

# Annalise Enterprise Administration Guide

English

## Annalise Enterprise

This guide is applicable to:

- Annalise Viewer version: 3.2
- Annalise Backend version: 3.2
- Annalise Integration Adapter version: 3.2

Date of issue: 2023-04



Copyright © ANNALISE-AI PTY LTD, 2023





ANNALISE-AI PTY LTD Level P 24 Campbell Street Sydney NSW 2000 AUSTRALIA www.annalise.ai



QualRep Services B.V. Utrechtseweg 310 - Bldg B42 NL-6812 AR Arnhem THE NETHERLANDS



QUNIQUE GmbH Bahnhofweg 17 5610 Wohlen AG SWITZERLAND

#### India Authorised Representative

Asia Actual India (OPC) Pvt. Ltd. 523A, Tower A, Spaze-I-Tech Park Sector 49, Gurgaon, Haryana, 122018 INDIA Import License Number: IMP/MD/2023/000218

#### **Thailand Authorised Representative**

Asia Actual (Thailand) Co., Ltd. 8 T-One Building, Room No. 15-102 15th Floors, Soi Sukhumvit 40 Sukhumvit Road, Phra Khanong, Khlong Toei BANGKOK 10110 Registration Number: 45-2-2-2-0017147

#### New Zealand Sponsor AA-Med NZ Ltd. Level 7, 54 Gill Street New Plymouth, 4310 NEW ZEALAND

UK Responsible Person Qserve Group UK Ltd. 282 Farnborough Road GU14 7NA, Farnborough UNITED KINGDOM

#### Malaysia Authorised Representative

ARQon Medtech Sdn Bhd No. 20, Jalan Sasa 4 Taman Gaya, 81800, Johor MALAYSIA Registration Number: GA5216421-60402

#### Indonesia Authorised Representative

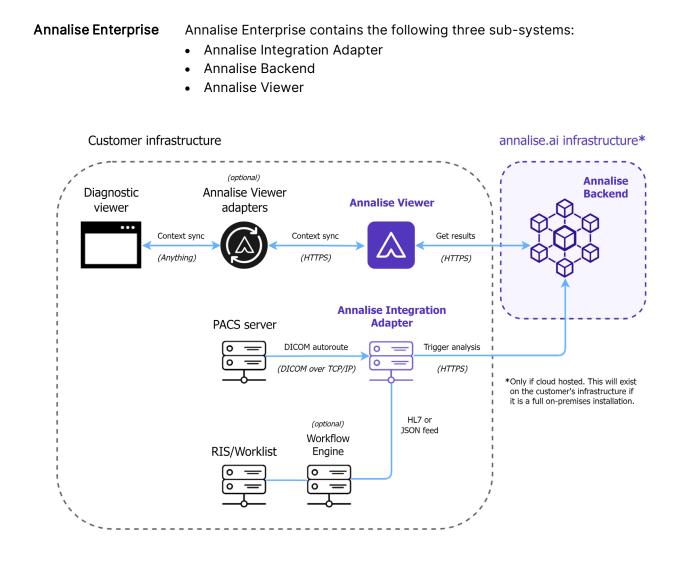
PT ARQon Solusi Medika Rukan Niaga Gunung Sahari B-2 JakPus 10720 INDONESIA Registration number: 126100071236600030002

OVERVIEW 5
Introduction
Who5
Intended purpose
Indications for use
Contraindications
ANNALISE ENTERPRISE OVERVIEW 6
Annalise Enterprise
Annalise Integration Adapter $eta$
Annalise Backend7
Annalise Viewer
Annalise product compatibility
Supported capabilities
Available customisations
Configuration backup/restoration of the product
Security and confidentiality11
ANNALISE INTEGRATION ADAPTER REQUIREMENTS 12
Overview
System requirements
ANNALISE BACKEND REQUIREMENTS 13
Overview
System requirements (on-premises)
System configuration (cloud)
ANNALISE VIEWER REQUIREMENTS 15
Overview
System requirements
Installation and configuration
Troubleshooting

INSTALL AND CONFIGURE ANNALISE VIEWER	16
Overview	16
Install Annalise Viewer	16
Install PDF reader	19
Login via Windows Credentials Manager: Configure and test organisation credentials	19
CONFIGURE PACS	21
Overview	21
Configure PACS interface with Annalise Viewer	21
Configure PACS interface with Annalise Integration Adapter	22
Integrate Annalise Viewer with Sectra Workstation IDS7	23
Install Adapter	24
Configure Sectra Workstation IDS7	24
INSTALLATION AND CONFIGURATION TROUBLESHOOTING	25
Problems and solutions	25
Support and feedback	29
Symbol glossary	29
APPENDIX: RUN ANNALISE VIEWER ON WINDOWS 7	30

