



Aperio Clinical Solution

IX Curso de Patología Digital

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Innovation Codes Our DNA

- 150+ years tackling pathology challenges head on, from better slide production to world-leading Digital Pathology empowering AI development. Our passionate experts drive our mission of Advancing Cancer Diagnostics, Improving Lives.

Digital Pathology innovators focused on workflow automation and industry standardization

- Offering proven technologies and data structures as part of the DICOM standard for Digital Pathology and Whole Slide Microscopy images.
- A history of innovation in exchange of pathology information through standardization.

Customer focused approach to integration

- To ensure robust performance and quality Leica Biosystems has been working with leading institutions to validate use of DICOM in clinical settings which include PACS, LIS, and Imaging integrations.

Integrated for Success

22+ Years
Digital
Pathology

9th
generation
of scanners

Global
install base

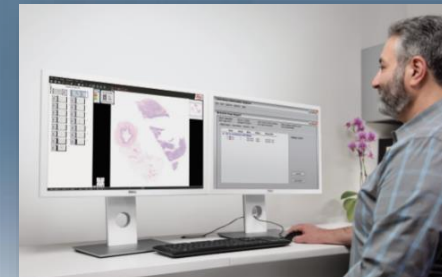
380+
image
capture
technology
patents

Thousands of users Generating Millions of SVS Images Worldwide

Aperio Clinical Solution - Proven Digital Pathology for Diagnostic Excellence

Aperio GT 450 DX, Aperio eSlide Manager with WebViewer DX, and LIS Connectivity

- A comprehensive digital pathology system
- Time-tested Aperio GT 450 DX scanner with secure and integrated image management system complete with validated clinical viewers and LIS/LIMS connectivity
- State-of-the-art DICOM imaging
- Excellent image quality
- Robust LIS connectivity for seamless and tighter integration



Designed for Histotechnicians/Lab Managers, IT Professionals, and Pathologists

APERIO CLINICAL SOLUTION - HARDWARE

IVDR

Aperio Clinical Solution elevates your diagnostic experience using the power of proven digital pathology – manifesting the potential of universal case access and borderless professional collaboration

Pathology Lab



Aperio GT 450 DX Scanners

IT Room



*SAM server
connected to multiple
Aperio GT 450 DX Scanners.*



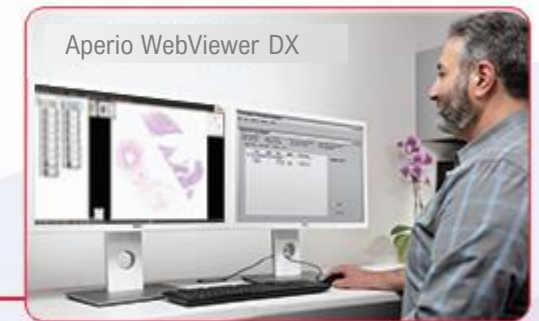
*DSR server stores images and
runs Aperio eSlide Manager.*

IT Manager's Office



*SAM applications software connected
to SAM server to set up and monitor
scanners.*

