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Annalise Enterprise 2.2
(Annalise CXR)

User Guide

English

Annalise Enterprise

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Contents

Intended Purpose

Annalise Enterprise is a medical device intended to assist clinicians with the interpretation ofradiological imaging studies and provide notification of suspected findings.

Indications For Use

Annalise Enterprise identifies suspected findings in digitised (CR) or digital (DX) chest X-raystudies taken in the anterior-posterior (AP) or posterior-anterior (PA) and optionally lateral (LAT) orientations of adult patients.

The device is intended to be used by clinicians who interpret chest X-rays as part of theirscope of practice.

The device is used on a PC workstation in conjunction with a medical imaging viewer & worklistsoftware (i.e. PACS system).

The device is not intended to provide direct diagnosis.

Contraindications

The device is not to be used on patients under the age of 16 years.

The device does not enable an increase in the clinician's scope of practice.The device is

not intended to provide direct diagnosis.

WARNING

Qualified clinicians who interpret chest X-rays as part of their scope of practice hold ultimate responsibility for interpreting the X-ray study.
The clinician must review the Annalise Enterprise output concurrently with the original X-ray images and all other relevant clinical informationbefore making their clinical decisions.

About Annalise Enterprise

Annalise Enterprise interfaces with Picture Archiving and Communication Systems (PACS) and Radiology Information Systems (RIS) to obtain the chest X-ray images to process. The Artificial Intelligence (AI) algorithm within the device uses deep learning techniques to identify the presence of the radiological findings. Annalise Enterprise also uses deep learning to localise the position of the clinical findings, where possible. This information is displayed to the clinicianwhen they view the study in the PACS Viewer.

Annalise Enterprise also analyses the chest radiographs using deep learning techniques toidentify the laterality or highlight the relevant areas of interest for a subset of findings as defined in Appendix A.

The suspected findings are communicated to the clinician viewing the study by displaying thefindings and associated localisation information when viewing the study in the PACS Viewer.

In addition, the Worklist Triage feature can elevate study's priorities in the worklist when the AIalgorithm predicts findings that warrant triaging.

* Worklist Triage is an additional licensed option and is not available in all regions.

Installation and System Requirements

For full details on installation and system requirements, please refer to the Administration Guide.

User Instructions

Introduction

Annalise Enterprise provides the following high-level functionality:

- Worklist Triage: Uses the AI to triage studies and provide notification in the reportingworklist (optional feature).

- Annalise Viewer: Displays AI results, including Findings and localisation information, toassist the interpreting clinican.

Worklist Triage

* Worklist Triage is an additional licensed option and is not available in all regions.

This optional feature sends AI results to the reporting worklist software to enable AI assisted triage of the reporting worklist. The exact functionality available depends on the worklist soft-ware being used (RIS, PACS).

The feature uses the Findings detected in each study by the AI model to provide information tothe worklist software to enable prioritisation of the reporting worklist.
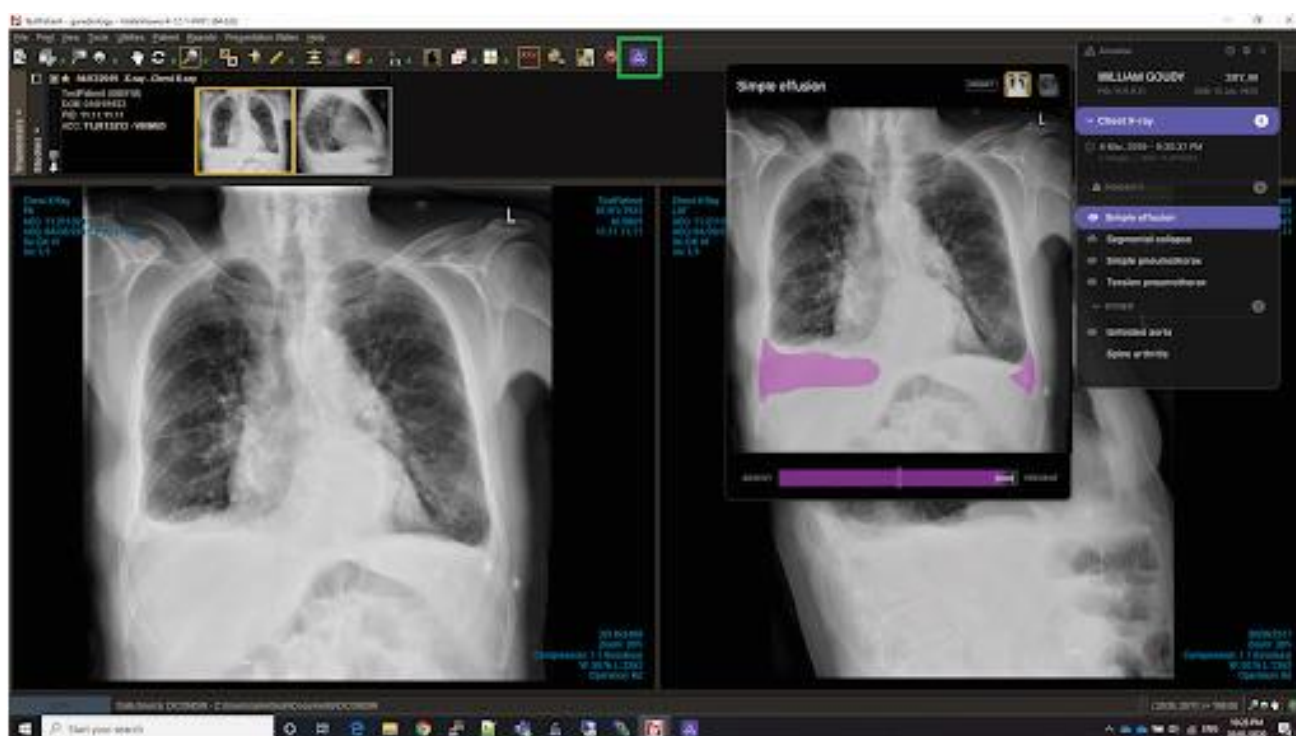
Each organisation can specify which Findings will result in triage and the relative priority ofeach Finding.

