

Aperio GT 450

IT Manager and Lab Administrator Guide



Aperio GT 450 IT Manager and Lab Administrator Guide

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

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Customer Resources

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

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

REF 23GT450, 23GT450SAM

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Notices

Revision Record

Rev.	Issued	Sections Affected	Detail
E	March 2022	Front matter, Chapter 5, "User Management"	Added revision history, cautions and notes. Chapter 5: Added steps to unlock a user account.
D	January 2021	Chapter 3, "Configuring the Aperio GT 450"	Updated for patch 1.0.1.8000. Added information on specifying characters to replace non-printable barcode characters.
С	April 2020	Page 7	Changed references to two monitors to "monitor(s)" to accommodate change in product configuration.
В	October 2019	Chapter 3, "Configuring the Aperio GT 450"	Added Time Zone setting information. Added new Image page section on setting image file name format and barcode identifier.
А	June 2019	All	New document.

Intended Use

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

Cautions and Notes

- **Serious Incidents Reporting** Any serious incident that has occurred in relation to the Aperio GT 450 shall be reported to the manufacturer and the competent authority of the member state in which the user is established.
- **Specifications and Performance** For device specifications and performance characteristics, refer to the document *Aperio GT 450 Specifications*.
- Installation Aperio GT 450 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 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 the Aperio GT 450 User's Guide.
- Maintenance and Troubleshooting For information on maintenance and troubleshooting problems, see the Aperio GT 450 User's Guide.
- **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. For Aperio recommendations on protecting your workstations and servers, see "Chapter 6: Cybersecurity and Network Recommendations" on page 37.

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 recommendations on protecting your workstations and servers, see "Chapter 6: Cybersecurity and Network Recommendations" on page 37.

If a suspected Aperio GT 450 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.

Symbols

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

Symbol	Standard/ Regulation	Description
•••	ISO 15223-1 - 5.1.1	Manufacturer
<u>~</u>	ISO 15223-1 - 5.1.3	Date of manufacture
SN	ISO 15223-1 - 5.1.7	Serial number
REF	ISO 15223-1 – 5.1.6	Catalog number
<u> </u>	ISO 15223-1 - 5.4.4	Caution
<u>^</u>	SO 7010 – W001	General warning
C SUD US	IEC 61010-1	TÜV Product Services have certified that the listed products comply with both U.S and Canadian safety requirements.
	IEC 60417 - 5031	This device is suitable for direct current only.
	IEC 60417 - 5007	On. To indicate connection to the mains, at least for mains switches or their positions, and those cases where safety is involved.

Symbol	Standard/ Regulation	Description
	IEC 60417 - 5008	Off. To indicate disconnection from the mains, at least for main switches, and all those cases where safety is involved.
A	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.
50	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.

Symbol	Standard/ Regulation	Description
CLASS 1 LASER PRODUCT IEC 60325-1 2014 COMPLIES WITH 21 CFR 1040 10 EXCEPT FOR DEVIATIONS PURSUANT TO LASER NOTICE NO: 56 DATED MAY 8; 2019	IEC 60825-1	Device is a Class 1 Laser Product that is in compliance with international standards and US requirements.
Info for USA only, California Proposition 65 WARNING Cancer & Reproductive Harm www.P85Warnings.ca.gov	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.
Made in USA of US and foreign components	N/A	Device is made in the USA of US and foreign components.

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Introduction

This chapter introduces the Aperio Scanner Administration Manager (SAM) for use with one or more Aperio GT 450 Scanners.

The Aperio GT 450 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 scanner was designed to fit into your network environment and offer the best in security and performance.

This system is intended for use by trained histotechnicians, IT professionals, and pathologists. 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 the *Aperio GT 450 User's Guide*.

Component	Description
Scanner Administration Manager (SAM) Server	The SAM server connects to multiple Aperio GT 450 scanners and runs the SAM Client Application Software.
SAM Client Application Software	The Scanner Administration Manager (SAM) client application software enables IT implementation, PIN configuration, and service access of multiple scanners from a single desktop client location for IT professionals.
Aperio Viewing Station	The viewing station includes monitor(s) and a workstation with Aperio ImageScope version 12.4 or higher.

The Aperio GT 450 system includes the Aperio Scanner Administration Manager (SAM) that enables IT implementation and service access of up to 4 scanners from a single desktop client location. SAM facilitates setup, configuration, and monitoring of each scanner. SAM is installed on a server that resides on the same network as the scanner(s) as well as other components for image management.

Features of SAM include:

- Web-based user interface, compatible with most current browsers to allow access throughout your facility network.
- Role-based user access. An operator role allows users to view configuration settings, while an administrative role allows the user to change the settings.
- Scanner-specific configuration settings for user-access PINs and timeouts. Access to each scanner on the system can be configured with separate access PINs.

- Central display of statistics and event logs. Information for each scanner on the system can be displayed and reviewed from the SAM interface for comparison.
- Support for multiple scanners, with centralized configuration and monitoring.
- Immediate display of scanner status. The home page displays which scanners are online and which are not.
- Integration with Aperio eSlide Manager for image management, if desired. The interface can be configured to use SSL or another communication method.
- Services to process log data and events via Mirth Connect to a database on the file system.

About This Guide

This guide is intended for laboratory administrators, IT managers, and anyone else responsible for managing the Aperio GT 450 scanner on their facility network. For general information on how to use the scanner, refer to the *Aperio GT 450 User's Guide*.

The next chapter of this guide explains the Aperio GT 450 network architecture and shows how data flows from one component of the system to another.

Chapters that follow discuss using the Aperio GT 450 Scanner Administration Manager (SAM) application to configure the Aperio GT 450 scanner(s), including how to add user accounts to SAM, and configure access PINs for each scanner. Tasks that are only available to Leica Support personnel are beyond the scope of this manual.

For information on specific tasks, use the following table.