Pathologist's Office

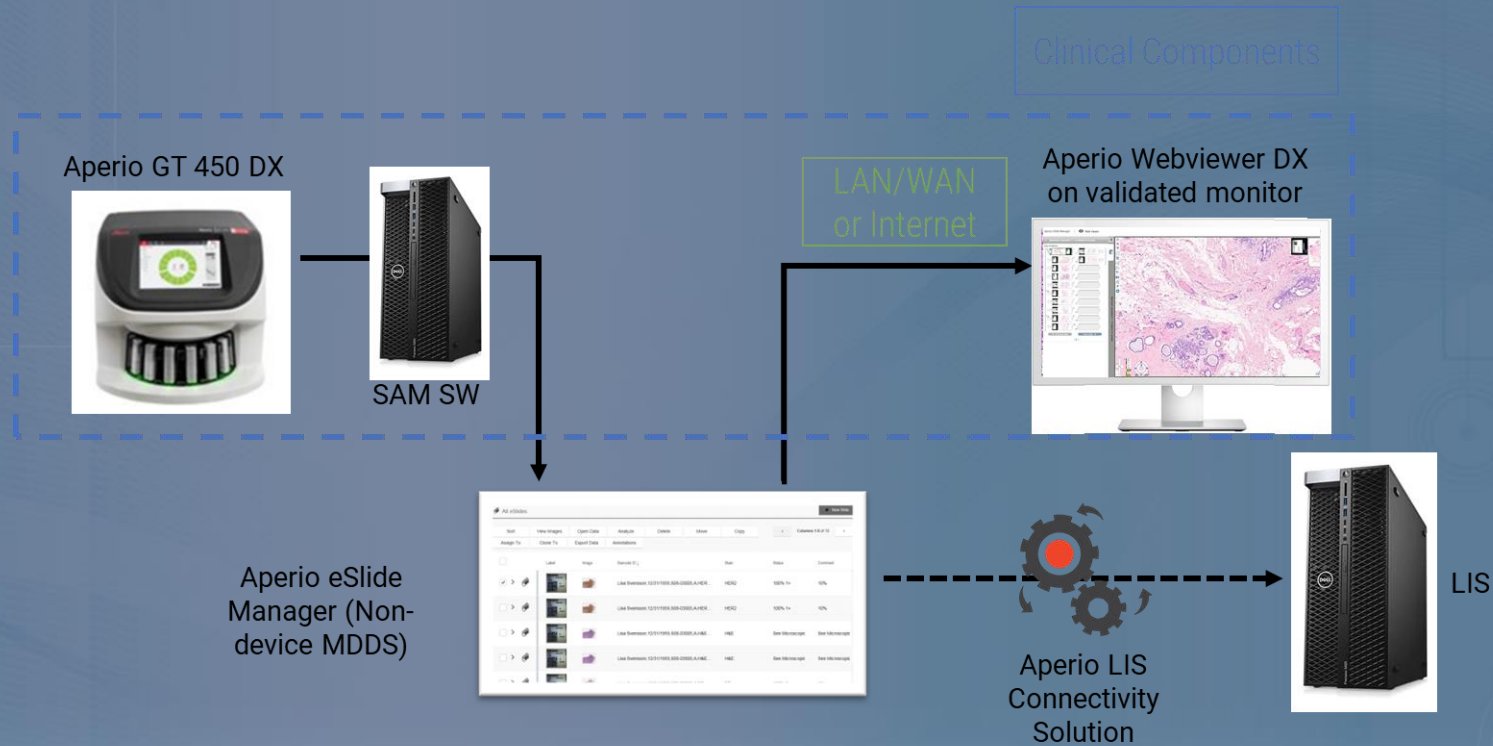


*Aperio WebViewer DX
supports every monitor*

SAM = Scanner Administration Manager – DSR = Digital Slide Repository

APERIO CLINICAL SOLUTION –COMPONENTS

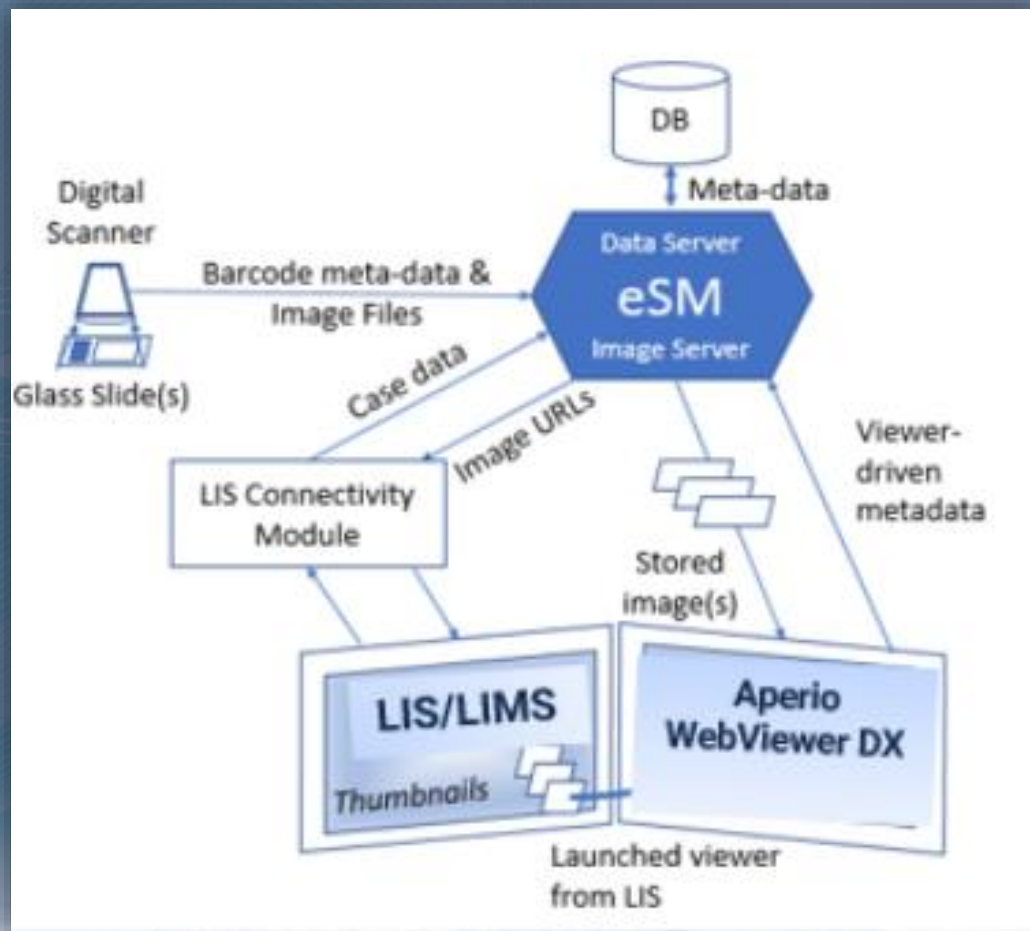
IVDR



Key Focus Areas are: 1) Complete Integrated Solution 2) Clinical Validation 3) Cybersecurity

APERIO ESLIDE MANAGER WITH WEBVIEWER DX

+ LIS Connectivity



Aperio eSlide Manager (eSM) and Aperio WebViewer DX* with Aperio LIS Connectivity Module* together offer a clinical laboratory a comprehensive workflow, centered around a visualization portal (**Aperio WebViewer DX**) that continually accesses a proven image management system (**Aperio eSM**) which includes a real time bi-directional communication pathway to the customer's chosen LIS.

*Aperio WebViewer DX and Aperio LIS Connectivity Module are designed to work with Aperio eSM, but they are separate products and additional costs are associated with their usage.

Real Time Bi-Directional Communication Pathway to the Customer's Chosen LIS



Choice

- Freedom to select your preferred component parts and create a solution that is right for you
- Not vendor-locked to one provider

Peace of Mind

- Clinical quality images from the Aperio GT 450 DX scanner are shown on screen
- Responsibility for interoperability lies with the manufactures, not the users

Futureproof

- Ongoing, contractual relationship between Leica Biosystems and 3rd party software providers
- Rely on sustainability of integration following software updates through advance change management

Three Essential Digital Pathology Elements of the Aperio Clinical Solution

An Open Standard



DICOM is an open, vendor-agnostic standard for medical image data. While many vendors participate in the creation of this standard, it is not controlled by any one vendor. As an open standard, it may be implemented by any vendor and enables interoperability between systems.

Enterprise Compatibility



Aperio DICOM enables compatibility with a PACS System and tighter integration of digital pathology imaging into the diagnostic pathway. Aperio DICOM is designed to meet the need of enterprise healthcare organizations to standardize their medical imaging protocols.

