

CUSTOMER NOTICE

1. Introduction

The purpose of a Customer Notice is to provide timely communication regarding updates to Leica Biosystems product user manuals. This Customer Notice contains information about your Leica Biosystems product that will be included in a future release of one or more user manuals for your product. This information may include new instructional content, updated specifications, or additional information about the use or care of your product. Use this document as supplementary information until the revised user manuals are available.

This Customer Notice provides information and instructions for using the new features provided with the Aperio GT 450 Release 1.3.

This document contains the following sections:

1. Introduction
2. Aperio GT 450 Release 1.3 overview
3. Configure default Scan Settings in SAM
4. 20x magnification scanning
5. Z-Stack scanning
6. Set up Auto Narrow Stripe scanning on SAM
7. Aperio GT 450 optional DICOM upgrade
8. Specifications updates

Products Affected

Aperio GT 450 Scanner, Aperio GT 450 Software, and Aperio GT 450 Controller Version 1.3.

User Manuals Affected

The information contained in this document will be incorporated into the following user manuals upon their next major scheduled release:

Document Title	Base Document Number
Aperio GT 450 User's Guide	MAN-0391
Aperio GT 450 IT Manager and Lab Administrator's Guide	MAN-0394
Aperio GT450 Scanner Specifications	MAN-0393
Aperio GT 450 Quick Reference Guide	MAN-0392

2. Aperio GT 450 Release 1.3 overview

The Aperio GT 450 release 1.3 includes the following new features and updates:

20x magnification scanning

Prior to Aperio GT 450 release 1.3, the Aperio GT 450 scanner scanned all slides at 40x magnification. With Aperio GT 450 release 1.3, you have the option to scan slides at 20x or 40x magnification, depending on the needs of your organization or specific project.

The primary benefit to scanning at 20x is to reduce the image file size, which then increases your image storage capacity. When you scan your slides at 20x magnification instead of 40x magnification, the image size is approximately 71 percent smaller than a slide scanned at 40x magnification.

For more information on setting up and using 20x magnification, see [20x magnification scanning on page 4](#).

Z-Stack scanning

Z-Stack scanning enables you to scan a glass slide at different focal planes along the vertical z-axis, and stack the images on top of each other to produce a 3D composite multiplane image. Pathologists can review slide samples at varied “heights” using a software focus adjustment, comparable to the fine-focus knob of a conventional light microscope. To view z-stack images, use the Aperio ImageScope viewer.

For more information, see [Z-Stack scanning on page 7](#).

Auto Narrow Stripe quality check and rescan

The Auto Narrow Stripe scanning feature helps mitigate potential image quality issues by enabling the scanner to automatically rescan a slide using an alternative scanning process, Auto Narrow Stripe scanning, when the system detects an excessive tilt of the slide tissue. Excessive slide tissue tilt can occur when the slide does not sit level in the slide tray, or when tissue is not laid flat on the glass surface along the short axis (index axis) of the slide due to poor slide preparation. Auto Narrow Stripe scanning is not available when scanning z-stack images.

For more information, see [Set up Auto Narrow Stripe scanning on SAM on page 11](#).

Optional DICOM upgrade overview

Aperio GT 450 releases 1.3 and later support an optional DICOM feature pack that enables third-party developers to obtain digital slide images (and metadata) created by the Aperio GT 450 scanner to use in their own viewers or LIS (Laboratory Information System) products.

When the DICOM feature pack is enabled, the Aperio GT 450 scanner creates SVS and DICOM compatible images. The .svs format is the default.



The optional DICOM feature pack is not supported with the 20x magnification scanning, Z-stack scanning, or Auto Narrow Stripe scanning features.

For more information, see [Aperio GT 450 optional DICOM upgrade on page 12](#).

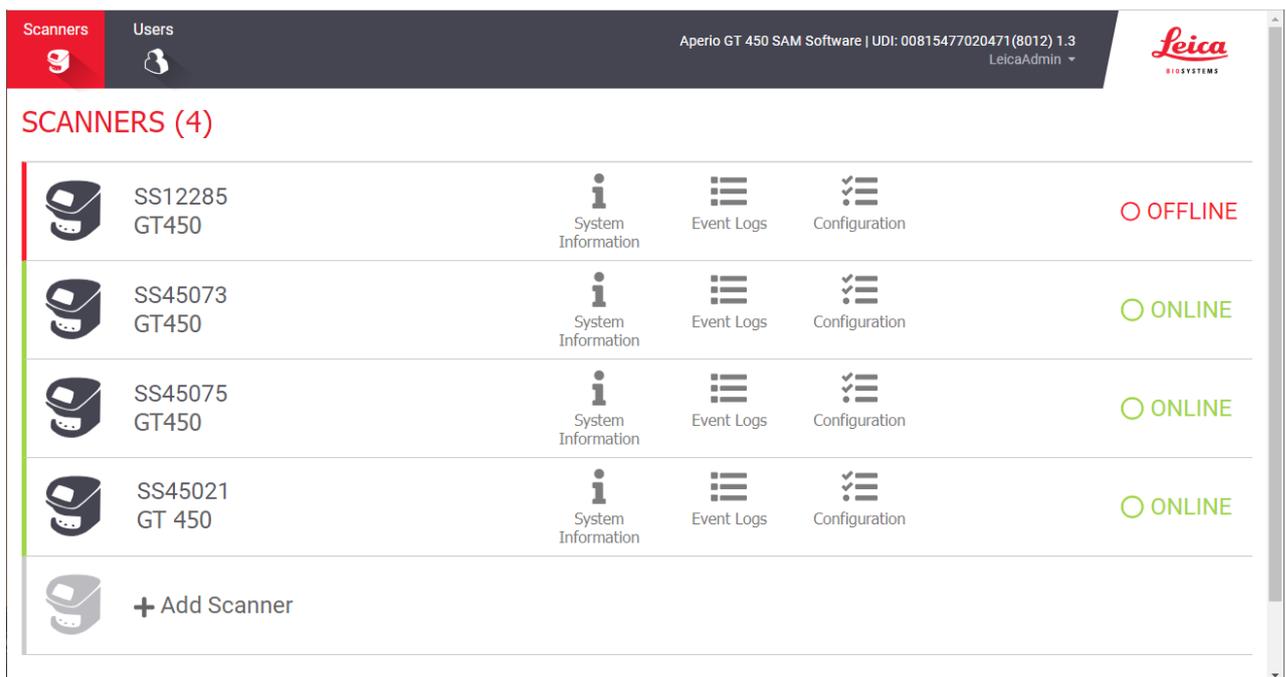
3. Configure default Scan Settings in SAM

