

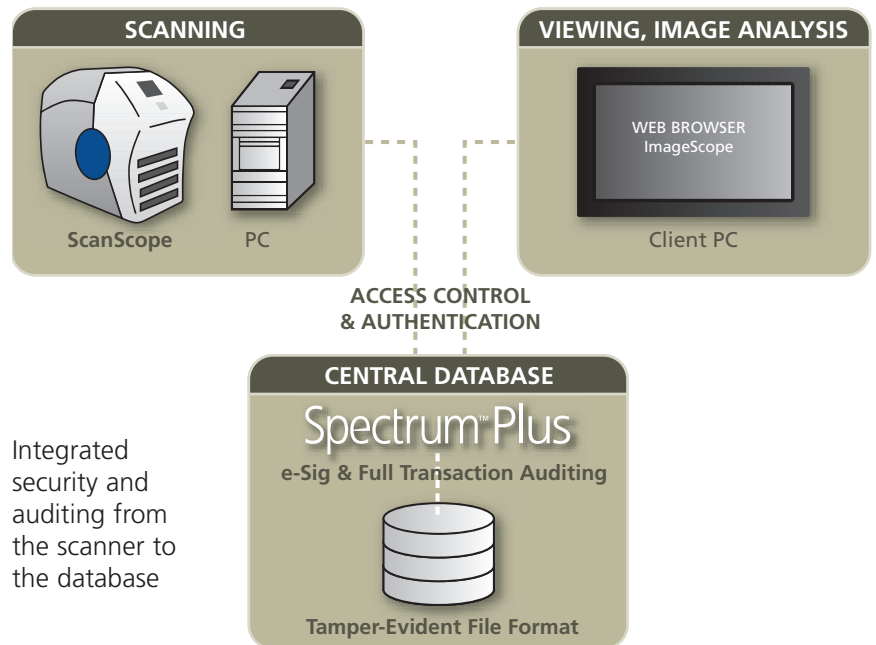
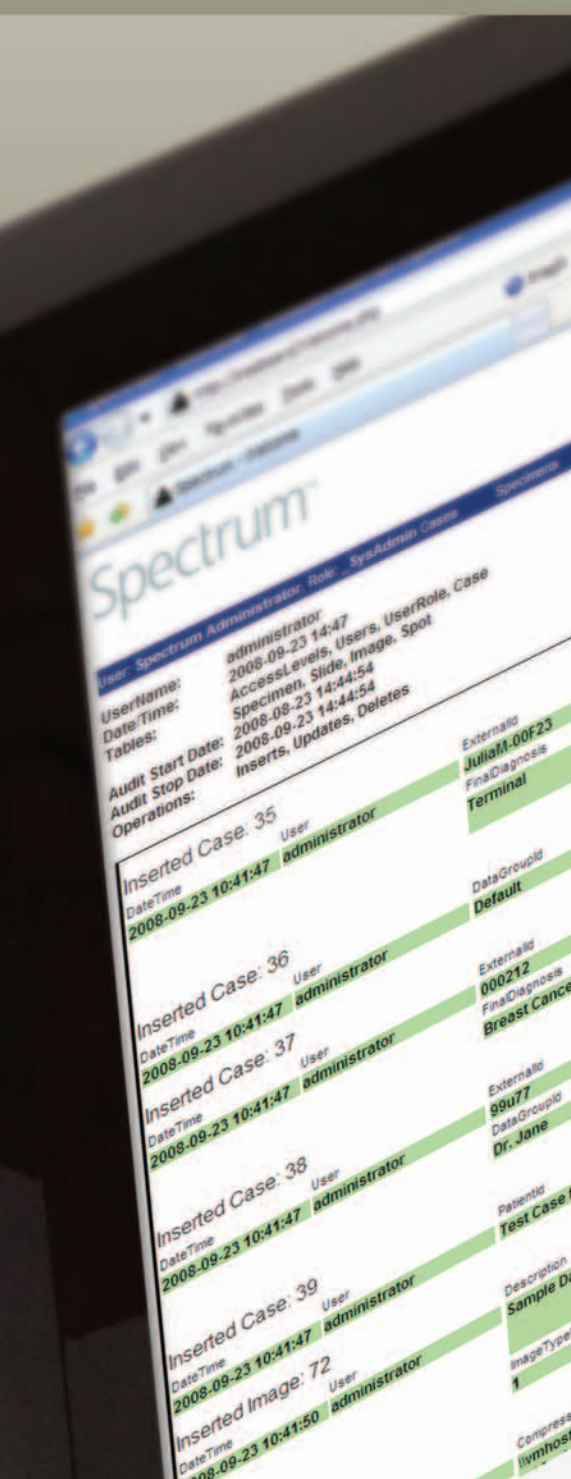
21 CFR Part 11 and Digital Pathology

The GLP Compliance Software Module is an option within Aperio's Spectrum™ Plus digital pathology management software that provides all the software functionality required to be compliant with 21 CFR 11 and its international equivalents. It provides security and data auditing from the scanner to the database so that organizations have a full record of scanning, annotations, and data analysis.