It is important to note that Worklist Triage will <u>never decrease</u> a study's rank in the worklist.In the instance that a worklist software vendor does not provide the current worklist priorityinformation, the product will only triage Findings with the highest rank. This ensures that worklist items will never have their priorities downgraded by the AI software.
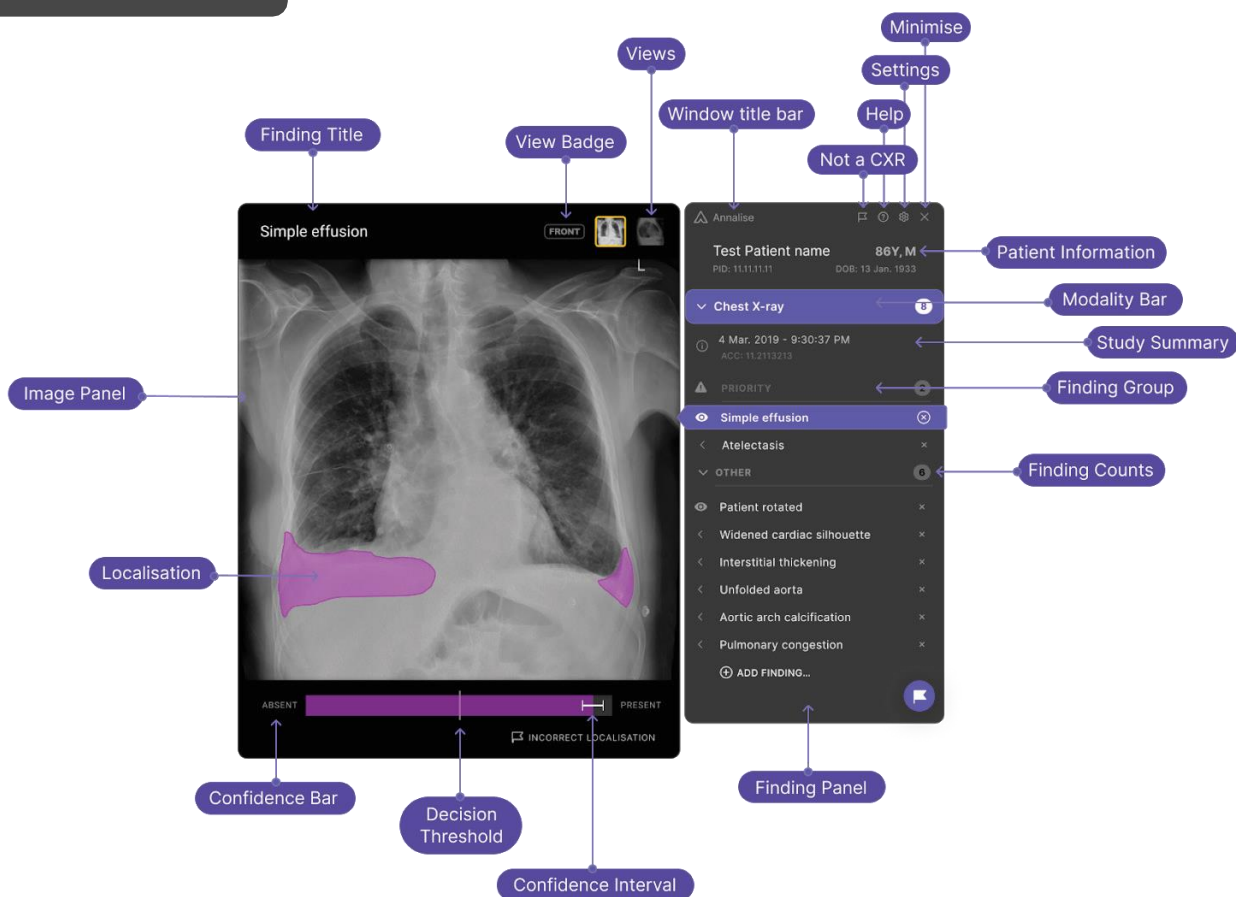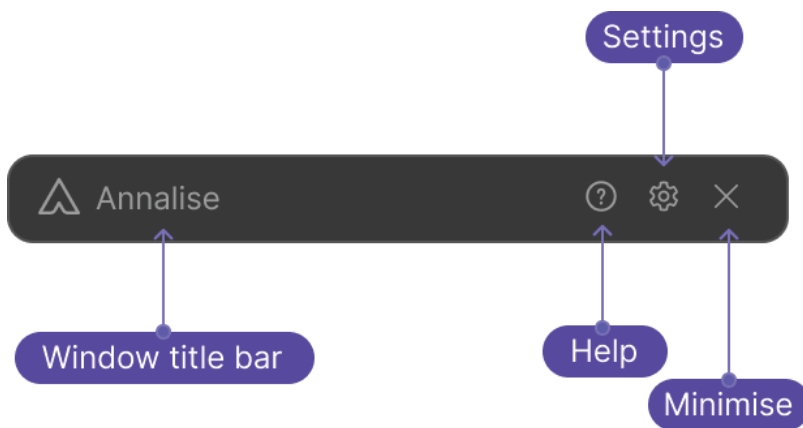
Annalise Viewer

Annalise Enterprise is designed to synchronise with compatible PACS Viewers. Where the automatic synchronisation functionality is not available, users have the option to manually synchronise the software with the PACS.

For users of Windows 7 computers that do not support Aero themes, the Viewer uses a simplified layout. The simplified layout supports all of the Viewer functionality and workflows.

Annalise Viewer

Views

Minimise

Settings

Window title bar

Help

Not a CXR

Finding Title

View Badge

Patient Information

Simple effusion   FRONT

Modality Bar

Test Patient name   86Y, M
PID: 11.11.11.11   DOB: 13 Jan. 1933

Chest X-ray

Study Summary

4 Mar. 2019 - 9:30:37 PM
ACC: 11.2113213

Image Panel

PRIORITY

Finding Group

Simple effusion

Atelectasis

Finding Counts

OTHER

Patient rotated

Widened cardiac silhouette

Localisation

Interstitial thickening

Unfolded aorta

Aortic arch calcification

Pulmonary congestion

ADD FINDING...

ABSENT   PRESENT

INCORRECT LOCALISATION

Confidence Bar

Decision
Threshold

Finding Panel

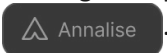Confidence Interval

Using the Annalise Viewer

Opening the Application: The Annalise Viewer can be launched:

- Automatically

- Manually from the Start menu

- Via a button in the PACS Viewer

The Annalise Viewer displays in the top right corner of the screen.

Moving the Application: to move the Annalise Viewer to another location or screen, click anddrag.

Minimising the Application: to minimise the Annalise Viewer to the task bar, click ⊗.
When minimised, the Annalise Viewer automatically re-opens when there are new AI findingsto be displayed.

Quitting the Application: to quit the Annalise Viewer, right-click the task bar icon andselect Quit.

Settings: to access the Annalise Viewer user preferences, click ⚙. The following preferencesare available:

- Viewer Size: to re-size the Viewer, select a zoom level.

- Optimised for Grayscale: when enabled, the user interface removes reliance on coloursto communicate findings. When disabled, the user interface uses colour to highlight findings and priority findings.

- Automatically show critical findings: when enabled, the findings panel expands whenloading a new study. When disabled, the findings panel must be manually expanded when loading each study.