The Configure Scan Settings page in SAM enables you to set the default scan magnification, to set z-stack scanning options, and to enable or disable the Auto Narrow Stripe feature.

Only a user who is assigned the Lab Admin role can make configuration changes.

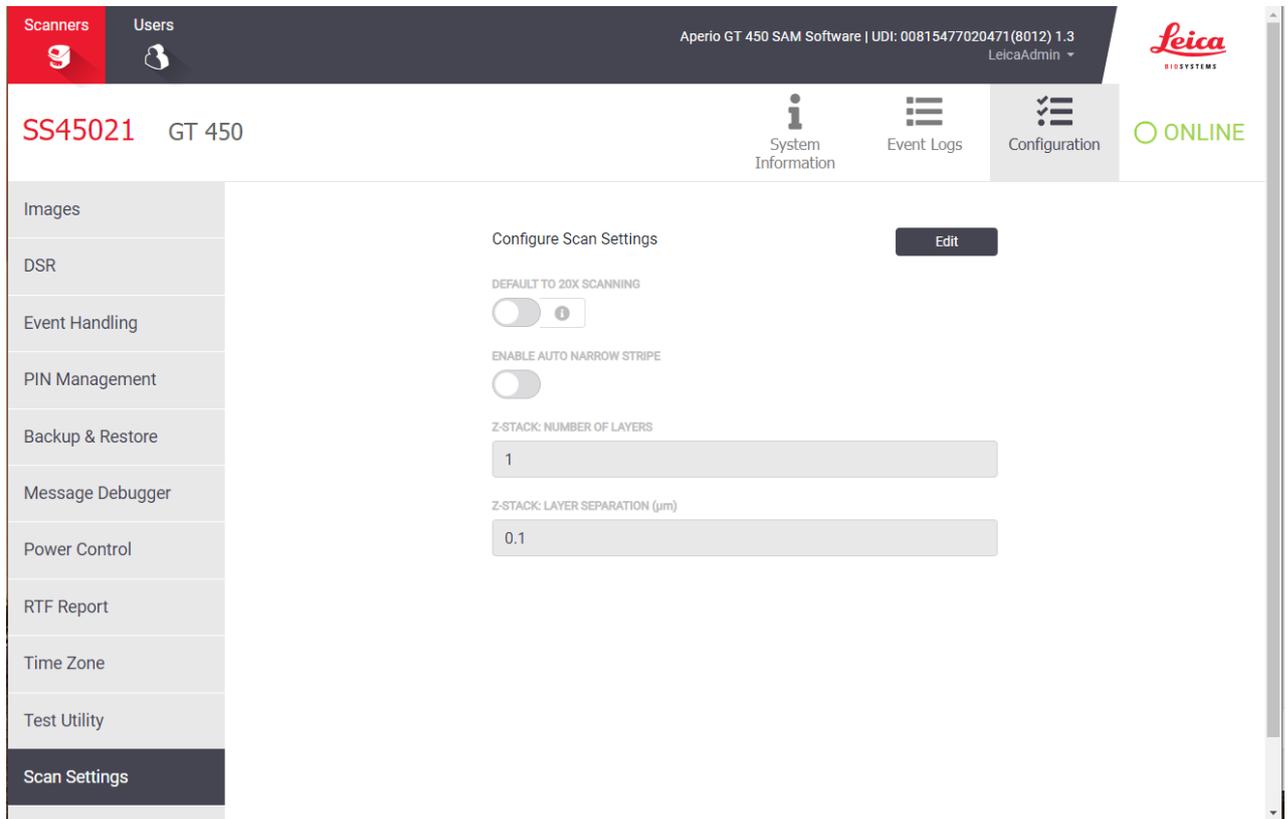
To configure scan settings for a scanner, follow these steps:

1. Log in to the SAM software.
2. When the SAM Home screen appears, confirm that the Scanners icon in the banner is selected, and the page shows the list of scanners. Click the **Scanners** icon to display the list, if necessary.



