Self-calibrating thermometers for use in hygienic process engineering

Theory and practice

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iTHERM TrustSens TM371/TM372

Whitepaper

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People for Process Automation

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1 Self-calibration: how it works

The self-calibration method uses the Curie temperature (T_c) of a reference material as a built-in temperature reference. Self-calibration is performed automatically when the process temperature (T_p) drops below the nominal Curie temperature (T_c) of the device. The Curie temperature is a material constant of the material used. At this temperature, the reference material undergoes a phase change, which is associated with a change in its electrical properties.

The electronics unit detects this change automatically and simultaneously calculates the deviation of the measured Pt100 temperature from the known Curie temperature, which is a physical fixed point. A flashing green LED indicates that the self-calibration process is progress. After this, the thermometer electronics unit saves the results of this calibration.

The calibration data can be read using an asset management software application, such as FieldCare or DeviceCare. A calibration certificate can be created for the self-calibration. This in-line self-calibration makes it possible to continuously and repeatedly monitor changes to the properties of the Pt100 sensor and the electronics unit. As the in-line calibration is performed under real ambient or process conditions (e.g. heating of the electronics unit), the result is more in line with reality than a sensor calibration performed under laboratory conditions [cf. Lit. 5].


Pt100
Reference

2 Application examples

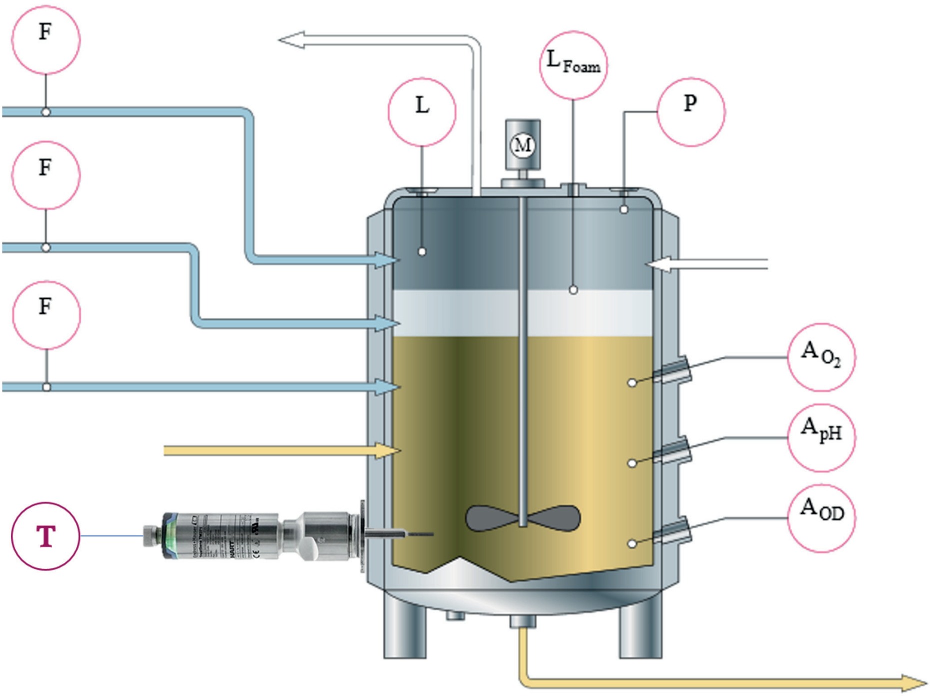
2.1 Use in the fermentation process (pharmaceutics)

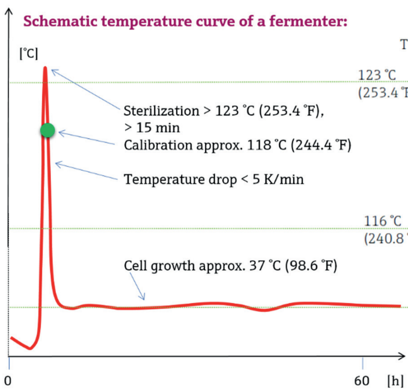
In a fermentation process, cells, fungi or bacteria with special properties are cultivated at approx. 37 °C (98.6 °F) and under optimum nutrient supply conditions until the desired concentration of cells and target product is reached for further exploitation. This process can take several weeks. To ensure clean and safe operation, it is extremely important that only the right cells grow, and that other germs from the environment do not multiply under the ideal conditions in the fermenter.

This is why the fermentation boiler and all the connected pipes must be sterilized before each batch. To this end, superheated steam is introduced and the temperature of over 121 °C (249.8 °F) (approx. 1.1 bar) is allowed to act for at least 15 minutes. The quality of the sterilization process must be monitored by calibrated thermometers.

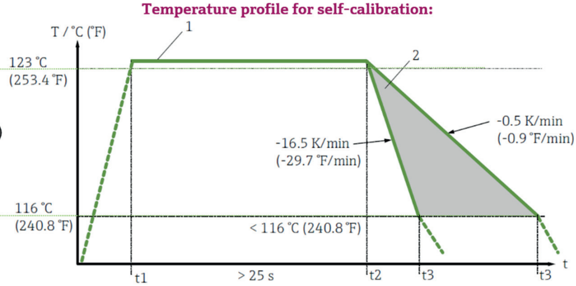
In the fermentation process, TrustSens self-calibration is initiated automatically after every fermenter sterilization once the temperature gradually drops from > 121 °C (249.8 °F). Active cooling is mostly avoided, as this could create a strong negative pressure which would damage the fermenter. Therefore, cold water is only injected - if at all - once the temperature is below 100 °C (212 °F).

Therefore self-calibration (green point) takes place reliably in every cooling phase before filling commences. The cooling rate after sterilization is approx. 5 K per minute with these systems.





Schematic temperature curve of a fermenter:



Temperature profile for self-calibration:

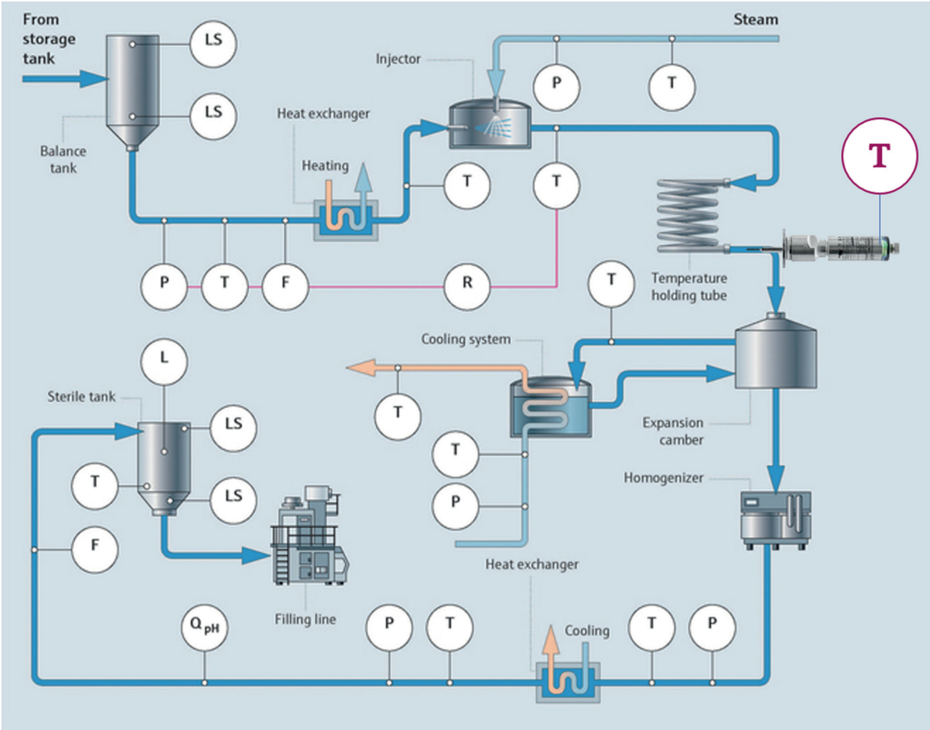
2.2 Use in the UHT process (dairy)

In the continuous UHT process, the product is generally heated to over 135 °C (275 °F) and cooled again after 4 to 5 seconds. Here too, the priority is to destroy as many microorganisms as possible in order to increase the milk's shelf life. On the other hand, if the temperature is too high, this could change the chemical properties of the product, which could impact the taste and quality of the milk. Therefore, the optimum combination of temperature and treatment duration needs to be found for every product. In order to guarantee this, the information regarding the current temperature must be reliable and exact, which is why regular calibration is required.