Meet Institutional Needs

- Simplify the integration of pathology imaging within your enterprise
Enable sharing of pathology images outside of the pathology department
- Standardize digital pathology imaging file format
Rather than proliferate the problem of multiple scanner file formats and challenges with compatibility, standardize on one - DICOM
- Storage consolidation
Supports institutional needs to consolidate archival under common enterprise storage infrastructure

Aperio Clinical Solution offers Interoperability between Systems

Interoperability with PACS workflow

- Standards-based open ecosystem for sharing across data systems and imaging modalities.
- DICOM images can be transferred directly into the enterprise imaging PACS or VNA.
- Integration of Lab Information System (LIS) data into the DICOM headers.

Diagnostic Image Quality

- DICOM image files are validated output of the Aperio GT 450 DX for diagnostic use
- Inclusion of color and dimension calibration data to ensure display and analysis of images can provide proper image fidelity

High-throughput & Secure DICOM Image Generation

- Robust interoperability approach to cybersecurity and data access
- High throughput image generation and transfer ensures DICOM output can keep pace with your lab

Interoperability, Diagnostic Image Quality, & Secure DICOM Image Generation



SVS & DICOM widely supported in 3rd party software

+ embedded colour management

SVS & DICOM +



Aperio GT 450 DX

- Industry leading scanner
- Clinical diagnostic image quality
- High-throughput
- 450 slide capacity
- Embedded colour management

Aperio GT 450 DX image quality faithfully rendered in 3rd party viewers

- Colour
- Dimensioning
- Calibration


Excellent Image Quality

APERIO GT 450 DX VALIDATION PAPER

IVDR

- Aperio GT 450 DX has been validated through robust user testing
 - All of specified performance end points were successfully validated during the study.
- Histotechnician users validated ease of use of the Aperio GT 450 DX, by performing a series of test scenarios following one hour of user training on Aperio GT 450 DX operation.
- Validation by IT Professionals involved performing a series of test scenarios using Aperio SAM DX software interface, following 1 hour of user training, to measure ease of use of SAM DX.

Advancing Cancer Diagnostics
Improving Lives



WHITE PAPER

Experience Speed to Quality in Digital Pathology Scanning

Advancing with the latest standards in digital pathology

Proven technology for improved workflow efficiency and patient care are set to define digital pathology and increase overall adoption. With the introduction of more rigorous controls under EU Regulation 2017/746 on in vitro Diagnostic Medical Devices (IVDR), manufacturers of digital pathology devices are being held to the highest standards of quality, security, and patient safety.

Leica Biosystems Aperio GT 450 DX is a high-throughput, continuous load slide scanner, designed to meet the needs of busy clinical laboratories. Its automated, hands-off design helps Histotechnicians deliver rapid results with confidence, while centralized management through the Scanner Administration Manager (SAM DX) enables IT Professionals to scale digital pathology operations easily and securely.

To ensure that the Aperio GT 450 DX meets user needs a Design Validation study¹ was carried out to test the performance and usability of the scanner and SAM DX software.

Aperio GT 450 DX has been validated through robust user testing

The design validation study took place across three independent laboratories with a total of twelve users, split between slide scanning and IT administration roles. A series of test scenarios were carried out to validate that the Aperio GT 450 DX performs as expected under laboratory conditions.

Validation by Histotechnicians used a set of approximately 75² typical coverslipped FFPE slides, in a mix of H&E, IHC, and ISH as shown in Table 1, provided by each of the testing sites and labeled with barcodes by Leica Biosystems. Product performance metric requirements were tested as follows:

- System shall have a first-time scan success rate of 98% for FFPE tissue histology slides stained with H&E.
- System shall encompass all stained portions of the tissue at 98% success rate for FFPE H&E stained slides and 90% for FFPE IHC.
- System shall handle ≥99.9% of glass slides successfully without damage.
- System shall successfully decode the identified barcode types at a rate of 99%.

All of these performance end points were successfully validated during the study.

