

### **Annalise Enterprise**

# Administration Guide

English

### **Annalise Enterprise**

### OPT-PRM-028 v5

This guide is applicable to Release 3.3 and Release 3.4.

#### Release 3.3 includes:

- Annalise Viewer version 3.4
- Annalise Backend version 3.3
- Annalise Integration Adapter version 3.3

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#### Release 3.4 includes:

- Annalise Viewer version 3.4
- Annalise Backend version 3.4
- Annalise Integration Adapter version 3.4









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### **Overview**

#### Introduction

This document provides an overview of the Annalise Enterprise product, including component requirements, supported capabilities, available customisations and configuration backup and security details.

It also shows you how to install and configure the Annalise Viewer and configure your PACS to interface with the Annalise Enterprise product.

#### Who

This document is for IT administrators and support staff only. It is not intended to be used by clinical users.

For the clinical use of this product, please refer to the *Annalise Enterprise User Guide*.

### Intended purpose

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

### Indications for use

Annalise Enterprise identifies suspected findings in:

- digitised (CR) or digital (DX) chest X-ray studies taken in the anteriorposterior (AP) or posterior-anterior (PA) and optionally lateral (LAT) orientations of adult patients
- non-contrast brain CT scans (brain kernel) of adult patients

For chest X-ray (CXR), the device improves the detection of radiological findings visible on chest X-rays. For CT Brain (CTB), the device improves the detection of radiological findings visible on non-contrast CT brain scans.

The device identifies 124 CXR findings and 130 CTB findings (as defined in the *Annalise Enterprise User Guide*).

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

The device may also be configured to provide input to worklist software to assist with notification and triaging. The device identifies studies with selected findings and communicates these studies to the worklist software which enables triaging of the worklist and notification.

### Contraindications

### The device:

- is not intended to provide direct diagnosis
- is not to be used on patients under the age of 16 for CXR and under the age of 18 years for CTB
- does not enable an increase in the clinician's scope of practice

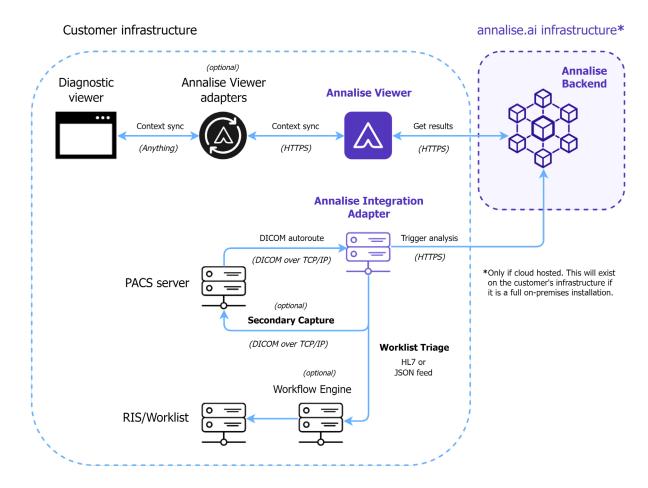
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### **Annalise Enterprise overview**

### **Annalise Enterprise**

Annalise Enterprise contains the following three sub-systems:

- Annalise Integration Adapter
- · Annalise Backend
- Annalise Viewer



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### Annalise Integration Adapter

The Annalise Integration Adapter receives images from the PACS server and converts the images and metadata into the appropriate format.

It then sends a trigger to the Backend API services to request AI processing.

The Annalise Integration Adapter can be configured to:

- send information to a worklist software (such as a RIS) to request a change in the study's priority in the worklist
- send Al results in the form of a Secondary Capture DICOM series to the PACS server

The Annalise Integration Adapter also:

- provides a stable interface between the PACS and RIS within the customer's network
- encrypts all data moving between the Annalise Integration Adapter and the Annalise Backend
- acts as a buffer with the Annalise Backend in the event of network outages

#### Annalise Backend

The Annalise Backend filters images, performs Al processing and stores results. It includes both Backend API services and the Al model.

The Backend API is responsible for performing the business logic of Annalise Enterprise. It manages:

- security for incoming requests from the Annalise Integration Adapter and the Annalise Viewer
- the storage of images and results (including periodic deletion of data as required by the customer)
- requests and responses from the Al Model, Annalise Viewer and Annalise Integration Adapter

The AI model includes AI algorithms (convolutional neural networks) and image pre-processing and post-processing modules. It processes a study's X-ray or CT images and generates suspected radiological findings and localisation information for that study.

#### Annalise Viewer

The Annalise Viewer is a desktop application that receives details about a patient's study from the PACS viewer then retrieves the study's results from the Annalise Backend.

The Annalise Viewer displays the Al results in its own window, enabling the user to review the study's suspected findings and localisation alongside the study's original images.

The Annalise Viewer application is installed on each workstation on the customer's network.

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### Annalise product compatibility

Annalise Enterprise Backend Services compatibility is as follows:

Release	Compatible with	
v3.3	<ul><li>Annalise Integration Adapter 3.1, 3.2, 3.3</li><li>Annalise Viewer 3.1, 3.2, 3.4</li></ul>	
v3.4	<ul><li>Annalise Integration Adapter 3.1, 3.2, 3.3, 3.4</li><li>Annalise Viewer 3.1, 3.2, 3.4</li></ul>	

### Supported capabilities

The following tables outline the supported DICOM capabilities of Annalise Enterprise.