- Automatically Expand Groups: when enabled, the Findings Panel expands all groups

when displayed. When disabled, the Findings Panel only expands the Critical Findingsgroup. Other groups configured for the organisation are collapsed and can be expanded by the user.

- Language: allows user to select the Annalise Viewer language.

- Inactivity: minimises the Annalise Viewer after a designated time period.

- Server Settings: the settings required for the Annalise Viewer to connect to the Annalise server. To access this information, select the Server Settings link. Enter thedetails as provided by Annalise.ai and click Test to confirm the information is correct.

Viewing AI Findings

1. AI findings for a study can be retrieved via two methods:

   a. Automatic: When a CXR study is opened in the PACS Viewer, if the study has beenprocessed by the Annalise Enterprise Backend, the Annalise Viewer displays the results. Automatic functionality is only available with selected PACS viewers.

   b. Manual: When viewing a CXR study in the PACS Viewer, click the Annalise icon in the PACS Viewer to send a request to display the AI findings in the Annalise Viewer ifavailable. This feature can also be mapped to a shortcut key in the PACS Viewer.
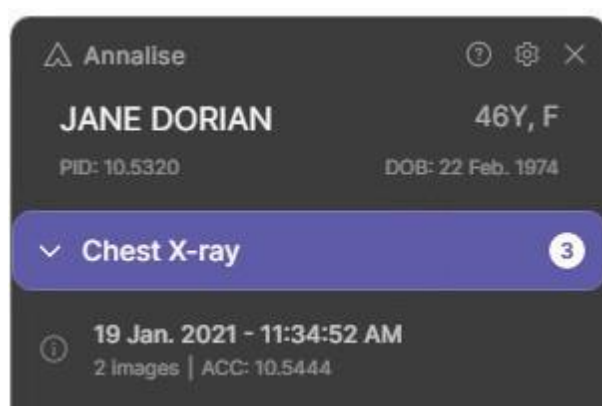

2. Confirm the Accession No. (ACC) for the AI results displayed in the UI application matchthe CXR study in the PACS Viewer.
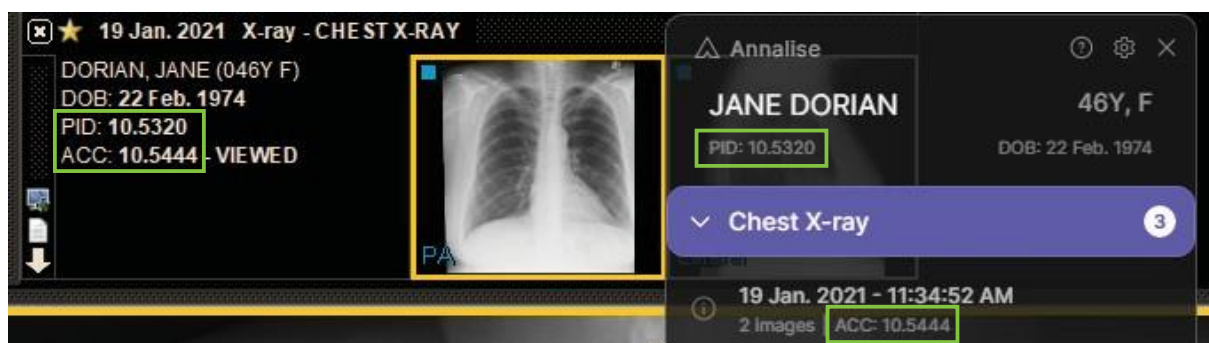
3. To show the images analysed for the current study, click the Study Summary to see the upto 3 images that can be processed in the Study Detail panel.

4. To see the AI results, left click the chest X-ray bar to expand the Findings Panel (if Automatically Show Findings is disabled). Annalise Enterprise shows the suspected radiological findings in the Findings Panel.

    a. When detected, priority findings are flagged separately as shown below.
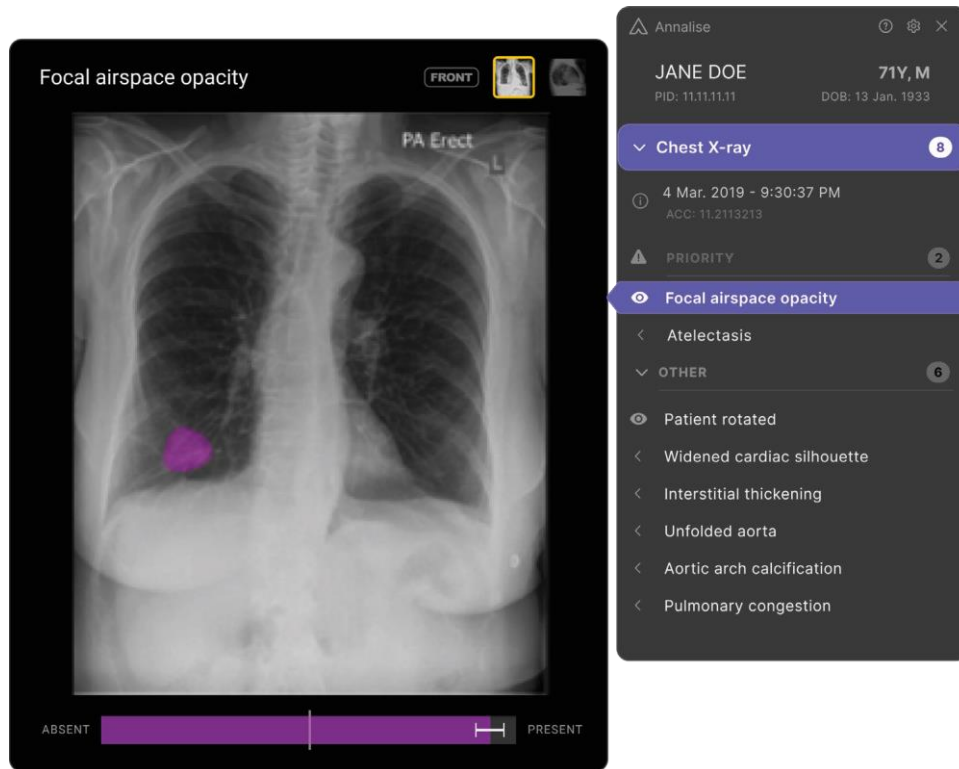
5. To view the AI confidence for each finding, position the mouse cursor on the finding name. The Confidence Bar displays below the primary image.

6. For a subset of suspected radiological findings, to indicate where localisation is associated with the finding, the Eye icon ⊚ displays next to the name. To show the localisation, hover the mouse cursor over the finding name.

