the institution's responsibility to prevent unauthorized physical access to all involved on-premise components, for example, teamplay Receiver.

User management and authentication

AI-Rad Companion user management and user authentication functionalities are handled by teamplay digital health platform. Users of AI-Rad Companion are always managed in the cloud. AI-Rad Companion (cloud or on-edge services) enforce unique user IDs with passwords for each access. If there is an error in Internet connectivity, users will not be able to login and view the application. It is recommended to turn on the multifactor authentication to teamplay digital health platform, by default, for all users. For AI-Rad Companion, automatic logoff is implemented after defined time of inactivity.

In case of the other on-premise deployments, user management and user authentication functionalities are configured on the specific machine or integrated in to the active directory network of the site. Unique user IDs with passwords for each access are enforced. Automatic logoff is implemented after defined time of inactivity.

Hardening and network controls

Necessary security measures are implemented for AI-Rad Companion deployed on Azure cloud. Azure web application gateway and firewall are enabled for cloud deployment to minimize the network attack surface. When AI-Rad Companion is configured to process data locally (on-edge/other on-premise), it is the institution's responsibility to enable network access control mechanisms. The institution has to ensure secure operation of the system on which it is installed. Hardening measures from institution on-edge/on-premise should include configuration of firewall, disable unwanted services, ports, shares, users, and malware protection using software restriction tools, encryption at rest using hardware modules like TPM (Trusted Platform Module), avoid installation of unnecessary software. AI-Rad Companion is designed to make limited use of network ports and protocols. For communication between institution systems with the AI-Rad Companion cloud services, https ports need to be enabled. AI-Rad Companion has implemented appropriate network controls in the cloud to reduce illicit access.

Firewall configuration

For cloud-based and AI-Rad Companion edge deployment, configure the following connectivity settings to access AI-Rad Companion for computers from which AI-Rad Companion is accessed or on which AI-Rad Companion Notifier is installed.

The following table lists the URLs that should be added to the allow list, if not already present.

URL pattern	Purpose
*.teamplay.siemens-healthineers.com (HTTPS) *.teamplay.siemens-healthineers.cn (HTTPS)[1)]	Access to AI-Rad Companion
*.siemens-healthineers.com	Single Sign-On
cdn.auth0.com (HTTP)	Siemens Healthineers identity provider
cdn.eu.auth0.com (HTTPS)	Siemens Healthineers identity provider
cdn.jp.auth0.com (HTTPS)	Siemens Healthineers identity provider

For more information on firewall settings for teamplay Receiver, see *teamplay digital health platform Installation and Startup – Configuration and Setup guide*.

Software restriction policies

It is the institution's responsibility to restrict additional unapproved software to be run in parallel with AI-Rad Companion deployed on edge/other on-premise machines by establishing appropriate allow or deny lists.

To learn more about the security of your AI-Rad Companion (Cardiovascular) and to obtain the Manufacturer Disclosure Statement for Medical Device Security (MDS2), contact your Siemens Healthineers representative and request for the documents entitled *Security Whitepaper and MDS2* and *Data Privacy and Security Whitepaper*.

1) For China only

- It is the institution's responsibility to maintain the medical IT network including hardware.
- In case of an institution timedown or loss of web connection, this can lead to temporary unavailability of AI-Rad Companion services.

Recommendations for Transport Layer Security configurations

It is the institution's responsibility to configure their client systems and browsers as per applicable state-of-the-art cybersecurity guidance, for example, NSA (National Security Agency, USA) advisory on “Eliminating Obsolete Transport Layer Security (TLS) Protocol Configurations”.

AI-Rad Companion uses HTTPS2.0 TLS1.2 protocol for network transfer.

AI-Rad Companion servers prefer TLS 1.2 cypher suites that are considered state-of-the-art and can block weak or obsolete cypher suites.

For compatibility reasons, AI-Rad Companion also supports selected cipher suites without “perfect forward secrecy”.

Usage of vulnerable TLS protocol configurations leads to elevated risk of exploitation by adversaries and may lead to exposure of sensitive data.

- Check for latest advisories and guidelines on vulnerable or obsolete TLS protocol configurations regularly.
- Manage operating system and browser trust stores to ensure all trusted certificates use recommended algorithms.
- Ensure that your browser has TLS 1.2 cipher suites that utilize strong encryption and authentication on top of the list of preferred TLS 1.2 cipher suites.

1.19 This documentation

This documentation for AI-Rad Companion (Cardiovascular) comprises the following information.

- Intended purpose of AI-Rad Companion (Cardiovascular)
- Workflow of AI-Rad Companion (Cardiovascular)
- Configuration of AI-Rad Companion (Cardiovascular)

The graphics, figures, and medical images used in this documentation are examples only. Their actual display and design may be slightly different on your application. This description addresses the authorized user. Basic knowledge about operating PCs and software is a prerequisite.

Please note that your software includes several documentation modules. Therefore, go through the information provided in other Instructions for Use or the AI-Rad Companion Help.

For cloud-based and AI-Rad Companion edge deployment, user documentation in AI-Rad Companion (Cardiovascular) is provided by an Online Help within the application. The AI-Rad Companion (Cardiovascular) software comes with Instructions for Use, one set for AI-Rad Companion (Cardiovascular) and one set for the AI-Rad Companion Engine. These manuals are available in local languages as online version. Depending on the local applicable law regulations, printed copies may also be available. For more information, see (➔ Page 41 *Accessing the Instructions for Use and the About tab cards*).

For on-premise deployment, user documentation for AI-Rad Companion (Cardiovascular) is provided as a PDF within the application.

1.19.1 Legal notes

The functions described in this document are not commercially available in all countries. Some functions may be protected by a software license that is currently restricted for regulatory reasons. Some functions may be available with an optional software license. Please contact your local Siemens Healthineers representative for further details.

Siemens Healthineers does not warrant that the material contained in its documentation is error-free. The information contained in this document is subject to change. Revisions and updates will be issued from time to time to document changes and additions.

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Comments and suggestions

We hope that this documentation gives you the support you need. This documentation is regularly updated in line with the software development, and your comments will be taken into account to improve the documentation. Please address your comments or suggestions to your local Siemens Healthineers service. We look forward to receiving your feedback.

Open Source Software

This product contains open-source software developed by third parties.

The open-source software used in this product is mentioned in the **Legal & Privacy Notice** tab. The license agreements concerning this software can be accessed by clicking the **Legal & Privacy Notice** icon on the Access bar.

1.20 Update and maintenance

Update of AI-Rad Companion happens automatically.

A notification e-mail is sent to all institutions in advance of the updates to alert users about the impending changes.

For other on-premise deployments, updates are made available through the Siemens Healthineers Digital Marketplace. Along with that, the user is notified about available updates. It is the users' responsibility to trigger the update from the Digital Marketplace on their own.

1.21 AI-Rad Companion (Cardiovascular): Summary of Standalone Performance Assessment

To validate the AI-Rad Companion (Cardiovascular) software from clinical perspective, the following algorithms underwent a scientific evaluation:

- **Segmentation of heart**

  The heart segmentation algorithm computes a segmentation mask of the heart for a given non-cardiac chest CT data set. The output segmentation mask is then used to compute of the heart volume and to define a region of interest for the coronary calcium detection algorithm.

- **Detection of coronary calcium**

  The algorithm detects calcifications in the coronary arteries for a given non-cardiac chest CT data set (without contrast, maximum slice thickness is 3mm). The output is the total volume of the detected coronary calcium.

Metal artefacts may have been detected as coronary calcium. In such cases, the detected coronary calcium volume may be too high.

- **Segmentation of aorta**

  The algorithm computes segmentation masks of the aorta for a given non-cardiac chest CT data set.

- **Detection of aortic landmarks**

  Detection of anatomical landmarks (salient 3D points) is used to find out if and where a particular structure is located within the 3D image data. In particular, the aortic landmarks are used to identify locations for diameter measurements.

- **Aorta diameter measurements**

  Based on a segmented mask of the aorta and a series of detected aortic landmarks, the algorithm computes aortic landmarks according to guidelines of the *American Heart Association* (AHA) provides the corresponding maximum aortic diameters.

  (→ Page 84 *Further reading on AI-Rad Companion (Cardiovascular)*)

- **Threshold- based categorization of diameter measurements**

  The algorithm receives maximum aortic diameters at AHA-locations and applies the thresholds given in the AHA guideline. The results are then labeled accordingly.

For each algorithm of AI-Rad Companion the analysis is structured as follows:

- Algorithm Description: purpose, functionality, technical description
- Data
  - Training class: size and properties of data used for training
  - Description of ground truth / annotations generation
  - Validation class: size and properties of data used for testing/validation
- Performance
  - Choice of performance metric
  - Actual performance results
  - Assessment of clinical relevance of achieved performance
- Related clinical research, e.g. publications (if applicable)

1.22 AI-Rad Companion (Cardiovascular): Performance testing

Segmentation of Heart

Performance of the heart segmentation has been tested on a retrospective cohort of N=274 patients (100 of them randomly drawn from a multi-site US lung cancer screening trial, 174 from an internal database collected from various hospitals inside and outside the US).

The following table displays the performance results for various subgroups.

