Operation Manual

Calantic™
Viewer

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A glossary of the symbols used on the Calantic™ Viewer can be found in Chapter 1 of this manual.

Switzerland

Bayer (Schweiz) AG
Uetlibergstrasse 132
8045 Zürich

Australian Sponsor

Imaxeon Pty Ltd
Unit 1, 38-46 South Street
Rydalmere NSW 2116
Australia
Phone: 02 8845 4999
Fax: 02 8845 4998
Customer Service: 1800 633 723

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1 Introduction

1.1 About the Software

The Calantic™ Viewer is part of the Calantic Digital Solutions. The Calantic Digital Solutions encompass multiple parts in addition to the Calantic Viewer:

- Calantic Marketplace and My Apps
- Calantic Cloud platform
- Calantic Edge Device

The Calantic Viewer is an image review software tool for exploration of the results of image post-processing applications (IPPAs), for example, those that automatically detect and size lung nodules. It is a zero-footprint (web-application) viewer designed to be operated as part of the radiologist's standard workflow. The Calantic Viewer displays results only as a viewing tool and is not intended for diagnosis. It is a support tool that provides relevant clinical data as a resource to the clinician. It is not intended to replace the clinician's review of the image or his or her clinical judgement.

> **Note:** The Calantic Viewer is not for use on a mobile platform.

The Calantic Viewer user interface allows clinical users to view the output of digital clinical imaging and workflow applications, including those from IPPAs, and accept or reject the output (i.e., images and findings acquired by the IPPAs) before optionally releasing the output to downstream systems such as PACS HIS, RIS, and departmental reporting systems. The Calantic Viewer provides basic image viewing capability and manipulation, including the ability to measure lengths and angles. Measurements and visualizations made in the Calantic Viewer are not permanent records on the Calantic Viewer and cannot automatically be released and transferred to PACS.

> **Note:** This Operation Manual is intended for global markets. Feature and clinical application availability will vary by market or by configuration in the same market; contact your authorized Bayer representative for more information per the information listed in 1.10 Contact of this manual.

The Calantic Marketplace and My Apps provides customers, such as radiologists, access to review a curated set of clinical applications, such as AI-enabled solutions, that can help simplify and drive efficiencies throughout the radiology workflow and as part of a larger disease management strategy. Customers can browse for applications (apps) and packages on the Calantic Marketplace by specialty or vendor, and purchase apps to integrate into their workflow. The Calantic Marketplace and My Apps allows Bayer representatives to configure the apps customers have purchased and track utilization and performance.

The Calantic Cloud platform and the Calantic Edge Device are the backend infrastructure that enable the day-to-day running of the Calantic Marketplace and My Apps.

The Calantic Edge Device allows a seamless and secure interface of the Calantic Cloud platform with various applications. The Calantic Edge Device is a virtual machine (software) that is deployed at the customer site that acts as the router between the hospital systems and the clinical applications.

1.2 Indications for Use

The Calantic Viewer is a standalone software application intended to enable qualified healthcare professionals to access results from digital clinical imaging and workflow applications. It provides image display, viewing, and transfers information of findings from digital clinical imaging and workflow applications, including AI-enabled solutions. The Calantic Viewer allows qualified healthcare professionals to review, accept, or reject results generated by workflow applications and solutions. The Calantic Viewer is not intended to detect or diagnose a disease for patient management.

1.3 Intended Users

The intended users for Calantic Viewer include qualified healthcare professionals who use it in context with PACS and reporting systems to report medical findings on humans. The Calantic Viewer is a decision support tool, not the system of record.

1.4 Disclaimers

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Screen images in this manual are for illustration purposes only. Actual screens may vary.

1.5 Interoperability Requirements

1.5.1 Browser

The Calantic Viewer application runs on 64-bit web browsers including Chrome, Safari, Firefox, and Edge (current version and previous-to-current version). Multi-Planar Reconstruction (MPR) mode requires WebGL support.

> **Note:** If the Calantic Viewer is launched on an unsupported browser such as Internet Explorer, a blank screen (black) will be presented. Exit from the unsupported browser and launch the application on a supported browser.

1.5.2 Minimum System Requirements

- CPU: 2.5 GHz Intel Core i5
- RAM: 8GB
- Display Resolution: 1440 x 900 pixels

1.6 Language Support

The tooltips, button text, and image overlays are displayed in the same language as the user's browser settings. The default user interface language is English.

1.7 Decommissioning and Disposal

In scenarios where decommissioning and disposal of application is concerned, contact an authorized Bayer representative or a designated site contact.

1.8 Contraindications

None known.

1.9 Required Training

The device is intended to be used by qualified healthcare professionals with experience in imaging diagnostic studies.

1.10 Contact

To provide feedback or request support, please use the contact form provided on https://www.radiologysolutions.bayer.com/contact.

Report any serious incident that has occurred in relation to this device to Bayer (https://www.radiologysolutions.bayer.com/contact) and to your local European competent authority (or, where applicable, to the appropriate regulatory authority of the country in which the incident has occurred).

1.11 Symbol Definitions

Manufacturer (ISO 15223-1, 5.1.1)
Indicates the medical device manufacturer

Rx Only

Prescription Use Only (Docket No. FDA-2013-N-0125)
Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.

Importer (ISO 15223- 1, 5.1.8)
Indicates the entity importing the medical device into the locale

Authorized representative in the European Community / European Union (ISO 15223-1, 5.1.2)
Indicates the authorized representative in the European Community/ European Union

Authorized Representative in a country (ISO 20417 Section 6.1.2 (d)(1))
Indicates the authorized representative for a specific country

Unique Device Identification (ISO 15223- 1, 5.7.10)
Indicates a carrier that contains Unique Device Identifier information

Medical device (ISO 15223- 1, 5.7.7)
Indicates the item is a medical device

CE Mark (EU Directive 2017-745, Annex V)
A marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017, and other applicable Union harmonization legislation providing for its affixing (CE mark with the notified body number is for Class I [sterile], Class Im, and Class II medical devices).

Consult instructions for use or consult electronic instructions for use (ISO 15223-1, 5.4.3)
Indicates the need for the user to consult the instructions for use

Date of manufacture (ISO 15223-1, 5.1.3)
Indicates the date when the medical device was manufactured

1.12 Catalog Numbers

	Catalog Number
Calantic Cloud Platform	**CAL-CLOUD**
Calantic MyApps	**CAL-MYAPPS**
Calantic Platform	**CAL-PLATFORM**
Calantic Viewer (measurement enabled)	**CAL-VIEWER**
Calantic Viewer (measurement disabled)	**CAL-VIEWER-NO-M**
Calantic Edge Device	**CAL-EDGE**

2 Logging In

When first visiting the Calantic™ Viewer, a login box will appear asking for a username and password (Figure 1).

> **Note:** To obtain a username and password for first-time login, contact a Bayer representative or a designated site contact.

Enter a username and password, then press **Enter** on the keyboard or click on **Join Us** to send the details to be authenticated.

If the username and password are valid, the Calantic Viewer will be logged in successfully.

If the username and/or password are incorrect, an error message will be displayed, and a different username and/or password must be entered.

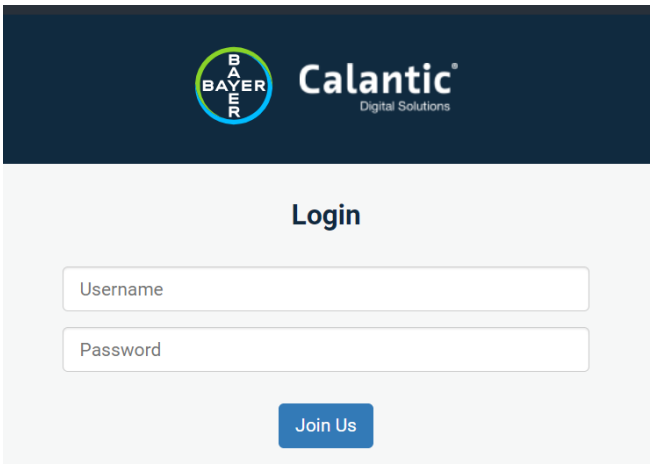


Figure 1: Login

3 Navigation

As shown in Figure 2, there are five main elements for the Calantic™ Viewer:

1. Findings Gallery
2. Toolbar
3. Main Viewport
4. Findings Table
5. Viewer Control

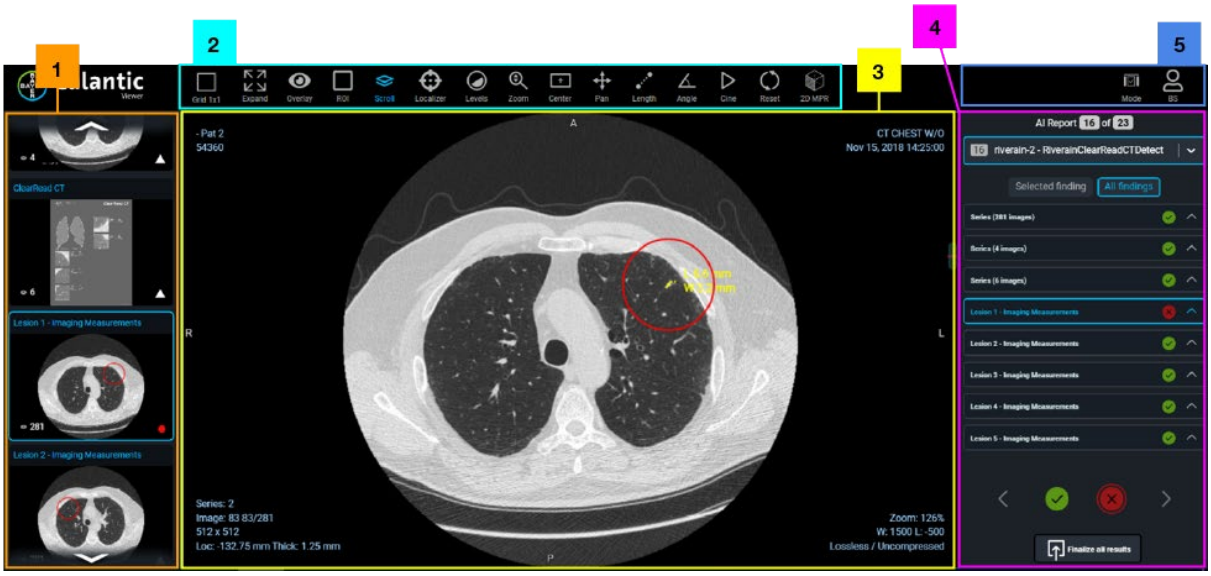


Figure 2: Calantic Viewer - Main Elements

3.1 Findings Gallery

The Findings Gallery contains a set of thumbnail images that are organized in two sections: Series and Findings. The Series section contains the original series of images processed by the IPPA. (If no original image series is present, there will be no Series section in the Findings Gallery). The Findings section contains each of the individual findings identified by the IPPA. Click on a thumbnail image within the Findings Gallery to bring it into focus in the Viewer. (The highlighted thumbnail image in the Findings Gallery will be outlined in blue). A green circle on each thumbnail image (bottom right) represents that the Finding is reviewed, a white triangle represents an unreviewed Finding. The finding or series in focus is displayed in the Main Viewport (refer to 3.3 Main Viewport) and also identified in the Findings Table (refer to 3.4 Findings Table).

3.2 Toolbar

The Calantic Viewer includes a comprehensive set of tools (based on the IPPA) that can be used to alter the layout of the Main Viewport or the displayed images in the views in the Main Viewport (refer to 3.3 Main Viewport) to allow for optimal reading. The various tools available to the user, via the Toolbar, for manipulating the displayed images are shown in Figure 3.

Examples include the ability to display multiple studies simultaneously, window, stack, pan, zoom, and take measurements quickly by using the toolbar icons, mouse, or a set of keyboard shortcuts (keyboard shortcuts are displayed in the tooltip when the mouse hovers over the tool in the toolbar).

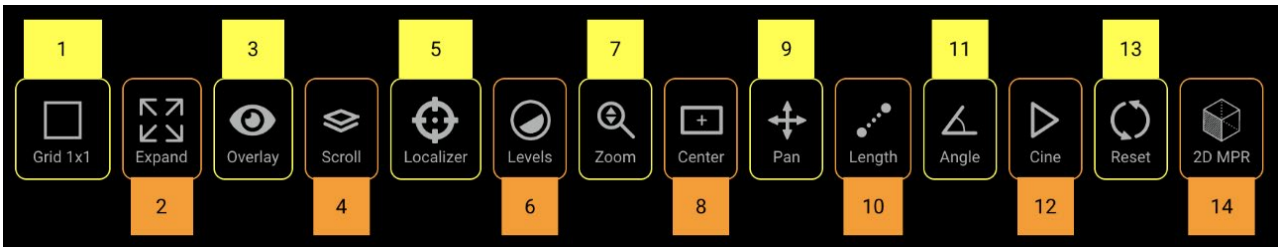


Figure 3: Toolbar - Overview

1	Grid (Layout)	**6**	Levels	**11**	Angle
2	Expand	**7**	Zoom	**12**	Cine
3	Overlay	**8**	Center	**13**	Reset
4	Scroll	**9**	Pan	**14**	2D MPR
5	Localizer	**10**	Length		

The tools in the toolbar may be invoked/activated by clicking the icon or using keyboard shortcut keys (refer to 4 Keyboard Shortcuts). When a tool is selected, the image and text of the item changes to blue.

3.2.1 Grid

When the **Grid** (Layout) tool (Figure 3, Item 1) is activated, a drop-down menu showing the available grid layout options is displayed (Figure 4).

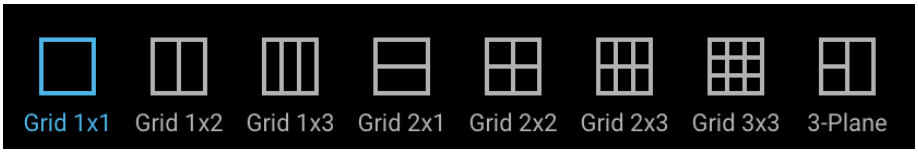


Figure 4: Grid layout options

A grid layout can be chosen by clicking it. The selected grid layout icon changes to blue and the Main Viewport will update to the selected grid layout.

3.2.2 Expand

When the **Expand** tool (Figure 3, Item 2) is activated, the viewport grid will only display the Active Viewport, making it grow to the maximum available space on the viewport grid. It will not have any effect for a 1x1 layout, as it is already the only viewport being displayed.

The **Expand** tool works as a toggle function (i.e., click once to activate, click again to deactivate). When it is activated, the icon is blue.

3.2.3 Overlay

Click on the **Overlay** tool (Figure 3, Item 3) to toggle overlay options (Figure 5). **Measurements** (e.g., measurements of a lesion), **Markers** (e.g., a circle around a region of interest) and **Image Details** in the corner of the views can each be toggled on or off. These overlays are generated by the clinical applications (where applicable) and not by the Viewer.

When an overlay is displayed on screen, an open eye icon will be displayed.

When the overlay is hidden, a crossed-out eye icon will be displayed.

Figure 5: Overlay display options

3.2.4 Scroll

When the **Scroll** (Stack) tool (Figure 3, Item 4) is activated, the user can scroll through a set of images in the Main Viewport by holding the left mouse button down on the Main Viewport while moving the mouse up or down.

When the view is active, as the mouse is over it, the default scroll action is active and may be used by rolling the mouse scroll wheel. The location in the stack is denoted by the scroll bar on the right-hand side of the viewport, which can also be used for this purpose. The location in the stack of the currently displayed image is shown in the text on the bottom left-hand corner of the viewport.

3.2.5 Localizer

When the **Localizer** tool (Figure 3, Item 5) is activated, the user can synchronize a specific anatomical location in an image across multiple viewports. When the left mouse button is clicked (or held down and dragged) on a source location in one viewport, green crosshairs markers will appear at the source location and the corresponding anatomical location in other viewports which have positional information, and which share a frame of reference with the source image. This tool will not have any effect when used in a 1x1 layout.

3.2.6 Levels

When the **Levels** tool (Figure 3, Item 6) is activated, it is possible to manipulate the Window Width and Window Level of the image in the Active Viewport. The Window Width is the range of the greyscale that can be displayed. The Window Level is the center of the greyscale range. As the Window Width and Window Level change, the overlay text on the viewport updates to reflect the updated numerical value of the Width and Level.

When the mouse hovers over the **Levels** tool, a list of preset values is displayed (Figure 6). For CT images, this allows different Window Width and Window Level settings to be quickly applied by selecting them with the mouse or by using the Keyboard Shortcut keys (refer to 4 Keyboard Shortcuts). For MR images, the presets are disabled. The active levels option(s) will be highlighted in blue.

