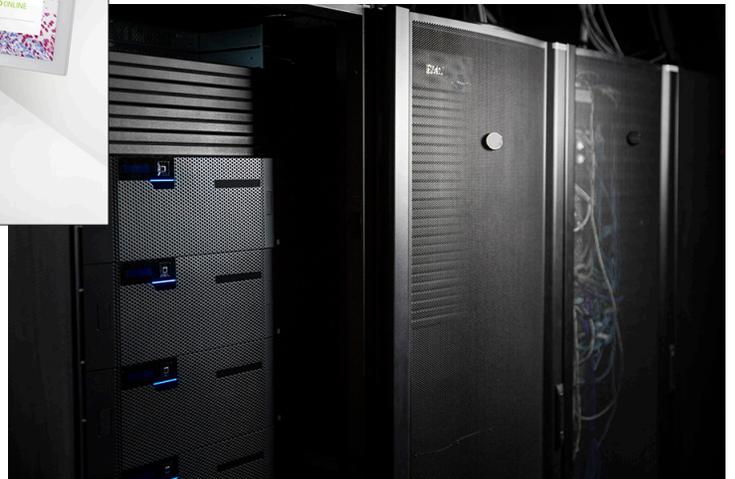


Aperio GT 450 DX

IT Manager and Lab Administrator Guide



Aperio GT 450 DX IT Manager and Lab Administrator Guide

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

Copyright Notice

- ▶ Copyright © 2022 Leica Biosystems Imaging, Inc. All Rights Reserved. LEICA and the Leica logo are registered trademarks of Leica Microsystems IR GmbH. Aperio, GT, and GT 450 are trademarks of Leica Biosystems Imaging, Inc. in the USA and optionally in other countries. Other logos, products, and/or company names might be trademarks of their respective owners.
- ▶ 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.

Headquarters	Customer Support	General Information
 <p>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</p>	<p>Contact your local support representative with any query and service request.</p> <p>https://www.leicabiosystems.com/service-support/technical-support/</p>	<p>US/Canada Tel: +1 (866) 478-4111 (toll free) Direct International Tel: +1 (760) 539-1100 Email: ePathology@LeicaBiosystems.com</p>

European Union Authorized Representative	United Kingdom Responsible Person
 <p>CEpartner4U Esdoornlaan 13 3951 DB Maarn The Netherlands</p>	<p>Leica Microsystems (UK) Limited Larch House, Woodlands Business Park Milton Keynes, England, United Kingdom, MK14 6FG</p>

Importers	
 <p>Leica Biosystems Deutschland GmbH Heidelberger Straße 17-19 69226 Nussloch, Germany</p>	<p>Leica Microsystems (UK) Limited Larch House, Woodlands Business Park Milton Keynes, England, United Kingdom, MK14 6FG</p>



UDI 00815477020297, 00815477020389

REF 23GT450DXIVD, 23SAMSWDXIVD

Contents

- Notices 5**
 - Revision Record 5
 - Cautions and Notes 5
 - Symbols 6

- Customer Service Contacts 8**

- 1 Introduction..... 10**
 - About This Guide..... 11
 - Related Documents 12
 - Log Into SAM DX 12
 - The SAM DX User Interface..... 12

- 2 Aperio GT 450 DX Network Architecture 15**
 - Image Types Supported 15
 - General Information 15
 - Network Bandwidth Requirements..... 16
 - How the Aperio GT 450 DX Fits into Your Network..... 16
 - Secure Access 16
 - Aperio GT 450 DX Recommended Network Configuration 17

- 3 Configuring the Aperio GT 450 DX 19**
 - General Instructions 19
 - Basic Scanner Settings..... 20
 - Scanner System Information: Info Page..... 21
 - Scanner System Information: Settings Page 22
 - Scanner Configuration Settings 23
 - Images Page..... 25
 - Image File Name Format 25
 - Barcode Management 26
 - PIN Management 27
 - Configuring a PIN and Timeout 27
 - Enabling DICOM Image Output..... 28

4	Viewing System Information.....	30
	Displaying Scanner Information and Settings.....	30
	Displaying Scanner Statistics.....	31
	Working with the Event Log.....	31
	Back Up Log Files	31
	Login Alerts	31
5	User Management	32
	Understanding Roles	32
	Managing Users	33
	Add a User.....	33
	Edit a User	34
	Delete a User	34
	Unlock a User Account	34
	Changing Your User Password	34
6	Cybersecurity and Network Guidelines	36
	Aperio GT 450 DX and Aperio SAM DX Cybersecurity Features.....	36
	Data Protection.....	37
	Physical Safeguards for Aperio GT 450 DX	37
	Protecting the SAM DX Server.....	37
	Password, Login, and User Configuration Safeguards.....	37
	Physical Safeguards for the SAM DX Server.....	37
	SAM DX Server Administrative Safeguards	38
	Use of Off the Shelf Software.....	39
	Support and Cybersecurity Patches.....	39
A	Troubleshooting	40
	Scanner Administration Manager DX (SAM DX) Server Troubleshooting	40
	Restart the DataServer	41
	Verify Mirth is Running	41
	IIS Configuration Error	41
B	Summary of Scanner Setting and Configuration Options	42
	Basic Scanner Information.....	42
	Scanner Configuration	43
C	Binding an SSL Certificate to Aperio SAM DX	45
	Assign the SSL Certificate to Your Website	45
	Bind the SSL Certificate.....	46
	Index	49

Notices

Revision Record

Rev.	Issued	Sections Affected	Detail
B	May 2022	All	Corrected several typographical errors.
A	April 2022	All	New version for Aperio GT 450 DX product. Based on existing <i>Aperio GT 450 DX IT Manager and Lab Administrator Guide</i> , MAN-0459, Revision B

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 Scanner 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 the *Aperio GT 450 DX User's Guide*.
- ▶ **Maintenance and Troubleshooting** - For information on maintenance, see the *Aperio GT 450 DX User's Guide*.
- ▶ **Cybersecurity** - Be aware that workstations and servers 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 SAM DX server, see "*Chapter 6: Cybersecurity and Network Guidelines*" on page 36.

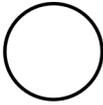
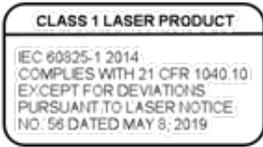
If a suspected Aperio GT 450 DX cybersecurity vulnerability or incident is detected, contact Leica Biosystems Technical Services for assistance.

- ▶ **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.

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 fulfills the requirements of EU Regulation 2017/746.
	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

Symbol	Regulation/ Standard	Description
	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.
	IEC 60825-1	Device is a Class 1 Laser Product that is in compliance with international standards and U.S. 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.

