LEICA BIOSYSTEMS IMAGING

Aperio WebViewer DX DIGITAL PATHOLOGY IMAGE VIEWING SOFTWARE

USER'S GUIDE







Aperio WebViewer DX User's Guide

MAN-0486, Revision A | April 2024

This manual applies to Aperio WebViewer DX 1.0.

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Customer Resources

• For the latest information on Leica Biosystems Aperio products and services, please visit www.LeicaBiosystems.com/Aperio.

Contact Information - Leica Biosystems Imaging, Inc.

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Notices

Intended Use

The Aperio GT 450 DX is an automated digital slide creation and viewing system. The Aperio GT 450 DX is intended for in vitro diagnostic use as an aid to the pathologist to review and interpret digital images of surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue. The Aperio GT 450 DX is for creation and viewing of digital images of scanned glass slides that would otherwise be appropriate for manual visualization by conventional light microscopy.

Aperio GT 450 DX is comprised of the Aperio GT 450 DX scanner, which generates images in the Digital Imaging and Communications in Medicine (DICOM) and in the ScanScope Virtual Slide (SVS) file formats, the Aperio WebViewer DX viewer, and the displays. The Aperio GT 450 DX is intended to be used with the interoperable components specified in Table 1.

Scanner Hardware	Scanner Output file format	Interoperable Viewing Software	Interoperable Displays
Aperio GT 450 DX	SVS	Aperio WebViewer DX	Barco MDPC-8127
			Dell UP3017
			Dell U3023E
			Dell U3223QE
Aperio GT 450 DX	SVS	Sectra Digital Pathology Module (3.3)	Dell U3223QE
Aperio GT 450 DX	DICOM	Sectra Digital Pathology Module (3.3)	Dell U3223QE

Table 1: Interoperable components of Aperio GT 450 DX

The Aperio GT 450 DX is not intended for use with frozen section, cytology, or non-FFPE hematopathology specimens. It is the responsibility of a qualified pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images obtained using the Aperio GT 450 DX.

Cautions and notes

- Aperio WebViewer DX is for professional use only.
- Serious Incidents Reporting Any serious incident that has occurred in relation to the Aperio WebViewer DX shall be reported to the manufacturer and the competent authority of the member state in which the user and/or the patient is established.
- Specifications and Performance For information on the requirements for monitors, refer to the document *Aperio WebViewer DX IT Administrator's Guide*.

- Installation Aperio WebViewer DX must be installed by a trained Leica Biosystems Technical Services representative.
- Accessories For information on using Aperio WebViewer DX with third-party accessories such as a Laboratory Information System (LIS) not provided by Leica Biosystems, contact your Leica Biosystems Technical Services representative.
- Quality Control For information on quality control procedures for Pathologist and Histotechnicians, see Quality control for pathologists and histotechnicians (on page 14).
- Maintenance and Troubleshooting For information on maintenance, see Maintenance (on page 92). For information on troubleshooting problems, see Troubleshooting (on page 98).
- Cybersecurity Be aware that workstations are susceptible to malware, viruses, data corruption, and privacy breaches. Use caution when inserting USB drives and other removable devices. Consider disabling USB ports that are not in use. If you plug in a USB drive or other removable device, you should scan the devices with an anti-malware utility. Work with your IT administrators to protect your workstation by following your institution's password and security policies.

As a system security measure, Leica Biosystems products capture and log external attempts to access system data. For more information, contact your Leica Biosystems representative.

IT staff: See thet *Aperio eSlide Manager Administrator Guide* for further cybersecurity recommendations, including:

- Protecting workstations and servers
- Setting passwords
- Monitoring and restricting login attempts
- Sensitive Data Protection This Leica Biosystems product is capable of input, storage, and handling of sensitive data, including personal identifier information (PII) and/or possibly protected health information (PHI). In addition to personal data such as name, address, and other obvious personal identifiers, sensitive data include barcodes, accession numbers, diagnostic information, and scan images, such as microscope slide labels and other labels or annotations embedded in image files. Please take appropriate precautions to protect from sensitive data exposure and theft. Handling of sensitive data is subject to local laws. Many countries have a data protection authority to ensure that data protection law is followed. For more information about your privacy rights, or if you are not able to resolve a problem directly with us and wish to make a complaint, contact your local authority.
- Protected Health Information Protection To ensure Protected Health Information (PHI) data is protected in transit, Leica Biosystems secures all network communications using TLS. Leica Biosystems recommends securing the user-facing web server as well. Customers should procure webserver certificates that are valid for the servers that will be hosting Aperio WebViewer DX and Aperio eSlide Manager. If not provided, the servers will be secured with self-signed certificates.

- Off-the-Shelf Software Potential impacts to cybersecurity in response to off-the-shelf (OTS) software are managed by Leica Biosystems Imaging, Inc.. A list of all OTS software is maintained by Leica Biosystems Imaging, Inc. For more information on OTS, contact your Leica Biosystems Sales Representative and ask for a copy of the Aperio WebViewer DX Software Bill of Materials (SBOM). OTS failures can cause errors when viewing or loading images in the viewer, including inaccurate color representation or other visual anomalies. If you experience issues with loading or viewing images, contact Leica Biosystems Technical Services.
- **Training** This manual is not a substitute for the detailed operator training provided by Leica Biosystems or for other advanced instruction. Leica Biosystems Technical Services should be contacted immediately for assistance in the event of any malfunction.



CAUTION: When viewing digital slides:

- Do not use the Image Enhancement tools to correct a suboptimal scanned image for diagnostic review. In this case, you should request a re-scan of the slide.
- Your monitor must meet the specifications detailed in the *Aperio WebViewer DX IT Administrator's Guide*.
- Your monitor's Display Mode must be set to sRGB.
- Your viewing station must use the supported browser and operating system, as described in Supported operating system and browsers (on page 17).

Limitations

The following limitations apply to the Aperio WebViewer DX:

- The use of Aperio WebViewer DX from a virtual viewing station (VM) is not supported.
- The use of SVS images from an Aperio scanner other than the Aperio GT 450 DX is for non-clinical use only.
- SVS images displayed in Aperio WebViewer DX are compressed to 94% of the source SVS file, or JPEG Q = 94.
- The use of Aperio WebViewer DX from Remote Desktop is not supported. By default, Remote Desktop does not engage the video card (GPU) on your viewing workstation. The use of a video card is required to ensure the highest quality viewing performance.
- The use of tablets and mobile devices is not supported.
- The use of touchscreens is not supported.
- The use of gaming mice (e.g., joysticks and 3-D mice) is not supported.
- The use of operating systems other than the Windows version specified in the *Aperio WebViewer DX IT Administrator's Guide* is not supported.

Revision record

Rev.	Issued	Sections Affected	Detail
А	April 2024	All	New manual for Aperio WebViewer DX 1.0.

Symbols

The following symbols appear in device labeling:

Symbol	Standard / Regulation	Description
	ISO 15223-1 - 5.1.1	Manufacturer
$R_{\!\!X^{\text{Only}}}$	21 CFR §809.10(a)(4)	Requires prescription in the United States.
UDI	ISO 15223-1 - 5.7.10	Unique Device Identifier
REF	ISO 15223-1 - 5.1.6	Catalog number
IVD	ISO 15223-1 - 5.5.1	In Vitro Diagnostic medical device
	ISO 7010 - W001	The exclamation point within an equilateral triangle is intended to alert you to the presence of important operating and maintenance (servicing) instructions.

Introduction

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Introducing Aperio WebViewer DX

Aperio WebViewer DX is a web-based digital slide viewing software product that enables you to navigate through whole slide images for a patient case in an organized manner for the purpose of on-screen primary diagnosis. You can open whole slide images in Aperio WebViewer DX from an image and data management system (IDMS), such as Aperio eSlide Manager, or from your Laboratory Information System (LIS).

The Aperio WebViewer DX is part of an overall clinical workflow solution, which also includes the Aperio GT 450 DX scanner, Aperio eSlide Manager, and an LIS connectivity solution.



Key features for pathologists

As a pathologist, Aperio WebViewer DX enables you to:

- Enhance images to optimize detection of important features such as chromatin, mitotic events, and intracellular bridges regardless of scanner source, stain, and/or tissue type.
- Annotate images for a variety of reasons, including delineating areas for special stain or a harvest zone for ancillary studies.
- Synchronize image magnification and rotation of multiple images within the same window.
- Compare a patient's current case with their past case(s) to provide needed context.

Quality control for pathologists and histotechnicians

As a Histotechnician or Pathologist, Aperio WebViewer DX enables you to perform visual quality control checks to ensure:

- There are no missing slides for a case.
- There is no missing tissue on a slide by navigating the image and referring to the whole image view.
- The image is clear and the metadata is present and legible.

You should perform quality control on digital slides based on your organization's standard procedures.

Pathologist responsibility

It is the responsibility of the pathologist to perform the quality checks described below.

- Pathologists should exercise professional judgment in each clinical situation and examine the glass slides by conventional microscopy if there is doubt about the ability to accurately render an interpretation using this device alone.
- Pathologists should confirm that all slides are present in the digital case, that the slides they are reviewing are for the correct patient, and that the slides match the gross description in their requisition.
- If a scanned image appears with a red tile, the image is corrupt or has missing data. In this case, do not use the image for diagnostic purposes. You should rescan the slide.

For a high-level workflow diagram of the quality control tasks, see the next section, Pathologist quality control workflow (on page 15).

Pathologist quality control workflow

The following workflow diagram provides a high-level overview of the quality control tasks a pathologist should perform for each case.



Digital slide scanning quality control

Specimen collection and preparation is performed prior to use of the Aperio WebViewer DX using a formal procedure associated with the compatible device. Acceptable specimens are surgical pathology slides prepared from FFPE tissue, which are digital images once introduced to Aperio WebViewer DX.

Well prepared slides are crucial to a successful scan. It is the responsibility of the lab to verify the quality of the tissue preparation, the physical characteristics of the slide, and the staining quality. For more information on slide preparation techniques, refer to the user's guide for your scanner.

Supported image types

Aperio WebViewer DX supports SVS images created from the Aperio GT 450 DX for use in your clinical workflow.

SVS image file compression

This section describes the image processing that occurs when you open a slide in Aperio WebViewer DX.

When a slide image is requested in Aperio WebViewer DX, a request for the specified image file is sent to ImageServer. ImageServer then parses the request and retrieves the specified image file. To improve the performance of transferring the requested image file back to Aperio WebViewer DX, ImageServer compresses the image using RGB-to-YCbCr Color Conversion, resulting in a JPEG image 94% the size of the original. The compressed image is then returned to Aperio WebViewer DX and displays in the Viewer window.

The following flow diagram shows this process:



Non-clinical use images

You can open and view SVS images from an Aperio scanner other than the Aperio GT 450 DX; however, they are for nonclinical use only. When you open such an image, a banner appears at the bottom of the viewer indicating the image is for non-clinical use only.