### These include:

- inputs that can be received by Annalise Enterprise, and
- outputs that are available from Annalise Enterprise.

### Inputs received by Annalise Enterprise

Supported inputs	Details	
Supported body part imaging	<ul><li>CXR: Chest X-ray</li><li>CTB: Non-contrast brain CT scan</li></ul>	
Supported scan types	<ul> <li>CXR:         <ul> <li>minimum one frontal (AP/PA) required for processing</li> <li>up to three images in total</li> </ul> </li> <li>lateral (LAT) is also supported</li> <li>Note: If a study contains more than three chest X-ray images, the Al model will select a combination of the best three frontal/lateral images.</li> <li>CTB:         <ul> <li>axial (coronal and sagittal views are generated by the axial view)</li> <li>slice thickness up to and including 1.5mm</li> <li>non-contrast CT brain scans</li> <li>brain reconstruction kernel</li> </ul> </li> </ul>	
Supported DICOM SOP class	<ul> <li>up to 1,000 images</li> <li>CXR:</li> <li>Computed Radiography (CR) – 1.2.840.10008.5.1.4.1.1.1</li> <li>Digital Radiography (DX) – 1.2.840.10008.5.14.1.1.1.1</li> <li>CTB:</li> <li>CT Image Storage – 1.2.840.10008.5.1.4.1.1.2</li> <li>Enhanced CT Image Storage – 1.2.840.10008.5.1.4.1.1.2.1</li> <li>Legacy Converted Enhanced CT Image Storage – 1.2.840.10008.5.1.4.1.1.2.2</li> </ul>	

continued

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Supported inputs	Details			
Supported DICOM transfer syntaxes	The following DICOM transfer syntaxes are supported:			
	Image format	8 bit	16 bit	
	JPEG 2000 image (lossy) 1.2.840.10008.1.2.4.91	CXR	CXR	
	JPEG 2000 image (lossless) 1.2.840.10008.1.2.4.90	CXR	CXR, CTB	
	Raw uncompressed image (Implicit VR Endian) 1.2.840.10008.1.2	CXR	CXR, CTB	
	Raw uncompressed image (Explicit VR Little Endian) 1.2.840.10008.1.2.1	CXR	CXR, CTB	
	Raw uncompressed image (Explicit VR Big Endian) 1.2.840.10008.1.2.2	CXR	CXR, CTB	
	JPEG lossless, non-hierarchical (Processes 14) 1.2.840.10008.1.2.4.57	CXR	CXR, CTB	
	JPEG lossless, non-hierarchical, first-order prediction (Processes 14 [Selection Value 1]) 1.2.840.10008.1.2.4.70	CXR	CXR, CTB	

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### Outputs available from Annalise Enterprise

Supported outputs	Details
Supported modalities	Annalise Viewer:  CXR CTB Worklist Triage: CXR CTB Secondary Capture (Annalise Enterprise v3.4 only): CXR
Supported output formats	Annalise Viewer  Desktop application installed on a workstation (used in conjunction with the PACS).  Worklist Triage  Priority message forwarded to reporting worklist software (such as a RIS).  Available in the following formats:  JSON  HL7  Secondary Capture (Annalise Enterprise v3.4 only)  DICOM series: Secondary Capture Image Storage – 1.2.840.10008.5.1.4.1.1.7
Supported DICOM transfer syntaxes	Secondary Capture (Annalise Enterprise v3.4 only) The following DICOM transfer syntaxes are supported (8 bit only):  Raw uncompressed image (Implicit VR Endian) 1.2.840.10008.1.2  Raw uncompressed image (Explicit VR Little Endian) 1.2.840.10008.1.2.1  JPEG Baseline (Process 1) 1.2.840.10008.1.2.4.50

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### Available customisations

Annalise Enterprise supports multiple configurations that enable your organisation to tailor the application to your specific needs.

As part of the deployment and on-boarding process, Annalise.ai will manage all product configuration in consultation with your IT/infrastructure team.

The following customisations are available:

Configuration item	Variables/controls		
Finding visibility	Enable/disable individual findings.		
Finding groups	Configure up to eight finding groups in the Annalise Viewer.		
Allocation of findings to groups	Allocate each finding to defined groups.		
Finding order	Select the order in which each finding will appear in the Annalise Viewer.		
	Note: By default, the findings display in order of clinical severity (as determined by Annalise.ai expert radiologists), but this order can be configured to meet your requirements.		
Finding sensitivity/specificity	Configure sensitivity/specificity for specific findings.		
Available languages	The viewer supports multiple languages.		
	Note: Additional languages are available on request.		
Analytics	Annalise Viewer sends tracking data to our privately hosted server to improve your experience.		
	This feature is optional.		
Data retention period	Enable/disable the period for which you want data to be stored in the Annalise Backend.		
Worklist Triage	The Worklist Triage can be integrated via HL7 or an API.		
	Depending on the columns available in the worklist, a study's Al priority in the worklist can be displayed in either:		
	a single 'Priority' column  Annalise Enterprise will only triage findings with the highest rank. This ensures that it will never decrease a study's existing priority in the worklist.		
	a dedicated 'Al priority' column		
	Annalise Enterprise can triage findings with all ranks in the dedicated Al priority column. This ensures that existing priorities are not changed.		
	The triage priority levels can be configured to suit the worklist configuration.		