7. For localisation that appears in multiple views, select the view above the currently displayed image.

Interpreting the Confidence Bar

The Confidence Bar provides a visual indication that the likelihood a finding reported by Annalise Enterprise is accurate.
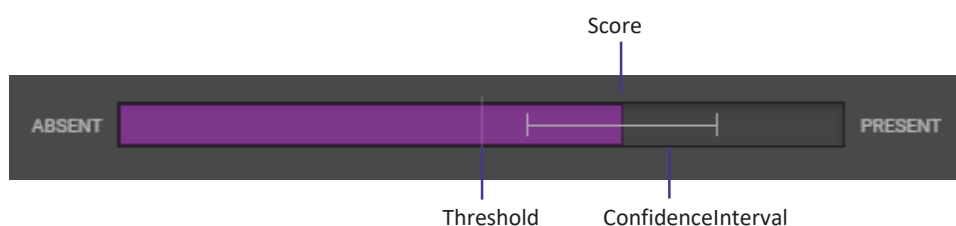
The Annalise Enterprise AI algorithms score each radiological finding. Only findings with ascore greater than the pre-set threshold are deemed to be present in the study.

As with all detection systems, Annalise Enterprise may incorrectly indicate a finding is presentin a study (i.e. a false positive).

The Annalise Enterprise AI algorithms provide a 95% confidence interval for each finding. Thisgives an indication of the probability of the algorithm reporting a false positive.

Confidence Bar Example	Interpretation
	Higher Confidence • The score is above the threshold • The confidence interval is above the threshold • The finding is most likely present in the study.
	Lower Confidence • The score is above the threshold • The lower bound of the confidence interval isbelow the finding threshold • The finding may be present in the study.

Providing AI Performance Feedback

The Annalise Viewer provides specific functionality to allow the user to input feedback on the AI model performance. Providing AI model feedback is not mandatory. Depending on your organisation's preference, this data may be provided back to Annalise to help improve product performance.

To enter feedback mode click the Feedback button that is located at the bottom of the Findings list. To exit Feedback mode, click the Feedback button again. Your feedback will be saved automatically when you move to a new study or exit feedback.

By clicking the Feedback button, you are indicating there are AI Model errors present in the current study, once in this mode you can optionally provide more specific feedback to Annalise, including
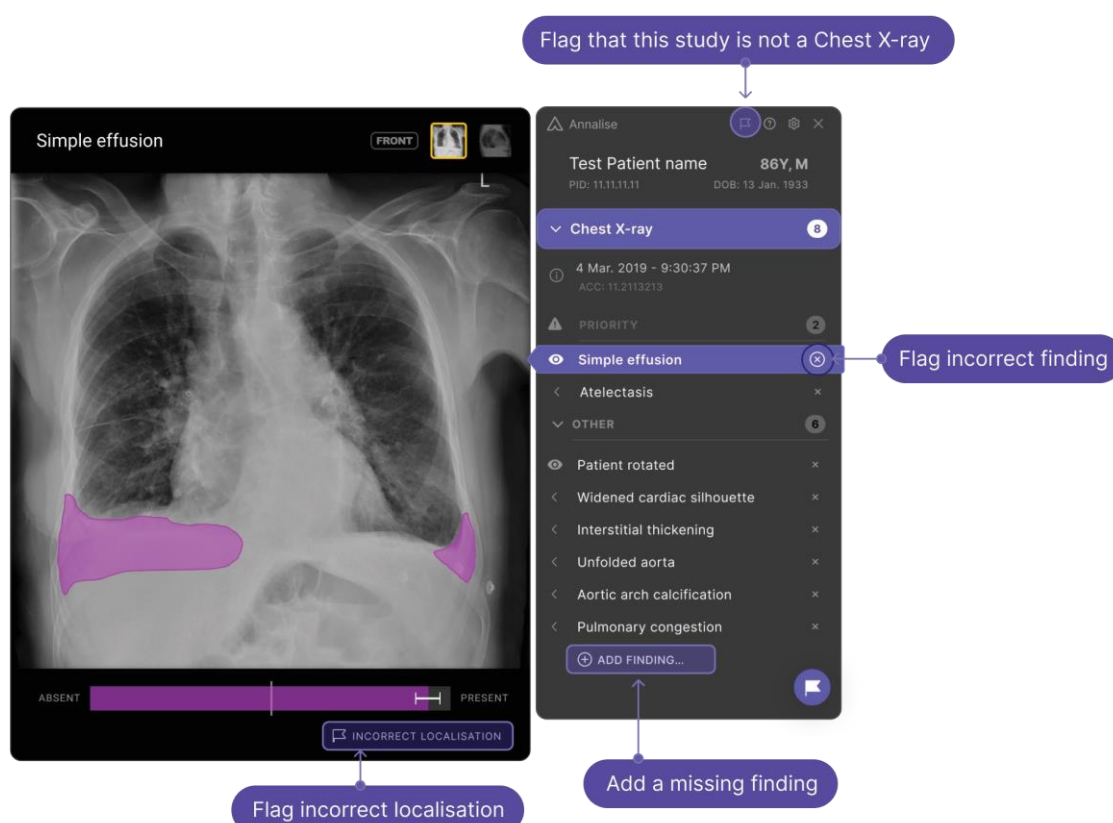
1. Flag where the scan has been incorrectly identified as a chest x-ray.

2. Flag incorrect findings by using the ⊗ button

3. Flag incorrect localisation by selecting the flag underneath the image.

4. Add a missing finding via the '+ add finding' option

Feedback mode off/No Feedback provided

Feedback mode on/Study flagged as containing AI model errors.

Flag that this study is not a 'Chest X-ray'

In the case that a study has been incorrectly identified as a chest x-ray, you can indicate this by clicking the flag button which is located at the top of the Annalise Viewer in the Window Title Bar.

Once flagged as incorrect, the button will appear highlighted as follows

In the case of an accidentally flagged a study, re-clicking the button will deactivate the flag.

Flag incorrect findings

To indicate a Finding as incorrect, first locate the Finding and click the ⊗ to the righthand sideof the Finding name.

Once flagged, the Finding name will appear with a strikethrough line.

If accidentally flagged, clicking the ⟲ to the righthand side of the Finding name willreinstate the Finding.

Flag incorrect localisation

For Findings that have associated localisation, you have the ability to flag where it isincorrect. To do this, click the button that is located underneath the image.

Once you have flagged localisation as incorrect, the button will appear as follows

If localisation was incorrectly flagged, you can re-click the button to return it to itsoriginal state.