Installation

Installation and setup of Aperio WebViewer DX and Aperio eSlide Manager should only be performed by a trained Leica Biosystems Service representative.



WARNING: Ensure Aperio WebViewer DX is installed only by a trained Leica Biosystems Service Representative. Incorrect installation can enable the use of incorrect color profiles.

Environment

Aperio WebViewer DX is intended for use in Histology and Pathology labs as well as within a pathologist's office for quality control tasks, routine diagnosis, and digital slide reviews. The pathologist's office may be at their home or place of work.

Supported operating system and browsers

Component	Supported Versions
Viewing Workstation Operating System	Microsoft Windows 10 Professional / Enterprise
Viewing Workstation Server	 Microsoft Windows Server 2022 Microsoft Windows Server 2019 Microsoft Windows Server 2016*
Web Browser	 Mozilla Firefox (Version 88 or newer) Google Chrome (Version 90 or newer) Microsoft Edge (Version 90 or newer)

*Leica Biosystems continues to support Microsoft Windows Server 2016 with Aperio WebViewer DX; however, to better secure your server we recommend upgrading to Microsoft Windows Server 2022.

Required viewing settings



WARNING: Your viewing workstation must meet the specifications provided in the *Aperio WebViewer DX IT Administrator's Guide* to ensure proper image rendering and display. Using a monitor that does not meet the required specifications can enable the use of incorrect color profiles.

Monitor settings

Ensure your monitor's Display Mode is set to sRGB.

For further details regarding setting up qualified Dell monitors, see Chapter 2: Set up the viewing workstation monitor.

Browser and operating system settings

To display your digital slides with optimal image quality, you must use the following browser and operating system settings:

Component	Setting
Web Browser	Zoom level is set to a multiple of 100% (100%, 200%, etc.).
Operating System	Display settings "scale" value is a multiple of 100% (100%, 200%, etc.).

If your settings are outside of the specified range, the 🛕 icon appears on the image to alert you that the image quality is reduced.

2 Set up the viewing workstation monitor

In this section:

Set up a Dell UP3017, Dell U3023E, or Dell U3223QE monitor	20

Set up a Dell UP3017, Dell U3023E, or Dell U3223QE monitor

If you are using a Dell UP3017, Dell U3023E, or Dell U3223QE monitor for your Aperio GT 450 DX display, follow the setup instructions in this chapter.

Dell UP3017, Dell U3023E, Dell U3223QE monitors are qualified for use with the Aperio GT 450 DX scanner (with 'For IVD Use' label). Leica Biosystems takes responsibility for recalls, since the specified Dell monitors are not FDA Cleared Displays under product code PZZ.

Leica Biosystems Field Service Engineers will provide customers with labels to affix to qualified monitors. This label indicates "for IVD Use" and includes the Leica Biosystems contact information. Leica Biosystems Field Service Engineers will affix the label during installation if the monitor is available at that time.



Customers must set up the monitors in accordance with the following instructions to ensure that the displays are in the same condition as those in the bench testing that Leica Biosystems conducted.

Set up the Dell UP3017

Assemble and use the Dell UP3017 Monitor as described below.

- 1 Assemble the monitor using the display stand included with the monitor.
- 2 Power off the computer workstation.
- 3 Connect the monitor to the computer workstation using a display port, HDMI, or VGA cable.
- 4 Connect the monitor to a 100 240 VAC 50 / 60 Hz power source.
- 5 Power on the computer workstation.
- 6 Power on the monitor.
- 7 Note that the monitor's default settings were used during testing. Follow the steps below to verify the monitor is configured to the specified settings .
- 8 Use the buttons on the display to navigate to the **Brightness/Contrast** menu in the on-screen display menu, and then verify the settings below:
 - Brightness 75%
 - **Contrast** 75%
- 9 Navigate to the **Color** menu and verify the setting below:
 - Preset Mode Color Space sRGB
- 10 Adjust monitor tilt, swivel, rotation and vertical extension as needed.

- 11 The Dell UP3017 is now ready for use.
- 12 Ensure that the label provided by Leica Biosystems that indicates "for IVD use" is affixed to the monitor.

For detailed information, refer to the user guide for your Dell UP3017: <u>Dell UltraSharp UP3017 User's Guide.</u>

Set up the Dell U3023E

Assemble and use the Dell U3023E Monitor as described below.

- 1 Assemble the monitor using the display stand included with the monitor.
- 2 Power off the computer workstation.
- 3 Connect the monitor to the computer workstation using a display port, HDMI, or VGA cable.
- 4 Connect the monitor to a 100 240 VAC 50 / 60 Hz power source.
- 5 Power on the computer workstation.
- 6 Power on the monitor.
- 7 Note that the monitor's default settings were used during testing. Follow the steps below to verify the monitor is configured to the specified settings .
- 8 Use the buttons on the display to navigate to the **Brightness/Contrast** menu in the on-screen display menu, and then verify the settings below:
 - Brightness 75%
 - Contrast 75%
- 9 Navigate to the **Color** menu and verify the setting below:
 - Preset Mode Color Space sRGB
- 10 Adjust monitor tilt, swivel, rotation and vertical extension as needed.
- 11 The Dell U3023E is ready for use.
- 12 Ensure that the label provided by Leica Biosystems that indicates "for IVD use" is affixed to the monitor.

For detailed information refer to the user guide for your Dell U3023E: <u>Dell UltraSharp 30 USB-C Hub Monitor -U3023E</u> User's Guide.

Set up the Dell U3223QE

Assemble and use the Dell U3223QE Monitor as described below.

- 1 Assemble the monitor using the display stand included with the monitor.
- 2 Power off the computer workstation.
- 3 Connect the monitor to the computer workstation utilizing a display port, HDMI, or VGA cable.

- 4 Connect the monitor to a 100 240 VAC 50 / 60 Hz power source.
- 5 Power on the computer workstation.
- 6 Power on the monitor.
- 7 Use the buttons on the display to navigate to the **Brightness/Contrast** menu in the on-screen display menu, and then verify the settings below:
 - Brightness 90%
 - Contrast 75%
- 8 Navigate to the **Color** menu and verify the setting below:

• Preset Mode Color Space - sRGB

- 9 Adjust monitor tilt, swivel, rotation and vertical extension as needed.
- 10 The Dell U3223QE is ready for use.
- 11 Ensure that the label provided by Leica Biosystems that indicates "for IVD use" is affixed to the monitor.

For detailed information refer to the user guide for your Dell U3223QE: <u>Dell UltraSharp 27/32 4K USB-C Hub Monitor –</u> <u>U2723QX/U2723QE/U3223QE User's Guide.</u>



For further detailed information and additional user manuals for your Dell display, visit Dell's support website at: <u>https://www.dell.com/support/home/en-us?app=manuals.</u>

3 Get started

In this section:

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Aperio WebViewer DX user interface overview

The following example shows the Aperio WebViewer DX with a case of slides open. The example shows the primary areas of the interface and the tools you can use to view and navigate your digital slides.



The two main areas are the Slide Tray and the Viewer window:

- Slide Tray The Slide Tray provides a simulation of the tray pathologists use to organize their glass slides. Slides are grouped in the tray by specimen. If configured in Aperio eSlide Manager, the slides may also be sorted by stain, block ID, and so on, within the specimen. For more details about using the Slide Tray, see View and organize digital slides in the Slide Tray (on page 56).
- Viewer Window The Viewer window is where you review and work with your digital slides. For more details, see Viewer Window (on page 60).

Training workflows for digital slide review

This section contains example digital slide review workflows that include typical tasks performed and tools you can use during your review, such as navigation and annotation tools. Note that these are examples only, and the workflows used at your institution may differ.

View digital slides

This section contains sample workflows in which you will:

- Log in to Aperio eSlide Manager.
- Open a case.

- Check image quality.
- Examine a digital slide for quality control.
- Examine the digital slide using Aperio WebViewer DX tools.
- Make the necessary annotations.
- Close Aperio WebViewer DX.
- Log out of all applications.

Open digital slides with Aperio eSlide Manager

From Aperio eSlide Manager, you can open one or more specific digital slides, or all of the digital slides for a case. Aperio WebViewer DX opens in a separate browser tab, with the selected digital slides loaded in the Slide Tray. For more details about using Aperio eSlide Manager, see the *Aperio eSlide Manager User's Guide*.

- 1 Log in to Aperio eSlide Manager.
 - a From your Internet browser, go to the URL of the Aperio eSlide Manager website.
 - b When the Aperio eSlide Manager website opens, click Login to eSlide Manager.
 - c Type your username and password, and then click Login.
- 2 Click Cases.



- 3 From the Case list, locate the case you want to review.
- 4 Click 📀 from the case list to open the digital slides in Aperio WebViewer DX.



The order the slides appear in the slide tray has already been set by the administrator. It can be changed to a multiple level sort within Specimen per your site's needs. For example, for each specimen, you can sort by the type of stain.

Perform the monitor display image validation

When viewing digital slides with Aperio WebViewer DX, ensure your monitor meets the specifications detailed in *Aperio WebViewer DX IT Administrator's Guide*.

When you open the viewer for the first time and anytime your browser is updated, the system performs an automatic monitor display image validation to ensure your monitor displays digital slide images correctly. Following the automatic check, the system prompts you to do a manual monitor display image validation.

Follow the instructions on the screen to complete the check. If any part of the manual monitor display image validation fails, contact your IT Department.



vertical gradient bars outlined in **blue** • Changes in intensity are smooth and uniform over the entire range from bright to dark.

- There are no noticeable bands of constant intensity (solid
- white, gray, or black) inside or near the edges of the bars



You should perform the manual monitor display image validation once per month. To do this, click the Leica logo in the upper-right area of the viewer, and then select **Perform Image Quality Check**.

For more information and instructions, see Automatic and manual monitor display image validation checks (on page 93).

Perform quality control for the digital case review

The purpose of quality control is to ensure the following:

- All the digital slides from the case or project are presented in Aperio WebViewer DX.
- All the tissue on the physical slide is included in the digital image.

High-quality, complete digital slides ensure the most accurate diagnosis for the patient. Depending on your organization's processes, quality control may be performed as slides are scanned into Aperio eSlide Manager or after cases are assembled.

- Marchand, Chantel | F | 2020-04892 22 slide(s) (22 unread) 4 Sorted By: Block ID ~ Stain ~ View All Memos ID OO)0 2 0)0 ID 005)0 Marchand, Chantel | F | 2020-04892 - 22 slide(s) (22 un 16 8 0 18 ID 007 9 10 20 « 1 2 » Edit Trays
- 1 Verify all the case slides are scanned and included in the digital case file.

- 2 Review the digital slides and relevant case metadata, per your standard operating procedures. Metadata may include:
 - Accession number and part number on the slide label match other artifacts.
 - Data on the physical slide matches the data on the digital slide, if applicable.

