## APERIO iQC<sup>™</sup> SOFTWARE MODULE

#### **USER'S GUIDE**





#### MAN-0545, Revision Revision A | December 2024

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

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#### Customer resources

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

#### Contact information – Leica Biosystems Imaging, Inc.

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



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# Notices

## 1.1 Revision record

Rev.	Issued	Sections Affected	Detail
Revision A	December 2024	All	Initial release

## 1.2 About this manual

This manual provides information about the Aperio iQC Module, a software-only device intended for Research Use Only. This manual is intended for use by research laboratory personnel.

## 1.3 Glossary of symbols

This section describes the regulatory and safety symbols used in the product labeling.

### 1.3.1 Regulatory symbols

Explanation of the regulatory symbols used for Aperio iQC Module.



This glossary provides images of the symbols as presented in the relevant standards, however, some of the symbols may vary in color.

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

#### 1 Notices

#### ISO 7000

Graphical symbols for use on equipment – Registered symbols.

Symbol	Standard/ Regulation	Reference	Description
	ISO 7000	0434A	<b>Caution</b> To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
REF	ISO 7000	2493	Catalog number / Reference number Indicates the manufacturer's catalog number so that the medical device can be identified.
	ISO 7000	3082	Manufacturer Identifies the manufacturer of a product. This symbol shall be used filled in all applications to differentiate it from ISO 7000-2497.

#### Other symbols and markings

Symbol	Standard/ Regulation	Description
RUO	N/A	<b>Research Use Only</b> This product is intended for research use only and not for use in diagnostic procedures.

## 1.4 General notes

General Aperio iQC Software Module notes appear below. Other notes appear in relevant sections in the manual.



Aperio iQC Software Module is designed to assist and enhance, but not replace, human evaluation for slide quality. It is not intended to replace professional evaluation and judgment. Users should always rely on their expertise and consider the outputs of Aperio iQC Module as supplementary information and as an additional tool in the quality control process, not as the sole determinant for decision-making. The user should review all Aperio iQC software output. The final decisions and actions should be made by qualified individuals.



iQC may not always flag slides with certain artifacts, and it might incorrectly flag slides that contain no artifacts. Users should exercise discretion and verify results accordingly. See 6.2 Performance specifications for artifact detection accuracies.



 $\mathsf{iQC}$  is not intended to be used in the diagnosis of disease.



The Aperio iQC Software Module does not have any control over any connected devices (the scanner or any other component of the WSI system). If changes are needed to the WSI system to communicate with the Aperio iQC Software Module, those changes are the responsibility of the WSI system.

## 1.5 Benefits of Aperio iQC Software Module

The key benefits of Aperio iQC Software Module include.

- Consistent and standardized quality control evaluations across WSIs
- Detection of WSI artifacts that require digital or histological rework as early in the workflow as possible to eliminate additional time and costs that grow as the workflow progresses.
- Provision of quality metrics for lab tissue/digital preparation.
- Improved turnaround time.
- Automation of the quality control step of large volumes of digital slides, so that users can prioritize slides detected with artifacts and have those reprocessed or rescanned earlier in the WSI review workflow.
- Reduction in number of staff required to perform quality control of scanned digital pathology images

Detected artifacts are highlighted on the Aperio GT 450 console, and on the iQC Dashboard for the user to analyze. The expected workflow efficiency takes these forms:

## 1.6 Training

Contact Leica Biosystems for training on Aperio iQC Software Module

## 1.7 Reference documents

The Aperio iQC Module resides on a hosted server. It is deployed within a network that includes the Aperio GT 450scanner and the Aperio GT 450SAM (Scanner Administration Manager) server. This manual describes the use of the Aperio iQC Software Module within that network. For specific details about the scanner, refer to the technical manuals listed below.

To find out how the network protects against cybersecurity threats, see the *IT Manager and Lab Administrator Guide*, which describes the SAM server.

