

APERIO GT 450 DX

DIGITAL PATHOLOGY SLIDE SCANNER

USER'S GUIDE



Advancing Cancer Diagnostics
Improving Lives

Aperio GT 450 DX User's Guide

MAN-0505, Revision A | April 2024

This manual applies to Aperio GT 450 DX and Aperio GT 450 SAM DX Software version 1.2.


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- This product is protected by registered patents. For a list of patents, contact Leica Biosystems.

Customer Resources

- For the latest information on Leica Biosystems Aperio products and services, please visit [LeicaBiosystems.com/Aperio](https://www.leicabiosystems.com/Aperio).

Contact Information – Leica Biosystems Imaging, Inc.

Headquarters	Customer Support
 Leica Biosystems Imaging, Inc. 1360 Park Center Drive Vista, CA 92081 USA Tel: +1 (866) 478-4111 (toll free) Direct International Tel: +1 (760) 539-1100	Contact your local support representative with any query or service request. https://www.leicabiosystems.com/contact-us/

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R_x Only

UDI

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Notices

Revision Record

Rev.	Issued	Sections Affected	Detail
A	April 2024	All	New manual for Aperio GT 450 DX 1.2.

Cautions and Notes

- **Serious Incidents Reporting** – Any serious incident that has occurred in relation to the Aperio GT 450 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 device specifications and performance characteristics, see the document *Aperio GT 450 DX Specifications*.
- **Installation** – Aperio GT 450 DX must be installed by a trained Leica Biosystems Technical Services representative.
- **Repair** – Repairs may be done only by a trained Leica Biosystems Technical Services representative. After repairs are done, ask the Leica Biosystems technician to perform operation checks to determine the product is in good operating condition.
- **Accessories** – For information on using Aperio GT 450 DX with third-party accessories such as a Laboratory Information System (LIS) not provided by Leica Biosystems, contact your Leica Biosystems Technical Services representative.
- **Interoperability** – Aperio GT 450 DX can be configured to send data to the Sectra Digital Pathology Module Version 3.3. For more information, refer to Chapter 2 of *Aperio GT 450 DX IT Manager and Lab Administrator's Guide*. Note that Aperio GT 450 DX is not designed to control other devices.
- **Quality Control** – For information on image quality checks, see [Image quality control for histotechnicians and pathologists \(on page 50\)](#).
- **Maintenance and Troubleshooting** – For information on maintenance, see [Chapter 5: Maintenance](#). For information on troubleshooting problems, see [Chapter 6: Troubleshooting](#).
- **Cybersecurity** – Be aware that workstations are susceptible to malware, viruses, data corruption, and privacy breaches. Work with your IT administrators to protect workstations by following your institution's password and security policies.

To protect workstations and servers from malware intrusion, 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. For Aperio recommendations on protecting your workstations and servers, see the document *Aperio GT 450 DX IT Manager and Lab Administrator's Guide*.

If a suspected Aperio GT 450 DX cybersecurity vulnerability or incident is detected, contact Leica Biosystems Technical Services for assistance

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.

- **Training** – This manual is not a substitute for the detailed operator training provided by Leica Biosystems or for other advanced instruction.
- **Safety** – This device is intended for indoor use only. Safety protection may be impaired if this device is used in a manner not specified by the manufacturer.

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.














Table 1: Interoperable components of Aperio GT 450 DX

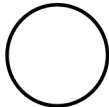



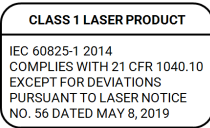
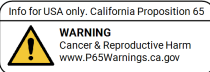

Scanner Hardware	Scanner Output file format	Interoperable Viewing Software	Interoperable Displays
Aperio GT 450 DX	SVS	Aperio WebViewer DX	Barco MDPC-8127 Dell UP3017 Dell U3023E Dell U3223QE
Aperio GT 450 DX	SVS	Sectra Digital Pathology Module (3.3)	Dell U3223QE
Aperio GT 450 DX	DICOM	Sectra Digital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

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.

Symbols

The following symbols appear on your product label or in this user guide:

Symbol	Regulation/Standard	Description
	ISO 15223-1 - 5.4.3	Consult instructions for use
	ISO 15223-1 - 5.1.1	Manufacturer
	ISO 15223-1 - 5.1.3	Date of manufacture
	ISO 15223-1 - 5.1.7	Serial number
	ISO 15223-1 - 5.5.1	In Vitro Diagnostic medical device
	ISO 15223-1 - 5.1.6	Catalog number
	21 CFR 809.10(a)(4)	Requires prescription in the United States.
	ISO 15223-1 - 5.7.10	Unique Device Identifier
	ISO 15223-1 - 5.4.4	Caution
	SO 7010 - W001	General warning
	IEC 61010-1	TÜV Product Services have certified that the listed products comply with both U.S. and Canadian safety requirements.
	IEC 60417 - 5031	This device is suitable for direct current only.
	IEC 60417 - 5007	On. To indicate connection to the mains, at least for mains switches or their positions, and those cases where safety is involved.

Symbol	Regulation/Standard	Description
	IEC 60417 - 5008	Off. To indicate disconnection from the mains, at least for mains switches, and all those cases where safety is involved.
	ISO 15523-1 5.7.3	Temperature limitation
	ISO 15223-1 5.3.8	Humidity limitation
	People's Republic of China Electronic Industry Standard SJ/T11364	Device contains certain toxic or hazardous elements and can be used safely during its environmental protection use period. The number in the middle of the logo indicates the environmental protection use period (in years) for the product. The outer circle indicates that this product can be recycled.
	IEC 60825-1	Device is a Class 1 Laser Product that is in compliance with international standards and US requirements.
	CA Proposition 65	This product can expose you to chemicals known to the State of California to cause Cancer and Reproductive Harm. For more information go to https://www.P65Warnings.ca.gov .
	N/A	Device is made in the USA of U.S. and foreign components.

1

Introduction

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The Aperio GT 450 DX is a high performance, brightfield whole slide scanner that includes continuous loading with 450-slide capacity across 15 racks, priority rack scanning, automated image quality check and a scan speed of ~32 seconds at 40x scanning magnification for a 15 mm x 15 mm area.

The Aperio GT 450 DX is intended for use by trained clinical pathology histotechnicians, while the Aperio GT 450 DX Aperio GT 450 SAM DX software is intended for use by IT professionals and laboratory administrators.

The Aperio GT 450 DX is intended for use in medium- to high-volume clinical pathology laboratories that support the pathology services of a hospital, reference laboratory or other clinical facility.

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. 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.

Use of the Aperio GT 450 DX requires the following components.

Component	Description
Scanner Administration Manager (Aperio GT 450 SAM DX) Server	The Aperio GT 450 SAM DX Client Application Software resides on a server, which is referred to in this document as the Aperio GT 450 SAM DX server. The Aperio GT 450 SAM DX server connects to multiple Aperio GT 450 DX scanners.
Aperio GT 450 Aperio GT 450 SAM DX Client Application Software	The Aperio GT 450 SAM DX client application software enables IT implementation, PIN configuration, and service access of multiple scanners from a single desktop client location for IT professionals.
Workstation, monitor, and keyboard	A workstation, monitor, and keyboard must be connected to your local area network with access to the Aperio GT 450 SAM DX server to administer the Aperio GT 450 DX scanners.

See the *Aperio GT 450 DX Specifications* for more information on these components.

Ensure you follow appropriate good laboratory practices and the policies and procedures required by your institution for slide preparation, processing, storage, and disposal. Use this equipment only for this purpose and in the manner described in this guide.

Resources

Resource	Description
Aperio GT 450 DX User's Guide	Provides reference information and instructions for scanning, troubleshooting, and maintenance.
Aperio GT 450 DX Quick Reference Guide	Contains quick instructions for scanning, basic troubleshooting, and maintenance. We recommend keeping this printed guide with your scanner. An electronic version of the quick reference guide is available from the Help area on the scanner's touchscreen interface.
Aperio GT 450 DX IT Manager and Lab Administrator's Guide	Contains information and instructions regarding IT administration of the scanner, including network administration and configuration.
Aperio GT 450 DX Specifications	Provides detailed specifications for the scanner.
Instructional videos	Provides video instruction on performing various tasks. You can view the videos from the Help area on the scanner's touchscreen interface.
Customer Support	If you have an issue with the scanner you cannot resolve, contact Leica Biosystems Technical Services.
Training	Leica Biosystems offers classroom and virtual training courses. Contact Leica Biosystems Customer Support for information about training options.

Warnings

This section contains important safety and operation warnings. For more details, see also [Scanner safety instructions \(on page 17\)](#).

Electromagnetic warnings

If the scanner is used in any manner not specified in this documentation, the protection provided by the equipment may be impaired.



Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the scanner, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

This device complies with the emissions and immunity requirements as specified in the EN/1EC 61326 series of Product Family Standards for a "basic electromagnetic environment". Such equipment is supplied directly at low voltage from public mains network. This equipment is not intended for residential use.

This device generates, uses, and can radiate unintentional radio-frequency (RF) energy. If this device is not installed and operated correctly, this RF energy can cause interference with other equipment. It is the responsibility of the end user to be sure that a compatible electromagnetic environment for the device can be maintained so that the device operates as intended.

This equipment is designed for use in a PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT. It is likely to perform incorrectly if used in a HOME HEALTHCARE ENVIRONMENT. If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference.

In addition, other equipment can radiate RF energy to which this device is sensitive. If one suspects interference between this device and other equipment, Leica Biosystems recommends the following actions to correct the interference:

- Evaluate the electromagnetic environment before installation and operation of this device.
- Do not operate this device close to sources of strong electromagnetic radiation (for example: unshielded intentional RF sources), as these can interfere with proper operation. Examples of unshielded intentional radiators are handheld radio transmitters, cordless phones, and cellular phones.
- Do not place this device near medical electrical equipment that can be susceptible to malfunctions caused by close proximity to electromagnetic fields.
- This device has been designed and tested to CISPR 11 Class A emission limits. In a domestic environment, this device can cause radio interference, in which case, you need to take measures to mitigate the interference.

Instrument warnings



WARNING: To reduce the risk of fire or electric shock, do not expose the scanner to rain or moisture.

Misuse of electrical equipment can cause electrocution, burns, fires, and other hazards.

Component and part replacement warnings

There are no user-replaceable parts or components in the Aperio GT 450 DX. Replacement of parts or components within the Aperio GT 450 DX must be performed by qualified Leica Biosystems Technical Services personnel using Leica Biosystems specified parts.



Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Compliance specifications

This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference, and;
- This device must accept any interference received, including interference that may cause undesired operation.

This device has been evaluated against and conforms to the following standards:

Feature	Details
Safety	 <p>IEC 61010-1: 2010/AMD1:2016 IEC 61010-2-101: 2018 CAN/CSA C22.2 No. 61010-1:2012/A1:2018 CAN/CSA C22.2 No. 61010-2-101:2019 UL 61010-1:2012/R2019-07 UL 61010-2-101:2019</p>
EMC	<p>IEC 61326-1:2013 IEC 61326-2-6:2021 CISPR 11: 2015 FCC Part 15 Subpart B ICES-003 Issue 6: 2016 CNS13438: 2006 KN 32: 2015-12 KN 35: 2015-12</p>

Installation



WARNING: Two people are required for lifting the scanner.

Installation and setup of the scanner should only be performed by a trained Leica Biosystems Service representative. After installation, the Leica Biosystems Service representative will check the scanner for proper operation.



WARNING: Incorrect installation could result in serious injury to the operator or ergonomic strain. For work surface and operating specifications, see the *Aperio GT 450 DX Specifications*, MAN-0506.

When you first receive the Aperio GT 450 DX and accessories, inspect the pallet and attached boxes for any damage. If the package has visible damage from shipment, contact Leica Biosystems Customer Service for assistance.

Disposal of the Aperio GT 450 DX

Contact Leica Biosystems Imaging, Inc. for assistance or questions regarding device disposal.

Scanner safety instructions

This section contains important safety information for the Aperio GT 450 DX.

When using your scanner, always take basic safety precautions, including all of those listed below.

- **Read All Instructions** – All safety and operating instructions must be read before operating the product.
 - **Retain All Instructions** – All safety and operating instructions must be retained for future reference.
 - **Heed All Warnings** – All warnings on the scanner and those listed in the operating instructions must be adhered to.
 - **Follow All Instructions** – All operating and scanner usage instructions must be followed.
- 1 **Heat** – The scanner must be situated away from any heat sources such as radiators, heat registers, stoves, or other products that produce heat.
 - 2 **Ventilation** – Slots and openings in the scanner are provided for ventilation. They ensure reliable operation of the product, keeping it from overheating. These openings must not be blocked nor covered during operation. Keep air openings free of lint, hair, fluff, etc. This product should not be placed into a rack unless proper ventilation is provided through following the manufacturer’s recommended installation procedures.
 - 3 **Biosafety Procedures** – Please refer to your institution’s biosafety policies and procedures regarding the proper handling of tissue and other potentially hazardous materials in connection with the use of this device.
 - 4 **Water and Moisture** – Do not use the scanner near water—for example, near a water bath, wash bowl, kitchen sink, or laundry tub; in a wet basement; or near an open pool of water or the like. If the scanner becomes wet, unplug it before touching it.
 - 5 **Environment** – This device is intended for indoor use only.
 - 6 **Attachments** – Do not use any attachments not recommended by the product manufacturer as they may cause hazards.
 - 7 **Power Sources** – The scanner must be operated from the type of power source indicated on the marking label and in the installation instructions. If you are not sure of the type of power supplied to your facility, consult your local power company. Check that the voltage setting matches the electrical supply voltage.
 - 8 **Grounding and Polarization** – The scanner AC/DC adapter is equipped with a polarized AC plug with integral safety ground pin. Do not defeat the safety ground in any manner.
 - 9 **Cable Protection** – Secure all external cables to avoid operator injury.

- 10 **Power Cord Protection** – Power supply cords must be routed so that they are not likely to be walked on nor pinched by items placed upon or against them. Pay particular attention to the cords at AC wall plugs and convenience receptacles and at the point where the cord enters the AC/DC adapter. The appliance coupler on the external AC/DC power supply is considered the mains disconnect device.
- 11 **Lightning** – For added protection for this scanner during a lightning storm, or when it is left unattended and unused for long periods of time, unplug it from the AC wall outlet. This will prevent damage to the product due to lightning and power line surges.
- 12 **Power Overloading** – Do not overload AC wall outlets, extension cords, or integral convenience outlets as this can result in a fire or electric shock hazard.
- 13 **Operating Environment** – Observe these basic safety requirements:
 - Do not operate the scanner out of doors.
 - Do not use where aerosol sprays are being used or where oxygen is being administered.
 - Do not let the scanner or its cables or accessories come into contact with surfaces which are too hot to touch.
 - Do not place anything on top of the scanner.
- 14 **Object and Liquid Entry** – Never push objects of any kind into the scanner through openings as they may touch dangerous voltage points or short-out parts that could result in a fire or electric shock. Never spill liquid of any kind on the scanner.
- 15 **Accessories** – Do not place the scanner on an unstable cart, stand, tripod, bracket, or table or the scanner may fall, causing serious injury and damage to the product. Any mounting of the scanner needs to follow manufacturer's installation instructions. Do not place anything on top of the scanner.



WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation.

- 16 **Moving** – Use care if you must slide the scanner around the workbench. If you need to pick up the scanner to move it off the workbench, contact Leica Biosystems Technical Services. Moving the scanner may void the applicable product warranty—contact Leica Biosystems for advice.
- 17 **Servicing** – Refer all servicing to qualified service personnel.
- 18 **Damage Requiring Service** – Unplug the scanner from the wall AC outlet and refer servicing to qualified service personnel under the following conditions:
 - When the AC cord or AC/DC adapter is damaged.
 - If liquid has been spilled or objects have fallen into the scanner.
 - If the scanner has been exposed to rain or water.
 - If the scanner does not operate normally (when you are following operating instructions).
 - If the scanner has been dropped or damaged in any way.
 - When the scanner exhibits a distinct change in performance. This indicates a need for service.

- 19 **Replacement Parts** – When replacement parts are required, be sure the service technician has used replacement parts specified by the manufacturer. Unauthorized substitutions may result in fire, electric shock, or other hazards and may affect product compliance.

The objective in the Aperio GT 450 DX scanner has been specifically designed for this device. Do not replace it with another type of objective.



WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. Unauthorized substitutions may result in fire, electric shock, or other hazards and may affect product compliance.

- 20 **Operational Check** – Upon completion of any repairs to this scanner, ask the service technician to perform operation checks to determine that the product is in proper operating condition.
- 21 **Cleaning** – Apply the recommended cleaning solution to a clean cloth to clean the equipment. Do not apply cleaning solutions directly to the equipment.

2

Aperio GT 450 DX overview

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This chapter provides an overview of the Aperio GT 450 DX Scanner.

Theory of operation

The Aperio GT 450 DX scanner contains an automated slide loader subsystem which is designed to process standard 1" x 3" (2.54 cm x 7.62 cm) microscope slides.

The scanner automatically loads the slides from the slide racks that the technician loaded into the scanner carousel. The slides are moved onto the scanning stage based on the automated processing and queuing of the racks.

Once the slide is on the stage, the imaging process begins with capturing the macro image, automatically detecting tissue, automatic placement of initial focus points (and reference stripe location), capturing the label image (including any barcode), and the image acquisition is initiated.

The tissue finding and scanning processes are automated without any need for the user to manipulate the slides being processed. If there is a need based on the quality review of the scanned image or tissue finder results, the device has the capability to reinitiate the scan with a different user selected mode (entire slide scan). The device images the slide using transmitted light from the Koehler Light Source through the specimen to the optical path (including the objective, tube lens, apertures, and mirrors). At this point the light travels to the line scan camera where the imaging data is captured and processed. The Aperio GT 450 DX scanner acquires images in stripes, as the motion subsystem moves the slide across the Koehler and optical path. These stripes of data are processed in the control VPU and sent to a database for use in later pathology workflow steps. Once the slide has finished scanning, it is automatically removed from the stage, returned to the slide rack, and the next slide is loaded.

Scanner overview

This section describes the parts of your scanner used in daily operation.



The following section describes the main scanner elements:

Element	Use	More details
Touchscreen Interface	View rack statuses, set rack options, and view other information.	See Touchscreen interface overview (on page 23) .
Carousel	The carousel contains 15 rack slots. After you load racks in the carousel, the carousel rotates the racks to the scanning area and the rack loading area.	See Carousel rotation (on page 35) .
Rack loading area	Provides access to the carousel to load and unload slide racks. This area is also referred to as the “front-six,” because the rack loading area gives you access to six rack slots at a time.	See Load racks in the carousel (on page 38) .
Safety light curtain	The infrared safety light curtain detects objects in the rack loading area. The carousel only rotates when the safety light curtain area is clear.	See Carousel rotation (on page 35) .
Status lights	The status lights are located below the rack slots in the rack loading area. They indicate the status of the front-six racks and the scanner. The colors of the status lights match the colors of the rack status Legend on the touchscreen interface.	See Check scan status (on page 43) . See Red blinking lights on carousel (on page 70) .
Fan filter	The fan filter is located on the back of the scanner. Clean the fan filter at least every six months. You can insert the fan filter from the left side, the right side, or the top (requires a different fan filter holder).	See Clean the fan filter (on page 65) .

Turn the scanner on and off

The On/Off switch is located on the right side of the scanner near the back.

- On position = |
- Off position = ○



When you are turning the scanner off and on, follow these procedures according to the situation:

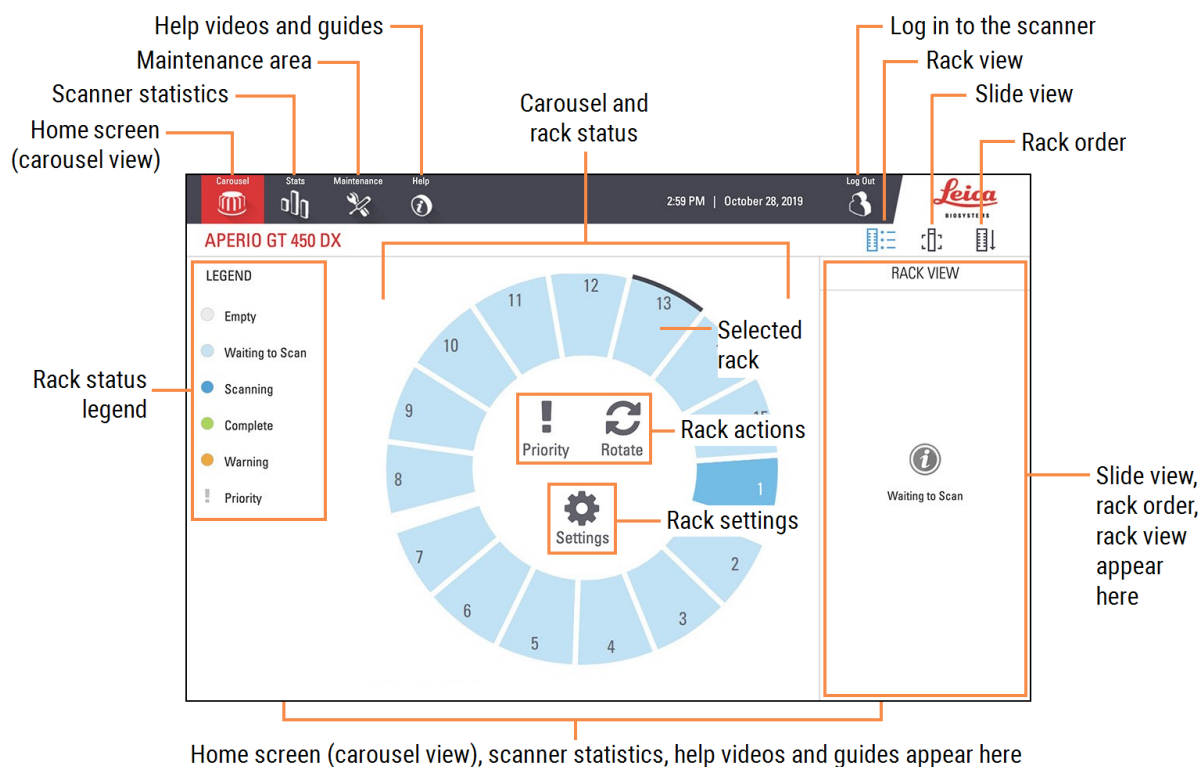
- Shut down the scanner (on page 55).
- Restart the scanner after interior maintenance (on page 67).
- Perform a safe restart after an error (on page 71).

