

Annalise Triage User Guide

US English (US)

Annalise Triage

OPT-PRM-103 v1

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Product overview

| Intended context | Annalise Triage is a device designed to be used in the medical care environment to aid in triage and prioritization of studies with features suggestive of the following findings: | | |
|--------------------------------|---|--|--|
| | Chest X-ray (CXR) | CT brain (CTB) | |
| | pleural effusion¹ pneumoperitoneum² pneumothorax tension pneumothorax | acute subdural/epidural hematoma³ acute subarachnoid hemorrhage³ intra-axial hemorrhage³ intraventricular hemorrhage³ | |
| | See Additional information on page 7. | | |
| | The device analyzes studies using an artificial intelligence algorithm to identify findings. It makes study-level output available to an order and imaging management system for worklist prioritization or triage. | | |
| | The device is not intended to direct attention to specific portions of an image and only provides notification for suspected findings. | | |
| | Its results are not intended: | | |
| | to be used on a standalone basis for to rule out specific findings, or other of CXR or CTB studies | or clinical decision making erwise preclude clinical assessment | |
| Intended modality | Annalise Triage identifies suspected fi | ndings in: | |
| | Chest X-ray (CXR) | CT brain (CTB) | |
| | Digitized (CR) or digital (DX) chest X-ray studies | Non-contrast brain CT studies | |
| Intended user | The device is intended to be used by trained clinicians who, as part of their scope of practice, are qualified to interpret: | | |
| | Chest X-ray (CXR) | CT brain (CTB) | |
| | Chest X-ray studies | Brain CT studies | |
| Intended patient population | The intended population is patients w | ho are 22 years or older. | |

Additional information

The following additional information relates to the findings listed above:

| Finding/s | Additional information |
|--|---|
| 1 Pleural effusion | specificity may be reduced in the presence of scarring and/or pleural thickening standalone performance evaluation was performed on a dataset that included supine and erect positioning use of this device with prone positioning may result in differences in performance |
| 2 Pneumoperitoneum | standalone performance evaluation was performed on a dataset that included supine and erect positioning where most cases were of unilateral right-sided and bilateral pneumoperitoneum use of this device with prone positioning and for unilateral left-sided pneumoperitoneum may result in differences in performance |
| 3 Acute subdural/epidural hematoma, acute subarachnoid hemorrhage, intra-axial hemorrhage and intraventricular hemorrhage | intended to be used together as one device |

Indications for use: Bone Health and Fracture Liaison Service programs

| Intended context | Annalise Triage is a device designed to be used in the medical care environment to aid in triage and prioritization of studies with features suggestive of the following finding: |
|-----------------------------|---|
| | Chest X-ray (CXR) |
| | vertebral compression fracture ¹ |
| - | See <i>Additional information</i> on page 9. |
| | The device analyzes studies using an artificial intelligence algorithm to identify findings. It makes study-level output available to an order and imaging management system for worklist prioritization or triage. |
| | The device is not intended to direct attention to specific portions of an image and only provides notification for suspected findings. |
| | Its results are not intended: |
| | to be used on a standalone basis for clinical decision making to rule out specific findings, or otherwise preclude clinical assessment of CXR studies |
| Intended modality | Annalise Triage identifies suspected findings in: |
| | Chest X-ray (CXR) |
| - | Digitized (CR) or digital (DX) chest X-ray studies |
| Intended user | The device is intended to be used by trained clinicians who, as part of their scope of practice, are qualified to interpret: |
| | Chest X-ray (CXR) |
| | Chest X-ray studies |
| Intended patient population | The intended population is patients who are 22 years or older. |

Additional information

The following additional information relates to the finding listed above:

| Finding/s | Additional information |
|-------------------------------------|---|
| 1 Vertebral compression fracture | intended for clinicians in Bone Health and Fracture Liaison service programs |
| | • standalone performance evaluation was performed on a dataset that included only erect positioning |
| | use of this device with supine positioning may result in differences in performance |

Contraindications

The device:

- is not intended to provide diagnosis
- is not to be used on patients under the age of 22 years
- does not enable an increase in the clinician's scope of practice

Warning



Qualified clinicians who interpret chest X-rays and/or brain CT scans as part of their scope of practice hold ultimate responsibility for interpreting studies.

The clinician must review the original chest X-ray images or brain CT scans and all other clinical information before making a clinical decision.