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)
Between 8:30 AM-5 PM, Monday-Friday, AEST
Email: lbs-anz-service@leicabiosystems.com

Austria:

Leica Biosystems Nussloch GmbH
Technical Assistance Center
Heidelberger Strasse 17
Nussloch 69226
GERMANY
Tel: 0080052700527 (toll free)
In-country Tel: +43 1 486 80 50 50
Email: support.at@leicabiosystems.com

België/Belgique:

Tel: 0080052700527 (toll free)
In-country Tel: +32 2 790 98 50
Email: support.be@leicabiosystems.com

Canada:

Tel: +1 844 534 2262 (toll free)
Direct International Tel: +1 760 539 1150
Email: TechServices@leicabiosystems.com

China:

17F, SML Center No. 610 Xu Jia Hui Road, Huangpu
District
Shanghai, PRC PC:200025
CHINA
Tel: +86 4008208932
Fax: +86 21 6384 1389
Email: service.cn@leica-microsystems.com
Remote Care email: tac.cn@leica-microsystems.com

Danmark:

Tel: 0080052700527 (toll free)
In-country Tel: +45 44 54 01 01
Email: support.dk@leicabiosystems.com

Deutschland:

Leica Biosystems Nussloch GmbH
Technical Assistance Center
Heidelberger Strasse 17
Nussloch 69226
GERMANY
Tel: 0080052700527 (toll free)
In-country Tel: +49 6441 29 4555
Email: support.de@leicabiosystems.com

Eire:

Tel: 0080052700527 (toll free)
In-country Tel: +44 1908 577 650
Email: support.ie@leicabiosystems.com

España:

Tel: 0080052700527 (toll free)
In-country Tel: +34 902 119 094
Email: support.spain@leicabiosystems.com

France:

Tel: 0080052700527 (toll free)
In-country Tel: +33 811 000 664
Email: support.fr@leicabiosystems.com

Italia:

Tel: 0080052700527 (toll free)
In-country Tel: +39 0257 486 509
Email: support.italy@leicabiosystems.com

Japan:

1-29-9 Takadanobaba, Shinjuku-ku
Tokyo 169-0075
JAPAN

Nederland:

Tel: 0080052700527 (toll free)
In-country Tel: +31 70 413 21 00
Email: support.nl@leicabiosystems.com

New Zealand:

96 Ricketts Road
Mount Waverly, VIC 3149
AUSTRALIA
Tel: 0800 400 589 (toll free)
Between 8:30 AM-5 PM, Monday-Friday, AEST
Email: lbs-anz-service@leicabiosystems.com

Portugal:

Tel: 0080052700527 (toll free)
In-country Tel: +35 1 21 388 9112
Email: support.pt@leicabiosystems.com

The Russian Federation

BioLine LLC
Pinsky lane 3 letter A
Saint Petersburg 197101
THE RUSSIAN FEDERATION
Tel: 8-800-555-49-40 (toll free)
In-country Tel: +7 812 320 49 49
Email: main@bioline.ru

Sweden:

Tel: 0080052700527 (toll free)
In-country Tel: +46 8 625 45 45
Email: support.se@leicabiosystems.com

Switzerland:

Tel: 0080052700527 (toll free)
In-country Tel: +41 71 726 3434
Email: support.ch@leicabiosystems.com

United Kingdom:

Tel: 0080052700527 (toll free)
In-country Tel: +44 1908 577 650
Email: support.uk@leicabiosystems.com

USA:

Tel: +1 844 534 2262 (toll free)
Direct International Tel: +1 760 539 1150
Email: TechServices@leicabiosystems.com

1

Introduction

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

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 was designed to fit into your network environment and offer the best in security and performance.

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.

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 DX User's Guide*.

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 Client Application Software.
Scanner Administration Manager DX (SAM DX) Client 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 are required to be connected to your Local Area Network (LAN) with access to the SAM DX server to use SAM DX to manage the GT 450 DX scanners.

The Aperio GT 450 DX includes the Scanner Administration Manager DX (SAM DX) that enables IT implementation and service access of up to 4 scanners from a single desktop client location. SAM DX facilitates setup, configuration, and monitoring of each scanner. SAM DX 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 DX 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 DX 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.
- ▶ 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 DX on their facility network. For general information on how to use the scanner, refer to the *Aperio GT 450 DX User's Guide*.

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

Chapters that follow discuss using the Scanner Administration Manager DX (SAM DX) application to configure the Aperio GT 450 DX scanner(s), including how to add user accounts to SAM DX, 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 DX scanners and the Scanner Administration Manager DX (SAM DX) server fit into your network	<i>"Chapter 2: Aperio GT 450 DX Network Architecture" on page 15</i>
Learn how data flows between the Aperio GT 450 DX, the SAM DX server, and optional image and data management servers.	<i>"Aperio GT 450 DX Recommended Network Configuration" on page 17</i>
Log in to the Scanner Administration Manager DX (SAM DX) client application software	<i>"Log Into SAM DX" on page 12</i>
Adjust configuration settings for DICOM or DSR communication with the SAM DX server and scanner	<i>"Scanner Configuration Settings" on page 23</i>
Display information about a scanner on the system	<i>"Chapter 3: Configuring the Aperio GT 450 DX" on page 19</i>
Check to see if a scanner is online	<i>"The SAM DX User Interface" on page 12</i>
Display the serial number, software version, or firmware version for a scanner on the system	<i>"Scanner System Information: Info Page" on page 21</i>
Review scanner statistics and history	<i>"Displaying Scanner Statistics" on page 31</i>
Review advanced configuration options such as camera settings	<i>"Displaying Scanner Information and Settings" on page 30</i>

Task	See...
Add a new user for Scanner Administration Manager DX (SAM DX)	<i>"Add a User" on page 33</i>
Delete a user account from SAM DX	<i>"Delete a User" on page 34</i>
Change the password for a user	<i>"Changing Your User Password" on page 34</i>
Unlock a locked user account	<i>"Unlock a User Account" on page 34</i>
Diagnose a problem by reviewing the event and error logs	<i>"Working with the Event Log" on page 31</i>
Check for updates to the software	<i>"Displaying Scanner Information and Settings" on page 30</i>
Review cybersecurity and network recommendations for the Aperio GT 450 DX	<i>"Chapter 6: Cybersecurity and Network Guidelines" on page 36</i>

Related Documents

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

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

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

Log Into SAM DX

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

1. Open an Internet browser and enter the address of the SAM DX 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 DX User Interface

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

Scanners Administration Manager (SAM v1.0.14)
LabAdmin

SCANNERS (4)

	Scanner Lab 1 Apero GT 450 DX	 System Information	 Event Logs	 Configuration	ONLINE
	Scanner Lab 2 Apero GT 450 DX	 System Information	 Event Logs	 Configuration	ONLINE
	PathLab 1 Apero GT 450 DX	 System Information	 Event Logs	 Configuration	OFFLINE
	PathLab 2 Apero GT 450 DX	 System Information	 Event Logs	 Configuration	OFFLINE

The four general areas of the page are described below.