Touchscreen interface overview







The touchscreen interface is where you view the scan status and interact with the scanner. Tap an area on the touchscreen interface to view information or perform an action.






Home screen

The Home screen (Carousel view) is where you view rack and slide status. The buttons along the top enable you to access other areas, such as Help and Maintenance.



The following section describes the Home screen elements.

Element	Icon	Use	More details
Rack status legend	not applicable	The Legend defines colors and icons that indicate rack status. Status colors appear on the rack slot positions on the touchscreen interface, and on the status lights in front of the carousel. Note: the Legend is for information only and is not interactive.	Check scan status (on page 43)
Scanner statistics		Tap Stats to view scan statistics, such as the number of slides or racks scanned within a certain time period.	Scan statistics (on page 52)
Maintenance		Tap Maintenance if you need to restart the scanner, or view the serial number and the hardware and firmware versions of your scanner.	Serial number and firmware version (on page 54) Shut down the scanner (on page 55) Restart the scanner (on page 57)
Help		Tap Help to view training and maintenance videos, or access an online version of the quick reference guide.	Help videos and guides (on page 26)
Carousel and rack status	not applicable	Use the carousel and rack position on the touchscreen interface to: <ul style="list-style-type: none"> View the rack status, indicated by the color of the rack position. Tap a rack position to select the rack. Apply an action to the selected rack, such as Priority or Rotate (described next). 	Carousel rotation (on page 35) Check scan status (on page 43)
Rack actions Note: Rack actions appear when you select a rack.		Select a rack and tap Priority to move the rack to the top of the scan queue.	Priority scanning (on page 40)
		Select a rack and tap Rotate to rotate the rack to the rack loading area.	Rotate a rack to the rack loading area (on page 41)
Rack settings Note: Rack settings appear when you select a rack.		Select a rack and tap Settings to select and apply a rack setting. The rack settings enable you to scan the entire slide for the whole rack.	Scan entire slide for whole rack (on page 49)

Element	Icon	Use	More details
		The rack settings enable you to scan the whole rack at 20x magnification, or scan the entire slide for the whole rack.	
Login, Logout		Tap Login to open a keypad and enter your pass code to access the scanner.	Log in and log out of the scanner (on page 35)
		Tap Logout to lock access to the scanner touchscreen interface.	
Rack View		Select a rack and tap Rack View to view the scan status for each slide in the rack.	View slide status for a rack (on page 45)
Slide View		Select a rack and tap Slide View to view macro images for each slide.	View macro images of scanned slides (on page 46)
Rack Order		Tap Rack Order to view scan order and status of the racks.	View rack scan order (on page 46)

Help videos and guides

You can access training videos and the *Aperio GT 450 DX Quick Reference Guide* directly from the touchscreen interface. We recommend that you watch the training videos before operating the scanner for the first time.

- 1 Tap **Help**, and then tap a video or guide to view.



Key features

This section describes some key features of your Aperio GT 450 DX.

Continuous load workflow

You can continuously load new racks and unload completed racks without interruption.

Scan magnification

Custom optics for native 40x scanning magnification.

Automatic image quality check

The Auto-Image QC automatically checks scan quality. If the scan status is green for “complete,” the scan and Image QC were successful. If there is a problem with the scan quality on a slide, the system alerts you.

Image types supported

The Aperio GT 450 DX creates SVS files or DICOM compatible images. The .svs image format is the default.

For information on enabling the optional DICOM feature, see the *Aperio GT 450 DX IT Manager and Lab Administrator's Guide*.

Slide types supported

The scanner supports 1 x 3 inch (2.54 cm x 7.62 cm) glass slides (per ISO 8037/1).

Coverslips

Fully-cured coverslips are required. The Aperio GT 450 DX supports common industry coverslips used for 1 x 3 inch slides.

Slide racks supported

Optimized and recommended for use with Leica HistoCore Spectra workstation racks (stainer and coverslipper), which include the Leica Universal Rack 30-slide capacity (part number 23RACKGT450). Sakura Prisma Stainer and Coverslipper Rack 20-slide capacity racks are also accepted.

Slide capacity

The maximum slide capacity depends on the racks used:

- 20-slide racks – load up to 300 glass slides.
- 30-slide racks – load up to 450 glass slides.

Barcodes supported

The Aperio GT 450 DX supports the following barcodes:

- NW7
- QR Code
- Data Matrix
- Interleaved 2 of 5
- Code 39
- Code 128
- PDF417
- MicroPDF41
- Aztec

3

Slide preparation

In this section:

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Staining	29
Slide preparation guidelines	29
Coverslips	30
Labels	31
Barcodes	31



When preparing slides for scanning, you must use the procedures required by the vendors of the stains and reagents you are using.

Well prepared slides are crucial to a successful scan. After reading this section, if you have questions about whether your slide preparation techniques will provide good scan quality, contact Leica Biosystems Technical Services for advice.

Always consult the material safety data sheets for the stains and re-agents you are using, as well as your institution's biosafety policies and procedures regarding safely handling biological materials.

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.



CAUTION: Ensure that the slides and racks you use meet the Aperio GT 450 DX specifications. For details, see the *Aperio GT 450 DX Specifications*, MAN-0506. Do not modify racks or attach labels to them.

Tissue preparation

For optimal scanner performance, slides must be well-prepared.

Staining

Reproducibility of the slide staining is important for consistent and accurate diagnosis.

- Make sure that the variations of the staining process are controlled and eliminated to the greatest extent possible.
- Use appropriate morphological studies and controls as specified in the reagent manufacturer's instructions.
- Avoid excessive stain residue, as this may affect scanner performance.

Slide preparation guidelines

Many scanning issues are avoided by checking slide quality. Ensure the following:

- **Slides are very clean and in good condition.** Wipe them with a clean cotton cloth (don't use chemical cleaners). Make sure the slides have no dirt, no fingerprints, no markings, no writing, no extra mounting media, no broken slides, no chips, no scratches, etc.
- **Slides are fully cured** (not "wet").
- **All slides have coverslips.** Coverslips are required when using the Aperio GT 450 DX scanner.
- **There is no mounting adhesive around the edges of a slide.** This can cause it to stick or catch in the scanner stage area.



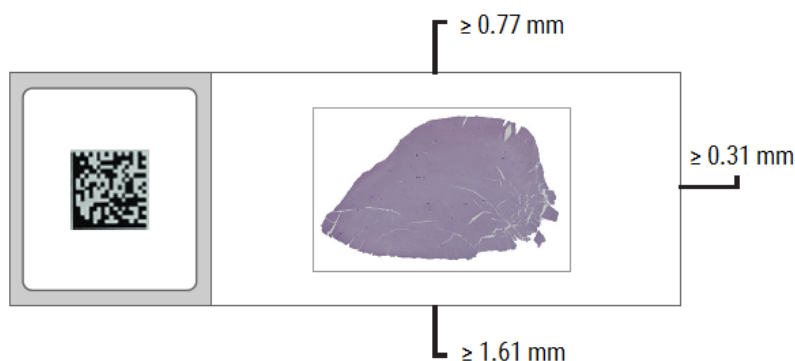
CAUTION: Do not attempt to scan damaged or broken slides, as doing so may damage the scanner.

Tissue placement

Place the tissue in the middle of the slide, a distance from the edges of the slide, the label, and any other markings. Ensure the following:

- The coverslip covers all the tissue.
- The label does not cover any tissue.

The example below shows minimum distances from the side and bottom edges of a 26mm x 76mm (1" x 3") slide.



For more details on slide specifications, see [Slide types supported \(on page 27\)](#).

Fixing slide preparation errors

Some physical problems of a slide can be resolved by cleaning the slide with a lint-free cloth or trimming the sides with a razor blade. Permanent problems with a slide may require the preparation of a new slide.

Coverslips

Coverslips are required when using the Aperio GT 450 DX. They must be fully-cured or have completed the on-board drying process for an automated coverslipper, such as the Leica Biosystems HistoCore SPECTRA Coverslipper.

The Aperio GT 450 DX supports common industry glass or plastic coverslips used for 1-inch x 3-inch (2.54 cm x 7.62 cm) slides. See the *Aperio GT 450 DX Specifications* for coverslip specifications. (Glass coverslips are recommended).

The quality of the scan is affected by the condition of the coverslip.

- Keep the mounting media that attaches the coverslip to the slide to a minimum. Excess mounting media makes it hard for the tissue finder to distinguish between actual tissue and the mounting media.
- Make sure there are no air pockets under the coverslip.
- For best results, do not mark or write on the coverslip.
- The coverslip must not hang over the side of the slide.

- Make sure there is only one coverslip attached to the slide.
- Wipe the coverslip clean of dust and fingerprints before loading the slide in the scanner.

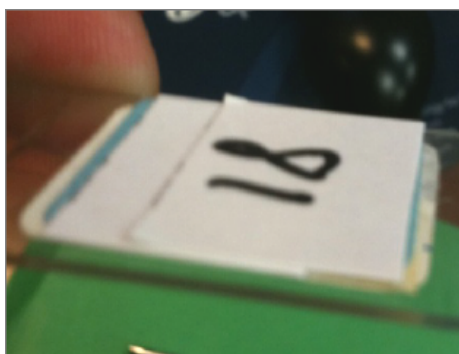
Labels

The Aperio GT 450 DX supports common industry labels used for 1 x 3 inch (2.54 cm x 7.62 cm) slides. Improperly applied slide labels can cause slides to jam.

Ensure the following:

- Do not apply multiple labels to the same slide—this can cause the slide to exceed the specification for slide thickness. See the *Aperio GT 450 DX Specifications* for slide specifications.
- Labels do not extend past the edges of the slide and do not cover any tissue.
- Labels are not underneath coverslips.
- Labels are firmly attached.
- Do not apply labels to the bottom surface of the slide.
- Always load slides into the rack with the label facing out and up, as shown in [Load slides in the rack \(on page 37\)](#).

The examples below show a slide with multiple labels that cause the slide to exceed the allowable maximum thickness, and a slide with the label peeling away:



Barcodes

For a list of supported barcodes, see [Barcodes supported \(on page 27\)](#). For best performance, we recommend using barcode labels that have a white background and black ink.

Improperly applied slide barcodes can cause slides to jam. Ensure the following:

- Barcode labels meet the same application requirements as slide labels. See [Labels \(on page 31\)](#).
- Apply barcode labels to the slide label region.
- Ensure a minimum of 0.5 mm between each side of the barcode and the edge of the label.

- Apply only one barcode label per slide.
- Use only supported barcode labels. See [Barcodes supported \(on page 27\)](#).
- Use only high-quality printed barcode labels.

4

Scan slides

In this section:

Scanning concepts	34
Log in and log out of the scanner	35
Load slides in the rack	37
Load racks in the carousel	38
Priority scanning	40
Rotate a rack to the rack loading area	41
Unload racks from the carousel	42
Check scan status	43
Scan entire slide for whole rack	49
Image quality control for histotechnicians and pathologists	50
Scan statistics	52

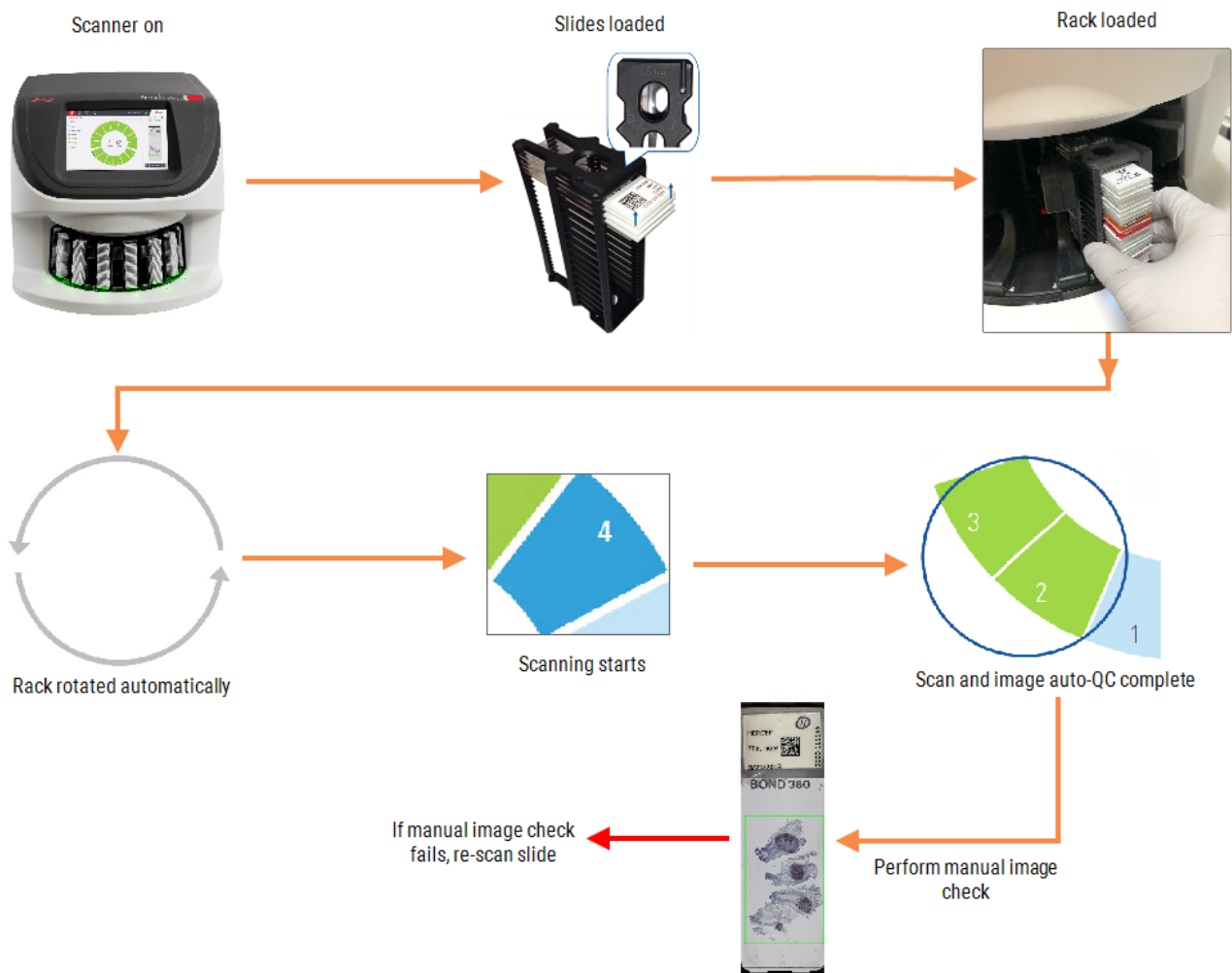
This chapter shows you how to scan slides.

Scanning concepts

This section provides basic concepts on the scanning workflow and the carousel rotation features. We recommend reviewing this section before using the scanner.

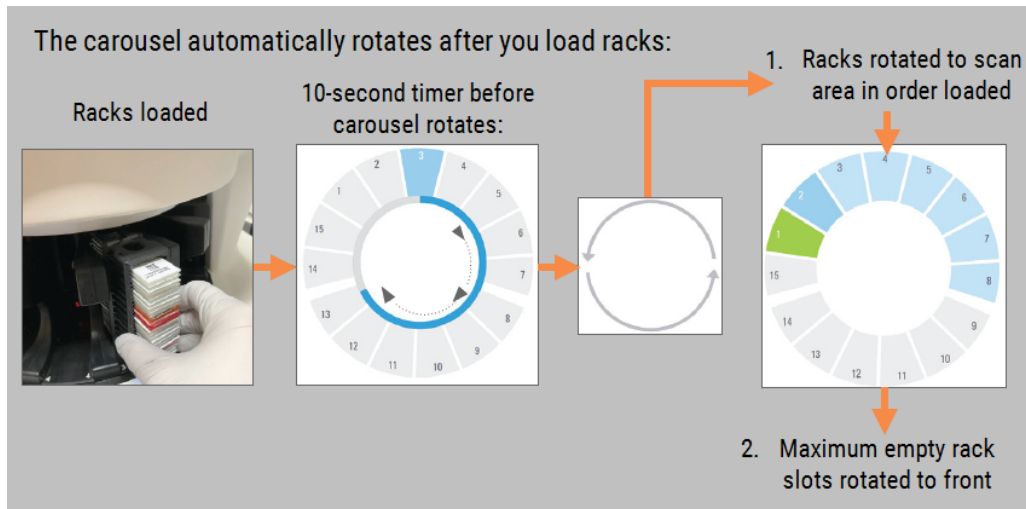
Scan workflow

The Aperio GT 450 DX is a continuous load scanner. You can continually load new racks and unload completed racks, as shown below:



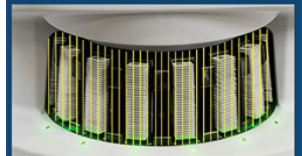
Carousel rotation

Review the following information to understand the carousel rotation and safety features.



Safety light curtain

An infrared safety light curtain detects objects in the loading area:



If an object breaks the light curtain:

- the carousel does not rotate
- the 10-second timer starts again



WARNING: Keep hands away from the carousel and pinch point areas when the carousel is rotating.



Log in and log out of the scanner

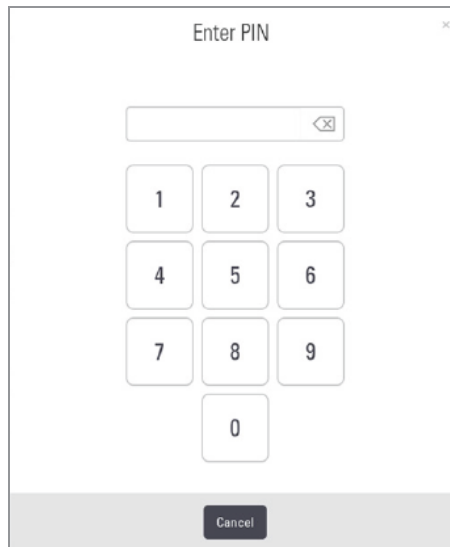
Your Lab Administrator sets up the scanner pass codes and timeout period for your lab using the Aperio GT 450 SAM DX client application software. You need to log into the scanner to interact with the touchscreen interface. You do not need to log in to load and unload racks for scanning.

As a security measure, the scanner logs you out after a period of time and requires you to enter the passcode.

- 1 From the touchscreen interface, tap **Login**.



- 2 When the keypad screen appears, enter your 5-digit passcode.



To log out:

Logging out locks the touchscreen interface until a valid passcode is entered.

- 1 From the touchscreen interface, tap **Logout**.



Load slides in the rack

For a successful scan, ensure you use the correct orientation of the slides and the rack.

To load slides in the rack:

- 1 Position the rack so the Leica logo and "SIDE UP" face up.
- 2 Insert each slide as shown with the label facing out and up.
- 3 Push each slide into the rack until the slide touches the back of the rack, ensuring each slide is fully inserted into the rack.



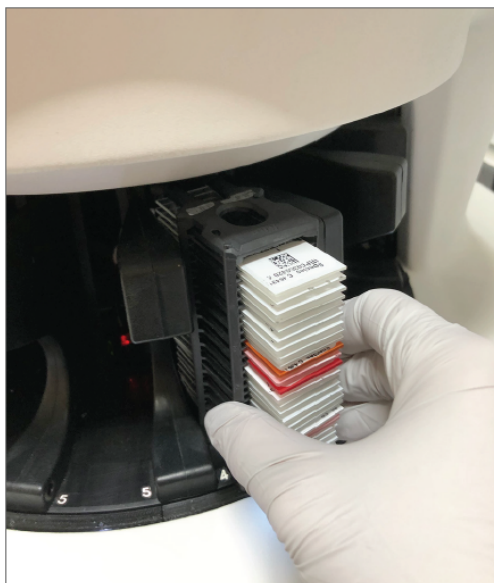
CAUTION: Use caution when loading slides into a rack to prevent improper slide orientation or damaged slides. Never use damaged slides in the scanner.



