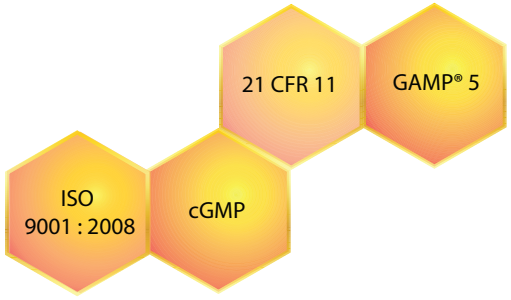
21 CFR 11 COMPLIANCE SPECIFICATIONS
FOR YSI 2900 SERIES ANALYZERS



What is 21 CFR Part 11?

Title 21 CFR Part 11(21 CFR 11), Electronic Records/ Electronic Signatures, is the part of the Code of Federal Regulations that establishes the United States Food and Drug Administration (FDA) regulations on electronic records and electronic signatures. In particular, 21 CFR 11 defines the requirements for submitting documentation in electronic form and the criteria for approved electronic signatures.

Who and What is required to comply with 21 CFR 11?

Who - FDA-regulated industries, including pharmaceutical, medical device, food & beverage and cosmetics, must comply with 21 CFR 11.

What - All computer systems which store data to make quality decisions or data which will be reported to the FDA. This includes any laboratory results used to determine quality, safety, strength, efficacy, or purity. In manufacturing environments, this includes data used to make decisions related to product release and product quality.

How does 21 CFR 11 apply to YSI 2900 Series Analyzers?

21 CFR 11 requires that closed computer systems must have a collection of technological and procedural controls to protect data within the system. YSI 2900 Series analyzers are closed computer systems that generate electronic records for FDA regulated processes, therefore, these systems must facilitate compliance with 21 CFR 11.

How do YSI 2900 Series Analyzers assure 21 CFR 11 compliance?

YSI 2900 Series Analyzers are fully compliant with 21 CFR Part 11 for electronic records. The system's software features include, but not limited to, audit & event trails, secure user sign-on, user level permissions and administrative configuration tools.

There is no evidence for electronic signature requirements for YSI analyzers per 21 CFR 11, section 11.2, Implementation. Therefore, YSI 2900 Series Biochemistry Analyzers have no e-signature function, although every event, including analysis and data generation, is traced to a unique user through their respective login ID and password.

YSI 2900 Series Analyzers are automated laboratory analyzers which employ Good Automated Manufacturing Practices (GAMP® 5) Category 4 software (configured software). In order to assure 21 CFR 11 compliance and fit for intended use, YSI 2900 Series Analyzers are designed and validated using GAMP 5 standards. GAMP 5, a risk-based approach to compliant GxP computerized systems, uses a formal quality management process of rigorous documentation, testing, and methodical process steps that validate the 2900 Series design specifications.

The chart on the next page provides detailed information regarding YSI 2900 Series Analyzer 21 CFR 11 compliance specifications.

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21 CFR 11 SECTION(S)	FUNCTION	SPECIFICATION	21 CFR 11 COMPLIANCE
11.10(d) 11.10(g) 11.300(a)(b)	Access Limitations	Password-protected individual user accounts	Yes
		Unique individual ID and password	Yes
		Password has minimum length and strength requirement	Yes
		Unauthorized login attempts automatically recorded	Yes
		Inability to view confidential passwords	Yes
		Automatically log users off when idle for long periods of time	Yes
		Automatically password protect system when idle for short periods	Yes
		Able to display or report user access profiles	Yes
		Able to remove access privileges for former users	Yes
11.10(d)(g)	User Management & Privileges	User level permissions based on functionality and authority, i.e., Operator, Administrator.	Yes
		Administrator level permissions not allowed for Operator level	Yes
11.10(b)(c)(h)	Electronic Data	Electronic data and report should be human readable and suitable for inspection and review	Yes
		Ensure data includes date and time stamp	Yes
		System ensures data input is valid	Yes
		System does not allow data input from non-validated sources	Yes
11.10(b)(c)	Electronic data storage	Generated data stored in protected drive	Yes
		Software controls data file save function and location.	Yes
		Generated data shall not be edited or altered	Yes
11.10(b)(c)(e)	Audit Trail & Event Log	System should track all creations, modifications, and deletions performed in the system, including old and new values.	Yes
		System automatically records identity of individual who made the change.	Yes
		Audit trail and event log provides secure, system-generated date and time stamp.	Yes
		All hardware related errors are logged in audit trail or event log.	Yes
		Security violations are recorded in audit trail or event log.	Yes
		Original data is maintained and not obscured when system changes are made.	Yes
		Time and date stamp change automatically, which shall be locked and not editable.	Yes
		System shall prevent modification or deletion of audit trail and event log.	Yes
		Audit trail and event log are available for viewing and downloading in human readable form.	Yes
		Audit trail and event log shall be retained as long as the original record.	Yes
11.10(k1)(k2) 11.300()	Change Controls	Data integrity maintained when changes are made to the system, including software updates	Yes
		All system changes recorded	Yes
11.10(b)	Data Backup	System shall be capable to integrate with an open system, i.e., DAS, SCADA, DCS	Yes
		Software shall have facility for auto data backup to any client or connected central server.	Yes[1]
11.10(b)(e)	Date & Time Controls	Ability to change time is limited to Administrator	Yes
		System clock, date and time stamp are accurate and secure from tampering	Yes
		All date/time changes are recorded	Yes
		Year, month, day, hour & minute included in time stamp	Yes
11.10(a)(i)	System Validation	GAMP 5 risk-based approach to system validation	Yes
11.10(f)(i)	Other	Documentation of software and hardware version	Yes
		System employs operational system checks to ensure proper sequences of steps and events	Yes
		System developers are trained in 21 CFR 11, GAMP 5 and quality systems management procedures.	Yes

1. Data back-up to a network drive, DAS or SCADA can be accomplished using the YSI 2900 Series FTP server or RS-232 serial communication. If the data is exported in this manner, the YSI analyzer is part of an open system. In this instance the open system is responsible for meeting 21 CFR 11 requirements.

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