

Aperio GT 450 DX

User's Guide



Aperio GT 450 DX User's Guide

This manual applies to Aperio GT 450 DX Controller, Aperio GT 450 DX Console, and Aperio GT 450 DX SAM DX versions 1.1 and later

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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 www.LeicaBiosystems.com/Aperio.

Contact Information – Leica Biosystems Imaging, Inc.

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Notices

Revision Record

Rev.	Issued	Sections Affected	Detail
B	May 2022	Page 75	Corrected a typographical error.
A	April 2022	All	New version for Aperio GT 450 DX product. Based on existing <i>Aperio GT 450 DX Scanner User's Guide</i> , MAN-0458, Revision A

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, refer to 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.
- ▶ **Quality Control** - For information on image quality checks, see, "*Image Quality Control for Histotechnicians and Pathologists*" on page 45.
- ▶ **Maintenance and Troubleshooting** - For information on maintenance, see "*Chapter 5: Maintenance*" on page 46. For information on troubleshooting problems, see "*Chapter 6: Troubleshooting*" on page 60.
- ▶ **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 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 Guide*.

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

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












Intended Purpose







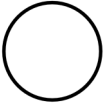




The Aperio GT 450 DX is a device for creation of digital images of scanned surgical pathology glass slides prepared from formalin-fixed paraffin embedded (FFPE) tissue that would otherwise be appropriate for manual visualization by conventional light microscopy. Aperio GT 450 DX is intended for in vitro diagnostic use with compatible viewing software and display that has been validated for use with this scanner as an aid to the pathologist in the qualitative review and interpretation of digital images.



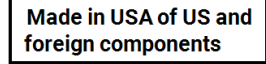
The Aperio GT 450 DX is not intended for use with frozen section, cytology, or non-FFPE hematopathology specimens. It is the responsibility of a qualified pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images obtained using the Aperio GT 450 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 the instructions for use.
	ISO 15223-1 - 5.1.1	Manufacturer
	ISO 15223-1 - 5.1.3	Date of manufacture
	ISO 15223-1 - 5.1.2	European Union Authorized Representative
	ISO 15223-1 - 5.1.8	Importer
	AS/NZS 4417.1	Device is in compliance with with the Australian Communications Media Authority (ACMA) requirements (safety and EMC) for Australia and New Zealand.
	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
	ISO 15223-1 - 5.7.10	Unique Device Identifier
	EU 2017/746 Article 18	Device carries the CE (Conformité Européenne) Mark and fulfils the requirements of EU Regulation 2017/746.

Symbol	Regulation/ Standard	Description
	Medical Devices Regulations 2002	Device is in compliance with UK Conformity Assessment requirements.
	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.
	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
	2012/19/EU	Device is regulated under 2012/19/EU (WEEE Directive) for Electrical and Electronic Equipment Waste and must be discarded under special conditions.
	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.

Symbol	Regulation/ Standard	Description
 <p>CLASS 1 LASER PRODUCT IEC 60825-1 2014 COMPLIES WITH 21 CFR 1040.10 EXCEPT FOR DEVIATIONS PURSUANT TO LASER NOTICE NO. 56 DATED MAY 8, 2019</p>	IEC 60825-1	Device is a Class 1 Laser Product that is in compliance with international standards and US requirements.
 <p>Info for USA only. California Proposition 65 WARNING Cancer & Reproductive Harm www.P65Warnings.ca.gov</p>	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 .
 <p>Made in USA of US and foreign components</p>	N/A	Device is made in the USA of US and foreign components.

Customer Service Contacts

Please contact the office for your country for technical assistance.

Australia:

96 Ricketts Road
Mount Waverly, VIC 3149
AUSTRALIA
Tel: 1800 625 286 (toll free)
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Technical Assistance Center
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USA:

Tel: +1 844 534 2262 (toll free)
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1

Introduction

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 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 DX (SAM DX) Server	The SAM DX server connects to multiple Aperio GT 450 DX scanners and runs the SAM DX Application Software.
Scanner Administration Manager DX (SAM DX) Application Software	The 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 SAM DX server to administer the 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 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. See <i>"Customer Service Contacts"</i> on page 11 for contact information.
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. Also refer to *"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.



CAUTION: 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.




CAUTION: 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: (1) This device may not cause harmful interference and (2) 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 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 EN 61010-1:2010/A1:2019 EN 61010-2-101:2017</p>
EMC	<p>EMC Directive (Directive 2014/30/EU) EN 61326-1:2013 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. Refer to *Aperio GT 450 DX Specifications, MAN-0479* for work surface and operating specifications.

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

The Aperio GT 450 DX is regulated as Electrical and Electronic Equipment Waste (WEEE) under 2012/19/EU and must be discarded under special conditions. Contact Leica Biosystems, Inc. for assistance or questions regarding device disposal.

Device Lifetime

The lifetime of the Aperio GT 450 DX is ten years.

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 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

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 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 <i>"Touchscreen Interface Overview"</i> on page 22.
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 <i>"Carousel Rotation"</i> on page 31.
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 <i>"Load Racks in the Carousel"</i> on page 33.
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 <i>"Carousel Rotation"</i> on page 31.
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 <i>"Check Scan Status"</i> on page 39. See <i>"Red Blinking Lights on Carousel"</i> on page 60.

Element:	Use:	More details:
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 <i>“Clean the Fan Filter”</i> on page 55.

Turn the Scanner On and Off

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

- ▶ On position = **I**; Off position = **O**.



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

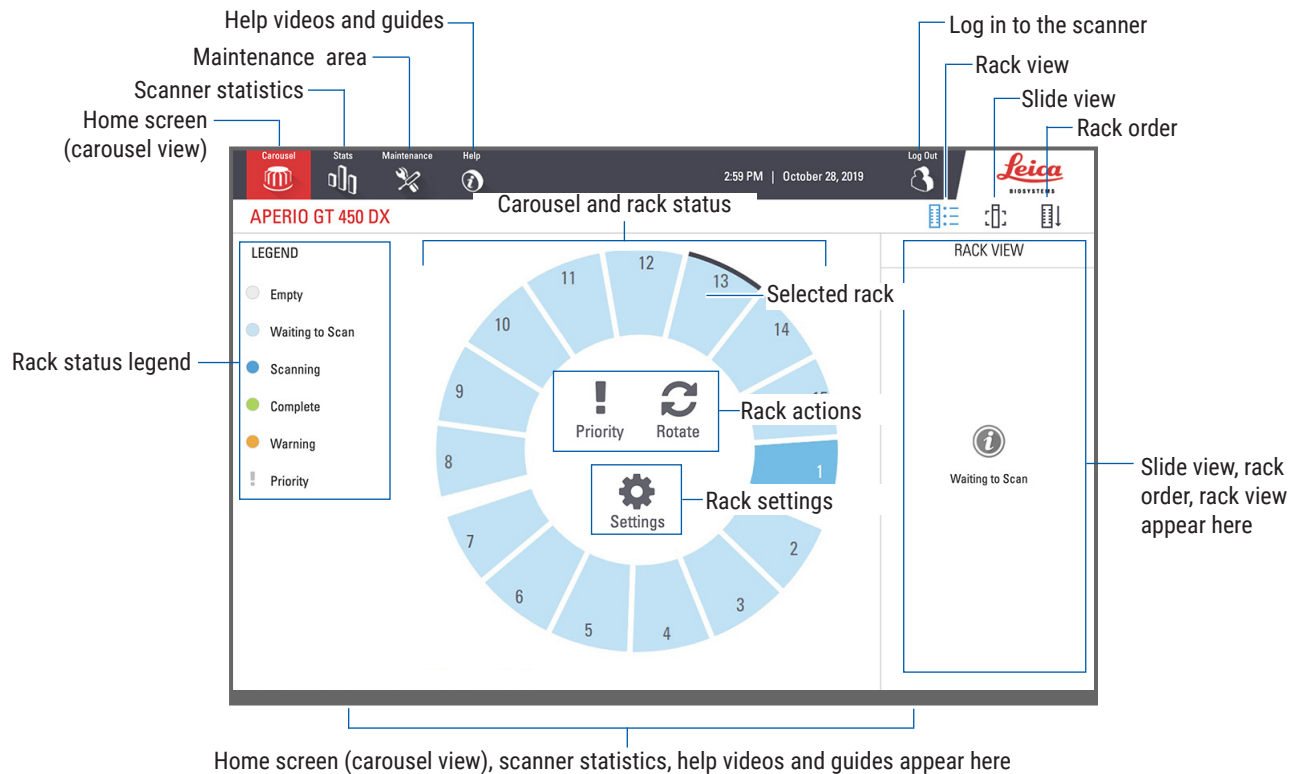
- ▶ *“Shut Down the Scanner”* on page 47.
- ▶ *“Restart the Scanner After Interior Maintenance”* on page 58.
- ▶ *“Perform a Safe Restart After an Error”* on page 61.

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:	Use:	More details see:
Rack status legend	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. <i>Note: the Legend is for information only and is not interactive.</i>	"Check Scan Status" on page 39.
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 45.
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 47. "Shut Down the Scanner" on page 47. "Restart the Scanner" on page 50.

Element:	Use:	More details see:
Help	Tap Help to view training and maintenance videos, or access an online version of the quick reference guide. 	" <i>Help Videos and Guides</i> " on page 25.
Carousel and rack status	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). 	" <i>Carousel Rotation</i> " on page 31. " <i>Check Scan Status</i> " on page 39.
Rack actions <i>Note: Rack actions appear when you select a rack.</i>	Select a rack and tap Priority to move the rack to the top of the scan queue. 	" <i>Priority Scanning</i> " on page 35.
	Select a rack and tap Rotate to rotate the rack to the rack loading area. 	" <i>Rotate a Rack to the Rack Loading Area</i> " on page 36.
Rack settings <i>Note: Rack settings appear when you select a rack.</i>	Select a rack and tap Settings to select and apply a rack setting. 	" <i>Scan Entire Slide for Whole Rack</i> " on page 43.
Login, Logout	Tap Login to open a keypad and enter your pass code to access the scanner. 	" <i>Log In and Log Out of the Scanner</i> " on page 31.
	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. 	" <i>View Slide Status for a Rack</i> " on page 40.
Slide View	Select a rack and tap Slide View to view macro images for each slide. 	" <i>View Macro Images of Scanned Slides</i> " on page 41.
Rack Order	Tap Rack Order to view scan order and status of the racks. 	" <i>View Rack Scan Order</i> " on page 41.

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 and DICOM compatible images. If you want your scanned images to be in DICOM format, this must be enabled on SAM DX and your IT environment must meet the requirements detailed in the *Aperio DICOM Conformance Statement*. For information on enabling DICOM format, see the *Aperio GT 450 DX IT Manager and Lab Administrator 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

3

Slide Preparation



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. Refer to **Aperio GT 450 DX Specifications**, MAN-0479.

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.



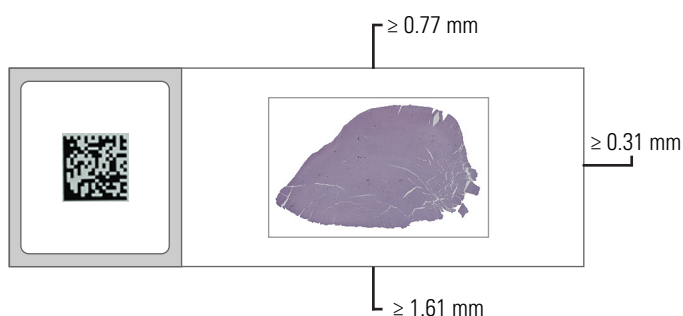
CAUTION: Do not attempt to scan damaged or broken slides, as doing so may damage the scanner.

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 slide.



For more details on slide specifications, see *"Slide Types Supported"* on page 26.

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 Scanner 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.

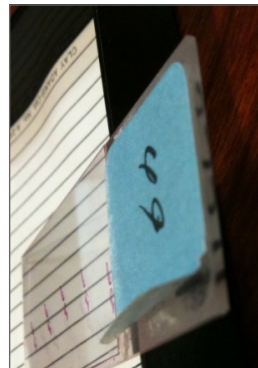
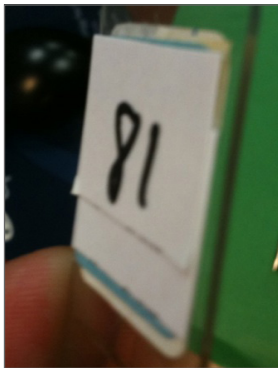
Labels

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 Scanner 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 32.

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 26. 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 29.
- ▶ 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 26.)
- ▶ Use only high-quality printed barcode labels.

