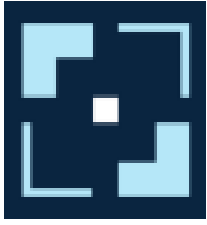


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v1.2.10



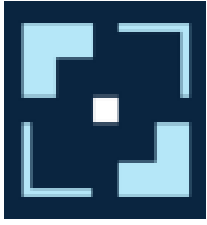
Radical Imaging LLC  
179 Great Road #233, Stow, MA 01775



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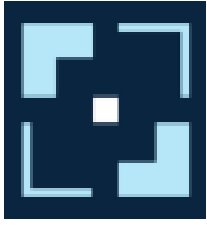
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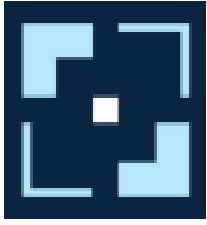
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## 1. INDICATIONS FOR USE

FlexView Diagnostic is a software application used for reference and diagnostic viewing and analysis of multi-modality medical imaging and non-imaging data (e.g., video information) with associated reports and information. FlexView Diagnostic enables qualified healthcare professionals, including (but not limited to) physicians, surgeons, nurses, and administrators to receive and view patient images, documents and data. FlexView Diagnostic allows qualified users to perform simple and complex image manipulations (including window/level, markups, 3D visualization) and measurements.

Not intended for primary diagnosis of mammographic images.

Not intended for diagnostic use on mobile devices.

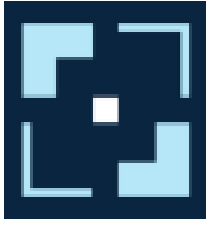
***Caution: Federal law restricts this device to sale by or on the order of a physician.***

## 2. DEVICE DESCRIPTION

The FlexView Diagnostic Viewer is a zero-footprint web-based medical imaging platform that supports DICOM images.

Key Features:

- Zero-footprint Web browser based.
- Medical image upload, transfer and display of medical images between facilities
- Allows access to images for all participants in the healthcare process, including radiologists, technologists, physicians, nurses and other patient care practitioners.
- Serves as an information and data management system for DICOM and non-DICOM medical images.
- Contains functionality to view and annotate images.
- Contains industry-standard tools for image manipulation, annotation and measurements.
- Advanced image manipulation functions like view synchronization across series, 3D visualization like MIP and MPR



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- Advanced image processing filters like histogram equalization (CLAHE) filter to aid in visualization of pathological features in the images.
- Encrypted transmission of medical images through secured networks
- HIPAA-compliant data management, including centralized storage of user activities via audit trails

### **3. INTENDED USER AND USER TRAINING**

FlexView Diagnostic is intended to be used by diagnostic or nondiagnostic clinicians to view and manipulate medical images.

A complete review of the FlexView Diagnostic user manual is required prior to using the system.

### **4. INTENDED PATIENT POPULATION**

FlexView Diagnostic is intended for use on patients who have had non-mammography medical images taken.

### **5. CONTRAINDICATIONS**

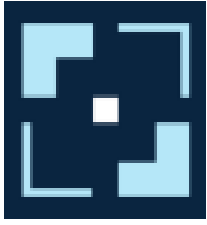
FlexView Diagnostic is not intended for primary diagnosis of mammographic images.

FlexView Diagnostic is not intended for diagnostic use on mobile devices.

### **6. WARNINGS AND PRECAUTIONS**

**The following warnings apply to the use of the FlexView Diagnostic system:**

- **CAUTION:** FlexView Diagnostic is not intended for primary diagnosis of mammographic images.
- Do not use the FlexView Diagnostic software for diagnostic use on mobile devices.
- Do not use the FlexView Diagnostic software without reviewing this user manual first.
- Users should regularly confirm that the FlexView Diagnostic software has been updated with the latest security patches.



## **7. SYSTEM REQUIREMENTS**

### **7.1. Software**

FlexView Diagnostic can run on Windows and MacOS operating systems. FlexView Diagnostic supports the following browsers: Safari, Google Chrome, and Microsoft Edge. Users can set up their accounts by visiting <https://flexview.ai>.

### **7.2. Hardware**

FlexView Diagnostic can run on any general-purpose computer or in a cloud environment. To protect against transient power failures, we recommend connecting your workstations to an uninterruptible power supply.

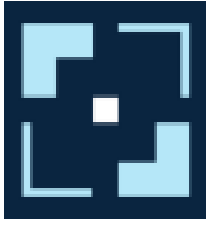
### **7.3. Minimum System Requirements**

- Modern web browser (Chrome v113, Safari for Mac v15, Edge v113)
- 1024 x 768 screen resolution
- 1 GHz or faster processor
- 4 GB of RAM

### **7.4. Recommended System Requirements**

- Modern web browser (Chrome v115 or newer, Safari for Mac v16.5 or newer, Edge v115 or newer)
- 1920 x 1080 screen resolution
- 1.4 GHz or faster processor
- 8 GB of RAM
- NEMA Grayscale calibrated monitor recommended for tasks requiring subtle grayscale detail.
- A GPU (e.g., NVIDIA 10 series or newer) is needed for tasks like MPR/3D or volume viewing manipulation.

To protect against transient power failures, we recommend connecting your workstations to an uninterruptible power supply.

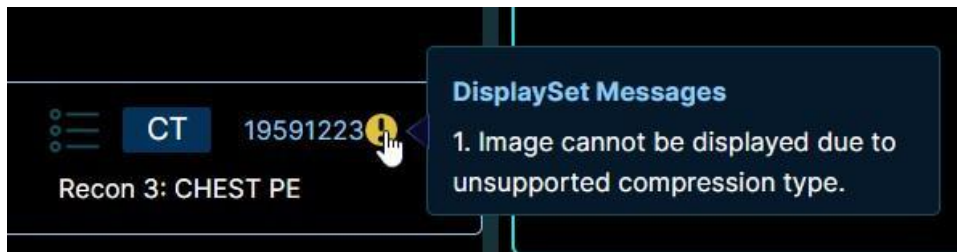


## 7.5. Input Requirements

FlexView Diagnostic has the following input requirements:

- DICOM images that are 1- or 8-16-bits grayscale.
- DICOM images that are 8 bits color.
- Segmentation images that are 1 bit

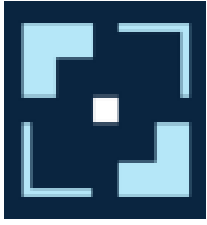
Note: If unsupported input formats are uploaded, FlexView Diagnostic will display a warning message, and the image will not be opened. Some examples are presented below.



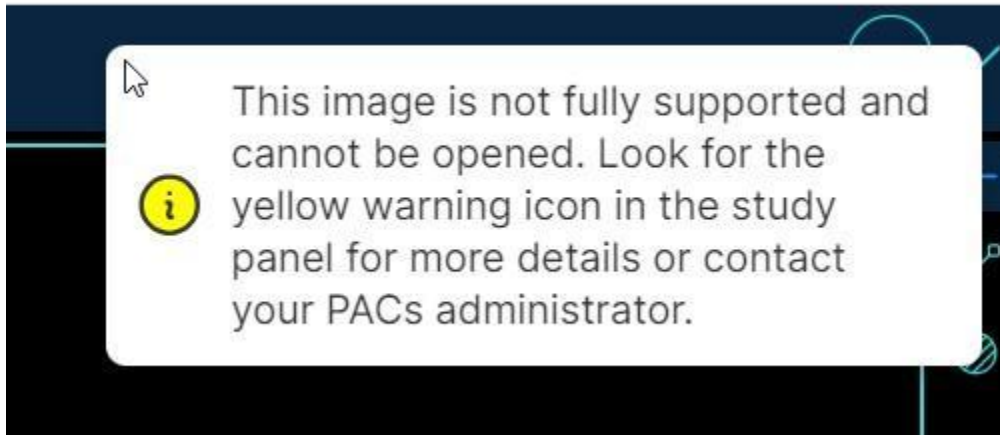
*Image description: Warning message displayed due to unsupported compression type.*



*Image description: Warning message displayed due to unsupported DICOM SOPClassUID.*



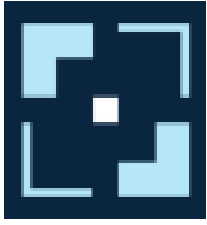
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*Image description: Warning message displayed when user attempts to move unsupported series into the viewport.*

## 7.6. Display Requirements and Recommendations

- **Recommended Pixel Pitch:**
  - Minimum pitch: 0.25 mm/pixel.
- **Laptop Display:**
  - Resolution: HD (high definition) or higher.
- **Desktop Monitor:**
  - Resolution: FHD (Full High Definition) or higher.
  - Larger screens may require double or quad definition.
- **Specialized Grayscale Work:**
  - NEMA Grayscale calibrated monitor recommended for tasks requiring subtle grayscale detail.
- **Graphics Processing Unit (GPU):**
  - A recent GPU is recommended for tasks like MPR/3D or volume viewing manipulation.



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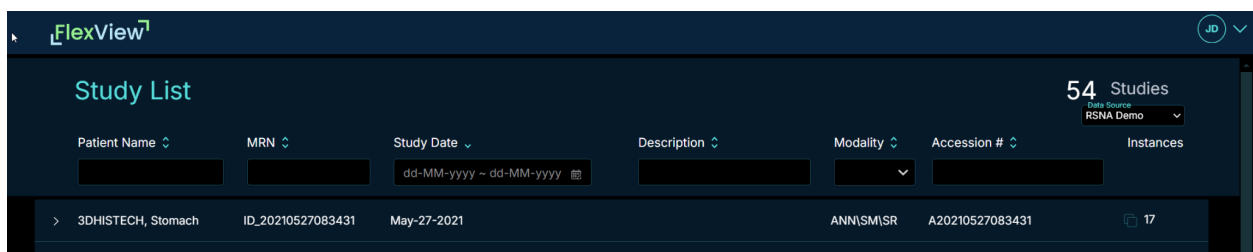
- **System Memory (RAM):**
  - Minimum 4 GB memory for basic viewing purposes.
  - Suggested 8 GB for more advanced tasks like MPR/3D volume work.
- **Cloud Environment:**
  - For running in a cloud environment, ensure a fast connection and lossless transmission of pixel values to the display environment.
  - Avoid using cloud environments for tasks like CINE or fast playback evaluation of image stacks.
- **FlexView Compatibility:**
  - FlexView Diagnostic is not supported on mobile devices such as tablets and smartphones.

## 8. NEW USER ACCOUNT CREATION

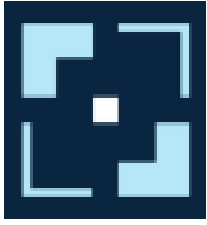
The admin for each FlexView organization account will add new users to that organization's account. The admin will invite a new user via email. The email will instruct a new user to accept the invite and set their password. The user's email address will be the login email.

## 9. STUDY LIST OVERVIEW

The first page that displays when FlexView Diagnostic is loaded is the Study Browser. In this page you can explore all the studies in the Study List.



*Image description: A screenshot of the Study List View in FlexView*



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## 9.1. Sorting

The Study List can be sorted by each of the following categories:

- Patient Name: Sorts alphabetically by patient name
- MRN: Sorts numerically by Medical Record Number
- Study Date: Sorts chronologically by date
- Description: Sorts by study description
- Modality: Sorts alphabetically by modality
- Accession: Sorts numerically by accession number

Each of the sorts can be changed from ascending to descending or removed by clicking the category name.

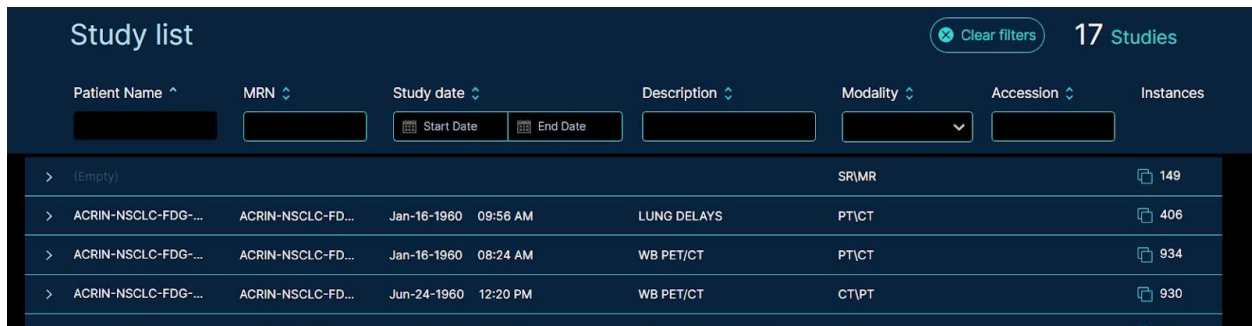
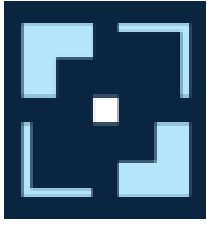


Image description: A Screenshot of the Study List Sorted by Patient Name

## 9.2. Filters

Applying a filter will limit the Study List to the specified criteria. The available filters in FlexView Diagnostic are as follows:

- Patient Name: Filters to all studies with the specified patient name
- MRN: Filters to all studies with the specified Medical Record Number
- Study Date: Filters to all studies with the specified date of image acquisition



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- Description: Filters to all studies containing the specified text in the study description
- Modality: Filters to all studies with specified modalities
- Accession: Filters to all studies with a specified accession number

Here is an example of the Study List with the Modality filter applied to find CT studies:

Study list								Clear filters	9 Studies
Patient Name	MRN	Study date		Description	Modality	Accession	Instances		
		Start Date	End Date		CT				
> Neptune	0000002	Sep-30-2014	10:11 AM	DFCI CT CHEST W CONTR...	CT	000041579	609		
> Neptune	0000002	May-22-2014	09:54 AM	DFCI CT CHEST W CONTR...	CT	000041576	381		
> Neptune	0000002	Mar-25-2014	03:29 PM	DFCI CT CHEST W CONTR...	CT	000041571	249		
> LUNG1-401	LUNG1-401	May-21-2010	10:21 AM		CT\SEG	2819497684894126	135		
> HCC_004	HCC_004	Oct-06-1997		LIVER/PELVIS	CT\SEG		179		

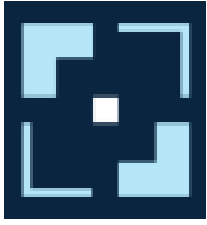
Image description: A screenshot of the Study List with the Modality filter applied.

When you apply a filter, you can apply additional filters or sort the filtered list.

Here is an example of the Study List with the Modality filter applied to find CT studies and the MRN filter applied to find a specific patient:

Study list								Clear filters	3 Studies
Patient Name	MRN	Study date		Description	Modality	Accession	Instances		
	0000002	Start Date	End Date		CT				
> Neptune	0000002	May-22-2014	09:54 AM	DFCI CT CHEST W CONTR...	CT	000041576	381		
> Neptune	0000002	Mar-25-2014	03:29 PM	DFCI CT CHEST W CONTR...	CT	000041571	249		
> Neptune	0000002	Sep-30-2014	10:11 AM	DFCI CT CHEST W CONTR...	CT	000041579	609		

Image description: A Screenshot of the Study List filtered by Modality and MRN



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### 9.3. Study Summary

Click on a study to expand the study summary panel.

A summary of the series available in the study will be displayed. The summary contains the series description, series number, modality of the series, instances in the series, and buttons to launch viewer modes to display the study.

Description	Series	Modality	Instances
R CC	1	MG	1
L CC	3	MG	1
L MLO	4	MG	1
R XCCL	5	MG	1
L XCCL	6	MG	1
L MLO	9	MG	1

Image description: A Screenshot of the Study Summary Panel

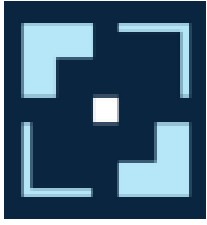
### 9.4. Study Specific Modes

All available modes are seen in the study summary view. Modes can be enabled or disabled for a study based on the modalities contained within the study.

In the screenshot below, there are 3 modes shown for the selected study:

- Diagnostic Viewer
- PET SUV
- AI

The modes that are not highlighted are not available for that study based on its modalities or license type.



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Description	Series	Modality	Instances
AP	1	CR	1
AP	3	CR	1
AP	4	CR	1

Image Description: Screenshot of a Study with 3 Modes Available

## 10. STUDY VIEWER

The Diagnostic Viewer mode is available for all studies by default. Click on the Diagnostic Viewer button to launch the viewer.