continued

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Configuration item	Variables/controls	
Workflow Engine	If implemented into your infrastructure, a message containing both the results and associated priority information will be sent from the Annalise Integration Adapter to the Workflow Engine once the study has been analysed.	
	The priority message may then be forwarded to reporting worklist software (such as a RIS) in the appropriate format.	
Secondary Capture (CXR Al results only)	Enable/disable output of Al results in Secondary Capture DICOM format to a configured PACS destination.  Note: This feature may not be available in all regions.	

For further information or configuration requests, contact the Annalise.ai Professional Services Team.

# Configuration backup/restoration of the product

Your IT/infrastructure team will be expected to make regular VM (virtual machine) snapshots to back up the product.

Note: Annalise.ai is not responsible for performing or testing backups, nor do they support any other backup mechanism.

### Security and confidentiality

Annalise Enterprise includes security features which protect against unauthorised access and data modification.

These features ensure the secure authentication and encryption of sensitive data when transmitted between:

- the Annalise Integration Adapter and the Annalise Backend
- the Annalise Viewer and the Annalise Backend
- the PACS Image Viewer and the Annalise Viewer (available only when using the HTTPS interface)

It also includes the encryption of sensitive data stored in the Annalise Backend.

Note:

Annalise.ai recommends that you use the most recent version of the Annalise Enterprise product to access the latest features and security improvements.

### Multi-tenant backend design

The Annalise product uses a multi-tenant backend design which separates data from different organisations via different organisational accounts.

Users must therefore have the appropriate credentials to access an organisation's internal data.

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### **Annalise Integration Adapter Requirements**

### Overview

This section outlines the requirements for the installation of the Annalise Integration Adapter.

For further information, see *Annalise Integration Adapter* on page 7.

### System requirements

The following components are required to host the Annalise Integration Adapter on your network:

Component	Requiremen	ts
Operating system	Linux (Ubuntu 20.04 LTS) VM image – provided as VMware EXSi or Azure image by Annalise.ai as part of the installation process.	
Hardware		Recommended
CXR studies only	CPU cores	8 at ~2.2 GHz
	RAM	24 GB
	Storage	SSD for optimal performance:  • <u>Disk 1</u> : 100 GB  • <u>Disk 2</u> : 100 GB minimum*
CVD and CTD studios	CDLLooroo	Recommended 16 at ~2.2 GHz
CXR and CTB studies	CPU cores	Supports AVX, FMA and SSE4.2 instruction sets
	RAM	32 GB
	Storage	SSD for optimal performance:  • <u>Disk 1</u> : 100 GB  • <u>Disk 2</u> : 100-900 GB minimum*
Internet connection		Recommended
	CXR	6 Mbps uplink (cloud-deployed)
		Typically supports 3 CXR studies per minute
	СТВ	25 Mbps uplink (cloud-deployed)
		Typically supports 3 CTB studies per minute
Annalise Backend hosted in the cloud	Requires an ou	tbound internet connection via port 443.

<sup>\*</sup>Storage requirements depend on the number of studies sent per hour and values are based on estimates. Contact the Annalise.ai Professional Services Team if you require amendments to your existing storage specifications.

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### **Annalise Backend Requirements**

### Overview

The Annalise Backend is hosted on either:

- your network ('on-premises' installation), or
- Annalise.ai's cloud infrastructure.

If you want the Annalise Backend hosted on your network, refer to the system requirements below.

# System requirements (on-premises)

The following components are required to host the Annalise Backend on your network ('on-premises').

Component	Requiremen	ts
Operating system	Linux (Ubuntu 20.04 LTS) VM image – provided as VMware EXSi image by Annalise.ai as part of the installation process.	
Hardware		Recommended
CXR studies only	CPU cores	16 at ~2.2 GHz
		Supports AVX, FMA and SSE4.2 instruction sets
		Supports (at minimum):  • 225 CXR studies per hour
	RAM	32 GB
	Storage*	<ul> <li>SSD for optimal performance:</li> <li><u>Disk 1</u>: 100 GB</li> <li><u>Disk 2</u>: 100 GB (plus additional 16GB per 1000 CXR studies)</li> </ul>
		Recommended
CXR and CTB studies	CPU cores	32 at ~2.2 GHz
		Supports AVX, FMA and SSE4.2 instruction sets
		Supports a typical load of:
		225 CXR studies per hour
		52 CTB studies per hour
	RAM	64 GB
	Storage*	SSD for optimal performance:
		• <u>Disk 1</u> : 100 GB OS drive
		• <u>Disk 2</u> : 130+ GB data drive, plus additional:
		- 16 GB per 1000 CXR studies
		- 100 GB per 1000 CTB studies