Task	See
Learn how the GT 450 scanners and the Scanner Administration Manager (SAM) server fit into your network	"Aperio GT 450 Network Architecture" on page 16
Learn how data flows between the Aperio GT 450 scanner, the SAM server, and image storage and optional Aperio eSlide Manager servers	"Data Communication Pathways" on page 18
Log in to the Scanner Administration Manager (SAM) client application software	"Log Into SAM" on page 13
Adjust configuration settings for DICOM (ImageServer) or DSR communication with the SAM server and scanner	"Scanner Configuration Settings" on page 25
Display information about a scanner on the system	"Configuring the Aperio GT 450 Scanner" on page 21
Check to see if a scanner is online	"The SAM User Interface" on page 14
Display the serial number, software version, or firmware version for a scanner on the system	"Scanner System Information: Info Page" on page 23
Review scanner statistics and history	"Displaying Scanner Statistics" on page 32
Review advanced configuration options such as camera settings	"Displaying Scanner Information and Settings" on page 31
Add a new user for Scanner Administration Manager (SAM) access or as a scanner operator	"Adding, Editing, and Deleting Users" on page 34

Task	See
Delete a user account from SAM	"Adding, Editing, and Deleting Users" on page 34
Change the password for a user	"Edit a User" on page 35
Diagnose a problem by reviewing the event and error logs	"Working With the Event Log" on page 32
Check for updates to the software	"Displaying Scanner Information and Settings" on page 31
Review cybersecurity and network recommendations for the Aperio GT 450 system	"Cybersecurity and Network Recommendations" on page 37

Related Documents

Videos available through the Aperio GT 450 touchscreen provide instructions for basic scanning tasks such as loading and unloading racks.

For additional information on operating the Aperio GT 450 scanner, refer to the following documents:

- Aperio GT 450 Quick Reference Guide Get started with the Aperio GT 450.
- Aperio GT 450 User's Guide Learn more about the Aperio GT 450.
- Aperio GT 450 Specifications Detailed specifications on the Aperio GT 450.

Aperio GT 450 System Components

The diagram below illustrates the components of a typical Aperio GT 450 scanner system, using a DSR server and Aperio eSlide Manager for image file management. Other configurations may be possible. Consult with your Leica Biosystems technical representative for more information.

Deploying the Aperio GT 450 System

The following diagram shows how the Aperio GT 450 system fits into the different departments of your organization.



Aperio GT 450 Scanner



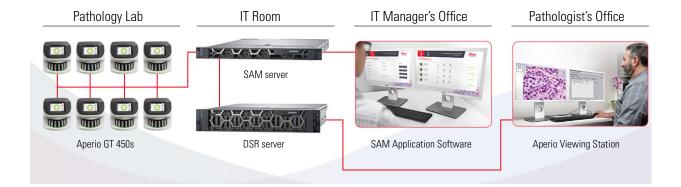
SAM Server

- Microsoft Windows Server software
- SAM software
- DICOM converter software
- Mirth Connect server software
- Storage for logs and events



DSR Serve

- Microsoft Windows Server software
- Aperio eSlide Manager software
- Storage for image data



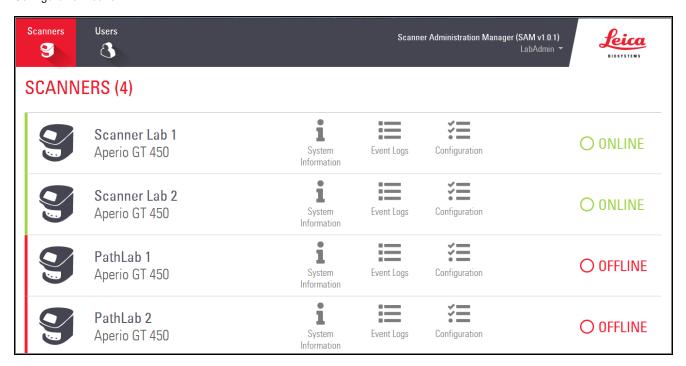
Log Into SAM

After the Aperio GT 450 system is installed and configured, the next step is to use the Scanner Administration Manager (SAM) to manage the Aperio GT 450 scanners and users.

- 1. Open an Internet browser and enter the address of the SAM server. (The Leica installation representative provides this address to the IT representative at the facility when the system is installed. Contact your IT staff for this address if you don't have it.)
- 2. Enter your login (user) name and password. If this is the first time you are logging in, use the login information provided by your system administrator or the Leica Biosystems installer.
- 3. Click Log In.

The SAM User Interface

The SAM home page with the scanner list is shown below. Note that users with the Operator role will not see the Configuration icons.



The four general areas of the page are described below.



Scanner List

This list displays each scanner in the system, including the custom or "friendly" name, and the scanner model. Lab Admin users can click a scanner name in this area to display the Edit Scanner options.



Scanner Status Area

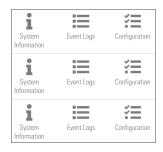
This area displays the status of each scanner.



User Login

This displays the user name for the current SAM user.

Select your login name to display links for changing the password and logging out.



Commands Area

The icons used to display System Information, Event Log, and Configuration pages are included in this area.

Note that the Configuration icons are only available to users with the Lab Admin role.

Aperio GT 450 Network Architecture

This chapter presents a basic architectural overview of how the Aperio GT 450 scanner and the SAM server fit in your network.

Aperio GT 450 Architecture

The Aperio GT 450 was designed with IT ease of use and security in mind. It is integration-ready for Aperio eSlide Manager, an LIS, and other networked systems.

The Aperio GT 450 system includes an Aperio GT 450 scanner, Aperio Scanner Administration Manager (SAM) server, cables, and plugs. Each instance of the SAM server can accommodate four Aperio GT 450 scanners and multiple SAM servers can exist on your network.

The SAM client application software resides on the SAM server, and includes the following:

- ▶ SAM software for configuration of the scanner
- Web-based user interface for scanner administration and configuration
- Logging and messaging services for events and errors
- ▶ DICOM server to convert the DICOM image files to SVS and transfer them to the image storage system

General Information

The following guidelines apply:

- The network share where images are stored (DSR) can exist on the same server as the Aperio eSlide Manager, or it may reside elsewhere on the local network.
- Messaging includes an instance of Mirth Connect and the deployment of various channels used to transform and route scanner messages (scan events and logs).

Before the installation of the Aperio GT 450 scanners, SAM client application software, SAM server, and Aperio Viewing Station, the Leica Biosystems technical representative determines the best architecture for the installation based on projected usage, current network configuration, and other factors. This includes deciding which components (SAM, DICOM converter, etc.) are installed on each physical server in the network. The various components and services can be installed on different servers, or co-located on a single server.

Network Bandwidth Requirements

For the connection between the Aperio GT 450 and the SAM server, the required minimum bandwidth is a gigabit ethernet with a speed equal to or greater than 1 gigabits per second (Gbps). For the connection between the SAM server and the image repository (DSR), the required minimum bandwidth is 10 gigabits per second.