Document No.	Description
MAN-0391	Aperio GT 450 User's Guide
MAN-0393	Aperio GT 450 Scanner Specifications
MAN-0394	Aperio GT450 IT Manager and Lab Administrator Guide
MAN-0556	Aperio iQC Software Module IT Administrator's Guide

# 2 Introduction

The Aperio iQC Software Module is a standalone software application intended to assist in identifying artifacts in whole slide images (WSIs) produced by the Aperio GT 450 Scanner. It is installed on the customer's server. The Aperio iQC Software Module analyzes copies of WSIs of hematoxylin and eosin (H&E) and immunohistochemistry (IHC) stained slides in SVS and DICOM formats.

When Aperio iQC Software Module is running, copies of WSIs from connected Aperio GT 450 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 Aperio iQC Module results and add comments for each scan.

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





# **3** Principles of operation

The Aperio iQC Software Module detects and identifies the artifacts shown below.



A dashboard displays the results once they become available. On the dashboard, the user can interact with each image to perform image quality review. The dashboard is the central hub for managing scanned slides and artifact detection within the system.

## 3.1 System architecture

The Aperio iQC Software Module is deployed on the customer's server. It doesn't interact directly with the Aperio GT 450, but rather it retrieves SVS files produced by the scanner. Figure 3-1 iQC Software Module system architecture shows how the Aperio iQC Module fits into the overall Aperio iQC Module system. Together, these components work to ensure monitoring, processing, and analysis of whole slide images (WSIs).



Figure 3-1: iQC Software Module system architecture

## 3.2 Operational overview

The operation of Aperio iQC Module follows the steps below.

- 1 The Aperio iQC Module continuously monitors the iQC file system for new data, including WSIs, high-resolution macro images, metadata JSON files, and hash files. This data is then transmitted to iQC using secure protocols (for example, mTLS) to ensure data integrity and security.
- 2 Data incoming to the Aperio iQC Module is validated to ensure that it meets the required format and licensing conditions. The validated data is then queued for processing.
- 3 Al algorithms detect artifacts in the WSIs. See 3.2 Operational overview for details about how Aperio iQC Module detects each type of artifact.
- 4 The results are collected and stored in a location that can be accessed by the iQC dashboard and scanner software.
- 5 Any errors encountered during artifact detection, including issues with AI model loading, data corruption, or resource constraints, are logged. All significant events, including data processing and artifact detection are logged.
- 6 The dashboard retrieves and displays the iQC reults. The user's assessment of those results is in turn stored by iQC.
- 7 The iQC support package polls the Aperio iQC Module for results and relays them to connected scanners.

## 3.3 About the artifact detection algorithms

iQC algorithms process the scanned data exported from the scanner and perform a series of AI techniques to identify the presence of artifacts on each slide. These algorithms use AI to capture and quantify known features related to specific artifacts. The inference results generated from the algorithms are further processed by a rules engine (based on predefined or user-defined sensitivity parameters) to determine the presence of each artifact.

iQC uses different machine learning paradigms to address different artifacts.3.3.2 iQC algorithm details describes the algorithms used to detect each artifact, along with notes on how that algorithm was trained.

### 3.3.1 Training of algorithms

The iQC algorithms are static, non-continuous-learning AI software algorithms. The presence of artifacts is determined using convolutional neural network (CNN) machine learning, a type of deep learning network specifically designed for image classification and object recognition. The algorithms learned features from images containing artifacts using supervised learning. The trained algorithms are used to detect, classify, and label artifacts. With static AI, the algorithm is trained and tested in a controlled environment and then locked before deployment. In other words, it doesn't learn or adapt on its own once deployed.

#### 3.3.1.1 Training and test data

The data used to train, validate, and test Aperio iQC was from histology slide samples that exhibit variability in their input features. These variable input features include stain type, tissue type, tissue size, and disease state. The training dataset contained a balanced representation of tissue samples both with and without artifacts.