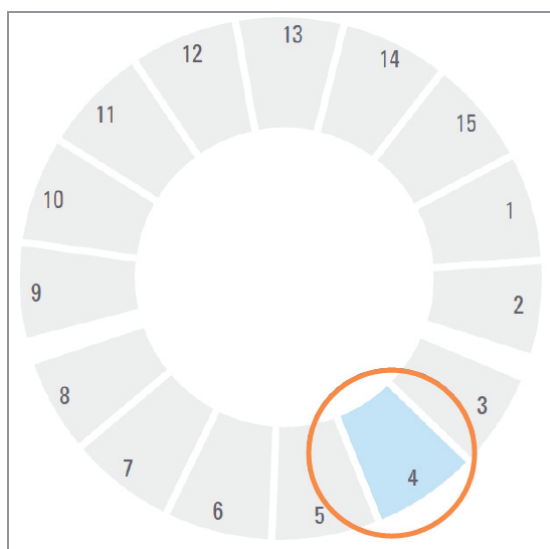
Load racks in the carousel

Slides are scanned in the order you load them.

- 1 Place the loaded rack into an open slot in the carousel.
- 2 Push the rack forward until it stops and you hear a click.



When the rack is fully inserted, there is a “click” sound, and the rack position on the Home screen turns light blue.



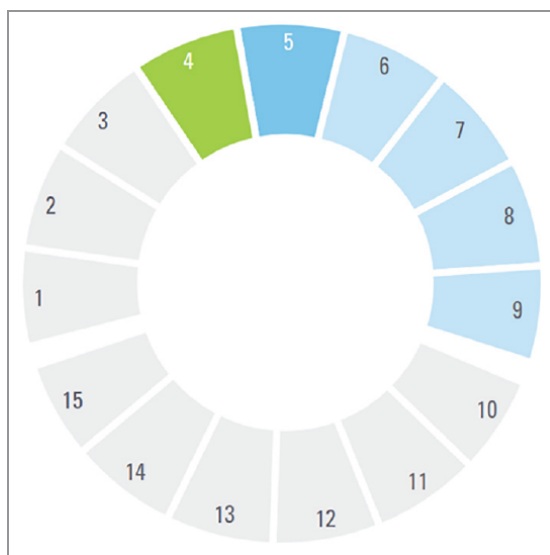
- 3 Continue loading racks as needed or until you fill the front six rack slots.

- 4 When you've finished loading the first set of racks:
 - The first rack is rotated to the scan area.
 - Any empty rack slots are rotated to the loading area.



WARNING: To prevent injury, keep hands away from the carousel and pinch point areas when the carousel is rotating. Never manually rotate the carousel unless you are performing maintenance and power is off to the scanner as discussed in [Chapter 5: Maintenance](#).

- 5 When a rack is scanned successfully, the rack status turns green.



- 6 You can unload any completed racks and continue loading new racks.

If the completed rack is in the back of the carousel, you can rotate it to the rack loading area. See [Rotate a rack to the rack loading area \(on page 41\)](#).

Priority scanning

Use Priority to move a rack to the front of the scan queue. You can apply the Priority option on up to three racks at a time.

1. Tap the rack position.

The Priority option appears when you select the rack position.



2. Tap Priority.



The priority icon and scan queue number appear on the rack position.

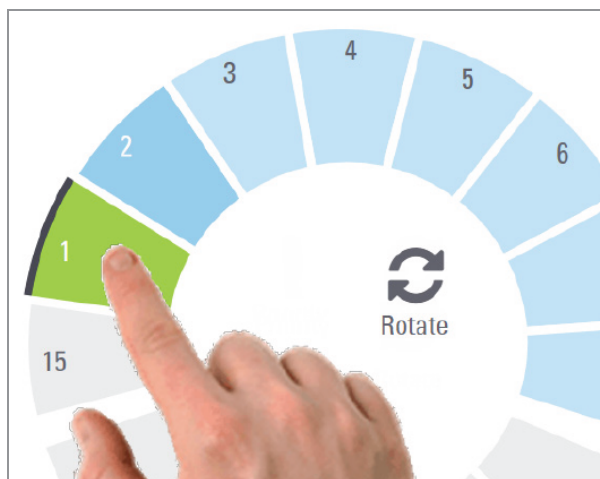


Rotate a rack to the rack loading area

The main reason for using the rotate feature is to rotate a completed rack to the loading area. If you try to rotate the rack that is currently being scanned, the system asks you for confirmation before continuing.

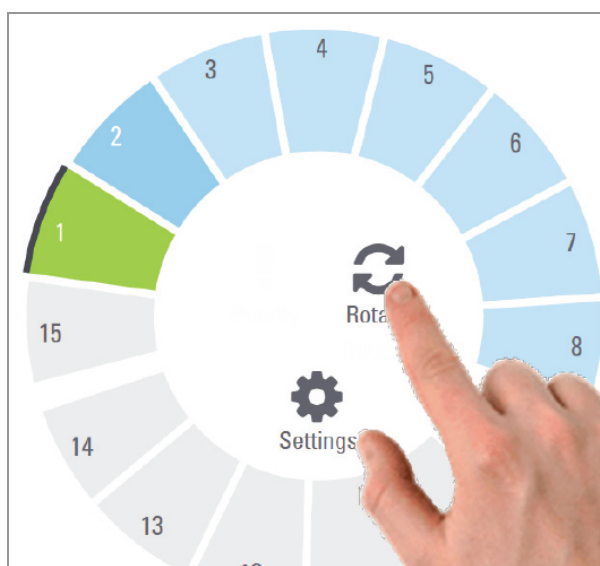
To rotate a rack to the rack loading area:

- 1 Tap the rack position.



The Rotate option appears when you select the rack position.

- 2 Tap **Rotate** to rotate the rack to the loading area.



- 3 After the rack is rotated to the front, you can remove the rack. (The status light in the loading area blinks to indicate the location of the rotated rack).

Unload racks from the carousel



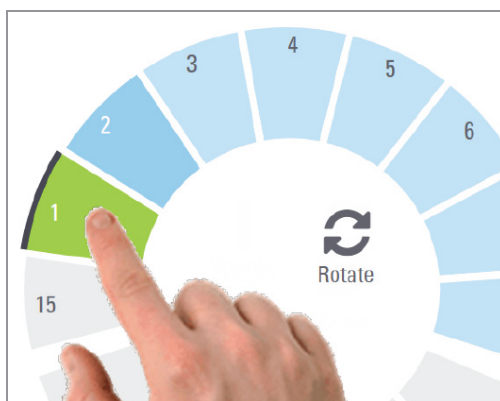
CAUTION: Use caution when unloading racks from the carousel and when unloading slides from a rack to prevent damaged slides or operator injury. Never use damaged slides in the scanner.

To unload racks from the carousel:

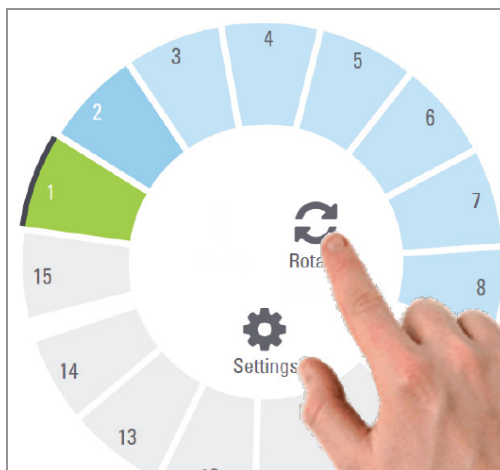
- 1 Make sure all the slides in the rack were successfully scanned (the rack status is green). If the rack status is orange, see [Rack warnings \(on page 47\)](#).
- 2 If the rack is in the loading area, carefully remove the rack from the rack slot.



- 3 If the rack is not in the loading area, you can rotate it to the front:
 - a Tap the rack position.



b Tap Rotate.



If you try to rotate the rack that is currently being scanned, the system asks you for confirmation.

4 After the rack is rotated to the loading area, you can remove the rack.

Check scan status

This section describes the different ways to check scan status.

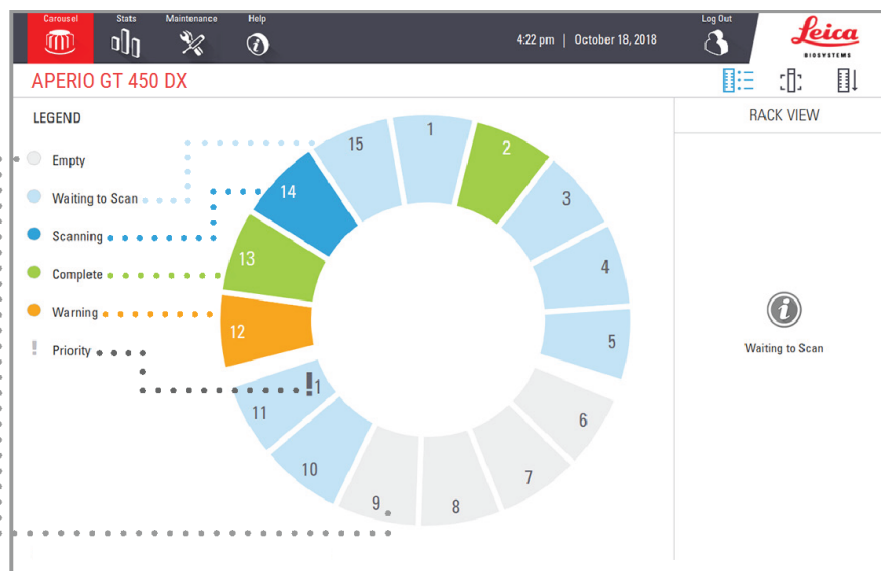


CAUTION: If you must remove a rack before all slides in the rack are scanned, note the rack and slide status. After removal, the rack's scan status is no longer available.

Check rack status

To check the scan status of a rack:

- 1 Check the rack position status color against the Legend.



The rack statuses are:

	Empty	Rack is empty and available for use.
	Complete	All slides in the rack scanned successfully and passed image QC. Scanned images are saved to the specific location.
	Scanning	The rack is currently being scanned.
	Waiting to Scan	The rack is loaded successfully and is waiting to scan.
	Warning	There is an issue with the rack, or one or more slides in the rack. If you get a rack warning, see Rack warnings (on page 47) .
	Priority	The rack is set for priority scanning. See Priority scanning (on page 40) .

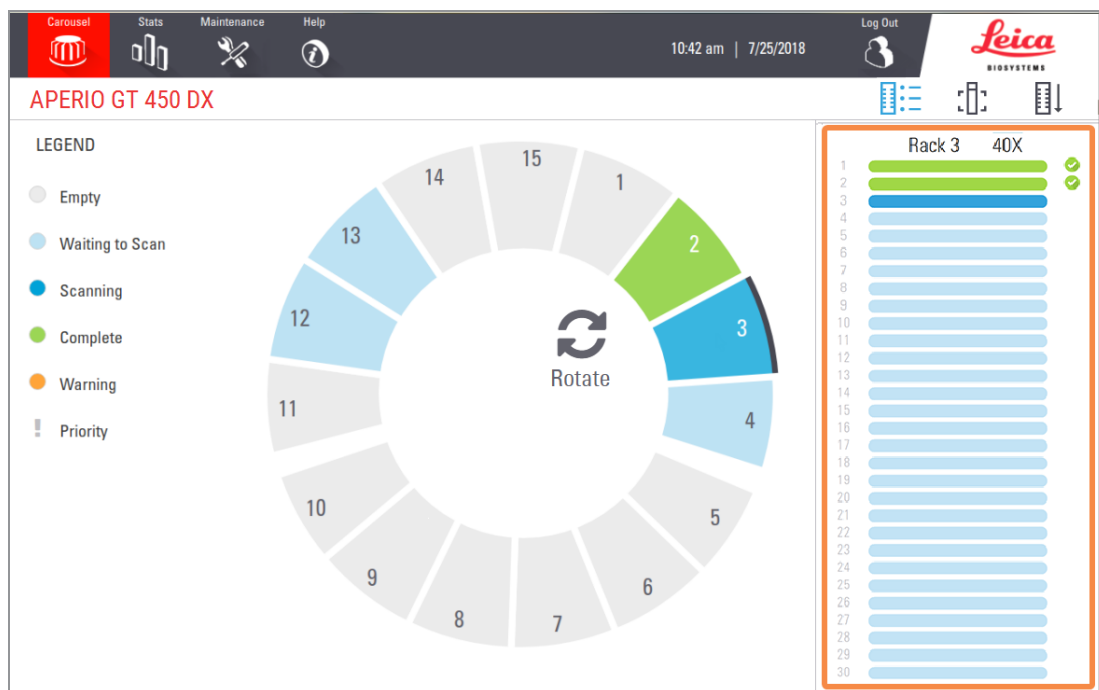
Rack error on current scan

If there is an error on at least one slide in the rack that is currently scanning, the rack position pulses blue and orange. See [Rack warnings \(on page 47\)](#).








View slide status for a rack

To view the status for slides in a rack:

- 1 Tap the rack position on the touchscreen interface.
- 2 Tap the **Rack View** icon.






Slide status colors correspond to the Legend:

	The slide is scanning.
	The slide is waiting to scan.
	The slide slot is empty.
	The scanned image was successfully transferred to the specific image location.
	No scanned image created. See Rack warnings (on page 47) .
	The slide scanned successfully, passed image QC, and was transferred to the specific image location.
	The slide has a scan warning. See Rack warnings (on page 47) .


View macro images of scanned slides

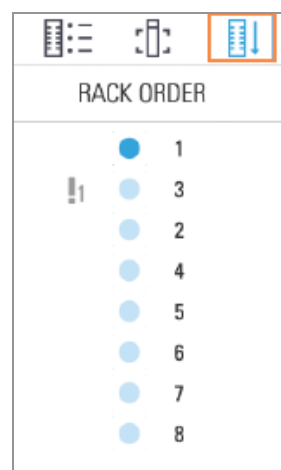
To view a macro image of a scanned slide:

- 1 Tap the rack position on the touchscreen interface.
- 2 Tap the **Slide View**  icon to view individual images for the selected rack.
 - Tap  and  to view other slides in the rack.
 - If any tissue is outside the scan area, you can tap **Scan Entire Slide** to rescan the whole slide.
 - If there is an error scanning the slide, a message appears in the box. See [Slide errors and solutions \(on page 93\)](#).



View rack scan order

- 1 Tap the **Rack Order**  icon to show the scan order of the racks.
 - Racks in the list appear in the scan order.
 - The scan status is indicated for each rack.
 - In the example, rack 3 is set as priority.

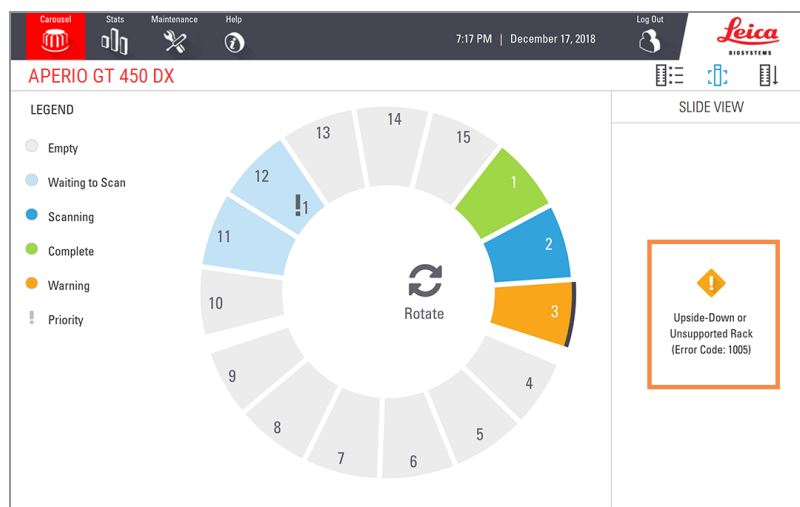


Rack warnings

A rack has a warning if the status color is orange or if the rack position is pulsating blue and orange.

To check the rack for errors:

- 1 Tap the rack position you want to check.
- 2 If there is a problem with the rack, a message appears similar to the example below.



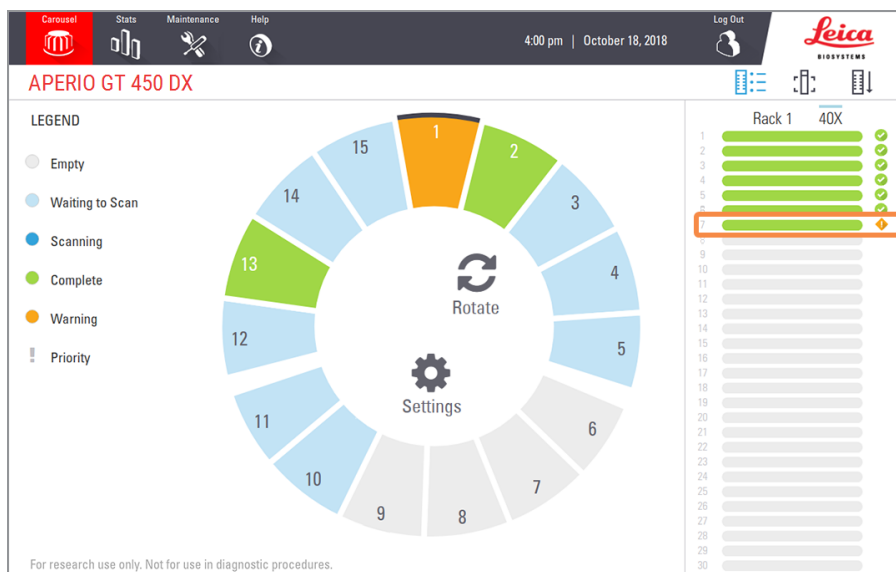
- 3 Take note of the error code and message. For information and steps to resolve the rack error, go to [Rack warnings and solutions \(on page 91\)](#).

- 4 If there is a problem with one or more slides in the rack, a warning icon appears next to the slide in Rack View:

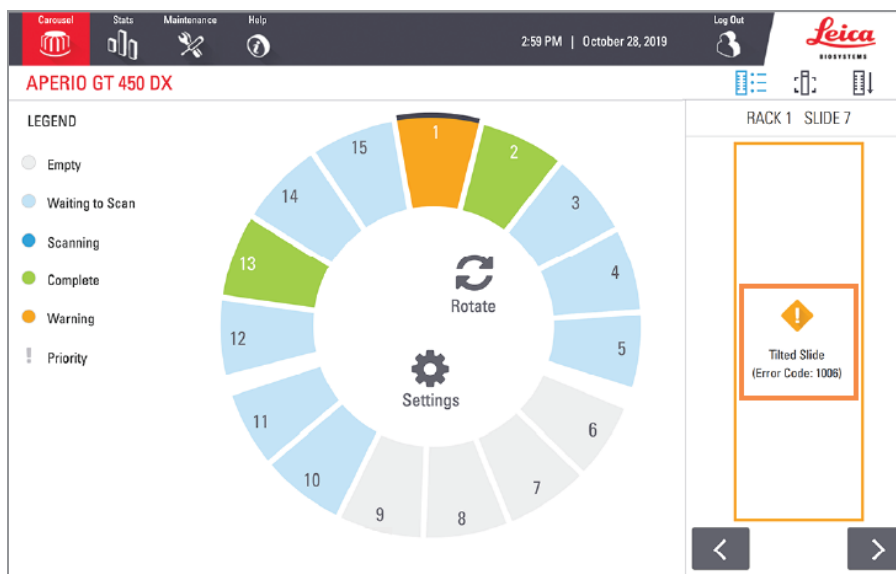
 The scanner created an image, but there is an error.

 An error prevented the scanner from creating an image.

In the example below, slide 7 in the selected rack has a warning.




- 5 Tap the **Slide View** icon to view the macro image for the slide that has a warning.

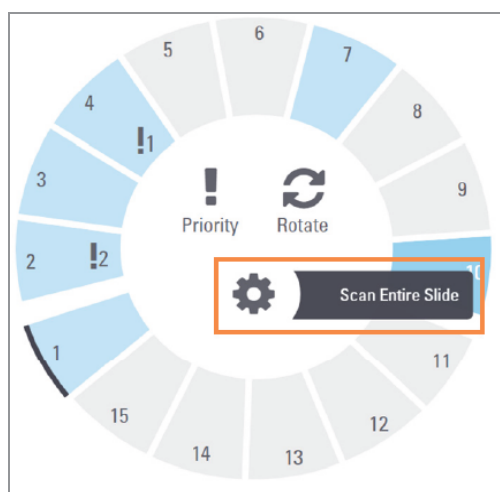


- 6 Take note of the error code and message. For information and steps to resolve the error, go to [Slide errors and solutions \(on page 93\)](#).

Scan entire slide for whole rack

This feature enables you to scan the full slide area for an entire rack of slides.

- 1 Load only the slides that require a full slide area scan in the rack.
- 2 Load the rack in the carousel.
- 3 Tap to select the rack position.
- 4 Tap **Settings** , and then tap **Scan Entire Slide**.