For In Vitro Diagnostic Use. The clinical use claims described for the products in the information supplied have not been cleared or approved by the U.S. FDA or are not available in the United States

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Experience Speed to Quality in Digital Pathology Scanning



Hub 1 – Introduction

- Touchpoint – Power up (introduction)



Hub 2 – Major features/benefits

- Touchpoint – Slide capacity
- Touchpoint – Safety light curtain
- Touchpoint – Intuitive user interface
- Touchpoint – Histotechnicians (major benefits)
- Touchpoint – IT Professionals (major benefits)



Hub 3 – More than 30 Patents SMARTER

- Touchpoint – Continuous loading (SPECTRA)
- Touchpoint – No touch scanning
- Touchpoint – Workflow efficiency
- Touchpoint – Small footprint
- Touchpoint – Stay on 24/7

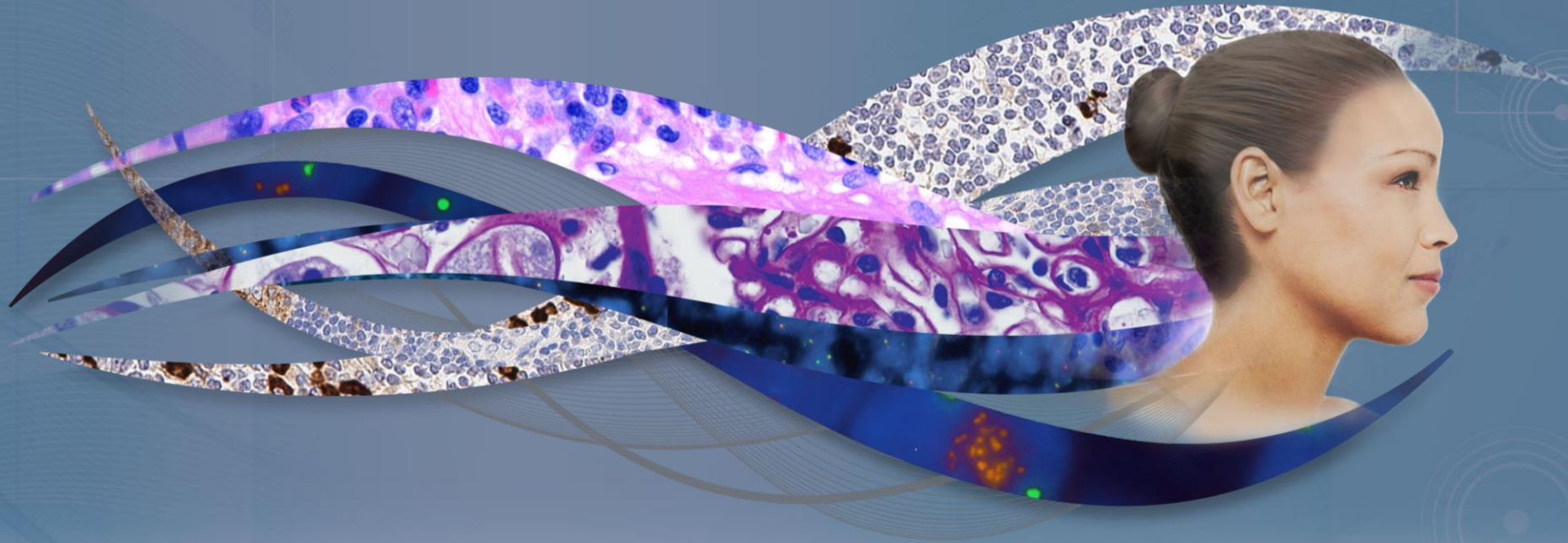


Hub 4 – Excellent image quality and sharing

- Touchpoint – Rapidly deliver images with excellent quality
- Touchpoint – Easily view and share images
- Touchpoint – Contact us
- Touchpoint – Download PDF (white paper download)

Interactive Video is a demo and ‘tour’ of the Aperio GT 450 DX scanner with DICOM

Questions?



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