Category	Subgroup	N	DICE
All		**274**	**0.93 [0.89, 0.97]**
CT Manufacturer	GE	29	0.92 [0.88, 0.96]
	Siemens	18	0.92 [0.88, 0.96]
	Philips	44	0.92 [0.88, 0.96]
	Toshiba	9	0.92 [0.87, 0.97]
Cohort	Lung cancer screening	100	0.92 [0.88, 0.96]
Slice thickness [mm]	≤1.5	186	0.94 [0.90, 0.98]
	(1.5 – 2.5]	62	0.92 [0.88, 0.96]
	(2.5 – 3.2]	26	0.92 [0.88, 0.96]

Performance results of heart segmentation. Mean DICE coefficients with corresponding 95%-confidence intervals are displayed.

Detection of Coronary Calcium

Performance of the calcium detection has been tested on a retrospective cohort of N=381 patients (100 of them randomly drawn from a multi-site US lung cancer screening trial, and 281 consecutive cases from two US-hospitals).

The following table displays the performance results for various subgroups.

Category	Subgroup	N	Logarithmic correlation coefficient
All		**376**	**0.96 [0.95, 0.97]**
CT Manufacturer	GE	29	0.93 [0.85, 0.97]
	Siemens	294	0.96 [0.95, 0.97]
	Philips	44	0.97 [0.95, 0.98]
	Toshiba	9	0.94 [0.73, 0.99]
Cohort	US site 1	90	0.93 [0.90, 0.95]
	US site 2	186	0.96 [0.95, 0.97]
	Lung cancer screening	100	0.96 [0.94, 0.97]
Slice thickness [mm]	(0.5 – 1.5]	111	0.94 [0.91, 0.96]
	(1.5 – 2.5]	60	0.96 [0.93, 0.98]
	(2.5 – 3.2]	205	0.96 [0.95, 0.97]
Patient Age	[22 – 50)	30	0.95 [0.90, 0.98]
	[50 – 60)	120	0.92 [0.89, 0.94]
	[60 – 70)	149	0.97 [0.96, 0.98]
	[70 – 80)	65	0.97[0.95, 0.98]
	≥80	12	0.95 [0.83, 0.99]

Performance results of coronary calcium detection. Logarithmic correlation coefficients with 95% confidence intervals are displayed.

Segmentation of Aorta

Performance of the aorta segmentation has been tested on a retrospective cohort of N=100 patients (randomly drawn from a multi-site US lung cancer screening trial).

The following table displays the performance results for various subgroups.

Category	Subgroup	N	DICE
All		**100**	**0.955 [0.954; 0.957]**
CT Manufacturer	GE	29	0.957 [0.953, 0.960]
	Philips	44	0.955 [0.953, 0.958]
	Siemens	18	0.953 [0.947; 0.959]
	Toshiba	9	0.955 [0.951, 0.959]
Slice thickness [mm]	≤1.5	20	0.955 [0.950, 0.960]
	(1.5 – 2.5]	39	0.955 [0.953, 0.958]
	(2.5 – 3.2]	41	0.955 [0.953, 0.958]
Patient age	[50 - 60)	42	0.954 [0.951, 0.957]
	[60 - 70)	51	0.956 [0.954, 0.958]
	≥70	7	0.957 [0.949, 0.964]

Aorta diameter measurements

Performance of the aorta diameter measurements has been tested on a retrospective cohort of N=193 patients (100 of them randomly drawn from a multi-site US lung cancer screening trial, and 93 consecutive cases from one US-hospital).

The following tables display the performance results for various subgroups.

Category	Sub-group	N	Bias [mm]	MAE [mm]
All		**1480**	**0.49 [0.39, 0.60]**	**1.57 [1.50, 1.64]**
AHA-location	#1	181	0.02 [-0.30, 0.35]	1.74 [1.54, 1.94]
	#2	186	0.77 [0.44, 1.09]	1.77 [1.54, 2.00]
	#3	189	0.88 [0.67, 1.10]	1.37 [1.22, 1.52]
	#4	190	-0.60 [-0.93, -0.28]	1.81 [1.61, 2.02]
	#5	190	0.28 [0.05, 0.51]	1.21 [1.06, 1.36]
	#6	190	0.66 [0.39, 0.94]	1.56 [1.38, 1.75]
	#7	190	0.69 [0.49, 0.89]	1.16 [1.01, 1.30]
	#8	83	1.26 [0.83, 1.70]	1.81 [1.49, 2.14]
	#9	81	1.45 [0.89, 2.01]	2.21 [1.79, 2.62]
Cohort	US site	641	-0.01 [-0.15, 0.13]	1.34 [1.25, 1.43]
	Lung cancer screening	839	0.88 [0.74, 1.02]	1.75 [1.65, 1.84]
Patient Age	[22 - 50]	63	0.88 [0.74, 1.02]	1.46 [1.09, 1.84]
	[50 - 60)	447	-0.65 [-1.15, -0.15]	1.73 [1.60, 1.86]
	[60 - 70)	652	0.55 [0.35, 0.75]	1.57 [1.46, 1.68]
	≥70	318	0.65 [0.50, 0.80]	1.36 [1.23, 1.49]
Patient sex	Female	633	0.66 [0.53, 0.80]	1.52 [1.42, 1.62]
	Male	847	0.66 [0.53, 0.80]	1.61 [1.51, 1.70]
CT Manufacturer	GE	249	0.75 [0.49, 1.01]	1.68 [1.51, 1.86]
	Philips	352	0.90 [0.69, 1.11]	1.67 [1.52, 1.82]

Category	Sub-group	N	Bias [mm]	MAE [mm]
	Siemens	798	0.17 [0.03, 0.30]	1.46 [1.37, 1.55]
	Toshiba	81	1.18 [0.72, 1.64]	1.82 [1.48, 2.16]
slice thickness [mm]	≤1.5	330	0.26 [0.05, 0.48]	1.52 [1.38, 1.65]
	(1.5 - 2.5]	803	0.37 [0.24, 0.51]	1.51 [1.41, 1.60]
	(2.5 - 3.2]	347	0.99 [0.77, 1.21]	1.77 [1.61, 1.93]

Performance results of aorta diameter measurements on the 9 AHA-locations. Note that 3 out of the 193 cases were rejected by the annotators due to poor image quality. MAE = mean absolute error. Displayed are mean values for bias and MAE with corresponding 95%-confidence intervals.

Category	Sub-group	N	Bias [mm]	MAE [mm]
All		**383**	**1.23 [1.06, 1.39]**	**1.64 [1.52, 1.77]**
Location	Max ascending	192	1.05 [0.81, 1.29]	1.63 [1.47, 1.79]
	Max descending	191	1.41 [1.18, 1.63]	1.65 [1.46, 1.84]
Cohort	US site	185	1.09 [0.85, 1.33]	1.52 [1.33, 1.71]
	Lung cancer screening	198	1.36 [1.13, 1.59]	1.75 [1.59, 1.92]
Patient Age	[22 - 50]	18	0.35 [-0.56, 1.26]	1.38 [0.77, 1.98]
	[50 - 60)	113	1.08 [0.77, 1.39]	1.57 [1.35, 1.80]
	[60 - 70)	164	1.28 [1.03, 1.53]	1.70 [1.52, 1.89]
	≥70	88	1.50 [1.17, 1.83]	1.66 [1.37, 1.95]

Category	Sub-group	N	Bias [mm]	MAE [mm]
Patient sex	Female	168	1.00 [0.77, 1.22]	1.43 [1.27, 1.60]
	Male	847	1.41 [1.18, 1.64]	1.80 [1.62, 1.98]
CT Manufacturer	GE	56	1.40 [0.92, 1.88]	1.83 [1.47, 2.19]
	Philips	88	1.39 [1.05, 1.72]	1.76 [1.51, 2.00]
	Siemens	221	1.13 [0.91, 1.35]	1.58 [1.41, 1.75]
	Toshiba	18	1.14 [0.74, 1.54]	1.25 [0.95, 1.55]
slice thickness [mm]	≤1.5	86	1.24 [0.89, 1.60]	1.64 [1.37, 1.92]
	(1.5 - 2.5]	215	1.19 [0.96, 1.41]	1.62 [1.45, 1.79]
	(2.5 - 3.2]	82	1.32 [0.98, 1.66]	1.70 [1.46, 1.95]

Performance results of aorta diameter measurements of maximum ascending/ descending aorta. Note that for 1 out of the 193 cases the algorithm failed. MAE = mean absolute error. Displayed are mean values for bias and MAE with corresponding 95%-confidence intervals.

1.23 Safety information

To ensure the safe use of your product and the safety of people, you must adhere to the safety information provided in the Instructions for use documents. In addition, also observe your country-specific regulations and guidelines.

The residual risk is acceptable according to the defined risk acceptance criteria. User-relevant safety information is provided in this section.

If you become aware of any (potential) malfunction of our device which has resulted or could result in serious health consequences for the user, patient or any other person, please inform Siemens Healthcare GmbH immediately and if legally required, inform the Competent Authority of your country.

1.23.1 Safety information on AI-Rad Companion algorithms

CAUTION

Insufficient image information due to failure in algorithm

Wrong diagnosis

- Complete the interpretation for diagnosis with the original data.

CAUTION

Incorrect input data set used with algorithms leads to incorrect results

Wrong basis for diagnosis.

- Make sure that you use the specified input data.
- Verify algorithm results with the original data set.

1.23.2 Safety information on derived images

CAUTION

Incorrect orientation information in derived images

Wrong diagnosis

- Results of the application must not be used for diagnosis. Complete your interpretation for diagnosis with the original data only.

