



AI-Rad Companion

Instructions for Use – AI-Rad Companion
(Pulmonary)
VA31

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



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 (Pulmonary)	7
	1.1	Legal notes	7
	1.1.1	Intended purpose	7
	1.1.2	Intended Use	7
	1.1.3	Indications for use	7
	1.1.4	Contraindications	8
	1.1.5	Clinical benefits	8
	1.1.6	Side-effects	8
	1.1.7	Residual risk	9
	1.1.8	Incident reporting	9
	1.1.9	Storage and handling conditions	9
	1.1.10	Intended patient population	9
	1.2	User profiles	9
	1.3	Measurement accuracy	10
	1.3.1	Display accuracy in AI-Rad Companion (Pulmonary)	11
	1.4	Functional overview	11
	1.5	Open Source Software	12
	1.6	Cybersecurity	12
	1.7	Operating environment of AI-Rad Companion (Pulmonary)	14
	1.7.1	Supported Internet browsers	16
	1.8	Image requirements for data loading	16
	2	Safety information	18
	2.1	Safety information on AI-Rad Companion algorithms	19
	2.2	Safety information on derived images	19
	3	Getting started with AI-Rad Companion (Pulmonary)	20
	3.1	Minimum hardware requirements	21
	4	AI-Rad Companion documentation overview	23
	4.1	Accessing the Instructions for Use and the About tab cards	24
	4.2	Ordering a paper copy of the Instructions for Use	25
	4.3	User training	26
	5	Using the Results Notifications	28
	5.1	Screen layout of the result notifications	28
	5.2	Types of result notifications	29

6	Working with AI-Rad Companion (Pulmonary)	31
6.1	AI-Rad Companion (Pulmonary) image processing	32
6.2	AI-Rad Companion (Pulmonary) results	36
6.2.1	Lung lesions and lung parenchyma	37
6.2.2	Pulmonary Density	45
6.3	Screen layout of the Results Preview	49
6.4	Adjusting the image display	51
6.5	Unlinking and relinking lesions	52
6.6	Confirming or declining findings	54
6.7	Sending confirmed findings to the PACS	56
6.8	Update and maintenance	56
7	Results configuration	57
7.1	Screen layout of the Settings menu	57
7.2	Configuring input data selection	59
7.3	Configuring Lung Lesion results	60
7.3.1	Detecting Lung Lesions	61
7.3.2	Enabling Lung Lesions Follow-Up	61
7.3.3	Configuring retention period in long-term storage	62
7.3.4	Configuring MPR series generation of prior lesions	63
7.3.5	Configuring MPR series generation for sub-solid lesions	64
7.3.6	Generating MPR with overlay or burned-in graphics	65
7.3.7	Generating lesion findings	65
7.3.8	Displaying findings label	66
7.3.9	Modifying windowing parameters	67
7.3.10	Modifying the VRT series parameters	67
7.3.11	Sending results for confirmation	68
7.3.12	Creating structured report	69
7.3.13	Restoring default settings	69
7.4	Configuring Lung Parenchyma results	70
7.4.1	Activating Lung Parenchyma Analysis	70
7.4.2	Generating MPR series for Lung Parenchyma	71
7.4.3	Modifying range parameters	72
7.4.4	Displaying findings label	72
7.4.5	Modifying the VRT series parameters	73
7.4.6	Sending results for confirmation	74
7.4.7	Creating structured report	74
7.4.8	Restoring default settings	75
7.5	Configuring Pulmonary Density results	75
7.5.1	Assessing Pulmonary Densities results	76
7.5.2	Displaying high opacity segmentation contours	76

7.5.3	Modifying windowing parameters	77
7.5.4	Modifying the VRT series parameters	77
7.5.5	Sending results for confirmation	78
7.5.6	Creating structured reports	79
7.5.7	Restoring default settings	79

1 AI-Rad Companion (Pulmonary)

1.1 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.

1.1.1 Intended purpose

Intended Purpose Statement under the European Medical Device Regulation 2017/745:

Software solutions intended to process, communicate, display, read, and archive medical data for informing and driving clinical management.

1.1.2 Intended Use

AI-Rad Companion (Pulmonary) is intended to assist the physician in evaluating the lung.

1.1.3 Indications for use

AI-Rad Companion (Pulmonary) is an image processing software that provides quantitative and qualitative analysis from previously acquired Computed Tomography DICOM images to support radiologists and physicians from emergency medicine, specialty care, urgent care, and general practice in the evaluation and assessment of disease of the lungs.

It provides the following functionality:

- Segmentation and measurements of complete lung and lung lobes.
- Identification of areas with lower Hounsfield values in comparison to a predefined threshold for complete lung and lung lobes.
 - Dedication of found lung nodules to corresponding lung lobe.
- Detection of lung nodules (Lung CAD).
- Segmentation and measurements of solid lung nodules.
- Correlation of segmented lung nodules of current scan with known priors and quantitative assessment of changes of the correlated data.
- Identification of areas with elevated Hounsfield values, where areas with elevated versus high opacities are distinguished.

The software has been validated for data from Siemens Healthineers (filtered backprojection and iterative reconstruction), GE Healthcare (filtered backprojection reconstruction), and Philips (filtered backprojection reconstruction).

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

1.1.4 Contraindications

There are no known specific situations that contraindicate the use of this device.

1.1.5 Clinical benefits

AI-Rad Companion (Pulmonary) is an image post-processing software that uses original CT DICOM data to support clinicians in the evaluation and assessment of lung diseases and may be used for lung cancer screening.

1.1.6 Side-effects

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

1.1.7 Residual risk

The residual risk is acceptable according to the defined risk acceptance criteria.
(→ Page 18 *Safety information*)

1.1.8 Incident reporting

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.

1.1.9 Storage and handling conditions

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

1.1.10 Intended patient population

Automation support requires images of patients of 22 years and older.

1.2 User profiles

The following profiles may vary in practice depending on (hospital) organization, qualification, and personal responsibilities and can only be considered as a general guide.

The following user roles and profiles have been identified for AI-Rad Companion:

Radiologist

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

Technologist

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 (Pulmonary), typical prior to the radiological interpretation, to support radiologist in their jobs to be done.

1.3 Measurement accuracy

The measurement tools provided by AI-Rad Companion 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

1.3.1 Display accuracy in AI-Rad Companion (Pulmonary)

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

Tool	Property	Unit	Display accuracy
Lung Lesions	Max. 2D Ø	mm	0.1 mm
	Min 2D Ø	mm	0.1 mm
	Mean 2D Ø	mm	0.1 mm
	Volume	mm ³	0.1 mm ³
Parenchyma Analysis	LAV950 volumetric percentage	%	0.1 %
Pulmonary Density	Total Volume	ml	0.01 ml
	Opacity Volume	ml	0.01 ml
	Opacity Percentage	%	0.01 %
	High Opacity Volume	ml	0.01 ml
	High Opacity Percentage	%	0.01 %
	Mean HU Total	HU	0.01 HU
	Mean HU of Opacity	HU	0.01 HU
	Standard Deviation Total	HU	0.01 HU
	Standard Deviation of Opacity	HU	0.01 HU

1.4 Functional overview

The AI-Rad Companion (Pulmonary) extension provides automatic segmentation of the lungs and the lung lobes. In addition, it detects solid lung lesions, measures their size, and evaluates the lung parenchyma.

The AI-Rad Companion (Pulmonary) extension assists in the detection of any changes in the lesion size on the follow-up CT images.

1.5 Open Source Software

The product contains, among other things, Open Source Software developed by third parties. These Open Source Software files are protected by copyright.

The Open Source Software used in the product and the license agreements concerning this software can be accessed on the **About** tab by clicking the **Open Source Licenses** link.

1.6 Cybersecurity

AI-Rad Companion supports Azure cloud and on-edge 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.

It is the institution's responsibility to prevent unauthorized physical access to teamplay Receiver where AI-Rad Companion on-edge deployment components are deployed. For AI-Rad Companion on-edge deployment, the hardware requirements specify to use a hardware lock or mechanism for the usage of locks.

User management and authentication

AI-Rad Companion user management and user authentication functionalities is 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.

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.

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), 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 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

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
*.teampplay.siemens.com (HTTPS)	Access to AI-Rad Companion
*.blob.core.windows.net (HTTPS)	AI-Rad Companion Notifier package hosting
*.siemens-healthineers.com	Single Sign-On
cdn.auth0.com (HTTP)	Siemens Healthineers identity provider
cdn.eu.auth0.com (HTTPS)	Siemens Healthineers identity provider



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

Software restriction policies

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

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



- 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.
-

1.7 Operating environment of AI-Rad Companion (Pulmonary)

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

AI-Rad Companion (Pulmonary) supports cloud-based and on-edge deployment services. 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

As a prerequisite, you must install Docker Engine Enterprise (EE) on Microsoft Windows 2019 Server, version 1809.