About Annalise Triage

| Device description | Annalise Triage is a medical device software application which uses artificial intelligence (AI) algorithms to prioritize suggested findings within a clinical triage workflow of radiological imaging studies. |
|-------------------------------|---|
| | It is compatible with image and order management systems such as picture archiving and communication systems (PACS) and radiological information systems (RIS). |
| | Annalise Triage contains the following:Annalise ViewerWorklist Triage |
| Annalise Viewer (optional) | The Annalise Viewer displays the AI results of adult chest X-ray studies and non-contrast CT brain studies. |
| Worklist Triage | Annalise Triage uses an AI algorithm to provide notification of selected findings for worklist prioritization and triage. This enables users to review the studies containing features suggestive of these clinical findings earlier than in the standard clinical workflow. |
| | The device workflow is performed parallel to and in conjunction with the standard clinical workflow for interpretation of chest X-ray studies and brain CT studies. |
| | The device is intended to aid in prioritization and triage of radiological medical images only. |
| | Configuration options |
| | Each organization can specify the findings that will result in triage and the priority of each finding. The exact functionality available depends on the worklist software used. |
| | Depending on the columns available in your worklist you can receive and display a study's AI priority in the worklist in either: |
| | a single 'Priority' column |
| | Annalise Triage will only triage findings with the highest rank. This ensures that it will <u>never</u> decrease a study's existing priority in the worklist. |
| | a dedicated 'AI priority' column |
| | Annalise Triage can triage findings with all ranks in the dedicated Al priority column. This ensures that any existing priorities are not changed. |
| | Note: Contact the Annalise.ai Professional Services Team for assistance with your preferred configuration. |
| | continued |

| Artificial intelligence (AI) algorithm | The Artificial Intelligence (AI) algorithms used in the device are convolutional neural networks trained on over 750,000 CXR and 200,000 CTB imaging studies. | |
|---|---|---|
| | The images used to train these algor with a range of patient demographics including different X-ray and CT man | ithms were sourced from datasets s and technical characteristics, ufacturers and machines. |
| Supported scan types | Annalise Triage supports the following scan types: | |
| | CXR | СТВ |
| | minimum one frontal (AP/PA)*up to three images in total | axial (coronal and sagittal views are generated by the axial view) |
| | <u>Note</u> : If a study contains more than three CXR images, the AI model will select a combination of the best three frontal/lateral images. | slice thickness up to and including 5mm non-contrast brain CT scans brain reconstruction kernel up to 1,000 images |
| | *Vertebral compression fracture also requires a la | ateral view. |
| Operating points | Operating points for each finding are deployment (with assistance from Ar | defined by your organization during nalise.ai). |
| | If you need to adjust an operating po internal IT support team who can the Annalise.ai. | int for your organization, contact your n request adjustments from |
| Active notification | Active notification services notify des finding and its priority within minutes | signated individuals of a suspected of being identified by Annalise Triage. |
| | Some of the findings identified by An notification. Refer to the <i>Annalise Tri</i> information and eligibility criteria. | nalise Triage are eligible for active <i>age Administration Guide</i> for further |
| Security features | Annalise Triage includes security fea unauthorized access and data modifi | tures which protect against ication. |
| | These features ensure the secure authentication and encryption of sensitive data when transmitted between: | |
| | the Annalise Triage Integration Ad Backend | lapter and the Annalise Triage |
| | the Annalise Viewer and the Anna the diagnostic viewer and the Anna HTTPS interface) | lise Triage Backend nalise Viewer (available when using the |
| | It also includes the encryption of sen Triage Backend. | sitive data stored in the Annalise |

Annalise product
compatibilityAnnalise Triage Backend Services (version 3.3) is compatible with Annalise
Viewer 3.4.

Installation and system requirements

Refer to the *Annalise Triage Administration Guide* for details about system requirements and installation.

Annalise Viewer

Annalise Viewer functions

OverviewThe following section outlines the functions available on the Annalise
Viewer for both CXR and CTB studies.

If your organization has enabled the feedback function, extra functions will display when you are in 'feedback mode'.

See Feedback mode on page 19

Main components The Annalise Viewer includes the Image Panel and the Findings List.



For further details, see:

- Image Panel: CTB on page 16
- Image Panel: CXR on page 17
- *Findings List* on page 18
- Study Details Panel (CXR only) on page 18
- Feedback mode on page 19

Image Panel: CTB Components and functions of the Image Panel (for CTB studies) are shown below.

See Image Panel functions on page 20.



Image Panel: CXR Components and functions of the Image Panel (for CXR studies) are shown below.

See Image Panel functions on page 20.



Findings ListComponents and functions of the Findings List are shown below.See Findings List functions on page 21.



Study Details Panel (CXR only)

Components and functions of the Study Details Panel are shown below. See *Study Details Panel functions (CXR only)* on page 22.



Feedback mode If the feedback function has been enabled by your organization, some or all of the following options will display, depending on the type of feedback enabled.

See Feedback mode functions on page 23.