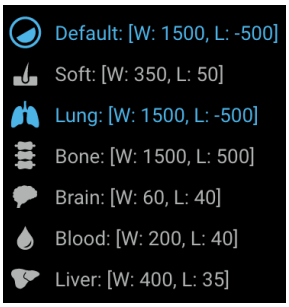


Figure 6: Levels preset options

3.2.7 Zoom

When the **Zoom** tool (Figure 3, Item 7) is activated, a specific area of the image can be zoomed to increase its magnification. In an Active Viewport, the Zoom function defaults to the right mouse button. When selecting the **Zoom** tool, magnification is performed in an Active Viewport using the left mouse button. For both cases, holding the mouse button (right or left) down and dragging down or up on the viewport increases or decreases the zoom level. The zoom level is displayed in an overlay on the Active Viewport and the numerical percentage updates as the image is magnified.

3.2.8 Center

When the **Center** tool (Figure 3, Item 8) is activated, the position of the image in the Active Viewport is reset such that the center of the image is aligned with the center of the viewport. Any changes made with the **Pan** tool will be reset.

3.2.9 Pan

When manipulating images, the region of interest may move outside the Main Viewport. The position of the images in the viewport can be altered by using the **Pan** tool (Figure 3, Item 9).

Any modification of the pan is applied to all images in the stack displayed in the Main Viewport. Depending on the current mouse configuration, the **Pan** tool can be accessed when certain other tools are selected (for example, the center mouse button or mouse wheel can be pressed and held down and the mouse dragged on the Active Viewport to pan the image).

To pan an image:

1. Select the image that is to be panned in the Active Viewport.
2. Select the **Pan** tool from the toolbar (the cursor changes to indicate that **Pan** tool is active and the color of the **Pan** tool icon changes to blue).
3. Click the image and drag in the required direction.
4. You can choose the **Center** button to revert the view to its original position.
5. You can choose the **Reset** button to revert the view to its original position (pan), zoom percentage, and levels setting.

3.2.10 Length

Note: This Operation Manual is intended for global markets. Feature and clinical application availability will vary by market or by configuration in the same market; contact your authorized Bayer representative for more information per the information listed in the 1.10 Contact section of this manual.

Note: The measuring tools provided in the Calantic Viewer provide a means to measure length with an accuracy of +/-2 mm and angles with an accuracy of +/- 2 degrees on images based on the DICOM pixel size information provided by the image file exclusively. They are not intended to correct for any distortions that may be present in the images they receive.

When the **Length** tool (Figure 3, Item 10) is activated, the user can measure distances (mm) on the displayed image if the image supports distance measurement (e.g., have the appropriate set of DICOM tags).

Note: The **Length** tool will not be visible when disabled.

To measure a distance/length on an image:

1. Select the **Length** tool.
2. In the Active Viewport, left click on the location on the image where the length measurement should begin.
3. Drag the mouse to the location on the image where the length measurement should end.

   Note: As the mouse is dragged from start to end, the measured length is denoted by an overlay line.
4. At the end location of the measurement on the image, left click using the mouse.
5. The measured length is shown next to the length line as an overlay on the image (Figure 7).

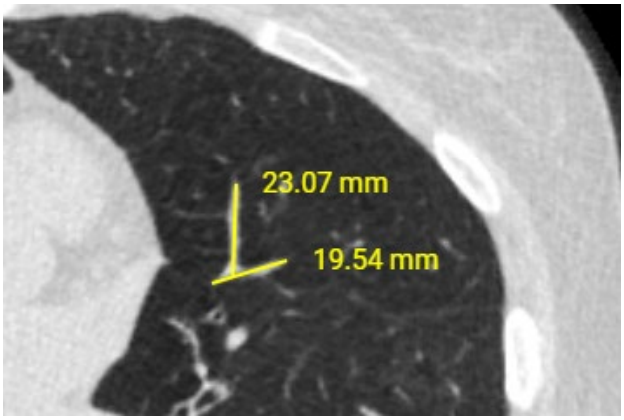


Figure 7: Measurement overlay

Measurements created on images are in units of millimeters.

To update a length measurement, move the mouse cursor to one end of the measurement (either the start or the end). Select the end with the left mouse button and holding the mouse button down, drag the end to the updated location. The text describing the length measured updates automatically.

To remove a length measurement that was previously made, move the mouse cursor to either end of the measured length. Select the end with the left mouse button and drag the end out with the bounds of the image viewport. Release the mouse button. The measured length will be removed. To remove the length measurement, right click on the circular icon and click on **Delete measurement**.

Active measurements turn green when the mouse moves over them to indicate which ones are being interacted with.

Note: Any measurement (length) created is only for reference while viewing to aid in visualization of the data and is not a permanent record stored or saved by the Calantic Viewer. The measurements made are not automatically released to the PACS or sent to any reporting system when the report is finalized.

When a report is hung on the Active Viewport, this tool will be automatically disabled. The enabled state shall be recovered as soon an applicable image is loaded on the Active Viewport.

3.2.11 Angle

Note: This Operation Manual is intended for global markets. Feature and clinical application availability will vary by market or by configuration in the same market; contact your authorized Bayer representative for more information per the information listed in 1.10 Contact of this manual.

Note: The measuring tools provided in the Calantic Viewer provide a means to measure length with an accuracy of +/-2 mm and angles with an accuracy of +/- 2 degrees on images based on the DICOM pixel size information provided by the image file exclusively. They are not intended to correct for any distortions that may be present in the images they receive.

When the **Angle** tool (Figure 3, Item 11) is activated, the user can measure angles on the displayed images.

Note: The **Angle** tool will not be visible when disabled.

To measure an angle on the image:

1. Select the **Angle** tool.
2. In the Active Viewport, left click on the image in the location where the angle measurement should begin.
3. Move the mouse to the apex of the angle to be measured and left click where the apex should be placed (Figure 8).
4. Move the mouse to create the angle to be measured and left click to create the point where the measurement should end.

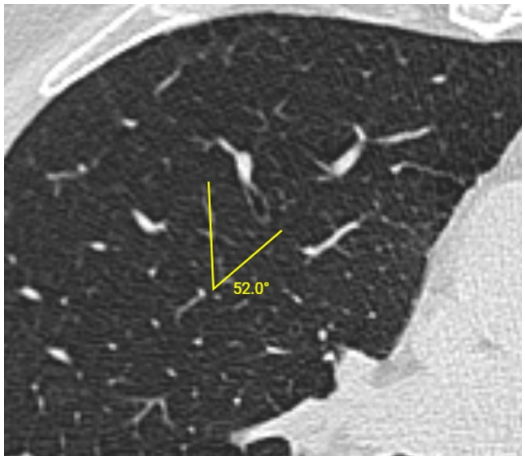


Figure 8: Angle tool

The measured angle is displayed in an overlay next to the drawn angle overlay on the image. Angle measurements are in units of degrees.

To update an angle measurement, left click any of the three points (start, apex, or end) and drag to the new desired location. The numerical text describing the size of the angle updates automatically.

To delete a previously created angle measurement, left click any of the three points (start, apex, or end) and drag it out with the bounds of the image viewport. To remove the angle measurement, right click on the circular icon and click on **Delete measurement**.

> **Note**: Any measurement (angle) created is only for reference while viewing to aid in visualization of the data and is not a permanent record on the Calantic Viewer. The measurements made are not automatically released to the PACS or sent to any reporting system when the report is finalized.

When a report is hung on the Active Viewport, this tool will be automatically disabled. The enabled state shall be recovered as soon an applicable image is loaded on the Active Viewport.

3.2.12 Cine

Instead of stacking through a series of images manually, the **Cine** tool (Figure 3, Item 12) allows the user to stack through images in the Active Viewport by playing them as if they were a movie clip. Typically, this is used with a "temporal-series" or "spatial-series" where there is a change in time or space from one image to the next in the series (common for CT/MR series).

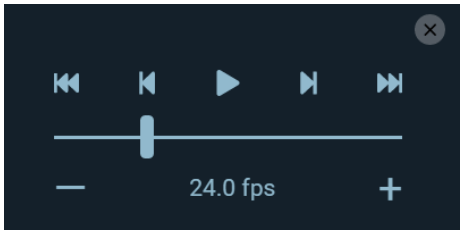


Figure 9: Cine tool controls

To use the **Cine** tool:

1. Select the Active Viewport containing the series of images to cine.
2. Using the mouse, select the **Cine** tool.
3. A set of controls for the **Cine** tool is displayed (Figure 9).

The slider can be used to change the rate at which images are displayed (the playback speed).

The **Play** button can then be pressed. This commences the cine of the images. (Note that this turns the **Play** button to a **Stop** button.)

Pressing the **Stop** button stops the cine.

The **Previous Image** and **Next Image** buttons allow the user to move one image forward/backward in the stack.

The **Skip to First Image** and **Skip to Last Image** buttons allow the user to quickly skip to the start/end of the stack.

Pressing the **Cine** button again hides the controls.