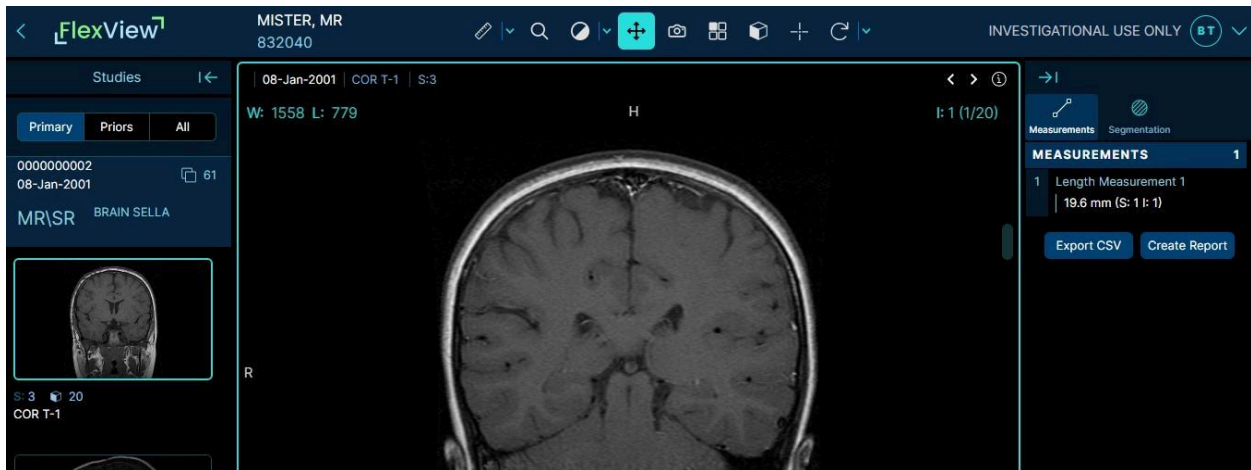


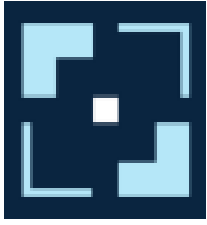
Image Description: Screenshot of a Study Displayed in the Diagnostic Viewer Mode

### 10.1. Study Panel

In Diagnostic Viewer mode, the left panel includes studies related to the current patient. There are three main types of studies:

**Primary:** The currently open study from the study list. This study is always expanded by default.

**Priors:** Two studies prior to the date of Primary for the same patient.



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**All:** All studies available for the patient contained within the source repository.

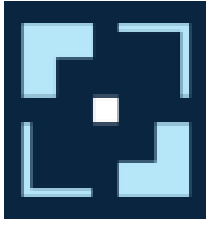


*Image Description: Screenshot of the study panel*

Studies can be expanded or collapsed by clicking on the study information in the Study Panel.

## 10.2. Measurement Panel

In Diagnostic Viewer mode, the right panel is the Measurement Panel. The Measurement Panel can be expanded or hidden by clicking on the arrow to the left of Measurements.

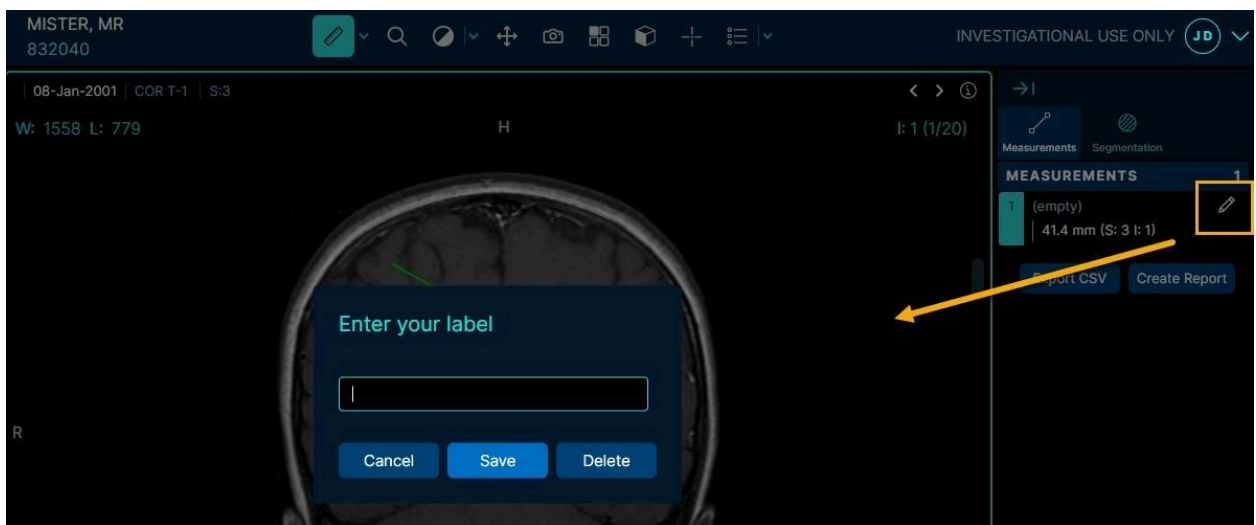
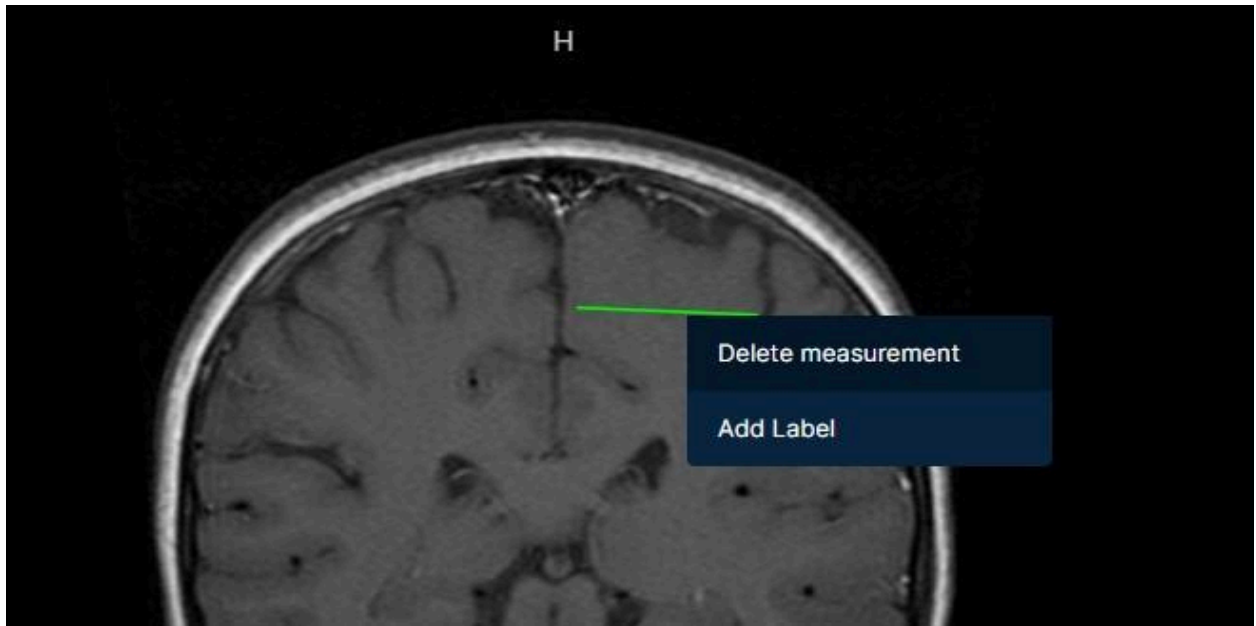


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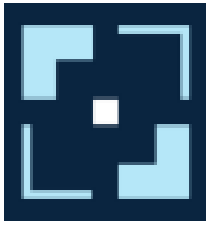
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## 10.2.1. Labeling Measurements

You can edit the measurement name by hovering over the measurement and selecting the edit icon. You can also label or relabel a measurement by right-clicking on it in the viewport.



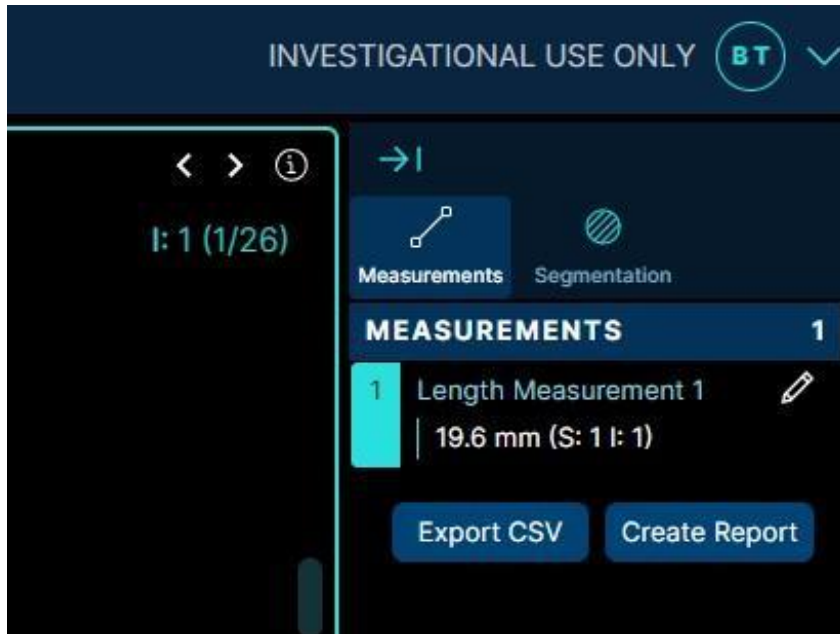
*Image Description: Screenshot of the prompt to annotate a measurement.*



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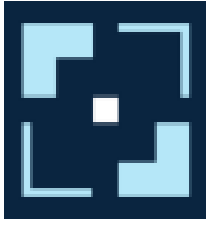
Entering an annotation will create a label for a measurement.



*Image Description: Screenshot of a measurement annotation label*

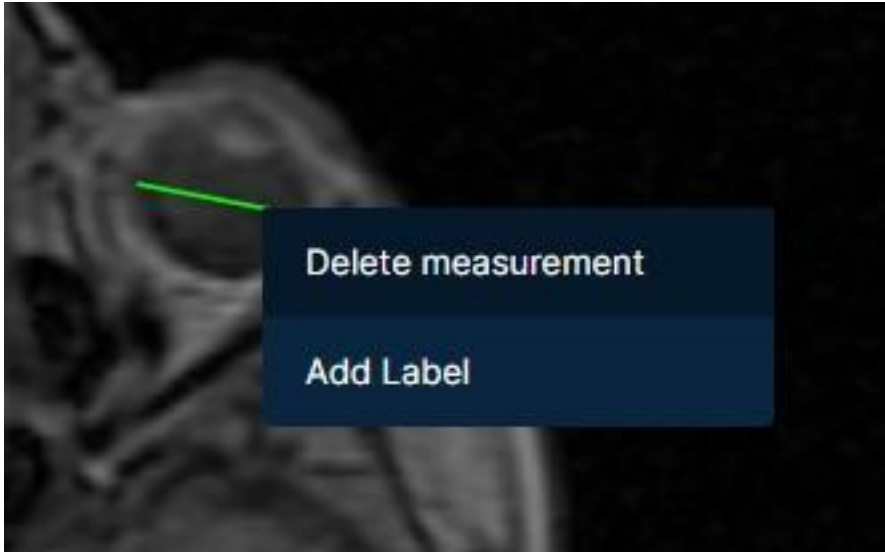
## 10.2.2. Deleting a Measurement

A measurement can be deleted by either right-clicking on the measurement in the viewport and selecting “Delete measurement” or by clicking the edit button next to the measurement label in the table and using the dialog to delete.

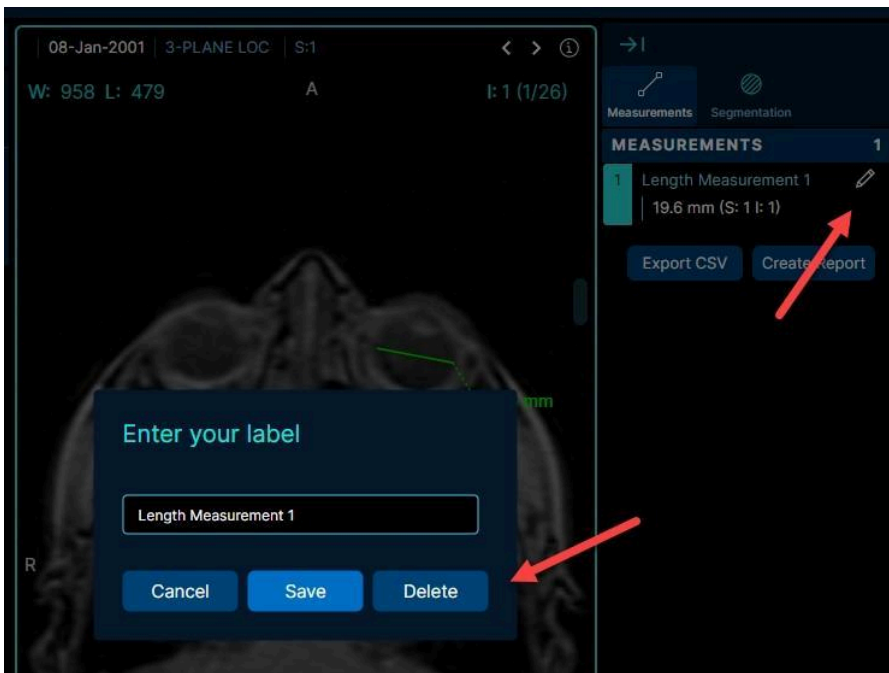


# Radical Imaging

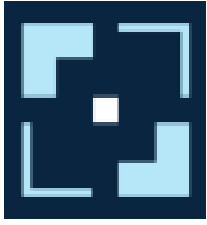
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*Image Description: Screenshot of right-clicking a measurement and deleting it*



*Image Description: Screenshot of the 2 ways to delete a measurement*

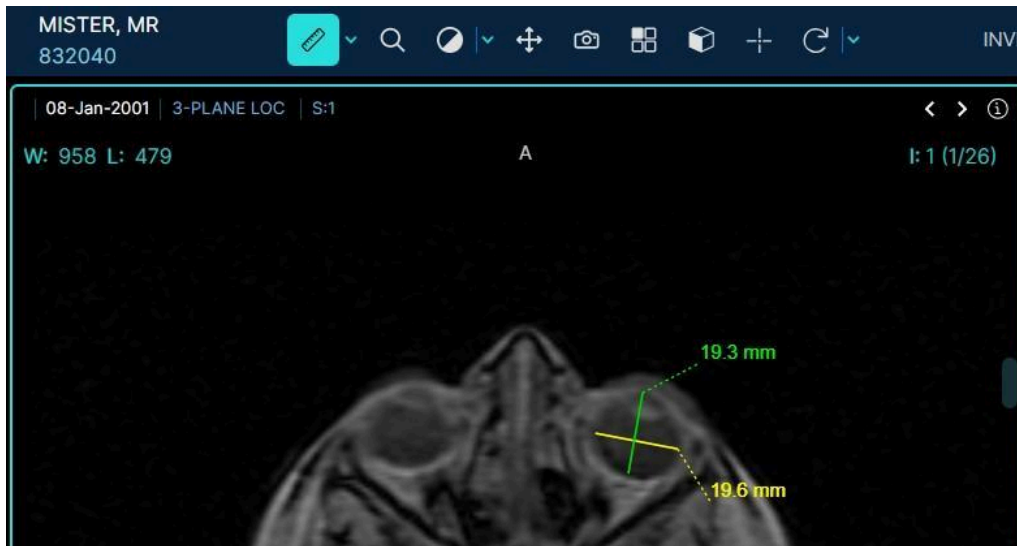


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### 10.2.3. Navigating Between Measurements

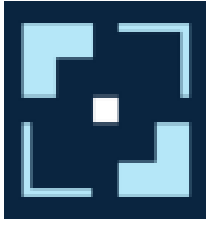
The top of the viewport contains a set of arrows that allow you to navigate between measurements.



*Image Description: Screenshot of the arrows at the top of the viewer that allow navigating between measurements.*

### 10.2.4. Exporting Measurements

Clicking on the “Export” button in the measurements panel will generate a .csv file containing all the measurements in the panel.