3. Click the **Configuration** icon to the right of the scanner you want to configure.

- In the left pane, click **Scan Settings** to open the Configure Scan Settings page.



- To change the scan settings, click **Edit**.
- To save your changes, click **Save**.

For more information and instructions for adjusting specific settings, see:

- [20x magnification scanning on page 4](#)
- [Z-Stack scanning on page 7](#)
- [Set up Auto Narrow Stripe scanning on SAM on page 11](#)

4. 20x magnification scanning

This section contains instructions for setting the scan magnification default in SAM, and performing rack-level scans at 20x or 40x magnification.

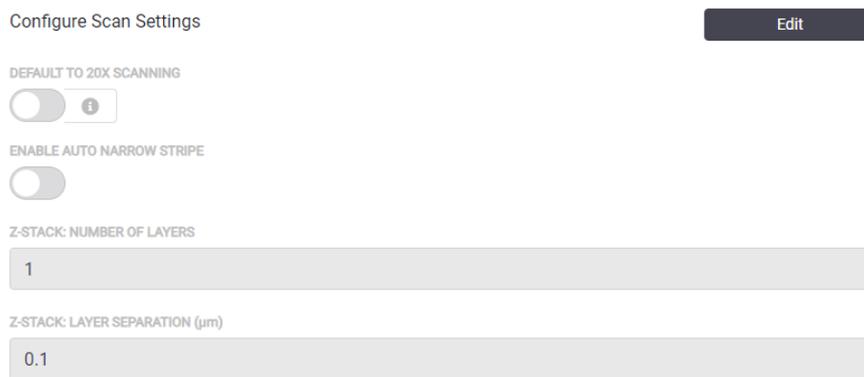
Your Aperio GT 450 scanner is initially set to scan all racks using 40x magnification. If you want this scanner to scan using 20x magnification by default, turn on the DEFAULT TO 20X SCANNING option in SAM.

When scanning slides, you can override the default scan magnification using the rack settings on the scanner console.

Set the scan magnification default on SAM

Follow the steps below to set the default scan magnification for a specific Aperio GT 450 scanner:

1. Log on to SAM.
2. Confirm that the Scanners icon in the banner is selected, and the page shows the list of scanners. (For an example, see [Configure default Scan Settings in SAM on page 3.](#))
3. Click the **Configuration** icon to the right of the scanner.
4. Click **Scan Settings** in the side menu bar.
5. On the Configure Scan Settings page, click **Edit**.



6. To set the scan magnification default to 20x, click to turn on the **DEFAULT TO 20X SCANNING** option. (If this setting is turned off, the scanner uses the default of 40x magnification.)

Configure Scan Settings



7. To save your settings, click **Save**.

Change the scan magnification for a rack of slides

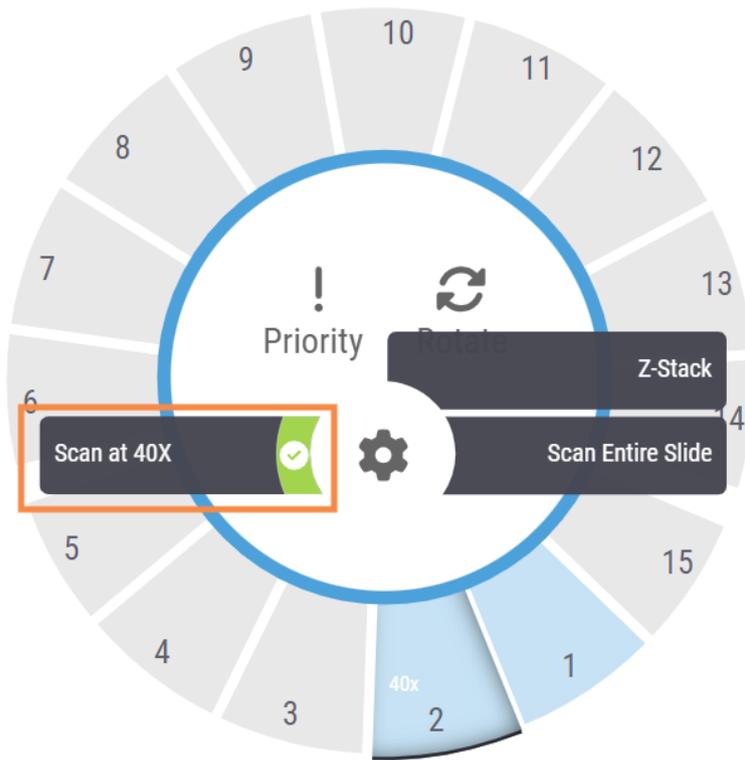
For each Aperio GT 450 scanner, your Lab Administrator has the option of changing the default scan magnification from 40x to 20x within the SAM software. This section shows how to override the default during scanning, and manually change the scan magnification for a rack of slides.

This procedure describes how to scan a rack of slides at 40x magnification, when the default scan magnification is set to 20x. (If the default scan magnification is set to 40x, use the same process to scan a rack of slides at 20x magnification.)

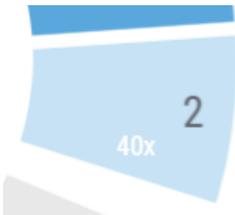
To scan a rack of slides at 40x when the scan magnification is set to 20x, follow these steps:

1. Load the rack with only the slides that you want to scan at 40x.
2. Tap the rack position that contains the slides you just loaded.