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 (Pulmonary) supports small-grade server configuration. The minimal server configuration must meet the small-grade server configuration for running AI-Rad Companion (Pulmonary). For more information on minimum hardware requirements, see (→ Page 21 *Minimum hardware requirements*).

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

AI-Rad Companion Notifier indicates whether AI-Rad Companion (Pulmonary) 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 (Pulmonary).

For more information on result notifications, see (→ Page 28 *Using the Results Notifications*).

1.7.1 Supported Internet browsers

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

AI-Rad Companion does not support Internet Explorer.

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

1.8 Image requirements for data loading

AI-Rad Companion 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.
- Reconstruction
 - 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.
 - Topograms are not accepted.
 - Image size must be 512x512 pixels.

- Image format
 - Image orientation of the patient must be 110\0\0\1\0.
 - Image type must be ORIGINAL, PRIMARY, and AXIAL.
 - 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.
 - The image format must be Uncompressed or Lossless Compressed.



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.

2 Safety information

Follow the safety information in this document.



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.

Safety information is located in the safety section and repeated within context where a hazardous situation may occur. To make sure safety information is understood, always read it in context of the situation.

WARNING and CAUTION are highlighted in the text:

 WARNING	Indicates a hazardous situation which, if not avoided, could result in death or serious injury.
 CAUTION	Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.

WARNING and CAUTION have the same structure. The following example CAUTION instructs you how to read a WARNING or a CAUTION:

 **CAUTION**

This text describes the hazardous situation: Images with lossy compression are used for diagnosis!

This text describes the hazard: Wrong diagnosis.

- ◆ **This text describes how to avoid the hazardous situation:** Always verify your evaluation results with the original DICOM images (first reader duty).
- ◆ Never use lossy ...

2.1 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.

2.2 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.

3 Getting started with AI-Rad Companion (Pulmonary)

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

AI-Rad Companion (Pulmonary) 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 21 *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.



Data minimization has no impact on result generation, if the privacy level **Standard privacy** or **High privacy** is selected during installation. Restrictive privacy setting is not recommended as results from AI-Rad Companion cannot be mapped back to the correct patient in PACS. For an overview about the effects of the privacy options on AI-Rad Companion, refer to *AI-Rad Companion Data Privacy and Security Whitepaper*.

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 (Pulmonary).



- 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 57 *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 31 *Working with AI-Rad Companion (Pulmonary)*)

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.

3.1 Minimum hardware requirements



As a prerequisite, install Docker EE on Microsoft Windows 2019 Server, version 1809.

For 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.

4 AI-Rad Companion documentation overview

On your system, electronic Instructions for Use are provided in local languages. AI-Rad Companion consists of several medical devices. Each medical device is accompanied by its own Instructions for Use. (→ Page 24 *Accessing the Instructions for Use and the About tab cards*)

The Instructions for Use are also available in electronic form on the Internet. <https://doclib.siemens-healthineers.com/home>

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. (→ Page 25 *Ordering a paper copy of the Instructions for Use*)

The documentation for AI-Rad Companion comprises the following manuals:

- **Instructions for Use of AI-Rad Companion Engine** contains a functional overview of AI-Rad Companion, the login procedure, technical prerequisites, a detailed description of the Patient List tab, general configuration settings, and administrative tasks.
- **Instructions for Use of AI-Rad Companion Extensions** contain image requirements for the use of the respective AI-Rad Companion Extension, detailed descriptions of the respective workflow, and a detailed overview of the respective algorithms and their functionality, including result configuration.
- **Release Information documents** contain latest information about your device, including helpful hints and known issues, if applicable.

Legal notes on documentation

Siemens Healthcare GmbH provides this documentation “as is” without the assumption of any liability under any theory of law. Manuals are subject to change. Siemens Healthcare GmbH reserves the right to modify the design and specifications contained herein without prior notice.

All product designations and company names are trademarks or registered trademarks of the corresponding companies.

Comments and suggestions

We hope that this documentation gives you the support you need. The documentation is regularly updated along 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.



AI-Rad Companion supports English, German, French, Spanish, Japanese, Korean, Russian and Chinese user interface languages.

4.1 Accessing the Instructions for Use and the About tab cards

User documentation in AI-Rad Companion (Pulmonary) is provided by an online help in the system. The AI-Rad Companion (Pulmonary) software comes with Instructions for Use.

To get help, read the product information and license agreements, 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 **Help** icon.
A drop-down menu is displayed.
- 2 To access the **About** tab, select **About AI-Rad Companion**.
The **List of Products** menu is displayed.

- 3 Select **AI-Rad Companion Chest CT** to view the related device information.
On the **About** 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
 - Information on how to access the license agreements for related open-source software
- 4 To access the Instructions for Use, select **Instructions for Use**.
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.

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://teampay.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.

4.3 User training

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



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

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

For more information, see (→ Page 24 *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 9 *User profiles*).

5 Using the Results Notifications

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

This section contains the following topics.

(→ Page 28 *Screen layout of the result notifications*)

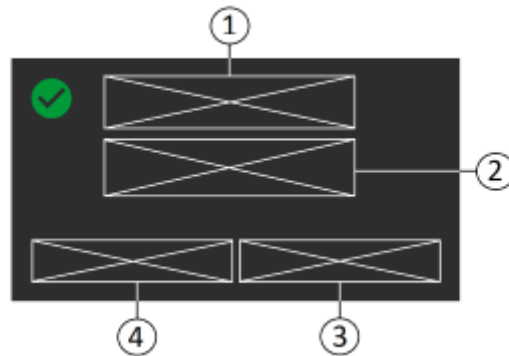
(→ Page 29 *Types of result notifications*)

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

5.1 Screen layout of the result notifications

A result notification consists of the following parts.



Example of a Result Notification with status-report information about successful detected findings

- (1) Patient information
- (2) Status-report information
- (3) **Close** button
- (4) **Open** button

5.2 Types of result notifications

The AI-Rad Companion Notifier indicates whether AI-Rad Companion (Pulmonary) 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 (Pulmonary) 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 (Pulmonary) 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 (Pulmonary) sends a notification when a case could not be processed.

6 Working with AI-Rad Companion (Pulmonary)

After images are received, AI-Rad Companion will process the images and create results. Depending on your configuration, all results of AI-Rad Companion, 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 (Pulmonary) 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 is displayed.
- 2 Optional: Adjust the image display.
(→ Page 51 *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 54 *Confirming or declining findings*)
- 5 Send your findings to the PACS.
(→ Page 56 *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.

6.1 AI-Rad Companion (Pulmonary) image processing



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.

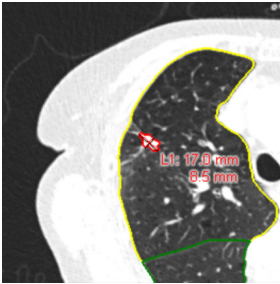
If configured, lung lesion, lung parenchyma and pulmonary density results are provided in the Results Preview where you can review the results.

(→ Page 54 *Confirming or declining findings*)

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

(→ Page 56 *Sending confirmed findings to the PACS*)

Processing images of the thorax with AI-Rad Companion (Pulmonary) comprises the following steps for different types of results:



Segmentation and
measurement results of lung
lesion

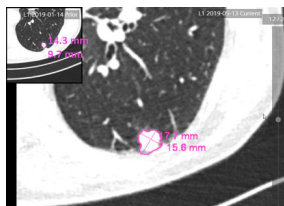
Lung lesions

- The lung lobes are automatically segmented by the Artificial Intelligence (AI) segmentation algorithm.
- The algorithms detect suspicious structures within the anatomy and separates them from their surroundings. For this, AI-Rad Companion (Pulmonary) consumes the *syngo*.CT Lung CAD algorithm. The findings are dedicated to the corresponding lung lobe.

Within the derived contours, the following is determined:

- Maximum diameter in axial direction (**Max. 2D Ø**, long axis)
- Maximum orthogonal diameter in axial direction (short axis)
- Mean value of the long and short axis (**Mean. 2D Ø**)
- Maximum diameter in 3D (**Max. 3D Ø**)
- **Volume** of the finding

For details on the usage of *syngo*.CT Lung CAD, see the Addendum to the AI-Rad Companion (Pulmonary) Instructions for Use.