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Component	Requirement	ts
Hardware (cont.)		Minimum
CXR and CTB studies	CPU cores	16 at ~2.2 GHz
		Supports AVX, FMA and SSE4.2 instruction sets
		Supports (at minimum):
		27 CXR studies per hour
		• 12 CTB studies per hour
	RAM	64 GB
	Storage*	SSD for optimal performance:
		• <u>Disk 1</u> : 100 GB OS drive
		• <u>Disk 2</u> : 130+ GB data drive, plus additional:
		- 16 GB per 1000 CXR studies
		- 100 GB per 1000 CTB studies

<sup>\*</sup>These numbers are a guide only. The true figures will depend on the series type, the transfer syntax (uncompressed or compressed) and the number of series processed that meet the scan criteria (see *Supported scan types* on page 8).

### System configuration (cloud)

The Annalise Backend can be hosted on Annalise.ai's cloud infrastructure.

To use this infrastructure, you will need to provide the outbound internet IP ranges for each workstation that uses the Annalise Viewer.

The Annalise.ai Professional Services Team will add these details to the Annalise Backend IP allow-list.

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### **Annalise Viewer Requirements**

### Overview

This section outlines the requirements for the installation of the Annalise Viewer.

For further information, see *Annalise Viewer* on page 7.

### System requirements

The following components are required to install the Annalise Viewer:

Component	Requirements
Workstation	The following must be installed and run on your workstation:  1 GB RAM  500 MB storage
Operating systems	The following operating systems are supported:  • Windows 10 (64-bit)  • Windows 11 (64-bit)
Other	<ul> <li>Check the following:</li> <li>ensure that port 8989 is not in use on the workstation</li> <li>if the Annalise Backend is hosted in the cloud, allow outbound HTTPS connection on port 443 to *.annaliseai.io</li> <li>ensure that the workstation CPU supports the SSE3 instruction set</li> <li>a PDF reader is required to view the supporting documentation (including the <i>User Guide</i>)</li> </ul>

### Installation and configuration

The Annalise.ai Professional Services Team will work with your IT/infrastructure team to help you install the Annalise Viewer on your required workstations.

### **Troubleshooting**

See Installation and configuration troubleshooting on page 28.

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### **Install and configure Annalise Viewer**

#### Overview

This section shows you how to install and configure the Annalise Viewer.

You will need to complete the following on each workstation:

- install the Annalise Viewer
- install a PDF reader
- enable Single Sign-On (SSO) via Azure Active Directory
- · configure and test your organisation's credentials

### Install Annalise Viewer

Follow these steps to install the Annalise Viewer on each relevant workstation.

You can install the Annalise Viewer via either:

- the user interface, or
- Windows command line or deployment tool.

Before installing, check that you are using the installation file provided by Annalise.ai.

#### Install via user interface

Follow these steps to install the Annalise Viewer via the user interface.

Note: Annalise.ai will provide the installer file.

- 1. Double-click the installer file and either:
  - select the installation path required for the PACS/RIS integration, or
  - use the default path C:\Program Files\Annalise.

See Configure PACS interface with Annalise Viewer on page 21.

- **2.** Click **Next** to progress through the installation options until the *Installation Complete* window displays.
- 3. Determine whether the organisation requires SSO.

If SSO is required	• go to step 4
If SSO is <b>not</b> required	<ul> <li>on the <i>Installation Complete</i> window, click <b>Close</b></li> <li>go to step 5</li> </ul>

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**4.** On the *Installation Complete* window, click to select **Use SSO login** then enter the following details:

Field	Requirements	
Annalise Server URL	The server URL to which the Viewer will connect.	
	This will be provided by Annalise.ai.	
App ID	The Application ID created by Azure Active Directory.	
	See Configure SSO via Azure Active Directory on page 26.	
Tenant ID	The Tenant ID created by Azure Active Directory.	
	See Configure SSO via Azure Active Directory on page 26.	
OpenId URL	The Open ID URL for your Azure Active Directory (normally https://login.microsoftonline.com).	
	Note: There are no trailing slashes after this URL.	

**5.** Once you have finished the installation, check that the Annalise Viewer opens from the shortcut.

Note: If you have any issues, contact the Annalise.ai Professional Services Team.

### Install via Windows command line or deployment tool

Follow these steps to install the Annalise Viewer using the Windows command line or a deployment tool.

- 1. Change the directory to the folder that contains the installer.
- 2. Check that the filename matches the version provided by Annalise.ai.
- 3. Type the following command then replace the angle brackets (<>) and their contents with the credentials provided by Annalise.ai:

"<Annalise filename 3.x.y.z.exe>" /S /allusers

Note: The installer version number changes each version.

**4.** Once you have finished the installation, check that the Annalise Viewer opens from the shortcut.

Note: If you have any issues, contact the Annalise.ai Professional Services Team.

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5. Determine whether the organisation requires SSO.

