



## **CALIBRATION AFTER SOFTWARE CHANGES--UNIVERSAL MATERIALS TESTING MACHINES**

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. Standards such as ISO 17025 and ISO 9001:2008 clearly recognize that software should be checked or validated prior to use and after any changes. Excerpts of those standards are copied on the reverse side for your reference.

Based on our software verification and validation testing during product development, we believe that Bluehill Universal upgrades have no effect on the values of transducer calibration and data, nor on subsequent calculations. If your internal standards or compliance to other regulatory bodies outside of ISO or ASTM require you to revalidate your testing instrument after the software change, we recommend a more comprehensive validation. This would include verification of the software calculations critical to your specific application, functionality checking of the software, as well as spot checking transducer readouts against known values. The validation of software calculations is similar to the IQ/OQ validation that we perform for 21 CFR FDA applications.

If you would prefer a recalibration of your transducers, Instron can provide this service and is fully accredited to the relevant ISO and ASTM standards.

Sincerely,

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**Relevant ISO Standards Excerpts:**

ISO 17025 (Para 5.4.7 and 5.5.2)

“When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory shall ensure that:

a) computer software developed by the user and (from the NOTE) laboratory software configuration/modifications are documented in sufficient detail and are suitably validated as being adequate for use.”

“Equipment and its software used for testing, calibration and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibrations concerned... it shall be checked and/or calibrated before use.”

ISO 9001:2008 (Section 7.6)

“When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.”