4

Scan Slides

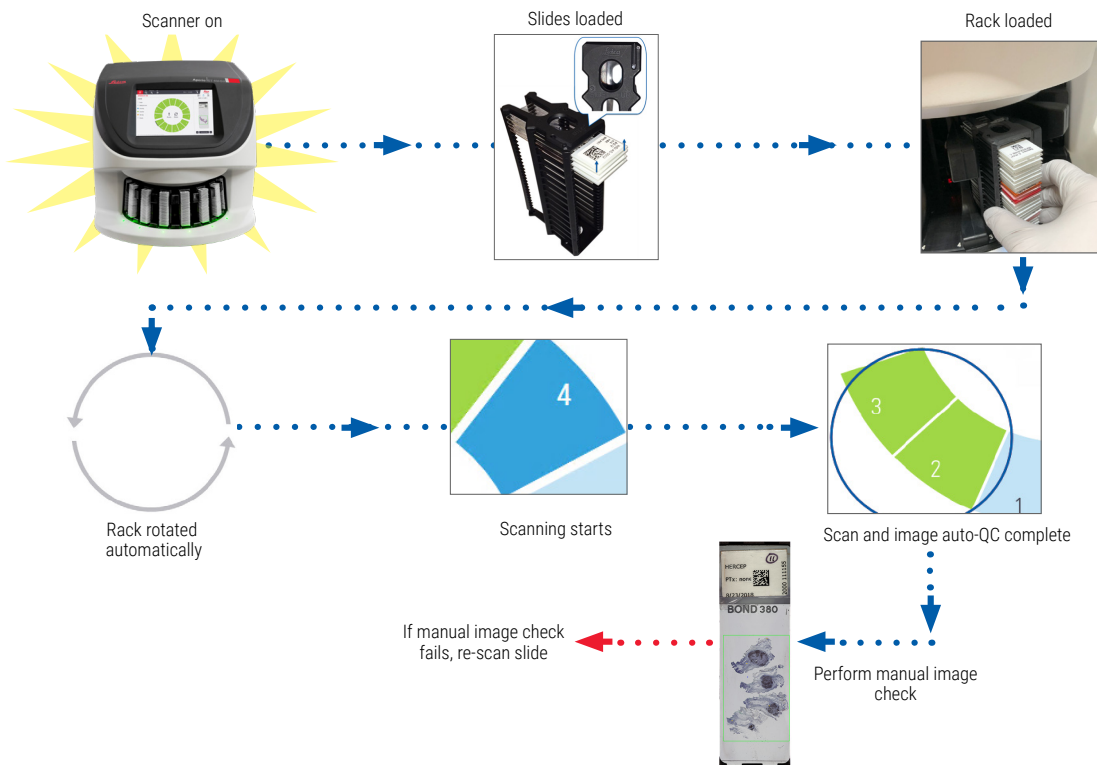
This chapter shows you how to scan slides.

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

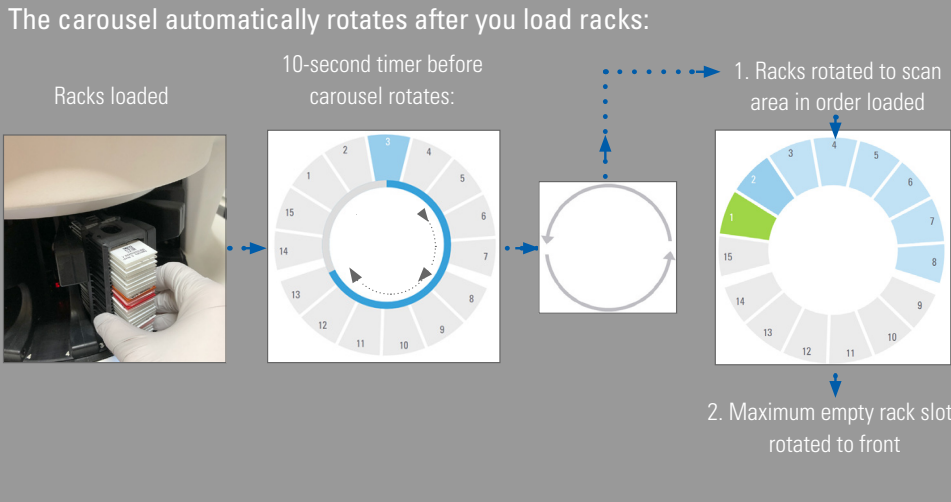
The Aperio GT 450 DX is a continuous load scanner. You can continually load new racks and unload completed racks, as shown below:




Carousel Rotation

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

The carousel automatically rotates after you load racks:

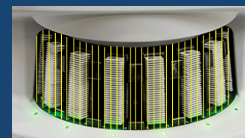


WARNING: Keep hands away from the carousel and pinch point areas when the carousel is rotating.



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

Log In and Log Out of the Scanner

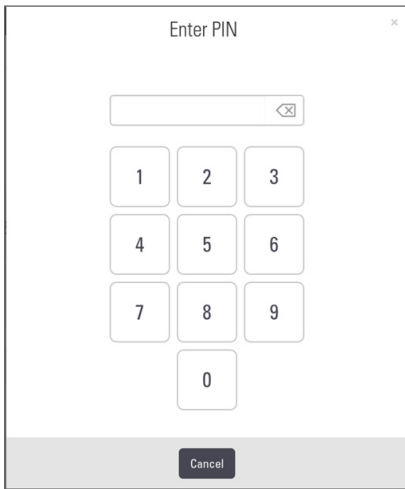
Your Lab Administrator sets up the scanner pass codes and timeout period for your lab using the SAM client application software. You need to log into the scanner to interact with the touchscreen interface. You do not need to log in to load and unload racks for scanning.

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" faces 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.



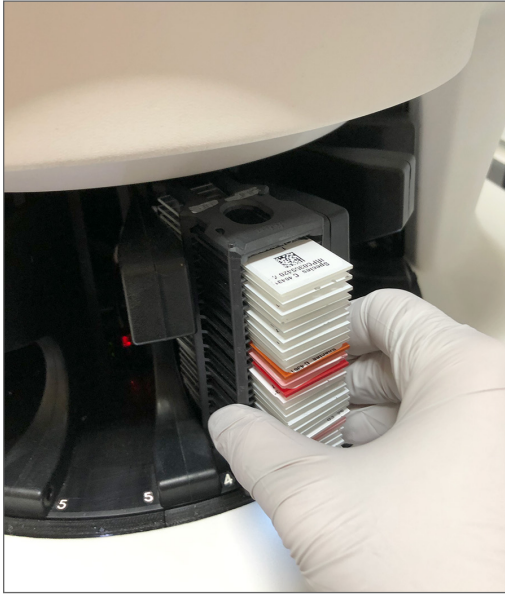
CAUTION: Use caution when loading slides into a rack to prevent improper slide orientation or damaged slides. Never use damaged slides in the scanner.



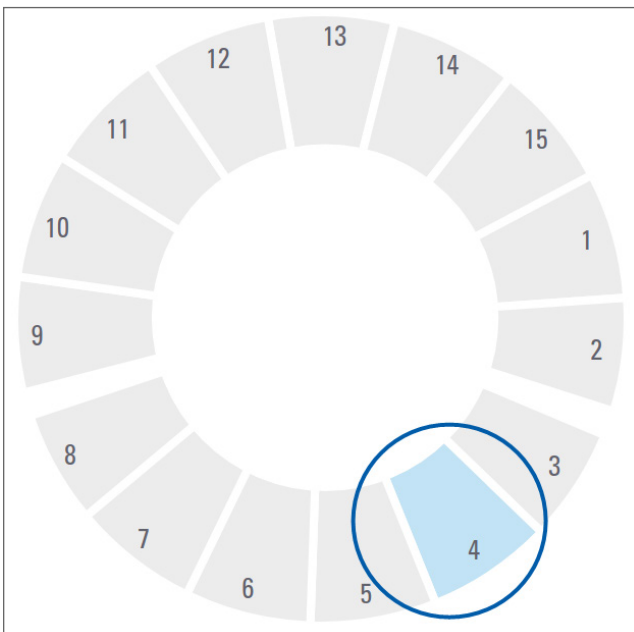
Load Racks in the Carousel

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.



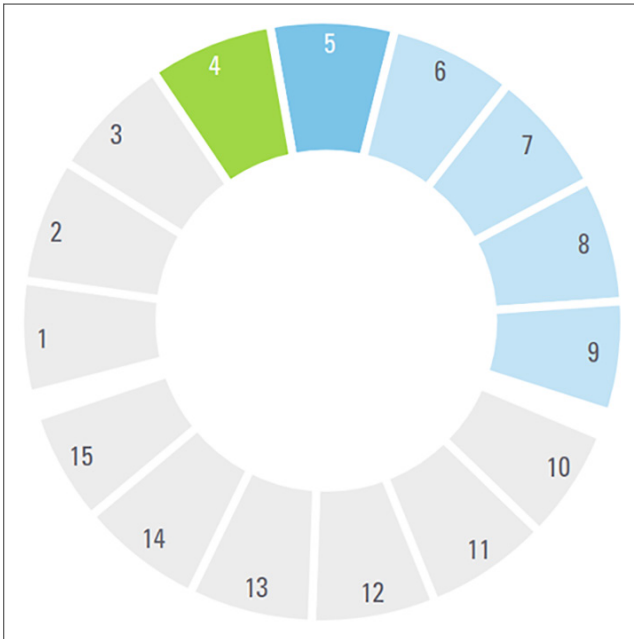
3. Continue loading racks as needed or until you fill the front six rack slots.
4. When you've finished loading the first set of racks:

- ▶ 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” on page 46.*

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



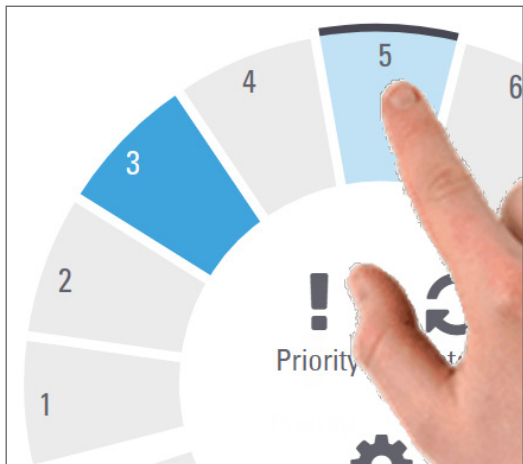
6. You can unload any completed racks and continue loading new racks.

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 36.*

Priority Scanning

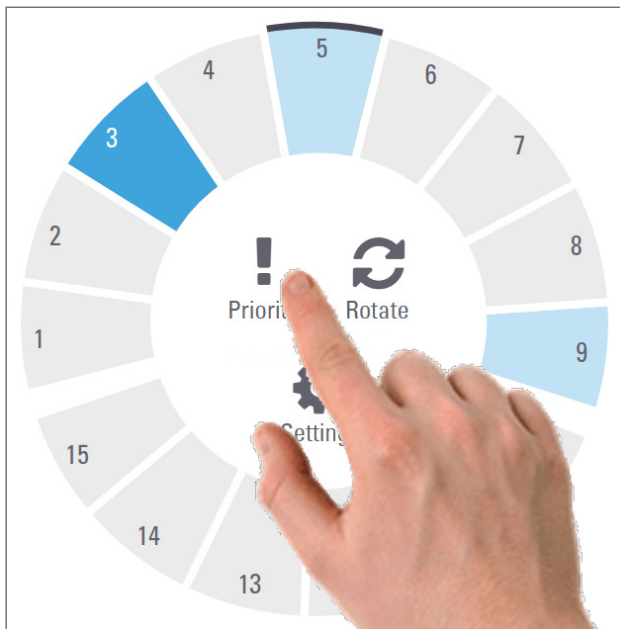
Use Priority to move a rack to the front of the scan queue. You can apply the Priority option on up to three racks at a time.

1. Tap the rack position.

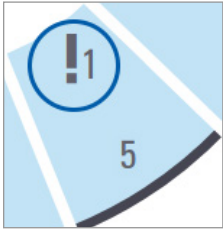


The Priority option appears when you select the rack position.

2. Tap **Priority**.



The Priority icon and scan queue number appear on the rack position:



The rack with the first level priority is moved to the top of the scan queue, and begins processing when the active rack is complete. To view the rack scan order, see “View Rack Scan Order” on page 41.

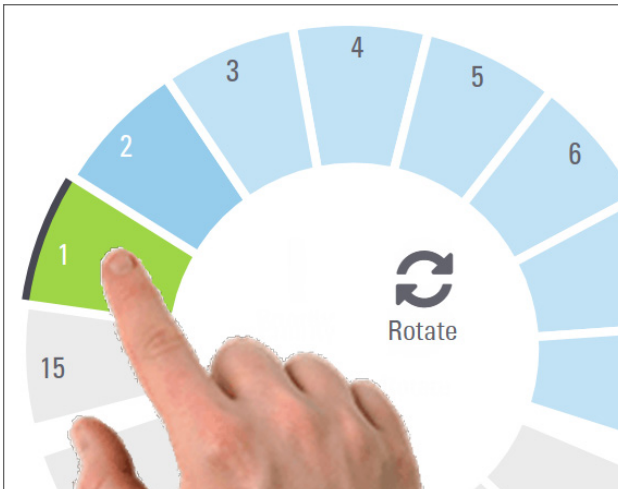
i To cancel a priority, you have to remove the rack.

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.

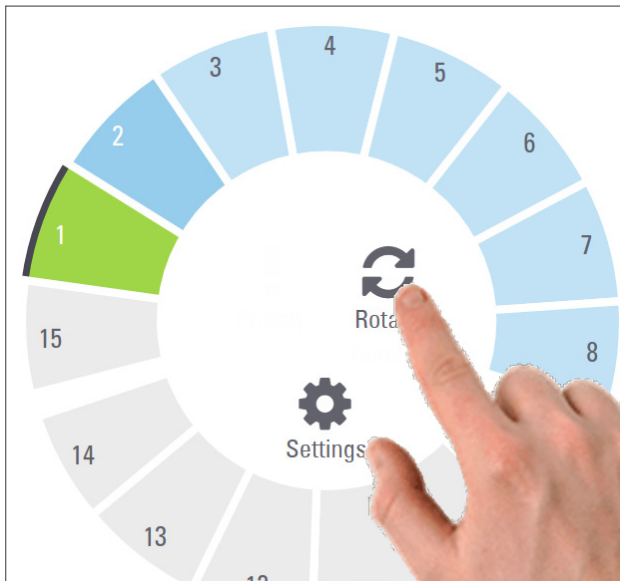
To rotate a rack to the rack loading area:

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.

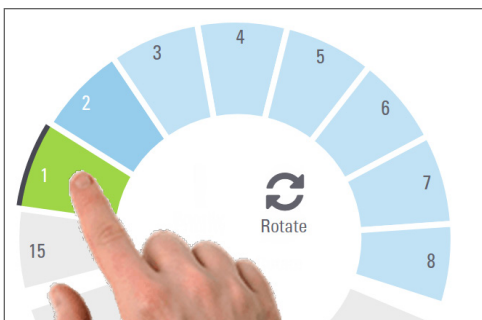
To unload racks from the carousel:

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 42.
2. If the rack is in the loading area, carefully remove the rack from the rack slot.