If there is missing tissue or metadata, or if the image is blurry or metadata is blurry, rescan.

a Click the 🚯 that appears next to the slide in the Slide Tray to view and verify detail data from Aperio eSlide Manager.



b Hover over the slide label to enlarge the view.



c Hover over the slide to see the macro overview to confirm tissue coverage. The green box defines the scanned area. If there is tissue outside the green box, it should be rescanned or prepared again.

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d Review the digital image for quality, using the required magnification. For example, ensure the digital slide shows the necessary level of detail.



3 Repeat step 2 for each of the digital slides you need to review. Click the **Next Slide** button or forward arrows to navigate to the next set of digital slides.

•	Previous Slide			Next Slide 🕨	
		≪	>>		

Review a single slide

- 1 Confirm the slide you are reviewing is for the correct patient, and that it matches the gross description in your requisition.
- 2 If the slides are not in the order you want, click a slide and drag it to the correct location.

3 Select a digital slide to review. The slide displays in the Viewer Window.



- 4 Turn on the Heat Map to document the areas of the digital slide you have visited. To turn it on:
 - a Click the **Settings** to button on the WebViewer toolbar.
 - b Select the Heat Map check box.
 - c Click the X to close the Visibility box. The Heat Map is now turned on



5 Click **2x** and visually review the digital slide for regions of interest at low magnification.



6 Identify a region of interest and click **10x**, **20x**, or **40x** or click and drag the zoom slider to the zoom level you desire.



7 The thumbnail box shows you where you are on the digital slide. The Heat Map shows what you have previously viewed. Click within the thumbnail to move to another location of interest.



8 Apply image enhancements to make slide areas stand out. Click the **Image Enhancement Toolbox** to open the options.



- 9 Click and drag the Gamma slider to the left to make the image darker.
- 10 Adjust the Brightness and Contrast, as needed.

The Image Enhancements notification icon appears at the top of the Viewer window to notify you that the image has been enhanced.



- 11 When you are satisfied with the image enhancements, save the setting. This allows you to use the new image enhancement settings for the next set of slides.
 - a Click Presets > Save as preset.



- **b** Type in a name for the setting.
- c Click Enter.

d Hover over the **Image Enhancements** notification icon at the top of the viewer to see the preset applied.



To automatically apply an image enhancement preset, click the User Preferences **L** icon in the Image Enhancements toolbox and select the option you want from the Preferences tab.



- 12 Use the Auto-Pan tool (see the Semi-Automated row in the table on on page 48), or click and drag to pan around the digital slide to identify a region of interest (ROI) to annotate.
- 13 Click the Annotation tool 🖍 to open the Annotations window.

14 Measure the ROI for further examination. Click the **Measurement** annotation tool. Measure the ROI.



- a On the digital slide click the beginning of the area to measure.
- b Move the mouse along the ROI and double-click to end the measurement.

A line is drawn along the area you measured with a total length in microns (μ m) or millimeters (mm), depending on how the measurement units are configured in the system.



- **15** Draw a green arrow pointing to the measured area.
 - a In the Annotations window, click the color icon and select green.
 - **b** Select the **Arrow** tool.



c Click and drag to create an arrow, leading with the arrowhead.



- d Release the mouse to finish.
- 16 Change the color of the arrow.
 - a Select the arrow.
 - b Click the **Color** icon.



c Select a different color. The arrow changes color.



You may need to select different colors until you find one that stands out against the tissue.
- 17 Move the arrow to a different location.
 - a Right-click and select the **Move** tool.



The arrow is now moving with your mouse pointer.

- b Right-click on the new location to release the arrow.
- 18 Add text to the measured area.
 - a In the Annotations window, click the **Aa** tool.

nnot	ations			>
		0	0	K
•	*	AA		

- b Click near the annotation to add the note box.
- c Type your note (for example, "ROI") and click OK.

Add on image te	xt X
ROI	
]
	Cancel Ok

- d The note should show in the color that was previously chosen. To change the color, select the note and click on the color icon. Select a new color.
- 19 Click the **Pin Drop** tool and click near the annotated area to add the pin.



- 20 Magnify the image to 20x and add another pin.
- 21 Close the Annotation toolbox.
- 22 Take a snapshot of the region of interest you annotated.
 - a Click the snapshot tool to save the region of interest as an image.



b The image is automatically saved to the browser's Downloads folder.



WARNING: The snapshot image (JPEG file) is not for use in diagnostic procedures.

- 23 Change the settings of the Snapshot tool and capture a user drawn section of the region of interest.
 - a Hover over the **Snapshot** tool to show the **Snapshot Settings** tool. Click the Snapshot Settings tool to change the settings and capture a user drawn section of the region of interest.



- b Select Image Settings.
- c In the Capture Mode field, select User Drawn from the list.

Snapshot Se	ttings	×
Capture Mode:	User Drawn	•
		Capture
Description: Captures an area t	hat you select.	

- d Click Capture.
- e Click and drag to select the region of interest to capture.
- f The image is saved in the Downloads folder.
- g Close the Snapshot Settings window.
- 24 Click on the next digital slide in the tray.

- 25 Click **20x** magnification.
- 26 Open the Annotation toolbox and add a pin.
- 27 Click the **Pin Drop Navigation** tool **9** to open the Pindrop Navigator.



28 Navigate to all the areas that contain pin drops. Click each number or the forward/back arrows to navigate.



The region of interest shows in the magnification that was set when the pin drop was added.

- 29 Close the Pindrop Navigator window.
- 30 Continue reviewing the digital slides by clicking the navigation arrows at the bottom of the Slide Tray.



31 Click the **Hide Workflow Tools** arrow to close the slide tray to create more room to view the digital slide in the Viewer Window.



Review multiple slides

To perform the steps below, verify you can view all the slides in the Slide Tray. If the Slide Tray is hidden, click the **Show Workflow Tools** icon to unhide it.

1 In the Slide Tray, click the circle to the left of two digital slides to show three digital slides in the viewing window. A pin appears in each slot. Choose three of the same images.



2 Confirm that each digital slide under review shows the whole tissue present on the glass slide. If tissue is off the screen, click and drag the digital image until it shows the whole tissue.



- 3 All images should show tissue orientation in the same direction. If the orientation needs adjusting, do the following:
 - a Click the slide.
 - b Click within the Rotation Dial tool and select your choice of adjustment.



• The dots change orientation by 90-degree increments.



- The Rotation Dial allows manual adjustments.
- The arrows adjust by one degree in either direction.

- 4 As needed, synchronize the digital slides to be able to simultaneously look at the same region of interest on the different slides. Prior to synchronization, verify all the slides you want to show in the viewer have the same zoom level.
 - a Click the **Synchronize** tool **T** to pan and zoom all the images at the same time.
 - b Click the Change Image Tiling Pattern tool 📰 to show the tiles horizontally.



- 5 Zoom in on specific regions of interest on the tissue on one slide (for example, H&E).
- 6 Pan around and change zoom magnification to examine the whole tissue. Aperio WebViewer DX shows the same region on all displayed digital images.
- 7 Use the Rotation Dial to adjust the rotation, as desired. Aperio WebViewer DX rotates all the open digital images in the same manner.
- 8 Close all of the digital slides when you are satisfied with your review.
- 9 Close the browser tab when you have completed reviewing all the digital slides.
- 10 Return to the Aperio eSlide Manager browser tab. From this tab, you can share the images and regions of interest with other pathologists in your network with the conferencing capabilities available in Aperio eSlide Manager. Refer to the Aperio eSlide Manager User's Guide for details.
- 11 Click the **Log out** icon and close the browser tab.



Ending a viewing session

To close a case and end your viewing session, do one of the following:

- Close your browser tab.
- Click the down arrow beside your user name in the upper-right corner of the Aperio WebViewer DX window, and click **Close WebViewer**.

Also, if you exit Aperio eSlide Manager or if the system times out, the viewer will close automatically. In this case, you need to log in to Aperio eSlide Manager again. (Refer to Open digital slides with Aperio eSlide Manager (on page 25)).



In this section:

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Navigate digital slides	
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Icon glossary	
Keyboard shortcuts	53
Close Aperio WebViewer DX	54

Open digital slides

You can open digital slides in Aperio WebViewer DX from Aperio eSlide Manager, from your image and data management system (IDMS), or your Laboratory Information System (LIS). This section describes how to open digital images from Aperio eSlide Manager. Contact your site administrator for instructions on using your IDMS or LIS.

Open digital slides from Aperio eSlide Manager

From Aperio eSlide Manager, you can open one or more specific digital slides, or all of the digital slides for a case. Aperio WebViewer DX opens in a separate browser tab, with the selected digital slides loaded in the Slide Tray. For more details about using Aperio eSlide Manager, see the *Aperio eSlide Manager User's Guide*.

- 1 Log in to Aperio eSlide Manager:
 - a From your Internet browser, go to the URL of the Aperio eSlide Manager website.
 - b When Aperio eSlide Manager opens, click Login to eSlide Manager.
 - c Type your user name and password, and click Login.
- 2 From the Aperio eSlide Manager Home page, use one of these methods to open your digital slides for review:

Open all digital slides for a case	 Go to the Case list, and locate the case you want to review. Click from the case list (shown below) or case detail page to open all digital slides for the specified case.
	13 ZJR-111 Zimmer J 1985/02/05
Open a single digital slide	 Go to the eSlide list, and locate the digital slide you want to review. Click the thumbnail image of the digital slide. (Press and hold the W key if Aperio WebViewer DX is not set as the default viewer in Aperio eSlide Manager.)
	Vanoff, Alaxis APERO Hospital P=2016-0153.44 HER2 NO

Open multiple digital slides from Go to the eSlide list, and locate the digital slides you want to review. the Aperio eSlide Manager eSlides Select the check box next to each digital slide image you want to open, and list. click View Images. All eSlides View Images Sort Open Data Analyze Delete Annotations Label Macro Image Image

3 Aperio WebViewer DX opens in a separate browser tab with the specified digital slides shown. See the following section for an example and overview of the Aperio WebViewer DX interface.

Navigate digital slides

There are several ways to move around the digital slide.

Navigation Type	Tool	Instructions
Manual		 Click and drag Click and hold the left mouse button to drag the digital slide within the Viewer window.
		 Keyboard Navigation Use the arrow keys for incremental vertical and horizontal movements. For larger vertical and horizontal movements, press Shift and an arrow key.

Navigation Type	Tool	Instructions
Semi-Automated	0	Auto-Pan
	Ø	 Click the boundary of the Viewer window to start auto pan. The Auto-pan symbol appears in the center of the window, and the digital slide scrolls from the center towards your mouse pointer.
		• The greater the distance between the mouse pointer and center, the faster the scroll speed.
		• The higher the zoom level, the faster the scroll speed.
		• Click anywhere in the Viewer window to stop the auto-pan.

Tools quick reference

This section provides quick reference information for the tools on the main toolbar.