How the Aperio GT 450 Fits into Your Network

These are the major components of the Aperio GT 450 scanner and SAM system:

- **Aperio GT 450 scanner -** One or more Aperio GT 450 scanners can be connected to a SAM server through the network. Each SAM server can support multiple scanners.
- Aperio Scanner Administration Manager (SAM) Server The SAM server contains the Scanner Administration Manager client application software, the subject of this guide. The SAM server provides the DICOM Image converter to convert DICOM images to SVS image file format. (Aperio GT 450 scanners stream encrypted DICOM images to the SAM server). SAM also manages scanner configuration settings, and manages messaging using Mirth connections.
- **Digital Slide Repository (DSR) Server -** This server (also known as an Image Storage System server) contains the whole slide images from the scanner and the infrastructure to manage them. The repository may be a network share available through a server on your network, or may reside on an optional Aperio eSlide Manager Server.
- **SAM Workstation/Console** Accessed through a web browser (Firefox, Chrome, or Edge) on PC or laptop on your network, administrators and operators use the console to view event data and statistics. Administrators can also add user accounts, configure PINs, and make configuration changes.
- **Database -** The MS SQL Server Database that contains user data, settings data, the data and events reported via the statistical reports, and the errors reported in the logs.
- **Network File Share -** The location on your network where event logs are stored.

Secure Access

Access via the SAM user interface is secured using SSL. Self-signed SSL certificates are provided at installation. To avoid security messages from the browser, customers may provide their own security certificates.

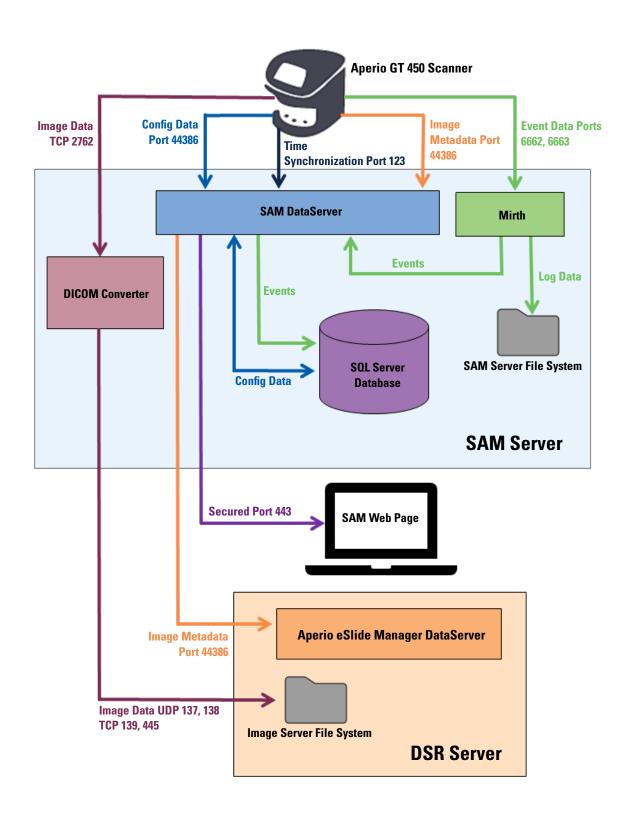


To protect your network from cybersecurity attacks, we recommend that you disable unused ports and services on your network.

Data Communication Pathways

The various components reside on servers on the network. In general, multiple components may be installed on the same physical server, depending on your specific laboratory configuration.

The following diagram shows a standard, secure configuration for the Aperio GT 450 system connected to a SAM server and a DSR server that is running Aperio eSlide Manager. Other configurations may apply to your specific network and use case. This diagram is intended to be used to help you visualize the movement of images and the associated data.



Data Type	Description	Port
Image Data	The Scanner sends DICOM image data to the DICOM Converter. The data is sent using TLS encryption.	TCP 2762
	Configure the communication between the scanner and the DICOM converter using the Hostname and Port settings on the Images configuration page.	
	The DICOM Converter sends the image data (either as a converted SVS file, or as raw DICOM data) to the Image File System on the DSR Server. The data is sent using SMB3 Encryption.	UDP 137, 138 TCP 139,
	Configure the communication between the DICOM converter and the DSR using the File Location setting on the Images page.	445
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.	44386
	The SAM DataServer stores the configuration data on the SQL Server Database on the SAM Server.	
	The SAM DataServer displays the configuration data through the SAM web page.	
Time Synchronization	Timeclock synchronization between SAM and Multiple Scanners is maintained using network time protocol.	UDP 123
Image Metadata	The Scanner sends Image Metadata to the SAM DataServer. The data is sent using TLS encryption. Communication between the scanner and the SAM DataServer is configured on the scanner.	44386
	The SAM DataServer sends image metadata to the Aperio eSlide Manager DataServer located on the DSR. The data is sent using TLS encryption.	
	Configure the communication between the SAM DataServer and the scanner using the Hostname and Port settings on the DSR page.	
Messaging and Event Data	The scanner sends logs and event data to the Mirth Connect Server. No sensitive data is transferred.	6662, 6663
	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 then the SAM DataServer sends this data to the SQL database. This is the data reported out via the SAM Event Logs.	
	The SAM DataServer displays the event data through the SAM web page.	
	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.	

[&]quot;Scanner Configuration Settings" on page 25 provides information on how to configure the various connections between the components and services through the SAM interface.

Configuring the Aperio GT 450 Scanner

This chapter provides information you will use if you need to change the scanner settings, system information, or configuration. The scanner configuration defines how the scanner communicates with SAM, and how SAM, in turn, communicates with the various components on the network, including the Aperio eSlide Manager server, the DICOM Image converter, and others. Also included are procedures for assigning scanner access PINs.

General Instructions

Only a user who is assigned the Lab Admin role can make configuration changes. Operators can view configuration settings, but cannot change them.



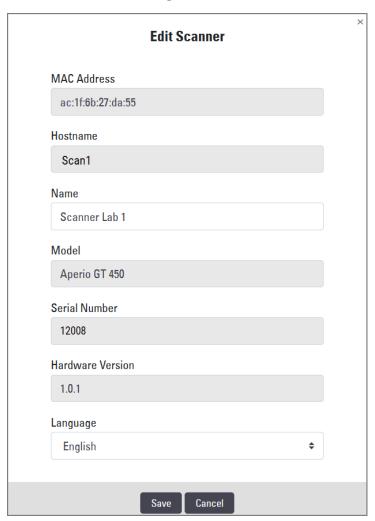
Some of the configuration settings define how the scanner communicates with SAM, such as the Mac Address and Hostname. The Serial Number uniquely identifies the scanner. Calibration settings define how the scanner operates. These settings can only be changed by Leica Support personnel, and are displayed in shaded fields.

There are three sets of scanner configuration parameters:

- Basic Scanner settings, such as the network address, name, and display language
- Scanner System Information, such as general information and detailed scanner and camera settings
- Scanner Configuration settings, such as communication settings for the DICOM Image converter and the DSR server, event management, time zone, and PIN management

Each set of parameters is discussed in this chapter.