Measurement results of
current and prior lesions

Lung Lesions Follow-Up

- Lung Lesions Follow-Up evaluation compares studies between two timepoints greater than 10 days and detects the changes in the lesion size on the follow-up CT images.

Within the derived contours, the following is determined:

- Lesion with lobe information, for example, L2 in left lower lobe
- Current and prior lesions
 - If there is no prior study available, no changes in lesion size are displayed.
- Lesion measurements, for example, **Max. 2D**, **Mean. 2D**, **Max. 3D**, and **Volume**.
- Growth or shrinkage percentage details for current lesions to the corresponding prior lesions. For changes in volume, the volume doubling time (VDT) is displayed per lesion in case of volume growth of a lesion between the scan time points. A percentage in volume is displayed in case of shrinkage of measured lesion volume.
- Ranges for lesion changes are indicated by color, for example, green, yellow, and red. Increase in lesion size is prefixed with '+' and decrease in the lesions size is prefixed with '-'.
 - If the lesion is found only in the current study, then all values in the prior study are displayed as '---'. Similarly, if a lesion is found only in the prior study, then all values in the current study are displayed as '---'.
- Any lesion measurement that is available only in the current or in the prior study is displayed in white.
- The **Sum of Max.2D** diameters of all accepted lesions of the current point is displayed.



Measurement results of current and prior sub-solid lesions

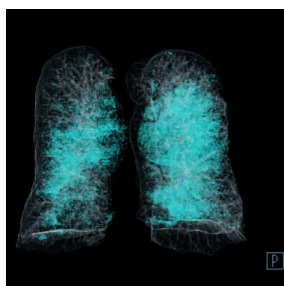
Sub-solid Lesions

- Sub-solid lesions do not contain segmentation contour and measurements. They can only be detected and are considered as a “to be measured” lesion in PACS.
- For a single timepoint sub-solid lesion, lesion measurements, for example, **Max. 2D**, **Mean. 2D**, and **Volume** are displayed as '---'.
- For a multi-timepoint sub-solid lesions, if a sub-solid lesion is detected in current study and solid lesion is found in prior study, **Max. 2D**, **Mean. 2D**, and **Volume** are displayed as '---'. and the solid lesions displays numerical measurements from the prior study. Similarly, if a sub-solid lesion is detected in prior study and solid lesion is found in current study, **Max. 2D**, **Mean. 2D**, and **Volume** are displayed as '---' and the solid lesions displays numerical measurements from the current study.

No growth or shrinkage information are available in these cases as the current and prior lesions are sub-solid respectively.

- If the detected lesions are sub-solid in both prior and current studies, **Max. 2D**, **Mean. 2D**, and **Volume** are displayed as '---' in both current and prior studies. No growth or shrinkage information is available as both lesions are sub-solid lesions.
- The **Sum of Max.2D** diameters is invalid and displayed as '---'.

Lung parenchyma



Percentage of lung voxels below -950HU (color-coded in blue)

- Both lungs and the lung lobes are automatically segmented by the AI segmentation algorithm. The resulting contours are displayed as a graphical overlay.

For both lungs and for each lung lobe, AI-Rad Companion (Pulmonary) counts image voxels below -950 HU and calculates the percentages of these voxels relative to the total number of voxels.

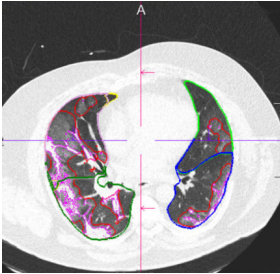
- All segmentation results of AI-Rad Companion (Pulmonary) are assigned to a certain range. Four ranges are defined by default based on the Low Attenuation Value (LAV).

Default ranges are defined. You can adapt the labels and the thresholds in the **Settings**.

(→ Page 70 *Configuring Lung Parenchyma results*)



Color coding of the ranges is only an indicator. Classification must be performed by a radiologist.



Segmentation and measurement results of Pulmonary Density

Pulmonary Density

- Both lungs and the lung lobes are automatically segmented by the AI segmentation algorithm. The resulting contours are displayed as a graphical overlay.
 - An AI algorithm segments opacity regions inside the lung. AI-Rad Companion (Pulmonary) counts image voxels inside opacity regions and calculates the percentages of these voxels relative to the total number of voxels per lobe, lung, and in total.
 - Opacity segmentation results of AI-Rad Companion (Pulmonary) are assigned to a certain range. Five ranges (opacity score from 0 to 4) are defined based on the relative opacity volume with respect to lung lobe volume. For both lungs, opacity scores from each of their lobes are summed. Additionally, for the total score for both lungs, the scores of left and right lung are summed to an opacity score between 0 and 20. For more information, see the publication with DOI: 10.1148/radiol.2020200463. In addition, regions of high opacity (≥ -200 HU) inside opacity regions are optionally highlighted.
- (→ Page 75 *Configuring Pulmonary Density results*)
- Pulmonary density highlights opacity regions in the lung for non-contrast data. An error message is displayed when opacity results are calculated for contrast data.



Color coding of the scores is only an indicator. Classification must be performed by a radiologist.

6.2 AI-Rad Companion (Pulmonary) results

Result series are generated after completing the case.

6.2.1 Lung lesions and lung parenchyma

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

- First series:

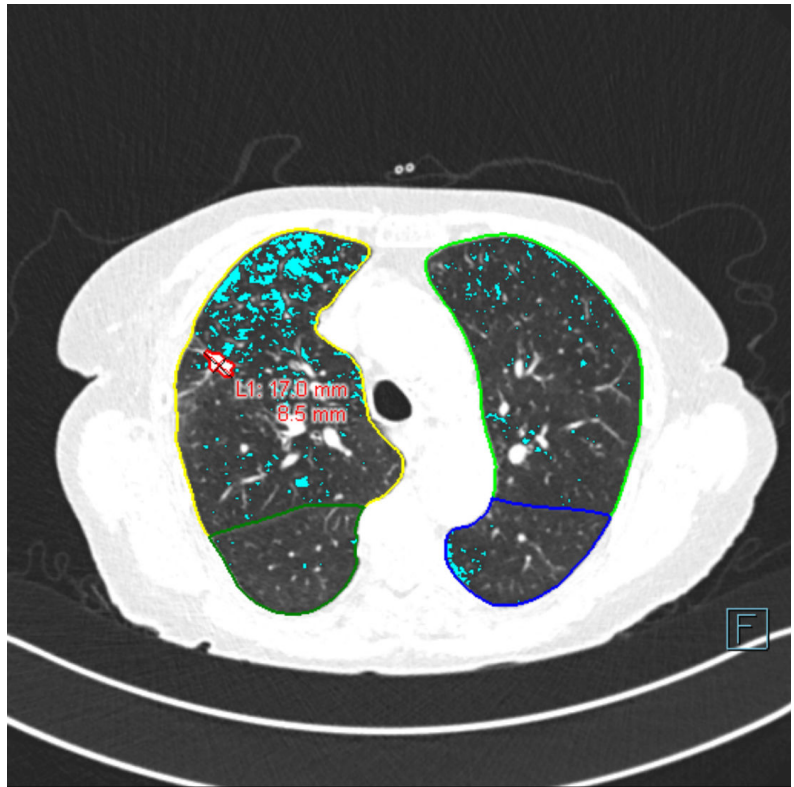
Is the original (input) series including lung lesion findings. These are lesion contours, diameter measurements (the maximum diameter in axial direction (2D, long axis) as well as the maximum orthogonal diameter in axial direction (short axis), and labels of lesions.

By reviewing the findings in the Results Preview, lung lesion findings can be marked to be remeasured in the PACS (for these images, measurements and contours are replaced by a marker). Declined lung lesion findings are removed from the result series.

In addition, lung parenchyma findings are indicating areas of the lung below -950 HU.

For segmented lung lobes, contours are drawn.

The contours of both lungs are implicitly given by the contours of the lobes.



The generated results are displayed as blue color-coded voxels with detected emphysema and lobe contours in the Results Preview.

