

Synthesis Vision Viewer

User Manual v 2.1.0, August 2025

A yellow triangle with a black exclamation mark inside, indicating a warning or important note.

A white 'X' icon used for closing the dialog box.

For continued safe use of this device, follow the instructions contained in this user manual. Read this guide carefully before using the device and refer to it as necessary.

Users should be aware of potential network issues that may affect the speed and reliability of image loading.

Carefully inspect image labels to identify and validate the patient and exam information. Take notice of image annotations and labels, including those related to image cropping or lossy data compression.

Interpretation of medical images with Synthesis VISION should only be performed by appropriately trained, licensed, and credentialed personnel.

Synthesis Vision Viewer is designed to be used with 2–10-megapixel monitors that meet clinical quality standards established by the American College of Radiology or other applicable organizations.

 A small icon representing a Unique Device Identifier (UDI).	(01)75401622502219(8012)2.1.0
 A small icon representing a Medical Device (MD).	Medical Device
 A small icon representing information or a user manual.	Click here to view user manual or contact support@synthesis.health
VERSION	2.1.0
Product Name	Synthesis Vision Viewer

Caution: Federal law restricts this device to sale by or on the order of a physician.

A stylized icon of a factory or manufacturing building.

Manufactured for Synthesis Health Intelligence Inc.
22420 Dewdney Trunk Road, Suite 300
Maple Ridge, BC, V2X 3J5

Note: The information provided in this user manual applies only to Synthesis Vision Viewer. Due to product innovation, specifications in this manual are subject to change without notice.

1.0 Introduction

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Synthesis Vision Viewer is a medical imaging viewing software used with off-the-shelf workstation hardware and web browsers for the 2D & 3D diagnostic visualization of DICOM and non-DICOM medical images by intended users such as trained radiologists, technologists and all others involved in the patient's care.

Synthesis Vision Viewer consists of configurable software-only modules that display and process DICOM and non-DICOM images and associated medical information to aid in the day-to-day operations and workflow of imaging healthcare professionals, clinicians and other healthcare practitioners.

Synthesis Vision Viewer has the following primary features and functions -

- Zero-footprint medical image upload, transfer, and display of medical images between facilities
- Easy access to images for all participants in the healthcare process, including radiologists, technologists, physicians, nurses and others who participate in patient care
- Serves as information and data management system for DICOM and non-DICOM medical images
- Industry-standard tools for image manipulation, annotation and measurement
- Metadata information and orientation labels display
- Advanced image manipulation functions like view synchronization across series, MIP and MPR
- Advanced image processing filters
- Encrypted transmission of medical images through secured networks
- Encrypted storage of medical images
- HIPAA-compliant data management, including centralized storage of user activities via audit trails.

Recommended Browser for Accessing the Viewer

To ensure optimal performance and compatibility, we recommend using **Google Chrome** as the preferred browser for accessing the device viewer. Chrome has been **verified for full functionality** with our viewer platform, including support for all interactive features and secure data handling.

1.1 Key Release Feature List

Here's a formatted Release Feature List with each feature followed by its benefits:

1. The Power Wheel tool is now disabled by default when an exam loads to prevent accidental activation that could disrupt workflows.
2. Added new localizer Lines & thumbnail bar to enhance navigation speed and efficiency.
3. Only the most recent prior mammography tomosynthesis images are displayed during mammography comparisons to speed up comparison workflows by focusing on the most relevant prior data.

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4. Double-click or wheel-click to enlarge by cursor position to enhance speed and precision in image navigation and comparison.

2.0 Regulatory Information

Manufacturer:



Synthesis Health Intelligence Inc.
22420 Dewdney Trunk Road, Suite 300
Maple Ridge, BC, V2X 3J5

For any questions or concerns not addressed in this manual go to synthesis.health or contact Synthesis Health Intelligence directly at support@synthesis.health.

3.0 Definitions and Symbols

3.1 Definitions

Term	Definition
DICOM	Digital Imaging and Communications in Medicine
PACS	Picture Archiving and Communication System
DSR	DICOM Structured Report
PHI	Protected Health Information
SOP	Standard Operating Procedure

3.2 Symbols

	Indicates the need for the user to consult the instructions for use
	Indicates that caution is necessary when operating the device to where the symbol is placed, or that the current situation needs physician/user awareness in order to avoid undesirable consequences
	Manufacturer
	Unique Device Identifier

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	Medical Device
	Importer

3.3 Recommended Cybersecurity Controls

Anti-Malware Software: Install reputable anti-malware software on all systems hosting this viewer. Configure the software to perform regular scans of the system and update malware definitions regularly. Ensure that the anti-malware software provides real-time protection and has the capability to scan incoming and outgoing data.

