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The Calibration of Embedded Sensors

References: ISO 14253-Part 1, Specification and Compliance Zone area

Using onboard sensors has been democratized in recent years, but the calibration of these sensors is a problem that is not framed by specific standards for thermal validation use. Their wide operating range allows use in extreme environments:

· Steam sterilizers (high temperature and pressure)
· Environmental chambers (low temperature and atmospheric pressure)
· Ovens/tunnels pyrogenic (high temperature)
· Sterilization in place (SIP/CIP)
· Cooking processes
· Cryo preservation freeze dryers

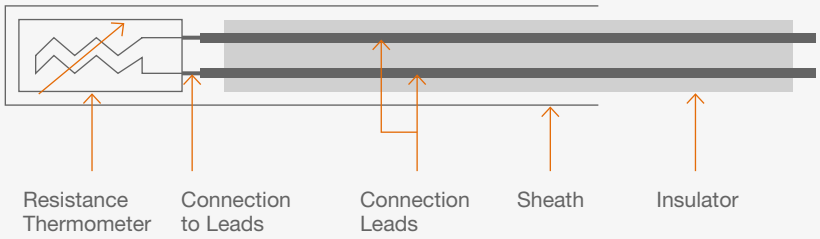
Their size, ease of use, and time-saving implementation of probes give embedded systems unmatched flexibility to meet the temperature monitoring applications in all industries. Particularly used in the food industry in its infancy, they have become essential for over 15 years in the pharmaceutical and biotech industries.

1. A Little History

To qualify production equipment, the solutions that were available to us were few. The use of central wireline acquisition was widespread. This technology offered and still offers advantages in terms of range of use, interchangeability of sensitive measuring elements (thermocouples), and reliability over the long term. But the implementation is difficult. These standards brought their recommendations for calibration and adjustment in a prior study (commonly known as Pre-Qual) and calibration performed after the acquisition (Post-Qual). This provides a framework for metrologically probing the state before and after the test, determining the metrological status of the measuring chain, and determining the compliance of the equipment under test. The industry employs the use of sensitive elements such as RTD (Resistance Temperature Detectors) or PRT (Platinum Resistance Thermometer), better known by the abbreviations PT-100, PT-1000, for stationary applications, system regulation, and online process monitoring. Such sensitive measuring elements are reputedly more accurate and less prone to drift compared to a thermocouple. But what about when the RTD becomes embedded?

2. RTD Technology (PT-100, PT-1000)

RTDs operate on the principle of electrical resistance variations in pure metals and are characterized by a positive linear change in resistance depending on the temperature. Specifically, when heated, the resistance of the metal increases, and vice versa—once cooled, it decreases. Typical elements used for RTDs include nickel (Ni) and copper (Cu), but platinum (Pt) is by far the most common, due to its extensive range of temperatures, precision, and stability. Passing current through an RTD generates a voltage across the RTD. By measuring this voltage, you can determine its resistance and, thus, its temperature. Also, because they require current excitation, they are subject to a temperature rise (self-heating). Popular for their stability, RTDs exhibit the most linear signal of all electronic sensors for temperature. However, they generally cost more than their counterparts because of their more delicate construction and use of platinum. RTDs are also characterized by a slow response time, low sensitivity, and vulnerability to physical shock and moisture.



Composition of a sensitive element RTD-type

3. Widespread Practices for the Metrological Monitoring of Embedded Sensors

With the development of this technology, different approaches to monitoring metrology probes were highlighted:

Method 1: The most common approach: the user does not perform any metrological control of the probes during the year and returns the probes for annual calibration in an accredited calibration laboratory or not.
Method 2: A growing approach is for the user to perform calibration of the probes internally or through a lab at higher frequencies (four times a year, for example), according to their level of use.
Method 3: Historical Approach: The user performs a calibration before and after each study/measurement campaign. This method was originally used with wired technology, such as thermocouples.

Each method has its advantages and disadvantages. To determine the appropriate method for your use, different criteria come into play:
- Criticality of the application
- MPE (maximum permissible error) applicable to applications
- Metrological traceability
- Frequency of use
- Metrological resources available internally
- Number of sensors

To choose the right method, one must ask the right questions and perform a risk analysis to determine the impact an improperly metrologically onboard sensor could have. For example, using method 1 (annual metrological verification only).