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

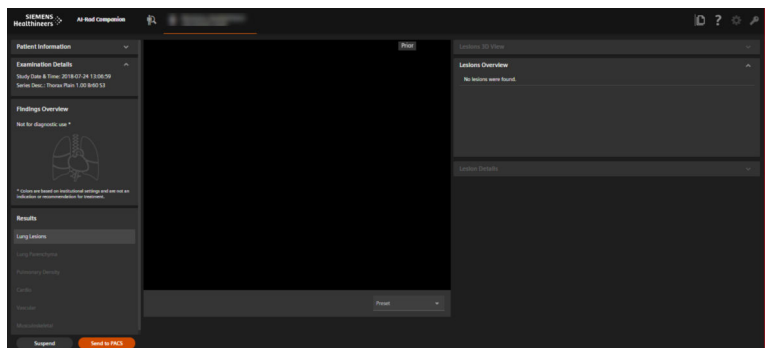
- Second series:

Contains a secondary capture DICOM image with a list of the lung lesion measurement results and the segmentation of lesions. The list is determined by the findings that are being accepted, marked to be remeasured, or that have been declined.

Contains a secondary capture image with a list of measurement results of lesions and of the parenchyma, and a lung pictogram summarizing the results of this extension and other extensions as well. It also contains another secondary capture with the parenchyma parameter applied to the lung pictogram.

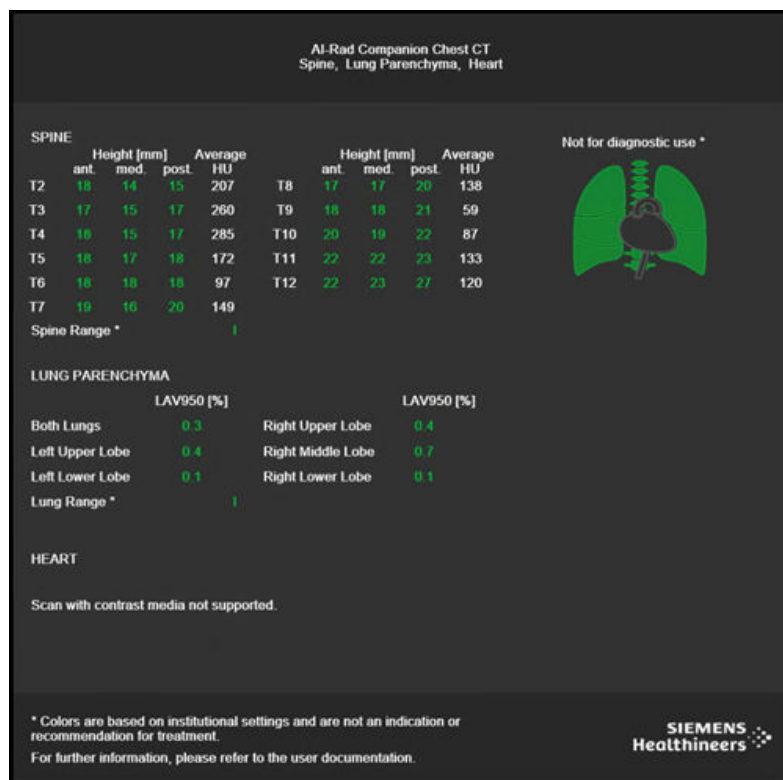
For lung lesion findings:

- For lung lesions marked to be remeasured, all measurement entries are empty.
- Declined findings are removed from the list.
- If all lung lesions findings have been declined or no lesions were detected, **no lesion found** is displayed on the list.
- In a lung lesion follow-up evaluation, if no lesions are available in the current and prior studies, no data is displayed in the **Lesions 3D View**, **Lesion Details**, and **Lesion Overview** sections. The following image provides an example.



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



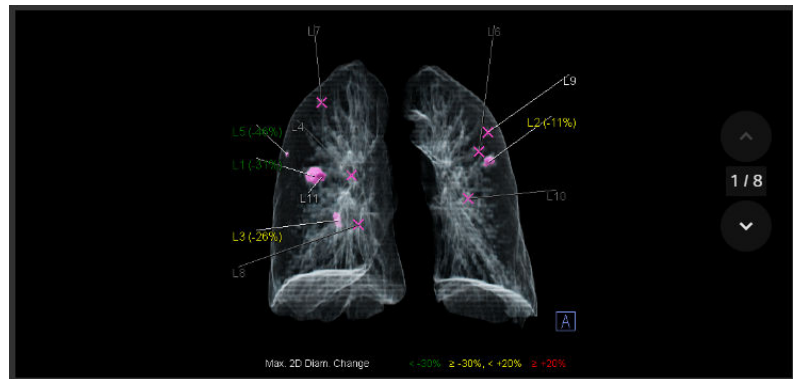


AI-Rad Companion Chest CT Legend				
PULMONARY DENSITY *				HEART *
	Opacity Score	lower [%]	upper [%]	Name lower [mm ³] upper [mm ³]
Green	0	0	<1	Green I 0 <10
Light Yellow	1	1	<25	Yellow II 10 <100
Yellow	2	25	<50	Orange III 100 <500
Orange	3	50	<75	Red IV 500 <999
Red	4	75	<100	
LUNG *				SPINE *
	Name	lower LAV950 [%]	upper LAV950 [%]	Name lower [%] upper [%]
Green	I	0.0	<12.5	Green I 0 <20
Yellow	II	12.5	<25.0	Yellow II 20 <25
Orange	III	25.0	<37.5	Orange III 25 <40
Red	IV	37.5	<100	Red IV 40 <100
* Colors are based on institutional settings and are not an indication or recommendation for treatment.				
				SIEMENS Healthineers

- Optional: Third series

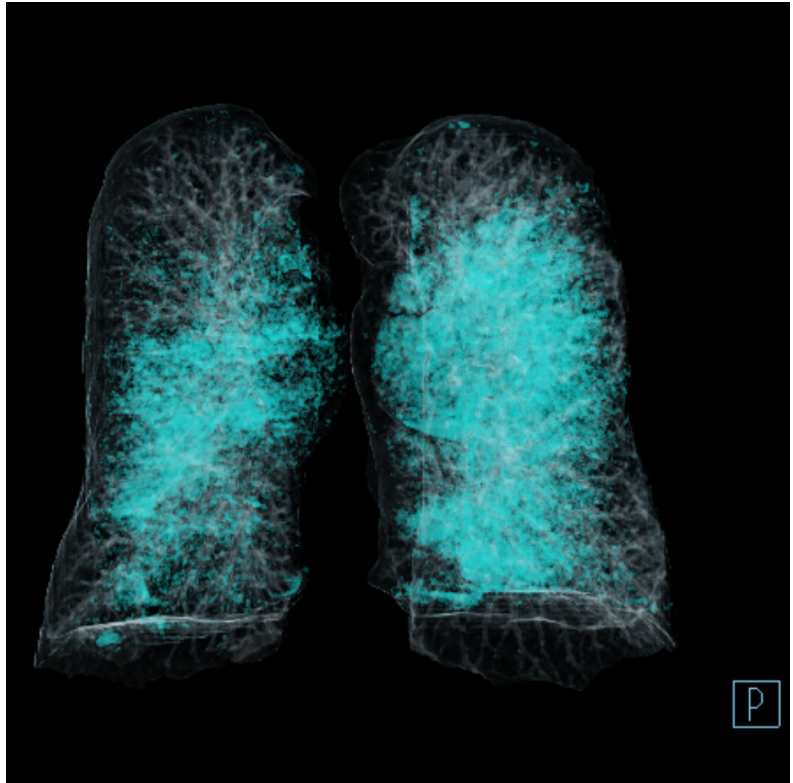
Contains VRTs of lungs and lesions as defined in the configuration.

The following image displays the sub-solid lesion with 'X' label.



- Optional: Fourth series

Contains VRTs of lungs and color overlays for parenchyma below -950 HU.



- Optional: Fifth series
Contains a DICOM Structured Report with measurement results.
- Optional: Sixth series
Contains individual lesion details

6.2.2 Pulmonary Density

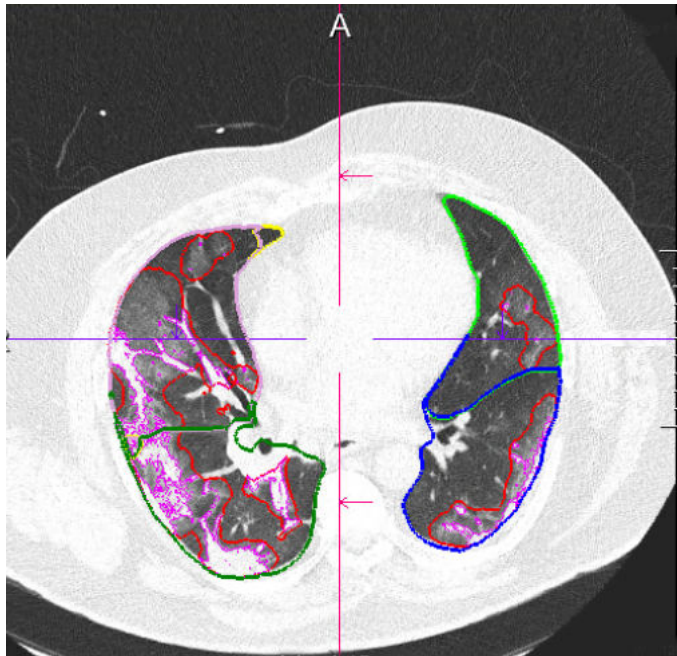
AI-Rad Companion creates the following result series that are sent to the PACS:

- First series:

Is the original (input) series including opacity segmentation contours and, if configured, high opacity segmentation contours.