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 <i>Annalise Enterprise User Guide.</i>
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	<ul> <li>Annalise Enterprise identifies suspected findings in:</li> <li>digitised (CR) or digital (DX) chest X-ray studies taken in the anterior-posterior (AP) or posterior-anterior (PA) and optionally lateral (LAT) orientations of adult patients</li> <li>non-contrast brain CT scans (brain kernel) of adult patients</li> </ul>
	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 <i>Annalise Enterprise User Guide).</i>
	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.
	<u>Note</u> : CTB is an additional licenced option and is not available in all regions (CTB is not available in the EU).
Contraindications	The device:
	<ul> <li>is not intended to provide direct diagnosis</li> </ul>
	<ul> <li>is not to be used on patients under the age of 16 for CXR and under the age of 18 years for CTB</li> </ul>
	<ul> <li>does not enable an increase in the clinician's scope of practice</li> </ul>

### **Annalise Enterprise overview**



#### 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.

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 AI processing and stores results. It includes both Backend API services and the AI 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 AI 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 AI results in its own window, enabling the user to review 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.

Annalise product Annalise Enterprise Backend Services (version 3.2) is compatible with: compatibility

- Annalise Integration Adapter 2.2, 3.1 and 3.2
- Annalise Viewer 2.1, 3.1 and 3.2

# Supported capabilities

The following table outlines the Annalise product's capabilities.

Supported items	Details		
Supported Body Part Imaging	• CXR: Chest X-ray		
	• <b>CTB</b> : Non-contrast brain CT sca	in	
Supported DICOM SOP Class	<ul> <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 - 1.2.940.10008.5.1.4.1.1.2.1</li> </ul>		
Supported DICOM Transfer	1.2.840.10008.5.1.4.1.1.2.2 The following DICOM transfer synta	ixes are	supported:
Syntaxes	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

Supported items	Details
Supported View Types	<ul> <li>CXR:</li> <li>minimum one frontal (AP/PA) required for processing</li> <li>up to three images in total</li> <li>lateral (LAT) is also supported</li> </ul>
	<u>Note</u> : If a study contains more than three chest X-ray images, the AI model will select a combination of the best three frontal/lateral images.
	CTB:
	<ul> <li>axial (coronal and sagittal views are generated by the axial view)</li> </ul>
	• slice thickness up to and including 1.5mm
	non-contrast CT brain scans
	brain reconstruction kernel
	• up to 1,000 images

## 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.	
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 feature can be integrated via HL7 or an API.	
	You can enable or disable the Worklist Triage for individual findings.	
	If you have a dedicated AI priority column in your RIS/PACS Reporting Worklist, you can also:	
	create additional priority levels	
	customise the name of the priority levels	
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.	

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. <u>Note</u> : Annalise.ai are 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:
	<ul> <li>the Annalise Enterprise Annalise Integration Adapter and the Annalise Backend</li> </ul>
	<ul> <li>the Annalise Viewer and the Annalise Backend</li> </ul>
	<ul> <li>the PACS Image Viewer and the Annalise Viewer (available only when using the HTTPS interface)</li> </ul>
	It also includes the encryption of sensitive data stored in the Annalise Backend.
	<u>Note</u> : 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.

## **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 6.

SystemThe following components are required to host the Annalise IntegrationrequirementsAdapter on your network:

Component	Requiremen	ts
Operating system	Linux (Ubuntu the installation	20.04 LTS) – provided by Annalise.ai as part of process.
Hardware		Recommended
CXR studies only	CPU cores	8 at ~2.2 GHz
	RAM	24 GB
	Storage	SSD for optimal performance: 200 GB*
		Recommended
CXR and CTB studies	CPU cores	16 at ~2.2 GHz
		Supports AVX, FMA and SSE4.2 instruction sets
	RAM	32 GB
	Storage	SSD for optimal performance:
		1 TB*
Internet connection		Recommended
	CXR	6 Mbps uplink (cloud-deployed)
		Supports 3 CXR studies per minute
	СТВ	25 Mbps uplink (cloud-deployed)
		Supports 3 CTB studies per minute
Annalise Backend hosted in the cloud	Requires an ou	tbound internet connection via port 443.

