

Instron® Professional Services | IQ/OQ Validation and Documentation (FDA 21 CFR 820.72)

Instron® Professional Services have provided on-site validation and documentation services to support Installation Qualification/Operational Qualification (IQ/OQ) validation for many years. This service, provided by the original equipment manufacturer, is designed to ensure that your Instron testing equipment is suitable for its intended purpose and is capable of producing valid results (per FDA 21 CFR 820.72). Additionally, you save time and resources by using Instron Professional Services to complete the IQ/OQ validation testing. Our experienced service team will use Instron's proven documentation pack that is tailored to your individual needs and contains necessary IQ/OQ documents, calculation work sheets, and manuals.

IQ/OQ validation should be considered for all new static and dynamic testing equipment installations, relocations, and upgrades.

Installation Qualification (IQ) Validation and Documentation

An installation qualification process is designed to establish that the system has been installed correctly. It will consider and document:

- Installation conditions
- Operation of safety features
- Provided system manuals and documentation
- Environmental conditions
- Appropriate services and utilities

Instron manuals are provided and utilized to verify system installation and operational requirements, when applicable. Pre-installation and installation documentation will ensure that the installation was performed correctly.

Operational Qualification (OQ) Validation and Documentation

An Operational Qualification process is designed to verify the proper operation of the testing system and its ability to produce valid results. A validation plan can include system operation validation, transducer(s) verification, functionality check of the software, and validation of calculations.

Transducer Verification

Transducers are verified per Instron's standard verification/calibration procedures. Data reports and Certificates are provided for each transducer, and all standards used are directly traceable to National Standards.



Software Functionality Check

The software functionality check is a “button pushing” test used to ensure that the software is performing as designed. Tailored specifically to your system, it verifies the “Test Types” and “Language” (e.g. English, Spanish, etc.) options that you are using.

Validation of Calculations

A Calculation Test Suite is a document compiled by the Instron Software Development Team. It consists of Test Methods and Data Files to be replayed on your system and compares results from the software under test with expected results using known data sets as input. The expected results are determined using a variety of independent methods including MathCAD, Excel, hand calculation, and visual inspection. A data sheet for each calculation specified is provided and attached to the results produced by the software under test.

Instron Professional Services can provide a quote to validate specific software calculations, and as part of this service, you will receive a detailed explanation of each algorithm used to calculate the result.

The documentation pack will support progress onto your Performance Qualification (PQ).



Bluehill® Software



WaveMatrix™ Software

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