Main Toolbar

	Close the current digital slide, if there is more than one digital slide open.
	View the previous digital slide in the tray.
▼	View the next digital slide in the tray.
•	Open the Pin drop navigation tool. See Use pin drops to navigate around case slides (on page 81).
~	Use synchronized navigation to pan, zoom, and rotate multiple digital slides together. See Synchronize navigation of multiple slides (on page 64).
+	Download the .sis file (ScanScope Image Set file) to open the active digital slide in the Aperio ImageScope viewing software.
	Host a conference to share digital slides with colleagues working in your Aperio eSlide Manager location. See the <i>Aperio eSlide Manager User's Guide</i> for details.
	Change the image tiling pattern when you have multiple digital slide images open. See View multiple images (on page 62).
0	Take a snapshot of the digital slide, and save it as a JPEG image file. See Take a snapshot of the digital slide (on page 84).
	Add or edit annotations. See Annotations (on page 76).



Enables you to resize the Viewer window.

O

Opens the Image Enhancement settings, which allow you to apply gamma, brightness, and contrast settings to the image. See Image enhancements (on page 68)

Open the Aperio WebViewer DX Visibility panel and Options window. See Aperio WebViewer DX options (on page 88).

Navigation Tools

Use this tool:	To do this:	
Label *	View and rotate the digital slide label. Click the digital slide label to rotate it 90 degrees to the right.	Breast
Thumbnail and heat map *	 Navigate in the main Viewer window using a small version of the entire digital slide. The Thumbnail shows you where you are in the digital slide. The heat map shows the areas of the digital slide you have viewed and the magnification level used. You can resize the thumbnail by dragging the bottom-left corner. 	
Zoom slider *	Zoom in and out of the digital slide.	20x
Zoom control with digital zoom*	 Select a specific magnification level (Fit, 1x, 20x, etc.). If you are using a high-resolution monitor (for example, a 4K monitor), digital zoom levels are available on the zoom control. This enables you to zoom to a viewing magnification that is higher than the scanned magnification. Digital zoom enlarges the image in increments of 100% (D2 = 200%, D3 = 300%, etc.). 	1x 2x 4x 10x 20x 40x D2

The following table describes the tools available from the Aperio WebViewer DX.

Use this tool:	To do this:	
Rotation dial *	Rotate the digital slide from 0° to 360° by clicking and dragging the rotation bar.	
Magnifier glass *	Drag the magnifier glass to view areas of the digital slide at twice the current magnification. Click and drag the handle to resize the magnifier.	
Scale bar *	View a measurement scale that adjusts with the magnification level. You can resize the scale bar by dragging the left or right edge. You can also drag it to a different area of the digital slide.	40x 0.025 mm
	The unit of measure is set in the Aperio eSlide Manager System Settings. Your Aperio eSlide Manager administrator can set the unit of measure to millimeters or microns.	
* Click 🏚 on th	ne bottom of the vertical toolbar to show or hide these tools.	

Annotation tools

Use annotations to mark the image, measure an area of interest, add a comment, etc. Click 🧪 to open the Annotations window.

Annota	ations				×
	ø	0	٥	K	
•	×	AA			
Ô	٩				
	¢				

In the Annotations window, click to use the following annotation tools:

	Draw a rectangle annotation.
P	Draw a free-form shape annotation.
Ο	Draw an elliptical annotation.
\mathbf{O}	Draw a polygon annotation.
	Click to set points, and then double-click to complete the polygon.
K	Draw an arrow annotation.
•	Place a pin drop annotation.
×	Perform a linear measurement.
	Click to set points, and then double-click to complete the measurement.
AA	Place a text label.
	Define the report image.
Ô	Delete the selected annotation.
0	Change the color of the selected annotation.



Add or edit notes for selected annotation.





Place the selected annotation in the center of the Viewer window at the magnification the annotation was created.

Go to next annotation.

Icon glossary

In addition to the icons described previously in this chapter, the following icons also appear on the Aperio WebViewer DX interface.

	Unsupported zoom level – Appears in the upper-left of the Viewer window when the system detects an unsupported zoom level. For optimal viewing quality, ensure your browser and operating system zoom levels are set to a multiple of 100%. See Unsupported zoom level notification (on page 99).
	Monitor Display Image Validation Failure – Appears in the upper-left of the Viewer window when your automatic or manual monitor quality check failed. If this occurs, repeat the manual check again. See Automatic and manual monitor display image validation checks (on page 93). If it still fails, contact your IT representative.
Ŀ	Memo – Appears next to the selected slide in the Slide Tray. Click the Memo icon to add a note to the specified slide.
lacksquare	Image Enhancement applied – Appears in the upper-left area of the Viewer window when you have applied an image enhancement to the digital slide.
	If you are using an image enhancement preset, you can hover over the image enhancement icon to view the name of the applied preset.
	See Image enhancements (on page 68) for more details.
	Image Enhancement Presets defined – The small triangle in the lower-right of the Image Enhancement tool appears if you have Image Enhancement presets defined.
	See Image Enhancement Presets (on page 70) for more details.
	Image Enhancement User Preferences – Appears on the Image Enhancement toolbox. Click to set Preferences for using Image Enhancement presets for all viewing sessions.
	See Image Enhancement Preset validation workflow (on page 74).
	See Set Image Enhancement preferences (on page 74).
6	Information – Appears on the user interface to provide additional information. Click the 🚺 to view information.

Show/Hide Workflow – Appears on the upper-right area of the Slide Tray. Click to show or hide the Slide Tray. When the Slide Tray is hidden, the arrow is reversed:

Product Information – The Leica Biosystems logo appears in the upper-right of the Viewer window.

Click the logo to access product information and the manual monitor display image validation. See Product information (on page 92).

Keyboard shortcuts

The Aperio WebViewer DX provides a number of keyboard shortcuts for frequently used actions.



feica

A list of keyboard shortcuts is also available in the Options window, which you can access by clicking the Settings tool 🔹 on the main toolbar. For details, see Aperio WebViewer DX options (on page 88).

View Next or Previous Digital Slide

q, Q	Step to the previous slide in the Slide \ensuremath{Tray}
e, E	Step to the next slide in the Slide Tray

Digital Slide Navigation

Arrow Keys	Move the view one-fourth of the view width or height
Shift + Arrow Keys	Move the view three-fourths of the view width or height

Magnification

Ctrl + Minus Sign	Zoom Out
Ctrl + Plus Sign	Zoom In
Double-click	Toggle between the last two magnifications

Rotation

r	Rotate clockwise 15°
Shift + R	Rotate clockwise 1°
Ctrl + r	Rotate counter-clockwise 15°
Ctrl + Shift + R	Rotate counter-clockwise 1°
0 (Zero)	Set rotation to 0°

Annotations

Ctrl + m	Move the selected pin. Press Ctrl+m, drag the pin to its new location, and press Ctrl+m again to place the pin.
Ctrl + c	Copy selected annotation
Ctrl + v	Paste copied or selected annotation
Delete	Delete the selected annotation

Close Aperio WebViewer DX

To close the viewer, click the small x in the upper-right corner of the viewer's browser tab. You can also click the downarrow beside your user name in the upper-right corner of the viewer's window, and click **Close WebViewer**.

To close a case and end your viewing session, do one of the following:

- To close the viewer only, click the small x in the upper-right corner of the viewer's browser tab.
- To close the viewer and log out of Aperio eSlide Manager, click the down-arrow beside your name in the upperright corner of the viewer window, and select Log out

Also, if you exit Aperio eSlide Manager or if the system times out, the viewer will close automatically. In this case, you need to log in to Aperio eSlide Manager again. For details, see Open digital slides (on page 46).

5 View and navigate digital slides

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View and organize digital slides in the Slide Tray

This section describes the various Slide Tray tools you can use while reviewing digital slides.

Depending on whether you opened digital slides from a case details page or the eSlide list in Aperio eSlide Manager, the Slide Tray can contain the following:

- All digital slides from a single case.
- All selected digital slides.

Slide Tray features

The following example shows the different parts of the Slide Tray, and introduces how you can view, open, and organize slides.



You can perform the following actions from the Slide Tray.

Organize the Slide Tray

5)
To do this:	Do this:
Define the digital slide sort order	Slides are always grouped by specimen in the Slide Tray. Optionally, your Aperio eSlide Manager administrator can further define how your slides are sorted under each specimen. For example, under each specimen, you can sort the slides by stain, block ID, and so on.
	The sort order is indicated in the upper portion of the slide tray. You can click (1) to view further details about the sort order, as shown below. (The \checkmark and \checkmark symbols indicate ascending or descending order.)
	Marchand, Chantel F 2020-04892 - 22 slide(s) (21 unread)
	ID 002 1 1 Within a specimen, the default slide sort order set by System Administrator is: • • • • • • • •
	Your site administrator defines the Slide Tray sort order in Aperio eSlide Manager. For more information, see the <i>Aperio eSlide Manager Administrator's Guide</i> .
Flip a digital slide	By default, after you view and interact with a digital slide in the Viewer window, it is flipped in the tray to indicate it was read.
horizontally to mark it as read or unread	If you have turned this feature off, you can flip the digital slides manually. Right-click the digital slide in the Slide Tray, and select Toggle Read/Unread . Use your keyboard Ctrl key to select multiple digital slides.
	To change the automatic slide flipping behavior in your personal settings, click 🔹 in the upper-right corner of the Aperio eSlide Manager window to go to My Settings , and select or clear the Disable Auto-Slide Flipping check box.
Move a digital slide to a different slot in the tray	Drag the digital slide to a different position within the same specimen. Depending on where you want to position a slide in the tray, you may choose to insert blank slots (see below) before moving a slide.
	If your site uses a custom slide sort for the Slide Tray and you manually change the slide order, the "Sorted By" section will say "Modified" to indicate the sort order has changed. In this case, the slide order remains changed for the current viewing session.
Insert a blank slot in the Slide	Right-click the digital slide located below the space where you want an extra slot and select Insert Blank Slot . To remove a blank slot, right-click the slot and select Remove Selected Blank(s) .
Tray	If your site uses a custom slide sort for the Slide Tray and you manually change the slide order, the "Sorted By" section will say "Modified" to indicate the sort order has changed.

To do this:	Do this:
Remove a	With one or more digital slides selected, right-click one of the selected digital slides and select
digital slide	Remove Selected Slide(s). This removes the slide from the tray, but does not remove the slide from
from the Slide	the associated case.
Tray	

Open digital slides

To do this:	Do this:
View a digital slide	Click a digital slide to open it in the Aperio WebViewer DX window.
Select multiple images to view	Select the circle next to the digital slide to open the digital slide image in the Viewer window. See View multiple images (on page 62) for details.

View digital slide and label information

To do this:	Do this:
View an enlarged version of the digital slide label or macro image	In the Slide Tray: • Hover over the slide label you want to view.
View one or more digital slide memos	To view a memo for a specific slide, click in the tray. To view existing memos for all slides in the tray, click the View All Memos link.
View metadata for the digital slide	To view metadata for the active digital slide, click the 🚯 that appears to the left of the digital slide in the Slide Tray. The data includes information such as Stain, Block ID, and Barcode ID.

