INSTRON®

CALIBRATION AFTER SOFTWARE CHANGES IN FDA REGULATED ENVIRONMENTS

Dear Instron Customer:

Instron is proud of its history of providing unequalled levels of data integrity and quality in its instruments and their calibration. We strive to not only meet but also exceed the letter and intent of guiding international standards for materials testing.

To ensure that your testing instrument is providing accurate data, we always recommend calibration of all transducers upon installation of the equipment on site (for a screw-driven machine, this would include force, speed and displacement of crosshead and strain if extensometers are used), and then recalibrations on a regular schedule thereafter. Also, we recommend, and international standards require, recalibration if transducers or signal conditioning electronics are changed or upgraded.

Since most materials testing instruments now utilize software, a common question from our customers is whether they should perform a recalibration when software is updated or upgraded. The FDA has provided guidance on this subject and recommends that whenever software is changed that revalidation is conducted to assess the impact of the change on the entire software system[1]. The guidance goes further to explain the importance of demonstrating that even unchanged portions of the software system have not been adversely affected.

For this reason, in an FDA regulated environment, Instron recommends that recalibration be conducted as part of system revalidation after changes to software. This revalidation process would include a new IQ/OQ/PQ on the system as well. Instron also offers a range of support including IQ/OQ services and assistance with your PQ work if desired. The Instron IQ/OQ includes documentation packages for standard and customized onsite IQ/OQ verification services. Please contact your local Instron representative for further details describing how Instron can assist with this process.

Sincerely,

James Ritchey
Global Services Innovation Director
james_ritchey@instron.com

1 - U.S. Dept. of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health. General principles of software validation: final guidance for industry and FDA staff, General principles of software validation: final guidance for industry and FDA staff (2002). Rockville, MD.