SCANNERS (4)

	Scanner Lab 1 Apero GT 450 DX
	Scanner Lab 2 Apero GT 450 DX
	PathLab 1 Apero GT 450 DX
	PathLab 2 Apero GT 450 DX

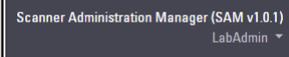
Scanner List

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.

ONLINE
ONLINE
OFFLINE

Scanner Status Area

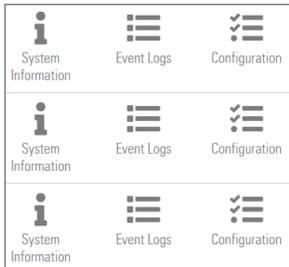
This area displays the status of each scanner.



User Login

This displays the user name for the current SAM DX 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.

2

Aperio GT 450 DX Network Architecture

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

i *IT network failure may lead to delay in diagnosis/prognosis until the network is restored.*

Aperio GT 450 DX Architecture

The Aperio GT 450 DX was designed with IT ease of use and security in mind. It is integration-ready for your image and data management system (IDMS), an LIS, and other networked systems.

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

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

- ▶ SAM DX 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

Image Types Supported

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

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 DX as a Leica Admin and enable Optional Features for the scanner you want to configure for DICOM. See “*Enabling DICOM Image Output*” on page 28 for details.

General Information

The following guidelines apply:

- ▶ The network share where images are stored (DSR) can exist on the same server as IDMS, 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 DX scanners, SAM DX client application software, and the SAM DX server, 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 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 DX and the SAM DX server, the required minimum bandwidth is a gigabit ethernet with a speed equal to or greater than 1 gigabit per second (Gbps). For the connection between the SAM DX server and the image repository (DSR), the required minimum bandwidth is 10 gigabits per second.

How the Aperio GT 450 DX Fits into Your Network

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

- ▶ **Aperio GT 450 DX** - One or more Aperio GT 450 DX scanners can be connected to a SAM DX server through the network. Each SAM DX server can support multiple scanners.
- ▶ **Aperio Scanner Administration Manager DX (SAM DX) Server** - The SAM DX server contains the Scanner Administration Manager client application software, the subject of this guide. The SAM DX server provides the DICOM Image converter to convert DICOM images to SVS image file format. (Aperio GT 450 DX scanners stream encrypted DICOM images to the SAM DX server). SAM DX 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 DX 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

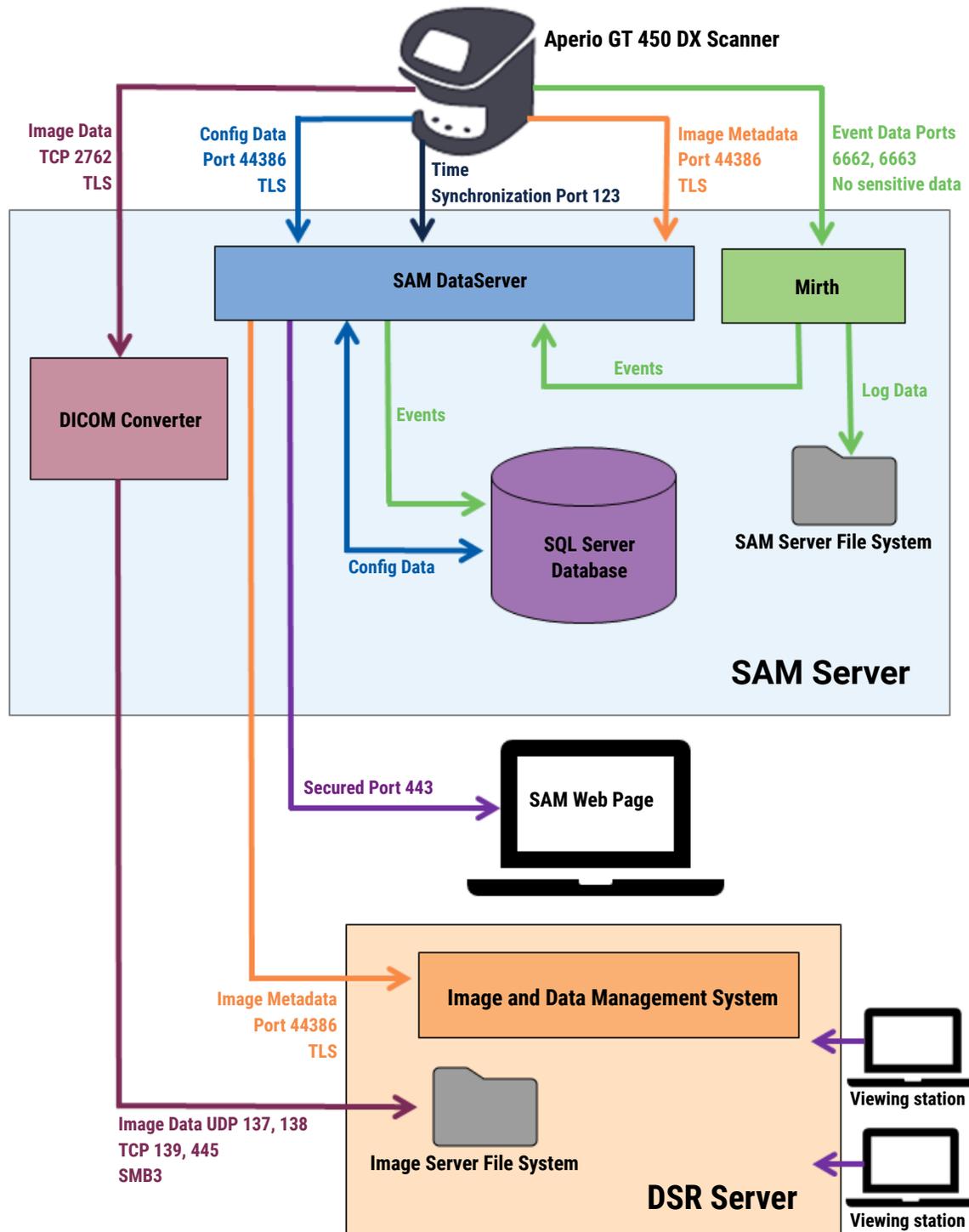
Access via the SAM DX user interface is secured using SSL. Self-signed SSL certificates are provided at installation. To avoid security messages from the browser, customers may provide their own security certificates.