Basic Scanner Settings

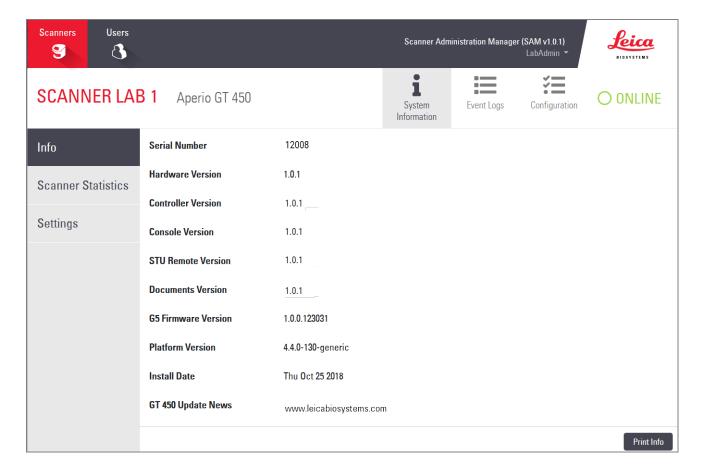


To display the Edit Scanner dialog box:

- 1. 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.
- 2. Hover over the name of the scanner until the edit symbol appears, then click the scanner name.
- 3. Customize the available settings as needed:
 - Enter a **Name** to identify the scanner for your facility. (The name is shown on the main page.)
 - Select a new language for the scanner control panel messages, if you wish.
 - Refer to "Appendix B: Summary of Scanner Setting and Configuration Options" on page 42 for additional information on each option.
- 4. Click **Save** to save your changes.

If you are setting up a new scanner or need to change how the scanner communicates with other servers on the network, continue with "Scanner Configuration Settings" on page 25.

Scanner System Information: Info Page



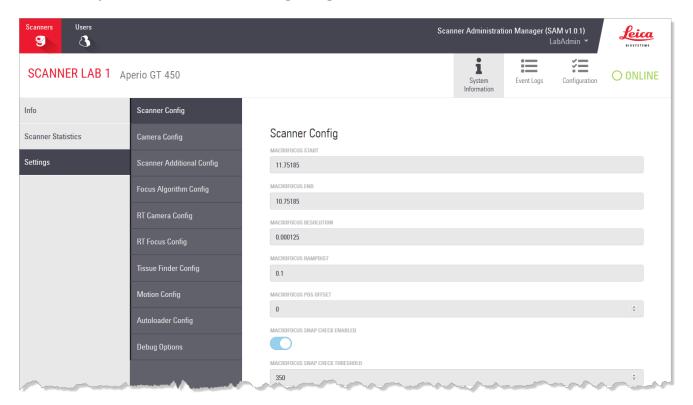
To display the System Information Info page:

- 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.
- 2. Click the **System Information** icon to the right of the scanner you want to review.
- 3. Click **Info** in the side menu.

Use the System Information Info page to review the scanner settings. (You cannot make changes on this page.)

The Firmware and Hardware versions are automatically updated once SAM establishes communication with the scanner.

Scanner System Information: Settings Page



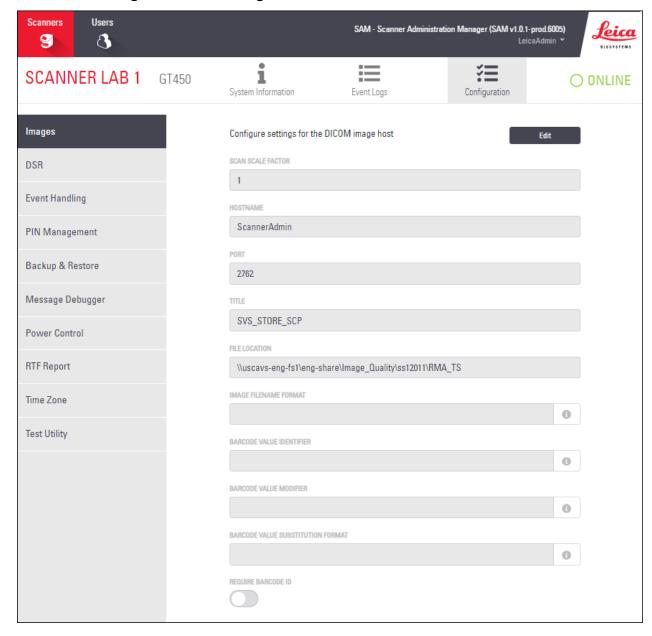
The System Information Settings page displays camera, scanner, focus algorithm, motion, and autoloader configuration settings. (The illustration above displays only some of the available settings.) Most or all of the settings on this page will be configured for you by a Leica Biosystems representative when the scanner is installed. However, you may be asked to check the settings during a troubleshooting procedure.

If a change must be made, you will be given specific instructions by a Leica Biosystems technical representative. Never make changes to these settings except when directed to do so by a Leica Biosystems technical representative.

To use the System Information Settings page to view or edit settings:

- 1. Confirm that the **Scanners** icon in the banner is selected, and the page shows the list of scanners.
- 2. Click the **System Information** icon to the right of the scanner you want to review.
- 3. Click **Settings** in the side menu bar.
- 4. Use the scroll bar to display the list of available settings.

Scanner Configuration Settings



The settings on these pages will be configured for you by a Leica Biosystems representative when the scanner is installed. However, you may be asked to check the settings during a troubleshooting procedure. You may also need to change settings if there are changes to your network that impact one or more of the communication settings. Only a user who is assigned the Lab Admin role can make configuration changes.

There are five Configuration pages, one each for Images (DICOM Converter), DSR, Event handling, PIN Management, and time zone settings.

The **Images** settings control communication with the server that hosts the DICOM converter, as well as defining where the converted SVS image data is stored. For more information on this page, see "Images Page" on page 27.