1.23.3 Safety information on input images

CAUTION

The measurement results are inaccurate due to imprecisions of the input images.

Incorrect data basis for diagnosis or treatment decision

- Quantitative values obtained cannot be used as the only basis for diagnosis.
- Observe the notes regarding measurement accuracy limitations in the Instructions for Use.
- In case of doubt, values must be checked in the original image.

1.23.4 Safety information on DICOM tag configuration

CAUTION

Incorrect routing of DICOM images due to improper DICOM tag configuration leads to incorrect results.

Incorrect data basis for diagnosis or treatment decision

- Check the image requirements for AI-Rad Companion Chest CT.
- Ensure that the specified routing rule is configured based on DICOM tags.
- Always contact your IT administrator before correcting the routing rules.

2 Getting started with AI-Rad Companion (Cardiovascular)

AI-Rad Companion (Cardiovascular) supports cloud-based, on-edge, and on-premise deployment options. This enables the institution to select the option that suits their requirements.

AI-Rad Companion (Cardiovascular) is deployed through the teamplay digital health platform.

For AI-Rad Companion on-edge deployment, data processing is performed within the institution. For information on minimum hardware requirements, see (➔ Page 39 *Minimum hardware requirements*).

For more information on hardware recommendations depending on the institution size and requirements, see *Hardware recommendations for AI-Rad Companion edge deployment* in the AI-Rad Companion Engine Instructions for Use.

✓ Necessary configurations have been made, for example, in the teamplay Receiver settings for data routing. For more information, see *Interface requirements* in the AI-Rad Companion Engine Instructions for Use.

Upon appropriate configuration, the input series are autorouted to AI-Rad Companion for processing and results generation.

Perform the following steps to get started with AI-Rad Companion (Cardiovascular) for cloud and on-edge deployment options.

1 From the teamplay digital health platform main menu, click the **AI-Rad Companion** icon.

   A message is displayed that you are transferred to a website.

   If you are using AI-Rad Companion for the first time, see *Getting started with AI-Rad Companion* in the AI-Rad Companion Engine Instructions for Use.

   For more information on how to get started with AI-Rad Companion on-edge deployment, see *Configuring AI-Rad Companion edge deployment* in the AI-Rad Companion Engine Instructions for Use.

2 If necessary, change your configuration settings.
(➔ Page 45 *Results configuration*)

3 Open the AI results from the **Patient List**.

– or –

If a result notification about successfully processed AI results is displayed, click **Open** to review the AI results of this case.

4 Use the Results Preview to view the result details. (➔ Page 61 *Working with AI-Rad Companion (Cardiovascular)*)

If necessary, upload a series manually. For details about how to upload a study, please refer to the teamplay digital health platform manuals.

In case of problems, contact the IT administrator of your institution.

For information on getting started with AI-Rad Companion (Cardiovascular) on-premise deployment, see *syngo*.via Quick Startup Guide.

2.1 Data minimization

AI-Rad Companion provides various privacy levels to minimize the PHI data uploaded to cloud. For proper mapping of patient data in PACS, certain PHI attributes are not to be minimized. Therefore, restrictive privacy setting shall not be selected.

For an overview about the effects of the privacy options on AI-Rad Companion, refer to *AI-Rad Companion Data Privacy and Security Whitepaper*.

2.2 Minimum hardware requirements

Cloud deployment

For efficient usage of AI-Rad Companion in cloud, the teamplay Receiver should be installed using following specifications.

- At least 8 core system
- At least 16GB memory
- >1TB free disk space

It is recommended to use Internet bandwidth of 100 Mbit/s.

AI-Rad Companion on-edge deployment

The following table lists the minimum hardware requirements. These requirements are for the small-grade server.

Processor Type	CPU: 1 × 8 Cores Intel Xeon - S 4215
Memory	RAM: 96 GB
Disk	Solid State Drive (SSD) with > 2TB; at least 500GB free disk space on Windows system drive
Operating System	Windows Server 2019 (1809)

For more information on medium-grade and large-grade server configurations, see *Hardware recommendations for AI-Rad Companion edge deployment* in the AI-Rad Companion Engine Instructions for Use.

- Optionally, if you want to use, AI-Rad Companion Notifier, see *Interfaces, Options, and Accessories* in the AI-Rad Companion Engine Instructions for Use.
- For AI-Rad Companion Notifier, it is recommended to use Microsoft Windows 10.

On-premise deployment

The following table lists the minimum hardware requirements. These requirements are indicated for a small-grade server.

Processor Type	CPU: 1x Intel® Xeon® Silver
Memory	RAM: 96 GB
Storage	~ 1.8 TB

Network	1x Dual NIC ports (1 GbE)
Operating System	Windows Server 2022

For more information on medium-grade and large-grade server configurations, see *Licensing and Server Grades* in the *syngo*.via Data sheet.

2.3 Monitor Resolution

AI-Rad Companion (Cardiovascular) recommends the monitor resolution to present the graphical user interface optimally for varying screen resolutions.

AI-Rad Companion (Cardiovascular) supports only the landscape monitor orientation.

The following are the monitor resolutions supported by AI-Rad Companion (Cardiovascular).

- 1366*768
- 1600*900
- 1680*1050
- 1920*1080

2.4 Accessing the Instructions for Use and the About tab cards

For cloud-based and AI-Rad Companion edge deployment, user documentation for AI-Rad Companion (Cardiovascular) is provided by an Online Help in the system.

For other on-premise deployments, user documentation for AI-Rad Companion (Cardiovascular) is provided as a PDF in the system. To access the **About** tab, see the *syngo*.via Quick Startup Guide.

To get help, read the product information, and access the Instructions for Use, perform the following steps.

✓ You are logged on to AI-Rad Companion Chest CT.

Perform the following steps to access the Instructions for Use and the **About** tab cards.

1 On the Access bar, click the **Legal & Privacy Notice** icon.

A drop-down menu is displayed.

2 Select **About Software** to access the **About Software** tab.

The **List of Products** menu is displayed.

3 Select **AI-Rad Companion Chest CT** to view the related device information.

On the **About Software** tab, you can view the following information.

- Product labeling information
- Information on how to access the Instructions for Use from the Siemens Healthineers Medical Imaging & Healthcare IT Document Library in the available languages
- Information on how to order hardcopies of the Instructions for Use

4 To access the Instructions for Use, click the **Help** icon on the Access bar.

AI-Rad Companion Help is displayed.

5 Click **AI-Rad Companion Chest CT** to access the Instructions for Use for AI-Rad Companion Chest CT.

6 From the **Language** drop-down list, select the language in which the Instructions for Use are to be displayed.

The language of the **AI-Rad Companion Help** is selected automatically based on the institution language setting. For example, if the institution language is set to English, the **AI-Rad Companion Help** is displayed in English by default. Individual language settings are ignored and not saved.

The latest Instructions for Use is always available in the Siemens Healthineers Document Library and as online help in the application.

2.4.1 Accessing the Instructions for Use in on-premise deployment

Perform the following steps to access the Instructions for Use in on-premise deployment.

✓ Siemens Healthineers Digital Marketplace is displayed.

1 On the **Installed Apps** page, select AI-Rad Companion Chest CT.

2 From the ⋮ menu on the right, select **Getting Started**.

The Instructions for Use is displayed on the **Documents** tab.

3 From the **Language** drop-down list, select the language in which the Instructions for Use are to be displayed.

2.4.2 Ordering a paper copy of the Instructions for Use

Instructions for Use (IFU) are supplied in electronic form. You can request printed documentation for your medical device. One printed copy may be free of charge, depending on your country-specific law. For example, if you are a customer inside the European Union, a paper copy of the IFU will be provided within 7 calendar days of receiving request at no additional cost.

To order a paper copy of the Instructions for Use, perform the following steps.

1 Go to **https://teamplay.siemens-healthineers.com/#/help**.

2 Select the **Contact** tab.

3 In the **Subject** field, enter **`Request for AI-Rad Companion IFU`**.

4 In the **Your Message** field, enter the following information in the text area provided.

- Your last name followed by your first name
- Delivery address, including town, postal code, and country of delivery
- Telephone number, including country dialing code
- E-mail address in which you could be contacted
- Device name for which you want to receive the paper copy
- Application version of the device for which you want to receive the paper copy
- Language in which you want to receive the paper copy
- Optional: Any other additional comments

5 Click **Send** to submit your request.

In case of questions, you will be contacted by e-mail or phone.

3 Results configuration

The **Settings** page provides information on how to activate and deactivate AI-Rad Companion (Cardiovascular) for cloud-based and AI-Rad Companion edge deployment.

The **Settings** page might differ in the appearance for on-premise deployment. For information on how to use AI-Rad Companion (Cardiovascular) for on-premise deployment, see the *syngo*.via OpensApps Welcome document.

You can activate or deactivate the calculation of results and optionally adapt the Result Settings. When the calculation has been activated, you can determine if all results are directly sent to the PACS or if they require a review in the Result Preview.

The configuration is valid as per institution. Every user of your institution can see and modify the configuration. Saved changes are only effective for data that is processed after this configuration change. In general, data is always processed using the configuration that was valid at the start of processing.