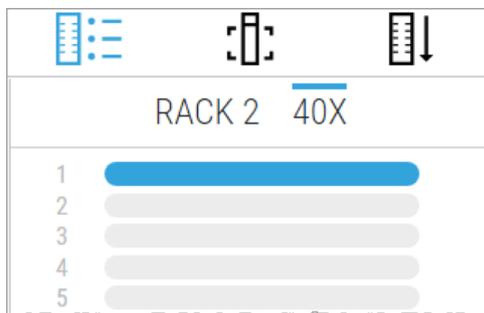
3. Tap **Settings** , and then tap **Scan at 40X**.



The **Scan at 40x** option is selected, and **40x** appears on the rack position.



During scanning, the Rack View indicates the scanner is scanning this rack at 40x magnification.



5. Z-Stack scanning

The scanner can create multiple digital images of slide tissue scanned at different focal depths, creating a 3D composite multiplane image that you can visually navigate through much as a microscope user can navigate through different tissue focal depths by using the microscope objective fine and coarse adjustments. This ability to create a 3D image is called “z-stack” scanning.

Pathologists can review slide samples at varied “heights” using a software focus adjustment, comparable to the fine-focus knob of a conventional light microscope. The Z-Stack scanning feature is specifically useful in cytology and dermatopathology.

For all types of scanning, the scanner determines the layer within the tissue that provides the optimal focus—this is called the best focus layer. For z-stack scanning, by default the best focus layer is placed in the middle of the z-stack, with an equal number of layers above and below it.

As described in the following section, you configure the default z-stack scan settings by indicating how many layers you want to scan and the distance between the layers (layer separation) in microns. For example, if you configure the z-stack to use 5 layers separated by .5 microns, there are two layers above the best focus layer and two layers below it.

Set up Z-Stack parameters on SAM

Follow the steps below to set the default Z-Stack parameters:

1. Log on to SAM.
2. Confirm that the Scanners icon in the banner is selected, and the page shows the list of scanners. (For an example, see [Configure default Scan Settings in SAM on page 3.](#))
3. Click the **Configuration** icon to the right of the scanner.
4. Click **Scan Settings** in the side menu bar.

- On the Configure Scan Settings page, click **Edit**.

The screenshot shows the 'Configure Scan Settings' page for scanner SS45021. The interface includes a top navigation bar with 'Scanners' and 'Users' tabs, and a main content area with a left sidebar menu. The 'Scan Settings' menu item is highlighted. The main content area displays the following settings:

- DEFAULT TO 20X SCANNING:** A toggle switch is currently turned off.
- ENABLE AUTO NARROW STRIPE:** A toggle switch is currently turned off.
- Z-STACK: NUMBER OF LAYERS:** A numeric input field containing the value '1'.
- Z-STACK: LAYER SEPARATION (µm):** A numeric input field containing the value '0.1'.

An 'Edit' button is located in the top right corner of the settings area.

- In the **Number of Layers** field, enter the default number of layers (focal planes) used for scanning z-stack images. You can select from 3 and 25 layers. (The number of layers includes odd numbers only.) Typically, the number of layers you choose depends on the type of tissue you are scanning. The scanner operator can adjust this setting on the scanner console when scanning a rack of slides. Note that scan time and file sizes increase based on number of focus planes you select.
- In the **Layer Separation** field, enter the default distance between planes from 0.25 to 1.0 micron. This setting controls the focus offset between layers. The scanner operator can adjust this setting on the scanner console when scanning a rack of slides.
- To save your changes, click **Save**.

Scan a rack of slides using z-stack scanning

Your Lab Administrator sets the default number of layers and the distance between layers (in microns) for each scanner. You can adjust these settings on the scanner console for each rack of slides you scan.

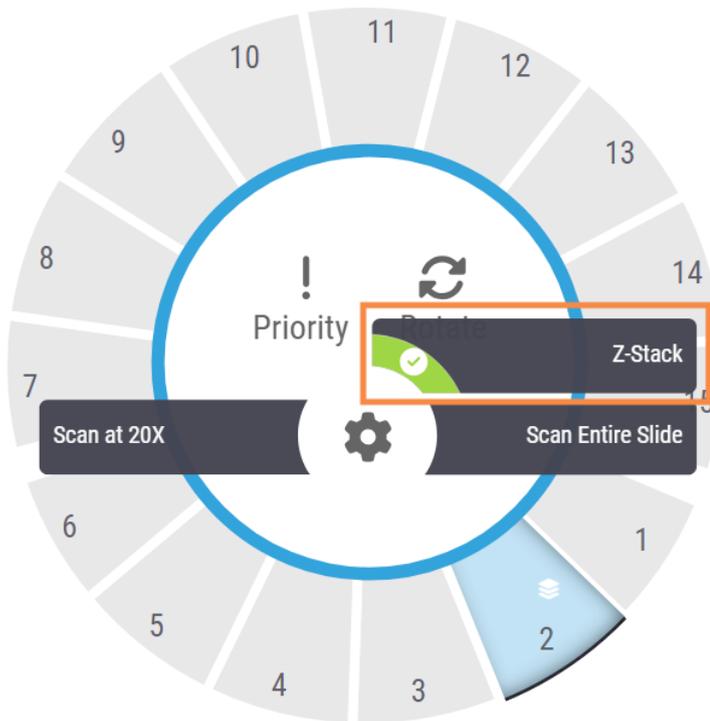


Note the following when using Z-Stack scanning:

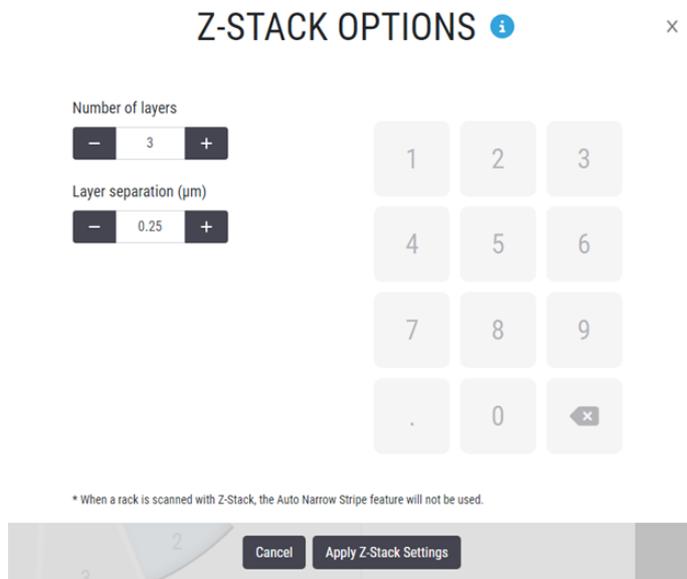
- The Auto Narrow Stripe feature is not used to scan z-stack images. If the Auto Narrow Stripe scanning feature is turned on in SAM, the system disables this feature during z-stack scanning.
- When using Z-stack scanning, the scan time and file size can increase, based on specified number of layers and the distance between layers.

To scan a rack of slides using z-stack scanning, follow these steps:

1. Load the rack with only slides that you want to scan as z-stack images. You should load slides of similar tissue types in the same rack. This is because you choose the number of layers to use depending on the type of tissue you are scanning.
2. Tap the rack position that contains the slides you just loaded.
3. Tap **Settings** , and then tap **Z-Stack**.



The Z-STACK OPTIONS screen appears with the default Number of layers and Layer separation (microns) that your Lab Administrator previously set in SAM.

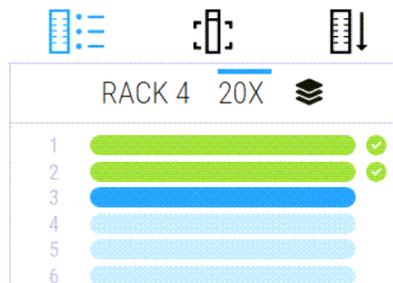


4. Follow these steps to adjust the z-stack scan settings for the rack you are scanning:
 - a. To adjust the **Number of layers**, tap the **Minus** and **Plus** buttons until you reach the desired number of layers. You can also use the number pad to enter the desired values directly. Tap inside the **Number of layers** field to activate the keypad. (Note that the number of layers must be an odd number.)
 - b. To adjust the **Layer separation**, tap the **Minus** and **Plus** buttons until you reach the desired number (in microns). As described in the step above, you can also use the number pad to enter the desired values directly.
5. Tap **Apply Z-Stack Settings** to start scanning the specified rack of slides.

After you tap **Apply Z-Stack Settings**, the Z-Stack icon  appears on the rack position.



During scanning, the Z-Stack icon  appears in Rack View to indicate the scanner is scanning this rack as z-stack images.



View z-stack images

To view the 3-dimensional z-stack images, you must use a digital slide viewer that supports z-stack viewing. For information on viewing z-stack images, refer to the *Aperio ImageScope User's Guide*, or the user manual for your viewer.

6. Set up Auto Narrow Stripe scanning on SAM

The Auto Narrow Stripe scanning feature helps mitigate potential image quality issues by enabling the scanner to automatically rescan a slide using an alternative scanning process, Auto Narrow Stripe scanning, when the system detects an excessive tilt of the slide tissue. Excessive slide tissue tilt can occur when the slide does not sit level in the slide tray, or when tissue is not laid flat on the glass surface along the short axis (index axis) of the slide due to poor slide preparation.

This feature works with a tilt threshold that is defined in SAM. When Auto Narrow Stripe scanning is enabled in SAM, the system evaluates every slide during the scanning process according to the tilt threshold. If the slide exceeds the tilt threshold, the scanner automatically rescans the slide using Auto Narrow Stripe scanning.

Your Leica Biosystems Technical Services representative can adjust the tilt threshold value according to the needs of your organization.

The Auto Narrow Stripe scanning feature is not available when scanning z-stack images.