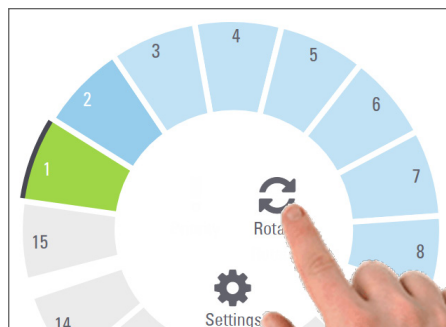


3. If the rack is not in the loading area, you can rotate it to the front:

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.

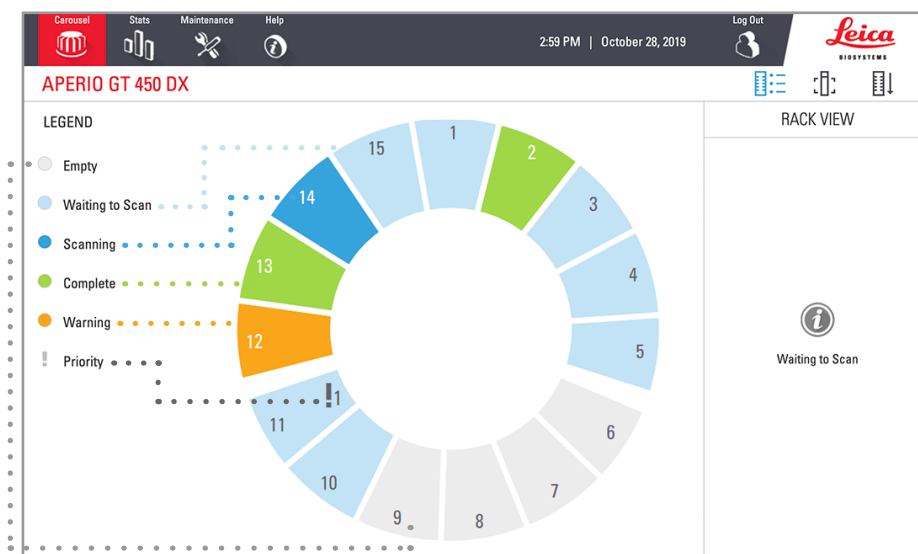


CAUTION: If you must remove a rack before all slides in the rack are scanned, note the rack and slide status. After removal, the rack's scan status is no longer available.

Check Rack Status

To check the scan status of a rack:

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



2. 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 page 42.
Priority	The rack is set for priority scanning. (See <i>"Priority Scanning"</i> on page 35.)

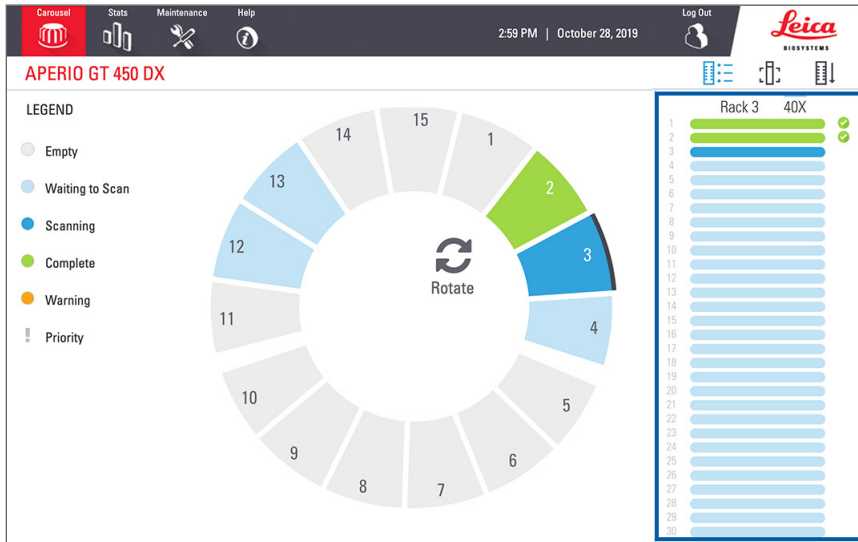
Rack Error on Current Scan

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 42.








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 page 42.)
	The slide scanned successfully, passed image QC, and was transferred to the specific image location.
	The slide has a scan warning. (See page 42.)

View Macro Images of Scanned Slides

To view a macro image of a scanned slide:

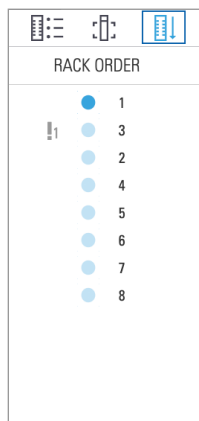
1. Tap the rack position on the touchscreen interface.
2. Tap the **Slide View** icon to view individual images for the selected rack.



- 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 76.

View Rack Scan Order

1. Tap the **Rack Order** icon to show the scan order of the racks.



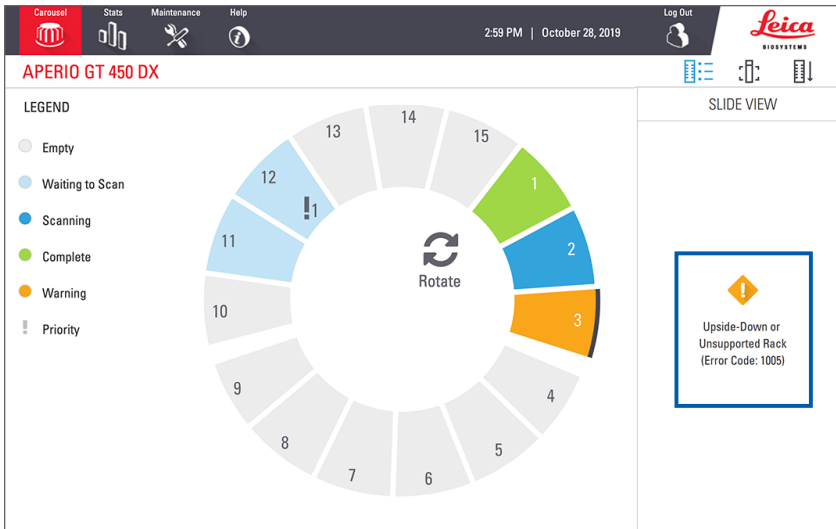
- Racks in the list appear in the scan order.
- The scan status is indicated for each rack.
- In the example, rack 3 is set as priority.

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:

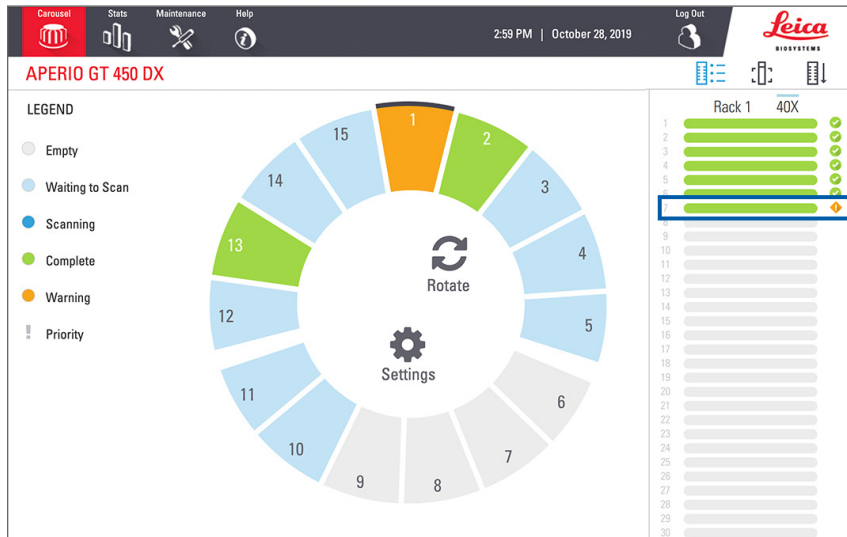
1. Tap the rack position you want to check.
2. If there is a problem with the rack, a message appears similar to the example below.



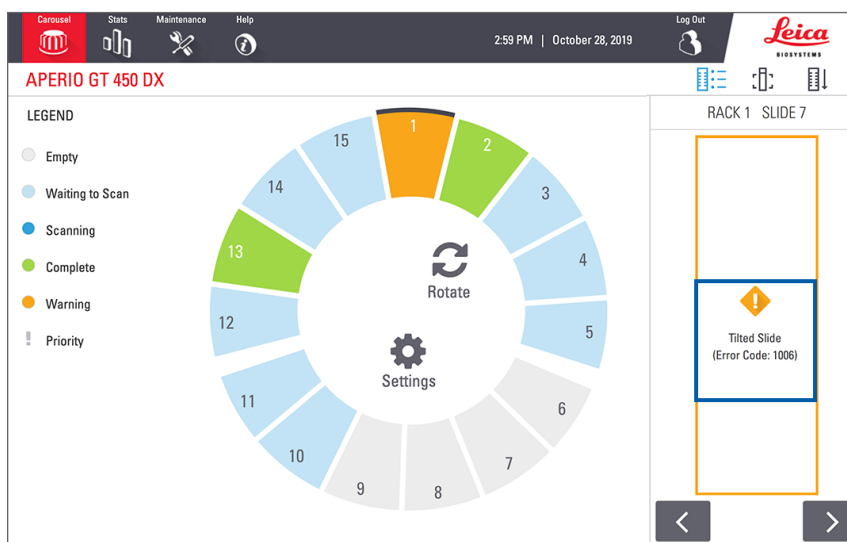
3. Take note of the error code and message. For information and steps to resolve the rack error, go to *“Rack Warnings and Solutions”* on page 74.
4. If there is a problem with one or more slides in the rack, a warning icon appears next to the slide in Rack View:

	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.




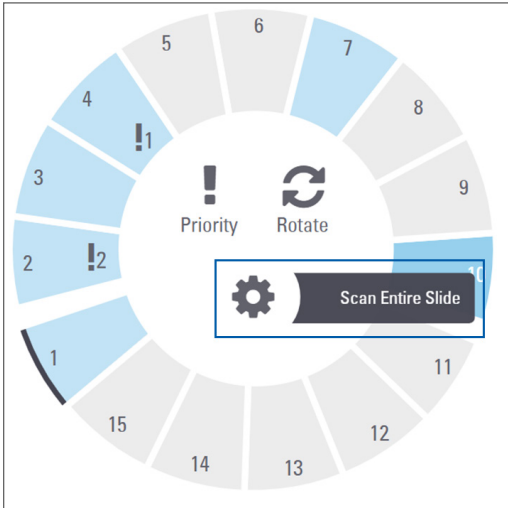
6. Take note of the error code and message. For information and steps to resolve the error, go to *"Slide Errors and Solutions"* on page 76.


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:

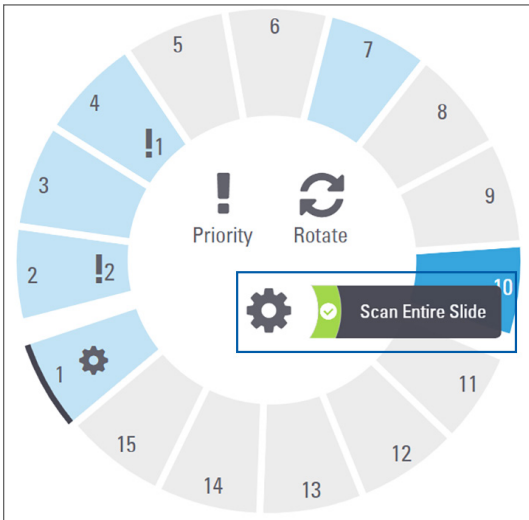


Image Quality Control for Histotechnicians and Pathologists



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 quality criteria that are important for primary diagnosis and that should be verified by scanner operators are: 1) that the entire tissue sample has been scanned, and 2) that the tissue is in focus.

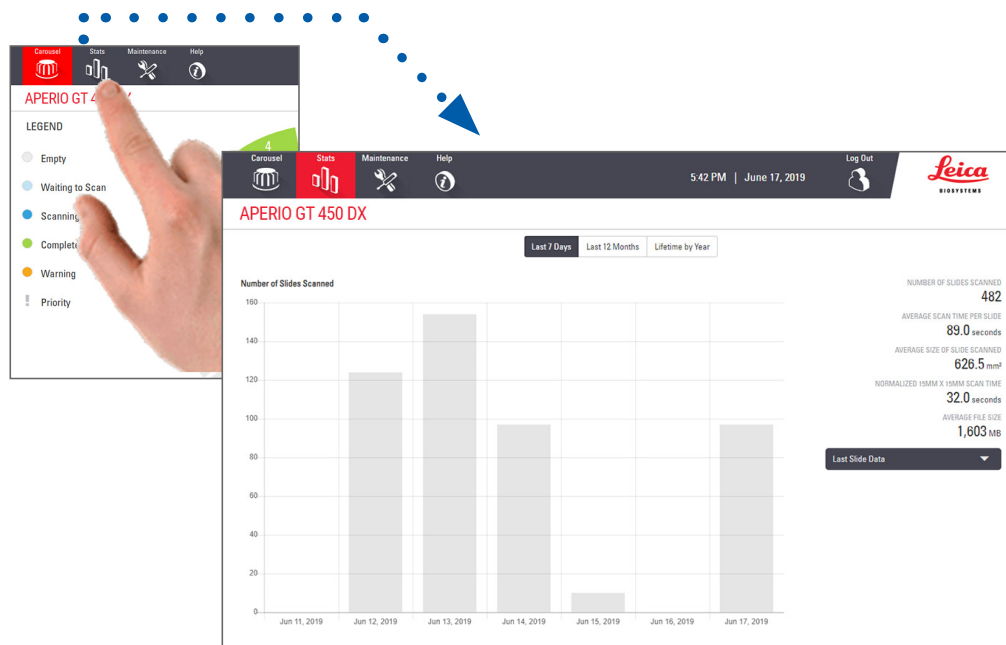
Apero scanners provide a macro image, a low-resolution image of the entire slide, that also provides a green outline of the scanned image. Check that image for the quality criteria mentioned above.