Integrated security and data auditing from the scanner to the database.

GLP ON-SITE VALIDATION SERVICE (IQ/OQ/PQ)

In addition to the features in the software, we offer an on-site validation service to ensure that both the hardware and software are installed (IQ), operating (OQ), and performing (PQ) correctly. This service includes an Aperio-trained compliance professional who runs an extensive series of tests onsite, as well as complete system tests and scalability testing.



Integrated security and auditing from the scanner to the database

**CONTENTS OF
OUR COMPLETE
VALIDATION BINDER**

Title Page and Index Contains:

Description of the subject of the validation

Table of contents

Validation Final Report Contains:

Summary of results from all IQ, OQ, PQ protocols

Resolutions of any deviations found during protocol executions

Signatures indicating that all equipment is validated

Validation Protocol(s): IQ, OQ, PQ Contains:

Completed IQ, OQ, and PQ protocol(s)

Signatures indicating that protocols were approved prior to execution

Signatures indicating that work was reviewed after execution

Exhibits and Attachments Contains:

Printouts and other data generated during protocol execution

Any supplemental testing required during protocol executions, e.g., to further explore and resolve deviations

Signatures indicating that data was reviewed after execution

Aperio's Data Audit version of Spectrum Plus is designed to facilitate compliance with 21 CFR Part 11, "Electronic Records; Electronic Signatures." The Tech Notes below show a snapshot of which features of Spectrum Plus comply with Part 11, as well as how you can develop a compliant solution for your company.

EU Annex 11 Compliance Matrix for the Compliance Version of Spectrum™ Plus

Aperio's Compliance Version table shows which features i solution for your company th

Topic	Article
Risk Management	
Personnel and Training	
Validation	3.1
System Inventory	
System Specifications	
Software QA and QMS	
Access Control and Logical Security	6.1, 6.2

21 CFR Part 11 Compliance Matrix for the Compliance Version of Spectrum™ Plus

Aperio's Compliance Version of Spectrum Plus was specifically designed to facilitate your compliance with 21 CFR Part 11, "Electronic Records; Electronic Signatures." This table shows which features of Spectrum Plus comply with Part 11, and shows how you can develop a solution for your company that is compliant with Part 11.

Section	Summary of Rule	Compliance Strategy
11.100a	Validation	<ul style="list-style-type: none"> Aperio has validated the ScanScope® instrumentation and Spectrum Plus software. Aperio provides a suite of validation protocols that comprehensively qualify the installation, operation, and performance of ScanScope® and Spectrum Plus at your company.
11.100b	Record Generation and Copying	Spectrum Plus has the ability to generate accurate and complete copies of records in both human-readable and electronic form suitable for FDA inspection, review, and copying.
11.100c	Record Protection	<ul style="list-style-type: none"> Slide images are stored in a restricted, protected system folder and employ a checksum algorithm to assure image integrity. Metadata, such as digital slide annotations, are maintained in a secure, protected relational database. Aperio provides you with record backup instructions. Aperio validates the record backup and restore feature at your company as part of the validation protocol suite.
11.100d	Access Limitation	Spectrum Plus contains security features, including login requirements and session inactivity timeouts, that limit access to authorized individuals.
11.100e	Audit Trail	Spectrum Plus audit trails are secure and time-stamped. They record the date and time of all entries and actions that create, modify, or delete data, along with the name of the person who performed the action.
11.100f	Operational System Checks	This does not apply to Spectrum Plus.
11.100g	Authority Checks	User credentials are required to access Spectrum Plus. Spectrum Plus also features a comprehensive set of permissions and roles that administrators can use to grant or restrict user privileges.
11.100h	Device/Terminal Checks	Spectrum Plus employs a checksum algorithm to determine the validity of digital slide images. The access limitation and authority checks also verify the source of data input.
11.100i and j	Training and User Accountability	Aperio can assist your company with preparation of a training plan so that your staff understands the implications of Part 11 on their work.

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Aperio products are FDA cleared for specific clinical applications, and are intended for research use for other applications.

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Please contact us for more information regarding United States FDA 21 CFR Part 11, European Union Annex 11, and Japanese 21 CFR Part 11 Equivalent compliance information at 866.478.4111.



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