

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
11.10(a)	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.
11.10(b)	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.
11.10(c)	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.
11.10(d)	Access Limitation	Spectrum Plus contains security features, including login requirements and session inactivity timeouts, that limit access to authorized individuals.
11.10(e)	Audit Trails	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.
11.10(f)	Operational System Checks	This does not apply to Spectrum Plus.
11.10(g)	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.
11.10(h)	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.
11.10(i) 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.

Section	Summary of Rule	Compliance Strategy
11.10(k)	System Document Control	Aperio follows change control and life cycle management procedures for document control. Aperio encourages customers to do the same, and can assist your company with development of a document control system.
11.30	Controls for Open Systems	<ul style="list-style-type: none"> While Spectrum Plus can be operated as an Open System per 21 CFR § 11.3 (9), Aperio encourages customers to configure Spectrum Plus as a Closed System per 21 CFR § 11.3(4). Aperio's validation protocols verify that your Spectrum Plus deployment functions as a closed system and preclude the need to establish the additional controls for open systems.
11.50	Electronic Signature: Manifestations	All signed records clearly indicate who signed the record, when the signature was executed, and the meaning of the signature.
11.70	Signature/Record Linking	Signatures are irrevocably linked to source records in the secure Spectrum Plus database, and signatures are maintained in that database.
11.100	Electronic Signature: General Requirements	<ul style="list-style-type: none"> As electronic signatures are based on unique usernames and passwords, they cannot be reused or reassigned among users. Before you begin to employ electronic signatures, it is your responsibility to: <ul style="list-style-type: none"> Verify the identity of individuals who will render electronic signatures. Certify to FDA that your electronic signatures are the legally binding equivalent to handwritten signatures. Aperio can assist with this step.
11.200(a)	Electronic Signature: Components & Controls	Electronic signatures require entry of both an identification code (user ID) and password. This also ensures that electronic signatures can be used only by their genuine owners.
11.300	Electronic Signature: Controls for ID Codes and Passwords	<p>Spectrum Plus contains many controls that ensure the security and integrity of electronic signatures. These include:</p> <ul style="list-style-type: none"> Ensuring the uniqueness of usernames. A configurable account lockout mechanism that protects against attempts at guessing username/password combinations. A configurable notification mechanism to alert system administrators of bad login attempts. <p>It is your responsibility to periodically verify the issuance of signing credentials and to properly administer users. Aperio can assist you with developing procedures to direct these activities.</p>

Trademarks and Patents

ScanScope is a registered trademark and ImageServer, TMLab, ImageScope, and Spectrum are trademarks of Aperio Technologies, Inc. All other trade names and trademarks are the property of their respective holders. Aperio products are protected by U.S. Patents: 6,711,283; 6,917,696; 7,035,478; and 7,116,440; and licensed under one or more of the following U.S. Patents: 6,101,265; 6,272,235; 6,522,774; 6,775,402; 6,396,941; 6,674,881; 6,226,392; 6,404,906; 6,674,884; and 6,466,690.

IMC-2021-06172008

United States of America		
Customer Service	Tel: 866-478-4111 (toll free)	Aperio
Technical Support	Tel: 866-478-3999 (toll free)	1360 Park Center Dr.
	Email: support@aperio.com	Vista, CA 92081
		www.aperio.com
Europe		
Customer Service	Tel: +44 (0) 1275 375123	3 The Sanctuary
Technical Support	Tel: +44 (0) 1275 375123	Eden Office Park
	Email: europesupport@aperio.com	Ham Green
		Bristol BS20 0DD, UK