If SSO is required	•	go to step 6
If SSO is <b>not</b> required		on the <i>Installation Complete</i> window, click <b>Close</b> go to step 8

**6.** Run SetupSSO.ps1 (provided by Annalise) via Powershell using the following command:

```
./SetupSSO.ps1 -AppId "<appId>" -TenantId "<tenantId>" -AnnaliseApiUrl "<annaliseApiUrl>" -OpenIdUrl "<openIdUrl>
```

Note: If Powershell is not available, move a .JSON file containing these parameters into *C:\ProgramData\Annalise*. Please contact Annalise.ai to request a pre-made JSON file.

7. Once installation is complete, click to select **Use SSO login** on the *Installation Complete* window then enter the following details:

Field	Requirements	
Annalise API URL	The server URL to which the Viewer will connect.	
	This will be provided by Annalise.ai.	
App ID	The Application ID created by Azure Active Directory.	
	See Configure SSO via Azure Active Directory on page 26.	
Tenant ID	The Tenant ID created by Azure Active Directory.	
	See Configure SSO via Azure Active Directory on page 26.	
OpenId URL	The Open ID URL for your SSO service (normally https://login.microsoftonline.com).	
	Note: There are no trailing slashes after this URL.	

**8.** Once you have finished the installation, check that the Annalise Viewer opens from the shortcut.

Note: If you have any issues, contact the Annalise.ai Professional Services Team.

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#### Install PDF reader

To enable users to view supporting documentation (including the *User Guide*):

- install a PDF reader on each relevant workstation
- ensure that the PDF reader is configured as the default application for files with a '.pdf' extension

Log in via Windows Credentials Manager: Configure and test organisation credentials To ensure system security, Annalise Enterprise uses organisation-level credentials to authenticate both the Annalise Viewer and Annalise Backend.

This applies to log in via Windows Credential Manager only.

The Annalise.ai Professional Services Team will provide both the credentials and the Annalise Backend Server URL during product installation and configuration.

You can either:

- · enter these details manually in the application, or
- add this information remotely via a distribution tool.

Note: Ensure that you store the organisation ID and password securely.

### Manual configuration

If the Annalise Viewer has not been configured for the user, the *Server Settings* screen will display automatically, prompting you to enter the relevant details.

- 1. On the Server Settings page, type the following:
  - Organisation ID
  - Organisation Password
  - Annalise Server URL
- 2. Click **Test** to check the settings.

If 'Connected' displays	The application is ready for testing.
If an error message displays	Check that:     you have entered the correct Organisation ID,     Organisation Password and Annalise Server URL
	<ul> <li>the computer can access the URL:</li> <li>check that the computer has network connectivity</li> <li>check whether firewall permissions allow access</li> </ul>
	Note: If you have any issues, contact the Annalise.ai Professional Services Team.

3. Once you have connected successfully, click Save.

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### **Configure PACS**

#### Overview

This section explains how to:

- · configure the interface between:
  - your PACS and the Annalise Viewer
  - your PACS and the Annalise Integration Adapter, and
- integrate the Annalise Viewer with the Sectra Workstation IDS7.

The Annalise.ai Professional Services Team will give you the information required to liaise with your PACS vendor to integrate these components.

Note: Annalise Enterprise is compatible with any PACS/RIS that conforms with the *Annalise Enterprise HL7 and DICOM Specification*. Contact the Annalise.ai Professional Services Team if you require a copy of this document.

## Configure PACS interface with Annalise Viewer

As the Annalise Viewer is intended to be used in conjunction with a PACS viewer, an interface must be established between the Annalise Viewer and either your PACS or RIS.

Depending on the functionality supported by your PACS/RIS, the Annalise Viewer can be configured to:

- automatically launch via the PACS/RIS
- automatically display Al findings after loading a study in the PACS viewer
- display Al findings for a study requested by the PACS viewer (i.e. display a manual synchronise button in the PACS)
- · stop showing Al findings after closing a study in the PACS viewer
- · quit when requested by the PACS/RIS

The Annalise Viewer supports requests via an HTTPS API (POST or GET) or via a command line interface.

Many PACS and RIS support integration with third-party applications via one of these interfaces. The commands and syntax are specified in the *Annalise Viewer Open API Specifications* and are available on request.

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# Configure PACS interface with Annalise Integration Adapter

The following details must be set up for the Annalise Integration Adapter to interface with your PACS:

- an Application Entity (AE), and
- auto-routing rules.

If using Secondary Capture, you can also configure your PACS to receive the Secondary Capture series from the Annalise Integration Adapter.

### Set up an Application Entity (AE)

Contact your PACS vendor (and/or refer to your PACS reference guide) to set up the Annalise Integration Adapter as an AE in your PACS.

- 1. Set up the Annalise Integration Adapter AE with the following:
  - the IP address or host name of the Annalise Integration Adapter for your infrastructure
  - a port where the Annalise Integration Adapter listens for DICOM messages

The default port is '11112'

- the AE title of the Annalise Integration Adapter
   The default title is 'ANNALISE-AI'
- 2. Perform a C-ECHO (ping) to the configured Annalise AE title to confirm that the connectivity test has been successful.

### Set up auto-routing rules

Refer to your PACS reference guide to set up auto-routing rules to the Annalise Integration Adapter.

Apply your own conventions to these rules. Any rules provided in this document are to be used as a guide only.

