Aperio GT 450 DX

Specifications

Aperio GT 450 DX Specifications

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

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Customer Resources

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

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Headquarters	Customer Support	General Information
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Revision Record

Rev.	Issued	Sections Affected	Detail
A	April 2022	All	New version for Aperio GT 450 DX product. Based on existing *Aperio GT 450 DX Scanner Specifications*, MAN-0444, Rev 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 information on performance characteristics, refer to this document, *Aperio GT 450 DX Specifications*.

▶ **Installation** - Aperio GT 450 DX must be installed by a trained Leica Biosystems Technical Services representative.

▶ **Repair** - Repairs may be done only by a trained Leica Biosystems Technical Services representative. After repairs are done, ask the Leica Biosystems technician to perform operation checks to determine the product is in good operating condition.

▶ **Accessories** - For information on using Aperio GT 450 DX with third-party accessories such as a Laboratory Information System (LIS) not provided by Leica Biosystems, contact your Leica Biosystems Technical Services representative.

▶ **Quality Control** - For information on image quality checks, see the *Aperio GT 450 DX User's Guide.*

▶ **Maintenance and Troubleshooting** - For information on maintenance and troubleshooting problems, see the *Aperio GT 450 DX 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 the document *Aperio GT 450 DX IT Manager and Lab Administrator Guide.*

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

▶ **Training -** This manual is not a substitute for the detailed operator training provided by Leica Biosystems or for other advanced instruction.

▶ **Safety -** Safety protection may be impaired if this device is used in a manner not specified by the manufacturer.

ⓘ *For additional information on this product, including intended use and symbols glossary, please refer to the primary instructions for use,* **Aperio GT 450 DX User's Guide**.

Introduction

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

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

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

It is the responsibility of a qualified pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images obtained using the Aperio GT 450 DX. Pathologists should exercise professional judgment in each clinical situation and examine the glass slides by conventional microscopy if there is doubt about the ability to accurately render an interpretation using this device alone.

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*.

ⓘ See the manuals for your digital slide viewer for specifications for monitors and workstations.

Aperio GT 450 DX Components
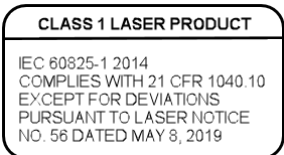
The Aperio GT 450 DX requires these components for administering the scanner:

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. For requirements for this server, see *"Scanner Administration Manager DX (SAM DX) Server Minimum Specifications" on page 9*.
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 must be connected to your local area network with access to the SAM DX server to administer the GT 450 DX scanners.

Aperio GT 450 DX Scanner Specifications

The following sections contain specifications for the Aperio GT 450 DX.

General Scanner Specifications

Feature	Details
Part number	23GT450DXIVD
Scanner on/off switch	Located on the right side, near the back of the scanner.
Scanning region	≤ 23.6 mm x 58 mm
Objective lens	Custom optics by Leica Microsystems for native 40x scanning with 1 mm FOV (Field of View).
Brightfield imaging	4k Trilinear camera
Scan output	SVS and DICOM[1]
Overview image resolution	13 µm/pixel for label, barcode, and tissue macro (overview image).
Label/barcode imaging	High resolution main imaging camera used to capture the label/barcode region.
Focusing system	Real-time automatic focusing (U.S. Patent 9841590B2).
Digital slide file format	Standard pyramid tiled TIFF with JPEG image compression.
Illumination	White LED
Operating system	Linux
Connections	The Aperio GT 450 DX has two connectors on the back panel: 1) Power. The appropriate power cord for your geographical region is shipped with the scanner. The power cord plugs into the AC/DC adapter that connects to the back panel. Only use the approved power cord supplied by the manufacturer. 2) Network. You will need to supply your own network cable.
CLASS 1 LASER PRODUCT IEC 60825-1 2014 COMPLIES WITH 21 CFR 1040.10 EXCEPT FOR DEVIATIONS PURSUANT TO LASER NOTICE NO. 56 DATED MAY 8, 2019	Laser Compliance. This symbol indicates that the product is a Class 1 Laser Product and is in compliance with international standards and US requirements.

