

Calibration Check System

The Problem

Medical device manufacturers relying on the ASTM F-88 test method depend on both accurate equipment and verified calibration. If a tensile tester drifts out of calibration between annual cycles, every data point collected becomes unreliable. This has historically led to false-positive results that allowed compromised seals to pass into distribution. Quality teams often assume the system is within tolerance, only to discover an out-of-calibration event at the end of the year putting sterile barrier validation and patient safety at risk.

The Solution

To ensure manufacturers can trust the data produced by their tensile testers, we developed the Calibration Check System (CCS). The CCS calibrated spring works with the tester's algorithm to evaluate load cell performance and confirm accuracy. Operators can run these checks at any interval based on their risk policies, reducing the chance of false peel-test data. When tensile testing determines whether a sterile barrier system is fit for distribution, the CCS provides a powerful way to derisk pouch testing and maintain confidence in every result.

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Connecting medical device packaging to patient safety.

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