The Scan Entire Slide option is selected, and the Settings icon  appears on the rack position:

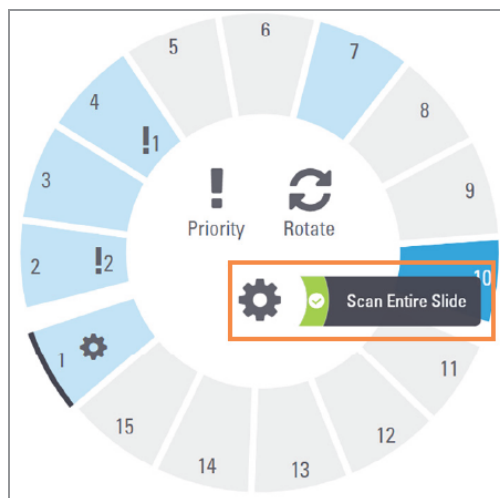


Image quality control for histotechnicians and pathologists

After scanning slides, it is important to review the digital slides to make sure the images are of good quality. Ultimately, it is up to the pathologist to look at digital slides to verify they are of sufficient quality to perform their task. In addition, scanner operators should verify digital slide quality after scanning.



The pathologist must verify that the label displayed on the digital slide is correct for that slide image based on the patient case being viewed. If it is not correct, the pathologist should request the slide to be rescanned.

The quality criteria that are important for primary diagnosis and should be verified by scanner operators are:

- that the entire tissue sample has been scanned, and;
- that the tissue is in focus.

Aperio scanners provide a macro image, a low resolution image of the entire slide, that also provides a green outline of the scanned image. Check that image for the quality criteria mentioned above. (For more details, see the next section, [Check that the scanned image covers all slide tissue.](#))




Re-scan any slides that failed to scan or failed the image quality review.

For additional image quality assessment instructions, refer to the user guide for your viewer.



Check that the scanned image covers all slide tissue

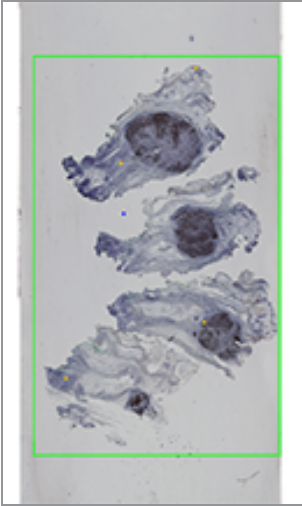
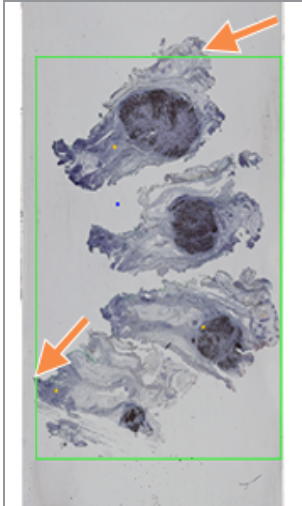
The steps below describe how to check that the scanned image covers all of the slide tissue.

- 1 Tap the rack position on the touchscreen interface that contains the slide images you want to review.
- 2 In the right pane of the touchscreen interface, tap the **Slide View** icon  to view the individual scanned images for the selected rack. (Tap  and  to navigate through the slides in the rack. You can view slide images only after the scanner has completed scanning the slide.)

3 The green box on the macro image indicates the scan area, as shown below.



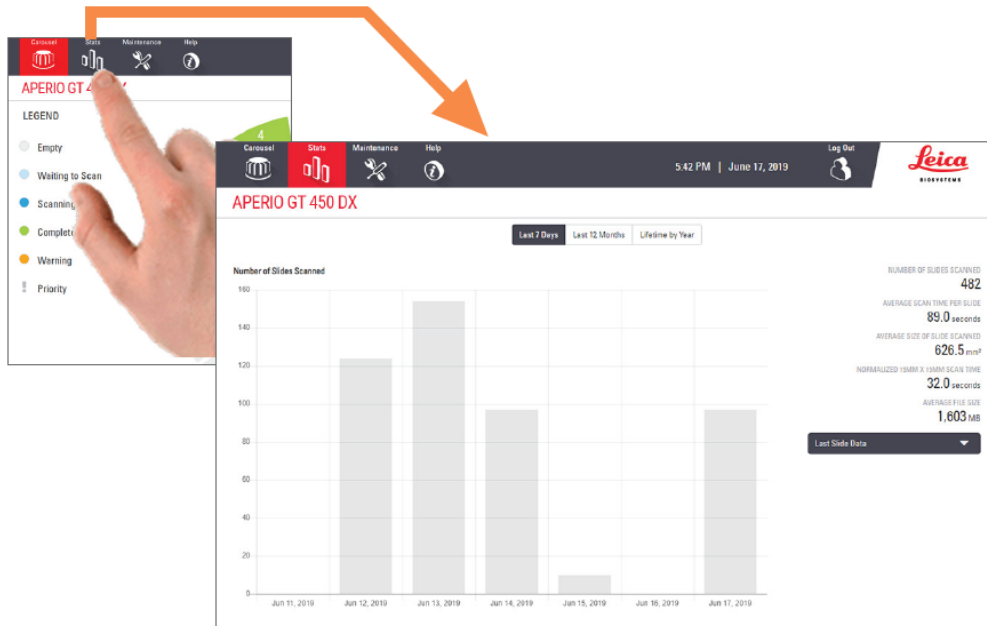
4 Visually check the macro image to ensure all of the tissue is inside the scan area. Tissue that extends outside of the scan area is not included in the scanned image.

Tissue is within the scan area	Tissue is outside the scan area
<p>In the example below, all of the tissue is inside the scan area. This means all of the tissue is included in the scanned image.</p>	<p>In the example below, tissue extends outside the scan area. This means some tissue is not included in the scanned image.</p>
	

5 If any tissue is outside the scan area, you can tap **Scan Entire Slide** to rescan the whole slide.

Scan statistics

The Aperio GT 450 DX provides scan statistics, such as the number of slides or racks scanned per day, per week, etc. Tap **Stats** to view statistics for the **Last 7 Days**, **Last 12 Months**, or **Lifetime by Year**.



5

Maintenance

This chapter contains a maintenance schedule and procedures for maintaining your Aperio GT 450 DX scanner.

Call Leica Biosystems Technical Services if you cannot perform a maintenance routine or if you discover a problem with your scanner.

Before performing maintenance, we recommend you watch the maintenance videos available on the touchscreen. See [Help videos and guides \(on page 26\)](#).



CAUTION: It is important that you perform the maintenance procedures listed below on a regular schedule. Not doing so could result in scanner misalignment which could impair image quality.

In this section:

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Open the scanner cover and access the interior components	55
Recommended daily maintenance	57
Six month maintenance	58
Restart the scanner after interior maintenance	67
Transporting or moving the Aperio GT 450 DX	68
Long term storage	68
Restore scanner	68

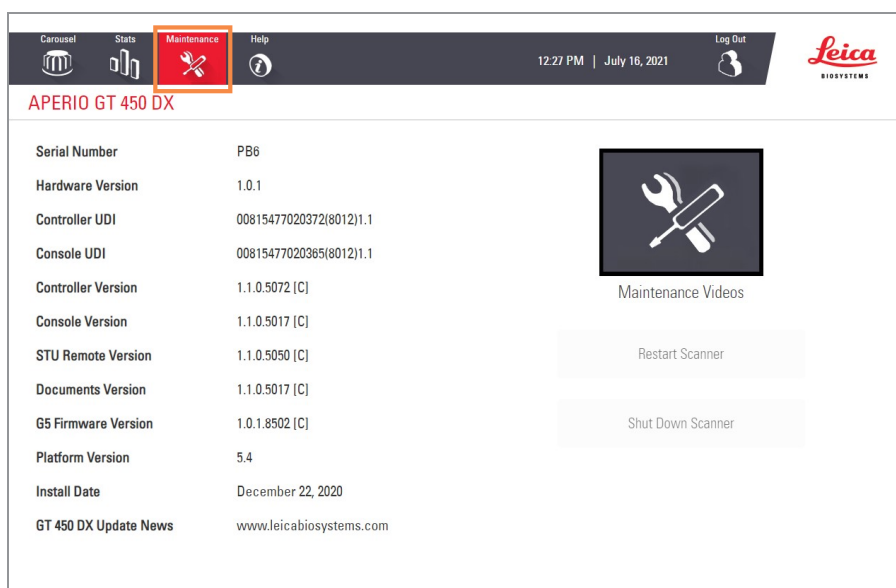
Maintenance schedule

To keep your Aperio GT 450 DX scanner in optimal working condition, follow these maintenance routines.

Frequency	Maintenance Task	Procedure
Daily (Recommended)	Restart the scanner.	Restart the scanner (on page 57)
Every Six Months	1. Clean the objective and Koehler	Clean the objective and Koehler (on page 58)
	2. Clean the stage slide tray	Clean the stage slide tray (on page 62)
	3. Clean the carousel	Clean the carousel (on page 63)
	4. Clean the slide racks	Clean the slide racks (on page 66)
	5. Clean the fan filter	Clean the fan filter (on page 65)
	6. Clean the touchscreen	Clean the touchscreen (on page 67)
	7. Clean the scanner cover	Clean the scanner cover (on page 66)
Once a year	Schedule annual maintenance visit by Leica Biosystems Technical Services.	Call Leica Biosystems Technical Services.

Serial number and firmware version

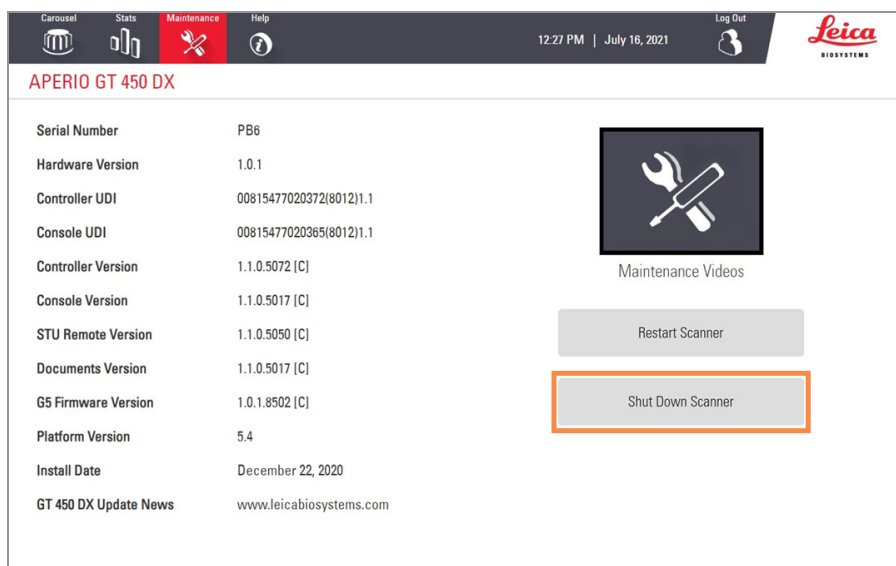
You need the serial number and current software version if you call Leica Biosystems Technical Support. Tap **Maintenance** on the touchscreen interface to view the serial number, firmware version, and other system information.



Shut down the scanner

Use this procedure when you need to turn off the scanner.

- 1 From the touchscreen interface, tap **Maintenance**.



- 2 Tap **Shut Down Scanner**.
- 3 After the touchscreen goes dark, turn the scanner off using the On/Off switch.

Open the scanner cover and access the interior components

Complete these steps to access the inside of the scanner for maintenance or troubleshooting.

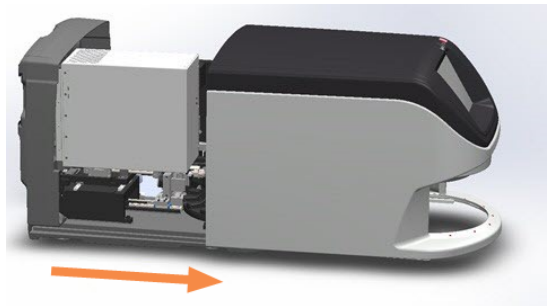


If you are performing maintenance on the scanner, you should first remove any racks from the carousel.

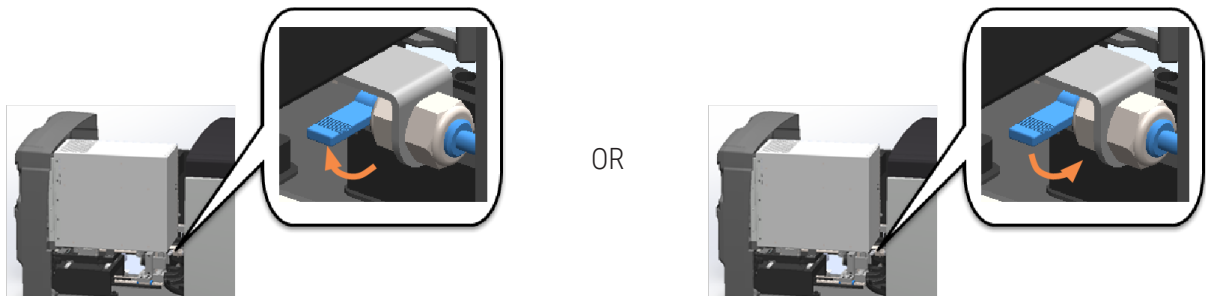
- 1 Shut down the scanner using the steps in [Shut down the scanner \(on page 55\)](#).
- 2 Grasp the cover using the handhold indentations:



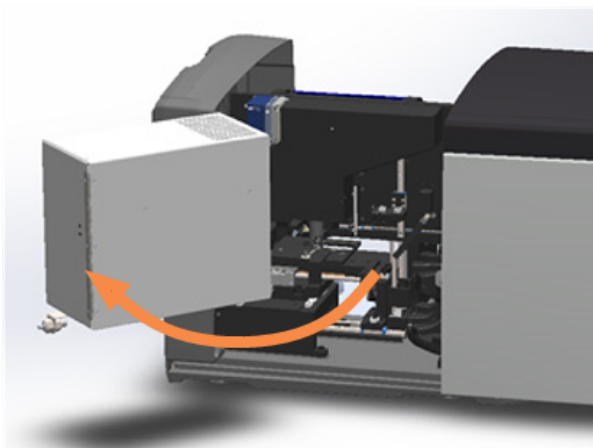
- 3 Slide the cover out until it reaches the point shown below.



- 4 Rotate the VPU latch 180 degrees, as shown below.



- 5 Carefully pivot the VPU outward as shown.



- 6 You can now access the interior components of the scanner for maintenance or troubleshooting purposes.

Recommended daily maintenance

This section provides the recommended daily maintenance procedures.

Restart the scanner

- **Frequency:** daily, and as needed to resolve a scanner issue.

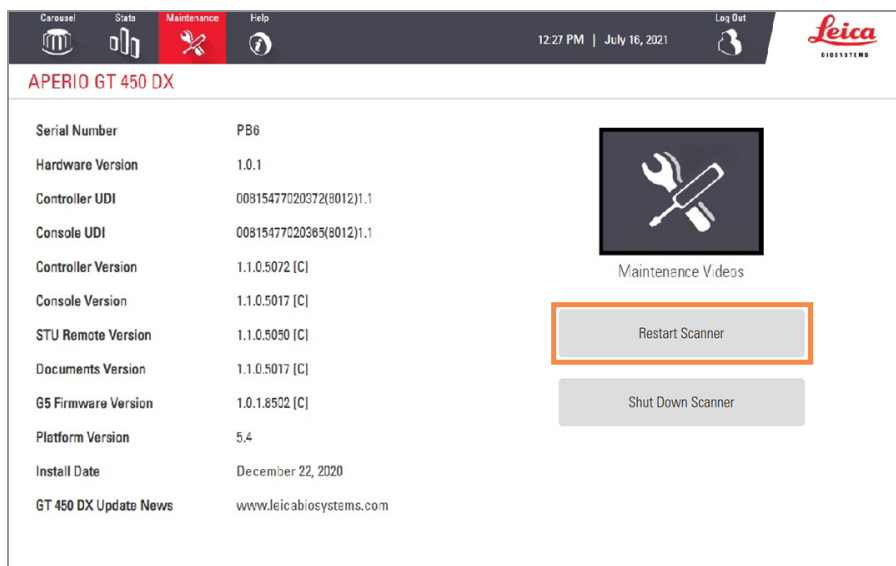
Restarting the scanner initializes the controller and puts the camera, stage, and autoloader in their home positions.



CAUTION: Restarting the scanner with a slide on the stage may damage the slide.

- 1 Before restarting the scanner, ensure the following:
 - All racks are unloaded from the carousel.
 - There are no slides scanning.
 - The system does not have any errors displayed.

- 2 From the touchscreen interface, tap **Maintenance** and tap **Restart Scanner**.



You can use the scanner again after initialization is complete and the Home screen appears.

Six month maintenance

This section provides the six-month maintenance procedures. The purpose of the six month maintenance is to clean the scanner components.

Clean the objective and Koehler

- **Frequency: at least every six months.**



CAUTION: When cleaning the scanner's objective:

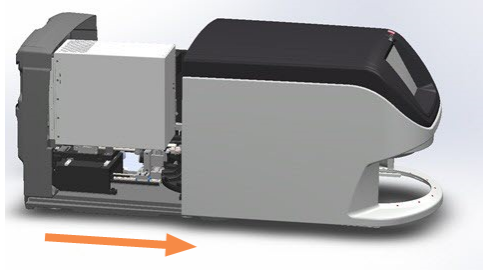
- **Do not remove the objective.**
- **Only use the recommended cleaning cloth and solution on the objective.** Otherwise, this may damage the objective and impact image quality.
- **Do not drag anything (including lens paper) across the lens surface using a lot of pressure.** This may damage the lens.

Materials needed

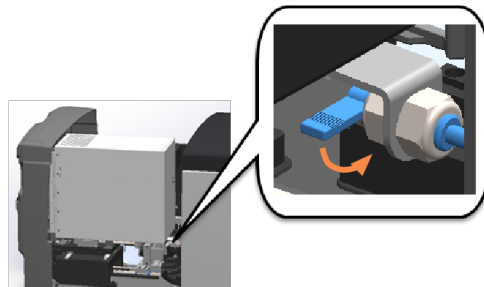
- Texwipe TX404 Absorbond Synthetic Wipers (lens cleaning wipes made of lint-free microfiber)
- Laboratory gloves

To clean the objective and Koehler:

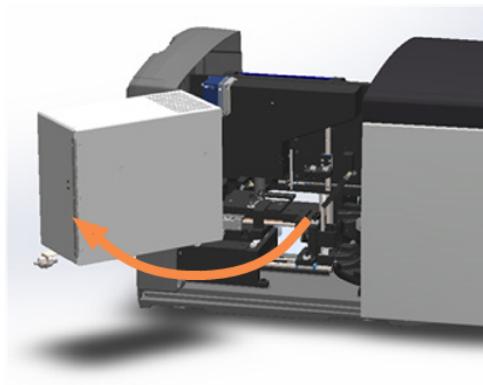
- 1 Ensure the scanner is turned off. (For instructions, see [Turn the scanner on and off \(on page 22\)](#)).
- 2 Open the cover and access the interior:
 - a Open the scanner cover.



- b Rotate the VPU latch.

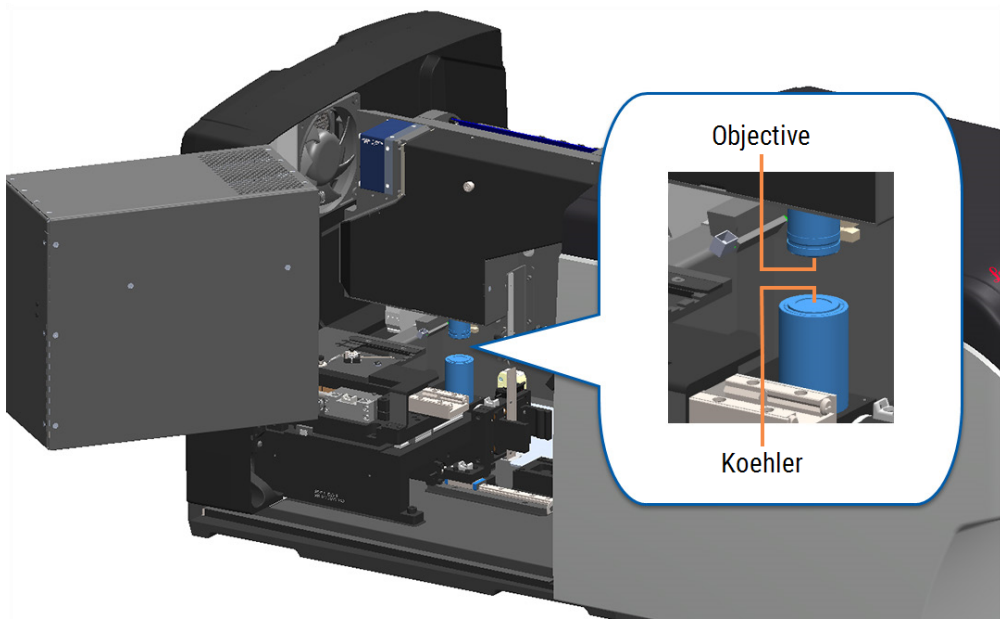


- c Pivot out the VPU.