View case data

To do this:	Do this:
Navigate through the digital slides in the Slide Tray	Click Previous Slide and Next Slide , or use the Previous 🔺 and Next 🔻 buttons from the Web Viewer toolbar.
Navigate through all open Slide Trays	If there are more than 20 digital slides in the open case, click the Previous or Next buttons or click the number of the tray you want to view $\$ \ll 1 $>$.
View prior cases for the patient	If you see a "Prior Case" link at the bottom of the Slide Tray, you can click the link to view digital slides for the referenced case. The Prior Case link only appears if the active case and associated prior cases were created using the Aperio eSlide Manager Network case workflows. See View prior cases for the same patient (on page 64).

Viewer Window

The Viewer window is where you view and annotate digital slides.



Thumbnail and heat map

The Thumbnail enables you to navigate in the main Viewer window using a small version of the entire digital slide. You can resize the thumbnail by dragging the bottom-left corner. If you do not see the Thumbnail, click 🏚 in the main toolbar, and ensure Thumbnail is selected in the Visibility box.

The navigation box within the Thumbnail shows you where you are in the digital slide. The size of the box varies depending on the current zoom level.



Using the Thumbnail, you can:

- See where you are in the digital slide.
- Click an area in the Thumbnail to move to the corresponding area in the digital slide.
- Drag the small Thumbnail navigation box around to navigate the digital slide.

If enabled, the heat map appears in the thumbnail window, and highlights the areas of the digital slide you have viewed and the magnification level used.



To use the heat map:

- 1 To enable the heat map, click the Settings button 🔹 on the Viewer's toolbar, and select the **Heat Map** check box.
- 2 As you navigate through different areas of the slide, the heat map highlights the viewed area. The color of the heat map corresponds to the color on the zoom control that represents the current zoom level.
- 3 To clear the heat map, click the Settings button 🏚 on the Viewer's toolbar, and click Clear.

View multiple images

From the Slide Tray, you can open up to four images in the Viewer window at a time. Follow these steps to open and view multiple images in the Aperio WebViewer DX window:

1 Click the circle next to each digital slide to select the images to open. Selected images appear with a push pin inside the circle, as shown below.



2 The selected images appear in the Viewer window.



The newly opened digital slides are "pinned" in the Viewer window.



When you have multiple digital slides open in the Viewer window, the tools selected in the Visibility box are available for the selected digital slide. If the tools do not appear as expected in the selected digital slide image, you might need to click inside the image.

See Aperio WebViewer DX options (on page 88) for details about setting Visibility options.

- 3 When multiple digital slide images are open, you can do the following:
 - Use the Synchronize tool ****** to pan and zoom multiple digital slides at the same time. (See the next section.)
 - Click **II** to change how the images appear in the Viewer window. For example, the images can appear horizontally, vertically, or in a tiled pattern.
 - Select a pinned image, and use any of the available navigation or annotation tools on that image.
 - View a different primary digital slide image by selecting a different digital slide from the tray, keeping the pinned images in place.

Synchronize navigation of multiple slides

The Synchronize tool enables you to pan, zoom, and rotate all open digital slides together. For example, if you rotate the active digital slide, the other open digital slides rotate too. This is useful for reviewing the same region of interest on multiple slides that are stained differently.

To view multiple digital slides using synchronized navigation:

- 1 Open the digital slides you want to view. You can open up to four images at one time.
- 2 Manually align the open digital slides so that they are at the same zoom level and show the same viewable area.
- 3 Go to the Aperio WebViewer DX toolbar, and click the Synchronization tool 🚏 .
- 4 In the active digital slide, pan, zoom, and rotate to view the digital slide. All open digital slides follow the same navigation.
- 5 To stop synchronized navigation, click 🚏 .

View prior cases for the same patient

If more than one case using the same MRN number was created in the Aperio eSlide Manager Network case workflows, you can view the linked cases together in the viewer. (The cases do not need to be assigned to the same pathologist in order to be linked.) This enables you to compare a current case with past linked cases to provide needed context. When linked cases exist, the Slide Tray includes a "prior case" link.

1 To view slides for the prior case, click the Prior Case link at the bottom of the Slide Tray.



The prior case expands into the Slide Tray, as indicated by the Prior Case information bar near the top of the Slide Tray.



- 2 View the prior case slides as needed.
- 3 To return to the original case opened, click the case bar at the top of the Slide Tray.

For information about using the Aperio eSlide Manager Network case workflows, see the Aperio eSlide Manager User's Guide.

6 Image enhancements and annotations

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Image enhancements

The Image Enhancements feature enables you to adjust the brightness, contrast, and gamma levels on your digital slides. The enhancements are for viewing purposes only and do not change the original scanned image.



WARNING: Do not use the Image Enhancement tools to correct a suboptimal scanned image for diagnostic review. In this case, you should request a re-scan of the slide.

Image Enhancements include:

- Gamma allows contrast adjustment to vary as a function of brightness. If the image appears too light and
 washed-out, reduce gamma and the image will become darker with more contrast. If the image appears too dark,
 increase gamma and the image will become lighter with less contrast.
- Brightness use to make the overall image brighter or darker.
- Contrast use to adjust the bright and dark areas of an image in relation to each other.

After making adjustments, you can save them as a preset to use in future viewing sessions. You can also specify which (if any) image enhancements you wish to use during each viewing session.



Image Enhancements are not saved with your digital slide image or case. They are applied for your active viewing session only. To ensure you can use the same image enhancement settings in a future viewing session, you should save them as a preset, as described in Image Enhancement Presets (on page 70). This way, you can reapply them as needed. If you want to start every viewing session with a particular image enhancement setting, you can save a default preset, as described in Set Image Enhancement preferences (on page 74).

Adjust the Brightness, Contrast, and Gamma

1 Click **O** on the main toolbar to open the Image Enhancements tool box:

Image Enhancements 🛛 🗙
Brightness (100)
Contrast (100)
Gamma (1)
Reset Presets -

- 2 Click and drag the **Gamma** slider to left to increase the gamma levels, or right to decrease the gamma levels.
- 3 Click and drag the **Contrast** slider left for less contrast, and right for greater contrast.
- 4 Click and drag the **Brightness** slider left to make the image darker, and right to make the image brighter.



You can use the Up Arrow and Down Arrow keyboard keys to fine-tune the adjustments in increments of 0.01 for Gamma, and 0.1 for Brightness and Contrast.

When you adjust one of the Image Enhancements sliders, the Image Enhancement notification icon appears in the upper-left of the viewer window. This is to inform you that the digital slide has an image enhancement applied.



To save your adjustments for future use, create a preset as described in Image Enhancement Presets (on page 70). To remove the image enhancements, click **Reset**.

Reset an Image Enhancement

To reset the brightness, contrast, and gamma to their original levels after applying an image enhancement:

• Click Reset in the Image Enhancements tool box.

The image enhancements are removed from the digital slide, and the Image Enhancement notification icon no longer appears in the viewer window.

Image Enhancement Presets

If you use the same Image Enhancement settings often, you can save them as a preset.

For example, you may find that a certain combination of brightness, contrast, and gamma settings work well for a particular stain type. Image enhancement presets enable you to apply a particular set of image enhancements without adjusting the settings each time.

Before you use the same image enhancement preset on a group of slides, ensure the image enhancement enables accurate evaluation of the slides, as described in Image Enhancement Preset validation workflow (on page 74).



WARNING: Misapplied image enhancements can lead to an incorrect interpretation of the digital slide image. Before using an image enhancement preset for a diagnostic review, the pathologist must first validate the accuracy of the preset (gamma, brightness, and contrast settings) on a representative group of digital slides. For more information on validating a group of slides, see Image Enhancement Preset validation workflow (on page 74).

- 1 Use the Image Enhancement toolbox to make the desired adjustments to Gamma, Brightness, and Contrast.
- 2 Click Presets, and then click Save as preset.



3 Type a name for the new preset.



- 4 Click Save as preset to finish.
- 5 To close the Image Enhancements Toolbox, click \times .



After you save an Image Enhancement preset, the Image Enhancement tool on the main toolbar appears with a small triangle \mathbf{Q} . This is to let you know Image Enhancement presets are available.

Apply a Preset

To apply a preset to the active digital slide:

1 Hover your mouse over the Image Enhancements tool $oldsymbol{Q}$.





The small triangle in the lower-right of the tool indicates that presets are available. If the triangle does not appear, this means you have not defined any presets yet.

2 Select the preset you want to apply.

The image is adjusted according to the preset you selected, and a green check mark appears next to the applied preset.





You can also apply a preset from the Image Enhancement toolbox. Click **Presets**, and then select the preset you want to apply.
View the applied Image Enhancement Preset

The viewer shows you which preset is applied in the following ways:

- Hover-over the Image Enhancement tool. The applied preset has a green check mark next to it:
- Hover-over the Image Enhancement Notification icon in the upper-left of the viewer window:
- Click Presets from the Image Enhancement toolbox:







Image Enhancement Preset validation workflow

Before applying an image enhancement preset for the purpose of performing a diagnostic review on multiple slides, ensure the applied preset enables accurate diagnosis on the type of slides you are reviewing. The following workflow diagram describes the process of validating a preset for use on a particular slide type.



Set Image Enhancement preferences

If you have defined Image Enhancement presets, you have the option of starting each viewing session with a specified preset. Automatically applied presets affect unread slides only. During your viewing session, the system doesn't overwrite an image enhancement adjustment or a preset you have already applied to a slide.



To use the Image Enhancement Preset Preferences, ensure **Image Enhancements** is selected in the Visibility window. For details on using the Visibility window, see Aperio WebViewer DX options (on page 88).

To set Image Enhancement preferences:

1 Click $\mathbf{O}_{\mathbf{A}}$ on the toolbar to open the Image Enhancements tool box.

Image Enhancements 🛛 🗙
Brightness (100)
Contrast (100)
Gamma (1)
≧ œ Reset Presets ▼

2 Click 🏖 to open the Preferences tab in the Options window.



- 3 Select one of the following:
 - Never Automatically Apply a Preset this is the default setting. Select if you do not want the system to automatically apply presets.
 - Apply My Last Used Preset to Unread Slides select if you want the system to automatically apply the last preset you used to all unread slides.

Example: Suppose you create a preset called "Preset 1," and apply that preset to the current active slide. The system then applies "Preset 1" to the remaining unread slides in your tray. If you then open a new case, the system remembers your setting, and applies "Preset 1" to all slides in your tray. If you then apply "Preset 2" to a slide, the system then remembers "Preset 2," and applies it to all remaining unread slides in your tray.

If you manually adjust the Image Enhancement values on a slide without using a preset, the system does not carry that value over to other slides.

• Apply the Following Preset to Unread Slides – select if you want the system to automatically apply the preset you select from the drop-down list. This option allows you to set a "default" preset to apply to all unread slides in your tray.