When a report is hung on the Active Viewport, this tool will be automatically disabled. The enabled state shall be recovered as soon an applicable image is loaded on the Active Viewport.

3.2.13 Reset

When the **Reset** tool (Figure 3, Item 13) is activated, the **Reset** button reverts an image back to its original Window Width, Window Level, Zoom, and Pan. Reversion is applied for all images in the stack in the Active Viewport and all applied settings are reset.

To reset the Active Viewport:

1. Select the image to be reset in the Active Viewport (all images in a stack will be reset).
2. Click the **Reset** tool button. All images in the Active Viewport will be reset.

3.2.14 Multi-Planar Reconstruction (MPR)

Note: This Operation Manual is intended for global markets. Feature and clinical application availability will vary by market or by configuration in the same market; contact your authorized Bayer representative for more information per the information listed in 1.10 Contact of this manual.

If a series that is amenable to reconstruction is hung in the Active Viewport, the **2D MPR** tool is displayed (Figure 3, Item 14 or Figure 10) and is selectable.

Note: The **2D MPR** tool will not be visible when disabled.

When the **2D MPR** tool is activated, the Viewer moves into multi-planar reconstruction (MPR) mode. Multi-planar reconstruction can be applied to a stack of images if the series has modality {'MR', 'CT', 'PT, 'NM'}, and if the number of images in the stack is greater than one. If the series in the Active Viewport does not meet these criteria, then the **2D MPR** tool is disabled.

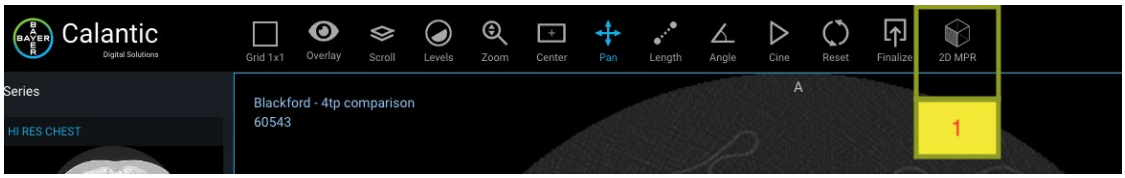


Figure 10: 2D MPR

When MPR mode is activated, a new 1x3 viewport layout is displayed. The three viewports contain reconstructions of the data in the XY, XZ, and YZ orthogonal planes to obtain the three tangent planes, defined as axial, sagittal or coronal planes respectively (Figure 11). Further, the toolbar is modified to show a set of MPR specific tools (Figure 12). These replace the buttons in the standard Viewer toolbar.

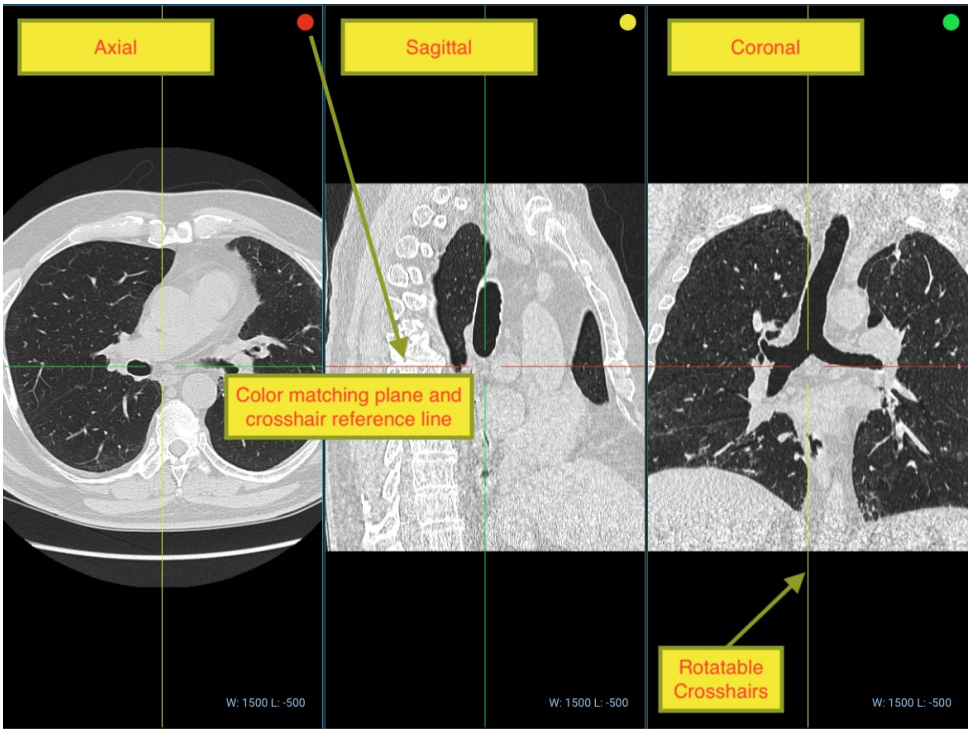


Figure 11: MPR Viewports (planes)

The buttons that become available include:

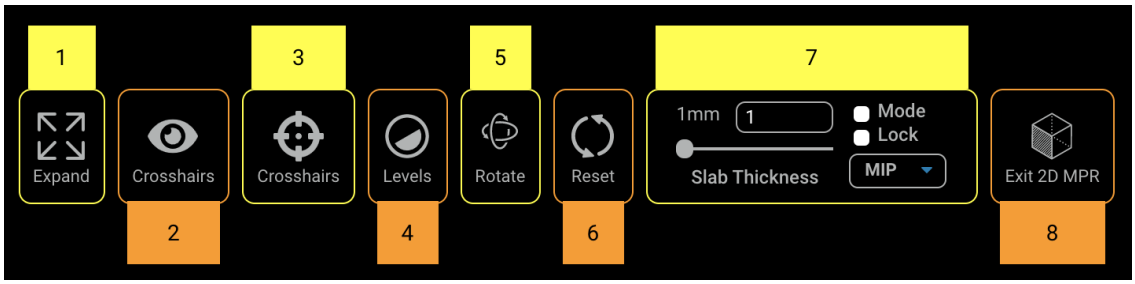


Figure 12: MPR Toolbar

1. Expand

The **Expand** tool has the same behavior for both default and MPR modes.

2. Crosshairs

The **Crosshairs** tool toggles the crosshairs overlay visibility. When the overlay is hidden, the **Crosshairs** tool will be automatically disabled, and the Levels tool will be activated as it's the default tool. When re-enabling the overlay, the **Crosshairs** tool will be automatically activated again.

This tool is used to toggle (show/hide) the visibility of the crosshairs (red & green lines in Figure 13).

3. Crosshairs

When the **Crosshairs** tool is activated, the three axes of X/Y/Z can be arbitrarily rotated around the origin of the three-dimensional coordinates by dragging the points rendered on top of each crosshair rendered on each viewport (Figure 13).

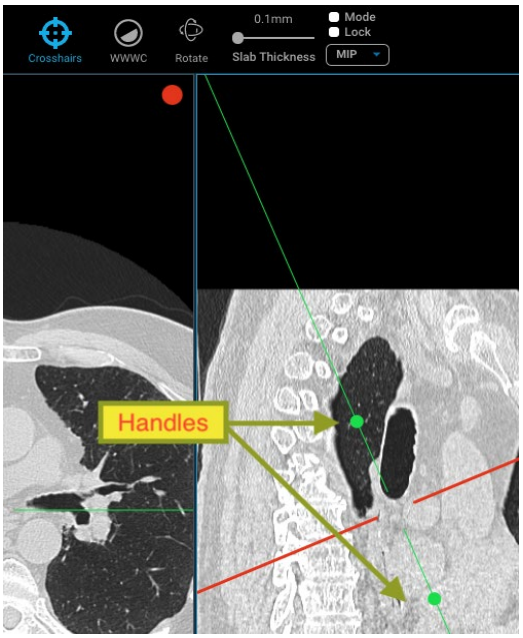


Figure 13: MPR Crosshairs (red & green lines) and Reference Line Handles

4. Levels

When the **Levels** tool is activated, the window center and window level of the Active Viewport can be updated, and the overlay information of the modified viewport will have its overlay window center and window level values at the bottom right of the view updated accordingly. If the lock checkbox is checked, changes to one viewport will affect all other viewports.

5. Rotate

The Active Viewport can be arbitrarily rotated around the origin of the three-dimensional coordinates and all viewport planes should update its crosshairs position if enabled. To rotate the viewport, select the **Rotate** tool, then select a location in the viewport using the mouse button and drag.

6. Reset

The **Reset** tool resets the orientation, slab thickness, intensity projection, crosshairs, window level, and window center to the original values.