TrustSens is the only self-calibrating thermometer that calibrates automatically each time the process temperature drops (e.g. when the system is switched off or before cleaning is performed). Here, the current thermometer measured value is compared against the actual process temperature. This ensures that a thermometer that is damaged or presenting a measured value drift is detected before each batch.

Self-calibration (green point) is performed reliably at every cooling phase after the system is shut down. The cooling rate after operation is about 10 K per minute with these systems.

Active cooling is mostly avoided, as this could create a strong negative pressure which would damage the system. Therefore, cold water is only injected - if at all - once the temperature is below 100 °C (212 °F).


From storage tank
Balance tank
LS
LS
Heat exchanger
Heating
Injector
Steam
P
T
T
T
T
P
T
F
R
T
Temperature holding tube
Cooling system
L
Sterile tank
LS
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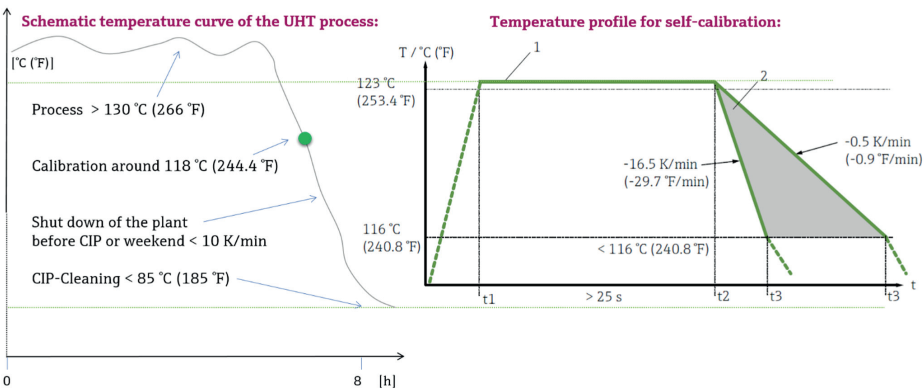
Expansion camber
Homogenizer
Heat exchanger
Filling line
Q pH
P
T
Cooling
T
P


Schematic temperature curve of the UHT process:
[°C (°F)]
Process > 130 °C (266 °F)
Calibration around 118 °C (244.4 °F)
Shut down of the plant
before CIP or weekend < 10 K/min
CIP-Cleaning < 85 °C (185 °F)
0
8
[h]
Temperature profile for self-calibration:
T / °C (°F)
1
2
123 °C
(253.4 °F)
116 °C
(240.8 °F)
-0.5 K/min
(-0.9 °F/min)
-16.5 K/min
(-29.7 °F/min)
< 116 °C (240.8 °F)
t1
> 25 s
t2
t3
t3
t

3 Increased process safety

This regular calibration ensures that a damaged thermometer is detected automatically. The TrustSens also indicates whether the sterilization was successful. This way, **no** product comes into contact with pipes that may still be contaminated.

By contrast, with the calibration intervals that would normally apply in conventional systems (generally 6–24 months), there is a much higher risk that a faulty thermometer is only detected once multiple batches have been produced with it. This results in complex risk management investigations and, at worst, products have to be recalled, causing considerable financial damage and damaging the brand's image.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RIA15
37.0
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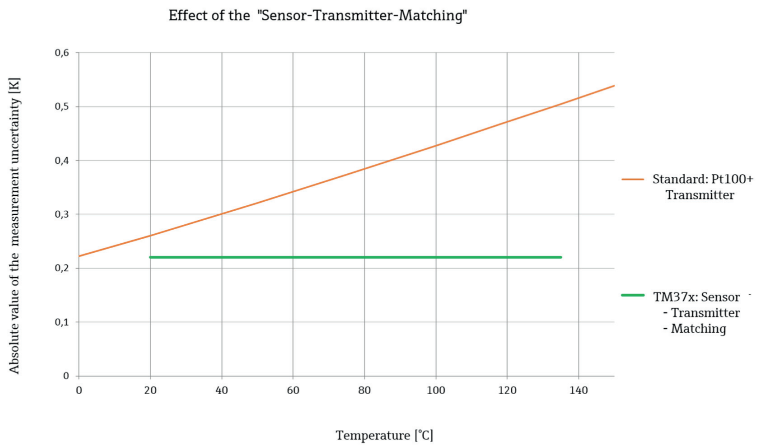
4 Reduced uncertainty of measurement

At T>0 °C (32 °F), the curve of a Pt100 follows the Callendar-van-Dusen equation:

$$R(T) = R_0 \, [1 + A\,T + B\,T^2]$$

IEC 60751 defines standard values for parameters A and B so that, together with the basic resistance value R_0 = 100 Ohm, each sensor is within the accuracy class which is also specified. However, as an electronics unit is always needed to measure the resistance and convert the value to a temperature value, the contribution of this evaluation to the measurement uncertainty must be considered as defined in the GUM rules [cf. Lit. 13].



Each TrustSens is calibrated very thoroughly during the production process. Here, the values for A, B and R_0 are determined individually and saved in the electronics. This means that there is precise knowledge of the characteristic curve and the measured errors are far lower than in the case of standard sensors. This is clear from the factory calibration certificate shown overleaf. This process is known as "sensor-transmitter matching" (STM). In contrast to a standard sensor, the STM process results in an uncertainty of measurement that remains consistently low in the measuring range under observation, rather than increasing with distance from the 0 °C (32 °F) point. This has the effect of halving the potential uncertainty of measurement in the sterilization temperature range (close to 120 °C (248 °F)).

Factory Calibration Certificate

Certificate-No.: N3042704487_2018
Revision: 1
Date of issue: 15.03.2018
Customer Order: BE175691
Description of the Test Unit: TM371-AA0A0A2A6B8A1A
S.N.: N3042704487
TAG: .

Standards used

Description of the standard	ID-number of the standard	Certificate number
Hart Scientific 1590-256	60007003	E57685
Agilent 3458 A	20120178	E50221
SPRT 25 Pt25 Model 5699	20130159	T94449
SPRT 25 Pt25 Model 162CE	60008002	T82011
Agilent 34420A	20110294	E46358
Tinsley 5685A 25 Ohm	20120012	E57467
SPRT 25 Pt25 Model 162CE	20140016	T93258

Procedure of calibration/Measurement and ambient conditions

Immersion depth: 85,0 mm
Range: 0...150 °C

The temperature values are according to the ITS-90. The calibrations at 0°C were made at the melting ice-point.
At all other temperatures comparison calibrations are carried out in an homogeneous temperature field, using a liquid stirred bath between −40°C ≤ t ≤ 300°C and within a tube furnace between 300°C < t ≤ 1050°C.
All measurements have been made in ambient controlled at 23°C ± 3K and R.H. 0%...80%.

Measurement results

Nominal calibration point	Standard reference temperature	Measured output	Temperature value	Deviation	Max. allowed deviation
(°C)	(°C)	(mA)	(°C)	(K)	(±K)
0	0,00	4,000	0,00	0,00	0,22
20	20,00	6,131	19,97	-0,03	0,22
80	79,98	12,529	79,96	-0,02	0,22
121,5	121,51	16,963	121,53	0,02	0,22
150	149,99	19,998	149,98	-0,01	0,22

The test unit has been calibrated and complies with the tolerances stated by the manufacturer.