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.

Scan Statistics

The Apero 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 25.



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.

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 50.
Every Six Months	1. Clean the objective and Koehler	“Clean the Objective and Koehler” on page 51
	2. Clean the stage slide tray	“Clean the Stage Slide Tray” on page 54
	3. Clean the carousel	“Clean the Carousel” on page 55
	4. Clean the slide racks	“Clean the Slide Racks” on page 57
	5. Clean the fan filter	“Clean the Fan Filter” on page 55
	6. Clean the touchscreen	“Clean the Touchscreen” on page 58
	7. Clean the scanner cover	“Clean the Scanner Cover” on page 57
Once a year	Schedule annual maintenance visit by Leica Biosystems Technical Services.	Call Leica Biosystems Technical Services. Refer to “Customer Service Contacts” on page 11.

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.

The screenshot shows the 'Maintenance' screen of the APERIO GT 450 DX scanner. The top navigation bar includes 'Carousel', 'Stats', 'Maintenance' (highlighted), and 'Help'. The status bar shows '12:27 PM | July 16, 2021' and a 'Log Out' button. The Leica Biosystems logo is in the top right. The main content area is titled 'APERIO GT 450 DX' and contains a table of system information, a 'Maintenance Videos' icon, and three buttons: 'Restart Scanner', 'Shut Down Scanner', and 'Maintenance Videos'.

Serial Number	PB6
Hardware Version	1.0.1
Controller UDI	00815477020372(8012)1.1
Console UDI	00815477020365(8012)1.1
Controller Version	1.1.0.5072 [C]
Console Version	1.1.0.5017 [C]
STU Remote Version	1.1.0.5050 [C]
Documents Version	1.1.0.5017 [C]
G5 Firmware Version	1.0.1.8502 [C]
Platform Version	5.4
Install Date	December 22, 2020
GT 450 DX Update News	www.leicabiosystems.com

Shut Down the Scanner

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

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

This screenshot is identical to the one above, but the 'Shut Down Scanner' button is highlighted with a blue border, indicating it is the target of the next step in the procedure.

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

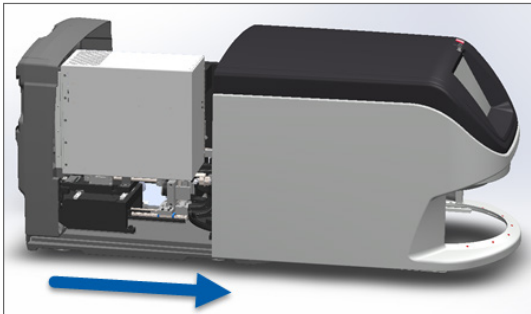
Complete these steps to access the inside of the scanner for maintenance or troubleshooting.

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

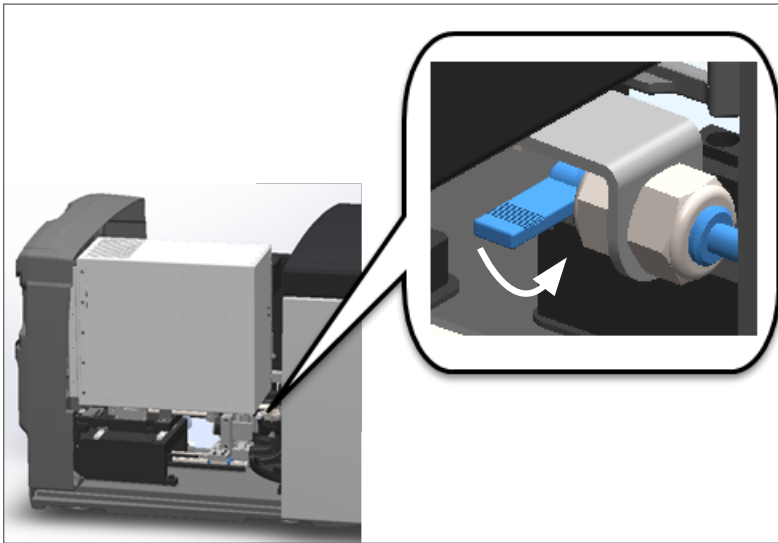
1. Shut down the scanner using the steps in “*Shut Down the Scanner*” on page 47.
2. Grasp the cover using the handhold indentations:



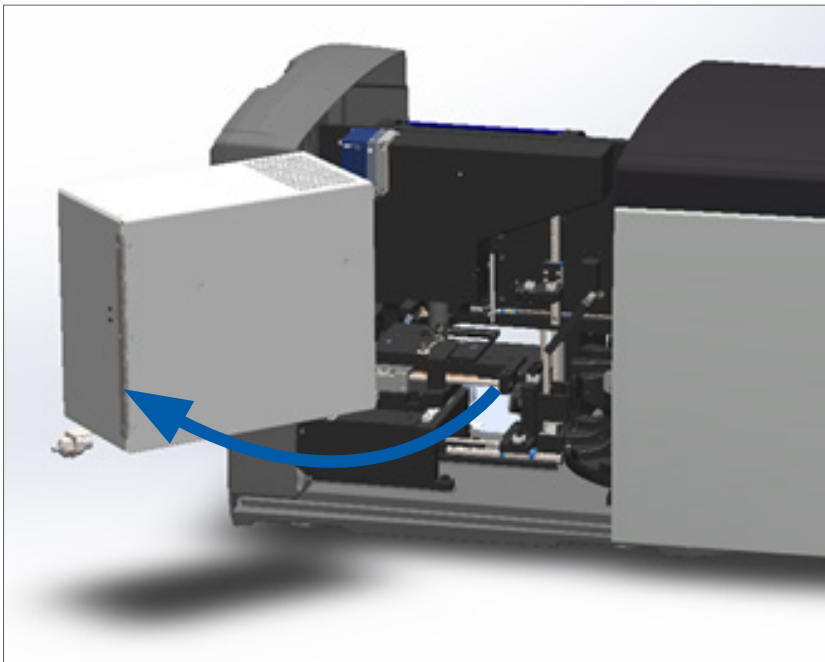
3. Slide the cover out until it reaches the point shown below.



4. Rotate the VPU latch 180 degrees to the open position, 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

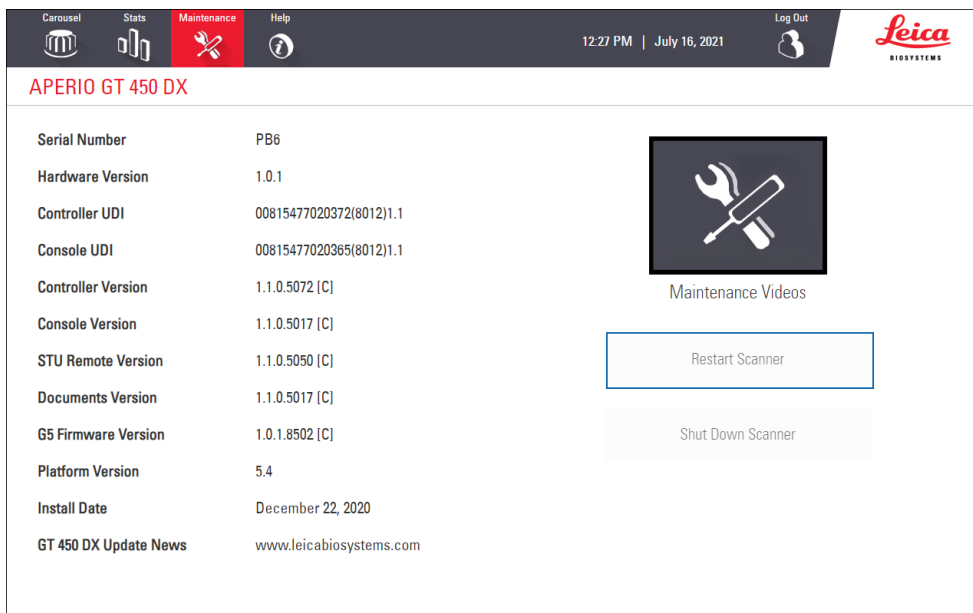
- ▶ **Frequency: daily**, and as needed to resolve a scanner issue.

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.

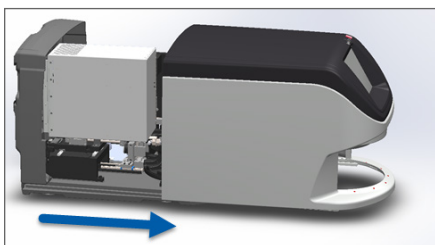
Materials Needed

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

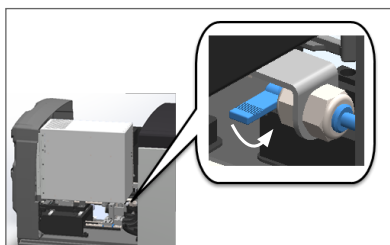
To clean the objective and Koehler:

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:

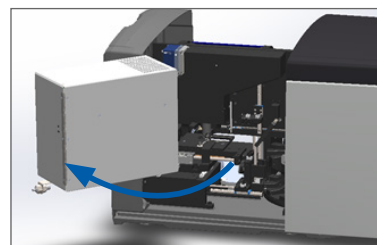
a. Open scanner cover.



b. Rotate VPU latch.

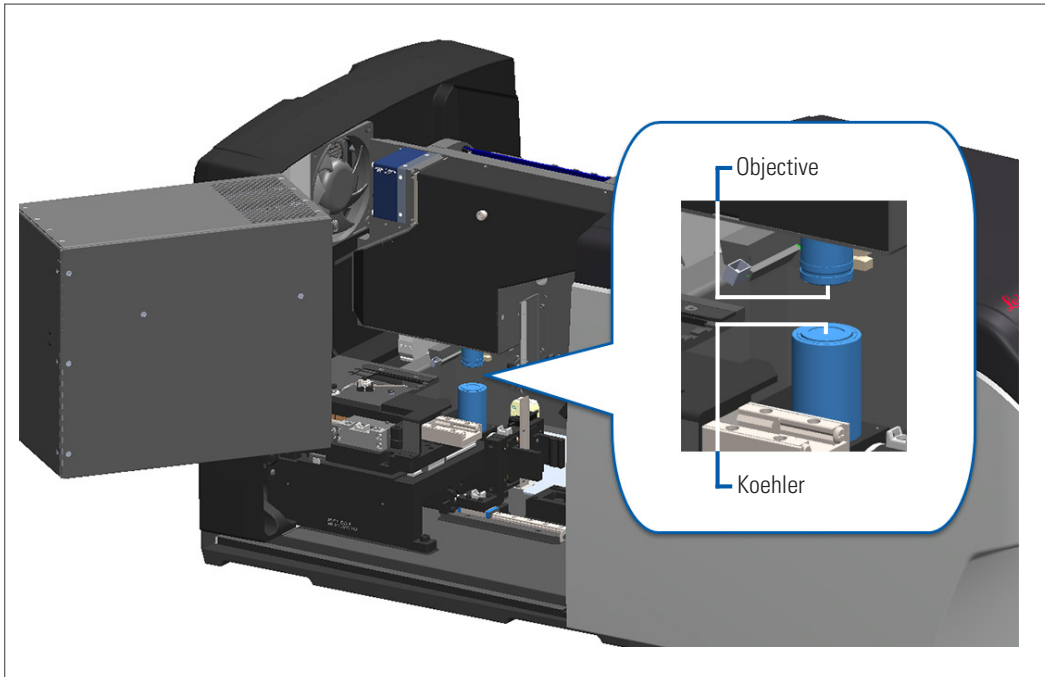


c. Pivot out VPU



For detailed steps, see *"Open the Scanner Cover and Access the Interior Components"* on page 48.

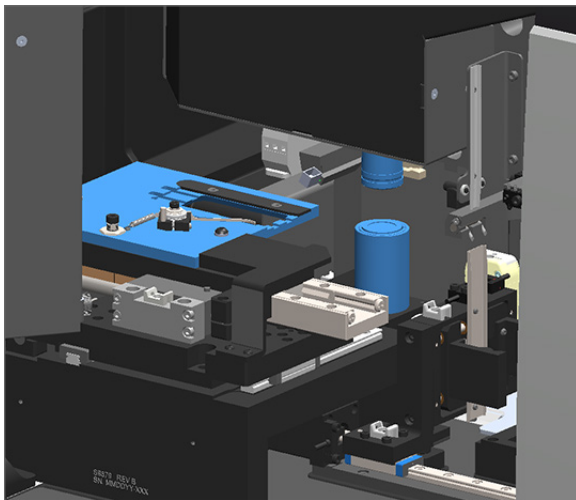
3. The objective and Koehler shown below in blue:



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



CAUTION: The objective may move when you are cleaning it.

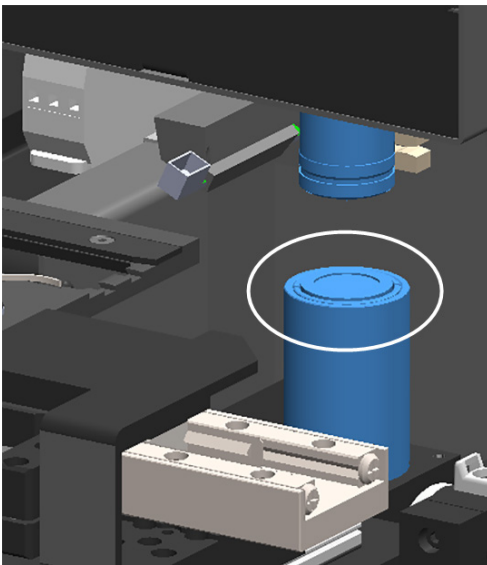


5. Wear gloves when cleaning the objective.

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 white below.



