

iTHERM TrustSens Calibration Monitoring

Equipment evaluation within the requirements of FDA Title 21, Code of Federal Regulations Part 11, latest revision (21 CFR Part 11)

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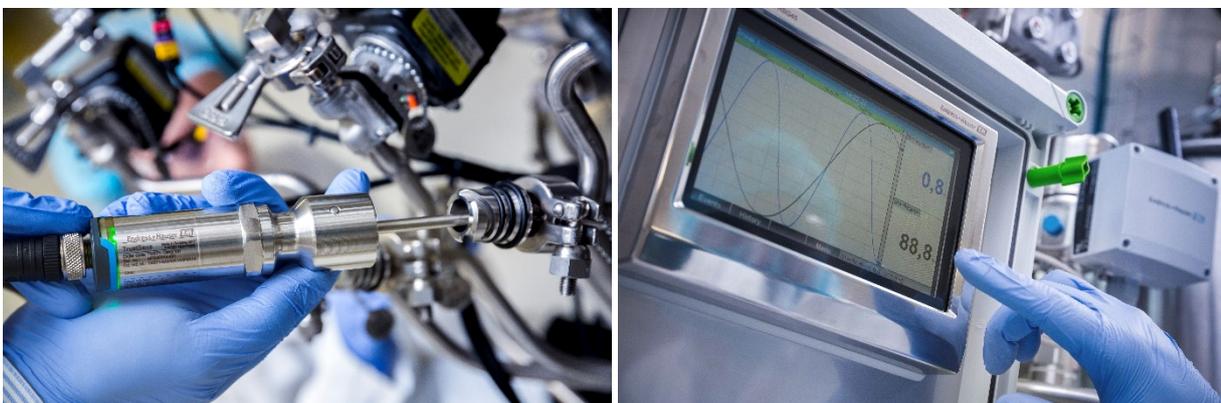
Executive Summary

Regulatory compliance and standard practice

Applications in the life sciences and food & beverage industries rely on the highest standards in terms of process safety. Sensor recalibration and (electronic) records management is mandatory to satisfy process and product safety as well as established regulatory requirements. To comply with these criteria, today's standard practice relies on periodic manual recalibration of temperature sensors, which typically incurs high cost, time and manual labor efforts.

Technological advances enable new process automation solutions

iTHERM TrustSens TM371 and TM372 temperature sensors by Endress+Hauser are capable of fully automated, traceable inline self-calibration and provide audit-compliant recalibration certificates (ref. addendum C) and device status documentation. In conjunction with Memograph M RSG45 data manager hardware and FDM software by Endress+Hauser (ref. addendum D), the solution enables reliable, secure automated calibration monitoring and electronic record management, including record creation (ref. addendum B), archiving and transmission as specified in the FDA 21 CFR Part 11, effectively eliminating the need for manual interventions.



Compliance to the general requirements of FDA 21 CFR Part 11

The solution comprising Memograph M RSG45 and FDM (Field Data Manager) software fulfills the general requirements of FDA 21 CFR part 11 related to system security and data traceability and integrity. Further details are laid out in the Whitepaper: *Memograph M RSG45 and FDM FDA 21 CFR part 11* (ref. Addendum F / WP01028L).

Solution applications

The graphic data manager Memograph M RSG45 securely records, archives, stores and transmits all relevant information it reads from connected device(s): Measured values are recorded, limit values are monitored, and recalibration certificates are created and securely stored in the internal system memory.

The “iTHERM TrustSens Calibration Monitoring” application is an embedded software functionality within the data managers firmware. The application performs as a closed system according to FDA 21 CFR section 11.3. The FDM software is archiving and visualizing the data captured.