Example: If you frequently start your viewing sessions with "Preset 3," you may wish to set "Preset 3" as your default preset. The system then always applies "Preset 3" to all unread slides in your tray. If you change the Image Enhancements settings or apply a different preset to a slide, only that slide is affected. All remaining unread slides in your tray still use the default preset you specify.

Annotations

Use annotations to mark or measure areas of interest on the digital slide image. The navigation tools enable you to easily move from one marked area of interest to another.

Open the Annotation Window

1 Click the Annotations tool 💉 on the Aperio WebViewer DX toolbar:



2 Select an annotation tool, and then click on the digital slide image to place or draw the annotation. Annotations are saved automatically.

Quick menu for annotations

After you add an annotation, you can right-click the annotation to access the quick menu. From here, you can delete, copy, edit, and move the annotation. You can also change the color of annotations.



Add annotations

This section provides instructions for using the different types of annotations to outline and identify regions of interest.

Rectangle and ellipse

- 1 From the Annotations window, click the Rectangle 🔲 or Ellipse 🔘 tool.
- 2 In the digital slide image, click and drag to outline the region of interest with a rectangle or ellipse.



3 Release the mouse button to complete the annotation.

Freeform

- 1 From the Annotations window, click the Freeform 🥓 tool.
- 2 In the digital slide image, click and drag to highlight a region of interest using a freeform annotation.



3 Release the mouse button to complete the annotation.

Polygon

- 1 From the Annotations window, click the Polygon \bigcirc tool.
- 2 In the digital slide image, click to set each point, and then double-click to close the polygon.



Arrow

- 1 From the Annotations window, click the Arrow \checkmark tool.
- 2 In the digital slide image, click where you want the arrowhead to appear, and drag to extend the arrow to the desired angle and length.



3 Release the mouse button to complete the annotation.

Pin Drops

Use the Pin Drop tool to mark multiple regions of interest on one or more slides. You can then use the Pin Drop Navigator to quickly navigate from one pin drop to the next. For more details, see Use pin drops to navigate around case slides (on page 81).

To add pin drops to your digital slide image:

- 1 From the Annotations window, click the Pin Drop 🌪 tool.
- Click anywhere in the digital slide image to set the pin drop. When adding multiple pin drops, you need to click the
 each time.



Add a text annotation

- 1 From the Annotations window, click the Text A_A tool.
- 2 In the digital slide image, click where you want to add a note.

3 When the text box appears, type your note, and click **OK**.

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4 The note appears in the specific location.



Add a linear measurement

The linear measurement tool enables you to set two or more points to measure a region of interest. The unit of measure is set by your administrator in Aperio eSlide Manager. For more details, see the *Aperio eSlide Manager User's Guide*. Follow the steps below to measure a region of interest. Ensure you are using the measurement tool correctly to avoid missing critical information.

- 1 From the Annotations window, click the Measurement 🎢 tool.
- 2 In the digital slide image, click to set each measurement point, and then double-click to end the measurement.



Define the report region

Use the Report Annotation to create the image that appears in Aperio eSlide Manager reports. You can create one report image per report. The Aperio eSlide Manager report template you are using determines whether images are included in reports.

Depending on your settings, you either draw a rectangle for the report annotation or click to add a fixed-size rectangle. For information on the report region settings, see Aperio WebViewer DX options (on page 88).

To create the report region:

- 1 From the Annotations window, click the Report 📃 tool.
- 2 Do one of the following to add the report region:
 - Click in the region of interest to add a fixed-size rectangle around the report region.
 - Click and drag to outline the report region with a rectangle.
- 3 The report region appears in a different annotation style:



Use pin drops to navigate around case slides

After you mark your digital slides with pin drops, you can navigate from pin to pin on one or more digital slides in your tray when you are reviewing a case.

1 Click the pin drop navigation icon 🐢 on the toolbar to access the Pindrop Navigator.



- 2 From the Pindrop Navigator, you can:
 - Click \checkmark or \bigcirc to move between the pin drops on this or other digital slides in the slide tray.
 - Click (or) to move to the first or last pin drop.
 - Click a number to go to a specific pin drop.

Edit freeform annotations

Follow these steps to redraw a freeform annotation.

- 1 On the digital slide image, select the annotation you want to redraw.
- 2 Right-click the annotation to display the annotation toolbar.



- 3 Select the Redraw tool 🥒 .
- 4 Click and hold the left mouse button, and drag the pointer in the direction you want to redraw the annotation.
- 5 Release the mouse button when you are finished drawing.
- 6 When asked to save, click **Yes** to save the revised annotation. If you want to return to the original annotation, click **No**.

Delete an annotation

1 Right-click on the annotation to select the annotation and display the quick menu.



2 Click the **Delete** tool to delete the annotation.

Copy an annotation

- 1 Right-click on the annotation to select the annotation and display the quick menu.
- 2 Click the **Copy** tool.



A copy of the annotation appears with your pointer.



3 Position the pointer where you want to copy the annotation, and then right-click to place the annotation.



Move an annotation

- 1 Right-click on the annotation to select the annotation and display the quick menu.
- 2 Click the Move tool.



The annotation appears with your pointer.



3 Position the pointer where you want to move the annotation, and then right-click to place the annotation.

Take a snapshot of the digital slide

The Snapshot feature enables you to capture an image of the digital slide. The snapshot image (JPEG file) is saved to the Downloads folder on your local computer. The viewer's tools (zoom slider, rotation dial, image enhancements, etc.) are not included in the snapshot image.



WARNING: The snapshot image (JPEG file) is not for use in diagnostic procedures.

Take a snapshot using the active capture mode

To take a snapshot using the last capture mode you selected, click the **Snapshot** tool on the Aperio WebViewer DX toolbar.

Snapshot capture modes

The following capture modes are available:

- Full View captures an image of the digital slide as it currently appears in the Viewer window.
- Fixed Sized captures an image of the selected area, at the size you specify. This setting is useful for reports or presentations that require a specific size for images.
- User Drawn captures an image that contains only the area you select.

To select a new capture mode and take a snapshot:

1 Point to the **Snapshot** tool on the Aperio WebViewer DX toolbar. The Snapshot Settings tool 🔹 appears to the right of the Snapshot tool.



2 Click the Snapshot Settings tool 🔹 to open the Snapshot Settings.

Snapshot Settings ×				
Capture Mode:	User Drawn	▼		
		Capture		
Description: Captures an area th	nat you select.			

3 From the Capture Mode list, select one of the three capture modes described in the next sections.

Full View

Select Full View from the Capture Mode list, and click Capture.

Fixed Size

- 1 Select Fixed Sized from the Capture Mode list.
- 2 Set the Width and Height (in pixels) for your snapshot image.
- 3 Click Capture.
- 4 When the rectangle appears, drag it to the area you want to capture and then click to take the snapshot.



User Drawn

- 1 Select User Drawn from the Capture Mode list.
- 2 Click Capture.
- 3 When the cross-hairs appear, drag the mouse pointer to select your area and then release the mouse button to take the snapshot.





To take more snapshots using the same mode and settings, you do not need to open the Snapshot Settings again. Just click the Snapshot tool 🏟 on the Aperio WebViewer DX toolbar.

Settings and options

In this section:

Aperio WebViewer DX options	
Global settings	

Aperio WebViewer DX options

You can select which features to display in the Aperio WebViewer DX window. You can also view information and change other options.

Follow these steps to view or change Aperio WebViewer DX settings.

1 Click the **Settings** button 🔹 on the Aperio WebViewer DX toolbar.



2 From the Visibility box, select or clear the check boxes to set the visibility of the different Aperio WebViewer DX tools.

- 3 To view or change other Aperio WebViewer DX options, click the **Options** button to open the Options window.
- 4 The following table describes the tabs available from the Options window.

Options tab	Description
Keyboard Shortcuts	Provides a list of keyboard shortcuts that you can use in the Aperio WebViewer DX. See also Keyboard shortcuts (on page 53).
Preferences	Enables you to set the following preferences:
	• Label rotation – Sets the default rotation of the digital slide label. With the label rotated as desired, click the Use Current button. This setting applies to your login only.
	• Thumbnail Enlarge on Hover – When selected, you can hover your mouse pointer over the thumbnail window to enlarge it.
	• Automatically Apply Image Enhancement Presets – If you have defined Image Enhancement presets, you have the option of starting each viewing session with a specified preset. You must have Image Enhancements selected in the Visibility window to use these settings.
	Clicking Default resets the default preferences.
Report	For the report image, specifies:
	• If it is a fixed size or if it can be drawn to any size.
	• If the image uses the maximum resolution (magnification) of the digital slide or its current resolution in the Viewer window.
	You can click the Default button to return to the default report settings.
Image	Provides details on the digital slide image, including dimensions, resolution, and compression type.
About	Provides release information for the Aperio WebViewer DX.

Global settings

Your site administrator sets the global settings for Aperio eSlide Manager and Aperio WebViewer DX. These settings apply to all users in your site. For any questions on these global setting configurations, consult your site administrator. For more information on how to configure these settings, see the *Aperio eSlide Manager User's Guide*.

Slide Tray sorting

When viewing a case in Aperio WebViewer DX, the Slide Tray groups the slides by specimen. The WebViewer Sort Order global setting in the Aperio eSlide Manager System Settings enables your administrator to further define the sort order of the slides within each specimen group, including multi-level sort order.

Unit of measure

The WebViewer Length Unit setting in the Aperio eSlide Manager System Settings determines whether Aperio WebViewer DX uses microns or millimeters when displaying measurements. The default value is Microns.

8 Maintenance and troubleshooting

In this section:

Maintenance	92
Froubleshooting	98

Maintenance

This section provides maintenance and troubleshooting information.

Product information

To view product information, including the Unique Device Identifier (UDI), service contact information, and Quality Check status:

1 Click the Leica Biosystems logo that appears in the upper-right corner of the viewer.



2 The Product Information pane appears, which includes the Unique Device Identifier (UDI), service contact information, monitor display image validation (Quality Check) status, as well as a Check Image Quality button for initiating a manual monitor display image validation.

Product Information					
Product Name	Aperio WebViewer DX				
REF	23WVUSIVD				
UDI	0815477020358(8012) 1.0				
Updated	2/14/22, 4:23:56 PM				
Quality Check	Passed 2/16/2022				
	Check Image Quality				
Customer Support					
North America +1 844 534 2262 techservices@leicabiosystems.com					
International Contact us online					
Leica Biosystems Imaging, Inc. 1360 Park Center Drive Vista, CA 92081 USA					
IVD RxOnly					

3 To close the Product Information pane, click the Leica Biosystems logo again.

Automatic and manual monitor display image validation checks

To ensure your digital slide images are displayed on your monitor as intended and that browser updates have not inadvertently affected the image display quality, Aperio WebViewer DX incorporates monitor quality checks.

Automatic monitor display image validation checks

The system performs this quality check the first time you open the viewer and anytime your browser is updated. The check happens automatically. If the test fails, a message displays to alert you. You should then perform the manual validation, as described in the next section.