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

Aperio GT 450 DX Recommended Network Configuration

This section describes the recommended way to connect your Aperio GT 450 DX in your IT environment for optimal performance.



Data Type	Description	Port
Image Data	<p>The Scanner sends DICOM image data to the DICOM Converter. The data is sent using TLS encryption.</p> <p>Configure the communication between the scanner and the DICOM converter using the Hostname and Port settings on the Images configuration page.</p> <hr/> <p>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.</p> <p>Configure the communication between the DICOM converter and the DSR using the File Location setting on the Images page.</p> <hr/> <p>Images can be sent to viewing stations connected to the DSR.</p>	<p>TCP 2762</p> <hr/> <p>UDP 137, 138 TCP 139, 445</p> <hr/> <p>80, 443</p>
Scanner Configuration Data	<p>The scanner sends a call to the SAM DX DataServer to request configuration data. The SAM DX DataServer returns the configuration data to the scanner. The data is sent using TLS Encryption. Communication between the scanner and the SAM DX DataServer is configured on the scanner.</p> <hr/> <p>The SAM DX DataServer stores the configuration data on the SQL Server Database on the SAM DX Server.</p> <hr/> <p>The SAM DX DataServer displays the configuration data through the SAM DX web page.</p>	44386
Time Synchronization	<p>Timeclock synchronization between SAM DX and Multiple Scanners is maintained using network time protocol.</p>	UDP 123
Image Metadata	<p>The Scanner sends Image Metadata to the SAM DX DataServer. The data is sent using TLS encryption. Communication between the scanner and the SAM DX DataServer is configured on the scanner.</p> <hr/> <p>The SAM DX DataServer sends image metadata to the IDMS located on the DSR. The data is sent using TLS encryption.</p> <p>Configure the communication between the SAM DX DataServer and the scanner using the Hostname and Port settings on the DSR page.</p>	44386
Messaging and Event Data	<p>The scanner sends logs and event data to the Mirth Connect Server. No sensitive data is transferred.</p> <p>Configure the communication between the scanner and the Mirth Connect Server on the Event Handling configuration page.</p> <hr/> <p>The Mirth Connect Server copies critical event and error data to the SAM DX DataServer, and then the SAM DX DataServer sends this data to the SQL database. This is the data reported out via the SAM DX Event Logs.</p> <hr/> <p>The SAM DX DataServer displays the event data through the SAM DX web page.</p> <hr/> <p>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 DX.</p>	6662, 6663

“Scanner Configuration Settings” on page 23 provides information on how to configure the various connections between the components and services through the SAM DX interface.

3

Configuring the Aperio GT 450 DX

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 DX, and how SAM DX, in turn, communicates with the various components on the network, including the IDMS 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 DX, 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

Edit Scanner

MAC Address
ac:1f:6b:27:da:55

Hostname
ScanAdmin

Name
Scanner Lab 1

Model
Aperio GT 450 DX

Serial Number
12008

Hardware Version
1.0.1

Language
English

Save Cancel

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 Friendly Name to identify the scanner for your facility. (The friendly 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 23.

Scanner System Information: Info Page

The screenshot shows the SAM - Scanner Administration Manager interface. The top navigation bar includes 'Scanners' and 'Users' tabs, the SAM title with version information, and the Leica Biosystems logo. The main content area displays the scanner ID 'SS45054' and 'GT 450 DX'. A navigation menu includes 'System Information', 'Event Logs', and 'Configuration'. The 'System Information' page shows a table of system details and an 'Advanced Maintenance' button.

Info	Serial Number	SS45054
Scanner Statistics	Hardware Version	1.0.1
Settings	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	1.1.0.5069 [C]
	Platform Version	5.4
	Install Date	Thu May 06 2021
GT 450 DX Update News	www.leicabiosystems.com	

To display the System Information Info page:

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. 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 DX establishes communication with the scanner.

Scanner System Information: Settings Page

The screenshot shows the SAM - Scanner Administration Manager interface. The top navigation bar includes 'Scanners' and 'Users' tabs, the version 'SAM - Scanner Administration Manager (SAM v1.0.0-prod.5020)', and the user 'ScanAdmin'. The main header displays 'SCANNER LAB 1' and 'Aperio GT 450 DX'. A sidebar on the left lists menu items: 'Info', 'Scanner Statistics', 'Settings', 'Scanner Config', 'Camera Config', 'Scanner Additional Config', 'Focus Algorithm Config', 'RT Camera Config', 'RT Focus Config', 'Tissue Finder Config', 'Motion Config', 'Autoloader Config', and 'Debug Options'. The main content area is titled 'Scanner Config' and lists several settings:

- MACROFOCUS START: 11.75185
- MACROFOCUS END: 10.75185
- MACROFOCUS RESOLUTION: 0.000125
- MACROFOCUS RAMPODIST: 0.1
- MACROFOCUS POS OFFSET: 0
- MACROFOCUS SNAP CHECK ENABLED:
- MACROFOCUS SNAP CHECK THRESHOLD: 350