Aperio GT 450 DX Features

Feature	Details
Scanning priority	By rack, up to 3 racks at a time.
Continuous loading	Continuous rack loading without interrupting scanning.
Slide loading	Automatic: up to 450 1-inch x 3-in (2.54 cm x 7.62 cm) slides.
Slide calibration	Each slide scan is automatically calibrated.

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1. To use the DICOM file format, this feature must be enabled for your scanner on SAM DX. See *Aperio GT 450 DX IT Manager and Lab Administrator Guide* for details. Also, your IT environment must meet the requirements detailed in the *Aperio DICOM Conformance Statement*.

Feature	Details
Automated image quality check	Each scan image is automatically checked for image quality during scanning.
Tissue finding	Automatic
Touch-screen	• 10.1" diagonal, IPS, 16:10, 1280 x 800 resolution • Viewing angles: 85/85/85/85 • Contrast ratio: 800:1
Embedded Vision Processing Unit (VPU)	The VPU is an embedded processor that runs the Aperio GT 450 DX controller software. Refer to the *GT 450 DX IT Manager and Lab Administrator Guide* for instructions on determining the version of the software included on this unit.

Performance Specifications

Feature	Details
Scan speed	< 32 sec/slide, 15 mm x 15 mm at 40x.
Throughput	Sustained throughput 81 slides per hour 15 mm x 15 mm (40x).
Scanning resolution	0.26 µm/pixel at 40x.

Power Specifications

Feature	Details
Input Power	External AC/DC adapter (Power Supply Unit): 100-240V, 50/60Hz, 5A max; Instrument: 24V ⎓ 10.5A.
Power consumption	+24vdc @ 10.5 amps RMS
Uninterruptible Power Supply (UPS)	To protect the scanner, Leica Biosystems recommends using a UPS rated at 2200VA with power conditioning that protects connected loads from electrical surges and spikes, lightning and other power disturbances. The UPS allows the scanner to run for an additional 20-30 minutes, giving you time to safely shut it down.

Slides and Rack Specifications

Feature	Details
Slides accepted	The Aperio GT 450 DX is optimized for scanning glass slides with coverslips affixed with mounting media. • 1-inch x 3-inch (2.54 cm x 7.62 cm) glass slides. Measurements comply with ISO 8037/1. • Minimum slide size: 25 mm (wide) x 75 mm (long) • Maximum slide size: 26 mm (wide) x 76 mm (long) • Thickness: Optimized for range of 0.9 mm to 1.1 mm, excluding coverslip The coverslip/label shall not protrude beyond the edge of the glass slide. The entire coverslip and label must be adhered to the glass slide. There must be no lifted edges or parts of the coverslip/label. The outer surface of the slide must be dry. Slides are typically prepared using: • Glass coverslip with mounting media such as Eukitt • Film coverslip with integrated glue Maximum tissue thickness (including mounting media) optimized for 3-5 µm.
Coverslips accepted	Optimized for coverslip with thickness of 0.17 mm, made of typical coverslip material: Standard microscope cover glass or Cellulose Tri-Acetate film (microscope cover film).
Racks accepted	Optimized and recommended for use with Leica HistoCore Spectra workstation racks (stainer and coverslipper), which include the Leica Universal Rack 30-slide capacity. Sakura Prisma Stainer and Coverslipper Rack 20-slide capacity racks also accepted.
Racks provided	15 Leica Universal racks, 30-slide capacity (part number 23RACKGT450) are provided with the Aperio GT 450 DX.
Label area	25 mm x 25 mm. Handwritten/printed non-transparent, matte (paper-like reflecting) sticker. Labels shall not protrude beyond the edge of the slides nor be lifted. Labels shall not be attached to the bottom of the slide, but only attached to the coverslip-side of the slide. Maximum label thickness 200 microns Minimum label size 12 mm x 25 mm There must be a minimum of 0.5 mm between each side of the barcode and the edge of the label.
Barcodes supported	NW7 QR Code Data Matrix Interleaved 2 of 5 Code 39 Code 128 PDF417 MicroPDF417