Measurement uncertainties

The total measurements uncertainty, evaluated at twice the standard deviation, is:
From −40°C to 300°C: ± 0,05 K (probability 95%)
From 300°C to 650°C: ± 0,20 K (probability 95%)
From 650°C to 1050°C: ± 1,50 K (probability 95%)

Nesselwang, 15.03.2018

Jakob Mayr
This certificate is produced automatically and is valid also without a signature

5 Detection of sensor errors

As previously explained, in terms of basic accuracy the TrustSens is far superior to standard thermometers due to sensor-transmitter-matching. In continuous service, it then regularly checks whether the condition of the thermometer has changed in relation to its as-delivered state. But is a single-point calibration enough to be able to detect a change in the Pt100?

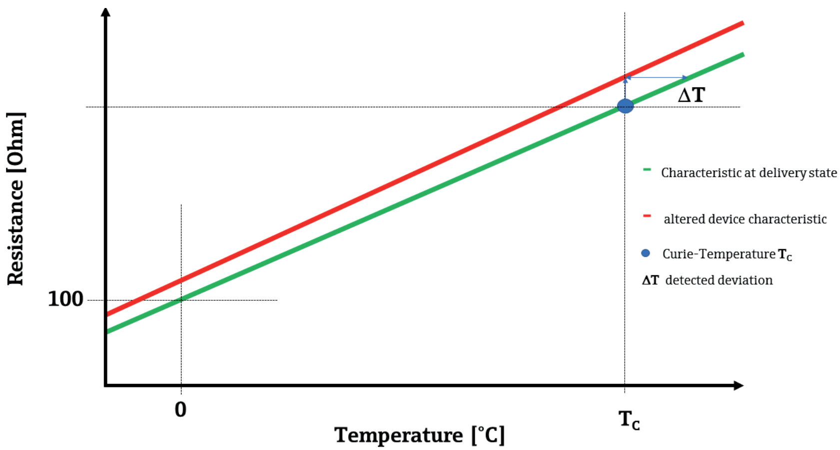
Generally speaking it is, because a "bad" Pt100 resistance also follows the Callendar-van-Dusen correlation but with different coefficients compared to the as-delivered state.

What can even change in the case of a Pt100?
Two characteristic values dominate in the temperature range under observation:

- R_0: the basic value (100 Ohm at 0 °C (32 °F))
- A: the slope of the curve (standard value = 0.3908 Ohm/Kelvin)

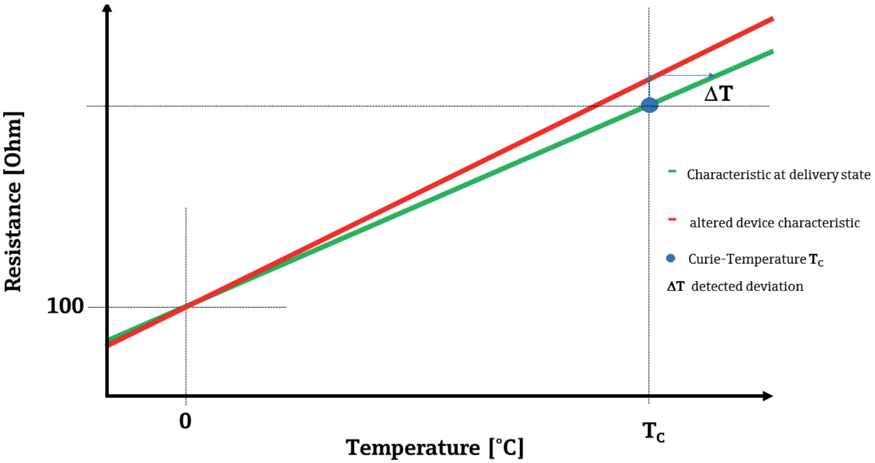
5.1 Offset error: change in the basic resistance R_0

A shift in the basic value R_0 is a typical error presented by RTD assemblies.



This shift can be caused by mechanical effects (steam hammering, following a drop etc.) because Pt100 thin-film resistors can respond to force like a strain gauge. If the basic value changes, the entire curve shifts, which is why this error can be easily detected with a single-point calibration.

5.2 Slope error: change in temperature dependence A

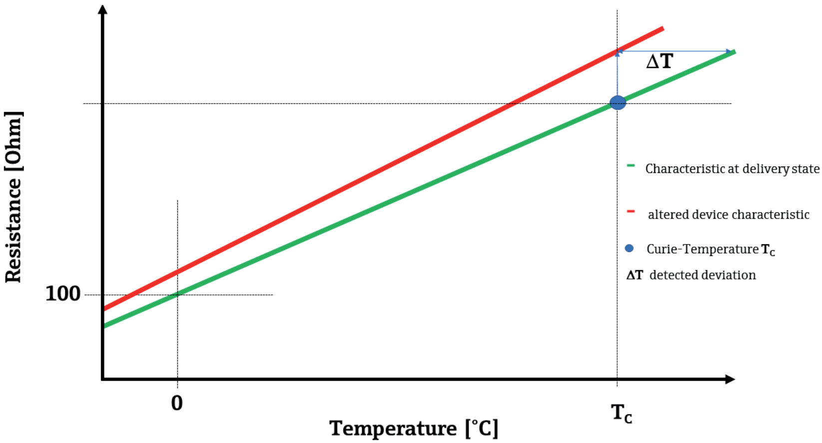


An incorrect curve slope or curvature is a less common error. This type of non-conformity is normally caused by direct contamination of the platinum in the measuring resistor and at temperatures over 400 °C (752 °F) [cf. Lit. 1]. Both these risks are virtually non-existent in applications in the pharmaceutical or food industry, as the sensors are always installed in closed inserts and an additional thermowell. In addition, temperatures of over 160 °C (320 °F) hardly ever occur here. As the total error of an incorrect slope has a more marked effect at higher temperatures than at temperatures close to the operating point, this type of error can be detected far better by a single-point calibration at a temperature of approx. 118 °C (244.4 °F) than a calibration at the operating point, e.g. at 37 °C (98.6 °F) in fermentation processes.

5.3 Combination of errors

If both types of error were to occur at the same time (e.g. mechanical change and chemical corrosion), this could affect the overall curve in many ways. This also dictates whether the single-point calibration can detect whether the sensor has changed since delivery.