Below is a risk assessment table for a concrete application (steam sterilizer) – simplified approach:

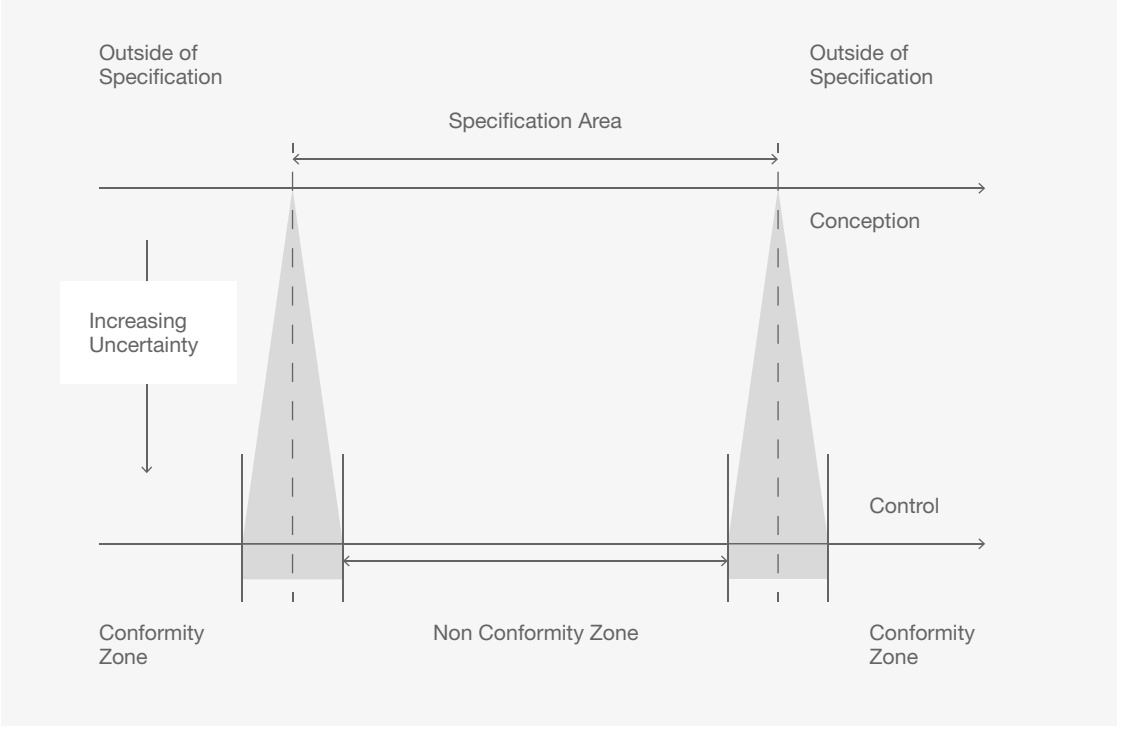
Criteria	Impact	Level of Criticality	Method 1	Method 2	Method 3
Criticality of the application	Recall of manufacturing batches	TOP	5	3	2
EMT (Maximum error tolerated)	Non-compliance of the equipment	TOP	5	3	1
Metrological traceability	Not tracking potential drifts	WAY	3	2	1
Frequency of use of the probe	Number of impacted cycles	TOP	4	3	2
Metrological resources available internally	Time limits on metrological controls	LOW	5	3	2
Number of users and turnover	Mishandling	WAY	4	3	2
		TOTAL :	26	17	10

1 = low risk | 2 = moderate risk | 3 = high risk | 4 = high risk | 5 = very high risk

Not surprisingly, it is clearly shown in this example that method 1 (score: 26) has multiple high-risk factors.

Example: An embedded probe sent for calibration and showing significant drift of ± 0.5°C highlights the impact on criticality as well as the MPE:

- *Application criticality: This involves questioning all measurements with this probe for each study/qualification of equipment. A drift of +0.5°C can render many of your cycles improper. The difficulty lies in assessing when the sensor started to drift, and in the absence of metrological testing throughout the year, it calls the entire past year's data into question. This can impact the recall of post-production batches.*
- *EMT: As the EMT for a sterilizer according to the procedures is around ± 1°C, the result is that the drift does not maintain a factor of 3 between the EMT of the equipment and the uncertainty of the probe. The same impact occurs on the criticality of the application. As shown in the illustration below, the more your probes deviate, the smaller the compliance area, increasing the risk of non-compliance.*



Calibration method for embedded probes

1

METHOD 1

As part of annual metrological monitoring from an accredited laboratory or not, you should ensure that the methods and calibration means are aligned with your hardware. It will primarily check:

- The level of uncertainty of the calibration laboratory is in line with the level of uncertainty of your sensors with a minimum factor of x3. Engaging an ISO 17025 accredited laboratory allows for validated methods and auditing by competent bodies.
- Their calibration procedure is in accordance with manufacturer recommendations.
- Focus on calibration with adjustment to avoid having to calculate the impact of derivatives yourself for the year ahead.

2

METHOD 2

With more frequent metrological monitoring by an external laboratory, it is still necessary to apply the same recommendations given in Method 1. It is now possible to perform this in-house. Current technology allows you to calibrate your sensors with an adequate level of uncertainty on-site (as long as you select the appropriate calibration methods). This involves:

- Defining an appropriate calibration frequency. It must match the intensity of use of the on-site equipment.
- Conducting a gap analysis between calibrations to decide whether to maintain or adjust that frequency.
- *Example: New embedded sensors will undergo calibrations after 3 consecutive trials, with the interval gradually spaced out to create a history and perform a risk analysis on the calibration interval. This approach will provide elements for internal or external audits to justify your metrological approach.*

3

METHOD 3

Method 3 differs mainly from Method 2 by requiring a more frequent and constant schedule for your calibrations.