For segmented lung lobes, contours are drawn.

The contours of both lungs are implicitly given by the contours of the lobes.



- Second series:

Contains a secondary capture DICOM image with a list of the measurement result, which are displayed for each lobe, each lung, and both lungs. A lung pictogram illustrates the results.

The following images display the generated measurement results.

AI-Rad Companion Chest CT					
Pulmonary Density					
LUNG OPACITY	Both Lungs	Right Lung	Left Lung	Not for diagnostic use *	
Opacity Score	0	0	0		
Total Volume [ml]	4094.86	2348.03	1746.83		
Opacity Volume [ml]	10.69	6.73	3.96		
Opacity Percentage [%]	0.26	0.29	0.23		
High Opacity Volume [ml]	1.49	1.39	0.11		
High Opacity Percentage [%]	0.04	0.06	0.01		
Mean HU Total [HU]	-802.76	-806.12	-798.24		
Mean HU of Opacity [HU]	-532.93	-469.39	-640.98		
Standard Deviation Total [HU]	137.73	136.86	138.75		
Standard Deviation of Opacity [HU]	247.79	259.75	180.37		
LUNG LOBE OPACITY	Right Upper	Right Middle	Right Lower	Left Upper	Left Lower
Opacity Score	0	0	0	0	0
Total Volume [ml]	769.51	532.01	1046.51	832.77	914.06
Opacity Volume [ml]	4.50	0.49	1.74	3.63	0.33
Opacity Percentage [%]	0.58	0.09	0.17	0.44	0.04
High Opacity Volume [ml]	1.37	0.01	0.00	0.11	0.00
High Opacity Percentage [%]	0.18	0.00	0.00	0.01	0.00
Mean HU Total [HU]	-811.87	-838.58	-785.38	-803.35	-793.58
Mean HU of Opacity [HU]	-405.24	-555.35	-610.66	-639.13	-661.66
Standard Deviation Total [HU]	121.36	120.36	151.14	127.66	147.98
Standard Deviation of Opacity [HU]	283.29	150.32	120.22	186.01	94.66
* Colors are based on institutional settings and are not an indication or recommendation for treatment. For further information, please refer to the user documentation.					
					

AI-Rad Companion Chest CT Legend

PULMONARY DENSITY *				HEART *			
	Opacity Score	lower [%]	upper [%]		Name	lower [mm ³]	upper [mm ³]
Green	0	0	<1	Green	I	0	<10
Light Yellow	1	1	<25	Yellow	II	10	<100
Yellow	2	25	<50	Orange	III	100	<500
Orange	3	50	<75	Red	IV	500	<999
Red	4	75	<100				

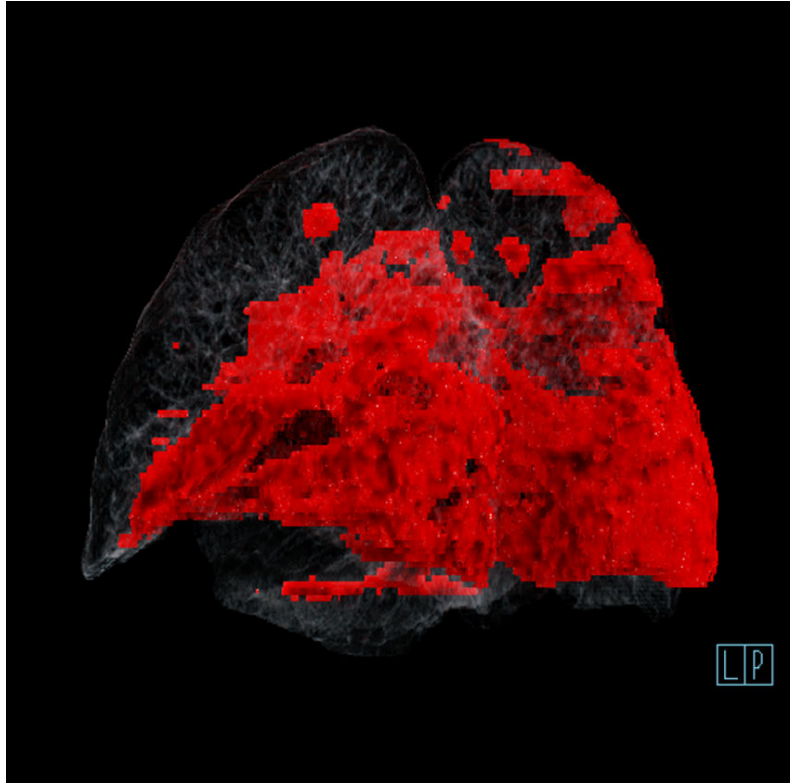
LUNG *				SPINE *			
	Name	lower LAV950 [%]	upper LAV950 [%]		Name	lower [%]	upper [%]
Green	I	0.0	<12.5	Green	I	0	<20
Yellow	II	12.5	<25.0	Yellow	II	20	<25
Orange	III	25.0	<37.5	Orange	III	25	<40
Red	IV	37.5	<100	Red	IV	40	<100

* Colors are based on institutional settings and are not an indication or recommendation for treatment.

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- Optional: Third series

Contains VRTs of lungs and opacity segmentations as defined in the configuration.



- Optional: Fourth series

Contains a DICOM Structured Report with measurement results.

6.3 Screen layout of the Results Preview



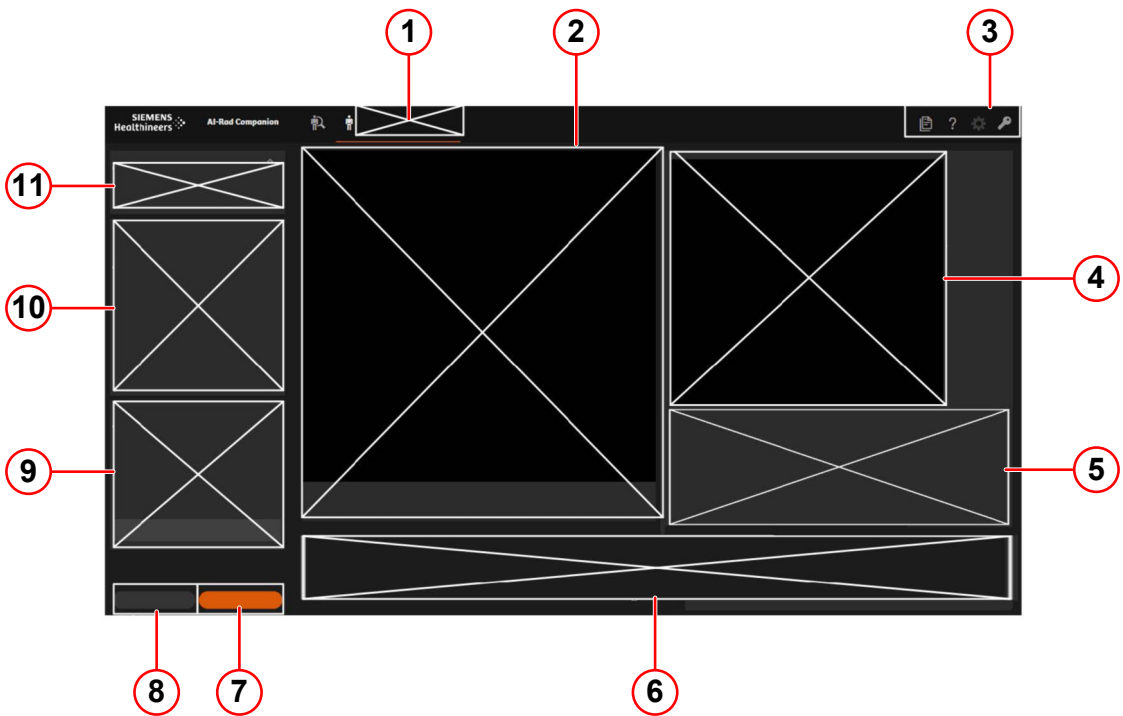
CAUTION

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 51 *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 51 *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, sex, ID, series description, and scan date.
Examination Information section
This section displays the following examination information: study date and time and series description.