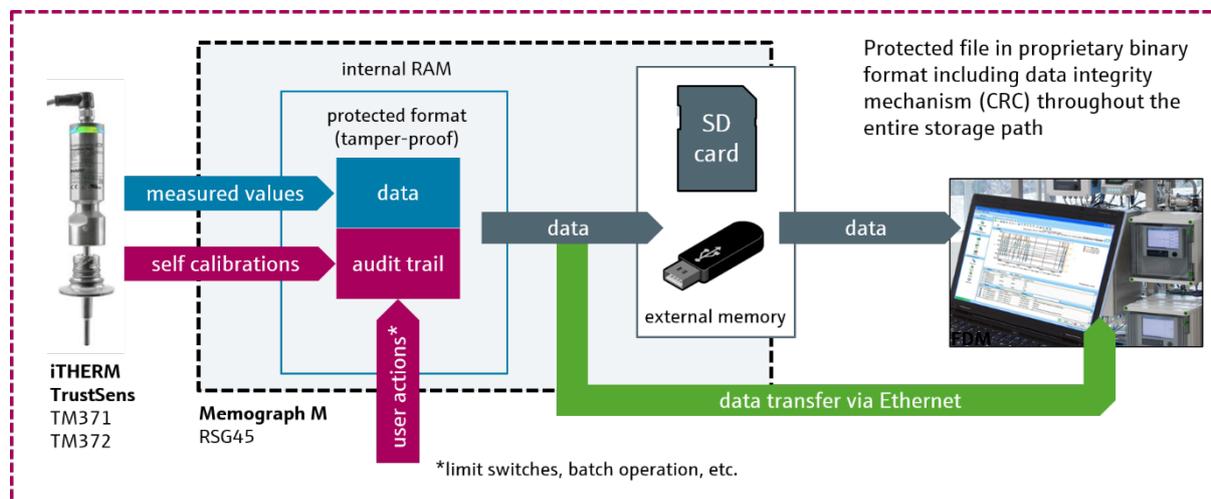


Figure 1: Data integrity from sensor to calibration certificate

The data - as defined by measured values and electronic records of audit trail - is stored in a proprietary binary file format to protect against undetected corruption. The integrity of the electronic records in the data manager is ensured by means of cyclic redundancy check (CRC). The CRC code is part of the raw data file.

Solution, system architecture and workflow

The iTHERM TrustSens Calibration Monitoring solution can be comprised of up to 20 iTHERM TrustSens TM371 or TM372 temperature sensors connected via HART® communication per every Memograph M RSG45 data manager. The data manager monitors the calibration counter of each connected iTHERM TrustSens.

Upon detection of every n+1 value change of the counter - indicative of a successfully completed self-calibration event - the data manager uploads the complete data set (such as device serial number, tag, calibration deviation value, measured process temperature value, temperature reference, etc.) from the iTHERM TrustSens and stores the data in its internal audit trail as a “calibration record” together with a system time stamp.

The electronic records of each self-calibration in the audit trail can be called up at any time to visualize the details of each record. A certificate in RTF file format can directly be generated by pressing a button on the data manager display or through the webserver interface (ref. addendum A). The RTF file can be printed and used for validation, batch documentation and more.

Note

With the generation of an RTF/PDF certificate and a printout of the certificate the responsibility of the document regarding manipulation is transferred to the user. The traceability of the raw data is still given at any time, since the electronic data record in the Memograph M RSG45 data manager is preserved.

The Endress+Hauser Group

Endress+Hauser is a global leader in measurement instrumentation, services and solutions for industrial process engineering. The Group employs approximately 14,000 personnel across the globe, generating net sales of over 2.4 billion euros in 2018.

WP01110T/09/EN/01.19

Addendum:

- A – Figure 2: Webserver view of audit trail (filtered by self-calibrations)
- B – Figure 3: Detail view of a self-calibration record
- C – Figure 4: Sample calibration certificate
- D – Feature list: Interaction with FDM software
- E – System requirements in detail
- F – Further reading and supplementary documents

Addendum A



Device name : Memograph M
Device tag : RSG45_MTS_jh_001
Status signal : OK

Menu > Operation > Search in trace > **Start search**

EH_TM371_N3044B04487: Selbstkalibrierung (ID=28)	21.03.2019 11:31:13	...
Neues HART Gerät erkannt: Kanal=1, Geräteadresse=0, Seriennummer=N3044B04487		
EH_TM371_N3044B04487: Self-calibration (ID=25)	13.02.2019 11:13:45	...
EH_TM371_N3044B04487: Self-calibration (ID=24)	05.02.2019 13:04:11	...
EH_TM371_N3044B04487: Self-calibration (ID=23)	05.02.2019 12:57:18	...
EH_TM371_N3044B04487: Self-calibration (ID=22)	05.02.2019 11:52:50	...
EH_TM371_N3044B04487: Self-calibration (ID=21)	05.02.2019 11:42:29	...

