

xylem



FDA Regulation Title 21 CFR Part 11

REFRACTOMETERS AND POLARIMETERS FROM BELLINGHAM + STANLEY



**Bellingham
+ Stanley**

a xylem brand

How to comply with FDA Regulation Title 21 CFR Part 11

What is FDA Regulation Title 21 CFR Part 11?

FDA Regulation Title 21 CFR Part 11 (also known as 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. Specifically, 21 CFR 11 defines the requirements for submitting documentation in electronic form and the criteria for approved electronic signatures.

Who needs to comply?

All FDA-regulated industries, which includes pharmaceutical, production of medical devices, food & beverage manufacturers and cosmetics companies, must comply with 21 CFR 11. Computer systems (including analytical instruments with onboard computers) which store or produce data to make quality control decisions, or reporting data for the FDA must comply with 21 CFR 11. 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.

Which Bellingham + Stanley products support 21 CFR Part 11?

Because 21 CFR 11 states that closed computer systems must have a collection of technological and procedural controls to protect data within the system, Bellingham + Stanley designed a selection of its instruments to help customers easily comply whilst using Bellingham + Stanley products. The current instruments that comply to 21 CFR Part 11 are:



ADP450 Polarimeter

Single wavelength polarimeter with internal Peltier temperature control and 3 decimal point precision.

ADP600 Series Polarimeters

Peltier temperature controlled polarimeters available as single, dual and multiple wavelength derivatives.

The ADP660 polarimeter excels due to its 3-decimal place accuracy and ability to measure at prescribed wavelengths between 325-633nm.

RFM900 Series Refractometers

Six decimal place Refractive Index precision digital refractometers with Peltier temperature control and state-of-the-art touchscreen interface.

Key benefits for 21 CFR 11

RFM900-T Series refractometers, ADP450 polarimeter & ADP600 Series polarimeters offer the following key benefits for 21 CFR 11.

- Compliance without an intermediate PC - less data security risk and lower system cost
- Server synchronised clock to prevent data tampering
- Multi-reading PHR Method for batch measurement as per GLP/PHR
- Print to Secure PDF with custom header (customer logo can be input)
- Electronic signatures including multi-verification (Submitter > Reviewer >> Approver)
- XML output strings with encryption & MD5 check for easy connection to LIMS/Server
- Configurable users enforcing unique login & signature credentials as well as strict password controls
- Full instrument configuration audit trail
- Full validation documentation, service & support

By removing the need for an intermediate PC, our 21 CFR 11 compliant refractometers and polarimeters can deliver great performance simply and efficiently

Intelligent software for simple data security

Latest Bellingham + Stanley RFM900 Series refractometers as well as ADP450 and ADP600 Series polarimeters now include updated onboard software to help laboratories comply with FDA regulation 21 CFR Part 11, without the need of an intermediate PC. A forward thinking approach to the core functions of these instruments negates the need to use an external PC or additional software and therefore eliminates further data security risks and any additional costs involved with extraneous equipment.

The recording of results, and the logging of instrument access and configuration is also possible. The Review & Approve electronic signature process can even be achieved locally or remotely. Encrypted Print to Secure PDF, .csv and .XML outputs makes data integration to LIMS simple, secure and auditable.



Xylem |'zīləm|

- 1) The tissue in plants that brings water upward from the roots;
- 2) a leading global water technology company.

Bellingham + Stanley is part of Xylem Analytics and a leading provider of refractometers and polarimeters.

Xylem Analytics' global brands have been leaders in the laboratory instrumentation market for decades, and are relied upon every day across more than 150 countries. Working in true partnership with our clients, we listen, learn and adapt to individual needs, offering deep application expertise built upon our long history of innovation in instruments and services. Our solutions for analysis, measurement and monitoring help enable many of today's modern laboratories and industrial processes, and provide our customers the trusted and high performing solutions they need to succeed.

Xylem Analytics is part of Xylem Inc., a global company focused on solving the world's most challenging and fundamental water issues. As accurate analysis is crucial to the water industry, Xylem Analytics taps its diverse product brands for leadership in that field and beyond, providing the best laboratory and field monitoring instrumentation across a wide variety of industries.

For more information on how Xylem can help you, go to www.xylem.com



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