7. Slab Thickness Controls

The **Slab Thickness Controls** tool is a set of inputs for controlling the slab thickness, mode, locking, and operation mode.

- **Slab thickness inputs:** Numeric input or slider that can be used to set the distance between clipping planes, adjusting both near and far centered on the focal point of the camera, measured in mm.
- **Operation mode (MIP, MINP, Avg IP):** The maximum, minimum, and average intensity projection profiles can be selected in the drop-down menu on the right side of the slab thickness input range in the toolbar.
- **Lock:** When it is checked (selected), changes to slab thickness and intensity projection profiles should be applied to all viewports, rather than just the Active Viewport.
- **Mode**: Enables or disables the slab thickness and intensity projection profile changes applied to the viewport. This button automatically checks if the user changes the slab thickness before activating the mode.

8. Exit 2D MPR

This button exits the MPR mode, returning the view to the last series or lesion that was displayed in the viewport prior to entering 2D MPR mode. The layout is set to 1x1.

3.3 Main Viewport

The Main Viewport (Figure 2) displays the images related to the individual finding under review. It allows the user to interact with the images via mouse control. Depending on the Grid layout, the Main Viewport may be split into multiple sub-viewports.

3.3.1 Active Viewport

The Main Viewport may contain multiple viewports depending on the Grid layout. From the set of displayed viewports, the Active Viewport is the one that is selected. It is denoted by a blue outline around the viewport (Figure 2).

3.3.2 Image Overlay

There are three types of overlays on the image: text overlay, annotations overlay, and markers overlay (refer to 3.2.3 Overlay). Each type of overlay can be toggled on and off using the **Overlay** tool option.

Figure 14: Text Overlay

The text overlay surrounds images in a viewport and contains study, patient, and image information.

The **Study Information** text overlay contains:

- Study Description
- Study Date/Time
- Series Number

The **Patient Information** text overlay contains:

- Patient Name
- Patient ID

The **Image Information** text overlay contains:

- Instance Number
- Image Dimensions
- Zoom Percentage
- Image Compression
- Window Width & Level
- Slice Location
- Slice Thickness

Many of the available tools will update these values based on the interaction between the tool and the imaging stack (for example scrolling through a stack of images will update the slice location).

3.3.3 Link Tool

The **Link** tool (Figure 15) is available in the upper left corner of each Viewport (green icon). It is used to link data in that Viewport. Clicking on the **Link** tool shows a grid of other views or groups of views with which can be linked.

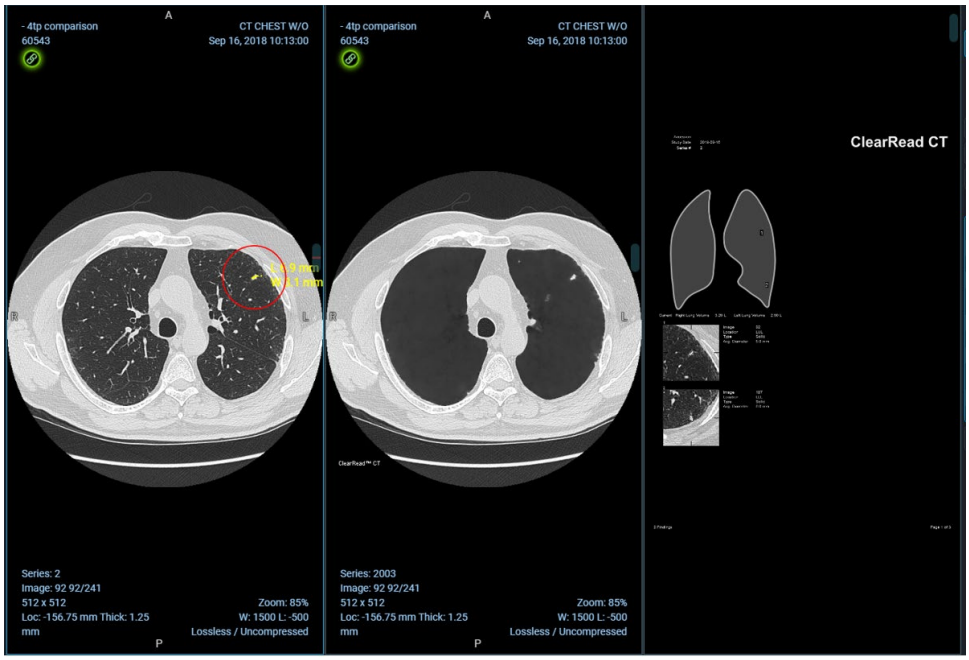


Figure 15: Link tool

Linked views will move together when scrolling through images. To unlink a view, click its **Link** tool again.

3.4 Findings Table

> **Note:** The clinical application findings provide data resources to the qualified healthcare professionals and are not intended to be a source of medical advice and should not be a substitute for professional medical judgment, diagnosis, or treatment. The findings and data should be reviewed by a qualified healthcare professional. Users should not rely solely on the app findings; a qualified healthcare professional should review all findings.

A finding includes clinical information (i.e., images and imaging measurements) acquired by the operation of the clinical application(s). For instance, a clinical application may identify three lesions on a CT scan and each lesion would be deemed a finding. The type of finding may vary by clinical application depending on the applications' output.

In the Findings Table section of the Viewer (Figure 16), it is possible to change the selected Clinical Application report (when the loaded case has more than one associated Clinical Application report), change the table view in order to

display all findings or just the one selected, approve and reject AI findings, navigate through all findings, and finalize the results from the loaded Clinical Application report.

Figure 16: Findings Table

3.4.1 Findings Display Mode

There is a button for switching the display mode of the findings (Figure 17), providing options for displaying all the findings associated with the current Clinical Application report, or displaying only the currently selected finding.

When the **Selected finding** button is active, it will display only a single finding which can be accepted or rejected by using the icon displayed on it or the accept and reject buttons in the Findings Navigation Menu (refer to 3.4.2 Findings).

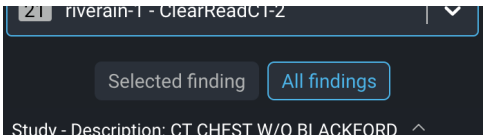


Figure 17: Display mode buttons

3.4.2 Findings

In the Findings section, all findings are displayed in a structured manner. The findings will always be displayed inside a group of findings (Figure 18), which can be navigated and accepted or rejected entirely by using the Findings Navigation Menu.

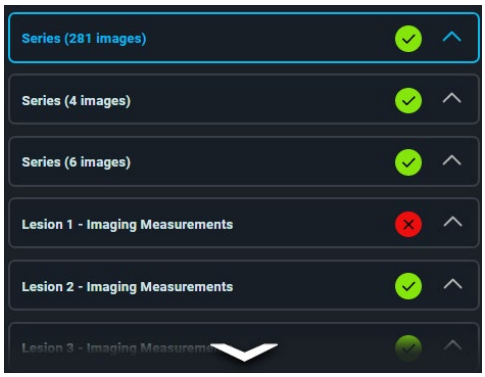


Figure 18: Types of findings

The selected finding will always be highlighted in blue. When the selection changes, it will also change the image or finding being displayed in the Active Viewport.

Each individual finding has an icon with its current accepted status (green when accepted and red when rejected). This status icon is clickable and will toggle the accepted status of the associated finding. These individual findings will be displayed in a collapsed view by default and will only expand their details once selected.

