



The difference is measurable®

IQOQ VALIDATION

Instron® Melt Flow MFi Series



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 Melt Flow Index testers such as the Instron MFi Series. Companies supplying raw materials into the FDA regulated industry can also benefit from documented validation that the system and associated software are installed properly and functioning as intended.

Instron Professional Services have provided on-site validation and documentation services to support Installation Qualification and Operational Qualification (IQOQ) software validation for many years, and have now expanded the validation service to the MFi Series. This service, provided by the original equipment manufacturer, is designed to ensure that your Instron MFi Melt Flow Tester 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 across your organization with validation protocols.

MFI TOUCHSCREEN

Each MFi testing system contains a built-in touchscreen through which users create test procedures, run tests, and view test data. IQOQ validation for the touchscreen confirms that these and other major processes are functioning as intended. User creation and permission levels are also validated. Tests are run using reference material included with the testing system and resulting data is compared and confirmed to be in the expected range.



BLUEHILL® MELT

The IQOQ validation for Bluehill Melt software is designed to evaluate the major components of the stand alone software and ensure that 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.

Both standard melt flow calculations (MFR, MVR, melt density) and statistical calculations for automatic bubble detection, are validated using sample data files that are provided and replayed on your system. Results from the software are compared with expected results from the data sets, which are determined using independent methods such as Excel and manual calculations. A data sheet for each calculation specified is included with the validation documents.

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