AI-Rad Companion (Pulmonary)

Release Information
VA20D

SIEMENS Healthineers

1 Release Information

Dear Customer, we would appreciate your feedback regarding this software version. If you have any suggestions for future improvements, please forward them to your local Siemens Healthineers representative.

Thank you for placing your trust in us. We wish you lots of success using your AI-Rad Companion application.

Welcome to AI-Rad Companion (Pulmonary), an image processing software that provides quantitative and qualitative analysis from previously acquired Computed Tomography DICOM images in the evaluation and assessment of disease of the lungs.

Please carefully read through this AI-Rad Companion (Pulmonary) Release Information, which is part of the user documentation.

Please note that the software includes several documentation modules. AI-Rad Companion (Pulmonary) comes with Instructions for Use, one set for AI-Rad Companion (Pulmonary) and one set for AI-Rad Companion Engine. These manuals are available in local languages as online version. Depending on the local applicable law and regulations, printed copies may also be available. User help in AI-Rad Companion (Pulmonary) is provided by an Online Help (electronic Instructions for Use) within the system.

For details on the features and functionalities of AI-Rad Companion (Pulmonary), refer to the Instructions for Use or the Online Help. Instructions for Use also includes information on required knowledge and experience and operating instructions for safe and proper use of the product.

Information on detailed technical data is provided in the AI-Rad Companion Chest CT Datasheet.

Information on how to access the AI-Rad Companion application and the Instructions for Use are provided in the AI-Rad Companion Addendum - General Information.

Screenshots depicted in the user documentation are for informational purposes only and do not depict the exact data that you would need to enter.

This Release Information informs you about all changes introduced within the specific version mentioned. The Release Information for all released versions of this product are available in the Siemens Healthineers Document Library.

2 Product overview

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

3 What's new in VA20D

3.1 New Improvements

This topic contains information on the improvements made in AI-Rad Companion (Pulmonary) VA20D.

3.1.1 Settings

The issue that decimal values for severity thresholds in the **Settings** were getting rounded off before saving the configuration was resolved.

The issue that decimal values in the **Settings** were not getting rounded off before saving the configuration was resolved.

3.1.2 Microsoft .NET version

Microsoft .NET version has been upgraded to latest version of .NET Core 6.0.18.

3.1.3 Local Labeling Information

This section contains information on the updated local labeling information for AI-Rad Companion (Pulmonary) VA20D.

Columbia Phone number of the Colombian importer label has been revised in the **About** tab.

India Indian labelling information has been revised and updated to comply with latest India CDSCO requirements, including new Import Licence under the Medical Device Rules, 2017 in the **About** tab.

Philippines To comply with Philippines FDA requirements, a new information has been added in the **About** tab to provide the CMDN number, name, and address of the importer and distributor.

3.2 User Documentation

There were no changes made in the Instructions for Use. The latest AI-Rad Companion (Pulmonary) Instructions for Use for VA20 remains valid.

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

3.3 Known Limitations

This section contains information on the known limitations in AI-Rad Companion (Pulmonary) VA20D.

Limitation	Workaround
In case of a failure of the algorithm, redundant messages are displayed: "Algorithm failure: Lung has not been found" and "Algorithm failure: Parts of the lung have not been found".	None
The consistency check on DICOM input data fails with duplicate slice instance numbers (0020,0013).	You can compare the input data with the original DICOM images to check the inconsistencies and the original images can be used for reading the specific case.
If lesions are found close to the border of the image, then part of the text of the measurement may be cut. This issue can occur sporadically.	None
In some cases, the labels of highlighted lesions can overlap with the legend in the VRT images.	None
Orthogonal measurements of the long and short axis diameters allow for a minor deviation from the 90° angle. In some cases, DICOM SR results might be rejected by selected PACS systems.	Proper angulation can be visually confirmed in the Results Preview or the DICOM SC images with burned in measurements or measurements can be repeated manually in PACS.

Limitation	Workaround
If the MPR segment has incorrect size and aspect ratio, dark patches are displayed on either side of the image.	None
In the SR DICOM IOD for the DCM Code 125007, “Measurement Group” shall be used instead of “Image Measurement Group” as the Code Meaning Value according to TID141.	None
Empty pages in the result table are displayed when the corresponding result settings for Heart, Lung Parenchyma, and Spine are not configured.	None
Lung lesion follow-up analysis cannot be performed when data minimization with standard privacy is enabled.	None
If no lesions are detected in the prior and current studies, instead of displaying the text,“ No lesions found” text, an algorithm error message is displayed.	None
The Results Preview takes some time to get displayed after you have selected a study in the **Worklist**.	None
Random date and time are displayed for a loaded study that does not have study date and time.	None
MPR series parameters do not accept decimal values.	This is a display issue only. The actual decimal values configured are considered for range calculation in the backend.

3.4 Additional Information

The build number for AI-Rad Companion (Pulmonary) VA20D:

`airc-chestct-processingunit:va20d.20230810.2`

`airc-chestct-webui:va20d.20230810.1`

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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)).

The original language of this document is English.

Made in Germany.

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