## 3.3.2 iQC algorithm details

Algorithm/artifact	Artifact definition	How the algorithm is trained and works
Out-of-focus region	An out-of-focus artifact in whole slide images (WSIs) is characterized by blurriness or a lack of sharpness in certain areas of the image, resulting from improper focus during scanning. These artifacts can obscure important details, making accurate tissue analysis difficult.	The out-of-focus algorithm generates a range of out- of-focus scores for the tissue region on WSIs. This output, combined with user-defined sensitivity threshold parameters—out of focus coverage and severity—determines the presence of the artifact.
Clipped and missing tissue	Clipped tissue is a section of tissue partially captured in the WSI, with some portion being outside the WSI boundary. Missing tissue is a section of tissue that is outside of the WSI and is only visible in the macro image of the slide. In both situations, the tissue is unavailable for assessment.	The clipped and missing tissue algorithm compares the detected tissue region to the scanned region used to produce the WSI. If tissue is detected outside of the scanned region, the slide is flagged for missing or clipped tissue.
Image striping	A scanner may occasionally generate faint, striped patterns on the WSIs. These stripes traverse the entire slide image exhibiting varying degrees of intensity. They can hinder visual image review and assessment.	The image striping algorithm can distinguish between striping and non-striping features. The ratio of striping regions to all regions, along with user-defined sensitivity for image striping, determines the presence of this artifact.
Air bubble	Air bubbles are histological artifacts that could obscure regions of interest on a glass slide or tissue. These artifacts appear as air pockets trapped in between the coverslip and the slide.	The air bubble algorithm identifies features that pinpoint air bubbles within tissue at the pixel level. This output, along with a user-defined sensitivity parameter for air bubbles, determines the presence of this artifact.
Pen/ink marks	Pen/ink marks are histological artifacts that can appear either as printed or hand-drawn markings (for example, by markers of distinct colors on the tissue), and they can obscure tissue features and regions of interest on the tissue.	The pen/ink marks algorithm identifies features that pinpoint pen/ink marks. This output, along with a user-defined sensitivity parameter for pen marks, determines the presence of this artifact.

### 3.3.3 Detection sensitivity settings

A user with the Lab Admin role can configure artifact detection sensitivity using the Settings function,.

#### 3.3.3.1 Out-of-focus threshold

**Out of Focus Coverage:** This threshold, set as a percentage, defines the minimum percentage of "in-focus" tissue at which a slide is flagged as out of focus. If the in-focus tissue percentage is smaller than this threshold, the slide is flagged for the out-of-focus artifact. Increasing the threshold (moving the pointer to the right) requires a higher percentage of in-focus tissue to flag the artifact. This makes the algorithm more sensitive to out-of-focus artifacts and may cause more slides to be flagged.

**Out of Focus Severity:** This threshold, set as a percentage, defines the minimum focus level of a tissue region required to identify as out-of-focus. If the detected focus level of the tissue region is smaller than this threshold, the region is identified as out-of-focus. Increasing the threshold (moving the pointer to the right) requires a higher focus level to identify a region as out-of-focus. This makes the algorithm more sensitive to out-of-focus artifacts and may cause more slides to be flagged.

#### 3.3.3.2 Image striping threshold

This threshold, set as a percentage, defines the minimum "non-striped" percentage for a slide to be flagged for the striping artifact.

If the non-striping percentage in a slide is less than this threshold, the slide is flagged for the image striping artifact. Increasing the threshold (moving the pointer to the right) requires a higher percentage of non-striped region to flag the slidei for image striping. This makes the algorithm more sensitive to image striping artifacts and may cause more slides to be flagged.

#### 3.3.3.3 Air bubbles threshold

This threshold, set as a percentage, is converted to the minimum number of pixels required to flag a slide for air bubbles.

If the detected air bubble pixels in a slide exceed this threshold, the slide is flagged for the air bubble artifact. Increasing the threshold (moving the pointer to right) requires fewer air bubbles pixels to flag the artifact. This makes the algorithm more sensitive to air bubble artifacts and may cause more slides to be flagged.

#### 3.3.3.4 Pen marks threshold

This threshold, set as a percentage, defines the minimum of pixels required to flag a slide for pen marks.

If the detected pen mark pixels in a slide exceed this threshold, the slide is flagged for the pen mark artifact. Increasing the threshold (moving the pointer to the right) requires fewer pen mark pixels to flag the artifact. This makes the algorithm more sensitive to the pen mark artifacts and may cause more slides to be flagged.

#### 3.3.4 Limitations of artifact detection

The Aperio iQC Software Module may not detect artfifacts in certain cases, as described below. .

#### 3.3.4.1 Missing/clipped tissue

- Tissue outside of the coverslip is not flagged as missing.
- Very small tissue fragments may not be detected.
- Faintly stained slides may prevent tissue from being detected.
- Air under the coverslip may cause tissue to be confused for debris, as the tissue appears black within the image.
- Excessive mounting media or similar artifacts that may occlude the tissue may prevent the tissue from being detected.