For detailed steps, see [Open the scanner cover and access the interior components \(on page 55\)](#).

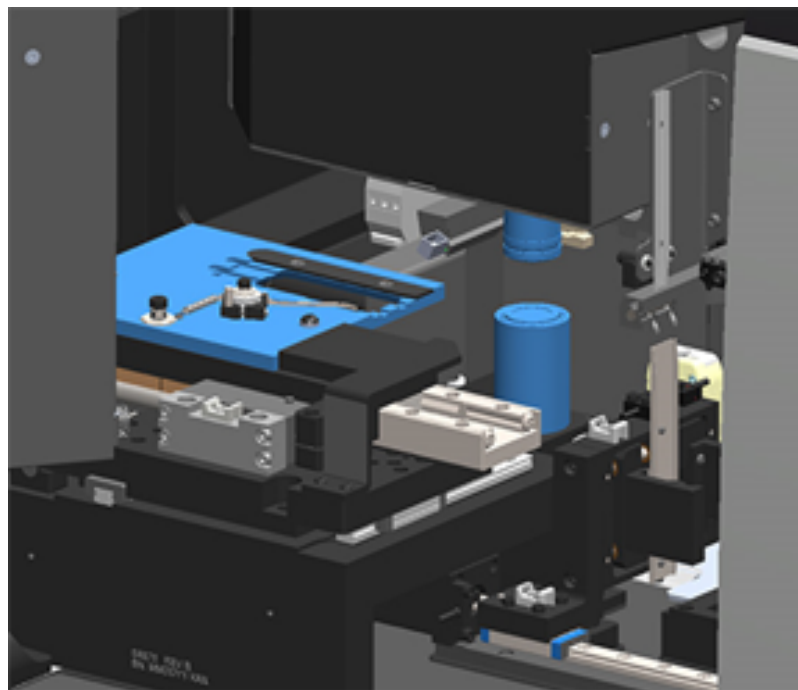
- The objective and Koehler are shown below in blue:



- Manually position the slide stage so that you have clear access to the objective, as shown below.



CAUTION: The objective may move when you're cleaning it.

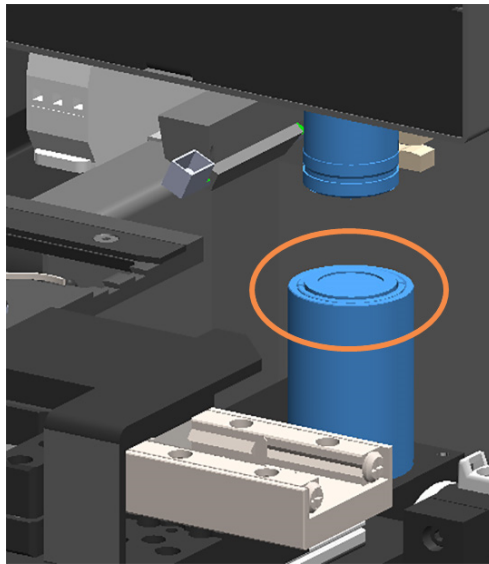


- Wear gloves when cleaning the objective.

- 6 Clean the objective using small circular motions with the recommended lint-free microfiber cloth.



- 7 With a clean lint-free microfiber cloth, use the same technique described in step 6 to clean the Koehler. The Koehler is located below the objective, as shown circled in orange below.



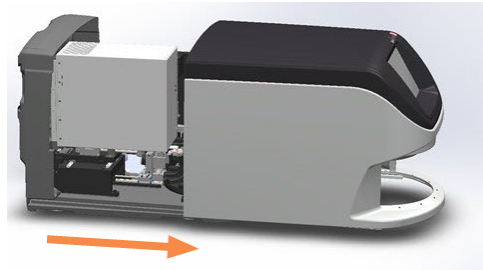
- 8 If you are performing the entire six-month maintenance routine, continue to the next procedure.
- 9 If you are ready to close the scanner cover and restart the scanner, follow the steps in [Restart the scanner after interior maintenance \(on page 67\)](#).

Clean the stage slide tray

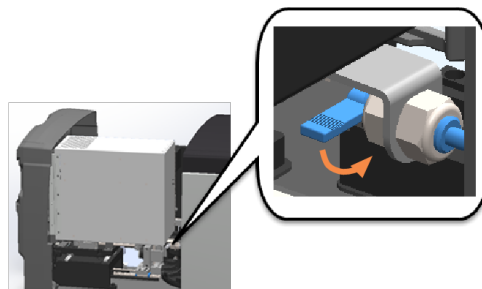
- Frequency: at least every six months.

To clean the stage slide tray:

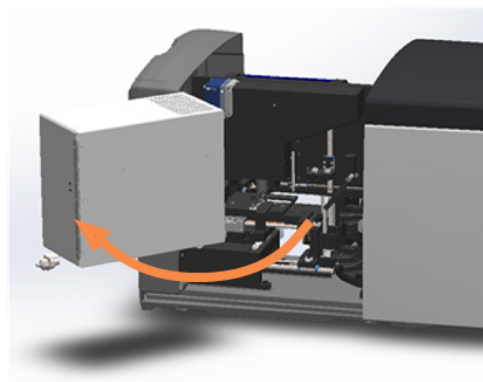
- 1 If the scanner is on, shut down the scanner by following the steps in [Shut down the scanner \(on page 55\)](#).
- 2 Open the cover and access the interior.
 - a Open the scanner cover.



- b Rotate the VPU latch.



- c Pivot out the VPU.



For detailed steps, see [Open the scanner cover and access the interior components \(on page 55\)](#).

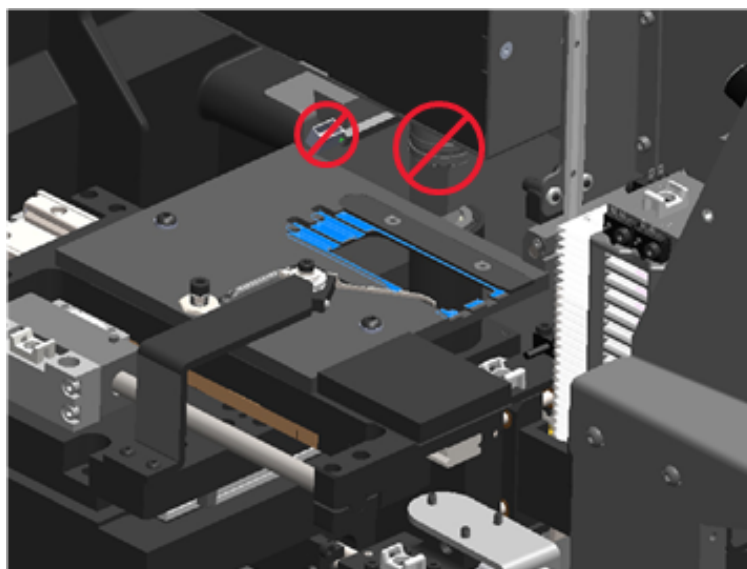


CAUTION: The stage slide tray is not removable. Do not attempt to remove it.

- 3 Gently wipe the slide tray (shown in blue) from back to front with a lint-free cloth.



CAUTION: Be careful not to bump the LED or the objective (highlighted in red).



- 4 Wipe the slide tray again from back to front using a microfiber cloth.
- 5 If necessary, use a gentle solvent such as denatured alcohol to remove any remaining residue.
- 6 If you are performing the entire six-month maintenance routine, continue to the next procedure.
- 7 If you are ready to close the scanner cover and restart the scanner, follow the steps in [Restart the scanner after interior maintenance \(on page 67\)](#).

Clean the carousel

- **Frequency:** at least every six months.

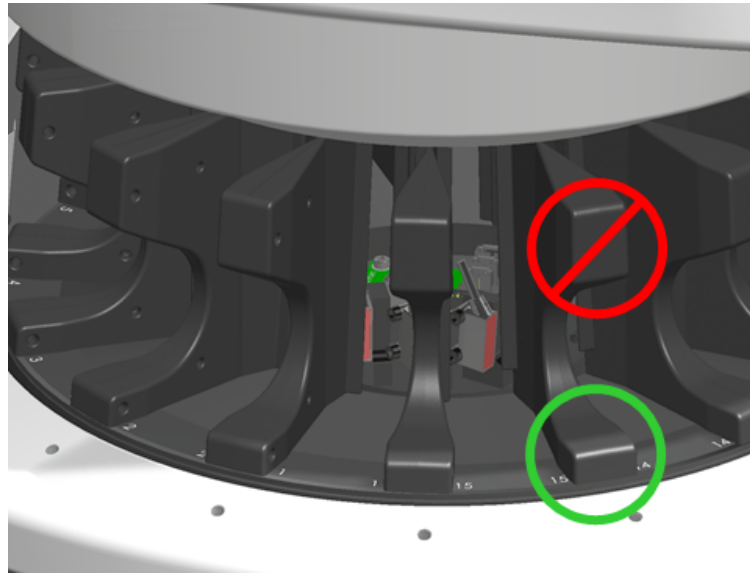
To clean the carousel:

- 1 If the scanner is on, shut down the scanner by following the steps in [Shut down the scanner \(on page 55\)](#).
- 2 Remove all slide racks from the carousel.

- 3 Use a cotton swab soaked in a cleaning solvent, such as denatured alcohol, to thoroughly clean the carousel. Be sure to clean inside the slide rack slots.



CAUTION: When manually rotating the carousel to access the rack slots, grasp the area circled in green. Do not grasp the area circled in red.



- 4 Manually rotate the carousel to access the rear slide rack slots.
- 5 Repeat the cleaning steps until you have cleaned every slide rack slot.
- 6 If you are performing the entire six-month maintenance routine, continue to the next procedure.
- 7 If you are ready to close the scanner cover and restart the scanner, follow the steps in [Restart the scanner after interior maintenance \(on page 67\)](#).

Clean the fan filter

The fan filter is located on the back of the scanner. You may need to pivot the scanner to access the fan filter.

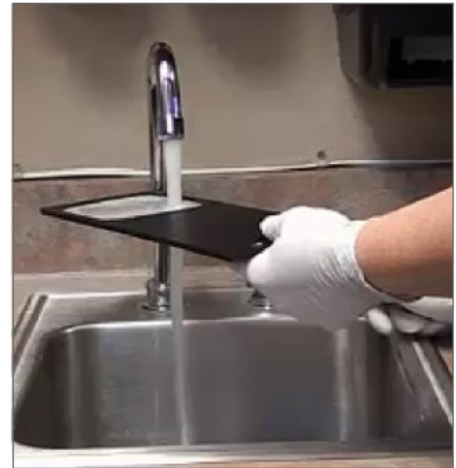
- **Frequency:** at least every six months.

To clean the fan filter:

- 1 If the scanner is on, shut down the scanner by following the steps in [Shut down the scanner \(on page 55\)](#).
- 2 Remove the fan filter by gripping the handle (shown in blue), and sliding it left, right, or up depending on your scanner's configuration.



- 3 With the front of the filter up toward the faucet (as shown below), rinse the filter under warm water.



- 4 Shake off any excess water.
- 5 Dry the filter thoroughly with a clean cloth or a dryer.



CAUTION: Ensure the fan filter is completely dry before inserting it in the scanner.

- 6 When the filter is completely dry, slide it back into position.



- 7 If you are performing the entire six-month maintenance routine, continue to the next procedure.
- 8 If you are ready to close the scanner cover and restart the scanner, follow the steps in [Restart the scanner after interior maintenance \(on page 67\)](#).

Clean the slide racks

- **Frequency: at least every six months.**

To clean the slide racks:

- 1 Check the racks for any damage or accumulated glass dust and mounting media.
- 2 If a rack is damaged, replace it immediately.
- 3 Use compressed air or a cleaning solvent to clean all grooves in the rack, ensuring the racks are clean and smooth. (We recommend Xylene cleaning solvent).
- 4 If you are performing the entire six-month maintenance routine, continue to the next procedure.
- 5 If you are ready to close the scanner cover and restart the scanner, follow the steps in [Restart the scanner after interior maintenance \(on page 67\)](#).

Clean the scanner cover

- **Frequency: at least every six months.**

To clean the scanner cover:

- 1 Wipe the outer cover of the scanner with a damp cloth.
- 2 Immediately dry the cover using a dry cloth.

Clean the touchscreen

- Frequency: at least every six months.

To clean the touchscreen:

- 1 Spray standard monitor cleaner directly on a clean non-scratch cloth. (Avoid spraying the touchscreen directly to ensure that no liquid gets inside the scanner).
- 2 Thoroughly wipe down the touchscreen with the cloth.
- 3 If you are ready to close the scanner cover and restart the scanner, follow the steps in [Restart the scanner after interior maintenance \(on page 67\)](#).

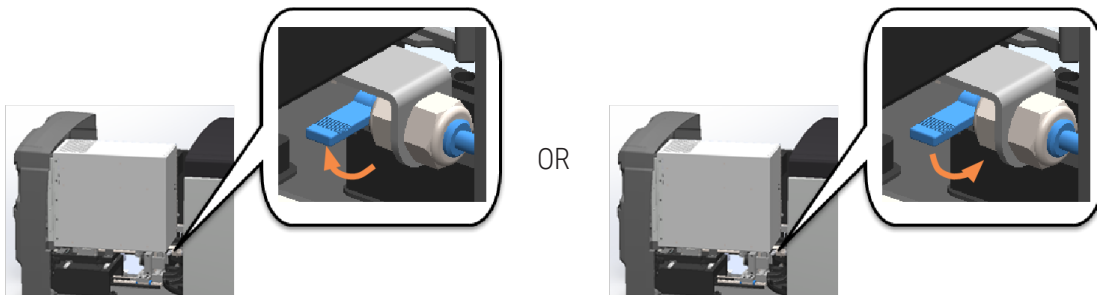
Restart the scanner after interior maintenance

Follow these steps to restart the scanner after you have accessed the scanner interior.

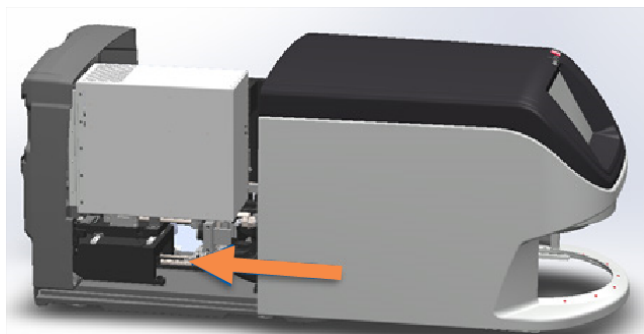
- 1 Pivot the VPU into the closed position.



- 2 Secure the VPU in place by rotating the VPU latch 180 degrees.



- 3 Slide the scanner cover back into position so that it is aligned with the rear latches and clicks closed.



- 4 Turn on the scanner.

Transporting or moving the Aperio GT 450 DX

If you need to relocate the scanner, contact Leica Biosystems Technical Services. Be aware that moving the scanner yourself may void the hardware warranty.

Long term storage

If you are not going to use the scanner for a considerable amount of time, shut it down and unplug it. To shut down the scanner, follow the steps in [Shut down the scanner \(on page 55\)](#).

If you want to store the scanner, contact Leica Biosystems Technical Services for assistance.

For information on disposing of the scanner, see [Disposal of the Aperio GT 450 DX \(on page 17\)](#).

Restore scanner

If you need to restore the scanner to its original configuration, contact Leica Biosystems Technical Services for assistance.

6

Troubleshooting

This chapter contains information and instructions to help you resolve troubleshooting issues with your scanner. For issues with the Scanner Administration Manager, see the *Aperio GT 450 DX IT Manager and Lab Administrator's Guide*.



WARNING: Do not attempt to perform troubleshooting procedures not shown in this chapter. For additional troubleshooting assistance, contact Leica Biosystems Technical Services.

In this section:

Personal protective equipment	70
Red blinking lights on carousel	70
How to use the troubleshooting steps	70
Perform a safe restart after an error	71
Error codes and solutions	75
Rack warnings and solutions	91
Symptoms and solutions	100

Personal protective equipment

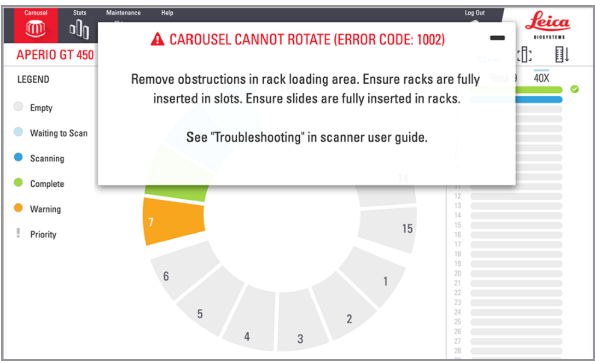

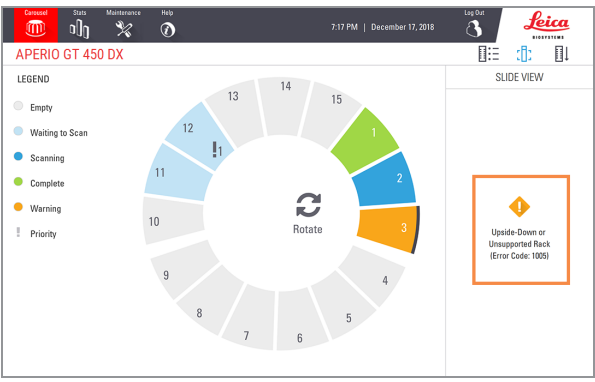
If you need to access the interior of the scanner while troubleshooting an issue, follow the policies and procedures of your institution, including the use of personal protective equipment (PPE).

Red blinking lights on carousel

If the lights in front of the carousel are blinking red, the scanner needs attention. If there is an issue with a rack in the rack loading area, the light below that rack position blinks red. See the next section for more details on resolving scanner issues.

How to use the troubleshooting steps

The following table describes how to find the appropriate troubleshooting section:

Type of issue	Scanner status	Steps to resolve the issue
<p>An error message box similar to this example appears on the touchscreen interface:</p> 	<p>Until the error is resolved:</p> <ul style="list-style-type: none"> You cannot interact with the carousel. The scanner cannot continue scanning. 	<ol style="list-style-type: none"> You can tap the  to minimize the message box. This enables you to view the rack status and access the Help resources. See Error codes and solutions (on page 75) for steps to resolve the specific error.
<p>A rack warning and error message similar to this example appears on the touchscreen interface:</p> 	<p>There is a problem with the rack or one or more slides in the rack.</p> <p>The scanner can continue scanning other racks or slides.</p>	<p>See Rack warnings and solutions (on page 91) for steps to resolve the specific error.</p>

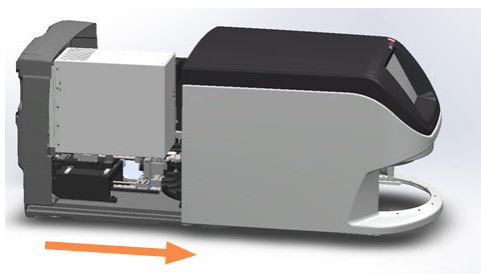
Type of issue	Scanner status	Steps to resolve the issue
No message or warning appears on the touchscreen interface, but there is a problem with the scanner. For example, the scanner does not power up when you turn it on.	Varies with the situation.	See Symptoms and solutions (on page 100) .

Perform a safe restart after an error

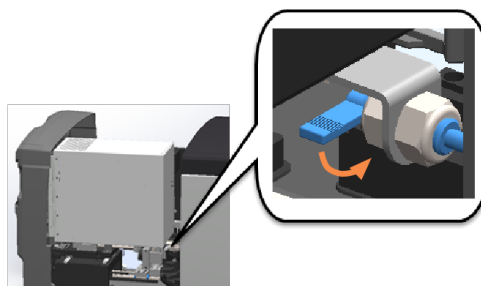
Some procedures in this chapter ask you to restart the scanner. Restarting the scanner initializes the controller and puts the stage and autoloader in their home positions. Before restarting the scanner, you need to ensure there is no slide on the stage.

Follow these steps to safely restart the scanner after an error:

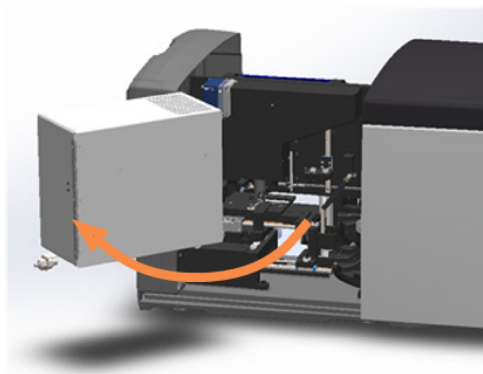
- 1 Open the cover and access the interior:
 - a Open the scanner cover.



- b Rotate the VPU latch.



- c Pivot out the VPU.



For detailed steps, see [Open the scanner cover and access the interior components \(on page 55\)](#).