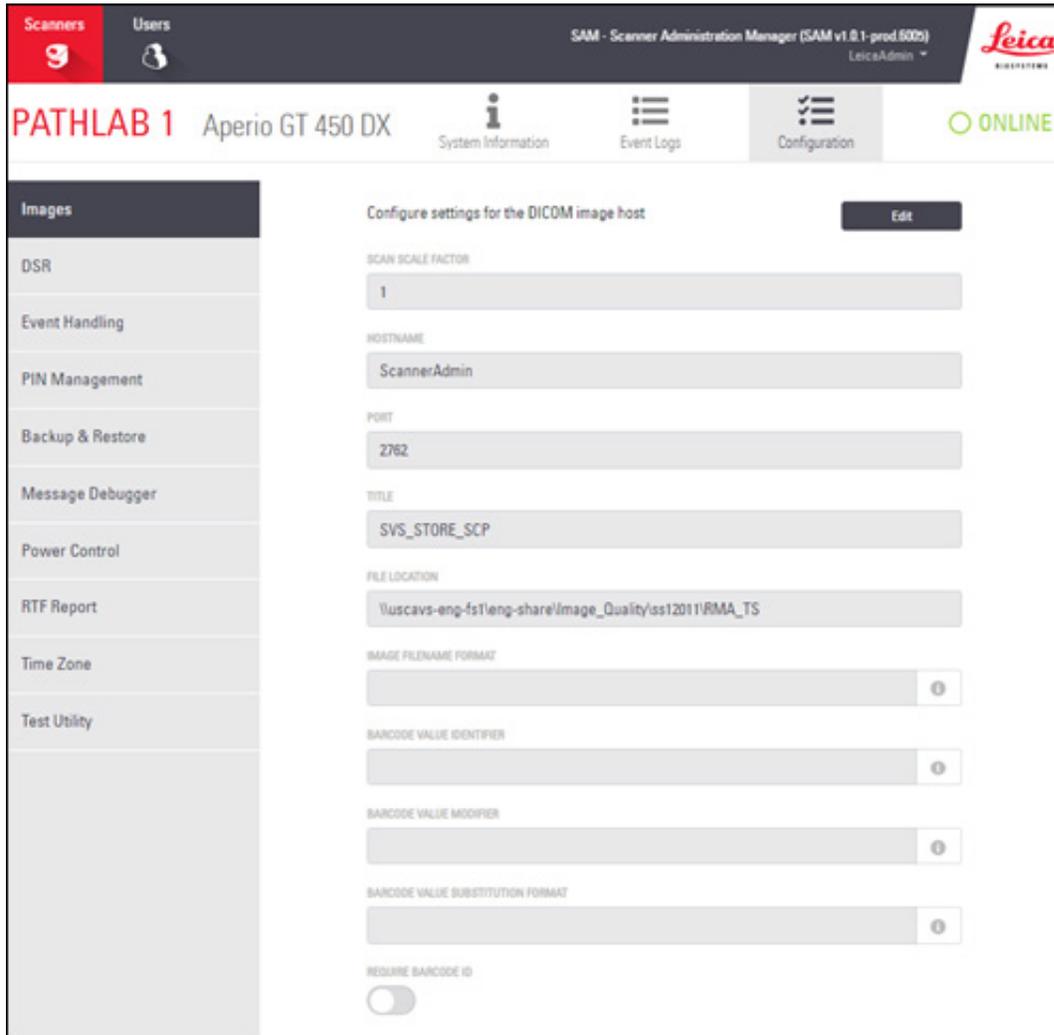
The System Information Settings page displays camera, scanner, focus algorithm, motion, and autoloader configuration settings. (The illustration above displays only some of the available settings.) Most or all of the settings on this page will be configured for you by a Leica Biosystems representative 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 several 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. You can also configure other items. See *"Images Page" on page 25*.
- ▶ 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). For information on event logs, see *"Working with the Event Log" on page 31*.

- ▶ The **PIN Management** settings allow you to create one or more PINs to be used to access the scanner. See *"PIN Management"* on page 27 for more information.

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 images (DICOM), DSR, Event Handling, PIN Management, or Time Zone.
 - ▶ Click **Images, DSR, Event Handling, PIN Management, or Time Zone** in the side menu bar.
 - ▶ Click **Edit** to make changes on the corresponding page. Note that you cannot make changes to settings in shaded fields.

Refer to *"PIN Management"* on page 27 to add, delete, or modify PINs or change the timeout.

4. 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).
- ▶ Note that 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, and ends 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 digital slide 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, `[\x00-\x1f\x7f]` 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 DX, 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 SAM DX 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

Use this page to manage the list of valid PINs and adjust the PIN timeout for the scanner.

Console PIN Timeout (minutes)

10

PIN	LOGIN NAME	DESCRIPTION	TASKS
32116	BEdwards	Senior Histotech, Lab2	 
72451	LeeAlvarez	Histotech I, Lab 1	 
00000	Operator		 
12333	ScanAdmin		 

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 32.)
- ▶ Optionally add a Description to identify the user who will be using this PIN.
- ▶ Click **Save** to return to the list of PINs.

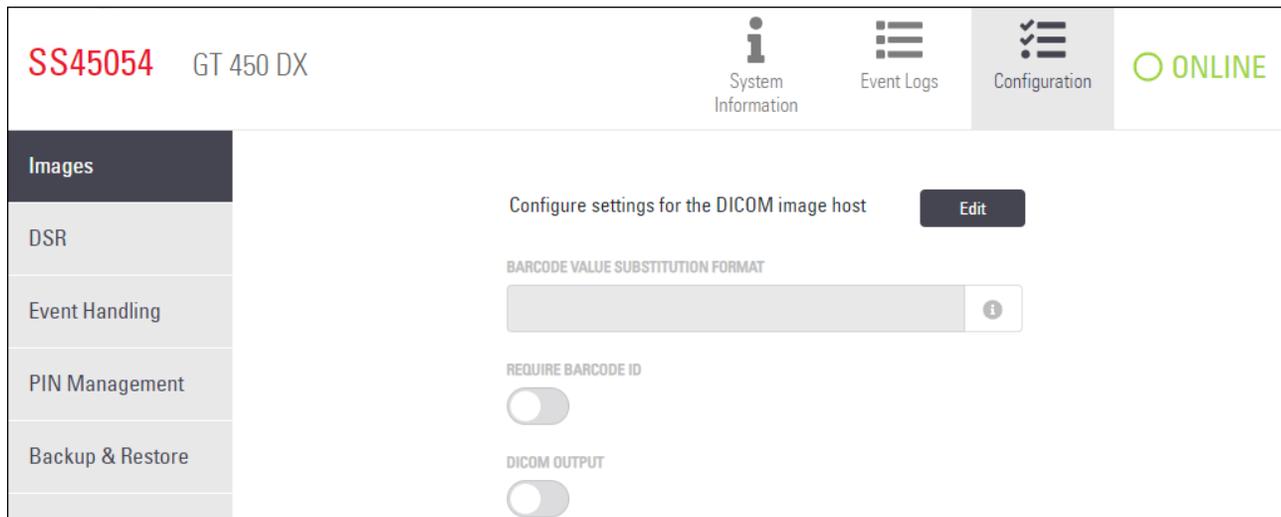
Enabling DICOM Image Output

The Aperio GT 450 DX has the ability to output image files in either SVS or DICOM format. (.SVS image file format is the default.)

You can use SAM DX to enable DICOM output for specific scanners.

i 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 DX as a Leica Admin and enable **Optional Features** for the scanner you want to configure for DICOM.

1. Log into SAM DX as an administrator, go to the main SAM DX page and click **Configuration** next to the scanner you want to configure for DICOM.
2. Click **Images** in the left-hand pane.



3. Click the **Edit** button next to **Configure settings for DICOM image host**.
4. Slide the **DICOM Output** button to the right. (The **Edit** button becomes a **Save** button.)
5. Click **Save**.

When using a scanner that has been configured to output DICOM images, the Console will show “(DICOM)” at the top of the Console page:

Aperio GT 450 DX (DICOM)

4

Viewing System Information

This chapter explains how to display the various configuration options and settings of the SAM DX 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 Friendly 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 menu
Scanner Additional Config Settings	
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 DX 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.