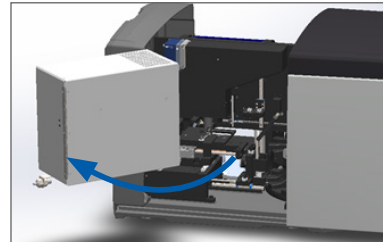
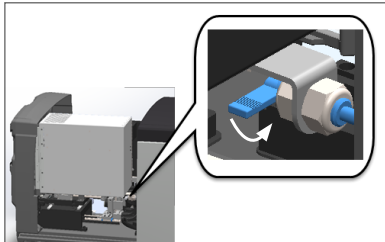
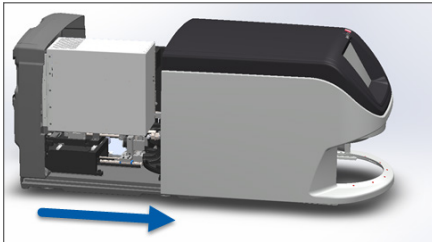
8. If you are performing the entire six-month maintenance routine, continue to the next procedure.
9. If you are ready to close the scanner cover and restart the scanner, follow the steps in *“Restart the Scanner After Interior Maintenance”* on page 58.

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 47.
2. Open the cover and access the interior.
 - a. Open scanner cover.
 - b. Rotate VPU latch.
 - c. Pivot out VPU



For detailed steps, see “*Open the Scanner Cover and Access the Interior Components*” on page 48.

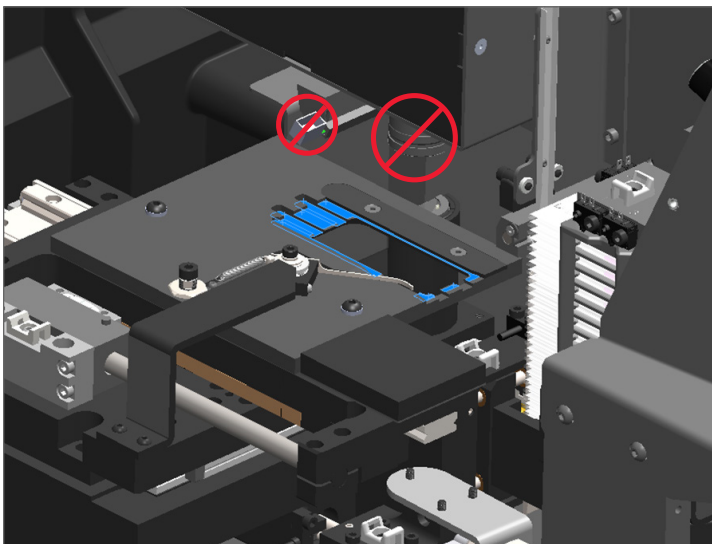


CAUTION: The stage slide tray is not removable. Do not attempt to remove it.

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 58.

Clean the Carousel

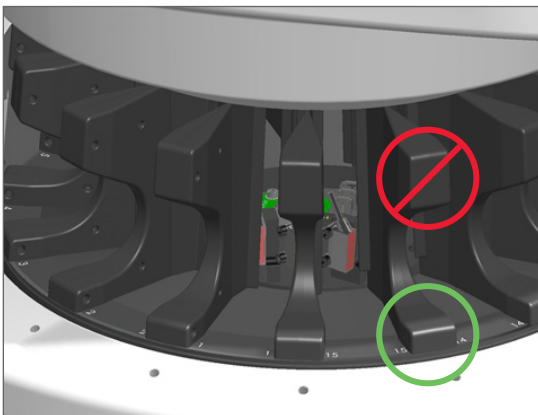
- ▶ **Frequency: at least every six months.**

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 47.
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 58.

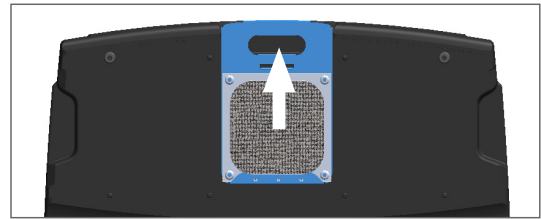
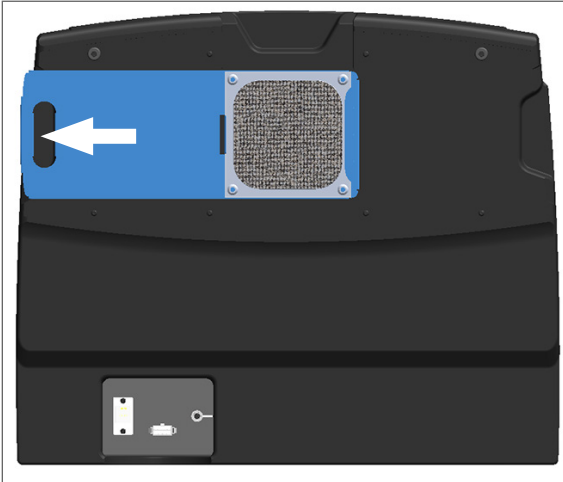
Clean the Fan Filter

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 47.
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 58.

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 58.

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.**

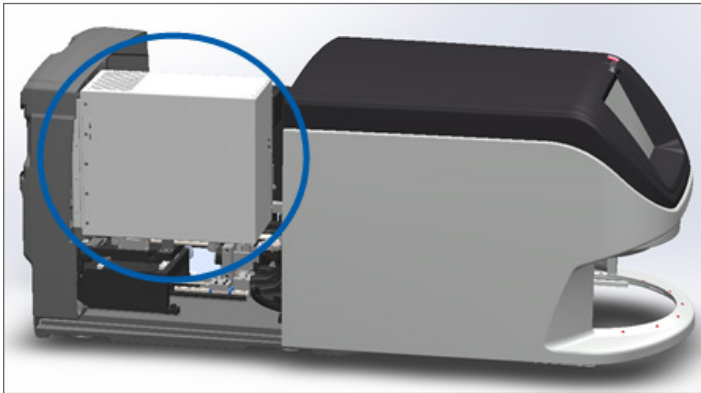
To clean the touchscreen:

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 58.

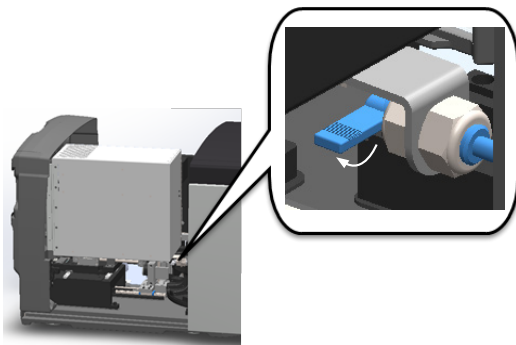
Restart the Scanner After Interior Maintenance

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

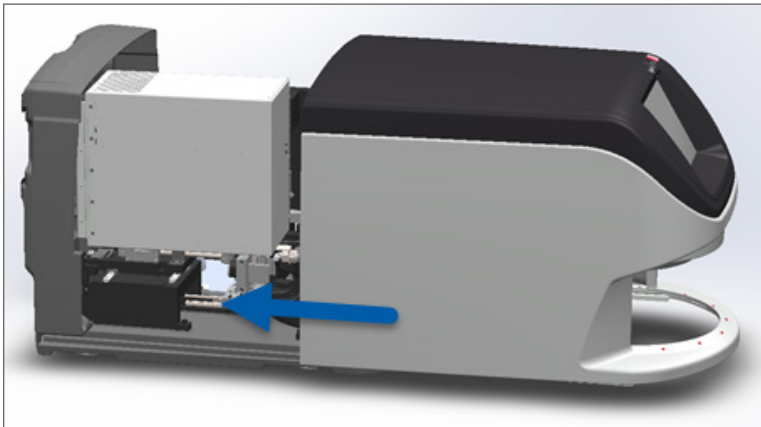
1. Pivot the VPU into the closed position.



2. Secure the VPU in place by rotating the VPU latch forward or backward 180 degrees, depending on its current position.



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 47.*

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.*

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 Scanner IT Manager and Lab Administrator Guide*.



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

Personal Protective Equipment

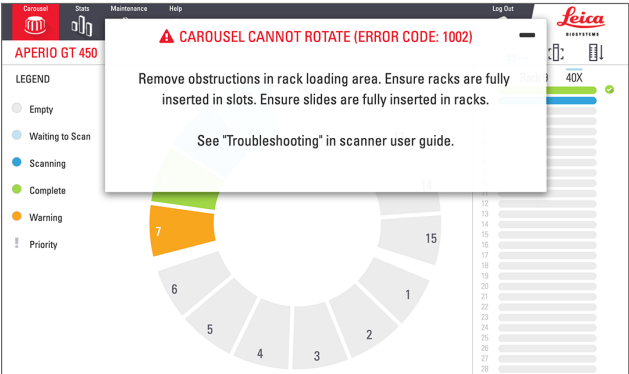

If you need to access the interior of the scanner while troubleshooting an issue, follow the policies and procedures of your institution, including the use of personal protective equipment (PPE).

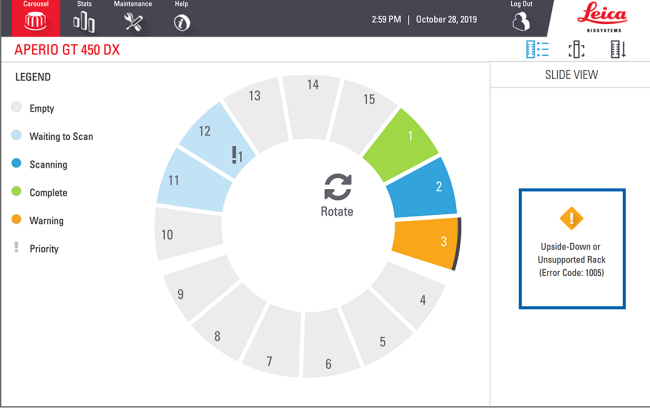
Red Blinking Lights on Carousel

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 carouselThe 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 <i>“Error Codes and Solutions”</i> on page 63 for steps to resolve the specific error.

Type of issue:	Scanner status:	Steps to resolve the issue:
<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 <i>“Rack Warnings and Solutions”</i> on page 74 for steps to resolve the specific error.</p>
<p>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.</p>	<p>Varies with the situation.</p>	<p>See <i>“Symptoms and Solutions”</i> on page 81.</p>

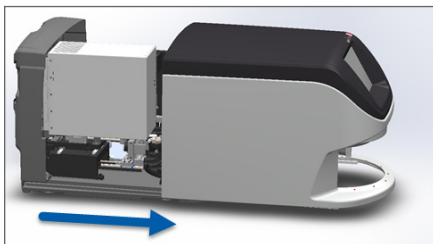
Perform a Safe Restart After an Error

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.

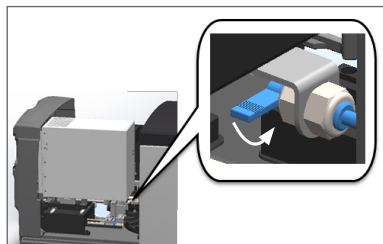
Follow these steps to safely restart the scanner after an error:

1. Open the cover and access the interior:

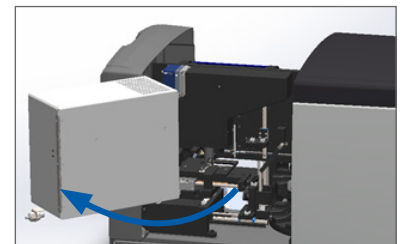
- a. Open scanner cover.



- b. Rotate the VPU latch.

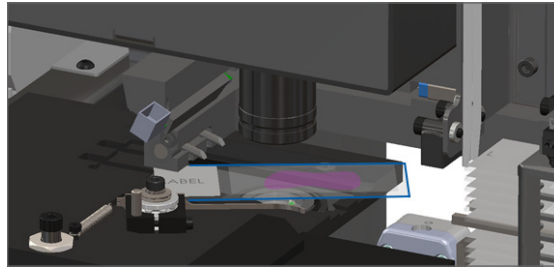
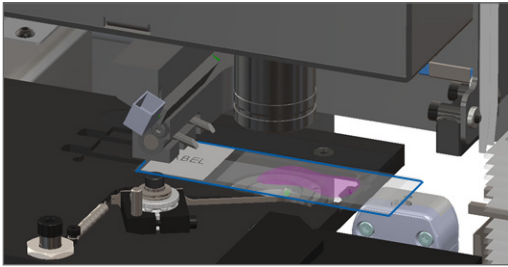


- c. Pivot out VPU



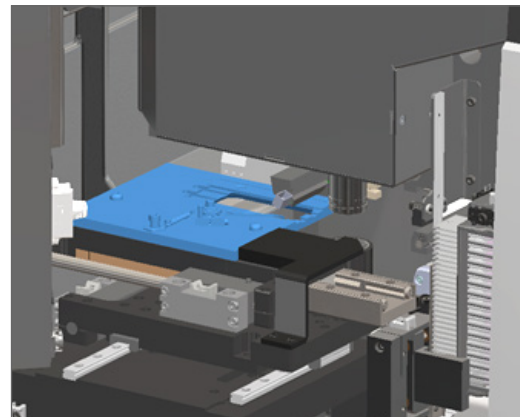
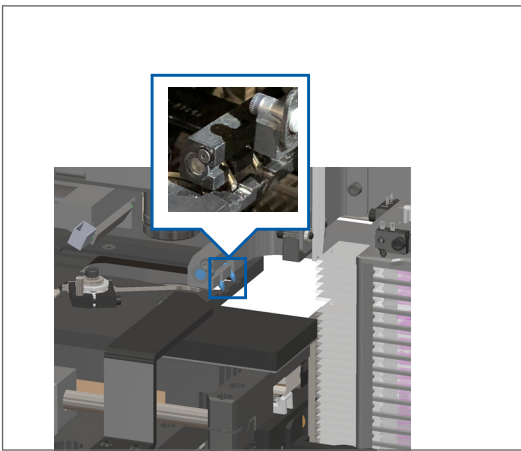
For detailed steps, see *“Open the Scanner Cover and Access the Interior Components”* on page 42.