\*Storage requirements depend on the number of studies sent per hour. Contact the Annalise.ai Professional Services Team if you require amendments to your storage specifications.

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

Component	Requirements	
Operating system	Linux (Ubunt	tu 20.04 LTS) – provided by Annalise.ai.
Hardware <i>CXR and CTB studies</i>	CPU cores	<ul> <li>Recommended</li> <li>32 at ~2.2 GHz</li> <li>Supports AVX, FMA and SSE4.2 instruction sets</li> <li>Supports (at minimum):</li> <li>225 CXR studies per hour</li> <li>52 CTB studies per hour</li> </ul>
	RAM Storage	64 GB 230 GB Plus additional: • 16GB per 1000 CXR studies • 100GB per 1000 CTB series Recommend SSD for optimal performance
	CPU cores	<ul> <li>Minimum</li> <li>16 at ~2.2 GHz</li> <li>Supports AVX, FMA and SSE4.2 instruction sets</li> <li>Supports (at minimum):</li> <li>27 CXR studies per hour</li> <li>12 CTB studies per hour</li> </ul>
	RAM Storage	<ul> <li>64 GB</li> <li>230 GB</li> <li>Plus additional: <ul> <li>16GB per 1000 CXR studies</li> <li>100GB per 1000 CTB series</li> </ul> </li> <li>Recommend SSD for optimal performance</li> </ul>

Component	Requiremen	ts
Hardware <i>(cont.)</i> <i>CXR studies only</i>	CPU cores	Recommended 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	200 GB
		Plus additional 16GB per 1000 CXR studies
		Recommend SSD for optimal performance

System	The Annalise
configuration (cloud)	To use this i

he Annalise Backend is 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.

### **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	<ul><li>The following must be installed and run on your workstation:</li><li>1 GB RAM</li><li>500 MB storage</li></ul>		
Operating systems	<ul> <li>The following operating systems are supported:</li> <li>Windows 7 (64-bit or 32-bit)</li> <li>Windows 10 (64-bit or 32-bit)</li> <li>Windows 11 (64-bit)</li> </ul>		
Windows 7 Aero Theme	Enable the Windows 7 Aero Theme on the computer to fully support the Annalise Viewer's features. See <i>Appendix: Run Annalise Viewer on Windows 7</i> on page 30 <u>Note</u> : If the Aero Theme is not available, the Annalise Viewer will use a simplified layout.		
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<br/>configurationThe Annalise.ai Professional Services Team will work with your<br/>IT/infrastructure team to help you install the Annalise Viewer on your<br/>required workstations.

Troubleshooting

See Installation and configuration troubleshooting on page 25.

## Install and configure Annalise Viewer

You will need to comple install the Annalise V install a PDF reader enable Single Sign-C	a how to install and configure the Annalise Viewer. ete the following on each workstation: /iewer On (SSO) via Azure Active Directory rour organisation's credentials	
<ul> <li>Follow these steps to install the Annalise Viewer on each relevant workstation.</li> <li>You can install the Annalise Viewer via either:</li> <li>the user interface, or</li> <li>Windows command line or deployment tool.</li> </ul>		
	that you are using the installation file provided by	
Install via user interface	e	
	nstall the Annalise Viewer via the user interface. provide the installer file.	
<ul> <li>Double-click the installer file and either:</li> <li>select the installation path required for the PACS/RIS integration, or</li> <li>use the default path C:\Program Files\Annalise.</li> </ul>		
See Configure PACS in	<i>terface with Annalise Viewer</i> on page 21.	
Click <b>Next</b> to progress through the installation options until the <i>Installatio Complete</i> window displays.		
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 Close</li> <li>go to step 5</li> </ul>	
	You will need to complete install the Annalise Value install a PDF reader enable Single Sign-California of the enable Single Sign-California of the enable Single Sign-California of the set of the enable steps to in workstation. You can install the Annalise of the user interface, of Windows command Before installing, check Annalise.ai. <i>Install via user interface</i> Follow these steps to in Note: Annalise.ai will Double-click the install select the installation use the default path See <i>Configure PACS in</i> Click Next to progress <i>Complete</i> window disp Determine whether the If SSO is required	

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. This will be arranged by your internal IT support team.
Tenant ID	The Tenant ID created by Azure Active Directory. This will be arranged by your internal IT support team.
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.
  - <u>Note</u>: 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.
  - <u>Note</u>: If you have any issues, contact the Annalise.ai Professional Services Team.