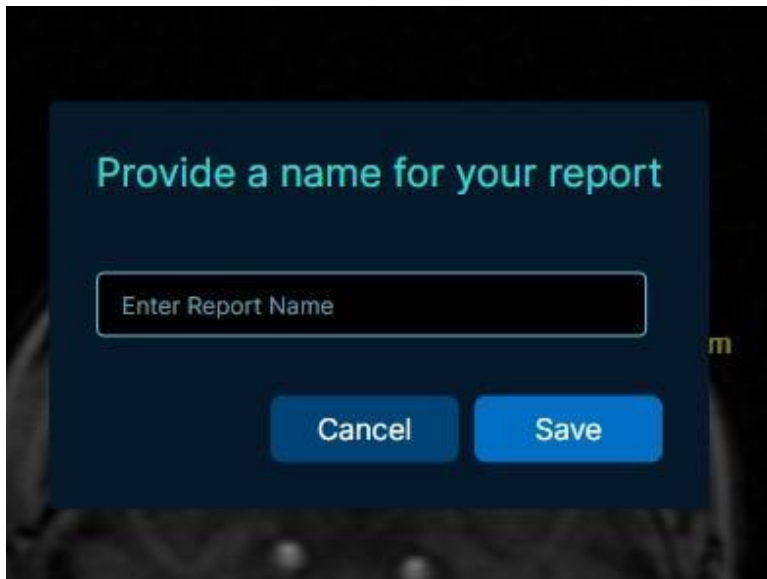
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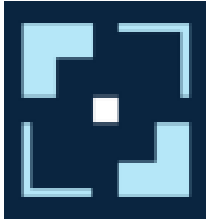


*Image Description: Screenshot of the arrows at the top of the viewer that allow navigating between measurements.*

You can create a DICOM Structured Report (SR) by clicking on “Create Report” in the measurements panel.



*Image Description: Screenshot of the DICOM SR Report Creation Prompt*

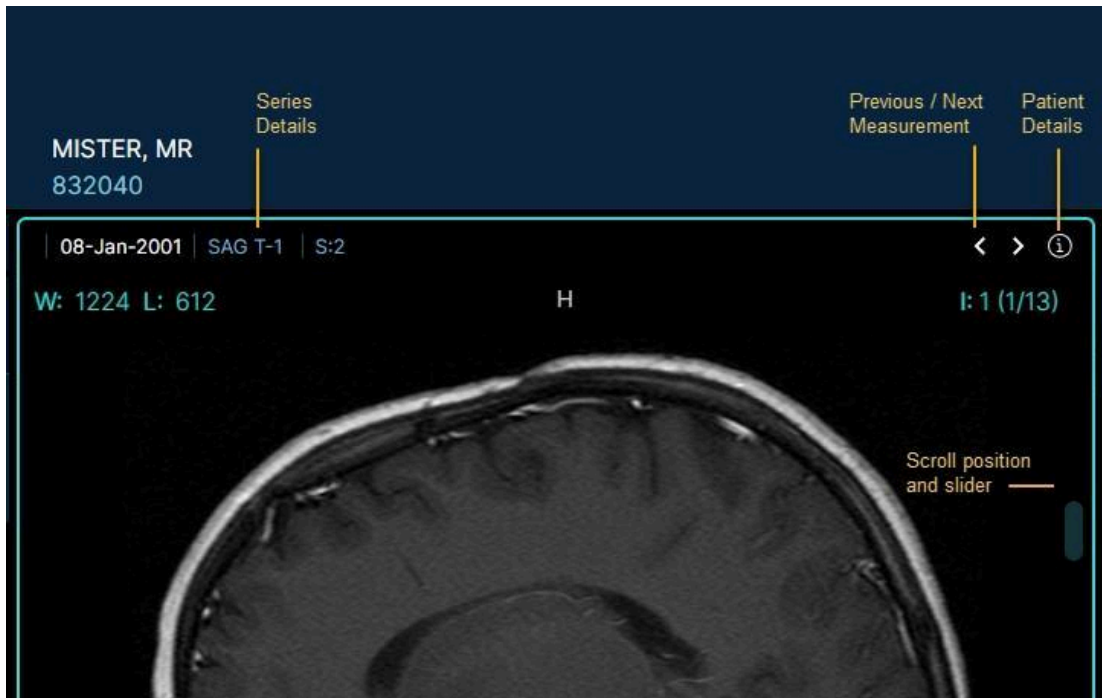


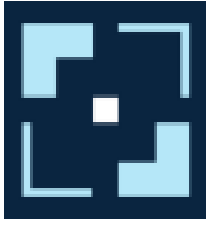
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## 11. VIEWPORT

The viewport displays canvases that render series.





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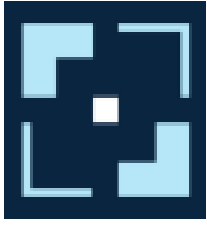
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The following tools allow you to modify image views in the viewport:

**Zoom:** Click and drag up to zoom out, click and drag down to zoom in



*Image Description: Screenshot of using the Zoom tool*



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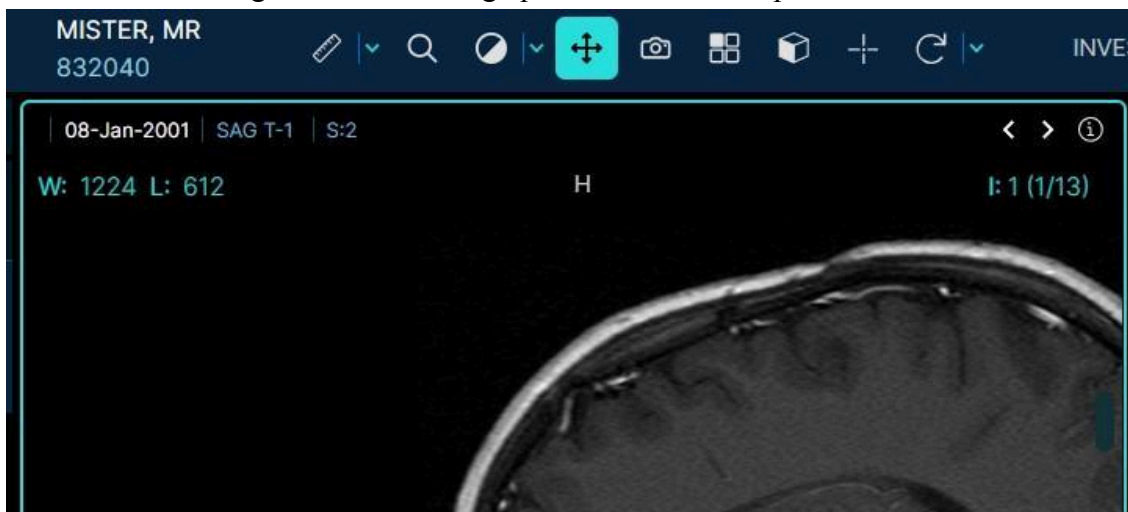
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**Window/level:** Click and drag up/down to change contrast, click and drag left/right to change brightness.

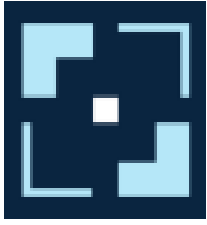


*Image Description: Screenshot of adjusting the window/level*

**Pan:** click and drag to move the image position in the viewport



*Image Description: Screenshot of adjusting image position*

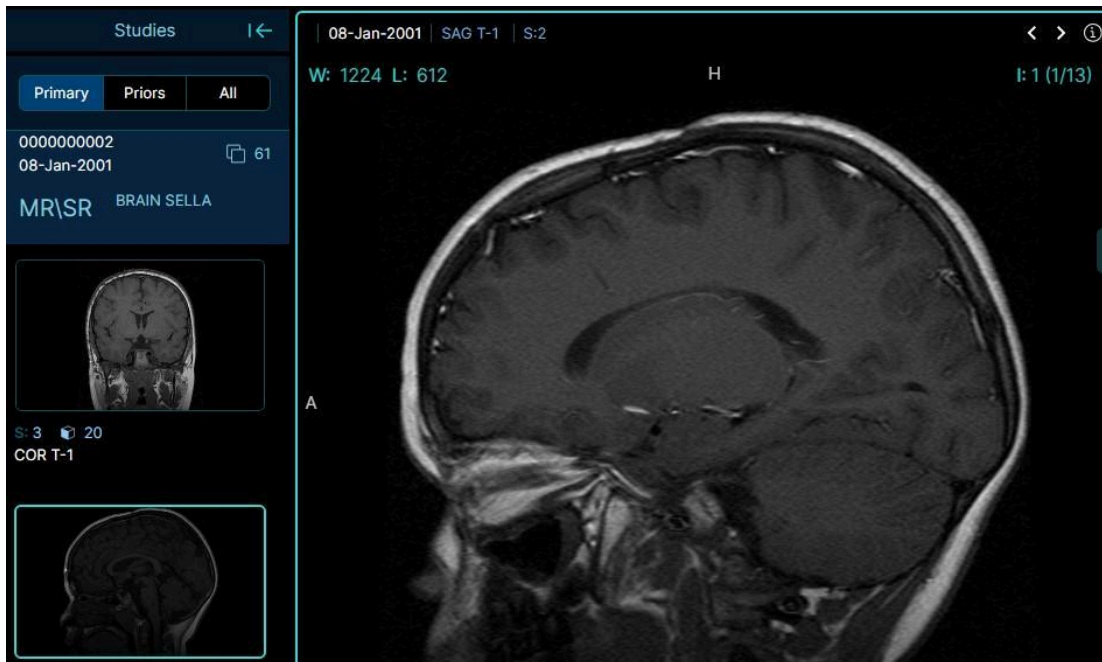


# Radical Imaging

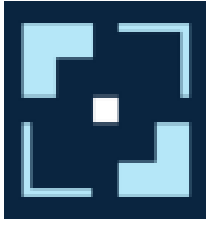
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## 11.1. Changing Series on Display

Double clicking or dragging and dropping the desired series from the left panel will change the series on display in the viewport.

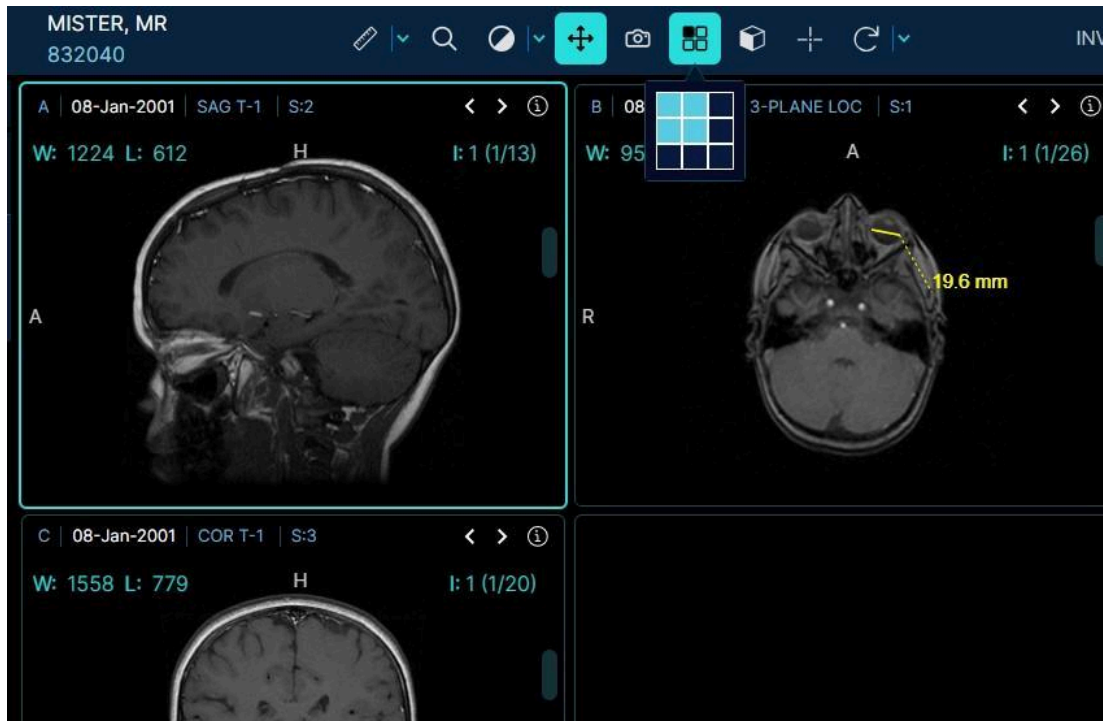


*Image Description: Screenshot of the series pane*

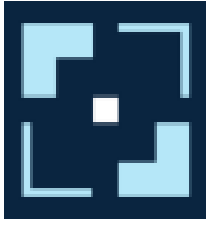


## 11.2. Changing Layout

The Grid Layout tool allows you to change the layout of the viewer by first selecting a grid size.



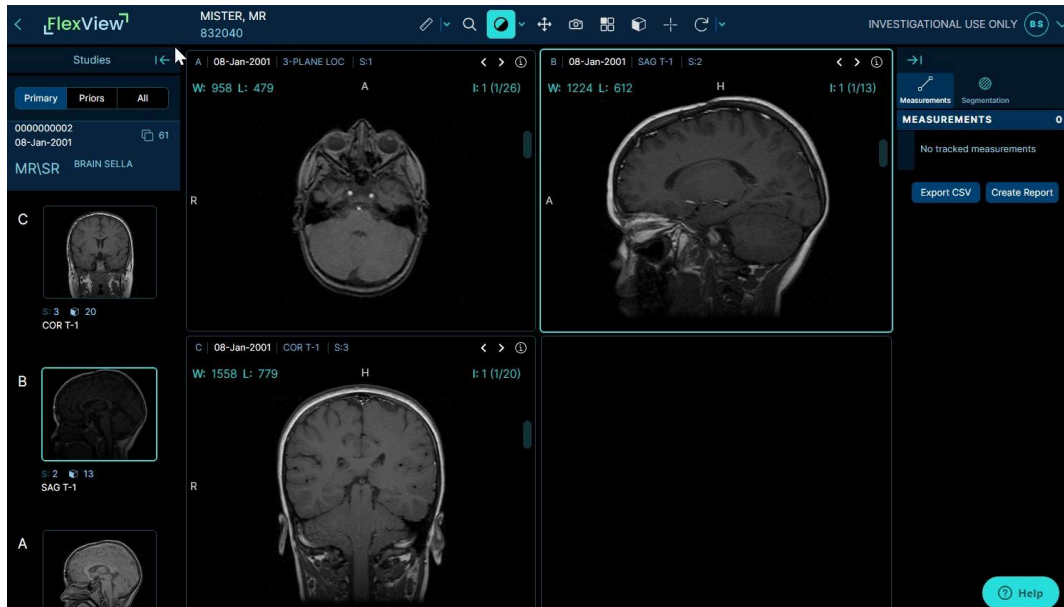
*Image Description: Screenshot of the grid layout tool being used to select a 4x4 grid*

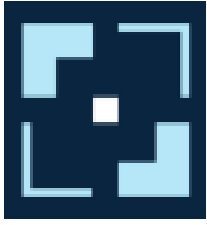


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After changing the layout grid, you can select studies for each viewport in the grid by dragging and dropping studies into the viewport.

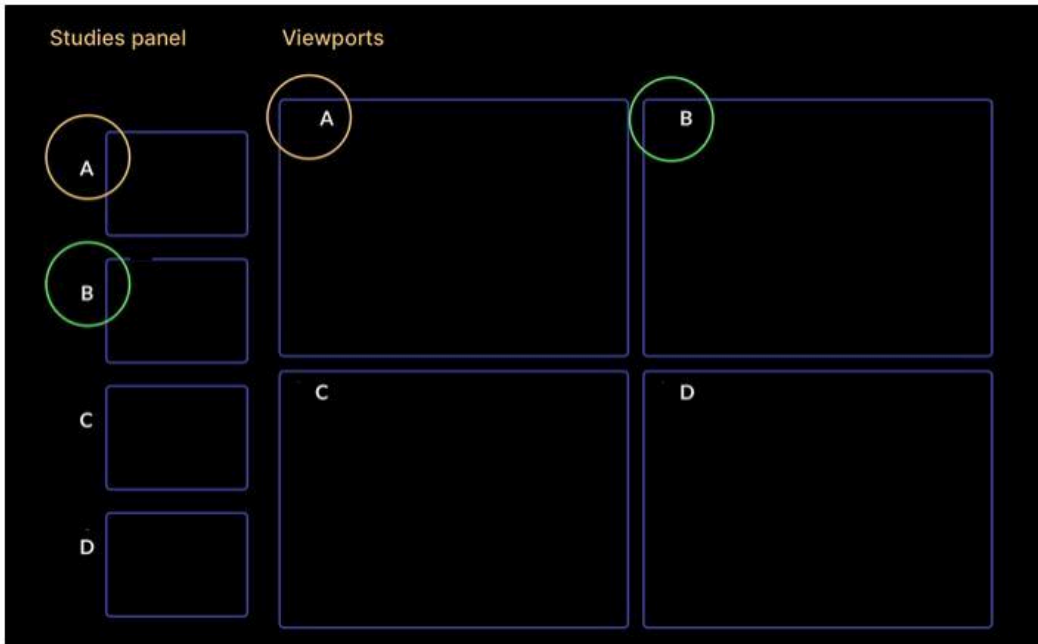




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After changing the layout from 1x1, each viewport will be labeled with a letter which matches its series section in the study list.