Feedback mode: Findings List (AI model feedback)



Feedback mode: Findings List (Trial feedback)



Image Panel functions

The Image Panel is located on the left of the Findings List.

It displays the current image associated with the selected finding and also enables you to access different views of the study.

The following functions display on the Image Panel:

| Function | Details |
|-------------------------------|--|
| View switcher | The View switcher icons enable you to switch between image views. |
| | The following views are available for CXR studies:Frontal |
| | Lateral (may not be present if not processed) |
| | The following views are available for CTB studies:AxialSagittalCoronal |
| | The active view is highlighted. |
| Finding name | The Finding name displays the name of the finding selected in the Findings List. |
| Width/level (CTB only) | The Width/level indicates the predetermined width and level of the selected grayscale spectrum: |
| | W – indicates window width |
| | L – indicates window level |
| Window presets (CTB only) | Window presets enable you to view the following pre-configured options (for CTB studies): |
| | • Brain |
| | • Bone |
| | Stroke |
| | Subdural Tissue |
| | |
| | When you select an option, the associated width/level values display (see <i>Width/level</i> , above). |
| | The active window is highlighted. |
| Slice scrollbar (CTB only) | The Slice scrollbar enables you to scroll through all available slices for the current CTB study (see <i>Scroll thumb/Current slice</i> , below). |
| Scroll thumb/Current slice | The Scroll thumb/Current slice enables you to scroll through the images. |
| (CTB only) | It also indicates the current slice position in the Slice scrollbar . |
| Scroll direction | The Scroll direction displays at both ends of the Slice scrollbar. |
| (CTB only) | These indicators show the direction you are moving in as you scroll through the images. |

Findings List functions The Findings List is located on the right of the Image Panel.

It displays details about the patient and the modality as well as information about the current study and its associated findings.

By default, the findings display in order of clinical severity (as determined by Annalise.ai expert radiologists), but you can configure this order to meet your requirements.

The Findings List enables you to access:

- the Help and Settings functions, and
- other analyzed images (for CXR studies).

See Study Details Panel (CXR only) on page 18.

The following functions display on the Findings List:

| Function | Details |
|-----------------|--|
| Patient details | The following patient details display for the current study: Name Age Gender Patient ID Date of birth (DOB) Note: You can choose how you would like the patient's name to display (see <i>Set user preferences</i> on page 30). Your organization may have also configured the patient ID label and/or date format used in the Annalise Viewer. If so, the details you see may not match the images in this guide. |
| Modality type | The Modality type indicates the current modality (i.e. 'Chest X-ray' or 'CT Brain'). It also displays the total number of findings for the current study. |
| Study details | The Study details display the following: study date* and time <i>The date and time the X-ray/CT machine recorded the study.</i> either: CTB: The series number within the current study and the series description, or CXR: The number of other analyzed images for the study study description <i>If the description is more than 64 characters, an ellipsis ('') will display at the end, indicating that there is further information in this field. If this occurs, hover your mouse over the ellipsis to see the full description.</i> accession number <i>A unique number used to identify a diagnostic report. All images within a study will have the same accession number.</i> *Note: Your organization may have configured the date format used in the Annalise Viewer. If so, the details you see may not match the images in this guide. |

continued

| Function | Details |
|----------------|---|
| Findings | The suspected radiological findings detected by the AI model. If you hover over a finding in the Findings List: it will be highlighted purple in the Findings List, and this finding will display on the Image Panel. If the model does not detect supported findings, a message will display to indicate that AI processing is complete. |
| Finding count | The Finding count that displays beside each finding group indicate the number of findings in that group. |
| Finding groups | Finding groups are located on the Findings List. All findings are grouped according to status or type. Each finding has both a pre-defined display order and a group to which it belongs. The default group is called 'Suspected Priority Findings'. Your organization can request to configure the following: group names displaying certain findings only adding another group, and/or determining the findings that display within each group. Note: All finding groups will start with the prefix 'Suspected'. Note: As the first group will always contain findings that are more clinically relevant (regardless of whether it is called 'Suspected Priority Findings' or has another name), it cannot be collapsed. |

Study Details Panel functions (CXR only)

The Study Details Panel displays for CXR studies only. It enables you to view up to three of the images that were analyzed to produce the Al findings.