Add missing findings

If there is a Finding that is missing from the study, you have the ability to search by Findingname and manually add it to the study. If the search does not return the finding, you can manually enter the complete Finding name.
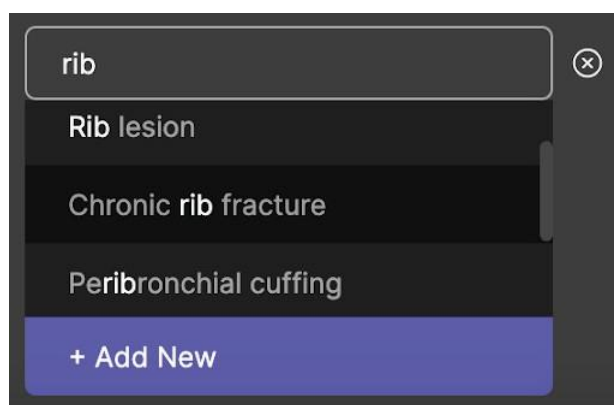
Predictive search requires three letters to be entered before any predictive text appears. Once a missed Finding has been added, it will appear under the "User Added"Finding group.
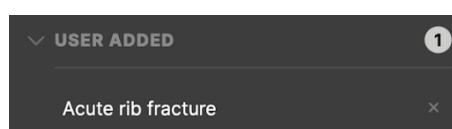
A manually added Finding can be removed by clicking the ✕ to the right of theFinding name.

Security features

Annalise Enterprise includes the following security features to protect against unauthorisedaccess and data modification:

- Secure authentication and encryption of sensitive data in transmission between theAnnalise Enterprise Integration Adapter and the Annalise Enterprise Backend.

- Secure authentication and encryption of sensitive data in transmission between theAnnalise Viewer and the Annalise Enterprise Backend.

- The option for secure authentication and encryption of sensitive data in transmission between the PACS Image Viewer and the Annalise Viewer is availablewhen utilising the HTTPS interface.

- Encryption of sensitive data stored at the Annalise Enterprise Backend.
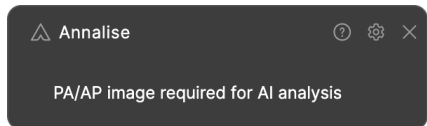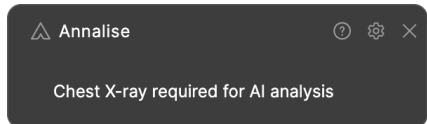
Sectra PACS Users

When using the Annalise Viewer with Sectra IDS7 PACS, the Annalise Viewer Adapter for Sectra IDS7 will need to be running for Sectra to sync with the Annalise viewer. If theAnnalise Viewer Adapter is not installed on your machine, please contact your system administrator.
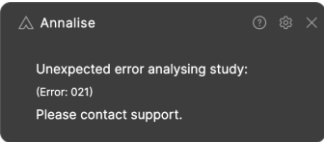
For full details on installation and system requirements, please refer to theAdministration Guide.

Troubleshooting

If you have issues with the Annalise Enterprise product, use following information to resolvethe issue. If you are unable to resolve the issue, please contact Annalise technical support.

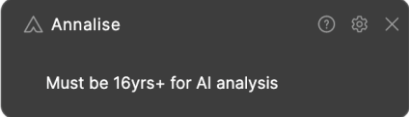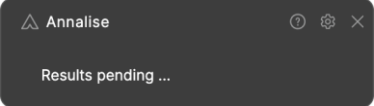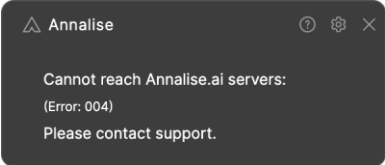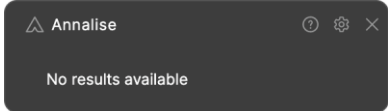| Problem	Solution
Missing server settings. Organisation details incomplete.	1. Contact Annalise Support.
Application unresponsive: After loading a study in the PACS Viewer, the AnnaliseViewer does not respond.	1. Check the study is of type CR or DX. 2. Check the version of PACS viewer is compatible with the Annalise Viewer. 3. Quit the Annalise Viewer, and re-open. 4. Attempt to re-load the study. If the problem persists, please contact support.
Application Unresponsive with SectraPACS: The Annalise Viewer is unresponsive when a study is loaded. Sectra PACS warns the Viewer is outof sync	1. Ensure the Annalise Viewer Adapter is runningin the System Tray. 2. Ensure the Sectra Desktop Sync functionalityis enabled 3. Quit and restart the Annalise Viewer Adapter
Unexpected Finding Change: When viewing a study, the AI findings changeunexpectedly.	1. Some software systems may encounter this error when viewing studies in multiplewindows. The Annalise Viewer will synchronise with the currently-selected window. 2. Ensure the shortcut key mapping in thePACS Viewer is mapped correctly.
Out of scope study: After loading a studyin the PACS Viewer, one of the following errors displays in the Annalise Viewer.	Study does not meet the minimum requirements for AI processing. 1. Annalise Enterprise only supports studies containing chest X-rays. 2. The study must contain at least one PA orAP image. 3. The Annalise Enterprise includes an AI feature that determines if the image is a chest X-ray, and whether there is a PA or APimage. AI models have an error margin; on rare occasions, Annalise Enterprise will not recognise a chest X-ray and will display thiserror.

Problem	Solution
Out of scope study: After loading a studyin the PACS Viewer, the following error displays: ⚠ Annalise ⑦ ⚙ ✕ Must be 16yrs+ for AI analysis	Annalise Enterprise only supports studies for patients at least 16 years of age. Annalise usesDICOM Tags to determine age.
Not processing: After loading a study in the PACS Viewer, the following messagedisplays in the Annalise Viewer: ⚠ Annalise ⑦ ⚙ ✕ Results pending ...	The study is currently being analysed. The application will wait for up to 1 minute forresults. If problem persists, please contact support.
Error 004: After loading a study in the PACS Viewer, Error: 004 displays in theAnnalise Enterprise Viewer: ⚠ Annalise ⑦ ⚙ ✕ Cannot reach Annalise.ai servers: (Error: 004) Please contact support.	Please check Internet connectivity. If you have Internet connectivity and the problem continues, please contact support.
No results: After loading a study in the PACS Viewer, the following error displaysin the Annalise Viewer. ⚠ Annalise ⑦ ⚙ ✕ No results available	The study is not CXR or the study may not have reached the Annalise EnterpriseIntegration Adapter. If the study was recently performed, it may nothave been forwarded to Annalise Enterprise. If the problem continues, please contact support.
Study Processing: After loading a studyin the PACS Viewer, one of the followingerror codes displays in the Annalise Viewer: Error: 029	The study has not yet completed AI processing. Please wait a while and try again. If the problem continues, please contact support.

Problem	Solution
Other error codes: After loading a studyin the PACS Viewer, one of the followingerror codes displays in the Annalise Viewer: Error: 001 Error: 002 Error: 003 Error: 009 Error: 010 Error: 011 Error: 014 Error: 015 Error: 016 Error: 020 Error: 021 Error: 022 Error: 026 Error: 027 Error: 031 Error: 099 ⚠ Annalise ⊙ ⚙ ✕ Unexpected error analysing study: (Error: 021) Please contact support.	Technical product error. Please contact support and quote the errorcode.