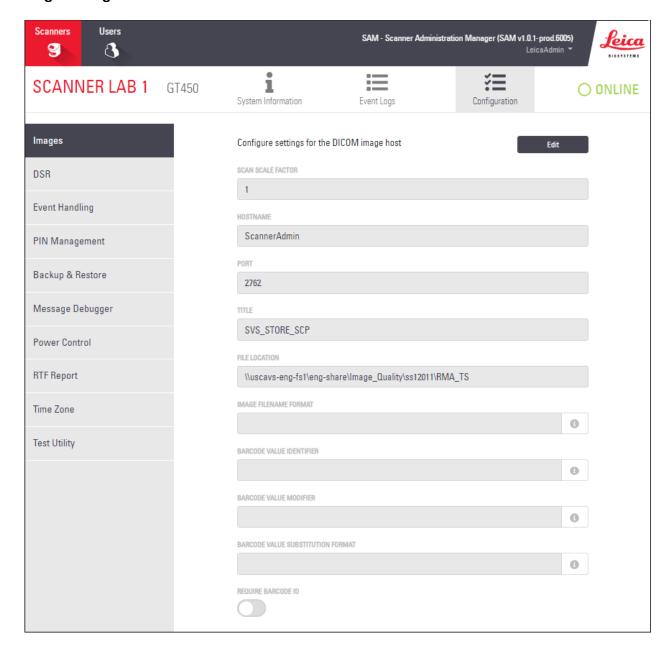
- The **DSR** (Digital Slide Repository) settings control communication with the image storage system, or DSR, where the image metadata is stored.
- The **Event Handling** settings control communication with the server where scanner messages and events are processed (Mirth).
- The **PIN Management** settings allow you to create one or more PINs to be used to access the scanner. See "PIN Management" on page 29 for more information.
- The **Time Zone** setting allows you to select the time zone for the scanner.

To use the Configuration pages to view or edit settings:

- 1. Confirm that the **Scanners** icon in the banner is selected, and the page shows the list of scanners.
- 2. Click the **Configuration** icon to the right of the scanner you want to configure. The Images configuration page displays.
- 3. Enter the configuration settings for DICOM, DSR, and Event Handling.
 - Click Images, DSR, Event Handling, or Time Zone in the side menu.
 - Click Edit to make changes on the corresponding page. Note that you cannot make changes to settings in shaded fields.
- 4. Refer to "PIN Management" on page 29 to add, delete, or modify PINs or change the timeout.
- 5. If you made changes, click **Save** to save the changes and return to viewing mode.

Refer to "Appendix B: Summary of Scanner Setting and Configuration Options" on page 42 for additional information on each option.

Images Page



The **Images** page contains settings for:

- The location where the scanned images are sent (including server name and file location).
- The Title and Scan Scale Factor fields are for internal use. You should not change these unless directed to do so by Leica Biosystems Technical Support.
- The image file name format (see below).
- Barcode management (see below).

The Lab Admin can click the **Edit** button to modify the settings on this page.

Image File Name Format

By default, the file name of the scanned image begins with the image's numeric ImageID followed by an underscore and a six-digit code ending with a file extension indicating the format of the file.

You can enter your own text at the beginning of this field and then use any of these keywords in any order. The keywords must be in all capitals and surrounded by { } symbols. We suggest separating the keywords with underscores for readability.

- ▶ BARCODEID Barcode value identifier (see the next section)
- RACK Rack number
- SLIDE Slide position in the rack
- ▶ IMAGEID Unique identifier for the image

For example, if you want to identify all of the scanned images from this scanner as coming from ScannerA, and also want to indicate what rack and what position in the rack the slide came from, you might create an image file name format like this:

ScannerA_{RACK}_{SLIDE}

The file name will begin with the text "ScannerA," followed by the rack number and the slide position in the rack. Following this will be an underscore, a six-digit code, and the file extension. For example:

ScannerA 5 2 210164.SVS

Barcode Management

The barcode is a text string saved with the scanned image file, and can be displayed in your eSlide management system.

Depending on your institution's procedures, you may have more than one barcode on the glass slide label. In this case, you will want to identify which barcode will be associated with the scanned image and displayed in the eSlide management system.

To do this, enter a search string in regular expression format in the **Barcode Value Identifier** field.

(A regular expression, regex or regexp, is a sequence of characters that define a search pattern. For example, \d{6} specifies that a barcode with six digits in a row will be used. If you are not familiar with regular expressions, contact Leica Biosystems Technical Support for assistance.)

Some institutions embed control (non-printable) characters in their barcodes. If you want to filter out or replace these characters, enter the characters you want to modify in regular expression format in the **Barcode Value Modifier** field. For example, [\text{Nx00-\x1fx7f}] specifies that all non-printable characters will be modified.

If there are non-printable characters you want to replace that are matched by the **Barcode Value Modifier** field, specify that value in the **Barcode Value Substitution Format** field. For example, a value of "?" combined with a **Barcode Value Modifier** field value of [\x00-\x1f\x7f] replaces all non-printable characters with a question mark "?." Leave this value empty to remove characters matched by characters in the **Barcode Value Modifier** field.

If your procedures require each scanned image be saved with a barcode, slide the **Require Barcode ID** slider button to the right. When this is enabled, the scanner will skip a slide if the slide does not have a barcode or if the scanner cannot read the barcode.

The features discussed in this section allow for more advanced modifications to the barcode. If you require additional control over the barcode string returned by the Aperio GT 450, contact Leica Biosystems Technical Services.

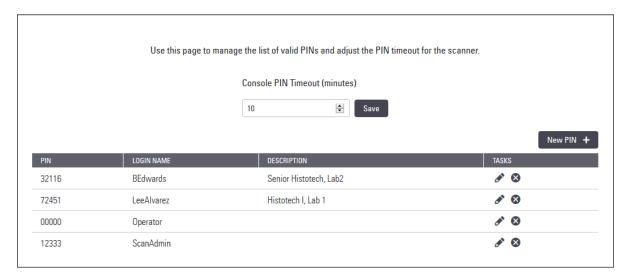
PIN Management

PINs control access to the scanner. (Each operator needs to enter a PIN to unlock the scanner.)

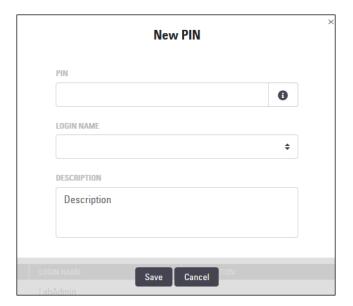
Each PIN is associated with a specific scanner user. When an operator accesses the scanner using a PIN, the scanner records the user name associated with the PIN in the internal scanner log. (The PIN itself is not logged.) The scanner controls remain unlocked as long as there is operator activity. If no one interacts with the scanner before the set time elapses, the scanner locks until an operator enters a valid PIN.

- You must have at least one PIN for each scanner, and PINs are specific to a scanner. You can assign either the same or different PINs to each scanner in the system, depending on what is best for the workflow at your facility.
- A PIN does not limit the features that an operator can access on the scanner.
- When configuring the Login Timeout, choose a time that is convenient for operators, without being so long that it allows the scanner to be left unattended and vulnerable to misuse.

