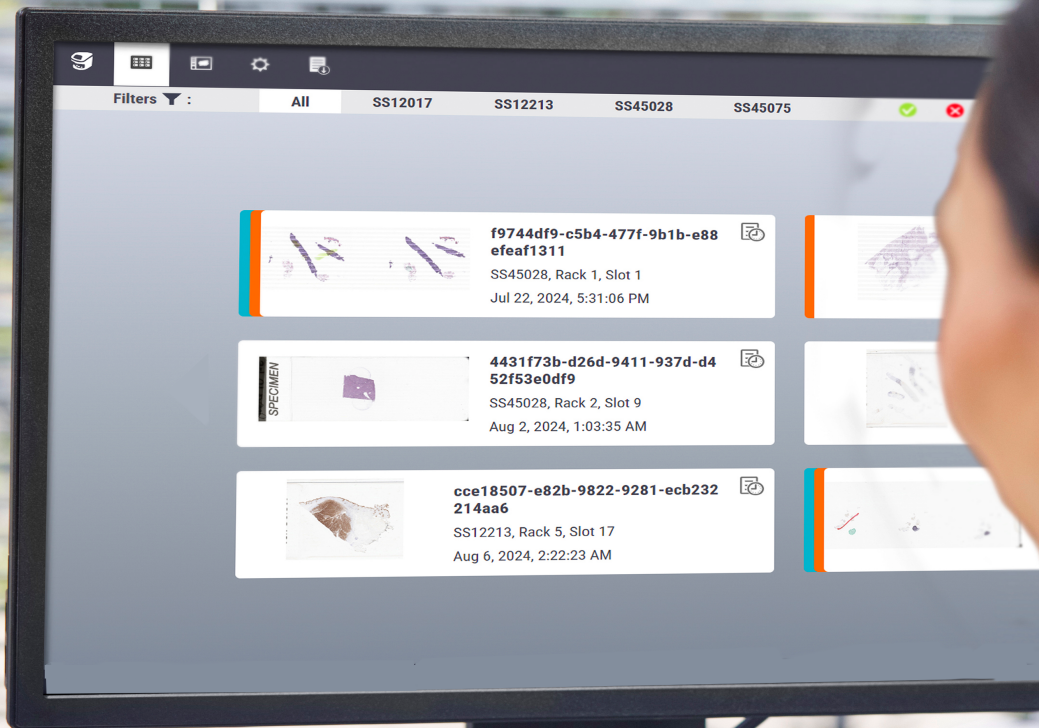


APERIO iQC™ DX

SOFTWARE

SPECIFICATIONS



CE

Advancing Cancer Diagnostics
Improving Lives

Aperio IQC DX Software Specifications

MAN-0570, Revision A | November 2025

This manual applies to the Aperio iQC DX Software version 1.0 and later.

Original instructions.


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- This product is protected by registered patents. For a list of patents, contact Leica Biosystems.




Customer resources

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

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For In Vitro Diagnostic Use

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1

Notices

1.1 Revision record

Rev.	Issued	Sections Affected	Detail
A	November 2025	All	Initial release.

1.2 About this manual

This manual provides specifications for the Aperio iQC DX, a software-only device intended for in vitro diagnostic use. This manual is intended for all users of the Aperio iQC DX Software, including laboratory technicians, administrators, and managers as well as IT administrators and managers.



The Aperio iQC DX Software is used with Aperio GT scanners. In this document the term "Aperio GT scanners" is used to refer to devices in the Aperio GT 450 and Aperio GT 180 scanner families.

1.3 Intended purpose

Aperio iQC DX Software is an artificial intelligence-based software intended to be used by laboratory professionals as an aid in the identification of digital (out of focus, image striping, and missing and clipped tissue) and/or histological (air bubbles and pen marks) artifacts in hematoxylin and eosin (H&E) and immunohistochemistry (IHC) stained, formalin-fixed paraffin embedded (FFPE) tissue, whole slide images (WSIs) from Aperio GT 450 DX and Aperio GT 180 DX scanners that should undergo further evaluation for quality prior to diagnostic review.

Laboratory professionals should only use Aperio iQC DX Software in conjunction with their complete in-house laboratory image quality control workflow. Aperio iQC DX Software is not intended to be used for the diagnosis, prognosis, or prediction of disease.

1.4 Standards

The Aperio iQC DX Software is designed and developed in strict accordance with industry standards. For a complete list of standards, contact Leica Biosystems.

1.5 Leica Biosystems warranty

View the Leica Biosystems Leica Biosystems warranty here:

<https://www.leicabiosystems.com/us/about/terms-and-conditions/>

1.6 Related documents

The Aperio iQC DX Software resides on a hosted server. It is deployed within a network that includes Aperio GT scanners and the Aperio SAM (Scanner Administration Manager) DX server.

For complete information about the use and deployment of the Aperio iQC DX Software into the laboratory environment, see the following documents. For specific details about the scanner, see the user documentation for the scanner. For specific details about Aperio SAM DX, see the *Aperio SAM DX IT Manager and Lab Administrator Guide*.