(➔ Page 45 *Screen layout of the Settings menu*)

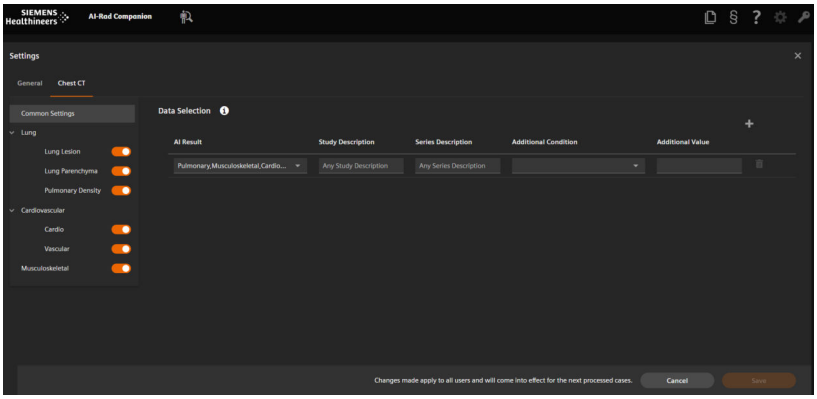
(➔ Page 48 *Configuring Cardio results*)

(➔ Page 53 *Configuring Vascular results*)

For general system settings and settings to adapt the **Patient List** views, see the AI-Rad Companion Engine Instructions for Use.

3.1 Screen layout of the Settings menu

The settings menu is used to activate the calculations and to determine all results that are sent to PACS or to the Result Preview.



3.2 Configuring Common Settings

You can configure the institution specific rules for incoming data so that AI-Rad Companion (Cardiovascular) processes only appropriate data.

Perform the following steps to configure the input data rules.

1 On the Patient List tab, click the **Settings** icon.

   The **Settings** menu is displayed.

2 Click the **Chest CT** tab.

   The **Common Settings** tab is displayed.

3 Click the **AI Result** drop-down list and select **Cardiovascular**.

4 Optional: Enter a value in the **Study Description** field.

5 Optional: Enter a value in the **Series Description** field.

6 Optional: Click the **Additional Conditions** drop-down list and select any of the following values.

- **ContrastMedia**
- **Kernel**
- **ScanProtocolName**
- **ScannerManufacturer**
- **ScannerName**
- **CardiacGated**

For any selected condition, configure the allowed values only.

7 Optional: Click **Add New Rule** to add another rule.

- The parameters within one rule follow the AND logical conjunction.
- If more than one rule is configured, OR logical conjunction is applied.
- You can also select **Pulmonary** or **Musculoskeletal** from the drop-down list.

8 Optional: Click **Delete Rule** to delete a rule.

9 Click **Save**.

Changes are applied only on cases that are uploaded after you save your configuration. (→ Page 59 *Saving your configuration settings*)

3.3 Configuring MPR and VRT image series

Perform the following steps to configure the MPR and VRT image series.

1 On the **Patient List** tab, click the **Settings** icon.

The **Settings** menu is displayed.

2 Click the **Chest CT** and then the **Cardiovascular** tab.

3 To send MPR image series results, select the **MPR** check box.

4 To send VRT image series, select the **VRT** check box.

The VRT series parameters are displayed.

On clearing the **VRT** check box, the **Rendering Quality** and **Number of Rotated Images per 360 Degrees** fields are disabled.

5 Click **Save**.

Changes are applied only on cases that are uploaded after you save your configuration. (→ Page 59 *Saving your configuration settings*)

3.4 Configuring Cardio results

Perform the following steps to configure the **Cardio** results.

1 On the Patient List tab, click the **Settings** icon.

The **Settings** menu is displayed.

2 Click the **Chest CT** tab.

3 Click to activate the **Cardio** option to enable the calculation of results.

Result settings are displayed and can be configured.

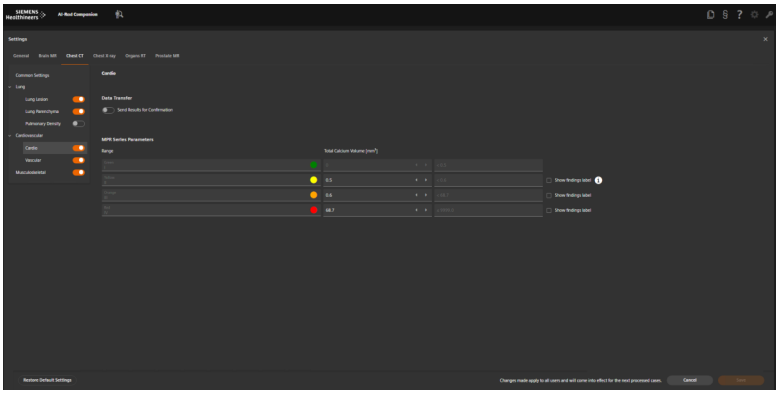
– or –

Click to deactivate the **Cardio** option to exclude the heart and coronaries from the results calculation.

Result settings are hidden.

4 Click the **Cardio** configuration tab.

The **Cardio** section is displayed.



5 Click **Save.**

Changes are applied only on cases that are uploaded after you save your configuration. (➔ Page 59 *Saving your configuration settings*)

3.4.1 Modifying MPR series parameters

Perform the following steps to edit the MPR series parameters.

✓ The **Cardiovascular** toggle button is displayed.

1 In the **Range** section under the **Cardio** tab, click to modify the color labels.

2 In the **Total Calcium Value [mm3]** section, enter the threshold values according to your institutional regulation..

3 Click **Save.**

Changes are applied only on cases that are uploaded after you save your configuration. (➔ Page 59 *Saving your configuration settings*)

3.4.2 Displaying findings label

Perform the steps to display the findings label in the **Patient List**.

This is an optional configuration step.

✓ The **Cardio** configuration tab is active.

1 Select the **Show findings label** check box to display findings labels in the **Worklist** view for cases with findings.

– or –

Select to clear **Show findings label** check box.

No finding labels are displayed in the **Worklist** view.

- By default, the **Show findings label** check box for **Red** ranges is selected.
- By default, the **Show findings label** check box is for **Yellow** and **Orange** ranges are cleared. No findings are displayed in the **Worklist** view.
- If you select **Yellow** range, then **Orange** and **Red** ranges gets selected.
- If you select **Orange**, **Red** range gets selected.

2 Click **Save**.

Changes are applied only on cases that are uploaded after you save your configuration. (➔ Page 59 *Saving your configuration settings*)

3.4.3 Modifying the VRT series parameters

Perform the following steps to modify the VRT series parameters.

✓ The **Cardiovascular** toggle button is active.

1 Under the VRT Image Series section, enter the value in the **Rendering Quality** field. By default, the value is **Excellent**.

2 Click to use the arrows to set the number of images in the **Number of Rotated Images per 360 Degrees** field. The default value is 8.

3 Click **Save**.

Changes are applied only on cases that are uploaded after you save your configuration. (➔ Page 59 *Saving your configuration settings*)

3.4.4 Sending results for confirmation

This functionality is not available for on-premise deployment.

Perform the following steps to confirm or decline the results and send them to PACS.

✓ The **Cardio** configuration tab is displayed.

1 Click to activate the **Send Results for Confirmation** toggle button to review and send all the images to the PACS.

– or –

Click to deactivate the **Send Results for Confirmation** toggle button to send results to the PACS without review. **Heart and Coronary Calcium Analysis** results are not available in the Results Preview.

2 Click **Save.**

Changes are applied only on cases that are uploaded after you save your configuration. (➔ Page 59 *Saving your configuration settings*)

3.4.5 Creating DICOM secondary capture report

Perform the following steps to create DICOM secondary capture (SC) reports for cardio.

✓ The **Cardiovascular** configuration tab is active.

1 Select the **AI Results Report (DICOM SC)** check box to generate DICOM SC reports.

– or –

Select to clear the **AI Results Report (DICOM SC)** check box if you do not want to generate DICOM SC reports.

2 Click **Save**.

Changes are applied only on cases that are uploaded after you save your configuration. (➔ Page 59 *Saving your configuration settings*)

3.4.6 Creating structured report

Perform the following steps to create structured reports for cardio.

✓ The **Cardiovascular** configuration tab is active.

1 Select the **Structured Report (DICOM SR)** check box to save the results in a report.

– or –

Select to clear the **Structured Report (DICOM SR)** check box if you do not want to create structured reports.

2 Click **Save.**

Changes are applied only on cases that are uploaded after you save your configuration. (➔ Page 59 *Saving your configuration settings*)

3.4.7 Restoring default settings

Perform the following steps to restore the settings to default values.

✓ The **Cardio** configuration tab is active.

1 Click **Restore Default Settings.**

You are notified by a pop-up message asking whether you want to restore your configuration to default or cancel.

2 Click **Restore** to reset the values to default.

– or –

Click **Cancel** to retain the values that you have entered.

3 Click **Save**.

Changes are applied only on cases that are uploaded after you save your configuration. (→ Page 59 *Saving your configuration settings*)

3.5 Configuring Vascular results

Perform the following steps to configure the vascular results.

1 On the **Patient List** tab, click the **Settings** icon.

The **Settings** page is displayed.

2 Click the **Chest CT** tab.

3 Click to activate the **Vascular** toggle button to enable the calculation of results.

Result settings are displayed and can be configured.