Click the **Study details** area in the Findings List to display the Study Details Panel (see *Findings List* on page 18).

| Function | Details | |
|-------------|--|--|
| Study date | Displays the date that the X-ray machine recorded the images. <u>Note</u> : Your organization may have configured the date format used in the Annalise Viewer. If so, the details you see may not match the images in this guide. | |
| View | Indicates the view from which the image was taken. | |
| Series time | Displays the time that the X-ray machine recorded the image. | |

| Feedback mode functions | The following extra functions display on the Findings List and Image Panel while you are using the Annalise Viewer in 'feedback mode' (see <i>Provide feedback</i> on page 33). |
|----------------------------|---|
| | recuback on page 55). |
| | |

- <u>Note</u>: The feedback feature is not to be used for reporting product complaints. If you have a product complaint or urgent product feedback, see *Support and feedback* on page 39.
- <u>Note</u>: Feedback mode is only available if it has been enabled by your organization.

| Function | Details | |
|-----------------------------|---|--|
| Feedback button | The Feedback button enables you to enter feedback mode and provide feedback about the AI model's performance. | |
| | <u>Note</u> : This button only displays if the feedback function has been enabled for your organization. | |
| Study processed incorrectly | The Study processed incorrectly button enables you to indicate that Annalise.ai either should or should not have processed the study. | |
| Add finding | The Add finding button enables you to add a finding that is missing from the study (i.e. was not identified by the Al model). | |
| Reject finding | The Reject button enables you to reject a finding. | |
| Undo reject | The Undo reject button enables you to 'unreject' a finding that you have rejected and reinstate it in the Findings List. | |
| Important find | The Important find button displays when you hover your mouse over a finding. It enables you to flag an important finding that the Al model has identified and triaged. | |
| | <u>Note</u> : This option is only available if your organization has enabled the 'trial' feedback function. | |
| AI Feedback | The AI Feedback questions enable you to provide specific feedback about the Annalise Viewer. | |
| | <u>Note</u> : This option is only available if your organization has enabled the 'trial' feedback function. These questions can be customized for your organization. | |
| Optional comments | The Optional comments field enables you to provide additional feedback comments about the Annalise Viewer. | |
| | <u>Note</u> : This option is only available if your organization has enabled the 'trial' feedback function. | |
| Submit feedback | The Submit feedback button enables you to save and submit any feedback you have added. | |
| | <u>Note</u> : This option is only available if your organization has enabled the 'trial' feedback function. | |

Getting started

| Overview | This section shows you run the Annalise Vie launch the Annalise access Annalise Tria access initial function set your user preference | i how to: wer Adapter (if required) Viewer age (via either single sign-on or legacy access) ons, and ences. | |
|--------------------------------|--|---|--|
| Run Annalise Viewer Adapter | Depending on the type the Annalise Viewer Ad | of PACS that you are using, you may need to run apter to access the Annalise Viewer. | |
| | If you are using a Sectr see whether the <i>Annali</i> installed on your comp | a IDS7 PACS, contact your system administrator to <i>ise Viewer Adapter for Sectra IDS7</i> has been uter. | |
| | For full details about in Annalise Viewer Adapte | stallation and system requirements, refer to the <i>er for Sectra IDS7 Administration Guide</i> . | |
| Launch Annalise Viewer | You can choose whether you want the Annalise Viewer to display automatically when you view a study in the PACS/RIS or you can open it manually. | | |
| | <u>Note</u> : Your options may depend on the integration capabilities of your PACS/RIS. | | |
| | Once open, the Annalis study. | e Viewer displays the Al results for the current | |
| 1. | Open the PACS/RIS wo | rklist. | |
| | If the Annalise Viewer doesn't automatically display, you can either: open it manually, or update your user settings so that it displays automatically (if available). | | |
| | Open Annalise Viewer manually | Either: open the Annalise Viewer via the Start menu on your computer, or click the button on the PACS/RIS viewer menu bar. | |
| | Update settings to open Annalise Viewer automatically | See Automatically show findings on page 31. | |

Access Annalise Triage (using single sign-on) Single sign-on enables you to sign into both Annalise Triage and your Microsoft work account using a single set of credentials.

If your organization has enabled single sign-on, you will need to enter your username and password via your internet browser through Microsoft.

<u>Note</u>: If you want to view the Annalise.ai *Privacy Policy* before you log in, click **Privacy policy** (then navigate back to the *Secure sign in* window once you have finished).



- 1. Click Sign in with Microsoft.
- **2.** On the sign-in screen that displays, type your username and password (as provided by your organization).

Once you have successfully signed in:

| If this is the first time you have signed into Annalise Triage | a window will display, prompting you to read the <i>User Guide</i> go to <i>Read User Guide</i> on page 26 |
|---|---|
| If you have signed in previously and chosen to hide the <i>User Guide</i> prompt | the Annalise Viewer will automatically display the Al results for the current study |

Read User Guide

Ensure that you read the *User Guide* so that you understand the features and limitations of the device as well as the indications for appropriate use.

| 🛆 Annalise |
|---|
| |
| Please read the User Guide before clinical use |
| Ensure you understand features, limitations and indications for appropriate use. |
| ▲ Not intended to provide diagnosis ▲ Read User Guide before use |
| > Guides are available at annalise.ai/Guides |
| Next |
| Don't show again |

- 1. Click the option to open the Annalise.ai guides, then read the User Guide.
- 2. If you don't want this window to display again, click to select the **Don't** show again checkbox.