Firewall Protection: Enable and configure firewalls on network perimeters, as well as on individual systems hosting the PACS viewer. Set firewall rules to allow only necessary network traffic, blocking unauthorized access.

Encryption: Enable encryption for data in transit (e.g., TLS/SSL) to protect data while being transmitted over the network. Implement encryption for stored data to safeguard patient information within this viewer.

3.4 Recommended Browser for Accessing the Viewer

To ensure optimal performance and compatibility, we recommend using **Google Chrome** as the preferred browser for accessing the device viewer. Chrome has been **verified for full functionality** with the viewer platform, including support for all interactive features and secure data handling.

4.0 Manual Information

4.1 Purpose

This manual contains the instructions necessary to safely operate Synthesis Vision Viewer in accordance with its functions and intended use.

4.2 Intended Audience

This manual is intended for use by qualified and trained healthcare professionals and information technology staff using Synthesis Vision Viewer. Patients may use the software for non-diagnostic viewing of medical images.

5.0 Indications for Use



Synthesis Vision Viewer is a software application that can be used within a web -browser to process and view DICOM and non-DICOM image data and associated medical information to aid in the day-to-day diagnostic activities of medical imaging professionals and those involved in the care of a patient.

Synthesis Vision Viewer displays both lossy-compressed and lossless images. Lossy compressed images are always clearly labeled with the type and degree of data compression. The user must determine if the degree of lossy compression is acceptable for their purposes. Prior to making any medical decisions, the user must view the images within the user's scope of practice.

Synthesis Vision Viewer allows for 2D, multi-planar reformatted and 3D image display and manipulation of medical images, including rotation, measurement, annotation, zoom, window width/level and a variety of other standard tools that a user might need to aid in their diagnostic work.

Any display devices must adhere to applicable regulatory standards. Mobile use for mammography is only for reference and referrals.

Synthesis Vision Viewer utilizes modern authorization and authentication mechanisms that enforce secure access for permissioned users who view the imaging data. The system extends beyond the hospital/clinic/health care provider and its internal network. With proper authorization, Synthesis Vision Viewer can be accessed by users outside of the provider's internal network.

Synthesis Vision Viewer does not contact the patient.

5.1 Limitations

Worklists, reporting information, image storage, image transmission, users, roles, and permissions are provided via connectivity to other information systems such as EMRs, Radiology Information Systems, Cardiology Information Systems, and Lab Information Systems and are not a part of the viewer.

5.2 Contraindications

Stratus Imaging Diagnostic Viewer should not be used for diagnostic interpretation of medical images by non-qualified personnel. When used for diagnostic reading of mammograms, FDA-cleared monitors must be used, calibrated, and maintained. The software should not be used for clinical or diagnostic purposes in environments that violate security and/or confidentiality regulations. Users should not share passwords or usernames.

6.0 Warnings and Precautions



6.1 Prerequisites

To operate Synthesis Vision Viewer safely and according to the intended use, the following prerequisites must be met:

- The network where Synthesis Vision Viewer is used must be secured from any external threat.
- The user must read and understand the Intended Use, Warnings, and Operating Instructions that are available through this user manual and the help center that can be accessed through the workflow and reporting software used to launch the viewer.

6.2 Warnings

User warnings are shown below and are visible when clicking HELP at the upper right of the display.

	For continued safe use of this device, follow the instructions contained in this user manual. Read this guide carefully before using the device and refer to it as necessary.
	Users should be aware of potential network issues that may affect the speed and reliability of image loading.
	Carefully inspect image labels to identify and validate the patient and exam information. Note image annotations and labels, including those related to image cropping or lossy data compression.
	Interpretation of medical images with Synthesis Vision Viewer should only be performed by appropriately trained, licensed, and credentialed personnel.
	Synthesis Vision Viewer is designed to be used with 2–10-megapixel monitors that meet clinical quality standards established by the American College of Radiology or other applicable organizations.

6.3 Adverse Effects

There are no known direct risks to the health or safety of the patient from the implementation of Synthesis Vision Viewer.

6.4 Exceptions

The list below contains SOP Classes that Synthesis accepts through DICOM, however, it does NOT display in the viewer.