Appendix A – Technical Specification

Annalise Enterprise Ontology Tree

The following table specifies the CXR ontology tree supported by the Annalise Enterprisedevice. For information on performance please refer to the Performance Guide.

Finding	Localisation Available	Definition
Abdominal clips	No	Surgical clips in the abdomen.
Acute clavicle fracture	Yes	Cortical breach of a clavicle. May be difficult to see if nondisplaced. No callus formation for acute fractures.
Acute humerus fracture	Yes	Cortical breach of the humerus, usually at the surgicalneck of humerus.
Acute rib fracture	Yes	Cortical breach of a rib without callus formation or union, does not include surgical rib resection or thoracotomy.
Multifocal airspace opacity	Yes	Multiple area of ill-defined airspace / ground glassopacity or consolidation.
Airway stent	No	Stents within the trachea or bronchi.
Aortic arch calcification	No	Calcification of the aortic arch. Does not include mitral valve calcification, descending aortic or pericardial calcification. Only includes Grade 2or 3 calcification i.e. thick calcification.
Aortic stent	No	Stent / graft in the aorta
Atelectasis		Includes subsegmental collapse, linear and bibasal atelectasis.
Axillary clips	Yes	Surgical clips in the axilla.
Basal interstitial thickening	No	Opacities within pulmonary lobules in a linear / branching pattern affecting predominantly lower zonesof one or both lungs. This also includes thickened chronic fibrotic changes from lung scarring. This finding may still be predicted if there are upperzone changes as long as the pattern is lower zone predominant.
Biliary stent	No	Stents within the biliary tree.

Finding	Localisation Available	Definition
Breast implant	No	Breast prosthesis usually of gel like material implanted behind or in place of the female breast as cosmetic or reconstructive surgery.
Bronchiectasis	No	Dilation of the bronchi which can be localized or diffuse.
Diffuse bullae	No	Multiple large lucencies due to emphysema in the upper and lower zones of one or both lungs.
Lower zone bullae	No	Multiple large lucencies due to emphysema in the lower zones of one or both lungs. This finding may still be predicted if there are upper zone changes as long as the pattern is lower zone predominant.
Upper zone bullae	No	Multiple large lucencies due to emphysema in the upper zones of one or both lungs. This finding may still be predicted if there are lower zone changes as long as the pattern is upper zone predominant.
Calcified axillary nodes	No	Calcified soft tissue density in the axilla.
Calcified granuloma(< 5mm)	Yes	Calcified intraparenchymal lesion or lesions which are smaller than 5mm.
Calcified hilar lymphadenopathy	No	Calcified lymph nodes in hilum.
Calcified mass(> 5mm)	Yes	One or more intraparenchymal lesions (>5mm) which may be partially or completely calcified.
Calcified neck nodes	No	Calcified soft tissue density in the neck.
Calcified pleural plaques	No	Calcified thickening along the pleura at the diaphragm, lateral thoracic wall, or apex.
Cardiac valve prosthesis	No	Replacement of native cardiac valve. Includes transcatheter aortic valve implantation.

Finding	Localisation Available	Definition
Cavitating mass with content	Yes	Collection of air with air fluid level or in crescent shapethat separates the wall of a cavity from an inner mass.
Cavitating mass(es)	Yes	Lucent walled lesion which arises from a solid lesion that then develops gas within it. As a result, the wall istypically thickened.
In position Central Line (CVC)	Yes	Internal jugular lines, subclavian lines and peripheralinserted catheters (PICC). Central venous lines should be placed with the tip in the SVC / cavoatrial junction. The line should not be inthe brachiocephalic, subclavian veins, or right atrium.
Cervical flexion	No	The chin is visible and obscuring the apex of the lungor superior mediastinum. Only the primary AP or PA view is assessed, not the Lateral view or any other view / postprocessed image.
Incompletely imaged chest	No	Part of the lungs not included in the image. This finding may be predicted if any image in the seriesis incomplete.
Chronic clavicle fracture	No	Corticated clavicle fractures with surrounding callusformation or union.
Chronic rib fracture	No	Cortical breach of a rib with surrounding callus formation or union.
Chronic humerus fracture	No	United, malunited or non-united humerus fracture.
Clavicle fixation	Yes	Internal fixation of clavicle fractures. When a fracture has been fixed, the acute claviclefracture may not be predicted.
Clavicle lesion	Yes	Sclerotic or lytic, malignant or benign lesion withinthe clavicle with or without pathological fracture. This includes lesions due to systemic conditions such as myeloma, osteogenesis imperfecta, renal osteodystrophy etc.
Coronary stent	No	Stents within the coronary arteries.

Finding	Localisation Available	Definition
Diaphragmatic elevation	No	Left hemidiaphragm is higher than the right or if theright is more than 3cm higher than the left. This finding only applies to the inspiratory view, not thelateral or expiratory views.
Diaphragmatic eventration	No	Abnormal contour of the diaphragm affecting only asegment of the hemidiaphragm. Contrast this with diaphragmatic elevation whichaffects the entire hemidiaphragm.
Diffuse airspace opacity	Yes	Diffuse ill-defined airspace / ground glass opacity or consolidation throughout one or both lungs.
Diffuse fibrotic volume loss	Yes	Opacities within pulmonary lobules in a linear / branching fashion affecting one or both lungs. Upper and lower zones affected. Associated with volume loss(hilar displacement, diaphragmatic elevation, tracheal displacement). This also includes thickened chronic fibrotic changes from lung scarring.
Diffuse interstitial thickening	Yes	Opacities within pulmonary lobules in a linear / branching pattern affecting both upper and lower zones of one or both lungs. This also includes thickened chronic fibrotic changes from lung scarring.
Diffuse lower airspace opacity	Yes	Diffuse ill-defined airspace / ground glass opacity or consolidation in predominantly the lower zones of oneor both lungs. Does not include interstitial opacities. This finding maystill be predicted if there are upper zone changes as long as the pattern is lower zone predominant.
Diffuse nodular / miliary lesions	Yes	Multiple tiny lung opacities of one or both lungs. Usually innumerable and too small to measure. Maybe calcified.
Diffuse pleural thickening	No	Pleural masses / opacities in multiple locations. Pleuralmass is distinguished from intraparenchymal mass by having an obtuse angle with the pleura. Diffuse nodular pleural thickening must affect more than half the lung height or be bilateral and must be greater than 1cm in maximal thickness.