4. Calibration Means

a. The Temperature Generator

The „embedded“ probe, true to its name, is inserted into your application. Specifically, the measuring elements PT and others are at the same temperature. To achieve an embedded sensor calibration, it is recommended to calibrate the probe under the same conditions, meaning the electronics and measuring elements are subjected to the same temperature.

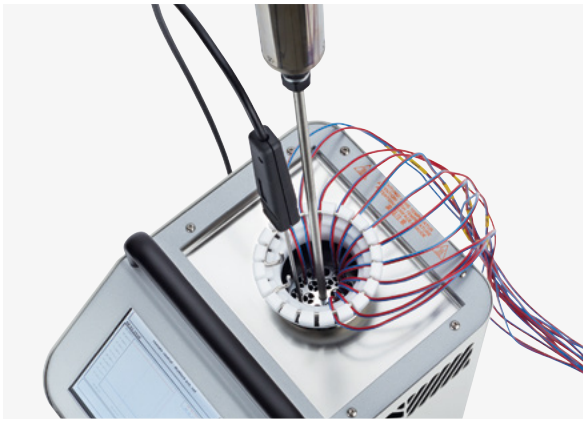
This implies the use of specific measuring equipment. We will then favor using a calibration bath, which will place several probes in a single environment with a level of consistency and unrivaled stability.

Liquid Calibration Bath

This solution offers the advantage of calibrating multiple probes at once, and via appropriate software, it can perform this function in automatic mode (controlling the bath, acquiring data from the temperature probes, and generating calibration certificates).

The drawbacks of using the bath include: inertia in raising or lowering the temperature (depending on the volume and nature of the heat transfer fluid), the necessity of cleaning probes due to the presence of oil, and the need to follow EHS (Environmental, Health, and Safety) rules for oil renewal (based on the Safety Data Sheet for oils).

An alternative is to use a calibration oven. This technology provides portable equipment that is more flexible, provided that the sensors are embedded with a sufficient cable length to reach the bottom of the insert well. However, the furnace is not suitable for short-stem probes.



Dry Block Calibrator

The use of a furnace can generate additional measurement uncertainties, which must be considered when the calibration temperature sensing element and electronics are at room temperature. In this case, it is important to evaluate the effect of temperature on the electronics. There is always an effect of temperature on electronics, and this can be a source of uncertainty. It is recommended to have a comparative approach by evaluating the observed difference between a calibration with an immersion probe and only the sensing element immersed.

Your supplier should be able to provide you with an estimate of the impact of temperature on the electronics, which will be expressed as ±0.001°C/°C, for example. For instance, if the difference between the calibration temperature of the sensitive element and the ambient temperature is 50°C, then there will be an impact of 0.05°C on our measurements.

b. The Temperature of the Probe

The most critical factor during calibration is the standard probe that you will use to compare its values with those of your onboard sensors. It is essential to use a sufficiently precise probe that has been calibrated by an accredited laboratory. The level of uncertainty of the standard probe should be at least three times lower than that of your embedded sensors.

IRTD-400

With appropriate software, you can perform your embedded sensors‘ calibrations in accordance with COFRAC or equivalent standards on-site. This method allows for a moderate initial investment (Bath/Oven/sensor calibration) by not using the calibration services of an external laboratory, enabling you to have metrological control of your embedded sensors internally and maintain cost control.

c. Other Physical Quantities

The set of recommendations, solutions, and methods can also be applied to pressure, relative humidity, CO_2, H_2O_2, among others.

Pressure

The calibration of physical quantities such as pressure is typically very strongly related to the temperature of your environment. Hence, it is important to calibrate your pressure sensor with respect to temperature.

Example: In a steam sterilizer, the combined study of temperature and pressure indicates whether the conditions for obtaining saturated steam are met. To maintain a constant pressure setting during calibration, an automatic pressure generator is recommended.

Automatic pressure calibrator

Relative Humidity

In the field of relative humidity, calibration involves constraints in terms of budget and training (such as a relative humidity generator and a stallion mirror hygrometer). If the number of relative humidity sensors is significant and/or the frequency of calibration is high, then it may be wise to invest in staff and resources for this purpose. Otherwise, it is recommended to outsource this type of calibration to an accredited laboratory with an appropriate level of uncertainty.

Relative Humidity Generators

5. Conclusion

The great convenience of onboard sensors should not overshadow aspects concerning their metrological control. Users should always have full confidence in the measurements performed to ensure reliable reports and conclusions. From the beginning of their use, it is important to define a strategy for monitoring embedded sensors, including decisions about whether to perform calibration internally or externally, the level of accreditation, calibration frequency, and the methods and procedures deployed. This strategy has consequences for the user, including the need for rigorous handling, management of sensor unavailability, certificate management, calibration schedules, risk management, preventive maintenance, and costs.

Training and experience should enable users to control sensor drift and optimize the durability and reliability of their embedded sensors in accordance with quality and metrology demands.

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