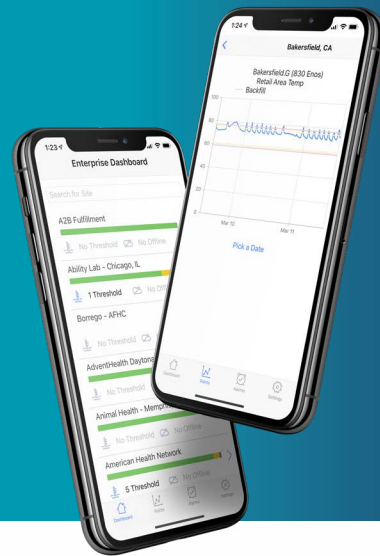# SONICU™ +

Validation for Life Science Compliance

IQ/OQ delivers affordable hardware and software validation

Sonicu's IQ/OQ validation service ensures that your Sonicu temperature and environmental monitoring solutions meet the rigorous certification standards required by regulatory and accreditation bodies.

Whether your equipment is newly installed, being relocated, or revalidation is required, our validation service provides extensive documentation, including all test procedures, complete hardware lists, and more.

Leveraging years of experience, Sonicu helps clients validate their system with a done-for-you IQ/OQ service. Sonicu's IQ/OQ detailed instruction packet can be purchased and completed on your own or purchased with the validation services completed by a Sonicu technician.

Sonicu personnel complete the IQ/OQ at your facility under operational conditions to verify that your equipment has been properly installed and performs as designed.

Comprehensive Qualification Services

The IQ/OQ service begins with a Sonicu equipment-specific comprehensive document that is executed at your facility by a Sonicu technician. This service includes three focus areas: General Information, Installation Qualification (IQ), and Operational Qualification (OQ)

General Information

- Outline of the test plan, including instructions and identification of the testing personnel
- Prerequisite information

Installation Qualification (IQ)

- Verify and provide evidence that the Sonicu hardware being qualified is installed according to relevant users' and Sonicu's recommendations.
- Verify that the Sonicu hardware has been configured according to the Sonicu monitoring system requirements
- Verify a fully traceable NIST calibration certificate is available for each sensor.
- Provide evidence that the SoniCloud setup is complete and accurate according to specifications.

Operational Qualification (OQ)

Performance of a set of rigorous tests to validate and document that all necessary features, operations, alarms, and procedures are tested and in place to successfully operate and maintain the equipment and SoniCloud platform at upper and lower boundary conditions.

- Verify and document the connection to SoniCloud
- Threshold and offline alarm testing and alarm resolution
- Sonicu accuracy comparison with any currently installed and validated legacy system
- Verify report accessibility and download capabilities

Following completion of the IQ/OQ service, each client receives:

- Documentation with objective evidence of all Sonicu hardware and software operating within the specified limits
- Signed Training Verification Roster
- Signed and executed final IQ/OQ documentation with test procedures and corresponding appendices
- Calibration certificates, compliance and regulatory reports, and final IQ/OQ conclusion and disposition statement

The simple and proven way to meet your compliance and regulatory requirements with our complete qualification program.