1.2.840.10008.5.1.4.1.1.66.4	Segmentation
1.2.840.10008.5.1.4.1.1.88.11	Basic Text SR
1.2.840.10008.5.1.4.1.1.88.22	Enhanced SR
1.2.840.10008.5.1.4.1.1.88.33	Comprehensive SR
1.2.840.10008.5.1.4.1.1.88.34	Comprehensive 3D SR



1.2.840.10008.5.1.4.1.1.88.59	Key Object Selection Document
1.2.840.10008.5.1.4.1.1.88.65	Chest CAD SR
1.2.840.10008.5.1.4.1.1.88.67	X-Ray Radiation Dose SR
1.2.840.10008.5.1.4.1.1.88.69	Colon CAD SR
1.2.840.10008.5.1.4.1.1.9.1.2	General ECG Waveform Storage << audio
1.2.840.10008.5.1.4.1.1.9.4.1	Basic Voice Audio Waveform Storage
1.2.840.10008.5.1.4.1.1.104.1	Encapsulated PDF Storage
1.2.840.10008.5.1.4.1.1.481.3	RT Structure Set
1.2.840.10008.5.1.4.1.1.481.5	RT Plan Storage
1.2.826.0.1.3680043.2.93.1.0.1	eRAD PACS private report

7.0 Product Information

7.1 How Synthesis Vision Viewer Works

Synthesis Vision Viewer software displays medical images for diagnostic interpretation, clinical communication, and patient education. Images are presented with labels derived from the DICOM metafile that accompanies medical images. The image labels are designed to display patient demographics, exam date/time/modality/type, and image information. The date annotation label of each image is designed to clearly distinguish images of the current exam from comparison exams, and to clearly label images that are lossy data compressed or displayed at less than full resolution.

7.2 Device Outputs

Synthesis Vision Viewer receives DICOM images and metafiles from imaging devices and storage devices. It may output images to third-party archives, secure networks, and appropriate printers.

7.3 Product Lifetime

Synthesis Vision Viewer is designed to be updated and upgraded in accordance with customer service contracts. However, the defined product lifetime of the viewer is 2 years. Users are advised to maintain and replace hardware as needed in accordance with clinical practice guidelines and applicable regulatory requirements—particularly in use cases such as diagnostic mammography reading, where specific standards may apply.

The software safety and performance is monitored as part of the post-market surveillance. Any emergent risks that require further mitigation are managed in accordance with the Change Control process.

7.4 Basics of Clinical and Diagnostic Viewing

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Synthesis Vision Viewer presents medical images in rectangular containers called viewports. The display may contain one or many such viewports (Figure 2 below). Each viewport may contain a single image or may contain multiple images virtually stacked in a series. The user may select from various “hanging protocols” that specify the arrangement and number of viewports.

For example, below the screen is divided into two panels, one on the left for the current exam and one on the right for the comparison exam. In this example, each panel included four viewports. The exam date in each of the prior exam’s viewports is shown with a white background to provide strong visual discrimination between the current and comparison images.



Figure 2: Synthesis Vision Viewer showing multiple viewports where the current exam in the left panel and comparison exam in the right panel.

Thumbnail views of the available image series for the current and comparison exam(s) are shown at the bottom of figure 2. The system may be configured such that the display shown in figure 2 is provided on a single landscape monitor, or alternatively, each panel may be shown on a portrait monitor.

Three icons in the thumbnail bar show whether the panel display shows exam images, key selected images, or the multiplanar views for a particular image series.