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

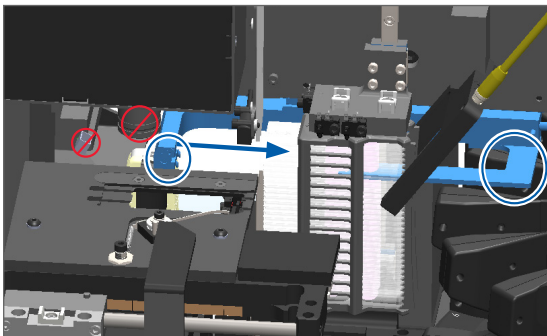


CAUTION: Restarting the scanner with a slide on the stage may damage the slide.

3. If there is a slide on the stage, carefully remove it from the stage without touching the surrounding components.
4. Return the pusher to the retracted (safe) position.
 - a. Align the pusher teeth with the slide stage grooves:
 - b. Slide the stage to the rear of the scanner, as shown:

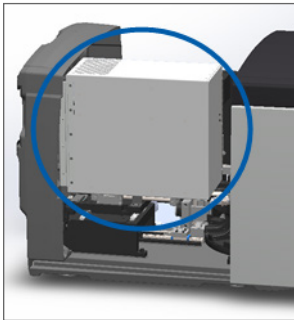


- c. Slide the pusher to the front of the scanner, as shown in the rightmost image below. Hold the pusher in one of the areas circled below. Avoid touching the LED and objective.

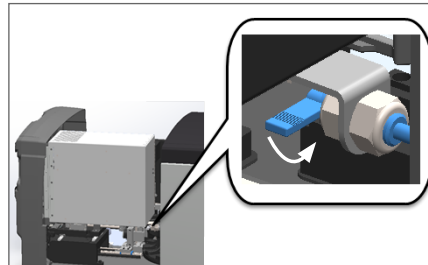


5. Close the scanner cover:

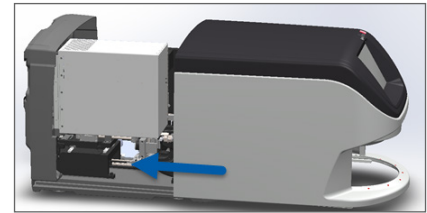
a. Pivot the VPU into place.



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 52.

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.

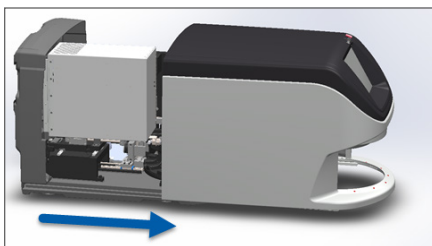
1000: Internal error

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

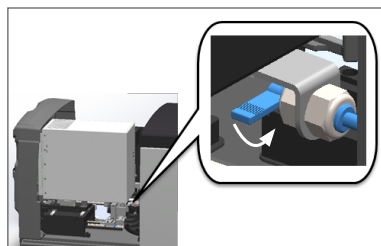
Follow these steps:

1. Open the cover and access the interior:

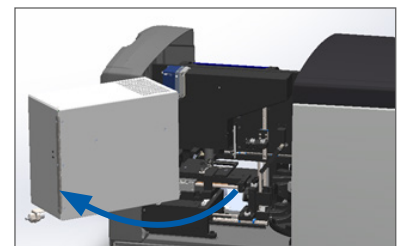
a. Open scanner cover.



b. Rotate the VPU latch.



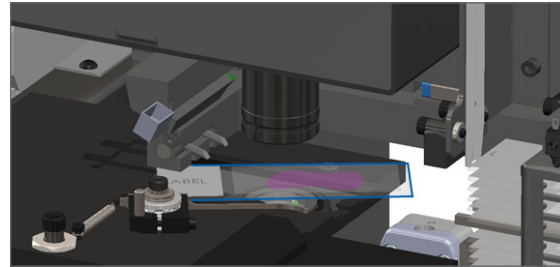
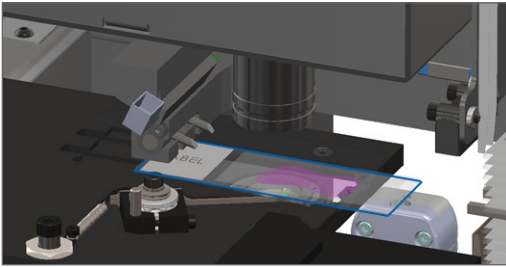
c. Pivot out VPU



For detailed steps, see *“Open the Scanner Cover and Access the Interior Components”* on page 42.

2. Take photos of any obstructions. Leica Biosystems Technical Services may request the photos if you need additional assistance after completing the steps below.

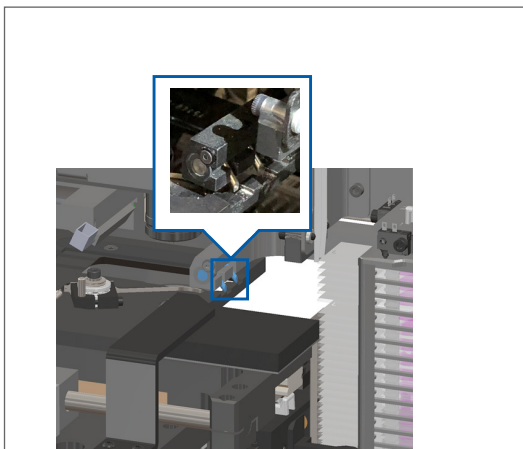
3. Check if there is a slide on the stage or partially on the stage.



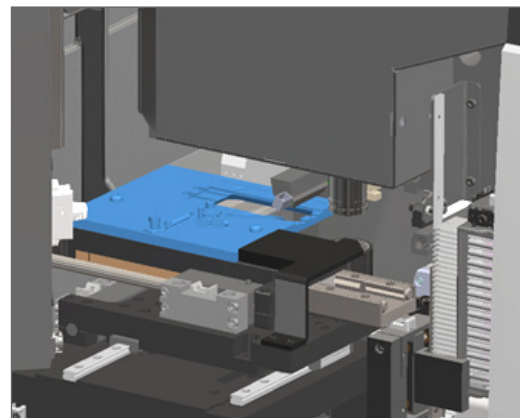
CAUTION: Restarting the scanner with a slide on the stage may damage the slide.

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 position.

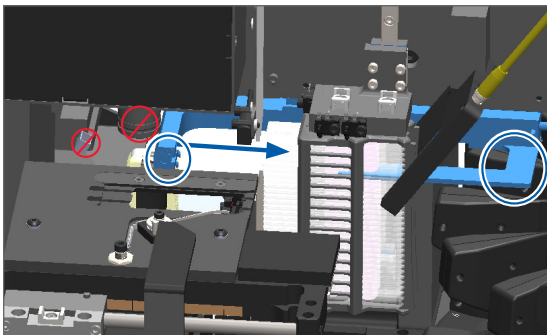
- a. Align the pusher teeth with the slide stage grooves:



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

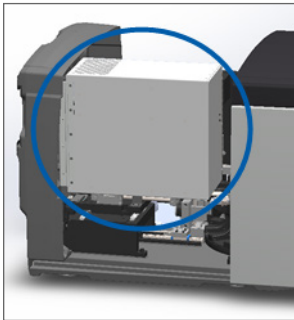


- c. Slide the pusher to the front of the scanner, as shown in the rightmost image below. Hold the pusher in one of the areas circled below. Avoid touching the LED and objective.

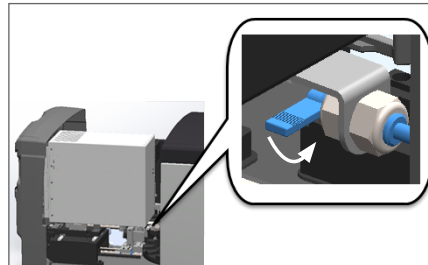


6. Close the scanner cover:

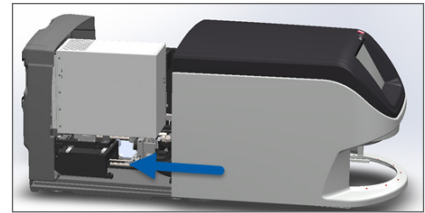
a. Pivot the VPU into place.



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 52.

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.

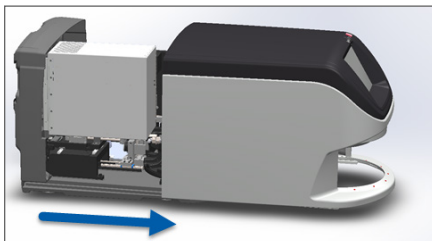
1001: Scanner cannot initialize

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

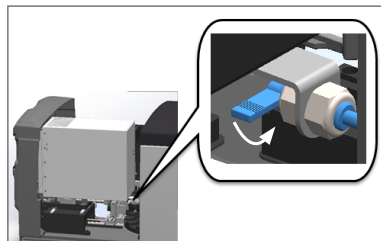
Follow these steps:

1. Open the cover and access the interior:

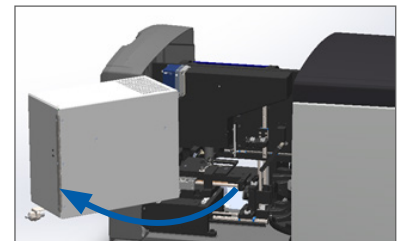
a. Open scanner cover.



b. Rotate the VPU latch.

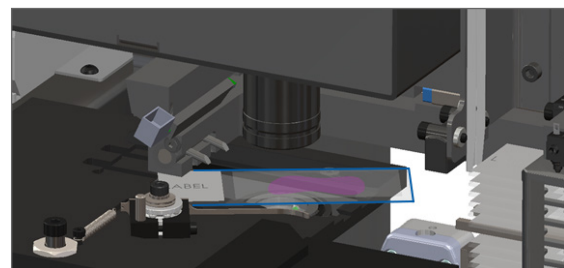
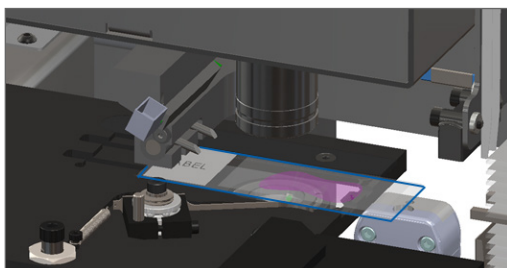


c. Pivot out VPU



For detailed steps, see *“Open the Scanner Cover and Access the Interior Components”* on page 42.

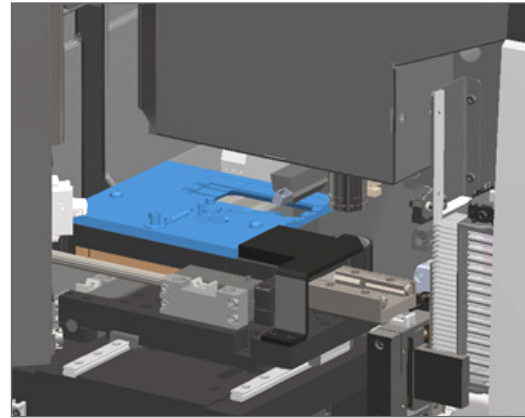
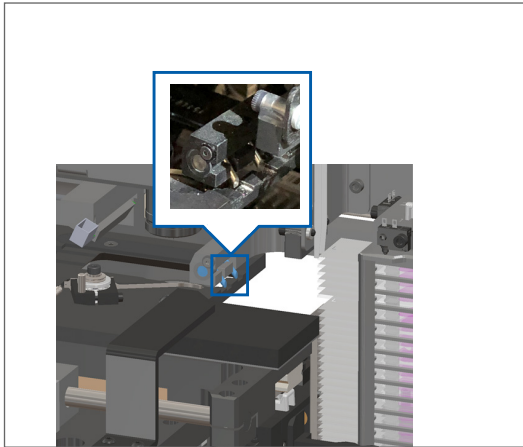
2. Check if there is a slide on the stage or partially on the stage.



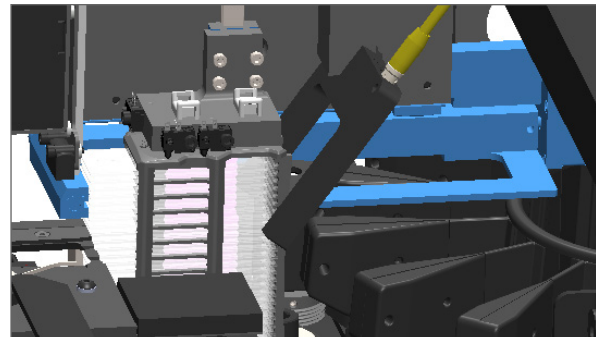
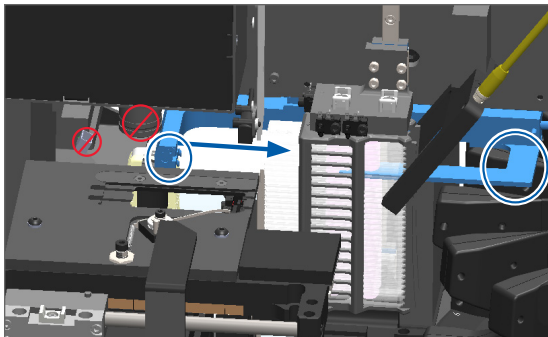


CAUTION: Restarting the scanner with a slide on the stage might damage the slide.

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 position.
 - a. Align the pusher teeth with the slide stage grooves:
 - b. Slide the stage to the rear of the scanner, as shown:

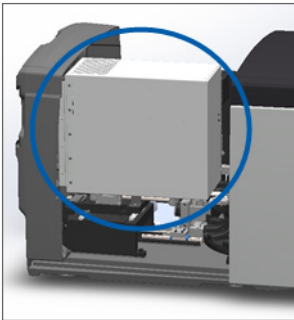


- c. Slide the pusher to the front of the scanner, as shown in the rightmost image below. Hold the pusher in one of the areas circled below. Avoid touching the LED and objective.