Environmental Specifications

Feature	Details
Dimensions	20.8" (52.83 cm) Width x 28" (71.12 cm) Depth x 19.5" (49.53 cm) Height
Weight	140 lbs (63.5 kg)
Work surface specifications and required clearances	Standard laboratory grade work bench with at least 24" (61 cm) Width x 28" to 32" (71.12 cm to 81.28 cm) Depth x 29.25" (74.3 cm) Height, open area leveled to +/- 1.0 degrees. Ensure you leave 13 inch (33 cm) clearance on the left side of each scanner to provide access for maintenance activities, and leave 3-4 inches (8 cm-10 cm) on the right side of each scanner for access to the power switch.
Operating conditions	The Aperio GT 450 DX is designed to be operated under the following environmental conditions: • Indoor use • Overvoltage Category II • 0% - 80% humidity, non-condensing • Operating temperature: 15-30° C (59-86° F)
Storage conditions	+5 to 40° C, 5 to 85% RH
Transport conditions	0 - 50° C, 10% - 95% humidity, non-condensing
System heat dissipation	Maximum 870 BTU/hr.
Maximum elevation	10,000 ft
Degree of pollution	2
Environmental	RoHS conform (Restriction of Hazardous Substances) according to Directive 2011/65/EU

Network Specifications

Feature	Details
Network interface	1 gigabit per second Ethernet
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.

Routine setup and functional verification is required by a Leica Biosystems Service representative after shipping.

Scanner Administration Manager DX (SAM DX) Server Minimum Specifications

This section provides the minimum specifications for the server that hosts the SAM DX application software. Your SAM DX server must meet or exceed these requirements. Leica Biosystems does not recommend using virtualized (VM) SAM DX server configurations.

i *The Scanner Administration Manager DX (SAM DX) supports up to 4 Aperio GT 450 DX scanners. Multiple SAM DX servers can be added to your network.*

For information on recommended network configuration and data flow for the Aperio GT 450 DX, refer to*"Aperio GT 450 DX Recommended Network Configuration" on page 12* and the *Aperio GT 450 DX IT Manager and Lab Administrator Guide*.

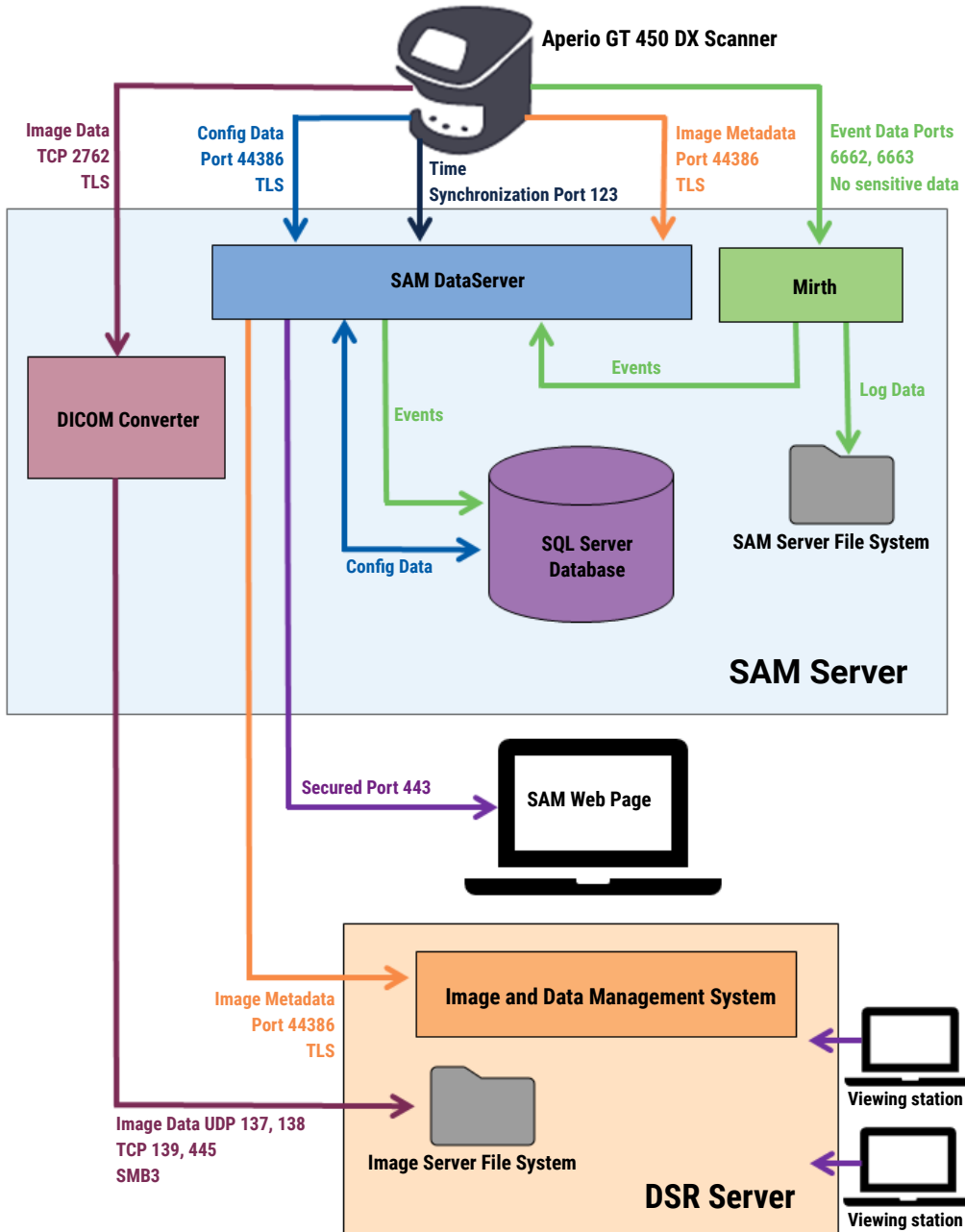| Feature	Details
CPU	Intel Xeon Silver 4114 2.2G, 10C/20T, 9.6GT/s, 14M Cache, Turbo, HT (85W) DDR4-2400
Hard disk space	(2) 800GB SSD SATA Mix Use 6Gbps 512n 2.5in Hot-plug Drive, Hawk-M4E, 3 DWPD,4380 TBW
Memory	Memory DIMM Type and Speed Quantity: (2) 16GB 2666MT/s RDIMMs
Network card	Intel Ethernet Converged Network Adapter X550-T2 2-port 1/10Gb Base-T network adapter - PCle 3
Operating system	Windows Server 2019