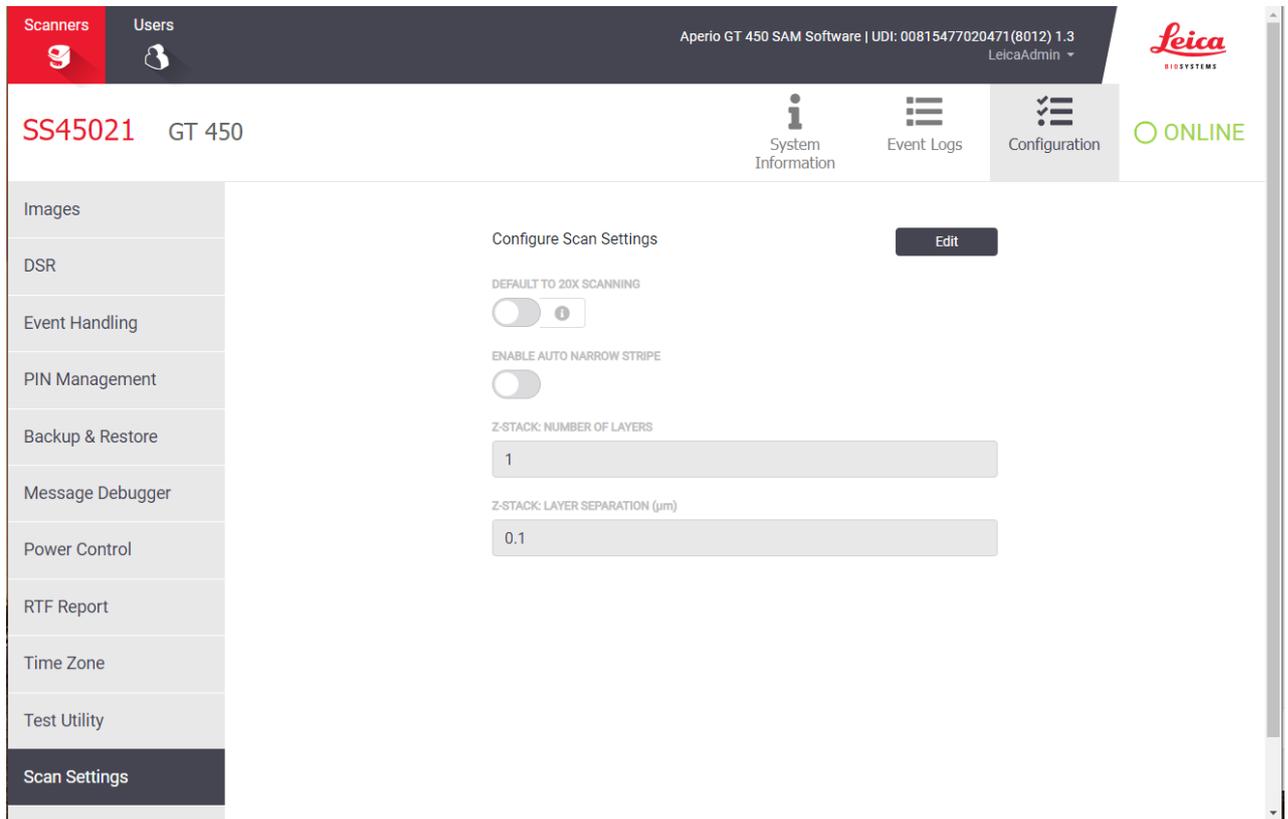
Note that the total scan time increases when the scanner rescans one or more slides using Auto Narrow Stripe scanning.

Your Leica Biosystems Technical Services representative can adjust the defined tilt threshold according to the needs of your organization.

Follow the steps below to enable Auto Narrow Stripe on SAM:

1. Log on to SAM.
2. Confirm that the Scanners icon in the banner is selected, and the page shows the list of scanners. (For an example, see [Configure default Scan Settings in SAM on page 3.](#))
3. Click the **Configuration** icon to the right of the scanner.
4. Click **Scan Settings** in the side menu bar.

- On the Configure Scan Settings page, click **Edit**.



- Click the **ENABLE AUTO NARROW STRIPE** button to turn on the Auto Narrow Stripe work flow feature.



- To save your changes, click **SAVE**.

7. Aperio GT 450 optional DICOM upgrade

The Aperio GT 450 has the ability to output image files in either SVS or DICOM format. (The default is .SVS image file format.) The optional DICOM feature is purchased and installed separately for each Aperio GT 450 scanner. You must use SAM to configure the final storage location for the DICOM images (PACS, IMS, or file share).

Before you can enable DICOM image output, your IT environment must meet the requirements detailed in the *Aperio DICOM Conformance Statement*. Also, a Leica Biosystems Technical Services representative will need to log into SAM as a Leica Admin and enable Optional Features for the scanner you want to configure for DICOM.

