FDA-Ready
Environmental Monitoring

SONICU™
Monitoring. Measured.

21 CFR Part 11 Made Easy

Sonicu's platform, by default, includes the built-in tools required to support 21 CFR compliance by maintaining data integrity, traceability, and control within FDA-regulated environments.

Our enhanced capabilities go a step further by streamlining daily operations and providing added peace of mind through professional system validation from day one.

21 CFR PART 11 — FDA — COMPLIANCE

User Access Controls

- **Expanded Role-Based Access:** Assign specific permissions based on job duties, so users can only access and modify data appropriate to their role. Meets regulatory requirements while matching your organizational structure.

- **Secure Access Controls:** Email and password login for basic controls. The Confirmation PIN feature provides an additional layer of security. Complies with regulations that require two distinct identification components.

Complete Calibration Documentation

- **Electronic Calibration Certificates:** Each sensor automatically uploads a calibration certificate onto your site, ensuring you always have it on hand.

- **Access to Calibration History:** Retrieve calibration certificates for any probe ever used in your system, proving measurement accuracy throughout the equipment lifecycle.

System Qualification

- **Detailed IQ/OQ Validation Package*:** Standardized protocols, documentation templates, and guidance provided to execute and document the Installation and Operational Qualification process.

- **White-Glove IQ/OQ Validation*:** Fully managed service where Sonicu's team executes all installation verification, testing, documentation, and delivers a complete turnkey validation package.

- **Validation Alarm Feature:** On-demand test alarms verify system detection and response to out-of-range conditions, providing documented evidence for Performance Qualification (PQ).

Inspection-Ready Reporting

- **Alarm Handling History:** Excursion reports document the complete record of issues, corrective actions, and timestamps, providing proof of proper response and resolution.

- **Robust Report Suite:** Schedule automated reports or generate on-demand delivery via email, so compliance documentation remains current and immediately accessible.

- **Report Review & Approval:** Captures approval signatures and stores signed environmental monitoring records in one centralized repository for streamlined regulatory compliance and audit preparedness.

Comprehensive Compliance Tools at Your Fingertips

Enhanced Group Reporting:
Review and approve reports directly within the system, creating documented oversight that prevents data fraud.
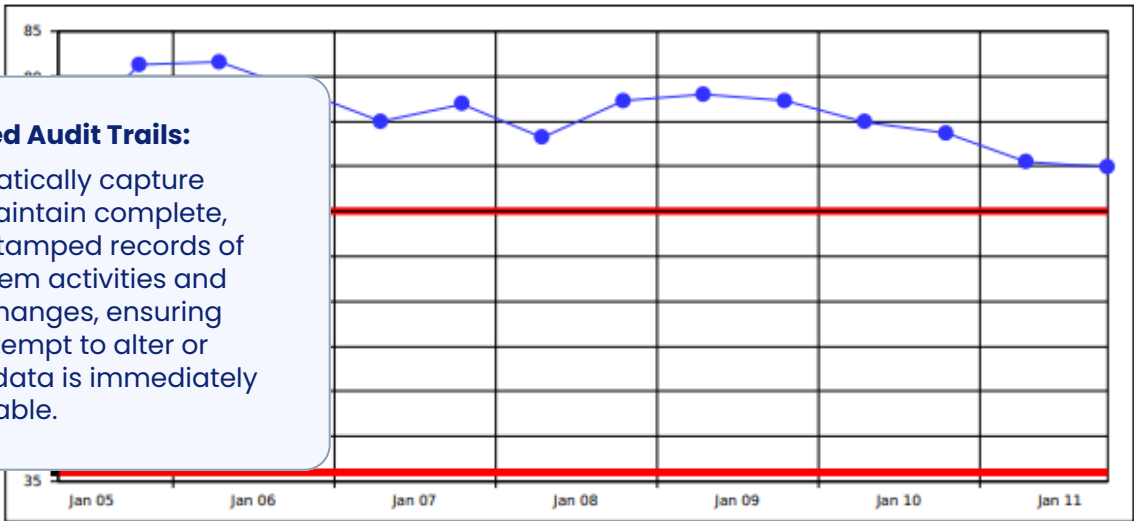
Sign Report ∨

Sign as Reviewer...

Sign as Approver...

Day	01/05/2026	01/06/2026	01/07/2026	01/08/2026	01/09/2026	01/10/2026	01/11/2026
Max	82.9	81.7	78.8	78.3	78.8	76	73.2
Min	63.5	76.7	74.8	73.2	76	73.3	69.6
Time 1 Reading	06:57 72.3	06:59 81.6	06:59 75	06:59 73.2	06:59 78	06:59 74.9	06:59 70.5
Time 2 Reading	18:59 81.3	18:59 78.4	18:59 76.9	18:59 77.3	18:59 77.3	18:59 73.7	18:59 69.9
Time out of Range (min)	1427	1435	1435	1435	1435	1435	1435

Detailed Audit Trails:

Automatically capture and maintain complete, time-stamped records of all system activities and data changes, ensuring any attempt to alter or falsify data is immediately detectable.

Threshold (Created 01/09/2026 13:57:05) - Resolved 1 hour, 28 minutes and 47 seconds after created.

User	Action	Date	Comment
SoniCloud	Outside of Thresholds	2026-01-09 13:57:05	This device was outside of the permitted range. The alarm was automatically generated at January 9, 2026, 13:57
SoniCloud	Automatically Resolved Alarm	2026-01-09 15:25:52	Alarm was automatically resolved by the system as the values were between the low caution threshold (68°F) and high caution threshold (80°F) for 35 minutes. The most recent reading was 68.3°F°F at 01/09/2026 15:19:07

Approve Report

Add any notes or comments to be included with the signature below.

Sign As Approver

Electronic Signatures:

Securely authenticate and document user actions with validated electronic signatures, establishing clear accountability and preventing repudiation of critical decisions.

*Additional fees apply