#### 3.3.4.2 Image striping

- A slide having an image striping outside the tissue is not flagged.
- Faint image striping (usually disappears at higher magnifications) that does not significantly affect the tissue may not be detected.
- Faintly stained slides (with very faint image striping) may prevent image striping from being detected.

#### 3.3.4.3 Out of focus

- Out-of-focus visualization may appear on non-tissue area, particularly if those areas are not clean.
- Out-of-focus areas caused by tissue folds may not always be detected and visualized.

#### 3.3.4.4 Air bubble/pen mark

- Air bubble visualization may appear blocky in the presence of large air bubbles.
- A severely out-of-focus slide may cause inaccurate predictions for air bubbles.
- When air bubbles overlap with pen marks, air bubbles are prioritized for visualization.

## 3.4 User authentication and security

A robust authentication and authorization system that leverages industry-standard mechanisms safeguards sensitive data and maintains the integrity of the Aperio iQC Module system.

Authentication of the Aperio iQC Module users is handled by an authentication service, which runs on the SAM server. Once the user is authenticated, the Aperio iQC Module grants access to the user based on roles and permissions, which are configured in SAM: Operator or Lab Admin. The Lab Admin role can perform all Aperio iQC Module functions. The Operator role can perform all functions except for configuring the sensitivity thresholds for the artifacts.

## Using the Aperio iQC Software Module

Follow these instructions to use the Aperio iQC Software Module.

## 4.1 Before you start

#### 4.1.1 Installing the Aperio iQC Software Module

The Aperio iQC Software Module is installed by Leica Biosystems. Contact Leica Biosystems for installation assistance.

When the Aperio iQC Software Module is properly installed, the log-in screen appears when you enter the hostname or address into your browser.

#### 4.1.2 Preparing to use the Aperio iQC Software Module

Scanned SVS and DICOM images from a Aperio GT 450 are automatically sent to the Aperio iQC Module for processing. There is no action required by the user.

See the Aperio GT 450 user documentation listed in 1.7 Reference documents for instructions on preparing and scanning slides.



**CAUTION:** Before running the Aperio iQC Module, make sure that user access restrictions are in place. Unauthorized actions taken during the session could lead to data corruption or integrity issues. For details, see the *Aperio GT 450 IT Administrator and Lab Administrator Guide*, MAN-0394.

## 4.2 Icons and toolbar

This section describes the the icons and toolbar used in Aperio iQC Module.

#### 4.2.1 Icons

See the table below for definitions of the icons on the Aperio iQC Module screens.

Symbol	Meaning
	Histological artifact A teal icon indicates that histological artifacts are present in the marked slide, or in one or more slides in the marked scanner.
S	<b>Digital artifact</b> An orange icon indicates that digital artifacts are present in the marked slide, or in one or more slides in the marked scanner.
<b>()</b>	These two icons denote the visibility of an overlay mask for the algorithm. Click on an icon to toggle the overlay mask on or off. The eye icon with a slash indicates that the overlay mask is hidden. Overlay masks are available only for out-of-focus, missed tissue, or air bubble artifacts.
Ð	Images that are not yet reviewed
¢	Settings Accesses the About window, log-out function, and for Lab Admin users only, sensitivity threshold setting for some artifacts.
$\checkmark$	Accepted slides
$\otimes$	Rejected slides
Z	No artifacts found
Q	Search

Symbol	Meaning
T	Filter bar
$\langle \rangle$	Results are pending
	<b>Error</b> There was an error running the algorithm for that artifact, and there are no results displayed for that artifact.

### 4.2.2 Toolbar

To access iQC functions, click the appropriate icon on the toolbar at the top of the screen.