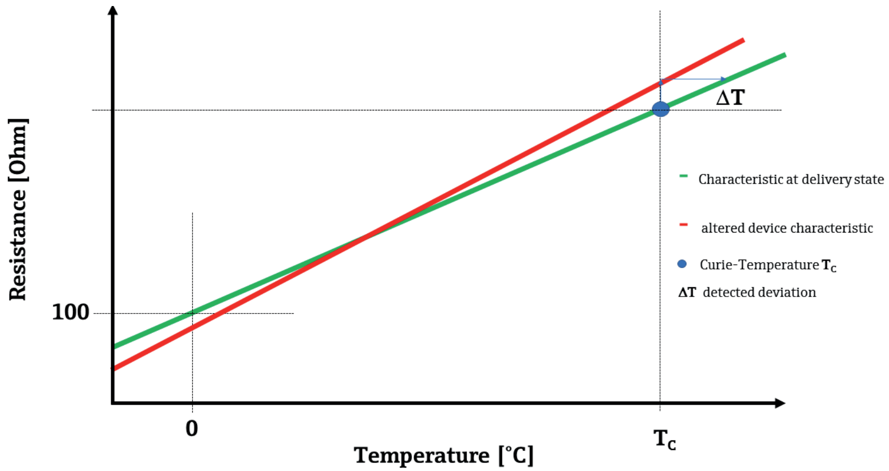
5.3.1 Addition of errors



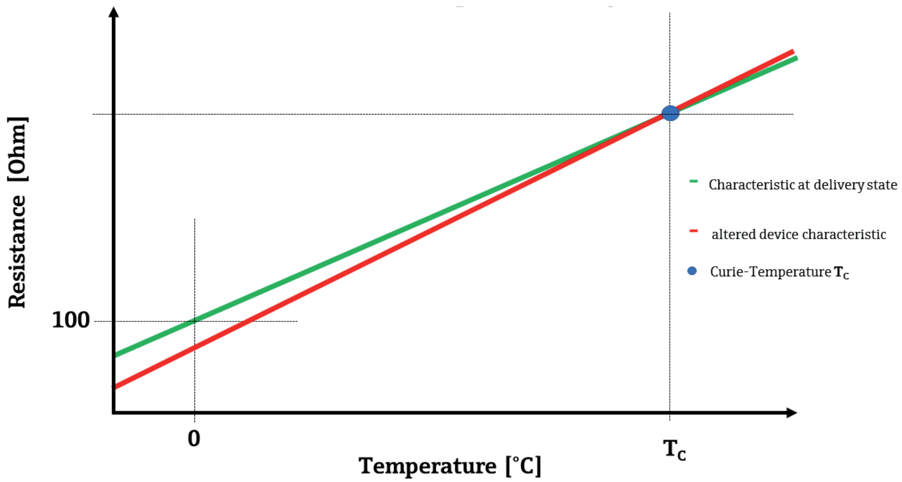
If both errors act in the same direction in the measuring range under observation, the curve shifts away completely from the as-delivered state and moves further and further away with increasing temperatures. This shift can be reliably detected by a single-point calibration.

5.3.2 Partial compensation between the offset and slope errors

It is also possible that both errors exist simultaneously but act in opposite directions, with the result that the new incorrect curve intersects the curve for the as-delivered state. Again, this deviation can be detected by a single-point calibration at the Curie point in the majority of cases.



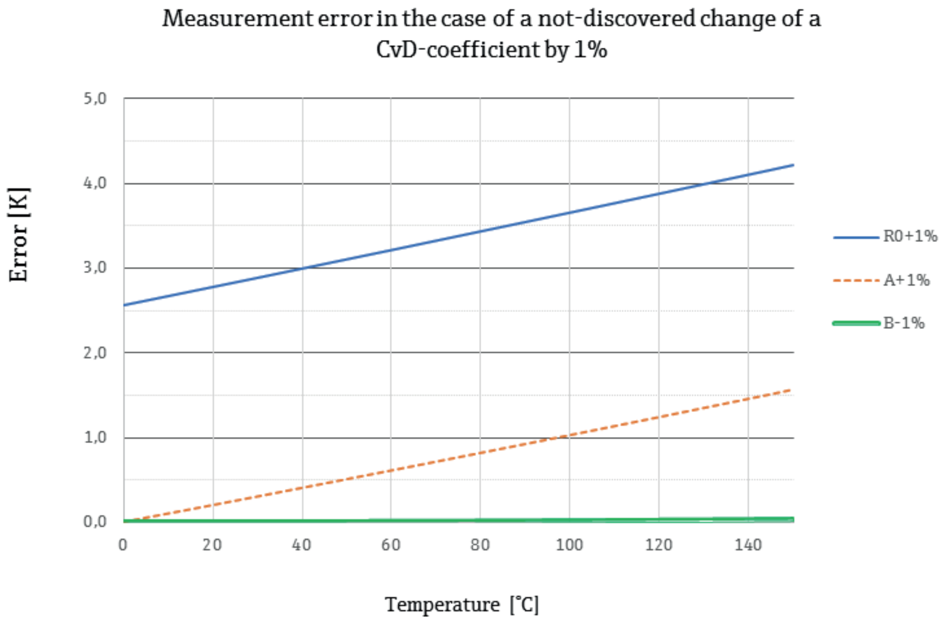
The single-point calibration would only be unable to detect the deviation in the very unlikely event that the new point of intersection between the as-delivered state and the incorrect curve is located, by pure chance, in the immediate vicinity of the Curie point. This scenario is extremely rare.



5.4 CvD coefficient B

Due to its very small numerical value (-5.775E-07), coefficient B does not play a significant role in the temperature range that is relevant for the industries under analysis. The influence of B can only be measured at high temperatures, as it is multiplied by the square of the temperature.

A theoretical experiment illustrates this: if one of the three coefficients changed by 1% without either of the two other values also changing, the resulting measured errors would be as follows:



As the effect of the change of B is hardly noticeable in the comparison and in reality it can be assumed that A + B, in particular, cannot change independently of one another, this error situation is not discussed in greater detail here.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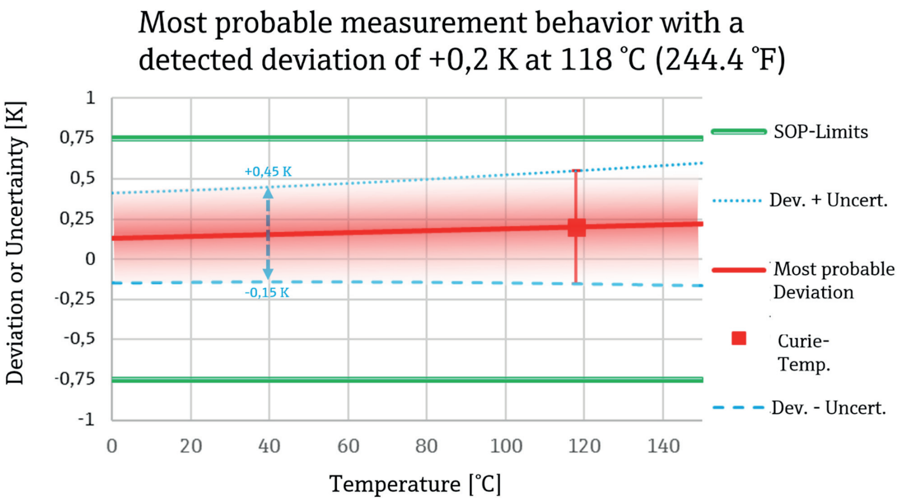
6 Uncertainty of measurement of single-point calibration

In real-life processes none of the TrustSens thermometers used so far have shown a deviation of more than ±0.15 K from the as-delivered state.
An analysis conducted by the University of Ilmenau verifies how a deviation determined at 118 °C (244.4 °F) affects the entire measuring range [cf. Lit. 2 and Lit. 3]. As already explained, a significant deviation is most likely attributable to a change in R_0. A new characteristic can then be determined (red). Depending on the value of the measured deviation at the Curie point and the distance from the calibration temperature, the uncertainty of this assumption increases in a non-linear manner. At the Curie point, the uncertainty corresponds exactly to the measurement uncertainty of the process as certified by the German Technical Inspection Association TÜV [cf. Lit. 14]. The following worst-case scenario illustrates this:

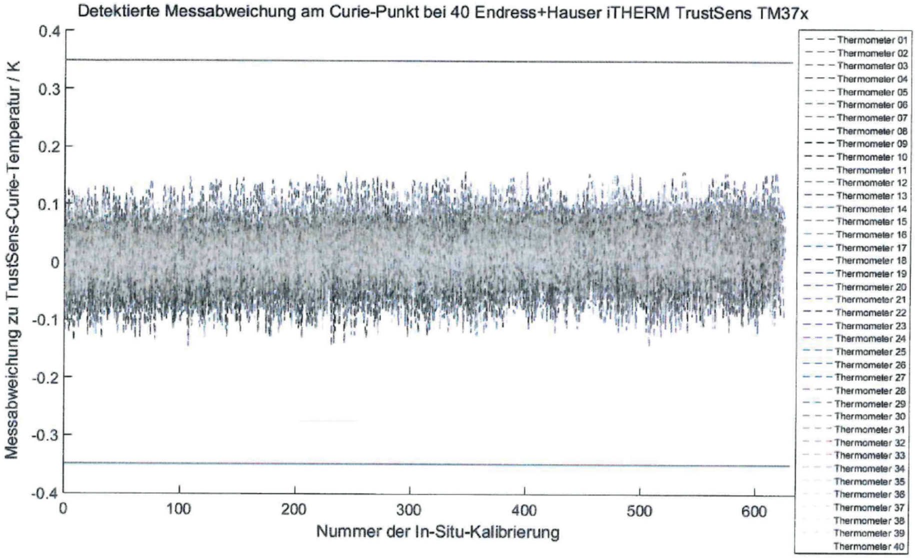


If a deviation of +0.2 K, for example, has been detected at the Curie point of approx. 118 °C (244.4 °F) (i.e. the deviation is still within the specified measurement uncertainty of ±0.22 K [cf. Lit. 5]), this implies a most likely deviation of less than 0.18 K at the process temperature (37 to 40 °C (98.6 to

104 °F)). If the uncertainty of measurement (in the range from -0.15 K to +0.45 K at 40 °C (104 °F), for instance) is also taken into account, it can be demonstrated that the TrustSens is more accurate than +0.6 K and -0.2 K over the entire range. As a general rule, a limit of ±0.75 K is defined. Temperature sensors presenting a deviation of ±0.75 K or more are removed from the system. Therefore, every sensor presenting a deviation of less than 0.2 K at the Curie point would be within the tolerance and comply with this requirement.

6.1 Calibration results of the TrustSens

TÜV was commissioned to examine the TrustSens process as part of a study. To this end, TÜV analyzed more than 24,000 calibration results [cf. Lit. 6]. None of the results analyzed presented a deviation of more than 0.2 K.



Scientifically based, proof of conformity for undamaged TrustSens sensors can therefore be deduced for every SOP that permits temperature deviations of < 0.75 K (based on a single-point calibration of 118 °C (244.4 °F)).

By configuring a warning or alarm limit value, the TrustSens can be programmed to alert the user as soon as damage (i.e. an "out of spec" situation) is detected [cf. Lit. 5].

6.2 Configuring the warning and alarm limits

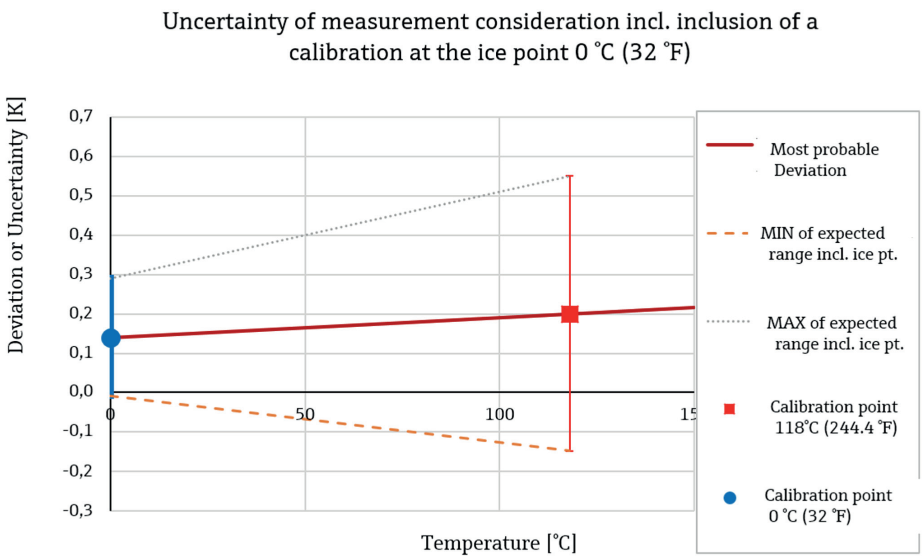
As explained above, a limit value from the Standard Operation Procedures (SOPs) can be assigned to a known deviation at the Curie point (taking the uncertainty of measurement of the process into account).

Conversely, a warning or alarm can be derived from the measurement of the calibration drift of the TrustSens that notifies the user that the thermometer is approaching this limit value or has exceeded it. This limit can either be detected in TrustSens or, as recommended, through continued HART protocol analysis, which provides information on both the number of calibrations performed and on the value determined for the calibration deviation.

Permitted limit value according to SOP (over the entire measuring range)	**Recommended warning limit [K]** (at Curie point 118 °C (244.4 °F))	**Remarks**
0.5 K	0.1 K	
0.6 K	0.2 K	(See image in Section 6.0)
1.0 K	0.5 K	Default value for warning message (HART, LED flashing red) [cf. Lit. 5]
1.5 K	0.8 K	Default value for error message error current, HART + LED permanently lit red [cf. Lit. 5]

6.3 Suggestion for application in practice: ice point calibration

If a TrustSens reports a larger deviation at the Curie point, the recommended course of action is to remove the sensor at the next available opportunity to check it first of all at the ice point of 0 °C (32 °F) [cf. Lit. 9]. If ice made from ultrapure water is available (conductivity at 20 °C (68 °F) < 1.1 µs/cm [cf. Lit. 10]), this type of calibration can be performed with an uncertainty of measurement that is less than ±0.15 K.



According to the assumption above, the deviation at the ice point should then be somewhat less than the reported calibration deviation at the Curie point. If this is true, this proves that the deviation has been caused by a change in the value R_0, i.e. probably as a result of mechanical influences. Generally speaking, the thermometer can continue to be used (where necessary following an adjustment by configuring an offset in the operating software).

Additional measures - such as a two-point or five-point calibration - need only be considered if the ice point calibration returns completely different results than anticipated.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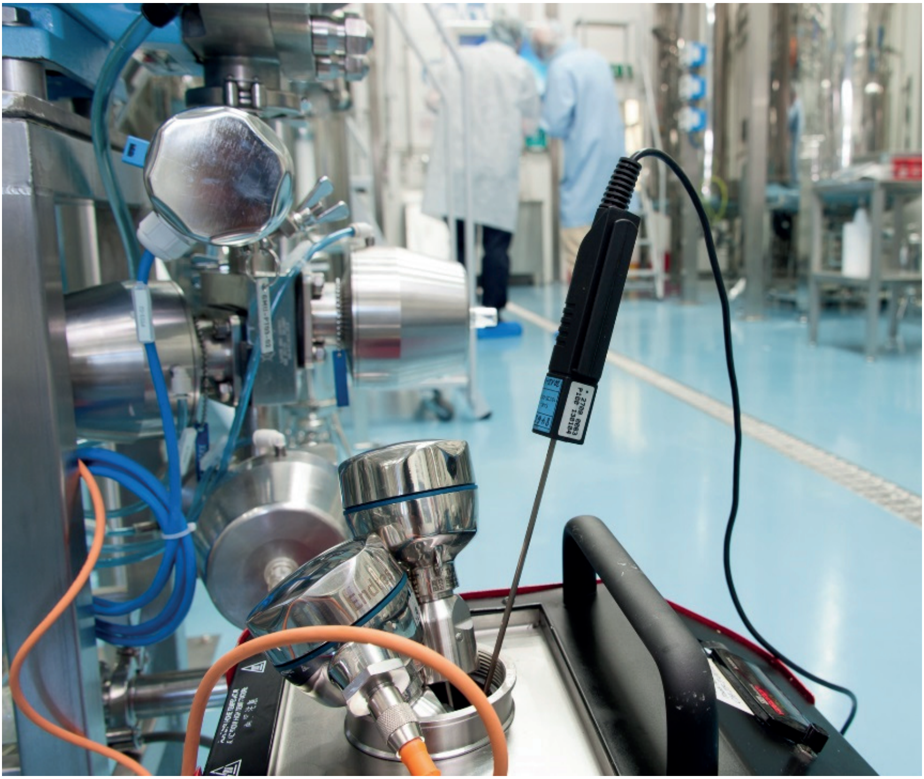
7 Uncertainty of measurement of a manual calibration

To be able to make a definitive assessment of the in-process self-calibration procedure, it is advisable to take a closer look at the method that is commonly used today.