<u>Note</u>: You can still access the *User Guide* via the **Help** button at the top of the Annalise Viewer (see *Access initial functions* on page 28).

3. When you have finished, click Next.

The Annalise Viewer will display the AI results for the current study.

Access Annalise Triage (using legacy access) If your organization has not enabled single sign-on, the following will occur when you first access Annalise Triage:

- a window will display prompting you to read the User Guide
- a message will prompt you to add your server settings (refer to the *Annalise Triage Administration Guide* for details)

Read User Guide

Ensure that you read the *User Guide* so that you understand the features and limitations of the device as well as the indications for appropriate use.

- 1. Click the option to open the Annalise.ai guides, then read the User Guide.
- 2. If you don't want this window to display again, click to select the **Don't** show again checkbox.
 - <u>Note</u>: If you select this checkbox, the Annalise Viewer will automatically display the AI results for the current study the next time you access Annalise Triage.

You can still access the *User Guide* via the **Help** button at the top of the Annalise Viewer (see *Access initial functions* on page 28).

3. When you have finished click Next.

The Annalise Viewer will display the AI results for the current study.

Access initial functions

Once open, the Annalise Viewer will display the AI results for the current study.

Study loading

The following will display (and the loading indicator will spin) while the study is loading:



Study loaded

Once the study has loaded, the Findings List on the Annalise Viewer will either be collapsed or expanded, depending on the **Settings** options you choose.

See *Automatically show findings* on page 31.

| Findings list collapsed | | Findings list expanded | |
|--------------------------------|-----------------------------|--|-----------------------------|
| Annalise | @ \$ × | Annalise | @ \$ × |
| Alex Perez PID: 11.11.11.11 | 87Y. M DOB: 13 Jan. 1934 | Alex Perez PID: 11.11.11.11 | 87Y. M DOB: 13 Jan. 1934 |
| ✓ Chest X-ray | 2 | ✓ Chest X-ray | 2 |
| ACC: 1.4.372.03.7691 | | 4 Mar. 2022 - 4:17:29 PM 3 images ACC: 1.4.372.0.3.7691 | |
| | | Suspected Priority Findings | 2 |
| | | < Pneumothorax | \$ × € |
| | | < Tension pneumothorax | ☆ × |
| | | | |

Initial functions

| Action | Details | |
|----------------------|--|--|
| Loading indicator | When you first launch the Annalise Viewer, the Loading indicator will spin to indicate that the study is loading. | |
| Access Help | Click the Help button to: • view the Annalise Viewer version and UDI • access the related User Guide, Performance Specifications, Legal Notices and Privacy Policy • Annalise • Initial triage support • Annalise VERSION Viewer: 3.4.0 UDI: *+G140ANNALISEENTP30/\$\$+7VE-C-3.4.0Y* • Viewer: 3.4.0 UDI: *+G140ANNALISEENTP30/\$\$+7VE-C-3.4.0Y* • User Guide to provide diagnosis • Performance Specifications • Legal Notices • Privacy Policy • Close Click the Close button to return to the Annalise Viewer. | |
| Set user preferences | Click the Settings button to update your user preferences (see Set user preferences on page 30). <u>Note</u>: If you are using legacy access and need to update your server settings, contact the Annalise.ai Professional Services Team for assistance. Click the Close button to return to the Annalise Viewer. | |
| Close viewer | Click the Close button to minimize the Annalise Viewer so that it displays on your task bar. The viewer will automatically re-open when there are new Al findings to display. | |
| Move viewer | To move the Annalise Viewer to another location or screen, click the viewer then drag it to the required position. | |
| Close application | To close the application, right click the Annalise icon on your task bar then select Quit . | |

Set user preferences Follow these steps to access the *Settings* screen to select your user preferences.