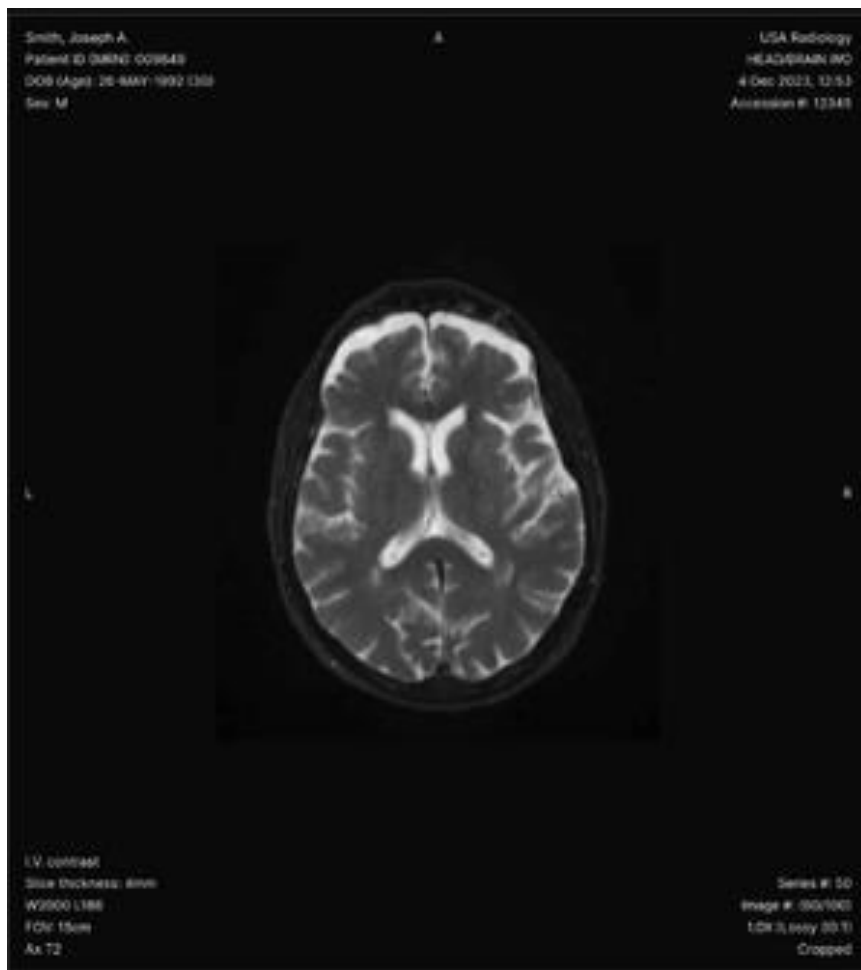


Figure 4: Viewport with image annotations.

Figure 4 shows a viewport displaying an axial MR image with DICOM annotations. Note that at the lower right, the text annotation shows the level of magnification (in this example 1.0x means all image pixels are displayed and none are replicated). “Cropped” indicates if a portion of the image is cropped (this actual image is not cropped, but Figure 2 shows the cropped annotation at the lower right for illustrative purposes). The patient’s name, ID, DOB, and exam always appear, although under special circumstances a user with appropriate rights may display a redacted image. Note also that location/orientation markers always appear in the mid-upper, mid-left, and mid-right margin of the image.

7.5 Using Thumbnails

Left click on a thumbnail (see Figure 2) to select it, then drag to a desired viewport on either panel to display the selected image series.

7.6 Using Tools

To access image manipulation and navigation tools (Figure 5), right click while the cursor is hovered over a viewport or use the T shortcut key. The toolbox appears as shown at the center of Figure 5. Left click on the desired tool. The cursor image will change to represent the selected tool icon. Drag the cursor to the desired viewport. Left click or left press to activate. Right click for a submenu of available tool options.

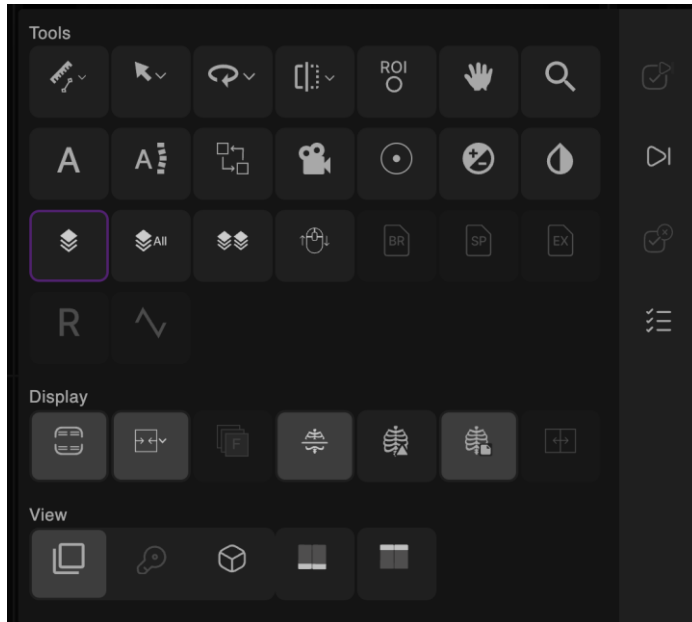


Figure 5: This figure shows the toolbox.