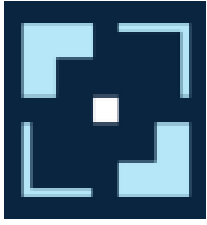


*Image Description: Screenshot of the 4x4 grid with series labels in the left panel*

## 12. TOOLBAR

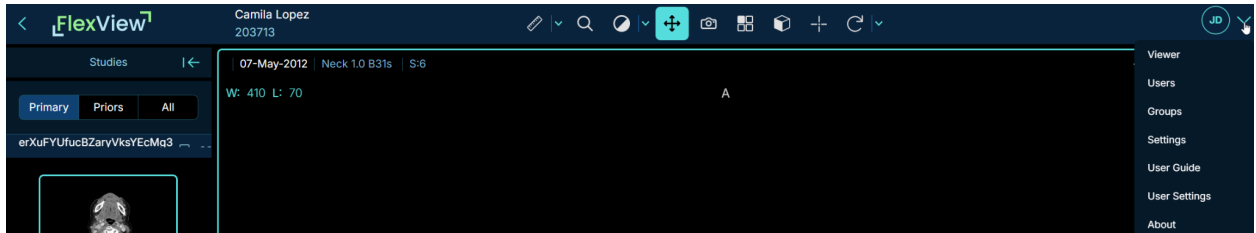
The main components of the toolbar are:

- Navigation back to the Study List
- Tools
- User Setting



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*Image Description: Screenshot of the toolbar at the top of the viewer*

The arrow on the left allows you to navigate back to the study list, the toolbar in the middle allows you to use tools, and the user settings can be selected from the menu on the right.

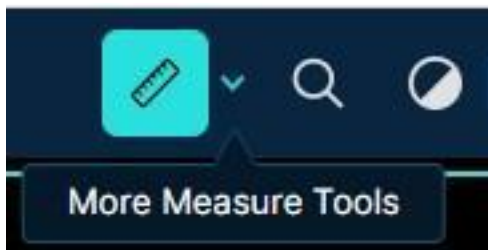
## 12.1. Available Tools

This section displays all the available tools inside the default Diagnostic mode. Some modes have only a subset of tools available.

## 12.2. Measurement Tools

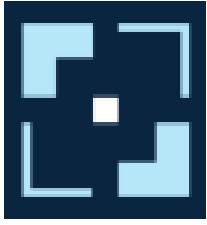
When a measurement tool is selected from the toolbar, it becomes the active tool. Use the dropdown menu to see the list of more measurement tools.

The first measurement tool available is the **Length tool**.



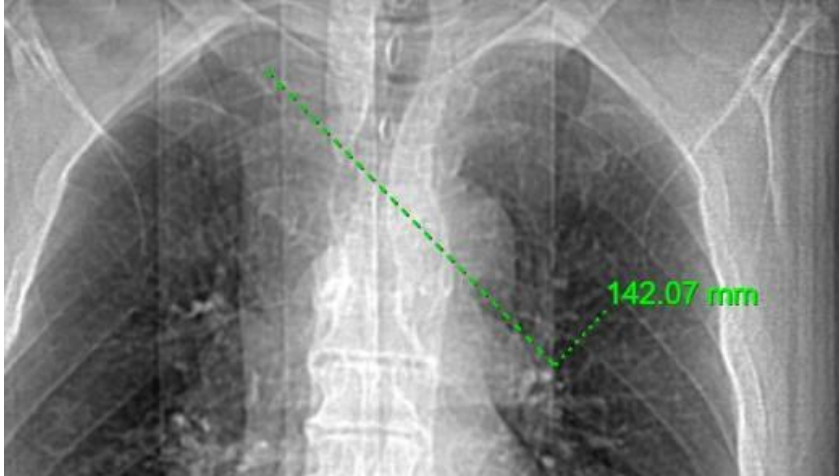
*Image Description: Screenshot of the length measurement tool being selected*

With this tool, you can measure a length in any linear direction by clicking and dragging.



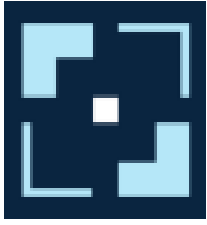
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*Image Description: Screenshot of a length measurement being created*

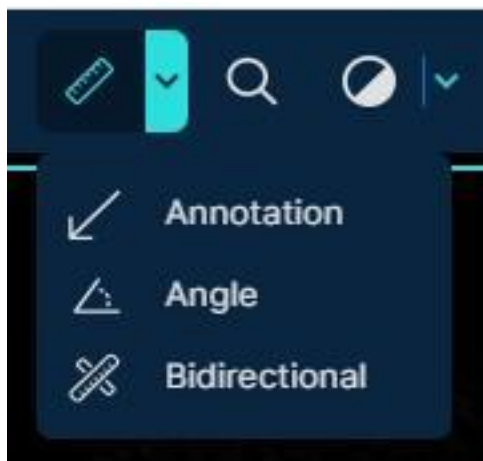
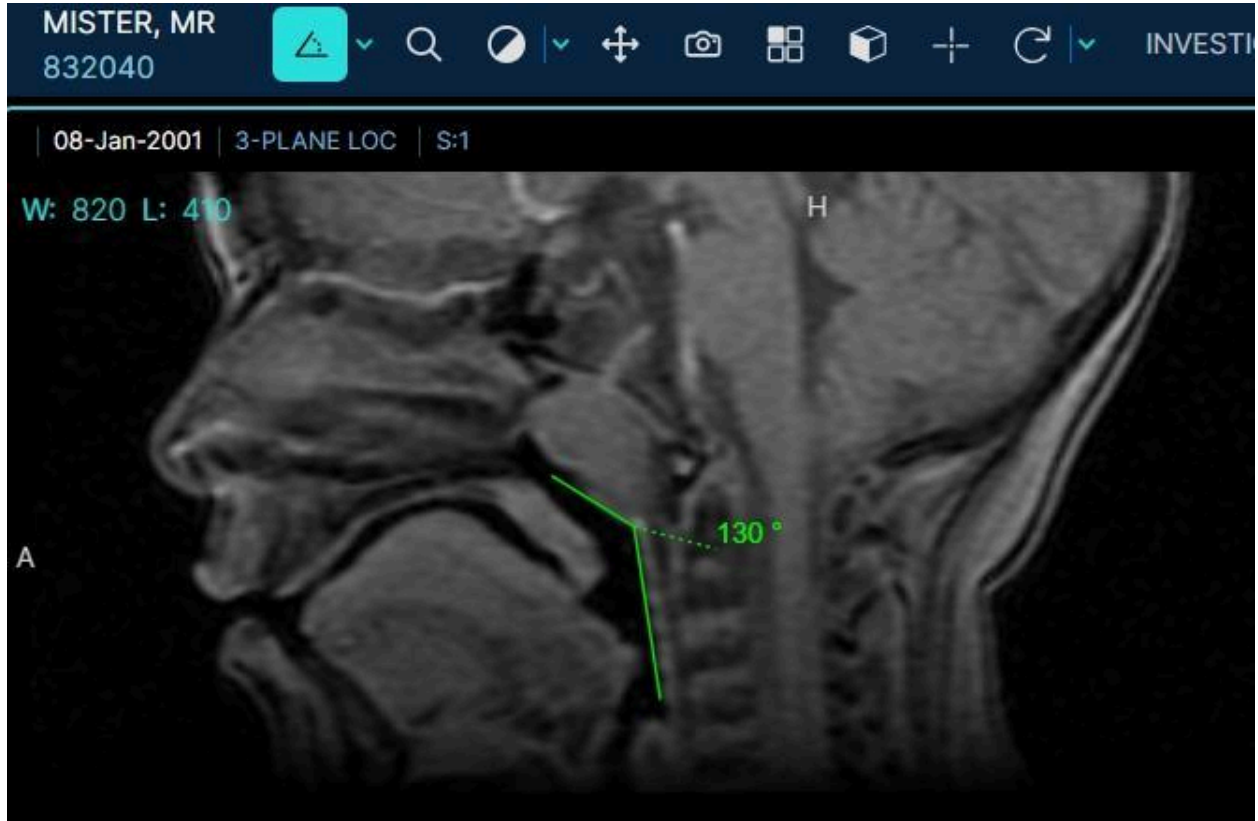
By clicking on the dropdown on the right side of the Length tool, you can see the other measurement tools listed:

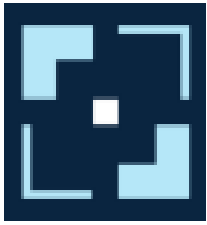


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**Angle:** This tool measures an adjustable angle on an image.

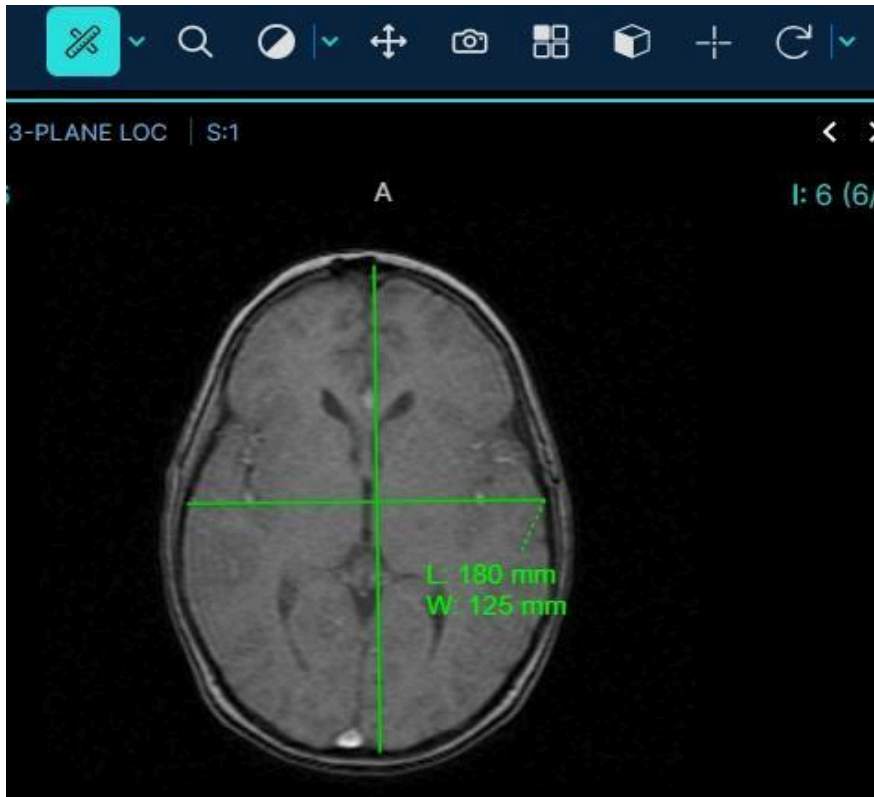


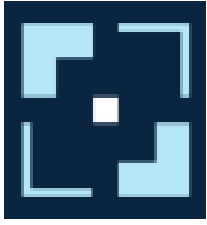


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**Bidirectional:** The Bidirectional measurement tool allows you to take 2 linear measurements orthogonal to one another and connected by a point in the center.

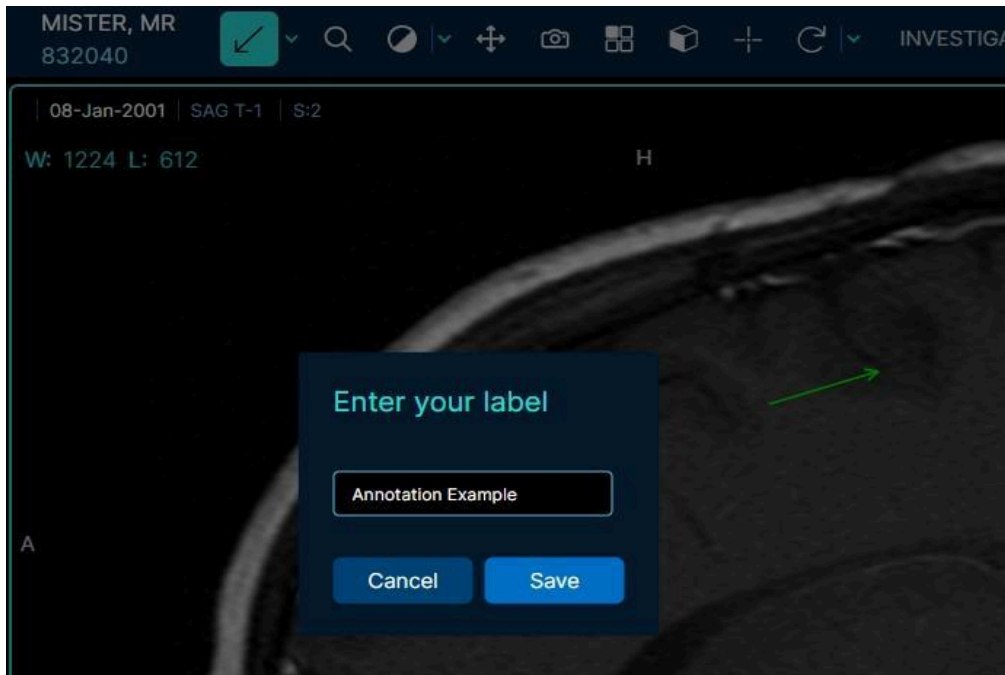


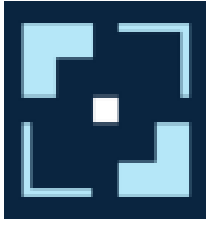


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**Annotation:** The Annotation tool allows you to create an annotation.

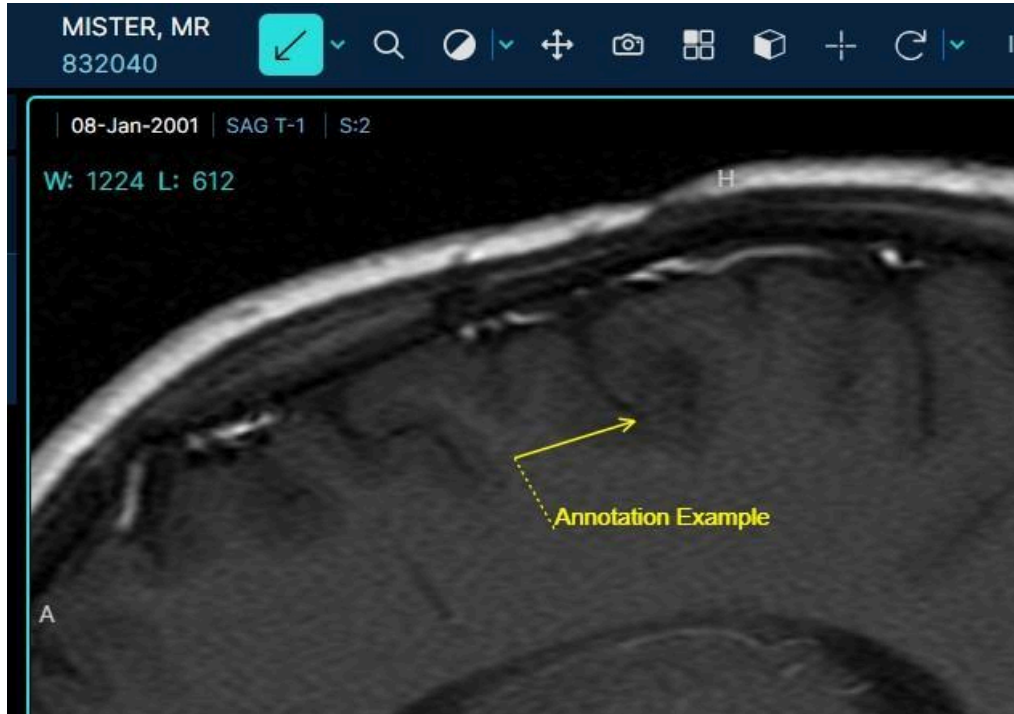


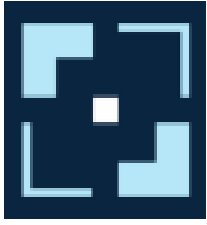


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First, you will be prompted to label your annotation.