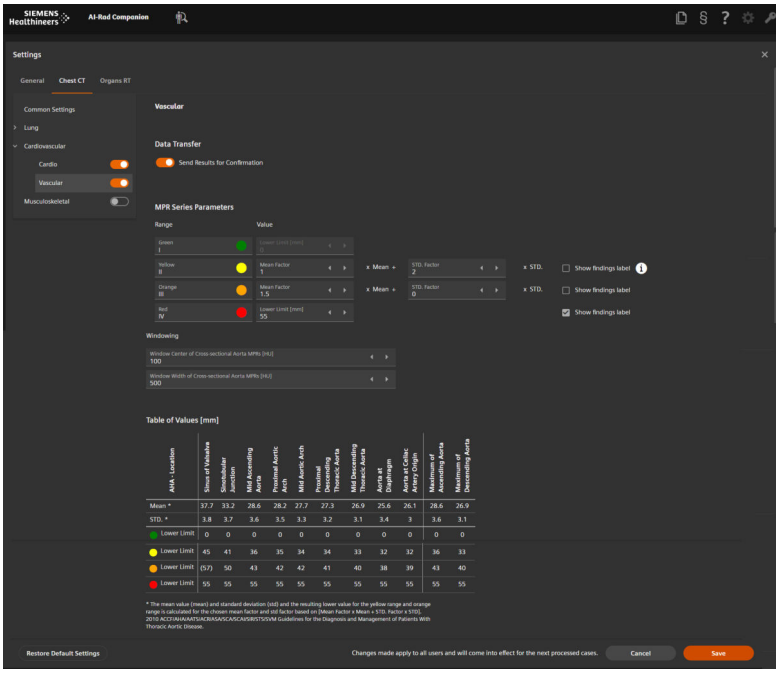
– or –

Click to deactivate the **Vascular** toggle button to exclude the aorta from the results calculation.

Result settings are hidden.

4 Click the **Vascular** configuration tab.

The **Vascular** section is displayed.



5 Click **Save**.

Changes are applied only on cases that are uploaded after you save your configuration. (➔ Page 59 *Saving your configuration settings*)

The following sections enable you to configure the Vascular results.

3.5.1 Modifying MPR series parameters

Perform the following steps to edit the MPR series parameters.

✓ The **Cardiovascular** configuration tab is active.

1 In the **Range** section under the **Vascular** tab, click to modify the color labels.

2 In the **Value** section, the threshold values are fixed.

The lower limit (LL) is fixed for the **Green** (0 mm).

The lower limits of the **Yellow** and the **Orange** are calculated depending on the **Mean Factor** and the **STD. Factor** (standard deviation factor). The mean value (**Mean**) and the standard deviation (**STD.**) are taken individually for each landmark from the reference **2010 ACCF/AHA/AATS/ACR/ASA/SCA/SCAI/SIR/STS/SVM Guidelines for the Diagnosis and Management of Patients With Thoracic Aortic Disease**.

For calculation, this formula is used:

LL = Mean Factor × Mean + STD. Factor × STD.

The LL of **Red** is non-editable. The default value is 55 mm.

3 Click **Save**.

Changes are applied only on cases that are uploaded after you save your configuration. (→ Page 59 *Saving your configuration settings*)

3.5.2 Displaying findings label

Perform the steps to display the findings label in the **Patient List**.

This is an optional configuration step.

✓ The **Vascular** configuration tab is active.

1 Select the **Show findings label** check box to display findings labels in the **Worklist** view for cases with findings.

– or –

Select to clear **Show findings label** check box.

No finding labels are displayed in the **Worklist** view.

- By default, the **Show findings label** check box for **Red** ranges is selected.
- By default, the **Show findings label** check boxes for **Yellow** and **Orange** ranges are cleared and disabled. No findings are displayed in the **Worklist** view.
- If you select **Yellow** range, then **Orange** and **Red** ranges gets selected.
- If you select **Orange**, **Red** range gets selected.

2 Click **Save**.

Changes are applied only on cases that are uploaded after you save your configuration. (→ Page 59 *Saving your configuration settings*)

3.5.3 Modifying windowing parameters

Perform the following steps to modify the windowing parameters.

✓ The **Vascular** configuration tab is active.

1 In the **Windowing** section, click to use the arrows to set the values for **Window Center of Cross-sectional Aorta MPRs [HU]** (default value: 100) and **Window Width of Cross-sectional Aorta MPRs [HU]** (default value: 500).

2 Click **Save**.

Changes are applied only on cases that are uploaded after you save your configuration. (→ Page 59 *Saving your configuration settings*)

3.5.4 Modifying the VRT series parameters

Perform the following steps to modify the VRT series parameters.

✓ The **Cardiovascular** configuration tab is active.

1 Under the VRT Image Series section, enter the value in the **Rendering Quality** field. By default, the value is Excellent.

2 Click to use the arrows to set the number of images in the **Number of Rotated Images per 360 Degrees** field. The default value is 8.

3 Click **Save**.

Changes are applied only on cases that are uploaded after you save your configuration. (➔ Page 59 *Saving your configuration settings*)

3.5.5 Sending results for confirmation

This functionality is not available for on-premise deployment.

Perform the following steps to confirm or decline the results and send them to PACS.

✓ The **Vascular** configuration tab is displayed.

1 Click to activate the **Send Results for Confirmation** toggle button to review and send all the images to the PACS.

– or –

Click to deactivate the **Send Results for Confirmation** toggle button to send results to the PACS without review. **Aorta Analysis** results are not available in the Results Preview.

2 Click **Save**.

Changes are applied only on cases that are uploaded after you save your configuration. (➔ Page 59 *Saving your configuration settings*)

3.5.6 Creating DICOM secondary capture report

Perform the following steps to create DICOM secondary capture (SC) reports for cardio.

✓ The **Cardiovascular** configuration tab is active.

1 Select the **AI Results Report (DICOM SC)** check box to generate DICOM SC reports.

– or –

Select to clear the **AI Results Report (DICOM SC)** check box if you do not want to generate DICOM SC reports.

2 Click **Save**.

Changes are applied only on cases that are uploaded after you save your configuration. (➔ Page 59 *Saving your configuration settings*)

3.5.7 Creating structured reports

Perform the following steps to create the structured reports.

✓ The **Cardiovascular** configuration tab is active.

1 Select the **Structured Report (DICOM SR)** check box to save the results in a report.

– or –

Select to clear the **Structured Report (DICOM SR)** check box if you do not want to create structured reports.

2 Click **Save**.

Changes are applied only on cases that are uploaded after you save your configuration. (➔ Page 59 *Saving your configuration settings*)

3.5.8 Restoring default settings

Perform the following steps to restore the settings to default values.

✓ The **Vascular** configuration tab is displayed.

1 Click **Restore Default Settings.**

You are notified by a pop-up message asking whether you want to restore your configuration to default or cancel.

2 Click **Restore** to reset the values to default.

– or –

Click **Cancel** to retain the values that you have entered.

3 Click **Save**.

Changes are applied only on cases that are uploaded after you save your configuration. (→ Page 59 *Saving your configuration settings*)

3.6 Saving your configuration settings

Perform the following step to save the configuration settings.

- Click **Save** to apply your settings.

  – or –

  Click **Cancel** to close the **Settings** screen without changes.

  The **Settings** screen closes.

Changes are applied to cases that are uploaded after you saved your configuration settings.

3.7 Unsaved changes

In the **Settings** screen, unsaved changes do not get saved automatically. If you have not saved your changes and want to navigate to another **Settings** page, you are notified by a message. This message informs you about your unsaved changes and you can decide either to save or leave the page.

4 AI-Rad Companion (Cardiovascular) workflow

AI-Rad Companion (Cardiovascular) automatically receives input data from existent systems (that is, scanner, PACS using DICOM auto-routing). AI-Rad Companion (Cardiovascular) dynamically applies AI algorithms based on an analysis of the input data and user configuration. AI-Rad Companion (Cardiovascular) processes data into results, and delivers results to the pre-configured output systems without any user interaction. User consumes results and completes clinical decision within existent (3rd party) systems. User can provide feedback at any time using dedicated AI-Rad Companion (Cardiovascular) UI.

The teamplay digital health platform and the AI-Rad Companion Engine serve as the transportation layer for the said inputs and outputs.

5 Working with AI-Rad Companion (Cardiovascular)

- **Suspend** functionality is not available for on-premise deployment.
- Accept or decline findings are not available for on-premise deployment.

After images are received, AI-Rad Companion (Cardiovascular) will process the images and create results. Depending on your configuration, all results of AI-Rad Companion (Cardiovascular), that are available for a case are provided in the Results Preview, where you can review the results. Accepted results are sent to the PACS, declined results are deleted.

✓ You have started the AI-Rad Companion (Cardiovascular) application and the Patient List is open.

Successfully processed data is available on the **Worklist** view.

If configured, a findings label is displayed next to cases with findings.

1 In the **Worklist** view, double-click a case to open it.

The Results Preview opens.

2 Optional: Adjust the image display.

(➔ Page 75 *Adjusting the image display*)

3 Optional: Click the **Suspend** button to pause the review of your case.

In the **Worklist** view, the case is displayed with the **Suspended** label.

– or –

In the **Worklist** view, double-click a **Suspended** case to continue reviewing.

4 Accept or decline findings for the required function. Depending on the function, you can do this for all findings at once or for each finding individually.

(➔ Page 75 *Adjusting the image display*)

5 Send your findings to the PACS.

(➔ Page 78 *Sending confirmed findings to the PACS*)

6 Optional: Open another case and review the findings.

7 Close the browser window to end AI-Rad Companion.

5.1 AI-Rad Companion (Cardiovascular) image processing

This functionality is not available for on-premise deployment.

CAUTION

Insufficient image information due to failure in algorithm!