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Filte	rs <b>T</b> :	Ali \$\$12017 \$\$12213 \$\$45028 \$\$45075		<b>8</b> 910		9 search
Lege	nd					
1	S	Opens the scanners screen	8	$\checkmark$	Shows accepted slides	
2		Opens the slides screen	9	$\bigotimes$	Shows rejected slides	
3		Opens the slide visualization screen	10	ē	Shows slides that are no	t yet reviewed
4	\$	Opens Settings	11	$\mathbb{Z}$	Shows slides with no art	ifacts
5		Exports a CSV (comma-separated values) file of rejected slide	12	Y	Show slides with digital	artifacts
6	T	Filters slide display To view a subset of the available slides, select one of more of the filters below. If no filters are selected, all available	13		Show slides with histolo	gical artifacts
		slides are shown, with the oldest scanned slide in the upper-left corner.	14	Q	Type a complete or parti to show slides that mate	al slide name ch the search
7	Example: <b>SS45022</b>	Shows slides from the indicated scanner			term	

## 4.3 Starting the Aperio iQC Software Module

- 1 Type the hostname or address of the iQC server into the browser.
  - The login window opens.



2 Click Log In, and enter your credentials.

3 The scanner selection screen opens. It displays the connected scanners. Click a scanner to open the slide selection screen for that scanner.

Y			¢	0		Leica DIOSYSTEMS
				Active 4		
				g	SS12017 GT450 GT450 GT450	
				S	<ul> <li></li></ul>	
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Scanners that have slides with detected artifacts are marked with one of these icons.



A teal icon in the scanner box indicates that one or more slides in that scanner have histological artifacts.



An orange icon in the scanner box indicates that one or more slides in that scanner have digital artifacts.



This symbol in the scanner box indicates that no artifacts were found in the slides in that scanner.

The **Active** section of the screen shows all connected scanners with active licenses. Scanners with expired licenses are initially hidden, but can be shown by clicking the arrow next to **Inactive**.

## 4.4 Navigating to a slide

On the slide selection screen, slides are displayed in a grid pattern, arranged from left to right, top to bottom, and oldest to newest. The earliest scanned slide is in the upper-left corner, and the most recently scanned slide is last.

#### 4.4.1 Paging through slides

To page through the slides, click an arrow icon to navigate to the previous or next page.



### 4.4.2 Applying filters

To filter iQC results to view just a subset of slides, do the following:

1 Locate the Filters bar below the top toolbar.



- 2 To view only the slides from one or more scanners, click one or more scanner names, or click **All** to view slides from all scanners.
- 3 Select one or more additional filters:

Example: Show only the accepted slides, only the rejected slides, or only the slides that have not been reviewed.

Ş			۵	Ð						_						Leica DIOSYSTEMS
	Filters `	<b>T</b> :	Α	I	SS12017	SS12213	SS45028	SS45075	0	8	Ð	Ø	9	<b>Ø</b>	Q Search	
With these two selections, only slides with accepted artifacts on all connected scanners are shown.																

**Example**: Show only slides without artifacts, only slides with histological artifacts, or only slides with digital artifacts.

S			۵	•										_		Leica BIOBYSTEMS
	Filters	<b>T</b> :		AII	SS12017	SS12213	SS45028	SS45075	<b>V</b>	8	Ð	Ž	g	Ø	Q Search	
	With these two selections, only slides with digital artifacts on all connected scanners are shown.															

### 4.4.3 Searching for a slide

To search for a slide by complete or partial slide name, type a term in the search box, and press Enter.



## 4.5 Performing quality checks

#### 4.5.1 Viewing the slide details

1 Click the selected slide.



2 The slide detail screen opens. For guidance when viewing the screen, see Figure 4-1 Interpreting the slide detail screen.

3 Note any detected artifacts (digital artifacts are highlighted in orange; histological artifacts are highlighted in teal).



4 If a detected artifact has an eye icon to the left, you can highlight the artifact by placing a visualization overlay on top of the artifact. Click on the name of the artifact to place the overlay. When the overlay is selected, the diagonal slash through the eye icon disappears. Unclick the name of the artifact to remove the overlay.



Below to the left is a slide with an air bubble artifact, which is not highlighted. To the right is the same slide with the overlay. Note the teal color used to highlight the artifact.



5 Inspect the scanned macro image.

To pan an image, click on the image and drag the full image, or click on the image and use the keyboard arrows to move around the image. You can also click on an area of the thumbnail image in the upper-right corner to navigate to that area of the slide image.

To zoom in or out, scroll using your mouse wheel.