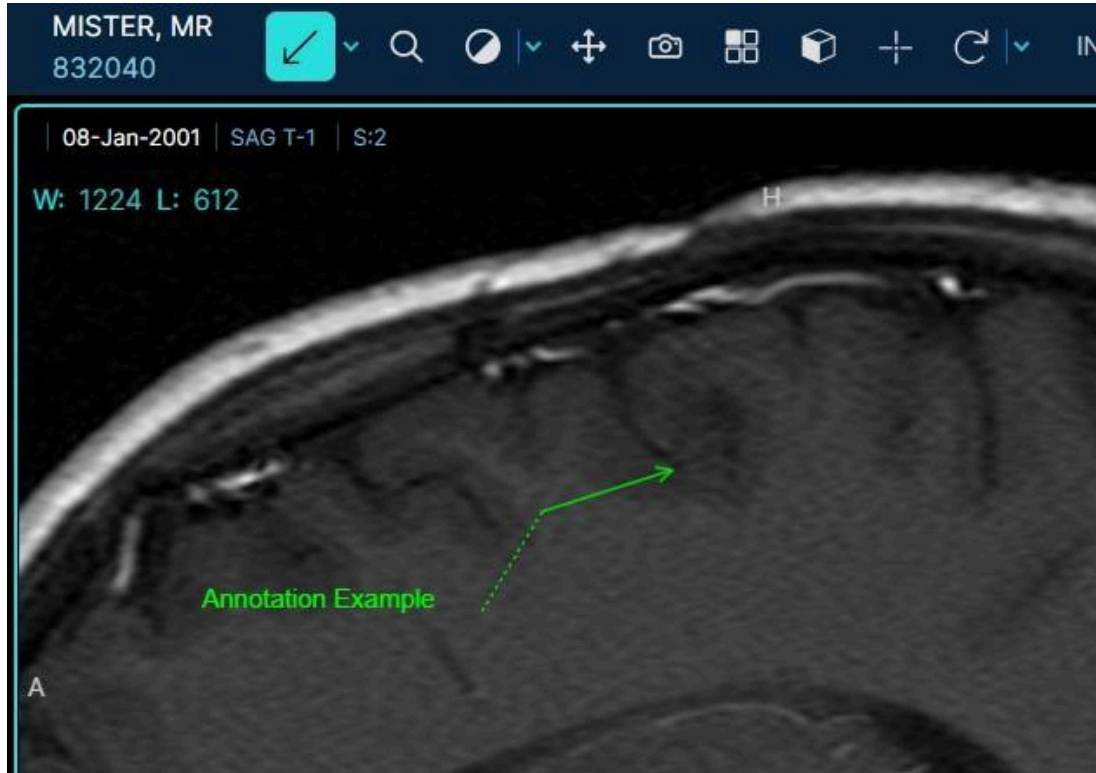




# Radical Imaging

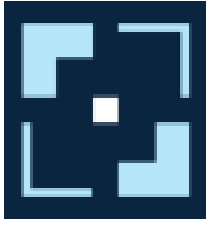
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Then, you can adjust the position of your label.



Linear measurement tools (e.g., length tool and bidirectional measurement tool) provide units in both the metric system (e.g., millimeters) and the US Imperial system (e.g., inches).

Additionally, the angle measurement tool utilizes degrees as its unit of measurement. The unit for the angle measurement tool is degrees. If no physical calibration is set, length will be shown in pixels (px).

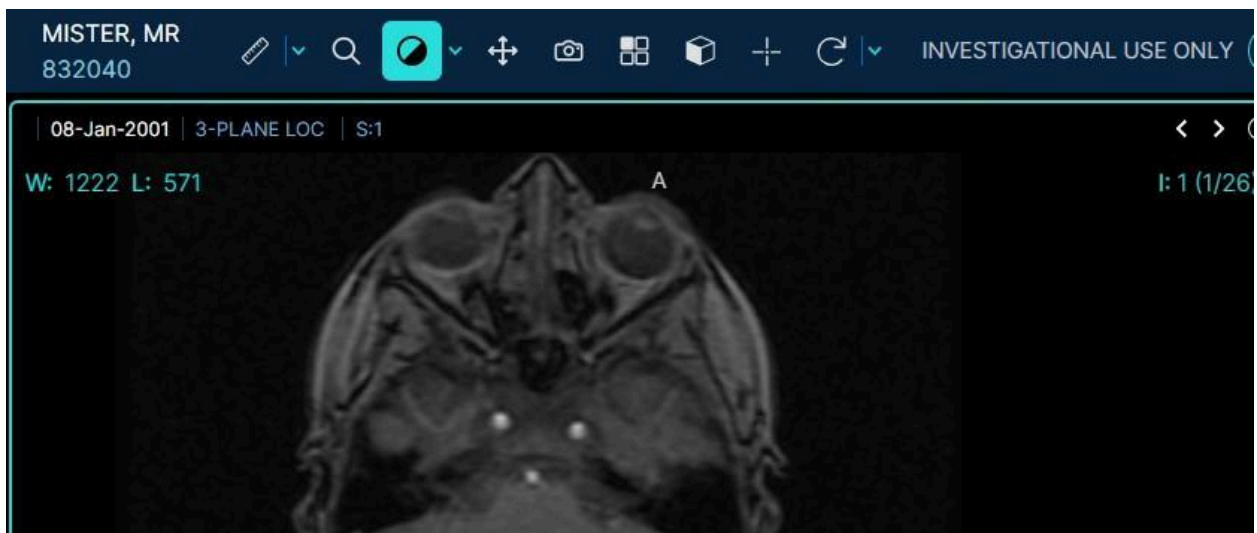


# Radical Imaging

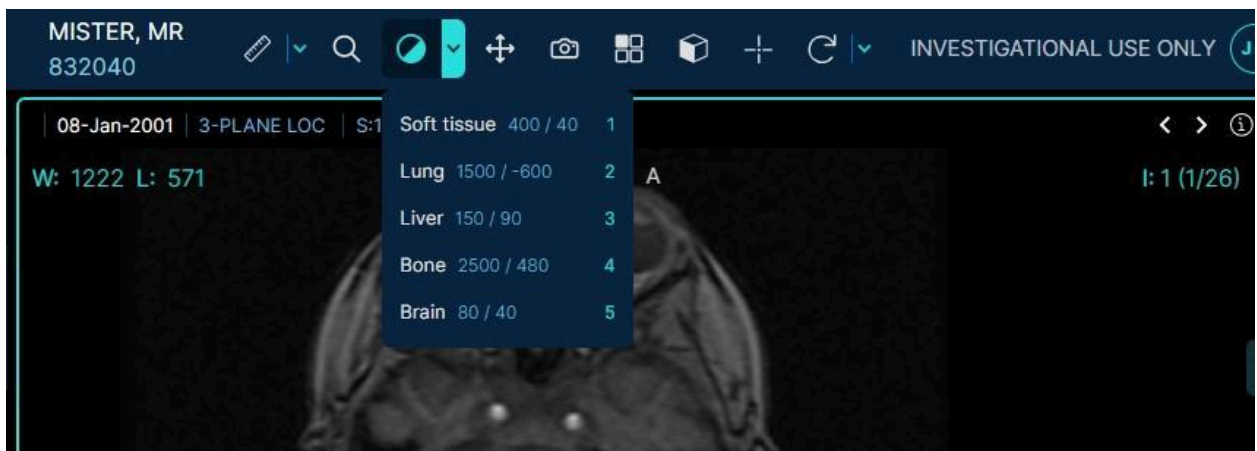
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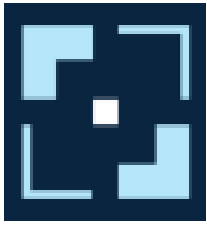
## 12.3. Window Level

The Window Level tool enables manipulating the window level and window width of the rendered image. Click on the tool to enable freeform Window Level adjustment, then click and drag on the viewport to adjust the window level.



Click on the dropdown to expand the tool and choose from predefined Window Level settings for common imaging scenarios.



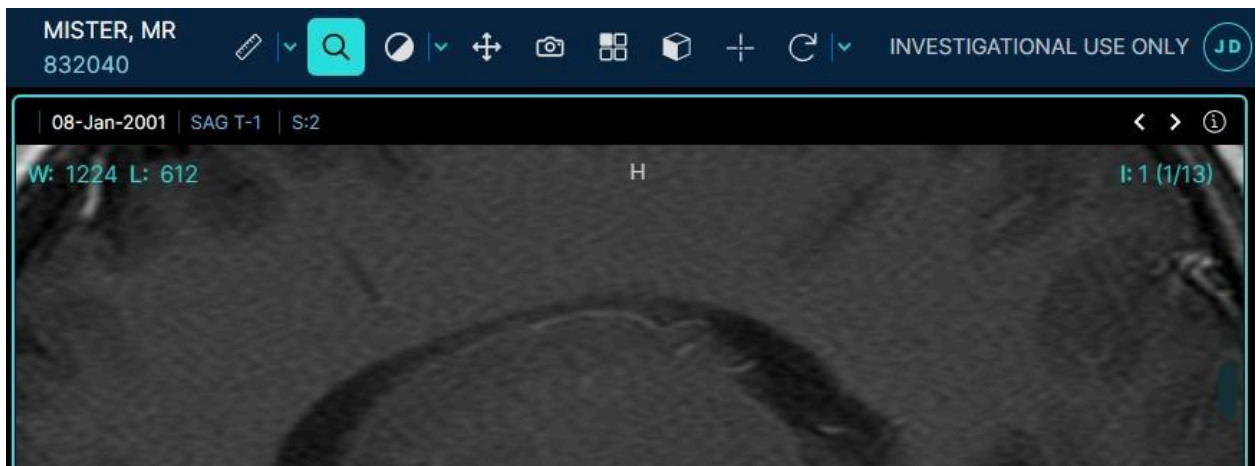


# Radical Imaging

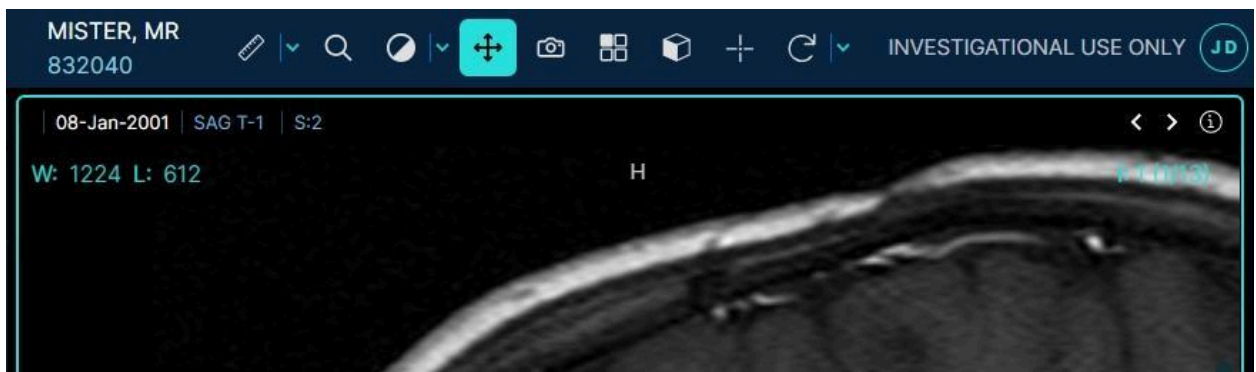
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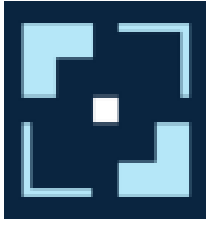
## 12.4. Pan and Zoom

With the Zoom tool selected, click and drag the cursor on an image to adjust the magnification.



With the Pan tool selected, click and drag the cursor on an image to adjust the image position.



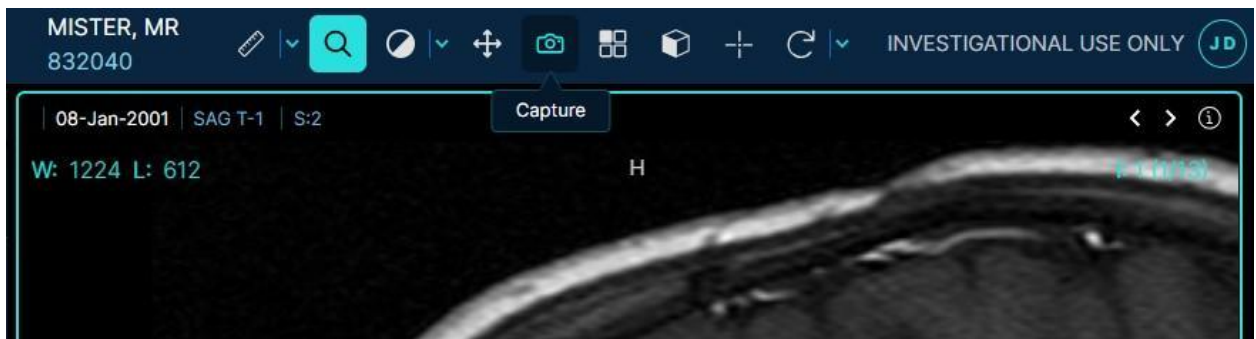


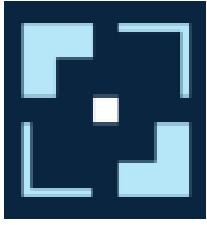
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## 12.5. Image Capture

The Image Capture tool allows you to download a high-quality image capture using common image formats (png, jpg).

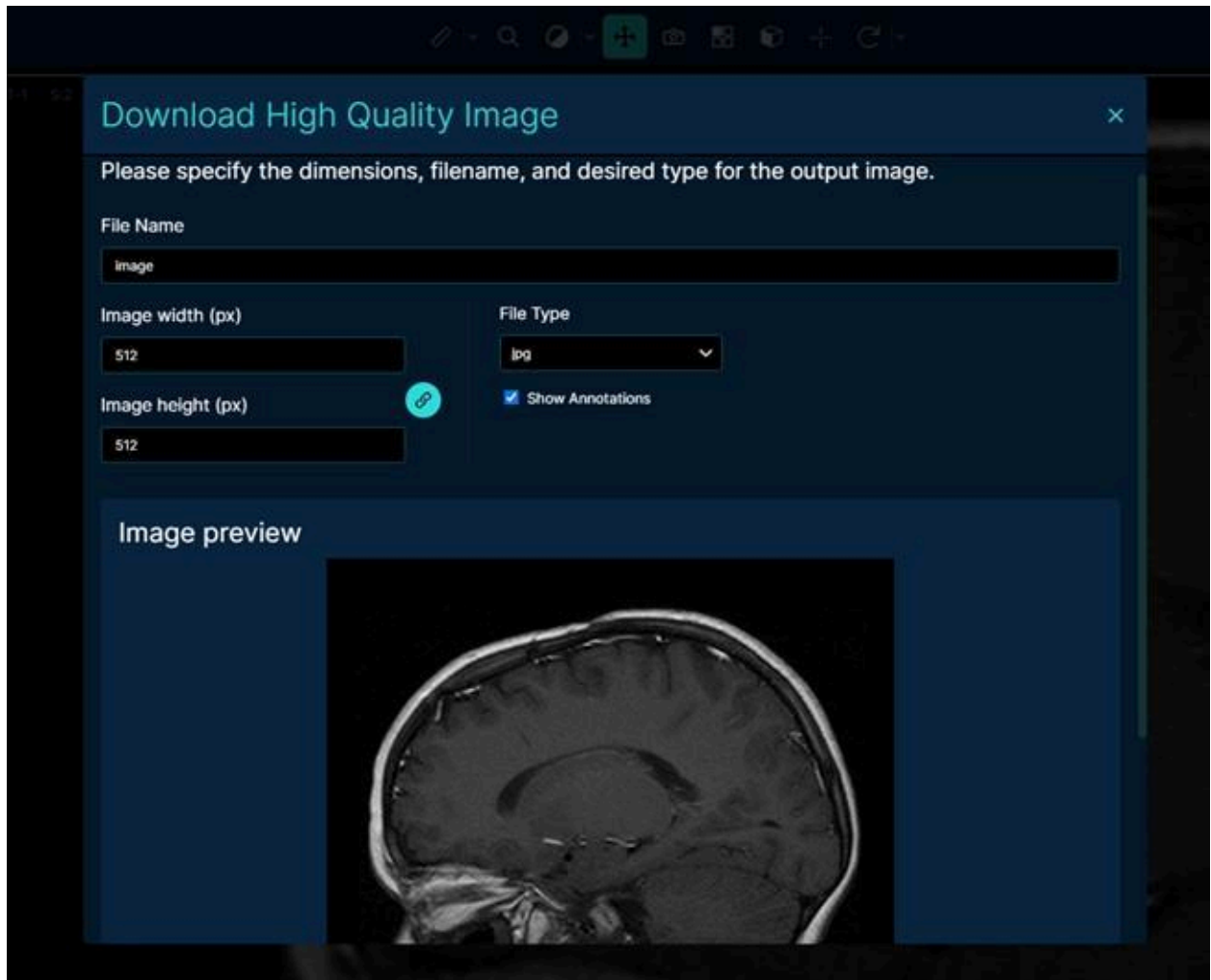


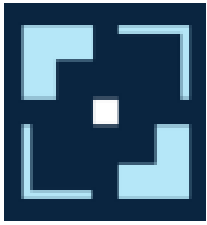


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In the dialogue that opens, you can configure the filename, image's width and height, and filetype before downloading the image.



