ACERTARA
acoustic laboratories

White paper

ISO17025:2017 accredited testing is essential to ensure validation of ultrasound transducer repair results

Laboratory accreditation is highly regarded both nationally and internationally as a reliable indicator of technical competence. Most ultrasound manufacturers routinely specify ISO/IEC 17025:2017 accreditation for suppliers of testing and calibration services. This accredited testing also applies to validating the materials and processes used in transducer repair activities.

ISO/IEC 17025-the World Standard

ISO/IEC 17025:2017 accreditation is the single most important standard for calibration and testing laboratories around the world. ISO/IEC 17025:2017 accredited laboratories have demonstrated that they are technically proficient and able to produce precise and accurate test and calibration data. This is a voluntary, third party-reviewed process that ensures a laboratory's quality management system is thoroughly evaluated on a regular basis to guarantee continued technical competence and compliance with ISO/IEC 17025:2017.

Accreditation

Laboratory accreditation bodies use the ISO/IEC 17025:2017 standard specifically to assess factors relevant to a laboratory's ability to produce precise, accurate test and calibration data including:

1) Traceability of measurements and calibrations to national standards
2) Technical competence of staff
3) Maintenance of test equipment
4) Quality assurance of test and calibration data
5) Validity and appropriateness of test methods
6) Appropriate handling and transportation of test items
7) Quality of testing environment and sampling

To ensure continued compliance, accredited laboratories are regularly reassessed to check that they are maintaining their standard of technical expertise. These laboratories are also required to participate in regular proficiency testing programs as an ongoing demonstration of their competence.

A matter of patient safety and regulatory compliance

For the safe and effectual repair of ultrasound transducers (probes) ISO/IEC 17025:2017 compliance is essential to determine if the materials, parts, and processes used have restored the transducer to substantial performance and safety equivalence to the manufacturers (OEM) specifications. Acertara's accredited acoustic testing laboratory performs FDA Guidance compliance for OEMs on a worldwide basis; testing that the OEMs use in their FDA 510(k) submissions to gain market clearance to sell their products. We use these same rigorous testing procedures to validate and document in our quality system, materials (e.g., for the ultrasound probe lens) and parts (e.g., acoustic stacks) that are used in the repair process to demonstrate objective evidence that substantial equivalence has been achieved. Acertara then incorporates those materials and parts into our ISO13485:2016 certified probe repair processes.

A partner you can trust

Acertara is the only probe repair facility in the world that has both an accredited ISO/IEC 17025:2017 acoustic testing laboratory and certified ISO 13485:2016 probe repair facility under one roof. Additionally, Acertara has developed the most sophisticated probe testing devices available such as ATLAS™ to diagnose failures in probes - crystal-by-crystal; including some of the most technologically advanced ultrasound probes on the market such as the Philips X5-1 and X8-2t. Post repair testing and evaluation is performed and documented to demonstrate a successful repair. Accreditation, certification, advanced probe testing, and highly trained probe repair technicians all working together to provide our valued clinical customers with the assurance that the repairs are performed correctly, economically, complying with both international standards as well as FDA Guidance. For more than twenty-five years our team has proven time and again that we are your trusted partner in providing for the safety of patients.