Configuring a PIN and Timeout



- 1. Confirm that the **Scanners** icon in the banner is selected, and the page shows the list of scanners.
- 2. Click the **Configuration** icon to the right of the scanner.
- 3. Click **PIN Management** in the side menu bar.
- 4. Enter a value (in minutes) in the **Console PIN Timeout** field. The scanner locks automatically after this period of inactivity.
- 5. Click **New PIN+** to add a new PIN. You see the New PIN screen.



- Enter the PIN in the PIN field (five digits). PINs can only contain digits, and may not contain alphabetical or special characters.
- From the Login Name drop-down list, select a user. This list only shows users who do not have a PIN. (For information on adding users, see "Chapter 5: User Management" on page 33.)
- Optionally add a Description to identify the user who will be using this PIN.
- Click Save to return to the list of PINs.

4

Viewing System Information

This chapter explains how to display the various configuration options and settings of the SAM server.

Displaying Scanner Information and Settings

Refer to the table below for instructions on how to display scanner and system settings.

In many cases you cannot modify these settings, but Leica Biosystems Technical Support may ask you for the information during troubleshooting or maintenance procedures. Some settings can only be seen by users with the Lab Admin role.

To View:	Do This:	
Mac Address	Select the scanner from the main screen to display the Edit Scanner dialog box	
Scanner Hostname		
Scanner Name		
Scanner Model		
Scanner Language		
Scanner Serial Number	Select the scanner from the main screen to display the Edit Scanner dialog box, or	
	Click System Information for the scanner, and then click Info from the side menu	
Scanner Firmware Version	Click System Information for the scanner, and then click Info from the side menu	
Scanner Hardware Version		
Scanner Installation Date		
DICOM Server Settings	Click Configuration for the scanner, and then click Images from the side menu	
DSR Server Settings	Click Configuration for the scanner, and then click DSR from the side menu	
Event Handling (Mirth server) Settings	Click Configuration for the scanner, and then click Event Handling from the side menu	
Camera Configuration Settings	Click System Information for the scanner, and then click Settings from the side	
Scanner Additional Config Settings	menu	
Focus Algorithm Config Settings		
Motion Config XML File		
Autoloader Config XML File		
List of Users	Click the Users icon in the top banner	
List of PINs	Click Configuration for the scanner, and then click PIN Management from the side menu	

Displaying Scanner Statistics

The SAM console can display the same scanner statistics as those that are available from the scanner control panel display.

Users with either Operator or Lab Admin roles can display the statistics and select from one of the following:

- Display the number of slides scanned in the last 7 days
- Display the number of slides scanned in the last 12 months
- Display all slides, by year

To display the scanner statistics:

- 1. Confirm that the Scanners icon in the banner is selected, and the page shows the list of scanners.
- 2. Click the **System Information** icon to the right of the scanner.
- 3. Click **Scanner Statistics** in the side menu bar.
- 4. Select the display period from the three choices above the grid.
- 5. Click to print the statistics. Use the printer dialog to specify the printer and other print options.

Working With the Event Log

To display the Event Log:

- 1. Confirm that the Scanners icon in the banner is selected, and the page shows the list of scanners.
- Click the Event Logs icon to the right of the scanner.
 The screen displays all of the errors and events since the screen was last cleared. From this screen you can do the following:
 - Click the **Download All Logs** button to save a .zip file in the SAM server Downloads folder that contains a set of diagnostic logs. User login events are contained in these logs.
 - 0

To use the **Download All Logs** button, your workstation must be connected to your institution's Local Area Network with access to the SAM server; you cannot access the SAM server remotely from outside the LAN to use this feature.

Click the **Clear Current Screen** to clear the entries from the screen. Note that this will not delete the entries in the log.

Back Up Log Files

We recommend backing up the scanner log files downloaded to the SAM server and storing the backups offsite. We also recommend backing up Windows Event logs on the SAM server and storing those backups offsite.

Login Alerts

The Console.log file contains user login events such as successful logins with user names. It also alerts you to failed logins.

The log can also show "Possible Intrusion Detected" in case of log-in discrepancies that occur while accessing the scanner remotely through SSH.

5

User Management

This chapter provides information on how to configure user accounts for SAM.

Before a user can log in to SAM to either view or edit system and scanner settings, they must have an account. SAM user accounts apply to all scanners on SAM.

The administrator creates accounts for each user and assigns a role to the user at that time. The user's role determines what that user can and cannot do on the system. If you want to assign a PIN to a user to access a scanner, you must first add the user on SAM.

Understanding Roles

There are three user roles:

- Operator Role
- Lab Admin Role
- ▶ Leica Support Role

Role	Description
Operator Role	This is a general-purpose role, appropriate for most users. Users with the Operator role can view most of the system settings, and do the following:
	View the status of each scanner
	View System Information for each scanner
	Info page
	Scanner Statistics
	Settings page
	View the Event Log
	Change his or her own password
	Operators cannot view or change the PINs assigned to a scanner.
	Operators cannot view the list of users, and cannot change settings for other users

Role	Description
Lab Admin Role	This role provides advanced administrative access, and is appropriate for users who will need to add or manage other user accounts, or make changes to the system. In addition to what is available to operators, users with the Administrator role can do the following:
	 Add, modify, and delete other user accounts
	Change user passwords
	 View System Information and edit some of the settings
	Edit the Configuration settings:
	• Images
	• DSR
	Event Handling
	PIN Management
Leica Support Role	This is a protected role, and cannot be assigned to users. This role (which has a user name of Leica Admin) cannot be deleted from the system.
	It is used by Leica Support Representatives for troubleshooting, maintenance, and repair functions, and also provides the ability to add and delete scanners from the system.

Adding, Editing, and Deleting Users

Only those users with the Lab Admin role can view or modify the list of users or modify existing user accounts.

Add a User

- 1. Select **Users** from the top ribbon on the main page.
- 2. Click **Add User** from the bottom of the user list page.
- 3. Enter the information for the new user account:
 - The login Name (1 to 296 characters, and may include letters, numbers, and special characters)
 - The user's full name.
- 4. Enter an initial password Passwords have the following requirements:
 - At least 8 characters
 - At least one uppercase letter and one lowercase letter
 - At least one number
 - At least one special character: ! @ # \$ % ^ * or _
 - Different from the previous 5 passwords
- 5. Select a Role: Lab Admin or Operator.
- 6. Click Save.

Edit a User

- 1. Select **Users** from the top ribbon on the main page.
- 2. Click **Edit** next to the name of the user you want to edit.
- Enter the new information.Note that you cannot change the Role for an existing user account.
- 4. Click Save.