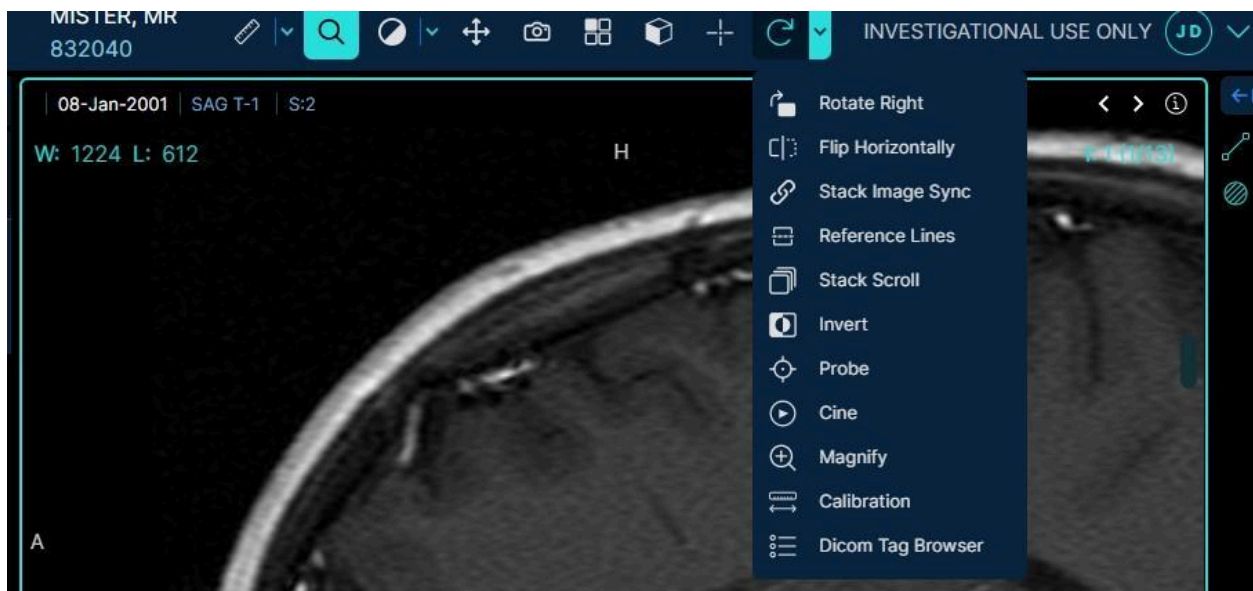


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## 12.6. More Tools Menu

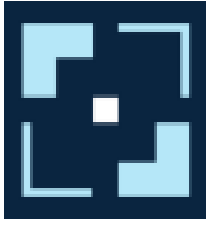
Hover over the dropdown to the right of the Reset View arrow to get a list of all the remaining tools available. When a tool is selected from the More Tools menu, it becomes the active tool until it is replaced by clicking on a different tool in the More Tools menu or main toolbar.



**Reset View:** This tool resets all image manipulation such as position, magnification, and window/level adjustments on the current image.



**Rotate Right:** This tool rotates the image 90 degrees clockwise.

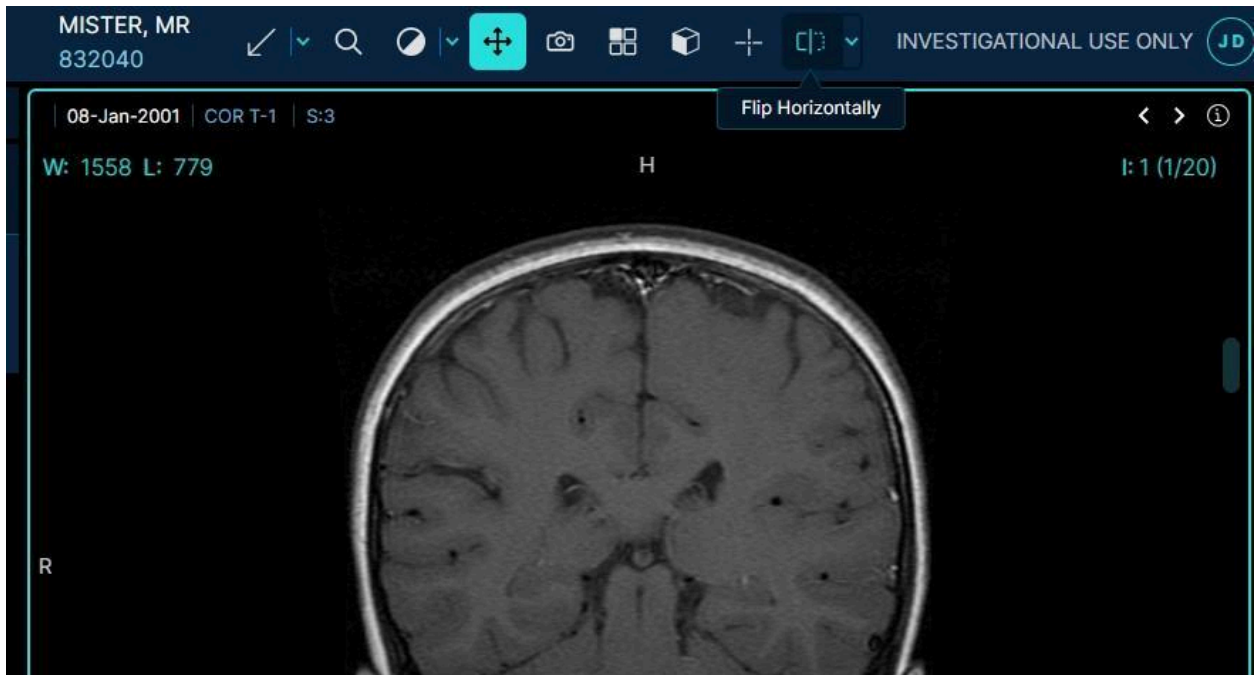


# Radical Imaging

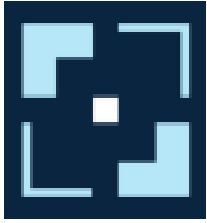
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**Flip Horizontally:** This tool flips the image 180 degrees horizontally.



**Stack Scroll:** This tool links all viewports containing images such that the viewports all scroll together.

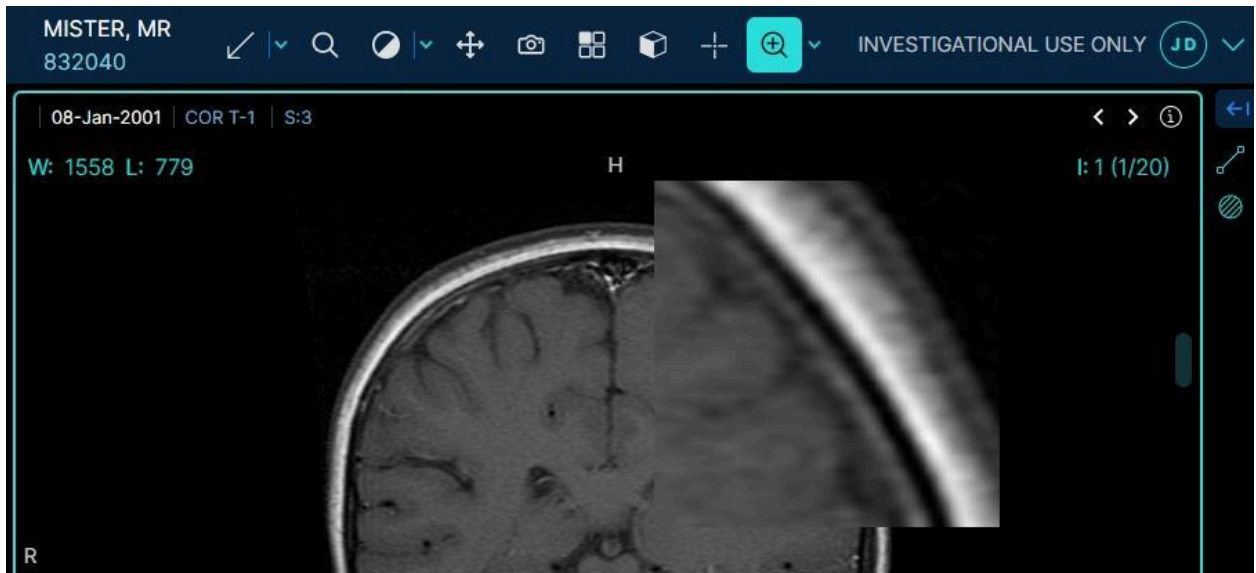


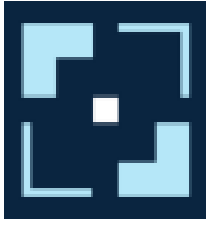
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**Magnify:** This tool allows you to magnify a particular area of interest.

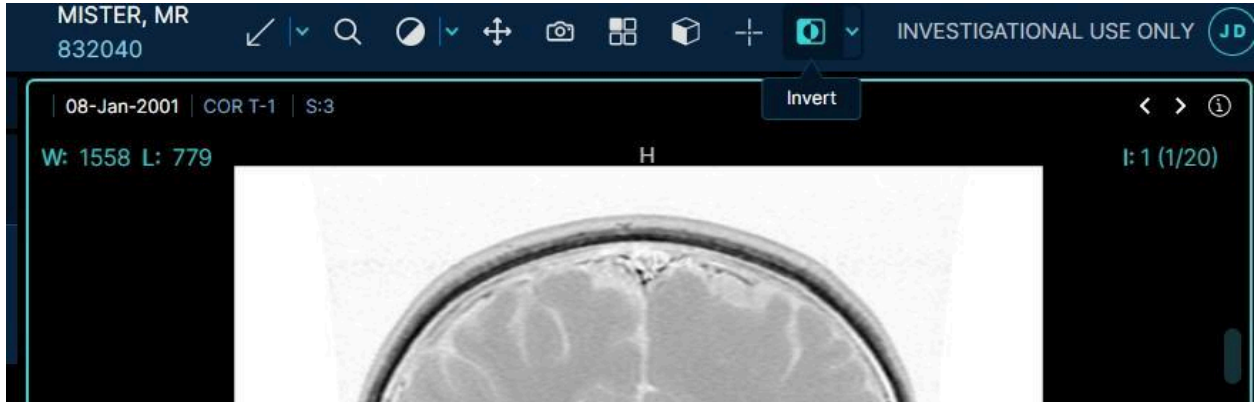


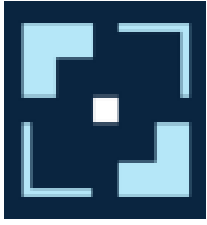


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**Invert:** This tool inverts the color scale of the current image.



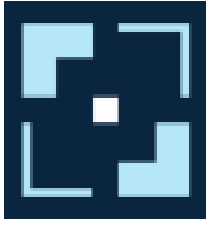


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**Cine:** This tool toggles the Cine player control in the currently selected viewport. Click the "x" on the Cine player or click the tool again to toggle off.





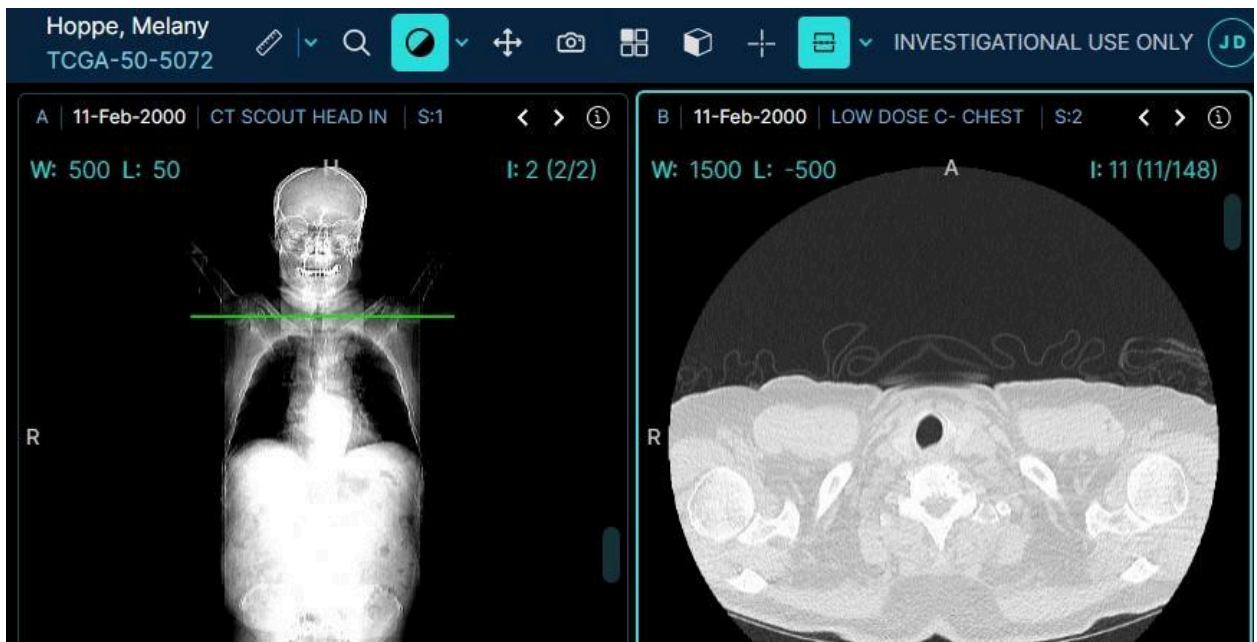
# Radical Imaging

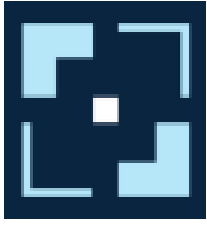
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**Probe:** Drag the probe to see pixel values and Hounsfield units.



**Reference Lines:** This tool shows lines in spatially related viewports to represent the planar position in the active viewport.