Figure 2: Webservice view of audit trail (filtered by self-calibrations)

Addendum B

Details

Date/time:	02.05.2018 11:10:43
Text:	EH_TM371_M7041504487: Self-calibration (ID=132)
Serial number:	M7041504487
Device name:	iTHERM TM371/372
Operating hours:	614 h
Reference temperature:	118,669 °C
Measured temperature value:	118,680 °C
Deviation:	0,011 °C
Meas. uncertainty (k=2):	0,349 °C
Max. allowed deviation:	-0,800 0,800 °C
Assessment:	OK
Certificate number:	M7041504487-0-132

OK RTF

Figure 3: Detail view of a self-calibration record

Addendum C



Calibration certificate

General information

Certificate number	DEMO0300000-0-40
Date of calibration	22.02.2019 17:06:01
E+H order number / position	88347352
Customer order number	3001649001/0180

Device information

Device name	iTHERM TM371/372
Order code	TM371-1020/115
Serial number	DEMO0300000
Extended order code	TM371-AA0A0A1AAA0A1A
Tagging (TAG), fieldbus	TM371-03-00-00

Procedure

Description of the standard	Built-in ceramic reference
Certificate number	DEMO0300000_2017

Calibration method

The temperature values are according to the ITS-90. The calibration at 118,30°C is performed automatically on the Curie point from the built-in reference ceramic. The Measurement uncertainty for the Curie point is < 0,35°C.

Calibration

The measurement uncertainty was determined at twice the standard deviation.

Operating hours	Reference temperature	Measured temperature value ¹⁾	Deviation ²⁾	Measurement uncertainty (k=2)	Max. allowed deviation	Assessment	Calibration ID
(h)	(°C)	(°C)	(°C)	(°C)	(°C)		
46	118,30	118,30	0,00	0,35	-0,80 0,80	ok	40

¹⁾ The measured temperature value includes a sensor adjustment of 0,00°C.

²⁾ The calculation of the "Deviation" is based on unrounded values. Therefore, the difference of the rounded values of the "Measured temperature" and the "Reference temperature" can differ by up to one one-hundredth of a degree to the rounded value of the "Deviation".

The test unit has been calibrated and complies with the tolerances stated by the manufacturer.
 This certificate is generated electronically and is also valid without signature.

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Figure 4: Sample calibration certificate

Addendum D

Interaction with FDM (Field Data Manager) software

The FDM software offers the following functionalities in relation with "iTHERM TrustSens Calibration Monitoring:

- Evaluation, analysis and further processing of calibration data
- Reading out the Memograph M RSG45 logbook with the related values for self-calibration (temperature during self-calibration, deviation from target value, status information, etc.)
- Generation of a calibration certificate as a PDF file
- Printout of the calibration certificate
- Automated function to store all recorded self-calibrations (certificates) on a configurable storage location (local, server, etc.)

Addendum E

System requirements in detail

Requirement	Implementation & comments
Real time stamp: Time and date of the calibration needs to be stated on the certificate.	The RSG45 features an integrated UTC-based real time clock. This time can be synchronized via Ethernet with the system time (e.g. of process control IT system). All changes in setup regarding system time (time setting, UTC time zone) are logged and traceable in the audit trail.
Can the connected sensors and the measuring point be uniquely identified?	On system startup the RSG45 identifies all connected sensors. In addition to the sensor serial number, procurement data such as order number and customer order reference are also recorded. A unique measuring point tag can also be configured. This information enters the audit trail the first time a sensor is detected.
Is an exchange of a sensor detected automatically?	Each newly connected sensor is recognized in the system and its identification data is entered into the audit trail.
The traceability of the certificate data shall be guaranteed at all times.	The data record of a self-calibration is an entry in the audit trail. All entries in the RSG45 audit trail are secure, computer-generated and time-stamped.
The link to the original reference shall be provided and documented in the certificate	The number of the original ex-works calibration certificate (ceramic reference sensor) is part of the electronic self-calibration record and provided with each self-calibration.
Are errors detected in the system (e.g. sensor errors, warning or alarm limit exceeding, temperature deviation, cable break, etc.)?	Yes, the RSG45 can evaluate and interpret each connected TrustSens' status information read out with the measurement signal, including error messages.
Can detected errors be reported to higher-level systems (e.g. PLC, DCS)?	The RSG45 can transmit detected errors to higher-level control systems via relay contact or via fieldbus protocols such as PROFINET or EtherNet/IP.

Addendum F

Further reading and supplementary documents

- Whitepaper: *Memograph M RSG45 and FDM FDA 21 CFR part 11 (WP01028L)*
- Whitepaper: *iTHERM TrustSens (WP01086T)*
- User manual: *iTHERM TrustSens Calibration Monitoring*
- User manual: *iTHERM TrustSens*
- User manual: *Memograph M RSG45*
- User manual: *FDM (Field Device Manager) software*

All listed documents are available on www.endress.com in the download area:
<https://www.endress.com/en/downloads>