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>
```

- <u>Note</u>: If Powershell is not available, move a .JSON file containing these parameters into *C*:|*ProgramData*|*Annalise*. Please contact Annalise to arrange for 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.	
	This will be arranged by your internal IT support team.	
Tenant ID	The Tenant ID created by Azure Active Directory.	
	This will be arranged by your internal IT support team.	
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.
  - <u>Note</u>: If you have any issues, contact the Annalise.ai Professional Services Team.

**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

Login 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 login 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.

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

3. Once you have connected successfully, click Save.

#### Remote configuration

If you are using Annalise Enterprise, you can configure the organisation credentials and Annalise Backend Server URL remotely.

**1.** Use the following distribution tool.

Replace the angle brackets (<>) and their contents with the credentials provided by Annalise.ai.

Note: You will need to run this for each user account.

```
cmdkey /generic:"Annalise/Annalise CredentialsV2"
/user:"Annalise CredentialsV2"
/pass:"%7B%22apiUrl%22%3A%22<annalise_endpoint>%22%2C%
22clientId%22%3A%22<client_id>%22%2C%22clientSecret%22%3A%2
2<client_ secret>%22%7D"
```

- 2. After installing, check that the Annalise Viewer opens from the shortcut.
  - <u>Note</u>: If you have any issues, contact the Annalise.ai Professional Services Team.

## **Configure PACS**

Overview	<ul> <li>This section explains how to:</li> <li>configure the interface between: <ul> <li>your PACS and the Annalise Viewer</li> <li>your PACS and the Annalise Integration Adapter, and</li> </ul> </li> <li>integrate the Annalise Viewer with the Sectra Workstation IDS7.</li> </ul>			
	The Annalise.ai Professional Services Team will give you the information required to liaise with your PACS vendor to integrate these components.			
	<u>Note</u> : Annalise Enterprise is compatible with any PACS/RIS that conforms with the <i>Annalise Enterprise HL7 and DICOM Specification</i> . 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:			
	<ul> <li>automatically launch via the PACS/RIS</li> <li>automatically display AI findings after loading a study in the PACS viewer</li> </ul>			
	<ul> <li>display AI findings for a study requested by the PACS viewer (i.e. display a manual synchronise button in the PACS)</li> </ul>			
	<ul><li>stop showing AI findings after closing a study in the PACS viewer</li><li>quit when requested by the PACS/RIS</li></ul>			
	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 <i>Annalise Viewer Open API Specifications</i> and are available on request.			

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.

#### 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)

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'

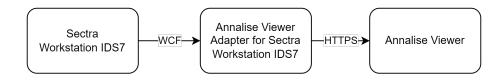
#### CTB:

- 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'

Integrate Annalise Viewer with Sectra Workstation IDS7 To integrate the Annalise Viewer with the Sectra Workstation IDS7:

- install the Annalise Viewer Adapter for Sectra Workstation IDS7 (the 'Adapter') on each workstation, and
- configure the Sectra IDS7 third-party interface.

The Adapter is a background application which provides an interface between the Sectra Context Manager and the Annalise Viewer's Open API 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="W ixPerMachineFolder" 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

#### 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 utilise 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	

## 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

Code	e and description	Possible resolution	
001 002	Authentication error: <i>'Cannot authenticate user'</i>	Check the Organisation ID and Password. If the problem persists, contact the Annalise.ai Professional Support Team.	
004	Connection error: <i>'Cannot reach Annalise.ai</i> <i>servers'</i>	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 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: ' <i>Port 8989 already in use'</i>	Port 8989 is currently being used by another application. Ensure that the port is available for the Annalise Viewer.	

Symptom	Root cause	Steps to resolve