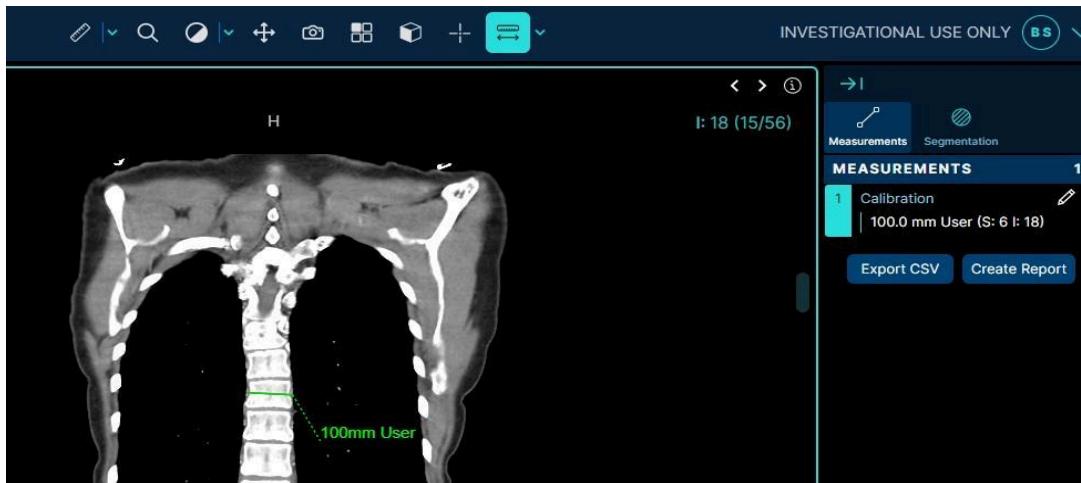
# Radical Imaging

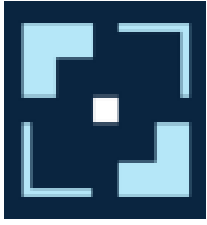
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**Stack Image Sync:** This tool synchronizes image scrolling in all spatially related viewports.



**Calibration Tool:** This tool calibrates the Pixel Spacing Attribute (Physical distance in the patient between the center of each pixel). Note that calibration done by the user will show "USER" after the measurements as in the image below.



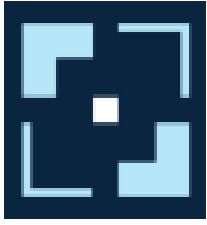


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**DICOM Tag Browser:** This tool displays top-level DICOM tags.

Tag	VR	Keyword	Value
(0008,0005)	CS	SpecificCharacterSet	ISO_IR 100
(0008,0008)	CS	ImageType	ORIGINAL\PRIMARY\OTHER
(0008,0016)	UI	SOPClassUID	1.2.840.10008.5.1.4.1.1.4
(0008,0018)	UI	SOPInstanceUID	1.2.840.113619.2.5.1762583153.215519.97895706 3.80
(0008,0020)	DA	StudyDate	20010108
(0008,0021)	DA	SeriesDate	20010108
(0008,0022)	DA	AcquisitionDate	20010108
(0008,0023)	DA	ContentDate	20010108
(0008,0030)	TM	StudyTime	120022

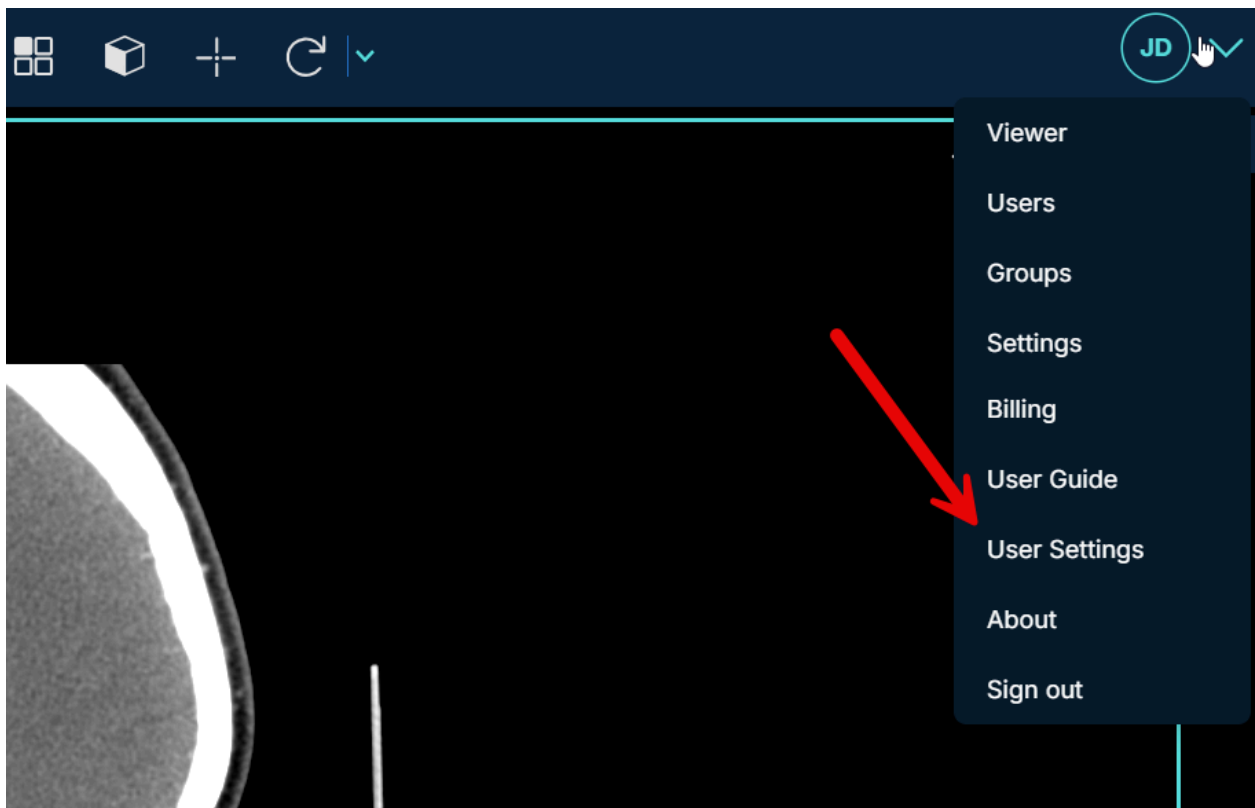


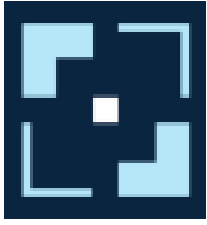
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## 13. USER Setting

To change your preferences, click on the menu at the top right of the viewer and select User Settings.

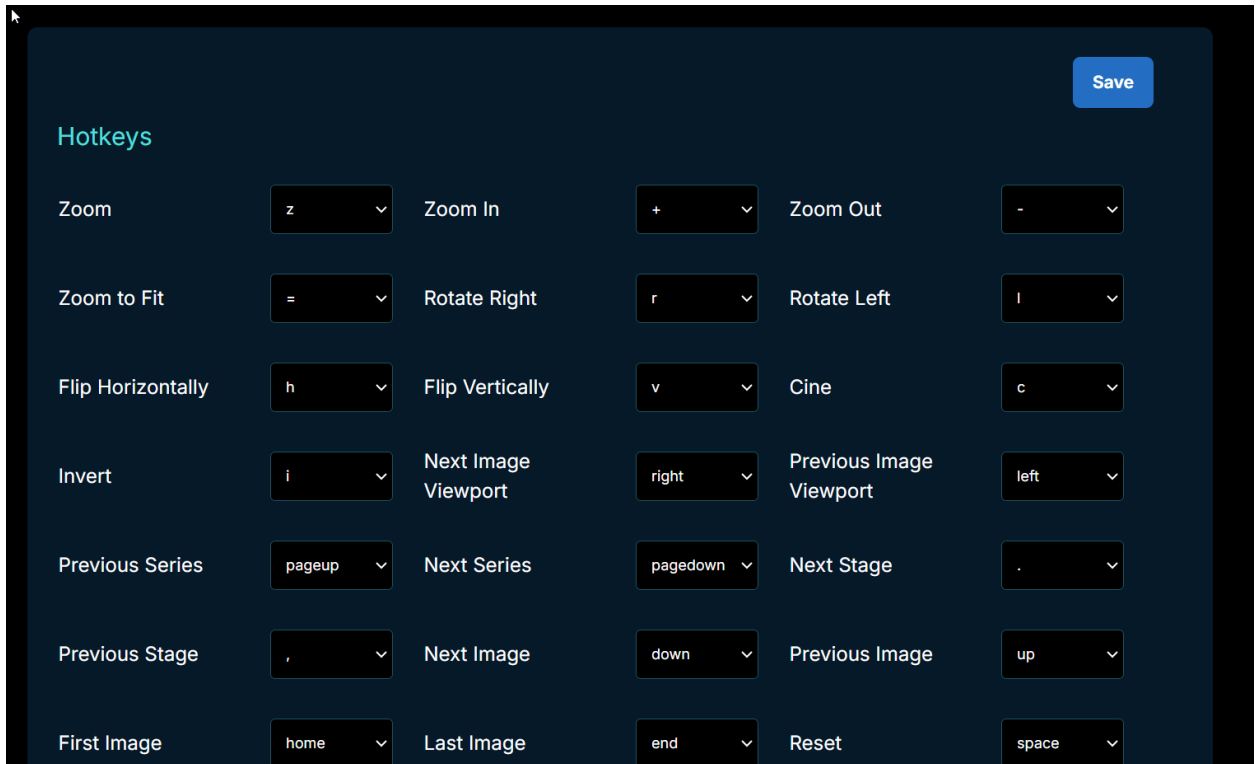




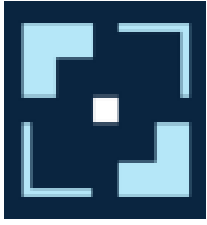
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The default preferences include hotkey assignments. You can reassign personal hotkeys from this dialogue.

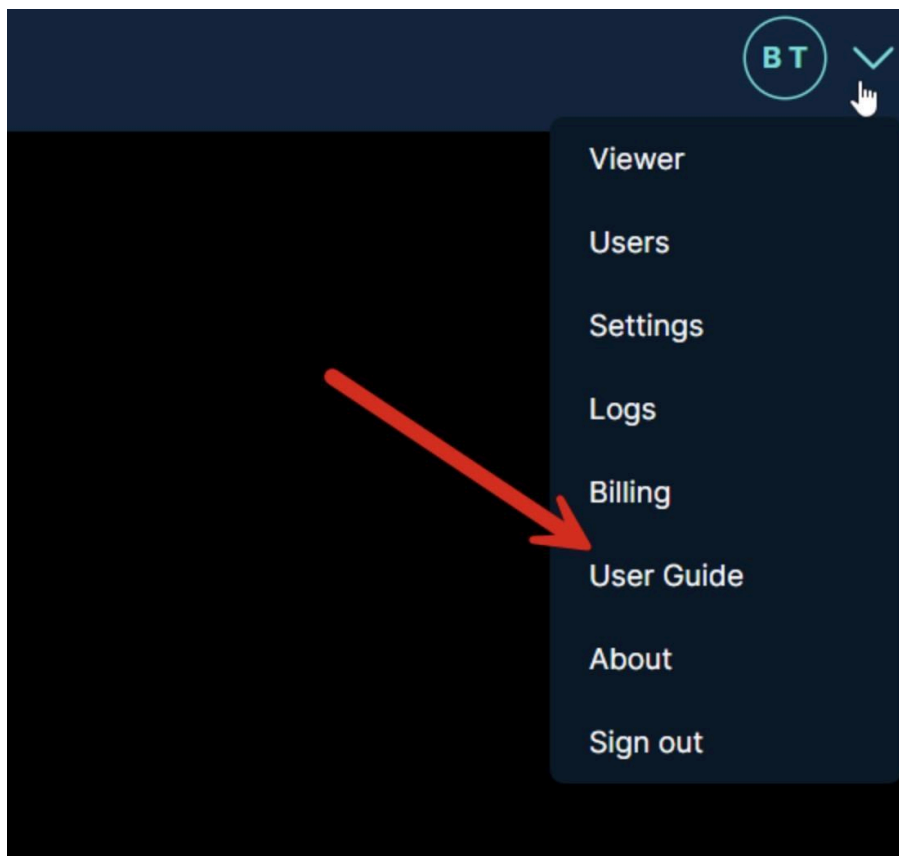


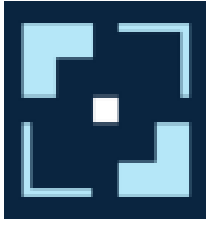
*Image Description: Screenshot of the user settings dialogue*



### 13.1. Unresolved Anomalies

A list of unresolved anomalies for the current software version can be found in the publicly available release notes, which can be accessed through the “User Guide” tab in the menu options in the release notes.





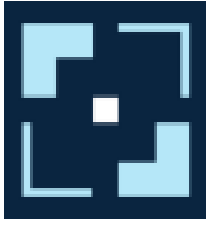
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### 13.2. Checking the Software Version

To check the version of the software, open the user menu and click “About” to open the version screen. There are two versions, the backend platform version and the frontend viewer version.



*Image Description: Screenshot of the about page.*



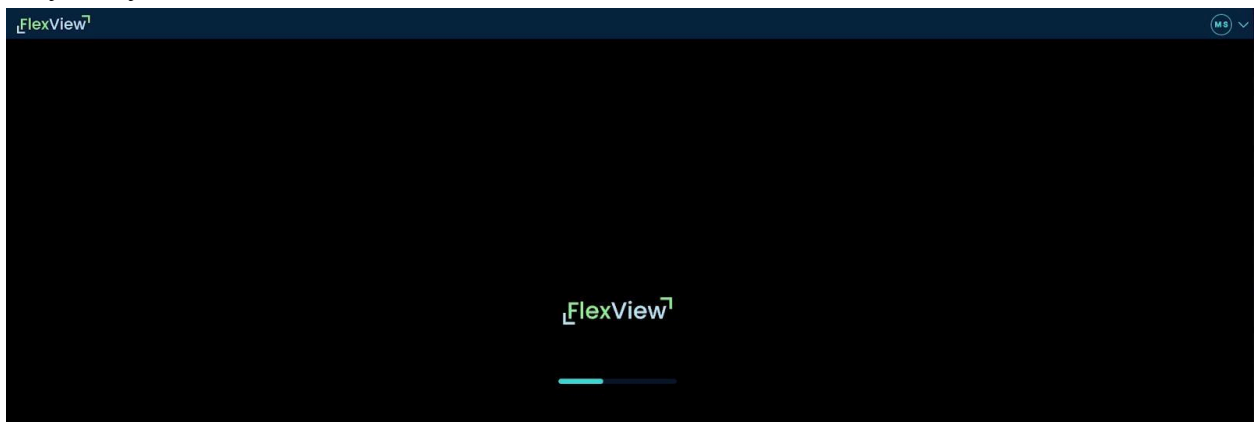
## 14. BASIC TROUBLESHOOTING

Here is a list of the most common issues you may encounter while using FlexView Diagnostic.

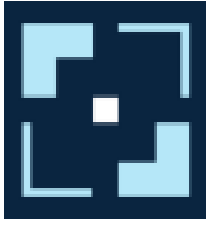
- The FlexView logo and progress indicator are shown on the screen, but the study list does not load after a few seconds.
- After selecting a study, no image loads in the viewer.
- Login Expired Warning displays at top left side of screen.
- Low Bandwidth Detected Warning
- Warning messages displayed while using the CINE tool.
- Create Report Failed warning appear while Creating a Report (SR)
- Some studies do not fully load, or viewports are empty (especially while using while using MPR Tool)

### 14.1. The FlexView logo and progress indicator are shown on the screen, but the study list does not load after a few seconds.

This issue occurs because your image data source is not configured correctly. If you are an administrator, go to Settings and verify all your configuration details for the data source and confirm that the dataset is set as default. If you do not have access to settings in FlexView, please ask your system administrator for assistance.



*Image Description: Study list not loading.*

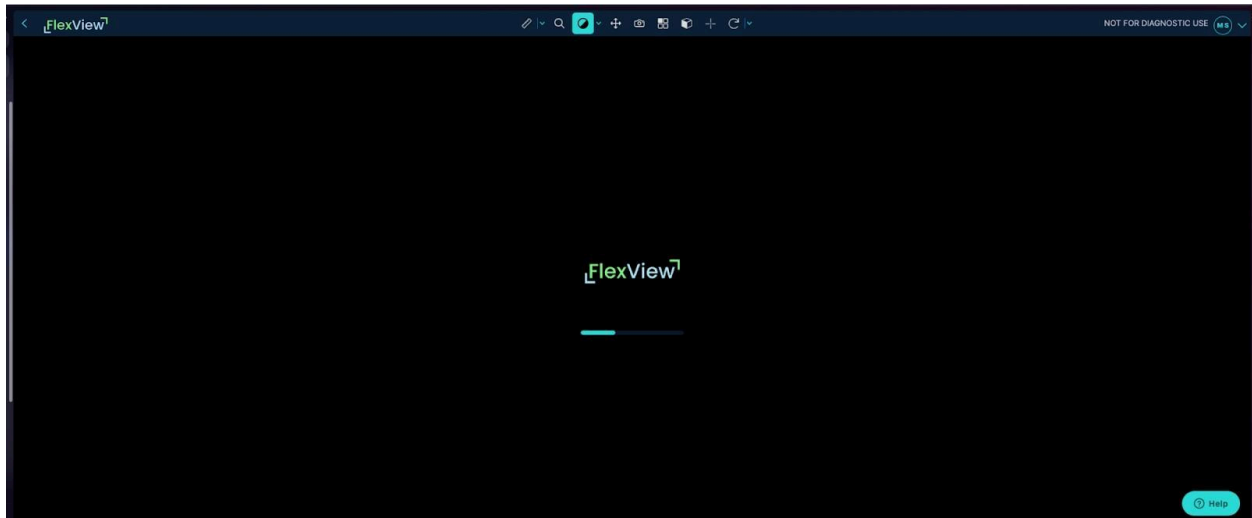


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## 14.2. After selecting a study, no image loads in the viewer.