To check the accuracy of RTD assemblies in hygienic applications, businesses often use dry block calibrators for onsite calibration. Three temperature points are usually approached in this process. However, it is important to bear in mind that thermometers in this industry usually have quite a short immersion length, as thin pipes or agitators in tanks only offer limited space for installation. This means that there is often a significant physical distance between the point where a reference thermometer measures the temperature of the calibrator and the position of the sensor which is to be tested.

To determine the uncertainty of measurement that a calibration of this kind can have at best, it is advisable to refer to the website of the German accreditation body, DAkkS. The directory of accredited bodies also contains a list of numerous businesses that are specialized in the performance of on-site calibrations. The DAkkS indicates how accurate such a calibration in the dry block calibrator can be.

Calibration body **D-K-15024-01-00** is suggested here as a benchmark: this company does not produce measuring instruments itself but is specialized in performing calibrations onsite at its customers' premises. According to the accreditation certificate, the company uses dry block calibrators to check RTD assemblies [cf. Lit. 4]:

Anlage zur Akkreditierungsurkunde D-K-15024-01-00

Vor-Ort-Kalibrierung

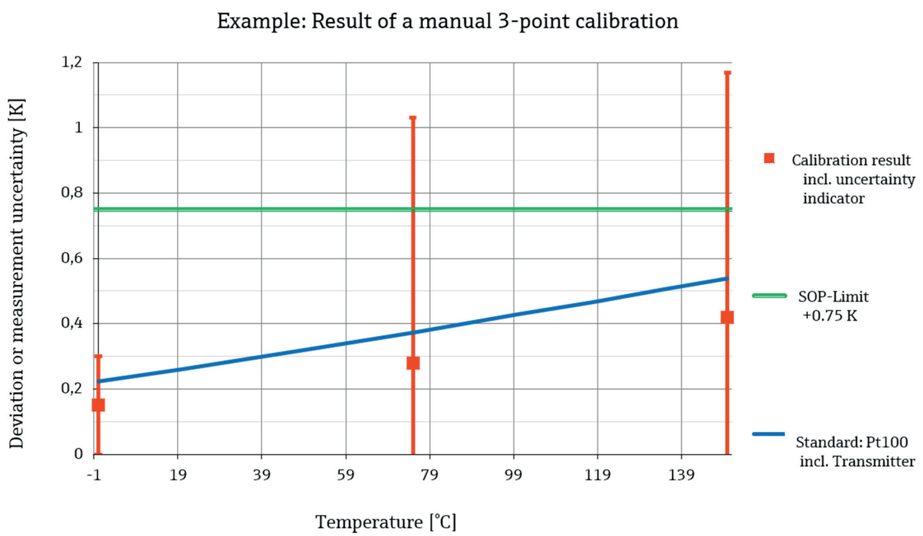
Messgröße / Kalibriergegenstand	Messbereich / Messspanne			Messbedingungen / Verfahren	kleinste angebbare Messunsicherheit 1)
Nichtselbsttätige elektronische Waagen		bis	30 kg	EURAMET Calibration Guide No. 18 Version 4.0	$2 \cdot 10^{-6}$
Temperatur Widerstandsthermometer und direktanzeigende Widerstandsthermometer		0 °C		Eispunkt	50 mK
	-15 °C	bis	50 °C	DAkkS-DKD-R 5-1:2010 Im Temperatur-Blockkalibrator	0,25 K
	> 50 °C	bis	400 °C		0,75 K
	> 400 °C	bis	600 °C		1,0 K

Specialists give ±0.75 K as the accredited best measurement capability in the sterilization temperature range.

For the industry user, this raises the following question: can a calibration in the dry block calibrator which is performed by the company itself be more accurate?

As this is rather unlikely, it makes sense to assess the conformity of a manual calibration (does the thermometer actually correspond to the application limits indicated in the SOPs?) while taking the aforementioned measuring uncertainties into account [cf. Lit. 4].

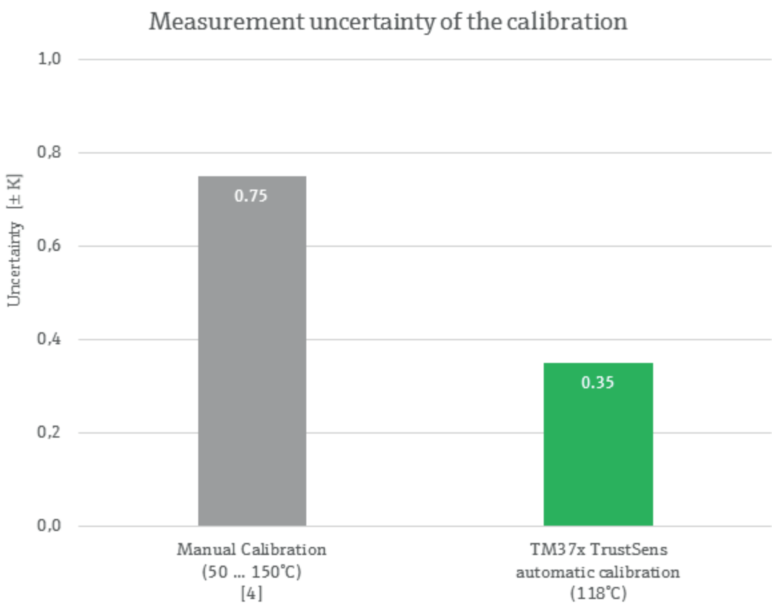
In many cases, however, this delivers an unclear statement of conformity, as shown in the following example involving a three-point calibration performed manually:



All the measurement results are below the limit values that would be expected for a Class A RTD assembly plus transmitter. In practice, a thermometer assessed in this way would be installed again in most cases without any modifications.

However, if the uncertainty of measurement of 0.75 K [cf. Lit. 4] for manual calibration is also factored in, there would be a significant likelihood that the thermometer could also operate outside the SOP limits (0.75 K in this example). The statement of conformity therefore formally adopts the third status "uncertain" with the result that additional measures would be necessary, e.g. the calibration is continuously repeated until the uncertainty of measurement is statistically lower.

A direct comparison reveals the following: thanks to its far lower uncertainty of measurement, an in-process single-point calibration provides a more reliable statement of conformity than a manual check performed at three points using a dry block calibrator, particularly for the critical temperature range around the sterilization temperature; this is especially true if you consider whether calibration is performed manually once a year or automatically for every cleaning process.



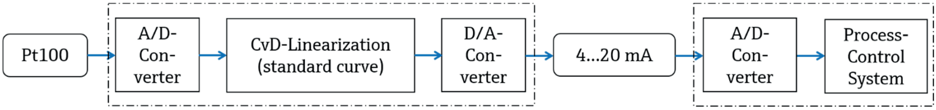
8 Accuracy and signal transmission

In modern transmitters (TMT82 or TrustSens TM37x), the temperature measured value is available as a digital value and can therefore be transmitted directly using a digital communication system. If analog measured value transmission is selected instead, e.g. using a 4 to 20 mA signal, this signal is only generated subsequently using a D/A converter and after transmission is then digitized again in the input card of the process control system using an A/D converter. This conversion and the associated influencing factors (A/D converter in the PLC input, voltage sources, ambient temperature etc.) cause errors to occur in the temperature measured value transmission chain which can be avoided if the signal is transmitted exclusively by digital means (e.g. HART).

In addition, inaccuracies in the thermometer curve can be reduced to a minimum by applying sensor-transmitter matching, i.e. by programming the individual thermometer curve determined in a calibration into the thermometer electronics. In contrast to conventional thermometers, sensor-transmitter matching is always performed in the TrustSens before it is delivered.