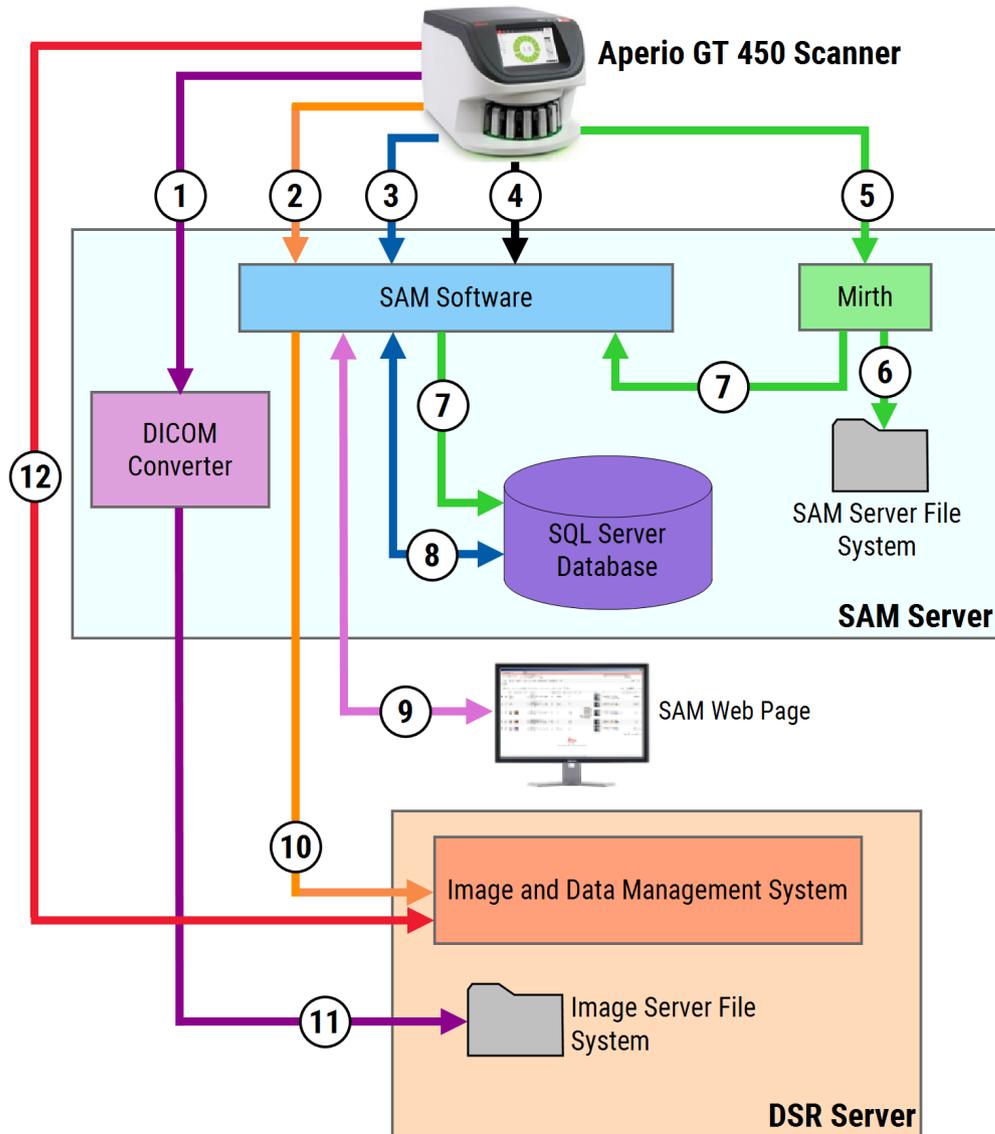
For information specific to configuring the Aperio GT 450 DICOM upgrade, including how to configure the Aperio SAM for DICOM, see the *Aperio GT 450 DICOM Upgrade Guide*.

This section includes updates to your Aperio GT 450 user manuals to support the new optional DICOM upgrade.

Recommended network configuration

This section describes the recommended way to connect your Aperio GT 450 in your IT environment for optimal performance. It includes details for those customers who are using the optional DICOM upgrade.

Figure 1: Recommended network configuration



Legend

- | | | | |
|---|---------------------------------------|----|--|
| 1 | Image Data, TCP 2762, TLS | 7 | Events, HTTPS 44386, TLS |
| 2 | Image metadata, Port 44386, HTTPS | 8 | Configuration data |
| 3 | Configuration data, Port 44386, HTTPS | 9 | WebApp, HTTPS 443 |
| 4 | Time synchronization, Port 123 | 10 | Image metadata, HTTPS 44386 |
| 5 | Event logs; Ports 6662, 6663 | 11 | Image data; SMB3 (uses UDP 137, 138; TCP 139, 445) |
| 6 | Log Data | 12 | Image data; TCP 2762 (stunnel optional) |

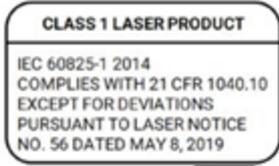
Data Type	Description	Port
Image Data	By default, the Scanner sends DICOM image data to the DICOM converter. The data is sent using TLS encryption. Configure the communication between the scanner and the DICOM converter using the Hostname and Port settings on the Images configuration page.	TCP 2762
	By default, the DICOM converter sends the image data (either as a converted SVS file, or as raw DICOM data) to the image and data management system (IDMS) on the DSR Server. The data is sent using SMB3 Encryption. Configure the communication between the DICOM converter and the DSR using the File Location setting on the Images page.	UDP 137, 138 TCP 139, 445
	Alternatively, the scanner may send image data to the Sectra module, bypassing the DICOM Converter. This option is only available when using the Sectra Digital Pathology Module. This connection is not encrypted by default. To secure this connection, you can configure stunnel to create a secure communication tunnel between Sectra and the scanner. DICOM C-Store communication between the scanner and Sectra is configured on SAM DX.	TCP 2762-SSL (default) 47823 (stunnel default)
	Images can be sent to viewing stations connected to the DSR.	HTTP(S) 80/443