You can see the view tools, but the FlexView logo and progress bar are the only things visible in the viewer.

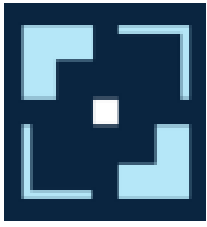


*Image Description: No image loads after selecting a study.*

First try refreshing your browser. If the problem persists, your study is likely missing metadata. Please contact your PACS administrator for support with the DICOM file.

## 14.3. Login Expired Warning displays at top left side of screen.

This warning appears when your FlexView session has expired. You will be directed to login again.

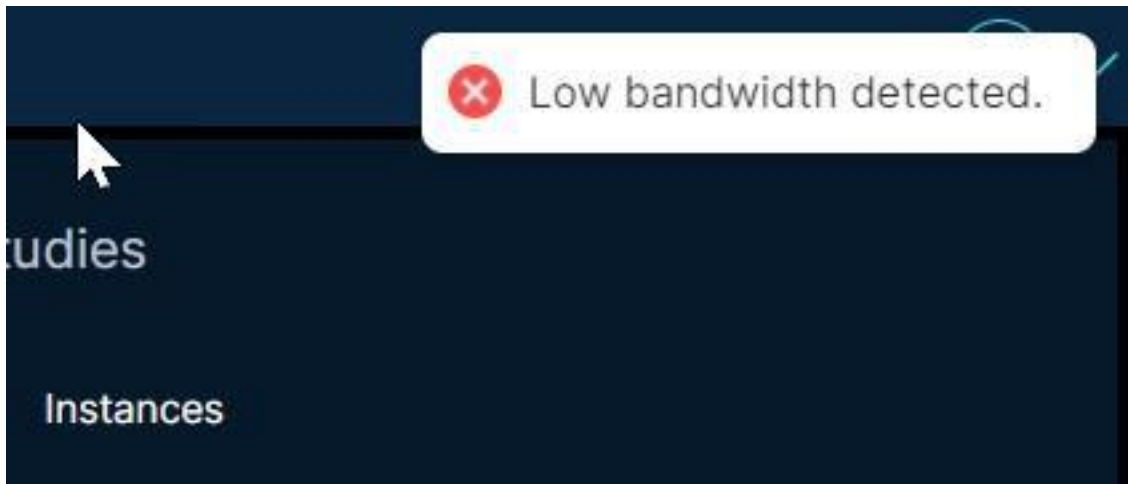


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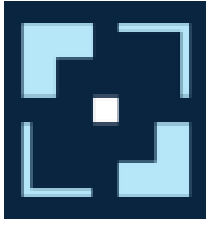
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## 14.4. Low Bandwidth Detected Warning

There is no action needed. This is usually temporary because of slower network speeds. While the warning is displayed, you may see slower loading time especially for large studies or warning messages while using the CINE tool.



*Image Description: Low Bandwidth Detected Warning*



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## 14.5. Warning messages displayed while using the CINE tool.

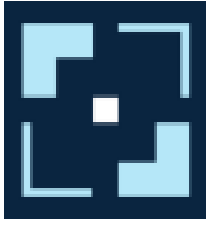
There are two common warnings that may appear when using the CINE tool. *Framerate Mismatch* or *Frames Skipped* may be displayed on the first round of playing a CINE loop.



*Image Description: Frame Skipped warning when using CINE tool.*

This can be caused by delayed loading of your study. You can either wait a few more seconds between selecting a study and starting the CINE tool or allow the study to play through one or two times.

If you are still seeing the warning, you can adjust the frame rate to a slower speed and the issue should be resolved.



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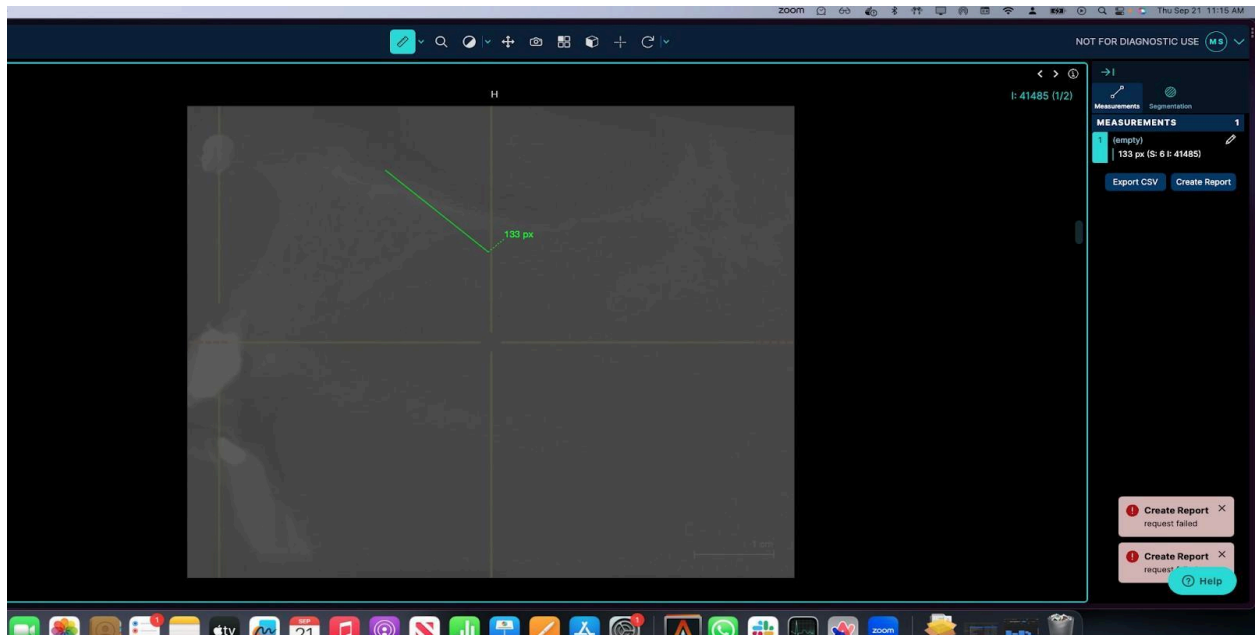
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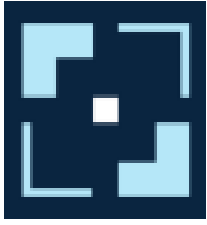
*Image Description: Frame rate may be adjusted to slower speed as shown to resolve warning.*

## 14.6. Create Report Failed warning appear while Creating a Report (SR)

If you see this warning, your data source may not support saving SR or may be misconfigured. Please contact your administrator.



*Image Description: Create Report "request failed" warning shown at bottom right corner.*



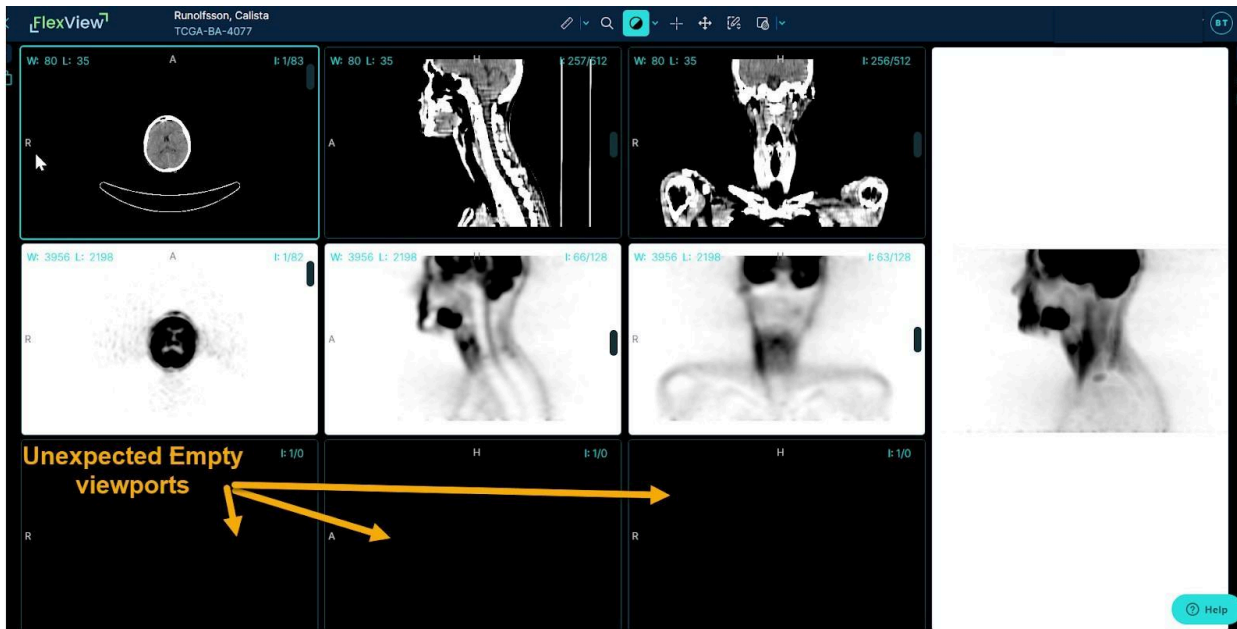
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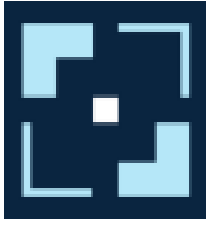
## 14.7. Some studies do not fully load, or viewports are empty (especially while using while using MPR Tool)

Your computer may not have sufficient GPU. To determine your computers, GPU details you can use this online tool. Simply put the link in your browser [\\_https://pmndrs.github.io/detect-gpu/](https://pmndrs.github.io/detect-gpu/) for information about your machine.

- If the fps (frames per second) number is less than 100 or your tier is less than 3, your machine will need to be upgraded for advanced rendering.
- If you are not using the MPR tool, try reducing the number of viewports open at one time as this will reduce some of the computing load on your GPU.



*Image Description: Unexpected empty viewports.*



## **15. CYBERSECURITY GUIDE**

### **15.1. Overview**

Radical Imaging LLC takes cybersecurity seriously.

For the software to be used in a secure manner, you must follow a number of best practices which are outlined in the following sections.

### **15.2. User Responsibilities**

#### **15.2.1. Account Configuration**

To protect patients' privacy and medical information, it is important to secure the computer or mobile devices used to access FlexView Diagnostic. The level of security required depends on your organization's computer and network policies and procedures. Small healthcare practices can benefit from following the guide provided by the U.S. Department of Health and Human Services: " Reassessing Your Security Practices in a Health IT Environment: A Guide for Small Health Care Practices ."

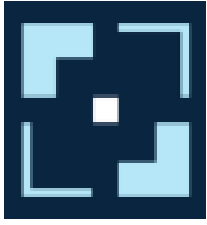
When choosing a password, users should select passwords that have not been previously used on other sites. This reduces the risk of unauthorized access should another password-protected account become compromised. Using a password generator and password manager can help create and store unique passwords.

When using FlexView Diagnostic, users must use a compatible and up-to-date browser. Using FlexView Diagnostic with an incompatible or outdated browser may result in unexpected software behavior or security risks.

#### **15.2.2. DICOM Web or Static WADO Configuration**

When configuring your Static WADO data source, use the principle of minimal privilege. I.e., restrict the permissions of the account keys to the minimal privilege required for FlexView Diagnostic to function. In particular, the keys should only have read access.

We suggest that you deploy your Static WADO server behind an authentication service protected by JWT (JSON Web Tokens) authentication with a short time-to-live (TTL).



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### **15.2.3. AWS HealthLake Imaging Configuration**

When configuring your AWS HealthLake Imaging data source, use the principle of minimal privilege. I.e., restrict the permissions of the account keys to the minimal privilege required for FlexView Diagnostic to function. In particular, the keys should only have read access to the HealthLake Imaging resources.

### **15.3. Ports and Networking**

FlexView Diagnostic is run on the cloud and accessed by users in their web-browser. Therefore, there are no network ports or interfaces, other than those used by the web-browser, which send or receive data for this device.

### **15.4. Software Bill of Materials**

A software bill of materials (SBOM) will be provided upon request. Please email [info@flexview.com](mailto:info@flexview.com). Please provide the FlexView Diagnostic version number with your request.

The SBOM is updated automatically for each released version of FlexView Diagnostic and it uses the SPDX 2.2 file format.

### **15.5. Maintenance**

#### **15.5.1. Software Updates**

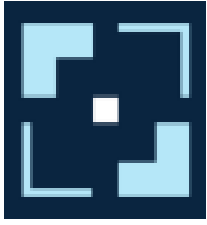
Software updates will be deployed without requiring any action from the user. Updates are verified prior to deployment.

Please email [info@flexview.com](mailto:info@flexview.com) for a log of all changes made to the software.

#### **15.5.2. Backups**

FlexView Diagnostic will not store any medical images. Those data are only stored in the organization's data source (e.g., PACS) and will be only temporarily accessed by FlexView Diagnostic for viewing, annotating, or analysis purposes. Thus, the organization is responsible for all backups of their medical images.

FlexView Diagnostic also will not store any payment information. Stripe, the payment processor, securely stores those data and handles backups for them directly.



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However, FlexView Diagnostic will store access information for the organization's data source (e.g., PACS server credentials) in encrypted form and other data necessary for service, such as first and last names, emails, and login passwords. This data will be backed up daily by our IT staff along with the rest of our cloud data, as a part of our disaster recovery procedures.

### **15.5.3. Logs**

FlexView Diagnostic will log user actions such as button clicks and navigation history, system events such as configuration changes, start-up, and shutdown, security-related events such as login attempts and network anomalies, and other application errors and warnings.

To store the logs, FlexView Diagnostic uses CloudWatch, a well-tested and secure centralized logging system from Amazon AWS. CloudWatch provides a unified view of all logs and allows for search, filtering, alerting, and automated security analysis.

### **15.5.4. End of Life**

If you stop using the FlexView Diagnostic software, to close an account, users should contact support at [info@flexview.com](mailto:info@flexview.com). Upon request, the support team at FlexView will delete the user account and any connections to their data sources. User contact information will be deleted with the user account. FlexView Diagnostic will continue to store log files for one year. Log files can be deleted on request.

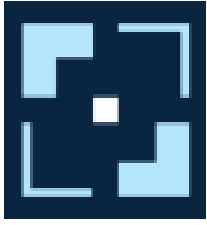
All closed account data will be removed one year after account deactivation.

## **15.6. Responding to Cybersecurity Incidents**

If you believe your FlexView account has been compromised, contact your IT department and notify Radical Imaging at [info@flexview.com](mailto:info@flexview.com).

You may also want to take a few additional steps after contacting Radical Imaging:

First, change your password to prevent further unauthorized access. Second, check your account and data source settings to verify if any changes have been made without your knowledge. Finally, monitor the activity on your organization's data source (e.g., PACS) for any unusual access. If there is any unusual activity, you should change your data source configuration settings immediately to prevent further unauthorized access.



## 16. SYMBOLS GLOSSARY

### 16.1. ISO 15223-1: 2021-07 Medical Devices - Symbols to be Used with information to be supplied by the manufacturer - Part 1: General requirements.



#### **Manufacturer (5.1.1)**

Indicates the *medical device manufacturer*.



#### **Consult instructions for use or consult electronic instructions for use (5.4.3)**

Indicates the need for the user to consult the *instructions for use*.

### 16.2. 21 CFR 801.109 Prescription devices



#### **Prescription use only**

Indicates that Federal law restricts the medical device to sale by or on the order of a qualified clinician.