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 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.
2. 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 DX server Downloads folder.
 -  *To use the **Download All Logs** button, your workstation must be connected to your institution's Local Area Network with access to the SAM DX server; you cannot access the SAM DX server remotely from outside the LAN to use this feature.*
 - ▶ Click **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 DX server and storing the backups offsite. We also recommend backing up Windows Event logs on the SAM DX 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 DX.

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

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.

Understanding Roles

There are three user roles:

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

Role	Description
Operator Role	<p>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:</p> <ul style="list-style-type: none">• View the status of each scanner• View System Information for each scanner<ul style="list-style-type: none">• Info page• Scanner Statistics• Settings page• View the Event Log• Change his or her own password <p>Operators cannot view or change the PINs assigned to a scanner.</p> <p>Operators cannot view the list of users, and cannot change settings for other users</p>

Role	Description
Lab Admin Role	<p>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:</p> <ul style="list-style-type: none"> • Add, modify, and delete other user accounts • Change user passwords • View System Information and edit some of the settings • Edit the Configuration settings: <ul style="list-style-type: none"> • Images • DSR • Event Handling • PIN Management
Leica Support Role	<p>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.</p> <p>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.</p>

Managing 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 10 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.
3. 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 login attempts to log into the SAM DX server, SAM DX 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.



The screenshot shows the 'User Administration' page. At the top, there are two tabs: 'Scanners' and 'Users', with 'Users' selected. Below the tabs is a table with the following columns: 'Login Name', 'Full Name', and 'Tasks'. The table contains five rows of user data. The 'Tasks' column for each row contains 'Edit' and 'Delete' buttons. The last row, for user 'DGarcia', also includes an 'Unlock' button, which is highlighted with a blue arrow.

Login Name	Full Name	Tasks
LabAdmin	Lab Admin	Edit Delete
Admin	Admin	Edit Delete
leicasupport1	leicasupport1	Edit Delete
DGarcia	DavidGarcia	Edit Delete 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 10 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**.

6

Cybersecurity and Network Guidelines

This chapter discusses how Aperio GT 450 DX and Aperio SAM DX protect electronic protected health information (EPHI) and provide protections against cybersecurity threats. We also discuss the measures you can take to protect the SAM DX server on your network. This chapter gives information for IT network administrators, Aperio product administrators, and Aperio product end users.



CAUTION: Review all guidelines in this chapter for information on protecting Aperio GT 450 DX and Aperio SAM DX from cybersecurity threats.

The recommendations in this section apply to the Windows-based server used to host SAM DX. 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.

i After installation of the Aperio GT 450 DX product, the Leica Biosystems representative will turn over to your IT staff sensitive cybersecurity items such as SSL certificate credentials, SAM DX 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 DX and Aperio SAM DX Cybersecurity Features

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

- ▶ To reduce cybersecurity vulnerability, the respective operating systems on the Aperio GT 450 DX VPU and SAM DX server are hardened with CIS (Center for Internet Security) benchmarks.
- ▶ The Aperio GT 450 DX scanner and SAM DX 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 DX scanner and the SAM DX server is authenticated through an encrypted, secure SSL/TLS connection.
- ▶ Allow/deny listing is used on the Aperio GT 450 DX scanner and recommended for use on the SAM DX server. This prevents unauthorized software from running on these components.
- ▶ The daily maintenance for the Aperio GT 450 DX scanner includes rebooting it every day. (See the *Aperio GT 450 DX User's Guide* for details.) This refreshes the firmware.

- ▶ The GT 450 DX 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 31.*

Data Protection

Data at rest is protected by encryption. However, due to limitations of the operating system, Private Health Information (PHI) data cannot be protected in transit. Leica Biosystems recommends that you protect data in transit by using SSL with strong security protocols such as Transport Layer Security (TLS) or network-level encryption such as IPsec or SSH tunneling.

Physical Safeguards for Aperio GT 450 DX

- ▶ Protect the Aperio GT 450 DX scanner from unauthorized access by limiting physical access to it.

Protecting the SAM DX Server

The following sections contain recommendations for protecting the SAM DX server.

Password, Login, and User Configuration Safeguards

- ▶ We recommend the following password complexity requirements for users logging into the SAM DX web-based client:
 - Passwords must contain at least 8 characters, including:
 - One upper-case letter
 - One numeric digit
 - One lower-case letter
 - One special character from this set: ! @ # \$ % ^ * _
 - The last five passwords recently used may not be reused
- ▶ After three invalid login attempts, the user account is locked. The user may contact a SAM DX administrator to unlock the account.
- ▶ We recommend you configure workstations used to log into SAM DX 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 SAM DX.

Physical Safeguards for the SAM DX Server

- ▶ Protect the SAM DX server and client workstations used to log into SAM DX from unauthorized access by limiting physical access to them.
- ▶ To protect the SAM DX server 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.

SAM DX Server Administrative Safeguards

- ▶ Set up users with permissions that allow them to access only the portions of the system required for their work. For the SAM DX server, the user roles are “Operator” and “Lab Admin,” which have different permissions.
- ▶ Protect the SAM DX server and client workstations from unauthorized access by using standard IT techniques. Examples include:
 - Firewalls - We recommend enabling the Windows firewall on client workstations.
 - Allow listing, an administrative tool that allows only authorized programs to run, should be implemented on the SAM DX server.
- ▶ Leica Biosystems recommends you use SQL Standard (2019 or later) or Enterprise SQL server which comes with database encryption.
- ▶ Use normal care in maintaining and using servers. Interrupting network connections or turning off the servers while they are processing data (such as when they are analyzing digital slides or generating an audit report) can result in data loss.
- ▶ 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 listing on the server so that only authorized applications are allowed to run. If you are not using allow listing we strongly recommend installing anti-virus software on the server. Run anti-virus scans at least every 30 days.

We also recommend that you configure the anti-virus software to exclude .SVS and DICOM 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.
- ▶ Periodically back up the hard disks on the server.
- ▶ For the SAM DX 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. You should also back up log files and store them at a remote site. See “Working with the Event Log” on page 31.

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 DX and SAM DX 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 DX and SAM DX.

Support and Cybersecurity Patches

Note that technical support and cybersecurity patches for the Aperio GT 450 DX and Aperio SAM DX may not be available after the product lifetime as defined in the *Aperio GT 450 DX User's Guide*.