7.7 Default Mouse Settings

If a standard two button mouse with clickable scroll wheel is employed, the default setting are:

- Left button activates the Image page tool. Drag forward or back to page through a series of images in a viewport. If the mouse is dragged quickly, the system may skip over images in a stack.
- Center wheel scroll to page through a stack of images in a viewport. The system will not skip images when the center wheel scroll is used.
- Right button displays the toolbox.
- Simultaneous press left and right buttons to adjust window/level.
- Double left click or single wheel click to toggle a viewport to fill the entire panel or return to prior display.
- Wheel press and push to magnify an image or pull to demagnify an image.
- Left mouse and wheel press to pan an image.

7.8 Hanging Protocols



The system provides a wizard for user configuration of image hanging protocols (Figure 6). Access the wizard by clicking on the username/profile displayed at the far right of the upper ribbon (Figure 2). There is an option to subscribe to the Default Protocols updated with each system update. The default protocols are available through the workflow and reporting module that is used to access the viewer.

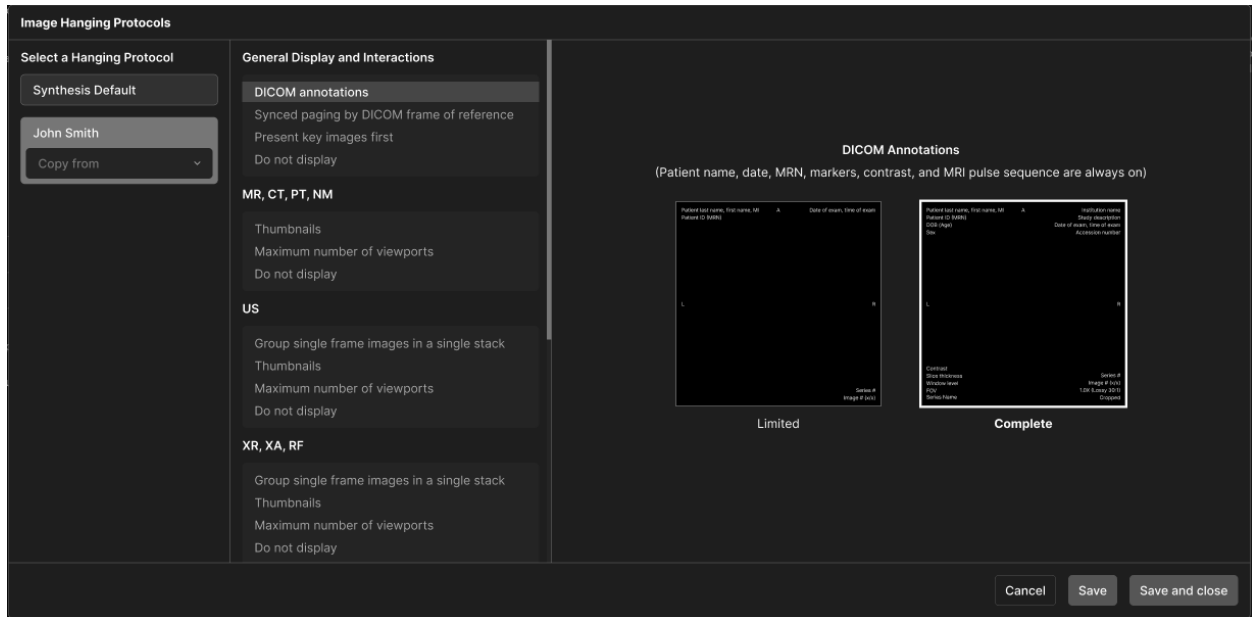


Figure 6. The hanging protocol wizard.

7.8.1 Using the "Do not display" functionality:

Slice thickness is just a number. If the slice thickness of a series is less than or equal to the number specified, the series will be excluded from display. For example, if a user specifies 2 then all series with slice thickness between zero and 2 (including 2.0) will be excluded from display.

Series description is text that might be found in a series description. Multiple text strings may be specified if they are separated by a comma. For example, if a user specifies "loc" then a series description of "loc", "LOC", "Local", etc. would match and the series would be excluded from display. If a user specifies "loc, scout" then a series description of "loc ax sag", or "SCOUT series", etc. would match and the series would be excluded. The comparison is NOT case sensitive.

Field of view is not implemented in this version.