 Click the Settings button at the top right of the Annalise Viewer. The Settings screen displays.

| If using legacy access | If using single sign-on |
|-----------------------------------|-----------------------------------|
| \bigwedge Annalise | Annalise |
| Settings | Settings |
| Changes take effect immediately | Changes take effect immediately |
| VIEWER SIZE | VIEWER SIZE |
| 100% | 100% |
| DISPLAY | DISPLAY |
| Optimize for grayscale (CXR only) | Optimize for grayscale (CXR only) |
| Automatically show findings | Automatically show findings |
| Automatically expand groups | Automatically expand groups |
| INACTIVE VIEWER MINIMIZE IN | INACTIVE VIEWER MINIMIZE IN |
| 5 minutes | 5 minutes |
| NAME DISPLAY | NAME DISPLAY |
| (Given name) (Family name) \sim | (Given name) (Family name) |
| | LOGGED IN AS |
| Close | email@annalise.ai |
| | Logout |
| | |
| | Close |

continued

2. Select your user preferences.

If you are using single sign-on, you can also:

- view the email of the user who is currently logged in, and
- click Logout to log out of Annalise Triage.

| Option | Details |
|---------------------------------------|---|
| Viewer size | Click to select the size that you want the viewer to display on your screen. |
| Optimized for grayscale (CXR only) | This option enables you to optimize the grayscale image: if you select this option (for example, if your CXR radiography monitor is grayscale only), the user interface will remove reliance on colors to display findings if you <u>don't</u> select this option, the user interface will use color to highlight a finding's name |
| Automatically show findings | This option enables you to automatically show findings when you are viewing a study: if you select this option, the Findings List will automatically display the findings if you <u>don't</u> select this option (or if the automatic option is not |
| | available), you will need to manually expand the Findings List: open the Annalise Viewer (see <i>Open Annalise Viewer manually</i> on page 24) click the Modality type on the Findings List (see <i>Modality type</i> on page 21) |
| Automatically expand groups | This option enables you to automatically expand all finding groups when the Findings List displays: if you select this option, all groups will be expanded if you <u>don't</u> select this option, only the 'Suspected Priority Findings' group (or your organization's equivalent) will be expanded See <i>Finding groups</i> on page 22. |
| Inactive viewer minimize in | Select the inactive time period after which the viewer will be automatically minimized. |
| Name display | You can choose how you would like the patient name to display. Options include: (Given name) (Family name) (Family name) (Given name) (Family name), (Given name) |

3. When you have finished, click **Close** to return to the Annalise Viewer.

Using the Annalise Viewer

Review Al findings The Annalise Viewer displays the suspected radiological findings for a study in the Findings List (the results that display depend on the configuration set by your organization).

This section shows you how to:

- verify the patient's details
- review the findings

Verify patient details

1. Launch the Annalise Viewer.

See Launch Annalise Viewer on page 24.

- To verify the patient's details, check that the Patient ID and Accession No. (ACC) on the Findings List match those on the study loaded in the PACS viewer.
 - <u>Note</u>: Your organization may have configured the patient ID label used in the Annalise Viewer. If so, the details you see may not match the images in this guide.

Review the findings

Multiple findings may display. In these instances, it is important to use your clinical judgement when reviewing all findings.

1. Use the following functions to help you review the findings:

| Function | Details |
|--|---|
| Show images analyzed for the current study | Select a finding in the Findings List to display it in the Image Panel: For <u>CXR</u> studies, you can view: both the current image in the Image Panel, and up to three other images that have been analyzed for the current study (click the Study details on the Findings List to display these images) See <i>Study Details Panel (CXR only)</i> on page 18. For <u>CTB</u> studies, all of the images display in the Image Panel. Click and drag the Scroll thumb (or use your mouse wheel) to scroll through these images. See: <i>Scroll thumb/Current slice</i> on page 20 <i>Slice scrollbar</i> on page 20 |

continued

| Function | Details |
|---|--|
| Switch between views | To switch between views, click the View Switcher to navigate to other available views (the highlighted icon indicates the active view). |
| | You can also use the Width/level to view the relevant pre- configured window presets. |
| | See: |
| | • View switcher on page 20 |
| | <i>Width/level</i> on page 20 |
| Identify the number of findings present | A number displays in the following locations to indicate the number of findings identified by the AI model: |
| | • beside the Modality type (total number of findings), and |
| | next to each findings group (total for that group). |
| | See Finding count on page Error! Bookmark not defined |

Provide feedback The feedback function enables you to provide feedback about the Al model's performance.

Depending on the feedback mode you are using, you can:

- flag an incorrect study
- add missing findings
- reject (and 'unreject') findings
- mark findings as an 'important find'
- <u>Note</u>: The feedback feature is not to be used for reporting product deficiencies. If you have feedback about a product deficiency, see *Support and feedback* on page 39.