A

Troubleshooting

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

Scanner Administration Manager DX (SAM DX) Server Troubleshooting

Symptom	Cause	Solution
"Credentials are Invalid" error message during login	Instance of DataServer used by SAM DX is not running	Restart the DataServer service on the SAM DX server. See <i>"Restart the DataServer"</i> 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 DX User Interface	Application is cached in the browser	Exit SAM DX and then clear the browser cache
Scanner is on and connected to SAM DX (retrieves its settings) but SAM DX shows the scanner as offline and no statistical data is being reported (number of scans, etc.)	Mirth on the SAM DX server is not running	See <i>"Verify Mirth is Running"</i> 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 in the scanner logs folder	Mirth on the SAM DX server is not running	See <i>"Restart the DataServer"</i> below.
	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 DX 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 DX is available on are open in the firewall.
	Anonymous Authentication configuration error in IIS	Check the IIS Configuration. See <i>"IIS Configuration Error"</i> 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 DX_Host) and Port (SAM DX_Port) and are using the correct SSL or non-SSL connection (SAM DX_UriSchema). If the Dashboard in Mirth Connect is reporting errors on the "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.

B

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
Friendly Name	Local administrator's name or description for the scanner, displayed on the Scanners home page	View/Edit	None
Model	Aperio GT 450 DX	View	None
Serial Number	Specified during installation and verified at start up	View	View
Hardware Version	Verified at start up	View	View
Language	Controls the language used for scanner menus and messages	View/Edit	None
Additional version information	Available to Lab Administrator from the Scanner Information page. Some of these fields can be viewed by the Operator from the System Information page.	View	View

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	For internal use. Do not change unless instructed to do so by Leica Biosystems Technical Support.	View/Edit	None
Hostname	Name of the server where the DICOM Image Converter resides. <ul style="list-style-type: none"> Use ScannerAdmin if the DICOM Converter is installed on the SAM DX server. Otherwise, use the hostname of the server that the DICOM Converter is installed on. 	View/Edit	None
Port	The port that the DICOM Converter is configured to use at installation. The default is 2762.	View/Edit	None
Title	For internal use. Do not change unless instructed to do so 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
Image filename format	Sets base file name for the scanned image file.	View/Edit	None
Barcode value identifier	Sets base format for barcode	View/Edit	None
DSR Configuration			
Hostname	Hostname of the server where the metadata will be stored. (The "File Location" option, above, is the file share where the images are stored.)	View/Edit	None
Port	The secured port used for the DSR. The default is 44386.	View/Edit	None
Event Handling Configuration			
Hostname	Name of the server where the Mirth Connect Server resides. <ul style="list-style-type: none"> Use ScannerAdmin if the Mirth Connect Server is installed on the SAM DX server. Otherwise, use the hostname of the server where the Mirth instance used for SAM DX is installed. 	View/Edit	None
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

Option	Description	View/Edit	
		Admin	Operator
PIN Management			
Login Timeout	Timeout interval (minutes); the scanner locks the display and control pad when there is no operator interaction for this period of time. Valid value is any whole number greater than zero.	View/Edit	None
Edit Settings: Pin	A 5-digit code to unlock the scanner. Numbers only	View/Edit	None
Edit Settings: Description	Identifying information for the PIN. This is a general description field, and can contain numbers, letters, and punctuation characters.	View/Edit	None
Time Zone			
Scanner time zone	Set by SAM DX administrator	View/Edit	None

C

Binding an SSL Certificate to Aperio SAM DX

Access via the Aperio SAM DX 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.

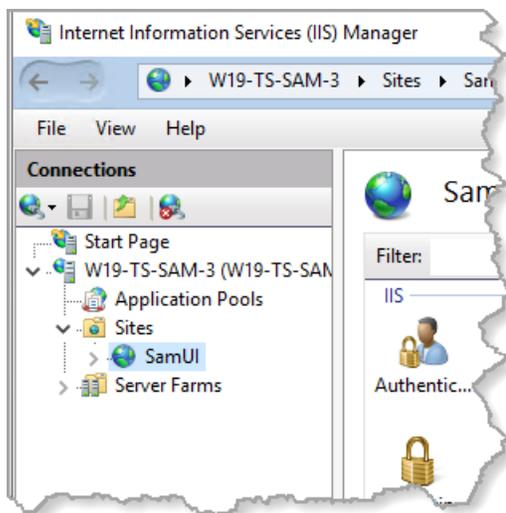
If your institution chooses to use their own SSL certificate to secure the Aperio SAM DX user interface, that SSL certificate will need to be imported and bound to SAM DX.

This section discusses how to update the SSL certificate binding to secure the SAM DX user interface in Microsoft IIS.

Follow the instructions from the SSL certificate provider to import the SSL certificate into Microsoft IIS. Then follow the instructions below to bind the certificate to SAM DX.

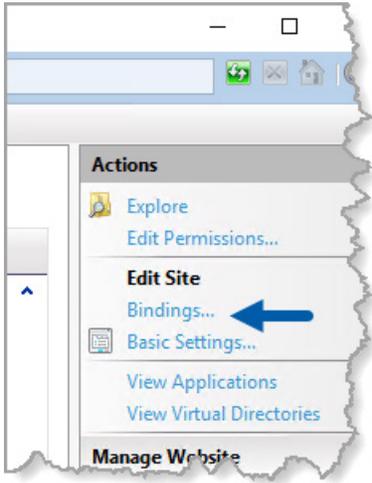
Assign the SSL Certificate to Your Website

1. On the SAM DX server click the Windows **Start** button  and type **inetmgr**.
2. Assign the SSL certificate to your website by expanding the **Sites** subsection in the **Connections** menu on the left and selecting your website:

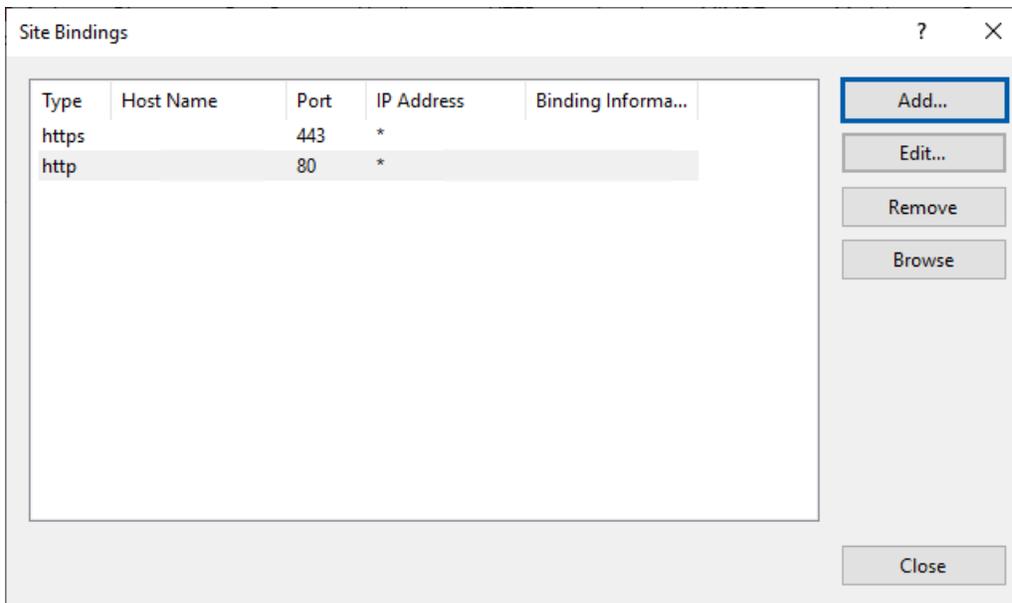


Bind the SSL Certificate

1. In the Actions panel on the right side, locate the **Edit Site** menu and select the **Bindings** option.



2. On the right side of the Site Bindings window, click **Add**:



3. In the Add Site Binding window, modify the fields shown below:
 - a. In the Type field select **https**.
 - b. In the IP address field, select your website's IP address or **All Unassigned**.
 - c. In the Port field, specify 443 (default).
 - d. In the SSL certificate field, select the previously imported certificate, which can be identified by the friendly name.

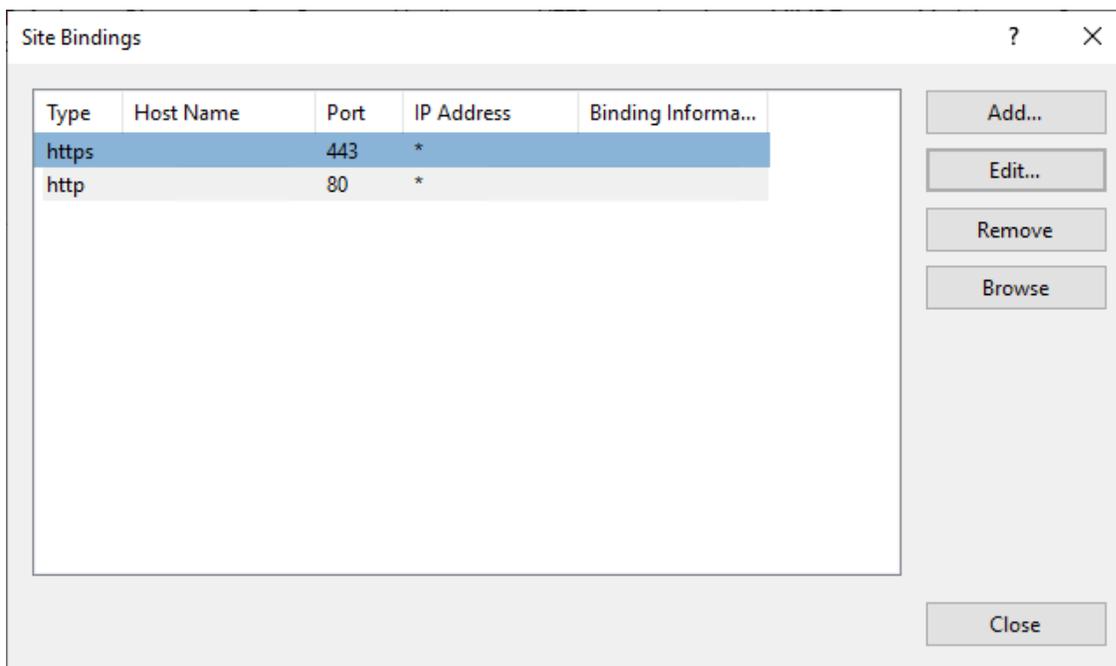


*The **Require Server Name Indication** box needs to be checked if there are multiple SSL certificates on the server.*

Dialog box titled "Edit Site Binding" with fields and options:

- Type: **A** (dropdown menu set to "https")
- IP address: **B** (dropdown menu set to "All Unassigned")
- Port: **C** (text box containing "443")
- Host name: (empty text box)
- Require Server Name Indication
- Disable HTTP/2
- Disable OCSP Stapling
- SSL certificate: **D** (dropdown menu set to "Not selected", with "Select..." and "View..." buttons)
- Buttons: OK, Cancel

- 4. Click **OK** for the new https entry to appear in the Site Bindings window:



The certificate is now installed and the SAM DX user interface should be accessible via HTTPS.

Index

A

Administrator role 34
allow listing 39
architecture 16

B

barcode 27
 requiring 27
 value identifier 27
basic scanner settings 43

C

certificate, SSL. *See* SSL certificate
configuration settings
 Scanner 24
customer service contacts 9
cybersecurity patches
 40
cybersecurity protection
 access logging 39
 administrative safeguards 39
 allow listing 39
 DSR, protecting 39
 IT standards 39
 physical safeguards 39

D

data communication pathways 18
 diagram 18
DICOM 16, 19
 configuring DICOM output 29
Digital Slide Repository (DSR) server 17
documents 13

DSR 17, 24
 settings 24, 31, 44

E

event handling settings 24, 31, 44
event logs 24, 32
events 24

F

file name format 26

H

hostname
 basic scanner setting 43
 DICOM converter 44
 Mirth Connect server 44
 scanner, displaying 31

I

image file name format, modifying 26
images settings 24
image types 16
intended use 12
intrusion alerts 32

L

Lab Admin role 34
log files 32
 downloading 32
login timeout 28, 45
 best practices 28

M

- MAC address 43
 - displaying 31
- Mirth server settings 31

N

- network bandwidth requirements 17
- network configuration 17
 - system 19

O

- off the shelf software 40
- Operator role 33

P

- passwords 33, 34, 35
- PIN 28, 45
 - configuration 28
 - management 25, 28
 - timeout 28
- PIN management
 - settings 45
- PIN, view current 31

R

- related documents 13
- roles 33

S

- SAM DX 11
 - features 11
 - home screen 13
 - logging in 13
 - network configuration 17
 - troubleshooting 41
 - user management 33
- scanner
 - event logs 32
 - time zone 45
- scanner settings 21
- settings
 - Images page 24

- SSL 17, 46
- SSL certificate
 - assigning to SAM DX 46
 - binding 47
 - obtaining 46
- support 40
- system information 31
 - Info page 22
 - Settings page 23

T

- timeout 28, 45
- time zone 25, 45
- troubleshooting 41

U

- unlocking user accounts 35
- user interface 13
- user roles 33
 - adding 34
 - definitions 33
 - deleting 35
 - editing 35
 - Lab Admin role 34
 - Operator role 33
 - passwords 34
 - unlocking accounts 35
- users, view current 31