- 2 Check if there is a slide on the stage or partially on the stage.

Figure 6-1: Slide on the stage

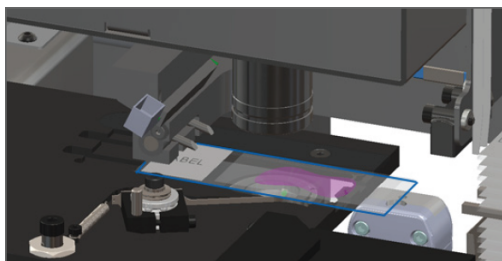
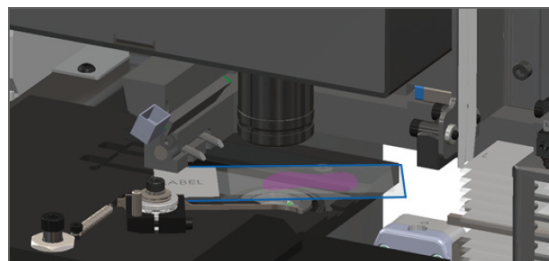
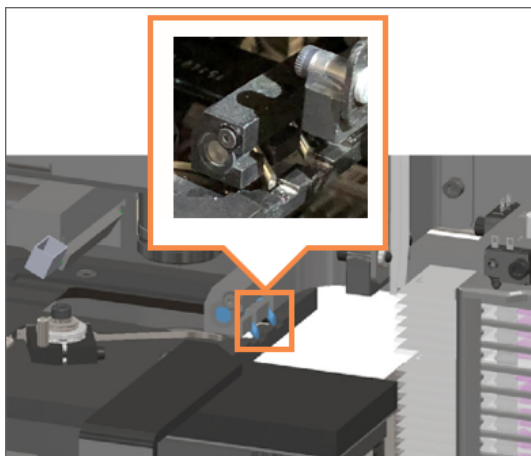


Figure 6-2: Slide partially on the stage

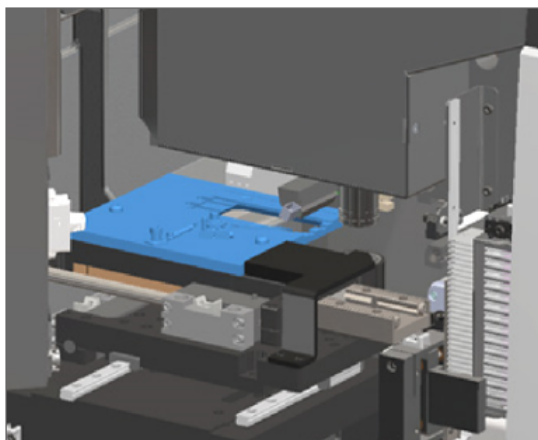


CAUTION: Restarting the scanner with a slide on the stage may damage the slide.

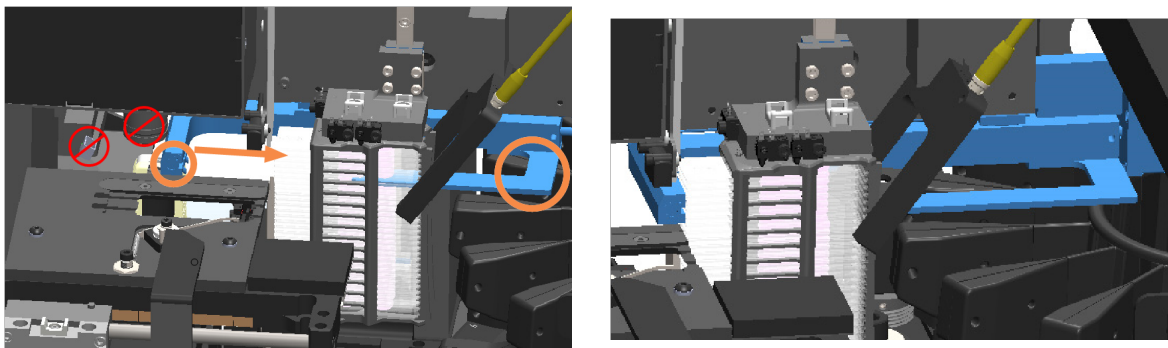
- 3 If there is a slide on the stage, carefully remove it from the stage without touching the surrounding components.
- 4 If the pusher is extended, return the pusher to the safe (retracted) position.
 - a Align the pusher teeth with the slide stage grooves.



- b Slide the stage to the rear of the scanner, as shown.

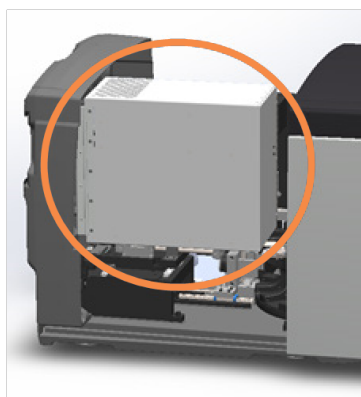


- c Slide the pusher to the front of the scanner, as shown in the rightmost image below. Hold the pusher in one of the areas circled below. Avoid touching the LED and objective.

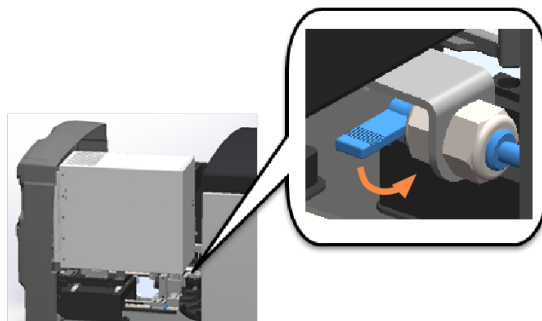


- 5 Close the scanner cover.

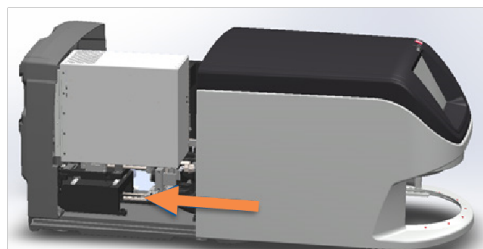
- a Pivot the VPU into place.



- b Rotate the VPU latch.



- c Slide the cover until it clicks closed.



For detailed steps, see [Restart the scanner after interior maintenance \(on page 67\)](#).

- 6 Tap **Maintenance** on the touchscreen interface, then tap **Restart Scanner**. Wait for the scanner to complete the restart process.

Error codes and solutions

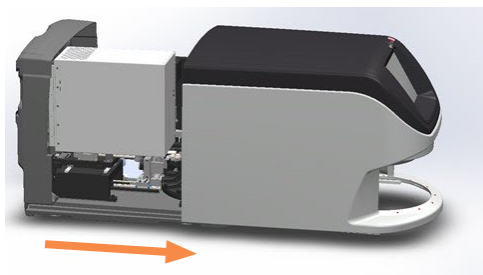
If an error box appears on the touchscreen, you must resolve the issue before the scanner can continue scanning. This section contains error codes and messages with troubleshooting steps.

1000: Internal error

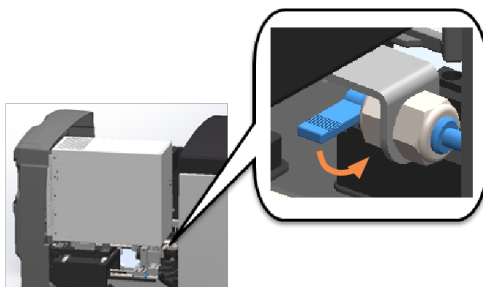
- **Cause:** An unexpected event occurred in the system that prevents it from continuing operation.

Follow these steps:

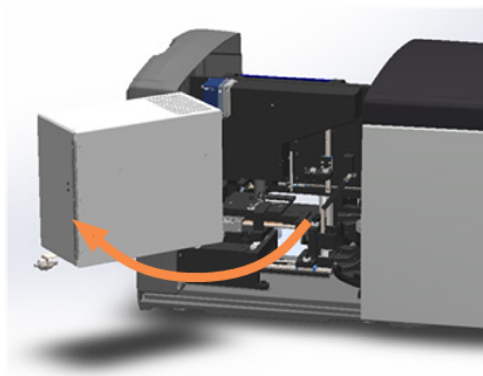
- 1 Open the cover and access the interior:
 - a Open the scanner cover.



- b Rotate the VPU latch.



- c Pivot out the VPU.



For detailed steps, see [Open the scanner cover and access the interior components \(on page 55\)](#).

- 2 Take photos of any obstructions. Leica Biosystems Technical Services may request the photos if you need additional assistance after completing the steps below.
- 3 Check if there is a slide on the stage or partially on the stage.

Figure 6-3: Slide on the stage

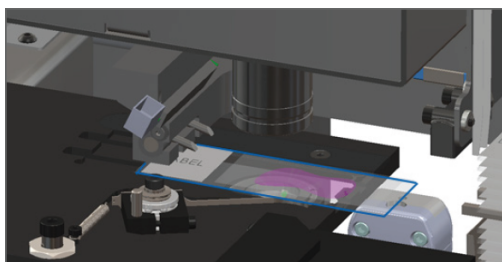
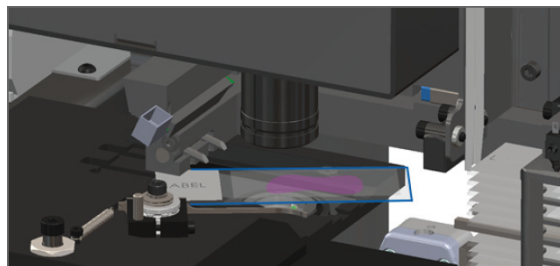
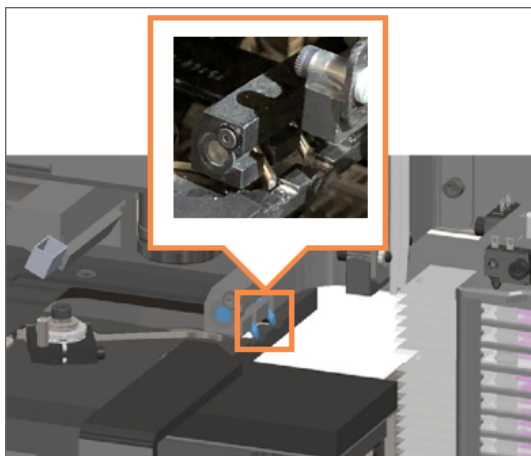


Figure 6-4: Slide partially on the stage

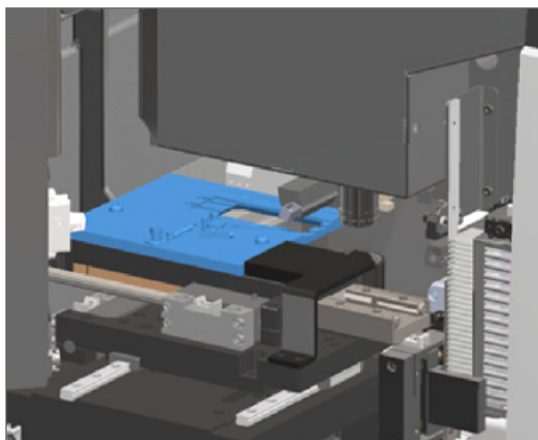


CAUTION: Restarting the scanner with a slide on the stage may damage the slide.

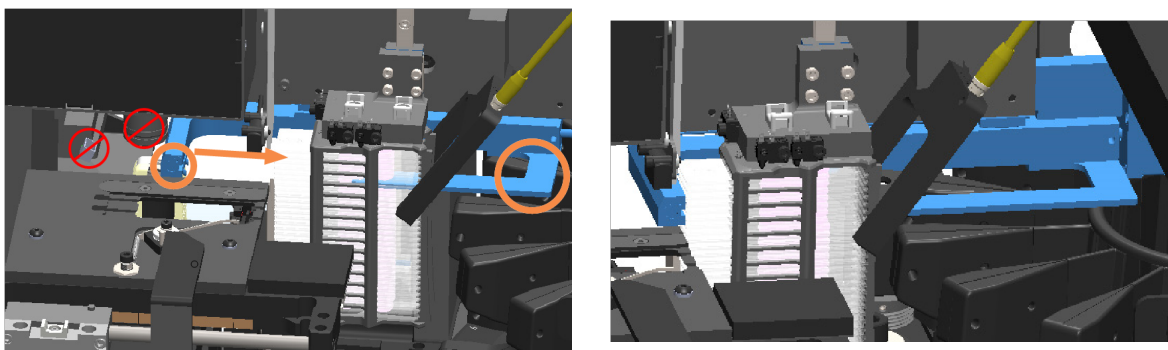
- 4 If there is a slide on the stage, carefully remove it from the stage without touching the surrounding components.
- 5 If the pusher is extended, return the pusher to the safe (retracted) position.
 - a Align the pusher teeth with the slide stage grooves.



- b Slide the stage to the rear of the scanner, as shown.

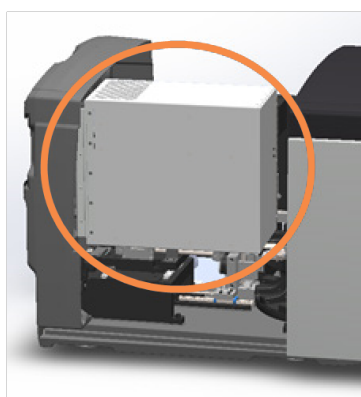


- c Slide the pusher to the front of the scanner, as shown in the rightmost image below. Hold the pusher in one of the areas circled below. Avoid touching the LED and objective.

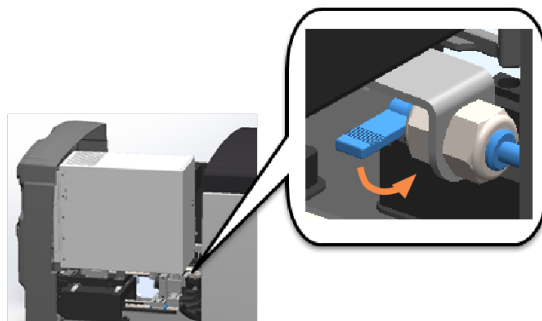


- 6 Close the scanner cover:

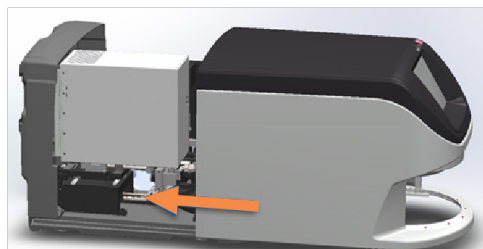
- a Pivot the VPU into place.



- b Rotate the VPU latch.



- c Slide the cover until it clicks closed.



For detailed steps, see [Restart the scanner after interior maintenance \(on page 67\)](#).

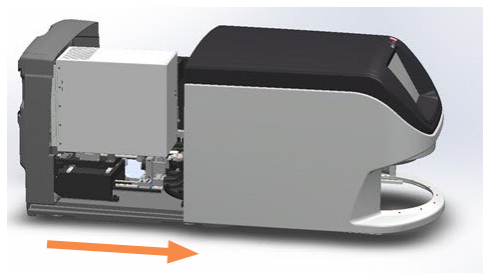
- 7 Tap **Restart Scanner** on the touchscreen interface, and wait for the scanner to complete the restart process.
- 8 If the issue persists, call Leica Biosystems Technical Services.

1001: Scanner cannot initialize

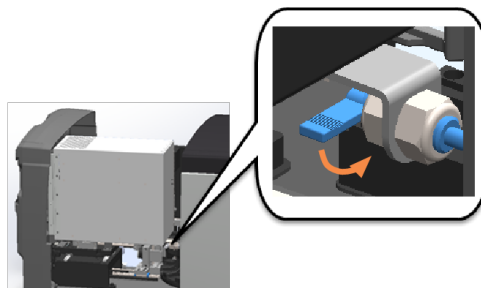
- **Cause:** The scanner cannot complete the initialization process.

Follow these steps:

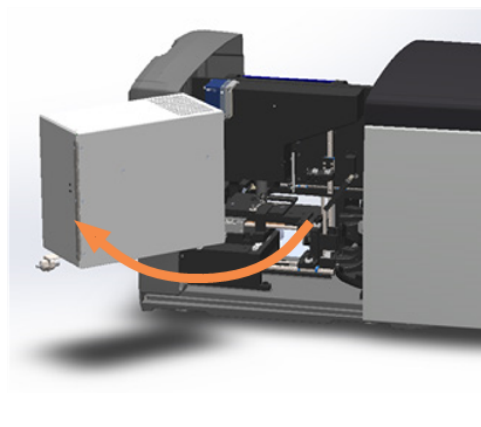
- 1 Open the cover and access the interior:
 - a Open the scanner cover.



- b Rotate the VPU latch.



- c Pivot out the VPU.



For step details, see [Open the scanner cover and access the interior components \(on page 55\)](#).

- 2 Check if there is a slide on the stage or partially on the stage.

Figure 6-5: Slide on the stage

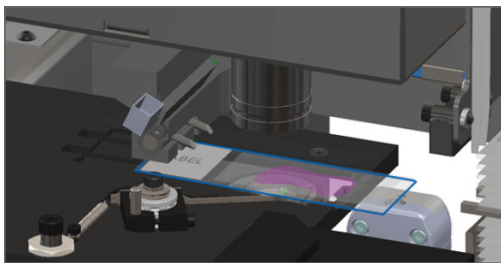
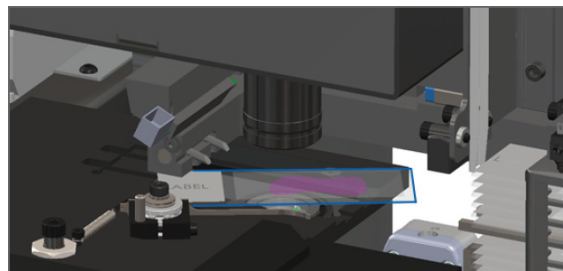


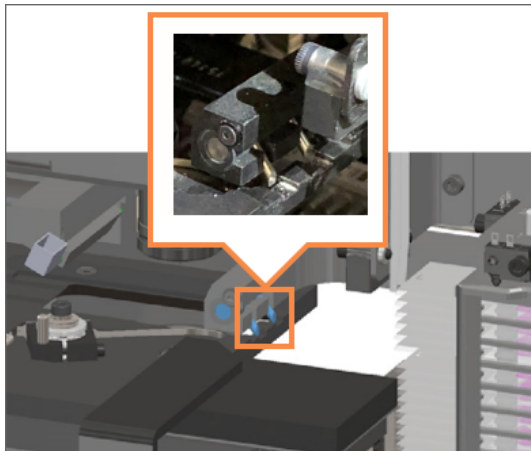
Figure 6-6: Slide partially on the stage



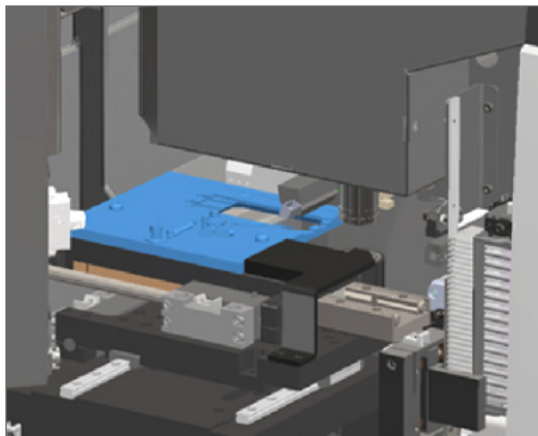
CAUTION: Restarting the scanner with a slide on the stage may damage the slide.

- 3 If there is a slide on the stage, carefully remove it from the stage without touching the surrounding components.

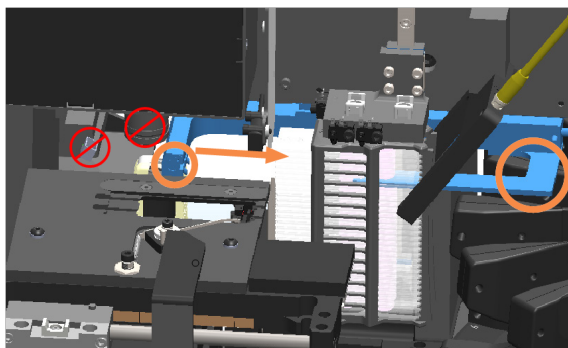
- 4 If the pusher is extended, return the pusher to the safe (retracted) position.
 - a Align the pusher teeth with the slide stage grooves.



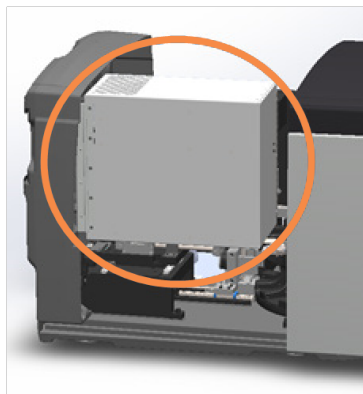
- b Slide the stage to the rear of the scanner, as shown.