Data Type	Description	Port
Scanner Configuration Data	The scanner sends a call to the SAM DataServer to request configuration data. The SAM DataServer returns the configuration data to the scanner. The data is sent using TLS Encryption. Communication between the scanner and the SAM DataServer is configured on the scanner.	HTTPS 44386
	The SAM software stores the configuration data on the SQL Server Database on the SAM Server.	TCP 1433
	The SAM DataServer displays the configuration data through the SAM web page.	HTTP(S) 80/443
Time Synchronization	Timeclock synchronization between SAM and multiple scanners is maintained using network time protocol.	UDP 123
Image Metadata	<p>When using Aperio eSlide Manager: The Scanner sends Image Metadata to the SAM DataServer using TLS encryption. Communication between the scanner and the SAM DataServer is configured on SAM. The SAM DataServer sends image metadata to the IDMS location on the DSR. Configure the communication between SAM DataServer using the Hostname and Port settings on the SAM DSR page.</p> <p>When using Sectra Digital Pathology Module: Image Metadata is embedded directly in the DICOM images that are sent to the Sectra module.</p>	HTTPS 44386
Log and Event Data	The scanner sends logs and event data to the Mirth Connect Server. No sensitive data is transferred.	
	Configure the communication between the scanner and the Mirth Connect Server on the Event Handling configuration page.	
	The Mirth Connect Server copies critical event and error data to the SAM DataServer, and then the SAM DataServer sends this data to the SQL database. This is the data reported out via the SAM Event Logs.	TCP 6662, 6663
	The SAM DataServer displays the event data through the SAM web page.	HTTPS 44386
The Mirth Connect Server processes the Log data and appends the Event Log, which resides on the file system. The communication between Mirth and the Event Log is configured within the Mirth Application setup. It is not accessible through SAM.	HTTP(S) 80/443	

8. Specifications updates

The following specifications are new or updated with Aperio GT 450 release 1.3.

Scanner specifications

Feature	Details
Scan output	SVS and DICOM ¹
Focusing system	Real-time automatic focusing (U.S. Patent 9841590B2). Z-Stack Scanning: Automatic point focusing.
Class 1 laser	Laser compliance. This symbol indicates that the product is a Class 1 Laser Product and is in compliance with international standards and US requirements. 

Performance specifications

Feature	Details
Scanning resolution	0.26 $\mu\text{m}/\text{pixel}$ at 40x. 0.52 $\mu\text{m}/\text{pixel}$ at 20x.

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 was evacuated against and complies to the following standards.

¹To use the DICOM file format, this feature must be enabled for your scanner. See *Aperio GT 450 DICOM Upgrade* document for details. Also, your IT environment must meet the requirements detailed in the *Aperio DICOM Conformance Statement*. Note that the DICOM feature is not compatible with 20x magnification scanning, Z-stack scanning, or Auto Narrow Stripe scanning features.

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>
Electromagnetic Compatibility (EMC)	<p>EMC 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>
Machinery and Materials	<p>IEC 60825-1:2014 (Class 1 Laser)</p> <p>2011/65/EU - Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 2)</p> <p>2015/863 - Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 3)</p> <p>2006/42/EC - Machinery Directive</p> <p>2014/35/EU – Low Voltage Directive</p> 

Safety notices

- This device is intended for indoor use only.
- Safety protection may be impaired if used in a manner not specified by the manufacturer.

Notices

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This manual applies to Aperio GT 450 Controller, Aperio GT 450 Console, and Aperio GT 450 SAM versions 1.3 and later.
Original Instructions.

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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 products and services, please visit [LeicaBiosystems.com/Aperio](https://www.leicabiosystems.com/Aperio).

Contact Information – Leica Biosystems Imaging, Inc.

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

For research use only. Not for use in diagnostic procedures.

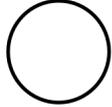


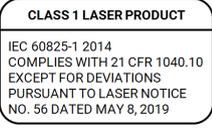
UDI 815477020228, 815477020464, 815477020471, 815477020563

REF 23GT450, 23GT450SAM, 23GT450SAMSW, 23GT450ZSTACKSW

Symbols

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

Symbol	Regulation/Standard	Description
	ISO 15223-1 - 5.4.3	Consult instructions for use
	ISO 15223-1 - 5.1.1	Manufacturer
	ISO 15223-1 - 5.1.3	Date of manufacture
	ISO 15223-1 - 5.1.7	Serial number
	ISO 15223-1 - 5.1.6	Catalog number
	ISO 15223-1 - 5.7.10	Unique Device Identifier
	Machinery Directive 2006/42/EC	Device carries the CE (Conformité Européenne) Mark and fulfils the requirements of Machinery Directive 2006/42/EC and additional EU Directives, as shown on page 17 .
	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.

Symbol	Regulation/Standard	Description
	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.
	National Standard of the People's Republic of China Requirements of concentration limits for certain restricted substances in electrical and electronic products GB/T 26572-201	Device contains certain toxic or hazardous elements and can be used safely during its environmental protection use period. The "e" inside circle indicates product is compliant with Requirements of concentration limits for certain substances in electrical and electronic products GB/T 26572-2011. The outer circle indicates that the product can be recycled.
	IEC 60825-1	Device is a Class 1 Laser Product that is in compliance with international standards and US requirements.
	CA Proposition 65	This product can expose you to chemicals known to the State of California to cause Cancer and Reproductive Harm. For more information go to https://www.P65Warnings.ca.gov .
	N/A	Device is made in the USA of U.S. and foreign components.