Finding	Localisation Available	Definition
Diffuse spinal osteophytes	No	Flowing osteophytes at the anterior or right lateral vertebral body connecting at least four contiguous vertebrae. Typically, smooth and thin connections.
Diffuse upper airspace opacity	Yes	Diffuse ill-defined airspace / ground glass opacity or consolidation in predominantly the upper zones of oneor both lungs. Does not include interstitial opacities. This finding maystill be predicted if there are lower zone changes as long as the pattern is upper zone predominant.
Distended bowel	No	Pathologically distended small or large bowel loops or stomach. Small bowel loops must measure > 3cm and large bowel loops > 6cm, or if the stomach causes mass effect upon the diaphragm. Air fluid levels may bepresent on erect view.
Electronic cardiac devices	No	Pacemakers, pacing wires (internal or external), internal defibrillators and loop recorders. ECG leads do not count as electronic cardiac devices.
In position Endotracheal Tube (ETT)	No	Endotracheal or tracheostomy tube within the tracheafor ventilation. Needs to be 3 to 7cm above the carina.
Focal airspace opacity	Yes	Single area of consolidation or air space / ground glassopacity in the lung. Air bronchogram may be present.
Gallstones	No	Calcified RUQ stones projected over the gallbladder.
Gastric band	No	Band around the gastro-oesophageal junction.
Hiatus hernia	No	Sliding or paraoesophageal hiatus hernia into the posterior mediastinum. Retrocardiac fluid level may bepresent.
Hilar lymphadenopathy	No	Increase in size and density of the hila with loss ofnormal hilar angle.
Humeral lesion	Yes	Sclerotic or lytic, malignant or benign lesion withinthe humerus with or without pathological fracture.This includes lesions due to systemic conditions such as myeloma, osteogenesis imperfecta, renal osteodystrophy etc.

Finding	Localisation Available	Definition
Hyperinflation	No	Increased total lung volumes as evidenced by flatteningof the diaphragm or increased retrosternal clear space on lateral view (or both).
Image obscured	No	Image obscured by object.
Inferior mediastinal mass	No	Masses within the mediastinum with the centre of themass below the superior border of the aortic arch.
Intercostal drain	Yes	This finding could mean either of the following: 1. Malpositioned intercostal drain: ICC with tip or side holes not within the pleural cavity, typicallymigrates out into the soft tissue. 2. In position intercostal drain: Catheter within the pleural space to drain fluid and / or gas.
Internal foreign body	Yes	Non-surgical internal foreign bodies such as inhaled foreign bodies, gunshot shrapnel that is internal to thepatient. This must be inside the patient and not a medical device. Does not include ECG leads or other objectsthat are external to the patient.
Kyphosis	No	Increased kyphosis of the thoracic spine with Cobbangle greater than 45 degrees on lateral view. Usually predicted off the lateral view.
Loculated effusion	Yes	Fluid within the pleural cavity that is trapped within afissure or at the apex or lateral wall on an erect view.
Lower zone fibrotic volume loss	Yes	Opacities within pulmonary lobules in a linear / branching pattern affecting one or both lungs. Lower zone predominant. Associated with volume loss (diaphragmatic elevation). This also includes thickenedchronic fibrotic changes from lung scarring. This finding may still be predicted if there are upperzone changes as long as the pattern is lower zone predominant.
Lung collapse	Yes	Collapse of the entire lung, or most of the lung.

Finding	Localisation Available	Definition
Lung sutures	No	Suture material within then lung parenchyma which is typically post lung resection.
Mastectomy	No	Absence or asymmetry of breast shadows suggesting mastectomy or partial mastectomy.
Mediastinal clips	No	Surgical clips in the mediastinum or hilum. Typically, small clips from coronary artery bypass grafts. Hilar clips from lung surgery also fall under this category.
Multiple masses or nodules	No	More than one pulmonary mass / nodule.
In position Nasogastric Tube (NGT)	Yes	Enteric tube from the mouth / nose into the stomach for feeding or drainage.
Neck clips	Yes	Any surgical clips in the neck.
Nipple shadow	No	Rounded well defined density projected over the expected locations of the nipple, sometimes bilateral. Must be prominent enough to be confused for a lesion.
Oesophageal stent	No	Stents within the oesophagus.
Osteopaenia	No	Severe reduced apparent bone density of the vertebrae such that there is difficulty distinguishing between bone and adjacent soft tissues even when windowing appropriately. Usually predicted off the lateral view.
Overexposed	No	Unable to see lung markings even after appropriate windowing. Only the primary AP or PA view is assessed, not the Lateral view or any other view / postprocessed image.
Patient rotation	No	The spinous process is laterally displaced by more than a quarter of the interclavicular distance. Only the primary AP or PA view is assessed, not the Lateral view or any other view / postprocessed image. If the patient is severely scoliotic, this finding may be unreliable.

Finding	Localisation Available	Definition
Pectus carinatum	No	Congenital chest wall deformity with anterior protrusion of the sternum. Only the primary AP or PA view is assessed, not the Lateral view or any other view / postprocessed image.
Pectus excavatum	No	Congenital chest wall deformity with concave depression of the sternum. Only the primary AP or PA view is assessed, not the Lateral view or any other view / postprocessed image.
Peribronchial cuffing	No	Thickening of the bronchial wall without dilation of the bronchial lumen.
Pericardial fat pad	No	Fat pad adjacent to the heart border. Can be mistaken for consolidation by referrers.
Perihilar airspace opacity	Yes	Diffuse perihilar airspace / ground glass opacity of one or both lungs. Does not include interstitial opacities. This finding can still be predicted if there are other changes as long as the pattern is perihilar predominant.
Pleural mass	Yes	Pleural mass / opacity in one location. Pleural mass is distinguished from intraparenchymal mass by having an obtuse angle with the pleura. A pleural mass is either nodular thickening of the pleura or pleural thickening greater than 1cm. The pleural mass should affect less than half the lung height and unilateral. Local pleural thickening less than 1cm is usually ignored.
Pneumomediastinum	No	Gas within the mediastinum, typically outlining the pericardium and mediastinal margin.
Post resection volume loss	Yes	Volume loss due to resection of lung e.g. pneumonectomy, lobectomy or segmentectomy, usually with staples / clips visible.
In position Pulmonary Arterial Catheter (PAC)	No	Pulmonary artery catheter with tip within the pulmonary artery or main pulmonary trunk.
Pulmonary artery enlargement	No	Enlargement of the pulmonary artery typically with loss of the aortopulmonary window. Width of the right descending pulmonary artery > 17mm on the PA film.

Finding	Localisation Available	Definition
Pulmonary congestion	No	Upper lobe diversion with loss of tapering of vesselstowards the apices with upper zone vessels having similar or larger diameter compared to lower zone

Only reliable on erect views |
| Reduced lung markings | No | Reduced lung markings. Distinguished from bullae asbullae will have a thin wall. |
| Rib fixation | Yes | Internal fixation of rib fractures.

May not be predicted if the fracture has been fixated. |
| Rib lesion | Yes | Sclerotic or lytic, malignant or benign lesion within therib with or without pathological fracture. This includeslesions due to systemic conditions such as myeloma, osteogenesis imperfecta, renal osteodystrophy etc.