Wrong diagnosis

- Complete the interpretation for diagnosis with the original data.

CAUTION

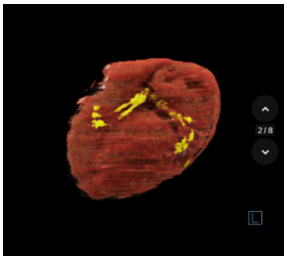
Incorrect input data set used with algorithms leads to incorrect results!

Wrong basis for diagnosis.

- Make sure that you use the specified input data.
- Verify algorithm results with the original data set.

Using the input of thorax images, AI-Rad Companion (Cardiovascular) automatically segments the heart and the aorta.

The following steps are performed:



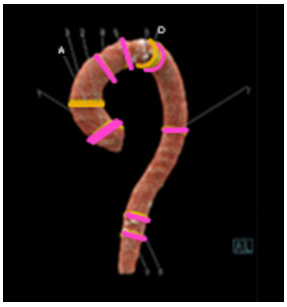
Segmented heart and measurement results

Heart and Coronary Calcium Analysis

- AI-Rad Companion (Cardiovascular) segments the heart by using the AI segmentation algorithm and measures its volume.
- The AI segmentation algorithm automatically detects structures of high Hounsfield values corresponding to calcified coronary plaque units, calculates their volumes, and sums them up.

  You can insert the thresholds in the **Settings**.
- Heart segmentation and calcium detection only works on data sets without contrast medium. This step is not performed on data sets with contrast medium. In this case an error message is displayed.

This color coding is only an indicator. Further classification must be performed by a radiologist.



Segmented aorta with numbered anatomical landmarks and maximum diameter in the ascending and descending arch

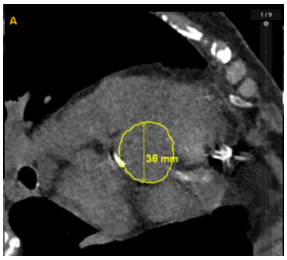
Aorta Analysis

An AI-algorithm detects anatomical landmarks and in combination with the segmentation computes the location of the following nine locations as recommended by the American Heart Association (AHA):

#	AHA-Location
1	Sinuses of Valsalva
2	Sinotubular junction
3	Mid Ascending Aorta
4	Proximal Aortic Arch
5	Mid Aortic Arch
6	Proximal Descending Aorta
7	Mid Descending Aorta
8	Aorta at Diaphragm
9	Aorta at Celiac Artery Origin

- AI-Rad Companion (Cardiovascular) segments the thoracic aorta and calculates its centerline.
- Afterwards, cross-section MPRs are calculated, orthogonal to the centerline at the landmark positions. For each cross-section, the maximum diameter of the aorta at this location is computed.
- In addition to these measurements at predefined location, the software also identifies the location of the maximum ascending and descending aorta, respectively. To this end it computes the maximum cross-sectional area at each point along the centerline within the following ranges:
  - Sinotubular junction (AHA-Loc. #2) to Proximal aortic arch (AHA-Loc. #4) for ascending aorta
  - Proximal descending aorta (AHA-Loc. #6) to Aorta at diaphragm (AHA-Loc. #8) for descending aorta, respectively.

  At the location of maximum area a cross-section MPR is calculated, orthogonal to the centerline and the maximum diameter of the aorta at this location is computed.
- Note that the location of the maximum ascending/descending aorta is identified using the maximum cross-sectional area. This metric is more robust towards singular outlier measurement as compared to searching of the maximum diameter directly. This implies that in case of severe deformation of the aorta presenting itself with a rather elliptical than a circular cross section, the location of max diameter might be off.
- The maximum aortic diameter in the ascending arch is labeled as A and the maximum aortic diameter in the descending arch is labeled as D.
- The results are color-coded depending on the predefined thresholds.



Cross-sectional MPR scan, corresponding to Landmark Maximum of Ascending Aorta

If configured, all results of AI-Rad Companion (Cardiovascular) are provided in the Results Preview, where you can review the results.

(➔ Page 76 *Confirming or declining findings*)

From the Results Preview, you can send the results to the PACS.

(➔ Page 78 *Sending confirmed findings to the PACS*)

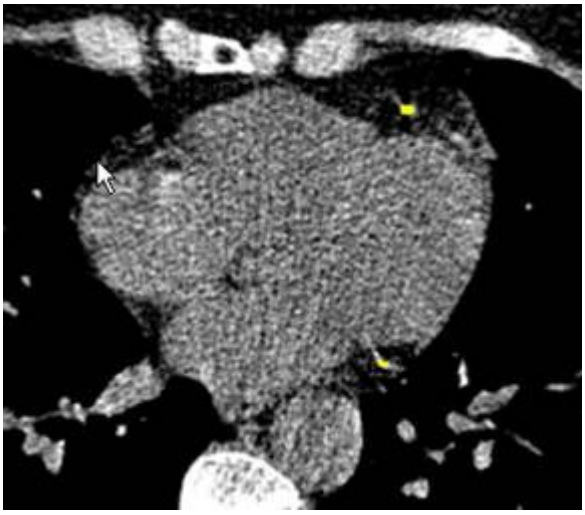
5.2 AI-Rad Companion (Cardiovascular) results

Result series are generated after completing the case, this includes your review decisions in the Results Preview.

AI-Rad Companion (Cardiovascular) creates result series in the following way that are sent to the PACS afterwards:

- First series:

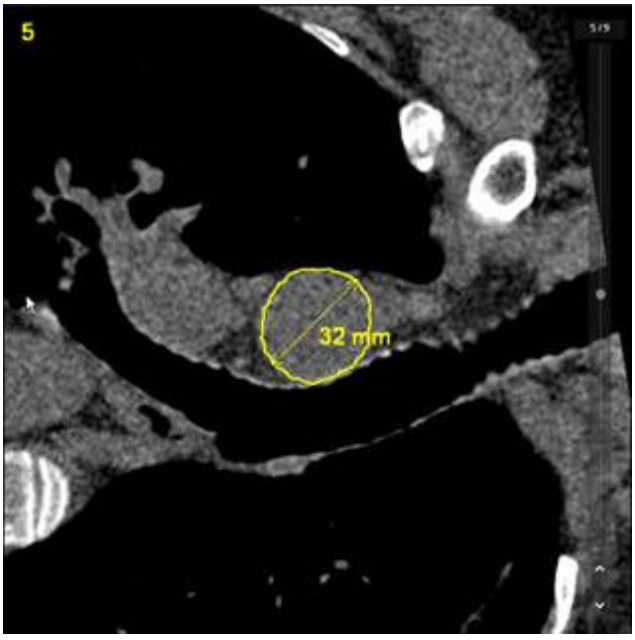
  Is the original (input) series including coronary calcium findings in yellow.



  By reviewing the findings in the Results Preview, either all findings are accepted or declined. Declined findings are removed from the result series.

- Second series:

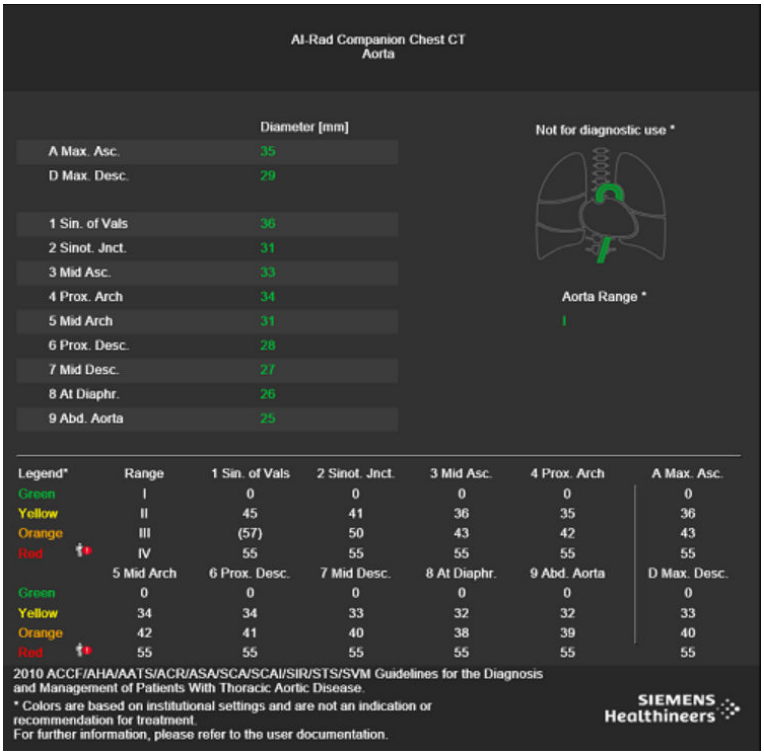
  MPRs orthogonal to the centerline of the aorta at 9 landmarks, defined by the American Heart Association (AHA), including contouring of the aorta, the maximum diameter arrow, and the maximum diameter value.