6 To move to the previous or next slide, click the arrows to the left and right of the detail image.

Alternatively, you can use the keyboard right and left arrows to move between slides. Click on the sidebar area to use these keyboard shortcuts.

#### Y .... ₽ ٦ Scanner SS12213 > Slide c37d265c-7b1e-4a04-935b-27268fafc625 > Rack 1 > Slot 1 leica 6 1 g Digita 7 9 8 2 Tek-Seleci 3 📀 АССЕРТ REJECT 4

Figure 4-1: Interpreting the slide detail screen

## Legend

1 Digital artifacts

Artifacts that are detected are highlighted in orange. Click on the eye icon to toggle the visualization overlay on or off.

2 Histological artifacts

Artifacts that are detected are highlighted in teal. indicates that the artifact was detected. Click on the eye icon to toggle the visualization overlay on or off.

#### 3 Slide assessment

Accept or reject the slide. If the slide is rejected, specify an action to take. Add comments.

- 4 Slide label image
- 5 Navigation arrows to move to the previous or next slide
- 6 Slide details
- 7 Macro image of entire slide
- 8 Slide detail view
- 9 Thumbnail of macro slide or detail slide

### 4.5.2 Assessing the image

Table 4-1: Summary of Aperio iQC Software Module algorithms/artifacts detected

Artifact detected	Visual location indicator	User-configurable sensitivity?
Out of focus	Yes	Yes
Clipped/missing tissue	No	No
Image striping	No	Yes
Air bubbles	Yes	Yes
Pen/ink marks	No	Yes

1 Assess the image. The iQC algorithms and the artifacts that can be detected are summarized in Table 4-1 Summary of Aperio iQC Software Module algorithms/artifacts detected.

- a If the image quality is acceptable, click Accept or press the A key on your keyboard.
- b If the image quality is unacceptable, click **Reject** or press the **R** key on your keyboard. Indicate the desired next action by clicking **Reprocess** or **Rescan**. Digital images typically require rescanning, while histological images typically require reprocessing.
- c Enter any comments.
- d Click Submit.



You do not need to select an action. If neither action applies, describe the action needed in the comments.

2 To navigate to the previous or next slide, click the arrows to the left and right of the slide images, or use the arrow keys on your keyboard.

If your cursor is in the image, first click off the image, in the sidebar, and then use the arrow keys to navigate between slides.



## 4.6 Settings

With the Settings function, you can view product details, log out, and adjust sensitivity thresholds (Lab Admin role only),

### 4.6.1 Viewing the About window

View details about Aperio iQC Module as follows:

- 1 Click the Settings (gear) icon in the upper-left corner of the screen
- 2 Click About.



The **About** window opens. It shows details such as the Aperio iQC Module version, revision, and host operating system (OS).



### 4.6.2 Adjusting artifact detection sensitivity



The sensitivity adjustment is restricted to Lab Admin users only.



Setting a sensitivity threshold too low may prevent iQC from flagging legitimate artifacts. Conversely, setting a sensitivity threshold too high may cause iQC to flag minor artifacts that do not impact clinical interpretation.

To adjust the sensitivity settings that Aperio iQC Module uses to detect artifacts, follow these steps. The sensitivity setting is applied to new scanned slides only, not already scanned slides.

- 1 Click the Settings (gear) icon in the upper-left corner of the screen
- 2 Click Algorithm Sensitivity.



3 The **Algorithm Sensitivity** window opens, showing the algorithms with sensitivity threshold adjustments and their current settings.

Adjust any desired settings by clicking and dragging the pointer in the middle of the adjustment bar or by typing the desired value into the box to the right of the adjustment bar. The lower the sensitivity threshold, the less sensitive the algorithm is. For details about how sensitivity settings work, see 3 Principles of operation.

н.	Algorithm Sensitivity 🗙
L	Out of Focus Coverage
L	Out of Focus Severity
	Image Striping
L	Pen Marks
L	Air Bubbles
L	Save



**CAUTION:** Avoid setting sensitivity threshold settings too low. If the sensitivity is set too low, The Aperio iQC Module may fail to identify legitimate artifacts.

#### 4 Click Save.

#### 4.6.3 Logging out

To log out of the Aperio iQC Module, follow these steps:

- 1 Click the Settings (gear) icon in the upper-left corner of the screen
- 2 Click Logout.