The following types of feedback are available:

| Feedback mode | Usage |
|-------------------|---|
| Trial feedback | Usually enabled when you are using Annalise Triage as part of an evaluation during a trial period. |
| | 1. Refer to the table below for feedback options. |
| | 2. To save and submit your feedback, click Submit feedback . |
| Al model feedback | Your organization can choose to switch this function on or off. |
| | If the feedback options don't automatically display, go to the bottom right of the Findings List and click the Feedback ('flag') button (see <i>Feedback mode: Findings List (Al model feedback)</i> on page 19). |
| | 2. Refer to the table below for feedback options. |
| | 3. To save and submit your feedback, click the Feedback button again. |

continued

Feedback options

| Option | Steps |
|--|---|
| Flag an incorrect study | If a study has been incorrectly processed, click the Study processed incorrectly ('flag') button at the top of the Findings List. |
| | To undo this action, click the button again to remove the flag. |
| Add a missing finding | If a finding is missing from the study: 1. Click Add Finding at the bottom of the Findings List 2. Type the name of the finding in the Enter Finding field if the finding displays, click to select the finding if the finding <u>doesn't</u> display, type the full name of the finding, then click Add New The new finding will display under the User added finding group. See Finding groups on page 22. |
| Reject an incorrect finding | If you determine that an AI finding that displays in the Findings List is not present in the study, click the Reject button beside the finding name. The finding name will display as strikethrough text. |
| Undo a rejected finding | If you have rejected a finding but want to undo this action (and reinstate the finding in the Findings List), click the Undo Reject button beside the finding name. |
| Mark a finding as an 'important find' | If you determine that the AI model has identified an important finding that may otherwise have been missed, click the Important find button. <u>Note</u> : This option can only be used during trial feedback. |
| Feedback questions | Click to select any question/s if they apply. |
| | <u>Note</u> : This option can only be used during trial feedback. The questions can be customized for your organization. |
| Provide extra | Type any extra comments in the Optional Comments field. |
| comments | Note: This option can only be used during trial feedback. |

Troubleshooting and support

Troubleshooting

| Problems and solutions | If you have issues with the Annalise Triage application, refer to the following table. | | |
|------------------------|---|--|--|
| | If you are unable to resolve the issue, contact the Annalise.ai Professional Services Team. | | |
| | Problem | Solution | |
| | Software version | Refer to the Annalise Triage Administration Guide. | |
| | How do I know which software version I am using? | | |
| | Product support | Refer to your organization's contract for details | |
| | When is my product no longer supported? | | |
| | Missing server settings | Contact the Annalise.ai Professional Services | |
| | Organization details are incomplete. | | |
| | Triage functionality | Contact the Annalise.ai Professional Services | |
| | Triage functionality seems inactive, or triage results are not accurate. | | |
| | Application unresponsive | Follow these steps: | |
| | After loading a study in the PACS viewer, the Annalise Viewer does not respond. | Check that the study is a CR (Computed Radiography), DX (Digital Radiography) or CT brain. Out the Annelies Viewer than one it ensite | |
| | | 2. Quit the Annalise Viewer, then open it again. 3. Attempt to re-load the study. | |
| | | If the problem persists, contact the Annalise.ai Professional Services Team. | |
| | Application unresponsive with | Follow these steps: | |
| | Sectra PACS The Annalise Viewer is unresponsive when a study is loaded. | Ensure the Annalise Viewer Adapter is running in the System Tray. | |
| | | Ensure the Sectra Desktop Sync functionality is enabled. | |
| | Sectra PACS warns the viewer is out of sync. | 3. Quit then restart the Annalise Viewer Adapter. | |
| | | for assistance. | |
| | Unexpected finding change When viewing a study, the Al findings change unexpectedly. | Some software systems may encounter this error when viewing studies in multiple windows. | |
| | | The Annalise Viewer will synchronize with the currently selected window. | |
| | | Ensure that the shortcut key mapping in the PACS viewer is mapped correctly. | |

continued

| Problem | Solution |
|--|--|
| Out of scope study After loading a study in the PACS viewer, the following error displays: 'Must be 22 yrs+ for Al analysis' | Annalise Triage only supports studies for patients who are 22 years or older. Annalise Triage uses DICOM tags to determine age. |
| Maintenance The following message displays: 'Maintenance in progress. Annalise.ai will be available soon' Out of scope study After leading a study in the PAOC | The application is currently undergoing maintenance (such as installing upgrades). Once maintenance is complete, you will be able to use the application as normal. The study does not meet the minimum requirements for Al processing: |
| After loading a study in the PACS viewer, one of the following errors displays in the Annalise Viewer: 'PA/AP image required for Al analysis' 'Chest X-ray required for Al analysis' 'Chest X-ray required for Al analysis' 'Study not supported' 'Unable to detect a non-contrast brain series' 'Unable to detect series for processing' 'Slice thickness is above the threshold of XX mm' 'Slice thickness is below the threshold of XX mm' Error codes: 007, 008, 032, 033, 034, 035, 036, 037, 038, 039, 040, 041, 042, 043, 044, 045, 046, 047, 048, 049, 050, 051, 053 | Annalise Triage only supports studies containing chest X-rays or brain CTs the study must contain at least one PA or AP image or supported CT views (see <i>Supported scan types</i> on page 12) Annalise Triage includes an AI feature that determines whether: the image is a chest X-ray or brain CT, and if there is a PA or AP image or supported brain image. Al models have an error margin. On rare occasions, Annalise Triage will not recognize a chest X-ray or brain CT and this error will display. For further details, contact the Annalise.ai Professional Services Team and quote the error code. |
| Not processing After loading a study in the PACS viewer, the following message displays in the Annalise Viewer: <i>Results pending</i> | The study is currently being analyzed. The application will wait for up to one minute for results. If the problem persists, contact your internal IT support team. |
| Error 004 After loading a study in the PACS viewer, the following message displays in the Annalise Viewer: 'Cannot reach Annalise.au servers: (Error: 004) Please contact support' | Check your internet connection. If your internet connectivity is OK and the problem continues, contact your internal IT support team. |