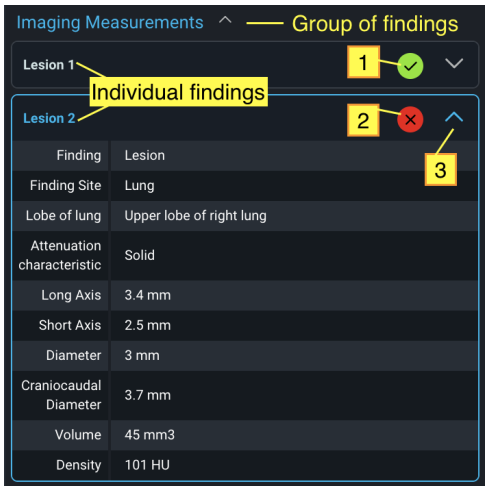


Figure 19: Groups of findings

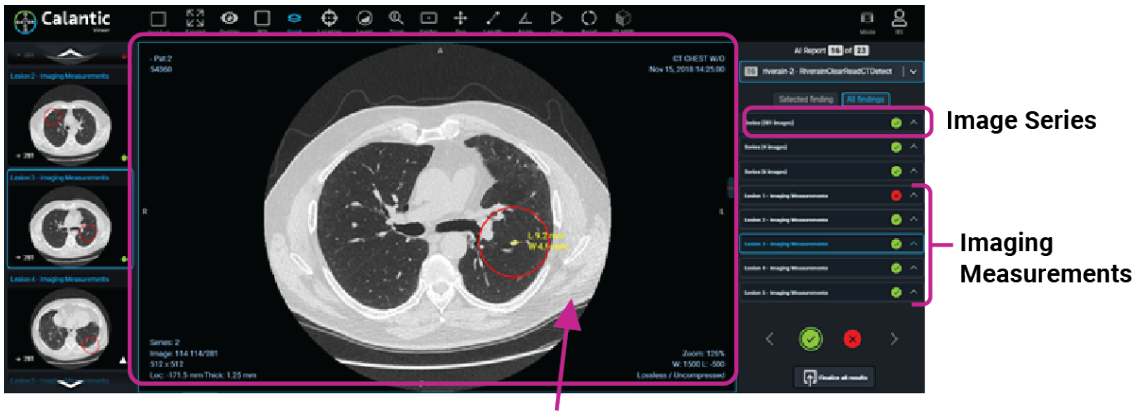
As shown in Figure 19, Lesion 1 and Lesion 2 are individual findings under the Imaging Measurements group of findings. The Lesion 2 is the selected finding, and it is viewable in an expanded view.

1. Individual finding Lesion 1 is accepted; if the status icon is clicked, it will reject the finding.
2. Individual finding Lesion 2 is rejected; if the status icon is clicked, it will accept the finding.
3. Expand/collapse icon - even when the finding is selected, it can be manually collapsed by clicking this icon.

Note: The Finding may change depending on the data and images acquired from the clinical applications.

For example, for a report included in Riverain's ClearRead CT Image Series:

- The report contains a summary of Imaging Measurements that are included separately as their own Findings.
- If one or more Imaging Measurements are rejected, it is required that the report in the image series be rejected.



- If desired, the Riverain application can be configured to not generate the summary report included in the Image Series.

3.4.3 Findings Navigation Menu

The Findings Navigation Menu (Figure 20) enables navigation through all findings on the Findings table. This menu has buttons for selecting next or previous finding and buttons for accepting or rejecting the selected finding.

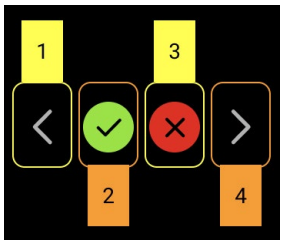


Figure 20: Findings Navigation Menu

The Findings Navigation Menu buttons are:

1. **Previous Finding:** Selects the finding that precedes the currently selected finding.

   When there are no other findings before the selected one, it will highlight the last finding, allowing the navigation to loop through the list of findings in both directions.

2. **Accept Selected Finding:** Click on this button to accept the selected finding. The button turns disabled once the finding is accepted.

3. **Reject Selected Finding:** Click on this button to reject the selected finding. The button turns disabled once the finding is rejected.

4. **Next Finding:** Selects the finding that succeeds the currently selected finding.

   If the selected finding is the last inside a group of findings and the display mode is "All findings," the next group of findings will be selected.

   When there are no other findings after the selected one, it will highlight the first group of findings, allowing the navigation to loop through the list of findings in both directions.

Note: The Calantic Viewer allows qualified healthcare professionals to review the findings and to accept or reject the findings. In some cases, a qualified healthcare professional may agree with some of the findings, but not all of the findings. In this situation, the results will appear as partially accepted in the App Gallery.

3.4.4 Finalize All Results

Once the set of findings have been accepted or rejected, click on **Finalize All Results** button. A confirmatory message will be displayed (Figure 21).

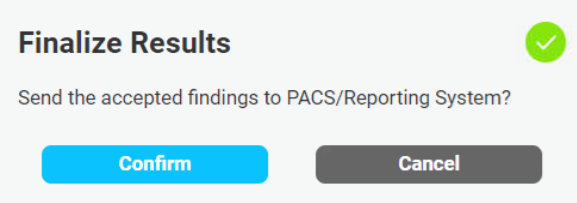


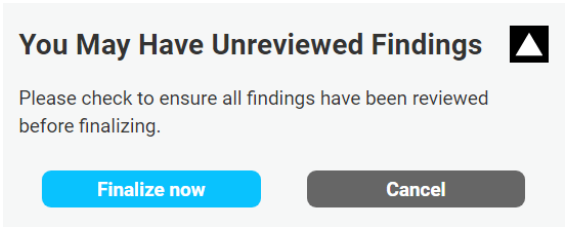
Figure 21: Confirm finalization action

Once the finalization action is confirmed, it will cause the Edge Device to:

- Send any accepted Findings to the reporting system.
- Send any accepted image series to the PACS for final storage.

Once pressed, the **Finalize** button and **Accept/Reject** buttons are disabled and no further updates can be performed. The Calantic software is not the system of record for results (i.e., images and findings) acquired from clinical applications.

Note: Prior to clicking **Finalize All Results** button, it is best practice to review each image, report, and detailed finding. If findings are not accepted or rejected by the user, a confirmatory message will be displayed –



The findings will be automatically accepted by default by clicking on **Finalize now**.

3.4.5 Finalize

Once the set of Findings have been accepted or rejected, the user can press the **Finalize** button. This causes the Edge Device to:

- Send any accepted measurements from clinical applications to the reporting system.

- Send any accepted image series from clinical applications to the PACS for final storage.

Once pressed, the **Finalize** button and **Accept/Reject** buttons are disabled and no further updates can be performed.

In the case that the **Finalize** button is inadvertently pressed, please contact Bayer Service.

3.5 Viewer Control

3.5.1 Mode Button

The **Mode** button is invoked by a mouse click. This button causes the Findings Gallery and Findings Table to collapse, allowing the Main Viewport to display over a larger portion of the visible window area (Figure 22). The Findings Gallery and Findings Table are reinstated by clicking on the **Mode** button.

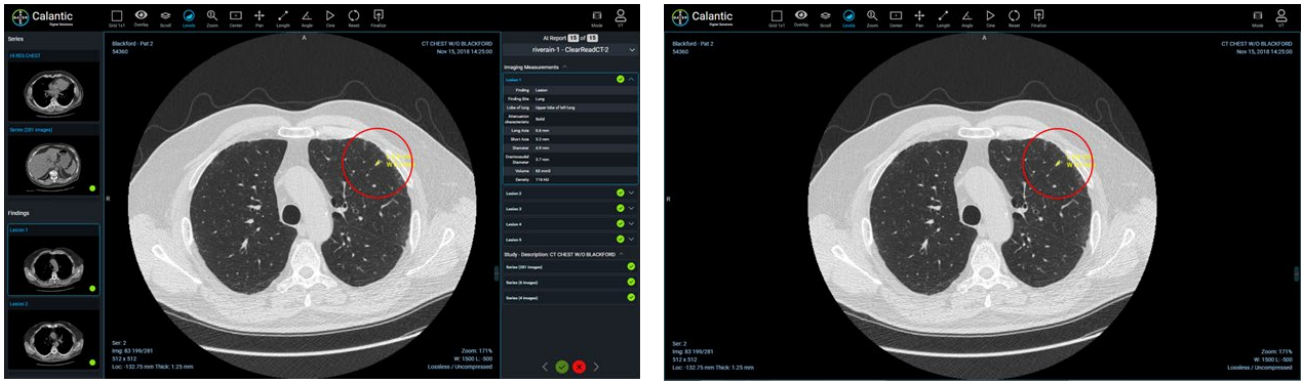


Figure 22: LEFT - Standard view with left and right panels displayed, RIGHT - Collapsed view with left and right panels hidden and the Main Viewport expanded

3.5.2 User Menu

The User Menu displays a list of options in a sub-menu when selected (Figure 23).

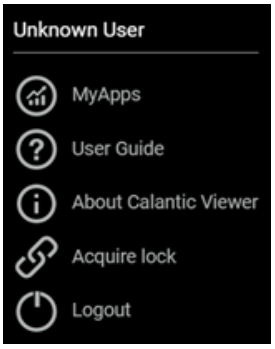


Figure 23: User Menu

This list contains:

- The currently logged in user (e.g., “Unknown User”).