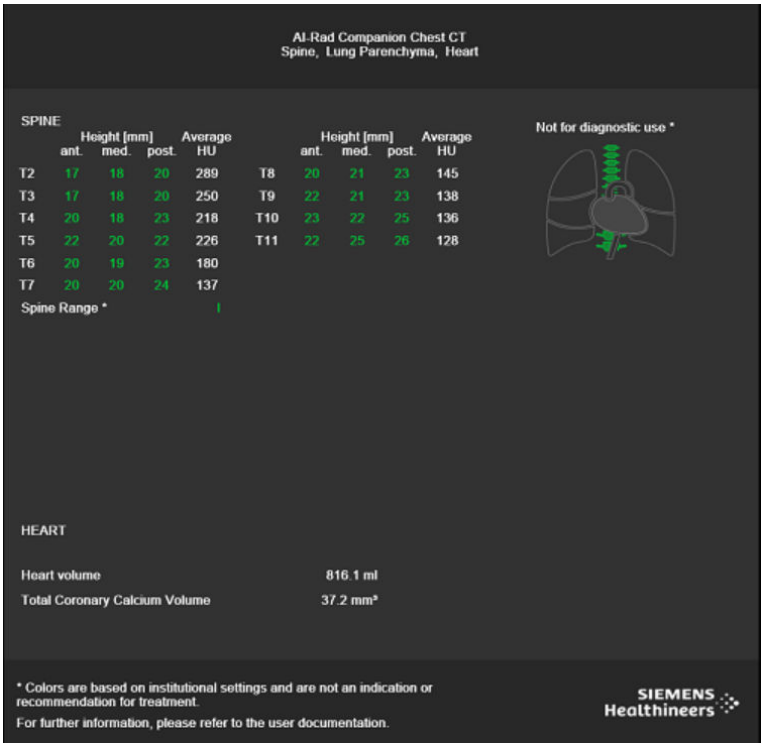


  By reviewing the findings in the Results Preview, findings are accepted or declined. Declined findings are removed from the result series.

  – Third series:

    Contains a secondary capture image with a list of measurement results of the heart and of the aorta, and a sketch summarizing the results of this extension and other extensions as well. It also contains another secondary capture with the aorta category. The list is determined by the findings that are being accepted or that have been declined.


AI-Rad Companion Chest CT
Aorta
Diameter [mm]
A Max. Asc. 35
D Max. Desc. 29
1 Sin. of Vals 36
2 Sinot. Jnct. 31
3 Mid Asc. 33
4 Prox. Arch 34
5 Mid Arch 31
6 Prox. Desc. 28
7 Mid Desc. 27
8 At Diaphr. 26
9 Abd. Aorta 25
Not for diagnostic use *
Aorta Range *
I
Legend* Range 1 Sin. of Vals 2 Sinot. Jnct. 3 Mid Asc. 4 Prox. Arch A Max. Asc.
Green I 0 0 0 0 0
Yellow II 45 41 36 35 36
Orange III (57) 50 43 42 43
Red IV 55 55 55 55 55
5 Mid Arch 6 Prox. Desc. 7 Mid Desc. 8 At Diaphr. 9 Abd. Aorta D Max. Desc.
Green 0 0 0 0 0 0
Yellow 34 34 33 32 32 33
Orange 42 41 40 38 39 40
Red 55 55 55 55 55 55
2010 ACCF/AHA/AATS/ACR/ASA/SCA/SCAI/SIR/STS/SVM Guidelines for the Diagnosis and Management of Patients With Thoracic Aortic Disease.
* Colors are based on institutional settings and are not an indication or recommendation for treatment.
For further information, please refer to the user documentation.
SIEMENS Healthineers



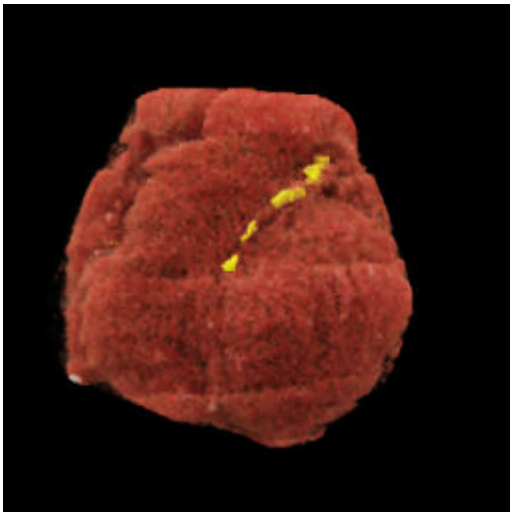
Note that these images contain result information from other extensions as well based on the configuration.

Patient information is saved with the DICOM image header and will be displayed when you open these images in a viewer.


AI-Rad Companion Chest CT
Legend
SPINE *
Name
lower [%]
upper [%]
Green
Yellow
Orange
Red
I
II
III
IV
0
20
25
40
<20
<25
<40
≤100
* Colors are based on institutional settings and are not an indication or recommendation for treatment.
SIEMENS Healthineers

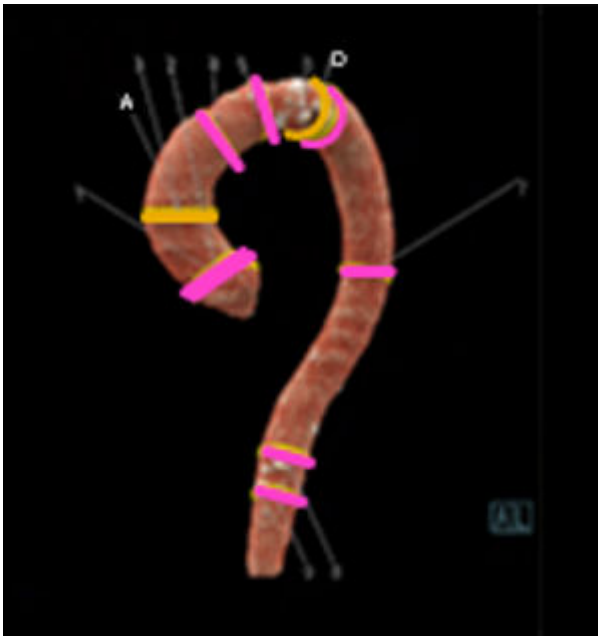
- Fourth series (configuration-based)

  Contains VRTs of the heart as defined in the configuration including color overlays for coronary calcium findings (yellow).



- Fifth series (configuration-based)

  Contains VRTs as defined in the configuration of the aorta overlays for found landmarks.



- Sixth series (configuration-based)

  Contains a DICOM Structured Report with measurement results.

5.3 Screen layout of the Results Preview

The Results Preview is not available for on-premise deployment.

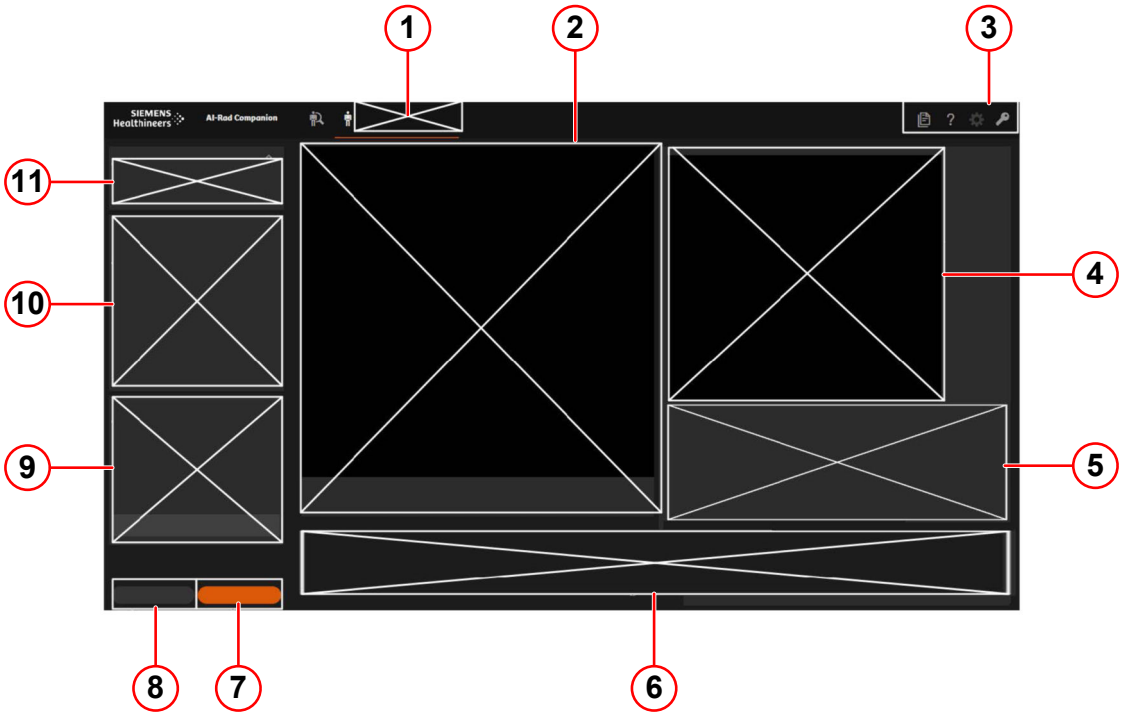
CAUTION

Incorrect orientation information in derived images

Wrong diagnosis

- Results of the application must not be used for diagnosis. Complete your interpretation for diagnosis with the original data only.

The Results Preview of AI-Rad Companion Engine is displayed after you have opened a data set from the **Worklist** view in the Patient List. The Results Preview comprises the following areas:



(1) **Confirmation** tab
The tab displays the following patient information: **Name**, **Date of Birth**, **Sex**, and **ID**.

(2) 2D segment
This section displays 2D images of the currently selected finding. You can use your mouse to zoom or pan the findings.
(➔ Page 75 *Adjusting the image display*)

(3) Access bar
These icons provide access to AI-Rad Companion training material, to the Instructions for Use, configuration settings of all Extensions and to logout.