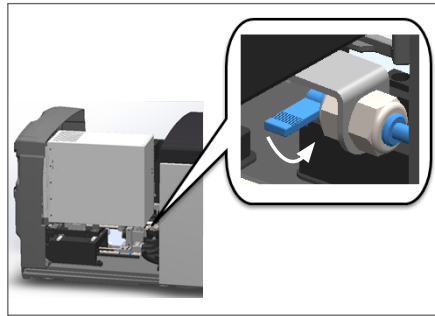


5. Close the scanner cover:

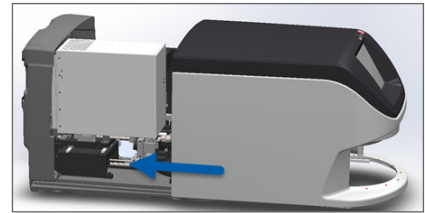
a. Pivot the VPU into place.



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 52.

6. Shut down the scanner using the steps in, “Shut Down the Scanner” on page 41.

7. Turn on the scanner, and wait for the initialization process to complete.

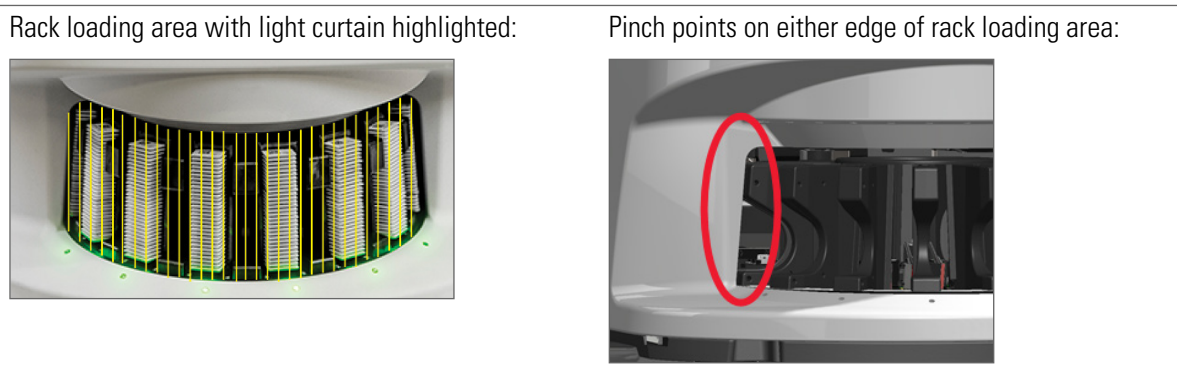
8. If the issue persists, call Leica Biosystems Technical Services.

1002: Carousel cannot rotate

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

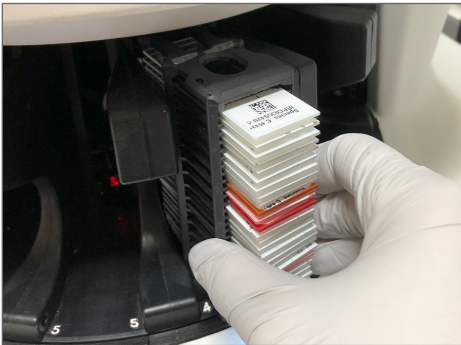
Follow these steps in order until the issue is resolved and the error message closes:

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



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

Leica logo facing out and up:

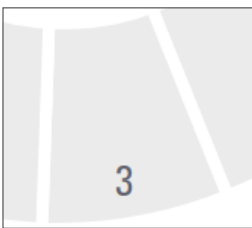


Rack inserted fully into the rack slot:

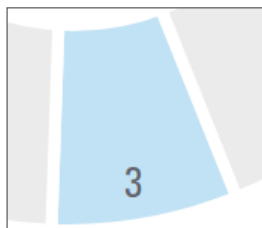


3. When you insert the rack, ensure the rack position and the rack status light turns light blue (waiting to scan):

Empty rack slot:



Rack inserted and waiting to scan:



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



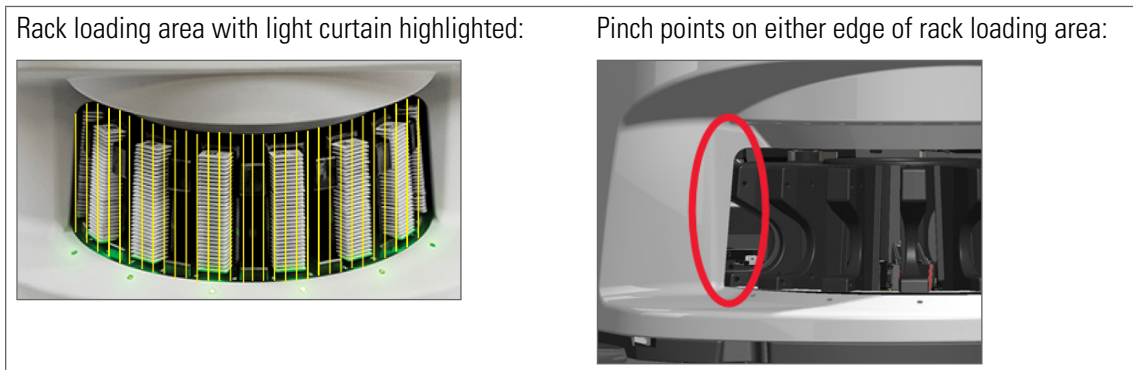
5. If there are no obstructions and the carousel still does not rotate, restart the scanner. See *“Perform a Safe Restart After an Error”* on page 61.
6. If the issue persists, contact Leica Biosystems Technical Services.

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.



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 61.*
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 SAM server.
2. Run network diagnostics.
3. Ensure the DICOM server is running. Restart the DICOM server if necessary.
4. If issue persists, contact Leica Biosystems Technical Services.

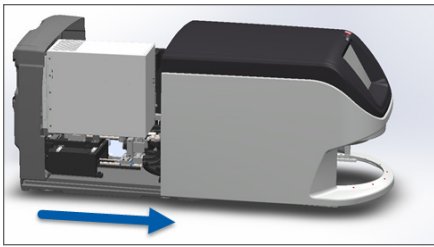
2000: Slide handling error at slide stage, rack, or pusher.

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

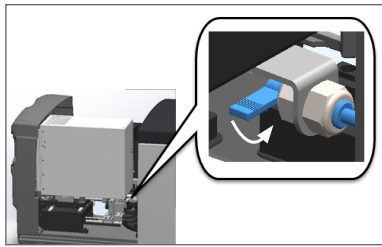
Follow these steps in order until the issue is resolved:

1. Open the cover and access the interior:

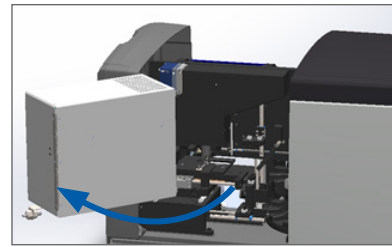
a. Open scanner cover.



b. Rotate the VPU latch.

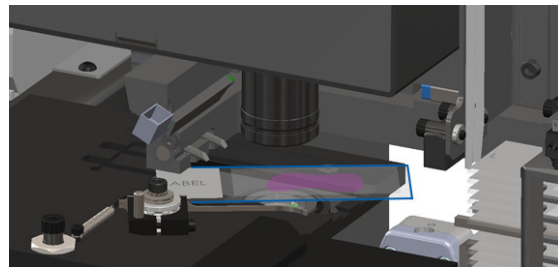
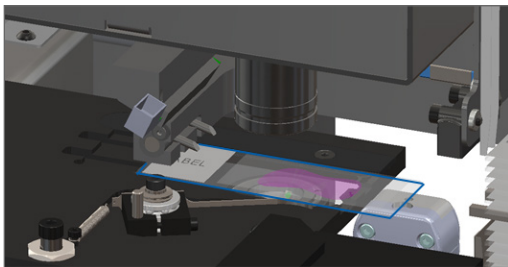


c. Pivot out VPU



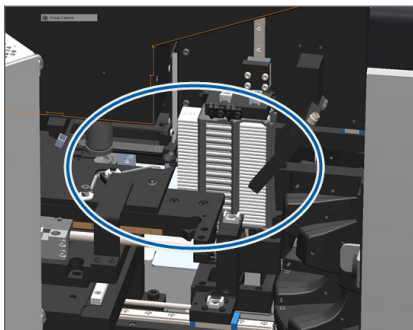
For detailed steps, see *“Open the Scanner Cover and Access the Interior Components”* on page 42.

- 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.**



CAUTION: Restarting the scanner with a slide on the stage might 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.**

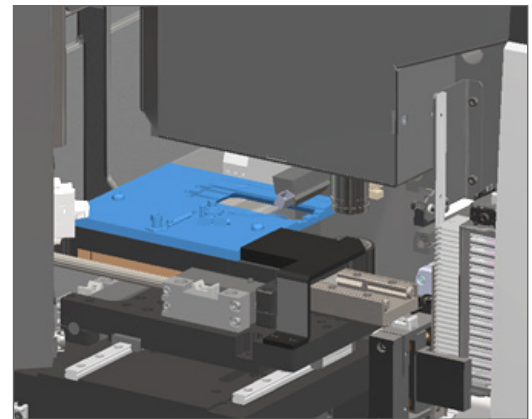
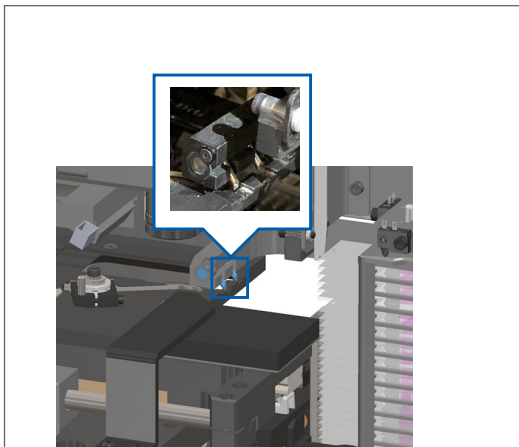


6. If possible, carefully remove the slide that is causing the obstruction.

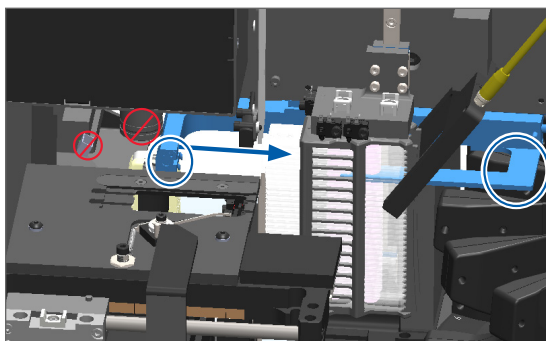


WARNING: Do not attempt to recover broken slides. Call Leica Biosystems Technical Services.

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 position.
- a. Align the pusher teeth with the slide stage grooves:
 - b. Slide the stage to the rear of the scanner, as shown:

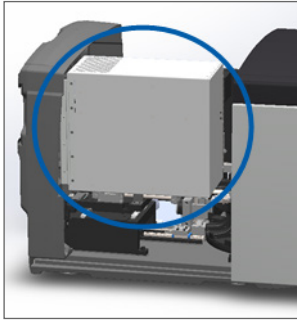


- c. Slide the pusher to the front of the scanner, as shown in the rightmost image below. Hold the pusher in one of the areas circled below. Avoid touching the LED and objective.

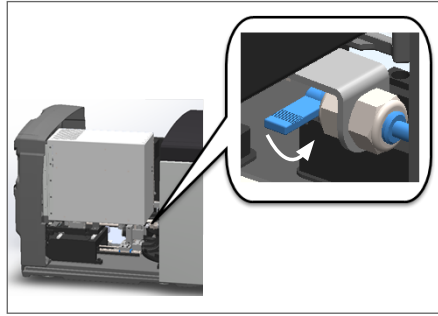


9. Close the scanner cover:

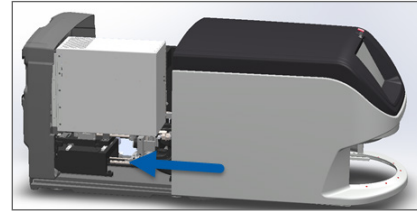
a. Pivot the VPU into place.



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 52.

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.

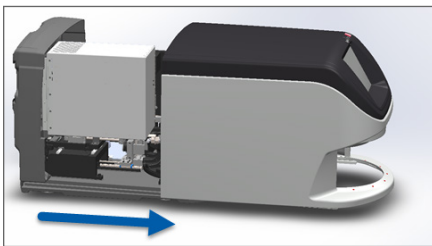
2001: Slide handling error at rack gripper, lift, or carousel.

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

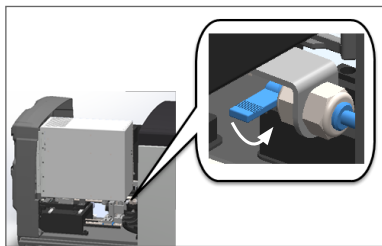
Follow these steps until the issue is resolved:

1. Open the cover and access the interior:

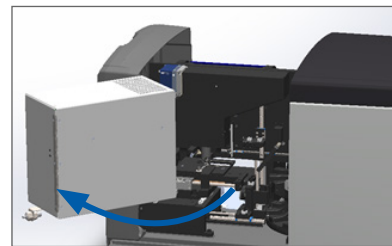
a. Open scanner cover.



b. Rotate the VPU latch.



c. Pivot out VPU



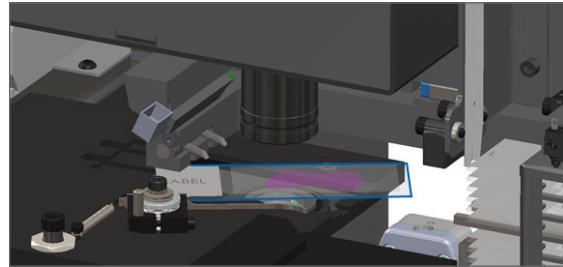
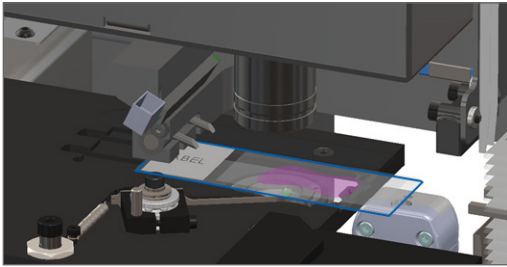
For detailed steps, see *"Open the Scanner Cover and Access the Interior Components"* on page 42.