Document No.	Description
MAN-0565	Aperio iQC DX Software User's Guide
MAN-0570	Aperio iQC DX Software Specifications
MAN-0566	Aperio iQC DX Software IT Administrator's Guide





1.7 Glossary of symbols

The following is a list of symbols used on the product labeling and their meanings.



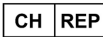
ISO 15223-1

Medical devices – symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.

Symbol	Standard/ Regulation	Reference	Description
	ISO 15223-1	5.1.1	Manufacturer Indicates the medical device manufacturer.
	ISO 15223-1	5.1.2	Authorized representative in the European community Indicates the Authorized representative in the European Community.

Symbol	Standard/ Regulation	Reference	Description
	ISO 15223-1	5.1.6	Catalog number / Reference number Indicates the manufacturer's catalog number so that the medical device can be identified.
	ISO 15223-1	5.1.8	Importer Indicates the entity importing the medical device into the European Union.
	ISO 15223-1	5.4.4	Caution Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	ISO 15223-1	5.7.10	Unique Device Identifier The unique device identification (UDI) is a unique numeric or alphanumeric code related to a medical device. It allows for a clear and unambiguous identification of specific devices on the market and facilitates their traceability.

Other symbols and markings

Symbol	Standard/ Regulation	Description
	The instrument Declaration of Conformity lists the Directives with which the system complies	European Conformity The instrument Declaration of Conformity lists the Directives with which the system complies.
	N/A	UK Conformity Assessment Device is in compliance with UK Conformity Assessment requirements.
	Ordinance on In Vitro Diagnostic Medical Devices (IVDO) of 4 May 2022.	Swiss Authorised Representative Indicates the Swiss Authorised representative.

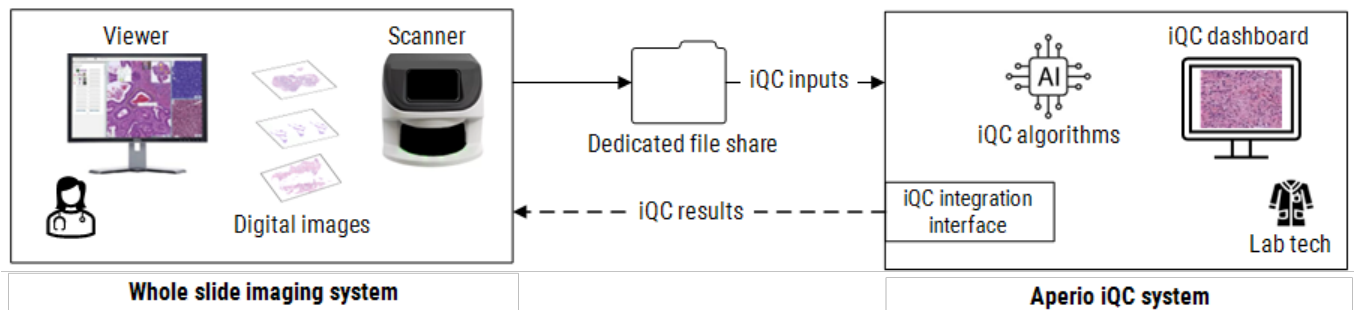
2 Introduction

The Aperio iQC DX Software is a standalone software application intended to assist in identifying artifacts in whole slide images (WSIs) produced by Aperio GT scanners. The Aperio iQC DX Software analyzes copies of WSIs of hematoxylin and eosin (H&E) and immunohistochemistry (IHC) stained slides in SVS format.

When Aperio iQC DX Software is running, copies of WSIs from connected Aperio GT scanners are automatically analyzed. The WSIs, along with the artifact detection results, are displayed on the iQC dashboard for laboratory staff review and disposition. The user can accept or reject the WSI and add comments for each scan.

To analyze images, Aperio iQC DX algorithms use locked AI. The Aperio iQC DX Software is executed on copies of the original images. The Aperio iQC DX Software does not modify those images.

Figure 2-1: System diagram showing Aperio iQC DX



The Aperio iQC DX Software is deployed within a network that includes Aperio GT scanners. Each copy of Aperio iQC DX Software can support up to four scanners, including a combination of scanners from both the Aperio GT 180 and Aperio GT 450 scanner families.

3

Technical specifications

3.1 System requirements

This section outlines the requirements for a successful installation of the Aperio iQC DX.

3.1.1 Aperio iQC server

3.1.1.1 Hardware

The Aperio iQC DX must be installed on a physical or virtual machine (VM) in the customer laboratory that meets the requirements below.



To run iQC properly on a virtual machine (VM), the setup must be almost identical to a physical computer. This means using a "type-1 hypervisor" that allows the computer's graphics card to be used directly by the VM. Using a VM to avoid installing Linux—especially on a lightly provisioned Windows host—is not recommended and is not supported for iQC deployment. This setup introduces performance and compatibility risks that conflict with the requirements for iQC's operation.