Delete a User

- 1. Select **Users** from the top ribbon on the main page.
- 2. Click **Delete** next to the name of the user you want to remove.
- 3. Confirm that you want to delete the user, or click **Cancel**.

Unlock a User Account

After three unsuccessful attempts to log into the SAM server, SAM locks that user out.

A user with the Lab Admin role can unlock operator accounts. (A LeicaAdmin user can unlock all accounts.)

- 1. Select **Users** from the top ribbon on the main page.
- 2. Click **Unlock** next to the name of the user account you want to unlock.



Changing Your User Password

After successfully logging in, each user can change his or her password:

- 1. Select the user name shown in the upper right-hand area of the main page.
- 2. Click the Change Password link.
- 3. Enter a new password. Password requirements are:
 - At least 8 characters
 - At least one uppercase letter and one lowercase letter
 - At least one number
 - At least one special character: ! @ # \$ % ^ * or _
 - Different from the previous 5 passwords
- 4. Confirm the password, and then click **OK**.

Cybersecurity and Network Recommendations

This chapter discusses how Aperio products protect electronic protected health information (EPHI) and provide protections against cybersecurity threats. We also discuss the measures you can take to protect client workstations and Aperio servers on your network. This chapter gives information for IT network administrators, Aperio product administrators, and Aperio product end users.

Many of the recommendations in this section apply to the Windows-based workstations that are used in conjunction with the Aperio scanners, and the servers used to host the Aperio applications and components, such as SAM. In these cases, the security and network settings are configured through the Windows operating system and administrative tools. The information here is provided for reference only. Refer to your Windows documentation for specific instructions.

In many cases, your facility may require security settings and configurations more restrictive than those listed here. If that is the case, use the stricter guidelines and requirements dictated by your facility.



After installation of the Aperio GT 450 product, the Leica Biosystems representative will turn over to your IT staff sensitive cybersecurity items such as SSL certificate credentials, SAM server disk encryption key, and so on. The customer assumes ownership of these items, and it is the customer's responsibility to safeguard this information

Aperio GT 450 and SAM Cybersecurity Features

Cybersecurity features included in the Aperio GT 450 product protect critical functionality despite cybersecurity compromise. These include:

- To reduce cybersecurity vulnerability, the respective operating systems on the Aperio GT 450 VPU and SAM server are hardened with CIS (Center for Internet Security) benchmarks.
- The Aperio GT 450 scanner and SAM are not intended to store sensitive data, only to export/upload data to connected applications on separate network servers. The connection between the Aperio GT 450 scanner and the SAM server is authenticated through an encrypted, secure SSL/TLS connection.
- Allow/deny listing is used on the Aperio GT 450 scanner and recommended for use on the SAM server. This prevents unauthorized software from running on these components.
- The daily maintenance for the Aperio GT 450 scanner includes rebooting it every day. (See the *Aperio GT 450 User's Guide* for details.) This refreshes the firmware.
- ▶ The GT 450 Console.log file contains user login events with user names. It can also show "Possible Intrusion Detected" in case of log-in discrepancies while accessing the scanner remotely through SSH. For details on downloading the log files, see "Working With the Event Log" on page 32.

Password, Login, and User Configuration Safeguards

- We recommend the following password complexity requirements:
 - Passwords must be a minimum of eight characters, including:
 - At least one non-alpha numeric character (special character)
 - At least one numeric digit
 - At least one lower-case letter
 - The last five passwords recently used may not be reused
 - Users must change their passwords every 90 days
 - Automatic 30 minute system lockout after five invalid login attempts. The operator may contact IT administration to reset the password before the 30 minute lockout expires.
- We recommend you configure client workstations to time out screen displays after 15 minutes of inactivity and require users to log in again after that time.
- For security reasons, do not use user names "Admin," "Administrator," or "Demo" when adding users to client workstations.

Physical Safeguards for Servers and Workstations

- We recommend you install and use a disk encryption utility to encrypt the data on client workstation hard disks to protect it.
- Be aware that workstations are susceptible to malware, viruses, data corruption and privacy breaches from physical media such as CDs, DVDs, or USB drives. To reduce the risk of data corruption or unauthorized setting changes, only use physical media that are known to be free from viruses or malware.
 - 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.
- Protect the SAM server and client workstations from unauthorized access by limiting physical access to them.

Physical Safeguards for Aperio GT 450 Scanners

Protect the Aperio GT 450 scanners from unauthorized access by limiting physical access to them.

Administrative Safeguards

- Set up users with permissions that allow them to access only the portions of the system required for their work. For the Aperio GT 450 SAM server, the user roles are "Operator" and "Lab Admin," which have different permissions.
- Protect the Aperio server and client workstations from unauthorized access by using standard IT techniques. Examples include:
 - Firewalls We recommend enabling the Windows firewall on client workstations.
 - Secure VPNs for remote access of the Aperio server by client workstations

• Allow/deny listing, an administrative tool that allows only authorized programs to run, should be implemented on Aperio servers and client workstations.

Protecting the DSR or Image Storage Server

Here are some recommendations for protecting the server where the scanned images are stored:

- Use normal care in maintaining and using servers. Interrupting network connections or turning off the servers while they are processing data can result in data loss.
- Leica Biosystems recommends you use SQL Standard (2019 or later) or Enterprise SQL server which come with database encryption.
- Your IT department must maintain the server, applying Windows and Aperio security patches and hot fixes that may be available for the system.
- You should select a server that can be configured to detect intrusion attempts such as random password attacks, automatically locking accounts used for such attacks, and notifying administrators of such events.
- Follow your institution's security policy to protect stored data in the database.
- We recommend implementing allow/deny listing on the server so that only authorized applications are allowed to run.
- If you are not using allow/deny listing we strongly recommend installing anti-virus software on the server. Run antivirus scans at least every 30 days.
 - We also recommend that you configure the antivirus software to exclude .SVS, .SCN, .TIF, JPG file types as well as the file storage from "on access scanning" as these files can be very large and are accessed continually as they are being scanned and users are viewing the digital slides. Virus scans should be configured to run during non peak hours as they are very CPU intensive and can interfere with scanning. (In rare circumstances, third-party applications such as virus or security software may prevent Aperio software from connecting to servers or devices. If you are having this problem, contact Leica Biosystems Technical Services for assistance.)
- Periodically back up the hard disks on the server.
- For the SAM to DSR network connection, we recommend you use a storage server that supports the SMB3 network protocol to protect data in transit. If the DSR server does not support SMB3 or later, mitigation is required to protect data in transit.
- We recommend encrypting the contents of the server hard disks.
- The file shares on the server should be protected from unauthorized access using accepted IT practices.
- You should enable Windows Event logging on your server to track user access and changes to data folders that contain patient information and images. Routinely back up the Windows Event log file and save the backup in a secure location so you have the information if a compromise occurs that you need to investigate.

