INSTRON®

The difference is measurable®

IQOQ VALIDATION

Dynamic & Fatigue Material Testing Systems

Software validation is a critical component of compliance with FDA 21 CFR Part 820 and ISO 13485 for medical device and pharmaceutical companies, including those using Instron dynamic and fatigue material testing systems.

Instron Professional Services has provided on-site validation and documentation services to support Installation Qualification and Operational Qualification (IQOQ) software validation for many years, and has now expanded the validation service to include our **WAVE**MATRIX™3 software on dynamic and fatigue material testing systems. This service, provided by the original equipment manufacturer, is designed to ensure that your dynamic or fatigue system is installed properly, functioning as intended, and is capable of producing valid results.

Our IQOQ package is completed at your site by a trained Field Service Engineer, along with purchased factory installation services and/or calibrations, and provides information that can be used during Performance Qualification (PQ) and other phases of software and system validation. Additionally, you save time and resources by using Instron Professional Services to complete the IQOQ validation testing. For companies with multiple sites, purchasing Instron IQOQ validation services ensures consistency with validation protocols across your organization.

WAVEMATIX3

IQOQ validation for dynamic and fatigue systems using WaveMatrix3 software details the steps necessary to ensure that standard aspects of Instron WaveMatrix3 software are in conformance with the manufacturer's specifications and produce valid results. The validation documentation includes checks within the *Test Review*, *Specimen & Test Inputs*, and *Security* features of the software.

BLUEHILL UNIVERSIAL®

For dynamic and fatigue systems that use Instron's Bluehill Universal software, IQOQ validation confirms the proper operation of the testing system and its ability to produce valid results in Bluehill Universal. A typical validation plan includes system operation validation, references to transducer verification(s), a functionality check of the software, and validation of customer chosen calculations.

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