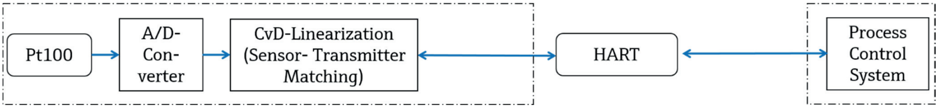
The following measuring uncertainty values are calculated at a process temperature of 37 °C (98.6 °F):

Case 1: Standard thermometer



- with standard curve for sensor Pt100 Class AA
- with 4 to 20 mA analog signal transmission
- with analog PLC input card
- **expected uncertainty of measurement < 0.8 K**

Case 2: TrustSens or iTEMP TMT8x



- with sensor-transmitter matching
- data transmission via HART
- with digital PLC input card
- **uncertainty of measurement = 0.22 K**

9 Enhanced functionality

In addition to supplying the measured value, HART devices also provide other data that can be evaluated. In the case of TrustSens, these data are the value of the last calibration deviation that was determined, and the counter for the self-calibrations performed. By continuously querying these values, an alarm can be generated (deviation too large, check needed) and the time of the calibration can be documented in a connected data manager (e.g. Memograph M RSG45). Effectively, it is possible to generate an online calibration certificate which can be viewed any time on site or in the network.

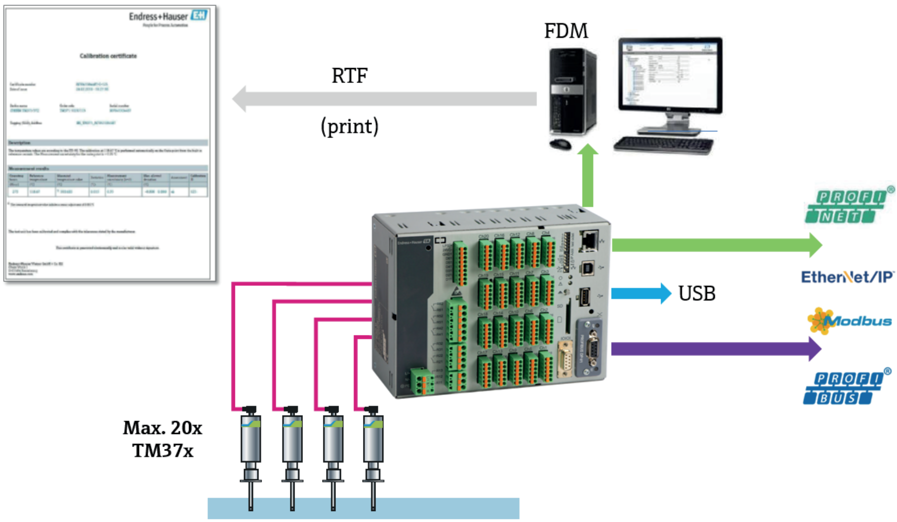
9.1 FDA-compliant data logging

The Memograph M RSG45 data manager saves all the data and therefore also the calibration results of connected TrustSens thermometers in a tamper-proof data format approved by the FDA [cf. Lit. 8]. These data are made available at the device and via the Web server. Users can search for specific reports in the Web server and create a certificate of calibration at the press of a button. Alternatively, certificates of calibration (RTF file) can also be created at the device and/or saved on the portable data storage medium of the RSG45 (SD card, USB stick).

All calibration reports are time-stamped, which simplifies the search for calibration report events.

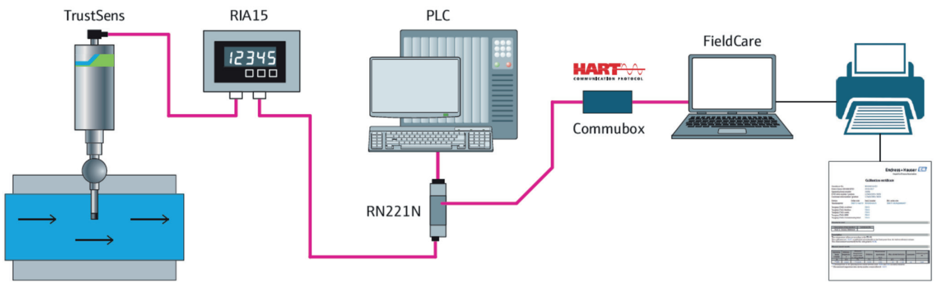
Furthermore, all the main measurement/calibration values can be visualized in customer-specific process graphics in the RSG45. If the measurement and calibration values are only to be transferred to the process control system, the DIN-rail version of the RSG45 (without a display) is another option. In this case, the values are then only visualized in the Web server.

In addition, the Memograph M can also be used as a fieldbus gateway in order to make the measured values of the temperature sensors or other measuring devices, which are read in via HART, available via a fieldbus system for further processing in the process control system.



9.2 Displaying the calibration data on site

If it is not possible to further process or save the calibration values provided via HART (e.g. the process control system is not HART-compatible AND it is not possible to use a data manager), the system operating staff can use a simple "tool-free" way to view the current calibration status.



When a 4 to 20 mA-powered RIA15 display unit is installed, it can be configured to display the HART measured values of the connected measuring device and show the status information as "scrolling text". Therefore, apart from the status LED, which is installed directly in the TrustSens (and is perhaps not accessible), the operator can also read a series of consecutive messages indicating whether the number of calibrations has increased since the last read-out, what calibration deviation was determined at that time, how high the process temperature is and what the current health of the electronic evaluation unit is.


Endress+Hauser
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10 Process safety and audit reliability

10.1 Existing SOPs and the change management process

Many companies today have established Standard Operation Procedures (SOPs) that stipulate a two-point or three-point calibration for thermometers. This reflected the state-of-the-art to obtain the clearest possible temperature curves for the calibration. This approach is also in line with the expectations of auditors and regulatory authorities as there was no alternative up until now.

However, it must be noted that the biggest risk for a thermometer in a hygienic system is the actual calibration process itself. Opening the devices, removing the insert, connecting and disconnecting electrical contacts, introducing the thermometer into the calibrator or transporting the thermometer to the laboratory increases the likelihood of mechanical damage, e.g. from impact, several times over. Furthermore, a question that is often raised is what is the best way to return the measurement to the exact same measuring position in the process after removing the insert for calibration purposes. These risks are reduced if the temperature sensor can stay at the same place and in the same position for longer without being moved.

10.2 Continuous process verification

Taking the example of temperature measurement, with the new technology presented in the self-calibrating thermometer users can immediately meet the requirement for "continuous process verification" - as required by the FDA for example [cf. Lit. 7]. This is because in-process single-point calibration reduces the risk of a deviation going undetected until the next calibration to the absolute minimum level possible with current technology. This is achieved without comprising on accuracy.

10.3 Definition of the term "calibration"

The term "calibration" is defined in the globally recognized "Vocabulaire international de Métrologie (VIM)" [cf. Lit. 11]. This requires that the measuring uncertainty of a calibration is known and expressed. With TrustSens calibration performed at the Curie point, this measuring uncertainty is ±0.35 K.

Under defined conditions, the value provided by the reference is correlated with the display value provided by the device under test. The uncertainty of measurement must also be taken into consideration here.

In the next step, the result of the calibration is derived from this information. In the case of TrustSens, the reference value is determined by comparing the value displayed by the Pt100 plus transmitter at the time the curve passes through the Curie temperature, and is used to assess whether the measuring system has changed in relation to the as-delivered state. The calibration result can be made available in numerical format, or it manifests itself in a change in the status information - either at the LED or the current output.

According to the VIM definition, the calibration can also be expressed by a statement, i.e. it is not mandatory to provide tables, diagrams or functions.

As this definition also does not set down a minimum number of values that need to be correlated to a reference during the calibration, all the requirements of VIM are met.