7.9 HELP and other User Directions

The viewer is accessed through a workflow and reporting platform. This platform provides a Help and



Learning Center designed to support users with instructional materials and keyboard shortcuts.

7.9.1 Accessing the Help Center

To access the Help Center:

- Click on the “HELP” button located in the upper-right corner of the software interface.
- This opens a comprehensive menu containing:
 - Keyboard shortcuts
 - Instructional guides
 - Support resources

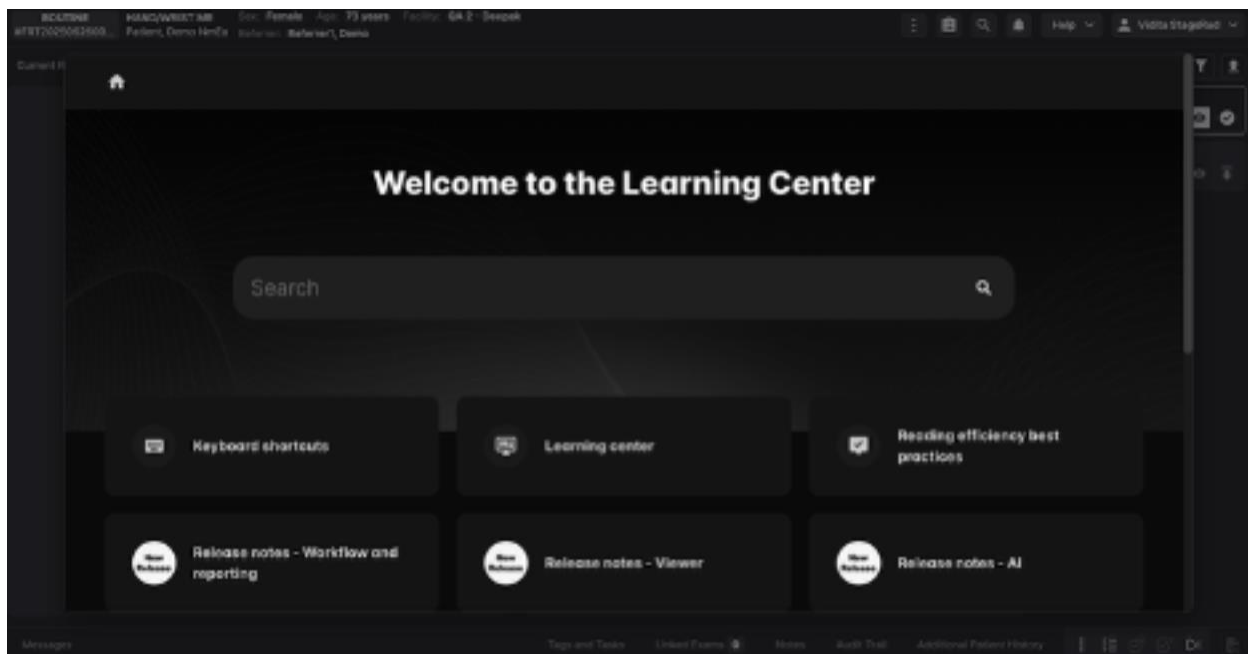


Figure 7. Searchable help.

7.9.2 Accessing the Viewer’s Electronic Labeling (eIFU)

To view the electronic Instructions for Use (eIFU) for the viewer:

- Launch an image within the viewer software.
- Press F1 on your keyboard to open the e-label documentation.

7.10 Annotations

Annotations in Vision

Vision automatically saves annotation changes, including additions, deletions, and modifications, in the following scenarios:



- Returning to the worklist
- Skipping to the next exam or selecting “Next”
- Clicking the eye icon in Exam Details for an already loaded exam

However, annotations **will not be saved** in the following cases:

- Annotations are made on a **comparison exam**
- Closing the **Vision window**
- Logging out of **Core**
- Closing the **Vision Chrome tab**
- Closing the **browser**

To ensure your annotations are saved, avoid these actions until you’ve completed and confirmed your work.

8.0 Reference Information

8.1 Viewer Integration Testing

Synthesis Vision Viewer has been successfully integrated and tested to comply with DICOM standards.

8.2 DICOM Conformance Standards

Please contact Synthesis Health for information on the DICOM conformance statement.



Synthesis Health Intelligence Inc.
22420 Dewdney Trunk Road, Suite
300 Maple Ridge, BC, V2X 3J5

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