INSTRON®
*The difference is measurable®*

Installation Qualification

Operational Qualification

For medical device and pharmaceutical companies, software validation is critical for compliance with FDA 21 CFR Part 820, also known as the Quality System Regulation (QSR), and ISO 13485. Instron® Professional Services have provided on-site validation and documentation services to support Installation Qualification/Operational Qualification (IQ/OQ) software 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.

Instron offers transducer calibration services as well as IQ/OQ Validation packages, completed at your site by trained Instron Field Service Engineers. Our services provide information that can be used during PQ and other phases of software and system validation.

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, MT torsion, dynamic (linear and biaxial) and custom (autoinjector) testing equipment installations, relocations, and upgrades.
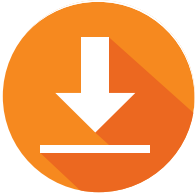
INSTALLATION QUALIFICATION (IQ)

An Installation Qualification demonstrates that the Instron software and testing system is installed correctly, and all required components and documentation needed for continued operation are installed and in place.
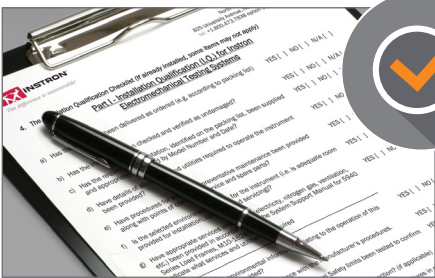
INSTALLATION CHECKLIST

The IQ process is designed to establish that the system and software have been installed according to the manufacturer's procedures. Instron manuals are provided and utilized to confirm system installation and operational requirements, when applicable.

The steps listed in the installation qualification consider the following:

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

OPERATIONAL QUALIFICATION (OQ)

An Operational Qualification process is designed to confirm the proper operation of the testing system and its ability to produce valid results. A typical validation plan includes 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. Transducer calibration services are purchased separately from the IQOQ validation package.
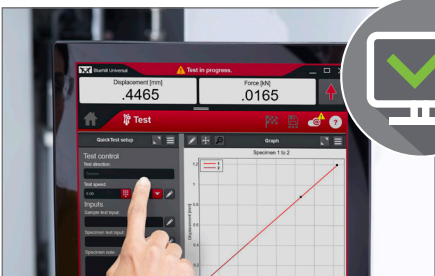
SOFTWARE FUNCTIONALITY CHECK

The software functionality check is designed to evaluate the major components of the Instron software under validation and ensure that the software features are operational and functioning as designed. Documented evidence, through screen shots and saved software files, is provided for future reference of the completed steps.

CALCULATION VALIDATION

The Instron IQ/OQ package includes validation of customer chosen calculations to match each customer's individual testing needs. Sample data files are provided and replayed on your system, and results from the software under test are compared with expected results for the data sets. The expected results are determined using a variety of independent methods, including Excel and hand calculations. A data sheet for each calculation specified is provided and attached to the results produced by the software under test.

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