6.4 Adjusting the image display

In the Results Preview, you can adjust the display of findings as you are reviewing.

(→ Page 54 *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** toggle button 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 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, to pan the image.
- 5 Use the scroll wheel or the arrows to scroll through the images.

6.5 Unlinking and relinking lesions

You can unlink the current lesion with the suggested prior lesion in the **Lesions Overview** section to remove the link between the current and prior lesions.

You can unlink:

- if the current lesion is a new one and a corresponding prior lesion is unavailable in prior data
- if the current lesion should be linked to another other lesion in the prior data.



- You cannot link the current lesion to any other lesion in the prior data other than the suggested prior lesion.
 - You can relink the current lesion to the suggested prior lesion after unlinking.
-

Perform the following steps to unlink and relink the lesions.

- 1 Click the ellipsis icon next to the **Accepted** check box.

The following options are displayed if a lesion is detected in the current and prior study.

- **Measure in PACS:** to remeasure the lesions in PACS
- **Unlink:** to unlink the current and prior lesions



Measure in PACS is also displayed if a lesion is available only in the current study.

-
- 2 Click **Unlink** to remove the link between the current and prior lesions.
 - The current lesion is considered as a new lesion.
 - The new lesion contains only current study values and does not provide growth or shrinkage details.
 - The original lesion retains the prior study values.
 - 3 To relink the lesion, click the ellipsis icon next to the **Accepted** check box of the original and newly created lesions.

The following options are displayed.

- **Measure in PACS:** to remeasure the lesions in PACS
- **Relink:** to relink the current and prior lesions



Measure in PACS option is displayed only for the new lesion created due to unlinking. The unlinked original lesion containing only prior values does not display the **Measure in PACS** option.

-
- 4 Click **Relink**.
 - The newly created lesion is discarded.
 - The lesion from the two timepoints is linked.
 - The original lesion is populated with current and prior study values.
 - Growth or shrinkage details are displayed.



For sub-solid lesions, you can unlink or relink the lesions when:

- the detected lesion is solid in prior study and sub-solid in the current study.
- the detected lesion is sub-solid in both prior and current studies

For sub-solid lesions, you can unlink or relink the lesions and measure in PACS when the detected lesion is sub-solid in prior study and solid in the current study.

6.6 Confirming or declining findings



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 of the list of results section visualize which findings are currently to be declined and are to be deleted, and which are to be sent to the PACS.

For **Lung Parenchyma** and Pulmonary Density, you can accept or decline all findings at once.

Perform the following steps to confirm or decline the findings.

- 1 From the **Worklist** view in the Patient List, double-click the required patient data.

The Results Preview is displayed.

(→ Page 49 *Screen layout of the Results Preview*)

- 2 In the **Results** navigation section, click **Lung Parenchyma**.

All **Lung Parenchyma** 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 51 *Adjusting the image display*)

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, click the **Decline All** button in the list of results section.

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

- 6 In the **Results** navigation section, click **Lung Lesions**.



- 7 To decline one single finding, select the finding in the list of results section and click the **Decline** icon.



- 8 If a finding shows inadequate measurement results, select the finding in the list of results section and click the **Measure in PACS** icon.

The contour is removed from the image. Instead, a marker is displayed on the image and **Measure in PACS** is displayed in the results table that is created after the findings evaluation. These findings need to be reevaluated in the PACS by the radiologist.



- 9 Optional: To re-accept declined findings, select the finding in the list of results section and click the **Accept** icon.

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

(→ Page 56 *Sending confirmed findings to the PACS*)

6.7 Sending confirmed findings to the PACS

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 54 *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 be deleted.

A confirmation window is displayed.

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

Confirmed results are archived in the PACS.

6.8 Update and maintenance

A pop-up message displays information about the scheduled update or maintenance period of AI-Rad Companion (Pulmonary). This message is displayed in the **Patient List**, Results Preview and **Settings** screen.

7 Results configuration

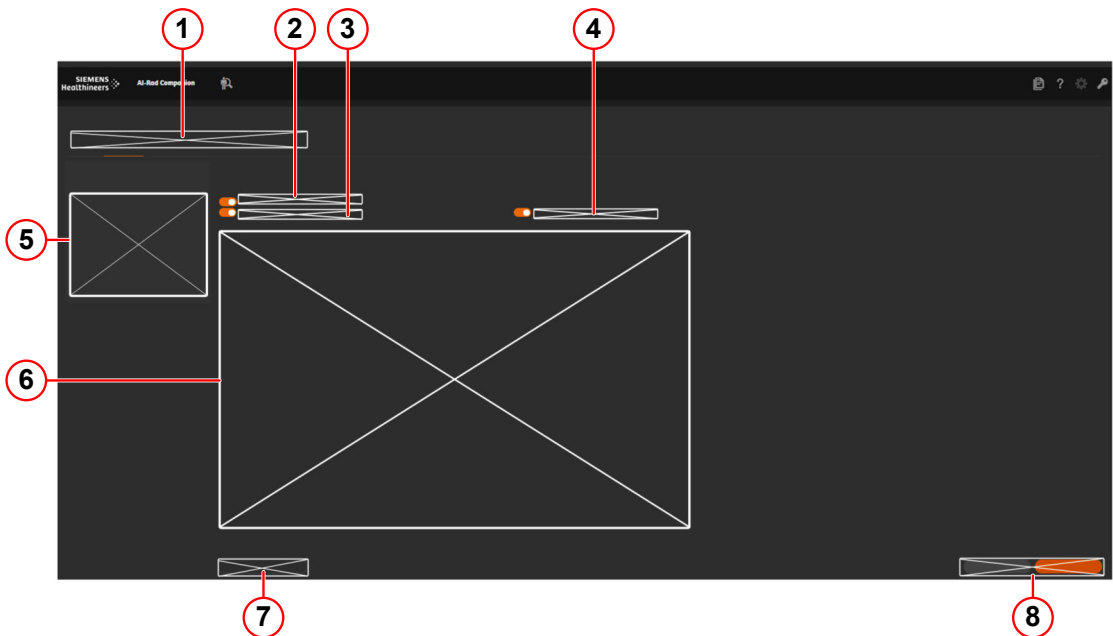
You can activate or deactivate the calculation of results and optionally adapt the result settings. When the calculation has been activated, you can determine if all results are directly sent to the PACS or if they require a review in the Results Preview.

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.

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

7.1 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. The settings menu comprises the following areas:



- (1) **Settings tabs**
The **Chest CT** tab displays sections that allow you to configure the results.
- (2) **Result Settings**
This option enables the calculation of results.
- (3) **Send Results for Confirmation**
Activates the option to review and individually send the images to the PACS.
- (4) **Create Structured Report**
Activates the option to save the results in a report.
- (5) **Configuration tabs**
The tabs display sections that allow you to configure the results related to the medical devices.
- (6) **Result Settings section**
You can configure the Result Settings, such as parameters, ranges, image windowing, and image volume rendering.
(→ Page 51 *Adjusting the image display*)
- (7) **Restore Default Settings** button
- (8) **Save** and **Cancel** buttons

7.2 Configuring input data selection

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



By default, **Pulmonary**, **Cardiovascular**, and **Musculoskeletal** are selected.



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 **Input Data Selection** tab is displayed.
- 3 Click the **AI Result** drop-down list and select **Pulmonary**.
- 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 **Cardiovascular** 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.

7.3 Configuring Lung Lesion results

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 you want to review results in the Results Preview and individually send them to the PACS.

Additionally, you can modify the settings for **Pulmonary Density** and **Lung Parenchyma**.

(→ Page 70 *Configuring Lung Parenchyma results*)

(→ Page 75 *Configuring Pulmonary Density results*)

Perform the following steps to configure the lung lesion results.



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

The **Settings** menu is displayed.

2 Click the **Chest CT** tab.

3 Click the **Lung** and then the **Lung Lesion** configuration tab.

The **Lung Lesion** section is displayed.

4 Click **Save**.



Changes are applied only on cases that are uploaded after you save your configuration.

The following sections enable you to configure the Lung Lesion results.

7.3.1 Detecting Lung Lesions

Perform the following steps to detect Lung Lesions.

- ✓ The **Lung Lesion** configuration tab is active.
 - 1 Click to activate the **Detection of Lung Lesions** toggle button to enable the calculation of results.
 Result settings are displayed and can be configured.
 – or –
 Click to deactivate the **Detection of Lung Lesions** toggle button to exclude the lung lesions from the results calculation.
 Result settings are hidden.
 - 2 Click **Save**.
-



Changes are applied only on cases that are uploaded after you save your configuration.