Manual monitor display image validation checks

After the system performs the automatic image quality check described previously, it prompts you to perform a manual monitor display image validation check by visually evaluating test images. You should perform the manual validation once per month, and any time you suspect an issue with the quality of the image display.

Follow these steps to manually validate the test image:

- 1 There are two ways to start the monitor display image validation:
 - If you are performing the monthly monitor display image validation, continue with <u>step 2</u>.
 - If the monitor display image validation appears automatically when you open the viewer, continue with <u>step 4</u>.
- 2 To open the monitor display image validation, click the Leica Biosystems logo in the upper right corner.
- 3 From the Product Information pane, click Check Image Quality.

Product Name	Aperio WebViewer DX
REF	23WVUSIVD
UDI	0815477020358(8012) 1.0
Updated	2/14/22, 4:23:56 PM
Quality Check	Passed 2/16/2022
	Check Image Quality

4 The test image and validation instructions appear:



Instructions and example image

Test images

5 Follow the on-screen instructions that appear on the left to validate the test image on the right. If the image passes your evaluation, click **Yes** to proceed to the next validation check.

The following table describes the four validations:

Image Validation Check 1:

Use the example image in the left pane of the viewer to validate the test image in the right pane of the viewer.

For the areas outlined in blue in the example, verify the following:

- Changes in intensity are smooth and uniform over the entire range from bright to dark.
- There are no noticeable bands of constant intensity (solid white, gray, or black) inside or near the edges of the bars.



Image Validation Check 2:

Use the example image in the left pane of the viewer to validate the test image in the right pane of the viewer.

Following the direction of yellow arrows shown in the example (from white to black), the change in intensity from one square patch to the next increases by the same relative amount.



Image Validation Check 3:

Use the example image in the left pane of the viewer to validate the test image in the right pane of the viewer.

For the areas outlined in green in the example, verify the following:

- The small 95% grayscale square patch inside the black square is clearly visible at normal viewing distance (30 - 60 cm).
- The small 5% grayscale square patch inside the white square is clearly visible at normal viewing distance (30 - 60 cm).



Image Validation Check 4:

Looking at the image in the right pane of the viewer, verify colors are present.



- 6 When you have answered Yes to every question, your specified case appears in the viewer. You can continue with your typical case review workflow.
- 7 If you answered No during the image check, see Monitor display image validation failure (on page 98).

Troubleshooting

This section provides troubleshooting information for viewing digital slides.



CAUTION: When viewing digital slides:

- Do not use the Image Enhancement tools to correct a suboptimal scanned image for diagnostic review. In this case, you should request a re-scan of the slide.
- Your monitor must meet the specifications detailed in the *Aperio WebViewer DX IT Administrator's Guide*.
- Your monitor's Display Mode must be set to sRGB.
- Your viewing workstation must use the supported browser and operating system, as described in Supported Operating System and Browsers on page 1.
- Tablets and mobile devices are not supported.

Monitor display image validation failure

As described in Automatic and manual monitor display image validation checks (on page 93), the web-based viewer incorporates automatic and manual monitor display image validation checks. If the automatic or manual check fails, the system alerts you in the following ways:

- The 🔝 icon appears in the upper-left corner of the Viewer window to indicate a potential issue with how your images appear on the monitor.
- The Quality Check status in the Product Information pane indicates the test failed:

Product Name	Aperio WebViewer DX
REF	23WVUSIVD
UDI	0815477020358(8012) 1.0
Updated	2/14/22, 4:23:56 PM
Quality Check	Failed 2/16/2022
	Check Image Quality

If your monitor display image validation check fails:

- 1 Click the 🔛 icon to perform the manual image quality check again.
- 2 If you answer No to any of the questions and the validation fails again, contact your site administrator to revert your browser to the last verified version.

Unsupported zoom level notification

The **A** icon appears to inform you that the viewer is not displaying the digital slide with optimal image quality. This happens when your viewing settings are not set to a multiple of 100% or you are using an unsupported operating system.

If the 🛕 icon appears:

- 1 Ensure your viewing settings are correct:
 - Browser ensure the zoom level is set to a multiple of 100% (100%, 200%, etc.).
 - Operating system ensure the Display settings "scale" value is a multiple of 100% (100%, 200%, etc.).
- 2 Ensure your viewing workstation is using the correct operating system. See the *Aperio WebViewer DX IT Administrator's Guide* for specifications and requirements.

Digital scan quality

If your digital slides require re-scanning, ensure your lab uses the best practices for slide preparation. It is the responsibility of the lab to verify the quality of the tissue preparation, the physical characteristics of the slide, and the staining quality. For more information on slide preparation techniques, refer to the user guide for your scanner.

Slide tray (DST) error

If you attempt to open a case with a large number of slides, the viewer may time out. If the viewer displays the message, "Error getting DST: error Internal Server Error," this means the viewer is unable to open the slide tray. If this happens, try reducing the number of slides you are attempting to open. If you continue receiving this error, contact Leica Biosystems Technical Services.

Missing image metadata error

In rare cases, you can encounter an image that is missing the MPP (microns per pixel) data. If this happens, the viewer alerts you by displaying the message, "Image metadata is missing. Measurements displayed in the application may be inaccurate." If you encounter this message, be aware that any annotation measurements that appear on the image may not be accurate.

Slowed performance when viewing slides

Depending on the quality of your organization's network, you may experience slowed performance when viewing slides from a location that is geographically distant from the server that is hosting Aperio WebViewer DX. In this situation, slides may load into the viewer more slowly, and panning and zooming may take more time than the typical experience. If you continue to experience this issue, consult your IT network team to identify the root cause and resolve the issue. If the issue persists and you need assistance, call Leica Biosystems Technical Services.

Slides have stopped loading, and the image is pixelated or out of focus when panning and zooming

On rare occasions you may encounter a situation when using Aperio WebViewer DX where images stop loading in the viewer, and the opened image remains out of focus or pixelated when you pan or zoom. When attempting to open additional slides in the tray, you may encounter a blank image and receive the following message, "Error loading data from the ImageServer, please try again". This indicates there is a significant issue with the network connectivity between your computer and the server hosting Aperio WebViewer DX. If you encounter this situation, stop using Aperio WebViewer DX and work with your IT team to resolve the network connectivity issue. When the issue is resolved, you can reconnect to Aperio WebViewer DX and resume viewing slides.

A Performance characteristics

This section discusses the clinical studies performed using the Aperio WebViewer DX:

Precision	
Accuracy	

Precision

Three studies were conducted to assess precision: Intra-System Study (within systems), Inter-System/Site (between systems), and Intra- and Inter-Pathologist Study (within and between pathologists). The assessments were based on the pathologists' identification (ie, reading) of select histological features (eg, chondrocytes, fat cells) observed in images created from the scanning of the precision panel. The panel was composed of 69 FFPE hematoxylin and eosin (H&E) stained tissue slides. The 69 slides included 23 unique histological features (12 features scanned at 20x magnification and 11 scanned at 40x magnification). Each feature was represented in 3 different specimen sources/organ types (23 unique features, each feature in 3 different specimen sources = 69 slides). Each slide contained at least 2 field of views (FOVs) (with most slides having 3 FOVs), each of which contained at least 1 histological feature. An additional 12 slides, presented as wild card slides, were scanned and reviewed with precision tissue panel FOVs to minimize recall bias and were excluded from the agreement analyses. The 3 studies were conducted using the same set of 69 slides across sites, systems, and pathologists. The FOVs generated from multiple scans of the same feature were rotated to different orientations. There was a washout period of more than 14 days between pathologist reading sessions. Precision was assessed for each study separately by analyzing agreement within systems, between systems/sites, and within and between pathologists. Overall agreements within systems, between systems/sites, and within and between pathologists were also estimated.

Intra-System Study

In this study, 3 systems housed at 3 different sites (1 system per site) were evaluated. The set of 69 slides was divided equally and randomly between the 3 systems/sites (23 slides per system). For each system/site, the 23 slides were scanned once on each of 3 scanning sessions, producing 3 sets of scans for each slide.

The FOVs were reviewed by a single pathologist over 3 reading sessions (FOVs from a single scanning session [combining systems] per reading session). The number of study histological features across systems was unequal because the number of FOVs and the number of histological features that could be extracted from each slide was not necessarily the same across the 69 slides (261, 276, and 222 histological features on system 1, 2, and 3, respectively). Overall systems/sites and scanning sessions, 759 histological features were evaluated.

For each system/site, agreements between scan 1 versus scan 2, scan 1 versus scan 3, and scan 2 versus scan 3 were analyzed (see Table A-1: Intra-System Precision Study: Agreement Within Systems). The overall intra-system precision was based on the pooled data of all 3 systems.

			Agreement Rate and 95% CI*		
System	Number of Pairwise Agreements	Number of Comparison Pairs	% Agreement	Lower	Upper
System 1	255	261	97.7	95.7%	99.3%
System 2	270	276	97.8	95.9%	99.3%
System 3	212	222	95.5	92.5%	98.1%
Overall	737	759	97.1	95.8%	98.3%

Table A-1: Intra-System Precision Study: Agreement Within Systems

Note:

1.95% CI was produced using the percentile bootstrapping approach on 5000 bootstrap samples.

2. System 1 is at Site 1, System 2 is at Site 2, and System 3 is at Site 3

Inter-System/Site Study

In this study, 3 systems housed at 3 different sites (1 system per site) were evaluated. The set of 69 study slides were scanned once on each system, producing 3 sets of scans for each slide. The FOVs were reviewed by a single pathologist over 3 reading sessions (FOVs from a single site per reading session).

Overall systems, 759 study features were evaluated. Agreements between system 1 versus system 2, system 1 versus system 3, and system 2 versus system 3 were analyzed (see Table A-2 Inter-System/Site Precision Study: Agreement Between Systems). The overall inter-system/site precision was based on the pooled data of all 3 systems.

Table A-2: Inter-System/Site Precision Study: Agreement Between Systems

			Agreement Rate and 95% CI		
System	Number of Pairwise Agreements	Number of Comparison Pairs	% Agreement	Lower	Upper
System 1 vs System 2	241	253	95.3	92.5%	97.7%
System 1 vs System 3	246	253	97.2	95.0%	99.2%
System 2 vs System 3	244	253	96.4	94.0%	98.5%
Overall	731	759	96.3	94.9%	97.6%
Note:					

1.95% CI was produced using the percentile bootstrapping approach on 5000 bootstrap samples.

			Agreement Rate and 95% CI						
System	Number of Pairwise Agreements	Number of Comparison Pairs	% Agreement	Lower	Upper				
2. System 1 is at Site 1, System 2 is at Site 2, and System 3 is at Site 3									

Table A-2: Inter-System/Site Precision Study: Agreement Between Systems (continued...)

Intra- and Inter-Pathologist Study

In this study, 1 system at 1 site was used to scan the set of 69 slides once. FOVs were extracted and each FOV was saved in 3 different orientations. All FOVs in all orientations were reviewed by 3 pathologists.