2. Take photos of the obstruction.



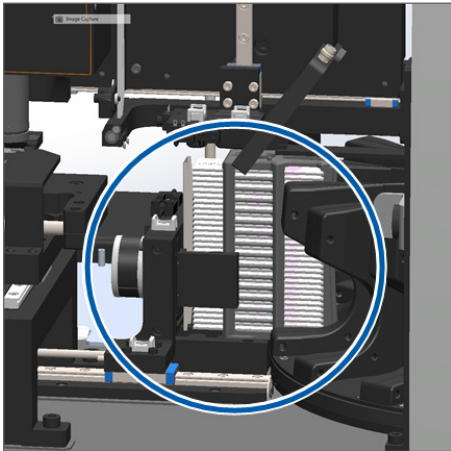
WARNING: Do not attempt to recover broken slides. Call Leica Biosystems Technical Services.

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



CAUTION: Restarting the scanner with a slide on the stage might 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.

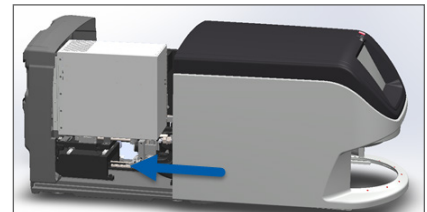
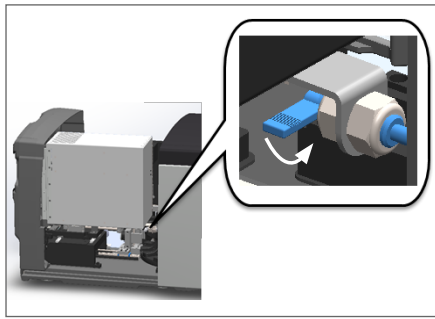
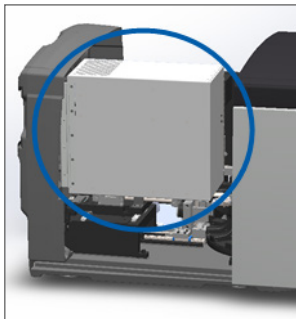


6. Close the scanner cover:

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 52.

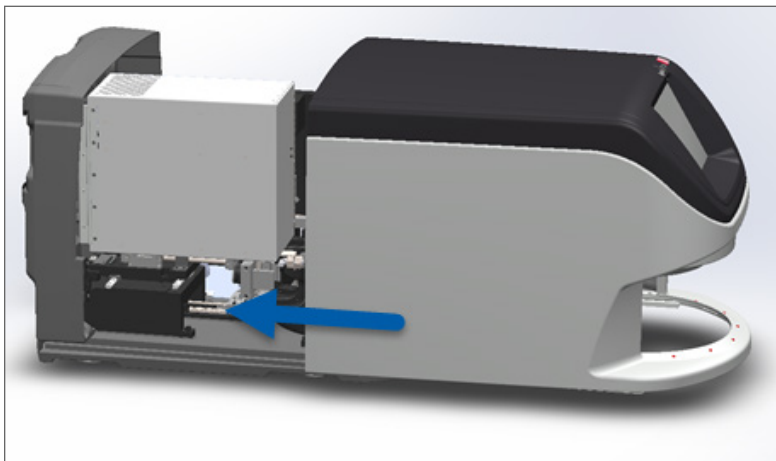
7. Contact Leica Biosystems Technical Services.

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 31.)
2. Ensure the rack is inserted correctly:



3. Remove the rack and check the following:
 - You are using a supported rack. (See *“Slide Racks Supported”* on page 21.)
 - 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 61.
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 76
 - ▶ *“No Barcode”* on page 77

- ▶ “No Tissue” on page 77
 - ▶ “No Macro Focus” on page 77
 - ▶ “Image Quality” on page 78
 - ▶ “Image Transfer Error – Pending Retry” on page 79
 - ▶ “Aborted” on page 79
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.

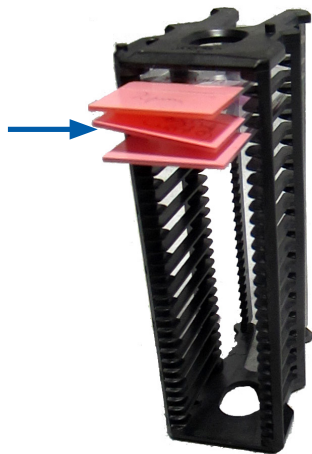
 You can temporarily hide some error messages by tapping the **x** in the top-right corner. This enables you to view the macro image.

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 also, *“Load Slides in the Rack” on page 27.*
2. Ensure barcodes meet specifications. See *“Barcodes Supported” on page 21.*
3. Ensure barcodes meet minimum quality requirements. See *“Barcodes” on page 24.*
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 *“Slide Preparation” on page 22.*
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 27.*)
 - ▶ 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 Scanner 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:
 - ▶ 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 37.)
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 44.)
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:
The system often resolves the issue without intervention.	The Lab Administrator should:
<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 eSlide Manager. 3. If necessary, rescan only the slides that are missing from eSlide Manager. 	<ol style="list-style-type: none"> 1. Check connectivity from the scanner to the DICOM server, and the DICOM server to your site's image storage location. 2. Check if your site's image storage location is full. 3. If the issue persists, consult with your organization's IT professionals prior to calling Leica Biosystems Technical Services.

Aborted

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

Follow these steps in order until the issue is resolved.

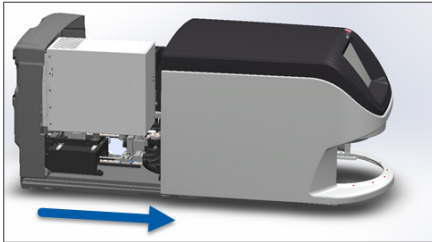
1. If the "Aborted" message appears on all slides, go to *"Aborted Message Appears on All Slides"* on page 80. If the message appears on one or some slides, continue to the next step.
2. Check for damage or common slide preparation issues and verify:
 - ▶ Coverslip is not missing or overhanging.
 - ▶ 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

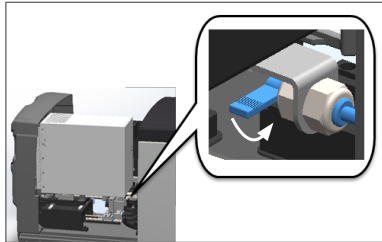
Follow these steps in order until the issue is resolved:

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

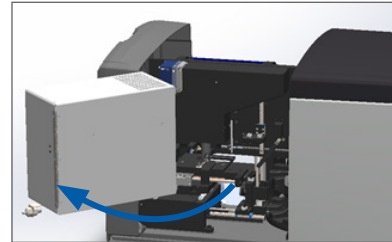
a. Open scanner cover.



b. Rotate the VPU latch.

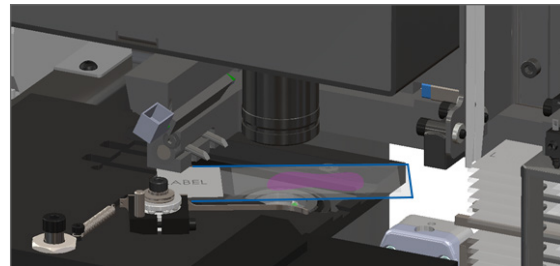
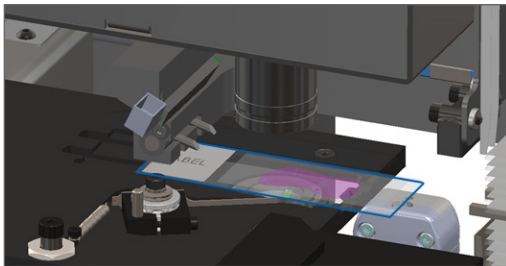


c. Pivot out VPU



For detailed steps, see *“Open the Scanner Cover and Access the Interior Components”* on page 42.

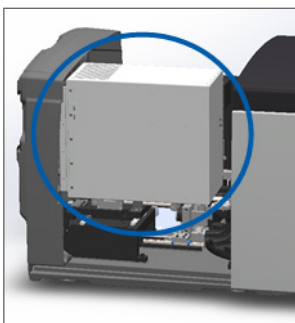
3. Check if there is a slide on the stage or partially on the stage.



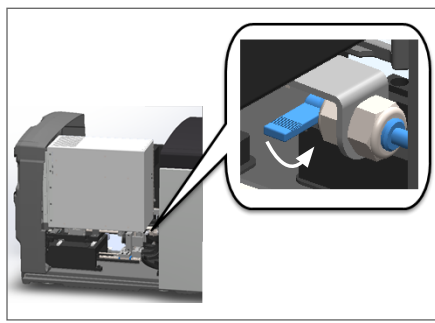
CAUTION: Restarting the scanner with a slide on the stage might damage the slide.

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:

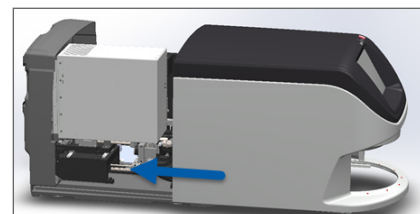
a. Pivot the VPU into place.



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 52.

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 41*.
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 41*.
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. Take photos of the location of the damage. Leica Biosystems Technical Services may request the photos when providing assistance.

Internet Connection Lost

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



You can attempt to re-establish network connection by typing the IP address of the SAM DX server. (Contact your IT staff for this information.) If this does not establish network connection, contact your IT staff for assistance.

A

Performance Information

Analytical Performance

This section gives a summary of the Aperio GT 450 DX analytical performance studies.

Trueness

Test	Acceptance Criteria	Test Purpose
Tissue Finder	<ul style="list-style-type: none">• System encompasses all stained portions of the tissue block at defined success rates for FFPE H&E-Stained slides – 98% success rate• System encompasses all stained portions of the tissue block at defined success rates for FFPE IHC Stained slides – 90% success rate• System scans ≤ 30% excessive area at a success rate of 90% for FFPE H&E-stained slides• System scans ≤ 30% excessive area at a success rate of 90% for FFPE IHC stained slides	Demonstrates that all tissue specimen on the glass slide is included in the digital image file.
Focus Error	System has a focus error within the allowable calculated limits for both auto-focusing and scanning methods: <ul style="list-style-type: none">• Focus low : -1.83 microns• Focus high : 1.21 microns	Demonstrates that the focus quality of the Aperio GT 450 DX scanner is acceptable even in the presence of uneven tissue.
Color	System provides color management using an ICC profile per established industry guidelines.	Measures the color differences between the input color stimuli and the output digital image file.

Test	Acceptance Criteria	Test Purpose
Stitching Error	System has > 85% analysis stripes for all the slides across all 3 Aperio GT 450 DX scanner devices and has actual stitching errors less than stitching error specification.	Analyzes potential stitching error sources, capture image/stripe data, executes the stitching algorithm, and measures the alignment of the stitching algorithm to the established ground truth image data (perfect stitching). This comparison is performed by comparing the stripe overlap statistics with the actual data generated by the stitching algorithm.

Precision (Repeatability and Reproducibility)

Test	Acceptance Criteria	Test Purpose
Image Repeatability	Image repeatability is $\geq 90\%$.	Assesses image quality repeatability, which is a key component to ensuring first time scan success rate.
Image Quality Reproducibility	Inter-device reproducibility is $\geq 90\%$ (90 of 100 slides must result in a "Pass").	Assesses image quality reproducibility, which is the key component to ensuring first time scan success rate.
Focus Reproducibility	Systems have an overall intra-system agreement of >85%.	Assesses that the intra-system focus quality of the Aperio GT 450 DX scanner is acceptable even in the presence of uneven tissue.
Stitching Reproducibility	Systems have an overall intra-system agreement > 85%.	Analyzes potential stitching error sources, capture image/stripe data, executes the stitching algorithm, and measures the alignment of the stitching algorithm to the established ground truth image data (perfect stitching) and compares intra-system agreement.

Accuracy (Resulting from Trueness and Precision)

Test	Acceptance Criteria	Test Purpose
Spatial Resolution	System has a Modulation Transfer function with MTF _{1/4} Nyquist >.70.	Evaluates the composite optical performance of all components in the image acquisition phase.

Clinical Performance

Clinical performance is based on the concordance between the Aperio GT 450 DX and traditional light microscopy.

Clinical performance of the Aperio GT 450 DX is based on available scientific literature as, to date, no clinical performance studies, data from routine diagnostic testing or other clinical performance data is available for the Aperio GT 450 DX. A systematic literature search was performed to identify relevant literature which supports the clinical performance of the Aperio GT 450 DX.

The clinical performance, measured in terms of concordance of pathology findings between the Aperio GT 450 DX and traditional light microscopy has been demonstrated by Hanna et al. 2020, who demonstrated that the Aperio GT 450 DX had a major diagnostic concordance of 100% and a minor diagnostic concordance of 98.8%.

Overall, based on the clinical performance evidence available, the Aperio GT 450 DX is able to perform as per its intended purpose in a clinical setting.

Results from the clinical performance studies reported in the literature are shown below.

Performance Outcome	Comparator	Results	Reference
Concordance	Glass slide microscopy	Major diagnostic concordance 100% (254/254) Minor diagnostic concordance 98.8% (251/254)	Hanna et al. 2020 ¹

¹ Hanna MG, Parwani A, Sirintrapun SJ: *Whole Slide Imaging: Technology and Applications*. Adv Anat Pathol, 27: 251-259, 2020 10.1097/pap.0000000000000273

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