1. Configure the rules to forward all studies from the relevant locations to the configured Annalise AE.

Use the following DICOM tags:

- Modality (0008,0060)
- StudyDescription (0008,1030)
- BodyPart (0018,0015)

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### For example:

#### CXR:

- Modality = 'CR' AND StudyDescription contains 'CHEST'
- Modality = 'DX' AND StudyDescription contains 'CHEST'
- Modality = 'CR' AND BodyPart contains 'CHEST'
- Modality = 'DX' AND BodyPart contains 'CHEST'

#### CTB:

- Modality = 'CT' AND Study Description contains 'STROKE'
- Modality = 'CT' AND Study Description contains 'BRAIN'
- Modality = 'CT' AND Study Description contains 'HEAD'
- Modality = 'CT' AND Body Part Examined contains 'STROKE'
- Modality = 'CT' AND Body Part Examined contains 'BRAIN'
- Modality = 'CT' AND Body Part Examined contains 'HEAD'

#### Configure Secondary Capture (optional)

A Secondary Capture series is generated by Annalise Enterprise and is presented as Al prediction results. The series contains the same study-level identifiers as the originating images.

The series is intended to be stored in your PACS and be viewable alongside the source images in a DICOM viewer.

The PACS server must be able to receive the Secondary Capture Image Storage SOP class with the appropriate transfer syntax from the Annalise Integration Adapter.

Follow these steps to configure your PACS to receive the Secondary Capture series from the Annalise Integration Adapter.

1. Set up the Annalise Integration Adapter AE in your PACS.

See Supported capabilities on page 8.

**2.** Annalise requires specific details about your PACS (which must be suitable for receiving C-STORE messages).

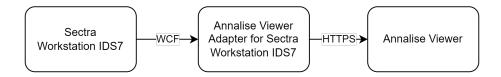
Provide the following to Annalise:

- · the IP address or host name of the PACS server
- a port where the PACS server can receive DICOM messages
- · the AE title of the PACS server
- your required transfer syntax (see Outputs available from Annalise Enterprise on page 10)

Note: The default preferred syntax is JPEG Baseline.

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Integrate Annalise Viewer with Sectra Workstation IDS7 The Annalise Viewer Adapter for Sectra Workstation IDS7 (the 'Adapter') is a background application which provides an interface between the Sectra Context Manager and the Annalise Viewer's Open API interface.



To integrate the Annalise Viewer with the Sectra Workstation IDS7, you will need to:

- · install the Adapter on each workstation, and
- configure the Sectra IDS7 third-party interface.

### Install Adapter

The Annalise.ai Professional Services Team will provide you with the Adapter via a Windows installer. This enables you to perform the installation via a graphical user interface (GUI) or a Windows command line interface (CLI).

Once you have completed the installation, the Adapter will automatically launch each time the user logs on to the workstation.

1. Install the Adapter on each workstation (either per user or system-wide). For a silent install, use the following list of CLI commands:

Operation	CLI command
System-wide command	msiexec.exe /i AnnaliseViewerSectraAdapterInstaller.msi WixAppFolder="WixPerMachineFolder" ALLUSERS=1 /qn
User-level install	msiexec.exe /i AnnaliseViewerSectraAdapterInstaller.msi WixAppFolder="WixPerUserFolder" INSTALLFOLDER="%LocalAppData%\ Apps\Annalise\Sectra Adapter" /qn
Uninstall	msiexec.exe /x AnnaliseViewerSectraAdapterInstaller.msi /q

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### Configure Sectra Workstation IDS7

To configure the Sectra Workstation IDS7 for use with the Annalise Enterprise product, contact your Sectra support team.

Use the following configuration:

Operation	CLI command	
Desktop sync	"Desktop sync enabled" = True	
	"Single log on enabled" = True	
External application	"Close external application" = Do not close	
startup	"Close workstation" = Do not close	
	"Multiply instance" = Use already running instance	
	"Startup File" = Path for Annalise Viewer installation (i.e. Annalise.exe)	
Third party application commands	Configure Sectra ID7 to use the command line interface (as defined in the Annalise Viewer Open API specification) to support the commands listed below:	
	<ul> <li>when starting: Implement STUDY_OPEN request parameters</li> </ul>	
	when changing patient: leave empty	
	when the user logs off: leave empty	

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### **Configure SSO via Azure Active Directory**

#### Overview

This section shows you how to configure Azure Active Directory settings to enable single sign-on (SSO) for the Annalise Viewer.

#### This includes:

- create a new app registration
- configure API permissions
- · enable automatic log in to the Annalise Viewer

### Create new app registration

Create a new app registration for Annalise Enterprise. This will enable you to allocate users or groups specifically for the Annalise Enterprise application.

Follow these steps to create a new registration.

- 1. Log into your Azure portal and go to **New registration**.
- 2. Type a name for the registration (for example, 'Annalise Enterprise').
- 3. Go to the Redirect URI field.

Select 'Public client/native (mobile & desktop)' then add the following callback URL: https://localhost:8989/auth/oauth/callback.

**4.** Ensure that you provide the generated application and directory (tenant) ID during installation of the Annalise Viewer.

See Install and configure Annalise Viewer on page 17.

### Configure API permissions

Follow these steps to configure the API permissions.