10.4 Using TrustSens technology in a regulated environment

From a technological standpoint, the TM37x TrustSens consists of two measuring circuits.

10.4.1 Process temperature measurement

The first measuring circuit which is used for the continuous measurement of the process temperature is based on the time-tested technology used in Endress+Hauser's premium temperature transmitter TMT82.

TrustSens is therefore a high-tech temperature transmitter that has been specially designed for the hygienic industry by Endress+Hauser, a highly regarded producer of measuring instruments and one of the top three brands in the world. Therefore, there is very little likelihood that approval authorities or auditors would object to the use of an Endress+Hauser thermometer.

10.4.2 Provision of additional information

The second measuring circuit in TrustSens only provides advanced data that do not, however, affect the first measuring circuit. The only possible interaction is in the form of a device safety shutdown if the deviation found during a calibration is too large (this is configurable). This means that even if the second measuring circuit malfunctions, this will never corrupt or negatively impact the temperature signal.

In regulated environments, therefore, the question is not whether such a new sensor may be used but actually what users would like to do with the new information that TrustSens makes available.

The additional measured values supplied via the HART protocol (1: how often was a calibration performed? 2: how large was the last calibration deviation?) can, of course, simply be recorded for subsequent analysis.

As a next step, these data can be used to schedule repair measures, e.g. if the measured calibration deviation was following a trend that could indicate that a limit value will be reached in the future.

Statements about the process itself can also be derived from the data. For example, when the TrustSens self-calibrated (calibration counter +1) the temperature exceeded 123 °C (253.4 °F) for a certain period of time. This also means that the last sterilization actually took place.

By contrast, a sudden but thereafter constant change in the measured calibration deviation is an indicator for a mechanical change. There may have been steam hammering in the system, for example.

10.5 Good Practice Guide (GAMP) and the change process

Rather than dismissing the technology presented, it is far more likely that approval authorities and auditors will demand the use of self-monitoring technologies as soon as they become available. Ultimately, the "Good Practice Guide" for calibration management in 2010 predicted the availability of devices with self-calibration and online alert capabilities [cf. Lit. 12]. It specifically states that the data collected in this way can be used to extend the intervals between the calibrations that require the device under test to be removed. At another point, the same document also mentions that it is possible and practical to regularly check the accuracy of a device at one point only.

Thanks to the constant self-calibration process, the upgraded temperature measurement technology not only offers more safety but also additional cost advantages as soon as the additional data recorded can verify that the calibration intervals can be extended without any risk.

This follow-up measure drives down the calibration costs and can reduce system downtime. It does, however, also present a change in QA that must be assessed. Endress+Hauser offers its customers assistance in the creation and establishment of new SOPs as part of the change management system. When it comes to calibration inspections and audits, Endress+Hauser is also available as a technical partner to answer any questions from the inspection authorities.

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Additional information

Video: Self-calibrating thermometer – iTHERM TrustSens
https://www.youtube.com/watch?v=AuRAlyWz0kc

Video: Temperature measurement with RTD assemblies
https://www.youtube.com/watch?v=iIsKYiXawbA

Video: iTHERM TM4xx thermometer
https://www.youtube.com/watch?v=YRRRXpZTGJ0

12 Hygiene product portfolio

1 2 3 4 5 6

1) TT411: Thermometer thermowells, e.g. hygienic design as an elbow piece or T-piece, no welds or dead legs

2) TMR35: Compact thermometer for hygienic applications without special calibration requirements

3) TM41x: Modular RTD assembly for hygienic applications with manual calibration requirements (i.e. thermowell with replaceable insert); options: iTHERM QuickNeck, iTHERM QuickSens, ATEX

4) TM37x: TrustSens: hygienic compact thermometer with automatic self-calibration function

5) RSG45: Memograph M, Data Manager with HART communication and FDA-compliant data logging, optional transmission of data via Ethernet, PROFINET, PROFIBUS, Modbus; display of TrustSens calibration data

6) RIA15: Loop-powered measured value indicator with HART functionality

Abbreviations used

CvD Callendar-van-Dusen equation: this equation describes the characteristic curve of a platinum RTD thermometer, i.e. the relationship between resistance (in ohms) and temperature (in °C).

GUM Guide to the Expression of Uncertainty in Measurement: ISO/BIPM.

Pt100 Temperature sensor partly made from platinum with resistance of 100 ohms at 0 °C (32 °F).

SOP Standard Operation Procedure: user-specific rules for dealing with measured values. Is used in this context as the limit value for a temperature deviation up to which a thermometer can be used. ±0.75 or ±1.0 Kelvin are commonly used limit values.

STM Sensor-transmitter matching: method to improve the accuracy of an RTD assembly mated with a temperature transmitter.

VIM Vocabulaire international de Métrologie: the metrology dictionary contains binding definitions of the most important terms used in metrology and calibration.


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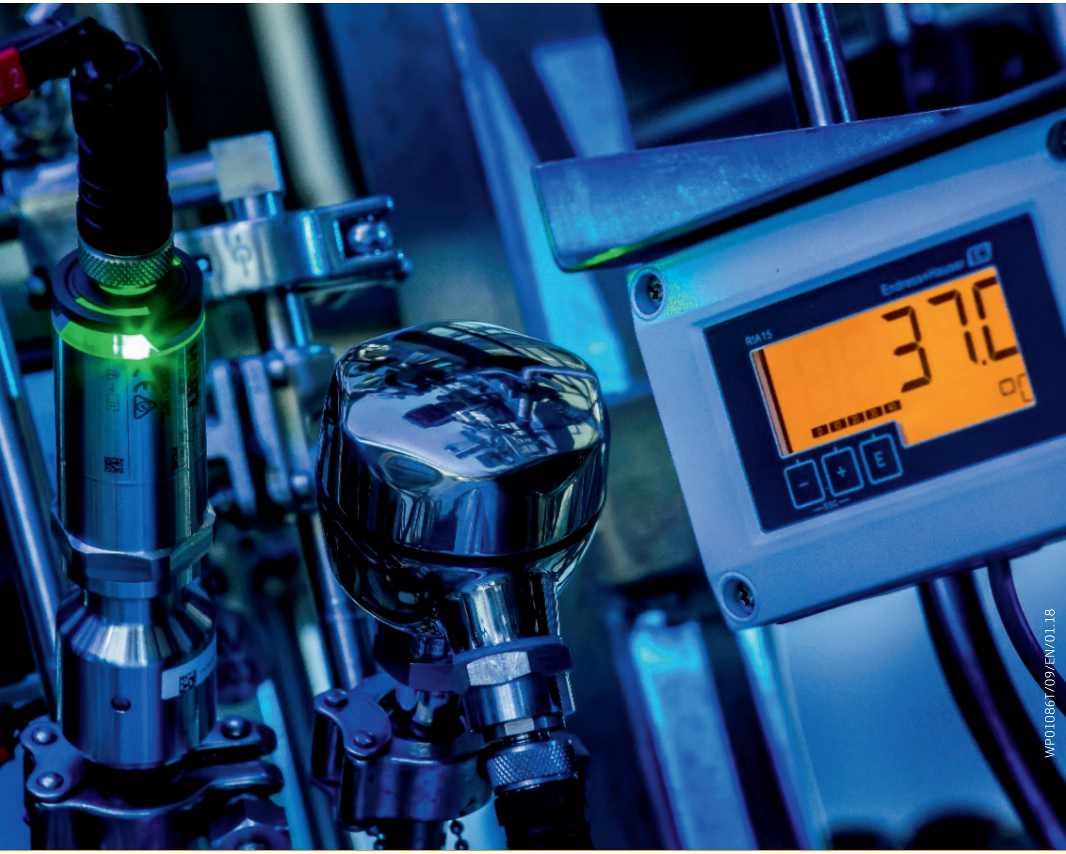

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