7.3.2 Enabling Lung Lesions Follow-Up

To assess the changes in lesion size on follow-up CT images, you can perform follow-up evaluation by comparing segmented lung lesions with known prior data. You can compare lesions in two timepoints and if more than one scan is found, the latest one is used for comparison.

For a scan to be considered as prior study for follow-up, the time interval between the current and the prior scan should be ≥ 10 days and $<$ the retention period.



By default, **Enable Follow-Up** option is disabled.

Perform the following steps to enable Lung Lesion follow-up.

✓ The **Lung Lesion** configuration tab is active.

1 Click to activate the **Enable Follow-Up** toggle button to initiate follow-up evaluation.

The retention period can be configured to store the prior scans for a longer period.

– or –

Click to deactivate the **Enable Follow-Up** toggle button to exclude the lung lesions from follow-up evaluation.

The retention period cannot be configured and no data is added to or retrieved.

2 Click **Save**.



Changes are applied only on cases that are uploaded after you save your configuration.

7.3.3 Configuring retention period in long-term storage

You can configure the retention period of lung lesion follow-up studies to store the prior scans in long-term storage (LTS). The prior scan information can be retrieved later to compare with the current scans. The prior scan information includes lung lobe landmarks, lung lobe mesh point, and result DICOM objects to display the picture-in-picture image in the Results Preview. The result DICOM objects includes the prior MPR series to align with the current time points image patient position. The data is automatically deleted from the LTS after the retention period is complete.



For more information on LTS, see *AI-Rad Companion Engine Instructions for Use*.

Perform the following steps to configure the retention period.

✓ **Enable Follow-Up** is active.

1 In the **Store Data for Follow-Up Studies for:** section, click to use the arrows to set the retention period in the **Months** and **Weeks** fields respectively.

The prior scans are stored in the LTS as per the required retention period.



- By default, the value for months is 14 and weeks is 0.
- The period of one month is counted as 30 days. The default number of days is 420 days.

2 Click **Save**.



Changes are applied only on cases that are uploaded after you save your configuration.

7.3.4 Configuring MPR series generation of prior lesions

You can generate MPR series of the prior lesions so that the prior lesion series is available in PACS along with the current study.

Perform the following steps to generate the MPR series of prior lesions.

✓ The **Lung Lesion** configuration tab is active.

1 Click to activate the **Generate MPR Series of the Prior Lesions in PACS** toggle button to enable the MPR series generation of prior lesions.

The prior lesion series is available in the PACS along with the current study.

– or –

Click to deactivate the **Generate MPR Series of the Prior Lesions in PACS** toggle button to disable the MPR series generation of prior lesions.

No prior lesion series is available in the PACS.

2 Click **Save**.



Changes are applied only on cases that are uploaded after you save your configuration.

7.3.5 Configuring MPR series generation for sub-solid lesions

You can generate MPRs of the selected sub-solid lesion and its corresponding prior lesions (if available) in PACS.

Perform the following steps to generate the MPR series for sub-solid lesions.

✓ The **Lung Lesion** configuration tab is active.

1 Click to activate the **Generate MPR Series of the Prior Lesions in PACS** toggle button to enable the MPR series generation for sub-solid lesions in the PACS.

The following functionalities are applicable.

- If sub-solid lesion is detected in the current study, current MPR displays sub-solid lesions marked as 'X' with no measurements.
- If sub-solid lesions are detected both in current and prior studies, current and prior MPRs displays sub-solid lesions marked as 'X' with no measurements.
- If sub-solid lesion is detected in the prior study, the prior MPR displays sub-solid lesions marked as 'X' with no measurements.
- If sub-solid lesion is detected only in prior or in current study, only prior or current MPRs are available in the PACS. The sub-solid lesions are marked as 'X' with no measurements.

2 Optional: To deactivate MPR series generation for sub-solid lesions, click to deactivate **Generate MPR Series of the Prior Lesions in PACS** toggle button.

A sub-solid lesion marked as 'X' with lesion label is available in the PACS.

3 Click **Save**.



Changes are applied only on cases that are uploaded after you save your configuration.

7.3.6 Generating MPR with overlay or burned-in graphics

Perform the following steps to generate MPR with overlay or burned-in graphics.



By default, **Burned-In Graphics** is selected.

✓ The **Lung Lesion** configuration tab is active.

1 In the **MPR Series Parameters** section, click **Burned-in Graphics**.

The result images are generated in RGB from secondary capture images.

But you cannot perform windowing and HU measurement.

– or –

Click **Overlay (DICOM 6000)**.

You can perform windowing and HU measurement on the result object.



Lobe contours are not generated if you select **Overlay (DICOM 6000)**.

2 Click **Save**.



Changes are applied only on cases that are uploaded after you save your configuration.

7.3.7 Generating lesion findings

Perform the following steps to create all detected lesions or lesions with segmented contours and measurements only..

✓ The **Lung Lesion** configuration tab is active.

1 Under the **MPR Series Parameters** section, click **All Lesions**.

All detected lesions including solid and sub-solid lesions are displayed.

Click to use the arrows to set the following entries.

- **Thickness of Segmentation Contour [pixel]** (values: 1 - 5)
- **Zoom Factor of Lesion Series** (values: 1 - 5)
- **Number of Outer Slices** (values: 1 - 5)



All displayed lesions do not have diameter and volumetric measurements assigned to them.

– or –

Click **Segmented Lesions Only**.

Only lesions with segmented contours and measurements are displayed.

Click to use the arrows to set the following entries.

- **Maximum Number of Lesions** (values: 1 - 99)
- **Ignore lesions with diameter less than [mm]** (values: 1 - 20)
- **Thickness of Segmentation Contour [pixel]** (values: 1 - 5)
- **Zoom Factor of Lesion Series** (values: 1 - 5)
- **Number of Outer Slices** (values: 1 - 5)

The sensitivity of Lung CAD detection may be influenced by the parameters **Maximum Number of Lesions** and **Ignore lesions with diameter less than [mm]**. Smaller lung lesions may be filtered out.



- 2 Optional: Move the mouse pointer over the **I** icons to display the parameter tooltips.
- 3 Click **Save**.



Changes are applied only on cases that are uploaded after you save your configuration.

7.3.8 Displaying findings label

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



This is an optional configuration step.

- ✓ The **Lung Lesion** configuration tab is active.
- 1 Select the **Show findings label** check box to display findings labels in the **Worklist** view if a lung lesion is detected.
 - or –
 - Select to clear **Show findings label** check box.
 - No findings are not displayed in the **Worklist** view.
- 2 Click **Save**.



Changes are applied only on cases that are uploaded after you save your configuration.

7.3.9 Modifying windowing parameters

Perform the following steps to modify the windowing parameters.

- ✓ The **Lung Lesion** configuration tab is active.
- 1 In the **Windowing** section, click to use the arrows to set the values for **Window Center** (values: -1000 - 3071) and **Window Width** (values: 1 - 2000).
- 2 Click **Save**.



Changes are applied only on cases that are uploaded after you save your configuration.

7.3.10 Modifying the VRT series parameters

Perform the following steps to modify the VRT series parameters.

- ✓ The **Lung Lesion** configuration tab is active.

- 1 Click to activate the **Show Volume Rendering of Lung Lesions** toggle button to display VRT data in the 3D segment of the Results Preview.
– or –
Click to deactivate the **Show Volume Rendering of Lung Lesions** toggle button to display no data in the 3D segment of the Results Preview.
- 2 Click the **Rendering Quality** drop-down list and select one of the following values.
 - **Good**
 - **Excellent**
- 3 Click to use the arrows to set the number of images in the **Number of Rotated Images per 360 Degrees** field. The values allowed are in the range (1 - 10).
- 4 Click **Save**.



Changes are applied only on cases that are uploaded after you save your configuration.

7.3.11 Sending results for confirmation

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

- ✓ The **Lung Lesion** configuration tab is active.
- 1 Click to activate the **Send Results for Confirmation** toggle button to review and individually send images to the PACS.
– or –
Click to deactivate the **Send Results for Confirmation** toggle button to send results to the PACS without review.

Lung Lesion 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.

7.3.12 Creating structured report

Perform the following steps to create structured reports.

✓ The **Lung Lesion** configuration tab is active.

1 Click to activate the **Create Structured Report** toggle button to save the measurement results in a report.

For each lesion, additional information is provided regarding whether the lesion has been accepted or marked to be reevaluated.