Aperio GT 450 DX Compliance Specifications

This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation. This device has been evaluated against and conforms to the following standards:

Feature	Details
Safety	IEC 61010-1:2010 IEC 61010-1: 2010/AMD1:2016 IEC 61010-2-101: 2018 CAN/CSA C22.2 No. 61010-1:2012/A1:2018 CAN/CSA C22.2 No. 61010-2-101:2019 UL 61010-1:2012/R2019-07 UL 61010-2-101:2019 EN 61010-1:2010/A1:2019 EN 61010-2-101:2017
EMC	EMC Directive (Directive 2014/30/EU) EN 61326-1:2013 CISPR 11: 2015 FCC Part 15 Subpart B ICES-003 Issue 6: 2016 CNS13438: 2006 KN 32: 2015-12 KN 35: 2015-12

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. For more details on this topic, see the *Aperio GT 450 DX IT Manager and Lab Administrator Guide*.

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

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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 and data management system (IDMS) on the DSR Server. The data is sent using SMB3 Encryption.	UDP 137, 138
		TCP 139, 445
	Configure the communication between the DICOM converter and the DSR using the File Location setting on the Images page.	
	Images can be sent to viewing stations connected to the DSR.	80, 443
Scanner Configuration Data	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.	44386
	The SAM DX DataServer stores the configuration data on the SQL Server Database on the SAM DX Server.	
	The SAM DX DataServer displays the configuration data through the SAM DX web page.	
Time Synchronization	Timeclock synchronization between SAM DX and Multiple Scanners is maintained using network time protocol.	UDP 123
Image Metadata	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.	44386
	The SAM DX DataServer sends image metadata to the IDMS located on the DSR. The data is sent using TLS encryption.	
	Configure the communication between the SAM DX 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 DX DataServer, then the SAM DX DataServer sends this data to the SQL database. This is the data reported out via the SAM DX Event Logs.	
	The SAM DX DataServer displays the event data through the SAM DX web page.	
	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 the SAM DX.	

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