Use of Off the Shelf Software

While conducting cybersecurity assessments, you may wish to consider which third party software components are used by Leica Biosystems software. Lists of all off-the-shelf software (OTS) used by Aperio GT 450 and SAM are maintained by Leica Biosystems. If you would like information on OTS used, contact your Leica Biosystems Sales or Customer Support representative and ask for the Software Bills of Materials for Aperio GT 450 and SAM.

A Troubleshooting

This appendix provides causes and solutions for problems related to the SAM server and related components. It also provides common troubleshooting procedures that may need to be performed by the Aperio GT 450 lab administrator. For general troubleshooting information for the scanner operator, refer to the *Aperio GT 450 User's Guide*.

Scanner Administration Manager (SAM) Server Troubleshooting

Symptom	Cause	Solution
"Credentials are Invalid" error message during login	Instance of DataServer used by SAM is not running	Restart the DataServer service on the SAM server.
		See "Restart the DataServer" on page 41.
	Incorrect credentials	Check for caps lock, etc.
		Verify credentials with the Administrator
After update, new features are not available in the SAM User Interface	Application is cached in the browser	Exit SAM and then clear the browser cache
Scanner is on and connected to SAM (retrieves its settings) but SAM shows the scanner as offline and no statistical data is being reported (number of scans, etc.)	Mirth on the SAM server is not running	See "Verify Mirth is Running" on page 41.
	Ports are not open	Ensure port 6663 is open in the firewall and reachable by the scanner.
Scanner log files are not appearing	Mirth on the SAM server is not running	See "Restart the DataServer" below
in the scanner logs folder	Log output folder configured incorrectly	Check the Configuration Map tab under settings (AppLog_Dir).
	Mirth error	Check the Mirth Dashboard for any errors related to the "ScannerAppLogWriter" channel and refer to the Mirth error log for more details.
	Ports are not open	Ensure port 6663 is open in the firewall and reachable by the scanner.

Symptom	Cause	Solution
The SAM UI is not reachable or is returning an error code when trying to connect	IIS error	Ensure that IIS and the site are running and the ports SAM is available on are open in the firewall.
	Anonymous Authentication configuration	Check the IIS Configuration.
	error in IIS	See "IIS Configuration Error" below.

Restart the DataServer

On the server, go to the Services manager and make sure the "ApDataService" service is running. If the service fails to start or the errors persist, view the DataServer logs for more information (usually found at C:\Program Files (x86)\Aperio\DataServer\Logs).

Verify Mirth is Running

On the server, ensure the Mirth Connect server is running. If it is running, ensure the Configuration Map Settings are configured to point to the correct DataServer Host (SAM_Host) and Port (SAM_Port) and are using the correct SSL or non-SSL connection (SAM_UriSchema). If the Dashboard in Mirth Connect is reporting errors on "ScannerEventProcessor" channel, refer to the Mirth error logs for more details. If DataServer is not running this could lead to Mirth channel errors. Ensure port 6663 is open in the firewall and reachable by the scanner.

IIS Configuration Error

To check this setting open the site in IIS and go to the Authentication setting. Find and edit the Anonymous Authentication item and ensure the Specific user is set to "IUSR" (no password). If the site is running and all settings are correct, please see the IIS logs for more details.

В

Summary of Scanner Setting and Configuration Options

This appendix provides a list of the settings and configuration options. Use these tables as a checklist as you gather the information you will need if you add or reconfigure a scanner. Note that during installation, most of these settings and configuration options will be set for you by the Leica Biosystems representative.

Basic Scanner Information

Lab Administrators may select the name of the scanner from the scanner page to display the basic scanner settings. (Operators can see some of the settings from the System Information page.) Any setting displayed in a gray box cannot be changed by a Lab Administrator or Operator.

Setting	Description	View/Edit	
		Admin	Operator
Mac Address	Specified during installation	View	None
Hostname	Specified during installation	View	None
Name	Description for the scanner, displayed on the Scanners home page	View/Edit	None
Model	Aperio GT 450	View	None
Serial Number	Specified during installation and verified at start up	View	View
Language	Controls the language used for scanner menus and messages	View/Edit	None

Scanner Configuration

Use the following table to gather the information you will need for each scanner on the system. After the Leica Support Representative installs your scanner, you may want to record the settings for future reference.

Option	Description	View/Edit	
		Admin	Operator
Images Configuration			
Scan Scale Factor	Set by Leica Biosystems Technical Support	View/Edit	None
Hostname	Name of the server where the DICOM Image Converter resides.	View/Edit	None
	 Use ScannerAdmin if the DICOM Converter is installed on the SAM server. 		
	Otherwise, use the hostname of the server that the DICOM Converter is installed on.		
Port	The port that the DICOM Converter is configured to use at installation. The default is 2762.	View/Edit	None
Title	Set by Leica Biosystems Technical Support	View/Edit	None
File Location	The complete path to the file share where the converter will place the images after the conversion. This is a location on the network where converted SVS files are stored.	View/Edit	None
DSR Configuration			
Hostname	Hostname of the server where the metadata will be stored.	View/Edit	None
	(The "File Location" option, above, is the file share where the images are stored.)		
Port	The secured port used for the DSR. The default is 44386.	View/Edit	None
Event Handling Configura	tion		
Hostname	Name of the server where the Mirth Connect Server resides.	View/Edit	None
	 Use ScannerAdmin if the Mirth Connect Server is installed on the SAM server. 		
	Otherwise, use the hostname of the server where the Mirth instance used for SAM is installed.		
Log Port	The port that Mirth is configured to use for log data at installation. The default is 6662	View/Edit	None
Event Port	The port that Mirth is configured to use for event data at installation. The default is 6663.	View/Edit	None
PIN Management			
Console PIN Timeout	Timeout interval (minutes); the scanner locks the display and control pad when there is no operator interaction for this period of time.	View/Edit	None
	Valid value is any whole number greater than zero.		

Option Des	Description	View/Edit	
	Description	Admin	Operator
Edit Settings: PIN	A 5-digit code to unlock the scanner.	View/Edit	None
	Numbers only		
Edit Settings: Description	Identifying information for the PIN.	View/Edit	None
	This is a general description field, and can contain numbers, letters, and punctuation characters.		
Time Zone			
Scanner time zone	Set by SAM administrator.	View/Edit	None

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