– or –

Click to deactivate the **Create Structured Report** toggle button 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.

7.3.13 Restoring default settings

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

✓ The **Lung Lesion** 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.

7.4 Configuring Lung Parenchyma results

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 you want to review results in the Results Preview and individually send them to the PACS.

Additionally, you can modify the settings for **Pulmonary Density** and **Lung Lesion**.

(→ Page 60 *Configuring Lung Lesion results*)

(→ Page 75 *Configuring Pulmonary Density results*)



- 1 On the Patient List tab, click the **Settings** icon.
The **Settings** menu is displayed.
- 2 Click the **Chest CT** tab.
- 3 Click the **Lung** and then the **Lung Parenchyma** configuration tab.
The **Lung Parenchyma** section is displayed.
- 4 Click **Save**.



Changes are applied only on cases that are uploaded after you save your configuration.

The following sections enable you to configure the Lung Parenchyma results.

7.4.1 Activating Lung Parenchyma Analysis

Perform the following steps to activate the Lung Parenchyma Analysis.

- ✓ The **Lung Parenchyma** configuration tab is active.
- 1 Click to activate the **Lung Parenchyma Analysis** toggle button to enable the calculation of results.

Result settings are displayed and can be configured.

– or –

Click to deactivate the **Lung Parenchyma Analysis** toggle button to exclude the lung from the results calculation.

Result settings are hidden.

2 Click **Save**.



Changes are applied only on cases that are uploaded after you save your configuration.

7.4.2 Generating MPR series for Lung Parenchyma

You can generate MPR series for Lung Parenchyma so that the series is available in PACS.

Perform the following steps to generate the MPR series for Lung Parenchyma.

✓ The **Lung Parenchyma** configuration tab is active.

1 Click to activate the **Generate MPR Series for Parenchyma** toggle button to enable the creation of MPR series.

The MPR series is available in PACS.

– or –

Click to deactivate the **Generate MPR Series for Parenchyma** toggle button.



By default, **Generate MPR Series for Parenchyma** toggle button is activated.

2 Click **Save**.



Changes are applied only on cases that are uploaded after you save your configuration.

7.4.3 Modifying range parameters

Perform the following steps to modify the range parameters.

- ✓ The **Lung Parenchyma** configuration tab is active.
- 1 In the **Range** section, click to modify the color labels.
- 2 Click to use the arrows to set the threshold values of **Value [%]**. The labels and default thresholds are **I** 0%-12.5%, **II** 12.5%-25%, **III** 25%-37.5%, **IV** 37.5%-100%.
- 3 Click **Save**.



Changes are applied only on cases that are uploaded after you save your configuration.



Default values of **Lung Lesion** and **Lung Parenchyma** are always restored together. If you restore the default values, the threshold values of **Range [%]** you entered are deleted.

7.4.4 Displaying findings label

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



This is an optional configuration step.

- ✓ The **Lung Parenchyma** 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 findings 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 a **Show findings label** check box other than **Red**, the higher ranges are selected too.

2 Click **Save**.



Changes are applied only on cases that are uploaded after you save your configuration.

7.4.5 Modifying the VRT series parameters

Perform the following steps to modify the VRT series parameters for Lung Parenchyma.

- ✓ The **Lung Parenchyma** configuration tab is active.
- 1 Click to activate the **Show Volume Rendering of Lung Parenchyma** toggle button to display VRT data in the 3D segment of the Results Preview.
– or –
Click to deactivate the **Show Volume Rendering of Lung Parenchyma** toggle button to display no data in the 3D segment of the Results Preview.
- 2 Click the **Rendering Quality** drop-down list and select one of the following values.
 - **Good**
 - **Excellent**
- 3 Click to use the arrows to set the number of images in the **Number of Rotated Images per 360 Degrees** field. The values allowed are in the range (1 - 10).
- 4 Click **Save**.



Changes are applied only on cases that are uploaded after you save your configuration.

7.4.6 Sending results for confirmation

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

✓ The **Lung Parenchyma** configuration tab is active.

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

– or –

Click to deactivate the **Send Results for Confirmation** toggle button to send results to the PACS without review. **Lung Parenchyma** 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.

7.4.7 Creating structured report

Perform the following steps to create structured reports.

✓ The **Lung Parenchyma** configuration tab is active.

1 Click to activate the **Create Structured Report** toggle button to save the measurement results in a report.

– or –

Click to deactivate the **Create Structured Report** toggle button 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.

7.4.8 Restoring default settings

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

✓ The **Lung Parenchyma** 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.

7.5 Configuring Pulmonary Density results

You can activate or deactivate the calculation of results and optionally adapt the result settings.

Additionally, you can modify the settings for **Lung Lesion** and **Lung Parenchyma**.

(→ Page 60 *Configuring Lung Lesion results*)

(→ Page 70 *Configuring Lung Parenchyma results*)



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

The **Settings** menu is displayed.

2 Click the **Chest CT** tab.

- 3 Click the **Lung** and then the **Pulmonary Density** configuration tab.

The **Pulmonary Density** section is displayed.

- 4 Click **Save**.



Changes are applied only on cases that are uploaded after you save your configuration.

The following sections enable you to configure the Pulmonary Densities results.

7.5.1 Assessing Pulmonary Densities results

Perform the following steps to configure the pulmonary densities results.

- ✓ The **Pulmonary Density** section is displayed.

- 1 Click to activate the **Assessment of Pulmonary Densities** toggle button to enable the calculation of results.

Result settings are displayed and can be configured.

– or –

Click to deactivate the **Assessment of Pulmonary Densities** toggle button to exclude **Pulmonary Density** results from the calculation.

Result settings are hidden.

- 2 Click **Save**.



Changes are applied only on cases that are uploaded after you save your configuration.

7.5.2 Displaying high opacity segmentation contours

Perform the following steps to display the high opacity segmentation contours.

- ✓ The **Pulmonary Density** section is displayed.

- 1 In the **MPR Series Parameters** section, click to activate the **Show High Opacity Segmentation Contours** toggle button to additionally display high opacity contours in the axial segment.

– or –

Click to deactivate the **Show High Opacity Segmentation Contours** toggle button to display only opacity contours without displaying high opacity contours in the axial segment.

- 2 Optional: Click to use the arrows to set the thickness of segmentation contours in the **Thickness of Segmentation Contour [pixel]** fields. The allowed values are in the range (1 - 5).



- 3 Optional: Move the mouse pointer over the **I** icons to display parameter tooltips.

- 4 Click **Save**.



Changes are applied only on cases that are uploaded after you save your configuration.

7.5.3 Modifying windowing parameters

Perform the following steps to modify the windowing parameters.

- ✓ The **Pulmonary Density** configuration tab is displayed.

- 1 In the **Windowing** section, click to use the arrows to set the values for **Window Center** (values: -1000 - 3071) and **Window Width** (values: 1 - 2000).

- 2 Click **Save**.



Changes are applied only on cases that are uploaded after you save your configuration.

7.5.4 Modifying the VRT series parameters

Perform the following steps to modify the VRT series parameters for Pulmonary Density.

- ✓ The **Pulmonary Density** section is displayed.
- 1 In the **VRT Series Parameters** section, click to activate the **Show Volume Rendering of Pulmonary Densities** toggle button to create the VRT result series.
 – or –
 Click to deactivate the **Show Volume Rendering of Pulmonary Densities** toggle button if you do not want to create the VRT result series.
- 2 Click the **Rendering Quality** drop-down list and select one of the following values.
 - **Good**
 - **Excellent**
- 3 Click to use the arrows to set the number of images in the **Number of Rotated Images per 360 Degrees** field. The values allowed are in the range (1 - 10).
- 4 Click **Save**.



Changes are applied only on cases that are uploaded after you save your configuration.

7.5.5 Sending results for confirmation

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

- ✓ The **Pulmonary Density** section is displayed.
- 1 Click to activate the **Send Results for Confirmation** toggle button to review and individually send images to the PACS.
 – or –
 Click to deactivate the **Send Results for Confirmation** toggle button to send results to the PACS without review.
Pulmonary Densities 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.

7.5.6 Creating structured reports

Perform the following steps to create structured reports.

- ✓ The **Pulmonary Density** section is displayed.
 - 1 Click to activate the **Create Structured Report** toggle button to save the measurement results in a report.
– or –
Click to deactivate the **Create Structured Report** toggle button 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.

7.5.7 Restoring default settings

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

- ✓ The **Pulmonary Density** section 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.



The original language of this document is English.

Made in Germany.

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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