continued

| Problem | Solution |
|---|--|
| No results After loading a study in the PACS viewer, the following error displays | Either the study is not supported, or the study may not have reached the Annalise Triage Integration Adapter. |
| in the Annalise Viewer: <i>'No results available'</i> | If the study was recently performed, it may not have been forwarded to Annalise Triage. |
| | If the problem continues, contact your internal IT support team. |
| Study processing After loading a study in the PACS viewer, the following error code displays in the Annalise Viewer: <i>'Error: 029'</i> | The study has not yet completed AI processing. Wait for a while and try again. If the problem continues, contact your internal IT support team. |
| Other error codes | Technical product error. |
| After loading a study in the PACS viewer, one of the following error codes displays in the Annalise Viewer: <i>001, 002, 003, 009, 010, 011, 014, 015, 016, 020, 021, 022, 026, 027, 031, 099</i> | Contact the Annalise.ai Professional Services Team and quote the error code. |

Support and feedback

Refer to the following table for support and feedback details:

| Support type | Details |
|---|--|
| Professional services, technical support, product feedback and complaints | Email <i>support@annalise.ai</i> Any serious incidents related to Annalise Triage should be reported to Annalise.ai and the competent authority or regulatory authority in which the user and/or patient is established. |
| Product user, performance and administration guides | Check our website: annalise.ai/guides |

Symbol glossary Definitions of symbols that may appear on the Annalise product or in the related documentation are listed below.

| Symbol | Information |
|---|--------------------------------|
| | Manufacturer |
| $R_{\!$ | Prescription only |
| \triangle | Indicates a warning or caution |
| | Read the instructions for use |
| MD | Medical device |

Appendices

OverviewThe following tables specify the chest X-ray and brain CT findings
supported by the Annalise Triage device.For information on the performance of the AI model, refer to the Annalise
Triage Performance Guide.

Annalise CXR findings list

The Annalise CXR findings list is outlined below.

| Finding | Definition |
|--------------------------------|---|
| Pleural effusion | Unilateral or bilateral fluid within the pleural cavity. |
| | May be simple or loculated. May form a meniscus. Present on at least one projection (PA, AP, lateral). |
| Pneumoperitoneum | Gas below the diaphragm not contained within a lumen. |
| Pneumothorax | Air within the thoracic cavity outside of the lung. |
| | May be associated with lung edge. May have features of tension. |
| Tension pneumothorax | Air within the thoracic cavity outside of the lung. May be associated with lung edge. Resultant mediastinal shift. |
| Vertebral compression fracture | Acute or chronic compression, wedge, distraction or translated fractures. Typically seen on lateral view. |
| | Usually chronicity cannot be reliably assessed so this is not differentiated. |
| | For compression or wedge fractures, there should be more than 20% loss in anterior height or central height as measured to the nearest normal vertebra or posterior vertebral body height (whichever is larger). |

Annalise CTB findings list

The Annalise CTB findings list is outlined below.

| Finding | Definition |
|----------------------------------|---|
| Acute subdural/epidural hematoma | Acute or subacute subdural or epidural hematoma. Includes acute on chronic subdural hematoma. |
| | Does not include chronic subdural hematoma (hypodense collection). |
| Acute subarachnoid hemorrhage | Acute subarachnoid hemorrhage of any cause (e.g. aneurysmal, trauma or amyloid angiopathy). |
| Intra-axial hemorrhage | Hemorrhage into the brain parenchyma from any cause (e.g. hemorrhagic contusion, hemorrhagic infarct, hypertensive bleed, diffuse axonal injury). |
| Intraventricular hemorrhage | Acute hemorrhage (hyperdense) within the ventricular system. |
| | It causes fluid/fluid levels that are usually seen in posterior horns of lateral ventricles. Can be due to trauma, intraventricular extension of hemorrhagic lesions. |

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