If the goal is to avoid installing Linux directly on bare metal, a VM is not a valid workaround. iQC requires a hosting environment that meets strict hardware and virtualization specifications, including GPU passthrough via a type-1 hypervisor.

Customers are responsible for setting up their systems correctly. Whether they choose a VM or a physical computer, it must meet the technical requirements. For customers lacking the expertise to provision such an environment, the recommended path is to deploy Linux directly on bare metal.

Requirement	Recommended specification
CPU	Model: Intel Core i7 or higher, or AMD EPYC 9004 and 8004 Series Cores: 12 (1 scanner), 24 (2 scanners), 36 (3 scanners), 48 (4 scanners) Base clock speed: 3.00 GHz
Memory (RAM)	64 GB (1 scanner), 128 GB (2 scanners), 192 GB (3 scanners), 256 GB (4 scanners)

Requirement	Recommended specification
Storage	2 TB SAS SSD (solid-state drive)
GPU	Model: NVIDIA L4 Quantity: 1 (1 scanner), 2 (2 scanners), 3 (3 scanners), 4 (4 scanners)
LAN speed for user	1 Gbps (minimum)
LAN speed for storage access	10 Gbps (minimum)
Internet upload speed	100 Mbps (minimum)
Network	Network card: 10 GbE (minimum)

3.1.1.2 Operating system

The Aperio iQC DX Software requires the following operating system:

- Ubuntu 24.04 LTS (Long Term Support) or higher

3.1.2 Aperio GT scanner and Aperio SAM DX

The Aperio iQC DX Software requires the following Aperio GT Platform system components:

- Aperio GT 450 DX scanner (with software version 1.5.1 or later) or Aperio GT 180 DX scanner (with software version 1.5.0)
- Aperio SAM DX hosting server with Windows Server 2022 or later and SAM software version 1.4 or later

3.1.3 Peripheral devices

The following user requirements are independent of the server hosting the Aperio iQC DX. These can be tailored to user preferences, as the user can also view the results of the Aperio iQC DX on a laptop as well as with a monitor, keyboard, and mouse attached to the iQC server. No tablet support is available.

Requirement	Recommended specification
Keyboard	Compatibility: Standard PC layout Connection type: USB Keyboard description: Accessible
Monitor	FHD (Full High Definition) 1080p

3.1.4 Browser

To view the dashboard, we recommend that you use one of the web browsers that has been tested with Aperio iQC DX. Other browsers may distort the display.

Requirement	Minimum specification	Recommended specification
Google Chrome	126.0.6478.126/127 / 24 June 2024	Latest stable version
Microsoft Edge	126.0.2592.87	Latest stable version
Firefox	127.0.2	Latest stable version

3.1.5 Other requirements

A successful installation of the Aperio iQC DX Software requires that these additional requirements be met:

- There must be a network samba share location that can be permanently mounted on the IQC server within the Linux environment. This image location must be accessible with read/write permissions by a domain service account and available to the DICOM service.
- An account with administrator access is required for Aperio iQC DX Software installation.
- A non-administrative account must be provided for each installation of the Aperio iQC DX Software.
- A directory should be created on the IQC server for storage of installation media and assets, so that they are easily accessible to the person installing the software. The directory should be created within the home directory of the administrator user account.

3.2 Performance specifications

Specification	Value
Artifacts detected	Out-of-focus, missing and clipped tissue, image striping, air bubbles, pen marks
Image type supported	SVS
Maximum image file size	32 GB
Maximum number of scanners supported	4
Artifact detection accuracy ¹	Out-of-focus: 94% Missing and clipped tissue: 94% Image striping: 99% Air bubbles: 94% Pen marks: 90%
Content of exported CSV file	Slide ID, location, user-specified action (reprocess or rescan), and user comments
Log retention	Event, error, and information logs: 6 months Slide, metadata, and review results: 7 days
Processing timeout	30 minutes (default); configurable during installation

¹Accuracies are based on datasets ranging from 298 to 580 test cases.

3.3 Artifact threshold setting ranges



CAUTION: Ensure that you set thresholds to obtain the results you expect to see. Be aware that if a threshold is set too high, the Aperio IQC DX Software may fail to identify legitimate artifacts.

Periodically confirm the threshold settings.

Threshold setting	Range	Default	Slider increment
Out of Focus Coverage	10%-100%	10%	5%
Out of Focus Severity	35%-100%	35%	5%
Image Striping	70%-100%	70%	10%
Pen Marks	9%-100%	9%	1%
Air Bubbles	9%-100%	9%	1%

Glossary

Abbreviation	Meaning
AI	Artificial intelligence
CSV	Comma-separated values
DICOM	Digital Imaging and Communications in Medicine, a standard protocol for the management and transmission of medical images and related data
FFPE	Formalin-fixed and paraffin-embedded, a type of surgical pathology slides.
H&E	Hematoxylin and eosin, which are stains used to highlight tissue structures in microscopic images.
IHC	Immunohistochemistry
IVD	In vitro diagnostics
SAM	Scanner Administration Manager
SSL	Secure Sockets Layer
SVS	ScanScope Virtual Slide