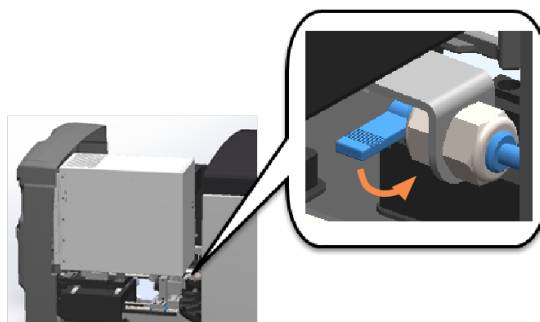
- c Slide the pusher to the front of the scanner, as shown in the rightmost image below. Hold the pusher in one of the areas circled below. Avoid touching the LED and objective.



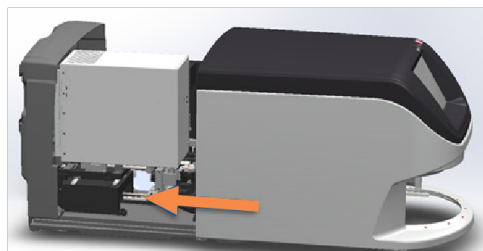
- 5 Close the scanner cover:
 - a Pivot the VPU into place.



- b Rotate the VPU latch.



- c Slide the cover until it clicks closed.



For step details, see [Restart the scanner after interior maintenance \(on page 67\)](#).

- 6 Shut down the scanner using the steps in [Shut down the scanner \(on page 55\)](#).
- 7 Turn on the scanner and wait for the initialization process to complete.
- 8 If the issue persists, call Leica Biosystems Technical Services.

1002: Carousel cannot rotate

- **Cause:** Something is blocking the light curtain.

Follow these steps in order until the issue is resolved and the error message closes:

- 1 Check the rack loading area and pinch points for any unexpected object.

Figure 6-7: Rack loading area with light curtain highlighted

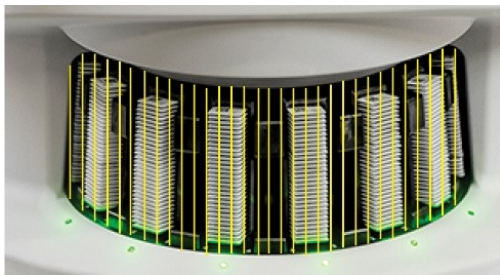


Figure 6-8: Pinch points on either edge of rack loading area



- 2 Ensure the racks in the rack loading area are inserted correctly:

Figure 6-9: Leica logo facing out and up



Figure 6-10: Rack inserted fully into the rack slot



- 3 When you insert the rack, ensure the rack position and the rack status light turns light blue (waiting to scan):

Figure 6-11: Empty rack slot

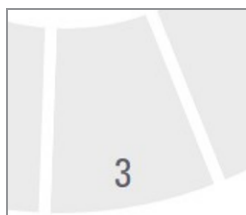
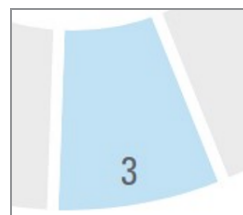


Figure 6-12: Rack inserted and waiting to scan



- 4 Ensure all the slides are fully inserted so that they touch the back of the rack.



- 5 If there are no obstructions and the carousel still does not rotate, restart the scanner. See [Perform a safe restart after an error \(on page 71\)](#).
- 6 If the issue persists, contact Leica Biosystems Technical Services.

1003: Carousel cannot rotate. Carousel pinch point obstructed.

- **Cause:** There is an obstruction at a pinch point.

Follow these steps in order until the issue is resolved and the error message closes:

- 1 Check the rack loading area and pinch points for any unexpected object that may break the light curtain.

Figure 6-13: Rack loading area with light curtain highlighted

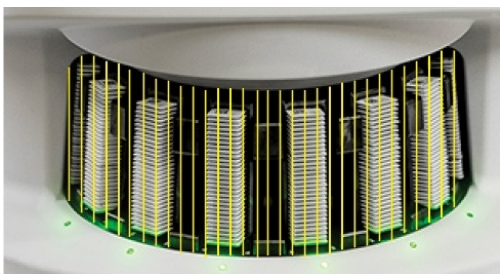


Figure 6-14: Pinch points on either edge of rack loading area



- 2 If there are no obstructions and the carousel still does not rotate, restart the scanner by following the steps in [Perform a safe restart after an error \(on page 71\)](#).
- 3 If the issue persists, contact Leica Biosystems Technical Services.

1007: Internal storage full. Cannot send images to DICOM converter.

- **Cause:** If the internal storage is full, the system cannot send the images to the DICOM converter.

The Lab Administrator should perform these steps:

- 1 Ensure the LAN cables are connected at the scanner LAN port and at the Aperio GT 450 SAM DX server.
- 2 Do not restart the scanner. If you restart the scanner, the scanned data is lost, and users have to rescan their slides.
- 3 Check the connectivity from the scanner to the DICOM server, and from the DICOM server to your site's image storage location.
- 4 Ensure the DICOM server is running. Restart the DICOM server if necessary.
- 5 Check if your site's image storage location is full.
- 6 Check if there is a permissions or account problem with the account running the DICOM server.
- 7 If the issue persists, consult with your organization's IT professionals prior to calling Leica Biosystems Technical Services.

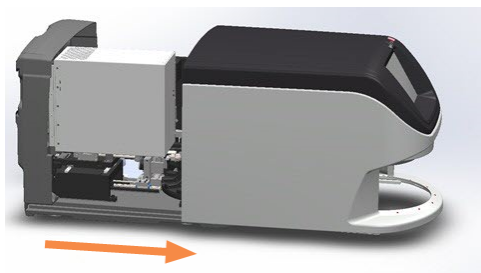
When the issue is resolved, if you have not restarted the scanner, the scanner starts transferring the slide images to the DICOM server.

2000: Slide handling error at slide stage, rack, or pusher.

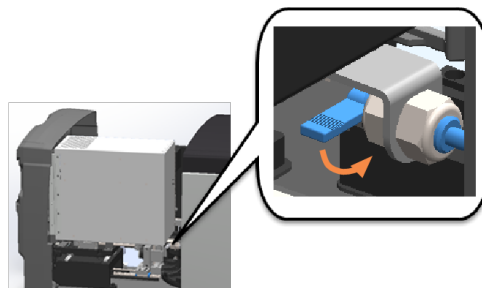
- **Cause:** There is an obstruction at the slide stage, rack, or pusher.

Follow these steps in order until the issue is resolved:

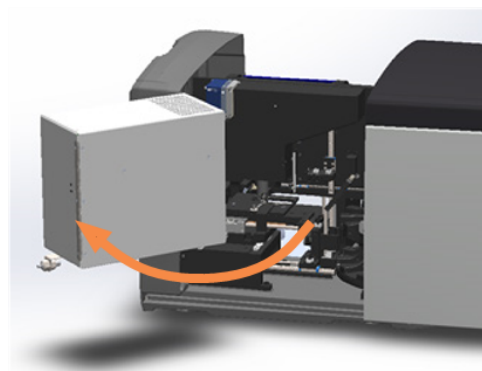
- 1 Open the cover and access the interior:
 - a Open the scanner cover.



- b Rotate the VPU latch.



- c Pivot out the VPU.



For detailed steps, see [Open the scanner cover and access the interior components \(on page 55\)](#).

- 2 Take photos of the obstruction. Leica Biosystems Technical Services may request the photos if you need additional assistance after completing the steps below.
- 3 Check if there is a slide on the stage or partially on the stage.

Figure 6-15: Slide on the stage

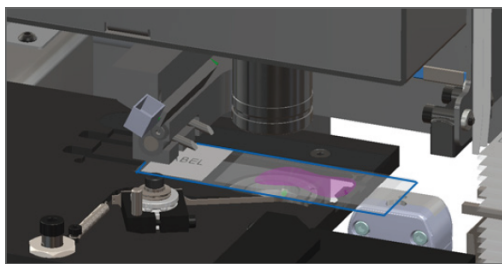
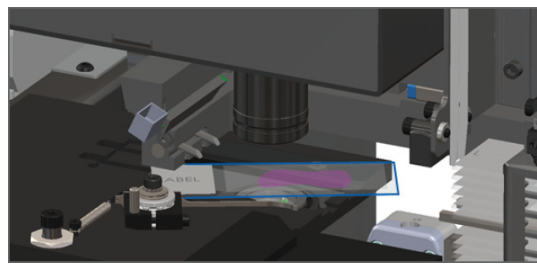


Figure 6-16: Slide partially on the stage



CAUTION: Restarting the scanner with a slide on the stage may damage the slide.

- 4 If there is a slide on the stage, carefully remove it from the stage without touching the surrounding components.

- 5 Check the slide stage, rack, and pusher area for an obstruction.

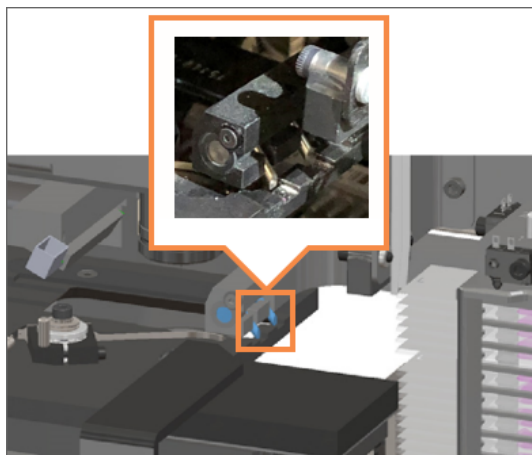


- 6 If possible, carefully remove the slide that is causing the obstruction.

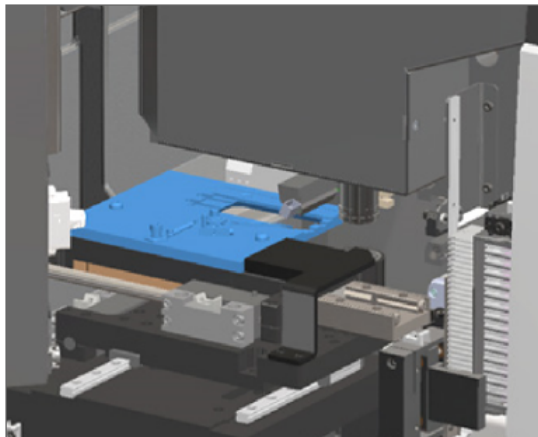


WARNING: Do not attempt to recover broken slides. Call Leica Biosystems Technical Services.

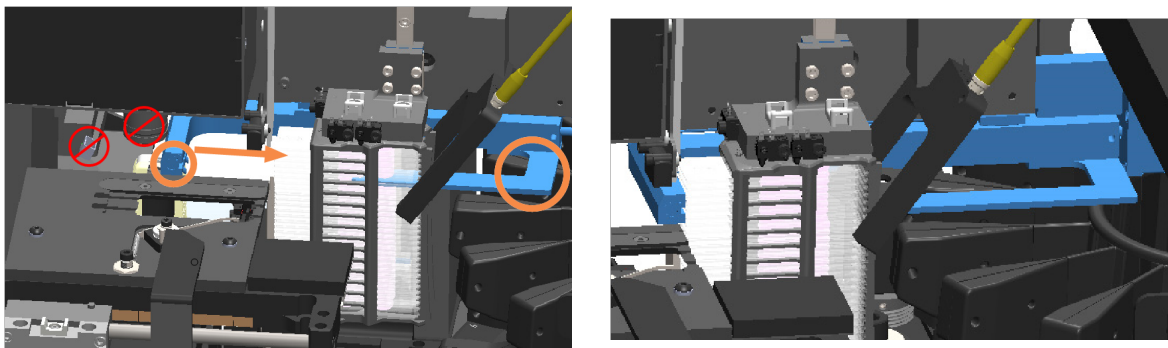
- 7 Check the slide for preparation issues, such as over-hanging coverslips and label issues.
 - If there are no obvious preparation issues, re-insert the slide in an available rack after you restart the scanner.
 - If there are slide preparation issues, correct the slide issues before rescanning.
- 8 If the pusher is extended, return the pusher to the safe (retracted) position.
 - a Align the pusher teeth with the slide stage grooves.



- b Slide the stage to the rear of the scanner, as shown.

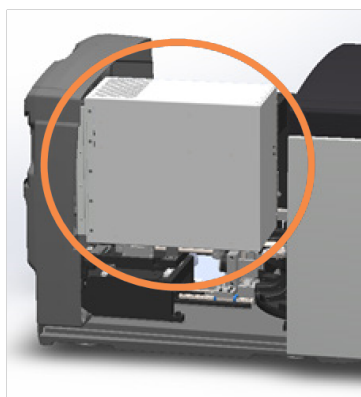


- c Slide the pusher to the front of the scanner, as shown in the rightmost image below. Hold the pusher in one of the areas circled below. Avoid touching the LED and objective.

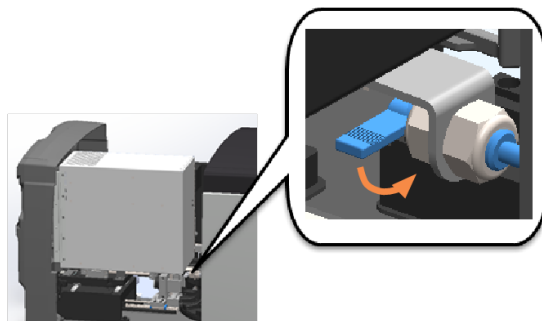


- 9 Close the scanner cover:

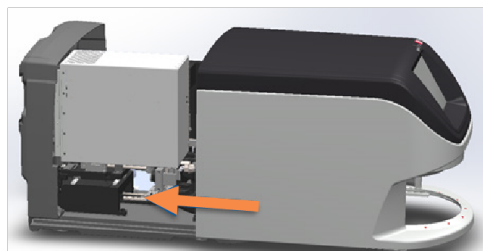
- a Pivot the VPU into place.



- b Rotate the VPU latch.



- c Slide the cover until it clicks closed.



For detailed steps, see [Restart the scanner after interior maintenance \(on page 67\)](#).

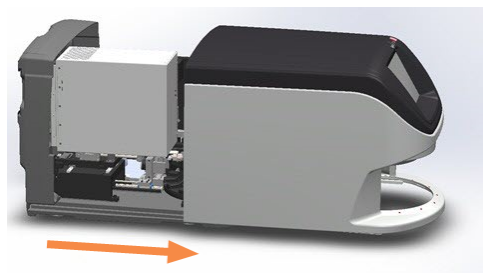
- 10 Tap **Restart Scanner** on the touchscreen interface, and wait for the scanner to complete the restart process.
- 11 If the issue persists, contact Leica Biosystems Technical Services.

2001: Slide handling error at rack gripper, lift, or carousel.

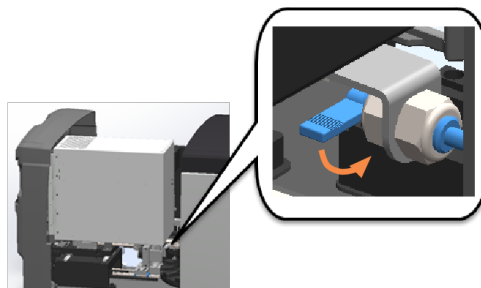
- **Cause:** There is an obstruction near the rack gripper, lift, or carousel.

Follow these steps until the issue is resolved:

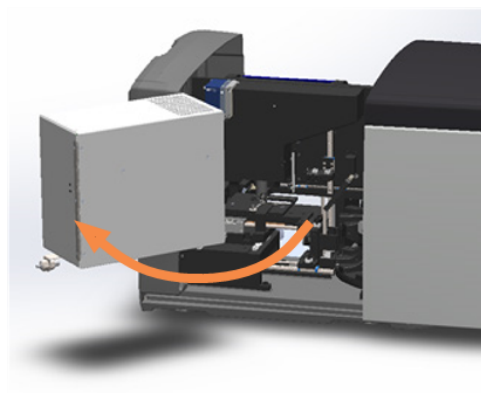
- 1 Open the cover and access the interior:
 - a Open the scanner cover.



- b Rotate the VPU latch.



- c Pivot out the VPU.



For detailed steps, see [Open the scanner cover and access the interior components \(on page 55\)](#).

- 2 Take photos of the obstruction.



WARNING: Do not attempt to recover broken slides. Call Leica Biosystems Technical Services.

- 3 Check if there is a slide on the stage or partially on the stage.

Figure 6-17: Slide on the stage

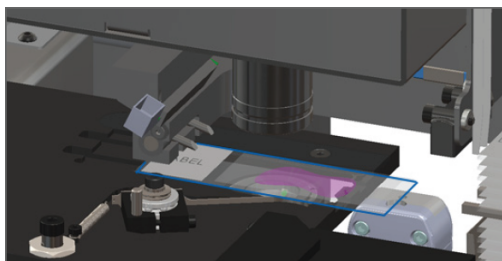
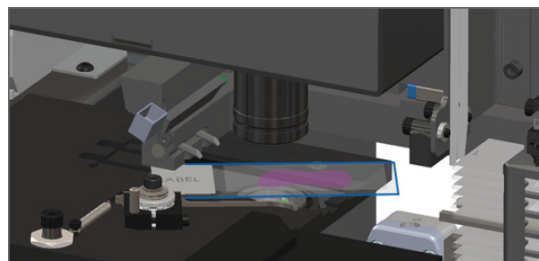


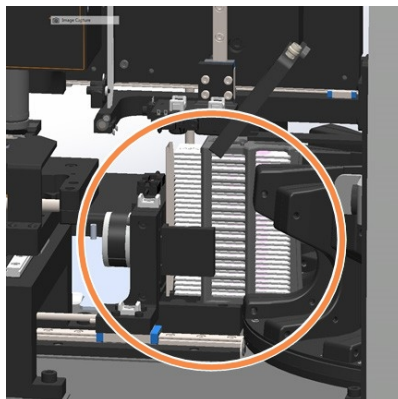
Figure 6-18: Slide partially on the stage



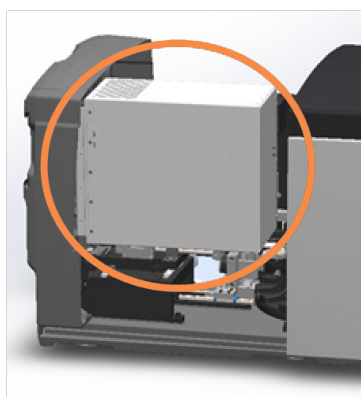
CAUTION: Restarting the scanner with a slide on the stage may damage the slide.

- 4 If there is a slide on the stage, carefully remove it from the stage without touching the surrounding components.

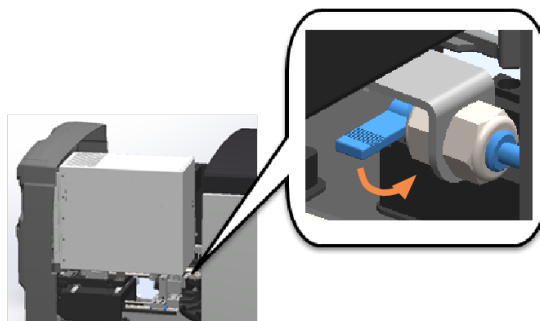
- 5 Check the rack gripper, lift, and carousel area for an obstruction.



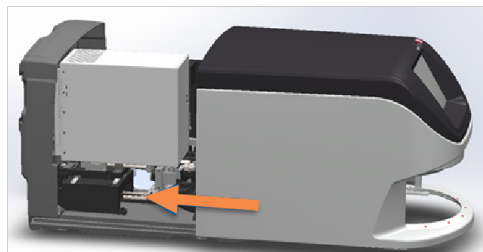
- 6 Close the scanner cover:
 - a Pivot the VPU into place.



- b Rotate the VPU latch.



- c Slide the cover until it clicks closed.



For detailed steps, see [Restart the scanner after interior maintenance \(on page 67\)](#).

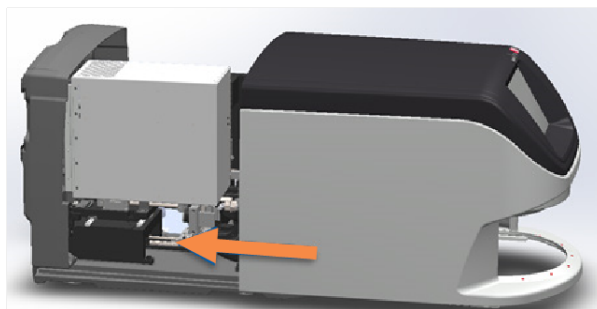
- 7 Contact Leica Biosystems Technical Services.

9000: Scanner cover is open

- The scanner cover is not closed completely.

Follow these steps until the issue is resolved:

- 1 Slide the cover to the closed position, making sure the cover aligns with rear latches and clicks closed:



Rack warnings and solutions

Rack warnings indicate a problem with the rack or one or more slides in the rack. The scanner can continue scanning when there is a rack warning.



CAUTION: If you need to remove a rack before all slides in the rack are scanned, first take note of the rack and slide status. After you remove a rack, the rack's scan status is no longer available on the Home screen.

1005: Cannot process rack

- **Cause:** There is an issue with a rack that prevents scanning.