- 1. In Azure Active Directory, go to the API Permissions page.
- 2. Check that the API permissions are set to 'User.Read'.

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# Enable automatic log in to the Annalise Viewer

You can update conditional access settings to enable automatic log in to the Annalise Viewer.

The automatic login period depends on the session expiry time that you set in Azure Active Directory.

Follow these steps to enable automatic log in to the Annalise Viewer.

- **1.** In Azure Active Directory, go to the *Security* page then navigate to the *Conditional Access Policies* section.
- 2. Under the Session options:
  - click to select Persistent browser session
  - in the **Persistent browser session** dropdown, select 'Always persistent'
- 3. Set the persistent session length to 'Always persistent'.
- **4.** Save your changes.

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### Installation and configuration troubleshooting

### Problems and solutions

If you have issues with the setup, installation or configuration of the Annalise Enterprise application, refer to the following tables.

If you are unable to resolve the issue, contact the Annalise.ai Professional Services Team.

### Troubleshooting: Error codes

The following table lists the error codes that may display and outlines the actions required to resolve these errors.

Code	e and description	Possible resolution
001 002	Authentication error: 'Cannot authenticate user'	Check the Organisation ID and Password.  If the problem persists, contact the Annalise.ai Professional Support Team.
004	Connection error: 'Cannot reach Annalise.ai servers'	Check internet/network connectivity.  If there is a connection but the problem persists, contact the Annalise.ai Professional Support Team.
003 009 010 011 012 014 021 022 023	Annalise service error	If the problem persists, contact the Annalise.ai Professional Support Team.
015 026	Error communicating with the PACS/RIS	<ol> <li>Follow these steps:</li> <li>Restart both the PACS/RIS and the Annalise Viewer.</li> <li>Confirm that the configuration of the communication interface within the PACS/ RIS is correct.</li> <li>Contact your PACS provider for support.</li> </ol>
016 099	Annalise Viewer local server error	Restart the Annalise Viewer.  If the problem persists, contact the Annalise.ai Professional Support Team.
027	Annalise Viewer port is unavailable: 'Port 8989 already in use'	Port 8989 is currently being used by another application.  Ensure that the port is available for the Annalise Viewer.

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### Troubleshooting: Viewing Al findings

The following table lists potential issues related to viewing the AI findings and the actions required to resolve them.

Symptom	Root cause	Steps to resolve
The following message displays when synchronising: 'No results available'	The study has not been routed to the Annalise Integration Adapter.	<ol> <li>Go to your PACS administration page.</li> <li>Check that the auto routing criteria has been met for the relevant study.</li> <li>Check that the image has been sent to the Annalise Integration Adapter through your PACS routing tools.</li> </ol>
	The Annalise Integration Adapter has no connectivity to the Annalise Backend.	If you have confirmed that the study has been routed to the Annalise Integration Adapter and the 'No results available' message still displays, check that there is connectivity between the Annalise Integration Adapter and the Annalise Backend.
Patient details are missing or a hyphen ('-') displays in place of the details. (Includes patient name, gender, age and date of birth).	The Annalise Viewer receives patient details from the PACS or RIS.  If the interface is not configured to send all patient details to the Annalise Viewer (and the information is not available in the Annalise Backend) a hyphen ('-') displays in place of the details.	Ensure that the PACS/RIS integration has been configured and enabled according to the vendor's instructions.  Note: Some PACS/RIS do not display all patient details on the interface.

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# Troubleshooting: PACS-viewer integration

The following table lists potential issues related to the PACS-viewer integration and the actions required to resolve them.

Symptom	Root cause	Steps to resolve
Can't see the Annalise button or Annalise features in the PACS viewer	The Annalise feature is not enabled for the user currently logged into the PACS/RIS.	Contact the PACS/RIS Admin and request that Annalise be enabled for the user.
Annalise Viewer does not automatically launch when PACS viewer launches	The Annalise Viewer has not been installed on the path required by the PACS/RIS configuration.	Ensure that the install location matches the location configured in the PACS/RIS.  Annalise.ai recommends:  C:/Program Files/Annalise/ Annalise.exe
Annalise Viewer does not respond when the user clicks the <b>Annalise</b> button in the PACS viewer	The Annalise configuration in the PACS/RIS is incorrect.	Ensure that the PACS/RIS integration has been configured and enabled according to the vendor's instructions.
		For further help, contact the Annalise.ai Professional Services Team.
	This feature may not be supported by the PACS/RIS.	Ensure that the PACS/RIS is configured as per the vendor's instructions.
Al findings still display after a study has been closed in the PACS viewer.	The Annalise configuration within the PACS/RIS is incorrect.	Ensure that the PACS/RIS integration has been configured and enabled according to the vendor's instructions.
		For further help, contact the Annalise.ai Professional Services Team.
Al findings still display after the PACS viewer has been closed or	This feature may not be supported by the PACS/RIS.	Ensure that the PACS/RIS is configured as per the vendor's instructions.
locked		The Annalise Viewer includes a timeout function which stops showing Al findings after a period of inactivity.
Al findings change unexpectedly	PACS viewer shortcut key is mapped incorrectly.	Ensure that any shortcut keys are configured correctly and not shared across multiple applications.
Al findings cease to display	Viewing multiple studies in different windows.	When moving between studies in multiple windows, the PACS viewer may send a request to the Annalise Viewer to display the current in-focus window.
	Annalise Viewer timeout is too short.	Increase the timeout period in the Annalise Viewer.