## 4.7 Exporting list of rejected iQC slides

You can export a list of rejected iQC slides, in CSV (comma-separated values) format, for import into spreadsheets. The CSV file includes the slide identifier; scanner identifier, rack and slot number; action (Rescan/Reprocess); as well as any comments you have entered. Only

To export the list, click the Export icon in the upper-left corner of the screen: The file is automatically downloaded.



## 4.8 Viewing iQC results on the scanner console

The Aperio GT 450 Scanner console indicates slides that are flagged for artifacts. For details, see the *Aperio GT 450* User's Guide.

# 5 Troubleshooting

Issues that occur while running Aperio iQC Module typically manifest as unavailable results. Results should be visible on the Aperio iQC Module dashboard within 30 minutes after scanning is completed.

If images aren't available in the iQC Module dashboard within that time, analyze the network path to try to determine the cause. If you can't resolve the issue, contact LBS for assistance.

# 6 Technical specifications

## 6.1 System requirements

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

#### 6.1.1 Aperio iQC server

#### 6.1.1.1 Hardware

Aperio iQC Module can be installed on a physical or virtual machine in the customer laboratory that meets the requirements below. The components need not be installed on the same system, although they may be.

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)
Storage	2TB SAS SSD (solid-stage drive)
GPU	Model: NVIDIA L4
	Quantity: 1 (1 scanner), 2 (2 scanners), 3 (3 scanners), 4 (4 scanners)
LAN speed for user	The more bandwidth the better, but need at least the minimum specification of 1 Gbps
LAN speed for storage access	10 Gbps
Internet upload speed	100 Mbps
Network	Network card: 10 Gb

#### 6.1.1.2 Operating system

The Aperio iQC Module requires the following operating system to support the use of Aperio iQC Module:

• Ubuntu 24.04 LTS (Long Term Support) or higher

#### 6.1.2 Aperio GT 450 Scanner and SAM

The Aperio iQC Module requires the following Aperio GT 450 system components:

- Aperio GT 450 Scanner [RUO] with software version 1.4 or higher
- Aperio GT 450 SAM [RUO] hosting server with Windows Server 2022 or later and SAM [RUO] software version 1.4 or higher

#### 6.1.3 Peripheral devices

The following user requirements are independent of the server hosting the Aperio iQC Module. These can be tailored to user preferences, as the user can also view the results of the Aperio iQC Module 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

#### 6.1.4 Browser

To view the dashboard, we recommend that you use one of the web browsers that has been tested with Aperio iQC Module. 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

#### 6.1.5 Other requirements

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

- There must be a network or server image location that is 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.
- Both administrator and non-administrator accounts must be set up on the iQC server.
- A directory should be created on the iQC server for storage of installers, license, and certificates, so that they are easily accessible to the person installing the software. The directory shold be created under the administrator user account.

## 6.2 Performance specifications

Specification	Value	
Artifacts detected	Out-of-focus, clipped/missing tissue, image striping, air bubbles, pen/ink marks	
Image type supported	SVS, DICOM	
Maximum number of scanners supported	4	
Artifact detection accuracy <sup>1</sup>	Out-of-focus: 94%	
	Clipped and missing 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	

## 6.3 Sensitivity threshold setting ranges



Setting a sensitivity threshold too low may prevent iQC from flagging legitimate artifacts. Conversely, setting a sensitivity threshold too high may cause iQC to flag minor artifacts that do not impact clinical interpretation.

<sup>1</sup>Accuracies are based on datasets ranging from 298 to 580 test cases.

Threshold setting	Recommended range	Default
Out of Focus Coverage	70%-95%	90%
Out of Focus Severity	50%-75%	65%
Image Striping	30%-55%	30%
Pen Marks	85%-95%	90%
Air Bubbles	85%-95%	90%

Glossary of abbreviations

Abbreviation	Meaning
AoS	Authentication and authorization server
API	Application programming interface
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
RUO	Research use only
SAM	Scanner Administration Manager
SVS	ScanScope Virtual Slide
UI	User interface
URI	User repository interface
VM	Virtual machine
WSI	Whole slide image

# B LEICA Biosystems warranty policy

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