(4) 3D segment
This section displays 3D images of the currently selected finding. You can use your mouse to zoom or pan the findings.
(➔ Page 75 *Adjusting the image display*)

(5) List of results section
This section displays all findings that AI-Rad Companion has detected for the current data set.

(6) Control section
With these icons, you can either confirm findings before they are sent to the PACS, or decline the findings. Declined findings are deleted.
(7) **Send to PACS** button
(8) **Suspend** button
(9) **Results** navigation section
Every AI-Rad Companion Extension consists of one or more functions. This section displays all functions that are available on your AI-Rad Companion Engine. If you select one function, the corresponding data of the current patient is displayed.
(10) **Findings Overview** section
This section displays a graphical overview of the regions AI-Rad Companion has analyzed. The regions are color-coded corresponding to your individual thresholds, and the positions of findings are highlighted.
(11) **Patient Information** section
This section displays the following patient information: name, date of birth, age, gender, patient ID and accession number.
Examination Information section
This section displays the following examination information: study date and time and series description.

5.4 Adjusting the image display

In the Results Preview, you can adjust the display of findings as you are reviewing. (➔ Page 76 *Confirming or declining findings*)

Perform the following steps to adjust the image display.

✓ In the Results Preview, the required case is open.

✓ Findings are available.

1 In the 2D section, click to activate the **Contour** option to display contours.

– or –

Click to deactivate the **Contour** toggle button to hide contours.

2 From the windowing list, select **Lung**, **Bone**, or **Soft Tissue**, to apply a windowing preset.

– or –

Select **Default 1** or **Default 2** to apply the window width and window center values from the DICOM image header. These values may have been defined in the scan protocol during image acquisition.

– or –

To window manually, click and drag the left mouse up or down to change the brightness, or move the mouse right or left to adjust the contrast.

3 In the 2D or 3D section, right-click and drag the mouse up or down, to zoom the image.

4 In the 2D or 3D section, click and drag the mouse up or down left or right, to pan the image.

5 Use the scroll wheel or the arrows to scroll through the images.

5.5 Confirming or declining findings

The Results Preview is not available for on-premise deployment.

CAUTION

Insufficient image information due to failure in algorithm

Wrong diagnosis

- Complete the interpretation for diagnosis with the original data.

CAUTION

Incorrect input data set used with algorithms leads to incorrect results

Wrong basis for diagnosis.

- Make sure that you use the specified input data.
- Verify algorithm results with the original data set.

CAUTION

Incorrect orientation information in derived images

Wrong diagnosis

- Results of the application must not be used for diagnosis. Complete your interpretation for diagnosis with the original data only.

On the Results Preview, you can confirm or decline findings and send the results to the PACS.

The red and green symbols in the **State** column for **Cardio** in the list of results section visualize which findings are to be sent to PACS or which findings are to be declined.

Perform the following steps to confirm or decline findings.

1 From the **Worklist** view in the Patient List, select the required patient data .

The Results Preview is displayed.

(➔ Page 72 *Screen layout of the Results Preview*)

2 In the **Results** navigation section, click **Cardio**.

All findings of the selected patient are displayed in the list of results section.

3 Optional: Use your mouse to scroll through the images, to zoom or pan the images, or to modify the brightness and contrast of the images.

(➔ Page 75 *Adjusting the image display*)

For **Cardio**, you must either accept or decline all findings for the currently processed function.

All findings are set to **Accepted** by default.

4 To decline all findings for **Cardio**, click the **Decline All** icon in the list of results section.

5 Optional: To re-accept declined findings for **Cardio**, click the **Accept All** icon.

6 All findings are set to **Accepted** by default for **Vascular.**

– or –

To decline all findings, click to clear the **Accepted** check box.

– or –

To decline an individual finding, select the finding in the list of results section and click the **Decline** icon.

– or –

Select to clear the check box for the selected finding.

7 Optional: To re-accept declined findings for **Vascular**, click the **Accept** icon.

– or –

Click to select the check box for the selected finding.

All accepted and declined findings are temporarily saved until all case data is sent to the PACS.

(➔ Page 78 *Sending confirmed findings to the PACS*)

5.6 Sending confirmed findings to the PACS

This functionality is not available for on-premise deployment.

On the Results Preview, you can confirm or decline findings and send the results to the PACS.

Perform the following steps to send the results to PACS.

✓ You have opened a data set from the **Worklist** view in the Patient List. The data set is displayed on the Results Preview.

✓ You have confirmed or declined all findings of an image series of the Patient List. (➔ Page 76 *Confirming or declining findings*)

1 To complete your findings evaluation, click the **Send to PACS** button.

The **Send to PACS** button closes the Results Preview. All accepted results will be sent to the PACS, all declined data will not be sent to PACS.

A confirmation window is displayed.

2 In the confirmation window, click **Send**.

Confirmed results are archived in the PACS.

6 Using the Results Notifications

This functionality is not available for on-premise deployment.

AI-Rad Companion (Cardiovascular) is supplied with the AI-Rad Companion Notifier, which is intended to send result notifications with status-reporting information for a given patient. The AI-Rad Companion Notifier is a pop-up message that is displayed if AI-Rad Companion (Cardiovascular) has some notifications for the given patient.

The appearance and the given status-report information of result notifications may vary depending on the configuration and on the version of Microsoft Windows used.

AI-Rad Companion (Cardiovascular) was tested with Windows 10.

This section contains the following topics.

(➔ Page 80 *Screen layout of the result notifications*)

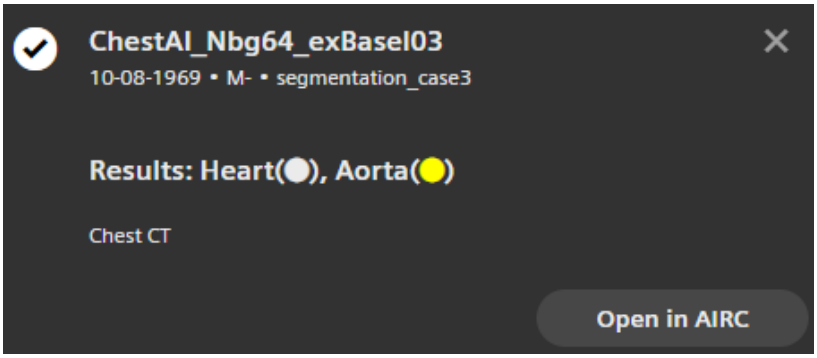
(➔ Page 81 *Types of result notifications*)

For more details about result notifications, see the following topics in the AI-Rad Companion Engine Instructions for Use.

- Handling Result Notifications
- Configuring Result Notifications

6.1 Screen layout of the result notifications

Following is an example of a result notification with status-report information about successful detected findings.



6.2 Types of result notifications

The AI-Rad Companion Notifier indicates whether AI-Rad Companion (Cardiovascular) has completed the processing, or processing is in progress, or processing has failed.

The following are the different types of result notifications that are visually supported with respective icons.

- Results available
- In Progress
- Failure
- Results available

  The icon indicates that the results are available.

  In this state, AI-Rad Companion (Cardiovascular) sends a notification when a case is processed and AI findings are available for confirmation.

- In Progress

  The icon indicates that the results are still in progress.

  In this state, AI-Rad Companion (Cardiovascular) sends a notification when a case is still being processed.

- Failure

  The  icon indicates there is a failure in generating the results.

  In this state, AI-Rad Companion (Cardiovascular) sends a notification when a case could not be processed.

7 Background Information: Turnaround Time for Result Generation

Cloud-based and AI-Rad Companion edge deployment

AI-Rad Companion (Cardiovascular) should not exceed TAT of 4 minutes until results are created.

The following assumptions apply in case of cloud and on-edge deployment.

- Default configuration settings
- Typical CT thorax dataset containing 500 images of 512x512 pixels.
- Connection bandwidth of > 100 Mbit / s.
- System requirements:
  - Cloud deployment: Scaleset SKU Standard_F32s_v2 (8 vcpus, 16 GiB).
  - On-edge deployment: Minimum hardware requirments as defined in the section (➔ Page 39 *Minimum hardware requirements*)

On-premise deployment

AI-Rad Companion (Cardiovascular) should not exceed TAT of 15 minutes on average until all results for a case are available.

The following assumptions apply in case of on-premise deployment.

- Time measurement starts when AI-Rad Companion (Cardiovascular) receives data from within the customer's IT infrastructure.
- Time measurement ends when results are generated and made available in the shared folder for OpenApps.
- Default configuration settings (By default, Pulmonary Density and LLFU are deactivated).
- Typical CT thorax dataset containing 500 images of 512x512 pixels.
- Connection bandwidth for DICOM node transfer inside premises of > 100 Mbit / s.

8 Further reading on AI-Rad Companion (Cardiovascular)

Hiratzka Loren F. et al. Guidelines for the Diagnosis and Management of Patients With Thoracic Aortic Disease. https://www.ahajournals.org/doi/full/10.1161/CIR.0b013e3181d4739e

9 Troubleshooting

If you encounter a problem with AI-Rad Companion (Cardiovascular), contact Siemens Healthineers Customer Care located within your region. You can also report an incident through teamplay Fleet.

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Caution: Federal law restricts this device to sale by or on the order of a physician (21 CFR 801.109(b)(1)).

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