JOFRA calibration AMETEK

Case Study

Is it possible to calibrate three short surface sensors in one run with documented uncertainty?

Application Overview

Bavarian Nordic, a life-saving vaccine manufacturer, faced a challenge in maintaining accurate temperature monitoring for their CIP (Clean-in-Place) and SIP (Sterilization-in-Place) processes. These systems, critical to ensuring product safety and sterility, utilize Labom pipe surface temperature sensors (model GA2610) to measure pipe surface temperatures without direct contact with the product. The sensors ensure the temperature stays within required limits, thus preserving the integrity of the sterile environment.

The problem, however, was the need to calibrate these surface sensors accurately while minimizing calibration uncertainty and ensuring that temperature stability is maintained throughout the process. The solution came in the form of the AMETEK RTC-168 dry block temperature calibrator.

Why the RTC-168 Temperature calibrator was Chosen

Bavarian Nordic selected the RTC-168 due to its unique ability to handle the calibration of sanitary temperature sensors, especially those with short contact depths like the Labom GA2610.

The RTC-168 offers several key advantages:

Dual-zone heating block: The device's two-zone heating capability ensures precise temperature control and compensates for heat loss at the sensor insertion point.

Set-follow-true feature: This feature allows the calibrator to measure and control the temperature in real time, providing accurate and stable temperature conditions at the sensor's tip.

High temperature uniformity: The RTC-168 ensures a high degree of temperature homogeneity, which is critical for maintaining low calibration uncertainty even when multiple sensors are calibrated simultaneously.

Efficiency in calibration: The system allows the calibration of up to three sensors at a time, increasing the calibration process efficiency.



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Problem Solved by RTC-168

The primary challenge Bavarian Nordic faced was the need to ensure the temperature sensors provided consistent readings while avoiding temperature drift that could affect product safety. The calibration needed to meet stringent accuracy requirements to ensure that the measurement uncertainty remained well below the Max Permissible Error (MPE).



The RTC-168 addressed these issues in the following ways:

Accurate Calibration with Low Uncertainty: The dual-zone design and the use of isothermal inserts allowed for uniform heat distribution, minimizing errors caused by heat loss at the sensor-transmitter junction.

- **Customized Modifications:** The isothermal insert of the RTC-168 was modified to fit the sensor head of the Labom GA2610 and further enhanced with thermal insulation to delay heat buildup in the sensor's transmitter. This helped reduce systematic errors during the calibration.
- **Improved Stability:** The set-follow-true function ensured that temperature stabilization was achieved within a shorter time, allowing for efficient calibration of multiple sensors in one run.

As a result, Bavarian Nordic achieved highly reliable and accurate temperature measurements, critical for their vaccine production processes.

Recommendations and Customer Value

To further optimize calibration efficiency and accuracy, it is recommended that Bavarian Nordic continues to:

Regularly monitor calibration intervals: FMECA risk assessments showed that frequent calibrations mitigate risks related to drift or inaccuracies in the sensor readings.

Use customized insulation: Enhancing thermal insulation in the isothermal insert can prevent heat transfer to the sensor housing, further reducing calibration errors.

Continue using RTC-168 for critical processes: The RTC-168 has demonstrated its reliability and efficiency, making it an ideal solution for other similar sanitary temperature sensors in use across the production facility.

The value added to Bavarian Nordic includes improved process safety, reduced downtime, and minimized product loss due to temperature misreadings. By adopting the RTC-168 for temperature calibrations, they have successfully met strict regulatory and operational standards while ensuring the accuracy required for life-saving vaccine production.

Company Description: Bavarian Nordic

Bavarian Nordic is an international biotechnology company specializing in the development, manufacturing, and commercialization of vaccines. The company is known for its focus on infectious diseases and cancer immunotherapies, with a strong commitment to public health and safety.

Bavarian Nordic's vaccines address critical health threats such as smallpox and monkeypox, and their products are used globally to protect vulnerable populations. Their state-of-the-art production facilities ensure sterile, high-quality vaccine output, adhering to the highest regulatory standards. The company's expertise in vaccine production makes precise temperature monitoring essential to maintaining the safety and efficacy of their products, underscoring the importance of accurate sensor calibration for processes like CIP/SIP.

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