Congenital rib anomalies such as bifid or fused ribs arenot included. |
Rib resection	No	Surgical removal of ribs - may be multiple. Typically, thoracotomies are performed for lung resection.
Rotator cuff anchor	Yes	Bone anchors within the humeral heads.
Scapular fracture	Yes	Cortical breach of the scapula. This includes bothacute and chronic fractures.
Scapular lesion	Yes	Sclerotic or lytic, malignant or benign lesion withinthe scapula with or without pathological fracture. This includes lesions due to systemic conditions such as myeloma, osteogenesis imperfecta, renal osteodystrophy etc.
Scoliosis	No	Increased lateral curvature of the thoracic spine withCobb angle greater than 10 degrees on frontal view.
Segmental collapse	Yes	Collapse of entire segment or lobe of the lung, or compressive collapse from adjacent pleural effusion.

Finding	Localisation Available	Definition
Shoulder arthritis	No	Loss of joint space, osteophyte formation, sclerosis and degenerative changes of the glenohumeral joint. Usually only predicted if there are significant changes – i.e. near complete loss of joint space.
Shoulder dislocation	Yes	Humeral head not articulating with glenoid fossa. Typically, anterior and inferior dislocation.
Shoulder fixation	Yes	Internal fixation of humerus or scapula fractures. May not be predicted if the fracture has been fixated.
Shoulder replacement	Yes	Total, partial or reverse total shoulder replacement.
Simple effusion	Yes	Fluid within the pleural cavity. In an erect radiographthis accumulates at the base. May form a meniscus.
Simple pneumothorax	Yes	Air within the thoracic cavity outside of the lung. Maybe associated with lung edge.
Solitary lung mass	Yes	Single rounded well-defined opacity. Measures 3cm orlarger.
Solitary lung nodule	Yes	Single rounded well-defined opacity. Measures lessthan 3cm.
Spinal fixation	No	Internal fixation of the spine for fractures or degeneration.
Spinal arthritis	No	Near complete loss of intervertebral space, fusion of vertebrae, or heavy calcification of intervertebral discsat multiple levels.
Spinal lesion	Yes	Sclerotic or lytic, malignant or benign lesion within thethoracic spine with or without pathological fracture. This includes lesions due to systemic conditions such as myeloma, osteogenesis imperfecta, renal osteodystrophy etc.

Finding	Localisation Available	Definition
Spinal wedge fracture	Yes	Acute or chronic compression, wedge, distraction or translated fractures. Typically seen on lateral view. Usually chronicity cannot be reliably assessed so this isnot differentiated. For compression or wedge fractures, there must bemore than 20% loss in anterior height or central height as measured to the nearest normal vertebra or posterior vertebral body height (whichever is larger).
Sternotomy wires	No	Metallic wires fixating a sternotomy.
Subcutaneous emphysema	Yes	Air within the soft tissues outside the abdominal or thoracic cavity. May be associated with pneumothoraxor pneumomediastinum.
Subdiaphragmatic gas	No	Gas below the diaphragm not contained within a lumen.
Suboptimal Central Line (CVC)	Yes	CVC or PICC line where the tip of the catheter is not positioned at the cavoatrial junction or the distal SVC,or if the catheter is looped or kinked.
Suboptimal Endotracheal Tube (ETT)	No	Endotracheal or tracheostomy tube that is too close to the carina or too far from it (not within 3 to 7cm), orwithin a bronchus.
Suboptimal gastric band	No	Band around the gastro-oesophageal junction with phiangle between the band and the spine not within 0 to 60 degrees. Malpositioned bands may be associated with oesophageal dilation.
Suboptimal Nasogastric Tube (NGT)	Yes	NGT where the tip and the sideholes are not projectedwithin the stomach, or the tip of the NGT is not visible and the image is cut-off within 5cm of the gastro- oesophageal junction. May be within the oesophagus or bronchus.
Suboptimal Pulmonary Arterial Catheter (PAC)	No	Pulmonary artery catheter with tip not in the main pulmonary trunk or pulmonary arterial branch e.g. in theright ventricle, or if the catheter is looped or kinked.

Finding	Localisation Available	Definition
Superior mediastinal mass	No	Masses within the mediastinum with the centre of the mass above the superior border of the aortic arch / lossof paratracheal stripes. If the patient is supine or rotated, the superior mediastinum can be widened due to benign causessuch as venous distension or projection.
Tension pneumothorax	Yes	Air within the thoracic cavity outside of the lung.May be associated with lung edge. Resultant mediastinal shift.
Tracheal deviation	No	Moving of the trachea across to one side secondary to increased pressure on one side or decreased pressure on the other side. Consideration of the extent of patient rotation must be taken into account.
Underexposed	No	Outline of any thoracic vertebral bodies not visible. Only the primary AP or PA view is assessed, not the Lateral view or any other view / postprocessed image.
Underinflation	No	The diaphragm is projected above the 9th posterior ribin a PA view or above the 7th rib in an AP view. Only reliable for inspiratory films. When this finding is predicted usually both lungs are underinflated.
Unfolded aorta	No	Widening of the aortic curve while maintaining a normalaortic diameter.
Upper interstitial thickening	Yes	Opacities within pulmonary lobules in a linear / branching pattern affecting predominantly upper zonesof one or both lungs. This also includes thickened chronic fibrotic changes from lung scarring. This finding can still be predicted if there are lower zone changes as long as the pattern is upper zonepredominant.

Finding	Localisation Available	Definition
Upper zone fibrotic volume loss	Yes	Opacities within pulmonary lobules in a linear / branching pattern affecting one or both lungs. Upper zone predominant. Has associated volume loss (hilar elevation). This also includes thickened chronic fibriotic changes from lung scarring. Includes apical scarring e.g. from previous TB. This finding can still be predicted if there are lower zone changes as long as the pattern is upper zone predominant.
Widened aortic contour	No	Widening of the aortic arch diameter to 4.5cm or greater or the descending aorta to 4cm or greater, typically due to aneurysm, dissection or rupture.
Widened cardiac silhouette	No	Increased cardiothoracic ratio > 0.5 on PA view and > 0.6 on AP view. Includes cardiomegaly and enlarged cardiac silhouette due to pericardial effusion. Measurement of heart diameter is taken from a single measurement, parallel to the measurement of the maximal diameter of the thoracic cage from the inner ribs. This finding is unreliable if the lungs are underinflated.

Symbol Glossary

Symbol	Information
CE	CE labelling in accordance with EC directive
(Manufacturer symbol)	Manufacturer
EC REP	European Authorised Representative
(Warning triangle symbol)	Indicates a warning or caution
(Instructions symbol)	Read the Instructions For Use
MD	Medical Device
UDI	Unique Device Identification
A→文	Translation

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