The following message displays when synchronising: ' <i>No results available'</i>	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 ' <i>No results available'</i> 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. <u>Note</u> : Some PACS/RIS do not display all patient details on the interface.

#### Troubleshooting: Viewing Al findings

Symptom	Root cause	Steps to resolve
Can't see the <b>Annalise</b> 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: <i>C:/Program Files/ Annalise/</i> <i>Annalise.exe</i>
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 locked	This feature may not be supported by the PACS/RIS.	Ensure that the PACS/RIS is configured as per the vendor's instructions. The Annalise Viewer includes a timeout function which stops showing AI 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.

#### Troubleshooting: PACS viewer integration

#### Troubleshooting: Miscellaneous

Symptom	Root cause	Steps to resolve
When the Annalise Viewer launches, the following message displays: <i>'Missing Credentials'</i>	The Organisation ID, Organisation Password and Annalise Server URL have not been configured for the user.	See <i>Login via Windows</i> <i>Credentials Manager</i> : Configure and test organisation credentials on page 19.
When the user tests the server settings, the following message displays: <i>'Error – failed to reach</i> <i>server'</i>	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: <i>'Error – invalid</i> <i>credentials'</i>	The <b>Organisation ID</b> or <b>Organisation Password</b> is incorrect.	Ensure that the <b>Organisation ID</b> and <b>Organisation Password</b> match those provided by the Annalise.ai Professional Services Team during the deployment and configuration process.
When the user attempts to open the <i>User Guide</i> , the following message displays: ' <i>Guides are available</i> <i>at Annalise.ai/Guides</i> '	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 <i>Settings</i> page then click <b>Server Settings</b>.</li> <li>Click <b>Test</b> to check whether the application can reach the Annalise Backend.</li> <li>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.</li> </ol>

# 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 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

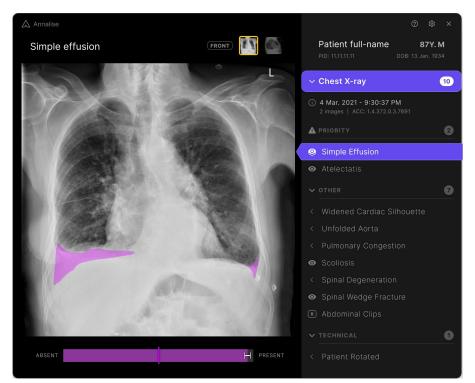
# **Symbol glossary** Definitions of symbols that may appear on the Annalise product or in the related documentation are listed below.

Symbol	Information
CE	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
<b>i</b>	Read the instructions for use
MD	Medical Device

Overview

If the user has Windows 7 installed on their computer, Windows Aero must be enabled for optimum functionality of the Annalise Viewer.

If the user's computer does not support Aero themes, the Annalise Viewer will use a simplified user interface design.



Check whether Windows Aero is enabled Follow these steps to check whether Windows Aero is enabled on the user's computer.

#### Check using File Explorer

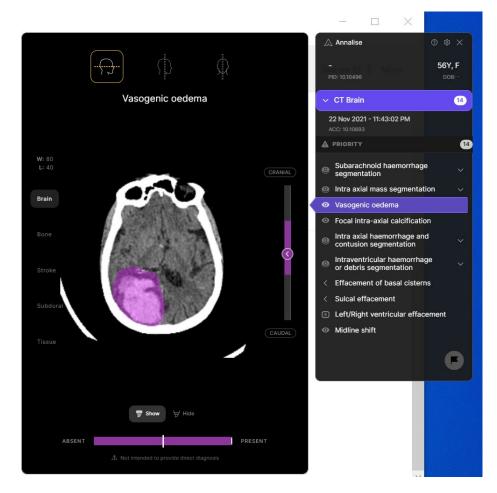
- **1.** Open File Explorer.
- **2.** Move the File Explorer window over another window or object on the screen.

If Windows Aero is enabled, the top section of the File Explorer window will be transparent:



#### Check Annalise Viewer

The Annalise Viewer should display in front of any other windows or items open on the screen:



Enable WindowsFollow these steps if Windows Aero is not enabled or operational on the<br/>user's computer.

Once you have completed each of the following sections, check whether the issue has been resolved.

#### Select an Aero theme

- 1. Right-click on the desktop, then select **Personalise**.
- Select one of the Aero Themes, then click Window Colour. The Window Colour and Appearance screen displays.
- 3. Click to select Enable transparency.

#### Ensure correct visual effects are enabled

1. Go to the Start menu and type 'Performance'.

The Performance Options menu displays.

- 2. Select Adjust the appearance and performance of Windows.
- 3. Check that the following minimum settings are enabled:
  - 'Enable desktop composition'
  - 'Enable transparent glass'
  - 'Use visual styles on windows and buttons'

#### Recalculate Windows Experience Index

- 1. Open a command prompt and right-click to run as an administrator (or run as another user with administrator privileges).
- 2. In the command prompt type 'winsat formal'.

Note: This may take up to 10 minutes to execute.

- 3. Open the Control Panel and click **Performance Information and Tools**.
- 4. Check that the **Base score** is above 4.0.

ANNALISE-AI PTY LTD Level P 24 Campbell Street Sydney NSW 2000 AUSTRALIA

support@annalise.ai www.annalise.ai

OPT-PRM-028 Ver.4