Follow these steps in order until the issue is resolved:

- 1 Rotate the rack to the rack loading area. See [Rotate a rack to the rack loading area \(on page 41\)](#).
- 2 Ensure the rack is inserted correctly:

Figure 6-19: Leica logo facing out and up



Figure 6-20: Rack inserted fully into the carousel



- 3 Remove the rack and check the following:
 - You are using a supported rack. See [Slide racks supported \(on page 27\)](#).
 - The rack is not damaged or modified.
- 4 Verify the error only occurs on one rack.
 - If the error only occurs on one rack, go to step 5.
 - If the error occurs on multiple racks, contact Leica Biosystems Technical Services.
- 5 If you verified the rack is a supported and undamaged rack, reinsert it into the carousel for scanning.
- 6 If the scanner still cannot process the rack, attempt to restart the scanner by following the steps in [Perform a safe restart after an error \(on page 71\)](#).
- 7 If the issue persists, remove the rack and contact Leica Biosystems Technical Services.

1006: Cannot process one or more slides in rack

- **Cause:** There is an issue with one or more slides in the rack.

Follow these steps in order until the issue is resolved:

- 1 On the touchscreen, tap the rack position that has the error, and tap **Rack View** to identify which slides have the error.
- 2 Tap **Slide View** to view the macro image of the slide and check for an error message.
- 3 Go to the section that matches the slide error:
 - [Tilted slide\(s\) \(on page 94\)](#)
 - [No barcode \(on page 94\)](#)
 - [No tissue \(on page 95\)](#)
 - [No macro focus \(on page 95\)](#)
 - [Image quality \(on page 96\)](#)
 - [Image transfer error – pending retry \(on page 97\)](#)
 - [Aborted \(on page 97\)](#)
- 4 If the issue persists after following the relevant procedure, keep the slide available for inspection and contact Leica Biosystems Technical Services.

Slide errors and solutions

If there is an issue scanning a slide, one of the following error messages appears in Slide View. Follow the steps in order until the issue is resolved. If you follow the steps and the issue persists, contact Leica Biosystems Technical Services.



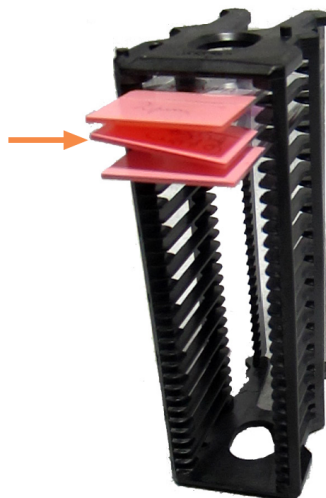
You can temporarily hide some error messages by tapping the x in the top-right corner. This enables you to view the macro image.

Tilted slide(s)

- **Cause:** The slide is tilted between two or more slots in the rack and cannot be scanned.

Follow these steps in order:

- 1 Remove the rack from the carousel, and locate the tilted slide:



- 2 Insert the slide in a new rack for scanning, ensuring it sits level horizontally in one slot.
- 3 Insert the rack into an empty rack slot for scanning.

No barcode

- **Cause:** The scanner does not detect a barcode on the slide.

Follow these steps in order until the issue is resolved:

- 1 Check the slides and rack are inserted correctly:
 - Slide label facing out and up.
 - Leica logo facing out and up.
 - See [Load slides in the rack \(on page 37\)](#).
- 2 Ensure barcodes meet specifications. See [Barcodes supported \(on page 27\)](#).
- 3 Ensure barcodes meet minimum quality requirements. See [Barcodes \(on page 31\)](#).
- 4 If the issue persists, call Leica Biosystems Technical Services.

No tissue

- **Cause:** The scanner does not detect tissue on the slide.

Follow these steps in order until the issue is resolved:

- 1 On the touchscreen interface, tap the rack position that has the error.
- 2 Tap the **Slide View** icon to view the macro image of the slide.



- 3 Tap the error message to temporarily hide it.
- 4 Verify there is tissue on the slide.
- 5 Take note of the slide number.
- 6 Rotate and remove the rack to access the slide.
- 7 Remove the slide from the rack, and then clean the slide.
- 8 Re-insert the slide into a new rack and scan it again.
- 9 If the issue persists, check for slide preparation errors. See [Chapter 3: Slide preparation](#).
- 10 If the issue persists after completing the previous steps, call Leica Biosystems Technical Services.

No macro focus

- **Cause:** The scanner's camera cannot focus on the tissue.

Follow these steps in order until the issue is resolved:

- 1 Check for slide loading issues:
 - Slide orientation is correct with the specimen-side facing up. See [Load slides in the rack \(on page 37\)](#).
 - Slide tray is clean.
- 2 Check the stain quality.
- 3 Check that the slide and coverslip thickness meet the requirements. See the *Aperio GT 450 DX Specifications*.
- 4 Check for common slide preparation issues and verify:
 - Coverslip is not missing or overhanging.
 - Labels are not overhanging or on wrong side.
 - There is only one label applied to the slide.
 - Slide is clean.
- 5 If every slide has the same error, or if the issue persists after following the previous steps, call Leica Biosystems Technical Services.

Image quality

- **Cause:** The scanner's Auto-Image QC feature detected an image quality issue.

Follow these steps in order until the issue is resolved:

- 1 Review the scanned slide image in your viewing software.
- 2 Check for common slide preparation issues and verify:
 - Coverslip is not missing or overhanging.
 - Labels are not overhanging or on wrong side.
 - There is only one label applied to the slide.
 - Slide is clean.
- 3 Scan the slide again. When the scan is finished, do not remove the rack from the scanner.
- 4 Review the newly scanned slide image in your viewing software.
- 5 If the issue persists, display the slide in Slide View, and tap **Scan Entire Slide**.
To scan the whole area for a rack of slides, see [Scan entire slide for whole rack \(on page 49\)](#).
- 6 Check if other slides are in focus.
- 7 If all slides are out of focus, clean the objective. See [Clean the objective and Koehler \(on page 58\)](#).
- 8 If the issue persists after following the previous steps, call Leica Biosystems Technical Services.

Image transfer error – pending retry

- **Cause:** The scanner cannot transfer the scanned image to the image storage location.

Follow the appropriate steps below:

Error appears on some slides	Error appears on all slides
<p>The system often resolves the issue without intervention.</p> <ol style="list-style-type: none"> 1 If all slides in the rack are finished scanning, remove the rack. 2 Check for the image in Aperio eSlide Manager. 3 If necessary, rescan only the slides that are missing from Aperio eSlide Manager. 	<p>The Lab Administrator should:</p> <ol style="list-style-type: none"> 1 Ensure the LAN cables are connected to the scanner LAN port and to the Aperio GT 450 SAM DX server. 2 Do not restart the scanner. If you restart the scanner, the scanned data is lost, and users have to rescan their slides. 3 Check the connectivity from the scanner to the DICOM server, and from the DICOM server to your site's image storage location 4 Ensure the DICOM server is running. Restart the DICOM server if necessary. 5 Check if your site's image storage location is full. 6 Check if there is a permissions or account problem with the account running the DICOM server. 7 If the issue persists, consult with your organization's IT professionals prior to calling Leica Biosystems Technical Services. <p>When the issue is resolved, if you have not restarted the scanner, the scanner starts transferring the slide images to the DICOM server.</p>

Aborted

- **Cause:** The scanner cannot scan the slide.

Follow these steps in order until the issue is resolved.

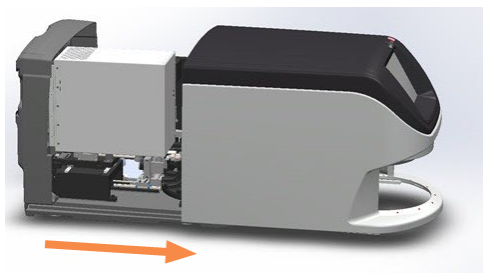
- 1 If the "Aborted" message appears on all slides, go to [Aborted message appears on all slides \(on page 98\)](#). If the message appears on one or some slides, continue to the next step.
- 2 Check for damage or common slide preparation issues and verify:
 - Coverslip is not missing or overhanging.
 - Labels are not overhanging or on wrong side.
 - There is only one label applied to the slide.
 - There is only one coverslip applied to the slide.
 - Slide is clean.
- 3 Clean the slide.

- 4 Insert the slide into a different rack and scan it again.
- 5 If the issue persists after following the previous steps, call Leica Biosystems Technical Services.

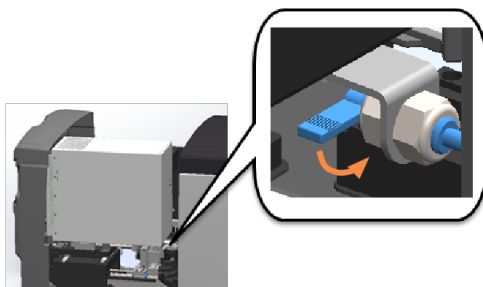
Aborted message appears on all slides

Follow these steps in order until the issue is resolved:

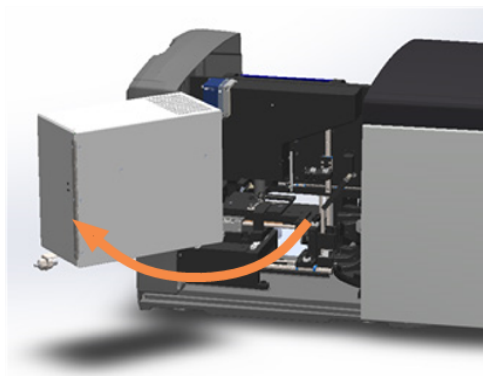
- 1 Remove any completed slide racks from the carousel.
- 2 Open the cover and access the interior:
 - a Open the scanner cover.



- b Rotate the VPU latch.



- c Pivot out the VPU.



For step details, see [Open the scanner cover and access the interior components \(on page 55\)](#).

- 3 Check if there is a slide on the stage or partially on the stage.

Figure 6-21: Slide on the stage

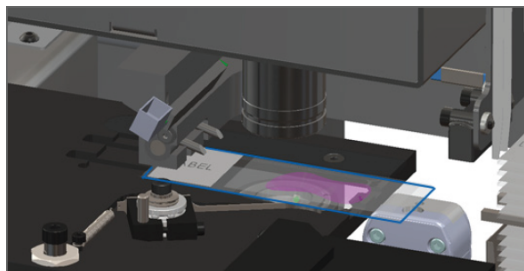
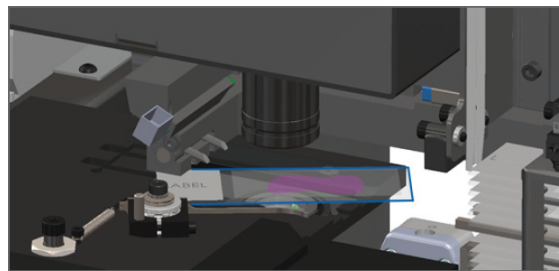
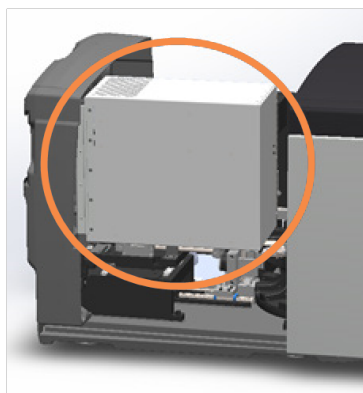


Figure 6-22: Slide partially on the stage

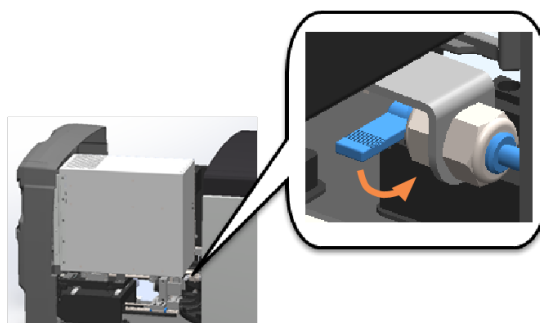


CAUTION: Restarting the scanner with a slide on the stage may damage the slide.

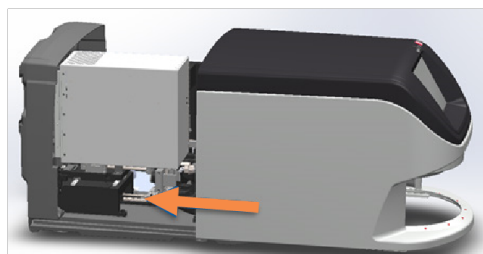
- 4 If there is a slide on the stage, carefully remove it from the stage without touching the surrounding components.
- 5 Close the scanner cover:
 - a Pivot the VPU into place.



- b Rotate the VPU latch.



- c Slide the cover until it clicks closed.



For detailed steps, see [Restart the scanner after interior maintenance \(on page 67\)](#).

- 6 Shut down the scanner by tapping **Maintenance**, then tapping **Shut Down Scanner**.
- 7 When touchscreen is dark, turn the scanner off using the On/Off switch.
- 8 Turn the scanner back on using the On/Off switch.
- 9 Allow the scanner to scan any remaining racks.
- 10 If the issue persists, call Leica Biosystems Technical Services.

Symptoms and solutions

This section contains troubleshooting information organized by symptom for scanner issues that do not have an error message or code.

Scanner does not power on

- 1 Ensure the scanner is turned on.
- 2 If you are using an optional uninterruptible power supply (UPS), ensure it is turned on.
- 3 Check the connections to wall outlet, and the Ethernet cable that attaches to the back of the scanner.
- 4 Ensure there is power available where the scanner is plugged in.
- 5 Verify there is a network connection to the device.
- 6 Ensure the main scanner cover is fully closed.
- 7 If the issue persists, call Leica Biosystems Technical Services.

Touchscreen does not respond to touch

- 1 Shut down the scanner by following the steps in [Shut down the scanner \(on page 55\)](#).
- 2 Turn the scanner on.
- 3 If the issue persists, contact Leica Biosystems Technical Services with details.

Touchscreen is black

- 1 Shut down the scanner by following the steps in [Shut down the scanner \(on page 55\)](#).
- 2 Turn the scanner on.
- 3 If the issue persists, contact Leica Biosystems Technical Services with details.

Slides are broken inside the scanner



WARNING: Do not attempt to recover broken slides. Call Leica Biosystems Technical Services.

- 1 Leica Biosystems Technical Services may request the photos when providing assistance.

Network connection lost

The Aperio GT 450 DX must be connected to the Scanner Administration Manager (Aperio GT 450 SAM DX) through your Local Area Network to function. If that connection is lost, you see:



Contact your IT Administrator for assistance. The IT Administrator should do the following:

- 1 Ensure the LAN cables are connected to the scanner LAN port and to the SAM DX server.
- 2 In the area provided on the scanner's touchscreen interface, enter the IP address of the SAM DX server.
- 3 Verify the network connections are up and working for the Scanner and Aperio GT 450 SAM DX server. (Consult your organization's IT professionals if needed.)
- 4 On the server, go to the Services Manager and restart all services. It may take a few minutes for all the services to restart.
- 5 Try to connect from the scanner again by manually entering the IP address again.

- 6 If the issue persists, consult with your organization's IT professionals prior to calling Leica Biosystems Technical Services.

A

Performance characteristics

This section discusses the clinical studies performed using the Aperio GT 450 DX:

Precision	104
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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.

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

Note:

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

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

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

			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					

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.

Table A-3: Intra- and Inter-Pathologist Precision Study: Agreement Within Pathologists

			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.

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

Pathologist	Number of Pairwise Agreements	Number of Comparison Pairs	Agreement Rate and 95% CI		
			% 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.					

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.

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

		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% CI	Major Discrepancy	Total	Major Discrepancy Rate (%)	Model 95% CI	%	Model 95% CI
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 model includes both local and remote cohorts.

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

		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% CI	Major Discrepancy	Total	Major Discrepancy Rate (%)	Model 95% CI	%	Model 95% CI
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%)

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

		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% CI	Major Discrepancy	Total	Major Discrepancy Rate (%)	Model 95% CI	%	Model 95% CI
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: WSIR diagnosis, MSRD: MSR diagnosis.

B

Technical performance assessment summary

This section provides a summary of the Aperio GT 450 DX Technical Performance Assessment (TPA).

TPA Guidance	Test Description	Result
Slide Feeder	Slide dimensions meet ISO8037/1 Optics and Optical Instruments	Pass
	Number of slides in queue	Pass
	Electro-mechanical automation	Pass
	HW (slide loading process)	Pass
	SW (automatic slide identification)	Pass
	LCD display provides user feedback (alarms, notifications, etc.)	Pass
	Failure modes and effects analysis	Pass

TPA Guidance	Test Description	Result
Light Source	Light Source component information verification	Pass
	Light Source output adjustment control	Pass
	Light Source expected intra-slide intensity variation (CV = coefficient of variation as a %)	Pass
	Light Source expected daily intensity CV	Pass
	Light Source expected intra-slide spectral CV	Pass
	Light Source expected daily spectral CV	Pass
	Light Source expected lifetime spectral CV	Pass
	Light Source intensity/spectral variation tracking capabilities	Pass
	Condenser illumination format (Koehler, critical, etc)	Pass
	Condenser component info verification	Pass
	Condenser numerical aperture	Pass
	Condenser focal length	Pass
	Condenser working distance	Pass
	Light source and condenser and wavelength accuracy and spectral efficiency	Pass
	Imaging	Optical schematic
Objective lens verification		Pass
Auxiliary lenses (TL, mag changer)		Pass
Magnification of imaging optics per ISO 8039:2014		Pass
Relative irradiance per ISO 13653:1996		Pass
Distortion per ISO 9039:2008		Pass
Chromatic aberrations per ISO 15795:2002		Pass

TPA Guidance	Test Description	Result
Scanner Movement	Stage size	Pass
	Stage manufacturing and model number	Pass
	Stage material	Pass
	Single multi-axis or stacked single-axis stages	Pass
	Type of guides/ways	Pass
	Slide holder	Pass
	Movement type	Pass
	Resolution for XY axes	Pass
	Movement of Z axis	Pass
	Speed(s) of axes	Pass
	Range of travel	Pass
	Scanning area	Pass
	Localization/barcode reading	Pass
	Open/Closed loop operation	Pass
	Positional accuracy (calibration) and repeatability	Pass
	Lost motion compensation (e.g., backlash)	Pass
	Physical control for single slide, non-batch mode	Pass
	Method for selecting area to be scanned	Pass
Failure modes and effects analysis	Pass	
Positional repeatability and accuracy per ISO 230-2:2014	Pass	

TPA Guidance	Test Description	Result
Digital Imaging Sensor	Sensor type	Pass
	Number and dimension of pixels	Pass
	Configuration of color filter array	Pass
	Spectral transmittance of color filter	Pass
	Quantum efficiency vs. wavelength	Pass
	Linearity	Pass
	Spatial uniformity	Pass
	Dark current (electrons/second)	Pass
	Read noise (electrons)	Pass
	Readout rate	Pass
	Output format	Pass
	Opto-electronic conversion function per ISO 14524:2009	Pass
	Noise measurements per ISO 15739:2003	Pass
Imaging Processing Software	Exposure control	Pass
	White balance	Pass
	Color correction	Pass
	Sub-sampling	Pass
	Pixel-offset correction	Pass
	Pixel-gain or flat-field correction	Pass
	Pixel defect correction	Pass

TPA Guidance	Test Description	Result
Image Composition	Single/multiple objectives	Pass
	Scanning pattern	Pass
	Scan overlap	Pass
	Stitching algorithms	Pass
	Background correction functions	Pass
	Single slide scan time	Pass
	Number of Z planes scanned	Pass
	Images of digitized calibration slides	Pass
	Analysis of focus quality metrics	Pass
	Analysis of coverage	Pass
File Formats	Compression method	Pass
	Compression ratio	Pass
	Compression type	Pass
	File format	Pass
	DICOM compliant	Pass
	File organization/structure	Pass
Computer Environment	Hardware	Pass
	OS	Pass
MTF - Spatial Resolution	Resolution and spatial frequency response per ISO 12233:2014 (E)	Pass
Focusing Test	Focusing data required	Pass
	Focus method (auto-focus)	Pass
	Selection of manual focus points (if applicable)	Pass
	Focus evaluation metrics	Pass
	Constructing focus map from sample points	Pass

TPA Guidance	Test Description	Result
Whole Slide Coverage	Tissue coverage test method including:	Pass
	<ul style="list-style-type: none"> • Selection of the input slide tissue 	Pass
	<ul style="list-style-type: none"> • Determine the complete coverage of the input tissue slide 	Pass
	<ul style="list-style-type: none"> • Measure the actual coverage of the WSI output 	Pass
	<ul style="list-style-type: none"> • Calculate the ratio of the actual to complete coverage 	Pass
Stitching Error	Selection of the input tissue slide	Pass
	Sampling of the stitching boundaries where stitching errors might occur	Pass
	Determine the perfect stitching as the ground truth	Pass
	Evaluate quality of the actual stitching boundaries with the perfect one that does not have stitching artifacts	Pass
Quality Control	Frequency and test methods, responsibility and quantitative limits	Pass

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