- **MyApps**: Click to open the Calantic Marketplace and MyApps application. The landing page is Manage Apps > My Apps.
- **User Guide**: Click to view, download, or print the Calantic Viewer operation manual.
- **About Calantic Viewer** (Figure 24): Click to view details about the software including:
    - **Calantic Version**: The software version of the Calantic Viewer.
    - **Build Number**:
        - Build Hash: The code commit hash used to build this version of the Viewer.
    - **Date of Manufacture**

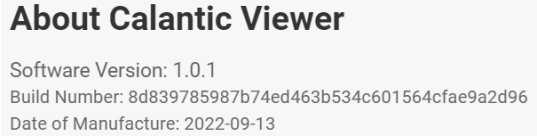


Figure 24: About Calantic Viewer

- **Acquire Lock**: Allows a user to acquire the lock on a report if it has been locked by another user. This option will not be available in the menu if a lock is already acquired on a respective report.

  When selecting this option, a confirmation box will appear to explain that this action will take the lock from another user (Figure 25).

  Note: To enable the second user to Finalize the results, it is mandatory for the first user (who opened the report first) to grant the acquire request to the second user.

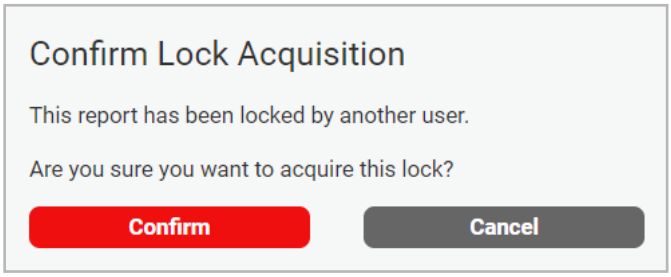


Figure 25: Confirm Lock Acquisition

- **Logout**: Allows the user to logout of the Viewer

3.6 Tooltips

Tooltips are displayed for many of the buttons available on the viewer. These appear when the mouse hovers over the item. The tooltip describes any Shortcut Key that may be used in lieu of selecting with the mouse.

3.7 Viewport Measurements and Markers

- **Measurements:** Represents a measurement with both the numerical size and a graphical representation (e.g., lines) rendered on the image in the viewport produced by clinical applications (Figure 26).

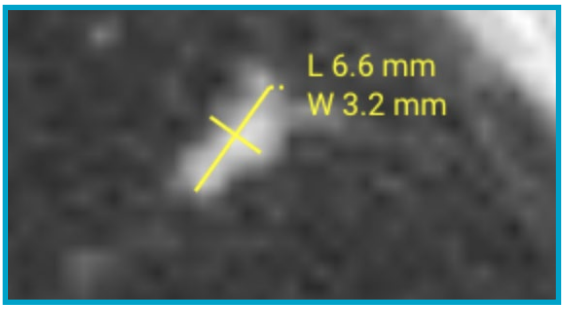


Figure 26: Example annotation showing the dimensions of an identified lesion

- **Markers:** Shown by a red circle overlaying the image in the viewport (Figure 27). Identifies the location of the region of interest (ROI) or finding produced from separate and independent clinical applications, not the Calantic Viewer, in the displayed image stack. It does not convey any semantic meaning regarding the ROI and is not intended to direct the qualified healthcare professional's attention to parts of the image that may reveal abnormalities. It is intended only as a fixture / visual utility (e.g., the red circle surrounding the ROI) which helps the user identify the ROI in the viewport.

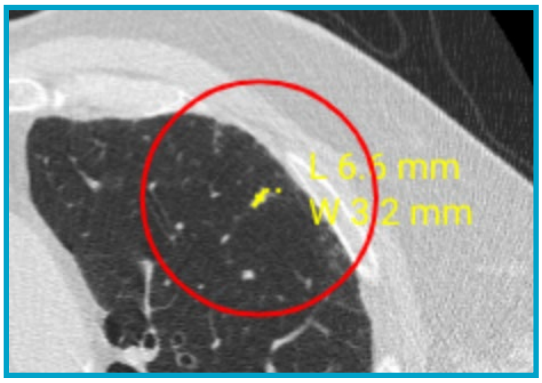


Figure 27: Red circle denoting the location of the finding (region of interest) on the image produced by the clinical application

Available viewport annotations and markers:

- **Annotations:**
  - **Bidirectional:** A bidirectional measurement.
- **Markers:**
  - **Findings Marker:** A toggleable red circle that surrounds measurements in the viewport. The visibility of the Findings Marker is switchable.

4 Keyboard Shortcuts

Note: The Keyboard Shortcuts illustrated in this table may not be applicable for all types of exams or clinical application reports.

This section describes the list of the available Keyboard Shortcuts. These are also available in the tooltips (visible by hovering the mouse over the items) in the Calantic™ Viewer.

Tool/Action	Shortcut
Levels:	W
Soft:	1
Lung:	2
Bone:	3
Brain:	4
Blood:	5
Liver:	6
Zoom:	Z
Pan:	P
Localizer:	L

Tool/Action	Shortcut
Previous Finding:	PageUp
Next Finding:	PageDown
Accept:	Enter
Reject:	Del
Finalize:	Shift + F
Expand:	Shift + E
Toggle Viewport Annotations:	Shift + A
Toggle Viewport Markers:	Shift + M
Toggle Image Overlay	Shift + O
Play/Pause Cine	Space

5 Mouse Cursors

Note: The Mouse cursors illustrated in the table may not be applicable for all types of exams or clinical application reports.

This section describes various Mouse cursors. Each mouse cursor is activated following selection of the respective tool/action.

Tool/Action	Cursor Image	Description
Scroll		Navigates through all images on active series.
Localizer		Navigates and draws crosshairs on all other viewports that share the same frame of reference, even if they have different anatomical planes.
Levels		Changes the Active Viewport's window width and window center levels, affecting the displayed image's brightness and contrast.
Zoom		Zooms in and out the image in the Active Viewport.
Center	N/A	This is not a toggleable tool, so the cursor is not changed when this tool is activated.
Pan		Used to reposition the image inside the Active Viewport's boundaries.
Length		Used for creating or editing existing length measurement annotations.
Angle		Used for creating or editing existing angle annotations.

6 Installation, Startup and Shutdown

6.1 Installation

Installation of Calantic™ Viewer is only installed by Bayer Service. Bayer Service has the system requirements for the platforms intended, operational security options, critical dependencies, system interface requirements, details of the supported platforms, and the installation instructions.

6.2 Startup

Invoke the on-premises viewer URL to start the web application.

6.3 Shutdown

Close the browser or log out of the web application.

7 Cybersecurity

The Calantic™ Digital Solutions, including the Calantic Viewer, contains software and is subject to cybersecurity concerns. Depending on the licensed software features, it may also contain data that is subject to privacy laws or is of a sensitive nature which should be protected. This section covers the following aspects of cybersecurity and information security:

- Cybersecurity Protection
- Information Security
- Expected Security Environment
- External Interfaces and Interoperability
- Decommissioning of Equipment

Note: In the event of a suspected or known cybersecurity breach, or for any cybersecurity related questions, please contact Bayer Service at radiology.bayer.com/contact.

7.1 Cybersecurity Protection

The design of the system includes technical measures that secure it against attackers. These are intended to protect the system against current and future threats. Calantic software updates are available periodically for the Calantic Solution and it is the client's responsibility to install security updates on the Calantic Edge Device. In addition, Bayer has a cloud service agreement with Google for security software updates. New cyber-attacks may require new technical controls. Bayer's cyber response policy ensures that software updates are developed and released when high-risk threats arise. Both planned updates and unplanned software patches are made available to authorized Bayer representatives for immediate deployment.

Google is responsible for updating Google managed services and the underlying infrastructure. Bayer is responsible for managing the VMs, containers, and Bayer-designed applications. Due to technical training requirements on device calibration and its operational checkout, Bayer is responsible for obtaining software or firmware and updating for Google Cloud Platform. Bayer is responsible for ensuring security maintenance with Google. Please refer to 6.8 Expected Security Environment and Security Control Provided by the Hospitals.

7.2 Cybersecurity Protection - Technical Controls

The technical controls for cybersecurity are built into the design of the system and do not require any user configuration. They include:

- Built-in authentication and secure tokenization of the user when accessing the Viewer.
- Built-in encryption in transit using SSH and TLS; encryption at rest in Google Cloud Platform using AES 256.
- Continuous real time code and vulnerability scanning of containers, code (Static Analysis/SAST) and VM vulnerability scanning using daily updated scan engines.
- Container hashing to ensure supply chain integrity.
- Third Party Penetration testing to include API fuzzing.
- Google Cloud Platform (GCP) Virtual Private Cloud (VPC) Firewalls.
- Enterprise Azure AD integration for development environment which requires Two Factor Authentication (2FA); restricted production code repository access.
- Robust threat modeling of all attack surfaces to ensure attack surfaces are not exposed.
- Modern web application firewall (Google Cloud Platform Cloud Armor) is used to prevent advanced attacks.
- Google Cloud Platform Security Command Center for threat detections.