For the intra-pathologist evaluation, agreements between orientation 1 versus orientation 2, orientation 1 versus orientation 3, and orientation 2 versus orientation 3 were analyzed for each pathologist (see Table A-3 Intra- and Inter-Pathologist Precision Study: Agreement Within Pathologists). The overall intra-pathologist precision was based on the pooled data from each pathologist.

			Agreement Rate and 95% CI				
Pathologist	Number of Pairwise Agreements	Number of Comparison Pairs	% Agreement	Lower	Upper		
Pathologist 1	729	759	96.0	94.7%	97.3%		
Pathologist 2 677		759	89.2	86.8%	91.3%		
Pathologist 3	723	759	95.3	93.7%	96.7%		
Overall	2129	2277	93.5	92.4%	94.5%		
Note:							

1. 95% CI was produced using the percentile bootstrapping approach on 5000 bootstrap samples.

For the inter-pathologist evaluation, agreements between pathologist 1 versus pathologist 2, pathologist 1 versus pathologist 3, and pathologist 2 versus pathologist 3 were analyzed (see Table A-4 Intra- and Inter-Pathologist Precision Study: Agreement Between Pathologists). The overall inter-pathologist precision was based on the pooled data from each pathologist to pathologist comparison.

			Agreement Rate and 95% CI							
Pathologist	Number of Pairwise Agreements	Number of Comparison Pairs	% Agreement	Lower	Upper					
Pathologist 1 vs Pathologist 2	686	759	90.4	88.2%	92.4%					
Pathologist 1 vs Pathologist 3	727	759	95.8	94.3%	97.2%					
Pathologist 2 vs Pathologist 3	676	759	89.1	86.9%	91.2%					
Overall	2089	2277	91.7	90.6%	92.8%					
Note:										
1. 95% CI was produced using the percentile bootstrapping approach on 5000 bootstrap samples.										

Table A-4: Intra- and Inter-Pathologist Precision Study: Agreement Between Pathologists

Accuracy

A noninterventional multicenter study was conducted to demonstrate that using the Aperio GT 450 DX to view, review, and diagnose digital images of surgical pathology formalin-fixed paraffin-embedded (FFPE) tissue slides is noninferior to using optical (light) microscopy. The primary endpoint was the difference in major discrepancy (discordance) rates between whole slide image review (WSIR) and light microscope slide review (MSR) diagnosis modalities when each modality was compared to the original sign-out pathologic diagnosis (also known as reference diagnosis). The secondary endpoint was the difference between the major discrepancy rates between WSIR diagnosis and MSR diagnosis when compared to the reference diagnosis for local and remote WSI access, respectively.

Across 3 sites, 1152 cases were evaluated. Enrolled cases were selected from the previous Aperio AT2 DX System Accuracy Study (510(k) no: K190332) and included a diverse mixture of pathologic diagnoses and tissue/organ types. At each site, technicians scanned slides from cases identified at their site using the Aperio GT 450 DX. Each reading pathologist at each site (3 or 4 pathologists per site) evaluated all study cases from their site using the Aperio GT 450 DX, as well as the case ancillary information to determine WSIR diagnosis. For each reading pathologist, approximately 50% of cases were reviewed from the site's local server (local access) and approximately 50% of cases were reviewed from the LBS image web hosting site (remote access). If the WSIR diagnosis could not be determined, the reading pathologist could defer the diagnosis.

At least 2 adjudication pathologists (also known as adjudicators) independently assessed concordance (concordant, minor discrepancy, major discrepancy) of the WSIR diagnosis against the reference diagnosis using predefined rules. A major discrepancy was defined as a difference in diagnosis that resulted in a clinically important difference in patient management, while a minor discrepancy would not be associated with a clinically important difference in patient management.

The 2 adjudicators' concordance scores for the same case were compared to determine a consensus score for major discrepancy status (no major discrepancy or major discrepancy). If consensus was not reached between the first 2 adjudicators, a third adjudicator reviewed the study diagnosis against the reference diagnosis. If consensus between 2 of 3 adjudicators was still not reached, then the 3 adjudicators convened as a panel to come to a consensus for the major discrepancy status. WSIR diagnosis consensus scores were used to estimate WSIR diagnosis major discrepancy rate. **Note:** if concordance could not be determined for a case, the adjudication pathologists could defer concordance assessment.

Major discrepancy rates were estimated for WSIR diagnosis and MSR diagnosis when each modality was compared to the reference diagnosis. To demonstrate the WSIR diagnosis modality was noninferior to the MSR diagnosis modality, the difference in overall major discrepancy rates between the 2 modalities was calculated. Additionally, the difference in the major discrepancy rates between the 2 modalities for local and remote WSI access (local and remote cohorts, respectively) was calculated. A generalized linear model was used to derive the estimates of the major discrepancy rates and the difference, along with their 95% CIs.

There were 1152 cases evaluated by 3 or 4 pathologists; 572 cases were locally accessed, and 589 cases were remotely accessed. Combining sites, pathologists, and local and remote accessed WSIs, 3549 WSIR and 3631 MSR diagnoses were established, had consensus scores, and were included in the statistical analysis. Deferred diagnoses were treated as missing data and excluded from the data analysis.

Table A-5 Overall Major Discrepancy Rates for the 2 Modalities and the Difference Between the Overall Major Discrepancy Rates for the Full Cohort shows the overall major discrepancy rates for both modalities for the full cohort (local and remote cohorts combined) based on observed results and by the generalized linear model. The estimated difference in major discrepancy rates (WSIR diagnosis minus MSR diagnosis) was 2.40%. The upper bound of the 95% CI of the estimated difference in major discrepancy rates was 3.39% which was less than the predefined acceptance criteria of \leq 4%. Thus, the primary endpoint was met.

Table A-6 Major Discrepancy Rates for the 2 Modalities and the Difference Between the Major Discrepancy Rates for Local and Remote Cohorts shows the overall major discrepancy rates for both modalities for the local and remote cohorts, respectively, based on observed results and by the generalized linear model. For local WSI access, the estimated difference in major discrepancy rates was 2.61% (95% CI: 1.23% to 3.99%), and for remote WSI access was 2.17% (95% CI: 0.78% to 3.57%). The upper bound of the 95% CI of the estimated difference in major discrepancy rates was 3.99% and 3.57% for the local and remote cohorts, respectively which was less than the predefined acceptance criteria of \leq 4%. Thus, both secondary endpoints were met.

	Whole Slide Image Review Diagnosis (WSIRD)			Light Microscope Slide Review Diagnosis (MSRD)				Difference in Major Discrepancy Rates (WSIRD minus MSRD)			
Cohort		Major Discrepancy	Total	Major Discrepancy Rate (%)	Model 95% Cl	Major Discrepancy	Total	Major Discrepancy Rate (%)	Model 95% Cl	%	Model 95% Cl
Full	Observed	218	3549	6.14%		133	3631	3.66%			
	Model			5.84%	(5.01%, 6.80%)			3.44%	(2.84%, 4.17%)	2.40%	(1.40%, 3.39%)
Note:											
Full mod	Full model includes both local and remote cohorts.										

Table A-5: Overall Major Discrepancy Rates for the 2 Modalities and the Difference Between the Overall Major Discrepancy Rates for the Full Cohort

Table A-6: Major Discrepancy Rates for the 2 Modalities and the Difference Between the Major Discrepancy Rates for Local and Remote Cohorts

		Whole Slic	le Image R	eview Diagnosi	is (WSIRD)	VSIRD) Light Microscope Slide Review Diagnosis (M				Difference in Major Discrepancy Rates (WSIRD minus MSRD)	
Cohort		Major Discrepancy	Total	Major Discrepancy Rate (%)	Model 95% Cl	Major Discrepancy	Total	Major Discrepancy Rate (%)	Model 95% Cl	%	Model 95% Cl
Local	Observed	119	1806	6.59%		71	1844	3.85%			
	Model			6.13%	(4.99%, 7.51%)			3.52%	(2.71%, 4.57%)	2.61%	(1.23%, 3.99%)
		Whole Slide Image Review Diagnosis (WSIRD)			Light Microscope Slide Review Diagnosis (MSRD)			Difference in Major Discrepancy Rates (WSIRD minus MSRD)			
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Cohort		Major Discrepancy	Total	Major Discrepancy Rate (%)	Model 95% Cl	Major Discrepancy	Total	Major Discrepancy Rate (%)	Model 95% Cl	%	Model 95% Cl
Remote	Observed	99	1743	5.68%		62	1787	3.47%			
	Model			5.51%	(4.40%, 6.88%)			3.34%	(2.52%, 4.40%)	2.17%	(0.78%, 3.57%)
Note: WSIRD: W	SIR diagnosis	, MSRD: MSR di	agnosis.								

Table A-6: Major Discrepancy Rates for the 2 Modalities and the Difference Between the Major Discrepancy Rates for Local and Remote Cohorts (continued...)

B Technical Performance Assessment summary

This section provides a summary of the Aperio WebViewer DX Technical Performance Assessment.

TPA Guidance	Test Description	Result
Image Review Manipulation	Panning and pre-fetching	Pass
Software	Zooming (magnification)	Pass
	Compare multiple images simultaneously	Pass
	Annotations	Pass
	Image enhancements	Pass
	Annotation tools	Pass
	Tracking of visited areas	Pass
	Digital bookmarks	Pass
	Virtual "multi-head microscope"	Pass

TPA Guidance	Test Description	Result
Display	User controls - Specified test settings (factory default)	Pass
	Spatial resolution	Pass
	Pixel defects	Pass
	Artifacts	Pass
	Temporal response	Pass
	Maximum luminance	Pass
	Minimum luminance	Pass
	Gamma value/gray scale display function (sRGB)	Pass
	Luminance uniformity	Pass
	Luminance stability	Pass
	Bidirectional Reflection Distribution Function (BDRF) and/or, Spectral/Diffuse Reflection Coefficients	Pass
	Gray tracking (chromaticity vs. luminance)	Pass
	Color scale (primary coordinates)	Pass
	Color gamut	Pass
	Mozilla Firefox (Version 88 or newer)	Pass
	Microsoft Edge (Version 90 or newer)	Pass
	Google Chrome (Version 90 or newer)	Pass
Color Reproducibility	Input color patches	Pass
	Ground Truth: CIELAB values. Measure using colorimeter	Pass
	Output digital image file	Pass
	Calculate color differences	Pass
	CIELAB values in digital images	Pass
	Output color stimuli	Pass
User Interface	User operation options	Pass
	Information presented to the user	Pass
	Human factors report	Pass
Labeling	Labeling sufficient to satisfy 21 CFR Part 801 and 21 CFR 809.10	Pass

TPA Guidance	Test Description	Result
Turnaround Time	Typical turnaround time including test method and test conditions	Pass
Quality Control	Frequency and test methods, responsibility and quantitative limits	Pass

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