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### Troubleshooting: Secondary Capture

The following table lists potential issues related to Secondary Capture and the actions required to resolve them.

Symptom	Root cause	Steps to resolve
There is no Secondary Capture series available	The study is still processing.	Wait a few moments then check whether the Secondary Capture series displays in the PACS.  If the series still doesn't display, refer to <i>The study is out-of-scope</i> , below.
	The study is out-of-scope.	Check that the study meets all the criteria for processing.  See:  • Contraindications on page 5  • Supported scan types on page 8  For further details, contact the Annalise.ai Professional Services Team.
	The study has not been routed to the Annalise Integration Adapter.	<ol> <li>Go to your PACS administration page.</li> <li>Check that the auto routing criteria has been met for the relevant study.</li> <li>Check that the image has been sent to the Annalise Integration Adapter through your PACS routing tools.</li> </ol>
	The Annalise Integration Adapter has no connectivity to the Annalise Backend.	<ol> <li>Confirm that the study has been routed to the Annalise Integration Adapter.</li> <li>Check that there is connectivity between the Annalise Integration Adapter and the Annalise Backend.</li> </ol>
	The system is under maintenance.	Contact the Annalise.ai Professional Services Team
	Technical product error.	Contact the Annalise.ai Professional Services Team

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### Troubleshooting: Secondary Capture (cont.)

Symptom	Root cause	Steps to resolve	
One or more images in the Secondary Capture series is missing	The Annalise Integration Adapter has no connectivity to the Annalise Backend.	<ol> <li>Confirm that the study has been routed to the Annalise Integration Adapter.</li> <li>Check that there is connectivity between the Annalise Integration Adapter and the Annalise Backend.</li> </ol>	
	The Annalise Integration Adapter failed to send the DICOM series to the PACS server.	<ol> <li>Check that there is connectivity between the Annalise Integration Adapter and the PACS.</li> <li>Check that the PACS is configured to accept the Secondary Capture SOP class with the appropriate transfer syntax.</li> <li>For further help, contact the Annalise.ai Professional Services Team.</li> </ol>	
	Technical product error.	Contact the Annalise.ai Professional Services Team.	
Not all X-rays in the study are present in the Secondary Capture result	Not all X-ray images in the study have been routed to the Annalise Integration Adapter.	Check that the affected image/s have been sent to the Annalise Integration Adapter through your PACS routing tools.	
	Some of the images in the study were received by the Integration Adapter after the first prediction result was completed.	Confirm that images in the same study are routed to the Annalise Integration Adapter within the configured timeframe for the Annalise Integration Adapter to trigger a prediction.	
	Annalise Secondary Capture results will only be sent for the first successfully completed Al result. If further images arrive after the first prediction is triggered, the new Secondary Capture results will not be sent to the PACS.	If required, contact the Annalise.ai Professional Services Team to discuss the configuration of your study trigger window.	

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### Troubleshooting: Miscellaneous

The following table lists other potential miscellaneous issues and the actions required to resolve them.

Symptom	Root cause	Steps to resolve
When the Annalise Viewer launches, the following message displays: 'Missing Credentials'	The Organisation ID, Organisation Password and Annalise Server URL have not been configured for the user.	See Log in via Windows Credentials Manager: Configure and test organisation credentials on page 20.
When the user tests the server settings, the following message displays:  'Error – failed to reach server'	Incorrect server URL.	Check that you have used the URL provided by the Annalise.ai Professional Services Team during the deployment and configuration process.
	Unable to access network.	Check that the computer is connected to the network and has permissions to access the server URL.
	Maintenance in progress.	The application is currently undergoing maintenance.  Once maintenance is complete,
		you will be able to use the application as normal.
When the user tests the server settings, the following message displays:  'Error – invalid credentials'	The <b>Organisation ID</b> or <b>Organisation Password</b> is incorrect.	Ensure that the Organisation ID and Organisation Password match those provided by the Annalise.ai Professional Services Team during the deployment and configuration process.
When the user attempts to open the User Guide, the following message displays:  'Guides are available at Annalise.ai/Guides'	The Annalise Viewer is unable to reach the Annalise Backend.	<ol> <li>Ensure that the computer is connected to the network.</li> <li>Open the Settings page then click Server Settings.</li> <li>Click Test to check whether the application can reach the Annalise Backend.</li> </ol>
		If the application is connected to the Backend, an error may be present in the Backend. If so, contact the Annalise.ai Professional Services Team.

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### 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 support@annalise.ai  Any serious incidents related to Annalise Enterprise 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
<b>C E</b> 2797	CE labelling
UK CA	UK Conformity Assessed marking
	Manufacturer
EC REP	European Authorised Representative
CH REP	Swiss Authorised Representative
$\triangle$	Indicates a warning or caution
[]i	Read the instructions for use
MD	Medical device

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