- Third party Compliance tools for near real time gap detection and management.
- Viewer Cross Site Scripting XSS Attacks (and other web/software attacks) prevention using built in mitigation using JSX library for React.
- Audit logs are maintained and reviewed on a periodic basis.
- Databases are restricted by VPC firewall, require authentication, and credentials are hashed and salted to provide a layer security approach.
- Masking/anonymization of patient data on transmission to external systems is provided as an option.
- Unique SSH keys used on The Calantic Edge Device for each client.
- Current Cloud Identity Access Management (IAM) solution.

7.3 Cybersecurity Protection - Operational Controls

The system software must be maintained and be kept up to date to ensure that it remains secure in the face of new cyber threats. For the Calantic Edge Device, the customer is responsible for the security. This includes patching, anti-virus, firewall, VM host security, network security, and Intrusion Prevention Systems or Intrusion Detection Systems (IPS/IDS). Bayer is responsible for updating the Calantic Edge Device and the Calantic Viewer application.

Bayer plans and releases one or more software updates per year which include cumulative security patches, and for the Calantic GCP instance, Bayer plans to release software updates one or more updates per year. Any new active cybersecurity threat that poses a risk to the operation of the system will trigger additional software releases to provide patches to the system.

During the subscription period, Bayer will provide maintenance and support services from a remote location via VirtualCare® Remote Support. Customers should plan for and accommodate system software updates, which may require on-site visits by an authorized Bayer representative or via VirtualCare® Remote Support.

The system license includes software support including updates. Customers should plan for and accommodate system software updates.

7.4 Cybersecurity Protection - Known Vulnerabilities

Keeping system software up to date is part of the operational controls and will help to reduce security risks due to known vulnerabilities. The system software will undergo periodic penetration testing and fuzz testing by a third-party test lab as well as automated vulnerability scanning. A full listing of all CVEs is available on request.

7.5 Cybersecurity Protection - Software Bill of Materials

Software Bill of Materials are available on request.

7.6 Information Security

The system contains information that may be either considered sensitive (e.g., network IP addresses), potentially governed by privacy laws (e.g., patient names), or which should be protected from access or accidental changes (e.g., protocols, product configuration). Information security depends on both technical controls embodied in the design of the system and operational controls which are the responsibility of the user to configure. Information in the Google Cloud Platform and the Calantic on-premises components is protected by the following:

- All data on Google Cloud is automatically encrypted in transit and at rest within Google Cloud. GCP uses AES 256 for data at rest and TLS 1.2 for data in transit.
- Data transmitted to GCP is encrypted in transit using SSH and TLS.

- Masking/pseudo-anonymization of patient data on transmission to external systems is provided as an option in the Calantic Edge Device.
- The Viewer can display ePHI but only after a user authentication and authorization.
- The Viewer uses TLS to encrypt ePHI and does not store ePHI in cache.

7.7 Information Security - Operational Controls

The system, as part of normal use, makes information available through a variety of means. This includes walk up viewing on the system's displays and making data available via a Node.js based user interface also called the Calantic Viewer. It can be accessed from anywhere within the customer's own network.

The following features give access to information that may be of security relevance:

- VirtualCare Set-up – Networking values such as IP addresses and ports.
- Web access to the Edge Device web interface via The Viewer.
- APIs

The following operational controls are provided to allow the product to be configured to close the above listed information security access paths:

- VirtualCare environment is ISO/IEC 27001:2013 compliant, requires a username and password, and encrypts all connections via TLS.
- The Viewer access is controlled by authentication and authorization, established by a TLS connection for data transmission.
- API access requires GCP service account credentials and a TLS connection, neither of which have direct access to ePHI.

7.8 Expected Security Environment and Security Control Provided by the Hospitals

Healthcare ecosystem stakeholders share responsibility for protecting patients and safeguarding data. As a healthcare device and solutions manufacturer, Bayer invests in infrastructure and developing policies and procedures that support evolving cybersecurity requirements and industry best-practices. At end user sites, cybersecurity protection and defense against the latest attack is strengthened through proper maintenance of networks and environments in which medical products and solutions are deployed. Hospital networks that are monitored and patched quickly provide the first line of defense for deployed medical solutions.

System owners must explicitly request that an authorized Bayer representative create the first user account on their behalf. After that point, the system owner is responsible for managing their own set user accounts.

As such, the customer is responsible for providing and securing the Edge Device VM, OS, and hospital network per their hospital policies to ensure further mitigations. It is the customer's responsibility to actively monitor security events that pertain to the Edge Device and surrounding network environment. In addition to keeping the system software updated, the following additional operational controls are suggested:

- Limit physical access to the Calantic Edge Device system as much as possible.
- Customers employ best security practice security measures (refer NIST 800-53 and NIST CSF) on their own network and their own virtual environments, especially around the Calantic Edge Device hosted in their data center. In addition, if the option to use a browser is used to connect to the Calantic Marketplace and My Apps, follow browser and OS best security practices.
- Snapshots/backups of the Calantic Edge Device are strongly suggested to be done by the customer.
- Encryption to internal resources, like PACS, is not enabled by default but can be enabled by the client.

- Antivirus, advanced endpoint detection, software security patches, and security configurations are not installed by default but can be installed and monitored by the client.
- Physical access to the Calantic Viewer and Edge Device should not be in public spaces nor where non-staff people are unsupervised. Use of a privacy screen is advised.
- Rooms are secured when staff are not present.
- Periodic inspection and maintenance of equipment is performed.
- Enable encryption, when possible, for any connection to the client environment. For example, RIS and PACS.
- Install, configure, and thoroughly test application whitelisting also known as AppLocker to prevent malicious code execution.
- Enable disk encryption on the VM OS and ensure strong key management practices are in place.
- Client can run vulnerability scans on the VM only in their data center and are responsible for those remediations.
- Proper placement in the client's datacenter virtual environment should be considered since the VM interfaces and works with ePHI.
- Monitoring of application security events detected and logged by the Calantic Viewer is strongly encouraged. Logs are in a standard format, comma-separated format (CSV) and are located at Drive:\Calantic Edge\Blackford Platform\BlackfordPlatformAudit.log for Security Information and Event Management (SIEM) ingestion via the client's log collector infrastructure.
- In the event that a customer detects a cyber signal event on the Calantic Edge Device and/or Calantic Viewer, it is strongly recommended that the customer stops using the product, follows institution best practices for incidence response, and notifies their authorized Bayer representative promptly.

7.9 Authentication and Authorization

During installation of the Calantic Edge Device, the client will be provisioned with administrator access. This access should be properly managed by the client according to their security policies. The Calantic Viewer requires authentication and depending on role, it allows authorization on basis of tokenization. The Calantic Viewer is the only place where ePHI is visible to the end user.

If a user forgets their password, a system administrator can reset it. If a system administrator forgets their password, an authorized Bayer representative can create a new account for them.

7.10 External Interfaces and Interoperability

The Calantic Solution has limited exposure to external interfaces. All interfaces were evaluated in the threat model as attack surfaces. Some optional features add connections to external systems. They are:

- Connection to RIS system(s)
- Connection to PACS system(s)
- API Gateway for service-to-service connections
- Browser access to the Calantic Marketplace and App Gallery
- VirtualCare (Bayer report support access via a secure internet connection)
- Bayer GitLab access
- Worklist access
- Reporting access
- Third party TLS access

8 Glossary

AES	Advanced Encryption Standard
AI	Artificial Intelligence
API	Application Programming Interface
API SDK	Application Programmable Interface Software Development Kit
Avg IP	Average Intensity Projection
CT	Computerized tomography
CVE	Common Vulnerabilities and Exposures
DICOM	Digital Imaging and Communications in Medicine
ePHI	Electronic Protected Health Information
IDS	Intrusion Detection System
IEC	International Electrotechnical Commission
IPPA	Image Post-Processing Applications (IPPAs)
IPS	Intrusion Prevention System
ISO	International Organization for Standardization
MINP	Minimum Intensity Projection
MIP	Maximum Intensity Projection
MR	Magnetic resonance
OS	Operating System
PACS HIS	Picture Archiving and Communications System Hospital Information System
PHI	Protected Health Information
RIS	Radiology Information System
ROI	Region of Interest
SAST	Static application security testing
SSH	Secure Shell
TLS	Transport Layer Security
TM	Trademark
VM	Virtual Machine

WebGL	Web Graphics Library
XXS	Cross Site Scripting

9 Licenses

The following third-party software is included as part of the Calantic™ Viewer and the license terms for such software are outlined below.

OHIF

MIT License

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dicom-parser

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Bayer Medical Care B.V.
Avenue Céramique 27
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